Comparison Between Unidirectional Barbed and Polyglactin 910 Suture in Vaginal Cuff Closure in Patients Undergoing Total Laparoscopic Hysterectomy

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ABSTRACT

The aim of the study was to compare the efficacy and safety of barbed unidirectional vs. polyglactin 910 suture in vaginal cuff closure on patients submitted to total laparoscopic hysterectomy. From November 2011 until March 2012, a prolective, comparative, longitudinal, non-randomized study was performed on patients submitted to total laparoscopic hysterectomy (TLH). On entry, patients were assigned to two different groups, Group 1: Vaginal cuff closure with unidirectional #00 (n = 25) barbed suture, and Group 2: Vaginal cuff closure with polyglactin 910 #1 suture. The length of closure time and the frequency of dehiscence in vaginal vault were measured on the 14th postoperative day. We did not find significant differences between
Hysterectomy is the most common gynecological surgery, with a frequency of 5.6 in 1,000 women, with an annual rate of around 650,000 hysterectomies performed in the United States. In 1988, Reich et al. described the first laparoscopic hysterectomy. Since then, the discussion as to which is the best approach — laparoscopic, vaginal, or abdominal — has been ongoing.

The number of laparoscopic hysterectomies has not increased as much as expected in the last years due to lack of formal laparoscopic surgery capacitation and the absence of regulations and implementations of academically pertinent programs regarding new technologies. The clear advantages in length of recovery and lower morbidity of the laparoscopic approach aren’t taken into account, for being a procedure dependent on a prolonged capacitation period for achieving competitive results at cost and shortened surgical times of the procedure compared with abdominal hysterectomy.

The laparoscopic hysterectomy has certain advantages over the laparotomic approach in which a shorter hospital stay, less postoperative pain, and better scar aesthetics are among the advantages. Although the complication rates have been reported as higher with the laparoscopic approach, mainly on the lower urinary tract (bladder and ureter) as well as in prolonged surgical time, this can even happen to the most experienced surgeons, as they may choose more difficult cases (large uterus, obese patients, previous surgery, etc.) for themselves.

Complications are primarily from low to moderate in severity, including bleeding of the epigastric vessels, fever, surgical site infection, and late bleeding due to vaginal cuff dehiscence. The closure of the vaginal vault during a laparoscopic hysterectomy can be done by performing either interrupted or continuous stitches, using delayed absorption materials #0 or #1, and either intracorporeal or extracorporeal knotting. Suturing in the laparoscopic approach requires advanced surgical abilities, which can be acquired with practice and experience. For novice surgeons, knotting is a step that consumes a lot of time, and therefore prolongs the surgical time.

Many automated devices have been designed to facilitate the vaginal vault closure, such as the Endostitch (Covidien, Mansfield, MA), Lapra-TY® (Ethicon Endosurgery, Cincinnati, OH), Rd 180® THE RUNNING DEVICE and TK Ti-Knot® DEVICE (LSI Solutions, Victor, NY). Recently, a new suture technology has been introduced into the market with the purpose of facilitating laparoscopic suturing; it’s called barbed suture for its unidirectional design and its helicoidal design, which allows tissue suturing without the need for knotting because once adjusted the suture doesn’t loosen itself due to its configuration.

This barbed suture is a new paradigm in which suture tension is distributed along the whole filament length, which is different from a knotting site on a traditional suture. It has been designed with the same materials and sizes.

**Figure 1.** First stitch on the right angle of the vaginal cuff with barbed suture.

**Figure 2.** Pass the needle through the loop of the barbed suture.
(absorbable and non-absorbable: polidioxanone, poliglecaprone 25, nylon, and polypropylene), which confer the same tensile strength and managing capacity among tissues. This new technology has the potential to greatly facilitate the laparoscopic suturing during any laparoscopic procedure such as myomectomy and total laparoscopic hysterectomy. It has no knotting requirements, which is an advantage, achieving an adequate tissue pairing, almost impenetrable by liquids, with a lower closing time that translates into lower operative time.

The purpose of the present study is to compare the use of unidirectional barbed suture and polyglactin 910 suture for the vaginal cuff closure during laparoscopic hysterectomy.

**MATERIAL AND METHODS**

Upon approval of the Civil Hospital of Culiacan Research and Ethics Committee, from November 2011 until March 2012, we carried out a prospective, comparative, longitudinal, non-randomized study to evaluate the efficacy and safety of laparoscopic vaginal cuff closure on total laparoscopic hysterectomy with barbed suture.

