

A simple proline stitch is safe and easy to use for sacrospinous fixation: a prospective cohort study

Abstract

Purpose: Pelvic organ prolapse (POP) is common and the health care impact of prolapse is likely to expand as life expectancy increases. Simple and safe approaches resulting in minimal short-and long-term complications are desirable. We therefore tested the reliability and efficacy of the use of a simple proline stitch for their pair of vaginal vault prolapse and POP.

Methods: This was a prospective cohort study conducted between 2005 and 2010. Fifty patients with vault prolapse after vaginal hysterectomy or complete procedentia with very weak pelvic floor muscles were selected for study. All the patients under went sacrospinous fixation (SSF) with a proline stitch using a cutting needle and traditional needle holder. Patients were followed up for two years. Sacrospinous fixation was done after vaginal hysterectomy in patients with complete procedentia. Patients had to fill Pelvic Floor Impact Questionnaire-short form 7 (PFIQ-7) preoperative and 12 months later.

Results: 16 patients completely recovered from prolapse. There were thirty four complications nine were short term six patients; three had post-operative dyspareunia with concurrent vaginal infection, three patients had vaginal candidiasis alone, and three had buttock pain. All received medical treatment and showed symptom free in their next postoperative visits. Twenty-five patients had long-term complications; six patients had recurrence 18 months, nine patients had cystocele two years after surgery and ten patients had sexual dysfunction. There was significant difference between Pelvic Floor Impact Questionnaire-short form 7 (PFIQ-7) preoperative and postoperative in all items.

Conclusion: Sacrospinous fixation using a simple proline stitch is a simple procedure that can be performed without any special needle or applicator. Operative results are compared to other standard surgical procedures with only minor post-operative complications requiring simple medical therapy. Quality of life is much more improved with sacrospinous fixation.

Keywords: pelvic organ prolapse, vaginal vault prolapse, sacrospinous fixation, gynecologic surgery

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Abbreviations: POP, pelvic organ prolapse; SSF, sacrospinous fixation; PFME, pelvic floor muscle exercises

Summary

A study evaluating clinical outcomes from the use of a simple and inexpensive operative procedure for pelvic organ prolapse.

Introduction

Pelvic organ prolapse (POP) commonly affects post-menopausal women and results in herniation of the pelvic organs into or beyond the vaginal wall. Many women with prolapse experience symptoms that have a severe impact on their daily activities, sexual function, and ability to exercise, as well as on body image and sexuality.¹ Treatment of POP requires significant health care resources; the annual cost of ambulatory care of pelvic floor disorders in the United States was almost \$300 million in 2005/6,² and surgical repair of prolapse was the most common inpatient procedure performed in women older than 70 years between 1979 and 2006.^{3,4}

As prolapse advances, women may experience improvements in SUI, but increased difficulty in voiding. In advanced anterior or apical prolapse, the prolapse may “kink” the urethra, thereby resulting in symptoms of obstructed voiding, such as a slow urine stream, the need to change position or manually reduce (splint) the prolapse to urinate, a sensation of incomplete emptying and, in rare cases, complete urinary retention.⁵ The correlation between obstructive symptoms and advancing prolapse has been reported in a study of women presenting to a pelvic floor clinic, in which urinary splinting was reported in 5 to 12 percent of women with stage II anterior prolapse and 23 to 36 percent of those with stage III or IV anterior prolapse.⁶

Conservative therapy is the first line treatment option for all women with POP, since any type of surgery carries a risk of complications and recurrence. However, prolapse is typically a chronic problem, and many women ultimately choose surgery over conservative therapy since successful surgery is permanent and does not require ongoing maintenance. The mainstay of non-surgical treatment for POP is the vaginal pessary. Pessaries are silicone devices that are manufactured

in a variety of shapes and sizes and are designed to support the pelvic organs. Approximately half of the women who use a pessary continue to do so for one to two years. Pessaries must be removed and cleaned on a regular basis. Pelvic floor muscle exercises (PFME) also appear to result in improvements in POP stage and POP-associated symptoms. Several randomized trials have investigated the efficacy of PFME, although most were small or of poor methodological quality.⁷⁻⁹

