Hysteroscopic Tubal Cannulation with Hydrotubation versus Hysteroscopic Tubal catheterization for Recanalization under Diagnostic Laparoscopy in patients with Proximal Tubal Block

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Abstract

Background: Fallopian tube disease includes factors such as proximal obstruction or damage of the fallopian tubes, which is related to previous pelvic inflammatory disease, endometriosis, or pelvic surgery. **Aim:** The purpose of this study is to investigate the fertility outcomes of infertile patients who have unilateral or bilateral proximal tubal obstruction and will be treated with HTC for recanalization under diagnostic laparoscopy. **Methods:** this was randomized controlled trial, 92 Patients who diagnosed as tubal factor infertility (unilateral or bilateral proximal tubal obstruction) by hysterosalpingography (HSG) in outpatient clinic at Suez Canal university hospitals included in our study according to inclusion and exclusion criteria. Patients were divided into two groups; Group (A) 46 patients undergo Hysteroscopic tubal cannulation with hydrotubation (HTCH) and Group (B) 46 patients undergo HTC Hysteroscopic tubal catheratization. **Results:** Overall, success rate in group A (75% with 48 tubes recanalized of 64 occluded tubes) is not significant (P <0.045) compared to group B (66% with 44 tubes recanalized of 64 occluded tubes). **Conclusion:** Both hysteroscopic tubal cannulations under laparoscopic guidance as well as hysteroscopic tubal catheterization should be recommended as choice for further diagnosis and treatment of infertile women with PTO.

Keywords: Hysteroscopic Tubal Cannulation; Hydrotubation; Hysteroscopic Tubal catheterization; Recanalization; Laparoscopy; Tubal Block.

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Introduction

Multiple causes account for female infertility, Fallopian tube disease is the most frequent cause of female infertility, it is responsible for 25-35% cases of female ovulatory infertility worldwide. Proximal tubal obstruction accounts for 10%-20% of cases with tubal factor infertility **(1)**.

Fallopian tube disease includes factors such as proximal obstruction or damage of the fallopian tubes, which is related to previous pelvic inflammatory disease, endometriosis, or pelvic surgery. Treatment options include surgical tubal repair, expectant management, and in vitro fertilization–embryo transfer IVF–ET. However, IVF–ET may not be necessary in all cases of infertility, implying that it is important to ascertain the cause of the tubal disease **(2)**.

Tubal reconstructive surgery allows women with normal tubal mucosa to achieve spontaneous pregnancy without undergoing IVF–ET, and is therefore an option for couples that limit the use of IVF–ET **(3)**.

Fallopian tube recanalization can be done with catheters, flexible a traumatic guide wires, or balloon systems under endoscopic (falloposcopy / hysteroscopy / laparoscopy), sonographic, fluoroscopic, or tactile guidance. Falloposcopy provides the possibility to accurately visualize and grade endotubal disease, and objectively classify the cause of proximal tubal obstruction. Laparoscopy is performed to accurately diagnose tubal obstruction, peritubal adhesion, and endometriosis. If tubal obstruction is identified by laparoscopic chromopertubation, hysteroscopic tubal catheterization (HTC) is performed for recanalization **(4)**.

The purpose of this study was to investigate the fertility outcomes of infertile patients who have unilateral or bilateral proximal tubal obstruction and will be treated with HTC for recanalization under diagnostic laparoscopy.

PATIENTS AND METHODS

Randomized clinical trial, the study was carried out in Obstetrics and gynecology Department at Suez Canal University Hospitals. Infertile female patients with proximal tubal obstruction was

included according to inclusion and exclusion criteria as follows:

Inclusion criteria: Unilateral or bilateral proximal tubal obstruction by (HSG) as a single cause of primary or secondary infertility.

Exclusion criteria: Hydrosalpinex, endometriosis, history of salpingectomy or salpingostomy, endometrial cysts revealed by ultrasound, patients with active genital infections, ovarian factor of infertility and uterine myomas

Tools And Data Collection: Full medical history, complete physical examination, laboratory investigation in form of; serum prolactin, LH, FSH, and TSH, combined Trans-abdominal& Trans-vaginal ultrasound for exclusion of ovarian endometrioma, hydrosalpinx and other pelvic diseases and HSG before and after recanalization.

Patients who diagnosed as tubal factor infertility (unilateral or bilateral proximal tubal obstruction) by hysterosalpingography (HSG) in outpatient clinic at Suez Canal university hospitals included in our study according to inclusion and exclusion criteria.

Patients were divided into two groups: **Group (A)** 46 patients undergo Hysteroscopic tubal cannulation with hydrotubation (HTCH). **Group (B)** 46 patients undergo HTC Hysteroscopic tubal catheratization.

Both interventions done under diagnostic laparoscopic guidance

Laparoscopic and hysteroscopic surgery:

In chromopertubation, a uterine cannula was inserted into the cervix and used for slow infusion of blue dye; this test was used to confirm tubal obstuction in patients included in our study.

