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ORIGINAL ARTICLE

Long-term follow-up of laparoscopic sacrocolpopexy

Dimitri Sarlos · LaVonne Kots · Gloria Ryu · Gabriel Schaer

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Abstract
Introduction and hypothesis This study evaluates the long-term results of laparoscopic sacrocolpopexy. In a prior publication, we demonstrated that laparoscopic sacrocolpopexy is a safe method with excellent anatomical results and low recurrence rates after a 12-month follow-up. This study now evaluates the long-term objectives and subjective outcomes of laparoscopic sacrocolpopexy after 5 years (mean).
Methods From 2003 to 2007, a prospective study enrolling 101 patients was conducted to evaluate laparoscopic sacrocolpopexy as a treatment for pelvic organ prolapse. The long-term results were assessed postoperatively after 5 years by gynecological examinations, including the Pelvic Organ Prolapse Quantification (POP-Q) system and quality of life assessments using validated questionnaires.
Results A total of 68 patients received a full clinical follow-up exam between July and September 2011, and 17 patients were assessed by questionnaires only. Altogether, six anatomical recurrences in the anterior, four in the posterior, and one in the apical compartment were found during the 5 years after surgery; 83.8 % of patients had no prolapse in any compartment or stage 0 prolapse according to the International Continence Society (ICS) classification. The total reoperation rate was 3.5 %. Two mesh erosions into the bladder occurred, though no vaginal erosion occurred. The preoperative quality of life index improved from 5.6 to 9.1 (12 months) and 8.3 (60 months) postoperatively, resulting in a subjective cure rate of 95.3 %.
Conclusions Laparoscopic sacrocolpopexy has demonstrated excellent anatomical and functional long-term results. With the ongoing debate about the complications of vaginal mesh surgery, laparoscopic sacrocolpopexy should be considered a favorable treatment option for patients with pelvic organ prolapse.

Keywords Laparoscopic sacrocolpopexy · Pelvic organ prolapse · Long-term outcome · Mesh surgery

Introduction

Genital prolapse repair is one of the most frequent procedures of benign gynecological surgery. Many different surgical techniques have been described in the past 60 years [1]. Procedures such as uterosacral vaginal vault suspension, sacrospinous fixation, and abdominal sacrocolpopexy are very common to repair an apical vaginal prolapse [2]. Also, prolapse repair with vaginal mesh augmentation has been shown to significantly reduce the risk of recurrence in the anterior compartment [3–5], but vaginal mesh surgery is associated with considerable morbidity such as mesh exposure, pain, dyspareunia, and infection. Furthermore, outcomes such as de novo dyspareunia and chronic pelvic pain have to be considered [6, 7]. After the US Food and Drug Administration (FDA) warning about vaginal mesh placement [8], its use has been questioned in many centers worldwide [9].

The abdominal approach has been reported to be superior to the vaginal method regarding anatomical outcome and functionality, especially regarding sexual activity [10]. However, the higher morbidity of the abdominal approach has to be taken into account [11]. A minimally invasive approach such

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D. Sarlos · L. Kots · G. Ryu · G. Schaer
Department of Gynecology, Kantonsspital Aarau, Aarau, Switzerland

D. Sarlos (✉)
Department of Obstetrics and Gynecology, Cantonal Hospital, Aarau, 5001 Aarau, Switzerland
e-mail: la.kots@ksa.ch

as laparoscopic sacrocolpopexy seems to offer all these advantages, but unfortunately there are not many studies reporting long-term results, including the anatomical and functional outcome of this promising technique.

Therefore, the aim of this study is to report on the long-term follow-up of laparoscopic sacrocolpopexy regarding anatomical results, recurrence rates, and postoperative quality of life after 60 months (mean follow-up).

Materials and methods

In 2003, we started to perform laparoscopic sacrocolpopexy at our urogynecology unit in the Department of Obstetrics and Gynecology of a public teaching hospital in Switzerland. In 2008, our group published the short-term results of a prospective study of 101 cases of laparoscopic sacrocolpopexy for uterine and post-hysterectomy prolapse reporting on surgical, anatomical, and functional outcome with a median follow-up of 12 months [12]. This study was approved by our local Ethics Committee, the Ethikkommission Kanton Aargau, and is registered with ClinicalTrials.gov under ID number NCT01394237. All patients participated after informed written consent was obtained.

