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## Original Research Article

# A study evaluation of tubal factors of infertility by hystero-salpingography and diagnostic laparoscopy

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### ABSTRACT

**Background:** Infertility is one of the commonest problems encountered in gynecology. Infertility appears to be a problem in 10-15% of Indian population. Tubal factors account for (20-40%) of infertility. The objective of the study was to demonstrate the role of hystero-salpingography and hystero-laparoscopy in evaluation of tubal factors for female infertility.

**Methods:** Present study was carried out on 70 women attending the gynaecology OPD for investigation of infertility admitted between March 2014 to December 2014 in Gynecology ward, SSG Hospital attached to Government Medical College, Vadodara, Gujarat.

**Results:** Out of 70 patients who underwent HSG tubal block was detected in 34 cases. Out of these 34 cases tubal block was detected only in 17 cases by laparoscopy and chromopertubation. One case which showed patent tubes on HSG had unilateral tubal block on chromopertubation test. Accordingly, sensitivity of HSG for tubal patency comes out to be 0.72, specificity of 0.94, positive predictive value of 97.43%, negative predictive value of 51.61%, positive likelihood ratio of 12.28 and negative likelihood ratio of 0.30.

**Conclusions:** HSG being simple and less invasive technique along with higher specificity and lesser complications. Hystero-laparoscopy is a valuable technique for the complete assessment of female infertility.

**Keywords:** Chromopertubation, Hysterosalpingography, Hysterolaparoscopy, Infertility

### INTRODUCTION

Infertility is one of the commonest problems encountered in gynecology. Although population explosion is a major problem in India, infertility appears to be a problem in 10-15% of Indian population.<sup>1</sup>

The prevalence of infertility does not differ significantly among racial and ethnic groups. Although patients seeking treatment for infertility are predominantly of high socio-economic status, infertility is more common among groups of relatively low socioeconomic status. Improved familiarity with and access to infertility services among

the affluent and better-educated patients probably accounts for their greater use of these medical resources.<sup>1</sup>

According to Shaw's 19 - Infertility implies apparent failure of a couple to conceive after one year of "unprotected" and regular intercourse.<sup>2</sup>

According to Seibel MM20 - Infertility denotes lack of fertility, an involuntary reduction in the ability to reproduce children.<sup>3</sup> According to Phelps JY21 - Infertility is defined as the failure of a couple of reproductive age to conceive after 12 months of regular coitus without contraception.<sup>4</sup>

### **Risk factors for infertility<sup>1</sup>**

- Increasing age
- Pelvic infection and pelvic inflammatory disease
- Lifestyle factors
- Multiple sexual partners leading to STD and PID
- Personal behaviour such as smoking and drinking
- Extremes of weight
- Environmental and occupational factors
- Additives
- Emissions
- Medications
- Pollutants
- Psycho-emotional factors
- Medical and surgical illness.

### **Etiology of infertility**

- According to Novak's
- Relative prevalence of the etiologies of infertility (%)<sup>1</sup>
  - a. Male factor: 25-40%
  - b. Female factor: 40-55%
  - c. Both male and female factors: 10%
  - d. Unexplained fertility: 10%
- Approximate prevalence of the causes of infertility in the female (%)<sup>1</sup>
  - a. Ovulatory dysfunction: 30-40%
  - b. Tubal or peritoneal factors: 30-40%
  - c. Unexplained infertility: 10-15%
  - d. Miscellaneous causes: 10-15%
- Infertility is classified into two types:
  1. Primary infertility in which no previous pregnancies have occurred.<sup>1</sup>
  2. Secondary infertility in which a prior pregnancy, although not necessarily a live birth has occurred.<sup>1</sup>
- The important causes of female infertility are<sup>5</sup>:
  1. Tubal factors (20-40%)
  2. Ovulatory dysfunction (20-40%)
  3. Miscellaneous causes (10-15%).

