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Original Research Article

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

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ABSTRACT

Background: In patients with abnormal uterine bleeding (AUB), differentiating whether the cause is anovulation or anatomic lesions can be challenging. Transvaginal sonography (TVS) has limitation in form of high false negative rate for diagnosing focal intrauterine pathology. To improve the image in TVS, saline injected into uterine cavity can be used as a negative contrast agent. Aim of our study was to evaluate the clinical value of saline infusion sonography (SIS) by comparing its diagnostic accuracy with that of established gold standard i.e. hysteroscopy.
Methods: The study was carried out in a referral and teaching public sector hospital in eastern India from July 2015 to June 2016. Study population consisted of 136 premenopausal women with AUB, who were scheduled to undergo diagnostic hysteroscopy. Patients were first evaluated by sis and then followed by hysteroscopy on a later date.
Results: Both SIS and hysteroscopy could be successfully performed in 136 out of 144 patients. When all findings by SIS (any pathological findings in uterine cavity vs. none) were combined and compared with hysteroscopy (gold standard), both sensitivity and specificity of sis were 0.88 whereas PPV and NPV were 0.85 and 0.90 respectively.
Conclusions: Because of comparable results obtained by evaluating patients by SIS as well as office hysteroscopy, we recommend saline infusion sonography as a valuable tool for evaluating premenopausal women with abnormal uterine bleeding, before consideration for hysteroscopy.

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

INTRODUCTION

Though abnormal uterine bleeding (AUB) is a common clinical problem, it presents to the gynecologist as diagnostic dilemma. The causes of AUB are diverse, and differentiating whether the source is the result of anovulation or anatomic lesions, can be challenging.[1]

Most common modalities used to assess anatomic causes of AUB have been endometrial biopsy, curettage, transvaginal sonography (TVS) and hysteroscopy. Office endometrial sampling devices offered reduced expense, less anesthesia requirements, increased convenience and safety.[2] However, such devices have shown to have severe short comings especially in cases where the abnormality is focal and not global.[3,4]

Hysteroscopy is accepted as the "Gold Standard" for the evaluation of uterine cavity. It allows direct visualization of uterine cavity, and abnormalities can be immediately biopsied. However, there are concerns that it is a costly invasive procedure associated with its share of discomfort and risks. It is even unnecessary in 50% of patients who have normal uterine cavity.[5]

TVS, though an excellent method for imaging uterine and endometrial abnormalities, but it has limitation in form of high false negative rate for diagnosing focal intrauterine pathology.[6,7] To improve the image in TVS, saline injected into uterine cavity can be used as a negative contrast agent. Saline injection also distends the uterine walls, thereby showing structural abnormalities of the endometrium. Saline infusion sonography (SIS) is a

diagnostic technique with many advantages. It is performed comparatively in lesser time, is more cost effective and is less painful for patients than hysteroscopy. Moreover, only few gynecologists perform office hysteroscopy, whereas the USG performed either by gynecologist or radiologist in office setting is more widely available than hysteroscopy. Hence, SIS has the potential to become a practical tool in office gynecology in evaluation of abnormal uterine bleeding.

The aim of this study was to evaluate the clinical value of SIS by comparing its diagnostic accuracy with that of established gold standard i.e. hysteroscopy.

METHODS

The study was carried out in a referral and teaching public sector hospital in eastern India. Study population consisted of premenopausal women with AUB, who were scheduled to undergo diagnostic hysteroscopy. Study population was first evaluated by SIS and then followed by hysteroscopy on a later date.

Inclusion criteria for the study were premenopausal nonpregnant women with AUB and normal cervical cytology. Exclusion criteria were suspected pelvic inflammatory disease, active menstrual bleeding, and presence of adnexal masses, cervical pathology or known genital tract malignancy.

Examination was done after cessation of menses but before 10th day of menstrual cycle. Procedure was explained to each patient and consent obtained. SIS and hysteroscopy were performed separately by two specialists on each patient, who recorded their results without knowledge of each other's findings. Same specialist performed the procedure throughout the study.

