Knotless barbed versus traditional sutures in laparoscopic myomectomy: A fellowship randomized trial

Youssef Abu Elkheir,
Mohamed El-Said Ghanem,
Hossam El-Sayed Gouda,
Hossam Abdou,
Valantino Remorgida

Abstract

Study Objective: To estimate the effectiveness of unidirectional barbed suture and continuous suture with intracorporeal knots in the repair of uterine wall defects during laparoscopic myomectomy.

Design: Randomized clinical study.

Setting: San Martino Hospital –Genoa University –Italy.

Patients: This study enrolled 39 women who underwent laparoscopic myomectomy.

Interventions: according to the randomization, the uterine wall defects were closed either with the traditional sutures in the traditional way (group V) 19 cases or a barbed suture (group L) 20 cases.

Measurements and Main Results: The time required to suture the uterine wall defect was significantly lower in group L [The barbed sutures group] (9.65 $\pm$ 1.57 minutes) than in group V [The traditional sutures group] (18.11 $\pm$ 1.41 minutes; $p < 0.001$). The total operative time was also significantly decreased on the use of barbed sutures (64 $\pm$ 8.77 minutes versus 95.32 $\pm$ 6.57 minutes) with a P value of < 0.001. The intraoperative blood loss was significantly lower in group L than in group V (P value of < 0.001). The degree of surgical difficulty [evaluated by the use of a VAS scale ranging from 1 (low difficulty) to 10 (high difficulty)] was significantly lower in group L (3.15 $\pm$ 0.88) than in group V (5.95 $\pm$ 1.81) with a P value of < 0.001.

Conclusion: The unidirectional knotless barbed sutures significantly facilitated the suturing of uterine wall defects during laparoscopic myomectomy. When compared with traditional suture with intracorporeal knots, the barbed suture reduces the time required to suture the uterine wall defect, reduces the total operative time and the intraoperative blood loss.

Introduction

Uterine myomas are the most common benign tumors of the uterus . Their management depends on age , parity ,severity of symptoms, the patient's desire to conceive, and the number and size of the myomas ***(1)***. Laparoscopic myomectomy was first described by Semm in 1979. Since then, many reports of this technique have been published worldwide. Its indications have increased with the improvements in laparoscopic techniques and instruments ***(2)***.

Three major steps are involved in laparoscopic myomectomy : excision of the myoma(s) ; suturing the uterine defect; and extraction of the myoma(s). The step of suturing in laparoscopic myomectomy is the most difficult step that needs a long experience in laparoscopic suturing, making laparoscopic myomectomy a challenging procedure ***(3)***.

Barbed sutures, after being approved by FDA in 2004, was first introduced in the market of the United States in January 2007. They consist of a barbed absorbable thread. The first production of these sutures was bidirectional armed with two needles in both ends (Quill Sel f-Retaining System;

Angiotech Pharmaceuticals, Inc., Vancouver, British Columbia). After that unidirectional sutures were introduced in the market .The unidirectional sutures are armed with a surgical needle at one end and a loop or knob at the other end, used to secure the suture ***(4)***.

Previous investigations have demonstrated that they reduce the time required, for closing gastrointestinal enterotomies in pigs ***(5)***, for laparoscopic partial nephrectomy in pigs ***(6)*** for abdominoplasty in humans ***(7)***. Barbed sutures have had limited application in gynecologic surgery. The aim of this study was to compare the effectiveness of barbed suture and traditional continuous suture during laparoscopic myomectomy , as regards : Difficulty in suturing , suturing time , total surgical time and intraoperative blood loss.

Patients and Methods

Patients:

This study was performed on 39 patients who had laparoscopic myomectomies in San Martino Hospital, Genoa University in the period between February 2012 and January 2013. Operations were performed by a single surgeon with deep experience in laparoscopic myomectomy (V.Remorgida) .

Inclusion criteria for this study was patients of the reproductive age with Intramural myomas (up to 3 intramural myomas, the largest diameter of which was 10 cm) that the suture of the myometrial edges after myomectomy could be performed in a single layer. So, a sonographically diagnosed free myometrial margin was 0.5 cm or more.

