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Research Article

## Role of saline infusion sonography in abnormal uterine bleeding

Megha Sharma<sup>1\*</sup>, Shubham Joshi<sup>2</sup>, Akash Sharma<sup>3</sup>, Oby Nagar<sup>1</sup>,  
Rakesh Khuteta<sup>1</sup>, Meenu Bagarahatta<sup>4</sup>

<sup>1</sup>Department of Obstetrics and Gynaecology, <sup>2</sup>Department of Medicine, <sup>4</sup>Department of Radiodiagnosis, SMS Medical College, Jaipur, Rajasthan, India

<sup>3</sup>Department of Pediatrics, Dr. S.N. Medical College, Jodhpur, Rajasthan, India

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**\*Correspondence:**

Dr. Megha Sharma,

E-mail: meg\_med5@yahoo.co.in

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### ABSTRACT

**Background:** To describe the diagnostic efficacy of Saline Infusion Sonography (SIS) in Abnormal Uterine Bleeding (AUB).

**Methods:** This is a hospital based observational descriptive study conducted in 121 women visiting the OPD with complain of AUB in any form, between September 2011-August 2012. SIS was done using Crooke's cannula followed by Diagnostic Hysteroscopy (DH) the following day. Results obtained were analysed.

**Results:** 61% of the cases of AUB were diagnosed to have some abnormality by hysteroscopy as compared to 51 % by SIS. The sensitivity of SIS was greatest (100%) for Mullerian anomalies, 75% for endometrial hyperplasia, 69% for endometrial polyps, 68.75% for submucous myomas and 66.67% for endometritis. The specificity was greatest for endometrial hyperplasia and adhesions (100%), 99% for submucous myomas, 98.3% for endometritis, 95.7% for endometrial polyps and mullerian anomalies. It had a 100% positive predictive value for endometrial hyperplasia, 92% and 83% for submucous myomas and endometrial polyps respectively. The overall sensitivity and specificity of SIS in our setting was 67.56% and 93.6% respectively. The diagnostic efficacy of SIS for Endometrial hyperplasia, Endometritis, Endometrial Polyps, Mullerian abnormalities, Submucous fibroid and Adhesions was 96.69%, 97.53%, 89.25%, 95.86%, 95.04% and 98.34% respectively.

**Conclusions:** We found Saline Infusion Sonography to be an easy and safe procedure, though being less sensitive, it cannot replace hysteroscopy as a whole. Though hysteroscopy is a gold standard, saline infusion sonography is an easy, safe procedure for diagnosing intracavitary pathologies in low resource setting and despite being less sensitive, it can still reduce the number of hysteroscopies.

**Keywords:** Efficacy, SIS, AUB, Crooke's, Hysteroscopy

### INTRODUCTION

The monthly changes in the hormonal, psychological, and physical milieu of a female in themselves are an example of dexterity and complexities. Since antiquity, the temporal relationship between the menses and the lunar phases has inspired names for menstruation, such as the "period". The regularity of menses was easily appreciated by the ancients, even if they had no understanding of its cause or purpose.

Any female with bleeding per vaginum outside her normal cyclical menses is said to have abnormal uterine bleeding.

AUB is the single most common complain that reproductive age women bring to the clinic. It is a symptom and not a disease. In women of child bearing age, AUB includes any change in menstrual period frequency or duration, or amount of flow, as well as bleeding between cycles.

Hysteroscopy combined with guided biopsy has been considered as 'gold standard' in uterine cavity evaluation for AUB. The search for a procedure which is less invasive, cost effective and accurate in diagnosis led to the advent of endometrial imaging by using saline as a contrast medium (SIS). First described by Nannin et al in 1981, it was Richman<sup>1</sup> in 1984 who used this technique first for evaluation of tubal patency in infertile women and the procedure was called as sonosalpingography.

Most of the studies conducted so far are from western developed countries and there is paucity of data from developing countries especially India. So this study was an attempt to find out an easier, better, more cost effective, less time consuming and an efficient diagnostic modality, with minimal morbidity in patients of AUB, as Hysteroscopy though is a gold standard, requires trained personnel, adequate equipment and infrastructure, and is associated with anaesthesia and other surgical complications, hospital stay and patient discomfort, which makes the procedure difficult to perform in all patients of AUB in a low resource setting.

