A Comparative Study of Saline Infused Sonohysterography and Conventional Hysterosalpingography in the Evaluation of Female Infertility

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ABSTRACT

Background and Objectives: Recognition of the causes of infertility, appropriate timely evaluation, and treatment with good outcome is the goal of the treating physician. Saline infused sonohysterography (SIS) is a cost-effective, safe, noninvasive, and a rapid procedure to visualize the female pelvic organs in the evaluation of infertility. The purpose of this study is to compare the diagnostic accuracy and the advantages of saline infused sonohysterography (SIS) over conventional hysterosalpingography (HSG). **Materials and Methods:** Thirty-five women who presented to the gynecology department between November 2005 and September 2007 for evaluation of infertility were included in the study. After taking informed consent, all the women were subjected to SIS, followed by conventional HSG on the next day. The study was conducted between 7th and 11th day of the menstrual cycle. Results of the two procedures were compared. **Results:** The sensitivity, specificity, positive predictive value, and negative predictive value of SIS in detecting tubal patency was 94.28%, 75%, 97.05%, and 50%, respectively. SIS was found to be superior to conventional HSG in the evaluation of uterine and ovarian factors of female infertility in the present study. SIS was also found to be cost-effective and less time-consuming than conventional HSG. **Interpretation and Conclusion:** SIS can be used as a simple, noninvasive, cost-effective primary diagnostic tool in the evaluation of female infertility and should be used in conjunction with conventional HSG in the evaluation of tubal, cervical, uterine, and ovarian factors of infertility to avoid unnecessary invasive diagnostic procedures.

Key words: Conventional hysterosalpingography; infertility; saline infused sonohysterography

Introduction

The clinical definition of infertility is the absence of conception after 12 months of regular, unprotected sexual intercourse.[1] This condition may be further classified as primary infertility, in which no previous pregnancies have occurred, and secondary infertility, in which a prior pregnancy, although not necessarily a live birth, has occurred.

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In many cases, infertility is caused by a combination of factors in both partners to prevent conception from occurring.[2]

The three main causes of male infertility are as follows (1) varicocele (38.17%), (2) idiopathic (24.78%), and (3) obstruction (13.15%).[3] Out of all causes of infertility in

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women, ovulatory dysfunction (30%) and tubal factors (25%) are the major factors. Unexplained infertility is found in about 5–10%.[2]

Ultrasound (US) examination of the anatomy of the uterus, tubes, and ovaries may give sufficient information to prioritize one investigation over the other and hence provide a treatment schedule.[4] The different methods used for investigation of infertility are as follows:

- Cervical factor – postcoital test
- Endometrial factor – hysterosalpingography (HSG), sonography, and magnetic resonance imaging
- Tubal factor – hysteroscopy/laparoscopy, HSG, sonography, magnetic resonance imaging, and color Doppler sonography with transcervical injection of echo contrast material
- Peritoneal factor – HSG, sonography, magnetic resonance imaging, laparoscopy
- Ovulatory factor – sonography, clinical assessment/endocrine studies, and endometrial biopsy.

HSG is a procedure that exposes the patient to ionizing radiation and contrast medium and provides information about the uterine cavity and tubal patency, but masses in the pelvis are only indirectly inferred or completely missed. To circumvent this problem, an outpatient procedure has been thought out, i.e., the assessment of tubal patency by injection of normal saline transcervically and visualization of saline in cul-de-sac by US referred to as "Sonosalpingography."[5]

Saline-infused sonohysterography (SIS) is a technique that may help in the visualization of the endometrium and endometrial cavity, differentiate lesions of endometrial and myometrial origin, and assess tubal patency. It involves instillation of fluid into the endometrial cavity with simultaneous transvaginal US.[6]

The objective of the present study is to evaluate and compare the diagnostic accuracy of the two procedures in the evaluation of female infertility, i.e., saline infused sonohysterography and conventional HSG.

