ORIGINAL ARTICLE

Reliability of out-patient hysteroscopy in one-stop clinic for abnormal uterine bleeding

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Abstract This study aims to estimate the effect of adding office hysteroscopy to the preoperative diagnostic work-up in abnormal uterine bleeding on the diagnostic accuracy. It is a prospective comparative diagnostic trial at a tertiary care referral facility and a university hospital. There were a total of 295 patients, more than 35 years old, with abnormal uterine bleeding. The patients had vaginal sonography, office hysteroscopy, and office endometrial biopsy on onestop bases. The diagnostic accuracy of each method in diagnosing focal lesion and endometrial hyperplasia was measured as the main outcome of this paper. Combined hysteroscopy and biopsy were taken as the gold standard for diagnosing focal lesion while endometrial biopsy alone was the gold standard for diagnosing endometrial hyperplasia. Office hysteroscopy was superior to other methods for diagnosing focal lesion with about half of the focal lesions failing to be diagnosed with the other two methods. Office hysteroscopy was superior to vaginal sonography in diagnosing endometrial hyperplasia. Office hysteroscopy is an indispensable tool for diagnosing abnormal uterine bleeding and without its use, half of the focal lesions could be missed. Office setting and the one-stop approach greatly facilitate the use of the combination of office hysteroscopy with vaginal sonography and office endometrial sample.

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Introduction

Abnormal uterine bleeding (AUB) is any vaginal bleeding unrelated to normal menstruation and represents a major gynecological problem in about 20% of all gynecological referrals [1]. Anatomic and histologic causes predominate after the age of 35 years which made the American College of Obstetrics and Gynecology recommend endometrial biopsy as a part of investigating any woman with AUB above 35 years and sometimes earlier if there is a risk factor [2]. In addition to a careful clinical examination, the traditional approach for diagnosis of AUB comprises both transabdominal ultrasonography (TAS) and transvaginal ultrasonography (TVS), and endometrial sampling. Ultrasonography, especially TVS, is generally accepted as an initial investigation of these patients as it is well tolerated, least invasive, easy to do, and gives idea about the uterine anatomy (the wall and the lining) and the adnexa with little cost. These diagnostic tools share some common disadvantages in the form of failure to diagnose minute causes that are not commonly seen, to localize the exact site of the lesion causing bleeding, to define its relationship to tubal ostea specially in infertile women and lastly to guide biopsy aid. For cavitary disorders, hysteroscopy is the gold standard for diagnosis of AUB which is widely performed as office hysteroscopy (OH) procedure with the possibility of see and treat in the setting. OH is a well-tolerated procedure and equally accepted as hysteroscopy under general anesthesia [3]. There is no consensus however that OH should be included in the initial evaluation of patients with AUB or be restricted to those with abnormalities at TVS. This study

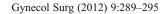




Fig. 1 Transvaginal sonohysterographic appereance of an endometrial polyp

aims to estimate the effect of adding OH to the preoperative diagnostic work-up in AUB on the diagnostic accuracy.

Materials and methods

After obtaining the acceptance of the ethics committee of the Assiut Faculty of Medicine, this study was conducted in the outpatient hysteroscopy unit of Woman's Health University Hospital from August 2006 to May 2011. It included women with AUB of 35 years or older. Exclusion criteria included suspected pregnancy, active pelvic infection, severe comorbidity, e.g., severe cardiac, neurologic, or chest disease, recent initiation of contraception in the previous 3 months, or cervical neoplasm. The patients were examined at the day of presentation on one-stop bases irrespective of the day of the cycle. All patients had clear description of the study and were asked to participate. An informed consent was taken from those who agreed.

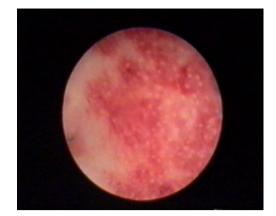


Fig. 3 Strawberry appearance of the congested endometrium

The included patients were subjected to complete history taking and meticulous physical examination. Both TAS and TVS were thereafter performed using a Medison 128 BW machine (MEDISON COR, South Korea). The uterus was examined in the saggital and coronal views for endometrial thickness, focal cavitary or intramural masse(s), evidence of adenomyosis uteri [4], or adnexal mass(s).

The endometrium was considered thick when it was 5 mm or more in postmenopausal patients and in premenopausal patients of 8 mm or more and 10 mm or more cutoff levels was tested. Because it was not possible in all cases to clearly discriminate between polyp and submucous myoma, focal lesion was used to describe either of them. Abnormal endometrium was used to describe endometrial line with which was either thick and/or shows signs of focal lesion. In case of suspicious diagnosis when TVS could not exactly differentiate intracavitary from intramural lesions, a quick office sonohysterography was performed according to our simplified technique [5] as shown in Fig. 1. TVS was performed by an ultrasonography team but sonohysterography was performed by the first author.

