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Original Article

Barbed Versus Conventional Suture: A Randomized Trial for Suturing the Endometrioma Bed After Laparoscopic Excision of Ovarian Endometrioma

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ABSTRACT **Objectives:** To determine whether the unidirectional knotless barbed suture can be used to control bleeding from the endometrioma bed after laparoscopic excision of ovarian endometrioma, and to detect whether the use of the unidirectional barbed suture is associated with shorter suturing time of the endometrioma bed compared with the continuous conventional smooth suture with intracorporeal knot tying.

Design: Randomized clinical trial (Canadian Task Force classification I).

Setting: Tertiary hospital.

Patients: Forty patients with unilateral ovarian endometrioma (mean diameter, 3–10 cm) were randomized in a 1:1 ratio to the barbed suture group or the conventional suture group.

Interventions: The endometrioma bed was sutured either with unidirectional barbed suture (V-Loc 180; Covidien, Mansfield, MA) or conventional suture (Vicryl; Ethicon, Somerville, NJ). Two layers of continuous sutures were used to control bleeding from the endometrioma bed and to reapproximate the ovarian edges.

Measurements and Main Results: The degree of suturing difficulty was evaluated by the surgeons using a visual analog scale (VAS) ranging from 1 (least difficult suturing) to 10 (most difficult suturing). Mean operating time was significantly shorter in the barbed suture group (43.3 ± 10.54 vs 52.8 ± 9.69 minutes; $p = .005$), as was mean suturing time (8.85 ± 2.52 vs 15.7 ± 4.12 minutes; $p < .001$). Suturing with barbed suture was less difficult than suturing with conventional suture (3.68 ± 1.37 vs 4.77 ± 1.56; $p = .025$). Intraoperative blood loss was similar in the 2 groups. No perioperative complications were reported in either group. A nonsignificant decrease in serum anti-mullerian hormone (AMH) levels was observed after the operation in the barbed suture group and the conventional suture group (3.04 ± 1.5 vs 2.52 ± 1.31 ng/mL; $p = .252$ and 2.76 ± 1.48 vs 2.13 ± 1.14 ng/mL; $p = .139$, respectively). The rate of decline in serum AMH levels after the operation was 18.32% in the barbed suture group and 22.84% in the conventional suture group.

Conclusion: The unidirectional knotless barbed suture (V-Loc) facilitates suturing of the endometrioma bed after laparoscopic excision of ovarian endometrioma. Compared with conventional smooth suture (Vicryl), the unidirectional barbed suture reduces the time needed to suture the endometrioma bed and the total operating time. Journal of Minimally Invasive Gynecology (2016) ■, ■–■ © 2016 AAGL. All rights reserved.

Keywords: Barbed suture; Conventional suture; Endometrioma; Endometriosis; Laparoscopy; Ovarian reserve; Suturing time

Ovarian endometrioma is a pseudocyst arising from the growth of ectopic endometriotic deposits within the ovary [1]. Ovarian endometriomas are usually seen in women of reproductive age. Pelvic pain, dyspareunia, rectal and urinary symptoms, and infertility are the main complaints of patients with ovarian endometriomas [2].

Surgery is typically indicated in patients with severe pain not responding to medical therapy, in infertile women, and before in vitro fertilization–embryo transfer [3]. Surgical management of ovarian endometriomas can be performed using open, laparoscopic, or robotic approaches. In recent years, laparoscopy has become the gold standard for the management of ovarian endometriomas [4]. Laparoscopy has several advantages over open surgery, including lower

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analgesia requirement, faster patient recovery, shorter hospital stay, and less hospital costs [5]. Moreover, laparoscopic surgery is less expensive than robotic surgery.

Laparoscopic procedures for treatment of ovarian endometriomas comprise excision of the endometrioma or ablation of the cyst wall with laser or electrocoagulation. A recent meta-analysis comparing excision of endometrioma with ablation of the cyst wall revealed that the excision of ovarian endometrioma is associated with less recurrence of the endometrioma, less recurrence of symptoms, and higher spontaneous pregnancy rates in patients with infertility [6].

