Article type : Original Article - Randomised Controlled Trial

Restored pelvic anatomy is preserved after laparoscopic and robot-assisted ventral rectopexy: MRI-based 5-year follow-up of a randomised controlled trial

KE Laitakari[1,2], JK Mäkelä-Kaikkonen[1,2], E Pääkkö[3], I Kata[3], P Ohtonen[2,4], J Mäkelä[1,2], TT Rautio[1,2]

[1]Department of Surgery, Division of Gastroenterology, Oulu University Hospital, Oulu, Finland

[2]Medical Research Center Oulu, Center of Surgical Research, University of Oulu, Oulu, Finland

[3]Department of Radiology, Oulu University Hospital, Oulu, Finland.

[4]Division of Operative Care, Oulu University Hospital, Oulu, Finland

Corresponding author: Kirsi Laitakari (kirsi.laitakari@fimnet.fi).

Conflict of interest: TT Rautio has a Surgeon Services Agreement with Intuitive. The other authors declare that they have no conflict of interest.

Authors' contributions:

KE Laitakari, MD: acquisition, analysis and interpretation of data, writing the article.
JK Mäkelä-Kaikkonen, MD, PhD: conception and design of the study, acquisition, analysis and interpretation of data, writing the article.
E Pääkkö, MD, PhD: design of the study, analysis and interpretation of data, writing the article, critical revision.
I Kata, MD: analysis and interpretation of data.
P Ohtonen, MSc: design of the study, analysis and interpretation of data, writing the article, critical revision.
J Mäkelä, MD, PhD: conception and design of the study.
TT Rautio, MD, PhD: conception and design of the study, acquisition, analysis and interpretation of data, writing the article.

Word count: 2971

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/codi.15195
This article is protected by copyright. All rights reserved

Accepted Article

Abstract

Aim

We compared the long-term anatomical outcomes between robot-assisted (RVMR) and laparoscopic ventral mesh rectopexy (LVMR) for external or internal rectal prolapse.

Method

This study is a follow-up of a single centre randomised controlled trial (RCT). Thirty patients were randomly allocated to RVMR (n=16) and LVMR (n = 14). The primary endpoint was the maintenance of the restored pelvic anatomy 5 years after the operation as assessed by magnetic resonance (MR) defaecography. Secondary outcome measures included the Pelvic Organ Prolapse Quantification (POP-Q) measures and functional results assessed using symptom questionnaires.

Results

Twenty-six patients (14 RVMR and 12 LVMR) completed the 5-year follow-up and were included in the study. The MR imaging (MRI) results, POP-Q measurements and symptom-specific quality of life measures did not differ between the RVMR and LVMR groups. The MRI measurements of the total study population remained unchanged between 3 months and 5 years. In the pelvic floor distress inventory (PFDI-20), the RVMR group had lower symptom scores (mean 96.0, SD 70.7) than the LVMR group (mean 160.6, SD 58.9; p=0.004). In the subscales of pelvic organ prolapse (POPDI-6) (mean 23.2, SD 24.3 vs mean 52.4, SD 22.4; p=0.001) and the colorectal-anal distress inventory (CRADI-8) (mean 38.4, SD 23.3 vs mean 58.6, SD 25.4; p=0.009), the patients in the RVMR group had significantly better outcomes.

Conclusion

After VMR, the corrected anatomy was preserved. There were no clinically significant differences in anatomical results between the RVMR and LVMR procedures 5 years after surgery based on MR defaecography. However functional outcomes were better after RMVR.

This article is protected by copyright. All rights reserved

What does this paper add to the literature?

This is the first randomised study with a 5-year follow-up indicating that the restored anatomy as confirmed by MR-defaecography, is preserved after VMR. Our study is the only randomised controlled trial showing equally good anatomical outcome after either RVMR or LVMR but functional outcomes were better after RVMR.

Accepted Article

This article is protected by copyright. All rights reserved

Introduction

The indications for ventral mesh rectopexy (VMR) have expanded from external rectal prolapse (ERP) to symptomatic internal rectal prolapse (IRP). The results of VMR performed for ERP are satisfactory, but out of 10 patients undergoing surgery for symptomatic IRP, 3 or 4 may continue to suffer functional disorders [1]. In part, the lack of symptomatic relief is explained by postoperative new-onset intussusception [2]. Because more than half of IRPs may be missed by clinical examination [3], pelvic floor imaging is useful when interpreting postoperative symptoms.

Current evidence shows no superiority of robot-assisted ventral mesh rectopexy (RVMR) over laparoscopic ventral mesh rectopexy (LVMR) [4,5]. Both techniques have been proven to be safe and effective [6-8] with the same results in terms of intraoperative, postoperative and mesh-related complications as well as low recurrence rates [4,8-13]. However, the comparative results are based on small patient populations and relatively short follow-up time This series, to date, is the only published randomised study [11,14].

In a previous publication, we demonstrated good anatomical restoration of the pelvic floor after LVMR and RVMR, evaluated by using postoperative dynamic magnetic resonance (MR) [14]. To date, there is no evidence from imaging studies to indicate whether or not the corrected pelvic anatomy is preserved in the long term.

The objective of this 5-year follow-up of a prospective randomised controlled trial (RCT) was to analyse the long-term anatomical and functional results after LVMR and RVMR for patients with ERP and IRP using MR defaecography, clinical examination and self-reported symptom questionnaires completed by patients.

Method

Study design

The results of this study are based on a prospective single-centre RCT conducted at an academic tertiary referral hospital in Finland, registered in Current Clinical Trials (ISRCTN88884232). The study with a protocol amendment to carry out this 5-year follow-up was approved by the local Ethics Committee of the Oulu University Hospital.

This article is protected by copyright. All rights reserved

Patients

Eligible participants were female patients between the ages of 18 and 85 with ERP or recto-anal IRP, with or without a descent of the middle pelvic compartment, combined with symptoms of faecal incontinence and/or obstructive defaecation. All patients gave their written informed consent. The patients were blinded to the type of operation they received. The inclusion and exclusion criteria and the randomisation and blinding details have been reported in a previous publication [11,14]. Preoperative examination and diagnostic investigations included clinical, anorectal and pelvic examination, colonoscopy and MR defaecography.

Outcomes

The primary outcome was assessement of the maintenance of the repaired pelvic anatomy 5 years after surgery. This was made by identifying the presence or absence of rectal prolapse and recto-anal invagination with or without an enterocele. We also evaluated the three-compartment pelvic anatomy by MR defaecography using the H-line, M-line and organ prolapse (HMO) classification [15] at 3 months and 5 years.

Secondary outcomes were the persistence of the effect of VMR on pelvic anatomy, which were measured using the Pelvic Organ Prolapse Quantification (POP-Q) method [16], and the functional results, which were evaluated using self-reported symptom questionnaires completed by patients at the 3-month and 5-year follow-up visits.

