# Comparison of the efficacy of transvaginal sonography (TVS) with and without saline infusion sonohysterography (SIS) in the evaluation of abnormal uterine bleeding

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## <u>Abstract</u>

**EXAMPLA** Background: Menstrual dysfunction is a commonly encountered problem in gynecological practice. The causes are many and require a thorough evaluation to accurately diagnose the cause of AUB. Endometrial pathology is one of the poorly evaluated areas often requiring invasive procedures like endometrial biopsy. TVS with SIS can offer a good alternative to the invasive procedures. Aims and Objectives: To compare the efficacy of Transvaginal ultrasonography and Saline infusion sonohysterography in the evaluation of abnormal uterine bleeding. To correlate their diagnostic accuracy after hysterectomy with histopathological examination report. Study Design: It is a prospective study of 200 patients with complaints of abnormal uterine bleeding who underwent Transvaginal ultrasonography, followed by saline infusion sonohysterography and the findings were interpreted. Results and Conclusion: Saline infusion sonohysterography is a simple, highly sensitive and specific technique to detect intrauterine pathology in the evaluation of abnormal uterine bleeding when Transvaginal sonography findings are inconclusive. Saline infusion sonohysterography outlines the uterine cavity, detects myoma, polyp or endometrial abnormality, missed on transvaginal ultrasound alone.

**Key Words:** Abnormal uterine bleeding (AUB), Saline infusion sonohysterography (SIS), Trans vaginal sonography (TVS), Histopathological examination (HPE).

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## **INTRODUCTION**

Menstrual dysfunction is a commonly encountered problem in gynecological practice, accounting for 15% of outpatients and almost 25% of gynecological surgeries<sup>1</sup>. Menorrhagia affects 10 to 30 % of reproductive-aged

women and up to 50% of premenopausal women. (Haynes, 1977; Prentice, 2000)<sup>2</sup>. The causes of AUB can be classified into organic pelvic pathology, endocrinal, blood dyscrasias, dysfunctional uterine bleeding and as a result of systemic diseases. Ultrasonography in gynaecology has an important role in the evaluation of female pelvic organs. USG compliments bimanual examination. Transvaginal sonography with improved resolution is chosen by many, instead of endometrial biopsy as a first line tool to assess abnormal bleeding. It minimizes patient discomfort due to a full bladder and shorter distance between the transducer and target organs. Hysteroscopy, which has been considered as gold standard for evaluating the uterine cavity abnormalities is expensive, associated with complications like perforation, embolism and cannot assess the myometrial and adnexal pathology. Saline infusion Sonography (SIS) is a simple, minimally invasive, and cost effective sonographic

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procedure, SIS can be used to accurately evaluate the endometrium and endometrial cavity. The infusion of saline serves as a contrast medium and distends the endometrial canal allowing exquisite display of the inner lining of endometrium during real time imaging. Today saline infusion sonography has evolved as a useful, safe and minimally invasive examination for women who have abnormal uterine bleeding, infertility and congenital uterine anomalies.<sup>3</sup>

## **MATERIALS AND METHODS**

This is a prospective study conducted on 200 patients with abnormal uterine bleeding who attended the department of Obstetrics and Gynecology, Shridevi institute of medical sciences and research hospital, Tumkur- 572106 during the period october 2016 to May 2018. All patients in the reproductive and perimenopausal age group were included. A detailed history was taken with special emphasis on menstrual history. Specific history was taken to rule out the systemic disorders responsible for abnormal uterine bleeding. Clinical examination was carried out including breast and pelvic examination. Laboratory investigations were conducted. After taking an informed consent, these patients underwent Transvaginal Sonography and Saline Infusion Sonohysterography. After emptying the bladder, a baseline transvaginal ultrasound was performed first using endovaginal probe of 7.5MHz (covered by a appearance of the endometrium, condom) the myometrium, and adnexae was noted. The cervix was swabbed with the povidine iodine solution. No.8 Foley's catheter was placed in the cervix and the balloon inflated with 1.5 to 2 ml of distilled water such that it lies just above the internal os and blocks the distension fluid from flowing out of the endometrial cavity. Gentle infusion of sterile saline was completed during real time sonography. Saline separated the echogenicities from the endometrium which appeared as hypoechoic area within the endometrial cavity. Uterine cavity was visualized in longitudinal plane from corner to corner and in coronal plane from fundus to endocervix.

**Inclusion Criteria:** All women in reproductive and perimenopausal age group with abnormal uterine bleeding in the form of metrorrhagia, menometrorrhagia, polymenorrhoea, polymenorrhagia were included in the study.

