

## Ultrasonographic Hydrotubation versus No Hydrotubation Before Intrauterine Insemination

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### ABSTRACT

**Background:** Intrauterine insemination (IUI) is a common reproductive treating for unexplained infertility (UI). To achieve conception, washed sperm is put into the uterine cavity. The success rate of IUI with simultaneous ovulation induction is a hot topic of discussion. In cases of unexplained infertility, hydrotubation has resulted in a significantly higher conception rate.

**Aim of the work:** To compare the effect of simple hydrotubation with 20 ml of saline and lidocaine one day before IUI with no hydrotubation on the conception rate in patients with unexplained infertility.

**Patients and methods:** This prospective randomized controlled trial included 214 women with unexplained infertility who attended Alzhar University Hospitals' Gynecology Outpatient Clinics.

**Results:** There was a statistically substantial variation between the two groups. Treatment results. Clinical pregnancy was observed in 50 (46.7 %) of included patients in group A. No OHSS was observed in both groups.

**Conclusion:** Hydrotubation with lidocaine one day before to IUI is a safe and well-tolerated technique. When comparing to nohydrotubation, it resulted in a greater conception rate, with a substantial change for couples with unexplained infertility. No significant complications of the procedure were reported with no to mild pain according to VAS score. However, More research is needed to look at the dose-dependency of Lidocaine hydrotubation and the impact of multiple sessions on the incidence of clinical gestation in these individuals.

**Keywords:** Hydrotubation; Intrauterine insemination; Lidocaine; Pregnancyrate; Unexplained infertility.

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### INTRODUCTION

After failure of anticipated therapy, intrauterine insemination (IUI) is regarded as the initial therapeutic choice for people with unexplained infertility. <sup>1</sup>

In partners with unexplained infertility, intrauterine insemination is normally done for a few cycles before turning to IVF. <sup>2</sup>

The gestation rates each cycle with IUI is generally considered to be rather low. <sup>3</sup>

ovarian stimulation with IUI, which greatly boosted the likelihood of pregnancy in couples with unexplained infertility, was one of many strategies tested to enhance the result of IUI. <sup>1</sup>

Tubal flushing or hydrotubation, has previously been shown to improve the chances of attaining pregnancy in couples with UI or who are in the initial phases of endometriosis. <sup>4</sup>

Hydrotubation may have a physical and immunological influence on fertility, such as

inhibiting spermatozoa phagocytosis and changing levels of peritoneal factors like cytokines. <sup>5</sup>

The goal of the research was to compare the effects of simple hydrotubation with 20 mL of saline and lidocaine one day before IUI vs no hydrotubation on pregnancy rates in individuals with unexplained infertility.

### PATIENTS AND METHODS

**Administrative and Ethical Design:** An Official permission was obtained from Faculty of Medicine. An official permission was obtained from obstetrics and gynaecology department at Al Azhar University Hospitals. Al Azhar University's faculty of medicine's ethics committee has given its approval (Institutional Research Board IRB)

**Study design:** 214 women with unexplained infertility who visited Alzhar University Hospitals' Gynecology Outpatient Clinics between April and December 2021 were enrolled in this prospective randomized controlled research.

Type of study: Prospective randomized controlled study. Eligible patients who attended infertility devices during the study period was enrolled in the research. They were randomly divided into two treatment groups (group A, Hydrotubation and group B, No Hydrotubation). A web computerized program used Stratified blocked randomization method (1:1 ratio) was used for patients' allocation.

Justification of sample size: Assuming that conception rate in Hydrotubation 20.7 and non Hydrotubation is 10.3% so the sample size will be 214 (107 in each group) using epi info at power 80% and CI 95%, where  $n$  is the needed sample size in each group ( $i=1,2$ ),  $Z$  is the value from the standard normal dispersion indicating the confidence level to be utilized, and  $E$  is the intended margin of error.  $\sigma$  again represents the result variable's standard deviation. Remember from the confidence intervals module that we utilized  $S_p$ , the pooled estimate of the basic standard deviation, as a measure of variability in the result when generating a confidence interval estimate for the variance in means (based on pooling the data), where  $S_p$  is computed as follows:

$$S_p = \sqrt{\frac{(n_1-1)s_1^2 + (n_2-1)s_2^2}{(n_1+n_2-2)}}$$

Inclusion criteria: All patients were under the age of 40, had been diagnosed with unexplained infertility for at least 24 months, had a body mass index of  $25 \pm 4$  Kg/m<sup>2</sup>, had patent fallopian tubes verified by hysterosalpingography and/or laparoscopy, and had a good semen assay as per modified WHO standards.