For saline infusion sonography, patient was put in dorsal lithotomy position. Conventional TVS, to obtain coronal and sagittal views of uterus and adnexa was performed. This was performed on Wipro GE Medical System USG machine with a 5.0 MHz transvaginal probe. TVS probe was then removed and with aseptic precautions, anterior lip of cervix was held using Sims speculum and valsellum forceps. A sterile disposable balloon catheter (size Ch 08) was introduced into cervical orifice until it reached the fundus. The speculum was then withdrawn and TVS probe introduced. 50ml sterile syringe was attached to the catheter and slow infusion of 20-25 ml saline was done until the intrauterine cavity was clearly observed. Uterine cavity was then evaluated in coronal and sagittal views. . With the use of SIS, the diagnosis was made on the basis of the criteria described by Parsons and Lense[8], findings were defined as normal cavity (smooth endometrium with the same thickness throughout the cavity and sharp border to the myometrium and the cavity), endometrial polyp (smooth margined, echogenic mass, emerging from the endometrium and does not disrupt the myometrial – endometrial interface), submucous myoma (solid, round structure of mixed echogenicity, emanating from the myometrium), hyperplasia (diffusely and irregularly thickened endometrium with an intact endometrial-myometrial interface).whenever any lesion was detected, operative hysteroscopic procedure was done as deemed necessary.

No antibiotic prophylaxis was given. Analgesics were given as on required basis. Patients were advised to review back if: Temperature >100ºF, Foul smelling discharge or abnormal bleeding per vaginum, persistent pelvic/abdominal pain, after the procedure. Hysteroscopy was performed in operation theatre under general anesthesia using 5mm rigid 30 degree hysteroscope. Distension medium used was normal saline. The hysteroscope was advanced under direct visualization into the uterus. The masses found were characterized, measured and recorded on a separate data sheet.

RESULTS

The study was carried out from July 2015 to June 2016. A total of 144 patients consented and were enrolled for the study. In 8 patients (5.55%) either or both procedures could not be performed because of various reasons. In 2 patients (1.38%) SIS could not be performed because of cervical stenosis.

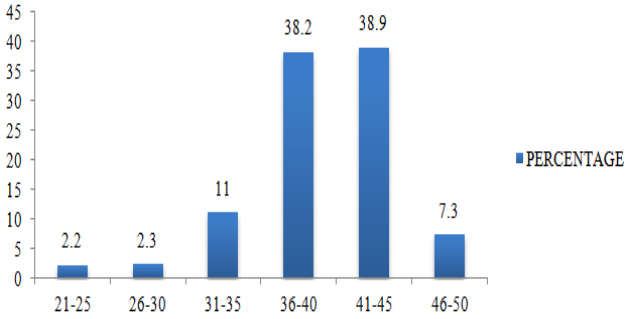

Figure 1: Age groups (years).

Four patients (2.77%) underwent SIS but did not report for hysteroscopy. In two patients (1.38%) SIS could not be successfully performed due to poor visualization due to failure of distension of uterine cavity. On hysteroscopy, these patients were found to have dense synechiae (Asherman's). These eight patients hence, were not included in the analysis. The age distribution of the patients is shown in Figure 1. Abnormal uterine bleeding was commonest in the age group 41-45 years (38.9%); followed closely by the age group between 36-40 years (38.2%).The mean age was 39.44 years (25-51years).

Nature of menstrual disorders

Patients presented with different forms of AUB. The duration of symptoms were ranging from three months to one year. Various symptoms presented and their

percentages are depicted in Figure 2. In our study, menorrhagia (58.8%) was the most common symptom.

