

Role of Doppler Saline Sonosalpingography in Evaluation of Tubal Factors in Women with Infertility: A Cross-sectional Study

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ABSTRACT

Introduction: The contribution of tubal factors to infertility is up to 30%. One of the tests used to evaluate tubal factor infertility is Doppler saline Sonosalpingography (SSG). The basic principle of SSG is to distend the uterine cavity with isotonic saline, which helps identify the uterine contour, intrauterine pathology, endometrial thickness and the presence of fluid in the Pouch of Douglas (POD). Adding Doppler increases its efficiency and accuracy.

Aim: To ascertain the role of Doppler saline SSG in tubal infertility.

Materials and Methods: This cross-sectional study was done for 18 months in the Obstetrics and Gynaecology Department of Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India involving 200 women with either primary or secondary infertility. These women were recruited in the mid-follicular phase after obtaining written informed consent. Patients underwent Doppler SSG to assess tubal patency and the findings were compared with Diagnostic Hysterolaparoscopy (DHL).

Diagnostic tests were used to calculate sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV). Inter-rater kappa agreement was used to find out the strength of the association between Doppler Saline SSG and diagnostic laparoscopy. A p-value of less than 0.05 was considered significant. The data was entered into an MS Excel spreadsheet and analysis was done using the licensed version of Statistical Package for Social Sciences (SPSS) version 21.0.

Results: The mean age and mean duration of infertility were reported to be 29 years and five years, respectively. The sensitivity of Doppler SSG for tubal patency was reported as 85.4%, the specificity as 95.8%, PPV as 95.3%, NPV as 86.8% and the accuracy for tubal patency was 90.6%. Doppler SSG and laparoscopic chromopertubation findings had substantial association (k value -0.62).

Conclusion: Doppler SSG is a reliable method for the assessment of tubal factors and can be used as a screening modality with high sensitivity and specificity.

Keywords: Diagnostic hysterolaparoscopy, Laparoscopic chromopertubation, Pouch of Douglas, Transvaginal ultrasound

INTRODUCTION

Infertility, defined as the inability to conceive even after one year of unprotected intercourse, poses a major concern in the field of female reproductive health [1]. The incidence, at 16.7%, is progressively rising globally, with an average of 10-15% of couples annually investing in treatment for either primary or secondary infertility [1,2].

Male and female factors leading to infertility have been further subdivided into endocrine, anatomic, genetic and behavioural. Out of these, male factors contribute to 25-40% of total infertility cases [2,3]. Meanwhile, female factors of infertility include tubal and peritoneal factors (25-35%), ovarian factors (30-40%), cervical factors (5%), uterine factors (10%) and other pelvic causes (5-10%) [4].

One of the major and most perplexing causal factors for infertility is the tubal factor. Laparoscopy is considered the gold standard for diagnosing tubal and peritoneal diseases and is frequently performed as the final step in determining the cause of infertility. However, it entails the risk of general anaesthesia for those bound to surgery [5]. Therefore, to evaluate tubal patency, the first choice is always a low-cost and low-risk approach, followed later by more complex and invasive procedures [5].

The basic principle of SSG is to distend the uterine cavity with isotonic saline, which delineates the contour, identifies intrauterine pathology, endometrial thickness and the presence of fluid in the POD and also checks for tubal patency. It is free of anaesthesia-related risks and is relatively simple, safe and easy to perform, devoid of radiation hazards and the risk of allergy to iodine contrast. This procedure can help make the infertility workup more acceptable, less expensive and less time-consuming [5]. On the other hand,

the addition of Doppler to SSG further increases its efficiency and accuracy, as suggested by a previous study [6]. However, Doppler-associated SSG is still evolving and has yet to find its place in the workup for tubal factor infertility. With this background, the present study was conducted with the aim of ascertaining the role of Doppler saline SSG in tubal infertility.

MATERIALS AND METHODS

The present was a cross-sectional study done from June 2022 to December 2023 in the Department of Obstetrics and Gynaecology, Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi, India, after obtaining Institutional Ethical Committee clearance (number 243).

Inclusion criteria: The study was carried out on 200 infertile women aged 21-37 years with unexplained infertility and >3 failed intrauterine inseminations.

Exclusion criteria: Women with moderate to severe endometriosis, pelvic inflammatory disease, hydrosalpinx on baseline transvaginal ultrasound, or women unfit for laparoscopy (such as those who have undergone laparotomy in the past or those with an ongoing pregnancy) were excluded.

