

Study to Evaluate the Efficacy of Barbed Unidirectional Suture in Total Laparoscopic Hysterectomy

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Abstract:

Background: The Hysterectomy procedure is the most frequently performed gynecological surgery in the world. The minimally invasive approach to hysterectomy has been associated with improved outcomes when compared to the abdominal approach, including decreased morbidity, shorter hospital stay, and quicker return to normal activities. Present study was conducted to evaluate the efficacy of barbed unidirectional suture compared to polyglactin 910 in total laparoscopic hysterectomy.

Material and Methods: Present study was single-center, prospective, comparative study conducted in female patients attending gynaecology OPD for complaints of uterine leiomyomas, adenomyosis, abnormal uterine bleeding, chronic pelvic inflammatory disease, endometriosis Not responding to medical management and willing for surgery were considered for this study.

Results The mean age, mean BMI & indication for surgery were comparable in both groups & no statistically significant difference was noted. In present study, no difference when two groups were compared statistically with respect to previous surgeries & preoperative morbidity. The mean time for surgery & mean time taken for Vaginal cuff closure in was more in group A compared to Group B with significant difference. ($p < 0.05$) The mean haemoglobin deficit, time taken for post operative mobility, time taken for First voiding of urine & duration of hospital stay were comparable in both groups & no statistically significant difference was noted. There was no difference when two groups were compared statistically with respect to post operative complaints (Fever, Ileus, Abdominal Pain, Spotting, Discharge P/V, Urinary Complaints & Low Back Ache) during follow up. ($p > 0.05$). There were no post operative complications among both the groups.

Conclusion: The present study concludes that the unidirectional barbed suture significantly reduces vaginal cuff closure time along with total operative time.

Keywords: Barbed Suture, Vaginal Cuff Closure Time, Total Operative Time, Polyglactin 910.

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Introduction

The Hysterectomy procedure is the most frequently performed gynecological surgery in the world. This procedure can be carried out using an abdominal, vaginal, and laparoscopic approach. The percentage of hysterectomies performed via laparoscopy varies. The most common benign indications for hysterectomy include uterine leiomyomas, adenomyosis, abnormal uterine bleeding, endometriosis, and uterine prolapse. [1]

Now, several variations of laparoscopic hysterectomy are available, including robot-assisted laparoscopic hysterectomy, laparoendoscopic single-site surgery (LESS), and natural orifice transluminal endoscopic surgery (NOTES). The minimally invasive approach to hysterectomy has been associated with improved outcomes when compared to the abdominal approach, including

decreased morbidity, shorter hospital stay, and quicker return to normal activities.[2]

Vaginal and laparoscopic hysterectomies have been clearly associated with decreased blood loss, shorter hospital stay, speedier return to normal activities, and fewer abdominal wall infections when compared with abdominal hysterectomies. [3,4] In minimally invasive hysterectomy, the vaginal cuff is sutured closed by a variety of possible techniques. Institutional and individual variation exists between the following elements of cuff closure: intracorporeal versus transvaginal closure, suture material, and suture technique. [5]

In recent years, a new class of suture material—barbed suture—has been introduced into the surgeon's armamentarium. These synthetic sutures eschew the traditional, smooth, knot-requiring

characteristic of sutures in favor of barbs that serve to anchor the sutures to tissue without knots.[6] Present study was conducted to evaluate the efficacy of barbed unidirectional suture compared to polyglactin 910 in total laparoscopic hysterectomy.

Material and Methods

Present study was single-center, prospective, comparative study conducted Obstetrics and Gynaecology department, S.N. Medical College, Agra. Ethical clearance was taken from the Institutional Ethical Committee. Study duration was of 2 years (November 2019 to October 2021).

Inclusion Criteria

- Female patients attending gynaecology OPD for complaints of uterine leiomyomas, adenomyosis, abnormal uterine bleeding, chronic pelvic inflammatory disease, endometriosis Not responding to medical management and willing for surgery were considered for this study.

Exclusion Criteria

- Women with gynecological carcinomas
- Women with abdominal skin lesions or infections
- Women having cardio-respiratory risk for general anaesthesia.

