

**Breast Implant Evaluation**  
**EVIDENCE TABLE**

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Study Quality
1. Adrada BE, Miranda RN, Rauch GM, et al. Breast implant-associated anaplastic large cell lymphoma: sensitivity, specificity, and findings of imaging studies in 44 patients. <i>Breast Cancer Res Treat.</i> 2014;147(1):1-14.	Observational-Dx	79 women.	To describe the imaging findings of patients with breast implant-associated anaplastic large cell lymphoma (BIA ALCL) and determine their sensitivity and specificity in the detection of the presence of an effusion or a mass related to BIA ALCL.	The sensitivity for detecting an effusion was 84, 55, 82, and 38 %, and for detecting a mass was 46, 50, 50, and 64 %, by US, CT, MRI, and PET, respectively. The sensitivity of mammography in the detection of an abnormality without distinction of effusion or mass was 73 %, and specificity 50 %. Progression-free survival was worse in patients with an implant-associated mass ( $p = 0.001$ ).	3
2. Gidengil CA, Predmore Z, Mattke S, van Busum K, Kim B. Breast implant-associated anaplastic large cell lymphoma: a systematic review. <i>Plast Reconstr Surg.</i> 2015;135(3):713-720.	Review/Other-Dx	102 articles.	To identify and analyze recently published cases of breast implant-associated anaplastic large cell lymphoma (ALCL), with an emphasis on diagnosis, staging, treatment, and outcomes.	Of 248 identified articles, only 102 were relevant to breast implant-associated anaplastic large cell lymphoma (ALCL), and 27 were included in this study. Fifty-four cases of ALCL in patients with breast implants were identified. Detailed clinical information was lacking in many cases. Most presented with a seroma (76 percent), and approximately half were associated with the capsule (48 percent). Most presented as stage IE (61 percent). All but one case were ALK-negative. Most received chemotherapy (57 percent) and radiation therapy (48 percent), and 11 percent received stem cell transplants. Approximately one-quarter recurred, and 9 percent died.	4

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3. Laurent C, Delas A, Gaulard P, et al. Breast implant-associated anaplastic large cell lymphoma: two distinct clinicopathological variants with different outcomes. <i>Ann Oncol.</i> 2016;27(2):306-314.	Observational-Dx	19 women.	To review the clinical, immunomorphologic, molecular and survival data of 19 cases collected from different institutions through Lymphopath over a 5-year period.	The median age of the patients was 61 years and the median length between breast implant and breast implant associated anaplastic large cell lymphoma (i-ALCL) was 9 years. Most implants were silicone-filled and textured. Implant removal was performed in 17 out of 19 patients with additional treatment based on mostly CHOP (cyclophosphamide, adriamycin, vincristine and prednisone) or CHOP-like chemotherapy regimens (n = 10/19) or irradiation (n = 1/19). CHOP alone or ABVD (adriamycine, bleomycine, vinblastine and dacarbazine) following radiation without implant removal have been given in two patients. The two clinical presentations, i.e. effusion and less frequently tumor mass correlated with distinct histopathologic features: in situ i-ALCL (anaplastic cell proliferation confined to the fibrous capsule) and infiltrative i-ALCL (pleomorphic cells massively infiltrating adjacent tissue with eosinophils and sometimes Reed-Sternberg-like cells mimicking Hodgkin lymphoma). Malignant cells were CD30-positive, showed a variable staining for EMA and were ALK negative. Most cases had a cytotoxic T-cell immunophenotype with variable T-cell antigen loss and pSTAT3 nuclear expression. T-cell receptor genes were clonally rearranged in 13 out of 13 tested cases. After 18 months of median follow-up, the 2-year overall survival for in situ and infiltrative i-ALCL was 100% and 52.5%, respectively.	3

