

Comparative Study of Saline Infusion Sonography with Hysterosalpingography in Evaluation of Tubal PatencySaikat Dey¹, Monojit Chakraborty², Kedarnath Pal³, Satarupa Roy⁴¹Postgraduate Trainee, Department of Obstetrics and Gynecology, Calcutta National Medical College, Kolkata, West Bengal, India.²Associate Professor, Department of Radiodiagnosis, Calcutta National Medical College, Kolkata, West Bengal, India.³Associate Professor, Diamond Harbour Government Medical College, 24 Parganas, West Bengal, India.⁴Assistant Professor, Department of Radiodiagnosis, Calcutta National Medical College, Kolkata, West Bengal, India.

Received: 25-10-2023 / Revised: 23-11-2023 / Accepted: 19-12-2023

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Conflict of interest: Nil

Abstract:**Background:** Objective of the study is comparing Saline infusion sonography versus hysterosalpingography with diagnostic laparoscopy as gold standard in the evaluation of tubal patency in infertility cases.**Methods:** A comparative study was performed in a tertiary care hospital in Kolkata, India. The study was performed for a period of one and a half year from July 2020 to December 2021 in which fifty infertile women were investigated and comparatively evaluated as per objective with inclusion of primary and secondary infertile patients in reproductive age group. Informed consent was obtained from the patients. Patients with active pelvic infection, active vaginal bleeding, genital tract malignancy, suspected pregnancy and abnormal semen analysis of husband were excluded from the study.**Results:** Tubal patency test with diagnostic laparoscopy (as gold standard) confirmed all cases of Saline infusion sonography and Hysterosalpingography with additional patent tubes in 8% of Saline infusion sonography and 12% of Hysterosalpingography making the Sensitivity & Specificity of Saline infusion sonography was 85.71% and 83.33 % and of Hysterosalpingography was 78.57% and 75.00%.**Conclusion:** The present study showed slight better results with Saline infusion of sonography compared to Hysterosalpingography.**Keywords:** Hysterosalpingography, Tubal Patency, Saline infusion sonography, diagnostic laparoscopy.**Advances in knowledge:** The routine use ultrasound, a non-ionizing radiation with saline (eliminating the remotest possibility of contrast induced hypersensitive reactions) to delineate the endometrium and evaluate tubal patency in real time by demonstrating the waterfall sign serves an effective primary diagnostic tool in infertility evaluation.

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Introduction

Infertility, also referred to as subfertility can be classified as primary indicating those patients who have never conceived and secondary indicating inability to conceive subsequently after a pregnancy.

It has been defined as the inability to conceive after one-year unprotected coitus 30 percent cases of infertility are attributed solely to male factors [1], 30 percent solely to female factors, a minority of 10 percent to unexplained causes while the remaining 30 percent to both male and female factors.

Female factor responsible for infertility are mainly owing to [2] of ovulatory dysfunction (30% to 40%), tubal factor disease (25% to 35%), uterine

factor (10%), cervical factor (5%), pelvic endometriosis (1% to 10%).

Tubo-peritoneal factors are responsible for about 30% to 40% of female infertility in India and it has been estimated to be about 40% [1] due pelvic inflammatory disease, genital tract tuberculosis and chronic infection. This prompted us to evaluate a more sensitive, cost effective primary diagnostic modality beneficial for patient health which also does not involve the use of an ionizing radiation.

Sono hysteron salpingography is performed in follicular phase of cycle under ultrasonic control in which about 200 ml of normal saline is infused into the uterine cavity with the help of a Foley's

catheter with its inflated bulb (8-10 ml saline) lying above the internal os to prevent leakage of saline [3].

It is particularly useful in determining whether the uterine cavity defect as seen in hysterosalpingography is polyp or a pedunculated fibroid. It can also determine what portion of a submucous myoma lies within the cavity and can help in planning of hysteroscopic resection of submucous myoma (if myoma is > 50% in cavity).

Under ultrasonic guidance, it is possible to visualize the fallopian tubes by following flow of saline in the uterus and out of tubes suggesting patency of tubes. Presence of free fluid in pouch of Douglas is usually indicative of patent tube. In this study we have conducted to emphasise evaluation of the efficacy of sono-salpingography regarding the tubal factors.

