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Laparoscopic myomectomy using barbed or conventional sutures: A randomized controlled study

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***Abstract*---**Objectives: To assess the differences in surgical outcomes between bidirectional barbed suture and conventional suture for myoma bed closure during laparoscopic myomectomy. Study design: Ninety-two patients with one to three symptomatic myomas were randomized in a 1:1 ratio to the barbed suture group or the conventional suture group. Myoma bed was sutured either with barbed suture (STRATAFIX™, Ethicon Inc, USA) or continuous conventional suture with intracorporeal knot tying (Vicryl; Ethicon, USA). The surgeon assessed the degree of suturing difficulty using a visual analog scale ranging from 1 (least difficult suturing) to 10 (most difficult suturing). Results: Suturing with barbed suture was easier than suturing with conventional suture (3.04±1.47 Vs. 4.75± 1.35, P < 0.001). Suturing time of the myoma bed was significantly shorter in the barbed suture group (14.98±4.81 Vs 22.09±6.9 min; P < 0.001). Operative time was comparable between both groups (69.67±17.63 Vs 74.15±19.79 min; P = 0.255). The mean intraoperative blood loss was

significantly higher in conventional suture group (337.24±234.15 ml Vs 211.3±107.62; P= 0.002). Conclusion: The barbed suture facilitates suturing of the myoma bed during laparoscopic myomectomy. Compared with conventional suture, barbed suture reduces the time needed to suture the myoma bed and the intraoperative blood loss.

***Keywords*---**laparoscopy, myomectomy, barbed suture, conventional suture, stratafix, vicryl.

Introduction

Uterine leiomayoma is the commonest tumor of the female genital system. About one forth of the patients with uterine leiomayomas complain of heavy or prolonged menstrual bleeding, infertility, habitual abortion, abdominal pain and pelvic pressure symptoms (1). Surgery is the treatment of choice for symptomatic uterine fibroids. Hysterectomy is usually indicated in patients who do not desire fertility and myomectomy is the typical management for patients who desire future fertility or decline hysterectomy (2). Laparotomy has been the traditional route for myomectomy. During the past two decades, laparoscopic, hysteroscopic, and robotic myomectomy have largely replaced open myomectomy (3).

A meta-analysis revealed that laparoscopic myomectomy is associated with less decline in hemoglobin concentration, operative blood loss, pain and complications as compared with open myomectomy. On the other hand, the operative time is significantly shorter with open myomectomy (4). During laparoscopic myomectomy, suturing of uterine defect after enucleation of the myoma is the most challenging and time consuming step of the procedure. Difficulties are usually encountered during knot tying and during applying tension on continuous suture. These difficulties limit the widespread use of laparoscopic myomectomy by the gynecologists (5,6,7).

Barbed sutures are new class of sutures that were recently used in different surgical specialties to facilitate laparoscopic suturing. Barbed sutures have barbs on the surface of suture thread that prevent backwards slippage of the thread through tissues and therefore can suture the tissues without knot tying on either end of suture line and without the need to apply tension on the thread during suturing (8,9). In gynecology, several studies revealed the safety and efficacy of barbed sutures in minimally invasive hysterectomy, myomectomy, sacrocolpopexy and ovarian cystectomy (8,10,11). Till now, only three small randomized controlled studies compared the surgical outcomes after laparoscopic myomectomy using conventional or barbed sutures (12,13,14). Whereas, the three studies reported that the use of barbed sutures is associated with a reduction in suturing time and intraoperative blood loss, only one study revealed that the use of barbed sutures isassociated with a reduction in operative time (14). The aim of this study was to assess the differences in surgical outcomes between bidirectional barbed suture and conventional suture for myoma bed closure during laparoscopic myomectomy.