Materials and Methods

The present study was carried out at the radiodiagnosis and Obstetrics and Gynecology Departments of the Hospitals attached to Jagadguru Jayadeva Murugarajendra (J. J. M) Medical College on 35 patients in the reproductive age, who presented with the inability to conceive.

The main sources of data are patients from the following teaching hospitals attached to J. J. M. Medical College, Davanagere, Karnataka, India.

- Bapuji Hospital
- Chigateri Hospital
- Women and Children Hospital.

The women were included in the study only if they met the following criteria:

Inclusion criteria

- Primary and secondary infertile female patients in the reproductive age.

Exclusion criteria

- Patients having active pelvic infection, active vaginal bleeding, malignancy of the genital tract, suspected pregnancy, and abnormal semen analysis of the husband.

All eligible patients were properly counseled and gave informed consent before entry into the study. Detailed menstrual, obstetric, and medical histories of each patient were obtained, and general physical, systemic, and gynecological examinations were performed. Relevant investigations were performed according to clinical findings.

Technique of saline infused sonohysterography

All patients were subjected to transabdominal ultrasonography with full bladder using a 3.5 MHz probe and then transvaginal sonography with empty bladder technique with a 6.5 MHz transvaginal transducer.

Two machines were used for the study namely:

- SONOLINE ADARA (Siemens) in Bapuji Hospital
- SONOLISA (Larsen and Toubro) in Chigateri General Hospital.

Initially, the patients were evaluated with an abdominal transducer to measure the uterus and evaluate any potential pathologic conditions outside the focal length of the vaginal transducer. Following this, the patient was put in dorsal position, perineum painted with Betadine and draped. Vagina was cleaned with a sterile swab, those patients with evidence of cervical erosion or vaginitis were excluded from the study or the study was undertaken after treatment. Using a Sims Cannula and a tenaculum, uterine cervix was exposed. The uterine sound was passed, both to know the position and the size of the uterus as well as to rule out cervical stenosis. Then, a semi-rigid Foley's Catheter 8 French was directed into the uterine cavity and the balloon was inflated with 2 ml of normal saline and pulled back to occlude the internal os. The uterine myometrium and endometrium were then more clearly defined with the vaginal probe.

For transvaginal scan, transducer was prepared for use by first applying standard coupling gel followed by sheathing by a condom which was again lubricated with coupling gel before insertion. The transducer was introduced into posterior vaginal fornix when uterus was retroverted and into anterior vaginal fornix when it was anteverted.

In the uterus, observations included size, shape, and echotexture of the uterus and cervix in sagittal and

transverse planes, endometrial regularity, thickness of each wall, and echogenicity relative to contiguous myometrium. Endometrial thickness was measured at the broadest diameter in the longitudinal plane. The measurements included both endometrial layers.

The size of the ovaries was measured, and shape, position, and echo pattern of the ovaries noted. Then, 20–30 ml of normal saline was injected into the uterine cavity through the Foley's Catheter. The resistance to the free entry of normal saline was noted as well as the subjective feeling of pain or discomfort expressed by the patient. The distension of the endometrial cavity with saline was visualized simultaneously, and the presence of any intrauterine pathology was ruled out. The right and left ovarian fossae, paracolic gutters, and the pouch of Douglas were visualized. Flow of fluid and air – "Turbulence" was looked for in the region of right and left ovarian fossae and this "turbulence" – "The waterfall sign"[7] was taken as patency of the respective fallopian tube. Later, the cul-de-sac was also visualized to look for free fluid.

In the presence of obstructed tube, the uterine cavity expanded in size and no waterfall sign was observed. The patient also experienced discomfort and complained of minimal lower abdominal pain. The pain subsided with the deflation of the bulb and removal of catheter. This procedure was performed between 7th and 11th day of the menstrual cycle. All the patients were allowed to rest for about half an hour and were then sent home on a 7-day course of ampicillin and metronidazole.

Hysterosalpingography technique

The procedure was carried out between the 8th and 10th day of the menstrual cycle. The procedure was explained to the patient, and the patient was reassured before the examination was carried out. Atropine sulfate (0.65 mg in 1 ml), an antispasmodic, was given through intravenous route to relieve uterotubal spasm as a precautionary measure.

