Comparative Evaluation of Hysterosalpingography vs. Laparoscopy in the Determination of Tubal Factors in Female Infertility

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ABSTRACT

BACKGROUND

Approximately 15% of couple are affected by infertility. Tubal factor is one of the most frequent causes of infertility in women. As tubo-peritoneal factor is accountable for 30 - 40% of female infertility, evaluation of tubal patency is the basic investigation for assessment of female infertility. Hysterosalpingogram (HSG) and laparoscopy are the two most commonly conducted tests to evaluate the tubal factor of female infertility. The aim of the study was to compare hysterosalpingogram with laparoscopy in the diagnosis of tubal factor of female infertility.

METHODS

This is an observational cross-sectional study conducted among 80 infertile women either primary or secondary in the Department of Gynaecology and Obstetrics, R.G. Kar Medical College, Kolkata, a tertiary care hospital in North-East, over a period of one and half years (January 2018 to July 2019). Primary infertility incidence was 56.3% and that of secondary infertility was 43.8%. More than half the subjects (66.3%) were between 26 to 35 years of age. Mean age of the study population was 27.43 ± 5.14 years. The mean period of infertility (Mean ± S.D.) of patients was 4.3375 ± 2.3164. Both procedures were done in the same patient. HSG was done in preovulatory phase. Laparoscopy was performed under general anaesthesia. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables.

RESULTS

Association of spillage of dye in HSG vs. laparoscopy was statistically significant ($p<0.0001$). Association of tubal block in HSG vs. laparoscopy was also significant. Association of abnormal tubal architecture in HSG vs. abnormal tubal architecture in laparoscopy is statistically significant ($p= 0.0111296452$). Difference in uterine filling defect in HSG and fibroid in laparoscopy was statistically significant ($p=0.0013005280$). Laparoscopy shows presence of fibroid in more no. of cases. In diagnosis of peritubular adhesion and abnormal tubal architecture, laparoscopy was significantly better than HSG.

CONCLUSIONS

HSG and laparoscopy are the two classic methods for evaluation of tubal patency in infertile women and are complementary to each other. HSG is less invasive, less expensive, more informative with regard to tubal luminal architecture; whereas, laparoscopy is the gold standard for tubal assessment.

KEY WORDS

HSG, Laparoscopy, Tubal Factor, Infertility

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BACKGROUND

Infertility is a critical component of the reproductive health and has often been neglected.[1] The inability to have children affects men and women across the globe. For many couples, infertility and its treatment cause a serious strain on their interpersonal relationship, and cause disturbed relationships with other people.[2] Common causes of infertility include male factor (45 %), ovulation disorders (37 %) and tubal damage (18 %). One third of infertility cases are due to anatomical abnormalities of the female reproductive tract such as tubal blockage.[3,4] A combination of several factors is found in approximately 20% of all couples worldwide.[5]

Tubo-peritoneal factors are responsible for about 30-40% of cases of female infertility and hence evaluation of tubal patency represents a key step and a basic investigation in the assessment of infertile women.[6,7] A number of diagnostic tests are being used in clinical practice to assess tubal patency as part of the work-up for subfertility.[8] The most commonly used tests are hysterosalpingography (HSG) and laparoscopy.

The HSG has been a test in the routine workup of infertile couples as a minimally invasive and low-cost method of evaluating tubal patency and is performed as the first line approach for assessing tubal pathology. Whereas laparoscopy is considered the clinical reference test and gold standard for diagnosing tubal pathology[9]. Laparoscopy allows visualization of peri-tubular and adnexal adhesions and the presence of endometriosis, which cannot be done with HSG.[10]

So, we conducted this study to compare HSG and Laparoscopic finding in diagnosis of tubal factors, or tubal with other associated factors for female infertility. We wanted to compare hysterosalpingography and laparoscopic findings in the diagnosis of infertile women to assess tubal factors in terms of tubal patency or obstruction, site of tubal occlusion, tubal architecture (i.e. tubal dilatation, tubal fibrosis/ filling defect).Tubal factors (unilateral/bilateral) with other associated factors like intra uterine factors, polyp, adhesion, endometriosis, PID, pelvic pathology etc.