OH was done using posterior wall Sims' speculum to expose the cervix where the anterior lip is grasped with

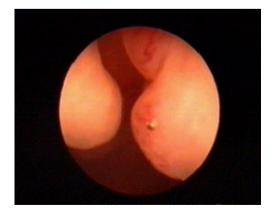


Fig. 2 Kissing endometrial polyp

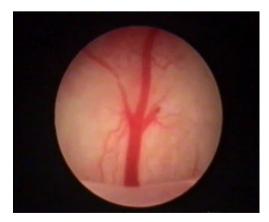


Fig. 4 Telangiectatic vessel of the endometrium

Fig. 5 Office sampling



single-toothed tenaculum without any premedication or local anesthesia. We used 2.9° mm 30° rigid scope with 4 mm single flow sheath (Promis, Germany) and the uterus was distended with normal saline at 100 mmHg generated from a pneumatic cuff of sphygmomanometer. We used 250-W halogen light source for the video OH. The scope was introduced gently through the cervical canal without previous dilatation using the saline to expand the way in front of the scope. The cervical canal was examined for polypi, Nabothian cysts, or micropolypi suggestive of chronic cervicitis. The uterine cavity was examined systematically (panoramic view) starting by its anterior and posterior walls; the fundus, and the borders and examination was considered complete if the both tubal ostia were reached describing any gross pathology, e.g., polyp, myoma, growth, etc. (Fig. 2).

Focused OH was then performed to describe endometrial appearance (atrophic, normal thick, papillary, suspicious of atypical hyperplasia or cancer), vasculature (normal, congestion, petechiae, ecchymosis, or abnormal suspicious vascular pattern), and color (whitish, pink, reddish, or dark red; Figs. 3 and 4). The scope was finally gradually withdrawn with confirmation of previous findings. Then a 5-mm uterine curette or a 4-mm Novak curette with suction was introduced in multiprous uterus or nulliprous uterus, respectively, for endometrial biopsy (office sample, OS) from the anterior and/or the posterior walls of the uterus just below the fundus and directed towards any suspicious area previously defined on hysteroscopic examination (Fig. 5).

The statistical analysis was done using SPSS 16 program. Categorical date were described as percentages and

	Global	35–40	40 or more	Menopausal	Sig.	
Mean age (years)	45.3 (7.9)	36.4 (1.5)	45.6 (4.2)	55.6 (8.3)	NA	
Parity	6.3 (3.1)	4.7 (2.2)	6.6 (3)	7.6 (3.3)	0.000	
Abortions	1.3 (1.5)	0.9 (1.2)	1.4 (1.6)	1.3 (1.5)	0.06	
Nulliparity	3.1%	4.3%	2.9%	1.8%	0.72	
Contraceptive use	21% ^a	30%	17%	NA	0.04 ^a	
Progestin treatment	37%	37%	39%	31%	0.5	
Previous D&C	31%	27%	36%	20%	0.051	
Hypertension	18.6%	4.3%	19.4%	35%	0.000	
DM	10%	4.3%	8.2%	22%	0.003	
BMI	30.6 (6.3)	28.4 (6)	30.7 (5.7)	33 (7.4)	0.000	
Obesity(BMI>/=30)	51%	37%	53%	62%	0.000	

Table 1Characteristics of thestudy patients

^aComparisons were made between premenopausal groups only. *NA* Not applicable

Table 2Transvaginal sono- graphic findings.		Global	35–40	40 or more	Menopausal	Sig.
	Endometrial thickness (mm)	10.9±5.7	9.7±5.2	10.3 (4.8)	14.2 (7.6)	0.000
	8 mm or more	67%	59%	64%	87.3% ^b	0.001
	10 mm or more	51%	34%	46%	87.3% ^b	0.000
	Myometrial thickness (cm)	1.9 (0.5)	1.8 (0.4)	2 (0.5)	1.7 (0.4)	0.000
	Signs of adenomyosis	41%	27%	52%	24%	0.000
	Focal lesion	21%	16%	21%	29%	0.187
	Abnormal endometrium 8 mm ^a	74%	67%	73%	87.3% ^b	0.032
	Abnormal endometrium 10 mm	60%	43%	59%	87.3% ^b	0.000
^a Either thick endometrium or	Fibroid	17%	10%	21%	13%	0.072
focal lesion ^b At 5 mm cut off level	Ovarian mass	6.4%	8.6%	5.9%	5.5%	0.81

compared with chi square and exact Fischer tests. Continuous data were described as mean \pm SD or median (according to data distribution) and compared using *t* test, Man–Whitney test, and analysis of variance test with least significant difference post hock test when appropriate. Correlation was used when appropriate. The diagnostic performance is calculated using 2×2 tables using EB as the gold standard for diagnosing hyperplasia or cancer and the combined hysteroscopy and biopsy for diagnosing focal lesion.

