UNIDIRECTIONAL BARBED SUTURE VERSUS CONTINUOUS SUTURE WITH INTRACORPORAL KNOTS IN LAPAROSCOPIC MYOMECTOMY: RANDOMIZED CONTROLLED TRIAL

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INTRODUCTION

After laparoscopic enucleation of myomas, the repair of uterine wall defects may be challenging for surgeons with limited experience in endoscopic suturing.

Two major difficulties in laparoscopic suturing of uterine wall defect:

- difficulties in knot tying
- difficulties in maintaining adequate tension of the suture line
→ increased length of the surgical procedure
Barbed sutures have recently been proposed to facilitate suturing.

V-Loc TM 180 (Covidien, Mansfield, MA, USA) consists of a barbed absorbable thread, armed with a surgical needle at one end and a loop at the other end, which is used to secure the suture. The barb and loop end allow approximating the tissues without the need to tie surgical knots.

Up to now, barbed sutures have had limited application in gynecological surgery (Greenberg and Einarsson, 2008; Einarsson, 2010).
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AIM OF THE STUDY

TO COMPARE THE EFFECTIVENESS OF:

- UNIDIRECTIONAL KNOTLESS BARBED SUTURE (EXPERIMENTAL SUTURE)

- CONTINUOUS SUTURE WITH INTRACORPoreal KNOTS (STANDARD SUTURE)

IN THE REPAIR OF UTERINE WALL DEFECTS DURING LAPAROSCOPIC MYOMECTOMY.
MATERIALS AND METHODS

Study design: single-centre randomized prospective study

Inclusion criteria for the study:
- intramural myomas
- suture of the myometrial edges after myomectomy could be performed in single layer defined as sonographically diagnosed free myometrium margin (distance between the deeper part of the myoma and the endometrial cavity) ≥ 0.5 cm
- reproductive age
- presence of up to 3 myomas
- largest diameter of the myoma ≤ 10 cm

Exclusion criteria for the study:
- previous uterine surgery
- additional diseases requiring surgical treatment (such as endometriosis, tubal surgery, appendicitis)
- body mass index > 29 kg/m²
- contraindications for general anesthesia
- psychiatric disorders precluding informed consent
Randomization: computer-generated randomization list concealed in sealed opaque envelopes.
At the time of starting the uterine suture, a theatre nurse opened the envelope that contained the randomization assignment.

Accordingly to the randomization, the uterine wall defects were closed with:
- a continuous absorbable suture with intracorporeal knots (Vicryl®, Ethicon Inc, Sommerville, NJ, USA; standard suture, defined as group V)
- an absorbable unidirectional knotless barbed suture (V-Loc TM 180®, Covidien, Tyco Healthcare Group, Norwalk, Connecticut, USA; experimental suture, defined as group L)

Power calculation: The mean (± SD) time required to perform the suture of the uterine wall defect in the last 100 laparoscopic myomectomies was calculated. A reduction of at least 30% in the time required to perform the suture was arbitrarily considered of clinical interest. A 1 sided test power calculation was performed because the unidirectional knotless barbed suture was expected to be faster than the monofilament suture requiring intracorporeal knots. The SD of the time required for suturing during the 100 laparoscopic myomectomies (6.3 minutes) was used as sigma value. This power calculation indicated that 22 patients in each group would be necessary to detect a 30% difference in the time required to perform the suture of the uterine wall defect with a power ≥ 80% at a 1% level of significance.
Hemoglobin concentration was determined on the day before surgery and at 24 hours from surgery; the difference in hemoglobin concentration ($\Delta \text{Hb}$) was calculated in order to estimate the intraoperative blood loss.

At the end of each surgical procedure, the surgeons evaluated the degree of surgical difficulty of suturing the uterine wall defects by using a VAS scale ranging from 1 (low difficulty) to 10 (high difficulty).
RESULTS

Eligible (n = 54)

Refused participation to the study (n = 3)

Included in the study (n = 51)

Excluded from the study (n = 7):
- suture of the myometrial edges could not be performed in single layer (n = 6)
- undiagnosed pelvic disease requiring surgical treatment (endometriosis) (n = 1)

Randomized patients (n = 44)

Continuous suture with intracorporeal knots (n = 22)

Unidirectional knotless barbed suture (n = 22)
# DEMOGRAPHIC CHARACTERISTICS OF THE STUDY POPULATION AND INDICATIONS FOR SURGERY