Symptom information was obtained using the Obstructive Defecation Syndrome (ODS) score [17], the Wexner score for anal incontinence [18], the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ-12) [19], the Pelvic Floor Impact Questionnaire (PFIQ-7) and the Pelvic Floor Disorder Inventory (PFDI-20) [20], which includes the Urinary Distress Inventory 6 (UDI-6), the Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6) and the Colorectal-Anal Distress Inventory 8 (CRADI-8).

MR defaecography

MR defaecography was performed using a 1.5-T magnet device (Optima MR450w General Electric Healthcare, Chicago, IL, USA). Before the study, the rectum was filled with 200 ml of gel (Resource® Thickenup instant thickener, Nestle®, Vevey, Switzerland) using a rectal catheter. A phased array body coil was used while the patient was lying supine in the magnet. A dynamic FIESTA sequence was

This article is protected by copyright. All rights reserved

Accepted Article

obtained (TR 5.2 ms, TE 2.1 ms, matrix 256 x 256, field of view 33 cm, slice thickness 6 mm). A midsagittal plane was defined, and dynamic images were obtained during squeeze, after which the patient was asked to evacuate. Images were repeatedly obtained during the evacuation until it was evident that proper straining was performed multiple times. Each dynamic sequence lasted 54 s. The MR images obtained at the 3-month and 5-year follow-up visits were assessed visually for intussusception, rectal prolapse, rectocele and enterocoele [21]. A rectocele of ≥ 20mm was considered to be clinically relevant, and this size limit was used in the analysis [22]. The anatomical landmarks for assessing the magnetic resonance imaging (MRI) scans were the most distal part of the bladder for the anterior compartment, the cervix or the leading edge of the vaginal cuff (for patients after hysterectomy) for the middle compartment and the anorectal junction for the posterior compartment. From the pubococcygeal line, a perpendicular line was drawn to the anatomical landmarks and the distance was measured in millimetres. To measure pelvic organ prolapse (POP) at each landmark, the mid-sagittal sequence at rest and at maximum straining were used. The MR images taken at both follow-up visits were assessed using the pubococcygeal line as reference. The differences in the distances between each anatomical landmark at rest and at maximum straining were considered to be the pelvic organ mobility (POM). The H-line (the distance from the inferior border of the pubic symphysis to the posterior anorectal junction) [15] was assessed as the anteroposterior width of the levator hiatus. The first MR follow-up study at 3 months was evaluated by one radiologist (EP); the second follow-up study at 5 years was evaluated in consensus by two radiologists (EP, IK). The radiologists were blinded to the clinical data and the operative technique used.

Surgical technique

The surgical technique by D´Hoore and Penninckx [23] with slight modifications [8] was used. The rectovaginal space was dissected to the level of the levator. A polyester mesh (Parietex™, 3 cm x 20 cm; Covidien Dublin, Ireland) was fixed first caudally through the pelvic floor with two absorbable sutures using an endofascial closing device and then anteriorly to the rectum and to the apex of vagina with six to seven pairs of non-absorbable sutures. Spiral titanium helix-shaped tacks (Pro-Tack™ Fixation Device, Covidien) were used for the mesh attachment to the sacral promontory. The peritoneum was closed with a 15 cm long V-Loc™(Covidien) continuous suture. The RVMR operations were performed using the Da Vinci Si Surgical system (Intuitive Surgical Inc, Sunnyvale, CA, USA).

Accepted Article

This article is protected by copyright. All rights reserved

Statistical methods

Statistical analysis was performed using SPSS for Windows (released 2016, version 24.0. IBM, Armonk, NY, USA) and SAS (version 9.4, SAS Institute Inc., Cary, NC, USA). For all continuous variables (the primary and secondary outcomes), the linear mixed model (LMM) was used with time, group and interaction between time and groupas the fixed effects and patient as the random effect (repeated measurements at baseline, and at the 3-month and 5-year follow-up visits) with a two-sided 5% significance level. The covariance structure was chosen based on Akaike's Information Criterion, and degrees of freedom were calculated using the Kenward-Roger method. As the LMM allows for the analysis of unbalanced data sets without imputation, all available data, the full data set, were analysed. Between-group differences at the 5-year follow-up and the differences between the 3-month and 5-year measurements for all continuous outcomes with 95% confidence intervals (95% CI) were derived from the LMM model. Between group comparisons for the categorical data were performed using Fisher's exact test, and the change from 3 months to 5 years was compared using McNemar's test.

Results

Between February and May 2012, 33 consecutive female patients were initially considered eligible for the trial (Figure 1). 30 patients were randomly assigned, 16 to RVMR and 14 to LVMR. Detailed patient demographics, perioperative parameters and results of the 3-month follow-up have been presented in previous publications [11,14]. Baseline values for symptom scores, POP-Q and MR defaecography measurements are presented in an electronic supplementary table and in earlier publications [11, 14]. Four patients were lost to follow-up, so 26 patients (14 RVMR and 12 LVMR) completed the 5-year follow-up and were included in this analysis.

The MR findings for posterior compartment procidentia are presented in Table 1. At the 5-year follow-up, MR defaecography revealed rectoceles in 4 patients (29%) in the RVMR group (3 new-onset cases [21%], p=0.25) and 4 patients (33%) in the LVMR group (1 new-onset case [8%], p=0.50), RVMR vs LVMR p>0.9. One patient that had been treated with RVMR for ERP developed an enterocoele. Four of the 26 patients (15%) had new-onset recto-anal invagination, 2 in each study group (p>0.9).

The anatomical, functional and symptom-specific quality of life outcomes of both groups are presented in Table 2. At the 5-year follow-up, there were no significant differences in the MRI results or the POP-Q measurements between the RVMR and LVMR groups. In the pelvic floor distress inventory (PFDI-20), the symptom score values were lower in the RVMR group (mean 96.0, SD 70.7) than in the LVMR group (mean 160.6, SD 58.9; p=0.004). Also, the outcomes for the subscales of pelvic organ prolapse (POPDI-6) (mean 23.2, SD 24.3 vs mean 52.4, SD 22.4; p=0.001) and the colorectal-anal distress inventory

This article is protected by copyright. All rights reserved

Accepted Article

(CRADI-8) (mean 38.4, SD 23.3 vs mean 58.6, SD 25.4; p=0.009) were better for patients in the RVMR group than in the LVMR group.

