Palpable Breast Mass
EVIDENCE TABLE

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
1. American Cancer Society. *Cancer Facts and Figures 2008*: Atlanta: American Cancer Society; 2008.	15	N/A	Article on cancer facts and figures (2008) by American Cancer Society.	N/A	3
2. Donegan WL. Evaluation of a palpable breast mass. *N Engl J Med* 1992; 327(13):937-942.	12	N/A	Review evaluation of palpable breast mass.	Article recommends needle aspiration as the first step in diagnosis of a palpable mass.	4
3. Rosner D, Blaird D. What ultrasonography can tell in breast masses that mammography and physical examination cannot. *J Surg Oncol* 1985; 28(4):308-313.	9	400	Prospective study to examine the capability of US to provide additional information to the physical and mammographic examination for therapeutic decision.	Breast cancers were accurately diagnosed in 73% (88/120) by US and 84% (98/116) by mammography (P>0.10). Major limitation of US was in the diagnosis of minimal breast cancer (23%, 5/21) due to its inability to visualize microcalcifications. Study validates the importance of US in the diagnosis and therapeutic decision of cystic and fibrocystic masses but cannot substitute mammography in early detection of breast carcinoma.	2
4. Boyd NF, Sutherland HJ, Fish EB, Hiraki GY, Lickley HL, Maurer VE. Prospective evaluation of physical examination of the breast. *Am J Surg* 1981; 142(3):331-334.	10	100	Prospective evaluation of physical examination of the breast. Reliability of physical examination was evaluated by determining the extent of agreement among four experienced breast surgeons who examined the same patients.	Diagnostic accuracy of surgeons was very similar, and most disagreements concerned the findings in patients who did not have breast cancer. Breast examination carried out by more than one surgeon may reduce the frequency with which biopsy is performed in patients who do not have breast cancer.	3
5. Baker LH. Breast Cancer Detection Demonstration Project: five-year summary report. *CA Cancer J Clin* 1982; 32(4):194-225.	15	Data management Center had 1,074,019 final screening forms from annual exams and 276,593 initial patient history records on file at time of analysis	Review Breast Cancer Detection Demonstration Project (5-year summary report). The median age of participants was 49.5 years.	The relative contribution of mammography alone (in the absence of positive physical findings) was 41.6% compared with 8.7% for physical examinations (in the absence of positive mammogram findings).	2