After laparoscopic excision of ovarian endometrioma, bleeding usually occurs from the endometrioma bed, and hemostasis is achieved via bipolar coagulation, suturing, or hemostatic sealant. Studies comparing the effect of bipolar coagulation with suturing of endometrioma bed on ovarian reserve revealed that bipolar coagulation is more detrimental to ovarian reserve [7,8]. A recent meta-analysis revealed that the use of bipolar coagulation to control bleeding from the endometrioma bed is associated with a greater decline in the ovarian reserve compared with other hemostatic methods (suturing or hemostatic sealant) [9].

Suturing and knot tying are challenging laparoscopic skills that require extensive training [10,11]. Barbed suture is a new type of suture introduced to facilitate laparoscopic suturing. Three types of barbed sutures are currently available on the market: Quill (Angiotech Pharmaceuticals, Vancouver, BC, Canada), Stratafix (Johnson & Johnson, New Brunswick, NJ) and V-Loc (Covidien, Mansfield, MA). The Quill and Stratafix are bidirectional barbed sutures that have 2 needles swaged onto both ends of the suture. The V-Loc is a unidirectional knotless barbed suture that has a loop at 1 end of the suture and a needle swaged onto the other end [10–13].

Compared with conventional smooth suture, barbed suture has external barbs that anchor the suture to the tissues and prevent the retrograde movement of suture thread during suturing. Consequently, laparoscopic suturing can be readily performed without the need for suture locking, without applying traction on suture thread by the assistant, and without tying knots at both ends of the suture line [10–13].

In gynecology, barbed sutures have been used in minimally invasive myomectomy, hysterectomy, and sacrocolpopexy. There is a growing body of evidence suggesting that the use of barbed sutures in these procedures facilitates laparoscopic suturing and significantly reduces suturing time, total operating time, and intraoperative blood loss [10–13].

Although the efficacy and safety of barbed sutures have been demonstrated in various gynecologic surgeries [10–13], to date no studies have evaluated the use of barbed sutures in controlling bleeding from the endometrioma bed after laparoscopic excision of ovarian endometrioma.

The aim of the present study was to determine whether the unidirectional knotless barbed suture can be used to control bleeding from the endometrioma bed after laparoscopic excision of ovarian endometrioma, and to detect whether use of the unidirectional barbed suture is associated with shorter suturing time of the endometrioma bed compared with the continuous conventional smooth suture with intracorporeal knot tying.

Materials and Methods

This prospective randomized controlled trial was conducted at Aljazeera Hospital, Giza, Egypt between December 2014 and March 2016. The study protocol was approved by the Institutional Ethics Committee, and informed consent was obtained from each patient participating in the study.

To date, no studies in the literature have reported the time required to suture the ovarian endometrioma bed by conventional and barbed sutures. We reviewed video recordings of the last 30 laparoscopic excisions of endometrioma performed at our center by the investigators (U.F and K.E), to calculate the time needed to suture the endometrioma beds by continuous conventional suture (Vicryl) with intracorporeal knot tying. The mean ± SD time taken to suture the ovarian endometrioma bed was 15.54 ± 5.22 minutes. We considered a 30% difference in suturing time between the barbed suture group and the conventional suture group to represent a clinically significant difference. To detect this difference in suturing time between the 2 groups, 20 patients needed to be recruited to each study arm to achieve a study power of 80% at a significance level of 0.05 (as measured at https://www.sealedenvelope.com/power/continuous-superiority).

Forty women of reproductive age with an ultrasound-confirmed diagnosis of unilateral ovarian endometrioma were recruited to the study. The indications for laparoscopic excision of endometrioma were severe pain not responding to medical therapy and infertility. The exclusion criteria were age <20 years or >42 years, endometrioma mean diameter <3 cm or >10 cm, the presence of severe pelvic adhesions, uterine myoma requiring excision, previous ovarian cystectomy or myomectomy, use of hormonal treatments within 4 months before surgery, pelvic inflammatory disease, coagulation defects, pregnancy, infertile patients with anti-mullerian hormone (AMH) level <2 ng/mL, compromised cardiopulmonary status and contraindications for general anesthesia.