Exclusion criteria: -

Other reasons for infertility, liver or kidney diseases, patients with chronic medical diseases as HTN, DM, Thyroid diseases, hypersensitivity to lidocaine, past history of Hyper ovarian stimulation syndrome and patients with abnormal uterine lesions detected by ultrasound as fibroid, polyp, adenomyosis, HSG or hysteroscopy.

Patient preparation: -

The following was performed on all patients: It was taken before the start of the study. No risks were found and any unexpected risk appearing during the study was cleared to the patients and the committee on time. All the records were confidential. The results of this study were used only in scientific purpose. The participation was voluntary, and the patients can discontinue participation at any time without penalty or loss of benefits.

Full history taking with emphasis on: Personal history, complaint Duration – Type of infertility, menstrual History: Frequency, duration, recent change in interval or duration, hot flushes, dysmenorrhea, contraceptive use: Type – Duration – TTP interval, sexual: Coital Frequency, timing, and dyspareunia, obstetric History: TTP interval – Pregnancy complication – Birth details, social History: lifestyle factors as eating habits, weight gain, smoking, alcohol consumption and drug abuse and environmental factors: environmental

contaminants or toxins endocrine-disrupting chemicals (EDCs) as agricultural pesticides and herbicides, present History: symptoms of hyperprolactinemia, androgen excess or thyroid disease, and chronic pelvic pain, medications include over-the-counter agents, such as NSAIDs that may adversely affect ovulation. Herbal remedies, past History, medical and Gynecological: endometriosis, recurrent ovarian cysts, leiomyomas, sexually transmitted disease or PID, pelvic and Abdominal surgeries, especially if linked to endometriosis or adhesion formation and ethnicity and familial history of both partners influences the need for periconceptional testing.

Examination:

General Examination: Vital sign especially blood pressure, height, and weight (BMI), built and fat distribution (masculine-feminine) is recorded, thyroid and breast examination were performed, abdomen: Hair distribution, scars, etc and pelvic Examination: Vulva and vagina: any abnormalities noted, Cervix: Direction, shape, scars and any abnormalities (pin-hole OS, previous cervical surgeries, etc.), Uterine tenderness, size, shape (symmetrical or asymmetrical enlargement), Adnexa for masses or tenderness suggestive of ovarian mass or PID and DP for masses or tenderness suggestive of chronic PID.

Pelvic Ultrasound: A bladder full of urine was excellent for TA imaging of pelvic contents.

Transabdominal (TA): The transabdominal approach comprised of midline sagittal and parasagittal pictures oriented from the midline to both hemipelvis' peripheries.

Transvaginal (TV): When compared to normal TA imaging (near 3.5 MHz), TV scans employed extended transducers with high frequencies components in the range of 7 MHz to 8 MHz

Blood test for Hormonal profile including (Serum FSH, LH, Estradiol, TSH, Prolactin, and AMH) by Venous blood was obtained from the patients

Before hydrotubation, all patients were tested for bacterial vaginosis, Chlamydia trachomatis, and Neisseria gonorrhoeae, and positive cases were medically treated.

Method:

One day before to IUI, hydrotubation was performed. Using an empty bladder, the patient was positioned in the lithotomy posture, the cervix was opened with a Cusco speculum, and the portio was cleansed with a swab saturated with saline.



**Fig. 1:** Cusco Speculum

A pediatric Foley catheter (8F) was placed into the cervical canal, and the catheter balloon was inflated

with 0.5–1 cc saline before being pushed against the cervix to ensure minimum leaking. To produce a concentration of 0.1 mg Lidocaine/ml saline, 0.1 cc of 2 percent Lidocaine (Debocaine 2 percent, El-Debeiky Pharma, Egypt) was combined with 19.9 cc of saline. The sonographic hydrotubation procedure was carried out gently and methodically. The patient was told to relax for 10 minutes before returning the following day for IUI.