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4. Brody GS. Commentary on: Breast Implant-Associated Anaplastic Large Cell Lymphoma: Report of 2 Cases and Review of the Literature. <i>Aesthet Surg J.</i> 2014;34(6):895.	Review/Other-Dx	N/A	No abstract available.	No abstract available.	4
5. Clemens MW, Miranda RN. Commentary on: CD30+ T Cells in Late Seroma May Not Be Diagnostic of Breast Implant-Associated Anaplastic Large Cell Lymphoma. <i>Aesthet Surg J.</i> 2017;37(7):776-778.	Review/Other-Dx	N/A	No abstract available.	No abstract available.	4
6. Holmich LR, Fryzek JP, Kjoller K, et al. The diagnosis of silicone breast-implant rupture: clinical findings compared with findings at magnetic resonance imaging. <i>Ann Plast Surg.</i> 2005;54(6):583-589.	Observational-Dx	55 women with 109 implants	To evaluate the usefulness of clinical examination in the evaluation of breast-implant integrity, using the diagnosis at magnetic resonance imaging (MRI) as the "gold standard."	Twenty-four of 109 implants were clinically diagnosed with possible rupture or rupture. Eighteen of the 24 implants were ruptured according to the MRI examination (75%). Eighty-five implants were clinically classified as intact, and 43 of these were actually ruptured at MRI (51%). The sensitivity of the clinical examination for diagnosing rupture was thus 30% and the specificity 88%. The positive predictive value of a clinical diagnosis of rupture was 75%, and the negative predictive value was 49%.	4
7. Gorczyca DP, Gorczyca SM, Gorczyca KL. The diagnosis of silicone breast implant rupture. [Review] [29 refs]. <i>Plast Reconstr Surg.</i> 120(7 Suppl 1):49S-61S, 2007 Dec.	Review/Other-Dx	N/A	To illustrate the spectrum of imaging appearances of normal silicone gel implants and the appearances of silicone breast implant ruptures.	No results stated in abstract.	4
8. Lake E, Ahmad S, Dobrashian R. The sonographic appearances of breast implant rupture. <i>Clin Radiol.</i> 2013;68(8):851-858.	Review/Other-Dx	N/A	To demonstrate normal appearances and sonographic signs of implant rupture.	No results stated in abstract.	4

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9. Yang N, Muradali D. The augmented breast: a pictorial review of the abnormal and unusual. <i>AJR Am J Roentgenol.</i> 2011;196(4):W451-460.	Review/Other-Dx	N/A	To review the multimodality imaging features of breast augmentation complications as well as appearances of unusual breast augmentation techniques.	Cosmetic breast augmentation is an increasingly common procedure performed in our society. Although breast prosthesis implantation is the most common technique, other unusual techniques such as autologous fat implantation as well as direct liquid silicone and paraffin injections have also been used.	4
10. Bengtson BP, Eaves FF, 3rd. High-resolution ultrasound in the detection of silicone gel breast implant shell failure: background, in vitro studies, and early clinical results. <i>Aesthet Surg J.</i> 2012;32(2):157-174.	Observational-Dx	Phase 3: 15 patients	To evaluate the feasibility of portable, high-resolution ultrasound (HRUS) for imaging of silicone gel breast implants and perform preliminary comparisons of HRUS to MRI in the assessment of both intact and failed implants in a clinical setting by both radiologists and plastic surgeons.	In Phase 1, all hardware models easily detected both intact and intentionally damaged shells in currently marketed fourth-generation responsive gel implants and in investigational, fifth-generation highly-cohesive gel devices. Although multiple transducers were able to detect shell failure, the 12-MHz head produced the best images at the normal clinical depth range. In Phase 2, confirmatory HRUS scans correctly identified the side of rupture and were consistent with MRI and surgical findings in all patients. In Phase 3, MRI, surgeon-performed HRUS, and radiologist-performed HRUS scans were all accurate in predicting implant shell integrity in 29 of 29 imaged breasts (100%) as confirmed at the time of surgery in both symptomatic and asymptomatic patients.	2
11. Berry MG, Stanek JJ. PIP implant bi durability: a post-publicity update. <i>J Plast Reconstr Aesthet Surg.</i> 2013;66(9):1174-1181.	Observational-Dx	460 patients	To estimate rupture prevalence, assess the media effect and evaluate contemporary ultrasound scan (USS) accuracy.	Kaplan-Meier analysis places 10-year PIP mammary implant survival between 60 (95% confidence interval (CI): 54-67) and 81% (95% CI: 78-85). Post-publicity evaluatees were found to have occult device failure in 31.6%. Of 85 patients who had definitive confirmation of USS findings by surgical exploration, 79 (92.9%) were completely accurate. USS in our series had a sensitivity of 97.3% and specificity of 93.1%.	3

