

# Appendix A. Search Strategy

PubMed:

Search Jan. 8, 2012

Search	Query	Items found
#1	Search "Otitis Media with Effusion"[Mesh]	4535
#2	Search "Ear, Middle/secretion"[Mesh]	101
#3	Search "glue ear"[tiab]	251
#4	Search "otitis media"[tiab]	15150
#5	Search middle ear effusion*	1609
#6	Search (OME[tiab] OR SOM[tiab]) AND (otitis[tiab] OR ear*[tiab])	1463
#7	Search "nonsuppurative otitis"[tiab]	0
#8	Search "serous otitis"[tiab]	610
#9	Search "secretory otitis"[tiab]	940
#10	Search "adhesive otitis"[tiab]	165
#11	Search "exudative otitis"[tiab]	89
#12	Search (mucoid*[tiab] AND otitis[tiab]) OR (mucous[tiab] AND otitis[tiab]) OR (sero-muco*[tiab] AND otitis[tiab]) OR (sero[tiab] OR muco[tiab] AND otitis[tiab]) OR (otitis[tiab] AND serosa[tiab])	412
#13	Search (mucoid*[tiab] AND middle[tiab] AND ear*[tiab]) OR (mucous[tiab] AND middle[tiab] AND ear*[tiab]) OR (seromuc*[tiab] AND middle[tiab] AND ear*[tiab])	462
#14	Search #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13	17356
#15	Search "Steroids"[Mesh] OR oral steroid*	653912
#16	Search nasal*[tiab] AND (topical steroid*[tiab])	213
#17	Search "Anti-Bacterial Agents"[Mesh] OR antibiotic*	367969
#18	Search "ear popper"[tiab] OR manual therap*[tiab]	965
#19	Search autoinflation[tiab]	49
#20	Search pressure equalization tube*[tiab]	58
#21	Search "Adenoidectomy"[Mesh] OR adenoidectom*[tiab]	3873
#22	Search "Middle Ear Ventilation"[Mesh] OR tympanostomy[tiab] OR ((middle[tiab] AND (ear*[tiab] OR tympanic[tiab])) AND tube*[tiab])	4130
#23	Search grommet*[tiab]	445
#24	Search ventilation tube*[tiab]	777
#25	Search "Tonsillectomy"[Mesh] OR tonsillectomy[tiab]	8554
#26	Search "Leukotriene Antagonists/therapeutic use"[Mesh] OR "Leukotriene Antagonists" [Pharmacological Action]	4042
#27	Search "Acetates/therapeutic use"[Mesh]	2774
#28	Search "Quinolines/therapeutic use"[Mesh]	35055
#29	Search "Combined Modality Therapy"[Mesh] OR combined modality therap*[tiab]	177569
#30	Search myringotomy[tiab]	1061
#31	Search "Otologic Surgical Procedures"[Mesh]	13165
#32	Search "Phosphorylcholine/administration and dosage"[Mesh] OR "Phosphorylcholine/therapeutic use"[Mesh]	412
#33	Search "Watchful Waiting"[Mesh] OR watchful waiting*[tiab]	1517
#34	Search tubulation[tiab]	257
#35	Search #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #31 or #32 or #33 or #34	1231827
#36	Search #14 and #35	6961
#37	Search #36 or #30	7507
#38	Search #37 Limits: Humans	6659
#39	Search "Randomized Controlled Trial"[Publication Type] OR "Single-Blind Method"[MeSH] OR "Double-Blind Method"[MeSH] OR "Random Allocation"[MeSH]	398253
#40	Search #38 and #39	602
#41	Search #38 Limits: Controlled Clinical Trial	70
#42	Search #38 AND "Controlled Clinical Trials as Topic"[Mesh]	134

<b>Search</b>	<b>Query</b>	<b>Items found</b>
<a href="#">#43</a>	Search #40 or #41 or #42	<a href="#">763</a>
<a href="#">#44</a>	Search #38 AND systematic[sb]	<a href="#">258</a>
<a href="#">#45</a>	Search #38 Limits: Meta-Analysis	<a href="#">55</a>
<a href="#">#46</a>	Search #44 or #45	<a href="#">258</a>
<a href="#">#47</a>	Search ("Case-Control Studies"[MeSH] OR "Cohort Studies"[MeSH] OR "Epidemiologic Studies"[MeSH] OR "Cross-Sectional Studies"[MeSH] OR "Organizational Case Studies"[MeSH] OR "Cross-Over Studies"[MeSH] OR "Follow-Up Studies"[MeSH] OR "Seroepidemiologic Studies"[MeSH] OR "Multicenter Study"[Publication Type] OR "Multicenter Studies as Topic"[MeSH] OR "Evaluation Studies"[Publication Type] OR "Evaluation Studies as Topic"[MeSH])	<a href="#">2315890</a>
<a href="#">#48</a>	Search #38 and #47	<a href="#">2603</a>
<a href="#">#49</a>	Search #38 and harms	<a href="#">5</a>
<a href="#">#50</a>	Search #43 or #46 or #48 or #49 <b>ALL STUDY TYPES GATHERED EXCEPT LIT REVIEWS, SAVED SEPARATELY.</b>	<a href="#">2939</a>
<a href="#">#51</a>	Search #38 Limits: Review	<a href="#">979</a>
<a href="#">#52</a>	Search #51 not #46 <b>THE LIT. REVIEWS.</b>	<a href="#">851</a>

**Cochrane Library:**

**Search Jan. 8, 2012**

<b>ID</b>	<b>Search</b>	<b>Hits</b>
#1	<a href="#">"Otitis Media with Effusion" OR "otitis media" OR "middle ear secretion" OR "Ear, Middle/secretion" OR "glue ear" OR middle ear effusion* OR OME OR SOM OR (otitis AND ear) OR (otitis AND ears) OR "nonsuppurative otitis" OR "serous otitis" OR "secretory otitis" OR "adhesive otitis" OR "exudative otitis" OR (mucoid AND otitis) OR (mucous AND otitis) OR (sero-muco* AND otitis) OR ((sero OR muco) AND otitis) OR (otitis AND serosa) OR (mucoid AND middle AND ear*) OR (mucous AND middle AND ear*) OR (seromuc* AND middle AND ear*)</a>	2221
#2	<a href="#">"Steroids" OR oral steroid* OR (nasal* AND topical steroid*) OR "Anti-Bacterial Agents" OR antibiotic* OR "ear popper" OR manual therap* OR pressure equalization tube* OR adenoidectom* OR "Middle Ear Ventilation" OR tympanostomy OR (middle AND ear*AND tube*) OR (middle AND tympanic* AND tube*) OR grommet* OR ventilation tube* OR tonsillectomy OR "Leukotriene Antagonists/therapeutic use" OR "Leukotriene Antagonists" OR acetate* OR quinolone* OR phosphorylcholine OR combined modality therap* OR "Otologic Surgical Procedures" OR watchful waiting* OR tabulation OR autoinflation</a>	50759
#3	<a href="#">(#1 AND #2)</a>	1023
#4	<a href="#">(#3 OR myringotomy)</a>	1119
#5	<a href="#">"Randomized Controlled Trial" OR "Single-Blind Method" OR "Double-Blind Method" OR "Random Allocation" OR "Controlled Clinical Trial" OR "Controlled Clinical Trials as Topic" OR (control* AND trial)</a>	689256
#6	<a href="#">(#4 AND #5)</a>	1067
#7	<a href="#">("Case-Control Studies"[MeSH] OR "Cohort Studies"[MeSH] OR "Epidemiologic Studies"[MeSH] OR "Cross-Sectional Studies"[MeSH] OR "Organizational Case Studies"[MeSH] OR "Cross-Over Studies"[MeSH] OR "Follow-Up Studies"[MeSH] OR "Seroepidemiologic Studies"[MeSH] OR "Multicenter Study"[Publication Type] OR "Multicenter Studies as Topic"[MeSH] OR "Evaluation Studies"[Publication Type] OR "Evaluation Studies as Topic"[MeSH])</a>	120400
#8	<a href="#">(#4 AND #7)</a>	308
#9	<a href="#">(#4)</a>	172
#10	<a href="#">(#6 OR #8 OR #9)</a>	1119

**Embase:****Search Jan. 8, 2012**

<b>No.</b>	<b>Query</b>	<b>Results</b>
#1	'otitis media with effusion'/exp OR 'otitis media with effusion' OR 'otitis media'/exp OR 'otitis media' OR 'middle ear secretion' OR 'ear, middle/secretion' OR 'glue ear'/exp OR 'glue ear' OR middle AND ('ear'/exp OR ear) AND effusion* OR ome OR som OR ('otitis'/exp OR otitis AND ('ear'/exp OR ear)) OR ('otitis'/exp OR otitis AND ears) OR 'nonsuppurative otitis' OR 'serous otitis'/exp OR 'serous otitis' OR 'secretory otitis' OR 'adhesive otitis' OR 'exudative otitis' OR (mucoïd AND ('otitis'/exp OR otitis)) OR (mucous AND ('otitis'/exp OR otitis)) OR ('otitis'/exp OR otitis AND ('serosa'/exp OR serosa)) OR (mucoïd AND middle AND ('ear'/exp OR ear)) OR (mucous AND middle AND ('ear'/exp OR ear)) AND [humans]/lim AND ([embase]/lim OR [embase classic]/lim) Bottom of Form Bottom of Form	23,677
#2	'steroids'/exp OR steroids OR 'oral'/exp OR oral AND steroid* OR (nasal* AND ('topical'/exp OR topical) AND ('steroid'/exp OR steroid)) OR 'antibacterial agents' OR 'anti-bacterial agents' OR antibiotic* OR autoinflation OR 'ear popper' OR manual AND ('therapy'/exp OR therapy) OR 'pressure'/exp OR pressure AND equalization AND ('tube'/exp OR tube) OR 'adenoidectomy'/exp OR adenoidectomy OR 'middle ear ventilation'/exp OR 'middle ear ventilation' OR tympanostomy OR (middle AND ('ear'/exp OR ear) AND ('tube'/exp OR tube)) OR (middle AND tympanic* AND tube*) OR grommet* OR 'ventilation'/exp OR ventilation AND ('tube'/exp OR tube) OR 'tonsillectomy'/exp OR tonsillectomy OR 'leukotriene antagonists/therapeutic use' OR 'leukotriene antagonists'/exp OR 'acetate'/exp OR acetate OR quinolone* OR 'phosphorylcholine'/exp OR phosphorylcholine OR combined AND modality AND ('therapy'/exp OR therapy) OR 'otologic surgical procedures'/exp OR 'otologic surgical procedures' OR watchful AND waiting OR tubulation AND [humans]/lim AND ([embase]/lim OR [embase classic]/lim)	1,730
#3	#1 AND #2	96
#4	'myringotomy'/exp OR myringotomy AND [humans]/lim AND ([embase]/lim OR [embase classic]/lim)	1,989
#5	#3 OR #4	2,056
#6	#5 AND [review]/lim	264
#7	'randomized controlled trial'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'random allocation'	333,668
#8	#5 AND #7	140
#9	'controlled clinical trial'/exp OR 'controlled clinical trial (topic)'/exp	421,718
#10	#5 AND #9	162
#11	'follow up'/exp	602,436
#12	#5 AND #11	194
#13	'systematic review'/exp OR 'meta analysis'/exp	85,928
#14	#5 AND #13	36
#15	'case control study'/exp OR 'cohort analysis'/exp OR 'epidemiological study' OR 'cross-sectional study'/exp OR 'organizational case study' OR 'crossover procedure'/exp OR 'seroepidemiologic study' OR 'epidemiology'/exp OR 'multicenter study'/exp OR 'multicenter study (topic)'/exp OR 'evaluation research'/exp	1,850,275
#16	#5 AND #15	286
#17	#5 AND hams	1
#18	#8 OR #10 OR #12 OR #14 OR #16 OR #17	4571
#19	#18 NOT #6	499

**CINAHL:****Search Jan. 8, 2012**

<b>#</b>	<b>Query</b>	<b>Limiters/Expanders</b>	<b>Last Run Via</b>	<b>Results</b>
S35	S34 NOT S8	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	126
S34	S14 or S16 or S18 or S20 or S32 or S33	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	126
S33	S6 AND harms	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	1
S32	S6 AND S31	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	93
S31	S21 or S22 or S23 or S24 or S25 or S26 or S27 or S28 or S29 or S30	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	228629
S30	(MH "Evaluation Research+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	16072
S29	(MH "Multicenter Studies")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	5343
S28	(MH "Seroprevalence Studies")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	295
S27	(MH "Crossover Design")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	6732
S26	"organizational case studies"	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	3
S25	(MH "Cross Sectional Studies")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	45985
S24	(MH "Epidemiological Research")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	17482
S23	(MH "Prospective Studies+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	124579
S22	(MH "Case Control Studies+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	25256
S21	(MH "Observational Methods+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	11878
S20	S6 and S19	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	8
S19	(MH "Meta Analysis")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	11090
S18	S6 and S17	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	7
S17	(MH "Systematic Review")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search	9517

#	Query	Limiters/Expanders	Last Run Via	Results
S16	S6 and S15	Search modes - Boolean/Phrase	Database - CINAHL with Full Text Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	33
S15	"controlled clinical trial" OR (MH "Clinical Trials+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	100728
S14	S6 and S13	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	22
S13	S9 or S10 or S11 or S12	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	46815
S12	(MH "Random Assignment")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	26792
S11	(MH "Double-Blind Studies")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	17004
S10	(MH "Single-Blind Studies")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	4748
S9	(MH "Randomized Controlled Trials")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	7500
S8	S6 and S7	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	9
S7	(MH "Literature Review+")	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	12381
S6	S5	Limiters - Human Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	243
S5	S3 or S4	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	1475
S4	TX myringotomy	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	297
S3	S1 and S2	Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	1237
S2	TX "Histamine Antagonists" OR antihistamine* OR "Steroids" OR oral steroid* OR (nasal* AND topical steroid*) OR "Anti-Bacterial Agents" OR antibiotic* OR complementary medicine* OR alternative medicine* OR complementary therap* OR alternative therap* OR "ear popper" OR manual therap* OR pressure equalization tube* OR adenoidectom* OR "Middle Ear Ventilation" OR tympanostomy OR (middle AND ear*AND tube*) OR (middle AND tympanic* AND tube*) OR	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	96206

#	Query	Limiters/Expanders	Last Run Via	Results
	grommet* OR ventilation tube* OR tonsillectomy OR "Leukotriene Antagonists/therapeutic use" OR "Leukotriene Antagonists" OR acetate* OR quinolone* OR phosphorylcholine OR combined modality therap* OR "Otologic Surgical Procedures" OR watchful waiting* OR tubulation			
S1	TX "Otitis Media with Effusion" OR "otitis media" OR "middle ear secretion" OR "Ear, Middle/secretion" OR "glue ear" OR middle ear effusion* OR OME OR SOM OR (otitis AND ear) OR (otitis AND ears) OR "nonsuppurative otitis" OR "serous otitis" OR "secretory otitis" OR "adhesive otitis" OR "exudative otitis" OR (mucoid AND otitis) OR (mucous AND otitis) OR (sero-muco* AND otitis) OR (sero AND otitis) OR (sero AND muco*) OR (otitis AND serosa) OR (mucoid AND middle AND ear*) OR (mucous AND middle AND ear*) OR (seromuc* AND middle AND ear*)	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	Interface - EBSCOhost Search Screen - Advanced Search Database - CINAHL with Full Text	3096

**PubMed supplemental search for CAM:**

**Search Feb 28, 2012**

<b>Search</b>	<b>Query</b>	<b>Items found</b>
<a href="#">#1</a>	Search "Otitis Media with Effusion"[Mesh]	<a href="#">4555</a>
<a href="#">#2</a>	Search "Ear, Middle/secretion"[Mesh]	<a href="#">101</a>
<a href="#">#3</a>	Search "glue ear"[tiab]	<a href="#">251</a>
<a href="#">#4</a>	Search "otitis media"[tiab]	<a href="#">15224</a>
<a href="#">#5</a>	Search middle ear effusion*	<a href="#">1614</a>
<a href="#">#6</a>	Search (OME[tiab] OR SOM[tiab]) AND (otitis[tiab] OR ear*[tiab])	<a href="#">1471</a>
<a href="#">#7</a>	Search "serous otitis"[tiab]	<a href="#">612</a>
<a href="#">#8</a>	Search "secretory otitis"[tiab]	<a href="#">941</a>
<a href="#">#9</a>	Search "adhesive otitis"[tiab]	<a href="#">166</a>
<a href="#">#10</a>	Search "exudative otitis"[tiab]	<a href="#">89</a>
<a href="#">#11</a>	Search (mucoid*[tiab] AND otitis[tiab]) OR (mucous[tiab] AND otitis[tiab]) OR (sero-muco*[tiab] AND otitis[tiab]) OR (sero[tiab] OR muco[tiab] AND otitis[tiab]) OR (otitis[tiab] AND serosa[tiab])	<a href="#">414</a>
<a href="#">#12</a>	Search (mucoid*[tiab] AND middle[tiab] AND ear*[tiab]) OR (mucous[tiab] AND middle[tiab] AND ear*[tiab]) OR (seromuc*[tiab] AND middle[tiab] AND ear*[tiab])	<a href="#">463</a>
<a href="#">#13</a>	Search "nonsuppurative otitis"[tiab]	<a href="#">0</a>
<a href="#">#14</a>	Search #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12	<a href="#">17439</a>
<a href="#">#15</a>	Search "Complementary Therapies"[Mesh]	<a href="#">155090</a>
<a href="#">#16</a>	Search "Diet, Sodium-Restricted"[Mesh]	<a href="#">5155</a>
<a href="#">#17</a>	Search "Diet, Protein-Restricted"[Mesh]	<a href="#">1621</a>
<a href="#">#18</a>	Search "Diet, Carbohydrate-Restricted"[Mesh]	<a href="#">558</a>
<a href="#">#19</a>	Search "Diet, Fat-Restricted"[Mesh]	<a href="#">2350</a>
<a href="#">#20</a>	Search "Dairy Products"[Mesh]	<a href="#">66432</a>
<a href="#">#21</a>	Search dairy OR milk OR cream Or cheese OR butter	<a href="#">130562</a>
<a href="#">#22</a>	Search #15 or #16 or #17 or #18 or #19 or #20 or #21	<a href="#">294555</a>
<a href="#">#23</a>	Search #14 and #22	<a href="#">230</a>
<a href="#">#24</a>	Search #23 Limits: Humans	<a href="#">201</a>
<a href="#">#25</a>	Search "Randomized Controlled Trial"[Publication Type] OR "Single-Blind Method"[MeSH] OR "Double-Blind Method"[MeSH] OR "Random Allocation"[MeSH]	<a href="#">401536</a>
<a href="#">#26</a>	Search #24 and #25	<a href="#">17</a>

**Cochrane Library supplemental search for CAM:**

**Search Feb 28, 2012**

<b>ID</b>	<b>Search</b>	<b>Hits</b>
#1	<a href="#">"Otitis Media with Effusion" OR "otitis media" OR "middle ear secretion" OR "Ear, Middle/secretion" OR "glue ear" OR middle ear effusion* OR OME OR SOM OR (otitis AND ear) OR (otitis AND ears) OR "nonsuppurative otitis" OR "serous otitis" OR "secretory otitis" OR "adhesive otitis" OR "exudative otitis" OR (mucoïd AND otitis) OR (mucous AND otitis) OR (sero-muco* AND otitis) OR ((sero OR muco) AND otitis) OR (otitis AND serosa) OR (mucoïd AND middle AND ear*) OR (mucous AND middle AND ear*) OR (seromuc* AND middle AND ear*)</a>	2292
#2	<a href="#">MeSH descriptor <b>Complementary Therapies</b> explode all trees</a>	11569
#3	<a href="#">MeSH descriptor <b>Diet, Sodium-Restricted</b> explode all trees</a>	456
#4	<a href="#">MeSH descriptor <b>Diet, Protein-Restricted</b> explode all trees</a>	145
#5	<a href="#">MeSH descriptor <b>Diet, Fat-Restricted</b> explode all trees</a>	643
#6	<a href="#">MeSH descriptor <b>Diet, Carbohydrate-Restricted</b> explode all trees</a>	128
#7	<a href="#">MeSH descriptor <b>Dairy Products</b> explode all trees</a>	2342
#8	<a href="#">dairy OR milk OR cream Or cheese OR butter</a>	9224
#9	<a href="#">(#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8)</a>	22097
#10	<a href="#">(#1 AND #9)</a>	86
#11	<a href="#">"Randomized Controlled Trial" OR "Single-Blind Method" OR "Double-Blind Method" OR "Random Allocation" OR "Controlled Clinical Trial" OR "Controlled Clinical Trials as Topic" OR (control* AND trial)</a>	698608
#12	<a href="#">(#10 AND #11)</a>	86

**EMBASE supplemental search for CAM:**

Search Feb 28, 2012

No.	Query	Results
#1	'otitis media with effusion'/exp OR 'otitis media with effusion' OR 'otitis media'/exp OR 'otitis media' OR 'middle ear secretion' OR 'ear, middle/secretion' OR 'glue ear'/exp OR 'glue ear' OR middle AND ('ear'/exp OR ear) AND effusion* OR ome OR som OR ('otitis'/exp OR otitis AND ('ear'/exp OR ear)) OR ('otitis'/exp OR otitis AND ears) OR 'nonsuppurative otitis' OR 'serous otitis'/exp OR 'serous otitis' OR 'secretory otitis' OR 'adhesive otitis' OR 'exudative otitis' OR (mucoïd AND ('otitis'/exp OR otitis)) OR (mucous AND ('otitis'/exp OR otitis)) OR ('otitis'/exp OR otitis AND ('serosa'/exp OR serosa)) OR (mucoïd AND middle AND ('ear'/exp OR ear)) OR (mucous AND middle AND ('ear'/exp OR ear)) AND [humans]/lim AND ([embase]/lim OR [embase classic]/lim)	23,921
#2	'alternative medicine'/exp	28,963
#3	'sodium restriction'/exp	7,519
#4	'protein restriction'/exp	5,671
#5	'low carbohydrate diet'/exp	1,083
#6	'low fat diet'/exp	5,811
#7	'dairy product'/exp	74,303
#8	dairy OR 'milk'/exp OR 'cream'/exp OR 'cheese'/exp OR 'butter'/exp AND ([embase]/lim OR [embase classic]/lim)	63,357
#9	#2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8	140,00
#10	#1 AND #9	129
#11	'randomized controlled trial'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'random allocation'/exp AND ([embase]/lim OR [embase classic]/lim)	278.009
#12	#10 AND #11	6