The examination was conducted in association with a gynecologist. The patient was asked to empty her bladder immediately before the examination as full bladder may interfere with tubal filling and displace the uterus. The patient was made to lie on the radiographic table with the hips flexed and the vulva exposed. Following this, perineum was painted with Betadine and draped. Sims speculum was inserted and the anterior lip of the cervix was held by tenaculum and any visible cervical mucus removed, uterine sound was passed to know the size and position of the uterus. Water soluble contrast (urografin 76%) 20 ml (iodine content in 20 ml is 7.41 g) was kept in a 20 ml syringe. Next, Rubin's Cannula was filled with the contrast material to flush out the air because artifacts in the uterine cavity can be caused by air bubbles. Rubin's Cannula was then inserted into the external os under direct vision, and counter traction applied on the tenaculum to ensure a tight seal. The Sims speculum was then removed, and the patient's legs were extended. With fluoroscopic control, 10 ml of contrast was pushed. Contour of uterine cavity and spill from either end of tubes were noted. Spot radiographs were taken: One film to visualize the spill and another taken 5 min later to visualize the free dispersion of contrast in the pelvic peritoneal cavity. The initial radiograph clearly delineated the uterine cavity and fallopian tubes filled with contrast. The subsequent radiograph showed the peritoneal spillage if the tubes were patent.

Contrast material was injected very slowly (1) to avoid discomfort, (2) avoid contraction of the uterus, (3) avoid Spasm of the utero tubal junction, and (4) to avoid nonvisualization of lesions due to large quantity of contrast material.

Once the radiographs were found to be satisfactory, the cannula was removed, the vagina cleaned, and the patient was kept under observation for half an hour.

Before she went home and on subsequent visits, the patient was questioned about any serious reactions and these were noted.

The radiographs after processing were studied for the radiological anatomy of the female genital system which included the size, shape, position of the uterus, patency of the fallopian tubes, and peritoneal spillage.

Following parameters of both the above-mentioned procedures were compared, namely., the cost of procedure, time taken, diagnostic details, complaints, and complications.

Results and Discussion

All the patients in the study group belonged to the reproductive age. Most of the cases were in the age groups 20–25 years (48.6%) and 26–30 years (48.6%); only 2.85% of the cases were between 31 and 35 years. The mean age was 25.48 years (range 20–35 years). Fertility peaks by 25 years of age and one-third of women are no longer fertile by 40 years of age.[8] Since the fertility of women decreases progressively with age particularly after 30 years, the earlier the patient is investigated, the better the chance of success [Table 1].

In the present study, SIS showed that 14.28% of the cases had tubo-ovarian masses and 5.70% had hydrosalpinx. Tubal findings in the present study were slightly higher than Rahman and Sinha[9] with respect to tubo-ovarian masses (14.28%) as against 8%, whereas hydrosalpinx was 5.70% as against 18.70% in Mitri *et al.*[10] and 10% in Rahman and Sinha,[9] respectively [Table 2]. In the present study, ovarian pathology, especially polycystic ovarian disease (PCOD) was found in 14.28% which was almost equal to the findings by Rahman and Sinha[9] (13%) [Table 3]. The criteria for diagnosing PCOD were as per sonologic criteria:

Table 1: Age distribution of cases

Age (years) (%)	Present study	Rahman and Sinha[9]
20-25	48.60	30.50
26-30	48.60	51.00
31-35	02.85	15.50
35-40	00.00	03.00

Table 2: Tubal abnormalities in saline infusion sonohysterography

Finding (%)	Present study	Mitri *et al.*[10]	Rahman and Sinha[9]
Hydrosalpinx	5.70	18.70	10
Tubo-ovarian mass	14.28	00.00	08

Multiple small cysts in a single plane of the ovary; 8–10 echo free cysts and 2–8 mm in diameter[11] [Figure 1].

