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Reproductive Outcomes after Myomectomy: Intracapsular Rotary-cut Procedure (IRCP) Versus Conventional Myomectomy(CM)

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Keywords:

Fibroids; Intracapsular Rotary-cut Procedure (IRCP); Conventional myomectomy; Fertility outcomes

1. Abstract

1.1. Objective: There is a substantial body of literature on fertility outcomes following conventional myomectomy (CM), whereas limited research exists regarding fertility outcomes after Intracapsular Rotary-cut Procedure (IRCP).Our aim was to compare the reproductive outcomes between IRCP and CM.

1.2. Methods: This is a retrospective cohort study of patients admitted to Peking University Shenzhen Hospital(PUSH) for myomectomy between January 2013 and July 2021.A total of 147 patients who were managed with myomectomy were enrolled in this study. Among them 49 patiens were managed with IRCP as the study group, while the other 98 patients were managed with CM as the control group. The hospitalization data and postoperative reproductive outcome variables data of the two groups of patients were collected for statistical analysis.

1.3. Results(s): There was no significant difference in surgical age, body mass index, preoperative reproductive history, primary complaints, surgical procedures, fibroid location, number of fibroids, diameter of dominant fibroids, penetration of the endometrium, suture layers, postoperative fever between the two groups. The pregnant rate within six months after surgery was significantly higher in the study group than in the control group, with a statisti- cally significant difference(P<0.01).

1.4. Conclusion: Compared with the control group, the study group has a higher rate of the first postoperative pregnancy within 6 months and vaginal delivery after surgery. Intracapsular Rota- ry-cut Procedure （IRCP） myomectomy protects female fertility better.

2. Background

Uterine fibroids are the most common type of benign tumor that occurs in the female reproductive tract, which is composed of smooth muscle and connective tissue. The estimated prevalence of uterine fibroids among reproductive-aged women is 20%-40% [1].Up to 75% of premenopausal women are diagnosed with fibroids [2].Symptoms that are experienced by 25%-50% of women with uterine fibroids include heavy menstrual bleeding, abdominal pain, soreness and difficulties with fertility [3].Submucosal fibroid removal has been proven to improve pregnancy rates. By contrast, subserosal fibroids do not seem to affect fertility and surgery for them does not confer any benefit for infertile patients [4].The impact of intramural fibroids, which don't change the shape of the uterine cavity, on reproductive function is still controversial. Hart et al found that women with intramural fibroids measuring ≥5 cm in diameter have diminished rates of both conception and pregnan- cy. It is recommended by some clinicians that surgery be done for intramural fibroids that are ≥5cm in diameter [4-5].

There are various treatments for fibroids that can allow a woman to retain her fertility, including myomectomy, fibroid emboliza- tion, hormone therapy, MRI-guided high-intensity focused ultra sound,and myolysis [2-3,6].While some studies suggest that conventional and partial uterine fibroid embolization may be safe and effective for women who wish to preserve fertility, the procedure is still considered controversial by some. The relevant literature is quite limited. Myomectomy is the recommended treatment for symptomatic uterine fibroids[6-7].While previous studies on myomectomy have largely focused on short-term surgical variables, little is known about the effects of surgical modality on long-term outcomes such as fertility [2].Fertility preserving surgical options for uterine fibroids include laparotomic, laparoscopic, hysteroscopic and robotic-assisted myomectomy. Clinical pregnancy rates following these procedures are similar, ranging from 49.%-60.5% [4,8-11].When making decisions about which approach to take, clinicians should consider factors such as the number and size of fibroids to be removed, surgical time, and the patient's fertility desires. Minimally invasive surgery should be offered whenever possible, while still taking into account the benefits of laparotomy [12].

The pseudocapsule surrounding uterine fibroids and normal myometrium contains Substance P (SP) and Vasoactive Intestinal Peptide (VIP), which play a role in mediating inflammation and healing. Therefore, during myomectomy, it is beneficial to protect the pseudocapsulartissue as much as possible. Intracapsularmyomectomy enhances the integrity of the myometrium surrounding the fibroids and can significantly improve fertility, reduce blood loss, shorten hospital stays, and minimize antibiotic use [8,13].IRCP is a superior technique with respect to both intraoperative and postoperative benefits in terms of biology and muscle function.

