

# Laparoscopic sacral colpopexy versus total vaginal mesh for vault prolapse; comparison of cohorts

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**Abstract** The surgical treatment of vaginal vault prolapse can either be performed by the vaginal or the abdominal (laparoscopic) route. The objective of this study was to compare the laparoscopic sacral colpopexy (LSC) and total vaginal mesh (TVM) for vaginal vault prolapse. This study compared a prospective cohort of LSC with bone-anchor fixation and mesh limited to the apex to a prospective cohort of TVM as treatment modalities in patients with a symptomatic vaginal vault prolapse (pelvic organ prolapse-quantification (POP-Q) point C $\geq$ -3). Primary outcome was failure in the apical compartment after 6 month follow-up, defined as POP-Q stage $\geq$ II with prolapse complaints or re-treatment in apical compartment. Based on an overall failure in all compartments of 23 % in the LSC group and 57 % in the TVM group, 29 patients would be needed in each group with a power of 80 % and alpha 0.05. Ninety-seven women were included, 45 LSC and 52 TVM. The failure rate of symptomatic vault prolapse was 1 (2 %) in each group ( $p=0.99$ ). The failure rate (POP stage $\geq$ II) in any compartment was 23 (51 %)

in the LSC group and 11 (21 %) in the TVM group ( $p=0.002$ ). Each technique had its own type of complications. Short-term failure rates in the apical compartment after TVM and LSC were similar. In case of anterior or posterior prolapsed, additional mesh insertion or additional vaginal colporrhaphy is indicated in LSC surgery.

**Keywords** Bone anchor · Laparoscopic sacral colpopexy · Pelvic organ prolapse · Vaginal mesh · Vaginal vault

## Introduction

The incidence of post-hysterectomy vaginal vault prolapse that requires surgery has been estimated at 1.3 per 1,000 women-years [1]. The risk of pelvic organ prolapse surgery was 4.7 times higher in women whose initial hysterectomy was indicated by prolapsed [1]. The surgical treatment of vaginal vault prolapse can either be performed by the vaginal (e.g., vaginal sacrospinous colpopexy and total vaginal mesh (TVM), involving mesh placement in the anterior, and apical and posterior compartments) or the abdominal route (e.g., sacral colpopexy). A Cochrane systematic review and meta-analysis on the topic has shown that for the treatment of vaginal vault prolapse the abdominal sacral colpopexy was the superior procedure compared with vaginal sacrospinous colpopexy in terms of a lower rate of recurrent vault prolapse and less dyspareunia [2]. Vaginal sacrospinous colpopexy was, however, quicker and cheaper to perform and women returned earlier to activities of daily living. Laparoscopic sacral colpopexy (LSC) provides the potential to combine the success rate of an abdominal approach with the faster recovery associated with a minimally invasive technique. The success rate of LSC has been reported to be 90–100 % for the apical compartment [3–8].

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TVM aims at suspension of the apical compartment by means of a bilateral sacrospinous ligament fixation. The success rate of a TVM has been reported to be 96 to 99 % for the apical compartment and 91 % for all the compartments [9, 10].

Since the recent publication of the update of the FDA notification on complications of surgical mesh for transvaginal repair of POP, it is even more important to consider which treatment of apical compartment prolapse should be used in the individual patient [11]. Both abdominal and vaginal techniques treat the apical compartment, but the techniques are very different and not many gynecologists perform both procedures. As a result, only limited data are available that compare these two techniques. In a recent randomized controlled trial, success rate in all vaginal compartments was 77 % for LSC as compared with 43 % in the TVM group [12].

The aim of this study was to compare LSC and TVM with regard to the management of vaginal vault prolapse in centers with special expertise in either LSC or TVM.