## **Exclusion Criteria**

- 1. Menstruating women.
- 2. Patients suspected to have endometrial carcinoma.
- 3. Patients with Pelvic Inflammatory disease.

- 4. Patients with possibility of pregnancy.
- 5. Puberty menorrhagia.
- 6. Patients with severe cervical stenosis due to previous history of surgeries on cervix.
- 7. Abnormal cervical Pap's smear.
- 8. Uterus >12 weeks size.

#### **RESULTS AND DISCUSSION**

Abnormal uterine bleeding is one of the most frequently encountered conditions in gynecological practice. In the present study, 200 patients with AUB who were being subjected to hysterectomy and who fulfilled the inclusion and exclusion criteria were analyzed. 104 (52%) patients were in age group 36-40 years, 60 (30%) were in 41-45 years, 32 (16%) were in 46-50 years, 4(2%) were > 51 years. All patients in our study group belong to reproductive and perimenopausal age group wherein, it is important to determine the exact etiology of AUB for accurate management, with maximum number of patients being from 35-40 and 41-45 years. The mean age of the patients in this study was 36-51 years. All other studies also had women of reproductive, perimenopausal and postmenopausal age group, Cicinelli *et al*<sup>4</sup> 40-51 years, Widrich et al<sup>5</sup> 20-83 years, Williams et al<sup>6</sup> 35-50 years, Saidi et  $al^7$  40-89 years. The number of patients in different study group varied from 39-130 patients, Cicinelli et al<sup>4</sup> 52 patients, Widrich et al<sup>5</sup> 130 patients, Williams et  $al^6$  39 patients, Saidi et  $al^7$  68 patients. In our study parity wise distribution of patients was P0- 4 (2%), P1- 8 (4%), P2- 40 (20%), P3- 72 (36%), P4- 40 (20%), P5- 20 (10%), P6 and above 16 (8%). It was noted that in multipara who conceived 3 or more times, there was greater incidence of abnormal uterine bleeding. Among the 200 cases, 4 patients were nulliparous. Distribution according to socio economic Status Low-152 (76%), Middle-48 (24%). Majority of patients in our study were from low socio economic status compared to 24% in middle socioeconomic class. Distribution of patients according to duration of symptoms was found to be 1-3months 12 (6%) patients, 4 - 6 months 72 (36%) patients, 7-9 months 64 (32)% patients, 10-12 months 40 (20%) patients, 12 months and above 12 (6%) patients. The duration of symptoms ranged from less than 6 months to up to 2 years and maximum number patients had complaints within 4-6 months with standard deviation of 7.23. Distribution of patients according to clinical presentation Metrorrhagia 12(6%), Menorrhagia 140 (70%), Menometrorrhagia 8 (4%), Polymenorrhagia 32 (16%), Polymenorrhoea 8 (4%). In our study the commonest menstrual irregularity was menorrhagia (70% of cases).

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FINDINGS	TVS	Percentage	SIS	Percentage	HPE	Percentage
Anterior intramural fibroid	32	16%	24	12%	24	12%
Posterior intramural fibroid	36	18%	32	16%	32	16%
Multiple intramural fibroid	44	22%	44	22%	44	22%
Sub mucosal fibroid	08	4%	20	10%	20	10%
Endometrial polyp	-	-	08	4%	12	6%
Normal study	80	40%	72	36%	68	34%
TOTAL	200	100%	200	100%	200	100%

 

 Table: 1 Distribution of Results According To Diagnosis Made On TransVaginal Sonography (TVS), Saline Infusion Sonohysterography (SIS), Histopathological Examination (HPF)

In 40% cases of our study there was no pelvic pathology detected and the diagnosis of DUB was made. In 22% of cases there were multiple intramural fibroids, 16% of anterior and 18% posterior intramural fibroids, 4% sub mucosal fibroids. In our study by SIS in 36% cases, there was no pelvic pathology detected and the diagnosis of DUB was made. 22% with multiple intramural fibroids, 16% with posterior intramural fibroids and 12% with anterior intramural fibroids.10% of submucous fibroid and 4% with polyps were diagnosed. 8 endometrial polyps that were missed in TVS were detected by SIS. In 12 cases where TVS diagnosed as intramural fibroids were detected as submucosal fibroids by SIS. In our study by HPE, in 34% cases there was no intrauterine pathology detected. 22% cases with multiple intramural fibroids, 16% with anterior intramural fibroids, 10% with submucosal fibroids, 6% with endometrial polyps. One endometrial polyp that was missed in SIS was detected by HPE. The findings of SIS were confirmed by HPE report except for one small endometrial polyp that was missed by SIS. TVS findings were not correlated well with findings of HPE. Submucous myoma and endometrial polyps diagnosed by SIS were confirmed by HPE report.

