Diagnostic accuracy of endometrial thickness for the detection of intra-uterine pathologies and appropriateness of performed hysteroscopies among asymptomatic postmenopausal women

L. Giannella a,*, K. Mfuta a, T. Setti a, F. Boselli b, E. Bergamini a, L.B. Cerami a

a Local Health Authority of Reggio Emilia, Division of Obstetrics and Gynaecology, Cesare Magati Hospital, Scandiano, Italy
b Mother-Infant Department, Institute of Obstetrics and Gynaecology, University of Modena and Reggio Emilia, Modena, Italy

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Abstract

Objective: To measure the diagnostic accuracy of endometrial thickness for the detection of intra-uterine pathologies among asymptomatic postmenopausal women, and to test the diagnostic accuracy and appropriateness of performed hysteroscopies.

Study design: Prospective study of 268 asymptomatic postmenopausal women with endometrial thickness ≥4 mm referred to diagnostic hysteroscopy. The diagnostic accuracy of various endometrial thickness cut-off values was tested. Histological and hysteroscopic results were compared to measure the diagnostic accuracy of outpatient hysteroscopies.

Results: No endometrial thickness cut-off values had optimal diagnostic accuracy [positive likelihood ratio (LR+) >10 and negative likelihood ratio (LR−) <0.1]. The best endometrial thickness cut-off value for the detection of all intra-uterine pathologies was ≥8 mm (LR+ 10.05 and LR− 0.22). An endometrial thickness cut-off value ≥10 mm did not miss any cases of endometrial cancer. The success rate of diagnostic hysteroscopy was 89%, but 97% of these revealed a benign intra-uterine pathology. The diagnostic accuracy of hysteroscopy was optimal for all intra-uterine pathologies, except endometrial hyperplasia (LR− 0.52).

Conclusion: Using an endometrial thickness cut-off value ≥4 mm, only 3% of performed hysteroscopies were useful for the detection of pre-malignant or malignant lesions. Despite the finding that endometrial thickness did not show optimal diagnostic accuracy, using the best cut-off value (≥8 mm) may be helpful to decrease the number of false-positive results. No cases of endometrial cancer were diagnosed in asymptomatic postmenopausal women with endometrial thickness <10 mm.

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Introduction

The incidental finding of a thickened endometrium is common among postmenopausal women. Although there are endometrial thickness cut-off values to discriminate between postmenopausal women with vaginal bleeding at high and low risk for intra-uterine pathologies, no recommendations exist regarding the clinical management of asymptomatic postmenopausal women [1].

The lack of clear guidelines about good clinical practice has resulted in many physicians using the same clinical recommendations for both symptomatic and asymptomatic postmenopausal women. This has led to indiscriminate use of unnecessary assessments with considerable physical and psychological discomfort.

It has been shown that the risk of malignancy is higher among postmenopausal women with vaginal bleeding and endometrial thickness of 4 mm [2,3], and Menzies et al. observed the same risk of cancer among asymptomatic postmenopausal women with endometrial thickness of 15 mm [4]. These results suggest that the incidence of endometrial cancer is significantly lower in asymptomatic postmenopausal women compared with symptomatic postmenopausal women. Indeed, some studies have reported a malignancy rate of 0% among asymptomatic postmenopausal women with a thickened endometrium [5,6]. Likewise, it has been reported that approximately 90% of women with endometrial cancer experience vaginal bleeding, and a malignancy may occur without signs or symptoms in 20% of cases [7,8].

Previous studies have found that endometrial thickness is a non-optimal tool to identify asymptomatic postmenopausal women.
patients at high or low risk for endometrial pathology or malignancy [9,10].

As such, this study aimed to measure the diagnostic accuracy of endometrial thickness for the detection of all intra-uterine pathology among asymptomatic postmenopausal women. Furthermore, the study tested the diagnostic accuracy and appropriateness of outpatient hystereoscopies.

Materials and methods

This observational prospective study included 268 asymptomatic postmenopausal women with endometrial thickness ≥ 4 mm referred to diagnostic hysteroscopy. The study was performed at Cesare Magati Hospital, Italy from January 2008 to February 2013. The provincial ethical committee approved the study and each woman gave informed consent.

Exclusion criteria were: vaginal bleeding; treatment with tamoxifen, hormone replacement therapy or anticoagulants; and oncological disease. Postmenopausal status was defined as the absence of menstruation for at least 12 months after 40 years of age, with any pathological cause of amenorrhea excluded.

