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Original Article

Barbed Suture versus Conventional Suture for Vaginal Cuff Closure in Total Laparoscopic Hysterectomy: Randomized Controlled Clinical Trial

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ABSTRACT **Study Objective:** To determine the surgical time, suture time, presence of postoperative dyspareunia, and complications that occur after closing the vaginal cuff with a barbed suture compared with conventional suture.

Design: A randomized, controlled clinical trial (Canadian Task Force classification I).

Setting: Private gynecologic clinic in Medellin, Colombia.

Patients: One hundred fifty women who underwent total laparoscopic hysterectomy for benign pathology.

Interventions: The patients underwent total laparoscopic hysterectomy with intracorporeal closure of the vaginal cuff and were randomized to 2 groups, 1 using a barbed suture (V-Loc 90; Medtronic/Covidien, New Haven, CT) and 1 using polyglactin 910 (coated Vicryl suture; Ethicon/Johnson & Johnson, New Brunswick, NJ).

Measurements and Main Results: The total operative time, closing time of the vaginal vault, presence of complications in the cuff, and incidence of postoperative dyspareunia were recorded. The patients were evaluated at a postoperative office visit 2 weeks after the procedure and by telephone interview at 24 weeks. Seventy-five patients were included in the barbed suture group and 75 patients in the polyglactin 910 group. The average time to complete the suture of the vaginal cuff was 12.01 minutes ($\pm$ 5.37 standard deviation) for the barbed suture group versus 13.49 minutes ($\pm$ 6.48) in the polyglactin 910 group (95% confidence interval, $-.44$ to 3.4; $p = .130$). Blood loss was 31.56 $\pm$ 22.93 mL in the barbed suture group versus 30.82 $\pm$ 21.75 mL in the polyglactin 910 group (95% confidence interval, -7.95 to 6.47; $p = .840$). The frequency of postoperative events such as hematoma, cellulitis, cuff dehiscence, fever, emergency consultation, and hospitalization was not statistically significant between groups. No statistically significant difference was found regarding deep dyspareunia at 24 postoperative weeks.

Conclusion: No differences were found in surgical time or frequency of adverse events when comparing patients after vaginal cuff closure with barbed suture versus polyglactin 910. Journal of Minimally Invasive Gynecology (2019) 26, 1104−1109 © 2018 Published by Elsevier Inc. on behalf of AAGL.

Keywords: Knotless suture; Laparoscopy; Surgical time; Total hysterectomy

Hysterectomy is the most frequently performed gynecologic surgery [1]. Complications of closure of the vaginal cuff, although not frequent, can seriously compromise the health of patients after hysterectomy, thus increasing hospital length of stay, costs, and patient quality of life. Vaginal cuff dehiscence is reported between .1% and 4.1% of all hysterectomies including abdominal, vaginal, and laparoscopic approaches [2,3]. Some reports have described a higher incidence of vaginal vault dehiscence when closure is done laparoscopically [4,5]. However, this was not the case in a recent clinical trial [6].

Endoscopic suture, with knotting, requires a high level of surgical skill and increases surgical time considerably [7]. In animal models the tension obtained in the knots and in the laparoscopic and robotic suture was lower than that

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obtained with conventional suture, which in theory could increase the risk of postoperative bleeding, hematomas, and cuff dehiscence [8].

Barbed suture have been widely used in gynecologic procedures [9]. There is controversy regarding its use for vaginal cuff closure in terms of surgical time and bleeding. Studies by Alessandri et al [10] and Angioli et al [11] found that defect closure time was faster and intraoperative blood loss was less. Some authors have reported isolated complications associated with this type of suture, such as intestinal obstruction, volvulus, dyspareunia, and extrusion [12,13]. The objective of the current study was to provide evidence regarding this technology in terms of operative and suture times and incidence of complications in patients undergoing total laparoscopic hysterectomy for benign pathology.