Patients were randomly allocated in a 1:1 ratio to the barbed suture group or the conventional suture group using a computer-generated randomization sequence and sequentially numbered, opaque, sealed envelopes. The randomization sequence and the sealed envelopes were prepared by a colleague not directly involved in the study. Envelopes were opened sequentially by the study nurse in the operating theater just before the start of the operation to allocate the patients to the assigned group.

Transvaginal ultrasound examination was performed before surgery to confirm the diagnosis of endometrioma, to measure the dimensions of the endometrioma, and to measure the antral follicle count (AFC; number of ovarian follicles 2–10 mm in diameter).

All the procedures were performed under general anesthesia during the proliferative phase of the menstrual cycle by 2 laparoscopists (U.F and K.E) with comparable skill and experience in laparoscopic suturing. Operative laparoscopy was performed using a 10-mm umbilical trocar and three 5-mm ancillary trocars placed in the lower abdomen. Endometriosis was staged according to the revised American Fertility Society (rAFS) classification. Superficial peritoneal implants were excised or treated with bipolar coagulation. Adhesions between the ovary and nearby structures (bowel, sidewall of the pelvis, and uterus) were lysed using sharp dissection. A sharp transverse incision was made over the ovarian endometrioma using a unipolar hook, and the cleavage plane between the cyst wall and the normal ovarian tissue was developed by sharp dissection. The contents of the ovarian endometrioma were aspirated. The endometrioma wall was stripped from the surrounding ovarian tissue by means of adequate traction with a toothed grasper forceps and countertraction maneuvers with another toothed grasper forceps.

In the barbed suture group, 2 layers of continuous sutures were used to control bleeding from the endometrioma bed and to reapproximate the ovarian edges. A 2-0 polyglyconate monofilament barbed suture (V-Loc 180; Covidien, Mansfield, MA) was used for suturing. The initial suture was inserted at the right end of endometrioma bed and then the needle was passed through the tail loop. The first layer was sutured from the right end of the endometrioma bed to the left end of the endometrioma bed, and the second layer was sutured in the opposite direction (i.e., from left to right) to reapproximate the ovarian edges. The terminal end of barbed suture was cut flush with the surface of the ovary. In the conventional suture group, 2-0 polyglactin 910 suture (Vicryl; Ethicon, Somerville, NJ) was used for suturing. Two layers of continuous sutures with intracorporeal knot tying were used to control bleeding from the endometrioma bed and to reapproximate the ovarian edges. Bipolar coagulation was not used in either group to control bleeding from the endometrioma bed.

The time needed to tie the first knot in the conventional suture group or to pass the needle through the tail loop in the barbed suture group was measured. Total operating time (time between first skin incision and removal of trocars), time needed to suture the endometrioma bed (suturing time), intraoperative blood loss (difference between the aspirated and the irrigated fluid), and any perioperative complications (fever, blood transfusion, bowel injury or genitourinary tract injury) were recorded.

After the procedure, the degree of suturing difficulty was evaluated by the surgeons using a visual analog scale (VAS) ranging from 1 (least difficult suturing) to 10 (most difficult suturing). Excised endometriomas were sent for pathological examination. Follow-up visits were scheduled after the operation with 1 week, 3 months, and once each year thereafter.

