Discoid excision for colorectal endometriosis associated infertility: A balance between fertility outcomes and complication rates

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Short running title: Impact of discoid excision for deep endometriosis on fertility.

Abstract

Objective: The objective of our study was to study the impact of discoid excision for deep endometriosis (DE) with colorectal involvement on fertility outcomes.

Methods: 49 patients with a desire for pregnancy treated with discoid excision for colorectal endometriosis in our endometriosis expert center between January 2015 and August 2020 were selected from our prospectively maintained database. Indications for surgery were either infertility and / or pelvic pain. Postoperative complications were graded according to the Clavien-Dindo classification. Fertility outcomes, both spontaneous and post-ART pregnancies, were analyzed.

Results: Among the 49 patients who underwent discoid excision exclusively (no other digestive resection) with a desire to conceive, 25 had a pregnancy after surgery and 24 did not. Double discoid excision was performed in 6.1% of the cases (3/49). A colpectomy was performed in 12.2% of the patients (6/49), and a protective stoma in 12.2% (6/49). Fenestration of endometriomas was performed in 28.6% of the patients (14/49), and parametrectomy in 40.8 % (20/49). The postoperative complication rate was 24.5% (12/49) including 10.2% (5/49) grade I, 12.2% (6/49) grade II, and 2% (1/49) grade III. Prior to surgery, 28 (57.1%) patients had infertility including 13 (52%) that successfully conceived following surgery and 15 (62.5%) that remain infertile. Spontaneous pregnancy was achieved in 60% (15/25) of infertile patients' prior surgery. The live-birth rate in patients conceiving spontaneously was 75% (12/16).

Conclusion: Our results support that discoid excision is safe and associated with good fertility outcomes. Whether first-line surgery using discoid excision is superior to first-line ART remains to be determined.

Keywords: colorectal endometriosis; discoid excision; postoperative complication; infertility; pregnancy.

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Introduction

Endometriosis, particularly in its advanced stages, is a well-known cause of disabling pelvic pain and infertility. The exact prevalence of endometriosis is unknown, but it is thought to affect between 5 and 10% of women of reproductive age, and up to 50% of infertile women. Colorectal endometriosis is the most severe form of deep endometriosis (DE) and concerns 5 to 12% of endometriosis patients [1–3]. The main location of bowel endometriosis is the colorectum representing 85% of all bowel lesions [2,4–6].

Many studies have demonstrated that the main factor associated with recurrence in patients undergoing surgical management is incomplete excisional surgery with residual disease. Recurrence is associated with negative outcomes both in terms of pain, quality of life, and fertility. Historically, surgical management of colorectal endometriosis consisted of radical treatment with segmental resection. While segmental resection has been shown to have long term benefits on pain and probably on fertility [7,8], it is associated with significant morbidity, exposing women to the multiple risk of severe postoperative complications such as rectovaginal fistula and voiding dysfunction, sometimes with persistent sequelae decreasing quality of life [9–14].

As an alternative to systematic segmental resection, conservative techniques, such as rectal shaving and discoid excision, have been developed. Rectal shaving is mainly indicated in patients with serosal or superficial muscularis involvement, but is associated with a relatively higher risk of recurrence when compared to discoid excision or segmental resection [15]. Conversely, discoid excision allows for complete resection with a lower morbidity and a similar recurrence rate to segmental resection [16]. Discoid excision is mainly indicated in patients with a lesion involving less than 90° of the bowel circumference and up to 3 cm in length, although a larger resection (around 5 cm) can be achieved with double discoid excision [17]. Discoid excision has demonstrated its effectiveness in reducing morbidity

including the need for temporary stoma and postoperative complications [9,18]. This less morbid procedure could reduce time to conception as well as increase pregnancy and live-birth rates. However, insufficient data are available to support these hypotheses.

Therefore, the objective of the present study was to evaluate the impact of discoid excision on complication rates and fertility outcomes including both spontaneous and Assisted Reproductive Technique (ART) pregnancies.

