

Appendix A. Search Strings

Screening (KQ1, KQ2)

Database: Ovid MEDLINE(R)

Search Strategy:

- 1 exp mass screening/ or screening.tw. or exp early diagnosis/
- 2 (expression screening or throughput screening or molecular screening or pharmaceutical screening or mutation screening or genetic screening).tw. or exp genetic screening/ or cancer screening.tw. or compound screening.tw. or drug screening.tw. or exp drug evaluation, preclinical/
- 3 1 not 2
- 4 (randomized controlled trial or controlled clinical trial).pt. or random*.ti,ab. or placebo.ab. or exp Double-Blind Method/
- 5 exp albuminuria/ or exp proteinuria/ or exp glomerular filtration rate/ or exp creatinine/ or exp kidney function tests/ or exp cystatins/ or exp kidney diseases/ or kidney\$.ti. or nephr\$.ti. or renal.ti. or exp kidney/
- 6 3 and 4 and 5
- 7 exp animals/ not humans.sh.
- 8 6 not 7
- 9 limit 8 to english language
- 10 limit 9 to yr="1985 -Current"
- 11 limit 10 to "all child (0 to 18 years)"
- 12 limit 10 to "all adult (19 plus years)"
- 13 11 not 12
- 14 10 not 13

Monitoring (KQ3, KQ4)

Database: Ovid MEDLINE(R)

Search Strategy:

- 1 monitoring.tw. or exp disease progression/
- 2 cardiac monitoring.tw. or exp drug monitoring/ or exp environmental monitoring/ or drug monitoring.tw. or exp blood glucose self-monitoring/ or exp blood gas monitoring, transcutaneous/ or exp clinical trials data monitoring committees/ or exp esophageal pH monitoring/ or exp monitoring, immunologic/ or exp uterine monitoring/ or exp monitoring, intraoperative/ or exp radiation monitoring/ or exp monitoring, physiologic/
- 3 1 not 2
- 4 (randomized controlled trial or controlled clinical trial).pt. or random*.ti,ab. or placebo.ab. or exp Double-Blind Method/
- 5 exp albuminuria/ or exp proteinuria/ or exp glomerular filtration rate/ or exp creatinine/ or exp kidney function tests/ or exp cystatins/ or exp kidney diseases/ or kidney\$.ti. or nephr\$.ti. or renal.ti. or exp kidney/

- 6 3 and 4 and 5
- 7 exp animals/ not humans.sh.
- 8 6 not 7
- 9 limit 8 to english language
- 10 limit 9 to yr="1985 -Current"
- 11 limit 10 to "all child (0 to 18 years)"
- 12 limit 10 to "all adult (19 plus years)"
- 13 11 not 12
- 14 10 not 13

Treatment (KQ5, KQ6)

Database: Ovid MEDLINE(R)

Search Strategy:

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- 1 exp albuminuria/co, de, dh, dt, mo, pc, th or exp proteinuria/co, de, dh, dt, mo, pc, th or exp glomerular filtration rate/ or exp kidney diseases/co, de, dh, dt, mo, pc, th or exp kidney/co, de, dh, dt, mo, pc, th or exp diabetic nephropathies/co, de, dh, dt, mo, pc, th or exp kidney failure, chronic/co, de, dh, dt, mo, pc, th or exp chronic renal insufficiency/co, de, dh, dt, mo, pc, th or exp renal insufficiency/co, de, dh, dt, mo, pc, th or exp renal insufficiency, chronic/co, de, dh, dt, mo, pc, th
 - 2 exp *renal replacement therapy/ or exp renal dialysis/ or exp *kidney neoplasms/ or *nephritis/ or exp *urinary tract infections/ or exp *urolithiasis/ or exp anuria/ or exp diabetes insipidus/ or exp fanconi syndrome/ or exp hepatorenal syndrome/ or exp hydronephrosis/ or exp kidney cortex necrosis/ or exp Kidney Diseases, Cystic/ or kidney papillary necrosis/ or exp nephritis/ or exp renal artery obstruction/ or exp Renal Tubular Transport, Inborn Errors/ or exp Tuberculosis, Renal/ or exp Zellweger syndrome/ or exp AIDS-Associated Nephropathy/ or exp Hyperoxaluria/ or exp Nephrocalcinosis/ or exp Perinephritis/ or exp Renal Osteodystrophy/
 - 3 1 not 2
 - 4 (randomized controlled trial or controlled clinical trial).pt. or random*.ti.ab. or placebo.ab. or exp Double-Blind Method/ or randomized controlled trials as topic/
 - 5 3 and 4
 - 6 exp animals/ not humans.sh.
 - 7 5 not 6
 - 8 limit 7 to english language
 - 9 limit 8 to yr="1985 -Current"
 - 10 limit 9 to "all child (0 to 18 years)"
 - 11 limit 9 to "all adult (19 plus years)"
 - 12 10 not 11
 - 13 9 not 12

Appendix B. Excluded Studies

(Note that this set of references is different from those in the text, and the numbers are different.)

CKD screening (KQ1, KQ2)

1. Microalbuminuria in type I diabetic patients. Prevalence and clinical characteristics. Microalbuminuria Collaborative Study Group. *Diabetes Care* 1992; 15(4):495-501. *Not a randomized trial*
2. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. *New England Journal of Medicine* 1993; 329(14):977-86. *Not an intervention for screening for CKD*
3. The relationship of glycemic exposure (HbA1c) to the risk of development and progression of retinopathy in the diabetes control and complications trial. *Diabetes* 1995; 44(8):968-83. *Not a randomized trial*
4. Effects of ramipril on cardiovascular and microvascular outcomes in people with diabetes mellitus: results of the HOPE study and MICRO-HOPE substudy. Heart Outcomes Prevention Evaluation Study Investigators. *Lancet* 2000; 355(9200):253-9. *Not an intervention for screening for CKD*
5. Abetimus: Abetimus sodium, LJP 394. *Biodrugs* 2003; 17(3):212-5. *Less than 1000 patients in study*
6. Accetta NA, Gladstone EH, DiSogra C, et al. Prevalence of estimated GFR reporting among US clinical laboratories. *American Journal of Kidney Diseases* 2008; 52(4):778-87. *Not a randomized trial*
7. Adler AI, Stevens RJ, Manley SE, et al. Development and progression of nephropathy in type 2 diabetes: the United Kingdom Prospective Diabetes Study (UKPDS 64). *Kidney International* 2003; 63(1):225-32. *Not an intervention for screening for CKD*
8. Agarwal A, Silver MR, Walczyk M, et al. Once-monthly darbepoetin alfa for maintaining hemoglobin levels in older patients with chronic kidney disease. *Journal of the American Medical Directors Association* 2007; 8(2):83-90. *Not a randomized trial*
9. Agodoa LY, Francis ME, Eggers PW. Association of analgesic use with prevalence of albuminuria and reduced GFR in US adults. *American Journal of Kidney Diseases* 2008; 51(4):573-83. *Not a randomized trial*
10. Agrawal A, Sautter MC, Jones NP. Effects of rosiglitazone maleate when added to a sulfonylurea regimen in patients with type 2 diabetes mellitus and mild to moderate renal impairment: a post hoc analysis. *Clinical Therapeutics* 2003; 25(11):2754-64. *Duration of follow-up less than 1 year*
11. Ahmedani MY, Hydrie MZI, Iqbal A, et al. Prevalence of microalbuminuria in type 2 diabetic patients in Karachi: Pakistan: a multi-center study. [Erratum appears in *J Pak Med Assoc.* 2005 Nov;55(11):523]. [Erratum appears in *J Pak Med Assoc.* 2005 Dec;55(12):570]. *JPMA - Journal of the Pakistan Medical Association* 2005; 55(9):382-6. *Not a randomized trial*
12. Ahn CW, Song YD, Kim JH, et al. The validity of random urine specimen albumin measurement as a screening test for diabetic nephropathy. *Yonsei Medical Journal* 1999; 40(1):40-5. *Less than 1000 patients in study*
13. Akanji AO, Mainasara AS, Akinlade KS. Urinary iodine excretion in mothers and their breast-fed children in relation to other childhood nutritional parameters. *European Journal of Clinical Nutrition* 1996; 50(3):187-91. *Not an intervention for screening for CKD*
14. Al-Maskari F, El-Sadig M, Obineche E. Prevalence and determinants of microalbuminuria among diabetic patients in the United Arab Emirates. *BMC Nephrology* 2008; 9:1. *Not a randomized trial*
15. Alsuwaida A, Abdulkareem A, Alwakeel J. The Gulf Survey on Anemia Management (GSAM 2005). *Saudi Journal of Kidney Diseases & Transplantation* 2007; 18(2):206-14. *Patients already diagnosed with CKD*
16. Amato D, Alvarez-Aguilar C, Castaneda-Limones R, et al. Prevalence of chronic kidney disease in an urban Mexican population. *Kidney International - Supplement* 2005; (97):S11-7. *Not a randomized trial*
17. Andrassy J, Zeier M, Andrassy K. Do we need screening for thrombophilia prior to kidney transplantation? *Nephrology Dialysis Transplantation* 2004; 19 Suppl 4:iv64-8. *Not a randomized trial*
18. Atkins RC, Briganti EM, Zimmet PZ, et al. Association between albuminuria and proteinuria in the general population: the AusDiab Study. *Nephrology Dialysis Transplantation* 2003; 18(10):2170-4. *Not a randomized trial*
19. Atthobari J, Asselbergs FW, Boersma C, et al. Cost-effectiveness of screening for albuminuria with subsequent foscipril treatment to prevent cardiovascular events: A pharmacoeconomic analysis linked to the prevention of renal and vascular endstage disease (PREVEND) study and the prevention of renal and vascular endstage disease intervention trial (PREVEND IT). *Clinical Therapeutics* 2006; 28(3):432-44. *Not an intervention for screening for CKD*
20. Atthobari J, Brantsma AH, Gansevoort RT, et al. The effect of statins on urinary albumin excretion and

- glomerular filtration rate: results from both a randomized clinical trial and an observational cohort study. *Nephrology Dialysis Transplantation* 2006; 21(11):3106-14. *Less than 1000 patients in study*
21. Aththobari J, Gansevoort RT, Visser ST, et al. The effect of screening for cardio-renal risk factors on drug use in the general population. *British Journal of Clinical Pharmacology* 2007; 64(6):810-8. *Not an intervention for screening for CKD*
 22. Awai K, Imuta M, Utsunomiya D, et al. Contrast enhancement for whole-body screening using multidetector row helical CT: comparison between uniphasic and biphasic injection protocols. *Radiation Medicine* 2004; 22(5):303-9. *Less than 1000 patients in study*
 23. Azizi M, Menard J, Peyrard S, et al. Assessment of patients' and physicians' compliance to an ACE inhibitor treatment based on urinary N-acetyl Ser-Asp-Lys-Pro determination in the Noninsulin-Dependent Diabetes, Hypertension, Microalbuminuria, Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) study. *Diabetes Care* 2006; 29(6):1331-6. *Not a randomized trial*
 24. Bakris G. Inclusion of albuminuria in hypertension and heart guidelines. *Kidney International - Supplement* 2004; (92):S124-5. *Not a randomized trial*
 25. Bakris G, Hester A, Weber M, et al. The diabetes subgroup baseline characteristics of the Avoiding Cardiovascular Events Through Combination Therapy in Patients Living With Systolic Hypertension (ACCOMPLISH) trial. *J Cardiometab Syndr* 2008; 3(4):229-33. *Not an intervention for screening for CKD*
 26. Bakris GL, Fonseca V, Katholi RE, et al. Differential effects of beta-blockers on albuminuria in patients with type 2 diabetes. *Hypertension* 2005; 46(6):1309-15. *Not an intervention for screening for CKD*
 27. Bang H, Mazumdar M, Newman G, et al. Screening for kidney disease in vascular patients: SCReening for Occult RENal Disease (SCORED) experience. *Nephrology Dialysis Transplantation* 2009; 24(8):2452-7. *Not a randomized trial*
 28. Barbanel CS, Winkelman JW, Fischer GA, et al. Confirmation of the Department of Transportation criteria for a substituted urine specimen. *Journal of Occupational & Environmental Medicine* 2002; 44(5):407-16. *Not a randomized trial*
 29. Barrett BJ, Katzberg RW, Thomsen HS, et al. Contrast-induced nephropathy in patients with chronic kidney disease undergoing computed tomography: a double-blind comparison of iodixanol and iopamidol.[Erratum appears in *Invest Radiol*. 2007 Feb;42(2):94 Note: Ni, Zhao-hui [added]]. *Investigative Radiology* 2006; 41(11):815-21. *Patients already diagnosed with CKD*
 30. Baskar V, Kamalakannan D, Holland MR, et al. Uncertain clinical utility of contemporary strategies for microalbuminuria testing. *Diabetes, Obesity & Metabolism* 2003; 5(4):262-6. *Not a randomized trial*
 31. Baxter GM, Aitchison F, Sheppard D, et al. Colour Doppler ultrasound in renal artery stenosis: intrarenal waveform analysis. *British Journal of Radiology* 1996; 69(825):810-5. *Not a randomized trial*
 32. Beatovic S, Jaksic ED, Han RS. Measurement of renal function by calculation of fractional uptake of technetium-99m dimercaptosuccinic acid. *Nucl Med Rev Cent East Eur* 2004; 7(1):49-52. *Not an intervention for screening for CKD*
 33. Beatty OL, Ritchie CM, Hadden DR, et al. Is a random urinary albumin concentration a useful screening test in insulin-treated diabetic patients? *Irish Journal of Medical Science* 1994; 163(9):406-9. *Not a randomized trial*
 34. Beaulieu AJ, Gohh RY, Han H, et al. Enhanced reduction of fasting total homocysteine levels with supraphysiological versus standard multivitamin dose folic acid supplementation in renal transplant recipients. *Arteriosclerosis, Thrombosis & Vascular Biology* 1999; 19(12):2918-21. *Patients already diagnosed with CKD*
 35. Beevers DG, Lip GY. Does non-malignant essential hypertension cause renal damage? A clinician's view. *Journal of Human Hypertension* 1996; 10(10):695-9. *Not a randomized trial*
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 37. Beresford TP, Blow FC, Hill E, et al. Comparison of CAGE questionnaire and computer-assisted laboratory profiles in screening for covert alcoholism. *Lancet* 1990; 336(8713):482-5. *Not an intervention for screening for CKD*
 38. Berland LL, Koslin DB, Routh WD, et al. Renal artery stenosis: prospective evaluation of diagnosis with color duplex US compared with angiography. Work in progress. *Radiology* 1990; 174(2):421-3. *Not a randomized trial*
 39. Berthoux P, Dejean C, Cecillon S, et al. High prevalence of hepatitis G virus (HGV) infection in renal transplantation. *Nephrology Dialysis Transplantation* 1998; 13(11):2909-13. *Not a randomized trial*
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 41. Bobrie G, Clerson P, Menard J, et al. Masked hypertension: a systematic review. *Journal of Hypertension* 2008; 26(9):1715-25. *Not a randomized trial*
 42. Boero R, Prodi E, Elia F, et al. How well are hypertension and albuminuria treated in type II diabetic patients? *Journal of Human Hypertension* 2003; 17(6):413-8. *Less than 1000 patients in study*

43. Bosmans JL, De Broe ME. Renovascular hypertension: diagnostic and therapeutic challenges. *Jbr-Btr: Organe de la Societe Royale Belge de Radiologie* 2004; 87(1):32-5. *Not a randomized trial*
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46. Boucher BA, Coffey BC, Kuhl DA, et al. Algorithm for assessing renal dysfunction risk in critically ill trauma patients receiving aminoglycosides. *American Journal of Surgery* 1990; 160(5):473-80. *Not a randomized trial*
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49. Budde RJ, Ke S, Levin VA. Activity of pp60c-src in 60 different cell lines derived from human tumors. *Cancer Biochemistry Biophysics* 1994; 14(3):171-5. *Not an intervention for screening for CKD*
50. Budney AJ, Hughes JR, Moore BA, et al. Marijuana abstinence effects in marijuana smokers maintained in their home environment. *Archives of General Psychiatry* 2001; 58(10):917-24. *Not a randomized trial*
51. Buhimschi CS, Norwitz ER, Funai E, et al. Urinary angiogenic factors cluster hypertensive disorders and identify women with severe preeclampsia. *American Journal of Obstetrics & Gynecology* 2005; 192(3):734-41. *Not a randomized trial*
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54. Buxbaum J, Tagoe C, Gallo G, et al. The pathogenesis of transthyretin tissue deposition: lessons from transgenic mice. *Amyloid* 2003; 10 Suppl 1:2-6. *Not a randomized trial*
55. Canani LH, Costa LA, Crispim D, et al. The presence of allele D of angiotensin-converting enzyme polymorphism is associated with diabetic nephropathy in patients with less than 10 years duration of Type 2 diabetes. *Diabetic Medicine* 2005; 22(9):1167-72. *Not a randomized trial*
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57. Cardiel MH, Tumlin JA, Furie RA, et al. Abetimus sodium for renal flare in systemic lupus erythematosus: results of a randomized, controlled phase III trial. *Arthritis & Rheumatism* 2008; 58(8):2470-80. *Not an intervention for screening for CKD*
58. Carter JL, O'Riordan SE, Eaglestone GL, et al. Chronic kidney disease prevalence in a UK residential care home population. *Nephrology Dialysis Transplantation* 2008; 23(4):1257-64. *Not a randomized trial*
59. Cathelineau G, de Champvallins M, Bouallouche A, et al. Management of newly diagnosed non-insulin-dependent diabetes mellitus in the primary care setting: effects of 2 years of gliclazide treatment--the Diadem Study. *Metabolism: Clinical & Experimental* 1997; 46(12 Suppl 1):31-4. *Not a randomized trial*
60. Chadban SJ, Briganti EM, Kerr PG, et al. Prevalence of kidney damage in Australian adults: The AusDiab kidney study. *Journal of the American Society of Nephrology* 2003; 14(7 Suppl 2):S131-8. *Not a randomized trial*
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62. Chan JC, So WY, Yeung CY, et al. Effects of structured versus usual care on renal endpoint in type 2 diabetes: the SURE study: a randomized multicenter translational study. *Diabetes Care* 2009; 32(6):977-82. *Not an intervention for screening for CKD*
63. Chan YL, Leung CB, Yu SC, et al. Comparison of non-breath-hold high resolution gadolinium-enhanced MRA with digital subtraction angiography in the evaluation on allograft renal artery stenosis. *Clinical Radiology* 2001; 56(2):127-32. *Patients already diagnosed with CKD*
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65. Chen N, Wang W, Huang Y, et al. Community-based study on CKD subjects and the associated risk factors. *Nephrology Dialysis Transplantation* 2009; 24(7):2117-23. *Not a randomized trial*
66. Chen Y-C, Chiu W-T, Wu M-S. Therapeutic effect of topical gamma-linolenic acid on refractory uremic pruritus. *American Journal of Kidney Diseases* 2006; 48(1):69-76. *Patients already diagnosed with CKD*

67. Chen Z-h, Wang G-h, Wang X-p, et al. Effects of warm-supplementing kidney yang (WSKY) capsule added on risperidone on cognition in chronic schizophrenic patients: a randomized, double-blind, placebo-controlled, multi-center clinical trial. *Human Psychopharmacology* 2008; 23(6):465-70. *Not an intervention for screening for CKD*
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69. Chow FY, Briganti EM, Kerr PG, et al. Health-related quality of life in Australian adults with renal insufficiency: a population-based study. *American Journal of Kidney Diseases* 2003; 41(3):596-604. *Not a randomized trial*
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74. Cohen SD, Norris L, Acquaviva K, et al. Screening, diagnosis, and treatment of depression in patients with end-stage renal disease. *Clinical Journal of The American Society of Nephrology: CJASN* 2007; 2(6):1332-42. *Patients already diagnosed with CKD*
75. Col M, Ocaktan E, Ozdemir O, et al. Microalbuminuria: prevalence in hypertensives and diabetics. *Acta Medica Austriaca* 2004; 31(1):23-9. *Not a randomized trial*
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82. Craig KJ, Donovan K, Munnery M, et al. Identification and management of diabetic nephropathy in the diabetes clinic. *Diabetes Care* 2003; 26(6):1806-11. *Not a randomized trial*
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86. Cusick M, Meleth AD, Agron E, et al. Associations of mortality and diabetes complications in patients with type 1 and type 2 diabetes: early treatment diabetic retinopathy study report no. 27. *Diabetes Care* 2005; 28(3):617-25. *Not a randomized trial*
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90. de Silva R, Nikitin NP, Bhandari S, et al. Atherosclerotic renovascular disease in chronic heart failure: should we intervene? *European Heart Journal* 2005; 26(16):1596-605. *Not a randomized trial*
91. de Zeeuw D, Parving HH, Henning RH. Microalbuminuria as an early marker for cardiovascular disease. *Journal of the American Society of Nephrology* 2006; 17(8):2100-5. *Not a randomized trial*
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 99. Doig JK, MacFadyen RJ, Sweet CS, et al. Haemodynamic and renal responses to oral losartan potassium during salt depletion or salt repletion in normal human volunteers. Journal of Cardiovascular Pharmacology 1995; 25(4):511-7. *Not an intervention for screening for CKD*
 100. Dunn PJ, Jury DR. Random urine albumin:creatinine ratio measurements as a screening test for diabetic microalbuminuria--a five year follow up. New Zealand Medical Journal 1990; 103(902):562-4. *Not a randomized trial*
 101. Ejerblad E, Fored CM, Lindblad P, et al. Obesity and risk for chronic renal failure. Journal of the American Society of Nephrology 2006; 17(6):1695-702. *Not a randomized trial*
 102. Eleftheriadis T, Tsiaga P, Antoniadi G, et al. The value of serum antilipoarabinomannan antibody detection in the diagnosis of latent tuberculosis in hemodialysis patients. American Journal of Kidney Diseases 2005; 46(4):706-12. *Patients already diagnosed with CKD*
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Appendix C. Evidence Tables and Other Supporting Tables and Figures

Tables

Table C1	Overview of ACEI monotherapy versus control treatment trials	6
Table C2	Summary of study baseline characteristics for ACEI monotherapy versus control treatment trials	26
Table C3	Clinical outcomes (outcomes part A), ACEI monotherapy versus control treatment trials	28
Table C4	Clinical outcomes (outcomes part B), ACEI monotherapy versus control treatment trials	47
Table C5	Composite vascular outcome definitions for ACEI monotherapy versus control treatment trials	50
Table C6	Clinical renal outcomes (outcomes part C), ACEI monotherapy versus control treatment trials	51
Table C7	Composite renal outcome definitions for ACEI monotherapy versus control treatment trials	53
Table C8	Study withdrawals and adverse events (Outcomes Part D), ACEI monotherapy versus control treatment trials.....	54
Table C9	Overview of ARB monotherapy trials	57
Table C10	Summary of study baseline characteristics for ARB monotherapy trials	62
Table C11	Clinical outcomes (outcomes part A), ARB monotherapy trials	63
Table C12	Clinical outcomes (outcomes part B), ARB monotherapy trials	68
Table C13	Composite vascular outcome definitions for ARB monotherapy trials	69
Table C14	Clinical renal outcomes (outcomes part C), ARB monotherapy trials	70
Table C15	Composite renal outcome definitions for ARB monotherapy trials	71
Table C16	Study withdrawals and adverse events (outcomes part D), ARB monotherapy trials	72
Table C17	Overview of ACEI plus ARB versus ACEI trials.....	73
Table C18	Summary of study baseline characteristics for ACEI plus ARB combination trials	77
Table C19	Clinical outcomes (outcomes part A), ACEI plus ARB versus ACEI or ARB trials	78
Table C20	Clinical outcomes (outcomes part B), ACEI plus ARB versus ACEI or ARB trials	79
Table C21	Composite vascular outcome definitions for ACEI plus ARB versus ACEI or ARB trials.....	82
Table C22	Renal outcomes (outcomes part C), ACEI plus ARB versus ACEI or ARB trials	83
Table C23	Study withdrawals and adverse events (outcomes part D), ACEI plus ARB versus ACEI or ARB trials	84
Table C24	Overview of ACEI plus ARB versus ARB trials.....	86
Table C25	Overview of ACE plus ARB versus ACE plus aldosterone antagonist trial	90
Table C26	Clinical outcomes (outcomes part A), ACE plus ARB versus ACE plus aldosterone antagonist trial	91
Table C27	Clinical renal outcomes (outcomes part C), ACE plus ARB versus ACE plus aldosterone antagonist trial	93

Table C28	Study withdrawals and adverse events (outcomes part D), ACE plus ARB vs ACE plus aldosterone antagonist trial	93
Table C29	Overview of ACEI plus CCB versus ACEI monotherapy or CCB monotherapy trial.....	94
Table C30	Clinical outcomes (outcomes part A), ACEI plus CCB versus ACEI monotherapy or CCB monotherapy trial	96
Table C31	Clinical outcomes (outcomes part B), ACEI plus CCB vs. ACEI monotherapy or CCB monotherapy trial	96
Table C32	Study withdrawals and adverse events (outcomes part D), ACEI plus CCB versus ACEI monotherapy or CCB monotherapy	101
Table C33	Overview of ACEI plus diuretic versus ACEI plus Calcium CCB trial	102
Table C34	Clinical outcomes (outcomes part A), ACEI plus diuretic versus ACEI plus CCB trial	103
Table C35	Clinical outcomes (outcomes part B), ACEI plus diuretic versus ACEI plus CCB trial	103
Table C36	Clinical renal outcomes (outcomes part C), ACEI plus diuretic versus ACEI plus CCB trial	103
Table C37	Study withdrawals and adverse events (outcomes part D), ACEI plus diuretic versus ACEI plus CCB trial.....	105
Table C38	Overview of ACEI plus diuretic versus ACEI trial	106
Table C39	Clinical outcomes (outcomes part B), ACEI plus diuretic versus ACEI plus placebo trial.....	107
Table C40	Composite vascular outcome definitions, ACEI plus diuretic versus ACEI plus placebo trial.....	107
Table C41	Study withdrawals and adverse events (outcomes part D), ACEI plus diuretic vs. ACEI plus placebo trial.....	109
Table C42	Overview of ARB versus ARB Trials	110
Table C43	Clinical outcomes (outcomes part A), ARB versus ARB trials.....	113
Table C44	Clinical outcomes (outcomes part B), ARB versus ARB trials.....	113
Table C45	Clinical renal outcomes (outcomes part C), ARB versus ARB trials	114
Table C46	Study withdrawals and adverse events (outcomes part D), ARB versus ARB trials	115
Table C47	Summary of study baseline characteristics for ARB versus ARB trials.....	116
Table C48	Composite vascular outcome definitions, ARB versus ARB trials	120
Table C49	Composite renal outcome definitions, ARB versus ARB trials	120
Table C50	Overview of ACEI plus aldosterone antagonist versus ACEI trial.....	121
Table C51	Clinical outcomes (outcomes part A), ACEI plus aldosterone antagonist versus ACEI plus placebo trial	122
Table C52	Clinical outcomes (outcomes part B), ACEI plus aldosterone antagonist versus ACEI plus placebo trial	122
Table C53	Study withdrawals and adverse events (outcomes part D), ACEI plus aldosterone antagonist vs. ACEI plus placebo trial	124
Table C54	Overview of ACEI/ARB plus aldosterone antagonist versus ACEI/ARB plus placebo trial.....	125
Table C55	Clinical outcomes (outcomes part A), ACEI/ARB plus aldosterone antagonist versus ACEI/ARB plus placebo trial.....	126

Table C56	Study withdrawals and adverse events (outcomes part D), ACEI/ARB plus aldosterone antagonist versus ACEI/ARB plus placebo trial	128
Table C57	Overview of beta blocker versus placebo trial.....	129
Table C58	Clinical outcomes (outcomes part A), beta blocker versus placebo trial	131
Table C59	Clinical outcomes (outcomes part B), beta blocker versus placebo trial.....	131
Table C60	Composite vascular outcome definitions, BB versus placebo trial.....	131
Table C61	Study withdrawals and adverse events (outcomes part D), beta blocker versus placebo trial	133
Table C62	Overview of CCB versus placebo trials.....	134
Table C63	Summary of study baseline characteristics, CCB versus placebo trials	136
Table C64	Clinical outcomes (outcomes part A), CCB versus placebo trials.....	137
Table C65	Clinical outcomes (outcomes part B), CCB versus placebo trials.....	141
Table C66	Composite vascular outcome definitions, CCB versus placebo trials	141
Table C67	Clinical renal outcomes (outcomes part C), CCB versus placebo trials.....	142
Table C68	Composite renal outcome definitions, CCB vs. placebo trials	142
Table C69	Study withdrawals and adverse events (outcomes part D), CCB versus placebo trials.....	143
Table C70	Overview of diuretic versus placebo trial	144
Table C71	Clinical outcomes (outcomes part A), diuretic versus placebo trial	145
Table C72	Clinical outcomes (outcomes part B), diuretic versus placebo trial	145
Table C73	Composite vascular outcome definitions, diuretic versus placebo trial.....	147
Table C74	Study withdrawals and adverse events (outcomes part D), diuretic versus placebo trial.....	147
Table C75	Overview of ACEI versus conventional therapy without ACEI trial	148
Table C76	Clinical outcomes (outcomes part A), ACEI versus conventional therapy without ACEI trial	149
Table C77	Clinical renal outcomes (outcomes part C), ACEI versus conventional therapy without ACEI trial	149
Table C78	Composite renal outcome definitions, ACEI versus conventional therapy without ACEI trial	149
Table C79	Study withdrawals and adverse events (outcomes part D), ACEI versus conventional therapy without ACEI trial.....	151
Table C80	Overview of CCB versus BB trials.....	152
Table C81	Summary of study baseline characteristics, CCB versus BB trials	155
Table C82	Clinical outcomes (outcomes part A), CCB versus BB trials.....	156
Table C83	Clinical outcomes (outcomes part B), CCB versus BB trials.....	156
Table C84	Composite vascular outcome definitions, CCB versus BB trials	157
Table C85	Clinical renal outcomes (outcomes part C), CCB versus BB trials	160
Table C86	Study withdrawals and adverse events (outcomes part D), CCB versus BB trials	161
Table C87	Overview of CCB versus diuretic trial.....	162
Table C88	Summary of study baseline characteristics, CCB versus diuretic trial	163
Table C89	Clinical outcomes (outcomes part A), CCB versus diuretic trial.....	164
Table C90	Clinical outcomes (outcomes part B), CCB versus diuretic trial.....	164
Table C91	Clinical renal outcomes (outcomes part C), CCB versus diuretic trial	165
Table C92	Composite renal outcome definitions, CCB versus diuretic trial	168
Table C93	Overview of strict versus standard blood pressure control trials.....	169

Table C94	Summary of study baseline characteristics, strict versus standard blood pressure control trials	174
Table C95	Clinical outcomes (outcomes part A), strict versus standard blood pressure control trials	175
Table C96	Clinical outcomes (outcomes part B), strict versus standard blood pressure control trials	178
Table C97	Composite vascular outcome definitions, strict versus standard blood pressure control trials	178
Table C98	Clinical renal outcomes (outcomes part C), strict versus standard blood pressure control trials	179
Table C99	Composite renal outcome definitions, strict versus standard blood pressure control trials	180
Table C100	Study withdrawals and adverse events (outcomes part D), strict versus standard blood pressure control trials	181
Table C101	Overview of low protein diet versus usual protein diet and other dietary intervention trials	183
Table C102	Summary of study baseline characteristics for low protein diet versus usual protein diet and other dietary intervention studies	190
Table C103	Clinical outcomes (outcomes part A), low protein diet versus usual protein diet and other dietary intervention trials	191
Table C104	Clinical outcomes (outcomes part B), low protein diet versus usual protein diet and other dietary intervention trials	196
Table C105	Clinical renal outcomes (outcomes part C), low protein diet versus usual protein diet and other dietary intervention trials	197
Table C106	Study withdrawals and adverse events (outcomes part D), low protein diet versus usual protein diet and other dietary intervention trials	198
Table C107	Overview of glycemic control trials	200
Table C108	Summary of study baseline characteristics for glycemic control trials	202
Table C109	Clinical outcomes (outcomes Part A), glycemic control trials	203
Table C110	Clinical renal outcomes (outcomes part C), glycemic control trials	203
Table C111	Composite vascular outcome definitions, glycemic control trials	203
Table C112	Study withdrawals and adverse events (outcomes part D), glycemic control trials	205
Table C113	Overview of anti-lipid trials	206
Table C114	Summary of study baseline characteristics, anti-lipid (AL) monotherapy versus control treatment trials	217
Table C115	Clinical outcomes (outcomes part A), AL monotherapy versus control treatment trials	219
Table C116	Clinical outcomes (outcomes part B), AL monotherapy versus control treatment trials	233
Table C117	Composite vascular outcome definitions, AL monotherapy versus control treatment trials	235
Table C118	Clinical renal outcomes (outcomes part C), AL monotherapy versus control treatment trials	237
Table C119	Composite renal outcome definitions for AL trials	239
Table C120	Study withdrawals and adverse events (outcomes part D), AL monotherapy versus control treatment trials	240

Table C121	Overview of INT versus control treatment trials	243
Table C122	Summary of study baseline characteristics for INT versus control treatment trials	247
Table C123	Clinical outcomes (outcomes part A), INT versus control treatment trials	248
Table C124	Clinical outcomes (outcomes part B), INT versus control treatment trials	253
Table C125	Composite vascular outcome definitions for INT versus control treatment trials	254
Table C126	Clinical renal outcomes (outcomes part C), INT versus control treatment trials	255
Table C127	Composite renal outcome definitions for INT versus control treatment trials	255
Table C128	Study withdrawals and adverse events (outcomes part D), INT versus control treatment trials	256
Table C129	Assessment of individual study quality for KQ5 and KQ6	257

Figures

Figure C1	Forest plots for ACEI monotherapy versus control treatment trials	31
Figure C2	Forest plots for ARB monotherapy trials	64
Figure C3	Forest plots for ACEI plus ARB versus ACEI trials	80
Figure C4	Forest plots for ACEI plus ARB versus ARB trials	89
Figure C5	Forest plots for ACEI plus ARB versus ACEI plus aldosterone antagonist trial	92
Figure C6	Forest plots for ACEI plus CCB versus ACEI monotherapy trial	97
Figure C7	Forest plots for ACEI plus CCB versus CCB monotherapy trial	99
Figure C8	Forest plots for ACEI plus Diuretic versus ACEI plus CCB	104
Figure C9	Forest plot for ACEI plus Diuretic versus ACEI plus placebo trial	108
Figure C10	Forest plots for ARB versus ARB trials	117
Figure C11	Forest plots for ACEI plus aldosterone antagonist vs. ACEI plus placebo trial	123
Figure C12	Forest plot for ACEI/ARB plus aldosterone antagonist versus ACEI/ARB plus placebo trial	127
Figure C13	Forest plots for BB versus placebo trial	132
Figure C14	Forest plots for CCB versus placebo trials	138
Figure C15	Forest plots for diuretic versus placebo trial	146
Figure C16	Forest plots for ACEI versus conventional therapy without ACEI trial	150
Figure C17	Forest plots for CCB versus BB trials	158
Figure C18	Forest plots for CCB versus diuretic trial	166
Figure C19	Forest plots for strict versus standard blood pressure control trials	176
Figure C20	Forest plots for low protein diet versus usual protein diet and other diet intervention trials	192
Figure C21	Forest plot for glycemic control trials	204
Figure C22	Forest plots for anti-lipid monotherapy versus control trials and subgroup analyses	221
Figure C23	Forest plots for INT versus control trials	249
References for Appendix C		261

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
ACE inhibitor monotherapy versus placebo/no treatment trials (n=17 trials)				
Perkovic, 2007 ¹ PROGRESS	Inclusion Criteria: history of cerebrovascular disease (ischemic stroke, hemorrhagic stroke, or transient ischemic attack but not subarachnoid hemorrhage) within the previous 5 years and no clear indication for or contraindication to treatment with an ACE inhibitor.	N=1757 patients with CKD (Baseline GFR <60 ml/min/ 1.73m ²) of 6105 randomized. Age (yr): 70 Gender (Male %): 55 Race/Ethnicity (%): Asian 37 BMI: 24 Systolic BP (mm Hg): 149 Diastolic BP (mm Hg): 84 Serum creatinine (mg/dL): 1.2 (median) Creatinine clearance (ml/min/1.73m ²) (median): 50 Estimated GFR (ml/min/1.73m ²): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 11 History of HTN (%): NR (study reported 53% on HTN medication but did not report prevalence of untreated HTN) History of CHD (%): 20 History of CHF (%): NR History of MI (%): NR History of Stroke (ischemic) (%): 71 History of Stroke (hemorrhagic) (%): 10 History of transient ischemic attack (%): 22 Peripheral arterial disease (%): NR Current smoker (%): 16	Perindopril 4 mg/d (n=895) Placebo (n=862) Followup period: mean 4 years Study withdrawals (%): NR	Allocation Concealment: adequate (central) Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: NA, post hoc analysis
Multinational (Europe, Asia, Australia)	Exclusion Criteria: not described.			
Funding Source: Industry and other				
Asselbergs, 2004 ² PREVEND IT	Inclusion Criteria: persistent microalbuminuria (urinary albumin concentration >10 mg/L in 1 early morning spot urine sample and a concentration of 15 to 300 mg/24 hours in 2 24-hour urine samples at least once); BP <160/100 mm Hg and no use of antihypertensive medication; total cholesterol level <8.0 mmol/L, or <5.0 mmol/L in case of previous MI, and no use of lipid-lowering medication.	N=864 Age (yr): 51 Gender (Male %): 65 Race/Ethnicity (%): white 96 BMI: 26 Systolic BP (mm Hg): 130 Diastolic BP (mm Hg): 76 Albuminuria (mg/24 h): 23 Serum creatinine (mg/dL): 1 Estimated GFR (ml/min/1.73m ²): NR Total cholesterol (mg/dL): 222 LDL cholesterol (mg/dL): 157 Diabetes (%): 2.5	Fosinopril 20 mg/d (n=431) Placebo (n=433) Followup period: mean 3.8 years Study withdrawals (%): 28 Note: 2 x 2 factorial design with pravastatin	Allocation Concealment: unclear Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes
The Netherlands				
Funding Source: Industry and other				

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	Exclusion Criteria: creatinine clearance <60% of the normal age adjusted value; use of ACE inhibitors or ARB antagonists.	History of HTN (%): 0 (exclusion criterion) History of CVD (%): NR History of CHF (%): 0 History of MI (%): 0.5 History of Stroke (%): 0.8 Peripheral arterial disease (%): 0.6 Current/ever smoker (%): 73		
Marre, 2004 ³ DIABHYCAR	Inclusion Criteria: persistent micro-albuminuria or proteinuria (urinary albumin excretion ≥20 mg/L, in two successive random urine samples); <50 years of age; and type 2 diabetes (defined on the basis of receiving current treatment with at least one oral antidiabetic agent). Exclusion Criteria: serum creatinine concentration >150 mmol/L; treatment with insulin, an ACE inhibitor, or ARB blocker; documented CHF; MI during the past three months; urinary tract infection; previous intolerance to an ACE inhibitor.	N=4,912 Age (yr): 65 Gender (Male %): 70 Race/Ethnicity (%): NR BMI: 29 Systolic BP (mm Hg): 145 Diastolic BP (mm Hg): 82 Microalbuminuria (%): 74 Proteinuria (%): 26 Serum creatinine (mg/dL): 1.0 Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 7.8 Diabetes (%): 100 History of HTN (%): 56 History of CVD (%): 24 History of CHF (%): 0 History of MI (%): 6 History of Stroke (%): 4 Peripheral arterial disease (%): 10 Current smoker (%): 15	Ramipril 1.25 mg/d (n=2443) Placebo (n=2469) Followup period: median 4 years Study withdrawals (%): 17	Allocation Concealment: adequate Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes
Multinational (Europe and North Africa) Funding Source: Industry and other				
Katayama, 2002 ⁴ JAPAN-IDDM Sarafidis review Japan	Inclusion Criteria: UAE >30 mg/24 h at the time of screening in two consecutive sterile urine samples collected overnight; onset of type 1 diabetes before 20 years; and aged between 20 and 50 years of age. Exclusion Criteria: none stated.	N=53 (imdadpril arm excluded) Age (yr): 33 Gender (Male %): 35 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 127 Diastolic BP (mm Hg): 78 Albumin excretion rate (mg/day): 711 Serum creatinine (mg/dL): 0.76 Creatinine clearance (ml/min): 98.4 Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 8.8 Diabetes (%): 100 History of HTN (%): 18 History of CAD (%): NR	Captopril 37.5 mg (n=26) Placebo (n=27) Followup period: mean 1.5 years Study withdrawals (%): 30 (excluding subjects reaching endpoint)	Allocation Concealment: adequate Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Bojestig, 2001 ⁵ Sarafidis review Sweden Funding Source: Industry	Inclusion Criteria: microalbuminuria (AER of 20–200 µg/min in two of three collections); type 1 diabetes; and normotensive (clinic diastolic <90 mmHg). Exclusion Criteria: Patients treated with any form of hypertensive medication.	History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR N=55 Age (yr): 40 Gender (Male %): 75 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 126 (clinic) Diastolic BP (mm Hg): NR Albumin excretion rate (µg/min): median 69-103 Estimated GFR (ml/min/1.73m ²): median 100-108 HbA _{1c} (%): 7.4 Diabetes (%): 100 History of HTN (%): 0 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Ramipril 1.25 mg/d (n=19) Ramipril 15 mg/d (n=18) Placebo (n=18) Followup period: 2 years Study withdrawals (%): 7	Allocation Concealment: unclear Blinding: double Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes
Gerstein HOPE Trial, 2001 ⁶ Multinational (North and South America and in Europe) Funding Source: Industry and other	Inclusion Criteria: ≥55 years of age; history of CV disease (either CAD, stroke, or PVD) or with a history of DM; plus at least one other CV risk factor (total cholesterol >200 mg/dL, high-density lipoprotein cholesterol ≤35mg/dL, HTN, known microalbuminuria, or current smoker. Microalbuminuria was defined as an ACR of ≥2mg/mmol for both men and women; dipstick-positive (ie, ≥1+) proteinuria Exclusion Criteria: heart failure; intolerance of ACE inhibitors or vitamin E; serum creatinine concentration >200 mmol/L (2.3	N=1,140 patients with diabetes and microalbuminuria (urinary albumin-creatinine ratio >2mg/mmol, but not dipstick positive [≥1+] proteinuria) from 1963 with microalbuminuria and 9297 randomized overall in the larger HOPE trial. Patient characteristics not described for microalbuminuric subjects	Ramipril 10 mg/d (n=553) Placebo (n=587) Followup period: median 4.5 years Study withdrawals (%): NR Note: 2 x 2 factorial design with vitamin E.	Allocation Concealment: adequate (from background paper Can J Cardiol) Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: NA, post hoc analysis

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	mg/dL), or dipstick-positive proteinuria (>+1)			
O'Hare, 2000/ ATLANTIS	Inclusion Criteria: microalbuminuria, defined as overnight AER on screening of 20–200 µg/min in two of three collections; type 1 diabetes; and untreated blood pressure <150/90 mmHg for patients <50 years of age and <165/90 mmHg for patients 50–65 years of age.	N=140 Age (yr): 40 Gender (Male %): 71 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 132 Diastolic BP (mm Hg): 76 Albumin excretion rate (µg/min): 53 Estimated GFR (ml/min/1.73m ²): 104 HbA _{1c} (%): 11.4 Diabetes (%): 100 History of HTN (%): 0 (HTN was exclusion criterion) History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Ramipril 1.25 mg/d (n=47) Ramipril 5 mg/d (n=45) Placebo (n=48) Followup period: 2 years Study withdrawals (%): 30	Allocation Concealment: adequate Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
UK and Ireland Funding Source: Industry	Exclusion Criteria: those pregnant or lactating; were women of child-bearing potential not using adequate contraception; were on concomitant therapy for HTN; were on one or more nonsteroidal anti-inflammatory drugs; history of drug or alcohol abuse; had other known renal diseases or raised creatinine levels (>120 µmol/L) or liver function twice that of normal on repeat testing; or had iodine sensitivity, making them unable to partake in GFR measurements.			
Muirhead, 1999 ⁸ Kunz review	Inclusion Criteria: incipient diabetic nephropathy, defined as AER between 20 to 300 µg/min and a GFR 60 ≥ ml/min/1.73m ² at visit 1; aged ≥18 years; type 2 DM;	N=60 (excluding valsartan arms) Age (yr): 56 Gender (Male %): 82 Race/Ethnicity (%): white 87, black 2, Asian 5 BMI: NR Systolic BP (mm Hg): 136 Diastolic BP (mm Hg): 84 Serum creatinine (mg/dL): NR Albumin excretion rate (µg/min): 53.4 Estimated GFR (ml/min/1.73m ²): 87 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR HbA _{1c} (%): NR Diabetes (%): 100 History of HTN (%): 47% on HTN medication History of CAD (%): NR History of CHF (%): NR	Captopril 75 mg/d (n=29) Placebo (n=31) Follow-up period: 1 year Study withdrawals (%): 18	Allocation Concealment: unclear Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
Canada Funding Source: Industry	Exclusion Criteria: "brittle" diabetes (increased risk of hypoglycemia) or patients with a history of noncompliance with medical regimens.			

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR		
Ruggenti, 1999 ⁹ REIN, proteinuria stratum 1: ≥1 g to <3g/24 h Italy Funding Source: Industry	Inclusion Criteria: chronic nephropathy; persistent proteinuria (≥1 g to <3 g); aged 18 to 70 years; has not received ACEI for 2 months, corticosteroids, NSAIDs, immunosuppressive drugs for 6 months. Exclusion Criteria: treatment with corticosteroids, nonsteroidal anti-inflammatory drugs, or immunosuppressive drugs; acute MI or cerebrovascular accident in the previous 6 months; severe uncontrolled hypertension (diastolic BP ≥115 and/or systolic BP ≥220 mm Hg); evidence or suspicion of renovascular disease, obstructive uropathy, insulin-dependent diabetes mellitus, collagen disease, cancer, higher serum aminotransferase concentrations, or chronic cough; drug or alcohol abuse; pregnancy; breast feeding; and ineffective contraception.	N=186 Age (yr): 50 Gender (Male %): 75 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 143 Diastolic BP (mm Hg): 89 Urinary protein excretion (g/day): 1.7 Serum creatinine (mg/dL): 2.0 Creatinine clearance (ml/min/1.73m ²): 52 Estimated GFR (ml/min/1.73m ²): 46 Total cholesterol (mg/dL): 229 Diabetes (%): NR History of HTN (%): 82 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Ramipril 1.25 mg/d (n=99) Placebo (n=87) Followup period: median 2.6 years Study withdrawals (%): 22 (excluding subjects reaching endpoint)	Allocation Concealment: adequate (based on GISEN report) Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes
Crepaldi, 1998 ¹⁰ Sarafidis review Italy Funding Source: None stated	Inclusion Criteria: overt albuminuria - median AER value between 20 and 200 µg/min from 3 timed overnight urine collections; GFR ≥80 ml/min/1.73m ² at randomization; aged 18 to 70 years; onset of insulin-dependent DM before age 35 and insulin treatment within 3 years of diagnosis; clinical stability of DM during past 12 months; standing systolic BP ≥115 and ≤145 mmHg (without HTN therapy) and diastolic BP ≥75 and ≤90 mmHg.	N=96 (66 included in the baseline characteristics and nifedipine arm excluded) Age (yr): 37 Gender (Male %): 67 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 128 Diastolic BP (mm Hg): 83 Albumin excretion rate (µg/min): 71.5 Serum creatinine (mg/dL): 0.98 Creatinine clearance (ml/min/1.73m ²): 114 Estimated GFR (ml/min/1.73m ²): 114 HbA _{1c} (%): 8.6	Lisinoprol 2.5-20 mg/d (n=47) Placebo (n=49) Followup period: 3 years Study withdrawals (%): 32 (includes 21 patients excluded for not having AER values between 20 and 200 µg/min)	Allocation Concealment: unclear Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

C-11

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	Exclusion Criteria: impaired renal function (defined as serum creatinine >10% above the upper limit of normal (125 µmol/L) and median AER >200 µg/min at entry and visit 3 after randomization); nondiabetic renal disease; hematuria; evidence of clinically significant liver or hematological disease; evidence of aortic or mitral valve obstruction; arrhythmias; unstable angina; history of MI within previous 3 months; systemic malignancy; hyperkalemia, serum triglycerides >3.4mmol/L, or total cholesterol >6.5 mmol/L.	Diabetes (%): 100 History of HTN (%): 0 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): 58		
The GISEN Group, 1997 ¹¹ REIN, proteinuria stratum 2: ≥3 g/24 h Italy Funding Source: Industry	Inclusion Criteria: chronic nephropathy; persistent proteinuria (≥3 g); aged 18 to 70 years; has not received ACEI for 2 months, corticosteroids, NSAIDS, immunosuppressive drugs for 6 months. Exclusion Criteria: treatment with corticosteroids, nonsteroidal anti-inflammatory drugs, or immunosuppressive drugs; acute MI or cerebrovascular accident in the previous 6 months; severe uncontrolled hypertension (diastolic blood pressure ≥115 and/or systolic blood pressure ≥220 mm Hg); evidence or suspicion of renovascular disease, obstructive uropathy, insulin-dependent diabetes mellitus, collagen disease, cancer, higher serum aminotransferase concentrations, or chronic cough; drug or alcohol abuse; pregnancy; breast feeding;	N=166 Age (yr): 49 Gender (Male %): 78 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 149 Diastolic BP (mm Hg): 92 Urinary protein excretion (g/day): 5.3 Serum creatinine (mg/dL): 2.4 Creatinine clearance (ml/min/1.73m ²): 45 Estimated GFR (ml/min/1.73m ²): 39 Diabetes (%): NR History of HTN (%): 87 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Ramipril 1.25 mg/d (n=78) Placebo (n=88) Followup period: mean 1.3 years Study withdrawals (%): 21 (excluding subjects reaching endpoint) Note: combined endpoint stratified by baseline AER	Allocation Concealment: adequate Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Maschio, 1996 ¹² Europe Funding Source: Industry	<p>and ineffective contraception.</p> <p>Inclusion Criteria: chronic renal insufficiency caused by various diseases (glomerular disease (in 192 patients), interstitial nephritis (in 105), nephrosclerosis (in 97), polycystic kidney disease (in 64), diabetic nephropathy (in 21) unknown (in 104)); aged 18 to 70 years; serum creatinine concentration of 1.5 to 4.0 mg/dL and a 24-hour estimated creatinine clearance of 30 to 60 ml/min, with variations of <30 percent in at least three measurements of creatinine clearance during a three-month screening period and <15 percent during a subsequent two-week, single-blind placebo period.</p> <p>Exclusion Criteria: therapy-resistant edema; treatment with corticosteroids, nonsteroidal antiinflammatory drugs, or immunosuppressive drugs; a value for urinary protein excretion over 10 g/24 h and a value for serum albumin under 25 g/L (each measured at least three times, and twice during the screening period); renovascular hypertension; malignant HTN or a MI or CVA in the six months preceding the study; congestive heart failure (New York Heart Association class III or IV); insulin-dependent DM; elevated serum amino-transferase concentrations; collagen disease; obstructive uropathy; cancer; chronic cough; history of allergy to ACEI; drug or alcohol abuse; and pregnancy.</p>	<p>N=583</p> <p>Age (yr): 51</p> <p>Gender (Male %): 72</p> <p>Race/Ethnicity (%): NR</p> <p>BMI: NR</p> <p>Systolic BP (mm Hg): 143</p> <p>Diastolic BP (mm Hg): 87</p> <p>Urinary protein excretion (g/day): 1.8</p> <p>Serum creatinine (mg/dL): 2.1</p> <p>Creatinine clearance (ml/min): 43</p> <p>Estimated GFR (ml/min/1.73m²): NR</p> <p>Diabetes (%): 4 (n=21) have diabetic nephropathy</p> <p>History of HTN (%): 82</p> <p>History of CAD (%): NR</p> <p>History of CHF (%): NR</p> <p>History of MI (%): NR</p> <p>History of Stroke (%): NR</p> <p>Peripheral arterial disease (%): NR</p> <p>Current smoker (%): NR</p> <p>Severity of renal dysfunction:</p> <p>Creatinine clearance 46 to 60 ml/min (%): 39</p> <p>Creatinine clearance 30 to 45 ml/min (%): 61</p>	<p>Benazepril 10 mg/d (n=300)</p> <p>Placebo (n=283)</p> <p>Followup period: median 3 years</p> <p>Study withdrawals (%): 23 (excluding subjects reaching endpoint)</p>	<p>Allocation Concealment: unclear</p> <p>Blinding: double, end points adjudicated by blinded committee</p> <p>Intention to Treat Analysis: yes</p> <p>Withdrawals/Dropouts adequately described: yes</p>

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Trevisan, 1995 ¹³ Italy Funding Source: Industry	Inclusion Criteria: persistent microalbuminuria (AER 20-200 µg/min at screening and in at least two of three consecutive sterile urine samples collected overnight); aged 18 to 65 years; had non-insulin-dependent DM (diagnosed according to World Health Organization criteria) of at least 6 months duration; had stable metabolic control with a glycated hemoglobin concentration <10%. Exclusion Criteria: systolic blood pressure was ≥180 mm Hg or diastolic blood pressure ≥105 mm Hg; unstable angina, heart failure; serum creatinine >1.5 mg/dL; history of poor compliance; high serum potassium levels (>5.5 mEq/L); or liver, gastrointestinal, and connective tissue diseases.	N=122 Age (yr): 57 Gender (Male %): 77 Race/Ethnicity: NR BMI: 29 Systolic BP (mm Hg): 149 Diastolic BP (mm Hg): 91 Albumin excretion rate (µg/min): 67 Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 7.1 Diabetes (%): 100 History of HTN (%): NR (among 108 who completed study, 43 (39.8%) had baseline BP ≥160/95 mm Hg) History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): 22	Ramipril 1.25 mg/d (n=60) Placebo (n=62) Followup period: 6 months Study withdrawals (%): 11	Allocation Concealment: unclear Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
Laffel, 1995 ¹⁴ North American Micro- albuminuria Study Sarafidis review USA and Canada Funding Source: Industry	Inclusion Criteria: microalbuminuria - overnight AER 20–200 µg/min; aged 14 to 57 years with at least 4 years documented insulin-dependent DM before age 45; normotensive Exclusion Criteria: HbA _{1c} ≥11.5%; body weight outside of 75% to 125% of ideal; serum creatinine and potassium levels beyond normal ranges; white blood cell count <3500/mm ³ ; BP ≥140/90 mm Hg; antihypertensive therapy; pregnancy/lactation; histories of renal, cardiac, hepatic, gastrointestinal, or autoimmune diseases. No use of CCB, beta-blockers, and non-steroidal agents.	N=143 Age (yr): 33 Gender (Male %): 50 Race/Ethnicity (%): white 92 BMI: NR Systolic BP (mm Hg): 140 Diastolic BP (mm Hg): 90 Albumin excretion rate (µg/min): 62 Serum creatinine (mg/dL): 1.1 Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (ml/min/1.73m ²): 80 HbA _{1c} (%): 7.8 Diabetes (%): 100 History of HTN (%): 0 History of CAD (%): 0 History of CHF (%): 0 History of MI (%): 0 History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): 29	Captopril 100 mg (n=70) Placebo (n=73) Followup period: 2 years Study withdrawals (%): 30	Allocation Concealment: unclear Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Sano 1994 ¹⁵ Sarafidis review Japan Funding Source: None stated	Inclusion Criteria: noninsulin dependent diabetes mellitus; persistent microalbuminuria (AER 20-300 mg/24 h on 3-4 separate occasions over a 3 month period; aged 50 to 76 years; serum creatinine <1.2 mg/dL; systolic BP <150 mmHg and diastolic <90 mmHg over a long period; HbA _{1c} <10%; no history of nondiabetic renal disease; no medications other than oral hypoglycemic agents. Exclusion Criteria: none stated.	N=52 (48 included in the baseline characteristics) Age (yr): 64 Gender (Male %): NR Race/Ethnicity (%): NR BMI: 24 Systolic BP (mm Hg): 136 Diastolic BP (mm Hg): 74 Albumin excretion rate (mg/day): 72 Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (ml/min): 90 HbA _{1c} (%): 8.2 Diabetes (%): 100 History of HTN (%): 0 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Enalapril (n=26) No enalapril (n=26) Followup period: 2 years Study withdrawals (%): 8	Allocation Concealment: unclear Blinding: no Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
Lewis, 1993 ¹⁶ USA Funding Source: Industry and other	Inclusion Criteria: urinary protein excretion of ≥ 500 mg/24 h, and a serum creatinine concentration of ≤ 2.5 mg/dL; aged 18 to 49 years; insulin-dependent DM for ≥7 years, with an onset before the age of 30 years, and had diabetic retinopathy; Patients satisfying these criteria during a single examination were eligible for the study, regardless of previous BP status or a previous need for antihypertensive medication. Patients who were receiving ACE inhibitors or CCBs were eligible provided their BP could be maintained within the BP goals required by the trial without these drugs Exclusion Criteria: pregnancy; dietary evaluation that indicated marked departure from standard dietary	N=409 Age (yr): 35 Gender (Male %): 53 Race/Ethnicity (%): white 89; black 7 BMI: NR Systolic BP (mm Hg): 138 Diastolic BP (mm Hg): 85 Urinary protein excretion (g/day): 2.7 Serum creatinine (mg/dL): 1.3 Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (ml/min): 82 HbA _{1c} (%): 11.7 Diabetes (%): 100 History of HTN (%): 76 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Captopril 75 mg (n=207) Placebo (n=202) Followup period: median 3 years Study withdrawals (%): 26	Allocation Concealment: unclear Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes

C-14

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	recommendations; white-cell count <2500 per cubic millimeter; CHF (New York Heart Association class III or worse); and serum potassium concentration of ≥ 6 mmol/L.			
Ravid, 1993 ¹⁷ Sarafidis review Israel Funding Source: Other	Inclusion Criteria: microalbuminuria (urinary protein excretion 30 to 300 mg/24h on two consecutive visits without evidence of a urinary tract infection; type 1 diabetes <10 years with no evidence of systemic, renal, cardiac, or hepatic disease; age <50 years; BMI <27; normal BP on two consecutive examinations (systolic ≤ 140 mm Hg; diastolic ≤ 90 mm Hg; Exclusion Criteria: none stated.	N=108 (94 included in the baseline characteristics) Age (yr): 44 Gender (Male %): 45 Race/Ethnicity (%): NR BMI: 24 Mean BP (mm Hg): 98 Proteinuria (mg/day): 133 Serum creatinine (mg/dL): 1.2 Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 10.4 Diabetes (%): 100 History of HTN (%): 0 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Enalapril 10 mg (n=56) Placebo (n=52) Followup period: 5 years Study withdrawals (%): 13	Allocation Concealment: unclear Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
ACE inhibitor monotherapy versus ARB trials (n=6 trials)				
Mann, 2008 ¹⁸ ONTARGET Multinational Funding Source: Industry	Inclusion Criteria: aged 55 years or older with established atherosclerotic vascular disease or with diabetes with endorgan damage. Exclusion Criteria: major renal artery stenosis, uncorrected volume or sodium depletion, a serum creatinine concentration above 265 μ mol/L, and uncontrolled hypertension (>160 mm Hg systolic or >100 mm Hg diastolic), symptomatic congestive heart failure..	N=4,046 for patients with a baseline GFR <60 ml/min/ 1.73m ² (of a total of 17,118 randomized to ramipril vs. telmisartan, and not including 8502 subjects randomized to combination ramipril + telmisartan). 2673 patients had micro or macroalbuminuria. Patient characteristics not described for CKD subjects	Ramipril 10 mg/day (n NR for CKD patients) Telmisartan 80 mg/day (n NR for CKD patients) Followup period: median 4.7 years Study withdrawals (%): NR	Allocation Concealment: adequate Blinding: double Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes
Menne, 2008 ¹⁹ VALERIA	Inclusion Criteria: microalbuminuria (urine albumin creatinine ratio for women ≥ 3.5 mg/ mmol/L and ≤ 35.0	N=90 (133 total with combination arm) Age (yr): 58 Gender (Male %): 69	Lisinopril 40 mg/d (n=47) Valsartan 320 mg/d	Allocation Concealment: adequate

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Germany and Hungary Funding Source: Industry	mg/mmol and men ≥ 2.5 mg/ mmol/L and ≤ 25.0 mg/ mmol/L); aged 18 to 75 years; essential hypertension [defined as mean sitting diastolic BP ≥ 85 mmHg and < 110 mm Hg]. To fulfill the criteria of microalbuminuria, two of three first morning void urines needed to be positive during the screening phase. Exclusion Criteria: primary kidney disease, renal impairment (creatinine clearance < 30 ml/min using the Cockcroft and Gault formula; serum potassium values > 5.5 mmol/L; heart failure, significant arrhythmias or bradycardia; relevant valvular disease, type I DM, uncontrolled type II DM with HbA _{1c} $> 8.0\%$; history of MI; percutaneous transluminal coronary angioplasty, bypass surgery or stroke within the last 12 months prior to study inclusion; unstable angina pectoris; renal transplantation; severe hepatic disease or hepatic failure; malignant concomitant diseases or history of malignant diseases within the last 5 years; systemic inflammatory diseases; pregnancy or breast feeding; psychiatric disease; either history of alcohol or drug abuse or both.	Race/Ethnicity (%): NR BMI: 32 Systolic BP (mm Hg): 153 Diastolic BP (mm Hg): 91 Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (mg/min): 112 Urine albumin creatinine ratio (mg/ mmol): 9.4 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR HbA _{1c} (%): NR Diabetes (%): 74 History of HTN (%): 100 History of CAD "Cardiac disorders"(%): 19 History of CHF (%): 0 (exclusion criterion) History of MI (%): 0 (exclusion criterion) History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	(n=43) <i>Lisinopril + Valsartan</i> (n=43) Followup period: 2.5 years Study withdrawals (%): 14	Blinding: double plus outcome assessors and data analysts Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
Sengul, 2006 ²⁰ Turkey Funding Source: none stated	Inclusion Criteria: Type 2 diabetes, microalbuminuria (AER rate 30 to 300 mg/24 h for a minimum of three consecutive occasions); aged 40 to 65 years; previously diagnosed hypertension (systolic BP ≥ 140 mm Hg or diastolic BP ≥ 90 mm Hg), despite receiving ACE inhibitor monotherapy for ≥ 6 months.	N=219 Age (yr): 57 Gender (Male %): 37 Race/Ethnicity (%): NR BMI: 30 Systolic BP (mm Hg): 151 Diastolic BP (mm Hg): 89 Urinary AER (mg/24 h): 260 Serum creatinine (mg/dL): 1	Lisinopril 20 mg/d (n=110) Telmisartan 80 mg/d (n=109) After 24 weeks, half of the patients receiving lisinopril were randomized to receive telmisartan in	Allocation Concealment: unclear Blinding: open-label Intention to Treat Analysis: no Withdrawals/Dropouts

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	Exclusion Criteria: type 1 DM; BMI ≥ 40; secondary diabetes; alcoholism; thyroid disease; systolic BP >200 mm Hg, any non-diabetic cause of secondary HTN (including bilateral renal artery stenosis); urinary tract infection; persistent hematuria; chronic liver disease; overt carcinoma; any cardiovascular event in the previous 6 months; serum creatinine ≥ 150 mmol/L; serum potassium ≥ 5.5 mmol/L; or pregnancy.	Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (mg/min): 97 Total cholesterol (mg/dL): 211 LDL cholesterol (mg/dL): 135 HbA _{1c} (%): 7.9 Diabetes (%): 100 History of HTN (%): 100 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): 37	addition. Similarly, half the patients initially treated with telmisartan received a combination of lisinopril plus telmisartan. The remaining patients continued to be treated with monotherapy. Followup period: 1 year Study withdrawals (%): 12	adequately described: yes
Barnett, 2004 ²¹ DETAIL Europe Funding Source: Industry	Inclusion Criteria: urinary albumin excretion rate (mean of three consecutive overnight values) between 11 and 999 µg per minute, with two values > 10 µg per minute; aged 35 to 80 years; type 2 DM treated by diet, diet plus oral hypoglycemic drugs (for at least one year), or insulin preceded by treatment with oral agents (also for at least one year). Among those treated with insulin, onset of diabetes had to have occurred after the age of 40 years with a BMI >25 at the time of diagnosis; mild-to-moderate HTN, with a resting BP of less than 180/95 mm Hg after ≥ 3 months of ACE-inhibitor therapy before entry into the study; normal renal morphology; glycosylated hemoglobin value <12 %; serum creatinine < 1.6 mg/dL; GFR > 70 ml/min/1.73m ² . Exclusion Criteria: any condition (other than cardiovascular disease) that could restrict long-term survival and known allergy to study drugs or	N=250 Age (yr): 61 Gender (Male %): 73 Race/Ethnicity (%): white 98 BMI: 31 Systolic BP (mm Hg): 152 Diastolic BP (mm Hg): 86 Microalbuminuria (%): 82 Macroalbuminuria (%): 18 Urinary AER (µg/min): median 46 to 60 Serum creatinine (mg/dL): 1 Estimated GFR (ml/min/1.73m ²): 93 Total cholesterol (mg/dL): 223 LDL cholesterol (mg/dL): 137 HbA _{1c} (%): 8.3 Diabetes (%): 100 History of HTN (%): 100 History of CVD (%): 49 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): 25	Enalapril 20 mg/d (n=130) Telmisartan 80 mg/d (n=120) Followup period: 5 years Study withdrawals (%): 33	Allocation Concealment: adequate Blinding: double Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Lacourcière, 2000 ²² Canada Funding Source: Industry	iohexol. Inclusion Criteria: early nephropathy characterized by a UAE rate 20 to 350 µg/min without evidence of urinary tract infection; type 2 diabetes diagnosed at 30 years of age or later; mild to moderate essential HTN (sitting diastolic BP 90 to 115 mm Hg); Exclusion Criteria: evidence or suspicion of renovascular disease; history of malignant hypertension; systolic BP > 210 mm Hg; cerebrovascular accident in the previous 12 months or current transient ischemic attacks; myocardial infarction within the previous 12 months; clinically significant arteriovenous (AV) conduction disturbances and/or arrhythmias; unstable angina; history of heart failure, serum creatinine ≥ 200 mmol/L; serum potassium ≥ 5.5 mmol/L or ≤ 3.5 mmol/L; treatment with oral corticosteroids; concomitant use of agents that may affect BP except β-blockers and nitrates used in the treatment of stable angina; drug or alcohol abuse; pregnancy, breast feeding, and ineffective contraception.	N=103 Age (yr): 59 Gender (Male %): 81 Race/Ethnicity (%): white 96; Asian 3; black 1 BMI: NR Systolic BP (mm Hg): 160 Diastolic BP (mm Hg): 96 Urinary AER (µg/min): 69 Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): 96 HbA _{1c} (%): NR Diabetes (%): 100 History of HTN (%): 100 History of CAD (%): NR History of CHF (%): 0 (exclusion criterion) History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Enalapril 5 mg/d (n=51) Losartan 50 mg/d (n=52) Followup period: 1 year Study withdrawals (%): 11	Allocation Concealment: unclear Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
Muirhead, 1999 ⁸ Kunz review Canada Funding Source: Industry	Inclusion Criteria: incipient diabetic nephropathy, defined as AER between 20 to 300 µg/min and a GFR 60 ≥ ml/min/1.73m ² at visit 1; aged ≥ 18 years; type 2 DM Exclusion Criteria: "brittle" diabetes (increased risk of hypoglycemia) or patients with a history of non	N=91 (excluding placebo arm) Age (yr): 56 Gender (Male %): 67 Race/Ethnicity (%): white 90, black 1, Asian 4 BMI: NR Systolic BP (mm Hg): 136 Diastolic BP (mm Hg): 83 Urinary AER (µg/min): 54 Serum creatinine (mg/dL): NR	Captopril 75 mg/d (n=29) Valsartan 80 mg/d (n=31) Valsartan 160 mg/d (n=31) Followup period: 1 year	Allocation Concealment: unclear Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	compliance with medical regimens.	Estimated GFR (ml/min/1.73m ²): 91 HbA _{1c} (%): NR Diabetes (%): 100 History of HTN (%): 33% on HTN medication History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Study withdrawals (%): 13	adequately described: yes
ACE inhibitor monotherapy versus Calcium channel blocker trials (n=6 trials)				
Rahman, 2005 ²³ ALLHAT USA and Canada Funding Source: Industry and other	Inclusion Criteria: aged 55 years or older who had stage 1 or stage 2 hypertension; at least 1 additional risk factor for CHD events (previous (> 6 months) MI or stroke, left ventricular hypertrophy demonstrated by electrocardiography or echocardiography, history of type 2 DM, current cigarette smoking, high-density lipoprotein cholesterol level < 35 mg/dL, or documentation of other atherosclerotic cardiovascular disease). Exclusion Criteria: history of symptomatic heart failure and/or a known left ventricular ejection fraction <35%; serum creatinine level > 2 mg/dL as reported by the investigator.	N=3049 for patients with a baseline GFR <60 ml/min/ 1.73m ² (of a total of 17,118 randomized and minus the chlorthalidone arm) Age (yr): 70 Gender (Male %): 48 Race/Ethnicity (%): white 58; black 25; Hispanic 13 BMI: 29 Systolic BP (mm Hg): 147 Diastolic BP (mm Hg): 83 Albuminuria: NR Serum creatinine (mmol/L): NR Estimated GFR (ml/min/1.73m ²): 50 HbA _{1c} (%): NR Diabetes (%): 33 History of HTN (%): 100 History of CAD (%): 29 History of CHF (%): NR History of MI or stroke (%): 27 Peripheral arterial disease (%): NR Current smoker (%): 18	Lisinopril up to 40 mg/d (n=1533) Amlodipine up to 10 mg/d (n=1516) <i>Chlorthalidone arm</i> 3 x 2 factorial design, Followup period: mean 4.9 years Study withdrawals (%): Not reported for CKD subgroup	Allocation Concealment: adequate (from background paper) Blinding: double Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: Not reported for CKD subgroup
Fogari, 2002 ²⁴ Italy Funding Source: none stated	Inclusion Criteria: microalbuminuria; essential HTN and type 2 DM and noted by sitting diastolic BP values >90 mm Hg and <110 mm Hg; type 2 DM well controlled by diet or by metformin alone or metformin plus a sulfanylurea; UAE ≥30 and ≤300 mg/24 h in two distinct 24-h urine collections during 7 days before enrollment; BMI < 30 kg/m ² ; serum	N=205 (minus combination arm) Age (yr): 63 Gender (Male %): 58 Race/Ethnicity (%): NR BMI: 28 Systolic BP (mm Hg): 160 Diastolic BP (mm Hg): 99 Urinary AER (μg/min): 97 Serum creatinine (mmol/L): 1 Estimated GFR (ml/min/1.73m ²): NR	Fosinopril 10-30 mg/d (n=102) Amlodipine up to 10 mg/d (n=103) <i>Combination arm</i> Followup period: 4 years	Allocation Concealment: adequate Blinding: open-label Intention to Treat Analysis: no, 453 were randomized to a 3-month titration period but 144 were removed due to non

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	creatinine <1.5 mg/dL. Exclusion Criteria: history of previous CHD, stroke, CHF, cancer; smoking habits; electrocardiogram showing left ventricular hypertrophy; total cholesterol values >240 mg/dL; use of diuretics or b-blockers.	Creatinine clearance (mg/min): 90 HbA _{1c} (%): 7 Diabetes (%): 100 History of HTN (%): 100 History of CAD (%): 0 History of CHF (%): 0 History of MI (%): 0 History of Stroke (%): 0 Peripheral arterial disease (%): NR Current smoker (%):	Study withdrawals (%): 32% of all subjects (including combination arm) in titration period, 26% during study period.	response or adverse events Withdrawals/Dropouts adequately described: yes
Agodoa, 2002 ²⁵ Wright, 2002 ²⁶ Norris, 2006 ²⁷ (AASK) USA Funding Source: Industry and other	Inclusion Criteria: self-identified African Americans with HTN; aged 18 to 70 years; GFR between 20 and 65 mL/min/1.73 m ² and no other identified causes of renal insufficiency. Exclusion Criteria: diastolic BP of <95 mm Hg; known history of DM (fasting glucose ≥140 mg/dL or random glucose >200 mg/dL); urinary protein to creatinine ratio >2.5; accelerated or malignant HTN within 6 months; secondary HTN; evidence of non-BP-related causes of chronic kidney disease; serious systemic disease; clinical CHF; or specific indication for or contraindication to a study drug or study procedure.	N=653 (minus metoprolol arm of 1,094 randomized) Age (yr): 54 Gender (Male %): 61 Race/Ethnicity (%): African American 100 BMI: NR Systolic BP (mm Hg): 151 Diastolic BP (mm Hg): 96 Proteinuria (g/24 h): 0.5 (pooled men and women) Serum creatinine (mg/dL): 2.21 men; 1.76 women Estimated GFR (ml/min/1.73m ²): 46.3 Diabetes (%): 0 History of HTN (%): 100 History of CAD (%): 52 History of CHF (%): 0 History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Ramipril 2.5-10 mg/d (n=436) Amlodipine 5-10 mg/d (n=217) <i>Metoprolol arm</i> 3 x 2 factorial design with lower and usual blood pressure goal arms Followup period: mean 4 years (Norris 2006) Study withdrawals (%): 0 (not counting death or dialysis, or no GFR assessment)	Allocation Concealment: adequate (from background paper) Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes
Marin, 2001 ²⁸ ESPIRAL Spain Funding Source: None stated	Inclusion Criteria: aged 18 to 75 years; serum creatinine values between 1.5 and 5 mg/dl; hypertension (BP >140/90 mmHg, or by the use of antihypertensive agent(s); proven progression of chronic renal failure in the previous 2 years (increase by more than 25% or > 0.5 mg/dl in serum creatinine). Exclusion Criteria: DM; recent	N=241 Age (yr): 56 Gender (Male %): 59 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 156 Diastolic BP (mm Hg): 96 Albuminuria (g/dL): 4.3 Proteinuria (g/24 h): 1.7 Serum creatinine (mg/dL): 2.8 Creatinine clearance (ml/min/1.73m ²): 36	Fosinopril 10-30 mg/d (n=129) Nifedepine 30-60 mg/d (n=112) Followup period: minimum 3 years Study withdrawals (%): 34 (excluding death)	Allocation Concealment: unclear Blinding: open-label Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	history of cardiovascular disease (stroke, myocardial infarction, or heart failure); taking concomitant medications that could interfere with study results (steroids, immunosuppressant drugs, or NSAIDs); presenting intolerance to fosinopril or nifedipine.	Estimated GFR (ml/min/1.73m ²): NR Diabetes (%): 0 History of HTN (%): 100 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR		
Crepaldi, 1998 ¹⁰ Sarafidis review Italy Funding Source: None stated	Inclusion Criteria: age 18 to 70 years; onset of insulin-dependent DM before age 35 and insulin treatment within 3 years of diagnosis; clinical stability of DM during past 12 months; median AER value between 20 and 200 µg/min from 3 timed overnight urine collections; GFR ≥80 ml/min/1.73m ² at randomization; standing systolic BP ≥115 and ≤145 mmHg (without HTN therapy) and diastolic BP ≥75 and ≤90 mmHg. Exclusion Criteria: impaired renal function (defined as serum creatinine >10% above the upper limit of normal (125 µmol/L) and median AER >200 µg/min at entry and visit 3 after randomization); nondiabetic renal disease; hematuria; evidence of clinically significant liver or hematological disease; evidence of aortic or mitral valve obstruction; arrhythmias; unstable angina; history of MI within previous 3 months; systemic malignancy; hyperkalemia, serum triglycerides >3.4mmol/L, or total cholesterol >6.5 mmol/L.	N=88 (58 included in the baseline characteristics and nifedipine arm excluded) Age (yr): 37 Gender (Male %): 69 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 128 Diastolic BP (mm Hg): 83 Albumin excretion rate (µg/min): 61.2 Albumin (g/dL): 4.4 Serum creatinine (mg/dL): 0.96 Creatinine clearance (ml/min/1.73m ²): 109 Estimated GFR (ml/min/1.73m ²): 120 HbA _{1c} (%): 8.1 Diabetes (%): 100 (type 1) History of HTN (%): 0 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): 57	Lisinoprol 2.5-20 mg/d (n=48) Nifedepine 10-20 mg/d (n=41) Followup period: 3 years	Allocation Concealment: unclear Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
Zucchelli, 1995/1992 ^{29,30}	Inclusion Criteria: aged 18 to 70 years of age; established chronic renal failure (serum creatinine	N=121 Age (yr): 55 Gender (Male %): 58	Captopril 25-100 mg/d (n=60)	Allocation Concealment: unclear

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Italy Funding Source: None stated	ranging between 1.8 to 5 mg/dL); variation in plasma creatinine < 50% during 3 month observation period; HTN - baseline diastolic BP ≥ 95 mmHg; good general health. Exclusion Criteria: DM; potentially reversible renal disease; systemic diseases; severe cardiac or hepatic dysfunction; peripheral edema; proteinuria >5 g/24 h.	Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 165 Diastolic BP (mm Hg): 100 Proteinuria (g/24 h): 1.8 Serum creatinine (mg/dL): 3.0 Estimated GFR (ml/min/1.73m ²): NR Diabetes (%): 0 History of HTN (%): 100 History of CAD (%): NR (none with severe disease) History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Nifedepine 20-40 mg/d (n=61) Followup period: 3 years Study withdrawals (%): 26	Blinding: none stated Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes
ACE inhibitor monotherapy versus beta-blocker trials (n=3 trials)				
Wright, 2002 ²⁶ Norris, 2006 ²⁷ (AASK) USA Funding Source: Industry and other	Inclusion Criteria: self-identified African Americans with HTN; aged 18 to 70 years; GFR between 20 and 65 mL/min/1.73 m ² and no other identified causes of renal insufficiency. Exclusion Criteria: diastolic BP of less <95 mm Hg; known history of DM (fasting glucose ≥140 mg/dL or random glucose >200 mg/dL); urinary protein to creatinine ratio >2.5; accelerated or malignant HTN within 6 months; secondary HTN; evidence of non-BP-related causes of chronic kidney disease; serious systemic disease; clinical CHF; or specific indication for or contraindication to a study drug or study procedure.	n=877 (minus amlodipine arm of 1,094 randomized) Age (yr): 55 Gender (Male %): 61.5 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 150.5 Diastolic BP (mm Hg): 95.5 Albuminuria: NR Serum creatinine (mg/dL): 2.15 Estimated GFR (ml/min/1.73m ²): 45.6 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 0 History of HTN (%): 100 History of CAD (%): NR History of "heart disease" (%): 51 History of CHF (%): 0 History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Ramipril 2.5-10.0 mg/d (n=436) Metoprolol 50-200 mg/d (n=441) 3 x 2 factorial design with lower and usual blood pressure goal arms Followup period: 4 years Study withdrawals (%):0 (not counting death or dialysis, or no GFR)	Allocation Concealment: adequate (from background paper) Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes
van Essen, 1997 ³¹	Inclusion Criteria: modest chronic renal insufficiency defined as a creatinine clearance of 30-90	N=103 (89 with baseline characteristics and evaluated) Age (yr): 50	Enalapril 10 mg/d (n=52) Atenolol 50 mg/d (n=51)	Allocation Concealment: unclear

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
The Netherlands Funding Source: Industry	mL/min; aged 18 to 65 years old; no need for immunosuppressive agents or non-steroidal anti-inflammatory drugs; no proven renal artery stenosis, or other conditions for which beta blocking drugs or ACEI are contraindicated. Both patients with and without proteinuria could be included. Exclusion Criteria: NR	Gender (Male %): 64 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 152 Diastolic BP (mm Hg): 90 Proteinuria (g/24h): median 3.3 Serum creatinine (mg/dL): 1.8 Creatinine clearance (ml/min/1.73m ²): 55 Estimated GFR (ml/min/1.73m ²): 53 Diabetes (%): 0 History of HTN (%): 53% were reported to have untreated diastolic BP < 90 mm Hg History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Followup period: median 3.9 years Study withdrawals (%): 14	Blinding: double Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
Hannedouche, 1994 ³² France Funding Sources: Industry	Inclusion Criteria: aged 18 to 70 years; chronic renal failure as defined by a serum creatinine concentration of 200-400 µmol/L Exclusion Criteria: patients with the nephrotic syndrome (serum albumin concentration <30 g/L); systemic diseases including diabetes, malignant hypertension, renovascular hypertension, evolving obstructive nephropathy, and serious extrarenal disorders including malignancy, heart failure, and coronary artery disease; also excluded were women who were breast feeding, pregnant, or intending to become pregnant and patients who had taken converting enzyme inhibitors in the three months before inclusion; had contraindications to converting enzyme inhibitors or (B blockers; were unlikely to comply; or were	N=100 Age (yr): 51 Gender (Male %): 53 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 167 Diastolic BP (mm Hg): 102 Proteinuria (g/24h): 2.2 Serum creatinine (mg/dL): 3.0 Estimated GFR (ml/min/1.73m ²): NR Diabetes (%): 0 History of HTN (%): 100 History of CAD (%): 0 History of CHF (%): NR History of MI (%): 0 History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Enalapril 5-10 mg/d (n=52) Acebutolol 400 mg/d or Atenolol 100 mg/d (n=48) Followup period: 3 years Study withdrawals (%): 23	Allocation Concealment: adequate Blinding: open-label Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	unwilling to give consent			
ACE inhibitor monotherapy versus diuretic trials (n= 2 trials)				
Rahman, 2005 ²³ ALLHAT	Inclusion Criteria: aged 55 years or older who had stage 1 or stage 2 hypertension; at least 1 additional risk factor for CHD events (previous (> 6 months) MI or stroke, left ventricular hypertrophy demonstrated by electrocardiography or echocardiography, history of type 2 DM, current cigarette smoking, high-density lipoprotein cholesterol level <35 mg/dL, or documentation of other atherosclerotic cardiovascular disease).	N=4,146 for patients with a baseline GFR <60 ml/min/ 1.73m ² (of a total of 17,118 randomized and minus the amlodipine arm) Age (yr): 71 Gender (Male %): 49 Race/Ethnicity (%): white 57; black 26; Hispanic 12 BMI: 29 Systolic BP (mm Hg): 147 Diastolic BP (mm Hg): 83 Albuminuria: NR Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): 50 Diabetes (%): 33 (type 2) History of HTN (%): 100 History of CAD (%): 31 History of CVD (%): 61 History of CHF (%): 0 (by exclusion criteria) History of MI or stroke (%): 29 Peripheral arterial disease (%): NR Current smoker (%): 18	Lisinopril up to 40 mg/d (n=1533) Chlorthalidone up to 25 mg/d (n=2613) 3 x 2 factorial design, Followup period: mean 4.9 years Study withdrawals (%): Not reported for CKD subgroup	Allocation Concealment: adequate (from background paper) Blinding: double Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: Not reported for CKD subgroup
USA and Canada Funding Source: Industry and other	Exclusion Criteria: history of symptomatic heart failure and/or a known left ventricular ejection fraction <35%; serum creatinine level > 2 mg/dL as reported by the investigator.			
Marre, 2004 ³³ NESTOR	Inclusion Criteria: aged between 35 and 80 years; type 2 DM; persistent micro-albuminuria (AER between 20 and 200 µg/min on at least two of three overnight urine collections); essential HTN. Diabetes was required to be controlled by diet with or without one or more oral antidiabetic treatment, unchanged for at least 3 months. For selection, microalbuminuria had to be documented within the previous year.	N=570 Age (yr): 60 Gender (Male %): 65 Race/Ethnicity (%): white 86; black 4; Asian 2 BMI: 30 Systolic BP (mm Hg): 161 Diastolic BP (mm Hg): 94 Albumin excretion rate (µg/min): 58 Urinary albumin: creatinine ratio: 6.2 Serum creatinine (mg/dL): NR Creatinine clearance (ml/min/1.73m ²): 92 Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 7.6 Diabetes (%): 100 History of HTN (%): 100 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR	Enalapril 10 mg/d (n=286) Indapamide 1.5 mg/d (n=284) Followup period: 1 year Study withdrawals (%): 11.4	Allocation Concealment: Unclear Blinding: double Intention to Treat Analysis: no (one subject excluded) Withdrawals/Dropouts adequately described: yes
France Funding Sources: Industry	Exclusion Criteria: severe HTN; BMI > 40 kg/m ² ; ventricular rhythm disorders on ECG; urinary tract infection, haematuria or leucocyturia; plasma creatinine >			

Appendix Evidence Table C1. Overview of ACEI monotherapy versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	150 µmol/l; kalaemia < 3.5 mmol/l or > 5.5 mmol/l; uric acid > 536 µmol/l; treatment with potassium supplement or insulin and poor placebo compliance during the run-in period. Previously known intolerance to ACEI or diuretics was also a criterion for exclusion.	Peripheral arterial disease (%): NR Current smoker (%): 14		

AASK = African American Study of Kidney Disease and Hypertension Study Group; ACE = Angiotensin converting enzyme inhibitors; ACR = albumin/creatinine ratio; AER = albumin excretion rate; ALLHAT = Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial; ARB = Angiotensin II receptor blockers; ATLANTIS = Ace-Inhibitor Trial to Lower Albuminuria in Normotensive Insulin-Dependent Subjects; BP = blood pressure; CAD = coronary artery disease; CCB = calcium channel blockers; CHD = coronary heart disease; CHF = Congestive Heart Failure; ESPIRAL = Efecto del tratamiento antihipertensivo Sobre la Progresión de la Insuficiencia RenAL en pacientes no diabéticos; DIABHYCAR = non insulin dependent diabetes, hypertension, microalbuminuria or proteinuria, cardiovascular events, and ramipril study; DM = diabetes mellitus; HTN = Hypertension; LDL = Low density lipoprotein; MI = myocardial infarction; NESTOR = Natrilix SR versus Enalapril Study in hypertensive Type 2 diabetics with MicrOalbuminURia; NR = not reported; NSAIDS = Non-steroidal anti-inflammatory drug; PVD = peripheral vascular disease; REIN = Ramipril Efficacy in Nephropathy; UAE = urinary albumin excretion.