Sacrospinous fixations (SSFs) of the vagina and abdominal sacrocolpopexy have been regarded as therapeutic tools to be used only for the repair of vaginal vault prolapse and POP with enterocele. Both of these procedures can also be used as an adjunct to prevent post-hysterectomy vault prolapse. However, not every hysterectomy patient is a candidate and if a loss of pelvic support structures (the uterosacral/cardinal ligament complex) is noted during hysterectomy an attempt at repair using their proximal remnants should be made. However, successful sacrospinous fixation used as an adjunct therapy will prevent further vault prolapse.

The sacrospinous ligament is covered by the coccygeus muscle and may be deep in the body. Once the suture has been placed through the sacrospinous ligament and the coccygeus muscle, the sacrospinous ligament is then attached in an almost horizontal position in the pelvis. With this in mind, we sought to identify the efficacy of using a simple proline stitch without the use of specialist needle-holders for SSF, and examine complications occurring in the immediate post-operative period and over two years of follow-up.¹⁰

Material and methods

This prospective cohort study was carried out in the maternity hospital in the Al Sabah area in the State of Kuwait from 2005 to 2010. This maternity unit is one of the largest tertiary hospitals in Kuwait, serving a population of 12 thousand people yearly. Approval for the study was granted by the hospital ethics review board. Fifty patients attending gynecology outpatient clinic with vault prolapse after vaginal hysterectomy or complete procedentia with very weak pelvic floor muscles were selected for inclusion in the study. All patients with complete procedentia had vaginal hysterectomy prior to sacrospinous fixation. All patients had urodynamic study preoperative.

The inclusion criteria were:

- Patients with complete procedentia or vault eversion; the most distal prolapse protrudes to at least (TVL-2) cm.
- Patients fit for surgery with no major comorbidities
- Patients with no vaginal infection and no history of a permanent cause of increased intra-abdominal pressure.

Patients were excluded if they were unfit for surgery or a candidate for conservative management using a pessary due to their advanced age. All patients had anterior repair of cystocele with 30patients had Kelly` sutures at the bladder neck for associated SUI.

All patients were seen in the outpatient clinic and examined clinically to assess the degree of prolapse. Vaginal infections or cervical ulcers were treated with anti-microbial and pessaries were inserted to decrease tissue edema pre-operative. An anesthetist performed preoperative assessments and informed consent was taken and signed by each patient. After the operation, patients were followed up at 1 month, 3 months, and then every 6 months up to 2 years. Patient was asked to fill the quality of life questionnaire for

more objective results. Then patients were examined using POP-q staging for follow up.¹¹

Technique of sacrospinous fixation

The posterior vaginal wall was opened to the apex and the rectovaginal space entered. The rectovaginal space was dissected with the operator finger at the level of the ischial spine. At that time the descending rectal septum (pillar) was opened to enter the pararectal space, and with additional blunt dissection the ischial spine and coccygeus muscle/sacrospinous ligament complex were palpated and visually identified. Monofilament non-absorbable proline 1 was placed through the right-sided sacrospinous ligament before final suturing to the vaginal vault to complete the ligament fixation. In this technique, we did not fix the tape to the sacrospinous ligament alone; instead we used the coccygeus muscle/sacrospinous ligament in order to decrease complications and the possibility of injury to vessels and nerves that may happen during dissection. Technique was conducted on the right side unilaterally. Closure of the vagina was achieved by first closing the posterior wall of the vagina before pulling and tightening the stitch attached to the sacrospinous ligament. Postoperatively, the patient was examined for any prolapse, discharge, dyspareunia, numbness, bleeding, sexual dysfunction and any other complaints.