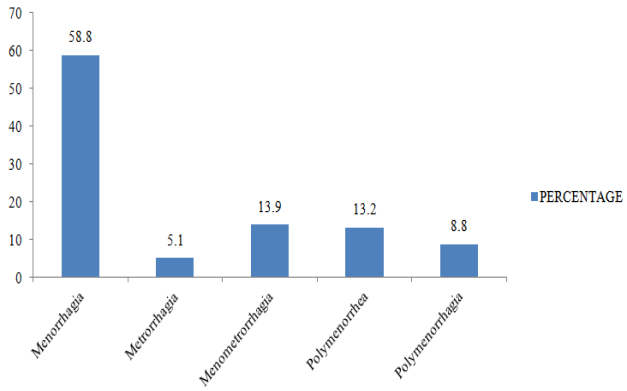

Figure 2: Symptoms.

Total no. of uterine cavity abnormalities, alone or in combination with other lesions as detected by SIS and hysteroscopy (gold standard) are shown in Figure 3.

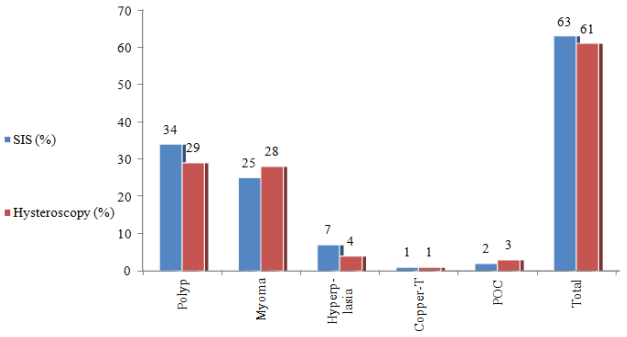

Figure 3: Uterine cavity abnormalities detected by SIS and hysteroscopy.

Figure-3 compares the number of various uterine lesions as detected by both SIS and hysteroscopy. SIS detected 30 patients with intrauterine polyps, submucous myoma in 19 patients, endometrial hyperplasia in 5 patients, polyps were diagnosed co-existing with myoma in 4 patients and 2 patients had myoma co-existing with endometrial hyperplasia. Intrauterine device (Copper-T) was found in 01 and products of conception (POC) were diagnosed in 2 patients.

Whereas hysteroscopy detected 26 patients with intrauterine polyps, submucous myoma in 24 patients, endometrial hyperplasia in 3 patients, polyps were diagnosed co-existing with myoma in 3 patients. One patient had myoma with coexisting endometrial

This data was used to construct 2 x 2 tables for calculating sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of SIS in diagnosing various uterine cavity lesions. When all findings (any pathological findings Vs none) were combined, both sensitivity and specificity of SIS were 0.88 whereas PPV and NPV were 0.85 and 0.90 respectively (Table 2).

SIS versus hysteroscopy

Both procedures were performed in 136 patients with AUB. Hysteroscopy identified 75 normal uterine cavities (55.1%) and 61 patients (44.85%) were detected to have abnormalities. The results obtained by SIS were compared with those found on hysteroscopy (Table 1).

Table 1: Uterine cavity evaluation by SIS and hysteroscopy.

Lesions	SIS	Hysteroscopy
Polyp	30	26
Polyp + Myoma	04	03
Myoma	19	24
Myoma + Hyperplasia	02	01
Hyperplasia	05	03
Cu T	01	01
Products of conception	02	03
No of uterine cavities with lesions (Total of above ser no 1-7)	63	61
Normal cavity	73	75
Total no of patients (II +III)	136	136

Table 2: Diagnostic potential of SIS with hysteroscopy as gold standard.

	Polyp	Myoma	Hyperplasia	Copper-T	POC	All intracavitory lesions
Sensitivity	0.79	0.85	1.0	1	0.66	0.89
Specificity	0.89	0.99	0.97	1	1	0.89
Positive Predictive Value (PPV)	0.67	0.96	0.57	1	1	0.87
Negative Predictive Value (NPV)	0.94	0.96	1.0	1	0.99	0.90

hyperplasia. Intrauterine device and POC were diagnosed in 01 and 03 patients respectively. Average time taken for SIS was 6.3 minutes from insertion of catheter to completion of the procedure.