Appendix Table C2. Summary of study baseline characteristics for ACEI monotherapy versus control treatment trials

Characteristic	Mean (Range) Unless Otherwise Noted	Number of Trials Reporting
ACEI versus placebo		
Total number of patients evaluated	10,845 (52-4,912)	17
Age of subjects, years	60 (33-70)	16
Gender, male (%)	66 (35-82)	15
Race/ethnicity, white (%)	77 (63-96)	5
Body Mass Index	28 (24-29)	5
Patients with diabetes (%)	69 (0-100)	17
Patients with diabetic nephropathy‡, n	6,193 (21-4,912)	13
% HbA _{1c} in patients with diabetes	8.2 (7.1-11.0)	10
Estimated GFR ml/min/1.73m ²	68.5 (39-114)	5
Serum creatinine, mg/dL	1.0 (0.8-2.4)	10
Creatinine clearance, ml/min/1.73m ²	64.1 (43-114)	8
Albumin excretion rate, µg/min	61.0 (53-71.5)	5
Albuminuria, mg/24 h	63.2 (72-711)	3
Proteinuria, g/24 h	2.34 (0.13-5.3)	5
Systolic blood pressure, mm Hg	144 (126-149)	15
Diastolic blood pressure, mm Hg	83 (74-92)	14
Patients with hypertension, %	50 (0-100)	16
Patients with cardiovascular disease, %	38 (0-100)	5
Patients randomized to Ramipril versus placebo, n	6,721 (62%) (55-4,912)	7
Patients randomized to Captopril versus placebo, n	665 (6.1%) (81-409)	4
Patients randomized to Perindopril versus placebo, n	1,757	1
Patients randomized to Fosinopril versus placebo, n	864	1
Patients randomized to Benazepril versus placebo, n	583	1
Patients randomized to Enalapril versus placebo, n	108	1
Patients randomized to Lisinopril versus placebo, n	97	1
Patients randomized to Enalapril versus no treatment, n	52	1
ACEI versus ARB		
Total number of patients evaluated, n	4,799 (90-4,046)	6
Age of subjects, years	59 (56-61)	5
Gender, male, %	62 (37-81)	5
Race/ethnicity, white, %	96 (91-98)	3
Body Mass Index	31 (30-32)	3
Patients with diabetes, %	97 (76-100)	5
Patients with diabetic nephropathy‡, n	730 (67-250)	5
% HbA _{1c} %in patients with diabetes	8.1 (7.9-8.3)	2
Estimated GFR, ml/min/1.73m ²	92 (91-96)	3
Serum creatinine, mg/dL	1.0 (1.0-1.0)	2
Creatinine clearance, ml/min/1.73m ²	101 (97-112)	2
Albumin excretion rate, µg/min	62 (53-69)	2
Systolic blood pressure, mm Hg	151 (136-160)	5
Diastolic blood pressure, mm Hg	87 (83-91)	5
Patients with hypertension, %	94 (33-100)	5
Patients with cardiovascular disease, %	99 (19-100)	3
Patients randomized to Ramipril versus ARB, n	4046	1
Patients randomized to Enalapril versus ARB, n	353 (103-250)	2
Patients randomized to Lisinopril versus ARB, n	309 (90-219)	2
Patients randomized to Captopril versus ARB, n	91	1
Patients randomized to Telmisartan versus ACEI, n	4,515 (219-4,046)	3
Patients randomized to Valsartan versus ACEI, n	181 (90-91)	2
Patients randomized to Losartan versus ACEI, n	103	1
ACEI versus CCB		
Total number of patients evaluated, n	4,357 (88-3,049)	6
Age of subjects, years	66 (37-71)	6
Gender, male, %	51 (48-69)	6

Appendix Table C2. Summary of study baseline characteristics for ACEI monotherapy versus control treatment trials (continued)

Characteristic	Mean (Range) Unless Otherwise Noted	Number of Trials Reporting
Race/ethnicity, white, %	48 (0-58)	2
Body Mass Index	29 (28 to 29)	2
Patients with diabetes, %	30 (0-100)	6
Patients with diabetic nephropathy‡, n	293 (88-205)	2
Patients with	1,015 (121-653)	3
% HbA _{1c} in patients with diabetes	7.2 (7.0-8.1)	2
Estimated GFR, ml/min/1.73m ²	50 (46-120)	3
Serum creatinine, mg/dL	2.0 (1.0-3.0)	5
Proteinuria, g/24 h	0.9 (0.5-1.8)	3
Systolic blood pressure, mm Hg	149 (128-165)	6
Diastolic blood pressure, mm Hg	87 (83-100)	6
Patients with hypertension, %	99 (0-100)	6
Patients with cardiovascular disease, %	29 (0-52)	5
Patients randomized to Lisinopril versus CCB, n	3,137 (88-3,049)	2
Patients randomized to Ramipril versus CCB, n	653	1
Patients randomized to Fosinopril versus CCB, n	446 (205-241)	2
Patients randomized to Captopril versus CCB, n	121	1
Patients randomized to Amlodipine versus ACEI, n	3,907 (205-3,049)	3
Patients randomized to Nifedipine versus ACEI, n	450 (88-241)	3
ACEI versus BB		3
Total number of patients evaluated, n	1,080 [100-877]	3
Age of subjects, years	54 [50-55]	3
Gender, male, %	61 (53-64)	3
Race/ethnicity, white, %	0*	1
Patients with diabetes, %	0	3
Estimated GFR, ml/min/1.73m ²	47 [46-53]	2
Serum creatinine, mg/dL	2.0 [1.8-3.0]	3
Proteinuria, g/24 h	0.7 [0.5-2.2]	2
Systolic blood pressure, mm Hg	152 (150-167)	3
Diastolic blood pressure, mm Hg	95 (90-102)	3
Patients with hypertension, %	96 (47-100)	3
Patients randomized to Ramipril versus BB, n	877	1
Patients randomized to Enalapril versus BB, n	203 (100-103)	2
Patients randomized to Metoprolol versus ACEI, n	877	1
Patients randomized to Atenolol or Acebutolol versus ACEI, n†	203 (100-103)	2
ACEI versus Diuretics		2
Total number of patients evaluated, n	4,716 [570-4,146]	2
Age of subjects, years	70 [60-71]	2
Gender, male, %	51 [49-65]	2
Race/ethnicity, white, %	61 [57-85]	2
Patients with diabetes, %	41 [33-100]	2
Estimated GFR, ml/min/1.73m ²	50	1
Creatinine clearance, ml/min/1.73m ²	92	1
Albumin excretion rate, µg/min	58	1
Systolic blood pressure, mm Hg	149 (147-161)	2
Diastolic blood pressure, mm Hg	84 (83-94)	2
Patients with hypertension, %	100	2
Patients randomized to Lisinopril versus Diuretic, n	4,146	1
Patients randomized to Enalapril versus Diuretic, n	570	1
Patients randomized to Chlorthalidone versus ACEI, n	4,146	1
Patients randomized to Indapimide versus ACEI, n	570	1

ACEI = angiotension converting enzyme inhibitor; HbA_{1c} = hemoglobin A_{1c}; GFR = glomerular filtration rate; ARB = angiotensin receptor blocker; CCB = calcium channel blocker; BB = beta blocker

* Only one trial reported ethnicity, the AASK study which limited enrollment to self-identified African Americans.

†In one trial, all participants assigned BB were assigned atenolol while in the other trial, all participants assigned BB were assigned to either atenolol or acebutolol.

‡Diabetic nephropathy defined as present in patients with diabetes and albuminuria or proteinuria.

Appendix Table C3. Clinical outcomes (outcomes part A), ACEI monotherapy versus control treatment trials

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial Infarction, Nonfatal n/N (%)		Stroke or CVA, Any n/N (%)	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
<i>ACEI versus placebo/no treatment trials (n=17)</i>												
Perkovic, 2007 ¹ (PRGRESS)												
Asselbergs, 2004 ² (PREVD)	5/431 (1.2)	4/433 (0.9)	5/431 (1.2)	3/433 (0.7)					12/431 (2.8)	11/433 (2.5)	1/431 (0.2)*	10/433 (2.3)
Marre, 2004 ³ (DIAB)	334/2443 (13.7)	324/2469 (13.1)	179/2443 (7.3)	175/2469 (7.1)	61/2443 (2.5)	78/2469 (3.2)			52/2443 (2.1)	59/2469 (2.4)	118/2443 (4.8)	116/2469 (4.7)
Katayama, 2002 ⁴	0/52	0/27										
Bojestig, 2001 ⁵	0/37	0/18										
Gerstein, 2001 ⁶ (MICROHOPE)	90/553 (16.3)	122/587 (20.8)										
O'Hare, 2000 ⁷ (ATLANTIS)	5/92 (5.4)	0/48							3/92 (3.3)	1/48 (2.1)		
Muirhead, 1999 ⁸												
REIN, 1999 ⁹ stratum 1	1/99 (1.0)	0/87									1/99 (1.0)	0/87
Crepaldi, 1998 ¹⁰	0/32	0/34			0/32	1/34 (2.9)			0/32	1/34 (2.9)		
REIN, 1997 ¹¹ stratum 2	2/78 (2.6)	1/88 (1.1)					1/78 (1.3)	0/88	1/78 (1.3)	1/88 (1.1)		
Maschio, 1996 ¹²	8/300 (2.7)	1/283 (0.4)					3/300 (1.0)	0/283	2/300 (0.7)	2/283 (0.7)		
Trevisan, 1995 ¹³					1/60 (1.7)	1/62 (1.6)			1/60 (1.7)	1/62 (1.6)		
Laffel, 1995 ¹⁴	1/70 (1.4)	0/73										
Sano, 1994 ¹⁵	1/31 (3.2)	0/31										
Lewis, 1993 ¹⁶	8/207 (3.9)	14/202 (6.9)										
Ravid, 1993 ¹⁷	0/49	0/45										

Appendix Table C3. Clinical outcomes (outcomes part A), ACEI monotherapy versus control treatment trials (continued)

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial Infarction, Nonfatal n/N (%)		Stroke or CVA, Any n/N (%)	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
ACEI versus ARB trials (n=6)												
Mann, 2008 ¹⁸ ONTARGET												
Menne, 2008 ¹⁹ VALERIA	1/47 (2.1)	0/43	1/47 (2.1)	0/43								
Sengul, 2006 ²⁰												
Barnett, 2004 ²¹ DETAIL	6/130 (4.6)	6/120 (5)	2/130 (1.5)	3/120 (2.5)					6/130 (4.6)	9/120 (7.5)		
Lacourcière, 2000 ²²	0/51	0/52	0/51	0/52	0/51	0/52	0/51	0/52	0/51	0/52	0/51	0/52
Muirhead, 1999 ⁸	0/29	0/62										
ACEI versus CCB trials (n=6)												
Rahman, 2006 ³⁵ ALLHAT											99/1533 (6.5)	100/1516 (6.6)
Rahman, 2006 ³⁵ ALLHAT, DM patients*											33/501 (6.6)	42/506 (8.3)
Fogari, 2002 ²⁴	3/102 (2.9)	4/103 (3.9)										
Norris, 2006 ²⁷ Agodoa 2001 ²⁵ (AASK)	34/436 (7.8)	22/217 (10.1)	12/436 (2.8)	7/217 (3.2)							23/436 (5.3)	9/217 (4.1)
Marin, 2001 ²⁸ ESPIRAL	4/129 (3.1)	6/112 (5.4)	3/129 (2.3)	6/112 (5.4)							1/129 (0.8)	2/112 (1.8)
Crepaldi, 1998 ¹⁰	0/48	1/41 (2.4)			0/32	0/26			0/32	0/26		
Zucchelli, 1995 ²⁹	1/60 (1.7)	0/61	1/60 (1.7)	0/61								
ACEI versus BB trials (n=3)												
Norris, 2006 ²⁷ (AASK)	34/436 (7.8)	49/441 (11.1)	12/436 (2.8)	12/441 (2.7)							23/436 (5.3)	23/441 (5.2)
van Essen, 1997 ³¹	2/43 (4.7)	1/46 (2.2)	2/43 (4.7)	1/46 (2.2)			2/43 (4.7)	1/46 (2.2)				
Hannedouche, 1994 ³²	1/52	2/48 (4.2)										

Appendix Table C3. Clinical outcomes (outcomes part A), ACEI monotherapy versus control treatment trials (continued)

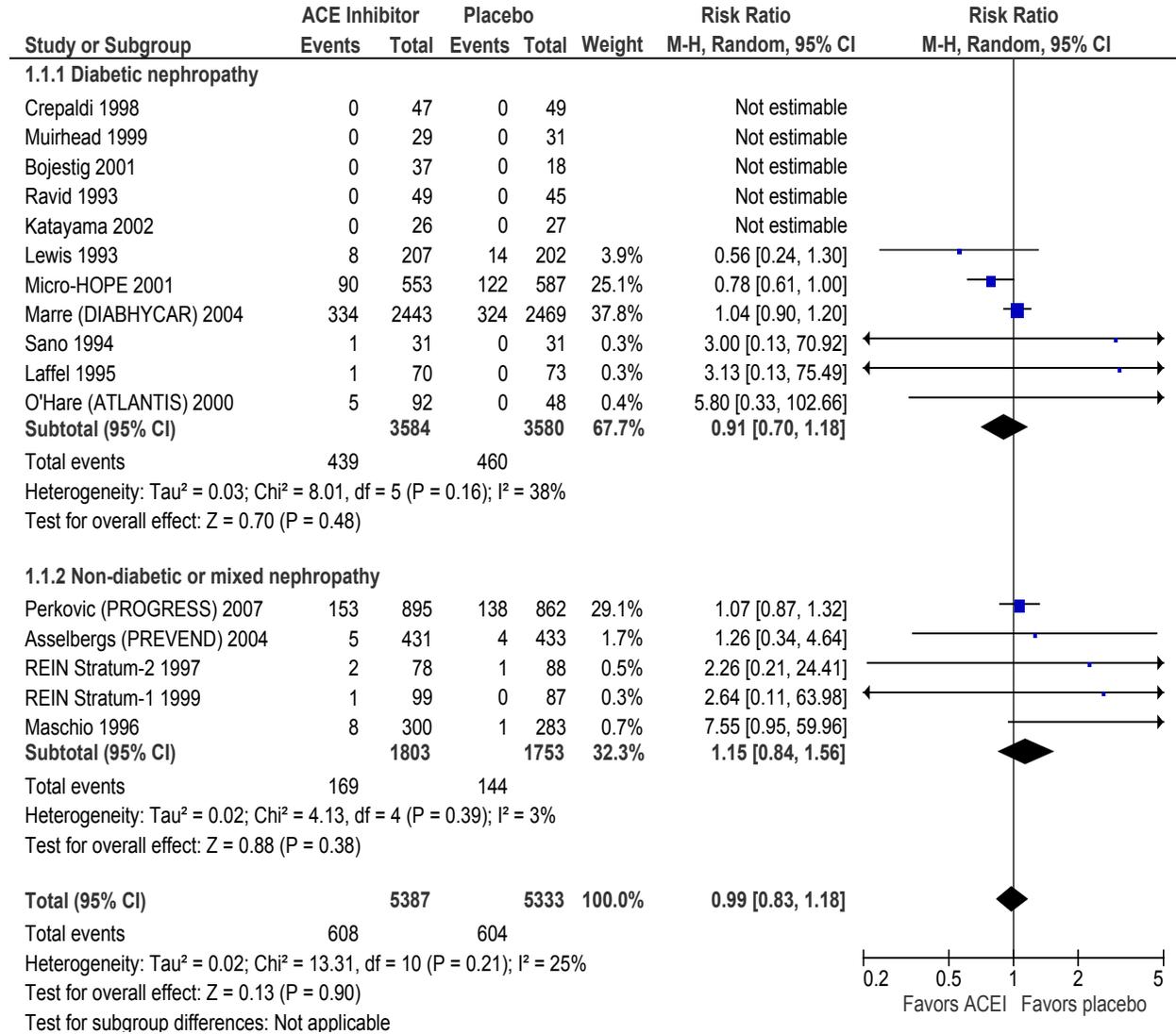
Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial Infarction, Nonfatal n/N (%)		Stroke or CVA, Any n/N (%)	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
ACEI versus diuretics trials (n=2)												
Rahman, 2006 ³⁵ ALLHAT											99/1533 (6.5)	157/2613 (6.0)
Rahman, 2006 ³⁵ ALLHAT, DM patients*											33/501 (6.6)	63/881 (7.2)
Marre, 2004 ³³ NESTOR	1/286 (0.3)	2/284 (0.7)	1/286 (0.3)	2/284 (0.7)			0/286	1/284 (0.3)				

ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor II blocker; CCB = calcium channel blocker; BB = beta blocker ; CVA = cerebrovascular accident (i.e., stroke); DM = diabetes mellitus*Rahman 2006 ALLHAT DM patients is a report on the subgroup of diabetic patients from the overall ALLHAT study

Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials

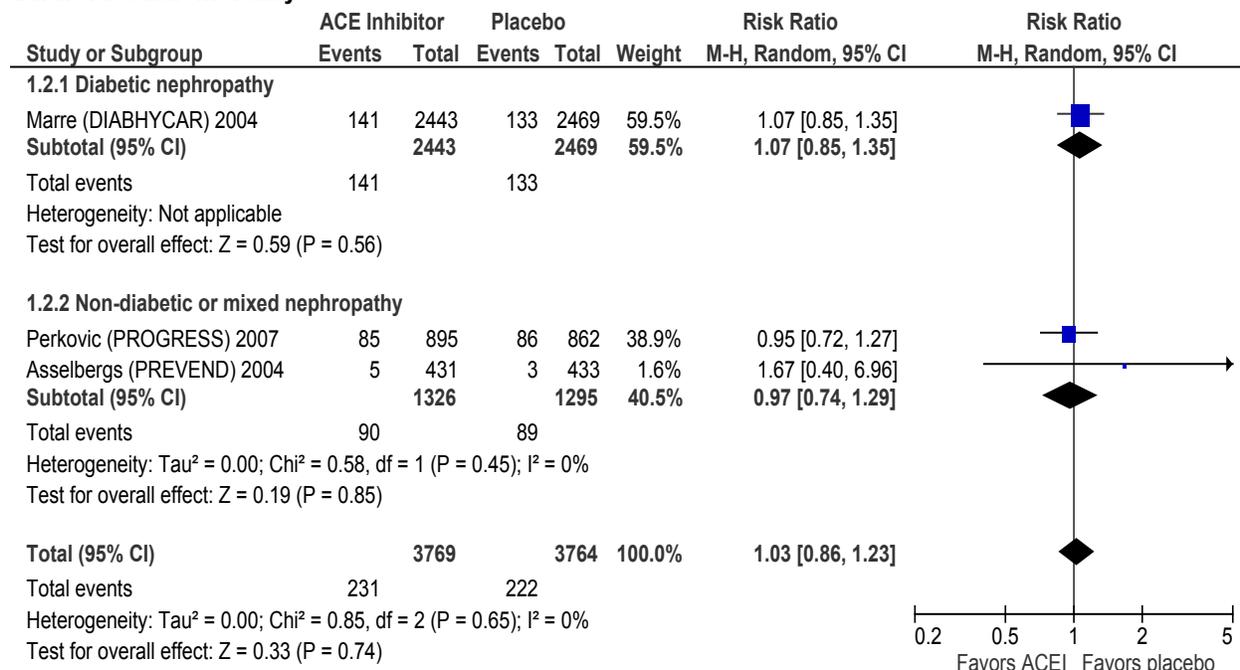
ACEI VERSUS PLACEBO

All-cause mortality

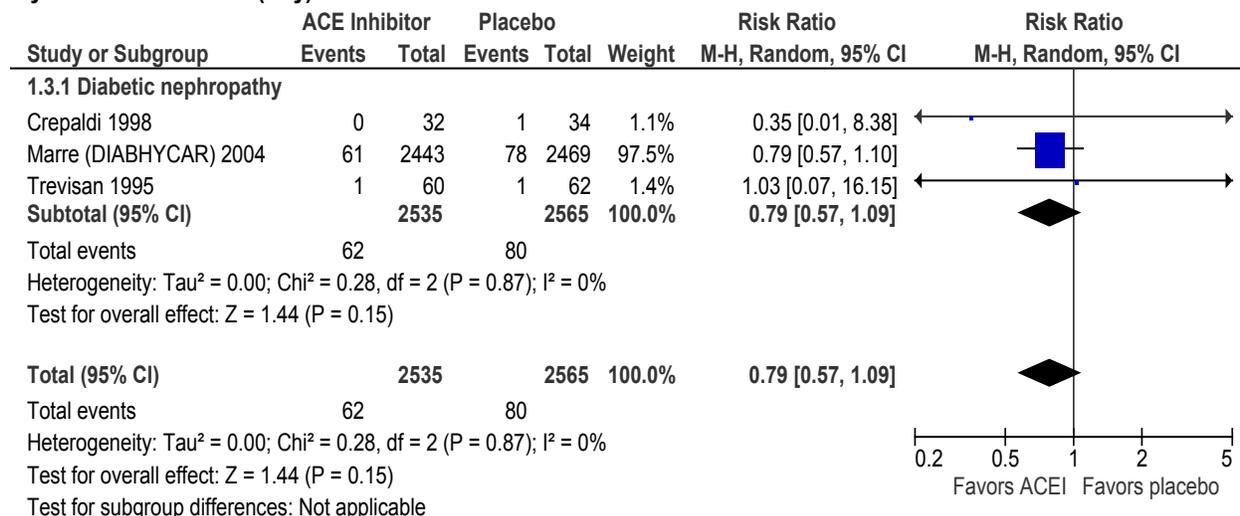


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

Cardiovascular mortality

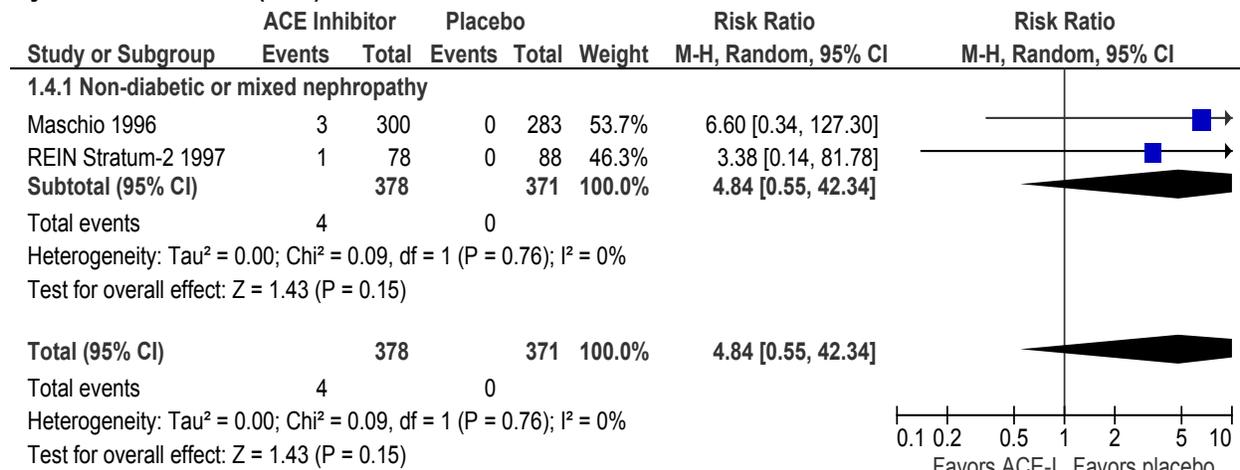


Myocardial infarction (any)

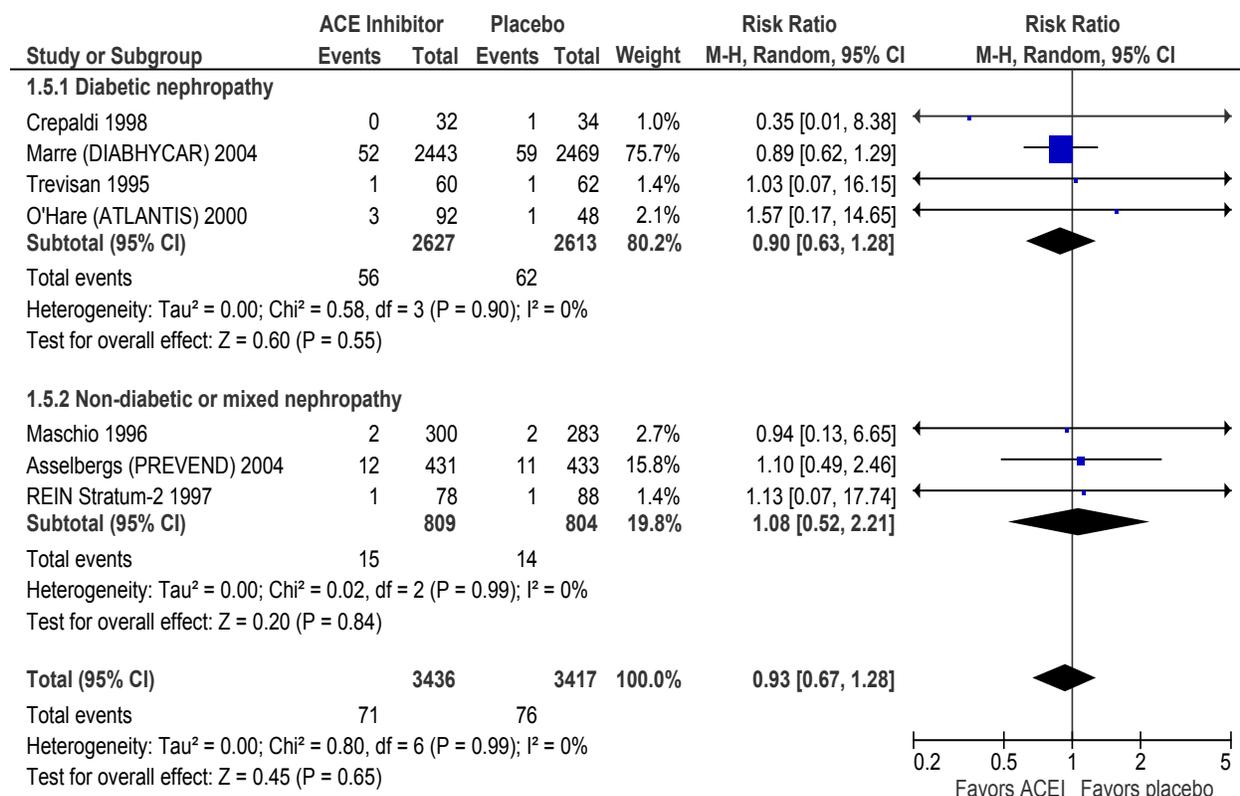


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

Myocardial infarction (fatal)

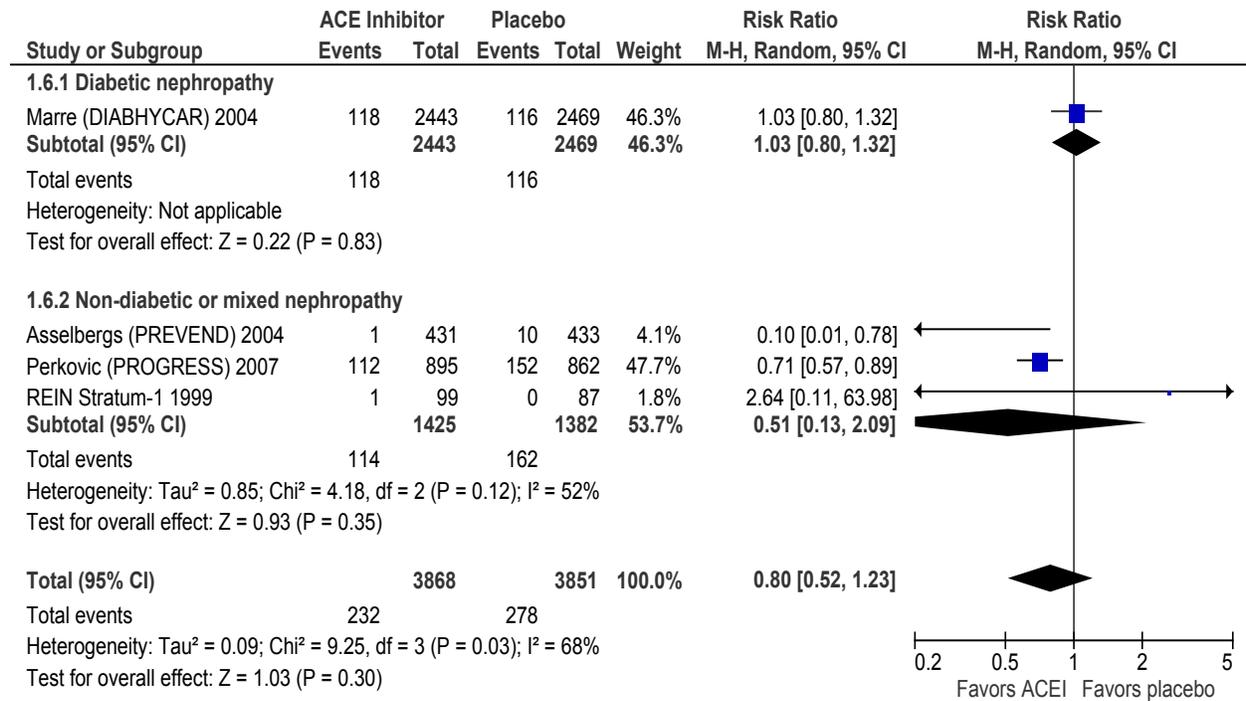


Myocardial infarction (nonfatal)

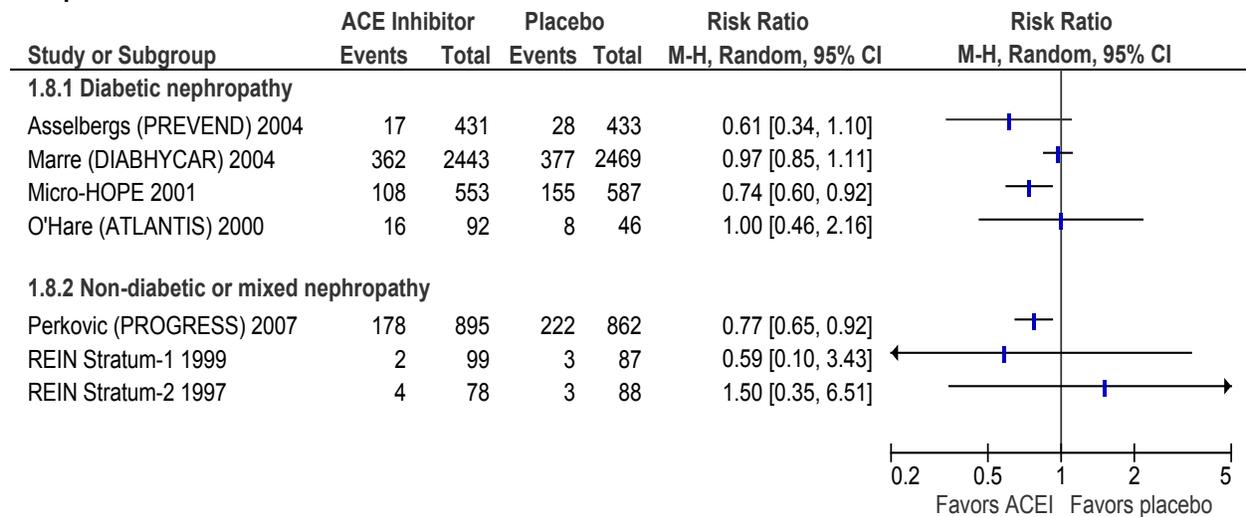


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

Stroke

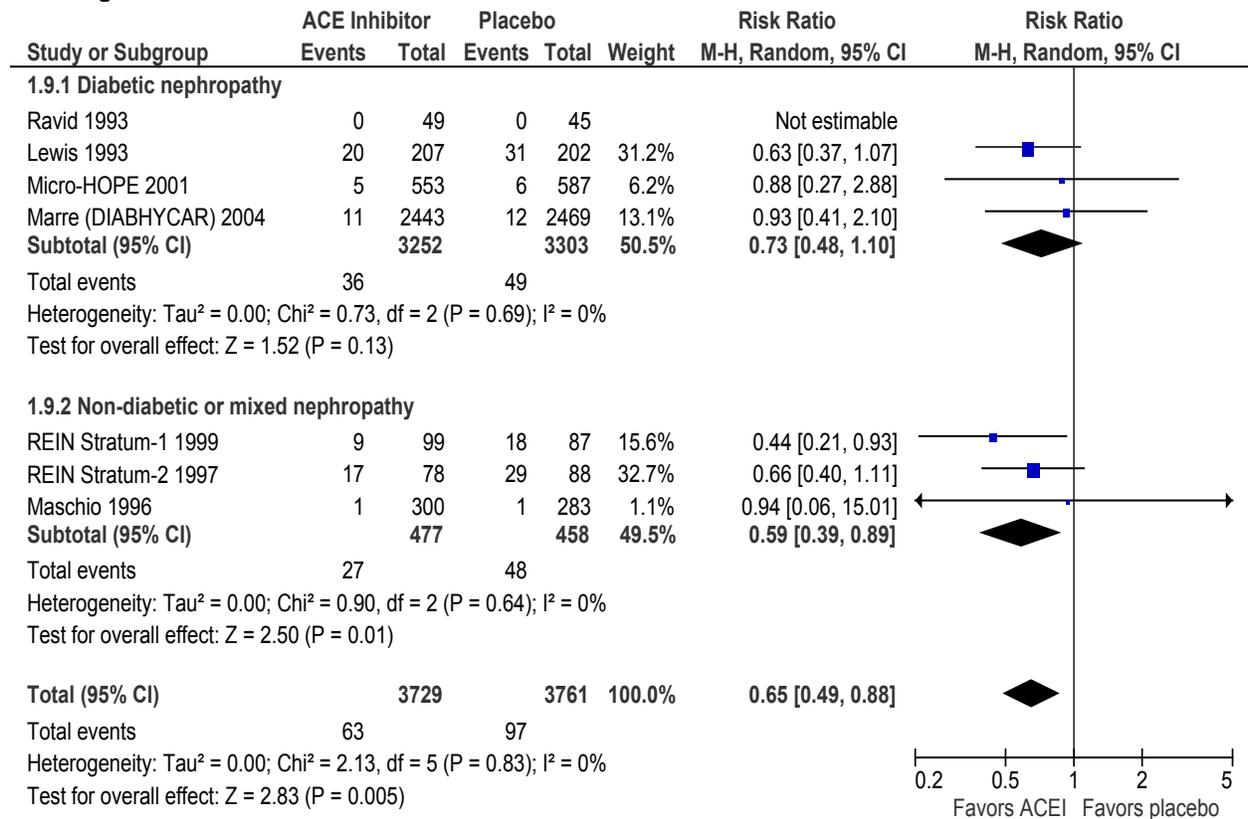


Composite vascular outcome



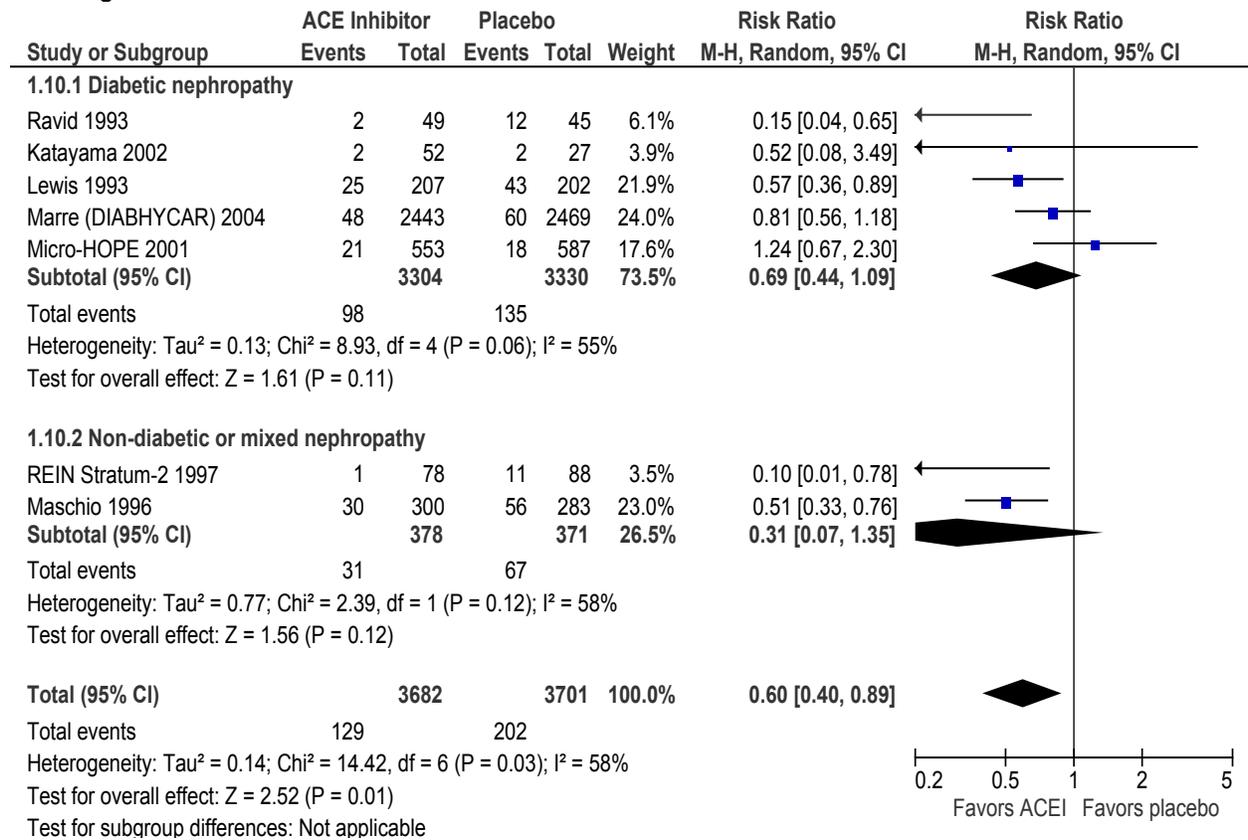
Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

End-stage renal disease

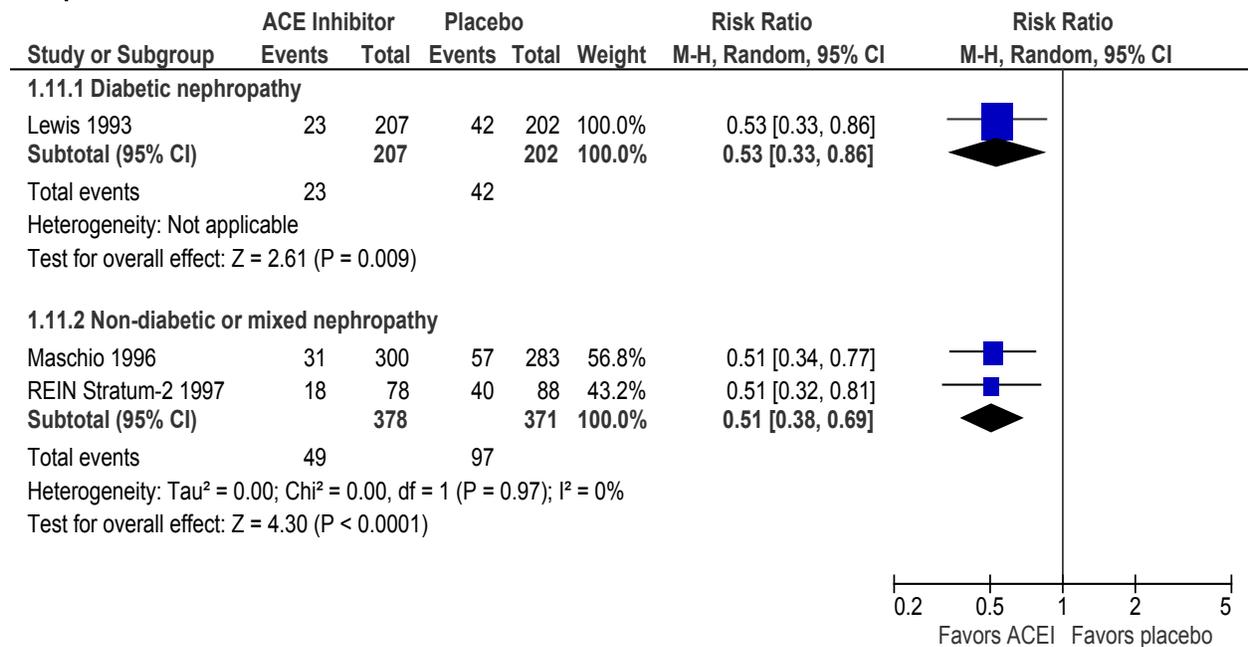


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

Doubling of serum creatinine

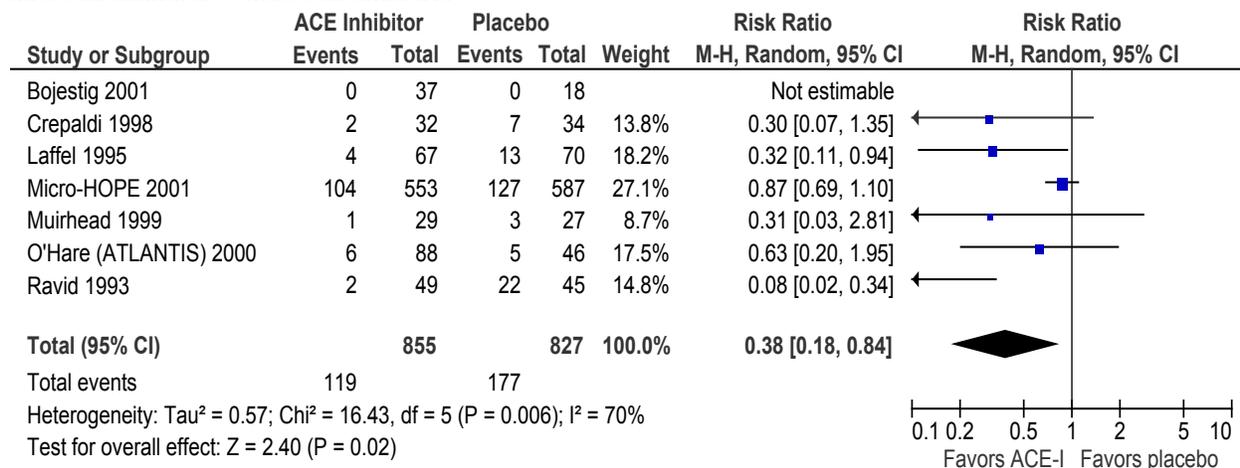


Composite renal outcome



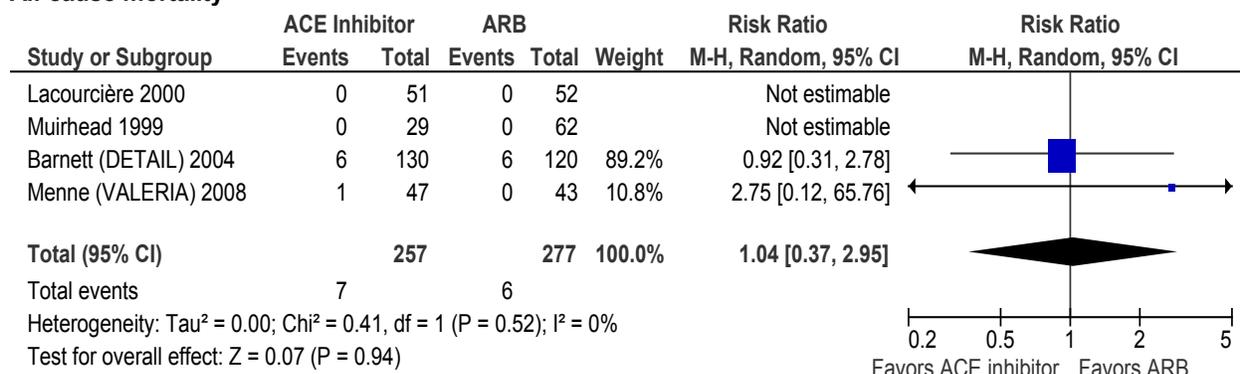
Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

Microalbuminuria to macroalbuminuria

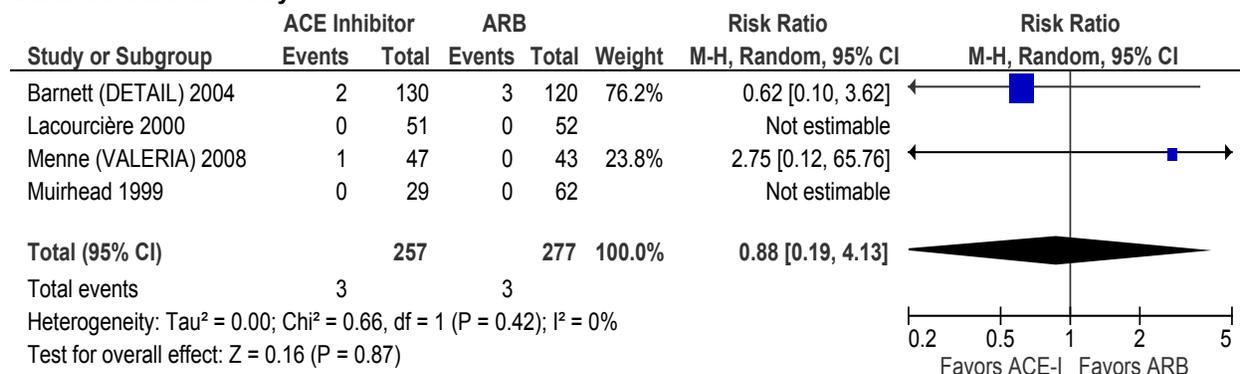


ACEI VERSUS ARB

All-cause mortality

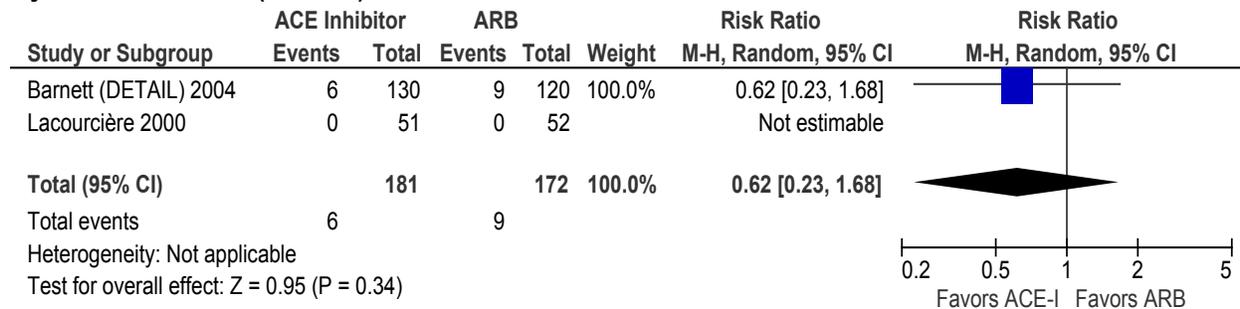


Cardiovascular mortality

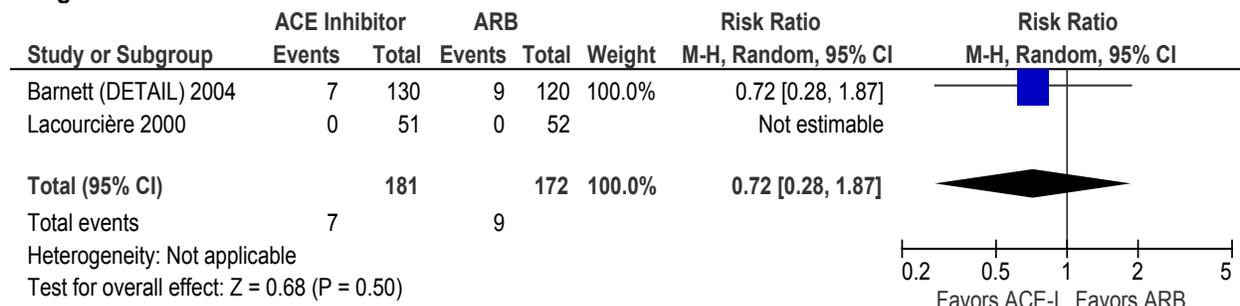


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

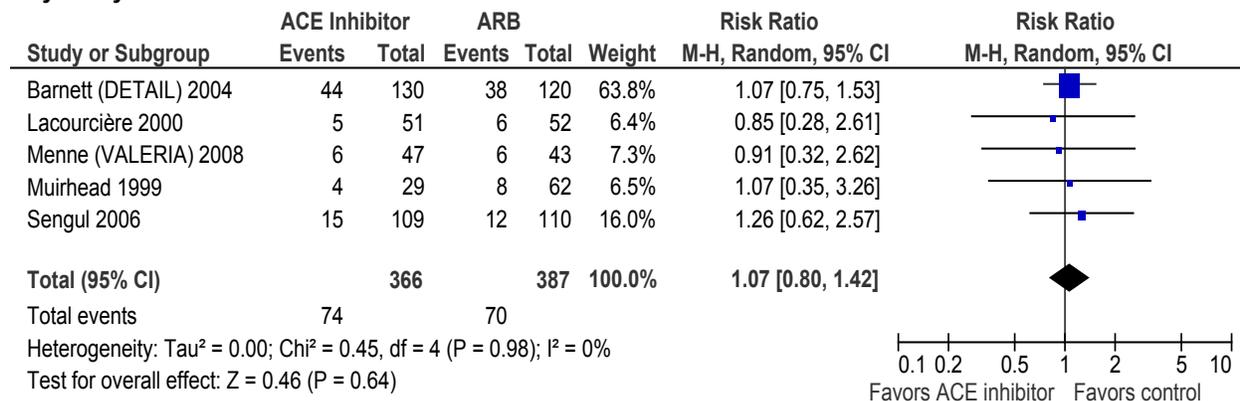
Myocardial infarction (nonfatal)



Congestive heart failure

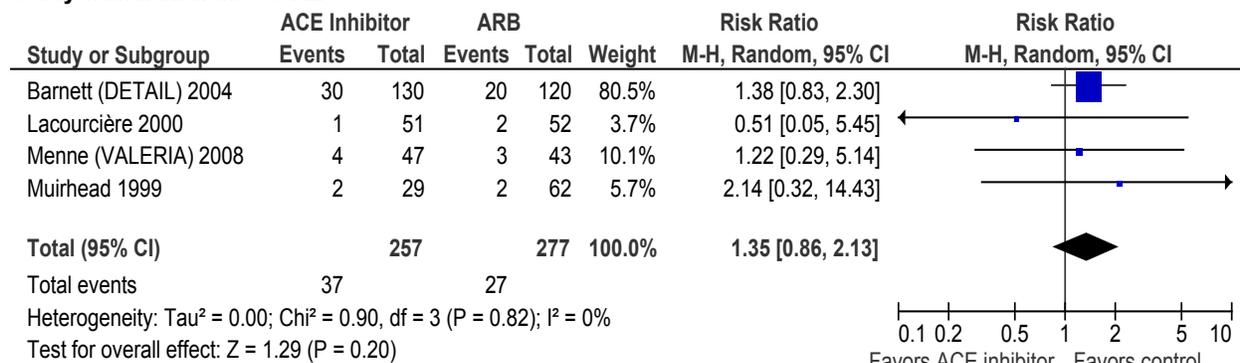


Any study withdrawal

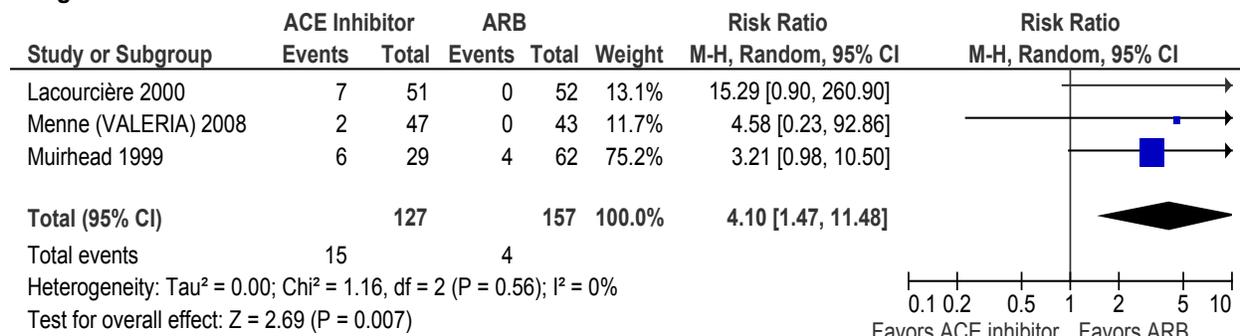


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

Study withdrawal due to AE

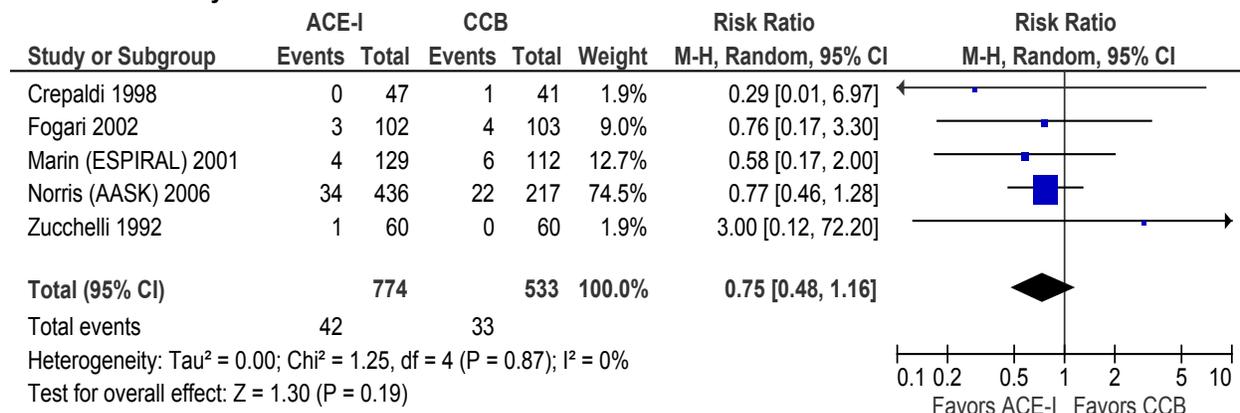


Cough



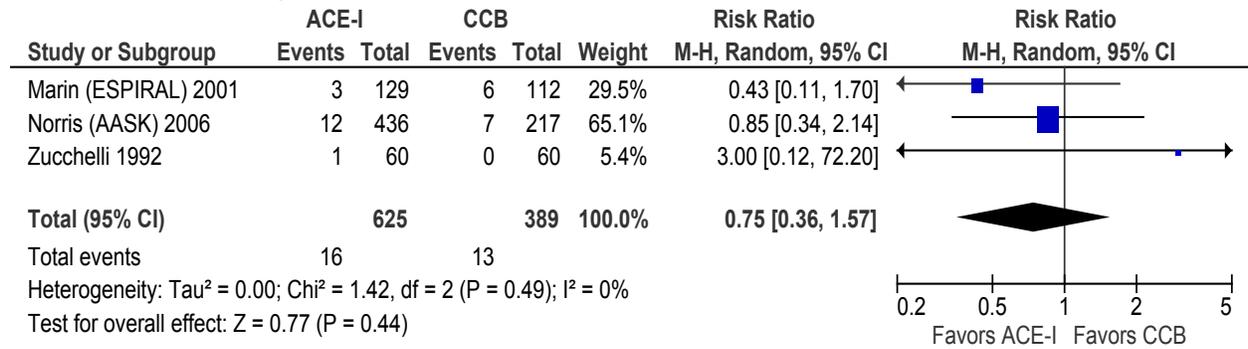
ACEI VERSUS CCB

All-cause mortality

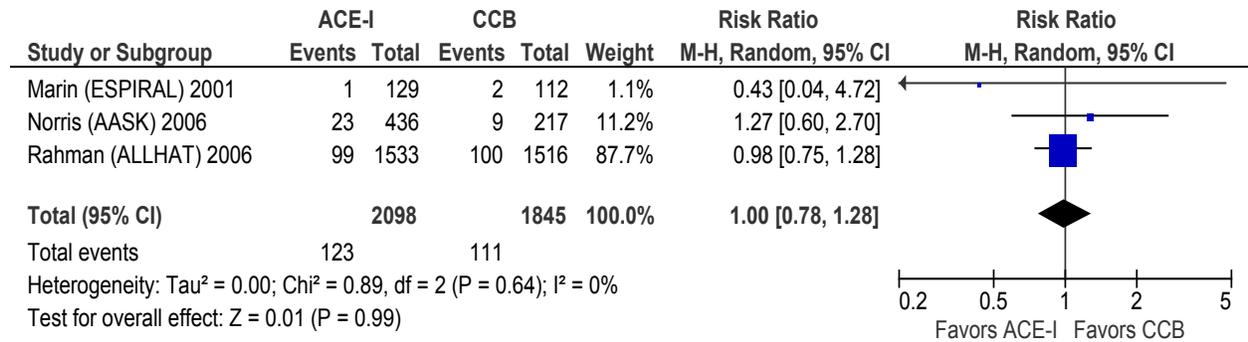


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

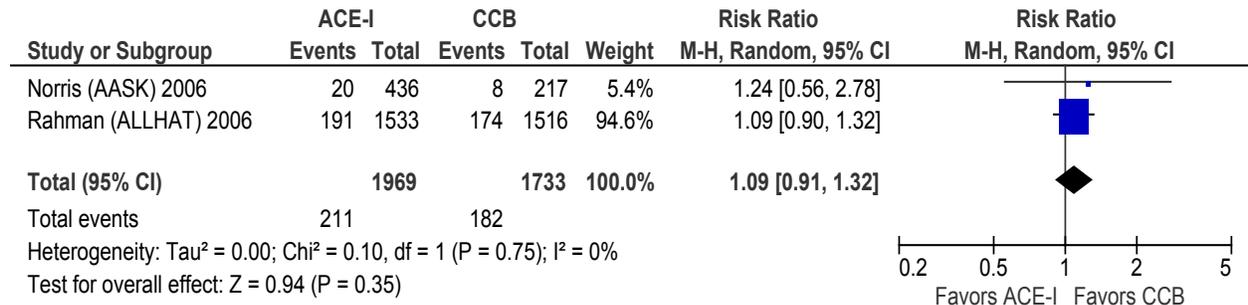
Cardiovascular mortality



Stroke

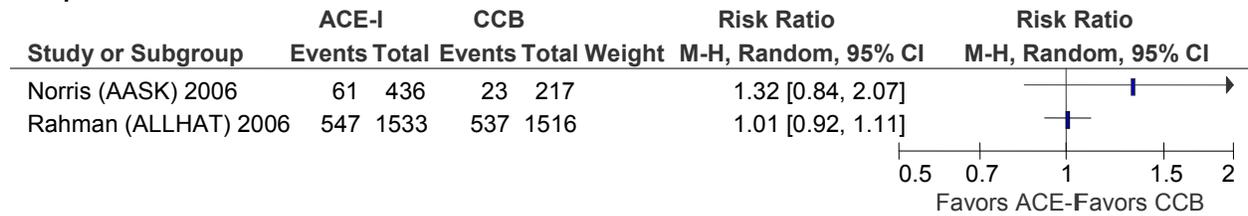


Heart failure



Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

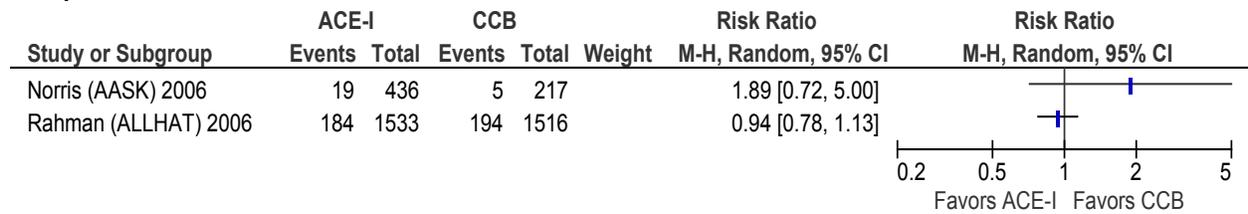
Composite vascular event



AASK: Cardiovascular mortality or first cardiovascular hospitalization

ALLHAT: Death from coronary heart disease, nonfatal MI, stroke, coronary revascularization procedures, hospitalized or treated angina, treated or hospitalized heart failure, and peripheral arterial disease requiring hospitalization or outpatient revascularization

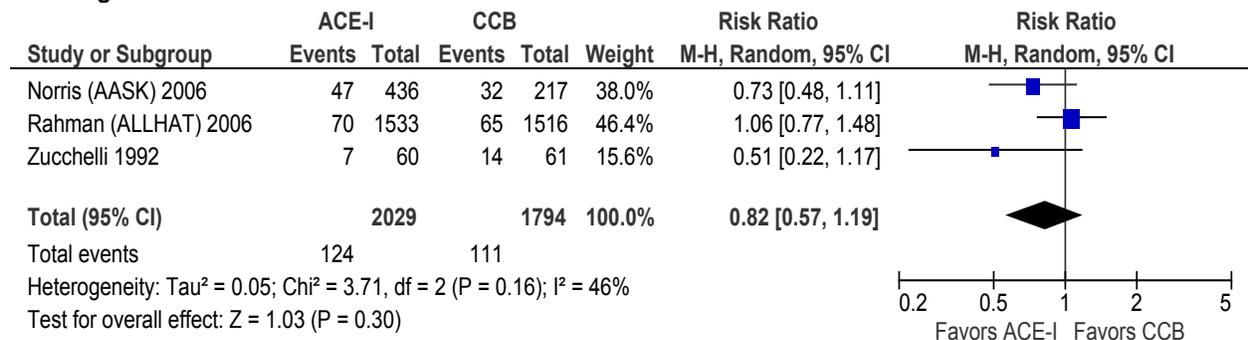
Composite vascular event



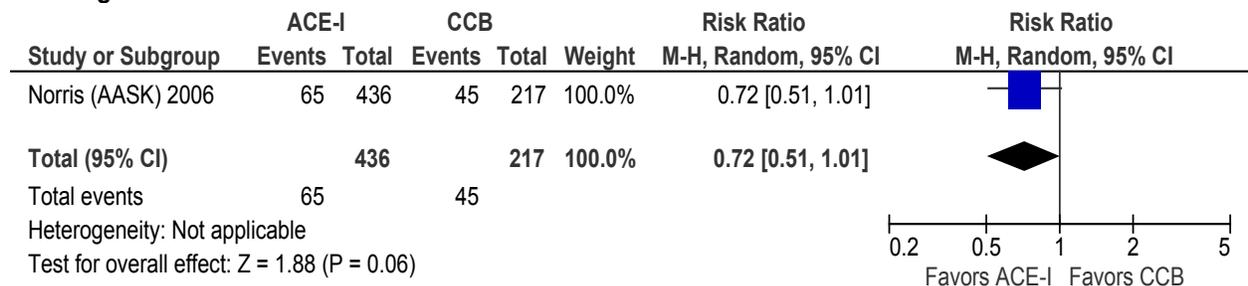
AASK: "Coronary heart disease event" defined as CAD hospitalization (probable MI) and/or fatal coronary heart disease death.

ALLHAT: "Coronary heart disease event" defined as nonfatal MI or fatal coronary heart disease death.

End stage renal disease

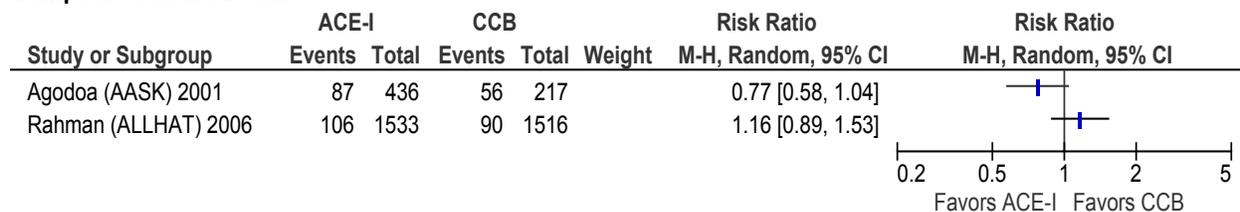


End stage renal disease and death

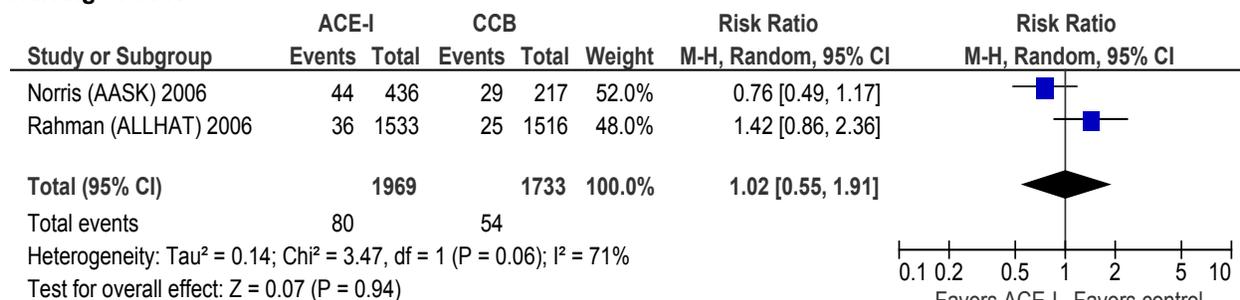


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

Composite renal outcome

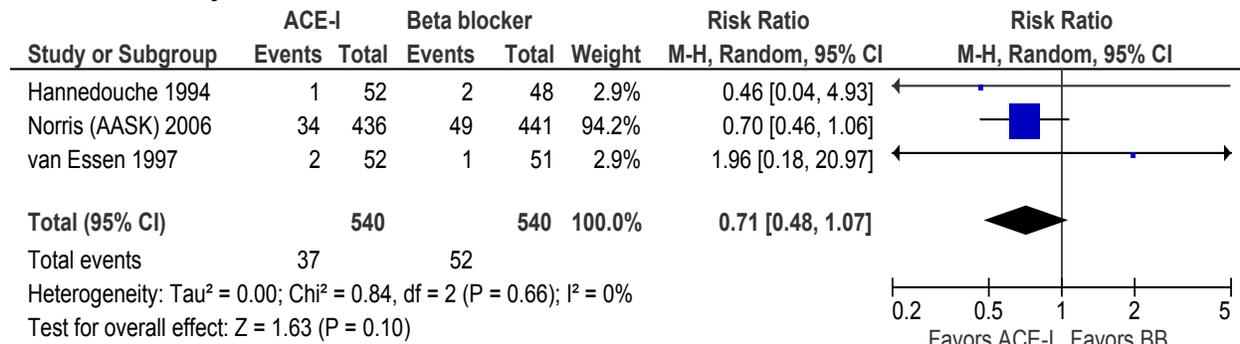


Halving of GFR

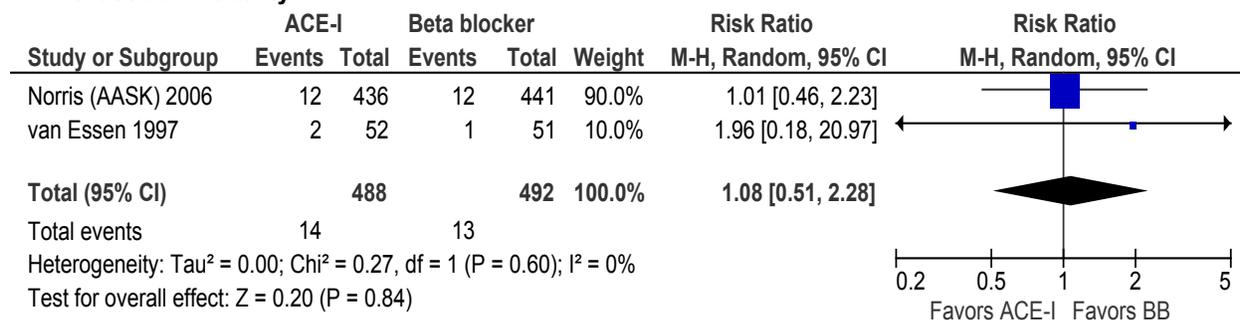


ACE VS. BB

All-cause mortality

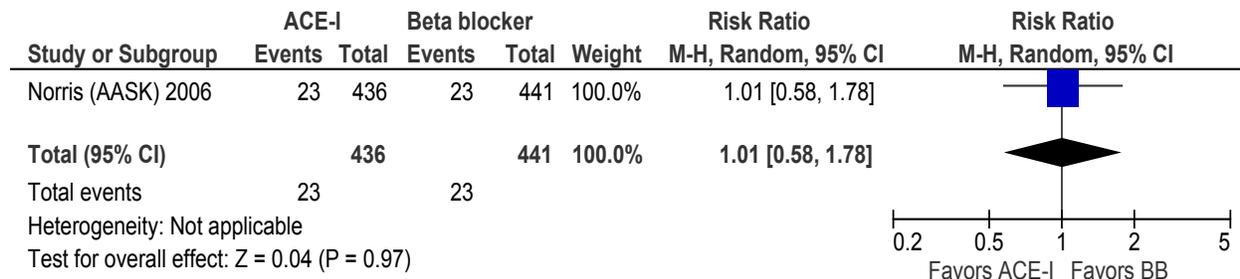


Cardiovascular mortality

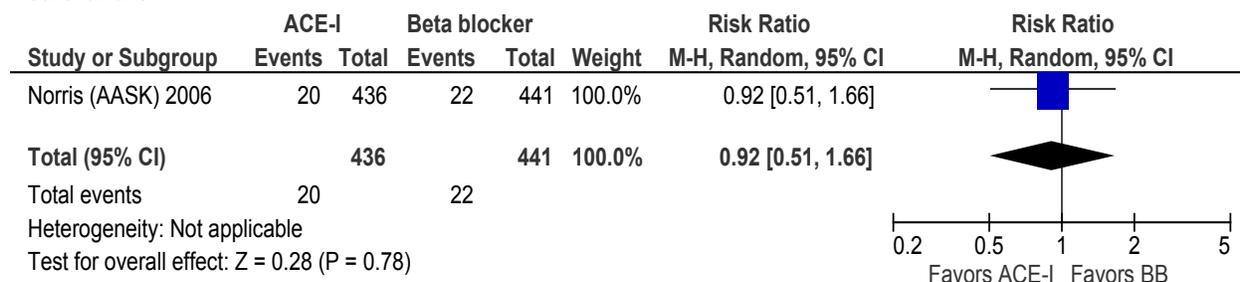


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

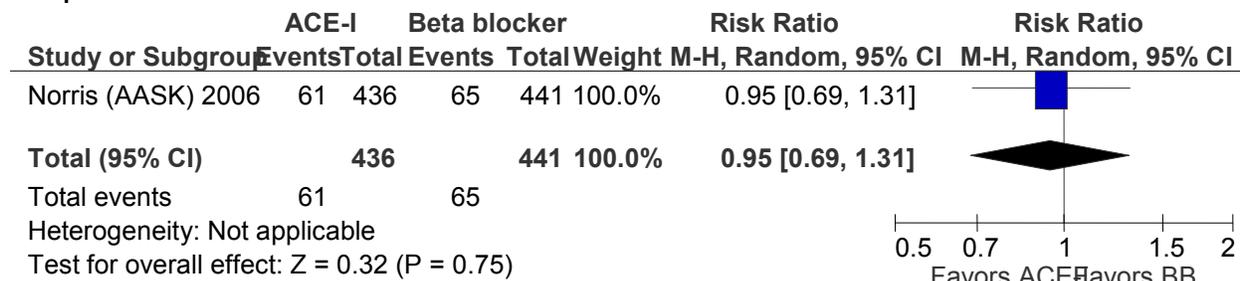
Stroke



Heart failure

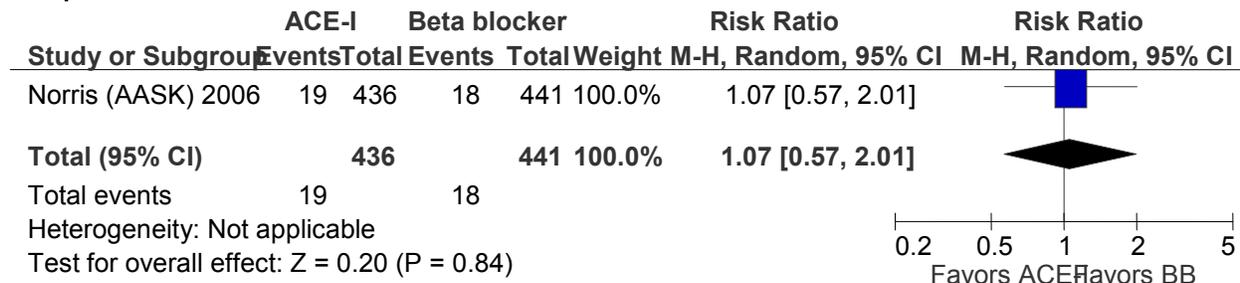


Composite vascular event*



* Cardiovascular mortality or first cardiovascular hospitalization

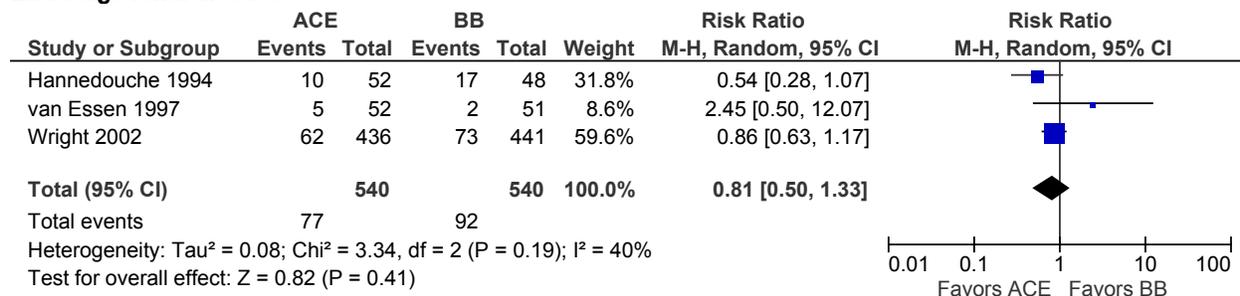
Composite vascular event**



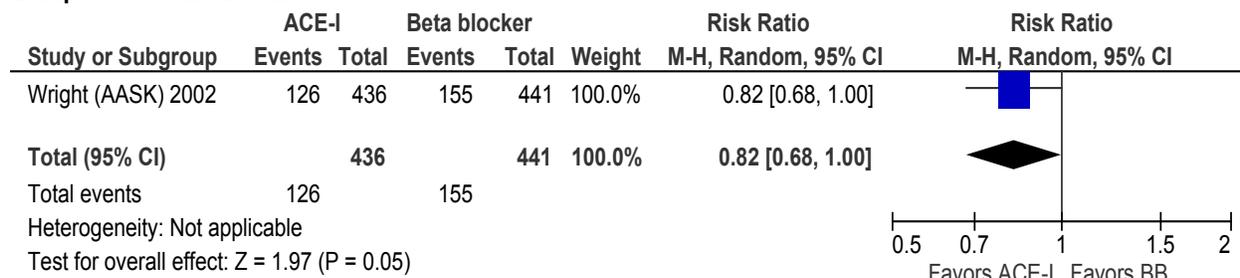
**Coronary heart disease event" defined as CAD hospitalization (probable MI) and/or fatal coronary heart disease death.

Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

End stage renal disease

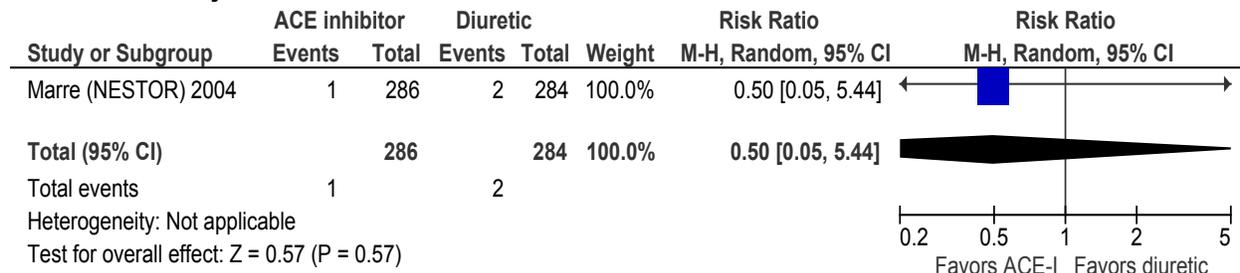


Composite renal outcome

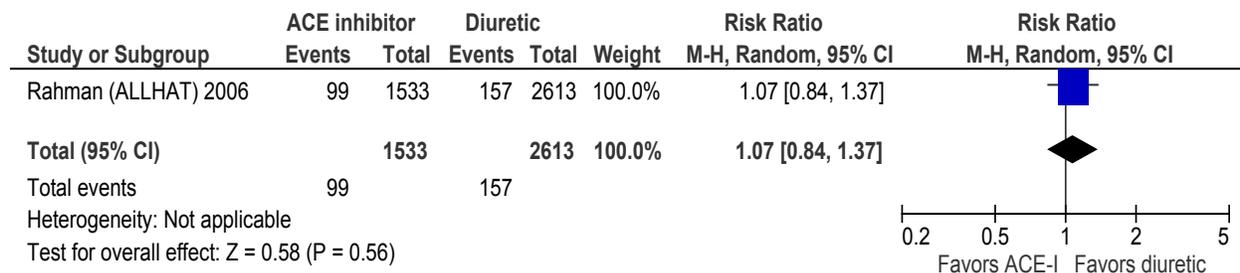


ACEI VERSUS DIURETICS

All-cause mortality

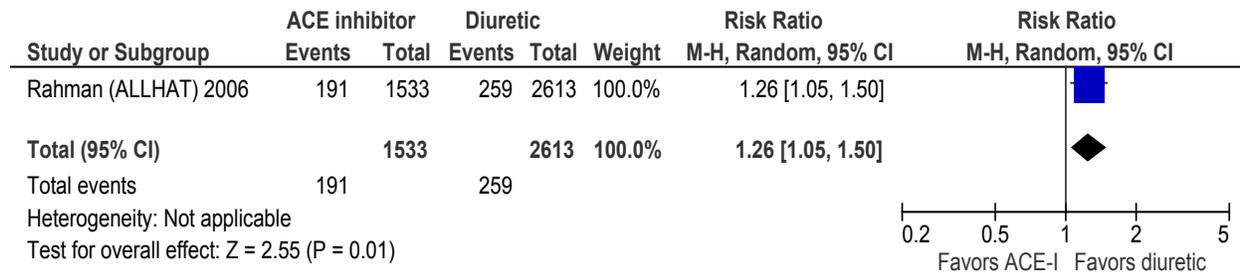


Stroke

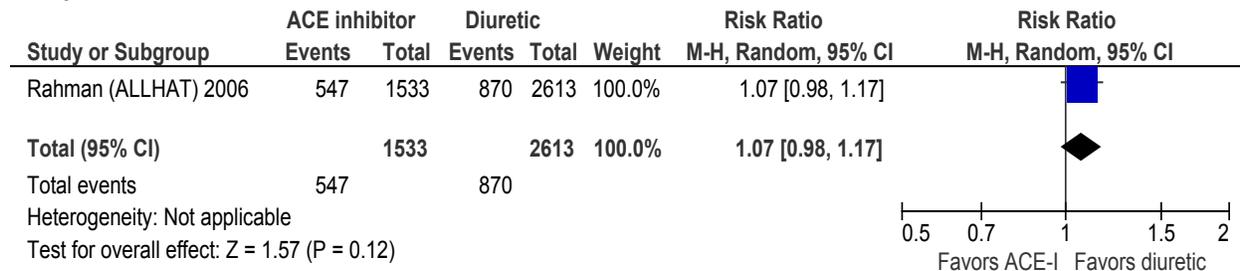


Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

Heart Failure

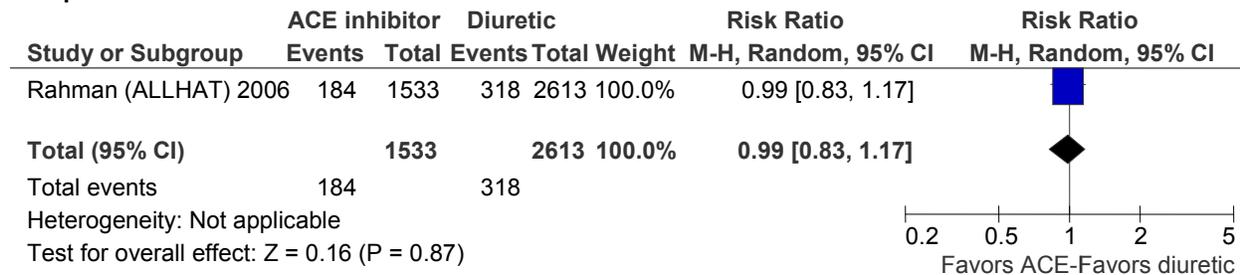


Composite vascular outcome*



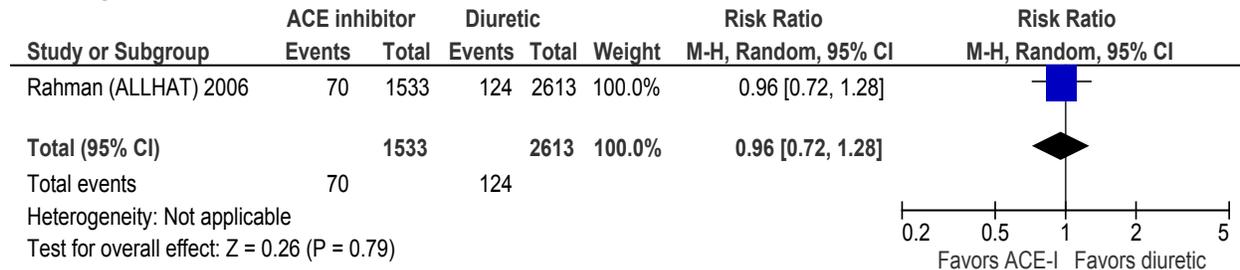
*Death from coronary heart disease, nonfatal MI, stroke, coronary revascularization procedures, hospitalized or treated angina, treated or hospitalized heart failure, and peripheral arterial disease requiring hospitalization or outpatient revascularization; and

Composite vascular outcome**



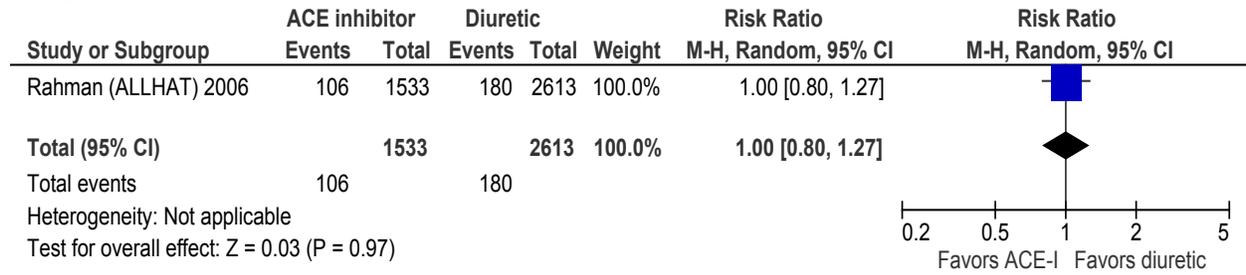
**Coronary heart disease event" defined as nonfatal MI or fatal coronary heart disease death

End-stage renal disease



Appendix Figure C1. Forest plots for ACEI monotherapy versus control treatment trials (continued)

Composite renal outcome



Appendix Table C4. Clinical outcomes (outcomes part B), Angiotensin converting enzyme inhibitor (ACEI) monotherapy versus control treatment trials

Study	Stroke or CVA, Nonfatal n/N (%)		Stroke or CVA, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B) or Any (C) n/N (%)		Composite Vascular Outcome n/N (%)	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
ACEI versus placebo/no treatment trials (n=17)										
Perkovic, 2007 ¹ (PRGRESS)										
Asselbergs, 2004 ² (PREVD)					0/431	2/433 (0.5)			17/431 (3.9)	28/433 (6.5)
Marre, 2004 ³ (DIAB)	89/2443 (3.6)	84/2469 (3.4)			76/2443 (3.1)	91/2469 (3.7)	85/2443 (3.5) (C)	102/2469 (4.1) (C)	362/2443 (14.8)	377/2469 (15.3)
Katayama, 2002 ⁴										
Bojestig, 2001 ⁵										
Gerstein, 2001 ⁶ (MICROHOPE)							38/553 (6.9)(A)	41/587 (6.9)(A)	108/553 (19.6)	155/587 (26.4)
O'Hare, 2000 ⁷ (ATLANTIS)									16/92 (17.4)	8/46 (17)
Muirhead, 1999 ⁸										
REIN, 1999 ⁹ stratum 1					0/99	2/87 (2.3)			2/99 (2.0)	3/87 (3.4)
Crepaldi, 1998 ¹⁰										
REIN, 1997 ¹¹ stratum 2									4/78 (5.1)	3/88 (3.4)
Maschio, 1996 ¹²	2/300 (0.7)	3/283 (1.1)								
Trevisan, 1995 ¹³										
Laffel, 1995 ¹⁴										
Sano, 1994 ¹⁵										
Lewis, 1993 ¹⁶										
Ravid, 1993 ¹⁷										
(ACEI) versus ARB trials (n=6)										
Mann, 2008 ¹⁸ ONTARGET										
Menne, 2008 ¹⁹ VALERIA										
Sengul, 2006 ²⁰										
Barnett, 2004 ²¹ DETAIL					7/130 (5.4)	9/120 (7.5)				
Lacourcière, 2000 ²²	0/51	0/52	0/51	0/52	0/51	0/52	0/51 (C)	0/52 (C)		
Muirhead, 1999 ⁸										

Appendix Table C4. Clinical outcomes (outcomes part B), Angiotensin converting enzyme inhibitor (ACEI) monotherapy versus control treatment trials (continued)

Study	Stroke or CVA, Nonfatal n/N (%)		Stroke or CVA, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B) or Any (C) n/N (%)		Composite Vascular Outcome n/N (%)	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
ACEI versus CCB trials (n=5)										
Rahman, 2005/2006 ^{23,35} ALLHAT					191/1533 (12.5)	174/1516 (11.5)			*(1) 547/1533 (35.7); (2) 184/1533 (12.0)	*(1) 537/1516 (35.4); (2) 194/1516 (12.8)
Rahman, 2006 ³⁵ ALLHAT, DM patients					81/501 (16.2)	87/506 (17.2)			*(1) 193/501 (38.5); (2) 76/501 (15.2)	*(1) 224/506 (44.3); (2) 83/506 (16.4)
Fogari, 2002 ²⁴										
Norris, 2006 ²⁷					20/436 (4.6)	8/217 (3.7)			** (1) 61/436 (14.0); (2) 19/436 (4.4)	** (1) 23/217 (10.6); (2) 5/217 (2.3)
Agodoa 2001 ²⁵ (AASK)										
Marin, 2001 ²⁸ ESPIRAL										
Crepaldi, 1998 ¹⁰										
Zucchelli, 1995 ²⁹										
ACEI versus BB trials (n=3)										
Norris, 2006 ²⁷					20/436 (4.6)	22/441 (5.0)			** (2) 19/436 (4.4)	** (2) 18/441 (4.1)
Agodoa 2001 ²⁵ (AASK)										
van Essen, 1997 ³¹										
Hannedouche 1994 ³²										
ACEI versus diuretics (n=2)										
Rahman, 2006 ³⁵ ALLHAT					191/1533 (12.5)	259/2613 (9.9)			*(1) 547/1533 (35.7); (2) 184/1533 (12.0)	*(1) 870/2613 (33.3); (2) 318/2613 (12.2)
Rahman, 2006 ³⁵ ALLHAT, DM patients					81/501 (16.2)	104/881 (11.8)			*(1) 193/501 (38.5); (2) 76/501 (15.2)	*(1) 326/881 (37.0); (2) 132/881 (15.0)
Marre, 2004 ³³ NESTOR										

Appendix Table C4. Clinical outcomes (outcomes part B), Angiotensin converting enzyme inhibitor (ACEI) monotherapy versus control treatment trials (continued)

ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor II blocker; CCB = calcium channel blocker; BB = beta blocker; CVA = cerebrovascular accident (or stroke); CHF = congestive heart failure; DM = diabetes mellitus; CAD = coronary artery disease.

