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Diagnostic Accuracy of Hysteroscopy Versus TVS in Patients with AUB in a Tertiary Care Center of Northern India

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Abstract

Abnormal uterine bleeding refers to any deviation of regularity, frequency, duration or amount of flow from the normal menstrual flow. It affects day to day life and can have serious impact such as anemia or may be the result of underlying malignancy. Total 43 female patients with abnormal uterine bleeding after meeting the inclusion and exclusion criteria participated in the study. Each patient underwent transvaginal sonography where uterus with uterine cavity, adnexa, cervix, vagina was studied meticulously and then they were subjected to hysteroscopy guided biopsy under anesthesia using saline as distension medium. Local pathology of uterine cavity was examined by hysteroscopy. Biospy of the endometrium or suspected lesion was curetted out and sent for histopathology. These patients were followed for HPR report which was taken as the confirmatory modality to compare the sensitivity, specificity, positive and negative predictive value of hysteroscopy with TVS. Our study showed 100% sensitivity for cervical polyp, endometrial hyperplasia, endometrial and fibroid polyp, 100% specificity for cervical polyp and fibroid polyp, 95% for endometrial polyp on hysteroscopy. TVS had a higher specificity (95%) for detecting endometrial hyperplasia when compared to hysteroscopy. For cervical and fibroid polyp there was 100% PPV and NPV on hysteroscopy and 100% PPV on TVS. Diagnostic hysteroscopy and TVS are complimentary to each other. So patients with abnormal uterine bleeding should undergo both TVS and hysteroscopy and findings should be confirmed by histopathological examination.

Keywords: Abnormal uterine bleeding, Endometrial hyperplasia, Endometrial polyp, Hysteroscopy, Submucous fibroid, Transvaginal sonography.

Introduction

Any excessive, unexpected, protracted, cyclic or acyclic bleeding, regardless of cause or diagnosis, is considered to be abnormal uterine bleeding (AUB). It describes irregular pattern of menstrual cycle involving regularity, frequency, duration and volume of flow. AUB can have major negative effects like anemia or can be the result of a primary tumor. It also impacts daily activities like intimate relationships and coping with life's challenges (1, 2). Heavy flow during menses, prolonged menses lasting >8 days, irregular menses where the shortest to longest cycle variation is >8-10 days, increased frequency (where the cycle lasts for less than 24 days), and contact bleeding (bleeding just after intercourse) are the most common clinical manifestations of AUB. Menorrhagia, which accounts for 33% of patients sent to gynecologists, is the most prevalent complaint that patients of reproductive age make to the doctors (3). AUB's differential diagnosis includes issues like cervical and vaginal abnormalities, infection, coagulopathies, endocrine disorders, benign and malignant uterine neoplasia, foreign bodies, systemic disease, trauma and medication-related bleeding (4). The best resource for beginning an evaluation of AUB is complete history and physical examination. Menstrual bleeding that is anovulatory is erratic, unexpected, and fluctuates in kind, duration, and amount, not preceded by premenstrual symptoms and without any palpable abnormalities of the genital tract. Anovulation is one of the causes of heavy or protracted regular monthly periods similar to structural lesions or bleeding disorders. Any procedure that can considerably increase the precision of identifying the source of bleeding can lessen the need for hysterectomy as a treatment. Dilatation and curettage (D & C) was the standard of care for

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Evaluating abnormal uterine bleeding, however it is ineffective for identifying specific intrauterine lesions like endometrial polyps or sub mucous fibroids that may be tiny or situated in locations that are challenging to curette (5-8). Currently diagnostic hysteroscopy and transvaginal sonography (TVS) are the two main diagnostic techniques utilized to assess AUB (9). Hysteroscopy is regarded as an essential modality to evaluate AUB which can also provide therapeutic treatment such asresection of submucosal fibroids avoiding hysterectomy (10).

