Complete manuscript title: COMPARISON OF TRANS-VAGINAL ULTRASONOGRAPHY WITH OFFICE HYSTEROSCOPY AS A SCREENING METHOD IN PATIENTS WITH ABNORMAL UTERINE BLEEDING.

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ABSTRACT:

Objective: To determine the effectiveness of trans-vaginal ultrasonography (TVS) incomparison to outpatient office hysteroscopy in detection of intrauterine pathology in patients with abnormal uterine bleeding.

Patients and method: This study included total of 120 patients with abnormal uterine bleeding in the childbearing period regardless their age during the period between December 2007 and Marsh 2011.

Setting: Endoscopy Unit and Early Cancer Detection Unit of Minia Maternity University Hospital, El-Minia University.

Intervention: Trans-vaginal ultrasonography, hysteroscopy and hysteroscopic endometrial samples.

Main outcome measures: Accurate diagnosis of normal endometrium, endometrial polyp, submucous fibroid, endometrial hyperplasia, polypoidal endometrium, endocervical polyp, endometritis, ovarian pathology, intramural fibroid and cervical stenosis in comparison to histopathological diagnosis.

Results: Trans-vaginal ultrasound can detect endometrial and pelvic pathology but failed to diagnose endometritis and some cervical pathology with sensitivity 68.5% and specificity 96.5%, hysteroscopy diagnosed endometrial and cervical pathology with sensitivity 42.5% and specificity 100%.

Conclusions: The data support a high success rate with the both modalities. Ultrasound can direct the patient towards one or more further advanced modalities.

KEY WORDS:

Abnormal uterine bleeding	<u>Hysteroscopy</u>	4
_tTrans-vaginal ultrasonography	Endometrial sampling.	4
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* hysteroscopy and endometrial sampling.

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INTRODUCTION:

In premenopausal women, polyps or submucosal myomas are the most common anatomic abnormalities encountered, reported to be present in up to 40% or more of patients under evaluation. Although the incidence of endometrial carcinoma is only 6.96 per 1000 women, it is important to exclude in cases of postmenopausal bleeding.

The recommended investigation of abnormal uterine bleeding from the Royal College of Obstetrig

cians and Gynecologists is that women, over the age of 45, should be investigated with hysteroscopy and endometrial biopsy.³

Outpatient endometrial sampling devices, unlike directed biopsy, the sample is obtained blind. As little as 4% of the cavity may be sampled and polypoid lesions are unlikely to be removed.⁴ However, the reported sensitivity for detecting endometrial abnormality is approximately 85%.⁵

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The first line diagnostic tool for uterine abnormalities is trans-vaginal sonography (TVS). It is an easy, fast and cheap technique that has became widely used. TVS has already proved to be a method with high reliability in diagnosing this pathology.⁶

TVS has been widely used during the last 10 years as an alternative method for identifying women at risk of endometrial disease. It is well accepted by most patients within the office setting. Brief transvaginal sonography can be used for visualization of the endometrium, uterus and adnexa, giving a global picture of the pelvis that hysteroscopy cannot.⁷

Hysteroscopy is the second step, which serves after an ultrasound examination as a form of screening.⁶ Since then, several large series have demonstrated that it is an acceptable and reliable alternative to examination under anaesthesia.8 The advantage of hysteroscopy is that we diagnose and treat the changes we notice at the same time. The standard advantages of hysteroscopy provide greater comfort for the patients, since it excludes the need to stay in hospital and decreases the time of treatment, but also the time needed to prepare the patient for further procedures, e.g. medically assisted conception.

Although median pain scores are significantly higher than those reported for inpatient hysteroscopy, anxiety levels are lower and there is no significant difference in overall patient acceptability between the two procedures. Because the hysteroscopy is introduced under direct vision, major complications are extremely rare and minor complications occur in less than 2% of patients. 9

Hysteroscopy has become the gold standard for the evaluation of patients with abnormal uterine bleeding but it is an invasive procedure and may need admission in some cases. Even in the United States, only 20% of gynecologists are doing office hysteroscopy. Direct visualization of uterine cavity is possible by using hysteroscopy but it does not give any information regarding myometrium and adnexa. 10

This study was designed to develop a normogram using transvaginal ultrasound results to select those women who do not need further evaluation with office hysteroscopy and patients with organic pathology and will be directed either to operative hysteroscopy, endoscopy or laparotomy. The study was also concerned with the time required to complete each investigation and also minor adverse effects of each investigation were reported.