Methods

A randomized controlled clinical trial was conducted in patients undergoing total laparoscopic hysterectomy because of benign pathology at Clinica del Prado, Medellín, Colombia. The study was approved by the University Ethics Committee, the provisions of the Declaration of Helsinki were followed, and the study was registered at ClinicalTrials.gov (NCT 03038945). After patients were invited to participate in the study and accepted, informed consent was signed. The recruitment period was between February and April 2016.

Patients over 18 years of age were included and admitted to the gynecologic endoscopy unit with operative risk I or II according to the classification of the American Society of Anesthesiology. Patients with risk factors for vaginal cuff dehiscence such as coagulopathies, chronic consumption of corticosteroids, collagen diseases, chronic coughing, or any medical or surgical condition that could increase the risk of bleeding or infections were excluded.

Before the intervention patient demographic data were collected, including age, weight, height, parity, and medical and surgical history. During the intraoperative period and with a chronometer, the total time of surgery (from Veress needle entry to removal of the trocars) and the time to suture the vaginal cuff (recorded from the surgeon preparing the needle for the first stitch until the assistant cuts the suture once finished) were documented. Blood loss was measured at the end of the surgery in the aspiration device, weight of the uterus was also recorded, and additional surgical procedures performed were documented. The primary outcome was cuff closure time.

All surgeries were completed by 8 expert gynecologic surgeons who completed fellowships in advanced laparoscopic surgery with an average of 8 years of experience and >100 high complexity procedures per year. Before entrance to the operating room a randomization was performed that assigned patients 1:1 to barbed suture or the control (polyglactin 910); simple randomization was done using numbers generated by an epidemiologic data analysis program (EPIDAT 4.2; Medtronic/Covidien, New Haven, CT). Patients underwent total laparoscopic hysterectomy with closure of the vaginal cuff by intracorporeal suture using barbed suture (V-Loc 90; Medtronic/Covidien; New Haven, CT) or polyglactin 910 (coated Vicryl suture; Ethicon/Johnson & Johnson; New Brunswick, NJ). Patients were blinded of the suture type.

The procedure was performed with patients in the lithotomy position and started with a uterine manipulator; the Veress needle was inserted abdominally using a closed technique until reaching 20 mm Hg of intra-abdominal pressure. At that time 4 trocars were placed in total: 1 umbilical of 10 mm and 3 accessories of 5 mm. Two were lateral to the left rectus abdominis (inferior and superior) and another to the right pararectal.

Bipolar energy (25 W) was used to coagulate vascular ligaments and pedicles, and monopolar energy (60 W) was used to perform the colpotomy with the monopolar hook, at the height of the uterine manipulator cup. The uterus was removed through the vagina. Bipolar coagulation was performed in the areas with active bleeding within the open vaginal borders and subsequently were closed with unidirectional barbed suture or polyglactin 910, according to the above-mentioned randomization.

Closure was performed in 2 planes by intracorporeal continuous sutures, first from right to left, taking mucosa and muscle, and the second from left to right, taking muscle and the fibrous structures that compose the pericervical ring (pubocervical fascia, rectovaginal fascia, uterosacral and cardinal ligaments) to ensure proper reconstruction. Finally, the hemostasis and ureteral trajectories were checked, carbon dioxide was evacuated, the trocars were removed, and the skin was closed.

All patients underwent postoperative evaluation between 10 and 15 days after the procedure, which was performed in the office by any of the surgeons who performed the surgical intervention and identical follow-up process. All patients underwent a vaginal examination to check for vaginal cuff complications. All abnormal findings were recorded.

At 24 weeks a follow-up telephone interview was conducted to identify any further complications associated with the surgery including whether dyspareunia was present in the patient or patient's partner.

Statistical Analysis

A sample size of 150 patients with a power of 80%, an alpha error of .05, and the detection of 5-minute differences in closure time between the 2 techniques were estimated. There was blinding in the postoperative follow-up. The qualitative variables were analyzed using measurements of absolute and relative frequencies; the quantitative variables used summary measures. The Mann-Whitney U test was used for mean difference, and the χ^2 and Fisher exact tests were used to analyze qualitative variables. Prevalence of preoperative and postoperative dyspareunia was calculated using the McNemar test.

