



A STUDY ON THE ROLE OF SALINE SONOSALPINGOGRAPHY AS A TEST FOR TUBAL PATENCY IN THE ASSESSMENT OF INFERTILITY

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ABSTRACT **Background:** Tubal pathology is one of the major causes of infertility and evaluation of fallopian tubes forms an essential part of work up of infertility patients. The aim of the study was to evaluate tubal patency by Saline Sonosalpingography and compare the results with that of hysterosalpingography.

Methods: A total of 22 patients with primary infertility and 13 patients with secondary infertility attending our Obstetrics and Gynecology department were recruited for the study from July 2019 to June 2020. All the study subjects underwent Saline Sonosalpingography on day 7 to day 9 and Hysterosalpingography on 7th to 11th day of the menstrual cycle. Data was collected and compared to assess the sensitivity and specificity of Sonosalpingography with Hysterosalpingography as reference standard.

Results: Sonosalpingography (SSG) has 98.18% sensitivity and 66.67% specificity in comparison to hysterosalpingography (HSG). Analysis of the raw data gave positive predictive value of 91.52% and negative predictive value of 90.9%. Near perfect agreement (Cohen's Kappa coefficient=0.9) was seen between the results of the two methods (SSG and HSG).

Conclusions: Sonosalpingography has a high sensitivity for tubal patency and is less invasive. It is found to be a reliable and relatively less expensive diagnostic procedure in the management of infertility in females. Easy availability and accessibility of ultrasound in all primary health care centres definitely can prove superior to conventional method of diagnosis of tubal patency in such patient.

KEYWORDS : Hysterosalpingography, Infertility, Sonosalpingography, Tubal patency

INTRODUCTION:

Infertility is a growing and important issue in the present time and it has become a challenge in reproductive medicine. It is defined as inability to conceive after 1 year of unprotected intercourse of reasonable frequency¹.

Tubal factor infertility is one of the major causes of infertility as the fallopian tubes form the portal for ovum pick up and site of fertilization and transfer of embryo to the uterine cavity. It occurs due to occlusion of the tubes and adhesions with surrounding intra peritoneal structures. This is most commonly due to pelvic inflammatory disease (PID) and acute salpingitis². The other causes being Endometriosis, Pelvic Tuberculosis, scarring from abdominal and pelvic surgeries, myomas near tubal ostia or any iatrogenic tubal occlusion.

Laparoscopy and chromopertubation, which is done under general anaesthesia is considered as the gold standard for the evaluation of tubal disease as well as tubal patency and when combined with hysteroscopy gives added advantage and also provides opportunity for both diagnosis and treatment. However, it brings along with it the operative and anaesthetic risks.

Traditionally tubal patency is seen using Hysterosalpingography (HSG) which is a standard outpatient, relatively less invasive procedure where X rays are used for imaging the pelvis after injection of a water or oil soluble contrast through the cervix. However, it provides moderate sensitivity (65%) but good specificity (83%) for tubal patency in the infertile population and carries the risk for radiation exposure.

Saline Sonosalpingography (SSG) is an ultrasound-based imaging modality which uses trans vaginal sonography to evaluate tubal patency as well as other uterine and ovarian pathology, with isotonic saline acting as the contrast media. It is a simple outpatient procedure which does not need anaesthesia or sedation. It is a fast, low cost, well tolerated procedure without radiation exposure and with fewer side effects. Studies have shown that it is superior to HSG and comparable to laparoscopic chromopertubation. The present study evaluates the diagnostic accuracy of SSG for the assessment of tubal patency in infertility patients, with HSG as the reference standard.

AIMS AND OBJECTIVES:

1. To evaluate tubal patency by Saline Sonosalpingography.

2. To compare the results of Saline Sonosalpingography with that of Hysterosalpingography in the evaluation of tubal patency in infertility patients

MATERIALS AND METHODS:

The present study was a prospective observational study conducted in the department of Obstetrics and Gynaecology in a tertiary centre in collaboration with the Department of Radiology from 1st July 2019 to 30th June 2020 after obtaining Institutional Ethics Committee clearance. 35 cases of both primary infertility and secondary infertility who fit in to the inclusion criteria were selected in the study.

INCLUSION CRITERIA:

Cases of unknown tubal function with complaints of infertility and willing to participate were recruited for the study.

EXCLUSION CRITERIA:

- 1) Active Pelvic Infection or PID
- 2) Patients with suspected pregnancy
- 3) Refused participation

PROCEDURE.

A detailed history was taken and general and gynaecological examination was done in all patients followed by basic Infertility workup of the couple which included Husband's Semen Analysis, Pelvic ultrasound, hormone analysis for thyroid and prolactin. This was followed by tubal patency testing by Saline Infusion Sonosalpingography on day 7 to day 9 of menstrual cycle. HSG was performed in the Radiology Department usually 1 day after SSG or in the subsequent menstrual cycle as per standard procedure.