The anatomical, functional and quality of life results at 3 months and 5 years postoperatively for the whole study population are summarised in Table 3. The measurements assessing the three-compartment anatomy results for MRI, including the elevating effect of VMR to the anorectum and cervix/vaginal cuff during straining, remained unchanged over time. The size of the rectocele increased from 6.0 mm (mean, SD 9.6) to 9.4 mm (mean, SD 11.3), p=0.13. In the POP-Q outcomes, the measurement indicating the most protruding point of the posterior wall (Bp) was better at 5-years (mean -3.0, SD 0.0) than at 3-months (mean -2.0, SD 1.6; p=0.006). The apex (cervix or hysterectomy scar) (C), had descended a little over time (mean -5.4, SD 2.2 vs. mean -4.2, SD 3.3; p=0.03). The symptom-specific quality of life measures (PFIQ-7) remained unchanged between 3 months and 5 years. However, some symptom score values increased. The Wexner score indicating faecal incontinence was higher at 5-years (mean 5.0, SD 4.5 vs mean 8.7, SD 6.0, p=0.003). Also, the total pelvic floor distress inventory score (PFDI-20) (mean 87.8, SD 45.5 vs mean 125.8, SD 72.1; p=0.001), the colorectal anal distress inventory score (CRADI-8) (mean 29.1, SD 16.0 vs mean 47.7, SD 25.9; p <0.001) and the pelvic organ prolapse distress inventory score (POPDI-6) (mean 24.1, SD 19.0 vs mean 36.7, SD 27.4; p=0.025) were higher at 5-years than at 3-months. However, the impact on urinary symptoms (UDI-6) remained unchanged.

Discussion

To the best of our knowledge, this is the first study to report the long-term anatomical outcomes, confirmed by MRI, after RVMR and LVMR,. The results of this RCT follow-up study show that the restored three-compartment pelvic floor anatomy is maintained over time based on postoperative MRI measurements. Although RVMR and LVMR give equal support to the rectovaginal septum and they result in similar correction of IRP and ERP 5 years after the operation, the functional results after RVMR appeared to be superior to the results after LVMR in this relatively small cohort of patients.

MR defaecography provides excellent morphological and functional information about the pelvic floor. Dynamic MRI is ideal for evaluating pelvic floor weakness, POP and possible defects of the surrounding anatomy [15,24-27] as well as functional disorders, such as outlet obstruction and incontinence. Therefore, dynamic MRI is useful in the evaluation of the therapeutic outcome [25,26]; in addition, when evaluating posterior compartment prolapse, the evacuation phase needs to be included [28]. Since the site of POP can be misdiagnosed by clinical examination in 45–90% of cases [28], and because more than half of IRPs may be missed [3], the use of imaging in our study provided a more accurate assessment of the operative outcomes and possible recurrence of prolapse after VMR than prospective

This article is protected by copyright. All rights reserved

or retrospective series have provided thus far [29-31]. Indeed, we also found that support to the posterior vaginal wall in clinical examination was well maintained and constant in all patients in both study groups; however, the MR defaecography revealed IRP in 15% (4/26) of the study patients.

In a Japanese study with a comparable study population size, 26 patients with IRP were evaluated 6 months after LVMR with evacuation proctography instead of MRI defaecography [32]. They found successful anatomical correction in all patients, although 8 patients (30.8%) developed new onset recto-rectal intussusception. A few years later, the same group reported defaecography confirmed anatomical correction of IRP in all but one of the 34 patients 6 months after LVMR, and again 38% (13/34) of the patients developed new onset recto-rectal intussusception [33]. In the present study, 15% (4/26) of the patients developed IRP again at 5-year follow-up (RVMR 14% and LVMR 17%), and MR defaecography revealed one IRP in a patient primarily operated on for ERP. Considering the prospective nature and use of imaging in our study, the results are similar to the symptomatic recurrence rates presented in the literature. To date, the largest LVMR follow-up study (n=916) by Consten et al. had IRP recurrence rates of 11.1% at 5-year follow-up and 14.2% at 10-year follow-up using Kaplan-Meier analyses [1]. To date, the largest RVMR follow-up by the same group found IRP recurrence in 10.4% of patients (mean follow-up of 23.5 months) [34].

Our study is the only randomised controlled study comparing LVMR and RVMR. Previous studies have compared RVMR to LVMR in terms of safety, effectiveness, cost and functional outcomes with no superiority of the use of the robot [4,5,8,9,13]. Due to the heterogeneity of the indications for surgery, follow-up times and imaging techniques in earlier studies, the comparison of our findings to the available data must be done cautiously. We previously found similar anatomical outcomes after RVMR and LVMR in short-term follow-up [11], but in the present study with a longer follow-up, some differences were observed. The support that RVMR and LVMR provide to the posterior vaginal wall in the POP-Q measurements was similarly well maintained or even somewhat better at 5-years in comparison with the postoperative measures at 3-months, while the apex had descended a little over time. The present results show that even though the long-term anatomical results are comparable between the RVMR and LVMR groups, the patients undergoing RVMR benefitted more from the operation in terms of lower symptom score values in the PFDI-20. Specifically, the difference was seen in the POP and colorectal-anal symptom subscales, the latter combining both incontinence and ODS symptoms.

There are several potential advantages of robot assisted surgery when operating in a narrow and deep pelvis. We hypothesized that these features could be beneficial in rectal prolapse surgery. As the anatomical results were similar, the potential explanation for better functional outcomes could be less damage to the hypogastric nerves. However, larger randomized studies with specific nerve function

This article is protected by copyright. All rights reserved

Accepted Article

measurements are needed to show whether surgeons can preserve nerves more precisely using robotic techniques.

Only a few studies have reported the functional outcomes after RVMR versus LVMR. Similar to the present study, a French group found RVMR to be superior to LVMR in functional outcomes, reporting a reduction in ODS scores with a relatively short follow-up time [35]. In a non-randomised study comparing LVMR and RVMR, the results did not show a true difference in the faecal incontinence severity index (FISI) or the Wexner scores when assessing faecal incontinence 12 months after surgery in patients with ERP [7].

We report adequately preserved function, which is in line with the recently published long-term results of large cohort studies [1,36,37]. These cross-sectional studies do not include anatomical results, and they had several methodological limitations, so it is difficult to compare their finding to the present data. Despite the good long-term anatomical results, patients with ODS might especially have prolonged or recurrent functional problems. This is explained by the complexity of the pathophysiology of pelvic floor dysfunction symptoms, including disorders in motility and sensitivity [38]. Similar to the findings reported in previous studies, our results cannot demonstrate the correlation between surgical correction of the pelvic anatomical abnormalities and improvement in functional outcomes.

The present study is clearly limited by its small sample size, which makes it susceptible to both type I and type II errors in terms of comparing the surgical techniques. Also the results reflect the experience of a single tertiary centre. However, the strengths of this study are the MRI methodology that was used, the prospective randomised study design and the relatively long follow-up time.

Conclusions

After undergoing VMR, the corrected anatomy was preserved and, based on MRI defaecography, there were no clinically significant differences in the anatomical results between the RVMR and LVMR procedures 5 years after surgery. The functional results after RVMR appeared to be superior to those after LVMR. However, larger randomised controlled studies are needed to confirm these findings.