Objective

General Objective: To compare Saline Infusion Sonography versus Hysterosalpingography with Diagnostic Laparoscopy as gold standard in the evaluation of Tubal Patency in Infertility cases.

Specific Objective

1. To find out tubal Patency in Infertility cases by Saline Infusion Sonography.
2. To find out tubal Patency by Hysterosalpingography.
3. To confirm the tubal Patency in all cases with Diagnostic Laparoscopy and dye test.
4. To point out the sensitivity and specificity of the two methods comparing with Diagnostic Laparoscopy with dye test as a gold standard.
5. To observe which of the two methods (Saline Infusion Sonography & Hysterosalpingography) is more efficacious as an initial method of assessment of tubal Patency testing.

Materials & Methods

The present Institution based prospective, analytic comparative study was conducted in the Department of Radiology and Department of Gynaecology & Obstetrics, Calcutta National Medical college and Hospital, Kolkata for a period of one and half year from July 2020 to Dec 2021. Fifty infertile women were investigated and comparatively evaluated as per objective.

Sampling Technique

Total data collection period was 10 months (40 weeks).

All the infertile women were included in the study who met inclusion and exclusion criteria. After the total data collection period, 50 (fifty) such samples were selected for the study.

Inclusion Criteria: Primary and Secondary infertile patients in reproductive age group.

Exclusion Criteria: Active pelvic infection, active vaginal bleeding, genital tract malignancy, suspected pregnancy and abnormal semen analysis of husband and those patients not consenting to take part in the study. Those having severe medical or surgical diseases were also excluded from the study.

Study Variables Included

1. Age
2. Educational status
3. Employment status
4. Menstrual patten
5. Socio-economic strata
6. Types of Infertility
7. Duration of infertility
8. Associated pathology

Statistical Analysis

All data was analysed using appropriate statistical procedures with the help of standard statistical software where required. Data was analysed by estimating sensitivity and specificity, Positive predictive value and Negative predictive value. Relationship between variables was established by charts and table.

Ethical Clearance

This study was conducted after getting due permission from Institutional Ethics Committee and approval of "The West Bengal University of Health Sciences."

Work Plan

- a) Preparatory phase-2 months
- b) Phase of data collection-10 months
- c) Phase of data analysis-3 months

Equipment's

- Philips HD7 machine equipped with 4-8 MHz transvaginal probe was used to perform sono-salpingography.
- SIEMENS X ray machine equipped with fluoroscopy 300 mA.

Procedure

Hysterosalpingography [3,4,5,6]:

The procedure was performed typically between Day 6 to Day 11 of the menstrual cycle, with at least 24 hours of cessation of menstruation. Prophylactic antibiotics and routine premedication analgesics were given prior to the procedure.

Hysterosalpingography was done with sterile technique. The procedure was done under direct fluoroscopic control usually in radiology department. The contrast was followed on fluoroscopic screen as it filled the uterine cavity, then tubal lumen and finally spilled out of tubal

fimbriae into the pelvic cavity if tubes were patent Usually about 10-15 ml of iodinated contrast agent was adequate (capacity of uterus is about 4-7 ml, of tubes is about 3 ml) to see patency of tubes. Two X-ray images were taken as a permanent record of uterine and tubal evaluation. The exposure factors were adjusted as per patient body habitus to keep the effective radiation dose below 1 mSV.

Saline Infusion Sonography [3,4,7,8]

Saline Infusion Sonography was performed during the follicular phase of the cycle by 1-2 examiners. The Patient was placed in the dorsal position, perineum was painted with povidone iodine solution and draped. Vaginal cleansing was done (cervical erosion was excluded in the study) with sterile swab. Using a Sim's speculum uterine cervix was exposed, the uterine sound was passed both to know the position and size of uterus. Then semi solid Foley's catheter 8 Fr was directed into the uterine cavity and balloon was inflated with normal saline and pulled back to the internal os. Then uterine myometrium and endometrium was more visible clearly by vaginal probe. Observation of uterine shape, size, echotexture and endometrial thickness of walls was done. The size, shape, position of ovary was observed.

