

## Original Research Article

# Abnormal uterine bleeding in peri and post menopausal women: comparison of efficacy of saline infusion sonography with transvaginal sonography

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## ABSTRACT

**Background:** Abnormal uterine bleeding (AUB) can present with menorrhagia or metrorrhagia but cannot indicate the cause of the bleeding, so further investigation is always needed. This study aimed to assess the role of Saline infusion sonography (SIS) in evaluating the intracavitary uterine lesions in comparison to transvaginal ultrasound (TVS) and thereby short listing the patients for hysteroscopy.

**Methods:** This prospective analytical study was conducted in 64 women presenting with AUB in OBG department, Mazumdar Shaw Medical Center, Bangalore from November 2014 to November 2015. Transvaginal ultrasound, followed by SIS were performed for all. Hysterectomy specimen (gross cut section and histopathology) taken as gold standard. Findings at TVS and SIS were compared with gold standard.

**Results:** Findings were analysed by Chi-square test. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of SIS and TVS in detecting intracavitary abnormalities were calculated. SIS found to be more sensitive and specific when compared to TVS. Discrepancies in detection of polyp seen. 13 cases of polyp were missed in TVS, indicating high false negative rate of TVS, whereas no polyps were missed by SIS. In our present study, ET (endometrial thickness) of more than 18 mm was observed in TVS in 6 cases and all these cases turned out to be polyp in SIS, indicating need of SIS or hysteroscopy whenever ET is more than 18 mm in TVS.

**Conclusions:** Study results have substantiated that SIS is a better tool as compared to TVS for the assessment of uterine intra-cavitary lesions especially polyps.

**Keywords:** Abnormal uterine bleeding, Intracavitary, Polyp, Saline infusion sonography, Thickened endometrium transvaginal sonography

## INTRODUCTION

Abnormal uterine bleeding is a distressing and important cause of ill health in peri and postmenopausal women because of increased number of uterine lesions, which require ruling out malignancy. The most frequent symptom suggestive endometrial pathology is abnormal uterine bleeding. It accounts for 30-40% of cases in the outpatient clinic.<sup>1</sup> Abnormal uterine bleeding includes heavy and/or prolonged periods (menorrhagia) as well as

those with bleeding in between periods (irregular uterine bleeding).<sup>2</sup> AUB cannot indicate the cause of the bleeding, so further investigation is always needed. The choice often lies between taking an out-patient endometrial pathology and arranging for an ultrasound scan to measure the endometrial thickness or performing an in-patient hysteroscopy, or arranging for an out-patient hysteroscopy.<sup>3,4</sup> A diagnostic hysteroscopy proves less effective unless a therapeutic procedure is followed. Saline infusion sonography causes distension of the

uterine cavity, thereby enabling visualization of the endometrial surface. This technique appears to be less discomforting, less invasive, affordable and in many cases as useful as a diagnostic hysteroscopy. The aim of this study was to assess the role of SIS in evaluating the intra-cavitary uterine lesions in comparison to transvaginal ultrasound (TVS) and thereby short listing the patients for hysteroscopy.

## METHODS

This was a prospective, analytical study was conducted in OBG and Ultrasound Department, Mazumdar Shaw Medical Center, Bangalore from November 2014-November 2015. The study was commenced after getting ethical approval from Institutional Ethical Committee. Sample size was 64.

### Inclusion criteria

Inclusion criteria were women of peri and postmenopausal age group between 40-57 years with abnormal uterine bleeding.

### Exclusion criteria

Women with pelvic inflammatory disease, frank malignancy of genital tract, systemic disorders like hypothyroidism, bleeding disorders were excluded from the study.

All women fulfilling the above inclusion criteria were included in the study after taking an informed written consent for participation in the study. They were subjected to a detailed history, clinical gynecological examination, systemic examination and routine Pap smear as per proforma. All the necessary blood investigations were done. Each procedure is explained in detail to every patient well before the procedure.

