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Functional Outcome after Laparoscopic Posterior Sutured Rectopexy Versus Ventral Mesh Rectopexy for Rectal Prolapse: Six-year Follow-up of a Double-blind, Randomized Single-center Study☆

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ABSTRACT

Background: Laparoscopic ventral mesh rectopexy (LVMR) for rectal prolapse has been implemented to reduce postoperative bowel symptoms. The preoperative-to-postoperative change in a double-blinded, randomized study comparing it to laparoscopic posterior sutured rectopexy (LPSR) found no significant difference between the two procedures after one year. The aim of this study was to investigate the long-term functional outcomes.

Methods: From November 2006–January 2014, 75 patients were randomized to LVMR (n = 37) or LPSR (n = 38). In March 2017, questionnaires containing constipation symptom score (PAC-SYM), quality of life score (PAC-QoL), obstructed defecation score (ODS), Cleveland clinic constipation and incontinence scores (CCCS, CCIS) were mailed to all the patients included in the RCT. Prolapse recurrences and mesh complications were recorded.

Finding: Sixty-nine patients were available for long-term follow-up. Questionnaires were completed by 64 patients (94.4%). The median follow-up was 6.1 years. The total PAC-QoL was significantly lower in the LVMR group 0.26 (0.14–0.83) compared to the LPSR group 0.93(0.32–1.61)(P = 0.008). The total PAC-SYM was significantly lower in the LVMR group 0.5 (0.21–0.87) compared to the LPSR group 1.0 (0.5–1.5)(P = 0.031). Except for CCIS, the ODS and the CCCS significantly favored the LVMR group at six years (P = 0.011 & 0.017). Only three(8.82%) patients in the LVMR group developed recurrence compared to seven(23.33%) in the LPSR group (P = 0.111).

Interpretation: The long-term functional outcome after LVMR is superior to that after LPSR. Larger multi-center studies are warranted.

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1. Introduction

Full-thickness rectal prolapse is a devastating condition that has a negative impact on quality of life [1]. Over the past decades, more than a 100 different operations have been developed for surgical treatment of full-thickness rectal prolapse [2,3]. However, none has managed to achieve the optimal outcome of curing the prolapse with low risk of recurrence while maintaining good long-term functional outcome. The long-term recurrence rates favor abdominal procedures over perineal procedures [4,5]. The two most widely adopted abdominal techniques are laparoscopic posterior sutured rectopexy (LPSR) and laparoscopic ventral mesh rectopexy (LVMR). LVMR was introduced by D'Hoore et al. to improve functional outcome with low risk of recurrence, but concerns over mesh complications have prompted alternative methods, such as LPSR, to be used [6]. The main differences between the two procedures are the method of rectal mobilization and fixation. Unlike LPSR, there is no posterior dissection in LVMR, in addition, the anterior wall of the rectum is fixed to the sacral promontory with a mesh.

Our group has performed the only double-blind randomized controlled trial (RCT) comparing the preoperative-to-postoperative functional outcomes for LVMR versus LPSR; the primary outcome of obstructed defecation syndrome (ODS) at one year was equival-

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Research in context

Evidence before this study

Full-thickness rectal prolapse is a disabling condition. Many abdominal and perineal procedures have been described to cure full-thickness rectal prolapse, but it is generally accepted that a laparoscopic abdominal approach is preferable in fit patients. The two most common abdominal procedures are laparoscopic posterior sutured rectopexy (LPSR) and the later introduced laparoscopic ventral mesh rectopexy (LVMR). In 2016, this journal published the only RCT comparing the preoperative-to-postoperative functional outcomes for LVMR versus LPSR. It showed no difference between the functional outcomes of the two procedures at 1-year follow-up, but there was a reported longer postoperative gastrointestinal transit time and more patients with internal intussusception of the rectum in LPSR group.

We did a systematic search of PubMed from Jan 2016 to May 31, 2019, using the terms "rectal prolapse", "VMR", "ventral mesh rectopexy", "rectopexy", and "functional results" with no data or language restriction and identified 58 publications, but there is hardly any evidence on long-term function, particularly there was no RCT comparing outcomes for LVMR versus LPSR.

Since the RCT from 2016 showed no functional differences, and there is a long-term risk of mesh related complications about 2%, many centers including us have become reluctant to perform LVMR.