Intracapsular myomectomy has been documented in medical literature. Our team is the only one who has reported on the method of IRCPmyomectomy, which is similar to intracapsular myomectomy in that it focuses on intracapsular procedure. However, our method also emphasizes another key surgical skill-removal of fibroids with minimal uterine incision. To date, only one study on laparoscopic or laparoscopic-assisted intracapsular myomectomy with one-layer continuous suture can be found in the literature. This surgical approach appears to be the same as the IRCP described in our study. However, the literature emphasizes that single layer continuous suture is enough for a successful wound healing, and uterine rupture has not been reported in subsequent pregnancies. It provides no further data on reproductive outcomes [14]. More detailed pregnancy data and reproductive outcomes following IRCP have not been reported. The primary objective of this study is to compare postoperative reproductive outcomes between IRCP and CM.

The study was approved by the Ethics Committee of PUSH.

3. Material and Methods

3.1. Study Subjects

The study subjects were selected from a pool of 3082 patients with complete surgical records who received either laparotomic or laparoscopic myomectomy in PUSH from January 2013 to July 2021. Out of these,493 patients were managed with IRCP while 2589 patients underwent CM. Pregnancy data was collected from the Shenzhen Maternal and Child Health Management Information System (https://fybj.newhealth.com.cn:8661/fyweb/#/login) and telephone return visits for 3082 patients. Patients who had completed fertility requirements prior to surgery, had no desire to bear children in the short term, had incomplete pregnancy data, or were lost to follow-up were excluded from the study. All of the enrolled patients met the inclusion and exclusion criteria. Among them,49 patients who managed with IRCP as the study group, and 98 patients with similar basic characteristics who managed with CM as the control group. Inclusion criteria: (1) fibroids≥5cm in diameter without degeneration; (2) complete data records; (3) postoperative pathological findings of benign leiomyomas; (4) postoperative evidence indicated diagnosis of pregnancy. Exclusion criteria: (1) fibroids＜5cm in diameter or with fibroid degeneration; (2) incomplete data; (3) postoperative pathological findings of malignant tumor or adenomyoma; (4) hysteroscopic or transvaginal myomectomy; (5) used GnRH agonists prior to surgery; [6] fibroids classified as 0 and 7 according to FIGO criteria [4,15].

3.2. Study Method

After full communication between the physician and the patient. Patients made a joint decision on the surgical method before surgery. Patients who chose laparoscopic surgery were informed that they may need to referred to laparotomy. The key step for the study group performed IRCP by using a unipolar electrotome to incise uterine deep into the fibroid and under the pseudocapsule, with the length of the incision should be about 1/3-1/2 the diameter of the fibroid, then using a unipolar electrotome to rotary-cut the fibroid multiple times can create a lobulated shape from the original spherical fibroid, this would allow for greater exposure of the gap between the fibroid and its capsule while still fairly protecting the fibers and vessels of the capsule. The CM procedures on control group of patients would need an incision with length nearly equaling to the diameter of the fibroid and required direct isolation of the fibroid from the pseudocapsule using a grasper, without multiple rotary-cut on the fibroid beforehand. This can often lead to the breakage of pseudocapsular fibers and blood vessels.1-3 layers of suture were performed according to the depth of incision in both groups.The surgical technique employed in this study is the same as that used in two previous studies by our team on the efficacy of IRCP[16-17].All procedures were performed by experienced surgeons in our department.

3.3. Statistical Analysis

Statistical analyses were performed with SPSS 24.0 software. The measurement data that obeyed normal distribution were represented by the mean ± standard deviation, while the data that did not conform to normal distribution were represented by the median and interquartile range. Qualitative variables were represented by the relative frequency. Comparisons between the two groups were performed using t-test, chi-square test, or rank sum test, when appropriate. A p-value of <0.05 was considered statistically significant difference. Cumulative probabilities of first pregnancy after surgery between two groups were estimated with the Kaplan-Meiermethod.

4. Results

The baseline characteristics and surgical variables of patients in the two groups were listed in Table 1.There was no significant difference in surgical age, body mass index, preoperative reproductive history, primary complaints, surgical procedures, fibroid location, number of fibroids, diameter of dominant fibroids, penetration of the endometrium, suture layers, postoperative fever between the two groups (P>0.05).The primary complaints from patients in both groups were enlarged uterine fibroids, changes in menstruation, and other reasons (including urinary frequency and urgency, palpable abdominal mass, and infertility history).Among the study group patients, 1 patient experienced urinary frequency and urgency, while 4 patients had a history of infertility. Among the control group patients, 1 patient had frequent urination and urgency, 1 patient had a palpable abdominal mass, and 1 patient had a history of infertility. The data for the maximum diameter of fibroid was not normally distributed among the two groups of patients. The maximum diameters of the fibroids in the study group ranged from 6.0-14.0cm, with a median of 6.0cm(6.0cm,8.8cm), while the range of fibroids in the control group was 5.0-13.0cm with a median of 7.0cm(6.0cm,8.0cm). The Mann-Whitney U test showed that there was no significant difference in the maximum diameters of the fibroids between the two groups (U=2311.0, Z=-0.74, P=0.70).

