

**Abnormal Vaginal Bleeding
EVIDENCE TABLE**

Reference	Study Type	Patients/ Events	Study Objective (Purpose of Study)	Study Results	Strength of Evidence
1. Bayer SR, DeCherney AH. Clinical manifestations and treatment of dysfunctional uterine bleeding. <i>JAMA</i> 1993; 269(14):1823-1828.	7	N/A	To review treatment of dysfunctional uterine bleeding.	Goals of treatment are to stop acute bleeding, avert future episodes, and prevent long-term complications.	4
2. Sheth S, Hamper UM, Kurman RJ. Thickened endometrium in the postmenopausal woman: sonographic-pathologic correlation. <i>Radiology</i> 1993; 187(1):135-139.	13	35	To correlate sonographic findings with microscopic examination to determine whether the sonographic appearance of the thickened endometrium can help in predicting the underlying pathologic process.	Careful analysis of the endometrial echotexture seen at endovaginal sonography (EVS) can assist in the evaluation of thickened endometrium in postmenopausal women. Specifically, the presence of small endometrial cysts in an otherwise regular, echogenic endometrium correlates with benign simple (cystic) hyperplasia or atrophy.	3
3. Karlsson B, Granberg S, Wikland M, Ryd W, Norstrom A. Endovaginal scanning of the endometrium compared to cytology and histology in women with postmenopausal bleeding. <i>Gynecol Oncol</i> 1993; 50(2):173-178.	9	105	To compare specificity and sensitivity of EVS with endometrial cytology and dilation and curettage to discriminate between a normal and pathological endometrium.	A specificity of 81% and a sensitivity of 97% in diagnosing morphological alterations by means of EVS were found. The corresponding figures for cytological evaluation were 81% and 58%, respectively. EVS is a valuable diagnostic instrument for detecting pathological conditions in the uterine mucosa and as sensitive as endometrial cytology or dilation and curettage.	2
4. Smith-Bindman R, Kerlikowske K, Fedlstein VA, et al. Endovaginal ultrasound to exclude endometrial cancer and other endometrial abnormalities. <i>JAMA</i> 1998; 280(17):1510-1517.	11	5,892	To determine accuracy of EVS in detecting endometrial disease in postmenopausal women with vaginal bleeding according to hormone replacement use.	In women not using hormone replacement therapy, 593 (8%) with normal histological findings had an abnormal EVS result (specificity, 92%; 95% CI, 90%-94%), whereas 1,544 (23%) using hormone replacement therapy had an abnormal EVS result (specificity, 77%; 95% CI, 75%-79%). EVS has a high sensitivity.	1
5. Hulka CA, Hall DA, McCarthy K, Simeone JF. Endometrial polyps, hyperplasia, and carcinoma in postmenopausal women: differentiation with endovaginal sonography. <i>Radiology</i> 1994; 191(3):755-758.	13	68	Retrospective study to determine whether endometrial hyperplasia, polyps, and carcinoma can be differentiated on the basis of their sonographic appearance. Pathologic and sonographic findings were correlated.	30 sonograms showed hyperechoic endometria in women with hyperplasia; 27 sonograms showed cystic spaces in women with polyps; and 11 sonograms showed heterogeneous endometria. EVS may be useful for differentiation.	3
6. Lin MC, Gosink BB, Wolf SI, et al. Endometrial thickness after menopause: effect of hormone replacement. <i>Radiology</i> 1991; 180(2):427-432.	13	112	US images of the pelvis were evaluated in asymptomatic postmenopausal women to investigate the normal range of endometrial thickness (double-layer measurement) and the effect of hormone replacement on these measurements.	A patient with endometrial thickness of at least 1.5 cm should undergo histologic diagnosis, regardless of symptoms or hormone status.	2