On the day of hysteroscopic examination, each woman completed a questionnaire regarding her medical history. Women who met the inclusion criteria were subjected to transvaginal ultrasound before hysteroscopy: this was performed by an experienced sonographer, and the surgeon was blinded to the ultrasound findings. Only asymptomatic postmenopausal women with endometrial thickness ≥ 4 mm were included in the study. When it was not possible to perform a hysteroscopy, these women were excluded from the study.

All diagnostic hystereoscopies were performed without anaesthesia in an outpatient setting, using a saline solution as the distension medium and a 3.5-mm diagnostic single-flow sheath with a viewing angle of 30°. Ultrasound examination was performed using a 5–9 MHz vaginal transducer, and the thickest part of the anteroposterior bilayer endometrium was measured in the sagittal plane.

All hysteroscopic findings were confirmed by a definitive histological diagnosis which was considered as the reference standard. The following criteria were used, based on the hysteroscopic appearance: (1) women without any intra-uterine lesions (atrophy) underwent Vabra endometrial sampling; (2) women with suspected pre-malignant or malignant lesions underwent a targeted biopsy and random biopsies of each uterine wall; (3) women with polyps or myomas underwent intra-uterine lesion resection; and (4) based on the progression rate of endometrial hyperplasia to endometrial cancer [11], all women with atypical endometrial hyperplasia, and all women with intra-uterine malignant lesions, underwent a hysterecctomy which represented the reference standard as the definitive histological finding; this was done in order to avoid several underdiagnoses as reported in the literature [12].

Patient characteristics taken into account were age, age at menarche, age at menopause, parity, body mass index [BMI = - weight (kg)/height(m)^2], hypertension and diabetes. Histological and hysteroscopic findings were compared to measure the diagnostic accuracy of hysteroscopy for intra-uterine pathologies. Likewise, different endometrial thickness cut-off values were tested to measure their diagnostic accuracy for intra-uterine lesions. Finally, the appropriateness of hysteroscopies was determined based on the number of negative hysteroscopies (atrophy), unrecognized benign lesions (polyps, myomas, endometrial hyperplasia without atypia), unrecognized pre-malignant lesions (atypical endometrial hyperplasia) and unrecognized endometrial cancers. Overall, unnecessary hysterescopies were represented by negative hysteroscopies (atrophy) and unrecognized benign lesions.

Categorical variables were evaluated using Chi-squared test, and one-way analysis of variance was used to test the difference between the means of several subgroups of a variable. The diagnostic test was used to calculate test characteristics such as sensitivity, specificity, positive and negative likelihood ratios (LR+ and LR−), and positive and negative predictive values (PPV and NPV) from a 2 × 2 table. Given that LR+ is given by the mathematical formula (sensitivity)/(1–specificity), LR+ would be +∞ in cases with specificity of 100%. In the latter case, its value has not been reported. Finally, a receiver operating characteristic (ROC) curve analysis was performed by dividing the sample into women without intra-uterine pathologies (atrophy) and women with intra-uterine pathologies (myoma, polyp, hyperplasia or cancer).

Statistical analyses were performed using MedCalc (MedCalc Software, Mariakerke, Belgium). p < 0.05 was considered to indicate statistical significance.

Results

In total, 268 asymptomatic postmenopausal women with endometrial thickness ≥ 4 mm referred to diagnostic hysteroscopy were evaluated. Two hundred and eighty-eight women with postmenopausal vaginal bleeding, 28 women receiving hormone replacement therapy, 32 women with a cervical canal stenosis that made outpatient hysteroscopy impractical, 52 women receiving tamoxifen, and 57 women with endometrial thickness < 4 mm were excluded from this study.

Histological examination revealed endometrial atrophy in 156 (56.8%) women, endometrial polyps in 92 (34.4%) women, submucosal myomas in 12 (4.5%) women, endometrial hyperplasia in eight (2.9%) women (two cases of complex hyperplasia with atypia, three cases of complex hyperplasia without atypia and three cases of simple hyperplasia without atypia), and endometrial