Personal history. Age, body mass index (BMI) and clinical and a detailed history including parity, obstetric history, symptoms and any surgical or medical history about each patient's disease were collected at the time of admission. A thorough pelvic examination was done to assess the version, size, mobility and tenderness of Uterus along with any palpable adnexal mass. All the required investigations were done to check fitness for surgery and detect any existing comorbidity.

After meeting the all above written criteria patients are randomly allocated in two groups-

1. **Group A:** In control group coated polyglactin 910 suture of No.1 of 90cm with 40mm half circle taper cut needle was used for vaginal cuff closure in total laparoscopic hysterectomy. Suturing of vaginal cuff also intend to bring the uterosacral and cardinal ligaments, as well as the rectovaginal fascia, together. The first suture is tied intracorporeally at the right lateral angle and securing it in a figure of eight manner. Same procedure repeated at left lateral angle. Rest of the vaginal cuff is closed taking one or two interrupted suture incorporating the uterosacral ligaments, cardinal ligaments, and posterior vaginal fascia together.
2. **Group B:** In the case group vaginal cuff closure was achieved laparoscopically using a 30 cm 1-

0 polyglyconate unidirectional barbed suture with a 37mm half circle taper point needle.[37] Barbed sutures are manufactured by slicing longitudinal "barbs" into straight sutures and then adding a looped closure or needle at each end. Maintaining the pneumoperitoneum using vaginal delineator tube first suture is taken at the lateral angle of the vaginal cuff, securing it by passing the needle in the loop at the end of the barbed suture. Next sutures were taken at every 1 cm distance in running fashion upto the lateral angle of the other side and then cut and left there without tying any knot. Uterosacral ligaments, cardinal ligaments and posterior vaginal fascia were incorporated in the vaginal cuff to provide support to the vault.

Indication for hysterectomy, total operative time, vaginal cuff closure time, Haemoglobin deficit, time taken for post operative mobility, time of first voiding of urine, time taken for post operative acceptance of oral liquids, duration of hospital stay, post operative complaints (fever, abdominal pain, urinary complaints, low backache, wound dehiscence, discharge or spotting from vagina were noted. Patient was fully informed about the warning sign and had received a follow up appointment and medication.

Postoperative complications were:

- Minor complications include Urinary Tract Infections, postoperative ileus, wound infection, postoperative pyrexia of $>101^{\circ}\text{F}$ and vault hematomas that are manageable conservatively.
- Major postoperative complications include significant bleeding requiring return to theatre, vault/ wound dehiscence and vault hematomas requiring surgical intervention.

Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi-square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

Results

The present study was conducted in 30 patients undergoing total laparoscopic hysterectomy. The mean age, mean BMI & indication for surgery were comparable in both groups & no statistically significant difference was noted. ($p>0.05$)

Table 1: General parameters

Parameter	Group A (Conventional Polyglactin 910)	Group B (Barbed Suture)	p-value
Mean age	48.67±6.99	47.47±6.82	0.6378
Mean BMI (kg/m ²)	28.60±5.99	27.81±5.41	0.695
Indication for surgery			0.558
Uterine leiomyomas	08 (53.3 %)	05 (33.3 %)	
Adenomyosis	02 (13.3 %)	04 (26.7 %)	
Abnormal uterine bleeding	01 (6.7 %)	02 (13.3 %)	
Chronic PID	03 (20 %)	01 (6.7 %)	
Endometriosis	01 (6.7 %)	02 (13.3 %)	
Uterine leiomyomas	08 (53.3 %)	05 (33.3 %)	
Adenomyosis	02 (13.3 %)	04 (26.7 %)	

In present study, no difference when two groups were compared statistically with respect to previous surgeries & preoperative morbidity. (p>0.05)

Table 2: Previous surgeries & preoperative morbidity

Surgery	Group A (Conventional Polyglactin 910)	Group B (Barbed Suture)	p-value
Previous surgeries			0.695
Caesarean	05 (33.3 %)	03 (20 %)	
Tubectomies	04 (26.7 %)	02 (13.3 %)	
Ectopic	01 (6.7 %)	02 (13.3 %)	
Adnexectomy or Cystectomy	01 (6.7 %)	02 (13.3 %)	
Conization	01 (6.7 %)	00	
Myomectomy	00	01 (6.7 %)	
Appendicectomy	02 (13.3 %)	01 (6.7 %)	
Preoperative Morbidity			0.527
Diabetes Mellitus	02 (13.3 %)	01 (6.7 %)	
Hypertension	03 (20 %)	02 (13.3 %)	
Asthma	01 (6.7 %)	00	
Tuberculosis	00	01 (6.7 %)	