Results

The characteristics of the study patients are shown in Table 1. Only five cases (1.7%) had failed OH with success rate of (295/300) 98.3% while 15 cases had failed OS with success rate of (295/310) 95%. The results of TVS, OH, and EB examinations are summarized in Tables 2, 3, and 4. Abnormal findings tended to increase with age with more prevalence of precancerous and cancerous lesions in the postmenopausal group.

Table 3	Office hysteroscopic
findings	

	Global	35–40	40 or more	Menopausal	Sig.
Appearance					
Atrophic	2%	1.4%	1.8%	3.6%	0.64
Normal	58.3%	66%	59%	43.6%	0.02
Thick	32.5%	30%	33%	36.4%	0.62
Plypoid	4.4%	2.9%	5.3%	3.6%	0.67
Suspecious	2.7%	0%	0.6%	13%	0.000
Vasculature					
Normal	24%	21%	25%	22%	0.76
Congestion	41%	47%	37%	47%	0.22
Petechiae and Ecchymosis	29%	30%	33.5%	16%	0.052
Abnormalvessles	5.4%	1.4%	4.1%	15%	0.003
Polyp	15%	5.7%	14%	29%	0.001
Submucous myomas	13%	5.7%	16%	12.7%	0.1
Either	25%	11.4%	26%	40%	0.001
Abnormal hysteroscopy	55%	39%	56%	71%	0.001
Blood clots	17.3%	24.3%	14%	18%	0.163
Adhesions	3.7%	2.9%	4.7%	1.8%	0.56
Access to tubal ostia					
Both	77.3%	87%	76.5%	67.3%	0.097
One	10.5%	7.1%	11.1%	12.75	0.097
Neither	12.2%	5.7%	12.4%	20%	0.097
Fluid volume (cc)	311 (115)	309 (133)	309 (107)	320 (116)	0.828

Table 4 Results of endometrial biopsy

	Global (%)	35–40 (%)	40 or more (%)	Menopausal (%)	Sig.	
Insufficient	2.4	2.9	2.9	0	0.439	
Proliferative	35.4	41.4	38.8	18.2	0.005	
Secretory	13	21.4	12.4	5.5	0.029	
Simple hyperplasia	34.2	24.3	35.3	43.6	0.045	
Atypical hyperplasia	3.4	1.4	1.8	10.9	0.003	
Cancer	1.4	0	0	7.3	0.000	
Others						
Atrophy	4	2.9	3.5	5.4	0.732	
Endometritis	2	1.4	1.8	3.6	0.169	
TB endometritis	0.7	1.4	0.6	0	0.342	
Polyp	2.4	1.4	1.2	5.5	0.03	
Submucous myoma	2.4	1.4	2.9	3.6	0.274	
Remnants of conception	1.4	2.9	1.2	0	0.372	
Menstruating	0.3	0	0.6	0	0.23	

 Table 6
 Patient and physician satisfaction with the different procedures

	TVS	ОН	EB	Sig.
Duration (min)	3.47 (0.78)	3.6 (0.97)	2.14 (0.33)	0.000
Pain score	1.4 (0.5)	3.25 (0.8)	4.67 (1)	0.000
Patient acceptance				
Easy	85.1%	23.1%	2.7%	0.000
Fair	14.6%	61.7%	39.7%	0.000
With difficulty	0.3%	15.3%	48.5%	0.000
Not accepted	0%	0%	4.1%	0.000
Not at all	0%	0%	0.3%	0.000
The procedure				
Easy	95%	44.1%	14%	0.000
Uncomfortable	5%	37.3%	23.4%	0.000
Painful	0%	18.6%	62.7%	0.000
Vagal reaction	0%	1.7%	5.4%	0.01
Physician satisfaction	9.7 (0.5)	9.6 (0.9)	NA	0.8

The diagnostic performance of the different methods in for either focal lesion or hyperplasia and cancer is shown in Table 5. OH showed better accuracy and agreement with histologic diagnosis of hyperplasia or cancer with larger area under the curve (AUC). It was much better than VUS and EB in diagnosing focal lesions with much better accuracy and agreement and larger AUC. The patient response to every procedure together with physician satisfaction is summarized in Table 6.