The patient was given injection hyoscine butylbromide and injection atropine, intramuscularly half an hour before the procedure. Prophylactic antibiotic (tablet azithromycin 1 gm) was given. The patient was asked to empty the bladder before the procedure and then placed in dorsal position with legs flexed. A baseline TVS was performed first using endovaginal probe of 7.5 MHz (covered by a condom) the appearance of the endometrium, myometrium, and adnexae was noted. The uterus was imaged in the midsagittal plane, which includes the entire length of the cervical canal, as a landmark for orientation. Maximum endometrial thickness was measured. The current convention was to measure both walls of the endometrium together, unless there was fluid in the cavity, in which case they were measured individually and added together. The transducer was turned 90°, and the uterus was scanned in the transverse view from cervix to fundus. TVS probe was then removed and cervix swabbed with the povidone iodine solution. Sonosalpingography catheter (SION

device) is inserted gently into the uterine cavity. The catheter can be primed with fluid before insertion in order to minimize air artifacts. The speculum is removed, holding the catheter in place, and the saline-filled syringe (20 cc) is attached to the catheter. The vaginal probe, with plenty of lubricant over the protective sheath, is re-inserted above the catheter in anteverted uterus, and below the catheter in retroverted uterus, to avoid dislodgement. The same sagittal and transverse maneuvers are performed to study the entire uterine cavity surface while slowly infusing saline until the walls are adequately expanded or the patient complains of pain. This amounts to about 2-4 cc of saline in a postmenopausal woman, and 5 to 20 cc in a premenopausal woman. The endometrial cavity was examined for the presence of polyps, adhesions, septum, or submucosal myoma. Any projection inside the uterine cavity was observed with special attention to its shape and echogenicity, evidence of abnormal endometrial thickening was also noted and documented. After the completion of procedure, the catheter is removed gently.

### Statistical methods

The statistical analysis was performed by STATA11.1 (College Station TX USA). To validate the findings between TVS and SIS, sensitivity and specificity, positive and negative predictive values are used. Findings were analyzed by Chi-square test. Categorical variables are described as frequency and percentage. Continuous variables are described as mean and standard deviation.  $P < 0.05$  was considered as statistically significant.

## RESULTS

This study was conducted in 64 peri and postmenopausal women to compare the ability of transvaginal ultrasonography and saline infusion sonography as initial modality for the diagnosis of intracavitary lesions in women with AUB. Hysterectomy specimen taken as gold standard. As the indications for hysterectomy was restricted to a few cases, so out of 64 patients, 44 cases underwent surgery (including 2 hysteroscopy and procedure) and 20 cases were either medically managed or lost follow up. The hysterectomy specimen was examined both grossly and histopathologically. Findings were compared with the findings at TVS and SIS.

**Table 1: Age distribution of patients studied.**

Age in years	Number of patients	%
40-45	34	53.1
46-50	16	25.0
51-55	10	15.6
>55	4	6.3
<b>Total</b>	<b>64</b>	<b>100.0</b>

Age range for the patients was 40-57 years. The maximum age incidence seen between 40-45 years

(53.1%). The youngest patient was 40 years old and the oldest was 57 years old. Majority of the patients, i.e., 40 (62.5%) presented with menorrhagia. The second most common presenting symptom was menometrorrhagia 11 (17.2%). 10 (15.6%) patients had presented with postmenopausal bleeding and 3 (4.7%) patients with polymenorrhagia. Of the 64 patients, 59 (92.2%) were multiparous women, 5 (7.8%) were nulliparous.

In the present study, the age range for the patients was 40-57 years. The maximum age incidence was between 40-45 years (53.1%). The youngest patient was 40 years old and the oldest was 57 years old.

**Table 2: TVS findings.**

TVS Findings	No. of patients (n=64)	%
Normal	9	14.1
Submucosal fibroid	15	23.4
Post i.m. fibroid	9	14.1
Thickened endometrium	9	14.1
Ant i.m. fibroid	7	10.9
Multiple i.m. fibroid	6	9.4
Polyp	5	7.8
Fundal i.m. fibroid	4	6.3
Focal irregular thickening	0	0.0
Synechiae	0	0.0

In the present study, cut off for thickened endometrium in postmenopausal women was taken as 4 mm and in premenopausal women as 12 mm. In the present study, minimum ET seen was 3 mm and maximum of 25 mm.