At the time of data collection, 49 patients (49/49,100.00%) in the study group with pregnancy later had live births, while 94 patients (94/98, 95.91%) in the control group with pregnancy later had live births. The study group and control group are similar in terms of later pregnancy with live births (P>0.05).In the study group,14 patients(14/49,28.6%) became pregnant within six months after surgery. Of these, 1 patient had a miscarriage, 1 patient underwent induced delivery at 17 weeks gestation due to fetal cardiac anomalies and polydactyly, 6 patients had vaginal delivery at term, 5 patients delivered via cesarean section at term, and 1 patient had premature (36+1 weeks) cesarean delivery. In the control group, 7 patients (7/98,7.14%) became pregnant within six months after surgery, 6 patients delivered via cesarean section at term,1 patient had premature (29+4 weeks)cesarean delivery. The interval between surgery and the first postoperative pregnancy in the study group ranged from 3-82 months, while in the control group it ranged from 2-84 months. The pregnant rate within six months after surgery was significantly higher in the study group than in the control group, with a statistically significant difference (P<0.01). Among the 14 patients in the study group who became pregnant six months after surgery, 3 patients had broad ligament fibroids (2 with single-layer suture and 1 with double-layer suture), 3 patients had subserosal fibroids (all with single-layer suture). The remaining 8 patients had intramural fibroids that did not penetrate the endometrium (all with double-layer suture). Among the 7 patients in the control group became pregnant six months after surgery, 1 patient had cervical fibroids (double-layer suture), 3 patients had subserous fibroids (1 with double-layer suture,2 with single-layer suture). The remaining 3 patients had intramural fibroids (all with double-layer suture). There were no instances of uterine rupture in either group of patients during post-operative pregnancy. The postoperative fertility rate and the interval between surgery and pregnancy are shown in Table 2.

Among the patients in the study group at the time of data collection, a total of 54 singleton pregnancies were observed among the 49 patients, 44 patients had one pregnancy and the other 5 patients had repeat pregnancies.1 patient were expecting a baby, 1 patient underwent induced delivery at 17 weeks gestation due to fetal cardiac anomalies and polydactyly. Of these, 54 pregnancies resulted in the delivery of 52 neonates, resulting in a current delivery rate of 96.30% (52/54). Among the 98 patients in the control group at the time of data collection, there were a total of 108 singleton pregnancies and 1 twin pregnancy.88 patients had one pregnancy and the other 10 patients had repeat pregnancies(9 patients with two pregnancies and 1 patient with three pregnancies).Of these pregnancies, 102 of the pregnancies resulted in delivery of 103 neonates, 7 of the pregnancies with miscarriage, yielding a current delivery rate of 93.58%(102/109).There was no significant difference in the delivery rate between the two groups (P=0.47). The two groups of pregnancies were shown below (Figure 1). Among the 54 pregnancies in the study, 7 were the result of in vitro fertilization-embryo transfer (IVF-ET),6 were spontaneously conceived after using ovulation-stimulating drugs, and 41 were spontaneously conceived. Meanwhile, the 109 pregnancies in the control group included 11 that were the result of in vitro fertilization-embryo transfer (IVF-ET) ,97 that were spontaneously conceived and the other 1 were spontaneously conceived after using ovulation-stimulating drugs.There was no significant difference in the methods of conception between the two groups(P=0.58).

