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Research Article

## Comparison of transvaginal sonography and saline infusion sonohysterography for the diagnosis of causes of abnormal uterine bleeding: a diagnostic accuracy study

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### ABSTRACT

**Background:** Abnormal uterine bleeding (AUB) is one of the frequently observed gynecological problems in outpatient settings. Diagnosis of the cause of AUB is important and hysteroscopy with biopsy is considered is best method for diagnosis of the same. Recent studies suggest the role of transvaginal sonography (TVS) and saline infusion sonohysterography (SIS) for the diagnosis of AUB though data about accuracy and comparison of these techniques with gold standard is not available. The study was designed with the aim of comparison of TVS and SIS for the diagnosis of abnormal uterine bleeding in reference to microscopical examination after hysterectomy.

**Methods:** 100 consecutive patients of AUB were included in the study on the basis of inclusion and exclusion criteria. TVS and SIS were performed on each patient before the surgery for hysterectomy. The findings of TVS and SIS were compared with microscopical examination of the specimen after the hysterectomy. Sensitivity, specificity, positive predictive and negative predictive values were measured.

**Results:** For sub mucosal myoma sensitivity, specificity, positive predictive value, negative predictive value and kappa statistics of SIS were 100%, 100%, 100%, 100%, 1 respectively while for TVS It were 18.1%, 98.8%, 66.6%, 90.7% and 0.25 respectively.

**Conclusions:** SIS has superior diagnostic accuracy and compared to TVS. These findings need to be confirmed by randomized studies with more sample size.

**Keywords:** AUB, SIS, TVS, Hysterectomy

### INTRODUCTION

Abnormal uterine bleeding (AUB) is one of the common gynaecologic complaints observed at outpatient department. The AUB may be because of the various reasons which may vary from simple dysfunction uterine bleeding to endometrial cancer. Thorough investigations need to rule out organic causes specifically in postmenopausal and perimenopausal age women, as chances of endometrial carcinoma in such women is high.<sup>1</sup>

Hysteroscopy with directed biopsy is considered as a standard investigation for AUB because of its precision. However it is not used as primary diagnostic procedure because of its high cost and invasive nature.<sup>2</sup> Transvaginal sonography (TVS) is also considered as useful method for evaluation of AUB, but it has some limitations for screening the lesions within the endometrial cavity. Thickened endometrium seen on TVS may be because of many reasons like polyp, fibroids, carcinoma or endometrial hyperplasia hence findings are not specific. Also, because of limitations of double layer thickness evaluation many focal lesions remain

undiagnosed in TVS.<sup>3</sup> Another such technique is saline infusion sonohysterography (SIS) in which the single layer evaluation of the endometrial lining is done by injecting saline during ultrasonic examination and it can be useful in differentiating single and distinguish focal from diffuse endometrial conditions. Few studies published so far indicated that SIS may have some advantages as compared to the TVS in differentiating diffuse mass but there is no clear advantage observed and more exploration is needed in this area.<sup>4-6</sup>

The study was designed with the aim of comparison of SIS and TVS for detecting intracavitary abnormalities in women with abnormal uterine bleeding, using the final diagnosis, established at hysterectomy as reference.

## METHODS

This study was done at department of obstetrics and gynecology of tertiary care centre of Gujarat, India from September 2011 to October 2013 after obtaining permission from the institutional ethics committee. In this prospective study, 100 consecutive premenopausal patients with abnormal uterine bleeding were 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 5.0 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 numbers or 10 numbers. 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

Descriptive statistics was reported in the form of frequency, percentages, mean and standard deviation based on type of data. Sensitivity, specificity, positive predictive value, negative predictive values were calculated. Cohen's kappa was used to see agreement between the procedures, value of Cohen's kappa >0.75 was considered excellent agreement, value between 0.40 to 0.75 was considered as intermediate to good agreement and value less than 0.40 was considered as poor agreement. Open epi software and SPSS Version 17 was used for data analysis.

## RESULTS

Majority of patient (92%) were between ages 31-50 years. More than 50% of patients were having uterine size between bulky to 6 week. Menorrhagia and polymenorrhea was most common complain on presentation. As per the histopathology report, among the patients with abnormal histopathology, most common types were Intramural myoma (19%) and adenomyosis (17%) (Table 1).

