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Late suture site complications of sacrospinous ligament fixation

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ABSTRACT

Study objective: To evaluate the late suture- related complications of sacrospinous ligament fixation (SSLF) as a treatment for uterovaginal prolapse and their impact on the quality of life.
Design: A prospective cohort study.
Settings: The Obstetrics and Gynecology Department of Suez Canal University Hospitals, Ismailia, Egypt from January 2014 to June 2018.
Patients: We recruited sixty women with uterovaginal prolapse.
Interventions: Patients underwent SSLF using the Capio suture recapturing device with non-absorbable suture material (0 braided Polyester). Postoperative visits were at six weeks then at 6, 12, 18, and 24 months after the procedure.
Measurements and main results: Outcome measures were the rate and timing of suture- related and the quality of life using the pelvic floor impact questionnaire-7 at 24 months postoperatively. The mean age of the studied population was 45.7 ± 9.8 years. Suture- related complications occurred in 55% (33/60) of patients, with vaginal discharge the most commonly reported symptom. Most of them presented in the 1st year after the procedure 72.7% (24/33), and 25% (15/60) had suture removal. However, there was a significant improvement in patients' quality of life.
Conclusion: Sacrospinous ligament fixation has a positive impact on the quality of life, yet associated with significant but prominent suture- related complications.

Introduction

Pelvic organ prolapse affects 5–10% of women with about 14% presented with evidence of apical prolapse [1–3]. Many surgical procedures are available to treat apical prolapse, including sacrospinous ligament fixation as a primary and straightforward procedure. It gives significant results; however, urinary, sexual, and rectal dysfunction are common consequences, which may be related to the anatomical alteration resulting from the procedure [4–6].

SSLF was done with non-absorbable suture material to achieve long-lasting repair and to decrease recurrence rates as much as possible. One of the most commonly used suture material is the braided polyester sutures; it has excellent handling properties and increased tensile strength over monofilament sutures of similar diameter [7].

However, whether such sutures may result in late morbidity or not is still away from the scope of evidence. So, the current work aims at evaluating delayed suture- related complications and their impact on patients' QOL.

Materials and methods

After approval of the Ethics Committee of Suez Canal University Hospitals, this prospective cohort study was conducted at the Obstetrics and Gynecology Department from January 2014 to June 2018. All participants gave oral and written informed consent before entering the study.

This study included (84) women with clinical evidence of uterovaginal prolapse. They met the following inclusion criteria; (a) patients with uterine prolapse, (b) patients with vault prolapse [(a) or (b) = prolapse more than grade (I) Pelvic Organ Prolapse/ Quantification (POP/Q) system] [8], and (c) patients underwent prophylactic SSLF during vaginal hysterectomy if the vault (point C on the POP-Q system) descends to the introitus during the closure (grade II) [9]. Patients failing to continue 24 months follow- up,

Abbreviation: POP-Q, pelvic organ prolapse quantification system; SSLF, sacrospinous ligament fixation; QOL, quality of life.

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either due to inability to maintain the study protocol, failed apical support after SSLF, or due to loss of contact were excluded. Only 60 women completed the study.

All included patients had a complete medical history, including name, contact details (address and telephone number), age, educational level, job, smoking status, parity, and mode of delivery. Patients' weight and height were measured, and BMI was calculated.

The pre-operative assessment included pelvic ultrasound to rule out any pelvic finding that indicates abdominal hysterectomy, Pap smear to exclude any abnormal cervical cytology mandating more evaluation, evaluation of the degree of uterovaginal prolapse during Valsalva's maneuver, and clinical assessment for evidence of urinary incontinence to consider the need for additional intervention.

The surgical technique used was as described by Stanford [10]. This procedure was done utilizing a disposable throw-and-catch suturing device (Capio, Boston Scientific Corp, Natick, MA). The Capio needle driver was used to deliver 0 braided polyester non-absorbable sutures, taper cut/half circle taper needle (Teleflex) through the sacrospinous ligament.

The vaginal mucosa of the posterior fornix was grasped with clamps. Midline incision in the mucosa downwards was done about 5 cm long. The dissection was made gently downward into the rectovaginal space. The loose tissue of the para-rectal space was divided gently with blunt dissection with the index finger. The ischial spine and sacrospinous ligament were palpated to identify the suture site accurately.

The 2 sutures were placed through the right sacrospinous ligament (unilateral SSLF) side by side 1 fingerbreadth medial to the ischial spine and then attached to the fibro-muscular layer of the vagina, in cases of vaginal vault prolapse (not including the surface epithelium), or to the body of the cervix underneath the suture line, in cases of uterine prolapse. Pulley stitches were done by the other end of the sutures on either side of the vaginal incision. The SSLF sutures - on either side of the vaginal incision- were tied first to bring the apex of the vagina up against the right sacrospinous ligament [10].