## Methods

This study compared two prospective observational cohorts of consecutive women with symptomatic vault prolapse referred to three centers: Sint Franciscus Gasthuis (SFG), Rotterdam, Radboud University Nijmegen Medical Centre (RUNMC), and Reinier de Graaf Group (RdGG) Delft, the Netherlands. SFG is specialized in LSC with bone-anchor fixation and at the time of the inclusion TVM was not an available therapy in this centre. Both RdGG and RUNMC are specialized in pelvic organ prolapse surgery, including TVM technique. At the time of the inclusion, LSC was not an available therapy in these centers.

Patients with a symptomatic vaginal vault prolapse with point C of the Pelvic Organ Prolapse Quantification (POP-Q) examination  $\geq -3$  were included in the study [13]. Exclusion criteria were the inability to understand Dutch, pregnancy or the consideration of pregnancy in the future, a compromised immune system, and treatment for malignancy in the past. Additional exclusion criteria for the LSC were a former rectosigmoid resection, extensive intra-abdominal/pelvic adhesions and a body mass index of  $>40 \text{ kg/m}^2$ .

Approval from the Central Medical Ethics Committee in Rotterdam, the Netherlands was obtained for the LSC cohort study on 22 of December 2004. The data concerning the TVM patients were collected as part of an ongoing outcome registration project, which was approved by the CME/IRB on 19th April 2006. All patients provided written informed consent before participation and were recruited between July 2004 and November 2009.

Baseline as well as postoperative evaluation after 6 weeks and 6 months included a medical history, a gynecologic

investigation including a POP-Q examination, and a validated urogynecological questionnaire, which contains the Dutch validated Urogenital Distress Inventory (UDI), Defecatory Distress Inventory (DDI), and the Incontinence Impact Questionnaire (IIQ) [14, 15].

In both groups the patients received, a single prophylactic dose of antibiotics. All LSC were performed by two of the authors together (RW and GM) using bone anchor fixation [16]. The operative procedure can be summarized as follows: after developing the presacral avascular plane, the cortical bone of the sacral segment 3 is penetrated in the midline with the laparoscopic bone anchor. Fixation to the sacrum is performed with a selftapping titanium Corkscrew Suture or with flat headed titanium screws. A  $4.0 \times 3.0$ -cm piece of monofilament knitted polypropylene mesh (Gynemesh Soft, Ethicon, Norderstedt, Germany) was sutured to the apical part of the posterior vaginal wall with four mersilene 1–0 sutures (Ethicon, Norderstedt, Germany) and was subsequently sutured to the polyester-2 ligatures attached to the bone anchor. The mesh was 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 [17] and placement of a posterior mesh might increase the risk of postoperative complications in patients without a patent posterior prolapse [18], additional prolapse procedures were not performed concomitantly. We anticipated on a low rate of postoperative cystocele and rectocele since fixation of the vaginal apex to sacral segment 3 restores the natural axis of the vagina [19–21].

All TVM procedures were performed by four gynecologists who were formally trained for the tension-free vaginal mesh procedure as described in the paper by Fatton et al. prior to the start of this study [22]. As recommended, a full thickness midline incision was made through the fibromuscular wall of the vagina in order to reduce the known risk of mesh exposure. The TVM was placed as one sheet and not divided, as described by Milani et al. [9]. The TVM procedure was in principle not combined with continence surgery to avoid complications [23]; however, in one case the protocol was ignored.

Primary outcome was failure in the apical compartment, defined as apical POP-Q stage  $\geq \text{II}$  with prolapse complaints or re-treatment in the apical compartment (failure outcome I). For secondary outcomes four different definitions for failure were tested:

- Failure outcome II: POP-Q stage  $\geq \text{II}$  in one or more compartment(s).
- Failure outcome III: POP-Q stage  $\geq \text{II}$  in one or more compartment(s) with prolapse complaints or re-treatment.
- Failure outcome IV: POP-Q at or beyond hymen in one or more compartment(s) with prolapse complaints or re-treatment.
- Failure outcome V: prolapse complaints or re-treatment.

