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Original Article

Safety and efficacy of unidirectional barbed suture in mini-laparotomy myomectomy

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Abstract

Objective: To estimate the safety and effectiveness of unidirectional knotless barbed suture compared to the traditional suture for repair of uterine wall defects through myomectomy via mini-laparotomy.
Materials and Methods: This was a prospective clinical study performed by a single surgeon in a medical center. Sixty-eight women with symptomatic myoma were enrolled. Their uterine wall defects were repaired either by unidirectional knotless barbed suture (Group A) or by traditional suture (Group B). The surgical time, intraoperative blood loss, and number of myomas in the two groups were analyzed by two-sample *t* test.
Results: Surgical time required from skin incision to complete closure was significantly lower in Group A than in Group B (50.2 ± 16.49 vs. 69.1 ± 25.33 min) ($p = 0.0008$). The intraoperative blood loss was also lower in Group A (mean, 260.9 mL; range, 20–850 mL) than in Group B (mean, 394.7 mL; range, 50–2200 mL) but not statistically significant.
Conclusion: The unidirectional knotless barbed suture may facilitate the repair of uterine defects during mini-laparotomy myomectomy by significantly lowering operative time. It may also reduce the intraoperative blood loss.

Keywords: mini-laparotomy; myomectomy; unidirectional knotless barbed suture

Introduction

Uterine myoma is the most common benign pelvic tumor in women. Its prevalence of 33% in women aged 40–60 years increases with age [1,2]. Approximately 25% of women with myoma have clinical symptoms such as heavy menstrual bleeding, pelvic pain, and pelvic compression. Some may even have reproductive dysfunction [3]. Surgery is the main treatment for symptomatic myoma. Abdominal myomectomy, first introduced by W. Alexander in 1898 to preserve the uterus, increased in frequency in the middle of the 20th century due to improvements in surgical technique, control of intraoperative bleeding, and advances in anesthesia and blood transfusion [4]. Laparoscopic myomectomy was first reported by Semm in 1979 [5]. Mini-invasive procedures have the advantage of shorter recovery time and less surgical blood loss [6]. Patients with a large myoma or multiple myomas may require more time for laparoscopic myomectomy. Moreover, its relative contraindications include diffuse leiomyoma, the presence of

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more than three myomas >7 cm, uterine size >20 week of gestation, one myoma >15 cm, or any medical condition that is not suitable for anesthesia or prolonged laparoscopy [7]. Hence, the alternative mini-laparotomy myomectomy is a feasible and safe procedure [8,9]. Its surgical technique includes pulling the uterine body through the abdomen when possible or *in situ* enucleation of large myomas and morcellation by cold knife.

Recently, a self-anchoring, unidirectional barbed suture that does not require knot tying was developed for laparoscopic surgery. In an animal study, the V-loc closure device (V-Loc 180 absorbable wound closure device 1-0, 30 cm; Covidien, Mansfield, MA, USA) was safe and convenient for gastrointestinal enterotomy closure [10]. In the randomized study of Alessandri et al [11], this novel knotless suture facilitated the suturing of uterine wall defects during laparoscopic myomectomy compared to continuous suture and intracorporeal knots. The surgical time and intraoperative blood loss were both significantly reduced. Zorn et al also have revealed that V-Loc suture facilitates robot-assisted vesicourethral anastomosis [12].

The V-loc closure device without knot tying has changed the laparoscopic suturing procedure and has saved on surgical time. The device can also be applied to traditional laparotomy. The present study aimed to determine the safety and efficacy of using the V-loc to repair uterine defects after myomectomy via mini-laparotomy.

Materials and methods

This prospective clinical study was conducted by a single surgeon in a tertiary medical center. From May 2011 to October 2012, 68 patients with symptomatic myoma had mini-laparotomy myomectomy. In Group A ($n = 34$), the uterine wall defects were repaired using a unidirectional knotless barbed suture with continuous two-layer suture. In Group B ($n = 34$), the bed of the myoma was repaired with 1-0 Safil (polyglycolic acid, braided coated, absorbable, 90 cm, Braun, Spain) by multiple interrupted sutures and the serosa was closed with a continuous "baseball" suture. All procedures were performed by one surgeon to exclude the bias of surgical techniques.