Transvaginal ultrasound examinations were performed 3 months postoperatively to measure AFC and to detect recurrence of endometrioma. Ultrasound examinations were performed in the early proliferative phase (day 2 or 3) by a physician who was blinded to the received treatment. Serum AMH was measured within few weeks before surgery and at 3 months postoperatively. The rate of decline in AMH serum level was measured according to the following formula:

$$\begin{aligned}&(\text{Rate of decline in AMH serum level } (\%)\\&\quad = 100\times[\text{preoperative AMH serum level}\\&\quad - \text{postoperative AMH serum level}]\\&\quad /\text{preoperative AMH serum level})\end{aligned}$$

The primary endpoint was the suturing time. The secondary endpoints were total operating time, suturing difficulty, intraoperative blood loss, perioperative complications, and the impact of surgery on ovarian reserve.

Statistical Analysis

Statistical calculations were performed using SPSS version 15 for Microsoft Windows (SPSS, Chicago, IL). The 2-tailed Student t test and χ^2 test were used to compare continuous and categorical variables, respectively. A p value $< .05$ was considered statistically significant.

Results

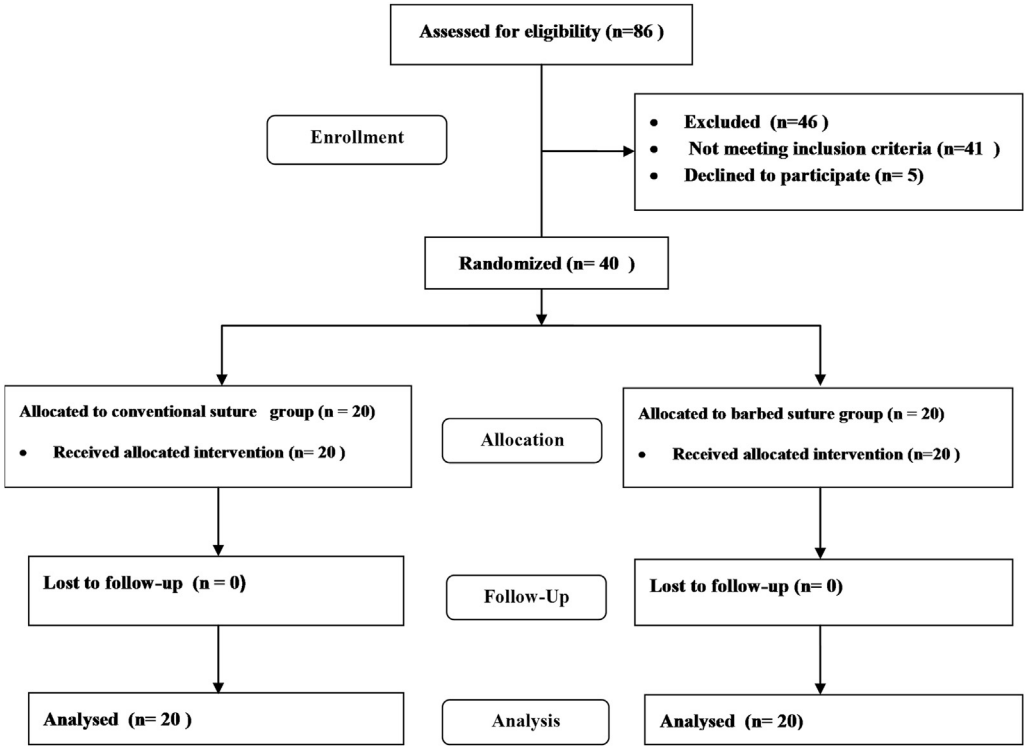
Between December 2014 and March 2016, 86 consecutive patients with endometriomas were assessed for eligibility. Forty-one women did not meet the inclusion criteria, and 5 women declined to participate in the study. Figure illustrates patient flow through the study.

Both groups were comparable with regard to age, body mass index, parity, indications for surgery, basal follicle-stimulating hormone level, and mean endometrioma diameter (Table 1). In both groups, suturing was effective in controlling bleeding from endometrioma bed. Operating time was significantly shorter in the barbed suture group (43.3 ± 10.54 [95% CI, 38.37–48.23] minutes vs 52.8 ± 9.69 [95% CI, 48.26–57.34] minutes; p = .005). Suturing time was significantly shorter in the barbed suture group (8.85 ± 2.52 [95% CI, 7.67–10.03] minutes vs. 15.7 ± 4.12 [95% CI, 13.77–17.63] minutes; p < .001).

