ABSTRACT

Background and Objectives: Our aim was to evaluate whether the use of barbed suture for vaginal cuff closure is associated with a decrease in postoperative vaginal bleeding compared with cuff closure with polyglactin 910 in patients who have undergone laparoscopic hysterectomy.

Methods: We performed a cohort study of patients who underwent laparoscopic hysterectomy between January 2008 and July 2012 by the minimally invasive gynecologic surgery division of the Gynecology, Obstetrics and Human Reproduction Department at Fundación Santa Fe de Bogotá University Hospital, Bogotá, Colombia.

Results: A total of 232 women were studied: 163 were in the polyglactin 910 group, and 69 were in the barbed suture group. The main outcome, postoperative vaginal bleeding, was documented in 53 cases (32.5%) in the polyglactin 910 group and in 13 cases (18.8%) in the barbed suture group (relative risk, 0.57; 95% confidence interval, 0.34–0.9; P = .03). No statistically significant differences were found in other postoperative outcomes, such as emergency department admission, vaginal cuff dehiscence, infectious complications, and the presence of granulation tissue.

Conclusion: In this study an inverse association was observed between the use of barbed suture for vaginal cuff closure during laparoscopic hysterectomy and the presence of postoperative vaginal bleeding.

Key Words: Laparoscopy, Hysterectomy, Suture techniques, Postoperative hemorrhage, Barbed suture, Postoperative vaginal bleeding.
MATERIALS AND METHODS

We performed a cohort study of patients who underwent laparoscopic hysterectomy between January 2008 and July 2012 by the minimally invasive gynecologic surgery division of the Gynecology, Obstetrics and Human Reproduction Department at Fundación Santa Fe de Bogotá University Hospital. This study was approved by the Health Studies and Research Center and by the ethics committee of our institution. The data were extracted by a research assistant. The information was obtained through the electronic-based medical records of our hospital and included admission notes, discharge summaries, clinic notes, emergency department visits, operative notes, and pathology reports; in cases of missing data, we obtained this information directly from the physician who performed the postoperative evaluation, who was not always the surgeon who performed the surgery. The researchers performed inspections for accuracy of the information and missing data every week. The exclusion criteria were patients whose vaginal cuff closure was performed through either the vagina or the abdomen, patients who underwent conversion to laparotomy, and patients whose hysterectomies were performed because of malignancy.

Two groups were studied. Group 1 consisted of patients in whom the vaginal cuff closure was performed with barbed suture, and group 2 consisted of patients in whom the vaginal cuff closure was performed with polyglactin 910. The sample size was calculated using the program Epidat 4.0 (Pan-American Health Organization, Washington, DC). A retrospective analysis of the cases with vaginal cuff complications between 2010 and 2012 in our institution was performed. In this analysis the proportion of cases in the exposed group (barbed suture) was 19% versus 38% in the non-exposed group (polyglactin 910). With a relative risk to detect a difference of 0.5, 95% confidence level, 80% power, and 2:1 ratio of exposed to non-exposed, a total sample size of 201 patients was examined (65 patients in group 1, barbed suture and 136 patients in group 2 Polyglactin 910). Each individual in group 1 was matched by age and by diagnostic indication for the procedure with 1 or 2 individuals in group 2.

Our main outcome was postoperative vaginal bleeding (yes or no), defined as genital bleeding or spotting after the surgical procedure at the time of the postoperative evaluations. The amount of vaginal bleeding was neither directly nor indirectly quantified, and its presence was evaluated qualitatively by the patient’s report during anamnesis or by findings during the physical examination; preoperative and postoperative hemoglobin levels were not measured. Secondary outcomes were defined as dichotomous nominal variables (yes or no), including admission to the emergency department for causes associated with the surgical procedure, infectious complications (based on clinical presentation, physical examination, and a prescription for antibiotics), vaginal cuff dehiscence (partial or complete separation of the anterior and posterior edges of the vagina), and the presence of inflammatory or granulation tissue. Additional measured variables included age, number of gestations, parity, previous cesarean section, previous laparotomy or laparoscopy, smoking status, immunosuppression, surgical indications, additional intraoperative procedures, intraoperative complications, procedure length, weight of the surgical specimen, number of hospitalization days, type of intervention (scheduled or emergency), and type of postoperative follow-up. In each patient the same method of vaginal cuff closure was performed, and only patients who had a minimum postoperative follow-up time of 1 month were included in the analysis. All procedures were performed by or with the participation of the main researcher (B.C.M.), who is a specialist in minimally invasive gynecologic surgery and who did not participate in the data analysis.