Abnormal TVS findings were noted in 55 patients (85.1%), whereas in the remaining 9 cases (14.1%) there was no abnormality detected on TVS as shown in Table 2. The most common finding on TVS was submucosal fibroid which constituted 15 cases out of 64 (23.4%). Polyp was noted in 5 cases (7.8%).

**Table 3: SIS findings.**

SIS findings	No. of patients (n=64)	%
Normal	5	7.8
Submucosal fibroid	15	23.4
Post i.m. fibroid	7	10.9
Thickened endometrium	3	4.7
Ant i.m. fibroid	6	9.4
Multiple i.m. fibroid	5	7.8
Polyp	18	28.1
Fundal i.m. fibroid	3	4.6
Focal irregular thickening	1	1.6
Synechiae	1	1.6

As shown in Table 3, abnormal SIS findings were noted in 59 patients (92.2%), whereas in the remaining 5 cases

(7.8%) there was no abnormality detected on SIS. The most common finding on SIS was polyp which constituted 18 cases out of 64 (28.1%).

**Table 4: Hysterectomy specimen: gross cut section.**

Hysterectomy specimen: gross cut section	No. of patients	%
Normal	3	6.8
Submucosal fibroid	13	29.5
Polyp	13	29.5
i.m. fibroid	12	27.3
Adenomyosis	3	6.8
Total	44	100.0

Out of 64 patients studied, 44 cases (68.8%) underwent surgery and 20 cases (31.3%) were managed medically or lost follow up as shown in Table 3. The hysterectomy specimen was examined both grossly and histopathologically.

On gross cut section of hysterectomy specimen abnormal findings were noted in 41 cases (93.2%) whereas 3 patients (6.8%) had normal finding. Most common abnormal finding noted were submucosal fibroid and polyp with equal frequency of 13 (29.5%) for both (Table 4).

**Table 5: Hysterectomy specimen- histopathology of endometrium.**

Hysterectomy specimen: histopathology of endometrium	No. of patients	%
Atrophic endometrium	3	6.8
Proliferative endometrium	19	43.2
Benign endometrial polyp	7	15.9
Disordered proliferative endometrium	4	9.1
Proliferative endometrium with focal areas of complex hyperplasia without cytological atypia	1	2.3
Basal endometrium	3	6.8
Atrophic endometrium+fibroid polyp	1	2.3
Exogenous progesterone effect with surface ulceration	1	2.3
Disordered proliferative endometrium+benign endometrial polyp	1	2.3
Pill endometrium+ benign endometrial polyp	1	2.3
Proliferative endometrium + benign endometrial polyp	2	4.5
Atrophic endometrium +benign endometrial polyp	1	2.3
Total	44	100.0

Table 5 shows most common finding was proliferative endometrium seen in 19 cases (43.2%) followed by polyp noted in 13 cases (29.6%).

**Table 6: Correlation of TVS with SIS findings for individual lesions.**

TVS versus SIS	Observation					Correlation					
	TP	FP	FN	TN	Total	Se	Sp	PPV	NPV	Accuracy	P value
Submucosal fibroid	9	6	6	43	64	60.0	87.8	60.0	87.8	81.3	<0.001**
Thickened endometrium	3	6	0	55	64	100.0	90.16	33.3	100.0	90.6	<0.001**
Polyp	5	0	13	46	64	27.8	100.0	100.0	77.9	79.7	<0.001**
Focal irregular thickening+	0	0	1	63	64	0.0	100.0	0.50	98.4	98.4	1.000
Synechiae+	0	0	1	63	64	0.0	100.0	0.50	98.4	98.4	1.000

**Table 7: Over all correlation of TVS findings with SIS findings.**

TVS	SIS		Total (n=64)	P value
	Present	Absent		
Present	26 (40.6%)	3 (4.7%)	29 (45.3%)	<0.001**
Absent	10 (15.7%)	25 (39.1%)	35 (54.7%)	
Total	36 (56.3%)	28 (43.7%)	64 (100.0%)	

 $\chi^2=24.046$ ,  $p<0.001^{**}$ .

