# Appendix A: Search Strategy and Exact Search Strings

**Table 1. Electronic database searches**

| Name | Date Limits | Platform/Provider |
|---|---|---|
| The Cochrane Central Register of Controlled Trials (CENTRAL) | Through September 9, 2010 | www.thecochranelibrary.com |
| The Cochrane Database of Methodology Reviews (Methodology Reviews) | Through September 9, 2010 | www.thecochranelibrary.com |
| The Cochrane Database of Systematic Reviews (Cochrane Reviews) | Through September 9, 2010 | www.thecochranelibrary.com |
| Database of Abstracts of Reviews of Effects (DARE) | Through September 9, 2010 | www.thecochranelibrary.com |
| EMBASE (Excerpta Medica) | Through September 9, 2010 | OVID |
| Health Technology Assessment Database (HTA) | Through September 9, 2010 | www.thecochranelibrary.com |
| Healthcare Standards | Through September 9, 2010 | www.ecri.org |
| MEDLINE | Through September 9, 2010 | OVID |
| U.K. National Health Service Economic Evaluation Database (NHS EED) | Through 2009, Issue 4 | www.thecochranelibrary.com |
| U.S. National Guideline Clearinghouse™ (NGC) | Searched December 1, 2009 | www.ngc.gov |

# Search Strategies

The search strategies employed combinations of freetext keywords as well as controlled vocabulary terms including (but not limited to) the following concepts. The strategy below is presented in OVID syntax; the search was simultaneously conducted across EMBASE, MEDLINE, and PsycINFO. A parallel strategy was used to search the databases comprising the Cochrane Library.

## Medical Subject Headings (MeSH), EMTREE, PsycINFO and Keywords

**Conventions:**

**OVID**

$ = truncation character (wildcard)

exp = "explodes" controlled vocabulary term (e.g., expands search to all more specific related terms in the vocabulary's hierarchy)

.de. = limit controlled vocabulary heading

.fs. = floating subheading

.hw. = limit to heading word

.md. = type of methodology (PsycINFO)

.mp. = combined search fields (default if no fields are specified)

.pt. = publication type

.ti. = limit to title

.tw. = limit to title and abstract fields

**PubMed**

[mh] = MeSH heading

[majr] = MeSH heading designated as major topic

[pt] = publication type

[sb] = subset of PubMed database (PreMEDLINE, Systematic, OldMEDLINE)

[sh] = MeSH subheading (qualifiers used in conjunction with MeSH headings)

[tiab] = keyword in title or abstract

[tw] = text word

**Table 2. Topic specific search terms**

| Concept | Controlled Vocabulary | Keywords |
|---|---|---|
| Breast diseases | breast cancer<br>breast carcinoma<br>breast diseases<br>breast neoplasms | breast cancer<br>breast carcinoma<br>breast lesions<br>breast lumps<br>breast neoplasms<br>breast tumors<br>breast tumours |
| Diagnosis | diagnosis<br>diagnostic accuracy<br>diagnostic imaging<br>diagnostic procedure<br>diagnostic value<br>early diagnosis<br>sensitivity and specificity<br>tumor diagnosis | accuracy<br>diagnosis<br>false negative<br>false positive<br>gold standard<br>likelihood<br>precision<br>predictive value<br>receiver operating characteristic<br>ROC<br>sensitivity<br>specificity<br>true negative<br>true positive |
| Non-invasive technique | | noninvasive<br>non-invasive |
| Ultrasonography | echomammography<br>ultrasonography<br>ultrasonography, mammary<br>ultrasound | echography<br>echomammography<br>sonography<br>sonomammography<br>ultrasonic<br>ultrasonography<br>ultrasound |
| Magnetic resonance imaging | magnetic resonance imaging<br>nuclear magnetic resonance imaging | magnet strength<br>magnetic resonance<br>MR<br>MRI<br>NMR<br>nuclear magnetic resonance<br>pulse sequence |

**Table 2. Topic specific search terms (continued)**

| Concept | Controlled Vocabulary | Keywords |
|---|---|---|
| Positron emission tomography | fluorodeoxyglucose F 18<br>positron emission tomography<br>tomography,emission-computed | computed tomography<br>F18<br>F-18<br>FDG<br>f-fluorodeoxyglucose<br>PET<br>positron emission tomography |
| Scintimammography | gamma cameras<br>gamma spectrometry<br>methoxy isobutyl isonitrile technetium tc-99<br>nuclear medicine<br>organotechnetium compounds [diagnostic use]<br>radionuclide imaging<br>radiopharmaceuticals<br>scintillation camera<br>scintimammography<br>spectrometry, gamma<br>technetium Tc 99m Sestamibi [diagnostic use] | BSGI<br>gamma camera<br>gammagraphy<br>gammagraphy<br>MIBI<br>miraluma<br>nuclear medicine<br>pem tetrofosomin<br>radionuclide<br>radiotracers<br>scintimammography<br>sestamibi<br>technetium<br>tetrofosmin |
| SPECT | single photon emission computer tomography<br>spectrometry, x-ray emission | SPECT<br>SPET |
| Tomosynthesis | three dimensional imaging | 3D<br>3-D<br>three dimensional<br>tomosynthesis |
| Computer-aided detection | computer assisted diagnosis<br>diagnosis, computer-assisted<br>digital mammography<br>image analysis<br>image interpretation, computer-assisted<br>image processing, computer-assisted<br>radiographic image interpretation, computer-assisted | CAD<br>computer aided detection<br>computer aided diagnosis<br>computer assisted detection<br>computer assisted diagnosis<br>digital mammography |
| Doppler ultrasound | doppler echography<br>ultrasonography, Doppler<br>ultrasonography, doppler, color<br>ultrasonography, doppler, duplex | doppler echography<br>doppler ultrasonography |

**Table 2. Topic specific search terms (continued)**

| Concept | Controlled Vocabulary | Keywords |
|---|---|---|
| Combined PET/CT | computer assisted tomography<br>positron-emission tomography<br>tomography, emission-computed<br>tomography, x-ray computed | PET/CT<br>positron emission tomography and computed tomography |

**Table 3. CINAHL/EMBASE/MEDLINE**

| Set N | Concept | Search Statement |
|---|---|---|
| 1 | Breast diseases | exp Breast neoplasms/ or exp breast diseases/ or exp breast cancer/ or breast carcinoma/ or ((breast or mammary) and (cancer$ or neoplasm$ or carcinoma$ or tumor$ or tumour$ or lump$ or lesion$)).mp. |
| 2 | Diagnosis | "sensitivity and specificity"/ or early diagnosis/ or diagnostic imaging/ or diagnostic value/ or diagnostic accuracy/ or diagnostic procedure/ or tumor diagnosis/ or diagnos$.mp. or di.xs. or "gold standard".mp. or ROC.mp. or "receiver operating characteristic".mp. or likelihood.mp. or ((false or true) adj (positive or negative)).tw. or "predictive value".mp. or accuracy.mp. or precision.mp. or sensitivity.mp. or specificity.mp. |
| 3 | Combine sets | 1 and 2 |
| 4 | Non-invasive technique (2005-2009) | 3 and (noninvasive or non-invasive).mp. |
| 5 | Ultrasonography (2005-2009) | 3 and (ultrasonography.fs. or ultrasonography, mammary/ or echogra$.mp. or echomammog$.mp. or sonogra$.mp. or sonomammogr$.mp. or ultrasound.mp. or ultrason$.mp. or echomammography/ or ultrasound/) |
| 6 | Magnetic resonance imaging (2000-2009) | 3 and (exp magnetic resonance imaging/ or "magnet strength".mp. or pulse sequence.mp. or MR.mp. or MRI.mp. or nuclear magnetic resonance.mp. or NMR.mp. or nuclear magnetic resonance imaging/ or magnetic resonance.mp.) |
| 7 | Positron emission tomography (2000-2009) | 3 and ((FDG$ or f-fluorodeoxyglucose or f18 or f-18).mp. or fluorodeoxyglucose F 18/ or PET.ti. or positron emission tomography.mp. or exp tomography,emission-computed/ or (comput$ ADJ tomograph$).tw. or positron emission tomography/) |
| 8 | Scintimammography (2005-2009) | 3 and ((gamma camera$ or gammagraph$ or nuclear medicine or radionuclide$).mp. or radionuclide imaging.fs. or radiotracer$.mp. or radiopharmaceuticals/ or sestamibi.mp. or technetium Tc 99m Sestamibi/du or gammagraph$.mp. or pem tetrofosomin.mp. or technetium.mp. or miraluma.mp. or tetrofosmin.mp. or scintimammogr$.mp. or spectrometry, gamma/ or methoxy isobutyl isonitrile technetium tc-99/ or nuclear medicine/ or scintillation camera/ or scintimammography/ or gamma spectrometry/ or exp organotechnetium compounds/du or MIBI.mp. or BSGI.mp. or gamma cameras/) |
| 9 | SPECT (2005-2009) | 3 and (exp spectrometry, x-ray emission/ or SPET.mp. or SPECT.mp. or single photon emission computer tomography/) |
| 10 | Tomosynthesis 2007-2009) | 3 and (tomosynthesis.mp. or three dimensional imaging/ or 3-D.mp. or 3D.mp. or imaging, three dimensional/ or ((three or 3) ADJ dimension$)).tw. |
| 11 | Computer-aided detection (2001-2009) | 3 and (diagnosis, computer-assisted/ or image interpretation, computer-assisted/ or radiographic image interpretation, computer-assisted/ or computer assisted diagnosis/ or digital mammography/ or (comput$ ADJ (aided or assisted) ADJ (detection or diagnos$)).tw. or digital mammogra$.mp. or CAD.mp. or exp image processing, computer-assisted/ or image analysis/) |

**Table 3. CINAHL/EMBASE/MEDLINE (continued)**

| Set N | Concept | Search Statement |
|---|---|---|
| 12 | Doppler ultrasound (1997-2009) | 3 and (ultrasonography, doppler/ or ultrasonography, doppler, duplex/ or ultrasonography, doppler, color/ or doppler echography/ or (doppler ADJ2 (ultraso$ or echograph$)).tw.) |
| 13 | Combined PET/CT (2000-2009) | 3 and (((positron-emission tomography/ or tomography, emission-computed/) and (tomography, x-ray computed/ or computer assisted tomography.mp.)) or (pet ADJ ct).tw. or pet/ct or (positron emission tomograph$ and comput$ tomograph$).mp.) |
| 14 | Combine sets | or/4-13 |
| 15 | Limit by publication type | 15 not ((letter or editorial or news or comment or case reports or note or conference paper).de. or (letter or editorial or news or comment or case reports).pt.) |

# Appendix B. Sample Data Abstraction Forms

## Abstract Screening Form

1. Is the topic of the article "diagnosis of breast cancer"?
2. Is the article a full-length published journal article?
3. Is the article written in English?
4. Is the article describing a clinical study?
5. Does the study use one of the technologies being considered in the report?
6. Does the study appear to address at least one of the Key Questions?
7. Is the study about diagnosis and not about screening asymptomatic individuals?
8. Did the study enroll at least 10 female humans?

## Inclusion/Exclusion Screening Form

1. Did the study directly compare the test of interest to an acceptable reference standard- core-needle biopsy, open surgery, or patient followup- in the same group of patients?
2. Were at least 85% of the originally enrolled patients evaluated by both the non-invasive imaging technology and an acceptable reference standard?
3. If the study is retrospective in design, did it enroll all patients, consecutive patients, or a randomized sample of patients? Retrospective case-control and case studies are excluded.
4. The studies must have used current generation scanners and protocols of the selected technologies only, as defined in the following list of technologies and cut-off publication dates (to present):
    - Ultrasound (B-mode grayscale, tissue harmonics, power Doppler, color Doppler, tomography): 1994+
    - Magnetic resonance imaging (MRI), without computer aided-detection (CADx), using breast-specific coils and gadolinium-based contrast agents: 2000+
    - Magnetic resonance imaging (MRI), with computer aided-detection (CADx) (breast-specific coils and gadolinium-based contrast agents, CAD package FDA approved): 2000+
    - Positron emission imaging (PET), with or without computed tomography (PET/CT), using 18-flurodeoxyglucose (FDG) as the tracer: 2000+
    - Scintimammography, including breast specific gamma imaging (BSG1) and single photon emission computed tomography (SPECT), using technetium-99m sestamibi (sestamibi or MIBI) as the tracer: 2005+

5. Did the study enrolled female human subjects? If male subjects were enrolled, the majority (90%+) of the patients must have been female.

6. Did the study enroll patients referred for the purpose of primary diagnosis of a breast abnormality detected by routine screening (mammography and/or physical examination)? Studies that enrolled subjects that were undergoing evaluation for any of the following purposes were excluded as being out of scope of the report: screening of asymptomatic women; breast cancer staging; evaluation for a possible recurrence of breast cancer; monitoring response to treatment; evaluation of the axillary lymph nodes; evaluation of metastatic or suspected metastatic disease; or diagnosis of types of cancer other than primary breast cancer. Studies that enrolled patients from high-risk populations such as BRCA1/2 mutation carriers, or patients with a strong family history of breast cancer, are also out of scope. If a study enrolled a mixed patient population and did not report data separately, it was excluded if more than 15% of the subjects did not fall into the "primary diagnosis of women at average risk presenting with an abnormality detected on routine screening" category.

7. Did the study report test sensitivity, specificity, or sufficient data to calculate these measures of diagnostic test performance; or (for Key Question 3) reported factors that affected the accuracy of the non-invasive test being evaluated.

8. Was a complete set of data reported for at least 50% or more of the originally enrolled patients? Studies with extremely high rates of attrition are prone to bias and were excluded.

9. Was the study published in English?

10. Study must be published as a peer-reviewed full article. Meeting abstracts were not included.

11. Did the study enroll 10 or more individuals per arm?

12. Does the study include data that was also published in a different manuscript?

## Quality Assessment (Risk of Bias) Form

1. Was patient recruitment either consecutive or random?

2. Was the study prospective in design?

3. Were more than 85% of the patients approached for recruitment enrolled in the study?

4. Were the patient inclusion/ exclusion criteria consistently applied to all patients?

5. Was the study free from obvious spectrum bias? Obvious spectrum bias was defined as more than 40% or less than 10% of the breast lesions were diagnosed as malignant; and/or the mean or median age of the enrolled population was less than 50 or greater than 70.

6. Did the study account for inter-reader/scorer differences?

7. Were the reader(s) of the biopsies blinded to the results of the reference standard?

8. Were readers of the reference standard blinded to the results of the biopsy?

9. Were the readers of the biopsy blinded to all other clinical information?
10. Were readers of the reference standard blinded to all other clinical information?
11. Were patients assessed by a reference standard regardless of the biopsy results?
12. Were the patients assessed by the gold standard (open surgical procedure) regardless of the initial biopsy results?
13. Was a diagnostic threshold chosen *a priori* by the study?
14. Were there no intervening treatments or interventions conducted between the time the diagnostic test was performed and the reference standard was performed?
15. Was a complete set of data reported for at least 85% of enrolled lesions?
16. Was funding for this study provided by a source that doesn't have an obvious financial interest in the findings of the study?
17. Was the report of the study free from unresolvable discrepancies?

## Study Design and Patients Data Abstraction Form

Study design:
Multi-center:
Country set in:
Source of funding:
Patient recruitment methods:
Patient enrollment criteria:
N patients enrolled:
N lesions enrolled:
N lesions completing study:
Patient age, mean or median, range:
Describe imaging methods:
Describe imaging operators/readers:
Care setting:
Reference standard:
% lesions malignant:
% lesions palpable:
Tumor size:
Other lesion descriptors:

## Data Abstraction Form

Category/type/descriptors:

| Number TP | Number FP |
|---|---|
| Number FN | Number TN |

# Appendix C: Evidence tables

## Magnetic Resonance Imaging (MRI)

Total of 41 studies

Total of 3,882 patients; 4,202 lesions

1 study of 3.0T; 2 studies of 0.5T; 3 studies of 1.0T; 33 studies of 1.5T; 1 study of mixed 1.0T and 1.5T; and 1 study NR

1 study comparing CAD assistance to not

26 studies of gadopentetic acid; 8 studies of gadodiamide; 3 studies of gadobenic acid; 2 studies of gadoteridol; 2 studies mixed or not reported; 2 studies compared gadopentetic acid to gadobenic acid.

**Table 4. Included studies of MRI**

| Study | MRI Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funded by |
|---|---|---|---|---|---|---|
| Akita et al. 2009[1] | 1.5T gadodiamide | Diagnostic cohort study | 50 | 50 | Japan | NR |
| Baltzer et al. 2009[2] | 1.5T gadopentetic acid<br>CAD assistance vs. not | Prospective diagnostic cohort study | 329 | 469 | Germany | NR |
| Hara et al. 2009[3] | 1.5T gadodiamide | Diagnostic cohort study | 103 | 93 | Japan | NR |
| Kim et al. 2009[4] | 1.5T gadopentetic acid | Diagnostic cohort study | 249 | 249 | South Korea | Pusan National University Research Grant |
| Lo et al. 2009[5] | 3T gadopentetic acid | Prospective diagnostic cohort study | 31 | 31 | Hong Kong | NR |
| Imbracio et al. 2008[6] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 44 | 55 | Italy | NR |
| Pediconi et al. 2008[7] | 1.5T gadopentetic acid vs. gadobenic acid | Prospective diagnostic cohort study | 47 | 78 | Italy | NR |

**Table 4. Included studies of MRI (continued)**

| Study | MRI Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funded by |
|---|---|---|---|---|---|---|
| Vassiou et al. 2009[8] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 69 | 78 | Greece | NR |
| Brem et al. 2007[9] | 1.5T gadopentetic acid | Diagnostic cohort study | 23 | 33 | U.S. | NR |
| Cilotti et al. 2007[10] | 1.5T gadoteridol | Retrospective diagnostic cohort study | 55 | 55 | Italy | NR |
| Pediconi et al. 2007[11] | 1.5T gadobenic acid | Prospective diagnostic cohort | 164 | 230 | Italy | NR |
| Zhu et al. 2007[12] | 1.5T gadodiamide | Retrospective diagnostic cohort study | 52 | 52 | Japan | NR |
| Bazzocchi et al. 2006[13] | 1.0 or 1.5 T gadoteridol | Prospective diagnostic cohort study | 174 | 112 | Italy; multi-centered | Supported by Bracco Imaging Spa |
| Gokalp and Topal 2006[14] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 43 | 56 | Turkey | NR |
| Kneeshaw et al. 2006[15] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 88 | 88 | U.K. | Yorkshire Cancer Research |
| Ricci et al. 2006[16] | 1.5T gadobenic acid | Prospective diagnostic cohort study | 48 | 50 | Italy | NR |
| Pediconi et al. 2005[17] | 1.5T gadobenic acid | Prospective diagnostic cohort study | 36 | 68 | Italy | NR |
| Pediconi et al. 2005[18] | 1.5T gadopentetic acid vs. gadobenic acid | Prospective diagnostic cohort study | 26 | 46 | Italy | States it was not industry funded |
| Wiener et al. 2005[19] | 1.5 T gadopentetic acid | Prospective diagnostic cohort study | 65 | 119 | U.S. | NR |
| Bluemke et al. 2004[20] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 960 | 960 | Many; multi-centered | National Cancer Institute |

**Table 4. Included studies of MRI (continued)**

| Study | MRI Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funded by |
|---|---|---|---|---|---|---|
| Huang et al. 2004[21] | 1.5T gadodiamide | Prospective diagnostic cohort study | 50 | 50 | U.S. | Susan G. Komen Breast Cancer Foundation |
| Bone et al. 2003[22] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 97 | 111 | Hungary | NR |
| Daldrup-Link et al. 2003[23] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 14 | 19 | Germany | NR |
| Heinisch et al. 2003[24] | 1.0T gadopentetic acid | Prospective diagnostic cohort study | 36 | 40 | Austria | NR |
| Walter et al. 2003[25] | 1.0T gadopentetic acid | Prospective diagnostic cohort study | 40 | 42 | Germany | NR |
| Guo et al. 2002[26] | 1.5T gadopentetic acid | Retrospective diagnostic cohort study | 52 | 47 | China | NR |
| Kelcz et al. 2002[27] | 1.5T gadodiamide | Prospective diagnostic cohort study | 62 | 68 | U.S. | Weizman Institute of Science, Rehovot, Israel and the Israel Binational Science Foundation in the United States |
| Schedel et al. 2002[28] | 1.5T gadopentetic acid | Diagnostic cohort study | 65 | 34 | Germany | NR |
| Trecate et al. 2002[29] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 28 | 28 | Italy | NR |
| Wiberg et al. 2002[30] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 93 | 114 | Sweden | NR |

**Table 4. Included studies of MRI (continued)**

| Study | MRI Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funded by |
|---|---|---|---|---|---|---|
| Brix et al. 2001[31] | 1.5T gadopentetic acid | Prospective diagnostic cohort study | 14 | 14 | Germany | Wilhelm Sanders-Stifttung grant |
| Cecil et al. 2001[32] | 1.5T gadopentetic acid | Diagnostic cohort study | 37 | 23 | U.S. | Grant funding through the National Institute of Health and U.S. Army |
| Furman-Haran et al. 2001[33] | 1.5T gadodiamide | Prospective diagnostic cohort study | 40 | 48 | U.S. | U.S.-Israel Binational Foundation |
| Imbriaco et al. 2001[34] | 0.5T gadopentetic acid | Prospective diagnostic cohort study | 49 | 49 | Italy | Associazione Italiana Ricerca Cancro |
| Malich et al. 2001[35] | 1.5T gadopentetic acid | Diagnostic cohort study | 94 | 100 | Germany | NR |
| Nakahara et al. 2001[36] | 0.5T gadopentetic acid | Retrospectivediagnostic cohort study | 40 | 40 | Japan | NR |
| Torheim et al. 2001[37] | 1.5T gadodiamide | Prospective diagnostic cohort study | 127 | 127 | Norway | Norwegian Research Council |
| Wedegartner et al. 2001[38] | 1.0T gadopentetic acid | Prospective diagnostic cohort study | 53 | 62 | Germany | NR |
| Yeung et al. 2001[39] | 1.5T gadopentetic acid | Diagnostic cohort study | 30 | 23 | China | NR |
| Kvistad et al. 2000[40] | 1.5T gadodiamide | Prospective diagnostic cohort study | 130 | 130 | Norway | Norwegian Cancer Society |

**Table 4. Included studies of MRI (continued)**

| Study | MRI Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funded by |
|---|---|---|---|---|---|---|
| Van Goethem et al. 2000[41] | NR T gadopentetic acid | Retrospective diagnostic cohort study | 75 | 75 | Belgium; multi-centered | NR |

NR Not reported
T Tesla
U.K. United Kingdom
U.S. United States

**Table 5. MRI studies: patient and lesion details**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Akita et al. 2009[1] | Patients with mammographically detected microcalcifications classified as BI-RADS 3 or higher | 50 | 50 | 50 | Mean: 50.6 | 28 to 80 | 26.0% (13/50) | NR |
| Baltzer et al. 2009[2] | Consecutive female patients with unclear or suspect findings on mammography who underwent surgery; patients who underwent preoperative chemotherapy were excluded. | 329 | 469 | 469 | 55.3 | 15 to 83 | 59.5% (279/469) | NR |
| Hara et al. 2009[3] | Patients with suspected malignancy in routine examination. | 103 | 93 | 93 | 49.1 | 21 to 75 | 23.6% (22/93) | NR |
| Kim et al. 2009[4] | Consecutive patients with palpable breast masses on physical examination and/or suspicious mammographic findings | 249 | 249 | 249 | 47 | 37 to 57 | 85.3% (205/249) | 59% |
| Lo et al. 2009[5] | Patients with suspicious lesions on mammography/US | 31 | 31 | 31 | 46 | 34 to 69 | 64.5% (20/31) | NR |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Imbracio et al. 2008[6] | Consecutive patients with lesions detected on physical exam or mammography/US; excluded were pregnant, lactating, under 18 years, prior history of breast cancer | 44 | 55 | 44 | 54 | NR | 81.8% (45/55) | NR |
| Pediconi et al. 2008[7] | Women with suspicious lesions diagnosed by physical examination or mammography, referred for biopsy; excluded were under 18 years; pregnant or lactating; had received any other contrast agent during 48 hours before MRI undergoing radiation therapy, chemotherapy, or anticancer hormonal therapy, or had any medical conditions or other circumstances that would decrease chances of obtaining reliable data, or were sensitive to gadolinium chelates. | 47 | 78 | 47 | 50.8 | 30 to 75 | 64.0% (50/78) | NR |
| Vassiou et al. 2009[8] | Women with suspicious lesions diagnosed by physical examination or mammography, referred for biopsy | 69 | 78 | 69 | 53 | 39 to 68 | 68% (53/78) | NR |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Brem et al. 2007[9] | Indeterminate breast findings that required a biopsy | 23 | 33 | 33 | 53 | 33 to 70 | 27.3% (9/33) | NR |
| Cilotti et al. 2007[10] | Patients with BIRADS 3-5 microcalcifications from mammography that were not opaque or distorted | 55 | 55 | 55 | 56 | 37 to 76 | 47.3% (26/55) | 0% |
| Pediconi et al. 2007[11] | Consecutive patients with suspicious clinical exam, mammogram and or US; excluded were patients contraindicated for MRI or with mammogram BIRADS 2 or 3 | 164 | 230 | 164 | NR | NR | 93.3% (211/226) | NR |
| Zhu et al. 2007[12] | consecutive patients with microcalcifications suspicious of DCIS; patients with palpable lesions | 52 | 52 | 52 | NR | 30 to 74 | 50% (26/52) | 0% |
| Bazzocchi et al. 2006[13] | Patients with mammographically detected microcalcifications (BIRADS 4-5); any race; associated or not with an opacity; excluded were younger than 18 years, contraindications to MRI, pregnant/breastfeeding, severe renal failure, sensitivity to gadolinium. | 174 | 112 | 112 | NR | NR | 67.0% (75/112) | 0% |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Gokalp and Topal 2006[14] | Nonpalpable lesions defined as BIRADS category 3 on screening mammography | 43 | 56 | 43 | 49.7 | 37 to 68 | 1.8% (1/56) | 0.00% |
| Kneeshaw et al. 2006[15] | Patients with microcalcifications on mammography | 88 | 88 | 88 | 58 | 50 to75 | 22.7% (20/88) | 0% |
| Ricci et al. 2006[16] | Consecutive patients with lesions detected on mammography | 48 | 50 | 50 | 58 | 40 to 81 | 76% (38/50) | NR |
| Pediconi et al. 2005[17] | Consecutive patients with suspected breast cancer based on mammogram/US; Excluded under 18 years of age; pregnant/lactating; undergoing cancer treatment; or had another contrast agent in the last 48 hours | 36 | 68 | 36 | NR | 31 to 78 | 79.4% (54/68) | NR |
| Pediconi et al. 2005[18] | Consecutive patients with suspected breast cancer based on mammogram/US; Excluded under 18 years of age; pregnant/lactating; undergoing cancer treatment; or had another contrast agent in the last 48 hours | 26 | 46 | 25 | 47.8 | 32 to 67 | 82.6% (38/46) | NR |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Wiener et al. 2005[19] | Women 18 to 80 years of age with suspicious lesions diagnosed by physical examination or mammography, referred for biopsy; Excluded if: a prior invasive breast procedure had been performed within 6 months of the surgery; contraindication to MRI (pacemaker, metallic implant, etc.); history of prior breast cancer in the affected breast; pregnancy | 960 | 960 | 821 | 53.2 | 42 to 65 | 49.2% (404/821) | 39% |
| Bluemke et al. 2004[20] | Patients with a BIRADS 4 or 5 at mammography scheduled for CNB/surgery | 50 | 50 | 50 | 50.2 | 34 to 71 | 36.0% (18/50) | NR |
| Huang et al. 2004[21] | Patients with indeterminate lesions on mammogram, US, or both; MRI done during the first 2 weeks of menstrual cycle, who were candidates for surgery; excluded were lesions larger than 5 cm, thought to have multicentric disease, not a candidate for radiation, small breast to lesion ratio | 65 | 119 | 65 | NR | NR | 58.0% (69/119) | 72.3% (47/65) |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Bone et al. 2003[22] | Consecutive patients scheduled for surgery after detection of lesions by palpation or mammography | 97 | 111 | 90 | 54 | 33 to 81 | 71.2% (79/111) | NR |
| Daldrup-Link et al. 2003[23] | Women with suspicious lesions diagnosed by physical examination, mammography, or ultrasound, scheduled for surgery; Excluded were: women less than 18 years of age, with implanted metal devices, claustrophobia, pregnant, lactating, or had been administered iron oxides with 7 days before the study, participation in antoher study, serious liver dysfunction, or a history of serious allergies or reactions to any drugs particularly contrast agents. | 14 | 19 | 19 | 55 | 35 to 77 | 47% (9/19) | NR |
| Heinisch et al. 2003[24] | Women with suspicious breast lesions detected by physical exam, mammography, and/or ultrasound, scheduled for biopsy, referred when there happened to be time on the scanners | 36 | 40 | 40 | 48.3 | 25 to 77 | 62.5% (25/40) | NR |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Walter et al. 2003[25] | A subset of patients were randomly selected from a consecutive series who were referred for biopsy due to findings on mammography, ultrasound, or physical examination | 40 | 42 | 42 | 52 | 21 to 77 | 45.2% (19/42) | NR |
| Guo et al. 2002[26] | No specific criteria reported | 52 | 47 | 47 | 58 | 25 to 75 | 56.4% (31/55) | NR |
| Kelcz et al. 2002[27] | Women with palpable masses, or who had mammographic or sonographic abnormalities thought to require biopsy. Women with prebiopsy studies indicating a high likelihood of a cyst were excluded | 62 | 68 | 57 | 50 | 31 to 80 | 46.0% (31/68) | NR |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Schedel et al. 2002[28] | Women with suspicious lesions diagnosed by physical examination or mammography, referred for biopsy; Excluded were women who had undergone tumor therapy or had diagnostic puncture of the breast to be evaluated within 3 months of the study, women who had undergone any kind of breast surgery within 6 months, or women who had irradiation treatment of the breast within 18 months. | 65 | 34 | 57 | 52 | 21 to 78 | 59.6% (34/57) | NR |
| Trecate et al. 2002[29] | Patients with mammographically suspicious clustered or diffuse microcalcifications | 28 | 28 | 28 | NR | 33 to 65 | 53.6% (15/28) | NR |
| Wiberg et al. 2002[30] | Consecutive patients scheduled for surgery between January 1996 to June 1997 after detection of lesions by palpation or mammography and after undergoing diagnostic triple assessment (diagnostic mammography, physical exam, and fine needle aspiration) who had no contraindications to MRI | 93 | 114 | 114 | 54 | 33 to 81 | 72% (82/114) | 54% |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Brix et al. 2001[31] | Patients with suspicious lesions detected on mammography or physical examination who were scheduled for a biopsy. | 14 | 14 | 14 | 49 | 35 to 66 | 64.2% (9/14) | NR |
| Cecil et al. 2001[32] | Women with a palpable or suspicious mass detected by mammography that was at least 1 cm in diameter but did not appear to be a focal mass. | 37 | 23 | 37 | 47 | 18 to 85 | 60.5% (23/38) | NR |
| Furman-Haran et al. 2001[33] | Patients had lesions at mammography/US and biopsy was recommended | 40 | 48 | 40 | NR | NR | 52.1% (25/48) | 71% |
| Imbriaco et al. 2001[34] | Consecutive patients with a suspicious breast lesion detected either by physical examination or mammography and US; Patients were excluded if they were pregnant, lactating, under 18 years of age, had a personal history of breast cancer or had undergone fine-needle aspiration before the MRI could be performed | 49 | 49 | 49 | 49 | 30 to 60 | 51% (25/49) | 37% |
| Malich et al. 2001[35] | Consecutive patients with equivocal mammographic abnormalities referred for biopsy | 94 | 100 | 90 | NR | NR | 67% (60/90) | NR |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Nakahara et al. 2001[36] | Only patients who proceeded to biopsy were included | 40 | 40 | 40 | 49.5 | 27 to 76 | 50.0% (20/40) | 0% |
| Torheim et al. 2001[37] | Patients with solid breast tumors | 127 | 127 | 126 | 53 | NR | 55.1% (70/127) | NR |
| Wedegartner et al. 2001[38] | Patients with palpable or mamographically suspicious lesions scheduled for excisional biopsy | 53 | 62 | 53 | 49 | 18 to 82 | 71.0% (44/62) | NR |
| Yeung et al. 2001[39] | Women that showed non-specific lesions larger than 1.5 cm on mammography or ultrasound. | 30 | 23 | 30 | 50 | 20 to 80 | 77.0% (23/30) | NR |
| Kvistad et al. 2000[40] | Patients with recently discovered solid breast tumors (palpable masses or mammographic screening) scheduled to undergo biopsy were invited; patients with cysts and microcalcifications but no solid mass were excluded, as were patients unable to undergo MRI due to old age, poor physical condition, claustrophobia, or lack of available time on the MRI schedule. | 130 | 130 | 130 | 59 | 37 to 82 | 55.4% (72/130) | 74% |

