

Accuracy and diagnostic value of outpatient hysteroscopy for malign and benign disease

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Summary

Background: The aim of the study was to evaluate accuracy of the outpatient hysteroscopy. **Materials and Methods:** This was a retrospective cohort study of 494 women who underwent outpatient hysteroscopy after administration of non-steroidal anti-inflammatory agents with the 3.2 mm hysteroscope. Normal saline solution was used as the distension medium. All women were discharged in good general condition afterwards. **Results:** In cases of abnormal uterine bleeding, there was no apparent pathology found in 112 cases (83.6%). Detection rate (DR) of endometrial polyps was 88.7% with false positive rate (FPR) of 4.6%. Positive predictive value (PPV) was 82.7% with negative predictive value (NPV) of 93.1%. Detection rate (DR) of the submucosal fibroids was 57.7%. Positive predictive value (PPV) was 57.7% with negative predictive value (NPV) of 95.0%. Endometrial cancer was confirmed in ten cases (2.0%), being suspected in eight cases during the procedure. DR in case of the endometrial cancer was 80.0% with FPR of 0.4%. PPV was 66.7% with NPV of 99.6%. **Conclusions:** Outpatient hysteroscopy seems to be an effective and accurate diagnostic tool.

Key words: Office hysteroscopy; Outpatient hysteroscopy; Hysteroscopy.

Introduction

Outpatient hysteroscopy also known as “office hysteroscopy” is an established diagnostic tool [1-4]. The procedure involves miniaturised endoscopic device to visualise and examine the uterine cavity, without the need for operating room facilities or any anaesthesia.

“Office hysteroscopy” is indicated mainly in the assessment of women with abnormal uterine bleeding [1-4]. It has been also employed in the work-up of reproductive problems. As a result of recent improvements in technology, modern hysteroscopy is a completely different technique than operative hysteroscopy. Instruments that combine endoscopes smaller than three mm and 5F forceps with a total external diameter less than five mm made it possible to perform diagnostic and operative procedures in an office setting [1] without the use of local anaesthesia. The AlphaScope is a fiberoptic hysteroscope of 1.7 mm calibre that uses plastic distensible external sheath so that its final diameter including the forceps does not exceed 3.5 mm. Common procedures include endometrial polypectomy [5], removal of small submucous fibroids [6], endometrial ablation [7], removal of lost intrauterine devices, and transcervical sterilisation [8]. Outpatient hysteroscopy, whether diagnostic or operative is considered as effective, safe, and well tolerated [9].

The aim for this study was to evaluate the accuracy and predictive value of outpatient hysteroscopy measured by comparison of initial and final diagnosis. Secondary, the study aimed in statistical work-up that might be useful for the patient specific counseling directly after the procedure.

Materials and Methods

The data for this study were derived from a retrospective cohort study. Between June 2011 and June 2012, 494 women had undergone outpatient hysteroscopy in our Department of Obstetrics, Women's Diseases and Oncogynecology, Central Clinical Hospital of Ministry of Interior, Warsaw. Data on the initial and intra-operative diagnoses were directly recorded in the authors' database, as well as patients' demographics. Data on procedure outcomes were obtained from computerised hospital records and were also recorded in their database.

There were 318 women referred to the present Department, due to suspected intrauterine abnormality on the ultrasound examination. Transvaginal sonography (TVS) was performed in an office setting by a various gynecologists. The uterine anatomy and adnexae were visualized using a 7.5 MHz vaginal probe transducer.

The procedure of “office hysteroscopy” was performed according to the Royal College of Obstetricians and Gynecologists Green-Top Guideline Nr 59 [10]. Briefly, the patient was informed about the procedure and signed the consent. Outpatient hysteroscopy was conducted outside of the formal operating theatre in a treatment room with adjoining private changing facilities and toilet. The procedure was performed approximately 30 minutes after administering iv. non-steroidal anti-inflammatory agents (NSAIDs, ketoprofen). The 3.2 mm hysteroscope was used with the normal saline solution as the distension medium. When appropriate, a Versapoint was used to cut the polyps or fibroid, and to facilitate extraction of fragments the 5F forceps were used. For the simple biopsy of myometrium, only the 5F forceps were used. A 300 W xenon lamp and video camera were used. Distension fluid pressure was generated using a simple fall-form bag suspended one m above the patient.