Table 2: Correla	ation of TVS	S results with HF	PE findings		
Histo pathological findings					
	Disease	No disease			
TVS test results					
Positive	116 (a)	0 (b)	116		
Negative	12(c)	72 (d)	84		
Total	128	72	200		
		11			
Table 3: Correl	ation of SIS	results with HP	E findings		
Histo pathological findings					
	Disease	No disease			
SIS test results					
Positive	124(a)	0(b)	124		
Negative	4(c)	72(d)	76		
Total	128	72	200		

True Positive b. False Positive c. False Negative d. True Negative

Table 4: Diagnostic Performance of SIS and TVS				
	SIS	TVS		
Sensitivity	96.88 (83.73 to 99.48)	90.62 (74.95 to 97.91)		
Specificity	100 (81.32 to 100)	100 (81.32 to 100)		
Positive Predictive Value (PPV)	100 (88.68 to 100)	100 (87.94 to 100)		
Negative Predictive Value (NPV)	94.74 (73.90 to 99.12)	85.71 (63.63 to 96.78)		
Diagnostic accuracy	98%	94%		
Negative Likelihood Ratio	0.03 (0.00 to 0.22)	0.09 (0.03 to 0.28)		

Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) data are percentages. All numbers in parentheses (in brackets) are 95% CIs (Confidence Intervals). The sensitivity of the TVS was 90.6%, specificity was 100%, the positive predictive value was 100% and the negative predictive value was 85.7%.with an accuracy rate of 94%. The sensitivity of the SIS was 96.8%, specificity was 100%, the positive predictive value was 94.7%.with an accuracy rate of 98%. Cicinelli *et al*<sup>4</sup> performed a study on 52 perimenopausal women, TVS had a sensitivity 90%, specificity 78%, for submucous fibroids predictive values of abnormal and normal scans were 90 and 98% respectively. Saline hysterography had a sensitivity, specificity and predictive value of 100%, as did hysteroscopy. Williams *et al*<sup>6</sup> conducted a study on 31 patients in which they found 12

of the 31 patients had masses that impinged on the intrauterine cavity at hysteroscopy or hysterectomy. In 4 of the 12 patients with confirmed masses, an intrauterine lesion was detected by sonohysterography that was not seen on routine vaginal probe ultrasonography. In no case was an intrauterine mass detected by hysteroscopy or after hysterectomy when sonography indicated a normal uterine cavity. In 4 cases sonohysterography suggested that masses were present that were not confirmed at sonohysterography recognized intracavitary direct visualization. Although pathologic conditions when existed, sonohysterography sometimes underestimated the number of intracavitary lesions present. Widrich *et al*<sup>5</sup>, evaluated 130 patients of AUB in the age group of patients ranged from 20- 83 years, out of which 73% of patients were premenopausal and the rest were postmenopausal. They compared sensitivity, specificity of sonohysterography with hysteroscopy as gold standard for evaluation of endometrium. The combined sensitivity was 96% and specificity was 88%. Similar study performed by Saidi *et al*<sup>7</sup>, on 68 women with AUB where sonohysterography was confirmed with hysteroscopy. Sensitivity and specificity of sonohysterography was 90% and 83%.

Table 5: Sensitivit	y and Specificity of SIS in vario	us Studies
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Authors	Sensitivity (%)	Specificity (%)
Cicinelli <i>et al</i> <sup>4</sup> (1995)	90	98
Widrich <i>et al<sup>s</sup></i> (1996)	96	88
Saidi <i>et al<sup>7</sup></i> (1997)	90	83
Wiiliams <i>et al<sup>e</sup></i> (1998)	100	78
Present study	96.8	100

Table 6: Overall efficiency of SIS compared with TVS							
					Predictive values		
Study	Procedure	Sensitivity %	Specificity %	PPV %	NPV %		
Ryu JA <i>et al</i> <sup>8</sup>	SIS	95	83	95	83		
	TVS	79	46	83	39		
Saidi <i>et al</i> 7	SIS	90.9	83.3	90.9	16.7		
	TVS	95.7	63.6	84.6	12.5		
Present study	SIS	96.8	100	100	94.7		
	TVS	90.6	100	100	85.7		
			and the second second				

# 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 is inconclusive. It is highly sensitive and specific especially for diagnosing submucous myoma, endometrial polyps. No complications, either related to insertion of catheter or any infection is associated. 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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