Randomized clinical trial of two laparoscopic treatments of endometriomas: cystectomy versus drainage and coagulation

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Objective: To assess the efficacy of two laparoscopic methods for the management of endometriomas with regard to pain relief, pregnancy rate, and disease recurrence.

Design: Prospective, randomized clinical trial.

Setting: Tertiary care hospital.

Patient(s): Sixty-four patients with advanced stages of endometriosis.

Intervention(s): Patients were randomly allocated at the time of laparoscopy to undergo either cystectomy of the endometrioma (group 1) or drainage of the endometrioma and bipolar coagulation of the inner lining (group 2).

Main Outcome Measure(s): Pain relief and pregnancy rate.

Result(s): Thirty-two patients were enrolled in each group. The 24-month cumulative recurrence rates of dysmenorrhea, deep dyspareunia, and nonmenstrual pelvic pain were lower in group 1 than in group 2 (dysmenorrhea: 15.8% versus 52.9%; deep dyspareunia: 20% versus 75%; nonmenstrual pelvic pain: 10% versus 52.9%). The median interval between the operation and the recurrence of moderate to severe pelvic pain was longer in group 1 than in group 2 (19 months [range, 13.5–24 months] versus 9.5 months [range, 3–20 months]). The 24-month cumulative pregnancy rate was higher in group 1 than in group 2 (66.7% versus 23.5%).

Conclusion(s): For the treatment of ovarian endometriomas, a better outcome with a similar rate of complications is achieved with laparoscopic cystectomy than with drainage and coagulation. (Fertil Steril® 1998;70:1176–80. ©1998 by American Society for Reproductive Medicine.)

Key Words: Advanced endometriosis, cystectomy, laparoscopy, pelvic pain, cumulative pregnancy rate

Although the endoscopic management of early stages of endometriosis is widely accepted, the best laparoscopic technique for the treatment of endometriomas is still controversial (1, 2). Various modalities of conservative laparoscopic surgery have been proposed for endometriotic cysts (3, 4).

Traditionally, laparoscopic cystectomy has been considered the method of choice for the treatment of endometriomas (5, 6). Fayez and Vogel (7) recently proposed that the laparoscopic treatment of endometriomas should not include excision but rather drainage with or without any further intracavitary manipulation except thorough washing. Conversely, Vercel-lini et al. (8) reported that aspiration and washing of endometriotic cysts, with or without postoperative administration of GnRH agonists, is ineffective. In addition, the cumulative pregnancy rate (PR) after the surgical treatment of advanced stages of endometriosis is reported to vary from 0% to 70% according to the type of surgery performed (8–12). However, prospective studies evaluating the PR after the use of different laparoscopic surgical techniques for the management of endometriomas are rare in the literature.

The purposes of this study were to assess the safety and efficacy of two laparoscopic methods for the management of ovarian endometri-

omas with regard to pain relief and disease recurrence and to investigate whether the type of laparoscopic surgery performed is an independent predictor for the occurrence of a subsequent pregnancy.

MATERIALS AND METHODS

Patients who underwent laparoscopy for endometriomas between October 1995 and December 1997 were considered eligible for the study. Inclusion criteria were age between 20 and 40 years and endometriotic cysts with a diameter of at least 3 cm confirmed at laparoscopy. Patients who previously had undergone surgical treatment of endometriosis or who had received steroids or estrogen-suppressing drugs in the preceding 6 months were not included in the study. With the use of a computer-generated randomization code, patients were randomly allocated at the time of laparoscopy to undergo either cystectomy of the endometrioma (group 1) or drainage of the endometrioma and bipolar coagulation of the inner lining (group 2). All operative techniques were performed under general anesthesia.

Operative laparoscopy was performed by video control through a subumbilical incision and two or three lower abdominal incisions. Instrumentation included 5-mm scissors and graspers. Irrigation was performed with lactated Ringer's solution. Hemostasis was achieved with bipolar coagulation. All endoscopic procedures included peritoneal washing for cytology, inspection of pelvic and peritoneal organs, and adhesiolysis. Lysis of adhesions was performed with the use of sharp dissection to fully mobilize the ovaries. In all cases, endometriomas were incised in the antimesenteric area and decompressed by suction drainage.

In group 1, the inner lining of the cysts was stripped from the normal ovarian tissue with the use of two atraumatic grasping forceps pulled slowly in opposite directions, removed from the abdominal cavity, and sent for histologic examination.

