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Surgery for Severe Endometriosis and ART Outcome and Effect of Time Interval Between Surgery and FET

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ABSTRACT

Background & Objective: To evaluate fertility outcomes in infertile women with severe endometriosis who underwent Frozen embryo transfer (FET) after laparoscopic surgery and assess the optimal time interval between laparoscopy and FET.

Materials & Methods: Number of 215 females with advanced-stage endometriosis were included in this retrospective cohort study. At first embryo were then laparoscopic surgery was performed. Patients received gonadotropin-releasing hormone agonist (GnRH agonist) for the next three months after the laparoscopic surgery. FET was scheduled during the next several time-points after the laparoscopic surgery. The results of treatment such as live birth, the interval between the operation and pregnancy, improved dysmenorrhea/dyspareunia, and post-operative complications were evaluated.

Results: A total of 215 patients with a mean ± SD age of 34.33 ± 6.62 were included, among which, 143 cases (86.2%) had no past medical history. Ninety-three individuals (44%) were referred for the first IVF procedure. The mean ± SD of the infertility period was 4.71 ± 5.43 years. The mean ± SD number of frozen embryos was 2.53 ± 3.36 and the period between the laparoscopic intervention and IVF was 1.58 ± 2.65 months.

Conclusion: Women with severe endometriosis may benefit from embryo freezing before laparoscopic surgery then FET. The optimal time between laparoscopy and embryo transfer is seemed to be between two and four months.

Keywords: Endometriosis, Laparoscopic Surgery, In vitro fertilization, Fertility

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Introduction

Endometriosis has been considered as a persistent inflammatory situation that plays a crucial role in fertility, with a prevalence rate of 25–40% in infertile women (1). Endometriosis is accountable for about 10% of the indications for In vitro fertilization (IVF) (2). This disease can make the in vivo atmosphere destructive for oocyte/embryo and reduce the ovarian reserve. Treatment of endometriosis depends on several factors, such as the severity of symptoms, extent and location of lesions, the patient's desire to become pregnant, and the age of the patient. In mild to moderate endometriosis, surgery may not have a significant and satisfactory result on PR (pregnancy rate). However, tubal blockage, toxicity of the environment, and formation of hydrosalpinx are usually detected in more advanced stages of endometriosis which may impair tube patency, cause infertility, and need excision before assisted conception (3). Pharmaceutical methods such as progestin, danazol, and Gonadotropin releasing hormone (GnRH) analogues are among the treatment's methods. According to the European society for human reproduction and embriology (ESHRE) guidelines, in women with endometriosis-associated infertility, surgical excision of deep nodular lesions previous to assisted reproductive technology (ART) is not recognized with regard to reproductive outcome (4). Surgical interventions of severe endometriosis are

effective in generating a constructive location for victorious conception **(5)**.

In addition, in suspicion of severe dysmenorrhea or cancer, surgery before IVF may be essential and warranted. However, some surgical methods may diminish the ovarian reserve, which may culminate in enhancing the risk of infertility **(6)**. Between primary surgery and ART, it is uncertain which gives the greatest managing. Laparoscopy is the most frequent technique applied to identify and treat patients with severe endometriosis, who suffer from pelvic pain. The probability of being pregnant in infertile cases with minimal/mild endometriosis is estimated to be about 30% several months after surgery, which can be reduced further **(7)**. In complex reproductive technology (ART)-related pregnancies, laparoscopic surgery of mild to moderate endometriosis has been detected to enhance PR as compared with diagnostic laparoscopy alone **(8)**. Colorectal endometriosis was determined by Deep infiltrating endometriosis (DIE) of at least the rectal muscularis. Rectal shaving requires the excision of subserosal/superficial muscularis, and full thickness discoid excision. Segmental colorectal resection also necessitates opening of the bowel lumen, which may culminate in infection and further complications such as suture/anastomotic dehiscence, configuration of rectovaginal fistula, neurogenic bladder, bowel dysfunction, and stenosis of the anastomosis **(9)**. The successful role of surgery in the management of endometriosis in patients with infertility is still controversial. In addition, modification of the chronic inflammatory alterations and changes of molecular biology of neighborhood tissue may not be capable by surgery alone **(10)**. Hence, surgery may not be competent to completely renovate the side effects of endometriosis on fertility. Numerous studies have recommended that the surgical removal of DIE and deep endometriosis nodules might have a favorable impact on IVF outcomes **(11)**. Additionally, the likelihood of spontaneous pregnancy after the surgery in cases undergoing total resection of DIE was acceptable in previously reported studies **(12)**. Therefore, it is of great importance to successfully forecast the possibility of fertility, avoid the reappearance of endometriosis, and manage this disease in the long-term. Performing the IVF practice in these patients seems to be logical and cost-effective.