Exclusion criteria were , previous uterine surgery, additional diseases requiring surgical treatment (such as endometriosis, tubal surgery, appendicitis) , body mass index > 29 kg/m2 , contraindications for general anesthesia and psychiatric disorders precluding informed consent.

Preoperative assessment:

Full clinical evaluation of the patients was done including full history taking and full clinical examination. Then all patients had transvaginal ultrasonography within the 2 weeks before surgery. Size, location (with respect to uterine layers), position (with respect to the uterine axis), and number of myomas were evaluated and recorded. In each intramural myoma, the depth of the development of the myoma in the uterine wall were estimated. Hemoglobin concentration was determined on the day before surgery.

The patients were randomized into two groups: ***Group V***, where the uterine wall defects were closed with a continuous absorbable suture (Vicryl; Ethicon Inc, Sommerville, NJ) (standard suture) which included 19 patients. ***Group L***, where the uterine wall defects were closed with an absorbable unidirectional barbed suture (V-Loc 180; Covidien, Tyco Healthcare Group,Norwalk, CN) (experimental suture) which included 20 patients. Randomization was performed by the use of a computer generated randomization list drawn up by a statistician and was concealed in a sealed opaque envelope. At the time of starting the uterine suture, a nurse in the operating room opened the envelope that contains the randomization assignment. Each woman was informed of the experimental design of the study and informed consent to participate was signed.

Surgical procedure:

The surgical procedures were performed with the patients under general anesthesia. An open-laparoscopy 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. Three 5-mm ports were inserted for the introduction of the surgical instruments (In very large myomas all trocars were displaced upwards).

After the pelvic organs were explored, Vasopressin 20 U/ml diluted in 100 ml of saline was injected in the plane between the pseudocapsule and the myometrium. An incision was made through the uterine wall and the pseudocapsule of the myoma by the use of a unipolar hook. When the cleavage plane was identified, the myoma was fixed with Manhes grasping forceps or a myoma drill, enucleated by means of traction in combination with countertraction with Manhes forceps or antevertion and lateral movements of the uterus. The myomas after extraction were put aside in the abdominal cavity. Coagulation by bipolar forceps only performed in cases of significant bleeding.

Suture of the myometrial edges with the standard sutures were performed as in open myomectomy: a stay suture in one end, start from the other side after making a knot, then start continous sutures till reaching the stay suture.

The unidirectional barbed sutures used in the study - the V-LocTM 180 (Covidien, Mansfield, MA) - 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 first stitch was done at one end and instead of making a knot the needle was passed through the loop and just adequate traction exerted to have a good tension. Then following

sutures were performed as usual with a good traction with no need for the assistant to hold the suture .The last stitch was done with adequate traction with no need to make a knot , and then the remaining suture was cut and removed from the abdomen. The myomas was removed by the use of an electromechanical morcellator through cuteneous opening of 15 mm, and was histopathologically evaluated.

Hemoglobin concentration was assessed again at 24 hours after surgery; the difference in hemoglobin concentration (Delta Hb) (D Hb) was calculated to estimate the intraoperative blood loss. All surgical procedures was recorded; the operative time was determined by reviewing the surgical procedures; 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 hysterotomies.

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

Statistical analysis

Statistical analysis was carried out via Statistical package for social Science (SPSS) version 17 program on windows XP. Qualitative data were represented in the form of number and frequency, Quantitative data were represented in the form of mean ± standard deviation (mean ± SD). Kolmogrov-smirnov test was used to test normality of quantitative data and all data were normally distributed. χ^2 and *Student's t* tests were used to compare groups. Results were considered significant if *p value* is less than or equal 0.05.

