

Hydrotubation in the female infertility management– An important tool in low resource settings

Shalini Chauhan¹, Priya Singh², Anand Shukla^{3*}

¹Associate Professor, Departement of Obst & Gynae, Autonomous State Medical College Society, Ayodhya, Uttar Pradesh, India

²Assistant Professor, Department of Obst & Gynae, MRA Medical College, Ambedkarnagar, Uttar Pradesh, India

³ Associate Professor and HOD, Department of Paediatrics, Rajarshi Dashrath Autonomous State Medical College Society, Ayodhya, Uttar Pradesh, India

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Abstract

Background: Infertility remains a major reason for gynaecological consultation in developing countries. HSG is the first line diagnostic tool for assessing the status of tubes. It was hypothesised that hydrotubation which is a simple, effective and non invasive for tubal factor increase the pregnancy rate. **Aim:** To determine the outcome of therapeutic hydrotubation (tubal flushing) in patients with tubal infertility and unexplained infertility. **Material and Methods:** This prospective study was carried out in MRA medical college, Ambedkar Nagar district of Uttar Pradesh, India among Infertile women with tubal and unexplained infertility. The study period was of 4 years from august 2014 to July 2018. During this period 178 hydrotubation were performed, but 150 cases that were followed up for at least 6 months post procedure were analysed in this study. All patients were routinely investigated with hormonal profile, HSG and semen analysis by known procedure. Tuberculosis was also excluded in all patients. For hormonal upset, proper interventions were done. SPSS software version 22.0 was used for data analysis. **Results:** One hundred and fifty patients that had therapeutic hydrotubation over 4 years were analysed. The age range was 23-38 years with mean of 34 years. Secondary infertility was found in 30 (20%) patients and primary infertility in 120 (80%) patients. Indication for hydrotubation were bilateral cornual blockage (8.66%), bilateral fimbrial blockage (20%), bilateral hydrosalpinges (24.66%), unilateral blockage (33.33%) and unexplained infertility (13.33%). Eighty three conceptions were recorded in this study and the overall conception rate was 55.3% and post-hydrotubation patency rate was 70.8%. Pregnancy outcome of 83 conceptions were 84.4%, preterm pregnancy 9.2%, miscarriage 4.2% and ectopic pregnancy 2.2%. Recorded complications were pelvic pain in 105(70%) patients and vaginal bleeding in 36(24%) patients. **Conclusion:** Therapeutic hydrotubation may be beneficial in low resource settings, especially in incomplete tubal blockage.

Key words: Hydrotubation, female infertility, tubal flushing, tubal infertility, unexplained infertility.

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Introduction

Infertility remains a major reason for gynaecological consultation in developing countries. It is associated with social consequences like marital instability, divorce, polygamy, prostitution and suicide in extreme cases. Tubal disease is the major cause of infertility[1]. Methods of managing tubal factors in infertility range from gaseous insufflation, hydrotubation, microsurgery, hysteroscopic catheterisation and in vitro fertilisation[2]. HSG is the first line diagnostic tool for assessing the status of tubes. It is a relatively easy procedure which provides a measure of tubal diameter, locates tubal occlusion and identifies pathologies such as hydrosalpinges and SIN. The study hypothesised that hydrotubation which is a simple, effective and non invasive for tubal factor increases the pregnancy rate and aimed to determine the outcome of therapeutic hydrotubation (tubal flushing) in patients with tubal infertility and unexplained infertility.

Materials and methods

This was a prospective study carried out in MRA medical college, Ambedkar Nagar district of Uttar Pradesh, India after taking permission from the institution ethical committee. The study period was of 4 years from August 2014 to July 2018.

*Correspondence

Dr. Anand Shukla

Associate Professor and HOD, Department of Paediatrics, Rajarshi Dashrath Autonomous State Medical College Society, Ayodhya, Uttar Pradesh, India.

