

Hydrotubation in the Management of Female Infertility: Outcome in Low Resource Settings

Prabodh S Soreng¹, Seema Das^{2*}, Javed Miyadad³

¹Associate Professor, Department of Obstetrics & Gynecology, Jalpaiguri Govt Medical College & Hospital, West Bengal, India

²Assistant Professor, Department of Obstetrics & Gynecology, Jalpaiguri Govt Medical College & Hospital, West Bengal, India

³Specialist Medical Officer, Department of Obstetrics & Gynecology, Baruipur SD & SSH, Kolkata, India

***Address for Correspondence:** Dr. Seema Das, Assistant Professor, Department of Obstetrics & Gynecology, Jalpaiguri Govt Medical College & Hospital, West Bengal, India

E-mail: cmadas0@gmail.com

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ABSTRACT

Background: Infertility is a main global concern, specifically for the resource-limited settings where the accessibility for the advancement of the fertility treatment is limited. The Tubal pathology is the main specific contributor for the female infertility. Hydrotubation is simple as well as cost-effective, which helps to improve the patency and fertility related outcomes.

Methods: The study was the prospective randomized controlled trial which was conducted among 128 patients who were infertile. Random allocation was performed for both of the hydrotubation (n=64) and control (n=64) groups. Baseline clinical and infertility evaluation were conducted. The pregnancy associated outcomes which were followed by the hydrotubation and standard infertility management were performed.

Result: Mostly women were of age between 24–29 years accounted for 73.4%, rather than the baseline parameters of the groups. 69.5% showed Primary infertility, while the 39.8% finding of HSG showed the left-sided tubal blockage. 28.1% (18/64) of women showed the hydrotubation rather than the 7.8% (5/64) in controls. Positive or delayed tubal spillage on laparoscopy was related with the improved rate of conception, while the unilateral tubal non-spillage was associated with the failure of pregnancy.

Conclusion: The study concluded that the Hydrotubation showed better rate of pregnancy among women with the tubal infertility.

Key-words: Hydrotubation, Female Infertility, Tubal Infertility, Pregnancy Outcome, Randomized Controlled Trial

INTRODUCTION

Infertility among women is a complicated problem with a wide range of aspects, such as biomedical, social-economic and psychosocial issues. In a predominantly pronatal society, such as India, it has not given fair consideration for infertility treatments until now. A large body of new research has uncovered many emotional issues that mothers are struggling with because of the extended time it is taking for them to have a child (i.e.

anxiety, depression and social isolation).

The problems are made much worse by the fact that access to inexpensive public fertility clinics is very limited across many geographic areas in India ^[1,2]. The large number of women is also experiencing pressure from their families to have a child, making it very difficult for them to figure out how to negotiate their way through a health system that is fragmented (both traditional and modern clinics) and has many structural obstacles (such as high costs and not enough social and psychological support/counselling) ^[1]. Therefore, there is an urgent need for fair, equitable and person-centred reproductive services that include mental health support in the care of women who are experiencing infertility ^[1,2].

Qualitative data from New Delhi demonstrates that masculine norms divert diagnostic label from male

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partners while many females are forced to seek care in more than one source because of economic insecurity combined with lack of social support ^[3]. With regards to etiology, there are clear differences when doing a cohort analysis showing primary infertility has largely due to ovulatory dysfunction; however, typically have polycystic ovary syndrome primarily and secondary infertility tends to have higher incidence of uterine factors than ovulatory factors ^[4]. The unfounded cases of infertility highlight continued diagnostic lag that should incorporate into clinical family planning practice both these sociocultural aspects and provide an outcome based on standardized type of identifiable cause ^[3,4].