The working group on menstrual diseases of the International Federation of Gynecology and Obstetrics has established a classification system (PALM-COEIN) for the etiologies of the AUB in women. In accordance with the acronym PALM-COEIN, it consists of: polyp, adenomyosis, leiomyoma, malignancy and hyperplasia, coagulopathy, ovulatory dysfunction, endometrial, iatrogenic, and not yet diagnosed (11).

When women have abnormal uterine bleeding, particularly those who are perimenopausal, TVS may be the most economical initial test (12). Any organic lesion in the uterine cavity as well as the thickness of the endometrium can be precisely measured with TVS. In the current period, hysteroscopy is increasingly gaining popularity as the preferred examination for assessing AUB. In most cases, the etiology can be determined due to the direct inspection of the cavity inside uterus (13). It is more capable of precisely diagnosing endometrial polyps, fibroids, hyperplasia, etc. that a TVS can frequently miss (14). The current study focuses to assess the specificity and sensitivity of both procedures TVS and hysteroscopy and to compare their outcomes using histopathology, which is considered the gold standard.

Materials and methods

This hospital based prospective comparative study was done in the department of Obstetrics and Gynaecology of Santokba Durlabhji Memorial Hospital, Jaipur Rajasthan, from 1st July 2018 to 1st July 2019. It consisted of women with AUB in the age group 20-70 years. Patients with pelvic inflammatory disease and who did not give consent for study were excluded from the same.

The study was approved by the IEC (Ref.no.NBE/THESIS/191282/2017/11370) and the patients were enrolled after proper consent approval.

Assuming an overall sensitivity of 100% for hysteroscopy and 78.6% for TVS to diagnose abnormal uterine bleeding based on the findings of the reference study, a sample size of 43 was needed for this case study with an 80% study power and alpha error of 0.01. 50 cases were selected for the current study, with an expected 20% dropout rate.

MEDCALC statistical software was used for sample size**.**

Sample size formula

$$n = \frac{2(\bar{p})(1-\bar{p})(Z_{\beta} + Z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

Z alpha =2.56 (when 99% confidence interval)
Z beta=0.84 (when 80% study power)
P1= sensitivity of hysteroscopy 100%
P2= sensitivity of TVS 78.6%
P1 = Sensitivity of hysteroscopy i.e., 0.9999
P2 = Sensitivity of TVS i.e., 0.786

After approval of ethical committee, subjects were approached by the investigator and were explained regarding the nature of the study for consent approval. A thorough medical history was taken from every eligible participant including information on the patient's age, socioeconomic standing, demography, parity, literacy, menstrual cycle characteristics (such as heavy, prolonged, frequent and continuous bleeding for greater than 21 days), history of contraception, hormonal use, menopausal symptoms, etc.), current use of medications and dietary supplements, as well as lifestyle factors like smoking and alcohol consumption. These individuals underwent a bimanual pelvic examination after undergoing a general, per speculum examination to check the status of the cervix and look for any lesions or vaginal fornices. Patients were then scanned by TVS with 7.5 MHz probe transducer in premenstrual phase to visualize the uterine anatomy, endometrial thickness and the adnexae. They were then subjected to hysteroscopy under anaesthesia using intravenous propofol. Telescope of 4 mm, 30 degree, fore-lens with a 5mm sheath (diagnostic), 6.2 mm (operative) was used. Illumination was by fibre-optic cable. Under direct eyesight, a hysteroscope was introduced

into the cervical canal. Hysterojet and distending media were used to maintain pressure between 80 and 100 mmHg. The hysteroscopy's inflow channel had the distending medium attached to it. The fluid washed away any blood clots that might have been present in the cavity. The uterine cavity was then thoroughly explored. Ostia were visible in the cornue and passages of air bubbles were noted. The endometrium's surface characteristics, colour, vascular pattern and glandular opening were noted. The lesions including polyps, submucosal fibroid or hyperplastic endometrium were excised and the material was preserved in 10% formalin before the pathologist stained it with hematoxylin and eosin for histopathological analysis.