Materials and methods

We queried a prospectively maintained database of patients surgically treated for endometriosis in Tenon University Hospital, AP-HP, Sorbonne University, Paris, France. Patients with colorectal endometriosis lesions treated by discoid excision between January 2015 and August 2020 were eligible. Inclusion was restricted to patients with a desire to conceive. The criteria used to define discoid eligibility were as classically described, i.e., preoperative length $\leq$3 cm and involving <90° of the bowel circumference [19,20], and confirmed by transvaginal ultrasonography, magnetic resonance imaging (MRI) and rectal echo-endoscopy (REE). Patients with multifocal lesions or requiring intraoperative conversion to segmental resection were excluded.

The study protocol was approved by the Ethics Committee of the National College of French Gynecologists and Obstetricians (reference number: CEROG 2022-GYN-1205) [21].

The following data were abstracted from the database: socio-demographic features, physical examination, fertility features, prior surgery, preoperative imaging workup, surgical details, and intra- and postoperative outcomes.

Indications for surgery were based on the European Society of Human Reproduction and Embryology (ESHRE) guidelines and could include medical treatment failure in symptomatic patients, and infertility before or after failure of two cycles of in vitro fertilization/intracytoplasmic sperm injections (IFV-ICSI) [22,23]. All decisions for surgery were systematically validated by a multidisciplinary committee. Infertility was defined as failure to achieve pregnancy after at least 12 months of regular unprotected sexual intercourse. Anti-Müllerian hormone (AMH) serum levels were assessed prior to surgery for all the patients. The option to preserve fertility was systematically discussed with the patient preoperatively.

Preoperative workup included physical examination, transvaginal ultrasonography, and pelvic MRI. The MRI protocol included 3D T2, 3D T1 sequences with and without fat saturation and gadolinium injection in accordance with French guidelines (HAS-CNGOF) [24]. REE was prescribed at the surgeon's discretion to accurately assess the distance between the lesion and the anal margin, as well as to assess the characteristics of the colorectal lesion.

Surgical procedure

All laparoscopies were performed by three experienced surgeons (SB, ED, CT) with the intention to perform complete excision of all endometriosis lesions. The surgical technique used has been previously described [16]. Briefly, the bowel procedure included two steps after extra bowel removal of lesions involving the torus uterinum, uterosacral ligaments, parametrium by ureterolysis, ovarian cystectomy or fenestration, salpingectomy for hydrosalpinx, and colpectomy when required. The first step consisted of rectal shaving to excise the extraserosal component of bowel endometriosis, and the second was the actual discoid excision using a transanal circular stapler (CDH 29 or 33A; Endo-Surgery, Ethicon, France). A double discoid excision was performed for large lesion size over 3 cm or in the case of positive margins on macroscopic analysis, and consisted of two consecutive discoid excisions for a single colorectal lesion. A protective stoma was performed only in the case of associated colpectomy when the interposition of the peritoneum was not possible between the vaginal and the digestive sutures.

The Endometriosis Fertility Index (EFI) score was calculated for each patient following surgery, and the severity of the endometriosis was staged using the revised American Society of Reproductive Medicine (rASRM) classification [25].

A postoperative visit was planned for all the patients 4 to 6 weeks after surgery. Postoperative complications were classified according to the Clavien-Dindo classification [27] as minor for grades I-II, and major for grades III-IV (complication requiring radiological intervention or surgery). Voiding dysfunction was defined as the need for intermittent bladder self-catheterization and was classified as immediate when lasting <30 days postoperatively, and persistent when lasting ≥30 days.

Fertility

Data

Fertility was assessed during follow-up visits using questionnaires investigating: (i) the desire to conceive after surgery; (ii) the occurrence of pregnancy after surgery; (iii) the number of pregnancies; (iv) the mode of conception (spontaneous or after ART); (v) the time between surgery and the occurrence of pregnancy; and (vi) pregnancy outcomes including abortion, miscarriage, ectopic pregnancy, late miscarriage, premature labor, and live birth. The ART protocol was determined by reproductive specialists based on the patient's features (age, AMH, ART history, cause of infertility…). IVF-ICSI could be performed using either fresh or frozen embryos. A biochemical pregnancy was defined by an hCG level >25 UI/L, and a live birth as a live delivery >25 weeks of gestation.

Statistical analysis

Databases were managed using Excel (Microsoft Corporation, Redmond, WA, USA) and statistical analyses were performed using R studio software (1.1.463 version, available online). Descriptive analysis included frequencies and percentages for qualitative variables and median (interquartile range (IQR)) for quantitative variables. Statistical analysis was based on the Student's t test for continuous variable and the $\chi 2$ test or Fisher's exact test for categorical variables. P-values <0.05 were considered to denote significant differences.