## METHODS

The study protocol was approved by the Regional Committee for Medical Ethics and Research. It was a hospital based observational descriptive study conducted in the Department of Obstetrics and Gynecology, SMS Medical College and Hospital, Jaipur between September 2011-August 2012. 126 females between 24-45 years of age were included after detailed history, clinical examination and informed consent. Females with known medical and surgical contraindications to Hysteroscopy, suspected endocrinological abnormality, genital Infections and TB, any evidence of genital malignancy and unhealthy cervix on PS were excluded from the study. SIS was done in 124 females using Crooke's cannula. The use of Crooke's cannula enabled us to visualise the cervix and its pathologies as well, because it lacks the conventional bulb which needs to be inflated, as in case of a foley's catheter, which obliterates the cervical canal. In 2 cases, SIS could not be performed due to cervical stenosis and 3 others didn't turn up for hysteroscopy. Thus, 121 cases underwent DH under GA the next day, using a 7mm 30° telescope and normal saline as distension medium. Appropriate information was obtained and diagnosis was made on the basis of the 2 procedures. The results were compared and analysed.

### *Criteria for Diagnosis in Saline Infusion Sonography*

1. Normal Endometrium: Normal looking endometrium with uniform thickness all around within the normal range.
2. Endometrial hyperplasia: Diffuse and irregularly thickened endometrium, without any breach in surface, with intact endo-myometrial interface; Thickness > 10mm.

3. Endometrial Polyps: Not as round and regular in outline as fibroid polyp; Smooth margined echogenic mass with homogenous echotexture; Sway with the movement of the fluid in cavity.
4. Endometritis: Bright echogenic foci with irregular surface.
5. Submucous fibroids: Solid round structures of mixed echogenicity that cause bulge or protrusion of the endometrium; Do not move with medium.
6. Intrauterine adhesions: Threadlike immobile strands.
7. Subseptate uterus/ bicornuate uterus.

## RESULTS

In our study, we found that the maximum no. of patients were in the age group of 38yrs and above (45%). Most of the patients (86%) included in the study were Hindus while the rest were Muslims. But no statistical difference was found between the complains and the diagnosis on the basis of religion. More than half of the patients (53%) were either illiterate or were just literate enough to write their own names. While only about 16% of the study population was graduate.

Irregular acyclic bleeding (Metrorrhagia) and Polymenorrhoea were the most common complain of the patients (69%) followed by excessive bleeding and passage of clots (54%) and prolonged periods(30%) together may be grouped as menorrhagia. Post coital bleeding was quite uncommon and was complained of by only 5 patients (in absence of any local vaginal or cervical pathology on PS).

Almost one fifth of the patients attending the OPD with complain of AUB, had been suffering from the same for more than a year. And almost 12 % had been bearing the brunt of the condition for almost 2 years and more, reflecting the state of negligence for the health and well being of a female in our society. About 53% of the patients were vigilant enough to seek advice within a few months of beginning of the problem. This mostly corresponded to the educated class of the society.

Total 121 cases underwent both SIS as well as hysteroscopy. There were 62 cases in which SIS could identify pathology while 74 such cases were identified by hysteroscopy. Out of the 29 cases of Endometrial polyps (EP) diagnosed by hysteroscopy, SIS identified 24 cases. Similarly, SIS diagnosed 12 cases of Submucous fibroids (SMF) and 12 cases of Endometrial Hyperplasia (EH) against 16 cases each diagnosed by hysteroscopy. On the other hand, SIS could not identify even a single case of endometrial carcinoma (EC) and uterine adhesions (ADH).

## DISCUSSION

The most common age group suffering from abnormal uterine bleeding is the Perimenopausal age (38-48yrs)

which constituted about 45% of the study subjects. There was no correlation between the woman's religion and education status with the cause and pathology of AUB, although it was found that the more educated women tend to be more vigilant and cautious towards their menstrual patterns, thus seeking medical advice earlier in case of disturbed menstrual molimina. 65 women sought medical advice within 3-7 months of AUB while 25 had been bearing the brunt of the condition for almost 2 years and more, reflecting the state of negligence for the health and well being of a female in our society.