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7. Smith P, Bakos O, Heimer G, Ulmsten U. Transvaginal ultrasound for identifying endometrial abnormality. <i>Acta Obstet Gynecol Scand</i> 1991; 70(8):591-594.	9	96	To evaluate the endometrium in patients referred for dilatation and curettage with transvaginal US (TVS). The sonographic display was correlated to the histopathologic diagnosis.	In 45 patients with postmenopausal bleeding, the sensitivity of US in diagnosing endometrial pathology was 100% and the specificity was 61%. PPV and NPV were 39% and 100% respectively. In 51 premenopausal women, the sensitivity in diagnosing endometrial pathology was 67% and the specificity 75%. PPV and NPV were 14% and 97% respectively.	2
8. Aleem F, Predanic M, Calame R, Moukhtar M, Pennisi J. Transvaginal color and pulsed Doppler sonography of the endometrium: a possible role in reducing the number of dilatation and curettage procedures. <i>J Ultrasound Med</i> 1995; 14(2):139-145; quiz 147-138.	10	42	Prospective study to establish color and pulsed Doppler sonographic characteristics of uterine vascularity in postmenopausal patients with pathologic endometrium in order to reduce the number of unnecessary diagnostic dilatation and curettage procedures.	Endometrial thickness was >8 mm in all cases of endometrial carcinoma (14/14 cases), endometrial hyperplasia (8/8 cases), and one endometrial polyp. In all cases of uterine myoma (9 cases) and in asymptomatic controls (11 subjects) the endometrium thickness was <8 mm. Percentage of visualization of myometrial and endometrial vessels in cases of endometrial carcinoma was 93% and 43% respectively, which was significantly higher than for cases with benign endometrium (P<0.05). Resistive index (RI) and pulsatility index (PI) values of these studied vessels of endometrial carcinoma were significantly lower than those for endometrial hyperplasia (P<0.05). In 80% of cases of endometrial carcinoma, dense vascularity was found in the myometrium (P<0.01)	2
9. Dorum A, Kristensen GB, Langebrekke A, Sornes T, Skaar O. Evaluation of endometrial thickness measured by endovaginal ultrasound in women with postmenopausal bleeding. <i>Acta Obstet Gynecol Scand</i> 1993; 72(2):116-119.	9	100	To evaluate value of EVS in scanning women with postmenopausal vaginal bleeding referred for dilatation and curettage. The US appearance of the endometrium was related to the histologic diagnosis.	The sensitivity of US to detect malignancy was 80%, the specificity was 60%. PPV and NPV were 26% and 94.4% respectively. The sensitivity and the NPV were not high enough to replace histologic examination of the endometrium.	2
10. Osmers R, Völksen M, Schauer A. Vaginosonography for early detection of endometrial carcinoma? <i>Lancet</i> 1990; 335(8705):1569-1571.	10	386	To determine accuracy of vaginosonography in detecting endometrial carcinoma.	Vaginosonography is a good method of screening for uterine neoplasms in presymptomatic women. Those with endometrial thickness of ≥4 mm should undergo curettage and histological examination.	2

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11. Botsis D, Kassanos D, Pyrgiotis E, Zourlas PA. Vaginal sonography of the endometrium in postmenopausal women. <i>Clin Exp Obst Gyn</i> 1992; 19(3):189-192.	9	120	To compare TVS scanning with histology of the endometrium obtained by curettage.	TVS is a reliable examination in the detection of endometrial abnormality.	2
12. Goldstein SR, Nachtigall M, Snyder JR, Nachtigall L. Endometrial assessment by vaginal ultrasonography before endometrial sampling in patients with postmenopausal bleeding. <i>Am J Obstet Gynecol</i> 1990; 163(1 Pt 1):119-123.	10	30	Prospective study of women with postmenopausal bleeding. Before endometrial sampling, a vaginal probe US examination was performed.	<ul style="list-style-type: none"> The absence of significant endometrial tissue on vaginal US is uniformly associated with tissue insufficient. When endometrial thickness is ≥ 6 mm the histologic diagnosis should be determined in the pathology laboratory. 	3
13. Nasri MN, Shepherd JH, Setchell ME, Lowe DG, Chard T. The role of vaginal scan in measurement of endometrial thickness in postmenopausal women. <i>Br J Obstet Gynaecol</i> 1991; 98(5):470-475.	9	111	To determine role of vaginal scan in measurement of endometrial thickness in postmenopausal women. A correlation of US findings and endometrial histopathology was possible in 94 patients.	In 59/94 patients, the endometrium was atrophic and the US endometrial thickness was ≤ 5 mm. In 29 (31%) patients the endometrial histology was abnormal and US endometrial thickness was >5 mm. In 6 patients the endometrium was atrophic, but the US endometrial thickness was apparently >5 mm due to intracavity fluid. Endometrial thickness of 5 mm is an appropriate cut-off level for conservative management of patients with postmenopausal bleeding, or in screening for endometrial carcinoma.	2
14. Reinhold C, McCarthy S, Bret PM, et al. Diffuse adenomyosis: Comparison of endovaginal US and MR imaging with histopathologic correlation. <i>Radiology</i> 1996; 199(1):151-158.	9	119	Prospective study to compare the accuracy of EVS and MRI in the diagnosis of adenomyosis.	Sensitivity and specificity was 89% for EVS and 89% for MRI. The PPV was 71% for US and 65% for MRI. The NPV was 96% for US and 95% for MRI. There was no statistically significant difference between the sensitivities (P=.65) and specificities (P=.75) of EVS and MRI.	1
15. Dubinsky TJ, Parvey R, Gormaz G, Makland N. Transvaginal hysterosonography in the evaluation of small endoluminal masses. <i>J Ultrasound Med</i> 1995; 14(1):1-6.	10	48	Prospective study to determine the usefulness of transvaginal hysterosonography (TVHS) in the evaluation of endoluminal masses.	Of 48 suspected lesions, TVHS confirmed 19 endoluminal masses: 11 fibroids and eight polyps. TVHS may prevent unnecessary biopsies and help direct subsequent biopsy procedures.	3