Procedure of Saline Infusion Sonosalpingography (SIS)/Saline Sonosalpingography (SSG)

Under all aseptic and antiseptic precautions, speculum was introduced into the vagina and cervix visualized after cleaning the perineum and vagina with povidone iodine. A Paediatric Foley's catheter of size 8F was introduced into the uterine cavity beyond the internal os and bulb inflated with 2 ml of saline.

Baseline transvaginal ultrasound pelvis was performed with Mindray UMT 150 Machine in dorsal lithotomy position. The position of Foley's bulb was confirmed and uterus with adnexa and cul de sac was scanned for the presence of any fluid.

About 20 to 30 ml of warm sterile saline was pushed slowly through the Foleys catheter intermittently after clamping the open end of the tube with an artery forcep. The uterus was scanned using TVS probe simultaneously in sagittal and coronal planes to delineate the entire endometrial cavity and appropriate image recorded. The uterine cavity was examined for any intracavitary lesion followed by scanning of the tubes which was begun from the interstitial part of the salpinx and the hyper echogenicity of air followed laterally towards the ovary by rotating the probe around the uterine angle in transverse section mode and the tube was visualized as a continuous or interrupted line.

Tubal patency was assessed by Doppler and B-mode ultrasound and by fluid accumulation in the Pouch of Douglas. The patent tubes distended with saline lead to fimbrial turbulence, also known as Water Fall Sign. The presence of free fluid in cul de sac is accepted as the evidence of the passage of saline through at least one tube

STATISTICAL ANALYSIS:

The data obtained was coded and entered into Microsoft Excel Worksheet. The categorical data was expressed as rates, ratios and proportions and continuous data was expressed as mean \pm standard deviation (SD). Categorical data was compared using Chi-square test and Fisher's Exact Test. $P < 0.05$ was taken as statistically significant. Agreement between the two procedures was checked by kappa statistical analysis. Statistical Analysis was done using Graphpad software.

RESULTS:

The present study was carried out in 35 patients in the age range of 19 to 40 years. Cases were divided into 4 age groups ≤ 20 years, 21-25 years, 26-30 years, 31-35 years, 36-40 years. The mean age was 28.17 years with a Standard Deviation (SD) of 5.58 years. The Standard Error of Mean was 0.9432 and the 95% confidence interval for age is between 26.32 years to 30.02 years. In the present study most of the women were aged between 26 to 30 years (34.29%). Out of 35 patients, 22 were of primary infertility and 13 patients were of secondary infertility.

Majority of the participants had duration of infertility ranging from 1 to 5 years, in both primary (81.81%) and secondary infertility (61.54%). The mean duration of infertility was around 4.86 years in this study with a standard deviation (SD) from mean of 2.587 years. Standard error of mean (SEM) was 0.4373 and the 95% CI was 4.000 years to 5.714 years.

Majority (82.86%) of the women reported regular cycles while 17.14% of the women reported irregular menstrual history. Regular cycles were seen in 95.45% of primary and 61.54% of secondary infertility. Irregular cycles were more common in secondary infertility which was statistically significant ($p < 0.05$).

The mean BMI of the 35 women was found to be 25.04 kg/m² with a Standard Deviation of 2.01 kg/m². The standard error of mean was 0.3395 and the 95 % confidence interval for BMI was from 24.37 to 25.7 kg/m². 19 women out of 35 had normal BMI and 16 women were overweight.

The average time taken for SSG was 14.31 minutes in our study with a standard deviation of 1.95 minutes. The volume of saline injected was from 20 to 40 mL, the mean of which was 29.28 \pm 7.85 mL. In our study, no any serious side effects were seen. 4 patients complained of mild pelvic discomfort which did not require any medications.

Table 1: Associated Pelvic Pathology Detected By SSG And HSG

	Saline Infusion Sonosalpingography (SSG)	Hysterosalpingography (HSG)
Fibroid	2	0
Endometrial polyp	1	0
Polycystic ovaries	4	0
Hydrosalpinx	0	0
Ovarian cyst	2	0
Septate Uterus	0	1
None	26	34

In the present study, pelvic pathology like fibroid uterus, endometrial polyp, polycystic ovaries, ovarian cyst were better detected by Saline Infusion Sonosalpingography as compared to HSG.

Table 2: Comparison Of SSG And HSG Among All The Patients

N=35	Sonosonosalpingography (SSG)	Hysterosalpingography (HSG)
Bilateral tubes patent	26	24
Right tube blocked	3	4
Left tube blocked	4	3
Bilateral tubes blocked	2	4
Total	35	35

From the Table 2 data showing results of SSG and HSG of the participants (n=35), it was clear that there was no significant difference between the results of the two procedures.