In group 2, a large biopsy was performed for histologic examination followed by bipolar coagulation of the inner lining. In all cases, no sutures were used and the ovaries were left open. Areas of superficial active endometriosis involving the other ovary or the pelvic peritoneum were cauterized. After completion of the laparoscopic procedure, 500 mL of lactated Ringer's solution was left in the pelvic cavity as a hydroflotation medium. This study was approved by the human research review committee at our hospital.

Endometriosis was classified according to the revised American Fertility Society classification (13). To evaluate variations in pelvic pain, each patient was asked to record the presence and severity of dysmenorrhea, nonmenstrual pelvic pain, and deep dyspareunia on a 10-cm linear analog scale marked from 0 to 10, with 0 representing no pain at all and 10 representing the worst pain they had experienced in their lives (a score of 1–4 was considered mild pain, 5–7 moderate pain, and 8–10 severe pain) (14).

To evaluate the effect of surgery on subsequent reproduction, we considered patients who had tried to conceive without success for at least 12 months before the laparoscopy and who had no other obvious causes of infertility (i.e., anovulation, male factor, müllerian anomalies). Pregnancies were documented by the presence of an intrauterine gestational sac on ultrasound (US). None of the patients received drugs to stimulate ovulation.

We recorded disease recurrence as ultrasonographic evidence of ovarian endometriomas (round-shaped cysts with thick walls, regular margins, and homogeneous low echogenicity of the fluid). All ultrasonographic examinations were performed during the proliferative phase of the menstrual cycle.

Patients were followed up at 3, 6, 12, and 24 months after the operation. At each visit, a standard gynecologic examination and transvaginal US were performed. The occurrence of a pregnancy was recorded, and pain symptoms were evaluated on the 10-cm linear analog scale.

Statistical analysis was performed with EpiStat 4.0 (Epi-Stat Services, Richardson, TX) and with SPSS 7.0 (SPSS Inc., Chicago, IL). Student's t-test and the Mann-Whitney U test were used for comparison of continuous variables, whereas proportions were compared with the χ^2 test or Fisher's exact test. Survival comparisons were conducted with the use of Wilcoxon's generalized test.

Patients who did not experience pain or who were not pregnant at the time of follow-up were considered censored observations with a censored time equal to the interval between the operation and the follow-up clinical examination (15). When a pregnancy occurred, the event datum used to construct the survival curves was the last menstrual period. A computed logistic regression analysis was used to investigate the regression relation between the occurrence of a pregnancy and several covariates that could influence the ability to conceive. $P < .05$ was considered statistically significant.

RESULTS

Sixty-four patients were enrolled during the study period. There were 32 women in group 1 and 32 in group 2. The clinical characteristics of the study population at the time of surgery are presented in Table 1. No difference was found between group 1 and group 2 in the median operative time (60 minutes [range, 20–100 minutes] versus 55 minutes [range, 20–90 minutes]), estimated blood loss (50 mL [range, 10–200 mL] versus 20 mL [range, 10–100 mL]), and postoperative length of stay (1 day [range, 1–3 days] versus 1 day [range, 1–2 days]).

The 24-month cumulative recurrence rate of dysmenor-

TABLE 1

Clinical characteristics of 64 patients with advanced stages of endometriosis.

| Variable	Patient group	
	Group 1: cystectomy of the endometrioma (n = 32)	Group 2: drainage of the endometrioma (n = 32)
Mean (±SD) age (y)	29.1 ± 4.3	30.2 ± 5.1
No. of nulliparous patients (%)	22 (68.7)	23 (71.9)
No. of patients with primary infertility (%)	9 (28.1)	17 (53.1)
No. of patients with dysmenorrhea (%)	19 (59.4)	17 (53.1)
Mild	3 (9.4)	1 (3.1)
Moderate	14 (43.8)	16 (50)
Severe	2 (6.2)	0
No. of patients with deep dyspareunia (%)	19 (59.4)	16 (50)
Mild	15 (46.9)	12 (37.5)
Moderate	3 (9.4)	4 (12.5)
Severe	1 (3.1)	0
No. of patients with nonmenstrual pelvic pain (%)	20 (62.5)	17 (53.1)
Mild	9 (28.1)	7 (21.9)
Moderate	10 (31.2)	10 (31.2)
Severe	1 (3.1)	0
Median rAFS score (range)	28 (18–98)	28 (20–102)
No. of patients with indicated rAFS stage (%)		
Stage III	25 (78.1)	27 (84.4)
Stage IV	7 (21.9)	5 (15.6)
No. of patients with indicated cyst diameter (%)		
Maximum (range)	5.0 (3–7)	4.5 (3–7)
≤4 cm	13 (40.6)	15 (46.9)
>4 cm	19 (59.4)	17 (53.1)
No. of patients with bilateral endometriomas (%)	5 (15.6)	3 (9.4)

Note: rAFS = revised American Fertility Society score.

rhea, deep dyspareunia, and nonmenstrual pelvic pain was lower in group 1 than in group 2 (dysmenorrhea: 3/19 (15.8%) versus 9/17 (52.9%), $P<.05$; deep dyspareunia: 3/15 (20%) versus 9/12 (75%), $P<.05$; nonmenstrual pelvic pain: 2/20 (10%) versus 9/17 (52.9%), $P<.05$). There was no difference in the median follow-up between the two groups (20 months [range, 3–26 months] versus 19.5 months [range, 4–26 months]).