Statistical analysis

The mean of the continuous variables was calculated, and the standard deviation was analyzed using the unpaired t-test and Pearson Correlation Coefficient. The Fischer Exact test and chi-square test were used to analyze nominal and categorical data, which were presented as proportions (%).P value 0.05 is taken to be significant. For all statistical calculations, software Med. Calc 16.4 version was used.

Results

In our study the diagnostic role of TVS for fibroid polyp has 100% sensitivity, specificity, PPV, and NPV. Sensitivity, specificity, and positive predictive value were all 100% for cervical polyps, whereas negative predictive value was 87.5%. When used to diagnose endometrial hyperplasia, TVS demonstrated sensitivity of 73.91%, specificity of 95%, positive predictive value of 94.44%, and negative predictive value of 76%. It has a sensitivity of 61.9%, specificity of 95.45%, positive predictive value of 92.85%, and negative predictive value of 72.41% for detecting endometrial polyp (Table 1).

The diagnosis of cervical polyp and fibroid polyp by hysteroscopy was 100% accurate. For endometrial hyperplasia, it demonstrated 100% sensitivity, 75% specificity, 82.14% positive predictive value, and 100% negative predictive value. Whereas for endometrial polyp it revealed 100% sensitivity, specificity, negative predictive value and 95.45% positive predictive value. (Table 2).

In our study it was found that on TVS the sensitivity of detecting cervical polyp was 37.50%, on hysteroscopy it was 100%, which was statistically comparable and significant. (p value = 0.031). The specificity and positive predictive value for cervical polyp detected by TVS and hysteroscopy was 100% which was not comparable. The negative predictive value for cervical polyp on TVS was 87.50%, on hysteroscopy it was 100% which was statistically comparable but not significant as (p value = 0.089). Sensitivity of detecting endometrial hyperplasia on TVS was 73.91%, it was 100% on hysteroscopy which was statistically significant as (p value = 0.029). The specificity of diagnosing endometrial hyperplasia on TVS was 95%, it was 75% on hysteroscopy which was statistically not significant (p value = 0.184). The positive predictive value for endometrial hyperplasia on TVS was 94.44%, it was 82.14% on hysteroscopy i.e., although PPV of TVS for endometrial hyperplasia was higher than hysteroscopy, it was not statistically significant, p value 0.447. The NPV for endometrial hyperplasia was 76% on TVS, it was 100% on hysteroscopy which was not statistically significant as (p value = 0.109). On TVS sensitivity of detecting endometrial polyp was 61.90%, whereas it was 100% on hysteroscopy which was statistically comparable and significant, (p value =0.006). The specificity of TVS and hysteroscopy for endometrial polyp was 95.45%, which was not statistically significant as (p value = 0.463). The PPV of TVS for endometrial polyp was 92.85%, it was 95.45% on hysteroscopy, not statistically significant as (p value = 0.678). The NPV of TVS for endometrial polyp was 72.41%, it was 100% on hysteroscopy which means the NPV of hysteroscopy was higher than TVS for endometrial polyp and statistically significant, (p value = 0.025). The sensitivity, specificity, PPV, NPV for diagnosing fibroid polyp on hysteroscopy and TVS could not be statistically compared as both the techniques showed 100%.

Table 1: Diagnostic role of TVS

HPR Diagnosis	Sensitivity		Specificity		PPV		NPV	
	No.	%	No.	%	No.	%	No.	%
Cervical Polyp	3/8	37.50	35/35	100.00	3/3	100.00	35/40	87.50
Endometrial Hyperplasia	17/23	73.91	19/20	95.00	17/18	94.44	19/25	76.00
Endometrial Polyp	13/21	61.90	21/22	95.45	13/14	92.85	21/29	72.41
Fibroid Polyp	1/1	100.00	42/42	100.00	1/1	100.00	42/42	100.00

