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Original Research Article

A comparative study on the efficacy of saline infusion sonography and transvaginal sonography in abnormal uterine bleeding in premenopausal females

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ABSTRACT

Background: Saline infusion sonography (SIS) and transvaginal ultrasonography (TVS) were widely used techniques for evaluation of cases with abnormal uterine bleeding (AUB). However, the superiority of these two techniques in terms of accuracy remains a question.

Methods: A total of 45 cases with AUB were subjected to both TVS and SIS and analysed for endometrial polyp or submucosal fibroids. The results of the imaging were compared with the histopathological results of the endometrium of the same patient. The data was analyzed using SPSS - Version 19.

Results: In diagnosing thickened endometrium, diagnostic accuracy of TVS was reported as 91.1% with sensitivity (Sn), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV) of 96.7%, 78.6%, 90.9% and 91.7%, respectively. Similarly, for SIS, diagnostic accuracy (DA) was 93.3% with Sn, Sp, PPV and NPV were 96.7%, 85.7%, 93.8% and 92.3%, respectively. In adenomyosis, diagnostic accuracy of TVS was reported as 95.6% with Sn, Sp, PPV and NPV of 100%, 94.7%, 77.8% and 100%, respectively. Similarly, for SIS, Diagnostic accuracy was 100% with Sn, Sp, PPV and NPV were also 100%. In diagnosing fibroid, diagnostic accuracy of TVS was reported as 100% with Sn, Sp, PPV and NPV of 87.5%, 100%, 100% and 97.4%, respectively. Similarly, for SIS, diagnostic accuracy was 100% with Sn, Sp, PPV and NPV were 100%, each.

Conclusions: We infer that SIS is found to be better efficacious in diagnosing different pathologies of AUB cases compared to TVS among the premenopausal women.

Keywords: Abnormal uterine bleeding, Premenopausal female, Saline infusion sonography, Transvaginal ultrasonography

INTRODUCTION

Women in the premenopausal age group experiencing AUB should consult a gynaecologist.¹ The most common cause of irregular menstruation in these women is DUB, which refers to bleeding without any identifiable organic cause. However, over 40% of cases show evidence of an underlying illness. Investigating irregular uterine bleeding is essential, especially in premenopausal and

postmenopausal women, who are at higher risk of endometrial cancer, with a reported incidence of 10-15%.² A variety of diagnostic techniques are available to identify focal endometrial conditions. TVS is the most commonly used initial test for evaluating the cause of AUB, as it is simple, non-invasive and generally reliable.³ However, studies suggest that basic grey-scale TVS may not detect focal lesions due to difficulties in measuring the endometrial thickness.⁴ Diagnostic hysteroscopy, along

with guided biopsy, is considered the gold standard as it allows direct visualization of the uterine cavity and detection of even small lesions.⁵ Hysteroscopy also has the advantage of being therapeutic, as many conditions can be treated during the procedure. However, it is invasive and not a cost-effective first-line diagnostic tool for endometrial evaluation.⁶ In resource-limited settings, where hysteroscopy is less accessible, alternative diagnostic methods are sought. Saline infusion sonography (SIS) has emerged as a promising technique that improves diagnostic accuracy by using saline to distend the uterine cavity, allowing better differentiation between diffuse and focal endometrial lesions, such as polyps or tumors.⁷

SIS is a less invasive and more affordable alternative to hysteroscopy, offering various advantages.⁸ It is well-tolerated by most patients and complications are rare, with only minor discomfort or cramps reported. SIS can be performed without anaesthesia, making it a practical option for both premenopausal and postmenopausal women. Given these benefits, SIS is increasingly favoured in evaluating AUB.⁹ This study aimed to compare the accuracy of SIS and TVS in diagnosing AUB and to correlate with the endometrial biopsy findings in premenopausal women.

METHODS

Study design

This was a prospective observational study.

Study place

This study was conducted in the department of Obstetrics and Gynecology in Trichy SRM Medical College Hospital and Research Centre, Trichy.

Study duration

This study was conducted during the period of November 2022 to June 2024.