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

Parameters	Subjects (n=100)
Age (years)	
31-40	48 (48)
41-50	44 (44)
51-60	08 (8)
Uterine size	
Normal	13 (13)
Bulky to 6 weeks	51 (51)
6-8 weeks	21 (21)
8-10 weeks	09 (9)
10-12 weeks	06 (6)
Symptoms	
Menorrhagia	46 (46)
Polymenorrhea	19 (19)
Dysmenorrhea	14 (14)
Metrorrhagia	06 (6)
Menometrorrhagia	07 (7)
Continuous bleeding per vaginal	08 (8)
HPE report	
Intramural myoma	19 (19)
Submucosal myoma	11(11)
Polyp	07 (7)
Adenomyosis	17 (17)
Abnormal endometrium	12 (12)
Normal endometrium	34 (34)

Values in parenthesis are percentages.

Comparison of TVS and SIS findings with histopathology examination is mentioned in table 2. TVS findings were not correlated well with sub mucosal myoma and polyp and abnormal endometrium whereas SIS findings correlated well with intra operative findings and HPE.

(Table 3) shows comparison of TVS findings with HPE reports. It shows that, 9 cases of sub mucosal myoma were falsely diagnosed as intramural myoma (2), polyp (1), adenomyosis (2), abnormal endometrium (3), and normal (1) on TVS. Out of 7 cases polyp, 5 cases were falsely diagnosed as abnormal endometrium on TVS. 3 cases of abnormal endometrium were falsely diagnosed as sub mucosal myoma (1) and polyp (2) on TVS. For TVS findings for sub mucosal myoma false positive was 1, false negative were 9, sensitivity 18.18% and

specificity 98.88%. For polyp false positive were 3, false negative were 5, sensitivity 28.57% and specificity 96.77%.

**Table 2: Comparison of TVS and SIS findings with intra operative hysterectomy and HPE.**

	TVS	SIS	HPE
Intramural myoma	18 (18)	19 (19)	19 (19)
Sub mucosal myoma	03 (3)	11 (11)	11 (11)
Polyp	05 (5)	09 (9)	07 (7)
Adenomyosis	19 (19)	18 (18)	17 (17)
Abnormal endometrium	19 (19)	12 (12)	12 (12)
Normal endometrium	36 (36)	31 (31)	34 (34)

Values in parenthesis are percentages.

**Table 3: Comparison of TVS findings with HPE report.**

HPE/TVS	Intramural myoma (n=19)	Sub mucosal myoma (n=11)	Polyp (n=7)	Adenomyosis (n=17)	Abnormal endometrium (n=12)	Normal (n=34)	Total (n=100)
Intramural myoma	16	2	0	0	0	0	18
Sub mucosal myoma	0	2	0	0	1	0	3
Polyp	0	1	2	0	2	0	5
Adenomyosis	1	2	0	14	0	2	19
Abnormal endometrium	0	3	5	0	9	2	19
Normal	2	1	0	3	0	30	36

**Table 4: Comparison of SIS findings with HPE report.**

HPE/SIS	Intramural myoma (n=19)	Sub mucosal myoma (n=11)	Polyp (n=7)	Adenomyosis (n=17)	Abnormal endometrium (n=12)	Normal (n=34)	Total (n=100)
Intramural myoma	19	0	0	0	0	0	19
Sub mucosal myoma	0	11	0	0	0	0	11
Polyp	0	0	7	0	2	0	9
Adenomyosis	0	0	0	16	0	2	18
Abnormal endometrium	0	0	0	0	10	2	12
Normal	0	0	0	1	0	30	31

(Table 4) 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. In this study SIS correlation with intra operative findings and HPE for sub mucosal myoma showed sensitivity of 100% and specificity of 100% and for polyp showed sensitivity of 100% and specificity of 97.85%.

Table 5 and 6 shows diagnostic performance of TVS and SIS in identifying various causes. SIS has higher sensitivity and specificity when compared with 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%).