There are two definite indications for surgery, severe pain unresponsive to Conservative treatment and hydrosalpinx.

In order to discover the fertility rate in patients with severe endometriosis and infertility after laparoscopic surgery, we performed a retrospective cohort study and analyzed the clinical data of patients, with the aim of improving the pregnancy rate, using IVF method.

Methods

A total of 215 patients with severe endometriosis, infertility, previous history of laparoscopic surgery or drug therapy, and several previous unsuccessful IVF in Infertility Clinic of Yas and Arash Hospitals from January 2018 to March 2019 were enrolled in this retrospective cohort study. However, 49 patients were excluded from the study and 166 cases were finally included in the study. We had also 72 patients with history of more than two previous IVF, and endometriosis with implantation failure, that underwent surgery for removal of deep DIE. Following DIE resection, they underwent FET for further pregnancy. The diagnosis of advanced stage endometriosis was made, based on American Society of Fertility (ASF) in 1985 (13). Most of the cases had colorectal endometriosis, with length of colorectal specimen 78 (mm) (range: 21–19). These patients had severe endometriosis infiltrating the rectum up to 14 cm from the anus, with more than 21 mm in length, and with at least the muscular layer in depth, and up to 45% of rectal circumference. The diameter of the largest rectal nodule was 28 mm (range: 14-39). Height of the lowest nodule (mm from anal verge) was 83 (range: 29–146).

After providing the informed consent, all patients underwent laparoscopic surgery and followed-up for two years. The surgeon-specific method volume is about 50 cases each year. The Committee of Human Research and institutional review board at Yas and Arash Hospitals and Tehran University of Medical Sciences approved the using clinical information in our study. The inclusion criteria included patients with histologically confirmed diagnosis of severe endometriosis and infertility, and women who had entire and detailed clinical, follow-up data evidence. Non-childbearing age patients, cases with previous history of hysterectomy, and any female with incomplete clinical or follow-up data were excluded from the study (54 patients) in Fig1 and Table 1.

Table 1. Demographic data of patient

Parameters	Number=161
Age (years)	19-45 (34.33±6.62)
BMI	16.4–34.2
Surgical antecedents	47 (28.1%)
History of IVF	72 (57%)

Parameters	Number=161
Infertility period (years)	0- 27 (4.71±5.43)
Anti-müllerian hormone (AMH) (pmol/L)	0.1-17 (3.93±4.2)
Irregular periods	46 (27.5%)
Unsuccessful pregnancy attempt for >12 months	143±3.25
dysmenorrhea	26 (7.2±0.25)
Dyschezia	31 (2.42±0.27)
Dyspareunia	52 (4.1±0.28)