Study population

Patients with abnormal uterine bleeding.

Inclusion criteria

Women in premenopausal age group (40-50 years) with AUB who have completed their family.

Exclusion criteria

Pelvic inflammatory disease, cervical stenosis, patient with vaginal infection, post-menopausal women.

Sample size

A total of forty-five cases with AUB were included in the study.

Procedure

After obtaining informed written consent and conducting a relevant clinical examination, TVS was performed. Participants then underwent SIS to evaluate for endometrial polyps or submucosal fibroids. The imaging results were compared with the histopathological findings of the endometrium.

Transvaginal ultrasonography and Saline infusion sonography procedure

TVS and SIS were conducted using a vaginal probe operating at 5.0 MHz. If a sonogram revealed a hyperechoic line in the center of the uterus, with a homogeneous endometrial lining and clear myometrial boundaries, the endometrium and cavity were considered normal. Any deviation from this, such as deformities of the uterine lining, absence of the central hyperechoic line or the presence of structures with fluctuating echogenicity or well-defined boundaries, was considered abnormal.

An endometrial polyp was defined as a smooth-margined, echogenic mass with a uniform texture that arose from the endometrium without disrupting the myometrial-endometrial interface. A submucosal myoma was described as a solid, round mass with mixed echogenicity, protruding into the uterine cavity, disrupting the inner circular muscle layer and originating from the myometrium. Endometrial measurements were taken at the thickest point in the longitudinal plane, from cornu to cornu and any intracavitary pathologies, such as polyps or myomas, were documented.

Saline infusion sonography procedure

A sterile 8-F Foley catheter was inserted through the cervix to the fundus and the ultrasound probe was reinserted into the vaginal canal after speculum removal. The catheter was then attached to a 50 ml syringe filled with sterile saline, which was instilled into the uterine cavity. Approximately 20 mL of saline was used to distend the cavity and sonographic observations were made to assess the displacement of the cavity and the saline infusion.

The endometrium was measured at its thickest portion and any suspicious intracavitary lesions were noted. The uterine cavity outlines were examined for any abnormalities, using the same criteria for abnormal findings as with TVS.

Final diagnosis

The final diagnosis was based on the combined visual and histological analysis of the material, with histopathological findings compared to TVS and SIS results.

Ethical committee approval

The study received approval from the Institutional Ethics Committee of Trichy SRM Medical College Hospital and Research Centre, Trichy (Approval No.: 1064/TSRMMCH&RC/ME-1/2022-IEC.No:212).

Data analysis

The data was entered into an Excel sheet and analyzed using the Statistical Package for Social Sciences (SPSS) - Version 19. Descriptive statistics, including mean, standard deviation and proportions (%), were calculated for the quantitative variables. Diagnostic efficacy measures were used to test the hypothesis, with a p value of <0.05 considered statistically significant.

RESULTS

Table 1, displays the baseline details of the participants (n=45). Based on the TVS, endometrial thickness was found to be ≤4 mm, 5-8 mm, 9-12 mm, 12-16 mm and >16 mm among 20%, 22.2%, 28.9%, 22.2% and 6.7% of the cases respectively. The mean Endometrial Thickness among the participants was recorded as 12.4±4.7 mm. Based on the findings on TVS, 33 (73.3%) of the women had Thickened endometrium while 9 (20%) of the women had Adenomyosis, 5 (11.1%) of the women had Adnexal mass, 7 (15.6%) of the cases had fibroid uterus whereas 3 (6.7%) of the women were found with endometrial polyp. On assessing the uterine findings by SIS, thickened endometrium was noted among 32 (71.1%) of the cases, Adenomyosis was seen among 7 (15.6%) of the cases, 5

(11.1%) of the cases had Adnexal mass while 8 (17.8%) of the cases had fibroid and 3 (6.7%) of the cases were noted with endometrial polyp and 13 (28.9%) of the cases were normal by SIS (multiple findings). Findings of histopathological examination in Table 2. Comparative diagnosis based on TVS, SIS and HPE given in table 3.