In present study while performing SIS, we could detect eleven patients with intramural fibroids; five had ovarian cysts and two patients had adnexal mass (Figure 4). No infection or complication occurred during the study while performing SIS or hysteroscopy.

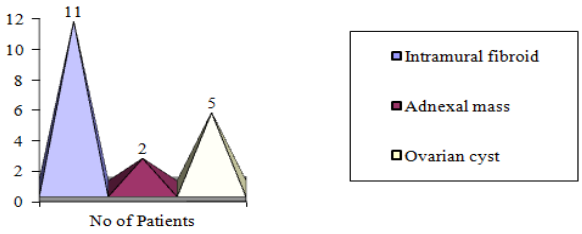

Figure 4: Evaluation beyond endometrium.

Table 3: Incidence of uterine cavity abnormalities.

Study	Normal cavity (%)	Polyp (%)	Myoma (%)	Polyp and myoma (%)	Hyperplasia (%)	Other lesions
Widrich et al N=113[11]	49.4	21.2	18.6	3.5	2.7	Endometrial cancer-0.9%, Synechiae-2.7%
Indman N= 234[9]	41	20	31	3	2	Endometrial cancer 1%, others 2%
Towbin N= 149[12]	24	22	33	5	4	Adenomyosis 11%, others 1%
Rudra[13] N=200	56	14	24.5	1	1.5	Synechiae- 2.7%, POC-3%
Present study (N=136)	55.14	19.1	17.6	2.2	2.2	Cu- T 0.7%, POC 2.2%, Myoma and Hyperplasia- 0.7%

Table 4: Studies reporting diagnostic accuracy of SIS for endometrial abnormalities.

First author	Year	No. patients (status)	Reference test	SIS			
				Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Widrich[11]	1996	113 (Pre and Postmenopausal)	Hysteroscopy	96	88	89	96
Rudra[13]	2009	200 (Pre and Postmenopausal)	Hysteroscopy	90	88	86	92
Kroon[16]	2003	877 (Pooled homogenous data from pre and post menopausal)	Hysterectomy and/or Hysteroscopy	95 (CI 93 to 97)	88 (CI 85 to 92)	-	-
Chawla[17]	2014	60 (Pre and Postmenopausal)	Hysteroscopy	89	100	100	73
Current study	2016	136 Premenopausal	Hysteroscopy	88	88	85	90

DISCUSSION

In our study, the age distribution was from 25 years to 51 years. Age group 36-45 years constituted 77.1% patients our study group. Maximum patients (38.9%) were from age group 41-45 years. Indman PD[9] in his study of abnormal uterine bleeding reported 43.2% patients from the age group 40-49 years. We found menorrhagia to be the commonest symptom (58.8% of patients reported with AUB). Finikiotis G also reported menorrhagia in 62% of the cases of AUB.[10]

Incidence of various uterine abnormalities reported in literature (Table 3), in patients with AUB has been in the range of 44% to 76%. We found the incidence of uterine cavity abnormality to be 44.7 % and we did not come across any patient with endometrial carcinoma or synaechiae. Many studies (Table 4) have been done using SIS to diagnose endometrial abnormalities and they have reported upon diagnostic accuracy of SIS compared with the gold standard of hysteroscopy or hysterectomy in prospective, blinded fashion.[11,14,15] Present study determined both sensitivity and specificity to be 0.88 for

SIS, when compared with hysteroscopy. For diagnosing endometrial polyps, our study revealed sensitivity of 79% and specificity to be 89%. The PPV and NPV were 67% and 94% respectively. While evaluating submucous myomas, SIS showed sensitivity of 85% and specificity of 99%. The PPV and NPV were both 96%.

Table 5: Diagnostic accuracy of SIS for various endometrial pathologies.