After dilating the cervix up to No. 6 Hegar dilator, a flexible catheter guide cannula with a ball-shaped tip was introduced into the uterine cavity along with its stilette. The guiding cannula is of varying flexibility and adapts well to the curvature of the uterus.

A 4-mm 30 degrees fore-oblique angle hysteroscope (Karl Storz, Tuttlingen, Germany) fitted to a 5-mm diagnostic sheath was then gently introduced into the uterine activity alongside the guide cannula. Normal saline was utilized as the uterine distending medium. Once the uterine cavity was entered by the hysteroscope, it was explored properly for detecting any uterine intracavitary lesions, and then both tubal ostia were carefully localized and examined. Then, the tip of the guide cannula was positioned exactly in front of the tubal ostium and lodged securely inside it under direct hysteroscopic vision.

A 4-Fr end-hole Teflon ureteric catheter with a tapered end (tapered to 2.5 Fr) in its distal 3 cm and a Teflon coated stainless-steel urologic guidewire 0.018 inch (0.043 cm) in diameter with an atraumatic flexible blunt tip (Cook Co, Bloomington, Indiana, USA) were utilized for tubal catheterization. As the guidewire exits from the catheter, it is relatively stiff; as the guidewire becomes longer, it becomes more flexible.

Group (A): Hysteroscopic tubal cannulation with hydrotubation (HTCH): First, a hysteroscopy introduced into the uterine cavity and the tubal ostia was identified. 4-French ureteric catheter is used through the operating channel of the hysteroscopy selective catheterization and cannulation of the proximal fallopian tube(s). The wire guide is intended only to facilitate placement of the inner catheter. Once tubal ostia cannulated about 1 cm guidewire removed and methylene blue is injected directly into the catheter and the success of the recanalization is assessed by diagnostic laparoscopy.

Group (B): HTC will be performed under laparoscopy to restore tubal patency: First, a hysteroscopy introduced into the uterine cavity and the tubal ostia was identified. A 4-French ureteric catheter then advanced into the ostium.

The guidewire was advanced till its tip was seen to enter the tubal ampulla or until significant resistance was met. If the guidewire could not be easily advanced into the tubal ampulla with application of gentle pressure and rotation, the tapered end of the 4-Fr catheter was advanced over the guidewire until the resistance was felt by the catheter, and then minimally withdrawn, leaving only a short length of the guidewire protruding from the tip of the catheter. This maneuver provides extra stability for the guidewire tip, makes it relatively stiffer, enables, with advancement of the guidewire, application of relatively greater force in the proper direction against the site of resistance, and minimizes the possibility of tubal perforation.

Next, the 4-Fr catheter with the guidewire shortly protruding out of its tip was pushed with relatively greater force and gentle rotation to negotiate the locked area of the tube, and then advanced to reach the tubal ampulla. The guidewire was then withdrawn completely outside the body, leaving the 4-Fr catheter in place with its tip inside the uterine tubal ostium.

Selective chromo-pertubation under laparoscopic observation was then performed to confirm tubal patency. The 4-Fr catheter was then withdrawn into the lumen of the catheter guide cannula. The cannula was rotated through 180 degree and positioned into the other internal tubal ostium. The procedure was then repeated on the other side.

At the end of the procedure, the guide cannula, the 4-Fr catheter, and the guidewire were removed from the uterus and tubal patency was checked once again using methylene blue.

Laparoscopy helps monitor both the procedure and visual assessment of tubal patency.

Post-operative HSG was done for all patients the next cycle to confirm patency of tube(s) then six cycles of timed intercourse.

Outcome Measures: Discharge time: Measured in days after end of surgery. Operative time: Calculated from insertion to removal of laparoscopy. Blood loss: Calculating blood volume of the suction machine during surgery, excluding liquid utilized for peritoneal washing, preoperative and postoperative hemoglobin and hematocrit difference. Intraoperative complications as false passage of the catheter to broad ligament or perforation of the tube and bleeding from site of perforation. GIT motility (paralytic ileus time calculated in hours from the end of procedure to the ability to pass stool or gas). Febrile morbidity: body temperature ≥38 □c in two consecutive measurements ≥4 hours apart. Post-operative HSG was compared for both groups regarding tubal patency done the next cycle to confirm tubal patency and to detect any re-occlusion of the tube(s). Laparoscopy: helps monitoring both the procedure and visual assessment of tubal patency before and after canalization.

Data analysis: The data were coded, organized and the final study results were stated using the SPSS (statistical package for social sciences) version 20 and data were presented through tables and graphs. As appropriate numerical data will be expressed as mean with or without SD and categorical data were expressed as number %. Student t test will be used to test statistical significance of continuous variable between two groups, while chi-square test will be used for categorical variables. Statistical significance were considered at P-value < 0.05.