**Table 8: Detection of abnormal lesions on TVS when compared to final detection of abnormality by hysterectomy specimen.**

TVS	Hysterectomy specimen (gross cut section and histopathology)		Total	P value
	Abnormal	Normal		
Abnormal	18 (40.9%)	3 (6.8%)	21 (47.7%)	0.004**
Normal	10 (22.7%)	13 (29.5%)	23 (52.3%)	
Total	28 (63.6%)	16 (36.4%)	44 (100.0%)	

 $\chi^2=8.462$ ,  $p<0.004^{**}$ .

Out of 36 cases (56.3%) which were found to be abnormal in SIS, TVS could detect 29 cases only. Findings considered to be abnormal include intracavitary lesions (submucosal fibroid, polyp and thickened endometrium). Of the 35 cases (54.7%) which were considered normal in TVS, 10 cases (15.7%) were found to be abnormal in SIS. All the 10 cases had polyp which was missed by TVS but detected by SIS. Out of 9 cases of thickened endometrium in TVS, 6 cases turned out to be Polyp in SIS. In all 6 cases ET (endometrial thickness) was >18 mm (Table 6 and 7). P value<0.001 (significant).

There was a difference in the positive response of both the test.

In 18 (40.9%) cases, abnormality was documented by both TVS and hysterectomy specimen. Abnormality

include intracavitary lesions (submucosal fibroid, polyp and thickened endometrium). In 13 (29.5%) number of cases no findings were detected by both. In 10 cases (22.7%) abnormality was detected by hysterectomy specimen only not by TVS. All the 10 cases were of polyp, which was missed by TVS. P value =0.004 (significant) (Table 8).

**Table 9: Detection of abnormal lesions on SIS when compared to final detection of abnormality by hysterectomy specimen.**

SIS	Hysterectomy specimen (gross cut section and histopathology)		Total	P value
	Abnormal	Normal		
Abnormal	27 (61.4%)	0	27 (61.4%)	<0.001**
Normal	1 (2.3%)	16 (36.4%)	17 (38.6%)	
Total	28 (63.6%)	16 (36.4%)	44 (100.0%)	

 $\chi^2=39.933$ ,  $p<0.001^{**}$ .

In 27 cases (61.4%) abnormality was detected by both SIS and hysterectomy specimen. Abnormality include intracavitary lesions (submucosal fibroid, polyp and thickened endometrium). In 16 cases (36.4%), both had normal findings. Of the 28 abnormal cases (63.6%) detected on hysterectomy specimen, SIS could detect 27 cases (61.4%). This 1 case was found to be submucosal fibroid on hysterectomy specimen whereas posterior intramural fibroid in SIS. P value was <0.001. No polyps were missed by SIS.

Table 10 shows overall sensitivity, specificity, PPV and NPV of TVS for detecting intracavitary lesion was 64.3%, 81.3%, 85.7% and 56.5% respectively with diagnostic accuracy of 78.5%.

Over all sensitivity, specificity, PPV and NPV of SIS for detecting intracavitary lesion was 96.4%, 100%, 100% and 94.1% respectively with diagnostic accuracy of 97.8%.