PATIENTS AND METHODS:

This study was carried out in Endoscopy Unit of Minia Maternity University Hospital, El-Minia University, between December 2007 and Marsh 2011. Scientific ethical committee of the department of and Gynecology, Obstetrics October 2007, and the Institutional Review Board of the University Hospital-Quality control unit of the Faculty of Medicine, Minia University on December 2007, approved the study. A total of 120 patients were referred to this Unit due to abnormal uterine bleeding in the childbearing period regardless their age during this period.

Routine evaluation tests were done with a complete blood count, TSH, and coagulation studies,

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including pregnancy testing for all women, written consent and approval to participate in this study were taken before starting.

The patient was placed in the lithotomy position with her ankles supported by stirrups. A bimanual vaginal examination was performed to note the size, position and shape of the uterus and the presence or absence of adnexal pathology.

Trans-vaginal sonography (Toshiba SSA-340, Japan) performed using a 7.5 MHz transvaginal transducer. Application of sonography trans-vaginal methodical for diagnostic accuracy. An organ-oriented approach was done for systematic pelvic assessment. The uterus was used for organ orientation. The endometrium measured from myometrial interface to myometrial interface (double thickness) should appear homogenous

The midline echo considered to be normal when a straight endometrial lining with well defined margins and without echo dense foci was found. Heterogeneous variations within the echogenicity of the endometrium are highly significant. Polyps may appear hyperechoic or hypoechoic with regard to the surrounding endometrium. The polyp itself may appear homogeneous or heterogeneous, especially when cystic components are present. Myomas, regardless of their location, had a specific sonographic appearance. They are usually hyperechoic (brighter) with regard to the remainder of the myometrium, generally homogenous, and cause a distal shadowing of the image because sound is unable to pass easily through the muscle whorls that form the myomas. The location of myomas could be distinctly discerned by sonography. Differences between mostly submucosal, intramural or subserosal myomas was done correctly.

Through vaginoscopic approach and without dilation of cervical os hysteroscopy (versapoint, Gynecare, USA angle of vision 0 and diameter 2.7) the telescope is advanced through the cervical canal under vision with the application of the camerabefore the introduction. The telescope was attached to the light source (Karl Storz) by a fibreoptic light cable and the images displayed on a Sony Trinitron monitor using a Telecam Pal three chip camera system (Karl Storz). The outer sheath is connected to the manual infusion pump that allowed distension of the uterus with fluid medium.

The endometrium was serially inspected for pathology. When the inspection of the cavity was complete the fluid and scope were removed from the uterus.

Hysteroscopic endometrial samples were obtained. The specimen was placed in formalin and sent for histopathological analysis. Neither analgesia nor anesthesia was routinely used and was not required by any patient in this series.

RESULTS:

The average age of the patients referred was 40.5 years (29-51). Nine subjects were nulliparas, twelve were grand multiparas and the remainder had had between one and five vaginal deliveries. Of the 120 patients, it was not possible to perform outpatient hysteroscopy in four cases due to cervical stenosis. Presenting complaints of participating women were as

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follow: 23 patients (19.2%) complained of heavy periods, 14 patients (11.7%) presented with Post-coital bleeding, 19 (15.8%) patients presented with Inter-menstrual bleeding, Irregular periods was the main complaint in 13 patients (10.8%), Long periods in 20 patients (16.7%), Frequent periods in 12 patients (10%)

and Metrorrhagia in 19 (15.8%) patients

The duration of hysteroscopic procedures was 5–35 minutes (15.3 \pm 0.59) while the duration of ultrasound was 9–21(13.1 \pm 0.52)

*There is no statistically significant difference between duration of each procedure (P 0.231).

