

Laparoscopic Tubal Adhesiolysis Versus ICSI in Cases of Post-Cesarean Adhesions: Which Is the Best?

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ABSTRACT

Background & Objective: Secondary infertility resulting from tubal adhesions following cesarean section are not uncommon. The decision to do adhesiolysis or direct IVF/ICSI is to some extent difficult. This study was conducted to evaluate the benefits/risks of either adhesiolysis or direct IVF/ICSI for patients with secondary infertility due to post-cesarean tubal adhesions.

Materials & Methods: Three hundred infertile women with post-cesarean adhesion were recruited and divided into 2 groups either laparoscopic adhesiolysis or ICSI procedure.

Results: Demographic data of enrolled patients in both groups were comparable. Regarding types of adhesions, mild adhesions were found in (47.65%) cases, moderate adhesions in (24.83%) cases and severe adhesions in (27.52%) cases. Pregnancy rates were found to be higher in cases with mild adhesions (62.67%) when compared to cases with moderate or severe adhesions (28.00%) and (9.33%) respectively. The overall pregnancy rate in group 1 was 67 (44.97%), while it was 83 (55.70%) in group 2. The pregnancy rate was higher in group 2 but didn't reach statistical significance. The cost of the procedure was significantly higher in group 2 but with significantly lower complication rates.

Conclusion: Although assisted reproduction gives the patient higher pregnancy rates with less possibility of complications, it should not be considered the first-choice treatment for patients with post-cesarean adhesions, especially in mild and moderate cases.

Keywords: IVF/ICSI, Laparoscopy, Pregnancy rate, Secondary infertility, Tubal adhesions



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Introduction

Cesarean section rates have increased worldwide, exceeding the world health organization (WHO) recommendations. The rise in cesarean section rates has exposed women to several risks, including maternal morbidity and delayed complications. These complications include pelvic adhesions, post-cesarean infertility, cesarean scar defect, cesarean scar ectopic pregnancy, and placenta accrete spectrum (PAS) (1).

Many studies reported the occurrence of pelvic adhesions following cesarean section with its related consequences. Chronic pelvic pain is one of the most common consequences related to pelvic adhesions. It may result from scarring and distorted pelvic anatomy following surgery. Bowel obstruction is another life-threatening condition resulting from pelvic adhesions. Some digestive disorders may result from adhesions, such as constipation or irritable bowel syndrome (2-5).

On the same side, pelvic adhesions may affect both reproductive system anatomy and function, causing various associated conditions. Pelvic adhesions may cause secondary infertility, which might be due to dyspareunia, disturbing tubo-ovarian relationship, or disturbing peristaltic movement of fallopian tube. On the other hand, post-cesarean adhesions were accused of delayed delivery of babies during the next cesarean delivery with prolongation of operative time and increasing the risk of surgical trauma or laceration of the adjacent organs (6-10).

Post-cesarean infertility could be managed by laparoscopic adhesiolysis as this treatment modality is less invasive and has become more accepted than traditional surgery. Laparoscopic adhesiolysis helps not only in restoring normal pelvic anatomy but also in the restoration of normal tubal function and tubo-ovarian relationship (11, 12). On the other side, some clinicians advise those patients with pelvic adhesions

to shift to the intra-cytoplasmic sperm injection (ICSI) without adhesiolysis. Their rationale for this advice is the rapid progress in assisted reproductive technologies and not exposing patients to the risks of laparoscopic surgery. This debate puts gynecologists in a dilemma when confronted with cases with pelvic adhesions, which is the best management strategy for those patients. Each treatment strategy's value, safety, and cost should be discussed thoroughly for those patients before advising one procedure and declining the other (13).

In this study, the value of laparoscopic adhesiolysis was compared in the patients previously diagnosed with pelvic and peritoneal adhesions following cesarean delivery with direct IVF/ICSI procedures.

Methods

Patients

Study Design and Settings

This randomized controlled study was conducted at Tanta University, Al-Yasmin, Ingab, and Om Elqura Fertility Centers. This study was conducted from May 1, 2018, to October 31, 2021.