**Table 5. MRI studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable |
|---|---|---|---|---|---|---|---|---|
| Van Goethem et al. 2000[41] | Consecutive patients from 9 hospitals having MRI for any indication. | 75 | 75 | 74 | NR | NR | 36.5% (27/74) | NR |

MRI Magnetic resonance imaging
NR Not reported
US Ultrasound

**Table 6. Details of MRI methodology**

| Study | Tesla | Machine Used | Precontrast Sequence | Contrast Agent | Post-contrast Sequence | Other/Final Sequence | Readers | Reference Standard |
|---|---|---|---|---|---|---|---|---|
| Akita et al. 2009[1] | 1.5T | Signa HD (General Electric, Milwaukee, WI) | T2 weighted FSE with fat suppression, and T1 weighted SPGR | Gadodiamide hydrate (Omniscan) 0.1 mmol/kg | Dynamic 3D fat-suppressed | Fat-suppressed delayed-phase sagittal | Consensus of two radiologists | All patients underwent stereotactic vacuum-assisted breast biopsy |
| Baltzer et al. 2009[2] | 1.5T | Magnetom Symphony or Sonata (Siemens, Erlangen, Germany) | T1 weighted SPGR | Gd-DTPA 0.1 mmol/kg | Dynamic FLASH | T2 weighted TSE | Consensus of two blinded reviewers vs. CAD | Open surgery |
| Hara et al. 2009[3] | 1.5T | Magnetom Symphony (Siemens, Erlangen, Germany) | T2 and T1 weighted fat suppressed | Gadodiamide hydrate (Omniscan) 0.15 mmol/kg | Dynamic | None reported | One blinded radiologist | Fine needle biopsy and follw-up every 3 or 6 months (median follow-up 309 days) |
| Kim et al. 2009[4] | 1.5T | Somatom Vision (Siemens, Erlangen, Germany) | T1 weighted FLASH | Gd-DTPA 0.16 mmol/kg | Dynamic T1 weighted 3D FLASH | None reported | Consensus of two radiologists | Open surgical biopsy (n = 215) or core needle biopsy (n = 24) |

**Table 6. Details of MRI methodology (continued)**

| Study | Tesla | Machine Used | Precontrast Sequence | Contrast Agent | Post-contrast Sequence | Other/Final Sequence | Readers | Reference Standard |
|---|---|---|---|---|---|---|---|---|
| Lo et al. 2009[5] | 3T | Magnetom Tim Trio (Siemens, Erlangen, Germany) | Diffusion-weighted single-shot followed by T1 and T2-weighted fat saturated | Gd-DTPA 0.1 mmol/kg | Dynamic 3D | T1 weighted fat-saturated | Consensus of two radiologists | Needle or excisional biopsy |
| Imbracio et al. 2008[6] | 1.5T | Gyroscan Intera (Philips Healthcare) | FFE | Gd-DTPA 0.1 mmol/kg | Dynamic T1-weighted 3D FFE | None reported | One radiologist | Excisional or core needle biopsy |
| Pediconi et al. 2008[7] | 1.5T | Visions Plus (Siemens) | T1 weighted gradient echo | Gd-DTPA or gadobenate dimeglumine, 0.1 mmol/kg | Dynamic T1-weighted 3D gradient echo | None reported | Consensus of two blinded radiologists | Surgery, excisional biopsy, or core biopsy in all patients 24 hours to 1 month after MRI |
| Vassiou et al. 2009[8] | 1.5T | Magnetom Vision (Siemens, Erlangen, Germany) | T2 weighted TSE | Gd-DTPA 0.2 mmol/kg | Dynamic T1 weighted SPGR | None reported | Not reported | Surgery, excisional biopsy, or core biopsy in all patients within 2 months after MRI |
| Brem et al. 2007[9] | 1.5T | General Electric Healthcare, Milwaukee, WI | T1 and T2 weighted fat saturated | Gd-DTPA 0.1 mmol/kg | Dynamic T1 weighted | T1 fat saturated | Two experienced non-blinded breast imagers | MRI-guided biopsy and follow-up if needed |

**Table 6. Details of MRI methodology (continued)**

| Study | Tesla | Machine Used | Precontrast Sequence | Contrast Agent | Post-contrast Sequence | Other/Final Sequence | Readers | Reference Standard |
|---|---|---|---|---|---|---|---|---|
| Cilotti et al. 2007[10] | 1.5T | Symphony (Seimens) | T1 weighted, then T2 weighted fat saturated, then T1 3D FLASH | Gadoteridol (Prohance, Bracco) 0.1 mmol/kg | Dynamic | None reported | Not reported | Vaccumm assisted steotactic core needle biopsy or surgery |
| Pediconi et al. 2007[11] | 1.5T | Seimens Vision Plus (Seimens, Erlangen, Germany) | T1 weighted gradient echo | Gadobenate dimeglumine (MultiHance; Bracco Imaging, Milan, Italy) 0.1 mmol/kg | Dynamic 3D T1 weighted gradient echo | None reported | Two radiologists in consensus | Open surgery or core needle biopsy or followup |
| Zhu et al. 2007[12] | 1.5T | Intera Master (Phillips Medical Systems, Cleveland, OH) | T2 weighted TSE and T1 weighted FFE fat saturated | Gadodiamide hydrate (Omniscan; Daiichi Pharma-ceuticals) 0.1 mmol/kg | Dynamic T1 weighted | None reported | One radiologist | Vacuum assisted core needle biopsy or surgery |
| Bazzocchi et al. 2006[13] | 1.0 or 1.5 T | Various | 3D gradient echo | Gadoteridol (ProHance, Bracco Imaging) 0.1 mmol/kg | Dynamic | None reported | Consensus of two blinded radiologists | Surgical biopsy after preoperative localization with a hook wire technique |
| Gokalp and Topal 2006[14] | 1.5T | Magnetom Vision (Siemens, Erlangen, Germany) | T2 weighted TSE fat suppressed then T1 weighted 3D FLASH | Gd-DTPA 0.1 mmol/kg | Dynamic T1 weighted 3D FLASH | None reported | One radiologist | Follow up or biopsy |

**Table 6. Details of MRI methodology (continued)**

| Study | Tesla | Machine Used | Precontrast Sequence | Contrast Agent | Post-contrast Sequence | Other/Final Sequence | Readers | Reference Standard |
|---|---|---|---|---|---|---|---|---|
| Kneeshaw et al. 2006[15] | 1.5T | Signa Echospeed (General Electric, Milwaukee, WI) | T1 weighted 3D | Gd-DTPA 0.1 mmol/kg | Dynamic T1 weighted SPGR | T1 weighted 3D fat suppressed | One radiologist | Open surgery or follow-up |
| Ricci et al. 2006[16] | 1.5T | Magnetom Vision Plus (Seimens, Elrangen, Germany) | T2 weighted and T1 weighted 3D FLASH | Gadobenate dimeglumine 0.1 mmol/kg | Dynamic T1 weighted 3D SPGR | None reported | Not reported | Open surgical biopsy |
| Pediconi et al. 2005[17] | 1.5T | Vision Plus (Siemens, Erhlangen, Germany) | T1 weighted | Gadobenate dimeglumine 0.1 mmol/kg | Dynamic 3D T1 weighted | None reported | Two blinded radiologists in consensus | Surgery, biopsy, or follow-up |
| Pediconi et al. 2005[18] | 1.5T | Vision Plus (Siemens, Erhlangen, Germany) | T1 weighted | Gd-DTPA or gadobenate dimeglumine, 0.1 mmol/kg | Dynamic 3D T1 weighted | None reported | Two blinded radiologists in consensus | Surgery, biopsy, or follow-up |
| Wiener et al. 2005[19] | 1.5 T | Symphony (Seimens) | T1 and T2 weighted | Gd-DTPA 0.1 mmol/kg | Dynamic 3D FLASH T1 weighted SPGR | None reported | One radiologist | Open surgery or core-needle biopsy; all core-needle biopsies were followed by either surgical excision or at least 1 year of clinical and mammographic followup |

**Table 6. Details of MRI methodology (continued)**

| Study | Tesla | Machine Used | Precontrast Sequence | Contrast Agent | Post-contrast Sequence | Other/Final Sequence | Readers | Reference Standard |
|---|---|---|---|---|---|---|---|---|
| Bluemke et al. 2004[20] | 1.5T | Various | T2 weighted, then 3D T1-weighted | Gd-DTPA 0.1 mmol/kg | 3D T1 weighted fat suppressed; women with enhancing lesions also underwent 2D dynamic T1 weighted | None reported | One reader per center | Excisional or core needle biopsy |
| Huang et al. 2004[21] | 1.5T | Edge (Marconi Medical Systems, Cleveland, OH) | None reported | Gadodiamide hydrate (Omniscan; Daiichi Pharma-ceuticals) 0.1 mmol/kg | Dynamic 3D T1 weighted SPGR | T2 weighted FLASH perfusion imaging | Not reported | Excisional biopsy or image guided core needle biopsy |
| Bone et al. 2003[22] | 1.5T | Magentom SP63 (Seimens) | 3D T1 weighted FLASH | Gd-DTPA 0.2 mmol/kg | Dynamic 3D T1 weighted FLASH | None reported | One radiologist | Surgical biopsy |
| Daldrup-Link et al. 2003[23] | 1.5T | Philips ACS NT (BEST, the Nether-lands) | 2D T2 weighted TSE | Gd-DTPA 0.2 mmol/kg | Dynamic 3D T1 weighted FLASH | None reported | Two radiologists | Open surgery |
| Heinisch et al. 2003[24] | 1.0T | Not reported | T2 weighted TSE | Gd-DTPA 0.2 mmol/kg | Conventional dynamic | High-resolution 3D FFE with fat suppression including an additional contrast media injection | One radiologist | Open surgery |

**Table 6. Details of MRI methodology (continued)**

| Study | Tesla | Machine Used | Precontrast Sequence | Contrast Agent | Post-contrast Sequence | Other/Final Sequence | Readers | Reference Standard |
|---|---|---|---|---|---|---|---|---|
| Walter et al. 2003[25] | 1.0T | Gyroscan T10 NT (Philips, Eindhoven, the Nether-lands) | T2 weighted TSE | Gd-DTPA 0.1 mmol/kg | Dynamic T1 weighted 3D FFE | None reported | Two radiologists in consensus | Biopsy |
| Guo et al. 2002[26] | 1.5T | Signa Horizon (General Electric, Milwaukee, WI) | T2 weighted FSE with fat suppression and diffusion weighted spin echo | Gd-DTPA 0.1 mmol/kg | Fast gradient echo | None reported | Not reported | Excisional surgery |
| Kelcz et al. 2002[27] | 1.5T | Sigma (General Electric, Milwaukee, WI) | 3D gradient echo | Gadodiamide hydrate (Omniscan; Daiichi Pharma-ceuticals) 0.1 mmol/kg | 3D gradient echo | None reported | One radiologist | 57 excisional biopsy and 11 fine needle biopsy |
| Schedel et al. 2002[28] | 1.5T | Magnetom 63 SP (Seimens, Erhlangen, Germany) | 3D T1 weighted FLASH | Gd-DTPA 0.2 mmol/kg | 3D T1 weighted FLASH | None reported | Not reported | Open biopsy or mastectomy |
| Trecate et al. 2002[29] | 1.5T | Seimens Vision | 3D T1 weighted FLASH | Gd-DTPA 0.1 mmol/kg | 3D T1 weighted FLASH | None reported | Not reported | Surgical biopsy after preoperative localization with a hook wire technique |
| Wiberg et al. 2002[30] | 1.5T | Magnetom SP 63 (Seimens) | 3D T1 weighted FLASH | Gd-DTPA 0.2 mmol/kg | Dynamic 3D T1 weighted FLASH | None reported | One blinded radiologist | Open surgery |

**Table 6. Details of MRI methodology (continued)**

| Study | Tesla | Machine Used | Precontrast Sequence | Contrast Agent | Post-contrast Sequence | Other/Final Sequence | Readers | Reference Standard |
|---|---|---|---|---|---|---|---|---|
| Brix et al. 2001[31] | 1.5T | Magnetom SP 4000 (Seimens, Erhlangen, Germany) | 3D FLASH | Gd-DTPA 0.1 mmol/kg | Dynamic specially optimized saturation-recovery turbo FLASH | Static 3D FLASH | Not reported | Biopsy |
| Cecil et al. 2001[32] | 1.5T | Signa (General Electric, Milwaukee, WI) | T1 weighted spin echo then fat saturated T2 weighted FSE | Gd-DTPA 0.1 mmol/kg | 3D fat-saturated SPGR | None reported | Two radiologists and one blinded radiologist | Excisional or needle biopsy |
| Furman-Haran et al. 2001[33] | 1.5T | Signa (General Electric, Milwaukee, WI) | Fast gradient echo | Gadodiamide hydrate (Omniscan; Daiichi Pharma-ceuticals) 0.1 mmol/kg | Dynamic fast gradient echo | None reported | One radiologist | Biopsy |
| Imbriaco et al. 2001[34] | 0.5T | General Electric, Milwaukee, WI | T1 weighted spin echo | Gd-DTPA 0.1 mmol/kg | 3D gradient echo | None reported | One radiologist | Open surgery or 1 year of followup (n = 6) |
| Malich et al. 2001[35] | 1.5T | Gyroscan ACSII (Phillips, Hamburg, Germany) | T1 weighted FFE | Gd-DTPA 0.1 mmol/kg | Dynamic 2D T1 weighted FFE | T1 weighted FFE and then T2 weighted TSE | Not reported | Open surgical biopsy |
| Nakahara et al. 2001[36] | 0.5T | Signa (General Electric) | T2 weighted | Gd-DTPA 0.1 mmol/kg | Fat-saturated SPRG | T1 weighted | Not reported | Biopsy after preop localization by hook wire |

**Table 6. Details of MRI methodology (continued)**

| Study | Tesla | Machine Used | Precontrast Sequence | Contrast Agent | Post-contrast Sequence | Other/Final Sequence | Readers | Reference Standard |
|---|---|---|---|---|---|---|---|---|
| Torheim et al. 2001[37] | 1.5T | Picker Edge II (Picker, Cleveland, OH) | None reported | Gadodiamide hydrate (Omniscan; Daiichi Pharma-ceuticals) 0.1 mmol/kg | Dynamic 3D SPRG | T2 weighted perfusion imaging | Not reported | Excisional biopsy or FNA plus imaging follow up |
| Wedegartner et al. 2001[38] | 1.0T | Magentom 63 SP or Magnetom Impact (Seimens) | None reported | Gd-DTPA 0.2 mmol/kg | Dynamic 3D or 2D FLASH | None reported | Panel of five blinded radiologists | Excisional biopsy, image guided biopsy |
| Yeung et al. 2001[39] | 1.5T | Gyroscan ACS NT (Philips, Best, the Netherlands ) | T1 weighted spin echo fat saturation | Gd-DTPA 0.2 mmol/kg | T1 weighted spin echo fat saturation and T2 weighted TSE | None reported | Not reported | 15 mastectomy; 1 hook-wire guided excision; 16 core biopsy; and 5 fine-needle aspiration |
| Kvistad et al. 2000[40] | 1.5T | Picker Edge II (Picker, Cleveland, OH) | 3D T1 weighted SPGR | Gadodiamide hydrate (Omniscan; Daiichi Pharma-ceuticals) 0.1 mmol/kg | Dynamic 3D T1 weighted SPGR | T2 weighted perfusion imaging | Not reported | Open surgery (n = 100) or a mean of 18 months followup (n = 30) |
| Van Goethem et al. 2000[41] | NR | Various | None reported | Gd-DTPA 0.1 mmol/kg | 3D FLASH | None reported | Not reported | Biopsy and follow-up |

3D Three dimensional
FFE Fast field echo
FLASH Fast low-angle shot
FSE Fast spin echo
Gd-DTPA Magnevist, also called gadolinium diethylenetriamine penta-acetic acid dimeglumine, also called gadopentetic acid
NR Not reported

**Table 6. Details of MRI methodology (continued)**

| | |
|---|---|
| SPGR | Spoiled gradient echo |
| T | Tesla |
| TSE | Turbo spin echo |

**Table 7. MRI studies: Information for meta-regressions**

| Study | Magnet | Tracer[a] | Consecutive or All Enrollment (1 = Yes) | Prospective Design (1 = Yes) | Probably Affected by Spectrum Bias[b] (1 = Yes) | Accounted for Inter-reader Differences (1 = Yes) | Readers Blinded to Clinical Information (1 = Yes) | All Diagnoses Confirmed by Histopathology (1 = Yes) | Multi-centered (1 = Yes) | Funded by (1 = Declared No Financial Conflicts of Interest) | Geographic Region[c] | Proportion Malignant |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Akita et al. 2009[1] | 1.5 | 2 | 1 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 0.26 |
| Baltzer et al. 2009[2] | 1.5 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 0 | 0 | 3 | 0.60 |
| Hara et al. 2009[3] | 1.5 | 2 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0.24 |
| Kim et al. 2009[4] | 1.5 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 0.85 |
| Lo et al. 2009[5] | 3.0 | 1 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0.65 |
| Imbracio et al. 2008[6] | 1.5 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0.82 |
| Pediconi et al. 2008[7] | 1.5 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 2 | 0.64 |
| Vassiou et al. 2009[8] | 1.5 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 0.68 |
| Brem et al. 2007[9] | 1.5 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 4 | 0.27 |
| Cilotti et al. 2007[10] | 1.5 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0.47 |

**Table 7. MRI studies: Information for meta-regressions (continued)**

| Study | Magnet | Tracer[a] | Consecutive or All Enrollment (1 = Yes) | Prospective Design (1 = Yes) | Probably Affected by Spectrum Bias[b] (1 = Yes) | Accounted for Inter-reader Differences (1 = Yes) | Readers Blinded to Clinical Information (1 = Yes) | All Diagnoses Confirmed by Histopathology (1 = Yes) | Multi-centered (1 = Yes) | Funded by (1 = Declared No Financial Conflicts of Interest) | Geographic Region[c] | Proportion Malignant |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Pediconi et al. 2007[11] | 1.5 | 3 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 2 | 0.93 |
| Zhu et al. 2007[12] | 1.5 | 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0.50 |
| Bazzocchi et al. 2006[13] | 1.2 | 4 | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 2 | 0.67 |
| Gokalp and Topal 2006[14] | 1.5 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0.02 |
| Kneeshaw et al. 2006[15] | 1.5 | 1 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 3 | 0.23 |
| Ricci et al. 2006[16] | 1.5 | 3 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 0.67 |
| Pediconi et al. 2005[17] | 1.5 | 3 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 0 | 2 | 0.79 |
| Pediconi et al. 2005[18] | 1.5 | 1 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 2 | 0.83 |
| Wiener et al. 2005[19] | 1.5 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0.49 |
| Bluemke et al. 2004[20] | 1.5 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 6 | 0.36 |
| Huang et al. 2004[21] | 1.5 | 2 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 4 | 0.58 |

**Table 7. MRI studies: Information for meta-regressions (continued)**

| Study | Magnet | Tracer[a] | Consecutive or All Enrollment (1 = Yes) | Prospective Design (1 = Yes) | Probably Affected by Spectrum Bias[b] (1 = Yes) | Accounted for Inter-reader Differences (1 = Yes) | Readers Blinded to Clinical Information (1 = Yes) | All Diagnoses Confirmed by Histopathology (1 = Yes) | Multi-centered (1 = Yes) | Funded by (1 = Declared No Financial Conflicts of Interest) | Geographic Region[c] | Proportion Malignant |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Bone et al. 2003[22] | 1.5 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 3 | 0.71 |
| Daldrup-Link et al. 2003[23] | 1.5 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 3 | 0.47 |
| Heinisch et al. 2003[24] | 1.0 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 3 | 0.63 |
| Walter et al. 2003[25] | 1.0 | 1 | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 3 | 0.45 |
| Guo et al. 2002[26] | 1.5 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0.56 |
| Kelcz et al. 2002[27] | 1.5 | 2 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 4 | 0.46 |
| Schedel et al. 2002[28] | 1.5 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 3 | 0.60 |
| Trecate et al. 2002[29] | 1.5 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 2 | 0.54 |
| Wiberg et al. 2002[30] | 1.5 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 3 | 0.72 |
| Brix et al. 2001[31] | 1.5 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 0 | 1 | 3 | 0.70 |
| Cecil et al. 2001[32] | 1.5 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 4 | 0.60 |

**Table 7. MRI studies: Information for meta-regressions (continued)**

| Study | Magnet | Tracer[a] | Consecutive or All Enrollment (1 = Yes) | Prospective Design (1 = Yes) | Probably Affected by Spectrum Bias[b] (1 = Yes) | Accounted for Inter-reader Differences (1 = Yes) | Readers Blinded to Clinical Information (1 = Yes) | All Diagnoses Confirmed by Histopathology (1 = Yes) | Multi-centered (1 = Yes) | Funded by (1 = Declared No Financial Conflicts of Interest) | Geographic Region[c] | Proportion Malignant |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Furman-Haran et al. 2001[33] | 1.5 | 2 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 1 | 4 | 0.52 |
| Imbriaco et al. 2001[34] | 0.5 | 1 | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 2 | 0.51 |
| Malich et al. 2001[35] | 1.5 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 3 | 0.67 |
| Nakahara et al. 2001[36] | 0.5 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 | 0.50 |
| Torheim et al. 2001[37] | 1.5 | 2 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 3 | 0.55 |
| Wedegartner et al. 2001[38] | 1.0 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 0 | 3 | 0.71 |
| Yeung et al. 2001[39] | 1.5 | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.77 |
| Kvistad et al. 2000[40] | 1.5 | 2 | 0 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 3 | 0.55 |
| Van Goethem et al. 2000[41] | 1.2 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 3 | 0.37 |

[a] For Tracer, 1 = gadopentetic acid; 2 = gadodiamide; 3 = gadobenic acid; 4 = gadoteridol; 0 = mixed or not reported. For the studies directly comparing tracers, data for gadopentetic acid was used in the primary meta-regression.

[b] Spectrum bias defined as median/mean age greater than 50 and/or % lesions malignant less than 10% or greater than 40%

[c] China = 0; Asia = 1; Turkey, Greece, Italy = 2; Europe and United Kingdom = 3; North America = 4; South America = 5; multiple = 6

# Positron Emission Tomography (PET)

Total of 8 studies

Total of 438 patients, 459 lesions

7 studies of PET; 1 study of PET/CT

**Table 8. Included studies of PET**

| Study | PET Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funded by |
|---|---|---|---|---|---|---|
| Imbriaco et al. 2008[6] | PET/CT | Diagnostic cohort study | 44 | 55 | Italy | Not reported |
| Kaida et al. 2008[42] | PET | Prospective diagnostic cohort | 118 | 122 | Japan | Not reported |
| Buchmann et al. 2007[43] | PET | Prospective diagnostic cohort | 29 | 29 | Germany | Not reported |
| Hienisch et al. 2003[24] | PET | Prospective diagnostic cohort | 36 | 40 | Austria | Not reported |
| Walter et al. 2003[25] | PET | Prospective diagnostic cohort | 40 | 42 | Germany | Not reported |
| Brix et al. 2001[31] | PET | Prospective diagnostic cohort | 14 | 14 | Germany | Wilhelm Sanders-Stiftung |
| Schirrmeister et al. 2001[44] | PET | Prospective diagnostic cohort | 117 | 117 | Germany | Not reported |
| Yutani et al. 2000[45] | PET | Prospective diagnostic cohort | 40 | 40 | Japan | Not reported |

**Table 9. PET studies: patient and lesion details**

| Study | Inclusion/Exclusion Criteria | N Patients | Mean or Median Age and Range (Years) | % 65 or Older | % Post-menopausal | % Palpable | Tumor Size Mean (Range) |
|---|---|---|---|---|---|---|---|
| Imbriaco et al. 2008[6] | Patients with suspicious breast lesions (detected by mammography, sonography, or physical examination) confirmed on the basis of histopathologic results. Patients who were pregnant or lactating, younger than 18, had a personal history of breast cancer, or who underwent fine needle aspiration biopsy prior to MRI or PET/CT were excluded. | 45 | Mean: 54<br>Standard deviation: 12 | NR | NR | NR | 17mm<br>(7 to 30 mm) |
| Kaida et al. 2008[42] | Women for whom breast cancer was suggested based on clinical examination and mammography. Exclusion criteria not reported. | 118 | Mean: 58<br>Range:<br>28 to 91 | NR | NR | 88.0% | Not reported for all tumors |
| Buchmann et al. 2007[43] | Women suspected of having breast cancer on mammography and/or ultrasound. Patients were excluded if they were younger than 18, pregnant or lactating, had a second malignancy, or had been treated for drug/alcohol abuse. | 29 | Mean: 50.5<br>Standard deviation: 11.5 | 10% | NR | NR | 26.9 mm<br>(10 to 80 mm) |

**Table 9. PET studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | Mean or Median Age and Range (Years) | % 65 or Older | % Post-menopausal | % Palpable | Tumor Size Mean (Range) |
|---|---|---|---|---|---|---|---|
| Hienisch et al. 2003[24] | Women with suspicious breast lesions detected by physical exam, mammography, and/or ultrasound, scheduled for biopsy, referred when there was time on the scanners. Pregnant women were excluded. | 36 | Mean: 48.3<br>Range:<br>25 to 77 | NR | NR | NR | 16.7 mm<br>(5 to 45 mm) |
| Walter et al. 2003[25] | Patients referred to the clinic for biopsy of suspicious lesions on the basis of mammography, ultrasound, or physical examination. Referred patients were chosen randomly from 550 possible patients to fill restricted scanner time. | 44 | Mean: 52<br>Range:<br>21 to 77 | NR | NR | NR | Mean NR<br>(0.5 to 6.0 cm) |
| Brix et al. 2001[31] | Women with suspicious breast lesions detected by physical exam, mammography, and/or ultrasound, scheduled for biopsy, referred when there was time on the scanners. Women with lesions smaller than 10 mm, elevated blood glucose, younger than age 18, pregnant, or had metal implants were excluded. | 14 | Mean: 49<br>Range:<br>35 to 66 | NR | NR | NR | Excluded lesions <10 mm<br>Mean and range NR |

**Table 9. PET studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | Mean or Median Age and Range (Years) | % 65 or Older | % Post-menopausal | % Palpable | Tumor Size Mean (Range) |
|---|---|---|---|---|---|---|---|
| Schirrmeister et al. 2001[44] | Women with palpable breast tumors or suspicious lesions on mammography and/or ultrasound. Pregnant women and women younger than 18 were excluded from the study. | 117 | Mean: 56.8<br>Range:<br>28 to 86 | NR | 51.3% | 76% | Not reported for all tumors |
| Yutani et al. 2000[45] | Patients with suspicious lesions (detected by mammography, ultrasound, or physical exam) scheduled for excisional biopsy. | 40 | Mean: 51<br>Range:<br>25 to 86 | 15% | NR | 93% | 21 mm<br>(4 to 45 mm) |

CT Computer tomography
FDG 18-fluorodeoxyglucose
NR Not reported
PET Positron emission tomography

**Table 10. Details of PET methodology**

| Study | Type of Scanner | PET Parameters | Tracer FDG Parameters | Reference Standard |
|---|---|---|---|---|
| Imbriaco et al. 2008[6] | Whole body PET/CT | Prone position, 60 minutes after injection (Time 1) and 3 hours after injection (Time 2) CT images were reconstructed using standard iterative algorithm | 5.2 MBq/kg of body weight, fast of 6 to 8 hours | Biopsy or surgery |
| Kaida et al. 2008[42] | Whole body | Supine position, 60 minutes after tracer followed by prone imaging 85 minutes after tracer | 263 MBq, fast of at least 4 hours | Biopsy or surgery<br>Benign patients followed for up to 2 years |
| Buchmann et al. 2007[43] | Whole body | Supine position, 60 minutes after tracer followed by prone imaging 135 minutes after tracer. | 263 (±15) MBq, injected in fasting state (total fast time not reported) | All surgery |
| Hienisch et al. 2003[24] | Whole body | Prone position, 70 minutes after tracer | 120 to 180 MBq, fast of 12 hours or longer | All surgery |
| Walter et al. 2003[25] | Whole body | Prone position, 40 to 60 minutes after tracer | 300 to 370 MBq, fast of 12 hours or longer | All surgery |
| Brix et al. 2001[31] | Whole body | Prone position, 60 minutes after tracer | 138 to 248 MBq, fast of 6 hours or longer | Biopsy or surgery |
| Schirrmeister et al. 2001[44] | Whole body | Prone position, 45 to 60 minutes after tracer | 370 MBq, fast of 8 hours | Biopsy or surgery |
| Yutani et al. 2000[45] | Whole body | Supine position, 60 minutes after tracer | 370 MBq, fast of 4 hours or longer | All surgery |

CT Computed tomography
FDG 18-fluorodeoxyglucose
MBq Mega becquerel
NR Not reported
PET Positron emission tomography

**Table 11. PET Studies: information for meta-regressions**

| Study | Patient Position (1 = Prone) | Palpable Lesions Only (1 = All Palpable) | Readers Blinded to Clinical Information (1 = Yes) | All Diagnoses Confirmed by Histopathology (1 = Yes) |
|---|---|---|---|---|
| Kaida et al. 2008[42] | 1 | 1 | 1 | 1 |
| Buchmann et al. 2007[43] | 1 | 0 | 0 | 0 |
| Hienisch et al. 2003[24] | 1 | 0 | 0 | 0 |
| Walter et al. 2003[25] | 1 | 0 | 0 | 0 |
| Brix et al. 2001[31] | 1 | 0 | 0 | 0 |
| Schirrmeister et al. 2001[44] | 1 | 1 | 1 | 0 |
| Yutani et al. 2000[45] | 0 | 1 | 1 | 0 |

# Scintimammography (SMM)

Total of 11 studies

Total of 1,074 patients, 1,074 lesions

10 studies of conventional SMM, 1 study of BSG1

**Table 12. Included studies of scintimammography**

| Study | SMM Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funding Source |
|---|---|---|---|---|---|---|
| Grosso et al. 2009[46] | SMM at 5 minutes after administration of 99m Tc sestamibi, planar images with patient supine and prone. | Prospective diagnostic cohort | 283 | 283 | Italy | NR |
| Habib et al. 2009[47] | Double-phase SMM images were acquired 5-10 minutes and one hour after administration of with 99m Tc sestamibi, planar images patients prone and supine | Prospective diagnostic cohort | 22 | 22 | Karachi | NR |
| Kim et al. 2009[4] | Double-phase SMM at 10 minutes and 3 hours after 99m Tc sestamibi administration, planar images in prone and lateral positions. | Prospective diagnostic cohort | 249 | 249 | Republic of Korea | Pusan National University Research Grant |
| Kim et al. 2008[48] | Double-phase SMM images after 10 minutes and three hours after IV administration of 99m Tc sestamibi; planar images with patient in the lateral and prone positions and planar anterior chest image with patient in supine position | Prospective diagnostic cohort | 75 | 75 | Republic of Korea | NR |
| Wang et al. 2008[49] | SMM with 99mTc-MIBI; planar images with patient supine (anterior and oblique views) and prone (lateral views) | Prospective diagnostic cohort | 55 | 55 | China | Jiangsu Government Science Grant and Nanjing Health Bureau Grant, China |

