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Original Research Article

## Role of saline infusion sonography in evaluation of abnormal uterine bleeding

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### ABSTRACT

**Background:** Abnormal uterine bleeding (AUB) is one of the most common reasons for women seeking gynaecological advice. The objective of this study was to determine the accuracy of Transvaginal sonography (TVS) and Saline Infusion Sonography (SIS) in evaluation of Abnormal Uterine Bleeding (AUB) and to compare the diagnostic accuracy after hysterectomy.

**Methods:** Prospective, comparative study of TVS and SIS in evaluation of AUB in patients who are being subjected to hysterectomy with uterus of less than 12 weeks.

**Results:** 100 patients were included in the study. 98% were of 30-50 years. Heavy menstrual bleeding was the commonest symptom (52%) and most common finding was fibroid, and Polyp followed by abnormal endometrium. The overall sensitivity and specificity when correlated with operative and HPE were 66% and 88% respectively for TVS and 82% and 95% for SIS respectively. The false positive and false negative rates were more in TVS compared to SIS. Commonest histopathology was intramural fibroid in 42% followed by sub mucus myoma in 21%, polyp 18% and endometrial hyperplasia 10%.

**Conclusions:** SIS is a simple highly sensitive and specific technique to detect intra uterine pathology in the evaluation of AUB when TVS findings are inconclusive.

**Keywords:** DH (Diagnostic Hysteroscopy), HPE (Histopathology), HMB (Heavy menstrual bleeding), SIS, TVS

### INTRODUCTION

Abnormal uterine bleeding (AUB) is one of the most common reasons for women seeking gynaecological advice. It accounts for 15% of office visits and about 25% of gynaecological surgeries.<sup>1</sup> Other than dysfunctional uterine bleeding (DUB), intrauterine abnormalities are the leading cause of AUB.

The most common anatomical causes of AUB in 40% pre-menopausal women are sub-mucosal fibroids, endometrial polyps and endometrial hyperplasia.<sup>1,2</sup> The most frequent procedure performed on women with

abnormal uterine bleeding is transvaginal ultrasound. For many years the most common accepted approach for the management of abnormal uterine bleeding has been the TV scan followed by therapeutic hysteroscopy combined with a histological examination of the obtained specimen.

Trans-vaginal sonography (TVS) is used as an initial investigation because it is easy, rapid and cost effective, but it is unable to differentiate intrauterine pathology with complete certainty.<sup>3</sup>

The gold standard for diagnosis of intrauterine abnormalities is diagnostic hysteroscopy combined with a

histological examination of endometrial aspiration or biopsy. Hysteroscopy is invasive, reasonably expensive, time consuming, and involves anaesthesia. Hysteroscopy is also associated with risks like uterine perforation and ascending genitourinary infection.<sup>4</sup>

Saline infusion sonography (SIS) in comparison to hysteroscopy is less invasive, cheaper, and does not require anaesthesia. SIS reliably evaluates uterine contour, adhesions, and focal pathologies. Furthermore, in SIS, after distending the cavity with saline, there is clear visualization of the inner surface of both sides of the endometrium.<sup>5</sup> Focal and diffuse abnormalities can be distinguished, and in most cases an endometrial polyp can be differentiated from the submucous fibroid based on the imaging characteristics. The polyps are typically round in shape, smooth in outline, and are generally echogenic, compared to the endometrium or are isoechoic to it. The underlying endometrial-myometrial interface is preserved.

The presence of a vascular pedicle has a positive predictive value of up to 81.3%. Fibroids are more homogeneous, hypoechoic, and there is a loss of endometrial-myometrial interface. The percentage of the intracavitary portions of the submucous fibroids can be assessed by SIS. In addition, the submucous fibroids can be differentiated from the intramural fibroids that are distorting the cavity. Thus, by distending the inner walls of the endometrium, focal and diffuse lesions can be identified, along with the location and size of the pathology, with reasonable accuracy.<sup>6-9</sup>

SIS is easily accepted by most patients as an outpatient procedure. Complications are rare with SIS. The patient may experience anxiety, discomfort, and mild lower abdominal cramps during balloon inflation and instillation of saline.<sup>10</sup> However, the symptoms abate soon after the end of the procedure.

Vaginal spotting may also occur for one or two days after the procedure. Only 1% to 2% infection was reported, mostly as endometritis.<sup>11,12</sup> The procedure is usually well-tolerated. The purpose of the study was to assess whether saline infusion sono-hysterography (SIS) can replace diagnostic hysteroscopy (DH) for the diagnosis of endometrial pathology in patients with abnormal uterine bleeding.

