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Original Research Article

Evaluation of tubal patency in infertile patients with saline infusion sonosalpingogram

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ABSTRACT

Background: The incidence of tubal disease in infertility in India is as high as 40%. The aim of our study is to evaluate the diagnostic accuracy of Saline Infusion Sonosalpingogram (SSG) in the assessment of tubal patency in infertile patients with laparoscopy as the gold standard.

Methods: This is a prospective study conducted in the department of obstetrics and gynaecology on 50 consecutive infertile patients. Patients with acute pelvic inflammatory disease were excluded from the study. After complete examination and basic infertility work up, the tubal patency testing by Saline Infusion Sonosalpingogram was performed on day 8 of the cycle, followed by diagnostic laparoscopy with chromopertubation to confirm the tubal patency.

Results: Out of 50 enrolled patients, 3 were excluded during the course of study. Thus, the study population comprised of 47 infertile women. During our study, 42 patients had tubes patent on SSG, out of which 41 patients had patent tubes on laparoscopy. 2 patients with blocked tubes on SSG had patent tubes on laparoscopy. 3 patients had blocked tubes on both SSG and laparoscopy. On statistical analysis, the sensitivity of SSG in diagnosing tubal patency is 95.34%, specificity 75%, positive predictive value 97.65% and negative predictive value 60%.

Conclusions: Saline Infusion Sonosalpingogram is a simple, safe, convenient procedure for assessment of tubal patency in infertile women. It can be included in basic infertility work up. Hence, laparoscopy can be reserved for patients with tubal block, suspected pelvic pathology and unexplained infertility.

Keywords: Infertility, Laparoscopy, Sonosalpingogram, Tubal patency

INTRODUCTION

The incidence of tubal disease in infertility in India is as high as 40%.¹ This high prevalence may be attributed to genital tract tuberculosis, pelvic inflammatory disease and chronic infection which is quite common. The anatomical evaluation of the tubes plays a fundamental role in the workup of infertile couple. Hysterosalpingogram (HSG) is the first line investigation of infertile women for the assessment of tubal patency and uterine anomalies.² However, HSG is associated with disadvantages like pelvic pain, discomfort, radiation exposure and major complications like anaphylaxis to

contrast medium and vaso vagal shock. Laparoscopy is the gold standard for diagnosis of tubal block and for early diagnosis of endometriosis and pelvic adhesions.³ Laparoscopy has been included in the basic fertility studies by the American fertility society in 1923. However, it is an invasive procedure with the risk of minor complications like nausea, shoulder tip pain and major complications like bowel, bladder, vessel and ureteric injury.

Saline Infusion Sonosalpingogram has evolved recently as a better option for evaluation of tubal patency as it is a non-invasive procedure, no radiation hazard and no risk

of hypersensitivity to contrast agent.⁴ It can be done as an office procedure. Fewer studies are done using saline infusion sonosalpingogram for assessment of tubal patency.

This study evaluates the diagnostic accuracy of Saline Infusion Sonosalpingogram for assessment of tubal patency in infertile patients, with laparoscopy as the gold standard.

METHODS

This is a prospective study conducted in the department of obstetrics and gynaecology from January 2017 to February 2018 in a tertiary care centre after obtaining Institutional Ethics Committee clearance. 50 consecutive infertile patients with both primary and secondary infertility attending the infertility clinic were enrolled for the study after getting informed and written consent. Patients with acute pelvic inflammatory disease were excluded from the study.

A detailed history, general physical examination and gynaecological examination was done in all patients. Basic infertility work up of the couple which includes husband semen analysis, pelvic ultrasound and hormone analysis for thyroid and prolactin was done in all patients. Then tubal patency testing by saline infusion sonosalpingogram was performed on day 8 of the cycle. Oral analgesic mefenamic acid is given one hour prior to the procedure.

Saline Infusion Sonosalpingogram procedure

Patient is asked to empty the bladder. Perineum is cleaned, pelvic examination is performed to know the size, position and mobility of the uterus.

