

Original Article

Comparative study between saline infusion sonohysterography and diagnostic hysteroscopy in diagnosing endometrial pathology in patients of abnormal uterine bleeding

Pranab Kumar Biswas¹, Sushanta Kumar Pain², Sandhya Das², Fakra Masroor³, Sohini Munshi⁴, Manoshi Santra⁴, Soumen Patra⁴

Background : Abnormal Uterine Bleeding (AUB) is a common but complicated clinical presentation, diagnosis of which is often difficult. The cause may be variable of which endometrial pathology is an important component. Saline infusion sonohysterography (SIS) is a procedure in which a transvaginal scan is done after instilling normal saline into the uterine cavity, thus providing a better visualisation of endometrial cavity.

Objective : This study was aimed at the comparison of the diagnostic accuracy of SIS for each of the individual endometrial pathologies (endometrial polyps, endometrial hyperplasia and submucous fibroids) taking versus hysteroscopic findings, accepting hysteroscopic assessment as the gold standard. Precisely, Positive predictive values Sensitivity, specificity, and negative predictive values of SIS were evaluated here.

Material and Method : The study was performed in Department of Gynaecology and Obstetrics, Calcutta National Medical College and Hospital on 50 cases for a period of 1 year (June 2015-May 2016). Cases of AUB with suspected endometrial pathology diagnosed in GOPD clinically and by commonly available diagnostic tools (USG, blood parameters etc.) were included. The sensitivity (SN), specificity (SP), positive (PPV) and negative predictive value (NPV) for polyps were 83.3, 92.1, 76.9 and 94.6 respectively. For submucous fibroids SN, SP, PPV and NPV were respectively 84.6, 97.3, 91.2, 94.7. Endometrial hyperplasia detection showed similar values (SN=73.3, SP=97.1, PPV=91.7, NPV=89.7).

Conclusion : The study concluded that, compared to hysteroscopy SIS is cost effective. The sensitivity and specificity of SIS are comparable to hysteroscopy in evaluating endometrial pathology. Its use as a pre-operative evaluation shows promise as it may help avoid major surgical interventions and its associated morbidities.

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Key words : Saline Infusion Sonography (SIS), Trans-vaginal Sonography (TVS), Hysteroscopy, Submucous fibroids, Polyps, Endometrial hyperplasia.

AUB or Abnormal Uterine Bleeding is a common but complicated clinical presentation, diagnosis of which is often difficult as the cause may be variable from simple Dysfunctional Uterine Bleeding to endometrial carcinoma. AUB is said to occur in 9-14% women between menarche and menopause¹. The prevalence varies in each country. In India the reported prevalence of AUB is around 17. Frequently, patients with Abnormal Uterine Bleeding undergo a transvaginal

Department of Obstetrics & Gynaecology, Calcutta National Medical College & Hospital, Kolkata 700014

¹MBBS, MD (Obstat & Gynae), Professor and Corresponding Author

²MBBS, MD (Obstat & Gynae), Assistant Professor

³MBBS, MD (Obstat & Gynae), Assistant Professor

³MBBS, DNB, RMO cum Clinical Tutor

⁴Postgraduate Trainee

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Editor's Comment :

- AUB is a very common presentation in Gynecology OPD.
- Diagnosis of AUB is often difficult with available diagnostic procedures.
- Endometrial pathology (like polyp, submucous fibroid, hyperplasia etc) needs MRI or Hysteroscopic evaluation.
- Hysteroscopy is considered as gold standard in diagnosing endometrial pathology but it is costly and there is procedure related complications.
- MRI is costly and not readily available everywhere.
- SIS is simple, affordable, without any major procedural complications, and is comparable in Sensitivity, Specificity, Positive and Negative predictive values with Hysteroscopy in diagnosing endometrial pathology.

scan followed by diagnostic or therapeutic hysteroscopy. These approaches rarely evaluate the endometrial components and hence falsely stamp

them as DUB (ie, bleeding in absence of any pelvic pathology. Sonosalpingography (SIS) is a modified transvaginal scan wherein scanning is done during infusion of normal saline into uterine cavity to diagnose endometrial pathologies. The study was done to see if saline infusion sonohysterography could compare with hysteroscopy for the diagnosis of endometrial pathology in patients with menstrual abnormalities. SIS and hysteroscopic findings of endometrial polyps, submucous myomas, endometrial hyperplasia etc. were recorded and subsequently compared.