RESULTS

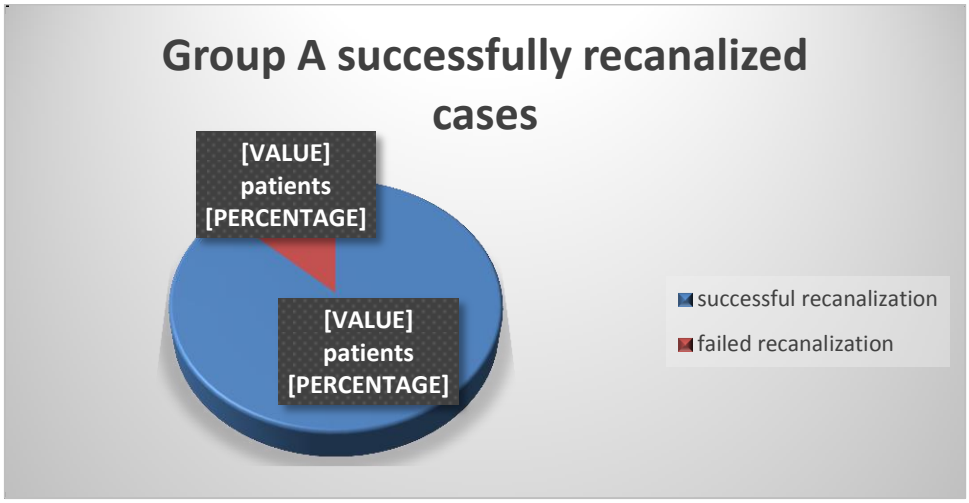
We enrolled 92 Infertile female patients with proximal tubal obstruction to investigate the fertility outcomes of infertile patients who have proximal tubal obstruction and was treated by Hysteroscopic tubal cannulation with hydrotubation (HTCH) versus Hysteroscopic tubal catheterization (HTC) for recanalization both interventions done under guidance of diagnostic laparoscopy in the Obstetrics and gynecology Department at Suez Canal University Hospitals.

Table 1: patient's characteristics of the study groups

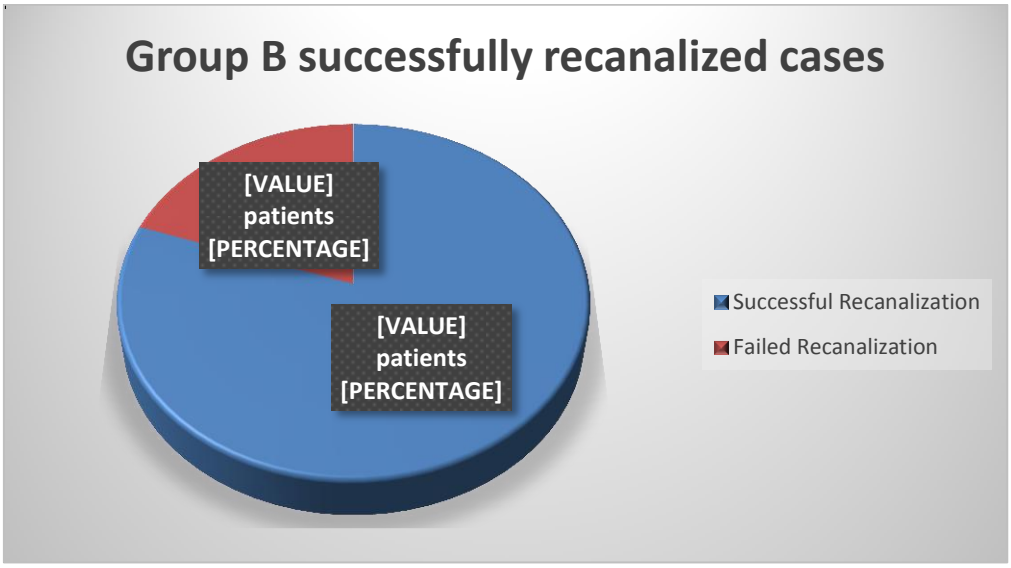
Variable		Group A (N=46) HTCH	Group B (N=46) HTC	P value
Age (year)		28.8 ± 5.76	27.9 ± 4.99	0.47
Duration of infertility		3.8 ± 1.7	3.4 ± 1.5	0.31
Type of infertility	**Primary**	14 (30%)	16 (35%)	0.42
	Secondary	32 (70%)	30 (65%)	

Table 1 showed the characteristics of study population. The mean age of the study population was 28.08 ± 5.42 years with range of 23 to 35 years old. The mean duration of infertility in study population was 3.8 ± 1.7 with range of 2-5 years of infertility. Both study groups were mainly secondary infertility 70% in group A to 65% in group B while primary infertility rates were lower in both groups (30% group A and 35% group B).

