

Saline Infusion Sonography: Can it be a less invasive, cheaper alternative to hysteroscopy in the management of Abnormal Uterine Bleeding.

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Abstract

Aim and Objectives: Aim of this study was to explore the role of saline infusion sonography(SIS) as initial investigative modality in the diagnosis and management of Abnormal Uterine Bleeding(AUB). Diagnostic Hysteroscopy(DH) which is a gold standard method is taken as a bench mark for final diagnosis.

Introduction: AUB is an important cause of women attendance in Gynecological OPD. Till now we are dependent on Hysteroscopy examination for diagnosis and management of AUB. But both hysteroscopy and histopathology are invasive method. So efficacy of SIS should be explored.

Material Methods: Study was conducted over 85 women suffering from AUB between the age group 40 – 55 years, between 6th – 10th day of menstrual cycle.

First Trans Vaginal Sonography(TVS) screening was done followed by SIS and DH. Data collected was analyzed and sensitivity, specificity, PPV, NPV was calculated.

Result: Upon comparison of saline infusion sonography with gold standard hysteroscopy for submucosal fibroid sensitivity, specificity, positive and negative predictive values were 88.8%, 100%, 100% and 92.5% respectively. Similarly for endometrial hyperplasia and endometrial polyp sensitivity, specificity, positive and negative predictive values were 100%, 83%, 80%, 100% and 71.4%, 100%, 100% and 92.5% respectively.

Conclusion: Saline infusion sonography is easy to do method, cheap, minimally invasive outdoor procedure in the diagnosis and management of AUB.

Keywords: Hysteroscopy, Trans vaginal sonography, Submucosal fibroid, endometrial polyp.

Introduction

Abnormal uterine bleeding is one of the important concerns for women attending outdoor of gynecology department. It is of more concern in perimenopausal and postmenopausal women due to Cancer phobia. For early diagnosis of any malignancy, screening procedures are gaining more and more importance these days. Newer techniques are developing for the early diagnosis and best management of abnormal uterine bleeding. Besides dysfunctional uterine bleeding, one of the important cause (40% of affected women) of abnormal uterine bleeding is intrauterine abnormalities¹. Abnormal uterine bleeding accounts for 33% of Gynecological outdoor attendance and among 69% of women aged 48 years or above (perimenopausal and postmenopausal women). AUB²⁻⁴ is still on the top of list of “indication of hysterectomy”. Saline infusion sonography is a cost effective, minimally invasive, easy to perform, easily available and safe method to access uterine cavity.

In perimenopausal and postmenopausal women, fractional curettage of endometrium was main investigation in the management of AUB. Gradually it shifted towards hysteroscopic guided biopsy. Hysteroscopy remain the gold standard to diagnose intracavitary uterine lesion in AUB cases and its management. But it is costly, require skill and expertise and not within the reach of majority of population. So SIS can be a safe, cheap, efficient, easily available alternative. So the objective of this study was to assess the efficacy of combined TVS plus SIS in evaluation of endometrial pathology in comparison to diagnostic hysteroscopy (D/H). Plan of study is to assess the possibility of SIS as initial investigation modality in the

diagnosis of endometrial pathology instead of expensive D/H.

Material and Method

This study (a prospective study) was conducted over 85 patients after taking informed consent and following ethical guidelines, between 2013 Jan to 2016 December.

Inclusion Criteria

- Women of age group between 40 – 55 years with presenting complain of abnormal uterine bleeding.
- In TVS, endometrial thickness > 4 mm
- Normal BT, CT, PT, INR and APTT.

Exclusion Criteria

- Abnormal vaginal discharge or any clinical evidence of pelvic infection (tender adnexae during pelvic examination).
- Women with history of hormonal treatment in last 6 month or history of taking oral contraceptive pills in last 3 month.
- Women suspicious of pregnancy or pregnancy related complications (Urinary pregnancy test done before procedure)
- Women taking oral or injectable anticoagulants drug.
- Women with abnormal liver function tests or with endocrinal disorder.
- Endometrial thickness in TVS \leq 4mm
- Bleeding per vaginum

Transvaginal ultrasound was done in postmenstrual phase with empty bladder following detail history, medical and gynaecological examination.