This article is protected by copyright. All rights reserved

Acknowledgements

Open access funding provided by University of Oulu including Oulu University Hospital.

Figure 1. Flow diagram of the study.

Accepted Article

This article is protected by copyright. All rights reserved

Table 1. Magnetic resonance findings for rectal prolapse, enterocoele and rectocoele.

	RVMR		LVMR		Total group		*P*[a]	*P*[b]
	3 months (n=16)	**5 years (n=14)**	**3 months (n=13)**	**5 years (n=12)**	**3 months (n=29)**	**5 years (n=26)**		
External rectal prolapse, n (%)	0	0	0	0	0	0	n.d.	n.d.
Internal rectal prolapse, n (%)	0	2(14)	0	2(17)	0	4(15)	>0.9	0.78
Enterocoele, n (%)	0	1(7)	0	0	0	1(4)	n.d.	>0.9
Rectocoele ≥ 20mm, n (%)	1(6)	4(29)	2 (15)	4(33)	4(14)	8(31)	0.063	>0.9
Rectocoele size, mm, mean (SD)	21 (SD n.d.)	25 (SD 6)	24 (SD 3)	24 (SD 5)	23 (SD 3)	24 (SD 5)	0.62	n.d.

Continuous variables are reported as the mean and standard deviation (SD); categorical variables are reported as counts and percentages (in parentheses)

[a] *P*-value for the change (3 months–5 years)

[b] *P*-value for difference (3 months–5 years) between groups

n.d. not definable

Accepted Article

This article is protected by copyright. All rights reserved

Table 2. MR defaecography and POP-Q measurements, functional and symptom-specific quality of life scores 5 years after RVMR and LVMR.

	5-years postoperative						
	RVMR		LVMR				
	Patients (n)	Mean (SD)	Patients (n)	Mean (SD)	Difference between the means	95% CI	*p*
MR measurements, mm							
Anorectum strain[a]	14	51.9 (13.1)	12	48.8 (12.9)	3.9	-6.8 to 14.6	0.47
Anorectum POM[b]	14	29.9 (15.3)	12	25.3 (8.4)	5.2	-5.2 to 15.6	0.32
Rectocoele strain[a]	14	10.1 (11.5)	12	8.7 (11.6)	-1.1	-10.8 to 8.7	0.83
H strain[a]	14	81.7 (15.6)	12	78.5 (19.0)	4.1	-9.0 to 17.2	0.53
H POM[b]	14	16.9 (12.4)	12	19.6 (9.2)	-1.3	-10.4 to 7.9	0.78
Cervix/vaginal cuff strain[a]	14	-0.2 (13.7)	12	7.8 (20.1)	-6.7	-19.9 to 6.5	0.31
Cervix/vaginal cuff POM[b]	14	32.5 (8.6)	12	29.8 (15.8)	4.1	-7.9 to 16.1	0.50
Bladder strain[a]	14	26.0 (6.8)	12	27.9 (17.3)	-0.1	-10.7 to 10.4	>0.9
Bladder POM[b]	14	36.1 (8.6)	12	38.6 (18.0)	-1.5	-11.8 to 8.7	0.76
POP-Q measurements, cm							
Ap	14	-2.9 (0.2)	11	-2.7 (0.4)	-0.3	-1.1 to 0.5	0.45
Bp	14	-3.0 (0.0)	12	-3.0 (0.0)	0.0	n.d.	n.d.
C	14	-4.7 (2.0)	12	-3.7 (4.3)	-1.4	-3.5 to 0.7	0.18
D	9	-5.4 (5.1)	6	-6.9 (2.2)	1.2	-3.9 to 6.3	0.62
Aa	14	-1.1 (1.3)	12	-0.8 (1.5)	-0.4	-1.5 to 0.6	0.42
Ba	14	-1.4 (1.3)	12	-1.4 (1.5)	0.0	-1.2 to 1.2	>0.9
Symptom-specific quality of life measures							
CRAIQ-7	14	24.3 (32.0)	10	43.8 (27.1)	-20.4	-43.2 to 2.5	0.08
POPIQ-7	13	9.5 (26.4)	10	26.0 (27.9)	-16.1	-39.7 to 7.5	0.17
UIQ-7	14	25.7 (32.7)	10	33.0 (31.4)	-9.4	-32.3 to 13.6	0.42
PFIQ-7 Score	14	58.8 (82.1)	10	102.7 (69.9)	-47.8	-103.7 to 8.0	0.09
Symptom scores							
Wexner	14	8.9 (6.9)	12	8.3 (5.1)	0.3	-4.3 to 5.0	0.89
CRADI-8	14	38.4 (23.3)	12	58.6 (25.4)	-21.0	-36.5 to -5.5	0.009
POPDI-6	14	23.2 (24.3)	12	52.4 (22.4)	-30.1	-47.9 to -12.2	0.001
UDI-6	14	34.4 (27.8)	12	49.7 (22.3)	-14.8	-34.4 to 4.8	0.14
PFDI-20	14	96.0 (70.7)	12	160.6 (58.9)	-66.2	-109.9 to -22.5	0.004

Continuous data are reported as mean and standard deviation (SD). Student`s t test, statistically significant at p=0.05 level (two-tailed). RVMR: robotic ventral mesh rectopexy; LVMR: laparoscopic ventral mesh rectopexy; MR: magnetic resonance; [a] In MR defecography the distance between the defined anatomical landmarks and the pubococcygeal line; [b] POM: pelvic organ mobility defined as the difference in the measured distances at rest and at maximum strain for each anatomical landmark; POP-Q: pelvic organ prolapse quantification in which all measures were taken at maximum strain with reference to the level of the hymen; Ap: the point 3 cm above the hymen in the posterior wall; Bp: the most protruding point of the posterior wall; C: cervix or hysterectomy scar; D: posterior fornix of vagina; Aa: the point 3 cm above hymen in the anterior wall; Ba: the most protruding point of the anterior wall; n.d.: not definable; CRAIQ-7: Colorectal-Anal Impact Questionnaire; POPIQ-7: Pelvic Organ Prolapse Impact Questionnaire; UIQ-7: Urinary Impact Questionnaire; PFIQ-7: Pelvic Floor Impact Questionnaire; Wexner Continence Grading Scale; CRADI-8: Colorectal-Anal Distress Inventory; POPDI-6: Pelvic Organ Prolapse Distress Inventory; UDI-6: Urinary Distress Inventory; PFDI-20: Pelvic Floor Distress Inventory.

Accepted Article

This article is protected by copyright. All rights reserved

Table 3. MR defecography and POP-Q measurements, functional and symptom-specific quality of life change from 3 months to 5 years after VMR in the total study population.

