



## A PROSPECTIVE COHORT STUDY EVALUATING THE ROLE OF SALINE SONOHYSTEROGRAPHY IN ABNORMAL UTERINE BLEEDING IN COMPARISON WITH TRANSVAGINAL SONOGRAPHY

Dr. K. Arthi

Assitant Professor Dept Of Radiodiagnosis

Dr. G.

Perriyanayaki alias  
Barani\*

Assitant Professor Dept Of Radiodiagnosis \*Corresponding Author

### ABSTRACT

**OBJECTIVES AND BACKGROUND:** Menstrual dysfunction is the most common gynecological problem in women of reproductive age. And it is the most common health problem encountered in women, accounting for 15% of outpatients and 25% of gynaecological surgeries. Both transvaginal sonography and saline infusion sonohysterography plays a vital role in the evaluation of the causes of menstrual dysfunction. The main aim of the study is to know the accuracy and detective ability of intrauterine pathology by saline Infusion sonohysterography in cases of abnormal uterine bleeding.

**MATERIALS AND METHODS:** It was a Hospital Based Prospective Cohort Study conducted on 50 patients in the reproductive and perimenopausal age group with complaints of abnormal uterine bleeding. Specific history was taken to rule out the systemic disorders responsible for abnormal uterine bleeding. After taking an informed consent, these patients were subjected to Transvaginal sonography and Saline sonohysterography and lesions were detected.

**RESULTS:** The age group of the patients in this study was 22-55years. Majority of the patients had complaints for a duration of 4-6 months (36%). Menorrhagia (70%) was the most common complaint of the patients. The present study showed statistically significant association between the detection of endometrial polyp and the diagnostic method used either SIS or TVS [Chi-square value=6.383 and P value=0.012]. SIS detected seven endometrial polyp cases whereas TVS detected none. In conclusion SIS was superior to TVS in detection of endometrial polyps. Also the diagnostic efficacy of both the tests were compared using paired "t" test showed significant difference between TVS and SIS [t-value-2.824 and P-value=0.007]. From the mean value observed it was concluded that SIS [mean=0.52060] is more effective than TVS [mean=0.44309] in detecting intrauterine pathologies. The overall sensitivity of the saline infusion sonohysterography was 92.5%, specificity was 100%, the negative predictive value was 76.9%, the positive predictive value was 100% and the accuracy rate was 94%.

**CONCLUSION:** In the evaluation of menstrual dysfunction by saline infusion sonohysterography, saline outlines the uterine cavity and is very sensitive in detecting submucous fibroid and endometrial polyps which are missed on using transvaginal ultrasound. In conclusion saline infusion sonohysterography when combined with transvaginal sonography is more sensitive, accurate, cost-effective, acceptable and simple method in the evaluation of the causes of AUB.

**KEYWORDS :** Transvaginal sonography, Saline infusion sonohysterography, abnormal uterine bleeding, submucous fibroid, endometrial polyp, intramural fibroid.

### INTRODUCTION:

Menstrual dysfunction is the most common gynecological problem in women of reproductive age. And it is the most common health problem encountered in women, accounting for 15% of outpatients and 25% of gynaecological surgeries<sup>1</sup>. Menstrual dysfunction can be of various forms like menorrhagia, polymenorrhea, menometrorrhagia, oligomenorrhea and dysmenorrhea. Menorrhagia is the most common problem affecting 10% to 30% of women in reproductive age and upto 50% of premenopausal women (Haynes, 1977; Prentice 2000).

Menstrual dysfunction can be due to organic pelvic pathology like fibroids, polyps, adenomyosis. Other causes are contraceptive use related (IUCD), hormonal imbalance and systemic disease related. Abnormal uterine bleeding (AUB) is defined as irregular uterine bleeding that occurs in the absence of recognizable pelvic pathology, general medical disease or pregnancy<sup>2</sup>. The causes of AUB are classified by PALM-COEIN classification formulated by FIGO. It has four visually objective criteria and four causes unrelated to structural anomalies.