Prolapse complaints were considered present if patients responded affirmative to the questions of the UDI referring to seeing or feeling a vaginal bulge and the experience of at least a little bother from either of these symptoms [14]. Data on symptom scores of the UDI, DDI, and IIQ questionnaires, duration of surgery, blood loss, length of hospitalization, and complications were collected. Pain was a secondary outcome as well and considered significant in case 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 in case a patient responded “yes; moderately to quite a bit” to the question “Do you experience pain during intercourse?” Stress urinary incontinence was considered significant in case a patient responded “yes, moderately to quite a bit” to the UDI question “Do you experience urinary leakage during physical activity, coughing, or sneezing?”

Sample size calculation prior to the comparison study was performed as follows: given the success rates for the apical compartment in literature of 90–100 % [3–7] after LSC and 96 % after TVM [9, 10], we hypothesized that we would not find a significant difference in primary outcome. Based on an overall failure in all compartments of 23 % in the LSC group and 57 % in the TVM group [12], 29 patients would be needed in each group to detect a difference of 34 % in failure rate with a power of 80 % and alpha 0.05.

Continuous variables were analyzed using the independent-samples *t* test to compare means, the Mann–Whitney *U* test to compare independent medians and the Wilcoxon signed-rank test to compare related medians. Categorical variables were compared using the Chi-square test and the Fisher exact test in case of small numbers. Related samples were compared using the paired-samples *t* test to compare means. A *p* value of <0.05 was considered statistically significant. After using the Bonferroni correction for multiple testing for the eight different POP-Q points, the *p* value for statistical significance regarding these points was lowered from 0.05 to 0.006 (alpha 0.05). Statistical analysis was performed using Statistical Package for the Social Sciences, version 18.0 (SPSS inc., Chicago, IL).

## Findings

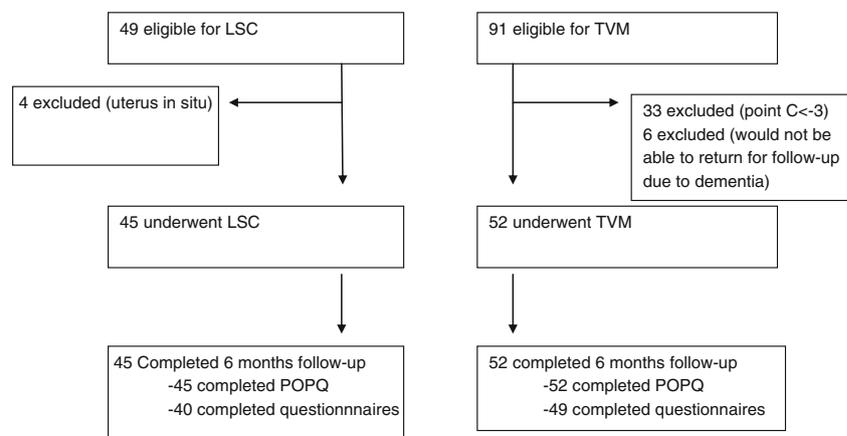
Forty-five women were included in the LSC group and 52 women were included in the TVM group. A flow-chart of the two groups is presented in Fig. 1. All women undergoing LSC and 20 out of 52 (38 %) undergoing TVM have previously been described [9, 24]. Baseline characteristics are shown in Table 1. The TVM group had significantly more patients with overall a higher stage of POP; however, the apical compartment prolapse was similar in the two groups (point C, Table 1). The 2 patients with a POP-Q stage I and point C<sub>≥-3</sub> in the LSC group both experienced bulging symptoms.

Peri- and postoperative data are shown in Table 2. POP-Q measurements are shown in Table 3. Improvement was found for each compartment in both groups. No difference was found in the improvement of the apical compartment between the two cohorts.

In Table 4, failure rates for various failure definitions are shown. The failure rate of symptomatic vault prolapse (failure I: apical compartment POP stage<sub>≥</sub>II with prolapse complaints or apical re-treatment) was 2 % in de LSC group and 2 % in de TVM group (*p*=0.99). Definitions considering the apical compartment with or without prolapse complaints (I, II apical) showed similar failure rates between the groups. However, when definitions of failure included other compartments or prolapse complaints alone (II–V), the LSC group had a significant higher failure rate compared with the TVM group.