Sample Size Justifications

This study was planned to enroll independent cases and controls with 1:1 ratio. The null hypothesis (H_0) assumed that failure rates for adhesiolysis and ICSI subjects are equal. Previous studies reported 40% pregnancy rate among ICSI cases. Assuming that true pregnancy rate following laparoscopic adhesiolysis is 30%, we needed to study 144 in each group to reject the null hypothesis with a probability (power) of 0.8 and Type I error probability of 0.05. An uncorrected Chi-squared test was used to evaluate the null hypothesis.

Eligibility: Three hundred patients, suffering from secondary infertility due to post-cesarean adhesions, were included in the study. Inclusion criteria were (a) age ≤ 35 years, (b) post-cesarean adhesions confirmed by the prior laparoscopic surgery, and (c) no other causes of secondary infertility.

Exclusion criteria were (a) patient's age >35 years, (b) other causes of infertility as male factor, ovulatory or endocrinological disorder, (c) endometriosis, (d) history of recurrent pregnancy loss, and (e) prolonged sexual abstinence.

Randomization and Allocation: Simple randomization was used in the current study where patients were given sealed envelopes containing either letter L or I, denoting either laparoscopy or ICSI. The patients were randomly allocated into either **group 1**, which included patients who underwent laparoscopic tubal adhesiolysis and/or tuboplasty or **group 2**, which included patients who underwent ICSI procedures. The patient and the operator were blinded (open label trial).

All demographic data, type of adhesions in each group, treatment strategy parameter and related complications, cost of each treatment strategy, and clinical pregnancy in either group.

Follow-up: patients in both groups were followed up for one year for the occurrence of pregnancy.

Study Outcomes: The primary outcome was the clinical pregnancy confirmed by the presence of a gestational sac in ultrasound at 6 weeks. Secondary outcomes included the cost of each procedure and the occurrence of any complications.

Ethical Approval and Trial Registration: The study objectives, treatment strategies, and risks were discussed with all participants before signing the written consent to participate. The current study was approved by the Ethical Committee of Tanta University before recruitment and was given the unique ID of 32235/04/18. This clinical trial was also registered on clinicaltrials.gov with the following ID: NCT03476759. It is available in the following link: https://register.clinicaltrials.gov/prs/app/action/SelectProtocol?sid=S0007_VL5&selectaction=Edit&uid=U000404_W&ts=6&cx=qg2jvl.

Statistical Analysis

The Stata 16.1 (Stata Corp- College Station- TX- USA) was used for the analysis of the data obtained in the current study. Mean and standard deviation (SD) was used for the continuous data with normal distribution, while the median (25th - 75th percentiles) was used for non-normally distributed data. We used t-test and Mann-Whitney U test to compare the continuous data. Categorical data were presented as frequencies and percentages and compared with the Chi-square or Fisher exact test. A P-value less than 0.05 was considered as statistical significance.

Results

Initial enrollment included 311 cases where the eligible cases were 300, and the others (n=11) were excluded either not meeting inclusion criteria (n=5) or declined to participate (n=6). The flow of cases during the study is presented in [Figure 1](#).

Patients were divided into two groups; group 1 (n=149) included patients who had adhesiolysis and group 2 (n=149) included patients who had ICSI without adhesiolysis. There were no differences in the age, body mass index (BMI), gravidity, parity and duration of infertility between both groups. These data are presented in [Table 1](#).

Regarding types of adhesions in group 1, mild adhesions were found in 72 (48.32%), moderate in 33 (22.15%) and severe in 44 (29.53%) compared to 70 (46.97%), 41 (27.52%) and 38 (25.50%) in group 2, respectively as shown in [Figure 2](#). In group 1, electrocautery was used for adhesiolysis in 65 patients (43.62%) and blunt/sharp dissection was used in 84

patients (56.38%). The operative time was 45 (35- 65) minutes. These data are presented in [Table 2](#).

