Rectal prolapse

in search of the holy grail

Jan van Iersel

RECTAL PROLAPSE IN SEARCH OF THE HOLY GRAIL

Jan J. van Iersel

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Cover design: Thijs van Iersel, thijsvaniersel.nl

Lay-out: Saskia de Best

Drukwerk: drukbedrijf.nl

Paranimfen: Jan-Paul Briët and Tim Paulides

This thesis was financially supported by:

Universiteit van Twente, Meander Medisch Centrum, Duomed B.V., Dynamesh FEG

Textiltechnik mbH, Chipsoft en de Nederlandse Vereniging voor Endoscopie Chirurgie (NVEC).

**RECTAL PROLAPSE
IN SEARCH OF THE HOLY GRAIL**

PROEFSCHRIFT

Ter verkrijging van de graad van doctor
aan de Universiteit Twente,
op gezag van de rector magnificus, prof. dr. T.T.M. Palstra
volgens besluit van het College voor Promoties
in het openbaar te verdedigen op
vrijdag 31 maart 2017 om 12:45 uur

door

Jan Jeroen van Iersel

geboren op 7 december 1986
te Leiden, Nederland.

PROMOTOREN

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ISBN: 978-90-365-4311-8

DOI: 10.3990/1.9789036543118

<https://dx.doi.org/10.3990/1.9789036543118>

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Chapter 1

General introduction and thesis outline

RECTAL PROLAPSE

Symptomatic pelvic floor disorders are increasingly common. The prevalence in the general population is 23.7%, rising to almost 50 percent for women aged 80 years or older¹. In the Netherlands, the lifetime risk of requiring surgery for a pelvic floor disorder is approximately 20%². Over the coming decades, the prevalence of pelvic floor disorders will double, taking into account the rising population³⁻⁵. Considering the high costs and the major impact on the quality of life, this constitutes a significant health issue⁶⁻⁷. The posterior compartment is responsible for a large proportion of these pelvic floor disorders¹. The treatment of rectal prolapse, and its affiliated rectocele and enterocele, has become an increasingly important part of health care over the years.

Rectal prolapse is anatomically subdivided in internal rectal prolapse (IRP, also referred to as intussusception) and external rectal prolapse (ERP). An ERP is defined as a circumferential full-thickness protrusion (evisceration) of the rectum through the anal verge and an IRP is a telescopic infolding of the rectal wall during defecation. IRP and ERP are considered a continuum of the same condition, starting with a recto-rectal IRP, progressing to recto-anal IRP and finally to ERP^{8,9}. This is reflected in the widely used Oxford rectal prolapse grade system (see table 1, chapter 3)⁸. The exact epidemiology of IRP is unknown, but the incidence of ERP is low with an annual incidence of 2.5 (range, 0.79–6.08) per 100.000 population¹⁰. Some authors question the importance of an IRP, as intussusceptions are also observed in radiological studies of asymptomatic patients¹¹⁻¹³. One of these authors, however, reported intussusceptions were twice as common in patients with defecatory problems than in asymptomatic volunteers¹². Other research showed that IRP in symptomatic patients is more advanced morphologically than that seen in asymptomatic controls with IRP¹⁴. Although benign, rectal prolapse is associated with a myriad of debilitating symptoms including fecal incontinence, obstructed defecation syndrome (ODS) and pelvic discomfort^{7,15}. It is assumed that the different grades of IRP, whether or not combined with a rectocele, cause ODS and that fecal incontinence is caused by anal sphincter damage and continuous stimulation of the

recto-anal inhibitory reflex secondary to increased mechanical stress of the high-grade prolapse^{16–18}. Recent research demonstrates that increasing grades of IRP are associated with increasing fecal incontinence¹⁹.

DIAGNOSTICS AND CURRENT PRACTISE

A proper pre-operative assessment is crucial as multiple factors impact on the decision to perform surgery. A prolapse of the posterior compartment is often complex and can be missed or underestimated at physical examination²⁰. Additional imaging, used by the majority of surgeons treating rectal prolapse, leads to potential changes to the initial operative plan in 40-70% of patients^{21,22}. High long-term re-operation rates following a pelvic organ prolapse repair may be caused by an incomplete surgical repair of a preoperatively unrecognised prolapse or an incorrect indication and emphasize the necessity of adequate preoperative diagnostics, including imaging^{23,24}. The two most used radiological imaging techniques for the pelvic floor are conventional dynamic defecography (CD, gold standard) and dynamic magnetic resonance imaging (MR defecography, D-MRI). Even though both imaging modalities are used to diagnose prolapse of the posterior compartment, there is no consensus about the best technique. Evacuation of rectal contrast during these investigations, allowing for complete levator ani relaxation, is crucial in detecting a prolapse and should always be achieved^{25,26}. However, head to head studies including rectal evacuation of contrast are limited.

Two recent international surveys showed a lack of uniformity in the evaluation, treatment and follow-up of patients with IRP and ERP^{27,28}. A symptomatic IRP grade 1-2 can be treated with conservative measures such as pelvic floor physiotherapy^{29,30}. Generally, patients with symptomatic high-grade IRP (Oxford grades ≥ 3 , with or without additional rectocele or enterocele) who have failed to respond to conservative therapy are candidates for surgery³¹. An ERP is considered a definite indication for surgery. The general objective of surgery is to correct the anatomical defect, improve functional

outcomes and prevent recurrent disease. The difficulty in treating rectal prolapse is shown by the astounding number of surgical procedures—more than 300—that have been developed³². This high number of procedures illustrates how difficult it is to achieve a good outcome. Different procedures have aimed at fixing a rectal prolapse by inducing anorectal inflammation, encircling the anus; shorten the rectum without resection; amputating the prolapse; obliterating the cul-de-sac or to suspend and fixate the rectum with or without a resection of redundant colon³². The optimal technique to correct rectal prolapse is, however, unclear.

Currently, surgical techniques are divided into perineal and transabdominal procedures. Perineal approaches seem to be associated with a greater risk of postoperative faecal incontinence and recurrence than abdominal procedures (level-III evidence) and therefore abdominal procedures are preferred by most surgeons³³. Previous research showed that abdominal dissection of the lateral ligaments of the rectum was associated with a higher rate of (new-onset) postoperative constipation than abdominal rectopexy without lateral ligament division^{33,34}. Against this backdrop, laparoscopic ventral mesh rectopexy (LVMR) was developed and has become the preferred technique by many surgeons, especially in Europe³⁵. In this procedure, the rectum is mobilised ventrally and attached to the sacral promontory using a mesh³⁶. By avoiding posterolateral rectal mobilization, autonomic nerves are spared and the risk of postoperative constipation is minimised. By lifting the middle compartment of the pelvic floor, correction of other frequently co-presenting pelvic prolapses and celes is achieved.

SURGICAL TECHNIQUES

LVMR has gained increasing worldwide acceptance for rectal prolapse and is now the most used technique in the Netherlands^{31,35,37–39}. In recent years, the indication for ventral mesh rectopexy has become wider as it also successfully treats large symptomatic rectoceles and IRP^{31,40–42}. Robot-assistance has the theoretical advantage during ventral mesh rectopexy of enhanced visualization, dexterity and precision, especially for dissecting the rectovaginal septum down to the pelvic floor and suturing a mesh to

the ventral aspect of the rectum as distally as possible⁴³. Although increasingly applied, the exact role of ventral mesh rectopexy, and specifically the robotic assistance, in the treatment of rectal prolapse remains unclear. Traditionally, prolapse repair is performed per compartment by the relevant surgical specialty. However, prolapse of the posterior compartment may occur concomitantly with abnormalities of other pelvic organs, commonly a combination of urogenital and rectal prolapse^{44,45}. A high prevalence of concurrent IRP (55%), rectal prolapse (38%), rectocele (53%) and enterocele (14%) has been found in patients with urogynaecological symptoms and/or prolapse of the middle compartment^{44,46}. These data illustrate the need for a standardised multi-compartment procedure for multi-compartment prolapse, but there is no consensus yet on the exact indication for such a procedure. To determine which patients are suitable for multi-compartment treatment, in a field marred by a lack of evidence, is complex. The gold standard for female genital prolapse is abdominal sacrocolpopexy⁴⁷. To date, only two flawed and outdated studies combined ventral mesh rectopexy with sacrocolpopexy^{48,49}. None of the articles describing multi-compartment procedures involved robotic assistance or reported on sexual or quality of life outcomes.

SEQUELAE AND EFFECTS OF SURGERY

In the Meander Medical Centre, where our studies were conducted, many patients were found to suffer from high-grade hemorrhoids following LVMR. The incidence of high-grade hemorrhoids following various types of rectopexy has been quoted as up to 18%, but literature regarding ventral mesh rectopexy specifically is scarce⁵⁰. In addition, it is unclear whether stapled hemorrhoidectomy following ventral mesh rectopexy is safe to perform considering the presence of a mesh in the rectovaginal septum. The risk of mesh-related complications is a key topic and its use in pelvic reconstructive surgery has been under debate for over 20 years. The US Food and Drug Administration (FDA) reports in 2008 and 2011 fuelled the discussion by reporting numerous mesh-related complications following a transvaginal prolapse repair⁵¹. This was supported by a systematic review suggesting a summary incidence of mesh erosion following

transvaginal pelvic organ prolapse repair as high as 10.3% (range 0 – 29.7%, n=11.785) in the first postoperative year⁵². The FDA reports led to a global reticence towards the use of mesh, resulting in an under-treatment of serious, disabling pelvic floor disorders regardless of the approach. It is, however, not clear to what extent the FDA warning is relevant to abdominally placed synthetic meshes.

THESIS OUTLINE

The studies presented in this thesis were guided by the following research questions:

- Which imaging technique is the best to diagnose a prolapse of the posterior compartment of the pelvic floor?
- What is, based on the available evidence, the optimal surgical treatment for IRP and ERP?
- Is ventral mesh rectopexy a safe and effective technique to treat ERP and IRP in a large cohort of patients?
- What is the effect of a multi-compartment pre-operative assessment and what are the results of a robot-assisted multi-compartment procedure?
- What are the sexual outcomes following a multi-compartment procedure with synthetic mesh?
- Does robotic assistance influence the morbidity and the outcomes of pelvic reconstructive surgery?
- Are abdominally placed synthetic meshes safe?

Eight studies, divided in three sections, were performed in order to answer the above mentioned questions. In **chapter two** of this thesis D-MRI is compared to CD with rectal evacuation of contrast as an inclusion criterion. In **chapter three**, an overview of all of the procedures currently used in rectal prolapse surgery mentioned in the Dutch national prolapse guideline is given. The position of ventral mesh rectopexy in this field is described in **chapter four**. In **chapters five to seven** the outcomes of several popular minimally invasive surgical techniques to treat rectal prolapse are described. **Chapter eight** reports on the incidence of high-grade hemorrhoids requiring surgery following LVMR. In **chapter nine** a prospective long-term assessment of mesh-related morbidity following abdominal robot-assisted pelvic floor repair is undertaken.

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Chapter 2

Comparison of dynamic magnetic resonance defecography with evacuation of rectal contrast and conventional defecography for posterior pelvic floor compartment prolapse

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Colorectal Disease 2017 Jan;19(1)046-053

Abstract

Aim

The study compared the diagnostic capabilities of dynamic magnetic resonance defecography (D-MRI) with conventional defecography (CD, reference standard) in patients with symptoms of prolapse of the posterior compartment of the pelvic floor.

Method

Forty-five consecutive patients underwent CD and D-MRI. Outcome measures were the presence or absence of rectocele, enterocele, intussusception, rectal prolapse and the descent of the anorectal junction on straining measured in millimetres. Patients without rectal evacuation of contrast on D-MRI or CD were excluded. Cohen's Kappa, sensitivity, specificity, positive (PPV) and negative predictive value (NPV) and the positive and negative likelihood ratio of D-MRI were compared with CD. Cohen's Kappa and Pearson's correlation coefficient were calculated and regression analysis was performed to determine interobserver agreement.

Results

Forty-one patients were available for analysis. D-MRI underreported rectocele formation with a difference in prevalence (CD 77.8% vs. D-MRI 55.6%), mean protrusion (26.4 vs. 22.7 mm, $p=0.039$) and 11 false negative results, giving a low sensitivity of 0.62 and an NPV of 0.31. For the diagnosis of enterocele, D-MRI was inferior to CD with five false negative results, giving a low sensitivity of 0.17 and high specificity (1.0) and PPV (1.0). Nine false positive intussusceptions were seen on D-MRI with only two missed.

Conclusion

The diagnostic accuracy of D-MRI for diagnosing rectocele and enterocele is less than conventional defecography. D-MRI, however, appears superior to CD in identifying intussusception. D-MRI and CD are complementary imaging techniques in the evaluation of patients with symptoms of prolapse of the posterior compartment.