First, we compared the features of the patients wishing to conceive following surgery. Then, we investigated the impact of postoperative complications on fertility outcomes.

Results

Epidemiological and surgical characteristics of the population

During our inclusion period, 406 patients underwent surgery for colorectal endometriosis excluding those who underwent rectal shaving: 67% (273/406) underwent segmental colorectal resection, and 33% (133/406) discoid excision. Discoid excision was performed from january to December 2015 in 23% of the cases (8/35); in 2016 for 27% (29/107); in 2017 for 30% (28/94); in 2018 for 40% (28/71); in 2019 for 42% (29/69) including the first wave of the Covid-19 pandemic, and from January to August 2020 for 37% (11/30) including the second wave of the Covid-19 pandemic.

Forty nine patients fitted inclusion criteria and were selected for analysis, including 25 that successfully conceived following surgery and 24 that did not (Figure 1). Median follow-up was 15 months (range: 1–57).

The main characteristics of the patients included are displayed in Table 1. Patients that successfully conceived following surgery were similar to those remain infertile regarding clinical and imaging disease extension. There was no significant difference between the group pregnancy after surgery and no pregnancy after surgery. Prior to surgery, 28 (57.1%) patients had infertility, 13 (52%) in the group pregnancy after surgery and 15 (62.5%) in the group without. Most patients were primarily infertile. Twenty-two patients (44.9%) had undergo ART prior surgery including 10 (40%) that successfully conceived following surgery and 12 (50%) that remain infertile.

Regarding painful symptoms, 83.7% of patients (41/49) had dysmenorrhea, 69.4% (34/49) deep dyspareunia, 30.6% (15/49) chronic pelvic pain, 28,6% (14/49) dyschezia and 22.4% (11/49) voiding dysfunction. The main surgical indication was pelvic pain in 38.8% (19/49) of the patients. Of the 28 patients who had associated infertility, 78.6% (22/28) had experienced a previous IVF-ICSI failure. Nine patients (18.4%) who underwent discoid

excision had no digestive lesions detected on preoperative MRI. The median MRI size of the lesion resected was 20 mm (range: 10-40).

The surgical procedures performed are displayed in Table 2. Double discoid excision was performed in 6.1% of the cases (3/49). A colpectomy was performed in 12.2% of the patients (6/49), and a protective stoma in 12.2% (6/49). Fenestration of endometriomas was performed in 28.6% of the patients (14/49), and parametrectomy in 40.8 % (20/49).

The median hospital stay was 6.5 days (range: 4–10) and the postoperative complication rate was 24.5% (12/49) including 10.2% (5/49) grade I, 12.2% (6/49) grade II, and 2% (1/49) grade III. The grade III complication consisted of a vaginal dehiscence that required a second surgery on postoperative day 20. No grade IV complication, rectovaginal fistulas or anastomotic leakage were observed. Postoperative voiding dysfunction requiring bladder self-catheterization occurred in 10.2% of the cases (5/49), mostly during the immediate postoperative period (80%, 4/5).

Fertility outcomes.

Prior to surgery, 34 patients out of 49 wished to conceive and the remaining ones desired a pregnancy solely after resolution of pain symptoms following surgery (Figure 2). Pregnancy rate was 51% following surgery (25/49). Patients that successfully conceived were more often operated on because of infertility (65% versus 26%, $p < 0.001$) and were more likely to have undergo ART (45% versus 17%, $p=0.03$) (Supplementary Table 1). Among the patients who achieved pregnancy, 60% (15/25) had spontaneous pregnancies, and 40% (10/25) underwent ART (Figure 2). As several women had more than 1 pregnancy, we recorded 29 pregnancies, 16 natural conceptions (55%) and 12 deliveries (75%). Some patients had more than one pregnancy following surgery.

Patients requiring ART to achieve pregnancy were more likely to be infertile prior to surgery (80% versus 47%, p=0.04), and have a lower EFI score (4 (2-9) versus 9 (4-10), p=0.003) than those who achieved a spontaneous pregnancy (Supplementary Table 2). The rASRM scores were similar in these two groups.