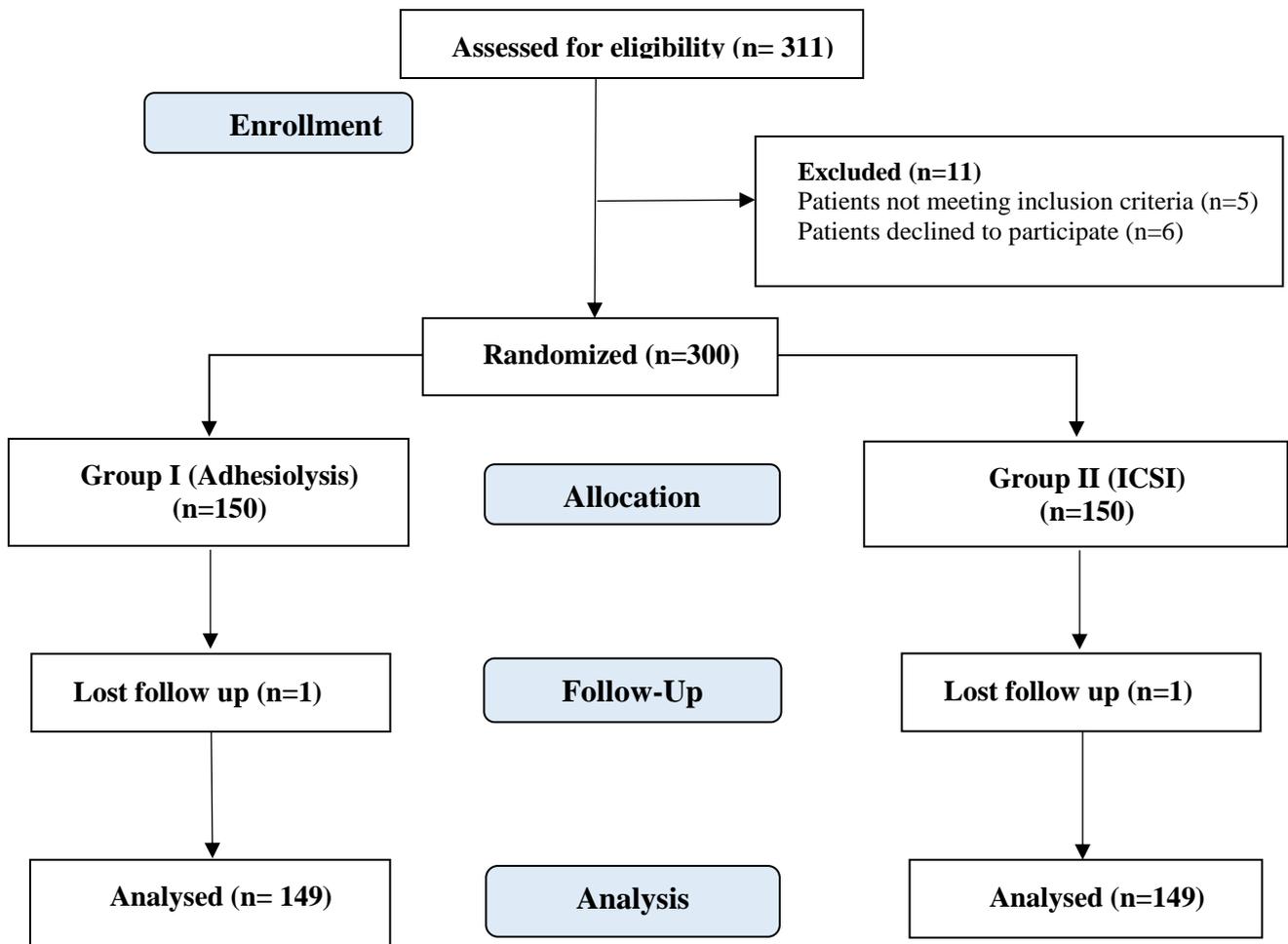


Figure 1. CONSORT Flow chart of cases through the study

Table 1. Comparison of the baseline data between both groups

	Group 1 (n= 149)	Group 2 (n= 149)	P-value
Age	27.56± 3.74	27.978± 3.71	0.34
Gravidity			
One	76 (51.01%)	87 (58.39%)	0.44
Two	53 (35.57%)	45 (30.20%)	
Three	20 (13.42%)	17 (11.41%)	
Parity			
One	117 (78.52%)	108 (72.48%)	0.23
Two	32 (21.48%)	41 (27.52%)	
Body mass index (Kg/m ²)	26.1 (23.8- 28.5)	26.1 (23.6- 28.3)	0.65
Duration of infertility (months)	29 (24- 33)	30 (25- 35)	0.12

