

SALINE INFUSION SONOGRAPHY: A VALID TOOL FOR DETECTION OF INTRAUTERINE PATHOLOGIES IN WOMEN WITH ABNORMAL UTERINE BLEEDING

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ABSTRACT

Background: Transvaginal ultrasound and hysteroscopy are commonly used modalities to detect endometrial pathologies in women with abnormal uterine bleeding. Saline infusion sonography is recently introduced for assessment of endometrium. Several studies have documented that saline instillation seems to be superior to and it can improve the specificity of TVS to differentiate the focal from diffuse intra-cavity lesions.

Objective: To determine the diagnostic accuracy of transvaginal ultrasound and saline infusion sonography for the detection of intra-cavity lesions of uterus taking histopathology on hysterectomy specimens as the final diagnosis.

Methods: Cross-sectional (validation) study. Present study was conducted in Department of Obstetrics & Gynecology, Madina Teaching Hospital, Faisalabad from January 18, 2022 to September 30, 2022. Sixty subjects with complaint of abnormal uterine bleeding were enrolled for the study. All participants were evaluated by transvaginal ultrasound (TVS) and saline infusion sonography (SIS) to assess endometrial pathologies. Findings at TVS and SIS were correlated with histo-pathological results on hysterectomy specimens. Sensitivity, specificity, predictive values and diagnostic accuracy were calculated.

Results: Mean age was 49.68±5.9 years. Polyps and proliferative endometrium were noted in 32 (53.3%) and 16 (26.7%) patients. Sensitivity, specificity, PPV, NPV and diagnostic accuracy of TVS are 61.36%, 100%, 100%, 48.48% and 71.67% for SIS and are 88.64%, 100%, 100%, 76.19% and 91.67% respectively.

Conclusion: SIS is highly sensitive and specific investigation to detect intra-cavity abnormalities of uterus. It can be used as an alternative investigation tool in low resource settings whenever hysteroscopy is not readily available.

Key Words: Uterine cavity lesions, sensitivity, specificity, saline infusion sonography

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INTRODUCTION

Abnormal uterine bleeding (AUB) is a common menstrual disorder affecting women of child bearing age to seek

gynecological help.¹ Dysfunctional uterine bleeding (DUB) is the term used when no organic lesion is detected and is the leading cause of menstrual abnormality in peri menopausal women; however, in more than 40% of affected women some underlying pathology is recorded. The causes of abnormal bleeding usually need to be investigated to preclude structural lesions particularly in perimenopausal and postmenopausal patients when the risk of endometrial malignancy is increased to 10% to 15%.² Menstrual disorders may also have profound impact on personal and

psychosocial health related quality of life that emphasizes the need to evaluate the causes of abnormal bleeding early and with modalities that are reliable and valid.

Several diagnostic modalities are used to detect focal endometrial pathologies. Among the established methods available for the evaluation of endometrial cavity, trans-vaginal ultrasound (TVS) is the most commonly employed initial investigation to assess the causes of AUB. TVS is a simple, noninvasive and cost-effective tool.³ Though widely used, many investigators conclude that focal endometrial lesions may not be diagnosed on simple grey scale evaluation because of limitations to measure the thickness of endometrial echo complex.⁴ Furthermore, endometrial polyps, submucous fibroids, endometrial hyperplasia and carcinoma may be simply diagnosed as thickened endometrium on TVS.

Diagnostic hysteroscopy and guided biopsy are considered the standard investigation as it demonstrates very small endometrial lesions by directly visualizing the uterine cavity⁵. Added advantage of hysteroscopy is to treat the underlying pathology at the time of initial diagnostic evaluation with a minimally invasive solution for some of the patients. However, hysteroscopy is an invasive procedure and not cost effective as a first line diagnostic approach to assess the endometrium.⁶ Despite high accuracy, adoption of hysteroscopy in low-income countries is limited due to lack of expertise and insufficient resources. This led to the search for an alternative diagnostic modality that has comparable accuracy with hysteroscopy, but also cost-effective, less invasive and widely acceptable by women having intra-uterine pathologies.

Saline infusion sonography (SIS) is recently introduced for more precise assessment of endometrial pathologies. Procedure involves distention of the uterine cavity with saline and ultrasound is performed to differentiate polypoidal lesions from diffuse endometrial thickening. Several studies have documented that saline instillation seems to be superior to and it can improve the specificity of TVS to differentiate the focal from diffuse intra-cavity lesions.⁷

There are several benefits of using saline instillation sonography as a primary evaluation modality in the cases of AUB. It is cheap, less invasive, less time consuming and more acceptable to patients than hysteroscopy⁸. The procedure is well tolerated by most patients as an outpatient procedure. Some patients may experience discomfort, anxiety and lower abdominal cramps but serious complications are rare with SIS. No anesthesia is required to perform the procedure. SIS is a safe and less invasive substitute to hysteroscopy in both pre and postmenopausal women with high accuracy.