Of the 49 patients in the study group, those who delivered singleton pregnancies amounted to 52 in total, with 52 neonates delivered. The 98 patients in the control group experienced 102 successful pregnancies, 101 of these were singleton pregnancies, and 1 was a twin pregnancy. This resulted in the delivery of 103 neonates. Among the study group, there were 11(11/52,21.15%) vaginal deliveries and 34(41/52,78.85%) cesarean section. While in the control group, there were 9(9/102,8.82%) vaginal deliveries and 93(93/102,91.18%) cesarean section. The study group had a higher vaginal delivery rate than the control group, with a statistically significant difference(x2=5.60, P=0.08).The study group had 3(3/52,5.77%) preterm births and 49(49/52m,94.23%) term births while the control group had 11(11/102,10.78%) preterm births and 91(91/102,89.22%) term births. There was no significant difference between the two groups(x2=1.05,P=0.31).The mean gestational week of delivery was found to be 34±3 weeks for preterm births and 38±4 weeks for term births in the study group. The control group had a mean gestational week of delivery of 34±4 weeks for preterm births and 39 weeks for term births. The weights of newborns delivered by singleton pregnancy in the two groups were not normally distributed. The weight range of newborns delivered by the study group was 2350-4460g,with a median of 3270g(2975-3500g).While the weight range by the control was 980-4460g,and the median was 3300g (3050-3500g) (Figure 2).The results of the Mann-Whitney U test showed that there was significant difference in the weight of newborns delivered by singleton pregnancy between the two groups (U=3775654.0.0,Z=-2.261,P=0.024).It should be noted that, in the control group, the weights of 2 neonates delivered as a result of twin pregnancy in 1 patient were 1850/1950g,respectively.

Table 1: The essential characteristics and surgical variables of the two groups of patients

	The study group (N=49)	The control group (N=98)	t/x^2	P
Surgical age(year)	32.33±4.22	31.35±3.82	1.41	0.16
Body mass index(kg/m²)	22.42±2.43	22.40±2.56	0.05	0.96
Previous pregnancy(n[%])	9(18.37%)	32 (32.65%)	3.72	0.07
Primary complaints(n[%])				
Asymptomatic (enlarged Uterine fibroids)	33（67.34%)	69(70.41%)	0.14	0.7
Changes in menstruation	11(22.45%)	26(26.53%)	0.29	0.59
Other reasons	5(10.20%)	3(3.06%)	3.23	0.07
Surgical procedures (Laparoscopy)(n[%])	41(83.67%)	75(76.53%)	1	0.32
Location of dominant fibroids(n[%])				
Subserous	8(16.33%)	12(12.24%)	0.46	0.5
Intramural	37(75.51%)	77(78.57%)	0.18	0.68
Cervical and broad ligament fibroids	4(8.16%)	9(9.18%)	0.04	0.84
Number of fibroids(n[%])				
1	27(55.10%)	57(58.16%)	0.13	0.72
2-5	16(32.65%)	30(30.61%)	0.06	0.8
>5	6(12.24%)	11(11.22%)	0.03	0.86
Diameter of dominant fibroids(cm)	6.0cm（6.0-8.8）	7.0cm（6.0-8.0）	-	0.7
Penetration of the endometrium(n[%])	1(2.0%)	8(6.2%)	1.26	0.26
Suture layers(n[%])	1(2.04%)	5(5.10%)	0.78	0.34
Single-layer	10(20.41%)	24(24.49%)	0.31	0.58
Double-layer	38(77.55%)	68(69.39%)	1.08	0.3
Three-layer	1(2.04%)	6(6.12%)	1.2	0.27
Postoperative fever(n[%])	10(20.41%)	35(35.71%)	3.6	0.06
Postoperative transfer to the ICU (n[%])	1(2.0%)	2(1.5%)	0.054	0.82