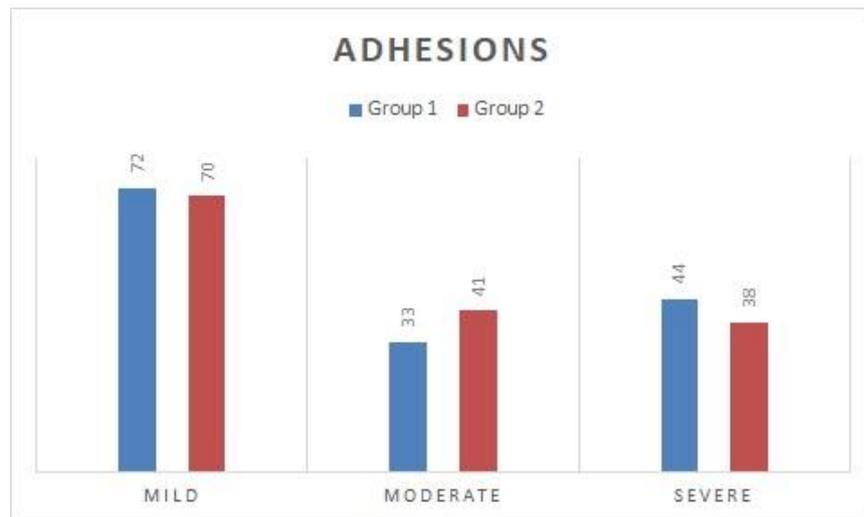


Figure 2. Type of adhesions

In group 2, the simulation method was antagonist in 90 (60.40%) patients and long agonist in 59 (39.60%) patients. The gonadotropin dose was 1975 (1650-2425) IU. The number of oocytes was 12, and the number of embryos was 7, as shown in [Table 2](#). The costs of both procedures are presented in [Table 2](#) and [Figure 3](#), which were higher in ICSI group with significant difference between both groups ($P < 0.001$). Pregnancy rates were presented in [Table 2](#) and [Figure](#)

[4](#), where pregnancy rates were found higher in ICSI group than in the adhesiolysis group but did not reach a significant level ($P = 0.06$).

Regarding the relation of pregnancy to adhesions, mild adhesions were correlated to the highest pregnancy rates, while severe adhesions were correlated to the lowest pregnancy rates, as shown in [Table 3](#).

Table 2. Comparison of the outcomes between groups

	Group 1 (n= 149)	Group 2 (n= 149)	P-value
Operative time (minutes)			
Range	45.7±4.56	-	
Mean±SD	35-65	-	
Methods of adhesiolysis			
Electrosurgery	65 (43.62%)	-	
Mechanical	84 (56.38%)	-	
Stimulation protocol			
Antagonist	-	90 (60.40%)	
Agonist	-	59 (39.60%)	
Dose of gonadotropins (IU)			
Range	-	1975	
Mean±SD	-	1650- 2425	
Number of retrieved oocytes			
Mean±SD (range)	-	12 (10-14)	
Number of embryos			
Mean±SD (range)	-	7 (5-9)	
Complications			
No complications	136 (91.28%)	146 (97.99%)	0.02
Complications	13 (8.72%)	3 (2.01%)	

	Group 1 (n= 149)	Group 2 (n= 149)	P-value
• Bleeding	7 (4.70%)	0	
• Visceral injury	3 (2.01%)	0	
• Surgical emphysema	3 (2.01%)	0	
• OHSS	0	2 (1.34%)	
• Tubo-ovarian abscess	0	1 (0.67%)	
Cost (Dollars)	140 (130- 170)	440 (410- 530)	<0.001
Pregnancy	67 (44.97%)	83 (55.70%)	0.06