*ALLHAT study reported two different composite cardiovascular endpoints: (1) Death from coronary heart disease, nonfatal MI, stroke, coronary revascularization procedures, hospitalized or treated angina, treated or hospitalized heart failure, and peripheral arterial disease requiring hospitalization or outpatient revascularization; and (2) "Coronary heart disease event" defined as nonfatal MI or fatal coronary heart disease death.

**AASK study reported two different composite cardiovascular endpoints: (1) Cardiovascular mortality or first cardiovascular hospitalization; and (2) "Coronary heart disease event" defined as CAD hospitalization (probable MI) and/or fatal coronary heart disease death.

Appendix Table C5. Composite vascular outcome definitions for ACEI monotherapy versus control treatment trials

Study	Definition
<i>ACEI versus placebo/no treatment trials</i>	
Perkovic, 2007 ¹ PROGRESS	Major cardiovascular events, defined as any of the following: nonfatal stroke, nonfatal MI, or cardiovascular death.
Asselbergs, 2004 ² PREVEND IT	Cardiovascular death or hospitalization for cardiovascular morbidity (latter defined as hospitalization for either nonfatal MI or myocardial ischemia, heart failure, peripheral vascular disease, and/or cerebrovascular accident).
Marre, 2004 ³ DIABHYCAR	Cardiovascular death (including sudden death), nonfatal acute MI, stroke, heart failure requiring admission to hospital, or end stage renal failure (defined as dialysis or kidney transplant)
Gerstein, 2001 ⁶ Micro-HOPE	Cardiovascular death, MI, or stroke
O'Hare, 2000 ⁷ ATLANTIS	Incident "cardiovascular adverse events" reported but not defined. Incidence of death, MI and angina/chest pain separately provided.
REIN, 1999 ⁹ stratum 1	Incident "nonfatal cardiovascular events" reported but not defined.
REIN, 1997 ¹¹ stratum 2	Nonfatal cardiovascular events included any of the following: MI, aortic aneurysm, or uncontrolled hypertension.
Maschio, 1996 ¹²	Nonfatal cardiovascular events included any of the following: MI, stroke, transient ischemic attack, hypertensive crisis, angina, hypotension or dizziness.
<i>ACEI versus CCB trials</i>	
Rahman, 2006 ³⁵ ALLHAT	Defined two composite vascular endpoints, as follows: (1) Death from coronary heart disease, nonfatal MI, stroke, coronary revascularization procedures, hospitalized or treated angina, treated or hospitalized heart failure, and peripheral arterial disease requiring hospitalization or outpatient revascularization; and (2) "Coronary heart disease event" defined as nonfatal MI or fatal coronary heart disease death
Wright, 2002 ²⁶ AASK	Defined two composite vascular endpoints, as follows: (1) Cardiovascular mortality or first cardiovascular hospitalization and (2) "Coronary heart disease event" defined as CAD hospitalization (probable MI) and/or fatal coronary heart disease death.
<i>ACEI versus diuretic trials</i>	
Rahman, 2006 ³⁵ ALLHAT	Defined two composite vascular endpoints, as follows: (1) Death from coronary heart disease, nonfatal MI, stroke, coronary revascularization procedures, hospitalized or treated angina, treated or hospitalized heart failure, and peripheral arterial disease requiring hospitalization or outpatient revascularization and (2) "Coronary heart disease event" defined as nonfatal MI or fatal coronary heart disease death

ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor II blocker; CCB = calcium channel blocker; BB = beta blocker; MI = myocardial infarction; CAD = coronary artery disease

Appendix Table C6. Clinical renal outcomes (outcomes part C), ACEI monotherapy versus control treatment trials

Study	End-Stage Renal Disease n/N (%)		Doubling of Serum Creatinine n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome n/N (%)	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
ACEI versus placebo trials (n=17)										
Perkovic, 2007 ¹ (PRGRESS)										
Asselbergs, 2004 ² (PREVD)										
Marre, 2004 ³ (DIAB)	11/2443 (0.5)	12/2469 (0.5)	48/2443 (2.0)	60/2469 (2.4)						
Katayama, 2002 ⁴			2/52 (3.8)	2/27 (7.4)						
Bojestig, 2001 ⁵							0/37	0/18		
Gerstein, 2001 ⁶ (MICROHOPE)†	5/553 (0.9)	6/587 (1.0)	21/553 (3.8)*	18/587 (3.1)			104/553 (18.8)	127/587 (21.6)		
O'Hare, 2000 ⁷ (ATLANTIS)							6/88 (6.8)	5/46 (10.9)		
Muirhead, 1999 ⁸							1/29 (3.4)	3/27 (11.1)		
REIN, 1999 ⁹ stratum 1	9/99 (9.1)	18/87 (20.7)								
Crepaldi, 1998 ¹⁰							2/32 (6.3)	7/34 (20.6)		
REIN, 1997 ¹¹ stratum 2	17/78 (21.8)	29/88 (33.0)	1/78 (1.3)	11/88 (12.5)					18/78 (23.1)	40/88 (45.5)
Maschio, 1996 ¹²	1/300* (0.3)	1/283 (0.4)	30/300 (10)*	56/283 (19.8)					31/300 (10.3)	57/283 (20.1)
Trevisan, 1995 ¹³										
Laffel, 1995 ¹⁴							4/67 (6.0)	13/70 (18.6)		
Sano, 1994 ¹⁵										
Lewis, 1993 ¹⁶	20/207 (9.7)	31/202 (15.3)	25/207 (12.1)	43/202 (21.3)					23/207 (11.1)	42/202 (20.8)
Ravid, 1993† ¹⁷	0/49*	0/45	2/49 (4.1)*	12/45 (26.7)			2/49 (4.1)	22/45 (48.9)		
ACEI versus ARB trials (n=6)										
Mann, 2008 ¹⁸ ONTARGET							§	§	Numbers not provided for CKD subgroup	
Menne, 2008 ¹⁸ VALERIA										
Sengul, 2006 ²⁰							0/110	0/109		
Barnett, 2004 ²¹ DETAIL										
Lacourcière, 2000 ²²							NR‡	NR‡		
Muirhead, 1999 ⁸							1/29 (3.4)	1/62 (1.6)		

Appendix Table C6. Clinical renal outcomes (outcomes part C), ACEI monotherapy versus control treatment trials (continued)

Study	End-Stage Renal Disease n/N (%)		Doubling of Serum Creatinine n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome n/N (%)	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
ACEI versus CCB trials (n=6)										
Rahman, 2005 ²³ ALLHAT	70/1533 (4.6)	65/1516 (4.3)					36/1533 (2.3)	25/1516 (1.6)	106/1533 (6.9)	90/1516 (5.9)
Rahman, 2005 ²³ ALLHAT, DM patients††									61/501 (12.2)	56/506 (11.1)
Fogari, 2002 ²⁴										
Agodoa, 2001 (AASK)	47/436 (10.8)	32/217 (14.7)					44/436 (10.1)	29/217 (13.4)	*(1) 70/436 (16.1); (2) 87/436 (20.0)	*(1) 43/217 (19.8); (2) 56/217 (25.8)
Marin, 2001 ²⁸ ESPIRAL									27/129 (20.9)	40/112 (35.7)
Crepaldi, 1998 ¹⁰										
Zucchelli, 1995 ²⁹	7/60 (11.7)	14/61 (23.0)								
ACEI versus BB trials (n=3)										
Wright, 2002 ²⁶	62/436 (14.2)	73/441 (16.6)							126/436 (28.9)	155/441 (35.1)
van Essen, 1997 ³¹	5/52 (9.6)	2/51 (3.9)								
Hannedouche, 1994 ³²	10/52 (19.2)	17/48 (35.4)								
ACEI versus diuretic trials (n=3)										
Rahman, 2006 ³⁵ ALLHAT	70/1533 (4.6)	124/2613 (4.7)							106/1533 (6.9)	180/2613 (6.9)
Rahman, 2006 ³⁵ ALLHAT, DM patients	41/501 (8.2)	68/881 (7.7)							61/501 (12.1)	96/881 (10.9)
Marre, 2004 ³³ NESTOR							18/286 (6.3)	26/283 (9.2)		

ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor II blocker; CCB = calcium channel blocker; BB = beta blocker; GFR = glomerular filtration rate

* AASK study reported two different composite renal outcomes, defined as: (1) decline in glomerular filtration rate or incident end stage renal disease; and (2) decline in glomerular filtration rate, incident end stage renal disease, or death.

† Data obtained from Ksirsagar Am J Kidney Dis 2000;35(4):695-707 or Stroppoli BMJ/Cochrane review 2004.

‡ Study reported that 3/103 participants converted from micro- to microalbuminuria, but did not report results by treatment group.

§ Study reported in text that progression from microalbuminuria to macroalbuminuria occurred in 166 (2.12%) of ramipril subjects, 138 (1.8%) of telmisartan subjects, but this is not possible given that in figure study reports that 2673 subjects had either microalbuminuria or macroalbuminuria at baseline.

†† Rahman 2006 ALLHAT DM patients is a report on the subgroup of diabetic patients from the overall ALLHAT study.

Appendix Table C7. Composite renal outcome definitions for ACEI versus control treatment trials

Study	Definition
<i>ACEI versus placebo/no treatment trials</i>	
REIN, 1997 ¹¹ stratum 2	Doubling of baseline serum creatinine concentration or end stage renal disease.
Maschio, 1996 ¹²	Doubling of baseline serum creatinine concentration or the need for dialysis.
Lewis, 1993 ¹⁶	Death, dialysis, or renal transplantation.
<i>ACEI versus ARB trials</i>	
Mann, 2008 ¹⁸ ONTARGET	Dialysis, renal transplantation, doubling of serum creatinine, or death.
<i>ACEI versus CCB trials</i>	
Rahman, 2005 ²³ ALLHAT	End stage renal disease (death due to kidney disease, dialysis, or renal transplantation) or reduction in GFR by 50% or by 25 mL/min/1.73 m ² from the mean of the two baseline GFRs.
Agodoa, 2001 ²⁵ AASK	End stage renal disease (need for renal replacement therapy), reduction in GFR by 50% or by 25 mL/min/1.73 m ² from the mean of the two baseline GFRs, or death.
Marin, 2001 ²⁸ ESPIRAL	Doubling of baseline serum creatinine concentration or the need for dialysis.
<i>ACEI versus BB trials</i>	
Wright, 2002 ²⁶ (AASK)	End stage renal disease (need for renal replacement therapy), reduction in GFR by 50% or by 25 mL/min/1.73 m ² from the mean of the two baseline GFRs, or death.
<i>ACEI versus diuretic trials</i>	
Rahman, 2005 ²³ ALLHAT	End stage renal disease (death due to kidney disease, dialysis, or renal transplantation) or reduction in GFR by 50% or by 25 mL/min/1.73 m ² from the mean of the two baseline GFRs.

ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor II blocker; CCB = calcium channel blocker; BB = beta blocker; GFR = glomerular filtration rate

Appendix Table C8. Study withdrawals and adverse events (outcomes Part D), ACEI monotherapy versus control treatment trials

Study	Any Study Withdrawals		Any or Serious Adverse Events Leading to Study Withdrawal		Adverse Event: Cough		Adverse Event: Hyperkalemia		Renal Adverse Events Leading to Withdrawal*		Renal Adverse Events	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
<i>ACEI versus placebo/no treatment trials (n=17)</i>												
Perkovic, 2007 ¹ (PRGRESS)												
Asselbergs, 2004 ² (PREVD)	103/431 (24)	110/433 (25.4)										
Marre, 2004 ³ (DIAB)	334/2443 (13.7)**	324/2469 (13.1)**	609/2443 (24.9)	554/2469 (22.4)	80/2443 (3.3)	21/2469 (0.9)						
Katayama, 2002 ⁴	12/52 (23.1)	10/27 (37)	2/52 (3.8)	1/27 (3.7)								
Bojestig, 2001 ⁵	4/37 (10.8)	0/18	3/37 (8.1)	0/18	1/37 (2.7)	0/18						
Gerstein, 2001 ⁶ (MICROHOPE)												
O'Hare, 2000 ⁷ (ATLANTIS)	31/92 (33.7)	11/48 (22.9)	15/92 (16.3)	5/48 (10.4)								
Muirhead, 1999 ⁸	4/29 (13.8)	7/31 (22.6)	2/29 (6.9)	0/31	6/29 (20.7)	1/31 (3.2)						
REIN, 1999 ^{9,11} Stratum 1	20/99 (20.2)†	20/87 (23)†	11/99 (11.1)	6/87 (6.9)	1/99 (1.0)	0/87	0/99	1/87 (1.1)	1/99 (1.0)	0/87	Worsening renal insufficiency	
Crepaldi, 1998 ¹⁰	2/32 (6.3)	6/34 (17.6)	1/32 (3.1)	6/34 (17.6)					0/32	1/34 (2.9)	Diabetic nephropathy	
REIN, 1997 ¹¹ Stratum 2	14/78 (17.9) †	21/88 (23.9) †	9/78 (11.5)	11/88 (12.5)			1/78 (1.3)	1/88 (1.1)	0/78	2/88 (2.3)	Worsening renal insufficiency	
Maschio, 1996 ¹²	68/300 (22.7)	61/283 (21.6)	52/300 (17.3)	41/283 (14.5)	25/300 (8.3)	10/283 (3.5)	5/300 (1.7)	3/283 (1.1)	3/300 (1.0)	6/283 (2.1)	Worsening renal insufficiency	
Trevisan, 1995 ¹³	6/60 (10)	8/62 (12.9)	4/60 (6.7)	7/62 (11.3)	1/60 (1.7)	1/62 (1.6)						
Laffel, 1995 ¹⁴	22/70 (31.4)	21/73 (28.8)	4/70 (5.7)	5/73 (6.8)	15/70 (21.4)	16/73 (21.9)	0/70	0/73				
Sano, 1994 ¹⁵			0/26	0/26	0/26	0/26						
Lewis, 1993 ¹⁶			46/207 (22.2)	58/202 (28.7)			3/207 (1.4)	0/202				

Appendix Table C8. Study withdrawals and adverse events (outcomes Part D), ACEI monotherapy versus control treatment trials (continued)

Study	Any Study Withdrawals		Any or Serious Adverse Events Leading to Study Withdrawal		Adverse Event: Cough		Adverse Event: Hyperkalemia		Renal Adverse Events Leading to Withdrawal*		Renal Adverse Events	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
Ravid, 1993 ¹⁷	3/56 (5.3)	3/52 (5.8)	4/56 (7.1)	3/52 (5.8)	4/56 (7.1)	2/52 (3.8)						
ACEI versus ARB trials (n=6)												
Mann, 2008 ¹⁸ ONTARGET												
Menne, 2008 ¹⁹ VALERIA	6/47 (12.8)	6/43 (14.0)	4/47 (8.5)	3/43 (7)	2/47 (4.3)	0/43	1/47 (2.1)	1/43 (2.3)				
Sengul, 2006 ²⁰	15/109 (13.8)	12/110 (10.9)										
Barnett, 2004 ²¹ DETAIL	44/130 (33.8)	38/120 (31.7)	30/130 (23.1)	20/120 (16.7)					2/130 (1.5)	2/120 (1.7)	Elevated serum creatinine	
Lacourcière, 2000 ²²	5/51 (9.8)	6/52 (11.5)	1/51 (2)	2/52 (3.8)	7/51 (13.7)	0/52						
Muirhead, 1999 ⁸	4/29 (13.8)	8/62 (12.9)	2/29 (6.9)	2/62 (3.2)	6/29 (20.7)	4/62 (6.5)			0/29 0	1/62 (1.6)	Decreased GFR and creatinine clearance	
ACEI versus CCB trials (n=5)												
Rahman, 2006 ³⁵ ALLHAT												
Fogari, 2002 ²⁴	26/102 (25.5)	27/103 (26.2)	3/102 (2.9)	4/103 (3.9)	2/102 (2.0)	0/103			2/102 (2.0)	2/103 (1.9)	Worsening kidney function	
Wright, 2002 ²⁶ (AASK)	0/436	0/217	0/436	0/217	54.9*	46.3*	3/436 (0.7)	0/217				
Wright, 2002 ²⁶ (AASK)	Other adverse events that were significantly different between groups (p<0.5): angioedema ACE 6.4* vs. 2.3* for CCB; Syncope ACE 6.7* vs. 2.3* for CCB; Edema ACE 46* vs. 59.8* for CCB											
Marin, 2001 ²⁸ ESPIRAL	45/129 (34.9)	38/112 (33.9)	15/129 (11.6)	12/112 (10.7)	3/129 (2.63)	0/112			4/129 (3.1)	1/112 (0.9)	Impaired kidney function	
Crepaldi, 1998 ¹⁰	17/47 (36.2)	17/41 (41.2)	1/32 (3.1)	0/26					0/32	0/26		
Zucchelli, 1995 ²⁹	15/60 (25)	16/61 (26)	5/60 (8.3)	7/61 (11.5)	2/60 (3.3)	0/61						
ACEI versus BB trials (n=3)												
Wright, 2002 ²⁶ (AASK)	0/436	0/441	0/436	0/441	54.9*	41.5*	3/436 (0.7)	1/441 (0.2)				
van Essen, 1997 ³¹	9/52 (17.3)	5/51 (9.8)	9/52 (17.3)	5/51 (9.8)			1/52 (1.9)	0/51				
Hannedouche, 1994 ³²	11/52 (21.2)	12/48 (25.0)	3/52 (5.8)	3/48 (6.3)			2/52 (3.8)	0/48				

Appendix Table C8. Study withdrawals and adverse events (outcomes Part D), ACEI monotherapy versus control treatment trials (continued)

Study	Any Study Withdrawals		Any or Serious Adverse Events Leading to Study Withdrawal		Adverse Event: Cough		Adverse Event: Hyperkalemia		Renal Adverse Events Leading to Withdrawal*		Renal Adverse Events	
	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control	ACEI	Control
ACEI versus diuretics (n=2)												
Rahman, 2006 ³⁵ ALLHAT												
Marre, 2004 ³³ NESTOR	30/286 (10.5)	35/284 (12.3)	15/286 (5.2)	14/284 (4.9)								

* Results reported as percent of patients experiencing adverse event per patient year of followup (patients were followed up for 3 to 6.4 years)
ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor II blocker; CCB = calcium channel blocker; BB = beta blocker

Appendix Evidence Table C9. Overview of ARB monotherapy trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
ARB versus placebo/no treatment trials (n= 4 trials)				
Makino, 2007 ³⁶	Inclusion Criteria: Age 30 to 74, type 2 DM and urinary albumin-to-creatinine ratio 100-300 mg/g, serum creatinine <1.5 mg/dl (men) and <1.3 mg/dl (women).	N=527 Age (yr): 61.7 Gender (Male %): NR Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 137 Diastolic BP (mm Hg): 77 Albuminuria: NR, see Inc. criteria Serum creatinine (mg/dL): NR, see Inc. criteria Estimated GFR (ml/min/1.73m2): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): NR History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	n= 168 to Telmisartan 80mg/day n= 172 to Telmisartan 40mg/day n= 174 to placebo period: median 1.3 +/- 0.5 years Study withdrawals (%): 2.4 % excluded from primary analysis due to suspected type 1 DM or for missing UACR measurements	Allocation Concealment Unclear Blinding: Double blinded Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes
Brenner, 2001 ³⁷ RENAAL	Inclusion Criteria: Age 31 to 70 years with type 2 DM and nephropathy defined as 2 occasions of urinary albumin/creatinine ratio ≥300 mg/g (or urinary protein excretion ≥0.5 g/day) and serum creatinine 1.3 – 3.0 mg/dL with lower limit of 1.5 mg/dL for male patients weighing >60kg. Exclusion Criteria: Type 1 DM or nondiabetic renal disease including renal-artery stenosis. MI or CABG within the previous month, PCI within the previous six months, CVA or TIA within the previous year. History of CHF. Patients on ACEI or ARB prior to study had these medications stopped.	N=1513 Age (yr): 60 Gender (Male %): 63.2 Race/Ethnicity (%): Asian: 16.7, Black: 15.2, White: 48.6, Hispanic: 18.2, Other: 1.3 BMI: 29 Systolic BP (mm Hg): 153 Diastolic BP (mm Hg): 82 Albuminuria: Median Urine Alb/Cr: 1250 mg/g Serum creatinine (mg/dL): 1.9 Estimated GFR (ml/min/1.73m2): NR Total cholesterol (mg/dL): 228 LDL cholesterol (mg/dL): 142 Diabetes (%): 100 History of HTN (%): 93.5 History of CAD (%): 0.1 (not all CAD as only refers to history of coronary revascularization procedure) History of CHF (%): 0	n= 751 for 50-100mg/day Losartan (71% reached 100 mg/day) n= 762 Placebo All patients also given "standard antihypertensive therapy" (CCB, Diuretics, Alpha blockers, Beta-blockers and centrally acting agents) to maintain BP<140/90. Followup period: median 3.4 years Study withdrawals (%): 7.8 46.5 Losartan	Allocation Concealment Adequate Blinding: Double blind Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes

Appendix Evidence Table C9. Overview of ARB monotherapy trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		History of MI (%): 11.2 History of Stroke (%): 0.1 Peripheral arterial disease (%): NR Current smoker (%): 18.3		
Parving, 2001 ³⁸ IRMA-2	Inclusion Criteria: HTN, age 30 to 70, type 2 DM, persistent microalbuminuria (UAER 20 to 200 µg/min in 2 of 3 consecutive, sterile, overnight samples), serum creatinine ≤1.5 mg/dl for men and ≤1.1 mg/dl for women.	N=590 Age (yr): 58 Gender (Male %): 68.5 Race/Ethnicity (%): White: 97.3, Non-White: 2.7 BMI: 30 Systolic BP (mm Hg): 153 Diastolic BP (mm Hg): 90 Albuminuria: 55.5 µg/min Serum creatinine (mg/dL): 1.18 Estimated GFR (ml/min/1.73m2):NR Total cholesterol (mg/dL): 224 LDL cholesterol (mg/dL): 140 Diabetes (%): 100 History of HTN (%): 100 History of CAD (%): 4.5 History of CHF (%): NR History of MI (%): 3.0 History of Stroke (%): 3.1 Peripheral arterial disease (%): 5.2 Current smoker (%): 18.6	n= 201 placebo n= 195 Irbesartan 150mg n= 194 Irbesartan 300mg Followup period: median 2 years Study withdrawals (%): 13	Allocation Concealment: Not defined Blinding: Double blind Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes
Location: 96 centers worldwide				
Funding Source Industry	Exclusion Criteria: Nondiabetic kidney disease, cancer, life-threatening disease with death expected to occur within two years, and an indication for ACEI or ARBs.			
Lewis, 2001 ³⁹ IDNT	Inclusion Criteria: Age 30 - 70, documented diagnosis of type 2 DM, HTN (SBP>135 mm Hg, DBP>85 mm Hg, or documented treatment with antihypertensive agents), proteinuria (urinary protein excretion ≥ 900 mg per 24 hours), serum creatinine 1.0 - 3.0 mg/dL in women and 1.2 - 3.0 mg/dL in men	N=1,148 Age (yr): 59 Gender (Male %): 68 Race/Ethnicity (%): White 74.3 Hispanic 4.7 Black 12.3 Asian 4.4 Other 4.3 BMI: 30.7 Systolic BP (mm Hg): 159 Diastolic BP (mm Hg): 87 Albuminuria: NR Median Urine Protein Excretion 2.9 g/24hr Median Urine Albumin Excretion 1.9 g/24hr Serum creatinine (mg/dL): 1.68 Estimated GFR (ml/min/1.73m2): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100% History of HTN (%): 100% History of CAD (%): 28.0 with history of	n= 579 Irbesartan 300 n= 569 Placebo Additional antihypertensives (excluding ACEI, ARB or CCB) allowed to maintain SBP <135mmHg (or 10mmHg less than baseline if SBP >145) and DBP <85. Followup period: median 2.6 years Study withdrawals (%): 0.8	Allocation Concealment : Adequate Blinding: Patients, investigators, and assessors Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: yes
Location USA				
Funding Source: Industry	Exclusion Criteria: NR			

Appendix Evidence Table C9. Overview of ARB monotherapy trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		"cardiovascular disease" History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR		
ARB versus CCB trials (n=4 trials)				
Saruta, 2009 ⁴⁰ CASE-J	Inclusion Criteria: For main study, inclusion criteria were: SBP >180mmHg or DBP >110mmHg, type II diabetes, history of stroke or transient ischemic attack, left-ventricular hypertrophy, angina pectoris or a history of myocardial infarction, proteinuria or a serum creatinine \geq 1.3mg/dL, or arteriosclerotic peripheral artery obstruction. For this post-hoc analysis, CKD defined as proteinuria (positive urine dipstick) and/or decreased GFR (<60ml/min/1.73m ²).	N= 2720 (subset with GFR <60ml/min/1.73m ² from among larger study cohort of 4728) Age (yr): 65 Gender (Male %): 51.8 Race/Ethnicity (%): NR BMI: 24.5 Systolic BP (mm Hg): 163 Diastolic BP (mm Hg): 91 Albuminuria: NR Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL):NR Diabetes (%): 42.4 History of HTN (%): 100 History of CAD (%): NR History of CHF (%): NR History of MI (%): 4.8 History of Stroke (%): 11.8 Peripheral arterial disease (%): 1.2 Current smoker (%): NR	n=1376 Candesartan 4 to 12mg daily titrated to target BP n=1344 Amlodipine 2.5 to 10mg daily titrated to target BP Doses titrated to goal BP <130/85 for ages <60 years <140/90 for ages 60-69 <150/90 for ages 70-79 <160/90 for ages >80 Followup period: Total 36 months Study withdrawals (%):No data were reported	Allocation Concealment: Not defined Blinding: Assessor Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Inadequate
Location Japan				
Funding Source Industry and Government				
	Exclusion Criteria: SBP \geq 200 mmHg or DBP \geq 120 mmHg, Type I DM, MI or CVA \leq 6 months before screening, PTCA or CABG \leq 6 months before screening or currently scheduled, current treatment for CHF (New York Heart Association functional class II-IV) or ejection fraction <40%, CAD requiring beta blocker or calcium channel blocker, atrial fibrillation or atrial flutter, serum creatinine \geq 3 mg/dL, AST and/or ALT \geq 100 IU/L, malignancy \leq 5 years before enrollment, suspected contraindication for candesartan or amlodipine, pregnancy, possible pregnancy, or plan to conceive a child within 5 years of enrollment, not suited to the clinical trial as			

Appendix Evidence Table C9. Overview of ARB monotherapy trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	judged by a collaborating physician, inability to give informed consent.			
Ogawa, 2007 ⁴¹	Inclusion/Exclusion Criteria: Type 2 DM outpatients who previously had untreated moderate hypertension (130/80 – 200/110 mmHg); microalbuminuria with repeat x 3 urinary albumin-to-creatinine ratio (ACR) of 100-300 mg/g; glycated hemoglobin Alc (HbA1c)<8.0%; no changes in medications or hospitalization during past 3 years; body mass index (BMI)<30 kg/m ² ; serum creatinine < 1.2 mg/dl; no other renal diseases; no severe cerebral or cardiovascular diseases or liver dysfunction; and no active retinopathy.	N=58 Age (yr): 62.7 Gender (Male %): 46.6 Race/Ethnicity (%): NR BMI: 23.6 Systolic BP (mm Hg): 152 Diastolic BP (mm Hg): 90 Albuminuria: 100% Mean urine Alb/Cr ratio= 237 Serum creatinine (mg/dL): 0.74 Estimated GFR (ml/min/1.73m ²): NR Total cholesterol (mg/dL): 199.6 LDL cholesterol (mg/dL): NR Diabetes (%): 100% History of HTN (%): 100% Peripheral arterial disease (%): NR Current smoker (%): NR History of CHF (%): NR History of CAD (%): NR History of MI (%): NR History of Stroke (%): NR	n=40 Candesartan 4 - 8mg/d n=18 Nifedipine 20 - 40mg/d Followup period: median 56 weeks Study withdrawals (%): 2/58 (3.4) Candesartan and Nifedipine doses were 4 mg and 20mg daily, respectively, for first 48 weeks, then doses increased to 8mg and 40 mg daily, respectively.	Allocation Concealment: Not defined Blinding: Patient only Intention to Treat Analysis (ITT): Unclear Withdrawals/Dropouts adequately described: Yes
Viberti, 2002 ⁴² MARVAL	Inclusion Criteria: 35 to 75 years of age, type 2 diabetes mellitus, persistent microalbuminuria (median UAER of 3 nonconsecutive timed overnight urine collections 20 to 200 g/min during 5 week period before entry), normal serum creatinine, BP <180/105 mm Hg. Exclusion Criteria: Type 1 DM (onset at <35 years of age and requiring insulin within the first year), use of ACEIs, alpha 2 blockers, or CCB ≤5 weeks before random assignment; child-bearing potential for women; heart failure within preceding 6 months requiring ACE inhibitor therapy; MI, PTCA or CVA within the preceding 3 months; severe diabetic	N=332 Age (yr): 58 Gender (Male %): 79.8 Race/Ethnicity (%): White: 86.5 Asian: 10 BMI: 30.8 Systolic BP (mm Hg): 148 Diastolic BP (mm Hg): 86 Albuminuria: 100% Baseline UAER 56.7 µg/min Serum creatinine (mg/dL): 1.08 Estimated GFR (ml/min/1.73m ²):NR Total cholesterol (mg/dL): 198.5 LDL cholesterol (mg/dL):NR Diabetes (%): 100 History of HTN (%): 65 History of CAD (%): NR History of CHF (%): NR History of MI (%): 0 History of Stroke (%): NR	n= 169 valsartan initiated at 80 mg/d, could be titrated to 160 mg/d to reach target BP 135/85 mm Hg n= 163 amlodipine initiated at 5 mg/d, could be titrated to 10 mg/d to reach target BP 135/85 mm Hg Mean daily doses at end of study were 122 mg valsartan and 8 mg amlodipine. If BP target not reached with maximum study drug dose, 2.5 mg/d	Allocation Concealment: Yes Blinding: Patients, investigators Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes

Appendix Table C10 Summary of study baseline characteristics for ARB monotherapy trials

Characteristic	Mean (Range) (unless otherwise noted)	Number of Trials Reporting
<i>ARB versus placebo trials</i>		4
Patients randomized, n	3,778 (527-1513)	4
Age of subjects, years	59.6 (58-61.7)	4
Male gender, %	65.9 (63.2-68.5)	3
White race/ethnicity, %	66.5 (48.6-97.3)	3
Body Mass Index	29.8 (29-30.7)	3
Patients with diabetic nephropathy, n	3,778 (527-1,513)	4
Serum creatinine, mg/dL	1.7 (1.2-1.9)	3
Estimated GFR, ml/min/1.73m ²	Not reported	0
Albuminuria, µg/min	55.5	*1
Systolic blood pressure, mm Hg	153 (137-159)	4
Diastolic blood pressure, mm Hg	84 (77-90)	4
History of Hypertension, %	99.1 (93.5-100.0)	4
History of Cardiovascular disease, %	28.0	1
History of CAD, %	4.5	1
History of MI, %	8.9 (3.0-11.2)	2
Patients randomized to Irbesartan versus placebo, n	1,738 (590-1,148)	2
Patients randomized to Losartan versus placebo, n	1,513	1
Patients randomized to Telmisartan versus placebo, n	527	1
<i>ARB versus CCB trials</i>		3
Patients randomized, n	3,924 (58-2,720)	3
Age of subjects, years	63.2 (59 - 65)	3
Male gender, %	55.4 (46.6-64.3)	3
Race/ethnicity, white, %	72.1	1
Body Mass Index	26.4 (23.6-30.9)	3
Patients with diabetic nephropathy, n	†1,204 (58-1,146)	2
Serum creatinine, mg/dL	1.6 (0.74-1.66)	2
Estimated GFR, ml/min/1.73m ²	Not reported	0
Systolic blood pressure, mm Hg	162 (152-163)	3
Diastolic blood pressure, mm Hg	90 (87-91)	3
History of HTN, %	100 (100-100)	3
History of Cardiovascular disease, %	28.7	1
History of CAD, %	Not reported	0
Patients with history of MI, %	4.8	1
Patients randomized to Candesartan versus CCB, n	2,778 (58-2,720)	2
Patients randomized to Irbesartan versus CCB, n	1146	1
Patients randomized to Amlodipine versus ARB, n	3,866 (1,146-2,720)	2
Patients randomized to Nifedipine versus ARB, n	58	1

ARB = angiotensin receptor blocker, GFR = glomerular filtration rate, CAD = coronary artery disease, MI = myocardial infarction, CCB = calcium channel blocker

*All 4 trials that compared ARB versus placebo required that participants have albuminuria or proteinuria at baseline for entry, but all reported this measure differently, as albumin-to-creatinine ratio 100-300 mg/g (no baseline mean or median reported), urinary albumin/creatinine ratio (UACR) ≥300 mg/g or urinary protein excretion ≥0.5 g/day (median UACR 1250 mg/g), urinary albumin excretion rate (UAER) 20 to 200 µg/min (mean UAER 55.5 µg/min), and urinary protein excretion ≥900 mg per 24 hours (median urinary albumin excretion 1.9gm/24 hrs), respectively.

†One additional study included 2,720 participants with diabetes and CKD, defined by either impaired GFR or proteinuria, but did not specify how many participants had proteinuria. These study subjects were not counted toward the total number of patients with diabetic nephropathy.

Appendix Table C11. Clinical outcomes (outcomes part A), ARB monotherapy trials

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke or CVA, Any, n/N (%)	
	ARB	Control	ARB	Control	ARB	Control	ARB	Control	ARB	Control	ARB	Control
ARB versus placebo trials (n=4)												
Makino, 2007 ³⁶												
Brenner, 2001 ³⁷	158/751 (21.0)	155/762 (20.3)			50/751 (6.7)	68/762 (8.9)						
RENAAL												
Parving, 2001 ³⁸	IRB 150mg	1/201 (0.5)										
IRMA-2	0/195											
	IRB 300mg											
	3/194 (1.5)											
Lewis, 2001 ³⁹	87/579 (15.0)	93/569 (16.3)										
IDNT												
ARB versus CCB trials (n=3)												
Saruta, 2009 ⁴⁰	*NR	*NR	*NR	*NR			*NR	*NR			44/1376 (3.1)	40/1344 (3.0)
CASE-J												
Ogawa, 2007 ⁴¹	0/40	0/18	0/40	0/18			0/40	0/18				
Lewis, 2001 ³⁹	87/579 (15.0)	83/567 (14.6)										
IDNT												

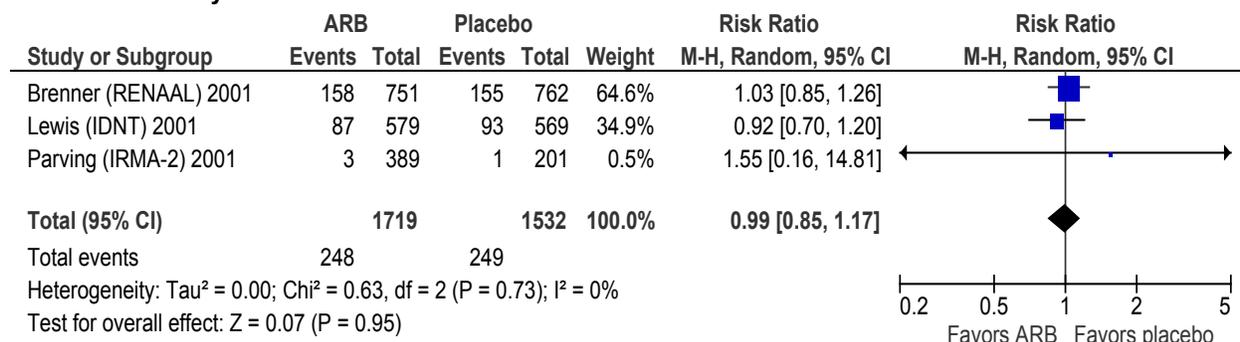
ARB = angiotensin receptor blocker; IRB = irbesartan; CCB = calcium channel blocker

*Study did not report results for all cause mortality, but reported incidence of "sudden deaths" as 8/1376 (0.6%) in candesartan (ARB) group vs. 12/1344 (0.9%) in amlodipine (CCB) group, p=0.34.

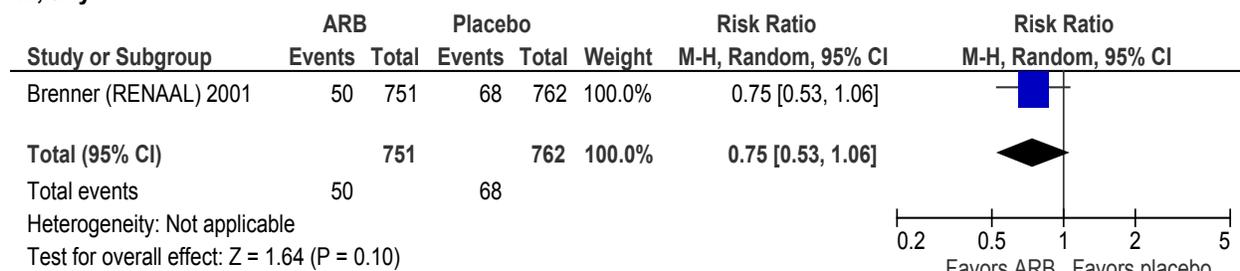
Appendix Figure C2. Forest plots for ARB monotherapy trials

ARB VERSUS PLACEBO

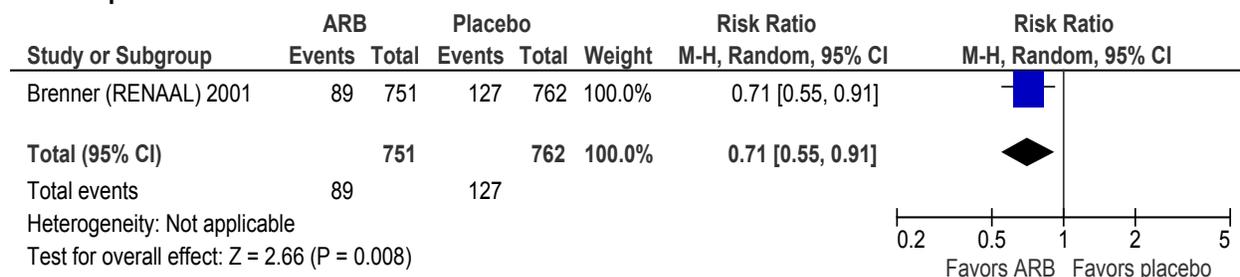
All-cause mortality



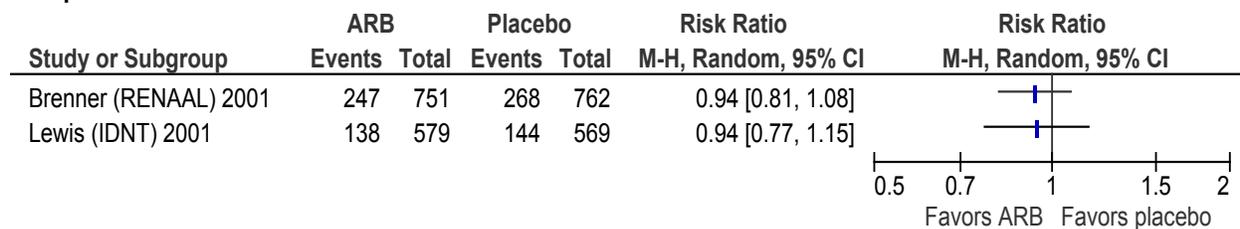
MI, any



CHF hospitalization

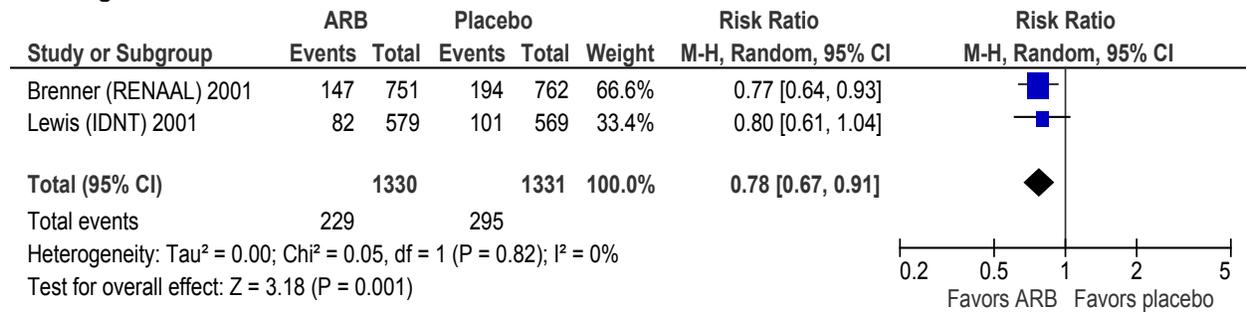


Composite vascular outcome

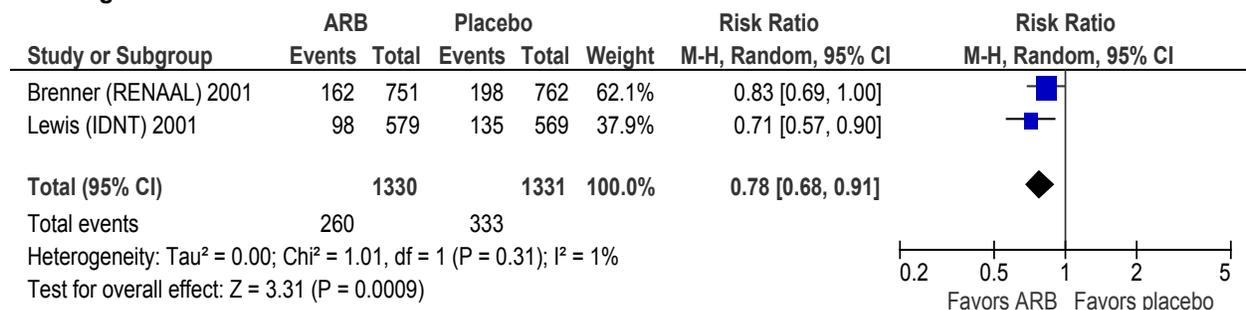


Appendix Figure C2. Forest plots for ARB monotherapy trials (continued)

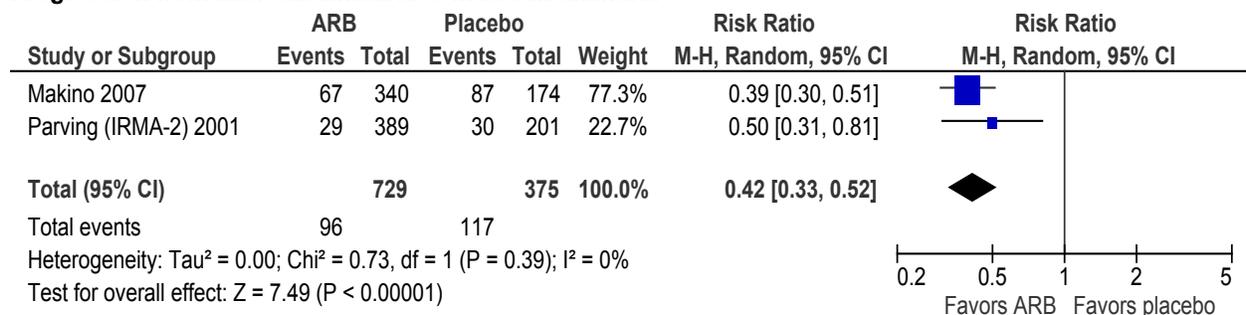
End-stage renal disease



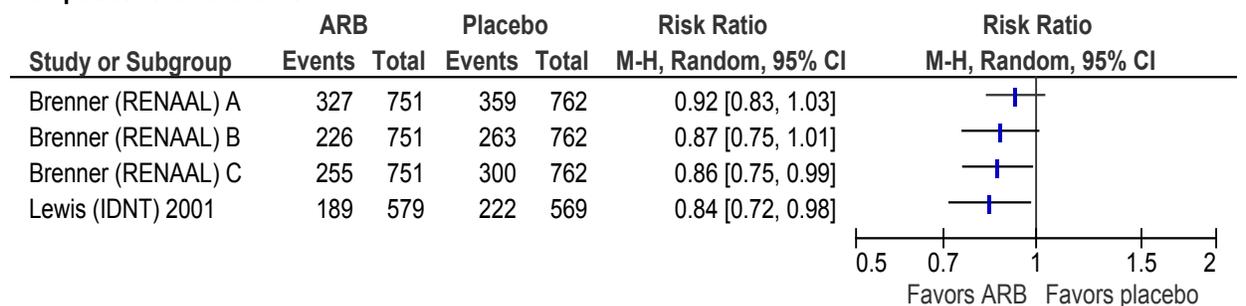
Doubling of serum creatinine



Progression from microalbuminuria to macroalbuminuria



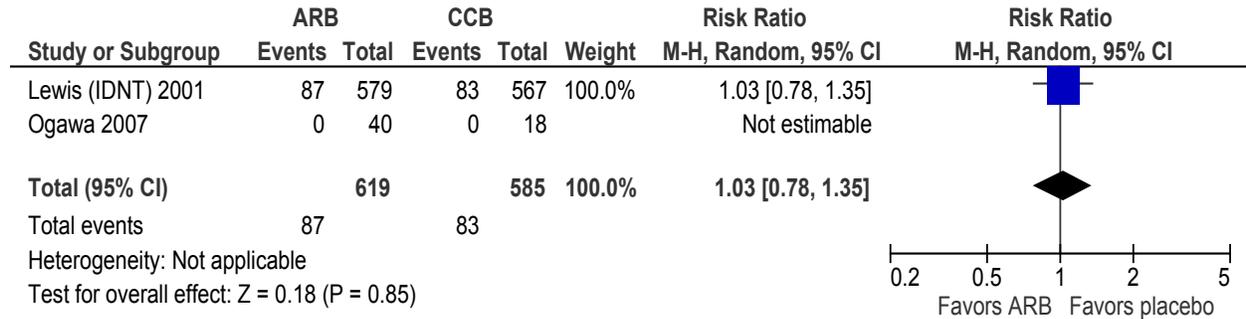
Composite renal outcome



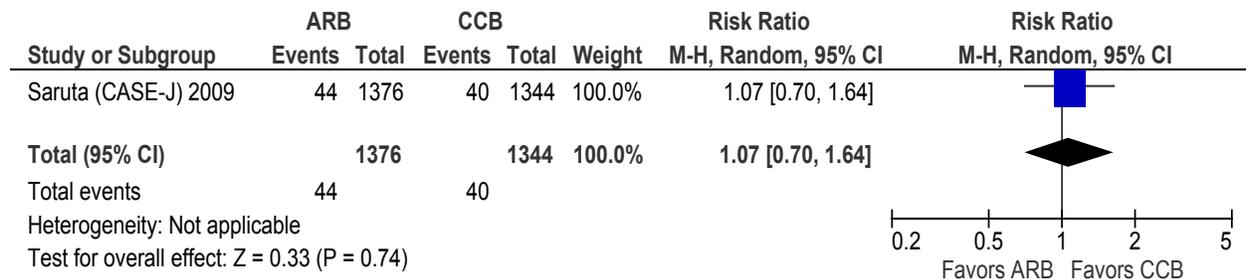
Appendix Figure C2. Forest plots for ARB monotherapy trials (continued)

ARB VERSUS CCB

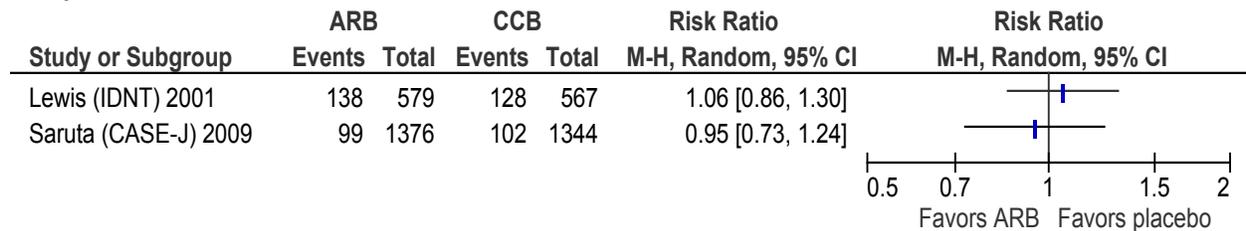
All-cause mortality



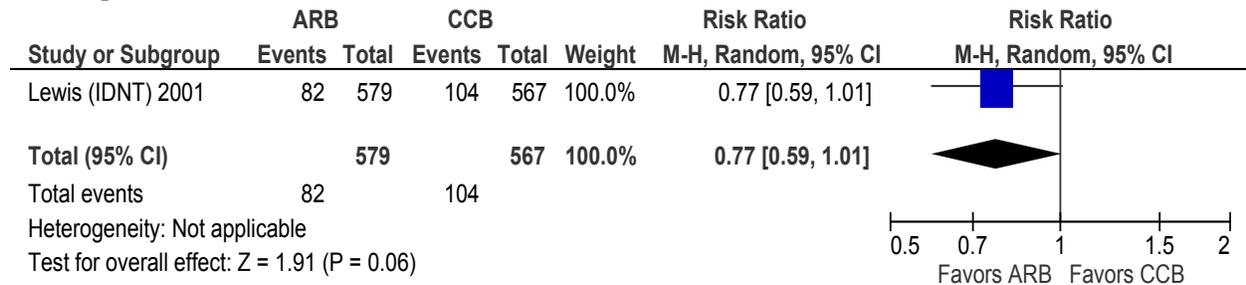
Stroke



Composite vascular outcome

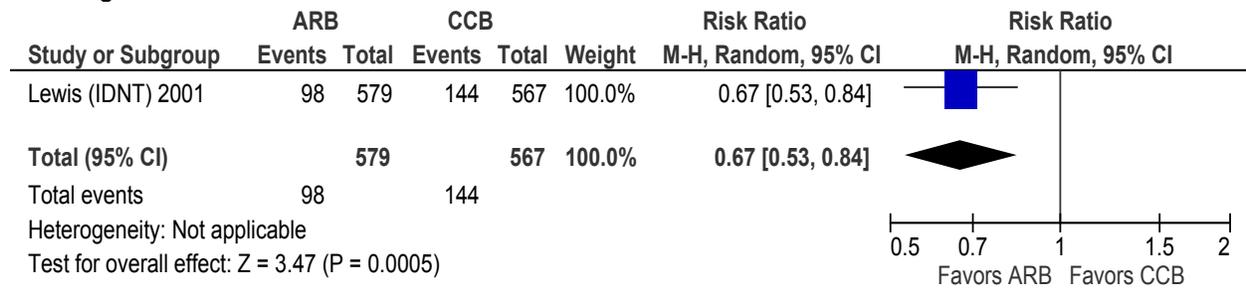


End-stage renal disease

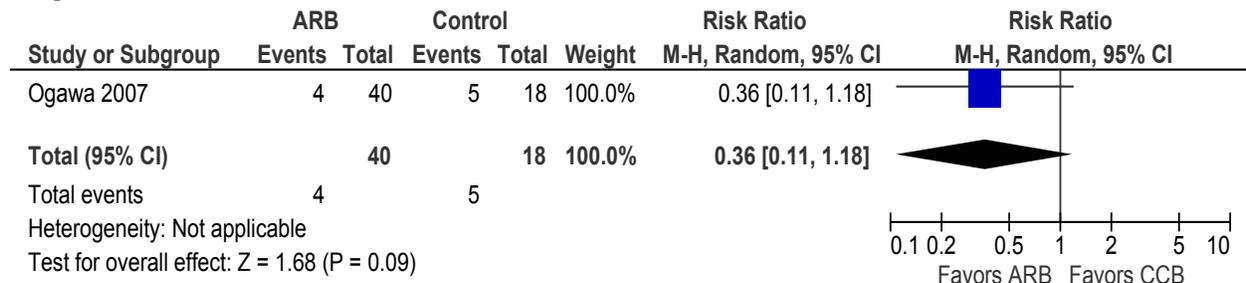


Appendix Figure C2. Forest plots for ARB monotherapy trials (continued)

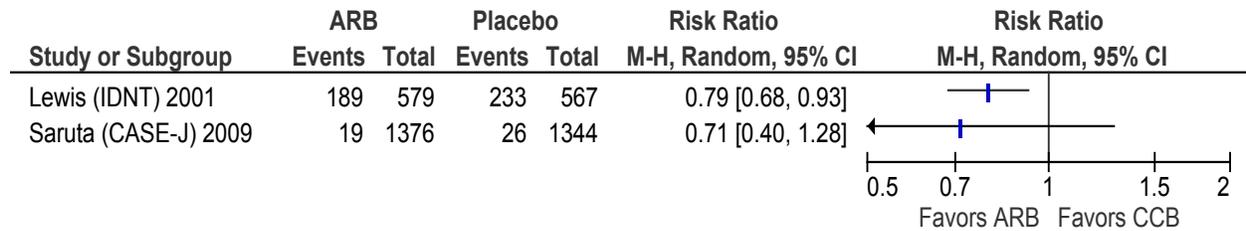
Doubling of serum creatinine



Progression from microalbuminuria to macroalbuminuria



Composite renal outcome



Appendix Table C12. Clinical outcomes (outcomes part B), ARB monotherapy trials

Study	Stroke or CVA, Nonfatal n/N (%)		Stroke or CVA, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B), n/N (%)		Composite Vascular Outcome n/N (%)	
	ARB	Control	ARB	Control	ARB	Control	ARB	Control	ARB	Control
ARB versus placebo trials (n=4)										
Makino, 2007 ³⁶										
Brenner, 2001 ³⁷ RENAAL							(A): 89/751 (11.9)*	(A): 127/762 (16.7)	247/751 (32.9)	268/762 (35.2)
Parving, 2001 ³⁸ IRMA-2									#	#
Lewis, 2001 ³⁹ IDNT							§(A): NR	§(A): NR	138/579 (23.8)	144/569 (25.3)
ARB versus CCB trials (n=3)										
Saruta, 2009 ⁴⁰ CASE-J									†99/1376 (7.2)	†102/1344 (7.6)
Ogawa, 2007 ⁴¹			0/40	0/18			(B): 0/40	(B): 0/18		
Lewis, 2001 ³⁹ IDNT									138/579 (23.8)	128/567 (22.6)

ARB = angiotensin receptor blocker; CCB = calcium channel blocker; NR = not reported

* P < 0.05 versus control

† In addition to defined composite cardiovascular events presented in this table, study also reported results for undefined, but apparently composite “cerebrovascular events” and “cardiac events.” “Cerebrovascular events” occurred in 44/1376 (3.1%) in candesartan (ARB) group vs. 40/1344 (3.0%) in amlodipine (CCB) group, p=0.73, while “cardiac events” occurred in 30/1376 (2.2%) in candesartan (ARB) group vs. 32/1344 (2.4%) in amlodipine (CCB) group, p=0.71.

§ Study did not report proportion of participants with hospitalization due to CHF, but stated that “patients assigned to receive irbesartan (ARB) had a rate of congestive heart failure necessitating hospitalization that was 23 percent lower than that among the patients assigned to receive placebo.”

Study reported that nonfatal cardiovascular events (undefined) occurred in 8.7% of patients in the placebo group vs. 4.5% of those in the irbesartan (ARB) 300 mg/daily group, p=0.11, but the proportion of subjects in each group with these events was not reported and was not possible to calculate.

Appendix Table C13. Composite vascular outcome definitions for ARB monotherapy trials

Study	Definition
<i>ARB versus placebo/no treatment trials</i>	
Mann, 2009 ⁴³ TRANSCEND	Cardiovascular death, MI, fatal or nonfatal stroke, or hospitalization for heart failure.
Brenner, 2001 ³⁷ RENAAL	MI, stroke, first hospitalization from heart failure or unstable angina, coronary or peripheral revascularization, or death from cardiovascular causes.
Lewis, 2001 ³⁹ IDNT	Death from cardiovascular causes, nonfatal MI, heart failure resulting in hospitalization, stroke resulting in permanent neurological defect, lower limb AKA.
<i>ARB versus CCB trials</i>	
Saruta, 2009 ⁴⁰ CASE-J	First cardiovascular event defined as any of the following: sudden death (unexpected death within 24 h without external cause); cerebrovascular event (stroke or transient ischemic attack); cardiac event (heart failure, angina pectoris, or acute myocardial infarction); renal event (included serum creatinine concentration of 4.0 mg/dl or higher, doubling of serum creatinine concentration, or end-stage renal disease); and/or vascular event (dissecting aortic aneurysm or arteriosclerotic occlusion of a peripheral artery).
Lewis, 2001 ³⁹ IDNT	Death from cardiovascular causes, nonfatal MI, heart failure resulting in hospitalization, stroke resulting in permanent neurological defect, or lower limb AKA

ARB = angiotensin receptor blocker; MI = myocardial infarction; AKA= above the knee amputation

Appendix Table C14. Clinical renal outcomes (outcomes part C), ARB monotherapy trials

Study	End Stage Renal Disease, n/N (%)		Doubling of Serum Creatinine n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome n/N (%)	
	ARB	Control	ARB	Control	ARB	Control	ARB	Control	ARB	Control
ARB versus placebo trials (n=5)										
Makino, 2007 ³⁶							TEL 80 mg 28/168 (16.7)*	87/174 (49.9)		
							TEL 40 mg 39/172 (22.6)*			
Brenner, 2001 ³⁷ RENAAL	147/751 (19.6)*	194/762 (25.5)	162/751 (21.6)*	198/762 (26.0)					†(1)327/751 (43.5)*; (2)226/751 (30.1)*; (3)255/751 (34.0)*	†(1)359/762 (47.1); (2)263/762 (34.5); (3)300/762 (39.4)
Parving, 2001 ³⁸ IRMA-2							‡ IRB 150 mg 19/195 (9.7) IRB 300 mg 10/194 (5.2)*	‡30/201 (14.9)		
Lewis, 2001 ³⁹ IDNT	82/579 (14.2)	101/569 (17.8)	98/579 (16.9)*	135/569 (23.7)					189/579 (32.6)*	222/569 (39.0)
ARB versus CCB trials (n=4)										
Saruta, 2009 ⁴⁰ CASE-J									‡19/1376 (1.4)	‡26/1244 (1.9)
Ogawa, 2007 ⁴¹							4/40 (10.0)	5/18 (27.8)		
Lewis, 2001 ³⁹ IDNT	82/579 (14.2)	104/567 (18.3)	98/579 (16.9)*	144/567 (25.4)					189/579 (32.6)*	233/567 (41.1)

ARB = angiotensin receptor blocker; TEL = telmisartan; IRB = irbesartan; CCB = calcium channel blocker; GFR = glomerular filtration rate.

*P < 0.05 versus control

† Study defined multiple composite renal endpoints, including: (1) doubling of the serum creatinine concentration, end-stage renal disease, or death; (2) doubling of serum creatinine concentration or end-stage renal disease; and (3) end-stage renal disease or death.

‡ Composite renal events reported overall, as above, and stratified by baseline CKD stage: Stage 1+2 = 2/152 (1.2%) candesartan group vs. 3/158 (1.9%) amlodipine group (p=0.58); Stage 3 = 14/1140 (1.2%) candesartan group vs. 9/1125 (0.8%) amlodipine group (p=0.32), and Stage 4 = 3/64 (4.7%) candesartan group vs. 14/61 (23.0%) amlodipine group (p=0.008).

Appendix Table C15. Composite renal outcome definitions for ARB monotherapy trials

Study	Definition
<i>ARB versus placebo/no treatment trials</i>	
Brenner, 2001 ³⁷ RENAAL	Time to doubling serum creatinine, incident ESRD (hemodialysis or renal transplant), or death.
Parving, 2001 ³⁸ IRMA-2	Time to first detection of overt nephropathy (overnight urinary albumin excretion rate greater than 200 µg per minute and at least 30 percent higher than baseline rate on at least two consecutive visits).
Lewis, 2001 ³⁹ IDNT	Doubling of baseline serum creatinine, incident ESRD (hemodialysis, renal transplant, serum creatinine concentration at least 6.0mg/dl), or death from any cause.
<i>ARB versus CCB trials</i>	
Saruta 2009 ⁴⁰ CASE-J	Serum creatinine concentration of 4.0 mg/dl or higher, doubling of the serum creatinine concentration or end-stage renal disease.
Lewis 2001 ³⁹ IDNT	Doubling of baseline serum creatinine, incident ESRD (hemodialysis, renal transplant, serum creatinine concentration at least 6.0mg/dl), or death from any cause.

ARB = angiotensin receptor blocker; ESRD = end stage renal disease; CCB = calcium channel blocker

Appendix Table C16. Study withdrawals and adverse events (outcomes part D), ARB monotherapy trials

Study	Study Withdrawals: Any		Serious Adverse Event: Any		Serious Adverse Event: Any Leading to Withdrawal		Adverse Event: Any		Adverse Event: Cough		Adverse Event: Hyperkalemia		Renal Adverse Events*	
	ARB	Control	ARB	Control	ARB	Control	ARB	Control	ARB	Control	ARB	Control	ARB	Control
ARB vs. placebo/no treatment trials														
Makino, 2007 ³⁶	#NR	#NR					NR*	NR*						
Brenner, 2001 ³⁷	59/751 (7.9)	59/762 (7.8)									8/751 (1.1)	4/762 (0.5)	11/751 (1.5)	9/762 (1.2)
RENAAL														
Parving, 2001 ³⁸	IRB 150mg 27/195 (13.8)	30/201 (14.9)	§ 60/389 (15.4)	46/201 (22.9)	IRB 150mg 18/195 (9.2)	17/201 (8.5)								
IRMA-2	IRB 300mg 20/194 (10.3)				IRB 300mg 8/194 (4.1)									
Lewis, 2001 ³⁹	5/579 (0.9)	4/569 (0.7)	NR‡	NR‡			NR**	NR**			11/579 (1.9)†	2/569 (0.4)	NR††	NR††
IDNT														
ARB versus CCB trials														
Saruta, 2009 ⁴⁰														
CASE-J														
Ogawa, 2007 ⁴¹	0/40	2/18 (11.1)			0/40	0/18								
Lewis, 2001 ³⁹	5/579 (0.9)	2/567 (0.4)	NR‡	NR‡			NR**	NR**			11/579 (1.9)†	3/567 (0.5)	NR††	NR††
IDNT														

ARB = angiotensin receptor blocker; CCB = calcium channel blocker; NR = not reported

* Study reported that "one or more adverse event was recorded in >90% of patients in each treatment group;" no additional adverse events information was provided, including on specific types of adverse events.

† p < 0.05

‡ 61% of overall cohort had serious adverse event; results were not provided by treatment group, but were reported to not differ significantly between treatment groups.

§ Study reported serious adverse events for the two ARB treatment dose groups combined only.

#Study reported that 13 of 527 (2.4%) randomized participants were excluded from analyses** Results were not reported for the proportion of study participants with any adverse event, either overall or within groups; subjects in the irbesartan group had a significantly lower rate of adverse events per 1000 days of treatment than those in the placebo and amlodipine groups (P=0.002).

†† Study reported one episode of an early increase in serum creatinine concentration suggestive of renal artery stenosis that necessitated stopping the study medication, but did not indicate in which treatment group this adverse event occurred.

Appendix Evidence Table C17. Overview of ACEI plus ARB versus ACEI trials (n=6 trials)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Sengul, 2006 ²⁰ Turkey Funding Source: none stated	Inclusion Criteria: microalbuminuria (AER rate 30 to 300 mg/24 hours for a minimum of three consecutive occasions); aged 40 to 65 years; previously diagnosed hypertension (systolic BP ≥140 mm Hg or diastolic BP ≥90 mm Hg), despite receiving ACEI monotherapy for ≥6 months. Exclusion Criteria: type 1 DM; BMI ≥ 40; secondary diabetes; alcoholism; thyroid disease; systolic BP >200 mm Hg, any nondiabetic cause of secondary HTN (including bilateral renal artery stenosis); urinary tract infection; persistent hematuria; chronic liver disease; overt carcinoma; any cardiovascular event in the previous 6 months; serum creatinine ≥150 mmol/L; serum potassium ≥5.5 mmol/L; or pregnancy.	N=219 Age (yr): 57 Gender (Male %): 37 Race/Ethnicity (%): NR BMI: 30 Systolic BP (mm Hg): 151 Diastolic BP (mm Hg): 89 Urinary AER (mg/24 h): 260 Serum creatinine (mg/dL): 1 Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (mg/min): 97 Total cholesterol (mg/dL): 211 LDL cholesterol (mg/dL): 135 HbA _{1c} (%): 7.9 Diabetes (%): 100 History of HTN (%): 100 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): 37	Lisinopril 20 mg/d (n=110) Telmisartan 80 mg/d (n=109) After 24 weeks, half of the patients receiving lisinopril were randomized to receive telmisartan in addition. Similarly, half the patients initially treated with telmisartan received a combination of lisinopril plus telmisartan. Follow up for the combination period was 28 weeks. The remaining patients continued to be treated with monotherapy Followup period: 1 year Study withdrawals (%): 12	Allocation Concealment: unclear Blinding: open-label Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
Menne, 2008 ¹⁹ VALERIA Germany and Hungary Funding Source: Industry	Inclusion Criteria: microalbuminuria (urine albumin creatinine ratio for women ≥3.5 mg/ mmol/L and ≤35.0 mg/mmol and men ≥2.5 mg/ mmol/L and ≤25.0 mg/mmol); aged 18 to 75 years; essential hypertension [defined as mean sitting diastolic BP ≥85 mmHg and <110 mm Hg]. To fulfill the criteria of microalbuminuria, two of three first morning void urines needed to be positive during the screening phase. Exclusion Criteria: primary kidney disease, renal impairment (creatinine clearance <30ml/min using the Cockcroft and Gault formula; serum potassium values	N=90 (in addition, there was 3 rd trial arm of ARB monotherapy with n=43) Age (yr): 58 Gender (Male %): 69 Race/Ethnicity (%): NR BMI: 32 Systolic BP (mm Hg): 153 Diastolic BP (mm Hg): 91 Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (mg/min): 112 Urine albumin creatinine ratio (mg/ mmol): 9.4 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR HbA _{1c} (%): NR Diabetes (%): 74 History of HTN (%): 100	Lisinopril 40 mg/d + Valsartan 320 mg/d (n=43) Lisinopril 40 mg/d (n=47) Followup period: 30 weeks Study withdrawals (%): 14	Allocation Concealment: adequate Blinding: double plus outcome assessors and data analysts Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C17. Overview of ACEI plus ARB versus ACEI trials (n=6 trials) (continued)

C-74

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	>5.5mmol/L; heart failure, significant arrhythmias or bradycardia; relevant valvular disease, type I DM, uncontrolled type II DM with HbA _{1c} >8.0%; history of MI; percutaneous transluminal coronary angioplasty, bypass surgery or stroke within the last 12 months prior to study inclusion; unstable angina pectoris; renal transplantation; severe hepatic disease or hepatic failure; malignant concomitant diseases or history of malignant diseases within the last 5 years; systemic inflammatory diseases; pregnancy or breast feeding; psychiatric disease; either history of alcohol or drug abuse or both.	History of CAD "Cardiac disorders"(%): 19 History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR		
Mann, 2008 ¹⁸ ONTARGET Multinational Funding Source: Industry	Inclusion Criteria: aged 55 years or older with established atherosclerotic vascular disease or with diabetes with end-organ damage. Exclusion Criteria: major renal artery stenosis, uncorrected volume or sodium depletion, a serum creatinine concentration above 265 µmol/L, and uncontrolled hypertension (>160 mm Hg systolic or >100 mm Hg diastolic).	N=3988 with eGFR <60 ml/min/1.73m ² from larger 17,078 randomized to ramipril vs. ramipril + telmisartan in ONTARGET trial. Estimated GFR (ml/min/1.73m ²) 51.0* Urine albumin creatinine ratio (mg/mmol): 0.81* *Patient characteristics not described for the different arms or for CKD subgroup	Ramipril 10 mg/d + telmisartan 80 mg/d (n=8502 overall) Ramipril 10 mg/d (n=8576 overall) Followup period: median 4.7 years (Followup is for the entire cohort) Study withdrawals (%): NR	Allocation Concealment: adequate Blinding: double Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes
Kanno, 2006 ⁴⁴ Japan Funding Source: none stated	Inclusion Criteria: serum creatinine concentration of between 1.2 and 5.0 mg/dl; systolic BP (SBP) of >130 and <180 mmHg; diastolic BP (DBP) >80 and <120mmHg; and a daily urinary protein excretion of >1.0g Exclusion Criteria: secondary hypertension, including patients who were on dialysis therapy or receiving renal transplantation; patients who	N=90 Age (yr): 60.1 Gender (Male %): 40 Race/Ethnicity (%): 100 Japanese BMI: NR Total BP (mm Hg): 137.5 Urinary protein excretion (g/24 h): 1.7 Serum creatinine (mg/dL): 3.01 Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (mg/min): NR Total cholesterol (mg/dL): NR	ACEI + candesartan 2-12 mg/d (n=45) ACEI (n=45) The main ACEI used were benazepril 2.5-10 mg/d or trandolapril 2-4 mg/d Followup period: 3.1 years	Allocation Concealment: unclear Blinding: not blinded Intention to Treat Analysis: no Withdrawals/ Dropouts adequately described: yes

Appendix Evidence Table C17. Overview of ACEI plus ARB versus ACEI trials (n=6 trials) (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	had chronic renal diseases and were receiving corticosteroid hormone; patients with myocardial infarction or stroke within the previous 6 months or angina pectoris that required treatment with B blockers or calcium channel blocker; and patients with heart failure or left ventricular ejection fraction of 40% or less or with a disorder that in the treating physician's opinion for other types of ARB	LDL cholesterol (mg/dL): NR HbA _{1c} (%): NR Diabetes (%): NR History of HTN (%): 100 History of CAD (%): NR History of CHF (%): NR History of MI (%): 0 History of Stroke (%): 0 Peripheral arterial disease (%): NR Current smoker (%): NR	Study withdrawals (%): 5.6	
Mehdi, 2009 ⁴⁵ United States, single-site Funding Source: Government	Inclusion Criteria: Age 20 to 65; type 1 or 2 DM; seated systolic BP<130mmHg; proteinuria (2-24-h UACR≥300 mg/g despite treatment with ACEI or ARB for at least 3 months* Exclusion Criteria: BMI>45kg/m ² ; serum creatinine>3.0mg/dl (females) or >4.0 mg/dl (males); known nondiabetic kidney disease; serum potassium >5.5 mEq/L; hemoglobin A1c>11%; stroke or myocardial infarction within preceding 12 mo; heart failure; known adverse reaction to losartan or spironolactone; anticipated need for dialysis within 12 months *Effort was made to recruit younger patients with type 2 DM as recommended by study sponsor	Baseline characteristics based on 26 in losartan group (excluded 1 patient who withdrew prior to first dose) N=53 Age (yr): 50.8 Gender (Male %): 47 Race/Ethnicity (%): 45% Hispanic, 34% black, 19% non-Hispanic white, 2% Native American Weight (kg): NR BMI: 31.3 Clinic Systolic BP (mm Hg): 134.0 Clinic Diastolic BP (mm Hg): 73.0 CKD stage: NR Serum creatinine (mg/dl): 1.6 Creatinine clearance (mL/min): 64.5 Albuminuria (µg/min): NR Proteinuria (g/day): NR Albumin/creatinine ratio (mg/g): 907.2 GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 7.9 Total cholesterol (mg/dl): 193.4 LDL cholesterol (mg/dl): 97.5 Diabetes (%): 100 History of HTN (%): NR Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR	n= 27 to losartan 50 mg/day for 1 week then 100mg/day# n= 27 to placebo# Followup period: 48 weeks Study withdrawals (%): 24.1 #All patients were taking lisinopril 80 mg/day	Allocation Concealment: Unclear Blinding: Double blinded Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes

C-75

Appendix Evidence Table C17. Overview of ACEI plus ARB versus ACEI trials (n=6 trials) (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Anand, 2009 ⁴⁶ United States, Multi-site Funding Source: Industry	<p>Inclusion Criteria: Ages 18 and older; stable symptomatic heart failure (HF); receiving recommended HF therapy; left ventricular ejection fraction <40%; left ventricular internal diameters in diastole adjusted for body surface area ≥ 2.9 cm/m²</p> <p>Exclusion Criteria: Persistent mean standing SBP <90 mm Hg or serum creatinine >2.5 mg/dL</p> <p>NOTE: results presented are from subgroup analysis of patients with CKD</p>	<p>History of MI, CABG, PCTA (%): 9.4 History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR</p> <p>N=2916 Age (yr): 65.9 Gender (Male %): 88 Race/Ethnicity (%): 91% white Weight (kg): NR BMI: 27 Systolic BP (mm Hg):123.8 Diastolic BP (mm Hg): 74.5 CKD stage: NR Serum creatinine (mg/d/l): NR Serum albumin (g/dL): 4.2 Creatinine clearance (mL/min): NR Albuminuria (μg/min): NR Proteinuria (g/day): NR Dipstick Proteinuria Albumin/creatinine ratio (mg/g): NR GFR (ml/min/1.73m²): 47.8 HbA_{1c} (%): NR Total cholesterol (mg/dl): NR LDL cholesterol (mg/dl): NR Diabetes (%): 29.1 History of HTN (%): 6.9 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): 100 Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR</p>	<p>n= 1477 with CKD to valsartan 40 mg twice per day; dose doubled every 2 weeks to reach target of 160 mg twice per day*#</p> <p>n= 1439 with CKD to placebo#</p> <p>Followup period: 23 months (mean)</p> <p>Study withdrawals (%): 10% discontinued treatment (other withdrawals not reported for subgroup)</p> <p>*provided SBP ≥ 90 mmHg; no signs or symptoms of hypotension; serum creatinine not >150% of baseline</p> <p>#91% of patients in CKD subgroup were taking an ACEI at randomization</p>	<p>Allocation Concealment: Adequate</p> <p>Blinding: Double blind</p> <p>Intention to Treat Analysis (ITT): Yes for the outcomes we are recording</p> <p>Withdrawals/Dropouts adequately described: Yes</p>

Appendix Table C18, Summary of study baseline characteristics for ACEI plus ARB versus ACEI or ARB trials

Characteristic	Mean (range unless otherwise note)	Number of Trials Rreporting
ACEI plus ARB versus ACEI (n=6)		
Total number of patients evaluated	18962 (53 to 15594*)	6
Age of subjects, years	64.7 (51 to 66)	5
Gender, male (%)	83.4 (37 to 88)	5
Race/ethnicity, white (%)	89.7 (19 to 91)	2
Race/ethnicity, black (%)	34	1
Race/ethnicity, Asian/Pacific Islander (%)	100% (Japanese)	1
Body Mass Index	27.4 (27 to 32)	4
Weight (kg)		
SBP (mmHg)	126.6 (123.8 to 153)	4
DBP (mmHg)	75.9 (73 to 91)	4
Proteinuria or AER (g/day)	0.68 (0.26 to 1.7) #	5
Serum creatinine (mg/dL)	1.46 (1 to 3)	3
Creatinine Clearance (ml/min/1.73m ²)	96.0 (64.5 to 112)	3
Estimated GFR (ml/min/1.73m ²)	49.8 (47.8 to 50.7)	2
Total cholesterol (mg/dl)	207.6 (193.4 to 211.0)	2
LDL Cholesterol (mg/dl)	127.7 (97.7 to 135.0)	2
DM (%)	36.2 (29.1 to 100)	4
HbA _{1c} (%)	7.9 (both 7.9)	2
HTN (%)	18.5 (6.9 to 100)	4
CAD (%) *	19	1
CHF (%) *	100	1
MI (%) *	3.5 (0 to 9.4)	2
Stroke (%) *	0	1
AKI (%)		
PAD (%)		
Current Smoker (%)	37	1
ACEI plus ARB versus ARB (n=3)		
Total number of patients evaluated	16143 (90 to 15834*)	3
Age of subjects, years	57.3 (57 to 58)	2
Gender, male (%)	46.3 (37 to 69)	2
Race/ethnicity, white (%)		
Race/ethnicity, black (%)		
Body Mass Index	30.6 (30 to 32)	2
Weight (kg)		
SBP (mmHg)	151.6 (151 to 153)	2
DBP (mmHg)	89.6 (89-91)	2
MAP (mmHg)		
Proteinuria or AER (g/day)	0.26 #	2
Serum creatinine (mg/dL)	1	1
Creatinine Clearance (ml/min/1.73m ²)	101.4 (97 to 112)	2
Estimated GFR (ml/min/1.73m ²)	50	1
Total cholesterol (mg/dl)	211	1
LDL Cholesterol (mg/dl)	135	1
DM (%)	92.4 (74 to 100)	2
HbA _{1c} (%)	7.9	1
HTN (%)	100 (100 to 100)	2
CAD (%) *		
CHF (%) *		
MI (%) *		
Stroke (%) *		
AKI (%)		
PAD (%)		
Current Smoker (%)	37	1

ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker

*N for Mann 2008 ONTARGET study based on back calculation of reported progression to macroalbuminuria; # data from one trial not included in calculations as value in mg/mmo

Appendix Table C19. Clinical outcomes (outcomes part A), ACEI plus ARB versus ACEI or ARB trials

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial Infarction, Non-fatal n/N (%)		Stroke or CVA, Any n/N (%)	
	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI
ACEI plus ARB versus ACEI trials (n=6)												
Sengul, 2006 ²⁰												
Menne, 2008 ¹⁹ VALERIA	0/43 (0)	1/47 (2.1)										
Mann, 2008 ¹⁸ ON-TARGET												
Kanno, 2006 ⁴⁴												
Mehdi, 2009 ⁴⁵	1/26 (3.8)	0/27 (0.0)										
Anand, 2009 ⁴⁶	362/1477 (24.5)	341/1439 (23.7)										
ACEI plus ARB versus ARB trials (n=3)												
	ACEI+ARB	ARB	ACEI+ARB	ARB	ACEI+ARB	ARB	ACEI+ARB	ARB	ACEI+ARB	ARB	ACEI+ARB	ARB
Sengul, 2006 ²⁰												
Menne, 2008 ¹⁹ VALERIA	0/43 (0)	0/43 (0)										
Mann, 2008 ¹⁸ ON-TARGET												

ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker
 *reported for the overall participants but not for the CKD subgroup

Appendix Table C20. Clinical outcomes (outcomespart B), ACEI plus ARB versus ACEI or ARB* trials

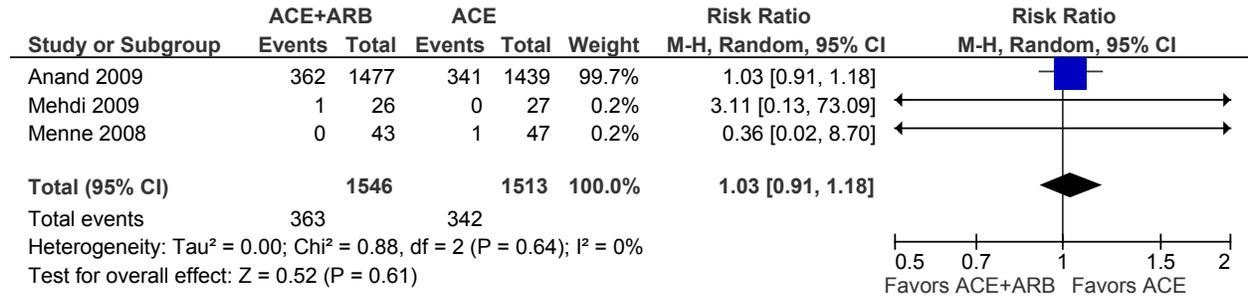
Study	Stroke or CVA, Nonfatal n/N (%)		Stroke or CVA, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B) n/N (%)		Composite Vascular Outcome n/N (%)	
	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI
<i>ACEI plus ARB versus ACEI trials (n=6)</i>										
Sengul, 2006 ²⁰										
Menne, 2008 ¹⁹ VALERIA										
Mann, 2008 ¹⁸ ON TARGET										
Kanno, 2006 ⁴⁴										
Mehdi, 2009 ⁴⁵	1/26 (3.8)	1/27 (3.7)			2/26 (7.7)	0/27 (0.0)				
Anand, 2009 ⁴⁶									499/1477 (33.8)	549/1439 (38.1)

ACEI = angiotensin converting enzyme inhibitor; ARB = angiotensin receptor blocker

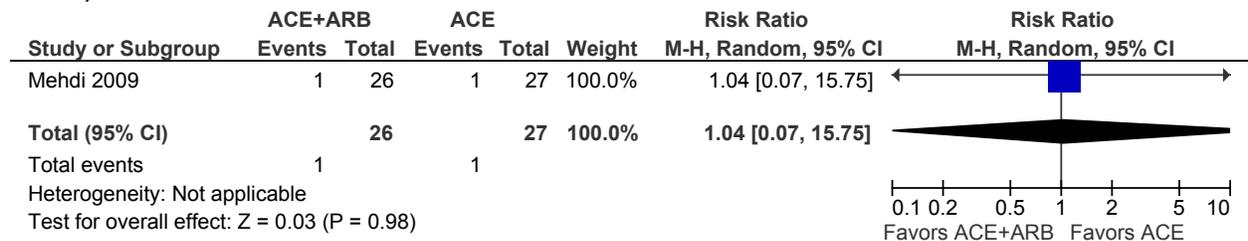
*No ACE+ARB versus ARB studies reported these outcomes

Appendix Figure C3. Forest plots for ACEI plus ARB versus ACEI trials

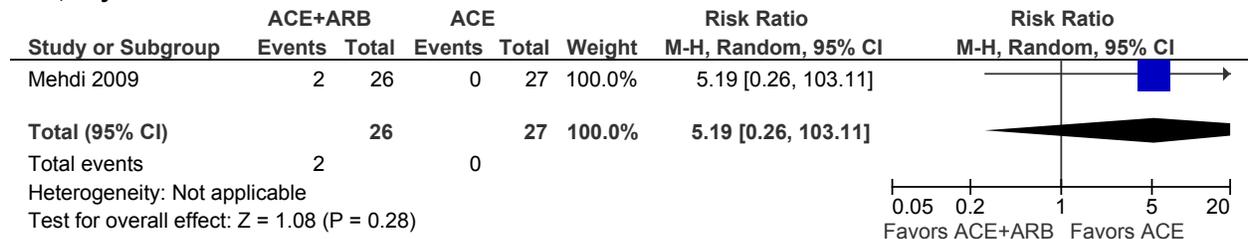
All-cause mortality



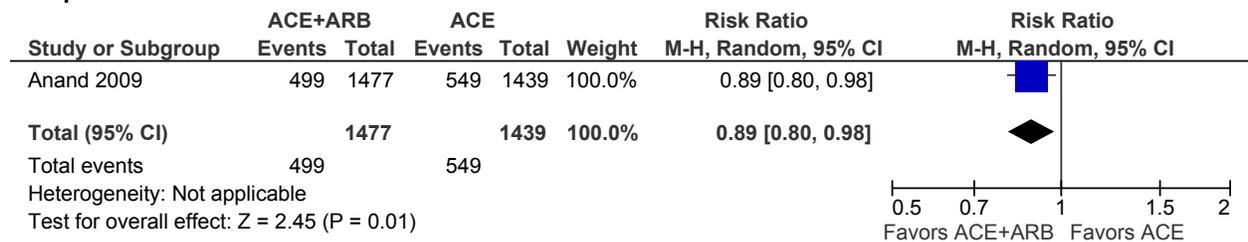
Stroke, nonfatal



CHF, any

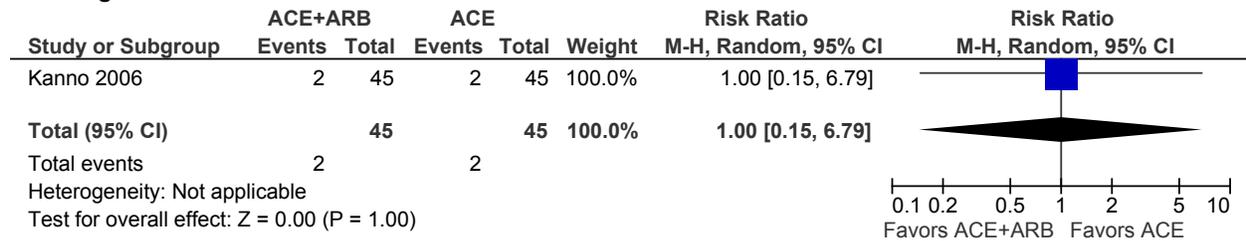


Composite vascular

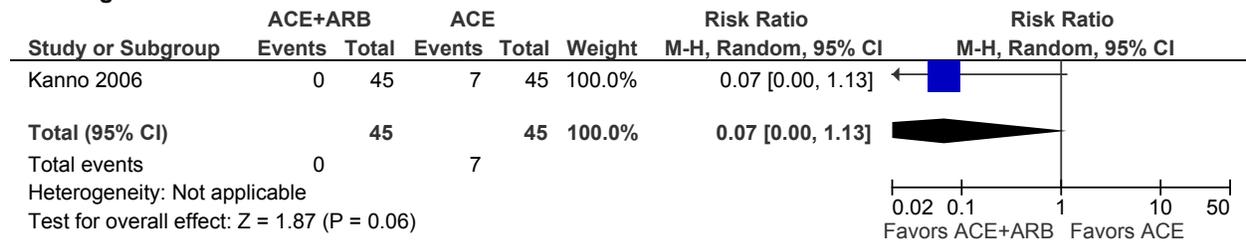


Appendix Figure C3 ACE+ARB vs. ACE (continued)

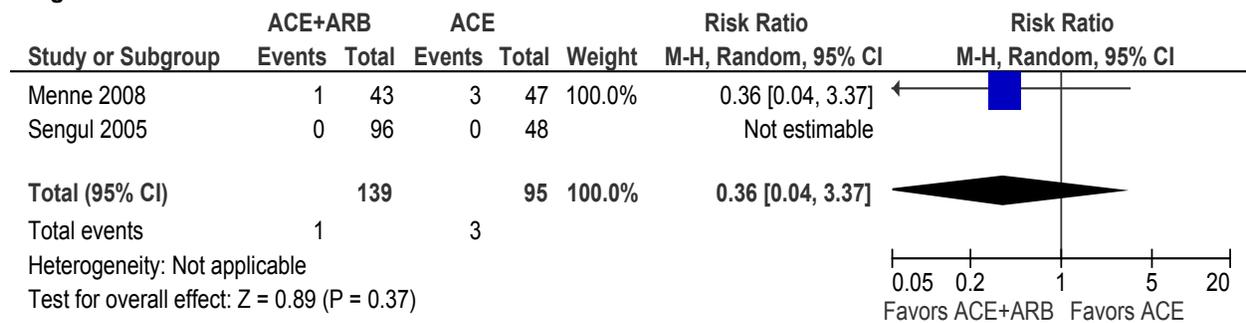
End-stage renal disease



Doubling of serum creatinine



Progression to macroalbuminuria



Appendix Table C21. Composite vascular outcome definitions for ACEI plus ARB versus ACEI or ARB trials