Five years (mean) after surgery, 99 of 101 patients from the initial cohort were invited for a follow-up exam and were asked to fill out two questionnaires, the German version of the Kings Health Questionnaire and the validated German version of the pelvic floor prolapse questionnaire [13, 14]. Two patients who had a conversion to laparotomy in the initial cohort were excluded.

The follow-up visit, performed by an experienced urogynecologist, included documentation of history, clinical examination, and a quality of life assessment by means of a visual analog scale using the same questionnaires applied in the 2008 study—the German version of the Kings Health Questionnaire and the validated German version of the pelvic floor prolapse questionnaire [13, 14].

The degree of prolapse was documented using the International Continence Society (ICS) Pelvic Organ Prolapse Quantification (POP-Q) system [15]. The objective cure rate was defined as no prolapse in any compartment or stage 0 prolapse according to the ICS classification.

For final analysis of the anatomical outcome, the recurrences which occurred in the 12 months follow-up were also recorded as recurrences in the 60 months follow-up even if these patients were treated between the two follow-up exams.

If a patient was not able to attend the follow-up exam due to age, morbidity, or because she moved to another area or country, we asked her to send back the completed questionnaires. A significant effort was made to find all patients of the previous study by searching phone books and the Internet.

Due to the high number of dropouts, we calculated the objective and subjective cure rates with different numbers. For the objective cure rate the 68 patients who were seen clinically were considered. The subjective cure rate was calculated for the 85 patients who completed the questionnaire. Also for both objective and subjective cure rates the numbers were also calculated with every dropout considered as failure (see Tables 1 and 2).

All surgical procedures were performed by two senior urogynecologists experienced in laparoscopic surgery adhering to a standardized surgical technique. In summary, we started with a supracervical hysterectomy if a uterine prolapse was present. Then, the dissection started at the level of the promontory with exposure of the anterior longitudinal ligament and the peritoneum was incised parallel to the sigmoid from the promontory to the pouch of Douglas.

The posterior dissection was performed down to the ventrolateral part of the levator ani muscle. The paravaginal fascia was dissected anteriorly down to the lower third of the vagina just below the trigone of the bladder. Two separate macroporous multifilament polypropylene meshes (Gynemesh®, Ethicon, Johnson & Johnson) were used for the anterior and posterior compartments. Both meshes were manually tailored for the posterior (15–18 cm × 3–4 cm) and anterior (12–15 cm × 3–4 cm) applications. The most distal part of the posterior mesh was sutured to the levator ani muscle and the proximal mesh to the apex of the vagina or to the cervix. The anterior mesh was placed underneath the bladder and attached to the caudal part of the vagina and the apex with a four-point fixation by laparoscopic suturing using Ethibond® 2–0 with the extracorporeal knotting technique. The anterior and posterior meshes were sutured together at the level of the vaginal apex and then attached without tension to the longitudinal sacral ligament at the level of the promontory. Sutures to the vagina were performed tangentially to minimize the risk of postoperative erosion of the suture material. Finally, the mesh was covered with peritoneum by a laparoscopic running suture with absorbable material.

Results

Of 99 patients, 68 attended the clinical follow-up exams, which were scheduled between July and September 2011. The mean follow-up time for all included patients was 60 months. All of the patients received a standardized full clinical follow-up exam. Seventeen patients could not come to the outpatient clinic for the follow-up exam because of age and comorbidities or relocation. These patients were assessed only by questionnaires. Despite thorough investigations, 14 patients were completely lost to follow-up because of relocation or not answering our letters.

