



Role of Saline Infusion Sonohysterography (SIS) In Infertility Evaluation

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Abstract

Introduction : Etiology of Infertility is multifactorial and fallopian tube abnormalities being one of the most important cause accounts for up to 40% of female sub fertility if not less and is further increasing. Saline infusion sonohysterography (SIS) procedure is gaining popularity and is being widely practiced and accepted as a screening tool in assessing tubal patency in infertile patients attending infertility clinic and has become popular as a routine test for the evaluation of the uterine cavity in the investigation of infertility and abnormal uterine bleeding.

Objective: To compare the results of SIS with that of Hysterosalpingography (HSG) in infertility evaluation and to observe the role of SIS to find out endometrial pathology and tubal patency in infertility patients.

Study Methodology: Retrospective Observational study was done on the basis of record maintained in Ultrasound register and case record sheet of all infertile women who underwent infertility treatment and fulfilled the inclusion criteria from June 2015 to August 2016.

Results: SIS had sensitivity of 91 % specificity 76% PPV 95% NPV 66% and accuracy of 89% of SIS in evaluating tubal patency. Also SIS showed sensitivity of 83.3 % specificity 60% PPV 75% NPV 75% and accuracy of 72% in detecting pelvic pathology.

Conclusion:. In a low resource country like India where patients are also less educated SIS can prove to be a useful tool in initial workup of infertility patients with better compliance, less cost and better results in a single visit.

Keywords: Saline infusion sonography, tubal patency, hysterosalpingography, intrauterine pathology

Introduction

Problem of infertility (sub fertility) is increasing day by day in a country like India. According to the reports of World Health Organization¹ around 10 % of women are facing problems of infertility globally . Etiology of Infertility is multifactorial and fallopian tube abnormalities being one of the most important cause accounts for up to 40% of female sub fertility if not less and is further increasing.²⁻³ Hence screening for tubal occlusion is one of the first important steps in fertility

assessment of the investigation of sub fertile couples. Till date hysterosalpingography (HSG) is the preferred choice of investigation followed by laparoscopy with chromotubation.⁴ Hysterosalpingography (HSG) is a contrast enhanced fluoroscopic radiological study which has been a standard test in the workup of infertile females. It not only gives information about tubal patency and contour but also helps to assess the uterine cavity giving information for its size, shape, contour, filling defect suggestive of polyp, septa, adhesions, fibroids etc. It has its own drawbacks and limitations like Iodinated contrast and X-rays are used and is painful & uncomfortable for patients. Laparoscopy with chromopertubation is largely accepted as the gold standard for diagnosing tubal occlusion but is usually preferred for the assessment or treatment of other associated pelvic pathology. It is an invasive procedure also needing anaesthesia thus adding to the cost and side effects.

Saline infusion sonohysterography (SIS) also known as Sono Hysterography (SHG) or hysterosonography (HSN) procedure is gaining popularity and is being widely practiced and accepted as a screening tool in assessing tubal patency in infertile patients attending infertility clinic⁵ and has become popular as a routine test for the evaluation of the uterine cavity in the investigation of infertility and abnormal uterine bleeding.⁶⁻¹⁰ SIS can be done with B mode US and Doppler. SIS refers to a procedure in which fluid is instilled into the uterine cavity transcervically through a catheter to provide enhanced endometrial visualization during transvaginal ultrasound examination¹¹⁻¹². There are many studies which suggests application of SIS also in evaluating uterine defects in patients with recurrent pregnancy loss as well as in those undergoing In Vitro Fertilization. SIS can demonstrate a patent tube but if blocked, the site of block is difficult to illicit. SIS aids in improved sonographic detection of endometrial pathology, such as polyps, hyperplasia,

leiomyomas and sometimes adhesions. In addition, it can help in avoiding invasive diagnostic procedures in some patients as well can optimize the preoperative evaluation process for those women who require therapeutic intervention. It is a well-tolerated technique could be easily and rapidly performed at minimal cost and is virtually has lower risk of adverse effects and severe complications. The American College of Obstetricians and Gynaecologists (ACOG) in conjunction with the American College of Radiology and the American Institute of Ultrasound in Medicine developed a technology assessment document for saline infusion sonohysterography.¹³⁻¹⁴ The current study was done to observe the role of SIS to find out endometrial pathology and tubal patency in infertility patients and to compare the results of SIS with that of Hysterosalpingography (HSG) in infertility evaluation.