**CINAHL supplemental search for CAM:**

**Search Feb 28, 2012**

<b>#</b>	<b>Query</b>	<b>Limiters/Expanders</b>	<b>Results</b>
S17	S11 and S16	Search modes - Boolean/Phrase	
S16	S12 or S13 or S14 or S15	Search modes - Boolean/Phrase	47751
S15	(MH "Random Assignment")	Search modes - Boolean/Phrase	27104
S14	(MH "Double-Blind Studies")	Search modes - Boolean/Phrase	17138
S13	(MH "Single-Blind Studies")	Search modes - Boolean/Phrase	4834
S12	(MH "Randomized Controlled Trials")	Search modes - Boolean/Phrase	8205
S11	S1 and S10	Search modes - Boolean/Phrase	465
S10	S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9	Search modes - Boolean/Phrase	122594
S9	TX dairy OR milk OR cream Or cheese OR butter	Search modes - Boolean/Phrase	33567
S8	(MH "Dairy Products+")	Search modes - Boolean/Phrase	2989
S7	(MH "Dietary Proteins+")	Search modes - Boolean/Phrase	3917
S6	(MH "Diet, Low Carbohydrate")	Search modes - Boolean/Phrase	266
S5	(MH "Diet, Fat-Restricted")	Search modes - Boolean/Phrase	1304
S4	(MH "Restricted Diet+")	Search modes - Boolean/Phrase	5270
S3	(MH "Diet, Sodium-Restricted")	Search modes - Boolean/Phrase	593
S2	(MH "Alternative Therapies+")	Search modes - Boolean/Phrase	84028
S1	TX "Otitis Media with Effusion" OR "otitis media" OR "middle ear secretion" OR "Ear, Middle/secretion" OR "glue ear" OR middle ear effusion* OR OME OR SOM OR (otitis AND ear) OR (otitis AND ears) OR "nonsuppurative otitis" OR "serous otitis" OR "secretory otitis" OR "adhesive otitis" OR "exudative otitis" OR (mucoïd AND otitis) OR (mucous AND otitis) OR (sero-muco* AND otitis) OR (sero AND otitis) OR (sero AND muco*) OR (otitis AND serosa) OR (mucoïd AND middle AND ear*) OR (mucous AND middle AN ...	Limiters - Exclude MEDLINE records Search modes - Boolean/Phrase	3118

## Appendix B. Excluded Studies

### Excluded for Ineligible Publication Type or Study Type:

1. . Antibiotics for otitis media. *Br Med J*. 1976 Dec 11;2(6049):1407. PMID: 795497.
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#### Excluded for inclusion in one or more of 5 systematic reviews

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## Appendix C. Evidence Tables

**Evidence Table 1. Study characteristics**

First author's last name, Year Country Setting Funding Source	Study Design	Overall Sample Size Formation of Groups Wait Period Between Diagnosis and Randomization Group Sample Sizes Other Information
Abdullah et al., 1994 <sup>1</sup>	NRCT	25
United Kingdom Large ENT Hospital NR	G1: Trimmed high-grade silicone shah permavent TT G2: Polyethylene conventional Shah TT	Unilateral by ear NR  In cohort: G1: 25 G2: 25 Analyzed (12 mo): G1: 25 G2: 25 Analyzed (29 mo): G1: 17 G2: 17
Austin, 1994 <sup>2</sup>	Parallel RCT	62
United States Teaching hospital NR	G1: TT + adenoidectomy G2: Adenoidectomy	Unilateral by ear NR  Randomized: G1: 31 G2: 31 Analyzed: G1: 31 G2: 31

**Evidence Table 1. Study characteristics (continued)**

<b>First author's last name, Year</b>	<b>Country</b>	<b>Setting</b>	<b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b>	<b>Formation of Groups</b>	<b>Wait Period Between Diagnosis and Randomization</b>	<b>Group Sample Sizes</b>	<b>Other Information</b>
Brown et al., 1978 <sup>3</sup>				Parallel RCT	55 (110 ears)				
	Wales			G1: TT+ adenoidectomy G2: Adenoidectomy		By ear			
		University Hospital of Wales					NR		
			NR				Randomized: G1: 55 G2: 55 Analyzed: G1: 55 G2: 55 (Over 5 years, no attrition was reported)		
D'Eredità and Shah, 2006 <sup>4</sup>				Parallel RCT	30				
	Italy			G1: Contact diode laser for myringotomy G2: Myringotomy + TT		By person (but outcomes reported by ear)			
		Tertiary care pediatric institution					≥ 3 months		
			NR				Randomized :30 (60 ears) G1: 15 (30 ears) G2: 15 (30 ears) Analyzed: 30 (60 ears) G1: 15 (30 ears) G2: 15 (30 ears)		

**Evidence Table 1. Study characteristics (continued)**

<b>First author's last name, Year</b>	<b>Country</b>	<b>Setting</b>	<b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b>	<b>Formation of Groups</b>	<b>Wait Period Between Diagnosis and Randomization</b>	<b>Group Sample Sizes</b>	<b>Other Information</b>
Iwaki et al., 1998 <sup>5</sup>				Retrospective cohort	137 (220 ears)				
	Japan			G1: Shepard grommet tube G2: Silicone Goode-T tube G3: Silicone Paperella type II tube		By ear			
		Academic hospital							NR
			NR						Received intervention: 220 G1: 75 G2: 39 G3: 106 Analyzed:220 G1:75 G2:39 G3: 106
									Adenoidectomy was performed at time of tube placement in 69 patients (50.4%) however distribution across treatment arms is NR.
Koopman et al., 2004 <sup>6</sup>				Parallel RCT	208 (416 ears)				
	Netherlands			G1: Laser myringotomy G2: TT insertion with cold knife myringotomy		By ear			
		7 Dutch hospitals							NR
			The Sophia Fondation for Medical Research and the Revolving Fund Sophia Children's Hospital, Erasmus Medical Center, Rotterdam, Theia Foundation, and Silver Cross Company.						Randomized: G1: 208 G2: 208 Analyzed: G1: 208 G2: 208

**Evidence Table 1. Study characteristics (continued)**

<b>First author's last name, Year</b>	<b>Country</b>	<b>Setting</b>	<b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b>	<b>Formation of Groups</b>	<b>Wait Period Between Diagnosis and Randomization</b>	<b>Group Sample Sizes</b>	<b>Other Information</b>
Licameli et al., 2008 <sup>7</sup>				Parallel RCT	70				
	United States	Academic clinic	GYRUS Inc.	G1: Phosphorulcholine-coated fluoroelastic Armstrong tubes G2: Uncoated fluoroelastic Armstrong tubes		By ear	3-4 months		Randomized: G1: 70 G2: 70 Analyzed: G1: 70 G2: 70
Lildholdt, 1979 <sup>8</sup>				NRCT	91 (182 ears)				
	Denmark	Vejle Hospital	NR	G1: TT + adenoidectomy G2: Adenoidectomy		By ear	Randomized at surgery; wait period NR		Randomized: G1: 91 ears G2: 91 ears Analyzed: G1: 91 ears G2: 91 ears

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**Evidence Table 1. Study characteristics (continued)**

<b>First author's last name, Year</b> <b>Trial Name</b> <b>Country</b> <b>Setting</b> <b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b> <b>Formation of Groups</b> <b>Wait Period Between Diagnosis and Randomization</b> <b>Group Sample Sizes</b> <b>Other Information</b>
Mandel et al., 1989 <sup>9</sup>  United States  University of Pittsburgh Medical Center  Bureau of Maternal and Child Health and the NIH	Cluster RCT  Without significant hearing loss (HL) G1: Myringotomy G2: Myringotomy + Armstrong TT G3: No surgery Without significant hearing loss (HL) G4: Myringotomy G5: Myringotomy + Armstrong TT	109  Children were randomized by group. One set of children (86) had no sig hearing loss nor defined symptoms. This cluster was randomized to one of the three groups. A second cluster had significant hearing loss and was assigned to G4 or G5  MEE of at least 2 months duration. Time from then NR  Randomized: Without significant HL G1: 27 G2: 30 G3:29 With Significant HL: G4: 12 G5: 11  Analyzed: 93 (85.3%) analyzed at end of 3 yr study G1: 26 of 27 G2: 27 of 30 G3: 25

**Evidence Table 1. Study Characteristics**

<b>First author's last name, Year</b>	<b>Country</b>	<b>Setting</b>	<b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b>	<b>Formation of Groups</b>	<b>Wait Period Between Diagnosis and Randomization</b>	<b>Group Sample Sizes</b>	<b>Other Information</b>
McRae et al., 1989 <sup>10</sup>				Parallel RCT	110				
	United Kingdom			G1: Shah TT+ aspiration prior to tube placement G2: Shah TT without aspiration prior to tube placement		By ear			
		Hospital							NR
			NR						Randomized: G1: 55 G2: 55 Analyzed: 38 participants total
Ovesen et al., 2000 <sup>11</sup>				Parallel RCT	150				
	Denmark			G1: TT + N-acetylcysteine after insertion of tubes G2: TT + placebo after insertion of tubes G3: TT in contralateral ear, exclusively		By ear			
		University hospital							3 months
			NR						Randomized: G1: 37 G2: 38 G3: 75 Analyzed: G1: 37 G2: 38 G3: 75

**Evidence Table 1. Study characteristics**

<b>First author's last name, Year</b>	<b>Country</b>	<b>Setting</b>	<b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b>	<b>Formation of Groups</b>	<b>Wait Period Between Diagnosis and Randomization</b>	<b>Group Sample Sizes</b>	<b>Other Information</b>
Popova et al., 2010 <sup>12</sup>				Parallel RCT	90				
	Bulgaria	Academic ENT Clinic	No funding source	G1: TT + myringotomy + adenoidectomy G2: Adenoidectomy + myringotomy		By person	3 months		Randomized: 90 G1: NR G2: NR Analyzed: 78 G1: NR G2: NR
Ragab, 2005 <sup>13</sup>				Parallel RCT	60 (120 ears)				
	Egypt	University hospital	NR	G1: Radiofrequency tympanostomy + Mitomycin C G2: Radiofrequency tympanostomy (no mitomycin C)		By person			NR Randomized: G1: 30 G2: 30 Analyzed: G1: 30 G2: 30

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**Evidence Table 1. Study characteristics (continued)**

<b>First author's last name, Year</b>	<b>Country</b>	<b>Setting</b>	<b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b>	<b>Formation of Groups</b>	<b>Wait Period Between Diagnosis and Randomization</b>	<b>Group Sample Sizes</b>	<b>Other Information</b>
Shishegar and Hoghoghi, 2007 <sup>14</sup>	Iran	Hospital	NR	Parallel RCT	30 children; 60 ears	By ear			
				G1: Adenoidectomy + myringotomy G2: Adenoidectomy + myringotomy + TT					Randomized: 60 ears G1: 30 G2: 30 Analyzed: (Unclear; assume same as randomized) G1:30 G2:30
Slack et al., 1987 <sup>15</sup>	UK	Hospital	NR	Retrospective cohort	463 individuals (708 ears)	By ear			
				G1: Shepard tube G2: Shah tube G3: Paprella tube G4: Goode tube G5: Reuter Bobbin tube G6: Unknown or other tube types					Received Intervention: 708 ears Analyzed: 654 ears G1: 214 G2:70 G3: 275 G4: 4 G5: 28 G6: 63

**Evidence Table 1. Study characteristics (continued)**

<b>First author's last name, Year</b> <b>Country</b> <b>Setting</b> <b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b> <b>Formation of Groups</b> <b>Wait Period Between Diagnosis and Randomization</b> <b>Group Sample Sizes</b> <b>Other Information</b>
Szeremeta et al., 2000 <sup>16</sup>  USA  University Hospital  NR	Retrospective cohort  G1: Laser myringotomy (laser) + adenoidectomy G2: Incisional myringotomy + adenoidectomy	64 children 117 ears  By person and by ear  NR  Population G1: 29 (51 ears) G2: 35 (66 ears) Analyzed: G1: 23 (39 ears) G2: 26 (48 ears)
Tos and Stangerup, 1989 <sup>17</sup>  Denmark  University Hospital  NR	Nonrandomized control trial  G1: TT + adenoidectomy G2: Myringotomy + adenoidectomy	224  By ear  >3 months  Randomized: G1: 224 (ears) G2: 224 (ears) Analyzed: (at age 2-3) G1: 193 G2: 193 Analyzed: (at age 6-7) G1:146 G2:146

**Evidence Table 1. Study characteristics (continued)**

<b>First author's last name, Year</b>	<b>Country</b>	<b>Setting</b>	<b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b>	<b>Formation of Groups</b>	<b>Wait Period Between Diagnosis and Randomization</b>	<b>Group Sample Sizes</b>	<b>Other Information</b>
Vlastos et al., 2011 <sup>18</sup>				Parallel RCT	52				
	Greece	University Hospital	NR	G1: Adenoidectomy + TT G2: Adenoidectomy + myringotomy		Bilateral by person			
									Randomized: G1: 25 G2: 27 Analyzed for primary outcome (6 mo): G1: 22 G2: 23 Analyzed for primary outcome (12 mo): G1: 20 G2: 21
Wielinga et al., 1990 <sup>19</sup>				Parallel RCT	30				
	Northern Ireland	University hospital	NR	G1: Armstrong T-tube G2: Goode tube		Unilateral by ear			
									6 months Randomized: G1: 15 G2: 15 Analyzed: G1: 15 (ears) G2: 15

C-10

**Evidence Table 1. Study characteristics (continued)**

<b>First author's last name, Year</b> <b>Country</b> <b>Setting</b> <b>Funding Source</b>	<b>Study Design</b>	<b>Overall Sample Size</b> <b>Formation of Groups</b> <b>Wait Period Between Diagnosis and Randomization</b> <b>Group Sample Sizes</b> <b>Other Information</b>
Williamson et al., 2009 <sup>20</sup> Williamson et al., 2009 <sup>21</sup>  UK  Research Medical Council General Practice Research Framework practices throughout the UK  Government	Parallel RCT  G1: Mometasone furoate nasal spray G2: Placebo spray	217  By person  Yr 1: 3 mos of active monitoring if failed the first screening (B/B or B/C2) and were invited into main study if failed a second time. After that, children with history of bilateral tympanometric failure randomized after first failed screen  Randomized: G1: 105 G2: 112 Analyzed: 201 (93%) at 1 months 182 (84%) at 3 months 158 (73%) at 9 months

**Evidence Table 2. Populations**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Popova et al., 2010 <sup>12</sup>	<p>Age</p> <p>Overall: G1: 60 months G2: 61 months</p> <p>Criteria for Diagnosis Tympanometry (interacoustics AT-235h) - Type B tympanograms with fluid level on otoscopy. Pneumatic otoscopy by validated otoscopist.</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• 2007-2009</li> <li>• Documented bilateral middle effusion for &gt;3 months</li> <li>• 20 db conductive hearing loss</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Previous myringotomy (+/- TT)</li> <li>• Previous adenoidectomy or tonsillectomy</li> <li>• Hx of ear surgery</li> <li>• Cleft palate</li> <li>• Down's syndrome</li> <li>• Congenital malformation of ear</li> <li>• Cholesteatoma or chronic mastoiditis</li> <li>• Perforation of TM</li> <li>• Conductive hearing loss due to destructive changes in ME</li> <li>• Sensoneural hearing loss</li> </ul>	<p>Baseline Tympanometry NR</p> <p>Baseline Hearing or Hearing Loss (500-4000 Hz) Overall: G1: 31.4 dB G2: 32.3 dB ns p=0.39</p> <p>Other Baseline Symptoms NR</p> <p>Baseline Relevant Comorbidities NR</p> <p>Baseline % Female Overall: G1: 45 G2: 44</p> <p>Baseline % Nonwhite NR</p>	<p>Insured Status NR</p> <p>Study Population Broadly Applicable? Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Williamson et al., 2009; <sup>20</sup> Williamson et al., 2009 <sup>21</sup>	<p>Age Range: 4-11 yrs old Mean months (SD), (range) G1: 73.3 (20.2) (49-129) G2: 72.1 (18.6) (48-125)</p> <p>Criteria for Diagnosis Tympanometry</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Dx of bilateral OME by a nurse</li> <li>• In the first yr of study children positive screening entered a 3 month period of watchful waiting.</li> <li>• In yr 2 the protocol was changed and children with histories of bilateral tympanic failure were allowed to be randomized at the first failed screen (50:50).</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Tympanometry screen passed</li> <li>• Large amounts of wax</li> <li>• Uninterpretable tympanogram</li> <li>• Children with cleft palate</li> <li>• Down syndrome</li> <li>• Primary ciliary dyskinesia</li> <li>• Kartegagner's syndrom</li> <li>• Immuniodeficiency states</li> <li>• TTs or tympanic perforation</li> <li>• Frequent or heavy epistaxis</li> <li>• Hypersensitivity to mometasone</li> <li>• Hx of steroid use in previous 3 months</li> <li>• Children under 4 yrs</li> </ul>	<p>Baseline Tympanometry Type C2 (middle ear pressure -200 to -399) n=54 Type B (middle ear pressure ≤-400) n=88</p> <p>Baseline Hearing or Hearing Loss Scale: Sweep audiometry at 25 dB (pass/fail) All enrolled children failed audiometric screen</p> <p>Other Baseline Symptoms NR</p> <p>Baseline Relevant Comorbidities History, No. (%) Adenoidectomy: 51 (24.5) Tonsillectomy: 23 (11.1) Cleft palate: 17 (8.2) Grommets 49 (23.6) Allergies: 7 (3.4)</p> <p>Baseline % Female G1: 48 G2: 68</p> <p>Baseline % Nonwhite G1: 3 G2: 4</p>	<p>Insured Status NHS England</p> <p>Study Population Broadly Applicable? Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Licameli et al., 2008 <sup>7</sup>	<p>Age</p> <p>Mean months, (range)</p> <p>Overall: 19 (8-51 )</p> <p>Criteria for Diagnosis</p> <p>Not specified</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• 3-4 months of medical management for OME prior to randomization</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Previous TT</li> </ul>	<p>Baseline Tympanometry</p> <p>NR</p> <p>Baseline Hearing or Hearing Loss</p> <p>NR</p> <p>Other Baseline Symptoms</p> <p>NR</p> <p>Baseline Relevant Comorbidities</p> <p>NR</p> <p>Baseline % Female</p> <p>Overall: 35.7</p> <p>Baseline % Nonwhite</p> <p>NR</p>	<p>Insured Status</p> <p>NR</p> <p>Study Population Broadly Applicable?</p> <p>Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Ragab, 2005 <sup>13</sup>	<p>Age G1: 4.8 yr G2: 5.2 yr</p> <p>Criteria for Diagnosis Hx, pneumo-otoscopic exam, and tympanograms</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Nov 2002-Jan 2004 patients undergoing surgery for OME</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• NR</li> </ul>	<p>Baseline Tympanometry NR</p> <p>Baseline Hearing or Hearing Loss Air Bone Gap: G1: 24.7 dB G2: 24.1 dB</p> <p>Other Baseline Symptoms NR</p> <p>Baseline Relevant Comorbidities NR</p> <p>Baseline % Female NR</p> <p>Baseline % Nonwhite NR</p>	<p>Insured Status NR</p> <p>Study Population Broadly Applicable? Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Koopman et al., 2004 <sup>6</sup>	<p>Age Children aged &lt; 11 yrs</p> <p>Criteria for Diagnosis Binocular otoscopy in combination with Type B tympanogram or pure tone audiometry used for diagnosis. Bilateral tympanogram Type C1 or C2 (Jerger) considered to support diagnosis of OME. If child was too young or failed at audiometric testing, diagnosis based solely on otoscopic findings and hx</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Children aged less than 11 years</li> <li>• Impaired hearing noticed by parents during at least 3 successive months</li> <li>• Bilateral OME</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Unilateral OME</li> <li>• Ear effusions without fever, otalgia, or otorrhea</li> <li>• Poorly cooperative children</li> <li>• Clinically admitted patients</li> <li>• Asymmetric perceptive hearing loss (HL)</li> <li>• Previously operated ears with other than myringotomy or ventilation tubes</li> </ul>	<p>Baseline Tympanometry Type B: 362 ears (172 bilaterally) C1: 5 ears C2: 18 (3 bilateral) ears</p> <p>Baseline Hearing or Hearing Loss Mean duration of hearing loss (months [range]) Overall: 6 [3-12] PTAs NR # of children referred for TT because of hearing loss NR</p> <p>Other Baseline Symptoms NR</p> <p>Baseline Relevant Comorbidities No. (%) History of: Adenoidectomy: 51 (24.5) Tonsillectomy: 23 (11.1) Cleft palate: 17 (8.2) Ever grommets 49 (23.6) Allergies: 7 (3.4)</p> <p>Baseline % Female Overall: 48.1</p> <p>Baseline % Nonwhite Overall: 18.3 Mediterranean: 7.7 Black: 6.3 Asian: 1.9 Other: 2.4</p>	<p>Insured Status NR</p> <p>Study Population Broadly Applicable? Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Ovesen et al., 2000 <sup>11</sup>	<p>Age Mean (range) Overall: 38 months (1-7 yrs)</p> <p>Criteria for Diagnosis Otomicroscopical exam, tympanometry (middle ear pressure &lt; 200 mm H2O)</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Children undergoing TT insertion bilaterally for the first time due to OME</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Patients with antibiotics within 1 month of surgery</li> <li>• Patients with other diseases</li> <li>• Patients with AOM at time of surgery</li> </ul>	<p>Baseline Tympanometry NR</p> <p>Baseline Hearing or Hearing Loss NR</p> <p>Other Baseline Symptoms NR</p> <p>Baseline Relevant Comorbidities Generally excluded</p> <p>Baseline % Female Overall: 36</p> <p>Baseline % Nonwhite NR</p>	<p>Insured Status NR</p> <p>Study Population Broadly Applicable? Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Wielinga et al., 1990 <sup>19</sup>	<p>Age Mean, yrs Males: 7 Females: 6</p> <p>Criteria for Diagnosis Otoscopy, pure tone audiometry, tympanometry</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Bilateral OME</li> <li>• 6 months of unsuccessful treatment with standard decongestive medications</li> <li>• Mucoid secretion aspiration</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• NR</li> </ul>	<p>Baseline Tympanometry NR</p> <p>Baseline Hearing or Hearing Loss Airconduction thresholds &gt;20 dB G1: 13 G2: 11</p> <p>Other Baseline Symptoms NR</p> <p>Baseline Relevant Comorbidities NR</p> <p>Baseline % Female Overall: 40</p> <p>Baseline % Nonwhite NR</p>	<p>Insured Status NR</p> <p>Study Population Broadly Applicable? Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Mandel et al., 1989 <sup>9</sup>	<p>Age</p> <p>Overall: 7 mos -12 yrs</p> <p>Groups without hearing loss, by age grp</p> <p>G1: 7-23 mos n=6 ; 2-5 yrs n=14; 6-12 yrs n=7</p> <p>G2: 7-23 mos n=8 ; 2-5 yrs n=17; 6-12 yrs n=5</p> <p>G3: 7-23 mos; n=7; 2-5 yrs n=17; 6-12 yrs n=5</p> <p>Groups with hearing loss, by age grp</p> <p>G4: 7-23 mos n=7; 2-5 yrs n= 3; 6-12 yrs n=2</p> <p>G5: 7-23 mos n=6; 2-5 yrs n=4; 6-12 yrs n=1</p> <p>Criteria for Diagnosis</p> <p>Validated otoscopy, tympanometry, middle-ear muscle reflex testing</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Children between 7 mos and 12 yrs of age</li> <li>• Documented MEE of at least 2 mos duration persisting after at least one 14 day course of antimicrobial drug and pseudoephedine hydrochloride-chlorpheniramine maleate syrup.</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Craniofacial malformations</li> <li>• Down syndrome</li> <li>• Systemic illness such as asthma, cystic fibrosis or diabetes</li> <li>• Seizure disorder</li> </ul>	<p>Baseline Tympanometry</p> <p>Acoustic reflex thresholds were estimated for 1000 Hz tone ipsilaterally and contralaterally.</p> <p>Baseline Hearing or Hearing Loss</p> <p>Audiologic procedures depended upon age.</p> <ul style="list-style-type: none"> <li>• &lt; 2.5 yrs: were tested in sound field using a head turn response. Speech awareness thresholds and minimum response levels for warbled pure tones were estimated for these children.</li> <li>• 2.5 – 5 yrs: were tested with play audiometry.</li> <li>• &gt; 5 yrs: traditional clinical protocol was used for children older. Bilateral thresholds under earphones from 500 to 4000 Hertz were obtained.</li> <li>• SRT for each ear were obtained using age appropriate responses (picture, id or word rep)</li> </ul> <p>Other Baseline Symptoms</p> <p>Significant hearing loss for randomization: pure tone avg of &gt;20 dB bilaterally or &gt;40 dB unilaterally or a speech awareness threshold &gt;20 dB above the age-appropriate level or otalgia or vertigo unresponsive to medical treatment among those who do not have hearing or speech deficiencies.</p> <p>Baseline Relevant Comorbidities</p> <p>Otalgia or vertigo</p> <p>Baseline % Female</p> <p>Overall: 33</p>	<p>Insured Status</p> <p>NR</p> <p>Study Population Broadly Applicable?</p> <p>Yes</p> <p>Comments</p> <p>Participants were divided into 2 groups: those with "significant" hearing loss (defined arbitrarily as a pure-tone average of &gt;20 dB bilaterally or &gt;40 dB unilaterally, or a speech awareness threshold &gt;20 dB above the age appropriate level) or symptoms consisting of otalgia or vertigo unresponsive to medical treatment, and those who had none of these findings. Within these groups, the subjects were stratified according to age.</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Mandel et al., 1989 <sup>9</sup>	<ul style="list-style-type: none"> <li>History of tonsillectomy, adenoidectomy, or TT insertion</li> <li>Structural middle-ear abnormality such as tympanic membrane perforation or adhesive OM; cholesteatoma; sensorineural hearing loss or conductive loss not attributable to MEE; severe upper airway obstruction; AOM; or purulent rhinitis.</li> </ul>	Baseline % Nonwhite Overall Black: 25.7	