Materials and Methods

This prospective, allocation concealed, open labeled, mono-center, two arm randomized controlled trial was carried out during the period between January 2014 and January 2020. The study included 92 patients with symptomatic uterine fibroid attending Obstetrics and Gynecology hospital, Cairo University, Egypt. The study protocol was approved by the hospital ethics committee. Written informed consent was obtained from the patients before participation in the study. Our inclusion criteria were the presence of one to three symptomatic intramural or subserosal myomas, largest myoma diameter ≤ 10 cm and age between 18 and 40 years. The indications of myomectomy were heavy or prolonged menstrual bleeding, pain, pressure symptoms and infertility. The exclusion criteria were the presence of submucosal myoma, calcified myomas, uterine size more than 16 weeks, suspension of genital malignancy, coagulation defects or concurrent anticoagulant therapy, pregnancy and previous treatment with gonadotropin-releasing hormone analogue.

Ninety two patients who underwent laparoscopic myomectomy were enrolled in the study. Patients were randomized in a 1;1 ratio to the barbed suture group or the conventional suture group using computer-generated random numbers concealed in a sequentially numbered opaque sealed envelopes. The study nurse opened the envelopes before the start of the operation to allocate the patients to the assigned group. The patients were blind to the type of suture used in the operation.

All the procedures were performed during the proliferative phase of the menstrual cycle by an experienced laparoscopist (M.Z). Laparoscopic myomectomy was performed by using 10-mm scope (Karl Storz, Tuttlingen, Germany) and three secondary ports. Diluted vasopressin (20 U in 60 ml of saline, 10 units was maximally injected at a time) was injected subserosally at the planned hysterotomy site and transverse hysterotomy incision was performed using unipolar hook. After the identification of the cleavage plane, the fibroid was enucleated by means of adequate traction with a strong grasper and counter traction maneuvers with another grasping forceps. Bipolar forceps was used to coagulate bleeding points. In barbed suture group, two layers of continues barbed sutures were used to close myoma bed [24-cm × 24-cm 0 polydioxanone double-armed suture on a 26-mm half circle reverse cutting needle (STRATAFIX™ Spiral PDO Knotless Tissue Control Device, Ethicon Inc, Somerville, NJ, USA)]. The ends of the barbed sutures were cut flushed with uterine surface. In the conventional suture group, the myoma bed was closed by two layers of continuous conventional suture with intracorporeal knot tying [2-0 polyglactin 910 suture (VICRYL™.; Ethicon Inc, Sommerville, NJ)]. The fibroids were removed with a Steiner (Karl Storz Tuttlingen, Germany) automatic morcellator. Surgically removed myomas were sent for pathological examination. The surgeon assessed the degree of suturing difficulty after the end of the operation using a visual analog scale (VAS) ranging from 1 (least difficult suturing) to 10 (most difficult suturing). The patients were asked to attend the follow up visits every 3 months till the end of the first year after the operation.

The primary outcome was the operative time (from the insertion of Veress needle till desufflation) and the secondary outcomes were suturing difficulty, suturing time of myoma bed, blood loss during the procedure (the difference between the aspirated and irrigated fluids), the decline in hemoglobin percent (difference between Hb% measured one week before the procedure and Hb % measured 24h after the procedure), paralytic ileus time (time from the end of the procedure to the passage of stool or gas, and perioperative complications (hemorrhage, fever, injury of bowel, genital system or urinary tract).

Statistical methods

The largest randomized controlled trial comparing laparoscopic myomectomy using conventional suture with open myomectomy was used for sample size calculation (4). This study revealed that the mean operative time in the laparoscopic myomectomy group was 98 ± 13 min. We estimated that 10 % reduction in the operation time is of clinical interest. Power calculation indicated that a sample size of 46 patients was needed in each group to detect more than 10 % decrease in operative time in laparoscopic myomectomy using barbed suture group with an alpha error level of 5% and a beta error of 95%. Chi square (x^2) test was used to compare categorical variables and Student's t was used to compare continuous variables. We used Yats correction equation when the expected frequency was less than 5. A probability value (p value) of less than 0.05 was considered statistically significant.

Results

During the study period, 158 consecutive patients with symptomatic myomas were assessed for eligibility. Fifty eight patients did not meet the inclusion criteria and 8 patients declined to participate in the study. The flow of the patients through the study is shown in Fig 1.

