

**Clinically Suspected Adnexal Mass  
EVIDENCE TABLE**

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
1. Benacerraf BR, Finkler NJ, Wojciechowski C, Knapp RC. Sonographic accuracy in the diagnosis of ovarian masses. <i>J Reprod Med</i> 1990; 35(5):491-495.	9	100	US findings were compared with final pathology reports to determine the accuracy of the sonographic diagnosis of adnexal masses in women undergoing laparotomy for ovarian masses.	US was misleading in 15% of the cases, misreading whether the lesions were benign or malignant. The identification of ovarian malignancy was correct in 24/30 patients (sensitivity 80%), and the specificity for correctly diagnosing a benign condition was 87%. The PPV of a sonographic diagnosis of an adnexal malignancy was 73%. The NPV of US for excluding a malignancy was 91%.	2
2. Fleischer AC. Transabdominal and transvaginal sonography of ovarian masses. <i>Clin Obstet Gynecol</i> 1991; 34(2):433-442.	12	N/A	Review use of transabdominal (TAS) and transvaginal (TVS) US for detection of ovarian carcinoma.	TAS and TVS US seem promising for the early detection of ovarian carcinoma and should be pursued in several institutions as clinical trials.	4
3. Mendelson EB, Bohm-Velez M, Joseph N, Neiman HL. Gynecologic imaging: comparison of transabdominal and transvaginal sonography. <i>Radiology</i> 1988; 166(2):321-324.	9	200	Comparative study evaluating TAS and TVS in patients who underwent concurrent TAS and TVS. All scans were retrospectively reviewed.	TVS image quality was better in 79%-87% of scans; TAS image quality was better in 3%-5% of scans; images of both techniques were equally good in 10%-18% of scans. The techniques provided equivalent diagnostic information in 60%-84% of cases. TVS was particularly helpful when exclusion of ectopic pregnancy was the clinical concern.	2
4. Coleman BG. Transvaginal sonography of adnexal masses. <i>Radiol Clin North Am</i> 1992; 30(4):677-691.	12	N/A	Review article on how TVS can contribute to the diagnosis of cystic, complex, and solid adnexal masses.	TVS is recommended for evaluation of patients with suspected ectopic pregnancy. It can also be used as the initial procedure in the follow-up of a known adnexal process.	4
5. Goldstein SR, Subramanyam B, Snyder JR, Beller U, Raghavendra BN, Beckman EM. The postmenopausal cystic adnexal mass: the potential role of ultrasound in conservative management. <i>Obstet Gynecol</i> 1989; 73(1):8-10.	13	42	The US scans of postmenopausal women with simple adnexal cysts were reviewed to see if these patients can benefit from conservative (non-surgical) management.	Serial US follow-up without surgical intervention may play a role in the clinical management of such patients.	3
6. Alcazar JL, Castillo G, Jurado M, Garcia GL. Is expectant management of sonographically benign adnexal cysts an option in selected asymptomatic premenopausal women? <i>Hum Reprod</i> 2005; 20(11):3231-3234.	13	120	Prospective observational longitudinal study to assess whether expectant management of US benign ovarian cysts may be an option for selected asymptomatic premenopausal women.	Most lesions remained unchanged both in size and sonographic appearance. In ten patients (8.3%) the lesion disappeared, no patient developed signs or symptoms of ovarian cancer.	2
7. Levine D, Gosink BB, Wolf SI, Feldesman MR, Pretorius DH. Simple adnexal cysts: the natural history in postmenopausal women. <i>Radiology</i> 1992; 184(3):653-659.	13	184	To determine prospectively, the frequency of simple adnexal cysts in postmenopausal women using TAS and TVS associated with hormones and time since menopause.	Cyst frequency 17%; 53% disappeared, 28% constant, 11% enlarged, 3% decreased, 6% decreased and increased. No relationship with hormones or time from menopause.	2

\* See Last Page for Key

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8. Modesitt SC, Pavlik EJ, Ueland FR, DePriest PD, Kryscio RJ, van Nagell JR, Jr. Risk of malignancy in unilocular ovarian cystic tumors less than 10 centimeters in diameter. <i>Obstet Gynecol</i> 2003; 102(3):594-599.	13	15,106	To determine the natural history and estimate the risk of malignancy of unilocular ovarian cystic tumors <10 cm in diameter followed by TVS.	The risk of malignancy in unilocular ovarian cystic tumors <10 cm in diameter in women 50 years or older is extremely low. Majority will resolve and can be followed with serial TVS.	1