Effect of surgery on symptom bother and health related quality of life scores is shown in Table 5. UDI domain score of genital prolapse, overactive bladder, obstructive micturition, and pain improved significantly after surgery in both groups. The domain score of genital prolapse 6 months after TVM was significantly lower (less bother) compared with the score of de the LSC group.

**Fig. 1** Patient enrollment and follow-up



**Table 1** Patient characteristics

Characteristics	LSC (n=45)	TVM (n=52)	p value
Age (years) <sup>a</sup>	65.6 (9.7)	69.1 (11.6)	0.12
Parity (number) <sup>b</sup>	2 (0–6)	3 (0–6)	0.12
BMI (kg/m <sup>2</sup> ) <sup>a</sup>	25.6 (3.1)	26.2 (3.6)	0.33
Comorbidity <sup>c</sup>	5 (11 %)	25 (48 %)	<0.001
Previous surgery <sup>c</sup>			
Abdominal hysterectomy	18 (40 %)	13 (25 %)	0.15
Vaginal hysterectomy	27 (60 %)	39 (75 %)	0.11
Anterior colporrhaphy	24 (53 %)	23 (44 %)	0.54
Anterior mesh procedure	0 (0 %)	1 (2 %)	0.54
Posterior colporrhaphy	24 (53 %)	18 (35 %)	0.11
Sacrospinous ligament fixation	0 (0 %)	2 (4 %)	0.12
Sacrococcolpopexy	0 (0 %)	2 (4 %)	0.17
Colpocleisis	0 (0 %)	2 (4 %)	0.17
Previous POP procedure	29 (64 %)	28 (54 %)	0.29
More than one POP procedure	2 (4 %)	6 (12 %)	0.14
Previous incontinence surgery <sup>c</sup>	9 (20 %)	4 (8 %)	0.08
Overall POP-Q stage <sup>c</sup>			
I <sup>d</sup>	2 (4 %)	0 (0 %)	0.21
II	31 (69 %)	5 (10 %)	<0.001
III	12 (27 %)	43 (83 %)	<0.001
IV	0 (0 %)	4 (7 %)	0.08
Point C <sup>b</sup>	0 (–3 to 4)	1 (–3 to 9)	0.41

POP pelvic organ prolapse, POP-Q pelvic organ prolapse quantification, LSC laparoscopic sacral colpopexy, TVM total vaginal mesh

<sup>a</sup>Data presented as mean (standard deviation), and *p* value calculated with independent sample *t* test

<sup>b</sup>Data presented as median (range), and *p* value calculated with Mann–Whitney *U* test

<sup>c</sup>Data presented as number of patients (in percent), and *p* value calculated with Chi-square test and the Fisher exact test in case of small numbers

<sup>d</sup>POP-Q point C<sub>≥</sub>–3

## Discussion

Comparison of LSC with bone anchor fixation and mesh limited to the apex to TVM revealed significantly higher overall POP-Q failure rate (symptomatic failure in any of the compartments) in the LSC group with no statistically significant differences regarding the vaginal vault. We anticipated a positive effect of fixation of the vaginal apex also on the anterior and posterior compartment due to restoration of the vaginal axis [19–21]. However, the results in the LSC cohort demonstrate that apical support alone does not adequately prevent prolapse of the anterior and posterior compartment and support the necessity of anterior and posterior fixation of the vaginal cuff at the time of LSC. This finding also has its repercussions on the power analysis which was based on overall failure rates in all compartments.

Different types of complications were seen in the two groups. Scores in the UDI domain genital prolapse improved significantly in both groups, but the postoperative genital prolapse score was lower (less complaints) in the TVM group.

The strengths of this study are the prospective design of the study and the use of standardized and validated instruments of measurement. Furthermore, since comparative data on these two main techniques for vaginal

vault prolapse are limited, this is an actual and highly relevant topic in urogynecological practice [25]. The short follow-up of 6 months and the nonrandomized selection of intervention were important limitations of this study. Furthermore, an independent clinical investigator who was not involved in the management of the patients would ideally have performed the pre- and postoperative examinations.