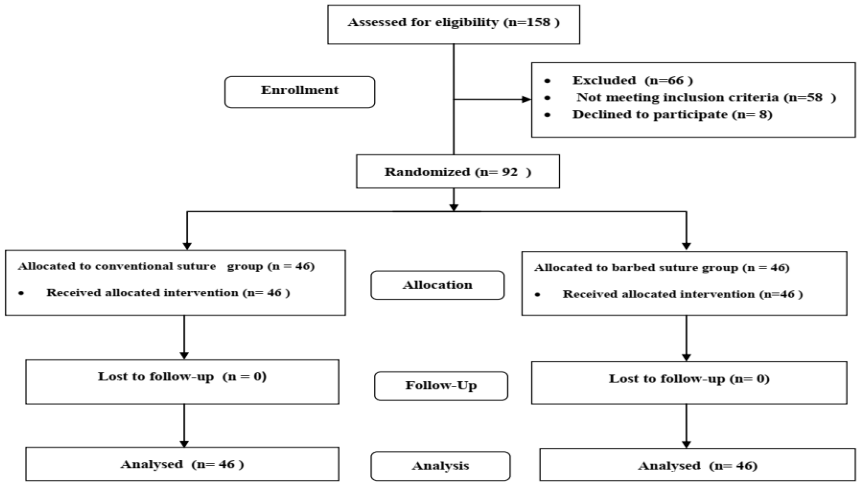

Figure (1): Flow chart

Both group were comparable with regard to age, gravidity, parity, body mass index and indications of myomectomy (Table 1). No significant differences were detected between both groups with respect to number, site and location of myomas. Moreover, the uterine size and the diameter of largest myoma were comparable between both groups (Table 2).

Table (1) Demographic characteristics

	Conventional suture	Barbed suture	p-value
Age	32.83±4.24	32.98 ±5.97	0.888
Gravidity	1.17±1.18	1.22±1.41	0.873
Parity	0.72±0.93	0.74±1.08	0.918
BMI(kg/m²)	27.32±3.37	26.53±2.89	0.23
Indications of myomectomy			
• **Pain**	8/46(17.39%)	6/46(13.04%)	0.933
• **Bleeding**	12/46(26.09%)	13/46(28.26%)	
• **Infertility**	22/46(47.83%)	22/46(47.83%)	
• **Pressure symptoms**	4/46(8.7%)	5/46(10.87%)	

Values are expressed as mean ± SD or n/n%

Suturing with barbed suture was easier than suturing with conventional suture (3.04±1.47 Vs. 4.75± 1.35, P < 0.001). Suturing time of the myoma bed was significantly shorter in the barbed suture group (14.98±4.81 Vs 22.09±6.9 min ; P < 0.001). Operative time was comparable between both groups (69.67±17.63 Vs 74.15±19.79 min; P = 0.255). The drop in Hb% and the mean intraoperative blood loss were significantly higher in conventional suture group (1.13±0.53 Vs 0.82±0.44; p =0.003 and 337.24±234.15 ml Vs 211.3±107.62 ; P = 0.002, respectively) (Table 3). No peri-operative complications were reported in either group. During the first year after the operation, 22 patients in each group attempt to conceive either naturally or by assisted conception. Table. 4 shows the pregnancy outcomes of those patients.

Table (2) Myoma characteristics

	Conventional suture	Barbed suture	p-value
Uterine size(weeks)	12.65±2.068	13.04±2.18	0.38
Diameter of greatest myoma (cm)	6.49±1.7	6.78±1.66	0.405
Number of myomas			
• **1 myoma**	32/46 (69.57%)	28/46 (60.87%)	0.561
• **2 myomas**	7/46 (15.22%)	11/46 (23.91%)	
• **3 myomas**	7/46 (15.22%)	7/46 (15.22%)	
Type of myoma			
• **Subserous**	20/67 (29.85%)	19/71 (26.76%)	0.734
• **Interstitial**	45/67 (67.16%)	51/71 (71.83%)	
• **Broad ligament**	2/67 (2.99%)	1/71 (1.41%)	
Location of myoma			
• **Anterior**	17/67 (25.37%)	19/71 (26.76%)	0.629
• **Posterior**	17/67 (25.37%)	23/71 (32.39%)	
• **Lateral**	7/67 (10.45%)	4/71 (5.63%)	
• **Fundal**	26/67 (38.81%)	25/71 (35.21%)	