Introduction

Up to 25% of the population is affected by defecation disorders and pelvic organ prolapse (POP), with a lifetime risk of undergoing surgery of 10-20%¹⁻³. The prevalence of such disorders has been increasing for many years and is likely to continue doing so⁴⁻⁶. In addition, considering the high cost of treatment and their major impact on quality of life, defecation disorders and POP are a significant public health matter^{2,7}. Prolapse of the posterior compartment is often complex and can be missed or underestimated by physical examination⁸. Additional imaging can lead to changes in the initial operative plan in 40-70% of patients^{9,10}. Traditionally, conventional defecography (CD) has played an important role in the radiologic detection of prolapse of the posterior compartment and is still considered the gold standard^{11,12}. In contrast, dynamic magnetic resonance imaging (MR defecography, D-MRI) provides a multi-compartment overview with structural soft tissue details and without exposure to radiation. Because of these advantages, it has become a frequently used alternative technique for evaluation of the pelvic floor^{13,14}. Even though both techniques are accepted for diagnosing prolapse of the posterior compartment, there has been limited research directly comparing them with the evacuation of rectal contrast (allowing for complete levator ani relaxation) as an inclusion criterion. The aim of this study was to compare D-MRI with dynamic CD as the reference standard with rectal evacuation assessed with the use of radiological contrast in patients with symptoms of prolapse of the posterior compartment of the pelvic floor.

Method

Study design

All consecutive patients of one gastrointestinal surgeon (ECJC) with symptoms of pelvic floor dysfunction of the posterior compartment requiring radiologic assessment between June 2010 and June 2011, prospectively underwent D-MRI and CD. Patients without rectal evacuation of contrast on D-MRI or CD were excluded. All patients were routinely investigated by a history, physical examination and proctoscopy. The D-MRI examinations were all performed in our institution. The defecographies were conducted in a nearby university hospital (University Medical Centre Utrecht) as our hospital does not offer this service. All patients gave their informed consent prior to inclusion in the study, which was approved by the local medical ethics committee and carried out in accordance with the ethical standards of the Declaration of Helsinki.

Imaging techniques

Dynamic conventional (entero-colpo) defecography (CD)

For small bowel contrast, 65mL of thick barium paste (barium sulphate, E-Z-HD) mixed with water (515% wt/vol) and 5mL microlax (sodium laureth sulphate/sodium citrate/sorbitol) were administered to each patient by mouth two hours before the examination. The patient was asked to pass urine before the examination, to avoid pelvic crowding. No bladder contrast was used. The distal sigmoid colon was opacified with 300 mL of barium paste (barium sulphate, Liquid Polibar) and water (35% wt/vol) instilled *per rectum* through a colon cannula. The rectum was opacified using 150 mL barium paste mixed with Metamucil to create a consistency similar to stool. The anal canal was also demonstrated by contrast during removal of the syringe used to inject the contrast and the vagina was opacified with 10 mL of barium paste. The patient was seated on a radiolucent commode with the fluoroscopic table vertically upright. A lateral radiograph was taken with the patient at rest. Cineradiography (two images/second) was performed at rest and during puborectalis contraction, a Valsalva manoeuvre, squeezing, evacuation and after evacuation. For measurements of midline structures

corrected for magnification, a radiopaque chain of beads 4.4 mm from each other was attached to the patient's anal cleft.

Dynamic MR defecography (D-MRI)

All D-MRI imaging studies were performed on a 1.5T closed magnet (Intera rel.2.6.3, Philips, Best, Netherlands). All patients were imaged supine with a body-phased-array receiver coil (Torso-XL). The patient was asked to remain on a low fibre diet 24 hours before the examination. To ensure adequate bladder filling, the patient was asked to avoid micturition two hours before the examination. The vagina and rectum were filled with 50 mL and 200 mL of warm ultrasonographic gel. After an initial localizer in three different planes, the study protocol included a TSE T2-W axial sequence (voxel size : 1 x 1.25 mm; 53 images; thickness, 4 mm; TR/TE, 6,430/114; flip angle, 90 , Turbo factor 15, scan time 3.10 min.), a TSE T2-W sagittal sequence (voxel size 1.0 x 1.2 mm; 35 images; thickness 4 mm; TR/TE, 846/11; flip angle, 90, Turbo factor 15, scan time 3.04 min.), and a functional dynamic sequence with a balanced FFE T2-W sequence sagittal during squeezing, pushing, evacuation and after evacuation (voxel size 1.8 x 1.4 mm; 60 images in total; 1.5 sec. per image; thickness, 8 mm; TR/TE, 3.75/ 1.6; flip angle, 45, scan time 1.32 min.) through the midline. No micturition/voiding was pursued and did not occur during this series. The dynamic images of this last sequence were presented in cinematic form.

Image analysis

Two radiologists (BGFH, IS) independently reviewed the D-MRI images. The CD examinations were independently reported by two different radiologists (JJF, MvdL). All the radiologists were experienced in pelvic floor imaging and were blinded of the medical history and clinical findings. Disagreement on dichotomized variables such as the presence or absence of enterocele, intussusception or rectal prolapse was resolved at a consensus meeting after establishing the interobserver variability. For the numeric variables including the size of rectocele or the degree of descent of the anorectal junction (ARJ) on straining, the mean of the two measures independently measured

by the two radiologists was taken. The images were scored according to the presence or absence of anterior rectocele, enterocele, intussusception, rectal prolapse and the degree of descent of the ARJ on straining. A rectocele was defined as a protrusion during evacuation or during maximal straining of the rectal wall of more than 20 mm anterior to a longitudinal line parallel to the axis of the anal canal, in conformity with the literature¹³. The pubococcygeal line (PCL) extended from the inferior border of the symphysis pubis to the most distal coccygeal joint^{14,15}. An enterocele, defined as small bowel in the recto-vaginal septum extending below the PCL, was scored as present or absent. An intussusception was also dichotomized as being present or absent, as a circumferential rectal wall invagination or infolding descending toward the anal canal. The distance of the line perpendicular to the PCL to the cranial side of the anal canal (ARJ descent) during maximal straining or evacuation was measured in millimetres. An ARJ which descended by more than 30mm on straining signified excessive descent¹⁶. Rectal prolapse was characterised as a full-thickness circumferential protrusion through the anal canal. All D-MRI measurements were performed in the mid-sagittal image.

Statistical analysis

Data are presented as percentage, mean $\pm$ standard deviation (SD) and range with 95% confidence intervals (CI). The interobserver variability for dichotomized variables was calculated with Cohen's Kappa. To determine inter-observer variability for numeric variables, regression analysis and Pearson's correlation coefficient was used. Since at present CD is generally considered the gold standard, this was used as the reference investigation for determining sensitivity, specificity, positive (PPV) and negative predictive value (NPV) and positive and negative likelihood ratio with associated confidence-intervals of D-MRI^{1,11,12,15,17-23}. Cohen's Kappa (κ) is a measure of agreement beyond chance to compare diagnostic tests without designating one test as the gold standard²⁴. Whether CD is the appropriate reference point has been a longstanding subject for debate in the contemporary literature. Therefore, κ values were also reported to assess agreement between CD and D-MRI, despite the official statistical misuse of κ ²⁴. The mean differences in the size of the of rectocele and ARJ descent were analysed

statistically using the paired t test. A p-value of less than 0.05 was considered to be statistically significant. Statistical analysis was performed using Statistical Package for the Social Science, version 20.0 (IBM Corp., Armonk, NY).

Results

Patient characteristics and symptoms

Forty-one of 45 patients (39 female), of mean age of 64.3 ± 12.0 SD (range 38.3 – 85.1) years were included (Table 1). Two patients were excluded from further analysis because no rectal evacuation was achieved on D-MRI with no faecal obstruction in either. Two further patients were excluded because of extensive anal sphincter damage with an inability to retain the rectal contrast in one and owing to the presence of a pessary during D-MRI in the other. Eighteen (43.9%) patients had faecal incontinence and 18 (43.9%) had obstructed defaecation.

Table 1. Patient characteristics, medical history and complaints

		CD vs. D-MRI
		N = 41 (%)
Gender	Male/female	2/39
Age (range)	Years	64.3 (38.3 – 85.1)
History		
	Para (range) [no. episiotomy/rupture]	2.4 (0-5) [10/6]
	Rectopexy	5 (12.2)
	Hysterectomy	19 (46.3)
	Cystopexy	7 (17.1)
	Colporrhaphy anterior	11 (26.8)
	Colporrhaphy posterior	10 (24.4)
	Sphincter operation	1 (2.4)
	PPH	3 (7.3)
	Other abdominal surgery	15 (36.6)
Complaints		
	Faecal incontinence	18 (43.9)
	Obstructed defecation	18 (43.9)
	Constipation	4 (9.8)
	Change defecation <3 months	5 (12.2)
	Faecal urgency without success	7 (17.1)

PPH: procedure for prolapse and hemorrhoids

Imaging

The degree of ARJ descent could not be measured in eight patients in the CD series because of an inability to draw the PCL, or a difficulty in calculating accurate magnification. For this last reason it was not possible to measure the depth of the rectocele in five of these patients. Table 2 shows the pathologies of CD and D-MRI. The prevalence of rectocele (77.8 vs. 55.6%) and enterocele (14.6 vs. 2.4%, Fig. 1) was higher on CD and intussusception was more frequently seen on D-MRI (14.6 vs. 31.7%, Fig. 2). The measurement of agreement between CD and D-MRI was poor for rectocele ($\kappa = 0.171$, $p=0.244$), fair for enterocele ($\kappa = 0.255$, $p=0.014$) and for intussusception ($\kappa = 0.275$, $p=0.064$). There was a significant difference in the mean size of the rectocele of 3.7mm (26.4 vs. 22.7 mm, $p=0.039$) anterior to the longitudinal axis of the anal canal. The incidence of descent of the ARJ by more than 30mm was approximately the same for each investigation (90.9 vs. 97.0%), but a non-significant poor agreement was measured between CD and D-MRI ($\kappa = -0.048$, $p=0.748$). The mean ARJ descent measured by each examination was similar (51.7mm vs. 55.1mm), and not statistically significant ($p=0.839$). Rectal prolapse was not observed on either CD or D-MRI. The results of CD compared with D-MRI are given in Table 3. The sensitivity, specificity, positive and negative predictive values and the positive and negative likelihood ratios are given in Table 4.

Table 2. Findings on CD and D-MRI

	CD n (%)	D-MRI n (%)	κ	P value
Rectocele^a	28 (77.8)	20 (55.6)	0.171	0.244
Rectocele ^a depth<2 cm	8 (22.2)	16 (44.4)	-	-
Rectocele ^a depth 2–4 cm	25 (69.4)	17 (47.2)	-	-
Rectocele ^a depth>4 cm	3 (8.3)	3 (8.3)	-	-
Mean rectocele, mm (SD)	26.4 (± 8.6)	22.7 (± 9.6)	0.353	0.035
Enterocele	6 (14.4)	1 (2.4)	0.255	0.014
Intussusception	6 (14.6)	13 (31.7)	0.275	0.064
Anorectal junction^a >30mm	30 (90.9)	32 (97.0)	-0.048	0.748
Mean anorectal junction, mm (SD)	51.7 (± 13.7)	51.1 (± 13.5)	0.334	0.058

κ : Cohen's Kappa.^a measured at maximal straining/evacuation. Rectocele calculations based on 36 patients, anorectal junction on 33 patients

Figure 1. An enterocoele (white arrow) as seen on conventional defecography (left) and dynamic MR defecography (right).

Figure 2. An intussusception (white arrows) as seen on conventional defecography (left) and dynamic MR defecography (right).

Table 3. Findings on CD and D-MRI

			CD	
			Yes	No
Rectocele^a depth > 2 cm	D-MRI	Yes	17	3
		No	11	5
Enterocoele	D-MRI	Yes	1	0
		No	5	35
Intussusception	D-MRI	Yes	4	9
		No	2	26
Anorectal junction^a >30mm	D-MRI	Yes	29	3
		No	1	0

^a measured at maximal straining/evacuation. Rectocele calculations based on 36 patients, anorectal junction on 33 patients.

Table 4. Diagnostic characteristics of D-MRI compared with CD (reference standard)

	Prevalence	Sens 95 % CI	Spec 95 % CI	PPV 95 % CI	NPV 95 % CI	Pos. LR 95 % CI	Neg. LR 95 % CI
Rectocele depth > 2cm	77.8%	0.61 0.41-0.78	0.63 0.26-0.90	0.85 0.61-0.96	0.31 0.12-0.59	1.62 0.63-4.16	0.63 0.34-1.15
Enterocoele	14.6%	0.17 0-0.6	1.0 0.88-1	1.0 0.05-1	0.88 0.72-0.95	Inf.	0.83 0.58-1.19
Intussusception	14.6%	0.67 0.24-0.94	0.74 0.56-0.87	0.31 0.10-0.61	0.93 0.75-0.99	2.59 1.17-5.7	0.45 0.14-1.42
Anorectal junction >30mm	90.9%	0.97 0.81-1	0 0-0.70	0.91 0.74-0.98	0 0-0.95	0.97 0.90-1.03	Inf.