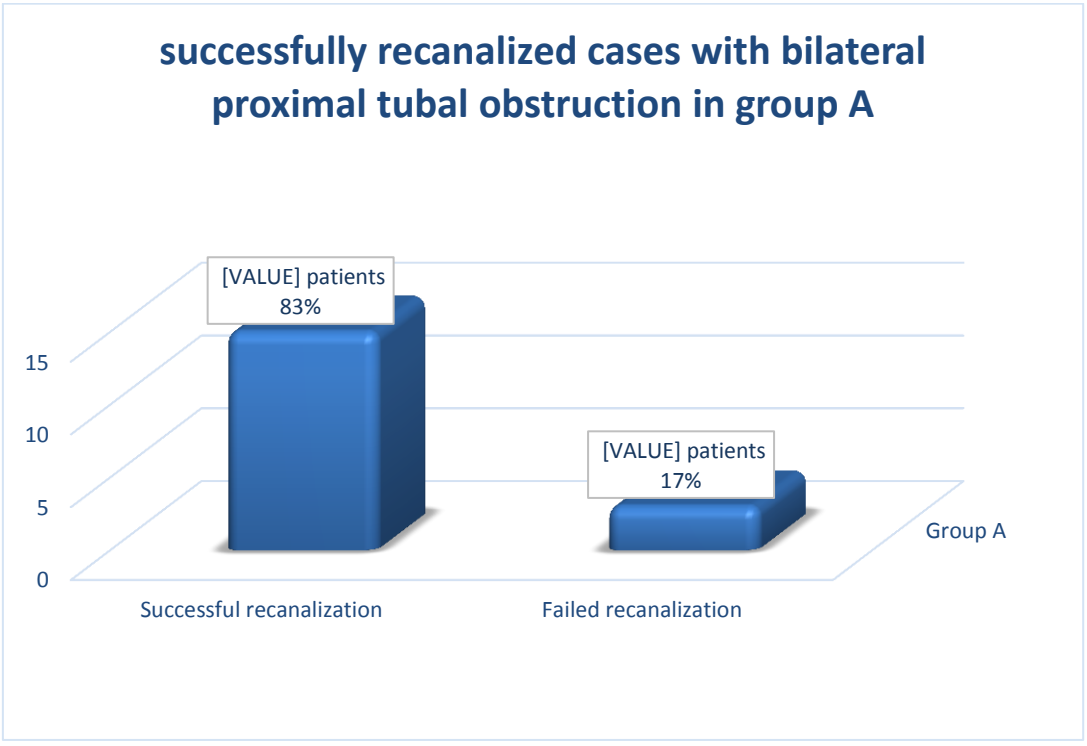
The results showed insignificant statistical difference between both study groups.



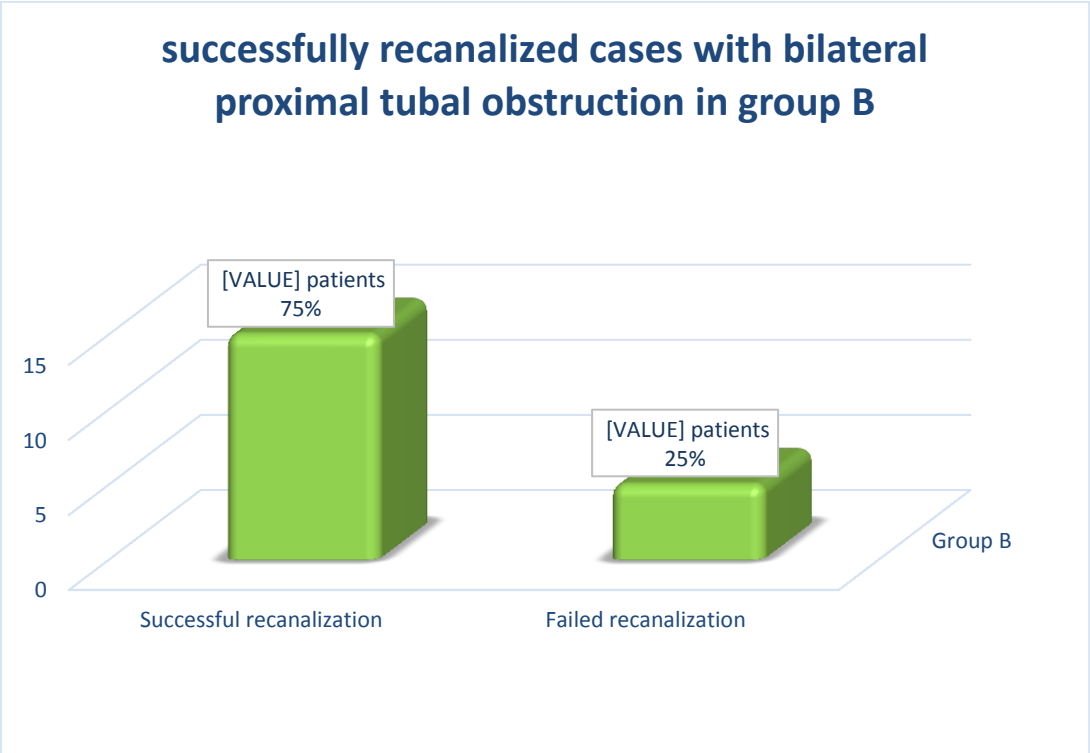
This figure shows cases with successful intervention in group A in which we used hysteroscopic cannulation for the blocked tube(s) with hydrotubation and free spill of methylene blue dye confirmed by diagnostic laparoscopy. Successful recanalization of 40 cases from total 46 cases with 87% recanalization rate.