	Total group						
	3-months postoperative		5-years postoperative				
	Patients (n)	Mean (SD)	Patients (n)	Mean (SD)	Mean difference	95%CI	*p*
MR measurements, mm							
Anorectum strain[a]	29	51.6 (12.1)	26	50.5 (12.8)	0.8	-3.5 to 5.2	0.71
Anorectum POM[b]	29	28.6 (11.3)	26	27.7 (12.6)	1.1	-3.5 to 5.7	0.64
Rectocoele strain[a]	29	6.0 (9.6)	26	9.4 (11.3)	-3.5	-8.1 to 1.1	0.13
H strain[a]	29	77.2 (14.4)	26	80.2 (17.0)	-4.0	-9.7 to 1.7	0.16
H POM[b]	29	21.2 (10.2)	26	18.2 (11.0)	3.1	-0.6 to 6.9	0.10
Cervix/vaginal cuff strain[a]	29	0.6 (15.8)	26	3.5 (17.1)	-3.0	-9.2 to 3.1	0.33
Cervix/vaginal cuff POM[b]	29	30.8 (17.5)	26	31.3 (12.2)	-0.3	-7.1 to 6.5	>0.90
Bladder strain[a]	29	26.4 (12.5)	26	26.9 (12.5)	-0.4	-4.2 to 3.4	0.82
Bladder POM[b]	29	40.3 (12.1)	26	37.2 (13.5)	3.5	-0.7 to 7.7	0.10
POP-Q measurements, cm							
Ap	29	-2.6 (0.5)	26	-2.8 (0.3)	0.2	-0.3 to 0.7	0.36
Bp	29	-2.0 (1.6)	26	-3.0 (0.0)	1.0	0.3 to 1.6	0.006
C	29	-5.4 (2.2)	26	-4.2 (3.3)	-1.2	-2.3 to -0.1	0.03
D	17	-8.3 (1.2)	15	-6.0 (4.2)	-2.3	-4.9 to 0.2	0.07
Aa	29	-1.1 (1.2)	26	-1.0 (1.4)	0.0	-0.5 to 0.4	0.86
Ba	29	-1.5 (1.4)	26	-1.4 (1.4)	-0.1	-0.7 to 0.5	0.74
Symptom-specific quality of life measures							
CRAIQ-7	28	26.0 (26.8)	24	32.4 (31.0)	-8.4	-20.4 to 3.6	0.17
POPIQ-7	28	8.3 (20.3)	23	16.7 (27.7)	-8.1	-22.2 to 6.0	0.25
UIQ-7	28	24.0 (25.2)	24	28.7 (31.7)	-6.4	-16.8 to 4.0	0.23
PFIQ-7 Score	28	58.3 (61.6)	24	77.1 (78.8)	-22.7	-51.9 to 6.5	0.13
Symptom scores							
Wexner	29	5.0 (4.5)	26	8.7 (6.0)	-3.9	-6.4 to -1.4	0.003
CRADI-8	29	29.1 (16.0)	26	47.7 (25.9)	-19.9	-28.4 to -11.4	<0.001
POPDI-6	28	24.1 (19.0)	26	36.7 (27.4)	-13.0	-24.3 to -1.7	0.025
UDI-6	28	33.8 (25.1)	26	41.4 (26.1)	-9.2	-20.4 to 2.0	0.10
PFDI-20	26	87.8 (45.5)	26	125.8 (72.1)	-41.4	-66.0 to -16.8	0.001

Continuous data are reported as mean and standard deviation (SD). Student`s t test, statistically significant at p=0.05 level (two-tailed). VMR: ventral mesh rectopexy; MR: magnetic resonance; [a] In MR defecography the distance between the defined anatomical landmarks and the pubococcygeal line; [b] POM: pelvic organ mobility defined as a difference in the measured distances at rest and at maximum strain for each anatomical landmark; POP-Q: pelvic organ prolapse quantification in which all the measures are taken at maximum strain with reference to the level of the hymen; Ap: the point 3 cm above the hymen in the posterior wall; Bp: the most protruding point of the posterior wall; C: cervix or hysterectomy scar; D: posterior fornix of vagina; Aa: the point 3 cm above the hymen in the anterior wall; Ba: the most protruding point of the anterior wall; n.d.: not definable; CRAIQ-7: Colorectal-Anal Impact Questionnaire; POPIQ-7: Pelvic Organ Prolapse Impact Questionnaire; UIQ-7: Urinary Impact Questionnaire; PFIQ-7: Pelvic Floor Impact Questionnaire; Wexner Continence Grading Scale; CRADI-8: Colorectal-Anal Distress Inventory; POPDI-6: Pelvic Organ Prolapse Distress Inventory; UDI-6: Urinary Distress Inventory; PFDI-20: Pelvic Floor Distress Inventory.

This article is protected by copyright. All rights reserved

References

1. Consten, E.C., van Iersel, J.J., Verheijen, P.M., Broeders, I.A., Wolthuis, A.M., D'Hoore, A. (2015), Long-term Outcome After Laparoscopic Ventral Mesh Rectopexy: An Observational Study of 919 Consecutive Patients. *Annals of Surgery,* 262: 742-7; discussion 747-8. doi: 10.1097/SLA.0000000000001401 [doi].

2. Tsunoda, A., Takahashi, T., Ohta, T., Fujii, W., Kusanagi, H. (2016), New-onset rectoanal intussusception may not result in symptomatic improvement after laparoscopic ventral rectopexy for external rectal prolapse. *Techniques in coloproctology,* 20: 101-7. doi: 10.1007/s10151-015-1395-1 [doi].

3. Karlbom, U., Graf, W., Nilsson, S., Pahlman, L. (2004), The accuracy of clinical examination in the diagnosis of rectal intussusception. *Diseases of the colon and rectum,* 47: 1533-8. doi: 10.1007/s10350-004-0626-8 [doi].

4. van Iersel, J.J., Paulides, T.J., Verheijen, P.M., Lumley, J.W., Broeders, I.A., Consten, E.C. (2016), Current status of laparoscopic and robotic ventral mesh rectopexy for external and internal rectal prolapse. *World journal of gastroenterology,* 22: 4977-87. doi: 10.3748/wjg. v22.i21.4977 [doi].

5. Albayati, S., Chen, P., Morgan, M.J., Toh, J.W.T. (2019), Robotic vs. laparoscopic ventral mesh rectopexy for external rectal prolapse and rectal intussusception: a systematic review. *Techniques in coloproctology, 2*3: 529-535. doi: 10.1007/s10151-019-02014-w [doi].

6. Brunner, M., Roth, H., Gunther, K., Grutzmann, R., Matzel, K.E. (2018), Ventral rectopexy with biological mesh: short-term functional results. *International journal of colorectal disease, 3*3: 449-457. doi: 10.1007/s00384-018-2972-3 [doi].