Sample size calculation: In a previous study by Soliman AA et al., the sensitivity and specificity of power Doppler hysterosalpingography were observed to be 94.4% and 100%, respectively [7]. Using these values as a reference, the minimum required sample size with a desired precision of 10%, 80% power of the study and a 5% level of significance was calculated to be 50 patients. The final sample size of the study was 200 patients due to an increased influx of patients meeting the eligibility criteria.

Study Procedure

Women presenting to the infertility clinic (meeting the inclusion criteria) were subjected to detailed history-taking, provided written informed consent and received a clinical examination. The enrolled women underwent Doppler SSG for tubal patency and the findings were compared with DHL. All infertility investigations for the couple, like premenstrual endometrial biopsy, hysterosalpingography, hormonal assessment in females and semen analysis in males, were performed as per hospital protocol. The women were recruited in the mid-follicular phase (Day 6th to Day 10th of the menstrual cycle) but before ovulation to decrease the risk of dislodging an early pregnancy and to avoid the dispersion of menstrual debris into the peritoneal cavity.

The Doppler settings were as follows: frequency 4.0 MHz, gain 20, Pulse Repetition Frequency (PRF) 0.3 KHz, Wall Filter (WF) 24 Hz. All scans and laparoscopies were performed by the same clinician and the same settings were used for all patients. Oral analgesic (ibuprofen 400 mg) was given 1-2 hours before the procedure. A detailed baseline transvaginal ultrasound was done using the SonoAce R7 ultrasound machine from Samsung Medison with a 7.5 MHz vaginal transducer just before the Doppler saline SSG to assess pelvic, ovarian, endometrial, cervical, uterine pathologies and free fluid in the POD.

After completing the baseline transvaginal ultrasound, the transvaginal probe was removed and the patient was laid in the lithotomy position. A speculum was inserted in the vagina to visualise the cervix. The cervix and vagina were cleaned with betadine. The anterior lip of the cervix was held by a vulsellum. An 8F Foley catheter was inserted through the cervical os into the uterine cavity, with its tip placed just beyond the internal os. The catheter balloon was inflated with 2 mL of normal saline for occlusion and stabilisation at the internal cervical os. Subsequently, the vulsellum was removed and the transvaginal probe was gently introduced into the posterior fornix of the vagina. The uterine cornua and ovaries were visualised in both sagittal and coronal sections.

With the cornua and the ipsilateral ovary under vision on the monitor, 50 mL of sterile saline solution was pushed by a 50 mL syringe into the Foley catheter under sonographic guidance and the same procedure was repeated on the opposite side. The morphology of the uterine cavity was observed for various endometrial pathologies and the flow of saline was detected in the corresponding tube by power Doppler. The placement of the first colour box was done on the transverse section of the uterus. The passage of fluid in the uterine cavity was confirmed by the colour signals flowing upwards as the saline was injected through the cannula in the uterus.

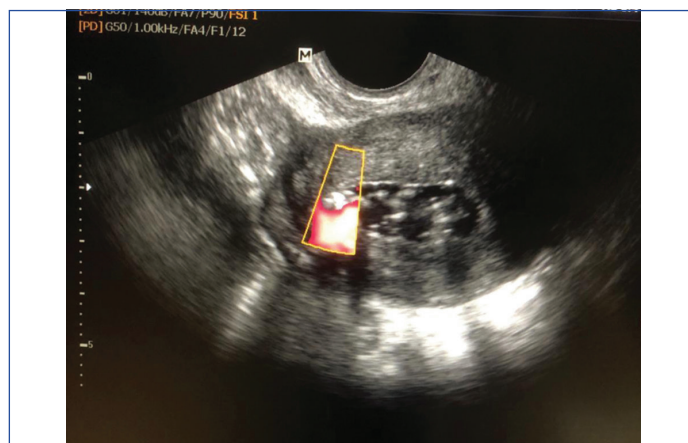
An immediate change of the field of vision was done to view the ovary and the adnexa by spanning the probe laterally from the transverse section of the uterus. While injecting saline, the colour box was placed for visualisation of the adnexa and the ovary. Tubal patency was indicated by filling up the box with colour and the absence of such signals indicated tubal blockage. A similar procedure was repeated on the opposite side.

Diagnostic criteria for tubal patency: The following diagnostic criteria were used to classify tubes as patent or non patent:

- Filling up of the box with colour signals;
- Detection of spill at the fimbrial end, also known as the waterfall sign;
- Flow of air bubbles visualised in the tubal lumen;
- Flow of air bubbles directly visualised around the ovary;
- Saline detection in the Pouch of Douglas (POD);
- Flow of air bubbles into the interstitial part of the salpinx showing cornual patency;
- Steady flow signals detected in a segment of the tube for at least five seconds.