9. Taylor KJ, Schwartz PE. Screening for early ovarian cancer. <i>Radiology</i> 1994; 192(1):1-10.	12	N/A	Review role of screening for early ovarian cancer.	There are impediments to earlier diagnosis of ovarian cancer, and more sensitive and specific tumor markers may be required. Current techniques may show acceptable cost-effectiveness only in women at elevated risk (family history of the disease).	4
10. Gjelland K, Ekerhovd E, Granberg S. Transvaginal ultrasound-guided aspiration for treatment of tubo-ovarian abscess: a study of 302 cases. <i>Am J Obstet Gynecol</i> 2005; 193(4):1323-1330.	4	302 consecutive women	Review women treated with TVS US-guided aspiration for tubo-ovarian abscess to evaluate the usefulness of TVS guided aspiration and antibiotic therapy for treatment of tubo-ovarian abscess.	282 women (93.4%) were successfully treated. TVS-guided aspiration combined with antibiotics is recommended for treatment of tubo-ovarian abscess.	2
11. Caspi B, Ben-Arie A, Appelman Z, Or Y, Hagay Z. Aspiration of simple pelvic cysts during pregnancy. <i>Gynecol Obstet Invest</i> 2000; 49(2):102-105.	4	10	To determine the value of aspiration of simple pelvic cysts during pregnancy.	Aspiration was a definitive treatment for 5/10 women. Aspiration of simple cysts during pregnancy is safe and may prevent surgery.	3
12. Guariglia L, Conte M, Are P, Rosati P. Ultrasound-guided fine needle aspiration of ovarian cysts during pregnancy. <i>Eur J Obstet Gynecol Reprod Biol</i> 1999; 82(1):5-9.	4	29	To evaluate the safety and efficacy of US-guided fine needle aspiration in the treatment of ovarian cysts during pregnancy.	In 9 patients, US-guided fine needle aspiration was safely performed as an alternative treatment to surgery.	3
13. Kurjak A, Predanic M. New scoring system for prediction of ovarian malignancy based on transvaginal color Doppler sonography. <i>J Ultrasound Med</i> 1992; 11(12):631-638.	9	812 patients 174 masses	Prospective study. Ovarian lesions assessed by morphological and color Doppler scoring systems to distinguish benign from malignant masses.	<ul style="list-style-type: none"> <li>• Color Doppler: sensitivity 97.3%, specificity 100%.</li> <li>• Morphological scoring system: sensitivity 92.1%, specificity 94.8%.</li> </ul>	1
14. Timor-Tritsch LE, Lerner JP, Monteagudo A, Santos R. Transvaginal ultrasonographic characterization of ovarian masses by means of color flow-directed Doppler measurements and a morphologic scoring system. <i>Am J Obstet Gynecol</i> 1993; 168(3 Pt 1):909-913.	9	93 patients 115 masses	Prospectively analyze scoring system and color flow-directed Doppler measurements to test the hypothesis that a combination of a previously devised morphologic scoring system and color flow-directed Doppler measurements would afford better discrimination between benign and malignant ovarian masses.	<ul style="list-style-type: none"> <li>• Score alone: sensitivity 94%, specificity 87%, PPV 60%.</li> <li>• With resistance index (RI) or pulsatility index (PI): sensitivity 94%, specificity 99%, PPV 94%.</li> <li>• Results suggest Doppler flow measurements alone and in conjunction with a scoring system help differentiate benign from malignant masses.</li> </ul>	2

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15. Alcazar JL, Galan MJ, Garcia-Manero M, Guerriero S. Three-dimensional sonographic morphologic assessment in complex adnexal masses: preliminary experience. <i>J Ultrasound Med</i> 2003; 22(3):249-254.	10	41 women (44 masses)	To evaluate the role of 3D TVS in assessing complex masses. 41 women with the diagnosis of complex adnexal masses on the basis of 2D TVS were reevaluated by 3-D TVS.	Sensitivity, specificity, PPV, NPV, and accuracy for 2 and 3-dimensional TVS were 90%, 61%, 68%, 87%, and 75% and 100%, 78%, 81%, 100%, and 89%, respectively. 3D TVS does not improve 2D TVS morphologic assessment of complex adnexal masses.	3