The surgeons judged suturing with barbed suture as less difficult than suturing with conventional suture (3.68 ± 1.37 [95% CI, 3.04–4.32] vs. 4.77 ± 1.56 [95% CI, 4.04–5.5]; p = .025). The mean rAFS scores for endometriosis were similar in the 2 groups. The laparoscopists who performed the procedures (U.F and K.E) were evenly distributed between the 2 study groups (Table 2). The time needed to pass the needle through the tail loop of the barbed suture was shorter than the time needed to tie the first knot (mean, 31.6 ± 9.56 [95% CI, 27.13–36.07] seconds vs. 111.15 ± 28.45 [95% CI, 97.83–124.47] seconds; p < .001).

Fig

The flow of patients through the study.



The preoperative and postoperative serum AMH levels were comparable in the 2 groups. The rate of decline in serum AMH levels after the operation was 18.32% in the barbed suture group and 22.84% in the conventional suture group (Table 2). A nonsignificant decrease in serum AMH levels was observed after the operation in the barbed suture group and the conventional suture group (3.04 ± 1.5 vs. 2.52 ± 1.31 ng/mL; p = .252 and 2.76 ± 1.48 vs. 2.13 ± 1.14 ng/mL; p = .139, respectively) (Table 3).

The preoperative and postoperative AFC of the affected ovary and the contralateral ovary were comparable in the 2 groups (Table 2). In both groups, the AFC was lower in the diseased ovary compared with the contralateral ovary before and after the operation. The decrease in AFC of the affected ovary after the operation was not clinically significant (5.15 ± 2.37 vs 4.35 ± 1.9; p value = .246 and 5.45 ± 1.9 vs 4.45 ± 2.01; p = .115) (Table 3).

There were no perioperative complications in either group. All of the patients were discharged on the second postoperative day. Pathological examination confirmed the diagnosis of endometriosis in all patients. The mean follow-up period was comparable between the 2 groups (8.8 ± 4.03 vs 9.9 ± 3.65 months; p = .372). No patient experienced a recurrence of ovarian endometrioma.

Table 1

Patient characteristics

Characteristic	Barbed suture group (n = 20)	Conventional suture group (n = 20)	p value
Age, y, mean ± SD	30.9 ± 6.37	28.8 ± 5.92	.287
Body mass index, kg/m^2, mean ± SD	26.67 ± 4.51	28.3 ± 4.79	.276
Parity, n, mean ± SD	0.95 ± 1.28	0.85 ± 1.18	.799
Endometrioma diameter, mm, mean ± SD	67.9 ± 21.53	62.9 ± 19.37	.445
Main indication for surgery, n (%)			.749
Pain	12 (60)	11 (55)	
Infertility	8 (40)	9 (45)	
Basal follicle-stimulating hormone, IU, mean ± SD	6.31 ± 2.16	5.87 ± 2.41	.547

Discussion

The data presented in this study reveal that the unidirectional knotless barbed suture (V-Loc) facilitates suturing of the endometrioma bed after laparoscopic excision of ovarian endometrioma. When compared with conventional suture (Vicryl), unidirectional barbed suture reduces the time