Study	Definition
Anand, 2009 ⁴⁶	Death, sudden death with resuscitation, hospitalization for heart failure, or administration of intravenous inotropic or vasolilator drugs for 4 hours or more without hospitalization

ACEI = angiotensin converting enzyme; ARB = angiotensin receptor blocker

Appendix Table C22. Clinical renal outcomes (outcomes part C), ACEI plus ARB versus ACEI or ARB trials

Study	End-stage Renal Disease n/N (%)		Doubling of Serum Creatinine n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome n/N (%)	
	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI
ACEI plus ARB versus ACEI trials (n=6)										
Sengul, 2006 ²⁰							0/96 (0)	0/48 (0)		
Menne, 2008 ¹⁹ VALERIA							1/43 (2.5)	3/47 (6.4)		
Kanno, 2006 ⁴⁴	2/45 (4.4)	2/45 (4.4)	0/45 (0)	7/45 (15.6)						
Mehdi, 2009 ⁴⁵			**NR	**NR						
Anand, 2009 ⁴⁶										
ACEI plus ARB versus ARB trials (n=3)										
			ACEI+ARB	ARB			ACEI+ARB	ARB	ACEI+ARB	ARB
Sengul, 2006 ²⁰							0/96 (0)	0/48 (0)		
Menne, 2008 ¹⁹							1/43 (2.5)	3/43 (7.1)		

ACEI = angiotensin converting enzyme; ARB = angiotensin receptor blocker

*Reported for the overall participants but not for the CKD subgroup

**Reported 50% increase in serum creatinine in 13/26 (50%) of ACEI+ARB group and 10/27 (37%) of ACEI group

†Had microalbuminuria at baseline; N based on back calculation using percentage with progression

Appendix Table C23. Study withdrawals and adverse events (outcomes part D), ACEI plus ARB versus ACEI or ARB trials

Study	Study Withdrawals: Any, n/N (%)		Serious Adverse Event: Any, n/N (%)		Serious Adverse Event: Any Leading to Withdrawal, n/N (%)		Adverse Event: Any, n/N (%)		Adverse Event: Any Specific, n/N (%)		Renal Adverse Event: Any, n/N (%)	
	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI	ACEI+ARB	ACEI
ACEI plus ARB versus ACEI trials (n=6)												
Sengul, 2006 ²⁰	*NR	*NR					**NR	**NR	***NR	***NR		
Menne, 2008 ¹⁹ VALERIA	6/43 (14.0)	5/47 (10.6)	4/43 (9.3)	5/47 (10.6)	3/43 (7.0)	4/47 (8.5)	31/43 (72.1)	29/47 (69.7)	Hypotension: 5/43 (11.6); Hyperkalemia: 1/43 (2.3); Cough: 2/47 (4.3)§	Hypotension: 1/47 (2.1); Hyperkalemia: 1/47 (2.1); Cough: 1/43 (2.3)§		
Mann, 2008 ¹⁸ ON-TARGET	#NR	#NR										
Kanno, 2006 ⁴⁴	2/45 (4.4)	3/45 (6.7)	†NR	†NR	†NR	†NR	†NR	†NR				
Mehdi, 2009 ⁴⁵	8/27 (29.6)	6/27 (22.2)					2/27 (7.4)	1/27 (3.7)	Heart failure: 2/27 (7.4)	Stroke: 1/27 (3.7)		
Anand, 2009 ⁴⁶									Hyperkalemia: 126/1477 (8.5)	Hyperkalemia: 65/1439 (4.5)		
ACEI plus ARB versus ARB trials (n=3)												
Sengul, 2006 ²⁰	*NR	*NR					**NR	**NR	***NR	***NR		
Menne, 2008 ¹⁹ VALERIA	6/43 (14.0)	6/43 (14.0)	4/43 (9.3)	1/43 (2.3)	3/43 (7.0)	3/43 (7.0)	31/43 (72.1)	27/43 (62.8)	Hypotension: 5/43 (11.6); Hyperkalemia: 1/43 (2.3); Cough: 2/47 (4.3)§ §	Hypotension: 4/43 (9.3); Hyperkalemia: 1/43 (2.3); Cough: 0/43 (0)§		
Mann, 2008 ¹⁸ ON-TARGET	#NR	#NR										

Appendix Table C23. Study withdrawals and adverse events (outcomes part D), ACEI plus ARB versus ACEI or ARB trials (continued)

ACEI = angiotensin converting enzyme; ARB = angiotensin receptor blocker

*Reported withdrawals for original randomization groups (ACEI: 15/110 [13.6%], ARB: 12/109 [11.0%])

**Adverse events not distinguished from withdrawals

***Reported most frequent adverse events were cough (only in patients receiving lisinopril) and headache, experienced by <10% of patients; other noted side effects were nausea, stomach upset, respiratory infection, dizziness, feeling weak, gastrointestinal problems

§Other reported adverse events: vertigo (2.3% ACEI+ARB, 4.3% ACEI), dizziness (2.3% ACEI+ARB, 2.1% ACEI), headache (0% ACEI+ARB, 2.1% ACEI)

§§Other reported adverse events: vertigo (2.3% ARB), dizziness (2.3% ARB), headache (2.3% ARB)

#Reported follow-up of all but 43/25,620 (0.2%)

^Reported as "renal abnormalities"

†Reported "few" discontinuations as a result of AE and discontinuations as a result of drug-related AE

~reported for the overall participants but not for the CKD subgroup

Appendix Evidence Table C24. Overview of ACEI plus ARB versus ARB trials (n=3 trials)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Sengul, 2006 ²⁰ Turkey Funding Source: none stated	Inclusion Criteria: microalbuminuria (AER rate 30 to 300 mg/24 hour for a minimum of three consecutive occasions); aged 40 to 65 years; previously diagnosed hypertension (systolic BP ≥140 mm Hg or diastolic BP ≥90 mm Hg), despite receiving ACEI monotherapy for ≥6 months. Exclusion Criteria: type 1 DM; BMI ≥40; secondary diabetes; alcoholism; thyroid disease; systolic BP >200 mm Hg, any nondiabetic cause of secondary HTN (including bilateral renal artery stenosis); urinary tract infection; persistent hematuria; chronic liver disease; overt carcinoma; any cardiovascular event in the previous 6 months; serum creatinine ≥ 150 mmol/L; serum potassium ≥ 5.5 mmol/L; or pregnancy.	N=219 Age (yr): 57 Gender (Male %): 37 Race/Ethnicity (%): NR BMI: 30 Systolic BP (mm Hg): 151 Diastolic BP (mm Hg): 89 Urinary AER (mg/24 h): 260 Serum creatinine (mg/dL): 1 Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (mg/min): 97 Total cholesterol (mg/dL): 211 LDL cholesterol (mg/dL): 135 HbA _{1c} (%): 7.9 Diabetes (%): 100 History of HTN (%): 100 History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): 37	n= 110 lisinopril 20 mg/d n= 109 telmisartan 80 mg/d After 24 weeks, half of the patients receiving lisinopril were randomized to receive telmisartan in addition. Similarly, half the patients initially treated with telmisartan received a combination of lisinopril plus telmisartan. The remaining patients continued to be treated with monotherapy Followup period: 1 year Study withdrawals (%): 12	Allocation Concealment: unclear Blinding: open-label Intention to Treat Analysis: no Withdrawals/Dropouts adequately described: yes
Menne, 2008 ¹⁹ VALERIA Germany and Hungary Funding Source: Industry	Inclusion Criteria: microalbuminuria (urine albumin creatinine ratio for women ≥3.5 mg/ mmol/L and ≤35.0 mg/mmol and men ≥2.5 mg/ mmol/L and ≤25.0 mg/mmol); aged 18 to 75 years; essential hypertension [defined as mean sitting diastolic BP ≥85 mmHg and	N=90 (133 total with combination arm) Age (yr): 58 Gender (Male %): 69 Race/Ethnicity (%): NR BMI: 32 Systolic BP (mm Hg): 153 Diastolic BP (mm Hg): 91 Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): NR Creatinine clearance (mg/min): 112	n= 43 lisinopril 40 mg/d + valsartan 320 mg/d n= 43 valsartan 320 mg/d Followup period: 30 weeks Study withdrawals (%): 14	Allocation Concealment: adequate Blinding: double plus outcome assessors and data analysts Intention to Treat Analysis: no

Appendix Evidence Table C24. Overview of ACEI plus ARB versus ARB trials (n=3 trials) (continued)

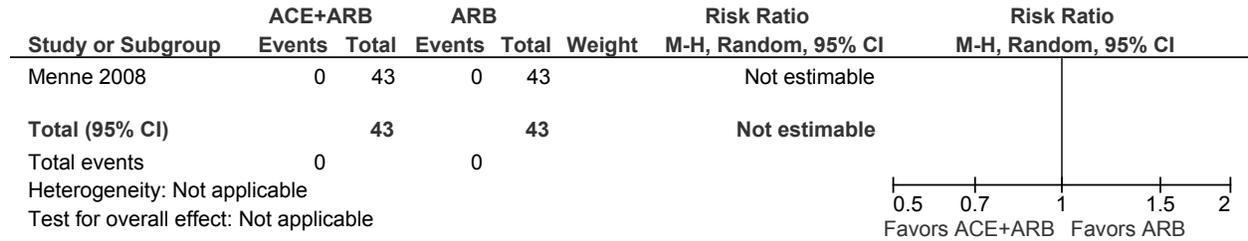
Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	<p><110 mm Hg]. To fulfill the criteria of microalbuminuria, two of three first morning void urines needed to be positive during the screening phase.</p> <p>Exclusion Criteria: primary kidney disease, renal impairment (creatinine clearance <30ml/min using the Cockcroft and Gault formula; serum potassium values >5.5mmol/L; heart failure, significant arrhythmias or bradycardia; relevant valvular disease, type I DM, uncontrolled type II DM with HbA_{1c} >8.0%; history of MI; percutaneous transluminal coronary angioplasty, bypass surgery or stroke within the last 12 months prior to study inclusion; unstable angina pectoris; renal transplantation; severe hepatic disease or hepatic failure; malignant concomitant diseases or history of malignant diseases within the last 5 years; systemic inflammatory diseases; pregnancy or breast feeding; psychiatric disease; either history of alcohol or drug abuse or both.</p>	<p>Urine albumin creatinine ratio (mg/ mmol): 9.4 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR HbA_{1c} (%): NR Diabetes (%): 74 History of HTN (%): 100 History of CAD "Cardiac disorders"(%): 19 History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR</p>		<p>Withdrawals/Dropouts adequately described: yes</p>

Appendix Evidence Table C24. Overview of ACEI plus ARB versus ARB trials (n=3 trials) (continued)

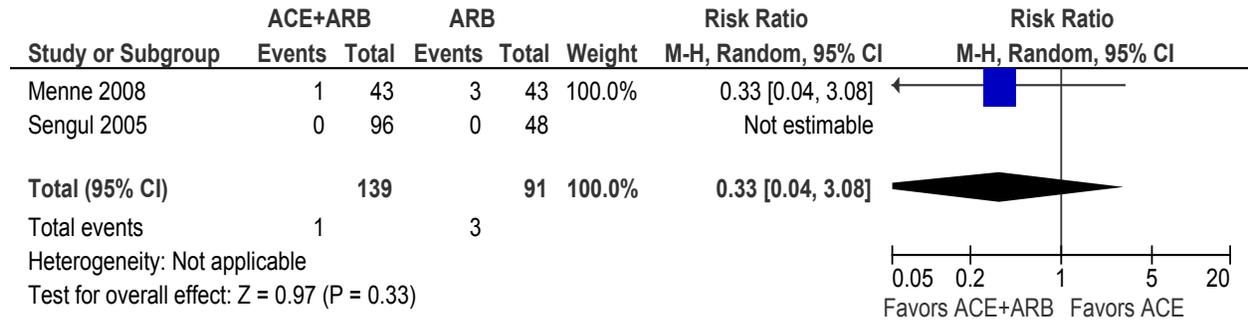
Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Mann, 2008 ¹⁸ ONTARGET	Inclusion Criteria: aged 55 years or older with established atherosclerotic vascular disease or with diabetes with end-organ damage.	This was a 3-arm trial of 25,620 subjects; number with CKD is not specified	ramipril 10 mg/d + telmisartan 80 mg/d (n= 8502 overall)	Allocation Concealment: adequate
Multinational Funding Source: Industry	Exclusion Criteria: major renal artery stenosis, uncorrected volume or sodium depletion, a serum creatinine concentration above 265 µmol/L, and uncontrolled hypertension (>160 mm Hg systolic or >100 mm Hg diastolic).	Estimated GFR (ml/min/1.73m ²): 51.0* Urine albumin creatinine ratio (mg/mmol): 0.81* *Patient characteristics not described for the different arms or for CKD subgroup	telmisartan 80 mg/d (n= 8542 overall) Followup period: median 4.7 years (followup is for the entire cohort) Study withdrawals (%): NR	Blinding: double Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes

Appendix Figure C4. Forest plots ACE plus ARB versus ARB trials

All-cause Mortality



Progression to Macroalbuminuria



Appendix Evidence Table C25. Overview of ACEI plus ARB versus ACEI plus aldosterone antagonist trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Mehdi, 2009 ⁴⁵	Inclusion Criteria: Age 20 to 65; type 1 or 2 DM; seated systolic BP >130mmHg; proteinuria (24-h UACR≥300 mg/g despite treatment with ACEI or ARB for at least 3 months*	Baseline characteristics based on 26 in Losartan group (excluded 1 patient who withdrew prior to first dose) and 27 in spironolactone group N=53 Age (yr): 52 Gender (Male %): 49 Race/Ethnicity (%): 55% Hispanic, 28% black, 15% non-Hispanic white, 2% Native American Weight (kg): NR BMI: 32.0 Clinic Systolic BP (mm Hg): 134.0 Clinic Diastolic BP (mm Hg): 72.5 CKD stage: NR Serum creatinine (mg/dl): 1.75 Creatinine clearance (ml/min): 58.0 Albuminuria (µg/min): NR Proteinuria (g/day): NR Albumin/creatinine ratio (mg/g): 997.4 GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 7.5 Total cholesterol (mg/dl): 186.8 LDL cholesterol (mg/dl): 87.3 Diabetes (%): 100 History of HTN (%): NR Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%):0 Peripheral arterial disease (%): NR History of MI (%): 0 in past 12 months History of MI, CABG, or PCTA (%): 7.5 History of Stroke (%): 0 in past 12 months Current smoker (%): NR History of AKI (%): NR	n= 27 to Losartan 100mg/day# n= 27 to Spironolactone 25mg/day# Followup period: 48 weeks Study withdrawals (%): 35.2 #All patients were taking Lisinopril 80 mg/day	Allocation Concealment: Unclear Blinding: Double blinded Intention to Treat Analysis (ITT): No (excluded 1 subject who withdrew prior to first losartan dose from analyses) Withdrawals/Dropouts adequately described: Yes
Location United States, single-site				
Funding Source Government	Exclusion Criteria: BMI >45kg/m ² ; serum creatinine >3.0mg/dl (females) or >4.0 mg/dl (males); known nondiabetic kidney disease; serum potassium >5.5 mEq/L; hemoglobin A1c >11%; stroke or myocardial infarction within preceding 12 months; heart failure; known adverse reaction to losartan or spironolactone; anticipated need for dialysis within 12 months *Effort was made to recruit younger patients with type 2 DM as recommended by study sponsor			

ACR = albumin/creatinine ratio; UAER = urinary albumin excretion rate; ARB = Angiotensin II receptor blockers; CCB = calcium channel blocker; TIA = transient ischemic attack; CAD = coronary artery disease; HTN = Hypertension; LDL = Low density lipoprotein; MI = myocardial infarction; NR = not reported; PVD = peripheral vascular disease; ACEI = Angiotensin converting enzyme inhibitors; ACR = albumin/creatinine ratio; ARB = Angiotensin II receptor blockers; BP = blood pressure; CHF = Congestive Heart Failure; DM = diabetes mellitus; NSAIDS = Non-steroidal anti-inflammatory drug; CVA= cerebrovascular accident. SBP=systolic blood pressure, DBP=diastolic blood pressure. PTCA= Percutaneous transluminal coronary angioplasty, CABG= coronary artery bypass grafting, PCTA= percutaneous transluminal coronary angioplasty, BMI = body mass index, GFR = glomerular filtration rate, ITT = intention to treat, HbA1c = hemoglobin A1c.

Appendix Table C26. Clinical outcomes (outcomes part A), ACEI plus ARB versus ACEI plus aldosterone antagonist trial

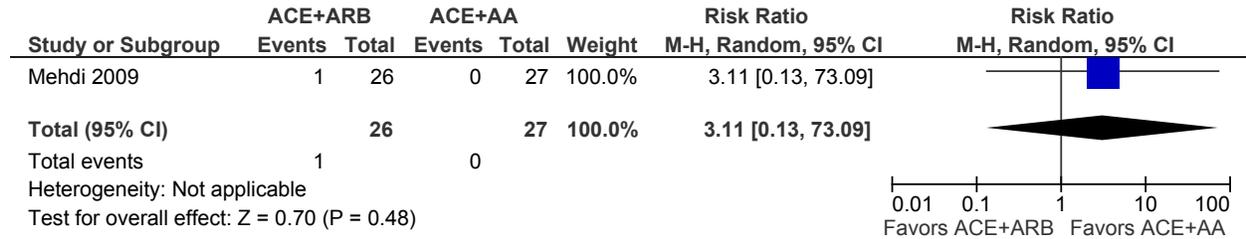
Study	All-Cause Mortality, n/N (%)		Cardiovascular Death, n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any, n/N (%)	
	ACEI+ ARB	ACEI+ Aldo Antag	ACEI+ ARB	ACEI+ Diuretic	ACEI+ ARB	ACEI+ Diuretic	ACEI+ ARB	ACEI+ Diuretic	ACEI+ ARB	ACEI+ Diuretic	ACEI+ ARB	ACEI+ Diuretic
Mehdi, 2009 ⁴⁵	1/26 (3.8)	0/27			0/26 (0.0)	1/27 (3.7)					NR*	NR*

ACEI = angiotensin converting enzyme; ARB = angiotensin receptor blocker; Aldo Antag = aldosterone antagonist

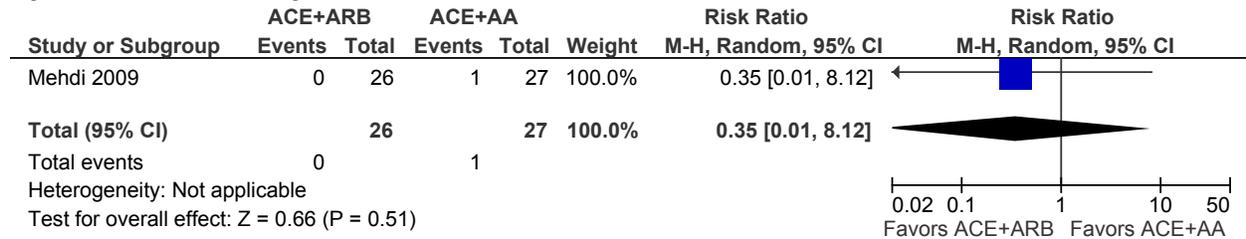
* The study reports both that hospitalizations for stroke occurred in no subjects assigned to ACEI plus ARB and two subjects assigned to ACEI plus diuretic, and that withdrawals for stroke occurred in one subject assigned to ACEI plus ARB and two subjects assigned to ACEI plus diuretic. It is unclear whether one of the reports is in error or whether there is nonoverlap between the strokes leading to hospitalization and those leading to withdrawal.

Appendix Figure C5. Forest plots for ACEI plus ARB versus ACEI plus aldosterone antagonist trial

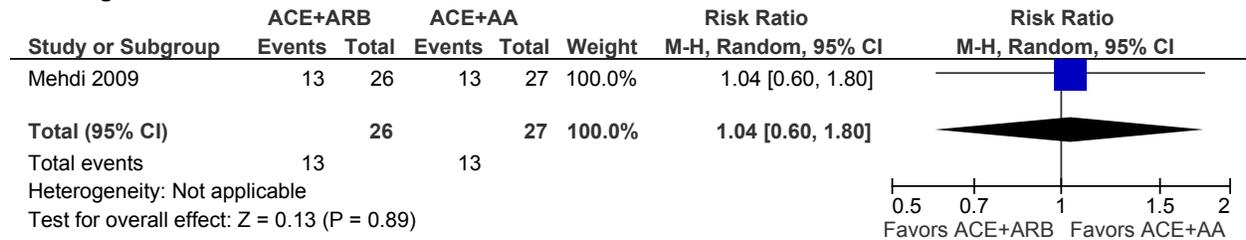
All-cause mortality



Myocardial infarction, any



Doubling of serum creatinine



Appendix Table C27. Clinical renal outcomes (outcomes part C), ACEI plus ARB versus ACEI plus aldosterone antagonist trial

Study	End-Stage Renal Disease, n/N (%)		Doubling of Serum Creatinine, n/N (%)		Halving of GFR, n/N (%)		Progression from Micro- to Macroalbuminuria, n/N (%)		Composite Renal Outcome, n/N (%)	
	ACEI+ ARB	ACEI+ AA	ACEI+ ARB	ACEI+ AA	ACEI+ ARB	ACEI+ AA	ACEI+ ARB	ACEI+ AA	ACEI+ ARB	ACEI+ AA
Mehdi, 2009 ⁴⁵			13/26 (50.0)	13/27 (48.0)						

GFR = glomerular filtration rate; ACEI = angiotension converting enzyme; ARB = angiotensin receptor blocker; AA = aldosterone antagonist

Appendix Table C28. Study withdrawals and adverse events (outcomes part D), ACEI plus ARB versus ACEI plus aldosterone antagonist trial

Study	Study Withdrawals, Any, n/N (%)		Serious Adverse Events, Any, n/N (%)		Withdrawals Due to Adverse Events, Any, n/N (%)		Adverse Events, Any, n/N (%)		Adverse Events, Specific, n/N (%)		Renal Adverse Events, Any, n/N (%)	
	ACEI+ ARB	ACEI+ AA	ACEI+ ARB	ACEI+ AA	ACEI+ ARB	ACEI+ AA	ACEI+ ARB	ACEI+ AA	ACEI+ ARB	ACEI+ AA	ACEI+ ARB	ACEI+ AA
Mehdi, 2009 ⁴⁵	9/27 (33.3)	10/27 (37.0)			2/26 (7.7)	7/27 (25.9)			0/26 (0.0)	1/27 (3.7)	Recurrent hyperkalemia: 0/26; Withdrawn due to increased SCr: 0/27	Recurrent hyperkalemia: 2/27 (7.4); Withdrawn due to increased SCr: 1/27

ACEI = angiotensin converting enzyme inhibitor; ARB = antiogensin receptor blocker; AA = aldosterone antagonist ; SCr = serum creatinine

Appendix Evidence Table C29. Overview of ACEI plus CCB versus ACEI monotherapy or CCB monotherapy trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Fogari, 2002 ²⁴ Italy Multisite Funding Source: none stated	<p>Inclusion: microalbuminuria (UAE \geq30 and \leq300 mg/24 h in two distinct 24-hour urine collections during 7 days before enrollment); essential hypertension (sitting diastolic BP values $>$90 mmHg and $<$110 mmHg); type 2 diabetes well controlled by diet or by metformin alone or metformin plus a sulfanylurea; BMI $<$30 kg/m²; serum creatinine $<$1.5 mg/dL.</p> <p>Exclusion Criteria: history of previous coronary heart disease, stroke, CHF, cancer; smoking habits; electrocardiogram showing left ventricular hypertrophy; total cholesterol values $>$240mg/dL; use of diuretics or beta-blockers.</p>	<p>N=453 randomized</p> <p>Baseline characteristics reported only for N=309 who were judged responders on completion of dose titration phase and did not complain of side effects.</p> <p>N=206 ACE+CCB vs. ACE Age (yr): 62.5 Gender (Male %): 57 Race/Ethnicity (%): NR Weight (kg): NR BMI: 27.6 Systolic BP (mm Hg): 160.3 Diastolic BP (mm Hg): 99.3 CKD stage: NR Serum creatinine (mg/dL): 1.0 Creatinine clearance (mg/min): 89.9 Albuminuria (μg/min): 97.9 Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m²): NR HbA_{1c} (%): 7.1 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 100 History of CAD (%): 0 History of CHF (%): 0 Peripheral arterial disease (%): NR History of MI (%): 0 History of Stroke (%): 0 Peripheral arterial disease (%): NR Current smoker (%): NR (excluded for "smoking habits" – not defined) History of AKI (%): NR</p> <p>N=207 ACE+CCB vs. CCB Age (yr): 62.2 Gender (Male %): 55</p>	<p>n= 102 Fosinopril 10-30 mg/day*</p> <p>n=103 Amlodipine 5-15 mg/day*</p> <p>n=104 Amlodipine 5 to 15 mg/day + Fosinopril 10 to 30 mg/day *</p> <p>Followup period: 4 years</p> <p>Study withdrawals (%): 47% (215/453), including 144/453 (32%) in titration period and 71/309 (23%) during study period.</p> <p>*N=453 randomized to 3 month dose titration period with goal of DBP $<$90 mmHg for monotherapy groups and $<$85 mmHg for combined therapy group.</p>	<p>Allocation Concealment: Adequate</p> <p>Blinding: Open-label</p> <p>Intention to Treat Analysis: No</p> <p>Withdrawals/Dropouts adequately described: No</p>

Appendix Evidence Table C29. Overview of ACEI plus CCB versus ACEI monotherapy or CCB monotherapy trial (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		Race/Ethnicity (%): NR Weight (kg): NR BMI: 27.8 Systolic BP (mm Hg): 160.8 Diastolic BP (mm Hg): 99.4 CKD stage: NR Serum creatinine (mmol/L): 1.0 Creatinine clearance (mg/min): 89.3 Albuminuria (µg/min): 96.6 Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 7.0 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 100 History of CAD (%): 0 History of CHF (%): 0 Peripheral arterial disease (%): NR History of MI (%): 0 History of Stroke (%): 0 Peripheral arterial disease (%): NR Current smoker (%): NR (excluded for “smoking habits” – not defined) History of AKI (%): NR		

Appendix Table C30. Clinical outcomes (outcomes part A), ACEI plus CCB versus ACEI monotherapy or CCB monotherapy trial

Study	All-Cause Mortality, n/N (%)			Cardiovascular Death, n/N (%)			Myocardial Infarction, Any, n/N (%)			Myocardial Infarction, Fatal, n/N (%)			Myocardial Infarction, Nonfatal, n/N (%)			Stroke, Any, n/N (%)		
	ACEI+ CCB	ACEI	CCB	ACEI+ CCB	ACEI	CCB	ACEI+ CCB	ACEI	CCB	ACEI+ CCB	ACEI	CCB	ACEI+ CCB	ACEI	CCB	ACEI+ CCB	ACEI	CCB
Fogari, 2002 ²⁴	2/104 (1.9)	3/102 (2.9)	4/103 (3.9)	1/104 (1.0)	2/102 (1.9)	2/103 (1.9)	1/104 (1.0)	3/102 (2.9)	4/103 (3.9)	0/104	1/102 (1.0)	2/103 (1.9)	1/104 (1.0)	2/102 (1.9)	2/103 (1.9)	1/104 (1.0)	3/102 (2.9)	2/103 (1.9)

ACEI = angiotensin converting enzyme inhibitor; CCB = calcium channel blocker

Appendix Table C31. Clinical outcomes (outcomespart B), ACEI plus CCB vs ACEI monotherapy or CCB monotherapy trial

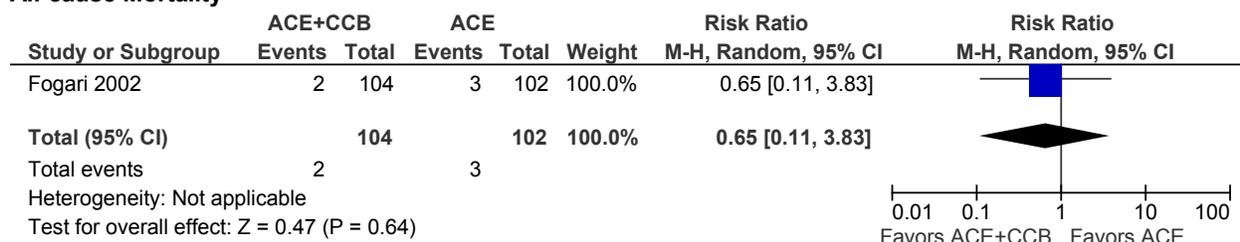
Study	Stroke, Nonfatal, n/N (%)			Stroke, Fatal, n/N (%)			CHF, Any, n/N (%)			CHF Hospitalization (A) or Death (B), n/N (%)			Composite Vascular Outcome, n/N (%)		
	ACEI+ CCB	ACEI	CCB	ACEI+ CCB	ACEI	CCB	ACEI+ CCB	ACEI	CCB	ACEI+ CCB	ACEI	CCB	ACEI+ CCB	ACEI	CCB
Fogari, 2002 ²⁴	1/104 (1.0)	2/102 (1.9)	2/103 (1.9)	0/104	1/102 (1.0)	0/103									

ACEI = angiotensin converting enzyme; CCB = calcium channel blocker; CHF = congestive heart failure

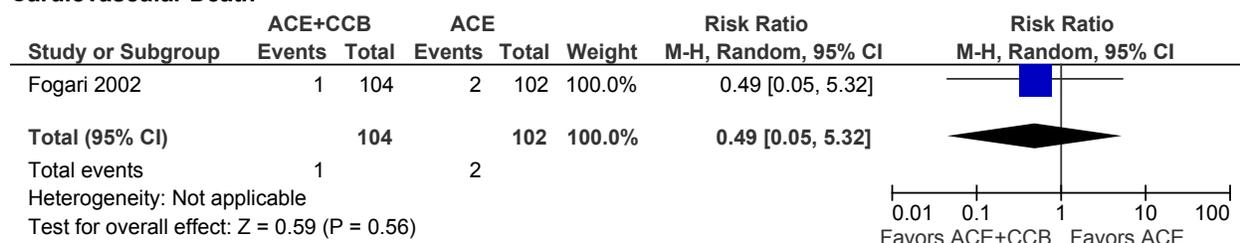
*Other no-fatal cardiovascular events (not defined): ACEI+CCB: 1/104 (1.0%), ACEI: 1/102 (1.0%), CCB: 2/103 (1.9%)

Appendix Figure C6. Forest plots for ACEI plus CCB versus ACE monotherapy trial

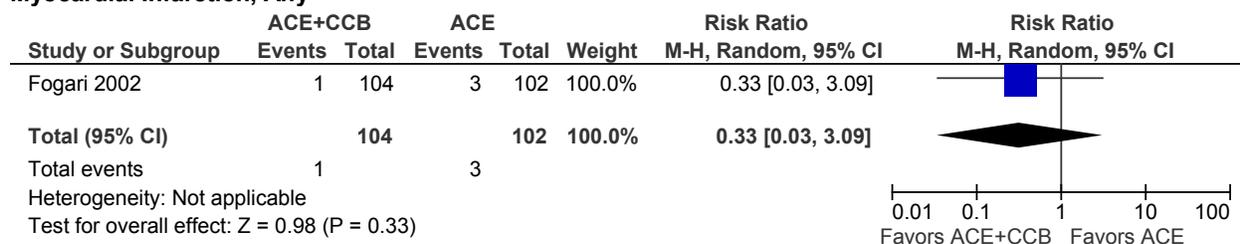
All-cause Mortality



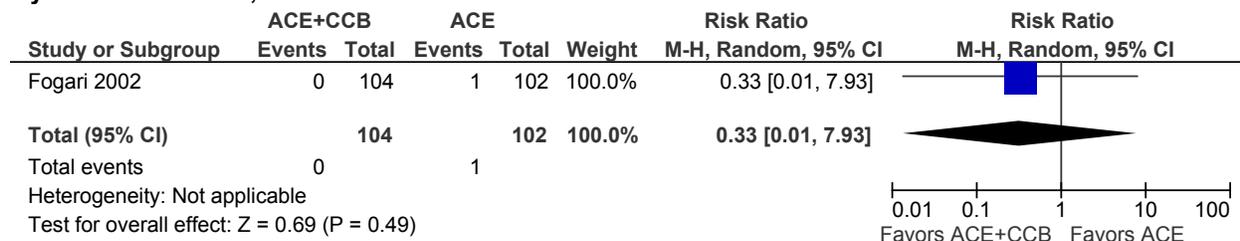
Cardiovascular Death



Myocardial Infarction, Any

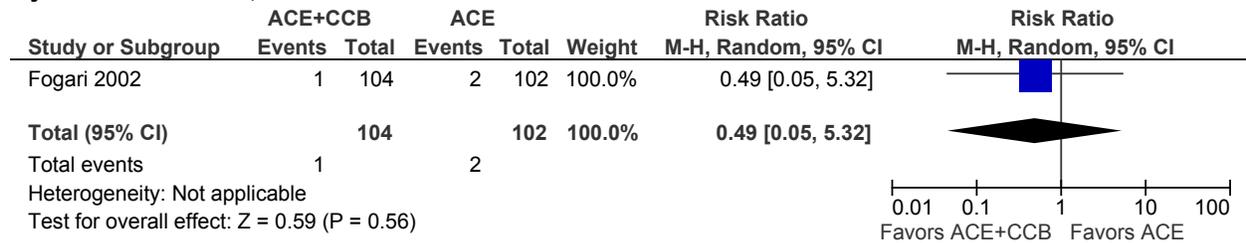


Myocardial Infarction, Fatal

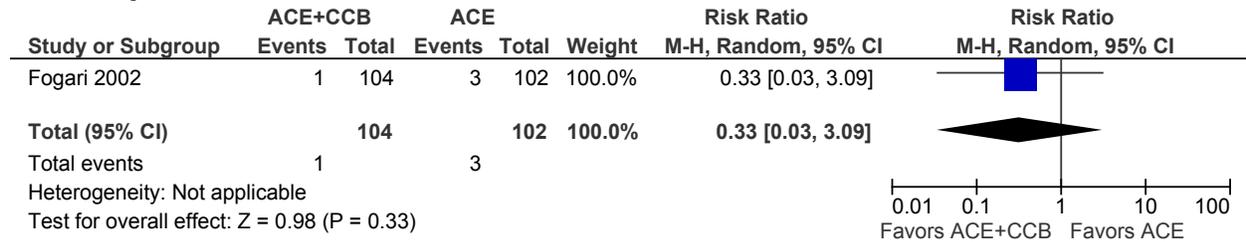


Appendix Figure C6. Forest plots for ACEI plus CCB versus ACE monotherapy trial (continued)

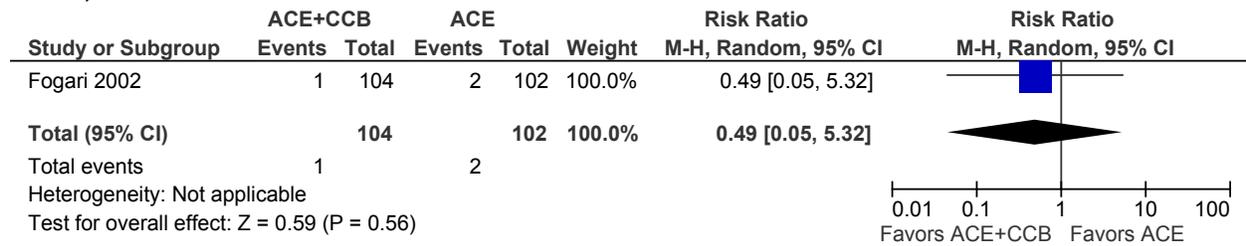
Myocardial Infarction, Nonfatal



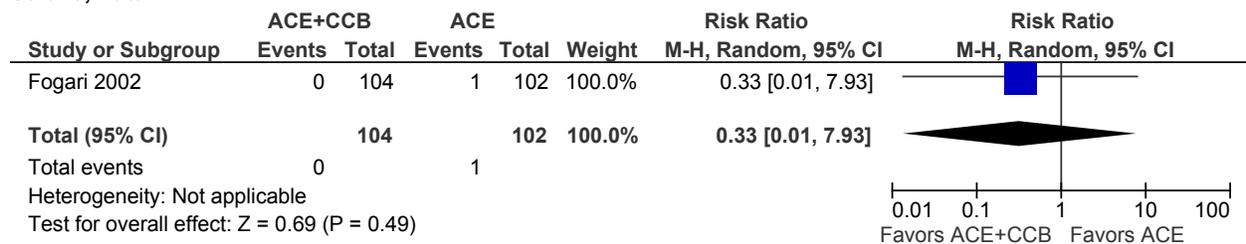
Stroke, Any



Stroke, Nonfatal

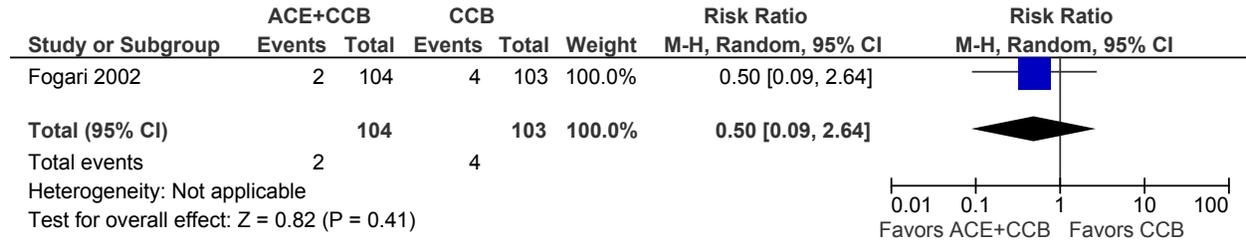


Stroke, Fatal

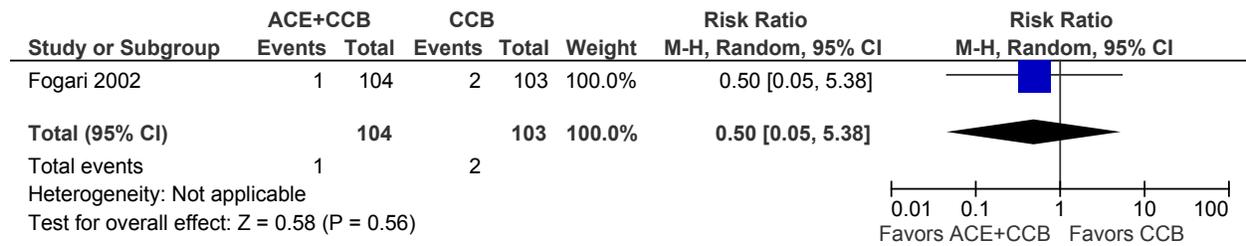


Appendix Figure C7. Forest plots for ACEI plus CCB versus CCB monotherapy trial

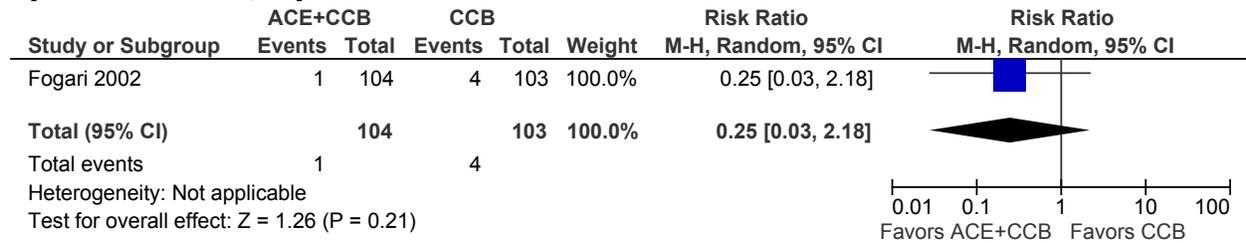
All-cause Mortality



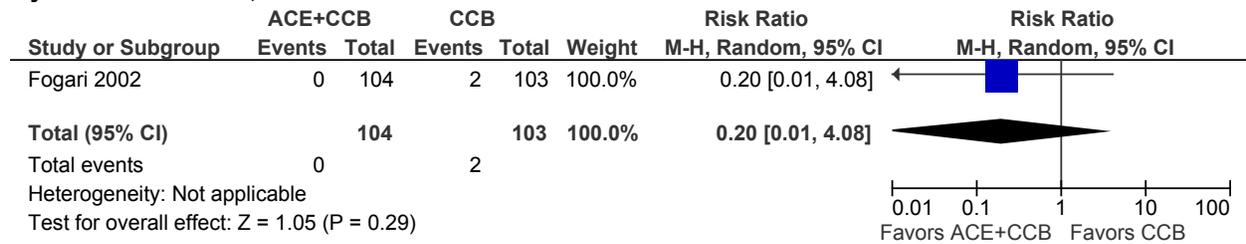
Cardiovascular Death



Myocardial Infarction, Any

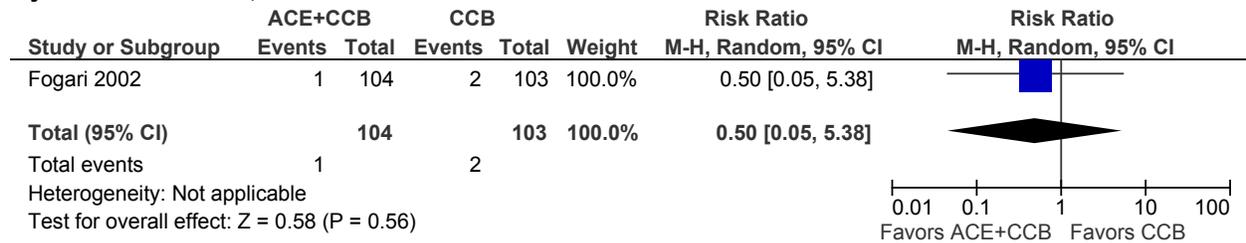


Myocardial Infarction, Fatal

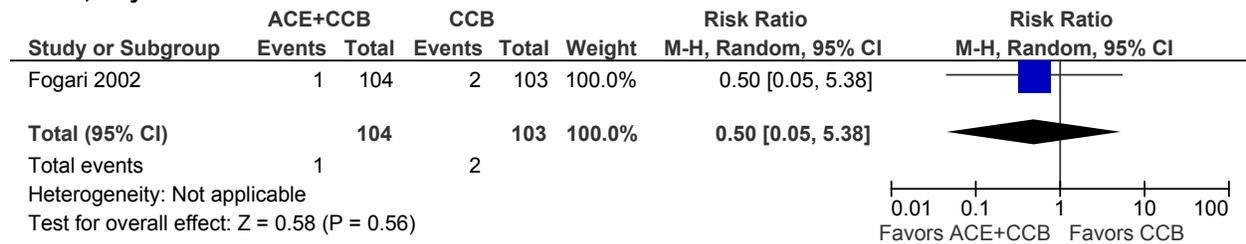


Appendix Figure C7. Forest plots for ACEI plus CCB versus CCB monotherapy trial (continued)

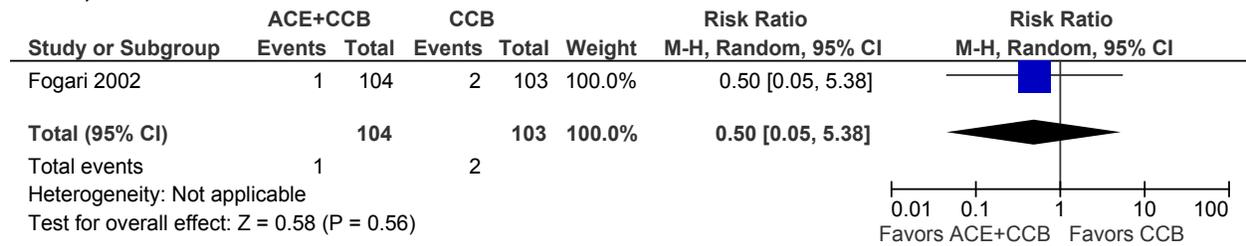
Myocardial Infarction, Nonfatal



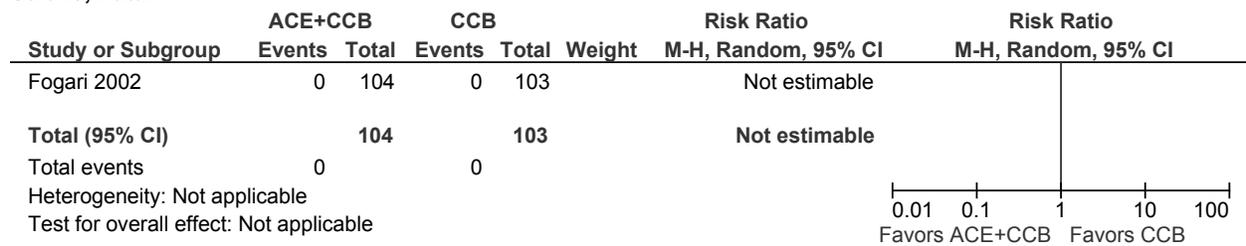
Stroke, Any



Stroke, Nonfatal



Stroke, Fatal



Appendix Table C32. Study withdrawals and adverse events (outcomes part D), ACEI plus CCB versus ACEI monotherapy or CCB monotherapy trial

Study	Any Study Withdrawals, n/N (%)			Withdrawals Due to Serious Adverse Events, n/N (%)			Serious Adverse Events, n/N (%)			Adverse Events, Any, n/N (%)			Adverse Events, Specific, n/N (%)			‡Renal Adverse Events, n/N (%)		
	ACEI + CCB	ACEI	CCB	ACEI + CCB	ACEI	CCB	ACEI + CCB	ACEI	CCB	ACEI + CCB	ACEI	CCB	ACEI + CCB	ACEI	CCB	ACEI + CCB	ACEI	CCB
Fogari, 2002 ²⁴	*NR	*NR	*NR	†NR	†NR	†NR							Cough: 1/104 (1.0); Edema 0/104	Cough: 2/102 (1.9) Edema 0/102	Cough: 0/103 Edema 2/103	1/104 (1.0)	2/102 (1.9)	2/103 (1.9)

ACEI = angiotensin converting enzyme inhibitor; CCB = calcium channel blocker

*Study reported that after randomization, during dose titration phase, 144/453 subjects discontinued due to their being nonresponders or because of side effects, but their treatment group was not reported. Following dose titration, another 71/309 subjects dropped out of the study (18/104 [17.3%] ACEI+CCB, 26/102 [25.4%] ACEI, and 27/103 [26.2%] CCB).

†Study reported that of 309 completing dose titration phase, 4/103 CCB subjects, 3/102 ACEI subjects, and 2/104 ACEI+CCB subjects withdrew due to adverse events, though no data were reported on withdrawals due to serious adverse events.

‡Study reported renal adverse event of discontinuing study medication due to worsening kidney function.

Appendix Evidence Table C33. Overview of ACEI plus diuretic versus ACEI plus CCB trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Bakris, 2008 ⁴⁷ (GUARD)	Inclusion Criteria: age 21 to 85 years; type 2 diabetes; albuminuria (repeated UACR 20-500 mg/g); hypertension (mean SBP≥130 mmHg and <180 mmHg, mean DBP≥80 mmHg and <110 mmHg)	N=332 Age (yr): 57.7 Gender (Male %): 65.4 Race/Ethnicity (%): 60.2% white, 26.2% black, 1.5% Asian, 12.0% other Weight: NR BMI: 35 Systolic BP (mm Hg): 150.5 Diastolic BP (mm Hg): 87.8 CKD stage: NR HbA _{1c} (%): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 100 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): 0 Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR	n=166 (ACEI/Diuretic) benazepril/HCTZ (B+HCTZ) initiated at 20/12.5 mg/day; titrated to 40/12.5 mg/day at 4 weeks if not at <130/80 mm Hg target; titrated to 40/25 mg/day at 8 weeks if not at target <130/80 mm Hg* n=166 (ACEI/CCB) benazepril/amlodipine (B+A) initiated at 20/5 mg/day; titrated to 40/5 mg at 4 weeks if not at <130/80 mm Hg target; titrated to 40/10 mg/day at 8 weeks if not at target <130/80 mm Hg* All other antihypertensive medications were discontinued during pre-randomization wash-out phase. Followup period: 12 months Study withdrawals (%): 18.7%	Allocation Concealment: Adequate Blinding: Double blind Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes
Location United States Multisite				
Funding Industry	Exclusion Criteria: kidney disease not caused by diabetes and/or hypertension; confirmed or suspected renal artery stenosis; cardiovascular disease event (MI, stroke, TIA, CABG, PTCA) within previous 6 months; evidence of heart failure or documented left ventricular ejection fraction <40%; type 1 diabetes or uncontrolled type 2 diabetes (hgb A1C >9.5%, serum creatinine >1.5 mg/100ml (men) or >1.3 mg/100ml (women))	Following baseline characteristics available only from n=304 subjects who completed followup (n=151 (B+HCTZ) and n=153 (B+A)): Serum creatinine (µmol/L): NR Creatinine clearance (mL/min): NR Albuminuria (g/100ml)*: 4.2 (median) Albumin/creatinine ratio (mg/g): 60.5 (median) Estimated GFR (ml/min/1.73m ²): 90.6 (median)	*At 12 weeks and all subsequent visits, patients titrated to next dose if not at target BP; if at max dose (40/25 mg B+HCTZ or 40/10 mg B+A), other anti-hypertensives added (alpha blockers, beta blockers, etc.); no added ACEi, ARB, or aldosterone receptor blocker	

Appendix Table C34. Clinical outcomes (outcomes part A), ACEI plus diuretic versus ACEI plus CCB trial

Study	All-cause Mortality, n/N (%)		Cardiovascular Death, n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any, n/N (%)	
	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB
Bakris, 2008 ⁴⁷	2/166 (1.2)	1/166 (0.6)										

ACEI = angiotensin converting enzyme; CCB = calcium channel blocker

Appendix Table C35. Clinical outcomes (outcomes part B), ACEI plus diuretic versus ACEI plus CCB trial

Study	Stroke, Nonfatal, n/N (%)		Stroke, Fatal, n/N (%)		CHF, Any, n/N (%)		CHF Hospitalization (A) or Death (B), n/N (%)		Composite Vascular Outcome, n/N (%)	
	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB
Bakris, 2008 ⁴⁷									*NR	*NR

ACEI = angiotensin converting enzyme inhibitor; CCB = calcium channel blocker; CHF = congestive heart failure

*Study reported discontinuation due to "cardiac disorders" in 3/166 ACEI + Diuretic subjects and in 2/166 ACEI + CCB subjects as well as due to "vascular disorders" in 2/166 ACEI + Diuretic subjects.

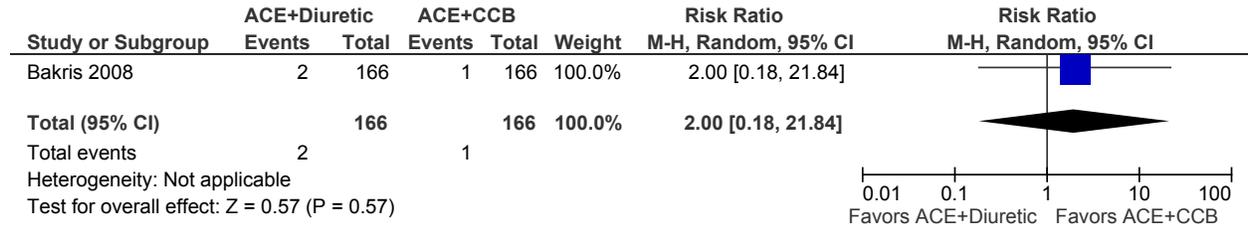
Appendix Table C36. Clinical renal outcomes (outcomes part C), ACEI plus diuretic versus ACEI plus CCB trial

Study	End-Stage Renal Disease, n/N (%)		Doubling of Serum Creatinine, n/N (%)		Halving of GFR, n/N (%)		Progression from Micro- to Macroalbuminuria, n/N (%)		Composite Renal Outcome, n/N (%)	
	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB
Bakris, 2008 ⁴⁷							6/153 (4.0)	7/150 (4.6)		

ACEI = angiotensin converting enzyme inhibitor; CCB = calcium channel blocker; GFR = glomerular filtration rate

Appendix Figure C8. Forest plots for ACEI plus Diuretic versus ACEI plus CCB trial

All-cause Mortality



Progression from Micro- to Macroalbuminuria



Appendix Table C37. Study withdrawals and adverse events (outcomes part D), ACEI plus diuretic versus ACEI plus CCB trial

Study	Any Study Withdrawals, n/N (%)		Withdrawals Due to Serious Adverse Events, n/N (%)		Serious Adverse Events, n/N (%)		Adverse Events, Any, n/N (%)		‡Adverse Events, Specific, n/N (%)		Renal Adverse Events, n/N (%)	
	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB	ACEI + Diuretic	ACEI + CCB
Bakris, 2008 ⁴⁷	*NR	*NR	†NR	†NR					Edema: 12/166 (7.2); Cough: 17/166 (10.2); Dizzy: 11/166 (6.6)	Edema: 29/166 (17.5); Cough: 23/166 (13.9); Dizzy: 15/166 (9.0)		

ACEI = angiotensin converting enzyme inhibitor; CCB = calcium channel blocker

*Study reported 215/453 (47%) withdrawals after randomization overall, including 144/453 (32%) during dose titration period who were considered to be either nonresponders to treatment or had complained of side effects (treatment group not reported) and 71/309 (23%) during study period (36/166 [21.7%] in ACEI + Diuretic group and 26/166 [15.7%] in ACEI + CCB group).

†Study reported adverse event reasons for study medication discontinuations due to adverse events (18/166 [10.8%] for ACEI + Diuretic group and 9/166 [5.4%] for ACEI + CCB group), but did not report serious adverse events or discontinuations due to serious adverse events.

‡Study reported additional side effects by treatment group, including: fatigue (13/166 [7.8%] in each treatment group); headache (16/166 [9.6%] in ACEI + Diuretic group and 14/166 [8.4%] in ACEI + CCB group).

Appendix Evidence Table C38. Overview of ACEI plus diuretic versus ACEI trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (Expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Mogensen, 2003 ⁴⁸ Country: Multinational Funding Source: Industry	Inclusion: ages 40 to 75 years; type 2 diabetes; hypertension (SBP ≥140 mmHg but < 180 mmHg; DBP <110 mmHg); urinary albumin excretion rate ≥20 µg/min but <500 µg/min in at least 2 of 3 assays Exclusion: HbA1c ≥9% within 3 months before study; presumed nondiabetic kidney disease; serum creatinine ≥140 µmol/L (=1.58 mg/dL); known contraindication to ACEI or indapamide; other severe disease.	N=481 (baseline results reported for n=457 [n=233 perindopril/indapamide; n=224 enalapril] with albuminuria at baseline, who took at least one dose of treatment, and had albuminuria measured at least once under treatment) Age (yr): 58.9 Gender (Male %): 61.3 Race/Ethnicity (%): 91.0 white, 4.4 black, 0.7 Asian, 3.7 other Weight: 82.5 kg BMI: 30 Systolic BP (mm Hg): 158.4 Diastolic BP (mm Hg): 93.3 CKD stage: NR Serum creatinine (µmol/L): NR Creatinine clearance (mL/min): NR Albuminuria (µg/min): 82.1 Albumin/Creatinine ratio (mg/mmol): 8.5 HbA _{1c} (%): 7.2 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 100 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR	n=244 Initiated with combination of 2 mg perindopril/0.625 mg indapamide once daily, titrated to maximum of 8 mg perindopril/2.5 mg indapamide for BP target.* n= 237 Initiated with 10 mg enalapril, titrated to maximum of 40 mg enalapril for BP target* Nonstudy antihypertensive drugs were not allowed. Diabetic management left to discretion of investigator. Followup period: mean 10.7 months Study withdrawals (%): Text says 20% did not complete the study, but list of reasons for early withdrawal add to 50/244 (20.5%) for perindopril and 60/237 (25.3%) for enalapril (110/481=22.9% overall) *Dose adjustment (doubling) allowed at weeks 12, 24, or 36 if SBP ≥140 mm Hg or DBP ≥90 mm Hg based on BP permitted after week 12 (doubling of dosage in 2 steps at 12 week intervals if SBP ≥ 140 mmHg or DBP ≥90 mmHg)	Allocation Concealment: Unclear Blinding: Double Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: No

Appendix Table C39. Clinical outcomes (outcomes part B), ACEI plus diuretic versus ACEI plus placebo trial

Study	Stroke, Nonfatal n/N (%)		Stroke, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B) n/N (%)		Composite Vascular Outcome n/N (%)	
	ACEI + Diuretic	ACEI + Placebo	ACEI + Diuretic	ACEI + Placebo	ACEI + Diuretic	ACEI + Placebo	ACEI + Diuretic	ACEI + Placebo	ACEI + Diuretic	ACEI + Placebo
Mogensen, 2003 ⁴⁸									6/244 (2.5)	15/237 (6.3)

ACEI = angiotensin converting enzyme inhibitor; CHF = congestive heart failure

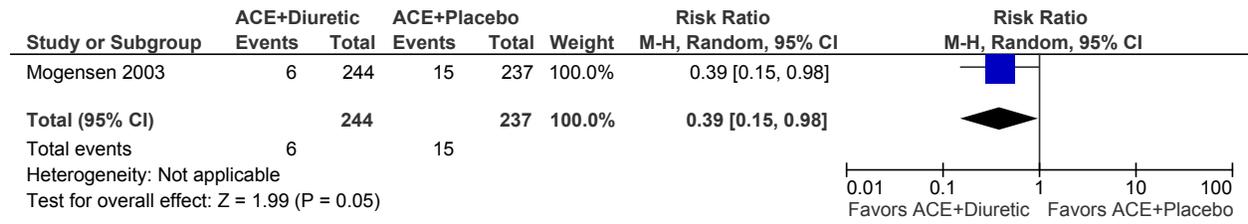
Appendix Table C40. Composite vascular outcome definitions, ACEI plus diuretic versus ACEI plus placebo trials

Study	Definition
Mogensen, 2003 ⁴⁸	“Serious cardiovascular events,” with serious defined as “fatal or requiring prolonged hospitalization” and cardiovascular events defined according to ICD9-1975 revision, codes 7981 (sudden death) and 390-448 (rheumatic fever with or without acute or chronic heart involvement, diseases of cardiac valves, essential hypertension, hypertensive heart or renal disease, MI, angina, chronic ischemic heart disease, cardiac aneurysm, pulmonary artery disease, pericarditis, endocarditis, myocarditis, cardiomyopathy, heart conduction disorders/dysrhythmias, heart failure, stroke, atherosclerosis, aortic aneurysm disease, peripheral arterial disease, arterial embolism/thrombosis, other disorders or the arteries/arterioles/capillaries)

ACEI = angiotensin converting enzyme; MI = myocardial infarction

Appendix Figure C9. Forest plot for ACEI plus Diuretic versus ACEI plus placebo trial

Composite Vascular Outcome



Appendix Table C41. Study withdrawals and adverse events (outcomes part D), ACEI plus diuretic vs. ACEI plus placebo trials

Study	Any Study Withdrawals, n/N (%)		Withdrawals Due to Serious Adverse Event, n/N (%)		Serious Adverse Event: Any, n/N (%)		Adverse Event: Any, n/N (%)		Adverse Event, Specific, n/N (%)		Renal Adverse Event, n/N (%)	
	ACEI + Diuretic	ACEI + Placebo	ACEI + Diuretic	ACEI + Placebo	ACEI + Diuretic	ACEI + Placebo	ACEI + Diuretic	ACEI + Placebo	ACEI + Diuretic	ACEI + Placebo	ACEI + Diuretic	ACEI + Placebo
Mogensen, 2003 ⁴⁸	*50/244 (20.5)	*60/237 (25.3%)	†NR	†NR			‡NR	‡NR	HyperK: 8/244 (3.3); Cough: 9/244 (3.7)	HyperK: 13/237 (5.5); Cough: 5/237 (2.1)		

ACEI = angiotensin converting enzyme inhibitor; HyperK = hyperkalemia

* Study also reported that one patient was lost to follow-up, but didn't indicate the patient's treatment group assignment.

† Study reported withdrawal due to adverse events by treatment group, 19/244 (7.8%) for ACEI + diuretic group and 21/237 (8.8%) for ACEI + placebo group, but did not report serious adverse events or withdrawals due to serious adverse events.

‡ Study did not report adverse events overall or by treatment group, but only reported results for participants with adverse events related to drug treatment: ACEI + diuretic group 34/244 (13.9%) and ACEI + placebo group 35/237 (14.8%).

Appendix Evidence Table C42. Overview of ARB versus ARB trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
ARB versus different ARB trials				
Bakris, 2008 ⁴⁹ (AMADEO)	Inclusion: ages 21-80 years; history of type 2 diabetes mellitus; total HbA _{1c} ≤10%; serum creatinine ≤3 mg/dl (women) or ≤3.2 mg/dl (men); first-morning spot urine protein/creatinine ratio ≥700 mg/g; mean BP ≥130/80 but less than 160/110 mmHg or receiving antihypertensive(s) for hypertension	N=860 Age (yr): 60.3 Gender (Male %): 62.2 Race/Ethnicity (%): 47% Caucasian, 12% black, 41% Asian, 0.1% missing Weight (kg): NR BMI: 30.0* Systolic BP (mm Hg): 143.4 Diastolic BP (mm Hg): 79.7 CKD stage: NR Serum creatinine (mg/dl): 1.55 Creatinine clearance (mL/min): NR Albuminuria (µg/min): NR Proteinuria (mg/day): NR Urine protein/creatinine ratio (m/g): 1991.2 Urine albumin/creatinine ratio (mg/g): 1393.7* Estimated GFR (ml/min/1.73m ²): 49.6 HbA _{1c} (%): 7.9* Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 100 Dyslipidemia (%): NR History of CAD (%): 0 (clinically significant excluded) History of CHF (%): 0 (clinically significant excluded) Peripheral arterial disease (%): NR History of MI (%): 0 (clinically significant excluded) History of Stroke (%): 0 (clinically significant excluded) Current smoker (%): 15.6 History of AKI (%): NR *sample size <860 for these characteristics	n= 419 Telmisartan 40 mg/day for 2 weeks then 80 mg/day for 50 weeks* n= 441 Losartan 50 mg/day for 2 weeks then 100 mg/day for 50 weeks* Follow-up period: mean of 324.25 days (i.e. 10.7 months) Study withdrawals (%): 18.4 *Additional antihypertensive medications (except other ARBs, ACEIs, or direct vasodilators) allowed after forced titration period to reach BP target <130/80 mmHg	Allocation Concealment: Unclear Blinding: Double blind Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: No
Multinational (Argentina, Australia, Brazil, Canada, Mexico, New Zealand, South Korea, Taiwan, Thailand, United States)	Exclusion: women who were nursing, pregnant, or surgically sterile and not using effective contraception; >35% increase in serum creatinine during washout period or serum potassium level >5 mEq/l; nondiabetic renal disease; clinically significant heart disease, stroke, renal artery stenosis, hepatic dysfunction, or electrolyte imbalance; known hypersensitivity to any component of study medications; requiring chronic immunosuppressive therapy; hematuria.			
Funding Source: Industry				

Appendix Evidence Table C42. Overview of ARB versus ARB trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Galle, 2008 ⁵⁰ Multinational (11 countries in Europe, 3 countries in Asia, South Africa) Funding Source: Industry	Inclusion: ages 30-80 years; history of type 2 diabetes mellitus; overt nephropathy (serum creatinine ≤3.0 mg/dl and proteinuria ≥900 mg/24h); hypertensive (mean BP > 130/80 mm Hg or receiving antihypertensive therapy at enrollment) Exclusion: HgbA1c >10%; premenopausal women not surgically sterile or using acceptable contraception or who were pregnant or breast feeding; recent acute cardiovascular event; congestive heart failure; receipt of metformin in patients with elevated serum creatinine levels; nondiabetic renal disease; >30% increase in serum creatinine during run-in; secondary hypertension; hepatic dysfunction; biliary obstructive disorders; renal arterial stenosis; chronic immunosuppressive therapy; history of drug or alcohol dependency; SBP >180 mmHg and/or DBP >110 mmHg on two consecutive visits during run-in	N=885 Age (yr): 61.2 Gender (Male %): 64.1 Race/Ethnicity (%): 79% white, 2% black, 19% Asian Weight: NR BMI: 30.2 Systolic BP (mm Hg): 148.1 Diastolic BP (mm Hg): 82.0 CKD stage: NR Serum creatinine (mg/dl): NR Creatinine clearance (mL/min): NR Albuminuria (µg/min): NR Proteinuria (g/24h): 2.78 Albumin/Creatinine ratio (mg/mmol): NR Estimated GFR (ml/min/1.73m ²): 56.6 HbA _{1c} (%): 7.8 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 100 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): 0 Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): 18.2 History of AKI (%): NR	n= 443 Telmisartan 40 mg/day for 2 weeks then 80 mg/day for 50 weeks* n= 442 Valsartan 80 mg/day for 2 weeks then 160 mg/day for 50 weeks* Followup period: mean of 363.5 days (1 yr) Study withdrawals (%): 19.1 *Additional antihypertensive medications (except other ARBs or ACEIs) allowed if SBP/DBP >130/80	Allocation Concealment: Unclear Blinding: Double blind Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes
ARB (high dose) versus ARB (standard dose) trial				
Burgess, 2009 ⁵¹ Canada, Multisite Funding Source: Industry	Inclusion: ages 18 to 80 years; primary glomerular disease not currently treated with any disease- specific treatment; diabetic nephropathy or hypertensive nephrosclerosis; urine protein ≥1g/d on at least 2 occasions in previous 6 months; not taking immunosuppressant drugs, corticosteroids, or nonsteroidal anti-inflammatory medications; stable hypertension (no new	N=269 Age (yr): 55.3 Gender (Male %): 79.6 Race/Ethnicity (%): 83.2% white, 3.7% black, 9.3% Asian, 3.7% other Weight (kg): 91.9 BMI: 31.8 Systolic BP (mm Hg): 132.5 Diastolic BP (mm Hg): 77.4 CKD stage: NR Serum creatinine (µmol/L): 127.0 (=1.44 mg/dl)	n= 90 Candesartan 16 mg/day* n= 90 Candesartan 64 mg/day# n= 89 Candesartan 128 mg/day## Followup period: 30 weeks Study withdrawals (%): 14	Allocation Concealment: Adequate Blinding: Double blind Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes

Appendix Evidence Table C42. Overview of ARB versus ARB trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	<p>antihypertensive medications within 6 weeks of visit 1); if taking ACE or ARB use stable for at least 3 months before visit 1; SBP <170 and DBP <100 mm Hg with use of antihypertensive medications</p> <p>Exclusion: presence of known or suspected secondary hypertension including bilateral renal artery stenosis or unilateral renal artery stenosis to a solitary kidney; pregnancy; serum creatinine >300 µmol/L (=3.4 mg/dl) or eGFR <30 ml/min/1.73m²; presence of polycystic kidney disease, systemic lupus erythematosus; polyarteritis nodosa, amyloidosis or myeloma, or serum potassium ≥ 5.5 mmol/L at baseline or on >1 occasion in 6 months before visit 1.</p>	<p>Creatinine clearance (mL/min): NR Albuminuria: NR Proteinuria (g/day): 2.83 Degree of Proteinuria: 57.3% with 1-3 g/day, 42.7% with >3 g/day Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m²): 52.0 HbA_{1c} (%): NR Total cholesterol: NR LDL cholesterol: NR Diabetes (%): NR History of HTN (%): 100 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR</p>	<p>*16 mg/day was highest approved antihypertensive dosage of candesartan in Canada at the time the study was initiated</p> <p>#dose titrated from 16 mg/day over 4 weeks</p> <p>##dose titrated from 16 mg/day over 6 weeks</p>	

Appendix Table C43. Clinical outcomes (outcomes part A), ARB versus ARB trials

Study	All-Cause Mortality, n/N (%)		Cardiovascular Death, n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial Infarction, Nonfatal n/N (%)		Stroke, Any, n/N (%)	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Bakris, 2008 ⁴⁷	TEL: 2/419 (0.5)*	LOS: 13/441 (2.9)										
Galle, 2008 ⁵⁰	TEL: 15/428 (3.5)	VAL: 8/429 (1.9)	TEL: 8/428 (1.9)	VAL: 6/429 (1.4)	TEL: 4/428 (0.9)	VAL: 11/429 (2.6)					TEL: 11/428 (2.6)	VAL: 5/429 (1.2)
Burgess, 2009 ⁵¹	CAN 64mg/d: 0/90; CAN 128mg/d: 0/89	CAN 16mg/d: 0/90	CAN 64mg/d: 0/90; CAN 128mg/d: 0/89	CAN 16mg/d: 0/90			CAN 64mg/d: 0/90; CAN 128mg/d: 0/89	CAN 16mg/d: 0/90				

ARB = angiotensin receptor blocker; TEL = telmisartan; LOS = losartan; VAL = valsartan; CAN = candesartan

C-113

Appendix Table C44. Clinical outcomes (outcomes part B), ARB versus ARB trials

Study	Stroke, Nonfatal, n/N (%)		Stroke, Fatal, n/N (%)		CHF, Any, n/N (%)		CHF Hospitalization (A) or Death (B), n/N (%)		Composite Vascular Outcome, n/N (%)	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Bakris, 2008 ⁴⁹									TEL: 21/419 (5.0)	LOS: 37/441 (8.4)
Galle, 2008 ⁵⁰							(A)7/428 (1.6)	(A)6/442 (1.4)	TEL: 31/428 (7.2)	VAL: 33/429 (7.7)
Burgess, 2009 ⁵¹			CAN 64mg/d: 0/90; CAN 128mg/d: 0/89	CAN 16mg/d: 0/90			(B) CAN 64mg/d: 0/90; CAN 128mg/d: 0/89	(B) CAN 16mg/d: 0/90		

ARB = angiotensin receptor blocker; CHF = congestive heart failure; TEL = telmisartan; LOS = losartan; VAL = valsartan

Appendix Table C45. Clinical renal outcomes (outcomes part C), ARB versus ARB trials

Study	End-Stage Renal Disease, n/N (%)		Doubling of Serum Creatinine, n/N (%)		Halving of GFR, n/N (%)		Progression from Micro- to Macroalbuminuria, n/N (%)		Composite Renal Outcome, n/N (%)	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Bakris, 2008 ⁴⁷									TEL: 14/419 (3.3)	LOS: 25/441 (5.7)
Galle, 2008 ⁵⁰	TEL: 7/428 (1.6)	VAL: 8/429 (1.9)	TEL: 3/428 (0.7)	VAL: 3/429 (0.7)					TEL: 22/428 (5.1)	VAL: 18/429 (4.2)
Burgess, 2009 ⁵¹										

ARB = angiotensin receptor blocker; GFR = glomerular filtration rate; TEL = telmisartan; LOS = losartan; VAL = valsartan; CAN = candesartan

Appendix Table C46. Study withdrawals and adverse events (outcomes part D), ARB versus ARB trials

Study	Any Study Withdrawals, n/N (%)		Serious Adverse Events, Any, n/N (%)		Withdrawals Due to Serious Adverse Events, n/N (%)		Adverse Event, Any, n/N (%)		Adverse Event, Specific, n/N (%)		Renal AE	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
Bakris, 2008 ⁴⁷	TEL: 74/419 (17.7)	LOS: 99/441 (22.4)	TEL: 65/419 (15.5)	LOS: 99/441 (22.4)	TEL: 6/419 (1.4)	LOS: 6/441 (1.4)	TEL: 352/419 (84.0)	LOS: 362/441 (82.1)	*NR	*NR		
Galle, 2008 ⁵⁰	TEL: 81/443 (18.3)	VAL: 88/442 (19.9)	TEL: 116/443 (26.2)	VAL: 104/442 (23.5)	TEL: 14/443 (3.2)	VAL: 9/442 (2.0)	TEL: 320/443 (72.3)	VAL: 316/442 (71.6)	TEL: HyperK: 10/443 (2.2)	VAL: HyperK: 12/429 (2.9)	TEL: "Renal & urinary disorders": 18/443 (4.0)	VAL: "Renal & urinary disorders": 17/442 (3.8)
Burgess, 2009 ⁵¹	C64: 6/90 (6.7); C128: 14/89 (15.7);	C16: 18/90 (20.0)	†NR	†NR	C64: 5/90 (5.5); C128: 8/89 (9.0)	C16: 11/90 (12.2)			C64: HyperK: 4/90 (4.4); C128: HyperK: 3/89 (3.3)	C16: HyperK: 4/90 (4.4)	Withdrawn for high SCr: C64: 0/90 C128: 2/89; Withdrawn for ARF: C64: 0/90 C128: 0/89	‡Withdrawn for high SCr: C16: 1/90 Withdrawn for ARF: C16: 1/90

ARB = angiotensin receptor blocker; TEL = telmisartan; LOS = losartan; VAL = valsartan; C16 = Candesartan 16mg/day; C64 = candesartan 64mg/day; C128 = candesartan 128mg/day; ARF = acute renal failure; SCr = serum creatinine; HyperK = hyperkalemia

*Study reported that 1.8% of entire cohort had hyperkalemia, but didn't report results by treatment group.

†Study reported that 24 patients (8.9%) had one or more serious adverse event but didn't report this result by treatment group.

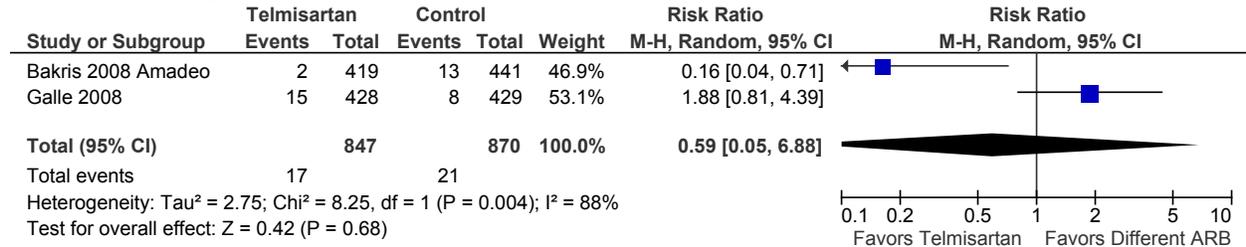
‡Study also reported that 1/90 patients in C16 treatment group was withdrawn after developing crescentic glomerulonephritis superimposed on pre-existing IgA nephropathy.

Appendix Table C47. Summary of study baseline characteristics for ARB versus ARB studies

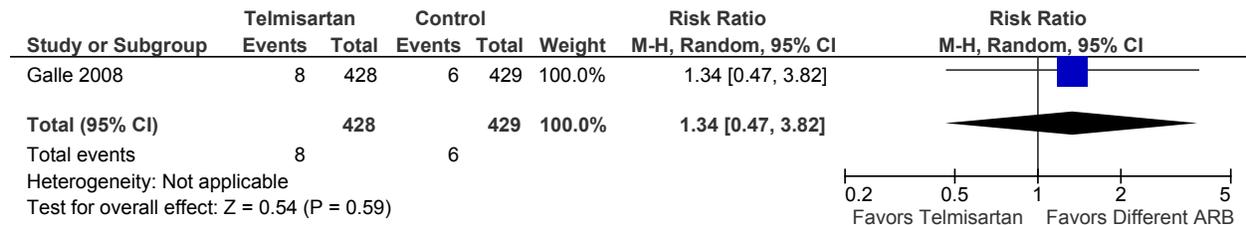
Characteristic	Mean (range unless otherwise noted)	Number of Trials Reporting
ARB versus Different ARB (n=2)		
Total number of patients evaluated	1745 (860-885)	2
Age of subjects, years	60.8 (60.3-61.2)	2
Gender, male, %	63.2 (62.2-64.1)	2
Race/ethnicity, white, %	63.2 (47-79)	2
Race/ethnicity, black, %	6.9 (2-12)	2
Body Mass Index, kg/m ²	30.1 (30.0-30.2)	2
SBP, mmHg	145.8 (143.4-148.1)	2
DBP, mmHg	80.9 (79.7-82.0)	2
Proteinuria, g/day	2.78	1
Albuminuria, mg/day or µg/min	NR	0
Serum creatinine, mg/dL	1.55	1
Creatinine clearance, ml/min/1.73m ²	NR	0
Estimated GFR, ml/min/1.73m ²	53.2 (49.6 to 56.6)	2
History of diabetes mellitus, %	100 (both 100)	2
HbA _{1c} , %	7.85 (7.8 to 7.9)	2
History of hypertension, %	100 (both 100)	2
Coronary artery disease, %	0	1
Congestive heart failure, %	0 (both 0)	2
Myocardial infarction, %	0	1
Stroke, %	0	1
Current smoker, %	16.9 (15.6 to 18.2)	2

Appendix Figure C10. Forest plots for ARB versus ARB trials

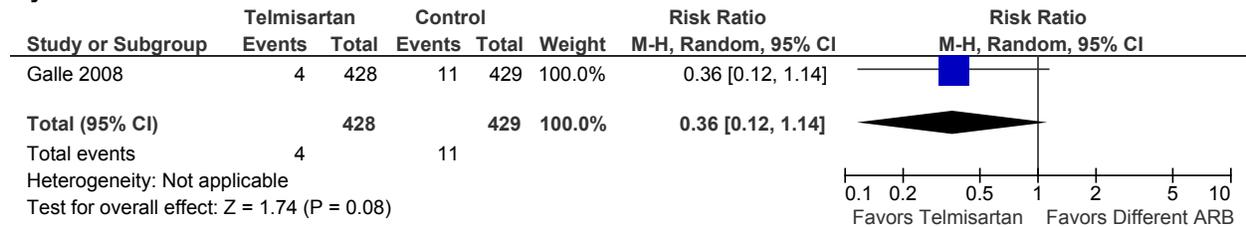
All cause mortality



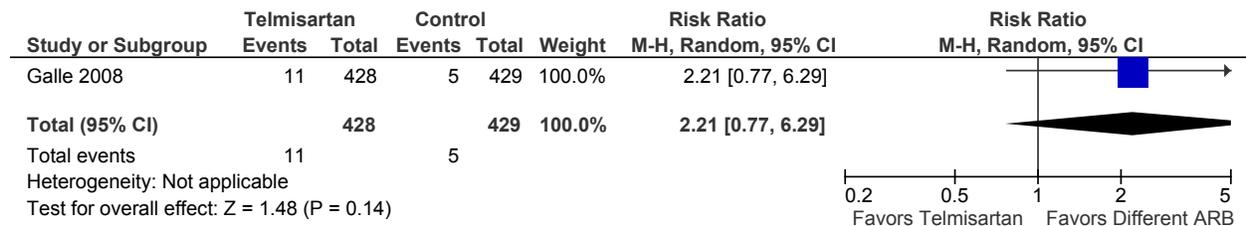
Cardiovascular death



Myocardial infarction

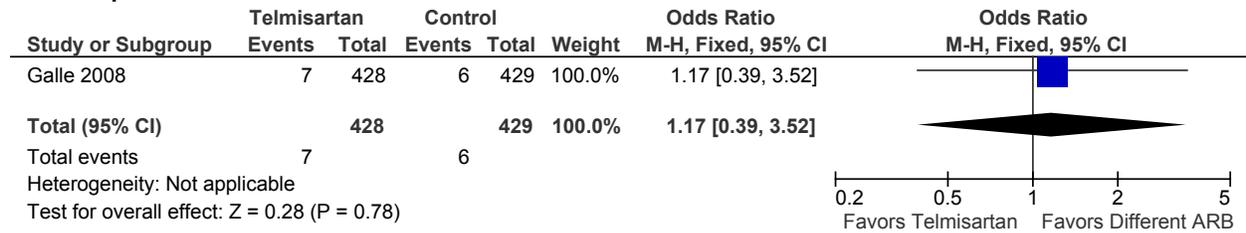


Stroke

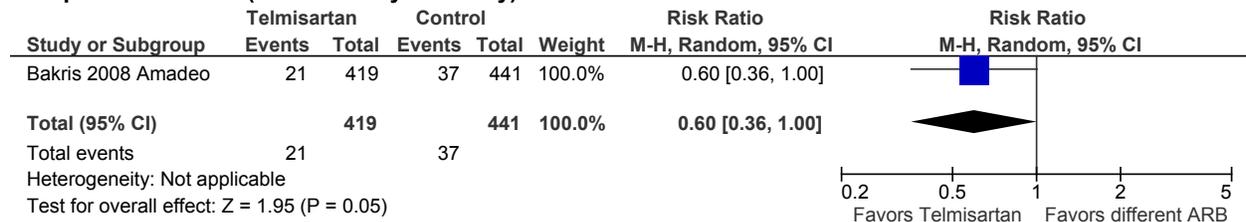


Appendix Figure C10. Forest plots for ARB versus ARB trials (continued)

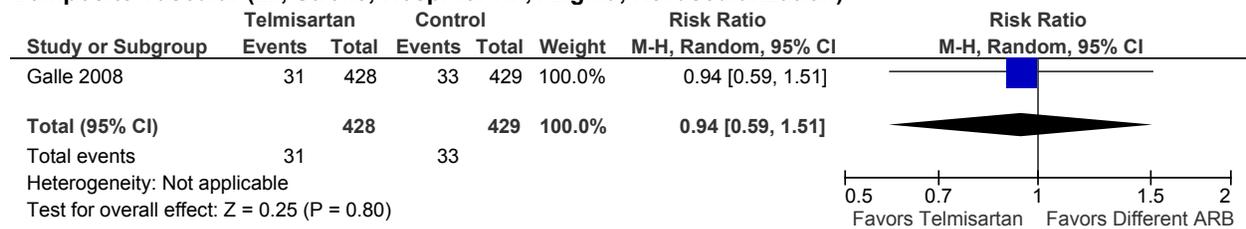
CHF Hospitalization



Composite Vascular (CV morbidity/mortality)



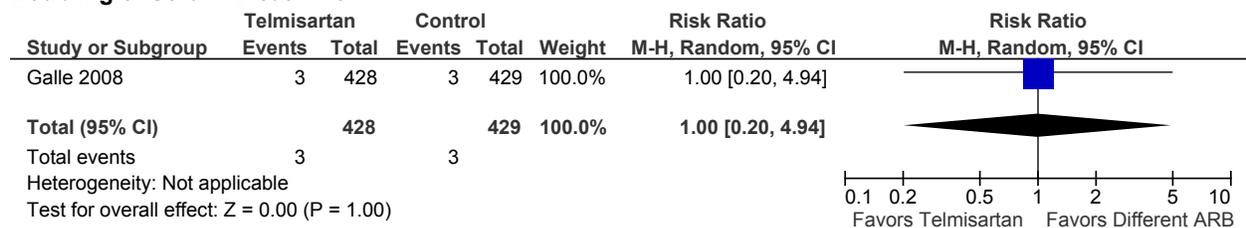
Composite Vascular (MI, Stroke, Hosp. for HF, Angina, Revascularization)



End-stage Renal Disease

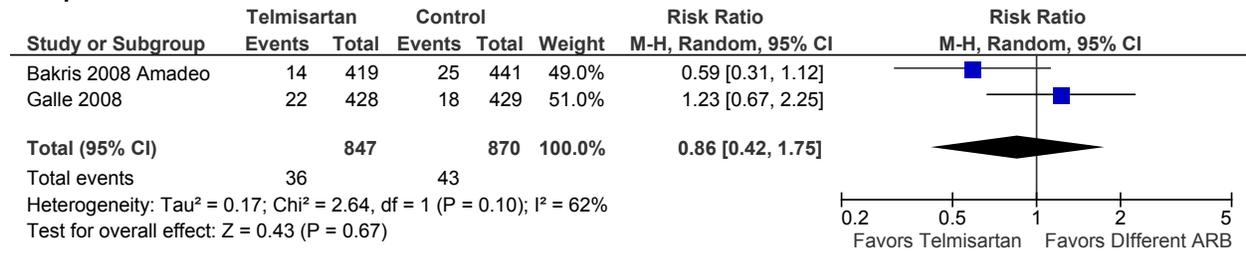


Doubling of Serum Creatinine



Appendix Figure C10. Forest plots for ARB versus ARB trials (continued)

Composite Renal Outcome



Appendix Table C48. Composite vascular outcome definitions, ARB versus ARB trials

Study	Definition
Bakris, 2008 ⁴⁷	Cardiovascular morbidity (not defined) or mortality
Galle, 2008 ⁵⁰	Myocardial infarction, stroke, or hospitalization for heart failure or unstable angina, coronary or peripheral revascularization

ARB = angiotensin receptor blocker; ACE = angiotensin converting enzyme; MI = myocardial infarction; CAD = coronary artery disease

Appendix Table C49. Composite renal outcome definitions, ARB versus ARB trials

Study	Definition
Bakris, 2008 ⁴⁷	Doubling of serum creatinine concentration, end-stage renal disease (need for long-term dialysis, renal transplantation, or serum creatinine ≥ 6 mg/dl), or death.
Galle, 2008 ⁵⁰	Doubling of serum creatinine, end-stage renal disease (need for long-term dialysis, renal transplantation, or serum creatinine ≥ 6 mg/dl), and all-cause death

ARB = angiotensin receptor blocker

Appendix Evidence Table C50. Overview of ACEI plus aldosterone antagonist versus ACEI trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Mehdi, 2009 ⁴⁵ Location United States, Single-site Funding Source Government	<p>Inclusion Criteria: Age 20 to 65; type 1 or 2 DM; seated systolic BP >130mmHg; proteinuria (24-h UACR≥300 mg/g despite treatment with ACEI or ARB for at least 3 months*</p> <p>Exclusion Criteria: BMI>45kg/m²; serum creatinine >3.0mg/dl (females) or >4.0 mg/dl (males); known nondiabetic kidney disease; serum potassium >5.5 mEq/L; hemoglobin A1c >11%; stroke or myocardial infarction within preceding 12 months; heart failure; known adverse reaction to losartan or spironolactone; anticipated need for dialysis within 12 months</p> <p>*Effort was made to recruit younger patients with type 2 DM as recommended by study sponsor</p>	<p>N=54 Age (yr): 50.5 Gender (Male %): 46.3 Race/Ethnicity (%): 31.5% black, 53.7% Hispanic, 11.1% non-Hispanic white, 3.7% Native American Weight: NR BMI: 33 Systolic BP (mm Hg): 132 Diastolic BP (mm Hg): 73.5 CKD stage: NR Serum creatinine (mg/dL): 1.6 Creatinine clearance (mL/min): 62.2 Albuminuria: NR Urine albumin/creatinine ratio (mg/g): 1005.5 Estimated GFR (ml/min/1.73m²): NR HbA_{1c} (%): 7.8 Total cholesterol: 182.5 LDL cholesterol: 85 Diabetes (%): 100 History of HTN (%): 100 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): 0 Peripheral arterial disease (%): NR History of MI (%): NR History of MI/CABG/PTCA(%): 9.3 History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR</p>	<p>n= 27 to Spironolactone 12.5 mg/day for 1 week then 25mg/day† n= 27 to placebo †All patients were taking Lisinopril 80 mg/day at baseline and throughout treatment Followup period: 11.1 months Study withdrawals (%): 29.6</p>	<p>Allocation Concealment: Unclear Blinding: Double blinded Intention to Treat Analysis (ITT): No While the overall study analysis was not by intention-to-treat, this pertains to exclusion from analyses of a single subject randomized into the ACE plus ARB treatment group that is not the focus of this section of the report. Withdrawals/ Dropouts adequately described: No</p>

Appendix Table C51. Clinical outcomes (outcomes part A), ACEI plus aldosterone antagonist versus ACEI plus placebo trial

Study	All-Cause Mortality, n/N (%)		Cardiovascular Death, n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any, n/N (%)	
	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo
Mehdi, 2009 ⁴⁵	0/27	0/27	0/27	0/27	1/27 (3.7)	0/27	0/27	0/27	1/27 (3.7)	0/27	2/27 (7.4)	1/27 (3.7)

ACEI = angiotensin converting enzyme; Aldo Antag = aldosterone antagonist

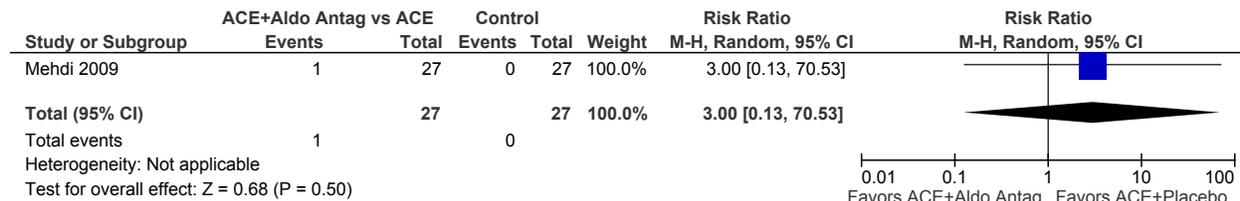
Appendix Table C52. Clinical outcomes, part B, ACEI plus aldosterone antagonist versus ACEI plus placebo trial

Study	Stroke, Nonfatal, n/N (%)		Stroke, Fatal, n/N (%)		CHF, Any, n/N (%)		CHF Hospitalization (A) or Death (B), n/N (%)		Composite Vascular Outcome, n/N (%)	
	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo
Mehdi, 2009 ⁴⁵	2/27 (7.4)	1/27 (3.7)					(A)2/27 (7.4)	(A)0/27		

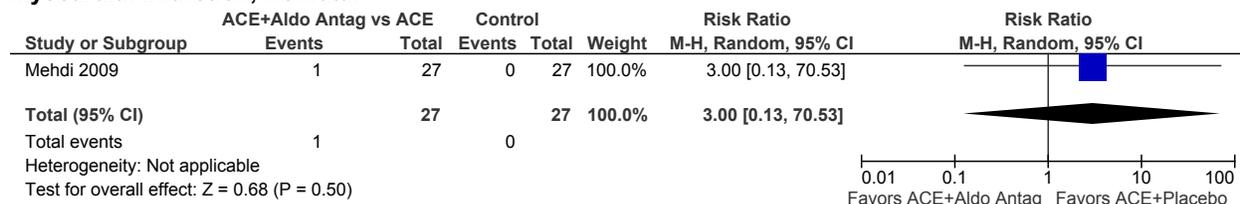
ACEI = angiotensin converting enzyme inhibitor; CHF = congestive heart failure; Aldo Antog = aldosterone antagonist

Appendix Figure C11. Forest plots for ACEI plus Aldosterone Antagonist versus ACEI plus placebo trial

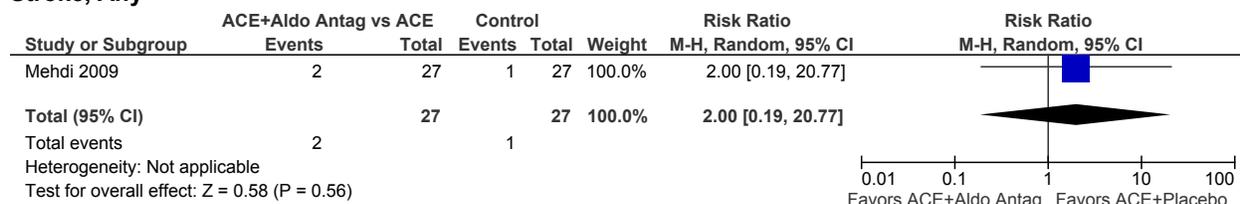
Myocardial Infarction, Any



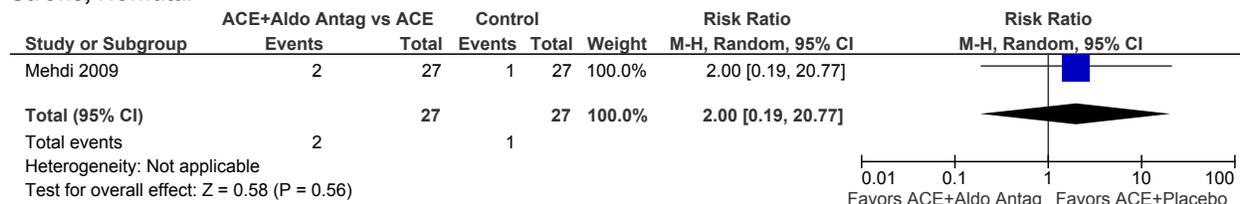
Myocardial Infarction, Nonfatal



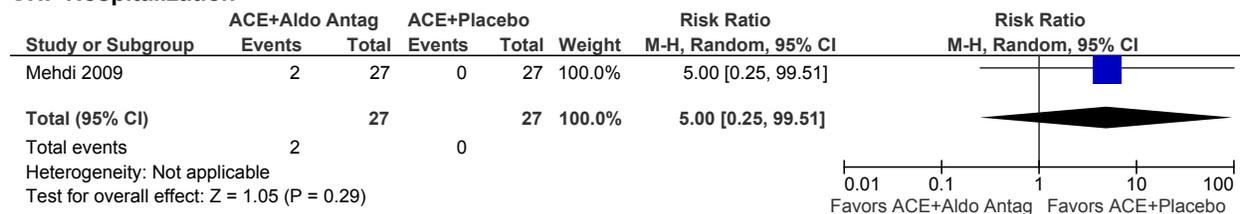
Stroke, Any



Stroke, Nonfatal



CHF Hospitalization



Appendix Table C53. Study withdrawals and adverse events (outcomes part D), ACEI plus aldosterone antagonist versus. ACEI plus placebo trials

Study	Any Study Withdrawals, n/N (%)		Withdrawals Due to Serious Adverse Event, n/N (%)		Serious Adverse Event: Any, n/N (%)		Adverse Event: Any, n/N (%)		Adverse Event, Specific, n/N (%)		Renal Adverse Event, n/N (%)	
	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo	ACEi + Aldo Antag	ACEI + Placebo	ACEI + Aldo Antag	ACEI + Placebo
Mehdi, 2009 ⁴⁵	10/27 (37.0)	6/27 (22.2)	*NR	*NR					HyperK: 2/27 (7.4)	HyperK: 0/27		

ACEI = angiotensin converting enzyme inhibitor; HyperK = hyperkalemia; Aldo Antag = aldosterone antagonist

*Study reported withdrawals due to adverse events, but not specifically due to serious adverse events: ACEI + Aldo Antag (2 hyperkalemia, 2 stroke, 1 hypotension, 1 increased serum creatinine, 1 gynecomastia) and ACEI + placebo (1 stroke, 1 increased serum creatinine).