Sens: sensitivity; Spec: specificity; PPV: positive predictive value; NPV: negative predictive value; Pos. LR: positive likelihood ratio; Neg. LR: negative likelihood ratio, 95 % CI: 95% confidence interval; Inf.: infinity.

Inter-observer variability

The inter-observer agreement (Cohen's Kappa) of CD for diagnosing enterocoele was 0.80 (95% CI) 0.6 - 1.0; $p < 0.05$) and for intussusception 0.09 (95% CI 0 - 0.4; $p = 0.554$). The D-MRI showed inter-observer variability Kappa values of 1.0 (95 % CI 1.0 - 1.0; $p < 0.05$) for enterocoele and 0.95 (95 % CI 0.85 - 1.0, $p < 0.05$) for intussusception. The Pearson correlation coefficients of CD and D-MRI were 0.96 and 0.93 for rectocele and 0.96 and 0.93 for ARJ descent.

Discussion

The present study has demonstrated substantial differences in the prevalence of rectocele, enterocele and intussusception determined by conventional defecography and dynamic magnetic resonance imaging. A missed prolapse may have serious consequences and therefore appropriate radiologic assessment is essential. The recent literature quotes a 10 year risk of re-operation of 17%²⁵. This high percentage is partly due to inadequate surgical repair of a preoperatively unrecognised prolapse or to an incorrect indication for surgery²⁶.

D-MRI underestimated the prevalence of rectocele and protrusion with an additional 11 false negatives. In these eleven *missed* patients D-MRI only showed a small degree of anterior projection (mean difference 12.3 mm, $P < 0.05$) from the longitudinal axis of the anal canal, a source of error which has been previously described^{9,15,17,21,27}. Differences in the volume of radiological contrast instilled and the variable magnification in CD may lead to inaccurate measurements and could also be a factor to explain the difficulty in comparing the two imaging modalities. The point of maximal prolapse may additionally be missed because of the fixed mid-sagittal plane used in D-MRI. These reasons may cause the low sensitivity (0.61) and low NPV (0.31) for the diagnosis of rectocele.

Theoretically, an enterocele should be clearly visible on D-MRI since small intestine is surrounded by mesenterial fat¹², but in the present study detection of enterocele was poor compared with CD, as has been reported by others^{15,23}. Repeated straining to achieve evacuation and provoke the prolapse may be needed to detect an enterocele¹². One study found that 43% of enteroceles were only seen in the post-evacuation phase²³. In the present study, all the patients achieved evacuation during D-MRI and CD, but with the patient in the supine position it is difficult to repeat the post-evacuation phase of the examination, because the evacuated rectal contrast makes it uncomfortable. The supine position required for D-MRI, providing less gravitational influence, is thought to play a role in the detection the different forms of prolapse. Complete levator ani relaxation is needed to reach maximal pelvic descent and the sitting position is superior to the supine to accomplish this¹. There is a greater degree of pelvic floor laxity on MRI taken

in the sitting rather than the supine position^{28,29}. Bertschinger et al reported two missed enteroceles on MRI with the patient supine than when sitting²⁸. Furthermore, the thin-section sagittal imaging of D-MRI may have caused an enterocele to be missed in the present study. The specificity and PPV of the diagnosis of enterocele were, however, excellent and in accordance with the literature¹⁸.

A symptomatic recto-anal intussusception (Oxford grade III/IV) is considered an indication for surgery. Intussusception is strongly associated with impaired defecation; one report showed intussusception was twice as likely to be present in patients with defecatory difficulty than in asymptomatic volunteers³⁰. The present study found that D-MRI generated nine false positives compared with CD. To our knowledge, a difference of that order has not been previously described. D-MRI can detect very small rectal wall abnormalities due to its outstanding soft tissue resolution¹¹ and it may be more accurate than CD for diagnosing intussusception. This is supported by the study of Dvorkin et al., in which two of the three missed intussusceptions on CD proved to be mucosal prolapse on MRI²¹. In our cohort, only two intussusceptions were missed. This is in accordance with the findings of Dvorkin et al although these patients were examined in an open-magnet MRI²¹. Two other studies using a closed magnet MRI showed none of the intussusceptions diagnosed on CD^{9,17}. When compared by Bertschinger et al, all intussusceptions missed in the supine position were seen using upright D-MRI²⁸. The supine series of this study were, however, carried out without rectal evacuation. The combination of a supine position and the lack of adequate repeated straining in the post-evacuation phase may explain the two missed intussusceptions in the present study. There are contrasting results of the accuracy of MRI in the literature^{9,12,15,17-23,27} which may be due to technical differences in how MRI was performed. Studies in which patients did not evacuate the rectal contrast during dynamic MRI, report a lower sensitivity for rectocele, enterocele, intussusception and rectal prolapse^{9,12,17,19,20}. In the case of MRI with evacuation the literature describes an equivalent prevalence of rectocele, but a lower detection rate of enterocele and intussusception compared with CD^{18,21-23,27}.

The inter-observer agreement for diagnosing intussusception on CD was poor with 0.09, but this was not significantly different from chance ($p = 0.554$). A similar agreement for intussusception on CD has been described¹⁵. All other Kappa values for diagnosing enterocele and intussusception showed almost perfect or substantial inter-observer agreement ($p < 0.05$), with a strong agreement for rectocele and ARJ descent. The advantages of MR imaging should be considered when interpreting the findings of the present study. D-MRI shows soft tissue details and an overall intra-pelvic interaction of multiple organ prolapse. It is less invasive and avoids ionising radiation. CD does not show soft tissue and uses radiation, which is especially important for women of child bearing age³¹.

CD is widely available, however, is cost effective and can be performed with the patient in an upright position. In conclusion, the diagnostic ability of D-MRI is less than CD for diagnosing rectocele and enterocele, but it appears to be superior in identifying intussusception. CD and D-MRI are complementary imaging techniques in the evaluation of prolapse of the posterior pelvic floor compartment.

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Chapter 3

Richtlijn prolaps

Chirurgische behandeling van een rectum prolaps

Dutch national prolapse guideline

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Initiatiefnemer richtlijn

Nederlandse Vereniging voor Obstetrie en Gynaecologie

In samenwerking met

Nederlandse Vereniging voor Heelkunde
Nederlandse Vereniging van Maag-Darm-Leverartsen
Nederlandse Huisartsen Genootschap
Nederlandse Vereniging voor Radiologie
Nederlandse Vereniging voor Urologie
Nederlandse Vereniging voor Fysiotherapie bij Bekkenproblematiek en Pré- en Postpartum
gezondheidszorg

Samenstelling van de volledige werkgroep

J.P. Roovers (voorzitter), E. Everhardt, V. Dietz, A.L. Milani, A.H.P. Meier, E.C.J. Consten,
J.J. Futterer, R.J.F. Felt-Bersma, M.C.Ph. Slieker-ten Hove, T. Steenstra Touissant,
C.A.L. van Rijn, F. Vlemmix, K. Notten, J.J. Van Iersel, T.A. van Barneveld, K.Y. Heida

*Gepubliceerd december 2014 (o.a. op Heelkunde, NVOG, NHG, richtlijnen database en
kwaliteitskoepel.nl).*

Hieronder de Nederlandse publicatie met een Engelse samenvatting.

Achtergrondinformatie

Epidemiologie

Prolaps, afkomstig van het Latijnse *prolabi*, betekent letterlijk ‘vallen’ of ‘uitglijden’. Een rectum prolaps (RP) komt verreweg het meeste voor bij vrouwen (80-90%) en voornamelijk bij vrouwen tussen de 60 en 70 jaar¹. In de Verenigde Staten is de incidentie voor interne en externe rectum prolaps 420 per 100.000 personen. Bij patiënten ouder dan 65 jaar loopt deze incidentie op naar 1.000 per 100.000 patiënten. Onderzoek uit Finland vindt een incidentie van 2.5 per 100.000 mensen voor een externe rectum prolaps (ERP)².

Etiologie

Het ontstaan van een prolaps is multifactorieel bepaald (figuur 1). De factoren die bijdragen aan het ontwikkelen van een prolaps kunnen worden verdeeld in predisponerend, uitlokkend, bevorderend en decompenserend. Door het beperkte inzicht in de etiologie van prolaps is er nog weinig kennis over preventie van prolaps. Bekende risicofactoren voor het ontwikkelen van een RP zijn een abnormaal diep cavum Douglassi, een mobiel mesorectum en een laxiteit van de laterale rectale ligamenten en de bekkenbodemspieren. Zwakte van de interne en externe anale sfincter, vaak gecombineerd met een pudendus neuropathie, zijn ook predisponerend voor het verkrijgen van een RP³.

Figuur 1⁴

Aanvullend onderzoek

Bij patiënten met een prolaps kan soms aanvullend onderzoek nodig zijn. Er zijn 2 soorten aanvullend onderzoek: [1] functie-onderzoek en [2] beeldvormend onderzoek.

Anorectaal functieonderzoek⁵

Door middel van anorectaal functieonderzoek (ARFO) kan worden onderzocht hoe de rustdruk en de knijpkracht van de anale sfincter is; hoe de anorectale sensibiliteit is en bij welk rectaal volume de eerste aandrang, het gevoel van defecatie en de maximaal tolerabele aandrang optreden. Soms wordt ook neurofysiologisch onderzoek verricht, zoals geleidingstijd van de n. pudendus en een EMG. Vaak wordt ARFO gecombineerd met anale endoechografie voor het aantonen of uitsluiten van defecten van de interne en externe sfincter. De literatuur is schaars over het belang van ARFO voor indicatie en prognostische waarde bij de keuze van behandeling of uitkomsten van behandeling. Wel wordt vaak ARFO verricht voor en na een anorectale of prolaps operatie of voor het geven van bekkenfysiotherapie. Er zijn situaties denkbaar waarbij de bevindingen van een ARFO gebruikt zouden kunnen worden om een betere voorlichting te geven.

Beeldvorming van het achterste compartiment⁶

Een achterste compartiment verzakking kan worden veroorzaakt door het uitzakken in de vagina van rectum (rectocele) of dunne darm (enterocele), maar ook door een interne of externe rectum prolaps. Er zijn meerdere beeldvormende technieken die toegepast kunnen worden om vast te stellen welke anatomische afwijkingen van het achterste compartiment aanwezig zijn.

Bij een defecogram wordt de dunne darm met contrast gevuld door de patiënt 1 tot 2 uur voor het onderzoek contrastmiddel te laten drinken. Direct voorafgaand aan het onderzoek wordt het rectum gevuld met contrastmiddel. Dit rectale contrastmiddel wordt door de patiënt geëvacueerd onder röntgen doorlichting. Het onderzoek geeft ook informatie over de aanwezigheid van een eventuele interne of externe rectum prolaps.

Met een MRI-defecogram kan het achterste compartiment ook in beeld gebracht worden. Sommige klinieken maken gebruik van coating van het ano-rectum in plaats

van daadwerkelijk vullen van het rectum. De verbeterde sequentie van de MRI in de afgelopen jaren heeft het inzicht in de 3-dimensionale anatomie verbeterd.

Classificatie

Een veel gebruikt classificatiesysteem is het Oxford rectal prolapse grade system, zie tabel 1⁷.

Behandeling van prolaps

Het aantal patiënten dat geopereerd wordt vanwege een verzakking is de afgelopen jaren explosief toegenomen. Dit is het gevolg van een aantal factoren: [1] patiënten worden ouder en blijven tot op hogere leeftijd actief; [2] geneeskunde richt zich steeds meer op kwaliteit van leven en niet meer alleen op levensduur; [3] mogelijke afname van coping of acceptatie van ziekte en [4] operaties worden minder invasief (kortere opnameduur, sneller hervatten van normale werkzaamheden). Tegen de achtergrond van de huidige chirurgische mogelijkheden verdient het aanbeveling om patiënten met een prolaps en/of bekkenbodempunctie klachten laagdrempelig te verwijzen voor een diagnostisch consult en eventueel behandeladvies. Primair hoort de zorg voor de prolaps echter in de 1^e lijn. Uiteraard staat het de huisarts vrij om het resultaat van een niet invasieve behandeling eerst met de patiënt te exploreren.