Table 1 Subjective outcome after laparoscopic sacrocolpopexy 12 and 60 months after surgery

	12 months (n=99)		60 months (n=85)	
	Total number	%	Total number	%
De novo stress incontinence	24	24.2	32	37.6
Surgery for postoperative stress incontinence	15	15.2	16	18.8
Postoperative constipation	1	1.0	4	4.7
Postoperative voiding disorders	8	8.1	11	12.9
De novo urge incontinence	2	2.0	7	8.2
Severe de novo dyspareunia	1	2.1[a]	10	24.4[a]
Quality of life score	9.1		8.3	
Subjective cure rate for prolapse symptoms (in parentheses: number and percentage if every dropout is counted as a failure)	97/99	98.0	81/85 (81/99)	95.3 (81.8)

The numbers after 60 months are cumulative numbers after initial surgery

[a] As only 41 (60-month follow-up) and 47 patients (12-month follow-up), respectively, declared themselves as sexually active, 41 or 47 were taken as 100 %

Of the 68 patients who received a complete clinical follow-up, 57 did not show any evidence of prolapse in any compartment (stage 0) and required no additional treatment after the initial surgery, resulting in an objective cure rate of 83.8 % (see Table 2).

After 60 months of follow-up we found a total of six recurrences of the anterior compartment that occurred after the initial surgery. Two of these six patients had to be reoperated because of severe prolapse symptoms, one 12 months (POP-Q score preoperatively: Aa −2, Ba +1, C −5) and the other 36 months (POP-Q score preoperatively: Aa −2, Ba +2, C −4) after the initial surgery, both with an anterior vaginal wall mesh augmentation (Prolift®) (see Tables 2 and 3).

The other four patients with anterior wall recurrence showed symptoms such as mild urge to urinate or prolapse sensation and did not require further surgery but were treated conservatively.

One patient presented with a recurrence in the apical compartment which occurred 40 months after the initial surgery. This patient showed minor symptoms such as vaginal bulge during coughing and lifting of heavy weights and was treated with a pessary. In the posterior compartment there were four recurrences. One of these patients underwent a successful posterior repair 48 months after the initial surgery (POP-Q score preoperatively: Ap +1, Bp +1, C −6) (Tables 2 and 3). The other three patients with posterior recurrence were completely asymptomatic and did not require further treatment.

In summary, 11 of the 68 patients had an objective recurrence resulting in a objective cure rate of 83.8 %. If every dropout would have been counted as a failure, there would be 31 additional recurrences resulting in a objective cure rate of 57.6 % (Table 2).

A total of 3 of 85 patients needed to undergo further surgery for symptomatic recurrent prolapse, resulting in a reoperation rate for recurrent prolapse of 3.5 % after 60 months follow-up. There were two postoperative mesh protrusions into the bladder, one case 12 months after surgery and the other case 60 months after surgery. Both cases had an accidental bladder incision during the sacrocolpopexy surgery. The protruded mesh was removed by laparoscopy with partial excision of the anterior mesh and reconstruction of the bladder. One of these two patients developed an anterior recurrence after partial resection of the anterior mesh and had to be treated with an anterior Prolift®. The other of these two patients did not show any prolapse of the anterior vaginal wall until the follow-up visit, which was performed 15 months after the mesh resection. No mesh erosion into the vagina was found in any patient.

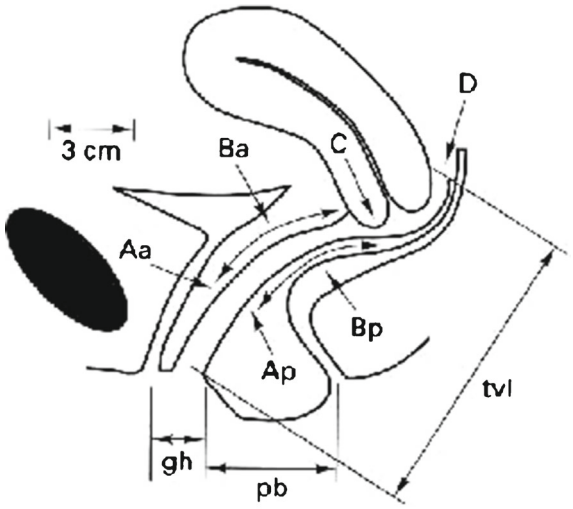
Of 85 patients completing the questionnaire at the 5-year follow-up, 81 reported no further symptoms of prolapse, resulting in a subjective cure rate of prolapse symptoms of 95.3 %. If every dropout is counted as a failure, 14 additional cases would have to be considered as failures resulting in a subjective cure rate of 81.8 %.

