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Diagnostic accuracy of saline infusion sonography as compared to hysteroscopy in premenopausal women with abnormal uterine bleeding

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Abstract

Objective: To diagnose various intrauterine pathologies that causing Abnormal uterine bleeding (AUB) by Saline infusion sonography (SIS). To compare diagnostic accuracy of saline infusion sonography to gold standard investigation hysteroscopy in premenopausal women with abnormal uterine bleeding.

Methods: The study was conducted in the D.Y. Patil hospital Pune from September 2017 to August 2019. A total of 40 premenopausal women with abnormal uterine bleeding were included in the study. All patients were subjected to saline infusion sonography followed by hysteroscopy at a later date.

Results: Sensitivity and specificity of saline infusion sonography when compared to hysteroscopy for submucous fibroids were 100% and 100%, for endometrial polyps were 100% and 97.4%, for endometrial hyperplasia were 100% and 97.14%, for adenomyosis 77.78% and 100%, for endometritis 0% and 100% respectively.

Conclusion: The diagnostic accuracy of SIS in detecting the lesions like endometrial polyps, submucous fibroids, endometrial hyperplasia is almost comparable to hysteroscopy. But early changes of adenomyosis and endometritis are better detected on hysteroscopy. Based on results obtained, saline infusion sonography can be used as preliminary investigation before performing hysteroscopy.

Keywords: AUB, SIS, NPV, PPV, hysteroscopy, TVS

Introduction

Abnormal uterine bleeding constitutes one among the most frequent gynecological complaints referred to outpatient department. It presents as a diagnostic dilemma to the gynaecologist. Incidence of AUB is 25-30% among women of reproductive age and 50% in perimenopausal women. Life time chance to have menorrhagia for a woman is 1 in 20^[1]. There are many causes of AUB and differentiating whether due to ovulatory abnormalities or anatomic lesions can be challenging.

International Federation of Gynecology and Obstetrics (FIGO) classification system for causes of AUB include 9 categories that follows acronym PALM-COEIN. Structural causes includes Polyp, Adenomyosis, leiomyomas, malignancy and hyperplasia, nonstructural causes include coagulopathy, ovulatory dysfunction, endometrial, iatrogenic, not yet classified^[2].

Imaging modalities used to assess AUB are Hysteroscopy, Transvaginal sonography (TVS), Saline infusion sonography, Magnetic resonance imaging (MRI). MRI can be used in women who cannot be imaged properly by ultrasonography. The disadvantage is the cost and therefore it is not used routinely.

Hysteroscopy is considered as the "Gold Standard" for the evaluation of uterine cavity as it allows direct visualization of uterine cavity^[3]. It has got both diagnostic and therapeutic advantage. It has the advantage of see and treat approach. Any abnormal lesions can be biopsied at the same setting. Disadvantages include it is expensive, invasive procedure, it cannot diagnose myometrial and adnexal pathologies, poor visualization when uterine bleeding is present, and it can cause complications like perforation and infection^[4].

TVS is a non-invasive alternative for imaging uterine and endometrial abnormalities but it has a disadvantage of having high false negative rate in diagnosing focal intra uterine pathology. Saline Infusion Sonography (SIS) also known as Sonohysterography is the infusion of saline into the uterine cavity via balloon catheter during TVS to distend uterine cavity and to delineate the endometrium. Saline can be used as a negative contrast agent to improve the imaging in

transvaginal sonography. Advantage of SIS over hysteroscopy is that myometrial and adnexal pathologies can be detected and in addition to this it is cost effective, performed in short duration and less painful. Limitations include blood clot can be misinterpreted as polyps [5]. Because of smaller volume of distention media used, SIS is generally better tolerated than hysteroscopy [6, 7]. Saline infusion sonography can become complementary method to conventional Transvaginal sonography in evaluating the cases with Abnormal uterine bleeding.

Methods

40 patients of abnormal uterine bleeding presenting to gynaecology outpatient department in Dr. DY Patil medical college were enrolled to further study. Inclusion criteria include premenopausal women, normal cervical cytology, not pregnant. Exclusion criteria were evidence of pelvic inflammatory disease, sexually transmitted disease, suspected or diagnosed cases of endometrial cancer, active menstrual bleeding. The consent was taken from the patients who fulfilled inclusion and exclusion criteria. All the patients were explained regarding both SIS and hysteroscopy procedures and their complications.

Detailed history was taken from all participants which includes symptoms, onset, duration, past history, family history, personal history.

History was followed by detailed general examination, systemic examination, local examination, per speculum examination and bi-manual pelvic examination.

Venous sample was obtained for regular, routine, relevant investigations.

Saline infusion sonography followed by hysteroscopy at later date were performed in all cases

Patients were examined after the menses, during early-mid follicular phase of menstrual cycle, but before 10th day of same menstrual cycle [8].