Terminologies:

Any deviation from normal parameter was treated as abnormal in our study. In order to define normal menstrual bleeding we took the following guideline as our reference.

Suggested terminologies for normal Menstrual Parameters in the Mid-Reproductive Years³ (Fig 1).

Usual Menstrual cycle parameters	Descriptive terms	Normal limits (5 th -95 th percentile)
Interval between menstruation	Normal	24-38 days
Variation of menstruation over 12 months	Regular	Variation 2-20 d
Number of days the flow happens	Normal	4.5-8 days
Amount of blood loss (ml)	Normal	5-80ml

Causes of A.U.B (FIGO classification)

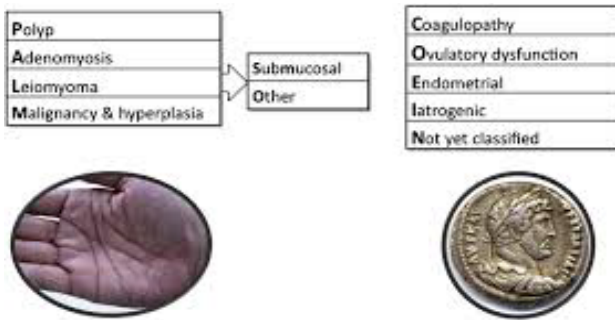


Fig 1

MATERIALS AND METHODS

STUDY LOCATION : Department of Obstetrics and Gynaecology and Department of Radiology of Calcutta National Medical College and Hospital.

STUDY POPULATION : Women admitted in OBGYN dept. with Abnormal Menstruation.

STUDY PERIOD : One year (June 2015-May 2016)

SAMPLE SIZE : 50 (fifty) cases.

SAMPLE DESIGN : Those patients who attended Outpatient Department in Obstetrics and Gynaecology department with Abnormal Uterine Bleeding were

examined clinically and selected for SIS and Diagnostic Hysteroscopy

INCLUSION CRITERIA : AUB (as defined by bleeding not following the normal menstrual parameters) with suspected endometrial pathology diagnosed in GOPD clinically and by commonly available diagnostic and ancillary aids

EXCLUSION CRITERIA : 1. Pregnancy 2. Virgin women 3. Pelvic inflammatory disease 4. Morbid medical illness 5. Any diagnosed cause of menstrual abnormality by clinical or diagnostic aids. 6. Patients whose uterine cavity could not be distended by saline infusion or SIS could not be performed due to other causes.

STUDY DESIGN : Prospective comparative study for assessing the efficacy of Saline Sonography in diagnosing uterine cavity abnormalities in comparison with hysteroscopy.

PARAMETERS STUDIED : Endometrial thickness, uterine cavity contour, polyps and synechia seen by SIS along with Hysteroscopic findings of uterine cavity including polyps, endometrium, etc.

STUDY TOOLS : (1) **Saline infusion sonohysterography :** TVS probe, standard HD7 philips mode USG machine, SIS cannula (polyethylene, 26cm with acorn shaped guard), vaginal speculum and other minor aids for cleaning and draping , analgesics. (2) **Hysteroscopy :** A 30 degrees rigid hysteroscope was used with a telescope of 4mm outer diameter. The outer sheath had an outer diameter of 8 mm, and contained ports for instillation of the distending medium. An obturator fitting the outer sheath was also provided to simulate a smooth, blunt dilator.

STUDY TECHNIQUE : Those patients who attended GOPD with clinically undiagnosed A.U.B. were asked to participate voluntarily after explaining the purpose of the study and consent taken. Relevant history was taken from such patients regarding age, weight, parity, menstrual history, family history, surgical history. A brief pelvic examination was done and investigations reviewed. Patients were selected for the study matching the inclusion and exclusion criteria. Such patients were then examined by saline infusion sonohysterography. Observations such as endometrial hyperplasia, polyps, synechia, submucous myomas as well as normal findings were recorded. The same patients were kept for diagnostic hysteroscopy under general anaesthesia. The findings of SIS were compared with hysteroscopic findings set as gold standard.