An intent-to-treat analysis was performed. Data were analyzed by the Statistical Package for Social Sciences software (version 17.0; SPSS Inc., Chicago, IL).

Results

A total of 180 patients were invited to participate, and 150 were included according to inclusion criteria. All participants completed the trial. Seventy-five patients were randomized for vaginal cuff closure with barbed suture and 75 patients for closure with polyglactin 910 (Fig. 1).

Demographic and clinical characteristics were similar in both groups, other than for the preoperative diagnosis of abnormal uterine bleeding. A greater number of patients were found with abnormal uterine bleeding in the polyglactin 910 group (p = .01). However, it is important to highlight that randomization was done for the distribution of surgical sutures, and this finding was the product of chance (Table 1).

In the data obtained in the intraoperative phase, the difference in total surgical time between groups was 6 minutes (95% confidence interval [CI], −2.02 to 15.4), and the difference in the time of cuff suture between groups was 1.48 minutes (95% CI, −.44 to 3.4). Both findings, according to the authors, have no clinical importance or statistical significance. Ten- to 15-day follow-up data showed no differences regarding presence of fever, hospitalizations, abnormal findings, bleeding, hematoma formation, cellulitis, abscesses, or dehiscence.

Regarding emergency admissions at the 10- to 15-day follow-up, 13 patients (17.1%) from the polyglactin 910 group and 17 patients (23%) from the barbed suture group were evaluated emergently without statistically significant difference. In both groups the most frequent reason for consultation was bleeding, pain, and fever (Table 2). Similarly, in the variables recorded at 24 weeks, no differences were observed between groups with respect to deep dyspareunia; 12 patients (15%) in the polyglactin 910 group and 11 (14.9%) in the barbed suture group reported pain (p = .87; risk ratio, .93; 95% CI, .38−2.26) and 2 (2.6%) male partners of patients in the polyglactin 910 group and 1 (1.4%) in the barbed suture group reported pain (p = .57; risk ratio, .50; 95% CI, .04−5.71).

Fig. 1

Study flow diagram.

