Evaluation of the Woman With Postmenopausal Bleeding

Society of Radiologists in Ultrasound–Sponsored Consensus Conference Statement


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Objectives: A panel of 14 physicians practicing medicine in the United States with expertise in radiology, obstetrics and gynecology, gynecologic oncology, hysteroscopy, epidemiology, and pathology was convened by the Society of Radiologists in Ultrasound to discuss the role of sonography in women with postmenopausal bleeding. Broad objectives of this conference were (1) to advance understanding of the utility of different diagnostic techniques for evaluating the endometrium in women with postmenopausal bleeding; (2) to formulate useful and practical guidelines for evaluation of women with postmenopausal bleeding, specifically as it relates to the use of sonography; and (3) to offer suggestions for future research projects. Setting: October 24 and 25, 2000, Washington, DC, preceding the annual Society of Radiologists in Ultrasound Advances in Sonography conference. Procedure: Specific questions to the panel included the following: (1) What are the relative effectiveness and cost-effectiveness of using transvaginal sonography versus office (nondirected) endometrial biopsy as the initial examination for a woman with postmenopausal bleeding? (2) What are the sonographic standards for evaluating a woman with postmenopausal bleeding? (3) What are the abnormal sonographic findings in a woman with postmenopausal bleeding? (4) When should saline infusion sonohysterography or hysteroscopy be used in the evaluation of postmenopausal bleeding? (5) Should the diagnostic approach be modified for patients taking hormone replacement medications, tamoxifen, or other selective estrogen receptor modulators? Conclusions: Consensus recommendations were used to create an algorithm for evaluating women with postmenopausal bleeding. All panelists agreed that because postmenopausal bleeding is the most common presenting symptom of endometrial cancer, when postmenopausal bleeding occurs, clinical evaluation is indicated. The panelists also agreed that either transvaginal sonography or endometrial biopsy could be used safely and effectively as the first diagnostic step. Whether sonography or endometrial biopsy is used initially depends on the physician’s assessment of patient risk, the nature of the physician’s practice, the availability of high-quality sonography, and patient preference. Similar sensitivities for detecting endometrial carcinoma are reported for transvaginal sonography when an endometrial thickness of greater than 5 mm is considered abnormal and for endometrial biopsy when “sufficient” tissue is obtained. Currently, with respect to mortality, morbidity, and quality-of-life end points, there are insufficient data to comment as to which approach is more effective. The conference concluded by identifying several important unanswered questions and suggestions that could be addressed by future research projects. Key Words: postmenopausal bleeding; menopause; sonography; ultrasound; transvaginal sonography; endometrium; endometrial cancer.

DEFINITION

The term postmenopausal bleeding (PMB) refers to any vaginal bleeding in a postmenopausal woman other than expected cyclic bleeding that occurs with sequential hormone replacement therapy (HRT).
SUMMARY OF ISSUES ADDRESSED BY THE PANEL

The consensus panel addressed the role of transvaginal sonography (TVS) in the evaluation of women with PMB. The majority of the debate and discussion focused on 3 issues: whether TVS can be used safely as the initial diagnostic test in women with PMB; whether a thin endometrium can be used to obviate the need for additional attempts at tissue sampling (in women in whom office endometrial biopsy [EMB] is nondiagnostic); and formulation of recommendations for an appropriate threshold of endometrial thickness, measured sonographically, below which the sonographic findings can safely be interpreted as “negative.” The panel also discussed the clinical importance of detecting other benign uterine abnormalities that may be the cause of PMB. The potential role of saline infusion sonohysterography (SIS) and hysteroscopy was discussed.

