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Original Article

Study of Saline Infusion Sonography and Hysterosalpingography to See the Tubal Patency in Infertile Women

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Mst Jesmin Akter[1], Sultana Afroj[2]

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ABSTRACT

Background: *Infertility is a global issue in reproductive health. Etiology Of infertility is multifactorial and fallopian tube abnormality being one of the most important causes accounts for up to 40%of female infertility. saline infusion sonography (SIS) is gaining popularity and being widely practiced and accepted as a screening tool in assessing tubal patency.* ***Objectives:*** *To compare the efficacy of tubal patency test with saline infusion sonography and hysterosalpingography in infertile women.* ***Methods and material****: It is a quasi-experimental study .120 consecutive infertile women in 25-40 years, who are ovulating spontaneously or by ovulation induction who was needed tubal assessment included here. 60 patients went for saline infusion sonography, 60 went for hysterosalphingography which was allocated by lottery.* ***Result****: Main outcome was find out the diagnostic accuracy of saline infusion sonography over conventional hysterosalpingography for evaluation of tubal patency. tubal patency confirmed by SIS 54(89.99%) had at least one tube patent. Tubal block 6(10.01%). HSG bilateral tubal patency 40(66.67%), bilateral tubal block 15(25.00%), unilateral block 5(8.33%) .SIS had sensitivity 86% specificity 97%,positive predictive value 97% and negative predictive value 83% in tubal patency.* ***Conclusion:*** *SIS employed as a screening procedure to pick up subjects needing HSG and laparoscopy Low risk subjects for tubal factors in infertility, sonohysterosulphingography can be. It is simple, relatively less expensive, minimally invasive procedure.*

Keywords: *saline infusion sonography (SIS), hysterosalpingography (HSG), tubal patency.*

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1. *Assistant Professor Gynaecology &Obstetrics department, Dhaka Medical College, Dhaka, Bangladesh*
2. *Associate Professor Sultana Afroj, Gynaecology &Obstetrics department, Dhaka Medical College, Bangladesh*

INTRODUCTION

Infertility is defined as the failure to conceive after one year of regular unprotected intercourse [1]. There are many potential causes of infertility in females, among them, tubal factors are increasingly being identified. It is about 30-35% of all infertility cases. It is often recommended that women over 35 years of age are evaluated after 6 months of failure to conceive and women >40 years are evaluated immediately [2]. ESHRE 2008 guidelines recommend that semen analysis and ovulation assessment before a test of tubal patency is performed.

Subfertility (infertility) is a growing problem in countries like Bangladesh. According to WHO data, an estimated 1 in 6 people worldwide have infertility issues[3]. Although there are many potential reasons for infertility like male factors, and female factors including endocrine, anatomic, and genetic problems with the fallopian tubes are one of the major contributors, accounting for as much as 40% of female subfertility and perhaps much more. Therefore, assessment of the tubal patency of sub-fertile women is very important. It can be assessed by Hysterosalpingography (HSG), saline infusion sonography, or hysteroscopy with laparoscopic chromotubation. HSG is the easy and available and common diagnostic method for the evaluation of tubal patency. It is highly sensitivity 60-98% but low specificity 15-80% detecting the uterine and adnexal abnormality [4]. It is a contrast-enhanced fluoroscopic radiological scan. It aids in the evaluation of the uterine cavity by providing data on its size, shape, contour, filling defect, and tubal patency ,& uterine developmental anomalies. The use of iodinated contrast and X-rays, and other things may be unpleasant and uncomfortable for individuals[5]. Laparoscopy with chromopertubation is the method of choice for assessing or the gold standard for diagnosing tubal occlusion [6].

Saline infusion sonography (SIS), also known as sonohysterography or Hyster sonography procedure. It is gaining popularity and is being widely practiced and accepted as a screening tool in assessing tubal patency in infertile patients attending infertility hospitals [7], because of its ease of use, lack of invasiveness, and lack of potential for serious consequences. several preliminary studies have shown that patient satisfaction and tolerability with SIS was more than that of HSG [8].