Discussion

Thanks for the development in optics that allowed the use of small caliber instruments that could pass through the cervix without the need of dilatation. This allowed the use of hysteroscopy in the office in a one-stop setting where all the investigations needed could be done at the time of presentation with the possibility of see-and-treat policy [6]. The addition of office hysteroscopy to vaginal sonography in the initial evaluation of abnormal uterine bleeding was associated with decrease number of visits with shorter duration to diagnosis [7]. In a qualitative trial, most women preferred office hysteroscopy for varying reasons as they could cope without anesthesia, dislike of general anesthesia, do not like to wait, or do not like to be admitted to hospital [8].

This study was performed by the conventional OH; but nowadays, we perform all OH with the vaginoscopic approach which seems less painful and well tolerated by the patients. Nevertheless, in this study, we did not use any pre

Table 5 Diagnostic performance of different methods in diagnosing hyperplasia and focal lesions

	SN%	SP%	PPV%	NPV%	DA%	PLR	NLR	Kap.	AUC
Focal lesion									
Focal lesion at US	42	87	55	80	75	3.2	0.67	0.31	0.65
Abnormal US 8 mm	85	30	32	84	45	1.2	0.5	0.1	0.574
Abnormal US 10 mm	81	47	37	87	57	1.5	0.4	0.21	0.643
OH myoma or polyp	91	100	100	97	98	91	0.09	0.94	0.96
EB	17	100	100	69	78	17	0.83	0.24	0.59
Hyperplasia and cancer									
Thick end. 8 mm	82	42	48	78	58	1.4	0.43	0.22	0.612
Thick end 10 mm	74	63	56	79	67	2	0.41	0.36	0.674
OH thick or suspicious endometrium	76	83	75	84	80	4.5	0.29	0.6	0.77
Abnormal OH	85	65	61	87	73	2.4	0.23	0.47	0.73

or intraprocedure analgesia or anesthesia as most studies suggests that OH in experienced hands is a well-tolerated technique and requires the use of analgesics only in selected patients [9]. Office hysteroscopy was well tolerated by our patients with mean pain score of 3.25 ± 0.8 which is comparable to previous studies with a range of 3–4.8 with variable caliber of the hysteroscopes used [10–14]. The procedure also has high patient acceptance with 85% of patients had easy or faire acceptance and in the other 15% it was accepted with some difficulty. The corresponding figures were 88.7% and 83% with others [11, 13]. The addition of office hysteroscopy to the initial evaluation was associated with decrease number of visits. Our results are intermediate in comparison to previous trials regarding hysteroscopic diagnosis of endometrial hyperplasia with 80% diagnostic accuracy. Some trials had low-diagnostic accuracy of 59% [15], others had comparable accuracy of 73% [16], 79% [17], and 81% [18] while others had higher accuracy of 90% [19] or 96% [20]. This could be explained partially by difference in patient population as Loizzi et al. [21] had a sensitivity of 100% in a population of postmenopausal women with bleeding and thick endometrium. It was found that combining endometrial biopsy and finding of focal lesion in vaginal sonography missed about 50% of focal lesions in our trial. Vaginal sonography had 42% sensitivity in detecting focal lesions. Previous studies had very wide range of sensitivity ranging from 12% to 86% [22, 23], with many of them having very near figures to our study ranging from 39% to 50% [24, 25]. This was also the case for endometrial biopsy which detected only 17% of focal lesions and this also was comparable to previous trials with detection rate varying from 11% to 19% [19, 26].

Considering low-resource countries like Egypt with high parity and consequently very high load of obstetric cases (the average rate of deliveries in our hospital is 18,000 per year), it is crucial to decrease the inpatient case load with adopting policies like one-stop outpatient service. This also much decrease the costs associated with the inpatient service.

In conclusion, the addition of office hysteroscopy in initial evaluation of women with abnormal uterine bleeding appears very beneficial as it allows complete diagnosis in fewer visits within shorter duration with the possibility of see-and-treat action and subsequently saving of the inpatient hospital resources especially in low-resource high-load countries. Regarding endometrial pathology, if performed alone, OH is superior to TVS in all diagnostic indices except being less sensitive. If combined with TVS, OH improves all diagnostic indices. As regards intrauterine lesions, OH is superior to TVS, OS, and even histopathology in detection of IU lesions. Future research should focus on comparing the diagnostic accuracy of OH to 4-D ultrasonography or MRI.

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