We included 50 patients who fit the criteria for hysterectomy. Having previously been informed about the procedure and having signed a written consent for the laparoscopic hysterectomy approach, the patients were willing to participate in the study: 25 patients were assigned to the polyglactin 910 vaginal cuff closure group and 25 patients to the unidirectional barbed suture (V-LocTM90, Covidien, Mansfield, MA) vaginal cuff closure group.

Total laparoscopic hysterectomy was performed in a standard way using bipolar and monopolar electrosurgery. After removal of the uterus, the vagina was closed with continuous unanchored points using unidirectional barbed suture 00 (study group, Figs. 1–5) or two separate points in eight polyglactin 910 (control group, Figs. 6–8) with the #1 suture, binding the anterior and posterior vaginal edge. Closure of the vaginal cuff always included the uterosacral ligaments. At the end of the vaginal cuff closure, we cut the suture 1 cm away from the vaginal edge and proceeded to carefully assess the cuff closure integrity transvaginally.
necessary, additional stitches were given in the vaginal cuff center by extracorporeal knotting. Each patient’s hospital stay was at least 24 hours, and examination and evaluation of vaginal cuff healing were performed at 7 and 14 days postoperatively.

In each group, the following variables were analyzed. Vaginal cuff closure time was measured in minutes starting at the needle's introduction on one edge of the vaginal cuff for the suturing start, until the suture reached the contralateral vaginal angle. Early (first 48 hours) and late (> 48 hours and before 14 days) vaginal vault bleeding referred by the patient was confirmed by vaginal examination, and considered significant if equal to or greater than three dressings completely soaked with bright red blood per day.

Statistical analysis was carried out using descriptive and inferential statistics using the Student’s t-test for comparison of numerical variables and the chi-square test for comparison of categorical variables. A p-value equal to or less than 0.05 was considered statistically significant. For the analysis of the data we used an SPSS version 15.0 and Epi-Info version 6.04 statistical package.

RESULTS

No significant differences were found between the groups in the general characteristics (Table I).

When performing a comparison between the two groups with regard to the various subgroups such as BMI (normal, overweight, and obese), socioeconomic environment (low, medium, and high), and the preoperative diagnosis, it was found that these factors were similar between both the closure and the vaginal cuff groups (Table II).

Regarding the previous surgical history, there were no differences in the frequency of previous surgeries between the two groups, with 72% (n = 18) in the barbed suture group and 76% (n = 19) in the polyglactin 910 group having previous surgeries (P = .747). We used the closed access laparoscopic technique for the pneumoperitoneum creation in 100% of the cases.

There were significant differences found between the groups on vaginal cuff closure time (12.7 ± 3.1 min. for the barbed suture and 20.4 ± 7.1 min. for the polyglactin 910 group; P = .029). There were no vaginal cuff dehiscence cases in any group during the follow-up period.

No postoperative, transoperative, immediate, or late complications were found, nor were there any laparotomy conversions.

<table>
<thead>
<tr>
<th>Table I</th>
<th>General Characteristics of the Studied Population</th>
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<tbody>
<tr>
<td>Study group</td>
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<table>
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<th>Table II</th>
<th>BMI, Socioeconomic Level, and Preoperative Diagnosis Between the Study Groups</th>
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<td>Middle</td>
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<td>Fibroids without abnormal genital bleeding</td>
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<td>Abnormal uterine bleeding and fibroids</td>
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The goal of the minimally invasive or minimal access surgery is to achieve the same clinical effectiveness as conventional open surgery, with faster recovery rates. However, the laparoscopic hysterectomy has a longer learning curve, with initial lengthened surgical times, and a more frequent complication rate than open hysterectomy.10

These lengthened surgical times are mainly due to three factors: first, the difficulty of working in a bi-dimensional plane; second, identification of the surgical planes; and third, the handling of intracorporeal and extracorporeal suture, the latter being the most difficult for the surgeon in training when the whole procedure must be achieved by laparoscopic approach, including closure of the vaginal vault.