It has become popular as a routine test for the evaluation of the uterine cavity in the investigation of infertility and abnormal uterine bleeding [8]. SIS has been shown to have higher positive predictive value (PPV) and negative predictive value (NPV). Identification of uterine and adnexal pathology demonstrated that this method is between 70 to 100% sensitive and 60 to 100% specific [7].

Tubal factor evaluation is necessary before going to treatment of infertility by SIS or HSG. Discuss the procedure with the patient before doing HSG or SIS. Antibiotics and oral analgesics are routinely used before HSG but analgesic is needed if the patient is required in SIS. It should not have a pelvic infection or uterine bleeding at the time of the procedure [1].

The American college of obstetricians and Gynecologists in conjuction with the

American college of radiology and the American institute of ultrasound in medicine have developed a technology assessment document for saline infusion sonography [5].

The current study was done to observe the role of SIS to find out the tubal patency and endometrial pathology, and acceptability in infertility patients to compare the result of SIS with that of HSG in infertile women.

Rationale of the Study

The assessment of tubal patency is an important part of evaluation of infertile women. Commonly used procedures are HSG, and SIS and laparoscopy with chromotubation. All fertile patients require a baseline ultrasound to assess ovaries, adnexal or uterine diseases such as fibroid, polyp, ovarian tumor, and tubal patency. SIS has many advantages like a relatively short procedure that provides an view of endometrial abnormalities along with tubal patency. patients may not be able to afford many visits as a result, a care strategy must be established that allows for the detection of the abnormalities in a single visit. It is a widely available, easy-to-use, safe, not used radiation but gives us information of soft tissue abnormalities of infertile women. This study also evaluated the level of patient satisfaction with SIS vs HSG which showed more satisfaction for the former group.

Although conventional HSG is used for many years in Bangladesh, SIS has been done in the recent few years. There is limited research regarding the use of SIS for tubal patency in our country. So, this study would help as a screening test in the future in our country.

METHODS AND MATERIALS

It was a Quasi-experimental study, which was carried out at the Reproductive Endocrinology and Infertility Unit, Department of Obstetrics and Gynecology, Dhaka Medical College.it was done from November 2021to October 2022. 120 consecutive infertile patients in the reproductive age group were enrolled for this study who fulfilled the inclusion criteria, The criteria was 25-40 years old infertile ovulatory lady who ovulate spontaneously or by ovulation by induction and needed tubal assessment. Husband semen parameter normal or sperm count more than 10 million / ml.Here 60 patients went for SIS and 60 patients went for HSG. Patient allocation was done by randomized in both natural and induced cycles by lottery. After a full history was taken, all women underwent a complete physical and pelvic examination to exclude pregnancy, vaginal cervical or pelvic infection, or vaginal bleeding. Before the procedure, ovulation was checked for all patients by day 21 progesterone. Semen analysis was done before SIS & HSG. Azoospermia was excluded from the study. A routine laboratory investigation was done. Test parameters, safety, and acceptability of both methods were assessed. The study result was presented as a percentage and by statistical analysis was done by SPSS 26 . using the P value <.05 is significant. Ethical consideration was done by ethical committee in Dhaka medical college hospital

Operational Definition and Procedure:

Saline infusion Sonography (SIS)

Saline infusion sonography (SIS or SHG) is a procedure to evaluate the uterus and the uterine cavity and the tubal patency. In

SIS transvaginal ultrasound (TVS) and the sterile normal saline are needed for evaluation.

The procedure was performed between days 7 to day 10 of the menstrual cycle at least 48 hours after menses had ceased. The women were advised to avoid unprotected intercourse during this period. After the evacuation of the bladder, the patient was kept in the lithotomy position, and a vaginal speculum was inserted. The balloon catheter was inflated within the endocervical canal or lower uterine cavity. Approximately 5-15 ml of normal saline was injected manually through the cannula. Now observe The filling of the uterine cavity and the flow of fluid through the tube. These are monitored by transvaginal ultrasound. Tubal patency can be observed by the appearance of fluid in the Cul de sac. Before the installation of fluid, we see the uterine and adnexal pathology through TVS. Prior to the procedure antibiotics but analgesics given it was needed.