The presence of the above criteria for a particular tube signifies patency.

The tubal patency on the colour Doppler is shown in [Table/Fig-1].



[Table/Fig-1]: Colour doppler box with passage of air bubbles and fluid through fallopian tube (Patent).

All the findings of Doppler saline SSG were noted down. The patient was well-counselled regarding the risk of mild pelvic cramping or spotting post-procedure. Recruited women underwent DHL in a day or two following the Doppler saline SSG. During laparoscopy, the pelvis and abdomen were inspected and perihepatic or intraperitoneal adhesions, morphology of the uterus and tubes, fluid in the POD, endometriosis, endometrioma, endometrial cyst and ovarian cyst were demonstrated under vision. Laparoscopic chromoperturbation was done to look for bilateral spill.

STATISTICAL ANALYSIS

Categorical variables were presented as numbers and percentages (%), while continuous variables were presented as mean±SD and median. Diagnostic tests were used to calculate sensitivity, specificity, NPV and PPV. Inter-rater kappa agreement was used to find out the strength of association between Doppler saline SSG and diagnostic laparoscopy. A p-value of less than 0.05 was considered significant. The data were entered into an MS Excel spreadsheet and the analysis was done using the licensed version of SPSS version 21.0.

RESULTS

In the study, most infertile women 92 (46%) were in the age group of 26-30 years. The mean age of enrolled infertile women was 28.92 years. Additionally, the maximum number of infertile couples 104 (52%) had a marriage duration of 6-10 years and the average duration of marriage was found to be 7.62 years. Primary infertility was the most common 124 (62%) among study participants, with the mean duration of infertility being 5.32 years [Table/Fig-2].

Parameters	n	Percentage (%)
Age (in years)		
21-25	44	22.0%
26-30	92	46.0%
31-35	44	22.0%
36-37	20	10.0%
Total	200	100%
Mean±SD	28.92±4.22	
Duration of married life		
2-5 y	64	32.0%
6-10 y	104	52.0%
>10 y	32	16.0%
Total	200	100%
Mean±SD	7.62±3.48	

Type of infertility		
Primary	124	62.0%
Secondary	76	38.0%
Total	200	100%
Duration of infertility		
1-5 y	112	56.0%
6-10 y	76	38.0%
11-15 y	12	6.0%
Total	200	100%
Mean±SD	5.32±2.95	

[Table/Fig-2]: Demographic details of the study participants.

In eight women, Doppler SSG was not done as the internal os was found closed, so the results were compared for 192 women and these eight women were excluded. As per the study results [Table/Fig-3], 24 women (12.5%) had their right fallopian tube appear patent on Doppler SSG, whereas on DHL, 20 women (10%) had a similar finding.

Tubes	Doppler SSG		Diagnostic Hysterosalpingography (DHL)	
	n	%	n	%
Right tube patent	24	12.5%	20	10.0%
Left tube patent	12	6.3%	12	6.0%
Both patent	68	35.4%	84	42.0%
Both blocked	88	45.8%	84	42.0%

[Table/Fig-3]: Laparoscopic chromopertubation and doppler SSG for tubal patency and their frequencies.

In eight women, Doppler SSG was not done as the internal os was found closed, so the results were compared for 192 women and these eight women were excluded.

Among a total of 192 women, 88 women (46%) were reported to have bilateral fallopian tube blockage on Doppler saline SSG. Of these 88 women, 76 women (86%) had bilateral tubes blocked on laparoscopic chromopertubation and among the remaining 12 women (14%), four had both tubes patent, four had the right tube patent and four women had the left tube patent on laparoscopic chromopertubation [Table/Fig-4].

Doppler Sonosalpingography (SSG)	Total	Laparoscopy				p-value
		Both block on DHL	Right tube patent on DHL	Left tube patent on DHL	Both patent on DHL	
Bilateral block on SSG	88	76	4	4	4	<0.001
Right tube patent on SSG	24	-	16	-	8	
Left tube patent on SSG	12	-	-	8	4	
Both patent on SSG	68	4	-	-	64	
Total	192	80	20	12	80	

[Table/Fig-4]: Association of tubal patency in patients between doppler saline Sonosalpingography (SSG) and laparoscopic chromopertubation.

Amongst a total 384 fallopian tubes evaluated in the study, 172 tubes (44.8%) were found to be patent on Doppler saline SSG. Out of these 172 tubes, 164 tubes (95.3%) were found to be patent on laparoscopic chromopertubation, while 8 tubes (4.6%) were found to be blocked on laparoscopic chromopertubation [Table/Fig-5]. It was also found that both Doppler saline SSG and laparoscopic chromopertubation were substantially associated in terms of tubal patency findings (k value -0.62).