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16. Kelekci S, Kaya E, Alan M, Alan Y, Bilge U, Mollamahmutoglu L. Comparison of transvaginal sonography, saline infusion sonography, and office hysteroscopy in reproductive-aged women with or without abnormal uterine bleeding. <i>Fertil Steril</i> 2005; 84(3):682-686.	9	50	Prospective blinded study to compare accuracy and acceptability of TVS, saline infusion sonography (SIS) and office hysteroscopy (OHS).	<ul style="list-style-type: none"> The sensitivity and specificity of TVS, SIS, and OHS in detecting intracavitary abnormalities were 56.3% and 72%, 81.3% and 100%, and 87.5% and 100%, respectively. The diagnostic accuracy of SIS was equal to that of OHS in diagnosing intracavitary abnormalities. Moreover, SIS was less painful than OHS for patients. 	1
17. Mendelson EB, Bohm-Velez M, Joseph N, Neiman HL. Endometrial abnormalities: evaluation with transvaginal sonography. <i>AJR</i> 1988; 150(1):139-142.	9	29	TVS were compared with conventional transabdominal scans in patients whose sonograms revealed endometrial abnormalities to evaluate transvaginal depiction of the endometrium.	23% of TVS provide unique information not provided by transabdominal study. TVS is the preferred technique.	2
18. Chan FY, Chau MT, Pun TC, et al. Limitations of transvaginal sonography and color Doppler imaging in the differentiation of endometrial carcinoma from benign lesions. <i>J Ultrasound Med</i> 1994; 13(8):623-628.	9	67	To test hypothesis that TVS and color Doppler imaging are complementary methods in the assessing postmenopausal bleeding.	TVS is superior to color Doppler imaging in detecting conditions of the endometrium. Both methods cannot distinguish benign from malignant lesions.	2
19. Timmerman D, Verguts J, Konstantinovic ML, et al. The pedicle artery sign based on sonography with color Doppler imaging can replace second-stage tests in women with abnormal vaginal bleeding. <i>Ultrasound Obstet Gynecol</i> 2003; 22(2):166-171.	10	3,099	Prospective observational study to determine accuracy of pedicle artery test in detecting endometrial polyps.	The pedicle artery test had an apparent sensitivity for detection of endometrial polyps of 76.4%, specificity of 95.3%, PPV of 81.3%, and NPV of 93.8%. When extending the test to the prediction of any focal intracavitary pathology the PPV was 94.2%.	1
20. Lev-Toaff AS, Pinheiro LW, Bega G, et al. Three-dimensional Multiplanar Sonohysterography. <i>J Ultrasound Med</i> 2001; 20(4):295-306.	9	20	Compare findings to assess the value of transvaginal sonohysterography and 3D multiplanar US to optimize assessment of the uterus.	In 9 (69%) of 13 comparisons between 3D sonohysterography and 2D sonohysterography and in 11 (92%) of 12 comparisons between 3D sonohysterography and X-ray hysterosalpingography, 3D sonohysterography was advantageous. The coronal plane was most useful for displaying the relationship between lesions and the uterine cavity. 3D sonohysterography provided additional information compared with standard accepted techniques in the vast majority of women.	2

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21. Andreotti RF, Fleischer AC, Mason LE, Jr. Three-dimensional sonography of the endometrium and adjacent myometrium: preliminary observations. <i>J Ultrasound Med</i> 2006; 25(10):1313-1319.	13	90	3D reconstructed images to determine additional information obtained in the coronal plane.	3D view is most helpful after a conventional transvaginal study, but is of little benefit if the conventional findings are normal.	2
22. Andreotti RF, Fleischer. The sonographic diagnosis of adenomyosis. <i>Ultrasound Q</i> 2005; 21(3):167-170.	12	N/A	To review sonographic and MRI features were developed in the diagnosis of adenomyosis emphasizing sonography as the initial study performed in the symptomatic patient.	MRI and US can now diagnose adenomyosis with a high accuracy.	4
23. American College of Radiology. <i>Manual on Contrast Media</i> . Available at: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/contrast_manual.aspx .	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.