Hysterosalpingography (HSG)

Hysterosalpingography (HSG) was done in the radiology department. The using machine RM = 10000 MA CR machine SEMENS. It is a radiologic procedure to investigate the shape of the uterine cavity and the patency of the fallopian tubes. It is a special x-ray using dye to look at the womb (uterus) and Fallopian tubes. A radio-opaque dye was injected into the cervical canal and usually fluoroscopy with image intensification. Four X-ray films were taken, images of early and maximal opacification of the uterine cavity, fallopian tubes & peritoneal contrast spillage were obtained.

The patients were routinely premedicated with oral analgesics & antibiotics prior to the procedure. The result of HSG was evaluated by a radiologist.

Tubal Patency

Radio-opaque dye and or fluid freely spilled through both tubes which indicates bilateral tubal patency. If spilled through one tube it indicates unilateral tubal patency. No spilled of dye or fluid indicates bilateral tubal block. In SIS when fluid found in culde sac indicates at least one tube patent.

Pain score

Pain score was done by a pain rating scale 1-10 [9]. this score was done by asking questions and observing.1-3 score described pain that is uncomfortable or minor pain. It is distressing but not severe. 4-6 score is considered moderate pain which is constantly increasing but still patient can tolerate. 7-9 is severe pain which is an intense pain leading to crying.10 score is usually uncommon and extremely overwhelming.

RESULT

This quasi-experimental study was carried out among infertility patients in the reproductive age group who attended Reproductive Endocrinology and Infertility unit and IVF Centre, Dhaka Medical College for 12 months including a total 120 women where 60 patients underwent saline infusion sonography (SIS) group whereas another 60 patients underwent hysterosalpingography (HSG). Allocation was done by lottery. Maximum patients (about 55% in SIS and 58% in HSG) were within 31-36 years of age (**Table I**).

Table I: Age distribution of 120 cases of infertile female patients (N=120)

Age (in years)	SIS, N=60 No. (%)	HSG N = 60 No. (%)
25-30	10(16.67%)	8 (13.33%)
31-36	33 (55%)	35 (58%)
37-40	17 (28.33%)	17 (28.34%)
Total	60 (100%)	60 (100%)

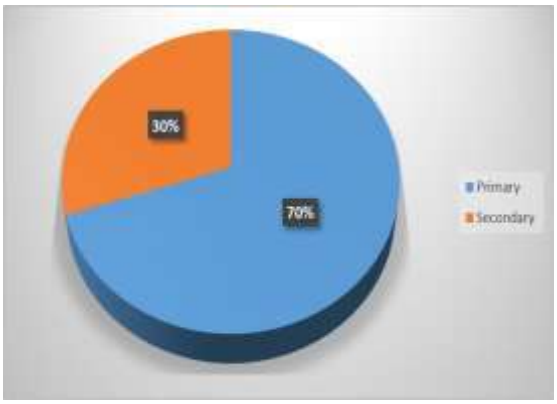

Figure-1 shows fertility distribution of patients where 84(70%) had primary infertility and 36(30%) had secondary infertility.

Figure 1: Infertility status

Duration of infertility was >7 years in 46.67% of patient in both SIS and HSG group (**Table II**)

Table II: Menstrual and obstetric history of patients (N=120)

Duration of infertility	SIS, N=60 No. (%6.67)	HSG N = 60 No. (%)
1-3 years	11(18.33%)	10 (16.67%)
4-7 years	21 (35%)	22 (36.67%)
>7 years	28 (46.67%)	28 (46.67%)
Total	60 (100%)	60(100%)

In SIS group irregular menstrual cycle was 83.33% and in HSG group it was 80% (**Table III**).