<table>
<thead>
<tr>
<th></th>
<th>group V (n = 22)</th>
<th>group L (n = 22)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years; mean ± SD)</td>
<td>35.5 ± 4.6</td>
<td>35.2 ± 4.5</td>
<td>0.843</td>
</tr>
<tr>
<td>BMI (kg/m²; mean ± SD)</td>
<td>23.4 ± 2.9</td>
<td>23.5 ± 3.2</td>
<td>0.941</td>
</tr>
<tr>
<td>Previous live birth (n; %)</td>
<td>9 (40.9%)</td>
<td>12 (54.5%)</td>
<td>0.546</td>
</tr>
<tr>
<td>Previous abdominal surgery * (n; %)</td>
<td>4 (18.2%)</td>
<td>2 (9.1%)</td>
<td>0.664</td>
</tr>
<tr>
<td>Indication for myomectomy (n; %)</td>
<td></td>
<td></td>
<td>0.737</td>
</tr>
<tr>
<td>- abnormal uterine bleeding</td>
<td>- 8 (36.4%)</td>
<td>- 9 (40.9%)</td>
<td></td>
</tr>
<tr>
<td>- infertility</td>
<td>- 8 (36.4%)</td>
<td>- 7 (31.8%)</td>
<td></td>
</tr>
<tr>
<td>- abortion</td>
<td>- 1 (4.5%)</td>
<td>- 0 (0.0%)</td>
<td></td>
</tr>
<tr>
<td>- pain / pelvic pressure</td>
<td>- 2 (9.1%)</td>
<td>- 4 (18.2%)</td>
<td></td>
</tr>
<tr>
<td>- growing rapidly</td>
<td>- 3 (13.6%)</td>
<td>- 2 (9.1%)</td>
<td></td>
</tr>
</tbody>
</table>

* other than appendectomy
## Characteristics of the Myomas

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group V (n = 22)</th>
<th>Group L (n = 22)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of myomas (n; median, range)</td>
<td>1 (1-3)</td>
<td>1 (1-3)</td>
<td>0.790</td>
</tr>
<tr>
<td>Main diameter of the largest myoma (cm; mean ± SD)</td>
<td>7.3 ± 1.8</td>
<td>7.7 ± 1.7</td>
<td>0.424</td>
</tr>
<tr>
<td>Proportion of patients according to number of myomas (n; %)</td>
<td></td>
<td></td>
<td>0.948</td>
</tr>
<tr>
<td>- one</td>
<td>13 (59.1%)</td>
<td>12 (54.5%)</td>
<td></td>
</tr>
<tr>
<td>- two</td>
<td>7 (31.8%)</td>
<td>8 (36.4%)</td>
<td></td>
</tr>
<tr>
<td>- three</td>
<td>2 (9.1%)</td>
<td>2 (9.1%)</td>
<td></td>
</tr>
<tr>
<td>Localization of myomas (n/total, %)</td>
<td></td>
<td></td>
<td>0.676</td>
</tr>
<tr>
<td>- anterior</td>
<td>12/33 (36.4%)</td>
<td>12/34 (35.3%)</td>
<td></td>
</tr>
<tr>
<td>- posterior</td>
<td>10/33 (30.3%)</td>
<td>9/34 (26.5%)</td>
<td></td>
</tr>
<tr>
<td>- lateral</td>
<td>2/33 (6.1%)</td>
<td>5/34 (14.7%)</td>
<td></td>
</tr>
<tr>
<td>- fundal</td>
<td>8/33 (24.2%)</td>
<td>8/34 (23.5%)</td>
<td></td>
</tr>
<tr>
<td>- intraligamentary</td>
<td>1/33 (3.0%)</td>
<td>0/34 (0.0%)</td>
<td></td>
</tr>
</tbody>
</table>
Operative Time

<table>
<thead>
<tr>
<th>Group</th>
<th>Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>V</td>
<td>80.7</td>
</tr>
<tr>
<td>L</td>
<td>73.3</td>
</tr>
</tbody>
</table>

p = 0.177
**Operative Time**

- Group V: 80.7 min
- Group L: 73.3 min

**Time to Suture the Hysterotomy**

- Group V: 17.4 min
- Group L: 11.5 min

- $p = 0.177$
- $p < 0.001$

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The mean preoperative hemoglobin concentration was similar in the two study groups:
- group L: 11.4 ± 1.3 g/dl
- group V: 11.2 ± 1.2 g/dl
The mean preoperative hemoglobin concentration was similar in the two study groups:

- group L: 11.4 ± 1.3 g/dl
- group V: 11.2 ± 1.2 g/dl

p = 0.004

O-04 Ferrero et al. - Unidirectional barbed suture versus continuous suture with intracorporeal knots in laparoscopic myomectomy: randomized controlled trial
DEGREE OF SURGICAL DIFFICULTY

GROUP V

GROUP L

p < 0.001

DEGREE OF SURGICAL DIFFICULTY

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CONCLUSIONS

The use of a knotless barbed suture reduces the time required to repair the uterine wall defect during laparoscopic myomectomy.

A further advantage of using barbed sutures during laparoscopic myomectomy consists in the fact that this suture resists migration; this tension of the suture line (combined with the faster closure of the uterine wall defects) may contribute to the reduction in the intraoperative blood loss observed in the current study.

Future prospective studies including patients wishing to conceive after myomectomy should determine whether the use of a knotless barbed suture affects the risk of uterine rupture during pregnancy.
CONFLICT OF INTEREST

The authors have no conflict of interest to disclose.
Dear Dr. Ferrero,

Congratulations! Your abstract paper “Unidirectional Barbed Suture Versus Continuous Suture with Intracorporeal Knots in Laparoscopic Myomectomy: Randomized Controlled Trial” (Control # 510; Presentation # O-04) has been selected as the recipient of the Society of Reproductive Surgeons (SRS) Prize Paper Award to be presented during the upcoming 2010 Annual Meeting of the American Society for Reproductive Medicine (ASRM) in Denver, Colorado. You are scheduled to present your work in a 15-minute oral presentation scheduled as follows:

Day/Date: Monday, October 25, 2010
Time: 12:00 PM