Description of Procedure and Follow-Up

The laparoscopic technique used 3 accessory ports, one 10-mm umbilical port and two 5-mm accessory ports in both iliac fossae. Culdotomy was performed with a monopolar electrode at a power setting of 30 W using cutting current supported over a KOH Vaginal Colpotomizer Ring (Cooper-Surgical, Trumbull, CT) initiating in the posterior toward the anterior part until the ectomy was completed. Specimen extraction was performed vaginally. Morcellation was needed in certain cases and was performed vaginally with Mayo scissors and/or a No. 11 blade scalpel with previous traction of the specimen with a tenaculum. Vaginal cuff hemostasis was verified by use of Maryland bipolar forceps (KARL STORZ GmbH and co. KG, Tuttingen, Germany) at a power setting of 25 W.

For vaginal cuff closure, in the cases in which a polyglactin 910 needle (ct-1 or ct-2) was used, stitches in an X shape were made at the angles and in the middle third, extracorporeal knots were tied, and a Clarke laparoscopic knot pusher was used. In the barbed suture cases, closure was transverse; we began at the right angle and fixed the sutures to the uterosacral ligaments, pericervical fascia, and mucosa and then fixed the sutures on the anterior part to the mucosa and pericervical fascia. The first stitch was brought through the eye of the
suture and continued in a total running fashion in 2 continuous layers.

There were 2 mandatory postoperative evaluations; the first was always performed 7 to 10 days after the procedure, and the second was performed after 4 to 6 weeks. During the first postoperative evaluation, sutures were removed and an anamnesis was performed; the patients were asked specifically about alarm symptoms related to postoperative complications, such as fever, abdominal distention, emesis, and erythema of the surgical wound. During the physical examination, both an evaluation with a vaginal speculum and a digital vaginal examination were performed to determine the integrity of the vaginal cuff, as well as whether bleeding was present, and to rule out the presence of masses such as hematomas or abscesses. This same examination was also repeated during the second postoperative evaluation. Immediately after the surgical procedure, patients were instructed to abstain from sexual activity for at least 2 months; this recommendation was also repeated during each postoperative visit. If the patient had additional complaints or had specific findings, additional consultations were scheduled or the patient was instructed to go to the emergency department. In case vaginal bleeding was found, the treatment options were determined according to the etiology and amount and ranged from observation to incision and drainage if a hematoma was diagnosed or suture under anesthesia if dehiscence was present. If an abscess was found, it was treated with incision and drainage plus antibiotic therapy.

**RESULTS**

A total of 232 women were studied; 163 were in the polyglactin 910 group, and 69 were in the barbed suture group. The results of the univariate analysis stratified by suture type are shown in Table 1. The mean age of the study population was 45.3 years (range, 30–83 years), and there were no statistically significant differences between the 2 groups. The mean follow-up time was 8.82 months (SD, 10.2 months) in the polyglactin 910 group and 6.8 months (SD, 3.6 months) in the barbed suture group. Fifty percent of the patients in the polyglactin 910 group had a previous laparotomy, as did 66% of patients in the barbed suture group; the difference was statistically significant ($P < .05$). No statistically significant differences were observed in terms of obstetric history, number of pregnancies, parity, or cesarean sections. The surgical time was similar in both groups, with a mean of 181.8 minutes (SD, 51.7 minutes). The mean weight of the surgical specimen was 204.2 g (SD, 117.7 g) in the polyglactin 910 group and 206 g (SD, 110.2 g) in the barbed suture group. No statistically significant differences were observed in other variables, such as intraoperative bleeding (mean, 137.5 mL) and length of hospital stay (mean, 2.67 days). Of the patients, 87 (37.66%) underwent surgical procedures in addition to hysterectomy; 66 patients had only 1 additional procedure, and 21 had >1 additional procedure. The most common additional procedure was bilateral adnexectomy, followed by unilateral adnexectomy, and there were no statistically significant differences between the groups. There were 8 intraoperative complications reported (3.5%), of which 4 cases were vaginal tears, 1 case was an ascending colon laceration, 1 case was a rectal serosa laceration, and 1 case was a bladder tear.