1. P-Polyp 1.C-Coagulopathy
2. A-Adenomyosis 2.O-Ovulatory dysfunction
3. L-Leiomyoma 3.E-Endometrial
4. M-Malignancy 4.I-Idiogenic
5. N-Not yet classified

It has been introduced in 1958 by Sir Ian Donald, after the field of medical ultrasonography has attained tremendous technical growth. Ultrasonography plays a vital role in the

evaluation of female pelvic organs and compliments bimanual examination in diagnosis gynecological problems. Transabdominal sonography with full bladder using 3-5MHz transducer is the initial investigation of choice but has shown poor results in differentiating between adenomyosis and leiomyomas.

*International Journal of Current Medical And Pharmaceutical Research, Vol. 2, Issue, 10, pp.776-780, October, 2016* Transvaginal sonography done using 7.5MHz probe with improved resolution is the first line tool to assess abnormal uterine bleeding. Due to proximity to pelvic organs transvaginal sonography gives an increased resolution of the pelvic organs. Increased resolution is also due to higher frequency of the probe<sup>3</sup>. Transvaginal sonography can detect the presence of uterine fibroids and fibroid characteristics, including volume, number, location, and position. But the mass may appear as an area of increased echogenicity bulging into the endometrial cavity with echogenicity similar to that of the myometrium may not be clearly defined. In addition, it may be difficult to distinguish a fibroid from a blood clots or a polyp.

In 1981 a new technique called Saline sonohysterography was described by Nannini et al.<sup>4</sup> to overcome this problem. Transvaginal saline sonohysterography is a minimally invasive technique that enables the visualisation of uterine cavity and its pathology after installation of saline into the uterine cavity. It is usually done in proliferative phase of the menstrual cycle (Day-8 to Day-10). The infused saline distends the cavity thus providing an excellent visualisation of endometrial lining and improved clarification of intraluminal

abnormalities like polyps, submucous fibroid and endometrial hyperplasia. Several studies have proved that saline sonohysterography is superior to transvaginal sonography in detecting endometrial pathologies. Especially in detecting submucous fibroid which is most common cause of AUB and infertility.<sup>5</sup> The findings of Saline sonohysterography correlates well with diagnostic hysteroscopy and histopathological diagnosis. The post procedure complications are very minimal in case of Saline sonohysterography compared to other invasive procedures like hysteroscopy.<sup>6</sup> Thus Saline sonohysterography has evolved into a useful, safe and minimally invasive examination for women with abnormal uterine bleeding, infertility and congenital uterine abnormality etc.

#### **Aims and Objectives:**

1. To know the accuracy and detective ability in diagnosing intrauterine pathology by Saline Infusion Sonohysterography in cases of abnormal uterine bleeding.
2. Saline Infusion Sonohysterography used as an adjuvant to TVS to improve the accuracy of diagnosis of endometrial pathologies like endometrial polyps, submucous fibroid and intramural fibroid.

#### **MATERIALS AND METHODS:**

A Hospital Based Prospective Cohort Study was conducted on 50 patients [outpatients and inpatients] coming to the department of Radiodiagnosis, Government Villupuram Medical college, Mundiampakkam for the purpose of doing ultrasound for abnormal uterine bleeding referred from the Department of Obstetrics and Gynecology, Government Villupuram Medical college, Mundiampakkam from Nov 2018 to Sep 2019.

Patients in the reproductive and perimenopausal age group with complaints of abnormal uterine bleeding, in the form of menorrhagia, metrorrhagia and polymenorrhea were included in the study. A detailed history was taken, with menstrual history. After proper clinical examination, laboratory investigations were carried out.

An informed consent is taken before, undergoing Transvaginal sonography and Saline sonohysterography.

#### **Inclusion Criteria:**

1. Patients with abnormal uterine bleeding in reproductive and perimenopausal age group.

#### **Exclusion Criteria:**

1. Menstruating women.
2. Patients suspected or confirmed to have endometrial carcinoma/cervical carcinoma.
3. Patients with pelvic inflammatory disease.
4. Patients with possibility of pregnancy.
5. Puberty menorrhagia
6. Patients with severe cervical stenosis due to previous history of surgeries of cervix.
7. Unmarried women
8. Thyroid related disorder

#### **METHOD:**

After getting informed consent the patients were asked to empty the bladder. Then placed in dorsal position with legs flexed.