Posthydrotubation: Intrauterine insemination was accomplished utilizing an intrauterine catheter (Wallace or Cook IUI catheters) linked to a 2 ml syringe 24 hours after hCG treatment. After 2–4 days of sexual abstinence, sperm was collected via masturbation into a sterile container. For semen preparation, the conventional swim-up approach was utilized.



**Fig. 2:** Wallace Catheter

Statistical Analysis: For data processing, SPSS version 23 was utilized to validate, input, and analyze the data. The findings of this investigation were analyzed using the following statistical approaches. For qualitative variables, data were reported as number and proportion, and for quantitative variables, mean + standard deviation (SD).

## RESULTS

573 cases were recruited in our department, 359 cases were excluded and 214 cases were included. With 1:1 ratio allocation all included patients were allocated into two groups, group A with 107 patients and group B with 107 patients.

	Group A (Hydrotubation) (n= 107)	Group (No (n=107)	B Hydrotubation)	P - Value
Age (Years)	33.4 (8.4)	32.8 (6.4)		>0.05 <sup>1</sup>
BMI (Kg/m <sup>2</sup> )	25.2 (3.2)	24.8 (4.6)		
Menstrual regularity				
Regular	107 (100)	107 (100)		
Irregular	0	0		

BMI: Basal Metabolic Index. 1: t-test|2: Chi square test. P > 0.05 is considered non-significant. Continuous Data represented as Mean (SD)|Discrete data represented as number (percentage)

**Table 1:** General demographic characteristics of included patients in both groups

In terms of general features, there was no statistical variation between the two groups.

	Group A (Hydrotubation) (n= 107)	Group (No (n=107)	B Hydrotubation)	P - Value
Complete cycles	104 (97.2)	106 (99.07)		>0.05 <sup>2</sup>
Number of follicles > 16 mm	2.32 (0.5)	2.15 (0.46)		>0.05 <sup>2</sup>
Duration of stimulation (Days)	12.58 (1.08)	12.32 (1.12)		>0.05 <sup>2</sup>

1: t-test P > 0.05 is considered non-significant. Continuous Data represented as Mean (SD)|Discrete data represented as number (percentage).

**Table 2:** Intrauterine insemination cycle characteristics

There was no statistical variation between the included groups according to intrauterine insemination cycle characteristics.

On day of hCG administration	Group A (n= 107)	(Hydrotubation)	Group B (No Hydrotubation) (n=107)	P - Value
Endometrial thickness (mm)	9.72(1.24)		9.18 (1.23)	>0.05 <sup>2</sup>
Serum E2 (pg/mL)	642.4(98.24)		629 (101.3)	

E2: Estradiol hormone. 2: Chi square test. P > 0.05 is considered non-significant.

Continuous Data represented as Mean (SD)|Discrete data represented as number (percentage).

**Table 3:** Characteristics of patients at day of hCG administration.

There was no statistical variation between the included groups according to Characteristics of patients at day of hCG administration.

	Group A (n= 107)	(Hydrotubation)	Group B (No Hydrotubation) (n=107)	P - Value
Bleeding	3 (2.8)		5 (4.67)	
Infection	3 (2.8)		1 (0.93)	>0.05 <sup>2</sup>
Hard intubation	13 (12.15)		-	-

2: Chi square test. P > 0.05 is considered non-significant. Data represented as number (percentage).