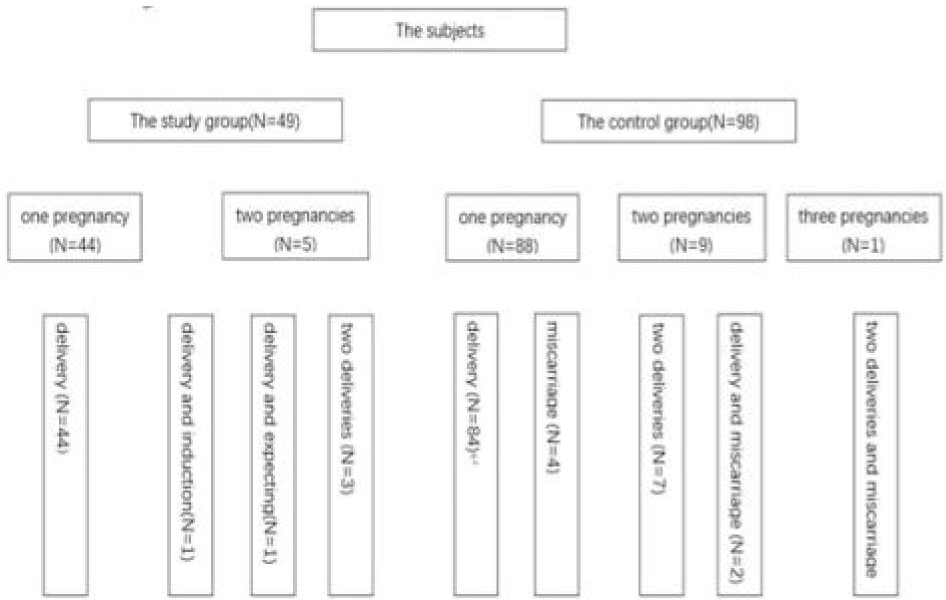

Figure 1: Fertility outcomes following surgery of the two groups of patients.

Table 2: The postoperative fertility rate and the interval between surgery and the first postoperative pregnancy

	The study group (N=49)	The control group (N=98)	t/x^2	P
Fertility following surgery				
Pregnancy with live births	49(100.0%)	94(95.92%)	2.06	0.15
Interval between surgery and the first postoperative pregnancy				
≤6 months	14(28.57%)	7(7.14%)	14.89	0
7-12months	13(26.53%)	26(26.53%)	0.14	0.71
13-24months	12(24.49%)	31(31.63%)	1.23	0.27
25-60months	8(16.32%)	28(28.57%)	3.78	0.05
≥61months	2(4.08%)	6(6.12%)	0.13	0.72
Uterine rupture	0(0.0%)	0(0.0%)	-	-

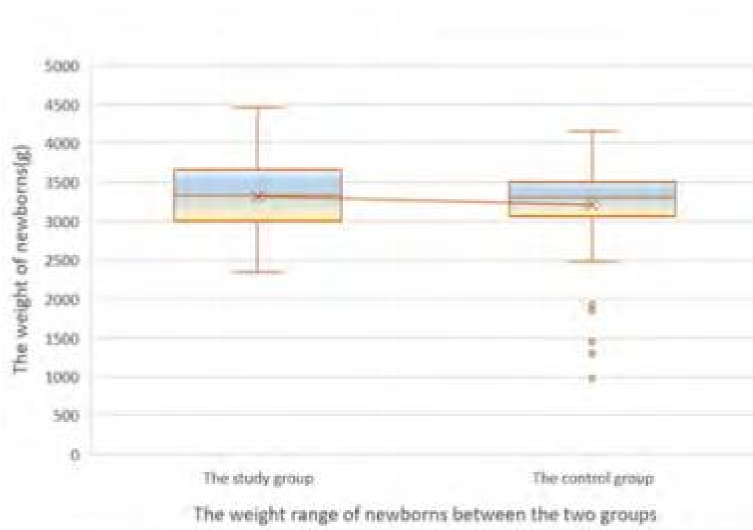

Figure 2: The weights of newborns between the two groups of patients

5. Discussion

This is the first comprehensive comparative analysis of the long-term fertility outcomes between IRCP and CM. To date, there are no detailed studies reporting on fertility outcomes after IRCP. However, previous articles published by our team had focused on the evaluation of IRCP, highlighting various advantages such as surgical techniques and reduced blood loss. The current study corroborates these earlier findings. Although the article previously published also mentioned the fertility outcomes of the 25 patients who wished to have children after IRCP, these patients were followed for a shorter period of time, and there were fewer studies on fertility outcomes. The findings from this study suggest that IRCP is associated with better post-operative fertility outcomes than CM, including shorter postoperative pregnancy intervals and higher rates of vaginal delivery.

The American College of Obstetricians and Gynecologists guidelines state that the two main issues associated with myomectomy are removing large fibroids through a small abdominal incision and repairing the uterus [18].So far, there is no clear consensus on the best approach to uterine repair [19].Surgical factors that may be associated with myometrial wound healing include, but are not limited to, the method of incising the myometrium, the method of myometrial hemostasis, the degree of local tissue destruction, the method used to close the myometrial incision, intramuscular infection or hematoma formation, the presence of growth factors, and Individual healing characteristics with excess collagen deposition [20].Myometrial healing after myomectomy was assessed using an MRI study, which concluded that the healing process was complete at 12 weeks following a myomectomy [21].Numerous radiological studies have demonstrated that the uterine healing process appears to be achieved 3-6 months after surgery. Ultrasound studies have shown that the scar area improves over time after myomectomy [22].The length of the incision has been correlated with an increased risk of fibrous tissue formation, postoperative adhesions, and future pregnancy complications. Themyomectomy technique, which takes into account biological reasoning, allows for the preservation of the fibroid pseudocapsule. This, in turn, protects the muscle and the fiber-neurovascular system. This technique ensures a complete and bloodless resection of the fibroid[23].IRCP uses minimal uterine incision length and preserves the pseudocapsular tissue during the operation. This is beneficial for the repair and healing process of the uterine incision.

