Ovarian cystectomy versus laser vaporization in the treatment of ovarian endometriomas: a randomized clinical trial with a five-year follow-up

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Objective: To investigate the effect of two laparoscopic techniques for treatment of ovarian endometriomas on recurrence rate.
Design: Prospective randomized clinical trial.
Setting: University teaching hospital.
Patient(s): Ninety women with ovarian endometriomas.
Intervention(s): Patients were randomly selected to undergo either laparoscopic cystectomy (group 1) or laser vaporization (group 2) of ovarian endometrioma.
Main Outcome Measure(s): Recurrence, evaluated by ultrasound scan examination, was assessed at 12 and 60 months of follow-up.
Result(s): Endometrioma recurrence rate was higher, though not significantly different, in group 2 at 60 months of follow-up. Nevertheless, at 12 months of follow-up recurrences were statistically higher in group 2.
Conclusion(s): The comparison between laparoscopic laser ablation and laparoscopic cystectomy for ovarian endometriomas after long-term follow-up showed earlier recurrences and a higher recurrence rate in the laser group, although at 5 years of follow-up there were no statistically significant differences. (Fertil Steril® 2011;96:251–4. ©2011 by American Society for Reproductive Medicine.)

Key Words: Ovarian endometrioma, laparoscopic surgery, endometriosis, cystectomy, laser vaporization, ovarian reserve, recurrence

One of the most frustrating aspects of treating endometrioma is disease recurrence after surgery, which varies between 10% and 50% after 2–5 years depending on the surgical approach and the time of follow-up (1–7). Excisional surgery of endometriomas reportedly seems to be more beneficial than ablative techniques in this respect (8–11). However, laser vaporization has also been proposed as the best method to preserve ovarian function (12, 13). A randomized comparison of laser vaporization with cystectomy has recently been published evaluating the impact of both types of surgery on ovarian reserve, but recurrences were not evaluated (13).

To date, no randomized prospective or comparative studies have compared laser vaporization versus cystectomy to assess long-term recurrences after the laparoscopic treatment of endometriomas. Therefore, we provide the first report on the rate of long-term recurrence after laser vaporization and cystectomy.

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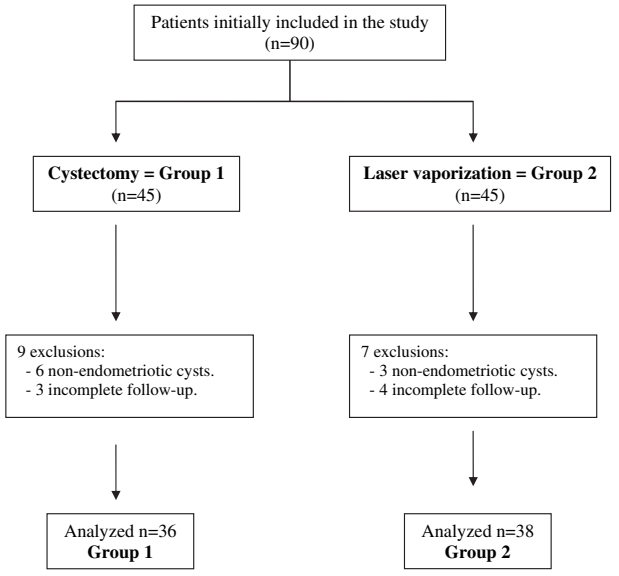
MATERIALS AND METHODS

Ninety patients undergoing laparoscopy for adnexal mass with the diagnosis of endometrioma(s) were enrolled in this prospective randomized clinical trial at the Hospital Clínic of Barcelona. Each of the patients gave informed consent to participate in the study, which was approved by the hospital Ethics Committee. Inclusion criteria were: age between 18 and 40 years, uni- or bilateral symptomatic endometriomas $\geq$3 cm, and no counterindication for the use of GnRH-agonists. The exclusion criteria were: previous pelvic surgery, history of cancer, suspected malignancy, presurgical suspicion or evidence of deep endometriosis, presurgical suspicion or evidence of premature ovarian failure, and the use of estrogen suppressive drugs, including oral contraceptives (OC), GnRH-agonists, progestins, or danazol in the preceding 6 months. We excluded patients with suspicion of deep endometriosis according to an extensive preoperative work-up (including magnetic resonance imaging when necessary) routinely performed in such patients.

Patients, when surgery was proposed, were randomly allocated according to a computer-generated randomization list generated using the method of simple randomization to undergo either endometrioma cystectomy (group 1) or drainage and laser coagulation of the inner lining (group 2; Fig. 1). Group 2 was treated for 2 months with intramuscular doses of triptorelin (3.75 mg), as previously recommended (12). Concealment of treatment allocation was achieved with the use of sealed opaque envelopes,

FIGURE 1

Flow chart of the patients included and excluded/lost to follow-up.