Tubal factors account for (20-40%) of infertility. The mechanism responsible for tubal factor infertility involves anatomic abnormalities that prevent the union of sperm and ovum. Proximal tubal obstructions prevent sperm from reaching the distal fallopian tube where fertilization normally occurs. Distal tubal occlusions prevent ovum capture from the adjacent ovary whereas the proximal tubal obstruction is an all or none phenomenon.<sup>5</sup> Tubal factor of infertility accounts for a large portion of female infertility. The most prevalent cause of tubal infertility is pelvic inflammatory diseases and acute salpingitis. Proximal, distal, and peritubal damage can be caused by a number of pathologic processes such as inflammation, endometriosis, and surgical trauma.<sup>6</sup>

Tubal pathology impairs functions of the fallopian tube and reduces fertility. The degree of tubal pathology determines the possibility of fertility. The evaluation of the fallopian tube is necessary to determine the management plan of infertility.<sup>6</sup>

Hystero-salpingography (HSG) is often performed as a first line approach to assess tubal patency because it has a sensitivity of 85 to 100%. The particular specificity of identifying PID related tubal occlusion is 90%; however HSG has limitations in detecting tubal pathology.<sup>7</sup>

In today's practice, however, the number of HSG examinations has increased dramatically over the past few years. This increase is likely due to (a) advances in reproductive medicine, resulting in more successful in vitro fertilization procedures; and (b) the trend toward women delaying pregnancy until later in life. HSG is a minimally invasive procedure with rare complications. It is a diagnostic test but often it can unblock tubes.<sup>7</sup>

Laparoscopy has emerged in recent years as an accurate method of assessing, evaluating and testing infertility. Direct visualization of the abdominal and pelvic organs in laparoscopy allow a definitive diagnosis to be made in many conditions where clinical examination and less invasive procedures such as HSG fail to identify the problem.<sup>8</sup> Hystero-laparoscopy and chromopertubation is widely considered as the gold standard test for investigating tubal patency. Additionally, it allows assessment for peritubal disease, adhesions and endometriosis. This has led to a recommendation by the NICE(UK) that women suspected of having comorbidities (such as endometriosis and pelvic inflammatory disease) should undergo laparoscopy so that pelvic and tubal pathology can both be assessed.<sup>8</sup>

Hence this study was done to evaluate the tubal factors in an infertile patient by HSG and Laparoscopy.

Aims of the study was to evaluate hystero-salpingographic and hystero-laparoscopic of tubal factors of infertility.

### **Objectives**

- To demonstrate the role of hystero-salpingography and hystero-laparoscopy in evaluation of tubal factors for female infertility.
- To diagnose tubal block causing infertility.
- To compare efficacy of HSG against diagnostic hystero-laparoscopy for tubal blocks.
- To find out other factors associated with tubal factors for infertility.

### **METHODS**

Present cross sectional study was carried out on 70 women for investigation of infertility admitted in Gynecology ward, SSG Hospital attached to Government

Medical College, Vadodara from March 2014 to December 2014.

On the basis of a studies carried previously, the prevalence of tubal factors in fertility is around 60%. So taking 60% as expected prevalence rate and maximal allowable error 20% sample size comes to be around 70. Patients attending the gynaecology OPD for infertility were included in the study. After taking detailed history, they were subjected to clinical examination and routine investigations. Special investigations like semen analysis and USG was carried out.

### **Inclusion Criteria**

All infertility patients (primary and secondary) want to conceive and willing to undergo hysterosalpingography and diagnostic hysterolaparoscopy for evaluation of the same.

### **Exclusion Criteria**

Patients with absolute or relative contraindications for laparoscopy ie severe cardiopulmonary disease, presence of large abdominal masses, diaphragmatic hernia, massive intraperitoneal haemorrhage, paralytic ileus, generalized peritonitis, bowel obstruction. Presence of azoospermia or severe oligospermia in the semen of the husband's of infertile patients. Active PID/recently treated PID in past 3 months. Recent uterine /tubal surgery. Active uterine bleeding.

After selecting patients according to the inclusion and exclusion criteria mentioned above, hysterosalpingography was carried out after taking written informed consent between day 6 to day 10 of menstrual cycle using 75% trazograff dye. Patients were called in the next cycle for performing diagnostic hysterolaparoscopy which will be performed under general anaesthesia. Chromopertubation with methylene blue dye was done to assess the patency of tubes.

### **Findings were assessed for**

- Tubal block-bilateral/unilateral and segment affected
- Peritubal adhesions
- Hydrosalpinx
- Tuberculous salpingitis
- Congenital anomalies.

Patients were sent to ward and if there are no complications, they were discharged in the evening on the 2<sup>nd</sup> day. Patients were explained advice and given follow up to attend OPD after 1 week.

### **Statistical analysis**

All data will be reviewed and analysed by following methods. Association of age distribution in cases of primary and secondary infertility, Comparison of

incidence of tubal block between HSG and DHL findings will be analysed by chi-square test as test of association. Tubal patency will be analysed by percentage and proportion, p-value < 0.05 will be considered statistically significant.