Among the patients who conceived spontaneously, 60% (9/15) succeeded within the first year. The live-birth rate in the patients conceiving spontaneously was 75% (12/16). Nineteen percent (3/16) of these patients had an early miscarriage and one had an ongoing pregnancy at the time of the study.

The median time between surgery and a first ART attempt was 10.2 months (range: 4–24). The live-birth rate following ART was 38% (5/13), significantly lower than for spontaneous pregnancies ($p < 0.01$). Conversely, the early miscarriage rate was significantly higher at 38% (5/13) ($p < 0.01$)

There were no significant differences in postoperative complication rates, but voiding dysfunction was more frequent in patients not wishing to conceive prior surgery (30% versus 10%, p=0.04).

Among the patients experiencing postoperative complications, 52% (12/23) desired to conceive following surgery and 58% (7/12) achieved a pregnancy. The occurrence of a postoperative complication had no impact on the probability of achieving pregnancy, including spontaneously (71% versus 55%, p=0.67). However, the occurrence of a post operative complication was associated with longer delay prior achieving pregnancy (19 $\pm$ 9.9 months versus 16 $\pm$ 6.7 months) (Table 3).

Discussion

The present study demonstrates that discoid excision for colorectal endometriosis is associated with a high pregnancy rate. Moreover, discoid excision was found to be associated with a high live-birth rate –the principal goal of surgery for both patients and practitioners– especially in patients who conceived spontaneously. Finally, in patients with prior infertility, surgery enhanced fertility.

This is the first study to focus on fertility outcomes after discoid excision in patients with DE and colorectal endometriosis. So far, little is known about fertility outcomes following discoid excision rending shared decision-making difficult. Half of the patients in our study who wished to conceive became pregnant (51%, 25/49). Moreover, we observed a high spontaneous pregnancy rate of 60%. It is well known that patients with colorectal endometriosis have a low spontaneous pregnancy rate ranging between 0 and 10%. However, these rates are brut and not stratified based on the size of the colorectal lesion or according to colorectal surgeries [28–31]. Previous studies evaluating fertility outcomes after colorectal resection (mainly based on segmental resection) reported a spontaneous pregnancy rate of 40 to 59%, lower than in our cohort [23,32,33].

Our data suggest a higher positive impact of surgery on fertility outcomes for small colorectal lesions. Besides patients undergoing double discoid excision, commonly used eligibility criteria for this technique are a lesion size under 3 cm and involving less than 90° of the bowel circumference. These criteria could explain the better fertility outcomes after discoid excision (when compared to segmental resection) by selecting less severe lesions and limited disease extension [16]. Although not designed to evaluate fertility after colorectal surgery for endometriosis, Roman et al. reported a similar overall pregnancy rate (spontaneous and after ART) in the radical surgery group (segmental resection) of the

ENDORE trial compared to the conservative group (rectal shaving and discoid excision) without specifically reporting results for discoid excision [33].

The low intra- and postoperative severe complication rates observed in our cohort are probably because the procedures were performed by experienced surgeons in an expert center, as has already been demonstrated [34]. In our cohort, a total of 6 patients had protective stoma at the end of surgery. While this rate is already low, recent reports by Roman et al. is in favor of aiming a near zero rate which could improve patients' quality of life following surgery [35]

Furthermore, Netter et al. found that discoid excision is associated with very high satisfaction rates [36]. The occurrence of a complication had no effect on the desire to conceive: out of the six patients or couples who no longer desired to conceive following surgery, only two experienced postoperative complications. This is in line with the work of Ferrier et al. reporting a 41.2% pregnancy rate, 80% of which were spontaneous in patients who experienced severe complications after colorectal endometriosis resection [37].

Another crucial result in the current study, is the low early miscarriage rate after discoid excision. In our cohort, patients conceiving spontaneously had a significantly lower early miscarriage rate than those undergoing ART. Previous meta-analyses have underlined a higher risk of miscarriage in patients with endometriosis compared to control groups [38,39]. Huang et al., in their meta-analysis, demonstrated the high risk of early miscarriage for spontaneous pregnancies in women with endometriosis [39]. However, they did not take into account the benefits of laparoscopic surgery for endometriosis [39]. Moreover, Huang et al. underlined that the risk of miscarriage was influenced by the endometriosis phenotype and was higher for DE than for endometrioma [39]. Finally, in agreement with the meta-analysis of Hodgson et al., evaluating the various medical and surgical options to enhance fertility in patients with endometriosis, both laparoscopy alone and a GnRH agonist alone offered

similarly high pregnancy rates while the data were insufficient to evaluate their impact on live-birth and miscarriages rates [40].