In India, persistent inflammatory and fibrotic damage to the fallopian tubes causing impaired ciliary function and obstructed tube openings has been identified as the most prevalent cause of tubal factor infertility. Female genital tuberculosis can lead to a condition called granulomatous salpingitis with significant amounts of fibrous tissue causing disruption of gamete transport ^[5]. This condition also presents with immune dysfunction and an abnormal immune response (Th1–Th2) as well as being associated with altered endometrial receptivity which adversely affects embryo implantation. For these reasons, there are currently stratified clinical pathways recommending an integrated approach to treat females with irreversible damage to their fallopian tubes with both anti-tuberculosis medications and assisted reproductive technology such as in-vitro fertilization (IVF) ^[5]. In addition, in India, few studies showed a number of host-genomic factors such as TLR8 polymorphisms and a variety of metabolic biomarkers that when measured will inform more precise risk profiles for patients and lead to better targeted and effective fertility-preservation techniques ^[5]. The lack of insurance, high out-of-pocket expenses and inadequate public health service capacity lead to delays in seeking care and poor quality of care; therefore, converting these advanced tertiary standards into equitable clinical outcomes requires strong financial support ^[6,7].

Hydrotubation is used to assess and, where needed, correct any issues with the fallopian tubes. Hydrotubation is typically performed transcervically by integrating the insertion of a liquid into the fallopian tube, which can be considered an effective, non-invasive way for women in India to achieve pregnancy ^[8]. Infertility due to genital tuberculosis is a significant cause

of tubal infertility in endemic areas; however, there is often a low yield of positive culture results, leading to the need for timely intervention through the uterus and fallopian tubes to avoid permanent fibrotic changes ^[9]. In addition to the mechanical flushing motion associated with hydrotubation, the liquid used for hydrotubation has a therapeutic effect, as the oil used to perform hydrotubation can increase fertility by creating a suitable environment for implantation in the uterus and fallopian tubes and excessive fluid can be used in conjunction with antimicrobials to reduce cases of infertility due to suspected subclinical infection prior to progression to permanent endosalpingeal scar formation ^[8,9].

The research assessed hydrotubation and explored it as a viable low-cost, outpatient alternative to high-cost assisted reproductive technologies in resource-deprived Indian locations.

MATERIALS AND METHODS

Study design- The study was an institution-based prospective randomized controlled trial to evaluate the Hydrotubation for the management of the female infertility. The study was conducted for the Department of Obstetrics and Gynecology, Eden Hospital, Medical College Kolkata, for the duration of about 18 months from March 2019 to August 2020. Total 128 patients were of age between 24–36 years with the tubal infertility were selected for the study. All of the participants were taken with the informed consent. All patients were categorized into two groups, by the simple randomization software, where the n=64 for the hydrotubation and n=64 for the control groups, which have received with the standard process of infertility management. Baseline demographic, clinical, hormonal, radiological, and semen analysis were analysed. Hydrotubation was performed for the three days after the menstruation cycle. Follow up was performed for the evaluation of the reproductive outcomes, and comparative analysis was done to evaluate the efficacy of the hydrotubation to improve the pregnancy outcomes.

Inclusion Criteria

- Patients of age between 24 to 36 years
- Patients with the primary or secondary infertility of more than 2 years of duration were selected.

- Patients of regular menstrual cycle were selected for the study.
- Those who have normal profile of hormone like FSH, LH, prolactin, thyroid function tests were selected.
- Those who have the evidence of the ovulation diagnosed by the USG folliculometry was selected.
- Patients with the unexplained fertility were confirmed by the HSG and laparoscopy was selected.

Exclusion Criteria

- Those who had tubal blockage or infection in the pelvic region
- Patients with diabetes mellitus or hypertension or hepatitis or renal or cardiac disease were excluded
- Patients with known hypersensitivity to specific drugs

Procedure- Those who have fulfilled the inclusion and exclusion criteria were selected for the study after the verbal and written consent. The demographic, menstrual, obstetric, medical, and surgical information were measured and stored, which was followed by the baseline evaluation of the hematological, hormonal, biochemical, radiological, and infertility assessment. Total 128 women with the tubal infertility were allocated into the study group of n=64, and a control group (n=64). Patients in the study group had undergone with the hydrotubation for 3 days, between the day 7 and day 11 of the menstrual cycle, which was followed by the menstruation. The other group had received with the standard care of the infertility management, those who had received without the hydrotubation. The procedure was conducted aseptically by the use of the HSG cannula to instill the solution, which contained the gentamicin, dexamethasone, and normal saline by the cervix inside the fallopian tubes. Tubal patency was evaluated by the hissing sound and the pain at the time of the fluid instillation. All of the patients were administered with the antibiotics, analgesics, and supportive treatment, and were systematically followed up for the menstrual cycles. Half of the cases of the hydrotubation group provided with the ovulation induction with letrozole for 3 cycles. Pregnancy was evaluated by the testing of the pregnancy which was followed by the USG along with the fetal cardiac activity.