Tabel 1: Oxford rectal prolapse grade system⁷

	Grade of rectal prolapse	Radiological characteristics of rectal prolapse
Internal (RI)		
Recto-rectal Intussusception (RRI)	I (high rectal)	Descends no lower than proximal limit of the rectocele
	II (low rectal)	Descends into the level of the rectocele, but not onto sphincter/anal canal
Recto –anal Intussusception (RAI)	III (high anal)	Descends onto sphincter/anal canal
	IV (low anal)	Descends into sphincter/anal canal
External (ERP)		
External rectal prolapse (ERP)	V (overt rectal prolapse)	Protrudes from anus

Mucosa prolaps

Het is belangrijk de RP niet te verwarren met de mucosa prolaps (MP) waarbij enkel het slijmvlies door de anus prolabeert. Graad I en II van de MP worden in de regel met rubber band ligatie behandeld, alwaar een hooggradige MP (III/IV) chirurgie behoeft. De meest gebruikte chirurgische opties voor een vergevorderde MP zijn een PPH (Procedure for Prolapse and Hemorrhoids) en een conventionele drie pijler hemorrhoidectomie. De MP wordt verder niet behandeld in deze richtlijn.

Chirurgische behandeling van een rectum prolaps

Uitgangsvragen:

- 1 Wat is de optimale chirurgische correctie van een externe rectale prolaps?
- 2 Wat is de optimale chirurgische correctie van een interne rectale prolaps?

Inleiding

De rectum prolaps (RP) kan worden onderverdeeld in een interne en een externe variant. De externe rectum prolaps (ERP) is een circumferentiële ('full-thickness') intussusceptie van de gehele rectumwand, die zich uitstrekt voorbij het anale kanaal. Van een interne rectum prolaps (IRP, ook wel intussusceptie genoemd) wordt gesproken wanneer deze intussusceptie zich boven het niveau van de anus (recto-recto of recto-anaal, zie achtergrondinformatie voor gradaties RP) bevindt. RP gaat vaak gepaard met andere verzakkingen van het posterieure compartiment zoals een rectocele of enterocele. Een RP moet niet verward worden met een mucosa prolaps, waarbij enkel het slijmvlies door de anus prolabeert. Een prolaps van het posterieure compartiment van de bekkenbodem is geassocieerd met invaliderende klachten als obstipatie (*obstructed defecation*), fecale incontinentie en (chronische) pijn.

De behandeling van RP is conservatief of chirurgisch. Bij een symptomatische IRP graad 1-2 wordt bekkenfysiotherapie voorgesteld. In 33% van de gevallen verbeteren de functionele resultaten met conservatieve behandeling op voorwaarde dat de patiënt het gehele behandel traject afmaakt⁸. Vanaf een IRP graad 3 wordt operatief ingrijpen aangeraden. Heden ten dage wordt IRP graad 3-4 al dan niet in combinatie met een recto- of enterocele behandeld middels een laparoscopische ventrale rectopexie (LVR) of een stapled transanal rectal resection (STARR), waarvan veel verschillende varianten zijn beschreven. Voor de behandeling van ERP wordt onderscheid gemaakt in perineale technieken, de Delorme- en Altemeier procedure, en abdominale technieken, verdeeld in laparoscopische rectopexie met of zonder resectie van het rectosigmoid. Tot nu toe wordt perineale chirurgie vooral voorbehouden aan (oudere) patiënten met een hoge comorbiditeit aangezien deze procedure geen laparoscopie of laparotomie behoeft en

vaak met behulp van locoregionale anesthesie kan worden uitgevoerd. Bij de operatie volgens Delorme wordt de prolaberende mucosa gestript en de spierlagen van de prolaps geëxposeerd⁹. Bij de techniek volgens Altemeier wordt de gehele prolapse full-thickness geresecteerd vanuit de perineale benadering¹⁰. De meest gebruikte abdominale technieken zijn LVR en laparoscopische resectie rectopexie (LRR). Bij beide technieken wordt het rectum alleen ventraal gemobiliseerd wat inhoudt dat de autonome zenuwen aan de laterale zijde worden gespaard. Bij de LVR wordt het ventrale rectum met een mat aan het promotorium bevestigd¹¹. Bij de LRR wordt het rectosigmoïd geresecteerd en vervolgens wordt het rectum met hechtingen ('suture rectopexie') aan het sacrum gefixeerd¹². Met het resecteren van het rectosigmoïd wordt de knik in het distale colon opgeheven. De theorie is dat dit tot minder postoperatieve obstipatie leidt¹³. Daartegenover staat het aanleggen van een anastomose met alle risico's van dien. Vanwege het risico op naadlekkage wordt geen mat gebruikt bij de LRR. Bij de meeste varianten van rectopexie, zowel laparotomisch als laparoscopisch, wordt een mat gebruikt. Hoewel meer dan 300 verschillende technieken voor behandeling van RP zijn beschreven bestaan er weinig tot geen goede vergelijkende studies^{14,15}.

Bewijs is veelal gebaseerd op losse observationele series waarin een enkele techniek wordt beschreven. Vanwege dit feit is de richtlijn genoodzaakt betreffende dit onderwerp bewijs van dergelijke series te presenteren. In dit hoofdstuk worden alleen de operaties beschreven die heden ten dage vaak worden uitgevoerd en beschreven.

Samenvatting van de literatuur

Er zijn 19 studies geselecteerd voor het beantwoorden van deze uitgangsvraag (Boccasanta 2011¹⁶, Cadeddu 2012¹³, Chun 2004¹⁷, Collinson 2010¹⁸, De Hoog 2009¹⁹, Fleming 2012²⁰, Isbert 2010²¹, Johnson 2012²², Karas 2011²³, Leal 2010²⁴, Lehur 2008²⁵, Renzi 2011²⁶, Samaranayake 2010²⁷, Schiedeck 2005²⁸, Sileri 2012²⁹, Tou 2008¹⁵, Tsunoda 2003³⁰, Youssef 2013⁹, Zbar 2002³¹). De zoekverantwoording staat op pagina 74.

Vergelijkende studies behandeling externe rectum prolaps

Laparotomische versus laparoscopische benadering

In een meta-analyse is door Cadeddu (2012) laparotomische rectopexie vergeleken met laparoscopische rectopexie voor de behandeling van ERP¹³. In deze analyse werden acht studies geïnccludeerd met in totaal 467 patiënten (275 laparotomisch, 192 laparoscopisch). De studies hadden een follow-up van 16 tot 59 maanden. Er werd tussen de twee behandelingen geen verschil gevonden in aantal recidieven en functionele uitkomst. De Cochrane review van Tou (2008) beschrijft twee studies die een vergelijking makentussen laparoscopische en laparotomische rectopexie bij patiënten met een ERP¹⁵. Er was geen verschil in het aantal recidieven en in verbetering van incontinentie en obstipatie klachten. Het aantal postoperatieve complicaties en de kosten waren wel lager in de laparoscopie groep. In een patiëntcontrole studie (2009) zijn laparoscopische (n=15), robot-geassisteerde (n=20) en laparotomische (n=47) rectopexie voor de behandeling van rectum prolaps met elkaar vergeleken¹⁹. Er was bij respectievelijk vier (27%), vier (20%) en één (2%) patiënt(en) sprake van een recidief prolaps. Incontinentie en obstipatie klachten verbeterden bij alle drie de ingrepen maar onderling waren er geen verschillen.

Laparotomische versus perineale benadering

In de Cochrane review van Tou (2008) is één studie gevonden die deze vergelijking heeft onderzocht bij patiënten met een ERP¹⁵. In beide behandelingsgroepen waren 10 patiënten geïnccludeerd. Alleen in de perineale benadering groep was één patiënt met een recidief rectum prolaps. Zes van de 10 patiënten in de perineale groep hadden na de operatie klachten van fecale incontinentie in vergelijking met één patiënt in de laparotomie groep (OR 13.50, 95% CI 1.20-152.21). Postoperatieve complicaties waren niet significant verschillend tussen de twee groepen. In een cohortstudie van Fleming (2012) is gekeken naar de morbiditeit en mortaliteit tot 30 dagen postoperatief bij patiënten die een laparotomie (resectie en conventionele rectopexie; n=569) danwel perineale ingreep (n=706) hebben ondergaan in verband met een rectum prolaps²⁰.

Patiënten in de perineale groep waren ouder en hadden meer comorbiditeit dan de laparotomie groep. Een perineale ingreep was geassocieerd met minder postoperatieve complicaties (ernstige complicaties: OR 0.46, 95% CI 0.31-0.80; P = 0.0038) en klinisch niet significante (*minor*, urineweg en/of wondinfectie) complicaties: OR 0.35, 95% CI 0.20-0.60; P = 0.0002).

Behoud versus klieven van de laterale ligamenten van het rectum bij een laparotomische rectopexie

In de Cochrane review van Tou (2008) zijn twee bruikbare kleine studies gevonden die deze vergelijking (behoud versus klieven) hebben onderzocht bij patiënten met een rectum prolaps¹⁵. Een recidief kwam bij vier van de 21 (19%) patiënten voor in de behoud groep en in nul van de 23 patiënten in de gekliefte groep (OR 15.35, 95% CI 0.73-321.58). Het aantal patiënten dat na de ingreep klachten had van obstipatie was vier van de 21 in de behoudende groep en 10 van de 23 in de gekliefte groep (OR 0.32, 95% CI 0.008-1.23). Er waren geen complicaties in beide groepen.

Resectie versus geen resectie bij laparotomische rectopexie

Ook heeft Tou (2008) naar deze vergelijking gekeken (2 trials, n=48) bij patiënten met een ERP¹⁵. In beide groepen was geen recidief van de prolaps en een klein verschil in postoperatieve complicaties ten faveure van de 'geen resectie' groep (een trial, ernstige complicaties 2/15 vs. 3/15). Hoewel niet significant werd er klein verschil in postoperatieve fecale incontinentie gevonden met 8/24 (33%) incontinentie in de 'resectie' groep vs. 5/24 (21%) in de 'geen resectie' groep. De 'resectie' groep scoorde echter wel significant beter wat betreft obstipatie (2/24, 8% versus 12/24, 50%). Fleming (2012) onderzocht de complicaties tussen de verschillende technieken²⁰. In de laparotomie groep werd een vergelijking gemaakt tussen een resectie en rectopexie die een significante toename van ernstige complicaties in de resectie groep liet zien (OR 2.15, 95% CI 1.10-4.41).

Rectopexie versus geen rectopexie

In een multicenter RCT voor patiënten met een ERP werd het rectum bij beide groepen gemobiliseerd tot aan de levator ani²³. Echter bij een groep werd er een mesh of suture rectopexie (n=136, 45 laparoscopisch, 91 open) uitgevoerd en vergeleken met een groep (n=116, 48 laparoscopisch, 68 open) waarbij het bleef bij mobilisatie. In hoeverre het rectum verder werd gemobiliseerd (ook posterior of 360°) werd ter plekke door de chirurg bepaald. Patiënten met preoperatieve obstipatie, in welke groep dan ook, ondergingen bijkomend een rectosigmoïd resectie. Er werd geen verschil in het aantal complicaties gevonden. Na vijf jaar follow-up was het aantal recidieven in de 'geen rectopexie' groep hoger in vergelijking met de 'rectopexie' groep (8.6% vs. 1.5%, log-rank, p=0.003). In de 'geen rectopexie' werd in bijna 59% van de gevallen het rectosigmoïd geresecteerd, in de 'rectopexie' groep was dit 18.3%.

Delorme versus Delorme met levatorplastiek

In een RCT (2013) is de Delorme procedure (n=41) vergeleken met een Delorme procedure met levatorplastiek (n=41) bij patiënten met een ERP⁹. Patiënten die alleen een Delorme procedure ondergingen hadden één jaar postoperatief vaker een recidief prolaps (14.3% vs 2.4%, p 0.048). Obstipatie en incontinentie scores waren significant meer verbeterd in de Delorme met levatorplastiek groep. Er was onderling geen verschil in complicaties.

Altemeier versus Altemeier met levatorplastiek

Chun (2004) onderzocht deze vergelijking in een cohort met 120 patiënten (52 zonder, 68 met levatorplastiek) voor de behandeling van ERP met een gemiddelde follow-up van 28 maanden¹⁷. Er werden kleine verschillen in morbiditeit gevonden (20.6% zonder, 15.3% met). Recidief percentages verschilden nogal tussen de twee technieken, met 20.6% voor Altemeier versus 7.7% voor Altemeier met levatorplastiek. Incontinentie scores (Wexner) verbeterden het meest in de groep met levatorplastiek (12.9 preoperatief naar 5.8 postoperatief) vergeleken met de conventionele Altemeier groep (11.1 naar 7.7).

