Laparoscopic sacrocolpopexy with bone anchor fixation: short-term anatomic and functional results

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Abstract

Introduction and hypothesis The aim of this study was to evaluate short-term anatomic and functional outcomes and safety of laparoscopic sacrocolpopexy with bone anchor fixation.

Methods A prospective cohort study of women undergoing laparoscopic sacrocolpopexy between 2004 and 2009. Anatomic outcome was assessed using the pelvic organ prolapse quantification score (POP-Q). Functional outcomes were assessed using the Urogenital Distress Inventory, Defecatory Distress Inventory, and the Incontinence Impact Questionnaire preoperatively and at 6 months postoperatively. The Wilcoxon signed rank test was used to test differences between related samples.

Results Forty-nine women underwent laparoscopic sacrocolpopexy. The objective success rate in the apical compartment was 98%, subjective success rate was 79%. One mesh exposure (2%) was found. One conversion was necessary due to injury to the ileum.

Conclusions Laparoscopic sacrocolpopexy with bone anchor fixation is a safe and efficacious treatment for apical compartment prolapse. It provides excellent apical support and good functional outcome 6 months postoperatively.

Keywords Bone anchor fixation · Functional outcome · Laparoscopy · Pelvic organ prolapse · Sacrocolpopexy

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Introduction

A challenging aspect in the treatment of pelvic organ prolapse is the prolapsed apical compartment. The incidence of post-hysterectomy vault prolapse that requires surgery has been estimated at 1.3 per 1,000 women-years [1]. The risk of prolapse surgery was 4.7 times higher in women whose initial hysterectomy was indicated by prolapse and 8.0 times higher if preoperative prolapse stage II or more was present [1].

Numerous surgical procedures have been described for the management of vault prolapse but few have been subject to rigorous assessment of their anatomical and functional outcome. The abdominal sacrocolpopexy is regarded the best procedure compared to vaginal sacrospinous colpopexy in terms of a lower rate of recurrent vault prolapse and less dyspareunia [2]. However, the vaginal sacrospinous colpopexy is quicker and cheaper to perform and women return earlier to activities of daily living. Laparoscopic sacrocolpopexy provides the potential to combine the success rate of an abdominal approach with the faster recovery time associated with a minimally invasive technique. Tissue dissection and mesh placement are facilitated by magnification of the operating field. The success rate of laparoscopic sacrocolpopexy has been reported to be 77–100% [3–9].

To reduce the risk of injuries to the presacral venous and nervous plexus and to make the procedure more feasible, a

modified laparoscopic sacrocolpopexy operation using bone anchor fixation and synthetic mesh was developed [10].

The aim of this study was to evaluate the clinical outcomes, surgical morbidity, and functional outcomes of laparoscopic sacrocolpopexy with bone anchor fixation.

Material and methods

This study was undertaken after obtaining approval from the Central Medical Ethics committee "Toetsing Wetenschappelijk Onderzoek Rijnmond" (TWOR), the Netherlands. All patients provided written informed consent before participation and were recruited between July 2004 and November 2009. Consecutive women with a symptomatic apical compartment prolapse requiring surgical correction were eligible for participation. Exclusion criteria were inability to understand Dutch, pregnancy or contemplating future pregnancy, former rectosigmoid resection, extensive intra-abdominal / pelvic adhesions, body mass index >40 kg/m^2, and treatment for malignancy in the past.

Baseline evaluation included medical history, a gynecologic investigation including a pelvic organ prolapse quantification (POP-Q)examination [11], and validated urogynecologic questionnaire, which contains the Dutch validated Urogenital Distress Inventory (UDI), Defecatory Distress Inventory (DDI), and the Incontinence Impact Questionnaire (IIQ) [12, 13].