The mean time for surgery & mean time taken for Vaginal cuff closure in was more in group A compared to Group B with significant difference. (p<0.05) The mean haemoglobin deficit, time taken

for post operative mobility, time taken for First voiding of urine & duration of hospital stay were comparable in both groups & no statistically significant difference was noted. (p>0.05)

Table 3: Study related parameter

Parameter	Group A (Conventional Polyglactin 910)	Group B (Barbed Suture)	p-value
Time Taken for Complete Surgery (in Min)	74.40±10.82	62.80±7.40	0.0019
Time Taken for vaginal Cuff closure (in Min)	16.53±3.80	9.67±2.87	<0.0001
Blood loss measured by haemoglobin Deficit (pre & post operative Hb difference)	1.04±0.49	0.92±0.46	0.4949
Time Taken for post op mobility (in hours)	29.80±8.07	29.73±8.12	0.9733
Time Taken for first voiding of urine (in hours)	26.87±7.28	26.20±5.53	0.7786
Duration of hospital stay (in days)	3.07±1.03	2.67±1.23	0.3425

There was no difference when two groups were compared statistically with respect to post operative complaints (Fever, Ileus, Abdominal Pain, Spotting, Discharge P/V, Urinary Complaints & Low Back

Ache) during follow up. (p>0.05). There were no post operative complications among both the groups.

Table 4: Post operative complaints during follow up

Complaints	Group A (Conventional Polyglactin 910)	Group B (Barbed Suture)
Fever	02 (13.3 %)	01 (6.7 %)
Ileus	00	01 (6.7 %)
Abdominal Pain	03 (20 %)	02 (13.3 %)
Spotting	02 (13.3 %)	01 (6.7 %)
Discharge P/V	04 (26.7 %)	02 (13.3 %)
Urinary Complaints	01 (6.7 %)	00
Low Back Ache	02 (13.3 %)	01 (6.7 %)

Discussion

In the scientific literature, the rate of complications of vaginal cuff closure post laparoscopic hysterectomy ranges from 0 to 5%, [2] the most common complications being: vaginal bleeding, dehiscence of the vaginal cuff and infection. Numerous strategies were undertaken in order to decrease such complications. One solution has been the introduction of the unidirectional barbed suture for vaginal cuff closure. The latter has demonstrated a lower technical difficulty [3,4] as well as a decrease in the surgical time, intraoperative complications and a lower incidence of suture dehiscence. The use of the barbed suture has been described in multiple gynecological procedures, such as the hysterectomy, myomectomy and colposacropexy.

An ideal suture for vaginal cuff closure should minimize bacterial growth, elicit minimal tissue reactivity, be pliable, and maintain a reasonable amount of tensile strength for at least 3 to 4 weeks. This suture is not chromic gut, which has been demonstrated to lead to more postoperative granulation tissue.[7] In open or vaginal procedures in which cold-knife techniques are typically used at the cuff, polyglactin 90 usually performs well given its low stiffness pliability and early absorption profile. However, in closed procedures such as laparoscopic or robotic hysterectomies where thermally injured tissues heal more slowly and the risk of cuff dehiscence is increased, polyglactin 90 is a less attractive option.[8]

In the present study, the mean age in group A was 48.67±6.99 years and group B was 47.47±6.82 years. There was no significant difference in age distribution in two groups. ($p>0.05$). Prathap Talwar et al., [9] observed Mean age of women in group I (barbed) was 45.74 ± 4.96 years and that in group II (Polyglactin 910) was 44 ± 6.29 years, without significant differences in age. Similar findings were noted by Kavita Khoiwal et al.,[10]

In a study done by Herraiz RJL et al., [11] The use of barbed suture for vaginal cuff closure also observed in previous surgeries most common was Caesarean (14.9%) followed by Adnexectomy (6%) but no statistical significance was noted between the two groups in terms of previous surgeries. Similar findings were noted in present study.

Lopez et al., [12] study Myomatosis was the most common indication for surgery in both the groups (68.4% in conventional group and 79.9% in Barbed group) followed by Abnormal uterine bleeding with no significant difference (p value 0.13). Similar findings were noted in present study.