Statistical Analysis- SPSS version 27 was performed for the statistical analysis. Descriptive statistics was performed for the summarisation of the mean $\pm$ standard deviation and percentages. Chi-square test, Fisher's exact test, Z-test for proportions, and Student's t-test was performed for the comparison between the groups. Odds ratios (OR) with 95% confidence intervals (CI) were estimated to evaluate the association. The p-value <0.05 was maintained for the statistical significance.

RESULTS

Table 1 showed the majorly women for both of the groups hydrotubation (71.9%) and non-hydrotubation (75.0%) were between the range of 24–29 years, with the mean value of 27.98 ± 2.38 and 28.19 ± 2.81 years. 34.4% of cases showed the low socioeconomic status, specifically those who were without hydrotubation 42.2%. 28.9% of cases received higher secondary education and 27.3% of cases received secondary education. 1.6% of cases showed the postgraduate education. The majority of patients showed hydrotubation (70.3%) and non-hydrotubation (71.9%) group with their 10–11 years of age of menarche, while the 29.7% and 28.1% of cases showed the menarche age at 12–13 years. comparable mean age was noted among the groups, with the 11 years as the median age. Regular menstrual cycle was noted among 89.1% of women in the first group and 92.2% for the non-hydrotubation group. 10.9% and 7.8% of cases showed menstrual cycles. The study also showed that infertility was the most common type of infertility, affected around 89 (69.5%) of women. The hydrotubation group comprised of 38 (42.7%) and the non-hydrotubation group comprised of about 51 (57.3%). 39 (30.5%) women showed the secondary infertility. High proportion of cases were observed for the hydrotubation group (66.7%) rather than the non-hydrotubation group (33.3%).

Table 1: Comparative analysis of demographic characteristics, menstrual history, and infertility profile between the study groups

Variable	Category	With Hydrotubation n (%)	Without Hydrotubation n (%)	Total n (%)
Age (Years)	24–29	46 (71.9)	48 (75.0)	94 (73.4)
	30–35	18 (28.1)	16 (25.0)	34 (26.6)
	Total	64 (100)	64 (100)	128 (100)
	Mean ± SD	27.98 ± 2.38	28.19 ± 2.81	—
	Median	28	28	—
	Range	24–33	24–35	—
	χ ² , p-value	colspan=3: χ ² = 3.08, p = 0.55 (NS)		
Socioeconomic Status	Lower	17 (26.6)	27 (42.2)	44 (34.4)
	Lower Middle	12 (18.8)	1 (1.6)	13 (10.2)
	Middle	11 (17.2)	16 (25.0)	27 (21.1)
	Upper	3 (4.7)	3 (4.7)	6 (4.7)
	Upper Lower	11 (17.2)	10 (15.6)	21 (16.4)
	Upper Middle	10 (15.6)	7 (10.9)	17 (13.3)
	Total	64 (100)	64 (100)	128 (100)
Educational Status	Graduate	12 (18.8)	20 (31.3)	32 (25.0)
	Higher Secondary	21 (32.8)	16 (25.0)	37 (28.9)
	Middle	13 (20.3)	9 (14.1)	22 (17.2)
	Post- Graduate	0 (0.0)	2 (3.1)	2 (1.6)
	Secondary	18 (28.1)	17 (26.6)	35 (27.3)
	Total	64 (100)	64 (100)	128 (100)
	χ ² , p-value	colspan=3: χ ² = 5.43, p = 0.24 (NS)		
Menstrual Cycle History				
Age of Menarche (Years)	10–11	45 (70.3)	46 (71.9)	91 (71.1)
	12–13	19 (29.7)	18 (28.1)	37 (28.9)
	Total	64 (100)	64 (100)	128 (100)
	Mean ± SD	11.05 ± 0.74	11.02 ± 0.79	—
	Median	11	11	—
	Range	10–12	10–13	—
Menstrual Cycle Regularity	Irregular	7 (10.9)	5 (7.8)	12 (9.4)
	Regular	57 (89.1)	59 (92.2)	116 (90.6)
	Total	64 (100)	64 (100)	128 (100)
Type of Infertility				