All procedures were performed by the two last authors with the technique as previously described by van der Weiden et al. [10]. The operative procedure can be summarized as follows: at the lowest point of the pouch of Douglas, the right peritoneal fold is opened medially of the rectosigmoid by unipolar diathermy. Next, the presacral avascular plane is developed. The cortical bone of the sacral segment 3 is penetrated in the midline with the laparoscopic bone anchor inserter (SFG prototype, van der Weiden TM or KS 02158-1-LAP TM prototype, Karl Storz, Tuttlingen, Germany). Fixation to the sacrum is performed with a self-tapping titanium Corkscrew Suture Anchor (AR-1925S, Arthrex, Naples, Florida, USA) with two attached non-absorbable braided polyester-2 sutures (cases with the SFG prototype, van der Weiden TM) or with flat headed titanium screws (cases with the KS 02158-1-LAP TM prototype, Karl Storz, Tuttlingen, Germany). A 4.0×3.0 cm piece of monofilament knitted polypropylene mesh (Gynemesh Soft, Ethicon, Norderstedt, Germany) sutured to the apical part of the posterior vaginal wall with four Mersilene 1-0 sutures (Ethicon, Norderstedt, Germany) is subsequently sutured to the polyester-2 ligatures attached to the bone anchor. The mesh is covered with peritoneum placing it in a retroperitoneal position. Since the rate of

vaginal mesh exposure is significantly higher when abdominal surgery is combined with vaginal surgery [14], additional prolapse or incontinence procedures such as posterior colpoperineorrhaphy, anterior colporrhaphy, paravaginal repair, surgery for stress urinary incontinence or ventral rectopexy, were not performed concomitantly. Patients received a single prophylactic dose of antibiotics.

Postoperative evaluations were performed during the hospital stay, at 6 weeks and 6 months post-operatively. POP-Q measurements were recorded and questionnaires completed at 6 months.

The primary end point was anatomic failure in any of the vaginal compartments, defined as pelvic organ prolapse stage II or higher. Secondary outcomes were anatomic failure in the apical compartment and subjective failure. Subjective failure was considered significant if a patient responded at least: "yes, a bit bothered" to the questions "Do you feel bulging or protrusion in the vaginal area?" or "Do you see a bulge or protrusion in the vaginal area?" Other secondary outcomes were duration of surgery, blood loss, length of hospitalization, and change in bother and quality of life measured by UDI, DDI, and IIQ. Pain was a secondary outcome as well and considered significant if a patient responded "yes, moderately to quite a bit" to the question "Do you experience pain in the lower abdomen or genital region?" Dyspareunia was considered significant if a patient responded "yes; moderately to quite a bit" to the question "Do you experience pain during intercourse?"

Data are presented as numbers with corresponding percentages or medians with range. The Wilcoxon signed rank test was used to test differences between related samples for statistical significance. A p value below 0.05 was considered statistically significant. Statistical analysis was performed using SPSS 18.0 for Windows (SPSS Inc., Chicago, Ill., USA).

Results

Forty-nine women were included in the study, 45 cases of laparoscopic sacrocolpopexy (including two cases of cervicopexy after a previous supracervical abdominal hysterectomy) and four cases of laparoscopic hysteropexy. All patients returned for follow-up and a POP-Q measurement was taken; however, only 47 patients completed the questionnaires. Baseline characteristics are shown in Table 1. Two patients had a bothersome stage I prolapse with the most descending point at hymen minus 2 cm and underwent surgery. All other patients had a stage II or III prolapse. Twenty patients were sexually active and three (15%) had dyspareunia.

Peri- and postoperative data are presented in Table 2. In one patient, conversion was necessary due to injury to the

Table 1 Baseline characteristics

	Data available for number of patients	N (%) or median (range)
Age	49	66 (45–86)
Parity	47	2 (0–6)
BMI	29	24 (21–32)
Comorbidity	49	5 (10%)
Previous surgery[a]		
Abdominal hysterectomy	49	18 (37%)
Vaginal hysterectomy	49	27 (55%)
Anterior colporraphy	49	28 (57%)
Anterior mesh procedure	49	1 (2%)
Posterior colporrhaphy	49	27 (55%)
One POP procedure	49	28 (57%)
More than one POP procedure	49	5 (10%)
Previous incontinence surgery	49	9 (18%)
Overall POP-stage	49	
I		2 (4%)
II		33 (67%)
III		14 (29%)
IV		0 (0%)
Point C	49	−1 (−3 to 4)
Pain (lower abdomen/genital area)	47	11 (23%)
Dyspareunia	20	3 (15%)

