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Treatment of Proximal Tubal Occlusion by Transcervical Fluoroscopic Guide Wire Mediated Fallopian Tube Recanalization in Female Infertility

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Abstract: ***Introduction: As tubal factors comprise 25 to 30% cases of infertility and proximal tubal occlusion is associated with 30 - 35% of cases of tubal disease, the assessment of patency of fallopian tubes is an essential part of any infertility work up. Transcervical fluoroscopic guide wire mediated catheterization provides an access that makes cornual or proximal fallopian tube obstruction amenable to selective recanalization. In fallopian tube recanalization, a catheter and guide wire system are used to clear proximal fallopian tube obstructions. The aim of the study was to evaluate the role of transcervical guide - wire mediated fallopian tube recanalization in the treatment of proximal fallopian tube occlusion. Observations and Results: Total 60 subjects showed either unilateral or bilateral block on HSG. Bilateral block was more common than unilateral block. Total number of tubes showing blockage were 106. Prevalence of tubal blockage responsible for infertility was seen in 20% of study population. Prevalence of proximal tubal obstruction in infertile population under study was 15.33%. Prevalence of distal tubal occlusion in infertile population in this study was 5.66%. Tubal recanalization procedural rate was successful in 94.82%. Only tubes showing cornual block were subjected to catheterization. Four patients complained of mild discomfort or cramp like pain and 3 patients had spotting. Follow - up after 3 months for tubal patency showed re - occlusion in 4 patients whereas major complications like perforation or flare up of infection and allergic reaction to HSG contrast were not observed in this study. Conclusion: In the present study, transcervical guide wire mediated fallopian tube recanalization was successful in 94.82% of tubes. The procedure is advocated to diagnose precise site or sites of obstruction and to recanalize proximal obstructions of the tube. It does not affect the outcome of other treatment modalities such as GIFT, microsurgery or in vitro fertilization. Thus, it is an easy, non - surgical, comparatively non - invasive alternative to the standard treatment of surgical correction by hysteroscopy or resection anastomosis***

Keywords: Hysterosalpingography (HSG), Fallopian Tube Recanalization (FTR), Selective salpingography (HSS), Proximal tubal occlusion, Female infertility

1. Introduction

As tubal factors comprise 25 to 30% cases of infertility and proximal tubal occlusion is associated with 30 - 35% of cases of tubal disease, the assessment of patency of fallopian tubes is an essential part of any infertility work up.1Presently hysterosalpingography (HSG) and laparoscopic chromopertubation are the most commonly used techniques. Other new modalities are sonosalpingography, hysteroscopy, transcervical falloposcopy and ampullary and fimbrial salpingoscopy.2 The etiology of proximal tubal occlusion is not always clear. The causes could range from uterine fibroids, peritubal adhesions, infections, intratubal disease (endometriosis, salpingitis isthmicanodosa), etc resulting in intraluminal debris, intraluminal adhesions, stenosis, fibrotic occlusion, etc[3]. Microsurgical oviduct reconstruction remains the gold standard in terms of pregnancy rates with in vitro fertilization as an alternative therapy. But it is expensive, invasive, time consuming and requires frequent office visits.4 Moreover these do not have any encouraging results and is performed at a limited number of medical centres across the country. It also requires considerable expertise and experience. But the last decade has seen changes in the surgical management of proximal tubal occlusion away from resection anastomosis towards transcervical fallopian tube catheterization. Transcervical fluoroscopic guide wire mediated catheterization provides an access that makes cornual or proximal fallopian tube obstruction amenable to selective recanalization.5 Use of selective salpingography and fallopian tube recanalization has revolutionized the diagnosis and treatment of infertility. In fallopian tube recanalization, a catheter and guide wire system are used to clear proximal fallopian tube obstructions, the recanalization procedure is simple for intervention radiologist to perform and is successfully performed in most subjects (71 - 92%). Pregnancy rate after the procedure has been variable, with an average rate of 30%.6 The advantages of this procedure are - it is less expensive, less time consuming, little analgesia or no anesthesia is required, it is an office procedure, convenient to the patient and simultaneous diagnosis and correction of proximal tubal block can be carried out.

2. Aims and Objectives

Aim: To evaluate the role of transcervical guide - wire mediated fallopian tube recanalization in the treatment of proximal fallopian tube occlusion

Objectives:

1) To calculate procedural success rate.
2) To decide the prevalence of proximal tube occlusion in infertility.

3) To establish standardized procedure for guide wire mediated fallopian tube recanalization.
4) To note approximate number of subjects showing positive pregnancy tests during the study period.