Type of Infertility	With Hydrotubation n (%)	Without Hydrotubation n (%)	Total n (%)
Primary	38 (59.4)	51 (79.7)	89 (69.5)
Row %	42.7	57.3	100
Secondary	26 (40.6)	13 (20.3)	39 (30.5)
Row %	66.7	33.3	100
Total	64 (100)	64 (100)	128 (100)
Row %	50	50	100

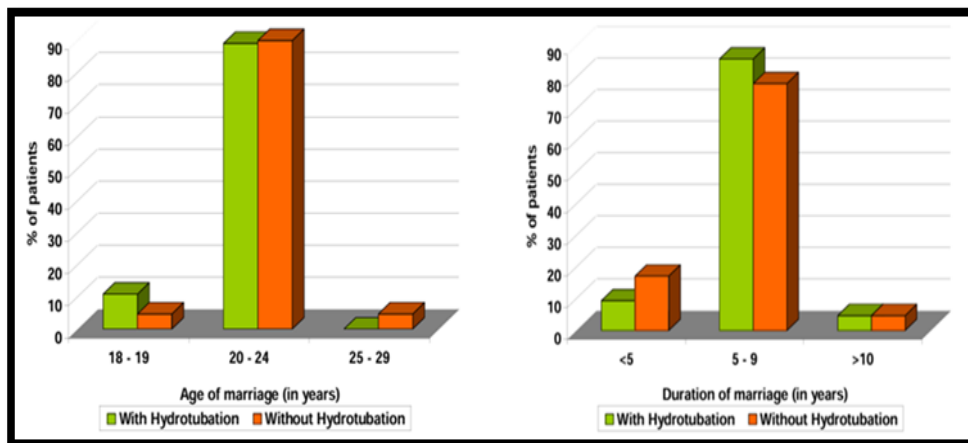


Fig. 1: The comparative analysis of the age during Marriage and Duration of Marriage for both of the groups

Table 2 showed that the most common type of multiparity was the Primary parity (primi), which accounted for about 69.5% of cases. 72.7% of cases showed no previous history of the abortion or stillbirth, while 10.9% of cases showed the spontaneous abortion

as the unfavourable reproductive outcome. 91.4% showed normal hormonal profiles, while 3.1% of cases showed high prolactin and 5.5% with high TSH. 88.3% of cases showed no previous history of the pelvic tuberculosis or chronic PID.

Table 2: The comparative analysis of the Parity, Reproductive History, Hormonal Profile, Pelvic Infection History, and Previous Surgical History for both of the groups

Variable	Category	With Hydrotubation n (%)	Without Hydrotubation n (%)	Total n (%)
Parity	Primi	38 (59.4)	51 (79.7)	89 (69.5)
	Multi	26 (40.6)	13 (20.3)	39 (30.5)
	Total	64 (100)	64 (100)	128 (100)
	χ^2 , p-value	$\chi^2 = 3.23$; p = 0.31 (NS)		
History of Abortion or Stillbirth	IA	4 (6.3)	3 (4.7)	7 (5.5)
	IA f/b D&E	3 (4.7)	0 (0.0)	3 (2.3)
	IA f/b D&E + SA	1 (1.6)	0 (0.0)	1 (0.8)
	SA	8 (12.5)	6 (9.4)	14 (10.9)
	SA f/b D&E	3 (4.7)	0 (0.0)	3 (2.3)
	Stillborn	4 (6.3)	3 (4.7)	7 (5.5)
	Nil	41 (64.1)	52 (81.3)	93 (72.7)
	Total	64 (100)	64 (100)	128 (100)
Hormonal Profile	Rise in PRL	2 (3.1)	2 (3.1)	4 (3.1)
	Rise in TSH	4 (6.3)	3 (4.7)	7 (5.5)