Pathology		Our study (%)	Widrich et al[11] (%)	Rudra et al[13] (%)	Meta-analysis by Kroon et al[16] (%)	Nallapati et al[18] (%)
Endometrial polyp	Sensitivity	79	87	93	86% (95% CI 81%-91%)	90.9
	Specificity	89	90	94.1	81% (95% CI 72%-88%)	92.68
Submucosal fibroid	Sensitivity	85	93	88.2	87% (95% CI 79%-92%)	86.36
	Specificity	99	99	97.3	92% (95% CI 86%-95%)	83
Endometrial hyperplasia	Sensitivity	100	100	100		100
	Specificity	97	95	97.9		94

Various studies (Table 5) have shown similar results in diagnosing polyps, submucous fiborids and hyperplasia. Widrich et al[11] in his study found sensitivity of 87% and specificity of 90% for diagnosing polyp by SIS, where as for diagnosis of submucous fibroids, sensitivity and specificity were 93% and 99% respectively. He suggested that, distinguishing between large polyps and pedunculated myoma is difficult with either technique, since both these pathologic conditions can be treated with hysteroscopic resection; hence the treatment does not change even if lesions are confused with each other.

In the meta-analysis done by Kroon et al[16], pooled sensitivity and pooled specificity of SIS for endometrial polyps was 86% (95% CI 81%-91%) and 81% (95% CI 72%-88%) respectively. For intrauterine fibroids pooled sensitivity and pooled specificity of SIS was 87% (95% CI 79%-92%) and 92% (95% CI 86%-95%) respectively. For hyperplasia, sensitivity of SIS in our study was very high i.e. 100% and the specificity was 97%. Various other studies of SIS also reported 100% sensitivity and 94%-97.9% specificity for hyperplasia (Table 5). In three patients having retained POC, SIS could diagnose correctly in two patients. Thus by SIS, sensitivity and specificity for products of conception was 66% and 100% respectively.

The average time for SIS was 6.3 minutes from insertion of catheter to completion of the procedure. During initial part of the study, time taken was comparatively longer, but as the expertise gained, the procedure could be completed in lesser and lesser time. Usually it took < 15 minutes to complete transvaginal sonography and SIS. Widrich et al[11] have reported an average time of 3.5 minutes in their study.

No infection or complication occurred during the study while performing SIS or hysteroscopy. There have been no published reports of uterine perforation with SIS. SIS decreases the need of expensive equipment for outpatient hysteroscopy and it may be helpful especially in hospitals where office hysteroscopy is not available. Moreover, it may be a valuable technique even when hysteroscopy is available, as an initial screening test to triage patients who may benefit from hysteroscopy. Chambers and Chambers[2] concluded that the expense and time involved in the use of hysteroscopy are not justified for routine evaluation of women with abnormal uterine bleeding. Williams and Marshburn[19], in their study found that, if SIS had been used to triage their patients to determine whether hysteroscopy was indicated, 23 out of 39 women (59%) would not have needed diagnostic (office) hysteroscopy. In present study, SIS could successfully rule out abnormality in 48.5% patients. The results were comparable with both diagnostic techniques i.e. SIS as well as office hysteroscopy. Hence, we too believe in the conclusion, as derived by Goldstein et al[20] that, hysteroscopy with curettage should be reserved for those patients with demonstrated focal abnormality on SIS, who are in need of visually directed removal or whose ultrasonographic triage was unable to exclude significant abnormality.

CONCLUSION

PIH was the most common etiology of high risk pregnancy. Doppler velocimetry was better in predicting

fetal compromise in comparison to NST in high risk pregnancies. Normal NST and normal Doppler velocimetry were not significantly different in prediction of fetal outcome. Abnormal Doppler value was better in predicting fetal compromise in comparison to abnormal NST. Cerebroplacental ratio was very accurate and was good predictor of adverse perinatal outcome. Both NST and Doppler velocimetry complemented each other in fetal surveillance of high risk pregnancy, although Doppler studies were more efficacious.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee of SMIMS

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