Sometimes the vault may be prolapsed clinically to a significant extent and yet be measured as POP-Q stage I, demonstrating a limitation of the POP-Q scoring system with respect to the apical compartment [26]. We had two patients, included in the LSC cohort, with a vault prolapse and vaginal bulge symptoms (UDI score on domain genital prolapse $\geq$ 16.6) despite an overall POP<stage II. In these two patients, the POPQ point C was $\geq$ –3 cm.

The high success rates of the LSC and TVM in the apical compartment were comparable to the rates reported in literature [3–9, 27]. However, the overall failure rate of 51 % in the LSC group was high compared with the 23 % failure rate after two years follow-up reported in a recent randomized controlled trial on LSC versus TVM for vaginal vault prolapse [12]. This may be explained by the fact that mesh was only applied to the apex without combining LSC with

**Table 2** Peri- and postoperative data

Variable	LSC (n=45)	TVM (n=52)	p value
(Concomitant) surgery <sup>a</sup>	2 (4 %)	1 (2 %)	0.35
TVT-O	0	1 (2 %)	0.54
Laparoscopic adhesiolysis	1 (2 %)	0	0.46
Laparoscopic aspiration pseudocysts	1 (2 %)	0	0.46
Spinal analgesia <sup>a</sup>	0	33 (63 %)	<0.001
Operating time (min) <sup>b</sup>	120 (60–240)	70 (44–110)	<0.001
Blood loss (ml) <sup>b</sup>	50 (10–100)	100 (50–1,300)	<0.001
Duration urinary catheter (days) <sup>b</sup>	1 (1)	2 (1–10)	<0.001
Hospital stay (days) <sup>b</sup>	2 (0–5)	3 (0–8)	<0.001
Complications <sup>a</sup>			
Blood loss>500 ml	0 (0 %)	1 (2 %)	0.54
Bladder perforation	0 (0 %)	1 (2 %)	0.54
Repeat surgery for postoperative hemorrhage	0 (0 %)	1 (2 %)	0.54
Hematoma	0 (0 %)	2 (4 %)	0.28
Temporary urinary retention	0 (0 %)	10 (19 %)	0.001
Conversion laparotomy due to injury ileum	1 (2 %)	0 (0 %)	0.46
Temporary neurologic complaints caused by irritation left lumbar plexus	1 (2 %)	0 (0 %)	0.46
Outcome/complications at follow-up 6 months <sup>a</sup>			
Cumulative mesh exposure	1 (2 %)	4 (8 %)	0.19
Re-treatment for POP	2 (4 %)	0 (0 %)	0.21
Pain (lower abdomen/genital area)			
Baseline	9/43 (21 %)	11/44 (25 %)	0.65
At 6 months	1/40 (3 %)	1/45 (2 %)	0.50
De novo pain	0 (0 %)	0 (0 %)	0.99
Dyspareunia			
Baseline	3/18 (17 %)	4/17 (24 %)	0.29
At 6 months	3/21 (14 %)	3/18 (17 %)	0.33
De novo dyspareunia	2/18 (11 %)	1/17 (6 %)	0.40
Stress urinary incontinence			
Baseline	3/43 (7 %)	11/45 (24 %)	0.02
At 6 months	3/41 (7 %)	5/46 (11 %)	0.25
De novo stress urinary incontinence	2/41 (5 %)	2/41 (5 %)	0.38

TVT tension free vaginal tape—obturator system, POP pelvic organ prolapse, LSC laparoscopic sacral colpopexy, TVM total vaginal mesh

<sup>a</sup>Data presented as number of patients (in percent), and *p* value calculated with Chi-square test and the Fisher exact test in case of small numbers