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12. Di Benedetto G, Cecchini S, Grasseti L, et al. Comparative study of breast implant rupture using mammography, sonography, and magnetic resonance imaging: correlation with surgical findings. <i>Breast J.</i> 2008;14(6):532-537.	Observational-Dx	63 women with 82 implants	To evaluate the accuracy of mammography, ultrasonography, and magnetic resonance imaging (MRI), in the detection of breast implant rupture and to make a correlation with findings at explantation.	The respective sensitivity and specificity of investigations are reported. Our experience suggests that MRI is the more accurate method for identification of breast implant rupture, even if it should be performed following the diagnostic algorithm proposed.	3
13. Rietjens M, Villa G, Toesca A, et al. Appropriate use of magnetic resonance imaging and ultrasound to detect early silicone gel breast implant rupture in postmastectomy reconstruction. <i>Plast Reconstr Surg.</i> 2014;134(1):13e-20e.	Observational-Dx	102 patients	To compare magnetic resonance imaging and ultrasound evaluation with intraoperative findings and provide a reliable description of the occurrence of each radiological sign.	Magnetic resonance imaging performs better than ultrasound for diagnosis of breast implant rupture, with overall accuracies of 94 and 72 percent, respectively. The negative predictive value of ultrasound was 85 percent, meaning that in the case of negative ultrasound findings, magnetic resonance imaging may be avoided. Teardrop sign and water droplets are the most common findings on magnetic resonance imaging.	3
14. Scaranelo AM, Marques AF, Smialowski EB, Lederman HM. Evaluation of the rupture of silicone breast implants by mammography, ultrasonography and magnetic resonance imaging in asymptomatic patients: correlation with surgical findings. <i>Sao Paulo Med J.</i> 2004;122(2):41-47.	Observational-Dx	44 patients with 83 implants	To compare the efficacy of mammography, sonography and magnetic resonance imaging in the detection of breast implant rupture in an asymptomatic population.	The respective sensitivity and specificity of mammography were 20% and 89%; sonography, 30% and 81%; and magnetic resonance imaging, 64% and 77%. The differences between patients with breast implants for cosmetic and oncological reasons were discussed.	2

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15. Holmich LR, Vejborg I, Conrad C, Sletting S, McLaughlin JK. The diagnosis of breast implant rupture: MRI findings compared with findings at explantation. <i>Eur J Radiol.</i> 2005;53(2):213-225.	Observational-Dx	64 women with 188 implants	To evaluate the accuracy of Magnetic Resonance Imaging (MRI) as performed according to a strict study protocol in diagnosing rupture of silicone breast implants.	At MRI, 66 implants were diagnosed as ruptured, nine as possibly ruptured and 43 as intact. Among the ruptured implants, 27 were categorized as extracapsular. At surgery, on average 297 days after the MRI, 65 of the 66 rupture diagnoses were confirmed, as were 20 of the cases with extracapsular silicone. Eight of the nine possibly ruptured implants were in fact ruptured at surgery. Thirty-four of the 43 intact implants were described as intact at surgery. When categorising possible ruptures as ruptures, there were one false positive and nine false negative rupture diagnoses at MRI yielding an accuracy of 92%, a sensitivity of 89%, and a specificity of 97%. Correspondingly, the predictive value of a positive MRI examination was 99% and the predictive value of a negative MRI examination was 79%.	2
16. Maijers MC, Niessen FB, Veldhuizen JF, Ritt MJ, Manoliu RA. MRI screening for silicone breast implant rupture: accuracy, inter- and intraobserver variability using explantation results as reference standard. <i>Eur Radiol.</i> 2014;24(6):1167-1175.	Observational-Dx	107 women with 214 implants	To assess the accuracy and interobserver variability of MRI screening in the detection of rupture and extracapsular silicone leakage.	In 208 of the 214 explanted prostheses, radiologists agreed independently about the condition of the implants. In five of the six cases they disagreed (2.6 %), but subsequently reached consensus. A sensitivity of 93 %, specificity of 93 %, positive predictive value of 77 % and negative predictive value of 98 % was found. The interobserver agreement was excellent (kappa value of 0.92).	2
17. Maijers MC, Niessen FB, Veldhuizen JF, Ritt MJ, Manoliu RA. Magnetic resonance imaging screening results compared with explantation results in poly implant prothese silicone breast implants, recalled from the European market in 2010. <i>Plast Reconstr Surg.</i> 2014;133(2):114e-120e.	Observational-Dx	112 women with 224 implants	To compare magnetic resonance imaging screening with explantation results to study the diagnostic value of magnetic resonance imaging in this unique unselected and nonbiased group.	Of 107 women, 29 (27 percent) had at least one ruptured implant at explantation, and 44 of 214 explanted implants (21 percent) were ruptured. The magnetic resonance imaging results correctly diagnosed 154 intact and 35 ruptured implants. Sensitivity and specificity were 80 percent and 91 percent, respectively. The positive predictive value was 69 percent, and the negative predictive value was 95 percent.	3