Postoperative evaluation was done at six weeks then 6, 12, 18, and 24 months. The assessment focused on suture related complications as exposed suture, granulation tissue formation, vaginal bleeding, discharge, and pain, as well as patients, needed suture removal. For each case of suture-related complications, we recorded the time of presentation. For patients requiring additional surgery or medical treatment, we also recorded the date of treatment and the surgical outcomes. Also, we evaluated recurrence rates after the operation.

Quality of life was assessed using pelvic organ prolapse impact questionnaire-7 (POPIQ7) part of pelvic floor impact questionnaire-7once preoperative and again 24 months after the procedure. The questionnaire included seven questions that evaluate the patient's quality of life as part of the pelvic floor impact questionnaire-7. All of the items use a response scale: 0, Not at all; 1, somewhat; 2, moderately; 3, quite a bit. Scale Scores are obtained using the mean value for all of the answered items within the corresponding scale (possible value 0–3) and then multiply by (100/3) to obtain the scale score (range 0–100). Missing items are dealt with by using the mean from answered questions only [11]. One of the research team was always available for any help.

Institutional review board

This study was conducted after approval from our IRB.

Informed consent

Was obtained from all participants before recruitment.

Table 1
Summary data.

Data	Number (%)
Total number of cases	84
Cases excluded	24
Cases analyzed	60
Mean patient age (years)	45.7
The total length of follow up (months)	24
Patients with prior surgery	50 (78 %)
Patients with prior hysterectomy	12 (20 %)

Results

This study included 84 women who underwent SSLF from January 2014 to December 2015. The follow-up period was 24 months after the procedure. Twenty-four patients dropped out (loss of contact, failed apical support in three patients, or unable to continue the study), leaving a total number of 60 patients completed the follow- up visits [Table 1].

The women's age ranged between 28–65 years, with a mean age of 45.7 years. More than half of the patients were multipara (75%) and delivered vaginally (75%). Most of the patients (70%) were free of risk factors for the development of POP [Table 2].

The included patients had grade II or more apical compartment prolapse according to the POP-Q system. Recurrent prolapse, with or without symptoms, affected the anterior compartment (15 cases, 25%), predominantly. Only three patients had a failure of apical support and were excluded from the study [Table 3].

Suture-related complications occurred in 55% of patients (33 out of 60). The majority of complicated cases, (24/33) presented in the 1st year after the procedure.

Vaginal bleeding, in the form of intermenstrual bleeding as well as contact bleeding, was reported in 15% of the patients (9 of 33). Fifteen patients (25%) required suture removal because of bothersome bleeding or discharge. We removed the stitches successfully in the office in three women. However, twelve required a return to the operating room. Eighteen (30%) patients suffered from more than one complication (pain and watery vaginal discharge were predominant). There was no significant difference between patients who undergone vault fixation and those who had hysteropexy except for bothersome watery vaginal discharge and deep-seated pain. Regarding buttock pain, there was

Table 2
Demographic data among the studied population.

Variable		No (%)
Age (years)	< 36	9 (15 %)
	36–50	36 (60 %)
	>50	15 (25 %)
Parity	Para1	3 (5 %)
	MP	45 (75 %)
	GMP	12 (20 %)
Education	Non-educated	24 (40 %)
	Educated	27 (45 %)
	Highly educated	9 (15 %)
Job	Housewife	33 (55 %)
	Employee	18 (30 %)
	Advanced employee	8 (15 %)
Risk Factors	None	42 (70 %)
	One RF	12 (20 %)
	Two or more RF	6 (10 %)
BMI	19–24.9	6 (10 %)
	25–29.9	27 (45 %)
	30–40	21 (35 %)
	≥ 40	6 (10 %)

MP = multipara, GMP = grandmultipara, VD = Vaginal Delivery, CS = Cesarean Section, RF = Risk Factor (ascites, occupation related heavy weight lifting, chronic cough, and chronic constipation), BMI= Body Mass Index.

Table 3
Preoperative pelvic organ prolapse according to POP-Q system.

Grade of prolapse	Apical compartment N (%)	Anterior compartment N (%)	Posterior compartment N (%)
Grade I	0 (0%)	3 (5%)	15 (25%)
Grade II	9 (15%)	33 (55%)	33 (55%)
Garde III	36 (60%)	18 (30%)	6 (10%)
Grade IV	15 (25%)	6 (10%)	6 (10%)

Three patients reported failed apical support after SSLF and were excluded from the study. Recurrent anterior compartment prolapse was reported in 15 (25%) cases. No case had recurrent posterior compartment prolapse.