Primary objective: To compare the results of SIS with that of Hysterosalpingography (HSG) in infertility evaluation

Secondary objective: To observe the role of SIS to find out endometrial pathology and tubal patency in infertility patients.

Study Methodology: Retrospective Observational study was done on the basis of record maintained in Ultrasound register and case record sheet of all infertile women who underwent infertility treatment and fulfilled the inclusion criteria from June 2015 to August 2016 at Gynecology OPD, AIIMS, Raipur. After revising the test validity parameters of HSG in comparison to SIS from the literature at alpha = 0.05 and a study power of 80% a total sample size of minimum 90 participants was calculated after adding a percentage of 10% for possible drop out cases during the study. Initial workup of detailed clinical history to identify possible predisposing factors leading to infertility and the duration of symptoms were obtained from all the patients. According to standard treatment

protocol all patients would have underwent detailed general examination as well as pelvic examination. Routine Laboratory investigations like screening patients for anemia and blood grouping Rh typing, FBS, 75gm 2hr GTT, RPR, Husband's semen analysis, serum TSH, Prolactin, Human immunodeficiency virus (HIV) test (on opt out basis) would have been already done before undergoing SIS. SIS would have been done on the 7th or 8th day of menstrual cycle. They would have been first subjected to baseline transvaginal sonography and then sonosalpingography. Their outcome of diagnosing tubal patency was subsequently analyzed to compare the results of SIS with Hysterosalpingography done by an independent observer in the evaluation of uterine cavity and tubal patency. The primary outcome of the study was to test parameters of Saline infusion sonography (SIS) and Hysterosalpingography (HSG) in terms of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV).

Procedure for saline infusion sonohysterography:

Procedures were done after obtaining a valid informed consent. Premedication with ibuprofen 500 or hyoscine 10 mg was given half an hour before the procedure. Emergency cart will be kept ready for any vasovagal attack. A bimanual examination was performed, after putting Cusco's self retaining speculum antiseptic cleaning of cervix and vagina and a Foleys catheter of size-8 was introduced into the external os with the help of artery forceps, which was kept intracervically. In patulous os it was kept above internal os. 2 to 3 ml of normal saline pushed to inflate the bulb. Around 20 ml normal saline kept ready with a 20 ml syringe. After removing stellate of catheter, normal saline was slowly pushed into catheter. Maximum 50 ml of normal saline could be instilled. Once adequate distension of uterine cavity achieved a sagittal sweep from cornua to cornua followed by an axial sweep from fundus to external cervical os was performed with a

transvaginal probe. The cavity will be evaluated for presence of any abnormality. Subsequently each tube was visualized separately for the presence of fimbrial turbulence (water fall sign) which was taken as a sign of tubal patency. Presence of fluid in pouch of Douglas after SIS was also taken as a sign of tubal patency.

Parameters studied:

- Endometrial thickness
- Length of endometrial cavity
- Contour of endometrial cavity
- Any detectible mass with its dimension
- Filling defect inside cavity
- Myometrial thickness
- Dimension of uterus
- Any congenital anomaly of uterus noticed coincidentally
- Tubal passage of fluid and air bubble (indicator of tubal patency)
- Fluid collection in pouch of Douglas

Inclusion criteria

- All cases of primary infertility
- All cases of secondary infertility
- Previous history of recurrent spontaneous abortion

Exclusion criteria

- Suspected case of genital tuberculosis
- Pelvic infection
- Active vaginal bleeding
- Suspected pregnancy
- Genital malignancy

Type of study: Retrospective observational study

Department where the study was conducted:

Department of Obstetrics and Gynecology, AIIMS Raipur.

Results:

Table 1: Demographic Characteristic

| Type of Infertility | | |
|---------------------|-----------|------|
| | Frequency | % |
| PRIMARY | 58 | 73.4 |
| SECONDARY | 21 | 26.6 |

| Age Distribution Of Participants | | |
|----------------------------------|-----------|-------|
| | Frequency | % |
| 18-22 | 06 | 07.5 |
| 23-27 | 34 | 43.03 |
| 28-32 | 32 | 40.05 |
| 33-37 | 07 | 08.86 |

Table 1 highlight the demographic characteristics of patients and hence we observe that there were more cases of primary infertility (73.4 %) than secondary infertility (26.6%). Approximately 84% of the patients fall between age group 23-32 years.