| Variable                                      | Polyglactin 910 | Barbed Suture | Significance* ($P$ value) |
|-----------------------------------------------|-----------------|---------------|--------------------------|
| No. of patients                               | 163             | 69            |                          |
| Age (y)                                       | 45.5 (7.1)      | 44.9 (6.1)    | .54                      |
| Pregnancies                                   | 2.2 (1.3)       | 2 (1.2)       | .16                      |
| Vaginal deliveries                            | 1 (1.1)         | 0.9 (1)       | .5                       |
| Previous cesarean section                     | 75 (47%)        | 32 (49%)      | .81                      |
| Previous laparotomy or laparoscopy            | 81 (50%)        | 45 (66%)      | .02                      |
| Diabetes                                      | 4 (2%)          | 0             | .19                      |
| Immunosuppression                             | 3 (1.8%)        | 0             | .26                      |
| Smoking                                       | 20 (12%)        | 11 (16%)      | .42                      |
| Additional intraoperative procedure           | 60 (37%)        | 27 (41%)      | .67                      |
| Surgical time (min)                           | 180.4 (46.7)    | 185 (61.5)    | .54                      |
| Specimen weight (g)                           | 204.2 (118)     | 206 (112)     | .92                      |
| Blood loss (mL)                               | 143 (113.7)     | 115.4 (53.4)  | .06                      |
| Intraoperative complication                   | 4 (2.5%)        | 4 (5.8%)      | .19                      |
| Length of hospitalization (d)                 | 2.6 (0.8)       | 2.6 (0.6)     | .74                      |
| Emergency surgery                             | 1 (0.6%)        | 3 (4.4%)      | .04                      |
| Follow-up time (mo)                           | 8.82 (10.2)     | 6.8 (3.6)     | .12                      |

Data are expressed as n (%) or mean (SD).

*Significance was determined based on the $\chi^2$ test for categorical variables and Student $t$ test for continuous variables. $P < .05$ indicates a significant difference between groups.
These complications were not related to the suture but were related to the surgical process (eg, dissection issues) or the presence of adhesions.

Table 2 shows the study outcomes. The main outcome, postoperative vaginal bleeding, was documented in 53 cases (32.5%) in the polyglactin 910 group versus 13 cases (18.8%) in the barbed suture group (relative risk, 0.57; 95% confidence interval [CI], 0.34–0.9; \( P = .03 \)); none of the patients required a blood transfusion. A total of 5 cases (2.15%) of vaginal cuff dehiscence were reported overall, of which 4 (2.4%) occurred in the polyglactin 910 group versus 1 (1.4%) in the barbed suture group (relative risk, 0.6; 95% CI, 0.07–5.3; \( P = .6 \)). We documented no statistically significant differences related to infectious complications, but we documented 4 cases of vaginal cuff abscesses overall, 2 in each group. No patient presented with granulation tissue as a postoperative complication. In relation to the final evaluated outcome, 24 women (14.7%) in the polyglactin 910 group and 11 women (15.9%) in the barbed suture group presented to the emergency department in the early postoperative period. The main reasons for presentation to the emergency department during the follow-up time were vaginal bleeding (30%), abdominal and pelvic pain (19%), fever (16%), abdominal distention (5%), and urinary symptoms (5%). In addition, there was 1 case of leg pain due to thrombophlebitis.