Table 4, compares the diagnostic accuracy of TVS and SIS. In diagnosing thickened endometrium, DA of TVS was reported as 91.1% with Sensitivity (Sn), Specificity (Sp), (PPV) and (NPV) of 96.7%, 78.6%, 90.9% and 91.7%, respectively. Similarly, for SIS diagnostic accuracy was 93.3% with Sn, Sp, PPV and NPV were 96.7%, 85.7%, 93.8% and 92.3%, respectively. In diagnosing adenomyosis, diagnostic accuracy of TVS was reported as 95.6% with Sn, Sp, PPV and NPV of 100%, 94.7%, 77.8% and 100%, respectively. Similarly, for SIS DA was 100% with Sn, Sp, PPV and NPV were also 100%. In diagnosing adnexal mass, diagnostic accuracy of TVS was reported as 95.6% with Sn, Sp, PPV and NPV of 80%, 97.5%, 80% and 97.5%, respectively. Similarly, for SIS DA was 100% with Sn, Sp, PPV and NPV were 100%, each.

In diagnosing fibroid, diagnostic accuracy of TVS was reported as 100% with Sn, Sp, PPV and NPV of 87.5%, 100%, 100% and 97.4%, respectively. Similarly, for SIS, DA was 100% with Sn, Sp, PPV and NPV were 100%, each. In diagnosing endometrial polyp, diagnostic accuracy of TVS was reported as 95.7% with Sn, Sp, PPV and NPV of 66.7%, 97.7%, 66.7% and 97.7%, respectively. Similarly, for SIS, DA was 100% with Sn, Sp, PPV and NPV were 100%, each.

Table 1: Baseline details of the participants (n=45).

History findings		Frequency (N)	(%)
Age group (in years)	40-42	12	26.7
	43-45	20	44.4
	46-48	9	20.0
	49-50	4	8.9
Parity	Primiparous	13	28.9
	Multiparous	32	71.1
BMI categories	Normal	23	51.1
	Overweight	15	33.3
	Obese	7	15.6
Presenting complaints	Menorrhagia	28	62.2
	Polymenorrhea	12	26.7
	Menometrorrhagia	9	20.0
	Metropathia haemorrhagica	5	11.1
Duration of complaints (in months)	≤2	11	24.4
	3-4	14	31.1
	5-6	13	28.9
	>6	7	15.6
Diabetes mellitus	Present	8	17.8
Hypertension	Present	10	22.2
Thyroid dysfunction	Present	3	6.7
Anemia	Present	13	28.9

Table 2: Histopathological examination finding.

HPE findings	Frequency	(%)*
Proliferative	29	64.4
Secretary	14	31.1
Atrophic	6	13.3
Cystoglandular hyperplasia	8	17.8
Hyperplasia	26	57.8

*Multiple responses.

Table 3: Diagnosis-TVS vs SIS vs HPE.

Diagnosis*	TVS	SIS	HPE
Endometrial hyperplasia	33 (73.3)	32 (71.1)	31 (68.9)
Adenomyosis	9 (20.0)	7 (15.6)	7 (15.6)
Adnexal mass	5 (11.1)	5 (11.1)	5 (11.1)
Fibroid	7 (15.6)	8 (17.8)	8 (17.8)
Endometrial Polyp	3 (6.7)	3 (6.7)	3 (6.7)

*Multiple responses.

Table 4: Comparison of diagnostic accuracy of TVS and SIS based on HPE.

Diagnosis based on HPE*	TVS values	SIS values
Thickened endometrium	91.1	93.3
Adenomyosis	95.6	100
Adnexal mass	95.6	100
Fibroid	100	100
Endometrial polyp	95.7	100

DISCUSSION

In the present study, it was found that SIS is more efficacious in diagnosing different pathologies of AUB cases compared to TVS among the premenopausal women. The findings of this study were consistent with several others. Goldstein et al assessed a triage paradigm for premenopausal patients with AUB based on ultrasound.¹⁰ In 79% of instances, dysfunctional uterine bleeding was present, requiring no further investigation and ultrasonographic data did not reveal any anatomical abnormalities. Focal polypoid masses were present in 13% of cases, all of which were removed hysteroscopically and pathologically confirmed. Five cases had submucous myomas and 23% exhibited endometrial thickening on SIS. Additionally, five cases had proliferation and five cases had hyperplasia on nondirected office sampling. Due to technical deficiencies in two patients, hysteroscopy with curettage was required.

