

Efficacy of ovarian suspension to round ligament with a resorbable suture to prevent postoperative adhesions in women with ovarian endometrioma: follow-up by transvaginal hydrolaparoscopy

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Abstract The aim of this study was to assess the effect of ovarian suspension to the round ipsilateral ligament with a resorbable suture, performed during laparoscopic surgery for endometrioma, on postoperative ovarian adhesion formation. The tool used to assess this effect was not conventional laparoscopy but outpatient transvaginal hydrolaparoscopy. Fifty women with single ovarian endometrioma were divided in two groups (group A, 24 and group B, 26). All patients underwent laparoscopic ovarian cystectomy for endometriosis. In group A, the ovary was suspended to the ipsilateral round ligament. In group B, ovarian suspension was not performed. All patients underwent transvaginal outpatient hydrolaparoscopy as follow-up. A significantly lower rate of postsurgical ovarian adhesion in group A in comparison with group B (33.3 vs 80.8 %— $p=0.001$) was observed. Operative time and postoperative pain were similar in both groups. Ovarian suspension to the ipsilateral round ligament with a resorbable suture during surgery for endometrioma is associated with a lower rate of postoperative ovarian adhesion formation.

Keywords Endometrioma · Laparoscopy · Ovarian suspension · Adhesion prevention · Transvaginal hydrolaparoscopy

Background

Ovarian endometriomas are a form of ovarian endometriosis, classified as cysts within the ovaries [1] accounts for 35 % of benign ovarian cysts [2], and are present in 17–44 % of patients with endometriosis. Expectant management is not an option for women with endometrioma because of severe symptoms [1].

Operative laparoscopy is the first-line treatment option available to the general consensus in the treatment of endometriomas >3 cm. However, debate still continues on the type of laparoscopic procedure. The main point of debate is excision or ablation of the cyst capsule [3, 4]. Since the ovarian endometrioma is a pseudocyst, excisional surgery involves the removal of ovarian cortex with primordial follicles, reducing the fertility potential of the affected ovary, especially when extensive hemostasis irreversibly diminishes or impairs the blood supply towards the affected ovary. Ovarian cystectomy for endometriomas seems to cause significant damage to ovarian reserve with up to 40 % fall in serum AMH concentration [5, 6]. According to Donnez et al., cystectomy may be destructive for the ovary, whereas ablation may be incomplete with a greater risk of recurrence [7]. With the combined technique (excision of a large part of endometrioma wall with vaporization of the remaining 10–20 % of endometrioma wall close to the hilus), we achieve the benefits of stripping on symptoms and recurrence, and a less harmful effect of ablation on ovarian reserve.

Adhesions formation rate after laparoscopic endometriosis surgery has been reported in more than 80 % cases [8–11]. The most common site of postoperative adhesions formation is between the ovary and the pelvic wall [12]. Notwithstanding the advances in surgical techniques [13] and the use of surgical

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anti-adhesive agents, the incidence of adhesion-related complications do not seem to have significantly declined [14].

The aim of this study was to assess the effect of ovarian suspension to the round ipsilateral ligament with a resorbable suture, during laparoscopic surgery for endometrioma in terms of postoperative ovarian adhesions after surgical procedure evaluated with office transvaginal hydrolaparoscopy.

Methods

This study was performed in the Infertility Clinic of our Department. During the period from March 2010 to March 2012, 185 women affected by endometriosis were evaluated for inclusion in the study. Inclusion criteria were: age between 18 and 40 years; history of infertility >2 years; single endometrioma cysts ≥ 4 or ≤ 7 cm [15] on preoperative ultrasound screen. Patients with smaller endometriomas were excluded because treatment of endometriomas of 1–3 cm was recommended only for the treatment of pain. When endometriosis is identified at laparoscopy, it is recommended to surgically treat endometriosis, as this is effective for reducing endometriosis-associated pain [16]. In these cases, we performed drainage and coagulation of the endometrioma wall because of the possible difficulty in the removal of very small cysts, due to the absence of a clear surgical plane.