DISCUSSION

Similar to other institutions from around the globe, our institution has adopted the use of new materials and techniques for minimally invasive gynecologic surgery. One technique is the use of barbed suture for vaginal cuff closure during laparoscopic hysterectomies, which has been used in our hospital since 2010. Since then, barbed suture has been used simultaneously with polyglactin 910 suture; this simultaneous use has given us the opportunity to evaluate the relationship between the use of these 2 types of sutures and postoperative vaginal bleeding, which in our institution is the most common chief concern during the postoperative period after hysterectomy for benign pathology.

When compared with the use of polyglactin 910 suture during vaginal cuff closure in patients who underwent laparoscopic hysterectomy, the use of barbed suture showed a decrease of 43% in the proportion of patients who presented with postoperative vaginal bleeding (\( P < .03 \)). These results are consistent with those reported by Siedhoff et al,\(^8\) who reported more patients with postoperative vaginal bleeding when comparing vaginal cuff closure with braided suture versus barbed suture (odds ratio [OR], 2.3; 95% CI, 1.3–3.9). This difference was statistically significant when comparing barbed suture with both types of braided suture (\( P < .001 \) for Endo Stitch [Covidien, Norwalk, CT] and \( P < .05 \) for Vicryl [Ethicon, Somerville, New Jersey]). In contrast to these results, Neubauer et al\(^11\) did not find any statistically significant differences when comparing the rates of heavy postoperative vaginal bleeding and spotting in patients who underwent robotic hysterectomies and vaginal cuff closure with monofilament suture versus barbed suture. The rates of postoperative vaginal spotting in their group of patients were 12% and 13% for monofilament and barbed suture, respectively, and heavy vaginal bleeding occurred in 1.7% and 2.6% of patients in these groups, respectively. It is possible that Neubauer et al did not find a difference in postoperative vaginal bleeding (similar to the difference found by Siedhoff et al and our group) because the hysterectomies were performed robotically and because their comparison was made between monofilament suture and barbed suture.

Although they were not the main objective of the study, the relationships between the use of both types of sutures

| Outcome                          | Polyglactin 910 [n (%)] | Barbed Suture [n (%)] | RR*       | 95% CI   | Significance (\( P \) Value) |
|----------------------------------|-------------------------|-----------------------|-----------|----------|-------------------------------|
| Postoperative vaginal bleeding   | 53 (32.5%)              | 13 (18.8%)            | 0.57      | 0.34–0.9 | .03                           |
| Admission to emergency department| 24 (14.7%)              | 11 (15.9%)            | 1.1       | 0.57–2.1 | .81                           |
| Vaginal cuff dehiscence          | 4 (2.4%)                | 1 (1.4%)              | 0.6       | 0.07–5.2 | .63                           |
| Infectious complications         | 2 (1.2%)                | 2 (2.9%)              | 2.4       | 0.34–16.4| .37                           |
| Inflammatory or granulation tissue | 0                      | 0                     | —         | —        | —                             |

*RR = relative risk.
and other postoperative outcomes, such as emergency department admission, vaginal cuff dehiscence, infectious complications, and the presence of granulation tissue, were also evaluated in our study. No statistically significant differences were found in any of these secondary outcomes when comparing the use of both types of sutures. Regarding vaginal cuff dehiscence, these results are consistent with those reported by Blikkendaal et al, who did not find statistical superiority in vaginal cuff dehiscence when comparing the use of barbed suture versus continuous Vicryl with Transanal endoscopic microsurgery (TEM) clips for vaginal cuff closure in laparoscopic hysterectomy. This finding was also reported by Neubauer et al, who also did not find any differences regarding vaginal cuff infection.

Unlike the previously mentioned authors and our group, Siedhoff et al reported a dehiscence rate of 3.1% for vaginal cuff closure with braided suture in laparoscopic hysterectomy, which is significantly different when compared with closure with barbed suture ($P < .04$). They also reported that patients whose closure was performed with braided suture had a greater probability of presenting with granulation tissue (OR, 1.9; 95% CI, 0.92–3.9) and cellulitis (OR, 4.6; 95% CI, 1.0–21.1). This difference was only observed when they compared barbed suture with Endo Stitch and not with Vicryl, which is also consistent with the results of our study.