For saline infusion sonography, the patient was positioned in dorsal lithotomy position. TVS probe inserted to obtain coronal and sagittal views and it is removed.

Sterile speculums are introduced into the vagina. Cervix was cleansed with povidone iodine solution for antisepsis.

Anterior lip of cervix was held with vulsellum forceps.

A Foley's catheter no 10 and stiffener were introduced into cervix until it touched fundus. The inflatable balloon of Foley's was inflated with 3cc of normal saline in order to keep the catheter in place. Traction is given to Foley's to keep the bulb at the internal os. Speculums are removed. TVS probe (5MHZ) was introduced into vagina, 10-20 ml of normal saline was infused until there is clear visualization of uterine cavity. Uterine cavity is evaluated in both coronal and sagittal views and findings noted. No need for local anaesthesia and prophylactic antibiotics.

In hysteroscopic procedure, patient is placed in lithotomy position under general anaesthesia. Painting and draping done. Per vaginal examination done and findings are confirmed. Sims speculum were introduced. Cervix is cleaned with betadine solution. Anterior lip of cervix is held with Vulsellum forceps. A 5mm rigid endoscope was introduced into vagina, from there into cervical canal into uterine cavity. Normal saline was introduced for distension of uterine cavity and allows adequate and direct visualization of endometrial cavity. Biopsy of suspected lesions were done at the same sitting. Prophylactic antibiotic therapy is required.

After the both procedures, findings obtained in SIS were

compared to hysteroscopy and diagnostic accuracy was expressed in terms of sensitivity, specificity, positive predictive value, and negative predictive value.

Results

The study was conducted from September 2017 to August 2019. A total of 40 patients who attended to gynecological OPD with abnormal uterine bleeding were enrolled to study.

Table 1: Show the Age

Mean age	44.725
Std. Dev	2.98704
Range of age	40-50 years

Table 2: Distribution of study population according to age

Age distribution	No of cases N=40	Percentage
40-42 years	10	25%
43-45 years	13	32.50%
46-48 years	11	27.50%
49-50 years	6	15%

Mean age at presentation is 44.725 years with standard deviation of 2.98704 years with majority of women in the age distribution between 43-45years (32.50%). AUB was commonest in the age group of 40-50 years.

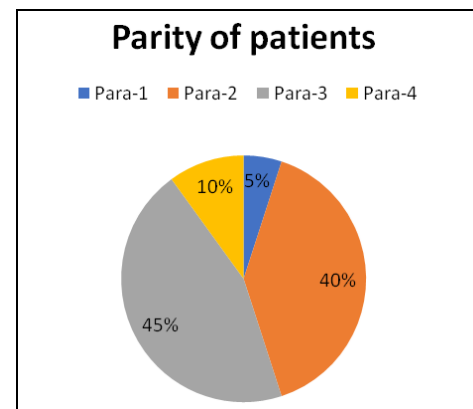


Fig 1: Pie chart showing parity status of study population.

Majority of patients were para 3 which constitutes 45%. Multiparous women constitutes 95%.

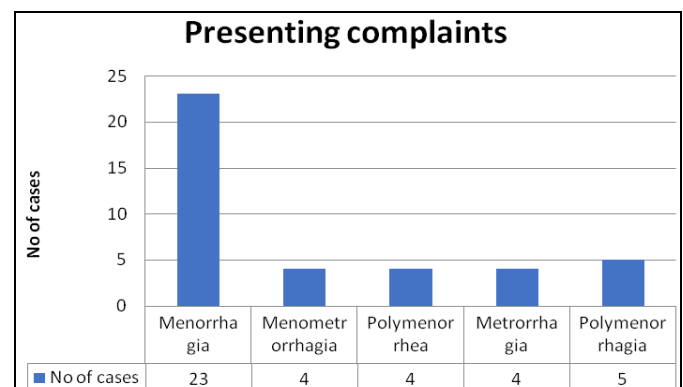


Fig 2: Bar diagram of presenting complaints in the patients

Most common presenting complaint among the patients is menorrhagia which is present in 57.50% of cases followed by Polymenorrhagia which is present in 12.5% of cases.