Methodology

Study Design: Hospital based prospective study

Study setting: The study was conducted at Department of Obstetrics and Gynaecology and Interventional Radiology, Department of Radiodiagnosis, Government Medical College and Hospital, Nagpur.

Study period: The study was carried out over a period of thirteen months.

Sample size: Three hundred women undergoing routine check up for infertility, attending out patientDepartment of Gynaecology.

Target population: Subjects with primary as well as secondary infertility and who are willing to participate in the study.

Timing of study: The procedure is done in the early follicular phase of the menstrual cycle, approximately 8 - 10 days after the onset of menstruation. The timing of the procedure is similar to that of conventional hysterosalpingography and can be done simultaneous with the procedure.

Inclusion criteria:
1) Cases of primary as well as secondary infertility of any duration
2) Subjects whose partners semen analysis is normal.
3) Subjects willing to participate in the study.

Exclusion Criteria:
1) Subjects with suspected pregnancy
2) Subjects with active tuberculosis or pelvic inflammatory disease
3) Subjects with genital tract infection
4) Patients' husbands showing abnormal semen analysis
5) Subjects with history of tubal surgery
6) Subjects with associated anomalies of uterus and tubes
7) Subjects not willing to participate in the study.

3. Methodology

The study included subjects attending the out - patient Department of Obstetrics and Gynaecology, Government Medical College and Hospital, Nagpur for infertility work up. Patient's selection was done as per the inclusion criteria i. e. patients of primary as well as secondary infertility who were willing to participate in the study with no active focus of tuberculosis or genital tract infection and in whom the pregnancy is ruled out. Detailed history pertaining to infertility and other relevant history was asked and recorded. This was followed by thorough clinical examination. The subjects were then advised preliminary investigations including semen analysis of husbands of these subjects and ultrasound examination for pelvic pathology. Selected subjects (according to inclusion criteria) were then subjects to hysterosalpingography and subsequent fallopian tube recanalization in those showing proximal (cornual) tubal blockage (nipple sign). Subjects whose history would suggest the presence of adhesions, tubal surgery or pelvic inflammatory disease were excluded.

Procedure: Informed written consent was taken and under IV sedation and in lithotomy position, cervix visualised with sims speculum and a double balloon hysterosalpingography cannula inserted and HSG was performed. In those subjects showing proximal fallopian tube occlusion on HSG, a thin wall 5.5 French soft "Hockey stick" polyethylene catheter was manipulated into the ostium of the obstructed fallopian tube. Selective salpingography was then performed. Fallopian proximal tubal obstruction (FPO) was then confirmed. It helped to eliminate subjects with pseudo - obstruction or cornual spasm. Those subjects showing tubal blocks distal to isthmus with tubal pathology or abnormal fimbria were excluded from study. A steerable J shaped 0.035 F hydrophilic Terumo guide wire was advanced coaxially through the 3.5 French catheter. The guide wire was manipulated across the proximal obstruction and negotiated through the fallopian tube. The guide wire was advanced towards the end of the tube across the obstruction by to and fro movements. Selective salpingography through the 3.5 f catheter was then performed which confirmed reconstituted fallopian tube patency and the free contrast spillage into the peritoneal cavity. If the contralateral side was also blocked, then the procedure was repeated by reinserting the guide wire and directing the 5.5f catheter to the contralateral cornual end. The films were taken under fluoroscopic guidance. the whole dynamic procedure was recorded on a digital VCR and stored in cassette. The patient was observed for an hour and sent home with antibiotics and followed after a week and month. The outcome was measured in terms of patency of tubes attained and maintained, complications, organic pathology of tubes

4. Observations and Results

In this study, patients with primary infertility were more than secondary infertility. The discrepancy may be due to over anxiety and increased awareness about the curability of infertility problems. Majority of the subjects were in the age group 21 - 25 years (45.29%) followed by 106 patients in age group pf 26 - 30 years. The oldest subject was 40 years old. Out of 103 patients showed infertility of 1 - 2 years of duration (34.33%). Eleven subjects had infertility more than 10 years of duration (3.52%). Prevalence of secondary infertility was more in patients with longer duration of infertility. Total 60 subjects showed either unilateral or bilateral block on HSG. Bilateral block was more common than unilateral block. Total number of tubes showing blockage were 106. Prevalence of tubal blockage responsible for infertility was seen in 20% of study population. Proximal fallopian tube obstruction was responsible for 77% of causes of tubal pathology. Prevalence of proximal tubal obstruction in infertile population under study was 15.33%. prevalence of distal tubal occlusion in infertile population in this study was 5.66%.17 subjects with isthmic and fimbrial block were excluded from tubal recanalization i. e.26 tubes (24.52%). Tubal recanalization procedural rate was successful in

94.82%. Only tubes showing cornual block were subjected to catheterization. Successful recanalization was defined in our study as negotiation of guide wire beyond cornual block. Four patients complained of mild discomfort or cramp like pain and 3 patients had spotting. Follow - up after 3 months for tubal patency showed re - occlusion in 4 patients whereas major complications like perforation or flare up of infection and allergic reaction to HSG contrast were not observed in this study.