BACKGROUND AND SUMMARY OF LITERATURE

Endometrial cancer may be found in 1% to 25% (typically quoted as 10%) of women with unexpected PMB, depending on age and risk factors.\(^1\) Endometrial cancer is the most common gynecologic malignancy. More than 90% of cases occur in women older than 50 years, and abnormal bleeding is the most common presenting symptom. Vaginal bleeding, however, may be due to many causes other than cancer and is a common problem in postmenopausal women, occurring in as many as 1 per 10 women older than 55 years.\(^6\) Although PMB is often due to other conditions, endometrial cancer is the most serious. Thus, accepted practice in the United States includes further evaluation to exclude endometrial carcinoma in women with PMB.\(^8\)

Before 1982, diagnostic evaluation was routinely accomplished by surgical dilation and curettage (D&C) of the endometrium. More recently, a suction catheter technique for endometrial tissue sampling, performed in an office setting, has been shown to be more than 85% sensitive for the detection of endometrial carcinoma and is more convenient and less costly. Unlike surgical D&C, EMB can easily be performed in the office with minimal or no analgesia.

Transvaginal sonography has also become an increasingly popular tool for endometrial assessment and, in comparison with office EMB, has similar (or slightly lower) false-negative rates for cancer detection.\(^7\) Although tissue is not obtained during sonography, sonographic imaging of the endometrium can be extremely helpful, because endometrial cancer is nearly always associated with thickening and heterogeneity of the endometrium and is rarely present when the endometrium is thin. In fact, the positive predictive value for cancer on a sonogram increases with the thickness of the endometrium.\(^6,7,12–14\) Furthermore, a large number of studies from the United States and Europe have confirmed that a very thin endometrial lining almost never harbors carcinoma.\(^7,15\)

To determine how thin an endometrium should be to reasonably exclude cancer, many large studies have been performed. These studies have shown that when an endometrial thickness threshold of 4 or 5 mm is used, the sensitivity for detecting endometrial carcinoma approaches 95%.\(^6,7\) Furthermore, in part because the prevalence of endometrial cancer is low, the negative predictive value of a thin endometrium is very high. Thus, the presence of a thin endometrium can be used reliably to exclude cancer. These observations, in combination with evidence that TVS assessment of endometrial thickness is highly reproducible,\(^16\) have fueled interest in using TVS in 2 important settings. The first is to assess the endometrium with TVS as the initial diagnostic test (after history and physical examination) in women with PMB. Some physicians and patients may elect to begin the evaluation with TVS because office EMB may be uncomfortable.\(^17\) In comparison with EMB, TVS is better tolerated and has a higher rate (>95%) of diagnostic results.\(^7,14\) Furthermore, in some patients, office EMB cannot be adequately performed because of cervical stenosis or patient intolerance or, as occurs in 5% to 15% of patients, because the specimen may not provide sufficient information to exclude endometrial cancer.\(^2,3,14,18,19\) The second setting in which TVS can be extremely helpful is in the group of women in whom EMB has been attempted but has not been diagnostic. In this setting, the high negative predictive value of a thin, homogeneous endometrium can be used to obviate the need for a more invasive procedure such as surgical D&C.

PANEL DISCUSSION

The consensus panel addressed the following 5 questions:

1. What are the relative effectiveness and cost-effectiveness of using sonography versus blind EMB as the initial test for PMB?

The panelists concluded that, after a history and physical examination, either TVS or EMB would be effective and diagnostic as the first step in the evaluation of women with PMB. The relative cost-effectiveness of using EMB versus TVS as the first diagnostic procedure has not been determined by prospective testing. The choice will depend on the physician’s practice and expertise and the availability of high-quality sonography. Some of the panelists thought that in women considered to be at high risk for endometrial cancer (e.g., women older than 60 years, not receiving HRT or treatment with unopposed estrogen, or women with obesity or diabetes), EMB may be preferred as the first step in
this evaluation, although the efficacy of using a 5-mm endometrial threshold in this particular subset of patients has not been carefully studied.