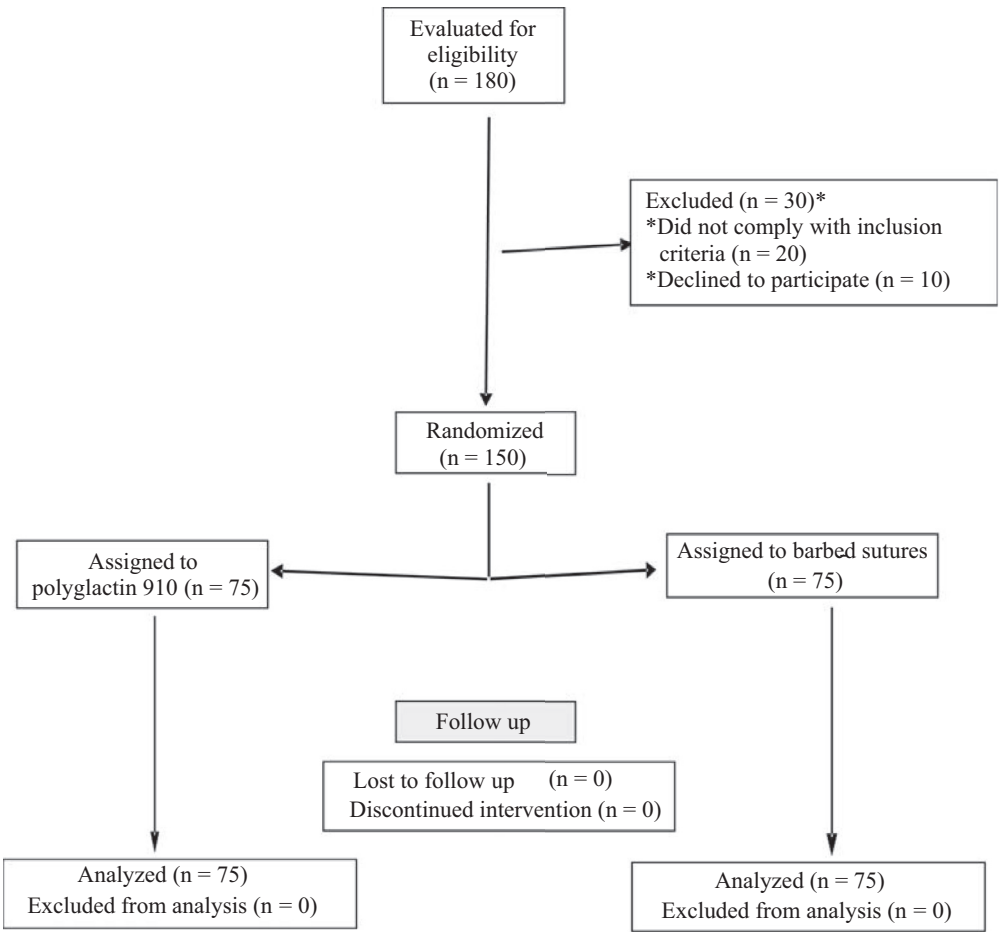

Table 1

Demographic patient characteristics

	Polyglactin (n = 75)	Barbed suture (n = 75)	p
Patient characteristics			
Mean age, yr (SD)	43.01 (6.28)	43.16 (5.9)	.88
Mean body mass index, kg/m^2 (SD)	26.40 (4.07)	27.17 (4.34)	.28
Mean parity (SD)	1.57 (1.37)	1.61 (1.21)	.84
History of smoking	3 (3.9)	8 (10.8)	.10
Arterial hypertension	10 (13.2)	11 (14.9)	.56
Previous pelvic surgeries*	55 (72.4)	56 (75.7)	.64
Deep dyspareunia before hysterectomy	27 (35.5)	25 (33.8)	.82
Presurgical diagnosis			
Myomatosis	52 (68.4)	59 (79.7)	.13
Abnormal uterine bleeding	75 (98.7)	66 (89.2)	.01
Pelvic pain	45 (59.2)	39 (52.7)	.46
Cervical dysplasia	1 (1.3)	3 (4.1)	.29
Endometriosis	4 (5.3)	8 (10.8)	.21
Intraoperative data			
Concomitant ovarian surgery	4 (5.3)	1 (1.4)	.18
Concomitant salpingectomy	32 (42.1)	37 (50)	.33
Mean weight of the uterus, g (SD)	216.26 (109.55)	228.31 (99.48)	

Values are n (%) unless otherwise defined. SD = standard deviation.
* Pelvic surgeries = history of laparoscopy or laparotomy.

Table 2

Ten- to 15-day postoperative follow-up findings

	Polyglactin (n = 75) n (%)	Barbed suture (n = 75) n (%)	p	Risk ratio	Risk ratio 95% confidence interval
Emergency consultation	13 (17.1)	17 (23)	.36	1.44	.64−3.23
Bleeding	7 (4.7)	5 (3.3)	.58	.71	.21−2.36
Pain	10 (6.7)	11 (7.3)	.76	1.15	.45−2.9
Fever	4 (2.7)	3 (2)	.72	.76	.16−3.52
Required hospitalization	4 (2.7)	2 (1.3)	.42	.50	.08−2.81

When analyzing complications no statistical difference was found when comparing both groups in a grouped or individual way (Table 3). Four cases of vaginal cuff cellulitis were diagnosed in each group; all were managed with in-hospital antibiotics for 48 hours and then ambulatory oral treatment, with all cases resolved. One patient in the polyglactin 910 group had a cuff abscess, required hospitalization with antibiotic parenteral therapy, and had resolution confirmed by ultrasound. One patient in each group presented with cuff dehiscence. Both underwent vaginal cuff closure under general anesthesia with adequate resolution and ambulatory management. Regarding the interview conducted at week 24 postoperatively, a decrease of 20% was observed in the prevalence of dyspareunia in the barbed suture group (p <.01) and 19% in the polyglactin 910 group (p = .009, from McNemar test), compared with preoperative assessment, without a significant statistical difference between groups.