Results

The characters of the patients were comparable between the two groups , the age , BMI , previous birth and previous surgery. The number , mean diameter and position of the myomas were comparable between the two groups . Also , the indications of myomectomy in both groups were comparable . ***(Table 1)***

The suturing difficulty was statistically significant between the two groups. Using Visual Analogue Scale (VAS) ranging from 0-10 , in the traditional sutures it was 5.95 ± 1.81 while in the barbed sutures was 3.15 ± 0.88 with a P value of <0.001 ***(Figure 1)*** .

The suturing time for hystrotomies and the total surgical time (estimated after reviewing the recordings of the procedures) was statistically significant between the two groups . In the traditional sutures, they were 18.11 ± 1.41 , 95.32 ± 6.57 minutes respectively while in the barbed sutures they were 9.65 ± 1.57 and 64 ± 8.77 minutes respectively with a P value of < 0.001 (***figures 2 & 3***) .

The preoperative Hb was comparable between the two groups ***(Table 1)*** . The postoperative Hb was statistically significant : 10.21±0.91 gm/dl and 10.88±0.76 gm/dl respectively with a P value of 0.013. Delta Hb (substracting preoperative Hb from Postoperative Hb) indicating intraoperative loss was statistically significant between the two groups : 0.9 ± 0.22 gm/dl and 0.43 ± 0.14 gm/dl respectively with a P value of < 0.001 ***(Figures 4)***.

Discussion

The step of suturing in laparoscopic myomectomy is the most difficult step that needs a long experience in laparoscopic suturing. Laparoscopic suturing makes laparoscopic myomectomy a challenging procedure. Therefore most updates in laparoscopic myomectomy were directed to facilitate the step of suturing .One of these innovations are the barbed sutures.

This prospective randomized clinical study have shown that the use of unidirectional barbed sutures will significantly facilitate the laparoscopic suturing and significantly decrease the the intraoperative blood loss, suturing time and total operative time.

The suturing difficulty was assessed in this study by Visual Analogue Scale (VAS) ranging from 0-10 , in the traditional sutures it was 5.95 ± 1.81 while in the barbed sutures was 3.15 ± 0.88 (P value o <0.001) ***(Figure 1)*** .This can be explained by the fact the most difficult step in laparoscopic suturing is the knotting which is not needed in the barbed sutures . Also, the sutures resist the migration and so, no need for the assistant to hold the sutures. On the other hand, passing the suture through the loop at the start may represent an obstacle, but it will be much easier than knotting, plus after few cases it will be an easy step.

The suturing time for hystrotomies was estimated after reviewing the recordings of the procedures. The suturing time in the traditional sutures was 18.11 ± 1.41 minutes while in the barbed sutures was 9.65 ± 1.57 minutes with a P value of < 0.001. The suturing time was logically decreased due to the absence of the step of knotting. (***Figure 2***). The decrease in the suturing time was reflected on the total surgical time . (***Figure 3***) .

The previous two findings were reflected on the intraoperative blood loss. It was estimated by Delta Hemoglobin (substracting preoperative Hb from Postoperative Hb). The preoperative Hb was

comparable between the two groups (Due to well designed randomization) while the postoperative Hb was statistically significant with a P value of 0.013 . Therefore Delta Hb in the traditional sutures was 0.9 $\pm$ 0.22 gm/dl while in the barbed sutures was 0.43 $\pm$ 0.14 gm/dl with a P value of < 0.001 ***(Figure 4)***.

Another possible advantage of the barbed sutures that they may be suitable for the surgeons with less experience in laparoscopic suturing. First, they don't need knotting which will significantly facilitate suturing. Second, the role of the assisstant will be less important than the traditional sutures; the assisstant should hold the sutures firmly in the traditional sutures, while in the barbed sutures no need to hold the sutures.

The definite obstacle against widespread use of the barbed sutures will be the cost. In Egypt, they cost about 450 L.E while the traditional Polyglactin 910 (Vicryl) sutures will cost only 20 L.E .This big difference in cost will be balanced by decreasing the time of operation, time of anasthesia, the rate of conversion into laparotomy and hospital stay .