Exclusion criteria were: masses occupying the Douglas pouch; previous surgery for endometriosis or additional concomitant surgical procedure planned during the laparoscopic procedure; current pregnancy, including ectopic pregnancy; serum glutamic-oxaloacetic transaminase (sgot), serum glutamate pyruvate transaminase (sgpt), and/or bilirubin >20 % above the upper limit of the normal range; azotemia and creatinine >30 % above the upper limit of the normal range; concurrent use of systemic corticosteroids, antineoplastic agents, and/or radiation; and active pelvic or abdominal infection.

The study was approved by the Institutional Review Boards of our Institution and all patients gave informed consent to participate in the study. Eighty-three patients matched the inclusion criteria and agreed with the study protocol, 21 however refused to participate to the study. Sixty-two patients were divided into two groups (group A, $n=31$; group B, $n=31$). Patients in group A underwent ovarian suspension to round ligament, while patients in group B did not undergo additional procedures other than that indicating laparoscopy. Both patients and surgeons performing THL were blinded with regard to which cases had their ovaries suspended and which cases did not.

The laparoscopic procedure was performed in the modified dorso-lithotomic position under endotracheal general anesthesia. After pneumoperitoneum induction with a Veress needle and introduction of a 10-mm laparoscope (Karl Storz—

Tuttlingen, Germany) in the standard umbilical position, three 5-mm trocars were placed in the following positions: suprapubic, left iliac fossa, and right iliac fossa. After careful exploration of the pelvic organs and upper abdomen, patients with single endometrioma adherent to the ipsilateral fossa were included, while patients with clinical evidence of cancer, rectovaginal endometriosis or bilateral endometriosis were excluded.

Light adhesions on the contralateral adnexa and/or small subserosal uterine myomas observed at first surgery were not considered as exclusion criteria. Ovarian endometriomas were removed following the technique described by Donnez [7]. Briefly, the ovarian cyst was opened and its content drained, the cleavage plane was found and the pseudo-capsule was separated from the ovarian parenchyma by means of repeated diverging traction applied with atraumatic forceps. Light coagulation with bipolar forceps was performed only if necessary, exclusively inside the ovarian parenchyma, before closure of the ovary. The suture was performed using a single running suture with an absorbable monofilament suture (Vicryl Rapid 2.0, CT-1 needle, Sommerville, NJ, USA, Ethicon) with intraovarian knots. Ovarian suture was performed so that no coagulated tissue was detectable outside as previously reported [13]. In group A, the ovary was suspended to the ipsilateral round ligament using an absorbable monofilament suture (Vicryl Rapid 2.0, CT-1 needle, Sommerville, NJ, USA, Ethicon). The suture was performed approximately 1 cm from the inguinal canal, to separate the ovary approximately 1.5–2 cm from the ovarian fossa (Fig. 1). In group B, ovarian suspension was not performed.

The operation time was calculated from the induction of pneumoperitoneum to desufflation. Blood loss during surgery was estimated by measuring the aspirated blood volume. Surgery was performed with an indwelling Foley catheter in situ that was removed as soon as the patient could independently reach the toilet. Twenty-four hours after the procedure,