Added value of this study

Ventral mesh rectopexy (LVMR) has, especially in Europe, gained popularity as the preferred treatment for full-thickness rectal prolapse to obtain good postoperative functional results with low recurrence rates. Our study is long-term follow-up of the double-blinded randomized controlled trial that was comparing the functional outcome after LVMR versus laparoscopic posterior sutured rectopexy (LPSR) in patients with full-thickness rectal prolapse. Unlike at 1-year follow-up, our result clearly shows that the long-term functional outcome after LVMR is superior to that after LPSR with a trend toward a lower recurrence rate. We couldn't evaluate with statically felicity risk of recurrence and complications since this study was not originally powered toward recurrence and risk of complication including mesh erosions.

Implications of all the available evidence

This study suggests that LVMR would be appropriate as the best available abdominal procedure that could cure the external rectal prolapse with a low risk of recurrence and obtaining good long-term functional outcome. Larger multicenter studies are warranted to validate these results — especially the risk of long-term complications.

ent between the two procedures [7]. However, the postoperative gastrointestinal transit time was significantly prolonged after LPSR. Furthermore, significantly more patients in the LPSR group had rectal intussuception detected by postoperative defecography. Given the prolonged gastrointestinal transit time and higher prevalence of rectal internal intussuception in the LPSR group we believe it is important to establish whether this leads to differences in long-term functional outcome between the techniques.

The aims of this study are to compare the long-term functional outcomes between LVMR and LPSR and their impact on quality of life.

2. Methods

This study aimed to investigating the long-term follow-up of the double-blinded RCT that compared functional outcomes after LVMR versus LPSR in patients with full-thickness rectal prolapse. Patients were recruited between November 2006 and January 2014. The trial methodology, including details relating to the surgical techniques, has been reported [4]. The primary endpoint was one-year change in obstructed defecation syndrome (ODS) score [7]. After one year, the patients were informed which procedure they have received, and later they were informed that there was no difference in functional outcome between the two procedures.

2.1. Preoperative and One-year Follow-up Questionnaires

Patients completed questionnaires to assess their obstructed defecation syndrome (ODS) score, developed by Altomare and colleagues [8], along with the Cleveland Clinic constipation score (CCCS) [9], and Cleveland Clinic fecal incontinence score (CCIS) [10]. A research nurse assisted the patients who needed help to ensure that all questionnaires were completed.

2.2. Long-term Follow-up Questionnaire

In March 2017, all surviving patients were mailed the original questionnaires as well as "The Patient Assessment of Constipation Quality of Life questionnaire" (PAC-QOL) [11] and "The Patient Assessment of Constipation symptom score" (PAC-SYM) [12]. The PAC-QOL is a self reporting questionnaire, which investigates the patient's quality of life. The PAC-QOL consists of 28 items divided into four scales: worries/concern (11 items), physical discomfort (four items), psychosocial discomfort (eight items), and satisfaction (five items) [13]. A lower score indicates a higher quality of life. While the PAC-SYM is a 12-item self-report questionnaire subdivided in three symptom subscales (i.e., abdominal, stool, and rectal) [14]. A higher score indicates more severe symptom. All items in both scores are reported on a Likert scale from 0 to 4 points. These scores were included in order to quantify the overall burden of constipation. They were not available in Danish in 2006 when this RCT was planned and started.

Patients were asked if they had any sign or symptom of recurrence of the prolapse. If yes, they were invited to a clinical examination by a specialized pelvic floor colorectal surgeon to exclude a recurrence.

Recurrence was defined as development of a new external rectal prolapse, which was confirmed by clinical examination including straining on the toilet seat.

The randomized controlled study was approved by the Danish Ethical Committee (reference number M-ÅA-20060096) and the Danish Data Protection Agency. Informed consent was obtained from all patients according to the Declaration of Helsinki. This long-term follow-up study was classified as a quality project and a new approval from the Ethical Committee was not needed according to Danish regulations.

2.3. Long-term Outcomes

The primary outcome was PAC-QOL compared between the two groups.

Secondary outcomes were PAC-SYM, ODS, CCCS, CCCI at six-years follow-up between the two groups. The mean differences in outcomes between baseline and six-year follow-up were also compared between the two groups for ODS, CCCS, CCCI.

Recurrence of full thickness prolapse and mesh extraction were also reported.

2.4. Statistical Analysis

The sample size calculation and the power of the study was described in details in the original study [7]. In brief, the original study was powered for Δ in ODS score as primary outcome. We calculated that a sample of 32 patients in each group was necessary to provide 80% power at an α of 0.05 (two-tailed) expecting obstructed ODS in 50% of patients who received posterior suture rectopexy and 15% who received ventral mesh rectopexy.