About 30ml of normal saline was injected into the uterine cavity through Foley's catheter. The resistance to free entry of normal saline was noted as well as the subjective feelings of pain or discomfort expressed by the patient was noted.

The distension of endometrial cavity and intrauterine pathology was ruled out. The right and left ovarian fossa, paracolic gutter and the pouch of Douglas was visualised. Flow of fluid and air turbulence was looked for in the region of right and left ovarian fossae and this turbulence "The water fall sign" was taken as patency of respective fallopian tube, later the Cul-de-sac was visualised to look for free fluid.

Diagnostic Laparoscopy/ Chromotubation [3,9,10,11,12]

It is also popularly called Lap and Dye Test. Laparoscopy is the gold standard method for the accurate assessment of condition of fallopian tubes. It is performed at the same time using a uterine cannula (Rubin, Leech Wilkinson's) or Foley's catheter and using methylene blue dye. Video recording can be performed for keeping the record. Hysteroscopy can be combined with laparoscopy for better visualization of uterine cavity and its abnormalities (polyp, septum, myoma etc.). Interventions like adhesiolysis, ovarian drilling or ablation of endometriotic tissue can be performed in the same sitting, making laparoscopy both diagnostic and therapeutic procedure.

Results and Analysis

The present study was carried out in a total of 50 cases of infertility. Tubal patency tests were done in all the cases enrolled.

Table 1: Types of infertility

	No of case	Percentage(%)
Primary	40	80
Secondary	10	20
Total	50	100

There were 40 cases of primary infertility and 10 cases of secondary infertility.

Table 2: Age group distribution of patients

Age in yrs.	No. of cases	Percentage (%)
20-25	31	62
26.-30	11	22
31-35	3	6
36-40	5	10
Total	50	100

Table 3: Educational level

Educational status	No. of cases	Percentage (%)
Class I- V	2	4
Class VI- X	16	32
Class XI- XII	22	44
Graduate	10	20
Total	50	100

Educational level showed maximum cases having high school level education (76%) and Graduate level of education being observed in 20% cases.

Table 4:

Employment status	No of cases	Percentage
Employed	11	22
Non-Employed	39	78
Total	50	100

About 22% of the cases were employed, others were home makers.

Table 5: Table showing patterns of menstrual cycle in the present study (n-50)

Pattern of menstruation	Primary infertility		Secondary infertility		Total	
	No. of cases	Percentage (%)	No. of cases	Percentage (%)	No. of cases	Percentage (%)
Regular pattern	29	72.5	6	60	35	70
Irregular pattern	11	27.5	4	40	15	30
Total	40	100	10	100	50	100

Regular menstrual pattern was observed in majority of cases with primary and secondary infertility respectively.

Table 6: Table showing associated pathology according to types of infertility (n-50)

Associated pathology	Primary infertility (n=40)		Secondary infertility (n=10)		Total (n=50)	
	No. of cases	Percentage (%)	No. of cases	Percentage (%)	No. of cases	Percentage (%)
Hypothyroidism	3	7.5	2	20	5	10
Hyperprolactinemia	1	2.5	1	10	2	4
Endometriosis	6	15	2	20	8	16
PCOD	7	17.5	0	0	7	14
Pelvic adhesion	3	7.5	2	20	5	10
Total	20	50	7	70	27	54

Associated pathologies like hormonal imbalances and pelvic adhesions were observed in 50% cases of primary infertility and 70% cases of secondary infertility. Endometriosis and pelvic adhesion could only be picked up with diagnostic laparoscopy in our series.