[a] Multiple surgeries possible

Table 2 Peri- and post-operative data

	Data available for number of patients	N (%) or median (range)
Sacrocolpopexy	49	43 (88%)
Cervicopexy	49	2 (4%)
Hysteropexy	49	4 (8%)
Operating time (min)	49	120 (60–240)
Blood loss (ml)	49	50 (10–100)
Duration urinary catheter (days)	49	1 (1)
Hospital stay (days)	49	1 (0–5)
Complications (intra-operative)		
Conversion laparotomy due to injury ileum	49	1 (2%)
Complications at 6 months		
Neurologic complaints caused by irritation left sacral plexus	49	1 (2%)
Cumulative mesh exposure	49	1 (2%)
Pain (lower abdomen/genital area)	47	3 (6%)
De novo pain	47	0 (0%)
Dyspareunia	20	4 (20%)
De novo dyspareunia	20	3 (15%)

ileum. The lesion was sutured and subsequently healed without any long-term sequelae. One patient had neurologic complaints post-operatively, caused by irritation of the left sacral plexus. These complaints, although diminishing gradually, persisted to some extent at the 6 months follow-up and resolved spontaneously in the following 6 months. One patient developed a mesh exposure, which was successfully excised and the defects covered with vaginal mucosa in a day-care procedure. There were no patients that developed de novo pain in the abdomen or genital area and three patients (15%) reported de novo dyspareunia. In two patients (10%), dyspareunia disappeared.

The POP-Q measurements are shown in Table 3. At 6 months follow-up, a significant improvement was seen in the apical (point C) and posterior (point Bp) compartments. Anatomical failure per compartment is presented in Table 4. The apical compartment had only 2% failures, in contrast with the anterior compartment with 31% failures. Subjective failure was demonstrated in 10 out of 47 (21%) patients. Of the 26 patients with an overall anatomic failure, only 7 patients (27%) had bothersome prolapse complaints (subjective failure). Of the 23 patients with an overall POP stage 0 or I, three patients (13%) had bothersome prolapse complaints (subjective failure). Changes in anterior (point Ba), apical (point C), and posterior (point Bp) compartments are shown in Table 5. Improvement in the apical compartment ranged from 5 to 12 cm and was present in all cases but one. The majority of patients had no change in the anterior and posterior compartment.

At 6 months, the bother scores of genital prolapse, obstructive micturition, overactive bladder, pain, and obstructed defecation were significant improved (Table 6). Bother scores were higher when the POP stage increased, although this was not statistically significant.

Discussion

The data in this study show that that laparoscopic sacrocolpopexy with bone anchor fixation is a safe and effective surgical treatment for apical compartment prolapse. The procedure provided excellent vault support in 48 out of 49 women (98%). This high success rate for the apical compartment is comparable with other studies [4–9].

Subjective success was 79%, comparable with numbers reported by Higgs et al. [8], and just below the previously reported subjective success rates of 86% to 97% [4, 9]. This lower rate of subjective success was probably due to the persistent prolapse of the anterior or posterior vaginal wall that was found in 26 women (53%). This results in a high number of overall failures. A cause for this high overall

Table 3 POP-Q measurements at baseline and 6 months post-surgery

POP-Q point	Data available for number of patients	Baseline		6 months		p value
		Median (range)	Mean (SD)	Median (range)	Mean (SD)	
Aa	49	−2 (−3 to 1)	−1.3 (1.0)	−2 (−3 to 0)	−1.7 (0.7)	0.007
Ba	49	−2 (−3 to 3)	−0.9 (1.6)	−2 (−3 to 2)	−1.4 (1.2)	0.003
C	49	−1 (−3 to 4)	−0.1 (1.8)	−8 (−8 to −3)	−7.7 (0.9)	<0.001
GH	49	3 (2 to 5)	3.0 (0.7)	3 (2 to 5)	3.0 (0.7)	0.99
PB	49	3 (2 to 3)	2.7 (0.5)	3 (2 to 3)	3.0 (0.5)	0.16
TVL	49	8 (7 to 9)	8.0 (0.2)	8 (7 to 9)	8.0 (0.2)	0.99
Ap	49	−2 (−3 to 2)	−1.4 (0.9)	−2 (−3 to 0)	−1.9 (0.5)	<0.001
Bp	49	−1 (−3 to 2)	−0.9 (1.4)	−2 (−3 to 2)	−1.6 (0.9)	<0.001
D	4	−2.5 (−4 to 0)	−2.3 (1.7)	−8 (−8 to −5)	−7.3 (1.5)	0.07