Vaginal cuff dehiscence after hysterectomy is a rare but serious complication of total hysterectomy. In most cases, this is a minor complication; but in rare cases, it becomes a surgical emergency that causes peritonitis and intestinal evisceration requiring an immediate surgical treatment for resolution.16

The TLH has a significantly higher risk of vaginal cuff dehiscence than other hysterectomy approaches, which may be due to excessive vaginal vault electrosurgical coagulation causing large thermal tissue damage or due to cuff closure technique.17–18

The frequency of vaginal cuff dehiscence and evisceration reported is 0.79% (with variation from 0% to 4.93%) subsequent to a TLH, still higher than for the abdominal (0.29%) and vaginal (0.12%) hysterectomy.19,20 This differs from the results of this study that included 50 patients with two types of vaginal vault closure, in which there was no case of dehiscence in a follow-up at 14 days.

Even though dehiscence as a complication is rare, and the number of patients presenting it among the different hysterectomy approaches is very small, the differences have been sufficient to achieve statistical significance of an increased risk to patients submitted to TLH, although these differences have no clinical significance.

The vaginal cuff dehiscence can be partial or complete, with the partial cuff dehiscence manifesting itself by weak to moderate bleeding early or late (after 10 days), infection (vaginal cuff cellulitis), or the presence of a suture site granuloma in the vaginal cuff. The complete cuff dehiscence is manifested by bleeding and bowel evisceration through the vaginal vault.19

In the absence of infection, radiation, or history of medical comorbidities explaining vaginal cuff dehiscence, this will always be secondary to a technique that involves too much surgical coagulation at the cuff edges, in the cuff closure technique, or the type of stitches used.

Most authors agree that one of the main factors contributing to an increased risk of vaginal cuff dehiscence is excessive electro coagulation on the bleeding edge of the vaginal cuff, which translates as increased tissue necrosis and devascularization.21 This does not happen when the cold-cut culdotomy is performed without performing edge coagulation, as in the abdominal and vaginal hysterectomy.

There are theoretical risks that the incomplete vaginal cuff closure or inadequate vaginal cuff edges approach due to laparoscopic image magnification is another factor contributing to dehiscence. To avoid the incomplete vaginal cuff closure, it is recommended that during the application of each stitch enough healthy tissue be taken.19,20

Few studies have evaluated the vaginal cuff closure technique and associated complications. One of the issues addressed in this work was the evaluation of the type of suture used for vaginal cuff closure with the aim of measuring the vaginal cuff closing time, as well as early and late complications referent to the vaginal cuff (early and late bleeding). With no need for intracorporeal and extracorporeal knotting, surgical times were significantly lower when using unidirectional barbed suture compared with polyglactin 910, using the technique of two points in eight, which is traditionally recommended. These findings are consistent with lowered surgical times when using unidirectional barbed suture compared with traditional suture as reported in the literature.11,22

With regard to the frequency of vaginal vault complications, the present study did not show any vaginal cuff dehiscence in either of the two groups, which differs with those reported previously by other authors, who reported frequencies of vaginal cuff dehiscence of 0.79% in TLH. The absence of vagi-
nal cuff dehiscence cases could be due to the small sample size, and also the fact that no excessive electro-coagulation on the vaginal edges was used. In addition, certain physical variables inherent to patients were controlled. Patients were advised to avoid physical exertion or sexual activity until 10 weeks postoperatively because these activities have been considered factors that trigger the clinical manifestations of cuff dehiscence.\textsuperscript{19,20}

Another factor to consider is patients’ postoperative follow-up time. In this study, the patients were followed for only 2 weeks (14 days), and the dehiscence may occur later (4 weeks) or even up to 96 days (according to reported cases) after a total laparoscopic hysterectomy.\textsuperscript{19–22}

Currently, it’s difficult to make comparisons with other studies regarding the use of barbed suture in the vaginal cuff closure because of the relatively short release time on this new product and the absence of studies on the topic. These existing studies only account for the characteristics of each type of suture: differences in tensile strength, knotting in laparoscopic surgery is difficult even in the hands of the most skilled surgeons trained in this kind of approach.\textsuperscript{11}

\textbf{CONCLUSIONS}

The use of unidirectional barbed sutures reduces surgical time and is just as efficient and safe as conventional sutures for vaginal cuff closure during laparoscopic hysterectomy. Likewise, it facilitates the surgical procedure by saving time, in particular because making knots in laparoscopic surgery is difficult even in the hands of the most skilled surgeons trained in this kind of approach.\textsuperscript{11}

\textbf{REFERENCES}