Using published data on sensitivities and cost projected onto varying algorithms, Weber et al addressed theoretical considerations to assess cost-effectiveness, but some of the assumptions used by these authors may not be universally applicable (i.e., costs and outcomes may vary). They concluded that the costs are reasonably comparable for either approach. The panel speculated that if a study were done prospectively, the false-positive rates and patient referral patterns would likely have the greatest influence on cost.

2. What are the sonographic standards for evaluating a woman with PMB?

To use sonography to exclude cancer in a woman with PMB, sonography must be performed according to the following standards. The sonography should be performed transvaginally with a 5- to 10-MHz transducer and an empty bladder, for resolution of the endometrial echotexture, margins, and double-layer thickness measurement. The transabdominal portion of the sonographic endometrium and its borders (Fig. 2). Many panelists thought that the transabdominal portion of the sonographic examination, however, should be included to ensure that a large mass or fluid collection is not missed (owing to the limited field of view of TVS). Most agreed that the transabdominal scan could be performed with either a full or an empty bladder.

Endometrial thickness should be measured on a sagittal (long-axis) image of the uterus, and the measurement should be performed on the thickest portion of the endometrium, excluding the hypoechoic inner myometrium (Figs. 3 and 4). The endometrial thickness should be reported as the “double-thickness” measurement. A small amount of fluid will be found in the endometrial canal of some postmenopausal women without abnormalities. This fluid should not be included in the endometrial measurement. In these cases, the reported endometrial thickness should be the sum of the thickness of the 2 endometrial layers, excluding the fluid (Fig. 5).

The endometrium should be visualized completely. If the entire endometrium cannot be imaged because of obscuration by fibroids, or if the endometrial margins are indistinct such that the borders of the endometrium cannot be delineated to measure the double wall thickness, the study should be considered inadequate, and other means of evaluating the endometrium should be used (Fig. 6). Practitioners are reminded that nondiagnostic findings may occur more commonly in women with invasive carcinoma because of indistinct endometrial margins. With recognition of the potentially pivotal role of TVS in the diagnostic evaluation of these patients, a statement should be included in the report regarding the technical adequacy of the sonogram.

3. What are the abnormal sonographic findings in a woman with PMB?

A. The sonogram should be interpreted as abnormal if the double thickness of the endometrium is greater than 5 mm. This conclusion is based on 2 important observations: (1) nearly all patients with proven endometrial cancer had an endometrial thickness of greater than 5 mm; and (2) when this threshold is used, the sensitivity of detecting endometrial cancer with TVS is comparable with that of EMB. A meta-analysis of 85 published studies that included 5892 women showed that an endometrial thickness of greater than 5 mm identified 96% of endometrial cancer. These sensitivities did not vary with the use of HRT (see question 5). The panel discussed whether 4 mm might be a more sensitive and, therefore, a better threshold. They noted, however, that Smith-Bindman and coworkers found that decreasing the threshold to 4 mm negligibly alters the sensitivity for cancer detection but substantially decreases the specificity (more false-positive results). As a result, most panelists favored using a threshold of 5 mm.

The panel agreed that it is important to emphasize that this threshold does not apply to an asymptomatic woman with an incidentally observed endometrium of greater than

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**FIG. 1.** Complete endometrial imaging has been accomplished on this sagittal image of the uterus using TVS. A small amount of fluid is shown in the endometrial canal. In the postmenopausal woman, this is not necessarily pathologic. The endometrium is visualized in its entirety, including the cervix (arrow). An incidentally observed nabothian cyst is seen in the cervix (arrowhead). Image courtesy of Peter M. Doubilet, MD, PhD (Brigham and Women’s Hospital, Boston, MA).
5 mm. Among these postmenopausal women, a normal maximal endometrial thickness measurement has not yet been established.

B. The sonogram should be interpreted as nondiagnostic if the endometrium cannot be visualized in its entirety. This observation, found in approximately 5% to 10% of patients, is not specific for disease, but an incompletely visualized endometrium cannot be interpreted as benign or reassuring. Because this appearance can occur with endometrial cancer, a nondiagnostic sonogram should lead to the further evaluation, similar to positive sonographic findings (Fig. 6).