	WNL	58 (90.6)	59 (92.2)	117 (91.4)
	Total	64 (100)	64 (100)	128 (100)
	χ^2 , p-value	$\chi^2 = 0.15$; p = 0.92 (NS)		
History of Pelvic TB or Chronic PID	Chronic PID	6 (9.4)	3 (4.7)	9 (7.0)
	Pelvic TB	4 (6.3)	2 (3.1)	6 (4.7)
	Nil	54 (84.4)	59 (92.2)	113 (88.3)
	Total	64 (100)	64 (100)	128 (100)
	χ^2 , p-value	$\chi^2 = 1.88$; p = 0.38 (NS)		
History of Previous Surgery	Appendectomy	4 (6.3)	2 (3.1)	6 (4.7)
	Cholecystectomy	1 (1.6)	1 (1.6)	2 (1.6)
	Left-sided Ovarian Cystectomy	2 (3.1)	0 (0.0)	2 (1.6)
	Right-sided Ovarian Cystectomy	0 (0.0)	1 (1.6)	1 (0.8)
	LSCS	1 (1.6)	0 (0.0)	1 (0.8)
	Nil	56 (87.5)	60 (93.8)	116 (90.6)
	Total	64 (100)	64 (100)	128 (100)

Table 3 showed that the HSG findings indicated the left-sided tubal blockage as the most common abnormality noticed, among 51 (39.8%) women, which was followed by the right-sided tubal blockage among 23 (18.0%) of cases. The bilateral partial tubal blockage was noticed for about 16 (12.5%). Left-sided tubal blockage was more

frequently seen in the 42.2% of non-hydrotubation group and 37.5% of cases in the hydrotubation group. 4.7% of cases showed the bilateral fimbrial end occlusion and left-sided fimbrial blockage. 1.6% of cases frequently showed the bilateral incomplete tubal blockage.

Table 3: The comparative analysis of the HSG findings between both of the groups

HSG Findings	With Hydrotubation	Without Hydrotubation	Total
B/L cornual blockage			
Row %	66.7	33.3	100
Col %	3.1	1.6	2.3
n	2	1	3
B/L fimbrial end occlusion			
Row %	66.7	33.3	100
Col %	6.3	3.1	4.7
n	4	2	6
B/L incomplete tubal blockage			
Row %	100	0	100
Col %	3.1	0	1.6
n	2	0	2
B/L partial tubal blockage			
Row %	50	50	100
Col %	12.5	12.5	12.5
n	8	8	16
Left sided fimbrial blockage			
Row %	83.3	16.7	100
Col %	7.8	1.6	4.7
n	5	1	6
Left sided partial tubal blockage			

Row %	33.3	66.7	100
Col %	4.7	9.4	7
n	3	6	9
Left sided tubal blockage			
Row %	47.1	52.9	100
Col %	37.5	42.2	39.8
n	24	27	51
Right sided fimbrial blockage			
Row %	62.5	37.5	100
Col %	7.8	4.7	6.3
n	5	3	8
Right sided partial tubal blockage			
Row %	25	75	100
Col %	1.6	4.7	3.1
n	1	3	4
Right sided tubal blockage			
Row %	43.5	56.5	100
Col %	15.6	20.3	18
n	10	13	23
Total			
Row %	50	50	100
Col %	100	100	100
n	64	64	128

Fig. 2 showed no complication for some of the cases, which was followed by the hydrotubation. The mild pain the abdomen was the most prevalent complication, while frequent complications noticed are vomiting, right shoulder tip pain, mild spotting, and nausea. NSAIDs and

reassurance were the management strategy for the major complications. Altogether, the complications were mild and were well responsive for the symptomatic treatment regimen.