Cusco's speculum is introduced in to the vagina, cervix visualised, a paediatric Foleys catheter (8 French) with plastic stilette is introduced through the cervix into the uterine cavity beyond the internal os, Foley's bulb inflated with 2-3 ml of distilled water, to stabilise the catheter within the uterine cavity.

Baseline transvaginal ultrasound pelvis is performed with Mindray Z 5 machine. The position of the Foleys bulb is confirmed first.

Then about 30-40 cc of sterile saline with air is pushed through the Foleys catheter. The uterine cavity is examined for intra cavitary lesions after uterine distension (Figure 1).

For visualisation of the tubes, the scanning is 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.



Figure 1: Ultrasound picture showing uterus - Foley's bulb with distended cavity.

The salpinx can be visualized as a continuous or interrupted line. The tube if patent distends the mixture of saline and air bubbles gush past the ovary to give rise to what is known as the "water fall sign". Then Pouch of Douglas is observed for free fluid. Patients were observed for pelvic pain, discomfort and any other complications for one hour.

Criteria to diagnose tubal patency

- Cornual patency by flow of air bubbles into the interstitial part of the Salpinx.
- Water fall sign
- Fluid in the Pouch of Douglas

Then all the patients underwent diagnostic laparoscopy with chromopertubation to confirm the tubal patency and to look for any other pelvic pathology. The results were tabulated and analysed.

RESULTS

50 patients were enrolled for the study. But two patients refused laparoscopy after Saline Infusion Sonosalpingogram and one patient who had a risk for anaesthesia denied for laparoscopy. These patients were excluded from the study. Thus, the study population comprised of 47 infertile women.

Table 1 shows the demographic profile of the study patients. The mean age of the patients was 27 ± 3.4 years. The mean Body Mass Index was 28 ± 2.2 . The average duration of infertility was 5.6 years with the range of 2-11 years.

29 patients had primary infertility (61.7%) and 18 patients (38.3%) presented with secondary infertility. 10 patients (21.2%) had previous history of Pelvic Inflammatory Disease treated.

Table 1: Demographic characteristics of study patients.

Parameter	Value/Percentage (n=47)
Mean age	27±3.4 years
Mean BMI	25±2.2
Duration of infertility	5.6 years (2-11 years)
Primary infertility	29 patients (61.7%)
Secondary infertility	18 patients (38.3%)
Previous history of pelvic inflammatory disease	21.2%

Table 2: Assessment of tubal patency by Saline infusion Sonosalpingogram and Laparoscopic chromopertubation.

	Laparoscopy findings (n=47)		Total
	Patent tubes	Blocked tubes	
*SSG	41	1	42
	2	3	5
Total	43	4	47

*Saline infusion Sonosalpingogram

The results of both the procedure is illustrated in Table 2. During the present study, on SSG, 42 patients had tubes patent out of which 41 patients had patent tubes on laparoscopy. Two patients with blocked tubes on SSG was reported to have patent tubes on laparoscopy.

Three patients had blocked tubes on both SSG and laparoscopy. On statistical analysis, the sensitivity of Saline Infusion Sonosalpingogram in diagnosing tubal patency is 95.34%, specificity 75%, positive predictive value 97.65% and negative predictive value 60%.

With regard to uterine cavitary lesion, there was sub mucosal fibroid in one patient. SSG helped to differentiate a thickened endometrium from endometrial polyp in another patient. 4 patients had mild spasmodic pain during the procedure and 7 patients had pelvic discomfort after 4 hours. None of them had vaso vagal syncope or infection.

DISCUSSION

Infertility is defined as the failure to conceive after 1 year of regular unprotected intercourse.⁵ It affects 10% to 15% of couples. Polycystic Ovarian Syndrome (PCOS) is the most common endocrine disorder in infertile women.⁶ Main causes of infertility in women include anovulation, a tubal or peritoneal factor, and uterine, cervical, and unexplained infertility.⁷

Tubal factors account for 25-35% of infertility.⁸ The anatomical evaluation of the tubes plays a fundamental role in the work up of infertile patients. Hysterosalpingography became an accepted procedure in 1925 ever since the discovery of an effective medium lipiodol. However, it has its limitations and complications. It is associated with risks such as iodine

allergy, pelvic infections, and pain. It can cause venous or lymphatic intravasation of medium and also involves the risks of radiation exposure.