Fibroids may be the sole cause of infertility in 2%-3% of women. Fibroids are associated with recurrent miscarriages and infertility depending on their location in the uterus. Approximately 10-28% of pregnancy women who have uterine fibroids will experience complications, typically abdominal pain [4].Additionally, fibroids can affect pregnancy in various ways, including mode of delivery, postpartum hemorrhage, and associated pain [24].Therefore, it is imperative that women who have surgical indications undergo a myomectomy. The current evidence does not suggest that any one approach (laparoscopy, laparotomy, or other) is superior in terms of reproductive outcomes [25].There is evidence to suggest that surgical removal of fibroids may result in the formation of pelvic adhesions, which may have a negative impact on reproductive potential. This may increase the risk of complications in subsequent pregnancies. The length of the uterine incision is a significant factor in the development of adhesions, with each additional centimeter of incision length increasing the total adhesion area on the uterine serosal surface by 0.55 cm^2 [26].High-quality surgery and the use of anti-adhesive barriers can significantly reduce the risk of postoperative adhesions [1].To lessen surgical bleeding, techniques such as intracapsular myomectomy, sutured uterine incision with barbed wire, and the “baseball” suture of the uterus have been employed [35].Intracapsular myomectomy may offer benefits such as reduced blood loss, decreased risk of postoperative adhesions, improved wound healing, and reduced risk of uterine rupture during future pregnancy or childbirth [2,27-28].Therefore, it is recommended that women with uterine fibroids who wish to conceive have IRCP to remove their fibroids and improve their fertility.

The time interval between myomectomy and pregnancy can have a significant impact on the development of complications such as uterine rupture during pregnancy. There is no definitive answer from the international gynecological association about the optimal time from myomectomy to conception, or the minimum time necessary to conceive after surgery. Attempts to conceive are generally recommended at least 6 months after myomectomy to allow for proper healing of the uterine wound [3].A literature review of 43 studies found that, on average, it takes 17.6 months to become pregnant after a myomectomy. The shortest reported time was one month, and the overall incidence of uterine rupture was 0.5% [22]. Other reports suggest that the incidence of uterine rupture in pregnancies after myomectomy may be between 0.1%-10.% [1,24].In clinical practice, the mechanical stress of labor may be considered a risk factor for uterine rupture inpatients with a history of uterine surgery. The mode of delivery for pregnancies after myomectomy is controversial, as most cases of uterine rupture occur before labor begins [29-30].Although there is little evidence to suggest that elective cesarean delivery is beneficial for pregnancies after myomectomy, many obstetricians recommend this course of action for patients who have undergone the procedure, particularly those who had myomectomy surgery that entered the uterine cavity [31]. Currently, it is not possible to identify factors that may predict the likelihood of uterine rupture, which can be caused by various surgical factors, such as tissue damage from electrocoagulation, poor wound healing, single-layer suture technique, infection, or hematoma [25].A study of 152 cases of pregnancy following myomectomy found that, of the 73 patients who attempted vaginal delivery, vaginal delivery was successful in 90.4% of cases, with no uterine rupture reported. The authors believe that vaginal delivery is a feasible and relatively safe option for pregnancy following myomectomy [31].In this study, up to 14 (28.6%) patients in the study group became pregnant within 6 months after surgery, while 9 (6.9%) patients in the control group became pregnant within the same time frame. None of them had uterine rupture in any surgical approach. Although only a limited number of patients delivered vaginally, the majority delivered by cesarean section, this is probably attributable to the obstetrician's recommendation, the patient's conception of the risk of uterine rupture, and the choice of delivery method.

In this study, the study group's outcomes were superior in this study, with a statistically significant difference in pregnancy outcomes between the two groups. However, its retrospective data collection limits it. The lack of data on potential influential obstetric factors limited the ability of researchers to collect accurate data on obstetrician attitudes towards mode of delivery. Consequently, further prospective or randomized controlled trials are necessary to corroborate our findings. A comprehensive analysis of the surgical techniques of IRCP and the current research reports on uterine incision repair reveals that IRCP is beneficial in reducing the incidence of subsequent pregnancy complications.

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