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18. Song JW, Kim HM, Bellfi LT, Chung KC. The effect of study design biases on the diagnostic accuracy of magnetic resonance imaging for detecting silicone breast implant ruptures: a meta-analysis. <i>Plast Reconstr Surg</i> . 2011;127(3):1029-1044.	Meta-analysis	21 studies	To examine the effect of study design biases on the estimation of magnetic resonance imaging diagnostic accuracy measures.	Among 1175 identified articles, 21 met the inclusion criteria. Most studies using magnetic resonance imaging (10 of 16) and ultrasound (10 of 13) examined symptomatic subjects. Magnetic resonance imaging studies evaluating symptomatic subjects had 14-fold higher diagnostic accuracy estimates compared with studies using an asymptomatic sample (relative diagnostic odds ratio, 13.8; 95 percent confidence interval, 1.83 to 104.6) and 2-fold higher diagnostic accuracy estimates compared with studies using a screening sample (relative diagnostic odds ratio, 1.89; 95 percent confidence interval, 0.05 to 75.7).	M
19. Vestito A, Mangieri FF, Ancona A, Minervini C, Perchinunno V, Rinaldi S. Study of breast implant rupture: MRI versus surgical findings. <i>Radiol Med (Torino)</i> . 117(6):1004-18, 2012 Sep.	Observational-Dx	157 implants	To evaluate the role of breast magnetic resonance (MR) imaging in the selective study breast implant integrity.	The linguine and the salad-oil signs were statistically the most significant signs for diagnosing intracapsular rupture; the presence of siliconomas/seromas outside the capsule and/or in the axillary lymph nodes calls for immediate explantation.	3
20. Johnson TR, Himsl I, Hellerhoff K, et al. Dual-energy CT for the evaluation of silicone breast implants. <i>Eur Radiol</i> . 2013;23(4):991-996.	Review/Other-Dx	7 implants plus 2 patients	To evaluate whether it is feasible to identify silicone in breast implants by dual-energy CT and to reliably diagnose or rule out ruptures. No contrast.	The silicone of the implant specimens showed a strong dual-energy signal. In one patient, both implants were intact, while a rupture was identified in the other patient. Ultrasound, MRI, surgical findings and histology confirmed the dual-energy CT diagnosis.	4
21. Mainiero MB, Moy L, Baron P, et al. ACR Appropriateness Criteria(R) Breast Cancer Screening. <i>J Am Coll Radiol</i> . 2017;14(11S):S383-S390.	Review/Other-Dx	N/A	Evidence-based guidelines to assist referring physicians and other providers in making the most appropriate imaging or treatment decision for breast cancer screening.	No results stated in abstract.	4
22. Middleton MS.. MR evaluation of breast implants. [Review]. <i>Radiol Clin North Am</i> . 52(3):591-608, 2014 May.	Review/Other-Dx	N/A	To describe the rationale and indications for breast implant-related magnetic resonance (MR) imaging, alone or in combination with breast cancer-related MR imaging.	No results stated in abstract.	4