Vries et al reported that TVS had a specificity of 93% and sensitivity of 60% in identifying intracavitary abnormalities.¹¹ TVS showed 85% sensitivity and 21% specificity when defining an abnormality as direct visualization or an endometrial thickness (ET) of more than 5 mm. SIS had a sensitivity of 88% and specificity of 95% for the presence or absence of intracavitary pathologies. They concluded that SIS is more accurate

than TVS in diagnosing intracavitary pathologies in premenopausal women. Krampfl et al evaluated the diagnostic accuracy of hysteroscopy and TVS in patients with AUB.¹² Sonohysterography had a 94% detection rate for focal intrauterine pathology, while TVS had a much lower rate of 24%. Around 75% of cases had endometrial hyperplasia, which could not be accurately detected by any of the approaches. They concluded that sonohysterography significantly outperforms TVS in identifying focal intrauterine pathology. Visual inspection during surgical hysteroscopy did not provide more information than outpatient sonohysterography in identifying or excluding focal lesions. Similarly, Nanda et al similarly reported that TVS is less reliable than SIS in identifying endometrial polyps and submucosal fibroids in AUB patients.¹³ TVS remains an essential part of routine OPD management for AUB. Farquhar et al found that, despite variations across studies, all three diagnostic techniques were fairly accurate at detecting intrauterine pathology.¹⁴ However, sonohysterography and hysteroscopy were superior to TVS in identifying submucosal fibroids. Kelekci S et al, examined the acceptability and diagnostic accuracy of TVS, SIS and hysteroscopy for detecting intracavitary abnormalities in women with or without AUB.¹⁵ They reported sensitivities and specificities of 56% and 72% for TVS, 81% and 100% for SIS and 87% and 100% for hysteroscopy, respectively, in identifying intracavitary abnormalities. There was no difference in the prevalence

of endometrial polyps between women with and without AUB. Additionally, patients reported that SIS caused less pain than hysteroscopy (OHS) and the diagnostic accuracy of SIS was comparable to that of OHS. Cepni et al found that in premenopausal patients, the positive predictive value (PPV) for endometrial polyps was 69% for TVS, 78% for SIS and 81% for hysteroscopy.¹⁶ Only 24% of endometrial polyps were detected by TVS and SIS in postmenopausal patients, compared to 70% detected by hysteroscopy. In premenopausal patients, the PPV for submucosal fibroids was 47% for TVS, 81% for SIS and 77% for hysteroscopy. The study concluded that SIS and hysteroscopy are equally accurate in diagnosing endometrial polyps and submucosal fibroids in premenopausal patients, while hysteroscopy remains the most reliable method for polypoid lesions in postmenopausal women. Performing TVS, SIS and D&C in premenopausal patients could reduce diagnostic hysteroscopies by 71.5%, although this reduction is only 40% in postmenopausal patients.

In alignment with this study, Algazzar et al stated that SIS is a cost-effective, non-invasive method that can provide more information than TVS, allowing for better differentiation between subendometrial and focal endometrial lesions. SIS offers significant advantages over hysteroscopy, with similar sensitivity and NPV to a hysteroscope.¹⁷ It can be routinely performed in AUB patients, regardless of TVS findings and prior to hysteroscopy. Kaspas et al found that 16% of women in the infertile group had intracavitary abnormalities, including adhesions (0.3%), submucosal fibroids (3%) and polyps (13%). Interestingly, intracavitary abnormalities were present in 40% of AUB patients, with polyps (30%), submucosal fibroids (9%) and adhesions (0.7%) being the most common.¹⁸ They reported that SIS detected a significant number of uterine anomalies and intracavitary abnormalities in the infertility work-up.