Table 2

Procedure details and follow-up

Variable	Barbed suture group (n = 20)	Conventional suture group (n = 20)	p value
rAFS score, mean ± SD	66.1 ± 27.65	60.8 ± 30.01	.565
Laparoscopist, n			.749
First laparoscopist	8	9	
Second laparoscopist	12	11	
Operating time, min, mean ± SD	43.3 ± 10.54	52.8 ± 9.69	.005
Suturing time, min, mean ± SD	8.85 ± 2.52	15.7 ± 4.12	<.001
Intraoperative blood loss, mL, mean ± SD	63.85 ± 34.82	78.8 ± 31.78	.164
Suturing difficulty, mean ± SD*	3.68 ± 1.37	4.77 ± 1.56	.025
Serum AMH, ng/mL, mean ± SD			
Preoperative	3.04 ± 1.5	2.76 ± 1.48	.557
Postoperative	2.52 ± 1.31	2.13 ± 1.14	.317
Rate of decline in AMH level, %, mean ± SD	18.32 ± 12.06	22.84 ± 11.52	.232
Total AFC, mean ± SD			
Preoperative	12.45 ± 4.35	13.25 ± 3.52	.527
Postoperative	11.75 ± 3.19	12.15 ± 2.76	.674
AFC of ovary with endometrioma, mean ± SD			
Preoperative	5.15 ± 2.37	5.45 ± 1.9	.662
Postoperative	4.35 ± 1.9	4.45 ± 2.01	.872
AFC of contralateral ovary, mean ± SD			
Preoperative	7.3 ± 2.7	7.8 ± 3.58	.621
Postoperative	7.4 ± 1.88	7.7 ± 2.11	.637

AFC = antral follicle count; AMH = anti-mullerian hormone; rAFS = revised American Fertility Society.
* Evaluated by the surgeons using VAS ranging from 1 (least difficult suturing) to 10 (most difficult suturing).

Table 3

Effect of surgery on the markers of ovarian reserve

Biomarker	Preoperative	Postoperative	p value
Serum AMH, ng/mL, mean ± SD			
Barbed suture group (n = 20)	3.04 ± 1.5	2.52 ± 1.31	.252
Conventional suture group (n = 20)	2.76 ± 1.48	2.13 ± 1.14	.139
AFC of ovary with endometrioma, mean ± SD			
Barbed suture group (n = 20)	5.15 ± 2.37	4.35 ± 1.9	.246
Conventional suture group (n = 20)	5.45 ± 1.9	4.45 ± 2.01	.115

AFC = antral follicle count; AMH = anti-mullerian hormone.

needed to suture the endometrioma bed and the total operating time.

The results of our study compare with several studies that revealed that the use of barbed sutures in minimally invasive myomectomy, hysterectomy, and sacrocolpopexy procedures significantly reduces suturing time and operating time compared with conventional sutures [10–13].

Three meta-analyses compared the clinical efficacy and safety of barbed sutures with conventional sutures in minimally invasive hysterectomy and myomectomy. Zhang et al. [14] reported that the use of barbed sutures for repair of uterine defect during laparoscopic myomectomy significantly reduces suturing time, operating time, and intraoperative blood loss. Bogliolo et al. [15] reported that the vaginal vault suturing time is significantly reduced with the use of barbed sutures. Iavazzo et al [16] reported that the use of barbed sutures significantly reduces vaginal vault suturing time during hysterectomy and intraoperative blood loss during myomectomy. On the other hand, the intraoperative blood loss during hysterectomy and the uterine defect suturing time during myomectomy are not reduced.

The present study shows that the unidirectional knotless barbed suture (V-Loc) facilitates suturing of the endometrioma bed after laparoscopic excision of endometrioma. Our results are in agreement with 2 randomized controlled trials demonstrating that barbed sutures facilitate suturing of the uterine defect during laparoscopic myomectomy and the vaginal vault during laparoscopic hysterectomy [10,17].

Continuous suturing is the best option for controlling bleeding from endometrioma bed and reconstructing the ovary. The use of conventional smooth sutures requires tying knots at both ends of the suture line to maintain tissue approximation. Knot tying and suturing with conventional smooth sutures are time-consuming and technically challenging for laparoscopic surgeons. Knots decrease the tensile strength of suture, induce a foreign body reaction, and create an unequal distribution of tension across the suture line that may affect uniform tissue healing [18]. Moreover, knots tied laparoscopically are weaker than knots tied manually or robotically [19,20].