7. Mehmood, R.K., Parker, J., Bhuvimanian, L., Qasem, E., Mohammed, A.A., Zeeshan, M., Grugel, K., Carter, P., Ahmed, S. (2014), Short-term outcome of laparoscopic versus robotic ventral mesh rectopexy for full-thickness rectal prolapse. Is robotic superior? *International journal of colorectal disease, 2*9: 1113-8. doi: 10.1007/s00384-014-1937-4 [doi].

8. Makela-Kaikkonen, J., Rautio, T., Klintrup, K., Takala, H., Vierimaa, M., Ohtonen, P., Makela, J. (2014), Robotic-assisted and laparoscopic ventral rectopexy in the treatment of rectal prolapse: a matched-pairs study of operative details and complications. *Techniques in coloproctology,* 18: 151-5. doi: 10.1007/s10151-013-1042-7 [doi].

9. Wong, M.T., Meurette, G., Rigaud, J., Regenet, N., Lehur, P.A. (2011), Robotic versus laparoscopic rectopexy for complex rectocele: a prospective comparison of short-term outcomes. *Diseases of the colon and rectum,* 54: 342-6. doi: 10.1007/DCR.0b013e3181f4737e [doi].

10. van Iersel, J.J., de Witte, C.J., Verheijen, P.M., Broeders, I.A., Lenters, E., Consten, E.C., Schraffordt Koops, S.E. (2016), Robot-Assisted Sacrocolporectopexy for Multicompartment Prolapse of the Pelvic Floor: A Prospective Cohort Study Evaluating Functional and Sexual Outcome. *Diseases of the colon and rectum,* 59: 968-74. doi: 10.1097/DCR.0000000000000669 [doi].

11. Makela-Kaikkonen, J.K., Rautio, T.T., Koivurova, S., Paakko, E., Ohtonen, P., Biancari, F., Makela, J.T. (2016), Anatomical and functional changes to the pelvic floor after robotic versus laparoscopic ventral rectopexy: a randomised study. *International urogynecology journal,* 27: 1837-1845. doi: 10.1007/s00192-016-3048-y [doi].

This article is protected by copyright. All rights reserved

12. Rondelli, F., Bugiantella, W., Villa, F., Sanguinetti, A., Boni, M., Mariani, E., Avenia, N. (2014), Robot-assisted or conventional laparoscoic rectopexy for rectal prolapse? Systematic review and meta-analysis. *International journal of surgery (London, England),* Suppl2: S153-S159. doi: S1743-9191(14)00843-7 [pii].

13. Heemskerk, J., de Hoog, D.E., van Gemert, W.G., Baeten, C.G., Greve, J.W., Bouvy, N.D. (2007), Robot-assisted vs. conventional laparoscopic rectopexy for rectal prolapse: a comparative study on costs and time. *Diseases of the colon and rectum,* 50: 1825-30. doi: 10.1007/s10350-007-9017-2 [doi].

14. Makela-Kaikkonen, J., Rautio, T., Paakko, E., Biancari, F., Ohtonen, P., Makela, J. (2016), Robot-assisted vs laparoscopic ventral rectopexy for external or internal rectal prolapse and enterocele: a randomized controlled trial. *Colorectal disease: the official journal of the Association of Coloproctology of Great Britain and Ireland,* 18: 1010-1015. doi: 10.1111/codi.13309 [doi].

15. Comiter, C.V., Vasavada, S.P., Barbaric, Z.L., Gousse, A.E., Raz, S. (1999), Grading pelvic prolapse and pelvic floor relaxation using dynamic magnetic resonance imaging. *Urology,* 54: 454-7. doi: S0090-4295(99)00165-X [pii].

16. Bump, R.C., Mattiasson, A., Bo, K., Brubaker, L.P., DeLancey, J.O., Klarskov, P., Shull, B.L., Smith, A.R. (1996), The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. *American Journal of Obstetrics and Gynecology,* 175: 10-17. doi: S0002-9378(96)70243-0 [pii].

17. Altomare, D.F., Spazzafumo, L., Rinaldi, M., Dodi, G., Ghiselli, R., Piloni, V. (2008), Set-up and statistical validation of a new scoring system for obstructed defaecation syndrome. *Colorectal disease: the official journal of the Association of Coloproctology of Great Britain and Ireland,* 10: 84-8. doi: CDI1262 [pii].

18. Jorge, J.M.N., Wexner, S.D. (1993), Etiology and management of fecal incontinence. *Diseases of the colon and rectum,* 36: 77-97.

19. Rogers, R.G., Coates, K.W., Kammerer-Doak, D., Khalsa, S., Qualls, C. (2003), A short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). *International urogynecology journal and pelvic floor dysfunction,* 14: 164-8; discussion 168. doi: 10.1007/s00192-003-1063-2 [doi].

20. Barber, M.D., Walters, M.D., Bump, R.C. (2005), Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). *American Journal of Obstetrics and Gynecology,* 193: 103-13. doi: S0002937804021088 [pii].

21. Colaiacomo, M.C., Masselli, G., Polettini, E., Lanciotti, S., Casciani, E., Bertini, L., Gualdi, G. (2009), Dynamic MR imaging of the pelvic floor: a pictorial review. *Radiographics: a review publication of the Radiological Society of North America, Inc,* 29: e35. doi: 10.1148/rg. e35 [doi].

22. Maccioni, F. (2013), Functional disorders of the ano-rectal compartment of the pelvic floor: clinical and diagnostic value of dynamic MRI. *Abdominal Imaging,* 38: 930-51. doi: 10.1007/s00261-012-9955-6 [doi].

23. D'Hoore, A. & Penninckx, F. (2006), Laparoscopic ventral recto(colpo)pexy for rectal prolapse: surgical technique and outcome for 109 patients. *Surgical endoscopy,* 20: 1919-23. doi: 10.1007/s00464-005-0485-y [doi].

This article is protected by copyright. All rights reserved

24. Alt, C.D., Brocker, K.A., Lenz, F., Sohn, C., Kauczor, H.U., Hallscheidt, P. (2014), MRI findings before and after prolapse surgery. *Acta Radiologica (Stockholm, Sweden: 1987),* 55: 495-504. doi: 10.1177/0284185113497201 [doi].

25. Gufler, H., DeGregorio, G., Dohnicht, S., Allmann, K.H., Rohr-Reyes, A. (2002), Dynamic MRI after surgical repair for pelvic organ prolapse. *Journal of computer assisted tomography,* 26: 734-9. doi: 00004728-200209000-00012 [pii].