Table 7: showing duration of infertility in the present study group

Duration of infertility (in years)	No of cases (n=50)					
	Primary (n=40)		Secondary (n=10)		Total	
	No	%	No	%	No	%
< 2	0	0	0	0	0	0
2-4	12	30	4	40	16	32
> 4-8	19	47.5	3	30	22	44
> 8	9	22.5	3	30	12	24
Total	40	100	10	100	50	100

The table above shows majority of patients having infertility for more than 4 years

Table 8: showing various findings (Tubal patency) in different procedures in our study (n=50)

Procedures	Saline Infusion Sonography		Hysterosalpingography		Diagnostic Laparoscopy	
	No of cases	Percentage	No of cases	Percentage	No of cases	Percentage
Bilateral patent	32	64	30	60	36	72
Bilateral Block	7	14	9	18%	4	8
Unilateral block	11	22	11	22	10	20

Saline Infusion Sonography and Hysterosalpingography had agreement in findings in 48 out of 50 cases (96%) Saline Infusion Sonography and diagnostic Laparoscopy with dye test had similar findings of tubal patency in 46 cases (92%) Hysterosalpingography and diagnostic Laparoscopy with dye test showed agreement in 44 cases (88%).

Table 9: Statistical analysis in the present study as follows

Statistical Analysis	Saline Infusion Sonography	Hysterosalpingography
Sensitivity	12/ (12+2) X 100% =85.71%	11/ (11+3) x 100% = 78.57%
Specificity	30/ (30+6) X 100% =83.33%	27/ (27+9) X100% = 75.00%
Positive predictive value	12/ (12+6) X 100% = 66.66%	11/ (11+9) X 100% = 55.00%
Negative predictive value	30/ (2+30) X 100% =93.75%	27/ (3+27) X 100% = 90.00%

Considering diagnostic laparoscopy with dye test as gold standard the sensitivity of Saline Infusion Sonography and Hysterosalpingography was noted in 85.71 % and 78.57 % respectively.

On the other hand, specificity of Saline Infusion Sonography and Hysterosalpingography was 83.33% and 75.00 % respectively.

Block with Saline Infusion Sonograph 18

Block with Hysterosalpingography 20

Block with Laparoscopy 14

Positive predictive value

- Saline Infusion Sonography: 66.66%
- Hysterosalpingography: 55.00%

Negative predictive value

- Saline Infusion Sonography: 93.75%
- Hysterosalpingography: 90.00%

Bilateral patent tubes observed in our study in laparoscopy was in 36 cases (72%) compared to 32 cases (64%) with Saline Infusion Sonography and 30 cases (60%) with Hysterosalpingography.

Saline Infusion Sonography and Hysterosalpingography had dissimilarity in two cases (32 versus 30). Bilateral block was observed in 4 cases with laparoscopy (8%) compared to 7 cases (14%) with Saline Infusion Sonography and 9 cases (18%) with Hysterosalpingography. Saline Infusion Sonography and Hysterosalpingography had dissimilar findings in 2 cases (4%)

Discussion

The present study carried out with a total of 50 cases of infertility were subjected to tubal patency tests with Saline Infusion Sonography, Hysterosalpingography and Diagnostic Laparoscopy with dye test. In our study 80% were suffering from primary infertility compared to a figure of 69% to 75% in some other studies as shown in the table below.

Table 10: Types of infertility in various studies in comparison with our study

Infertility	Foroozanfard et al. [13]	Subarata L et al. [14]	Samal S et al. [15]	Suttipichate J et al. [16]	Reddy S et al. [17]
Primary	69	73	75	75	75
Secondary	31	27	25	25	25

Age distribution showed maximum cases (62%) in the age group 20 to 25 years in the present study which was indicative of inclusion of a younger population as compared to few other studies where the percentage of 20-25 years age group ranged from 18-57.5 percent.

- Duration of infertility in our series shows almost 3 quarter cases of both primary and secondary infertility having duration of 2 to 8 years, whilst one fourth of more than 8 years of duration. This trend is also observed in the study of Tripathy S et al.[19].
- Seventy percent of cases in our series had regular menstruation compared to 76% noticed by Reddy et al.[17]
- Associated pelvic pathology was detected by various methods in 54% cases in the present study compared to 41% to 63% detected in the
- Endometriosis and pelvic adhesion could only be diagnosed with diagnostic laparoscopy in our series, though in the study mentioned endometriosis could also be picked-up by Saline Infusion Sonography. So, 8 cases of endometriosis and 5 cases of pelvic adhesion was missed by Saline Infusion Sonography and Hysterosalpingography in the present study.
- Findings of tubal patency show bilateral patent tubes with Saline infusion sonography in 64%, almost similar to the study of 62.5% Samal S et al [15] and 68% by Reddy S et al. [17], but