All patients provided informed consent for the mini-laparotomy myomectomy (skin incision <8 cm) and possible conversion to a larger skin incision if surgical difficulties were encountered. The possibility of blood transfusion or hysterectomy due to uncontrolled intraoperative bleeding was also discussed. All of the patients underwent mini-laparotomy myomectomy under general anesthesia, with one dose of 1 g prophylactic cefazolin before surgery. Hemostatic techniques such as vasopressin injection, uterine artery ligation, or use of preoperative gonadotropin-releasing hormone to decrease intraoperative blood loss were not used. The total intraoperative blood loss was estimated by weight gain of the gauze and the blood collected in the suction bottles. Operative time was calculated from skin incision to complete closure.

In Group A, the V-loc suture was used to repair the uterine defect. This novel suture material had spiral–helical barbs that allowed their tips to penetrate and grasp the surrounding tissue. The first step of surgery was removal of the uterine myoma. This study utilized a small uterine incision (<6 cm) through which most myomas were removed as much as possible. The second step was repair of the defect. Unlike the traditional suture, the novel suture had a mini-loop on the tail that eliminated the need for knots. The first secure tie was completed by passing the needle through the tail mini-loop. The barbs were anchored on the surrounding uterine tissue to prevent loosening of the suture. Continuous suture was then used to obliterate the bed of myomectomy, while a baseball suture was done to close the serosa without knot tying (Fig. 1).

In Group B, the base of the myoma was repaired by multiple interrupted sutures using 1-0 Safil. After repair of the uterine defect, the serosa was also repaired by 1-0 Safil with baseball continuous suturing. In both Groups A and B, the peritoneum was closed by 3-0 Safil, while the fascia was repaired by 1-0 Safil. Subcutaneous fat was apposed by 3-0 Safil and the skin was closed by 4-0 Polysorb (braided lactomer, Syneture, Covidien, Mansfield, MA, USA).

All of the patients were checked at least three times for blood hemoglobin levels: preoperatively, 2–3 hours postoperatively, and 1 day after surgery. Additional tests were made if the patient's vital signs were unstable or if there was severe anemia or an unusual drop in hemoglobin. Blood transfusion was administered to such patients.

Age, body mass index (BMI), number of myomas, length of hospitalization, surgical time, intraoperative blood loss, and drop in hemoglobin level in the two groups were analyzed by Student's t test. The rates of febrile morbidity, blood transfusions, unusual drop in hemoglobin, and failure of mini-laparotomy were compared by Fisher's exact test.

Results

The mean age and BMI were 38 ± 6.3 years and 22.5 ± 3.3 in Group A, and 37.8 ± 4.0 years and 23.2 ± 3.0 in Group B.

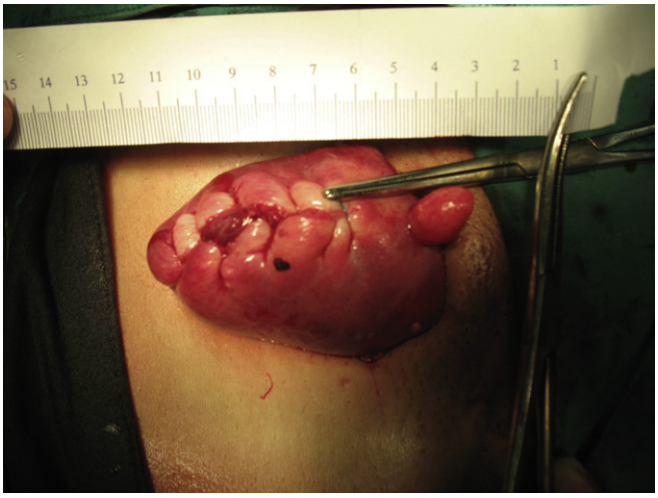

Fig. 1. The uterine defect was repaired by using a unidirectional barbed suture without knot tying through mini-laparotomy.

The number of myomas removed was 3 ± 2.5 and 2.3 ± 1.9 in Groups A and B, respectively, and the preoperative hemoglobin level was 12.2 ± 1.5 g/dL and 12.1 ± 1.8 g/dL, respectively. These values were not significantly different between the two groups (Table 1). Total surgical time required was significantly lower in Group A (50.24 ± 16.5 minutes) than in Group B (69.1 ± 25.3 minutes) ($p = 0.0008$). About 27% of total surgical time was saved by using the novel unidirectional knotless barbed suture.