E-mail: dranandshukla28@gmail.com

During this period 178 hydrotubation were performed after taking informed consent, but 150 cases that were followed up for at least 6 months post procedure and were included in the final analysis in this study. The inclusion criteria and indications for hydrotubation were unilateral and bilateral tubal pathology, hydrosalpinx and unexplained infertility. The patients were screened and appropriately treated for pelvic infection before they were subjected to hysterosalpingogram (HSG) and subsequently hydrotubation. Patients also had pelvic sonogram pre- and post-procedure. The essence of the pre-HTB pelvic sonogram was to rule out free fluid collection in the pelvis, so as not to mistake it for successful HTB evidenced by free fluid collection in the pelvis post-HTB. Tuberculosis was also excluded in all patients. All patients were routinely investigated with hormonal profile, HSG and semen analysis by known procedure. For hormonal upset, proper interventions were done.

Hydrotubation was carried out as an outpatient procedure during the 6th to 10th day of a menstrual cycle. The patients received short acting intravenous analgesic agent. The cervix was cannulated with a Leech-Wilkinson cannula and 50ml loaded syringe attached to the cannula was used to flush the fallopian tubes. The solution for HTB was made up of normal saline, crystalline penicillin and hydrocortisone; 50 to 100 ml of the solution was used per procedure.

Post procedure, patients were transferred to the recovery room, where they were given a dose of injectable non-steroidal anti-inflammatory analgesia. Following full recovery, they were discharged on analgesics and prophylactic antibiotics. Repeat HTB was done on day

8 and day 10 of menstrual cycle. Same procedure was repeated in subsequent 2 or 3 menstrual cycles depending on resistance encountered during tubal flushing.

They were followed up in the gynaecological clinic. Their first visit was the next menstrual cycle, during which ultrasound scan was performed to confirm ovulatory cycle and were counselled on timed intercourse. Those patients with anovulatory cycle were placed on clomiphene citrate in subsequent menstrual cycles.

The 150 patients that have hydrotubation were divided into three main groups as follows:

Group A: patients that had bilateral cornual or fimbrial blockage and bilateral hydrosalpinges.

Group B: patients that had unilateral tubal (cornual or fimbrial) blockage.

Group C: patients that had unexplained infertility i.e. normal HSG.

SPSS software version 22.0 was used for data analysis.

Results

A total of 150 patients that had hydrotubation over a period of 4 years were analysed. Of the 150 patients, 92(70.8%) had evidence of post-HTB patency of the fallopian tube(s) confirmed with sonogram and 83(55.3%) patients out of the latter went ahead to conceive.

Patients profile: the mean age of the patients was 34 years with age range of 23-38 years. Of the 150 patients, 55 (36.66%) had never delivered before and the highest number of childbirth amongst the category of patients that had delivered before was three. 42(28%) patients had no history of previous abortions. Spontaneous abortion accounted for 28(25.9%) patients of cases and induced abortion 69 (63.88%) patients while the remaining eleven (10.18%) patients had both spontaneous and induced abortions (Table 1).

Table 1: Profile of Patients (n=150)

| Variable | No. | (%) |
|----------------------------|-----|-------|
| Age(years) | | |
| 22-27 | 57 | 38 |
| 28-33 | 77 | 51.33 |
| 34-38 | 16 | 10.66 |
| Previous delivery | | |
| 0 | 55 | 36.66 |
| 1 | 62 | 41.33 |
| 2 | 21 | 14 |
| 3 | 12 | 8 |
| Previous abortion | | |
| Nil abortion | 42 | 28 |
| Spontaneous | 28 | 25.9 |
| Induced | 69 | 63.88 |
| Spontaneous and induced | 11 | 10.18 |
| Type of infertility | | |
| Primary | 120 | 80 |
| Secondary | 30 | 20 |
| Duration of infertility | | |
| 1-5 | 97 | 64.66 |
| 6-10 | 35 | 23.33 |
| >11 | 18 | 12 |
| Frequency of hydrotubation | | |
| Once | 13 | 8.66 |
| Twice | 122 | 81.33 |
| Thrice | 15 | 10 |

Primary infertility was the commonest type of infertility in 120 (80%) patients and maximum patients had been infertile for durations of 1 to 5 years. Frequency of hydrotubation in this study showed that 13 (8.66%) patients had it in one cycle, 122(81.33%) patients in two cycles and 15(10%) patients had it in three cycles.