Irregular bleeding and polymenorrhoea (69%) was the most common form of AUB encountered in the outdoor clinics followed by menorrhagia (54%). Post coital bleeding as a form of AUB, was the least common, in absence of any gross cervical pathology.

Patients with previous history of hormonal intake in any form (OCPs, Progesterone etc) tend to have a propensity to AUB but the relation was statistically insignificant. It was more attributed to erratic use and irregular intake of hormones that cause changes in menstrual pattern.

Endometrial polyps and submucous myomas are the 2 pathologies found in women of almost all ages while

endometrial hyperplasia and endometrial carcinoma predominantly affect women of higher ages. Both these pathologies are the major causes of polymenorrhoea and menorrhagia in females of reproductive age.

The degree of anemia correlated well with the amount of bleeding and the chronicity of the problem. 58 women had Hb level between 7-9gm%, while 13 women had <7gm% Hb.

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**Table 1: Distribution of various pathologies diagnosed by SIS and hysteroscopy.**

Hysteroscopy									
SIS	ADH	EC	EH	ENDO	EP	MA	NAD	SMF	Grand Total
EH			12						12
ENDO				2			2		4
EP		3	1		20				24
MA					5	5			10
NAD	2		3	1	4		44	5	59
SMF							1	11	12
<b>Grand Total</b>	<b>2</b>	<b>3</b>	<b>16</b>	<b>3</b>	<b>29</b>	<b>5</b>	<b>47</b>	<b>16</b>	<b>121</b>

Abbreviations: ADH – Adhesions, EC – Endometrial carcinoma, EP – Endometrial Polyp, EH – Endometrial Hyperplasia, MA – Mullerian Anomaly, SMF – Submucous Fibroid, ENDO – Endometritis, NAD – No abnormality detected

On the other hand, SIS could not identify even a single case of endometrial carcinoma (EC) and uterine adhesions (ADH). This was in agreement with the study conducted by Epstein, Ramirez et al,<sup>3</sup> 2001 that concluded that Hysteroscopy was superior to both SIS and conventional ultrasound in discriminating between benign and malignant lesions (Table 1, 2).

Mullerian anomalies (MA) like bicornuate uterus, septate uterus etc was over diagnosed by SIS as even a

fundal polyp or fundal fibroid was interpreted on SIS as septa. 59 cases (49%) were found to have no abnormality on SIS while on hysteroscopy, the no. of cases was 47 (39%).

According to our study, SIS was found to be most sensitive (100%) for detection of Mullerian abnormalities (MA) with a specificity of 95.7%, a negative predictive value of 100% but a PPV of only 50%. It is found

to be least sensitive (67%) for endometritis (ENDO) (Table 3).

**Table 2: Pathologies detected by SIS and hysteroscopy.**

Diagnosis	Diagnosis of SIS		Diagnosis of Hysteroscopy	
	No.	%	No.	%
EP	24	19.84	29	23.97
SMF	12	9.92	16	13.22
EH	12	9.92	16	13.22
MA	10	8.26	5	4.13
ENDO	7	5.78	3	2.48
EC	0	0.00	3	2.48
ADH	0	0.00	2	1.65
NAD	59	48.76	47	38.84
Total	121	100.00	121	100.00

SIS had a sensitivity of 75% for diagnosing endometrial hyperplasia (EH) with specificity, NPV and a PPV of 100%, 100% and 96.3% respectively. This was much less as compared to the results obtained by Valenzano et al<sup>4</sup>, SIS had a 100% sensitivity and 100% specificity in diagnosis of EH. But was better as compared to results obtained by Grigoris F Grimbizis et al<sup>5</sup> in Greece. He found a sensitivity of 29% and a specificity of 99% for endometrial hyperplasia. Similarly our results also matched to those obtained by Krampf et al<sup>6</sup> who showed SIS had sensitivity of 33% and specificity of 92% in diagnosis of endometrial hyperplasia and carcinoma (Table 3).