To investigate the temporal relation between the type of operation performed and the recurrence of dysmenorrhea, deep dyspareunia, and nonmenstrual pelvic pain, we considered patients who were admitted with at least one of the three symptoms in their moderate to severe form (n = 38). The median interval between the operation and the recurrence of pain was longer in group 1 than in group 2 (19 months [range,

FIGURE 1

Survival analysis of the interval between operation and the recurrence of moderate to severe pain (dysmenorrhea, deep dyspareunia, or nonmenstrual pelvic pain) according to the type of surgery performed (*closed circles* = cystectomy of the endometriomas; *open circles* = drainage and coagulation) (generalized Wilcoxon's test for survival analysis, $P<.05$).
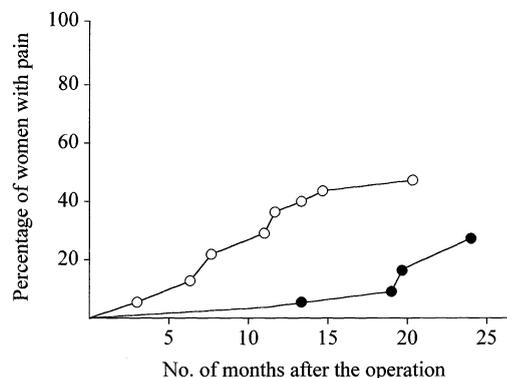

13.5–24 months] versus 9.5 months [range, 3–20 months], $P<.05$) (Fig. 1).

The 24-month cumulative PR was significantly higher in group 1 than in group 2 (6/9 (66.7%) versus 4/17 (23.5%), $P<.05$). Figure 2 shows the monthly PR according to the type of laparoscopic surgery performed. Logistic regression revealed that when conditions such as the patient's age, the presence of deep dyspareunia and/or nonmenstrual pelvic pain after the operation, and the type of treatment were used as covariates, the only variable that was strongly associated

FIGURE 2

Survival analysis of the interval between operation and the occurrence of a pregnancy according to the type of surgery performed (*closed circles* = cystectomy of the endometriomas; *open circles* = drainage and coagulation) (generalized Wilcoxon's test for survival analysis, $P<.05$).
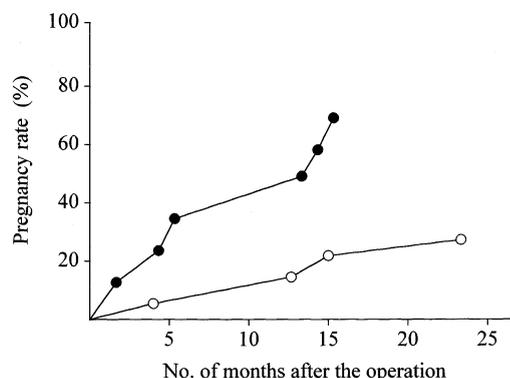
with the occurrence of a pregnancy was the type of surgery performed (odds ratio = 8.25; 95% confidence interval = 1.15–59; $P<.05$).

No statistically significant difference in the rate of disease recurrence was found between group 1 and group 2 (2/32 (6.2%) versus 6/32 (18.8%). However, the power ($\alpha = 0.05$) of the present study to detect such a difference was only 20%.

None of the patients included in the study required conversion of the operation from laparoscopy to laparotomy. No intraoperative or postoperative complications occurred in either group. Glands and stroma were identified on histologic examination in 89% (n = 57) of cases, with no difference between group 1 (n = 30) and group 2 (n = 27).

DISCUSSION

A MEDLINE search from January 1980 to March 1998 was performed to identify studies on laparoscopic techniques used for the treatment of advanced stages of endometriosis. The present study was found to be the first randomized trial that compared two laparoscopic techniques for the management of moderate to severe endometriosis in patients who did not receive preoperative or postoperative medical treatment. In addition, the present study is the first prospective study to assess the unique contribution of the type of laparoscopic surgery performed to the postoperative ability to conceive.