Vergelijkende studies behandeling interne rectum prolaps of rectocele (met of zonder enterocele)

Laparotomische versus laparoscopische resectie rectopexie voor interne rectum prolaps

In een cohortonderzoek (2012) is gekeken naar de korte (6 maanden) en lange termijn (76 maanden) gevolgen van (laterale ligament sparende) resectie rectopexie (25 laparoscopisch en 23 laparotomisch) in 48 patiënten met een IRP²². Er waren in totaal acht gevallen (4 in beide groepen, 16.7%) van ernstige morbiditeit. Postoperatieve obstipatie klachten waren significant verbeterd in beide groepen maar er werd geen verschil gevonden tussen open of laparoscopisch.

STARR versus conservatieve behandeling

Lehur (2008) heeft in een multicenter RCT de STARR (n=59) vergeleken met bekkenfysiotherapie (n=60) bij vrouwen met het obstructief defecatie syndroom (ODS) en een rectocele en/of IRP²⁵. Van de vrouwen die voor bekkenfysiotherapie gerandomiseerd waren was na 12 maanden follow-up de helft beschikbaar. Acht (15%) van de vrouwen in de STARR groep en 1 (2%) in de bekkenfysiotherapie groep hadden een adverse event. ODS scores verbeterden in beide groepen significant maar succesvolle behandeling, gedefinieerd als een verbetering in klachten van meer dan 50%, werd significant vaker gezien in de STARR groep ten opzichte van de bekkenfysiotherapie groep (81.5% vs 33.3%, $p < 0.0001$).

Double-stapling (PPH) STARR versus Countour Transtar

In een RCT (2011) ondergingen 50 vrouwen een STARR (met dubbele PPH stapler) en 50 een Countour Transtar (CT) ingreep in verband met een rectocele of IRP gecombineerd met ODS klachten¹⁶. Na een follow-up van 3 jaar had 12% in de STARR en 0% in de CT groep een recidief van de prolaps ($p = 0.035$). Postoperatieve complicaties waren vergelijkbaar (STARR 4% vs. CT 2%). Er waren nauwelijks verschillen in klachten reductie. Echter in de STARR groep werden na 3 jaar klachten beschreven van fecale drang ('fecale urgency') in 34% van de gevallen versus 14% in de CT groep ($p = 0.035$). De kosten van de CT waren hoger met een gemiddelde van 2998 euro versus 2410 euro per patiënt.

Renzi (2011) heeft in een RCT de STARR met 2 PPH staplers (n=31) en de CT (n=32) met elkaar vergeleken bij patiënten met ODS en IRP en/of rectocele²⁶. Na een follow-up van 12 maanden waren er geen verschillen in obstipatie en continentiescores. Na 24 maanden follow-up waren de functionele uitkomsten van de STARR groep wat verslechterd ten opzichte van de CT groep. Postoperatieve complicaties waren gelijk. In een cohortonderzoek van Isbert (2010) ondergingen vrouwen een double-stapling (met PPH) STARR of CT vanwege ODS in combinatie met een rectocele met of zonder een IRP of enterocele²¹. De technieken werden 12 maanden postoperatief met elkaar vergeleken. Postoperatieve complicaties waren niet verschillend (beide ongeveer 7.3%). Beide ingrepen lieten een flinke verbetering zien in obstipatie scores. De Wexner obstipatie (0 tot 30) score ging na de STARR van 15.5 naar 8.25 en na de CT van 15.7 naar 8.0. Er werden dus nauwelijks verschillen tussen de groepen gemeten.

Beschrijvende studies behandeling externe rectum prolaps

Laparoscopische rectopexie

In een systematisch review van Samaranayake (2010) is gekeken naar de uitkomsten van patiënten die een (laparoscopische) ventrale rectopexie (VR) met matplaatsing hebben ondergaan vanwege een ERP waarbij onderscheid werd gemaakt in studies met en zonder posterieure mobilisatie²⁷. Verdeeld over 12 studies werden er 505 (29 laparoscopisch) patiënten geïnccludeerd met VR met posterieure mobilisatie (7 studies, VRMPM) en 223 (217 laparoscopisch) patiënten zonder posterieure mobilisatie (5 studies, VRZPM). VRZPM noteerde in alle studies verbetering van de obstipatie (pre-operatief min post-operatief percentage) met getallen variërend tussen 15.4 tot 83.3% en een gemiddelde van 40.3% klachten reductie. VRMPM rapporteerde -13.6 tot 28.8% klachten reductie betreffende obstipatie met een gemiddelde waarde van 6.1% (5 van de 7 studies). Obstipatie *de novo* wordt in 5.5 tot 10.5% voor VRZPM en in 2.7 tot 58.3% voor VRMPM vermeld. Voor de reductie van fecale incontinentie klachten worden soortgelijke getallen gevonden met een algehele (met en zonder posterieure mobilisatie) verbetering tussen 13.6 – 77.3% met een gemiddelde reductie van 44.9%. Recidief

percentage varieert tussen 0 en 15.4% voor VRZPM (gemiddeld 5.5%, 4 studies) en 0 en 9.1% voor de VRMPM (gemiddeld 3.6%, 6 studies). Complicaties worden in 4.8 - 38.5% bij de VRZPM (gemiddeld 19.2%) en in 1.4 – 46.9% bij de VRMPM (gemiddeld 19.4%, 6 studies) van de gevallen beschreven. Zie tabel 2.

Een andere systematische review (Cadeddu 2012) beschrijft uitkomsten van patiënten met een laparoscopische rectopexie met matplaatsing verdeeld in drie groepen: posterieure matplaatsing, ventrale matplaatsing en de Orr-Loygue techniek (uitleg zie overwegingen)¹³. De 3 studies (n= 80) die posterieure matplaatsing beschrijven rapporteren 10 tot 92% (gemiddeld 59%) verbetering van continentie, 0% verbetering van obstipatie en 0 tot 3.4% (gemiddeld 1.7%, 2 studies) aan recidieven na een gemiddelde follow-up van 24 maanden. In twee van de drie studies werd een verslechtering van de obstipatie gevonden: in 1 studie 38% en 1 studie 21% verslechtering. De 5 studies (n=216) betreffende Orr-Loygue noteren 27-96% (gemiddeld 65%, 4 studies) verbetering van continentie, 19-54% (gemiddeld 33%, 4 studies) verbetering van obstipatie klachten en 0-7.1% recidief percentage (gemiddeld 4.2%) met een gemiddelde follow-up van 46 maanden. De obstipatie verslechterde in drie van de vijf studies met respectievelijk 27, 54 en 58%. Cadeddu (2012) includeerde 5 studies (n=311) inzake LVR met tussen de 90-91% (3 studies) aan incontinentie verbetering (gemiddeld 90%), 78-84% aan obstipatie verbetering (gemiddeld 81%) en 0-4.7% aan recidieven (gemiddeld 1.8%). De gemiddelde follow-up was 43 maanden (4 studies). De functionele verbetering is in dit review de verhouding tussen pre en postoperatieve waarden, en niet het verschil zoals in het vorige review waardoor de getallen van Cadeddu et al hoger uitvallen. Hetzelfde geldt voor de laparoscopische resectie rectopexie hieronderstaand. Zie tabel 3.

Tabel 2: Laparoscopische ventrale rectopexie²⁷

Study	N	Operation technique group*	Laparoscopic VR/ n (%)	Follow-up months (range)	Outcomes								Quality score max = 8
					Constipation assessment tool and scores			Incontinence assessment tool and scores			Complications/ n (%)	Recurrence/ n (%)	
					Tool	Pre	Post	Tool	Pre	Post			
D'Hoore <i>et al.</i> [10]	42	A	40 (95.2)	Median = 61 (29-98)	Rome II [40]	–	–	CCIS	Mean (SD): 11.2 (7.3)	Mean (SD): 3.6 (6.1)	2 (4.8)	2 (5)	7
Cristaldi <i>et al.</i> [11]	58	A	57 (98.3)	Median = 3	Wexner [41]	Median = 9	Median = 4	FISI	Median = 40	Median = 4	11 (19.0)	1 (1.72)†	6
Collinson <i>et al.</i> [8]	30	A	30 (100)	Median = 3	Wexner [41]	Median = 13	Median = 4	FISI	Median = 33	Median = 8	4 (13)		6
Slawik <i>et al.</i> [15]	80	A	79 (98.8)	Median = 6	Hiller 2002 [42]	–	–	CCIS	Median (range): 11 (2–17)	Median (range): 1 (0–19)	17 (21)	0 (0)‡	6
Verasdonk <i>et al.</i> [16]	13	A	11 (84.6)	Median = 7	Not stated	–	–	Parks	Median: Grade 4	Median: Grade 3	5 (38.5)	2 (15.4)	4
Portier <i>et al.</i> [17]	73	B	26 (35.6)	Mean = 27.5 (6–84)	Self reported	–	–	CCIS	Mean = 12.8	Mean = 3.3	1 (1.4)	3 (4.1)	6
Marchal <i>et al.</i> [18]	49	B	3 (6.1)	Mean = 106 (14–276)	Self reported	–	–	Self reported	22 (44.9%)	6 (12.2%)	23 (46.9)	2 (4.1)	4
Douard <i>et al.</i> [19]	31	B	0 (0)	Mean = 28 (12–57)	Self reported	–	–	CCIS	Mean (SD): 11.7 (7.8)	Mean (SD): 3.2 (4.2)	10 (32)	0 (0)	3
Marceau <i>et al.</i> [20]	22	B	0 (0)	Mean = 25	Self reported	–	–	CCIS	4.9 (n =28)	2 (n = 22)	5 (22.7)	2 (9.1)	3
Detry <i>et al.</i> [21]	20	B	0 (0)	Mean = 24 (2–48)		No results stated	–	Not stated			2 (10)	0 (0)	3
Loygue <i>et al.</i> [9]	257	B	0 (0)	<5 years in 53% >5 years in 47%		No results stated	–	Not stated			9 (3.5)	13 (5.6)	2
Sielezniew <i>et al.</i> [22]	53	B	0 (0)	Mean = 15.5 (1–144)	Self reported	–	–		No results stated				4

*Group A, studies that used ventral rectopexy without posterior rectal mobilization; Group B, studies that used ventral rectopexy with posterior rectal mobilization.

†Nineteen months median (3-41 range) follow-up for recurrence assessment.

‡Fifty-four months median (30-96 range) follow-up for recurrence assessment.

VR, ventral rectopexy; CCIS, Cleveland Clinic Incontinence Score [43]; FISI, Faecal Incontinence Severity Index [44].

Tabel 3: Laparoscopische (ventale, posterieure en Orr-Loygue) rectopexie¹³

Authors	Year	Procedure	N Pts	Continence improvement %	Constipation improvement %	Recurrence N (%)	Follow-up (months)
Himpens <i>et al.</i> [44]	1999	Post mesh	37	92	0 (38 worsening)	0	26
Zittel <i>et al.</i> [45]	2000	Post mesh	29	76	0	1 (3, 4)	22
Benoist <i>et al.</i> [41]	2001	Post mesh	14	10	0 (21 worsening)	NS	47
Lechaux <i>et al.</i> [46]	2005	Orr-Loygue	35	27 (4 worsening)	19 (27 worsening)	2 (5, 7)	36 (7-77**)
Douard <i>et al.</i> [47]	2003	Orr-Loygue	31	96	26 (54 worsening)	0	28 (13-57**)
D'Hoore <i>et al.</i> [48]	2004	Ventral mesh	42	90	84	2 (4, 7)	61 (29-98**)
Slawik <i>et al.</i> [49]	2007	Ventral mesh	80	91	80	0	54
D'Hoore and Penninckx [50]	2006	Ventral mesh	109	NS	NS	3 (2, 75)	NS
Marchal <i>et al.</i> [51]	2005	Orr-Loygue	49	73	33 (58 worsening)	2 (4, 08)	106 (14-276**)
Portier <i>et al.</i> [52]	2006	Orr-Loygue	73	62, 5†	54†	3 (4, 1)	27, 5 (6-84**)
Vanden Esschert <i>et al.</i> [53]	2008	Ventral mesh	17	*	*	0	38
Cristaldi <i>et al.</i> [54]	2007	Ventral mesh	63	90	78	1 (1, 6)	18 (3-36**)
Marceau <i>et al.</i> [55]	2005	Orr-Loygue	28	*	*	2 (7, 1)	34 (5-82**)

N Pts number of patients, NS not stated

* Grouped data; ** range; † patients cured

Laparoscopische resectie rectopexie

De uitkomsten van patiënten geopereerd met een laparoscopische resectie rectopexie voor ERP worden beschreven in een systematisch review van Cadeddu (2012)¹³. Zes studies met 244 patiënten werden geïncludeerd. Incontinentie verbetering werd gezien in 38 tot 100% (gemiddeld 71%, 4 studies) en obstipatie verbetering in 8-76% (gemiddeld 44.8, 4 studies). Een negatief effect van de operatie werd in 8% voor zowel incontinentie als obstipatie vermeld in 1 studie. Postoperatieve morbiditeit kwam in 5 tot 30.4% voor met een gemiddelde van 15.4% (totaal 4 lekkages). Met een gemiddelde follow-up van 28.5 maanden werd een recidief percentage van 0% beschreven (5 studies). Zie tabel 4.