26. Siegmann, K.C., Reisenauer, C., Speck, S., Barth, S., Kraemer, B., Claussen, C.D. (2011), Dynamic magnetic resonance imaging for assessment of minimally invasive pelvic floor reconstruction with polypropylene implant. *European Journal of Radiology,* 80: 182-7. doi: 10.1016/j.ejrad.2010.03.014 [doi].

27. Goodrich, M.A., Webb, M.J., King, B.F., Bampton, A.E., Campeau, N.G., Riederer, S.J. (1993), Magnetic resonance imaging of pelvic floor relaxation: dynamic analysis and evaluation of patients before and after surgical repair. *Obstetrics and gynecology,* 82: 883-91.

28. Maglinte, D.D., Hale, D.S., Sandrasegaran, K. (2013), Comparison between dynamic cystocolpoproctography and dynamic pelvic floor MRI: pros and cons: which is the "functional" examination for anorectal and pelvic floor dysfunction? *Abdominal Imaging,* 38: 952-73. doi: 10.1007/s00261-012-9870-x [doi].

29. de Bruijn, H., Maeda, Y., Tan, K.N., Jenkins, J.T., Kennedy, R.H. (2019), Long-term outcome of laparoscopic rectopexy for full-thickness rectal prolapse. *Techniques in coloproctology,* 23: 25-31. doi: 10.1007/s10151-018-1913-z [doi].

30. Postillon, A., Perrenot, C., Germain, A., Scherrer, M.L., Buisset, C., Brunaud, L., Ayav, A., Bresler, L. (2019), Long-term outcomes of robotic ventral mesh rectopexy for external rectal prolapse. *Surgical endoscopy,10*. doi: 10.1007/s00464-019-06851-6 [doi]. [Epub ahead of print]

31. Maggiori, L., Bretagnol, F., Ferron, M., Panis, Y. (2013), Laparoscopic ventral rectopexy: a prospective long-term evaluation of functional results and quality of life. *Techniques in coloproctology,* 17: 431-6. doi: 10.1007/s10151-013-0973-3 [doi].

32. Tsunoda, A., Ohta, T., Kiyasu, Y., Kusanagi, H. (2015), Laparoscopic ventral rectopexy for rectoanal intussusception: postoperative evaluation with proctography. *Diseases of the colon and rectum,* 58: 449-56. doi: 10.1097/DCR.0000000000000328 [doi].

33. Tsunoda, A., Takahashi, T., Hayashi, K., Yagi, Y., Kusanagi, H. (2018), Laparoscopic ventral rectopexy in patients with fecal incontinence associated with rectoanal intussusception: prospective evaluation of clinical, physiological and morphological changes. *Techniques in coloproctology,* 22: 425-431. doi: 10.1007/s10151-018-1811-4 [doi].

34. van Iersel, J.J., Formijne Jonkers, H.A., Paulides, T.J.C., Verheijen, P.M., Draaisma, W.A., Consten, E.C.J., Broeders, I. A. M. J. (2017), Robot-Assisted Ventral Mesh Rectopexy for Rectal Prolapse: A 5-Year Experience at a Tertiary Referral Center. *Diseases of the colon and rectum,* 60: 1215-1223. doi: 10.1097/DCR.0000000000000895 [doi].

35. Mantoo, S., Podevin, J., Regenet, N., Rigaud, J., Lehur, P.A., Meurette, G. (2013), Is robotic-assisted ventral mesh rectopexy superior to laparoscopic ventral mesh rectopexy in the management of obstructed defaecation? *Colorectal disease: the official journal of the Association of Coloproctology of Great Britain and Ireland,* 15: e469-75. doi: 10.1111/codi.12251 [doi].

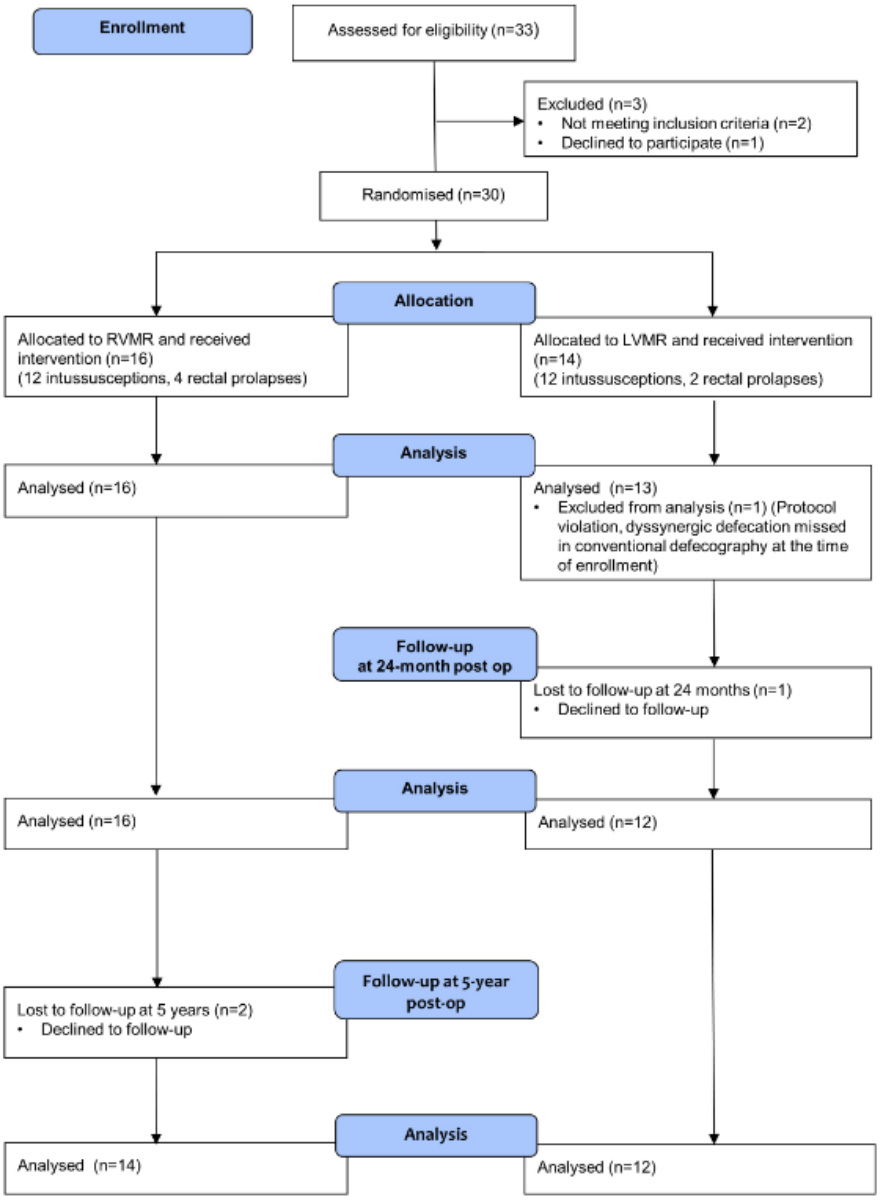
36. Mackenzie, H., Dixon, A.R. (2014), Proficiency gain curve and predictors of outcome for laparoscopic ventral mesh rectopexy. *Surgery,* 156: 158-67. doi: 10.1016/j.surg.2014.03.008 [doi].