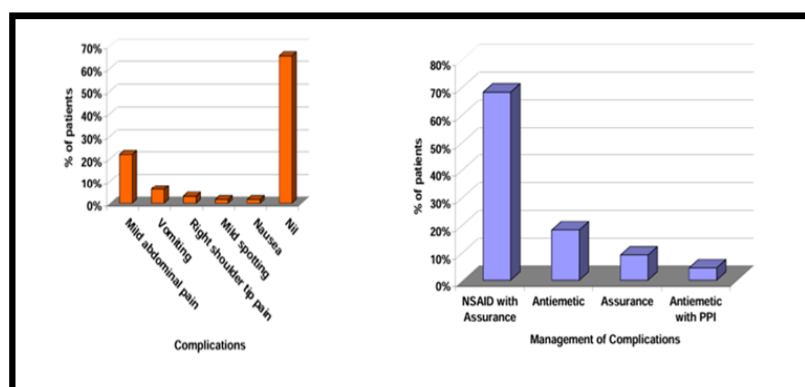


Fig. 2: The distribution of the Post-Hydrotubation Complications and their management strategies

Table 4 showed that 64 women showed the hydrotubation, 18 (28.1%) showed the pregnancy, 46 (71.9%) of women did not conceive. The most frequent among women was successful pregnancy. Contrastingly, the left-sided and right-sided spillage-negative findings

were related with the adverse outcome of pregnancy, estimated to be around 90.3% and 90% of failures. Those who had received with two cycles of hydrotubation, showed high rate of pregnancy, rather than those who received 3 cycles, estimated to be as 25%.

**Table 4:** The relationship with the outcome of pregnancy with the Laparoscopy Findings, Dye Test Results, and Number of Hydrotubation Cycles

Variable	Category	Successful Pregnancy / With Hydrotubation	Failed Pregnancy / Without Hydrotubation	Total
Final outcome	Pregnancy	18	5	23
	Row %	78.3	21.7	100
	Col %	28.1	7.8	18
	No pregnancy	46	59	105
	Row %	43.8	56.2	100
	Col %	71.9	92.2	82
	TOTAL	64	64	128
	Row %	50	50	100
	Col %	100	100	100
Laparoscopy findings and Dye test	Bilateral spillage delayed positive	5	3	8
	Row %	62.5	37.5	100
	Col %	27.8	6.5	12.5
	Right sided spillage delayed positive	4	1	5
	Row %	80	20	100
	Col %	22.2	2.2	7.8
	Left sided spillage delayed positive	1	1	2
	Row %	50	50	100
	Col %	5.6	2.2	3.1
	Bilateral spillage positive	2	1	3
	Row %	66.7	33.3	100
	Col %	11.1	2.2	4.7
	Bilateral spillage negative	2	3	5
	Row %	40	60	100
	Col %	11.1	6.5	7.8
	Left sided spillage negative	3	28	31
	Row %	9.7	90.3	100
	Col %	16.7	60.9	48.4
	Right sided spillage negative	1	9	10
	Row %	10	90	100
	Col %	5.6	19.6	15.6
	TOTAL	18	46	64
	Row %	28.1	71.9	100
	Col %	100	100	100
Number of hydrotubation cycles	2	3	1	4
	Row %	75	25	100
	Col %	16.7	2.2	6.3
	3	15	45	60
	Row %	25	75	100
	Col %	83.3	97.8	93.8
	TOTAL	18	46	64
	Row %	28.1	71.9	100
	Col %	100	100	100

DISCUSSION

Hydrotubation is an effective first-line outpatient approach for evaluating and treating tubal factor infertility that is inexpensive and delivers non-invasive care as is demonstrated by clinical studies performed in India [10,11]. When compared to conventional hysterosalpingography, diagnostic hydrotubation had a sensitivity of 84.61% and specificity of 95.12% as a means of determining tubal patency based on data collected from 50 women enrolled in a study [11]. A prospective study of 150 women with tubal occlusions due to unilateral blockage (33.33%), hydrosalpinges (24.56%), fimbrial occlusion (20%) found that 70.8% of the patients who received hydrotubation experienced tubal patency following this procedure, with an overall conception rate of 55.3% [10]. Of the 83 pregnancies reported in this group, 84.4% successfully reached term; temporary adverse events reported included pelvic pain (70%) and vaginal bleeding (24%) [10]. These results indicate that hydrotubation can be considered a therapeutic option for use in the context of limited-resource healthcare systems [10,11].