Table 2: Diagnostic role of Hysteroscopy

HPR Diagnosis	Sensitivity		Specificity		PPV		NPV	
	No.	%	No.	%	No.	%	No.	%
Cervical Polyp	8/8	100.00	35/35	100.00	8/8	100.00	35/35	100.00
Endometrial Hyperplasia	23/23	100.00	15/20	75.00	23/28	82.14	15/15	100.00
Endometrial Polyp	21/21	100.00	21/22	95.45	21/22	95.45	21/21	100.00
Fibroid Polyp	1/1	100.00	42/42	100.00	1/1	100.00	42/42	100.00

Table 3: Comparison of Diagnostic role of TVS & Hysteroscopy

HPR Diagnosis	Sensitivity	Specificity	PPV	NPV
Cervical Polyp	0.031	NA	NA	0.089
Endometrial Hyperplasia	0.029	0.184	0.447	0.109
Endometrial Polyp	0.006	0.463	0.678	0.025
Fibroid Polyp	NA	NA	NA	NA

Chi-square test; ('p' values)

Discussion

In our discussion we have focused on comparing the various diagnostic parameters i.e., sensitivity, specificity, positive and negative predictive values for various etiologies detected by TVS with hysteroscopy. In contrast to other studies by K Srinivas *et al.* (67.86%) and Sannyasi *et al.* (50%) our study showed 100% sensitivity in identifying endometrial hyperplasia by hysteroscopy (15, 16). This is in agreement with other studies by Padma *et al.* (100%) and Meena *et al.* (100%) but differs from other studies by Padma *et al.* (98.04%) (17, 18). Our study's specificity, which is 75%, is comparable to that of Meena *et al.* (75.3%) but differs from other studies conducted by Padma *et al.* (98.04%) (17, 18). Our study's PPV of 82.14% is comparable to those of Sannyasi *et al.* (70%) and Padma *et al.* (90%) research (16, 17). In contrast to other studies conducted by K. Srinivas *et al.* (70.97%), the NPV in our study is 100%, matching to that of Padma *et al.* (15, 17). Possible reason could be due to difference in study method, study period, study population and interobserver variation.

While earlier tests conducted by Sanyasi *et al.* (43.75%) demonstrate a sensitivity of 73.91%, our study using TVS shows a sensitivity of 73.91% (16). The current study's specificity of 95% is comparable to other investigations carried out by Padma *et al.* (94.1%) (17). There is a 94.44% PPV, which is comparable to K. Srinivas *et al.*'s study (100%) (15) and a 76% NPV, which is comparable to Sannyasi *et al.* (88%) study (15, 16). Differences in the study could be the result of a limited sample size, a lengthy current study, the radiologist's expertise, or instrumental variance.

In contrast to TVS (95%), our study found that hysteroscopy had a lower specificity for endometrial hyperplasia (75%). In a study done by Meena *et al.* similar findings were obtained where hysteroscopy demonstrated 78.5%

specificity in assessing endometrial hyperplasia (18). Failures of hysteroscopic assessment may result from screening patients during the premenstrual phase and from a lack of clear diagnostic criteria for separating an endometrial secretory phase from a hyperplastic phase. To increase its accuracy, it is vital to have a better understanding of the connection between hysteroscopic imaging and the pathophysiologic conditions of the endometrium. So, in all hysteroscopies, endometrial sample is advised.

Our study's findings of 100% sensitivity and 100% NPV are consistent with those of Padma *et al.*'s study (which also showed 100% sensitivity and 100% NPV) (17). The specificity is 95.45%, which is similar to study done by Garuti *et al.* (95.4%) (19). Our study's PPV and NPV, which are 95.45% and 100%, respectively, are comparable to those of Padma *et al.* study (PPV: 92.8% and NPV: 100%) (17). While Padma *et al.* study (46.1%) and Pitia *et al*. (88.7%) sensitivity ratings are different from those of TVS, which reveals a sensitivity of 61.90% (17,20). It demonstrates specificity of 95.45%, which is comparable to studies done by Sannyasi *et al.* (89.16%), Padma *et al.* (95.7%), Meena *et al.* (93.3%), (16-18,). It differs from earlier studies like Padma *et al.* (which had a 75% PPV, 86.5% NPV) in that there is a 92.85% PPV and 72.41% (17). The aforementioned results may differ as a function of the sample size, study population, duration, interobserver discrepancies, and instrumentation.