METHODS

This cross-sectional study was carried out in the OB/GYN department of Madina Teaching Hospital,

Faisalabad from January 18, 2022 to August 18, 2020 after approval by institution ethical committee. Sixty patients who had excessive or irregular menstrual bleeding and postmenopausal bleeding were enrolled for the study. Informed consent was obtained from all participants who fulfilled the inclusion criteria. Patients who had bleeding due to acute pelvic inflammatory disease, pregnancy, genital tract malignancy or cervical pathology were not included in the study.

Preliminary history was obtained and general physical examination was performed in all patients. Relevant investigations were carried out and participants were submitted to sequential examination by TVS and SIS in single sitting before surgery. Detailed uterine evaluation was performed by the same experienced gynecologist to eliminate inter observer variations.

Transvaginal imaging was performed to measure the endometrial thickness and uterine pathologies were noted in all patients. In premenopausal women, endometrial thickness of ≥ 12 mm and in postmenopausal women thickness of ≥ 4 mm was considered significant.

Premenopausal women were subjected to TVS after cessation of menstrual bleeding in early follicular phase (no later than 10 days). There was no such limitation in post-menopausal patients and procedure was performed on convenience basis. Verbal informed consent was obtained from the patients before procedure.

Saline infusion was performed in dorsal lithotomy position. An appropriately sized sterile bivalve speculum was introduced in the vagina to visualize the cervix and Foley's catheter no. 10/12 was advanced in endometrial cavity through the external os. Balloon was inflated and approximately 15-20 ml saline instillation was done to distend the uterine cavity. Speculum was removed and transvaginal USG was performed to evaluate the uterine cavity pathologies.

Findings recorded on ultrasonography and saline sonography were correlated with histopathology findings reported on hysterectomy specimens.

Data collection was completed and analysis was done using SPSS V-16. Descriptive statistics were calculated. Sensitivity, specificity, predictive values and diagnostic accuracy were calculated. ROC and area under curve were also calculated.

RESULTS

Mean age of patients was 49.68 ± 5.9 years. Table I shows that endometrial polyp is the most common finding in study group (53.35%), followed by proliferative endometrium (26.7%). Interpretation of diagnostic accuracy of SIS and TVS in comparison to final histopathology diagnosis is indicated in Table II and III.

The sensitivity and specificity of SIS was 88.64% and 100% respectively as compared to transvaginal ultrasound which was 61.36% sensitive and 100% specific. Although final results showed similar positive predictive value of 100% for both modalities but negative predictive value was significantly different for SIS (76.19%) and TVS (48.48%) in the study group. Area under curve for TVS was 0.193 and for SIS it was 0.057.

Table I: Type of Endometrial Pathology

Pathology	Frequency	Percentage (%)
Uterine polyps	32	53.3
Proliferative Endometrium	16	26.7
Submucous fibroid	9	15.0
Endometrial Hyperplasia	3	5.0
Total	60	100

Table: II Diagnostic Accuracy of Saline Infusion Sonography

	Endometrial pathology on histopathology		Total
	Yes	No	
Endometrial pathology on Yes	39	0	39
Saline hystero-graphy No	05	16	21
Total	44	16	60

Sensitivity = 88.64%
 Specificity = 100%
 PPV = 100%
 NPV = 76.19%
 Diagnostic Accuracy = 91.67%

Table III: Diagnostic Accuracy of Transvaginal Ultrasound

	Endometrial pathology on histopathology		Total
	Yes	No	
Endometrial pathology on Yes	27	0	27
transvaginal ultrasound No	17	16	33
Total	44	16	60

Sensitivity = 61.36%
 Specificity = 100%
 PPV = 100%
 NPV = 48.48%
 Diagnostic Accuracy = 71.67%

DISCUSSION

TVS has been widely used as primary imaging modality for evaluation of abnormal uterine bleeding over the past two decades. Many researchers have also verified that TVS is non-invasive and highly accurate screening tool for evaluation of endometrial lesions⁹. Recent advances in the field of noninvasive radiology have introduced newer diagnostic modalities including 2D

and 3D fluid instillation Sono hystero-graphy to detect intra-uterine lesions with improved precision.

Several studies have compared the diagnostic performance of trans-vaginal ultrasound with saline instillation sonography and most of the researchers have concluded that SIS is a better diagnostic modality to detect focal endometrial lesions.¹⁰ Recent literature also indicates that TVS is not always adequate in diagnosing small polypoidal lesions despite its widespread use as an initial evaluation tool.