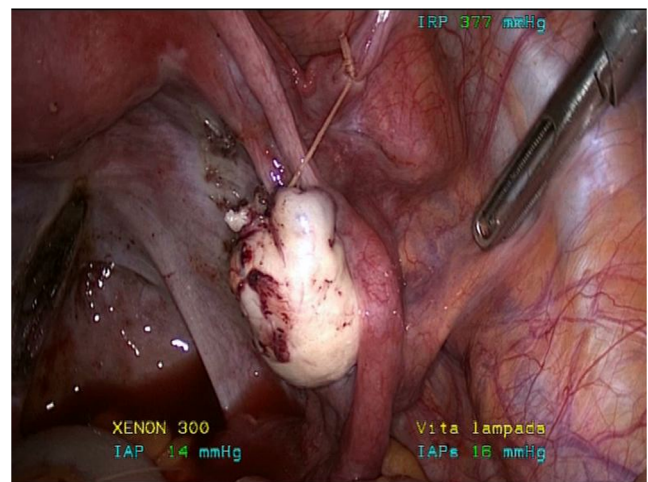


Fig. 1 Ovarian suspension to round ligament

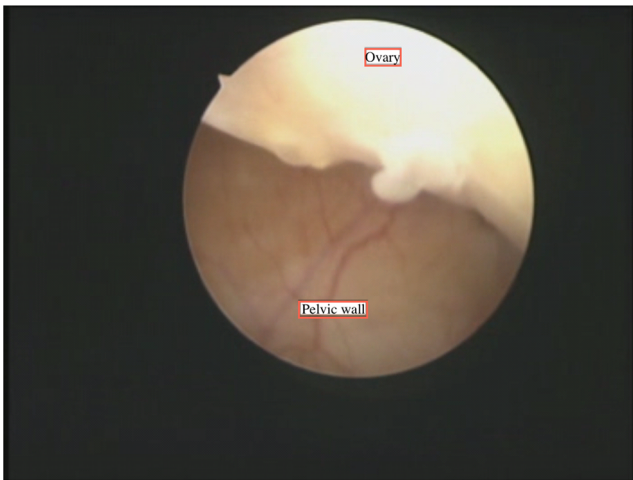


Fig. 2 Transvaginal hydrolaparoscopy follow-up

postoperative pain was evaluated using a pain visual analogue scale (VAS) ranging from 0 (absence of pain) to 10 (maximum pain). Per protocol, patients were discharged from the hospital 2 days after the procedure if no complication arose during the postoperative period. All patients were evaluated 60–90 days after surgery with transvaginal outpatient hydrolaparoscopy (THL). THL was not performed before because patients may not agree to undergo a second invasive procedure immediately after the initial surgery.

Transvaginal hydrolaparoscopy was performed by three surgeons: M.P. who performs approximately 100 procedures per year; U.C. and P.G. who perform about 25 procedures per year. Fertiloscopy was performed under local anesthesia with the patient in the lithotomic position. A Collin's speculum was placed in the vagina and a local anesthetic solution containing mepivacaine hydrochloride 3 % was injected in the posterior fornix, 1–2 cm below the cervix and on the posterior lip of the cervix which was grasped. A specially designed needle dilating trocar system with a total diameter of 3.9 mm (reusable system by Karl Storz Endoscopy—Tuttlingen, Germany) was placed 10–20 mm below the insertion of the posterior vaginal wall to the cervix. A 2.7-mm-diameter semi-rigid endoscope was used with an optical angle of 30°. The correct intra-abdominal trocar position was confirmed visually, and a slow continuous infusion of warmed saline solution was started [17, 18]. To keep the bowel and tubo-ovarian structures afloat the illumination was provided by a high-intensity cold-light source via fiber-optic lead. The images were viewed on high-resolution color monitor. The posterior wall of the uterus was inspected. Subsequently, by rotation and deeper insertion of the scope, the tubo-ovarian structures were visualized. Success was defined as the absence of any adhesion between the ovary and the ovarian fossa (Fig. 2). The vaginal fornix was left to close spontaneously, and antibiotic prophylaxis was prescribed.

The primary end-point was the proportion of women without ovarian adhesions as evaluated by THL 60–90 days after the primary surgical procedure. We hypothesized that women underwent ovarian suspension would develop ovarian adhesion in 30 % of cases as opposed to 70 % of women not undergoing this procedure. Considering these proportions, we calculated that we would need a sample size of 24 in group A and 24 in group B to give 90 % power to detect a significant difference between ovarian suspension and non ovarian suspension procedures with a one-sided type 1 error of 5 %. To account for loss to follow-up, we chose to enroll 31 patients in group A and 31 in group B. Secondary end-points were operative times, intra-operative blood loss, and intra- and postoperative complication rate.

Statistical analysis was performed using the Statistical Package for Social Science, version 15.0 (SPSS, Chicago, IL, USA). Data distribution for continuous variables was assessed with the Shapiro–Wilk's test. Difference in proportions between groups for the primary end-point was analyzed using the χ^2 test and the odds ratios were calculated. Student's *t* test for unpaired samples was used to compare parametric variables between groups. The Mann-Whitney test was used to analyze differences in non parametric parameters between groups. Analysis was performed both per protocol and on an intention-to-treat basis. Separate analysis was carried out considering all drop-outs as having formed adhesions (failures) or not having formed adhesions (successes) between the ovary and its fossa. Significance was set for a value of $p < 0.05$.