N=numbers of patients, Mean±SD, %=percent of the patients

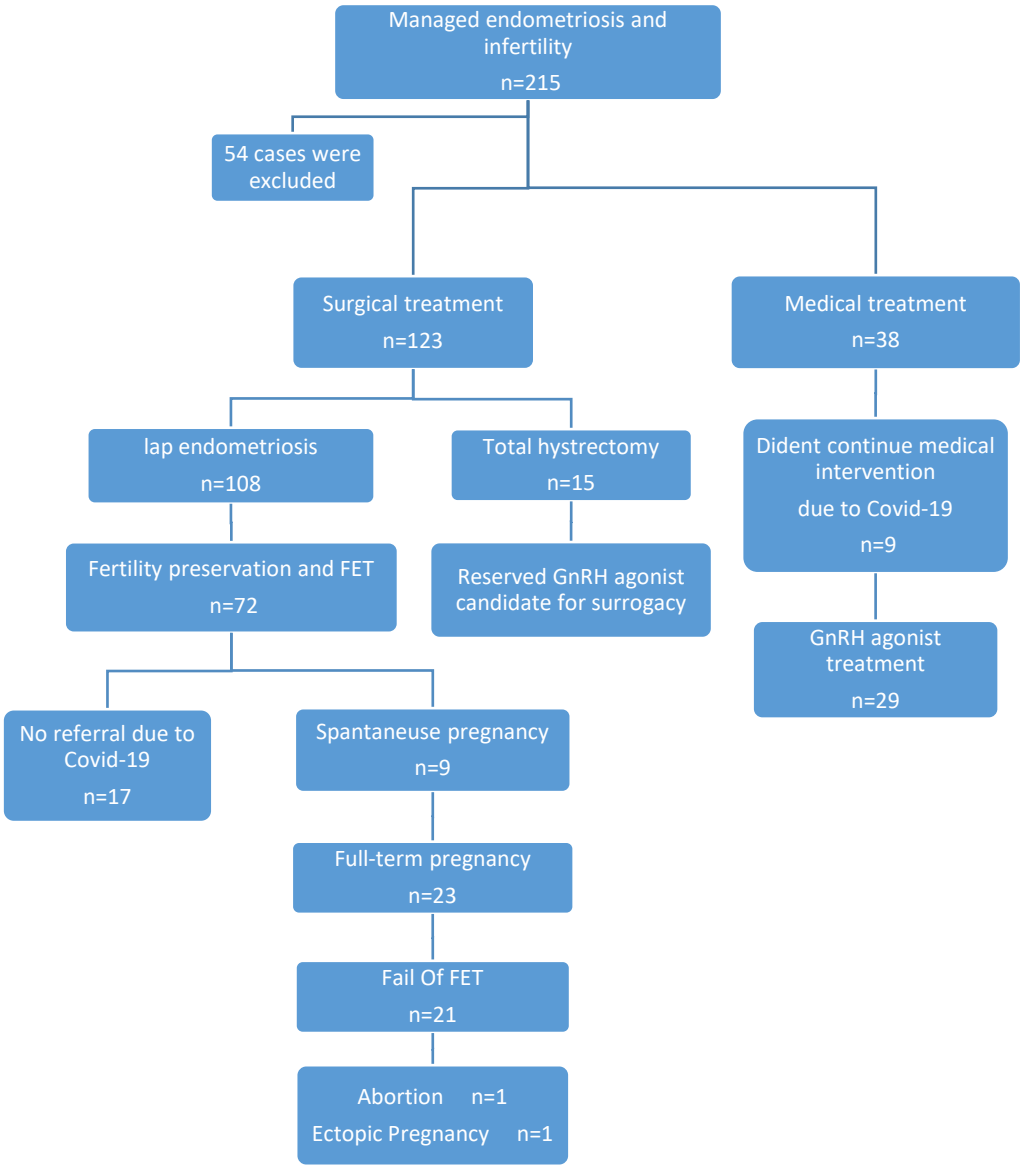


Figure 1. The diagram of allocated patients and fertility outcome of included patients.

At first fertility preservation was scheduled by embryo freezing, and then all patients underwent laparoscopic surgery by an extremely expert surgeon specializing in treatment for severe endometriosis. We performed rectal shaving for endometriotic invasion to serosal or inadequate infiltration of the rectal muscularis. Depending on multifocality and lesion size, excision of a full-thickness disc or resection of segmental colorectal was performed, if patients confronted with deep muscularis infiltration. All patients received Gonadotropin-releasing hormone agonist (GnRH agonist) for the next three months after the laparoscopic surgery. After this time-point, patients were followed-up after surgery till spontaneous pregnancy was occurred in some cases or according to her accompanied disorders, we performed Frozen embryo transfer (FET) during next several time-points after the laparoscopic surgery and investigated the pregnancy. Only patients with evidence of severe endometriosis in the pathology specimens were included. The purpose of surgery was to correct anatomical disorders, remove hydrosalpinx, cyst, and release pelvic floor adhesions. Fever, infection, bleeding, leukocytosis, and hematoma were considered as minor postoperative complications.