Tabel 4: laparoscopische resectie rectopexie voor ERP¹³

Authors	Year	N Pts	Procedure	Continence improvement %	Constipation improvement %	Recurrence N (%)	Follow-up
Stevenson et al. [61]	1998	34	SR + Res	70	64	0	18
Xynos et al. [62]	1999	10	SR + Res	100	NS	NS	12
Bruch et al. [38]	1999	40	SR + Res	64	76	0	24
Demirbas et al. [12]	2005	23	SR + Res	85	30	0	36
Lechaux et al. [46]	2005	13	SR + Res	38 (8 worsening)	8 (8 worsening)	0	36
Rose et al. [63]	2002	124	SR + Res	NS	NS	NS	NS

SR suture rectopexy, Res resection, N Pts number of patients, NS not stated

Delorme procedure

Tsunoda (2003) heeft in een cohortonderzoek gekeken naar de uitkomsten van de Delorme procedure bij 31 patienten met een ERP³⁰. Na gemiddeld 14 maanden was bij vier patiënten een recidief prolaps (12.9%). Ook was bij vier patiënten een postoperatieve complicatie. Incontinentie scores waren significant verbeterd met Wexner incontinentie scores van 11.5 (1-20) pre- en 6.0 postoperatief.

Schiedeck (2005) et al. beschrijven meerdere studies betreffende de Delorme procedure in een review. De acht geïncludeerde studies (totaal n = 323) laten een recidief percentage tussen 6.8 en 22% (gemiddeld 14.4%) zien²⁸. Het morbiditeit percentage was 0 - 62.5% (gem. 22.4%) met een mortaliteit van tussen 0 en 2.5% (gemiddeld 0.5%). Functionele uitkomsten werden niet gegeven. Zie tabel 5.

Tabel 5: Delorme procedure²⁸

Author	Year	Number	Recurrence (%)	Morbidity (%)	Mortality (%)
Uhlig and Sullivan [10]	1979	44	6.8	34	0
Lechaux et al. [11]	1995	85	13.5	14	1.2
Senapati et al. [12]	1994	32	12.5	6.3	0
Oliver et al. [13]	1994	40	22	62.5	2.5
Kling et al. [14]	1996	6	16.7	0	0
Pescatori et al. [15]	1998	33	21	45	0
Watkins et al. [16]	2003	52	10.0	4	0
Tsunoda et al. [17]	2003	31	13.0	13.0	0

Alteimeier procedure

Een review van Zbar (2002) includeerde 18 studies met een totaal van 972 patiënten³¹. Recidief rectum prolaps vond tussen 0 en 58% (gemiddeld 14.3%, 17 studies) plaats. De fecale incontinentie was tussen 5 - 100 % preoperatief (gemiddeld 59.3%, 8 studies) en tussen 0 en 56 % postoperatief (gemiddeld 29.2%, zelfde 8 studies). Zie tabel 6.

Tabel 6: Alteimeier procedure³¹

Reference	Year	Patients		Follow-up, months ^a	Resection length, cm ^a	Recurrence, %	Stricture, %	Leak, %	Mortality, n	Fecal incontinence, %		Hospital stay, days
		n	Age ^a							Preop	Postop	
Theuerkauf et al. [54]	1970	13	54	NG	NG	38	NG	NG	0	NG	23	NG
Alteimeier et al. [55]	1971	106	60–89 ^b	NG	NG	3	2	4	0	NG	NG	NG
Porter [24]	1971	110	NG	12–60	NG	58	NG	NG	1	66	56	NG
Friedman et al. [56]	1983	27	61	NG	NG	50	NG	NG	0	NG	NG	8.8 (6–10)
Gopal et al. [57]	1984	18	76 (35–96)	12	NG	16	NG	NG	1	NG	NG	NG
Prasad et al. [58]	1986	25	71	36	NG	0	NG	NG	0	NG	Improved in 88%	NG
Vasilevsky, Goldberg [59]	1987	66	NG	31	NG	0	NG	NG	0	41	Improved in 78%	7
Ramanujam, Venkatesh [60]	1987	41	70–80 ^c	20 (6–48)	NG	6	NG	NG	0	100	22	NG
Finlay, Atchison [61]	1991	17	60–92	24 (9–40)	14 (3–36)	10	NG	NG	1	NG	47	NG
Williams [62]	1991	20	82	26	NG	NG	NG	NG	0	NG	NG	NG
Williams et al. [63]	1992	114	78 (21–100)	12 (3–90)	NG	10	1	NG	0	58.8	50.7 ^e	NG
Thorne, Polglase [64]	1992	16	81 (72–96)	16 (3–37)	NG	12	NG	NG	0	62.5	18.8	NG
Johanssen et al. [65]	1993	20	82 (68–101)	26 (6–36)	23 (7–40)	0	NG	NG	1	70	45	6.4 (4–8)
Agachan et al. [66]	1997	32	NG	26.5 (6–72)	26.4 (6–40)	12.5	3	2	1	NG	NG	NG
Agachan et al. [67] ^d	1997	21	NG	29.6 (6–72)	25.2 (9–71)	4	1	NG	0	NG	NG	NG
Kim et al. [68]	1999	183	NG	NG	NG	16	NG	NG	0	NG	NG	5
Kimmins et al. [69]	2001	63	79 (39–96)	21 (6–88)	11.6 (5–22)	6.3	2	2	0	71	30	62% DC
Current series	2002	80	69 (16–91)	6–132	NG	3.8	NG	1.9	0	5	0	NG

^a Values are mean (range)

^b 75% of treated patients

^c 63.5% of treated patients

^d Perineal rectosigmoidectomy plus levatorplasty

^e Compares continence improvement in perineal rectosigmoidectomy cases, 11 of whom also had levatorplasty
NG, not given; Preop, preoperative; Postop, postoperative; DC, day case

Beschrijvende studies behandeling interne rectum prolaps of rectocele (met of zonder enterocele)

Laparoscopische ventrale rectopexie voor interne rectum prolaps

Collinson et al. (2010) beschrijven 75 patiënten die een LVR ondergingen vanwege een symptomatische IRP met een follow-up van 12 maanden¹⁸. Er werd 86% verbetering van de obstipatie klachten gevonden met een verschil in Wexner obstipatie score van 12 preoperatief vs. 5 postoperatief (mediaan). Van de patiënten die met incontinentie kampten, kon in 85% van de gevallen verbetering van de continentie met een significant verschil in FISI score (mediaan preoperatief 28 vs 8 postoperatief) worden genoteerd. De algehele morbiditeit was 4% en er werd een recidief percentage van 5% beschreven. In een soortgelijk cohort rapporteert Sileri (2012) (n=65) de uitkomsten van patiënten die een LVR kregen voor een symptomatische IRP met een gemiddelde follow-up van 12 maanden²⁹. De gemiddelde FISI incontinentie score verbeterde van 9 preoperatief naar 3 postoperatief na 6 maanden. De gemiddelde Wexner obstipatie score daalde van 16 naar 7. Complicatie percentage was 23.5%. Een (1.5%) prolaps werd niet opgeheven door de LVR en er trad een (1.5%) recidief op.

TRREMS (transanal repair of rectocele and rectal mucosectomy with a single circular stapler)

Leal (2010) heeft in een cohortstudie bestaande uit 35 vrouwen met ODS klachten ten gevolge van een rectocele en mucosa prolaps naar de uitkomst van een TRREMS procedure gekeken²⁴. Na gemiddeld 18 maanden waren obstipatie (Wexner obstipatie score 15.2 vs. 4.5) en continentie scores (Wexner incontinentie score 2.8 vs. 1.7) significant verbeterd ten opzicht van de preoperatieve metingen. Er waren vijf patiënten (14%) met een postoperatieve complicatie waarvan drie ernstig (8.6%) en waarvan 2 een re-interventie behoeften.

Grade tabel

Uitgangsvraag 1: Wat is de optimale chirurgische correctie van een externe rectale prolaps?

Beoordeling van studiekwaliteit							
Aantal studies	Studie ontwerp	Studie beperkingen	Inconsistentie	Indirectheid	Imprecisie	Andere opmerkingen	Kwaliteit
Laparotomisch versus laparoscopische rectopexie							
3	RCT ^a	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Geen ernstige imprecisie	Geen	HOOG
Laparotomische versus perineale benadering							
2	RCT/ observationale studie ^b	Ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Geen ernstige imprecisie	Geen	MATIG
Behoud versus klieven van de laterale ligamenten van het rectum bij een laparotomische rectopexie							
1	RCT ^c	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Ernstige imprecisie	Geen	MATIG
Resectie versus geen resectie bij laparotomische rectopexie							
2	RCT/ observationale studie ^d	Ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Geen ernstige imprecisie	Geen	MATIG
Rectopexie versus geen rectopexie							
1	RCT ^e	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Ernstige imprecisie	Geen	MATIG
Delorme versus Delorme met levatorplastiek							
1	RCT ^f	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Ernstige imprecisie	Geen	MATIG
Alteimeier versus Alteimeier met levatorplastiek							
1	Observationale studie ^g	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Ernstige imprecisie	Geen	ZEER LAAG
Laparoscopische rectopexie							
2	Observationale studie ^h	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Geen ernstige imprecisie	Groot effect	MATIG
Laparoscopische resectie rectopexie							
1	Observationale studie ⁱ	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Ernstige imprecisie	Geen	ZEER LAAG
Delorme procedure							
2	Observationale studie ^j	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Geen ernstige imprecisie	Geen	LAAG
Alteimeier procedure							
2	Observationale studie ^k	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Geen ernstige imprecisie	Geen	LAAG

^a Twee meta-analyses (Cadeddu 2012¹³, Tou 2008¹⁵) en één patient-controle onderzoek (De Hoog 2009¹⁹), aantal recidieven >300; ^b Eén meta-analyse (Tou 2008¹⁵) en één cohort onderzoek (Fleming 2012²⁰). Meta-analyse heeft 20 patiënten geïncludeerd, Fleming (2012) totaal 1275; ^c Eén meta-analyse (Tou 2008¹⁵), er is één studie geselecteerd met een totale N van 44.; ^d Eén meta-analyse (Tou 2008¹⁵) en één cohort onderzoek (Fleming 2012²⁰). Tou et al. heeft 48 patiënten geïncludeerd en Fleming et al. in totaal 569; ^e Eén RCT (Karas 2011²³), totale N = 252; ^f Eén RCT (Youssef 201³⁹), totale N = 82; ^g Eén cohort onderzoek (Chun 2004¹⁷), totale N = 120; ^h Twee systematische reviews (Cadeddu 2012¹³, Samaranyaka 2010²⁷) waarin enkel cohort onderzoeken zijn geselecteerd. Gezien grote effect van uitkomsten geügrade.; ⁱ Eén systematische review (Cadeddu 2012¹³) waarin enkel cohort onderzoeken zijn geselecteerd. Totale N = 244; ^j Eén systematische review (Schiedeck 2005²⁸) waarin enkel cohort onderzoeken zijn geselecteerd en één cohort onderzoek (Tsunoda 2003³⁰). Totale N van deze studies = 354; ^k Twee systematische review (Schiedeck 2005²⁸, Zbar 2002³¹) waarin enkel cohort onderzoeken zijn geselecteerd. Totale N van deze studies = 972

Uitgangsvraag 2: Wat is de optimale chirurgische correctie van een interne rectale prolaps?

Beoordeling van studiekwaliteit							
Aantal studies	Studie ontwerp	Studie beperkingen	Inconsistentie	Indirectheid	Imprecisie	Andere opmerkingen	Kwaliteit
Laparotomische versus laparoscopische resectie rectopexie							
1	observationale studie ^a	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Ernstige imprecisie	Geen	ZEER LAAG
STARR versus conservatieve behandeling							
1	RCT ^b	Ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Ernstige imprecisie	Geen	MATIG
Double-stapling (PPH) STARR versus Countour Transtar							
3	RCT/observationale studie ^c	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Geen ernstige imprecisie	Geen	HOOG
TRREMS							
1	observationale studie ^d	Geen ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Ernstige imprecisie	Geen	ZEER LAAG
Laparoscopische ventrale rectopexie voor IRP							
2	observationale studies ^e	Ernstige beperkingen	Geen ernstige inconsistentie	Geen ernstige indirectheid	Ernstige imprecisie	Geen	ZEER LAAG

^a Eén cohort onderzoek (Johnson 2012²²), totale N = 48; ^b Eén RCT (Lehur 2008²⁵), totale N = 119; ^c Twee RCT's (Boccasanta 2011¹⁶, Renzi 2011²⁶) en één cohort onderzoek (Isbert 2010²¹), totale N = 313; ^d Eén cohort onderzoek (Leal 2010²⁴), totale N = 35. Tevens geen controle groep; ^e Twee cohort onderzoeken (Collinson 2010¹⁸, Sileri 2012²⁹), totale N = 140. Tevens geen controle groep.