16. Geomini PM, Kluivers KB, Moret E, Bremer GL, Kruitwagen RF, Mol BW. Evaluation of adnexal masses with three-dimensional ultrasonography. <i>Obstet Gynecol</i> 2006; 108(5):1167-1175.	9	181 women: 144 benign, 26 malignant, 11 borderline	Prospective, multicenter study to estimate whether 3D US and 3D power Doppler investigation can contribute to the differentiation between benign and malignant ovarian masses.	Central vessels found in 15% benign, 69% malignant, 27% borderline. Central localization of vessels in an adnexal mass, as observed by 3D-US, the mean gray index, and the flow index are potentially important parameters for distinguishing benign from malignant adnexal masses.	2
17. Salem S, White LM, Lai J. Doppler sonography of adnexal masses: the predictive value of the pulsatility index in benign and malignant disease. <i>AJR Am J Roentgenol</i> 1994; 163(5):1147-1150.	10	99 patients with 102 masses	Study in which all patients with an adnexal mass on US were followed to determine whether pulsed Doppler US can be used to distinguish between benign and malignant masses on the basis of pulsatility index.	Pulsatility indexes showed considerable overlap between benign and malignant lesions, indicating that Doppler US has severe limitations in the differentiation of benign from malignant adnexal disease on the basis of low-impedance flow.	2
18. Jain KA. Prospective evaluation of adnexal masses with endovaginal gray-scale and duplex and color Doppler US: correlation with pathologic findings. <i>Radiology</i> 1994; 191(1):63-67.	9	42 patients 50 masses	Prospective study to compare TVS morphologic characteristics with color and duplex Doppler US.	TVS diagnosed 95% of benign masses, 100% malignant masses. Color and duplex US diagnosed 82% of benign and 78% of malignant. RI values cannot be relied on because of overlap in the RI value of benign and malignant masses.	2
19. Hata K, Hata T, Manabe A, Sugimura K, Kitao M. A critical evaluation of transvaginal Doppler studies, transvaginal sonography, magnetic resonance imaging, and CA 125 in detecting ovarian cancer. <i>Obstet Gynecol</i> 1992; 80(6):922-926.	9	63 patients ovarian tumors (36 benign and 27 malignant)	Comparative study to evaluate if TVS Doppler is better than TVS, MRI, and CA 125 in differentiating malignant from benign ovarian tumors.	RI in detecting malignancy: sensitivity 92.6%, specificity 52.8%, not different from TVS (sensitivity 85.2%, specificity 69.4%), but lower specificity than MRI 97.1% with CA125 level 91.7%. TVS Doppler (RI cut off .7) does not provide more information than TVS, MRI, and CA 125 for malignant vs. benign ovarian tumors. TVS Doppler higher sensitivity and lower specificity. Results show TVS Doppler US does not provide more useful diagnostic information than TVS, MRI, and CA 125.	2

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Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
20. Brown DL, Doubilet PM, Miller FH, et al. Benign and malignant ovarian masses: selection of the most discriminating gray-scale and Doppler sonographic features. <i>Radiology</i> 1998; 208(1):103-110.	10	194 patients (211 lesions)	To determine the gray-scale and Doppler US features that best enable discrimination between malignant and benign ovarian masses and develop a scoring system for accurate diagnosis with these features.	28 malignant, 183 benign masses. Masses with markedly hyperechoic solid component or no solid component were benign. In masses with non-hyperechoic solid component, other features helped to discriminate between benign and malignant masses. Scoring formula developed, cut off score yielded sensitivity of 93% and specificity of 93%.	2
21. Guerriero S, Ajossa S, Risalvato A, et al. Diagnosis of adnexal malignancies by using color Doppler energy imaging as a secondary test in persistent masses. <i>Ultrasound Obstet Gynecol</i> 1998; 11(4):277-282.	9	192 consecutive lesions	Prospective study to compare the accuracy of B-mode TVS alone and in combination with color Doppler energy (or power Doppler) imaging in differentiating benign from malignant adnexal masses.	159 benign, 33 malignant. Intratumoral arterial blood flow detected in 100% malignant and in 94% benign. Combined use of TVS and color Doppler has greater accuracy for diagnosing ovarian malignancy than TVS alone (kappa: 0.81 and 0.63).	2