METHODS

Observational descriptive study with cross sectional study-design conducted at R.G. Kar Medical College and Hospital among the patients admitted in department of Obstetrics and Gynaecology for a period of one year six months. (January 2018 to July 2019). Age group of the patient is 18 to 40 years. Proper relevant history is taken at first then physical examination. Patients (fulfil the inclusion criteria of the study) with history of primary or secondary infertility are admitted for diagnostic laparoscopy with HSG report.

The study 'Comparison between hysterosalpingography and laparoscopic for the assessment of tubal patency in infertile women' by Dr. Anjana Choudhary and Dr. Shreya Tiwari[11] over Indian population shows that 28% Bilateral tubal block and 72% patent tube was detected in hysterosalpingography and 10% bilateral tubal block and 90% patent tube in diagnostic laparoscopic chromotubation. The study by Chakraborti et al (22.7%) and Goynumer G et al (24 %)[12,13] 156 which shows bilateral tubal block to be the common tubal cause of Infertility. P1 = 90% bilateral tubal patency was detected in laparoscopy, and P2 =72% bilateral tubal patency was detected in HSG.

From this

$[(1.96+0.84)\ 2\ \{90\ (100-90) + 72\ (100-72)\}]/\ (90-72) = 70.56 \sim 71$

Power of the study (1- β) = 80%.
Confidence interval (1-α) = 95%
'Z' value for significances 0.05

Extra 10% sample will be taken for dropout case so sample size will be

$71 + (71 \times 10/100) = 78.1$ approximately 80.

Both procedures will be applied over same patient. So, single group of patients will be compared in two different procedural view.

Inclusion Criteria

Includes those patients who are given informed consent, patients coming for treatment of infertility age group 18 to 40 years, hormonal investigation within normal limit Or, hormonal profile became normal after management in the partner.

Exclusion Criteria

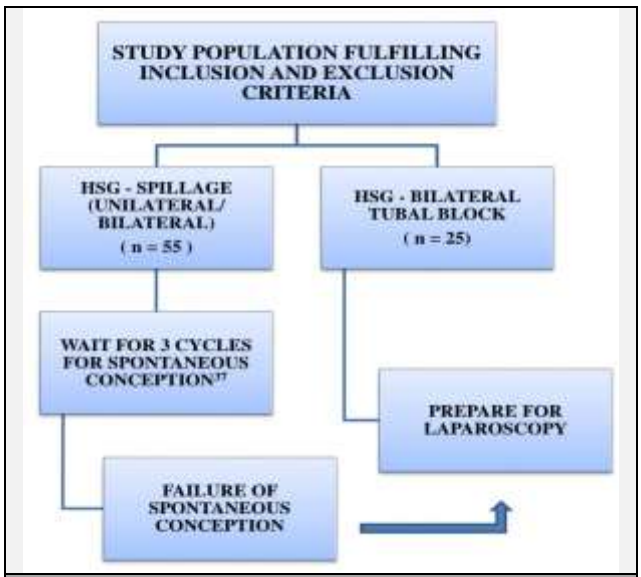
Includes active Pelvic Inflammatory Disease, active cervical or vaginal infection, other medical and surgical disorders (primary amenorrhea, h/o tubal surgery, recanalization surgery etc. and contraindication for laparoscopy or HSG. Independent variables are age, Parity, Gravidity, Ethnicity, BMI, Socioeconomic status, Period of infertility.

The case records in terms of tubal patency (spillage of dye unilateral or bilateral), site of tubal block, tubal dilatation, tubal fibrosis/filling defect uterine factors. Peritubular adhesion, endometriosis, PID, other pelvic pathology to be studied, analysed and compared with suitable statistical method.

Statistical Analysis

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analysed by SPSS (version 25.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true.

P-value ≤0.05 was considered as statistically significant.