Table 2 Objective outcome after laparoscopic sacrocolpopexy 12 and 60 months after surgery

	12 months (n=99)		60 months (n=68)	
	Total number	%	Total number	%
Recurrence of anterior wall	6	6.1	6 (37)	8.8 (37.4)
Recurrence of posterior wall	2	2.0	4 (35)	5.9 (35.4)
Apical recurrence	0	0.0	1 (32)	1.5 (32.3)
Mesh erosion	1	1.0	2	2.9
Objective cure rate	91/99	91.9	57/68 (57/99)	83.8 (57.6)

The numbers after 60 months are cumulative numbers after initial surgery. The numbers in parentheses after 60 months show the figures if every dropout is counted as a failure

Table 3 Long-term results of laparoscopic sacrocolpopexy according to POP-Q as illustrated [15]. Preoperative, 12-month, and 60-month postoperative results are given



POP Q	pre-operative N=99	12 months N=99	60 months N=68
Aa	-1(±1.8)	-2(±0.4)	-2(±1.0)
Ba	+1(±2.3)	-2(±1.5)	-2(±1.5)
C	-1(+-3.4)	-7(+-2)	-6(±1.2)
Ap	-2(±1.3)	-3(±0.6)	-3(±0.6)
Bp	-2(+ 3.1)	-3(+1.1)	-3 (±3.2)

Results are given as mean and standard deviation in parenthesis

Of 85 patients, 32 reported to have suffered from de novo stress urinary incontinence symptoms after the initial surgery at the 60-month follow-up. Our short-term results (the first 12 months) revealed that 15 of 99 patients had a sling procedure because of stress urinary incontinence. One additional subject had a sling procedure during the long-term follow-up. The overall operation rate for stress urinary incontinence after 60 months was 18.8 % (see Table 1). Seven patients reported de novo urge incontinence after 60 months of follow-up and received medical treatment with anticholinergics.

Four patients reported moderate constipation after 60 months. Eleven patients reported to have suffered from voiding dysfunction after the initial surgery. Two of them had to undergo sling transection in the first few weeks after surgery; the other nine patients were managed conservatively. One patient was also diagnosed with multiple sclerosis, with documented residual urine of more than 200 ml at the 60-month follow-up. The other ten patients did not demonstrate any relevant residual urine in a perineal ultrasound at the 60-month follow-up.

Of the 85 patients who completed the questionnaire after 60 months, 41 declared themselves as sexually active. Ten patients complained of dyspareunia. Four of them reported more severe symptoms and three of these patients were treated with local estrogen therapy because of atrophic colpitis.

Quality of life was assessed by a linear visual analog scale from 1 to 10. The long-term follow-up showed a value of 8.3

and remained relatively stable. In the study published in 2008, the quality of life index improved from 5.6 preoperatively to 9.1 postoperatively at the 12-month follow-up (Table 1).

Discussion

With this study, we can demonstrate that laparoscopic sacrocolpopexy for uterine or vaginal vault prolapse has excellent anatomical and functional results in a long-term follow-up. Mesh-associated complications like protrusion into the bladder may occur in the long term as well.

The main strength of this study is its prospective character, the long follow-up time of 60 months, and the standardized evaluation of anatomical and functional results using the POP-Q system and validated questionnaires.

A weakness of the present study is the rather high rate of patients who were lost to follow-up after 60 months. It is therefore difficult to assess those outcomes or complications that might have a low incidence. However, 85 of the initial 99 patients were eligible for evaluation of subjective outcomes, which may be more clinically relevant than the objective POP-Q results, as demonstrated by Chmielewski et al. [16].

However, regarding objective outcomes, the anatomical results reported in our study are similar to those reported by Maher et al. [17]. In this randomized study comparing laparoscopic sacrocolpopexy with vaginal mesh surgery with a median follow-up of 2 years, the mean postoperative POP-Q point C was at −7.48 cm compared with −6.2 cm in our study, thus showing that laparoscopic sacrocolpopexy is an excellent technique to suspend the apex of the vagina even in a long-term follow-up.