C. The sonographic findings are abnormal if a focal endometrial abnormality is detected. Among women with PMB, endometrial cancer is found in approximately 10%, but polyps, hyperplasia, and fibroids will be found in as many as 40%. A focal area of thickening, a mass, or inhomogeneity on TVS warrants further evaluation in a woman with PMB. Tissue sampling, SIS, or hysteroscopy with D&C should be performed.

D. The sonographic findings are abnormal if the margins of the endometrium are indistinct. Endometrial cancer often expands the endometrial cavity and, in addition to thickening, may result in an indistinct appearance of the endometrial lining (Fig. 7). An indistinct endometrium can also be seen in benign conditions, such as adenomyosis.

4. When should SIS or hysteroscopy be used in the evaluation of PMB?

Consensus was uniform among panelists that either SIS or hysteroscopy is appropriate when a focal abnormality is suspected on the transvaginal sonogram. One advantage of hysteroscopy is that it permits biopsy of a focal mass. Most panelists favored surgical hysteroscopy compared with office hysteroscopy, although this requires considerable anesthesia and expense. Saline infusion sonohysterography is a relatively new imaging procedure during which TVS is performed while sterile saline is infused into the endometrial cavity via a transcervically placed catheter. Saline infusion sonohysterography can be performed safely and easily as an outpatient procedure. Anesthesia is not required, and detection rates for focal abnormalities are comparable with those

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**FIG. 2.** Endometrial polyp shown to better advantage with TVS than transabdominal sonography. A, Transabdominal sonogram (4-MHz transducer). The endometrium is not adequately visualized, although there is a vague abnormality of the endometrium (arrows). Calipers mark the margins of the uterus. B, Transvagal sonogram performed with an 8-MHz transducer in same patient as in A. A cystic and solid endometrial polyp (arrows) is resolved better with TVS.

**FIG. 3.** Measuring the endometrium. Endometrial measurement should include the double thickness (arrows) excluding the hypoechoic myometrium (asterisks).
of hysteroscopy. Thus, many on the panel favored SIS when a focal endometrial abnormality is suspected on the transvaginal sonogram to confirm that a focal abnormality is indeed present (Figs. 2 and 8) and to define the nature of the focal abnormality better (e.g., polyp versus fibroid). Subsequent hysteroscopy could then be used to remove the focal abnormality, if appropriate.

Saline infusion sonohysterography may also be helpful when a thickened endometrium has been identified on the sonogram to allow more efficient triaging of patients. The SIS will show whether the endometrium is diffusely thickened, in which case EMB or D&C would be the next step, or focally thickened, in which case hysteroscopy would be the next step (Fig. 8). Saline infusion sonohysterography is also helpful if there is a discrepancy between the findings on the transvaginal sonogram and the EMB (Fig. 9).

An issue is the clinical importance of finding benign endometrial abnormalities in women with PMB. The majority agreed that in patients in whom a focal abnormality was suspected on TVS, SIS might be helpful to characterize the abnormality more fully. The panelists agreed that there is good evidence that SIS is more sensitive than TVS alone to detect focal abnormalities in women with PMB. The important but as yet unanswered question is whether finding and treating these benign conditions improve the patient’s quality of life, morbidity, and survival. The panelists concluded that further investigation into this issue is warranted. A minority of panelists thought that all women with PMB should undergo SIS. The opinion of these panelists is a reflection of recent published evidence that suggests that SIS is more sensitive for detecting focal endometrial abnormalities than either TVS or EMB. It is becoming apparent that focal endometrial abnormalities are more common than previously thought. Many of these abnormalities are benign polyps and fibroids, and these may account for abnormal bleeding. In a multicenter study investigating the utility of SIS, Bree et al reported polyps in 47% and

**FIG. 4.** Focal endometrial mass. Care should be taken to scrutinize the entire endometrium carefully in real time. The thickest portion of the endometrium should be reported as the double-thickness measurement. A, A portion of the endometrium appears homogeneous and thin (calipers). B, Further evaluation discloses a focal abnormality, which was an endometrial polyp (calipers).