The sensitivity and specificity for endometrial polyps (EP) in our study is 69% and 95.7%, and that for submucous fibroids is 68.75% and 99% respectively. This was in contrast to the findings suggested by Bernard et al<sup>7</sup> who studied 109 premenopausal and 53 postmenopausal women and determined the sensitivity of 87.8% and 89.6% and specificity of 90.7% and 95% for diagnosis of Polyps and Submucous Myomas, respectively. Ramirez et al<sup>8</sup> obtained a sensitivity of 79.4% for detection of EP and SMF (Table 3).

**Table 3: Efficiency of saline infusion sonography for detection of causal pathology of abnormal uterine bleeding.**

	Sensitivity		Specificity		PPV		NPV	
		%		%		%		%
EH	12/16	75	105/105	100	12/12	100	105/109	96.3
ENDO	2/3	66.67	116/118	98.3	2/4	50	116/117	99
EP	20/29	69	88/92	95.7	20/24	83	88/97	90
MA	5/5	100	111/116	95.7	5/10	50	111/111	100
NAD	44/47	93.2	63/78	80.8	44/59	75	59/62	95
SMF	11/16	68.75	104/105	99	11/12	92	104/109	95.5
ADH	0/2	0	119/119	100	-	-	119/121	98.3

**Table 4: Diagnostic efficacy of SIS.**

	Diagnostic Efficacy (true positives + true negatives)/ total study subjects
EH	96.69%
ENDO	97.52%
EP	89.25%
MA	95.86%
SMF	95.04%
ADH	98.34%

**Table 5: Positive diagnosis: Hysteroscopy v/s SIS.**

Test	No	%
Hysteroscopy	74	61.16
SIS	62	51.24

Overall, about 61% of the cases of AUB were diagnosed to have some abnormality by hysteroscopy as compared to 51% by SIS.

**Table 6: Overall efficacy of saline infusion sonography.**

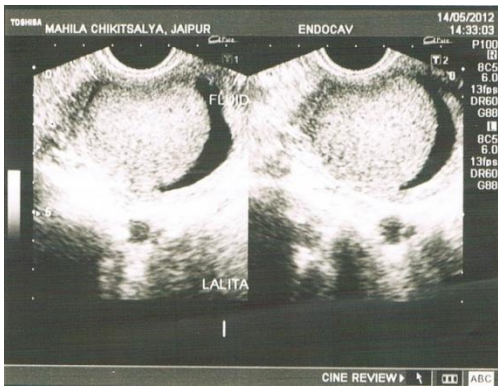
	Sensitivity	Specificity	PPV	NPV
SIS	67.56%	93.6%	80.6%	74.57%



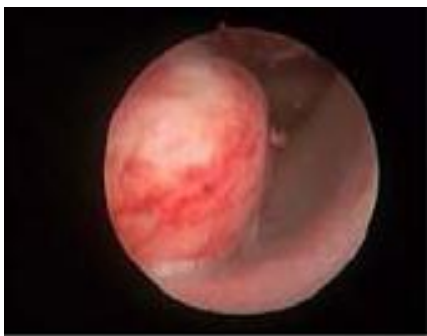
**Figure 1: Crooke's cannula.**



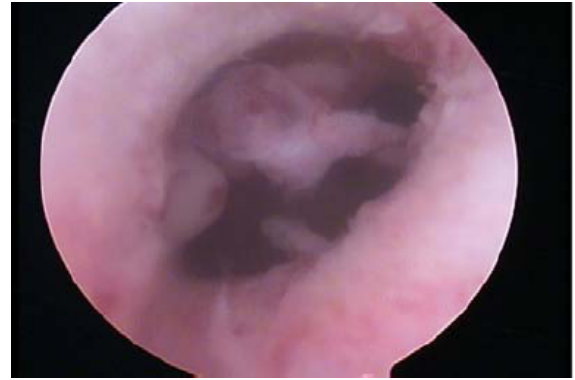
**Figure 2: Endometrial polyp in saline infusion sonography.**