A baseline transvaginal ultrasound was performed first using 7.5MHz endovaginal probe of MINDRAY and SAMSUNG machine [covered with a condom]. The appearance of the endometrium, myometrium and adnexae were noted.

Patient was instructed to lie in lithotomy position. Under asepetic precaution a bivalve speculum was inserted, the

cervix was swabbed with povidine/iodine solution. Then anterior lip of the cervix was grasped with tenaculum. Then a No.8 Foley's catheter was introduced through the external os of cervix upto the fundus of uterus. It was then withdrawn 1 to 1.5cm back and the catheter was fixed by inflating its balloon with 1.5 to 2 ml of distilled water so that it lies just above the internal os. The Foleys bulb blocks the fluid from flowing out of the endometrial cavity. Then the speculum was removed without dislodging the Foley's catheter and the Transvaginal probe was reinserted.

Gently the sterile isotonic saline was infused with real time sonography. Saline separates the echogenicities from the endometrium which appears as hypoechoic area within the endometrial cavity. Uterine cavity was visualized both in the longitudinal plane from corner to corner and in the coronal plane from fundus to endocervix.

The endometrial cavity was examined for the presence of polyps or submucosal myoma or fibroid. Any projection inside the uterine cavity was observed meticulously for its shape and echogenicity, in addition evidence of any abnormal endometrial thickening was also noted. The balloon was deflated and the catheter was removed gently to complete the study.

#### **RESULTS:**

The present study was conducted in 50 cases with complaints of abnormal uterine bleeding. Patients were subjected to both Transvaginal sonography and Saline sonohysterography for the evaluation of abnormalities in uterine cavity, after obtaining an informed consent.

1. In the present study, the age of the patient ranged from 22 to 55 years, with maximum number of patients belonging to the age group of 36 to 40 years (34%).
2. The most common bleeding complaint among the patients was Menorrhagia (70%).
3. Parity of patient's ranges from 1-5. Maximum number of patients were of the birth order P3 (40%).
4. The duration of symptoms in the patients ranged from 2 months to 3 years. Maximum number of cases had complaints for 4-6 months (36%).
5. On transvaginal sonographic evaluation the cases showed anterior intramural fibroid in 18%, posterior intramural fibroid in 16%, bulky uterus in 18%, multiple intramural fibroid in 20%, and endometrial hyperplasia in 2% of cases. Non structural cause of abnormal uterine bleeding was diagnosed in 26% of patients.
6. On Saline sonohysterographic evaluation the cases showed anterior intramural fibroid in 18%, posterior intramural fibroid in 16%, multiple intramural fibroid in 18%, submucous fibroid in 6% and endometrial polyp in 14% of cases. Combination of intramural fibroid and endometrial polyps were seen in 6% of cases. And non structural cause of abnormal uterine bleeding was diagnosed in 20% of the total cases
7. The sensitivity of the Saline infusion sonohysterography was 92.5%, specificity was 100%, the negative predictive value was 76.9%, the positive predictive value was 100% and the accuracy rate was 94%.
8. The association between saline sonohysterography and transvaginal sonography were statistically significant [Chi-square value-35.577 and P value =0.000]
9. There was statistically significant association between the detection of endometrial polyp and the diagnostic technique used either SIS or TVS [Chi-square value-6.383 and P value =0.012]. Out of 50 cases SIS detected polyp in seven patients whereas TVS detected none. Therefore SIS is superior to TVS in detection of endometrial polyps.
10. There was no statistically significant association between the detection of submucosal fibroid and the diagnostic

method used either SIS or TVS [Chi-square value-3.093 and P value=0.079]. Out of 50 cases 3 cases were detected by SIS and none by TVS.

- The diagnostic efficacy were compared using paired t test. It showed significant difference between TVS and SIS [t-value-2.824 and P-value=0.007]. We concluded that SIS [mean=0.52060] was far more effective method than TVS [mean=0.44309] in detecting uterine pathologies in AUB cases by using mean values.