Age distribution in years	Samal S et al. [15]	Subrata L et al. [14]	Sheety SK et al. [18]	Reddy S et al. [17]	Present Study
20-25	57.5	20	18	34	62
26- 30	33.75	38	36	52	22
31-35	5	35	34	12	6
36-40	3.75	8	12	2	10

study of Kalpana et al [20]. Types of associated pelvic pathology were similar in the present study and the study by Kalpana et al.

dissimilar to 53% by Bushra et al [21] and 73% by Subrata L et al [14] and 75.5% by Yeshita P

et al.[22]
 On Hysterosalpingography bilateral patent tubes were observed in 60% of the present study. This is in contrast to 38% to 71% in the studies shown in the

table below. Sonosalpingography, hysterosalpingography and laparoscopy finding in comparison with our study are shown in the table below

Sonosalpingography finding	Samal S et al. [15] (%)	Subrata L et al. [14] (%)	Bushra Jet al. [21] (%)	Yeshita Pet al. [22] (%)	Reddy S et al.[17] (%)	Present Study
Bilateral patency	62.5	73	53	75.5	68	64
Bilateral block	12.5	7	13	11.3	24	14
Unilateral block	25	20	34	13.2	8	22
Hysterosalpingography						
Bilateral patency	52.5	71	38	69.4	58	60
Bilateral block	18.75	9	31	16.1	28	18
Unilateral block	28.75	20	31	14.5	14	22
Laparoscopic finding						
Bilateral patency	66.25	75	53	72.6	64	72
Bilateral block	13.75	6	8	11.3	24	8
Unilateral block	20	19	39	16.1	12	20

Table comparing our findings with other studies
 On diagnostic laparoscopy bilateral patent tubes were observed in 72% in our study, almost similar to the studies of 75% by Subrata L et al [14], 72.6% by Yeshita P et al [22], this contrasts with studies by Samal S et al (15) (66.25%), Bushra J et al [21] , (53%) and Reddy S et al [17], (64%). In analyzing our study the following findings were derived:-

- Sensitivity of saline infusion sonography 85.71 %
- Sensitivity of Hysterosalpingography 78.57%
- Specificity of Saline infusion sonography 83.33

%

- Specificity of Hysterosalpingography 75.00%
- Positive predictive value of Saline infusion sonography 66.66%
- Positive predictive value of Hysterosalpingography 55.00%
- Negative predictive value of Saline infusion sonography 93.75%
- Negative predictive value of Hysterosalpingography 90.00%

This can be compared with the other studies as shown in the following table

Parameter	Ranaweera AKP et al. [23] (%)	Suttipic HJ et al. [16] (%)	Hajishafha et al. [24] (%)	Chan CC et al. [25] (%)	Reddy S et al. [17] (%)	Present study (%)
Sensitivity	84.9	96.97	94	100	92.1	85.71
Specificity	81.8	88.89	100	67	75	83.3
Positive predictive value	96.8	96.97	100	89	86.8	66.6
Negative Predictive value	45	88.89	75	100	84.4	93.75
Parameter	Foroozanfard et al. [26] (%)	Sarkar MN et al. [27] (%)	Jara d et al. [28] (%)	Sarwat R et al. [29] (%)	Reddy S et al. [17] (%)	Present study (%)
Sensitivity	92.1	63	77.4	90.9	84	78.57
Specificity	85.7	98.3	80.2	89.4	88.8	75
Positive predictive Value	97.2	92	79.7	83.3	93.1	55
Negative Predictive value	66.7	55	78.1	55.5	76.1	90

Conclusion

- Sensitivity & specificity of Saline infusion sonography and Hysterosalpingography was compared with diagnostic laparoscopy as gold standard.

- Sensitivity & Specificity of Saline infusion sonography was 85.71% and 83.33 % and of Hysterosalpingography was 78.57% and 75.00%.
- Findings of Saline infusion sonography show

slightly better results than Hysterosalpingography in detecting tubal patency & bilateral block.

Any of the above methods may be considered for initial assessment of tubal patency considering their advantages and disadvantages, as well as contraindications and availability of necessary set.

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