Continuous variables were presented as means and standard deviation (SD), or median and interquartile range (IQR) according to their distribution, while categorical variables were presented as numbers and their percentages. Student's *t*-test and Wilcoxon rank-sum test were used to detect differences between groups for continuous variables based on their distribution, and Chi-square test or Fisher's exact test was used for categorical data when appropriate. P-values < 0.05 were considered statistically significant. Statistical analyses were performed using STATA statistical software version 12 (StataCorp LP, College Station, Texas, USA).

3. Results

A total of 75 consecutive patients with rectal prolapse were randomized to LPSR (37 patients) or LVMR (38 patients) between November 2006 and January 2014. A total of 69 patients were available for long-term follow-up. The questionnaires were completed by 64 patients (94.4%) (Fig. 1).

The median (IQR) follow-up was 6.1 years (5.4–6.8) in the LVMR group and 6.1 years (5.4–6.9) in the LPSR group.

Patients' characteristics were balanced between the two treatment groups as shown in Table 1.

Table 1
Baseline characteristics for patients attending follow-up.

	LVMR	LPSR	P-value
Age	56.5(42–73)	48.5(33–63)	0.119
Gender (F/M)	31/3	27/3	0.873
ASA	1(1–2)	1.5(1–2)	0.720
BMI	23.1(21.4–25.9)	23.4(21.9–25.7)	0.983

All values are presented as mean (± SD) and median (IQR).

3.1. Primary Outcome — Patient Assessment of Constipation Quality of Life (PAC-QoL)

The total PAC-QoL was significantly lower in the LVMR group 0.26 (0.14–0.84) compared to the LPSR group 0.93 (0.32–1.61) (P = 0.008). All domains of the score were in favor of the LVMR

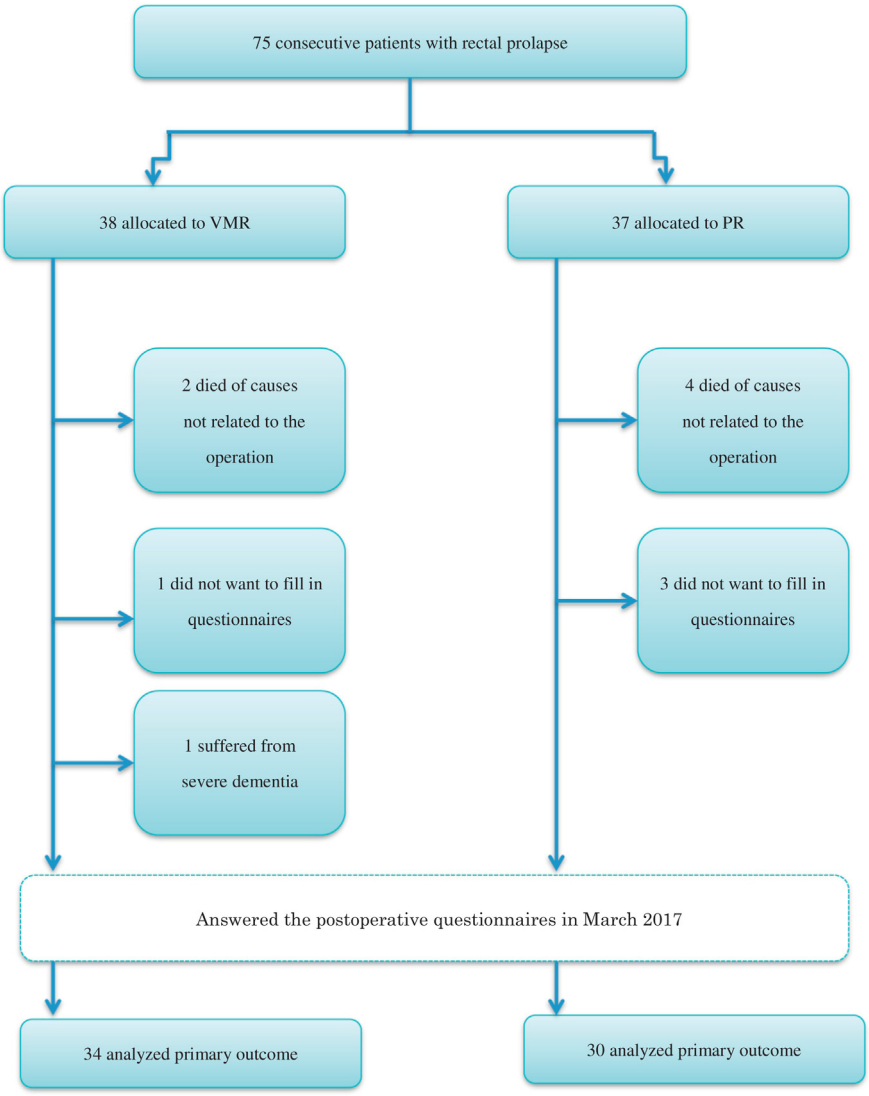

Fig. 1. Trial profile.