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23. Lalonde L, David J, Trop I. Magnetic resonance imaging of the breast: current indications. <i>Can Assoc Radiol J.</i> 2005;56(5):301-308.	Review/Other-Dx	N/A	To review current indications for MR imaging of the breast.	MRI is recognized as the most sensitive modality for the detection of invasive breast cancer. Several valuable clinical applications of MRI have emerged for breast cancer detection and diagnosis from clinical investigations. Breast MRI is helpful for women diagnosed with breast cancer who contemplate breast conserving surgery; it provides valuable information on the extent of the disease. MRI can also help assess for residual invasive cancer in patients who have undergone lumpectomy with positive margins at pathology. It is very reliable in differentiating scar tissue from recurrence at the lumpectomy site. MRI is also reliable in finding a breast cancer in women with axillary nodal metastases and unknown primary tumour. MRI can help to monitor the response to chemotherapy. Breast MRI could be a better screening tool than mammography in women with very high risks of developing breast cancer, such as breast cancer gene carriers and patients treated with chest radiation. Other potential uses of MRI include evaluation of the integrity of silicone breast implants and evaluation of the parenchyma in women with silicone gel implants or free injection of silicone gel. However, like any other technique, breast MRI has some drawbacks, including low-to-moderate specificity, high costs, and variability in technique and interpretation.	4
24. Brenner RJ. Evaluation of breast silicone implants. <i>Magn Reson Imaging Clin N Am.</i> 2013;21(3):547-560.	Review/Other-Dx	N/A	To outline the approach toward optimal imaging and expected results.	No results stated in abstract.	4



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25. Chung KC, Malay S, Shauver MJ, Kim HM. Economic analysis of screening strategies for rupture of silicone gel breast implants. <i>Plast Reconstr Surg.</i> 130(1):225-37, 2012 Jul.	Review/Other-Dx	19 studies	To determine optimal screening strategies by considering the diagnostic accuracy of the screening tests, costs of the tests, and subsequent implant removal.	The cost per rupture of screening and management of rupture with ultrasound in asymptomatic women was \$1090; in symptomatic women, it was \$1622. A similar cost for magnetic resonance imaging in asymptomatic women was \$2067; in symptomatic women it was \$2143. A similar cost for ultrasound followed by imaging in asymptomatic women was \$637; in symptomatic women, it was \$2908.	4
26. McCarthy CM, Pusic AL, Kerrigan CL. Silicone breast implants and magnetic resonance imaging screening for rupture: do U.S. Food and Drug Administration recommendations reflect an evidence-based practice approach to patient care? <i>Plast Reconstr Surg.</i> 2008;121(4):1127-1134.	Review/Other-Dx	N/A	To (1) outline the principles of a screening program; (2) examine the evidence for a magnetic resonance imaging screening program for the detection of silent implant rupture; (3) review lessons learned from the premature proliferation of unproven screening tests in other clinical arenas; and (4) define the process of and the advantages to using shared decision making in the setting of clinical uncertainty.	Screening decisions are complex, and relevant information is lacking. Although the detection of silent silicone implant ruptures may prove to be prudent, there is no conclusive evidence at this time to show that using magnetic resonance imaging screening of asymptomatic women leads to a reduction in patient morbidity. Furthermore, based on existing data, it is unclear whether the potential benefits of screening magnetic resonance imaging tests outweigh the risks and potential costs for the patient.	4
27. Collis N, Litherland J, Enion D, Sharpe DT. Magnetic resonance imaging and explantation investigation of long-term silicone gel implant integrity. <i>Plast Reconstr Surg.</i> 2007;120(5):1401-1406.	Observational-Dx	149 patients; 21 with explantation	To present the results of a magnetic resonance imaging study, examining one manufacturer's third-generation textured silicone gel breast implants placed in a subglandular position.	One hundred forty-nine patients with bilateral subglandular implants (median +/- SD age, 8.9 +/- 2.3; range, 4.8 to 13.5 years) were imaged and reported by two independent radiologists. Twenty-three patients were reported to have 33 radiologically ruptured implants. Twenty-one patients (30 radiologically ruptured implants) agreed to explantation. Statistical analysis using maximum likelihood estimation of survival curve for cross-sectional data suggests that implant rupture starts at 6 to 7 years and that by 13 years approximately 11.8 percent of implants will have ruptured.	2