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each containing a unique study number, and prepared independently by a secretary. Envelopes were opened at diagnosis. Histologic examination was performed in all cases to confirm the preoperative and intraoperative diagnosis of ovarian endometrioma. Forty-five patients were enrolled in each group. A total of 16 patients were excluded (Fig. 1).

Operative laparoscopy was performed through insertion of a 12-mm umbilical trocar and two or three 5-mm ancillary trocars in the lower abdomen. All interventions were performed by the same team of surgeons who had a wide experience in both techniques, having performed such surgical operations ≥2–3 times per week over the preceding 5 years. The same protocol was used during the diagnostic phase of laparoscopy. Standard laparoscopic instruments and 0-degree video laparoscope were used in all procedures (Olympus Europe Holding). Endometriosis was staged according to the revised American Society for Reproductive Medicine classification (ASRM) (14).

After identification of the cleavage plane in group 1, the wall of the cyst was stripped from the healthy surrounding normal ovarian tissue and sent for histologic examination. Patients in group 2 underwent drainage of the cyst content and irrigation and inspection of its inner wall. A biopsy of the cyst wall was sent for routine histologic examination to confirm the diagnosis of endometriosis. Vaporization of the internal wall was performed using a CO_2 laser at a power density of 30 W/cm^2. No sutures were placed after surgery.

Patients without gestational desire received OC after surgery throughout the follow-up (10/36 [28%] in group 1 and 14/38 [36%] in group 2; *P*=NS). Patients were followed with standard gynecologic examination and transvaginal ultrasound exploration at 6, 12, 18, 24, 36, 48, and 60 months after surgery, or earlier if symptoms related to possible recurrence were reported. Recurrence was defined as an endometrioma ≥3 cm in the operated ovary. The same investigators performed all ultrasonic scans with the use of an endovaginal probe. Antral follicle count (AFC) and basal (menstrual cycle days 3–5) FSH serum levels were determined in all patients at 5 years of follow-up according to methods previously reported (15, 16).

Data analysis was performed with the SPSS 15.0 software. The chi-square or Fisher exact test was used for comparison of categoric variables. The Student *t* test and the Mann-Whitney test were used for comparison of continuous variables. Comparison of cumulative recurrence and pregnancy rates was conducted with the use of Kaplan-Meier test. Results are presented as mean ± SD. $P<.05$ was considered to be statistically significant.

TABLE 1

Baseline clinical characteristics and ultrasonographic findings of the two groups of patients with ovarian endometriomas.

Characteristic	Group 1 (n = 36)	Group 2 (n = 38)	*P* value
Age (y)	32.5 ± 6	32.3 ± 5.9	NS
Diameter of the larger endometrioma (mm)	54.7 ± 14.1	53.6 ± 16.3	NS
Mean diameter of all endometriomas (mm)	62.8 ± 17.2	62.5 ± 16.8	NS
Bilateral endometrioma	8 (22.2)	12 (31.6)	NS
Nulliparous	27 (75)	29 (76.3)	NS
Infertility	7 (19.4)	13 (34.2)	NS
Dysmenorrhea	25 (69.4)	22 (57.9)	NS
Chronic pelvic pain	4 (11.1)	6 (15.8)	NS

Note: Values are mean ± SD or number of patients (%). NS = not significant.

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RESULTS

The baseline clinical characteristics and ultrasonographic findings of the two study groups were similar regarding age, mean cyst diameter, bilaterality, mean diameter of all endometriomas, nulliparity, infertility, dysmenorrhea, and chronic pelvic pain, as shown in Table 1. There were no conversions to laparotomy or complications during or after surgery in either group. Similarly, the operative time, length of hospitalization, and follow-up time were also similar between the two groups (Table 2). The endometriosis stage according to the revised ASRM classification showed no differences between groups (Table 2).

The endometrioma recurrence rate was higher, though not statistically different, in group 2 than in group 1 at 60 months of

TABLE 2

Surgical characteristics, follow-up, and sonographic recurrence rate of the two groups of patients with ovarian endometriomas.

Characteristic	Group 1 (n = 36)	Group 2 (n = 38)	*P* value
Median rAFS score (range)	27 (19–96)	28 (20–94)	NS
Mean operating time (min)	72 ± 33	65 ± 39	NS
Hospital stay (d)	1.6 ± 0.6	1.5 ± 0.7	NS
Follow-up (mo)	64.8.7 ± 13.3	63.1 ± 17.6	NS
Recurrence at 12 mo			
Per patient	4/36 (11)	12 (31)	.04
Per endometrioma	4/44 (9)	4/50 (8)	.1
Recurrence at 60 mo			
Per patient	8 /36 (22)	14/38 (37)	.2
Per endometrioma	8/44 (18)	14/50 (28)	.4
Time of recurrence (mo)	18.1 ± 10.1	7.5 ± 4.3	<.003

Note: Values are mean ± SD or number of patients (%). NS = not significant; rAFS = revised American Fertility Society.

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