Table 2: Pelvic Organs Abnormalities

| Pathology | HSG (n =79) | | SIS (n=79) | |
|-------------------------|-------------|-------------|------------|-------------|
| | Frequency | Percentage% | Frequency | Percentage% |
| Normal Pelvic Organs | 74 | 93.6 | 65 | 82.2 |
| Endometrial Hyperplasia | 00 | 00 | 01 | 1.27 |
| Sumucous Fibroid | 00 | 00 | 01 | 1.27 |
| Endometrial Polyp | 00 | 00 | 03 | 3.79 |
| Ovarian Cyst/To Mass | 00 | 00 | 05 | 6.32 |
| Hydrosalpinx | 01 | 1.27 | 01 | 1.27 |
| Synaechiae | 01 | 1.27 | 01 | 1.27 |
| Congenital | 03 | 3.79 | 02 | 2.53 |

Table 2 shows that SIS was superior to HSG in picking up pelvic organ pathology and definitely had an added advantage of detecting adnexal pathology which HSG lacked.

Table 3:

| Pathology | Lap/Hys (N=20) | | Hsg(N=20) | | Sis(N=20) | |
|-------------------------|----------------|----|-----------|----|-----------|----|
| | Freq | % | Freq | % | Freq | % |
| Endometrial Hyperplasia | 01 | 05 | 00 | 00 | 01 | 05 |
| Sumucous Fibroid | 01 | 05 | 00 | 00 | 01 | 05 |
| Endometrial Polyp | 02 | 10 | 00 | 00 | 03 | 15 |
| Ovarian Cyst/To Mass | 03 | 15 | 00 | 00 | 05 | 25 |
| Hydrosalpinx | 03 | 15 | 01 | 05 | 01 | 05 |
| Synaechiae | 01 | 05 | 01 | 05 | 01 | 05 |
| Congenital | 01 | 05 | 03 | 15 | 02 | 10 |

All the patients who showed pathology or any abnormality were subjected for diagnostic hysterolaproscopy. Hence from table 3 it is evident that SIS is superior to HSG in picking up pelvic organ pathology which was confirmed by diagnostic hysterolaproscopy.

Table 4: Tubal Patency on SIS V/S HSG

| SIS n=79 | | HSG | | |
|-------------------|----|-----|-----|-----|
| | | B/P | B/B | U/B |
| Bilateral Patency | 59 | 56 | 02 | 01 |
| Bilateral Block | 15 | 10 | 03 | 02 |
| Unilateral block | 4 | 00 | 01 | 03 |
| Inconclusive | 1 | 01 | 00 | 00 |

Table 4 shows that SIS detected 15 tubes with bilateral block out of which HSG showed only 10 tubes with bilateral occlusion and laparoscopy agreed to only 8 occluded tubes. So concordance is 53.3% in SIS and 66.7 percent in HSG.

Table: 5

| method | sensitivity% | specificity% | ppv% | npv% | accuracy% |
|------------------------------|--------------|--------------|------|------|-----------|
| sis(tubal patency) | 91.0 | 76.0 | 95.0 | 66.0 | 89.0 |
| sis (pelvic organ pathology) | 83.3 | 60.0 | 71.4 | 75.0 | 72.0 |
| hsg (pelvic organ pathology) | 30.0 | 80.0 | 60.0 | 53.3 | 55.0 |

Table 5 summarizes the findings of the current study showing sensitivity of 91 % specificity 76% PPV 95% NPV 66% and accuracy of 89% of SIS in evaluating tubal patency . Also SIS showed sensitivity of 83.3 % specificity 60% PPV 75% NPV 75% and accuracy of 72% in detecting pelvic pathology.