Table 3: Showing Comparison Between The Results Of SSG And HSG

		Hysterosalpingography (HSG)				Total
		BTP	LTP+RTB	RTP+LTB	BTB	
Saline Sonosalpingography (SSG)	BTP	23	1	—	2	26
	LTP+RTB	—	3	—	—	3
	RTP+LTB	1	—	3	—	4
	BTB	—	—	—	2	2
	Total	24	4	3	4	N=35

(BTP: Bilateral Tubes Patent, LTP: Left Tube Patent, RTP: Right Tube Patent, LTB: Left Tube Blocked, RTB: Right Tube Blocked, BTB: Bilateral Tube Blocked)

Table 4: Showing Comparison Of The Results Of Ssg And Hsg With Respect To Individual Tubes

Total 70 tubes	No of tubes patent in HSG	No of tubes blocked in HSG	Total
No of tubes patent in SSG	54	5	59
No of tubes blocked in SSG	1	10	11
Total	55	15	70
Cohen's Kappa Coefficient = 0.9 (Near perfect agreement)			

The overall observed agreement between HSG and SSG was seen in 64 tubes (91.43%). On Kappa statistical analysis, near perfect agreement was seen between HSG and SSG.

The sensitivity of SSG for tubal patency with HSG as the reference standard was found to be 98.18%, specificity was 66.7%, PPV was 91.52% and NPV was 90.9%.

DISCUSSION:

Our study had a mean age of 28.17 \pm 5.58 years which is comparable to studies done by Daniel et al (27.92 years)³, Ranaweera et al⁴ (29.92 years) and Hajishafaha et al⁵ (29.09 years). Secondary Infertility patients were more in the older age groups when compared to primary infertility and it was found to be statistically significant ($P < 0.05$). Average duration of infertility in present study was 4.86 years with the range from 1-11 years which is comparable to various studies.

The present study estimated the sensitivity of SSG for tubal patency (with HSG as gold standard) to be 98.18% and specificity 66.67%. PPV was 91.52% and NPV was 90.9%. A high sensitivity of SSG in the diagnosis of tubal patency in this study which is similar to the studies by Nnah et al⁶, Shanmugham et al⁷ and Lakshmi et al⁸ implies that there is an increased possibility of SSG detecting those with patent tube. However, SSG had a lower specificity in the diagnosis of tubal patency in this study when compared to 94% by Lakshmi et al⁸, 100% by Hajishafaha et al⁵ and Malik et al⁹ in their studies. The lower specificity of SSG in this study implies that SSG has an increased possibility of missing women with tubal blockage in this study. The relatively low value of specificity is explained by the increased number of false positive cases with relation to HSG (SSG patent but HSG blocked). A metanalysis based on three studies gave pooled estimates of sensitivity for HSG as a test for tubal obstruction of 0.65. Because of its low sensitivity (0.65), HSG is of limited use for detecting tubal blockage. When HSG suggests the presence of tubal obstruction, this will be confirmed by laparoscopy (Gold standard) in only 38% of the women. When HSG suggests that the tubes are patent, this will be confirmed at laparoscopy in 94% of the women and, thus, HSG is a reliable indicator of tubal patency but not of tubal obstruction¹⁰. Thus, this low specificity is acceptable as in our study we compared SSG with HSG instead of the gold standard i.e. Laparoscopy.

Transvaginal Sonosalpingography, when compared with HSG is as accurate in demonstrating the presence of tubal patency, potentially safer and more convenient and less expensive. The evidence of tubal patency by the presence of fluid in Pouch of Douglas can be picked by relatively unexperienced sonologists. There is no risk of reaction to the contrast agent and no radiation hazards. The procedure could be performed on an ambulatory basis as a screening procedure. No anaesthesia is required and it also helps in diagnosing both uterine anomalies and pelvic pathology. Baseline sonography is needed to be done in all infertile patients to look for antral follicular count, ovaries, pathology in the uterus, adnexa, and uterine cavity along with endocrinological tests and tests for tubal patency. Saline infusion sonography is the single most investigation which when done on day 7–9 can reveal maximum information in an average time span of 10–15 min along with information on tubal patency. Baseline TVS would detect any uterine pathologies such as fibroid, ovarian mass, and polyp and also give idea of growing follicle and its size and any fluid in pouch of Douglas.

However, the technique does not provide an accurate assessment of intrauterine and tubal anatomy and the findings cannot be recorded. Site of tubal blockage cannot be determined by SSG. Also, peri-tubal adhesions and mobility of tube and intratubal pathology cannot be determined. And as with any other sonographic test, it is observer dependent.

CONCLUSION

Transvaginal Saline Sonosalpingography appears to be a reliable, simple, relatively inexpensive, accurate, quick and well-tolerable first-line diagnostic method for determining the tubal status and uterine cavity and can be performed at the time of conventional ultrasound scan. In low resource settings like India where infertility services are at the higher end cost wise, also not available everywhere and patients cannot always afford multiple visits, SSG appears to be a promising investigation in first line basic infertility work up as maximum abnormalities and pathologies could be detected in a single visit with it.

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