In the present study, 17.20% of the cases had fibroids; out of these, 2.85% were intramural, 8.60% were posterior wall fibroids, 2.85% were submucosal fibroids, and multiple fibroids were seen in 2.85%.

Majority of patients (65.70%) were found to be having primary infertility in the present study which was similar to the findings by Sudha,[12] Rahman and Sinha,[9] and Allahbadia[13] [Table 4]. In the present study, a maximum number of patients had 4–6 years infertility period (40%) followed by 7–10 years infertility (31.40), only 28.60% of patients had infertility period for 1–3 years. The shortest duration was 2 years, and the longest duration was 10 years. The mean duration was 5.28 years (range 2–10 years).

Majority of the patients 68.60% had a normal menstrual pattern; 17.10% had menorrhagia, 11.40% had oligomenorrhea, and only 2.85% had polymenorrhea. Enlarged uterus was found in 17.10% of the cases, whereas majority (82.90%) had a normal sized uterus on SIS. The uterine size was measured by transvaginal US and 6–8.5 cm × 3–5 cm × 2–4 cm (length × width × thickness) was regarded as a normal value; any size larger was regarded as enlarged uterus.[14,15]

Endometrial thickness as measured by transvaginal US was more than 12 mm (cut off value for thickening) in 8.60%. About 12 mm was taken as cutoff value as several studies suggest that transvaginal US is a sensitive test for diagnosing endometrial hyperplasia in premenopausal women when endometrial thickness is ≥12 mm.[13] Majority of the cases 68.60% showed a proliferative pattern (6–9 mm). Nearly, 17.10% showed a periovulatory pattern. The mean endometrial thickness was 5.79 ± 2.45 mm (range 2.80–12.80 mm).

The endometrial pattern in the current study predominantly (68.6%) is early proliferative pattern which is almost equal to

Table 3: Ovarian pathology

Study	Ovarian cyst (%)	PCOD (%)
Present study	2.85	14.28
Sudha[12]	-	8.80
Rahman and Sinha[9]	16.50	13

PCOD – Polycystic ovarian disease

Table 4: Type of infertility

Type of infertility (%)	Present study	Sudha[12]	Rahman and Sinha[9]	Allahbadia[13]
Primary	65.70	73	72.50	80
Secondary	34.30	27	27.50	20

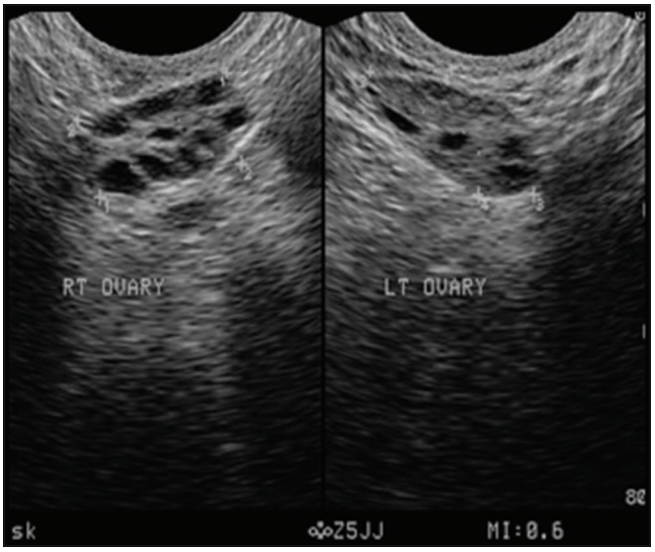


Figure 1: Gray scale transvaginal ultrasonography of both ovaries showing multiple echo-free cysts seen peripherally arranged in the ovarian stroma consistent with polycystic pattern of ovaries

the study by Rahman and Sinha[9] in which it was 62%. Thin or absent endometrium was found in 5.70% as against 3.5% in the study by Rahman and Sinha.[9]

Fibroids (17.20%) and tubo-ovarian masses (14.28%) were the most common findings on SIS [Figure 2] followed by PCOD (14.28%), ovarian cysts, polyps, and intrauterine adhesion were (2.85% each). Normal pelvic organs were found in 37.15% of the cases [Table 5].