Table III Menstrual History

Menstrual History	**SIS, N=60 No. (%6.67)**	**HSG N = 60 No. (%)**
Regular	10(16.67%)	12 (20%)
Irregular	50 (83.33%)	48 (80%)
Total	60 (100%)	60 (100%)

Table-IV shows that need of analgesia, syncopal attack, cervical laceration, and Shivering was significant.

Table IV: Procedural complication

Previous treatment history	**SIS, N=60 No. (%**	**HSG10 N =60** No(%)	**P value**
Pain requiring analgesia	40(66.66%)	60(100%)	P<.002
Syncopal attack	2(3.34%)	8(13.33%)	P<.003
Cervical laceration	4(6.68%)	15(24.99%)	P<.002
Shivering	4(6.68%)	6(10.02%)	P<.002

Chi Square Test P<0.05 Considered as significant

In **Table V**, P value of, congenital anomaly of the uterus, uterine synechia, were found significant <.05. On the other hand polyp and hydrosalpinx were not significant.

Table V: Uterine and adnexal pathology with SIS and HSG

Uterine & Adnexal Pathology	**SIS, N=60 No. (%)**	Mean± SD	**HSG N = 60 No. (%)**	Mean ± SD	**P value**
Congenital anomaly of uterus	0(00%)	0.00±.00	3(5.01%)	0.101	0.01
Uterine synechia	0(00%)	0.00. ±.00	2 (3.33%)	0.10±. 1	0.001
Hydrosalpinx	1(1.67%)	0.33±.18	6(9.99%)	.00±.0	0.15

				0	
Polyps	2 (3.33%)	0.33±.18	0 (00%)	.00±.0	0.15
None	57 (94.96%)	0.40±.49	49(81.63%)	.91±2 7	<.05
Total	60 (100%)		60 (100%)		

Unpaired T Test P<0.05 Considered as significant

Table VI describes Tubal patency at least one tube patent on saline infusion sonography was 89.99% and bilateral tubal block at 10.01%. In hysterosalpingography where bilateral tubal patency was 66.67%, the bilateral block was 25%, and the unilateral block was 8.33%.

Table VI: Tubal patency on saline infusion sonography versus hysterosalpingography

Tubal patency on HSG

Tubal patency	HSG no =60	%
Bi lateral tubal patency	40	66.67%
Bi lateral tubal block	15	25.00%
Uni lateral tubal block	5	8.33%
Total	60	100%

Unpaired T Test P<0.05 Considered as significant.

Table VII: this point down by asking about pain tolerability using 0 to 10 point numerical rating. 1-3 score. In SIS 66.66% but HSG5 %. 4-6 Score In SIS it is 30% but HSG 66.67%. 7-9 Score in SIS 3.33% HSG 23.33%, 10 score in SIS 0% but HSG 1.67% P<.05 which was significant.

Table VII: Pain score in 10 point scale

Pain Score	SIS, N=60 No. (%)	HSG N = 60 No. (%)	P value
1-3 score	40 (66.67%)	5 (8.33%)	
4-6 score	18 (30%)	40(66.67%)	
7-9 score 10 score Total	2 (3.33%) 0(00%) 60(100%)	14(23.33%) 1(1.67%) 60(100%)	