The application of them in gynecologic surgery has been studied by very few authors .The first study was performed by Greenberg et al in 2008 but it was an initial trial using bidirectional barbed sutures (Quill SRS) with only 8 cases performed (5 laparoscopic myomectomies and three laparoscopic hystrectomies) which was not enough to judge the efficacy of the barbed sutures ***(8)***.

The same group after three years have published their experience in the use of the bidirectional barbed sutures .They retrospectively compared the bidirectional barbed sutures in 107 patients to the traditional sutures in 31 patients. They found that the use of bidirectional barbed suture significantly shortened the mean (SD) duration of surgery and suturing time [118(52) Versus 162(69)] (P value =0.003) and reduced the duration of hospital stay [0.58 day versus 0.97 day] (P value = 0.001). No significant differences were observed between the 2 groups in the incidence of perioperative complications and estimated blood loss ***(9)***.

The limitations in that study was the retrospective nature. Besides, cases were performed in order (107 patients with barbed sutures following 31 cases using traditional sutures) which will affect the results plus the building up of the experience which by itself may decrease the suturing time. On the other hand, the advantage in that study was that they used the bidirectional sutures which allow closure of the hystrotomy in layers not necessitating one layer like our study.

In 2011, Angioli et al. have published their experience in the use of the unidirectional barbed sutures (V-loc), 19 women with single symptomatic intramural myoma were prospectively enrolled in the closure of the uterus with unidirectional barbed sutures while a control group of 20 women with characteristics meeting the criteria for study inclusion was retrospectively identified from the hospital databases , were closed by classical continuous suture with intracorporeal knots. They found that the suturing time was significantly lower in the V-Loc than in the control (9.9±4.3 versus 15.8±4.7 min; P=0.0004) group, but the shortening of the mean operative time didn't reach statistical significance. They gave a reason for this that the total surgical time depend on many factors not only the suturing. They also found that the intraoperative bleeding and drop in hemoglobin were significantly lower in the V-Loc group (P=0.0076 and P=0.0176, respectively) ***(10)***.

That study go with the results of our study except the total surgical time. But the limitation in that study is the retrospective nature of the study. Besides, the patients had only single myoma with exclusion of the lateral and infraligamentary myomas.

A limitation of our study may be the relatively small number of cases, so further studies may be needed with larger number of cases in the future. Another possible limitation may be the selection of the uteri that could be closed in a single layer. Further studies may be directed to the use of the barbed sutures in a multilayer closure of the uterus.

A possible further study may be directed to the use of the barbed sutures by the less experienced surgeon in laparoscopic suturing, as our study was performed by a highly experienced surgeon with long expertise in laparoscopic myomectomy and laparoscopic suturing.

Conclusion

Barbed sutures facilitate the suturing step in laparoscopic myomectomy by eliminating the need of knotting and the need of holding the suture by the assisstant. Barbed sutures decrease the time of suturing hystrotomies, total surgical time and the intraoperative blood loss.

Although much expensive than the traditional sutures, the difference in cost will be balanced by the decrease in operative time, anesthesia time, the rate of conversion into laparotomy and hospital stay. Barbed sutures are ideal for the less experienced surgeons in laparoscopic suturing.

		Group V Traditional sutures (n=19)	Group L Experimental sutures (n=20)	P value
Age		34.95 ± 2.55	35.35 ± 3.23	0.669
BMI		23.76 + 1.39	23.78 + 1.28	0.968
Previous birth		7 (36.8%)	12 (60%)	0.26
Previous surgery		4 (21.1%)	4 (20%)	0.935
Indication of myomectomy	**Abnormal Uterine bleeding**	7 (36.8%)	7 (35%)	0.905
	Infertility	6 (31.6%)	8 (40%)	0.831
	Abortion	1 (5.3%)	1 (5%)	0.97
	Pain	3 (15.8%)	2 (10%)	0.951
	Abdominal enlargment	2 (10.5%)	2 (10%)	0.957
Mean diameter of myomas		7.31 ± 1.21	7.02 ± 1.16	0.449
Number of myomas	**1**	16 (84.2%)	16 (80%)	0.985
	2	2 (10.5%)	3 (15%)	0.978
	3	1 (5.35)	1 (5%)	0.984
Position of myomas	**Anterior**	12 (63.2%)	7 (35%)	
	Posterior	5 (26.3)	6 (30%)	
	Lateral	3 15.8%)	0 (0%)	
	Fundal	3 (15.8%)	10 (50%)	
	Infra-ligamentary	0 (0%)	2 (10%)	
Preoperative Hemoglobin		11.11 ± 0.85 gm/dl	11.31 ± 0.62 gm/dl	0.405