SIS showing endometrial polyp



SIS showing submucous fibroid.

**Distribution of Age**

Age in years	No. of patients	Percentage
<30	4	8.0
31-35	9	18.0
36-40	17	34.0
41-45	11	22.0
46-50	5	10.0
51-55	4	8.0
Total	50	100.0

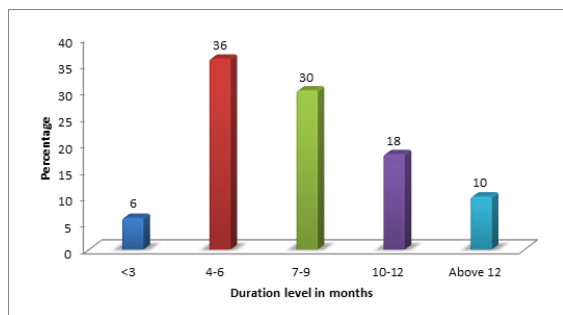
This table represents the distribution of patients based on their age. Out of fifty patients, majority of the patients falls in the age group of 36-40 yrs (34%) which is followed by 41-45 yrs (22%). About 18% of patients falls under 31-35yrs, 10% of the patients falls under 46-50yrs.

**Frequency of Symptoms**

SYMPTOMS	No. of patients	Percentage
Intermenstrual Bleeding	3	6.0
Menometrorrhagia	2	4.0
Menorrhagia	35	70.0
Polymenorrhagia	8	16.0
Polymenorrhea	2	4.0
Total	50	100.0

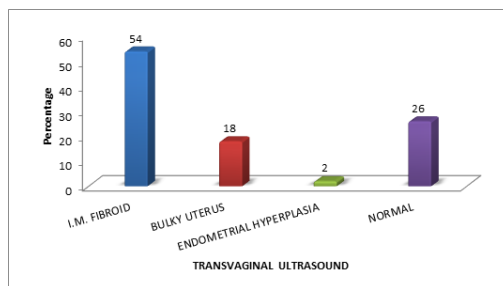
The above table shows the distribution of patients on the basis of the symptoms noted .Majority 70% of the patients had complaints of Menorrhagia, followed by polymenorrhagia (16%) and intermenstrual bleeding (6%). Menometrorrhagia and polymenorrhea was noted in 4% of the patients each.

**Duration of Symptoms**



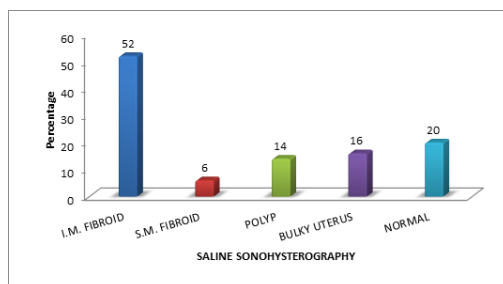
This graph shows the distribution of patients based on the duration of symptoms in months. Majority 36% of the patients have the symptoms for a period of 4-6months and 30% of the patients have the symptoms for 7-9months.18% of patients have duration of symptoms for 10-12months and 10% of patients fall above 12 months of duration. Only 6% of the patients having symptoms less than 3 months is seen.

**Diagnosis in Transvaginal Ultrasound**



In TVS more than half of the patients (54%) have Intramural fibroid.18% of patients showed bulky uterus and 2% have endometrial hyperplasia. In 26% of patients transvaginal sonography appears normal.

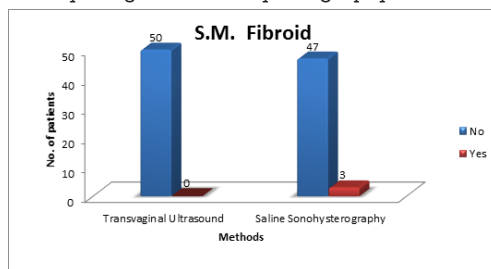
**Diagnosis in Saline Sonohysterography**



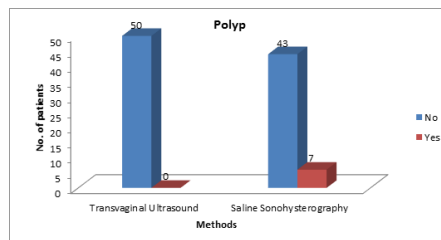
In SIS more than half of the patients (52%) have Intramural fibroid.16% of patients showed bulky uterus and 14% of patients have endometrial polyps. In 6% of patients submucous fibroids are detected.