**Table 12. Included studies of scintimammography (continued)**

| Study | SMM Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funding Source |
|---|---|---|---|---|---|---|
| Brem et al. 2007[9] | BSGI 10 minutes after 99mTc-sestamibi injection, images were obtained in the cranial caudal and medial lateral oblique projections | NR | 33 | 33 | U.S. | NR |
| Gommans et al. 2007[50] | SMM mages were taken 5 minutes after injection of 99m Tc sestamibi; anterior, left and right lateral images (10 minute acquisition, 256x256), patient supine and prone | Prospective diagnostic cohort | 101 | 101 | Netherlands | NR |
| Kim et al. 2007[51] | Double-phase SMM performed 10 minutes and 3 hrs after IV 99m Tc sestamibi; Planar images, patient prone and lateral and anterior chest images in the supine position. | Prospective diagnostic cohort | 78 | 78 | South Korea | Pusan National University Research Grant |
| Schillaci et al. 2007[52] | 99m Tc sestamibi; planar images were acquired (left and right lateral images with patient prone and an anterior chest image, with patient supine) | Prospective diagnostic cohort | 53 | 53 | Italy | NR |
| Pinero et al. 2006[53] | Double-phase Sestamibi gammagraphy; planar images 5 minutes and one hour after injection of 99m Tc sestamibi, patient prone and supine | Prospective diagnostic cohort | 88 | 88 | Spain | NR |
| Mathieu et al. 2005[54] | Patient supine 10 minutes after 99mTc-MIBI, and prone position, 256x256 matrix, SPECT and planar images | Retrospective chart review | 37 | 37 | Belgium | NR |

U.S. United States

**Table 13. Scintimammography studies: patient and lesion details**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size |
|---|---|---|---|---|---|---|---|---|---|
| Grosso et al. 2009[46] | Patients with non-palpable breast lesions (microcalcifications) detected on screening mammography. Other inclusion criteria: SMM within 2 weeks after conventional mammography, breast lesion operated upon within 1 month after SMM; a minimum follow-up of 5 years after SMM; mental capacity and age above 18 years.<br>Exclusion criteria: a palpable lesion suspicious of malignancy; palpable nodes in the axillary region; a history of prior carcinoma; prior FNA or CNB within one week prior to SMM, pregnancy and lactation. | 283 | 283 | 283 | 53 ±8.2 | 32-79 | 11.3% | 0% | NR |

**Table 13. Scintimammography studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size |
|---|---|---|---|---|---|---|---|---|---|
| Habib et al. 2009[47] | Women with a palpable mass or lump or with positive or indeterminate findings on mammography. Exclusion criteria: medically unstable patients; lactating or pregnant women; patients with a history of surgery within the past week. | 22 | 22 | 22 | Mean: 36.5<br>Median: 40.0 | 17 to 80 | 68.2% | 90.9% | NR |
| Kim et al. 2009[4] | Patients with palpable masses on physical examination and/or suspicious mammographic findings. No exclusion criteria presented. | 249 | 239 | 239 | 47 ±9.7 | NR | 85.3% | 85.3% | Malignant: 0.3 to 3.5 cm, Mean: 1.61 ±0.69 cm<br>Benign: 0.7 to 3.5, Mean: 1.87 ±0.67 cm |
| Kim et al. 2008[48] | Patients with palpable breast masses on physical examination and/or suspicious mammograms. No exclusion criteria presented. | 75 | 75 | 75 | 46.9 ±9.5 | NR | 65.3% | 54.7% | NR |
| Wang et al. 2008[49] | Patients with palpable breast lesions. No exclusion criteria presented. | 55 | 55 | 55 | 48 ±14.7 | 7 to 77 | 67.3% | 100% | NR |

**Table 13. Scintimammography studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size |
|---|---|---|---|---|---|---|---|---|---|
| Brem et al. 2007[9] | Indeterminate breast findings that required BSGI and MRI follow-up as determined by the patient's clinician. No exclusion criteria presented. | 33 | 33 | 33 | 53 ±10 | 33 to 70 | 27.3% | NR | Malignant lesions ranged from 8 mm to extensive and multifocal |
| Gommans et al. 2007[50] | Patients with non-palpable lesions on mammography suspicious for malignancy, over 18 years of age and with the mental capacity to participate in the study. Exclusion criteria included a palpable lesion suspicious for malignancy, palpable nodes in the axillary region, a history of prior carcinoma, prior thin needle biopsy, pregnancy and lactation. | 101 | 101 | 101 | 61 ±7.3 | 50 to 75 | 44.6% | 0% | NR |
| Kim et al. 2007[51] | Women with indeterminate US findings. No exclusion criteria presented. | 78 | 78 | 78 | 49.6 ±6.8 | NR | 84.6% | NR | 0.8 to 7.5 cm |

**Table 13. Scintimammography studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size |
|---|---|---|---|---|---|---|---|---|---|
| Schillaci et al. 2007[52] | Patients with suspicious lesions on mammography. No exclusion criteria presented. | 53 | 53 | 53 | NR | 27 to 78 | 69.8% | 60.4% | NR |
| Pinero et al. 2006[53] | Palpable or non-palpable lesions with a BIRADS score of either 4 or 5 on mammography. Excluded were men and pregnant women. | 88 | 88 | 88 | 57.65 | 33 to 87 | 77.3% | 64.8% | NR |
| Mathieu et al. 2005[54] | Patients with inconclusive/ contradictory triple screen (mammography, US, FNA) result. Retrospective chart review. No exclusion criteria presented. | 37 | 37 | 37 | NR | NR | 54.1% | NR | NR |

FNA Fine-needle aspiration
NR Not reported
US Ultrasound

**Table 14. Details of scintimammography methods**

| Study | Tracer | Imager Specifications | Brand | Type of Imaging | Matrix | Method |
|---|---|---|---|---|---|---|
| Grosso et al. 2009[46] | 740 MBq $^{99m}$Tc-sestamibi | A dual head large fied of view gamma camera equipped with low energy, high resolution collaminators | GE Medical Systems Millennium MG, Milwaukee, WI, USA | Planar images with patient supine and prone. | 256 x 256 pixels | Not specified |
| Habib et al. 2009[47] | 740 MBq (20 mCi) Tc-99m sestamibi | Single headed gamma camera equipped with a low energy all purpose collimator | NR | Planar images with patients prone and supine | NR | Double-phase SMM at 10 mins and 60-90 mins |
| Kim et al. 2009[4] | 925 MBq Tc-99m MIBI | Dual headed gamma camera equipped with low energy high resolution collimators | Vertex™, ADAC, Milpitas, CA, USA) | Planar images in prone and lateral positions. | 128 x 128 pixels | Double-phase SMM at 10 minutes and 3 hours |
| Kim et al. 2008[48] | 925 MBq Tc-99m MIBI | Dual headed gamma camera equipped with low energy high resolution collimators | Vertex™, ADAC, Milpitas, CA, USA) | Planar images with patient in the lateral and prone positions and planar anterior chest image with patient in supine position | 128 x 128 pixels | Double-phase SMM images after 10 minutes and three hours |
| Wang et al. 2008[49] | 740 MBq (20mCi) $^{99m}$ Tc-MIBI | Dual headed gamma camera equipped with a high resolution parallel hole collimator | Millennium VG, Hawkeye; General Electric Medical Systems | Planar images with patient supine (anterior and oblique views) and prone (lateral views) | 256 x 256 | Not specified |

**Table 14. Details of scintimammography methods (continued)**

| Study | Tracer | Imager Specifications | Brand | Type of Imaging | Matrix | Method |
|---|---|---|---|---|---|---|
| Brem et al. 2007[9] | 25.0-30.0 mCi $^{99m}$Tc-sestamibi (925-1110 MBq) | High resolution breast specific gamma camera | Dilon 6800, Dilon Technologies, Inc., Newport News, VA | Images were obtained in the cranial caudal and medial lateral oblique projections | Not reported | BSGI |
| Gommans et al. 2007[50] | 700 MBq 99mTc-sestamibi | One head used; Low energy high resolution collimator | GE-Millenium VG | To label 99mTc sestamibi, 99mTc pertechnetate in saline was added to Cardiolite; SMM mages were taken 5 minutes after injection; anterior, left and right lateral images (10 minute acquisition, 256x256), patient supine and prone | 256 x 256 | Not spcified |
| Kim et al. 2007[51] | 925 MBq of Tc-99m MIBI | Dual headed gamma camera equipped with low energy high resolution collimators | Vertex, ADAC, Milpitas, CA, USA | Planar images, patient prone and lateral and anterior chest images in the supine position. | 128 x 128 | Double-phase SMM performed 10 minutes and 3 hrs |

**Table 14. Details of scintimammography methods (continued)**

| Study | Tracer | Imager Specifications | Brand | Type of Imaging | Matrix | Method |
|---|---|---|---|---|---|---|
| Schillaci et al. 2007[52] | 740 MBq Tc-99m sestamibi | Combined SPECT/CT system composed of a dual head variable angle gamma camera. This system allowed for sequential interchangeable acquisition of nuclear medicine and CT images | Millenium VG and Hawkeye;General Electric Medical Systems, Milwaukee, WI, USA | 99m Tc sestamibi; planar images were acquired (left and right lateral images with patient prone and an anterior chest image, with patient supine) | 256 x 256 | SMM |
| Pinero et al. 2006[53] | 740 MBq (20 mCi) Cardiolite | gamma camera equipped with a high resolution collimator | Elscint SP6 | Planar images twith patient prone and supine | NR | Double-phase Sestamibi gamma-graphy |
| Mathieu et al. 2005[54] | 740 MBq (20 mCi) $^{99m}$Tc-MIBI | Triple head system using a high resolution lowenergy collimator | Multispect; Siemens | Patients in the supine and prone position | 256 x 256 | SPECT and planar images |

NR Not reported

**Table 15. Scintimammography studies: information for meta-regression**

| Study | Consecutive or All Enrollment (1 = Yes) | Readers Blinded to Clinical Information (1 = Yes) | All Diagnoses Confirmed by Histopathology (1 = Yes) | Percent Malignant |
|---|---|---|---|---|
| Grosso et al. 2009[46] | 1 | 1 | 0 | 11.3% |
| Habib et al. 2009[47] | 0 | 1 | 0 | 68.2% |
| Kim et al. 2009[4] | 1 | 0 | 0 | 85.3% |
| Kim et al. 2008[48] | 0 | 1 | 0 | 65.3% |
| Wang et al. 2008[49] | 1 | 1 | 1 | 67.3% |
| Gommans et al. 2007[50] | 1 | 1 | 0 | 44.6% |
| Kim et al. 2007[51] | 1 | 1 | 0 | 84.6% |
| Schillaci et al. 2007[52] | 0 | 0 | 1 | 69.8% |
| Pinero et al. 2006[53] | 1 | 0 | 1 | 77.3% |

# Ultrasound

**Included Studies of Ultrasound**

Total of 31 studies

Total of 8,642 patients; 9,044 lesions

Types of Ultrasound Studied: (many articles studied more than one type of ultrasound)

B-mode 2D grayscale: 21 studies

B-mode 2D grayscale contrast enhanced: 2 studies

B-mode 3D grayscale: 1 study

Color Doppler: 6 studies

Color Doppler, contrast enhanced: 2 studies

Combination of methods: 4 studies

Power Doppler: 9 studies

Power Doppler, contrast enhanced: 7 studies

Tissue harmonics: 1 study

**Table 16. Included studies of ultrasound**

| Study | US Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funding Source |
|---|---|---|---|---|---|---|
| Gokalp et al. 2009[55] | B-mode 2D grayscale, power Doppler, and combination of both methods | Prospective diagnostic cohort | 49 | 94 | Turkey | NR |
| Vassiou et al. 2009[8] | B-mode 2D grayscale | Prospective diagnostic cohort | 69 | 78 | Greece | NR |

**Table 16. Included studies of ultrasound (continued)**

| Study | US Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funding Source |
|---|---|---|---|---|---|---|
| Liu et al. 2008[56] | B-mode 2D grayscale, with and without contrast (with Sono Vue [Bracco, Italy]), and combination of both methods | Diagnostic cohort study | 108 | 108 | China | Authors report no financial conflicts of interest |
| Vade et al. 2008[57] | B-mode 2D grayscale | Retrospective chart review | 20 | 21 | USA | NR |
| Cha et al. 2007[58] | B-mode 2D grayscale and tissue harmonic imaging | Prospective diagnostic cohort | 88 | 91 | Korea | NR |
| Chala et al. 2007[59] | B-mode 2D grayscale | Retrospective chart review | 203 | 229 | Brazil | NR |
| Zhi et al. 2007[60] | B-mode 2D grayscale | Diagnostic cohort study | 232 | 296 | China | NR |
| Cho et al. 2006[61] | B-mode 2D and 3D grayscale | Prospective diagnostic cohort | 141 | 150 | Korea | NR |
| Pinero et al. 2006[53] | Combination power Doppler and color Doppler using a contrast agent (Levovist [Schering AG, Berlin, Germany]) | Prospective diagnostic cohort | 88 | 88 | Spain | NR |
| Ricci et al. 2006[16] | B-mode grayscale with and without contrast (with Sono Vue [Bracco, Italy]); also compared US to MRI | Prospective diagnostic cohort | 48 | 50 | Italy | NR |
| Forsberg et al. 2004[62] | B-mode 2D grayscale and power Doppler, with and without contrast (Levovist or Optison) | Diagnostic cohort study | 55 | 55 | USA | U.S. Army Medical Research and Material Command and National Institutes of Health |
| Meyberg-Solomayer et al. 2004[63] | B-mode 2D gray-scale | Prospective diagnostic cohort | 65 | 65 | Germany | NR |

**Table 16. Included studies of ultrasound (continued)**

| Study | US Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funding Source |
|---|---|---|---|---|---|---|
| Ozdemir et al. 2004[64] | Power Doppler, with or without contrast (Levovist) | Prospective diagnostic cohort | 80 | 81 | Turkey | NR |
| Chen et al. 2003[65] | B-mode 2D gray scale | Prospective diagnostic cohort | 32 | 32 | China | NR |
| Kook and Kwag 2003[66] | B-mode US and power Doppler, with and without contrast (Levovist) | Prospective diagnostic cohort | 36 | 36 | South Korea | NR |
| Marini et al. 2003[67] | B-mode 2D grayscale | Diagnostic cohort study | 238 | 238 | Italy | NR |
| Caruso et al. 2002[68] | Color Doppler with and without contrast (Levovist) | Prospective diagnostic cohort | 36 | 36 | Italy | NR |
| Koukouraki et al. 2001[69] | Color Doppler | Prospective diagnostic cohort | 116 | 116 | Greece | NR |
| Malich et al. 2001[35] | Combination of B-mode, power Doppler, and color Doppler; also compared US to MRI | Diagnostic cohort study | 94 | 100 | Sweden | NR |
| Milz et al. 2001[70] | Power Doppler | Prospective diagnostic cohort | 102 | 118 | Germany | NR |
| Reinikainen et al. 2001[71] | B-mode US and power Doppler, with and without contrast (Levovist) | Prospective diagnostic cohort | 63 | 69 | Finland | Finnish Breast Cancer Group and Cancer Society of Northern Finland |
| Moon et al. 2000[72] | Power Doppler, with and without contrast (Levovist) | Prospective diagnostic cohort | 69 | 69 | South Korea | Seoul National University Hospital Research Fund |

**Table 16. Included studies of ultrasound (continued)**

| Study | US Methods Studied | Design | N Patients | N Lesions | Geographical Location | Funding Source |
|---|---|---|---|---|---|---|
| Blohmer et al. 1999[73] | B-mode 2D gray-scale and color Doppler | Prospective diagnostic cohort | 200 | 200 | Germany | NR |
| Chao et al. 1999[74] | B-mode 2D gray-scale | Prospective diagnostic cohort | 3050 | 3093 | Taiwan | NR |
| Schroeder et al. 1999[75] | Power and color Doppler, with and without contrast (Levovist) | Prospective diagnostic cohort | 92 | 110 | Germany | NR |
| Albrecht et al. 1998[76] | Power Doppler, with or without contrast (EchoGen) | Prospective diagnostic cohort | 20 | 20 | United Kingdom | NR |
| Wilkens et al. 1998[77] | B-mode 2D gray-scale and color Doppler | Diagnostic cohort study | 53 | 55 | USA | NR |
| Buadu et al. 1997[78] | Color Doppler | Diagnostic cohort study | 114 | 117 | Japan | NR |
| Stavros et al. 1995[79] | B-mode 2D gray-scale | Prospective diagnostic cohort | 622 | 750 | USA | NR |
| Ciatto et al. 1994[80] | B-mode 2D gray scale | Prospective diagnostic cohort | 2079 | 2079 | Italy | NR |
| Perre et al. 1994[81] | B-mode 2D gray-scale | Prospective diagnostic cohort | 380 | 400 | Netherlands | NR |

NR Not reported
US Ultrasound
USA United States of America

**Table 17. Ultrasound studies: patient and lesion details**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size Mean (Range) |
|---|---|---|---|---|---|---|---|---|---|
| Gokalp et al. 2009[55] | Patients with solid breast lesions referred for US-guided core needle biopsy | 49 | 94 | 49 | 53.6 | 27 to 89 | 41.5% (39/94) | NR | 16.35 mm (5 to 35 mm) |
| Vassiou et al. 2009[8] | Women with suspicious lesions diagnosed by physical examination or mammography, referred for biopsy | 69 | 78 | 69 | 53 | 39 to 68 | 68% (53/78) | NR | NR |
| Liu et al. 2008[56] | Consecutive patients with US-visible breast lesions who were referred for open surgical biopsy | 108 | 108 | 104 | 44 | 19 to 86 | 41.3% (43/104) | NR | 2.4 cm (0.5 to 7.6 cm) |
| Vade et al. 2008[57] | Consecutive patients under the age of 20 with palpable breast masses | 20 | 21 | 21 | 14.8 | 13 to 19 | 0% | 100% | NR |
| Cha et al. 2007[58] | Consecutive patients with solid breast lesions that were visible on US who were scheduled to undergo biopsy due to findings on mammography and/or physical exam | 88 | 91 | 91 | 45 | 25 to 67 | 33% (30/91) | 32% | 13 mm (4 to 28 mm) |

**Table 17. Ultrasound studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size Mean (Range) |
|---|---|---|---|---|---|---|---|---|---|
| Chala et al. 2007[59] | Consecutive female patients with solid breast lesions who were referred for biopsy due to findings on mammography and/or physical exam | 203 | 229 | 229 | 56 | 30 to 77 | 22.7% (52/229) | 56.3% (129/229) | 19 mm (5 to 62 mm) |
| Zhi et al. 2007[60] | Consecutive patients with solid breast lesions | 232 | 296 | 296 | 42 | 17 to 87 | 29.4% (87/296) | NR | 15.5 mm (3.1 to 100.6 mm) |
| Cho et al. 2006[61] | Consecutive patients with solid breast lesions that were visible on US who were scheduled to undergo biopsy due to findings on mammography and/or physical exam | 141 | 150 | 150 | 46 | 25 to 71 | 40% (60/150) | 38.70% | 4 to 36 mm (range NR) |
| Pinero et al. 2006[53] | Consecutive patients who were scheduled to undergo biopsy due to findings on mammography and/or physical exam, who were not pregnant | 88 | 88 | 88 | 57.7 | 33 to 87 | 77% (68/88) | 65% | NR |
| Ricci et al. 2006[16] | Consecutive patients with breast lesions detected on mammography | 48 | 50 | 50 | 58 | 40 to 81 | 76% (38/50) | NR | NR |

**Table 17. Ultrasound studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size Mean (Range) |
|---|---|---|---|---|---|---|---|---|---|
| Forsberg et al. 2004[62] | Patients with solid breast lesions detected on mammography and/or physical exam, who were mentally stable, not pregnant, and not breast-feeding | 55 | 55 | 50 | 52 | 26 to 72 | 29% (16/55) | NR | NR |
| Meyberg-Solomayer et al. 2004[63] | Female patients with breast lesions | 65 | 65 | 65 | 54 | 16 to 96 | 64.6% (42/65) | NR | 21.5 mm (2 to 70 mm) |
| Ozdemir et al. 2004[64] | Patients with breast lesions that were not clearly cystic or benign, that were visible on US, who were likely to have followup data due to living near the study center, who were scheduled to undergo biopsy due to findings on mammography and/or physical exam | 80 | 81 | 69 | 47.3 | 19 to 75 | 40.5% (28/69) | 32% | 16.1 mm (6 to 44 mm) |
| Chen et al. 2003[65] | Patients with palpable lesions that had indeterminate mammographic results due to dense breasts | 32 | 32 | 32 | 44.6 | 34 to 55 | 75% (24/32) | 100% | NR |

**Table 17. Ultrasound studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size Mean (Range) |
|---|---|---|---|---|---|---|---|---|---|
| Kook and Kwag 2003[66] | Patients referred for diagnostic US after discovery of a palpable mass or mammographic abnormality that was 2 cm or smaller in diameter | 36 | 36 | 36 | 43.5 | 18 to 69 | 47% (17/36) | NR | 2 cm or less<br>Mean and range NR |
| Marini et al. 2003[67] | Consecutive patients with microcalcifications detected on mammography who were older than 27 years of age, and who had an US exam followed by either a biopsy or at least three years of clinical followup | 238 | 238 | 238 | 55 | 31 to 98 | 39% (94/238) | NR | NR |
| Caruso et al. 2002[68] | Patients with a single breast lesion 1 to 2 cm in diameter with no microcalcifications that was detected on mammography | 36 | 36 | 36 | 55 | 42 to 63 | 56% (20/36) | NR | 1 to 2 cm<br>Mean and range NR |

**Table 17. Ultrasound studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size Mean (Range) |
|---|---|---|---|---|---|---|---|---|---|
| Koukouraki et al. 2001[69] | Women with abnormal findings on screening mammography who were scheduled for an open surgical biopsy | 116 | 116 | 116 | NR | 25 to 78 | 74% (86/116) | 32.70% | NR |
| Malich et al. 2001[35] | Consecutive patients with equivocal mammographic abnormalities | 94 | 100 | 100 | NR | NR | 62% (62/100) | NR | NR |
| Milz et al. 2001[70] | Patients with indeterminate findings after mammography and examination who were referred for diagnostic US | 102 | 118 | 118 | 51 | 15 to 77 | 47% (55/118) | NR | NR |
| Reinikainen et al. 2001[71] | Patients with an US-visible breast lesion detected by palpation or mammography that was suggestive of malignancy or not conclusively benign | 63 | 69 | 65 | 51 | 20 to 81 | 52.3% (34/65) | 81.50% | NR |

**Table 17. Ultrasound studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size Mean (Range) |
|---|---|---|---|---|---|---|---|---|---|
| Moon et al. 2000[72] | Consecutive patients with suspicious non-palpable lesions detected on mammography who were scheduled to undergo surgical biopsy | 69 | 69 | 50 | 52 | 30 to 67 | 44% (22/50) | 0% | NR |
| Blohmer et al. 1999[73] | Patients referred for biopsy because of a suspicious breast lesion | 200 | 200 | 168 (regular US), 150 (Doppler US) | NR | NR | 49.5% (99/200) | NR | NR |
| Chao et al. 1999[74] | Patients with solid breast masses | 3,050 | 3,093 | 3,093 | 38.7 | 14 to 86 | 24% (733/3093) | NR | 2.1 cm (0.5 to 24 cm) |
| Schroeder et al. 1999[75] | Patients with clinically suspected breast tumors after mammography and examination | 92 | 110 | 110 | 46.1 | 17 to 79 | 65.5% (72/110) | NR | NR |
| Albrecht et al. 1998[76] | Patients with breast lesions | 20 | 20 | 20 | 47 | 22 to 74 | 55% (11/20) | NR | NR |
| Wilkens et al. 1998[77] | Patients with palpable masses; those with obvious simple cysts were excluded | 53 | 55 | 55 | NR | 13 to 81 | 40% (22/55) | 100% | NR |
| Buadu et al. 1997[78] | Consecutive patients referred for surgery due to breast masses or suspicious mammograms | 114 | 117 | 116 | 49 | 15 to 78 | 72.4% (84/116) | NR | NR |

**Table 17. Ultrasound studies: patient and lesion details (continued)**

| Study | Inclusion/Exclusion Criteria | N Patients | N Lesions | N Completed Study | Median or Mean Age (Years) | Age Range (Years) | % Lesions (n/N) Malignant | % Lesions Palpable | Lesion Size Mean (Range) |
|---|---|---|---|---|---|---|---|---|---|
| Stavros et al. 1995[79] | Patients with indeterminate mammographic findings of solid lesions; obviously malignant lesions were excluded | 622 | 750 | 750 | 47 | 18 to 88 | 16.7% (125/750) | NR | most were 1.5 cm or smaller<br>Mean and range NR |
| Ciatto et al. 1994[80] | Consecutive women with clinical or mammographic abnormalities who were referred for diagnostic US | 2,079 | 2,079 | 2,079 | 48 | 14 to 93 | 12.5% (259/2079) | NR | NR |
| Perre et al. 1994[81] | Female patients with palpable breast lesions | 380 | 400 | 400 | 49.3 | 13.7 to 98.9 | 43.5% (174/400) | 100% | NR |

NR Not reported
US Ultrasound

**Table 18. Ultrasound studies: details of methods**

| Study | US Method | US Device | US MHz | US Operators | Reference Standard |
|---|---|---|---|---|---|
| Gokalp et al. 2009[55] | B-mode 2D grayscale, power Doppler, and combination of both methods | ATL HDI 5000 (Philips-ATL Medical Systems, Bothell, WA) | 5 to 12 MHZ | One radiologist | Core needle biopsy followed by surgery or 2 years followup |
| Vassiou et al. 2009[8] | B-mode 2D grayscale | Technos, Esaote | 7 to 12 MHz | One radiologist | Core needle biopsy or surgery |
| Liu et al. 2008[56] | B-mode 2D grayscale, with and without contrast (with Sono Vue [Bracco, Italy]), and combination of both methods | HDI 5000 or iU22 (Phillips Medical Systems, Bothell, WA) | 4 to 7 or 8 MHZ | Two radiologists in consensus | Open surgical biopsy |
| Vade et al. 2008[57] | B-mode 2D gray-scale | Sequoia (Siemens Medical Solutions) | 7 to 15 MHz | NR | 14 had open biopsy, 3 had FNA, and 4 had 3 to 6 months of followup |
| Cha et al. 2007[58] | B-mode 2D gray-scale and tissue harmonic imaging | LIGIQ 700 (GE Medical Systems, Milwaukee, WI) | 5 to 13 MHz | One operator obtained all of the image, and then four other radiologists evaluated all images | Open sugery (n = 30) or core-needle biopsy and followup (n = 61) |
| Chala et al. 2007[59] | B-mode 2D gray-scale | HDI 3000 or 5000 (Phillips Ultrasound, Bothell, WA) or Logiq 700 (GE medical Systems, Milwaukee, WI) | 5 to 12 MHZ | One of three operators | Core-needle biopsy except 20 cases had FNA followed by 28 to 30 months of followup |
| Zhi et al. 2007[60] | B-mode 2D gray-scale | EUB-8500 (Hitachi Medical Corp., Tokyo, Japan) | 7.5 to 13.0 MHZ | 2 operators in consensus | Open surgical biopsy |

**Table 18. Ultrasound studies: details of methods (continued)**

| Study | US Method | US Device | US MHz | US Operators | Reference Standard |
|---|---|---|---|---|---|
| Cho et al. 2006[61] | B-mode 2D and 3D gray-scale | Voluson 530D (GE Kretz, Zipf, Austria) | 5 to 10 MHz | One operator obtained all of the image, and then three other radiologists evaluated all images | Open surgery (n = 78) or core-needle biopsy and followup (n = 72) |
| Pinero et al. 2006[53] | Combination power Doppler and color Doppler using a contrast agent (Levovist [Schering AG, Berlin, Germany]) | SSA-370 A Power Vision 6000 (Toshiba Corp.) | 6 to 11 MHz | One radiologist | Open surgery |
| Ricci et al. 2006[16] | B-mode grayscale with and without contrast (with Sono Vue [Bracco, Italy]); also compared US to MRI | Esatune (Esaote, Genova, Italy) | 5 to 10 MHz | Two radiologists in consensus | Open surgical biopsy |
| Forsberg et al. 2004[62] | B-mode 2D grayscale and power Doppler, with and without contrast (Levovist or Optison) | HDI 3000 (Philips Medical Systems, Bothell, WA), for 3D a LIS 6000A (Life Imaging Systems Inc., London, Ontario, Canada) | 5 to 10 MHz | One of two radiologists | Open surgical biopsy |
| Meyberg-Solomayer et al. 2004[63] | B-mode 2D gray-scale | HDI 3000 (ATL, Zipf, Austria) or Voluson 730 (General Electric, Bothell, WA) | 5 to 12 or 5 to 10 MHz | One operator, entire study | Core biopsy or lumpectomy |
| Ozdemir et al. 2004[64] | Power Doppler, with or without contrast (Levovist) | HDI 5000 (Phillips Medical Systems, Bothwell, WA) | 5 to 12 MHZ | One radiologist | Open surgical biopsy, core needle biopsy, or patient followup for at least 2 years |
| Chen et al. 2003[65] | B-mode 2D gray scale | Aloka 650 (Aloka, Tokyo, Japan) | 7.5 MHz | Two radiologists in consensus | Open surgical biopsy or excision |
| Kook and Kwag 2003[66] | B-mode US and power Doppler, with and without contrast (Levovist) | Logiq 700 (GE Medical Systems, Milwaukee, WI) | 9 to 12 MHz | Two radiologists in consensus | Open surgical or core needle biopsy |

**Table 18. Ultrasound studies: details of methods (continued)**

| Study | US Method | US Device | US MHz | US Operators | Reference Standard |
|---|---|---|---|---|---|
| Marini et al. 2003[67] | B-mode 2D grayscale | AU530 (Esaote, Genoa, Italy) | 10 to 13 MHz | Two radiologists in consensus | Core biopsy or at least three years followup |
| Caruso et al. 2002[68] | Color Doppler with and without contrast (Levovist) | ATL HDI 5000 (Philips-ATL Medical Systems, Bothell, WA) | 5 to 10 MHz | NR | Open surgical biopsy |
| Koukouraki et al. 2001[69] | color Doppler | Accuson 128XP/10 | 7.5 MHz | NR | Open surgery |
| Malich et al. 2001[35] | Combination of B-mode, power Doppler, and color Doppler; also compared US to MRI | HDI 5000 (ATL, Bothwell, WA) or SONOLINE Versa Pro (Siemens, Solna, Sweden) | 7.5 to 10 MHz | One of several operators | Histological examination |
| Milz et al. 2001[70] | Power Doppler | AU 4 Esaote (Biomedica, Milan, Italy) | 4.7 MHz | One of two radiologists | Open surgical biopsy or fine needle (n = 2) aspiration |
| Reinikainen et al. 2001[71] | B-mode US and power Doppler, with and without contrast (Levovist) | Power Vision (Toshiba) | 10 MHz | Two radiologists independently, then in consensus about disagreements | Open surgical biopsy |
| Moon et al. 2000[72] | Power Doppler, with and without contrast (Levovist) | HDI 3000 (Advanced Technology Laboratories, Bothell, WA) | 5 to 10 MHz | Two radiologists in consensus | Open surgical biopsy |
| Blohmer et al. 1999[73] | B-mode 2D gray-scale and color Doppler | NR | NR | NR | Open surgical biopsy |
| Chao et al. 1999[74] | B-mode 2D gray-scale | Aloka SSD-2000 (Aloka, Tokyo, Japan) | 7.5 MHz | One of three operators | Histological examination |
| Schroeder et al. 1999[75] | Power and color Doppler, with and without contrast (Levovist) | Elegra (Siemens AG, Berlin, Germany) | 9.0 MHz | Two radiologists independently | Open surgery (n = 75), or 9 to 12 months of followup |
| Albrecht et al. 1998[76] | Power Doppler, with or without contrast (EchoGen) | Acuson 128 XP10 (Mountain View, CA) | 7.0 MHz | Two radiologists independently | Histological examination, FNA (n = 3), or followup six months (n = 1) |

**Table 18. Ultrasound studies: details of methods (continued)**

| Study | US Method | US Device | US MHz | US Operators | Reference Standard |
|---|---|---|---|---|---|
| Wilkens et al. 1998[77] | B-mode 2D gray-scale and color Doppler | Advanced Technologies Laboratory (Bothell, WA) | 10 MHz | One radiologist | Open surgical biopsy |
| Buadu et al. 1997[78] | Color Doppler | Toshiba SSA-260-A (Toshiba Ltd, Japan) | 7.5 MHz | NR | Open surgical biopsy |
| Stavros et al. 1995[79] | B-mode 2D gray-scale | Diasonics Spectra (Milpitas, CA), Advanced Technology Laboratories (High Definition Imaging, Bothell, WA) or Acoustic Imaging Modell 5200 (Phoeniz, AZ) | 7.5 to 10.0 MHz | One of five radiologists | Open surgery (44%) or core-needle biopsy (55%) |
| Ciatto et al. 1994[80] | B-mode 2D gray scale | Esaote (Esaote Ansaldo, Milano, Italy) | 10 MHz | One radiologist | Open surgical biopsy (n = 320) or 1 to 2 years of followup (n = 1,759) |
| Perre et al. 1994[81] | B-mode 2D gray-scale | Toshiba SSA-270-A (Toshiba Ltd, Japan) | 7.5 MHz | One operator, entire study | Open surgical biopsy except cysts |