Table 4
Suture related complications.

Complication			Patients with a uterus (48) No (%)	Patients without a uterus (12) No (%)	Total (60)	P-value
Granulation tissue			18 (37.5%)	3 (25%)	21 (35%)	0.417
Bleeding			6 (12.5%)	3 (25%)	9 (15%)	0.278
Discharge			15 (31.25%)	0 (0.0%)	15 (25%)	0.025*
Pain	Deep- seated pain		9 (18.75%)	6 (50%)	15 (25%)	0.025*
	Deep dyspareunia		4 (8.3%)	3 (25%)	7 (11.6%)	0.108
	Buttock pain	3 m	44 (73.3%)			0.001*
		6 m	10 (16.6%)			
Suture removal			12 (25%)	3 (25%)	15 (25%)	1.000
Exposed suture/erosion			6 (12.5%)	2 (16.6%)	8 (35%)	0.704
Asymptomatic erosion			6 (12.5%)	3 (25%)	9 (15%)	0.278
Total suture-related complications			24 (50%)	9 (75%)	33 (55 %)	0.260

No case reported buttock pain at 24 months after the operation.

a noticeable decline in the rates of such complication over time, with no case reporting buttock pain at 24 months after the operation [Table 4].

Patients' quality of life showed significant improvement 24 months after the procedure with a p-value < 0.001 [Table 5]. There was a substantial improvement of dyspareunia six months after the operation with a P-value of 0.005.

Discussion

Principle findings

Complications due to nonabsorbable suture material occurred in more than half of the patients undergoing SSLF. These included a wide range of symptoms and signs; the most significantly reported ones were watery vaginal discharge and deep-seated vaginal pain. As a result of these suture related complications, suture removal was required in 25% of patients. There was a significant improvement in patients' quality of life 24 months after the procedure.

Results and clinical implications

Sacrospinous ligament fixation is a widely practiced surgical procedure for the treatment of uterovaginal prolapse. It can be done either using an open technique with dissection of the para-rectal space down to the ischial spine or using a minimal access surgery using the Capio suture recapturing device. Different sutures materials were used in such operation as nonabsorbable sutures (Prolene, braided polyester sutures) and absorbable ones such as (Vicryl and PDS). Non-absorbable sutures are characterized by durable repair with lower rates of recurrence. Braided polyester sutures are characterized by excellent handling properties and increased tensile strength over monofilament ones. PDS suture is characterized by prolonged tensile strength retention than Vicryl, while Vicryl is superior in easy handling [12].

Table 5
Preoperative and postoperative assessment of the quality of life.

	Pre-operative Mean ± SD	Post-operative Mean ± SD	P value
QOL (POPIQ7)	55.64 ± 23.2	12.02 ± 21.66	< 0.001*

QOL = quality of life, POPIQ7= pelvic organ prolapse impact questionnaire-7.

Each suture material would result in a wide range of complications. We used braided polyester sutures with the Capio device. Suture-related complications were seen in a high percentage of patients (55%) of cases. Exposed suture and granulation tissue occurred in 13.3% and 35% of patients, respectively. There was a similar result to Luck et al. experience with braided polyester suture with reported 31% suture erosion rates with the permanent suture compared to 9% with the absorbable suture (Vicryl) [13]. Also, Toglia showed similar results to the current findings with a total suture related complications of 36%, and vaginal bleeding was the most common bothering symptom (74%) [7].

Several factors would explain these complications. Patients with pelvic organ prolapse are commonly postmenopausal, with evidence of vaginal atrophy. In the current study, more than 50% of postmenopausal patients developed suture erosion. Besides, the sutures may be subject to constant mechanical abrasion, possibly with sexual intercourse [7].

The vaginal incision lies directly over the leading edge of the prolapsed vagina, which is typically the thinnest wall of the prolapsed tissue. The sutures for the suspension are placed directly underneath the line of the incision, which can be considered to be the most likely site for wound separation, which would explain the rates of suture erosion in our study population. Also, the development of subclinical infection or a chronic foreign body reaction to the suture material may play a role. However, this was present in only one patient with a clinically persistent vaginal infection.

Faber et al., 2008 reported a case of myositis of the gluteal region one year after SSLF with the use of prolene suture. The

infection was suggested to spread to the gluteal region through an entry port caused by the non- absorbable suture used in the procedure, which was confirmed by the presence of the causative organism in vaginal cultures. Also; MRI images reported the presence of a fistulous tract between the vaginal apex and the gluteal region [14]. Another case of an ischiorectal abscess was reported nine months after the procedure and required incision and drainage with suture removal [15].