Conclusies uit de literatuur

Uitgangsvraag 1: Wat is de optimale chirurgische correctie van een externe rectale prolaps?

Kwaliteit van bewijs: HOOG	<p><i>Laparotomisch versus laparoscopische rectopexie</i></p> <p>Over het algemeen zijn er geen verschillen in recidieven of verbetering van functionele klachten tussen de twee benaderingen in de behandeling van ERP. Hierbij genereert de laparoscopische benadering minder complicaties en is deze techniek goedkoper.</p> <p><i>Cadeddu 2012¹³, De Hoog 2009¹⁹, Tou 2008¹⁵</i></p>
Kwaliteit van bewijs: MATIG	<p><i>Laparotomische versus perineale benadering</i></p> <p>Perineale ingrepen zijn geassocieerd met minder postoperatieve complicaties bij de behandeling van ERP. Er zijn aanwijzingen dat de perineale benadering meer recidieven en meer postoperatieve fecale incontinentie oplevert in vergelijking met de laparotomische benadering.</p> <p><i>Fleming 2012²⁰, Tou 2008¹⁵</i></p>
Kwaliteit van bewijs: MATIG	<p><i>Behoud versus klieven van de laterale ligamenten van het rectum bij een laparotomische rectopexie</i></p> <p>Bij de behandeling van ERP lijkt het klieven van de laterale ligamenten van het rectum tijdens de mobilisatie bij een laparotomische rectopexie geassocieerd te zijn met het ontwikkelen van minder recidieven maar meer postoperatieve obstipatie in vergelijking met het behouden van de laterale ligamenten.</p> <p><i>Tou 2008¹⁵</i></p>
Kwaliteit van bewijs: MATIG	<p><i>Resectie versus geen resectie bij laparotomische rectopexie</i></p> <p>Er lijken aanwijzingen te zijn dat laparotomische resectie rectopexie beter is voor het reduceren van postoperatieve obstipatie bij de behandeling van ERP. Aan de andere kant lijkt laparotomische resectie rectopexie ook geassocieerd met een hoger (ernstig) complicatie percentage en verhoogde postoperatieve fecale incontinentie wanneer afgezet tegen een laparotomische rectopexie zonder rectosigmoid resectie.</p> <p><i>Fleming 2012²⁰, Tou 2008¹⁵</i></p>
Kwaliteit van bewijs: MATIG	<p><i>Rectopexie versus geen rectopexie</i></p> <p>Het toevoegen van een rectopexie aan de mobilisatie van het rectum bij de behandeling van patiënten met een ERP verlaagt de kans op een recidief.</p> <p><i>Karas 2011²³ respectively.</i></p>

Kwaliteit van bewijs: MATIG	<p><i>Delorme versus Delorme met levatorplastiek</i></p> <p>Er zijn aanwijzingen dat het toevoegen van een levatorplastiek aan de klassieke Delorme procedure voor de behandeling van ERP leidt tot een lager recidief percentage en grotere verbetering in functionele klachten dan een Delorme procedure alleen.</p> <p><i>Youssef 2013⁹</i></p>
Kwaliteit van bewijs: ZEER LAAG	<p><i>Altemeier versus Altemeier met levatorplastiek</i></p> <p>De procedure van Altemeier gecombineerd met een levatorplastiek genereert betere functionele uitkomsten, minder complicaties en minder recidieven dan een conventionele Altemeier.</p> <p><i>Chun 2004¹⁷</i></p>
Kwaliteit van bewijs: MATIG	<p><i>Laparoscopische rectopexie</i></p> <p>De LVR lijkt superieur te zijn aan de ventrale rectopexie met posterieure mobilisatie, de laparoscopische Orr-Loygue rectopexie en de laparoscopische posterieure benadering wat betreft functionele uitkomsten.</p> <p><i>Caddedu 2012¹³, Samaranayaka 2010²⁷</i></p>
Kwaliteit van bewijs: ZEER LAAG	<p><i>Laparoscopische resectie rectopexie</i></p> <p>Voor behandeling van ERP laat de LRR goede functionele resultaten, een acceptabele complicatie en zeer lage recidief percentages zien.</p> <p><i>Caddedu 2012¹³</i></p>
Kwaliteit van bewijs: LAAG	<p><i>Delorme en Altemeier procedure</i></p> <p>De Delorme en Altemeier zijn beide perineale technieken welke een goede functionele verbetering met een acceptabel complicatie percentage kunnen overleggen. Echter in vergelijking met de abdominale technieken komen beide perineale procedures slechter uit wat betreft recidieven en functionaliteit. Vanwege het voordeel dat de patiënt niet onder algehele anesthesie gebracht hoeft te worden bij de perineale benadering kunnen deze technieken een rol spelen bij (oudere) patiënten met veel comorbiditeiten.</p> <p><i>Schiedeck 2005²⁸, Tsunoda 2003³⁰, Zbar 2002³¹</i></p>

Uitgangsvraag 2: Wat is de optimale chirurgische correctie van een interne rectale prolaps?

Kwaliteit van bewijs: ZEER LAAG	<i>Laparotomische versus laparoscopische resectie rectopexie</i> Voor de behandeling van IRP lijkt er geen verschil te zijn tussen laparotomische en laparoscopische resectie rectopexie in termen van morbiditeit en postoperatieve obstipatie. <i>Johnson 2012</i> ²²
Kwaliteit van bewijs: ZEER LAAG	<i>Laparotomische versus laparoscopische resectie rectopexie</i> Voor de behandeling van IRP lijkt er geen verschil te zijn tussen laparotomische en laparoscopische resectie rectopexie in termen van morbiditeit en postoperatieve obstipatie. <i>Johnson 2012</i> ²²
Kwaliteit van bewijs: MATIG	<i>STARR versus conservatieve behandeling</i> Zowel STARR als bekkenfysiotherapie verbeteren ODS klachten bij patiënten met een rectocele en/of IRP. STARR genereert meer verbetering in de ODS klachten dan bekkenfysiotherapie maar is wel geassocieerd met een hogere morbiditeit. <i>Lehur 2008</i> ²⁵
Kwaliteit van bewijs: HOOG	<i>Double-stapling (PPH) STARR versus Countour Transtar</i> Het lijkt dat de Countour Transtar stapler voor het behandelen van patiënten met ODS klachten in combinatie met een rectocele en/of IRP op lange termijn een betere uitkomst wat betreft recidieven en functionele klachten heeft in vergelijking met de conventionele Double-stapling (PPH) STARR stapler. <i>Boccasanta 2011</i> ¹⁶ , <i>Isbert 2010</i> ²¹ , <i>Renzi 2011</i> ²⁶
Kwaliteit van bewijs: ZEER LAAG	<i>TRREMS</i> Er lijkt een aanwijzing te zijn dat TRREMS een goede uitkomst heeft op de functionele klachten bij patiënten met ODS klachten ten gevolge van een rectocele gecombineerd met een mucosa prolaps. <i>Leal 2010</i> ²⁴
Kwaliteit van bewijs: ZEER LAAG	<i>Laparoscopische ventrale rectopexie voor IRP</i> De LVR als behandeling voor de IRP geeft goede functionele resultaten en acceptabele complicatie en recidief percentages. <i>Collinson 2010</i> ¹⁸ , <i>Sileri 2012</i> ²⁹

Overwegingen

Uitgangsvraag 1: Wat is de optimale chirurgische correctie van een externe rectale prolaps?

Vergelijkende studies behandeling externe rectum prolaps

Laparotomische versus laparoscopische benadering

Een grote meta-analyse met 467 patiënten en een Cochrane review tonen aan dat er geen verschil in recidieven of verbetering van functionele klachten tussen de laparotomische en laparoscopische rectopexie is^{13,15}. De studie van de Hoog (2009) bevestigt dit op functioneel gebied maar niet wat betreft het aantal recidieven (20 vs. 2%)¹⁹. Een verklaring hiervoor kan zijn dat er binnen de laparoscopie groep verschillende technieken en materialen zijn gebruikt. Zo werd bijvoorbeeld een deel geopereerd volgens de procedure van Wells (Wells 1959³²) en een deel volgens de techniek van D'Hoore (D'hoore 2006¹¹). De learning curve zou in deze studie ook een rol kunnen hebben gespeeld.

Aangezien de studie van de Hoog hierbij ook een zeer klein aantal patiënten behandeld met de laparoscopische benadering (n=15) beschrijft, in tegenstelling tot beide andere studies, is uiteindelijk is voor de bovenstaande conclusie gekozen. Omdat er nauwelijks verschillen bestaan in recidieven en functionele uitkomsten en omdat de laparoscopische benadering minder complicaties genereert geniet deze techniek de voorkeur bij ERP. Een bijkomend voordeel zijn de lagere kosten en het verschil in cosmetisch effect voor de patiënt.

Laparotomische versus perineale benadering

Aangezien perineale ingrepen minder belastend zijn voor de patiënt en daarom worden voorbehouden aan patiënten met meer comorbiditeiten ligt het feit dat perineale ingrepen met minder postoperatieve complicaties zijn geassocieerd voor de hand. Zeker bij een resectie rectopexie waarbij een anastomose wordt aangelegd zijn complicaties te verwachten. De perineale benadering is echter ook geassocieerd met een hoger recidief en postoperatieve fecale incontinentie percentage. Deze conclusie is echter getrokken

uit de enige, kleine (n=20) studie die er is¹⁵. Bij het interpreteren van deze conclusie moet hier dus ook rekening mee worden gehouden. Recent onderzoek toont echter aan dat abdominale technieken tegenwoordig ook veilig zijn voor ouderen met een hoge comorbiditeit. Zodoende wordt bovenstaande stelling langzaamaan meer verlaten³⁶. Per patiënt zal moeten worden afgewogen of algehele anesthesie een optie is, maar (oudere) patiënten met veel comorbiditeiten hoeven niet per se perineaal geopereerd te worden. In vergelijking met laparotomische benadering geniet de perineale benadering echter wel de voorkeur bij (oudere) patiënten met veel comorbiditeiten. Over het algemeen kan gesteld worden dat de abdominale benadering betere uitkomsten wat betreft functionaliteit en recidieven heeft (zie verder richtlijn). Deze benadering krijgt dan ook de voorkeur bij jongere en gezonde patiënten. Als een intra-abdominale ingreep verantwoord is, krijgt deze dus de voorkeur.

Behoud versus klieven van de laterale ligamenten van het rectum bij een laparotomische rectopexie

Een van de standaard stappen tijdens een rectopexie is de mobilisatie van het rectum. Er zijn in het verleden veel verschillende varianten van deze mobilisatie beschreven. Zo kan er alleen ventraal, alleen dorsaal, posterolateraal of 360 graden rondom gemobiliseerd worden. Bij veel van deze technieken worden de laterale ligamenten gekliefd. Het mag duidelijk zijn dat aan de uitkomsten van de Cochrane review betreffende deze stelling zowel voor- als nadelen zitten¹⁵. De werkgroep heeft echter in de aanbeveling gekozen voor het behouden van de laterale ligamenten om de volgende redenen. Ten eerste is het klieven een onomkeerbaar proces. De verhoogde postoperatieve obstipatie wordt geweten aan de autonome rectale zenuwen die worden doorgenomen met het klieven van de laterale ligamenten. Dit kan niet meer hersteld worden. Een recidief is weliswaar erg vervelend maar kan vaak wel met een nieuwe ingreep verholpen worden. Ten tweede is veel gebeurd sinds de artikelen, waar de Cochrane review aan refereert, gepubliceerd zijn. Tegenwoordig zijn nagenoeg alle ingrepen aan de ERP in de Westerse wereld laparoscopisch en worden gelijke recidief percentages vermeld tussen technieken met en zonder posterolaterale mobilisatie. Het probleem van postoperatieve

obstipatie na het klieven van de laterale ligamenten blijft echter. Om deze redenen denkt de werkgroep dat het behouden van de laterale ligamenten belangrijk is. Overigens moet ook bij dit punt rekening worden gehouden met het geringe bewijs; hoewel het drie goede vergelijkende studies betrof waren de aantallen klein.