This study was conducted to determine the diagnostic yield of both modalities (TVS vs. SIS) and our results confirmed that SIS has higher diagnostic accuracy as compared to TVS for the detection of uterine cavity lesions. In a recent meta-analysis, SIS was found to be 96.9% sensitive and 99.5% specific which is in agreement with the present study.¹¹

Polypoidal lesion was the most frequently observed pathology in present study. Kamabbe and colleagues also described an improved efficacy of SIS compared to TVS for identifying uterine myomas and endometrial nodules. In their study, uterine myomas were diagnosed with accuracy of 90.2% when SIS was performed as compared to diagnostic accuracy of 75.4% with TVS.¹² Low efficacy of TVS was confirmed in many other studies showing significantly low PPV (65.2%) for detection of polyps than PPV of SIS (88.5%).¹³ Shiva et al., concluded that TVS has low sensitivity (50%) and specificity (98%) for detection of polyps, fibroids (80%) and uterine anomalies¹⁴. The positive predictive value of TVS was significantly inferior (65.2%) than SIS (88.5%), even when clinical suspicion for the presence of polyp was very high.¹⁵

Despite the fact that transvaginal ultrasound is first line noninvasive technique for endometrial assessment, various studies have confirmed low detection rate for small intra-cavity lesions when ultrasound is used alone. Our study also verified that accuracy of TVS in diagnosing polypoidal lesions, fibroids and endometrial hyperplasia was limited with an overall sensitivity of 61.36 % and accuracy of 71.67% when compared to SIS. Similar findings were recorded in a study showing that TVS is more sensitive but less specific to outline the intra-cavity pathologies.¹⁶

The ability of TVS is questionable to distinguish among diffuse focal lesions and endometrial hyperplasia. On the other hand, saline infusion sonography allows more precise identification of uterine cavity pathologies and may still be required to improve diagnostic reliability of ultrasound where it fails to diagnose small endometrial lesions. On this point, our findings are reinforced by many other workers, reporting a significant number of false positive and false negative diagnoses of endometrial pathologies when TVS is performed alone

in cases of AUB.¹⁷ Available evidence also supports that SIS is more reliable primary screening tool to assess diffuse endometrial problems. Thus, the number of unnecessary hysteroscopies can be limited to further delineate uterine cavity when pathology is missed on TVS. TVS can be substituted with SIS as a safe and less invasive technique for appropriate patient selection and to guide for further need of hysteroscopy.

Both SIS and TVS found to have high sensitivity (100%); however, SIS was found to be more specific than TVS in our study. The results are comparable to a local study, demonstrating 97.6 5 specificities of saline hystero-sonography with diagnostic accuracy of 92% .¹⁸

Many researchers have further suggested that sensitivity of transvaginal scan can be improved when combined with saline hystero-sonography. Saline instillation enables the operator to map the exact size, number and location of nodular/polypoidal lesions in relation to myometrium. Distension of endometrial cavity with a sonolucent medium provides a chance to diagnose other uterine pathologies at the same sitting with less patient discomfort and inconvenience. Same findings were recorded in present study; and a recent analysis showing sensitivity, specificity, PPV and NPV of 79.65, 89.1%, 89.6%, and 78.8% respectively.¹⁹

With respect to accuracy, author concluded superior accuracy of SIS which is in line with many other recent studies. Excellent sensitivity and specificity have been reported for SIS (95.1% and 83.3%) when compared to trans- vaginal ultrasound (79% and 45.8%), particularly for endometrial polyps and submucous fibroids²⁰. In a recent comparison of SIS with hysteroscopy to diagnose focal endometrial lesions, SIS was found to be 85% sensitive and 99% specific with 96% NPPV & PPV.²¹

SIS is a valuable diagnostic modality for sub fertile women and can be used as an alternative to hysteroscopy when intra-cavity pathology is described as a potential cause of AUB in these females.²² This diagnostic approach is valid in both pre and postmenopausal woman for initial outpatient screening. In one analysis, overall diagnostic accuracy of TVS was 47.5% for detection of endometrial pathologies.²³ Low sensitivity of TVS to delineate a thickened but otherwise normal endometrium is a matter of current debate and may have relevance in clinical settings.²⁴

Recent ACOG recommendations highlight that TVS alone is not a suitable screening method for detection of intracavity problems in postmenopausal women and the use of saline instillation can provide an enhanced visualization of uterine cavity lesions in such patients.²⁵ Therefore, SIS is highly recommended for initial evaluation of abnormal uterine bleeding and associated intra-uterine pathology.

CONCLUSION

SIS is a safe, less invasive and practically more precise radiological technique that can be used as a primary screening modality to outline the uterine cavity lesions in pre and postmenopausal bleeding. In view of high accuracy, SIS can be considered as an alternative investigation in low resource settings for appropriate patient selection and to obviate the future need of more invasive investigations like hysteroscopy.

However, more research is needed to establish protocols for better utility of SIS as an optimal diagnostic approach in clinical practice.

Ethical Approval: Submitted

Conflict of Interest: Authors declare no conflict of interest.

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