The use of delayed absorbable suture PDS is not free from complications as would be expected. Sutures were removed in 3 cases due to different reasons from days 2–15 after the procedure in a previous study [16]. It was also associated with persistent buttock pain at six months after the operation in 5/38 (13.1%) patients [16], while we reported 10/60 (16.6%) patients in the current research at six months after the surgery.

Vicryl sutures were used in SSLF as described by Kumar et al. 2016 together with prolene sutures. However, they did not mention suture related complications in their work. They only reported that dyspareunia occurred in 1 (2.2%) patient at 6–32 months after the operation [17], while we reported deep dyspareunia in 7 patients (11.6%). In the study conducted by Ray et al., they used Vicryl and PDS sutures in two groups of patients. The reported suture related complications were granulation tissue formation with resultant vaginal bleeding in 5% and 6.1%, respectively [18] while we reported higher percentages with non- absorbable sutures (35% and 15% respectively).

There was a significant improvement in buttock pain, which decreased from 73.3% (at 3 months) to 16.6% (at six months) after the operation, with no cases of persistent buttock pain at 24 months. Valecha et al. reported that buttock pain occurred in 17.6% of his study population but resolved spontaneously in few days while Feiner et al. reported persisting thigh pain in one patient, which gradually settled in 12 months [19,20]. Our results were similar to the above- mentioned studies. This pain can be explained by injury to surrounding nerves of the sacral plexus and branches of the pudendal nerve. In an anatomical study, the pudendal nerve was found to have variable relations to the sacrospinous ligament (a branch of the pudendal nerve was seen to be piercing through the ligament in 11%) [21].

There was no significant difference between the patients who had vault fixation and those who had hysteropexy in the rates of suture related complications except vaginal discharge and deep-seated pain which was more in the patients with hysteropexy (p-value 0.025). Whether this is related to the presence of the uterus or not needs further evaluation with a large number of cases.

Although these complications are grave, they were not appropriately evaluated in previous researches with the use of non- absorbable or absorbable sutures [18,22]. The available data mentioned the harmful effects of permanent sutures in uterosacral ligament suspension or reconstructive posterior vaginal surgery with scarce data about SSLF [16,23]. It worth note that absorbable sutures were associated with fewer suture related complications than permanent ones.

The most common site of failure was the anterior compartment (15 cases, 25%). Failed apical support was noted in 3 patients only (excluded from the study). Recurrent anterior compartment prolapse was asymptomatic or minimally symptomatic in the majority of patients requiring no further treatment. All the women with a recurrent cystocele had surgery of the anterior compartment combined with SSLF, so there were no de novo cystoceles. Recurrent apical prolapse was noted three months after the operation. These results agreed with others [24,25]. Additionally, these represent higher success rates than those reported with the use of Vicryl and PDS (91.25% and 92.68%, respectively) [19].

The high rate of recurrent cystoceles may be related to the damaged neuromuscular support or maybe the result of the retroverted axis of the vagina after SSLF which is considered as an overcorrection, is responsible for the high rate of cystoceles [26]. Besides, we adopted a longer follow up period than what was reported above. Symptomatic anterior vaginal wall descent requiring treatment occurred in 3–5% of patients undergoing SSLF [27], with this study reporting no cases of symptomatic anterior wall prolapse.

These results played a significant role in the improvement of patients' quality of life after the operation that also agreed with David-Montefiore et al. [28]. Additionally, this improvement can be rendered to the disappearance of the previous POP related complications (lower abdominal pain, low back pain, recurrent heavy vaginal infections, and urinary infections).

Research implications: In this study, estrogen cream was used for two weeks, postoperatively in postmenopausal women. Whether this would alter the results or not, needs to be evaluated. Also, the effect of the bilateral fixation on the rates of suture related complications needs to be evaluated. The use of other suture materials as PDS, Vicryl, and Prolene requires more evaluation. The current study included 12/60 patients who had vault fixation. Although there was no significant difference between them and those who had a hysteropexy, more substantial number of cases would be more conclusive.

Strengths and limitations of the study

The current study was carried out with a minimal access technique to decrease postoperative morbidity. Even though we reported high rates of suture related complications compared to the literature [7,23], the study also contributes to the evaluation of the quality of life after SSLF. Weaknesses in our study included a small follow up period, a lack of comparison between premenopausal and postmenopausal women, and a lack of contrast between unilateral and bilateral SSLF.

Conclusions

In conclusion, the use of braided polyester suture for SSLF resulted in a high rate of suture-related complications. Patients presented 1–2 years after the procedure, highlighting the need for long term surveillance of patients who undergo reconstructive vaginal surgery with permanent suture materials.

Declaration of Competing Interest

The authors declare that there was no competing interest.

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