2D Two dimensional
FNA Fine needle aspiration
MHz mega Hertz

**Table 19. Ultrasound studies: information for meta-regressions**

| Study | Consecutive or All Enrollment (1 = Yes) | Prospective Design (1 = Yes) | Probably Affected by Spectrum Bias[a] (1 = Yes) | Accounted for Interreader Differences (1 = Yes) | Readers Blinded to Clinical Information (1 = Yes) | All Diagnoses Confirmed by Histopathology (1 = Yes) | Funded by (1 = Declared No Financial Conflicts of Interest) | Geographic Region[b] | Proportion Malignant |
|---|---|---|---|---|---|---|---|---|---|
| Gokalp et al. 2009[55] | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 2 | 0.415 |
| Vassiou et al. 2009[8] | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 2 | 0.68 |
| Liu et al. 2008[56] | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0.413 |
| Vade et al. 2008[57] | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0% |
| Cha et al. 2007[58] | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 0.33 |
| Chala et al. 2007[59] | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 5 | 0.227 |
| Zhi et al. 2007[60] | 1 | 0 | 0 | 1 | 0 | 1 | 0 | 0 | 0.294 |
| Cho et al. 2006[61] | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 0.4 |
| Pinero et al. 2006[53] | 1 | 1 | 0 | 0 | 0 | 1 | 0 | 3 | 0.77 |
| Ricci et al. 2006[16] | 1 | 1 | 0 | 1 | 0 | 1 | 0 | 3 | 0.76 |
| Forsberg et al. 2004[62] | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 4 | 0.29 |

**Table 19. Ultrasound studies: information for meta-regressions (continued)**

| Study | Consecutive or All Enrollment (1 = Yes) | Prospective Design (1 = Yes) | Probably Affected by Spectrum Bias[a] (1 = Yes) | Accounted for Interreader Differences (1 = Yes) | Readers Blinded to Clinical Information (1 = Yes) | All Diagnoses Confirmed by Histopathology (1 = Yes) | Funded by (1 = Declared No Financial Conflicts of Interest) | Geographic Region[b] | Proportion Malignant |
|---|---|---|---|---|---|---|---|---|---|
| Meyberg-Solomayer et al. 2004[63] | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 3 | 0.645 |
| Ozdemir et al. 2004[64] | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 2 | 0.405 |
| Chen et al. 2003[65] | 0 | 1 | 0 | 1 | 0 | 1 | 0 | 0 | 0.75 |
| Kook and Kwag 2003[66] | 0 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 0.47 |
| Marini et al. 2003[67] | 1 | 0 | 1 | 1 | 1 | 0 | 0 | 2 | 0.39 |
| Caruso et al. 2002[68] | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 2 | 0.56 |
| Koukouraki et al. 2001[69] | 0 | 1 | 0 | 0 | 1 | 1 | 0 | 2 | 0.74 |
| Malich et al. 2001[35] | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0.62 |
| Milz et al. 2001[70] | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 3 | 0.47 |
| Reinikainen et al. 2001[71] | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 3 | 0.523 |
| Moon et al. 2000[72] | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 0.44 |

**Table 19. Ultrasound studies: information for meta-regressions (continued)**

| Study | Consecutive or All Enrollment (1 = Yes) | Prospective Design (1 = Yes) | Probably Affected by Spectrum Bias[a] (1 = Yes) | Accounted for Interreader Differences (1 = Yes) | Readers Blinded to Clinical Information (1 = Yes) | All Diagnoses Confirmed by Histopathology (1 = Yes) | Funded by (1 = Declared No Financial Conflicts of Interest) | Geographic Region[b] | Proportion Malignant |
|---|---|---|---|---|---|---|---|---|---|
| Blohmer et al. 1999[73] | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 3 | 0.495 |
| Chao et al. 1999[74] | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0.24 |
| Schroeder et al. 1999[75] | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 3 | 0.655 |
| Albrecht et al. 1998[76] | 0 | 1 | 0 | 1 | 1 | 0 | 0 | 3 | 0.55 |
| Wilkens et al. 1998[77] | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 4 | 0.4 |
| Buadu et al. 1997[78] | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 1 | 0.724 |
| Stavros et al. 1995[79] | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 4 | 0.164 |
| Ciatto et al. 1994[80] | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 2 | 0.125 |
| Perre et al. 1994[81] | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 3 | 0.435 |

[a] Spectrum bias defined as median/mean age greater than 50 and/or % lesions malignant less than 10% or greater than 40%
[b] China = 0; Asia = 1; Turkey, Greece, Italy = 2; Europe and United Kingdom = 3; North America = 4; South America = 5

# Data Analysis

## MRI

**Table 20. MRI accuracy data**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Akita et al. 2009[1] | All | 11 | 0 | 2 | 37 | 84.6% (57.6% to 95.4%) | 100.0% (90.3% to 99.9%) |
| Baltzer et al. 2009[2] | Readers | 202 | 51 | 59 | 139 | 77.4% (71.9% to 82.0%) | 73.2% (66.4% to 78.9%) |
| | CAD | 220 | 51 | 59 | 139 | 78.9% (73.7% to 83.2%) | 73.2% (66.4% to 78.9%) |
| Hara et al. 2009[3] | All | 26 | 6 | 3 | 58 | 89.7% (73.4% to 96.3%) | 90.6% (80.9% to 95.5%) |
| Kim et al. 2009[4] | All | 48 | 82 | 2 | 117 | 96.0% (86.4% to 98.8%) | 58.8% (51.8% to 65.4%) |
| Lo et al. 2009[5] | All | 19 | 1 | 1 | 10 | 95.0% (76.1% to 98.9%) | 90.9% (61.9% to 98.1%) |
| Imbracio et al. 2008[6] | All | 44 | 2 | 1 | 8 | 97.8% (88.3% to 99.5%) | 80.0% (48.9% to 94.0%) |
| Pediconi et al. 2008[7] | Gadopentetic acid | 24 | 8 | 8 | 10 | 75.0% (57.8% to 86.6%) | 55.6% (33.8% to 75.3%) |
| | Gadobenic acid | 31 | 5 | 1 | 13 | 96.9% (84.0% to 99.3%) | 72.2% (49.1% to 87.3%) |
| Vassiou et al. 2009[8] | All | 52 | 14 | 1 | 11 | 98.1% (89.9% to 99.6%) | 44.0% (26.7% to 62.9%) |
| Brem et al. 2007[9] | All | 9 | 18 | 0 | 6 | 100.0% (69.5% to 99.7%) | 25.0% (12.2% to 45.0%) |
| Cilotti et al. 2007[10] | Microcalcifications | 19 | 7 | 7 | 22 | 73.1% (53.8% to 86.2%) | 75.9% (57.8% to 87.6%) |
| Pediconi et al. 2007[11] | All | 211 | 15 | 0 | 4 | 100.0% (98.2% to 100.0%) | 21.1% (8.7% to 43.5%) |

**Table 20. MRI accuracy data (continued)**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Zhu et al. 2007[12] | Microcalcifications | 23 | 2 | 3 | 24 | 88.5% (70.8% to 95.8%) | 92.3% (75.6% to 97.7%) |
| Bazzocchi et al. 2006[13] | Microcalcifications | 65 | 12 | 10 | 25 | 86.7% (77.1% to 92.5%) | 67.6% (51.4% to 80.3%) |
| Gokalp and Topal 2006[14] | BIRADS 3 | 1 | 2 | 0 | 53 | 100.0% (20.8% to 99.2%) | 96.4% (87.5% to 98.9%) |
| Kneeshaw et al. 2006[15] | Microcalcifications | 15 | 7 | 5 | 61 | 75.0% (53.0% to 88.6%) | 89.7% (80.2% to 94.8%) |
| Ricci et al. 2006[16] | All | 38 | 2 | 0 | 11 | 100.0% (90.6% to 99.9%) | 84.6% (57.6% to 95.4%) |
| Pediconi et al. 2005[17] | All | 49 | 1 | 5 | 13 | 90.7% (80.0% to 95.9%) | 92.9% (68.2% to 98.5%) |
| Pediconi et al. 2005[18] | Gadopentetic acid | 29 | 0 | 9 | 8 | 76.3% (60.7% to 86.9%) | 100.0% (67.0% to 99.7%) |
| | Gadobenic acid | 36 | 1 | 2 | 7 | 94.7% (82.5% to 98.4%) | 87.5% (52.6% to 97.4%) |
| Wiener et al. 2005[19] | All | 68 | 14 | 1 | 36 | 98.6% (92.1% to 99.7%) | 72.0% (58.3% to 82.5%) |
| Bluemke et al. 2004[20] | All | 356 | 136 | 48 | 281 | 88.1% (84.6% to 90.9%) | 67.4% (62.7% to 71.7%) |
| | Premenopausal | 123 | 68 | 21 | 134 | 85.4% (78.7% to 90.2%) | 66.3% (59.6% to 72.5%) |
| | Postmenopausal | 222 | 72 | 38 | 142 | 85.4% (80.6% to 89.1%) | 66.4% (59.8% to 72.3%) |
| | Palpable | 194 | 51 | 19 | 81 | 91.1% (86.5% to 94.2%) | 61.4% (52.8% to 69.2%) |
| | Nonpalpable | 162 | 85 | 29 | 198 | 84.8% (79.0% to 89.2%) | 70.0% (64.4% to 75.0%) |

**Table 20. MRI accuracy data (continued)**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Bluemke et al. 2004[20] (continued) | Microcalcifications | 106 | 42 | 21 | 131 | 83.5% (76.0% to 88.9%) | 75.7% (68.8% to 81.5%) |
| | No microcalcifications | 232 | 84 | 25 | 129 | 90.3% (86.0% to 93.3%) | 60.6% (53.9% to 66.9%) |
| | Mostly fat | 49 | 25 | 5 | 27 | 90.7% (80.0% to 95.9%) | 51.9% (38.7% to 64.9%) |
| | Dense | 32 | 17 | 5 | 25 | 86.5% (71.9% to 94.0%) | 59.5% (44.5% to 72.9%) |
| Huang et al. 2004[21] | All | 18 | 12 | 0 | 20 | 100.0% (82.0% to 99.8%) | 62.5% (45.2% to 77.0%) |
| Bone et al. 2003[22] | All | 74 | 17 | 5 | 15 | 93.7% (85.9% to 97.2%) | 46.9% (30.9% to 63.5%) |
| Daldrup-Link et al. 2003[23] | All | 7 | 5 | 2 | 5 | 77.8% (45.1% to 93.3%) | 50.0% (23.8% to 76.2%) |
| Heinisch et al. 2003[24] | All | 23 | 2 | 4 | 11 | 85.2% (67.4% to 93.9%) | 84.6% (57.6% to 95.4%) |
| Walter et al. 2003[25] | All | 17 | 2 | 6 | 17 | 73.9% (53.4% to 87.3%) | 89.5% (68.4% to 96.8%) |
| Guo et al. 2002[26] | All | 28 | 2 | 2 | 15 | 93.3% (78.5% to 98.0%) | 88.2% (65.4% to 96.5%) |
| Kelcz et al. 2002[27] | All | 27 | 6 | 4 | 31 | 87.1% (71.0% to 94.7%) | 83.8% (68.8% to 92.2%) |
| Schedel et al. 2002[28] | All | 32 | 8 | 2 | 15 | 94.1% (80.7% to 98.2%) | 65.2% (44.9% to 81.1%) |
| Trecate et al. 2002[29] | Microcalcifications | 15 | 5 | 0 | 8 | 100.0% (79.2% to 99.8%) | 61.5% (35.5% to 82.1%) |
| Wiberg et al. 2002[30] | All | 77 | 17 | 5 | 15 | 93.9% (86.4% to 97.3%) | 46.9% (30.9% to 63.5%) |
| | Dense breasts | 17 | 9 | 1 | 5 | 94.4% (73.9% to 98.8%) | 35.7% (16.5% to 61.2%) |

**Table 20. MRI accuracy data (continued)**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Brix et al. 2001[31] | All | 8 | 1 | 2 | 2 | 80.0% (48.9% to 94.0%) | 66.7% (21.0% to 93.3%) |
| Cecil et al. 2001[32] | All | 22 | 2 | 1 | 13 | 95.7% (78.7% to 99.0%) | 86.7% (61.9% to 96.0%) |
| Furman-Haran et al. 2001[33] | All | 21 | 2 | 4 | 21 | 84.0% (65.2% to 93.4%) | 91.3% (73.0% to 97.4%) |
| Imbriaco et al. 2001[34] | All | 24 | 6 | 1 | 22 | 96.0% (80.2% to 99.1%) | 78.6% (60.4% to 89.6%) |
| | Younger than 50 yrs | 11 | 3 | 0 | 9 | 100.0% (73.6% to 99.7%) | 75.0% (46.7% to 90.8%) |
| | 50 and older yrs | 13 | 3 | 1 | 9 | 92.9% (68.2% to 98.5%) | 75.0% (46.7% to 90.8%) |
| | Lesion 10 mm or larger | 19 | 3 | 1 | 13 | 95.0% (76.1% to 98.9%) | 81.3% (56.8% to 93.2%) |
| | Lesion smaller than 10 mm | 5 | 3 | 0 | 5 | 100.0% (56.0% to 99.6%) | 62.5% (30.6% to 86.0%) |
| Malich et al. 2001[35] | All | 53 | 7 | 1 | 29 | 98.1% (90.1% to 99.6%) | 80.6% (64.9% to 90.1%) |
| Nakahara et al. 2001[36] | Microcalcifications | 19 | 3 | 1 | 17 | 95.0% (76.1% to 98.9%) | 85.0% (63.8% to 94.6%) |
| Torheim et al. 2001[37] | All | 57 | 7 | 13 | 50 | 81.4% (70.7% to 88.7%) | 87.7% (76.7% to 93.8%) |
| Wedegartner et al. 2001[38] | All | 37 | 4 | 7 | 14 | 84.1% (70.5% to 92.0%) | 77.8% (54.7% to 90.8%) |
| Yeung et al. 2001[39] | All | 22 | 1 | 2 | 5 | 91.7% (73.9% to 97.5%) | 83.3% (43.5% to 96.5%) |
| Kvistad et al. 2000[40] | All | 63 | 12 | 9 | 46 | 87.5% (77.8% to 93.2%) | 79.3% (67.2% to 87.7%) |

**Table 20. MRI accuracy data (continued)**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Van Goethem et al. 2000[41] | All | 19 | 8 | 1 | 29 | 95.0% (76.1% to 98.9%) | 78.4% (62.7% to 88.5%) |
| | Microcalcifications | 6 | 2 | 1 | 8 | 85.7% (48.4% to 97.0%) | 80.0% (48.9% to 94.0%) |

95% CI 95% confidence interval
FN False negative
FP False positive
TN True negative
TP True positive

META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES

Accuracy of MRI in General

SUMMARY DATA AND PERFORMANCE ESTIMATES

Bivariate Binomial Mixed Model

Number of studies = 41

Reference-positive Subjects = 2,209

Reference-negative Subjects = 1,843

Pretest Prob of Disease = 0.545

Between-study variance (varlogitSEN) = 0.831 (95% CI: 0.402 to 1.718)

Between-study variance (varlogitSPE) = 0.901 (95% CI: 0.493 to 1.649)

Correlation (Mixed Model) = -0.607

ROC Area, AUROC = 0.93 (95% CI: 0.90 to 0.95)

Heterogeneity (Chi-square): LRT_Q = 128.856, df = 2.00, LRT_p = 0.000

Inconsistency (I-square): LRT_$I^2$ = 98.4% (95% CI: 97.6 to 99.3%)

Summary Parameter Estimates (95% CI)

Sensitivity: 91.7% (88.5 to 94.1%)

Specificity: 77.5% (71.0 to 82.9%)

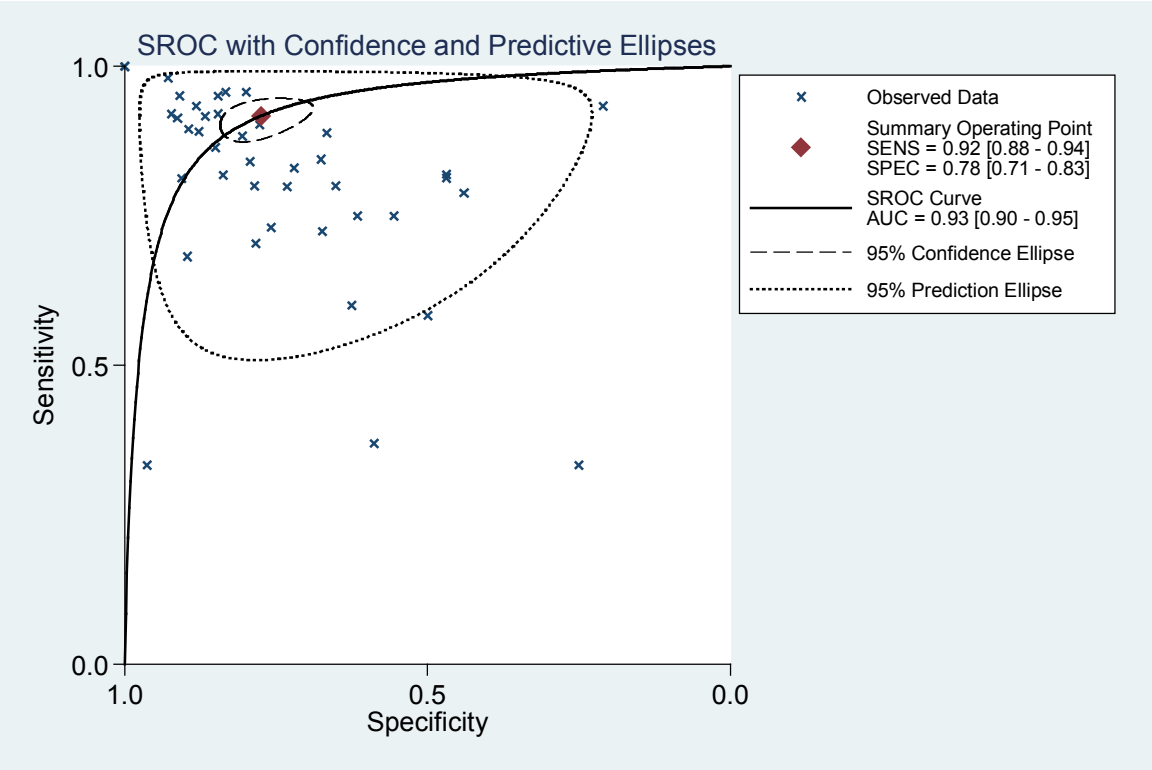
Positive Likelihood Ratio: 4.08 (3.10 to 5.30)

Negative Likelihood Ratio: 0.11 (0.079 to 0.15)

Diagnostic Score: 3.638 (3.253 to 4.023)

Diagnostic Odds Ratio: 38.008 (25.864 to 55.856)

**Figure 1. Summary ROC of MRI accuracy: all data**



## Exploration of Heterogeneity: Accuracy of MRI

### Meta-regressions of All Data

**Bivariate Model**

| Variable | p-Value |
|---|---|
| Prevalence of disease | 0.02 |
| Readers blinded to clinical information | 0.03 |
| Geographical location | 0.08 |
| Enrolled consecutive or all patients | 0.13 |
| Prospective design | 0.18 |
| All diagnoses verified by histopathology | 0.28 |
| Funding source | 0.36 |
| Multi-centered | 0.52 |
| Accounted for inter-reader differences | 0.56 |
| Spectrum bias | 0.64 |
| Magnet strength | 0.87 |
| Contrast agent | 0.97 |

**Statistically Significant Models**

| Parameter | Prevalence of Disease | Readers Blinded to Clinical Information |
|---|---|---|
| $I^2$ (95% CI) | 74.4% (43.5 to 100.0%) | 70.2% (33.7 to 100.0%) |
| Heterogeneity (LRTChi) | 7.80 | 6.72 |
| Sensitivity: | 96% | 87% |
| 95% CI | 91 to 98% | 80 to 92% |
| Coefficient | 3.23 | 1.93 |
| z | 2.69 | -2.04 |
| p of z | 0.01 | 0.04 |
| Specificity: | 56% | 75% |
| 95% CI | 36 to 73% | 63 to 85% |
| Coefficient | 0.23 | 1.12 |
| z | -3.55 | -0.39 |
| p of z | 0.00 | 0.70 |

**Subgroup Analyses of Statistically Significant Models**

Accuracy of Studies with Readers Blinded to Clinical Information vs. Not

META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES

SUMMARY DATA AND PERFORMANCE ESTIMATES

**Bivariate Binomial Mixed Model**

| Parameter | Blinded | Not Blinded (or Not Reported) |
|---|---|---|
| Number of studies | 13 | 28 |
| Number of patients | 1,289 | 2,763 |
| Prevalence of disease | 63.4% | 50.4% |
| $I^2$ | 89.9% | 98.1% |
| Sensitivity (95% CI) | 86.8% (82.1 to 90.4%) | 93.9% (90.0 to 96.4%) |
| Specificity (95% CI) | 74.7% (64.4 to 82.9%) | 78.0% (70.0 to 84.5%) |
| AUROC (95% CI) | 0.89 (0.86 to 0.92) | 0.94 (0.91 to 0.96) |

**Figure 2. Graph of MRI sensitivity and specificity relative to prevalence of disease**

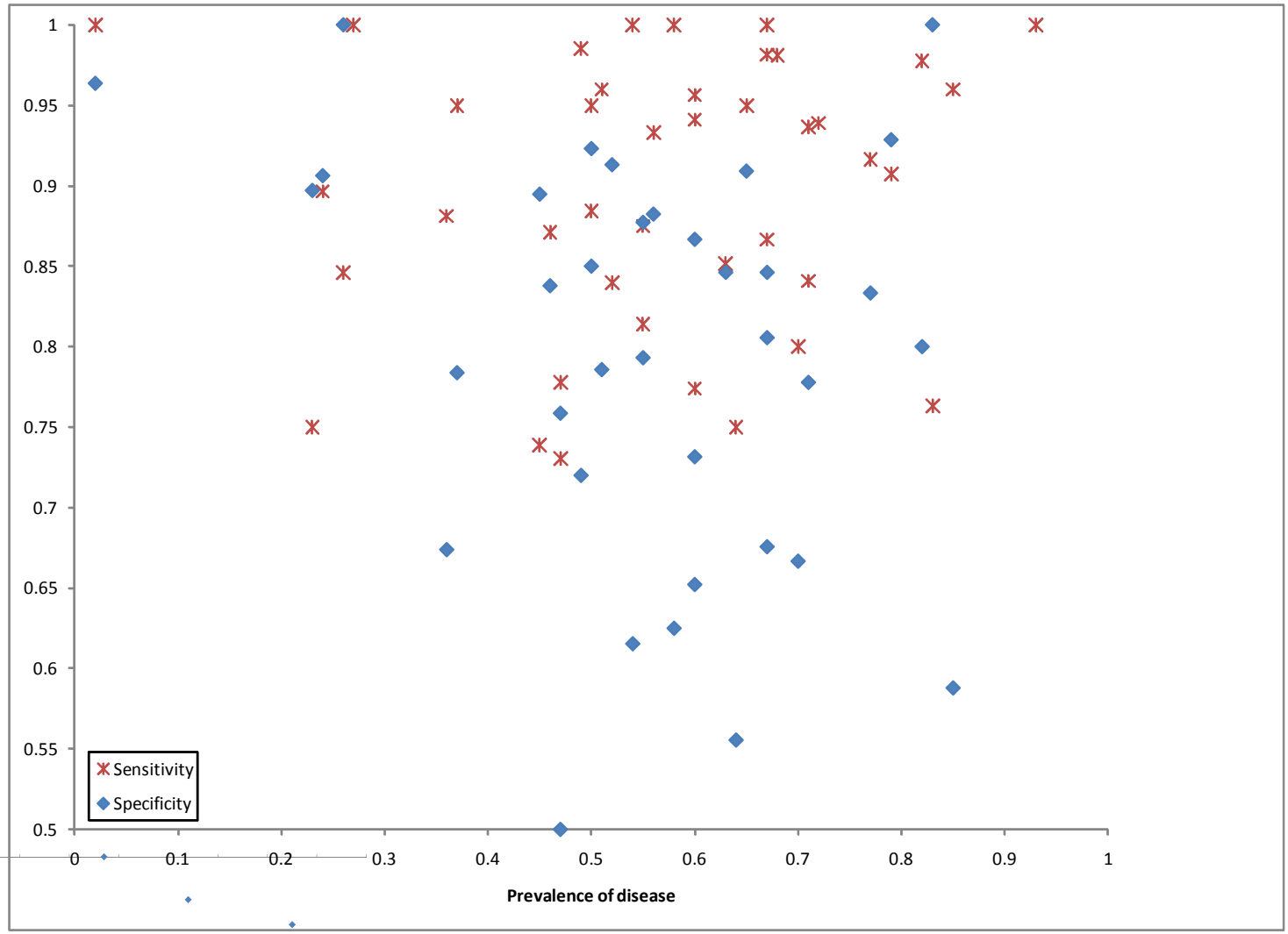
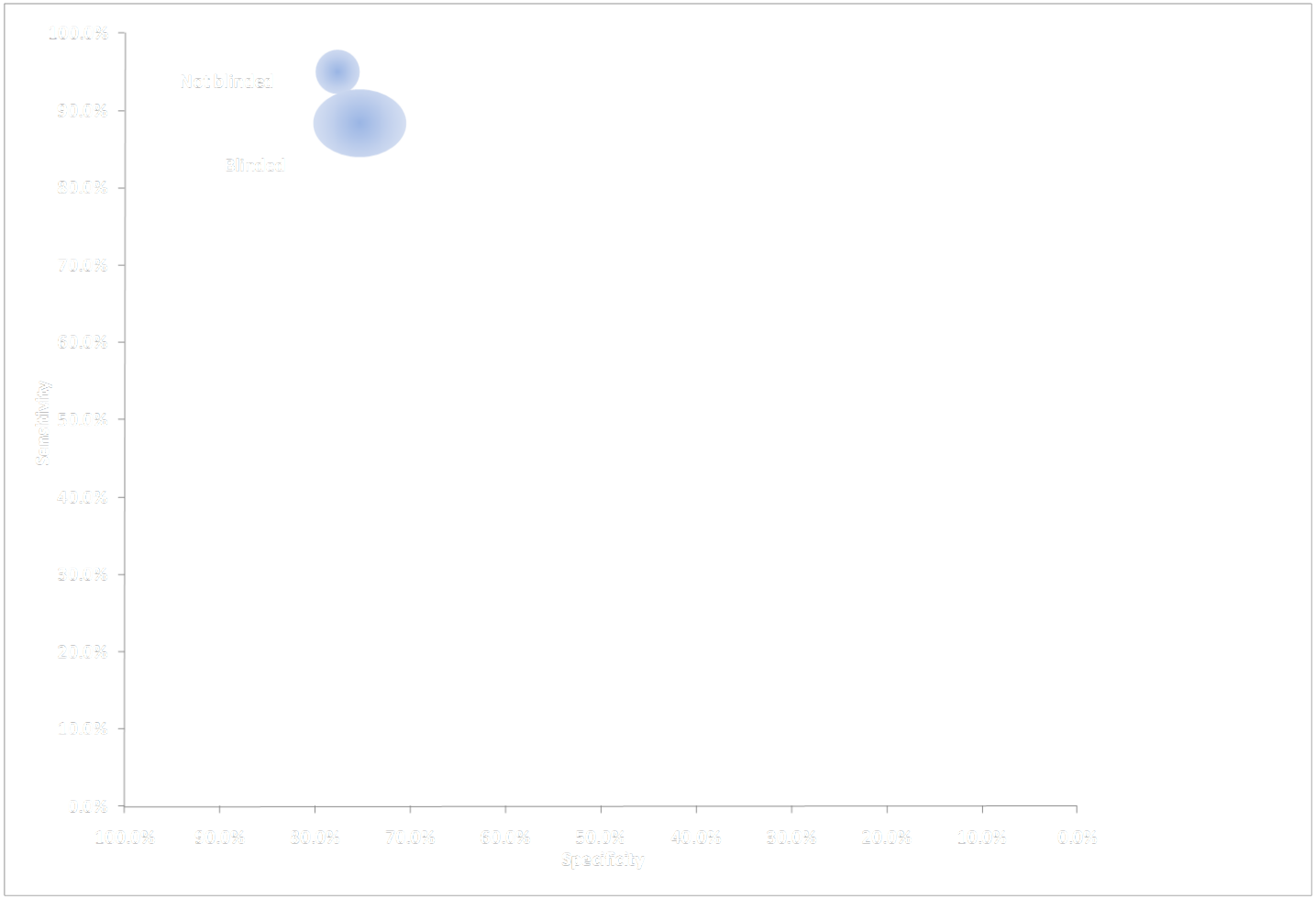


**Figure 3. Accuracy of MRI: blinded study design vs. not**



**Accuracy of Studies with Disease Prevalence Greater or Less than 60%**

META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES

SUMMARY DATA AND PERFORMANCE ESTIMATES

**Bivariate Binomial Mixed Model**

| Parameter | Prevalence >60% | Prevalence 60% or less[a] |
|---|---|---|
| Number of studies | 17 | 24 |
| Number of patients | 1,430 | 2,622 |
| Prevalence of disease | 65.5% | 44.5% |
| $I^2$ | 96.0% | 64.1 sensitivity; 82.3 specificity |
| Sensitivity (95% CI) | 93.8% (89.1% to 96.6%) | 86.3% (84.3% to 88.2%) |
| Specificity (95% CI) | 70.3% (58.1% to 80.1%) | 76.1% (73.7% to 78.3%) |
| AUROC (95% CI) | 0.91 (0.88 to 0.93) | 0.91 |

[a] Could not fit a bivariate model; individual parameters estimated using Meta-Disc

## Subgroup Analyses of MRI Data

## Methods Factors

### CAD assistance in interpreting images

**Table 21. Accuracy of MRI: CAD**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Baltzer et al. 2009[2] | Readers alone | 202 | 51 | 59 | 139 | 77.4% (71.9% to 82.0%) | 73.2% (66.4% to 78.9%) |
| | CAD assistance | 220 | 51 | 59 | 139 | 78.9% (73.7% to 83.2%) | 73.2% (66.4% to 78.9%) |

FN False negative
FP False positive
TN True negative
TP True positive

### Contrast agent

**Table 22. MRI accuracy: studies directly comparing different contrast agents**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Pediconi et al. 2008[7] | Gadopentetic acid | 24 | 8 | 8 | 10 | 75.0% (57.8% to 86.6%) | 55.6% (33.8% to 75.3%) |
| | Gadobenic acid | 31 | 5 | 1 | 13 | 96.9% (84.0% to 99.3%) | 72.2% (49.1% to 87.3%) |
| Pediconi et al. 2005[18] | Gadopentetic acid | 29 | 0 | 9 | 8 | 76.3% (60.7% to 86.9%) | 100.0% (67.0% to 99.7%) |
| | Gadobenic acid | 36 | 1 | 2 | 7 | 94.7% (82.5% to 98.4%) | 87.5% (52.6% to 97.4%) |

FN False negative
FP False positive
TN True negative
TP True positive

**Accuracy of Studies: Subgroup analysis comparison of Contrast Agents**

META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES

SUMMARY DATA AND PERFORMANCE ESTIMATES

**Bivariate Binomial Mixed Model**

| Parameter | Gadopentetic Acid | Gadodiamide | Gadobenic Acid | Gadoteridol[a] |
|---|---|---|---|---|
| Number of studies | 28 | 8 | 5 | 2 |
| Number of patients | 2,918 | 618 | 445 | 167 |
| Prevalence of disease | 52.1% | 46.0% | 83.8% | 60.5% |
| $I^2$ | 96.7% | 76.2% | 92.8% | 57.6% (sensitivity)<br>0.0% (specificity) |
| Sensitivity (95% CI) | 91.8% (88.0 to 94.4%) | 86.5% (81.4 to 90.4%) | 98.3% (90.9 to 99.7%) | 83.2% (74.4 to 89.9%) |
| Specificity (95% CI) | 74.4% (66.0 to 80.9%) | 87.8% (79.2 to 93.1%) | 75.5% (44.9 to 92.1%) | 71.2% (58.7 to 81.7%) |
| AUROC (95% CI) | 0.92 (0.89 to 0.94) | 0.91 (0.89 to 0.94) | 0.97 (0.95 to 0.98) | NA with only 2 studies |