**Table 4:** Complications occurrence in both groups

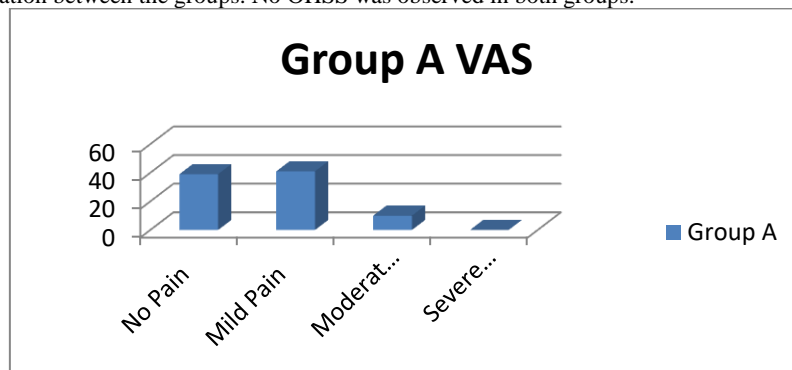
Concerning the incidence of complications, there was no substantial distinction between the included groups. Hard intubation was in 13 (12.15) cases.

	Group A (Hydrotubation) (n= 107)	Group B (No Hydrotubation) (n=107)	P - Value
Chemical Pregnancy	56 (52.34)	18 (16.82)	<0.05 <sup>2</sup>
Clinical Pregnancy	50 (46.73)	13 (12.15)	
Multiple Pregnancy	5 (4.67)	3 (2.8)	
First trimester abortion	3 (2.8)	5 (4.67)	
Ectopic Pregnancy	1 (0.93)	1 (0.93)	>0.05 <sup>2</sup>
OHSS	0	0	

OHSS: Ovarian hyperstimulation syndrome. 2: Chi square test. P < 0.05 is considered significant. P > 0.05 is considered non-significant. Data represented as number (percentage).

**Table 5:** Treatment outcomes in both groups

There was a substantial distinction in treatment results across the included groups. In group A, clinical pregnancy was found in 50 (46.7 percent) of the individuals. In terms of ectopic pregnancy, there was no statistically substantial variation between the groups. No OHSS was observed in both groups.



**Fig. 3:** Pain intensities measured by visual analog scale (VAS) score in Hydrotubation group

In the Hydrotubation group, the majority of patients (38.3%) had minor discomfort as measured by the visual analog scale (VAS) score. No pain was felt in 39 patients (36.44%). No patient felt severe pain. Only 90 patients completed VAS test during follow up.

**DISCUSSION**

Hydrotubation is now widely regarded as a complementary treatment to reproductive surgery. However, it has been used alone or in conjunction with other medications to treat tubal infertility. When used a day before intrauterine insemination (the initial choice for individuals with unexplained infertility), hydrotubation considerably enhanced the conception rate when compared to no hydrotubation.<sup>6</sup>

This prospective randomized controlled trial will involve 214 women with unexplained infertility who visit Alzhar University Hospitals' Gynecology Outpatient Clinics. The patients were assigned to one of two therapy groups at random (group A, Hydrotubation and group B, No Hydrotubation).

In terms of general features of the study groups, we discovered no statistical differences between them in terms of age, BMI (kg/m2), family history of infertility, or menstrual regularity. In terms of demographic data and infertility features, there was no statistical variation between the groups.

The present study was supported by the prospective randomized, blinded control trial by Srivastava et al.<sup>5</sup> investigated Intrauterine Insemination with Hydrotubation in Women with Infertility. Out of 60 women with unexplained infertility, 30 were taken for saline instillation while 30 were given lidocaine. In terms of age, BMI, primary infertility, secondary infertility, and infertile years, they discovered no

statistically substantial variations between the research groups.

As well, our study was further supported by Prospective randomized controlled trial of Saaqib et al.<sup>7</sup> compare the results of hydrotubation in cases of unexplained infertility in clomiphene citrate-stimulated cycles to the results of a control group (no Hydrotubation). The research involved 128 women, including 64 women in each of the experimental and control groups. regarding age, infertile years, kind of infertility, previous surgeries, and previous miscarriages, they discovered no statistically substantial differences between the research groups.

There was no substantial variation between the groups in terms of intrauterine insemination cycle features such as complete cycles, number of follicles, and stimulation time in the present research. There was also no substantial variation between the groups when it came to patient characteristics on the day of hCG administration, such as endometrial thickness and serum E2.

In harmony with the current results the study conducted by Morad & Abdelhamid,<sup>4</sup> revealed that in terms of the number of completed cycles, the number of follicles >16 mm, and patient characteristics on the day of hCG injection, such as endometrial thickness and serum E2, there was no substantial variation between the groups.