Ultrasound visualization of the internal genital tract using exogenous contrast medium was first described by Nannini et al, Richman et al and Randolph et al who performed abdominal sonography after intracervical injection of fluid.⁹⁻¹¹

Saline Infusion Sonosalpingogram (SSG) is an easy, cost effective, safe, more convenient and non-invasive procedure. In Saline Infusion Sonosalpingogram, isotonic saline which is a physiological solution is used, so least chance of any side effects. With the advent of high resolution ultrasound machine, the diagnosis of tubal patency is made possible with this procedure. However as with any diagnostic technique, SSG is associated with limitations.

The expertise required to interpret the findings, or the images is greater compared to HSG. But a person with good experience on transvaginal sonogram can be able to do this procedure with confidence in short span of time. In present study this was not a major problem. Another drawback is the inability to visualise the cornu properly which can decrease the diagnostic accuracy which we also faced during the study period.

The Royal college of obstetricians and gynaecologists of London in NICE guidelines recommends that, where appropriate expertise is available, screening for tubal occlusion using hysterosalpingo-contrast-ultrasonography should be considered because it is an effective alternative to hysterosalpingography.

The guideline also suggests that further randomised controlled trials are needed to evaluate the potentially therapeutic effects of tubal flushing with water-soluble media.¹²

The mean age of the patients in our study was 27±3.4 years comparable to studies done by Daniel (27.92 years) and 13. Hajishafiha (29.09 years).^{4,13} Majority of our patients had primary infertility similar to other studies.^{4,13-18} The average duration of infertility in present study, patients was 5.6 years with the range of 2-11 years which is comparable to various studies.¹³⁻²⁰

In present study, the sensitivity of Saline Infusion Sonosalpingography in diagnosing tubal patency is 95.34%, specificity 75%, positive predictive value 97.65% and negative predictive value 60%. The results of present study are comparable with other studies and is illustrated in Table 3.

Daniel et al compared the Sonosalpingogram with laparoscopic chromopertubation in the evaluation of tubal patency on 50 infertile women. In their study, the mean age of the patients was 27.92 years and the average

duration of infertility was 6.12 years comparable to present study. They reported the sensitivity of 93.3%, specificity of 44.4%, positive predictive value (PPV) of

94.38% and negative predictive value of 36.3% of saline infusion sonosalpingogram.⁴

Table 3: Review of literature on diagnostic accuracy of Saline Infusion Sonosalpingography in assessment of tubal patency in infertile women

	No of patients	Age of patients (years)	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Lakshmi et al	95	26.9±4.9	97%	94%	98.3%	75%
Daniel et al	50	27.92	93.3%	44.4%	94.38%	36.3%
Ranaweera et al	42	29.92	84.9%	81.8%	96.8%	45%
Dwivedi et al	60	25-35	72.91%	81.33%	-	-
Pujar et al	60	25-34	83.3%	82.9%	42.9%	97.5%
Hajishafiha et al	40	29.09	94%	100%	100%	75%
Subatra lall et al	100	22-30	97.3%	92%	-	-
Finland study	32	-	90.2%	83.3%	94.9%	71.4%
Present study	47	27	95.34%	75%	97.65%	60%

Lakshmi et al compared the diagnostic accuracy of HSG with SSG involving 95 patients with a mean age of 26.9 years. The sensitivity of sonosalpingography (SSG) in diagnosing tubal patency was 97% and the specificity 94%. Analysis of the raw data gave positive predictive value of 98.3% and negative predictive value of 75%. It is accepted that there is no statistically significant difference ($p = 0.237$) between the results of the two methods (HSG and SSG).¹⁴

In a study on 35 infertile women by Dasan et al, comparing sonohysterography and hysterosalpingography for evaluation of infertility, the sensitivity, specificity, positive predictive value and negative predictive value of Saline Infusion Sonosalpingography was 94.28%, 75%, 97.05% and 50% respectively. They concluded that SSG is more superior to conventional HSG and cost effective.¹⁵