Table 1

<table>
<thead>
<tr>
<th>Intra-uterine findings</th>
<th>Patient characteristics</th>
<th>Age (years)</th>
<th>Age at menarche (years)</th>
<th>Age at menopause (years)</th>
<th>Body mass index (kg/m²)</th>
<th>Parous n = 254</th>
<th>Nulligravid n = 14</th>
<th>Diabetic n = 21</th>
<th>Not diabetic n = 247</th>
<th>Hypertensive n = 147</th>
<th>Not hypertensive n = 121</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrophy</td>
<td></td>
<td>63.6</td>
<td>12.3</td>
<td>50.7</td>
<td>26.8</td>
<td>144 (56.6%)</td>
<td>8 (57.2%)</td>
<td>12 (57.1%)</td>
<td>140 (56.7%)</td>
<td>68 (46.2%)</td>
<td>84 (69.4%)</td>
</tr>
<tr>
<td>Polyp</td>
<td></td>
<td>63</td>
<td>12.6</td>
<td>51</td>
<td>29.3</td>
<td>92 (36.2%)</td>
<td>0 (0%)</td>
<td>4 (19.1%)</td>
<td>88 (35.6%)</td>
<td>60 (40.8%)</td>
<td>32 (26.4%)</td>
</tr>
<tr>
<td>Myoma</td>
<td></td>
<td>61.6</td>
<td>12.6</td>
<td>50.3</td>
<td>27.6</td>
<td>12 (4.8%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>12 (4.9%)</td>
<td>8 (5.4%)</td>
<td>4 (3.3%)</td>
</tr>
<tr>
<td>Hyperplasia</td>
<td></td>
<td>69</td>
<td>11.5</td>
<td>54.5</td>
<td>28</td>
<td>4 (1.6%)</td>
<td>4 (28.5%)</td>
<td>4 (19.1%)</td>
<td>4 (1.6%)</td>
<td>8 (5.4%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td>64</td>
<td>12.2</td>
<td>52.2</td>
<td>29.7</td>
<td>2 (0.8%)</td>
<td>2 (14.3%)</td>
<td>1 (4.7%)</td>
<td>3 (1.2%)</td>
<td>3 (2.2%)</td>
<td>1 (0.9%)</td>
</tr>
<tr>
<td>p-Value</td>
<td></td>
<td>0.37b</td>
<td>0.29a</td>
<td>0.19</td>
<td>0.13b</td>
<td>-0.0001b</td>
<td>0.0001c</td>
<td>0.0011d</td>
<td>0.0011f</td>
<td>0.0011g</td>
<td>0.0011g</td>
</tr>
</tbody>
</table>

a Using one-way analysis of variance.

b Using Chi-squared test.

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Table 2

Endometrial thickness range and intra-uterine findings of study participants.

<table>
<thead>
<tr>
<th>Histology</th>
<th>Endometrial thickness (mm)</th>
<th>4–7</th>
<th>8–11</th>
<th>12–15</th>
<th>&gt;15</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrophy</td>
<td></td>
<td>140</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>152 (56.8)</td>
</tr>
<tr>
<td>PolyP</td>
<td></td>
<td>20</td>
<td>48</td>
<td>8</td>
<td>16</td>
<td>92 (34.4)</td>
</tr>
<tr>
<td>Myoma</td>
<td></td>
<td>4</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>12 (4.5)</td>
</tr>
<tr>
<td>Hyperplasia</td>
<td></td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>8 (2.9)</td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>4 (1.4)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>164 (61.2%)</td>
<td>66 (24.6%)</td>
<td>22 (8.2%)</td>
<td>16 (6%)</td>
<td>268 (100)</td>
</tr>
</tbody>
</table>

Table 3

Hysteroscopic findings and histological results.

<table>
<thead>
<tr>
<th>Histology</th>
<th>Hysteroscopic findings</th>
<th>Atrophy</th>
<th>PolyP</th>
<th>Myoma</th>
<th>Hyperplasia</th>
<th>Cancer</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrophy</td>
<td></td>
<td>144</td>
<td>0</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>152</td>
</tr>
<tr>
<td>PolyP</td>
<td></td>
<td>0</td>
<td>88</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>92</td>
</tr>
<tr>
<td>Myoma</td>
<td></td>
<td>0</td>
<td>0</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>Hyperplasia</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>144</td>
<td>88</td>
<td>16</td>
<td>12</td>
<td>8</td>
<td>268</td>
</tr>
</tbody>
</table>

Table 4

Diagnostic accuracy of hysteroscopy for each intra-uterine finding.

<table>
<thead>
<tr>
<th>Intra-uterine findings</th>
<th>Hysteroscopic diagnostic accuracy (%)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>LR+</th>
<th>LR−</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrophy</td>
<td></td>
<td>94.7</td>
<td>100</td>
<td>100</td>
<td>91.5</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>PolyP</td>
<td></td>
<td>95.6</td>
<td>100</td>
<td>100</td>
<td>97.8</td>
<td>0.04</td>
<td></td>
</tr>
<tr>
<td>Myoma</td>
<td></td>
<td>100</td>
<td>98.4</td>
<td>75</td>
<td>100</td>
<td>64</td>
<td>0.00</td>
</tr>
<tr>
<td>Hyperplasia</td>
<td></td>
<td>50</td>
<td>96.9</td>
<td>33.3</td>
<td>98.4</td>
<td>16.2</td>
<td>0.52</td>
</tr>
<tr>
<td>Cancer</td>
<td></td>
<td>100</td>
<td>98.4</td>
<td>50</td>
<td>100</td>
<td>66</td>
<td>0.00</td>
</tr>
</tbody>
</table>