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6. Eklund GW, Cardenosa G. The art of mammographic positioning. *Radiol Clin North Am* 1992; 30(1):21-53.	12	N/A	A review on the art of mammographic positioning for breast cancer detection.	Mammographic positioning plays a role in breast cancer detection. Optimal mammographic positioning is achieved by understanding the capabilities of available dedicated mammographic equipment and applying this understanding to take full advantage of natural breast mobility in overcoming various anatomic limitations.	4
7. Dershaw DD, Eddins G, Liberman L, et al. Sonographic and clinical findings in women with palpable breast disease and negative mammography. *Breast Dis* 1995; 8:13-17.	10	114 women with 126 lesions 76 patients had sonography	Prospective study of women to determine the clinical importance of palpable lesions and the role of sonography in their evaluation.	Sonography most useful in women 30-50 years of age in whom 19/20 (95%) cysts were found. Of 7 cancers, 2 had no sonographic findings. Sonography should be first examination in women under 30 years of age.	2
8. Georgian-Smith D, Taylor KJ, Madjar H, et al. Sonography of palpable breast cancer. *J Clin Ultrasound* 2000; 28(5):211-216.	10	616 palpable lesions (293 malignant)	Retrospective study analyzing a subset of patients with palpable malignant breast lesions to determine the rate of sonographically occult malignancy. Sonography detected all 293 palpable malignity lesions.	Sonography detected all 293 palpable malignant lesions (95% CI for sensitivity, 99%-100%). All palpable malignant breast lesions were visible by sonography in patients in whom a biopsy was recommended. Authors caution that until false-negative rate of sonography for equivocal palpable abnormalities is determined prospectively, sonography cannot be accurately applied to rule out malignancy in this setting.	3
9. Liberman L, Ernberg LA, Heerdt A, et al. Palpable breast masses: is there a role for percutaneous imaging-guided core biopsy? *AJR* 2000; 175(3):779-787.	10	107 women 115 palpable masses	Review findings to evaluate percutaneous imaging-guided core biopsy in assessment of selected palpable breast masses.	Percutaneous image-guided core biopsy spared additional diagnostic tissue sampling in 74% of selected women. Imaging-guided core biopsy is useful in evaluating palpable breast masses that are small, deep, mobile, vaguely palpable, or multiple. In this study, percutaneous imaging-guided core biopsy spared additional diagnostic tissue sampling in 74% women with palpable breast masses.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
10. Garg S, Mohan H, Bal A, Attri AK, Kochhar S. A comparative analysis of core needle biopsy and fine-needle aspiration cytology in the evaluation of palpable and mammographically detected suspicious breast lesions. *Diagn Cytopathol* 2007; 35(11):681-689.	9	50	To compare value of needle core biopsy and fine-needle aspiration cytology (FNAC) in the evaluation of palpable and mammographically detected suspicious breast lesions.	Sensitivity and specificity of mammography for malignant diagnosis was 84.37% and 83.33%, respectively. Sensitivity and specificity of FNAC for malignant diagnosis was 78.15% and 94.44%, respectively, and of needle core biopsy was 96.5% and 100%, respectively. Needle core biopsy is superior to FNAC in the diagnosis of breast lesions in terms of sensitivity, specificity, correct histological categorization of the lesions and tumor grading.	2
11. Homesh NA, Issa MA, El-Sofiani HA. The diagnostic accuracy of fine needle aspiration cytology versus core needle biopsy for palpable breast lump(s). *Saudi Med J* 2005; 26(1):42-46.	8	296	Prospective randomized controlled clinical trial to compare the accuracy of FNAC and core needle biopsy in patients with palpable breast masses.	• FNAC had sensitivity of 66.66%, specificity of 81.8% accuracy of 75.7%, PPV of 100% and NPV of 90%. • Core needle breast biopsy had sensitivity of 92.3%, specificity of 94.8%, and accuracy of 93.4%, PPV of 100% and NPV 100%. • Core needle biopsy is more accurate than FNAC.	1
12. Pisano ED, Fajardo LL, Caudry DJ, et al. Fine-needle aspiration biopsy of nonpalpable breast lesions in a multicenter clinical trial: results from the radiologic diagnostic oncology group V. *Radiology* 2001; 219(3):785-792.	8	442	Multicenter study to determine the diagnostic accuracy US and stereotactically guided FNAB in the diagnosis of nonpalpable breast lesions.	• Sensitivity and specificity of FNAB were 85%-88% and 55.6%-90.5%, respectively; accuracy ranged from 62.2% to 89.2%. • Diagnostic accuracy of FNAB was significantly better for detection of masses than for detection of calcifications (67.3% vs. 53.8%, P =.006) and with US guidance than with stereotactic guidance (77.2% vs. 58.9%; P=.002).	1
13. Stavros AT, Thickman D, Rapp CL, Dennis MA, Parker SH, Sisney GA. Solid breast nodules: use of sonography to distinguish between benign and malignant lesions. *Radiology* 1995; 196(1):123-134.	10	622 women 750 lesions	Prospective classification of nodules to determine whether sonography could accurately distinguish benign from malignant lesions and whether this distinction could be definite enough to obviate biopsy.	Classification scheme had NPV of 99.5%. Of 125 malignant lesions, 123 were correctly classified (sensitivity 98.4%). Sonography can classify some solid lesions as benign and allow imaging follow-up.	2
14. Park YM, Kim EK, Lee JH, et al. Palpable breast masses with probably benign morphology at sonography: can biopsy be deferred? *Acta Radiol* 2008; 49(10):1104-1111.	10	274 patients 312 palpable masses	To determine the NPV for sonographic evaluation of palpable breast masses with probably benign morphology, and to assess whether follow-up may be an acceptable alternative to immediate biopsy.	310/312 masses were benign and 2/312 were malignancies, resulting in a false-negative rate of 0.6% (NPV 99.4%, P=0.0432, 95% CI: 0.0%-1.5%). NPV of sonography for palpable breast masses with probably benign morphology is high (99.4%).	2