The first observation of our study is that cystectomy compared with drainage and coagulation of endometriomas resulted in longer-lasting pain relief and a lower recurrence rate of dysmenorrhea, deep dyspareunia, and nonmenstrual pelvic pain in women with severe to moderate endometriosis. This is at variance with the results of Fayez and Vogel (7), who conducted a prospective trial comparing four different types of endoscopic treatment of endometriomas and concluded that drainage of the endometriotic cyst alone produces the same results as complete excision of the cyst, stripping of the lining, or CO_2 laser ablation of the lining with regard to disease recurrence and pain relief.

A possible explanation for this discrepancy has three components. First, in the study by Fayez and Vogel (7), when cystectomy was not performed, the lining of the endometriomas was either left intact or evaporated with the CO_2 laser, whereas in our study the inner lining was destroyed by bipolar coagulation. Second, the proportion of patients who had endometriomas with a diameter of >4 cm was higher among those who underwent drainage and coagulation in our study than among those who underwent drainage of the cyst alone in the study by Fayez and Vogel (7) (59.4% [19/32] versus 34% [15/44], $P = .05$); similarly, the proportion of patients who had large endometriomas (>4 cm) was higher in the drainage and coagulation group in our study than in the group who underwent CO_2 laser ablation of

the inner lining in the study by Fayez and Vogel (7) (59.4% [19/32] versus 37% [11/30]) . Third, none of the patients in our study received any medical treatment before or after the operation, whereas in the study by Fayez and Vogel (7), all the patients were given danazol (200 mg/d every 8 hours) for 8 weeks after the operation.

In addition, these investigators did not mention whether the patients received steroids or estrogen-suppressing drugs before the operation. However, they reported that none of the walls of the excised endometriomas showed endometriosis on histologic examination. In our study, glands and stroma were present in 89% of cases, which is in agreement with previous reports in which no medical therapy was instituted before surgery.

Donnez et al. (16) reported that typical endometriotic glandular epithelium was found at a first-look laparoscopy in about 85% of their patients who underwent cystectomy and that, at a second-look laparoscopy performed 12 weeks later, the presence of active endometriosis on histologic examination was significantly lower in patients who had received postoperative SC injection of goserelin implants than in those who had not (46% versus 83%).

Finally, an important advantage obtained with cystectomy of endometriomas is the ability to make the most accurate diagnosis of the ovarian lesion. Considering that up to 31% of frankly malignant endometrioid tumors of the ovary are associated with endometriosis in the same ovary or elsewhere (17, 18), and that those carcinomas that arise within an endometriotic cyst present in women younger than the average by 10 or more years (19), we believe that drainage alone of endometriomas is associated with an increased chance that the true diagnosis will be missed.

The second important finding of the present study is that the cumulative PR is significantly higher when the cyst wall is stripped than when the endometrioma is drained and coagulated. The PR among patients who underwent cystectomy of the endometrioma in our study was similar to that of patients in the study by Adamson et al. (10), who used a similar laparoscopic technique (66.7% versus 62%).

Further, our results are in keeping with those of Bateman et al. (9), who found a 1-year PR of 42.8% after laparoscopic cystectomy of endometriomas. A possible explanation for the higher PR seen after cystectomy compared with drainage and coagulation is that the rate of disease recurrence seems to be lower with the former than with the latter. Canis et al. (20) reported a 7.6% recurrence rate of deep ovarian endometriosis at second-look laparoscopy in patients who underwent cystectomy of endometriomas >3 cm. This is in accordance with the results of the present study, in which the recurrence rate in the group of patients who underwent cystectomy of endometriomas was 6.2%, and with the results of the study by Bateman et al. (9), who found an 11.1% recurrence rate after the same surgical treatment.

In contrast, Vercellini et al. (8) reported a 100% rate of disease recurrence in 33 women who underwent laparoscopic aspiration of endometriomas with or without the subsequent administration of GnRH analogues for infertility and/or chronic pelvic pain. In addition, these investigators reported that none of the patients who underwent only aspiration of the cysts became pregnant during the next 6 months. Finally, Donnez et al. (16) reported that endometriomas recur quickly after drainage alone and that drainage followed by GnRH analogue therapy is effective only in reducing cyst size and glandular mitotic activity.

In conclusion, the present study clearly demonstrates that cystectomy of endometriomas offers better results with regard to pain relief and cumulative postoperative PR compared with drainage and coagulation. Therefore, we suggest that cystectomy should be the preferable procedure for the laparoscopic management of ovarian endometriomas, especially those that are >4 cm.

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