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
McRae et al.,1989 <sup>10</sup>	<p>Age</p> <p>Mean, years (range)</p> <p>Overall: 5.8</p> <p>Range: (2.3 -10)</p> <p>Criteria for Diagnosis</p> <p>Otoscopy and impedance audiometry</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Children at head of waiting list for bilateral myringotomy and ventilation tube insertion</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Subsequent surgery in study duration</li> </ul>	<p>Baseline Tympanometry</p> <p>NR</p> <p>Baseline Hearing or Hearing Loss</p> <p>NR</p> <p>Other Baseline Symptoms</p> <p>NR</p> <p>Baseline Relevant Comorbidities</p> <p>NR</p> <p>Baseline % Female</p> <p>Overall: 34</p> <p>Baseline % Nonwhite</p> <p>NR</p>	<p>Insured Status</p> <p>NR</p> <p>Study Population Broadly Applicable?</p> <p>Yes</p>

**Evidence Table 2. Populations (continued)**

<b>Author, Year</b>	<b>Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria</b>	<b>Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite</b>	<b>Insured Status Study Population Broadly Applicable? Comments</b>
Lildholdt 1979 <sup>8</sup>	<p>Age</p> <p>Mean years (range)</p> <p>Overall: 4 (1-10)</p> <p>Criteria for Diagnosis</p> <p>Bilateral middle ear pressure below -150mm H2O. If audiogram was possible a maximum 15dB diff at 500, 1000, 2,000 Hz</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Not clearly specified</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Previous use of TT, recurrent acute suppurative OM, unequal involvement of ears, congenital defects such as cleft palate</li> </ul>	<p>Baseline Tympanometry</p> <p>Bilateral middle ear pressure below -150mm H2O.</p> <p>Baseline Hearing or Hearing Loss</p> <p>Overall: If audiogram was possible a a maximum 15dB diff at 500, 1000, 2,000 Hz</p> <p>Other Baseline Symptoms</p> <p>NR</p> <p>Baseline Relevant Comorbidities</p> <p>NR</p> <p>Baseline % Female</p> <p>G1: 41</p> <p>G2: 41</p> <p>Baseline % Nonwhite</p> <p>NR</p>	<p>Insured Status</p> <p>NR</p> <p>Study Population Broadly Applicable?</p> <p>No</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Brown et al., 1978 <sup>3</sup>	<p>Age Range overall, years: 4 to 10</p> <p>Criteria for Diagnosis Hx, otoscopy and pure tone audiometry</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Not specified</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Not specified</li> </ul>	<p>Baseline Tympanometry NR</p> <p>Baseline Hearing or Hearing Loss Pure tone audiometry at 500, 1000, 2000, 4000 Hz G1: 25 dB G2: 23.1 dB</p> <p>Other Baseline Symptoms NR</p> <p>Baseline Relevant Comorbidities NR</p> <p>Baseline % Female NR</p> <p>Baseline % Nonwhite NR</p>	<p>Insured Status NR</p> <p>Study Population Broadly Applicable? No</p> <p>Comments The subject population is very marginally described.</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Szeremeta et al., 2000 <sup>16</sup>	<p>Age</p> <p>Mean years, (range)</p> <p>G1: 6.52 (2.74 - 12.52)</p> <p>G2: 7.37 (3.86 - 5.34)</p> <p>Criteria for Diagnosis</p> <p>NR</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Children &gt; 4 years with refractory OME or 2nd middle ear intubation</li> <li>• Spring operations</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• NR</li> </ul>	<p>Baseline Tympanometry</p> <p>NR</p> <p>Baseline Hearing or Hearing Loss</p> <p>NR</p> <p>Other Baseline Symptoms</p> <p>NR</p> <p>Baseline Relevant Comorbidities</p> <p>NR</p> <p>Baseline % Female</p> <p>NR</p> <p>Baseline % Nonwhite</p> <p>NR</p>	<p>Insured Status</p> <p>NR</p> <p>Study Population Broadly Applicable?</p> <p>Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Iwaki et al., 1998 <sup>5</sup>	<p>Age</p> <p>Overall: range 3-12 yrs</p> <p>Mean, years</p> <p>G1: 6.2</p> <p>G2: 6.5</p> <p>G3: 5.8</p> <p>Criteria for Diagnosis</p> <p>NR</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Continuous conductive hearing loss with over 25 dB air-bone gap</li> <li>• ≥ 6 months resistance to conservative therapy with medication and politzerization</li> <li>• Retracted and glue-colored tympanic membrane with type B tympanogram</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Craniofacial problems such as cleft palate</li> </ul>	<p>Baseline Tympanometry</p> <p>NR</p> <p>Baseline Hearing or Hearing Loss</p> <p>NR</p> <p>Other Baseline Symptoms</p> <p>NR</p> <p>Baseline Relevant Comorbidities</p> <p>NR</p> <p>Baseline % Female</p> <p>Overall:38</p> <p>Baseline % Nonwhite</p> <p>NR</p>	<p>Insured Status</p> <p>NR</p> <p>Study Population Broadly Applicable?</p> <p>Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Austin, 1994 <sup>2</sup>	Age NR  Criteria for Diagnosis NR  Inclusion <ul style="list-style-type: none"> <li>• Indication for adenotonsillectomy and OME, Resistant to ENT or pediatric management</li> </ul> Exclusion <ul style="list-style-type: none"> <li>• NR</li> </ul>	Baseline Tympanometry NR  Baseline Hearing or Hearing Loss Air-Bone Gap G1: 29.9 dB G2: 26.6 dB  Other Baseline Symptoms NR  Baseline Relevant Comorbidities NR  Baseline % Female NR  Baseline % Nonwhite NR	Insured Status NR  Study Population Broadly Applicable? No  Comments Regarding applicability: Not enough information on the sample so it is hard to generalize.

**Evidence Table 2. Populations (continued)**

<b>Author, Year</b>	<b>Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria</b>	<b>Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite</b>	<b>Insured Status Study Population Broadly Applicable? Comments</b>
Abdullah et al., 1994 <sup>1</sup>	<p>Age</p> <p>Mean years (range)</p> <p>Overall: 6 (3-10)</p> <p>Criteria for Diagnosis</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• De novo OME</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• No significant hx of AOM</li> <li>• No evidence of tympanosclerosis</li> </ul>	<p>Baseline Tympanometry</p> <p>NR</p> <p>Baseline Hearing or Hearing Loss</p> <p>NR</p> <p>Other Baseline Symptoms</p> <p>NR</p> <p>Baseline Relevant Comorbidities</p> <p>NR</p> <p>Baseline % Female</p> <p>Overall: 36</p> <p>Baseline % Nonwhite</p> <p>NR</p>	<p>Insured Status</p> <p>NR</p> <p>Study Population Broadly Applicable?</p> <p>Yes</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Tos and Stangerup, 1989 <sup>17</sup>	<p>Age</p> <p>5 years (no range reported) this is not the baseline age of the initial population, but average age of the 146 people in the study conducted in 1984</p> <p>Criteria for Diagnosis NR</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• Bilateral OME</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• NR</li> </ul>	<p>Baseline Tympanometry NR</p> <p>Baseline Hearing or Hearing Loss Specify Scale (mean of 250, 1000, 4000 Hz) (250 Hz) G1: 21.7 G2: 19.6 (1000 Hz) G1: 23 G2: 20.4 (4000 Hz) G1: 22.8 G2: 20.5 (Mean) G1: 22.5 G2: 20.2</p> <p>Other Baseline Symptoms NR</p> <p>Baseline Relevant Comorbidities NR</p> <p>Baseline % Female Overall: NR for baseline cohort; for participants of 1984 study, Overall: 40%</p> <p>Baseline % Nonwhite NR</p>	<p>Insured Status NR</p> <p>Study Population Broadly Applicable? Yes</p>

**Evidence Table 2. Populations (continued)**

<b>Author, Year</b>	<b>Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria</b>	<b>Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite</b>	<b>Insured Status Study Population Broadly Applicable? Comments</b>
Slack et al., 1987 <sup>22</sup>	Age < 16 years	Baseline Tympanometry NR	Insured Status NR
	Criteria for Diagnosis NR	Baseline Hearing or Hearing Loss NR	Study Population Broadly Applicable? Yes
	Inclusion <ul style="list-style-type: none"> <li>• Children &lt;16 years old</li> <li>• TT inserted for OME in 1983</li> </ul>	Other Baseline Symptoms NR	
	Exclusion <ul style="list-style-type: none"> <li>• NR</li> </ul>	Baseline Relevant Comorbidities NR	
		Baseline % Female NR	
		Baseline % Nonwhite NR	

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Shishegar and Hoghoghi, 2007 <sup>14</sup>	<p>Age Range, years Overall: 4-8</p> <p>Criteria for Diagnosis Physical examinations; otoscopy, audiometry, tympanometry</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>Not specified</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>Hx of prior adenotonsillectomy, tympanostomy tube placement, dry middle ear, cleft palate, and perforated tympanic membrane</li> </ul>	<p>Baseline Tympanometry NR</p> <p>Baseline Hearing or Hearing Loss Mean pure tone averages in decibels hearing level (db HL) at 500, 1,000 and 2,000 Hz G1: 25.1 db HL G2: 26.3 db HL Mean ears difference, dB (SD): 1.15 (3.25)</p> <p>Decreased hearing level: 30/30 patients Preoperatively 27 of 30 participants had hearing loss Mean speech Reception Threshold (SRT) Mean paired ear as difference (SD): 0.83 dB (5.105) G1: 24.8 G2: 25.6 95%CI=NR p=NR</p> <p>Other Baseline Symptoms N (%): Nasal obstruction and snoring: 26 (87) Recurrent otitis media: 24 (80) Serious otitis media 19 (63) History of allergy: 4 (13) Smoking in parents: 10 (33) Allergic signs: 10 (33) Adenoid enlargement 23 (77) Turbinate hypertrophy: 13 (43) Septal deviation: 5 (17)</p>	<p>Insured Status NR</p> <p>Study Population Broadly Applicable? No</p> <p>Comments Unrepresentative comorbidities, but study says "no significant differences in clinical and demographic variables among treatment groups preoperatively."</p>

**Evidence Table 2. Populations (continued)**

<b>Author, Year</b>	<b>Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria</b>	<b>Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite</b>	<b>Insured Status Study Population Broadly Applicable? Comments</b>
Shishegar and Hoghoghi, 2007 <sup>14</sup> (continued)		Baseline Relevant Comorbidities NR  Baseline % Female Overall: 37 (11/30 children) G1: 37 G2: 37  Baseline % Nonwhite NA	

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
D'Eredità and Shah, 2006 <sup>4</sup>	<p>Age</p> <p>Mean years (range)</p> <p>Overall: 3.7 (2-6)</p> <p>G1:3.8 (2-6)</p> <p>G2:3.6 (2-6)</p> <p>Criteria for Diagnosis</p> <p>Tympanometry</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• OME for at least 3 months duration</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• Hx of prior middle ear surgery or PE tube insertion or previous pharyngeal surgery</li> <li>• Cleft palate, Down syndrome or other syndrome involving the head and neck</li> <li>• Mental retardation or other known cognitive or psychiatric disorder</li> </ul>	<p>Baseline Tympanometry</p> <p>NR</p> <p>Baseline Hearing or Hearing Loss</p> <p>NR</p> <p>Other Baseline Symptoms</p> <p>NR</p> <p>Baseline Relevant Comorbidities</p> <p>NR</p> <p>Baseline % Female</p> <p>G1: 47</p> <p>G2: 47</p> <p>Baseline % Nonwhite</p> <p>NR</p>	<p>Insured Status</p> <p>NR</p> <p>Study Population Broadly Applicable?</p> <p>Yes</p> <p>Comments</p> <p>Total followup was 12 months with post-op evaluations at day 10, 20, 30, 40, 60, and 80 and mo 3,4,6,8, and 12</p>

**Evidence Table 2. Populations (continued)**

Author, Year	Age Criteria for Diagnosing OME Inclusion Criteria Exclusion Criteria	Baseline Tympanometry Baseline Hearing or Hearing Loss Other Baseline Symptoms Baseline Relevant Comorbidities Baseline % Female Baseline % Nonwhite	Insured Status Study Population Broadly Applicable? Comments
Vlastos et al., 2011 <sup>18</sup>	<p>Age</p> <p>Mean years (range)</p> <p>G1: 4.6 (3-7)</p> <p>G2: 4.4 (3-7)</p> <p>Criteria for Diagnosis</p> <p>Otoscopy ,tympanometry, pure tone audiometry</p> <p>Inclusion</p> <ul style="list-style-type: none"> <li>• &gt; 3 yrs</li> <li>• Scheduled adenoidectomy due to sleep-disordered breathing</li> <li>• Presence of bilateral OME (the presence of an opaque or thickened tympanic membrane, air–fluid level, or bubbles, or the inability to visualise the incudostapedial joint, were considered signs of OME</li> <li>• Type B tympanogram (compliance &lt;0.2ml).</li> <li>• Audiogram with an air–bone gap of 20 dB or a hearing loss of 30 dB but no more than 55 dB in at least one frequency in both ears.</li> </ul> <p>Exclusion</p> <ul style="list-style-type: none"> <li>• No signs of effusion at time of myringotomy</li> <li>• Children with chronic otitis media</li> <li>• Structural changes (e.g. tympanic membrane retraction pockets, ossicular chain erosion or cholesteatoma</li> <li>• Previous ear surgery</li> <li>• Language delays</li> <li>• Behavioural problems</li> <li>• Syndromes</li> </ul>	<p>Baseline Tympanometry</p> <p>NR</p> <p>Baseline Hearing or Hearing Loss</p> <p>Mean hearing losses at 250, 500, 1000, 2000 and 4000 Hz (range)</p> <p>G1: 31.2 dB (21-39)</p> <p>G2: 32.7 dB (27-37)</p> <p>Other Baseline Symptoms</p> <p>OM-6 Score</p> <p>G1: 2.2</p> <p>G2: 2.0</p> <p>Obstructive Sleep Disorders -6 (OSD-6)</p> <p>G1: 3.3</p> <p>G2: 3.4</p> <p>Ears with mucoid fluid</p> <p>G1: 68%</p> <p>G2: 61%</p> <p>Baseline Relevant Comorbidities</p> <p>Generally excluded</p> <p>Baseline % Female</p> <p>G1: 44</p> <p>G2: 44</p> <p>Baseline % Nonwhite</p> <p>NR</p>	<p>Insured Status</p> <p>NR</p> <p>Study Population Broadly Applicable?</p> <p>Yes</p>

**Evidence Table 3. Interventions**

<b>Author, Year</b>	<b>Group 1 Intervention Specification Co-intervention(s):</b>	<b>Group 2 Intervention specification Co-intervention(s):</b>	<b>Group 3 Intervention specification Co-intervention(s):</b>	<b>Comments</b>
Abdullah et al., 1994 <sup>1</sup>	Trimmed high-grade silicone shah permavent TT	Polyethylene conventional Shah TT	NA	
Austin, 1994 <sup>2</sup>	TT+ adenoidectomy  Flared polyethylene TT inserted into random ear  Tonsillectomy	Adenoidectomy  Tonsillectomy	NA	
Brown et al., 1978 <sup>3</sup>	TT+ adenoidectomy	Adenoidectomy	NA	
D'Eredità and Shah, 2006 <sup>4</sup>	Myringotomy using Contact diode laser + Adenoidectomy  CDLM was performed on both TMs in the antero-inferior quadrant. Laser settings were 2 W power, 0.5 s pulse duration, with 5 pulses in the contact mode. The resultant myringotomy measured 2.5 mm.	Myringotomy + TT	NA	

**Evidence Table 3. Interventions (continued)**

<b>Author, Year</b>	<b>Group 1 Intervention Specification Co-intervention(s):</b>	<b>Group 2 Intervention specification Co-intervention(s):</b>	<b>Group 3 Intervention specification Co-intervention(s):</b>	<b>Comments</b>
Iwaki et al., 1998 <sup>5</sup>	Shepard grommet tube  Adenoidectomy performed in those with mouth breathing and hyponasality and found to have hypertrophic adenoids; treatment with antibiotics if sinusitis present.	Silicone Good-T tube  Adenoidectomy performed in those with mouth breathing and hyponasality and found to have hypertrophic adenoids; treatment with antibiotics if sinusitis present	Silicone Paperella type II tube  Adenoidectomy performed in those with mouth breathing and hyponasality and found to have hypertrophic adenoids; treatment with antibiotics if sinusitis present	Adenoidectomy was performed at time of tube placement in 69 patients (50.4%) however distribution across treatment arms is NR.
Koopman et al., 2004 <sup>6</sup>	Laser myringotomy  Power setting varied from 7-20 W; diameter of circumferential perforation : 1.8-2.6 mm. Fluid not aspirated. No antibiotics given.  Children in whom adenoidectomy was indicated underwent this procedure using a sharp curette according to guidelines. Otorrhea persisting for more than 1 week treated by eardrops of dexamethasone/framycetine/gramicidin or ofloxacin; otorrhea with fever treated with amoxicillin oral antibiotics.	TT inserted using cold-knife myringotomy  A Donaldson tube was used but in the case of OME with atelectasis of the middle ear, a Goode-T tube was inserted.  Children in whom adenoidectomy was indicated underwent this procedure using a sharp curette according to guidelines. Otorrhea persisting for more than 1 week treated by eardrops of dexamethasone/framycetine/gramicidin or ofloxacin; otorrhea with fever treated with amoxicillin oral antibiotics.	NA	Children who underwent adenoidectomy as a combined procedure: 97; Adenoidectomy + tonsillectomy: 1