Table (1): Minor adverse events with hysteroscopy, ultrasound and biopsy:

	Hysteroscopy	Ultrasound	Biopsy •
Shock	4	0	1 •
Possible perforation /wrong cavity	2	0	0 •
Patient distress	20	0	1 •
Trauma to cervix	2	0	0 •
Pain	12	1	1 •

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table (2): Success rates for visualization by ultrasound and hysteroscopy compared to biomsy

	*Hysteroscopy (n=116)	Ultrasound (n=120)	Pathology (n=116)	•
Normal	101	93	96	4
Endometrial polyp	4	13	4	
Submucous fibroid	3	(Thickened	3	4

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Endometrial hyperplasia	3	endometrium)	3	•
Polypoidal endometrium	.1	0	1	•
Endo-cervical polyp	3	0	3	•
Suspicious cervix	1	0	1	•
Endometritis	-Ve	0	6	•
Ovarian pathology	-Ve	8	-ve	•
Intramural fibroid	-Ve	6	-ve	•

^{*}Total number of patients underwent hysteroscopy and hysteroscopic biopsy is 116 as the technique failed in 4 cases due to cervical stenosis.

Table (3): Sensitivity, specificity, positive and negative predictive values for all three-outpatient methods of evaluation:

	Hysteroscopy	Ultrasound	Biopsy •
Sensitivity	42.5 %	68.5 %	60 %
Specificity	100 %	96.5 %	100 %
PPV	100 %	88.9 %	100 %
NPV	80.2 %	88.2 %	85.2 %
DA	82.7 %	88.3 %	88 %



Fig (1): Normal cavity during office hysteroscopy

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Fig (1): Normal cavity during office hysteroscopy

O: Fice hysteroscopy

Fig (2): Polyp seen by office hysteroscopy

DISCUSSION:

This study undertook an actual evaluation of three outpatient methods for diagnostic evaluation of AUB, in terms of ability of the technique itself to solve the problem and minor adverse effects. This study aimed to establish what investigation is most acceptable and most efficient in achieving diagnosis in the majority of referrals with an AUB complaint. Furthermore, it aimed to determine in premenopausal women which investigation strategy allows best management of their menstrual bleeding problem.

For benign but clinically relevant uterine disease, the estimation of the sensitivity and specificity of a

diagnostic method is difficult because there is no gold-standard diagnosis that could be used for research. It is well known that not all fibroids cause heavy bleeding, and the clinical significances of polyps are not yet clear. In both conditions some occurrences may be associated with symptoms, but not necessarily all. Therefore, an investigation method that detected (and led to treatment of) structural variants of the uterus that were not of clinical relevance would waste resources, and

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sometimes subject women to needless risks.

Hysteroscopy and ultrasound were compared to assess the number of abnormalities and conditions that each investigation picked up. Increased endometrial thickness (> 4 mm) is an indication of risk of endometrial cancer. However, the majority of the cases of increased thickness detected with the ultrasound will be false positives rather than true cases of endometrial cancer. The aim of biopsy is to exclude premalignant or malignant changes.

All adverse events were minor. There were one patient suffering adverse event for ultrasound, but for hysteroscopy 58 adverse events occurred in 24 patients (20.6%) and for biopsy there were three adverse events occurred in 3 patients (2.5%).

Ultrasound evaluation was completed in all cases where the woman attended, but there were 4 cases where hysteroscopy was not possible owing to a failure to introduce the telescope due to cervical stenosis.

Across all patients, ultrasound was demonstrated to be the best investigation for the detection of uterine wall fibroids while hysteroscopy performed better for the detection of endometrial polyps and cervical pathologies, the significance of intrauterine polyps is not known and the majorities are associated with benign pathology. A recent prospective survey of some 1500 UK consultant gynecologists reported the variation in opinion concerning the role for both inpatient and outpatient treatment of polyps. The majority of gynecologists favored inpatient removal, with half performing inpatient hysteroscopy to localize the polyp before blind removal.—¹¹ If there is considerable benefit then it might have been expected that postmenopausal women having hysteroscopy (and likely detection of polyps if present) would have had better outcome than those having ultrasound, and vice versa in respect of detection of fibroids.

In the present study, the sensitivity of ultrasound was 68.5 %, specificity was 96.5 %, positive predictive value was 88.9% negative predictive value was 88.2% and diagnostic accuracy was 88.3%

Abnormalities within the adnexa may be relevant to the immediate problem of abnormal bleeding or part of a separate disease. Ovarian findings, especially in older women, were evaluated. The presence or absence of cul-de-sac fluid was noted. Other unexpected disease related to the bladder or bowel may be visualized.