All patients were given single i.m injection of aqueous diclofenac 30 min before the procedure. SIS was performed between 6th to 10th days of menstrual cycle. This period was selected to avoid any very early

abortion and to avoid confusion with thickened endometrium of secretory phase of menstrual cycle.

TVS was conducted on “Acuson NX3, SIEMENS ultrasound system” with 7.5 MHz probe. TVS probe was covered with pre sterilised (sterilized with ETO), packaged, disposable probe cover with full antiseptic and aseptic precaution. First detail study of uterus and adnexa was done with TVS. Sim’s speculum was inserted and anterior lip of cervix was held with a allis tissue forcep. No. 8 foley’s catheter was introduced inside cervical canal and inflated with 1.5 ml of normal saline only. Prepared TVS probe was reinserted and uterine cavity as slowly distended with 10 ml to 15 ml of normal saline (Incase with enlarged uterus 20 ml instillation of normal saline was required. Detailed scanning was done in both sagittal and coronal plane from one end to other end. Foley’s Balloon was deflated and endometrium underlying balloon was carefully reviewed for any pathology. Finally the collected data record included (i) TVS findings (ii) SIS findings (iii) Hysteroscopic finding.

Result

In our study maximum patients (72 – 95%) were between the age group 40 – 50 years. Most of the women were multiparous (80.00%) and maximum patients were (63.33%) from low socioeconomic group (table-1). Most common presenting complaint was menorrhagia (63%). Menometrorrhagia was presenting complain in 11% of women, 4% had dysmenorrhoea and rest (7%) had other menstrual abnormalities.

In our study endometrial hyperplasia was diagnosed in 20 (23.53%) cases and submucosal fibroid (37.65%) was diagnosed in 32 cases. In Hysteroscopy, normal uterine cavity was found in 2 (2.35%) cases. However in SIS, normal uterine cavity was diagnosed in 9 cases (10.58%) (Table- 2). We diagnosed mainly three

pathologies, endometrial hyperplasia, endometrial polyp, submucous fibroid besides others less common pathologies like atrophic endometrium, focal thickening of endometrium, intrauterine adhesion and uterine septum. Table – 3, shows sensitivity, specificity, positive predictive value and negative predictive value of all above pathologies in comparison to Hysteroscopy.

Discussion

Abnormal uterine bleeding is most common complain of women attending gynecological OPD. There are many modalities to differentiate between functional and organic causes of AUB. Till now Hysteroscopy is known to be gold standard for diagnosis of AUB after histopathological examination.

It is important to differentiate between organic and functional causes because organic causes require surgical intervention, whereas functional causes need medical management.

Hysteroscopy provides direct visualization of endometrial cavity and can diagnose and differentiate endometrial polyp, endometrial hyperplasia, submucous fibroid and endometrial cancer. At the same sitting, hysteroscopy provides the opportunity to do therapeutic management and opportunity to take biopsy from the suspicious area under direct visualization. With hysteroscopy accurate assessment of interacavitary lesion of uterus is possible and accurate removable of submucosal fibroid and endometrial polyp can be performed. However Hysteroscopy has some limitations also. It is excellent in providing intracavitary view but myometrial extension of lesion like submucous fibroid, its depth cannot be assessed by hysteroscopy. At the same time adnexal assessment is not possible by hysteroscopy .