failure rate could be the fact that we did not combine the apical compartment repair with anterior or posterior repairs (either with laparoscopic mesh placement or with vaginal colporrhaphia). In order to decrease the risk for mesh exposure [14] and to avoid irritable bladder symptoms, such as de novo urgency of 18% [15], and to avoid rectal or bladder lesions we did not perform combined repairs. Theoretically, the fixation of the mesh to sacral segment 2 to 4, instead of the promontorium, could prevent the occurrence or recurrence of prolapse, since the axis of the vagina is more natural and further support is provided by the levator plate against which the upper vagina is compressed by intra-abdominal pressure [16]. Furthermore, adequate level I support has a critical role on the position of the anterior and posterior vagina [17, 18]. However, this adequate level I support has not prevented the occurrence of anterior and posterior wall prolapse in all cases.

For the definition of failure, we used the National Institutes of Health (NIH) criteria [11, 19]. However, according to Barber, the presence of "bulge" symptoms together with a pelvic organ prolapse beyond the hymen or re-treatment would be more appropriate. If we look at our data in this way, we have a failure rate of 6 out of 49 (12%) [20].

Intraoperative complications were rare. Suspending the vault to the sacral segment 2–4 with a bone anchor avoids large difficult promontory dissection, declining the risk of presacral hemorrhage which can be difficult to control resulting in conversion to laparotomy [21]. Blood loss during surgery was lower (median 50 ml (10–100 ml), compared to 100 ml (range 20–300 ml) in a previous study [3]. Furthermore, no blood transfusion peri-operatively was given, in contrast with 2% transfusions in the study of Maher et al. [3]. Neither bladder lesions nor rectum lesions were described, due to the minimum dissection at the bladder and rectum site, since mesh was only used at the apex of the posterior vaginal wall. Other studies described 2% bladder lesions and 1% rectum lesions [7, 9]. However, one conversion to laparotomy was necessary due to injury to the ileum in a patient with extensive adhesion formation.

Table 4 Anatomic failure

POP-stage	Anterior compartment		Apical compartment		Posterior compartment		Overall	
	Baseline	6 months	Baseline	6 months	Baseline	6 months	Baseline	6 months
Stage 0	2 (4%)	3 (6%)	2 (4%)	49 (100%)[a]	1 (2%)	3 (6%)	0(0%)	2 (4%)
Stage I	25 (51%)	31 (63%)	9(19%)	0 (0%)	23 (47%)	34 (69%)	2 (4%)	21 (43%)
Stage II	17 (35%)	12 (24%)	30 (61%)	0 (0%)	21 (43%)	11 (22%)	33 (67%)	22 (45%)
Stage III	5 (10%)	3 (6%)	8 (16%)	0 (0%)	4 (8%)	1 (2%)	14 (29%)	4 (8%)
Stage IV	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Failure		15 (31%)		1 (2%)		12 (24%)		26 (53%)

Data presented as numbers (%)

Failure=POP≥stage II or POP<stage II with repeat surgery

[a] Including one repeat sacrocolpopexy within 6 months

Table 5 Change in POP-Q point Ba, C, and Bp 6 months post-surgery

	Ba	C	Bp
Improvement			
1 cm	9 (19%)		10 (21%)
2 cm	3 (6%)		3 (6%)
3 cm	4 (8%)		8 (16%)
4 cm	1 (2%)		
5 cm		4 (8%)	
6 cm		10 (20%)	
7 cm		13 (27%)	
8 cm		11 (23%)	
9 cm		5 (10%)	
10 cm		1 (2%)	
11 cm		2 (4%)	
12 cm		2 (4%)	
No change	28 (57%)	0	27 (55%)
Deterioration			
1 cm	2 (4%)	0	
2 cm	2 (4%)	0	1 (2%)
Repeat surgery		1 (2%)	