Findings

Characteristics of patients are listed in Table 1. No statistical differences were observed in any variable between the two groups. In group A, three patients were excluded intraoperatively from the study for the presence of contralateral ovarian adhesions at laparoscopy and one patient for the presence of

Table 1 Characteristics of patients. Value are given as mean±SD or median [range], as appropriate p =NS for all comparisons

	Group A ($n=31$)	Group B ($n=31$)
Age (years)	26.5±16.5	28.2±15.8
Weight (kg)	63.1±8.9	62.2±10.5
Height (cm)	170.3±35.6	172.2±28.2
BMI (cm)	25.2±3.5	23.2±2.9
Primary infertility	21 (67.7)	23 (74.2)
Endometrioma diameter (cm)	5.2±1.1	6.1±2.1
Hb (g/dl)	12.3±1.5	13.1±2.1
Hospital stay (days)	2.2±2[2–4]	2.1±2 [2–3]
Operative time (min)	65.6±9.8	62.1±8.5

two ovarian cysts; in group B three patients were excluded for endometriosis stages III–IV (ASRM).

Five patients (three from group A and two from group B) dropped out of the study: one patient was pregnant to follow-up, two patients refused to undergo THL, and in two patients THL was not possible to perform for poor compliance (pain in the positioning of speculum or trocar in the posterior fornix).

Thus, a total of 24 women in group A and 26 women in group B were available for the analysis. In all the 50 procedures, it was possible to enter the pelvic cavity and visualize the pouch of Douglas.

At the THL control, a significant higher proportion of patients for group A were free of adhesions in comparison with patients from group B (Table 2; $p=0.001$). Analyses considering all patients as failures (i.e., with adhesions formation between the ovary and its fossa) or success (i.e., non adhesions formation) confirmed that ovarian suspension leads to a significantly higher proportion of patients who did not develop adhesions (Table 2).

We did not observe any difference in terms of postoperative pelvic pain between the two groups, according to VAS scale (4.78 ± 1.48 in group A vs 4.05 ± 1.67 in group B; $p<0.16$).

The operating time was similar between group A and group B ($p=0.11$). No major complications (rectum perforation) were reported in both groups. At follow-up, no ovary was still suspended to the round ligament; in all patients from group A, the ovary was found in its anatomical location.

Discussion

Endometriosis is a complex and heterogeneous condition characterized by a continuous state of inflammation that causes symptoms of pelvic pain and infertility. In this condition, fibrosis and adhesions are common. Some authors support that the inflammatory response may be the first cause of adhesion formation [19]. It leads to an upregulation of tissue factors by peritoneal cells and local macrophages. This causes

activation of the extrinsic pathway of the coagulation cascade and the formation of an exudate rich in fibrin [19]. Adhesions can lead to infertility, dyspareunia, chronic pelvic pain, and complications at repeated surgery [20, 21]. Adhesions may produce disruption of the normal anatomy, thus altering normal tubal performance. Thus, follicular growth, pick-up of the oocyte after ovulation and spermatozoa or embryo transport may be impaired [20]. Several women develop postoperative adhesions after laparoscopy surgery. The most common site of postoperative adhesions formation is the ovary [12, 22]. Although several surgical measures and systemic pharmacologic treatments for adhesions prevention have been proposed, the rate of periovarian adhesion formation was not significantly reduced [13, 20–22]. The high incidence of postoperative adhesions in endometriosis patients and their clinical significance underline the importance of modifying surgical technique in order to reduce potential adhesion formation.

Adhesions may develop in locations previously unaffected (de novo) or in locations where adhesiolysis was performed (recurrence). The process of adhesions formation begins during surgery; the possible development of adhesions is determined within the first 7 days of the injury. In the injured area, a gel matrix of fibrin will form and macrophages recruit new mesothelial cells over the damaged surface which reaches the reconstruction of the mesothelial lining within 5–7 days. The adhesions will take place if the surfaces damaged remain in contact [23, 24]. This finding supports the idea of an ovariopexy.

