



#### **Original Article**

### Reproducibility of Endometrial Pathologic Findings Obtained on Hysteroscopy, Transvaginal Sonography, and Gel Infusion Sonography in Women With Postmenopausal Bleeding

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# ABSTRACT Study Objective: To evaluate and compare interobserver variation in endometrial pattern recognition with hysteroscopy (HY) and transvaginal sonography (TVS) and gel infusion sonography (GIS) with regard to the diagnosis of endometrial pathology.

Design: Prospective study (Canadian Task Force II-1).

Setting: University clinic.

**Patients:** One hundred twenty-two consecutive women with postmenopausal bleeding and an endometrium thickness  $\geq 5$  mm. **Intervention:** Two observers using HY and 2 others using TVS and GIS evaluated the endometrial pattern in recorded video clips. Interobserver agreement regarding findings obtained with TVS, GIS, and HY for a diagnosis of cancer, hyperplasia, polyps, and no endometrial pathology was expressed by  $\kappa$  coefficients and compared.

**Measurement and Main Results:** Interobserver agreement ( $\kappa$ ) was as follows: identification of normal endometrium: HY (.74), TVS (.68), and GIS (.48); diagnosis of cancer: HY (.56), TVS (.59), and GIS (.34); classification in all categories of endometrial pathology: HY (.70), TVS (.47), and GIS (.41) (p < .05 HY vs GIS). The presence of additional endometrial polyps decreased agreement on HY in patients with hyperplasia or cancer. Observer agreement was poor regarding the diagnosis of hyperplasia by all techniques.

**Conclusion:** Observer agreement regarding both HY and TVS was reliable for the diagnosis of a normal endometrium but poor with HY, TVS, and especially GIS for a diagnosis of cancer. In patients with hyperplasia or cancer, agreement between observers was especially low in the presence of additional polyps when HY was used. These findings call attention to the need for systematic methods to improve reliability in endometrial pattern recognition. Journal of Minimally Invasive Gynecology (2015) 22, 1036–1044 © 2015 AAGL. All rights reserved.

*Keywords:* Hysteroscopy; Ultrasonography; Endometrial neoplasms; Postmenopause; Uterine hemorrhage; Observer variation

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Endometrial carcinoma is the most common gynecologic malignancy, and postmenopausal bleeding (PMB) is the cardinal symptom. The survival of patients with endometrial cancer is good when it is diagnosed at an early stage [1]. Therefore, early, accurate, and timely diagnosis in women with PMB is important. Transvaginal sonography (TVS) is the first-line diagnostic technique with the lowest cost [2]. In a large multicenter study [3] and a meta-analysis [4], an endometrial thickness less than or equal to 4 to 5 mm effectively excluded malignancy. Furthermore, according to the American College of Obstetrics and Gynecology, in women with PMB, when an endometrial thickness of less than or equal to 4 mm is identified by ultrasound, endometrial sampling is not required [5]. Conversely, an endometrial thickness at least 4 to 5 mm may indicate malignancy [6], and second-line invasive tools are recommended. There is still no consensus or evidence regarding the most optimal second-line diagnostic technique [7], which include saline infusion sonography (SIS), gel infusion sonography (GIS), hysteroscopy (HY) [8], and endometrial samples (ES) [8,9].

ES is the most simple second-line technique used either in all women with increased endometrial thickness [9] or in the small group of women without localized pathology on GIS or SIS [8]. In the presence of focal changes of the endometrium, ES is less efficient [10,11]; SIS or GIS [12] may be added to identify those women who have focal changes. In these women HY is often performed [13–15].