**FIG. 5.** Transvaginal sonogram of a postmenopausal woman with a small volume of fluid in the central canal. Fluid should not be included in the endometrial thickness measurement. In this case, each endometrial wall should be measured separately (lines) and summed for the reported double-thickness measurement. Image courtesy of Peter M. Doubilet, MD, PhD.
endometrial hyperplasia in 4% of women with PMB. These results should be considered, however, in light of a recent study published by Neale et al., who found that nearly 35% of asymptomatic postmenopausal women had endometrial abnormalities detected with SIS.

5. Should the diagnostic approach be modified for patients taking HRT medications, tamoxifen, or other selective estrogen receptor modulators?

Women taking sequential regimens of HRT may have cyclic alterations in endometrial thickness. For these women, the TVS should be performed 4 to 5 days after completion of the cyclic bleeding. For those taking continuous regimens of HRT, including unopposed estrogen, or no HRT, sonography can be performed any time during the monthly cycle. Sensitivities for the detection of cancer do not differ for women taking HRT compared with those not taking HRT.

In considering cost-effectiveness, the rate of false-positive sonographic findings among hormone users is considerably higher than that among those who do not take HRT. Although the rate of cancer detection does not differ, if TVS is the first diagnostic test, a greater rate of “positive” sonographic findings is likely to lead to more additional testing and higher cost for a complete evaluation for patients taking HRT.

The panelists acknowledged that treatment with tamoxifen (used in adjuvant therapy for breast cancer) is associated...
with increased risk of endometrial proliferation, including polyp formation, endometrial hyperplasia, and endometrial cancer (Fig. 10). This is especially true with increasing durations and dosages of this medication. Panelists thought there was insufficient evidence to warrant recommendation of routine evaluation of asymptomatic women treated in this way. The panel recommended that bleeding women treated with tamoxifen or other selective estrogen receptor modulator therapy be evaluated in a fashion similar to that of other women with PMB (use an endometrial thickness threshold of 5 mm, and sonography can be performed anytime during the month).

RESEARCH AGENDA

1. The prevalence of benign endometrial abnormalities in women with PMB is higher than previously thought. Further investigation into the clinical significance of benign endometrial abnormalities associated with PMB is warranted. This might include better documentation of the rate of malignancy in polyps detected in patients with PMB and investigation into the impact of detecting, treating, and removing these benign abnormalities on outcome.

2. Hormone replacement therapy appears to influence the specificity of TVS. More false-positive sonographic results (by definition abnormal) are found in women taking HRT. The panelists suggested studies to determine how HRT affects the cost-effectiveness of doing TVS or EMB first for the detection of cancer.

3. Further investigation into the relative effectiveness of using TVS versus EMB as the initial test in women with PMB is suggested. This would ideally represent a prospective trial with end points of not only cancer detection but also quality-of-life measures (e.g., patient preference, risk of additional tests, and tolerance of the need for additional testing).

4. Quality control of TVS in the community should be studied further. If TVS may replace EMB as the first diagnostic step in the evaluation of PMB, reproducibility of endometrial measurements in the community setting should be investigated. The Society of Radiologists in Ultrasound (SRU) has funded an educational program to provide standards for performing TVS in this setting.

5. Because TVS has become an acceptable means of commencing the evaluation of PMB, methods of standardizing the sonographic evaluation may be useful. The value of an educational program for improving the quality of TVS in the community should be investigated.

6. Some think that the causes of PMB in women taking HRT or tamoxifen are present before the commencement of therapy. Whether it would be beneficial to perform pretreatment TVS on women before commencement of tamoxifen or HRT should be investigated.