Several authors previously proposed ovarian suspension techniques [25–30] (Table 3). The technique most frequently described has been temporary ovarian suspension to anterior abdominal wall [25–28]. This technique showed only limited results, with success rates ranging from 80 to 40 %. Moreover, this technique carries potential risks of infection due to the proximity of the ovary to the external abdominal wall. Only one author reported [26] an ovarian suspension to the round ligament, showing no dense adhesion of the ovary to the pelvic sidewall after definitive ovarian suspension to the round ligament. These results are in accordance with our

Table 2 Rate of postsurgical adhesions between patients treated with ovarian suspension (group A) and patients treated without ovarian suspension (group B)

	Group A	Group B	OR (95 %CI)	<i>p</i>
Analysis per protocol	<i>n</i> =24	<i>n</i> =26	0.119 (0.03–0.55)	0.001
Postoperative ovarian adhesion formation	8 (33.3 %)	21 (80.8 %)		
No postoperative ovarian adhesion	16 (66.7 %)	5 (19.2 %)		
Considering all drop-outs as failures	<i>n</i> =27	<i>n</i> =28	0.149 (0.04–0.60)	0.002
Postoperative ovarian adhesion formation	11 (40.7 %)	23 (82.1 %)		
No postoperative ovarian adhesion	16 (59.3 %)	5 (17.9 %)		
Considering all drop-outs as successes	<i>n</i> =27	<i>n</i> =28	0.140 (0.04–0.53)	0.001
Postoperative ovarian adhesion formation	8 (29.6 %)	21 (75 %)		
No postoperative ovarian adhesion	19 (70.4 %)	7 (25 %)		

Table 3 Ovarian suspension for adhesion prevention

	Number patients	Suspension	Suture type	Post operative removal stitch	Number second-look	No adhesion at second-look
Sedbon 1983	61	Pelvic rim outside the iliac artery	Catgut	No	17	76 %
Redwine 2001	3	Ipsilateral round ligament	Vicryl	No	3	100 %
Abuzeid 2001	20	Anterior abdominal wall	Prolene	Yes	5	80 %
Ouahba 2004	20	Anterior abdominal wall	Prolene	Yes	8	40 %
Mitwally 2006	59	Anterior abdominal wall	Prolene	Yes	–	50 %
Carbonnel 2011	218	Anterior abdominal wall	Prolene Mersuture	Yes	24	50 %

findings. The main drawback of previous analysis was the significant loss to follow-up. Indeed, in all previous studies, second-look surgery was performed only in a small number of patients (Table 3), since systematic laparoscopic second-look may be frequently refuted by patients. In this study, we used an office-based procedure performed under local anesthesia that should increase the compliance of patients in undergoing follow-up second-look.

Indeed, only five patients refused to undergo second-look with THL, supporting this hypothesis. This is to our knowledge, the first study using Vicryl Rapid to suspend the ovary to the round ligament. Because development of adhesion is determined within the first 5–7 days after surgery, we prefer to use Vicryl Rapid 2.0 suture for its characteristics loss of tensile strength in 5–7 days and fast reabsorption process. The ovary so remains separated from the peritoneum of the ovarian dimple for about 7 days, the time necessary for adhesions formation. In the present study, no significant difference was observed in terms of operative time.

Moreover, we did not observe a difference in terms of postoperative pain evaluated according to VAS scale. We believe that no difference in postoperative pain between the two groups is linked to the ovarian suspension technique used. We suspend the ovary approximately 1.5 cm from ovarian fossa with tension-free suture.

This study has several advantages. It can rely on effective blinding of the surgeon performing THL, so that a bias in determining adhesion formation is unlikely. Moreover, it was correctly powered to detect significant differences between the two groups. Finally, sensitivity analysis was performed to address differences in losses to follow-up in the two arms. A potential limitation of the study may be the nonrandomized design of the study that may lead to an allocation bias. Nevertheless, the population selected for the study was homogeneous, so that differences in the two groups are unlikely. Another potential limitation is the low external validity due to strict inclusion criteria. These criteria were chosen in order to evaluate the net effect of the proposed technique on adhesion formation rate due to the suturing of the ovary, avoiding interference of other factors.

Prospective comparative studies including more patients should be conducted to confirm our preliminary results.

In conclusion, this study seems to indicate that ovarian suspension to the round ligament with short-term resorbable suture may be a simple and effective surgical technique for the prevention of periovarian adhesion formation and could be included into the routine surgical procedure for single endometrioma. Moreover, THL can be considered to be a simple and minimally invasive technique with a good compliance for the postoperative follow-up, to evaluate adhesion formation.

Conflict of interest Massimiliano Pellicano, Pierluigi Giampaolino, Giovanni Tommaselli, Ursula Catena, Carmine Nappi and Giuseppe Bifulco declare that they have no conflict of interest.

Ethical standards All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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