Patients were asked to fill the Pelvic Floor Impact Questionnaire-7 pre operatively and 12 months post operatively.¹²

- Ability to do household chores (cooking, laundry housecleaning)?
- Ability to do physical activities such as walking, swimming, or other exercise?
- Entertainment activities such as going to a movie or concert?
- Ability to travel by car or bus for a distance greater than 30 minutes away from home?
- Participating in social activities outside your home?
- Emotional health (nervousness, depression, etc.)?
- Feeling frustrated?

All of the items use the following response scale: 0, Not at all; 1, somewhat; 2, moderately; 3, quite a bit PFIQ-7 Score.

Scales

Scale scores: Obtain 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 items only (12) the mean was collected and statistically analyzed using t-test for p value calculation.

Results

The demographics of the patients studied are shown in (Table 1). All patients were followed up for two years postoperatively to assess complications. On examination postoperative there was no prolapse anterior and posterior points are all -3 cm, and C is between -TVL and - (TVL-2) cm. The mean age of the patients was 52.7 years old, the median parity was P5, and there were 40 patients with uterovaginal prolapse and 10 patients with vault prolapse after vaginal hysterectomy. The mean time of operation was 27.81 minutes (SD 6.15) we measured the time taken during sacrospinous fixation and not vaginal

hysterectomy. 30 patients had stress urinary incontinence corrected by Kelly's suture (Table 2). Thirty four patients developed a post-operative complication (Table 3), and there were no intra-operative complications. Nine patients had short term complications include three patients had vaginal infections presenting with discharge and itching, which on high vaginal swab revealed *Candida albicans* that was subsequently treated with antifungals, and no further symptoms were reported follow-up. The same three patients with candidiasis also developed dyspareunia that resolved after medical treatment. Three

patients complained of post-operative buttock pain that was treated with simple analgesics; one-month later at their next follow-up visit they were symptom free. 25 patients' had long term complications in the form of six patients had recurrence of vault prolapse after 18 months follow up, nine patients develop cystocele after 2 years follow up. Regarding Pelvic Floor Impact Questionnaire short form 7 (PFIQ-7) there was statistical significance regarding all the 7 items between preoperative and postoperative periods as shown in (Table 4).

Table 1 Shows Demographics of the patients in this study

-	Range	Percentage	Median	Mean	SD
Age	55-65		55.5	52.76	±2.2
Parity	P4-P9		5	P 5.5	±1.61
Uterovaginal prolapse	40	80%	-	-	-
Vault prolapse	10	20%	-	-	-

Table 2 Operative results and post-operative complications

	Average	Mean	SD	After 1 year	18 months	After 2 years
Time of procedure	20-40 min	27.81 min.	±6.15			
Complications	34	34.61%		-		-
Short term complications	9	18%		-		-
Infection	3	11.53%		-		-
Hemorrhage	-	0.00%		-		-
Dyspareunia	3	11.53%		-		-
Buttock pain	3	11.53%		-		-
Numbness	-	0.00%		-		-
Long term complications	25	50%				
Recurrence	6	12%		-	6	6
Cystocele	9	18%		-		9
Sexual dysfunction	10	20%			10	10

Table 3 Shows the result of Pelvic Floor Impact Questionnaire-short form 7 (PFIQ-7)

Item number	Mean PR	Mean PO	SD PR	SD PO	T test PR	P value<.05 significant
1	56.65	81.338	30.32	27.898	4.236	0.000864 significant
2	56.01	77.336	23.7702	29.697	3.965	0.001332 significant
3	24.6632	84	32.166	26.269	12.801	0.00001 significant
4	31.996	71.676	26.059	32.97	6.677	0.000569 significant
5	39.324	89.344	24.68	15.69	12.094	0.00001 significant
6	23.98	84.012	32.32	19.32	11.294	0.00001 significant
7	29.398	88.012	26.372	16.146	13.403	0.00001 significant

Table 4 Shows number of patients had cystocele repair and Kelly's sutures

	Number of cases	Percentage	Anterior repair	Kelly's suture	Postoperative 1 year	18 month	Postoperative 2year
Cystocele	50	100%	All	15	Free	-	9 (18%)
SUI	30	60%	All	All	Free	-	Free