In our study, hysteroscopy had a 100% sensitivity, specificity, PPV, and NPV for cervical polyps while TVS had a 37.5% sensitivity, 100% specificity, 100% PPV, and 87.5% NPV. Since no previous studies investigated for cervical polyps, the data could not be compared.

TVS and hysteroscopy have 100% sensitivity, specificity, PPV, and NPV for fibroid polyp detection. This finding contrasts with the study done by Lubna *et al.* which determined that an abnormal TVS scan had a 0.60 sensitivity rating when compared to hysteroscopy for the diagnosis of fibroid polyp (21). This could be explained by the fact that we had only patient with fibroid polyp which was diagnosed by both modalities and confirmed by HPR.

The p value was found to be significant, i.e. 0.031, 0.029, and 0.006 correspondingly, when comparing the sensitivity of hysteroscopy with TVS for cervical polyp, endometrial polyp, endometrial hyperplasia, and fibroid polyp. This leads us to the conclusion that hysteroscopy is significantly more sensitive than TVS because it allows for a complete exploration of the uterine cavity under vision.

Conclusion

Transvaginal sonography is affordable, non-invasive which is used as the first diagnostic modality to study the lower abdomen and pelvis in patients with AUB. However, due to limitations of double layer thickness measurement it has a limited capacity for detecting lesions like endometrial polyp, hyperplasia, or cancer.

With hysteroscopy, a quick diagnosis and efficient therapy are possible. By doing so, a focused biopsy of the suspected lesion which can be the source of the bleeding can be carried out. It is a great operative and diagnostic tool for detecting submucosal fibroids, hyperplasia, and other endometrial conditions as well as to remove them in the same sitting.

When compared to TVS in our study, hysteroscopy demonstrated high sensitivity, PPV, and NPV for a variety of disorders including endometrial polyp, cervical polyp, fibroid polyp and endometrial hyperplasia as it directly inspects the uterine cavity. Whereas the overall specificity for endometrial hyperplasia by TVS was more than hysteroscopy as patients were screened during the premenstrual or secretory phase, when the endometrium is already hyperplastic and it is challenging to determine the exact cause on hysteroscopy.

To conclude, both modalities are supportive. This means that a patient with abnormal uterine bleeding should receive both hysteroscopy and TVS, and their results should be verified by histopathology.

Limitations

1. A small sample size and a brief study time could lead to biased results.
2. A large number of patients were screened during the premenstrual phase, which reduced the hysteroscopy's specificity.
3. Since hysteroscopy is only used to detect intrauterine pathology, detection parameters of many other causes of irregular uterine bleeding,

such as adenomyosis, subserosal fibroids, and any adnexal pathology, cannot be compared.

Abbreviations

AUB: Abnormal Uterine Bleeding
D & C: Dilatation and curettage
TVS: Transvaginal Sonography
PALM-COEIN: Polyp, Adenomyosis, Leiomyoma, Malignancy and Hyperplasia, Coagulopathy, Ovulatory dysfunction, Endometrial, Iatrogenic, and Not yet diagnosed.

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Author's contributions

All authors contributed to the study's conception and design. Concept of study was given by Dr. Brinderjeet Kaur. Statistical analysis was done by Dr. Nishi Gupta. Material preparation, data collection and analysis were performed by Dr. Alpana Behera. The first draft of the manuscript was written by Dr. Alpana Behera. The final draft of the manuscript and subsequent revisions and modifications were done by Dr. Rachita Pravalina and Dr. Alpana Behera. All the authors have read and approved the final manuscript.

Conflict of interest

We have no conflict of interest to declare.

Ethics approval

The study was approved by the IEC of the institute with reference letter number (Ref.no.NBE/THESIS/191282/2017/11370).

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