The initial outcome would be considered as spontaneous pregnancy after surgical intervention. The secondary outcome was defined as chemical pregnancy (positive human chorionic gonadotropin (hCG) two weeks after FET), clinical pregnancy (detection of gestational sac and detection of heart beat in six weeks of gestation), and take-home baby which is defined as a successful delivery of a healthy baby. All the patients received Diphereline drug for three months after surgery. The follow-up assessments included general information, live birth, the interval between the operation and pregnancy, improved dysmenorrhea/ dyspareunia, and post-operative complications. A beta-hCG test was performed two weeks after embryo transfer. If it was positive, it was considered that the woman had a biochemical pregnancy. Several ultrasound examinations were performed in follow-ups, to confirm the fetal heart and visualization of one or more gestational sacs.

Regarding ART, women were supervised as claimed by institutional clinical protocols. Controlled ovarian stimulation (COS) protocols were used with Gonadotrophin-releasing hormone (GnRH) antagonist fixed protocol. Several patients' characteristics such as age, Body mass index (BMI), Antral follicles count (AFC), and AMH were explanatory for starting dose of gonadotropins. Retrieval of oocyte was scheduled 36 hours after HCG injection, and IVF was accomplished according to standard operating procedure. Fertilization was defined as the manifestation of two pronuclei. Embryos were frozen on the third check to fifth day. Specially selected embryos were frozen and we discarded others. Pregnancies were defined by an increasing concentration of serum b-hCG 14 days after ET.

Statistical analysis

Statistical analysis was performed using SPSS®, v19 (IBM SPSS Statistics, IBM Corporation. Chicago, IL, USA). The distribution of the quantitative variable was checked for normality and then for the study of quantitative data based on the type of distribution, Mann-Whitney U Test or independent t-test. The cumulative pregnancy rate was compared by Kaplan–Meier (KM) method and log rank test. P value < .05 was considered statistically significant.

Results

According to Table 2, a total of 166 patients with mean ± SD age of 34.33 ± 6.62 (range: 19-45) were included in this study. When reviewing the past medical history of cases, one patient (0.6%) had hyperthyroidism, 21 individuals (12.6%) had hypothyroidism, and 144 cases (86.8%) had no past medical history. Past abdominal surgical history was reported in 47 women (28.1%); while 71.3% of cases (n=119) had not undergone any surgical procedure. History of IVF was detected in 73 cases (56%); while 93 individuals (44%) were referred for the first IVF procedure. The mean ± SD of dysmenorrhea, N=numbers of patients, dyschezia, and dyspareunia score according to visual analog pain score (0-10) was 7.2 ± 0.25, 2.42 ± 0.27, and 4.1 ± 0.28. The mean ± SD of the infertility period was 4.71 ± 5.43 years (ranged: 0- 27). The mean ± SD of anti-müllerian hormone (AMH) was 3.93± 4.2 pmol/L (range: 0-21). A total of 46 women (27.5%) had irregular periods; while regular cycles were detected in 72.5% of included patients (n=120). Analysis of the treatment strategy revealed that 30 patients (18.1%) received the drug (Gnrh-a for three months before embryo transfer); while 110 individuals (66.3%) underwent the surgical process. A total of 10 cases (6%) did not receive surgical care due to the COVID-19 pandemic. Those individuals undergoing FET following laparoscopic technique had more take home baby than drugs group (p<0.0001). Adhesiolysis on posterior cul-de-sac was performed in 28 cases (16.86%); while segmental resect anastomosis and shaving were applied in four (3.21%) and 40 (28.07%) patients, respectively. The mean ± SD numbers of frozen embryos transferred were 2.53 ± 3.36 (range: 0-4). The period between the laparoscopic surgery of endometriosis and FET was 2.58 ± 3.65 months (range: 3-12). Rectal endometrial nodules were detected in 87 individuals (52.4%). The rate of minor complications was 3% (n=5). The fertility outcomes are depicted in Figure 1. A total of 32 live births (19.3%) occurred at the end of the follow-up; while 134 women (80.7%) did not undergo the IVF procedure. Those with a time interval of three to six months after surgery had more favorable outcomes with a significantly higher PR compared with those with six to 12 months (p<0/03). Biochemical pregnancy was defined as positive B-hCG 14 days after embryo transfer (ET). Ultrasound examinations in follow-ups

at six weeks after ET also confirmed the fetal heart and clinical pregnancy.