Table 3

Postoperative complications after 24 weeks

	Polyglactin (n = 75)	Barbed suture (n = 75)	p
Complications	6 (7.9)	7 (9.5)	.73
Hematoma	0	2 (2.7)	.12
Cellulitis	4 (5.3)	4 (5.4)	.36
Abscess	1 (1.3)	0	.21
Dehiscence	1 (1.3)	1 (1.4)	.98
Emergency consultation	11 (14.5)	5 (6.8)	.12

Values are n (%).

Discussion

The main finding of this study was the demonstration of nonsuperiority of barbed suture with respect to

conventional suture regarding surgical time and incidence of complications. In this study, similar to that presented by Einarsson et al [14], when the suture was performed by an expert gynecologic laparoscopist, no clinical or statistical difference was observed in total operative time or time required for closure of the vaginal cuff when comparing the 2 suture materials. Because it is not necessary to perform intracorporeal knots when using barbed sutures and taking into account that performing intracorporeal knots is complex and requires considerable training, the use of this type of material may facilitate the endoscopic suture technique.

In their first series with 82 patients in whom barbed suture was used to close the vaginal cuff, Einarsson et al [12] reported an incidence of postoperative dyspareunia of 13.7%, persistent dyspareunia (>6 months after surgery) of 6.8%, and an incidence of dyspareunia of the couple of 8.2%. These data motivated the current study to search for a difference in dyspareunia incidence in patients and/or their partners in the 2 groups that could be attributed to the barbed suture for its design in "fish spine," but the incidence found for both variables was similar and without statistical significance.

Medina et al [15] performed a cohort study and found a lower rate of postoperative vaginal bleeding in patients who underwent surgery with barbed suture compared with polyglactin 910. Another retrospective cohort study conducted by Cong et al [16] described shorter surgical time and blood loss as well as shorter hospital length of stay. No differences were found between cohorts regarding the type of suture and incidence of complications. With regard to bleeding and surgical time, the current study data do not agree. Both variables obtained similar and nonsignificant results in the analysis. Siedhoff et al [17] in a retrospective cohort in 2011 describeda lower frequency of cellulitis in patients after vaginal cuff closure with barbed suture compared with other methods of closure. In the current randomized and controlled clinical study, no differences were found regarding cellulitis between groups.

There is no doubt that barbed suture is a safe and effective alternative for use in vaginal cuff closure during laparoscopic hysterectomy. However, the current study data, obtained after intervention by expert laparoscopists, noted no differences in either surgical time or incidence of complications when comparing the barbed suture and conventional suture (polyglactin 910) groups. These findings are similar to those of the meta-analysis by Lin et al [18] published in 2016, where no significant differences were found in any of these variables.

Although Siedhoff et al [17] qualified barbed suture as easy and inexpensive, this statement may not be true, as in the current study the cost of the barbed suture reaches almost 5 times that of a conventional suture such as polyglactin 910. Taking into account that the data obtained by the current study note no statistically significant differences in variables that impact cost such as surgical time and complication rate, it warrants a cost-efficiency study to identify the true role of the barbed suture in laparoscopic hysterectomy, especially in a health system like ours where any saving in the cost of materials can have an important impact on the finances of the health system itself.

One of the limitations of the current research is that no data were identified regarding time required to train surgeons or residents, a fact that could be important to determine regarding the competitive advantage of barbed suture to decrease the time used for closing the vaginal cuff. The current data conclude no advantage in terms of surgical time when comparing both suture materials when the procedures are performed by personnel trained in intracorporeal laparoscopic suturing.

In conclusion, the current study findings conclude that the use of barbed suture in total laparoscopic hysterectomy for benign pathology does not show advantages in the surgical time of cuff closure or incidence of complications.

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