Selection and Allocation of Study Population

Digital HSG is advised and performed (inside or outside our institution facilities) or HSG was done previously. Patients with an abnormal HSG usually underwent laparoscopy without delay, whereas in patients with a normal HSG Laparoscopy was performed three months after HSG.[14] HSG is best scheduled during the 2-5-day interval immediately following the end of menstruation, to minimize risk for infection, avoid interference from intrauterine blood and clot, and to prevent any possibility that the procedure might be performed after conception. HSG does not require any specific preparation, although pre-treatment with a NSAID (30-60 minutes before) is helpful to decrease discomfort associated with the procedure. Infectious complications from HSG are relatively uncommon, even in high risk women (1-3%).[15,16] Treatment with antibiotics (doxycycline 100 mg twice daily for 5 days, beginning 1-2 days before HSG) is prudent when tubal disease is highly suspected, and specifically indicated when HSG reveals distal tubal obstruction, because risk for acute salpingitis is increased (approximately 10%) and treatment can prevent clinical infection.[17]

The study of HSG should be performed by using image intensification fluoroscopy/ X-ray with a limited number of radiographs. The average HSG requires only 20-30 seconds of fluoroscopic/X-ray time with minimal radiation exposure and has very low risk. Usually, only three basic films are required (a scout, one film to document the uterine contours and tubal patency, and a post-evaluation film to detect any areas of contrast loculation). Additional oblique films may be needed when the uterus obscures the tubes, or the uterine cavity appears abnormal. Contrast can be introduced using a common metal "acorn" cannula or via a balloon catheter.

Patients will be carefully selected after excluding the contraindications for Laparoscopy. Patients will be sent for pre anaesthetic check-up (PAC). Patient will be admitted for laparoscopic evaluations. During laparoscopic evaluation, we used 30-degree laparoscope and pneumoperitoneum achieved by CO2.

Diagnostic laparoscopy is usually performed under general anaesthesia. With few exceptions, a systematic and thorough inspection of the pelvis will accurately define the location and extent of any disease. Examination should include the uterus, the anterior and posterior cul-de-sacs, the ovarian surfaces and fossae, and the fallopian tubes.

Injection of a dilute blue dye through a cannula attached to the cervix or an intrauterine manipulator permits evaluation of tubal patency (chromotubation). Indigo carmine is preferred over methylene blue, which rarely may induce acute methemoglobinemia, particularly in individuals with glucose-6-phosphate dehydrogenase deficiency. As with,[18,19] HSG, slow injection of fluid helps to reduce the incidence of false-negative results. Laparoscopy provides both a panoramic view of the pelvic reproductive anatomy and a magnified view of the uterine, ovarian, tubal, and peritoneal surfaces. Consequently, it can identify milder degrees of distal tubal occlusive disease (fimbrial agglutination, phimosis), pelvic or adnexal adhesions, and endometriosis that adversely affect fertility but escape detection by HSG. Most importantly, laparoscopy offers the opportunity to treat disease at the time of diagnosis.

The collected data will be compiled, and proper statistical formulas will be applied to analyze the collected data.

RESULTS

In our study out of total 80 infertile patients, more than half of the subjects (66.3%) were between 26 to 35 years of age. Incidence of infertility was higher for subjects between 26 to 35 years as compared to those above 35 years of age (26.2%). The mean age of the study population was 27 years. The mean age (Mean ± S.D.) of patients was 27.4375 ± 5.1431 years. In this study there was a roughly equitable distribution of subjects based on the type of infertility. Incidence of primary infertility is only slightly higher in the study population. Primary infertility incidence was 56.3% and that of secondary infertility was 43.8%.

Period of Infertility	Frequency	Percent
1 - 5 Years	60	75%
6 - 10 Years	18	22.5%
>10 Years	2	2.5%
Total	**80**	**100.0%**

Table 1. Distribution According to Period of Infertility

Table 1 shows that three quarters of the study population had a period of infertility of up to 5 years. A meagre 2.5% of the subjects were those who had a history of infertility of over 10 years. The mean period of infertility in the study population was 4 years. The mean period of infertility (Mean ± S.D.) of patients was 4.3375 ± 2.3164.

Spillage of Dye in HSG	Frequency	Percent
Unilateral	18	22.5%
Bilateral	37	46.2%
Bilateral Block	25	31.3%
Total	**80**	**100.0%**

Table 2. Distribution of Spillage of Dye in HSG

The table 2 shows that the incidence of unilateral spillage of dye in hysterosalpingography was 22.5% and 46.3% of the study population showed bilateral spillage of dye in hysterosalpingography. 31.3% of the study population either had no spillage i.e. bilateral block in HSG.