[a] Could not fit a bivariate model; individual parameters estimated using Meta-Disc

## Patient Factors

**Table 23. Accuracy of MRI: miscellaneous patient factors**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Bluemke et al. 2004[20] | All | 356 | 136 | 48 | 281 | 88.1% (84.6% to 90.9%) | 67.4% (62.7% to 71.7%) |
| | Premenopausal | 123 | 68 | 21 | 134 | 85.4% (78.7% to 90.2%) | 66.3% (59.6% to 72.5%) |
| | Postmenopausal | 222 | 72 | 38 | 142 | 85.4% (80.6% to 89.1%) | 66.4% (59.8% to 72.3%) |
| Imbriaco et al. 2001[34] | All | 24 | 6 | 1 | 22 | 96.0% (80.2% to 99.1%) | 78.6% (60.4% to 89.6%) |
| | Younger than 50 years | 11 | 3 | 0 | 9 | 100.0% (73.6% to 99.7%) | 75.0% (46.7% to 90.8%) |
| | 50 and older years | 13 | 3 | 1 | 9 | 92.9% (68.2% to 98.5%) | 75.0% (46.7% to 90.8%) |

FN False negative
FP False positive
TN True negative
TP True positive

## Lesion Factors

**Microcalcifications on mammography**

**Accuracy of Studies: Subgroup analysis comparison of studies that enrolled patients with microcalcifications to all studies**

META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES

SUMMARY DATA AND PERFORMANCE ESTIMATES

**Bivariate Binomial Mixed Model**

| Parameter | All | Microcalcifications |
|---|---|---|
| Number of studies | 41 | 8 |
| Number of patients | 4,052 | 692 |
| Prevalence of disease | 54.5% | 45.7% |
| $I^2$ | 98.4% | 3.86% |
| Sensitivity (95% CI) | 91.7% (88.5% to 94.1%) | 84.0% (79.5% to 88.3%) |
| Specificity (95% CI) | 77.5% (71.0% to 82.9%) | 79.4% (71.5% to 85.6%) |
| AUROC (95% CI) | 0.93 (0.90 to 0.95) | 0.88 (0.85 to 0.91) |

**Figure 4. Summary ROC MRI: patients with microcalcifications on mammography**

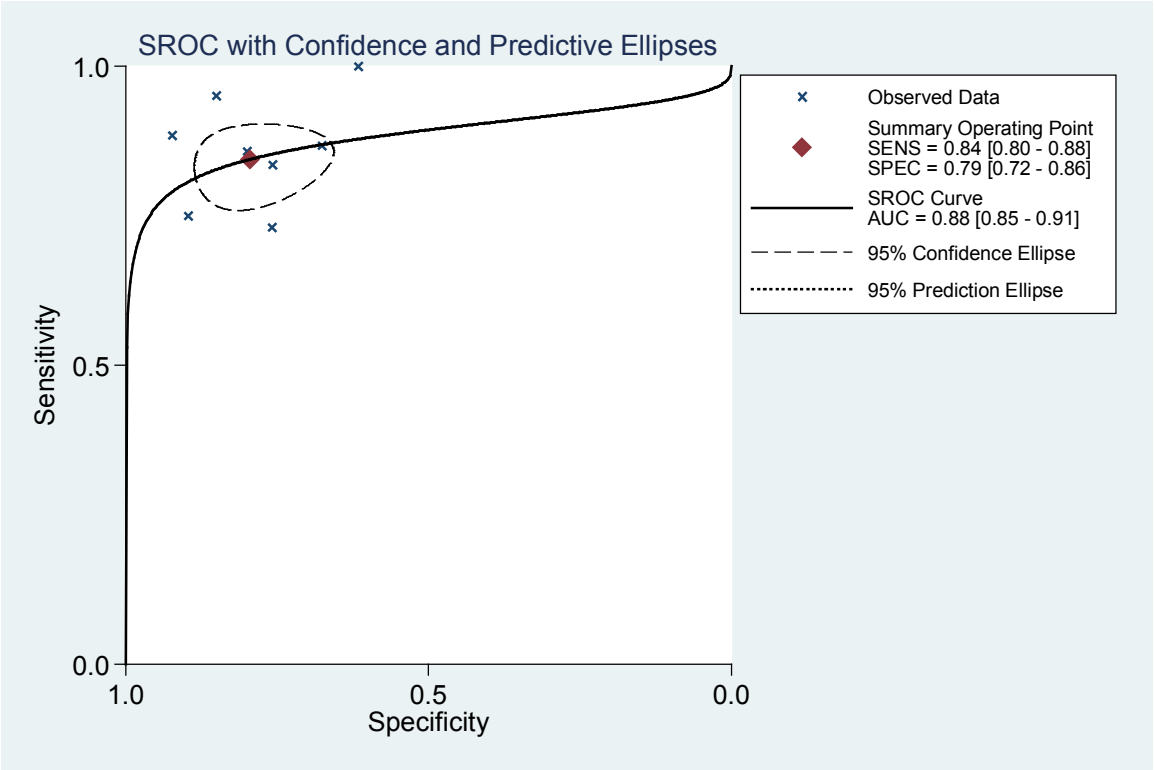


**Table 24. Accuracy of MRI for microcalcifications: studies that directly compared microcalcifications to other**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Bluemke et al. 2004[20] | No microcalcifications | 232 | 84 | 25 | 129 | 90.3% (86.0% to 93.3%) | 60.6% (53.9% to 66.9%) |
| | Microcalcifications | 106 | 42 | 21 | 131 | 83.5% (76.0% to 88.9%) | 75.7% (68.8% to 81.5%) |
| Van Goethem et al. 2000[41] | All | 19 | 8 | 1 | 29 | 95.0% (76.1% to 98.9%) | 78.4% (62.7% to 88.5%) |
| | Microcalcifications | 6 | 2 | 1 | 8 | 85.7% (48.4% to 97.0%) | 80.0% (48.9% to 94.0%) |

FN False negative
FP False positive
TN True negative
TP True positive

**Table 25. Accuracy of MRI: miscellanous lesion factors**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Gokalp and Topal 2006[14] | BIRADS 3 | 1 | 2 | 0 | 53 | 100.0% (20.8% to 99.2%) | 96.4% (87.5% to 98.9%) |
| Bluemke et al. 2004[20] | All | 356 | 136 | 48 | 281 | 88.1% (84.6% to 90.9%) | 67.4% (62.7% to 71.7%) |
| | Palpable | 194 | 51 | 19 | 81 | 91.1% (86.5% to 94.2%) | 61.4% (52.8% to 69.2%) |
| | Nonpalpable | 162 | 85 | 29 | 198 | 84.8% (79.0% to 89.2%) | 70.0% (64.4% to 75.0%) |
| | Mostly fat | 49 | 25 | 5 | 27 | 90.7% (80.0% to 95.9%) | 51.9% (38.7% to 64.9%) |
| | Dense | 32 | 17 | 5 | 25 | 86.5% (71.9% to 94.0%) | 59.5% (44.5% to 72.9%) |
| Wiberg et al. 2002[30] | All | 77 | 17 | 5 | 15 | 93.9% (86.4% to 97.3%) | 46.9% (30.9% to 63.5%) |
| | Dense breasts | 17 | 9 | 1 | 5 | 94.4% (73.9% to 98.8%) | 35.7% (16.5% to 61.2%) |
| Imbriaco et al. 2001[34] | All | 24 | 6 | 1 | 22 | 96.0% (80.2% to 99.1%) | 78.6% (60.4% to 89.6%) |
| | Lesion 10 mm or larger | 19 | 3 | 1 | 13 | 95.0% (76.1% to 98.9%) | 81.3% (56.8% to 93.2%) |
| | Lesion smaller than 10 mm | 5 | 3 | 0 | 5 | 100.0% (56.0% to 99.6%) | 62.5% (30.6% to 86.0%) |

FN False negative
FP False positive
TN True negative
TP True positive

## PET

**Table 26. PET accuracy data**

| Study | Position | Patient Subgroup | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Kaida et al. 2008[42] | Supine | All | 81 | 12 | 17 | 12 | 82.7% (73.7% to 89.6%) | 50.0% (29.1% to 70.9%) |
| | Prone | All | 109 | 4 | 5 | 4 | 95.6% (90% to 98.6%) | 50.0% (15.7% to 84.3%) |
| Buchmann et al. 2007[43] | Prone | All | 25 | 0 | 3 | 1 | 89.3% (71.8% to 97.7%) | 100.0% (02.5% to 100.0%) |
| Hienisch et al. 2003[24] | Prone | All | 17 | 4 | 8 | 11 | 68.0% (46.5% to 85.1%) | 73.3% (44.9% to 92.2%) |
| Walter et al. 2003[25] | Prone | All | 12 | 2 | 7 | 21 | 63.2% (38.4% to 83.7%) | 91.3% (72.0% to 98.9%) |
| Brix et al. 2001[31] | Prone | All | 8 | 2 | 1 | 2 | 88.9% (51.8% to 99.7%) | 50.0% (06.8% to 93.2%) |
| Schirrmeister et al. 2001[44] | Prone | All | 83 | 7 | 6 | 21 | 93.3% (85.9% to 97.5%) | 75.0% (55.1% to 89.3%) |
| Yutani et al. 2000[45] | Supine | All | 30 | 0 | 8 | 2 | 78.9 (62.7% to 90.4%) | 100.0% (15.8% to 100.0%) |
| | | BIRADS 5 | 26 | 0 | 2 | 2 | 93% (76.5% to 99.1%) | 100.0% (15.7% to 84.3%) |
| | | Lesion 1.5 cm or larger | 27 | 0 | 1 | 1 | 79.4% (62.1% to 91.3%) | 100.0% (02.5% to 100.0%) |
| | | Palpable lesion | 29 | 0 | 7 | 1 | 80.6% (64.0% to 91.8%) | 100.0% (02.5% to 100.0%) |
| | | Younger than 65 | 25 | 0 | 7 | 2 | 78.1% (60.0% to 90.7%) | 100.0% (15.8% to 100.0%) |

FN False negative
FP False positive
TN True negative
TP True positive

**Table 27. PET/CT accuracy data**

| Study | Time of Scan | Patient Subgroup | True Positive | False Positive | False Negative | True Negative | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|---|
| Imbriaco et al. 2007[6] | Early | All | 22 | 0 | 14 | 8 | 61.1% (43.5% to 76.9%) | 100% (63.1% to 100%) |
| | Late | All | 29 | 0 | 7 | 8 | 80.6% (64.0% to 91.8%) | 100% (63.1% to 100%) |
| | Early | Lesions >10 mm | NR | NR | NR | NR | 74.1% (53.7% to 88.9%) Reported by authors | 100.0% (63.1% to 100.0%) Reported by authors |
| | Late | Lesions >10 mm | NR | NR | NR | NR | 87.1% (70.2% to 96.4%) Reported by authors | 100.0% (39.8% to 100.0%) Reported by authors |
| | Early | Lesions <10 mm | NR | NR | NR | NR | 27.3% (06.0% to 61.0%) Reported by authors | 100.0% (66.4% to 100.0%) Reported by authors |
| | Late | Lesions <10 mm | NR | NR | NR | NR | 60.0% (32.3% to 83.7%) Reported by authors | 100.0% (47.8% to 100.0%) Reported by authors |

FN False negative
FP False positive
TN True negative
TP True positive

META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES

Accuracy of PET

SUMMARY DATA AND PERFORMANCE ESTIMATES

Bivariate Binomial Mixed Model

Number of studies = 7

Reference-positive Subjects = 306

Reference-negative Subjects = 97

Pretest Prob of Disease = 0.759

Between-study variance (varlogitSEN) = 0.308 (95% CI: 0.051-1.868)

Between-study variance (varlogitSPE) = 0.393 (95% CI: 0.043-3.623)

Correlation (Mixed Model) = -0.456

ROC Area, AUROC = 0.86 (95% CI: 0.82 to 0.89)

Heterogeneity (Chi-square): LRT_Q = 5.623, df = 2.00, LRT_p = 0.030

Inconsistency (I-square): LRT_$I^2$ = 64.4% (95% CI: 19.99 to 100.00%)

Summary Parameter Estimates (95% CI)

Sensitivity: 82.6% (73.5 to 89.1%)

Specificity: 73.9% (57.5 to 85.5%)

Positive Likelihood Ratio: 3.16 (1.86 to 5.38)

Negative Likelihood Ratio: 0.235 (0.15 to 0.37)

Diagnostic Score: 2.599 (1.794 to 3.404)

Diagnostic Odds Ratio: 13.449 (6.011 to 30.090)

**Figure 5. Summary ROC of PET**

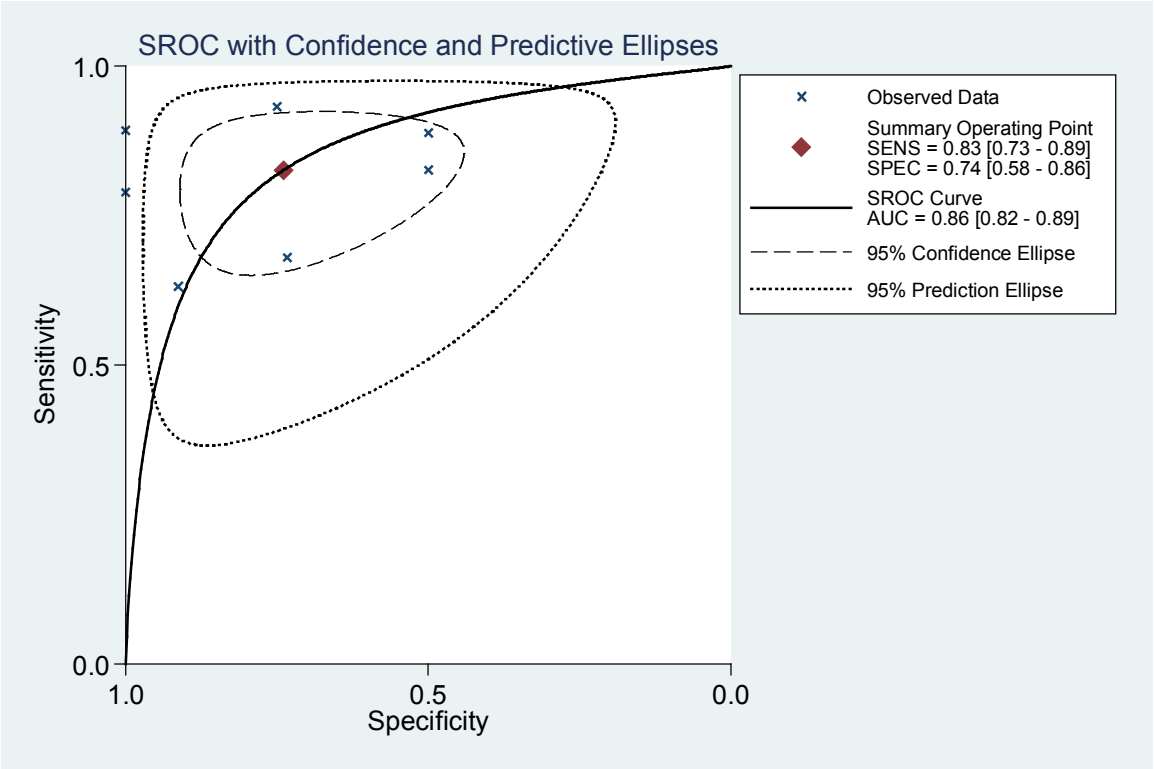



**Table 28. PET studies: results of meta-regression**

| Variable | p-Value |
|---|---|
| Patient postion | 0.52 |
| Palpable lesions only | 0.25 |
| Readers blinded to clinical information | 0.05 |
| All diagnoses verified by histopathology | 0.08 |

## Scintimammography

**Table 29. Accuracy of scintimammography**

| Study | Patient Subgroup | True Positive | False Negative | False Positive | True Negative | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Brem et al. 2007[9] | All patients | 8 | 1 | 7 | 17 | 88.9% (51.8 to 99.7) | 70.8% (48.9 to 87.4) |
| Grosso et al. 2009[46] | Nonpalpable lesions | 25 | 7 | 44 | 207 | 78.1% (60.0 to 90.7) | 82.5% (77.2 to 87.0) |
| Habib et al. 2009[47] | Palpable lesions | 14 | 1 | 2 | 5 | 93.3% (68.1 to 99.8) | 71.4% (29.0 to 96.3) |
| Kim et al. 2009[4] | All patients | 169 | 34 | 10 | 26 | 83.3% (77.4 to 88.1) | 72.2% (54.8 to 85.8) |
| Wang et al. 2008[49] | Palpable lesions | 34 | 3 | 12 | 6 | 91.9% (78.1 to 98.3) | 33.3% (13.3 to 59.0) |
| Kim et al. 2008[48] | All patients | 30 | 19 | 5 | 21 | 61.2% (46.2 to 74.8) | 80.8% (60.6 to 93.4) |
| Gommans et al. 2007[50] | Non-palpable lesions | 37 | 8 | 4 | 52 | 82.2% (67.9 to 92.0) | 92.9% (82.7 to 98.0) |
| Kim et al. 2007[51] | All patients | 57 | 9 | 0 | 12 | 86.4% (75.7 to 93.6) | 100% (75.3 to 100.0) |
| Schillaci et al. 2007[52] | All patients | 27 | 10 | 1 | 15 | 73.0% (55.9 to 86.2) | 93.8% (69.8 to 99.8) |
| Pinero et al. 2006[53] | All patients | 63 | 5 | 10 | 10 | 92.6% (83.7 to 97.6) | 50.0% (27.2 to 72.8) |
| Mathieu et al. 2005[54] | All patients | 19 | 1 | 5 | 12 | 95.0% (75.1 to 99.9) | 70.6% (44.0 to 89.7) |

FN False negative
FP False positive
TN True negative
TP True positive

**META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES**

Planar Scintimammography

SUMMARY DATA AND PERFORMANCE ESTIMATES

Bivariate Binomial Mixed Model

Number of studies = 9

Reference-positive Units = 552

Reference-negative Units = 442

Pretest Prob of Disease = 0.56

Between-study variance in sensitivity (ICC_SEN) = 0.09 (95% CI: 0.00-0.21)

Between-study variance in sensitivity (MED_SEN) = 0.63 (95% CI: 0.56-0.75)

Between-study variance in specificity (ICC_SPE) = 0.23 (95% CI: 0.00-0.46)

Between-study variance in specificity (MED_SPE) = 0.72 (95% CI: 0.62-0.86)

Correlation (Mixed Model) = -0.76

ROC Area, AUROC = 0.88 (95% CI: 0.85 to 0.91)

Heterogeneity (Chi-square): LRT_Q = 27.288, df = 2.00, LRT_p = 0.000

Inconsistency (I-square): 93.0 % (95% CI: 86.0% to 99.0%)

Summary Parameter Estimates (95% CI)

Sensitivity: 84.0% (76.0% to 89.0%)

Specificity: 79.0% (63.0% to 89.0%)

Positive Likelihood Ratio: 3.9 (2.2 to 6.8)

Negative Likelihood Ratio: 0.21 (0.15 to 0.29)

Diagnostic Odds Ratio: 19 (10 to 35)

**Figure 6. Summary ROC of scintimammography**

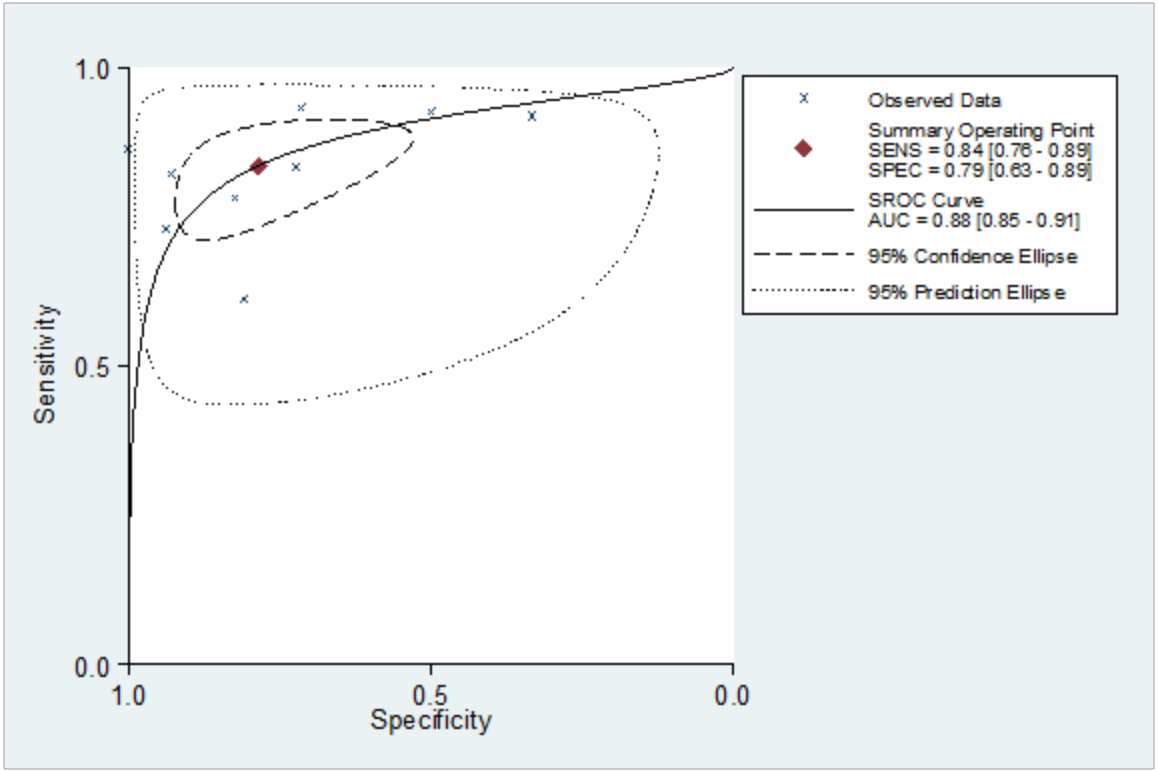



**Table 30. Scintimammography studies: results of meta-regression**

| Variable | p-Value |
|---|---|
| Consecutive or all enrollment | 0.11 |
| All diagnoses verified by histopathology | 0.24 |
| Readers blinded to clinical information | 0.93 |

## Ultrasound

### Ultrasound B-mode 2D grayscale

21 studies, 8,199 lesions

**Table 31. Ultrasound accuracy data: B-mode 2D grayscale**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Gokalp et al. 2009[55] | All | 39 | 23 | 0 | 32 | 100.0% (91.0% to 100.0%) | 58.2% (44.1% to 71.3%) |
| Vassiou et al. 2009[8] | All | 44 | 6 | 9 | 19 | 83.0% (70.7% to 90.7%) | 76.0% (56.5% to 94.3%) |
| Liu et al. 2008[56] | All | 41 | 15 | 2 | 46 | 95.3% (84.2% to 99.4%) | 75.4% (62.7% to 85.5%) |
| Vade et al. 2008[57] | Palpable lesions | 0 | 6 | 0 | 15 | Not calculated | Not calculated |
| Cha et al. 2007[58] | All | 29 | 23 | 1 | 38 | 96.7% (82.8% to 99.9% | 62.3% (49.0% to 74.4%) |
| Chala et al. 2007[59] | All | 51 | 96 | 1 | 81 | 98.1% (89.7% to 100.0%) | 45.8% (38.3% to 53.4%) |
| Zhi et al. 2007[60] | All | 62 | 56 | 25 | 153 | 71.3% (60.6% to 80.5%) | 73.2% (66.7% to 79.1%) |
| Cho et al. 2006[61] | All | 58 | 32 | 2 | 59 | 96.7% (88.5% to 99.6%) | 64.8% (54.1% to 74.6%) |
| Ricci et al. 2006[16] | All | 26 | 4 | 12 | 8 | 68.4% (51.3% to 82.5%) | 66.7% (34.9% to 90.1%) |
| Forsberg et al. 2004[62] | All | 10 | 5 | 14 | 24 | 41.7% (22.1% to 63.4%) | 82.8% (64.2% to 94.2%) |
| Meyberg-Solomayer et al. 2004[63] | All | 42 | 0 | 0 | 23 | 100.0% (91.6% to 100.0%) | 100.0% (85.2% to 100.0%) |
| Chen et al. 2003[65] | Palpable lesions | 22 | 5 | 2 | 3 | 91.7% (73.0% to 99.0%) | 37.5% (8.5% to 75.5%) |

**Table 31. Ultrasound accuracy data: B-mode 2D grayscale (continued)**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Kook and Kwag 2003[66] | 2 cm or less | 17 | 10 | 0 | 9 | 100.0% (80.5% to 100.0%) | 47.4% (24.4% to 71.1%) |
| Marini et al. 2003[67] | Microcalcifications | 81 | 96 | 13 | 48 | 86.2% (77.5% to 92.4%) | 33.3% (25.7% to 41.7%) |
| Reinikainen et al. 2001[71] | All | 34 | 28 | 0 | 3 | 100.0% (89.7% to 100.0%) | 9.7% (2.0% to 25.8%) |
| Blohmer et al. 1999[73] | All | 76 | 4 | 81 | 70 | 48.45 (40.4% to 56.5%) | 94.6% (86.7% to 98.5%) |
| Chao et al. 1999[74] | All | 639 | 797 | 103 | 1,554 | 86.1% (83.4% to 88.5%) | 66.1% (64.1% to 68.0%) |
| Wilkens et al. 1998[77] | Palpable lesions | 19 | 0 | 3 | 33 | 86.4% (65.1% to 97.1%) | 100.0% (89.4% to 100.0%) |
| Stavros et al. 1995[79] | All | 123 | 202 | 2 | 424 | 98.4% (94.3% to 99.8%) | 67.7% (63.9% to 71.4%) |
| Ciatto et al. 1994[80] | All | 176 | 42 | 84 | 1,777 | 76.7% (61.6% to 73.3%) | 97.7% (96.%9 to 98.3%) |
| Perre et al. 1994[81] | Palpable lesions | 168 | 4 | 4 | 211 | 97.7% (94.2% to 99.4%) | 98.1% (95.3% to 99.5%) |

FN False negative
FP False positive
TN True negative
TP True positive

**META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES**

Ultrasound B-mode Grayscale 2D

SUMMARY DATA AND PERFORMANCE ESTIMATES

Bivariate Binomial Mixed Model

Number of studies = 21

Reference-positive Subjects = 2,115

Reference-negative Subjects = 6,084

Pretest Prob of Disease = 0.258

Between-study variance (varlogitSEN) = 2.662 (95% CI: 1.162 to 6.096)

Between-study variance (varlogitSPE) = 2.455 (95% CI: 1.200 to 5.022)

Correlation (Mixed Model) = -0.331

ROC Area, AUROC = 0.92 (95% CI: 0.90 to 0.94)

Heterogeneity (Chi-square): LRT_Q = 612.405, df = 2.00, LRT_p = 0.000

Inconsistency (I-square): 99.7 % (95% CI: 99.6% to 99.78%)

Summary Parameter Estimates (95% CI)

Sensitivity: 92.4% (84.6% to 96.4%)

Specificity: 75.8% (60.8% to 86.3%)

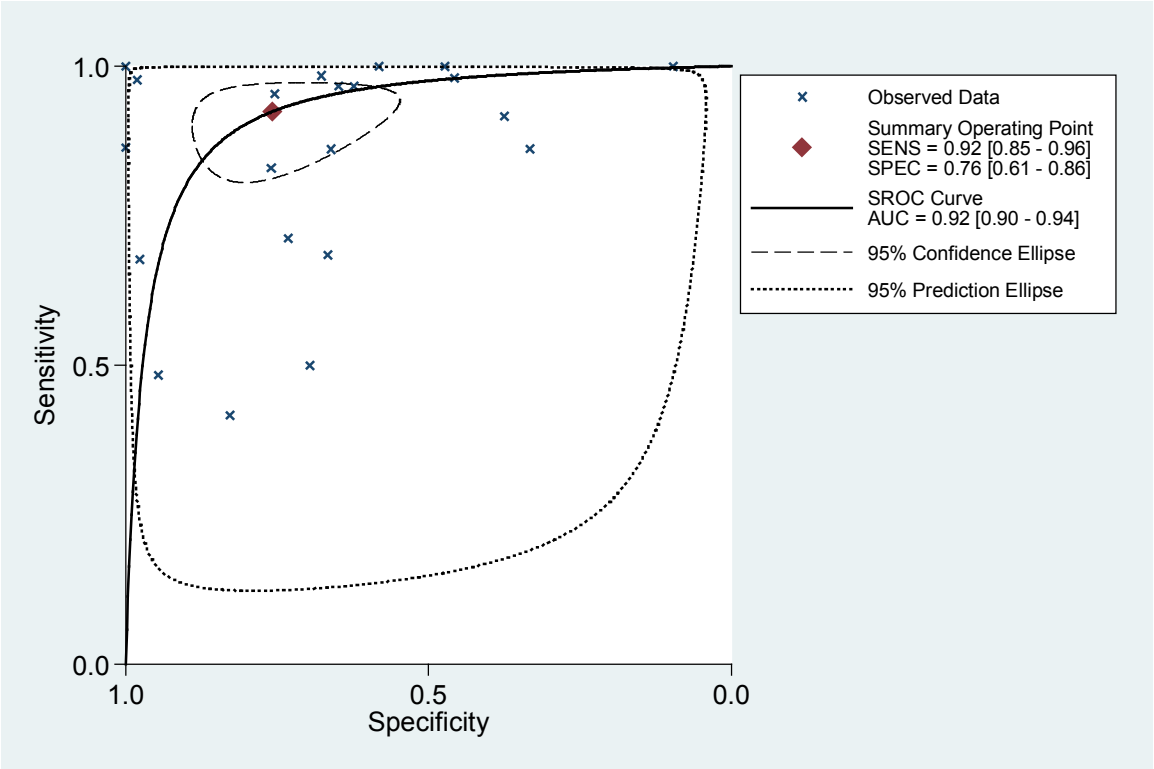
Positive Likelihood Ratio: 3.814 (2.272 to 0.964)

Negative Likelihood Ratio: 0.100 (0.049 to 0.203)

Diagnostic Score: 3.64 (2.738 to 6.403)

Diagnostic Odds Ratio: 38.083 (15.458 to 93.824)

**Figure 7. Bivariate binomial mixed-effects model of ultrasound B-mode grayscale 2D: summary ROC**



## Exploration of Heterogeneity

**Bivariate Model**

| Variable | p-Value |
|---|---|
| Accounted for inter-reader differences | 0.01 |
| Readers blinded to clinical information | 0.03 |
| All diagnoses verified by histopathology | 0.06 |
| Prospective design | 0.18 |
| Funding source | 0.20 |
| Enrolled consecutive or all patients | 0.40 |
| Geographical location | 0.53 |
| Type of lesion enrolled | 0.85 |
| Prevalence of disease | 0.86 |

**Statistically Significant Models**

| Parameter | Accounted for Inter-reader Differences | Readers Blinded to Clinical Information |
|---|---|---|
| $I^2$ (95% CI) | 76.8% (49.44 to 100.0%) | 72.1% (38.05% to 100.0%) |
| Heterogeneity (LRTChi) | 8.63 | 7.16 |
| Sensitivity: | 94% | 98% |
| 95% CI | 82% to 98% | 92% to 99% |
| Coefficient | 2.80 | 3.70 |
| z | 0.33 | 2.46 |
| p of z | 0.74 | 0.01 |
| Specificity: | 52% | 59% |
| 95% CI | 30% to 73% | 33% to 81% |
| Coefficient | 0.08 | 0.38 |
| z | -3.10 | -1.84 |
| p of z | 0.00 | 0.07 |