**Figure 3: Submucous fibroid in saline infusion sonography.**



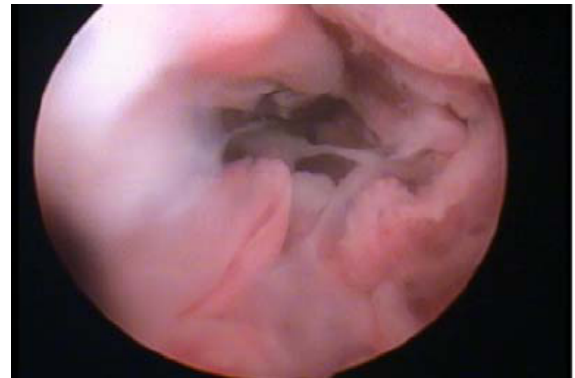
**Figure 4: Hysteroscopic view of submucous fibroid.**



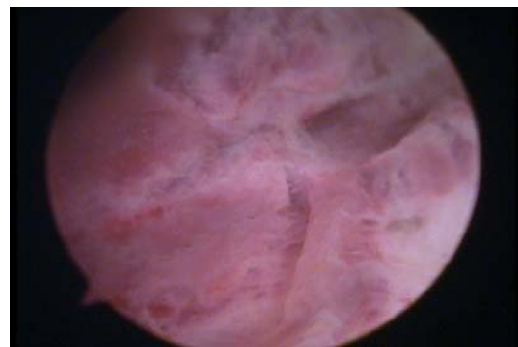
**Figure 5: Hysteroscopic view of endometrial polyps.**



**Figure 6: Hysteroscopic view of secretory endometrium.**



**Figure 7: Hysteroscopic view of endometrial hyperplasia.**



**Figure 8: Hysteroscopic view of endometrial cancer.**

This study showed that the sensitivity of SIS is greatest (100%) for Mullerian anomalies, 75% for endometrial hyperplasia, 69% for endometrial polyps, 68.75% for submucous myomas and 66.67% for endometritis. The specificity is greatest for endometrial hyperplasia and adhesions (100%), 99% for submucous myomas, 98.3% for endometritis, 95.7% for endometrial polyps and mullerian anomalies. It has a 100% positive predictive value for endometrial hyperplasia, 92% and 83% for submucous myomas and endometrial polyps respectively. Thus the final diagnostic efficacy of SIS for endometrial hyperplasia, endometritis, endometrial polyps, mullerian abnormalities, submucous fibroid and adhesions was 96.69%, 97.53%, 89.25%, 95.86%, 95.04% and 98.34% respectively.

The overall sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of SIS in our setting is 67.56%, 93.6%, 80.6% and 74.5% respectively (Table 6). There have been conflicting results in for the efficiency of SIS. Wildrich et al<sup>9</sup> in 1996 studied evaluated 130 patients with abnormal bleeding by SIS as well as hysteroscopy and determined that for all findings combined, sensitivity was 96% and specificity was 88%. Lynne Rogerson et al<sup>10</sup> studied 117 women of AUB an reported a sensitivity of 85.2%, specificity of 87.3%, PPV and NPV of 74.2% and 93.2% respectively. In India, Pasrija, Trivedi, et al<sup>11</sup> found the sensitivity, specificity, positive predictive value and negative predictive value of SIS to be 94.4%, 88.5%, 91.4% and 92% respectively.

## CONCLUSION

On concluding the present study, there was a variation in sensitivity and specificity of the procedure in relation to our co workers, though SIS turned out to be an easy procedure. We can affirm that, in a Government setup in India like ours, where the number of patients is large and the resources are limited, SIS is an easier procedure. Though is not very sensitive, but it has a good positive and negative predictive value, and can certainly reduce and avoid the unnecessary hysteroscopies performed and the morbidity related to it. If there is any ambiguity of diagnosis, hysteroscopy may be performed. It cannot replace diagnostic hysteroscopy on the whole.

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*Ethical approval: The study was approved by the Regional Committee for Medical Ethics and Research*

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