In the present study, tubal patency was assessed first by SIS, which was later compared with HSG, which was considered the gold standard. About 65.71% had bilateral tubal patency in SIS, whereas 62.85% showed bilateral patency in HSG. Bilateral tubal occlusion was seen in 08.57% in SIS, whereas it was 05.70% in HSG. Unilateral patency was seen in 25.71% in SIS, whereas it was 31.42% in HSG.

SIS missed two cases of unilateral patency which was eventually diagnosed on HSG, and one case was falsely

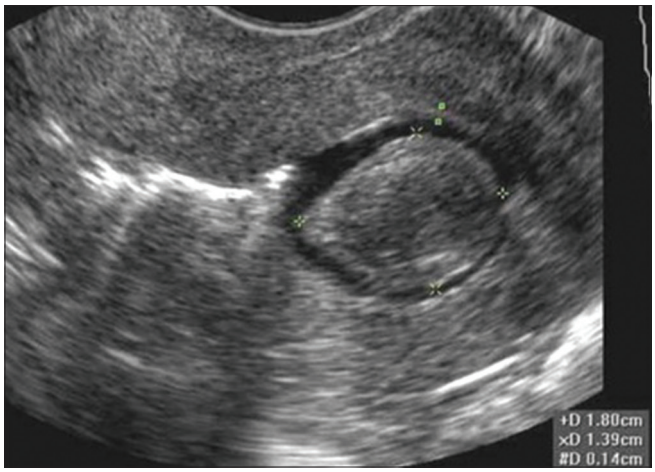
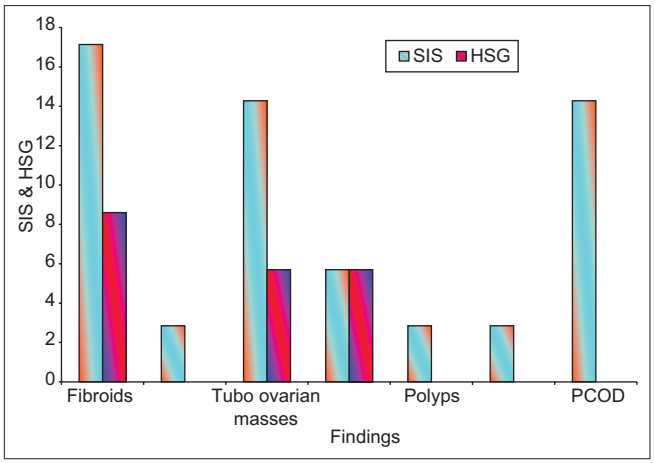


Figure 2: Gray scale transvaginal sonosalpingography showing a well-defined isoechoic lesion within the endometrial cavity filled with normal saline consistent with intracavitary fibroid



Graph 1: Comparison of findings in SIS and hysterosalpingography

diagnosed as bilateral occlusion while it was actually a unilateral occlusion which was proved by HSG. Hence, HSG is superior to SIS in the evaluation of the fallopian tubes, especially with respect to tubal blocks. Tubal patency can be assessed far better with HSG than SIS with regard to site and side.

As compared to HSG, the sensitivity, specificity, positive predictive value, and negative predictive values (NPVs) of SIS in detecting tubal patency were 94.28%, 75%, 97.05%, and 50%, respectively.

The sensitivities of SIS in diagnosing tubal patency were similar to other studies, Inki *et al.*[16] (90.2%), Allahbadia[13] (93%), Deichert *et al.*[17] (89%), whereas the specificities obtained were slightly higher Inki *et al.*[16] (83.3%) and Deichert *et al.*[17] (100%) as compared to the present study (66.66%) [Table 6].