Indications for hydrotubation and pregnancy attainment: the indication for hydrotubation showed that patients with bilateral tubal blockage (group A) accounted for 80 (53.33%) of cases. This was followed by unilateral tubal (group B) in 50 (33.33%) cases

and patients with unexplained infertility (group C) accounted for 20 (13.33%) patients of cases.

Percentage ratio of conception per indications for hydrotubation, showed that the highest conception per indication (70%) was achieved in group A and the least (32%) in group B. This reveals that hydrotubation is more effective in treating patients with bilateral tubal blockage followed by unexplained infertility and unilateral blockage (Table 2). In this study, the overall conception rate following hydrotubation was 55.3%.

Table 2: Group distribution of patients and post hydrotubation attainment of conception (n=150)

| Group | | | Attainment of conception | | Percentage ratio of conception per group (%) |
|-------|-----|-------|--------------------------|-------|--|
| | No. | (%) | No. | (%) | (%) |
| A | 80 | 53.33 | 56 | 37.33 | 70 |
| B | 50 | 33.33 | 16 | 10.66 | 32 |
| C | 20 | 13.33 | 11 | 7.33 | 55 |

Overall rate of conception is 55.3%.

Post hydrotubation tubal patency and attainment of conception: tubal patency was confirmed in 112 patients out of 150 with pelvic sonography and of these 83 patients conceived. All patients that conceived in this study had evidence of tubal patency post-HTB. This gives us an overall percentage ratio of 74.10% conceptions following post-HTB evidence of tubal patency.

Except for patients with unexplained infertility (group C), the percentage ratio of conception positively correlated with evidence of tubal patency following hydrotubation (Table 3). This means that patients with post-HTB confirmation of tubal patency with sonogram have more chances to conceive compared to patients with no evidence of post-HTB tubal patency.

Table 3: Evidence of post hydrotubation tubal patency and conception rate in the groups

| Group | Post-HTB tubal patency (n=112) | | Attainment of conception (n=83) | | Percentage ratio of conception post-HTB patency (%) |
|-------|--------------------------------|-------|---------------------------------|-------|---|
| | No. | (%) | No. | (%) | |
| A | 67 | 59.8 | 56 | 67.47 | 83.58 |
| B | 25 | 22.3 | 16 | 19.28 | 64 |
| C | 20 | 17.86 | 11 | 13.25 | 55 |

Overall percentage ratio of conception following evidence of post-HTB tubal patency = 74.10%.

*HTB= hydrotubation

Complications of hydrotubation and pregnancy outcome: there was no major complication recorded in this study that warrants hospitalisation. Minor complication/ complaints encountered were pelvic pain in 105(70%) patients and vaginal bleeding in 36(24%) patients. These patients were treated on outpatient basis.

The outcome of the 83 conceptions revealed that 70(84.4%) ended up in term pregnancy, 8(9.2%) in preterm delivery and three (4.6%) in miscarriage. 2 (1.8%) conception were ectopic pregnancies (Table 4).

Table 4: Outcome of pregnancy (n=83)

| Variable | No. | (%) |
|-------------------|-----|------|
| Term pregnancy | 70 | 84.4 |
| Preterm pregnancy | 8 | 9.2 |
| Miscarriage | 3 | 4.6 |
| Ectopic pregnancy | 2 | 1.8 |

Table 5 depicts that the distribution of patients with respect to conception and patency, in which majority of patients having conception as well as patency were belongs to group A, followed by group B.

Table 5: Distribution of patients with respect to conception and patency

| Group | | Conception | | Patency | | P-Value |
|-------|--------------------|------------|------|---------|------|---------|
| | Number of Patients | n | (%) | n | (%) | |
| A | 80 | 56 | 70.0 | 63 | 78.8 | <0.0001 |
| B | 50 | 16 | 32.0 | 42 | 84.0 | |
| C | 20 | 11 | 55.0 | 0 | 0.0 | |

Table 6 shows the ANOVA table. The one way analysis of variance (ANOVA) is used to compare therapeutic hydrotubation (tubal flushing) in patients from all Group A(patients that had bilateral cornual or fimbrial blockage and bilateral hydrosalpinges), Group B(patients that had unilateral tubal (cornual or fimbrial) blockage) and Group C(patients that had unexplained infertility i.e. normal HSG, shows significance difference between them.

