

Comparison of Saline Infusion Sonography with Hysterosalpingography for its Accuracy in Diagnosing Tubal Status in Subfertile Females

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ABSTRACT

Background: Subfertility is seen in approximately 10-15% of couples of reproductive ages. Tubal factors account for 25-35% of cases of subfertility. Commonly used tests for tubal patency are hysterosalpingography (HSG), laparoscopy and saline infusion sonohysterography (SIS). Saline infusion sonohysterography is a non-invasive test and used in many countries for checking tubal patency with promising results, but local data is not available. The objective of this study was to compare saline infusion sonohysterography (SIS) with hysterosalpingography (HSG) in terms of diagnostic accuracy in determining tubal patency in subfertile females in a charity hospital.

Patients and methods: A prospective cross-sectional study conducted in the Obstetrics and Gynaecology Department, Akhtar Saeed Trust Hospital Lahore from 15.10.2017 to 14.10.2019. Non-probability consecutive sampling was done and women presented between 18-40 years of age, for evaluation of primary and secondary subfertility and trying to conceive for more than one year were included. Patients with active pelvic infection, active vaginal bleeding or husband having azoospermia were excluded. After informed consent SIS and HSG were done on same day to see the patency of tubes and any complication with both procedures. The data was collected on predesigned Performa and SPSS version 23 was used for statistical analysis.

Results: Total 166 patients underwent SIS and HSG simultaneously. SIS showed tubal patency in 106 (63.86%) patients and out of these patients, 96 were true positive and 10 were false positive. HSG confirmed tubal patency in 103 (62.05%) cases, out of which 7 patients (false negative) had no patency on SIS. The sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of SIS with HSG in determining tubal patency of subfertile female was 93.20%, 84.13%, 90.57%, 88.33% and 89.76%, respectively. No patient had any serious complications with SIS.

Conclusion: This study concluded that saline infusion sonography is a safe and effective tool with high diagnostic accuracy for determining the tubal patency in subfertile females.

Keywords:

Tubal patency, Saline infusion sonography, Hysterosalpingography

INTRODUCTION

Subfertility implies the inability of a couple to conceive after one year or more of unprotected regular sexual intercourse.¹ It is seen in approximately 10-15% of couples of reproductive ages.² There is overall small but steady increase in fertility problems and more women consult medical help for this cause.³ Subfertility is divided into primary and secondary subfertility. Primary subfertility is when a pregnancy has never been achieved, for at least one year in a sexually active couple who are not using any contraception. Secondary

subfertility is when a couple fails to conceive after having achieved previous conception.⁴ There are multiple causes of female subfertility and thorough physical examination, hormonal profile and imaging are necessary for complete workup of patient. Subfertility can be caused by both male and female partners (30% each). Sometimes multiple factors of both partners contribute to the subfertility (15%). In the rest of 25% cases the cause is unknown.⁵

Tubal factor accounts for 25-35% of cases of subfertility.^{6,7} Therefore, the assessment of patency of fallopian tubes is a key investigation in the workup of a subfertile female. Commonly used tests for tubal patency are hysterosalpingography (HSG), laparoscopy and saline infusion sonohysterography (SIS).^{8,9} Laparoscopy is gold standard for tubal evaluation, but it is an expensive and invasive test requiring operation

Conflict of interest: The authors declared no conflict of interest exists.

Citation: Salahuddin N, Mumtaz A, Iftikhar S, Siddique U, Sheikh M, Waheed A. Comparison of saline infusion sonography with hysterosalpingography for its accuracy in diagnosing tubal status in subfertile females. J Fatima Jinnah Med Univ. 2024; 18(2):64-68.

DOI: <http://doi.org/10.37018/JFJMU/6468>

theatre and associated risk of surgical and anaesthetic complications. Hysterosalpingography is mostly used to assess the tubal patency and it also helps to diagnose the congenital anomalies of uterus and fibroids. It has the advantage that it gives a permanent record and shows the site of tubal blockage. However, some patients may be allergic to urograffin; the procedure is slightly more painful and gives radiological exposure to the patient.^{10,11} Hysterosalpingography is considered as first line test in the evaluation of subfertile females in the United States. Saline infusion sonohysterography is a safe and practical method for evaluating tubal patency and to study the uterine cavity with low risk of adverse effects and severe complications. It helps in detection of uterine pathologies like endometrial polyps, endometrial hyperplasia and submucosal fibroids.^{12,13} Hysterosalpingo-contrast sonography (HyCoSy) is done along with transvaginal scan by many Europeans investigators (one stop shop) for investigating female tract and tubal patency at the same time.¹⁴⁻¹⁶ International data showed sensitivity of hysterosalpingo-contrast sonography for determination of tubal patency 76%-96% and the specificity is 67%-100%.¹ Such data is scarcely available in local studies. The objective of this study was to determine the diagnostic accuracy of saline infusion sonography in determining tubal patency in subfertile females with hysterosalpingography in a charity hospital.