It is possible that we did not find a difference among the secondary outcomes of lesser incidence because the study sample might not have had the necessary power to establish the relationship among these variables. However, similar findings regarding granulation tissue and vaginal cuff infection have been reported by other groups, supporting our findings.

Regarding our overall complication rate, we report 36.2% in the polyglactin 910 group and 22.3% in the barbed suture group, both of which are much greater than our previously reported institutional complication rate of 5.4%; the reason is that we excluded vaginal spotting as a postoperative complication in our previous report. However, during this study, because we wanted to evaluate the whole spectrum of postoperative bleeding as a main outcome, we also included vaginal spotting as a complication, thus artificially inflating our overall complication rate in both groups.

We consider our main outcome findings important because vaginal bleeding, either scarce or heavy, is one of the main reasons for concern among patients and is therefore one of the most common reasons for consultations during the postoperative period. The fact that we are able to decrease the bleeding during this period has an impact on the patient, leading to a decreased sense of concern and a subjective perception that the postoperative course is evolving favorably. In addition, the occurrence of less postoperative bleeding might represent a much better closure of the vaginal cuff edges and a decreased dehiscence probability. Even though we did not find a statistically significant difference between the 2 groups, we did find a tendency toward less dehiscence in the barbed suture group.

Among the strengths of our study is the fact that there were no patients lost to follow-up; therefore all postoperative complications were able to be evaluated because of our particular institutional circumstances. A total of 90% of our patients who undergo surgery and have some type of postoperative complication return directly to our hospital, and the other 10% go directly to the office of the physician who is responsible for their postoperative care, who is affiliated with the hospital. This scenario allowed us to have information about the follow-up of 100% of our patients who underwent a laparoscopic hysterectomy for benign pathology in our institution. The postoperative bleeding evaluation is performed in a standardized manner during the postoperative follow-up of all the hospital's patients, and all patients who have undergone a laparoscopic hysterectomy for benign pathology are evaluated for postoperative bleeding either in the emergency department or during the postoperative follow-up by the physician responsible for their postoperative care. Other strengths of our study include the matching of controls by age and surgical indication to avoid any confounding factors and having the same surgeon (B.C.M.) perform the surgical procedures in all patients included in the sample, which allowed us to assume that the surgical technique used until the moment of vaginal cuff closure was identical for both groups.

The aforementioned strengths are reflected in the similarities between the 2 groups for most analyzed variables. Given the more recent incorporation of barbed suture at our institution, the follow-up period was shorter. However, our follow-up period was longer than that reported by other studies.

In this study an inverse association was observed between the use of barbed suture for vaginal cuff closure during laparoscopic hysterectomy and the presence of postoperative vaginal bleeding. It is possible that part of this result might be attributable to the fact that cuff closure was performed in 2 continuous layers; however, it might also be because barbed suture allows a much better tensile distribu-
tion throughout the suture. These results are consistent with those reported in the literature and thus allow us to conclude that vaginal cuff closure with barbed suture during laparoscopic hysterectomies has several advantages, including having technical ease, addressing other already established complications in the literature, and being associated with a decrease in postoperative vaginal bleeding. Regarding technical ease, as was previously mentioned, barbed suture allows a much better distribution of the tension throughout the suture; in addition, it does not require knotting, in contrast to Vicryl. This is why we consider it technically easier to use barbed suture when closing the vaginal cuff when compared with the use of polyglactin 910. Besides, in our experience we have noted that the level of complexity, skill, and training is less when barbed suture is used for vaginal cuff closure than when Vicryl is used. One of the reasons we might not have found a difference in the surgical time between the 2 groups may be that all the surgeries were performed by the same highly skilled and experienced surgeon (B.C.M.); if the surgical time had been measured among less experienced surgeons, a difference might have been found. Another reason could be the fact that the barbed suture group had a much greater proportion of patients with previous surgeries, thus adding more complexity to the procedure; if this variable had been the same in both groups, a difference in surgical time might have been found during this study. To our knowledge, this is the first study that describes the use of barbed suture as an intervention to decrease postoperative vaginal bleeding.

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