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15. Smith GE, Burrows P. Ultrasound diagnosis of fibroadenoma - is biopsy always necessary? *Clin Radiol* 2008; 63(5):511-515; discussion 516-517.	10	447	To retrospectively review US characteristics of fibroadenoma and the necessity to biopsy all fibroadenomas in patients under 25 years.	357/447 patients had US diagnosis of fibroadenoma. This was histologically proven in 281 (78.8%) cases. In 75 (21.5%) of these patients, the final histology was either another benign pathology or normal. Most patients in the 25 years and under age group have benign breast pathology, most commonly fibroadenoma. US is a reliable technique to diagnose fibroadenoma.	2
16. Shin JH, Han BK, Ko EY, Choe YH, Nam SJ. Probably benign breast masses diagnosed by sonography: is there a difference in the cancer rate according to palpability? *AJR* 2009; 192(4):W187-191.	13	352	Retrospective study to determine whether there is a difference in cancer rates between palpable and nonpalpable probably benign breast nodules detected by US.	Of 288 masses with follow-up, cancer rate was 2.4%. The cancer rate of the nonpalpable masses was 2.1% and the cancer rate of the palpable masses was 3.2%. Of 7 cancers, 5 were diagnosed by a sonographically guided core biopsy and 2 were diagnosed by surgical excision after a benign biopsy. There is no statistically significant difference between the cancer rates of palpable and nonpalpable masses.	2
17. Soo MS, Rosen EL, Baker JA, Vo TT, Boyd BA. Negative predictive value of sonography with mammography in patients with palpable breast lesions. *AJR* 2001; 177(5):1167-1170.	10	420 patients 455 palpable breast lesions	Retrospective study of palpable breast lesions in patients examined with mammography and sonography to determine NPV.	The NPV of sonography and mammography in the setting of a palpable lesion was 99.8%.Only one clinically suspicious lesion, an invasive lobular carcinoma, had negative imaging examinations. The mean imaging follow-up time for the study was 25 months. NPV of sonography and mammography is high, and together these imaging modalities can be reassuring if follow-up is planned when the physical exam is not highly suspicious. Biopsy should not be delayed if the physical exam is suspicious.	2
18. Shetty MK, Shah YP. Prospective evaluation of the value of negative sonographic and mammographic findings in patients with palpable abnormalities of the breast. *J Ultrasound Med* 2002; 21(11):1211-1216; quiz 1217-1219.	10	172 patients 186 palpable abnormalities	Prospective study to evaluate the value of combined negative sonographic and mammographic findings in patients with palpable breast abnormalities.	The NPV of combined mammography and sonography in patients with palpable breast abnormalities was 100% determined by biopsy or follow-up no less than 24 months.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
19. Moy L, Slanetz PJ, Moore R, et al. Specificity of mammography and US in the evaluation of a palpable abnormality: retrospective review. *Radiology* 2002; 225(1):176-181.	10	829	Retrospective study to determine the number of patients who received diagnosis of breast cancer after having an area of clinical concern and combined negative mammographic and US findings.	374/829 women had follow-up information. 233 had negative imaging findings with more than 2 years of follow-up. 6 (2.6%) of 233 had a diagnosis of breast cancer in the area of the palpable abnormality. A negative mammographic and US finding of a palpable abnormality does not exclude breast cancer, but the likelihood of breast cancer is low, approximately 2.6%-2.7%. It may be higher if the breast tissues are dense and lower if they are predominantly fatty.	2
20. ACR Practice Guideline for the Performance of a Breast Ultrasound Examination. *In: Practice Guidelines and Technical Standards.* Reston, Va: American College of Radiology; 2007:569-573.	15	N/A	Practice guideline on the performance of breast US to assist practitioners.	N/A	3
21. Sabate JM, Clotet M, Torrubia S, et al. Radiologic evaluation of breast disorders related to pregnancy and lactation. *Radiographics* 2007; 27 Suppl 1:S101-124.	12	N/A	Review imaging of breast disorders related to pregnancy and lactation.	US is the most appropriate radiologic method and is useful in the diagnosis and treatment of abscesses. Knowledge of the unique entities that are specifically related to pregnancy and lactation and of their radiologic-pathologic appearances can help the radiologist make the correct diagnosis.	4