The current research found a substantial statistical variation between the included groups Treatment

results when it came to the outcomes among the analyzed groups. Clinical pregnancy was observed in 50 (46.7 %) of included patients in group A. No OHSS was observed in both groups.

The current results were supported by Saaqib et al.<sup>7</sup> who reported that Hydrotubation was shown to be successful in improving fertility in unexplained instances, and right shoulder tip discomfort was proven to be a statistically useful indicator for predicting pregnancy. They also stated that the majority of the patients conceived during the same cycle as hydrotubation. In the next cycle, the number of pregnancies reduced, and in the third cycle, no conceptions occurred. Using the chi-square test, this variation was shown to be very substantial.

The current results were supported by Adesiyun et al.<sup>8</sup> The research involved 257 individuals who underwent therapeutic hydrotubation, and it revealed that 109 conceptions were documented, with a 42.4 percent overall conception rate. In these 154 individuals with signs of post-hydrotubation tubal patency, the percentage ratio of conception was 70.8 percent. The pregnancy result of the 109 conceptions was 84.4 percent term pregnancy, 9.2 percent premature pregnancy, 4.6 percent miscarriage, and 1.8 percent ectopic pregnancy. They also stated that therapeutic hydrotubation may be effective in resource-poor nations with careful case selection, particularly in individuals with partial tubal blockage (bilateral peritubal adhesions) and as part of therapy for unexplained infertility.

In contrast to the current findings, Srivastava et al.<sup>5</sup> found that although the gestation rate was greater in the control group, the difference was not substantial when compared to the study group (P = 0.296). When they looked at biochemical and clinical pregnancies, they found that the study group had a gestation rate of 17.8% while the control group had a gestation rate of 23.8 percent.

Similarly, the study by Morad & Abdelhamid,<sup>4</sup> reported that the diagnostic pregnancy rates in the Lidocaine hydrotubation group (17.43%) were greater than in the saline group (11.2%), but the variation was not substantial. In terms of multiple pregnancy, first trimester abortion, and ectopic pregnancy, there were no substantial variations between the two groups. There were no occurrences of ovarian hyperstimulation syndrome in either group.

In an investigation by Edelstam et al.<sup>9</sup> Perturbation's influence on conception rate in couples with unexplained infertility was studied. Prior to ovulation, perturbation was conducted. There was a total of 130 cycles studied. There was a considerable variation in pregnancy rates between the two groups (14.9 vs. 3.2 percent). Perturbation, in combination with ovulation induction and IUI, might be utilized as a first-line treatment approach in couples with unexplained infertility, according to the authors.

As regard Pain severity is measured using a visual analog scale (VAS) score in Hydrotubation group, we found that most patients (38.3%) felt mild pain. No pain was felt in 39 patients (36.44%). No patient

felt severe pain. Only 90 patients completed VAS test during follow up.

The current study was in line with Morad & Abdelhamid,<sup>4</sup> who reported that (90 & 91) women who completed the VAS in the saline and lidocaine groups, respectively, reported mild (50 & 47.25 percent) to moderate (16.67 percent & 13.19 percent) discomfort. There were no substantial variations between the two groups when it came to the frequency of pain severity as measured by VAS. Furthermore, regardless of the material used for hydrotubation, 63.54 percent of all women evaluated had pelvic discomfort as a result of tube inflation.

Furthermore, Aboulghar et al.<sup>6</sup> reported that There were no adverse effects or problems, save for minor pain during saline injection for hydrotubation in 25% of patients.

As well the study by Adesiyun et al.<sup>8</sup> stated that Pelvic discomfort was reported in 177 (68.9%) individuals and vaginal hemorrhage was reported in 63 (24.5%) patients after therapeutic hydrotubation.

## CONCLUSION

Hydrotubation with lidocaine one day before to IUI is a safe and well-tolerated technique. When compared to nohydrotubation, it resulted in a greater pregnancy rate, with a substantial change for couples with unexplained infertility. No significant complications of the procedure were reported with no to mild pain according to VAS score.

Conflict of interest : none

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