All the endometrial samples were immediately fixed in buffered formalin and then wholly embedded in paraffin, cut into sections, mounted on slides and stained with hematoxylin and eosin (H&E). All the histological slices were coded and archived. Microscopic evaluation was then performed on all the

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Table 1. — *Patients' characteristics.*

Characteristics	
Age in years, median (IQR)	50.0 (43.3 – 59.8)
Weight kg, median (IQR)	65.0 (65.0 – 68.0)
Height cm, median (IQR)	165.0 (162.0 – 168.0)
Postmenopausal, n (%)	276 (55.6)
Parity, n (%)	
Nulliparous	119 (24.0)
Chronic diseases, n (%)	
Arterial hypertension	105 (21.2)
Diabetes mellitus	23 (4.6)
Cardiac ischemic disease	35 (7.1)
Previously performed endometrial biopsy, n (%)	22 (4.4)
Abnormal gynaecological examination, n (%)	133 (26.8)

IQR: interquartile range

slides by a pathologist. Histological diagnoses were made according to the current World Health Organization (WHO) classification. The statistical software package SPSS 20.0 was used for data analyses.

Results

Patients' characteristics are presented in Table 1. Abnormal uterine bleeding (AUB) was an indication for the admission and the procedure in 134 cases, abnormal appearance of the endometrium on the ultrasound examination in 318 cases and submucosal fibroids in 42 cases.

Out of 134 women admitted for the outpatient hysteroscopy due to AUB there was no apparent pathology found during the procedure in 112 cases (83.6%). Endometrial cancer was confirmed only in two cases (1.5%) leaving the other 20 women with the diagnosis of benign intrauterine pathology.

There were 318 women referred due to suspected intrauterine abnormality on the ultrasound examination with 162 cases of suspected endometrial polyps and 156 cases of suspected endometrial hyperplasia. During the procedure the initial diagnosis of the polypus was confirmed in 144 cases (92.3%) and the hypertrophy of the endometrium only in 100 cases (64.1%) suggesting other intrauterine pathology in 54 cases.

During the procedure the diagnosis of endometrial polyp was established in 208 cases being confirmed with pathology studies in 172 cases (82.7%). Endometrial cancer was found in four cases (1.9%). The detection rate (DR) of the "office hysteroscopy" in case of the endometrial polypus was 88.7% with the false positive rate (FPR) of 4.6%. The positive predictive value (PPV) was 82.7% with the negative predictive value (NPV) of 93.1%. The accuracy of "office hysteroscopy" was 88.7%.

During the procedure the diagnosis of submucosal fibroid was established in 52 cases being confirmed with pathology studies in 30 cases (57.7%). The DR of the "office hysteroscopy" in case of the submucosal fibroid was 57.7% with the false positive rate (FPR) of 0%. The PPV was 57.7% with the NPV of 95.0%. The accuracy of "office hysteroscopy" was 91.1%.

Endometrial cancer was confirmed in ten cases (2.0%) being suspected in eight cases during the procedure. The DR of the outpatient hysteroscopy in case of the endometrial cancer 80.0% with

the FPR of 0.4%. The PPV was 66.7% with the NPV of 99.6%. The accuracy of outpatient hysteroscopy in case of endometrial cancer was 98.8%.

Discussion

The findings of this study demonstrate that the outpatient hysteroscopy seems to be effective, accurate and reliable diagnostic tool.

Despite the fact that hysteroscopy is now being performed in an ambulatory setting, there is still continuing debate about the value of hysteroscopy in diagnosis of serious endometrial diseases, such as cancer or hyperplasia. For example, as it was mentioned above, AUB is common gynecologic problem. Up to 33% of woman referred to gynecological outpatient clinics have AUB, and it rises to 69% in a perimenopausal or postmenopausal group of patient [11]. The prevalence of benign intracavitary abnormalities, such as submucous myomas and endometrial polyps, is approximately 35% [12] in a group of premenopausal women with AUB. The prevalence of endometrial polyps and submucous myomas in this patient group without AUB is not known completely, but it supposed too not different statistically [13]. In women with AUB, the reported sensitivity of "office hysteroscopy" for the detection of endometrial abnormalities is 90% and specificity 91% [14].

TVS is increasingly being used as a first-line of investigation of patients with abnormal bleeding [15]. However, reports on the diagnostic accuracy of TVS are conflicting [16, 17]. A sensitivity of TVS in diagnosing intracavitary abnormalities by direct observation varies depends from studies from 56% to 96% and also specificity varies from 72% to 89% [18, 19]. The general consensus of opinion is that an endometrial thickness of less than five to six mm in a patient presenting with postmenopausal bleeding does not warrant an extensive workup, as the risk of endometrial carcinoma or/and endometrial hyperplasia is very small [20, 21]. Results also indicated that in this group of patients, when a double layer of endometrial thickness was greater than five mm, the sensitivity for the detection of any endometrial disease was 92% and specificity was 81% [22].