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28. Heden P, Bone B, Murphy DK, Slicton A, Walker PS. Style 410 cohesive silicone breast implants: safety and effectiveness at 5 to 9 years after implantation. <i>Plast Reconstr Surg.</i> 2006;118(6):1281-1287.	Observational-Tx	144 patients	To evaluate the intermediate to long-term safety and effectiveness for Inamed Style 410 cohesive silicone gel implants through magnetic resonance imaging, clinical examination, and quality-of-life assessment.	The 144 subjects provided 286 implants for magnetic resonance imaging assessment, with a median implantation time of 6 years (range, 5 to 9 years). Overall, 99.0 percent of implants showed no evidence of rupture, 0.3 percent showed evidence of rupture, and 0.7 percent were indeterminate. The most common complication noted at physical examination was capsular contracture (5.6 percent). All other complications occurred in less than 3 percent of subjects. Quality-of-life results found an improvement in overall sense of well-being for 87 percent of subjects. Most compelling is that 97 percent stated an overall feeling that their breast implantation had been advantageous.	3
29. Heden P, Nava MB, van Tetering JP, et al. Prevalence of rupture in inamed silicone breast implants. <i>Plast Reconstr Surg.</i> 2006;118(2):303-308; discussion 309-312	Observational-Tx	106 patients with 199 implants	To acquire long-term rupture data specific to Inamed's third-generation silicone breast implants using magnetic resonance imaging technology.	A total of 199 implants were evaluated, with a median implantation time of 10.9 years (range, 9.5 to 13.2 years). Overall, 183 implants (92.0 percent) showed no evidence of rupture, 12 (6.0 percent) showed evidence of rupture, and four (2.0 percent) were indeterminate. All indeterminate evaluations were considered ruptures, providing a worst-case rupture prevalence of 8.0 percent.	3

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30. Maxwell GP, Van Natta BW, Murphy DK, Slicton A, Bengtson BP. Natrelle style 410 form-stable silicone breast implants: core study results at 6 years. <i>Aesthet Surg J.</i> 2012;32(6):709-717.	Observational-Tx	941 women	To update the safety and effectiveness findings for the Natrelle Style 410 implants through 6 years of study.	As expected after breast implantation, capsular contracture (CC) was one of the most common complications, with 6-year risk rates of 4.6% for augmentation, 6.9% for revision-augmentation, 10.7% for reconstruction, and 18.3% for revision-reconstruction. The rates for CC among augmentations and revision-augmentations were significantly lower with the Natrelle 410 implants than with other standard gel implants. The rupture rate (confirmed plus suspected) across all cohorts was 6.4% by subject and 3.8% by implant. The most common reasons for reoperation were style or size change (augmentation), implant malposition (revision-augmentation), scarring (reconstruction), and CC (revision-reconstruction). The satisfaction rate exceeded 80% in all cohorts.	1
31. Helyar V, Burke C, McWilliams S. The ruptured PIP breast implant. <i>Clin Radiol.</i> 2013;68(8):845-850	Review/Other-Dx	N/A	To discuss possible approaches to screening the PIP cohort and the salient characteristics of a ruptured implant.	No results stated in abstract.	4
32. American College of Radiology. ACR Appropriateness Criteria® Radiation Dose Assessment Introduction. Available at: <a href="https://www.acr.org/-/media/ACR/Files/Appropriateness-Criteria/RadiationDoseAssessmentIntro.pdf">https://www.acr.org/-/media/ACR/Files/Appropriateness-Criteria/RadiationDoseAssessmentIntro.pdf</a> .	Review/Other-Dx	N/A	Guidance document on exposure of patients to ionizing radiation.	No results stated in abstract.	4

## Evidence Table Key

### Study Quality Category Definitions

- *Category 1* The study is well-designed and accounts for common biases.
- *Category 2* The study is moderately well-designed and accounts for most common biases.
- *Category 3* There are important study design limitations.
- *Category 4* The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:
  - a. The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description);
  - b. The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence;
  - c. The study is an expert opinion or consensus document.
- Meta-analysis
  - a. *Good quality* – the study design, methods, analysis, and results are valid and the conclusion is supported.
  - b. *Inadequate quality* – the study design, analysis, and results lack the methodological rigor to be considered a good meta-analysis study.

## Abbreviations Key

Dx = Diagnostic

Tx = Treatment