CONCLUSIONS

Conclusions from the panel discussion are summarized in algorithms 1 and 2 (Figs. 11 and 12) and include the following:

FIG. 10. Tamoxifen effect. Transvaginal sonogram shows marked endometrial thickening. This appearance is nonspecific and may represent endometrial hyperplasia, polyp, or carcinoma.

FIG. 11. Proposed algorithm for evaluating PMB commencing with EMB. ET indicates endometrium; and *, physician preference.
1. Transvaginal sonography can be used safely as the initial diagnostic test to evaluate the endometrial lining in a woman with PMB.

2. If the sonogram shows a normal-appearing endometrium with a double-thickness measurement of less than 5 mm, the test can be considered negative for endometrial cancer.

3. In women in whom office EMB is nondiagnostic, a thin endometrium can be used safely to obviate additional attempts at tissue sampling.

4. Both office EMB and TVS may miss benign causes of vaginal bleeding. However, whether cost or clinical benefit results from their detection is not known at this time. Further investigation of this issue would be helpful.

APPENDIX: SUMMARY OF CONFERENCE ACTIVITIES

Preconference Activities

The conference directors (R.B.G. and R.L.B.) and consultants (The Lewin Group, Falls Church, VA [Sean Tunis, MD, MS, Senior Research Scientist]) together determined the key topics and identified experts to participate in the conference. A literature search was performed on the topic of PMB and reviewed for content and authorship. Our intention was to assemble a panel of experts with representatives from general gynecology, gynecologic oncology, hysteroscopy, radiology, pathology, and epidemiology. The consultants and Drs Goldstein and Bree wrote the objectives and formulated 5 questions to the panelists. These were distributed to them before the conference. Several months before the conference, the consensus conference presenters were asked to identify 4 or 5 key references. These were distributed to the participants before the conference. A general announcement of the conference was placed in the SRU newsletter, and a number of organizations and journal editors were invited to send representatives to participate in the audience. These included the American Academy of Family Physicians, American College of Physicians–American Society of Internal Medicine, American Institute of Ultrasound in Medicine, American College of Obstetricians and Gynecologists, National Cancer Institute, National Institutes of Health, Office of Women’s Health, Health Care Financing Administration, and the editors of Radiology, American Journal of Roentgenology, Journal of Ultrasound in Medicine, and Journal of Women’s Imaging.

Conference Activities

The consensus conference, sponsored by the SRU, was held on October 24 and 25, 2000, at L’Enfant Plaza Hotel (Washington, DC). A series of presentations (each ≈30 minutes) were made from 8 AM until 5 PM with two 30-minute discussion sessions. Questions were taken during the presentations so that discussion was ongoing during the day.

Topics of the presentations included Clinical Summary of Postmenopausal Bleeding; Pathology of the Endometrium in Postmenopausal Women; American College of Obstetricians and Gynecologists Guidelines for the Evaluation of Postmenopausal Bleeding; Nonimaging Means of Assessing the Endometrium in Women With Postmenopausal Bleeding (Pipelle, D&C, etc); Transvaginal Sonography; Sonohysterography; Hysteroscopy–Office and Operative; The Effects of Tamoxifen; and Summary of Cost of Transvaginal Sonography, Pipelle, Sonohysterography, D&C, Office Hysteroscopy, and Operative Hysteroscopy.

The consensus panel members met in the evening after the day of presentations and discussions to outline the salient features and conclusions reached during the conference. The next day, all participants met to further refine the consensus outline. Dr Goldstein presented this material at the plenary session of the annual meeting of the SRU, held on October 27, 2000.

Presenters and Panelists

Presenters

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Panelists
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Postconference Activities
In addition to the outline generated and presented on the final day of the conference, all handouts, slides, and notes taken during the conference were reviewed and summarized by the conference codirectors. This summary was sent to each conference participant, who was asked to contribute comments and suggestions. This article represents the culmination and summary of those activities.

REFERENCES