Another issue for clinicians is to decide whether to opt for first-line surgery or to attempt ART first. In our cohort, the live-birth rate was higher among patients who conceived spontaneously after surgery. Moreover, half of the patients achieving spontaneous pregnancy following surgery were infertile prior to surgery including 27% with ART failure. Despite our results, insufficient data are available to draw a definitive conclusion on whether discoid excision enhances fertility compared to ART raising the issue of combined surgery and ART. In our cohort, 80% of the patients who achieved pregnancy using ART were infertile prior to surgery. Bendifallah et al. [23] reported an increase in the cumulative live-birth rate after first-line surgery with a specific cumulative live-birth rate at the first ICSI-IVF cycle compared with first-line ART alone of 32.7% vs 13.0%; after two ICSI-IVF cycles 58.9% vs 24.8%; and after three ICSI-IVF cycles 70.6% vs 54.9% for patients with colorectal endometriosis. Similar findings were reported by Barri et al. [29] with higher pregnancy rates in combined strategies but including few patients with colorectal endometriosis. In our cohort, the EFI scores were significantly lower in patients who required ART to achieve pregnancy following surgery. This is in line with the recent meta-analysis of Vesali et al. showing that patients with EFI scores between 0 – 2 had a lower chance of spontaneous pregnancy at 36 months than those with EFI scores ranging from 9 – 10 [41]. The location of the lesions is one of the main criteria involved. Tuominen and al. showed that patients with rectovaginal endometriosis have comparable and good reproductive prognosis regardless of the treatment method (surgery or ART) [42]. Ferrier et al. highlighted the higher cost associated with ART management following surgery and the relevant use of the EFI scores to help decide between spontaneous conception, immediate, or delayed ART [43]. In our cohort, ART was associated with a lower

time to pregnancy and EFI scores could help determine which patients could attempt spontaneous pregnancy following surgery and which should be referred for ART.

Our study has some limitations. First, the sample size remains limited with only one center included. These results can be considered only preliminary and can limit the generalizability of the findings. A multi-center study might provide more diverse and representative data. Second is a potential bias due to the lack of information about fertility outcomes in 10% of our patients. Third, only female parameters were taken into account to evaluate fertility with no information about male characteristics. This could have led to an underestimation of the benefit of surgery as ART was systematically required for couples with both female and male infertility. Moreover, these couples might have a lower chance of success even if surgery outperforms expectations by increasing fertility. Furthermore, some patients were relatively young at the time of surgery and might not have desired pregnancy at the time we completed this study with only a 5-year time frame. Fourth, most patients undergoing ART (before or after surgery) were managed outside our center and the protocols used could not therefore be reported. This could have influenced the success / failure rate as not all centers report similar pregnancy rates. Finally, this work focused on fertility outcomes but eluded the question of the functional digestive outcomes which were not evaluated by a specific questionnaire. However, secondary analysis of the ENDORE trial showed that the main factor impacting bowel movement following rectal surgery for endometriosis was preoperative constipation and not the type of surgery (radical or conservative) [44]. Eventually, best option between first line surgery and primary ART for patients with severe disease wishing to conceive remain undetermined. The results of the ENDO FERT trial are highly expected to help the clinical decision making [45].

Conclusion

Our results support that discoid excision is safe and associated with good fertility outcomes. Whether first-line surgery using discoid excision is superior to first-line ART remains to be determined.

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Author's roles: YD, LE, CT and ED were involved in study design. YD, LE, AF, KK, AP, AJ, CF were involved in execution and acquisition of data and YD, LE, AF, KK, AP, AJ, CF, CT, SB and ED were involved in data analysis and interpretation. YD, LE, SB and ED were involved in manuscript drafting and all authors were involved in critical discussion and in revising the manuscript critically for important intellectual content. All authors have given the final approval of the version to be published.

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