Spillage of Dye in Laparoscopy	Frequency	Percent
Unilateral Spillage	20	25.0%
Bilateral Spillage	38	47.5%
Bilateral Block	22	27.5
Total	**80**	**100.0%**

Table 3. Distribution of Spillage of Dye in Laparoscopy

The table 3 shows that the incidence of unilateral spillage of dye in laparoscopy was 25%. Incidence of bilateral spillage of dye in laparoscopy was 47.5% 27.5% of the subjects had no spillage i.e. bilateral tubal block in laparoscopy.

In laparoscopy- U/L spillage of dye in 20 patients. In HSG U/L spillage of dye in 18 patients which also shows U/L spillage in laparoscopy. Association of U/L spillage of dye in HSG vs. U/L spillage of dye in laparoscopy was statistically significant (p<0.0001). (Chi-square value: 64.6117; p-value: 0.00000000)

In laparoscopy- B/L spillage of dye in 38 patients. In HSG B/L spillage of dye in 37 patients which also shows B/L spillage in laparoscopy. Association of B/L spillage of dye in HSG vs. B/L spillage of dye in laparoscopy was statistically significant (p<0.0001). (Chi-square value: 72.2169; p-value: 0.000000000)

In laparoscopy- B/L block in 22 patients. In HSG B/L block in 25 patients. Association of B/L tubal block in HSG vs. B/L tubal block in laparoscopy was statistically significant (p<0.0001).

Findings	Present: Lap/HSG	Absent: Lap/ HSG
1. Abnormal Tubal Architecture [n=80 (100%) frequency (%)	38 (47.5%) / 10 (12.5%)	42 (52.5%) / 70 (87.5%)
2. Peritubal Adhesion [n=80 (100%)]	36 (45%) / 7 (8.8%)	44 (55%) / 73 (91.2%)
3. Fibroid in Laparoscopy vs. Uterine Filling Defect in HSG	25 (31.3%) / 8 (10%)	55 (68.7%) / 72 (90%)
4. Cystic changes or SOL in ovary	38 (47.5%)	42 (52.5%)
5. Pelvic Endometriosis	36 (45%)	45 (55%)

Table 4. Comparative Distribution of Associated Pathology Detected in Laparoscopy and HSG

Chi-square value: 6.4447; p-value: 0.0111296452

In laparoscopy- 38 patients had abnormal tubal architecture. In HSG - 9 patients had abnormal tubal architecture. Association of abnormal tubal architecture in HSG vs. abnormal tubal architecture in laparoscopy is statistically significant (p = 0.0111296452).

In this study, 7 patients have loculated spillage of dye in HSG. In laparoscopy 36 patients has peritubular adhesion. Association of loculated spillage of dye in HSG vs. peritubular adhesions in laparoscopy was statistically significant (p = 0.0077148195). (Chi-square value: 7.0988; p-value: 0.0077148195)

8 patients had uterine cavity filling defects in HSG. In laparoscopy 25 patients shows fibroid. Association of uterine cavity filling defects in HSG vs. presence fibroid in laparoscopy was statistically significant (p = 0.0013005280).

DISCUSSION

In our study shows that more than half of the subjects were between 26 to 35 years of age. Incidence of infertility was higher for subjects between 26 to 35 years as compared to those above 35 years of age. The mean age of the study population was 27 years.

Overall, fertility rates are 4-8% lower in women aged 25-29 years, 15-19% lower in those aged 30-34, 26-46% lower in women aged 35-39, and as much as 95% lower for women aged 40-45 years.[20,21]

In present study shows that there was a roughly equitable distribution of subjects based on the type of infertility, but incidence of primary infertility is only slightly higher in the study population. The prevalence of primary and secondary infertility was similar to the study Sharma N et al (2012).[22] There is overall higher incidence of primary infertility in the population.[23]

In our study shows that three quarters of the study population had a period of infertility of up to 5 years. 2.5% of the subjects were those who had a history of infertility of over 10 years. The mean period of infertility in the study population was 4 years.

In present study HSG shows proximal tubal block in 14 (17.5%) cases and distal tubal block in 22 (27.5%) cases in right side, and left side 10 (12.5%) shows proximal block and 23 (28.8%) cases presented with distal block. According to the Al-Jaroudi D et al[24] study proximal tubal occlusions represent approximately one-third of all tubal obstructions observed with HSG, many of which are not real (20-40%).