22. Yang WT, Dryden MJ, Gwyn K, Whitman GJ, Theriault R. Imaging of breast cancer diagnosed and treated with chemotherapy during pregnancy. *Radiology* 2006; 239(1):52-60.	9	23 women with 24 cancers	To retrospectively assess mammography, high-frequency-transducer US, and color Doppler US for the initial and subsequent evaluation of breast cancer diagnosed and treated with chemotherapy during pregnancy.	Findings were positive for malignancy in 18/20 (90%) cancers. A mass in all 21 cancers (100%) was depicted in the 20 women who underwent breast and nodal US. US correctly depicted axillary metastasis in 15/18 women who underwent US nodal assessment. Of 12 patients who were evaluated for response to chemotherapy, US demonstrated complete response in two patients, partial response in three, stable findings in one, and progression of disease in six. Breast cancer diagnosed during pregnancy is mammographically evident despite dense parenchymal background. US, when performed, demonstrates all masses and provides information regarding response to neoadjuvant chemotherapy.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
23. Obenauer S, Dammert S. Palpable masses in breast during lactation. *Clin Imaging* 2007; 31(1):1-5.	9	27	To examine the value of various radiological methods in patients with palpable breast masses during the lactation period.	18 US guided biopsies performed revealed 3 cysts, 7 hyperplasias/mastopathia, 3 cases of papilloma, and 2 carcinomas. US should be the method of choice. If possible mammography and MR mammography should be done after lactating period.	3
24. Swinford AE, Adler DD, Garver KA. Mammographic appearance of the breasts during pregnancy and lactation: false assumptions. *Acad Radiol* 1998; 5(7):467-472.	13	18 women 18 controls	Retrospective study to examine the accuracy of the assumption that pregnant and lactating women have dense breasts, thus limiting the usefulness of mammography.	Pregnant and lactating women do not always have dense breasts, and so mammography can be performed. Mammography can be as useful in these women as it is in other women with breast signs and symptoms.	3
25. Orel SG, Schnall MD. MR imaging of the breast for the detection, diagnosis, and staging of breast cancer. *Radiology* 2001; 220(1):13-30.	12	N/A	Review MRI of the breast for detection, diagnosis, and staging of breast cancer.	MRI as a method to help detect, diagnose, and stage breast cancer remains in the developmental stage.	4
26. Berg WA, Gutierrez L, NessAiver MS, et al. Diagnostic accuracy of mammography, clinical examination, US, and MR imaging in preoperative assessment of breast cancer. *Radiology* 2004; 233(3):830-849.	4	111	To prospectively assess the diagnostic accuracy of mammography, clinical examination, US, and MRI in the preoperative imaging of breast cancer.	In non-fatty breasts, US and MRI were more sensitive than mammography for invasive cancer, but both overestimated tumor extent. US showed no detection benefit after MRI. Combined mammography, clinical examination, and MRI were more sensitive than any other individual test or combination of tests.	2
27. Yeh E, Slanetz P, Kopans DB, et al. Prospective comparison of mammography, sonography, and MRI in patients undergoing neoadjuvant chemotherapy for palpable breast cancer. *AJR* 2005; 184(3):868-877.	9	41 patients 2 reviewers	To prospectively compare mammography, US, and MRI in patients undergoing neoadjuvant chemotherapy for palpable breast cancer.	Agreement about the rate of response as measured by clinical examination, mammography, US, and MRI compared with the gold standard (pathology) was 19%, 26%, 35%, and 71% respectively. Of the four, MRI correlated with the gold standard more often.	2
28. Yutani K, Shiba E, Kusuoka H, et al. Comparison of FDG-PET with MIBI-SPECT in the detection of breast cancer and axillary lymph node metastasis. *J Comput Assist Tomogr* 2000; 24(2):274-280.	9	40	Compare (FDG) PET to Tc-99m methoxyisobutylisonitrile (MIBI) SPECT for breast cancer diagnosis.	The sensitivities of FDG-PET and MIBI-SPECT were 78.9% and 76.3% for breast cancer and 50.0% and 37.5% for axillary lymph node metastasis, respectively. MIBI-SPECT is comparable with FDG-PET in detecting breast cancer. Neither FDG-PET nor MIBI-SPECT is sufficiently sensitive to rule out axillary lymph node metastasis.	3
29. Mathieu I, Mazy S, Willemart B, Destine M, Mazy G, Lonneux M. Inconclusive triple diagnosis in breast cancer imaging: is there a place for scintimammography? *J Nucl Med* 2005; 46(10):1574-1581.	9	104 patients 118 procedures	Retrospective study to evaluate impact of scintimammography (SM) in patients with doubtful or discordant triple diagnosis—that is mammography, US, and FNAC.	SM-SPECT had a sensitivity of 88.4% and a specificity of 67%. Overall, SM-SPECT modified patient management in 58/118 cases (49%).	2