Subfertility was defined as the failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse. The included females must have their husband's semen analysis report. Primary subfertility will be considered if the patient had never conceived before and secondary subfertility if she had conceived before irrespective of the outcome of pregnancy or pregnancies.

Tubal patency on HSG was defined as initial radiograph delineated the uterine cavity and fallopian tubes filled with contrast and free peritoneal spillage seen on subsequent radiograph. Tubal patency on SIS was defined as flow of fluid and air turbulence in the region of right and left ovarian fossae and this turbulence or waterfall sign was taken as patency of respective fallopian tube, later cul de sac was visualized to look for free fluid.

True Positive (TP) was labeled if tubal patency was found on SIS and on HSG as well. False positive (FP) was labeled if tubal patency was found on SIS but not diagnosed on HSG. False negative (FN) was labeled if tubal patency was not found on SIS but found on HSG. True negative (TN) was said if tubal patency was not

found on SIS and not on HSG.

PATIENTS AND METHODS

The study was carried out in the Department of Obstetrics and Gynecology, Akhtar Saeed Trust Hospital Lahore, from 15th October 2017 to 14th October 2019, and approval was taken from the hospital's ethical committee. The study was prospective cross-sectional, and patients were enrolled by non-probability, consecutive sampling. Sample size of 166 females was estimated using prevalence of tubal factors in female infertility as 35% and 95% confidence level. Inclusion criteria was women between the ages of 18 - 40 years, who presented for evaluation of primary and secondary subfertility and trying to conceive for more than one year. Patients with pelvic infection, vaginal bleeding, carcinoma of the genital tract and if her husband having azoospermia were excluded from the study. The cases were enrolled after taking informed consent of all females meeting inclusion criteria and explaining them about the nature of tests. Detailed history including demographic data including age, duration of marriage, type and duration of subfertility, body mass index and thorough examination was done. These females underwent HSG and SIS procedures in collaboration of radiology department to check the tubal patency.

Both procedures were performed between 8th to 12th day of the menstrual cycle or at least 48 hours after cessation of menses under aseptic measures on the same day. Foley's catheter (10fr) balloon was inflated within the uterine cavity and the inflated bulb was pulled above the internal os to prevent leakage. Then, while doing transvaginal ultrasound a slow injection of 20-50 ml saline injected into the uterine cavity. The flow of saline and bubbles through the uterine cavity and along the tubes was visualized as turbulence or waterfall sign. The presence of free fluid in the pouch of Douglas was seen if one or both tubes were patent and if both tubes were blocked then the uterine cavity expanded in size and no fluid was observed in cul de sac. After that the patient was shifted to X-ray room and approximately 10-15 ml of a water-soluble contrast was injected. Fluoroscopic examination was performed during the injection to check the tubal patency and x ray films were taken. There was free spill of dye if tubes were patent and no fill/spill of dye in blocked tubes. The results of SIS and HSG were evaluated. The patients were kept for 1-2 hours post-procedure in the hospital and any complication like pain, excessive bleeding, allergic/anaphylactic reaction or others were noted.

Table 1: Demographic profile including age, BMI, duration and type of subfertility (N=166)

Characteristics	No. of Patients	Percentage
Age (years)		
18-30	101	60.84
31-40	65	39.16
Total	166	100.0
BMI (kg/m²)		
≤25	68	40.96
>25	96	59.03
Duration (years)		
≤3 years	54	32.53
>3 years	112	67.47
Type of subfertility		
Primary	109	65.66
Secondary	57	34.34

Table 2: Diagnostic accuracy of saline infusion sonography to determine tubal patency in subfertile female with hysterosalpingography

Hysteroscopy	Patent tubes on HSG	Blocked tubes on HSG	p-value
Patent tubes on SIS	96 (TP)*	10 (FP)***	0.0001
Blocked tubes on SIS	07 (FN)**	53 (TN)****	
Sensitivity: 93.20%, Specificity: 84.13%, Positive Predictive Value: 90.57%, Negative Predictive Value: 88.33%, Diagnostic Accuracy: 89.76%			

Abbreviations: TP = True Positive, FP = False Positive, FN = False Negative, TN = True Negative, SIS = saline infusion sonohysterography, HSG = hysterosalpingography.

Prophylactic antibiotics and analgesics were prescribed to all patients. All the patient's data and results of SIS and HSG tests were entered on predesigned Performa. All the data was collected, and SPSS version 23 was used for analysis with the help of descriptive statistics. Mean \pm SD were used for quantitative data like age of female, duration of marriage, weight, height, and BMI. Frequency and percentages were used for categorical data like diagnosis of tubal patency of SIS and HSG. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and diagnostic accuracy were calculated with SIS in comparison to HSG. To address effect modifiers, data was stratified for age, duration of marriage, duration of subfertility and type of subfertility. Post-stratification Chi-square test was applied, taking p-value <0.05 as significant.