LR+, positive likelihood ratio; LR−, negative likelihood ratio; PPV, positive predictive value; NPV, negative predictive value.

adenocarcinoma in four women (1.4%). Excluding all negative cases (atrophy), 80% of cases of intra-uterine pathology were endometrial polyps (92/116). Overall, 262 (97%) women showed no or benign intra-uterine lesions: atrophy (N = 152), polyps (N = 92), myoma (N = 12) and endometrial hyperplasia without atypia (N = 6). The hysteroscopic success rate was 89.3% (268/300 women); hysteroscopy was not possible in 32 women (10.7%) due to cervical stenosis that did not permit examination of the uterine cavity.

Patient characteristics showed no significant differences with regard to age, age at menarche, age at menopause and BMI (Table 1). Conversely, significant differences were present with regard to parity, diabetes and hypertension (Table 1).

Endometrial thickness was 4–7 mm for 164 (61.2%) women referred to hysteroscopy, 8–11 mm for 66 (24.6%) women, 12–15 mm for 22 (8.2%) women, and >15 mm for 16 (6%) women (Table 2).

Hysteroscopic results and definitive histological examinations were compared in order to measure the diagnostic accuracy of hysteroscopy for each intra-uterine pathology (Tables 3 and 4). The diagnostic accuracy of hysteroscopy was optimal for normal endometrium (atrophy), polyps, myomas and malignant lesions (LR+ > 10 and LR− < 0.1) (Table 4). However, hysteroscopy was less accurate for the exclusion of endometrial hyperplasia (LR− 0.52) (Table 4).

No endometrial thickness cut-off value showed optimal diagnostic accuracy for the detection of all intra-uterine pathologies (LR+ > 10 and LR− < 0.1) (Table 5). The best cut-off value was endometrial thickness ≥8 mm (sensitivity 79.3%, specificity 92.1%, PPV 88.5%, NPV 85.4%, LR+ 10.05 and LR− 0.22) (Table 5). The area under the ROC curve was 0.937 (95% confidence interval 0.912–0.963; p < 0.0001). This value would reduce the percentage of unnecessary hysteroscopies to 37.4%, with no unrecognized pre-malignant or malignant lesions (Tables 2 and 5). The highest endometrial thickness cut-off value that did not miss any cases of endometrial cancer was ≥10 mm (Table 5). At this cut-off value, the cancer rate was 6.25% (4/64).

Comment

This study found a low incidence of endometrial cancer among asymptomatic postmenopausal women with endometrial thickness ≥4 mm (1.4%). The best endometrial thickness cut-off value for intra-uterine pathologies was >8 mm. A higher percentage of women with pre-malignant or malignant pathologies were nulligravid, diabetic and/or hypertensive. The hysteroscopic failure rate was approximately 11%, and the success rate was 89%. Previous studies have reported a wide range of hysteroscopic success rates, with percentages ranging from 81% to 99% [13]. Furthermore, it is known that postmenopausal status is one of the most important factors influencing the practicability of hysteroscopic procedures [14]. In this regard, the hysteroscopic outcomes of this study were in line with the literature.

Strengths of this study included its prospective design, which allowed standardization of the type of measurement or evaluation (e.g., transvaginal ultrasound, diagnostic hysteroscopy, women’s medical history), thus making the data more reliable. Furthermore, all women had a definitive histological diagnosis which provided an optimal reference standard. Finally, the study of hysteroscopic appropriateness showed which and how many intra-uterine pathologies were missed for each endometrial thickness cut-off value. Limitations of the study included the very low incidence of cancer in the study population, as the prospective assessment provided poor information on a very rare occurrence. This meant that the patients had to be dichotomized into women with or without intra-uterine pathologies, rather than women with or without intra-uterine malignancies. Finally, it should be emphasized that Vabrat sampling, used for women with hysteroscopic appearance of atrophy, only samples a minority of the uterine cavity [15].