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30. Feig SA, Ehrlich SM. Estimation of radiation risk from screening mammography: recent trends and comparison with expected benefits. *Radiology* 1990; 174(3 Pt 1):638-647.	12	N/A	To examine recent trends of estimation of radiation risk from screening mammography and compare with expected benefits.	In 1985, National Institute of Health provided a new estimate for radiation risk to the breast that used a relative risk model and acknowledged greater dependence on age at exposure. Lifetime risks from a single mammogram may be calculated from this estimate. Possible years of life expectancy lost from annual mammography beginning at age 40 years may also be calculated and are negligible compared with estimates for years of life expectancy gained from such screening.	4
31. Bennett IC, Freitas R, Jr., Fentiman IS. Diagnosis of breast cancer in young women. *Aust N Z J Surg* 1991; 61(4):284-289.	13	227 patients 235 biopsies	Retrospective analysis to determine if breast cancer is more difficult to diagnose in the 30-40 year old age group.	Positive biopsy rate 15%. With cancer average duration of symptoms 26 weeks and mean tumor size 3.3 cm. Sensitivity of mammography for cancer 76%. Mammography may have limited value in younger women.	2
32. Ciatto S, Bravetti P, Bonardi R, Rosselli del Turco M. The role of mammography in women under 30. *Radiol Med (Torino)* 1990; 80(5):676-678.	10	305	To determine the appropriate use of mammography in younger women with a solid palpable mass.	Mammography missed 5/18 cancers (28%) and is not recommended in women under 30 except for preoperative cases with a strong suspicion of cancer.	2
33. Feig SA. Breast masses. Mammographic and sonographic evaluation. *Radiol Clin North Am* 1992; 30(1):67-92.	12	N/A	Review role of mammography and US in the evaluation of breast masses.	Characteristics that may allow a benign diagnosis for a circumscribed mass include the presence of fat and certain calcification patterns on the mammogram and features of a simple cyst on the sonogram. For palpable breast masses, selection of mammography or US as the primary imaging modality will depend on patient's age and risk factors.	4
34. Harris VJ, Jackson VP. Indications for breast imaging in women under age 35 years. *Radiology* 1989; 172(2):445-448.	9	625	Correlated patient histories with mammographic and/or sonographic findings and biopsy or follow-up results for patients to determine appropriate indications for breast imaging in younger women.	Important indications: palpable mass and suspected abscess. Imaging helpful in 4/15 suspected abscesses. In patients with palpable masses, 6 cancers were found. No other significant indications. Women with low yield indications should be followed clinically and not referred for imaging.	2
35. Williams SM, Kaplan PA, Petersen JC, Lieberman RP. Mammography in women under age 30: is there clinical benefit? *Radiology* 1986; 161(1):49-51.	10	76 patients 2 observers	Retrospective study to determine the utility of mammography in women less than 30 years of age referred for mammography.	55% had a palpable mass. In this group, no mass seen by mammography in 74%. But 14% had a definite lesion found by other means. No cancers were found. US may be best initial approach with mammography reserved for preoperative cases.	3