22. Fleischer AC, Rodgers WH, Rao BK, et al. Assessment of ovarian tumor vascularity with transvaginal color Doppler sonography. <i>J Ultrasound Med</i> 1991; 10(10):563-568.	10	43	Correlate TVS color Doppler US with surgically proven ovarian masses.	TV color Doppler US has NPV 100%, therefore, effective in excluding malignant masses but PPV 73%. 1 in 4 called malignant lesions by TV color Doppler US will be benign.	3
23. Hamper UM, Sheth S, Abbas FM, Rosenshein NB, Aronson D, Kurman RJ. Transvaginal color Doppler sonography of adnexal masses: differences in blood flow impedance in benign and malignant lesions. <i>AJR Am J Roentgenol</i> 1993; 160(6):1225-1228.	10	31 masses (25 benign and 6 malignant)	To assess the blood flow characteristics of adnexal masses before surgical excision and to determine whether color flow Doppler US is useful for distinguishing benign from malignant masses.	Benign tumors and cysts had higher PI (mean, 1.93 +/- 1.02; range, 0.23-3.99) and RI (mean, 0.77 +/- 0.22; range, 0.2-1.0) than did malignant tumors (PI: mean, 0.77 +/- 0.33; range, 0.31-1.09; RI: mean, 0.5 +/- 0.17; range, 0.27-0.67). Data suggest that high PI and RI indicate benign adnexal processes; however, considerable overlap in PI and RI between benign and malignant lesions was noted.	3
24. Schelling M, Braun M, Kuhn W, et al. Combined transvaginal B-mode and color Doppler sonography for differential diagnosis of ovarian tumors: results of a multivariate logistic regression analysis. <i>Gynecol Oncol</i> 2000; 77(1):78-86.	9	257	To determine if color-coded Doppler US can improve the diagnostic accuracy of B-mode US in ovarian masses. Preoperative B-mode and Doppler US was performed prospectively in 63 patients with unclear adnexal lesions prior to operation. Using multiple logistic regression, the independent variables of each procedure were selected and combined to yield a diagnostic flow chart.	39 malignant, 218 benign. Combining independent significant variables of 2 procedures raised the diagnostic accuracy to 90% (sensitivity 86%, specificity 93%). The validity achieved by this combination was confirmed by the independent application of this method to the 257 adnexal tumors with unclear malignancy status (diagnostic accuracy 93%, sensitivity 92%, specificity 94%). Combination of US and Doppler US yields high and reproducible diagnostic accuracy.	2

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25. Schneider VL, Schneider A, Reed KL, Hatch KD. Comparison of Doppler with two-dimensional sonography and CA 125 for prediction of malignancy of pelvic masses. <i>Obstet Gynecol</i> 1993; 81(6):983-988.	9	55	Cross-sectional study to assess the validity of Doppler flow US for the prediction of malignancy in adnexal masses and to compare the results with 2D US examination and CA 125 levels.	Doppler US evaluation of RI in the vessels of adnexal masses increased the sensitivity of 2D US and CA 125. However, 46% of positive Doppler results were false and 37.5% of the benign tumors had low RI, thus limiting the validity of this technique for screening programs.	2
26. Chou CY, Chang CH, Yao BL, Kuo HC. Color Doppler ultrasonography and serum CA 125 in the differentiation of benign and malignant ovarian tumors. <i>J Clin Ultrasound</i> 1994; 22(8):491-496.	9	108	To evaluate the use of Color Doppler US and CA 125 in adnexal masses before surgery.	A combination of color Doppler US and CA 125 is effective in differentiating benign from malignant tumors. A combination of RI and CA 125 gives sensitivity of 100%, NPV 100%.	2
27. Mancuso A, De Vivo A, Triolo O, Irato S. The role of transvaginal ultrasonography and serum CA 125 assay combined with age and hormonal state in the differential diagnosis of pelvic masses. <i>Eur J Gynaecol Oncol</i> 2004; 25(2):207-210.	9	125	To evaluate the ability of CA125 and US alone and in combination with clinical parameters (> 50 years and postmenopausal state) in the diagnosis of a malignant pelvic mass.	The best results were obtained from the association of CA125 and menopause; an increase in CA125 in menopausal women most likely suggests pelvic mass is malignant.	2