This study addressed the clinical management of asymptomatic postmenopausal women with an incidental finding of thickened endometrium on ultrasound. Approximately 95% of women with endometrial cancer experience vaginal bleeding, and approximately 10% of symptomatic women have a malignancy [16]. Furthermore, it is known that the cancer rate is 7.3% among asymptomatic postmenopausal women with endometrial thickness >5 mm [17]. However, are these percentages also valid for asymptomatic postmenopausal women, and what is the risk of endometrial malignancy in asymptomatic postmenopausal women with a thickened endometrium? A retrospective study reported a cancer rate of 0% among 65 asymptomatic postmenopausal women with endometrial thickness ≥5 mm [5]. Gambacciani et al. only identified one case (0.7%) of endometrial cancer among 148 hysteroscopies performed in asymptomatic postmenopausal women with endometrial thickness >5 mm [18]. Lev-Sagie et al. found no cases of endometrial cancer among 82 asymptomatic postmenopausal women with a suspected polyp on ultrasound [6]. Finally, Schmidt et al. reported an endometrial adenocarcinoma rate of 3.9% among 304 asymptomatic postmenopausal women with endometrial thickness >6 mm [19]. These results are in line with the present finding of an endometrial cancer rate of 1.4% for asymptomatic postmenopausal women with endometrial thickness >4 mm. A recent meta-analysis reported prevalence rates of endometrial cancer and atypical hyperplasia of 0.62% and 0.59%, respectively, among asymptomatic postmenopausal women [10].
Based on these data, the use of a test with an optimal NPV would be limited because the risk of malignancy is already low in this population, and the question is represented by countless unnecessary examinations.

This study found that the majority of women (61.2%) referred to hysteroscopy had an endometrial thickness of 4–7 mm. None of these women had pre-malignant or malignant lesions, so all of these hysteroscopies were unnecessary. Furthermore, if only one considers hysteroscopies that lead to the diagnosis of atypical endometrial hyperplasia or cancer as necessary examinations, only 3% of the hysteroscopies were appropriate. Gambacciani et al. reported that 93.2% of hysteroscopies among asymptomatic postmenopausal women with endometrial thickness >5 mm were unnecessary [18].

The best endometrial thickness cut-off value to detect all intra-uterine pathologies was >8 mm (PPV 88.5% and NPV 85.4%). The same cut-off value was reported by Dreisler et al. for the diagnosis of focal intra-uterine pathology among asymptomatic postmenopausal women (PPV 70% and NPV 87.8%) [9]. As reported by other authors, this study found that no endometrial thickness cut-off values had optimal diagnostic accuracy for all intra-uterine pathologies (LR+ >10 and LR− <0.1) [9,10]. However, on closer inspection, an endometrial thickness cut-off value of >8 mm had good diagnostic accuracy for the prediction of intra-uterine pathologies (LR+ 10.05), but lower accuracy for the exclusion of any intra-uterine lesions (LR− 0.22). However, no false-negative findings were pre-malignant or malignant lesions. Therefore, in a population with a low prevalence of malignancy, an endometrial thickness cut-off value with a good LR+ and a less accurate LR− may be acceptable in clinical practice to decrease the number of false-positive findings or unnecessary examinations.

This study found that 80% of detected intra-uterine pathologies were endometrial polyps. Schmidt et al. reported the same result (79.3%) among asymptomatic postmenopausal women [19]. It is of interest to determine the rate of endometrial cancer among these intra-uterine polyps in such a population. Fernández-Parra et al. found no cases of malignancy among 117 endometrial polyps in asymptomatic postmenopausal women [20], and Shushan et al. found no cases of malignancy among 73 asymptomatic polyps in peri- and post-menopausal women [21]. Therefore, in this population, an endometrial thickness cut-off value that would ignore some benign intra-uterine pathologies, such as intra-uterine polyps, may not expose women to the risk of unrecognized cancer.

An endometrial thickness cut-off value of ≥10 mm did not miss any cases of endometrial cancer. At this cut-off value, the cancer rate was 6.25%. These results are similar to those of a previous study which showed a cancer rate of 6.7% with an endometrial thickness cut-off value >11 mm in the same population [17].

Finally, in line with previous studies, this study had optimal hysteroscopic diagnostic accuracy for all intra-uterine pathologies except for endometrial hyperplasia [22–25]. However, it should be emphasized that 262 (97%) unnecessary diagnostic hysteroscopies were performed with considerable psychological discomfort, and the hysterectomy failure rate was 11% with considerable physical discomfort. All these findings reveal that it is not cost-effective to adopt the same diagnostic work-up for both symtomatic and asymptomatic postmenopausal women. Although it is very important not to miss any cases of cancer, the objective in populations with very low prevalence should be to reduce the number of unnecessary examinations (or false-positive results) including cases of atrophy and benign intra-uterine lesions. In this regard, and limited to the study population, this study showed that the use of a higher endometrial thickness cut-off value (≥8 mm) could reduce the number of unnecessary hysteroscopies without missing any pre-malignant or malignant lesions.

Conflict of interest

None declared.

References

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