Appendix Evidence Table C54. Overview of ACE/ARB plus aldosterone antagonist versus ACE/ARB plus placebo trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
van den Meiracker, 2006 ⁵² Location Netherlands, multiple clinic sites Funding Source None reported	<p>Inclusion Criteria: Patients with type 2 diabetes and macroalbuminuria (24-hour urinary albumin excretion >300 mg or urinary albumin to creatinine ratio >20 mg/mmol) despite use of an ACEI inhibitor or ARB in recommended dosages for at least 1 year; ages 20 to 80 years</p> <p>Exclusion Criteria: Serum creatinine >265 µmol/l (i.e. >3.0 mg/dl); serum potassium >5.0 mmol/l; renal disease other than diabetic nephropathy; underlying malignant, hepatic, or gastrointestinal disease; myocardial infarction or stroke within the past 3 months; unstable angina pectoris; alcohol or drug abuse; psychological illness</p>	<p>N=59 Age (yr): 52.2 Gender (Male %): 66 Race/Ethnicity (%): NR Weight (kg): NR BMI: 31.0 Systolic BP (mm Hg): 147.6 Diastolic BP (mm Hg): 80.7 CKD stage: NR Serum creatinine (µmol/l): 98.2 (=1.11 mg/dl) Creatinine clearance (mL/min): NR Albuminuria (µg/min): NR Proteinuria (g/day): NR Urine Albumin/creatinine ratio (mg/mmol): 81.0 Urine Protein/creatinine ratio (mg/mmol): 128.5 estimated GFR (ml/min/1.73m²): 70.5 (MDRD formula) HbA_{1c} (%): 8.1 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): NR Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR</p>	<p>n=29 Spironolactone 50 mg/day*</p> <p>n=30 Placebo, matched tablets*</p> <p>Study medication added to antihypertensive medication already used by patients (71% of spironolactone group and 86% of placebo group taking an ACE inhibitor, with remainder taking an ARB)</p> <p>*Medication halved if potassium >5.5 mmol/l when checked 2 weeks after start; patients withdrawn if potassium >5.5 mmol/l after 2 weeks on half dose</p> <p>Antihypertensive medications kept constant throughout study</p> <p>Followup period: 1 year</p> <p>Study withdrawals (%): 11.9</p>	<p>Allocation Concealment: Adequate</p> <p>Blinding: Double</p> <p>Intention to Treat Analysis (ITT): No</p> <p>Withdrawals/Dropouts adequately described: Yes</p>

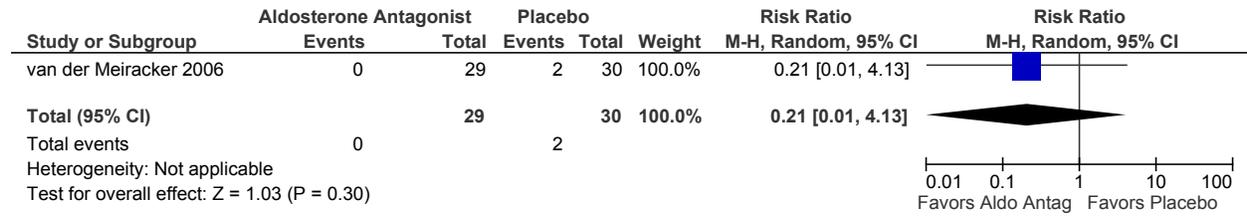
Appendix Table C55. Clinical outcomes (outcomes part A), ACEI/ARB plus aldosterone antagonist versus ACEI/ARB plus placebo trial

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial infarction, Nonfatal, n/N (%)		Stroke, Any n/N (%)	
	ACEI/AR B+ AA	ACEI/ ARB + PBO	ACEI/AR B + AA	ACEI/ ARB + PBO	ACEI/ARB + AA	ACEI/A RB + PBO	ACEI/ARB + AA	ACEI/A RB + PBO	ACEI/ARB + AA	ACEI/A RB + PBO	ACEI/ARB + AA	ACEI/A RB + PBO
van der Meiracker, 2006 ⁵²	0/29	2/30 (6.7%)					0/29	2/30 (6.7%)				

ACEI/ARB = angiotensin converting enzyme inhibitor or angiotensin receptor blocker; AA = aldosterone antagonist; PBO = placebo

Appendix Figure C12. Forest plot for ACEI/ARB plus aldosterone antagonist versus ACEI/ARB plus placebo trial

All-cause Mortality



Appendix Table C56. Study withdrawals and adverse events (outcomes part D), ACEI/ARB plus aldosterone antagonist versus ACEI/ARB plus placebo trial

Study	Study Withdrawals: Any, n/N (%)		Serious Adverse Event: Any, n/N (%)		Study Withdrawals Due to Serious Adverse Event: Any, n/N (%)		Adverse Event: Any, n/N (%)		Adverse Event: Specific, n/N (%)		Renal Adverse Events, n/N (%)	
	ACEI/ARB + AA	ACEI/ARB + PBO	ACEI/ARB + AA	ACEI/ARB + PBO	ACEI/ARB + AA	ACEI/ARB + PBO	ACEI/ARB + AA	ACEI/ARB + PBO	ACEI/ARB + AA	ACEI/ARB + PBO	ACEI/ARB + AA	ACEI/ARB + PBO
van der Meiracker, 2006 ⁵²	5/29 (17.2)	2/30 (6.7)							HyperK: 5/29 (17.2)	HyperK: 1/30 (3.3)		

ACEI/ARB = angiotensin converting enzyme inhibitor or angiotensin receptor blocker; AA = aldosterone antagonist; PBO = placebo

Appendix Evidence Table C57. Overview of beta blocker versus placebo trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Ghal, 2009 ⁵³ MERIT-HF Country U.S., Sweden Norway, multi- site Funding Source: NA	<p>Inclusion: Eligible patients were men and women, aged 40-80 years, supine resting heart rate ≥ 68/min. who had had symptomatic heart failure (New York Heart Association [NYHA] functional class II-IV) for 3 months or more before randomization and who were receiving optimum standard therapy at enrollment (2 weeks before randomization), defined as any combination of diuretics and an ACEI. If an ACEI was not tolerated, hydralazine, long-acting nitrate, or an angiotensin-II-receptor antagonist could be used. Digitalis could also be prescribed. Other inclusion criteria were a stable clinical condition during the 2-week run-in phase between enrollment and randomization, and a left-ventricular ejection fraction of 0.40 or lower within 3 months before enrollment. Patients with ejection fraction 0.36 to 0.40 included only if their maximum walking distance was 450 m or less in a 6 min walk test.</p> <p>Exclusion: acute myocardial infarction or unstable angina within 28 days before randomisation; indication or contraindication for treatment with B-blockade or drugs with B-blocking properties such as amiodarone; B-blockade within 6</p>	<p>n=1,469 (this is subgroup with GFR ≤ 60 ml/min/1.73m² from larger MERIT study of 3991 patients) Age (yr): 68.1 Gender (Male %): 68.3 Race/Ethnicity (%): NA Weight (kg): NA BMI: 26.8 Systolic BP (mm Hg): 130.3 Diastolic BP (mm Hg): 76.7 CKD stage: NA Serum creatinine (umol/L): 134.1 (=1.52 mg/dL) Creatinine clearance (mL/min): NA Albuminuria (μg/min): NA Proteinuria (mg/day): NA Albumin/creatinine ratio (mg/g): NA GFR (ml/min/1.73m²): 47.7 HbA_{1c} (%): NA Total cholesterol (mg/dL): NA LDL cholesterol (mg/dL): NA Diabetes (%): 29.3 History of HTN (%): 49.0 Dyslipidemia (%): NA History of CAD (%): NA History of CHF (%): 100 Peripheral arterial disease (%): NA History of MI (%): 55.3 History of Stroke (%): NA Current smoker (%): 9.7 History of AKI (%): NA</p>	<p>n= 735 Metoprolol CR/XL, 12.5 mg daily for NYHA III-IV pts and 25.0 mg daily for NYHA II pts, to a targeted 200 mg daily over 8 weeks</p> <p>n=734 Placebo</p> <p>Followup period: 1 year</p> <p>Study withdrawals (%): Not reported for CKD subgroup</p>	<p>Allocation Concealment: adequate</p> <p>Blinding: double blind</p> <p>Intention to Treat Analysis (ITT): yes</p> <p>Withdrawals/Dropouts adequately described: Unclear</p>

Appendix Evidence Table C57. Overview of beta blocker versus placebo trial (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	<p>weeks before enrolment; heart failure secondary to systemic disease or alcohol abuse; scheduled or performed heart transplantation or cardiomyoplasty, or implanted cardioversion defibrillator (expected or performed), or procedures such as coronary-artery bypass grafting or percutaneous transluminal coronary angioplasty planned or performed in the past 4 months; atrioventricular block of the second and third degree, unless the patient had an implanted pacemaker and a spontaneous heart rate of 68 beats per min or more; unstable decompensated heart failure (pulmonary oedema, hypoperfusion) or supine systolic blood pressure lower than 100 mm Hg at enrolment; any other serious disease that might complicate management and followup according to the protocol; use of calcium antagonists such as diltiazem or verapamil; use of amiodarone within 6 months before enrolment; or poor compliance, defined as more than a 25% deviation of the number of observed compared with number of expected consumed placebo tablets during the run-in period.</p>			

C-130

Appendix Table C58. Clinical outcomes (outcomes part A), beta blocker versus placebo trial

Study	All-Cause Mortality, n/N (%)		Cardiovascular Death, n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any, n/N (%)	
	BB	Placebo	BB	Placebo	BB	Placebo	BB	Placebo	BB	Placebo	BB	Placebo
Ghali, 2009 ⁵³	63/735 (8.6)	105/734 (14.3)										

BB = beta blocker

Appendix Table C59. Clinical outcomes (outcomes part B), beta blocker versus placebo trial

Study	Stroke, Nonfatal, n/N (%)		Stroke, Fatal, n/N (%)		CHF, Any, n/N (%)		CHF Hospitalization (A) or Death (B), n/N (%)		Composite Vascular Outcome, n/N (%)	
	BB	Placebo	BB	Placebo	BB	Placebo	BB	Placebo	BB	Placebo
Ghali, 2009 ⁵³							(A)90/735 (12.2); (B)15/735 (2.0)	(A)147/734 (20.0); (B)36/734 (4.9)	(A)136/735 (18.5); (B)64/735 (8.7)	(A)214/734 (29.2); (B)107/734 (14.6)

CHF = congestive heart failure; BB = beta blocker

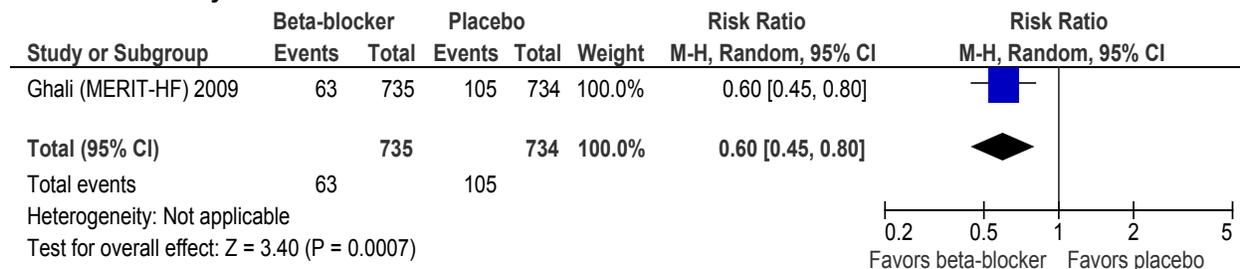
Appendix Table C60. Composite vascular outcome definitions, beta blocker versus placebo trial

Study	Definition
Ghali, 2009 ⁵³	Study defined multiple composite vascular outcomes, including: (A) all-cause mortality and CHF hospitalization; and (B) cardiac death and nonfatal MI.

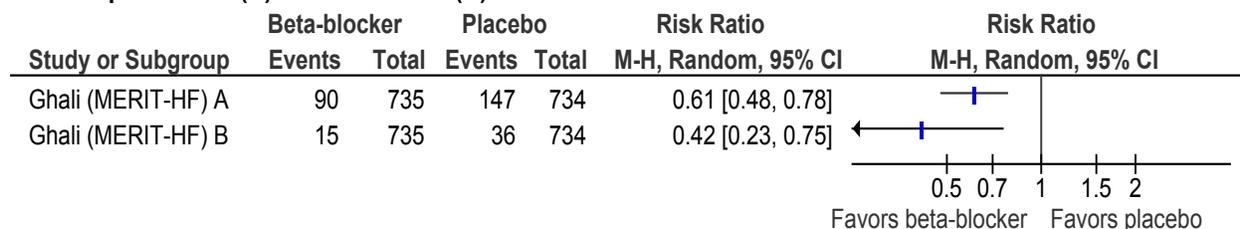
BB = beta blocker; CHF = congestive heart failure; MI = myocardial infarction

Appendix Figure C13. Forest plots for beta blocker versus placebo trial

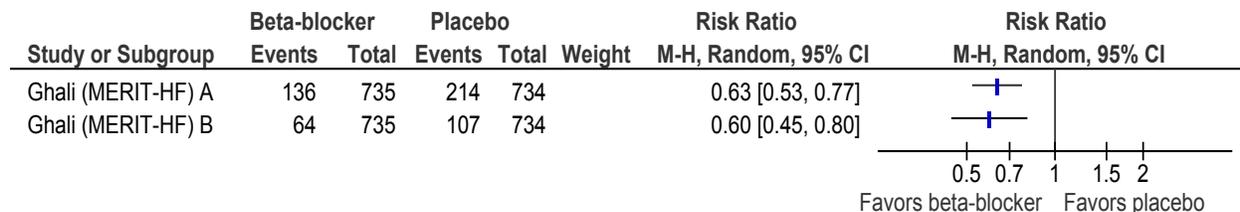
All-cause mortality



CHF hospitalization (A) and CHF death (B)



Composite vascular outcome



Appendix Table C61. Study withdrawals and adverse events (outcomes part D), beta blocker versus placebo trial

Study	Study Withdrawals: Any		Serious Adverse Event: Any		Serious Adverse Event: Any Leading to Withdrawal		Adverse Event: Any		Adverse Event: Other Specific		Renal Adverse Events: Any	
	BB	Placebo	BB	Placebo	BB	Placebo	BB	Placebo	BB	Placebo	BB	Placebo
Ghali, 2009 ⁵³							NR*	NR*				

BB = beta blocker; NR = not reported

*Study reported rates of discontinuation of study medication due to adverse events per 100 person years but did not report data on the number of patients with any withdrawal or adverse event endpoint by treatment group. The most commonly reported adverse events leading to discontinuation of study medication were cardiac failure, fatigue, bradycardia, dizziness, and hypotension, with no data reported by treatment group.

Appendix Evidence Table C62. Overview of CCB versus placebo trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Berl, 2003 ⁵⁴ Lewis, 2001 ³⁹ IDNT International (North America, Latin America, Europe, United Kingdom, Israel, Australia, New Zealand, Southeast Asia) Multi-site Funding Source: Industry	Inclusion: ages 30-70; documented diagnosis of type 2 DM; hypertension (sitting SBP >135 mm Hg, sitting DBP >85 mm Hg, or documented treatment with antihypertensive agents); proteinuria (urinary protein excretion >900 mg/24h); serum creatinine between 1.0 and 3.0 mg/dL (women) and 1.2-3.0 mg/dL (men) Exclusion: none stated	N=1,136 Age (yr): 58.7 Gender (Male %): 67 Race/Ethnicity (%): 71.0% white, 14.5% African American, 5.0% Hispanic, 5.5% Asian/Pacific Islander, 4.5% other Weight (kg): NR BMI: 30.7 Systolic BP (mm Hg): 158.5 Diastolic BP (mm Hg): 87.0 CKD stage: NR Serum creatinine (mg/dL): 1.7 Creatinine clearance (mL/min): NR Albuminuria (g/day): 1.9 Proteinuria (g/day): 2.9 Albumin/creatinine ratio (mg/g): NR GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 8.2 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 100 Dyslipidemia (%): NR History of cardiovascular disease (%): 29.5 History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR	n= 567 amlodipine (titrated from 2.5 to 10 mg/day)* n= 569 placebo* Followup period: 2.5 years (mean) Study withdrawals (%): 0.5 *Antihypertensives other than ACEIs, ARBs, and CCBs used as needed; target blood pressure was SBP ≤135 mm Hg (or 10 mm Hg lower than screening value if that value was >145 mmHg) and DBP ≤85 mm Hg	Allocation Concealment: Adequate Blinding: Double blind Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes
Crepaldi, 1998 ¹⁰ Italy Multi-site Funding Source: None reported	Inclusion: ages 18 to 65 years; onset of insulin-dependent diabetes mellitus before age 35; insulin treatment within 3 years of diagnosis; clinical stability (HbA _{1c} <11% at entry and within 30% of value at entry during past 12 months; standing SBP from 115 to 140 mm Hg	N= 90 (baseline data reported for 60 patients who were not excluded during run-in phase) Age (yr): 36.6 Gender (Male %): 70 Race/Ethnicity (%): NR Weight (kg): 67.4	n= 41 10 mg nifedipine* n= 49 placebo* Followup period: 3 years Study withdrawals (%):	Allocation Concealment: Unclear Blinding: Double blind Intention to Treat Analysis (ITT): No

Appendix Evidence Table C62. Overview of CCB versus placebo trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	<p>(without antihypertensives) and DBP from 75 to 90 mmHg at entry; median albumin excretion rate between 20 and 200 µg/min from 3 timed overnight urine collections within 2 weeks of entry; GFR ≥80 ml/min/1.73m² at randomization</p> <p>Exclusion: impaired renal function; serum creatinine >10% above upper limit of normal laboratory range (125 µmol/l) and median (from 3 measures) albumin excretion rate >200 µg/min at entry (after randomization); history of any nondiabetic renal disease; hematuria; evidence of clinically significant liver or hematological disease; evidence of aortic or mitral valve obstruction, arrhythmias, unstable angina, or history of myocardial infarction within the previous 3 months; clinical evidence of autonomic neuropathy; systematic malignancy; hyperkalemia (serum potassium >5.5 mmol/l at pretrial screen or entry; serum triglycerides >3.4 mmol/l or total cholesterol >6.5 mmol/l at routine pretrial check; known familial lipid disorders; known risk of transmitting AIDS or viral hepatitis; known hypersensitivity or contraindications to ACEIs, nifedipine, or atenolol; women of child-bearing age not using medically acceptable methods of birth control (oral contraceptives were not allowed) or those planning pregnancy during the treatment period; treatment compliance over the 4 wk placebo run in of <85%; on antihypertensive treatment</p>	<p>BMI: NR Systolic BP (mm Hg): NR Diastolic BP (mm Hg): NR CKD stage: NR Albumin (g/dl): 4.4 Serum creatinine (µmol/L): 85.8 (=0.97 mg/dL) Creatinine clearance (mL/min): 107.8 Albuminuria (µg/min): 80.2 Albumin/Creatinine ratio (mg/mmol): NR GFR (ml/min/1.73m²): 111.8 HbA_{1c} (%): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 0 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): 58.3 History of AKI (%): NR</p>	<p>32.2</p> <p>*If BP not controlled at 1 month after randomization (reduction of SBP and DBP by <5% of baseline), dose was doubled; if BP not controlled at 3 months (reduction of SBP and DBP by <5% of baseline and standing BP >140/90 mm HG) 50 mg/day atenolol added; if BP not controlled (standing BP >140/90 mm Hg) atenolol doubled; if BP still not adequately controlled (standing BP > 160/90 mmHg) patient withdrawn</p>	<p>Withdrawals/Dropouts adequately described: Yes</p>

CCB = calcium channel blocker; SBP = systolic blood pressure; DBP = diastolic blood pressure; NR = not reported

Appendix Table C63. Summary of study baseline characteristics, CCB versus placebo trials

Characteristic	Mean (range unless otherwise noted)	Number of Trials Reporting
Patients randomized, n	1226 (90-1,136)	2
Age of subjects, years	57.6 (36.6-58.7)	2
Gender, male, %	67.2 (67-70)	2
Race/ethnicity, white, %	71	1
Race/ethnicity, black, %	14.5	1
Body Mass Index	30.7	1
Weight (kg)	67.4	1
Systolic blood pressure, mmHg	158.5	1
Diastolic blood pressure, mmHg	87.0	1
Albuminuria, g/day	1.9	1
Albuminuria, μ g/min	80.2	1
Proteinuria, g/day	2.9	1
Serum creatinine, mg/dL	1.7 (0.97-1.7)	2
Creatinine clearance, ml/min	107.8	1
GFR, ml/min/1.73m ²	111.8	1
History of diabetes, %	100 (both studies)	2
% HbA _{1c}	8.2	1
History of hypertension (%)	95 (0-100)	2
History of cardiovascular disease, %*	29.5	1
History of CHF, %	NR	0
Current smoker, %	58.3	1

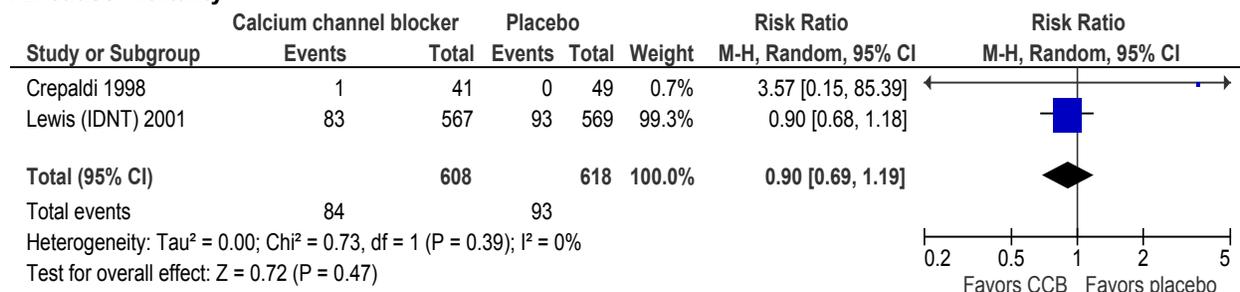
Appendix Table C64. Clinical outcomes (outcomes part A), CCB versus placebo trials

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial infarction, Nonfatal n/N (%)		Stroke, Any n/N (%)	
	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo
Berl, 2003 ⁵⁴	83/567	93/569	37/567	46/569	27/567	46/569					15/567	26/569
Lewis, 2001 ³⁹	(14.6)	(16.3)	(6.5)	(8.1%)	(4.8)	(8.1)					(2.6)	(4.6)
Crepaldi, 1998 ¹⁰	1/41 (2.4)	0/49	1/41 (2.4)	0/49	0/41	1/49 (2.0)						

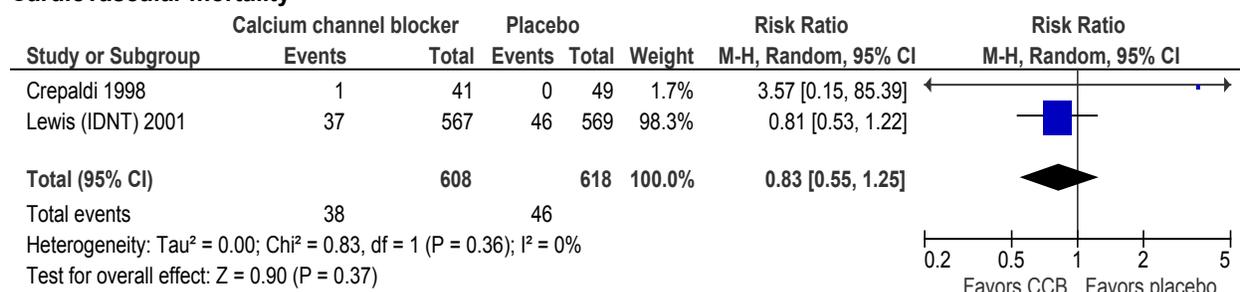
CCB = calcium channel blocker

Appendix Figure C14. Forest plots for CCB vs. versus placebo trials

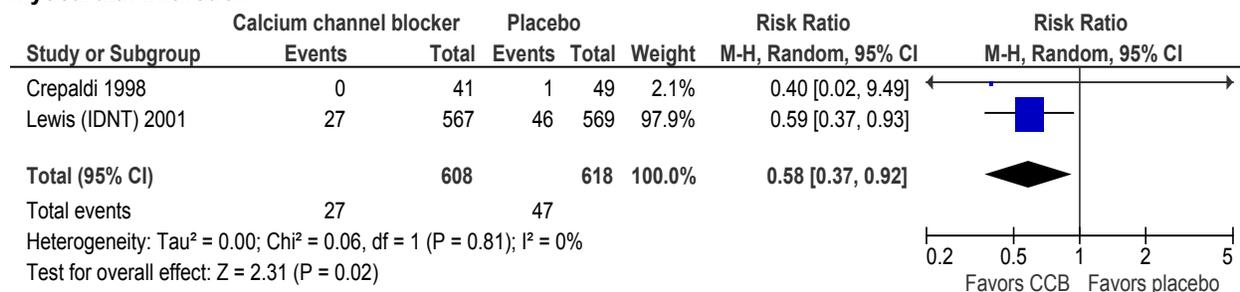
All-cause mortality



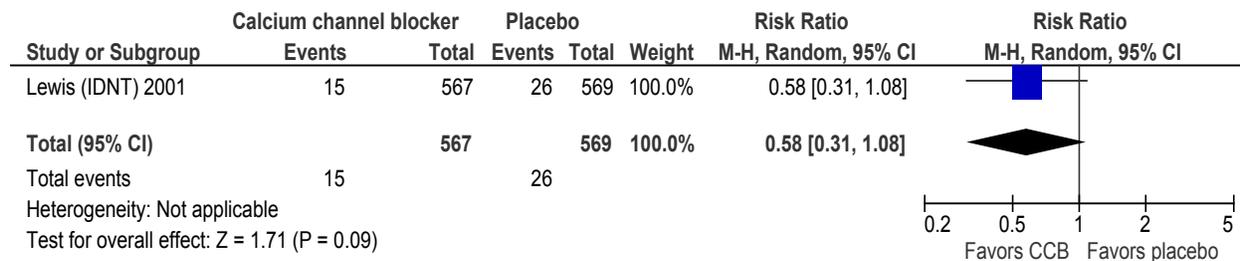
Cardiovascular mortality



Myocardial infarction

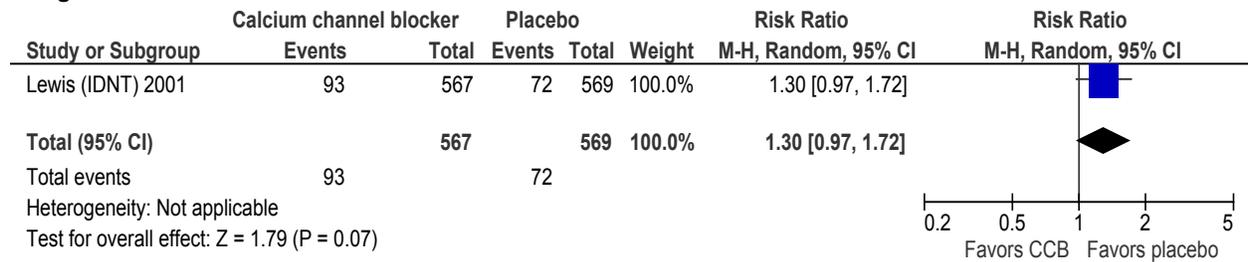


Stroke

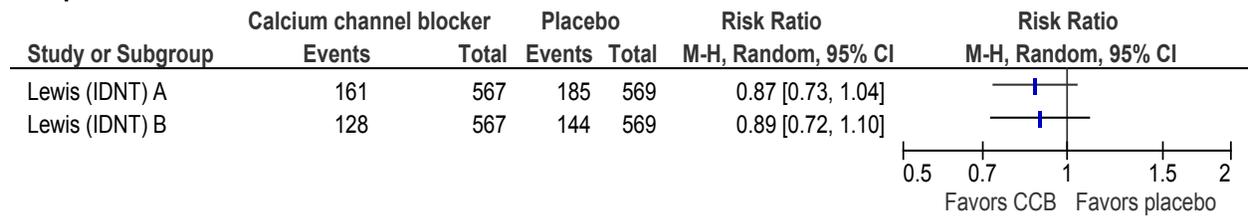


Appendix Figure C14. Forest plots for CCB vs. versus placebo trials (continued)

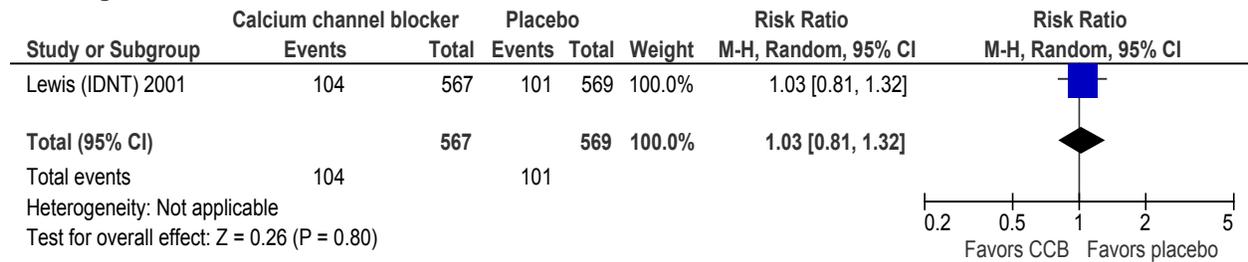
Congestive heart failure



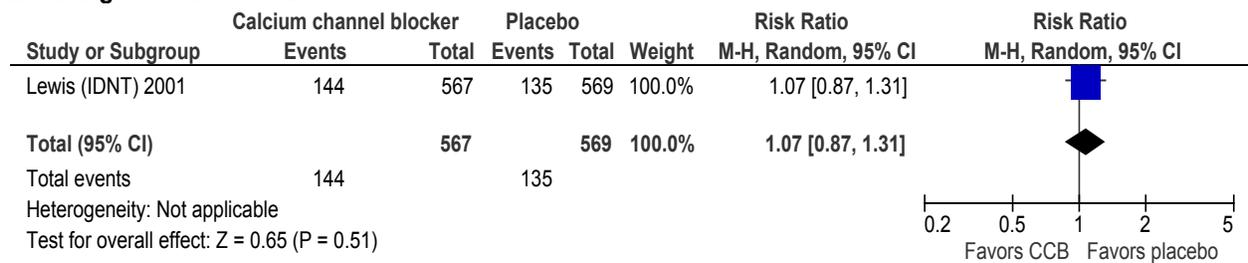
Composite vascular outcome



End-stage renal disease

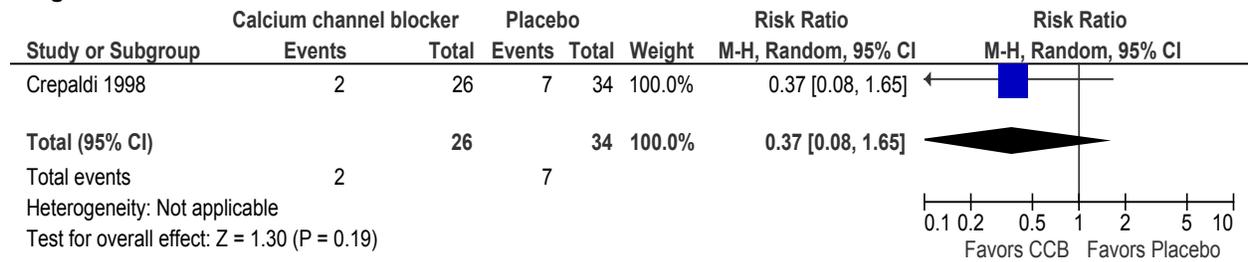


Doubling of serum creatinine

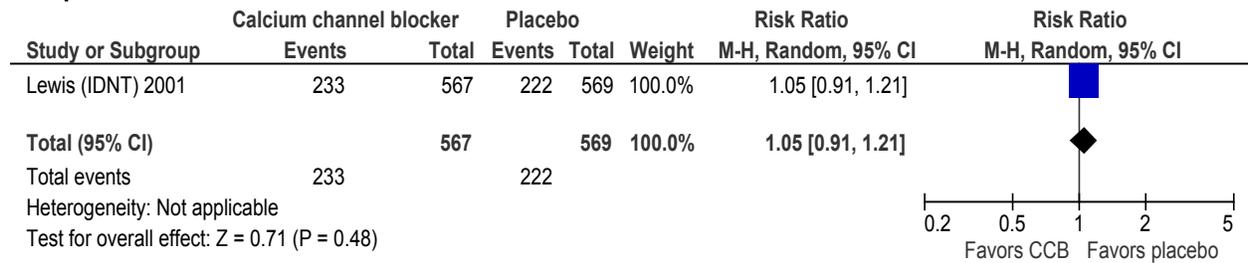


Appendix Figure C14. Forest plots for CCB vs. versus placebo trials (continued)

Progression from microalbuminuria to macroalbuminuria



Composite renal outcome



Appendix Table C65. Clinical outcomes (outcomes part B), CCB versus placebo trials

Study	Stroke, Nonfatal n/N (%)		Stroke, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B) n/N (%)		Composite Vascular Outcome n/N (%)	
	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo
Berl, 2003 ⁵⁴ Lewis, 2001 ³⁹					93/567 (16.4)	72/569 (12.7)			(A)161/567 (28.4)	(A)185/569 (32.5)
									(B)128/567 (22.6)	(B)144/569 (25.3)
Crepaldi, 1998 ¹⁰										

CCB = calcium channel blocker; CHF = congestive heart failure

Appendix Table C66. Composite vascular outcome definitions, CCB versus placebo trials

Study	Definition
Berl, 2003 ⁵⁴ Lewis, 2001 ³⁹	Study defined two composite vascular endpoints as follows: (A) Myocardial infarction, heart failure, permanent neurologic deficit of at least 24-hour duration attributed to stroke, or unplanned (at time of randomization) coronary artery revascularization procedure (all before renal failure, death, or censorship) ⁵⁴ and (B) Death from cardiovascular causes, nonfatal myocardial infarction, heart failure resulting in hospitalization, permanent neurologic deficit caused by a cerebrovascular event, or lower limb amputation above the ankle. ³⁹

CCB = calcium channel blocker

Appendix Table C67. Clinical renal outcomes (outcomes part C), CCB versus placebo trials

Study	End-stage Renal Disease n/N (%)		Doubling of Serum Creatinine n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome n/N (%)	
	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo
Berl, 2003 ⁵⁴	104/567	101/569	144/567	135/569					233/567	222/569
Lewis, 2001 ³⁹	(18.3)	(17.8)	(25.4)	(23.7)					(41.1)	(39.0)
Crepaldi, 1998 ¹⁰							2/26	7/34		
							(7.7)	(20.6)		

CCB = calcium channel blocker; GFR = glomerular filtration rate

Appendix Table C68. Composite renal outcome definitions, CCB vs. placebo trials

Study	Definition
Berl, 2003 ⁵⁴	Doubling of baseline serum creatinine concentration, onset of end-stage renal disease (initiation of dialysis, renal transplantation, or serum creatinine concentration ≥ 6.0 mg/dL), or death from any cause
Lewis, 2001 ³⁹	

CCB = calcium channel blocker

Appendix Table C69. Study withdrawals and adverse events (outcomes part D), CCB versus placebo trials

Study	Study Withdrawals, Any, n/N (%)		Serious Adverse Event: Any, n/N (%)		Serious Adverse Event: Any Leading to Withdrawal, n/N (%)		Adverse Event: Any, n/N (%)		Adverse Event: Any Specific, n/N (%)		Renal Adverse Events: Any, n/N (%)	
	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo	CCB	Placebo
Berl 2003 ⁵⁴	2/567 (0.4)	4/569 (0.7)	*NR	*NR	†NR	†NR	†NR	†NR	HyperK: 3/567 (0.5)	HyperK: 2/569 (0.4)	‡NR	‡NR
Lewis 2001 ³⁹												
Crepaldi 1998 ¹⁰	15/41 (36.6)	15/49 (30.6)					#NR	#NR	#NR	#NR		

CCB = calcium channel blocker; ARB = angiotensin receptor blocker; HyperK = hyperkalemia

*Study reported that 61% of participants had at least one serious adverse event but didn't report results by treatment group (note that study also included an ARB arm).

† Results were not reported for the proportion of study participants with any adverse event, or any serious adverse event leading to withdrawal, either overall or within groups. However, study reported that 51/567 (9.0%) of CCB group and 41/569 (7.2%) of placebo group discontinued treatment due to adverse event.

‡ Study reported one episode of an early increase in serum creatinine concentration suggestive of renal artery stenosis that necessitated stopping the study medication, but did not indicate in which treatment group this adverse event occurred.

During run-in period, three adverse events resulted in withdrawal from placebo group (two lower limb edema, one hyperkalemia); during randomized study, six adverse events resulted in withdrawal from placebo group (one each herpes zoster, lung cancer, flulence, tuberculosis, severe diabetic neuropathy, and myocardial infarction; also reported that 27% of those on CCB and 20% of those on placebo experienced side effects that did not cause withdrawal from study.

Appendix Evidence Table C70. Overview of diuretic versus placebo trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Pahor, 1998 ⁵⁵ Multi-center United States Funding Source: Government	<p>Inclusion: aged 60 and above; BP inclusion criteria were a systolic BP of 160 to 219 mm Hg and a diastolic BP of less than 90 mm Hg assessed as the average of 4 measurements (2 measurements were obtained at each of the 2 baseline visits).</p> <p>Exclusion: a systolic BP of 220 mm Hg or higher, a recent myocardial infarction or stroke, or the presence of a major illness such as cancer, alcoholic liver disease, renal failure, insulin-treated diabetes mellitus, and depression. Participants who were receiving an antihypertensive treatment were considered potentially eligible if they had a systolic BP between 130 and 219 mm Hg and a diastolic BP of less than 85mmHgand were free of major illnesses.</p>	<p>n=393 (subgroup with baseline serum creatinine above normal level [119.4-212.2 μmol/L or 1.35-2.40 mg/dL from overall cohort of 4,336)</p> <p>Baseline characteristics from n=393 with elevated baseline creatinine:</p> <p>Age (yr): 74.0 Gender (Male %): 81.4 Race/Ethnicity (%): White 76.1 Black 19.8 Asian 2.8</p> <p>Weight (kg): NA BMI: 27.2 Systolic BP (mm Hg): 172 Diastolic BP (mm Hg): 77 CKD stage: NA Serum creatinine (umol/L): NR Creatinine clearance (mL/min): NR Albuminuria (μg/min): NR Proteinuria (mg/day): NR Albumin/creatinine ratio (mg/g): NA GFR (ml/min/1.73m²): NA HbA_{1c} (%): NA Total cholesterol (mg/dL): NA LDL cholesterol (mg/dL): NA Diabetes (%): 11.7 History of HTN (%): 100 Dyslipidemia (%): NA History of CAD (%): NA History of CHF (%): NA Peripheral arterial disease (%): NA History of MI (%): 5.4 History of Stroke (%): 3.8 Current smoker (%): NA History of AKI (%): NA</p>	<p>n= 216 Initiated chlorthalidone 12.5mg/day (if goal BP not met, dose may be increased, followed by addition of atenolol, then reserpine)</p> <p>n=177 Placebo</p> <p>Treatment goal was SBP <160 mm Hg or at least 20 mm Hg reduction from baseline.</p> <p>Followup period: 5 years</p> <p>Study withdrawals (%): Not reported for elevated serum creatinine group.</p>	<p>Allocation concealment: adequate</p> <p>Blinding: double blinded (though open-label potassium supplement given to all participants with serum potassium levels <3.5 mmol/L)</p> <p>Intention to Treat Analysis (ITT): yes</p> <p>Withdrawals/Dropouts adequately described: yes (in original RCT)</p>

Appendix Table C71. Clinical outcomes (outcomes part A), diuretic versus placebo trial

Study	All-Cause Mortality, n/N (%)		Cardiovascular Death, n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any, n/N (%)	
	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo
Pahor, 1998 ⁵⁵	37/216 (17.1)	26/177 (14.7)									14/216 (6.5)	22/177 (12.4)

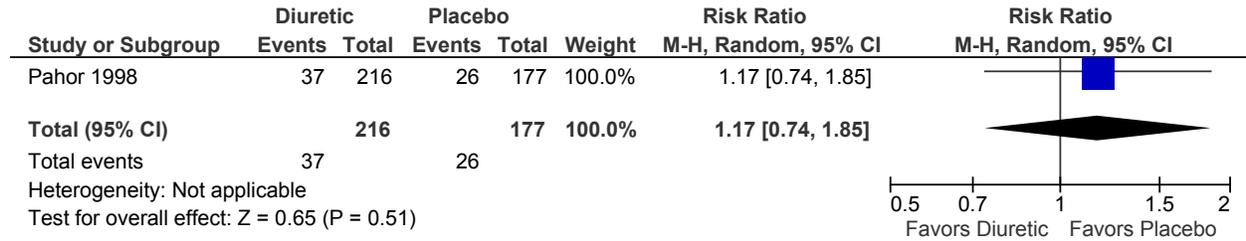
Appendix Table C72. Clinical outcomes (outcomes part B), diuretic versus placebo trial

Study	Stroke, Nonfatal, n/N (%)		Stroke, Fatal, n/N (%)		CHF, Any, n/N (%)		CHF Hospitalization (A) or Death (B), n/N (%)		Composite Vascular Outcome, n/N (%)	
	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo
Pahor, 1998 ⁵⁵									(A)36/216 (16.7) (B)16/216 (7.4)	(A)47/177 (26.6); (B)21/177 (11.9)

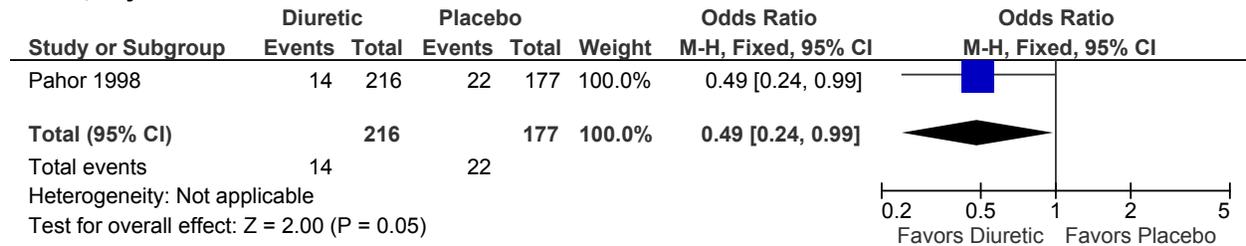
CHF = congestive heart failure

Appendix Figure C15. Forest plots for diuretic versus placebo trial

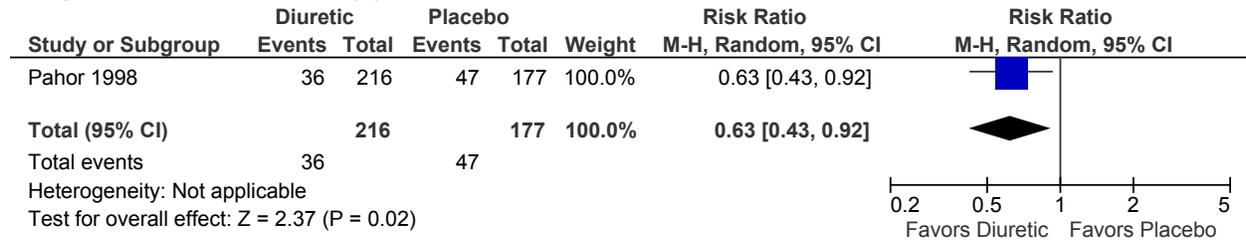
All-cause mortality



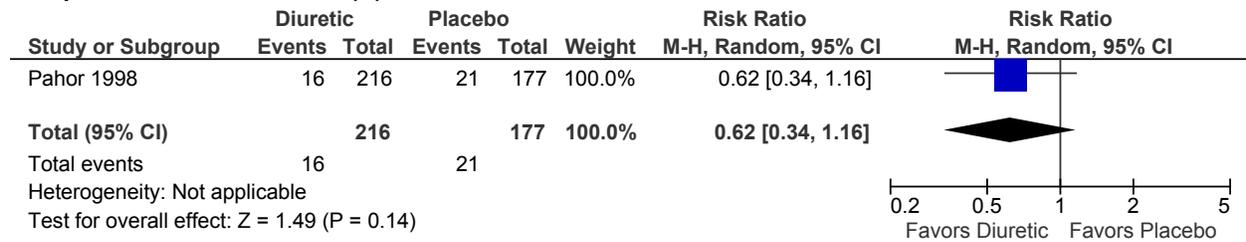
Stroke, any



Composite vascular outcome (A)



Composite vascular outcome (B)



Appendix Table C73. Composite vascular outcome definitions, diuretic versus placebo trial

Study	Definition
Pahor, 1998 ⁵⁵	Study defined multiple composite vascular outcomes, including: (A) "Any cardiovascular event" defined as stroke, TIA, MI, heart failure, CABG, angioplasty, aneurysm, endarterectomy, sudden death, or rapid cardiac death (within 1-24 hours of onset of severe cardiac symptoms unrelated to other known causes); and (B) "Any coronary event" defined as fatal and nonfatal coronary heart disease.

TIA = transient ischemic attack; MI = myocardial infarction; CABG = coronary artery bypass grafting

Appendix Table C74. Study withdrawals and adverse events (outcomes part D), diuretic versus placebo trial

Study	Study Withdrawals: Any		Serious Adverse Event: Any		Serious Adverse Event: Any Leading to Withdrawal		Adverse Event: Any		Adverse Event: Other Specific		Renal Adverse Events: Any	
	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo	Diuretic	Placebo
Pahor, 1998 ⁵⁵												

Study did not report withdrawals or adverse events overall or by treatment group within the strata of participants with CKD (i.e. baseline serum creatinine 119.4 to 212.2 µmol/L [corresponding to 1.35 to 2.40 mg/dL]).

Appendix Evidence Table C75. Overview of ACEI versus conventional therapy without ACEI trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Cinotti, 2001 ³⁴ Country Italy, multisite Funding Source: Industry	<p>Inclusion: ages 18-70 years; chronic renal insufficiency due to primary renoparenchymal diseases; no ACEI therapy for at least 3 months; renal insufficiency of at least 12 months with creatinine clearance between 20 and 50 ml/min/1.73m² with variation <30% in at least 3 determinations during past 3 months; hypertension (either nontreated DBP ≥95 mmHg or well-documented treatment with antihypertensive drugs*); proteinuria ≤1.0 g/day</p> <p>Exclusion: nephropathy secondary to diabetes or other systemic diseases; malignant hypertension or previous antihypertensive treatment with >2 drugs; cerebrovascular events in the last 6 months or MI in the last 3 months; heart failure, angina, or other major cardiac diseases; significant liver, hemopoietic, or endocrine pathology; concomitant therapy with steroids or immunosuppressive drugs and erythropoietin; pregnancy; lactation; serum potassium <3 mEq/l or >5.8 mEq/l; hypersensitivity or any contraindication to use of ACEI</p>	<p>N=131 Age (yr): 50.8 Gender (Male %): 66 Race/Ethnicity (%): NR Weight (kg): 71.4 BMI: NR Systolic BP (mm Hg): 141.6 Diastolic BP (mm Hg): 85.7 CKD stage: NR Serum creatinine (mg/dL): 2.3 Creatinine clearance (mL/min): 36.3 Albuminuria (µg/min): NR Proteinuria (mg/day): 512 Albumin/creatinine ratio (mg/g): NR measured GFR (ml/min/1.73m²): 35.8 HbA_{1c} (%): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 0 History of HTN (%): 100 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): 0 Peripheral arterial disease (%): NR History of MI (%): NR (no recent) History of Stroke (%): NR (no recent) Current smoker (%): NR History of AKI (%): NR</p>	<p>n=66 Lisinopril 5-10 mg/day or Lisinopril 10 mg/day with other antihypertensive drug (L)</p> <p>n=65 Conventional antihypertensive therapy (without ACEI) (C)</p> <p>NSAID use limited to 7 days, ASA allowed at <500 mg/d.</p> <p>Followup period: 22.5 months</p> <p>Study withdrawals (%): No information reported on study withdrawals</p>	<p>Allocation Concealment: Unclear</p> <p>Blinding: Open-label</p> <p>Intention to Treat Analysis (ITT): Yes</p> <p>Withdrawals/Dropouts adequately described: No data reported on withdrawals/dropouts.</p>
	<p>*During 3 month run-in period, patients to follow 0.8 g/kg IBW protein and 3-4 g/day salt diet. Antihypertensive agents (CCB, BB or alpha blocker) continued or added. Patients required to be “compliant” and have stable DBP ≤90 mm Hg with one or two drugs at end of run-in to proceed to randomization.</p>			

Appendix Table C76. Clinical outcomes (outcomes part A), ACEI versus conventional therapy without ACEI trial

Study	All-cause Mortality, n/N (%)		Cardiovascular Death, n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any, n/N (%)	
	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI
Cinotti, 2001 ³⁴					0/66	1/65 (1.5)						

ACEI = angiotensin converting enzyme inhibitor

Appendix Table C77. Clinical renal outcomes (outcomes part C), ACEI versus conventional therapy without ACEI trial

Study	End-Stage Renal Disease, n/N (%)		Doubling of Serum Creatinine, n/N (%)		Halving of GFR, n/N (%)		Progression from Micro- to Macroalbuminuria, n/N (%)		Composite Renal Outcome, n/N (%)	
	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI
Cinotti, 2001 ³⁴	2/66 (3.0)	5/65 (7.7)			3/66 (4.5)	7/65 (10.8)			5/66 (7.8)	12/65 (18.5)

ACEI = angiotensin converting enzyme inhibitor; GFR = glomerular filtration rate

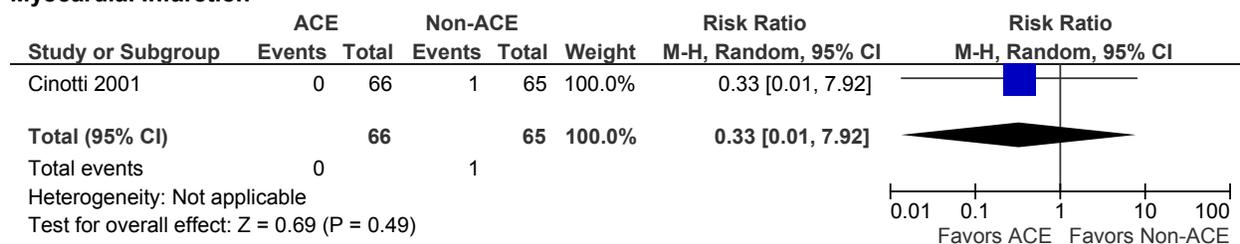
Appendix Table C78. Composite renal outcome definitions, ACEI versus conventional therapy without ACEI trial

Study	Definition
Cinotti, 2001 ³⁴	Halving of GFR or need for dialysis.

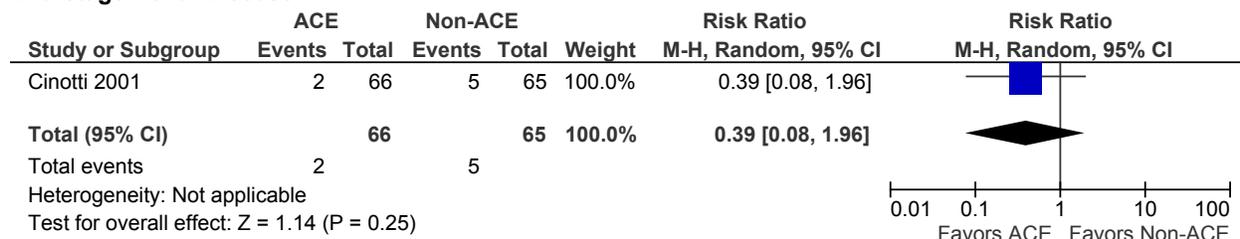
ACEI = angiotensin converting enzyme inhibitor; GFR = glomerular filtration rate

Appendix Figure C16. Forest plots for ACEI versus conventional therapy without ACEI trial

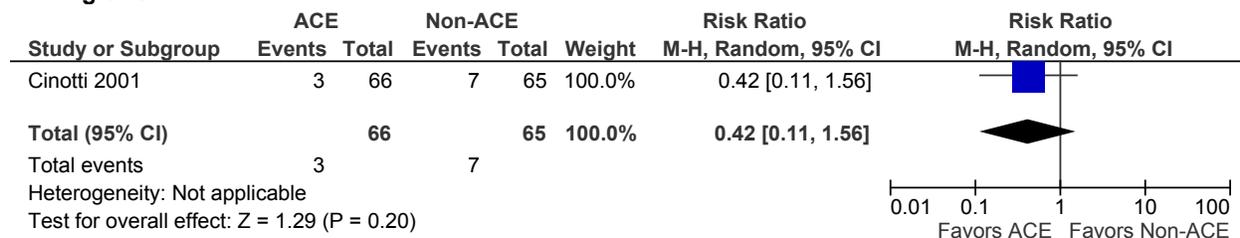
Myocardial Infarction



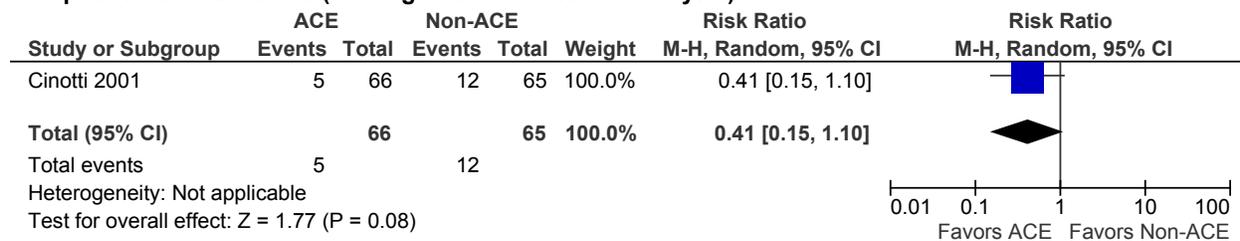
End-stage Renal Disease



Halving of GFR



Composite Renal Outcome (Halving of GFR or need for dialysis)



Appendix Table C79. Study withdrawals and adverse events (outcomes part D), ACEI versus conventional therapy without ACEI trial

Study	Study Withdrawals, Any, n/N (%)		Study Withdrawals Due to Serious Adverse Events, n/N (%)		Serious Adverse Events, Any, n/N (%)		Adverse Events, Any, n/N (%)		Adverse Events, Specific, n/N (%)		Renal Adverse Events, Any, n/N (%)	
	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI	ACEI	Non-ACEI
Cinotti, 2001 ³⁴	*NR	*NR	*NR	*NR	*NR	*NR			HyperK: 1/66 (1.5%); Uncontrolled hypotension: 1/66 (1.5%)	HyperK: 0/65; Uncontrolled hypotension: 0/65		

ACEI = angiotensin converting enzyme inhibitor

*Study did not report withdrawals, serious adverse events, or withdrawals due to serious adverse events, but did report discontinuation of treatment due to adverse events (4/66 [6.1%] in ACEI group and 3/65 [4.6%] in non-ACEI group).

Appendix Evidence Table C80. Overview of CCB versus BB trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Bakris ⁵⁶ 1996 United States, Single-site Funding Source: Private (Foundation)	Inclusion: non-insulin dependent diabetes for ≥8 years; diabetic retinopathy; proteinuria ≥2.0 g/day; renal insufficiency (creatinine clearance <1.16 ml/sec [i.e. <70ml/min]); hypertension for ≥8 years; age ≥45 years Exclusion: Diastolic blood pressure >125 mm Hg on three consecutive readings during 2 week wash out period with no antihypertensive medications. Heart failure (ejection fraction ≤40%); history of poor diabetes control (blood glucose 11 mmol/l or HbA _{1c} >13%; history of difficult blood pressure control (maximum dose of ≥3 medications or diastolic blood pressure >105 mm Hg with medication); blindness, documented coronary artery disease; severe claudication (peripheral arterial disease); orthostatic hypotension (diabetic neuropathy); required intake of antiarrhythmic medications, calcium channel blockers, or angiotensin converting enzyme inhibitor; documented psychiatric disease; active urine sediment; blood glucose control by insulin therapy alone.	N=34 (CCB and BB groups) Age (yr): 62.1 Gender (Male %): 44.4 Race/Ethnicity (%): 56% black, 44% white Weight (kg): 105.6 BMI: 32.6 (calculated from given height & weight) Systolic BP (mm Hg): 158.4 Diastolic BP (mm Hg): 97.9 CKD stage: NR Serum creatinine (mmol/l): 163.8 (=1.85 mg/dL) Creatinine clearance (ml/s/1.73m ²): 1.01 (=60.6 ml/min/1.73m ²) Albuminuria (g/day): NR Proteinuria (g/day): 4.36 Albumin/creatinine ratio (mg/g): NR GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 10.5 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 100 Dyslipidemia (%): NR History of cardiovascular disease (%): NR History of CAD (%): 0 History of CHF (%): 0 Peripheral arterial disease (%): NR (severe claudication is excluded) History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR	n= 18 to either verapamil SR (n=8) or diltiazem SR (n=10)* n= 16 atenolol* Study including additional treatment arm of lisinopril (n=16) Followup period: 64 months (median) Study withdrawals (%): 11.5 *initial dose not reported; dosages titrated over two week period and then periodically throughout study to ensure similar arterial pressure control among groups; if additional blood pressure reduction needed, furosemide added (100% received furosemide by year 4); other antihypertensives (including alpha blockers and/or vasodilators) added if further blood pressure reduction needed. All patients also instructed in 90 meq/day Na and 0.8 g/kg protein and 6300 kJ ADA diet.	Allocation concealment: Unclear Blinding: Not reported Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes
Wright, 2002 ²⁶ Wright, 1996 ⁵⁷ AASK United States Multi-site	Inclusion: self-identified African Americans; hypertension; ages 18 to 70; GFR between 20 and 65 mL/min/1.73m ² ; no other identified causes of renal insufficiency	N= 658 Age (yr): 54.8 Gender (Male %): 61.1 Race/Ethnicity (%): NR Weight (kg): NR BMI: NR	n= 217 amlodipine (5 to 10 mg/day)* n= 441 metoprolol (50 to 200 mg/day)*	Allocation Concealment: Adequate Blinding: Participants and investigators masked to randomized

Appendix Evidence Table C80. Overview of CCB versus BB trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Funding Source: Government, Industry	Exclusion: diastolic BP <95 mm Hg; known history of diabetes mellitus (fasting glucose ≥149 mg/dL or random glucose >200 mg/dL); urinary protein to creatinine ratio >2.5; accelerated or malignant hypertension within 6 months; secondary hypertension; evidence of non-BP-related causes of chronic kidney disease; clinical congestive heart failure; specific indications for or contraindication to a study drug or study procedure.	Systolic BP (mm Hg): 150.0 Diastolic BP (mm Hg): 95.3 CKD stage: NR Albumin (g/dl): NR Serum creatinine (mg/dL): 2.03 Creatinine clearance (mL/min): NR Albuminuria (µg/min): NR Proteinuria (g/24h): 0.54 Protein/Creatinine ratio: 0.33 Urine protein/creatinine ratio ≥0.22 (%): 32 GFR (ml/min/1.73m ²): 45.8 HbA _{1c} (%): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 0 History of HTN (%): 100 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): 0 Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR	Followup period: 3 years (median, for GFR outcome)** Study withdrawals (%): 0 *if BP goal could not be achieved by randomized drug, additional open- labeled antihypertensives were added sequentially (furosemide, doxazosin, clonidine, and hydralazine or minoxidil) **amlodipine arm stopped early on recommendation of the data and safety monitoring board; patients in this arm were switched to open-label medication.	drug but not BP goal; cardiovascular events classified by blinded end points committee Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes
Dahlof, 2005 ⁵⁸ ASCOT-BPLA Europe multi-site Funding Source: Industry	Inclusion: aged 40-79 years; untreated hypertension, SBP ≥160 mm Hg, DBP ≥100 mm Hg or both, treated hypertension with SBP ≥140 mm Hg or DBP 90 mm Hg or both; and at least 3 of the following risk factors (left ventricle hypertrophy, abnormalities on electrocardiogram, type II diabetes, PAD, previous stroke or TIA, male sex, age ≥55, microalbuminuria or proteinuria, smoking, ratio of plasma total cholesterol to HDL ≥6, family history of premature CHD) Exclusion: previous MI; currently treated angina; a cerebrovascular event within previous 3 months;	N=12,074 with “renal dysfunction” (undefined) in subgroup analysis out of 19,342 randomized overall Baseline data not presented for subgroup with renal dysfunction, though by entry criteria, the following characteristics could be determined: History of HTN (%): 100 History of MI (%): 0 History of CHF (%): 0	n=5,893 amlodipine 5-10 mg, adding perindopril 4-8 mg as required n=6181 atenolol 50-100 mg, adding bendroflumethiazide 1.25-2.5 mg and potassium as required Followup period: 5.5 years (median) (trial was stopped prematurely) Study withdrawals (%): 0.6 overall, but not reported for “renal dysfunction” subgroup	Allocation Concealment: adequate Blinding: Open with blinded end-point classification Intention to Treat Analysis (ITT): yes Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C80. Overview of CCB versus BB trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	fasting triglycerides >4.5 mmol/L; heart failure; uncontrolled arrhythmias; any clinical important hematological or biochemical abnormality on routine screening			

CCB = calcium channel blocker; BB = beta blocker; SBP = systolic blood pressure; DBP = diastolic blood pressure; NR = not reported

Appendix Table C81. Summary of study baseline characteristics, CCB versus BB trials

Characteristic	Mean (range unless otherwise noted)	Number of Trials Reporting
Patients randomized, n	12,766 (34-12,074)	3
Age of subjects, years	55.2 (54.8-62.1)	2
Gender, male, %	60.3 (44.4-61.1)	2
Race/ethnicity, white, %	2 (0-44)	2
Race/ethnicity, black, %	98 (56-100)	2
Body Mass Index	32.6	1
Systolic blood pressure, mmHg	150.4 (150.0-158.4)	2
Diastolic blood pressure, mmHg	95.4 (95.3-97.9)	2
Proteinuria, g/day	0.70 (0.54-4.36)	2
Serum creatinine, mg/dL	2.02 (1.85-2.03)	2
Creatinine clearance, ml/min/1.73m ²	60.6	1
GFR, ml/min/1.73m ²	45.8	1
Total cholesterol, mg/dl	NR	
LDL cholesterol, mg/dl	NR	
History of diabetes, %	4.9 (0 to 100)	2
% HbA _{1c}	10.5	1
History of hypertension (%)	100	3
History of cardiovascular disease, %*	NR	
History of CHF, %	0	3
Current smoker, %	NR	

CCB = calcium channel blocker; BB = beta blocker; NR = not reported

*One study (n=34) excluded patients with history of heart failure or coronary artery disease; one study (n=12,074) excluded patients with history of MI

Appendix Table C82. Clinical outcomes (outcomes part A), CCB versus BB trials

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial infarction, Fatal, n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any n/N (%)	
	CCB	BB	CCB	BB	CCB	BB	CCB	BB	CCB	BB	CCB	BB
Bakris, 1996 ⁵⁶	1/18 (5.6)	4/16 (25.0)	*NR	*NR			*NR	*NR				
Wright, 2002 ²⁶	13/217 (6.0)	38/441 (8.6)	†NR	†NR								
Dahlof, 2005 ⁵⁸												

CCB = calcium channel blocker; BB = beta blocker

* Study reported 5 (9.6%) cardiovascular deaths, 4 (7.7%) fatal myocardial infarctions, and 1 (1.9%) fatal stroke, but didn't indicate to which treatment group these patients had been assigned.

† Study did not report the number of participants with cardiovascular death, but instead the percentage of patients with cardiovascular death per patient year of followup: CCB 0.9%, BB 0.8%.

C-156

Appendix Table C83. Clinical outcomes (outcomes part B), CCB vs. BB trials

Study	Stroke, Nonfatal n/N (%)		Stroke, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B) n/N (%)		Composite Vascular Outcome n/N (%)	
	CCB	BB	CCB	BB	CCB	BB	CCB	BB	CCB	BB
Bakris, 1996 ⁵⁶			*NR	*NR						
Wright, 2002 ²⁶									†NR	†NR
Dahlof, 2005									825/5893 (14.0)	989/6181 (16.0)

CCB = calcium channel blocker; BB = beta blocker; CHF = congestive heart failure; NR = not reported

* Study reported 1 fatal stroke (1.9%), but didn't indicate participant treatment group.

† Study did not report number of patients with composite vascular endpoint, "cardiovascular event," overall or by treatment group, but reported results as percent of patients with event per patient-year of follow-up: cardiovascular event CCB 1.7%, BB 2.9%.

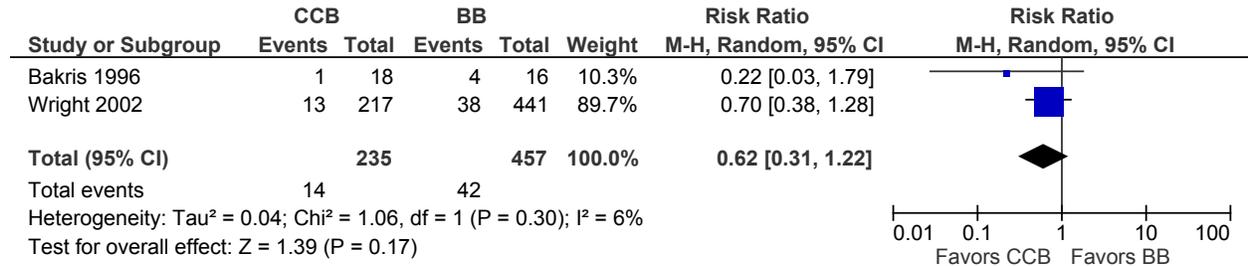
Appendix Table C84. Composite vascular outcome definitions, CCB versus BB trials

Study	Definition
Wright, 2002 ²⁶	Cardiovascular event, defined as cardiovascular mortality or first cardiovascular hospitalization.
Dahlof, 2005 ⁵⁸	Study defined six composite vascular endpoints, but reported results within the subgroup of participants with “renal dysfunction” only in one of the secondary composite vascular endpoints, as follows: (A) Cardiovascular mortality, nonfatal MI (symptomatic and silent), unstable angina, chronic stable angina, life threatening arrhythmias, silent nonfatal heart failure, nonfatal stroke, peripheral arterial disease, revascularization procedures, and retinal vascular thromboses.

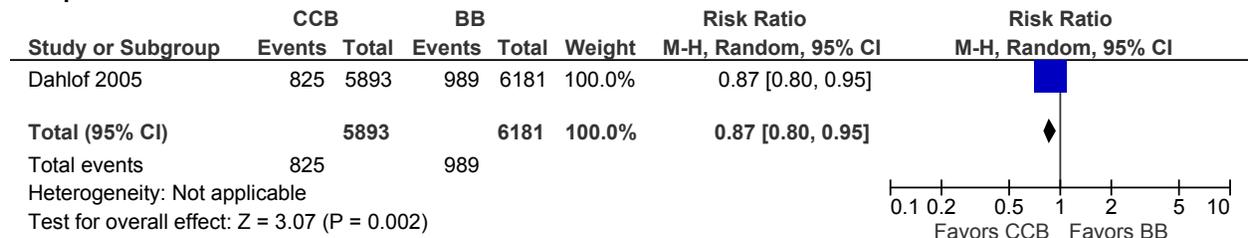
CCB = calcium channel blocker; BB = beta blocker

Appendix Figure C17. Forest plots for CCB versus BB trials

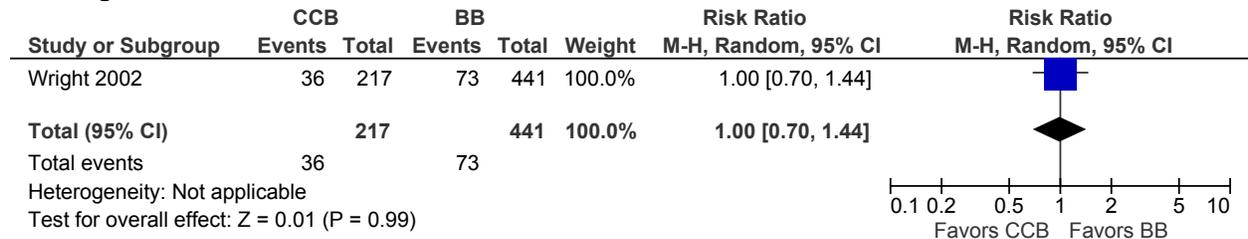
All-cause Mortality



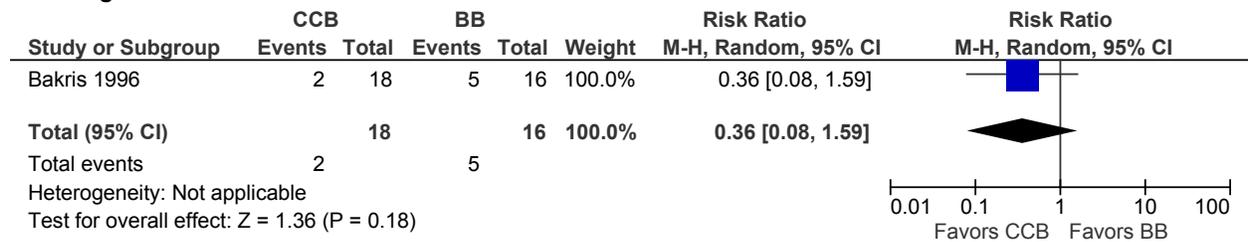
Composite Vascular Outcome



End-stage Renal Disease

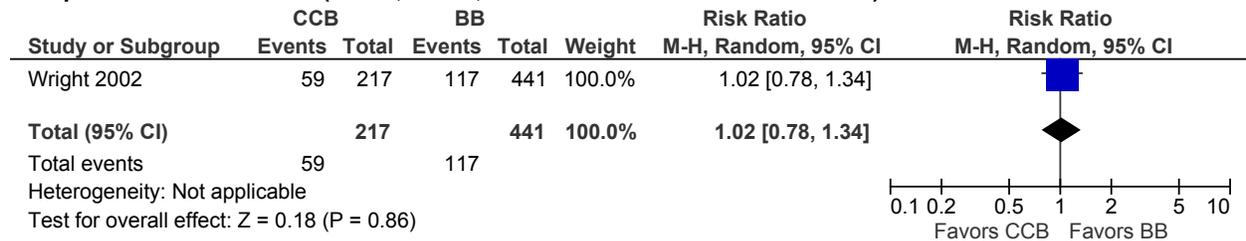


Doubling of Serum Creatinine

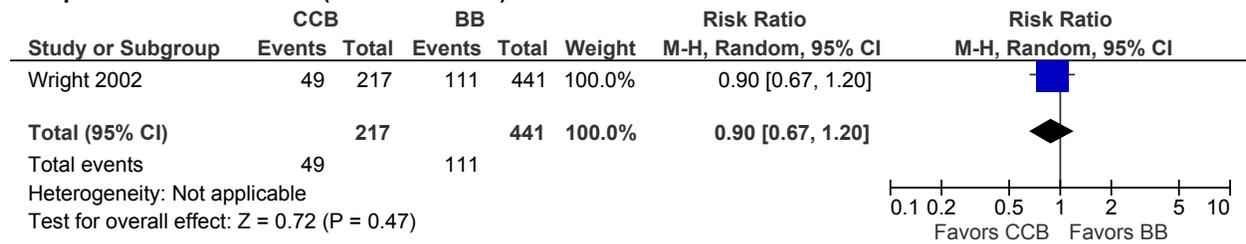


Appendix Figure C17. Forest plots for CCB versus BB trials (continued)

Composite Renal Outcome (Death, ESRD, or 50% or Greater Decline in GFR)



Composite Renal Outcome (ESRD or Death)



Appendix Table C85. Clinical renal outcomes (outcomes part C), CCB versus BB trials

Study	End-stage Renal Disease n/N (%)		Doubling of Serum Creatinine n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome, n/N (%)	
	CCB	BB	CCB	BB	CCB	BB	CCB	BB	CCB	BB
Bakris 1996 ⁵⁶	*NR	*NR	2/18 (11.1)	5/16 (31.3)						
Wright 2002 ²⁶	36/217 (16.6)	73/441 (16.6)							†(A)59/217 (27.2); (C)49/217 (22.5)	†(A)117/441 (26.5); (C)111/441 (25.2)
Dahlof 2005 ⁵⁸										

CCB = calcium channel blocker; BB = beta blocker; GFR = glomerular filtration rate; NR = not reported; ACEI = angiotensin converting enzyme inhibitor; ESRD = end-stage renal disease

*Study reported that 5/52 (9.6%) patients (includes the 18 in a separate ACEI group) started dialysis during trial, but didn't report results by treatment group.

†Study did not report number of participants with other composite renal outcomes reported, but instead reported multivariate adjusted relative risk (BB versus CCB) of these composite renal outcome events: (B) ESRD or death (RR 0.58; 95%CI, 0.40 to 0.83); and (C) ESRD or $\geq 50\%$ decline in GFR (RR 0.76; 95%CI, 0.53 to 1.09). Composite outcome (A) is GFR event (reduction in GFR by 50% or by 25 ml/min/1.73m² from baseline mean).

Appendix Table C86. Study withdrawals and adverse events (outcomes part D), CCB versus BB trials

Study	Study Withdrawals, Any, n/N (%)		Serious Adverse Event: Any, n/N (%)		Serious Adverse Event: Any Leading to Withdrawal, n/N (%)		Adverse event: Any, n/N (%)		Adverse Event: Any Specific, n/N (%)		Renal Adverse Events: Any, n/N (%)	
	CCB	BB	CCB	BB	CCB	BB	CCB	BB	CCB	BB	CCB	BB
Bakris, 1996 ⁵⁶	*NR	*NR			0/18	0/16			†Pedal edema: 2/18 (11.1) Constipation: 10/18 (55.6) Impotence: 3/18 (16.7) Insomnia: 1/18 (5.6) Lethargy: 0/18	†Pedal edema: 2/16 (12.5) Constipation: 7/16 (43.8) Impotence: 9/16 (56.3) Insomnia: 6/16 (37.5) Lethargy: 13/16 (81.3)		
Wright, 2002 ²⁶	‡0/217	‡0/441					†NR	†NR	†NR	†NR		
Dahlof, 2005 ⁵⁸												

CCB = calcium channel blocker; BB = beta blocker; HyperK = hyperkalemia

* 6 withdrawals, treatment group not specified

† Study reported additional participants with specific adverse events as follows: hyperkalemia (CCB 0/18, BB 1/16), dizziness (CCB 2/18, BB 3/16); headache (CCB 2/18, BB 1/16); exercise intolerance (CCB 0, BB 7); dry mouth (CCB 1, BB 13)

‡ Study reported no withdrawals in either treatment group, but also indicated that excluding deaths and dialysis, 23/217 randomized to CCB and 30/441 assigned to BB were no longer active study participants at its end.

† Study did not report the number and percentage of participants overall or by treatment group with any or specific adverse events, but instead reported as percentage of patients experiencing the adverse event per patient year of follow-up (%/pt-yr): hyperkalemia CCB 0, BB 0.2; angioedema CCB 2.3, BB 2.7; shortness of breath CCB 44.4, BB 45.8; syncope CCB 2.3, BB 6.3; dizziness CCB 46.7, BB 47.8; lightheadedness CCB 48.1, BB 47.8; edema CCB 59.8, BB 51.0; cough CCB 46.3, BB 41.5; sexual dysfunction CCB 25.7, BB 25.2.

Appendix Evidence Table C87. Overview of CCB versus diuretic trial

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
<p>Rahman 2005/2006^{23,35}</p> <p>U.S., Canada, Puerto Rico, U.S. Virgin Islands, multi-site</p> <p>Funding Source: government</p>	<p>Inclusion: men and women 55 years or older who had stage 1 or stage 2 hypertension with at least 1 additional risk factor for coronary heart disease events. The risk factors included previous (>6 months) myocardial infarction or stroke, left ventricular hypertrophy demonstrated by electrocardiography or echocardiography, history of type 2 diabetes mellitus, current cigarette smoking, high-density lipoprotein cholesterol level of <5 mg/dL (<0.91 mmol/L), or documentation of other atherosclerotic cardiovascular disease.</p> <p>Exclusion: Individuals with a history of symptomatic heart failure and/or a known left ventricular ejection fraction of <35% were excluded. Participants with a serum creatinine level >2 mg/dL (176.8 µmol/L) as reported by the investigator were excluded. However, if the serum creatinine level measured at the time of randomization was found to exceed 2 mg/dL (176.8 µmol/L), these participants were maintained in the trial and followed up according to the study protocol.</p>	<p>n= 4,129 (Post hoc subgroup analysis within participants with GFR <60 ml/min/1.73m² from overall study population for these treatment groups of 23,261)</p> <p>Age (yr): 70.8 Gender (Male %): 46.8 Race/Ethnicity (%): White non-Hispanic: 57.4 Black non-Hispanic: 25.3 White Hispanic: 11.6 Black Hispanic: 1.1 Other: 4.6</p> <p>Weight (kg): NA BMI: 29.1 Systolic BP (mm Hg): 146.7 Diastolic BP (mm Hg): 82.5 CKD stage: NA Serum creatinine (µmol/L): NA Creatinine clearance (mL/min): NA Albuminuria (µg/min): NA Proteinuria (mg/day): NA Albumin/creatinine ratio (mg/g): NA GFR (ml/min/1.73m²): 50.3 HbA_{1c} (%): NA Total cholesterol (mmol/L): NA LDL cholesterol (mmol/L): NA Diabetes (%): 33.6 History of HTN (%): 100 Dyslipidemia (%): NA History of CAD (%): 30.2 History of CVD (%): 59.7 History of CHF (%): 0 Peripheral arterial disease (%): NA History of MI or stroke (%): 28.0 Current smoker (%): 17.6 History of AKI (%): NA</p>	<p>n=1,516 amlodipine 2.5, 5 and 10 mg/d</p> <p>n= 2,613 chlorthalidone 12.5, 12.5 (sham titration), and 25 mg/d</p> <p>Followup period: 4.9 yr</p> <p>Study withdrawals (%): Not reported for low GFR by treatment groups</p>	<p>Allocation Concealment:Unclear</p> <p>Blinding: double blind</p> <p>Intention-to-Treat Analysis (ITT): yes</p> <p>Withdrawals/Dropouts adequately described: Yes for study overall, but not specified by treatment groups</p>

Appendix Table C88. Summary of study baseline characteristics, CCB versus diuretic trial

Characteristic	Mean (range unless otherwise noted)	Number of Trials Reporting
Patients randomized, n	4,129	1
Age of subjects, years	70.8	1
Gender, male, %	46.8	1
Race/ethnicity, white, %	69.0	1
Race/ethnicity, black, %	26.4	1
Body Mass Index	29.1	1
Systolic blood pressure, mmHg	146.7	1
Diastolic blood pressure, mmHg	82.5	1
Proteinuria, g/day	NR	
Serum creatinine, mg/dL	NR	
Creatinine clearance, ml/min/1.73m ²	NR	
GFR, ml/min/1.73m ²	50.3	1
Total cholesterol, mg/dl	NR	
LDL cholesterol, mg/dl	NR	
History of diabetes, %	33.6	1
% HbA _{1c}	NR	
History of hypertension (%)	100	1
History of cardiovascular disease, %	59.7	1
History of CHF, %	0	1
Current smoker, %	17.6	1

CCB = calcium channel blocker; NR = not reported; GFR = glomerular filtration rate; CHF = congestive heart failure

Appendix Table C89. Clinical outcomes (outcomes part A), CCB versus diuretic trial

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal, n/N (%)		Myocardial infarction, Nonfatal, n/N (%)		Stroke, Any n/N (%)	
	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic
Rahman, 2006 ³⁵											100/1516 (6.6)	157/2613 (6.0)

CCB = calcium channel blocker

Appendix Table C90. Clinical outcomes (outcomes part B), CCB versus diuretic trial

Study	Stroke, Nonfatal n/N (%)		Stroke, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B) n/N (%)		Composite Vascular Outcome n/N (%)	
	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic
Rahman, 2006 ³⁵					174/1516 (11.5)	259/2613 (9.9)			*(A)194/1516 (12.8) (B)537/1516 (35.4)	*(A)318/2613 (12.2) (B)870/2613 (33.3)

CCB = calcium channel blocker; CHF = congestive heart failure

*Study defined two composite vascular endpoints, as follows: (A) Nonfatal MI and fatal CHD; and (B) Combined CVD (CHD death, nonfatal MI, coronary revascularization, hospitalized or treated angina, stroke, treated or hospitalized heart failure, and peripheral arterial disease [hospitalized or outpatient revascularization]).