Furthermore, the intraoperative blood loss was 261 ± 230 mL in Group A and 394 ± 406 mL in Group B. Although the mean blood loss in the V-loc group (Group A) was only two-thirds that of Group B, there was no significant difference ($p = 0.108$). The hemoglobin loss was also not significantly different.

In Group A, 22 of 34 cases used one set of closure device, eight used two sets, and four used three sets (Table 2), for an average of 1.47 sets. The average number of myomas removed was 1.84, 4.0, and 7.25 for those who used one, two, and three sets of V-loc devices, respectively. The causes of using more than one set of closure devices included a large uterine incision, myomas on both the anterior and posterior uterine wall, and myomas that could not be removed by a single uterine incision. Fifteen patients had a myoma with mean diameter of 9.7 cm (range, 6.3–20 cm), and 13 of them used one set of devices to repair the uterine defect. The other two patients had large intramural myomas (12 and 15 cm in diameter, respectively) and large uterine incision wounds. Two V-loc devices were needed to repair these larger uterine defects.

Two patients in Group A and four in Group B needed blood transfusions (Table 3). We also estimated the change in hemoglobin between the day of operation and the day after surgery to evaluate the safety of the novel suture. Two patients in Group A and four in Group B had unusual hemoglobin loss >2 g/dL. After close observation, one patient in Group A and two in Group B had blood transfusions, but none required relaparotomy.

All of the patients had mini-laparotomy with an initial skin incision <8 cm. The uterine body was pulled out through the abdomen whenever possible to make the myomectomy easier, whereas large or unreachable myomas were removed by *in situ* excision. No adjuvant techniques were used to decrease intraoperative blood loss. Two patients in Group A had a large skin extension because of pelvic adhesions. In Group B, two patients had severe adhesions and one had a large broad ligament leiomyoma of 12 cm in diameter with rapid bleeding after removal of the myoma. To achieve a better surgical field for lysis of adhesions and hemostasis, these five cases were considered failed mini-laparotomy.

Postoperative fever was defined as body temperature >38°C that persisted for >1 day. Three cases in Group A and two in Group B had postoperative fever, and three of them required additional intravenous antibiotic treatment. All fever subsided without any complications. One case in Group A had dyspnea and an unusual drop of serum oxygen saturation 2 days after surgery. However, no pulmonary embolization or edema was found by chest computed tomography. A pneumonia patch was suspected but neither fever nor leukocytosis was noted. The patient received 4 days intravenous antibiotics and dyspnea subsided without complications after oxygen use.

The average length of hospitalization was 4.2 days and 4.3 days in Groups A and B, respectively. No patient had relaparotomy or postoperative admission to the intensive care unit.

Table 1
Comparison of the two groups with different suture materials.

Characteristics	V-loc ($n = 34$)	Safil ($n = 34$)	p
Age (y)	38.0 ± 6.3	37.8 ± 4.0	0.865
Body mass index	22.5 ± 3.3	23.2 ± 3.0	0.64
No. of myomas	3.0 ± 2.5	2.3 ± 1.9	0.241
Preoperative hemoglobin (g/dL)	12.2 ± 1.5	12.1 ± 1.8	0.767
Intraoperative blood loss (mL)	260.9 ± 230	394.7 ± 406	0.108
Drop in hemoglobin (g/dL)	2.2 ± 1.2	2.7 ± 1.4	0.152
Total surgical time (min)	50.2 ± 16.5	69.1 ± 25.3	0.0008
Hospitalization (d)	4.1 ± 0.7	4.3 ± 0.8	0.486

The age, body mass index, number of myomas, hospitalization, preoperative hemoglobin, total surgical time, intraoperative blood loss, and drop in hemoglobin in the two groups were comparisons of the variables made using Student's *t* test.

Table 2
Causes of more than one set of V-loc devices for closure of the uterine defect.