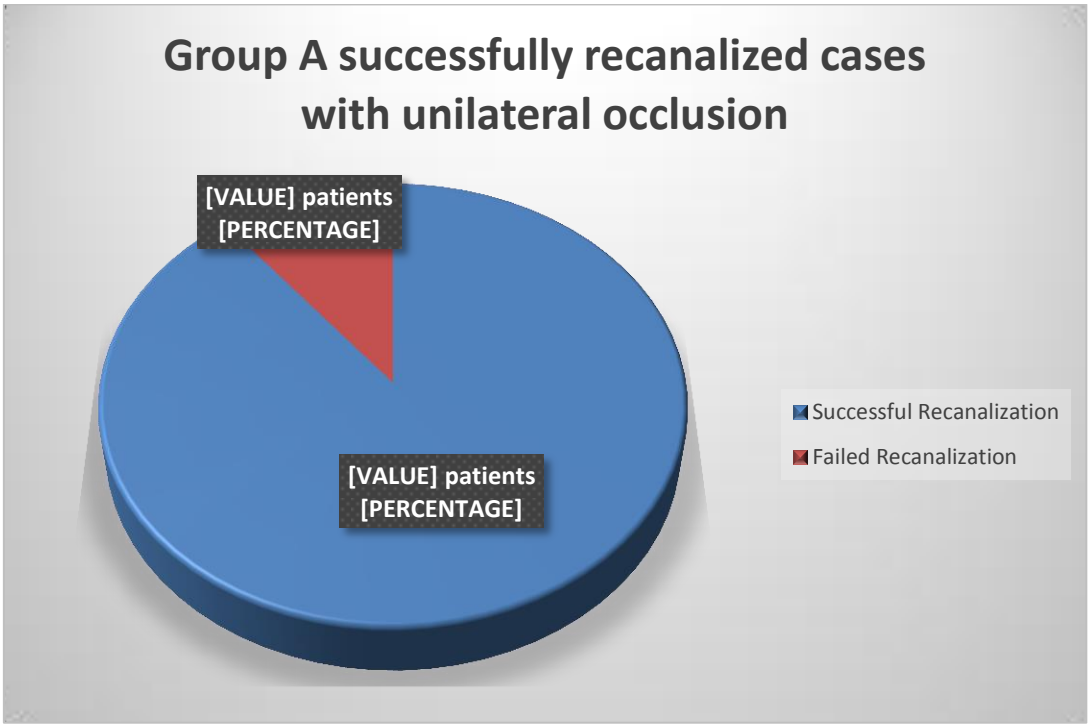
This figure shows cases with successful intervention in group B in which we used hysteroscopic catheterization of the blocked tube(s) till it's ampullary portion with free spill of methylene blue dye confirmed by diagnostic laparoscopy. Successful recanalization of 37 cases from total 46 cases with 80% recanalization rate.



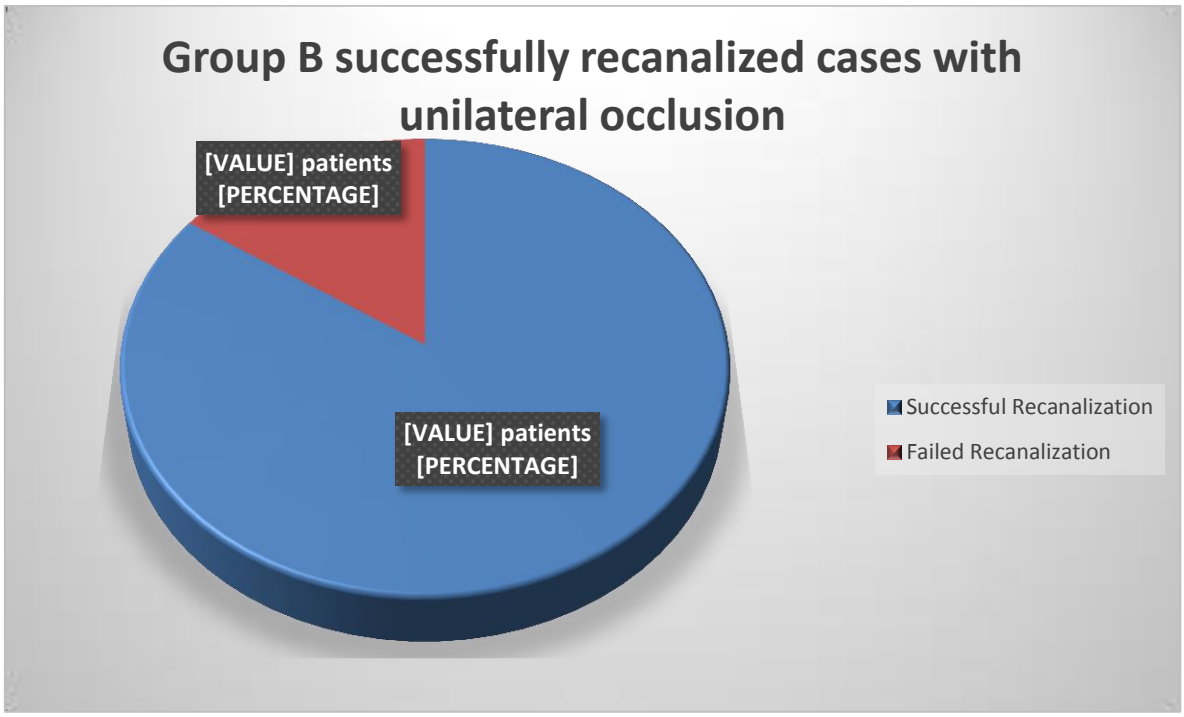
This figure shows cases with bilateral proximal tubal obstruction successfully recanalized (one or both tubes) in group A in which we used hysteroscopic cannulation for the blocked tube(s) with hydrotubation and free spill of methylene blue dye confirmed by diagnostic laparoscopy. Successful recanalization of 15 cases from total 18 cases with 83% recanalization rate.