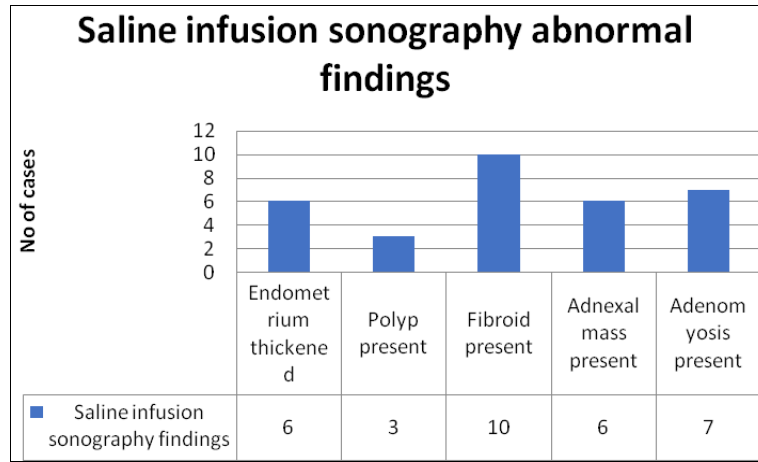


Fig 3: Bar diagram showing abnormal findings in saline infusion sonography

In saline infusion sonography, leiomyomas are present in 10(25%) patients, hyperplasia of endometrium is present in 6(15%), polyps present in 3(7.50%), adenomyosis present in 7 (17.50%), adnexal mass is present in 6(15%) cases. Among Leiomyomas out of 10, 2 were submucosal fibroids, 6 were intramural fibroids, 2 were subserosal fibroids.

Table 3: Hysteroscopic findings

	Hysteroscopic findings N=40	Percentage
Polyp present	2	5%
Fibroid present	2	5%
Intrauterine adhesions (Asherman’s syndrome)	5	12.50%
Adenomyosis present	9	22.5%
Endometritis present	1	2.5%
Endometrial hyperplasia	5	12.50%

In hysteroscopy, adenomyosis was present in 9(22.5%) patients, endometrial hyperplasia in 5(12.50%) patients, submucous fibroid present in 2(5%) patients, polyps present in 2(5%) patients, adhesions are present in 5(12.50%) patients, endometritis is present in 1patient(2.5%).

Table 4: Diagnostic accuracy of saline infusion sonography with hysteroscopy as gold standard.

	Submucous fibroid	Endometrial polyp	Endometrial hyperplasia	adenomyosis	endometritis
sensitivity	100%	100%	100%	77.78%	0%
specificity	100%	97.4%	97.14%	100%	100%
Positive predictive value (PPV)	100%	66.7%	83.33%	100%	0%
Negative predictive value (NPV)	100%	100%	100%	93.93%	97.5%

Discussion

Among premenopausal women with age group of 40-50 years, the average age of presentation was 44.72 years with standard deviation of 2.98. In present study, AUB was commonest in age group of 40-45 years. In the study performed by Indman P D *et al.*^[9]. Study of AUB demonstrated 43.2% of patients from age group of 40-49years. In the present study, 18 patients (45%) were found to be para 3 followed by para 2 who were 16(40%). 95% were multiparous. In the study conducted by Dasgupta *et al.*^[10]. 88.5% were found to be multiparous. In the present study, most common presenting symptom includes menorrhagia which is present in 23 patients (57.50%), followed by polymenorrhagia which is present in 5(12.50%) patients. This is similar to study conducted by Finikiotis *et al.*^[11]. where menorrhagia was reported in 62% cases of AUB. In the study conducted by Tabassum Kotagasti *et al.*^[12]. also most common presenting symptom was menorrhagia which accounts for 33%. In present study, Endometrial hyperplasia was present in 6 (15%) patients when Saline infusion sonography was performed, whereas it is present in 5(12.5%) patients on hysteroscopy. The sensitivity and specificity of saline infusion sonography when compared to gold standard procedure hysteroscopy to detect

endometrial hyperplasia are 100% and 97.14% respectively. This is similar to the study conducted by Rudra *et al.*^[13]. where sensitivity and specificity of SIS when compared to hysteroscopy in detecting endometrial hyperplasia were 100% and 97.9% respectively. In the study conducted by Wildrich *et al.*^[14]. Sensitivity and specificity of SIS when compared to hysteroscopy for detecting endometrial hyperplasia were 100% and 95% respectively. In present study in one case with normal endometrium SIS detected falsely as endometrial hyperplasia. In present study, Saline infusion sonography diagnosed endometrial polyps in 3(7.50%) patients with abnormal uterine bleeding, whereas hysteroscopy diagnosed endometrial polyps in 2(5%) patients with abnormal uterine bleeding. The sensitivity and specificity of SIS when compared to gold standard procedure hysteroscopy in detecting endometrial polyps were 100% and 97.4% respectively. This is similar to the study conducted by Pawel Radwan *et al.*^[15]. where sensitivity and specificity of SIS when compared to hysteroscopy in detecting endometrial polyps were 97.3% and 95.8% respectively. Another study conducted by Nallapati *et al.*^[16] the sensitivity and specificity of SIS when compared to hysteroscopy in imaging polyps were 90.9% and 92.68% respectively. The

diagnostic accuracy of SIS for detecting endometrial polyps is more than TVS but when compared to Hysteroscopy it is equally sensitive but less specific because blood clots in endometrial cavity were falsely interpreted as endometrial polyps.