**Detection of Submucosal Fibroid in TVS and Sis**

In the detection of submucous fibroid all the fifty cases falls under non-traceable by using transvaginal sonography method, whereas out of fifty cases three cases falls under traceable by using saline sonohysterography method.



**Detection of Endometrial Polyp in TVS and SIS**



In the detection of endometrial polyp all the fifty cases falls

under non-traceable by using transvaginal sonography method, whereas out of fifty cases seven cases are traceable by using saline sonohysterography method.

#### Comparison of Efficacy between TVS and SIS Paired Sample test

	Mean	N	Std. Deviation	t	Sig.
TVS	0.7400	50	0.44309	2.824	0.007
SIS	0.8800	50	0.52060		

From the observed t-value 2.824 and its p-value 0.007 it is concluded that the efficacy of diagnosing pathologies by both the methods differ significantly. From the mean value it is observed that out of two methods used in the study Saline sonohysterography is found to be the more effective method than Transvaginal sonography in detecting the intracavitary pathologies.

#### DISCUSSION:

The age group of the patients in this study was 22-55years i.e. largely in the reproductive and perimenopausal age group, wherein, it is important to determine the exact etiology of AUB for accurate management. Cicinelli et al.<sup>9</sup> included perimenopausal women with complaints of AUB. In the present study, the duration of symptoms in the patients ranged from 2 months to 3 years. Maximum number of patients had complaints for a duration of 4-6 months (36%). Parity of the patients included in the study ranged from 1-5, with maximum number of patients with birth order of P3.

In the study done by Reddi Rani P et al.<sup>7</sup> it was found out that menorrhagia (73%) is the most common symptom encountered by patients with the complaints of AUB. Similar results were obtained in the present study where it was found out that menorrhagia (70%) is the most common complaints of patient, followed by polymenorrhagia (16%).

In the present study transvaginal ultrasound revealed that the majority i.e. 54% of cases had intramural fibroid. In 26% of the patients the study appeared normal with no obvious intracavitary lesions and 2% of patient showed endometrial hyperplasia. Reddi Rani et al.<sup>7</sup> study showed that the most common diagnosis found in patients with AUB was intramural fibroid(42%) followed by submucous fibroid(21%).In the present study, Saline sonohysterographic evaluation showed intramural fibroid in 52%,submucous fibroid in 6% and endometrial polyp in 14% of cases. Combination of intramural fibroid with polyp was seen in 6% of cases. In 20% of cases the study was normal.

Elvire Jacques et al.<sup>8</sup> made a study to assess the accuracy of saline infusion sonohysterography versus transvaginal sonography in detecting intracavitary uterine pathology. Polyps were accurately diagnosed in 21 (91.3%) of the patients whereas by transvaginal sonography, polyps were correctly diagnosed in only 8 (34%) of the patients. In the present study also there was statistically significant association between the detection of endometrial polyp and the diagnostic method used either SIS or TVS [Chi-square value-6.383 and P value=0.012].Out of 50 cases SIS detected seven endometrial polyps whereas TVS detected none. Therefore it was concluded that SIS is superior to TVS in detection of endometrial polyps<sup>11</sup>. But there was no statistically significant association between the detection of submucosal fibroid and the diagnostic method used either SIS or TVS [Chi-square value-3.093 and P value=0.079]. Also the diagnostic efficacy of both the test were compared using paired't test showed significant difference between TVS and SIS [t-value-2.824 and P-value=0.007]. From the mean value observed it was concluded that SIS [mean=0.52060] was more effective method than TVS [mean=0.44309].

The overall sensitivity of the Saline infusion sonohysterography was 92.5%, specificity was 100%, the negative predictive value

was 76.9%, the positive predictive value was 100% and the accuracy rate was 94%.