Mean± SD	2.45 ± 1.64	3.35 ± 1.85	<.05

Unpaired sample T Test P<0.05 Considered as significant

DISCUSSION

Diagnostic imaging plays an important role in the assessment of women with infertility. The majority of infertile patients undergo a baseline TVS and HSG. TVS is used for evaluating ovaries, fallopian tubes, and adnexa and is a favored imaging modality in the infertility population. Because it is readily available and does not use ionizing radiation. It is valuable for monitoring ovarian folliculogenesis during the treatment of ART [10].In contrast, HSG provides information about tubal patency and uterine cavity abnormalities such as anomalies synechiae, and adhesion any of which could interfere with embryo implantation. HSG offers a limited evaluation of the cervix and myometrium and it has a small risk of contrast reaction and ionizing radiation exposure. SIS procedures are becoming more popular due to the ability to combine adnexal evaluation with tubal evaluation and evaluation of any pelvic pathologies [6]. HSG as a reference standard, one research compared SIS to HSG in making the diagnosis of tubal patency. Test performance metrics for SIS were quite similar to those of HSG, with an accuracy of about 90% for identifying tubal patency. When comparing SIS to HSG for the detection of pelvic pathology, SIS significantly outperformed HSG in terms of sensitivity, specificity, PPV, NPV, and accuracy [11]. In our investigation, SIS found tubal patency at least one tube patent at 89.99 %, Bilateral tubal block at 6% .In HSG found bilateral patency was 66.67%, bilateral block 25%, and unilateral block 8.33%. P-value 0.01 which was significant. This was supported by another study where it was found that SIS detected 9.8% of tubes with tubal block, of which HSG showed 25% of tubes with bilateral occlusion [12].

One research found that the sensitivity and specificity of SIS were more than 86% and 97% as compared to HSG 80% and 94% respectively. PPV and NPV were more for SIS (97% and 83%) as compared to HSG (95% and 77%) [13]. When it comes to identifying pelvic pathology, SIS was 83.3% sensitive, 60% specific, 75% positive predictive value (PPV), 75% negative predictive value (NPV), and 72.0% accurate.

When comparing SIS to HSG for determining tubal patency and diagnosing pelvic disease, similar research by Pujar et al, 2010 [14],found that SIS performed marginally better. By including hysteroscopy in the surgery, the intrauterine cavity may be evaluated concurrently, and this might reveal congenital or endometrial abnormalities [6]. Our research showed that SIS was more sensitive than HSG in detecting abnormalities in the uterine cavity but less specific. A study by Dasan TA et al (2016) [15], indicated that the diagnostic precision of SIS was superior to HSG in identifying tubal patency and evaluating uterine and ovarian causes of infertility. It is similar to our study.

This point down by asking about pain tolerability using a 0 to 10-point numerical rating. 1-3 usually score no pain or feel discomfort. In SIS 66.66% but HSG 8.33%. 4-6 score related to pain but tolerable. In SIS it is 30% but HSG is 66.67%. 7-9 scored intolerable in SIS at 3.33% HSG at 23.33%,10 scored SIS at 0% and HSG at 1.67% the P value was 0.02 which was significant. In one study it was found that Pain score on a ten-point scale, with a score of ten correlating with the greatest pain, was slightly higher in the HSG comparedto the SIS group (3.4 ± 1.9 vs. 2.4 ± 1.6, $p < 0.01$) [16].

In our study in both groups, the majority belonged to the 31-36 years age group, SIS (55%) and HSG (58.33%). This was similar to another study where the age of the study participants was 34.3 ± 4.7 years [17].

In our study pain requiring analgesia 66.66% in SIS group but 100% cases need analgesia in HSG. Syncopal attack and cervical laceration more in HSG. P-value was significant. Only 8.8% exhibited negative side effects, which included discomfort, vasovagal symptoms, nausea, vomiting, or fever [18], There was no difference in discomfort, side effects, or procedure time between SIS and HSG in one randomized experiment [18]. Because the ovaries and myometrium may be evaluated simultaneously, SIS has an advantage over HSG [19].

CONCLUSION

Laparoscopy with chromopertubation is the gold standard for diagnosis of tubal patency but it is relatively costly, expert personnel is needed and has anesthetic hazards. HSG is a contrast radiological scan.it is unpleasant and uncomfortable for individuals. In order to assess tubal patency and uterine pathology (intracavitary and extra cavitary) in infertile individuals, saline infusion sonography is gaining popularity as a diagnostic technique. Improved compliance, OPD procedure,lower costs in a single office visit, without referral to the radiology department make SIS a promising tool for the initial workup of infertile patients in resource-limited settings such as Bangladesh., SIS may be utilized as a straightforward, relatively noninvasive, economical, and evaluation technique in the assessment of female infertility.

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