**Subgroup Analyses of Statistically Significant Models**

Accuracy of Studies with Readers Blinded to Clinical Information vs. Not

META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES

SUMMARY DATA AND PERFORMANCE ESTIMATES

**Bivariate Binomial Mixed Model**

| Parameter | Blinded | Not Blinded (or Not Reported) |
|---|---|---|
| Number of studies | 8 | 12 |
| Number of patients | 1,301 | 6,820 |
| Prevalence of disease | 38.6% | 22.9% |
| $I^2$ | 90.7% | 99.6% |
| Sensitivity (95% CI) | 96.6% (92.3% to 98.5%) | 87.0% (69.7% to 95.1%) |
| Specificity (95% CI) | 59.5% (32.2% to 82.0%) | 85.1% (69.0% to 93.6%) |
| AUROC (95% CI) | 0.96 (0.94 to 0.97) | 0.93 (0.90 to 0.95) |

Accuracy of Studies with Interreader Differences Accounted for vs. Not

META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES

SUMMARY DATA AND PERFORMANCE ESTIMATES

**Bivariate Binomial Mixed Model**

| Parameter | Accounted for | Not |
|---|---|---|
| Number of studies | 9 | 11 |
| Number of patients | 1,063 | 7,037 |
| Prevalence of disease | 40.2% | 23.2% |
| $I^2$ | 96.7% | 99.6% |
| Sensitivity (95% CI) | 93.4% (83.1% to 97.6%) | 93.0% (77.3% to 98.1%) |
| Specificity (95% CI) | 52.7% (36.6% to 68.3%) | 90.1% (74.3% to 96.6%) |
| AUROC (95% CI) | 0.83 (0.79 to 0.86) | 0.97 (0.95 to 0.98) |

## Ultrasound B-mode 3D Grayscale

1 study, 150 lesions

**Table 32. Ultrasound accuracy data: B-mode 3D grayscale**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Cho et al. 2006[61] | All | 59 | 27 | 1 | 63 | 98.3% (91.1 to 100.0%) | 70.0% (59.4 to 79.2%) |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound B-mode Grayscale: 2D vs. 3D

1 study, 150 lesions

**Table 33. Ultrasound accuracy data: B-mode grayscale, 2D vs. 3D**

| Study | Technology | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Cho et al. 2006[61] | 2D | 58 | 32 | 2 | 59 | 96.7% (88.5 to 99.6%) | 64.8% (54.1 to 74.6%) |
| | 3D | 59 | 27 | 1 | 63 | 98.3% (91.1 to 100.0%) | 70.0% (59.4 to 79.2%) |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound B-mode 2D Contrast Enhanced

2 studies, 154 lesions

**Table 34. Ultrasound accuracy data: B-mode 2D grayscale contrast enhanced**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Liu et al. 2008[56] | All | 41 | 7 | 2 | 54 | 95.3% (84.2% to 99.4%) | 88.5% (77.8% to 95.3%) |
| Ricci et al. 2006[16] | All | 38 | 10 | 0 | 2 | 100.0% (90.7% to 100.0%) | Not calculated |
| Summary (random-effects) | | | | | | 97.5% (91.4% to 99.7%) $I^2$ = 61.2% | 76.7% (65.4% to 85.8%) $I^2$ = 96.0% |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound B-mode 2D Contrast Enhanced vs. Not Enhanced

2 studies, 154 lesions

**Table 35. Ultrasound accuracy data: B-mode 2D grayscale contrast enhanced vs. not enhanced**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Liu et al. 2008[56] | Contrast Enhanced | 41 | 7 | 2 | 54 | 95.3% (84.2% to 99.4%) | 88.5% (77.8% to 95.3%) |
| | Not Enhanced | 41 | 15 | 2 | 46 | 95.3% (84.2% to 99.4%) | 75.4% (62.7% to 85.5%) |
| Ricci et al. 2006[16] | Contrast Enhanced | 38 | 10 | 0 | 2 | 100.0% (90.7% to 100.0%) | Not calculated |
| | Not Enhanced | 26 | 4 | 12 | 8 | 68.4% (72.7% to 90.2%) | 66.7% (34.9% to 90.1%) |
| Summary (random-effects) Contrast Enhanced | | | | | | 97.5% (91.4% to 99.7%) $I^2$ = 61.2% | 76.7% (65.4% to 85.8%) $I^2$ = 96.0% |
| Summary (random effects) Not Enhanced | | | | | | 82.7% (72.7% to 90.2%) $I^2$ = 90.9% | 74.0% (62.4% to 83.5%) $I^2$ = 0.0% |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound Color Doppler

6 studies, 718 lesions

**Table 36. Ultrasound accuracy data: color doppler**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Caruso et al. 2002[68] | All | 16 | 1 | 4 | 15 | 80.0% (56.3% to 94.3%) | 93.8% (69.8% to 99.8%) |
| Koukouraki et al. 2001[69] | All | 76 | 4 | 9 | 26 | 89.4% (80.8% to 95.0%) | 86.7% (69.3% to 96.2%) |
| | Palpable lesions | 61 | 2 | 6 | 9 | 91.0% (81.5% to 96.6%) | 81.8% (48.2% to 97.7%) |
| | Non-palpable lesions | 14 | 2 | 5 | 17 | 73.7% (48.8% to 90.9%) | 89.5% (66.9% to 98.7%) |
| Blohmer et al. 1999[73] | All | 58 | 13 | 20 | 79 | 74.4% (63.2% to 83.6%) | 85.9% (77.0% to 92.3%) |
| Schroeder et al. 1999[75] | All | 72 | 23 | 0 | 15 | 100.0% (95.0% to 100.0%) | 39.5% (24.0% to 56.6%) |
| Wilkens et al. 1998[77] | Palpable lesions | 16 | 7 | 6 | 26 | 72.7% (49.8% to 89.3%) | 78.8% (61.1% to 91.0%) |
| Buadu et al. 1997[78] | All | 73 | 11 | 9 | 23 | 89.0% (80.2% to 94.9%) | 67.6% (49.5% to 82.6%) |

FN False negative
FP False positive
TN True negative
TP True positive

**META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES**

Ultrasound Color Doppler

Using All Lesions data from Koukouraki et al. 2001[69] and including Wilkens et al. 1998[77] (reported data from palpable lesions only)

SUMMARY DATA AND PERFORMANCE ESTIMATES

Bivariate Binomial Mixed Model

Number of studies = 6

Reference-positive Subjects = 359

Reference-negative Subjects = 243

Pretest Prob of Disease = 0.596

Between-study variance (varlogitSEN) = 1.201 (95% CI: 0.224 to 6.443)

Between-study variance (varlogitSPE) = 0.591 (95% CI: 0.149 to 2.352)

Correlation (Mixed Model) = -1.000

ROC Area, AUROC = 0.89 (95% CI: 0.86 to 0.91)

Heterogeneity (Chi-square): LRT_Q = 41.754, df = 2.00, LRT_p = 0.000

Inconsistency (I-square): 95.2% (95% CI: 91.4 to 99.1)

Summary Parameter Estimates (95% CI)

Sensitivity: 88.5% (74.4% to 95.4%)

Specificity: 76.4% (61.7% to 86.7%)

Positive Likelihood Ratio: 3.760 (2.399 to 5.892)

Negative Likelihood Ratio: 0.150 (0.072 to 0.314)

Diagnostic Score: 3.223 (2.635 to 3.811)

Diagnostic Odds Ratio: 25.096 (13.938 to 45.187)

**Exploration of Heterogeneity:**

Ultrasound Color Doppler

Using All data from Koukouraki et al. 2001[69] and not including Wilkens et al. 1998[77] (reported data from palpable lesions only)

SUMMARY DATA AND PERFORMANCE ESTIMATES

Bivariate Binomial Mixed Model

Number of studies = 5

Reference-positive Subjects = 337

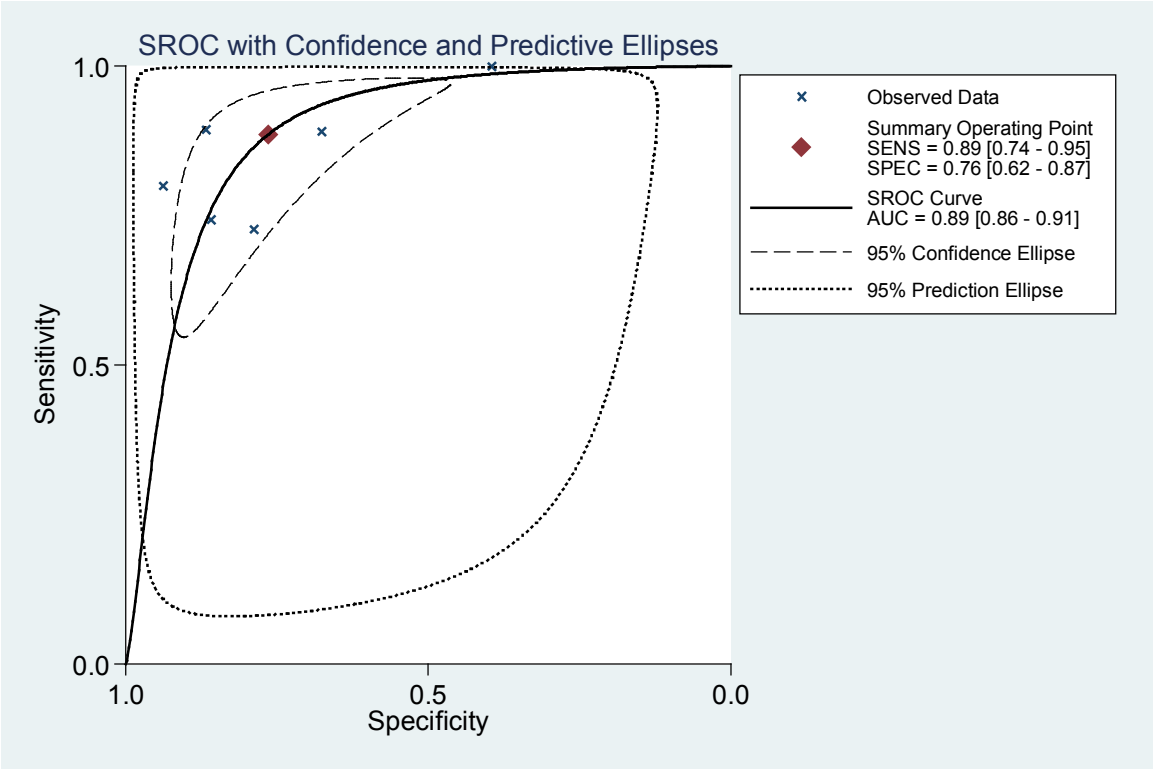
Reference-negative Subjects = 210

Heterogeneity (Chi-square): LRT_Q = 42.292, df = 2.00, LRT_p = 0.000

Inconsistency (I-square): 95.3% (95% CI: 91.48 to 99.06)

Compare to Inconsistency from full data set including Wilkens et al. 1998;[77] I-square: 95.2%, 95% CI (91.4 to 99.1)

**Figure 8. Bivariate binomial mixed-effects model of ultrasound color doppler: summary ROC**




Too few studies to perform meta-regression

## Ultrasound Color Doppler Contrast Enhanced

2 studies, 146 lesions

**Table 37. Ultrasound accuracy data: color doppler contrast enhanced**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Caruso et al. 2002[68] | All | 18 | 3 | 2 | 13 | 90.0% (68.3% to 98.8%) | 81.3% (54.4% to 96.0%) |
| Schroeder et al. 1999[75] | All | 72 | 2 | 0 | 36 | 100.0% (95.0% to 100.0%) | 94.7% (82.3% to 99.4%) |
| Summary (random-effects) | | | | | | 97.8% (92.4% to 99.7%) $I^2$ = 84.0% | 90.7% (79.7% to 96.9%) $I^2$ = 54.6% |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound Color Doppler Contrast Enhanced vs. Not Enhanced

2 studies, 146 lesions

**Table 38. Ultrasound accuracy data: color doppler contrast enhanced vs. not enhanced**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Caruso et al. 2002[68] | Contrast Enhanced | 18 | 3 | 2 | 13 | 90.0% (68.3% to 98.8%) | 81.3% (54.4% to 96.0%) |
| | Not Enhanced | 16 | 1 | 4 | 15 | 80.0% (56.3% to 94.3%) | 93.8% (69.8% to 99.8%) |
| Schroeder et al. 1999[75] | Contrast Enhanced | 72 | 2 | 0 | 36 | 100.0% (95.0% to 100.0%) | 94.7% (82.3% to 99.4%) |
| | Not Enhanced | 72 | 23 | 0 | 15 | 100.0% (95.0% to 100.0%) | 39.5% (24.0% to 56.6%) |
| Summary (random-effects) Contrast Enhanced | | | | | | 97.8% (92.4% to 99.7%) $I^2$ = 84.0% | 90.7% (79.7% to 96.9%) $I^2$ = 54.6% |
| Summary (random-effects) Not Enhanced | | | | | | 95.7% (89.2% to 98.8%) $I^2$ = 92.2% | 55.6% (41.4% to 69.1%) $I^2$ = 93.6% |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound Color Doppler vs. B-mode Grayscale 2D

2 studies, 225 lesions

**Table 39. Ultrasound accuracy data: color doppler vs. B-mode grayscale 2D**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Blohmer et al. 1999[73] | Color Doppler | 58 | 13 | 20 | 79 | 74.4% (63.2% to 83.6%) | 85.9% (77.0% to 92.3%) |
| | B-mode | 76 | 4 | 81 | 70 | 48.4% (40.4% to 56.5%) | 94.6% (86.7% to 98.5%) |
| Wilkens et al. 1998[77] | Color Doppler; palpable lesions only | 16 | 7 | 6 | 26 | 72.7% (49.8% to 89.3%) | 78.8% (61.1% to 91.0%) |
| | B-mode; palpable lesions only | 19 | 0 | 3 | 33 | 86.4% (65.1% to 97.1%) | 100.0% (89.4% to 100.0%) |
| Summary (random-effects) Color Doppler | | | | | | 74.0% (64.3% to 82.3%) $I^2$ = 0.0% | 84.0% (76.4% to 89.9%) $I^2$ = 0.0% |
| Summary (random-effects) B-mode | | | | | | 53.1% (45.5% to 60.6%) $I^2$ = 92.0% | 96.3% (90.7% to 99.0%) $I^2$ = 66.9% |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound Power Doppler

9 studies, 614 lesions

**Table 40. Ultrasound accuracy data: power doppler**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Gokalp et al. 2009[55] | All | 28 | 10 | 11 | 45 | 71.8% (55.1% to 85.0%) | 81.8% (69.1% to 90.9%) |
| Forsberg et al. 2004[62] | All | 11 | 4 | 16 | 22 | 40.7% (22.4% to 61.2%) | 84.6% (65.1% to 95.6%) |
| Ozdemir et al. 2004[64] | All | 23 | 26 | 5 | 14 | 82.1% (63.1% to 93.9%) | 35.0% (20.6% to 51.7%) |
| Kook and Kwag 2003[66] | 2 cm or less | 5 | 5 | 12 | 14 | 29.4% (10.3% to 56.0%) | 73.7% (48.8% to 90.9%) |
| Milz et al. 2001[70] | All | 41 | 16 | 14 | 47 | 74.5% (61.0% to 85.3%) | 74.6% (62.1% to 84.7%) |
| Reinikainen et al. 2001[71] | All | 20 | 8 | 14 | 23 | 58.8% (40.7% to 75.45) | 74.2% (55.4% to 88.1%) |
| Moon et al. 2000[72] | Non-palpable lesions | 8 | 4 | 14 | 24 | 36.4% (17.2% to 59.3%) | 85.7% (67.3% to 96.0%) |
| Schroeder et al. 1999[75] | All | 72 | 21 | 0 | 17 | 100.0% (95.0% to 100.0%) | 44.7% (28.6% to 61.7%) |
| Albrecht et al. 1998[76] | All | 9 | 1 | 2 | 8 | 81.8% (48.2% to 97.7%) | 88.9% (51.8% to 99.7%) |

FN False negative
FP False positive
TN True negative
TP True positive

**META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES**

Ultrasound Power Doppler

SUMMARY DATA AND PERFORMANCE ESTIMATES

Bivariate Binomial Mixed Model

Number of studies = 9

Reference-positive Subjects = 305

Reference-negative Subjects = 309

Pretest Prob of Disease = 0.497

Between-study variance (varlogitSEN) = 1.995 (95% CI: 0.606-6.566)

Between-study variance (varlogitSPE) = 0.576 (95% CI: 0.178-1.870)

Correlation (Mixed Model) = -0.797

ROC Area, AUROC = 0.77 (95% CI: 0.74 to 0.81)

Heterogeneity (Chi-square): LRT_Q = 76.788, df = 2.00, LRT_p = 0.000

Inconsistency (I-square): 97.4% (95% CI: 95.7%-99.1%)

Summary Parameter Estimates (95% CI)

Sensitivity: 70.8% (47.5% to 86.6%)

Specificity: 72.6% (59.9% to 82.5%)

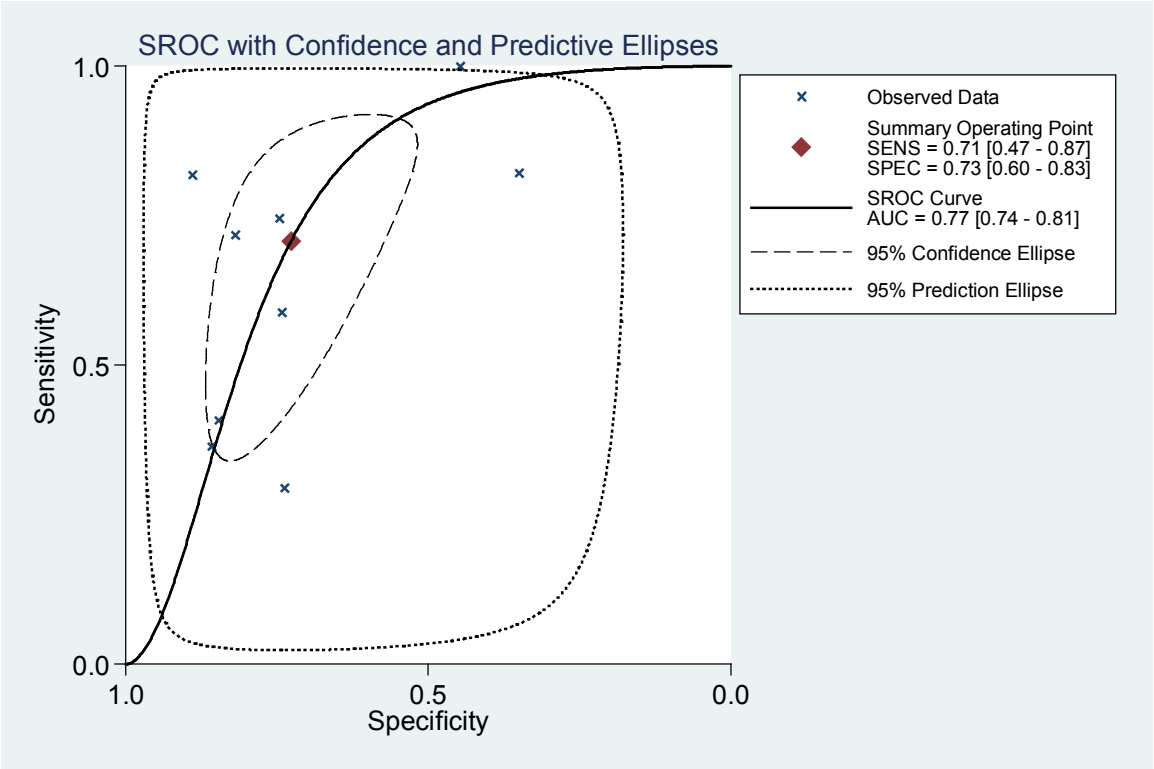
Positive Likelihood Ratio: 2.586 (1.882 to 3.555)

Negative Likelihood Ratio: 0.402 (0.219 to 0.738)

Diagnostic Score: 1.860 (1.110 to 2.611)

Diagnostic Odds Ratio: 6.426 (3.035 to 13.606)

**Figure 9. Bivariate binomial mixed-effects model of ultrasound power doppler: summary ROC**



## Ultrasound Power Doppler vs. B-mode 2D grayscale

4 studies, 248 lesions

**Table 41. Ultrasound accuracy data: power doppler vs. B-mode 2D grayscale**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Gokalp et al. 2009[55] | B-mode | 39 | 23 | 0 | 32 | 100.0% (91.0% to 100.0%) | 58.2% (44.1% to 71.3%) |
| | Power Doppler | 28 | 10 | 11 | 45 | 71.8% (55.1% to 85.0%) | 81.8% (69.1% to 90.9%) |
| Forsberg et al. 2004[62] | B-mode | 10 | 5 | 14 | 24 | 41.7% (22.1% to 63.4%) | 82.8% (64.2% to 94.2%) |
| | Power Doppler | 11 | 4 | 16 | 22 | 40.7% (22.4% to 61.2%) | 84.6% (65.1% to 95.6%) |
| Kook and Kwag 2003[66] | B-mode, lesions 2 cm or less | 17 | 10 | 0 | 9 | 100.0% (80.5% to 100.0%) | 47.4% (24.4% to 71.1%) |
| | Power Doppler, lesions 2 cm or less | 5 | 5 | 12 | 14 | 29.4% (10.3% to 56.0%) | 73.7% (48.8% to 90.9%) |
| Reinikainen et al. 2001[71] | B-mode | 34 | 28 | 0 | 3 | 100.0% (89.7% to 100.0%) | 9.7% (2.0% to 25.8%) |
| | Power Doppler | 20 | 8 | 14 | 23 | 58.8% (40.7% to 75.45) | 74.2% (55.4% to 88.1%) |
| Summary (random effects) B-mode | | | | | | 87.7% (80.3% to 93.1%) $I^2$ = 94.3% | 50.7% (42.0% to 59.5%) $I^2$ = 92.2% |
| Summary (random effects) Power Doppler | | | | | | 54.7% (45.2% to 63.9%) $I^2$ = 74.1% | 79.4% (71.4% to 86.0%) $I^2$ = 0.0% |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound Power Doppler with Contrast Agent

7 studies, 403 lesions

**Table 42. Ultrasound accuracy data: power doppler with contrast agent**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Forsberg et al. 2004[62] | All | 8 | 7 | 23 | 15 | 25.8% (11.9% to 44.6%) | 68.2% (45.1% to 86.1%) |
| Ozdemir et al. 2004[64] | All | 23 | 14 | 5 | 27 | 82.1% (63.1% to 93.9%) | 65.9% (49.4% to 79.9%) |
| Kook and Kwag 2003[66] | 2 cm or less | 12 | 8 | 5 | 11 | 70.6% (44.0% to 89.7%) | 57.9% (33.5% to 79.7%) |
| Reinikainen et al. 2001[71] | All | 19 | 17 | 15 | 14 | 55.9% (37.9% to 72.8%) | 45.2% (27.3% to 64.0%) |
| Moon et al. 2000[72] | Non-palpable lesions | 21 | 6 | 1 | 22 | 95.5% (77.2% to 99.9%) | 78.6% (59.0% to 91.7%) |
| Schroeder et al. 1999[75] | All | 72 | 2 | 0 | 36 | 100.0% (95.0% to 100.0%) | 94.7% (82.3% to 99.4%) |
| Albrecht et al. 1998[76] | All | 11 | 4 | 0 | 5 | 100.0% (71.5% to 100.0%) | 55.6% (21.2% to 86.3%) |

FN False negative
FP False positive
TN True negative
TP True positive

**META-ANALYTIC INTEGRATION OF DIAGNOSTIC TEST ACCURACY STUDIES**

Ultrasound Power Doppler with Contrast

SUMMARY DATA AND PERFORMANCE ESTIMATES

Bivariate Binomial Mixed Model

Number of studies = 7

Reference-positive Subjects = 215

Reference-negative Subjects = 188

Pretest Prob of Disease = 0.533

Between-study variance (varlogitSEN) = 5.785 (95% CI: 1.218-27.486)

Between-study variance (varlogitSPE) = 0.548 (95% CI: 0.117-2.560)

Correlation (Mixed Model) = 0.947

ROC Area, AUROC = 0.81 (95% CI: 0.77 to 0.84)

Heterogeneity (Chi-square): LRT_Q = 16.015, df = 2.00, LRT_p = 0.000

Inconsistency (I-square): 87.51% (95% CI: 74.55 to 100.00)

Summary Parameter Estimates (95% CI)

Sensitivity: 89.3% (52.4% to 98.4%)

Specificity: 70.4% (55.4% to 82.0%)

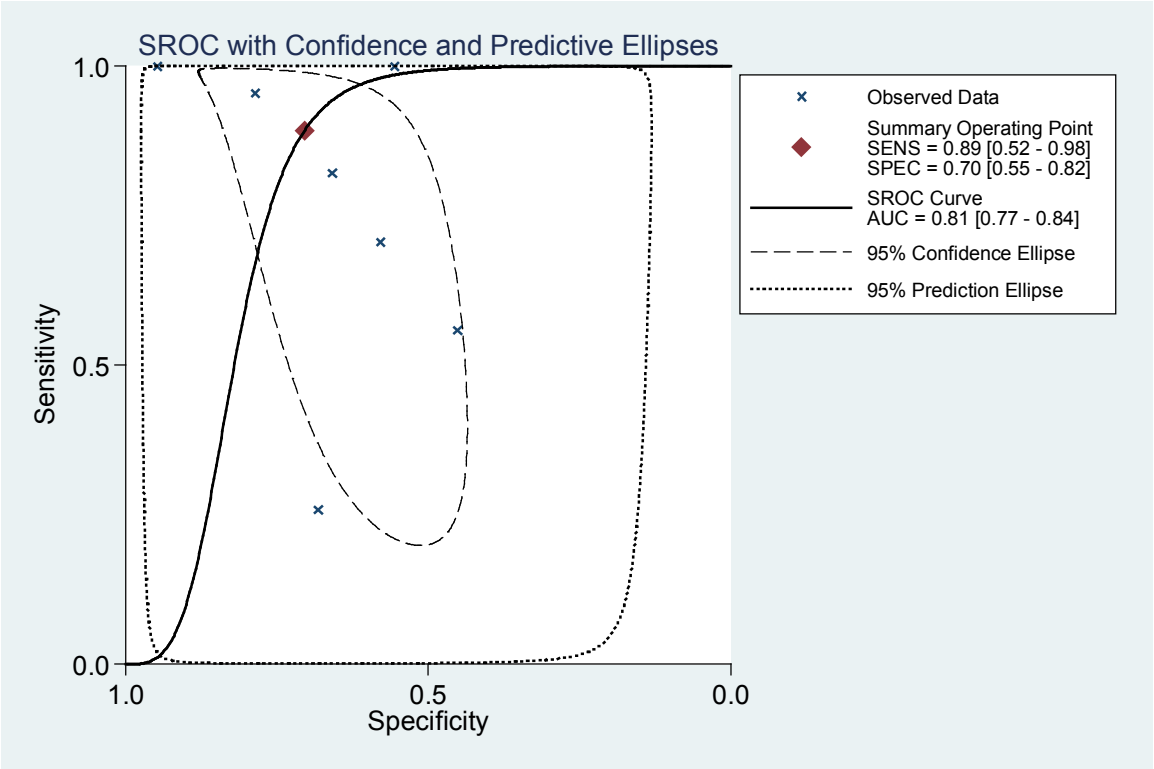
Positive Likelihood Ratio: 3.016 (1.603 to 5.675)

Negative Likelihood Ratio: 0.153 (0.022 to 1.072)

Diagnostic Score: 2.984 (0.452 to 5.517)

Diagnostic Odds Ratio: 19.772 (1.571 to 248.893)

**Figure 10. Bivariate binomial mixed-effects model of ultrasound power doppler with contrast: summary ROC**



## Ultrasound Power Doppler vs. Color Doppler

1 study, 110 lesions

**Table 43. Ultrasound accuracy data: power doppler vs. color doppler**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Schroeder et al. 1999[75] | Power Doppler Contrast Enhanced | 72 | 2 | 0 | 36 | 100.0% (95.0% to 100.0%) | 94.7% (82.3% to 99.4%) |
| | Power Doppler Non enhanced | 72 | 21 | 0 | 17 | 100.0% (95.0% to 100.0%) | 44.7% (28.6% to 61.7%) |
| | Color Doppler Contrast Enhanced | 72 | 2 | 0 | 36 | 100.0% (95.0% to 100.0%) | 94.7% (82.3% to 99.4%) |
| | Color Doppler Non enhanced | 72 | 23 | 0 | 15 | 100.0% (95.0% to 100.0%) | 39.5% (24.0% to 56.6%) |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound Tissue Harmonics

1 study, 91 lesions

**Table 44. Ultrasound accuracy data: tissue harmonics**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Cha et al. 2007[58] | All | 29 | 23 | 1 | 38 | 96.7% (82.8% to 99.9%) | 62.3% (49.0% to 74.4%) |

FN False negative
FP False positive
TN True negative
TP True positive

## Ultrasound Tissue Harmonics vs. B-mode Grayscale

1 study, 91 lesions

**Table 45. Ultrasound accuracy data: tissue harmonics vs. B-mode grayscale**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Cha et al. 2007[58] | Tissue harmonics | 29 | 23 | 1 | 38 | 96.7% (82.8% to 99.9%) | 62.3% (49.0% to 74.4%) |
| | B-mode grayscale | 29 | 23 | 1 | 38 | 96.7% (82.8% to 99.9%) | 62.3% (49.0% to 74.4%) |

FN false negative
FP false positive
TN true negative
TP true positive

## Ultrasound Combination Methods

4 studies that used multiple ultrasound methods, in combination, to diagnose breast lesions

**Table 46. Ultrasound accuracy data: combination methods**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Gokalp et al. 2009[55] | Combination of B-mode 2D grayscale and power Doppler | 39 | 26 | 0 | 29 | 100.0% (91.0% to 100.0%) | 52.7% (38.8% to 66.3%) |
| Liu et al. 2008[56] | Combination of B-mode and contrast-enhanced B-mode 2D grayscale | 42 | 6 | 1 | 55 | 97.7% (87.7% to 99.9%) | 90.2% (79.8% to 96.3%) |
| Pinero et al. 2006[53] | Combination power Doppler and color Doppler, contrast enhanced | | | | | | |
| | All lesions | 60 | 9 | 8 | 11 | 88.2% (78.1% to 94.8%) | 55.0% (31.5% to 76.9%) |
| | Palpable lesions | 42 | 2 | 5 | 8 | 89.4% (76.9% to 96.5%) | 80.0% (44.4% to 97.5%) |
| | Non-palpable lesions | 17 | 6 | 4 | 4 | 81.0% (58.1% to 94.6%) | 40.0% (12.2% to 73.8%) |
| Malich et al. 2001[35] | Combination of B-mode, power Doppler, and color Doppler | 48 | 4 | 14 | 34 | 77.4% (65.0% to 87.1%) | 89.5% (75.2% to 97.1%) |

FN false negative
FP false positive
TN true negative
TP true positive

**Table 47. Ultrasound accuracy: accuracy of different types of ultrasound**

| Type of Ultrasound | N Studies | N Lesions | Risk of Bias | Consistency | Precision | Summary Sensitivity (95% CI) | Summary Specificity (95% CI) | Strength of Evidence |
|---|---|---|---|---|---|---|---|---|
| B-mode grayscale 2D | 21 | 8,199 | Low | Inconsistent | Imprecise | 92.4% (84.6% to 96.4%) | 75.8% (60.8% to 86.3%) | Low |
| B-mode grayscale 2D contrast enhanced | 2 | 154 | Low | Inconsistent | Imprecise | 97.5% (91.4% to 99.7%) | 76.7% (65.4% to 85.8%) | Low |
| B-mode grayscale 3D | 1 | 150 | Low | Unknown | Imprecise | 98.3% (91.1% to 100.0%) | 70.0% (59.4% to 79.2%) | Insufficient |
| Color Doppler | 6 | 718 | Low | Inconsistent | Imprecise | 88.5% (74.4% to 95.4%) | 76.4% (61.% to 86.7%) | Low |
| Color Doppler contrast enhanced | 2 | 146 | Low | Inconsistent | Imprecise | 97.8% (92.4% to 99.7%) | 90.7% (79.7% to 96.9%) | Low |
| Power Doppler | 9 | 614 | Low | Inconsistent | Imprecise | 70.8% (47.5% to 86.6%) | 72.6% (59.9% to 82.5%) | Low |
| Power Doppler contrast enhanced | 7 | 403 | Low | Inconsistent | Imprecise | 89.3% (52.4% to 98.4%) | 70.4% (55.4% to 82.0%) | Low |
| Tissue harmonics | 1 | 91 | Low | Unknown | Imprecise | 96.7% (82.8% to 99.9%) | 62.3% (49.0% to 74.4%) | Insufficient |