Values are expressed as mean ± SD or n/n (%)

Table (3) Operative and postoperative outcomes

	Conventional suture	Barbed suture	p-value
Operative time (min.)	74.15±19.79	69.67±17.63	0.255
Suturing time (min.)	22.09±6.9	14.98±4.81	< 0.001
Blood loss (ml)	337.24±234.15	211.3±107.62	0.002
Weight of myomas (grams)	394.11±242.16	425.91±182.18	0.479
Suturing difficulty	4.75± 1.35	3.04±1.47	< 0.001
ΔHemoglobin (gm/dl)	1.13±0.53	0.82±0.44	0.003
Paralytic-ileus time (hours)	7.39±1.37	7.04±2.01	0.336
Discharge time (hours)	49.04±4.95	50.09±6.84	0.404

Values are expressed as mean ± SD

The surgeon assessed the degree of suturing difficulty using a VAS scale ranging from 1 (least difficult suturing) to 10 (most difficult suturing).

Table (4) Pregnancy outcomes in patients who attempted to conceive after laparoscopic myomectomy

	Conventional suture	Barbed suture	p-value
Number of patients	22	22	
Pregnancy rate	11/22 (50%)	12/22(54.54%)	0.763
Conception			
• **Assisted**	6/11 (54.54%)	7/12 (58.33%)	0.855
• **Spontaneous**	5/11 (45.45%)	5/12 (41.67%)	0.855
Miscarriage rate	2/22 (9.09%)	2/22(9.09%)	1.00
Live birth rate	9/22(40.91%)	10/22(45.45%)	0.761
Mode of delivery			
• **Cesarean section**	8/9 (88.89%)	9/10 (90%)	0.937
• **Vaginal delivery**	1/9 (11.11%)	1/10 (10%)	0.937
Gestational age at delivery	38.22± 0.97	37.9± 1.79	0.629

Values are expressed as n/n (%) mean ± SD unless otherwise stated

Discussion

The data presented in this study revealed that the bidirectional barbed suture (Stratafix) reduces the time needed to suture the myoma bed compared with the conventional suture (Vicryl). Moreover, the use of barbed suture resulted in a shorter mean operative time; however, the difference was not statistically significant. The reduction in the suturing time in the barbed suture group in comparison to conventional suture group can be attributed to the fact that there is no need to tie the knot on either ends of suture line or to apply tension on the continues suture. Rapid control of bleeding from myoma bed and uniform tension applied on the suture thread are probably the causes of less intraoperative blood loss in barbed suture group (12,13,14).

The results of the current study are in agreement of several prospective and retrospective studies which revealed that the use of barbed sutures in myoma bed closure during laparoscopic myomectomy was associated with a reduction in the suturing time of myoma bed and blood loss as compared with conventional sutures (12,13,14,15,16,17). A small randomized controlled study comparing the effectiveness of unidirectional knotless barbed suture and continuous suture with intracorporeal knots in the repair of myoma bed during laparoscopic myomectomy revealed that the use of barbed sutures reduced the suturing time of myoma bed and the intraoperative blood loss.

The operative time was shorter in the barbed sutures group but the difference failed to reach statistical significance (12). A randomized controlled study compared the effectiveness of barbed suture with conventional suture using either extracorporeal or intracorporeal knots in repairing the myoma bed after

laparoscopic myomectomy. The authors reported that the suturing time of myoma bed was shorter in the barbed suture group than in the conventional suture groups. The operative time was comparable between the three groups (13). A randomized controlled study comparing the use of barbed sutures with conventional sutures in the closure of uterine wall defect during laparoscopic myomectomy revealed that the use of barbed sutures in myoma bed closure was associated with reduction in the suturing time, operative time and intraoperative blood loss (14).