Table 3. Types of adhesions in pregnant and non-pregnant cases

	Pregnant (n= 150)	Not pregnant (n= 148)	Total (n=298)	P-value
Mild adhesions	94 (62.67%)	48 (32.43%)	142 (47.65%)	<0.001
Moderate adhesions	42 (28.00%)	32 (21.62%)	74 (24.83%)	
Severe adhesions	14 (9.33%)	68 (45.95%)	82 (27.52%)	
Total	150	148	298	

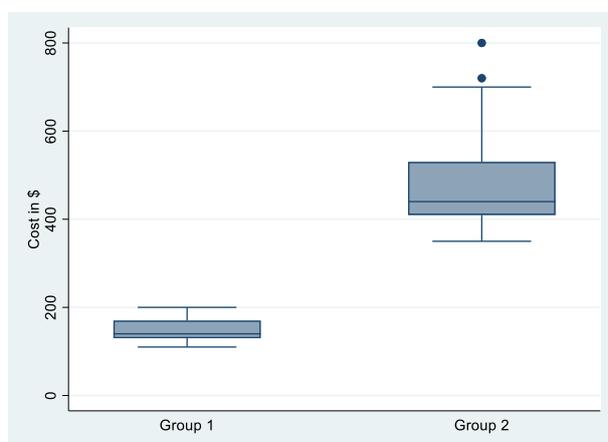


Figure 3. Box plot of the cost in both groups

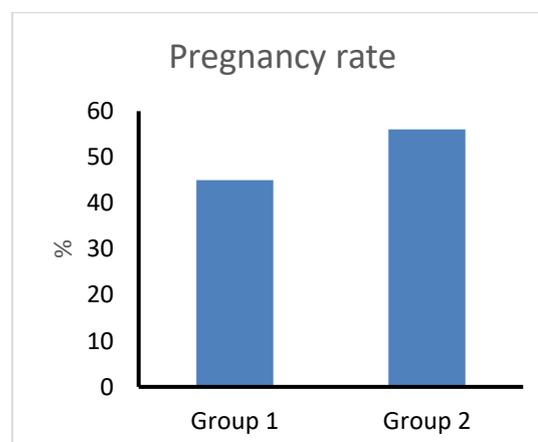


Figure 4. Pregnancy rate in both groups

Discussion

Abdominal and pelvic adhesions occurring after surgical interventions are associated with an increased risk of visceral injuries, increased postoperative complications, and increased surgical costs and workload. The rapidly increasing cesarean section rates expose more women to the post-cesarean adhesion syndrome (14).

Peritoneal healing following cesarean section differs from other abdominal surgeries in the puerperal uterine size that push omentum and intestines towards uterine and abdominal incisions, which delay the natural

healing process. These mechanisms lead to adhesion formation between the omentum and intestines on one side and the anterior abdominal wall, uterus, fallopian tubes, and ovaries on the other side (7-9).

Several reports revealed a high incidence of pelvic adhesions during diagnostic laparoscopy in patients with unexplained secondary infertility occurring after previous cesarean delivery. These studies stated that those patients had normal findings in hysterosalpingogram (HSG) (15, 16).

Post-cesarean infertility has become a well-known condition that all gynecologists consider unexplained secondary infertility. There is still a great debate among gynecologists on the solution to this condition. Some gynecologists prefer ART directly, while others prefer laparoscopic adhesiolysis. For this reason, this study was designed to put the best practice points for the gynecologists to follow when confronted with such cases. Most of those patients with suspected peritubal adhesions (with patent tubes) will benefit from both treatment strategies, and management should be individualized according to each patient's characteristics and economic status. Infertility is not just a medical issue; it has many other aspects, such as economic, social, and psychological aspects (15).

Currently, many gynecologists don't recommend diagnostic laparoscopy for those patients with suspected adhesions as the procedure is done under general anesthesia and may be associated with some potentially serious complications (16).