**Evidence Table 3. Interventions (continued)**

<b>Author, Year</b>	<b>Group 1 Intervention Specification Co-intervention(s):</b>	<b>Group 2 Intervention specification Co-intervention(s):</b>	<b>Group 3 Intervention specification Co-intervention(s):</b>	<b>Comments</b>
Licameli et al., 2008 <sup>7</sup>	Phophorylcholine coated fluroplastic Armstrong TT	Uncoated fluroplastic Armstrong TT	NA	
Lildholdt, 1979 <sup>8</sup>	TT + Adenoidectomy  If effusion was present, it was suctioned and a teflon coated Donaldson tube was palced anterially in TM	Adenoidectomy	NA	
Mandel et al., 1989 <sup>9</sup>	Myringotomy  In children without "significant" hearing loss	Myringotomy + Armstrong TT  In children without "significant" hearing loss	Watchful waiting  In children without "significant" hearing loss	G4: Myringotomy  In children with significant hearing loss  G5: Myringotomy + Armstrong TT  In children with significant hearing loss

**Evidence Table 3. Interventions (continued)**

<b>Author, Year</b>	<b>Group 1 Intervention Specification Co-Interventions</b>	<b>Group 2 Intervention specification Co-intervention(s):</b>	<b>Group 3 Intervention specification Co-intervention(s)</b>	<b>Comments</b>
McRae et al., 1989 <sup>10</sup>	Shah TT+ aspiration prior to TT placement  After myringotomy, glue was aspirated from the selected side using a microsucker.	Shah TT without aspiration prior to tube placement	NA	
Ovesen et al., 2000 <sup>11</sup>	TT + application of 0.5 ml of a Mucomyst solution 20 mg/ml in one ear after insertion of tubes	TT + application of 0.5 ml of a placebo in one ear	TT in contralateral ear, exclusively	
Popova et al., 2010 <sup>12</sup>	Fluoroplastic Donaldson grommet + adenoidectomy	Myringotomy + adenoidectomy	NA	

**Evidence Table 3. Interventions (continued)**

<b>Author, Year</b>	<b>Group 1 Intervention Specification Co-intervention(s):</b>	<b>Group 2 Intervention specification Co-intervention(s):</b>	<b>Group 3 Intervention specification Co-intervention(s):</b>	<b>Comments</b>
Ragab, 2005 <sup>13</sup>	<p>Radiofrequency myringotomy + Mitomycin C</p> <p>Topical mitomycin was applied to the tympanic membrane before radiofrequency tympanostomy. Mitomycin C application was performed using a saturated (not dripping) Gelfoam piece soaked in 0.4 mg/ml of mitomycin C placed over the tympanic membrane for 10 minutes. The myringotomy (2–3 mm in diameter) was placed in the anteroinferior segment of the tympanic membrane.</p> <p>Adenoidectomy in 26 patients (87%)</p>	<p>Radiofrequency myringotomy + Mitomycin C</p> <p>The myringotomy (2–3 mm in diameter) was placed in the anteroinferior segment of the tympanic membrane.</p> <p>Adenoidectomy in 29 patients (97%)</p>	NA	
Shishegar and Haghoghi, 2007 <sup>14</sup>	<p>Adenoidectomy + myringotomy</p> <p>Ten day courses of amoxicillin therapy (75 mg/day in 3 doses) prescribed for all patients post-operatively</p>	<p>Adenoidectomy + myringotomy + TT</p> <p>Ten day courses of amoxicillin therapy (75 mg/day in 3 doses) prescribed for all patients post-operatively</p>	NA	

**Evidence Table 3. Interventions (continued)**

<b>Author, Year</b>	<b>Group 1 Intervention Specification Co-intervention(s):</b>	<b>Group 2 Intervention specification Co-intervention(s):</b>	<b>Group 3 Intervention specification Co-intervention(s):</b>	<b>Comments</b>
Slack et al., 1987 <sup>22</sup>	Shepard tube	Shah tube	Paprella tube	G4: Goode tubes G5: Reuter Bobbin tubes G6: Unknown or other tube type
Szeremeta et al., 2000 <sup>16</sup>	Laser Myringotomy + adenoidectomy  Using CO2 laser	Incisional, cold knife Myringotomy + adenoidectomy	NA	
Tos and Stangerup, 1989 <sup>17</sup>	Right sided -Donaldson type TT + adenoidectomy  Evacuation of MEE	Myringotomy + adenoidectomy  Evacuation of ME effucion		
Vlastos et al., 2011 <sup>18</sup>	Shepard type TT + adenoidectomy	Myringotomy + adenoidectomy		
Wielinga et al., 1990 <sup>19</sup>	Cold steel tonsillectomy Teflon bevelled Armstrong TT  1.15 mm internal diameter and 7.5 mm length TT were used	Cold steel tonsillectomy Silicon Goode TT		
Williamson et al., 2009 <sup>20</sup>	Mometasone furoate nasal spray	Placebo	NA	
Williamson et al., 2009 <sup>21</sup>	Nasal spray with 140, 50 um doses of mometesone to be administered once per day for 1 month. Total time taking steroid was 3 mos.  Support call from staff			

**Evidence Table 4. Benefits KQ 1 and 2, Part 1**

<b>Author, Year</b>	<b>OME</b>	<b>AOM</b>	<b>Middle Ear Fluid</b>	<b>Other Ear Symptoms (Fullness)</b>	<b>Hearing (Specify Test)</b>	<b>Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)</b>
Abdullah et al., 1994 <sup>1</sup>	Recurrence of OME: G1: 1/17 = 5.9% G2: 9/17 = 52.9%	NR	NR	NR	NR	NR
Austin, 1994 <sup>2</sup>		NR	NR	NR	Air Bone Gap G1: 13.2 G2: 14.4 Mean Improvement in Air-Bone Gap G1: 16 dB G2: 12.2 dB p > 0.1 Mean Difference Between tx: 1.9 dB	NR
Brown et al., 1978 <sup>3</sup>	NR		At 5 years, no "significant difference" in fluid level between groups		Preoperative HL G1: 25 dB G2: 23.1 dB 48 hr Postoperative HL G1: 8.9 dB G2: 24.7 dB 3 month Postoperative HL G1: 11.4 dB G2: 16.6 dB 5 yr Postoperative HL G1: 17 dB G2: 14 dB	NR

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

<b>Author, Year</b>	<b>OME</b>	<b>AOM</b>	<b>Middle Ear Fluid</b>	<b>Other Ear Symptoms (Fullness)</b>	<b>Hearing (Specify Test)</b>	<b>Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)</b>
D'Eredità and Shah, 2006 <sup>4</sup>			Middle ear ventilation: mean G1: 3.5 mos G2: 6.3 mos (95% CI): NR p = 0.001 Still ventilated 3 mo followup: G1: 11 ears, 36.6% G2: 30 ears, 100%		"Normal in both groups at 1 year followup"	
Iwaki et al., 1998 <sup>5</sup>	OME healed, n (%) G1: 45 (60%) G2: 25 (64.1%) G3: 77 (72.6%) OME recurrence, n (%) G1: 30 (40%) G2: 11 (28.2%) G3: 18 (17%) G3 vs. G1, P < 0.01 OME recurrence with adenoidectomy G1: 20 (40%) G2: 5 (36%) G3: 12 (24%) OME recurrence without adenoidectomy G1: 8 (35%) G2: 7 (32%) G3: 8 (17%)	NR	NR	NR	NR	NR

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

<b>Author, Year</b>	<b>OME</b>	<b>AOM</b>	<b>Middle Ear Fluid</b>	<b>Other Ear Symptoms (Fullness)</b>	<b>Hearing (Specify Test)</b>	<b>Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)</b>
Koopman et al., 2004 <sup>6</sup>	Success rate defined as the absence of effusion or otorrhea documented by binocular otoscopy. 1 month: G1: 46.6% G2: 87.4 % 2 months: G1: 35.5% G2: 81.9% 3 months: G1: 37.1% G2: 81.5% 4 months: G1: 38.6 % G2: 75.5% 5 months: G1: 41.6% G2: 68.5% 6 months: G1: 39.1% G2: 70.7% Positive influence on success rate: Adenoidectomy: p=0.006	NR	NR	NR	NR	NR

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

Author, Year	OME	AOM	Middle Ear Fluid	Other Ear Symptoms (Fullness)	Hearing (Specify Test)	Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)
Licameli et al., 2008 <sup>7</sup>	NR	NR	NR	NR	NR	NR
Mandel et al., 1989 <sup>9</sup>	MEE (OME and AOM) Year 1: Subjects entering without sig hearing loss or symptoms in G1 (M) and 3 (WW): 56% of the time G2 (MandT): 16.4% Diff: (P<.001). Those entering with sig hearing loss or symptoms G4 (M): 57% G5 (M and T): 9.8%. Diff: (P<.001) YR 2: G1: 35.2 G2: 20.4 G3:28.2 G4: 39.9 G5: 28.3 YR 3: G1: 25.5 G2: 25.0 G3:19.2 G4: 14.4 G5: 30.3 G1, 2, 4 may have had tx failure and gotten TT, mostly YR 2 and 3	AOM (episodes/ person- year ) w/o sig HL G1: 0.58 G2: 0. 18 G3: 0.38 With sigHL G4: 0.31 G5: 0.41		NR	Speech-recognition threshold (dB) of right ear, during 3-yr study G1: Functional TT: 5.1 (2.9) Intact TM, no MEE: 7.4 (3.8) Intact TM, MEE: 17.5 (4.7) G2: Functional TT: 4.8 (2.5) Intact TM, no MEE: 6.2 (3.8) Intact TM, MEE: 19.0 (8.7) G3: Functional TT: 5.9 (3.1) Intact TM, no MEE: 7.1 (4.5) Intact TM, MEE: 21.3 (5.7) G4: Functional TT: 5.8 (3.6) Intact TM, no MEE: 7.9 (3.7) Intact TM, MEE: 20.9 (8.7) G5: Functional TT: 6.8 (3.5) Intact TM, no MEE: 5.6 (4.0) Intact TM, MEE: 26.3 (7.7)	NR

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

<b>Author, Year</b>	<b>OME</b>	<b>AOM</b>	<b>Middle Ear Fluid</b>	<b>Other Ear Symptoms (Fullness)</b>	<b>Hearing (Specify Test)</b>	<b>Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)</b>
McRae et al., 1989 <sup>10</sup>	NR	NR	NR	NR	NR	NR
Ovesen et al., 2000 <sup>11</sup>	Recurrence of OME: G1: 15/37 G2: 25/38 G3: 52/75	No. of episodes G1: 0/37 G2: 5/38 G3: 16/75	NR	NR	NR	NR
Popova et al., 2010 <sup>12</sup>	12 mo Mean Between-group difference 4% (95% CI): p = 0.547	Mean Between-group difference 3% (95% CI):	NR	NR	1 mo post op. 50-4000 hz Mean Between-group difference: 0.2 (95% CI): p = 0.83 6 mo post op. 50-4000 hz Mean Between-group difference 0.4 (95% CI): p = 0.68 12 mo post op. 50-4000 hz Mean Between-group difference .0.8 (95% CI): p = 0.24	NR
Ragab, 2005 <sup>13</sup>	Resolution G1: 59% G2: 28% p < 0.01	NR		NR	Air Bone Gap Improvement from pre-op: G1: 12 dB G2: 10 dB p=NS Both groups improved from pre-op p<0.01)	NR

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

<b>Author, Year</b>	<b>OME</b>	<b>AOM</b>	<b>Middle Ear Fluid</b>	<b>Other Ear Symptoms (Fullness)</b>	<b>Hearing (Specify Test)</b>	<b>Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)</b>
Shishegar and Hoghoghi, 2007 <sup>14</sup>	NR	NR	No. (%) of pts with fluid in ears: G1: 24 (80%) G2: 24 (80%) Fluid content of patients ears and No. (%) of patients in each group: Serous fluid: G1: 8 (33%) G2: 8 (33%) Mucoid fluid: G1: 14 (58%) G2: 14 (58%) Purulent fluid: G1: 2 (9%) G2: 2 (9%)	NR	Air-bone gap (pure tone average) at 1 month: Mean difference between G1 and G2: 1.43 db Improvement from baseline: G1: 16.04 db G2: 17.47 db 95% Cis: NR p=NR; NS (not sig) at 6 mos.: Mean difference between G1 and G2: 1.37 db G1: 16.5 db G2: 17.62 db 95% CIs NR p=NS Mean SRT: at 1 month: Mean difference between G1 and G2: 1.83 dB G1: 17 db HL G2: 18.3 db HL 95% CIs: NR p=NS at 6 mos.: Mean difference between G1 and G2: 2.16 db G1: 17.16 db HL G2: 19.33 db HL 95% CIs: NR p=NS	NR

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

<b>Author, Year</b>	<b>OME</b>	<b>AOM</b>	<b>Middle Ear Fluid</b>	<b>Other Ear Symptoms (Fullness)</b>	<b>Hearing (Specify Test)</b>	<b>Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)</b>
Slack et al., 1987 <sup>22</sup>	NR	NR	NR	NR	NR	NR
Szeremeta et al., 2000 <sup>16</sup>	NR	NR	At post post-op visit Me G1: 4/39 G2: 7/41 p = 0.365	NR	NR	NR
Tos and Stangerup, 1989 <sup>17</sup>	NR	NR	NR	NR	(Mean 250-4000 Hz) Total Gain 1977-1984 Mean between-group difference: 0.6 (Db) P=NS G1 Mean Change from Baseline: 17.8 (dB) G2 Mean Change from Baseline: 16.7 (dB) data is also broken out by frequency and years	NR
Vlastos et al., 2011 <sup>18</sup>	NR	NR	NR	NR	Change in Hearing (6 mo) G1: -7.41 G2: -4.06 Mean HL Change 3.35 dB (95% CI - 6.64 to 10.35) Change in Hearing at 12 mos G1: -8.06 dB G2: -7.40 dB Mean HL Change 0.66 dB(95% CI - 6.82 to 8.15)	NR

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

<b>Author, Year</b>	<b>OME</b>	<b>AOM</b>	<b>Middle Ear Fluid</b>	<b>Other Ear Symptoms (Fullness)</b>	<b>Hearing (Specify Test)</b>	<b>Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)</b>
Wielinga et al., 1990 <sup>19</sup>	Resolution: G1: 53% G2: 80%	NR	NR	NR	Mean Hearing Loss: G1: 11 dB G2: 14 dB	NR
Williamson et al., 2009 <sup>20</sup>	Cure rate (A or C1 tympanogram in at least 1 ear) adjusted results (OR and RR) controlling for season, age, atrophy, and clinical severity score 1 mo. G1: 39/96 (41%) G2: 44/98 (45%) Diff in OR (adj): 0.934 (0.498 to 1.751) Diff in RR (adj): 0.97 (0.74 to 1.26) 3 mos. G1: 50/86 (58%) G2: 44/86 (52%) Diff in OR (adj): 1.451 (0.742 to 2.838) Diff in RR (adj): 1.23 (0.84 to 1.80) 9 mos G1: 40/72 (56%) G2: 47/72 (65%) Diff in OR (adj): 0.822 (0.387 to 1.746) Diff in RR (adj): 0.90 (0.58 to 1.41)	NR	NR	NR	Pass/Fail Criteria on sweep audiometry (fail at 2 or more frequencies at 25 dB in the better ear) 3 mos. failure G1: 52/83 (63%) G2: 47/81 = 58% (63%)  At 9 mos failure G1: 44/74 (59%) G2: 34/67 (51%) Hearing loss from tympanograms, median (IQR) at baseline G1: 30.97 (23.8-32.65) G2: 30.94(24.03-2.21) at 3 months G1: 19.43 (14.64-1.21) G2: 21.15 (14.86-0.94)	NR

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

Author, Year	OME	AOM	Middle Ear Fluid	Other Ear Symptoms (Fullness)	Hearing (Specify Test)	Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)
Williamson et al., 2009; <sup>20</sup> (continued)					At 9 months G1: 19.56(14.88-0.84) G2: 17.89 (14.11-3.55) Reported hearing difficulties, median(IQR) at baseline G1: 6.06 (2.83-8.57) G2: 5.88 (2.33-7.60) at 3 months G1: 5.54 (0.90-8.43) G2: 3.92 (0.90-7.60) at 9 months G1: 2.33 (0.21 to 7.60) G2: 2.33 (0.42-6.60) Days with hearing loss, median (IQR) At 3 months G1: 4 (0 to 24.5) G2: 4 (0 to 18.5) p=0.45	

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

<b>Author, Year</b>	<b>OME</b>	<b>AOM</b>	<b>Middle Ear Fluid</b>	<b>Other Ear Symptoms (Fullness)</b>	<b>Hearing (Specify Test)</b>	<b>Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)</b>
Williamson et al., 2009 <sup>21</sup>	OME resolution at 1 month OR, unadj (95%CI): 0.84 (0.475 to 1.484) OR, adj (95%CI): 0.934 (0.498 to 1.751) at 3 months OR, unadj (95%CI): 1.265 (0.693 to 2.311) OR, adj (95%CI): 1.451 (0.742 to 2.838) at 9 months OR, unadj (95%CI): 0.665 (0.34 to 1.302) OR, adj (95%CI): 0.822 (0.387 to 1.746)	NR	NR	NR	Audiometry failing, % at baseline G1: 69.6 G2: 74.5 at 3 months G1: 62.7 G2: 58.0 at 9 months G1: 59.5 G2: 50.7 Hearing loss from tympanograms, median (IQR) at baseline G1: 30.97 (23.8-32.65) G2: 30.94(24.03-2.21) at 3 months G1: 19.43 (14.64-1.21) G2: 21.15 (14.86-0.94) at 9 months G1:19.56(14.88-0.84) G2: 17.89 (14.11-3.55)	NA

**Evidence Table 4. Benefits KQ 1 and 2, Part 1 (continued)**

Author, Year	OME	AOM	Middle Ear Fluid	Other Ear Symptoms (Fullness)	Hearing (Specify Test)	Speech and Language Development (Speech Discrimination, Acoustic Reflex, Static Acoustic Impedance)
Williamson et al., 2009 <sup>21</sup> (continued)					Reported hearing difficulties, median(IQR) at baseline G1: 6.06 (2.83-8.57) G2: 5.88 (2.33-7.60) at 3 months G1: 5.54 (0.90-8.43) G2: 3.92 (0.90-7.60) at 9 months G1: 2.33 (0.21 to 7.60) G2: 2.33 (0.42-6.60) Days with hearing loss, median (IQR) at 3 months G1: 4 (0 to 24.5) G2: 4 (0 to 18.5) p=0.45	
<sup>8</sup>	NR	NR	No significant difference between groups in middle ear pressure	NR	No significant difference between groups at entry into the study or at various points post treatment	NR

**Evidence Table 5. Benefits KQ 1 and 2, Part 2**

<b>Author, Year</b>	<b>Auditory Processing</b>	<b>Cognition (Tests of Ability)</b>	<b>Academic Achievement and School-based functioning</b>	<b>Quality of Life</b>	<b>Behavior and Attention</b>	<b>Balance and Coordination</b>	<b>Comments</b>
Abdullah et al., 1994 <sup>1</sup>	NR	NR	NR	NR	NR	NR	
Austin, 1994 <sup>2</sup>	NR	NR	NR	NR	NR	NR	
Brown et al., 1978 <sup>3</sup>	NR	NR	NR	NR	NR	NR	
D'Eredità and Shah, 2006 <sup>4</sup>							
Iwaki et al., 1998 <sup>5</sup>	NR	NR	NR	NR	NR	NR	
Koopman et al., 2004 <sup>6</sup>	NR	NR	NR	NR	NR	NR	
Licameli et al., 2008 <sup>7</sup>	nr	nr	nr	nr	nr	nr	
Mandel et al., 1989 <sup>9</sup>	NR	NR	NR	NR	NR	NR	
McRae et al., 1989 <sup>10</sup>	NR	NR	NR	NR	NR	NR	
Ovesen et al., 2000 <sup>11</sup>	NR	NR	NR	NR	NR	NR	Time tube remained functional G1: 9 mo G2: 7 mo G3: 8 mo p>0.1367
Popova et al., 2010 <sup>12</sup>	NR	NR	NR	NR	NR	NR	