Table 2
Symptom scores for all 64 patients six years after prolapse surgery.

	Laparoscopic ventral mesh rectopexy(n = 34)	Laparoscopic posterior sutured rectopexy(n = 30)	P value
PAC-QoL total	0.53 ± 0.54	0.96 ± 0.69	
	0.26 (0.14–0.84)	0.93 (0.32–1.61)	**0.008**
PACQ physical	0.43 ± 0.64	1.03 ± 0.72	
	0.25 (0–0.5)	1.25 (0.25–1.75)	**0.002**
PACQ psychological	0.30 ± 0.41	0.67 ± 0.81	
	0.13 (0–0.5)	0.25 (0–1.25)	0.109
PACQ worries	0.44 ± 0.60	0.83 ± 0.74	
	0.09 (0–0.64)	0.55 (0.36–1.55)	**0.009**
PACQ satisfaction	1.18 ± 0.96	1.63 ± 1.05	
	0.9 (0.5–1.9)	1.4 (0.8–2.2)	**0.088**
PAC-SYM	0.67 ± 0.68	1.0 ± 0.73	
	0.5 (0.21–0.87)	1 (0.5–1.5)	**0.031**
PACSYM abdominal	0.51 ± 0.7	1.08 ± 0.81	
	0.25 (0–0.75)	1(0.75–1.5)	**0.003**
PACSYM rectal	0.46 ± 0.63	0.9 ± 0.7	
	0.25 (0–0.75)	0.75 (0.5–1.25)	**0.004**
PACSYM stool	0.94 ± 0.91	1.36 ± 1.03	
	0.8 (0.3–1.3)	1.2 (0.4–2)	0.101

All values are presented as mean (± SD) and median (IQR).

group. The physical- and worries domains of the PAC-QoL score had significant lower values in the LVMR group than in the LPSR group, whereas the psychological- and satisfaction domains did not significantly differ (Table 2).

3.2. Secondary Outcome

The total PAC-SYM was significantly lower in the LVMR group 0.5 (0.21–0.87) compared to the LPSR group 1.0 (0.5–1.5) (P = 0.031). All domains of the PAC-SYM score were lower in the LVMR group. The abdominal- and the rectal domain were significantly lower, whereas the stool domain did not reach statistically significance (Table 2).

Similarly, the ODS and the CCCS were significantly in favor of the LVMR group at six years (P = 0.011 & 0.017). The mean difference of these scores between baseline and the six years follow-up was also in favor of the LVMR group, but it failed to reach statistical significance (P = 0.191 & 0.279) (Table 3).

There was no difference at six-year follow-up in CCIS between the two procedures (Table 3).

Only three (8.82%) patients in the LVMR group developed recurrence compared with seven (23.33%) in the LPSR group (P = 0.111). None of the patients developed mesh-related complications or re-operation.

4. Discussion

This study is a continuation of the first double-blinded RCT comparing the functional outcome before and after LVMR and LPSR. After one year, there was no difference in functional outcome between the two procedures [7]. However, our long-term results showed that functional outcome after LVMR was significantly better than for LPSR, with a trend toward a lower recurrence rate.

Numerous abdominal and perineal procedures have been described to treat full-thickness rectal prolapse. The key objectives in treatment of full-thickness rectal prolapse is to cure the prolapse with low risk of recurrence while maintaining minimal morbidity and good long-term functional outcome. LVMR was introduced to achieve these objectives, and was first described by D'Hoore and colleagues in 2004 [6]. In this procedure, autonomatic nerve damage is less likely because there is no posterior pelvic dissection, unlike LPSR.

The one-year outcomes for our LVMR versus LPSR RCT indicated that functional outcome after LVMR was not significantly superior to LPSR according to the mean changes in ODS score. However, the postoperative gastrointestinal transit time was significantly more prolonged in the LPSR group [7]. To the best of our knowledge, no RCT has reported the long-term follow-up for the functional outcome after LVMR versus LPSR in only full-thickness rectal prolapse. In the long-term follow-up of this RCT, our result clearly indicates that the functional outcome after LVMR is superior to that after LPSR measured by PAC-QOL. A possible explanation is that the longer postoperative gastrointestinal transit time and the more common presence of internal intussuception of the rectum at one-year follow-up after posterior sutured rectopexy may lead to symptomatic constipation over time, while there is still an improvement in constipation up to three years after LVMR [15].