In the present study, the mean time taken for total surgery in group A was 74.40±10.82 and group B was 62.28±7.40 minutes. The total operative time was significantly less with the barbed unidirectional suture (p value 0.0019). This also depends on the surgical difficulty due to obesity, pelvic adhesions, malfunctioning of instruments etc.

In a study done by Song et al., [13] on Barbed (Group I) vs Traditional suture (Group II) in single port total laparoscopic hysterectomy, observed that Mean (SD) operative time for the entire surgical procedure was shorter in the barbed suture group (92.0±33.5 min) than in the traditional suture group (105.2±31.4 min) ($p=0.002$). Similar findings were noted by Bogliolo et al., [14] and Zhou et al., [15]. There are some studies which shows no significant difference in overall operating time in both groups like Medina et al., [16] & Kavita Khoiwal et al., [10].

Prathap Talwar et al.,[17] study on Barbed (Group I) vs Polyglactin 910 (Group II) for use of laparoscopic vaginal cuff closure observed average time taken for suturing vaginal vault was 6.9 minutes (SD = 1.27 minutes) while using polyglactin 910 suture, whereas in group II where barbed suture was used, the suturing time was 5.39 minutes (SD = 0.76 minutes) with a significant p value of <0.0001 . This finding was similar to present study, Kavita Khoiwal et al., [10] & Kim et al., [18].

Barbed sutures have significantly reduced the time required for suturing and the degree of surgical difficulty in a randomized clinical study by Ardovino et al., [19] comparing the feasibility and safety of barbed bidirectional sutures vs standard sutures for vaginal cuff closure following total laparoscopic hysterectomy and lymph node dissection for early endometrial cancer.

In the present study, there was no difference when two groups were compared statistically with respect to post operative complaints during follow up. ($p>0.05$) There was no difference when two groups

were compared statistically with respect to post operative complications. ($p>0.05$)

Prathap Talwar et al., [17] study on Barbed (Group I) vs Polyglactin 910 (Group II) for use of laparoscopic vaginal cuff closure observed three intraoperative complications reported of which two cases had bladder injury due to previous LSCS and one case had a rectal serosal injury due to dense endometriotic adhesions. These were not related to the suturing technique but were related to the surgical difficulty due to adhesions.

Kavita Khoiwal et al., [10] studied unidirectional Barbed Suture Versus Polyglactin 910 Suture for Vaginal Cuff Closure in total laparoscopic hysterectomy observed postoperative variables, such as pain and complications, were comparable in both groups. At the six weeks, three months, and six months follow-up visits (physically or telephonically), no patients had vaginal discharge, vault hematoma, dehiscence, or abscess. No patient in either group had dyspareunia.

Rombaut et al., [20] reported a case of bowel obstruction due to bidirectional suture causing terminal ileal strangulation following laparoscopic myomectomy. In another case report by Thubert et al., [21] the patient was diagnosed 1 month after undergoing laparoscopic sacrocolpopexy with peritoneal closure using a barbed suture, with small bowel volvulus and mesenteric rupture.

Barbed sutures are absorbable sutures with a surgical needle at one end and an annular coil component at the other end. This suture self-anchors at approximately every 1 mm of tissue, resulting in an evenly distributed tensile strength along the total length of the wound without the need for tying knots. The presence of tiny barbs spaced evenly in a helical array require less technical skill for performing swift suturing and less time than conventional suturing.

Barbed sutures are expensive yet considered safe and well-tolerated for vaginal cuff suturing, and they decrease operative time, as it overcomes a major hurdle of intracorporeal knotting with conventional sutures. However, passing the needle through the end of the loop of the unidirectional barbed suture (V-Loc) is also a necessary skill. In the altered environments of laparoscopic and robotic hysterectomies, cuff closures with barbed sutures have flourished. The reduced operative times and simplicity of the closure make the use of barbed suture a good choice for this application. [22,23]

Conclusion

The present study concludes that the unidirectional barbed suture significantly reduces vaginal cuff closure time along with total operative time. It is a safe, effective and well tolerated alternative to the conventional polyglactin 910 suture for vaginal cuff

closure in total laparoscopic hysterectomy without increasing the risk of postoperative complications, particularly where affordability is not an issue and resources are accessible.

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