This figure shows cases with bilateral proximal tubal obstruction successfully recanalized (one or both tubes) in group B in which we used hysteroscopic catheterization of the blocked tube(s) till it's ampullary portion with free spill of methylene blue dye confirmed by diagnostic laparoscopy. Successful recanalization of 15 cases from total 20 cases with 75% recanalization rate.

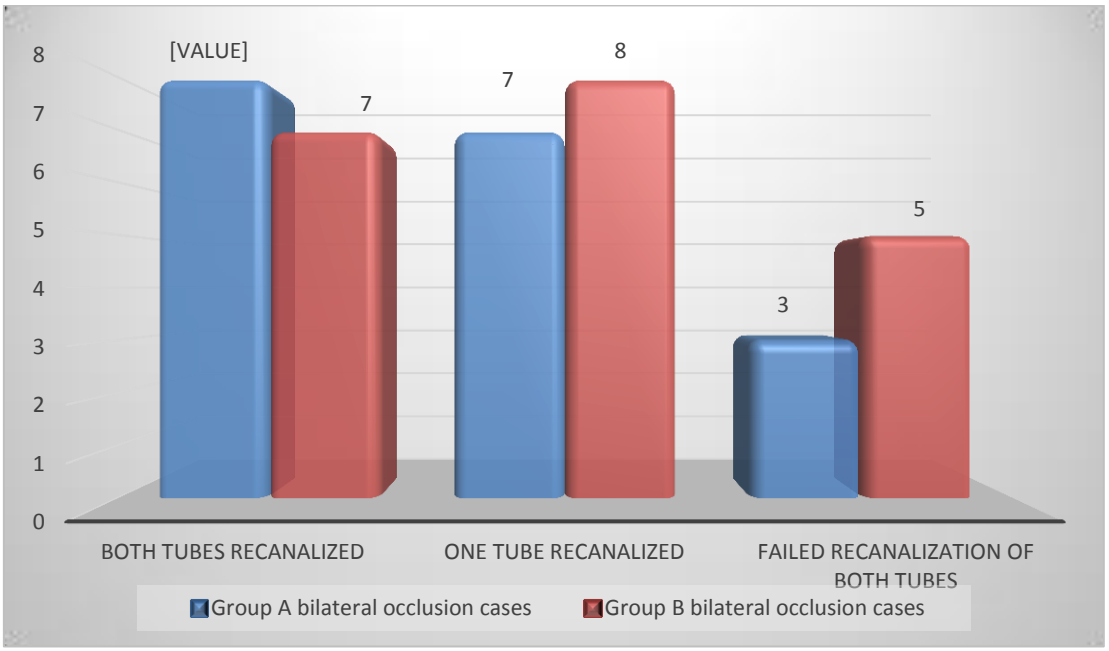


This figure shows cases with unilateral proximal tubal obstruction successfully recanalized in group A in which we used hysteroscopic cannulation for the blocked tube(s) with hydrotubation and free spill of methylene blue dye confirmed by diagnostic laparoscopy. Successful recanalization of 25 cases from total 28 cases with 89% recanalization rate.



This figure shows cases with unilateral proximal tubal obstruction successfully recanalized in group B in which we used hysteroscopic catheterization of the blocked tube(s) till it's ampullary portion with free spill of methylene blue dye confirmed by diagnostic laparoscopy. Successful recanalization of 22 cases from total 26 cases with 85% recanalization rate. Overall, success rate in group A (87%) is higher compared to group B (80%) which indicates that hysteroscopic cannulation with hydrotubation (HTCH) is more effective, safe and less complicated intervention than hysteroscopic tubal catheterization (HTC).

Results of interventions in bilaterally occluded cases in both groups:



Success of interventions in both study groups in cases with bilateral proximal tubal obstruction showed in figure VIII. Group A 18 patients with bilateral tubal occlusion (23 tubes recanalized of 36 occluded tubes) 3 patients failed recanalization of both tubes, 7 patients only one tube recanalized and 8 patients both tubes recanalized successfully compared to group B 20 patients with bilateral tubal occlusion (22 tubes recanalized of 40 occluded tubes) in 5 patients recanalization failed for both tubes, 8 patients only one tube recanalized and 7 patients were both tubes recanalized successfully.