Table 6: One way analysis between groups

| Source of Variation | SS | df | MS | F | P-value | F crit |
|---------------------|----------|-------|----------|----------|----------|----------|
| Between Groups | 961.4244 | 3 | 320.4748 | 5.346957 | 0.001118 | 2.605761 |
| Within Groups | 624772.1 | 10424 | 59.93593 | | | |
| Total | 625733.5 | 10427 | | | | |

Table 4 shows the ANOVA table. The one way analysis of variance (ANOVA) is used to compare the ALS of patients from all departments in different seasons <0.05 shows significance difference between average length of stay. LOS is maximum in monsoon (7.94 days) and minimum in summer (7.11 days).

Discussion

The assessment of fallopian tubes patency is an integral and pertinent step in the evaluation of female infertility[3]. Also, the treatment of tubal factor in infertility management is most difficult and subject to debates[2]. In this study, hysterosalpingogram was used to assess patency of the fallopian tubes though not as accurate as laparoscopy and dye test, it has been reported to have positive predictive value between 61.7 to 73%[4-5]. Hydrotubation for therapeutic intervention was employed as a last resort of treatment for these patients because it is a simple, cheap and minimally invasive procedure with low risk of complications. The inclusion of antibiotic (crystalline penicillin) and steroid (hydrocortisone) in the formulation of hydrotubation solution used in this study, was based on study by Johnson and Watson[6] that reported reduced infection and increased pregnancy with live birth rate when used after reproductive pelvic surgery to enhance fertility. Other studies[7,8] have reported fertility enhancing effect of tubal flushing especially with oil soluble medium, we used saline solution in our study due to the side effects of oil media and because our intervention was principally for therapeutic reason. Oil media have been associated with persistent contrast medium within the pelvis, allergy or anaphylaxis reaction from intravasation and formation of lipogranuloma on a long term. It is therefore not surprising that we only recorded minor complaints with the use of water medium in our study. The patients in our series had pre-HTB screening for pelvic

infection and post-HTB antibiotic prophylaxis. We were guided in this direction by the recommendation of the Royal College of Obstetricians and Gynaecologists[9] for women going for uterine instrumentation and the finding of clinical infection following hysterosalpingogram by Forsey et al[10]. We employed post-HTB sonogram to assess patency of the fallopian tube(s) following the procedure. This was based on the results of other studies that reported accuracy rate of diagnostic saline HTB ranging from 82.9 to 87.1%[5,11]. Excluding patients with unexplained infertility, our results show that the chances of conception increased with evidence of post-HTB tubal patency. Furthermore, evidence of post-HTB tubal patency is of most predictive value in terms of conception rate in patients with peritubal adhesions and least in patients with unexplained infertility. On the whole, the 70.8% conception rate recorded in patients with post-HTB evidence of tubal patency, also help to buttress the effectiveness of hydrotubation in the evaluation of tubal patency. In this study, the overall conception rate of 55.3% recorded in 150 patients that had therapeutic hydrotubation is encouraging, when we considered the "hopeless" nature of these cases in a resource constrained setting like ours. The hypothesis by Sulak et al[12] that proximal tubal blockage is caused by plugs of amorphous materials that occlude the tubal lumen without the presence of any tubal wall damage, made us to include bilateral cornual end tubal blockage as one of the indication for hydrotubation. The pregnancy outcome is also encouraging, with term pregnancies mainly recorded. Outcome of pregnancies are comparable to figures reported with the use of oil-soluble media. Though use of oil-soluble contrast is associated with an increase in the odds of live births but not pregnancy rates when compared with water soluble

media[13].Hydrotubation has been also used successfully in the treatment of tubal infertility in other low resource settings[14, 15].

Conclusion

The reliability on HSG for assessing the fallopian tubes was a major limitation of this study. Nonetheless, we found therapeutic HTB beneficial in the management of female infertility, especially incomplete tubal occlusion and unexplained infertility in resource poor settings, where modern technology for management are mostly unavailable and expensive. However, a randomised controlled trial with pre-HTB laparoscopic evaluation of the fallopian tubes is recommended, more especially for cases with incomplete tubal occlusion and unexplained infertility.

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