SIS diagnosed 17.14% of cases as fibroids, whereas HSG detected only 8.60% of cases. Ovarian pathology was diagnosed in 17% of the patients in SIS, whereas only 5.70% of ovarian pathology was detected by HSG. Similarly, intrauterine adhesions were detected by SIS 2.85% while HSG failed to detect it. This shows that SIS is very sensitive in diagnosing uterine and ovarian pathology and is superior to HSG [Graph 1]. In the present study, mean time taken for the procedure was 18.70 ± 2.9 (min) for SIS, whereas it was 31.10 ± 5.0 (min) for HSG. The range was 14–24 min for SIS, whereas it was 25–40 min for HSG [Graph 2]. In the present study, the mean ± standard deviation and the range of the cost of the procedure for SIS and HSG, respectively, were as follows: 230 ± 27 (Rs); 175–275 (Rs) and 367 ± 26 (Rs); 330–420 (Rs) [Table 7].

Giddiness was felt by 1 patient (2.85%) both in SIS and HSG. Nearly, 5.70% of patients had nausea and palpitations in HSG, whereas only 2.85% had nausea in SIS. Around 57% of patients had no complaints during the procedure in SIS, whereas 51.40% of patients did not complain during HSG.

Table 5: Details of pelvic findings by saline infusion sonohysterography

Findings	Present study percentage	Rahman and Sinha[9] (%)
Normal pelvic organs	37.15	59
Ovarian abnormalities	17.00	16.5
Tubo-ovarian mass	17.20	08
Hydrosalpinx	05.70	10
Polyps	02.85	00
Adhesions	02.85	00
Fibroids	17.20	4.5
Congenital	-	2

Table 6: Tubal patency - comparison of the present study results with other studies

	Present study	Inki *et al.*[16]	Allahbadia[13]	Deichert *et al.*[17]	Richman *et al.*[5]
Sensitivity (%)	94.28	90.2	93	89	100
Specificity (%)	75	83.3	00	100	96
PPV (%)	97.05	94.90	100	00	00
NPV (%)	50.00	71.40	69	00	00

PPV – Positive predictive value; NPV – Negative predictive value

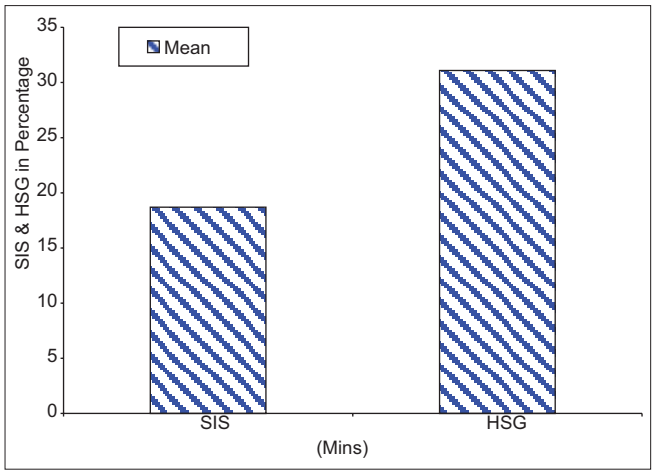
Table 7: Comparison of cost of the procedures

Rupees	SIS	HSG	*P*
Mean±SD	230	367	<0.05 significant
Range	175-275	330-420	

SD – Standard deviation; HSG – Hysterosalpingography, SIS: Saline infused sonohysterography

Conclusion

The present study shows that SIS is superior to HSG in the evaluation of uterine and ovarian factors of female infertility



Graph 2: Time taken for the procedures

and has a fairly comparable sensitivity, specificity, PPV, and NPV in comparison to HSG in the evaluation of tubal patency. SIS can be used as a simple, noninvasive, cost–effective, and primary diagnostic tool with no radiation exposure to the patient in the evaluation of female infertility. SIS should be used in conjunction with HSG in the evaluation of tubal, cervical, uterine, and ovarian factors of female infertility. Thus, we can prevent a large number of unnecessary invasive diagnostic procedures and save a great deal of money, time, and discomfort to the patient.

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Conflicts of interest
There are no conflicts of interest.

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