28. Murta EF, da Silva CS, Gomes RA, Tavares-Murta BM, Melo AL. Ultrasonographic criteria and tumor marker assay are good procedures for the diagnosis of ovarian neoplasia in preselected outpatients. <i>Eur J Gynaecol Oncol</i> 2004; 25(6):707-712.	9	373	Prospective study to identify parameters for diagnosis of ovarian neoplasia using US and serum tumor marker assay.	Sensitivity for neoplasia and malignant neoplasia for RI alone is 17% and 63.6% and 53.1% and 90.9% for RI plus tumor markers. US criteria and tumor marker assay were indicated for the diagnosis of ovarian neoplasia.	2
29. Sohaib SA, Sahdev A, Van Trappen P, Jacobs IJ, Reznik RH. Characterization of adnexal mass lesions on MR imaging. <i>AJR Am J Roentgenol</i> 2003; 180(5):1297-1304.	10	104 patients (163 lesions)	Prospective study to evaluate the accuracy of MRI in the detection and characterization of adnexal masses and to determine which imaging features are predictive of malignancy.	MRI: 95% lesions were detected. Accuracy 91%. MRI is highly accurate in characterization of adnexal masses and the best predictors of malignancy are vegetation in a cystic lesion and ascites.	1
30. Adusumilli S, Hussain HK, Caoili EM, et al. MRI of sonographically indeterminate adnexal masses. <i>AJR</i> 2006; 187(3):732-740.	10	87 patients (95 lesions)	Retrospective, blinded review to assess the ability of MRI to characterize sonographically indeterminate adnexal masses and to define the US features contributing to indeterminate diagnoses.	Sensitivity of MRI for identifying malignancy (n=5) was 100%, specificity for benignity (n=90) was 94%. Main reason for indeterminate US was inability to determine origin because of location and large mass size and appearance of purely solid or complex cystic masses.	2
31. Sohaib SA, Mills TD, Sahdev A, et al. The role of magnetic resonance imaging and ultrasound in patients with adnexal masses. <i>Clin Radiol</i> 2005; 60(3):340-348.	9	72	Prospective study to evaluate the accuracy of US and MRI in characterizing adnexal masses and to determine which patients may benefit from MRI.	Sensitivity (US 100%, MRI 96.6%). Specificity (US 39.5%, MRI 83.7%). Accuracy (US 63.9%, MRI 88.9%). MRI is more specific and accurate than US and Doppler assessment for characterizing adnexal masses.	2

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32. Togashi K. Ovarian cancer: the clinical role of US, CT, and MRI. <i>Eur Radiol</i> 2003; 13 Suppl 4:L87-104.	12	N/A	Review the clinical roles of US, CT and MRI in the diagnosis of ovarian cancer.	US is the modality of choice in evaluation of suspected adnexal masses. CT is not indicated for differential diagnosis of adnexal masses because of poor soft tissue discrimination. MRI may help in distinguishing benign from malignant.	3
33. Fenchel S, Grab D, Nuessle K, et al. Asymptomatic adnexal masses: correlation of FDG PET and histopathologic findings. <i>Radiology</i> 2002; 223(3):780-788.	9	99 consecutive patients	Prospective study to analyze the asymptomatic adnexal masses at PET with FDG in correlation with histopathologic findings and evaluate FDG-PET for assessing malignancy in comparison with TVS and Doppler and MRI.	<ul style="list-style-type: none"> <li>• FDG-PET: Sensitivity 58%, specificity 76%.</li> <li>• US: Sensitivity 92%, specificity 62%.</li> <li>• MRI: Sensitivity 83%, specificity 84%.</li> <li>• Combination of 3: Sensitivity 92%, specificity 85%.</li> <li>• The sensitivity of US is as high as that of PET, MRI and combination of 3 modalities.</li> </ul>	1
34. American College of Radiology. <i>Manual on Contrast Media</i> . Available at: <a href="http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual.aspx">http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual.aspx</a> .	15	N/A	Guidance document on contrast media to assist radiologists in recognizing and managing risks associated with the use of contrast media	N/A	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.