A multicenter retrospective study including 720 patients with symptomatic uterine fibroid compared the surgical outcome after laparoscopic myomectomy using conventional interrupted suture or continuous barbed suture. The study revealed that the operative time, drop in Hb% and blood loss were significantly lower in continuous barbed suture group (52 ± 19 Vs 67 ± 21 min, P = 0.001, 1.2 ± 0.2 Vs 2.1 ± 0.3 g/dl, P = 0.003 and 135 ± 35 Vs 215 ± 55 ml, P = 0.006 respectively) (16).

The data presented in the present study revealed that the barbed suture facilitates suturing the myoma bed during laparoscopic myomectomy. Our results are in agreement with several randomized controlled studies which revealed that the use of barbed sutures facilitates suturing of the uterine defect during laparoscopic myomectomy, vaginal vault during laparoscopic hysterectomy and endometrioma bed after laparoscopic excision of endometrioma (10,12,13,17,18). Since myomectomy is often performed in patients who desire future childbirth, the integrity of uterine scar and occurrence of postoperative adhesions are important aspects that should be considered in selection of the route of myomectomy and the type of suture used in the repair of uterine defect (14). The presence of barbs at equal distance on the surface of barbed suture thread allows perfect apposition of tissues and creates even distribution of tension across the wound and therefore improves tissue healing. Moreover, the absence of knots minimizes inflammatory reaction which interfere with proper wound healing (8,9). Giampaolino et al used office transvaginal hydrolaparoscopy to detect adhesions formation in a series of 32 who underwent laparoscopic myomectomy using conventional suture or bidirectional barbed suture. The authors reported that the adhesion formation rate was comparable between both groups (26.7% vs. 21.4% p = 0.5) (14).

Animal studies comparing adhesion formation rate following uterine incision closure using barbed or conventional sutures have controversial results. Einarsson et al reported that the closure of uterine incision in a sheep model with barbed suture was not associated with an increase in the severity of adhesions formation as compared with conventional suture (19). Api et al, compared the use of barbed suture with conventional suture for uterine incision closure in a rat model. The authors found that adhesions scores and inflammatory cell scores were significantly higher in the barbed suture group (20).

The current study is the first randomized controlled trial which compared pregnancy outcomes after laparoscopic myomectomy using barbed sutures and conventional sutures. The results of our study are in agreement with two studies which reported that the pregnancy outcomes after lapaoscopic myomectomy using

barbed sutures were comparable to pregnancy outcomes reported in the literature after lapaoscopic myomectomy using conventional sutures (21,22). In a retrospective study, Sandberg et al reported that 21 out of the 39 patients who attempted to conceive after lapaoscopic myomectomy using barbed sutures become pregnant either naturally or by assisted conception. The mean duration between the operation and the conception was 9.64 months. At the time of analysis, 13 patients had live births, 9 patients miscarried and 3 patients had ongoing pregnancies. Eleven patients delivered by cesarean section and 2 patients delivered vaginal. The mean gestational age at the time of delivery was 38 weeks and 6 days (21). Moreover, a prospective study evaluating the reproductive outcomes of 61 infertile patients who underwent laparoscopic hysterectomy using barbed suture revealed that 34 patients conceived spontaneously and 11 patients conceived by assisted conception during the follow up period (2.9 ±1.0 year). The mean duration between the operation and spontaneous conception was 5.7± 3.9 months. At the time of analysis, one patient terminated pregnancy voluntary, 5 patients miscarried and 10 patients had ongoing pregnancies. Seventeen patients delivered by cesarean section and 12 patients delivered vaginal (22). The randomized controlled design, large sample size, and the fact that all the operations were performed by the same operator are the main strengths of this study. On the other hand, the short follow up period was the main limitation of the study.

Conclusion

The knotless barbed suture facilitates suturing of the myoma bed during laparoscopic myomectomy. Compared with conventional suture, barbed suture reduces the time needed to suture the myoma bed and the intraoperative blood loss but not the operative time.

Conflict of interest

There is no conflict of interests

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