Table 2: Results of interventions regarding total number of obstructed tubes in both study groups:

Variable	Group A (N=64) HTCH	Group B (N=66) HTC	P value
Total number of obstructed tubes in each study group	48/64 (75%)	44/66 (66%)	<0.045

N= number of obstructed tubes P value = Significance (2-tailed)

Results of interventions regarding total number of obstructed tubes in both study groups showed in table 2.

Overall, success rate in group A (75% with 48 tubes recanalized of 64 occluded tubes) is not significant (P <0.045) compared to group B (66% with 44 tubes recanalized of 64 occluded tubes).

Table 3: Pregnancy outcome of the study groups patients with successful intervention.

Variable	Group A (N=40)	Group B (N=37)	P value
Intrauterine pregnancy	15 (37.5%)	8 (21.5%)	0.002
Tubal pregnancy	2 (5%)	5 (13.5%)	
Tubal patency without pregnancy	20 (50%)	17 (46%)	
Tubal re-occlusion	3 (7.5%)	7 (19%)	

N = number of patients with successful intervention

Regarding the pregnancy outcome, table 3 showed that 37.5% of group A (15 patients of 40 successful cases of tubal recanalization) had intrauterine pregnancy, 2 patients had tubal ectopic pregnancy and both originally had bilateral tubal occlusion compared to 21.5% of group B (8 patients of 37 successful cases of tubal recanalization and 5 patients had tubal pregnancy).However, group B had higher rate of tubal re-occlusion (19% 7 patients of total 37 cases 4 of them were bilaterally obstructed and the rest were unilaterally obstructed) compared to group A (7.5% with 3 patients of total 40 cases had successful recanalization and 2 of them were bilaterally obstructed) which indicates that HTC had higher rate of ectopic pregnancy and tubal re-occlusion especially in patients with originally bilateral proximal tubal obstruction than HTCH.

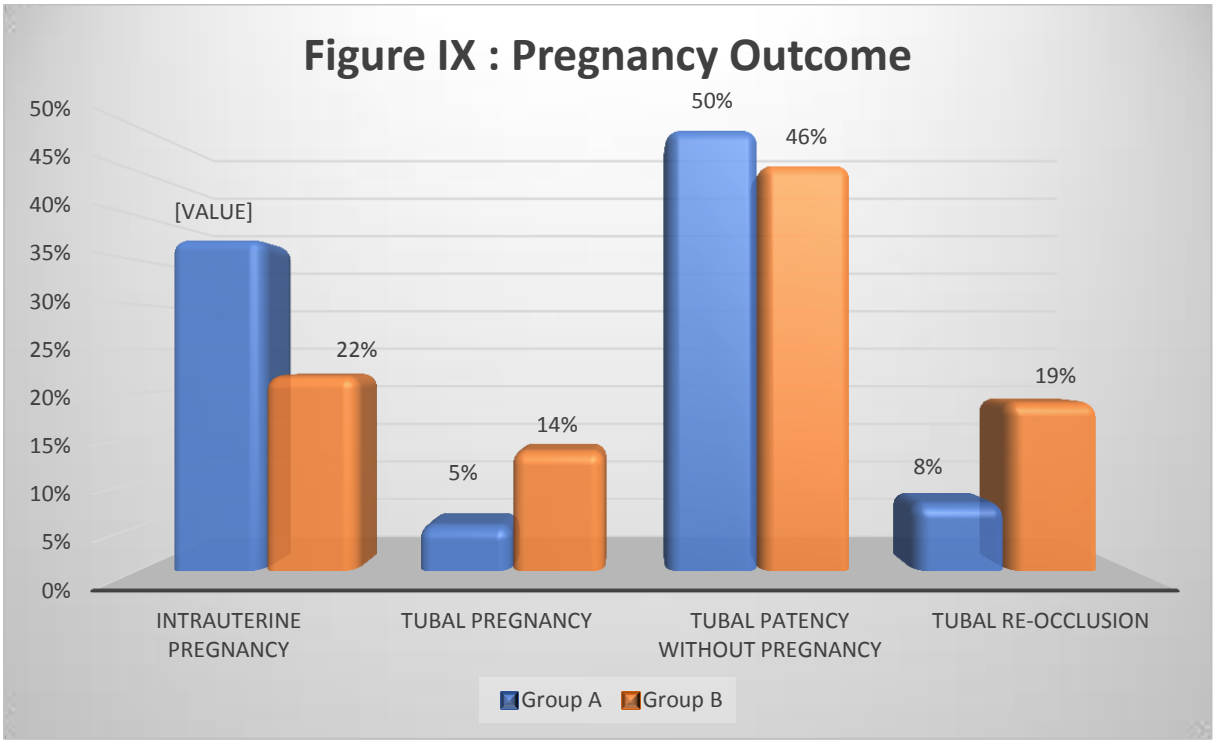


Figure IX showed the overall pregnancy outcome of both study groups with higher pregnancy rates in group A using HTCH and higher rate of tubal re-occlusion and ectopic tubal pregnancy in group B using HTC which fairly indicates that hysteroscopic tubal cannulation and hydrotubation (HTCH) is better safer way of recanalization than hysteroscopic tubal catheterization (HTC).