<sup>b</sup>Data presented as median (range), and *p* value calculated with Mann–Whitney *U* test

anterior or posterior repairs (either laparoscopically applied mesh or with vaginal colporrhaphia) in the present study. In a cohort study on 22 LSC, an overall failure rate of 73 % after 2 years was found when a mesh was attached to the apex and the posterior wall only [8]. Anterior mesh application during LSC therefore also seems important. Adequate level I support has a critical role on the position of the anterior and posterior vagina [28, 29]. However, this adequate level I support has not prevented the occurrence of anterior and posterior wall prolapse in many cases in the LSC group. Combining the LSC with anterior and/or posterior repair, either performed laparoscopically or vaginally, might have resulted in better overall results in the LSC group. After evaluation of these results this has now become the standard procedure in LSC.

Our overall success rate of the TVM was high compared with the results of Maher et al. [12], but in that study the follow-up was 1.5 years longer and 12 out of the 55 patients with TVM were considered as failures due to lost to follow-up in that study. Our success rate of the TVM was low compared with a previously published cohorts of a total mesh [9, 10].

In contrast with the results of the study by Maher et al. [12], the symptom score of genital prolapse after 6 months was significantly lower (less complaints) in the TVM group, compared with the LSC group. Recurrent prolapse symptoms in the LSC group generally arose from the untreated anterior or posterior compartment. The application of mesh to the apex only in the LSC group might also explain this difference.

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

POPQ point	Baseline		<i>p</i> value <sup>a</sup> LSC versus TVM	6 months		<i>p</i> value <sup>a</sup> LSC versus TVM	<i>p</i> value <sup>b</sup> within group LSC/TVM
	LSC ( <i>n</i> =45)	TVM ( <i>n</i> =52)		LSC ( <i>n</i> =45)	TVM ( <i>n</i> =52)		
Aa	−2 (−3 to 1)	3 (−3 to 3)	<0.001	−2 (−3 to 0)	−3 (−3 to 0)	<0.001	0.002/<0.001
Ba	−2 (−3 to 3)	3 (−2 to 9)	<0.001	−2 (−3 to 2)	−3 (−3 to 4)	<0.001	0.005/<0.001
C	0 (−3 to 4)	1 (−3 to 9)	0.41	−8 (−8 to −3)	−8 (−10 to 4)	0.074	<0.001/<0.001
GH	3 (2 to 5)	5 (2 to 7)	<0.001	3 (2 to 5)	3 (2 to 6)	0.21	1.00/<0.001
PB	3 (2 to 3)	3 (1 to 7)	0.13	3 (2 to 3)	3 (1 to 6)	<0.001	0.16/0.23
TVL	8 (7 to 9)	9 (5 to 10)	<0.001	8 (7 to 9)	9 (6 to 10)	<0.001	1.00/0.009
Ap	−2 (−3 to 2)	1 (−3 to 3)	<0.001	−2 (−3 to 0)	−3 (−3 to 0)	<0.001	<0.001/<0.001
Bp	−2 (−3 to 2)	2 (−3 to 9)	<0.001	−2 (−3 to 2)	−3 (−3 to 4)	<0.001	0.001/<0.001
POP-Q stage anterior	1 (0 to 3)	3 (1 to 4)	<0.001	1 (0 to 3)	0 (0 to 3)	<0.001	<0.001/<0.001
POP-Q stage apical	2 (0 to 3)	3 (0 to 4)	0.357	0 (0 to 1)	0 (0 to 3)	0.31	0.016/<0.001
POP-Q stage posterior	1 (0 to 3)	3 (0 to 4)	<0.001	1 (0 to 3)	0 (0 to 3)	<0.001	0.001/<0.001
Total POP-Q stage	2 (1 to 3)	3 (2 to 4)	<0.001	1 (0 to 3)	1 (0 to 3)	<0.001	<0.001/<0.001
Change C	−	−	−	7 (5 to 12)	7 (3–19)	0.97	−

POP pelvic organ prolapse, POP-Q pelvic organ prolapse quantification, LSC laparoscopic sacral colpopexy, TVM total vaginal mesh.