**Evidence Table 5. Benefits KQ 1 and 2, Part 2 (continued)**

<b>Author, Year</b>	<b>Auditory Processing</b>	<b>Cognition (Tests of Ability)</b>	<b>Academic Achievement and School-based functioning</b>	<b>Quality of Life</b>	<b>Behavior and Attention</b>	<b>Balance and Coordination</b>	<b>Comments</b>
Ragab, 2005 <sup>13</sup>	NR	NR	NR	NR	NR	NR	Tympanostomy closure week 1: G1: 3.3 G2: 0 Closure week 2: G1: 11.7 G2: 1.7 Closure week 3: G1: 60 G2: 15 Closure week 4: G1: 90 G2:41.7 Closure week 6: G1: 100 G2:83.3 Closure week 8: G1: G2:100
Shishegar and Haghoghi, 2007 <sup>14</sup>	NR	NR	NR	NR	NR	NR	
Slack et al., 1987 <sup>22</sup>	NR	NR	NR	NR	NR	NR	
Szeremeta et al., 2000 <sup>16</sup>	NR	NR	NR	NR	NR	NR	Patency of myringotomy at first post-op visit: G1: 8/39 20% G2: 0/48 0% P < 0.01
Tos and Stangerup, 1989 <sup>17</sup>	NR	NR	NR	NR	NR	NR	

**Evidence Table 5. Benefits KQ 1 and 2, Part 2 (continued)**

Author, Year	Auditory Processing	Cognition (Tests of Ability)	Academic Achievement and School-based functioning	Quality of Life	Behavior and Attention	Balance and Coordination	Comments
Vlastos et al., 2011 <sup>18</sup>	NR	NR	NR	OM-6 Score (6 mo) G1: 1.88 G2: 2.04 Mean Difference: -0.16 (95% CI: -0.43 to 0.10) Change from Baseline G1: -0.38 G2: -0.00 mean change: -0.38 (95% CI -0.65 to -0.10) OM-6 Score (12 mo) G1: 1.84 G2: 2.04 Mean Difference: -0.20 (95% CI: -0.57 to 0.17)	NR	NR	
Wielinga et al., 1990 <sup>19</sup>	NR	NR	NR	NR	NR	NR	
Williamson et al., 2009 <sup>20</sup>	NR	NR	NR	NR	NR	NR	
Williamson et al., 2009 <sup>21</sup>	NA	NA	NA	OM8-30 total score (results in figure 5) at baseline p=0.33 at 3 months p=0.55 at 9 months p=0.77	NA	NA	
<sup>8</sup>	NR	NR	NR	NR	NR	NR	

**Evidence Table 6. Subgroup analysis, Part 1**

<b>Author, Year</b>	<b>Subgroup Analysis? Subgroup Analyzed</b>	<b>Outcomes reported for OME?</b>	<b>Outcome reported for AOM?</b>	<b>Outcomes reported for Middle Ear Fluid?</b>	<b>Outcomes reported for Other ear symptoms?</b>	<b>Outcomes reported for Hearing?</b>
Abdullah et al., 1994 <sup>1</sup>	No	No	No	No	No	No
	NA					
Austin, 1994 <sup>2</sup>	No	No	No	No	No	No
	NA					
Brown et al., 1978 <sup>3</sup>	No	No	No	No	No	No
	NA					
D'Eredità and Shah, 2006 <sup>4</sup>	No	No	No	No	No	No
	No					
Iwaki et al., 1998 <sup>5</sup>	Yes	No	No	No	No	No
	NA					
Koopman et al., 2004 <sup>6</sup>	No	No	No	No	No	No
	NA					
Licameli et al., 2008 <sup>7</sup>	No	No	No	No	No	No
	NA					
Mandel et al., 1989 <sup>9</sup>	No	No	No	No	No	No
	NA					
McRae et al., 1989 <sup>10</sup>	No	No	No	No	No	No
	NA					
Ovesen et al., 2000 <sup>11</sup>	No	No	No	No	No	No
	NA					
Popova et al., 2010 <sup>12</sup>	No	No	No	No	No	No
	NA					

**Evidence Table 6. Subgroup analysis, Part 1 (continued)**

<b>Author, Year</b>	<b>Subgroup Analysis? Subgroup Analyzed</b>	<b>Outcomes reported for OME?</b>	<b>Outcome reported for AOM?</b>	<b>Outcomes reported for Middle Ear Fluid?</b>	<b>Outcomes reported for Other ear symptoms?</b>	<b>Outcomes reported for Hearing?</b>
Ragab, 2005 <sup>13</sup>	Yes  Those with adenoidectomy G1: 26 (87%) G2: 29 (97%)	Yes	No	No	No	No
Shishegar and Hoghoghi, 2007 <sup>14</sup>	No NA	No	No	No	No	No
Slack et al., 1987 <sup>15</sup>	No No	No	No	No	No	No
Szeremeta et al., 2000 <sup>16</sup>	No NA	No	No	No	No	No
Tos and Stangerup, 1989 <sup>17</sup>	No NA	No	No	No	No	No
Vlastos et al., 2011 <sup>18</sup>	No NA	No	No	No	No	No
Wielinga et al., 1990 <sup>19</sup>	No NA	No	No	No	No	No
Williamson et al., 2009 <sup>20, 21</sup>	Yes  Age: 4-6.49 years vs. 6.5+ years	Yes	No	No	No	No

**Evidence Table 7. Subgroup analysis, Part 2**

<b>Author, Year</b>	<b>Subgroup Analysis? Subgroup Analyzed</b>	<b>Speech and Language Development outcomes?</b>	<b>Balance and Coordination outcomes?</b>	<b>Auditory Processing outcomes?</b>	<b>Cognition outcomes?</b>	<b>Academic Achievement and School-based functioning outcomes?</b>	<b>Quality of Life outcomes?</b>	<b>Behavior and Attention Outcomes?</b>	<b>Comments</b>
Abdullah et al., 1994 <sup>1</sup>	No	No	No	No	No	No	No	No	
	NA								
Austin, 1994 <sup>2</sup>	No	No	No	No	No	No	No	No	
	NA								
Brown et al., 1978 <sup>3</sup>	No	No	No	No	No	No	No	No	
	NA								
D'Eredità and Shah, 2006 <sup>4</sup>	No	No	No	No	No	No	No	No	
	No								
Iwaki et al., 1998 <sup>5</sup>	yes	No	No	No	No	No	No	No	
	NA								
Koopman et al., 2004 <sup>6</sup>	No	No	No	No	No	No	No	No	
	NA								
Licameli et al., 2008 <sup>7</sup>	No	No	No	No	No	No	No	No	
	NA								
Mandel et al., 1989 <sup>9</sup>	No	No	No	No	No	No	No	No	
	NA								
McRae et al., 1989 <sup>10</sup>	No	No	No	No	No	No	No	No	
	NA								

**Evidence Table 7. Subgroup analysis, Part 2 (continued)**

<b>Author, Year</b>	<b>Subgroup Analysis? Subgroup Analyzed</b>	<b>Speech and Language Development outcomes?</b>	<b>Balance and Coordination outcomes?</b>	<b>Auditory Processing outcomes?</b>	<b>Cognition outcomes?</b>	<b>Academic Achievement and School-based functioning outcomes?</b>	<b>Quality of Life outcomes?</b>	<b>Behavior and Attention Outcomes?</b>	<b>Comments</b>
Ovesen et al., 2000 <sup>11</sup>	No NA	No	No	No	No	No	No	No	All other scales of Erickson and TAQOL were ns
Popova et al., 2010 <sup>12</sup>	No NA	No	No	No	No	No	No	No	
Ragab, 2005 <sup>13</sup>	Yes Those with adenoidectomy G1: 26 (87%) G2: 29 (97%)	No	No	No	No	No	No	No	Resolution of OME (in those with Adenoidectomy) G1: 72% G2: 34% P < .01 in G1 (Not clear who the comparison is with, may be with the 3 who didn't receive adenoidectomy)
Shishegar and Haghoghi, 2007 <sup>14</sup>	No. NA	No	No	No	No	No	No	No	
Slack et al., 1987 <sup>15</sup>	No No	No	No	No	No	No	No	No	
Szeremeta et al., 2000 <sup>16</sup>	No NA	No	No	No	No	No	No	No	
Tos and Stangerup, 1989 <sup>17</sup>	No NA	No	No	No	No	No	No	No	
Vlastos et al., 2011 <sup>18</sup>	No NA	No	No	No	No	No	No	No	

**Evidence Table 7. Subgroup analysis, Part 2 (continued)**

<b>Author, Year</b>	<b>Subgroup Analysis? Subgroup Analyzed</b>	<b>Speech and Language Development outcomes?</b>	<b>Balance and Coordination outcomes?</b>	<b>Auditory Processing outcomes?</b>	<b>Cognition outcomes?</b>	<b>Academic Achievement and School-based functioning outcomes?</b>	<b>Quality of Life outcomes?</b>	<b>Behavior and Attention Outcomes?</b>	<b>Comments</b>
Wielinga et al., 1990 <sup>19</sup>	No	No	No	No	No	No	No	No	
	NA								
Williamson et al., 2009 <sup>23, 24</sup>	yes	No	No	No	No	No	Yes	No	OME outcome measure: risk estimate for tympanometric cure Quality of Life measure: RESP score on OM8-30 questionnaire
	age: 4-6.49 years vs. 6.5+ years								
<sup>8</sup>	No	No	No	No	No	No	No	No	
	NA								

**Evidence Table 8. Harms, Part 1**

<b>Author, Year</b>	<b>Overall adverse events?</b>	<b>Withdrawals Due to Adverse Events</b>	<b>Segmental Atrophy</b>	<b>Tympanosclerosis</b>	<b>Otorrhea</b>	<b>Long Term Hearing impact if From PE Tube</b>	<b>Sedation</b>
Abdullah et al., 1994 <sup>1</sup>	Yes	NR	NR	Present G1: 15/17 = 88% G2: 15/17 = 88% Worse: G1: 2/17 = 12% G2: 8/17 = 47%	At least one episode of otorrhea G1: 0/17 = 0% G2: 3/17 18%	NR	NR
Austin, 1994 <sup>2</sup>	No	NR	NR	NR	NR	NR	NR
Brown et al., 1978 <sup>3</sup>	Yes	NR	NR	G1: 23 G2: 0	NR	NR	NR
D'Eredità and Shah, 2006 <sup>4</sup>	Yes	NR	NR	NR	G1: 2 at 2mos G2: 4 at 30 days and 3mos	NR	NR
Iwaki et al., 1998 <sup>5</sup>	Yes	NR	NR	NR	Simple Otorrhea G1: 7 (9.3%) G2: 13 (33.3%) G3: 39 (36.8%) G2 vs. G1, P<0.01 G3 vs. G1, P<0.01 Chronic Otorrhea G1: 2 (2.7%) G2: 1 (2.6%) G3: 1 (0.9%) ns	NR	NR
Koopman et al., 2004 <sup>6</sup>	Yes	55 children (26%) quit the study; Lost to f/u: 41 Failures: 14	NR	NR	Otorrhea occurred more frequently on the tube side than on the laser side: p=0.002. (By-group differences NR)	NR	NR
Licameli et al., 2008 <sup>7</sup>	Yes	NR	NR	NR	G1: 8.7% G2: 7.5% p=0.742	NR	NR

**Evidence Table 8. Harms, Part 1 (continued)**

Author, Year	Overall adverse events?	Withdrawals Due to Adverse Events	Segmental Atrophy	Tympanosclerosis	Otorrhea	Long Term Hearing impact if From PE Tube	Sedation
Lildholdt, T., 1979 <sup>8</sup>	Yes	NR	NR	G1: 3 cases of bleeding after several months, tube partially extruded, and granulation present. These had significant scarring. G2:	NR	NR	NR
Mandel et al., 1989 <sup>9</sup>	Yes	NR	NR	NR	G1: 0.15 G2: 0.41 G3: 0.23 G4: 0.34 G5: 0.61 In non-TT groups this would be limited to tx failures who got tubes	NR	NR
McRae et al., 1989 <sup>10</sup>	Yes	NR	NR	Specify: 24 mos. Bilateral: 17 G1: 8 G2: 1 p=0.045	nr	NR	NR
Ovesen et al., 2000 <sup>11</sup>	Yes	NR	NR	Nr	G1: 24% G2: 19% G3: 13% p>0.15	NR	NR
Popova et al., 2010 <sup>12</sup>	Yes	NR	NR	NR	G1: 40% G2: 0%	NR	NR
Ragab, 2005 <sup>13</sup>	Yes	NR	NR	NR	G1: 1 ( may have AOM ) G2: 0	NR	NR

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**Evidence Table 8. Harms, Part 1 (continued)**

<b>Author, Year</b>	<b>Overall adverse events?</b>	<b>Withdrawals Due to Adverse Events</b>	<b>Segmental Atrophy</b>	<b>Tympanosclerosis</b>	<b>Otorrhea</b>	<b>Long Term Hearing impact if From PE Tube</b>	<b>Sedation</b>
Shishegar and Hoghoghi, 2007 <sup>14</sup>	Yes	NA	NA	NA	Otorrhea G1: 7% G2: 27%	NR	NR
Slack et al., 1987 <sup>15</sup>	Yes	NR	NR	NR	Otorrhea at any time: G1: 12 (5.7%) G2: 4 (5.6%) G3: 110 (40%) G4: 3 (NR) G5: 1 (3.6%) G6: 5 (7.9%) G3 vs. G1, P<0.001 G3 vs. G2, P<0.001	NR	NR
Szeremeta et al., 2000 <sup>16</sup>	No	NR	NR	NR	NR	NR	NR
Tos and Stangerup, 1989 <sup>17</sup>	Yes	NR	NR	G1: 59% G2: 13%	NR	Reported in benefits	NR
Evidence Vlastos et al., 2011 <sup>18</sup>	No	No	NR	NR	NR	NR	NR
Wielinga et al., 1990 <sup>19</sup>	Yes	NR	NR	NR	G1: 20% G2: 13%	NR	NR
Williamson et al., 2009 <sup>23</sup>	Yes	NR	NR	NR	NR	NR	NR
Williamson et al., 2009 <sup>24</sup>	No	NR	NR	NR	NR	NR	NR

**Evidence Table 9. Harms, Part 2**

<b>Author, Year</b>	<b>Overall adverse events?</b>	<b>Withdrawals Due to Adverse Events</b>	<b>Procedure Related Harm</b>	<b>Cholesteatoma</b>	<b>Tubes in nontube Group or Repeated Tube</b>	<b>Other Adverse Effects</b>
Abdullah et al., 1994 <sup>1</sup>	Yes	NR	NR	NR	NR	Otalgia G1: 0/17 = 0% G2: 1/17 = 6%  residual perforation G1: 0/17 = 0% G2: 1/17 = 6%
Austin, 1994 <sup>2</sup>	no	NR	nr	NR	NR	
Brown et al., 1978 <sup>3</sup>	Yes	NR	nr	NR	NR	Retracted TM G1: 10/55 G2: 9/55
D'Eredità and Shah, 2006 <sup>4</sup>	Yes	NR	NR	NR	NR	Perforation: G1: 0 G2: 1 at 1 year

**Evidence Table 9. Harms, Part 2 (continued)**

<b>Author, Year</b>	<b>Overall adverse events?</b>	<b>Withdrawals Due to Adverse Events</b>	<b>Procedure Related Harm</b>	<b>Cholesteatoma</b>	<b>Tubes in Nontube Group or Repeated Tube</b>	<b>Other Adverse Effects</b>
Iwaki et al., 1998 <sup>5</sup>	Yes	NR	Specify: G1: G2:	G1: 1 (1.3%) G2: 0 (0%) G3: 0 (0%) na	NR	Perforation, n (%) G1: 0 (0%) G2: 3 (7.7%) G3: 11 (10.4%) G2 vs. G1, p<0.05 G3 vs. G1, p<0.01 Granulation: G1: 0 (0%) G2: 0 (0%) G3: 8 (7.5%) G3 vs. G1, p<0.05 Retraction: G1: 9 (12.0%) G2: 4 (10.2%) G3: 7 (6.6%) Atelactasis G1: 0 (0%) G2: 1 (2.6%) G3: 2 (1.9%) Adhesion G1: 1 (1.3%) G2: 0 (0%) G3: 4 (3.8%) Deep dimple G1: 1 (1.3%) G2: 2 (5.1%) G3: 6 (5.7%)

**Evidence Table 9. Harms, Part 2 (continued)**

<b>Author, Year</b>	<b>Overall adverse events?</b>	<b>Withdrawals Due to Adverse Events</b>	<b>Procedure Related Harm</b>	<b>Cholesteatoma</b>	<b>Tubes in Nontube Group or Repeated Tube</b>	<b>Other Adverse Effects</b>
Koopman et al., 2004 <sup>6</sup>	Yes	55 children (26%) quit the study; Lost to f/u: 41 Failures: 14	NR	NR	NR	Otalgia without inflammation: G1: 1 G2: 0 Epidemeral pearl of tympanic membrane: G1: 1 G2: 0
Licameli et al., 2008 <sup>7</sup>	Yes	NR	NR	NR	NR	Granulation G1: 4.4% G2: 6.0% p=0.662 Perforation G1: 4% G2: 0 p=0.235 Occlusion G1: 10.3% G2: 13.4% p=0.530 Extrusion G1: 79.0 G2: 72 p=0.841
Lildholdt, T., 1979 <sup>8</sup>	Yes	NR	NR	NR	G1: 13 G2: 6	G1: 25% of ears with tubes showed discharge with avg duration of 13 days.
Mandel et al., 1989 <sup>9</sup>	Yes	NR	NR	G3: Cholesteoma in 1 ear	NR	Tx failure: G1: 0.53 G2: 0 G3: 0.59 G4: 0.75 G5: 0
McRae et al., 1989 <sup>10</sup>	Yes	NR	NR	NR	NR	NR

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**Evidence Table 9. Harms, Part 2 (continued)**

<b>Author, Year</b>	<b>Overall adverse events?</b>	<b>Withdrawals Due to Adverse Events</b>	<b>Procedure Related Harm</b>	<b>Cholesteatoma</b>	<b>Tubes in Nontube Group or Repeated Tube</b>	<b>Other Adverse Effects</b>
Ovesen et al., 2000 <sup>11</sup>	Yes	NR	NR	NR	Repeat tubes: G1: 6/37 G2: 20/38 G3: 32/75	NR
Popova et al., 2010 <sup>12</sup>	Yes	NR	NR	NR	NR	NR
Ragab, 2005 <sup>13</sup>	Yes	NR	NR	NR	NR	NR
Shishegar and Hoghoghi, 2007 <sup>14</sup>	Yes	NA	NR	NR	NR	Over 6 mos. Percentage of TT occluded, resulting in non-functional state: 17%
Slack et al., 1987 <sup>15</sup>	Yes	NR	NR	NR	NR	Tubes needing removal due to persistent otorrhea G1: 0 (0%) G2: 2 (3%) G3: 17 (6%) G4: 0 (0%) G5: 1 (4%) G6: 0 (0%) G3 significantly worse than all other tubes combined, p<0.01; G1 significantly better, p<0.02
Szeremeta et al., 2000 <sup>16</sup>	No	NR	NR	NR	NR	NR
Tos and Stangerup, 1989 <sup>17</sup>	Yes	NR	NR	NR	NR	NR
Vlastos et al., 2011 <sup>18</sup>	No	No	NR	NR	G2: 20% (tubes in non tube group)	NR

**Evidence Table 9. Harms, Part 2 (continued)**

<b>Author, Year</b>	<b>Overall adverse events?</b>	<b>Withdrawals Due to Adverse Events</b>	<b>Procedure Related Harm</b>	<b>Cholesteatoma</b>	<b>Tubes in Nontube Group or Repeated Tube</b>	<b>Other Adverse Effects</b>
Wielinga et al., 1990 <sup>19</sup>	Yes	NR	NR	G1: 0 G2: 0	Repeat tube: G1: 47% G2: 20%	Peritubal Granulation: G1: 7% G2: 7% Blockage: G1: 40% G2: 20% Permanent Perforation: G1: 7% G2: 7%
Williamson et al., 2009 <sup>20</sup> and Williamson, 2009 <sup>21</sup>	Yes	NR	NR	NR	NR	At 1 mo G1: <ul style="list-style-type: none"> <li>• stinging nose 9/96</li> <li>• nose bleed 8/97</li> <li>• dry throat 13/96</li> <li>• cough 23/97</li> </ul> G2: 10/102 <ul style="list-style-type: none"> <li>• nose bleed 7/101</li> <li>• dry throat 14/102</li> <li>• cough 19/102</li> </ul> At 3 mos G1: <ul style="list-style-type: none"> <li>• stinging nose 9/85</li> <li>• nose bleed 10/86</li> <li>• dry throat 10/85</li> <li>• cough 19/867</li> </ul> G2: <ul style="list-style-type: none"> <li>• stinging nose 9/85</li> <li>• nose bleed 10/86</li> <li>• dry throat 7/83</li> <li>• cough 11/83</li> </ul> • Overall: No significant adverse outcomes reported

**Evidence Table 10. Study risk of bias: All studies**

<b>Author, Year Study Design</b>	<b>Was Allocation Concealment Generated Adequately? Was the Allocation of Treatment Adequately Concealed?</b>	<b>Did the Strategy for Recruiting Participants into the Study Differ Across Study Groups? Are Baseline Characteristics Similar Between Groups? If not, did the Analysis Control for Differences?</b>	<b>Were Cases and Controls (G1 and G2) Selected Appropriately?</b>	<b>Were Providers Blinded to the Intervention or Exposure Status of Participants?</b>
Popova et al., 2010 <sup>12</sup> Parallel RCT	Unclear or NR Unclear or NR	No Yes NA	NA No	No
Austin, 1994 <sup>2</sup> NRCT	NA NA	No Yes NA	NA Unclear or NR	Unclear or NR
Brown et al., 1978 <sup>3</sup> Parallel RCT	Unclear or NR Unclear or NR	Unclear or NR Yes Yes	Yes NA	NA
D'Eredità and Shah, 2006 <sup>4</sup> Parallel RCT	Unclear or NR Unclear or NR	Unclear or NR Unclear or NR No	NA NA	NA
Iwaki et al., 1998 <sup>5</sup> Retrospective cohort	NA NA	No Unclear or NR No	NA NA	NA
Koopman et al., 2004 <sup>6</sup> Parallel RCT	Yes Yes	No Yes NA	NA Unclear or NR	Unclear or NR
Licameli et al., 2008 <sup>7</sup> Parallel RCT	Unclear or NR Unclear or NR	No Yes	Yes Unclear or NR	Unclear or NR
Mandel et al., 1989 <sup>9</sup> Cluster RCT	Unclear or NR Unclear or NR	Unclear or NR Yes Yes	NA No	No
McRae et al., 1989 <sup>10</sup> Parallel RCT	Yes Unclear or NR	No Yes NA	NA Unclear or NR	Unclear or NR
Ovesen et al., 2000 <sup>11</sup> Parallel RCT	Yes Unclear or NR	NA NA NA	NA NA	NA
Popova et al., 2010 <sup>12</sup> Parallel RCT	Unclear or NR Unclear or NR	No Yes NA	NA No	No

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## Appendix D. Abstract and Full Text Forms

The following are lists of fields used in the abstract and full text review forms. Please see the Evidence Tables (Appendix C) for fields used in the data abstraction forms.