SIS is cheap, easy to perform, least invasive, very efficient method and does not require general anesthesia.^{5, 7} With SIS, myometrium and adnexal assessment is possible in detail, which is not possible with hysteroscopy. At the same time hysteroscopy is expensive, not available everywhere, require technical skill and expertise and associated with risk of complications (Uterine perforation and risk of anesthesia)^{6,7} Endometrial outline with overlying or underlying pathology, focal pathology, myometrial texture are reliably evaluated by SIS.⁸ On injection of isotonic saline, it distends endometrial cavity and provides an acoustic window, against which we can clearly visualize inner surface of both endometrium and thus both focal and diffuse abnormalities of endometrium are diagnosed.

In our study out of 85 cases, endometrial hyperplasia was diagnosed in 20 (23.5%) cases, whereas by hysteroscopy it was confirmed in 16 (19.5%) cases only. Four cases of endometrial hyperplasia (4.70%) as diagnosed by SIS, were actually cases of sessile endometrial polyp (false negative cases for SIS) confirmed by hysteroscopy and biopsy were also taken in same sitting. Sensitivity, specificity, PPV and NPV of our study for endometrial hyperplasia and endometrial polyp our given in Table 3. SIS is very reliable in differentiating endometrial polyp from submucous fibroid depending upon imaging characteristics against very good acoustic window provided by distended uterine cavity with isotonic saline.^{5,8} Endometrial myometrial interface is very beautifully visualized in SIS, which is not possible in hysteroscopy. This endometrial myometrial interface is preserved in endometrial polyp, whereas lost in submucous fibroid.^{8,9} Endometrial polyps typically have sharp margin, round shape, smooth outline and are

mostly echogenic compared to endometrium (sometime isoechoic also). Submucous fibroid are visualized as less sharp margins, mostly hypoechoic or sometime isoechoic, diffuse swelling with lost endometrial – myometrial interface. Our study result regarding submucous fibroid is shown in table- 2. For submucous fibroid assessment, MRI and 3D SIS are very reliable and found to be superior to hysteroscopy.⁶ In our study submucous fibroid was diagnosed by SIS in 32 (32.65%) cases. But by hysteroscopy in 36 (42.35%) cases submucous fibroid was confirmed (false negative for submucous fibroid by SIS). In discussion with one of the radiologist (team member) it is concluded that probably due to small size (all were <1cm) these four cases of submucous fibroid were missed in SIS. But regarding management point of view, such small sized fibroid mostly do not require surgical interventions. Erdem et al, reported sensitivity and specificity of SIS in diagnosis of endometrial polyp were 100% and 91.8% respectively and in the diagnosis of submucous fibroid were 95% and 100% respectively.⁷ This study was also supported by Ryu et al, where sensitivity and specificity were 95% and 83.3% respectively in diagnosis of endometrial pathology.¹⁰ All these studies are suggesting that SIS should be done as an initial alternative approach in investigation of women presented with AUB.^{11,12} In our study we diagnosed atrophic endometrium in four cases but in hysteroscopy atrophic endometrium was diagnosed in five cases (false negative finding in one case in SIS for atrophic endometrium. In hysteroscopy we get very minute, punctate hemorrhagic spot in case of atrophic endometrium which was the cause of failure to diagnose atrophic endometrium in one case by SIS.

In a large meta-analysis involving review of 2228 procedure of comparison of SIS with hysteroscopy or

hysterectomy, the result showed pooled sensitivity of 3D SIS for uterine cavity assessment as 0.95 (95% confidence interval (CI), [0.93-0.97]. and the pooled specificity was 0.88 (95% CI, 0.85-0.92). Conclusion of meta-analysis was that SIS was an accurate means of assessment of endometrial cavity in pre and

postmenopausal women with AUB.¹² Many studies concluded that combined TVS and SIS are more accurate and cost-effective than hysteroscopy.^{10,13} Many comparative studies were performed between SIS and hysteroscopy.^{14,18}

Table 1: Patient Profile

Age (years)	No	Percentage
40 – 45	30	35.29 %
46 – 50	32	37.65 %
51 – 55	23	27.06 %
Total	85	100 %
Parity		
Nulliparous	11	12.94 %
Primipara	6	7.05 %
Multipara	68	80.00 %
Total	85	100 %
Socio-economic status		
High	2	2.35 %
High middle	7	8.23 %
Low middle	22	25.89 %
Low	54	63.33 %
Total	85	100 %