In our study, the adhesions were mild in 72 patients (48.32%), moderate in 33 (22.15%), and severe in 44 (29.53%). Thus, most of the adhesions were mild, and most of the cases that got pregnant were in the mild adhesion group, which could explain the non-significant difference in the pregnancy rates between both groups.

On the other hand, Dawood *et al.* conducted a cross-sectional study to detect the percentage and types of adhesions in patients with post-cesarean infertility. They detected adhesions in 98/134 (73.13%) patients. Most adhesions were filmy in 86 (70.83%), thick in 21 (21.88%), and frozen pelvis in 7 (7.29%) cases (17). Similarly, Elgergawy *et al.* conducted a study to assess the value of adhesiolysis in post-cesarean infertility. They found mild adhesions in 52.4%, moderate adhesions in 31.7%, and severe type adhesions in 10.9%. The authors found that pregnancy rates were 50% in the adhesiolysis group compared to 10.86% in the conservative group undergoing conventional stimulation and intrauterine insemination (IUI) in a significant level ($P= 0.0008$) (18).

Seyam *et al.* studied 250 cases presented with secondary infertility following one cesarean delivery and were candidates for the diagnostic laparoscopy. On laparoscopy, 97 cases were found to have adnexal adhesions only. Adhesions were mild in 35 (36%), moderate in 44 (45%), and severe in 18 (18%) cases, with an overall pregnancy rate after laparoscopic tuboplasty of 20.6%, 10.3%, and 5.2%, respectively. In other words, 35 women (36%) out of 97 got pregnant after laparoscopic tuboplasty (19).

Another study was conducted on 50 patients with secondary infertility after previous cesarean delivery, of which 32 patients (64%) had previous one CS while 18 patients (36%) had two CS. Laparoscopic assessment of the study group showed that adhesions were filmy in 24 (70.6%), dense in 7 (20.6%), and

frozen pelvis in 3 (8.8%) patients of cases with a pregnancy rate after adhesiolysis of 41%, 5%, and 0%, respectively. In other words, 16 women (47%) out of 34 got pregnant after laparoscopic tuboplasty (20).

Our results were in line with other studies that the higher rates of pregnancy after laparoscopic adhesiolysis were in cases with mild tubal adhesions, and pregnancy rates decreased with the more severe tubal disease. This could explain the non-significant difference in pregnancy rates between the group with tubal adhesiolysis and the group that underwent ART. Therefore, if most of our patients in the group of adhesiolysis had moderate to dense adhesions, pregnancy rates would be lower than that in the group of ART.

According to this study's results, we believe that decisions should be individualized according to different factors, including patients' characteristics, economic status, psychological and emotional background, and last but not least, the surgical skills of the operator.

The strength points of this study were the randomized nature of the study, the inclusion of a relatively large number of cases, comparing between the most common management lines of infertility, adding to evidence that it is beneficial for the patients with post-cesarean infertility, and help gynecologist to take the best decision for each patient as one size doesn't fit all. The weak points were the open (non-blinded) nature, operations conducted by more than one surgeon, and ICSI done at different centers and with other stimulation protocols and drugs.

Conclusion

Adhesiolysis was associated with few complications and was a less costly procedure if compared to the ICSI procedure. Regarding pregnancy rates, they were comparable in the 2 procedures. We recommend applying laparoscopic adhesiolysis for patients with mild to moderate adhesions rather than ICSI, while ICSI is recommended in patients with severe adhesions from the start.

Declaration

Ethics approval and consent to participate: Approval was taken from Tanta University ethical committee with the following code: 32235/04/18

Consent for publication: Not applicable

Availability of data and material: The datasets used during the current study are available from the corresponding author on reasonable request.

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Authors' contributions:

Conceptualization: Ayman S. Dawood, Tamer M. Assar

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Data collection & Statistical analysis: Ayman S. Dawood, Tamer M. Assar

Writing & revision: Ayman S. Dawood, Walid M. Atallah, Tamer M. Assar

Submission: Ayman S. Dawood.

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Conflict of Interest

None.

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