## METHODS

This study was done at Department of Obstetrics and Gynaecology of tertiary care centre of Uttar Pradesh, India from January 2015 to July 2016 after obtaining permission from the institutional ethics committee.

In this prospective study, 100 pre and peri menopausal patients with abnormal uterine bleeding were at randomly included in the study. Only those women having AUB with uterine size less than 12 weeks and having no other

significant medical history were included in the study. Patients having acute pelvic infection, pregnancy, endometrial carcinoma (diagnosed/suspected) were excluded from the analysis.

Procedure of this study detailed history was taken, and relevant examination was done. TVS and SIS were performed with the help of 7.5 MHz vaginal probe a day before surgery. After performing baseline ultrasound, the uterus was imaged in the sagittal plane, which includes the entire length of cervical canal. As per the TVS normal endometrium and uterine cavity were defined by a centrally placed echo-dense line within the uterus and a homogeneous endometrial lining with distinct margins to the myometrium.

Thickness of endometrium was measured from basalis to basalis in the longitudinal plane. Both wall of the endometrium individually and added together was used for measuring endometrial thickness on SIS. SIS was performed just after TVS without scheduling for the phase of the menstrual cycle.

For SIS 8 number Foley's catheter was introduced into uterine cavity, bulb inflated with 3 ml of normal saline and mild traction given so as to place the bulb at the internal OS. 50 ml of syringe contain normal saline was attached to the catheter. Vaginal probe was introduced, and sterile saline was infused until the distension of uterine cavity was adequate to see any lesion or till pain appears and findings were noted. 15 to 30 ml saline was used in the majority cases.

Macroscopic inspection of hysterectomy specimen and histological examination were compared with the findings at SIS and TVS. Investigators involved in examination of these specimens were not aware about the findings of each other.

## Statistics analysis

The data was reported in the form of frequency, percentages. Sensitivity, specificity, positive predictive value, negative predictive values were calculated. Diagnostic accuracy test (DA test) was used to assess the accuracy for this method and the test was statistically significant ( $P < 0.05$ ). Open epi software and SPSS version 17 and Medcale was used for data analysis.

## RESULTS

Majority of patient (92%) were between ages 31-50 years. Maximum 52% of patients were having uterine size between bulky to 6 weeks. HMB, meno-metrorrhagia and polymenorrhea were most common complain on presentation (Table 1).

As per histopathology report among the patients with abnormal histopathology, most common types were

Intramural myoma (50%), Polyp (18%) and submucous fibroid (14%) (Table 2).

**Table 1: Demographical and clinical parameters of the subjects included in the study.**

Parameters	Subjects (n=100)
<b>Age (in years)</b>	
31-40	41
41-50	51
51-60	8
<b>Uterine size</b>	
Normal	14
Bulky to 6 weeks	52
6-8 weeks	20
8-10 weeks	8
10-12 weeks	6
<b>Parity</b>	
Primi parous	2
Multiparous (<4)	31
Grand multiparous (>4)	67
<b>Symptoms</b>	
Heavy menstrual bleeding (HMB)	64
Meno-metrorrhagia	10
Polymenorrhoea	10
Metrorrhagia	2
Dysmenorrhoea	2
Continuous bleeding	12

Values in parenthesis are percentages

**Table 2: Findings of TVS and SIS.**

Findings	TVS No. (%)	SIS No. (%)
Intramural fibroid uterus	48 (48)	50 (50)
Submucous fibroid	18 (18)	14 (14)
Polyps	16 (16)	18 (18)
Myohyperplasia/adenomyosis	10 (10)	10 (10)
Thickened endometrium	06 (6)	05 (5)
Normal endometrium	02 (2)	02 (2)
Endometrial cavity could not be distended	-	01 (1)
Total (n)	100	100

Table 3 shows comparison of TVS and SIS findings with HPE reports. It shows that, 2 cases of intramural myoma were falsely diagnosed as sub mucosal myoma, out of 18 cases of polyp, 2 cases were missed, and one case of abnormal endometrium was missed on TVS.

Comparison of TVS and SIS efficacy is mentioned in Table 4, TVS findings has overall sensitivity of 71.43, specificity 67.7, PPV 54.35, NPV 81.48, DA 69, LR positive 2.22 and negative 0.42 while SIS has sensitivity of 92.86, specificity 89.65, PPV 86.67, NPV 94.54, DA 91, LR positive 8.98 and negative 0.07 (P<0.05). For submucosal fibroid, Sensitivity was 61.54 and specificity 97.67%. For polyp false positive were 3, false negative was 5, sensitivity 70% and specificity 95.35%.