5. Discussion

Thurmond AS et al reported that obstruction of the uterine (proximal) end of the fallopian tube wasresponsible for female infertility and has variety of underlying causes[7]. In the setting of proximal FTO, fallopian tube recanalization (FTR) is a minimally invasive, ambulatory procedure with a technical success rate of up to 100%, with minimal postprocedural adverse events. One - year pregnancy rate following FTR is approximately 41%, with successful delivery of full - term infants in 84% of pregnancies. This minimally invasive, outpatient, image - guided procedure is an alternative to vitro fertilization (IVF) and intracytoplasmic sperm injection (ICSI) and should be top - of - mind in the setting of infertility due to proximal FTO.8Total 87 subjects (29%) showed either unilateralor bilateral block on hysterosalpingography. In these patients selective hysterosalpingography (HSS) was done to confirm the block and to exclude out the false positive cases. It is a diagnostic test in which the fallopian tube is directly opacified by injecting contrast medium through a catheter placed in tubal ostium. It helps to eliminate patients with pseudo - obstruction or cornual spasm (Wiedemann et al; Thurmond AS).9Selective salpingography revealed 27 subjects out of the 87 to have patent tubes (31.3%). Thus, the remaining 60 patients demonstrated true block. Study by N Inagaki et al twenty - seven (79.4%) of 34 patients with unilateral occlusion diagnosed by HSG were shown to have normal patency by HSS. Of 12 women with bilaterally normal patent tubes confirmed by HSS, 8 (66.7%) achieved normal pregnancies within 1 year. Seven (53.8%) of 13 patients with bilateral occlusion found by HSG were shown to have normally patent tubes by HSS.[10]False positive rate of hysterosalpingography was 39%.[11]Woolcott R et al achieved patency in 39 (34.5%) out of 113 tubes showing Proximal tubal occlusions by selective salpingography alone.1[2] In our study, the false positivity of HSG was found to be 31.03%. of the 60 patients with true block, 14 patients (6.33%) showed unilateral block and bilateral black was present in 46 (22%) subjects whereas 240 patients showed normal patent tubes (71%). Thus, the bilateral block was more common than unilateral block (23.33%). Similar findings were reported by Woolcott R et al where bilateral obstruction was present in 47 patients (71.21%) and unilateral in 19 patients (28.78%) of total 66 subjects.[12] Total number of blocked tubes in our study was thus found out to be 106.

Prevalence of tubal blockage responsible for infertility in the present study population was 20% (60 of 300 subjects). These 60 patients with 106 blocked fallopian tubes were further categorized according to the type of block. Cornual (interstitial) block was seen in 80 tubes (74, 83%) in 46 patients (77.01%), isthmic (mid tubal) block in 11 (10.96%) tubes in 8 subjects (13.79%) and 15 tubes (14.19%) showed fimbrial block in 9 (16.09%) subjects. Everyone has different idea of the term “proximal” and “distal”. We in this study have considered proximal as the portion of the fallopian tube in the cornual or interstitial portion. Obstruction in the ampullary or fimbrial region were considered to be distal obstruction and further excluded from the study. Thus, the prevalence of proximal tubal occlusion in infertile population under study was 15.33% (46 of 300 subjects in study). The prevalence of distal tubal occlusion in our study was 5.66%. Patients with isthmic or fimbrial block (26 tubes) were further excluded from the study.

Patients whose history would suggest the presence of adhesions, tubal surgery or pelvic inflammatory disease were excluded. The reason being tubal blocks in them were probably not due to flimsy adhesions or debris but more likely due to thick fibrous adhesions that can not be removed by transcervical FTR. Patients with associated tubal pathology would not benefit from recanalization of proximal ends with persistent pathology of distal ends of the tubes. Hence attempts to recanalize tubes distally than the interstitial or isthmic segments are not recommended.