Erdem et al reported that TVS had a sensitivity and specificity of 83% and 71%, respectively, in diagnosing endometrial disease when compared to pathological results, while SIS demonstrated 98% sensitivity and 82% specificity.¹⁹ In detecting endometrial polyps, SIS had 100% sensitivity and 92% specificity and for fibroids, 95% sensitivity and 100% specificity. The study concluded that SIS is more accurate than TVS in evaluating the endometrial cavity in AUB patients. However, Aslam et al similarly concluded that sonohysterography is more effective than TVS for evaluating endometrial intra-cavity lesions, helping select cases for biopsy or hysteroscopy by accurately differentiating between focal and diffuse endometrial abnormalities.²⁰ Yildizhan et al reported that histological examination revealed normal endometrial histology in 28 patients, intracavitary polyps in 46, submucosal fibroids in 18, intramural fibroids in 6 and endometrial hyperplasia in 6 participants. TVS showed sensitivity and specificity of 65% and 88%, respectively, for detecting endometrial polyps, compared to 91% and 93% for SIS. For uterine fibroids, TVS demonstrated 96%

sensitivity and 95% specificity, while SIS had 92% and 99%, respectively. Their findings indicated that SIS is superior to TVS in diagnostic accuracy and is a simple, affordable and user-friendly method. Given that SIS is less invasive than hysteroscopy, it should be associated with lower morbidity in AUB evaluations.²¹ Grimbizis et al found that hysteroscopy was significantly more accurate than both TVS and SIS in diagnosing intracavitary masses, with SIS being more precise than TVS. They concluded that SIS is a useful tool for diagnosing intracavitary masses.²² Choudry et al supported the use of SIS for diagnosing postmenopausal women with endometrial thickness greater than 5 mm and bleeding. SIS revealed abnormalities in 74% of patients, with 49% reporting no discomfort. Focal thickening and endometrial polyps were detected in 32% and 17% of cases, respectively. SIS detected three false-positive polyps and missed a submucosal fibroid near the cervix in 2% of cases.²³

Additionally, Hauge et al evaluated premenopausal women with AUB unresponsive to medical treatment, finding that SIS identified intracavitary abnormalities in 56% of cases. Twenty-four women underwent hysterectomy and eighty received successful minimally invasive treatment.²⁴ The study emphasized the frequent presence of focal intracavitary lesions in these women. Mathew et al compared the diagnostic accuracy of SIS and TVS, using hysteroscopy as the gold standard. SIS detected 35 suspected polyps or fibroids and 28 patients had normal results. SIS demonstrated 91% sensitivity, 93% specificity, 89% PPV and 94% NPV, compared to lower accuracy for TVS.²⁵ Bingol et al evaluated the diagnostic accuracy of TVS, SIS and hysteroscopy in postmenopausal women with AUB. SIS and hysteroscopy had higher sensitivity and specificity than TVS for detecting endometrial lesions, with SIS nearing hysteroscopy in diagnostic accuracy.²⁶ They concluded that SIS is a simple, safe and well-tolerated technique offering high diagnostic accuracy (DA).

In another study, Sharma et al also noted that SIS, while less sensitive than hysteroscopy, is simple and safe, particularly in low-resource settings where it can reduce the need for hysteroscopies.²⁷ Indu et al assessed TVS and SIS, with hysteroscopy as the gold standard and found that SIS was more sensitive and specific than TVS for identifying intracavitary abnormalities in AUB patients.²⁸ Nallapati et al confirmed SIS as a less invasive alternative to hysteroscopy, with high accuracy in detecting endometrial hyperplasia, polyps and submucosal fibroids.²⁹ This study is done in minimum sample and it is a single centre observational study. Hence, the obtained result cannot be generalised for different population. Further, multicentric study covering different population is recommended.

CONCLUSION

Both transvaginal sonography and saline infusion sonography are important diagnostic tools for evaluating

abnormal uterine bleeding in premenopausal women. While TVS serves as an effective first-line imaging modality, saline infusion sonography offers superior diagnostic accuracy for intracavitary uterine lesions. Therefore, SIS is considered a valuable complementary technique and may guide further management, including hysteroscopy or surgical treatment.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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