**Table 3: Comparison of TVS and SIS findings with intra operative hysterectomy and HPE.**

	TVS	SIS	HPE
Intramural fibroid uterus	48 (48)	50 (50)	50
Submucous fibroid	18 (18)	14 (14)	14
Polyps	16 (16)	18 (18)	18
Myohyperplasia/adenomyosis	06 (06)	6 (6)	6
Abnormal endometrium	04 (4)	05 (5)	5
Normal endometrium	08 (8)	07 (7)	7

**Table 4: Comparison between TVS and SIS.**

Test	TVS	SIS
Sensitivity	71.43 (54.94% to 83.67%)	92.86 (80.99 to 97.54)
Specificity	67.7 (55.61 to 77.79)	89.65 (73.82 to 93.74)
PPV	54.35 (40.18 to 67.84)	86.67 (73.82 to 93.74)
NPV	81.48 (69.16 to 89.61)	94.54 (85.14 to 98.12)
DA	69 (59.94 to 78.06)	91* (85.44 to 96.61)
<b>Likelihood ratio</b>		
Positive	2.22 (1.47 to 3.33)	8.98 (4.19 to 19.24)
Negative	0.42 (0.25 to 0.72)	0.07 (0.03-0.24)

\*p=0.002 Note Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy (DA) data are percentages. All numbers in parentheses are 95% CIs.

Table 5 shows comparison of SIS findings with HPE reports. For intramural myoma and sub mucosal myoma SIS findings were correlated well with intra operative findings and HPE reports with sensitivity of 100% and specificity of 100%, and for polyp showed sensitivity of 100% and specificity of 97.85% while sensitivity and specificity of TVS for submucous fibroid was 61.54 and 96.67 and for polyp was 70 and 95.35 respectively. Thus, it is clear from Table 4 and Table 5 SIS has higher sensitivity and specificity (P <0.05) in comparison to TVS.

Table 6 shows diagnostic performance of TVS and SIS. The SIS was more sensitive and specific as compared to TVS alone. The positive predictive value of SIS was 96.08% as compared to 95.56% for TVS. The diagnostic accuracy of SIS (98%) was better than that of TVS (92%).

## DISCUSSION

AUB is an important and common problem encountered in Gynecology practice. Endometrial and uterine abnormalities such as leiomyoma, polyps and hyperplasia are more common than was previously thought. Though

TVS is the first imaging modality of choice for the evaluation of endometrial cavity in AUB of less than 12 weeks size uterus, it has limitations in detecting small lesions, location of myoma and in differentiating diffuse

and focal lesion. Hysteroscopy has been considered as the gold standard, but it is expensive, invasive and does not contribute in the evaluation of myometrial or ovarian pathology.

**Table 5: Comparison of TVS and SIS findings with intra operative hysterectomy and HPE.**

Diagnosis	Endometrial Hyperplasia (abnormal Endometrium)		Endometrial Polyp		Submucous myoma	
	TVS	SIS	TVS	SIS	TVS	SIS
Test Performance						
Sensitivity	81.25 (56.99-93.40)	93.75 (71.75-98.88)	70 (39.67-89.22)	90 (59.58-98.21)	61.54 (35.52-82.29)	100 (77.19 to 100)
Specificity	73.68 (61.02-83.35)	91.23 (81.05-96.19)	95.35 (84.54-98.71)	98.11 (90.05-99.66)	97.67 (87.94-99.58)	100 (93.12-100)
PPV	46.43 (29.53-64.18)	75 (53.12-88.81)	77.78 (45.25-93.67)	90 (59.58-98.21)	88.89 (56.50-98.01)	100 (77.19-100)
NPV	93.33 (82.14-97.70)	98.11 (90.05-99.66)	93.18 (81.77-97.65)	98.11 (90.05-99.66)	89.36 (77.40-95.36)	100 (93.12-100)
DA	75.34 (65.45-85.23)	91.78* (85.48-98.08)	91.57 (82.70-98.44)	96.83 (92.50-101.15)	89.36 (81.18-97.39)	100.00**
Likelihood Ratio Positive	3.09 (1.88-.5.06)	10.69 (4.58-24.92)	15.05 (3.66-61.82)	47.7 (6.77-336.05)	26.46 (3.64-192.45)	CO
Likelihood Ratio Negative	0.25 (0.09-0.71)	0.07 (0.01-0.46)	0.31 (0.12-0.81)	0.10 (0.02-0.65)	0.39 (0.2-0.78)	0