Successful recanalization was defined when tubes distal to the obstruction were visualized irrespective of the tubal outcome. In our study, out of total, 80 tubes that showed proximal block, recanalization was attempted. Successful recanalization was achieved in 94.82% (75 of 80%). Different studies by different authors have documented technical success rate of overcoming obstruction and visualizing distal tubes between 71 - 92% according to Thurmond AS.[13] Large EKsuccessfully recanalized proximal portions of the tubes. In 79 (82%) of 96 patients with obstructed tubes. Kelekis Dreported success rate of 90% (18 of 20 tubes).[14] In the study of Mallarini G, catheterization and selective salpingograhy have been successful in 93.9% of the cases.[15] Failures have been ascribed to obstructive organic diseases, where it was impossible to overcome the stenosis with the catheter or the guide wire. Of the various studies done, some authors used the coaxial catheter system like Thurnmond et al, Capitanio et al and Lange and Dunaway. Confino et al used balloon catheter system, Gleicher et al documented recanalization rate of 77% in a study group of 25 patients using direct guide wire cannulation.[16] Our study which was done with similar technique, showed comparable results.

Studies	Number of patients	Percentage
Lange et al	157	82
Lelekis et al	20	80
Thurnmond AS et al	100	86
Mallarini G et al	246	93.9
Hayashi N et al	42	96
Motta et al	23	95
Gazzera et al	302	94
Atalah N et al	53	97.5
Confino et al	89	92
Capitanio et al	180	75.90
Gleicher et al	25	77
Present study	63	94.82

Because many patients with proximal tubal occlusion have bilateral involvement, recanalization of both tubes is

attempted during the same procedure. When one tube is patent, attempts to recanalize a contralateral proximally obstructed tube is justified because of the ease of the procedure and the presumed benefit.

The procedure was unsuccessful in 5.17% of tubesi. e. in 5 tubes showing obstruction. Failure of recanalization was attributed to organic tubal disease. In the study, A S Thurnmond pointed out that occasionally, it may be impossible to engage the fallopian tube because of surgical malformation or because of uterine leiomyomas or polyps. Successful catheterization of the tube but failure to recanalize is likely due to fibrotic scarring of the tube from salpingitis, endometriosis or surgery. Recanalization is possible but potentially less successful in women who have occluded tubes after surgical anastomosis for reversal of tubal ligation. Reported success rates per fallopian tube are presumably related to the degree of postoperative scarring at the anastomosis and range from 44% to 77%. In patients with salpingitis isthmica nodosa, recanalizaton was successful in 77% - 82% of tubes but was technically more challenging. Mallarini G et alascribed failures (5.6%) to obstructive organic diseases, where it was impossible to overcome the stenosis with the catheter or the guide - wire, but Hayashi N et alsuccessfully negotiated 6 out of the 13 tubes blocked at the distal portion.[17]

Successful recanalization of 75 tubes yielded 64 tubes with normal course, calibre and free intraperitoneal spillage, while 16 tubes (20%) had coexisting disease of the distal (ovarian - end) that was diagnosed after the proximal obstruction was cleared. Lange E K and Dunaway HE reported prevalence of coexisting distal tube disease in 29 (18%) of the patients.[18]

Complications: Complication of fallopian tube recanalization are unusual and are of little significance when they do occur. The possibilities of tubal perforation, vasovagal response, and adnexal infection were discussed with the patients. The theoretical possibility of idiosyncratic reaction to the contrast agent was mentioned, although this complication had never been reported following FTR or HSG. If one or both tubes are recanalized, the possibility of a tubal pregnancy was discussed with the patient and she was advised to visit again as soon as she misses a period and has a positive pregnancy test.

In this study no tubal perforations or continuous bleeding were reported. Out of the total, 30 patients (37.5%) complained of mild discomfort and pain during the procedure while “cramp like” pain was experienced by 4 patients (5%). In different studies identified, the rate of tubal perforation ranged from 1% (4/417) and 11% (4/38). Other reported complications were sepsis in 0.9% (2/234) of patients, and pain requiring medication in 3% (7/234 and 4/150) of patients. Thurmond AS reported rate of early tubal occlusion to be less than 30%.[7] In their follow up study, Mallarini GG et al reported, after 12 months 4 of 10 patients had normal tubes, while 6 presented a new unilateral or bilateral PTO; however no major complications occurred.1[5] Hayashi N observed perforation or subintimal injury in 3 of 52 tubes with PTO.1[5] In the study by Gazzera C et al a 12 month follow u of 10 women undergoing HSG showed in approximately 60% of cases a new unilateral or bilateral proximal tubal obstruction. No immediate or severe procedure related complications were observed. Helmy A revealed re - occlusion of 3 tubes in 2 non pregnant patients. Although recanalization of the fallopian tubes has high success rate, some tubes do occlude (Thurnmond A S1999).7In several series of patients who failed to achieve pregnancy 6 - 12 months after successful proximal tubal recanalization, only 62% of the tubes remained patent. Repeat recanalization is usually successful. According to Lange 18 of 25 with successful transvaginal catheter dilatation and 6 - month follow up salpingography, the tubes remained patent.[18]

