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Technical Reports

Bidirectional Barbed Suture in Laparoscopic Myomectomy: Clinical Features

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Abstract

Objective: To compare bidirectional knotless barbed suture versus standard sutures, with either extracorporeal or intracorporeal knots, and to assess the feasibility, safety, and rapidity in repairing a uterine wall defect after laparoscopic myomectomy.

Subjects and Methods: This was a randomized clinical study having a Canadian Task Force Classification of I. In tertiary-care university-based teaching hospitals, 117 women who underwent laparoscopic myomectomy were enrolled. In accord with randomization, uterine wall defects were closed with either extracorporeal (poliglecaprone 25; Monocryl™-1; Ethicon Inc., Somerville, NJ) or intracorporeal (polyglactin 910; Vicryl™-1; Ethicon Inc.) knots or a bidirectional knotless barbed suture (Quill™-0; Angiotech Pharmaceuticals, Inc., Vancouver, BC, Canada).

Results: Time required to suture was significantly lower in the group operated on with a bidirectional suture than in groups with traditional sutures ($P < .001$). No significant difference was observed in operative time among the study groups. The degree of surgical difficulty was significantly lower in the Quill group than in the other groups.

Conclusions: Use of barbed sutures reduces the time required to repair a uterine wall defect during laparoscopic myomectomy. In a follow-up of patients carried out at 3 months, 6 months, and 1 year after the surgery, there were no wound dehiscence, no bleeding, and no other potential major complications.

Introduction

In recent decades, gynecological surgery has changed considerably, especially with the advent of laparoscopic techniques making it even safer. There has been much debate about the advantages and disadvantages of using this technique for the treatment of benign or malignant pathologies. What is certain is, without a doubt, that the experience of the surgeon plays a key role in the selection of this surgical approach.[1]

One of the most common gynecological surgical procedures for benign pathologies is represented by laparoscopic myomectomy (LM). The repair of uterine wall defects after myoma enucleation requires a suture that adequately addresses the need for an optimal wound disruptive-force reduction, hemostasis, and minimal tissue reactivity.

Barbed sutures have recently been proposed to facilitate laparoscopic suturing and have been used in various surgical fields.[2–5] The barbed suture is a relatively new concept in gynecologic surgery. The Quill™ SRS bidirectional barbed suture (Angiotech Pharmaceuticals, Inc., Vancouver, BC, Canada) was approved by the Food and Drug Administration for soft tissue approximation in 2004 and has been commercially available in the United States since 2007. Recently the unidirectional V-Loc™ absorbable wound closure device product line (Covidien, Mansfield, MA) has been also introduced.

Bidirectional barbed sutures are created by cutting barbs into the suture with the barbs facing in the opposite direction from the needle. Up to now, barbed sutures have a preliminary application in gynecologic surgery, with a favorable impression.[2,611]

The present study was designed to compare the bidirectional knotless barbed suture versus standard sutures, with either extracorporeal or intracorporeal knots, and to assess the feasibility, safety, and rapidity in repairing a uterine wall

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defect after myomectomy. Additionally, we evaluated patients at 3-month, 6-month, 12-month, and 18-month follow-up.

Subjects and Methods

The present study was a clinical prospective controlled randomized trial designed to compare the effectiveness of the bidirectional knotless barbed suture versus standard suture, with either extracorporeal or intracorporeal knots, in the repair of the uterine wall defects after LM.

In total, 117 patients, who underwent LM in the period of July 2010–October 2011 were enrolled. These were patients at the Department of Obstetric, Gynaecology and Reproductive Medicine of the Second University of Naples, Naples, Italy, and at the Operative Unit of Obstetrics and Gynaecology, A.O.R.N. San Giuseppe Moscati, Avellino, Italy.

All the patients enrolled in the study gave their written informed consent at study inclusion. The study protocol received institutional review board approval before the beginning of the study, in accordance with The Code of Ethics of the Declaration of Helsinki. Exclusion criteria for the study were previous uterine surgery, additional diseases requiring surgical treatment (such as endometriosis, tubal surgery, or appendicitis), body mass index $\geq 29\,kg/m^2$, contraindications for general anesthesia, and psychiatric disorders precluding informed consent. No patient included in the study underwent medical treatment for ovarian suppression before surgery.

Demographic data of the patients included in the study were collected on the day before surgery. For the purpose of the study, hemoglobin (Hb) concentration was determined on the day before surgery and at 24 hours after surgery; the difference in Hb concentration (ΔHb) was calculated to estimate the intraoperative blood loss. In order to obtain results comparable in term of patient selection and numbers and diameters of myoma, only women with a single intramural myoma with the largest diameter being ≤ 6 cm were enrolled. All patients underwent transvaginal ultrasonography within the 2 weeks before surgery to evaluate size, location (with respect to uterine layers), and position (with respect to the uterine axis) of the myoma. Data on pregnancy outcome were collected at 18-month follow-up.