**Table 6: Overall efficiency of SIS compared with TVS.**

Study	Procedure	Sensitivity %	Specificity %	Predictive Value	
				PPV %	NPV %
Ryu JA et al	SIS	95	83	95	83
	TVS	79	46	83	39
Saidi et al	SIS	90.9	83.3	90.9	16.7
	TVS	95.7	63.6	84.6	12.5
Reddy Rani P et al	SIS	82	95	81	93
	TVS	65.5	88	68	90
Goyal et al	SIS	100	96.08	96.08	100
	TVS	87.76	96.08	95.56	89.09
Present Study	SIS	92.86	89.65	86.67	94.54
	TVS	71.43	67.7	54.35	81.48

Heavy menstrual bleeding (menorrhagia) was the commonest symptom in 64% of the cases and the most common lesion was intramural myoma in 50% similar to the finding of Laughead et al.<sup>1</sup> TVS failed to locate the exact site of myoma in 12% of the cases in our study. Hill in his study found that TVS was not able to determine the location of myoma in 10% the cases, whereas SIS helped to take exact measurement of myoma and also in determining the depth of penetration in to the myometrium.<sup>2</sup>

Present study showed that SIS has higher sensitivity 92.46 and specificity 89.65 when compared with TVS with sensitivity 71.43 and specificity 67.7. Similar findings were seen in the studies by Saidi et al (Table 6).<sup>5</sup>

De Kroon et al in a meta analysis reviewed 16 studies comprising 877 procedures to determine the diagnostic accuracy of SIS in perimenopausal women with AUB and comparing it to hysteroscopy with or without HPE or hysterectomy, found sensitivity of SIS for evaluating the uterine cavity was 0.95 and pooled specificity was 0.88 and the sonographic procedure was successful in 86.5%.<sup>4</sup>

Dueholm et al in their study of 105 patients found the sensitivity and specificity of saline infusion sonohysterography for detection of polyps were significantly higher than for transvaginal ultrasound alone (93 and 94 versus 75 and 76 percent for TVS) and were comparable to hysteroscopy.<sup>5</sup> SIS is found to be more accurate than TVS to visualize the endometrial cavity Kazandi et al.<sup>6</sup> TVS cannot distinguish endometrial hyperplasia from

polyps as both can cause thickening of the endometrium, are hyperechoic and can contain cystic spaces whereas SIS can detect focal lesions from diffuse thickening.

SIS correlation with intraoperative hysterectomy findings and HPE for submucous myoma showed sensitivity of 100% and specificity of 100% with 0% positive and negative LR, whereas with TVS there was good correlation for intramural myoma but with sub mucous myoma sensitivity was 61.54% and specificity was 97.67% with a LR positive rate of 26.46% and negative rate of 0.39%. All imaging techniques have a number of false results even in experienced hands. In the present study false positive and negative were higher in TVS than SIS which was due to large intramural myoma compressing the cavity, hemorrhagic debris, sessile polyps, and polyps arising from endocervix or when the inflated foley's bulb compresses these lesions. Ryu et al found 12% false negative and false positive cases in TVS which were due to small polyps of less than 5 mm, synechia and chronic endometritis.<sup>7</sup>

Overall sensitivity, specificity, PPV and NPV of SIS in present study were as 92.86, 89.65, 86.67 and 94.54 in comparison to that of TVS i.e.71.43, 67.7, 54.34 and 81.48. These are comparable with the results observed by Reddi et al and Goyal et al (Table 6).<sup>8,9</sup>

One postmenopausal women (1%) experienced severe pain in our study whereas in the study by Cicinelli et al 11% of the patients experienced severe pain.<sup>10</sup> The pain due to distension of uterine cavity can be minimized if saline instillation is controlled and stopped as soon as the lesion is detected. There was no evidence of infection in our study. Chung et al in their review of 900 procedures of SIS observed infection rate of 0.6%.<sup>11</sup> Bonnamy et al found 1% infection rate and 1% pelvic pain.<sup>12</sup>

## CONCLUSION

TVS is a simple, minimally invasive low-cost technique and it should be the first diagnostic method of choice in evaluating AUB. The appropriate clinical place for SIS is a second line diagnostic procedure in the evaluation of AUB if TVS findings are inconclusive.

It is highly sensitive and specific especially for diagnosing, submucous myoma, endometrial polyps and thickened endometrium. It is an alternative to hysteroscopy with the additional advantage of evaluating myometrial and adnexal pathology besides being less invasive and cost effective.

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