Medium-term complications included one case (2%) of mesh exposure. This finding is low to consistent with the 1–9% rate of mesh exposure previously reported for sacrocolpopexy by either the open or the laparoscopic route [3, 4, 6–9]. De novo pain was not found, compared to 4% in a group with vaginal native tissue repair, and 7.5% in a group with vaginal mesh repair previously described [22]. De novo dyspareunia rate of 15% is comparable to rates of 8–42% that have been reported in the literature after conventional vaginal prolapse surgery and after mesh repair [22–25].

The short follow-up of 6 months was an important limitation of this study. Furthermore, an independent clinical investigator who was not involved in the procedures would ideally have performed the postoperative examinations. The strengths of this study are the prospective design of the study, the uniform surgical technique performed by the same gynecologist and laparoscopic surgeon, and the use of standardized and validated instruments of measurement.

Conclusions

Laparoscopic sacrocolpopexy with bone anchor fixation is a safe surgical treatment and has a high short-term success rate for apical compartment prolapse. For anterior and/or posterior compartment prolapse in the same patient, additional surgery (with laparoscopic mesh or vaginal colporrhaphy) should be considered.

Table 6 Effect of surgery on symptoms and health related quality of life scores

Domain	Baseline	6 months	p value	Bother score in relation to POP stage at 6 months		
				POP stage 0 + I (n=21)	POP stage II (n=20)	POP stage III (n=4)
UDI						
Genital prolapse	67.8 (28.8)	13.3 (24.5)	<0.001	10.3 (23.3)	13.3 (24.5)	33.3 (33.3)
OAB	33.3 (25.7)	17.3 (18.9)	<0.001	12.7 (14.2)	16.1 (17.8)	47.2 (22.9)
Incontinence	15.6 (20.1)	10.0 (16.8)	0.09	7.9 (17.2)	10.0 (16.6)	20.8 (16.0)
Obstructive micturition	33.0 (24.7)	14.8 (21.3)	<0.001	11.9 (16.8)	13.3 (20.7)	44.4 (38.5)
Pain	26.8 (25.2)	15.2 (19.3)	0.002	11.1 (16.1)	18.3 (22.2)	22.2 (19.2)
DDI						
Constipation	13.0 (19.5)	12.4 (20.4)	0.56	5.6 (13.3)	17.5 (23.9)	27.8 (25.5)
Obstructed defecation	13.5 (14.4)	7.7 (11.1)	0.002	6.3 (12.3)	7.9 (9.4)	20.8 (5.9)
Pain	6.7 (15.8)	7.0 (15.5)	0.84	4.8 (15.0)	8.8 (16.1)	11.1 (19.3)
Incontinence	4.0 (11.2)	4.5 (9.8)	1.00	5.6 (12.2)	2.5 (6.1)	11.1 (9.6)
IIQ						
Physical functioning	19.8 (26.3)	13.6 (23.4)	0.14	15.0 (23.5)	11.4 (24.9)	16.7 (19.3)
Mobility	25.5 (20.5)	23.5 (24.8)	0.53	23.9 (23.7)	21.1 (26.7)	33.3 (24.0)
Social functioning	12.8 (11.6)	7.9 (13.6)	0.08	8.8 (16.0)	7.1 (11.7)	5.6 (7.9)
Embarrassment	11.5 (20.0)	6.5 (13.4)	0.15	6.7 (13.7)	4.6 (9.6)	16.7 (28.9)
Emotional health	22.2 (19.8)	16.1 (21.9)	0.17	17.8 (22.9)	14.2 (22.5)	16.7 (7.9)

UDI, DDI, IIQ data presented as mean (standard deviation)

Scores range between 0 (least bother) and 100 (maximum bother)

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