Out of 64 tubes with recanalization, 47 tubes (73.43%) were patent on HSG at the end of 3 months and 4 tubes demonstrated block which was cleared by repeat FTR. Lange et al reported that 6 - month follow up HSG showed a patency rate of 72%.[18]Thurnmond et al reported 63% patency rate after repeat HSG at 3 - 6 months.[7]

Pregnancy outcome:

As this was carried out during the short period of 13 months, it was practically impossible to study the pregnancy outcome of these patients. So, follow up was not done for pregnancy outcome. However during the course of the study, two patients with positive pregnancy tests were observed one of which had missed abortion.

6. Conclusion

In the present study, transcervical guide wire mediated fallopian tube recanalization was successful in 94.82% of tubes. There were minimal complications like uterine cramping and spotting. However, it was unsuccessful in 5.17% of tubes where other standard procedures like hysteroscopic recanalization under laparoscopic guidance is advocated. The results of the procedure are best in those patients whose tubes are blocked due to flimsy adhesions and debris and these constitute significant percentage of women with infertility. Transcervical fallopian tube recanalization offers information about fallopian tubes that may preclude the need for surgery. The procedure is advocated to diagnose precise site or sites of obstruction and to recanalize proximal obstructions of the tube.

It can be performed during HSG itself, thereby saving time and cost, thereby saving time and cost. There is as such no contraindication for repeat FTR in patients with re - occlusion. It does not affect the outcome of other treatment modalities such as GIFT, microsurgery or in vitro fertilization. Thus, it is an easy, non - surgical, comparatively non - invasive alternative to the standard treatment of surgical correction by hysteroscopy or resection anastomosis

Declaration of Conflict of Interest: There is no conflict of interest in the study.

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Table 1: Showing Type of Infertility (n=300)

Type of Infertility	Number of Patients	%
Primary	245	81.67
Secondary	55	18.33

Table 2: Showing Age Wise Distribution of Study Subjects

Age (years)	Number of Patients	%
<20	10	2.94
21 - 25	135	45.29
26 - 30	106	35.29
31=35	40	13.52
>35	9	2.94

Table 3: Showing Duration of Infertility

Infertility (years)	Number of Patients			%
	I	II	Total	
1 - 2	88	15	103	34.33
2.1 - 3	63	8	71	23.66
3.1 - 4	37	6	43	14.11
4.1 - 5	5	7	22	7.05
5.1 - 6	18	5	23	7.64
6.1 - 7	2	2	4	1.17
7.1 - 8	7	9	16	5.29
8.1 - 9	0	2	2	0.66
9.1 - 10	2	3	5	1.76
>10	4	7	11	3.52

Table 4: Showing Type of Block in fallopian Tubes

Block	Number of Patients	%
Unilateral	14	6.33
Bilateral	46	22.0

Table 5: Showing Site of Block in Fallopian Tubes

Site of Block	Number of Tubes n (%)	Number of Patients n (%)
Cornual	80 (74.83)	46 (77.01)
Isthmic	11 (10.96)	8 (13.79)
Fimbrial	15 (14.19)	9 (16.09)
Total	106	63

Table 6: Showing Tubal Recanalization Outcome

Tubal Recanalization	Number of Tubes n (%)	Number of Patients n (%)
Attempted	80 (74.83)	46 (77.01)
Successful	75 (94.82)	43 (93.47)
Unsuccessful	5 (5.71)	3 (6.52)
Not attempted	26 (24.52)	17 (26.98)
Patent tubes	64 (80.9)	40 (86.95)
Post Procedural Pathology	16 (20.0)	08 (17.39)

Table 7: Showing Complications of Procedure

Complications	Number of Patients	Percentage (%)
Mild discomfort/ “Cramp like pain”	4	8.69
Perforation	Nil	Nil
Sepsis	Nil	Nil
Spotting	3	6.52
Re - occlusion	4	6.25
Allergic reaction	Nil	Nil