**Table 10: Validity of TVS and SIS in comparison to final hysterectomy specimen.**

Tests	Observation				Correlation						
	TP	FP	FN	TN	Total	Se	Sp	PPV	NPV	Accuracy	P value
<b>TVS</b>	18	3	10	13	44	64.3	81.3	85.7	56.5	78.5	0.004**
<b>SIS</b>	27	0	1	16	44	96.4	100.0	100.0	94.1	97.8	<0.001**

## 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, it has limitations in detecting small lesions, location of myoma in relation to the endometrium and in differentiating diffuse and focal lesions. Hysteroscopy has been considered as the gold standard but it is expensive and invasive. SIS is found to be more accurate than TVS to visualize the endometrial cavity and it is a better alternative to hysteroscopy. Saline infusion sonography has been found to be less expansive, non-invasive, can be carried out by less experienced and may impart almost the same amount of information as good as invasive hysteroscopy. SIS has been proved to be more accurate than transvaginal sonography. The present study evaluated the diagnostic accuracy of TVS and SIS for detection of intracavitary abnormalities. Histopathological findings (intra-operative gross cut section and histopathology of endometrium) have been taken as the gold standard. A single investigator performed TVS and SIS to eliminate interobserver variation. All histopathological examinations were performed by single person (unbiased) and the results of SIS were not known to him/her.

In present study 64 women, presenting with abnormal uterine bleeding were studied. Similar results correlated with studies conducted by Chawla et al study where 60 women and by Aslam et al where 100 women were studied. In a study by Widrich et al 130 women were studied.<sup>5-7</sup> In spite of big sample size compared to present study, similar results have been observed with sensitivity and specificity of SIS being 96% and 88% respectively. The age group in this study was between 40-57 years and the maximum were between 40-45 years with mean age in the present study of 46.20 years. This is comparable with Van den Bosch et al where mean age was 50 years.<sup>8</sup> In our present study, polyp was present in 5 cases (7.8%) in TVS whereas there were 18 cases (28.1%) of polyp in SIS. There was huge discrepancy of 13 cases (20.3%) between the two, TVS and SIS. This indicates high false negative rates of TVS and also high sensitivity of SIS for detection of polyps.

In TVS, there were 9 cases (14.1%) of thickened endometrium but in SIS, there were 3 cases (4.7%). Thickened endometrium on TVS turned out to be polyp

on SIS in 6 cases (9.3%) indicating its high false positive rates. This is particularly important because the management for polyp and thickened endometrium differ in themselves. As for polyp, polypectomy alone will improve the symptoms but thickened endometrium requires further evaluation by histopathological examination. Treatment for thickened endometrium is based on histopathological report. Hence it was concluded that if we go with TVS alone, chances of overtreating the patients increase.

In our present study, ET of more than 18 mm was observed in TVS in 6 cases and all these cases on SIS was detected to be polyp. It is therefore important to rule out a polyp in such cases either by hysteroscopy or by saline infusion sonography. Both these procedures having the same efficacy but SIS is time saving, economical and non-invasive.

On comparison of SIS with hysterectomy specimen (gross cut section and histopathology) in detection of intracavitary abnormalities, all cases of polyp, that is, 13 cases (29.5%) detected on SIS was confirmed. This shows high sensitivity of SIS for detecting polyps, which was close to gold standard. In a study conducted by Feitosa et al, sensitivity and specificity of SIS for detecting polyp was found to be 90.9% and 89.5%.<sup>9</sup> Similar results were seen in study by Yildizhan et al.<sup>10</sup>

No polyp was missed in the present study which implies that the detection rate of polyp increased significantly on addition of SIS to TVS.

Over all sensitivity and specificity of SIS for detection of intracavitary abnormality in this study were found to be 96.4% and 100% respectively whereas the same for TVS was 64.3% and 81.3%. Comparable results were seen in study by Ryu et al and Reddy et al.<sup>11,12</sup> Similarly Chawla et al study result revealed sensitivity and specificity of 89.1% and 100% for SIS, and 43.4% and 78.3% for TVS.<sup>5</sup>

This study has a limitation. More and more studies are required with large sample size to decide whether SIS can be employed as 1<sup>st</sup> line investigative modality for detecting intracavitary lesions in comparison to TVS.

## CONCLUSION

The present study recommends that saline infusion sonography as a first line investigative modality to detect intrauterine pathology in cases of abnormal uterine

bleeding. Saline sonography enhances the value of ultrasound and thus guides the use of hysteroscopy.

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