Table 2: Comparison of SIS with Hysteroscopy

Findings	SIS		Hysteroscopy	
	No.	Percentage	No.	Percentage
Normal	9	10.58 %	2	2.35 %
Endometrial hyperplasia	20	23.53 %	16	18.82 %
Submucosal fibroid	32	37.65 %	36	42.35 %
Endometrial Polyp	10	11.76 %	14	16.47 %
Atrophic endometrium	4	4.70 %	5	5.88 %
Intrauterine adhesion	2	2.35 %	4	4.70 %
Uterine Septum	3	3.52 %	4	4.70 %
Focal thickening of endometrial	5	5.88 %	4	4.70 %
Total	85	100 %	85	100 %

Table 3 : Diagnostic accuracy of SIS

	Sensitivity	Specificity	PPV	NPV
Endometrial hyperplasia	100 %	83 %	80 %	100 %
Submucosal fibroid	88.8 %	100 %	100 %	92.5 %
Endometrial Polyp	71.4 %	100 %	100 %	95.3 %
Atrophic endometrium	80 %	100 %	100 %	98.7 %
Focal thickening of endometrium	100 %	98.7 %	80 %	98.9 %
Intrauterine adhesion	50 %	100 %	100 %	97.5 %
Uterine septum	75 %	100 %	100 %	98.8 %

Table 4: Comparison of different study

Pathology		Our study	Nallapati et al ¹⁴	Rudra et al ⁶	Btosis et al ¹⁵	Dasguptal et al ¹⁶
Endometrial hyperplasia	Sensitivity	100 %	100 %	97.9 %	-	88 %
	Specificity	95.20 %	94 %	100 %	-	90.6 %
Submucosal fibroid	Sensitivity	94.98 %	86.36 %	97.3 %	99 %	98.7 %
	Specificity	87.00 %	83.00 %	88.2 %	88 %	85.7 %
Endometrial polyp	Sensitivity	98.00 %	90.9 %	97.3 %	96 %	97.6 %
	Specificity	93.99 %	92.6 %	93 %	96 %	97.6 %
Atrophic endometrium	Sensitivity	95 %	-	-	-	-
	Specificity	98.29 %	-	-	-	-
Focal thickening of endometrium	Sensitivity	92.8 %	-	-	-	-
	Specificity	98.64 %	-	-	-	-
Intrauterine adhesion	Sensitivity	88.2 %	-	-	-	-
	Specificity	90.02 %	-	-	-	-
Uterine septum	Sensitivity	98.92 %	-	-	-	-
	Specificity	97.03 %	-	-	-	-

Table 5: Comparison of diagnostic potential of SIS with hysteroscopy

	Our study	Nallapati et al ¹⁴	Rudra et al ⁶	Dimitriu et al ²⁰	WIndrich et al ¹⁷	Krampl et al ¹⁸	Kamel et al ¹⁹
Sensitivity	97.7 %	100 %	90.9 %	97.4 %	96 %	94 %	93.1 %
Specificity	86.82 %	58.8 %	88.3 %	99.1 %	88 %	84 %	93.9 %
Positive predictive value	84.5 %	82.5 %	86 %	98.7 %	89 %	89 %	94.6 %
Negative predictive value	99.92 %	100 %	92.5 %	98.2 %	98 %	98 %	92 %

Conclusion

Saline infusion sonography is a highly effective, least invasive, well tolerated, rapid, cheap and safe outdoor procedure in comparison to hysteroscopy in the diagnosis of AUB. SIS can be used as a first line, initial investigation modality in evaluation of endometrial cavity in women with AUB. It should be combined with initial TVS screening to increase the diagnostic accuracy. But larger studies are required to establish the role of SIS.

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