### **HSG Procedure**

- All HSG were done on outpatient basis
- HSG appointment was given on postmenstrual dates. (6 to 10<sup>th</sup> day)
- Inj. Atropine 0.6 mg. I.M. was given ½ hour before actual procedure as premedication
- Aseptic precautions were observed in all stages of the procedure. Bladder was emptied. Patient was put in a lithotomy position and the part was painted and draped
- With the help of Sims speculum, and anterior vaginal wall retractor, cervix was visualized and held in position with a vulsellum forceps
- A 20 cc syringe filled with the dye Urografin 60%, (Diatrizoate Meglumine and Diatrizoate Sodium injection USP) was attached to Leech Wilkinson's cannula
- Leech Wilkinson's cannula filled with the dye was threaded along the cervical canal till the tip was just beyond the internal os
- Sims speculum removed
- Keeping cannula and syringe in place, patient was given dorsal position and initially 2 cc of dye was injected under fluoroscopy image intensifier
- The initial x-ray was taken after injecting 2-3 cc of dye. The second film was taken after injecting 5-7 cc of dye, only after tubal filling confirmed on image intensifier
- After the procedure patient was followed for 2 hours for immediate complications.

### **Diagnostic laparoscopy procedure**

- All patients were admitted for the laparoscopic examination during proliferative phase of the menstrual cycle
- Preoperative management and anesthesia fitness was taken
- Patients were kept NBM for at least 12 hours. Written informed consent was taken
- General anaesthesia was given to all of the cases. Lithotomy position was given. Painting and draping of the abdomen and genital region was performed with betadine and spirit
- Sims speculum inserted. Anterior cervical lip was held with vulsellum
- The Leech Wilkinson's cannula was threaded through the external os
- Through a small transverse incision at the lower margin of the umbilicus, the Veress needle was passed into the abdominal cavity. After confirming the proper placement of the needle,

pneumoperitoneum was created by connecting the needle to a tube which permitted CO<sub>2</sub>. 1-2 litre of the gas was introduced so as to obliterate liver dullness

- The trocar and cannula was inserted by directing the trocar towards the centre of the pelvis at an angle of 45°. Once in the peritoneal cavity, the trocar was removed from the cannula and replaced by Karl Storz laparoscope
- Double puncture was undertaken for visualizing the under surface of the ovaries or tubes and pouch of Douglas
- Trendelenberg position was given which allowed the intestinal loops to fall away from the anterior abdominal wall
- The uterus, both tubes along the whole length with fimbriae, both ovaries and the peritoneal cavity were examined serially for any pathology
- Diluted methylene dye was used for chromopertubation to determine tubal patency, if the diluted dye was seen in the tubes and definitive spill was observed from the fimbrial ends of the tubes, the tubes were considered patent
- The cannula was removed after the air in peritoneal cavity was removed. The incision was sutured with a single mattress suture with ethilon 2-0 reverse cutting. Postoperative management was done with antibiotics and IV fluids and analgesic. Analgesics were given when required.

**RESULTS**

Out of 70 patients who underwent HSG tubal block was detected in 34 cases. Out of these 34 cases tubal block was detected only in 17 cases by laparoscopy and chromopertubation. One case which showed patent tubes on HSG had unilateral tubal block on chromopertubation test. Accordingly, sensitivity of HSG for tubal patency comes out to be 0.72, specificity of 0.94, positive predictive value of 97.43%, negative predictive value of 51.61%, positive likelihood ratio of 12.28, land negative likelihood ratio of 0.30.

**DISCUSSION**

A cross sectional clinical study consisting of 70 infertility patients, both primary and secondary is undertaken to know the role of hystero-salpingography and diagnostic hystero-laparoscopy in the evaluation of infertility.

In present study, 50 cases (71.42%) were primary infertility and 20 cases (28.68%) were of secondary infertility (Table 1).

**Table 1: Type of infertility patients.**

Primary (n = 50)		Secondary (n = 20)		Total (n = 70)
No	%	No	%	
50	71.42	20	28.68	70

**Table 2: Age distribution in cases of primary and secondary infertility.**

Age in years	Primary		Secondary		Total	
	n = 50	%	n = 20	%	n = 70	%
21-25	20	40	2	10	22	31.42
26-30	27	54	9	45	36	51.42
31-35	3	6	8	40	11	15.71
36-40	0	0	1	5	1	1.4

chi square - 16.991 p < 0.002, significant.