**Table D1. Abstract review form fields**

REF ID
Author
Year
Title
Abstract
Is the publication original research and available in full text form (NOT editorials, letters, non-systematic reviews, abstract only material)? If no, X1.
Is the publication a controlled trial (randomized or non-randomized), a systematic review or meta-analysis, a cohort study (prospective or retrospective) or a case/control study? If no, X2.
Does the study present information in relation to a population with OME ? If no, X3.
Does the study present information in relation to an intervention of interest? If no, X4.
Does the study compare at least two of the interventions of interest? If no, X5.
Is the study published in the English language? If no X6.
Have met all previous inclusion criteria. Do any of the studies fall into the following categories (place appropriate X code)? Adenoidectomy for OME with a publication date before 2008? If yes, X7. Autoinflation for OME with a publication date before 2005? If yes, X8. Steroids for OME with a publication date before 2005? If yes, X9. Tympanostomy tubes for OME with a publication date before 2006? If yes, X10 Observational and case control studies for CAM? If yes, X11.
Background? (To suggest an abstract that would otherwise be excluded from the review for use as background information, mark it with BKG, along with EXC and the exclusion number/code. Use BKG judiciously!)
Comments: Please include a comment if you included an abstract, but did so do to a lack of clarity within the abstract. Explain why you think the FT will reveal that the study should be excluded.

**Table D2. Full text review form fields**

Ref ID
Authors
Year
Title
Is the publication original research and available in English and in full text form (NOT editorials, letters, non-systematic reviews, abstract only material)?
Is the publication a controlled trial (randomized or non-randomized), a cohort study (prospective or retrospective) or a case/control study?
Does the study present information in relation to a population with OME? Is the population being treated For OME (i.e., not a prevention study). If the population is mixed are the results stratified? Is the OME population a non-cancer population (i.e., not OME secondary to nasopharyngeal carcinoma)?
Does the study present information in relation to an intervention of interest (autoinflation, myringotomy, adenoidectomy, tympanostomy tubes, steroids, topical or nasal steroids, watchful waiting, variations in surgical techniques, or CAM)
Does the study compare at least two interventions listed above?
Adenoidectomy for OME: RCT of children with a publication date of 2008 or later?
Autoinflation for OME: RCT of children with with a publication date of 2005 or later?
Steroids for OME with a publication date of 2005 or later?
Tympanostomy Tubes for OME:RCT of children with a publication date of 2006 or later?
Randomized and non-randomized trials for CAM?
Comments
Does the study belong to a set of Companion Studies? (Yes/No)
Include citations of any Companion Studies here

## Appendix E. Risk of Bias Tables

**Table E-1. Risk of bias: RCTs and NRCTs**

Identifiers	Randomization Groups	Masked Statistical Analysis	Miscellaneous	Outcomes and Attritions	Risk of Bias
Author, Year Abdullah, et al., 1994 <sup>1</sup>	Randomization adequate? NA	Providers masked? Unclear or NR	Maintain fidelity to the protocol? Yes	If overall attrition was $\geq 20\%$ or differential attrition $\geq 15\%$ , were missing data handled appropriately? No	Risk of Bias Medium
Study design NRCT	Allocation concealment adequate? NA	Patients masked? Unclear or NR	Followup the same between the groups? Yes	Health outcome measures equal, valid and reliable? Yes	
	Strategy for recruiting participants differ across study groups? No	Outcome assessors masked? Unclear or NR	I/E criteria equally applied in both groups? Yes	Harms outcome measures equal, valid and reliable? Yes	
	Groups similar at baseline? Yes	Any impact from a concurrent intervention or exposure ruled out? Unclear or NR	All outcomes pre-specified? All pre-specified outcomes reported? Yes		
	If not, did the analysis control for differences? NA	ITT analysis? No			
		Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches? No (Not accounted for or not identified)			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Austin, 1994 <sup>2</sup>	<b>Randomization adequate?</b> NA	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> Medium
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> NA	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Unclear or NR	<b>Harms outcome measures equal, valid and reliable?</b> Unclear or NR	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Unclear or NR	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Brown et al., 1978 <sup>3</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> NA	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Yes	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> NA	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> Unclear or NR	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Unclear or NR	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Unclear or NR		
	<b>If not, did the analysis control for differences?</b> Yes	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> NA			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> D'Eredità and Shah, 2006 <sup>4</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> NA	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> Unclear or NR	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> No		
	<b>If not, did the analysis control for differences?</b> No	<b>ITT analysis?</b> No			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Koopman, et al., 2004 <sup>5</sup>	<b>Randomization adequate?</b> Yes	<b>Providers masked?</b> Unclear or NR  <b>Patients masked?</b> Yes	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Yes	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Yes  <b>Strategy for recruiting participants differ across study groups?</b> No  <b>Groups similar at baseline?</b> Yes  <b>If not, did the analysis control for differences?</b> NA	<b>Outcome assessors masked?</b> Unclear or NR  <b>Any impact from a concurrent intervention or exposure ruled out?</b> Yes  <b>ITT analysis?</b> Yes  <b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> NA	<b>Followup the same between the groups?</b> Yes  <b>I/E criteria equally applied in both groups?</b> Yes  <b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Unclear or NR	<b>Health outcome measures equal, valid and reliable?</b> Yes  <b>Harms outcome measures equal, valid and reliable?</b> Unclear or NR	

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Licameli, et al., 2008 <sup>6</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> No	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> NA	
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Unclear or NR	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Yes	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> No		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> No			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> NA			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Lildholdt, 1979 <sup>7</sup>	<b>Randomization adequate?</b> No	<b>Providers masked?</b> No	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> Medium
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> No	<b>Patients masked?</b> No	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> Unclear or NR	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Unclear or NR	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Unclear or NR		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Cannot determine			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Mandel, et al., 1989 <sup>8</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> No	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Yes	<b>Risk of Bias</b> Medium
<b>Study design</b> Cluster RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> Unclear or NR	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Yes	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> No		
	<b>If not, did the analysis control for differences?</b> Yes	<b>ITT analysis?</b> No	<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Yes		

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> McRae, et al., 1989 <sup>9</sup>	<b>Randomization adequate?</b> Yes	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> No	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> NA	
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Yes	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>ITT analysis?</b> Yes	<b>If not, did the analysis control for differences?</b> NA			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> NA			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Ovesen, et al., 2000 <sup>10</sup>	<b>Randomization adequate?</b> Yes	<b>Providers masked?</b> NA	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> No	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> NA	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> NA	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Unclear or NR	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Popova, et al., 2010 <sup>11</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> No	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Unclear or NR	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Yes	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> No		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> No			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> NA			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Ragab, 2005 <sup>12</sup>	<b>Randomization adequate?</b> Yes	<b>Providers masked?</b> No	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> No	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Yes	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Unclear or NR		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Yes			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Shishegar and Hoghoghi, 2007 <sup>13</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Unclear or NR		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Unclear or NR			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Cannot determine			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Tos and Stangerup, 1989 <sup>14</sup>	<b>Randomization adequate?</b> NA	<b>Providers masked?</b> No	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Yes	<b>Risk of Bias</b> Medium
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> NA	<b>Patients masked?</b> No	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> NA	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Vlastos, et al., 2011 <sup>15</sup>	<b>Randomization adequate?</b> Yes	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> No	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Yes	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Yes			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Wielinga, et al., 1990 <sup>16</sup>	<b>Randomization adequate?</b> Yes	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Yes	<b>Risk of Bias</b> Medium
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Unclear or NR	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-1. Risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Williamson, et al., 2009; <sup>17</sup> Williamson, et al., 2009 <sup>18</sup>	<b>Randomization adequate?</b> Yes	<b>Providers masked?</b> Yes	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Yes	<b>Risk of Bias</b> Low
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Yes	<b>Patients masked?</b> Yes	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Yes	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Yes	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Partial (some variables were taken into account)			

**Table E-2. Risk of bias: Observational**

<b>Identifiers</b>	<b>Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Szeremeta et al., 2000 <sup>19</sup>	<b>Recruitment strategy differ across groups?</b> Unclear or NR	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> No	<b>Risk of Bias</b> Medium
<b>Study design</b> Retrospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR  <b>If not, did the analysis control for differences?</b> No	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> No  <b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> Yes  <b>I/E criteria equally applied in both groups?</b> Unclear or NR  <b>All outcomes pre-specified? All pre-specified outcomes reported?</b> No	<b>Health outcome measures equal, valid and reliable?</b> Yes  <b>Harms outcome measures equal, valid and reliable?</b> NA	

**Table E-2. Risk of bias: Observational (continued)**

<b>Identifiers</b>	<b>Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Slack et al., 1987 <sup>20</sup>	<b>Recruitment strategy differ across groups?</b> No	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> NA	<b>Risk of Bias</b> Medium
<b>Study design</b> Retrospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR  <b>If not, did the analysis control for differences?</b> No	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> No  <b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Partial (some variables were taken into account)	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> NA  <b>I/E criteria equally applied in both groups?</b> NA  <b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> NA  <b>Harms outcome measures equal, valid and reliable?</b> Yes	

**Table E-2. Risk of bias: Observational (continued)**

<b>Identifiers</b>	<b>Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Iwaki et al., 1998 <sup>21</sup>	<b>Recruitment strategy differ across groups?</b> No	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> NA	<b>Risk of Bias</b> Medium
<b>Study design</b> Retrospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR  <b>If not, did the analysis control for differences?</b> No	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> Yes  <b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Partial (some variables were taken into account)	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> Yes  <b>I/E criteria equally applied in both groups?</b> Yes  <b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes  <b>Harms outcome measures equal, valid and reliable?</b> Yes	

**Table E-3. Quality reviews of systematic reviews**

<b>Author, Year</b>	<b>Country</b>	<b>Funding</b>	<b>Study Design</b>	<b>Quality Review</b>
Browning, 2010 <sup>22</sup>				<b>Is the Review Based on a Focused Question of Interest?</b> Yes
				<b>Did the Search Strategy Employ a Comprehensive, Systematic, Literature Search?</b> Yes.
	Denmark UK			The authors conducted systematic searches for randomized controlled trials with no language, publication year or publication status restrictions.
	National			The search included the following databases: the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials ; PubMed; EMBASE; CINAHL; LILACS; KoreaMed; IndMed; PakMediNet; CAB Abstracts; Web of Science; BIOSIS Previews; CNKI; ISRCTN; ClinicalTrials.gov; ICTRP and Google. Other resources were searched such as reference lists of identified publications and other systematic reviews; authors were contacted for clarification and further data if needed. The last search was in March 2010.
	Institute for Health Research Cochrane Review Incentive Scheme			<b>Are Eligibility Criteria for Studies Clearly Described?</b> Yes
				<b>Did at Least 2 Persons Independently Review Studies?</b> Yes
	Systematic review			<b>Did Authors use a Standard Method of Critical Appraisal Before Including Studies?</b> Yes
				<b>Was Publication Bias Assessed?</b> Yes
				<b>Was Heterogeneity Assessed and Addressed?</b> Yes
				<b>Did Statistical Analysis Maintain Trials as the Unit of Analysis?</b> Yes
				<b>Risk of Bias?</b> Low

**Table E-3. Quality reviews of systematic reviews (continued)**

<b>Author, Year</b>	<b>Country</b>	<b>Funding</b>	<b>Study Design</b>	<b>Quality Review</b>
van den Aardweg, 2010 <sup>23</sup>				<p><b>Is the Review Based on a Focused Question of Interest?</b> Yes</p> <p><b>Did the Search Strategy Employ a Comprehensive, Systematic, Literature Search?</b> Yes.</p> <p>Authors conducted systematic searches for randomized controlled trials with no language, publication year or publication status restrictions. The search included the following databases: the Cochrane Ear, Nose and Throat Disorders Group Trials Register; the Cochrane Central Register of Controlled Trials (CENTRAL); PubMed; EMBASE;CINAHL;Web of Science; BIOSIS Previews;Cambridge Scientific Abstracts;mRCTand additional sources for published and unpublished trials; authors were contacted for clarification and further data if needed. The date of the last search was 30 March 2009.</p>
	University medical Center Utrecht, Netherlands;		Systematic review	<p><b>Are Eligibility Criteria for Studies Clearly Described?</b> Yes</p> <p><b>Did at Least 2 Persons Independently Review Studies?</b> Yes</p> <p><b>Did Authors use a Standard Method of Critical Appraisal Before Including Studies?</b> Yes</p> <p><b>Was Publication Bias Assessed?</b> Yes</p> <p><b>Was Heterogeneity Assessed and Addressed?</b> Yes</p> <p><b>Did Statistical Analysis Maintain Trials as the Unit of Analysis?</b> Yes</p> <p><b>Risk of Bias?</b> Low</p>

**Table E-3. Quality reviews of systematic reviews (continued)**

<b>Author, Year</b>	<b>Country</b>	<b>Funding</b>	<b>Study Design</b>	<b>Quality Review</b>
Perra, 2009 <sup>24</sup>				<p><b>Is the Review Based on a Focused Question of Interest?</b> Yes</p> <p><b>Did the Search Strategy Employ a Comprehensive, Systematic, Literature Search?</b> Yes. The authors conducted systematic searches for randomized controlled trials with no language restrictions. The search included the following databases: the Cochrane Ear, Nose and Throat Disorders Group Trials Register, CENTRAL (The Cochrane Library Issue 1, 2006), MEDLINE (1951 to 2006), EMBASE (1974 to 2006), CINAHL, PubMed, AMED, BNI, Zetoc, SAMED, KoreaMed, IndMED, Cambridge Scientific Abstracts, MEDCARIB, LILACS and mRCT. Reference lists of identified publications were scanned for additional trials and authors contacted if necessary. The last search was in March 2006.</p> <p><b>Are Eligibility Criteria for Studies Clearly Described?</b> Yes</p> <p><b>Did at Least 2 Persons Independently Review Studies?</b> Yes</p> <p><b>Did Authors use a Standard Method of Critical Appraisal Before Including Studies?</b> Yes</p> <p><b>Was Publication Bias Assessed?</b> NR</p> <p><b>Was Heterogeneity Assessed and Addressed?</b> Yes</p> <p><b>Did Statistical Analysis Maintain Trials as the Unit of Analysis?</b> Yes</p> <p><b>Risk of Bias?</b> Low</p>

**Table E-3. Quality reviews of systematic reviews (continued)**

<b>Author, Year</b>	<b>Country</b>	<b>Funding</b>	<b>Study Design</b>	<b>Quality Review</b>
Thomas, 2010 <sup>25</sup>				<p><b>Is the Review Based on a Focused Question of Interest?</b> Yes</p> <p><b>Did the Search Strategy Employ a Comprehensive, Systematic, Literature Search?</b> Yes. The authors conducted systematic searches for randomized controlled trials with no language restrictions. The search included the following databases: Cochrane Ear, Nose and Throat Disorders Group Specialised Register, the Cochrane Central Register of Controlled Trials (CENTRAL) in The Cochrane Library, MEDLINE, EMBASE, and the CINAHL, LILACS, Zetoc, IndMED, SAMED, KoreaMed, MEDCARIB and Cambridge Scientific Abstracts. Previous systematic reviews and references of trials identified by the search strategy were also checked for further trials; authors were contacted for clarification and further data if needed. The last search was in January 2006.</p> <p><b>Are Eligibility Criteria for Studies Clearly Described?</b> Yes</p> <p><b>Did at Least 2 Persons Independently Review Studies?</b> Yes</p> <p><b>Did Authors use a Standard Method of Critical Appraisal Before Including Studies?</b> Yes</p> <p><b>Was Publication Bias Assessed?</b> Yes</p> <p><b>Was Heterogeneity Assessed and Addressed?</b> Yes</p> <p><b>Did Statistical Analysis Maintain Trials as the Unit of Analysis?</b> Yes</p> <p><b>Risk of Bias?</b> Low</p>
	University of Wales		College of Medicine, NHS Wales Office for Research and Development for Health and Social, UK	
			Systematic review	

**Table E-3. Quality reviews of systematic reviews (continued)**

<b>Author, Year</b>	<b>Country</b>	<b>Funding</b>	<b>Study Design</b>	<b>Quality Review</b>
Hellstrom, 2011 <sup>26</sup>	Swedish			<p><b>Is the Review Based on a Focused Question of Interest?</b> Yes</p> <p><b>Did the Search Strategy Employ a Comprehensive, Systematic, Literature Search?</b> Yes, 2 investigators independently evaluated a total of 493 abstracts obtained from Cochrane Library, PubMed, and Embase databases; 247 full-text articles were assessed for inclusion criteria and quality using structured evaluation forms, and 63 articles that were either high or medium quality were included in the review. Studies in English, Scandinavian, German, and French were accepted.</p> <p><b>Are Eligibility Criteria for Studies Clearly Described?</b> Yes</p> <p><b>Did at Least 2 Persons Independently Review Studies?</b> Yes</p> <p><b>Did Authors use a Standard Method of Critical Appraisal Before Including Studies?</b> Yes</p> <p><b>Was Publication Bias Assessed?</b> NR</p> <p><b>Was Heterogeneity Assessed and Addressed?</b> No</p> <p><b>Did Statistical Analysis Maintain Trials as the Unit of Analysis?</b> No statistical analysis</p> <p><b>Risk of Bias?</b> Moderate</p>

**Table E-4. High risk of bias: RCTs and NRCTs**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Caye-Thomasen et al., 2008 <sup>27</sup>	<b>Randomization adequate?</b> No	<b>Providers masked?</b> No	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Yes	<b>Risk of Bias</b> High
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> No	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Unclear or NR	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes Explaining Risk of Bias</b> Baseline characteristics are not reported adequately. Loss to followup was 50%, and while authors report that remaining participant's characteristics were the same as the original cohorts, they do not provide any other information.
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> No	<b>I/E criteria equally applied in both groups?</b> Unclear or NR	<b>Harms outcome measures equal, valid and reliable?</b> NA	
	<b>Groups similar at baseline?</b> No	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> No	<b>ITT analysis?</b> No			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Honjo et al., 1992 <sup>28</sup>	<b>Randomization adequate?</b> NA	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Unclear or NR	<b>Risk of Bias</b> High
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> NA	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes Explaining Risk of Bias</b> Authors equate randomization with similarity in age between groups which is not an adequate randomization scheme. Only baseline characteristics are age and sex; there is a high risk for uncontrolled confounding.
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> No	<b>Harms outcome measures equal, valid and reliable?</b> NA	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> Unclear or NR	<b>ITT analysis?</b> Unclear or NR			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Karlán et al., 1980 <sup>29</sup>	<b>Randomization adequate?</b> NA	<b>Providers masked?</b> NA	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> High
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> NA	<b>Patients masked?</b> NA	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> NA	<b>Notes Explaining Risk of Bias</b> No baseline characteristics reported; infection outcome not defined; potential confounders not taken into account.
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Unclear or NR	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> No	<b>ITT analysis?</b> NA			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Siegel and Chandra, 2002 <sup>30</sup>	<b>Randomization adequate?</b> No	<b>Providers masked?</b> No	<b>Maintain fidelity to the protocol?</b> Unclear or NA	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> High
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> No	<b>Patients masked?</b> No	<b>Followup the same between the groups?</b> yes	<b>Health outcome measures equal, valid and reliable?</b> No	<b>Notes Explaining Risk of Bias</b> Group assignment chosen by patient; statistically significant age difference between groups.
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> no	<b>Harms outcome measures equal, valid and reliable?</b> No	
	<b>Groups similar at baseline?</b> No	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> No		
	<b>If not, did the analysis control for differences?</b> No	<b>ITT analysis?</b> NA			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Tos, Bonding and Poulsen, 1983 <sup>31</sup>	<b>Randomization adequate?</b> no	<b>Providers masked?</b> no	<b>Maintain fidelity to the protocol?</b> unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> high
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> no	<b>Patients masked?</b> unclear or NR	<b>Followup the same between the groups?</b> yes	<b>Health outcome measures equal, valid and reliable?</b> yes	<b>Notes Explaining Risk of Bias</b> Treatment assignment was not done in randomized fashion, no baseline characteristics reported.
	<b>Strategy for recruiting participants differ across study groups?</b> no	<b>Outcome assessors masked?</b> unclear or NR	<b>I/E criteria equally applied in both groups?</b> unclear or NR	<b>Harms outcome measures equal, valid and reliable?</b> NA	
	<b>Groups similar at baseline?</b> unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> no	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> no		
	<b>If not, did the analysis control for differences?</b> no	<b>ITT analysis?</b> no			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> no			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Yaman et al., 2010 <sup>32</sup>	<b>Randomization adequate?</b> NA	<b>Providers masked?</b> NA	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> High
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> NA	<b>Patients masked?</b> NA	<b>Followup the same between the groups?</b> NA	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes Explaining Risk of Bias</b> No baseline characteristics reported; potential confounding factors not accounted for in analysis, no comparison group.
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> yes	<b>Harms outcome measures equal, valid and reliable?</b> NA	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> No	<b>ITT analysis?</b> NA			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Zakirullah et al., 2001 <sup>33</sup>	<b>Randomization adequate?</b> NA	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> No	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Unclear or NR	<b>Risk of Bias</b> No
<b>Study design</b> NRCT	<b>Allocation concealment adequate?</b> No	<b>Patients masked?</b> No	<b>Followup the same between the groups?</b> Unclear or NR	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes Explaining Risk of Bias</b> High
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Unclear or NR	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Yes	<b>Any impact from a concurrent intervention or exposure ruled out?</b> Unclear or NR	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> NA		
	<b>If not, did the analysis control for differences?</b> Unclear or NR	<b>ITT analysis?</b> Unclear or NR			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Yes			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Black et al., 1986 <sup>34</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> High
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes Explaining Risk of Bias</b> Many baseline characteristics were measured based on parental reports; difference in sex distribution between groups
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> NA	
	<b>Groups similar at baseline?</b> No	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> No	<b>ITT analysis?</b> Unclear or NR			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Gates et al., 1988 <sup>35</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> No	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> High
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes Explaining Risk of Bias</b> Analyzed by treatment received (27 subjects chose a treatment other than their assigned one), rather than by assigned treatment.
	<b>Strategy for recruiting participants differ across study groups?</b> Yes	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> NA	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> No		
	<b>If not, did the analysis control for differences?</b> Unclear or NR	<b>ITT analysis?</b> No	<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> Partial		