SIS Technique:

Timing : As soon as possible day 6 to day 11 -

during proliferative phase of menstrual cycle (regular cycle) after stoppage of bleeding. In cases of irregular cycles, it was done after the bleeding was controlled.

Patient preparation : Oral NSAIDS were given 1 hour before examination and a Routine TVS for pelvic assessment was done. Patient was placed in lithotomy position after a Brief bimanual examination.

Procedure : Sterile speculum was placed in vagina and cervix brought into view. Catheter was placed at internal os and advanced through stiffener into the endometrial canal. Speculum was gently withdrawn and Trans-vaginal probe inserted beside catheter. 5-30 ml of normal saline injected and 2d imaging was done in both sagittal and coronal sections. 3D imaging and doppler were done to differentiate blood clots from polypoid lesions. The patients were seen to tolerate the procedure well.

Diagnostic Hysteroscopy Technique :

A diagnostic hysteroscopy was performed subsequently in such subjects and uterine cavity was analysed thoroughly.

Analysis of Data :

The data collected was tabulated, compared and analysed by standard statistical methods in consultation with statistician, department of community medicine. Inferential analysis as performed using the chi-square test. Cohen’s kappa coefficient was used to measures inter-rater agreement for qualitative items.

DISCUSSION

Saline infusion sonohysterography has its own advantages. Apart from being associated with very minimal complications, it is cost effective, easy to perform and well tolerated by most patients. Thus, the American College of Radiology, the American Institute of Ultrasound in Medicine and The American College of Obstetricians and Gynecologists has developed a technology assessment document for saline sonography.

Indications of SIS include Post menopausal bleeding, endometrial polyps, Leiomyomata, endometrial hyperplasia / carcinoma, Tamoxifen therapy, Mullerian anomalies, masses and intra uterine adhesions, recurrent pregnancy loss etc.

Contraindications of SIS are Pregnancy, active Genital tract bleeding or acute genital infections.

SIS helps to presumptively diagnose the endometrial causes of AUB. Thus, it helps to select candidates for endometrial sampling. It gives a fair idea about candidates who needs a focal lesion to be

sampled versus candidates who can be taken up for opd based pipelle sampling.

Hysteroscopy is the inspection of the uterine cavity by endoscopy with access through the cervix. Besides diagnosing intrauterine pathologies, operative hysteroscopy may help in correcting such pathologies. Hysteroscopy is useful in diagnosing a number of uterine conditions:^[4]

- Asherman’s syndrome (i.e. intrauterine adhesions).
- Endometrial polyp.
- Gynecologic bleeding (submucous fibroids, endometrial hyperplasia)
- Congenital uterine malformations (also known as Mullerian malformations).

Apart from these, hysteroscopy has some definite therapeutic advantages like performance of polypectomy, endometrial ablations, submucous myomectomy etc which is beyond the scope of this study.

The use of hysteroscopy in endometrial cancer is not established^[5] as there is concern that cancer cells could be spread into the peritoneal cavity. Compared to blind procedures performed on delicate reproductive tissues of uterus, hysteroscopy performed under visualisation reduces iatrogenic trauma to a large extent.

Results						
SIS * HYSTEROSCOPY Crosstabulation						
HYSTEROSCOPY					Total SIS	
	A	B	C	D		
SIS	A	10	0	0	3	13
	B	0	11	1	0	12
	C	0	1	11	1	13
	D	2	1	3	6	12
Total Hyst.		12	13	15	10	50

A=polyp, B=submucous fibroid, C=endometrial hyperplasia, D=normal findings

Polyps			
SIS	HYST		TOTAL
	YES	NO	
YES	10	3	13
NO	2	35	37
TOTAL	12	38	50

Sensitivity	Specificity	Positive predictive value	Negative predictive value	Percentage agreement
83.3	92.1	76.9	94.6	90