**Table 5: Diagnostic performance of TVS and SIS in identifying various causes.**

Test performance/diagnosis	Sub mucosal myoma		Polyp		Abnormal endometrium	
	TVS	SIS	TVS	SIS	TVS	SIS
Sensitivity	18.18%	100%	28.57%	100%	75%	83.33%
Specificity	98.88%	100%	96.77%	97.85%	88.64%	97.73%
PPV	66.67%	100%	40%	77.78%	47.37%	83.33%
NPV	90.72%	100%	94.74%	100%	96.30%	97.73%
DA	90%	100%	92%	98%	87%	96%
Cohen's kappa	0.25	1	0.29	0.86	0.50	0.81

**Table 6: Diagnostic performance of TVS and SIS.**

Test	Sensitivity	Specificity	PPV	NPV	DA	Likelihood ratio	
						Positive	Negative
TVS	87.76 (75.76-94.27)	96.08 (86.78-98.92)	95.56 (8.17-98.77)	89.09 (78.17-94.9)	92 (85-95.89)	22.38 (8.34-60)	0.12 (0.09-0.17)
SIS	100 (92.73-100)	96.08 (86.78-98.92)	96.08 (86.78-98.92)	100 (92.73-100)	98 (93-99.45)	25.05 (9.57-67.94)	0

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.

## DISCUSSION

This study was designed with the aim of comparison of SIS and TVS for detecting intracavitary abnormalities in women with abnormal uterine bleeding in reference to hysterectomy diagnosis.

In present study, the mean age for women was 45 years, range 32-57 years. Menorrhagia was the commonest symptom in 46% of the cases and the most common lesion was intramural myoma in 19% of the cases. TVS cannot distinguish endometrial hyperplasia from polyp as both can cause thickening of the endometrium whereas SIS can detect focal lesions from diffuse thickening. SIS has higher sensitivity and specificity when compared to TVS. Similar findings were seen in the studies by Ryu et al and Reddi PR.<sup>7,8</sup>

The sensitivity and specificity of TVS for sub mucosal myoma were 18.18% and 98.88%, respectively as compared to sensitivity and specificity of SIS which were 100% and 100% respectively. The sensitivity and specificity of TVS for polyp were 28.57% and 96.77%, respectively as compared to sensitivity and specificity of SIS which were 100% and 97.85% respectively. All imaging techniques have a number of false results even in experienced hands. In present study false positive and negative results were higher in TVS than SIS. 2 cases of thickened endometrium were falsely diagnosed as polyp on SIS because of blood clot in endometrial cavity. Bleeding is not a contraindication to SIS. SIS is best performed as soon as possible after the cessation of menses to avoid the misinterpretation of menstrual blood clots as intrauterine pathology.

In this study, 6 women experienced severe pain. Whereas in the study by Cicinelli et al 11% of the cases experienced severe pain. The pain due to distension of uterine cavity can be minimized if saline installation is controlled and stopped as soon as the lesion is detected. NSAID given 30 minutes prior to the procedure will typically minimize any potential discomfort.

There was no evidence of infection in our study.<sup>8</sup>

Reddi PR reported for diagnosing sub mucosal myoma TVS sensitivity was 27.3% and specificity was 85%. For polyp TVS sensitivity was 71.4% and specificity was 97%. 2 cases of abnormal endometrium were falsely diagnosed as polyp on SIS.<sup>7</sup> In these 2 cases intra operatively cut section of specimen shows blood clots in endometrial cavity, which were falsely diagnosed as polyp on SIS. SIS is best performed as soon as possible after the cessation of menses, during the proliferative phase of the menstrual cycle to avoid the misinterpretation of menstrual blood clots as intrauterine pathology. Bleeding is not a contraindication to SIS. It has been observed that SIS has more accurate diagnostic parameters as compared to the TVS.

This study has some limitations. Looking at the pilot nature of this study formal sample size calculation was not done and all subjects were selected consecutively not randomly. A larger randomized comparative study with formal sample size calculation can give more accurate observations. Looking at the observed diagnostic parameters it can be concluded that SIS is superior as compared to the TVS.

## CONCLUSIONS

SIS has superior diagnostic accuracy and compared to TVS. These findings need to be confirmed by randomized studies with more sample size.

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