Table (1) : Criteria of both groups

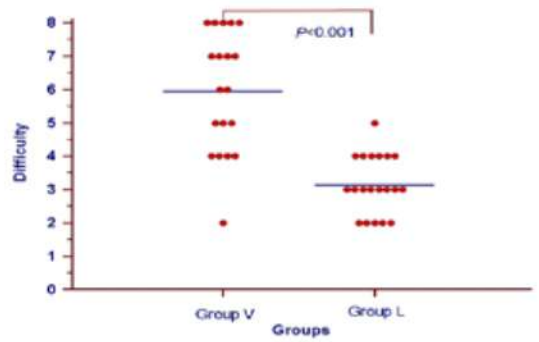

Fig.(1): The suturingdifficulty
(Using VAS scale 0-10) in both groups

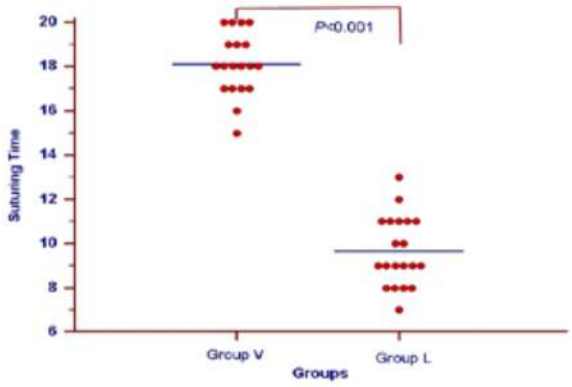

Fig.(2): The suturing time of hystrotomies
(in minutes) in both groups

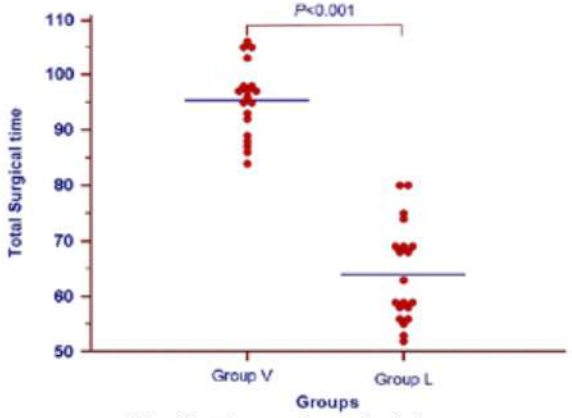

Fig.(3): The total surgical time
(in minutes) in both groups

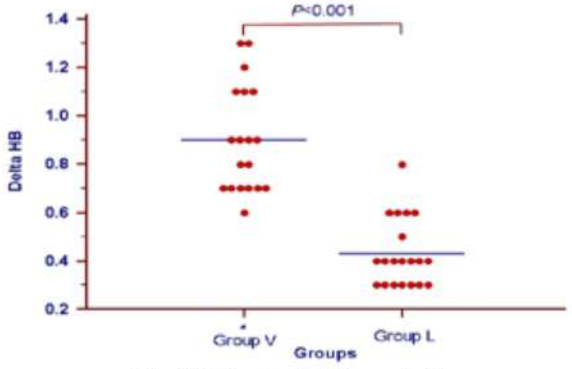

Fig.(4): The DeltaHemoglobin
(The difference between postoperative and preoperative
Hemoglobin in gm) in both groups

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