Table 2. Intraoperative finding and surgical procedures

Parameters	*Patients N=161*
Operative Rout	
Laparoscopic	108
Laparoscopic converted to open surgery	3
Procedure Performed On The Rectum	
Adhesiolysis	28
Shaving	29
Full thickness disc excision	1
Colorectal segmental resection	14
Rectal endometrial nodules	84
Diameter of Largest rectal nodule (mm)	28
Length of colorectal specimen (mm)	48
Height of the lowest nodule (mm from anal verge)	78
Management of Urethral Endometriosis	
Advanced ureterolysis	24
Resection of bladder nodule	3
Bladder endometriosis	12
Colostomy	1
Omentectomy	6
Resection of posterior vagina	6
Appendectomy	3
Adenomyosis	36
Salpingectomy	R=7 L=17 Both=15

Discussion

The results of the current study demonstrated improvement in the fertility rate after FET treatment in infertile women with advanced-stage endometriosis after laparoscopic surgical intervention. We also verified that patients undergoing ET after laparoscopic surgery obtained more satisfactory clinical pregnancy rate compared to group who received drug therapy before FET ($p<0.001$). The outcomes depicted higher accomplishment of laparoscopic surgical intervention compared to ART alone.

Endometriosis has been considered as the most common gynecologic disease with a negative impact on female fertility rate that can reduce the ovarian reserve **(14)**. There are several available data about the correlation between the severity of endometriosis and infertility **(15)**. This situation can be caused following oxidative stress, exacerbating surgical approach, and improved pelvic inflammatory responses **(16, 17)**.

The impact of surgical intervention in mild and severe endometriosis remains controversy regarding reproduction ability **(8)**. Although laparoscopic surgery demonstrated enhancement in fertility outcomes of minimum to mild endometriosis, it is still uncertain by how much it is improved. In addition, there is no obvious and accurate data about the improvement in the reproductive outcomes by the use of surgical intervention before IVF in advanced-stage endometriosis. However, in one study it was demonstrated that surgical intervention to renovate the uterine anatomy, may improve the results of IVF in women with severe endometriosis and infertility **(18)**. The results of one study in 2018 demonstrated that IVF

pregnancy rate was unenthusiastically associated with the severity of the endometriosis. They also concluded that endometrioma had no impact on IVF clinical results **(8)**. We confirmed that in severe endometriosis, surgery may be required prior to any intervention, and IVF technique may assist in contacting with follicles during oocyte recovery, and progress the response of the ovary.

Hydrosalpinx is a situation that happens while a fallopian tube is blocked and serous or clear fluid is filled distal to the uterus, which gives the tube a sausage-like or retort-like shape feature. This situation will reduce the PR after the laparoscopic surgery. As a result, in the current study if a noticeable hydrosalpinx was detected in sonography or hysterosalpingography and salpingectomy was scheduled before FET.

Bowel surgery for colorectal endometriosis has been considered as a fertility-enhancing interference. Segmental resection is associated with a higher complication rate compared with disk excision; however, the procedure of disk excision is not always practical and preferred choice for colorectal surgeons. Segmental colorectal resection is still frequently conducted, particularly in patients with various rectosigmoid nodules and sub-occlusive stenosis of the rectosigmoid junction.

In one study in 2017 on 60 patients with severe endometriosis, 15 patients experienced rectal shaving, three full thicknesses underwent excision of the disc and 42 cases underwent segmental colorectal resection. The results demonstrated that only one out of ten women was debilitated by colorectal resection **(19)**. In accordance with the previous mentioned article, present study was obtained satisfactory results following segmental resection anastomosis in infertile women with severe endometriosis.