**Table 48. Ultrasound accuracy: indirect and direct comparisons of different types of ultrasound**

| Type of Ultrasound | B-mode Grayscale 2D | B-mode Grayscale 2D Contrast Enhanced | B-mode Grayscale 3D | Color Doppler | Color Doppler Contrast Enhanced | Power Doppler | Power Doppler Contrast Enhanced | Tissue Harmonics |
|---|---|---|---|---|---|---|---|---|
| **B-mode grayscale 2D** | NA | Contrast-enhanced has a higher sensitivity<br>Strength of evidence: Low | Insufficient evidence | B-mode grayscale is more sensitive<br>Strength of evidence: Low | Insufficient evidence | B-mode grayscale is more sensitive<br>Strength of evidence: Low | Insufficient evidence | Insufficient evidence |
| **B-mode grayscale 2D contrast enhanced** | NA | NA | Insufficient evidence | Insufficient evidence | Insufficient evidence | Insufficient evidence | Insufficient evidence | Insufficient evidence |
| **B-mode grayscale 3D** | NA | NA | NA | Insufficient evidence | Insufficient evidence | Insufficient evidence | Insufficient evidence | Insufficient evidence |
| **Color Doppler** | NA | NA | NA | NA | Contrast-enhanced is more accurate<br>Strength of evidence: Low | Color doppler is more accurate<br>Strength of evidence Low | Insufficient evidence | Insufficient evidence |
| **Color Doppler contrast enhanced** | NA | NA | NA | NA | NA | Insufficient evidence | Insufficient evidence | Insufficient evidence |
| **Power Doppler** | NA | NA | NA | NA | NA | NA | Insufficient evidence | Insufficient evidence |
| **Power Doppler contrast enhanced** | NA | NA | NA | NA | NA | NA | NA | Insufficient evidence |
| **Tissue harmonics** | NA | NA | NA | NA | NA | NA | NA | NA |

## Direct Comparisons

**Table 49. Direct comparison of PET and MRI**

| Study | Category | TP | FP | FN | TP | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Heinisch et al. 2003[24] | PET | 17 | 4 | 8 | 11 | 68.0% (46.5% to 85.1%) | 73.3% (44.9% to 92.2%) |
| | MRI | 23 | 2 | 4 | 11 | 85.2% (67.4% to 93.9%) | 84.6% (57.6% to 95.4%) |
| Walter et al. 2003[25] | PET | 12 | 2 | 7 | 21 | 63.2% (38.4% to 83.7%) | 91.3% (72.0% to 98.9%) |
| | MRI | 17 | 2 | 6 | 17 | 73.9% (53.4% to 87.3%) | 89.5% (68.4% to 96.8%) |
| Brix et al. 2001[31] | PET | 8 | 2 | 1 | 2 | 88.9% (51.8% to 99.7%) | 50.0% (06.8% to 93.2%) |
| | MRI | 8 | 1 | 2 | 2 | 80.0% (48.9% to 94.0%) | 66.7% (21.0% to 93.3%) |
| Imbriaco et al. 2007[6] | PET-CT | 29 | 0 | 7 | 8 | 80.6% (64.0% to 91.8%) | 100% (63.1% to 100%) |
| | MRI | 44 | 2 | 1 | 8 | 97.8% (88.3% to 99.5%) | 80.0% (48.9% to 94.0%) |

FN False negative
FP False positive
TN True negative
TP True positive

**Table 50. Direct comparison of MRI and ultrasound**

| Study | Category | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|---|
| Vassiou et al. 2009[8] | MRI | 52 | 14 | 1 | 11 | 98.1% (89.9% to 99.6%) | 44.0% (26.7% to 62.9%) |
| | US, B-mode 2D grayscale | 44 | 6 | 9 | 19 | 83.0% (70.7 to 90.7%) | 76.0% (56.5 to 94.3%) |
| Ricci et al. 2006[16] | MRI | 38 | 2 | 0 | 11 | 100.0% (90.6% to 99.9%) | 84.6% (57.6% to 95.4%) |
| | US, B mode grayscale, contrast enhanced | 38 | 10 | 0 | 2 | 100.0% (90.7 to 100.0%) | Not calculated |
| | US, B mode grayscale, not enhanced | 26 | 4 | 12 | 8 | 68.4% (72.7 to 90.2%) | 66.7% (34.9 to 90.1%) |
| Malich et al. 2001[35] | MRI | 53 | 7 | 1 | 29 | 98.1% (90.1% to 99.6%) | 80.6% (64.9% to 90.1%) |
| | Combination of B-mode, power Doppler, and color Doppler | 48 | 4 | 14 | 34 | 77.4% (65.0 to 87.1%) | 89.5% (75.2 to 97.1%) |

FN False negative
FP False positive
TN True negative
TP True positive
US Ultrasound

**Table 51. Direct comparison of scintimammography to doppler ultrasound (combined method)**

| Study | Category | Patient Subgroup | TP | FP | FN | TN | Sensitivity (95%CI) | Specificity (95%CI) |
|---|---|---|---|---|---|---|---|---|
| Pinero et al. 2006[53] | Double phase SMM | All, mixed population | 63 | 10 | 5 | 10 | 92.6% (83.7 to 97.6) | 50.0% (27.2 to 72.8) |
| | Combination power Doppler and color Doppler, contrast enhanced | | 60 | 8 | 9 | 11 | 88.2% (78.1 to 94.8) | 55.0% (31.5 to 76.9) |
| Pinero et al. 2006[53] | Double phase SMM | Palpable lesions only | 43 | 3 | 4 | 7 | 91.5% (79.6 to 97.6) | 70.0% (34.8 to 93.3) |
| | Combination power Doppler and color Doppler, contrast enhanced | | 42 | 2 | 5 | 8 | 89.4% (76.9 to 96.5) | 80.0% (44.4 to 97.5) |
| Pinero et al. 2006[53] | Double phase SMM | Non-palpable | 20 | 1 | 6 | 4 | 95.2% (76.2 to 99.9) | 40.0% (12.2 to 73.8) |
| | Combination power Doppler and color Doppler, contrast enhanced | | 17 | 4 | 6 | 4 | 81.0% (58.1 to 94.6) | 40.0% (12.2 to 73.8) |

FN False negative
FP False positive
TN True negative
TP True positive

**Table 52. Comparison of scintimammography with MRI**

| Study | Category | TP | FP | FN | TN | Sensitivity (95%CI) | Specificity (95%CI) |
|---|---|---|---|---|---|---|---|
| Kim et al. 2009[4] | Double phase SMM | 169 | 10 | 34 | 26 | 83.3% (77.4 to 88.1) | 72.2% (54.8 to 85.8) |
| | Dynamic contrast enhanced MRI | 196 | 14 | 8 | 21 | 96.1% (92.4 to 98.3) | 60.0% (42.1 to 76.1) |

FN False negative
FP False positive
TN True negative
TP True positive

**Table 53. Comparison of BSGI to MRI**

| Study | Type of Scanner | TP | FP | FN | TN | Sensitivity (95%CI) | Specificity (95%CI) |
|---|---|---|---|---|---|---|---|
| Brem et al. 2007[9] | BSGI | 8 | 7 | 1 | 17 | 88.9% (51.8 to 99.7) | 70.8% (48.9 to 87.4) |
| | Dynamic contrast enhanced MRI | 9 | 18 | 0 | 6 | 100% (66.4 to 100) | 25.0% (10.0 to 46.7) |

FN False negative
FP False positive
TN True negative
TP True positive

# Grading the Strength of Evidence

We applied a formal grading system that conforms with the CER Methods Guide Manual recommendations on grading the strength of evidence.[82,83]

The overall strength of evidence supporting each major conclusion was graded as High, Moderate, Low, or Insufficient. The grade was developed by considering four important domains: the risk of bias in the evidence base, the consistency of the findings, the precision of the results, and the directness of the evidence. The grading system moves stepwise to consider each important domain. These steps are described below.

## Risk of Bias

According to the Methods Guide:[82]

> *Risk of bias is the degree to which the included studies for a given outcome or comparison have a high likelihood of adequate protection against bias (i.e., good internal validity) assessed through two main elements:*
>
> - *Study design of individual studies*
> - *Aggregate quality of the studies under consideration.*

The risk of bias of each individual study was rated as being Low, Medium, or High; and the risk of bias of the aggregate evidence base supporting each major conclusion was similarly rated as being Low, Medium, or High.

We used our inclusion/exclusion criteria to eliminate studies with designs known to be prone to bias from the evidence base. Namely, case reports, case-control studies, and retrospective studies that did not enroll all or consecutive patients were not included for analysis. Because we eliminated all studies with a High risk of bias from the evidence base, we consider the remaining evidence base to have either a Low or Medium risk of bias.

We initially used an internal validity rating instrument for diagnostic studies to grade the internal validity of the individual studies (Table 54). This instrument is based on a modification of the QUADAS instrument.[84] Each question in the instrument addresses an aspect of study design or conduct that can help to protect against bias. Each question can be answered “yes”, “no”, or “not reported,” and each is phrased such that an answer of “yes” indicates that the study reported a protection against bias on that aspect. See Table 55 through Table 58 for application of the instrument to the included studies.

**Table 54. Quality assessment instrument**

| N | Question |
|---|---|
| 1 | Was patient recruitment either consecutive or random? |
| 2 | Was the study prospective in design? |
| 3 | Were more than 85% of the patients approached for recruitment enrolled in the study? |
| 4 | Were the patient inclusion/exclusion criteria consistently applied to all patients? |
| 5 | Was the study free from obvious spectrum bias? Obvious spectrum bias was defined as more than 40% or less than 10% of the breast lesions were diagnosed as malignant; and/or the mean or median age of the enrolled population was less than 50 or greater than 70. |
| 6 | Did the study account for inter-reader/scorer differences? |
| 7 | Were the reader(s) of the biopsies blinded to the results of the reference standard? |
| 8 | Were readers of the reference standard blinded to the results of the biopsy? |
| 9 | Were the readers of the biopsy blinded to all other clinical information? |
| 10 | Were readers of the reference standard blinded to all other clinical information? |
| 11 | Were patients assessed by a reference standard regardless of the biopsy results? |
| 12 | Were the patients assessed by the gold standard (open surgical procedure) regardless of the initial biopsy results? |
| 13 | Was a diagnostic threshold chosen *a priori* by the study? |
| 14 | Were there no intervening treatments or interventions conducted between the time the diagnostic test was performed and the reference standard was performed? |
| 15 | Was a complete set of data reported for at least 85% of enrolled lesions? |
| 16 | Was funding for this study provided by a source that doesn't have an obvious financial interest in the findings of the study? |
| 17 | Was the report of the study free from unresolvable discrepancies? |

We conducted meta-regressions investigating the correlation between key individual items on the quality rating instrument and the results reported by the studies (see Appendix C for details). We consistently found that the majority of the items on the instrument had no statistically significant correlation with the reported results. Some (but not most) of the evidence bases were found to have a statistically significant impact of "reader blinded to other clinical information" and "accounted for inter-reader differences" on the study results.

We concluded that the quality instrument was not adequately capturing the potential for bias of the studies. Unlike studies of interventions, diagnostic cohort studies are quite simple in design- one group of patients acting as their own controls. As long as all enrolled patients receive both the diagnostic test and the reference standard test, opportunities for bias to affect the results are limited. As mentioned above, we eliminated all studies with a High risk of bias due to their study design from the evidence base. We did not identify any design flaws in the remaining studies that suggested they were at Medium risk of bias; therefore, we rated all of the included studies, and the aggregate evidence bases, as being at Low risk of bias.

### Consistency

According to the Methods Guide:[82]

> *The principal definition of consistency is the degree to which the reported effect sizes from included studies appear to have the same direction of effect. This can be assessed through two main elements:*
>
> - *Effect sizes have the same sign (that is, are on the same side of "no effect")*
> - *The range of effect sizes is narrow.*

The first definition, effect sizes being on the same side of "no effect", is not applicable to meta-analyses of the accuracy of a diagnostic test. Therefore, for these cases, we used the second definition, the range of effect sizes being narrow. We measured the "narrowness" of the range of effect sizes with the statistic $I^2$.[85,86] Data sets that were found to have an $I^2$ of less than 50% were rated as being "Consistent"; 50% or greater were rated as being "Inconsistent"; and data sets for which $I^2$ could not be calculated (e.g., a single study) were rated as "Consistency Unknown".

For qualitative comparisons between different diagnostic tests we used the first definition, that of effect sizes being on the same side of an effect. For example, when comparing the accuracy of ultrasound without a contrast agent to the accuracy of ultrasound with a contrast agent, if the estimates of sensitivity of the individual studies are consistently higher for studies that used a contrast agent, then the evidence base would be rated as "consistent".

### Precision

According to the Methods Guide:[82]

> *Precision is the degree of certainty surrounding an effect estimate…if a meta-analysis was performed, this will be the confidence interval around the summary effect size.*
>
> *A precise estimate is an estimate that would allow a clinically useful conclusion.*

Diagnostic test characteristics (sensitivity, specificity) are reported on a scale from 0.0 to 100.0%. We defined a "precise" estimate of sensitivity or specificity as one for which the upper AND lower bound of the 95% confidence interval was no more than 5 points away from the summary estimate; for example, sensitivity 98% (95% CI: 97 to 100%) would be a precise estimate of sensitivity, whereas sensitivity 95% (95% CI: 88 to 100%) would be an imprecise estimate of sensitivity. Precision could be rated separately for summary estimates of sensitivity and specificity for each major conclusion.

For qualitative comparisons between different diagnostic tests, the conclusion is Precise if the confidence intervals around the summary estimates being compared do not overlap.

### Directness

According to the Methods Guide:[82]

> *The rating of directness relates to whether the evidence links the interventions directly to health outcomes.*

For studies of diagnostic test accuracy, the evidence is always rated as "Indirect" because the outcome of test accuracy is indirectly related to health outcomes. However, the Key Questions in this particular comparative effectiveness review do not ask about the impact of test accuracy on

health outcomes. We therefore did not incorporate the "Indirectness" of the evidence into the overall rating of strength of evidence for Key Questions that did not ask about health outcomes.

### Overall Rating of Strength of Evidence

The initial rating is based on the risk of bias. If the evidence base has a Low risk of bias, the initial strength of evidence rating is High; if the evidence base has a Moderate risk of bias, the initial strength of evidence rating is Moderate; if the evidence base has a High risk of bias, the initial strength of evidence rating is Low. For this particular comparative effectiveness review, as explained above, the rating of risk of bias was Low for all evidence bases, and therefore the initial strength of evidence rating is High.

The remaining two domains are used to up- or down- grade the initial rating as per the following flow charts:

Consistent, Precise: High

Inconsistent, Precise: Moderate

Consistent, Imprecise: Moderate

Inconsistent, Imprecise: Low

"Consistency Unknown", Precise: Low

"Consistency Unknown", Imprecise: Insufficient

## MRI

**Table 55. MRI studies: quality evaluation**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Study** | **Consecutive** | **Prospective** | **≥85% Enrolled** | **Consistent Criteria** | **Spectrum Bias** | **Interreader Differences** | **Blinded to Reference Results** | **Blinded to Diagnostic Results** | **Dx Reader Blinded to Clinical Info** | **Ref Reader Blinded to Clinical Info** | **Reference Standard** | **Gold Standard** | ***A priori* Threshold** | **No Intervening Treatment** | **85% Accounted for** | **Funding** | **Discrepancy** |
| Akita et al. 2009[1] | Yes | NR | Yes | Yes | Yes | NR | Yes | NR | No | NR | Yes | Yes | Yes | NR | Yes | NR | Yes |
| Baltzer et al. 2009[2] | Yes | Yes | Yes | Yes | No | Yes | Yes | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Hara et al. 2009[87] | Yes | NR | NR | Yes | Yes | NR | Yes | NR | NR | NR | Yes | No | Yes | NR | Yes | NR | Yes |
| Kim et al. 2009[4] | Yes | NR | NR | Yes | No | NR | Yes | NR | No | NR | Yes | No | No | Yes | Yes | Yes | Yes |
| Lo et al. 2009[5] | NR | Yes | NR | Yes | No | NR | Yes | NR | Yes | NR | Yes | No | Yes | NR | Yes | NR | Yes |
| Imbriaco et al. 2008[6] | Yes | Yes | Yes | Yes | No | No | Yes | NR | No | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Pediconi et al. 2008[7] | NR | Yes | NR | Yes | No | NR | Yes | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | NR | No |
| Vassiou et al. 2009[8] | NR | Yes | NR | Yes | No | NR | Yes | NR | NR | NR | Yes | Yes | Yes | NR | Yes | NR | Yes |
| Brem et al. 2007[9] | NR | NR | NR | Yes | Yes | NR | Yes | NR | No | NR | Yes | No | Yes | NR | Yes | NR | Yes |

**Table 55. MRI studies: quality evaluation (continued)**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Consecutive | Prospective | ≥85% Enrolled | Consistent Criteria | Spectrum Bias | Interreader Differences | Blinded to Reference Results | Blinded to Diagnostic Results | Dx Reader Blinded to Clinical Info | Ref Reader Blinded to Clinical Info | Reference Standard | Gold Standard | *A priori* Threshold | No Intervening Treatment | 85% Accounted for | Funding | Discrepancy |
| Cilotti et al. 2007[10] | NR | No | NR | Yes | No | NR | NR | No | NR | No | Yes | No | Yes | NR | Yes | NR | Yes |
| Pediconi et al. 2007[11] | Yes | Yes | Yes | Yes | No | Yes | Yes | No | No | No | Yes | No | Yes | NR | Yes | NR | Yes |
| Zhu et al. 2007[12] | Yes | No | Yes | Yes | No | No | Yes | NR | No | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Bazzocchi et al. 2006[13] | NR | Yes | NR | Yes | No | Yes | Yes | NR | Yes | NR | Yes | Yes | Yes | Yes | No | Yes | Yes |
| Gokalp and Topal 2006[14] | Yes | Yes | Yes | Yes | No | No | Yes | NR | No | NR | Yes | No | Yes | NR | Yes | NR | Yes |
| Kneeshaw et al. 2006[15] | No | Yes | NR | Yes | Yes | No | Yes | NR | No | NR | Yes | No | Yes | NR | Yes | Yes | Yes |
| Ricci et al. 2006[16] | Yes | Yes | Yes | Yes | No | NR | Yes | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Pediconi et al. 2005[17] | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | NR | Yes |
| Pediconi et al. 2005[18] | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | No | Yes | No | Yes | Yes | Yes | Yes | Yes |
| Wiener et al. 2005[19] | No | Yes | No | Yes | No | No | Yes | NR | No | NR | Yes | No | Yes | NR | Yes | NR | Yes |

**Table 55. MRI studies: quality evaluation (continued)**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Consecutive | Prospective | ≥85% Enrolled | Consistent Criteria | Spectrum Bias | Interreader Differences | Blinded to Reference Results | Blinded to Diagnostic Results | Dx Reader Blinded to Clinical Info | Ref Reader Blinded to Clinical Info | Reference Standard | Gold Standard | *A priori* Threshold | No Intervening Treatment | 85% Accounted for | Funding | Discrepancy |
| Bluemke et al. 2004[20] | NR | Yes | Yes | Yes | No | No | Yes | NR | NR | NR | Yes | No | Yes | Yes | Yes | Yes | Yes |
| Huang et al. 2004[21] | NR | Yes | NR | Yes | Yes | NR | Yes | NR | NR | NR | Yes | No | Yes | Yes | Yes | Yes | Yes |
| Bone et al. 2003[22] | Yes | Yes | Yes | Yes | No | No | Yes | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Daldrup-Link et al. 2003[23] | No | Yes | No | Yes | No | NR | Yes | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Heinisch et al. 2003[24] | NR | Yes | NR | Yes | No | NR | Yes | NR | No | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Walter et al. 2003[25] | Yes | Yes | Yes | Yes | No | NR | Yes | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Guo et al. 2002[26] | NR | No | NR | NR | No | NR | NR | NR | NR | NR | Yes | Yes | Yes | NR | Yes | NR | Yes |
| Kelcz et al. 2002[27] | Yes | Yes | NR | Yes | No | NR | Yes | NR | No | NR | Yes | No | Yes | Yes | Yes | Yes | Yes |
| Schedel et al. 2002[28] | NR | NR | NR | Yes | No | NR | Yes | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Trecate et al. 2002[29] | NR | Yes | NR | Yes | No | NR | Yes | NR | NR | NR | Yes | Yes | Yes | NR | Yes | NR | Yes |

**Table 55. MRI studies: quality evaluation (continued)**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Consecutive | Prospective | ≥85% Enrolled | Consistent Criteria | Spectrum Bias | Interreader Differences | Blinded to Reference Results | Blinded to Diagnostic Results | Dx Reader Blinded to Clinical Info | Ref Reader Blinded to Clinical Info | Reference Standard | Gold Standard | *A priori* Threshold | No Intervening Treatment | 85% Accounted for | Funding | Discrepancy |
| Wiberg et al. 2002[30] | Yes | Yes | Yes | Yes | No | No | Yes | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Brix et al. 2001[31] | Yes | Yes | NR | Yes | No | NR | Yes | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Cecil et al. 2001[32] | Yes | NR | NR | Yes | No | NR | Yes | NR | No | NR | Yes | No | Yes | NR | Yes | Yes | Yes |
| Furman-Haran et al. 2001[33] | NR | Yes | NR | Yes | No | No | Yes | Yes | Yes | No | Yes | Yes | No | NR | Yes | Yes | Yes |
| Imbriaco et al. 2001[34] | Yes | Yes | NR | Yes | No | NR | Yes | NR | Yes | NR | Yes | No | Yes | Yes | Yes | Yes | Yes |
| Malich et al. 2001[35] | Yes | NR | Yes | Yes | No | No | Yes | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Nakahara et al. 2001[36] | No | No | No | Yes | No | NR | Yes | NR | NR | NR | Yes | Yes | Yes | NR | Yes | NR | Yes |
| Torheim et al. 2001[37] | NR | Yes | NR | Yes | No | No | NR | NR | NR | NR | Yes | No | Yes | NR | Yes | Yes | Yes |
| Wedegartner et al. 2001[38] | NR | Yes | NR | Yes | No | NR | Yes | NR | Yes | NR | Yes | Yes | Yes | NR | Yes | NR | Yes |
| Yeung et al. 2001[39] | Yes | NR | NR | Yes | No | NR | Yes | Yes | NR | NR | Yes | No | Yes | Yes | Yes | NR | Yes |

**Table 55. MRI studies: quality evaluation (continued)**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Consecutive | Prospective | ≥85% Enrolled | Consistent Criteria | Spectrum Bias | Interreader Differences | Blinded to Reference Results | Blinded to Diagnostic Results | Dx Reader Blinded to Clinical Info | Ref Reader Blinded to Clinical Info | Reference Standard | Gold Standard | *A priori* Threshold | No Intervening Treatment | 85% Accounted for | Funding | Discrepancy |
| Kvistad et al. 2000[40] | NR | Yes | NR | Yes | No | Yes | Yes | NR | Yes | NR | Yes | No | Yes | Yes | Yes | Yes | Yes |
| Van Goethem et al. 2000[41] | Yes | No | Yes | Yes | Yes | NR | Yes | NR | NR | NR | Yes | No | NR | NR | Yes | NR | Yes |

NR Not reported

## PET

**Table 56. Quality assessment of studies of PET**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Study** | **Consecutive** | **Prospective** | **≥85% Enrolled** | **Consistent Criteria** | **Spectrum Bias** | **Interreader Differences** | **Blinded to Reference Results** | **Blinded to Diagnostic Results** | **Dx Reader Blinded to Clinical Info** | **Ref Reader Blinded to Clinical Info** | **Reference Standard** | **Gold Standard** | ***A priori* Threshold** | **No Intervening Treatment** | **85% Accounted for** | **Funding** | **Discrepancy** |
| Kaida et al. 2008[42] | Yes | Yes | NR | Yes | No | NR | Yes | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Buchmann et al. 2007[43] | Yes | Yes | NR | Yes | No | Yes | Yes | NR | No | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Heinisch et al. 2003[24] | NR | Yes | NR | Yes | No | NR | Yes | NR | No | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Walter et al. 2003[25] | Yes | Yes | Yes | Yes | No | NR | Yes | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Brix et al. 2001[31] | Yes | Yes | NR | Yes | No | NR | Yes | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Schirrmeister et al. 2001[88] | Yes | Yes | NR | Yes | No | Yes | Yes | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Yutani et al. 2000[45] | Yes | Yes | NR | Yes | No | Yes | Yes | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Imbriaco et al. 2008[6] | Yes | NR | NR | Yes | No | Yes | NR | NR | No | NR | Yes | Yes | Yes | Yes | Yes | NR | No |

NR Not reported

## Scintimammography

**Table 57. Quality assessment of studies of scintimammography**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Consecutive | Prospective | >85% Enrolled | Consistent Criteria | Spectrum Bias | Interreader Differences | Blinded to Reference Results | Blinded to Diagnostic Results | Dx Reader Blinded to Clinical Info | Reference Reader Blinded to Clinical Info | Reference standard | Gold Standard | A Priori Threshold | No Intervening Treatment | 85% Accounted for | Funding | Discrepancy |
| Grosso et al. 2009[46] | Yes | Yes | Yes | Yes | Yes | Yes | Yes | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Habib et al. 2009[47] | NR | Yes | NR | Yes | No | Yes | Yes | NR | Yes | NR | Yes | No | Yes | NR | Yes | NR | Yes |
| Kim et al. 2009[4] | Yes | Yes | Yes | Yes | No | Yes | Yes | NR | NR | NR | Yes | No | Yes | NR | Yes | Yes | Yes |
| Kim et al. 2008[48] | NR | Yes | NR | Yes | No | Yes | Yes | NR | Yes | NR | Yes | No | Yes | NR | Yes | NR | Yes |
| Wang et al. 2008[49] | Yes | Yes | Yes | Yes | No | Yes | Yes | NR | Yes | NR | Yes | Yes | Yes | NR | Yes | Yes | Yes |
| Brem et al. 2007[9] | NR | NR | NR | Yes | Yes | NR | Yes | NR | No | NR | Yes | No | Yes | NR | Yes | NR | Yes |
| Gommans et al. 2007[50] | Yes | Yes | Yes | Yes | No | Yes | Yes | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Kim et al. 2007[51] | Yes | Yes | Yes | Yes | No | Yes | Yes | NR | Yes | NR | Yes | No | Yes | NR | Yes | Yes | Yes |

**Table 57. Quality assessment of studies of scintimammography (continued)**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Consecutive | Prospective | >85% Enrolled | Consistent Criteria | Spectrum Bias | Interreader Differences | Blinded to Reference Results | Blinded to Diagnostic Results | Dx Reader Blinded to Clinical Info | Reference Reader Blinded to Clinical Info | Reference standard | Gold Standard | A Priori Threshold | No Intervening Treatment | 85% Accounted for | Funding | Discrepancy |
| Schillaci et al. 2007[52] | NR | Yes | NR | Yes | No | Yes | Yes | NR | NR | NR | Yes | Yes | Yes | NR | Yes | NR | Yes |
| Pinero et al. 2006[53] | Yes | Yes | Yes | Yes | No | NR | Yes | NR | NR | NR | Yes | Yes | Yes | NR | Yes | NR | Yes |
| Mathieu et al. 2005[54] | NR | No | NR | Yes | No | Yes | NR | NR | NR | NR | Yes | No | No | NR | Yes | NR | Yes |

NR Not reported

## Ultrasound

**Table 58. Ultrasound studies: quality evaluation**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Study** | **Consecutive** | **Prospective** | **≥85% Enrolled** | **Consistent Criteria** | **Spectrum Bias** | **Interreader Differences** | **Blinded to Reference Results** | **Blinded to Diagnostic Results** | **Dx Reader Blinded to Clinical Info** | **Ref Reader Blinded to Clinical Info** | **Reference Standard** | **Gold Standard** | ***A Priori* Threshold** | **No Intervening Treatment** | **85% Accounted for** | **Funding** | **Discrepancy** |
| Gokalp et al. 2009[55] | NR | Yes | NR | Yes | No | No | NR | NR | NR | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Liu et al. 2008[56] | Yes | NR | No | Yes | No | Yes | NR | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Vade et al. 2008[57] | Yes | No | Yes | Yes | No | NR | NR | NR | NR | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Cha et al. 2007[58] | Yes | Yes | Yes | Yes | No | Yes | NR | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Chala et al. 2007[59] | Yes | No | Yes | Yes | Yes | No | NR | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Zhi et al. 2007[60] | Yes | NR | Yes | Yes | No | Yes | NR | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Cho et al. 2006[61] | Yes | Yes | Yes | Yes | No | Yes | NR | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Pinero et al. 2006[53] | Yes | Yes | Yes | Yes | No | No | NR | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |

**Table 58. Ultrasound studies: quality evaluation (continued)**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Consecutive | Prospective | ≥85% Enrolled | Consistent Criteria | Spectrum Bias | Interreader Differences | Blinded to Reference Results | Blinded to Diagnostic Results | Dx Reader Blinded to Clinical Info | Ref Reader Blinded to Clinical Info | Reference Standard | Gold Standard | *A Priori* Threshold | No Intervening Treatment | 85% Accounted for | Funding | Discrepancy |
| Ricci et al. 2006[16] | Yes | Yes | Yes | Yes | No | Yes | NR | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Forsberg et al. 2004[62] | NR | NR | Yes | Yes | Yes | No | NR | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | No | Yes |
| Meyberg-Solomayer et al. 2004[63] | NR | Yes | NR | Yes | No | No | NR | NR | NR | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Ozdemir et al. 2004[64] | NR | Yes | NR | Yes | No | No | NR | NR | NR | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Chen et al. 2003[65] | NR | Yes | NR | Yes | No | Yes | NR | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Kook and Kwag 2003[66] | NR | Yes | NR | Yes | No | Yes | Yes | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Marini et al. 2003[67] | Yes | NR | Yes | Yes | Yes | Yes | NR | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Caruso et al. 2002[68] | NR | Yes | Yes | Yes | No | NR | NR | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Koukouraki et al. 2001[69] | NR | Yes | NR | Yes | No | NR | NR | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |

**Table 58. Ultrasound studies: quality evaluation (continued)**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Consecutive | Prospective | ≥85% Enrolled | Consistent Criteria | Spectrum Bias | Interreader Differences | Blinded to Reference Results | Blinded to Diagnostic Results | Dx Reader Blinded to Clinical Info | Ref Reader Blinded to Clinical Info | Reference Standard | Gold Standard | *A Priori* Threshold | No Intervening Treatment | 85% Accounted for | Funding | Discrepancy |
| Malich et al. 2001[35] | Yes | NR | Yes | Yes | No | No | NR | NR | No | NR | Yes | NR | Yes | Yes | Yes | NR | Yes |
| Milz et al. 2001[70] | NR | Yes | NR | Yes | No | NR | NR | NR | NR | NR | Yes | Yes | No | Yes | Yes | NR | Yes |
| Reinikainen et al. 2001[71] | NR | Yes | Yes | Yes | No | Yes | NR | NR | Yes | NR | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Moon et al. 2000[72] | Yes | Yes | No | NR | No | Yes | NR | NR | NR | NR | Yes | Yes | No | Yes | No | Yes | Yes |
| Blohmer et al. 1999[73] | NR | Yes | NR | Yes | No | NR | NR | NR | NR | NR | Yes | Yes | Yes | Yes | No | NR | Yes |
| Chao et al. 1999[74] | NR | Yes | NR | Yes | No | No | NR | NR | NR | NR | Yes | NR | Yes | Yes | Yes | NR | Yes |
| Schroeder et al. 1999[75] | Yes | Yes | Yes | Yes | No | Yes | NR | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Albrecht et al. 1998[76] | NR | Yes | NR | Yes | No | Yes | NR | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Wilkens et al. 1998[77] | NR | NR | NR | Yes | NR | No | NR | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |
| Buadu et al. 1997[78] | Yes | NR | Yes | Yes | No | NR | NR | NR | NR | NR | Yes | Yes | Yes | Yes | Yes | NR | Yes |