The sensitivity, specificity, PPV, NPV and accuracy of Doppler SSG were found to be 85.4%, 95.8%, 95.3%, 86.8% and 90.6%, respectively.

Doppler Saline Sonosalpingography (SSG)	Total	Laparoscopy				p-value and K value
		Patent		Blocked		
		N	%	N	%	
Patent	172	164	85.4%	8	4.2%	p<0.001 K=0.62
Blocked	212	28	14.6%	184	95.8%	
Total	384	192	100%	192	100%	

[Table/Fig-5]: Association of tubal patency between doppler saline Sonosalpingography (SSG) and laparoscopic chromopertubation.

DISCUSSION

The study included 200 patients, with the mean age of the females included in the study reported as 28.92±4.22 years. The mean age of the husbands of the females included in the study was found to be 32.34±4.21 years. In the study conducted by Sambharam K et al., the median age of patients in the saline SSG group was 29.67 years and that in the diagnostic laparoscopy group was 27.03 years, which was comparable to the present study [8]. Another study by Daniel S et al., showed the average age to be 27.92±4.6 years, which was again similar to the present study [5]. The present study findings in terms of the mean age of the study population were also corroborating with the findings of the study done by Tiwari A et al., [9].

Duration of Infertility

In the present study, the mean duration of married life was found to be 7.62±3.48 years. The mean duration of infertility was found to be 5.32±2.95 years and the difference between the mean duration of married life and the mean duration of infertility was reported as 2.03±0.53 years. This difference signified that couples tried for spontaneous conception for around 2 years after marriage and did not seek infertility treatment. Soliman AA et al., conducted a study and reported the mean duration of infertility to be 4.3±2.86 years, which was slightly less but comparable to the present study [7]. In a study by Daniel S et al., mentioned above, the mean duration of infertility was reported to be 6.12 years, which was slightly higher but again comparable to the present study [5]. In another study by Malik B et al., the mean duration of infertility was found to be 7.7 years, which was slightly higher than the present study [3]. Anuradha J et al., studied 50 infertile women with either primary or secondary infertility [10]. The mean duration of infertility reported was 5.79±3.19 years and 5.97±3.36 years in primary and secondary infertility, respectively, which was similar to the present study.

Type of infertility: According to the present study, primary infertility was found in 124 women (62%), whereas secondary infertility was found in 76 women (38%). In 2015, a study was done by Sambharam K et al., on 60 infertile women [8]. Primary infertility was present in 30 women (73.3%) and the rest had secondary infertility. In 2014, Malik B et al., conducted a study in which 22 patients (73%) had primary infertility [3]. In the study by Anuradha J et al., 30 women (72%) had primary infertility and 14 women (28%) had secondary infertility [10].

Diagnostic Value of Doppler Saline SSG

Tubal patency: The sensitivity, specificity, PPV and NPV of Doppler saline SSG for tubal patency were found to be 85.4%, 95.8%, 95.3% and 86.8%, respectively. The accuracy of Doppler saline SSG for tubal patency was reported as 90.6%. In the study by Soliman AA et al., where they studied the accuracy of four-dimensional (4D) ultrasound and 2D power Doppler saline Sono hysterosalpingography mapping in detecting tubal patency in 50 infertile women [7]. Sensitivity, specificity, PPV, NPV and accuracy of 2D power Doppler hysterosalpingography were 94.4%, 100%, 100%, 89.2% and 96.2%, respectively and for 4D saline hysterosalpingography were 70.4%, 100%, 100%, 70.4% and 82.6%, respectively. They found that 4D saline hysterosalpingography had acceptable accuracy in detecting tubal patency but was surpassed by power Doppler