Clinical evaluations have determined that multi-cycle therapeutic hydrotubation using an antibiotic, steroid, and hyaluronidase combination is a safe and efficient outpatient intervention for enhancing pregnancy rates prior to reproductive assistance methods [12]. In a study of 250 women with infertility, the multi-cycle therapeutic hydrotubation method aided in achieving a 68% conception rate among the 27.6% of women presenting with both bilateral tubal blockages (within 3 months) and 36% of women presenting with unilateral blockages, along with a 62.5% conception rate among women with normal early imaging after treatment [12]. In contrast, structural infertility due to female genital tuberculosis is a major cause of barrenness in several developing countries due to its relatively high incidence, low bacillary load [5]. Use of a comprehensive and statistically valid reference standard to determine the presence of female genital tuberculosis among 100 infertile women (78% with primary infertility, 22% with secondary) yielded the following results: GeneXpert positivity (28%), histopathological detection of epithelioid granulomas (13%), confirmed laparoscopic pathology such as beaded fallopian tubes (57.19%), and probable signs such as extensive pelvic adhesions (48.8%), indicating that all

100 subjects would require 6 months of appropriate anti-tubercular treatment [5].

Studies have indicated that transcervical hydrotubation using hydrostatic pressure can be a valuable addition to the treatment of unexplained infertility [13, 14]. A randomized controlled trial investigated 60 women who had stimulation for ovulation through clomiphene citrate administration, receiving prophylactic oral doxycycline 1 day prior to a hydrotubation performed prior to IUI. This study compared two methods of treatment: using saline only versus using low-dose lidocaine mixed with saline [13, 14]. The outcome variables assessed were: clinical pregnancy rate; rate of abortion within the first trimester; rate of ectopic pregnancy; and rate of multiple pregnancies. The group receiving lidocaine in saline had a higher clinical pregnancy rate and better pain control than the group receiving saline only [13,14].

The use of low-cost, day-care interventions such as hydrotubation (hydrosalping) in public/combined delivery systems decentralizes the patient pathway; substitutes for socio-cultural delays, stigma, and geographic barriers experienced by rural women [15]. Hydrotubation is a practical, low-level supplementary intervention that can be applied in both secondary districts and hospitals and closes a large access gap where there are no sophisticated ART technologies available [16]. Consensus from Indian experts and practitioners indicates that low-cost alternatives can complement diagnostic testing as part of triage for women experiencing certain types of infertility due to tubal blockages, providing clarity on rural vs. urban discrepancies in access to ART [16, 17]. To promote equity in ART laws in India, future studies should be based on randomised clinical trials with local funding in the public sector comparing hydrotubation to other low-cost interventions and evaluating both standardised clinical outcomes and specific equity endpoints (continuity of service to rural patients and outcomes from a patient perspective) across various socioeconomic classes in India [16, 17].

CONCLUSIONS

The study concluded that the RCT evaluated the efficacy of the hydrotubation among women with the tubal infertility. All basic demographic, socioeconomic, reproductive, hormonal, and clinical parameters were compared between the hydrotubation and non-

hydrotubation groups. The most common abnormality of the HSG was the left-sided tubal blockage. Those who had undergone with the hydrotubation showed high rate of pregnancy rather than those who were not. Favourable laparoscopic dye test findings, and who had delay in the positive tubal spillage were related with better rate of conception. The spillage-negative findings were associated with poor outcome of pregnancy. While infrequent, mild complication were noticed this can be managed with the conservative treatment.

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CONTRIBUTION OF AUTHORS

Research concept – Prabodh S Soreng, Seema Das

Research design – Prabodh S Soreng, Seema Das

Supervision – Seema Das, Javed Miyadad

Literature search – Prabodh S Soreng, Javed Miyadad

Study selection – Prabodh S Soreng, Seema Das

Data extraction – Prabodh S Soreng, Seema Das

Quality assessment – Prabodh S Soreng, Seema Das

Data analysis and interpretation – Prabodh S Soreng, Seema Das

Writing article – Prabodh S Soreng, Javed Miyadad

Critical review – Seema Das, Javed Miyadad

Article editing – Prabodh S Soreng, Seema Das

Final approval – Prabodh S Soreng, Seema Das, Javed Miyadad

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