Two surgeons (L.C. and M.A.) performed the surgical procedures. The following parameters were analyzed: the time needed to perform, respectively, the intervention and the suture, the degree of surgical difficulty of suturing the uterine wall defects by use of a visual analog scale ranging from 1 (low difficulty) to 10 (high difficulty) as previously described by other authors,[2,12,13] and the blood and Hb loss.

All surgical procedures were recorded. The operative time was determined by reviewing the surgical procedures by use of Final Cut Pro™ (Apple, Inc., Cupertino, CA); it was calculated between the beginning of the operation (after the insertion of the trocars) and the removal of the trocars. The same technique was used to determine the time required to suture the uterine breaches.

Patients were randomized throughout a computer-generated list drawn up by a statistician into three groups: Group A ($n = 44$) underwent suture of the uterine wall defects with extracorporeal knots using poliglecaprone 25 (Monocryl™-1; Ethicon Inc., Somerville, NJ), and Group B ($n = 37$) underwent suture with intracorporeal knots using polyglactin acid 910 (Vicryl™-1; Ethicon Inc.). The hysterotomy in Group C ($n = 36$) was closed in layers using a 14-×14-cm 0 bidirectional knotless barbed suture (Quill).

Surgical procedure

Surgical procedures were performed with standard technique as follows. As in most laparoscopic procedures carried out in our centers, the patient is placed in a modified lithotomic position, with hands placed along the body, legs slightly flexed and abducted, and the pelvic floor protruding a few centimeters from the operating table to allow easy mobilization of the uterus, with an intrauterine device. Either a open laparoscopy or a Veress needle classic technique was used for laparoscopy, and a 10-mm port was inserted through the umbilicus to introduce the laparoscope. Pneumoperitoneum was obtained with carbon dioxide insufflation to 10–12 mm Hg. A 10-mm operative trocar was positioned under laparoscopic vision on the left-hand side, and one 5-mm ancillary trocar was positioned on the right-hand side. To perform myoma enucleation, we mainly used a 10-mm Martin (Karl Storz GmbH & Co. KG, Tuttlingen, Germany), a 5-mm myoma drill, a 5-mm Museaux™ (Karl Storz GmbH & Co. KG, Tuttlingen, Germany) as the traction instrument, and the PKS™ PlasmaSpatula® bipolar electrosurgical device (Gyrus Medical Inc., Minneapolis, MN).

Suture

In accord with randomization, for patients in Group A uterine wall defects were closed with intracorporeal knots in a single or double layer, depending on the deepness of the defect. Patients in Group B had uterine wall defects closed with extracorporeal knots in a single or double layer, depending on the deepness of the defect. In Group C the Quill-0 bidirectional barbed suture was used; one of the two needles of the bidirectional suture was inserted in the center of the uterine breach, and the suture was performed starting from the middle to one side, creating tension at each point, and then with the second needle with a similar technique to the other side. In the presence of a deeper wall defect, the first needle was used to close the deepest layer, and the second needle was used to close the more superficial layer and the serosa if possible (Fig. 1).

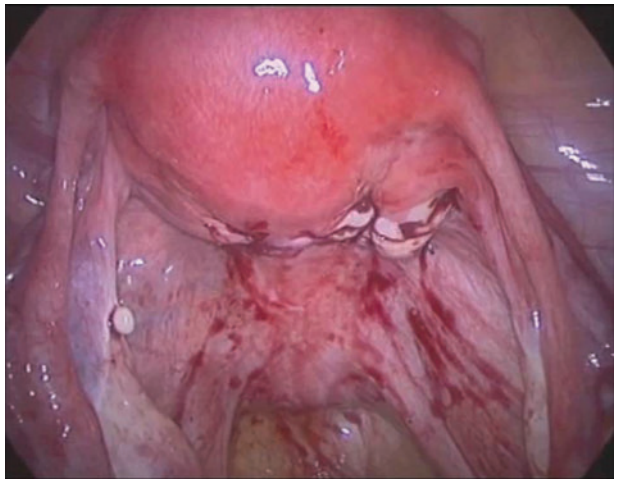

FIG. 1. Uterine wall defect sutured with a Quill bidirectional knotless barbed suture after laparoscopic myomectomy.