Ranaweera et al in their study, performed vaginal sonographic hydrotubation with agitated saline on 42 patients with a mean age of 31.95 years. He observed a sensitivity of 84.9%, specificity of 81.8%, Positive Predictive Value of 96.8% and Negative Predictive Value of 45.0%. In their study, the pretest probability was 86% and the posttest probability was 96%. In their study, two patients complained of pain and were treated by analgesics.¹⁶

Dwivedi et al evaluated the diagnostic accuracy of sonosalpingography for assessing tubal pathology and reported 72.91% sensitivity, 81.33 % specificity with a diagnostic accuracy of 78.05% and concluded that sonosalpingography is very useful complementary diagnostic modality in assessment of tubal pathology.¹⁷ In a cross-sectional study conducted by Pujar et al for diagnosis of uterine cavity abnormalities and tubal

patency, a total of 60 patients underwent SSG followed by hysterolaparoscopy with chromopertubation. In evaluation of tubal patency when SSG was compared with laparoscopy with chromopertubation, SIS had a sensitivity of 83.3%, specificity of 82.9%.PPV of 42.9% and NPV of 97.5%. In this study IUI catheter was used for infusion. For evaluate of uterine cavity, when compared with hysteroscopy, SSG had a sensitivity of 97.8%, specificity of 88.8%, PPV of 97.8% and NPV of 88.8%. He also reported that for evaluation of tubal patency with waterfall sign, SIS has a sensitivity of 83.3%, specificity of 82.9%, Positive Predictive Value of 42.9% and Negative Predictive Value of 97.5%. He also reported that 73.3% of the patients were pain free during the procedure.¹⁸

In a study by Hajishafila et al 40 patients who had tubal obstruction on HSG were included for the study. The mean age of the study participants \pm SD was 29.09±4.87 years (range, 20-38 years) and the mean duration of infertility was 4.9 years (range, 2-12 years). The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of SHG in comparison with laparoscopy were 94%, 100%, 100%, and 75%, respectively. Regarding the adverse events, one of the patients had a vasovagal reaction from insertion of the catheter, and 1 patient had severe pain, was not able to tolerate the procedure, and quit the study (failure rate, 4.8%).¹³

In a study conducted at Finland, thirty-two patients suffering from primary or secondary infertility were evaluated for tubal patency with sonosalpingography using a paediatric Foley urinary catheter and a combination of air and saline solution as a contrast medium. Four patients conceived before their scheduled laparoscopy and were excluded from the study. The sensitivity of sonosalpingography in diagnosing tubal

patency was 90.2% and the specificity 83.3%. The positive predictive value for tubal patency by sonosalpingography was 94.9% and the negative predictive value 71.4%. Adverse events of sonosalpingography included moderate to severe abdominal pain in three patients, one vasovagal reaction, and one case of shoulder pain¹⁹. Seal Subatra Lall et al observed that SSG had 97.3 % and 92% in comparison to laparoscopy in assessing tubal patency.²⁰

In addition to assessment of tubal patency, SSG helps to identify any uterine cavitary lesions. The basic principle of SSG is to distend the uterine cavity with isotonic saline, which will delineate the contour, identify intrauterine pathology and thickness of endometrium. In our study we observed sub mucosal fibroid in one patient. SSG helped to differentiate a thickened endometrium from endometrial polyp in another patient. Pujar et al stated that SSG is more sensitive and specific in the evaluation of uterine cavitary lesion compared to evaluation of tubal patency.¹⁸ However, it is not much sensitive in the diagnosis of intra uterine adhesions.

The adverse effects of SSG experienced during our study was pain and pelvic discomfort. Similar adverse effects were observed in studies done by Inky et al, Hajishafiha et al, Pujar et al and Daniel et al.^{4,14,18,19,21} There was no serious adverse event like vasovagal attack in our study similar to Daniel S.⁴ However in few studies, vasovagal attack is reported.^{13,19}

CONCLUSION

Saline Infusion Sonosalpingogram is a simple, safe, convenient procedure for assessment of tubal patency in infertile women. It can be included in basic infertility work up so that Laparoscopy can be reserved for patients with tubal block, suspected pelvic pathology and unexplained infertility.

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