Hysteroscopy can allow the observation of macroscopic changes to the endometrium suggestive of endometrial cancer. In this study the sensitivity for this in all women evaluated in this way was 42.5%, specificity was 100—%, positive predicpredict_tive value was 100% negative predicpredict_tive value was 80.2% and diagnostic accuracy was 82.7%

In the study of Jakab et al (2001), the sensitivity of hysteroscopy in the diagnosis of intrauterine lesions was 97%. Paschopoulos et al (2001) reported sensitivity and specificity of 92% and 95% for hysteroscopy in diagnosing intracavitary pathology in women with AUB. The research of Dueholm et al (2001) showed

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sensitivity and specificity of procedure as 84% and 88%, respectively. 14 Bonnamy et al (2002) reported sensitivity and specificity of hysteroscopy as 78% and 97% in patients with AUB. 15 Kelekci et al (2005) found sensitivity of 87.5% and specificity of 100% for hysteroscopy in detecting intracavitary abnormalities. 16 In Allameh and Mohammadizadeh (2007) study, sensitivity, specificity, PPV and NPV of hysteroscopy in patients with AUB were 100%, 80.5%, 88.9% and 100%, respectively. 17

The sensitivity and specificity of office hysteroscopy examination have been reported to be as high as 85-91% and 83-100%, respectively. 18 In a more recent study, 14% of 114 patients showing normal TVS findings revealed abnormalities upon hysterosonography examination.¹⁹ However, the study was limited to those patients' with normal TVS findings and there has not been any extensive study for actually evaluating the role of hysterosonography as a screening method for patients with abnormal uterine bleeding.

Hysteroscopy is believed to be the "gold standard" for diagnosis of abnormal uterine bleeding²⁰ and misses less than 0.5% of serious disease such as endometrial cancer.20 Regarding ultrasound scanning for the evaluation of abnormal uterine bleeding, two important studies compared diagnostic accuracy of vaginal-probe ultrasonography against hysteroscopy²⁰ and saline solutioninfusion–sonography (SIS) office hysteroscopy. 20 Both studies found that ultrasonography and hysteroscopy were effective for detecting intrauterine disease such as polyps, submucous myomata, and endometrial hyperplasia, but there were fewer false-positive and falsenegative results with hysteroscopy. The Widrich et al. study²¹ did show that patients had more discomfort with office hysteroscopy than with SIS, but they did not use any local anesthetic with either procedure.

The rate of abnormalities found in patients with abnormal uterine bleeding ranges from 40% to 85%, but precise diagnosis of suspicious tissue must always be done with histological examination of the tissue. ²² With such a high rate of positive findings, it is apparent that office hysteroscopy should be used for primary screening in evaluating the patient with abnormal uterine bleeding, because, in most situations, both the screening and the management can be affected in a single sitting.

In 46 women with histological examination, Balic and Balic 2011 reported that the sensitivity of TVS and hysteroscopy in the diagnosis of endometrial polyps were identical -100%, while the specificity was higher in hysteroscopy than in TVS (92.3% versus 56.4%, p<0.001). The sensitivity of TVS in the diagnosis of endometrial hyperplasia was higher than that of hysteroscopy (86.4% versus 22.7%, p<0.001), while specificity was identical, of 100%. Accordance between hysteroscopy and histology was good (k=0.79), between ultrasound and histology was moderate They concluded (k=0.59).hysteroscopy appeared to be more reliable in diagnosis than TVS. The use of a high frequency ultrasound probe leads us to a lack of diagnostic clarity between endometrial polyps hyperplasia.²³

Office hysteroscopy is a safe, comfortable, enormously convenient, and precise method of evaluating and managing at the same time most cases

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of abnormal uterine bleeding. As a screening tool, hysteroscopy may be costly and inappropriately time-consuming when one considers the patients for whom there is no anatomic defect inside the uterine cavity.²⁴

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Conclusion

Due to its low sensitivity office hysteroscopy is not an ideal test for screening of abnormal uterine bleeding. Trans-vaginal ultrasound can direct the patients with organic pathology either to do operative hysteroscopy, endoscopy laparotomy. Patients with normal endometrial thickness and morphology in vaginal scanning will not need further evaluation and may benefit from medical treatment

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