Table 1. Demographic and Clinical Characteristics of the 117 Patients Who Underwent Laparoscopic Myomectomy

	Group A (extracorporeal knots) (n = *44*)	*Group B (intracorporeal knots)* (n = *37*)	*Group C (bidirectional suture)* (n = *36*)	P *value*[a]
Age (years)	35. 1 ± 5.3	35.9 ± 8.6	33.9 ± 6.5	.85
Weight (kg)	62.3 ± 8.5	61.2 ± 6.8	61.9 ± 6.6	.81
Height (cm)	162.4 ± 6.7	160.2 ± 3.9	161.2 ± 5.3	.65
BMI (kg/m^2)	23.1 ± 3.1	23.5 ± 2.5	23.3 ± 3.4	.51
Main diameter of the myoma (cm) (mean ± SD)	4.7 ± 2.2	4.8 ± 2.0	5.3 ± 1.4	.50
Localization				
Anterior	11 (25.0%)	8 (21.6%)	9 (25.0%)	.74
Posterior	6 (13.6%)	6 (16.2%)	8 (22.2%)	.85
Lateral	8 (18.2%)	9 (24.3%)	5 (13.9%)	.53
Fundal	16 (36.3%)	11 (29.7%)	12 (33.3%)	.57
Infraligamentary	3 (6.9%)	3 (8.2%)	2 (5.5%)	.90

[a]$P < .05$ was considered statistically significant.
BMI, body mass index; SD, standard deviation.

The myomas were removed by use of an electromechanical morcellator (Steiner morcellator; Karl Storz GmbH & Co. KG). No adhesion barrier was left in the peritoneal cavity.

All patients received 3-month, 6-month, and 1-year follow-ups.

Statistical analysis

For the study, the primary aim of which was to estimate whether a bidirectional knotless barbed suture is significantly faster than a monofilament suture requiring either extra- or intracorporeal knots in repairing uterine wall defects after LM, a power calculation had been undertaken to determine an appropriate sample size for this pilot study. We calculated the mean ± standard deviation time required to perform the suture of the uterine wall defect in the last 100 LMs performed by the two investigators (L.C. and M.A.), which was 12.4 ± 4.1 minutes. Because there are no published data on the time required to perform the suture of the uterine wall defect by use of a bidirectional knotless barbed suture, we arbitrarily estimated that a reduction of at least 30% in the time required to perform the suture might of clinical interest. A two-sided test power calculation was performed. The standard deviation of the time required for suturing during the 100 LMs performed by the two investigators (4.1 minutes) was used as the sigma value.

This power calculation indicated that 21 patients in each group would be necessary to detect a 15% difference in the time required to perform the suture of the uterine wall defect with a power $\geq 80\%$ at a 5% level of significance.

Data were analyzed by use of Student's *t* test and the chi-squared test for parametric variables, whereas the Mann–Whitney U-test was used for nonparametric variables. Differences in operative time, suture time, and degree of surgical difficulty in suture performing were assessed by one-way analysis of variance, followed by Bonferroni's *post hoc* comparisons to investigate pairwise differences between individual groups. Statistical calculations were performed using Statistical Package for the Social Sciences software (version 17.0; SPSS Inc., Chicago, IL). A value of $P < .05$ was considered statistically significant.

Results

Demographic characteristics of the patients, given in Table 1, were globally homogeneous. All procedures were completed by laparoscopy, and no conversion to laparotomy was required. No significant difference was observed in the operative time (median ± standard deviation; 95% confidence interval) among patients included in Group A (38.7 ± 6.5 minutes; 30.7–47.1 minutes), Group B (40.0 ± 7.3 minutes; 32.5–48.7 minutes), and Group C (36.8 ± 6.7 minutes; 29.2–46.8 minutes) (Table 2). However, the time required to suture the uterine wall defects was significantly lower in Group C (6.6 ± 4.7 minutes; 4.3–12.5 minutes) than in Group A

Table 2. Analysis of Operative Time, Suture Time, and Degree of Surgical Difficulty in Suture Performing in Patients Who Underwent Laparoscopic Myomectomy (*N* = 117)

	Group A (extracorporeal knots) (n = *44*)	*Group B (intracorporeal knots)* (n = *37*)	*Group C (bidirectional suture)* (n = *36*)	P *value*[a]
Operative time (minutes)	38.7 ± 6.5 (30.7–47.1)	40.0 ± 7.3 (32.5–48.7)	36.8 ± 6.7 (29.2–46.8)	NS
Suture time (minutes)	11.5 ± 5.4 (6.5–15.8)	12.2 ± 6.8 (6.9–16.4)	6.6 ± 4.7 (4.3–12.5)	< .001
Degree of surgical difficulty in suture performing by VAS	7 ± 2 (5–9)	7 ± 2 (5–9)	6 ± 3 (4–9)	< .001

Data are mean ± standard deviation (95% confidence interval).
[a]$P < .05$ was considered statistically significant.
NS, not significant; VAS, visual analog scale.