Discussion

Sacrospinous fixation using a simple proline stitch is an effective, safe, and cost-effective procedure for the management of uterovaginal and vault prolapse. Although it is usually a relatively short and effective procedure it should not be taken lightly, since severe complications can occur including death from hemorrhage due to injury of the great vessels. Maher et al.⁴ demonstrated those sacrospinous and iliococcygeus fixations are equally effective for the repair of vaginal vault prolapse and have similar rates of postoperative cystocele, buttock pain, and hemorrhage requiring transfusion. Sacrospinous ligament fixation should not be discarded in favor of iliococcygeus fixation in the management of vaginal vault prolapse.

However, sacrospinous ligament fixation remains a well-known method for correction of vaginal vault prolapse. In a fairly recent study, ninety-nine women (mean 66 years old) underwent vaginal SSF for vault prolapse. All patients were contacted 2-15 years after surgery for examination (POP-Q survey). Sixteen out of 55 (29%) patients who completed follow-up reported cystocele, three patients had rectocele, and four patients had a recurrent vault prolapse. With respect to quality of life, 42/55 (76%) patients reported lower urinary tract symptoms, but only 9/55 (16%) felt a sensation of prolapse. Ten out of 24 sexually active patients reported symptoms of sexual dysfunction. There was no correlation between lengths of follow-up and anatomical or functional results. Vaginal sacrospinous fixation resulted in excellent vault suspension but 29% of the patients developed cystoceles. Only 16% of patients reported symptoms of descent.⁴

The procedure is primarily indicated after hysterectomy and as a prophylactic measure for total uterine prolapse. Neuman et al. studied eight women with post-hysterectomy vaginal vault prolapse aged 48-72 years who were referred 1-25 years following primary surgery. Sacrospinous ligament fixation was chosen to enable simultaneous correction of cystocele and rectocele, and to preserve sexual function. All operations were completed without significant complications. Of 6/8 patients undergoing long-term review, one reported mild bulging of the introitus, another mild urinary stress incontinence, urgency, and frequency, and one reported frequency alone. Four had normal sexual function, and no patient experienced defecation abnormalities. The data suggest that the operation is safe and effective, but the authors suggested that gynecologic surgeons gain specialist training prior to performing this procedure, since the surgery is not without risks and it is unfamiliar to many gynecologists.¹³

Lantsch et al.¹⁴ studied 200 women who underwent vaginal unilateral sacrospinous ligament fixation. In the early postoperative period, 8% of women developed urinary tract infections, 7.5% temporary irritation of the sciatic nerve, 5.5% temporary partial ureteral obstruction, and 3.5% blood loss less than 400 ml. In 123 patients with long-term follow-up (6 months to 9 years), 119 were completely cured without any signs of urinary incontinence and prolapse, although recurrent cystoceles, rectoceles, and enteroceles, were found in about 8% of cases. Sacrospinous ligament fixation

appears to be an effective and safe procedure with a low recurrence and complication rates. In this study all patients had to fill Pelvic Floor Impact Questionnaire - short form 7 (PFIQ-7) preoperative and 12 months postoperative the mean was collected and statistically analyzed using t-test for p value calculation. There was significant difference between the two results.

So this means all patients had much more improved after surgical intervention regarding the quality of life.

Our study has a few limitations, namely a relatively small number of patients, relatively short period of follow-up. However, in spite of this, sacrospinous fixation using a simple proline stitch is a simple procedure that can be performed without any special needle or applicator. Our operating results are compared to other standard surgical procedures with only minor post-operative complications requiring simple medical therapy and long term complications that needs further assessment. There was significant difference between Pelvic Floor Impact Questionnaire - short form 7 (PFIQ-7) preoperative and postoperative in all items.

Conclusion

The sacrospinous procedure is a safe, effective, and inexpensive procedure for the management of uterovaginal and vault prolapse and improving quality of life. Further studies and training is required to further develop this procedure.

Acknowledgments

None.

Conflicts of interest

The authors declare there is no conflict of interests.

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