Appendix Table C91. Clinical renal outcomes (outcomes part C), CCB versus diuretic trial

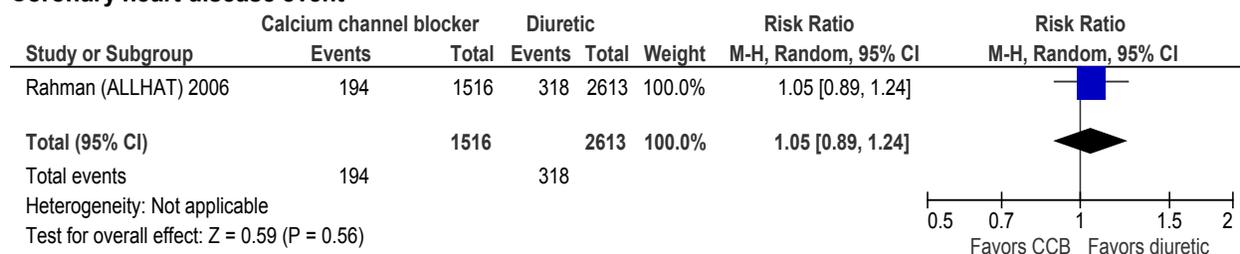
Study	End-stage Renal Disease n/N (%)		Doubling of Serum Creatinine n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome n/N (%)	
	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic	CCB	Diuretic
Rahman, 2005 ²³	Overall: 65/1516 (4.3)	Overall: 124/2613 (4.7)							*Overall: 90/1516 (5.9)	*Overall: 180/2613 (6.9)**
	Diabetics: 44/506 (8.7)	Diabetics: 68/881 (7.7)							Diabetics: 56/506 (11.1)	Diabetics: 96/881 (10.9)

CCB = calcium channel blocker; GFR = glomerular filtration rate; ESRD = end-stage renal disease

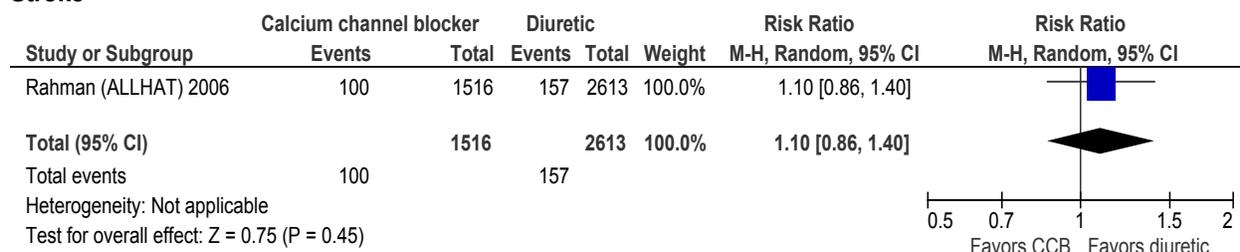
*Study reported composite renal outcome as ≥50% decline in GFR or incident ESRD (death due to kidney disease, kidney transplantation, or start of long-term renal dialysis). Study also reported no difference in risk (RR 1.02 [95% CI, 0.90-1.15]) between treatment groups for another composite renal outcome (≥50% decline in GFR, ESRD or death), but didn't report the number of participants reaching this event overall or by treatment group.

Appendix Figure D18. Forest plots for CCB versus diuretic trial

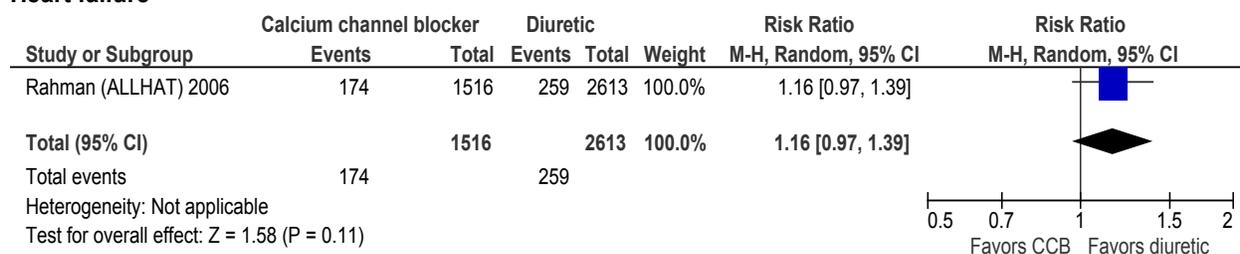
Coronary heart disease event



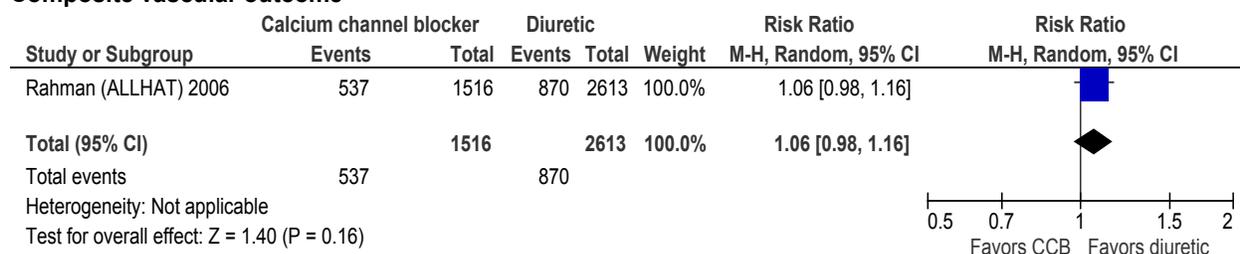
Stroke



Heart failure

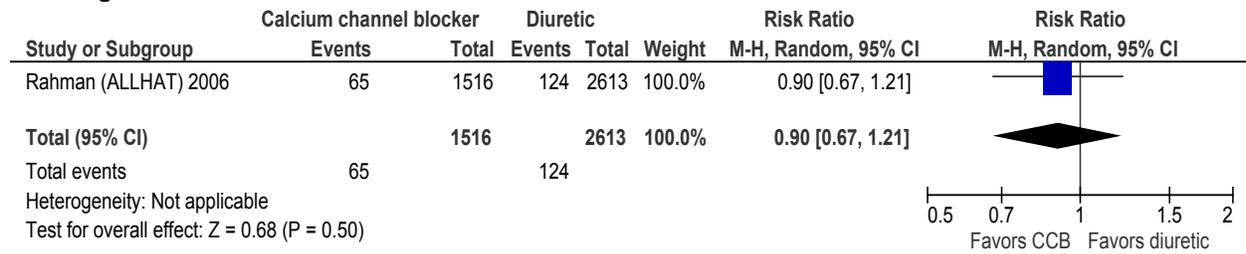


Composite vascular outcome

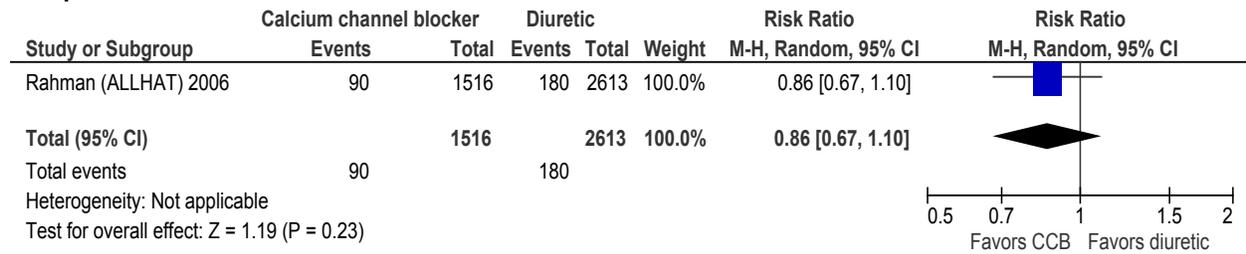


Appendix Figure D18. Forest plots for CCB versus diuretic trial (continued)

End-stage renal disease



Composite renal outcome



Appendix Table C92. Composite renal outcome definitions, CCB versus diuretic trials

Study	Definition
Rahman, 2005 ²³	50% or greater decline in GFR or incident end-stage renal disease (death due to kidney disease, kidney transplantation, or start of long-term renal dialysis)

CCB = calcium channel blocker; GFR = glomerular filtration rate

Appendix Evidence Table C93. Overview of strict versus standard blood pressure control trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Blood pressure target comparison trials (n= 6)				
Ruggenti, 2005 ⁵⁹ REIN-2 Multi-center Italy Industry and other (nonprofit research institute)	<p>Inclusion Criteria: Age 18–70 years, who had nondiabetic nephropathy and persistent proteinuria (urinary protein excretion ≥ 1 g/24 hr for at least 3 months without evidence of urinary-tract infection or overt heart failure) and who had not received ACEI therapy for at least 6 weeks. Patients with proteinuria of 1–3 g /24 hr were included if their creatinine clearance was less than 45 mL/min per 1.73m²; those with a proteinuria ≥ 3 g /24 h were included if their creatinine clearance was less than 70 mL/min per 1.73 m².</p> <p>Exclusion Criteria: Urinary tract infection, NYHA class III or IV heart failure, treatment with corticosteroids, non-steroidal anti-inflammatory drugs, or immunosuppressive drugs; acute myocardial infarction or cerebrovascular accident in the previous 6 months, severe uncontrolled hypertension, evidence or suspicion of renovascular disease, obstructive uropathy, type 1 diabetes mellitus, collagen disease, cancer, “higher” serum aminotransferase concentrations, or chronic cough, history of allergy, or poor tolerance to ACEI or dihydropyridine calcium-channel blockers; drug or alcohol abuse; pregnancy; breastfeeding; and ineffective contraception.</p>	<p>N= 338 (baseline characteristics reported on 335, excluding 3 subjects who never took study drugs)</p> <p>Age (yr): 53.8 Gender (Male %): 74.9 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 136.7 Diastolic BP (mm Hg): 84.1 MAP (mm Hg): 101.6 Proteinuria (g/day): 2.85 Serum creatinine (mg/dL): 2.7 Creatinine Clearance (ml/min/1.73m²): 38.8 Measured GFR (ml/min/1.73m²): 35.0 Total cholesterol (mg/dL): 217.5 LDL cholesterol (mg/dL): NR Diabetes (%): NR HgbA1C (%): NR History of HTN (%): NR History of CAD (%): NR History of CHF (%): NR History of MI (%): NR History of Stroke (%): NR History of AKI (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR</p>	<p>Conventional BP control (n= 169), with target DBP <90 mm Hg, irrespective of SBP</p> <p>Intensified BP control (n=169), with target <130/80 mm Hg, using felodipine, initially at 5 mg/day then titrated up as needed to 10 mg/day.</p> <p>During pre-randomization run-in, all participants started on ramipril and uptitrated as tolerated to 5 mg/day while concomitant blood pressure medications tapered down as tolerated to keep SBP <90 mm Hg. After randomization, adjustment of concomitant BP meds (excluding ACEI, ARB, or dihydropyridine CCB other than felodipine) allowed to meet BP target/avoid hypotension.</p> <p>Followup period (median): 19 months</p> <p>Study withdrawals (%): 15.4 (52/338)</p>	<p>Allocation Concealment Adequate. Centrally administered randomization process.</p> <p>Blinding: No. Investigators and patients aware of allocation.</p> <p>Intention to Treat Analysis (ITT): No. Three subjects not included in analysis after randomization.</p> <p>Withdrawals/Dropouts adequately described: Yes</p>
Wright, 2002 ²⁶ AASK Multi-center	<p>Inclusion Criteria: Self-identified African Americans with hypertension (n=1094), aged 18 to 70 yr, GFR 20 to 65 mL/min per 1.73 m², and no other identified</p>	<p>N= 1094 Age (yr): 54.6 Gender (Male %): 61.2 Race/Ethnicity (%): African</p>	<p>Target MAP 102-107 mm Hg (n=554)</p> <p>Target MAP ≤ 92 mm Hg</p>	<p>Allocation Concealment Unclear</p> <p>Blinding: No, not for BP target</p>

Appendix Evidence Table C93. Overview of strict versus standard blood pressure control trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
USA Funding Source: Industry and Government	causes of renal insufficiency. Exclusion Criteria: DBP ≥ 95 mm Hg, known history of diabetes mellitus (fasting glucose ≥ 140 mg/dL or random glucose > 200 mg/dL), urinary protein to creatinine ratio > 2.5, accelerated or malignant hypertension within 6 months, secondary hypertension, evidence of non-BP-related causes of chronic kidney disease, serious systemic disease, clinical CHF, or specific indication for or contraindication to a study drug or study procedure.	American 100 BMI: 30.6 Weight: 89.5 Systolic BP (mm Hg): 150.5 Diastolic BP (mm Hg): 95.5 MAP (mm Hg): 114 Proteinuria (g/24h): 0.53 Urine protein/creatinine ratio: 0.33 Serum creatinine (mg/dL): 2.0 Creatinine Clearance (ml/min/1.73m ²): NR Measured GFR (ml/min/1.73m ²): 45.6 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 0 HgbA1C (%): NR History of HTN (%): 100 History of CAD (%): NR History of CHF (%): 0 History of MI (%): NR Current smoker (%): NR	(n=540) Study was 3x2 factorial design, including 2 target BP groups and 3 BP drug groups (amlodipine, metoprolol or ramipril). If BP target couldn't be achieved by randomized drug, additional open-label BP meds could be added. Followup period: median 3.8 yrs (median 4.1 yr in ramipril and metoprolol groups, and 3.0 yr in amlodipine group) Study withdrawals (%): Study reported 0 withdrawals, but stated that 8.1% with no GFR in their final year of followup were not "active participants" at study end.	groups Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes
Lewis, 1999 ⁶⁰ Multi-center USA Industry	Inclusion Criteria: Previously participated in the Study of ACEI in Diabetic Nephropathy, which had randomized 409 subjects who met inclusion criteria to captopril vs. placebo as follows: age 18-40 yr, type 1 diabetes mellitus ≥ 7 years with onset before age 30 yr, presence of diabetic retinopathy, urinary protein excretion ≥ 500 mg/24 h, serum creatinine ≤ 2.5 mg/dL. Current study participants further had to have been receiving coded medication from the earlier study when it terminated, and current serum creatinine level had to be < 4 mg/dL. Patients were not required to have a history of hypertension Exclusion Criteria: Serum creatinine > 4.0	N= 129 Age (yr): 37 Gender (Male %): 47.3 Race/Ethnicity (%): White 94.6 BMI: NR Systolic BP (mm Hg): NR Diastolic BP (mm Hg): NR MAP (mm Hg): 96.0 Proteinuria (g/24h): 1.1 Serum creatinine (mg/dL): 1.3 Creatinine Clearance (ml/min/1.73m ²): NR Measured GFR (ml/min/1.73m ²): 63.0 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 HgbA1C (%): 10.8	Target MAP ≤ 92 mm Hg (n=63) Target MAP 100 -107 mm Hg (n=66) Ramipril used as primary antihypertensive agent to achieve target BP goals. If needed, other BP drugs could later be used, except other ACEI or ARB. All patients to restrict dietary protein to < 1 gm/kg/day, and diabetes managed "in accord with the historical treatment schedule." Followup period: Neither	Allocation Concealment Unclear Blinding: Unclear Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: No, n=5 not accounted for.

Appendix Evidence Table C93. Overview of strict versus standard blood pressure control trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	mg/dL, serum potassium ≥ 6.0 mEq/L, white blood cell count $< 2,500/\mu\text{L}$, or a medical or psychiatric problem that precluded the patient following the protocol or taking study medication. Documented acute myocardial infarction or overt coronary artery disease. Not enrolled if investigators at their site declined to participate in the study.	History of HTN (%): 77 History of CAD (%): 0 History of CHF (%): NR History of MI (%): 0 History of Stroke (%): NR History of AKI (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	mean nor median duration reported. Study reported that all subjects were followed a minimum of 2 yr, but also reported that 26% (n=33) did not complete 2 yr followup. Study withdrawals (%): 16.3	
Toto, 1995 ⁶¹ Multi-center USA Funding Source Government and Industry	Inclusion Criteria: Age 25 to 73 yr, with hypertensive nephrosclerosis, DBP ≥ 95 mm Hg, serum creatinine > 1.6 mg/dl, GFR of ≤ 70 ml/min/1.73 m ² , long-standing hypertension, an inactive urine sediment, a urinary protein excretion rate ≤ 2 g/day, and no physical or biochemical evidence for a humoral-mediated cause for hypertension. Among 87 eligible patients, only those 77 “responders” whose DBP was able to be lowered to ≤ 80 mm Hg during 3-6 month run-in were eligible for randomization. Exclusion Criteria: Patients with diabetes mellitus, a recent history (< 4 months) of malignant hypertension, stroke or myocardial infarction, acute renal failure of any cause, analgesic abuse, polycystic kidney disease, systemic lupus erythematosus, scleroderma, rapidly progressive glomerulonephritis, evidence of significant hepatic impairment (AST and ALT greater than 2.5 x normal or serum total bilirubin > 1.5 mg/dl), mental incapacity, pregnancy or lactation, primary aldosteronism, renovascular hypertension, pheochromocytoma, or a serum creatinine > 7.0 mg/dl	N= 77 Age (yr): 55.7 Gender (Male %): 62.3 Race/Ethnicity (%): Black 75.3, Nonblack 24.7 BMI: 28.7 Systolic BP (mm Hg): 123 Diastolic BP (mm Hg): 76 MAP (mm Hg) 92 Proteinuria (mg/day): 359 Serum creatinine (mg/dL): 2.3 Creatinine Clearance (ml/min/1.73m ²): NR Measured GFR (ml/min/1.73m ²): 37.8 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 0 HgbA1C (%): NR History of HTN (%): 100 History of cardiovascular disease (any of angina, MI, CHF or stroke) (%): 36.4 History of AKI (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR	Conventional target DBP 85-95 mm Hg (n=35) Strict target DBP 65-80 mm Hg (n=42) Stepped use of BP drugs during run-in to achieve DBP < 80 mm Hg (diuretic; BB; hydralazine or minoxidil; clonidine, alpha-methyldopa or alpha blocker). 2x2 factorial design to strict vs. conventional BP target and to enalapril vs. placebo. Followup period (Mean): 3.4 years Study withdrawals (%): No information reported	Allocation Concealment Unclear Blinding: Double Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Unclear
Peterson, 1995 ⁶² Klahr, 1994 Greene 1993	Inclusion Criteria: Age of 18 to 70 years; serum creatinine level of 1.2 to 7.0 mg/dL for women and 1.4 to 7.0 mg/dL	N= 585 (Reported baseline characteristics differed slightly	Low target MAP (≤ 92 mm Hg for patients ≤ 60 yr old, and ≤ 98 mm Hg for patients ≥ 61	Allocation Concealment Unclear

Appendix Evidence Table C93. Overview of strict versus standard blood pressure control trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
<p>MDRD (Study A)</p> <p>Multi-center USA</p> <p>Government</p>	<p>for men or a creatinine clearance less than 70 mL/min • 1.73 m²; and mean arterial pressure of 125 mm Hg or less (Study A+B). Study A had patients with GFR of 25-55 mL/min • 1.73 m²</p> <p>Dietary protein intake ≥0.9 g/kg body weight/day.</p> <p>Exclusion Criteria: Diabetes requiring insulin, proteinuria of 10 g/d or more, or body weight less than 80% or more than 160% of standard body weight, Pregnancy, history of renal transplant, chronic medical conditions or doubts about compliance</p>	<p>between different study reports. For characteristics reported by multiple studies, results from the most recent report were used.)</p> <p>Age (yr): 52</p> <p>Gender (Male %): 61.0</p> <p>Race/Ethnicity (%): White 84.6, Black 9.1, Other 6.3</p> <p>BMI: 27.6</p> <p>Systolic BP (mm Hg): 131</p> <p>Diastolic BP (mm Hg): 81</p> <p>MAP (mm Hg): 98</p> <p>Proteinuria (g/day): 0.9</p> <p>Serum creatinine (mg/dL): 1.9</p> <p>Creatinine Clearance (ml/min/1.73m²): 50.4</p> <p>Measured GFR (ml/min/1.73m²): 38.6</p> <p>Total cholesterol (mg/dL): 221</p> <p>LDL cholesterol (mg/dL): 150</p> <p>Diabetes (%): NR</p> <p>HgbA1C (%): NR</p> <p>History of HTN (%): 85.3</p> <p>History of CAD (%): NR</p> <p>History of CHF (%): NR</p> <p>History of MI (%): NR</p> <p>History of Stroke (%): NR</p> <p>History of AKI (%): NR</p> <p>Peripheral arterial disease (%): NR</p> <p>Current smoker (%): 80</p>	<p>yr old)</p> <p>Usual target MAP (≤107 mm Hg for patients ≤60 yr old, and ≤113 mm Hg for patients ≥61 yr old)</p> <p>Followup period: Mean 2.2 yrs</p> <p>Study withdrawals (%): 1.9</p>	<p>Blinding: Unclear</p> <p>Intention to Treat Analysis (ITT): Unclear</p> <p>Withdrawals/Dropouts adequately described: Yes</p>
<p>Shulman, 1989</p> <p>HDFP</p> <p>Location United States</p> <p>Funding Source: Government</p>	<p>Inclusion Criteria: From general population subgroups of the United States. Recruited through 2 stage community based, screening program for high blood pressure in 14 U.S. communities. Adults, 30 to 69 years of age with an average home screening DBP of 95 mm Hg or above and a confirmed followup average diastolic</p>	<p>N=297 (subgroup analysis of subjects with baseline serum creatinine ≥1.7 mg/dl from overall study of N=10, 940)</p> <p>Age (yr): NR</p> <p>Gender (Male %): 68.4</p> <p>Race/Ethnicity (%): White 40.4, Black 59.6</p> <p>Weight: NR</p>	<p>Stepped care (n= 5,485; of which n=159 had creatinine ≥1.7 mg/dl). Target goal DBP ≤90 mm Hg for those entering trial on BP drug treatment or with baseline DBP ≥100 mm Hg, or goal 10mm Hg DBP decrease if baseline DBP 90-99 mm Hg.</p>	<p>Allocation Concealment Adequate</p> <p>Blinding: No (participants and clinic staff aware)</p> <p>Intention to Treat Analysis (ITT): No</p>

Appendix Evidence Table C93. Overview of strict versus standard blood pressure control trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	<p>pressure of 90 mm Hg or above.</p> <p>Exclusion Criteria: Only terminally ill and institutionalized persons were excluded. Treated hypertensives with DBP below 95 were excluded.</p>	<p>BMI: NR</p> <p>Systolic BP (mm Hg): NR</p> <p>Diastolic BP (mm Hg): NR</p> <p>MAP (mm Hg): NR</p> <p>CKD stage: NR</p> <p>Serum creatinine (mg/dL): NR</p> <p>Creatinine clearance (mL/min): NR</p> <p>Albuminuria: NR</p> <p>Proteinuria (1+ proteinuria, %): 35.0 (Measured in 89.6% of patients with creatinine \geq1.7 mg/dl and 91.2% in overall study. Among HDFP subjects with creatinine <1.7 mg/dl, an additional 597/9556 = 6.2% had at least 1+ proteinuria.)</p> <p>Albumin/creatinine ratio (mg/g): NR</p> <p>Estimated GFR (ml/min/1.73m²): NR</p> <p>HbA_{1c} (%): NR</p> <p>Total cholesterol (mg/dL): NR</p> <p>LDL cholesterol (mg/dL): NR</p> <p>Diabetes (%): 15.8</p> <p>History of HTN (%): 100</p> <p>Dyslipidemia (%): NR</p> <p>History of CAD (%): NR</p> <p>History of CHF (%): NR</p> <p>Peripheral arterial disease (%): NR</p> <p>History of MI (%): NR</p> <p>History of Stroke (%): NR</p> <p>Current smoker (%): NR</p> <p>History of AKI (%): NR</p>	<p>Referred care (n=5,455; of which n=138 had creatinine \geq1.7 mg/dl)</p> <p>Followup period: 5 yrs</p> <p>Study withdrawals (%): Not reported</p>	<p>Withdrawals/Dropouts adequately described: No</p>

Appendix Table C94. Summary of study baseline characteristics, strict versus standard blood pressure control trials

Characteristic	Mean (Range) (unless otherwise noted)	Number of Trials Reporting
Patients randomized, n	2520 (77-1094)	6
Age of subjects, years	52.8 (37-55.7)	5
Gender, male, %	63.2 (47.3-74.9)	6
Race/ethnicity, white, %	35.0 (0-94.6)	4
Race/ethnicity, black, %	67.3 (9.1-100)	4
Body Mass Index	29.5 (27.6-30.6)	3
Systolic blood pressure, mmHg	141.8 (123-150.5)	4
Diastolic blood pressure, mmHg	88.9 (76-95.5)	4
Mean arterial blood pressure, mmHg	106.1 (92-114)	5
Proteinuria, g/day	1.0 (0.36-2.85)	5
Serum creatinine, mg/dL	2.0 (1.3-2.7)	5
Creatinine clearance, ml/min/1.73m ²	46.2 (38.8-50.4)	2
GFR, ml/min/1.73m ²	42.9 (35.0-63.0)	5
Total cholesterol, mg/dl	219.7 (217.5-221)	2
LDL cholesterol, mg/dl	150	1
History of diabetes, %	11.0 (0-100)	4
% HbA _{1c}	10.8	1
History of hypertension (%)	94.7 (77-100)	5
History of cardiovascular Disease, %*	36.4	1
History of CHF, %	0	1
Current smoker, %	80	1

*No study reported separate prevalence of coronary artery disease, myocardial infarction or stroke. However, one study (n=77) reported that 36.4% of participants had a history of either angina, myocardial infarction, congestive heart failure, or stroke.

Appendix Table C95. Clinical outcomes (outcomes part A), strict versus standard blood pressure control trials

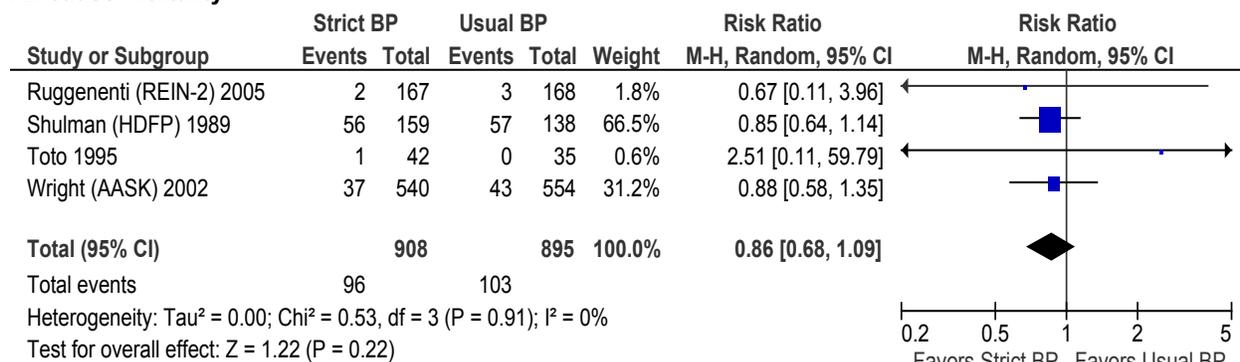
Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial infarction, Nonfatal n/N (%)		Stroke, Any n/N (%)	
	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP
Ruggenenti, 2005 ⁵⁹ REIN-2	2/167 (1.2)	3/168 (1.8)	1/167 (0.6)	2/168 (1.2)			1/167 (0.6)	1/168 (0.6)				
Wright, 2002 ²⁶ AASK	37/540 (6.9)	43/554 (7.8)										
Lewis, 1999 ⁶⁰ Toto, 1995 ⁶¹	1/42 (2.4)	0/35										
Peterson, 1995 ⁶² Klahr, 1994 ⁶³ MDRD, Study A	†NR	†NR	†NR	†NR								
Shulman, 1989 ⁶⁴ HDFP	56/159 (35.2)	57/138 (41.3)	32/159 (20.1)	33/138 (23.9)								

*Study did not report the proportion of patients with all-cause mortality or cardiovascular mortality, but instead reported only the percentage of patients experiencing these outcomes per patient year of followup (1.6 vs. 1.9% for all-cause mortality and 0.6 vs. 0.7% for cardiovascular mortality events per patient year for the strict target BP vs. control target BP groups, respectively).

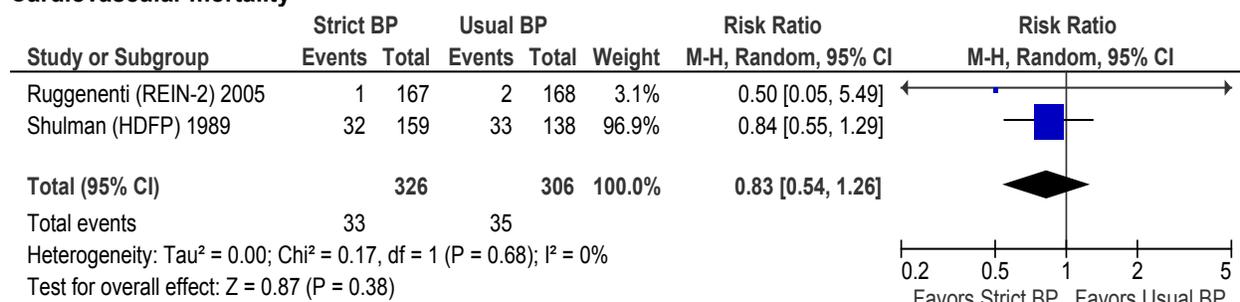
†Overall, study reported 30 deaths, including 18 cardiovascular deaths. It did not report the number of these events separately for each treatment group, though it stated that there were no significant differences in the number or causes of deaths between the two treatment groups.

Appendix Figure C19. Forest plots for strict versus standard blood pressure control trials

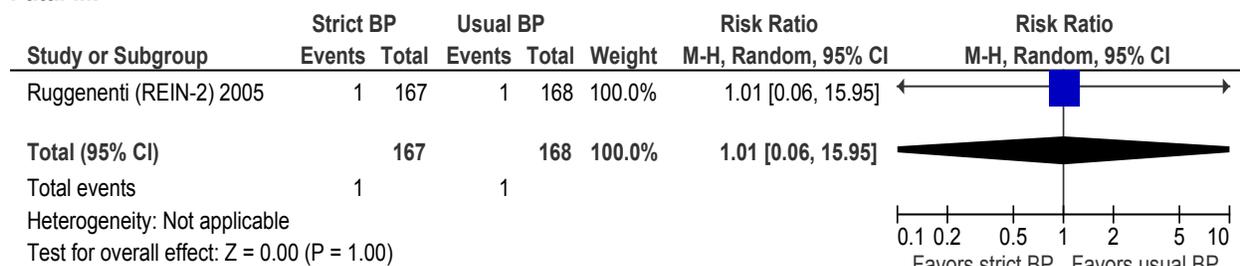
All-cause mortality



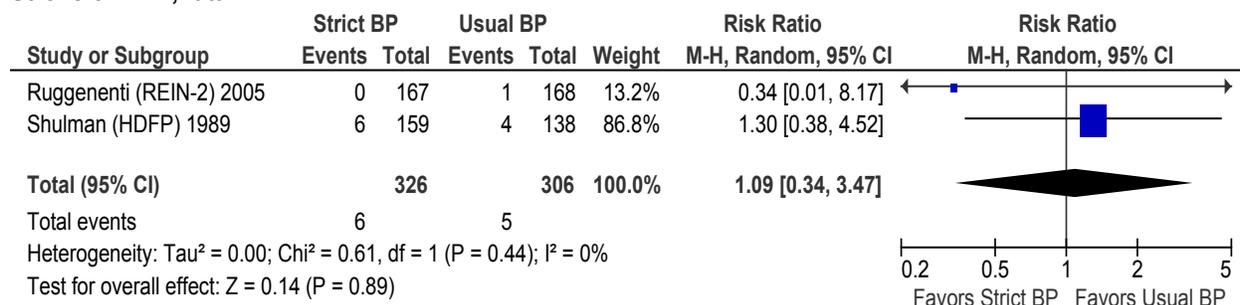
Cardiovascular mortality



Fatal MI

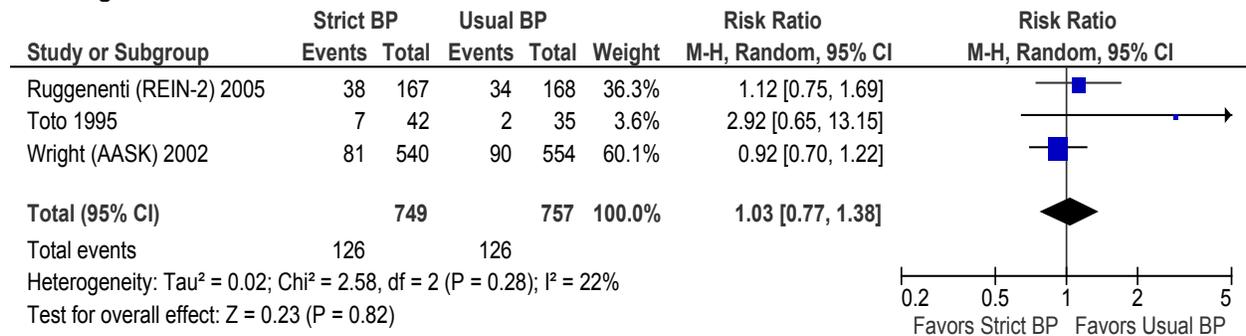


Stroke or CVA, fatal

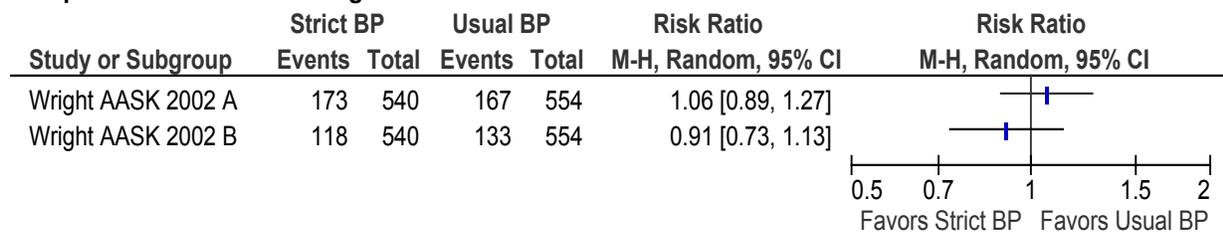


Appendix Figure C19. Forest plots for strict versus standard blood pressure control trials (continued)

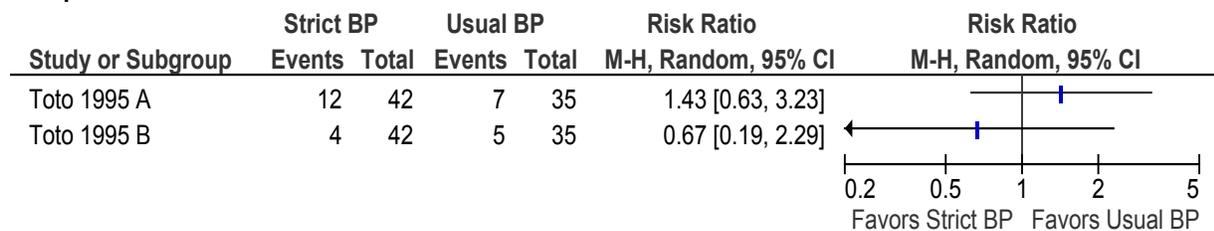
End-stage renal disease



Composite renal outcome/Wright AASK 2002



Composite renal outcome/Toto 1995



Appendix Table C96. Clinical outcomes (outcomes part B), strict versus standard blood pressure control trials

Study	Stroke, Nonfatal n/N (%)		Stroke, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B) n/N (%)		Composite Vascular Outcome n/N (%)	
	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP
Ruggenenti, 2005 ⁵⁹ REIN-2			0/167	1/168 (0.6)			(A) NR; (B) 0/167	(A) NR; (B) 0/168		
Wright, 2002 ²⁶ AASK									*NR	*NR
Lewis, 1999 ⁶⁰ Toto, 1995 ⁵¹ Peterson, 1995 ⁶² Klahr, 1994 ⁶³ MDRD, Study A										
Shulman, 1989 ⁶⁴ HDFP			6/159 (3.8)	4/138 (2.9)						

CHF = congestive heart failure; BP = blood pressure; NR = not reported

*Study did not report the proportion of patients with a composite vascular event (defined as cardiovascular mortality or first cardiovascular hospitalization), but instead reported only the percentage of patients experiencing a composite vascular outcome per patient year of followup (2.3 versus 2.7% per patient year for the strict versus control target blood pressure treatment groups).

C-178

Appendix Table C97. Composite vascular outcome definitions, strict versus standard blood pressure control trials

Study	Definition
Wright, 2002 ²⁶ AASK	"Cardiovascular event" defined as cardiovascular mortality or first cardiovascular hospitalization.

Appendix Table C98. Clinical renal outcomes (outcomes part C), strict versus standard blood pressure control trials

Study	End Stage Renal Disease n/N (%)		Doubling of Serum Creatinine n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome n/N (%)	
	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP
Ruggenenti, 2005 ⁵⁹ REIN-2	38/169 (22.5)	34/169 (20.1)								
Wright, 2002 ²⁶ AASK	81/540 (15.0)	90/554 (16.2)							*(A)173/540 (32.0) (B) 118/540 (21.9) (C) NR	*(A)167/554 (30.1) (B) 133/554 (24.0) (C) NR
Lewis, 1999 ⁶⁰	†NR	†NR								
Toto, 1995 ⁶¹	7/42 (16.7)	2/35 (5.7)							‡(A)12/42 (28.6) (B) 4/42 (9.5)	‡(A) 7/35 (20.0) (B) 5/35 (14.3)
Peterson, 1995 ⁶² Klahr, 1994 ⁶³ MDRD, StudyA	§NR	§NR			#NR	#NR				
Shulman, 1989 ⁶⁴ HDFP study			**NR	**NR						

GFR = glomerular filtration rate; BP = blood pressure; NR = not reported; ESRD = end stage renal disease

*Study reported composite renal outcomes, including: (A) Halving of GFR, ESRD or death; and (B) ESRD or death. It further reported that 263 participants experienced the composite endpoint of (C) halving of GFR or ESRD, but did not report results for this endpoint separately for the two treatment groups.

†Study reported that 12 patients reached ESRD, but didn't report this result separately for the two treatment groups.

‡Study reported two composite renal outcomes, including: (A) 50% decline in GFR, doubled serum creatinine, ESRD, or death; and (B) 50% decline in GFR or doubled serum creatinine.

§Study also reported that 12 participants developed end stage renal disease, but like the Lewis study did not report this result separately for the two treatment groups.

#Study reported that 60 patients overall reached a study stopping point due to "rapidly declining glomerular filtration rate." Though study did not report this result separately for the two treatment groups, it did state that there was no significant difference between the results for the two groups.

**In 59.6% of participants with baseline creatinine ≥ 1.7 mg/dl, study reported outcome of end of follow-up serum creatinine ≥ 2.0 mg/dl and at least 25% above the baseline level (29/106 = 27.4% for strict BP group, and 19/71 = 26.8% for control target BP group).

Appendix Table C99. Composite renal outcome definitions, strict versus standard blood pressure control trials

Study	Definition
Wright, 2002 ²⁶ AASK	Study defined three composite renal endpoints, including: (A) 50% or 25 mL/min reduction in GFR, ESRD (dialysis or transplantation), or death; (B) ESRD or death; and (C) 50% or 25 mL reduction in GFR, or ESRD
Toto, 1995 ⁶¹	Study defined two composite renal endpoints, including: (A) 50% decline in GFR, doubled serum creatinine, ESRD, or death; and (B) 50% decline in GFR or doubled serum creatinine.

GFR = glomerular filtration rate; ESRD = end stage renal disease

Appendix Table C100. Study withdrawals and adverse events (outcomes part D), strict versus standard blood pressure control trials

Study	Study Withdrawals: Any, n/N (%)		Serious Adverse Event: Any n/N (%)		Serious Adverse Event: Any Leading to Withdrawal n/N (%)		Adverse Event: Any n/N (%)		Adverse Event: Any Specific n/N (%)		Renal Adverse Events: Any, n/N (%)	
	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP	Strict Target BP	Control Target BP
Ruggenenti, 2005 ⁵⁹ REIN-2	22/169 (13.0)	30/169 (17.8)	37/169 (21.9)	25/169 (14.8)	6/169 (3.6)	3/169 (1.8)			Hyperkalemia 0/169	Hyperkalemia 0/169		
Wright, 2002 ²⁶ AASK	0/540†	0/554†							‡Hyperkalemia: 0/540 Cough: 295/540 (54.6)*	‡Hyperkalemia: 4/554 (0.7) Cough: 260/554 (47.0)		
Lewis, 1999 ⁶⁰	§NR	§NR			§NR	§NR			Postural hypotension: 11/63 (17.5)* Edema: 4/63 (6.3)* Bronchitis: 2/63 (3.2)* Sinusitis: 3/63 (4.8)*	Postural hypotension: 4/66 (6.1) Edema: 10/66 (15.2) Bronchitis: 7/66 (10.6)* Sinusitis: 13/66 (19.7)*		
Toto, 1995 ⁶¹												
Peterson, 1995 ⁶² MDRD, StudyA	#NR	#NR										
Shulman, 1989 ⁶⁴ HDFP											**Death due to renal disease: 9/159 (5.7)	**Death due to renal disease: 12/138 (8.7)

BP = blood pressure; NR = not reported; GFR = glomerular filtration rate

*p < 0.05

†Study reported no withdrawals, but described 8.1% of subjects with no GFR measurement in the final year of follow-up (n=42/540 and 47/554 from the strict and control target treatment groups, respectively) as not active participants at study end.

Appendix Table C100. Study withdrawals and adverse events (outcomes part D), strict versus standard blood pressure control trials (continued)

‡Study reported additional specific adverse events, all of which were not statistically different in incidence between strict and control target blood pressure treatment groups, including: angioedema (3.5 vs. 5.4%), shortness of breath (48.4 vs. 45.8%), syncope (6.3 vs. 5.2%), dizziness (53.4 vs. 49.0%), lightheadedness (51.2 vs. 49.2%), edema (55.1 vs. 54.2%), and sexual dysfunction (29.6 vs. 27.1%).

§Study reported 21/129 (16.3%) withdrawals overall, including 3 withdrawals for adverse events, but didn't specify either of these outcomes by treatment group.

#Study reported 11/585 (1.9%) participants lost to followup overall, but did not report results by treatment group.

**Deaths attributed to renal disease were those with ICD codes 580-599, which includes: acute or chronic glomerulonephritis, nephrotic syndrome, acute or chronic renal failure, hydronephrosis, urolithiasis, urethritis, urethral stricture, urinary tract infection, and other disorders of the kidneys and urinary tract.

Appendix Evidence Table C101. Overview of low protein diet versus usual protein diet and other dietary intervention trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Koya, 2009 ⁶⁵ (Low-Protein Diet Study Group) Japan Funding Source: Government	Inclusion Criteria: Japanese type 2 diabetics (at least 5 years duration); treated by diet or diet plus oral hypoglycemics or insulin injection; ages 30 to 70; urinary protein excretion >1g/day but <10g/day; urinary albumin excretion rate >200µg/min at least twice in 1 yr period; serum creatinine <176µmol/l; at least simple diabetic retinopathy; on normal-protein diet (1.2 g/kg/day) Exclusion Criteria: Type 1 diabetes; other renal diseases, body weight <80% of ideal; clinically significant illness such as CHF, hepatic disease, recent MI and stroke, urinary tract infection; current treatment with low protein diet (0.8 g/kg/day) and/or ACEI or ARB	N=112 Age (yr): 56.9 Gender (Male %): 58.9 Race/Ethnicity (%): NR Weight (kg): 63.4 BMI: 24.6 Systolic BP (mm Hg): 137.5 Diastolic BP (mm Hg): 77.0 CKD stage: NR Serum creatinine (mg/dL): 1.1 Creatinine clearance (mL/min): NR Albuminuria (µg/min): 507.5 Proteinuria (g/day): 1.15 Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m ²): 62.3 (MDRD formula) HbA _{1c} (%): 7.65 Total cholesterol (mg/dL): 222.4 LDL cholesterol (mg/dL): NR Diabetes (%): 100% (by inclusion criteria) History of HTN (%): 65.8 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): 0 Peripheral arterial disease (%): NR History of MI (%): NR (no recent) History of Stroke (%): NR (no recent) Current smoker (%): NR History of AKI (%): NR	Low-protein diet (0.8 g/kg/day); n=56 Normal-protein diet (1.2 g/kg/day); n=56 All participants met with dietician every 3 months, at which time their diet was modified as necessary to achieve assigned treatment group protein intake target. Followup period: 1 to 5 years (approximately 3.5 years) Study withdrawals (%): 21.4	Allocation Concealment: Adequate (central location) Blinding: Participants and investigators were not blinded; unclear if central laboratory outcomes assessors blinded Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes
Dussol, 2005 ⁶⁶ France Funding Source: Government	Inclusion Criteria: Recruited from Endocrinology Unit of 3 hospitals; ages 18 to 75 years; type 1 or 2 diabetes; either pathologic or clinical evidence of diabetic nephropathy (diabetes duration >10 yrs, diabetic retinopathy, no evidence of other kidney or urinary tract disease); at least two microalbuminuria levels >30 mg/day (incipient nephropathy) or macroalbuminuria levels >300	N=63 (baseline data presented for 47 completers only) Age (yr): 57.9 Gender (Male %): 83.0 Race/Ethnicity (%): NR Weight: 79.5 kg BMI: 27.5 Systolic BP (mm Hg): NR Diastolic BP (mm Hg): NR Mean BP (mm Hg): 98.9 CKD stage: NR	Low protein diet (0.8 g/kg/day, isocaloric). Received dietician telephone call every 6 weeks to counsel and reinforce dietary instructions; n=30 Usual protein diet (no higher than 1.2 g/kg/day); n=33	Allocation Concealment: Unclear Blinding: None Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes

Appendix Evidence Table C101. Overview of low protein diet versus usual protein diet and other dietary intervention trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	mg/day (overt nephropathy)* Exclusion Criteria: absence of nephropathy; ESRD (GFR<15 mL/min); pregnancy; cachexy, body mass index >33 *Note: 87% microalbuminuria	Serum creatinine (mg/dL): 1.1 Creatinine clearance (mL/min): NR Albuminuria (mg/d): 366 (320 for n=41 with microalbuminuria; 680 for n=6 with microalbuminuria) Albumin/creatinine ratio (mg/g): NR GFR (ml/min/1.73m ²): 85.7 HbA _{1c} (%): 8.1 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): NR Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): 14.9 History of AKI (%): NR	All participants in both groups received either ACEI or ARB treatment at study onset and throughout diet treatment course. Followup period: 2 years Study withdrawals (%): 25.4	
Kopple, 1997 ⁶⁷ Peterson, 1995 ⁶² Klahr, 1994 ⁶³ Greene, 1993 ⁶⁸ Modification of Diet in Renal Disease (MDRD) Study A only (GFR 25 to 55 ml/min/1.73m ²) United States Funding Source: Government	Inclusion Criteria: age 18-70 years; serum creatinine 1.4-7.0 mg/dl (men) or 1.2-7.0 mg/dl (women) or other objective evidence of kidney disease; mean arterial pressure (MAP) ≤125 mmHg; GFR 25-55 ml/min/1.73m ² ; urinary protein excretion <10g/day; protein intake >0.90g/kg/day Exclusion Criteria: insulin-dependent diabetes or fasting serum glucose >200 mg/dl; dialysis; kidney transplant recipient; lactating or pregnant woman or planning to become pregnant in time frame of study; doubtful compliance; body weight <80% or >160% of standard weight; serum albumin <3.0g/dl; selected renal disorders (UTI, renal artery stenosis, branched or staghorn calculi); serious medical	N=585 (end of baseline values reported where available) Age (yr): 52.6 Gender (Male %): 61.0 Race/Ethnicity (%): 84.6 white, 9.1 black, 4.3 Hispanic, 2.1 other Weight: 81.0 kg BMI: 27.6 Systolic BP (mm Hg): 131 Diastolic BP (mm Hg): 81 Mean arterial pressure (mm Hg): 98 CKD Stage: NR Serum creatinine (mg/dL): 1.9 Creatinine clearance (ml/min/1.73m ²): 50.4 Albuminuria: NR Proteinuria (g/day/1.73m ²): 0.18 (Females), 0.35 (Males) Albumin/creatinine ratio (mg/g): NR GFR (ml/min/1.73m ²): 38.6 HbA _{1c} (%): NR Total cholesterol (mg/dL): 218.2 LDL cholesterol (mg/dL): 148.4	Low protein diet (0.58g/kg/day); n=291 (140 to usual MAP, 151 to low MAP) Usual diet (1.3 g/kg/day); n=294 (145 to usual MAP, 149 to low MAP) Followup period: mean 2.2 years Study withdrawals (%): 1.9% lost to followup; 14.3% reached stop point including 10% with rapidly declining GFR, 2% with renal failure and 2% with other serious medical condition NOTE: 2 x 2 factorial	Allocation Concealment: Adequate Blinding: Double (for followup GFRs) Intention to Treat Analysis (ITT): Unclear Withdrawals/Dropouts adequately described: Yes

Appendix Evidence Table C101. Overview of low protein diet versus usual protein diet and other dietary intervention trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	conditions (NYHA class 3 or 4 HF, lung disease, liver disease, GI disease, chronic systemic infection, collagen vascular disease, frequent hospitalization or disability); immunosuppressive agents (including corticosteroids in excess of replacement dosage for ≥2 months/yr); gold or penicillamine in past month; >20 tablets salicylates per week; other NSAIDS >3 times/week in past 2 months; investigational drugs; allergy to iothalamate or iodine; inability or unwilling to give consent	Diabetes (%): NR Diabetic nephropathy (%): 2.9 History of HTN (%): 85.3 History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): 13.7 History of AKI (%): NR	design with usual (MAP=107 mmHg) or low (MAP=92mmHg) goal	
D'Amico, 1994 ⁶⁹ Italy Funding Source: Government	Inclusion Criteria: Consecutive patients with chronic renal insufficiency attending outpatient clinic; age >18; creatinine clearance between 70 and 15 ml/min stable or moderate decline over past 3 months; no evidence of potentially reversible diseases; not affected by systemic illness (including diabetes); no nephrotic syndrome (proteinuria >3g/24h and serum albumin <2.5 g/dl); no drugs in past 6 months that might alter natural history of disease; informed consent given Exclusion Criteria: none stated	N=134 (baseline data reported for 128 completers only) Age (yr): 54 Gender (Male %): 61 Race/Ethnicity (%): NR Weight: NR BMI: NR Systolic BP (mm Hg): NR Diastolic BP (mm Hg): NR Mean BP (mmHg): 115 CKD stage: NR Serum creatinine (mg/dL): NR Creatinine clearance (mL/min): 33 Albuminuria: NR Proteinuria (g/24 hr): 1.5 Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 0 (by inclusion criteria) History of HTN (%): NR Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR	Low protein diet (0.6 g/kg lean body weight/day) plus energy supplement of 35 kcal/kg daily; phosphate restricted to 0.26 mmol/kg; n=63 (analyzed) Control (1.0 g/kg lean body weight/day) plus 30 kcal/kg/day; phosphate restricted to 0.42 mmol/kg; n=65 (analyzed) Followup period: mean of 2.3 years Study withdrawals (%): 4.5% (6 withdrew at beginning of trial – group not specified)	Allocation Concealment Unclear Blinding: None Intention to Treat Analysis (ITT): No Withdrawals/ Dropouts adequately described: No

C-185

Appendix Evidence Table C101. Overview of low protein diet versus usual protein diet and other dietary intervention trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR		
Locatelli, 1991 ¹⁰ Northern Italy Cooperative Study Group Italy Funding Source: Not reported	Inclusion Criteria: ages 18 to 65 years; outpatients; plasma creatinine from 1.5 (men) or 1.35 (women) to 7.0 mg/dl, GFR <60ml/min (Cockcroft formula); written consent Exclusion Criteria: nephrotic syndrome (serum albumin <2.5 g/dl, proteinuria >3 g/l); ideal body weight <45 kg or >90 kg; diabetes; recent MI; acute renal failure; acute obstruction and infection of urinary tract; systemic diseases; previous gastrointestinal resection surgery; doubling of plasma creatinine during 3 month preliminary observation period	N=456 Age (yr): 48.5 Gender (Male %): 54.2 Race/Ethnicity (%): NR Weight: NR BMI: NR Systolic BP (mm Hg): NR Diastolic BP (mm Hg): NR CKD stage: NR Serum creatinine (mg/dL): NR Creatinine clearance (mL/min): NR Albuminuria: NR Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 0 (by exclusion criteria) History of HTN (%): NR Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): 0 (by exclusion criteria)	Low protein diet (0.6 g/kg ideal body weight) with energy supplement of 35 kcal/kg daily; phosphate restricted to 0.26 mmol/kg; n=230 Control (1.0 g/kg/ideal body weight) with energy supplement of 30 kcal/kg daily; phosphate restricted to 0.42 mmol/kg; n=226 Followup period: 2 years or until endpoint reached Study withdrawals (%): 15.6	Allocation Concealment Adequate Blinding: Not reported Intention to Treat Analysis (ITT): No Withdrawals/ Dropouts adequately described: Yes
Rosman, 1989/1984 ^{71,72} United Kingdom Funding Source: Foundation	Inclusion Criteria: nephrology outpatients who visited clinic between 1/1/82 and 4/1/84; creatinine clearance between 10 and 60 ml/min/1.73m ² or less; no lethal disease Exclusion Criteria: lupus erythematosus, active vasculitis and Wegener's disease	N=136 in 1984 publication (reported on subjects who entered study before 1/1/1984); N=151 in 1989 publication (reported on subjects who entered study before 4/1/1984). Inclusion here only of subgroup with creatinine clearance >30 and ≤60 ml/min/1.73m ² . Baseline data reported only for a subset of participants with 18 month followup data in 1984 paper, with sample size not stated: Weight: 72 kg (low protein); 70 kg (usual)	Low protein diet (0.6g/kg/day); n=74 Usual diet; n=77 NOTE: all patients received a vitamin and trace element preparation Followup period: minimum of 1.5 years for 1984 publication; minimum of 3	Allocation Concealment: Unclear Blinding: None reported Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: No

Appendix Evidence Table C101. Overview of low protein diet versus usual protein diet and other dietary intervention trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		Systolic BP (mm Hg): 140 (both groups) Diastolic BP (mm Hg): 90 (both groups) Serum albumin (g/l): 42 (both groups) Creatinine excretion (mmol/l in 24 hr): 10.4 (low protein), 11.0 (usual)	years for 1989 publication Study withdrawals (%): 4% for n=153 with 3 years followup (1989 publication)	
Facchini, 2003 ³ United States Funding Source: Not reported	Inclusion Criteria: Type 2 diabetes referred to nephrology clinics for renal failure (GFR 15-75 ml/min) and otherwise unexplained proteinuria (350-12,000 mg/day) Exclusion Criteria: None stated	N=191 Age (yr): 59.5 Gender (Male %): 53.0 Race/Ethnicity (%): NR Weight: 78 kg reported for CR-LIPE group, 79 kg for Control (for subset of completers, number per group not reported) BMI: 28 Systolic BP (mm Hg): 156 Diastolic BP (mm Hg): 88 CKD stage: NR Serum creatinine (mg/dL): 1.84 Creatinine clearance (mL/min): NR Albuminuria: NR Proteinuria: 2,469 mg/day Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m ²): 63.0 HbA _{1c} (%): 7.6 Total cholesterol: 5.6 mmol/l for subset of completers with fasting lipids LDL cholesterol: 3.6 mmol/l for subset of completers with fasting lipids Diabetes (%): 100 History of HTN (%): NR Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR	50% carbohydrate restricted, low-iron-available, polyphenol-enriched diet (CR-LIPE)† (suggested macronutrient composition: 35% CHO, 30% fat, 25-30% protein, 5-10% ethanol); n=100 Control (protein restricted (0.8g/kg/day) (suggested macronutrient composition: 65% CHO, 25% fat, 10% protein, 0% ethanol); n=91 Followup period: mean of 3.9 years Study withdrawals (%): 11 †Intended to complement angiotensin system inhibition and pharmacotherapy for glycemic and blood pressure control	Allocation Concealment: Unclear (“concealed” but no details) Blinding: Study personnel blinded to aim of study; outcomes unclear Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes
Williams, 1991 ⁴ United Kingdom Funding Source:	Inclusion Criteria: adults <70 yrs attending 1 of 2 hospital clinics; chronic renal failure (plasma creatinine >150 µmol/l for males, >150 µmol/l for women) with	N=98 Age (yr): 45.0 Gender (Male %): 66.3 Race/Ethnicity (%): NR Weight: 71.3 kg	Dietary protein (0.6g/kg/day) and phosphate (800 mg/day) restriction; n=33	Allocation Concealment: Adequate Blinding: None

Appendix Evidence Table C101. Overview of low protein diet versus usual protein diet and other dietary intervention trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Foundation	evidence of deteriorating renal function on serial plasma creatinine or creatinine clearance estimations; plasma creatinine <900 µmol/l and plasma phosphate < 2 µmol/l Exclusion Criteria: patients receiving active therapy for their primary disease; proven malignancy; psychologically unstable or noncompliant; dietary protein <0.8 g/kg/day; obese patients on a reducing diet	BMI: NR Systolic BP (mm Hg): 151 Diastolic BP (mm Hg): 90 CKD stage: NR Plasma creatinine (µmol/l): 398.1 Creatinine clearance (mL/min/1.73m ²): 26.8 Albuminuria: NR Proteinuria (g/24h): 3.15 Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): NR History of HTN (%): NR Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR	Phosphate restriction (1000 mg/day plus phosphate binders with each meal); n=30 Unrestricted (at least 0.8 g/kg/day protein); n=32 Followup period: mean 1.6 years Study withdrawals (%): 5.3 within 3 months	Intention to Treat Analysis (ITT): No Withdrawals/ Dropouts adequately described: No
Samuelsson, 1997 ⁷⁵ Sweden Funding Source: Government, Foundation	Inclusion Criteria: nondiabetic primary renal disease; moderately advanced renal insufficiency (GFR 10 to 70 ml/min/1.73m ²) Exclusion Criteria: none stated	N=57 Age (yr): 51.3 Gender (Male %): 75 Race/Ethnicity (%): NR Weight (kg): 81.4 BMI: 26.2 Systolic BP (mm Hg): 136.5 Diastolic BP (mm Hg): 84.0 CKD stage: NR Serum creatinine (mg/dL): 2.4 Creatinine clearance (mL/min): NR Albuminuria: 0.95g/24 hr Albumin/creatinine ratio (mg/g): NR GFR (ml/min/1.73m ²): 35.5 HbA _{1c} (%): NR Total cholesterol (mg/dL): 243.6 LDL cholesterol (mg/dL): 170.2 Diabetes (%): 0 (by inclusion criteria) History of HTN (%): NR	Triglyceride lowering diet (with dietary counseling), n=29 Gemfibrozil - 300mg/day increased to 300 mg twice/day after 1 month with further titration up to 450 mg twice/day at 3 months if triglyceride levels was above 1.7 mmol/l (no dietary counseling); n=28 Followup period: 1 year Study withdrawals (%): 15.8	Allocation Concealment Unclear Blinding: None Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes

Appendix Evidence Table C101. Overview of low protein diet versus usual protein diet and other dietary intervention trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		Dyslipidemia (%): unclear History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR		

Appendix Table C102. Summary of study baseline characteristics for low protein diet versus usual protein diet and other dietary intervention trials

Characteristic	Mean (Range) (unless otherwise noted)	Number of Trials Reporting
<i>Low protein versus usual protein diet trials (n=6)</i>		
Total number of patients evaluated	1480 (63-585)	6
Age of patients, years	51.9 (48.5-57.9)	5
Gender, male, %	59.3 (54.2-83.0)	5
Race/ethnicity, white, %	85.0	1
Body Mass Index	27.1 (24.6-27.6)	3
Patients with diabetes, %	21.4 (0-100)	4
Diabetic nephropathy trials, number of patients	159 (47-112)	2
% HbA _{1c} in patients with diabetes	7.8 (7.65-8.1)	2
Estimated or measured GFR, ml/min/1.73m ²	45.1 (38.6-85.7)	3
Serum creatinine, mg/dL	1.8 (1.1-1.9)	2
Creatinine clearance, ml/min/1.73m ²	47.3 (33-50.4)	2
Albumin excretion rate, µg/min	507.5	1
Albuminuria, mg/24 h	366.0	1
Systolic blood pressure, mm Hg	133.3 (131.0-140.0)	3
Diastolic blood pressure, mm Hg	81.9 (77.0-90.0)	3
Patients with hypertension, %	82.2 (66.1-85.3)	2
Patients with cardiovascular disease, %	NR	NR
<i>Low protein diet versus other diets (n=2)</i>		
Total number of patients evaluated	289 (98-191)	2
Age of patients, years	54.6 (45-59.5)	2
Gender, male, %	56.7 (52.9-64.3)	2
Race/ethnicity, white, %	NR	NR
Body Mass Index	28	1
Patients with diabetes, %	100	1
Diabetic nephropathy trials, number of patients	191	1
% HbA _{1c} in patients with diabetes	7.6	1
Estimated or measured GFR, ml/min/1.73m ²	63	1
Serum creatinine, mg/dL	1.84	1
Creatinine clearance, ml/min/1.73m ²	NR	NR
Albumin excretion rate, µg/min	NR	NR
Albuminuria, mg/24 h	NR	NR
Systolic blood pressure, mm Hg	154.3 (151-156)	2
Diastolic blood pressure, mm Hg	88.7 (88-90)	2
Patients with hypertension, %	NR	NR
Patients with cardiovascular disease, %	NR	NR
<i>Low triglyceride diet versus gemfibrozil (n=1)</i>		
Total number of patients evaluated	57	1
Age of patients, years	51.3	1
Gender, male (%)	75.4	1
Race/ethnicity, white (%)	NR	NR
Body Mass Index	26.2	1
Patients with diabetes (%)	0	1
Estimated or measured GFR (ml/min/1.73m ²)	35.5	1
Serum creatinine (mg/dL)	2.4	1
Creatinine clearance (ml/min/1.73m ²)	NR	NR
Albumin excretion rate (µg/min)	NR	NR
Albuminuria (mg/24 h)	950.0	1
Systolic blood pressure (mm Hg)	136.5	1
Diastolic blood pressure (mm Hg)	84	1
Patients with hypertension (%)	NR	NR
Patients with cardiovascular disease, %	NR	NR

*NR=Not reported

Appendix Table C103. Clinical outcomes (outcomes part A), low protein diet versus usual protein diet and other dietary intervention trials

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any n/N (%)	
	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein
Low protein diet versus usual protein diet trials (n=6)												
Koya, 2009 ⁶⁵	1/47 (2.1)	1/41 (2.4)					0/47	1/41 (2.4)				
Dussol, 2005 ⁶⁶												
Kopple, 1997 ⁶⁷	5/291 (1.7)	10/294 (3.4)	4/291 (1.4)	5/294 (1.7)								
Peterson, 1995 ⁶²												
Klahr, 1994 ⁶³												
Greene, 1993 ⁶⁸												
MDRD												
D'Amico, 1994 ⁶⁹												
Locatelli, 1991 ⁷⁰	2/230 (0.9)	3/226 (1.3)										
Rosman, 1989/1984 ^{71,72}	4/74 (5.4)	7/77 (9.1)										
Low protein diet versus other diet trials (n=2)												
	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet
Facchini, 2003 ⁷³	14/79 (17.7)	8/91 (8.8)										
Williams**, 1991 ⁷⁴	†1/31 (3.0)	†Lo-Phos: 4/29 (13.3); †Control: 1/29 (3.1)										
Low triglyceride diet versus gemfibrozil (GF) trials (n=1)												
	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF
Samuelsson, 1997 ⁷⁵												

GF = gemfibrozil; TG = triglyceride

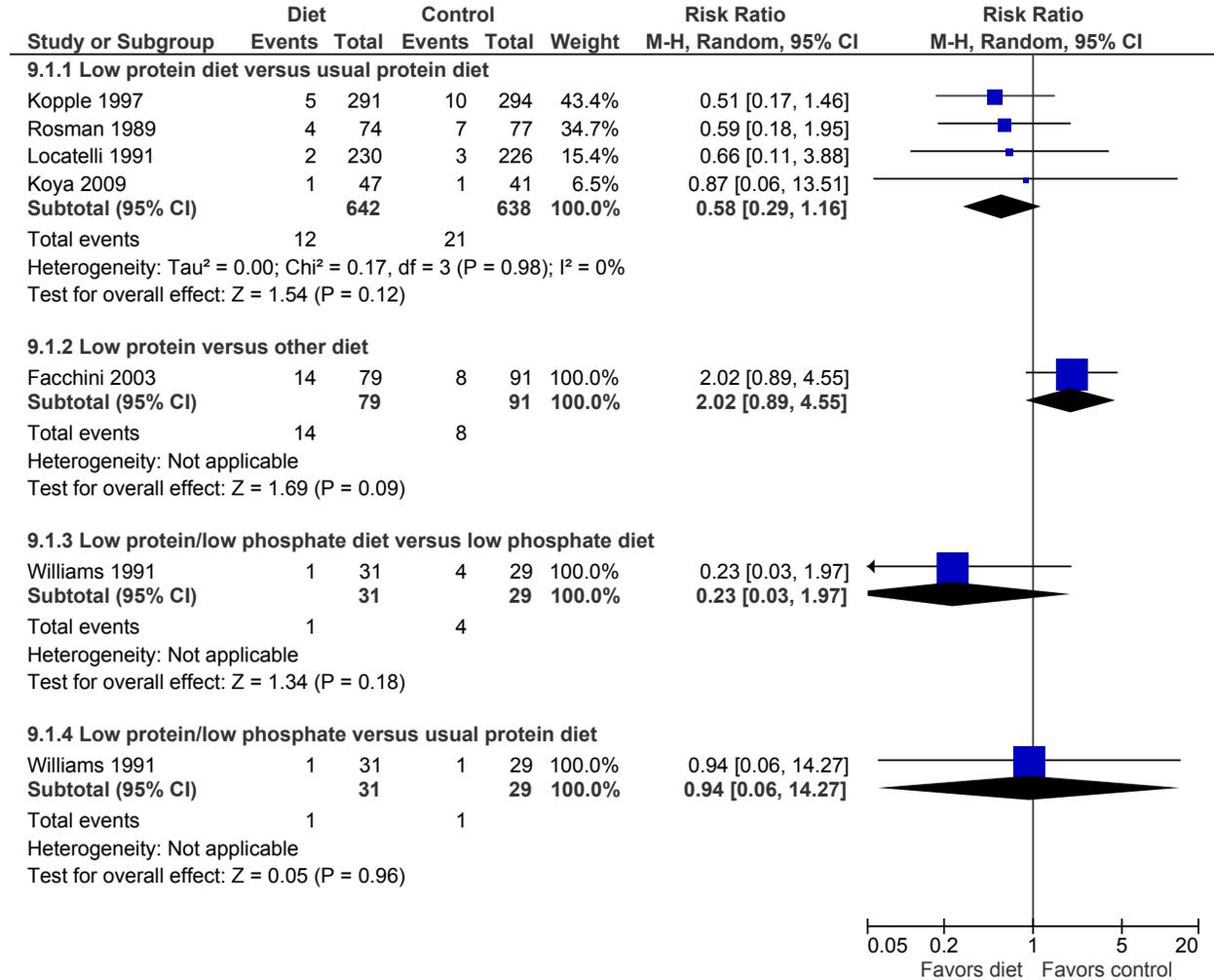
* p < 0.05 versus control

†Study also reported one death that occurred during the first 3 months of post-randomization followup, that they excluded from outcomes analyses, and for which they didn't report original treatment group assignment.

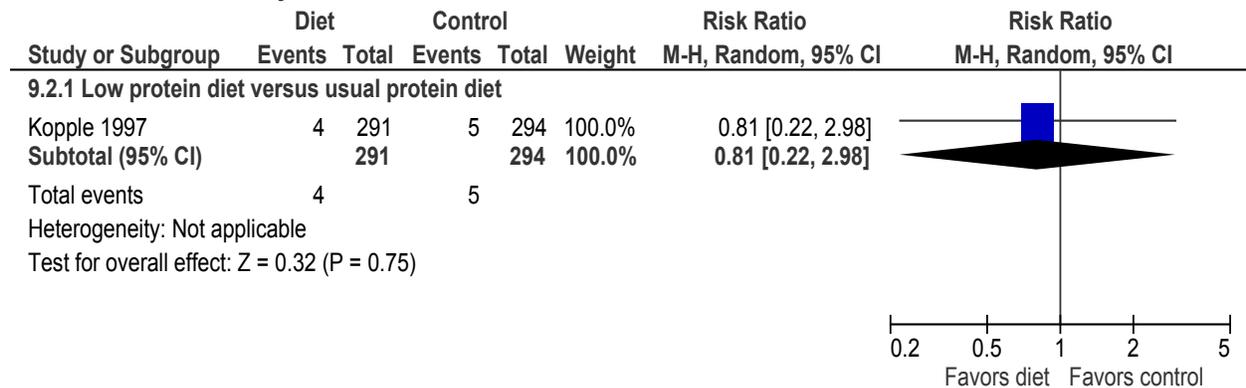
**Study compared a low protein and low phosphate diet to two different diets, a low phosphate diet, and a usual protein/usual phosphate diet.

Appendix Figure C20. Forest plots for low protein diet versus usual protein diet and other dietary intervention trials

All-cause mortality

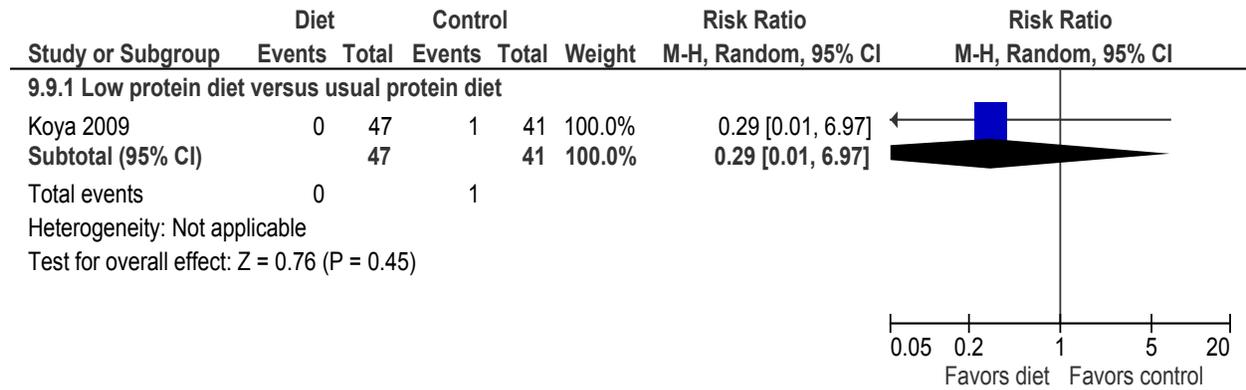


Cardiovascular mortality

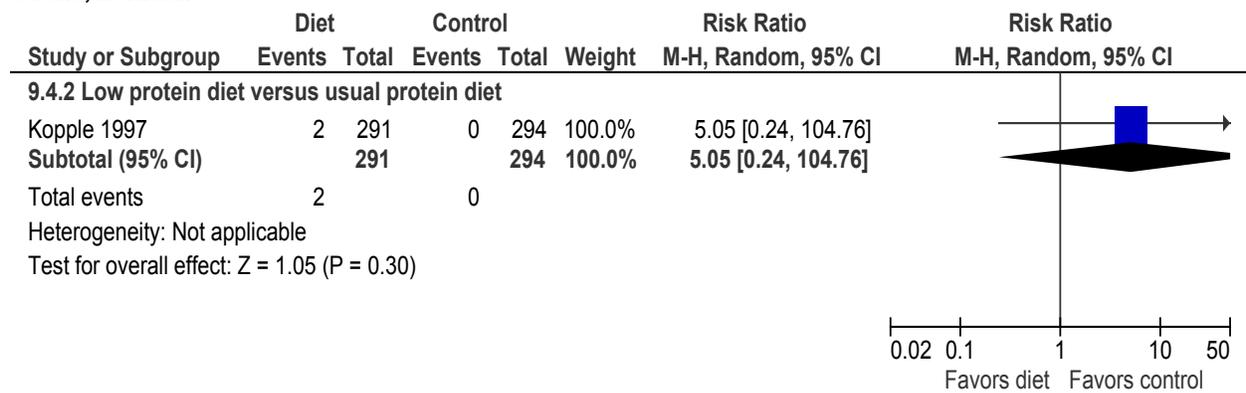


Appendix Figure C20. Forest plots for low protein diet versus usual protein diet and other dietary intervention trials (continued)

MI, fatal

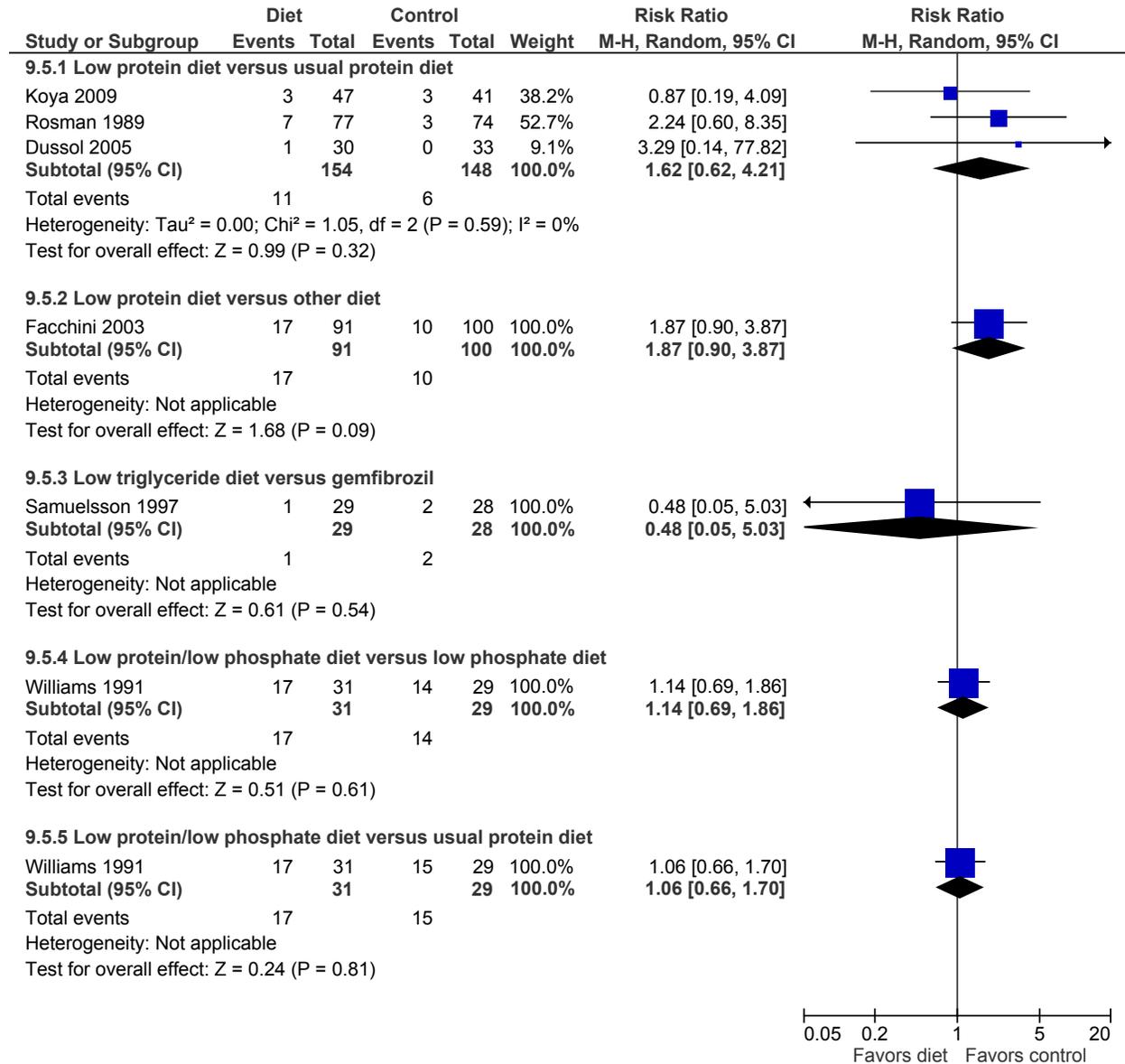


Stroke, nonfatal



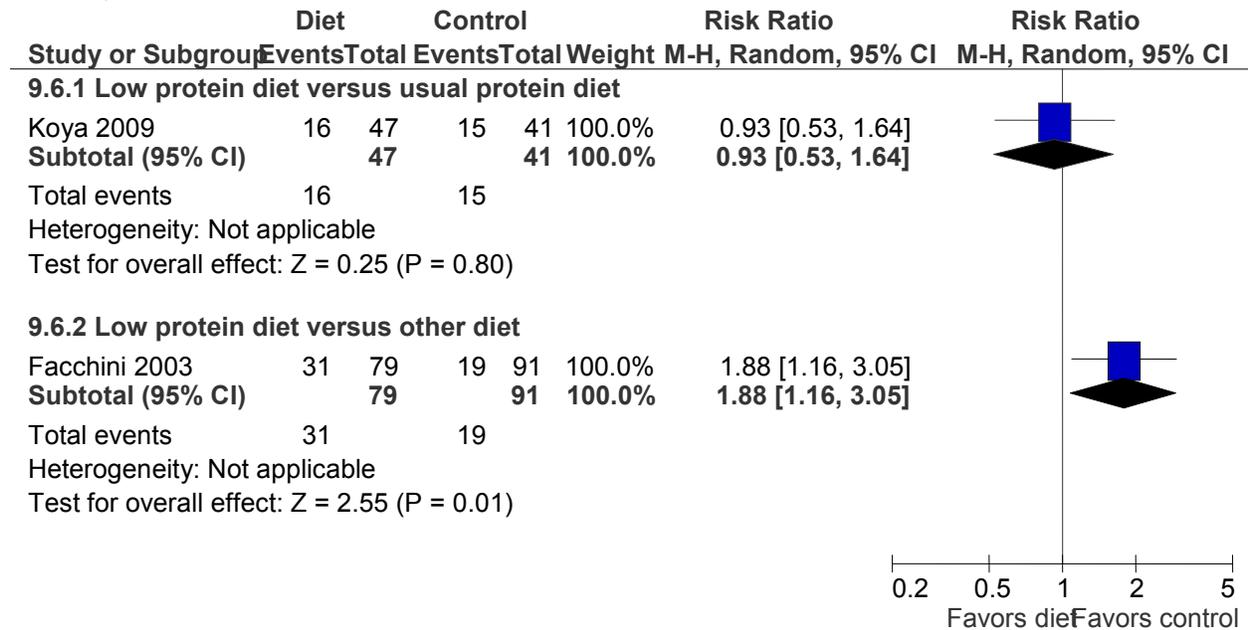
Appendix Figure C20. Forest plots for low protein diet versus usual protein diet and other dietary intervention trials (continued)

End-stage Renal Disease

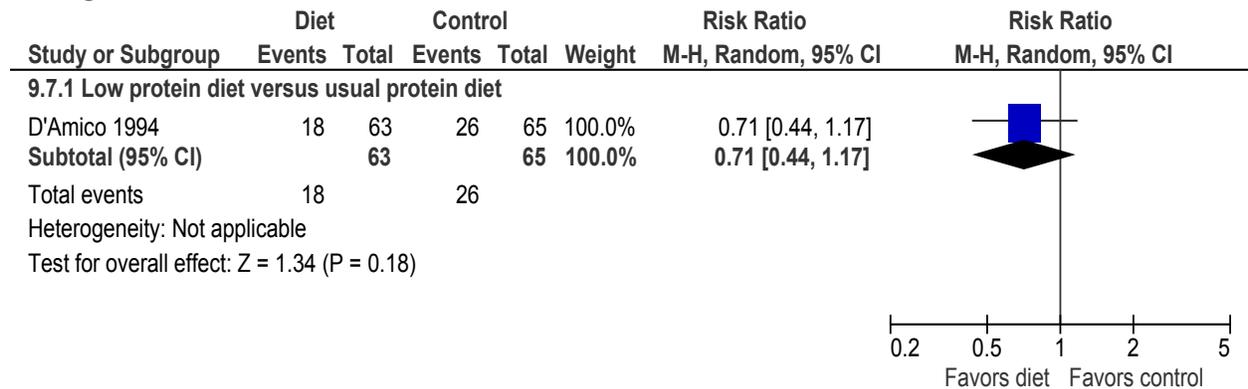


Appendix Figure C20. Forest plots for low protein diet versus usual protein diet and other dietary intervention trials (continued)

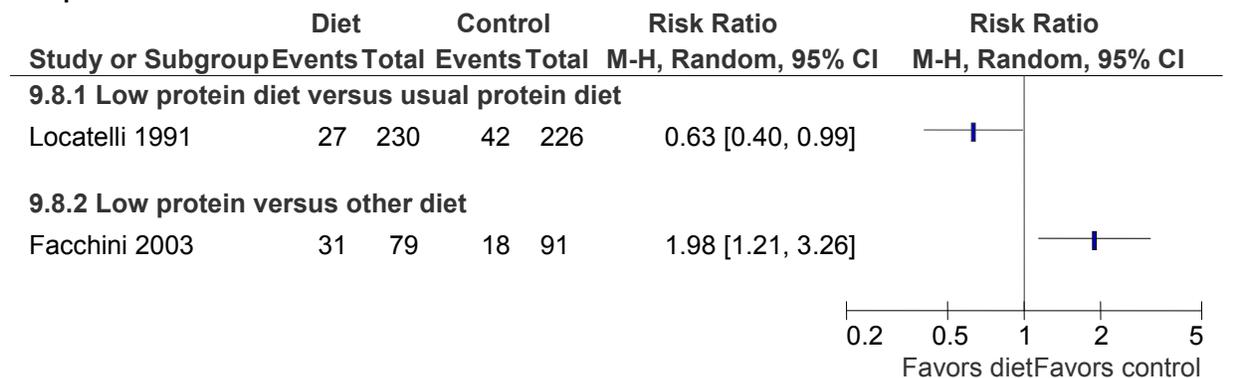
Doubling of serum creatinine



Halving of GFR



Composite renal outcome



Appendix Table C104. Clinical outcomes (outcomes part B), low protein diet versus usual protein diet and other dietary intervention trials

Study	Stroke, Nonfatal n/N (%)		Stroke, Fatal n/N (%)		CHF, Any n/N (%)		CHF Hospitalization (A) or Death (B) n/N (%)		Composite Vascular Outcome n/N (%)	
	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein
<i>Low protein diet versus usual protein diet trials (n=6)</i>										
Koya, 2009 ⁶⁵										
Dussol, 2005 ⁶⁶										
Kopple, 1997 ⁶⁷	2/291 (0.7)	0/294								
Peterson, 1995 ⁶²										
Klahr, 1994 ⁶³										
Green, 1993 ⁶⁸										
MDRD										
D'Amico, 1994 ⁶⁹										
Locatelli, 1991 ⁷⁰										
Rosman, 1989/1984 ^{71,72}										
<i>Low protein diet versus other diet trials (n=2)</i>										
	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet
Facchini, 2003 ⁷³										
Williams, 1991 ⁷⁴										
<i>Low triglyceride diet versus GF trials (n=1)</i>										
	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF
Samuelsson, 1997 ⁷⁵										

CHF = congestive heart failure; TG = triglyceride; GF = gemfibrozil

Appendix Table C105. Clinical renal outcomes (outcomes part C), low protein diet versus usual protein diet and other dietary intervention trials

Study	End Stage Renal Disease n/N (%)		Doubling of Serum Creatinine n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome n/N (%)	
	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein
Low protein diet vs. usual protein diet trials (n=6)										
Koya, 2009 ⁶⁵	3/47 (6.4)	3/41 (7.3)	16/47 (34.0)	15/41 (36.6)						
Dussol, 2005 ⁶⁶	1/30 (3.3)	0/33								
Kopple, 1997 ⁶⁷	†NR	†NR			†NR	†NR				
Peterson, 1995 ⁶²										
Klahr, 1994 ⁶³										
Greene, 1993 ⁶⁸ MDRD										
D'Amico, 1994 ⁶⁹					‡18/63 (28.6)	‡26/65 (40.0)				
Locatelli, 1991 ⁷⁰									27/230 (11.7)	42/226 (18.6)
Rosman, 1989/1984 ^{71,72}	7/77 (9.1)	3/74 (4.1)								
Low protein diet versus other diet trials (n=2)										
	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet	Low Protein	Other Diet
Facchini, 2003 ^{§3}	17/79 (21.5)	10/91 (11.0)	31/79 (39.2)	19/91 (20.9)					31/79 (39.2)	18/91 (19.8)
Williams, 1991 ^{#4}	17/31 (54.8)	Lo-Phos: 14/29 (48.3) Control: 15/29 (51.7)								
Low triglyceride diet versus GF trials (n=1)										
	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF
Samuelsson, 1997 ¹⁵	1/29 (3.4)	2/28 (7.1)								

GFR = glomerular filtration rate; NR = not reported; TG = triglyceride; GF = gemfibrozil; Lo-Phos = low phosphate diet

*Not statistically significant versus control

†Study reported that 12 participants developed end stage renal disease but did not report this result separately for the two treatment groups. Study further reported that 60 patients overall reached a study stopping point due to “rapidly declining glomerular filtration rate.” Although study did not report this result separately for the two treatment groups, it did state that there was no significant difference between the results for the two groups.

‡Study reported on outcome of halving of creatinine clearance.

§Facchini study compared a low protein diet to a CR-LIPE diet (Carbohydrate Restricted, Low-Iron-available, Polyphenol-Enriched).

#Williams study compared a low protein and low phosphate diet to two different diets, a low phosphate diet, and a usual protein/usual phosphate diet.