Discussion

Infertility rate is constantly growing in developing countries like India. India being a low resource country, patients cannot always afford multiple visits and we need to set a management protocol in which maximum abnormalities and pathologies could be detected in a single visit. Baseline sonography is needed to be done in all infertile patients to look for antral follicular count,

ovaries, pathology in uterus, adnexa, uterine cavity and also check for tubal patency. Saline infusion sonography is the single most investigation which when done on day 8-9 can reveal maximum information in an average time span of 10-15 minutes. Baseline transvaginal sonography would detect any uterine pathology like fibroid, ovarian mass, polyp and also give idea of growing follicle and its size, any fluid in pouch of Douglas etc. In a the meta-analyses by Seshadri et al¹⁵ SIS was declared as having a high degree of diagnostic accuracy in the detection of all types of intrauterine abnormalities with a sensitivity and specificity of 88 and 94%, respectively. SIS is quite efficient in analyzing various endometrial pathologies like endometrial polyps, submucous myomas, intrauterine adhesions, septas, and many other congenital uterine anomalies. So any patient suspected of having an endometrial pathology on conventional transvaginal scan, SIS must be done before taking them for hysteroscopy especially as there are few studies depicting comparable accuracy in detecting these pathologies. With advancement in ultrasound imaging, SIS and hysterosalpingo-contrast sonography (HyCoSy) are replacing HSG for evaluation of the uterine cavity and fallopian tubal patency in many centers worldwide.¹⁵⁻¹⁶

Our study compared the performance of SIS in diagnosing tubal patency in comparison to HSG keeping HSG as the gold standard. Also all those patients in whom tubal block was suspected or any pelvic pathology detected underwent diagnostic hysteroscopy with laparoscopy along with chromopertubation. The test performance parameters of SIS in terms of accuracy in detecting tubal patency were comparable to HSG being approximately 90%. SIS was much superior to HSG in detecting pelvic pathology in terms of sensitivity, specificity, PPV, NPV & accuracy. In our study, SIS detected 15 tubes with bilateral block out of which HSG showed only 10 tubes with bilateral occlusion and laparoscopy agreed to only 8 occluded tubes. So

concordance is 53.3% in SIS and 66.7 percent in HSG. These results are inferior to previous studies, which have yielded concordance values between 83 and 86% .¹⁷⁻¹⁹

The test results of our study showed sensitivity of 91 % specificity 76% PPV 95% NPV 66% and accuracy of 89% of SIS in evaluating tubal patency. Also SIS showed sensitivity of 83.3 % specificity 60% PPV 75% NPV 75% and accuracy of 72% in detecting pelvic pathology. Similar study by Pujar et al.²⁰ showed slightly better results of SIS in assessing tubal patency and detecting pelvic pathology. We could see that SIS was very accurate in detecting tubal patency both by seeing turbulence of fluid flowing in the tubes and also by collection of fluid in pouch of Douglas but we had difficulty in detecting side specific tubal patency as probably the turbulence was altered in the tubes with block . It was obvious from our study that SIS had more sensitivity but less specificity than hysteroscopy or HSG in the diagnosis of uterine cavity pathology. Hysteroscopy definitely gives most accurate results in the diagnosis of endometrial pathology when compared with SIS but sis can very well be incorporated as a screening tool of all infertile patients with more advantages than disadvantages . According to one study HSSG cannot be considered a reliable and accurate method for the diagnosis of tubal patency.²¹

There is a study which also comply with our results and says that SIS is a highly sensitive and specific investigative modality and comparable to the gold standard tool hysteroscopy in the diagnosis of intrauterine pathology and can be utilized as screening tool for sub fertile patients before taking them for IVF treatment.²²

Another study declared that routine SIS was only beneficial in patients with any suspicious findings on TVS (including extracavitary lesions) than in those with normal TVS.²³

Conclusion

Saline infusion sonography is becoming a popular diagnostic tool for evaluation of tubal patency and uterine pathology (both intracavitary & extracavitary) in patients with infertility. In a low resource country like India where patients are also less educated SIS can prove to be a useful tool in initial workup of infertility patients with better compliance, less cost and better results in a single visit. SIS should be the investigation of choice and hysterosalpingography and laparoscopic chromopertubation should only be reserved for those patients with doubtful diagnosis in saline infusion sonography or with long duration unexplained infertility.

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To women agreed to participate in this study.

Conflict of interest

No conflict of interest related to this study.

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Ethical Issues Nil:

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List of Figure