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
36. Bassett LW, Ysrael M, Gold RH, Ysrael C. Usefulness of mammography and sonography in women less than 35 years of age. *Radiology* 1991; 180(3):831-835.	9	1,016	To determine utility of mammography and US in symptomatic young women referred for imaging.	Mammographic findings prompted biopsy in 1/6 cancers and indicated a benign mass in 3/6 patients. US prevented biopsy of cysts, but was not useful in differentiating benign and malignant masses.	2
37. Kronemer KA, Rhee K, Siegel MJ, Sievert L, Hildebolt CF. Gray scale sonography of breast masses in adolescent girls. *J Ultrasound Med* 2001; 20(5):491-496; quiz 498.	10	57 girls 3 observers	Retrospective study of palpable breast masses to assess the sonographic findings and usefulness of sonographic patterns for suggesting a specific diagnosis.	Sonography is very useful in the evaluation of palpable breast masses in adolescent women. It has the ability to differentiate among cystic, inflammatory, and solid masses.	2
38. Palmer ML, Tsangaris TN. Breast biopsy in women 30 years old or less. *Am J Surg* 1993; 165(6):708-712.	13	40	To determine the characteristics of lesions undergoing surgical biopsy in women under 30.	Mammography was performed in 20/40 patients with 6 abnormal. Following aspiration to rule out a cyst and a possible brief period of observation, surgical biopsy is recommended for all young women with a breast mass.	3
39. Vade A, Lafita VS, Ward KA, Lim-Dunham JE, Bova D. Role of breast sonography in imaging of adolescents with palpable solid breast masses. *AJR* 2008; 191(3):659-663.	10	20	Retrospective study to assess the role of sonography in the diagnosis and management of palpable solid breast masses in adolescents and to correlate the sonographic findings with the histopathologic findings and clinical outcome.	Sonography showed 21 solid masses in 20 patients All but 6 solid masses were presumed benign according to the Stavros sonographic criteria. All solid masses were proved benign at histopathologic or clinical follow-up examination. Sonography was not useful for predicting the histologic diagnosis of all solid benign breast masses in adolescent patients. The Stavros sonographic criteria were useful for predicting benignity in 65% of the breast masses on which histopathologic examination was performed.	3
40. Jeffries DO, Adler DD. Mammographic detection of breast cancer in women under the age of 35. *Invest Radiol* 1990; 25(1):67-71.	10	42 cancers in 39 women	To determine the usefulness of mammography in young women subsequently proven to have breast cancer.	3/39 were symptomatic. 86% of all women in study had abnormal findings; 94% of findings were high-intermediate suspicion. Mammography was very useful in women under 35, even in dense breasts.	3
41. Meyer JE, Kopans DB, Oot R. Breast cancer visualized by mammography in patients under 35. *Radiology* 1983; 147(1):93-94.	10	31	Review records to determine the usefulness of mammography in young women subsequently proven to have breast cancer.	28/31 (90%) lesions seen and considered suspicious. 30/31 were palpable. Mammography should play a significant role in the diagnosis of breast cancer in women under 35.	3
42. Shaw de Paredes E, Marsteller LP, Eden BV. Breast cancers in women 35 years of age and younger: mammographic findings. *Radiology* 1990; 177(1):117-119.	10	74 cancers in 66 women	Retrospectively review mammograms and clinical data to determine the efficacy of mammography in women 35 years of age or younger subsequently proven to have breast cancer.	Mammography demonstrated the lesion in 89% of all cases. Mammography can be valuable in screening young women at high risk for breast cancer but not recommended on a routine basis.	3

Evidence Table Key

Study Type Key

Numbers 1-7 are for studies of therapies while numbers 8-15 are used to describe studies of diagnostics.

1. Randomized Controlled Trial — Treatment
2. Controlled Trial
3. Observation Study
    a. Cohort
    b. Cross-sectional
    c. Case-control
4. Clinical Series
5. Case reviews
6. Anecdotes
7. Reviews
8. Randomized Controlled Trial — Diagnostic
9. Comparative Assessment
10. Clinical Assessment
11. Quantitative Review
12. Qualitative Review
13. Descriptive Study
14. Case Report
15. Other (Described in text)

Strength of Evidence Key

- Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis and results.
- Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.
- Category 3 - The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.
- Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.