<sup>a</sup> Mann–Whitney *U* test

<sup>b</sup> Data presented as median (range)

<sup>c</sup> Wilcoxon signed-rank test

The types of complications were remarkably different between the two techniques. There was a high rate of temporary urinary retention in the TVM group. The complications with long lasting consequences were similar in both groups. Major complications such as bowel

injury, de novo dyspareunia, de novo pain, and exposure did not differ between both groups in this study. In comparison with earlier studies on these two techniques, no major differences were found [6, 9, 10, 27]. In the RCT of Maher et al. [12], the reoperation rate in the

**Table 4** Failure at 6 months for different definitions

Failure definition	LSC ( <i>N</i> =45)	TVM ( <i>N</i> =52)	<i>p</i> value <sup>a</sup>	OR (95 % CI)	RR (95 % CI)
(I) Apical compartment POP-Q stage ≥II with prolapse complaints or apical re-treatment	1 (2 %)	1 (2 %)	0.99	1.1 (0.07–18.7)	1.0 (0.9–1.1)
(II) POP-Q stage ≥II in one or more compartment POP in every separate compartment	23 <sup>b</sup> (51 %)	11 (21 %)	0.002	3.9 (1.6–9.4)	2.4 (1.3–4.4)
Anterior	14 <sup>c</sup> (31 %)	9 (17 %)	0.11	2.2 (0.8–5.6)	1.8 (1.0–2.2)
Posterior	10 (22 %)	4 (8 %)	0.04	2.2 (1.0–11.8)	2.9 (1.0–8.6)
Apical	1 <sup>d</sup> (2 %)	2 (4 %)	0.39	0.6 (0.1–5.9)	0.5 (0.1–5.7)
(III) Overall POP-Q stage ≥II with prolapse complaints or re-treatment	7/42 (17 %)	1/52 (2 %)	0.02	10.2 (1.2–86.6)	1.2 (1.0–1.4)
(IV) POP at or beyond hymen with prolapse complaints or re-treatment	6/44 (14 %)	1/52 (2 %)	0.04	8.1 (0.9–69.7)	1.1 (1.0–1.3)
(V) Prolapse complaints or re-treatment	12/41 (29 %)	3/45 (7 %)	0.006	5.8 (1.5–22.4)	1.3 (1.1–1.6)

Data presented as numbers (in percent)

POP pelvic organ prolapse, POP-Q pelvic organ prolapse quantification, LSC laparoscopic sacral colpopexy, TVM total vaginal mesh, OR = odds ratio, 95% CI 95 % confidence interval, RR relative risk

<sup>a</sup> Chi-square test and the Fisher exact test in case of small numbers

<sup>b</sup> Including one re-sacrocolpopexy and one anterior colporrhaphy within 6 months