Appendix Table C106. Study withdrawals and adverse events (outcomes part D), low protein diet versus usual protein diet and other dietary intervention trials

Study	Study Withdrawals: Any, n/N (%)		Serious Adverse Event: Any n/N (%)		Study Withdrawals Due to Serious Adverse Event: Any, n/N (%)		Adverse Event: Any, n/N (%)		Adverse Event: Specific n/N (%)		Renal Adverse Events n/N (%)	
	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein	Low Protein	Usual Protein
<i>Low protein diet versus usual protein diet trials (n=6)</i>												
Koya, 2009 ⁶⁵	9/56 (16.1)	15/56 (26.8)										
Dussol, 2005 ⁶⁶	5/30 (16.7)	7/33 (21.2)										
Kopple, 1997 ⁶⁷ Peterson, 1995 ⁶² Klahr, 1994 ⁶³ Greene, 1993 ⁶⁸ MDRD	†NR	†NR							‡“Stop point due to serious medical condition”: 6/291 (2.1); Weight loss 29%; Weight gain 25%; Hyperkalemia 10%	‡“ Stop point due to serious medical condition”: 6/294 (2.0); Weight loss 18%; Weight gain 40%; Hyperkalemia 17%	ARF: 1/291 (0.3)	ARF: 0/294
D’Amico, 1994 ⁶⁹	§NR	§NR										
Locatelli, 1991 ⁷⁰	36/230 (15.7)	35/226 (15.5)										
Rosman, 1989/1984 ^{71,72}	3/77 (3.9)	3/74 (4.1)										
<i>Low protein diet versus other diet trials (n=2)</i>												
	Low Protein	Other Diet	Low Protein	CR-LIPE Diet	Low Protein	CR-LIPE Diet	Low Protein	CR-LIPE Diet	Low Protein	CR-LIPE Diet	Low Protein	CR-LIPE Diet
Facchini, 2003# ⁷³	12/91 (13.2)	9/100 (9.0)										
Williams, 1991** ⁷⁴	††NR	††NR										

Appendix Table C106. Study withdrawals and adverse events (outcomes part D), low protein diet versus usual protein diet and other dietary intervention trials (continued)

Study	Study Withdrawals: Any, n/N (%)		Serious Adverse Event: Any n/N (%)		Study Withdrawals Due to Serious Adverse Event: Any, n/N (%)		Adverse Event: Any, n/N (%)		Adverse Event: Specific n/N (%)		Renal Adverse Events n/N (%)		
	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	Low TG Diet	GF	
<i>Low triglyceride diet versus GF trials (n=1)</i>													
Samuelsson, 1997 ⁷⁵	0/29	6/28 (21.4)								"Mild GI symptoms": 0/29	"Mild GI symptoms": 6/28 (21.4)		

NR = not reported; ARF = acute renal failure; GF = gemfibrozil

*p<0.05 versus control

†Study reported that 11/585 participants overall were lost to followup, but didn't report results by treatment group.

‡Specific causes of stop points due to serious medical condition were as follows, by treatment group: Low protein diet (pregnancy (1), stroke (2), acute renal failure (1), diabetes necessitating insulin (1), and cancer (1); and Usual protein diet (diabetes necessitating insulin (3), cardiomyopathy (1), cancer (1), severe liver disease (1).

§Study reported that 6/134 (4.5%) participants withdrew overall, but didn't report results by treatment group.

#Facchini study compared a low protein diet to a CR-LIPE diet (Carbohydrate Restricted, Low-Iron-available, Polyphenol-Enriched).

**Williams study compared a low protein and low phosphate diet to two different diets, a low phosphate diet, and a usual protein/usual phosphate diet.

††Study reported that 6/95 patients were withdrawn from the trial overall but didn't report results by treatment group.

Appendix Evidence Table C107. Overview of glycemc control trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Duckworth, 2009 ⁷⁶ VADT Multi-center United States Funding Source: Government, Foundation, and Industry	Inclusion: Veterans with type 2 diabetes inadequately controlled on maximal doses of an oral agent or insulin therapy. Exclusion: Glycated hemoglobin <7.5%, cardiovascular event during previous 6 months, advanced congestive heart failure, severe angina, live expectancy <7 years, BMI >40, serum creatinine >1.6 mg/dL, alanine aminotransferase >3 times upper limit of normal	N=491 (subgroup analysis of subjects with baseline microalbuminuria from overall study of N=1,791) Age (yr): NR Gender (Male %): NR Race/Ethnicity (%): NR Weight (kg): NR BMI: NR Systolic BP (mm Hg): NR Diastolic BP (mm Hg): NR CKD stage: NR Serum creatinine (mg/dL): NR Creatinine clearance (mL/min): NR Albuminuria (µg/min): NR Proteinuria (g/day): NR Albumin/creatinine ratio (mg/g): NR GFR (ml/min/1.73m ²): NR HbA _{1c} (%): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): NR Dyslipidemia (%): NR History of previous cardiovascular event (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR	Intensive therapy (n=251): Started on maximal doses of oral therapy*; insulin added if patients did not achieve glycated hemoglobin <6%. Subsequent changes per protocol and local assessment, though not specified. Standard therapy (n=240): Started on ½ of maximal doses of oral therapy*; insulin added if patients did not achieve glycated hemoglobin <9%. Subsequent changes per protocol and local assessment, though not specified. *Initial oral therapy was metformin plus rosiglitazone if BMI ≥27; initial therapy was glimepiride plus rosiglitazone if BMI <27 Followup period: median 5.6 years Study withdrawals (%): Reported for overall study, but not for microalbuminuria subgroup	Allocation Concealment: Adequate Blinding: No Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes
Microalbuminuria Collaborative Study Group, 1995 ⁷⁷	Inclusion Criteria: Insulin dependent diabetic patients attending 9 hospital-based diabetes centers; ages 16-60; onset of diabetes before	N=70 Age (yr): 37.0 Gender (Male %): 72.9 Race/Ethnicity (%): NR	Intensive therapy (n=36): Insulin by continuous infusion or multiple daily injections; goals were	Allocation Concealment: Adequate (central location)

Appendix Evidence Table C107. Overview of glycemc control trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
United Kingdom Funding Source: Government and Foundation	<p>age 39; sitting BP <160/95 mm Hg; no antihypertensive treatment; no clinical evidence of cardiovascular, peripheral vascular, or renal disease. Subjects must further have had no albuminuria on urine dipstick, but have had morning urine albumin ≥ 15 mg/L or albumin-creatinine ratio ≥ 3.5 mg/mmol, followed by overnight urine albumin excretion rate $>30\mu\text{g}/\text{min}$ but $<200\mu\text{g}/\text{min}$ on at least 1 of 2 samples.</p> <p>Exclusion Criteria: none stated</p>	<p>Weight (kg): NR BMI: 26.0 Systolic BP (mm Hg): 127.5 Diastolic BP (mm Hg): 77.5 CKD stage: NR Serum creatinine (mg/dL): 0.97 Creatinine clearance (mL/min): NR Albuminuria ($\mu\text{g}/\text{min}$): 47.9 Proteinuria (g/day): NR Albumin/creatinine ratio (mg/g): NR GFR (ml/min/1.73m²): 116.7 HbA_{1c} (%): 10.1 Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): NR Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): 47.1 History of AKI (%): NR</p>	<p>glycated hemoglobin concentration $\leq 7.5\%$, fasting blood glucose 4-6 mmol/l, and 2 hr postprandial blood glucose ≤ 10 mmol/l. Frequent visits and medication adjustment were made as needed to achieve targets. 24 hr/day consultation available if needed.</p> <p>Conventional therapy (n=34): 2 daily injections of insulin (except for 9 patients who were receiving >2 doses insulin per day at baseline); Conventional education given about diet, exercise and blood glucose monitoring, but no targets set. Insulin dose and regimen was adjusted only if patients became symptomatic.</p> <p>No changes were made to the usual diabetic diet of any patient. BP was assessed every 3 months, and all patients were treated to keep BP $<160/95$.</p> <p>Followup period: median 5 years</p> <p>Study withdrawals (%): 11.4</p>	<p>Blinding: Unclear</p> <p>Intention to Treat Analysis (ITT): Yes</p> <p>Withdrawals/Dropouts adequately described: Yes</p>

Appendix Table C108. Summary of study baseline characteristics for glycemic control trials

Characteristic	Mean (Range) (unless otherwise noted)	Number of Trials Reporting
Patients randomized, n	561 (70-491)	2
Age of subjects, years	37.0	1
Male gender, %	72.9	1
Body Mass Index, kg/m ²	26.0	1
Patients with diabetic nephropathy, n	561 (70-491)	2
Serum creatinine, mg/dL	0.97	1
Estimated GFR, ml/min/1.73m ²	116.7	1
Albuminuria, µg/min	47.9	1
Systolic blood pressure, mm Hg	127.5	1
Diastolic blood pressure, mm Hg	77.5	1
History of diabetes, %	100 (100-100)	2
HbA _{1c} (%)	10.1	1
Current smokers, %	47.1	1

GFR = glomerular filtration rate; HbA_{1c} = hemoglobin A_{1c}

Appendix Table C109. Clinical outcomes (outcomes part A), glycemic control trials

Study	All-cause Mortality n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any n/N (%)	
	IT	CT	IT	CT	IT	CT	IT	CT	IT	CT	IT	CT
Duckworth, 2009 ⁷⁶												
Microalbuminuria Collaborative, 1995 ⁷⁷	*NR	*NR										

IT = intensive treatment; CT = conventional treatment

*Study reported 1/70 (1.4%) deaths overall, but did not report this result by treatment group. included in withdrawals

Appendix Table C110. Clinical renal outcomes (outcomes part C), glycemic control trials

Study	End Stage Renal Disease, n/N (%)		Doubling of Serum Creatinine, n/N (%)		Halving of GFR n/N (%)		Progression from Micro- to Macroalbuminuria n/N (%)		Composite Renal Outcome, n/N (%)	
	IT	CT	IT	CT	IT	CT	IT	CT	IT	CT
Duckworth, 2009 ⁷⁶							19/251 (7.6)	29/240 (12.1)		
Microalbuminuria Collaborative, 1995 ⁷⁷							6/36 (16.7)	6/34 (17.6)		

GFR = glomerular filtration rate; IT = intensive treatment; CT = conventional treatment

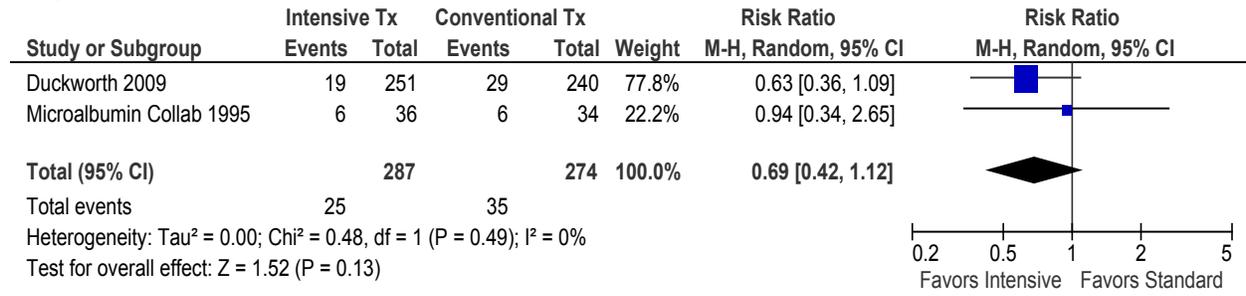
Appendix Table C111. Composite vascular outcome definitions, glycemic control trials

Study	Definition
Microalbuminuria Collaborative Study Group, 1995 ⁷⁷	First major cardiovascular event, which included MI, stroke, cardiovascular death, new or worsening CHF, surgery for cardiac, cerebrovascular or peripheral vascular disease, inoperable CAD, and amputation for ischemic gangrene.

MI = myocardial infarction; CHF = congestive heart failure; CAD = coronary artery disease

Appendix Figure C21. Forest plot for glycemic control trials

Progression from Micro to macroalbuminuria



Appendix Table C112. Study withdrawals and adverse events (outcomes part D), glycemic control trials

Study	Study Withdrawals: Any, n/N (%)		Serious Adverse Events: Any n/N (%)	Study Withdrawals Due to Serious Adverse Events: Any, n/N (%)		Adverse Event: Any n/N (%)		Adverse Event: Specific, n/N (%)		Renal Adverse Event: Any, n/N (%)	
	IT	CT		IT	CT	IT	CT	IT	CT	IT	CT
Duckworth, 2009 ⁷⁶								Severe hypoglycemia: 5/36 (13.9); DKA: 3/36 (8.3)	Severe hypoglycemia: 5/34 (14.7); DKA: 2/34 (5.9)		
Microalbuminuria Collaborative, 1995 ⁷⁷	5/36 (13.9)	3/34 (8.8)		*NR	*NR						

IT = intensive treatment; CT = conventional treatment; DKA = diabetic ketoacidosis

*Study reported 3/70 (4.3%) withdrawals due to serious adverse events overall (1 death, 1 leukemia, 1 acute renal failure), but did not report these outcomes by treatment group.

Appendix Evidence Table C113 Overview of anti-lipid trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
HMG-CoA Reductase Inhibitor versus Placebo trials				
Kendrick, 2010 ⁷⁸ AFCAPS/TexCA PS United States Funding Source: Industry and other	Inclusion Criteria: Men aged 45-73 years or postmenopausal women aged 55-73 years who met the lipid entrance criteria at both 4 and 2 weeks before randomization with a <15% difference in LDL-C values between visits. Lipid entry criteria included total cholesterol 180-264 mg/dL, LDL-C 130-190 mg/dL, HDL-C ≤ 45 mg/dL for men or ≤ 47 mg/dL for women, and triglycerides ≤ 400 mg/dL. Exclusion Criteria: Clinical evidence atherosclerotic CVD, secondary hyperlipoproteinemia, nephrotic syndrome, uncontrolled HTN, and type 1 or 2 diabetes mellitus.	N=304 (Post hoc analysis in subgroup with baseline GFR < 60 ml/min/ 1.73m ² from total of 6605 randomized). Age (yr): 62 Gender (Male %): 79 Race/Ethnicity (%): White NR, Mexican American NR, African American 1 BMI: 26 Systolic BP (mm Hg): 142 Diastolic BP (mm Hg): 79 Albuminuria (mg/24 h): NR Serum creatinine (mg/dL): 1.4 Estimated GFR (ml/min/1.73m ²): 53 Total cholesterol (mg/dL): 222 LDL cholesterol (mg/dL): 151 Diabetes (%): 2 History of HTN (%): 35 (p<0.05 between groups) History of CAD (%): 0 History of CHF (%): NR History of MI (%): 0 PTCA (%): 0 CABG (%): 0 History of Stroke (%): NR Peripheral arterial disease (%):NR Current smoker (%): 8	Lovastatin initiated at 20 mg/d, titrated up to 40 mg/d to reach goal LDL ≤110 mg/dL (n=145) Placebo (n=159) Followup period: mean 5.1 years Study withdrawals (%): No information reported for CKD group; stated both that all had complete data and that 24% of original AFCAPS/TexCAPS participants did not have data to calculate yearly change in GFR.	Allocation Concealment: Unclear Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis (ITT): yes Withdrawals/ Dropouts adequately described: Study reported available followup data on all participants
Nakamura, 2009 ⁷⁹ MEGA Japan Funding Source: Government and industry	Inclusion Criteria: Men and postmenopausal women aged 40-70 years with total cholesterol 220-270 mg/dL and no history of CHD and/or stroke. Exclusion Criteria: Familial hypercholesterolemia, history of CVD, cancer, serum creatinine ≥1.5 mg/dL, significant liver disease, and secondary hyperlipidemia	N=2,978 (Secondary analysis in subgroup with baseline GFR 30 to 59 ml/min/ 1.73m ² from total of 7,196 patients randomized). Age (yr): 60 Gender (Male %): 24 Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): 133 Diastolic BP (mm Hg): NR Albuminuria (mg/24 h): NR Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): 53 Total cholesterol (mg/dL): 244 LDL cholesterol (mg/dL): 155	Pravastatin (low dose) 10-20 mg/d + Step I diet counseling (n=1471) Diet counseling (n=1,507) Followup period 5.3 years Study withdrawals (%): No information reported	Allocation Concealment: Adequate (from main paper) Blinding: open-label Intention to Treat Analysis (ITT): yes Withdrawals/ Dropouts adequately described: No information reported

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		Diabetes (%): 19 History of HTN (%): 46 History of CAD (%): 0 History of CHF (%): NR History of MI (%): 0 PTCA (%): 0 CABG (%): 0 History of stroke (%): 0 Peripheral arterial disease (%): NR Current smoker (%): 13		
Colhoun, 2009 ⁸⁰ CARDS	Inclusion Criteria: Diabetes and at least 1 of the following risk factors: (1) history of HTN, (2) retinopathy (i.e., any retinopathy, maculopathy, or prior photocoagulation), (3) microalbuminuria (urinary albumin/creatinine ratio 22 to 221 mg/g) or microalbuminuria (urinary albumin/creatinine ratio >221 mg/g), or (4) current smoking.	N=970 (Secondary analysis in subgroup with baseline GFR <60 ml/min/ 1.73m ² from total of 2,838 randomized)	Atorvastatin 10 mg/d (n=482)	Allocation Concealment: Adequate (from main paper)
United Kingdom and Ireland		Age (yr): 65 Gender (Male %): 48 Race/Ethnicity (%): white 96 BMI: NR Systolic BP (mm Hg): NR Diastolic BP (mm Hg): NR Albuminuria (% > Micro): 21 Albumin/creatinine ratio: 10 Serum creatinine (mg/dL): 1.3 Estimated GFR (ml/min/1.73m ²): 54 Total cholesterol (mg/dL): 211 LDL cholesterol (mg/dL): 120 Diabetes (%): 100 History of HTN (%): NR History of CAD (%): 0 History of CHF (%): NR History of MI (%): 0 PTCA (%): 0 CABG (%): 0 History of Stroke (%): 0 Peripheral arterial disease (%): NR Current smoker (%): NR	Placebo (n=488)	Blinding: double, end points adjudicated by blinded committee
Funding Source: Industry			Followup period: median 3.9 years	Intention to Treat Analysis (ITT): yes
	Exclusion Criteria: History of MI, angina, coronary vascular surgery, cerebrovascular accident, or severe peripheral vascular disease (defined as warranting surgery); creatinine concentration > 1.7 mg/dL or glycated hemoglobin (hemoglobin A1c) level >12%.		Study withdrawals (%): No information reported	Withdrawals/ Dropouts adequately described: No information reported
Koren, 2009 ⁸¹	Inclusion Criteria: Male or female older than 18 years of age with known CHD, defined as prior acute MI, CABG, or unstable angina >3 months before screening, or PTCA >6 months before screening. LDL-C 110-200 mg/dL for patients on antilipid drugs or 130-250 mg/dL for	N= 579 (Secondary analysis in subgroup with baseline GFR <60 ml/min/ 1.73m ²) from total of 2,442 randomized).	Atorvastatin, started at 10 mg/day, then titrated up to achieve LDL goal of <80 mg/dL up to maximum of 80 mg/day (n=286)	Allocation Concealment: Adequate
Isaacsohn, 2000 ⁸² ALLIANCE		Age (yr): 65 Gender (Male %): 77 Race/Ethnicity (%): white 88; African American 9 BMI: 29	Usual care (n=293)	Blinding: open-label
United States				Intention to Treat Analysis (ITT): yes

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Funding Source: Industry	patients receiving no antilipid drugs. Exclusion Criteria: Patients with chronic stable angina or awaiting revascularization procedures. Breastfeeding or pregnancy; women of childbearing age planning to become pregnant during the study or who did not practice a method of birth control acceptable to the investigator; any significant abnormalities investigator believed may compromise the patient's safety or successful completion of the study; any disease process likely to limit life to less than the duration of the study; all cancers (excluding basal cell and squamous cell skin cancers); New York Heart Association class III or IV congestive heart failure; known hypersensitivities to hydroxymethylglutaryl coenzyme A reductase inhibitors.	Systolic BP (mm Hg): 137 Diastolic BP (mm Hg): 78 Albuminuria (mg/24 h): NR Serum creatinine (mg/dL): 1.5 Estimated GFR (ml/min/1.73m ²): 51 Total cholesterol (mg/dL): 228 LDL cholesterol (mg/dL): 147 Diabetes (%): 28 History of HTN (%): NR History of CAD (%): 100 History of CHF (%): 10 History of MI (%): 62 PTCA (%): 33 CABG (%): 53 History of Stroke (%): 10 Peripheral arterial disease (%): NR Current smoker (%): 15	Followup period: median 4.5 years Study withdrawals (%): 19% (n=465/2,442) withdrawals from main study, but data not reported for CKD subgroup.	Withdrawals/Dropouts adequately described: No information reported.
Rahman, 2008 ³⁵ ALLHAT-LLT United States, Puerto Rico, U.S. Virgin Islands, and Canada Funding: Government and Industry	Inclusion Criteria: age ≥55 years and stage 1 or 2 hypertension with at least 1 additional CHD risk factor); fasting LDL-C level of 120-189 mg/dL for those with no known CHD, or 100-129 mg/dL for those with known CHD, and fasting triglyceride levels lower than 350 mg/dL. Exclusion Criteria: currently using prescribed lipid-lowering agents or large doses (500 mg/day) of nonprescription niacin; were known to be intolerant of statins or to have significant liver dysfunction (serum alanine aminotransferase >100 IU/L); had other contraindications for statin therapy; or had a known secondary cause of hyperlipidemia.	N=1,557 (Secondary analysis in subgroup with baseline GFR < 60 ml/min/1.73m ²) from total of 10,060 randomized). Age (yr): 71 Gender (Male %): 46 Race/Ethnicity (%): white 51 , black 29, Hispanic 15 BMI: 29 Systolic BP (mm Hg): 146 Diastolic BP (mm Hg): 82 Albuminuria (mg/24 h): NR Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): 50 Total cholesterol (mg/dL): 225 LDL cholesterol (mg/dL): 146 Diabetes, type 2 (%): 31 History of HTN (%): 100 History of CAD (%): 18 History of CHF (%): NR History of MI or Stroke (reported pooled %	Pravastatin 40 mg/d (n=779) Usual care (n=778) Followup period: mean 4.8 years Study withdrawals (%): No information reported	Allocation Concealment: Unclear Blinding: open-label Intention to Treat Analysis (ITT): yes Withdrawals/Dropouts adequately described: No information reported

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Chonchol, 2007 ⁸⁴ 4S Trial	Inclusion criteria: Men and women aged 35-70 yrs, with history of CHD (MI and/or angina), total cholesterol 212-309 mg/dL, triglycerides <221 mg/dL	only): 22.0 History of coronary revascularization: 9 Peripheral arterial disease (%): NR Current smoker (%): 19 N=505 (Subgroup analysis of patients with eGFR <60 mL/min/1.73m ² performed within a post hoc analysis of patients with eGFR <75 mL/min/1.73m ² from the 4,420 with baseline creatinine measurements) from total of 4,444 participants randomized in 4S Trial.	Simvastatin (n=245), initiated at 20 mg/day, titrated up to 40 mg/day as needed to get total cholesterol to <200 mg/dL	Allocation concealment: Unclear
Huskey, 2009 ⁸⁵ Scandinavia	Exclusion criteria: Secondary hypercholesterolemia, unstable angina, planned CABG or PTCA, recent MI (recent not defined), CHF requiring treatment, hypersensitivity to HMG-CoA reductase inhibitors.	Baseline characteristics not reported for n=505 participants with eGFR <60 mL/min/1.73m ² in Chonchol paper, but are reported for n=409 participants (n=199 simvastatin, n=210 placebo) with eGFR <60 mL/min/1.73m ² in Huskey paper. Age (yr): 62.2 Gender (% male): 54 BMI (kg/m ²): 25.9 Systolic BP (mm Hg): 143.1 Diastolic BP (mm Hg): 83.7 Serum creatinine (mg/dL): 1.21 Estimated GFR (mL/min/1.73m ²): 54.7 Total cholesterol (mg/dL): 265 LDL cholesterol (mg/dL): 191.5 Diabetes (%): 2.7 History of HTN (%): 37.4 History of CAD (%): 100 History of CHF (%): NR History of MI (%): 77.8 PTCA or CABG (%): 7.1 History of Stroke (%): NR Peripheral arterial disease (%):NR Current smoker (%): 16	Placebo (n=260) Followup duration: median 5.4 years Study withdrawals (%): No data reported for eGFR<60 group	Blinding: Double blind. Outcome assessors blinded to treatment assignment Intention to treat analysis (ITT): No Withdrawals/dropouts adequately described: No data reported
Kjekshus, 2007 ⁸⁶ CORONA	Inclusion Criteria: ≥60 years of age, chronic NYHA class II, III, or IV heart failure of ischemic cause (as reported by investigators) and an ejection fraction of no more than 40% (no more than 35% in patients in NYHA class II); investigator did	N=1,635 patients with CKD (Subgroup analysis within patients with baseline GFR < 51 ml/min/1.73m ² from among total of 5,011 randomized in CORONA study). Baseline characteristics not reported for CKD subjects only except for those	Rosuvastatin 10 mg/day (n=1,418) Placebo (n=1,432) Followup period: Median 2.7 years	Allocation concealment: Adequate (centralized interactive Web-based response system) Blinding: double, end points adjudicated by

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
and South Africa Funding Source: Industry	<p>not think patient needed treatment with a cholesterol-lowering drug.</p> <p>Exclusion Criteria: Previous statin-induced myopathy/hypersensitivity reaction; decompensated heart failure or need for inotropic therapy; MI within past 6 months; unstable angina or stroke within past 3 months; PCTA, CABG, or the implantation of a cardioverter-defibrillator or biventricular pacemaker within past 3 months or planned implantation of such a device; previous or planned heart transplantation; clinically significant, uncorrected primary valvular heart disease or malfunctioning prosthetic valve; hypertrophic cardiomyopathy; acute endomyocarditis or myocarditis, pericardial disease, or systemic disease (e.g. amyloidosis); acute or chronic liver disease; levels of alanine aminotransferase or thyrotropin >2 times the ULN range; a serum creatinine level >2.5 mg/dL; chronic muscle disease or unexplained creatine kinase level >2.5 times the ULN range; previous treatment with cyclosporine; any other condition that would substantially reduce life expectancy or limit compliance with the protocol; or the receipt of <80% of dispensed placebo tablets during the run-in period.</p>	<p>identifiable from entry criteria.</p> <p>Age (yr): NR Gender (Male %): NR Race/Ethnicity (%): NR BMI: NR Systolic BP (mm Hg): NR Diastolic BP (mm Hg): NR Albuminuria (mg/24 h): NR Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m²): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): NR History of HTN (%): NR History of CAD (%): 100 History of CHF (%): 100 History of MI (%): NR PTCA (%): NR CABG (%): NR History of Stroke (%): NR Peripheral arterial disease (%):NR Current smoker (%): NR</p>	<p>Study withdrawals (%): No data reported for CKD subgroup</p>	<p>blinded committee</p> <p>Intention-to-treat analysis: yes</p> <p>Withdrawals/dropouts adequately described: No data reported for CKD subgroup</p>

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Lemos, 2005 ⁵⁷ LIPS Multinational Funding Source: Industry	Inclusion Criteria: Successful completion of a first percutaneous coronary intervention (successful defined as residual stenosis <50%, no post-procedural in-hospital myocardial necrosis, repeat vascularization or death); Eligible participants had to meet at least one of the following: (1) total cholesterol level of 135 to 270 mg/dl with a fasting triglyceride level <400 mg/dl, or (2) total cholesterol level <212 mg/dl for patients whose lipids levels were measured 24 hours to 4 weeks after an episode of MI, or (3) total cholesterol level <232 mg/dl for patients who had diabetes. Exclusion Criteria: baseline serum creatinine value >1.8 mg/dl	N=310 (post hoc subgroup analysis limited to patients with creatinine clearance in the lowest quintile or <55.9 ml/min from among 1,558 subjects with complete data for creatinine clearance calculation from among 1,677 randomized participants in the LIPS study) Age (yr): 69 Gender (Male %): 67 Race/Ethnicity (%): NR BMI: 25.0 (calculated from given weight and height) Systolic BP (mm Hg): 132 Diastolic BP (mm Hg): 75 Albuminuria (mg/24 h): NR Serum creatinine (mg/dL): 1.33 Creatinine clearance (ml/min): 47 Estimated GFR (ml/min/1.73m ²): NR Total cholesterol (mg/dL): 200 LDL cholesterol (mg/dL): 131 Diabetes (%): 12 History of HTN (%): 51 History of CAD (%): 100 History of CHF (%): NR History of MI (%): 47 PTCA (%): 100 CABG (%): NR History of Stroke (%): 5 Peripheral arterial disease (%): 11 Current smoker (%): 17	Fluvastatin 40 mg twice daily (n=150) Placebo (n=160) Followup period: 3 to 4 years Study withdrawals (%): No data reported, but 100% included in endpoint analysis	Allocation Concealment: Unclear in this report Blinding: double and outcomes assessors Intention to Treat Analysis (ITT): Yes Withdrawals/ Dropouts adequately described: No data reported, but 100% included in endpoint analysis
Asselbergs, 2004 ² PREVEND IT Single center Groningen, The Netherlands Funding Source: Industry and other (Foundations)	Inclusion Criteria: Age 28-75 years, urinary albumin concentration >10 mg/L in 1 early morning spot urine sample and urine albumin excretion rate of 15 to 300 mg/24 hours in at least one of two 24-hour urine samples); BP <160/100 mm Hg and no use of antihypertensive medication; total cholesterol level <309 mg/dL, or <193 mg/dL in case of previous MI, and no use of lipid-lowering medication.	N=864 Age (yr): 51.3 Gender (Male %): 65.0 Race/Ethnicity (%): white 96.1 BMI: 26.4 Systolic BP (mm Hg): 130.5 Diastolic BP (mm Hg): 76.5 Albuminuria (mg/24 h): 22.8 Serum creatinine (mg/dL): 1.0 Estimated GFR (ml/min/1.73m ²): NR Total cholesterol (mg/dL): 224 LDL cholesterol (mg/dL): 156 Diabetes (%): 2.6	Pravastatin 40 mg/d (n=433) Placebo (n=431) Followup period: mean 3.8 years Study withdrawals (%): NR. Study reported 199 (23.0%) withdrawals excluding deaths, but included 56 for "other	Allocation Concealment: Yes Blinding: double, end points adjudicated by blinded committee Intention to Treat Analysis: yes Withdrawals/Dropouts adequately described: yes

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	Exclusion Criteria: creatinine clearance <60% of the normal age adjusted value; use of ACE inhibitors or ARB antagonists.	History of HTN (%): 0 History of CAD (%): 3.3 History of CHF (%): 0 History of MI (%): 0.5 CABG or PTCA (%): 0.8 History of Stroke (%): 0.8 Peripheral arterial disease (%): 0.6 Current smoker (%): 39.9	medical reasons," which included but were not entirely comprised of subjects reaching study endpoints. Note: 2 x 2 factorial design with fosinopril 20 mg/day versus placebo	
Tonelli, 2004 ⁸⁸ WOSCOPS/ CARE/ LIPID Multinational Funding Source: Not stated in current report	Entry Criteria: WOSCOPS studied high-risk patients who had not previously experienced an MI. Excluded baseline creatinine >1.7 mg/dL CARE and LIPID were trials of subjects with previous acute coronary syndromes and average cholesterol levels. Excluded baseline creatinine levels of >2.5 mg/dL and >4.5 mg/dL, respectively. Current report restricted to subjects with GFR 30-59.99 ml/min/1.73m2 using Cockcroft-Gault formula. No further information on entry criteria provided.	N=4,491 (post hoc subject-level pooling of results in patients with GFR 30-59.99 mL/min per 1.73m2 body surface area from 19,700 subjects in three previously completed RCTs comparing pravastatin 40 mg/day to placebo, i.e. CARE, WOSCOPS and LIPID studies) Age (yr): 65.7 Gender (Male %): 81.7 Race/Ethnicity (%): NR BMI: 25.5 Systolic BP (mm Hg): 135.5 Diastolic BP (mm Hg): 79.5 Albuminuria (mg/24h):NR Serum creatinine (mg/dL): 1.4 Estimated GFR (ml/min/1.73m2, per MDRD): 55.0 Total cholesterol (mg/dL): 221.3 LDL cholesterol (mg/dL): 151.5 Diabetes (%): 9.9 History of HTN (%): 44.8 History of CAD (%): 73.7 History of CHF (%): NR History of MI (%): 67.6 PTCA (%): NR CABG (%): NR History of Stroke (%): 5.3 Peripheral arterial disease (%): NR Current smoker (%): 10.3	Pravastatin 40 mg/d (n=2217) Placebo (n=2,274) Followup period: approximately 5 years Study withdrawals (%): No data reported	Allocation Concealment: Not described in current report Blinding: double and outcomes assessors Intention to Treat Analysis (ITT): unclear Withdrawals/Dropouts adequately described: Not described in current report
Tonelli, 2003 ⁸⁹ CARE Multicenter	Inclusion Criteria: Men and post-menopausal women, 21-75 years, had acute MI 3-20 months before randomization, total plasma cholesterol <240 mg/dL; LDL 115-	N= 1,711 (post hoc subgroup analysis limited to patients with creatinine clearance ≤75 mL/min from among 4,159 randomized participants in the CARE study) Age (yr): 64.3	Pravastatin , 40 mg/d (n=844); Placebo (n=867)	Allocation Concealment: Yes Blinding: double

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Funding Source: Industry	174 mg/dL; triglyceride <350 mg/dL; fasting glucose <220 mg/dL, LVEF ≥25%; no symptomatic CHF. All lipid measures collected after 4 weeks treatment with National Cholesterol Education Program Step 1 diet. Exclusion Criteria: ≥2+ proteinuria on dipstick or serum creatinine >1.5 times upper limit of normal	Gender (Male %): 78.4 Race/Ethnicity (%): White 91.9, Other 8.1 BMI: NR Systolic BP (mm Hg): 131.0 Diastolic BP (mm Hg): 77.3 Proteinuria (dipstick positive, %): 31 Serum creatinine (mg/dL): 1.26 Creatinine clearance (ml/min): 61 Total cholesterol (mg/dL): 209.0 LDL cholesterol (mg/dL): 138.6 HDL cholesterol (mg/dL): 40.6 Diabetes (%): 13.9 History of HTN (%): 47.2 History of CAD (%): 100 History of CHF (%): 9.6 History of MI (%): 100 PTCA (%): NR CABG (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): 12.3	Followup Period: 4.9 yr Study withdrawals (%): No participants were lost to followup and 100% were included in analyses	Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes
High versus Low Dose HMG-CoA Reductase Inhibitor trials (n=1)				
Shepard, 2008 ⁹⁰ TNT	Inclusion Criteria: Men and women aged 35 to 75 years with clinically evident CHD (defined as previous myocardial infarction, previous or current angina with objective evidence of atherosclerotic CHD, or a history of coronary revascularization). LDL 130-250 mg/dL and triglycerides ≤600 mg/dL off anti-lipid drugs, with LDL <130 mg/dL after 8 week open label run-in on atorvastatin 10 mg/d.	N=3,107 (Post hoc analysis of subjects with eGFR <60 ml/min/1.73 m ² from among 10,003 randomized in TNT trial; 3,078 had CKD stage 3 (GFR 30-59) and 29 had CKD stage 4 (GFR 15-29) Age (yr): 65.5 Gender (Male %): 67.7 Race/Ethnicity (%): white 95.2; black 1.6, other 3.2 BMI: 28.5 Systolic BP (mm Hg): 133.0 Diastolic BP (mm Hg): 77.5 Albuminuria (mg/24 h):NR Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): 52.9 Total cholesterol (mg/dL): 175.9 LDL cholesterol (mg/dL): 96.4 Diabetes (%): 17.6 History of HTN (%): 62.7 History of CAD (%): 100 History of CHF (%): 12.2	Atorvastatin 10 mg/d (n=1505) Atorvastatin 80 mg/d (n=1602) Followup period: median 5 years Study withdrawals (%): 0.4	Allocation Concealment: unclear Blinding: double-blind, end points adjudicated by blinded committee Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes
La Rosa, 2005 ⁹¹ Waters, 2004 ⁹² Multinational Funding Source: Industry	Exclusion criteria: hypersensitivity to statins; active liver disease or hepatic dysfunction defined as alanine aminotransferase or aspartate aminotransferase >1.5 times the ULN; women who are pregnant or breastfeeding; nephrotic syndrome; uncontrolled DM; uncontrolled			

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	hypothyroidism; uncontrolled HTN (defined by the investigator) at the screening visit; a MI, coronary revascularization procedure or severe/unstable angina within 1 month of screening; any planned surgical procedure for the treatment of atherosclerosis; an ejection fraction <30%; hemodynamically important valvular disease; gastrointestinal disease limiting drug absorption or partial ileal bypass; any nonskin malignancy, malignant melanoma or other survival-limiting disease; unexplained creatine phosphokinase levels >6 times the ULN; concurrent therapy with long-term immunosuppressants; concurrent therapy with lipid-regulating drugs not specified as study treatment in the protocol; history of alcohol abuse; and participation in another clinical trial concurrently or within 30 days before screening.	History of MI (%): 57.5 PTCA (%): 50.4 CABG (%): 53.7 History of Stroke (%): 7.3 Peripheral arterial disease (%): 16.3 Current smoker (%): 9.0		
HMG-CoA Reductase Inhibitor versus Bile Acid Sequestrant trials (n=1)				
Tonolo, 2006 ⁹³ Single Center Funding Source: Other	Inclusion criteria: Type II diabetics with hemoglobin A1c >7% and proliferative or background retinopathy; hypertension (>130/85mm Hg) and microalbuminuria (median albumin/creatinine ratio between 30 and 300 µg/mg in three consecutive urine specimens), treated by angiotensin-converting enzyme inhibitors (5 mg ramipril or 20 mg lisinopril/day), 12.5 mg/day thiazides, and 100 mg/day atenolol in the last 3 years, with a glycemic control accomplished by 1,500 mg/day metformin with either three insulin analogs before meals or once daily long-acting insulin	N= 86 (Baseline characteristics reported in 82 who completed study) Age (yr): 61.5 Gender (Male %): NR Race/Ethnicity (%): NR BMI: 27.5 Systolic BP (mm Hg): 131 Diastolic BP (mm Hg): 76 Albuminuria (ug/mg): 82.5 Serum creatinine (mg/dL): NR Estimated GFR (ml/min/1.73m ²): 90.5 Total cholesterol (mg/dL): 229 LDL cholesterol (mg/dL): 149 Diabetes (%): 100 % Hemoglobin A1C: 7.35 History of HTN (%): 100 History of CAD (%): NR	Simvastatin, 40 mg/d (n=43) cholestyramine, 30 g/d (n=43) Followup Period: 4 yr Study withdrawals (%): 4 (5%)	Allocation Concealment: Unclear Blinding: double Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
	injection; a decrease of GFR >1 ml/min/1.73m ² /year had to be observed during the 3 years before the recruitment Exclusion Criteria: NR	History of CHF (%): NR History of MI (%): NR PTCA (%): NR CABG (%): NR History of Stroke (%): NR Peripheral arterial disease (%): NR Current smoker (%): NR		
<i>Gemfibrozil versus Placebo/Control trials (n=2)</i>				
Tonelli, 2004 ⁸⁸ VA-HIT Multi-center United States Funding source: Government and Industry	Inclusion criteria: Male veterans with coronary artery disease (previous MI, angina corroborated by objective evidence of ischemia, coronary revascularization, or angiographic evidence of stenosis >50% in 1+ major coronary arteries, age <74 yr, HDL ≤40 mg/dL, LDL ≤140 mg/dL, triglyceride ≤300 mg/dL Exclusion criteria: Serum creatinine > 2.0 mg/dL	N=470 (Subgroup analysis of patients with eGFR <60 mL/min/1.73m ² performed within a post hoc analysis of 1046 patients with creatinine clearance <75 mL/min/1.73m ² from the 2,505 with baseline creatinine measurements) from total of 2,531 participants randomized in VA-HIT Trial. Baseline characteristics not reported for n=470 participants with eGFR <60 mL/min/1.73m ² in Tonelli 2004 Kidney International paper, but are reported for n=399 participants (n=199 gemfibrozil, n=200 placebo) with eGFR <60 mL/min/1.73m ² in Tonelli 2004 Am J Kidney Disease paper: Age (yr): 67.4 Gender (% male): 100 Race (%): White 91.0 BMI (kg/m ²): NR Systolic BP (mm Hg): 134.0 Diastolic BP (mm Hg): 77.2 Serum creatinine (mg/dL): NR Creatinine clearance (mL/min/1.73m ²): 59.7 Estimated GFR (mL/min/1.73m ²): 52.2 Total cholesterol (mg/dL): 176 LDL cholesterol (mg/dL): 111 Diabetes (%): 30.3 History of HTN (%): 67.2 History of CAD (%): 100 History of CHF (%): 10.0 History of MI (%): NR PTCA or CABG (%): NR	Gemfibrozil 600 mg bid (n=242) Placebo (n=228) Followup period: 5.3 yr Study withdrawals (%): No participants were lost to followup	Allocation Concealment: Unclear Blinding: double Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Yes, because no subjects were lost to followup

Appendix Evidence Table C113 Overview of anti-lipid trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Samuelsson, 1997 ⁷⁵ Single Center Sweden Funding Source Government and Foundations	Inclusion Criteria: Nondiabetic primary renal disease and moderately advanced renal insufficiency (GFR 10-70 ml/min/1.73m ²) Exclusion Criteria: NR	History of Stroke (%): NR Peripheral arterial disease (%):NR Current smoker (%): 14.0 N=57 Age (yr): 51.3 Gender (Male %): 75 Race/Ethnicity (%): NR Weight (kg): 81.4 BMI: 26.2 Systolic BP (mm Hg): 136.5 Diastolic BP (mm Hg): 84.0 CKD stage: NR Serum creatinine (mg/dL): 2.4 Creatinine clearance (mL/min): NR Albuminuria: 0.95g/24 hr Albumin/creatinine ratio (mg/g): NR GFR (ml/min/1.73m ²): 35.5 HbA _{1c} (%):NR Total cholesterol (mg/dL): 243.6 LDL cholesterol (mg/dL): 170.2 Diabetes (%): 0 (by inclusion criteria) History of HTN (%): NR Dyslipidemia (%): unclear History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): NR Current smoker (%): NR History of AKI (%): NR	Gemfibrozil initiated at 300mg/day, and could be titrated up to 450 mg twice daily (n=28) Triglyceride lowering Diet (n=29) Followup Period: 1.0 yr Study withdrawals (%): 10.5	Allocation Concealment: Unclear Blinding: Open label Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes

AFCAPS/TexCAPS = Air Force/Texas Coronary Atherosclerosis Prevention Study; ALLIANCE = Aggressive Lipid-Lowering Initiation Abates New Cardiac Events; BP = blood pressure; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CCB = calcium channel blockers; CHD = coronary heart disease; CHF = Congestive Heart Failure; CORONA = Controlled Rosuvastatin Multinational Trial in Heart Failure; DM = diabetes mellitus; HTN = Hypertension; LDL = Low density lipoprotein; MI = myocardial infarction; NR = not reported; NSAIDS = Non-steroidal anti-inflammatory drug; NYHA = New York Heart Association; PTCA = percutaneous transluminal coronary angioplasty; PVD = peripheral vascular disease; ULN = upper limit of the normal.

Appendix Table C114. Summary of study baseline characteristics, anti-lipid (AL) monotherapy versus control treatment trials

Characteristic	Mean (range unless otherwise noted)	Number of Trials Reporting
<i>HMG-CoA Reductase Inhibitors versus Placebo trials</i>		
Patients randomized, n	14,193 (304-4491)*	12
Age of subjects, years	64 (51-71)	11
Gender, male, %	58 (24-82)	11
Race/ethnicity, white, %	82 (51-96)	5
Body Mass Index	26 (25-29)	9
Systolic blood pressure, mm Hg	136 (131-146)	10
Diastolic blood pressure, mm Hg	80 (75-84)	9
Albuminuria, mg/24	22.8	1
Serum creatinine (mg/dL)	1.3 (1.0-1.5)	9
Estimated GFR, ml/min/1.73m ²	53 (50 to 55)	9
Creatinine Clearance, ml/min/1.73m ²	59 (4-7-61)	2
Total Cholesterol, mg/dL	228 (200-265)	11
Low Density Lipoprotein Cholesterol, mg/dL	150 (120-192)	11
Diabetes, %	22 (2-100)	11
Hypertension, %	49 (0-100)	9
Coronary Artery Disease, %	46 (0-100)	12
Congestive Heart Failure, %	39 (0-100)	4
Myocardial Infarction, %	29 (0-100)	8
Stroke, %	1 (0-10)	7
<i>High versus Low Dose HMG-CoA Reductase Inhibitor trials</i>		
Patients randomized, n	3,107	1
Age of subjects, years	66	1
Gender, male, %	68	1
Race/ethnicity, white, %	95	1
Body Mass Index	29	1
Systolic blood pressure, mm Hg	133	1
Diastolic blood pressure, mm Hg	78	1
Albuminuria, mg/24	NR	0
Serum creatinine (mg/dL)	NR	0
Estimated GFR, ml/min/1.73m ²	53	1
Creatinine Clearance, ml/min/1.73m ²	NR	0
Total Cholesterol, mg/dL	176	1
Low Density Lipoprotein Cholesterol, mg/dL	96	1
Diabetes, %	18	1
Hypertension, %	63	1
Coronary Artery Disease, %	100	1
Congestive Heart Failure, %	12	1
Myocardial Infarction, %	58	1
Stroke, %	7	1
<i>HMG-CoA Reductase Inhibitor versus Bile Acid Sequestrant trials</i>		
Patients randomized, n	86	1
Age of subjects, years	62	1
Gender, male, %	NR	0
Race/ethnicity, white, %	NR	0
Body Mass Index	28	1
Systolic blood pressure, mm Hg	131	1
Diastolic blood pressure, mm Hg	76	1
Albuminuria, µg/mg	83	1
Serum creatinine (mg/dL)	NR	0
Estimated GFR, ml/min/1.73m ²	91	1
Creatinine Clearance, ml/min/1.73m ²	NR	0
Total Cholesterol, mg/dL	229	1
Low Density Lipoprotein Cholesterol, mg/dL	149	1

Appendix Table C114. Summary of study baseline characteristics, anti-lipid (AL) monotherapy versus control treatment trials (continued)

Characteristic	Mean (range unless otherwise noted)	Number of Trials Reporting
Diabetes, %	100	1
Hypertension, %	100	1
Coronary Artery Disease, %	NR	0
Congestive Heart Failure, %	NR	0
Myocardial Infarction, %	NR	0
Stroke, %	NR	0
<i>Gemfibrozil versus Placebo/Control trials</i>		
Patients randomized, n	527	2
Age of subjects, years	65 (51-67)	2
Gender, male, %	97 (75-100)	2
Race/ethnicity, white, %	91	1
Body Mass Index	26	1
Systolic blood pressure, mm Hg	134 (134-137)	2
Diastolic blood pressure, mm Hg	78 (77- 84)	2
Albuminuria, mg/24 hr	950	1
Serum creatinine (mg/dL)	2.4	1
Estimated GFR, ml/min/1.73m ²	50 (36-52)	2
Creatinine Clearance, ml/min/1.73m ²	60	1
Total Cholesterol, mg/dL	184 (176-244)	2
Low Density Lipoprotein Cholesterol, mg/dL	118 (111-170)	2
Diabetes, %	27 (0-30)	2
Hypertension, %	67	1
Coronary Artery Disease, %	100	1
Congestive Heart Failure, %	10	1
Myocardial Infarction, %	NR	0
Stroke, %	NR	0

AL = anti-lipid; CKD = chronic kidney disease; NR = not recorded; GFR = glomerular filtration rate

*4,491 were in pooled analysis of WOSCOP/LIPID/CARE patients with CKD. Otherwise, the largest single study of CKD patients was 2,978.

Appendix Table C115. Clinical outcomes (outcomes part A), AL monotherapy versus control treatment trials

Study	All-cause Mortality, n/N (%)		Cardiovascular Death n/N (%)		Myocardial Infarction, Any n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial Infarction, Nonfatal n/N (%)		Stroke, Any n/N (%)	
	AL	Control	AL	Control	AL	Control	AL	Control	AL	Control	AL	Control
HMG-CoA reductase inhibitors versus placebo trials (n=11)												
Kendrick, 2010 ⁷⁸ AFCAPS/ TexCAPS			0/145	1/159 (0.6)	2/145 (1.4)	6/159 (3.8)						
Nakamura, 2009 ⁷⁹ MEGA	16/1471 (2.3)*	34/1507 (4.8)									8/1471 (0.5)*	29/1507 (4.1)
Colhoun, 2009 ⁸⁰ CARDS	27/482 (5.6)	30/488 (6.1)									6/482 (1.2)*	15/488 (3.1)
Koren, 2009 ⁸¹ ALLIANCE	47/286 (16.4)	59/293 (20.1)	17/286 (5.9)	27/293 (9.2)					17/286 (5.9)	29/293 (9.9)	11/286 (3.8)	12/293 (4.1)
Rahman, 2008 ⁸³ ALLHAT-LLT												
Chonchol, 2007 ⁸⁴ 4S	37/245 (15.1)	40/260 (15.4)	§NR	§NR					§NR	§NR	§NR	§NR
Kjekshus, 2007 ⁸⁶ CORONA												
Lemos, 2005 ⁸⁷ LIPS	3/150 (2.0)	3/160 (1.9)	3/150 (2.0)	3/160 (1.9)								
Asselbergs, 2004 ² PREVD	6/433 (1.4)	4/431 (0.9)	4/433 (0.9)	4/431 (0.9)							7/433 (1.6)	4/431 (0.9)
Tonelli, 2004 ⁸⁸ WOSCOPS/ CARE/LIPID	322/2217 (14.5)	383/2274 (16.8)										
Tonelli, 2003 ⁸⁹ CARE	86/844 (10.2)	111/867 (12.8)			65/844 (7.7)	90/867 (10.4)					29/844 (3.4)	46/867 (5.3)
High versus low dose HMG-CoA reductase inhibitor trials (n=1)												
	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose
Shepherd, 2008 ⁹⁰ TNT	112/1602 (7.0)	113/1505 (7.5)										

C-219

Appendix Table C115. Clinical outcomes (outcomes part A), AL monotherapy versus control treatment (continued)

Study	All-cause Mortality, n/N (%)	Cardiovascular Death n/N (%)	Myocardial Infarction, Any n/N (%)	Myocardial Infarction, Fatal n/N (%)	Myocardial Infarction, Nonfatal n/N (%)	Stroke, Any n/N (%)
HMG-CoA reductase inhibitor versus bile acid sequestrant trials (n=1)						
Tonolo, 2006 ⁹³			‡NR	‡NR		
Gemfibrozil versus placebo/control trials (n=2)						
Tonelli, 2004 ⁸⁸	20/199	22/200				
VA-HIT	(10.1)	(11.0)				
Samuelsson, 1997 ⁷⁵						

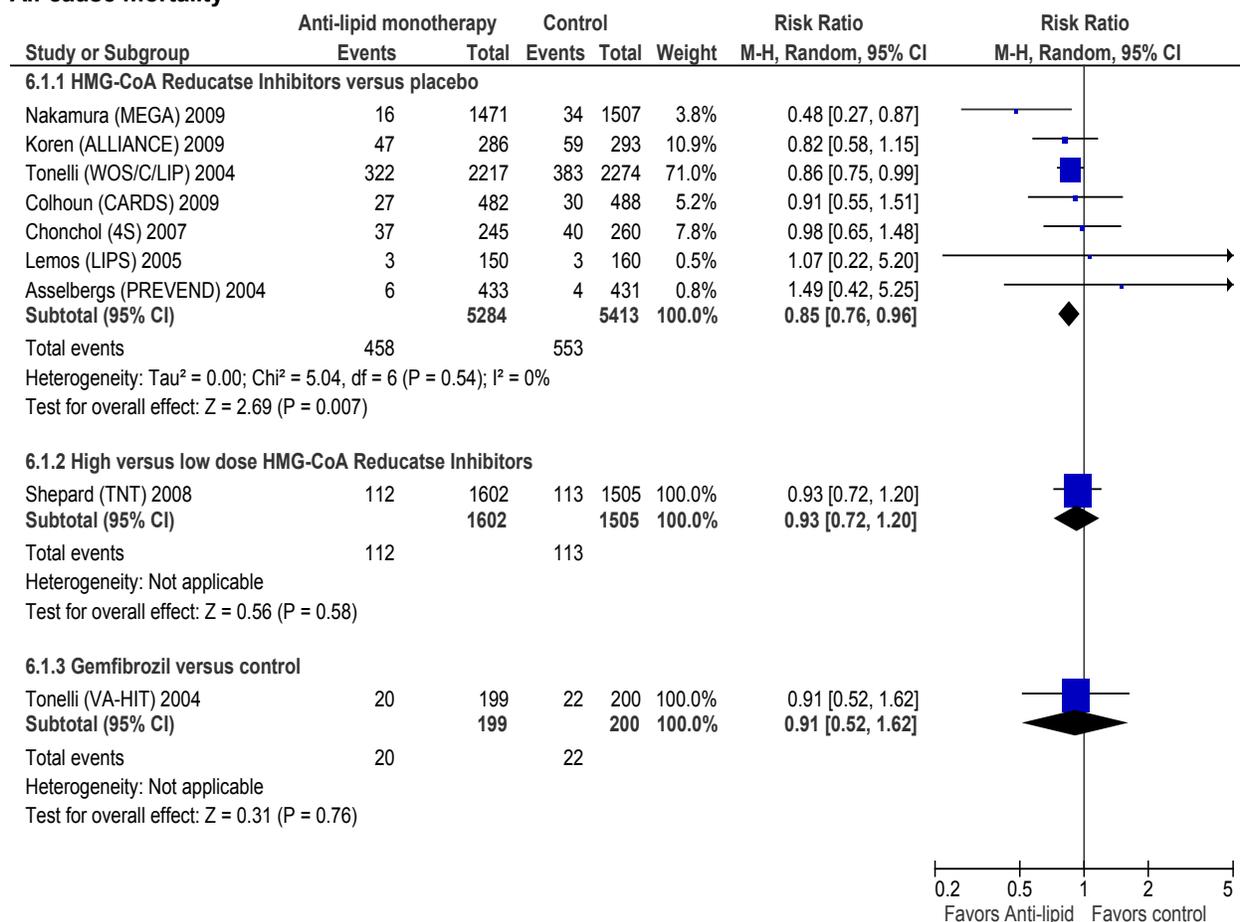
* p<0.05 versus control

‡Study reported that one participant had a myocardial infarction, but didn't indicate the patient's treatment group.

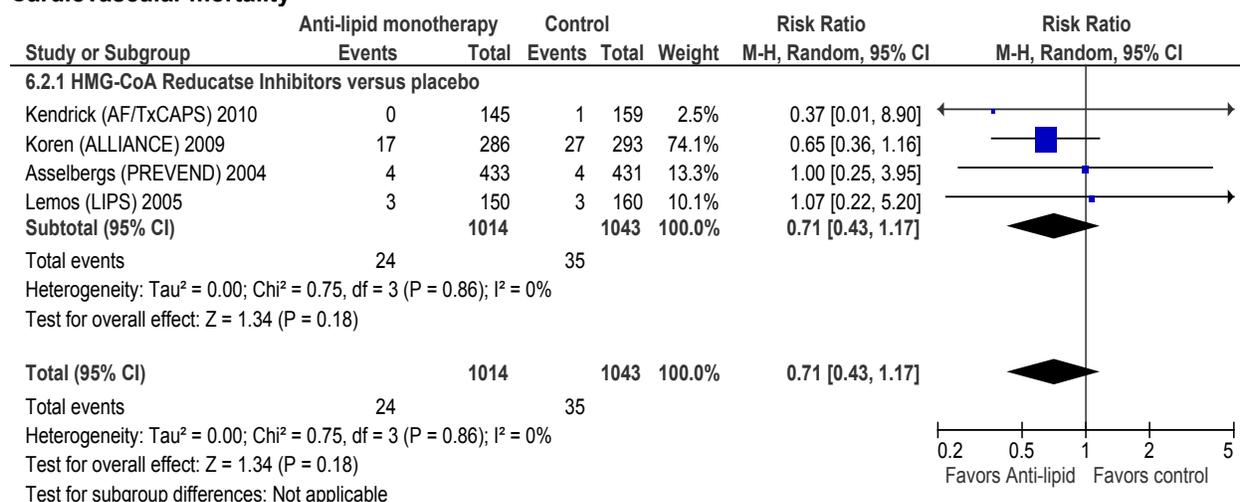
§Study did not provide the number of patients with and without the following events overall or by treatment group, but stated there was no significant difference in risk for simvastatin vs. placebo, respectively, for the following endpoints: CHD deaths (no data provided), nonfatal MI (HR 0.73, CI 0.51-1.04), and stroke (HR 1.07, CI 0.48-2.39).

Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials

All-cause mortality

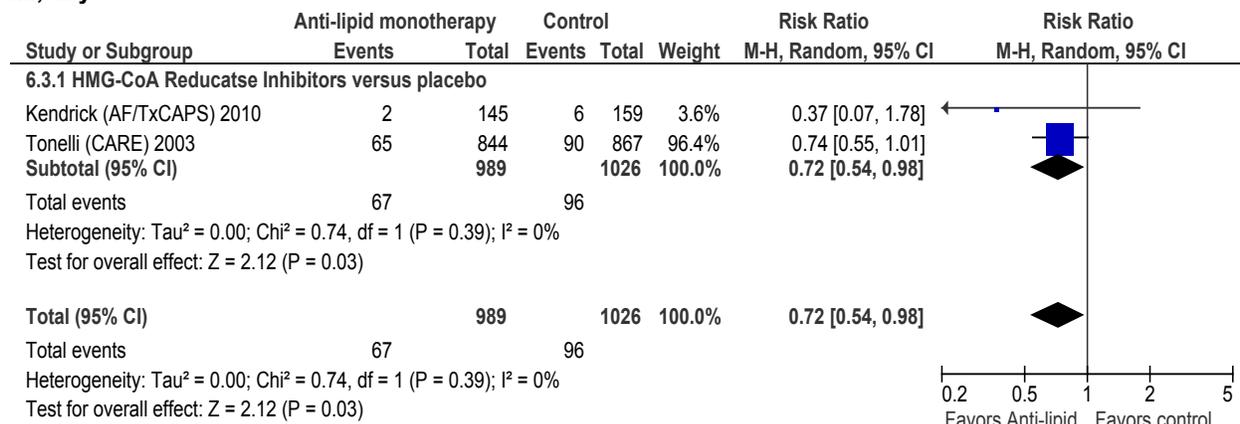


Cardiovascular mortality

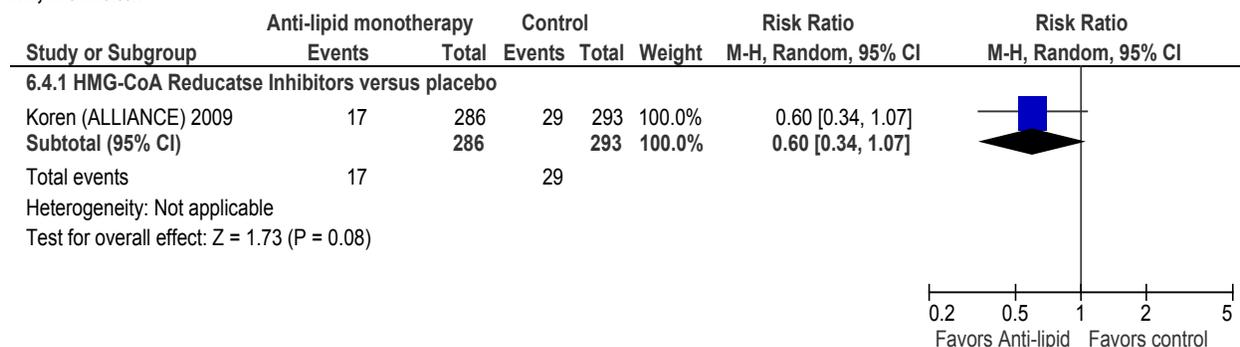


Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

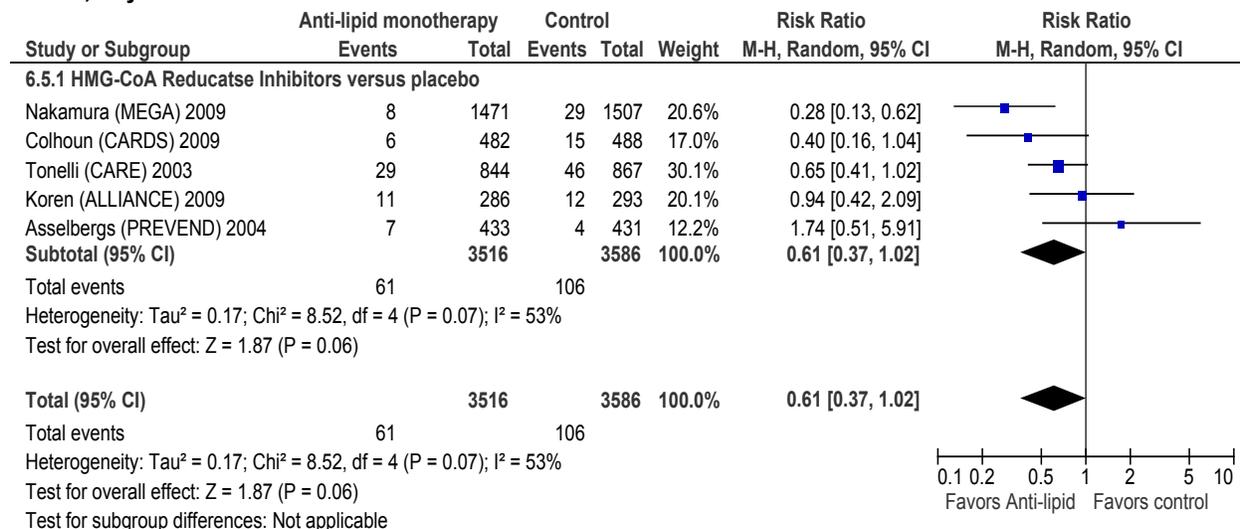
MI, any



MI, nonfatal

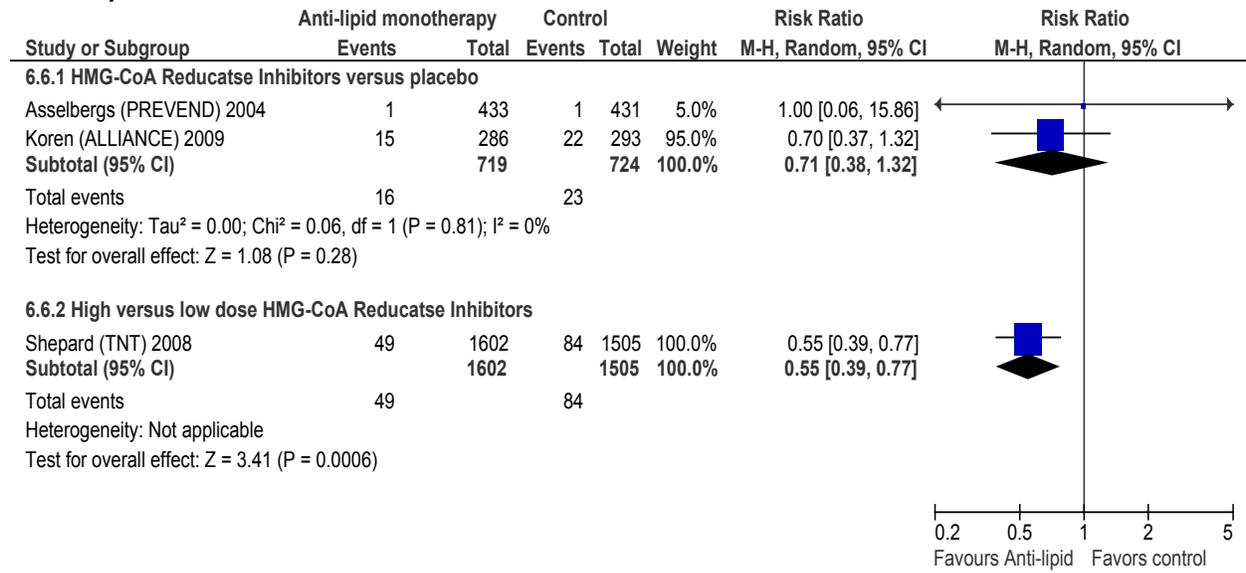


Stroke, any



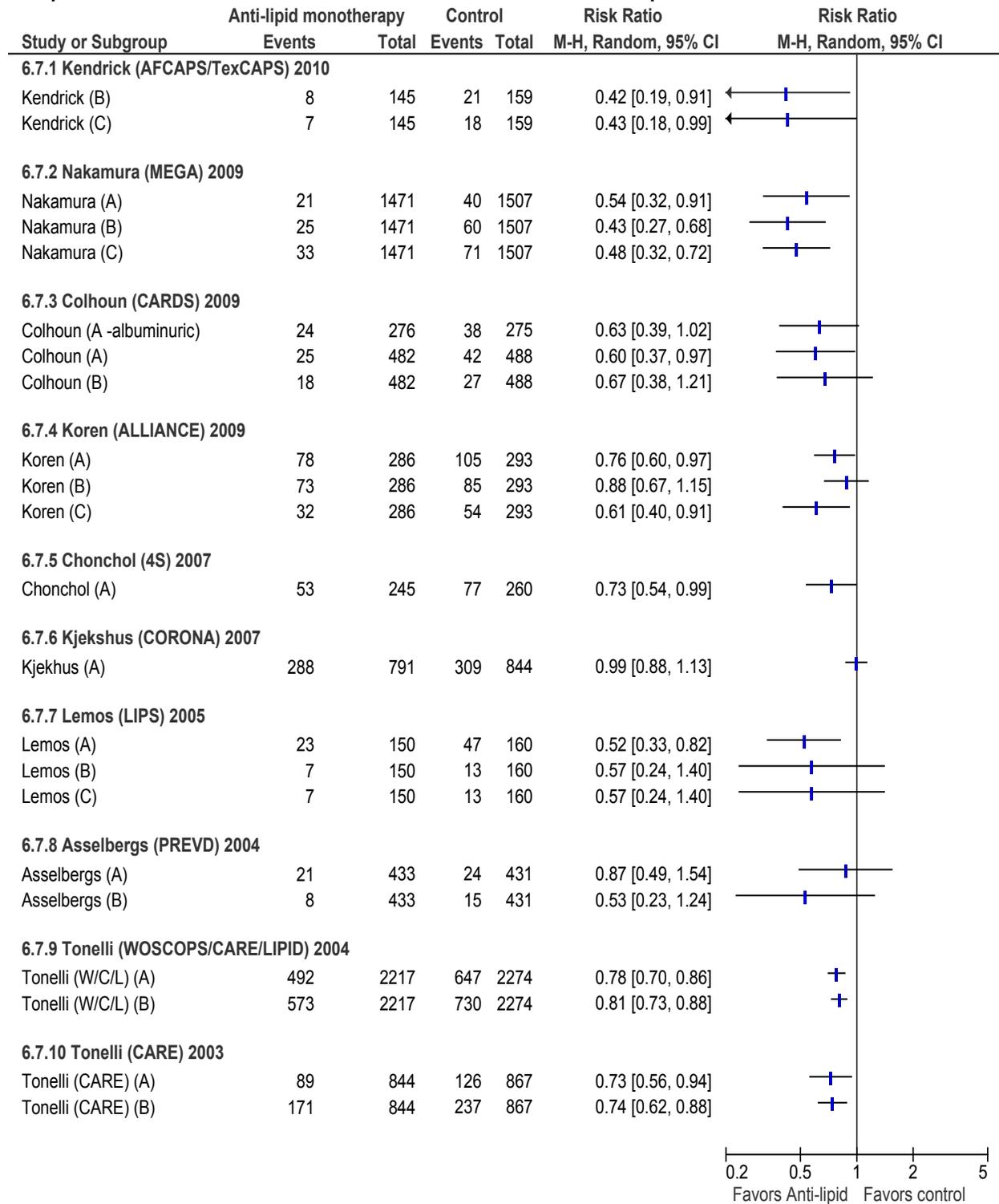
Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

CHF hospitalization



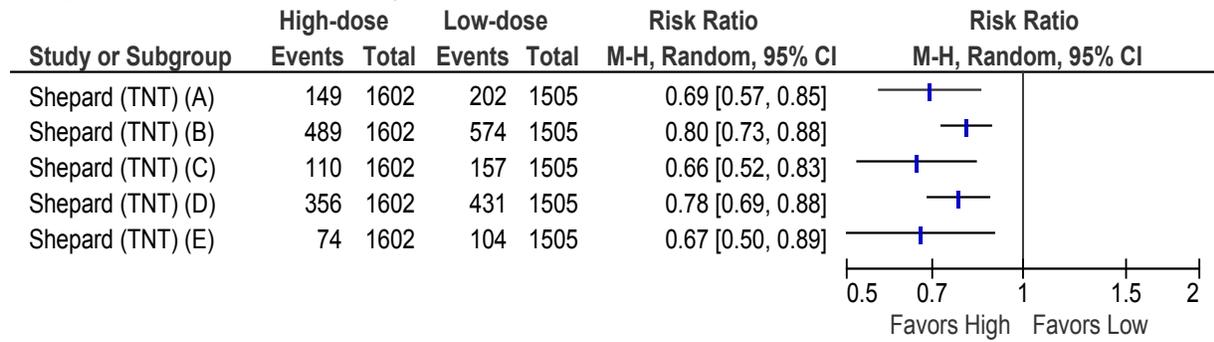
Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

Composite Vascular Outcome: HMG-CoA Reductase Inhibitors versus placebo*

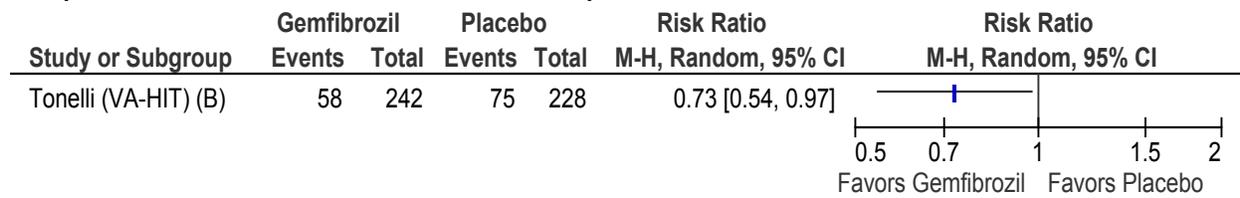


Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

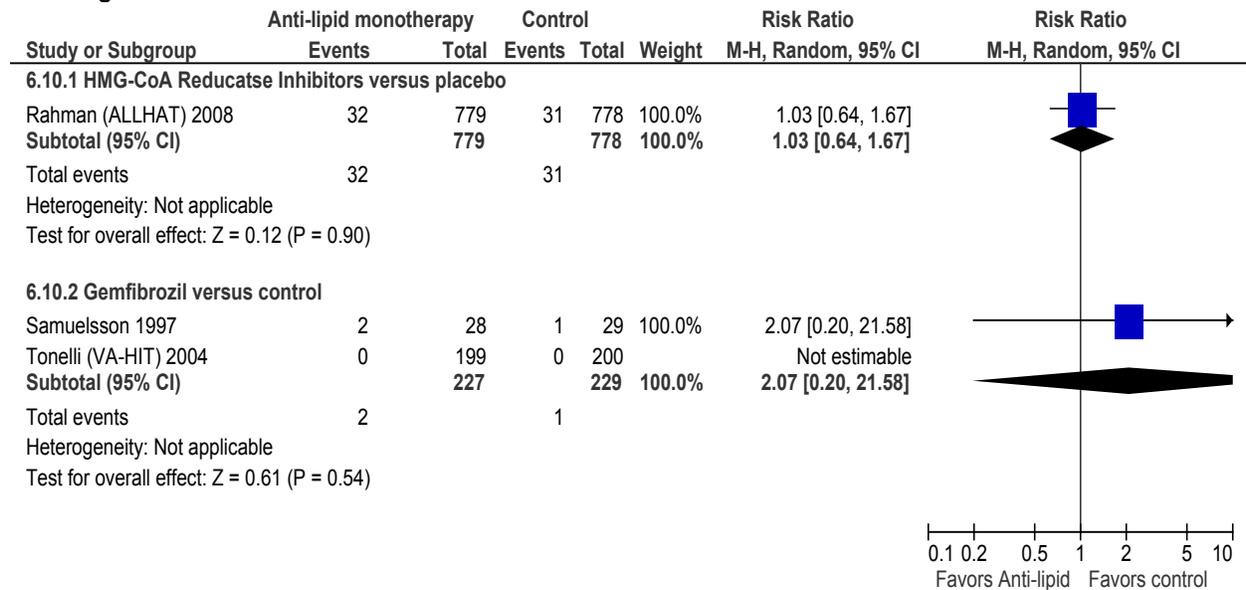
Composite Vascular Outcome: High versus Low-dose HMG-CoA Reductase Inhibitors*



Composite Vascular Outcome: Gemfibrozil versus placebo*

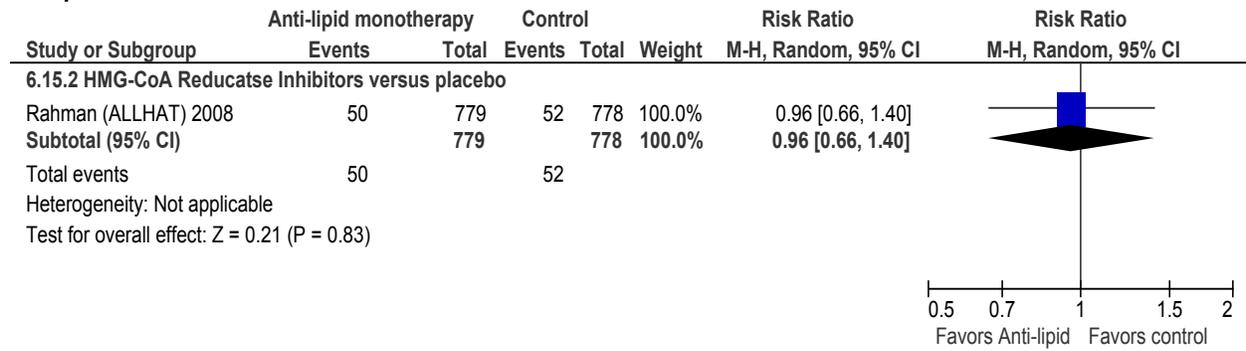


End-stage Renal Disease



Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

Composite Renal Outcome

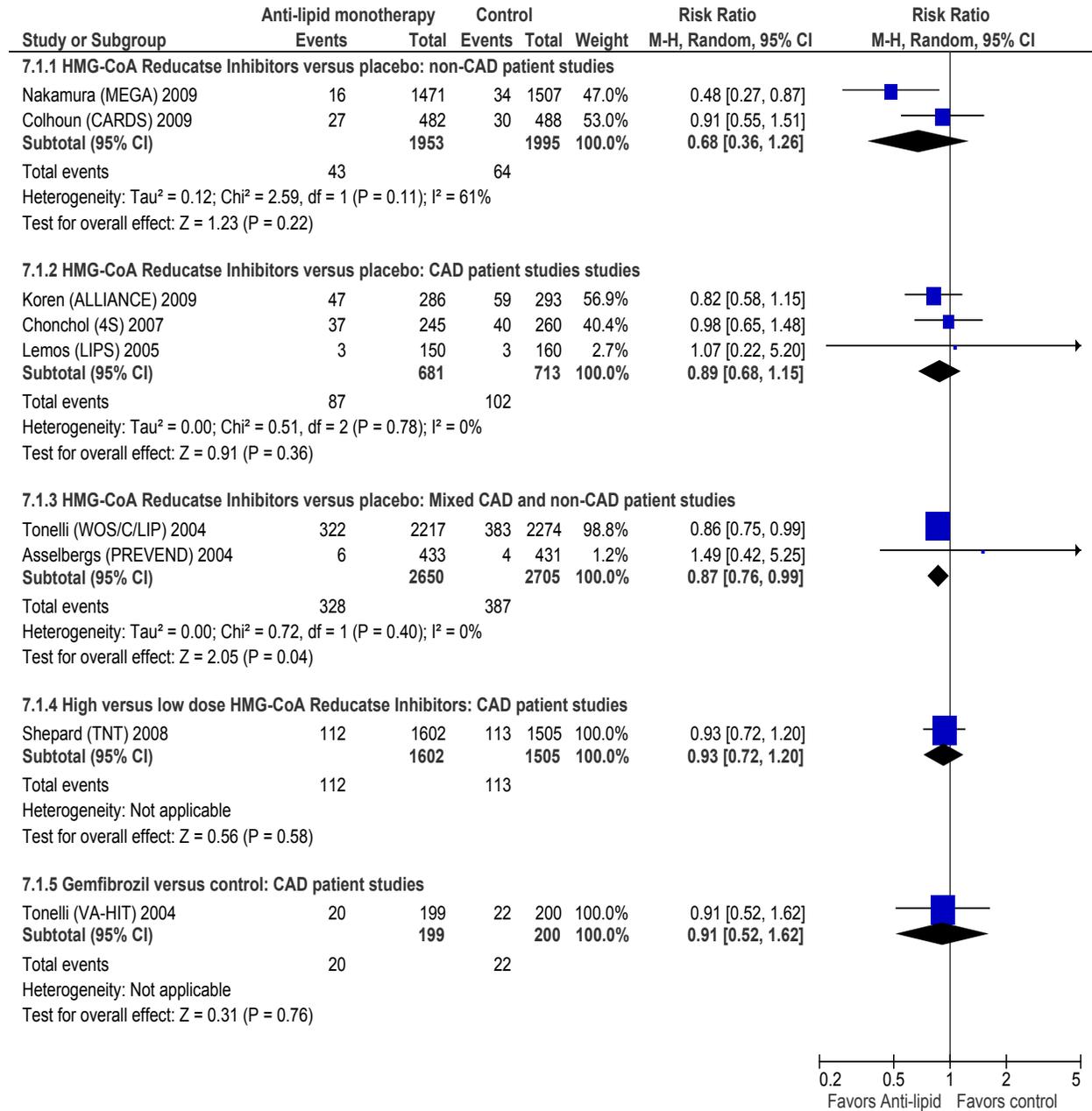


*When trials reported multiple composite vascular outcomes, these are denoted in the figure above by composite outcome (A), (B), (C), etc. The specific definitions for each of these outcomes are detailed in Table D117.

Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

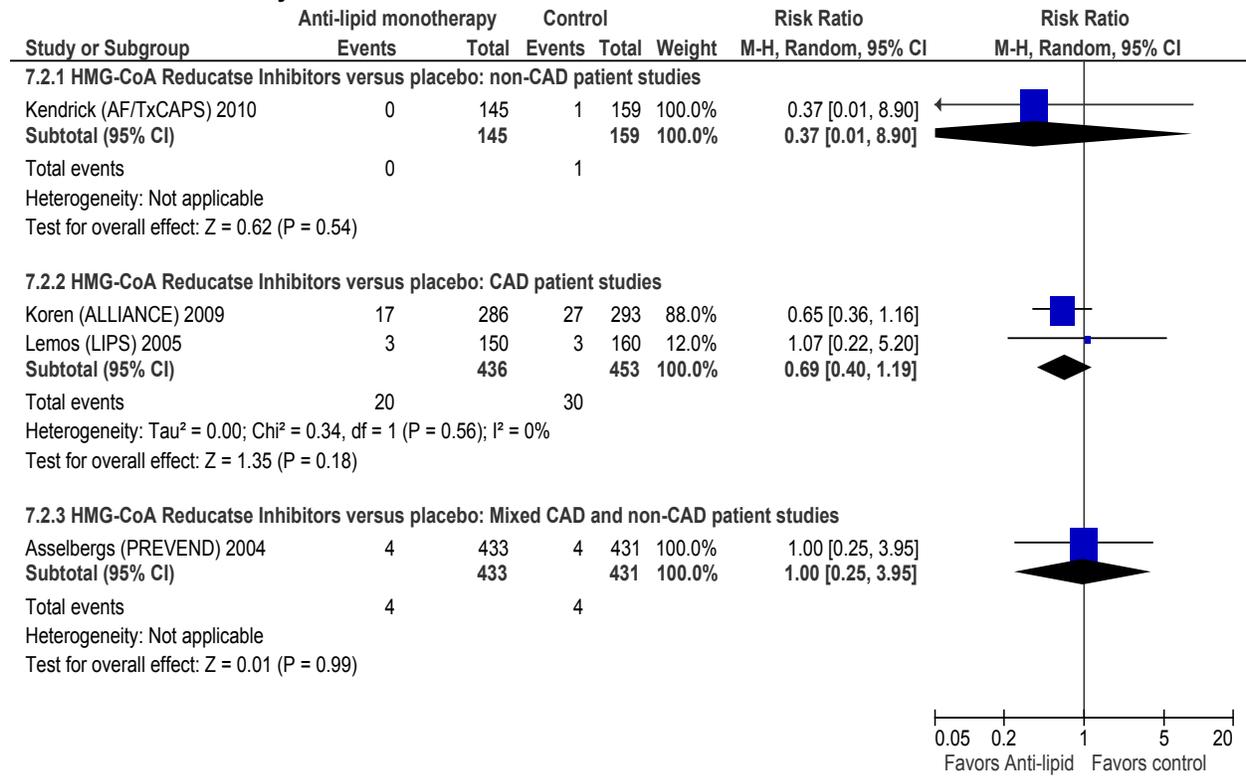
ANTI-LIPID MONOTHERAPY VERSUS CONTROL: SUBGROUP ANALYSES

All-cause mortality

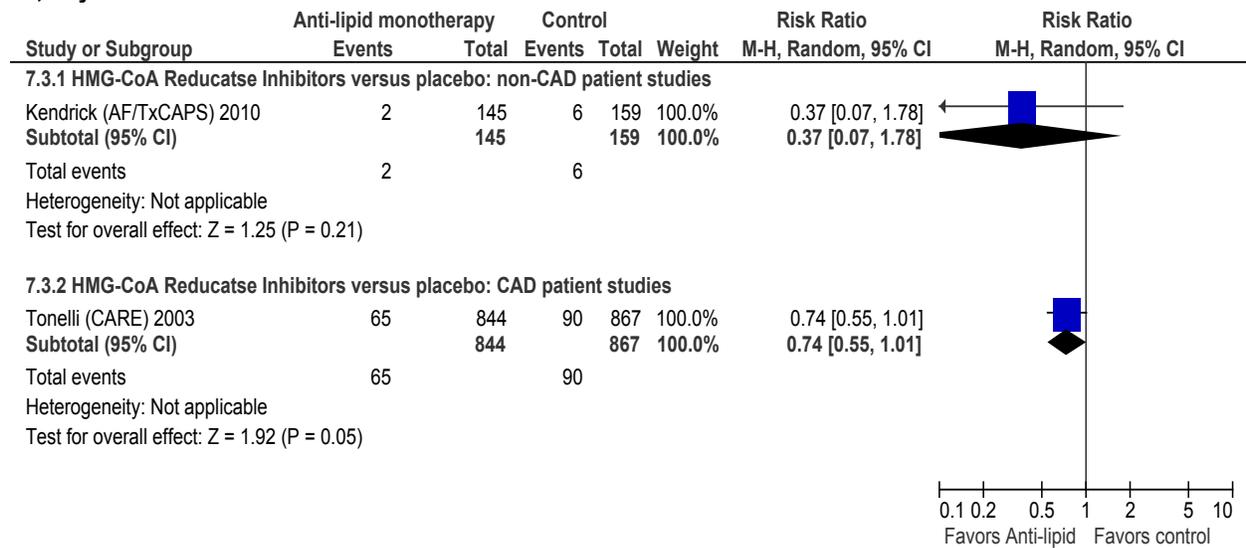


Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

Cardiovascular mortality

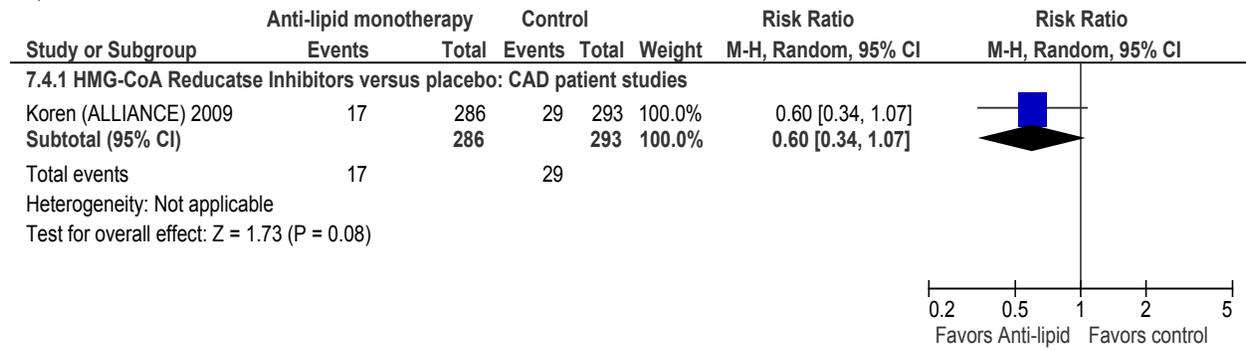


MI, any

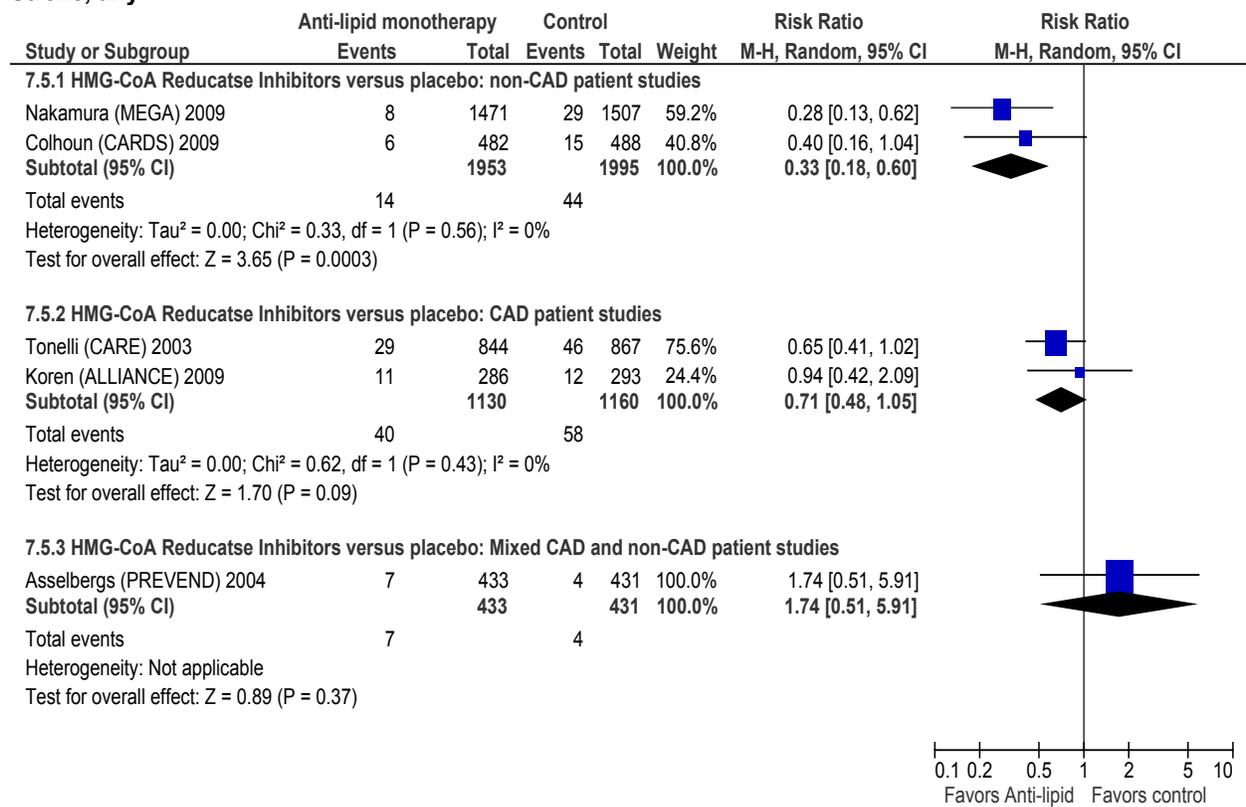


Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

MI, nonfatal

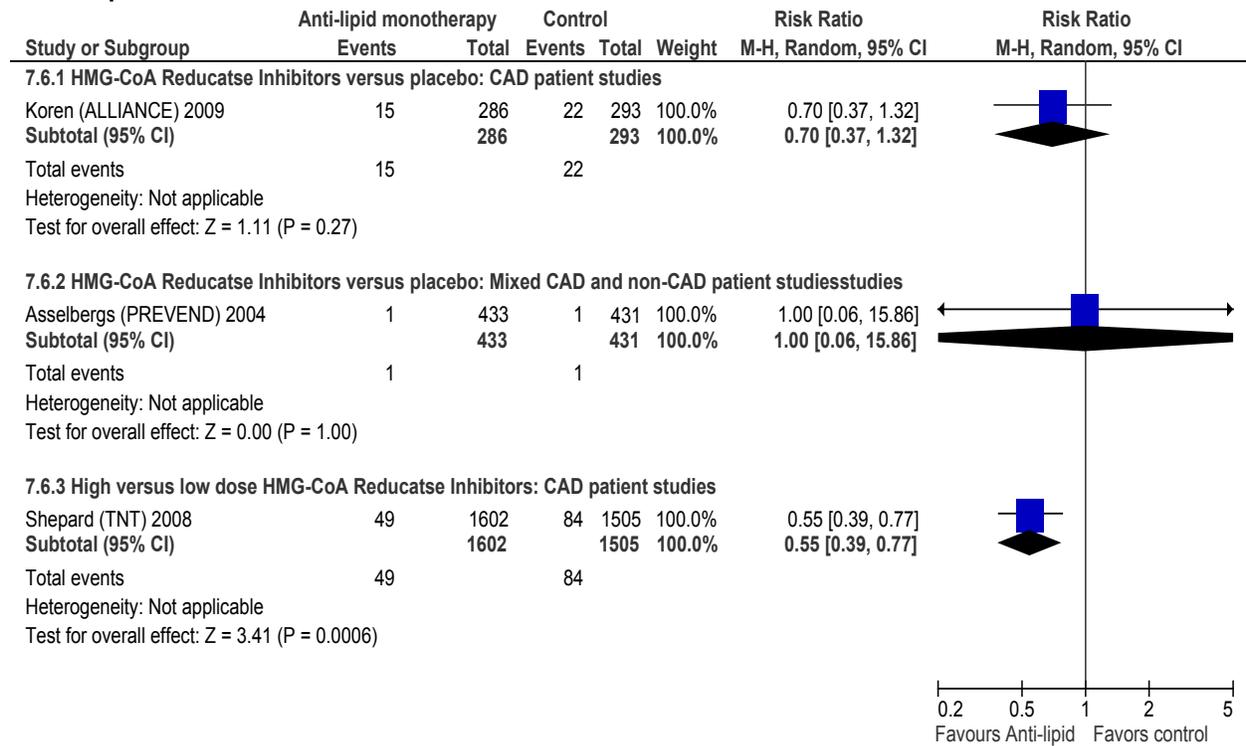


Stroke, any

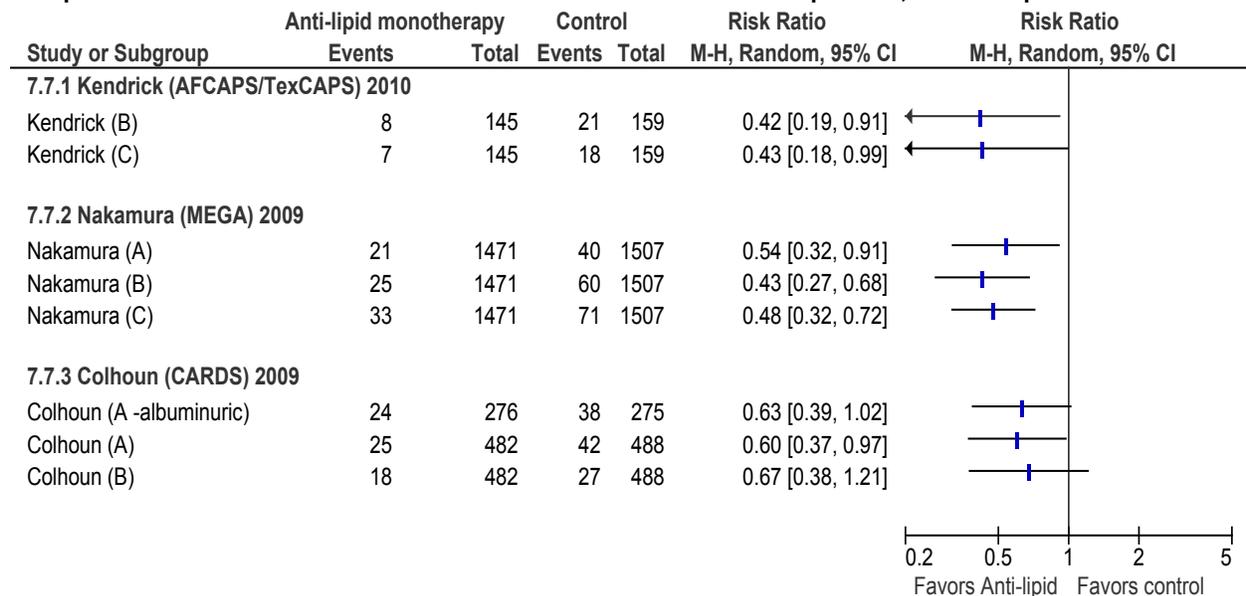


Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

CHF hospitalization

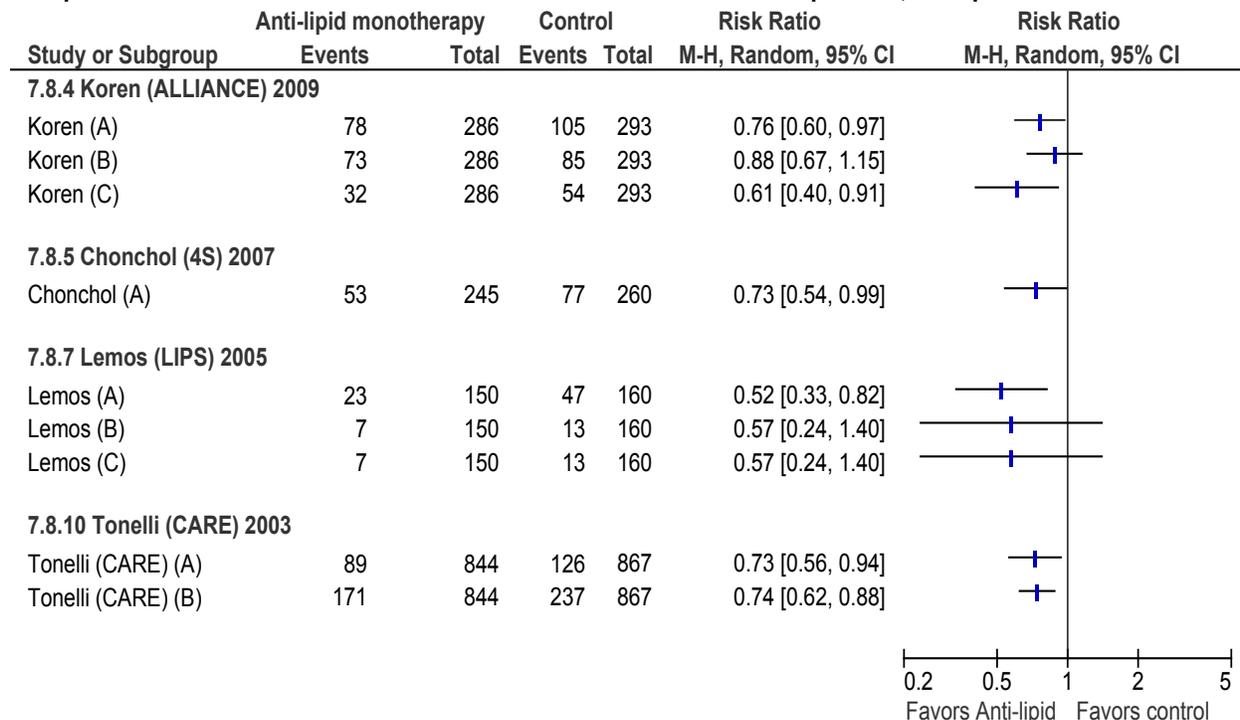


Composite Vascular Outcome: HMG-CoA Reductase Inhibitors versus placebo, non-CAD patient studies*

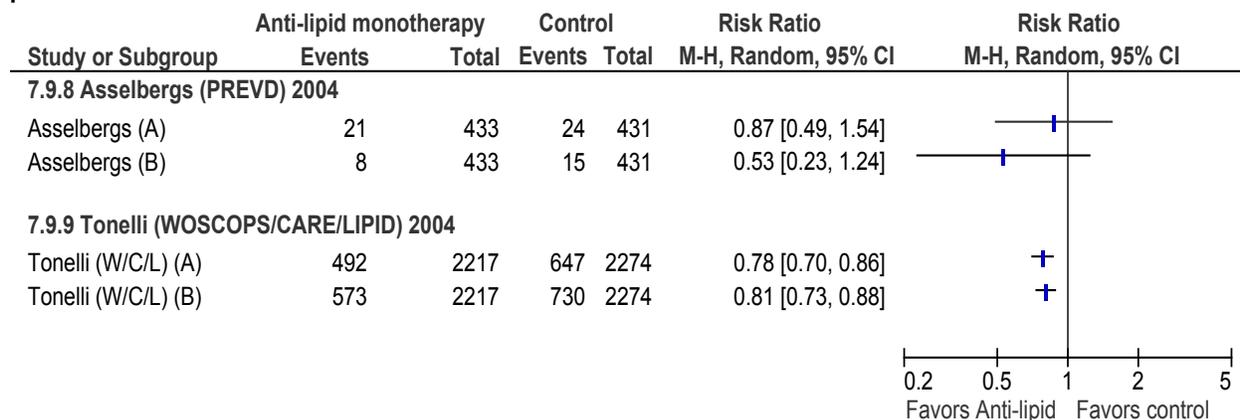


Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

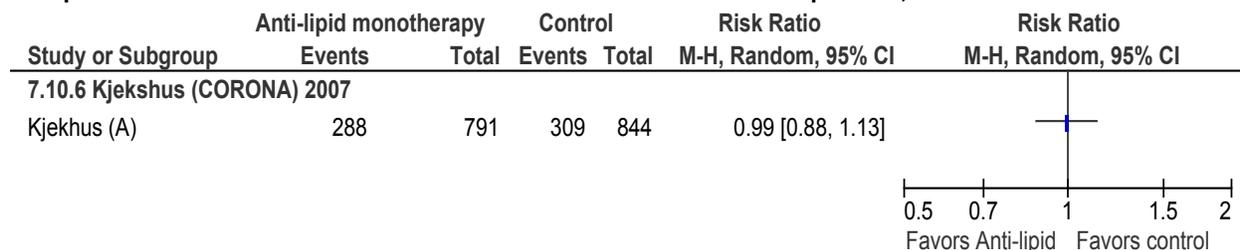
Composite Vascular Outcome: HMG-CoA Reductase Inhibitors versus placebo, CAD patient studies*



Composite Vascular Outcome: HMG-CoA Reductase Inhibitors versus placebo, Mixed CAD and non-CAD patient studies*

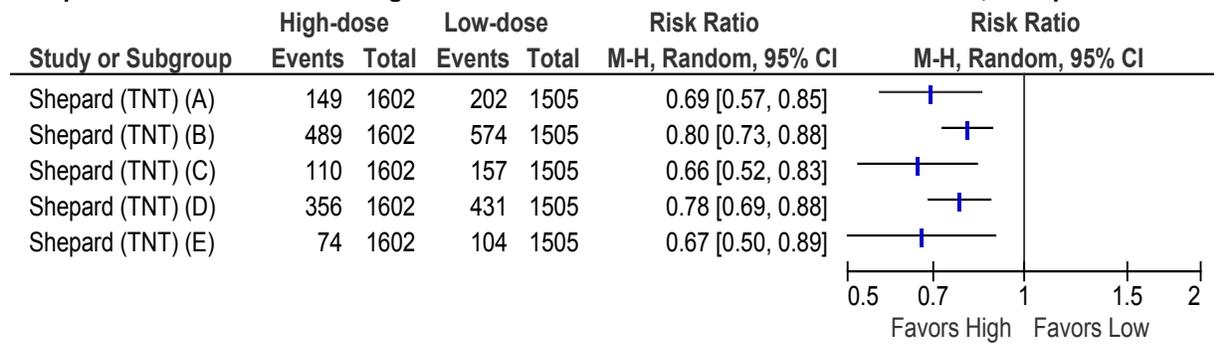


Composite Vascular Outcome: HMG-CoA Reductase Inhibitors versus placebo, Heart failure studies*

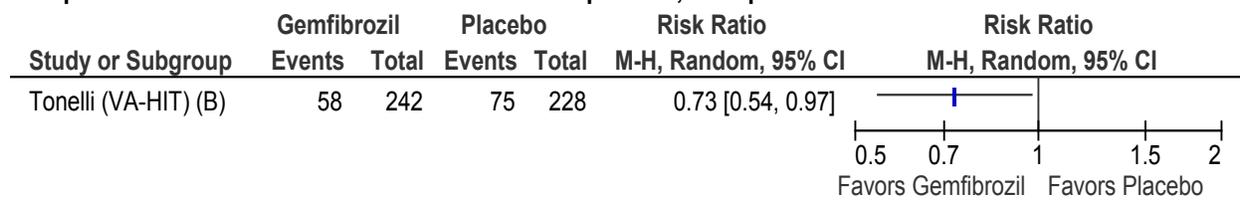


Appendix Figure C22. Forest plots for anti-lipid monotherapy versus control trials (continued)

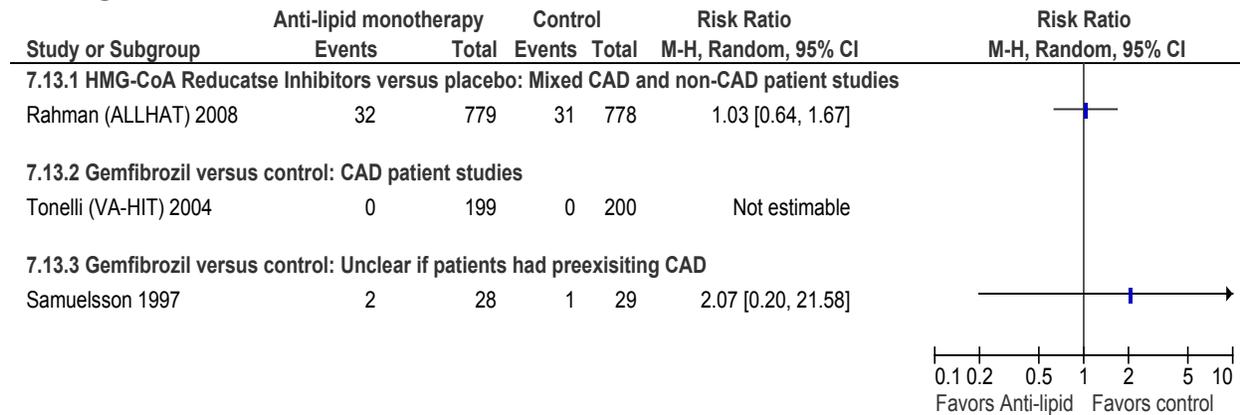
Composite Vascular Outcome: High versus Low-dose HMG-CoA Reductase Inhibitors, CAD patient studies*



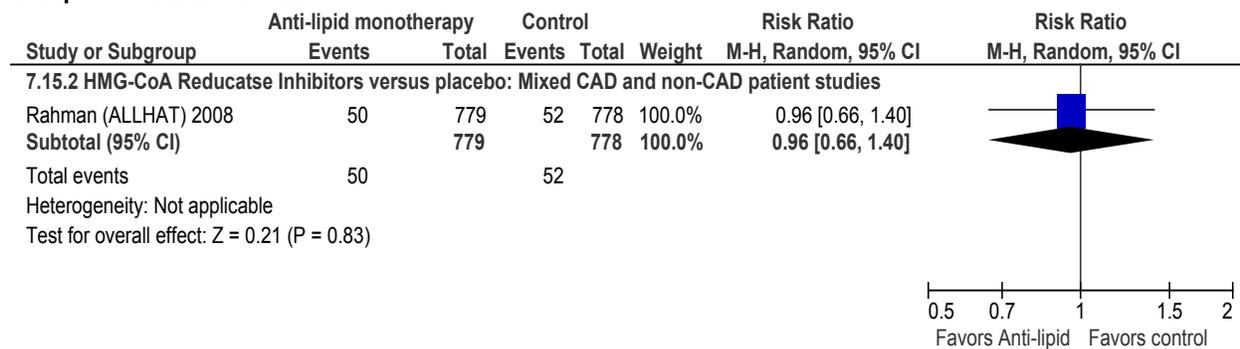
Composite Vascular Outcome: Gemfibrozil versus placebo, CAD patient studies*



End-stage Renal Disease



Composite Renal Outcome



*When trials reported multiple composite vascular outcomes, these are denoted in the figure above by composite outcome (A), (B), (C), etc. The specific definitions for each of these outcomes are detailed in Table D117

Appendix Table C116. Clinical outcomes (outcomes part B), AL monotherapy versus control treatment trials

Study	Stroke, Nonfatal n/N (%)		Stroke, Fatal n/N (%)		CHF Hospitalization (A) or CHF Death (B), n/N (%)		Composite Vascular Outcome n/N (%)	
	AL	Control	AL	Control	AL	Control	AL	Control
HMG-CoA reductase inhibitors versus placebo trials								
Kendrick, 2010 ⁷⁸ AFCAPS/ TexCAPS							†(A) NR; (B) 8/145 (5.5)*; (C) 7/145 (4.8)*	†(A) NR; (B) 21/159 (13.2); (C) 18/159 (11.3)
Nakamura, 2009 ⁷⁹ MEGA							‡(A) 21/1471 (1.2)*; (B) 25/1471 (3.7)*; (C) 33/1471 (4.9)*	‡(A) 40/1507 (5.7); (B) 60/1507 (8.7); (C) 71/1507 (10.3)
Colhoun, 2009 ⁸⁰ CARDS							§(A) Low GFR: 25/482 (5.2)*, Albuminuric: 24/276 (8.7)*; (B) Low GFR: 18/482 (3.7)	§(A) Low GFR: 42/488 (8.6)*, Albuminuric: 38/275 (13.8); (B) Low GFR: 27/488 (5.5)
Koren, 2009 ⁸¹ ALLIANCE					(A): 15/286 (5.2)	(A): 22/293 (7.5)	#(A) 78/286 (27.3)*; (B) 73/286 (25.5); (C) 32/286 (11.2)*	#(A) 105/293 (35.8); (B) 85/293 (29.0); (C) 54/293 (18.4)
Rahman, 2008 ⁸³ ALLHAT-LLT								
Chonchol, 2007 ⁸⁴ 4S							53/245 (21.6)	77/260 (29.6)
Kjekshus, 2007 ⁸⁶ CORONA							288/791 (15.8)	309/844 (16.3)
Lemos, 2005 ⁸⁷ LIPS							‡‡(A) 23/150 (15.3)*; (B) 7/150 (4.7); (C) 7/150 (4.7)	‡‡(A) 47/160 (29.4); (B) 13/160 (8.1); (C) 13/160 (8.1)
Asselbergs, 2004 ² PREVD					(A) 1/433 (0.2)	(A) 1/431 (0.2)	** (A) 21/433 (4.8); (B) 8/433 (1.8)	** (A) 24/431 (5.6); (B) 15/431 (3.5)
Tonelli, 2004 ⁸⁸ WOSCOPS/ CARE/ LIPID							## (A) 492/2217 (22.2); (B) 573/2217 (25.9)	## (A) 647/2274 (28.5); (B) 730/2274 (32.1)
Tonelli, 2003 ⁸⁹ CARE							†† (A) 89/844 (10.5)*; (B) 171/844 (20.3)*	†† (A) 126/867 (14.5); (B) 237/867 (27.0)
High versus low dose HMG-CoA reductase inhibitor trials (n=1)								
	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose
Shepherd, 2008 ⁹⁰ TNT					(A) 49/1602 (3.1)	(A) 84/1505 (5.6)	§§ (A) 149/1602 (9.3); (B) 489/1602 (30.5); (C) 110/1602 (6.9)*; (D) 356/1602 (22.2); (E) 74/1602 (4.6)	§§ (A) 202/1505 (13.4); (B) 574/1505 (38.1); (C) 157/1505 (10.4); (D) 431/1505 (28.6); (E) 104/1505 (6.9)

Appendix Table C116. Clinical outcomes (outcomes part B), AL monotherapy versus control treatment trials (continued)

Study	Stroke, Nonfatal n/N (%)	Stroke, Fatal n/N (%)	CHF Hospitalization (A) or CHF Death (B), n/N (%)	Composite Vascular Outcome n/N (%)
HMG-CoA reductase inhibitor versus bile acid sequestrant trials (n=1)				
Tonolo, 2006 ⁹³				
Gemfibrozil versus placebo/control trials (n=2)				
Tonelli, 2004 ⁸⁸ VA-HIT			58/242 (24.0)	75/228 (32.9)
Samuelsson, 1997 ⁷⁵				

AL = antilipid; CHF = congestive heart failure; NR = not reported; GFR = glomerular filtration rate; MI = myocardial infarction; CABG = coronary artery bypass grafting; CHD = coronary heart disease; CKD = chronic kidney disease; CVD = cardiovascular disease

*p < 0.05

†Study defined two composite vascular endpoints, as follows: (A) "First major cardiac event," which included any of unstable angina, fatal or nonfatal myocardial infarction, and/or sudden cardiac death; (B) "Fatal and nonfatal cardiovascular events;" and (C) "Fatal and nonfatal coronary events." Participants treated with lovastatin were reported to have an adjusted RR of 0.32 (95% CI, 0.10-1.11; P = 0.06) for the endpoint of "first major cardiac event," though the proportion of participants with this endpoint was not reported for either treatment group.

‡ Study defined the primary composite endpoint as: (A) the first occurrence of a CHD event, including fatal and nonfatal myocardial infarction, angina pectoris, cardiac/sudden death, and coronary revascularization. Additional composite endpoints included (B) first CHD event or ischemic stroke; and (C) total CVD events, which was not defined.

§Study defined the primary composite endpoint as: (A) "Major cardiovascular disease", including acute CHD event (MI, including silent infarction, unstable angina, acute CHD death, or resuscitated cardiac arrest), stroke, coronary revascularization, or death. An additional composite endpoint was (B) acute CHD event as defined above. Results for composite endpoint A were reported separately for participants with CKD defined based on albuminuria (urinary albumin/creatinine ratio ≥ 22 mg/g).

#Study defined three composite vascular endpoints, as follows: (A) First primary cardiovascular event, including cardiac death, nonfatal MI, resuscitated cardiac arrest, cardiac revascularization, or unstable angina requiring hospitalization; (B) All-cause mortality, peripheral revascularization, hospitalization for CHF, or stroke; and (C) Nonfatal MI or cardiac death.

**Study defined the primary composite endpoint as: (A) Cardiovascular mortality or hospitalization for any of the following: nonfatal MI, myocardial ischemia, CHF, peripheral vascular disease or stroke. An additional composite endpoint was: (B) Hospitalization for nonfatal MI or myocardial ischemia.

††Study defined the primary composite vascular endpoint as: (A) Death from coronary disease (including fatal myocardial infarction, sudden death, death during a coronary intervention, and death from other coronary causes) or a symptomatic nonfatal biochemically confirmed myocardial infarction. An additional composite endpoint was: (B) Major coronary events, defined as fatal coronary disease, nonfatal myocardial infarction, coronary artery bypass surgery, or coronary angioplasty.

‡‡Study defined the primary composite vascular endpoint as: (A) Adverse coronary atherosclerotic events, which included cardiac death, nonfatal MI, and all surgical or percutaneous coronary interventions not caused by restenosis after an index percutaneous coronary intervention. Additional composite vascular endpoints included: (B) Cardiac death or MI; and (C) All-cause mortality or MI.

§§Study defined the primary composite vascular endpoint as: (A) Major cardiovascular events, which included CHD death, nonfatal nonprocedure-related MI, resuscitation after cardiac arrest, and stroke. Additional composite vascular endpoints included: (B) Any cardiovascular event (defined as CHD death, nonfatal MI, resuscitation from cardiac arrest, revascularization procedure, documented angina, stroke, TIA, peripheral vascular disease, or CHF hospitalization); (C) Major coronary event (defined as CHD death, nonfatal nonprocedure-related MI, or resuscitation from cardiac arrest); (D) Any coronary event (defined as CHD death, nonfatal MI, resuscitation from cardiac arrest, revascularization procedure, or documented angina); and (E) Cerebrovascular event (stroke or TIA).

##Study defined the primary composite vascular endpoint as: (A) Fatal CHD, nonfatal MI, or coronary revascularization. An additional composite vascular endpoint was defined as: (B) Fatal CHD, nonfatal MI, coronary revascularization, or stroke.

Appendix Table C117. Composite vascular outcome definitions, AL monotherapy versus control treatment trials

Study	Definition
<i>HMG-CoA reductase inhibitors versus placebo trials</i>	
Kendrick, 2010 ⁷⁸ AFCAPS/TexCAPS	Defined two composite vascular endpoints, as follows: (A) "First major cardiac event," which included any of unstable angina, fatal or nonfatal MI, and/or sudden cardiac death; (B) "Fatal and nonfatal cardiovascular events;" and (C) "Fatal and nonfatal coronary events."
Nakamura, 2009 ⁷⁹ MEGA	The primary composite endpoint was defined as: (A) the first occurrence of a CHD event, including fatal and nonfatal MI, angina pectoris, cardiac/sudden death, and coronary revascularization. Additional composite endpoints included (B) first CHD event or ischemic stroke; and (C) total CVD events, which was not defined.
Colhoun, 2009 ⁸⁰ CARDS	The primary composite endpoint was defined as: (A) "Major cardiovascular disease", including acute CHD event (MI, including silent MI, unstable angina, acute CHD death, or resuscitated cardiac arrest), stroke, coronary revascularization, or death. An additional composite endpoint was (B) acute CHD event as defined above.
Koren, 2009 ⁸¹ ALLIANCE	Defined two composite vascular endpoints, as follows: (A) First primary cardiovascular event, including cardiac death, nonfatal MI, resuscitated cardiac arrest, cardiac revascularization, or unstable angina requiring hospitalization; (B) All-cause mortality, peripheral revascularization, hospitalization for CHF, or stroke; and (C) Nonfatal MI or cardiac death.
Chonchol, 2007 ⁸⁴ 4S	Study defined multiple composite vascular endpoints, as follows: (A) Major coronary event, including coronary death, nonfatal MI, resuscitated cardiac arrest, ECG confirmed silent MI; (B) Any coronary event, including coronary death, nonfatal MI, resuscitated cardiac arrest, ECG confirmed silent MI, myocardial revascularization procedure, hospitalization for acute CHD without MI diagnosis; and (C) Death, nonfatal MI, resuscitated cardiac arrest, ECG confirmed silent MI, myocardial revascularization procedure, hospitalization for acute CHD without MI diagnosis, and hospital-verified nonfatal coronary atherosclerotic events.
Kjekshus, 2007 ⁸⁶ CORONA	Study defined the primary composite vascular endpoint as: (A) Cardiovascular death, nonfatal MI, or nonfatal stroke. An additional composite vascular endpoint was: (B) Any coronary event, which included sudden death, fatal or nonfatal MI, coronary revascularization (CABG or PCI), ventricular defibrillation by an implantable cardioverter-defibrillator, resuscitation after cardiac arrest, or hospitalization for unstable angina.
Lemos, 2005 ⁸⁷ LIPS	Study defined the primary composite vascular endpoint as: (A) Adverse coronary atherosclerotic events, which included cardiac death, nonfatal MI, and all surgical or percutaneous coronary interventions not caused by restenosis after an index percutaneous coronary intervention. Additional composite vascular endpoints included: (B) Cardiac death or MI; and (C) All-cause mortality or MI.
Asselbergs, 2004 ² PREVEND IT	Study defined the primary composite endpoint as: (A) Cardiovascular mortality or hospitalization for any of the following: nonfatal MI, myocardial ischemia, CHF, PVD or stroke. An additional composite endpoint was: (B) Hospitalization for nonfatal MI or myocardial ischemia.
Tonelli, 2004 ⁸⁸ WOSCOPS/CARE/LIPID	Study defined the primary composite vascular endpoint as: (A) Fatal CHD, nonfatal MI, or coronary revascularization. An additional composite vascular endpoint was defined as: (B) Fatal CHD, nonfatal MI, coronary revascularization, or stroke.
Tonelli, 2003 ⁸⁹ CARE	Study defined the primary composite vascular endpoint as: (A) Death from coronary disease (including fatal MI, sudden death, death during a coronary intervention, and death from other coronary causes) or a symptomatic nonfatal biochemically confirmed myocardial infarction. An additional composite endpoint was: (B) Major coronary events, defined as fatal coronary disease, nonfatal MI, CABG, or coronary angioplasty.
<i>High versus low dose HMG-CoA reductase inhibitor trials</i>	
Shepard, 2008 ⁹⁰ TNT	Study defined the primary composite vascular endpoint as: (A) Major cardiovascular events, which included CHD death, nonfatal nonprocedure-related MI, resuscitation after cardiac arrest, and stroke. Additional composite vascular endpoints included: (B) Any cardiovascular event (defined as CHD death, nonfatal MI, resuscitation from cardiac arrest, revascularization procedure, documented angina, stroke, TIA, CABG, or CHF hospitalization); (C) Major coronary event (defined as CHD death, nonfatal nonprocedure-related MI, or resuscitation from cardiac arrest); (D) Any coronary event

Appendix Table C117. Composite vascular outcome definitions, AL monotherapy versus control treatment trials (continued)

Study	Definition
	(defined as CHD death, nonfatal MI, resuscitation from cardiac arrest, revascularization procedure, or documented angina); and (E) Cerebrovascular event (stroke or TIA).
<i>Gemfibrozil versus placebo/control trials</i>	
Tonelli, 2004 ⁶⁸ VA-HIT	Study defined the primary composite vascular endpoint as: (A) Coronary disease death (included fatal MI, sudden death, death during a coronary intervention, and death from other coronary causes) and nonfatal MI. An additional composite vascular endpoint was: (B) Major cardiovascular event, which included fatal CHD, nonfatal MI, and stroke.

AL = anti-lipid; CVA = cerebrovascular accident (i.e. stroke); HTN = hypertension; MI = myocardial infarction; PVD = peripheral vascular disease; CHD = coronary heart disease; CVD = cardiovascular disease; CHF = congestive heart failure; ECG = electrocardiogram; CABG = coronary artery bypass grafting; TIA = transient ischemic attack; PCI = percutaneous coronary intervention.

Appendix Table C118. Clinical renal outcomes (outcomes part C), AL monotherapy versus control treatment trials

Study	End Stage Renal Disease, n/N (%)		Doubling of Serum Creatinine, n/N (%)		Halving of GFR, n/N (%)		Progression from Micro- to Macroalbuminuria, n/N (%)		Composite Renal Outcome, n/N (%)	
	AL	Control	AL	Control	AL	Control	AL	Control	AL	Control
HMG-CoA reductase inhibitors versus placebo trials (n=11)										
Kendrick, 2010 ⁷⁸ AFCAPS/TexCAPS										
Nakamura, 2009 ⁷⁹ MEGA										
Colhoun, 2009 ⁸⁰ CARDS										
Koren, 2009 ⁸¹ ALLIANCE										
Rahman, 2008 ⁸³ ALLHAT	32/779 (4.1)	31/778 (4.0)							(B)50/779 (6.4)	(B)52/778 (6.7)
Chonchol, 2007 ⁸⁴ 4S										
Kjekshus, 2007 ⁸⁶ CORONA										
Lemos, 2005 ⁸⁷ LIPS										
Asselbergs, 2004 ² PREVD										
Tonelli, 2004 ⁸⁸ WOSCOPS/CARE/ LIPID										
Tonelli, 2003 ⁸⁹ CARE										
High versus low dose HMG-CoA reductase inhibitor trials (n=1)										
	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose
Shepherd, 2008 ⁹⁰ TNT										
HMG-CoA Reductase Inhibitor versus Bile Acid Sequestrant trials (n=1)										
Tonolo, 2006 ⁹³							*†(4)	†(15)		
Gemfibrozil versus placebo/control trials (n=2)										
Tonelli, 2004 ⁸⁸ VA-HIT	0/199	0/200								
Samuelsson, 1997 ⁷⁵	2/28 (7.1)	1/29 (3.4)								

C-237

Appendix Table C118. Clinical renal outcomes (outcomes part C), AL monotherapy versus control treatment (continued)

AL = antilipid; GFR = glomerular filtration rate;

* p < 0.05 versus control.

†Study reported that conversion from microalbuminuria to overt proteinuria occurred in 4 vs. 15% in simvastatin vs. cholestyramine subjects, respectively (p<0.01). However, from results reported, it was not possible to determine the numerator and denominator used to derive these results for both treatment groups.

Appendix Table C119. Composite renal outcome definitions for AL trials

Study	Definition
<i>HMG-CoA Reductase Inhibitors (Statins) versus Placebo/Usual care/No treatment trials</i>	
Rahman, 2008 ⁸³ ALLHAT-LLT	Study defined multiple composite renal outcomes, including: (A) ESRD (start of long-term dialysis, death due to kidney disease, or kidney transplantation) or $\geq 50\%$ decline in GFR; and (B) ESRD or $\geq 50\%$ decline in GFR.

AL = antilipid; ESRD = end stage renal disease; GFR = glomerular filtration rate

Appendix Table C120. Study withdrawals and adverse events (outcomes part D), AL monotherapy versus control treatment trials

Study	Study Withdrawals: Any, n/N (%)		Serious Adverse Event: Any, n/N (%)		Study Withdrawal Due to Serious Adverse Event, Any, n/N (%)		Adverse Event: Any, n/N (%)		Adverse Event: Specific, n/N (%)		Renal Adverse Events, n/N (%)	
	AL	Control	AL	Control	AL	Control	AL	Control	AL	Control	AL	Control
<i>HMG-CoA reductase inhibitors versus placebo trials (n=11)</i>												
Kendrick, 2010 ⁷⁸ AFCAPS/ TexCAPS									†Rhabdo: 0/145; CK>10x ULN: 0/159	†Rhabdo: 1/159 (0.6); CK>10x ULN: 1/159 (0.6)		
Nakamura† 2009 ⁷⁹ MEGA					166/1471 (11.3)	158/150 7 (10.5)			AST >100IU: 18/1471 (1.2); ALT >100IU: 37/1471 (2.5); CK >500IU: 38/1471 (2.6)	AST >100IU: 17/1507 (1.1); ALT >100IU: 41/1507 (2.7); CK >500IU: 39/1507 (2.6)	sCr >4mg/dl: 0.3%	sCr >4mg/dL: 0.2%
Colhoun, 2009 ⁸⁰ CARDS												
Koren, 2009 ⁸¹ ALLIANCE									Rhabdo 0/286; AST >3x ULN 1/286; ALT >3x ULN 1/286; CK >10xULN: 0/286	Rhabdo 0/293; AST >3x ULN NR; ALT >3x ULN NR; CK >10xULN: NR		
Rahman, 2008 ⁸³ ALLHAT-LLT												
Chonchol, 2007 ⁸⁴ 4S												
Kjekshus, 2007 ⁸⁶ CORONA												
Lemos, 2005 ⁸⁷ LIPS												
Asselbergs, 2004 ² PREVD	§NR	§NR										

C-240

Appendix Table C120. Study withdrawals and adverse events (outcomes part D), AL monotherapy versus control treatment trials (continued)

Study	Study Withdrawals: Any, n/N (%)		Serious Adverse Event: Any, n/N (%)		Study Withdrawal Due to Serious Adverse Event, Any, n/N (%)		Adverse Event: Any, n/N (%)		Adverse Event: Specific, n/N (%)		Renal Adverse Events, n/N (%)	
Tonelli, 2004 ⁸⁸ WOSCOPS/ CARE/ LIPID												
Tonelli, 2003 ⁸⁹ CARE	0/844	0/867			0/844	0/867			#Rhabdo: 0/844; CK>3x ULN: 6/844 (0.7); Abnormal LFTs: 5/844 (0.6)	#Rhabdo: 3/867 (0.3); CK>3x ULN: 3/867 (0.3); Abnormal LFTs: 5/867 (0.6)		
High versus low dose HMG-CoA reductase inhibitor trials (n=1)												
	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose	High Dose	Low Dose
Shepherd, 2008 ⁹⁰ TNT	6/1602 (0.4)	6/1505 (0.4)			68/1602 (4.2)	29/1505 (1.9)	140/1602 (8.7)	78/1505 (5.2)	ALT or AST >3x ULN: 22/1602 (1.4); CK >10xULN: 0/1602	ALT or AST >3x ULN: 1/1505 (0.1); CK >10xULN: 0/1505	Hematuria: 58/1602 (3.6)	Hematuria: 51/1505 (3.4)
HMG-CoA reductase inhibitor versus bile acid sequestrant trials (n=1)												
Tonolo, 2006 ⁹³	1/43 (2.3)	3/43 (7.0)					1/43 (2.3)	3/43 (7.0)	‡NR	‡NR	‡NR	‡NR
Gemfibrozil versus placebo/control trials (n=2)												
Tonelli, 2004 ⁸⁸ VA-HIT	0/199	0/200			0/199	0/200			**Rhabdo: 0/199; CK>3x ULN: 0/199	**Rhabdo: 0/200; CK>3x ULN: 0/200		
Samuelsson, 1997 ⁷⁵	8/28 (28.6)	1/29 (3.4)							"Mild GI symptoms": 6/28 (21.4)	"Mild GI symptoms": 0/29		

AL = antilipid agent; Rhabdo = rhabdomyolysis; NR = not reported; AST = aspartase aminotransferase; ALT = alanine aminotransferase; LFTs = liver function tests; IU = international units; ULN = upper limit of normal; CK = creatine phosphokinase; GI = gastrointestinal; sCr = serum creatinine

*p < 0.05 versus control

†Study reported that increases >3 times ULN in liver function test results were rare, and incidence was similar in both treatment groups.

‡Study reported that two patients developed renal cancer, and that one patient developed a 3 to 4-fold increase of AST and ALT above baseline levels, but didn't indicate either patient's treatment group.

Appendix Table C120. Study withdrawals and adverse events (outcomes part D), AL monotherapy versus control treatment trials (continued)

§Study reported total withdrawals of n = 92/433 (21.2%) and 117/431 (27.1%) in pravastatin and placebo groups, respectively. Among total withdrawals, however, the study reported those for "other medical reasons," which included but were not entirely comprised of subjects reaching study endpoints (i.e. cardiovascular mortality or hospitalization) (n = 23 and 33 for pravastatin and placebo groups, respectively).

#Study also reported the following specific adverse effects in pravastatin vs. placebo participants, respectively: depression (10/844 vs. 14/867), nondermatologic malignancy (133/844 vs. 146/867), and skin cancer (57/844 vs. 41/867, p = 0.08).

**Study also reported the following specific adverse effects in gemfibrozil vs. placebo participants, respectively: depression (4/199 vs. 7/200), nondermatologic malignancy (17/199 vs. 23/200), and skin cancer (0/199 vs. 2/200).

Appendix Evidence Table C121. Overview of intensive multicomponent intervention (INT) versus control treatment trials

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
Multi-component trials (n=4)				
Chan, 2009 ⁹⁴ Location China, Multi-site Funding Source Government	Inclusion Criteria: Type 2 DM and Plasma creatinine level 150-350 µmol/L, age 35-75 yrs Exclusion Criteria: Reversible cause of renal dysfunction (e.g. renal artery stenosis), malignancy or life threatening disease, nondiabetic renal disease, unstable psychiatric illness, and ≥20% difference in two consecutive plasma creatinine values within 3 months before recruitment.	N=205 Age (yr): 65 Gender (Male %): 66 Race/Ethnicity (%): NR Weight: NR BMI: 25.4 Systolic BP (mm Hg): 145 Diastolic BP (mm Hg): 74 CKD stage: NR Serum creatinine (mg/dL): NR Creatinine clearance (mL/min): NR Albuminuria: NR Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): NR Total cholesterol (mg/dL): NR LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 96 Dyslipidemia (%): NR History of CAD (%): 16 History of CHF (%): 7 Peripheral arterial disease (%): 1 History of MI (%): 2 History of Stroke (%): 15 Current smoker (%): NR History of AKI (%): NR	n=104 structured care (managed by multidisciplinary diabetes care team, including dietician, MD, and nurse educator, with regular lab monitoring, and treatment to target BP <130/80 mm Hg, HbA _{1c} <7%, LDL-C <2.6 mmol/L, triglycerides <2 mmol/L, and treatment with ACEI or ARB unless develop persistent hyperkalemia or increase in baseline creatinine by >30%) n= 101 Usual care/control Followup period: median 2 years Study withdrawals (%): 2.4%	Allocation Concealment Adequate Blinding: None (i.e. open) Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: Adequate
Joss, 2004 ⁹⁵ Location: Scotland/multi-site Funding Source Other-non industry	Inclusion Criteria: Pts w/ type 2 DM and nephropathy (albuminuria >300 mg/24h, characteristic diabetic retinopathy, kidneys w/near normal morphology on ultrasound), HTN Exclusion Criteria: NR	N= 90 Age (yr): 63 Gender (Male %): 63.3 Race/Ethnicity (%): NR Weight: NR BMI (kg/m ²): 30.4 Systolic BP (mm Hg): 165 Diastolic BP (mm Hg): 88 CKD stage: NR Serum creatinine (mg/dL): NR Creatinine clearance (mL/min): 55 mL/min	n= 47 Intensive therapy/Project team care (Managed by multidisciplinary project care team, including dietician, MD, and nurse, with initial visits as often as every 2-3 weeks.) n= 43 Control treatment (Patients managed in their usual clinic.)	Allocation Concealment Adequate Blinding: None (i.e. open) Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Yes

Appendix Evidence Table C121. Overview of intensive multicomponent intervention (INT) versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		Albuminuria: median 755 mg/24 hrs Albumin/creatinine ratio (mg/g): 78.8 mg/mmol Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): 7.9 Total cholesterol (mg/dL): 212.7 LDL cholesterol (mg/dL): NR Diabetes (%): 100 History of HTN (%): 100 Dyslipidemia (%): NR History of CAD (%): NR History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%):NR History of Stroke (%): NR Current smoker (%): 28 History of AKI (%): NR	Treatment goals were identical for both groups, including SBP <140 mm Hg, DBP <80 mm Hg, HbA _{1c} <8%, sodium intake <120 mmol/day, protein intake 0.7-1 g/kg of ideal body weight per day, cholesterol <4 mmol/L or cholesterol :HDL ratio <4. Exercise was encouraged and advice was given on smoking. For both groups, BP and lab measures were collected for monitoring every 3-6 months to guide management. Followup period: median 2 years Study withdrawals (%): 3.3%	
Gaede, 2003/1999 ^{96,97} STENO-2 Location Denmark, single site Funding Source Industry	Inclusion Criteria: Type 2 DM and microalbuminuria (defined as urinary albumin excretion rate of 30-300 mg/24hr in 4 of 6 urine samples). Exclusion Criteria: Age older than 65 or younger than 40; a stimulated serum C-peptide concentration less than 600 pmol/L 6 min after IV injection of 1 mg glucagon; pancreatic insufficiency or diabetes secondary to pancreatitis; alcohol abuse; nondiabetic kidney disease; malignancy; or life threatening disease with death probable within 4 years.	N=160 Age (yr): 55.1 yrs Gender (Male %): 74 Race/Ethnicity (%): NR Weight: NR BMI (kg/m ²): 29.8 Systolic BP (mm Hg): 148 Diastolic BP (mm Hg): 86 CKD stage: NR Serum creatinine (mmol/L): 77 Creatinine clearance (mL/min): NR Albuminuria: 73.5 mg/24 hr Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m ²): 117 HbA _{1c} (%): 8.6 Total cholesterol (mg/dL): 217 LDL cholesterol (mg/dL): 130 Diabetes (%): 100	n=80 Intensive care, with management by multidisciplinary Diabetes Center team, including a dietician, MD, and nurse. Targeted treatment goals of SBP <140 mm Hg, DBP <85 mm Hg, HbA _{1c} <6.5%, triglycerides <1.7 mmol/L, total cholesterol <5.0 mmol/L, HDL-cholesterol >1.1 mmol/L, aspirin for patients with known ischemia or peripheral vascular disease, ACEI regardless of blood pressure.	Allocation Concealment Adequate Blinding: No blinding Intention to Treat Analysis (ITT): No Withdrawals/Dropouts adequately described: Adequate in report with 7.8 yrs followup

Appendix Evidence Table C121. Overview of intensive multicomponent intervention (INT) versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		History of HTN (%): NR Dyslipidemia (%):NR History of CAD (%): 24 (based only on ischemia on resting or stress ECG) History of CHF (%): NR Peripheral arterial disease (%): NR History of MI (%): NR History of Stroke (%): 3 Current smoker (%): 38 History of AKI (%): NR	n= 80 Standard care, with management by their regular general practitioner, who was to follow Danish diabetes management guidelines, including treatment goals of SBP <160 mm Hg, DBP <95 mm Hg, HbA1c <7.5%, triglycerides <2.2 mmol/L, total cholesterol <6.5 mmol/L, HDL-cholesterol >0.9 mmol/L, aspirin for patients with known ischemia. Followup period: median 7.8 yrs for mortality outcome, median 3.8 yrs for other outcomes Study withdrawals (%): 3.1 for longer followup period, 1.9 for shorter followup period	
Harris, 1998 ⁹⁸	Inclusion Criteria: Primary care in the general medicine practice with ≥1 physician visit in the past year, and two serum creatinine levels at least 6 months apart with estimated creatinine clearances <50 mL/min both times, and most recent serum creatinine concentration before enrollment >1.4 mg/dL. Exclusion Criteria: Living in an institution (NH or prison), inability to communicate with the research assistants, either because of a sensory or neurologic deficit or because could not speak and/or understand English.	N=437 Age (yr): 68.5 Gender (Male %): 34 Race/Ethnicity (%): African American 80.5 Weight: 172.7 lbs BMI: NR Systolic BP (mm Hg): 144 Diastolic BP (mm Hg): 83 CKD stage: NR Serum creatinine (mg/dL): 2.1 Creatinine clearance (mL/min): 34 Albuminuria: NR Albumin/creatinine ratio (mg/g): NR Estimated GFR (ml/min/1.73m ²): NR HbA _{1c} (%): NR Total cholesterol (mg/dL): NR	n=206 Intensive case management in multidisciplinary renal clinic (nephrologist, renal nurse, renal dietician, social worker) including recommendations to patient's primary care provider to reduce use of nephrotoxic drugs, decrease dietary protein, initiate ACEI use if possible, with focus on improving medication compliance. n= 231 Standard care, with	Allocation Concealment Not described Blinding: No blinding Intention to Treat Analysis (ITT): Yes Withdrawals/Dropouts adequately described: No withdrawals were reported

Appendix Evidence Table C121. Overview of intensive multicomponent intervention (INT) versus control treatment trials (continued)

Study/Region/ Funding Source	Inclusion/Exclusion Criteria	Patient Characteristics (expressed in means unless otherwise noted)	Intervention/Duration	Study Quality
		LDL cholesterol (mg/dL): NR Diabetes (%): 43.5 History of HTN (%):98.6 Dyslipidemia (%): NR History of CAD (%): 47.8 History of CHF (%): 40 Peripheral arterial disease (%): NR History of MI (%): 37 History of Stroke (%): 20 Current smoker (%): NR History of AKI (%): NR	management by their regular general medicine physician. Followup period: median 5 years Study withdrawals (%): 0	

INT = Intensive Multi-Component Intervention

Appendix Table C122. Summary of study baseline characteristics for INT versus control treatment trials

Characteristic	Mean (range) (unless otherwise noted)	Number of Trials Reporting
INT trials		4
Patients randomized, n	892 (90 to 437)	4
Age of subjects, years	64.7 (55.1 to 68.5)	4
Male gender, %	51.5 (34 to 74)	4
African American Race/ethnicity, %	*80.5	1
Body Mass Index, kg/m ²	27.9 (25.4 to 30.4)	3
Patients with diabetic nephropathy, n	†250 (90 to 160)	2
Serum creatinine, mg/dL	1.8 (0.9 to 2.1)	2
Estimated GFR, ml/min/1.73m ²	117	1
Creatinine clearance (mL/min)	37.6 (34 to 55)	2
Albuminuria, mg/24 hr	‡	2
Systolic blood pressure, mm Hg	147 (144 to 165)	4
Diastolic blood pressure, mm Hg	82 (74 to 88)	4
History of hypertension, %	98.0 (96 to 100)	3
HbA _{1c} (%)	8.3 (7.9 to 8.6)	2
History of CAD, %	‡34.9 (16 to 47.8)	3
History of MI, %	25.8 (2 to 37)	2
History of CHF, %	29.5 (7 to 40)	2
History of Stroke, %	15.3 (3 to 20)	3
Total cholesterol, mg/dL	215 (213 to 216.5)	2
LDL cholesterol, mg/dL	129.5	1
Current smokers, %	34.4 (28 to 38)	2

INT = Intensive Multi-Component Intervention; GFR = glomerular filtration rate; HbA_{1c} = hemoglobin A_{1c}; CAD = coronary artery disease; MI = myocardial infarction; CHF = congestive heart failure; LDL = low density lipoprotein
 *This study reported data only for African American race/ethnicity, but did not report information regarding the race/ethnicity of its remaining participants.

†Two other studies included a total of 395 participants with diabetes and either impaired creatinine clearance or GFR, but did not report information on albuminuria or proteinuria. These study subjects were not counted toward the total number of patients with diabetic nephropathy.

‡Of the two studies reporting baseline albuminuria, one reported a mean of 73.5 mg/24 hours and the other a median of 755 mg/24 hours.

Appendix Table C123. Clinical outcomes (outcomes part A), INT versus control treatment trials

Study	All-Cause Mortality, n/N (%)		Cardiovascular Death, n/N (%)		Myocardial Infarction, Any, n/N (%)		Myocardial Infarction, Fatal n/N (%)		Myocardial Infarction, Nonfatal, n/N (%)		Stroke, Any, n/N (%)	
	INT	Control	INT	Control	INT	Control	INT	Control	INT	Control	INT	Control
INT versus control treatment trials (n=4)												
Chan, 2009 ⁸⁴	8/104 (7.7)	11/101 (11.0)			4/104 (3.8)	4/101 (4.0)					*NR	*NR
Joss, 2004 ⁹⁵	6/47 (12.8)	3/43 (7.0)	†4/47 (8.5)	†3/43 (7.0)	‡NR	‡NR	2/47 (4.3)	1/43 (2.3)	‡NR	‡NR	‡NR	‡NR
§Gaede, 2003/1999 ⁹ 6,97	12/80 (15.0)	15/80 (18.8)	7/80 (8.8)	7/80 (8.8)					4/80 (5.0)	8/80 (10.0)		
Harris, 1998 ⁹⁸	59/206 (28.6)	77/231 (33.3)										

INT = Intensive Multi-Component Intervention; NR = not reported

*Study reported results for composite endpoint of stroke or transient ischemic attack (2/104 in INT group vs. 3/101 in control group), but not for stroke outcome only.

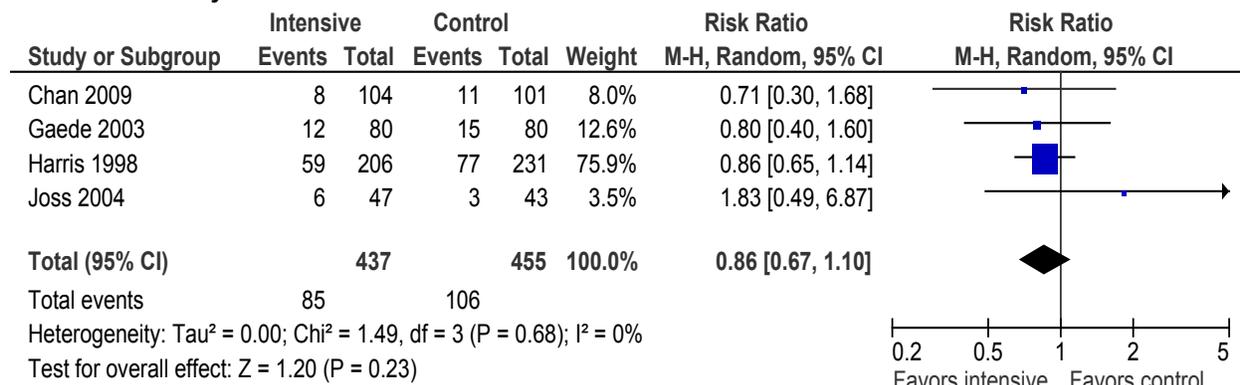
†Study didn't define cardiovascular death, but these results derived from sum of participants in each group with sudden death, fatal myocardial infarction, or fatal stroke.

‡Study reported myocardial infarction, nonfatal myocardial infarction, and stroke by number of events per treatment group and not by the proportion of participants in each treatment group with one or more event.

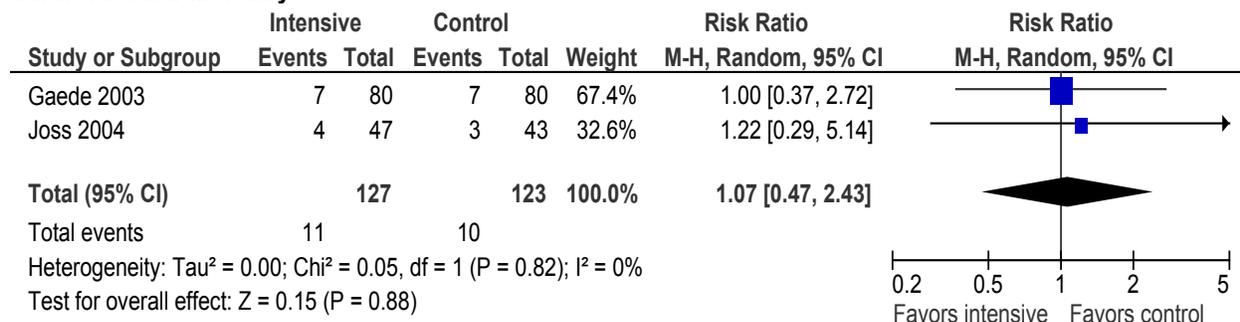
§Study results taken from 2003 report except when data for a specific outcome only was available from the earlier 1999 report.

Appendix Figure C23. Forest plots for INT versus control treatment trials

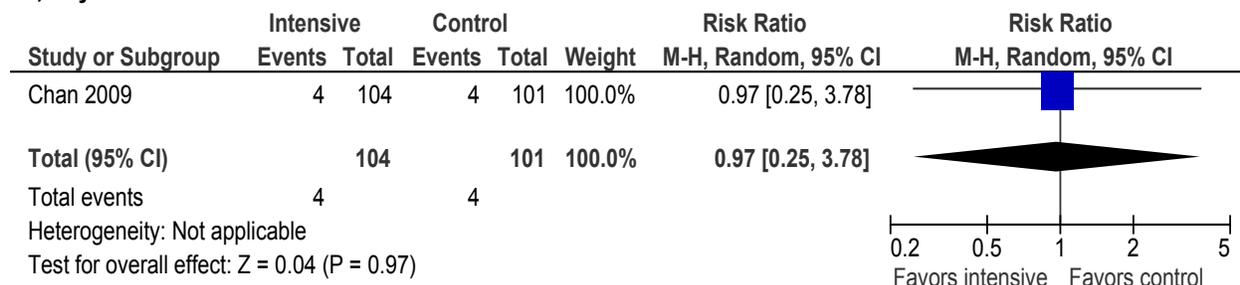
All-cause mortality



Cardiovascular mortality

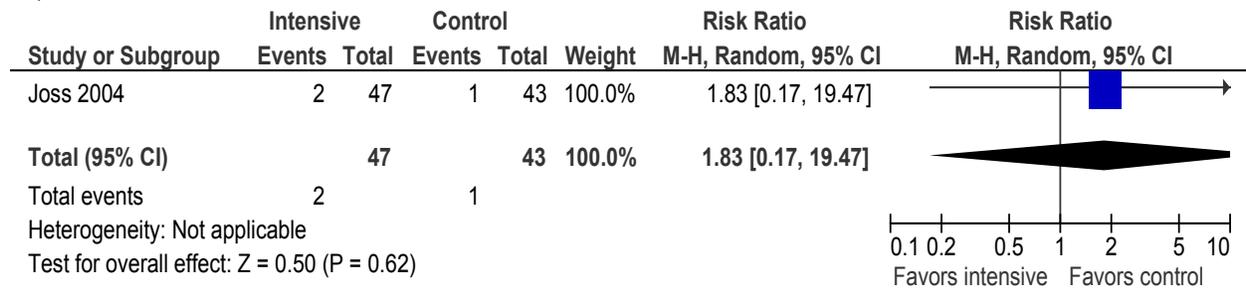


MI, any

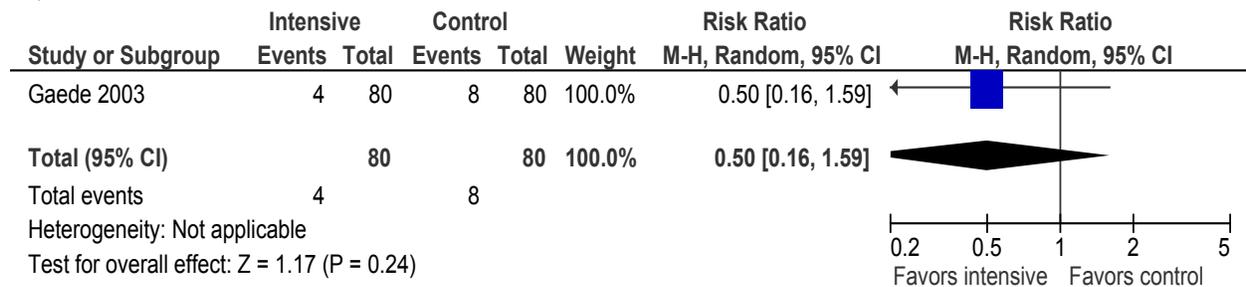


Appendix Figure C23. Forest plots for INT versus control treatment trials (continued)

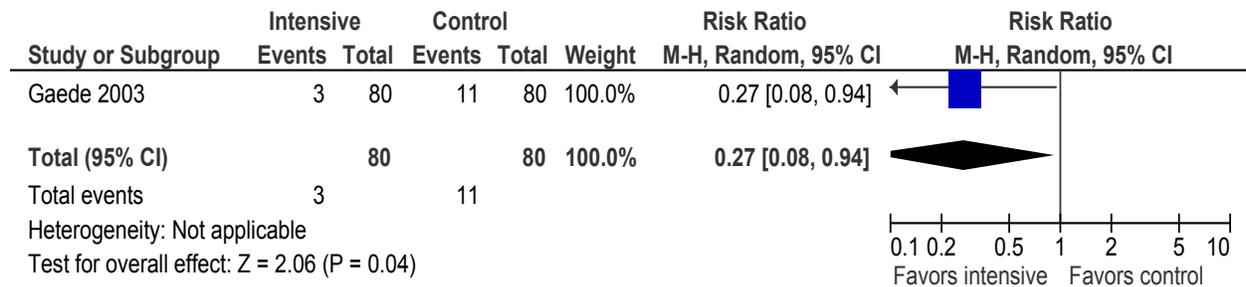
MI, fatal



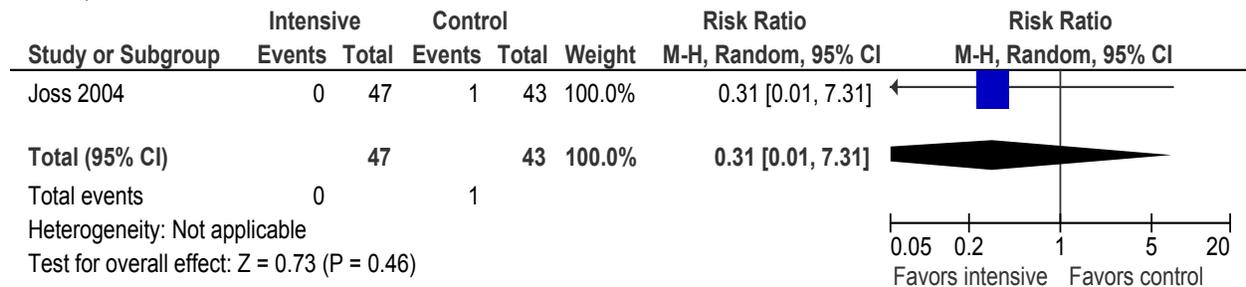
MI, nonfatal



Stroke, nonfatal

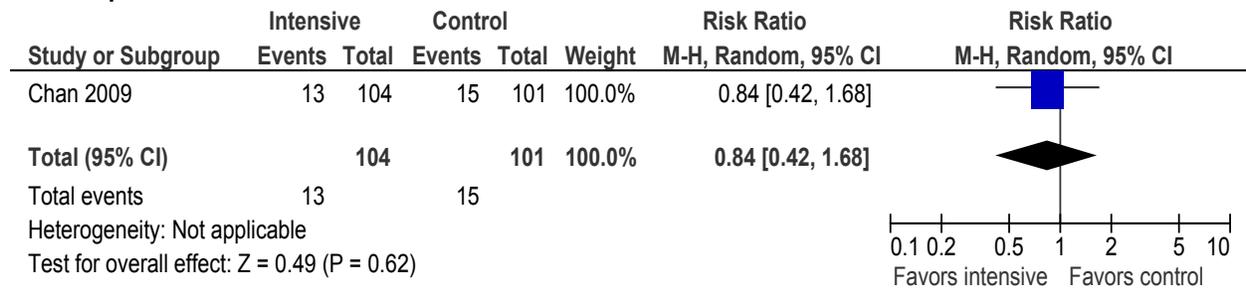


Stroke, fatal

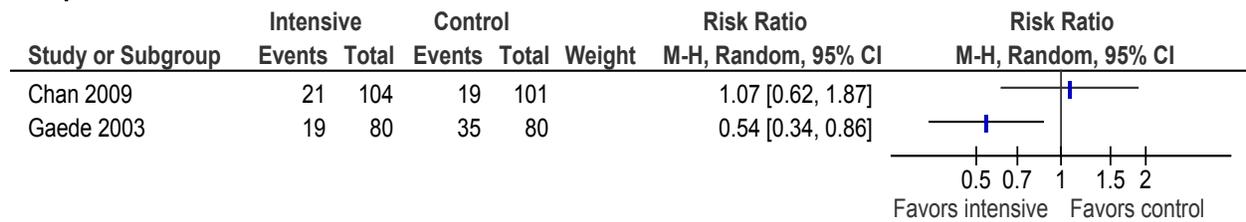


Appendix Figure C23. Forest plots for INT versus control treatment trials (continued)

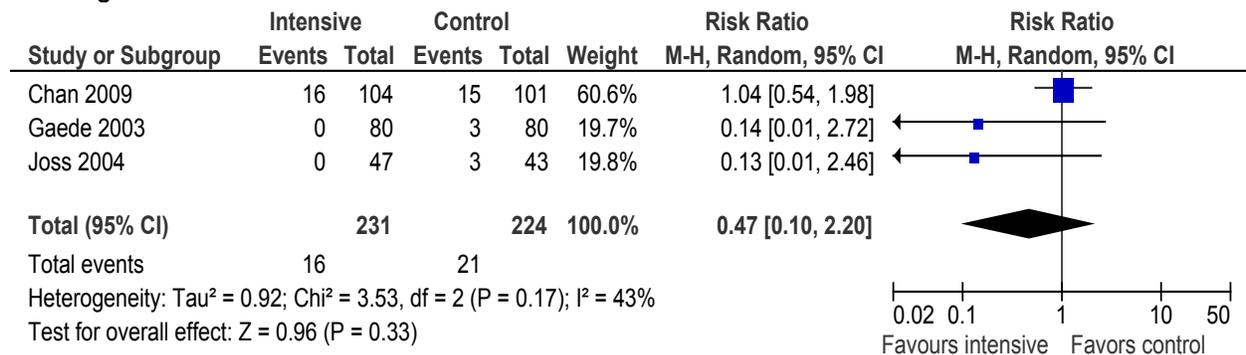
CHF hospitalization



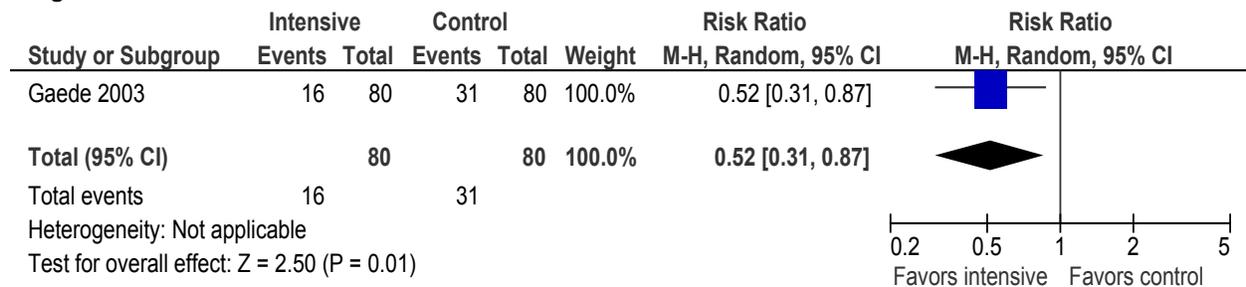
Composite vascular outcome



End stage renal disease

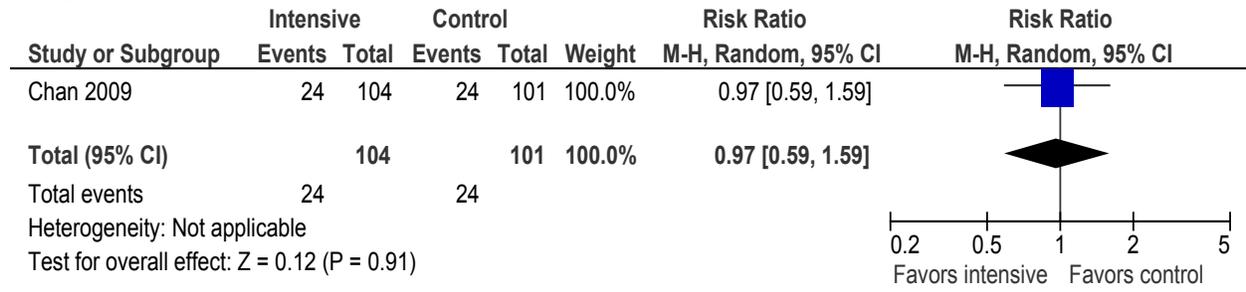


Progression from microalbuminuria to macroalbuminuria



Appendix Figure C23. Forest plots for INT versus control treatment trials (continued)

Composite renal outcome



Appendix Table C124. Clinical outcomes (outcomes part B), INT versus control treatment trials

Study	Stroke, Nonfatal, n/N (%)		Stroke, Fatal, n/N (%)		CHF, Any, n/N (%)		CHF Hospitalization (A) or Death (B), n/N (%)		Composite Vascular Outcome, n/N (%)	
	INT	Control	INT	Control	INT	Control	INT	Control	INT	Control
<i>INT versus control treatment trials (n=4)</i>										
Chan, 2009 ⁹⁴							(A)13/104 (12.5) (B) NR	(A)15/101 (14.8) (B) NR	21/104 (20.2)	19/101 (18.8)
Joss, 2004 ⁹⁵	†NR	†NR	0/47	1/43 (2.3)	†NR	†NR			†NR	†NR
*Gaede, 2003/1999 ^{96,97}	3/80 (3.8)	11/80 (13.8)							(A)19/80 (23.8)	(A)35/80 (43.8)
Harris, 1998 ⁹⁸										

INT = Intensive Multi-Component Intervention; CHF = congestive heart failure; NR = not reported

*Study results taken from 2003 report except when data for a specific outcome only was available from the earlier 1999 report.

†Study reported nonfatal stroke, CHF, and composite vascular outcomes by number of events per treatment group and not by the proportion of participants in each treatment group with one or more event.

Appendix Table C125. Composite vascular outcome definitions for INT versus control treatment trials

Study	Definition
<i>INT versus control treatment trials (n=4)</i>	
Chan, 2009 ⁹⁴	“Composite cardiovascular end point” included any of the following: hospitalization for heart failure, hospitalization for angina, hospitalization for arrhythmia, MI, coronary revascularization (PTCA/CABG), other revascularization, CVA or transient ischemic attack, and lower limb amputation.
Joss, 2004 ⁹⁵	“Cardiovascular events” included any of the following: sudden death, fatal and nonfatal MI, fatal and nonfatal CVA, CABG, CHF (undefined), amputation (undefined) or interventional vascular surgery.
Gaede, 2003/1999 ^{96,97}	The primary composite endpoint was defined as (A) death from cardiovascular causes, nonfatal MI, CABG, PCI, nonfatal stroke, amputation as a result of ischemia, or surgery for peripheral atherosclerotic artery disease. Additional composite vascular endpoints were defined as: (B) All cause mortality, nonfatal MI, nonfatal CVA, CABG, PTCA, arterial revascularization to the legs, or amputation to the legs for ischemia; (C) cardiovascular mortality, nonfatal MI, nonfatal CVA, CABG, PTCA, arterial revascularization to the legs, or amputation to the legs for ischemia; and (D) nonfatal MI, nonfatal CVA, CABG, PTCA, arterial revascularization to the legs, or amputation to the legs for ischemia.

INT = Intensive Multi-Component Intervention; PTCA = percutaneous transluminal coronary angioplasty; CABG = coronary artery bypass grafting; MI = myocardial infarction; CVA = cerebrovascular accident (i.e. stroke)

Appendix Table C126. Clinical renal outcomes (outcomes part C), INT versus control treatment trials

Study	End Stage Renal Disease, n/N (%)		Doubling of Serum Creatinine, n/N (%)		Halving of GFR, n/N (%)		Progression from Micro to Macroalbuminuria, n/N (%)		Composite Renal Outcome, n/N (%)	
	INT	Control	INT	Control	INT	Control	INT	Control	INT	Control
<i>Intensive Multi-Component Intervention (INT) versus Control treatment trials (n=4)</i>										
Chan, 2009 ⁹⁴	16/104 (15.4)	15/101 (14.9)							24/104 (23.1)	24/101 (23.8)
Joss, 2004 ⁹⁵	0/47	3/43 (7.0)								
*Gaede, 2003/1999 ^{96,97}	0/80	3/80 (3.8)					16/80 (20.0)	31/80 (38.8)		
Harris, 1998 ⁹⁸										

INT = Intensive Multi-Component Intervention; GFR = glomerular filtration rate

*Study results taken from 2003 report except when data for a specific outcome only was available from the earlier 1999 report.

C-255

Appendix Table C127. Composite renal outcome definitions for INT versus control treatment trials

Study	Definition
<i>INT versus control treatment trials (n=4)</i>	
Chan, 2009 ⁹⁴	ESRD (defined as the need for dialysis, or plasma creatinine level ≥ 500 $\mu\text{mol/l}$) or death.

INT = Intensive Multi-Component Intervention; ESRD = end stage renal disease

Appendix Table C128. Study withdrawals and adverse events (outcomes part D), INT versus control treatment trials

Study	Study Withdrawals: Any		Serious Adverse Event: Any		Serious Adverse Event: Any Leading to Withdrawal		Adverse Event: Any		Renal Adverse Events: Any		Adverse Event: Other Specific	
	INT	Control	INT	Control	INT	Control	INT	Control	INT	Control	INT	Control
INT versus control treatment trials (n=4)												
Chan, 2009 ³⁴	*NR	*NR			0/104	0/101						
Joss, 2004 ⁹⁵	2/47 (4.2)	1/43 (2.3)										
†Gaede, 1999/2003 ^{96, 97}	1/80 (1.3)	2/80 (2.5)	1/80 (1.3)	0/80	0/80	0/80					Hypoglycemia: Minor 42/80 (52.5), Major 5/80 (6.3)	Hypoglycemia: Minor 39/80 (48.8), Major 12/80 (15.0)
Harris, 1998 ⁹⁸	0/206	0/231										

INT = Intensive Multi-Component Intervention; NR = not reported

*Study reported withdrawals only for combined treatment groups (n=5 [2.4%]), but not for each treatment group by itself.

†Study results taken from 2003 report except when data for a specific outcome only was available from the earlier 1999 report.

Table C129. Assessment of individual study quality for KQ5 and KQ6

Study ID	Allocation Concealment	Blinding	Intention to Treat Analysis	Withdrawals/ Described	Study Eating
<i>Angiotensin converting enzyme inhibitor (ACEI) versus placebo/no treatment trials (n=17)</i>					
Perkovic, 2007 ¹ PROGRESS	adequate	double*	yes	NA, post hoc analysis	Good
Asselbergs, 2004 ²	unclear	double*	yes	yes	Fair
Marre, 2004 ³ DIABHYCAR	adequate	double*	yes	yes	Good
Katayama, 2002 ⁴ JAPAN-IDDM	adequate	double*	no	yes	Fair
Bojestig, 2001 ⁵ Gerstein HOPE Trial, 2001 ⁶	unclear adequate**	double double*	yes yes	yes NA, post hoc analysis	Fair Good
O'Hare, 2000 ⁷ ATLANTIS	adequate	double	no	yes	Fair
Muirhead, 1999 ⁸	unclear	double	no	yes	Fair
Ruggenenti, 1999 ⁹ REIN	adequate	double*	yes	yes	Good
Crepaldi, 1998 ¹⁰	unclear	double	no	yes	Fair
The GISEN Group, 1997 ¹¹	adequate	double*	yes	yes	Good
Maschio, 1996 ¹²	unclear	double*	yes	yes	Fair
Trevisan, 1995 ¹³	unclear	double	no	yes	Fair
Laffel, 1995 ¹⁴	unclear	double	no	yes	Fair
Sano 1994 ¹⁵	unclear	no	no	yes	Fair
Lewis, 1993 ¹⁶	unclear	double*	yes	yes	Fair
Ravid, 1993 ¹⁷	unclear	double	no	yes	Fair
<i>Angiotensin converting enzyme inhibitor (ACEI) versus angiotensin II-receptor blocker (ARB) trials (n=6)</i>					
Mann, 2008 ¹⁸ ONTARGET	adequate	double	yes	yes	Good
Menne, 2008 ¹⁹ VALERIA	adequate	double*	no	yes	Fair
Sengul, 2006 ²⁰	unclear	no	no	yes	Fair
Barnett, 2004 ²¹ DETAIL	adequate	double	yes	yes	Good
Lacourcière, 2000 ²²	unclear	double	no	yes	Fair
Muirhead, 1999 ⁸	unclear	double	no	yes	Fair
<i>Angiotensin converting enzyme inhibitor (ACEI) versus Calcium channel blocker (CCB) trials (n=6)</i>					
Rahman, 2005 ²³ ALLHAT	adequate**	double*	yes	NA, post hoc analysis	Good
Fogari, 2002 ²⁴	adequate	no	no	yes	Fair
Agodoa, 2002 ²⁵ Wright, 2002 ²⁶ Norris, 2006 ²⁷ (AASK)	adequate**	double*	yes	yes	Good
Marin, 2001 ²⁸ ESPIRAL	unclear	no	yes	yes	Fair
Crepaldi, 1998 ¹⁰	unclear	double	no	yes	Fair
Zucchelli, 1995/1992 ^{29,30}	unclear	no	yes	yes	Fair
<i>Angiotensin converting enzyme inhibitor (ACEI) versus beta-blocker trials (n=3)</i>					
Wright, 2002 ²⁶ Norris, 2006 ²⁷ (AASK)	adequate**	double*	yes	yes	Good
van Essen, 1997 ³¹	unclear	double	no	yes	Fair

Table C129. Assessment of individual study quality for KQ5 and KQ6 (continued)

Study ID	Allocation Concealment	Blinding	Intention to Treat Analysis	Withdrawals/ Described	Study Rating
Hannedouche, 1994 ³²	adequate	no	yes	yes	Fair
<i>Angiotensin converting enzyme inhibitor (ACEI) versus diuretics trials (n=2)</i>					
Rahman, 2005 ²³ ALLHAT	adequate**	double*	yes	NA, post hoc analysis	Good
Marre, 2004 ³³ NESTOR	unclear	double	no (one subject excluded)	yes	Fair
<i>ARB versus placebo trials (n=4)</i>					
Makino, 2007 ³⁶	unclear	double	no	yes	Fair
Brenner, 2001 ³⁷ RENAAL	adequate	double*	yes	yes	Good
Parving, 2001 ³⁸ IRMA-2	unclear	double	yes	yes	Fair
Lewis, 2001 ³⁹ IDNT	adequate	double*	yes	yes	Good
<i>ARB versus CCB trials (n=4)</i>					
Saruta, 2009 ⁴⁰ CASE-J	unclear	no	yes	no	Fair
Ogawa, 2007 ⁴¹	unclear	single (patient)	unclear	yes	Fair
Viberti, 2002 ⁴² MARVAL	adequate	double	yes	yes	Good
Lewis, 2001 ³⁹ IDNT	adequate	double*	yes	yes	Good
<i>ACEI plus ARB versus ACEI trials (n=6)</i>					
Sengul, 2006 ²⁰	unclear	no	no	yes	Fair
Menne, 2008 ¹⁹ VALERIA	adequate	double*	no	yes	Fair
Mann, 2008 ¹⁸ ON-TARGET	adequate	double	yes	yes	Good
Kanno, 2006 ⁴⁴	unclear	no	no	yes	Fair
Mehdi, 2009 ⁴⁵	unclear	double	no (one subject excluded)	yes	Fair
Anand, 2009 ⁴⁶	adequate	double	yes	yes	Good
<i>ACEI plus ARB versus ARB trials (n=3)</i>					
Sengul, 2006 ²⁰	unclear	no	no	yes	Fair
Menne, 2008 ¹⁹ VALERIA	adequate	double*	no	yes	Fair
Mann, 2008 ¹⁸ ON-TARGET	adequate	double	yes	yes	Good
<i>ACEI plus ARB versus ACEI plus aldosterone antagonist trial</i>					
Mehdi, 2009 ⁴⁵	unclear	double	no (one subject excluded)	yes	Fair
<i>ACEI plus CCB versus ACEI monotherapy or CCB monotherapy trial</i>					
Fogari 2002	adequate	no	no	yes	Fair
<i>ACEI plus diuretic versus ACEI plus CCB trial</i>					
Bakris, 2008 ⁴⁷ (GUARD)	adequate	double	no	yes	Fair
<i>ACEI plus diuretic versus ACEI trials</i>					
Mogensen, 2003 ⁴⁸	unclear	double	no	no	Fair
<i>ARB versus different ARB trials</i>					
Bakris, 2008 ⁴⁹ (AMADEO)	unclear	double	no	no	Fair
Galle, 2008 ⁵⁰	unclear	double	yes	yes	Fair
<i>ARB (high dose) versus ARB (standard dose) trial</i>					
Burgess, 2009 ⁵¹	adequate	double	yes	yes	Good

Table C129. Assessment of individual study quality for KQ5 and KQ6 (continued)

Study ID	Allocation Concealment	Blinding	Intention to Treat Analysis	Withdrawals/ Described	Study Rating
<i>ACEI plus aldosterone antagonist versus ACEI trial</i>					
Mehdi, 2009 ⁴⁵	unclear	double	no (one subject excluded)	yes	Fair
<i>ACEI/ARB plus aldosterone antagonist versus ACEI/ARB trial</i>					
van den Meiracker, 2006 ⁵²	adequate	double	no	yes	Fair
<i>Beta blocker versus placebo trial</i>					
Ghal, 2009 ⁵³ MERIT-HF	adequate	double	yes	yes	Good
<i>CCB versus placebo trials</i>					
Berl, 2003 ⁵⁴ Lewis, 2001 ³⁹	adequate	double	yes	yes	Good
Crepaldi, 1998 ¹⁰	unclear	double	no	yes	Fair
<i>Diuretic versus placebo trial</i>					
Pahor, 1998 ⁵⁵	adequate	double	yes	yes	Good
<i>ACEI versus conventional therapy without ACEI trial</i>					
Cinotti, 2001 ³⁴	unclear	no	yes	no	Fair
<i>CCB versus BB trials (n=3)</i>					
Bakris, 1996 ⁵⁶	unclear	unclear	yes	yes	Fair
Wright, 2002 ²⁶ AASK	adequate**	double*	no	yes	Good
Dahlof, 2005 ⁵⁸	adequate	open-label*	yes	yes	Good
<i>CCB versus diuretic trial</i>					
Rahman 2006 ALLHAT	adequate**	double*	yes	yes for overall study population	Good
<i>Strict versus standard blood pressure control trials (n=6)</i>					
Ruggenti, 2005 ⁵⁹ REIN-2	adequate	no	No, 3 subjects excluded	yes	Fair
Wright, 2002 ²⁶ AASK	adequate**	no	yes	yes	Good
Lewis, 1999 ⁶⁰	unclear	unclear	yes	no	Fair
Toto, 1995 ⁶¹	unclear	double	yes	unclear	Fair
Peterson, 1995 ⁶² Klahr, 1994 ⁶³	unclear	unclear	yes	yes	Fair
MDRD, Study A Shulman, 1989 ⁶⁴ HDFP	adequate	no	no	no	Fair
<i>Anti-lipid trials: HMG-CoA reductase inhibitor versus placebo trials (n=11)</i>					
Kendrick, 2010 ⁷⁸ AFCAPS/ TexCAPS	unclear	double*	yes	yes	Fair
Nakamura, 2009 ⁷⁹ MEGA	adequate**	open-label	yes	unclear	Good
Colhoun, 2009 ⁸⁰ CARDS	adequate**	double*	yes	NA, secondary or post hoc analysis	Good
Koren, 2009 ⁸¹ ALLIANCE	adequate	open-label	yes	NA, secondary or post hoc analysis	Good
Rahman, 2008 ⁸³ ALLHAT-LLT	adequate**	open-label*	yes	NA, secondary or post hoc analysis	Good
Chonchol, 2007 ⁸⁴ 4S	adequate**	double*	No (24 excluded, no serum creatinine at baseline)	NA, secondary or post hoc analysis	Fair

Table C129. Assessment of individual study quality for KQ5 and KQ6 (continued)

Study ID	Allocation Concealment	Blinding	Intention to Treat Analysis	Withdrawals/ Described	Study Rating
Kjekshus, 2007 ⁸⁶ CORONA	adequate**	double*	yes	yes	Good
Lemos, 2005 ⁸⁷ LIPS	unclear	double*	yes	NA, secondary or post hoc analysis	Fair
Asselbergs, 2004 ² PREVD	unclear	double*	yes	yes	Fair
Tonelli, 2004 ⁸⁸ WOSCOPS/ CARE/LIPID	adequate**	double*	yes	NA, secondary or post hoc analysis	Good
Tonelli, 2003 ⁸⁹ CARE	adequate	double*	yes	NA, secondary or post hoc analysis	Good
<i>Anti-lipid trials: high versus low dose HMG-CoA reductase inhibitor trial</i>					
Shepherd, 2008 ⁹⁰ TNT	unclear	double*	no	NA, secondary or post hoc analysis	Fair
<i>Anti-lipid trials: HMG-CoA reductase inhibitor versus bile acid sequestrant trial</i>					
Tonolo, 2006 ⁹³	unclear	double	yes	yes	Fair
<i>Anti-lipid trials: Gemfibrozil versus placebo/control trials (n=2)</i>					
Tonelli, 2004 ⁸⁸ VA-HIT	adequate	double*	yes	NA, secondary or post hoc analysis	Good
Samuelsson, 1997 ⁷⁵	unclear	open-label	no	yes	Fair
<i>Low protein diet versus usual protein diet and other dietary intervention trials (n=9)</i>					
Koya, 2009 ⁶⁵	adequate	no	no	yes	Fair
Dussol, 2005 ⁶⁶	unclear	no	no	yes	Fair
Kopple, 1997 ⁶⁷ Peterson, 1995 ⁶² Klahr, 1994 ⁶³ Greene, 1993 ⁶⁸ MDRD	adequate	double for followup GFRs	unclear	yes	Fair
D'Amico, 1994 ⁶⁹	unclear	no	no	no	Fair
Locatelli, 1991 ⁷⁰	adequate	unclear	no	yes	Fair
Rosman, 1989/1984 ^{71,72}	unclear	no	no	no	Fair
Facchini, 2003 ⁷³	unclear	study personnel blinded to aim of study	no	yes	Fair
Williams, 1991 ⁷⁴	adequate	no	no	no	Fair
Samuelsson, 1997 ⁷⁵	unclear	no	no	yes	Fair
<i>Glycemic control trials (n=2)</i>					
Duckworth, 2009 ⁷⁶	adequate	open-label*	yes	yes	Good
Microalbuminuria Collaborative, 1995 ⁷⁷	adequate	open-label	yes	yes	Good
<i>Intensive multi-component intervention trials (n=4)</i>					
Chan, 2009 ⁹⁴	adequate	open-label	yes	yes	Good
Joss, 2004 ⁹⁵	adequate	open-label	no	yes	Fair
Gaede, 2003/1999 ^{96,97}	adequate	open-label	no	yes	Fair
Harris, 1998 ⁹⁸	unclear	open-label	yes	yes	Fair

*plus end points adjudicated by blinded committee

** detailed in baseline/study design or main findings manuscript

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