RESULTS

A total of 166 patients were enrolled. Mean age was 28.61 ± 3.85 years (range, 18-40 years). Most of the patients, 101 (60.84%) were between 18 to 30 years. Mean BMI was 27.62 ± 4.96 . The mean duration of

subfertility was 4.90 ± 2.75 years. Distribution of patients according to type of subfertility is shown in Table 1. Saline infusion sonohysterography (SIS) showed tubal patency in 106 (63.86%) patients. Out of 106 SIS-positive patients, 96 (true positive) had tubal patency and 10 (false positive) had no tubal patency on HSG. Among 60 SIS-negative patients, 07 (false negative) had tubal patency on HSG whereas 53 (true negative) had no tubal patency on HSG as shown in Table 2. HSG confirmed tubal patency in 103 (62.05%) cases, out of which 7 patients (false negative) had no patency on SIS. Among 63 patents that showed blocked tubes on HSG, 53 were true negative whereas 10 patients showed patency on SIS. The sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of saline infusion sonography with hysterosalpingography in determining tubal patency of subfertile female was 93.20%, 84.13%, 90.57%, 88.33% and 89.76% respectively. A total of 15 patients (9%) complained of mild lower abdominal pain during HSG, which was treated with analgesics, and one patient (0.6%) had a vasovagal reaction during HSG. No serious complication like allergic/anaphylactic reaction was seen in the study patients with SIS.

DISCUSSION

Testing for tubal patency is an integral component in the assessment of subfertile couples and was routinely performed by hysterosalpingography (HSG) or diagnostic laparoscopy.^{6,8,9} Initially, saline infusion sonohysterography (SIS) was used for assessment of the uterine pathology but now it is also used to check the patency of fallopian tubes, as it is a simple and safe technique with minimum risk of adverse effects and complications¹⁷⁻¹⁹ In this study mean age was 28.61 ± 3.85 years and majority were between 18 to 30 years of age. In a study conducted in India, mean age was reported 31.95 ± 3.8 years.²⁰ In another study, 80% of females were between 23 to 32 years of age.²¹ This is comparable with results of this study showing that females seek fertility advice early because of family and social pressures in our societies. Majority of patients had BMI of >25 indicating that subfertility is more common in overweight patients. A total of 66% of patients had primary and 34% secondary subfertility, whereas previous authors reported primary subfertility in 90% & 73% and secondary subfertility in 10% and 27% of females in their study, respectively.^{20,21} This observation may be because studied population here is more keen to conceive even if they have kids previously.

In this study saline infusion sonohysterography (SIS) showed the tubal patency in 106 (63.86%) patients. HSG confirmed tubal patency in 103 (62.05%) cases and out of 106 SIS positive patients, 96 showed patent tubes and 10 had no tubal patency on HSG. The sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of saline infusion sonography to determine tubal patency in subfertile female with hysterosalpingography was 93.20%, 84.13%, 90.57%, 88.33% and 89.76% respectively. A recent study also reported that the sensitivity, specificity, positive predictive value, and negative predictive value of SIS for detection of tubal patency was 95%, 100%, 100%, and 75%, respectively, taking conventional hysterosalpingography as control.¹⁹ These results are comparable with our findings as we share the same cultural practices, being living in unprivileged countries of Asia. The results of this study are comparable with other studies conducted in India. In a study by Vanita et al., comparing HSG with SIS in 95 patients, the sensitivity of sonosalpingography (SIS) was 97%, and the specificity was 94% in diagnosing tubal patency, the positive predictive value of 98.3%, and the negative predictive value was 75%.²¹ The authors also concluded that there was no statistically significant difference between the results of the two methods (HSG and SIS) Ranaweera and coresearchers conducted a study in 42 patients and observed sensitivity of 84.9%, specificity of 81.8%, positive predictive value of 96.8% and negative predictive value of 45.0%.²⁰ These results are comparable with finding of the current study, except low negative predictive value (45.0%). In another study, authors concluded that diagnostic accuracy (sensitivity and specificity) of SIS was found to be higher than HSG for detection of both tubal patency and uterine abnormalities.²² A recent study is carried out in India with 117 women having subfertility, using lignocaine and saline with 2D/3D HyCoSy and compared it with HSG. Their results showed the sensitivity, specificity and overall accuracy of 91.86%, 89.18% and 90.59% respectively which is comparable with current study.²³ These similarities are most likely as both countries share similar geographical and racial characteristics. In the study, 9% females experienced mild pain with HSG, which was relieved by analgesics and only a few patients complained of minimal discomfort with SIS. One patient (0.6%) had vasovagal reaction during HSG and no other serious complication like allergic/ anaphylactic reaction was seen. Similar results were seen in other studies.^{19,23} This might be because contrast used in HSG was more

irritant when uterine cavity distends as compared to saline especially in blocked tubes. Results of current study are promising and comparable to these studies highlighting the high diagnostic accuracy of SIS with less side effects

CONCLUSION

Saline infusion sonography is a safe and effective tool with high diagnostic accuracy in determining the tubal patency in subfertile females. This simple, noninvasive, cost-effective technique may be recommended as initial step for evaluation of tubal pathology in female subfertility in resource-limited countries.

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