<sup>c</sup> Including one anterior colporrhaphy within 6 months

<sup>d</sup> Including one sacrocolpopexy within 6 months

**Table 5** Effect of surgery on symptoms and health-related quality of life scores

Domain	Baseline		6 months		<i>p</i> value within group <sup>a</sup> (LSC/TVM)	<i>p</i> value between groups <sup>b</sup> LSC versus TVM baseline/6 m
	LSC ( <i>n</i> =43)	TVM ( <i>n</i> =46)	LSC ( <i>n</i> =40)	TVM ( <i>n</i> =49)		
<b>UDI</b>						
Genital prolapsed	67.9 (30.2)	63.0 (18.7)	11.3 (22.5)	2.0 (9.9)	<0.001/<0.001	0.49/0.01
OAB	34.6 (26.0)	32.2 (26.8)	17.6 (19.2)	15.4 (19.7)	<0.001/0.001	0.68/0.59
Incontinence	16.3 (20.7)	24.2 (26.8)	10.6 (17.4)	15.9 (21.8)	0.11/0.10	0.15/0.20
Obstructive micturition	34.5 (24.8)	28.1 (29.9)	15.4 (21.8)	12.2 (23.8)	<0.001/<0.001	0.28/0.51
Pain	25.4 (24.8)	27.7 (27.6)	12.5 (15.9)	10.1 (16.8)	0.001/<0.001	0.69/0.49
<b>DDI</b>						
Constipation	12.7 (19.8)	14 (18.7)	11.1 (20.4)	8.2 (15.1)	0.36/0.12	0.75/0.45
Obstructed defecation	13.4 (14.6)	12.0 (17.1)	7.5 (11.1)	9.1 (13.4)	0.003/0.10	0.69/0.56
Pain	6.2 (15.9)	9.6 (21.5)	6.7 (15.5)	7.1 (15.9)	0.99/0.56	0.40/0.89
Incontinence	4.4 (11.7)	9.8 (15.8)	5.0 (10.1)	4.3 (8.8)	0.99/0.03	0.07/0.72
<b>IIQ</b>						
Physical functioning	20.8 (26.9)	25.0 (28.2)	14.1 (24.0)	11.2 (21.1)	0.17/0.004	0.50/0.56
Mobility	26.4 (20.4)	32.0 (24.6)	24.5 (25.4)	15.7 (19.5)	0.57/0.003	0.25/0.08
Social functioning	12.4 (11.9)	15.9 (18.1)	7.6 (13.9)	6.7 (10.6)	0.10/0.01	0.35/0.74
Embarrassment	12.6 (20.7)	21.8 (26.1)	7.2 (13.9)	6.9 (12.3)	0.15/0.002	0.09/0.92
Emotional health	21.4 (21.4)	24.9 (25.6)	15.7 (21.1)	9.3 (13.3)	0.51/0.002	0.51/0.10

UDI, DDI, and IIQ data presented as mean (standard deviation). Scores range between 0 (least bother) to 100 (maximum bother)

UDI urogenital distress inventory, DDI defecatory distress inventory, IIQ incontinence impact questionnaire, LSC laparoscopic sacral colpopexy, TVM total vaginal mesh

<sup>a</sup> Paired *t* test

<sup>b</sup> Independent *t* test

LSC group was significantly lower, compared with the reoperation rate in the TVM group. This discrepancy with our results might be explained by the shorter follow-up as mentioned before.

Reports on major complications have recently been published on both techniques subject to this study [12, 30–34]. In the LSC group injury of the bowels, bowel herniation though a port site and lumber/sacral osteomyelitis with sepsis are possible life-threatening complications [12, 30–32]. In this study, one serosal lesion to the ileum injury occurred. This injury was recognized immediately and sutured after conversion to a laparotomy [24]. In the TVM group, acute massive hemorrhage, retroperitoneal hematoma, and infected pelvic hematoma have been reported, indicating major, possible life-threatening complications as well [12, 33]. A FDA Public Health Notification update informed the USA public that “surgical mesh for transvaginal repair of POP is an area of continuing serious concern” and “serious complications associated with surgical mesh for transvaginal repair of POP are not rare” [11]. A definition for a serious complications was not given. Severe/serious complications, such as de novo dyspareunia, de novo pain, and exposure did not differ between both groups in this study.

The LSC and the TVM both involve a significant learning curve [35]. Both techniques are associated with potential serious complications. The FDA promulgated a number of recommendations including proper training of the surgeon, certification, and counseling of the patient. Therefore centralization of these procedures in the hands of surgeons with proven experience seems mandatory.

## Conclusions

Although either procedures (LSC or TVM) will be adequate in most patients with vault prolapse, specific indications for either technique may exist. For example, in elderly women with comorbidity, spinal analgesics and shorter duration of surgery connected with TVM may be advantageous. Furthermore, in patients with known pelvic/abdominal adhesions a TVM procedure could be preferable. In young, healthy, sexually active women, the more superficial vaginal insertion of mesh can be avoided when choosing LSC. In order to make a deliberate choice between these two types of surgery and to improve the guidance to our patients, further evaluation with long-term follow-up of both procedures is required, preferably by well-designed RCT's with a long-term follow-up of both procedures.

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