In the present study, of all patients of primary infertility 40% belonged to age group 21 to 25 years, 54% to 26 to 30 years, and 6% to 31 to 35 years. Out of all patients of secondary infertility 10% belonged to age group 21 to 25 years, 45% to 26 to 30 years, and 40% to 31 to 35 years, and 5% to 36 to 40 years.

The minimum and maximum age of patients with primary infertility was 21 and 34 years respectively. The minimum and maximum age of patients with secondary infertility was 23 and 37 years respectively (Table 2).

**Table 3: Results of chromopertubation on diagnostic hysterosalpingoscopy.**

	Primary		Secondary		Total	
	n = 50	%	n = 20	%	n = 70	%
Unilateral block	6	12	2	10	8	11.42
Bilateral block	6	12	3	15	9	12.85
Bilateral patent tube	38	76	15	75	53	75.71
Delayed spillage	0	-	0	-	0	-

**Table 4: Pattern of tubal pathology as seen on hystero-salpingography.**

Pathology	Number (n = 70)	%
Both normal	39	55.71%
Right normal tube, left blocked	8	12.85%
Left normal tube, right blocked	11	8.57%
Bilateral tubal blockage	12	15.71%
unilateral hydrosalpinx	3	4.20%
bilateral hydrosalpinx	2	2.80%

The results of chromopertubation test, which was done in all the 70 cases as shown in Table 3. 75.71% of patients had bilateral positive chromopertubation test, 11.42% showed unilateral tubal patency and 12.85% had bilateral tubal block (Table 3). In present study of all patients who underwent HSG, 55.71% cases had both normal tubes, 12.85% had left tubal block, 8.57% had right tubal block,

15.7% had bilateral tubal block, 4.2% had unilateral hydrosalpinx and 2.8% had bilateral hydrosalpinx (Table 4).

Table 5 shows that there is a significant difference in findings of HSG and hystero-laparoscopy for tubal patency. In the present study, of all patients of primary infertility 40% belonged to age group 21 to 25 years, 54% to 26 to 30 years, and 6% to 31 to 35 years.

**Table 5: Comparison of incidence of tubal block between hystero-salpingography and diagnostic hystero-laparoscopy findings.**

Patency	Procedure	
	HSG (n = 70)	Hysterolaparoscopy (n = 70)
Patent	39 (55.71%)	53 (75.71%)
Blocked	31 (44.28%)	17 (24.29%)

chi square - 5.358, p = 0.026 <0.05, significant

**Table 6: Age Distribution of patients.**

Age group	Study conducted by					
	Sharma et al		Shetty et al		Present study	
	Primary	Secondary	Primary	Secondary	Primary	Secondary
21-25	62.20%	37.80%	23.50%	6.25%	40%	10%
26-30	52.80%	47.20%	32.40%	43.75%	54%	45%
31-35	-	-	32.40%	37.50%	6%	40%
36-40	-	-	11.70%	12.50%	-	5%

**Table 7: Results of chromopertubation test on hysterolaparoscopy.**

Results	Shetty et al	Sharma R et al	Meenal et al	Present study
Bilateral tubal block	8%	17.70%	3%	12.85%
Unilateral tubal block	28%	3.50%	16%	11.42%
Bilateral patent tubes	64%	55.50%	7%	75.70%
Delayed spillage	-	6.20%	2%	-

Out of all patients of secondary infertility 10% belonged to age group 21 to 25 years, 45% to 26 to 30 years, and 40% to 31 to 35 years, and 5% to 36 to 40 years.

In the study by Shetty et al, of all patients of primary infertility 23.5% belonged to age group 21 to 25 years, 32.4% to 26 to 30 years, and 32.4% to 31 to 35 years, and 11.7% to 36 to 40 years, while out of all patients of secondary infertility 6.25% belonged to age group 21 to 25 years, 43.75% to 26 to 30 years, 37.5% to 31 to 35 years, and 12.5% to 36 to 40 years.<sup>9</sup>

In the study by Sharma et al, of all patients of primary infertility 62.2% belonged to age group 21 to 25 years, 52.8% to 26 to 30 years, while out of all patients of secondary infertility 37.8% belonged to age group 21 to 25 years, 47.2% to 26 to 30 years.<sup>10</sup>

Thus our study only partly correlates with that of Sharma et al and Shetty et al shown in the Table 6. Table 7 shows the results of chromopertubation test in our study compared to that of Shetty et al, Sharma R et al, and Meenal et al.