#### CONCLUSION:

In the evaluation of menstrual dysfunction both Transvaginal sonography and Saline infusion sonohysterography plays a vital role in diagnosing intrauterine pathologies. In saline infusion sonohysterography saline outlines the uterine cavity and appears to be very sensitive in detecting submucous fibroid and endometrial polyps which are missed on using transvaginal ultrasound alone as a diagnostic method. Thus Saline infusion sonohysterography when combined with Transvaginal sonography is more sensitive, accurate, cost-effective, acceptable and simple method in the evaluation causes of AUB.

#### REFERENCES

1. John O.Schorge MD, Joseph I schaffer MD, Lisa M. Halvorson MD, Barbara L. Hoffman MD, Karen D.Bradshaw MD, F.Gary Cunningham MD. Williams Gynecology 1st Edn. Mc Graw Hill Medical chapter 2: P 174-192.
2. Romano F, Cicinelli E, Anastasio P, Epifani S, Fanelli F, Galantino P "Sonohysterography versus hysteroscopy for diagnosing endouterine abnormalities in fertile women". International journal Gynaecology and Obstetrics 1994; 45: 253-260.
3. Nannini R, Chelo E, Branconi F, et al. in 1981 Dynamic echohysterography: a new diagnostic technique in the study of female infertility. Acta Eur Fert. 1981; 12:165-71.
4. S. Albori, M.E. Parsanezhad, N. Mahmoodian and M. Alborzi Sonography versus transvaginal Sonography for the screening of the patients with abnormal uterine bleeding. International Journal of Obstetrics and Gynecology 2007 Jan; 16(1): 20-23
5. Theresa windrich MD, Linda D. Bradley MD, Allison R.Mitchinson MPH and Robert L.Collins MD. Comparison of Saline Infusion Sonography with office hysteroscopy for the evaluation of the endometrium. American Journal of Obstetrics and Gynaecology. 1996 April; 174(4): 1327-1334
6. Daveyda: Dysfunctional uterine bleeding: In Dewhurst's text book of Obstetrics and Gynaecology for post graduates. Edn 6 Blackwell Science; 1995. P590-608.
7. Reddi Rani P, Lakshmikantha G. in 2010 Transvaginal Sonography(TVS) and Saline Infusion Sonohysterography (SIS) in the Evaluation of Abnormal Uterine Bleeding(AUB).Jobstet Gynecol India Vol.60:November/December 2010 pg 511-515.
8. Elvire Jacques MD,Usha Verma MD and R.W.Whitted in Apr 2001.Accuracy of Saline Infusion sonohysterography versus TVS in detecting intra cavity uterine pathology. Obstetric and Gynecology 2001 Apr;97(4):S18
9. Cicinelli E, Romano F, Anastasio PS, Blasi N, Prisi C. " Sonohysterography versus steroscopy in the diagnosis of endouterine polyps", Gynaecology Obstetrics invest, 1994, 38:266-271.
10. Shikha pasrija et al. in 2004 Prospective study of Saline Infusion Sonohysterography in Evaluation of perimenopausal and postmenopausal women with Abnormal Uterine bleeding. Journal of Obstetrics and Gynaecology Research-2004 February;Vol 30,Issue 1,Page 27-33. 10.1111/j.1341-8076.2004.00151
11. Smiti nanda et al. in 2004 Transvaginal sonography and Saline Infusion Sonohysterography in the Evaluation of Abnormal Uterine bleeding. October 28 2004;10.1111/j.0004-8666.2002.00530
12. Steven R. Goldstein MD. Abnormal uterine bleeding: the role of Ultrasound. Ultrasound clinics-2006 April; 1 (2): 415-424.
13. S. Senapati, K.C, Wang, D.I. Lbeoric, A.H. Song and AS-Sane, University of Michigan Ann Arbor, Fertility and sterility, 2008 September; 90: S38-S39.
14. David L.Olive, Steven F.Paltr. In Berek & Novak's Gynecology. Reproductive Physiology. Edn 14.Lippincott Williams & wilkins; 2007: p 171-180.