This article is protected by copyright. All rights reserved

37. Makela-Kaikkonen, J., Rautio, T., Kairaluoma, M., Carpelan-Holmstrom, M., Kossi, J., Rautio, A., Ohtonen, P., Makela, J. (2018), Does Ventral Rectopexy Improve Pelvic Floor Function in the Long Term? *Diseases of the colon and rectum,* 61: 230-238. doi: 10.1097/DCR.0000000000000974 [doi].

38. Lundby, L. & Laueberg, S. (2014), Laparoscopic ventral mesh rectopexy for ODS-time for a critical appraisal. *Colorectal Dis,* 17: 102-3.

Figure 1



This article is protected by copyright. All rights reserved

Accepted Article

Table 4. MR defaecography, POP-Q measurements and symptom scores before surgery, 3 months and at 5 years postoperatively for RVMR and LVMR groups.

	Before surgery				3 months after surgery				5 years after surgery			
	RVMR		LVMR		RVMR		LVMR		RVMR		LVMR	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
MR measurements, mm												
Anorectum strain[a]	64.1	15.9	65.1	15.1	50.8	13.3	52.6	10.8	51.9	13.1	48.8	12.9
Anorectum POM[b]	43.3	15.2	45.5	13.1	28.7	12.0	28.4	10.8	29.9	15.3	25.3	8.4
Rectocoele strain[a]	33.0	14.9	26.8	16.6	5.1	8.2	7.2	11.4	10.1	11.5	8.7	11.6
H strain[a]	87.2	16.3	87.5	17.7	77.4	17.7	77.0	15.0	81.7	15.6	78.5	19.0
H POM[b]	31.1	13.8	35.0	13.4	20.8	9.9	21.7	10.9	16.9	12.4	19.6	9.2
Cervix/vaginal cuff strain[a]	17.1	13.4	11.9	22.3	-0.1	16.2	1.5	15.9	-0.2	13.7	7.8	20.1
Cervix/vaginal cuff POM[b]	52.0	12.9	43.5	17.4	30.1	21.6	31.7	11.7	32.5	8.6	29.8	15.8
Bladder strain[a]	24.6	12.8	23.3	17.0	25.9	12.3	27.0	13.2	26.0	6.8	27.9	17.3
Bladder POM[b]	41.5	9.7	39.2	16.8	40.9	11.5	39.6	13.2	36.1	8.6	38.6	18.0
POP-Q measurements, cm												
Ap	-1.5	1.0	-0.4	2.2	-2.6	0.6	-2.5	0.5	-2.9	0.2	-2.7	0.4
Bp	-2.4	1.0	-1.0	2.5	-3.0	0.0	-3.0	0.0	-3.0	0.0	-3.0	0.0
C	-4.4	1.9	-3.2	3.7	-5.7	1.9	-5.1	2.7	-4.7	2.0	-3.7	4.3
D	-7.1	1.6	-3.6	7.8	-8.7	1.1	-7.9	1.4	-5.4	5.1	-6.9	2.2
Aa	-1.1	1.1	-0.8	1.8	-1.3	1.0	-0.7	1.3	-1.1	1.3	-0.8	1.5
Ba	-1.3	1.4	-0.6	2.3	-1.8	1.2	-1.0	1.5	-1.4	1.3	-1.4	1.5
Symptom-specific quality of life measures												
CRAIQ-7	52.1	28.7	56.3	22.9	17.0	15.2	38.1	34.2	24.3	32.0	43.8	27.1
POPIQ-7	13.4	17.3	41.9	33.3	1.8	4.2	17.1	29.0	9.5	26.4	26.0	27.9
UIQ-7	33.3	27.2	40.3	28.8	17.6	16.6	32.5	32.4	25.7	32.7	33.0	31.4
PFIQ-7 Score	98.8	58.2	134.3	79.2	36.3	29.9	87.7	80.4	58.8	82.1	102.7	69.9
Symptom scores												
Wexner	9.0	7.2	9.1	6.2	3.7	4.0	6.6	4.8	8.9	6.9	8.3	5.1
CRADI-8	54.9	16.6	56.5	16.7	26.8	14.6	32.0	17.6	38.4	23.3	58.6	25.4
POPDI-6	51.6	22.2	49.2	27.4	18.5	10.1	31.6	25.2	23.2	24.3	52.4	22.4

UDI-6	37.8	20.4	45.5	25.5	30.7	24.4	37.8	26.4	34.4	27.8	49.7	22.3
PFDI-20	144.2	47.3	149.0	57.2	76.0	36.8	103.6	52.6	96.0	70.7	160.6	58.9

Continuous data are reported as mean and standard deviation (SD). Student`s t test, statistically significant at p=0.05 level (two-tailed). RVMR: robotic ventral mesh rectopexy; LVMR: laparoscopic ventral mesh rectopexy; MR: magnetic resonance; [a] In MR defecography the distance between the defined anatomical landmarks and the pubococcygeal line; [b] POM: pelvic organ mobility defined as the difference in the measured distances at rest and at maximum strain for each anatomical landmark; POP-Q: pelvic organ prolapse quantification in which all measures were taken at maximum strain with reference to the level of the hymen; Ap: the point 3 cm above the hymen in the posterior wall; Bp: the most protruding point of the posterior wall; C: cervix or hysterectomy scar; D: posterior fornix of vagina; Aa: the point 3 cm above hymen in the anterior wall; Ba: the most protruding point of the anterior wall; n.d.: not definable; CRAIQ-7: Colorectal-Anal Impact Questionnaire; POPIQ-7: Pelvic Organ Prolapse Impact Questionnaire; UIQ-7: Urinary Impact Questionnaire; PFIQ-7: Pelvic Floor Impact Questionnaire; Wexner Continence Grading Scale; CRADI-8: Colorectal-Anal Distress Inventory; POPDI-6: Pelvic Organ Prolapse Distress Inventory; UDI-6: Urinary Distress Inventory; PFDI-20: Pelvic Floor Distress Inventory.

This article is protected by copyright. All rights reserved

Accepted Article

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	5
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	-
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	7
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1.
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1.
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	7
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	

This article is protected by copyright. All rights reserved

Tables 1-3.

	17b- 	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses -	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms -	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	9-10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	9-10
Other information			
Registration	23	Registration number and name of trial registry	4
Protocol	24	Where the full trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	11

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Accepted Article

This article is protected by copyright. All rights reserved