The interval from surgery of severe endometriosis to FET had a noteworthy consequence on the PR in our study. In one study Garcia-Velasco, Mahutte **(20)**, 133 women (147 cycles) who underwent laparoscopic cystectomy due to endometrioma were compared with 56 women (63 cycles) who underwent a transvaginal ultrasound for the diagnosis of endometrioma cysts. The first group entered the IVF cycle 12 months after surgery, and the second group underwent IVF immediately after the surgery. There was no significant difference between the two groups in terms of number of retrieved oocytes, mature oocytes, number of transferred embryos, fertilization rate, laboratory and clinical pregnancy rate, and abortion rate. They concluded that direct entry into ovarian stimulation cycle in asymptomatic endometrioma reduced the time to reach pregnancy and diminished the cost of treatment and surgical complications, and that laparoscopic cystectomy improved the IVF outcome. Although Nesbitt-Hawes, Campbell **(21)** have depicted a one-year median time in patients who conceive naturally following laparoscopic surgery for severe endometriosis, several studies demonstrated that interval from surgical intervention of endometriosis and FET does not play a crucial role on the PR **(22)**. The results of the present study showed that the maximum PR was attained in patients undergoing FET cycle in the first three months following endometriosis operation. It seems that FET would be better to be performed during the first months after the endometriosis surgery.

In a meta-analysis of women with endometrioma under IVF between 1985 and 2007, twenty studies were assessed, and in five studies surgical treatment was compared with expected treatment. The rate of clinical pregnancy was not different between the patients underwent surgical intervention and those with gonadotropin stimulation **(23)**. In the study of Sallam, Garcia-Velasco **(24)** patients with surgically diagnosed endometriosis were divided into two groups of patients receiving GnRH agonist treatment for three to six months before IVF and the control group with no intervention before IVF. The result of PR was significantly improved in study group by diminishing the concentrations of diverse inflammatory cytokines **(25, 26)**. They concluded that extended pituitary down-regulation prior to IVF could be supportive for infertile women with endometriosis. The results of the current study revealed that the PR rate was significantly higher in patients undergoing FET after laparoscopic surgical intervention, compared to patients who received drug therapy without surgery before FET.

In the current study, all patients undergoing endometriosis and laparoscopic surgery are candidates for pre-surgery embryo freezing, as the ovarian reserve is reduced, apoptosis will occur, and numerous healthy follicles are removed along with the cyst wall in these types of patients. The remained follicles will not respond satisfactory to induction and the number of M2 follicles is scarce. As a result, in this study at first oocytes retrieval and embryo freezing were scheduled before laparoscopic surgery.

Several publications have highlighted the effectiveness of laparoscopic surgery on PRs, in stages I-II of endometriosis **(8, 27)**. It seems that the efficacy of laparoscopy and further FET in severe form of disease is of great importance **(28)**. The novelty of the current study is that a triple approach was chosen according to the previously published studies. At first, embryos were collected and frozen and then the patient underwent laparoscopic surgery and finally GnRH agonist for three months. In the next step, the transfer of fetus is conducted via FET with a favorable successful rate. Finding the best approach for treating severe endometriosis is of great importance due to the high incidence of endometriosis among infertile patients. This goal may be more achievable with a long-term study period and large sample size, which will be performed in the near future. Further prospective studies are required to ascertain more-detailed strategies for maintaining the fertility of women with severe endometriosis.

Conclusion

In this study, the three-phase approaches to severe endometriosis (embryos collection, laparoscopic surgery, GnRH agonist for three months) were scheduled. Here we defined the optimal management such as surgery versus first-line ART for patients with severe deep endometriosis. Despite the lack of definitely recognized relation between severe endometriosis and infertility, IVF treatment may enhance the fertility rates in patients with severe endometriosis. Laparoscopic surgery for endometrioma cysts before FET improved fertility. Additionally, direct entry of individuals into the ovulation stimulation cycle does not cause surgical complications and saves costs and time.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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