Table 4: Incidence of tubal perforation during interventions in both study groups

Variable	Group A (N=46)	Group B (N=46)	P value
Perforation	3 (7%)	5 (12%)	0.67

Perforation of the occluded tubes during surgical intervention is one of the expected complications. Table 4 shows incidence of tubal perforation in both groups (7% group A to 12% group B) with insignificant difference between the groups (P value =0.67).

Discussion

Use of laparoscopy may not determine whether the visualized obstruction comes from a temporary cause, such as cornual occlusion by amorphous material, or whether true anatomical occlusion exists. True occlusion, by amorphous material, filmy adhesions, or a polyp, can be successfully treated by various uterotubal cannulation methods **(5)**.

In the present study, the mean of age of the study population was 28.08 ± 5.42 years with range of 23 to 35 years old. The results showed insignificant difference between the groups according to the demographic data.

Regarding to surgery procedure complications, Perforation of the occluded tubes during surgical intervention is one of the expected complications. Incidence rate of tubal perforation in both groups (7% group A to 12% group B) with insignificant difference between the groups (P value =0.67) with insignificant difference between the groups. Tubal perforation may occur due to forcible advancement of the guidewire either against true fibrous occlusion, or in a wrong direction creating a false passage. Also, it has been speculated that tubal perforation could occur during transcervical cannulation because of the tortuous nature of the interstitial and isthmic portions of the tube **(6)**.

In the present study, during intervention cases in which tubal perforation occurred or cannulation failed, Tubal perforation, are most likely attributable to true fibrous occlusion of the tubal lumen as seen in this study and in other studies **(7)**.

Similar study reported perforation of a successfully cannulated tube with resultant intrauterine pregnancy achieved through the cannulated and the only functioning tube. This case suggests that pregnancy can occur after guidewire perforation **(5)**.

Utilization of the coaxial cannulation set under direct hysteroscopic visualization flexibility of the guidewire presence of the laparoscopic guidance and experience of the surgeon are expected to decrease the risk of tubal perforation **(3)**.

Unilateral occlusion had higher success rate in both groups compared to bilateral occlusion success rate. Also, success rate in the bilateral occlusion is significantly higher (P value =0.02) in group A (63%) compared to group B (55%) as cases with bilateral proximal tubal obstruction considered successful when at least one tube is recanalized.

As noted in the present study that unilateral occlusion had higher success rates in both groups compared to bilateral occlusion success rate in both groups, usually cases with bilateral tubal blockage caused mainly by old infection which leads to fibrosis causing proximal obstruction of both tubes.

A study to assess the association between positive *Chlamydia trachomatis (C. trachomatis)* serology and unilateral or bilateral tubal obstruction found a strong and statistically significant association between bilateral tubal obstruction and *C. trachomatis* positive serology. Meanwhile, there was no association between unilateral obstruction and positive serology as it mainly caused as a result of tubal kinking or spasm **(8)**.

In the present study, pregnancy outcome of both study groups with higher pregnancy rates in group A using HTCH and higher rate of tubal re-occlusion and ectopic tubal pregnancy in group B using HTC.

A study Comparing pregnancy outcome between Ultrasound- Guided tubal recanalization and office-based microhysteroscopic ostial dilatation in patients with proximal blocked tubes reported that Successful recanalization with bilateral occlusion was (20%) and with unilateral occlusion was (65%) **(9)**.

Al-Jaroudi et al. (10) performed SSG on 72 patients with bilateral proximal obstructions, as confirmed by HSG (132 fallopian tubes), following which successful recanalization of both the tubes was achieved in 25 patients (34.7%) and 23 patients conceived (crude pregnancy rate, 31.9%).

Ikechebelu et al. (6) demonstrated that in 53 patients with proximal tubal blockage (94 fallopian tubes) who underwent HTC under laparoscopy, the success rate was 73.4% (69/94) per tube and 67.9% (36/53) per patient. Among the 36 patients whose complete pregnancy outcome data are available, 12 achieved spontaneous pregnancies (33.3%), including 1 ectopic pregnancy.

In most studies referenced previously, HTC or SSG was performed for both diagnosis and treatment, and so cases with an incorrect diagnosis of fallopian tube obstruction may have been included in the success group.

In the present study, there was a high frequency of peritubal adhesions in the unsuccessful recanalization of bilateral tubal occlusions. This may be one of the reasons for the low success rate of recanalization.

In addition, **Dobson et al. (11)** used a catheter system (ModiWed Novy Cornual Cannulation Set; Cook OB/GYN, Indiana, USA) that cannulates cornual segments by introducing a 3 Fr catheter through a 5 Fr catheter. This catheter system was not available at our institution during the study period, so this may also have contributed to the low success rate.

Both hysteroscopic tubal cannulation under laparoscopic guidance as well as hysteroscopic tubal catheterization should be recommended as choice for further diagnosis and treatment of infertile women with PTO.

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