In our study, we found one apical recurrence after 60 months corresponding to a failure rate in the apical compartment of 1.5 % (1 of 68). This fact is in line with the results reported by Sergent et al. [18], who stated a recurrence rate of 3 % in a prospective study with a mean follow-up of 34 months after laparoscopic sacrocolpopexy. They performed a comparable surgical technique with anterior and posterior placement of two separate meshes.

In our study, the majority of recurrences occurred in the anterior compartment. These recurrences occurred in the follow-up report at 12 months and no additional anterior recurrences occurred until the 60-month follow-up. The mean POP-Q score for point Ba in our study was −2.4 at 60 months, which is comparable with the results of Maher et al. [17], who reported point Ba at −2.17 cm.

All anterior recurrences (8.8 %) in our study occurred in the early follow-up phase. In our opinion, a suboptimal anterior mesh placement probably was not close enough to the trigone of the bladder to be a risk factor for anterior recurrence. In these cases, a de novo cystocele can occur between the bladder neck and the edge of the anterior mesh. However, only two of these six patients with an anterior recurrence were symptomatic and had to be treated with an anterior vaginal mesh procedure (Prolift®).

We had a total of four recurrences (5.9 %) in the posterior compartment, which is comparable with the results of Sergent et al. [18], who reported a rate of posterior recurrences of 2 %. Our mean POP-Q score for point Bp was −3.3 compared with −2.3 in the study by Maher et al. [17]. One of these four patients with a posterior recurrence in our cohort had to be treated with a posterior repair 32 months after the initial surgery. The other three patients were asymptomatic and did not require any further treatment.

In summary, our study showed that laparoscopic sacrocolpopexy has a low rate of objective recurrences in long-term follow-ups at 60 months. The objective recurrence rate for all three compartments of the pelvic floor was 16.2 %, leading to an objective cure rate of 83.8 %.

Comparing these results with other pelvic floor reconstruction techniques like abdominal sacrocolpopexy or sacrospinous fixation, for which objective cure rates ranging from 69 to 76 % have been reported [11, 19–22], our results are promising, regardless of the comparability issues.

The real rate of de novo dyspareunia after laparoscopic sacrocolpopexy is not well known. In our study, only 41 of 85 patients declared themselves as sexually active. We had a high number of cases of de novo dyspareunia (24.4 %). However, at the 12-month follow-up only 1 of 47 sexually active patients reported de novo dyspareunia after laparoscopic sacrocolpopexy. We assume that in most of the patients reporting de novo dyspareunia at the 60-month follow-up the dyspareunia was probably not related to the surgery but to other causes such as atrophy.

We had two mesh erosions into the bladder as long-term complications. In reference to the International Urogynecological Association (IUGA)/ICS terminology, these two complications are classified as B4B-T3-S3 and B4B-T4-S3 [26]. In both cases, the bladder was accidentally opened during the initial surgery, showing that a bladder lesion, even if it is recognized and repaired immediately, seems to be a risk factor for late mesh erosions into the bladder. It can be mentioned that mesh erosion into the bladder is probably related to surgery and not a mesh-associated problem. It might be useful to omit the anterior mesh and place only a posterior mesh if bladder opening occurs during surgery. Also, cases with prior prolapse surgery, especially after anterior repair causing fibrosis between the bladder and the vagina, have to be taken into account, making the dissection in the anterior compartment much more difficult and leading to a higher risk of bladder lesions. We did not have any mesh erosions into the vagina, which were reported in other studies with incidences ranging from 0 to 5.5 % [11, 17, 18].

After the already known risks of the insertion of vaginal meshes and the warning of the FDA in 2011 [8, 9], worldwide

interest in laparoscopic sacrocolpopexy has increased during the past few years [23–25]. With this study, we have demonstrated that the long-term anatomical and functional results after laparoscopic sacrocolpopexy are excellent and probably better than after conventional vaginal or abdominal pelvic floor reconstruction techniques.

Conflicts of interest None.

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