Suturing with unidirectional barbed suture (V-Loc) is easier and faster than suturing with conventional smooth sutures, because the V-Loc has helical barbs and a loop at the suture end that can anchor the tissues without the need for knots. Moreover, applying tension by the assistant on the suture thread during suturing is not necessary, because the barbs prevent backward movement of the suture thread.

The use of barbed sutures reduces foreign body reaction owing to absence of knots, better tissue opposition, and equal distribution of tension along the incision line, resulting in less ischemia and improved tissue healing [11,21].

The decline in ovarian reserve after laparoscopic excision of ovarian endometrioma has been confirmed by several studies. Removal of healthy ovarian tissues surrounding the endometrioma and thermal damage of ovarian follicles by bipolar coagulation used to control bleeding from the endometrioma bed are responsible for the detrimental effect of excision of endometrioma on the ovarian reserve [22]. In the present study, a nonsignificant decrease in mean serum AMH level after the operation was observed in both groups. In the present study, the rate of decline in serum AMH level after the operation was 18.32% in the barbed suture group and 22.84% in the conventional suture group. A recent meta-analysis including 8 randomized controlled trials and (237 patients) revealed that the serum AMH level is significantly decreased after laparoscopic excision of endometrioma. The rate of decline in serum AMH level after surgery is 38% [22].

Although the AFC of the affected ovary was decreased after the operation in both groups, this decrease did not reach statistical significance. Studies evaluating the effect of laparoscopic excision of endometrioma on the AFC have shown mixed results [23,24]. A recent meta-analysis revealed no decrease in the AFC of the affected ovary after laparoscopic excision of endometrioma [25].

The inability to detect a statistically significant decrease in the AMH level and the AFC of the affected ovary after surgery in the present study may be attributed to the small sample size, the technique of endometrioma excision, or the study population. In the present study, the cleavage plane between the endometrioma wall and normal ovarian tissues was carefully identified, and suturing was used instead of bipolar coagulation to control bleeding from the endometrioma bed. Several studies have shown that compared with suturing, bipolar coagulation of the ovarian parenchyma after laparoscopic excision of ovarian endometrioma causes more a greater in ovarian reserve compared with suturing [7–9]. Moreover, we excluded patients with bilateral endometriomas. Previous studies revealed that the excision of bilateral endometriomas is associated with marked declines in serum AMH levels [26,27].

The higher price of the barbed sutures compared with conventional sutures and the possible occurrence of intestinal obstruction are the main disadvantages of the barbed sutures [28]. However, barbed sutures shorten operating time and thereby reduce hospital expenses. Intestinal obstruction may occur if the cut end of the barbed suture is left long. The free end of the barbed suture can attach to the bowel or the mesentery, causing kinking and narrowing of the bowel or volvulus. Several authors recommended cutting the ends of the barbed sutures flush with the tissues, burying the ends of the barbed sutures or covering the ends of the barbed sutures with Surgicel or absorbable suture clips (LAPRA-TY; Ethicon, Cincinnati, OH) to reduce the risk of bowel obstruction [28].

The effect of barbed sutures on adhesions formation is not clear. Animal studies comparing adhesion formation following myometrial closure with barbed or conventional sutures have reported controversial results. Api et al [29] reported that the use of barbed suture was associated with a statistically significant increase in adhesion scores at suturing site. On the other hand, Einarsson et al [30] reported that the use of barbed suture was not associated with an increase in the rate or the severity of adhesion formation. In humans, a recent randomized controlled trial compared the rate of adhesion formation following laparoscopic myomectomy using barbed suture or conventional suture. The study found no difference in the rate of postoperative adhesion formation [31].

The main strength of the study is its prospective randomized controlled design. The small sample size and the short follow-up period are the main limitations of the study.

In conclusion, the unidirectional knotless barbed suture (V-Loc) facilitates suturing of the endometrioma bed after laparoscopic excision of ovarian endometrioma. Compared with conventional smooth suture (Vicryl), unidirectional barbed suture reduces the time needed to suture the endometrioma bed as well as the total operating time.

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