In women with PMB the main shortcoming of ES is a high failure rate (inadequate sample or inability to perform the biopsy). In meta-analysis the reported range of sampling failure was 0 to 58% with pipelle endometrial sampling [16]. Two studies confirmed a high failure rate (51% and 64%, of which 30% and 48% were insufficient samples) [17,18]. Malignancy cannot be excluded in women with insufficient ES [19,20], and HY is often added. Insufficient ES is costly and painful for patients, and the wait time can cause anxiety. Hysteroscopic samples have a higher diagnostic accuracy compared with ES [21,22], and HY can be performed as "see-and-treat" procedures with small diameter (mini) hysteroscopes without anesthesia [23–25].

See-and-treat HY is therefore being increasingly used [26]. Eye-directed biopsies are performed with the use of small forceps, and this technique has a high accuracy in the hands of experienced hysteroscopists [27]. However, the accuracy of this technique depends on the recognition of suspect endometrial pathology. Small-sized pathology can be removed, and see-and-treat HY may be feasible in half of the patients with PMB [28], whereas a narrow cervix and the total removal of larger polyps may indicate another operative HY [29]. Moreover, the safety of HY has to be considered in patients with malignancy. Perforation during HY of a soft, fragile uterus with a malignancy poses the risk of spread, and HY should only be performed by experienced operators.

Evaluation of the endometrial pattern at first-line TVS or GIS could be used to avoid the use of HY in women with suspected malignancy. These women could be offered ES and fast-track reference to oncologic centers, whereas women with a benign pattern based on cervical findings and the measured size and type of the endometrial pathology could be saved for the high numbers of insufficient samples or HYs and, when needed, undergo the most optimal type of HY, thereby increasing the feasibility and safety of see-and-treat HY [30]. Evaluation of the endometrial pattern on TVS or GIS had a high diagnostic accuracy for the diagnosis of endometrial cancer [13,30–33], which was slightly lower but almost comparable with the accuracy found with HY [30].

However, pattern evaluations on TVS, GIS, or HY are in general practice performed by different observers, and the reliability depends on the reproducibility between observers. Reproducibility between observers can be evaluated on the basis of interobserver agreement.

In women with PMB, observer agreement at TVS and SIS for endometrial thickness measurements [34–37] and identification of focal lesions [38,39] are described, whereas observer agreement with HY has only been described in a few premenopausal women [40,41]. HY has a higher image resolution than TVS, and a lower observer variation on HY could be expected. No study has described or compared the reproducibility of visual pattern evaluation on HY and TVS or GIS for the diagnosis of endometrial pathology. We accessed and compared the reproducibility of HY, TVS, and GIS in differentiating endometrial pathology and evaluated cases in which reproducibility was poor in women with malignant or premalignant endometrial pathology to suggest improvements.

#### Methods

HY, TVS, and GIS video recordings were obtained in a prospective trial of the diagnostic accuracy of ultrasound and HY for the diagnosis of endometrial cancer [30,33,42]. In the present study these videos were evaluated by different observers to measure interobserver variation.

#### **Observers**

Three months to 1 year after completion of the investigation, all video clips were evaluated in personal computers by the observers blinded to prior evaluations and in random order without knowledge of the patient's identity and pathology. Hysteroscopic clips were evaluated by 2 gynecologists from another university hospital (PS and AJ). One had special training in hysteroscopic staging (observer 1) in patients with endometrial cancer, whereas the other (observer 2) was a general specialist in HY and had more than 10 years of special experience in HY.

Two other observers (MD and GO) evaluated ultrasound videos. Observer A had extensive experience in the staging of endometrial cancer and GIS, whereas observer B had more than 10 years of general specialist experience in the evaluation of endometrial pathology by TVS.

#### Patients

The study group comprised consecutive women with PMB and an endometrial thickness of at least 5 mm either referred directly or referred from other hospitals. Two experienced gynecologists (MD and another hysteroscopist) performed TVS, GIS, and HY in 164 of 174 women referred to Aarhus University Hospital, Denmark, from October 2010 to February 2012 and evaluated endometrial patterns on TVS, GIS, and HY. Systematic videos of endometrium obtained with TVS, GIS, and HY were recorded at the end of each examination. Video clips were not performed or Download English Version:

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