From the above chart, it is clear that though SIS is highly sensitive for detection of polyp, it is more specific (92.1) than sensitive (83.3) in this regard

Submucous fibroids			
SIS	HYST		TOTAL
	YES	NO	
YES	11	1	12
NO	2	36	38
TOTAL	13	37	50

Sensitivity	Specificity	Positive predictive value	Negative predictive value	Percentage agreement
84.6	97.3	91.2	94.7	94

For submucous fibroids, sensitivity(84.6) is almost equivalent to polyp detection, but here again specificity (97.3) is more than sensitivity leading to a higher negative predictive value.

Endometrial hyperplasia			
SIS	HYST		TOTAL
	YES	NO	
YES	11	1	12
NO	4	34	38
TOTAL	15	35	50

Sensitivity	Specificity	Positive predictive value	Negative predictive value	Percentage agreement
73.33	97.14	91.7	89.7	90

Coming to endometrial hyperplasia detection, my study has shown a good sensitivity (73.3), but it is low compared to polyp and submucous fibroid detection. But here positive predictive value has been observed to be greater than negative predictive values when compared with polyps and fibroids.

Test Statistics			
SIS			
	Observed N	Expected N	Residual
A	13	12.5	0.5
B	12	12.5	-0.5
C	13	12.5	0.5
D	12	12.5	-0.5
Total	50		
HYSTEROSCOPY			
	Observed N	Expected N	Residual
A	12	12.5	-.5
B	13	12.5	.5
C	16	12.5	3.5
D	9	12.5	-3.5
Total	50		

Significance		
	SONOHYS	HYSTERO
Chi-Square	0.080 ^a	2.000 ^a
df	3	3
Asymp. Sig.	0.994	0.572

^a0 cells have expected frequencies less than 5. The minimum expected cell frequency is 12.5.

Symmetric Measures					
		Value	Asymp. Std. Error ^a	Approx. T ^b	Approx. Sig.
Measure of Agreement	Kappa	0.680	0.080	8.337	0.000
N of Valid Cases		50			

^aNot assuming the null hypothesis.
^bUsing the asymptotic standard error assuming the null hypothesis.

Saline sonography performed well in our study was comparable to diagnostic hysteroscopy^{6,7}. It's sensitivity in detecting polyps, submucous fibroids and endometrial hyperplasia was 83.3%, 84.6% and 73.3% respectively. Its specificity as found in our study for the detection of the above pathologies in the same order were 92.1%, 97.3% and 97.1% respectively. Apart from these, the predictive values found in our study (both positive and negative) and that done by bingo et al in 2011⁶ were comparable. The level of significance as determined by chi square tables were 0.08 for SIS and 2.00 for hysteroscopy (degrees of freedom-3) indicating the increased probability of erroneous findings being accepted as true. But, such findings are a result of a small sample size with increased number of variables observed in the study.

Undiagnosed AUB constitutes a large burden to gynaecological OPD in all hospitals. The socio demographic characteristics of such undiagnosed abnormal uterine bleeding has a variable pattern. Some of these undiagnosed cases are often stamped as dysfunctional uterine bleeding without assessing endometrial pathology. In our study, we established that endometrial pathologies like polyps and submucous fibroids constituted a major bulk of AUB often missed by common investigative tools. SIS proved to be an efficient process by which intrauterine pathologies were identified with ease. Compared to hysteroscopy it is cost effective, involves minimal aids and has lesser inter observer variability. It has some minor technical difficulties like stenosed internal os which may lead to inability to pass catheter or blood clots which may mimic polyp. The sensitivity and specificity of Saline infusion Sonohysterography are comparable to hysteroscopy in evaluating uterine cavity as demonstrated by our study and corroborated by other studies. Whereas hysteroscopy is still considered a costly investigation owing to its requirement of a hysteroscope and anaesthetic procedures, SIS is more cost effective and with lesser complications. Its use as a pre operative evaluation shows promise as it may help avoid major surgical interventions and its associated morbidities resulting

in better utilisation of hospital resources.

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Conflict of Interest : None

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