(11.5 ± 5.4 minutes; 6.5–15.8 minutes) and Group B (12.2 ± 6.9 minutes; 6.9–16.4 minutes) ($P < .01$). The intraoperative blood loss (ΔHb) was similar in the three groups: Group A, 0.2 g/dL; Group B, 0.4 g/dL; and Group C, 0.3 g/dL. No patient required a blood transfusion. The degree of surgical difficulty, evaluated by visual analog scale, was significantly lower in Group C (6 ± 3; 4–9) than in Groups A (7 ± 2; 5–9) and B (7 ± 2; 5–9) ($P < .01$) (Table 2).

At follow-up of patients, carried out at 3 months, 6 months, 12 months, and 18 months after the surgery, there were no wound dehiscence, no bleeding, and no other potential major complications. At the 18-month follow-up, of the 52 patients subjected to LM and wishing to conceive after surgery, 25 had conceived (48%). Assisted reproduction techniques were used in 36% of these women ($n = 9$). Following surgery overall there were 39 pregnancies, with the pregnancy rate being similar in all groups (Group A, $n = 15$; Group B, $n = 11$; and Group C, $n = 13$). There were 40 deliveries (4 twin pregnancies) and 3 spontaneous abortions. The cesarean section rate was 48.3%.

Discussion

The most difficult surgical procedure for a gynecologic laparoscopic surgeon is probably represented by suture knots (intra- or extracorporeal), which are essential for controlling intraoperative hemostasis and for the shelter of the uterine breach during LM. Therefore, in order to obtain a simple, safe, and functional suture during laparoscopic surgery, and thus more attractive to the eyes of the surgeon, various studies have been conducted, and many steps have been made forward.[11]

Greenberg and Einarsson[7] in 2008 reported the first use of barbed sutures in gynecologic surgery. Since this preliminary report, many publications have followed with increasing numbers of patients enrolled.[3,7–14]

Recently bidirectional barbed sutures were introduced into clinical practice and tested for performing abdominoplasty in humans,[4] for closing gastrointestinal enterotomies in pigs,[5] and for closing the collecting system and renal parenchyma during laparoscopic partial nephrectomy in pigs.[3,6]

In 2010 Einarsson[8] performed a retrospective analysis, calling patients 6 months after surgery to inquire about number of days of postoperative vaginal bleeding, visits to the hospital due to bleeding, dyspareunia, and other potential complications. Results showed that the use of bidirectional barbed suture appears to be safe for the hysterotomy site during an LM.

The unidirectional V-Loc absorbable wound closure device product line has also been described with encouraging results in LM.[2,15] Two randomized trials from Alessandri et al.[2] and Angioli et al.[15] clearly found that this unidirectional suture is safe and applicable to routine laparoscopic surgery.

Although previous authors described the use of a bidirectional barbed suture in the closure of a uterine wall defect after myomectomy,[3,7–9] up to now no study has prospectively compared the barbed suture and standard sutures with either intracorporeal or extracorporeal knots in gynecologic surgery. This prospective controlled randomized study demonstrates, for the first time, that the use of a barbed suture reduces the time required to repair the uterine wall defect during LM.[3] Indeed, the purpose of this study was just to verify the validity of this self-locking bidirectional device against the traditional techniques of laparoscopic suturing. Our results have shown that the bidirectional suture is generally more rapid and simple to perform, since the first use, in repairing the uterine defect after LM. Obviously, the decrease in the suturing time is due to the fact that there is no need to tie knots.[3]

Additionally, our data showed that at 3-month, 6-month, 12-month, and 18-month follow-up no wound dehiscence, no bleeding, and no other potential major complications were found, thus suggesting that the bidirectional barbed suture is free of possible collateral effects. Also, data on pregnancy outcome showed no difference among groups. These data strengthen the results of this study and set it apart from those of Alessandri et al.[2] and Angioli et al.,[15] which did not investigate pregnancy outcome. Indeed, the biggest unknown with the barbed suture in myomectomy is not speed (it seems fairly intuitive that avoiding knot-tying might save time) but whether the integrity of the uterine wall after closure with a barbed suture is equal to that of a traditional suture. Our results seem to address well this issue.

Potential limitation of the bidirectional barbed suture could be represented by the costs, which are higher than those of a conventional suture. It is well known, however, that the cost of sutures may decrease according to the number of wires needed. Indeed, the higher cost of the Quill is offset by the number of wires required to complete a traditional suture (three to five). In those circumstances, in our view, it may be valid in clinical practice to use the bidirectional barbed suture, the introduction of which cannot be further delayed because of an undefined distrust of the surgeon. These innovations, made by the technologic improvement, open new horizons to surgical techniques also to specialists who, because of the above-mentioned difficulties, had not yet approached the endoscopic practice.

Conclusions

In the context of the literature, this study serves to demonstrate that the bidirectional barbed suture can be used safely and effectively for laparoscopic suturing, and in particular in repairing a uterine wall defect after LM. Based on our experience, we believe that the further development and incorporation of this suture into clinical practice should be actively explored.

Disclosure Statement

No competing financial interests exist.

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