We used the PAC-QOL as primary endpoint, since we found that it is a better clinical tool to quantify the overall burden of constipation and its impact on quality of life. It is a patient-reporting, prospectively validated questionnaire, which is sensitive and able to reflect relatively minor changes in the patient's condition. All the secondary endpoints — except for CCIS — were significantly in favor of the LVMR group after six years. The mean of the change scores had the same tendency, but it didn't reach statistical significance. We decided to include the mean change scores as secondary endpoint, since it was reported in our original study [7]. However, it is well-known that change scores will become less sensitive (i.e., have larger variance) than the follow-up score, when the correlation between the baseline score and the follow-up score is smaller than 0.5. With extended follow-up the correlation is expected to decrease and the advantage of a within-person comparison may eventually disappear [16].

Some colorectal surgeons perform resection rectopexy for rectal prolapse by adding sigmoid resection to abdominal rectopexy. It was first described by Frykman HM et al. in 1969 to diminish the risk of constipation after sutured rectopexy [17], and it remains an established alternative which is commonly performed in the USA and Australia. The early outcome data by the inventor reported a high anastomotic leak rate, with five out the first 138 cases (3.6%) effected [18]. Although more favorable outcomes have since been published, these figures discouraged widespread uptake of this technique in Europe. For this reason, we didn't include this technique as a third group in this study.

Regarding recurrences rates, in concordance with the previously published study [7,19], it was lower in the LVMR group (8.82%) than in the LPSR group (23.33%). This didn't reach statistical significance, but the study was not powered for recurrence and a type II error is quite possible.

Table 3
Symptom scores for all 64 patients prior to prolapse surgery and then at one and six-year follow-up respectively.

	Pre-operative			1-year follow-up				6-year follow-up			
	VMR	PSP	P value	VMR	PSP	P value	Delta P	VMR	PSP	P value	Delta P
ODS	9.3 ± 5.6	10.8 ± 5.5	0.245	7.17 ± 4.92	8.44 ± 5.74	0.327	0.890	6.52 ± 6.11	9.5 ± 5.87	**0.011**	0.191
CCCS	9.4 ± 5.5	9.9 ± 4.3	0.584	6.55 ± 4.58	8.28 ± 4.71	0.115	0.275	5.52 ± 4.52	8 ± 4.16	**0.017**	0.279
CCIS	10.1 ± 5.8	10.2 ± 5.4	0.816	6.39 ± 5.30	6.65 ± 4.85	0.684	0.649	4.20 ± 4.16	5.66 ± 4.43	0.165	0.311

All values are presented as means ± SD.

A LVMR has been associated with several reports of mesh-related complications, especially mesh erosion [15,20,21]. In a multicenter study, including more than 2000 patients who underwent LVMR, by Evance C et al., a 2.0% (45 patients) mesh erosion rate was reported with a median follow-up of 36 months (range, 0–162 months) [22]. Fortunately in our study, none of the patients developed mesh-related complication or underwent re-operation.

The main strength of this study is that we have obtained long-term follow-up with high response rates (94%) from a well conducted high-quality double-blinded RCT using validated patient-reported outcome measures (PROMs). Furthermore, the despite long-term follow-up the sample size requirements for the primary endpoint were met. However, we acknowledge that this is a single-center study with a relatively low number of patients. A second limitation was that patients were informed about which arm of the trial they were in at one year, essentially this has become a single-blinded RCT for the six-year follow-up. We do not think this will lead to significant bias because patients were informed that there was no difference in functional outcome between treatments. Thirdly, we didn't have preoperative PAC-QOL data. Forth, PAC-QoL and PAC-SYM have not been validated in Danish, however all other questionnaires are validated, and these questionnaires are widely used in an outpatient setting without difficulty. Finally, in the current climate, we felt it is very important to report recurrence and complication rates, including mesh erosions, however these should be interpreted with caution as the study was not originally powered toward recurrence and risk of complication.

5. Conclusion

This study shows that the long-term functional outcomes after LVMR are better than that for LPSR. We also consider that LVMR may be associated with a lower risk of recurrence. Larger multicenter studies are needed to verify this finding, and to study the possible risk of complications including mesh erosions.

Role of the Funding Source

This study was conducted as a part of routine clinical work and no funding was receved. The corresponding author had full access to all data in the study and had final responsesibility for the decision to submit for publication.

Author Contribution

SL and LL were response for the study concept and design. LL and JJ acquired and monitored the data. JJ and HE did the statistical analysis, and JH and HE drafted the manuscript and analyzed and interpreted the data. All authors revised the manuscript for important intellectuall content. LL was the principal investigator.

Declaration of Competing Interest

The authors have nothing to declare.

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