V-loc using (sets)	1	2	3
Case no.	22	8	4
No. of removed myomas (range)	1.84 (1–5)	4 (1–10)	7.25 (5–9)
No. of large uterine incision wounds >6 cm	0	2	2
No. of cases with both anterior and posterior uterine wall myomas	2[a]	4	4
No. of myomas that could not be removed by a single incision	0	2	2

[a] Two cases had small myomas at different sides of the uterine wall. The small defect was repaired by one or two simple sutures using 1-0 Safil.

Discussion

Mini-laparotomy for myomectomy with skin incision <8 cm is an option in treating uterine myoma. It has the advantage of shorter hospitalization, faster recovery time, and less analgesic use [9]. In the present study, only five of 68 patients needed extension of the skin incision to >8 cm, including four with pelvic adhesions and one with a large

Table 3
Comparison of the safety in the two groups with different suture materials.

Characteristics	V-loc ($n = 34$)	Safil ($n = 34$)
Failure rate of mini-laparotomy	5.8% (2)	8.8 % (3)
Rate of febrile morbidity[a]	8.8 % (3)	5.8% (2)
Rate of postoperative hemoglobin loss >2 g/dL	5.8% (2)	12% (4)
Rate of blood transfusion	5.8% (2)	12% (4)

The rate of failed mini-laparotomy, febrile morbidity, blood transfusion, and postoperative hemoglobin drop >2 g/dL were variables compared by Fisher's exact test. All were not statistically significant in the two groups.

[a] Postoperative febrile morbidity was defined as body temperature >38°C persisting for >1 day.

intra-ligamental myoma. The total failure rate of mini-laparotomy was 7.8%, which is similar to other case series [9]. Pelvic adhesions caused by prior laparotomy or pelvic endometriosis are the main reasons for aborting mini-laparotomy, and obesity is another factor that increases surgical difficulty due to the relatively smaller surgical field. By the technique of cutting the fascia 2–3 cm more bilaterally than the skin incision, a larger surgical field is created. In our study, the average BMI was 23.8 and no patient had a BMI >30 or a large skin incision due to obesity.

The V-loc closure device has been proven advantageous in reducing blood loss and saving surgical time in laparoscopic myomectomy [11]. The present study is believed to be the first to use this closure device in abdominal myomectomy. This novel suture material has spiral–helical barbs that allow their tips to penetrate and grasp the surrounding tissue, while the mini-loop on the tail eliminates unnecessary knots that are traditionally made after each suture to prevent tissue bleeding and to hasten tissue healing. During suturing, the backward force caused by the wound tension when the traction on the V-loc is released enables the barbs to enter the surrounding tissue. This specific design can secure wound apposition. Hence, it is unnecessary for surgeons to maintain the suture line tension during suturing. As a result of the self-anchoring ability of the spiral–helical barbs, knot tying after each suture is also no longer required. This means that surgical time is much less than that for traditional suturing techniques.

However, the V-loc suture device is more expensive than the traditional suture material and cannot be reused because it has only one mini-loop. Nonetheless, there are two techniques to save devices. The first one is to make a smaller uterine incision. In our study, a V-loc device of 30 cm was used. When the incision wound is >6 cm, the uterine defect cannot be completely repaired by one single set of 30-cm devices. In the V-loc group, 15 patients had a single myoma, with a size ranging from 6.3 cm to 20 cm. For 13 of these, we used only one set of devices for repair of the uterine defect, even when the myoma was >6 cm. A small uterine incision can save more suture material. There are other different sizes and lengths of V-loc closure devices, from 15 cm to 60 cm. In the future, the appropriate size and length of the V-loc device should be used for different sizes of uterine wounds.

The other technique involves removing the myoma through the same incision. This makes the repair by V-loc easier and saves on suture devices. Hence, it is important to have a preoperative ultrasonographic evaluation to determine the size and position of the myoma.

One reason for using more than one set of V-loc devices is the differing locations of multiple myomas that may be too far away from each other, or both the anterior and posterior uterine walls have myomas. Hence, all of the myomas cannot be removed via the same incision. As such, more than one V-loc device will be needed.

Mini-laparotomy myomectomy with skin incision <8 cm is an alternative surgical method for symptomatic myomas. This surgical technique is even more convenient when combined with the novel V-loc absorbable wound closure device because it significantly reduces operative time and may even lessen blood loss. Pelvic adhesion due to prior laparotomy and endometriosis may be the main reason for failure.

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