S. No.	Authors, year of study	Type of study/ study duration	Sample size	Outcomes measured	Results
1	Luciano DE et al., [11] (2014)	Chart review	113	Newer method for evaluation of the uterus and fallopian tubes-Hysterosalpingo-Contrast Sonography (HyCoSy)	HyCoSy had a sensitivity of 96% and specificity of 100%. More accurate for tubal patency than HSG and laparoscopic chromopertubation.
2	Malik B et al., [3] (2014)	Cross-sectional study	30	Comparison of Sonosalpingography (SSG) and HSG for evaluation of uterotubal factors in female infertility	SSG was an inexpensive, quick, well tolerable first line diagnostic method for determining the tubal status and uterine cavity. SSG had sensitivity of 95.83% and specificity of 100%.
3	Soliman AA et al., [7] (2015)	Prospective study	50	Accuracy of four dimensional (4D) hysterosalpingosonography and power Doppler mapping in detecting tubal patency and its comparison with laparoscopy and chromopertubation	4D saline hysterosalpingography had acceptable accuracy in detecting tubal patency with a sensitivity of 70.4% and specificity of 100%.
4	Sambharam K et al., [8] (2015)	Prospective clinical study	60	Comparison of sonosalpingography and laparoscopy in evaluation of tubal patency	Tubal non patency was diagnosed more often on sonosalpingography than on diagnostic laparoscopy with chromopertubation.
5	Anuradha J et al., [10] (2016)	Prospective cohort study	50	Tubal factor evaluation by HSG, transvaginal Sonosalpingography (SSG) and laparoscopic chromopertubation	Sonosolpingography (SSG) could be employed as a screening procedure to pick up subjects needing HSG and laparoscopy.
6	Shanmugham D et al., [12] (2018)	Prospective study	50	Evaluation of diagnostic accuracy of Saline Infusion Sonosalpingogram (SSG) in the assessment of tubal patency in infertile patients with laparoscopy as the gold standard	The sensitivity of SSG in diagnosing tubal patency was 95.34%, specificity 75%, Positive Predictive Value (PPV) 97.65% and Negative Predictive Value (NPV) 60%.
7	Singh V et al., [13] (2018)	Retrospective, observational study	90	Role of saline infusion sonohysterography in infertility evaluation, tubal patency and endometrium pathology	Saline Infusion Sonohysterography (SIS) had sensitivity of 91%, specificity of 76% Positive Predictive Value (PPV) of 95%, Negative Predictive Value (NPV) of 66% and accuracy of 89% in evaluating tubal patency.
8	Tiwari A et al., [9] (2020)	Prospective comparative study	98	A comparative study to evaluate diagnostic accuracy and correlation between saline infusion sonography, hysterosalpingography and Diagnostic Hysteroscopy (DHL) in infertility	Sensitivity and specificity of SIS for uterine finding detection was calculated to be 100% and 61.90% while taking sensitivity and specificity of DHL as 100%.
9	Present study (2022-2023)	Observational cross-sectional study	200	Role of Doppler saline Sonosalpingography (SSG) in tubal factors of infertility	Doppler saline Sonosalpingography (SSG) appeared to be a reliable method for assessment of tubal factors.

[Table/Fig-6]: Comparative evaluation of present study with past studies [3,7-13].

saline hysterosalpingography. Daniel S et al., in his study, studied 50 women to evaluate the accuracy and efficiency of saline SSG in the assessment of tubal patency in comparison to laparoscopic chromopertubation [5]. The sensitivity, specificity, PPV and NPV of SSG were calculated to be 93.3%, 44.4%, 94.3% and 36.3%, respectively. In the study by Malik B et al., they enrolled 30 women with primary or secondary infertility to study Sonohysterography and correlate the results with HSG for the evaluation of uterotubal factors in female infertility [3]. All patients with positive findings of uterine cavity anomalies or those with a diagnosis of unilateral or bilateral blocked fallopian tubes underwent hysteroscopy along with chromopertubation, which was considered standard. SSG had a sensitivity of 95.83% and a specificity of 100% for the evaluation of tubal patency, which was slightly higher but still comparable to the present study. A comparative evaluation of the present study with past studies is shown in [Table/Fig-6] [3,7-13].

Doppler SSG is a low-risk, minimally invasive test with no radiation hazard. It is an Outpatient Department (OPD)-based procedure that consumes less time, is cost-effective, does not require any kind of anaesthesia and also helps in diagnosing both uterine anomalies, pelvic pathology, as well as tubal patency. The present study evaluated tubal factors of infertility along with uterine, ovarian and other pelvic pathologies in detail, which will help clinicians in better work-up of the patients and early initiation of treatment. There is a dearth of such studies in India; hence, the present study can act as a stepping stone for further larger studies to find out the usefulness of Doppler saline SSG in Indian women undergoing evaluation of infertility.

Limitation(s)

The technical difficulties encountered during the procedures in a few patients and observer-dependent radiological findings were limitations of the present study. The study design also limits future pursuit and follow-up of the patients as interventions and observations were done at one particular point in time only.

CONCLUSION(S)

The predictive values showed that power Doppler hysterosalpingography is good for positive tests but not comparatively good for negative results. By employing Doppler saline SSG for the evaluation of tubal patency and pelvic organ screening, a quick and timely approach towards finding solutions to problems can be made with an optimal recruitment schedule.

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