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Gibson et al., 1996 <sup>36</sup>	<b>Randomization adequate?</b> No	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> NA	<b>Risk of Bias</b> High
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes Explaining Risk of Bias</b> This study considers a subset of patients from the aboriginal cohort that was studied. There are no details about the subset of patients that were enrolled in this study, or the subgroups within the RCT.
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> NA	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Unclear or NR		
	<b>If not, did the analysis control for differences?</b> NA	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Ruckley and Blair, 1988 <sup>37</sup>	<b>Randomization adequate?</b> No	<b>Providers masked?</b> No	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> No	<b>Risk of Bias</b> High
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> No	<b>Notes Explaining Risk of Bias</b> Baseline characteristics not reported although some outcomes were reported pre-operatively; ITT analysis not conducted; additional myringotomy was performed on some of the patients and not clear how this impacted the results.
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> No	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> No	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> No		
	<b>If not, did the analysis control for differences?</b> No	<b>ITT analysis?</b> No			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Tatar et al., 2006 <sup>38</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> Yes	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Unclear or NR	<b>Risk of Bias</b> High
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> No	<b>Notes Explaining Risk of Bias</b> There are no patient characteristics. It is unknown the extent to which the results are impacted by differences across individuals. The study includes no health outcomes.
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Yes	<b>I/E criteria equally applied in both groups?</b> Unclear or NR	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Unclear or NR		
	<b>If not, did the analysis control for differences?</b> No	<b>ITT analysis?</b> Yes			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)			

**Table E-4. High risk of bias: RCTs and NRCTs (continued)**

<b>Identifiers</b>	<b>Randomization Groups</b>	<b>Masked Statistical Analysis</b>	<b>Miscellaneous</b>	<b>Outcomes and Attritions</b>	<b>Risk of Bias</b>
<b>Author, Year</b> Yagi, 1977 <sup>39</sup>	<b>Randomization adequate?</b> Unclear or NR	<b>Providers masked?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately?</b> Unclear or NR	<b>Risk of Bias</b> High
<b>Study design</b> Parallel RCT	<b>Allocation concealment adequate?</b> Unclear or NR	<b>Patients masked?</b> Unclear or NR	<b>Followup the same between the groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes Explaining Risk of Bias</b> No baseline characteristics reported
	<b>Strategy for recruiting participants differ across study groups?</b> No	<b>Outcome assessors masked?</b> Unclear or NR	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> NA	
	<b>Groups similar at baseline?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure ruled out?</b> No	<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
	<b>If not, did the analysis control for differences?</b> No	<b>ITT analysis?</b> Unclear or NR			
		<b>Does design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No			

**Table E-5. High risk of bias: Observational**

Identifiers	Groups	Masked and Statistical Analysis	Miscellaneous	Outcomes	Risk of Bias
<b>Author, Year</b> Bozkurt and Calguner, 2004 <sup>40</sup>	<b>Recruitment strategy differ across groups?</b> No	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> Unclear or NR	<b>Risk of bias</b> High
<b>Study design</b> Prospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> No	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes explaining risk of bias</b> Retrospective comparison group - all tubes had been extruded by time study was done.
	<b>If not, did the analysis control for differences?</b> No	<b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No	<b>I/E criteria equally applied in both groups?</b> No	<b>Harms outcome measures equal, valid and reliable?</b> NA	
			<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		
<b>Author, Year</b> D'Eredita, 2004 <sup>41</sup>	<b>Recruitment strategy differ across groups?</b> No	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> Unclear or NR	<b>Risk of bias</b> High
<b>Study design</b> Prospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> Unclear or NR	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Unclear or NR	<b>Notes explaining risk of bias</b> Very small sample size. Information about subjects is extremely limited. The outcome of presence or absence of sclerosis of the TM was determined by visual assessment by one individual. Time period of outcome evaluation not specific.
	<b>If not, did the analysis control for differences?</b> Unclear or NR	<b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)	<b>I/E criteria equally applied in both groups?</b> Yes	<b>Harms outcome measures equal, valid and reliable?</b> Unclear or NR	
			<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Unclear or NR		

**Table E-5. High risk of bias: Observational (continued)**

Identifiers	Groups	Masked and Statistical Analysis	Miscellaneous	Outcomes	Risk of Bias
<b>Author, Year</b> Hassmann et al., 2004 <sup>42</sup>	<b>Recruitment strategy differ across groups?</b> Yes	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> No	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> NA	<b>Risk of bias</b> High
<b>Study design</b> Prospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR  <b>If not, did the analysis control for differences?</b> No	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> No  <b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> No  <b>I/E criteria equally applied in both groups?</b> NA  <b>All outcomes pre-specified? All pre-specified outcomes reported?</b> NA	<b>Health outcome measures equal, valid and reliable?</b> NA  <b>Harms outcome measures equal, valid and reliable?</b> NA	<b>Notes explaining risk of bias</b> Comparison groups taken from different time periods; followup period was 2 yrs in one arm but ~1 year in the 2 other arms. The groups have children of different ages. Some in each group received adenoidectomy so concurrent treatment was not controlled.
<b>Author, Year</b> Hornigold et al., 2008 <sup>43</sup>	<b>Recruitment strategy differ across groups?</b> No	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was <math>\geq 20\%</math> or differential attrition <math>\geq 15\%</math>, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> Unclear or NR	<b>Risk of bias</b> High
<b>Study design</b> Prospective cohort	<b>Baseline characteristics similar between groups?</b> Yes  <b>If not, did the analysis control for differences?</b> NA	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> Yes  <b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> Yes  <b>I/E criteria equally applied in both groups?</b> Yes  <b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Unclear or NR	<b>Health outcome measures equal, valid and reliable?</b> Yes  <b>Harms outcome measures equal, valid and reliable?</b> Yes	<b>Notes explaining risk of bias</b> No discussion of randomization. Not certain if blinding of observers occurred at followup visits. Only 7 participants. No statistical analysis.

**Table E-5. High risk of bias: Observational (continued)**

Identifiers	Groups	Masked and Statistical Analysis	Miscellaneous	Outcomes	Risk of Bias
<b>Author, Year</b> Katz et al., 1995 <sup>44</sup>	<b>Recruitment strategy differ across groups?</b> NA	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> NA	<b>Risk of bias</b> High
<b>Study design</b> Retrospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> Unclear or NR	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> NA	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes explaining risk of bias</b> I/E criteria and outcomes not pre-defined; no baseline characteristics reported; study seems to be more of an exploratory analysis.
	<b>If not, did the analysis control for differences?</b> No	<b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No	<b>I/E criteria equally applied in both groups?</b> No	<b>Harms outcome measures equal, valid and reliable?</b> NA	
<b>Author, Year</b> Marshak et al., 1980 <sup>45</sup>	<b>Recruitment strategy differ across groups?</b> No	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> Unclear or NR	<b>Risk of bias</b> High
<b>Study design</b> Retrospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> No	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> NA	<b>Health outcome measures equal, valid and reliable?</b> Yes	<b>Notes explaining risk of bias</b> Only specifies age being similar between the 2 groups; otherwise no other baseline characteristics reported.
	<b>If not, did the analysis control for differences?</b> No	<b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No	<b>I/E criteria equally applied in both groups?</b> Unclear or NR	<b>Harms outcome measures equal, valid and reliable?</b> NA	
			<b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes		

**Table E-5. High risk of bias: Observational (continued)**

Identifiers	Groups	Masked and Statistical Analysis	Miscellaneous	Outcomes	Risk of Bias
<b>Author, Year</b> Matt et al., 1991 <sup>46</sup>	<b>Recruitment strategy differ across groups?</b> Unclear or NR	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> No	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> NA	<b>Risk of bias</b> High
<b>Study design</b> Retrospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> No	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> No	<b>Health outcome measures equal, valid and reliable?</b> Unclear or NR	<b>Notes explaining risk of bias</b> No characteristics of the groups werereported. Participants receiving TT had more severe disease at baseline and had previous procedures done on the TM. Additionally, the outcomes were reported from different date ranges at the two institutions.
	<b>If not, did the analysis control for differences?</b> No	<b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)	<b>I/E criteria equally applied in both groups?</b> Unclear or NR	<b>Harms outcome measures equal, valid and reliable?</b> Yes	
<b>Author, Year</b> Robinson, 1987 <sup>47</sup>	<b>Recruitment strategy differ across groups?</b> NA	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> No	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> NA	<b>Risk of bias</b> High
<b>Study design</b> Retrospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> No	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> NA	<b>Health outcome measures equal, valid and reliable?</b> Unclear or NR	<b>Notes explaining risk of bias</b> Unclear if this is a within person comparison or a comparison between ears with some individuals having 2 ears in same condition.
	<b>If not, did the analysis control for differences?</b> NA	<b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No	<b>I/E criteria equally applied in both groups?</b> No	<b>Harms outcome measures equal, valid and reliable?</b> NA	

**Table E-5. High risk of bias: Observational (continued)**

Identifiers	Groups	Masked and Statistical Analysis	Miscellaneous	Outcomes	Risk of Bias
<b>Author, Year</b> Strachan et al., 1996 <sup>48</sup>	<b>Recruitment strategy differ across groups?</b> No	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Unclear or NR	<b>If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> Unclear or NR	<b>Risk of bias</b> High
<b>Study design</b> Retrospective cohort	<b>Baseline characteristics similar between groups?</b> Unclear or NR  <b>If not, did the analysis control for differences?</b> No	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> No  <b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> NA  <b>I/E criteria equally applied in both groups?</b> Unclear or NR  <b>All outcomes pre-specified? All pre-specified outcomes reported?</b> Yes	<b>Health outcome measures equal, valid and reliable?</b> Yes  <b>Harms outcome measures equal, valid and reliable?</b> NA	<b>Notes explaining risk of bias</b> Matching between cases and controls only by age; I/E criteria not clearly defined or pre-specified.
<b>Author, Year</b> Zanetti et al., 2005 <sup>49</sup>	<b>Recruitment strategy differ across groups?</b> Unclear or NR	<b>Outcome assessors blinded to the intervention or exposure status of participants?</b> Unclear or NR	<b>Maintain fidelity to the protocol?</b> Yes	<b>If overall attrition was ≥20% or differential attrition ≥15%, were missing data handled appropriately (e.g., intention-to-treat analysis and imputation)?</b> NA	<b>Risk of bias</b> High
<b>Study design</b> Prospective cohort	<b>Baseline characteristics similar between groups?</b> NA  <b>If not, did the analysis control for differences?</b> NA	<b>Any impact from a concurrent intervention or exposure status ruled out?</b> No  <b>Design and/or analysis account for confounding and modifying variables through matching, stratification, multivariate analysis, or other approaches?</b> No (Not accounted for or not identified)	<b>Time of followup or time period between intervention/exposure equal in both groups?</b> Yes  <b>I/E criteria equally applied in both groups?</b> Unclear or NR  <b>All outcomes pre-specified? All pre-specified outcomes reported?</b> No	<b>Health outcome measures equal, valid and reliable?</b> Yes  <b>Harms outcome measures equal, valid and reliable?</b> Yes	<b>Notes explaining risk of bias</b> No characteristics about the case controls, or how they were chosen are reported. I/E criteria were not discussed.

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# Appendix F. Detailed Strength of Evidence Tables

## Key Question 1

### Clinical Outcomes

### Tympanostomy Tubes Versus Other Tympanostomy Tube or Variation in Tympanostomy Tube Insertion Technique

Table F-1. Detailed strength of evidence grading table, tube retention

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT v. TT + NAC addition, mean time	1; 75	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference
Shepard TT v. Sheehy TT	1, 146	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, Sheehy better
Shah Teflon tube +aspiration v. shah Teflon tube no aspiration, 3 mo	1; 55	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference
Shah Teflon tube +aspiration v. shah Teflon tube no aspiration, 6 mo	1; 55	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference
Shah Teflon tube +aspiration v. shah Teflon tube no aspiration, 12 mo	1; 55	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference
Permavent silicone Shah v. polyethelyne Shah, TT, 1 yr	1; 25	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, statistical difference not reported
Goode silicon TT v. Teflon Armstrong TT, 1 yr	1; 15	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference
Shah Teflon tube +aspiration v. shah Teflon tube no aspiration, 18 mo	1; 55	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference
Shah Teflon tube +aspiration v. shah Teflon tube no aspiration, 2 yrs	1; 55	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference
Phosphorylcholine-coated fluoroplastic Armstrong TT v. uncoated Armstrong TT,	1; 70	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
2 yrs Goode silicon TT v. Teflon Armstrong TT, 3 yr	1; 15	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference
Goode silicon TT v. Teflon Armstrong TT, 4 yr	1; 15	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, insufficient
Goode silicon TT v. Teflon Armstrong TT, 5 yr	1; 15	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, insufficient

Abbreviations: TT = tympanostomy tubes; v. = versus.

**Table F-2. Detailed strength of evidence grading table, OME recurrence**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
TT v. TT + NAC	1; 75	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference
Shah v. mini-shah tube	1, 116	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, Shah better
Teflon Shepard TT vs. silicone Goode TT vs. Silicone Paparella TT	1; 220	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single observational study, silicone best
Permavent silicone Shah v. polyethylene Shah	1; 25	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study, statistical difference not reported

Abbreviations: MEE, middle ear effusion; TT, tympanostomy tubes; yr, year.

**Table F-3. Detailed strength of evidence grading table, measured hearing**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Goode silicon TT v. Teflon Armstrong TT, mean hearing loss, mean time	1; 15	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single study, statistical difference not reported

Abbreviations: TT = tympanostomy tubes; v. = versus.

**Table F-4. Detailed strength of evidence grading table, AOM**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT vs. TT	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: TT = tympanostomy tubes; vs. = versus.

## Tympanostomy Tubes Versus Watchful Waiting or Myringotomy)

**Table F-5. Detailed strength of evidence grading table, middle ear effusion and time with effusion**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT, Time with MEE or OME, 1 yr,	MA 3, 574 1 study, 119	Medium	Consistent	Direct	Precise	High 32% less time with MEE, sig less % time with OME, favors TT
TT, Time with MEE or OME, 2 yrs	MA:3, 426 1 study, 119	Medium	Consistent	Direct	Precise	Moderate 13% less time with MEE, MA favors TT, single additional study found no diff
TT, Time with OME, 3 yrs	1 study, 119	Medium	Unknown, 1 study	Direct	Imprecise	Insufficient, one study found no diff

Abbreviations: MEE, middle ear effusion; TT, tympanostomy tubes; yr, year.

**Table F-6. Detailed strength of evidence grading table, OME recurrence and ventilation**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: MEE, middle ear effusion; TT, tympanostomy tubes

**Table F-7. Detailed strength of evidence grading table, AOM**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT, episodes/person yr, 3 yrs	1, 119	Medium	Unknown, single study	Direct	Imprecise	Insufficient: one study found no diff

Abbreviations: TT = tympanostomy tubes.

**Table F-8. Detailed strength of evidence grading table, measured hearing**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
TT, Hearing Levels by ear, 4-6 mos	MA: 2, 230 ears	Moderate	Consistent	Direct	Precise	High, 10.1 dB better with TT
TT, Hearing Levels by child, 6-9 mos	MA: 3, 523	Moderate	Consistent	Direct	Precise	Moderate 4.2 dB better with TT
TT, Hearing levels by ear, 7-12 mos	MA: 3, 234	Moderate	Consistent	Direct	Imprecise	Low, no difference -5.18 (95% CI, -10.43 to 0.07)
TT, Hearing Levels by child, 12 mos	MA: 2, 328	Moderate	Inconsistent	Direct	Precise	Moderate, no difference -0.41 dB (95% CI, -2.37 to 1.54)
TT, Hearing Levels by child, 18 mos	MA: 2, 283	Moderate	Inconsistent	Direct	Precise	Moderate, no difference -0.02 dB (95% CI, -3.22 to 3.18)
TT, Hearing Levels by ear, 24 mos	1 study, 72 ears	Moderate	Unknown, single study	Direct	Imprecise	Insufficient, single small study, no difference

Abbreviations: TT = tympanostomy tubes; v. = versus.

## **Tympanostomy Tubes and Adenoidectomy Versus Myringotomy and Adenoidectomy or Adenoidectomy Alone**

**Table F-9. Detailed strength of evidence grading table, reoccurrence of middle ear effusion**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
TT+adeno v. myring + adeno, Time with MEE or OME, 1 yrs	1;42	Medium	Unknown, single study	Direct	Imprecise	Insufficient, no difference
TT+adeno v adeno, Time with MEE or OME, 5 yr,	1; 55	Medium	Unknown, single study	Direct	Imprecise	Insufficient, no difference

Abbreviations: MEE, middle ear effusion; TT, tympanostomy tubes; yr, year

**Table F-10. Detailed strength of evidence grading table, Ventilation maintained**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
TT+adeno v. laser myro+adeno, episodes/ person yr, 3 mo	1; 15	Medium	Unknown, single study	Direct	Imprecise	Insufficient, one small study favoring TT

Abbreviations: TT, tympanostomy tubes; yr, year.

**Table F-11. Detailed strength of evidence grading table, AOM**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
TT+adeno, episodes/ person yr, 3 yrs	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: TT, tympanostomy tubes; yr, year.

**Table F-12. Detailed strength of evidence grading table, measured hearing**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
TT+adeno v. adeno, Hearing Levels, 3 mos	1; 55	Medium	Unknown, single study	Direct	Imprecise	Insufficient, one small study favoring TT
TT+adeno v. myring +adeno, Hearing Levels, 6 mos	3, 160	Medium	Consistent	Direct	Imprecise	Low, no difference
TT+adeno v. myring +adeno, Hearing levels, 12 mo	2; 130	Medium	Consistent	Direct	Imprecise	Insufficient, no difference in 2 small studies
TT+adeno v. myring+adeno, Hearing Levels, 2 years	1, 146	Medium	Unknown, single study	Direct	Imprecise	Insufficient, no difference in 1 small study
TT+adenoid v. myring+adeno/ adenoid alone, Hearing Levels >3 years	2; 201	Medium	Consistent	Direct	Imprecise	Low, no difference

Abbreviations: TT, tympanostomy tubes; yr, year.

## Myringotomy Comparisons

**Table F-13. Detailed strength of evidence grading table, resolution of OME**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy + Mitomycin C vs. myringotomy, resolution of OME	1, 60	Medium	Unknown, single study	Direct	Imprecise	Insufficient

**Table F-14. Detailed strength of evidence grading table, OME recurrence and ventilation**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy + Mitomycin C vs. myringotomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

**Table F-15. Detailed strength of evidence grading table, AOM**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy + Mitomycin C vs. myringotomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

**Table F-16. Detailed strength of evidence grading table, measured hearing**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy + Mitomycin C vs. myringotomy, air-bone gap improvement (3mos)	1, 60	Medium	Unknown, single study	Direct	Imprecise	Insufficient, no difference, one small study

## Myringotomy and Adenoidectomy Comparisons

**Table F-17. Detailed strength of evidence grading table, middle ear effusion**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy (laser) with adenoidectomy vs. Myringotomy (cold knife) with adenoidectomy, % with middle ear effusion, post-op	1, 87 ears*	Medium	Unknown, single study	Direct	Imprecise	Insufficient, no difference, one small study

\* number analyzed

**Table F-18. Detailed strength of evidence grading table, OME recurrence and ventilation**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy (laser) with adenoidectomy vs. Myringotomy (cold knife) with adenoidectomy, patency of ears, post-op	1, 87 ears*	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single smallstudy

\*number analyzed

**Table F-19. Detailed strength of evidence grading table, AOM**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy (laser) with adenoidectomy vs. Myringotomy (cold knife) with adenoidectomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

**Table F-20. Detailed strength of evidence grading table, measured hearing**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy (laser) with adenoidectomy vs. Myringotomy (cold knife) with adenoidectomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

## Adenoidectomy Versus Other Interventions

**Table F-21. Detailed strength of evidence grading table, middle ear effusion and time with effusion**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Adenoidectomy (+unilateral TT), OME resolution 6 mos	MA otoscopy: 2, 153 MA tympanometry: MA: 3, 297	Medium	Consistent	Direct	Precise	<b>High</b> Otoscopy: G1: 49%, G2: 21% Tympanometry: G1: 39%, G2: 17%
Adenoidectomy (+ unilateral TT), OME resolution by tympanometry), 12 mos	MA: 3, 298	Medium	Consistent	Direct	Precise	<b>High</b> G1: 47%, G2: 20%

**Table F-22. Detailed strength of evidence grading table, measured hearing**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Adenoidectomy vs no intervention, Change in hearing level, 6 mos, 12 mos	2 studies (N=302)	Medium	Inconsistent	Direct	Imprecise	Insufficient, mixed results
Adenoidectomy+ myringotomy vs. myringotomy, 2 years	1 study (N=237)	Medium	Unknown, single study	Direct	Precise	Low, less time with reduced hearing in adenoidectomy arm

## Steroids Versus Control

**Table F-23. Detailed strength of evidence grading table, middle ear effusion and time with effusion**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Oral, 1-2 mo, persisting	MA 3, 106	Medium	Consistent	Direct	Imprecise	Low: no difference
Oral (+antibiotic), 1-2 mo, persisting	MA 2, 243	Medium	Consistent	Direct	Precise	Medium: no difference
Topical, 1-2 mo	No studies	NA	NA	NA	NA	Insufficient: no evidence
Topical, cure rate, 3 & 9 mo	1, 217	Low	Unknown, single study	Direct	Precise	Low: no difference
Topical (+antibiotic), persisting, 6 mo	1, 59	Medium	Unknown, single study	Direct	Imprecise	Insufficient: no difference
Oral (+antibiotic), persisting, 6 mo	1, 15	Medium	Unknown, single study	Direct	Imprecise	Insufficient: no difference

**Table F-24. Detailed strength of evidence grading table, OME recurrence and ventilation**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Topical	No studies	NA	NA	NA	NA	Insufficient: no evidence
Oral	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable.