In the present study endometrial cancer was confirmed in ten cases (2.0%) being suspected in eight cases during the hysteroscopy procedure. The DR of the outpatient hysteroscopy in case of the endometrial cancer was 80.0% with the FPR of 0.4%. The PPV was 66.7% with the NPV of 99.6%. The accuracy of outpatient hysteroscopy in case of endometrial cancer was 98.8%.

Out of 134 women admitted for the outpatient hysteroscopy due to AUB, there was no apparent pathology found during the procedure in 112 cases (83.6%). Endometrial cancer was confirmed only in two cases (1.5%), leaving other 20 women with the diagnosis of benign in-

trauterine pathology. The present findings are in line with results of others [23], where in patient group with AUB prevalence of cancer was 4% but was much higher in postmenopausal group (11%). In this analysis LR of 0.15 (95% CI, 0.13-0.18) for a negative test result was not low enough to negate the need for further diagnostic testing in this patient group, and relates "office hysteroscopy" to diagnosing cancer rather than as a tool to exclude it. In the authors' opinion this seems to be not entirely correct as results of this study support hypothesis that normal findings during the procedure are of patient assurance with over 99% NPV.

The limitation of the present findings can be that transvaginal ultrasonography (TVUSG) were performed not by one gynecologist, and recognition of uterine pathology in USG can differ by each other, and it can be a reason for difference in USG diagnosis of uterine polypus or fibroid, but if we directly compared "office hysteroscopy" to TVS, we know that in hysteroscopy we have opportunity to direct visualization of endometrial cavity and hence detection of any pathology (for example lesion) which might not be seen in TVS. It also offers an opportunity of obtaining direct biopsy or removing fibroids or polypus from uterine cavity. Studies have also demonstrated a superior or yield of direct biopsies compared to dilatation and curettage in providing representative histological specimens [24, 25]. In the present trial there were 318 women referred due to suspected intrauterine abnormality on the ultrasound examination with 162 cases of suspected endometrial polyps and 156 cases of suspected endometrial hyperplasia. During the procedure, the initial diagnosis of the polyps was confirmed in 144 cases (92.3%) and the hypertrophy of the endometrium only in 100 cases (64.1%), suggesting other intrauterine pathology in 54 cases. During the procedure the diagnosis of endometrial polyp was established in 208 cases, being confirmed with pathology studies in 172 cases (82.7%). Endometrial cancer was found in four cases (1.9%). The DR of the "office hysteroscopy" in case of the endometrial polypus was 88.7% with the FPR of 4.6%. The PPV was 82.7% with the NPV 93.1 of %. The accuracy of "office hysteroscopy" was 88.7%.

During the procedure, the diagnosis of submucosal fibroid was established in 52 cases being confirmed with pathological studies in 30 cases (57.7%). The DR of the "office hysteroscopy" in case of the submucosal fibroid was 57.7% with the FPR of 0%. The PPV was 57.7% with the NPV of 95.0%. The accuracy of "office hysteroscopy" was 91.1%

The present authors were unable to perform to the end "office hysteroscopy" in 17 cases (3.3%). In 11 cases the reason was pain correlating with procedure and in six women they found atresia of external ostium of cervix, so it can be stated that technical problems were encountered in these cases, but an attempt was made to expand the external ostium of cervix with a forceps or bipolar each time, but in these cases it was correlated with patient pain and were withdrawn from the

procedure. In any cases of failed hysteroscopy, there were no problems with inadequate visualization of uterus. At the end, the present paper shows, that "office hysteroscopy" is safe procedure with a low incidence of failure rate, which can be used as very good diagnostic and therapeutic tool. In the present era of so-called "cost-effective medicine", the physicians should not only be interested in the relative informative yield, but also in the cost per investigation, and choosing the best diagnostic approach.

Results of the present study support main idea of professor Betocchi i.e. "See and threat theory". High accuracy of outpatient hysteroscopy allows medical professionals performing the procedure to suggest the diagnosis and counsel the patient before final pathological studies.

Conclusions

Our results indicate that "office hysteroscopy" is highly accurate and clinically useful in diagnosing endometrial cancer in women with or without AUB and what is also very important is that the present study support the hypothesis that normal findings during the procedure are of patient assurance with over 99% NPV.

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