In present study of all patients who underwent chromopertubation on hysterolaparoscopy, bilateral tubal block was found in 12.85% patients, unilateral tubal

block in 11.42% and bilateral patent tubes in 75.7% cases.

In study conducted by Shetty et al<sup>9</sup>, bilateral tubal block was found in 8% patients, unilateral tubal block in 28% and bilateral patent tubes in 64% cases.

In study conducted by Sharma R et al, bilateral tubal block was found in 17.7% patients, unilateral tubal block in 3.5% and bilateral patent tubes in 55.5% cases and delayed spillage seen in 6.2% cases.<sup>10</sup> In study conducted by Meenal et al, bilateral tubal block was found in 3% patients, unilateral tubal block in 16% and bilateral patent tubes in 79% cases and delayed spillage seen in 2% cases.<sup>11</sup>

**Table 8: Pattern of tubal pathology as seen on hysterosalpingography.**

Pathology	Bello TO	Present study
Both normal	60%	55.71%
Right normal tube, Left blocked	7.50%	14.20%
Left normal tube, Right blocked	1.70%	8.57%
Bilateral tubal block	7.50%	15.70%
Unilateral hydrosalpinx	7.50%	15.71%
Bilateral hydrosalpinx	3.30%	2.80%

Table 8 shows the results of hystero-salpingography in our study compared to that of T.O. Bello.<sup>12</sup> In present study of all patients who underwent HSG, 55.71% cases had both normal tubes, 14.2% had left tubal block, 8.57% had right tubal block, 15.7% had bilateral tubal block, 15.7% had unilateral hydrosalpinx and 2.8% had bilateral hydrosalpinx.

In Bello TO et al study of all patients who underwent HSG, 60% cases had both normal tubes, 7.5% had left tubal block, 1.7% had right tubal block, 7.5% had bilateral tubal block, 7.5% had unilateral hydrosalpinx and 3.3% had bilateral hydrosalpinx.<sup>12</sup>

**Table 9: Comparison of sensitivity and specificity.**

For tubal patency	Study	
	Swart et al	Present study
Sensitivity	0.65	0.72
Specificity	0.85	0.94

Table 9 shows a metanalysis that compared the diagnosis precision between HSG and hystero-laparoscopy demonstrated that HSG had sensitivity of 0.65 and specificity of 0.85 for tubal patency.<sup>13</sup> Accordingly they concluded that HSG was an important test for ruling out tubal obstruction however HSG has its limitations in detecting tubal patency. HSG was not reliable for detecting peritubal adhesions.

Compared to hystero-laparoscopy, HSG has only moderate sensitivity but relatively high specificity. If an occlusion is detected in HSG, there is 49% possibility of the tubes to be actually patent. However, when patency is demonstrated in HSG there is a little chance for the tubes to be actually occluded.

In HSG, while one tube can be observed to be patent, the other can be occluded. Whereas this observation may indicate one sided proximal tubal occlusion, most commonly this is due to the tendency of the contrast material during HSG, to enter into the tube with least resistance. Injection of contrast material during HSG can lead to the misdiagnosis of tubal occlusion following cornual spasm. Therefore, the occluded appearing tube is most likely to be normal.

## CONCLUSION

- Infertility is one of the major health problems affecting 10-15% of population
- Tubal pathology was detected in 38.57% cases of infertile women in the study
- This study emphasizes that patients with suspicious HSG frequently have normal tubes, but also have a significant likelihood of associated pelvic disease and so these patients require confirmatory hystero-laparoscopy

- HSG is a not a reliable indicator of tubal occlusion. However, when HSG suggests that the tubes are patent, this will be confirmed at hystero-laparoscopy in majority of women, and so HSG is a reliable indicator of tubal patency
- Nevertheless, incidence of associated pelvic disease is high enough to warrant hystero-laparoscopy if non-surgical treatment is unsuccessful
- These observations suggest that the use of hystero-laparoscopy and chromopertubation test should be considered as a gold standard in investigation of infertile women
- Hystero-laparoscopy enables formulating the line of management for infertile women
- Most effective treatment decisions and interventions can be made in the light of hysteron-laparoscopic findings in managing infertility
- Though hystero-laparoscopy is invasive the complications associated with the procedure can be minimized with good surgical skill
- HSG being simple and less invasive technique along with higher specificity and lesser complications, still should be considered as having significant role in management of patients with infertility and should be used as a preliminary measure in management of infertile couple
- Hystero-laparoscopy is a valuable technique for the complete assessment of female infertility, especially in symptomatic patients and should be used early in the diagnostic work up.

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