**Table 58. Ultrasound studies: quality evaluation (continued)**

| Question | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Study | Consecutive | Prospective | ≥85% Enrolled | Consistent Criteria | Spectrum Bias | Interreader Differences | Blinded to Reference Results | Blinded to Diagnostic Results | Dx Reader Blinded to Clinical Info | Ref Reader Blinded to Clinical Info | Reference Standard | Gold Standard | *A Priori* Threshold | No Intervening Treatment | 85% Accounted for | Funding | Discrepancy |
| Stavros et al. 1995[79] | NR | Yes | NR | Yes | No | NR | NR | NR | NR | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Ciatto et al. 1994[80] | Yes | Yes | Yes | Yes | Yes | No | NR | NR | NR | NR | Yes | No | Yes | Yes | Yes | NR | Yes |
| Perre et al. 1994[81] | NR | Yes | NR | Yes | No | No | NR | NR | Yes | NR | Yes | No | Yes | Yes | Yes | NR | Yes |

NR Not reported

# Appendix D: List of Excluded Studies

## MRI Exclusions

103 total excluded

### Reasons for Exclusion

Did not enroll the patient population of interest: 54 studies

Did not use an acceptable reference standard to verify diagnoses of at least 85% of patients: 12 studies

Study of experimental methods not clinically relevant: 14 studies

Did not address any of the Key Questions: 9 studies

Did not report sufficient data to calculate the outcomes of interest: 6 studies

Duplicate reports of the same studies/patients: 4 studies

Retrospective study that did not enroll all or consecutive patients: 3 studies

Reported data from fewer than 50% of the enrolled patients: 1 study

**Table 59. Studies of MRI that did not meet the inclusion criteria**

| Study | Reason for Exclusion |
|---|---|
| Baltzer et al. 2010[89] | Exploratory study of experimental diagnostic methods |
| Baltzer et al. 2010[90] | Did not enroll the patient population of interest |
| Baltzer et al. 2010[91] | Exploratory study of experimental diagnostic methods |
| Belli et al. 2010[92] | Did not use an acceptable reference standard |
| Benndorf et al. 2010[93] | Did not enroll the patient population of interest |
| Bhooshan et al. 2010[94] | Exploratory study of experimental diagnostic methods |
| Carbonaro et al. 2010[95] | Did not enroll the patient population of interest |
| Dietzel et al. 2010[96] | Exploratory study of experimental diagnostic methods |
| Dietzel et al. 2010[97] | Exploratory study of experimental diagnostic methods |
| El Khouli et al. 2010[98] | Exploratory study of experimental diagnostic methods |

**Table 59. Studies of MRI that did not meet the inclusion criteria (continued)**

| Study | Reason for Exclusion |
|---|---|
| Hauth et al. 2010[99] | Did not address any of the Key Questions |
| Meeuwis et al. 2010[100] | Did not enroll the patient population of interest |
| Peters et al. 2010[101] | Exploratory study of experimental diagnostic methods |
| Weinstein et al. 2010[102] | Did not enroll the patient population of interest |
| Arazi-Kleinman et al. 2009[103] | Enrolled only patients at very high risk of breast cancer |
| Baltzer et al. 2009[104] | Enrolled only patients at very high risk of breast cancer |
| Baltzer et al. 2009[105] | Did not enroll the patient population of interest |
| Baltzer et al. 2009[105] | Enrolled only patients at very high risk of breast cancer |
| Bluemke et al. 2009[20] | Duplicate patient population as in Bluemke et al.[20] |
| Calabrese et al. 2009[106] | Enrolled only patients at very high risk of breast cancer |
| Ciatto et al. 2009[107] | Exploratory study of experimental diagnostic methods |
| El Khouli et al. 2009[108] | Does not address any of the Key Questions |
| El Khouli et al. 2009[109] | Retrospective study that did not enroll all or consecutive patients |
| Gutierrez et al. 2009[110] | Does not address any of the Key Questions |
| Kim et al. 2009[111] | Enrolled only patients diagnosed with invasive breast cancer |
| Kurz et al. 2009[112] | Does not address any of the Key Questions |
| Palle and Reddy et al. 2009[113] | Did not report how or if the MRI diagnoses were verified |
| Pediconi et al. 2009[114] | Fewer than 85% of the lesions had their diagnoses verified with an acceptable reference standard |
| Pereira et al. 2009[115] | Exploratory study of experimental diagnostic methods |
| Perfetto et al. 2009[116] | Retrospective study that did not enroll all or consecutive patients |
| Perfetto et al. 2009[117] | Enrolled only patients at very high risk of breast cancer |

**Table 59. Studies of MRI that did not meet the inclusion criteria (continued)**

| Study | Reason for Exclusion |
|---|---|
| Pinker et al. 2009[118] | Did not report data for patients with diagnosis verified by followup instead of histopathology (45% of enrolled patients) |
| Potente et al. 2009[119] | Enrolled only patients at very high risk of breast cancer |
| Schuten et al. 2009[120] | Only enrolled patients diagnosed with breast cancer |
| Stadlbauer et al. 2009[121] | Only 60% of diagnoses were verified with an acceptable reference standard |
| Woodhams et al. 2009[122] | Does not address any of the Key Questions |
| Baek et al. 2008[123] | Enrolled only patients at very high risk of breast cancer |
| Ballesio et al. 2008[124] | Did not enroll the patient population of interest |
| Choudhury et al. 2008[125] | Did not enroll the patient population of interest |
| Ertas et al. 2008[126] | Did not report sufficient data to calculate the outcomes of interest |
| Hatakenaka et al. 2008[127] | Did not enroll the patient population of interest |
| Heusner et al. 2008[128] | Enrolled only patients diagnosed with breast cancer |
| Lieberman et al. 2008[129] | Enrolled only patients diagnosed with breast cancer |
| Okafuji et al. 2008[130] | Enrolled only patients at very high risk of breast cancer |
| Veltman et al. 2008[131] | Does not address any of the Key Questions |
| Di Nallo et al. 2007[132] | Did not report sufficient data to calculate the outcomes of interest |
| Grunwald 2007[133] | Reported MRI results for fewer than 50% of the enrolled patients |
| Iglesias et al. 2007[134] | Enrolled only patients with benign lesions |
| Klifa et al. 2007[135] | Retrospective study that did not enroll all or consecutive patients |
| Meinel et al. 2007[136] | The results of the MRI examination were used to decide which patients to enroll |
| Williams et al. 2007[137] | Enrolled only patients at very high risk of breast cancer |
| Bartella et al. 2006[138] | Enrolled only patients at very high risk of breast cancer |

**Table 59. Studies of MRI that did not meet the inclusion criteria (continued)**

| Study | Reason for Exclusion |
|---|---|
| Goto et al. 2006[139] | The results of the MRI examination were used to decide which patients to enroll |
| Liberman et al. 2006[140] | The results of the MRI examination were used to decide which patients to enroll |
| Penn et al. 2006[141] | Did not report sufficient data to calculate the outcomes of interest |
| Rubesova et al. 2006[142] | The results of the MRI examination were used to decide which patients to enroll |
| Schnall et al. 2006[143] | Did not report sufficient data to calculate the outcomes of interest |
| Deurloo et al. 2005[144] | The results of the MRI examination were used to decide which patients to enroll |
| Goethem et al. 2005[145] | Enrolled only patients with breast cancer |
| Howarth et al. 2005[146] | Enrolled only patients at very high risk of breast cancer |
| Lehman et al. 2005[147] | The results of the MRI examination were used to decide which patients to enroll |
| Meisamy et al. 2005[148] | Did not enroll the patient population of interest |
| Morakkabati-Spitz 2005[149] | Did not report sufficient data to calculate the outcomes of interest |
| Paakko et al. 2005[150] | Fewer than 85% of the lesions had their diagnoses verified with an acceptable reference standard |
| Sardanelli et al. 2005[151] | Enrolled only patients at very high risk of breast cancer |
| Takeda et al. 2005[152] | Enrolled only patients with breast cancer |
| Wright et al. 2005[153] | Enrolled only patients with breast cancer |
| Boetes et al. 2004[154] | Enrolled only women diagnosed with invasive lobular carcinoma |
| Brix et al. 2004[155] | Does not address any of the Key Questions |
| Chen et al. 2004[156] | Does not address any of the Key Questions |
| Fischer et al. 2004[157] | Verified diagnoses of only 76% of the enrolled patients using an acceptable reference standard |
| Gibbs et al. 2004[158] | Did not enroll the patient population of interest |
| Gibbs et al. 2004[159] | The results of the MRI examination were used to decide which patients to enroll |

**Table 59. Studies of MRI that did not meet the inclusion criteria (continued)**

| Study | Reason for Exclusion |
|---|---|
| Rotaru et al. 2004[160] | Did not enroll the patient population of interest |
| Schelfout et al. 2004[161] | Did not enroll the patient population of interest |
| Szabo et al. 2004[162] | The results of the MRI examination were used to decide which patients to enroll |
| Van Goethem et al. 2004[163] | Did not enroll the patient population of interest |
| Bagni et al. 2003[164] | Fewer than 85% of the lesions had their diagnoses verified with an acceptable reference standard |
| Gibbs and Turnbull 2003[165] | Did not report sufficient data to calculate the outcomes of interest |
| Knopp et al. 2003[166] | Fewer than 85% of the lesions had their diagnoses verified with an acceptable reference standard |
| LaTrenta et al. 2003[167] | Enrolled only patients at very high risk of breast cancer |
| Nakahara et al. 2003[168] | Did not enroll the patient population of interest |
| Szabo et al. 2003[169] | Exploratory study of experimental diagnostic methods |
| Baum et al. 2002[170] | Enrolled only patients at very high risk of breast cancer |
| Carriero et al. 2002[171] | Exploratory study of experimental diagnostic methods |
| Choi et al. 2002[172] | Exploratory study of experimental diagnostic methods |
| Del Maschio et al. 2002[173] | Discussion of the study Bazzocchi et al.[13] |
| Hlawatsch et al. 2002[174] | Did not enroll the patient population of interest |
| Liberman et al. 2002[175] | Enrolled only patients at very high risk of breast cancer |
| Nakahara et al. 2002[176] | Enrolled only patients diagnosed with breast cancer |
| Nunes et al. 2002[177] | Fewer than 85% of the lesions had their diagnoses verified with an acceptable reference standard |
| Reinikainen et al. 2002[178] | Did not enroll the patient population of interest |
| Teifke et al. 2002[179] | Only 48% of diagnoses were verified with an acceptable reference standard |
| Trecate et al. 2002[29] | Duplicate report of the same patients enrolled in Trecate et al.[29] |

**Table 59. Studies of MRI that did not meet the inclusion criteria (continued)**

| Study | Reason for Exclusion |
|---|---|
| Alamo et al. 2001[180] | Did not enroll the patient population of interest |
| Francis et al. 2001[181] | Enrolled only patients diagnosed with invasive lobular carcinoma |
| Hewwang-Kobrunner et al. 2001[182] | Exploratory study of experimental diagnostic methods |
| Khatri et al. 2001[183] | Excluded patients without evidence of a lesion at MRI |
| Lucht et al. 2001[184] | Exploratory study of experimental diagnostic methods |
| Malur et al. 2001[185] | Did not enroll the patient population of interest |
| Ando et al. 2000[186] | Only reported data for patients with MRI images suggestive of malignancy |
| Imbriaco et al. 2000[34] | Duplicate report of the same patients enrolled in Imbracio et al.[34] |
| Kinkel et al. 2000[187] | Retrospective study that did not enroll all or consecutive patients |

MRI Magnetic resonance imaging

# PET Exclusions

19 total excluded

## Reasons for Exclusion

Did not enroll the patient population of interest: 13 studies

Study of experimental methods not clinically relevant: 3 studies

Did not report sufficient information to calculate the outcomes of interest: 1 study

Duplicate report of the same studies/patients: 2 studies

**Table 60. Studies of PET that did not meet the inclusion criteria**

| Study | Reason |
|---|---|
| Caprio et al. 2010[188] | Duplicate report of data found in Imbracio et al.[34] |
| Heusner et al. 2008[128] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Zytoon et al. 2008[189] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Berg et al. 2006[190] | Did not study the population of interest. Forty-three percent (43%) of patients had a confirmed diagnosis of breast cancer and had undergone prior diagnostic biopsies. |
| Kumar et al. 2006[191] | Did not study the population of interest. Most of the enrolled patients had a confirmed diagnosis of breast cancer and had undergone prior diagnostic/excision biopsies. |
| Mavi et al. 2006[192] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Tatsumi et al. 2006[193] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Kumar et al. 2005[194] | Did not study the population of interest. Most enrolled patients had a confirmed diagnosis of breast cancer and had undergone prior diagnostic/excision biopsies |
| Roman et al. 2005[195] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Rosen et al. 2005[196] | Did not study the technology of interest-- experimental methods. |
| Inoue et al. 2004[197] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Marshall et al. 2004[198] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Smyczek-Gargya et al. 2004[199] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Levine et al. 2003[200] | Did not study the technology of interest-- experimental methods. |

**Table 60. Studies of PET that did not meet the inclusion criteria (continued)**

| Study | Reason |
|---|---|
| Buck et al. 2002[201] | Did not report any of the outcomes of interest. |
| Danforth et al. 2002[202] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Paul et al. 2002[203] | Did not study the population of interest. Enrolled only patients with confirmed breast cancer. |
| Avril et al. 2000[204] | Update, with additional patients, of Avril et al.,[204] which reports that it studied a mixed population of patients (some patients had a history of breast cancer). |
| Murthy et al. 2000[205] | Did not study the technology of interest-- experimental methods. |

# Scintimammography

18 total excluded

## Reasons for Exclusion

Did not use the tracer of interest: 5 studies

Did not use an acceptable reference standard to verify diagnoses of at least 85% of the patients: 5 studies

Did not enroll the patient population of interest: 3 studies

Did not address any of the Key Questions: 3 studies

Study of experimental methods not clinically relevant: 2 studies

**Table 61. Studies of scintimammography that did not meet the inclusion criteria**

| Study | Reason for Exclusion |
|---|---|
| Brem et al. 2010[206] | Did not address any of the Key Questions |
| Ozulker et al. 2010[207] | Did not use an acceptable reference standard |
| Brem et al. 2008[208] | Did not enroll the patient population of interest |
| Hruska et al. 2008[209] | Exploratory study of experimental diagnostic methods |
| Sharma et al. 2008[210] | 99mTc-methionine tracer |
| Spanu et al. 2008[211] | Tc99m tetrofosmin tracer |
| Spanu et al. 2008[212] | Tc99m tetrofosmin tracer |
| Buchmann et al. 2007[43] | 99mTechnetium-Perechnetate or Iodide |
| Spanu et al. 2007[213] | Tc99m tetrofosmin |
| Bekis et al. 2005[214] | Does not address any of the Key Questions |
| Brem et al. 2005[215] | Patients were at high-risk for breast cancer with normal mammograms/ clinical examination |
| Howarth et al. 2005[146] | 26% of subjects had previous breast surgery/29% were positive for a family history of breast cancer |
| Kim et al. 2005[216] | Did not use an acceptable reference standard to verify diagnoses of at least 85% of the patients |
| Myslivecek et al. 2005[217] | Did not use an acceptable reference standard to verify diagnoses of at least 85% of the patients |

**Table 61. Studies of scintimammography that did not meet the inclusion criteria (continued)**

| Study | Reason for Exclusion |
|---|---|
| Papantoniou et al. 2005[218] | Does not address any of the Key Questions |
| Rhodes et al. 2005[219] | Prototype device |
| Tiling et al. 2005[220] | Did not use an acceptable reference standard to verify diagnoses of at least 85% of the patients |
| Kim et al. 2003[221] | Did not use an acceptable reference standard to verify diagnoses of at least 85% of the patients |

Tc Technetium

# Ultrasound Exclusions

153 total excluded

## Reasons for Exclusion

Did not enroll the patient population of interest: 63 studies

Did not address any of the Key Questions: 27 studies

Did not use an acceptable reference standard to verify diagnoses of at least 85% of patients: 27 studies

Retrospective study that did not enroll all or consecutive patients: 11 studies

Did not report sufficient information to calculate the outcomes of interest: 8 studies

Study of experimental methods not clinically relevant: 9 studies

Duplicate reports of the same studies/patients: 3 articles

Reported data for fewer than 50% of the enrolled patients: 3 studies

Retrospective case-control design: 1 study

Did not report sufficient details of the US methods to permit analysis: 1 study

**Table 62. Studies of ultrasound that did not meet the inclusion criteria**

| Study | Primary Reason for Exclusion |
|---|---|
| Caproni et al. 2010[222] | Did not use an acceptable reference standard |
| Dave et al. 2010[223] | Study of experimental technology |
| Cheng et al. 2010[224] | Study of experimental technology |
| Hongjia et al. 2010[225] | Did not enroll the patient population of interest |
| Moon et al. 2010[226] | Retrospective study that did not enroll all or consecutive patients |
| Moriguchi et al. 2010[227] | Did not use an acceptable reference standard |
| Sorelli et al. 2010[228] | Did not use an acceptable reference standard |
| Wang et al. 2010[229] | Study of experimental technology |
| Baek et al. 2009[230] | Retrospective study that did not enroll all or consecutive patients |
| Balleyguier et al. 2009[231] | Did not verify the diagnoses with an acceptable reference standard |

**Table 62. Studies of ultrasound that did not meet the inclusion criteria (continued)**

| Study | Primary Reason for Exclusion |
|---|---|
| Barr et al. 2009[232] | Does not address any of the Key Questions |
| Devolli-Disha et al. 2009[233] | Did not enroll the patient population of interest |
| Habib et al. 2009[47] | Did not report any details of the US methods |
| Kim et al. 2009[234] | Data was reported for fewer than 50% of the enrolled patients |
| Kotsianos-Hermle et al. 2009[235] | Did not enroll the patient population of interest |
| Masroor et al. 2009[236] | Did not enroll the patient population of interest |
| Masroor et al. 2009[237] | Did not enroll the patient population of interest |
| McCavert et al. 2009[238] | Did not verify the diagnoses with an acceptable reference standard |
| Su et al. 2009[239] | Retrospective study that did not enroll all or consecutive patients |
| Barnard et al. 2008[240] | Did not report sufficient data to calculate the outcomes of interest |
| Bilali et al. 2008[241] | Did not report sufficient data to calculate the outcomes of interest |
| Choudhury et al. 2008[125] | Did not enroll the patient population of interest |
| Forsberg et al. 2008[242] | Exploratory study of experimental diagnostic methods |
| Kang et al. 2008[243] | Data was reported for fewer than 50% of the enrolled patients |
| Kwak et al. 2008[244] | Data was reported for fewer than 50% of the enrolled patients |
| LeCarpentier et al. 2008[245] | Did not report sufficient data to calculate the outcomes of interest |
| Park et al. 2008[246] | Did not enroll the patient population of interest |
| Singh et al. 2008[247] | Did not verify the diagnoses with an acceptable reference standard |
| Wenkel et al. 2008[248] | Only 65% of diagnoses were verified with an acceptable reference standard |
| Abbattista et al. 2007[249] | Did not verify the diagnoses with an acceptable reference standard |
| Ballesio et al. 2007[250] | Did not enroll the patient population of interest |

**Table 62. Studies of ultrasound that did not meet the inclusion criteria (continued)**

| Study | Primary Reason for Exclusion |
|---|---|
| Ciatto and Houssami 2007[251] | Only enrolled patients diagnosed with carcinomas |
| Constantini et al. 2007[252] | Only 72% of diagnoses were verified with an acceptable reference standard |
| Graf et al. 2007[253] | Did not enroll the patient population of interest |
| Jiang et al. 2007[254] | Does not address any of the Key Questions |
| Osako et al. 2007[255] | Only enrolled patients diagnosed with carcinomas |
| Prasad and Houserkova 2007[256] | Only 10% of diagnoses were verified with an acceptable reference standard |
| Scaperrotta et al. 2007[257] | Did not report data for patients diagnosed as “clearly benign” on the diagnostic test of interest (US) |
| Thomas et al. 2007[258] | Did not enroll the patient population of interest |
| Constantini et al. 2006[259] | Duplicate report of data from Constantini et al.[252] |
| Del Frate et al. 2006[260] | Did not enroll the patient population of interest |
| Grunwald et al. 2006[261] | Did not enroll the patient population of interest |
| Malik et al. 2006[262] | Did not verify the diagnoses with an acceptable reference standard |
| Regner et al. 2006[263] | Does not address any of the Key Questions |
| Thomas et al. 2006[264] | Did not enroll the patient population of interest |
| Adepoju et al. 2005[265] | Did not enroll the patient population of interest |
| Baez et al. 2005[266] | Only 37% of diagnoses were verified with an acceptable reference standard |
| Berg 2005[267] | Did not enroll the patient population of interest |
| Cawson et al. 2005[268] | Enrolled only patients diagnosed with radial scars |
| Cha et al. 2005[269] | Did not report sufficient data to calculate the outcomes of interest |
| Cho et al. 2005[270] | Did not verify the diagnoses of lesions diagnosed on US as benign |
| Cho et al. 2005[270] | Only 40% of diagnoses were verified with an acceptable reference standard |

**Table 62. Studies of ultrasound that did not meet the inclusion criteria (continued)**

| Study | Primary Reason for Exclusion |
|---|---|
| Eljuga and Susac 2005[271] | Retrospective study that did not enroll all or consecutive patients |
| Nagashima et al. 2005[272] | Enrolled only patients diagnosed with ductal carcinoma in situ |
| Shahid et al. 2005[273] | Did not enroll the patient population of interest |
| Szabo et al. 2005[274] | Only 62.7% of diagnoses were verified with an acceptable reference standard |
| Tohno and Ueno 2005[275] | Only enrolled patients diagnosed with carcinomas |
| Tumyan et al. 2005[276] | Did not enroll the patient population of interest |
| Benson et al. 2004[277] | Mixed patient population; primarily a study of screening asymptomatic patients |
| Boetes et al. 2004[154] | Enrolled only women diagnosed with invasive lobular carcinoma |
| Chen et al. 2004[278] | Retrospective study that did not enroll all or consecutive patients |
| Cid et al. 2004[279] | Did not enroll the patient population of interest |
| Cura et al. 2004[280] | Exploratory study of experimental diagnostic methods |
| Drukker et al. 2004[281] | Does not address any of the Key Questions |
| Foxcroft et al. 2004[282] | Enrolled only women diagnosed with breast cancer |
| Georgian-Smith 2004[283] | Enrolled only patients diagnosed with hamartoma |
| Gibbs et al. 2004[158] | Did not enroll the patient population of interest |
| Murad and Bari 2004[284] | Only 70% of diagnoses were verified with an acceptable reference standard |
| Rotaru and Luciani 2004[160] | Only enrolled patients that were difficult to diagnose by US |
| Santamaria et al. 2004[285] | Enrolled only patients diagnosed with invasive carcinoma |
| Schelfout et al. 2004[161] | Did not enroll the patient population of interest |
| Sehgal et al. 2004[286] | Does not address any of the Key Questions |
| Selinko et al. 2004[287] | Enrolled only women diagnosed with invasive lobular carcinoma |

**Table 62. Studies of ultrasound that did not meet the inclusion criteria (continued)**

| Study | Primary Reason for Exclusion |
|---|---|
| Strano et al. 2004[288] | Does not address any of the Key Questions |
| Van Goethem et al. 2004[163] | Did not enroll the patient population of interest |
| Yang and Tse 2004[289] | Enrolled only women with DCIS |
| Zonderland et al. 2004[290] | Does not address any of the Key Questions |
| Chen et al. 2003[291] | Does not address any of the Key Questions |
| Chen et al. 2003[292] | Enrolled only women diagnosed with carcinoma |
| Drukker and Giger 2003[293] | Does not address any of the Key Questions |
| Flobbe et al. 2003[294] | Did not report sufficient data to calculate the outcomes of interest |
| Kazimierz et al. 2003[295] | Did not verify the diagnoses with an acceptable reference standard |
| Martinez et al. 2003[296] | Did not enroll the patient population of interest |
| Mesaki et al. 2003[297] | Only 40% of diagnoses were verified with an acceptable reference standard |
| Nakahara et al. 2003[168] | Did not enroll the patient population of interest |
| Park et al. 2003[298] | Does not address any of the Key Questions |
| Puglisi et al. 2003[299] | Enrolled only women with papillary breast lesions |
| Shetty et al. 2003[300] | Did not report sufficient data to calculate the outcomes of interest |
| Chen et al. 2002[301] | Did not enroll the patient population of interest |
| Chen et al. 2002[302] | Does not address any of the Key Questions |
| Germer et al. 2002[303] | Does not address any of the Key Questions |
| Gunhan-Bilgen et al. 2002[304] | Enrolled only women diagnosed with inflammatory carcinoma |
| Hlawatsch et al. 2002[174] | Did not enroll the patient population of interest |
| Krestan et al. 2002[305] | Does not address any of the Key Questions |

**Table 62. Studies of ultrasound that did not meet the inclusion criteria (continued)**

| Study | Primary Reason for Exclusion |
|---|---|
| Kuo et al. 2002[306] | Does not address any of the Key Questions |
| Kuo et al. 2002[307] | Does not address any of the Key Questions |
| Lee et al. 2002[308] | Retrospective study that did not enroll all or consecutive patients |
| Muttarak et al. 2002[309] | Enrolled only patients diagnosed with phyllodes tumors |
| Reinikainen et al. 2002[178] | Did not enroll the patient population of interest |
| Tan et al. 2002[310] | Enrolled only patients diagnosed with invasive lobular carcinoma |
| Taylor et al. 2002[311] | Did not report sufficient data to calculate the outcomes of interest |
| Teifke et al. 2002[179] | Only 48% of diagnoses were verified with an acceptable reference standard |
| Wang et al. 2002[312] | Duplicate report of data from Chen et al.[312] |
| Wang et al. 2002[313] | Duplicate report of data from Chen et al.[312] |
| Yilmaz et al. 2002[314] | Enrolled only women diagnosed with medullary carcinomas |
| Alamo et al. 2001[180] | Did not enroll the patient population of interest |
| Allen et al. 2001[315] | Does not address any of the Key Questions |
| Arger et al. 2001[316] | Does not address any of the Key Questions |
| Bhatti et al. 2001[317] | Did not enroll the patient population of interest |
| Chou et al. 2001[318] | Does not address any of the Key Questions |
| Cwikla et al. 2001[319] | Enrolled only patients diagnosed with multi-focal carcinomas |
| Francis et al. 2001[181] | Enrolled only patients diagnosed with invasive lobular carcinoma |
| Malur et al. 2001[185] | Did not enroll the patient population of interest |
| Ozdemir et al. 2001[320] | Did not report sufficient data to calculate the outcomes of interest |
| Rosen and Soo 2001[321] | Does not address any of the Key Questions |

**Table 62. Studies of ultrasound that did not meet the inclusion criteria (continued)**

| Study | Primary Reason for Exclusion |
|---|---|
| Soo et al. 2001[322] | Enrolled only patients with negative US findings who were later diagnosed with carcinomas |
| Whitehouse et al. 2001[323] | Does not address any of the Key Questions |
| Chaudhari et al. 2000[324] | Does not address any of the Key Questions |
| Choi et al. 2000[325] | Retrospective study that did not enroll all or consecutive patients |
| Evans and Lyons 2000[326] | Enrolled only patients diagnosed with small invasive lobular carcinomas |
| Klaus et al. 2000[327] | Only enrolled patients who underwent a biopsy because of findings on the diagnostic test of interest (ultrasound) |
| Madjar et al. 2000[328] | Does not address any of the Key Questions |
| Stuhrmann et al. 2000[329] | Did not enroll the patient population of interest |
| Thibault et al. 2000[330] | Only 31% of diagnoses were verified with an acceptable reference standard |
| Baker et al. 1999[331] | Does not address any of the Key Questions |
| Blohmer et al. 1999[332] | Exploratory study of experimental diagnostic methods |
| Chao et al. 1999[333] | Exploratory study of experimental diagnostic methods |
| Eltahir et al. 1999[334] | Retrospective study with only 33.7% of the consecutively enrolled patients examined by ultrasound |
| Huang et al. 1999[335] | Did not enroll the patient population of interest |
| Kook et al. 1999[336] | Retrospective study that did not enroll all or consecutive patients |
| Moss et al. 1999[337] | Only 33% of diagnoses were verified with an acceptable reference standard |
| Obwegeser et al. 1999[338] | Did not verify the diagnoses with an acceptable reference standard |
| Rahbar et al. 1999[339] | Does not address any of the Key Questions |
| Rotten et al. 1999[340] | Did not enroll the patient population of interest |
| Skaane 1999[341] | Enrolled only patients diagnosed with malignant tumors |
| Zonderland et al. 1999[342] | Did not enroll the patient population of interest |

**Table 62. Studies of ultrasound that did not meet the inclusion criteria (continued)**

| Study | Primary Reason for Exclusion |
|---|---|
| Brnic et al. 1998[343] | Only 13% of diagnoses were verified with an acceptable reference standard |
| Carson et al. 1998[344] | Does not address any of the Key Questions |
| Delorme et al. 1998[345] | Exploratory study of experimental diagnostic methods |
| Giuseppetti et al. 1998[346] | Only 70% of diagnoses were verified with an acceptable reference standard |
| Hayashi et al. 1998[347] | Retrospective study that did not enroll all or consecutive patients |
| Huber et al. 1998[348] | Does not address any of the Key Questions |
| Wright et al. 1998[349] | Did not report what reference standard, if any, was used to verify the diagnoses |
| Cabasares et al. 1997[350] | Did not enroll the patient population of interest |
| Jain et al. 1997[351] | Did not verify the diagnoses with an acceptable reference standard |
| Madjar et al. 1997[352] | Did not enroll the patient population of interest |
| Muller-Schimpfle et al. 1997[353] | Does not address any of the Key Questions |
| Raza and Baum 1997[354] | Only enrolled patients that were referred for biopsy on the basis of the US examinations |
| Schelling et al. 1997[355] | Exploratory study of experimental diagnostic methods |
| Skaane et al. 1997[356] | Retrospective case-control study |
| Yang et al. 1997[357] | Only enrolled patients diagnosed with carcinomas |
| Edde 1994[358] | Did not enroll the patient population of interest |
| Saitoh et al. 1994[359] | Retrospective study that did not enroll all or consecutive patients |

US Ultrasound

# Appendix E: Peer Reviewers

**Table 63. Technical expert panel**

| Name | Title | Specialty | Organization |
|---|---|---|---|
| Carol Lee, MD | Chair, Breast Imaging Commission of the American College of Radiology<br>President, Society of Breast Imaging | Radiology | Memorial Sloan Kettering Cancer Center |
| Robert D. Rosenberg, MD | Chief, Mammography | Radiology | University of New Mexico |
| Deborah Laxague | Patient Advocate<br>Obstetrics Nurse | Advocacy | National Breast Cancer Coalition |
| Mark Robson, MD | Clinic Director, Clinical Genetics Service | Medical Oncology | Memorial Sloan-Kettering Cancer Center, Cornell University-Weill Medical College |
| Joann G. Elmore, MD, MPH | Professor of Medicine<br>Adjunct Professor of Epidemiology<br>Attending Physician, HMC Adult Medicine Clinic<br>Section Head, Division of General Internal Medicine | Epidemiology Internal Medicine | Harborview Medical Center |
| Constantine Gatsonis, PhD | Professor:<br>Community Health and Applied Mathematics | Biostatistics<br>(Methodologist Reviewer) | Brown University |

# ECRI Institute Personnel

All ECRI Institute personnel involved in the preparation of this report may be contacted at:

ECRI Institute
5200 Butler Pike
Plymouth Meeting, PA 19462
Telephone: (610) 825-6000
Facsimile: (610) 834-1275

**Karen M. Schoelles, M.D., S.M., F.A.C.P.**
Director, Evidence-based Practice Center
Medical Director, Health Technology Assessment Group

**Wendy Bruening, Ph.D.**
Associate Director, Evidence-based Practice Center and Health Technology Assessment Group

**Stacey Uhl, M.S.S.**
Senior Research Analyst, Evidence-based Practice Center and Health Technology Assessment Group

**Joann Fontanarosa, Ph.D.**
Research Analyst, Evidence-based Practice Center and Health Technology Assessment Group

**James T. Reston, Ph.D., M.P.H.**
Associate Director, Evidence-based Practice Center and Health Technology Assessment Group

**Jonathan R. Treadwell, Ph.D.**
Associate Director, Evidence-Based Practice Center and Health Technology Assessment Group

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