**Table F-25. Detailed strength of evidence grading table, AOM**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Topical	No studies	NA	NA	NA	NA	Insufficient: no evidence
Oral	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable.

**Table F-26. Detailed strength of evidence grading table, measured hearing**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Topical, 1-2 mo	No studies	NA	NA	NA	NA	Insufficient: no evidence
Topical, > 3 mo	1, 217	Medium	Unknown, single study	Direct	Precise	Low: no difference
Oral, 1-2 mo	1, 49	Low	Unknown, single study	Direct	Imprecise	Insufficient: no difference
Oral, 3+ mo	No studies	NA	NA	NA	NA	Insufficient: no evidence

## Autoinflation Versus Control

**Table F-27. Detailed strength of evidence grading table, middle ear effusion and time with effusion**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Autoinflation, improvement in tympanogram $\leq$ 1 mo	MA:2, 185	Medium	Consistent	Direct	Precise	Low, > improvement with autoinflation RR: 3.84
Autoinflation, improvement in tympanogram $\leq$ 1 mo	MA:2, 185	Medium	Consistent	Direct	Precise	Low, > improvement with autoinflation RR: 2.71
Autoinflation, improvement in tympanogram > 1 month	MA:2, 185	Medium	Consistent	Direct	Imprecise	Insufficient, no difference
Autoinflation, (3 wks and 3 mos)	No studies	NA	NA	NA	NA	Insufficient, no evidence
Autoinflation, 4 wks post tx and end of tx	No studies	NA	NA	NA	NA	Insufficient, no evidence

Abbreviations: NA = not applicable.

**Table F-28. Detailed strength of evidence grading table, OME recurrence and ventilation**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Autoinflation	No studies	NA	NA	NA	NA	Insufficient, no evidence

Abbreviations: NA = not applicable.

**Table F-29. Detailed strength of evidence grading table, AOM**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Autoinflation	No studies	NA	NA	NA	NA	Insufficient, no evidence

Abbreviations: NA = not applicable.

**Table F-30. Detailed strength of evidence grading table, measured hearing**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Autoinflation, ≤ 1 mo	No studies	NA	NA	NA	NA	Insufficient, no evidence
Autoinflation, >1 mo	No studies	NA	NA	NA	NA	Insufficient, no evidence
Autoinflation, end of tx improvement in PTA, post tx (3 wks and 3 mos)	MA:2, 125	Medium	Inconsistent	Direct	Imprecise	Insufficient, no difference
Autoinflation, PTA, 4 wks post tx and end of tx	MA 2, 179	Medium	Inconsistent	Direct	Imprecise	Insufficient, no difference

Abbreviations: Mo, month; PTA, pure tone average; tx, treatment; wks, weeks.

## Key Question 2

### Functional Outcomes

#### Tympanostomy Tubes Versus Other Tympanostomy Tube or Variation in Tympanostomy Tube Insertion Technique

**Table F-31. Detailed strength of evidence grading table, speech, language and cognitive development**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT vs. TT	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: mos = months; NA = not applicable; TT = tympanostomy tubes; vs. = versus.

**Table F-32. Detailed strength of evidence grading table, behavior**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT vs. TT	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: TT = tympanostomy tubes; vs. = versus.

**Table F-33. Detailed strength of evidence grading table, quality-of-life**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT vs. TT	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable; TT = tympanostomy tubes; vs. = versus.

**Table F-34. Detailed strength of evidence grading table, satisfaction with care**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT vs. TT	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable; TT = tympanostomy tubes; vs. = versus.

## Tympanostomy Tubes Versus Watchful Waiting or Myringotomy

**Table F-35. Detailed strength of evidence grading table, speech, language and cognitive development**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT, Language Comprehension, 6-9 mos	MA: 3, 394	Low	Inconsistent	Direct	Precise	Low, no difference
TT, Language Expression, 6-9 mos	MA:3, 393	Low	Inconsistent	Direct	Precise	Low, no difference
TT, Cognitive Development, 9 mos	1 study, 160	Low	Unknown, single study	Direct	Imprecise	Insufficient, no difference
TT, Cognitive Development, 3 yrs	1 study, 393	Low	Unknown, single study	Direct	Precise	Insufficient, no difference

Abbreviations: mos = months; TT = tympanostomy tubes; yrs = years.

**Table F-36. Detailed strength of evidence grading table, behavior**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT, Behavior, 6, 12 mos	1 study, 176, 165	Low	Unknown, single study	Direct	Imprecise	Insufficient, no difference
TT, Behavior, 9, 12 mos	1 study, 182	Medium	Unknown, single study	Direct	Imprecise	Insufficient, conflicting evidence
TT, Behavior, 3 yrs	1 study, 393	Low	Unknown, single study	Direct	Imprecise	Insufficient, no difference

Abbreviations: mos = months; TT = tympanostomy tubes; yrs = years.

**Table F-37. Detailed strength of evidence grading table, quality-of-life**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT, Quality of Life, 6, 12 mos	1, 176, 165	Low	Unknown, single study	Direct	Imprecise	Insufficient: no difference

Abbreviations: mos = months; TT = tympanostomy tubes.

**Table F-38. Detailed strength of evidence grading table, satisfaction with care**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable; TT = tympanostomy tubes.

## Tympanostomy Tubes Plus Adenoidectomy Versus Myringotomy Plus Adenoidectomy or Adenoidectomy Alone

**Table F-39. Detailed strength of evidence grading table, speech, language and cognitive development**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT+adeno	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable; TT = tympanostomy tubes.

**Table F-40. Detailed strength of evidence grading table, behavior**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT+adeno,	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: adeno = adenoidectomy; NA = not applicable; TT, tympanostomy tubes.

**Table F-41. Detailed strength of evidence grading table, quality-of-life**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT+adeno vs. myring+adeno, quality of Life, 6 mos	1; 52	Medium	Unknown, single study	Direct	Precise	Insufficient: no difference
TT+adeno v. myring+adeno, Quality of Life, 12 mos	1, 52	Medium	Unknown, single study	Direct	Precise	Insufficient: no difference

Abbreviations: adeno = adenoidectomy; myring = myringotomy; mos, months; TT, tympanostomy tubes.

**Table F-42. Detailed strength of evidence grading table, satisfaction with care**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT+adeno	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: adeno = adenoidectomy; NA = not applicable.

## Myringotomy Comparisons

**Table F-43. Detailed strength of evidence grading table, all functional outcomes**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy + Mitomycin C vs. myringotomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

Abbreviations: NA = not applicable; vs. = versus.

## Myringotomy With Adenoidectomy Comparisons

**Table F-44. Detailed strength of evidence grading table, all functional outcomes**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy (laser) with adenoidectomy vs. Myringotomy (cold knife) with adenoidectomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

Abbreviations: NA = not applicable; vs. = versus.

## Adenoidectomy Versus Other Interventions

**Table F-45. Detailed strength of evidence grading table, speech, language and cognitive development**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Adenoidectomy	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable.

**Table F-46. Detailed strength of evidence grading table, behavior**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Adenoidectomy	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable.

**Table F-47. Detailed strength of evidence grading table, quality-of-life**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Adenoidectomy	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable.

**Table F-48. Detailed strength of evidence grading table, satisfaction with care**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Adenoidectomy	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable.

## Steroids Versus Control

**Table F-49. Detailed strength of evidence grading table, speech, language and cognitive development**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Topical	No studies	NA	NA	NA	NA	Insufficient: no evidence
Oral	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable.

**Table F-50. Detailed strength of evidence grading table, behavior**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Topical	No studies	NA	NA	NA	NA	Insufficient: no evidence
Oral	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable.

**Table F-51. Detailed strength of evidence grading table, quality-of-life**

<b>Intervention, time to outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Topical, <3 mos	1, 39	Medium	Unknown, single study	Direct	Imprecise	Insufficient: no difference
Topical, ≥3 mos	1, 144	Low	Unknown, single study	Direct	Imprecise	Low, no difference
Oral	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: mos = months; NA = not applicable

**Table F-52. Detailed strength of evidence grading table, satisfaction with care**

<b>Intervention, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Topical	No studies	NA	NA	NA	NA	Insufficient: no evidence
Oral	No studies	NA	NA	NA	NA	Insufficient: no evidence

Abbreviations: NA = not applicable.

## Functional Outcomes

### Autoinflation Versus Control

**Table F. 53. Detailed strength of evidence grading table, all measures**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Autoinflation, any time period	No studies	NA	NA	NA	NA	Insufficient, no evidence

Abbreviations: NA = not applicable.

## Key Question 3

### Harms or Tolerability

### Tympanostomy Tubes Versus Other Tympanostomy Tube or Variation in Tympanostomy Tube Insertion Technique

**Table F-54. Detailed strength of evidence grading table, harms**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Goode silicon TT v. Teflon Armstrong TT, Repeat TT; repeat TT placement	1; 15	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study
TT v. TT + NAC addition, repeat tube placement, 29 mo; repeat TT placement	1; 75	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study
TT v TT, otorrhea	6; 939	Medium	Inconsistent	Direct	Imprecise	Insufficient, mixed results
TT v TT, perforation	3; 305	Medium	Inconsistent	Direct	Imprecise	Insufficient, mixed results
TT v TT, cholesteatoma	2; 235	Medium	Inconsistent	Direct	Imprecise	Insufficient, no difference
TT v TT, tympanosclerosis	3; 196	Medium	Inconsistent	Direct	Imprecise	Insufficient, mixed results
TT v TT, Occlusion	1; 70	Medium	Unknown, single study	Direct	Imprecise	Insufficient, single small study
TT v TT, Granulation	2; 290	Medium	Inconsistent	Direct	Imprecise	Insufficient, mixed results

## Tympanostomy Tubes Versus Watchful Waiting or Myringotomy

**Table F-55. Detailed strength of evidence grading table, harms**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
TT, Tx Failure, 3 yrs	1 study, 109	Medium	Unknown, single study	Direct	Imprecise	Insufficient, no difference
TT, Otorrhea, various	4 studies, 960	Medium	Consistent	Direct	Imprecise	Low, higher in TT group
TT, Atrophy, various	4 studies, 1024	Medium	Inconsistent	Direct	Imprecise	Insufficient, mixed results
TT, Perforation, various	3 studies, 466	Medium	Consistent	Direct	Imprecise	Insufficient, mixed results
TT, Tympanosclerosis, various	5 studies, 1129	Medium	Consistent	Direct	Imprecise	Low, higher in TT group
TT, Cholesteatoma, various	2 studies, 220	Medium	Consistent	Direct	Imprecise	Insufficient, no difference
Time with granulation	1 study, 150	Medium	Unknown, single study	Direct	Imprecise	Insufficient, 1 study

## Tympanostomy Tubes and Adenoidectomy Versus Myringotomy and Adenoidectomy or Adenoidectomy Alone

**Table F-56. Detailed strength of evidence grading table, harms**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
TT+adeno, Tx Failure, 3 yrs	1; 25	Medium	Unknown, single study	Direct	Precise	Insufficient, single studies
TT+adeno v. myring+adeno, Otorrhea, various	3; 87	Medium	Inconsistent	Direct	Precise	Insufficient, mixed results
TT+adeno, Atrophy, Various	No studies	NA	NA	NA	NA	Insufficient: no evidence
TT+adeno v. myring+adeno, Perforation, Various	1; 15	Medium	Unknown, single study	Direct	Imprecise	Insufficient; no difference
TT+adeno v. adeno alone or with myring, Tympanosclerosis, various	2; 237	Medium	Consistent	Direct	Imprecise	Low, rates higher in TT group
TT+adeno, Cholesteatoma, various	No studies	NA	NA	NA	NA	Insufficient: no evidence
Granulation	No studies	NA	NA	NA	NA	Insufficient: no evidence

## Myringotomy Comparisons

**Table F-57. Detailed strength of evidence grading table, all harms**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Myringotomy + Mitomycin C vs. myringotomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

## Myringotomy With Adenoidectomy Comparisons

**Table F-58. Detailed strength of evidence grading table, all harms**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Myringotomy (laser) with adenoidectomy vs. Myringotomy (cold knife) with adenoidectomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

## Adenoidectomy Versus Other Interventions

**Table F-59. Detailed strength of evidence grading table, harms**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Adenoidectomy	No studies	NA	NA	NA	NA	Insufficient: no evidence

## Steroids Versus Control

**Table F-60. Detailed strength of evidence grading table, harms**

Intervention, outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Topical, serious	3, 323	Medium	Consistent	Direct	Imprecise	Insufficient No events
Oral, serious	5, subjects: NR	Medium	Consistent	Direct	Imprecise	Insufficient No events
Topical, mild	1, 170	Medium	Unknown, single study	Direct	Imprecise	Low, no difference
Oral, mild	2, subjects: NR	Low	Consistent	Direct	Imprecise	Insufficient: no difference

## Autoinflation Versus Control

**Table F-61. Detailed strength of evidence grading table, harms**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Autoinflation	No studies	NA	NA	NA	NA	Insufficient, no evidence

## Key Question 4

### Patient Subgroups

## Tympanostomy Tubes Plus Adenoidectomy Versus Myringotomy Plus Adenoidectomy or Adenoidectomy Alone

**Table F-62. Detailed strength of evidence grading table, sleep apnea**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT+ adenoid v. myrin + adenoid, hearing, 6,12 mos.	1, 52	Medium	Unknown, single study	Direct	Imprecise	Insufficient, no difference, one small study
TT+ adenoid v. myrin + adenoid, quality of life, 6,12 mos.	1, 52	Medium	Unknown, single study	Direct	Imprecise	Insufficient, mixed findings, one small study

## Autoinflation Versus Control

**Table F-63. Detailed strength of evidence grading table, adults**

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Autoinflation, improvement in middle ear status end of tx. 50 days post tx	1, 198	Medium	Unknown, single study	Direct	Imprecise	Low Magnitude of difference 44 to 47%

## Key Question 5

### Health Care Factors

#### Tympanostomy Tubes Versus Other Tympanostomy Tube or Variation in Tympanostomy Tube Insertion Technique

Table F-64. Detailed strength of evidence grading table, health care factors

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT vs. TT	No studies	NA	NA	NA	NA	Insufficient: no evidence

#### Tympanostomy Tubes Versus Watchful Waiting or Myringotomy

Table F-65. Detailed strength of evidence grading table, health care factors

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT	No studies	NA	NA	NA	NA	Insufficient: no evidence

#### Tympanostomy Tubes and Adenoidectomy Versus Adenoidectomy Alone or With Other Intervention

Table F-66. Detailed strength of evidence grading table, health care factors

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
TT+adeno	No studies	NA	NA	NA	NA	Insufficient: no evidence

### Myringotomy Comparisons

Table F-67. Detailed strength of evidence grading table, all health care factors

Intervention, Outcome, Time to Outcome	Number of Studies; Subjects	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence Grade Magnitude of Effect
Myringotomy + Mitomycin C vs. myringotomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

## Myringotomy and Adenoidectomy Comparisons

**Table F-68. Detailed strength of evidence grading table, all health care factors**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Myringotomy (laser) with adenoidectomy vs. Myringotomy (cold knife) with adenoidectomy	No studies	NA	NA	NA	NA	Insufficient, no evidence

## Adenoidectomy Versus Other Interventions

**Table F-69. Detailed strength of evidence grading table, health care factors**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Adenoidectomy	No studies	NA	NA	NA	NA	Insufficient: no evidence

## Steroids Versus Control

**Table F-70. Detailed strength of evidence grading table, health care factors**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Topical	No studies	NA	NA	NA	NA	Insufficient: no evidence
Oral	No studies	NA	NA	NA	NA	Insufficient: no evidence

## Autoinflation Versus Control

**Table F-71. Detailed strength of evidence grading table, all outcomes**

<b>Intervention, Outcome, Time to Outcome</b>	<b>Number of Studies; Subjects</b>	<b>Risk of Bias</b>	<b>Consistency</b>	<b>Directness</b>	<b>Precision</b>	<b>Strength of Evidence Grade Magnitude of Effect</b>
Autoinflation, any time period	No studies	NA	NA	NA	NA	Insufficient, no evidence

## Appendix G. Glossary

**Acute otitis media:** An acute infection of the middle ear that can be viral and/or bacterial in origin.

**Audiometry:** The testing of hearing ability that includes determination of the hearing levels, ability to discriminate between various sound intensities, ability to distinguish speech from background noise and other aspects. Pure tone audiometry and impedance audiometry (tympanometry) are two of the commonly used tests for audiometric evaluation.

**Autoinflation:** A technique whereby the Eustachian tube (the tube that connects the middle ear and the back of the nose) is reopened by raising pressure in the nose. This can be achieved by forced exhalation with closed mouth and nose, blowing up a balloon through each nostril or using an anesthetic mask. The aim is to introduce air into the middle ear, via the Eustachian tube, equalizing the pressures and allowing better drainage of the fluid.

**Myringotomy:** A surgical procedure in which an incision is made in the tympanic membrane. It may be performed as a single procedure or as a preparation for insertion of a tympanostomy tube.

**Otitis media with effusion:** A collection of fluid in the middle ear without signs or symptoms of ear infection.

**Otoscopy:** The clinical examination of the ear canal and tympanic membrane, usually by means of a hand-held auriscope (also known as an otoscope) providing illumination and magnification. Sometimes an attachment is used that permits insufflation of air into the ear canal so that the mobility of the tympanic membrane can be assessed, and this is known as pneumatic otoscopy.

**Tympanogram:** A curve showing the transmission of energy through the middle ear at various air pressures in the external auditory canal. It gives a crude but objective assessment of conductive hearing loss, and various middle ear disorders yield distinctive patterns of tympanogram:

- **Tympanogram A:** a symmetrical triangular graph with its peak at zero pressure level represents normal middle ear function.
- **Tympanogram B:** a flat line on the graph represents the middle ear space filled with fluid, restricting movement of the tympanic membrane under the externally applied pressure.
- **Tympanogram C:** this pattern is found when there is a reduction of middle ear pressure relative to the air pressure in the external auditory canal, which causes inward retraction of the tympanic membrane; the graph shows the shift of the tympanographic peak into the negative value range, but it is of a normal shape.

**Tympanometry:** Also known as impedance audiometry, the test measures how readily the middle ear system (the tympanic membrane and the middle ear ossicles) can be set into vibration with a change of air pressure in the external auditory canal. In the normal ear, maximum sound transmission occurs when the air pressure within the middle ear space is the same as the atmospheric pressure, that is, equal to the air pressure in the external auditory canal.

**Watchful waiting:** Watchful waiting or active observation, as it has more recently been called, is the process of regular review and followup of the child, including assessments of hearing, development, and educational progress.

## Appendix H. Acronyms

ABG, Air-Bone Gap  
AHRQ, Agency for Healthcare Research and Quality  
AOM, acute otitis media  
CAM, complementary and alternative medicine  
CI, confidence interval  
CINAHL, Cumulative Index to Nursing and Allied Health Literature  
CDLM, contact diode laser for myringotomy  
CER, comparative effectiveness review  
CT, computed tomography  
dB, decibals  
EHC, effective health care  
EMBASE, Excerpta Medica Database  
ENT, Ear, Nose and Throat  
EPC, Evidence-based practice center  
FU, follow-up  
G, group  
HL, hearing level  
KQ, key question  
MA, meta-analysis  
MEE, middle ear effusion  
MeSH, medical subject headings  
mos, months  
MA, meta-analysis  
NA, not applicable  
NICE, National Institute for Health and Clinical Excellence  
NIDCD, National Institute on Deafness and Other Communication Disorders  
NRCT, nonrandomized controlled trial  
NR, not reported  
ns, not significant  
OME, otitis media with effusion  
PE, pressure equalization  
PICOTS, populations, interventions, comparators, outcomes, timeframes, and settings  
PRISMA, Preferred Reporting Items for Systematic Review and Meta-analyses  
PTA, pure-tone audiometry  
RCT, randomized controlled trial  
RR, relative risk  
SIP, scientific information packet  
SOE, strength of evidence  
SR, systematic review  
SRT, speech recognition threshold  
TEP, technical expert panel  
TM, tympanic membrane  
TT, tympanostomy tubes  
VT, ventilation tube  
WW, watchful waiting