In present study HSG shows u/l spillage of dye in 18 (22.5%) cases, b/l spillage in 37 (46.2%) cases and b/l tubal block in 25 (31.3%) cases. And in laparoscopy u/l spillage is found in 20 (25%) cases, b/l spillage in 38 (47.5%) cases and b/l tubal block in 22(27.5%) cases. (Table-2, 3) In this study comparison between HSG and laparoscopy for evaluation of tubal patency (spillage of dye) and tubal block shows that laparoscopy is better than HSG and which is statistically significant (p<0.0001).

Swart P et al[25] study showed that Compared to laparoscopy (the gold standard method) as a test of tubal patency, HSG has only moderate sensitivity (ability to detect patency when the tubes are open; 65%), but relatively high specificity (accuracy when patency is detected; 83%) in a typical infertile population.

In our study (Table-4) h/o PCOS is found in 41.2% cases and incidence of cystic change or space occupying lesions in the ovaries as per laparoscopy was 47.5%. Flood JT et al[26] and study showed laparoscopy is required to establish an accurate diagnosis, also providing the opportunity to treat coexisting tubo-ovarian and pelvic disease that may be observed in up to 20% of women with infertility. The prevalence of infertility in women with PCOS varies between 70 and 80%.[27]

In present study, (Table-4) HSG shows uterine filling defects in only 8% of the population and we found that laparoscopy detected the presence of a fibroid in almost 31.3% of the study population. Myoma and larger polyps generally produce curvilinear filling defects of various size

and shape. HSG in women with intrauterine adhesions usually reveals grossly irregular cavity contours and filling defects, and in many with severe disease, no cavity at all.

According to the Preutthipan Set al[28] the accuracy of HSG for detecting intrauterine pathology in infertile women varies with the nature of the abnormality.

Donnez J et al[29] study showed Myomas can be identified in 20-40% of all reproductive aged women.

In our study (Table-4) comparison with uterine filling defect in HSG and fibroid in laparoscopy shows association of statistically significant (p=0.0013005280). Laparoscopy shows presence of fibroid in more no. of cases.

Mol BW et al[30] study showed HSG may reveal bilateral tubal patency (60 - 75%) or unilateral (15 - 25%) or bilateral (15 - 25%) tubal occlusion. Both false-negative (obstructions that are not real) and false-positive results (patency that is not real) occur, the former being much more common than the latter.

Injection of contrast may cause "cornual spasm" (uterine contractions that transiently close the interstitial segment and prevent distal perfusion) that can be misinterpreted as proximal tubal occlusion. HSG may reveal unilateral tubal patency and contralateral proximal occlusion.

In this study (Table-4) HSG shows abnormal tubal architecture in 10 (12.5%) cases.

And laparoscopy shows incidence of abnormal tubal architecture in 38 (47.5%) cases.

In our study HSG shows loculated spillage of dye, suggestive of peritubular adhesion. Presence of convoluted or corkscrew fallopian tube, peritubular halo and loculated spillage dye in HSG is suggestive of peritubular adhesion (Textbook of Radiology and Imaging, edited Devid Sutton, 7th edition, volume II, page no 1089)[31] in 7 (8.8%) cases and laparoscopy shows peritubular adhesion in 36 (45%) cases.

In comparison between HSG and laparoscopy for diagnosis of peritubular adhesion and abnormal tubal architecture, laparoscopy shows statistically significant better result than HSG. (Table-4)

Moawad NS et al study shows endometriosis is the most common benign disease affecting approximately 10-15% of reproductive age women and frequently (30 ± 60%) is associated with infertility. In present study shows that pelvic endometriosis was detected by laparoscopy in 45% of subjects.

CONCLUSIONS

HSG and laparoscopy are not alternatives but complimentary investigations. HSG, a safe, inexpensive and minimally invasive method, can demonstrate the endometrial cavity and reveals the internal anatomy of the tubal lumen, neither of which can be assessed by laparoscopy. On the other hand, Laparoscopy is the gold standard for providing detailed information about the pelvic anatomy including peritubal adhesions, endometriosis and ovarian pathology which are not provided by HSG.

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