In the present study, adenomyosis was diagnosed in 7(17.50%) patients by using transvaginal sonography with Saline infusion sonography, whereas, adenomyosis was diagnosed in 9(22.5%) patients by using Hysteroscopy. In current study, The sensitivity and specificity of SIS in diagnosing adenomyosis when compared to hysteroscopy were 77.78% and 100% respectively. Another advantage of hysteroscopy in diagnosing adenomyosis is that early changes of adenomyosis can be made out in hysteroscopy which are not seen with SIS. Positive predictive value of SIS in diagnosing adenomyosis in the present study was 100%. In the study conducted by T Usha *et al.*^[17] where PPV of SIS in diagnosing adenomyosis was 90%.

In the present study submucous fibroids were diagnosed in 2(5%) patients by using Saline infusion sonography whereas by hysteroscopy, 2(5%) patients were found to have submucous fibroid. The sensitivity and specificity of submucous fibroid when compared to hysteroscopy in patients with AUB were 100% and 100% respectively. It is similar to study conducted by B Bingol *et al.*^[18] which showed sensitivity and PPV of SIS when compared to gold standard hysteroscopy were found to be 99% and 96% respectively. Another study conducted by M Kamel *et al.*^[19] shown that sensitivity and specificity of SIS in detecting submucous myomas were found to be 94.3% and 97.6% respectively. The advantage of SIS is it can measure depth and size of leiomyomas and by using color doppler simultaneously we can measure vascularity also, but during hysteroscopy only protruding part can be visualized. Chronic Endometritis which is one of cause of AUB is present in 1 patient which is best visualized in hysteroscopy than Saline infusion sonography. It was identified by the presence of micro polyps during hysteroscopy and later confirmed by histopathological examination. Hysteroscopy has the advantage of taking a biopsy in the same setting and to be sent for Histopathological examination and TB PCR if required which is not possible with Saline infusion sonography. Endometrial sampling devices like Pipelle are not helpful for focal lesions.

Transvaginal sonography with saline infusion sonography have the advantage of diagnosing adnexal pathologies which are found in 15% of patients in present study and intramural fibroids which are found in 15% of patients and sub serosal fibroids which are present in 5% of patients but these lesions cannot be seen during hysteroscopy. Intra uterine abnormalities like adhesions which were detected in 5 patients (12.5%) were better visualized in hysteroscopy than SIS. Myometrial cysts were best visualized in saline infusion sonography but not in hysteroscopy. Post procedure pain was less following SIS than hysteroscopy. No other complications were seen in either procedures. Anesthesia and antibiotic coverage were required in hysteroscopy but not in SIS.

Thus advantage of SIS is that, uterine cavity pathologies like polyp, submucous fibroid can be detected in addition to adnexal masses and myometrial pathologies like intramural fibroids, myometrial hyperplasia and adenomyosis. This can be done conveniently in an OPD setup. The advantage of hysteroscopy is detection of uterine cavity pathologies, taking a biopsy for HPE and TB PCR. Besides this it can also detect early changes of adenomyosis and chronic endometritis. Hysteroscopy has dual advantage of see and treat approach in the same setting. Therefore it is considered as Gold standard procedure in woman with AUB.

The limitation of our study is the small sample size. More studies with more number of patients are required to know the exact diagnostic accuracy of Saline infusion sonography in relation to hysteroscopy.

Conclusion

Saline infusion sonography is simple, less painful, causes little discomfort, better tolerated, cheap, noninvasive, shorter duration, and associated with less complications. Sensitivity and specificity of SIS in detecting intracavitary pathologies is more than Transvaginal sonography. The disadvantage is not able to identify endometritis which is also a cause of AUB.

Hysteroscopy is considered as gold standard because it allows direct visualization of uterine cavity. It is more sensitive in diagnosing intrauterine pathologies compared to other procedures, and has the advantage of see and treat approach and the lesions can be biopsied at same time but the disadvantage is cost of the procedure, requires anesthesia, causes discomfort. However all these disadvantages can be overcome by doing office hysteroscopy instead of conventional hysteroscopy.

To conclude

The diagnostic accuracy of SIS in detecting the lesions like endometrial polyps, submucous fibroids, endometrial hyperplasia is almost comparable to hysteroscopy. But early changes of adenomyosis and endometritis are better detected on hysteroscopy whereas, adnexal masses and myometrial lesions are detected in SIS not on hysteroscopy.

Hysteroscopy allows direct visualization of endometrial cavity with see and treat advantage. So, it is considered as a gold standard procedure in evaluation and management of AUB.

Thus, based on the results obtained, saline infusion sonography can be used as a preliminary investigation in the women with abnormal uterine bleeding before performing hysteroscopy.

However, our study has limitation of small sample size. More studies with large number of patients are required to know the exact diagnostic accuracy of Saline infusion sonography in relation to hysteroscopy.

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