Resectie versus geen resectie bij laparotomische rectopexie

Het bewijs voor deze onderzoeksvraag bestaat uit twee kleine trials (totaal n=48) waarvan er maar een (n=30) complicaties vermeldt¹⁵. Hierbij vergelijkt een trial resectie rectopexie met mesh rectopexie en de andere trial resectie rectopexie met suture rectopexie. Zodoende zijn het dus twee trials die niet precies hetzelfde vergelijken. In combinatie met de lage patiënt getallen kan de conclusie worden getrokken dat het bewijs mager is. Desalniettemin kan wel een voorzichtige en niet onlogische afleiding worden gemaakt. Het feit dat resectie rectopexie beter is voor het reduceren van postoperatieve obstipatie is voor te stellen. Met het reseceren van het rectosigmoid wordt de knik in het distale colon opgeheven. Sommige chirurgen beschouwen dit stuk darm als een deel die zijn functie door de verzakking verloren heeft en dus als overtollig ('redundant') te beschouwen is¹². Het verwijderen hiervan zou kunnen leiden tot minder postoperatieve obstipatie, zoals deze twee trials doen vermoeden. Wanneer preoperatief de obstipatie op de voorgrond staat kan men een resectie rectopexie overwegen. Ondanks dit voordeel lijken er ook wat serieuze nadelen aan de resectie rectopexie te kleven. Zowel in de Cochrane review van Tou als in de studie van Fleming (N = 1275) kwamen er meer postoperatieve complicaties voor in de resectie groep^{15,20}. Dit is voor te stellen aangezien er met de resectie van het rectosigmoid een anastomose wordt aangelegd met alle risico's van dien. Dit is een belangrijk punt in de overweging een patiënt een resectie aan te bieden. Bij een (oudere) patiënt met veel comorbiditeiten lijkt een resectie niet aangewezen. Bovendien moet een patiënt langer herstellen van een resectie dan wanneer deze niet wordt toegepast. De opnameduur zou langer zijn en daarmee de kosten hoger. Dit zijn allemaal overwegingen die er toe kunnen leiden niet voor een resectie te kiezen. Hiernaast zijn er aanwijzingen dat het postoperatieve fecale incontinentie percentage hoger is in de resectie groep¹⁵. Dit is echter niet significant en

zou dus in grotere trials verder uitgezocht moeten worden. Dit zou in de huidige praktijk echter eerder een vergelijkende studie van LVR vs. LRR zijn.

Rectopexie versus geen rectopexie

Uit de enige geïncludeerde studie die deze vraag onderzoekt blijkt het bewijs duidelijk dat het toevoegen van een rectopexie, open of laparoscopisch, de kans op een recidief (1.5 vs. 8.6%) vermindert²³. Deze uitkomst is begrijpelijk. Met een rectopexie bevestigt de operateur het rectum met het promotorium en wordt zodoende de verzakking tegengegaan. De rectopexie is een hoeksteen in de behandeling van de ERP. Het wekt dan ook geen verbazing dat het uitvoeren van de rectopexie naast de gebruikelijke mobilisatie van het rectum leidt tot een lager recidief percentage. Hierbij moet wel vermeld worden dat in de studie bij de patiënten met preoperatieve obstipatie klachten een bijkomende rectosigmoid resectie werd uitgevoerd. Er is echter niet bekend (zie ook stelling hierboven) dat er een verschil bestaat in voorkomen van recidieven tussen resectie en geen resectie, dus vermoedelijk kan dit feit genegeerd worden. Wat echter wel voor een verstoring van het resultaat kan leiden zijn de verschillende gradaties, preoperatief door de chirurg bepaald, van mobilisatie die worden gebruikt. Het is bekend dat verschil in mobilisatie kan leiden tot verschillende recidief percentages in de laparotomische setting (zie behoud versus klieven). Al met al is de werkgroep van mening dat het raadzaam is een rectopexie toe te voegen aan de mobilisatie in het geval van een ERP.

Delorme versus Delorme met levatorplastiek

Het toevoegen van een levatorplastiek aan de klassieke Delorme lijkt waardevol⁹. Zonder verschil in complicaties maar met een betere score op functioneel gebied en in het aantal gereduceerde recidieven lijkt de additionele waarde van de levatorplastiek groot te zijn. Wanneer een Delorme procedure wordt overwogen voor de behandeling van een ERP acht de werkgroep het zinvol een levatorplastiek toe te voegen.

Altemeier versus Altemeier met levatorplastiek

Het combineren van een procedure van Altemeier met een levatorplastiek geeft veel betere resultaten dan wanneer een losse conventionele Altemeier wordt uitgevoerd¹⁷. Het lijkt de werkgroep dan ook waardevol om een levatorplastiek aan de Altemeier procedure toe te voegen wanneer dit voor de behandeling van een RP wordt overwogen.

Beschrijvende studies behandeling externe rectum prolaps

Laparoscopische rectopexie

In de literatuur worden veel verschillende varianten van laparoscopische rectopexie voor de behandeling van ERP beschreven waarbij vooral de uitgebreidheid van de mobilisatie van het rectum en de plaatsing van de mat varieert. In deze richtlijn is gekozen voor, in de afwezigheid van vergelijkend onderzoek, een tweetal reviews welke de meest beschreven laparoscopische rectopexiën behandelen. De meest gebruikte techniek in Nederland is de LVR waarbij het rectum alleen ventraal wordt gemobiliseerd en de mat aan de ventrale zijde van het rectum wordt bevestigd, hiermee de laterale autonome zenuwen sparend. In de review van Samaranayake worden de resultaten van de LVR, in de regel zonder zonder posterieure mobilisatie, en de ventrale rectopexie (laparotomisch en laparoscopisch) met posterieure mobilisatie beschreven²⁷. Beide technieken overleggen goede functionele uitkomsten maar de LVR noteerde een veel betere uitkomst wat betreft obstipatie met een gemiddelde reductie van 40.3 vs. 6.1%. Hiernaast kwam obstipatie *de novo* vele malen vaker voor in de groep met posterieure mobilisatie. Beide uitkomsten worden gewijd aan het klieven versus het behouden van de laterale ligamenten. Scores betreffende fecale incontinentie en complicatie percentages waren gelijkwaardig. Als laatste valt op dat het recidief percentage bij beide technieken acceptabel is, met een klein voordeel ten faveure van VRMPM. De review van Cadeddu includeerde 3 studies betreffende LVR waarvan er 2 ook in de review van Samaranayake beschreven worden^{13,27}. De derde studie noteerde een recidief percentage van 2.75%, andere waarden werden niet genoemd.

Bij de laparoscopische Orr-Loygue rectopexie wordt het rectum zowel ventraal als posterieur gemobiliseerd met een ventrale plaatsing van de mat. Bij de posterieure benadering wordt het rectum alleen van deze zijde gemobiliseerd en wordt hier de mat geplaatst. Over het algemeen rapporteren alle studies betreffende alle verschillende technieken een verbetering van functionele klachten (met uitzondering van de posterieure benadering betreffende obstipatie) en acceptabele recidief en complicatie percentages. Wanneer men de technieken probeert te vergelijken noteren alle vier min of meer dezelfde uitkomst wat betreft fecale incontinentie. Echter met gemiddeld 40.3% reductie van de obstipatie klachten en slechts 5.5 tot 10.5% obstipatie *de novo* lijkt de LVR een voordeel te hebben ten opzichte van de andere technieken. De Orr-Loygue techniek toont gemiddeld 33% verbetering betreffende obstipatie klachten maar er viel ook in 3 van de 5 studies een gemiddelde van 46% aan obstipatie *de novo* te noteren. De posterieure benadering scoort erg slecht op obstipatie als uitkomst. De posterieure bandering scoorde wel het laagste recidief percentage met 1.7% (vs. 4.2% voor Orr-Loygue en 4.9% voor LVR, de 2 reviews gecombineerd). Hierbij moet de kortere follow-up duur wel in acht worden genomen (24 vs. 46 vs. 43 maanden). Complicaties worden door Cadeddu et al. helaas niet beschreven. Voor de LVR werd een acceptabel complicatie percentage gevonden (4.8 - 38.5%, gem. 19.2%), net als voor de ventrale rectopexie met posterieure mobilisatie (1.4 - 46.9%, gem. 19.4%)²⁷.

Een bijkomend voordeel van de LVR is dat deze ingreep gecombineerd kan worden met een abdominale gynaecologische ingreep; een gecombineerde verzakking komt immers vaak voor. De LVR is zodoende goed te combineren met een laparoscopische sacrocolpopexie, uitgevoerd door de gynaecoloog. De werkgroep acht het raadzaam om dergelijke operaties waar mogelijk gecombineerd uit te voeren.

Hoewel er geen vergelijkende studies bestaan tussen de verschillende laparoscopische rectopexiën, kan uit de bovenstaande reviews voorzichtig de conclusie worden getrokken dat op het gebied van functionele uitkomst de LVR superieur lijkt te zijn aan de ventrale rectopexie met posterieure mobilisatie, de laparoscopische Orr-Loygue rectopexie en de laparoscopische posterieure benadering. Het recidief percentage van de LVR is

echter hoger dan de voornoemde technieken. De werkgroep geeft in deze de voorkeur aan de LVR. Bij de andere technieken richt men vaak schade aan de autonome zenuwen van het rectum aan, resulterend in een motiliteitsprobleem. Eventuele beschadigingen hieraan zijn niet meer te herstellen, wat een eventueel recidief wel is, hoe vervelend ook voor de patiënt. De LVR heeft in grote series aangetoond effectief en veilig te zijn en een acceptabel recidief percentage te hebben. Wel dient aangetekend te worden dat de werkgroep voor onomstotelijk bewijs meer vergelijkend onderzoek nodig acht.

Laparoscopische resectie rectopexie

Bij de LRR wordt het rectum alleen ventraal gemobiliseerd en met hechtingen aan het promotorium bevestigd. Vanwege het risico op lekkage wordt er geen mat ingehecht. Dit heeft tot gevolg dat er geen varianten van deze techniek zijn beschreven. Uit de review van Cadeddu komt naar voren dat de LRR goede functionele resultaten, een gemiddeld complicatie percentage van 15.4% en een recidief percentage van 0% laat zien¹³. Hieruit kan geconcludeerd worden dat de LRR een adequate chirurgische behandeling voor ERP is. De behandelend arts moet zich echter wel realiseren dat bij de LRR een darm anastomose wordt aangelegd, met de risico's van dien. De artikelen uit dit review laten een lekkage percentage van 1.6% (4/244) zien. Hierbij dient gerealiseerd te worden dat de opnameduur langer is bij een resectie dan wanneer deze niet wordt uitgevoerd en dat hier kosten aan verbonden zijn. Wanneer LRR met LVR wordt vergeleken valt op dat de LRR betere incontinentie scores en een duidelijk lager recidief percentage toont. Hierbij wordt wel aandacht gevraagd voor de gemiddeld kortere follow-up duur van de LRR (28.5 vs. 46 maanden). Verbetering in obstipatie, voorkomen van functionele klachten *de novo* en complicatie percentage zijn te vergelijken tussen de twee technieken. Zo moet men dus de risico's van de anastomose van LRR en de langere opnameduur afwegen tegen het schijnbaar betere effect op de incontinentie en het minder voorkomen van recidieven, wanneer vergeleken met de LVR. De werkgroep geeft de voorkeur aan LVR bij ERP.

Delorme procedure

Over de Delorme procedure, een van de twee meest gebruikte perineale benaderingen, wordt een goede functionele verbetering gerapporteerd in de enige geïnccludeerde en beschrijvende studie³⁰. Het complicatie percentage is acceptabel. Het aantal recidieven is echter hoog, zeker wanneer dit vergeleken wordt met de abdominale technieken. Het complicatie percentage is iets hoger maar wel te vergelijken met de abdominale technieken. Het voordeel van de perineale techniek is dat de patiënt niet onder algehele anesthesie gebracht hoeft te worden. Bij (oudere) patiënten met veel comorbiditeiten waarbij dit een rol kan spelen is de Delorme procedure een uitkomst.

Altemeier procedure

De andere vaak gebruikte perineale benadering, de Altemeier procedure, laat lagere (gemiddelde) recidief en morbiditeit percentages zien in vergelijking met de Delorme³¹. Ook vergeleken met de abdominale techniek laat de Altemeier een lager gemiddeld morbiditeit percentage zien. Er zijn echter wel veel meer recidieven te noteren bij de perineale techniek. De functionaliteit verbeterde significant na de Altemeier, maar indien vergeleken met de abdominale procedures kwamen deze laatste er beter uit. Het lijkt erop dat ook deze perineale procedure effectief is maar ondergeschikt is aan de abdominale technieken. Zodoende kan de Altemeier een rol spelen bij (oudere) patiënten met veel comorbiditeiten. Bij jongere, fitte patiënten is een abdominale procedure echter aangewezen.

Uitgangsvraag 2: Wat is de optimale chirurgische correctie van een interne rectale prolaps?

Vergelijkende studies behandeling interne rectum prolaps of rectocele (met of zonder enterocele)

Laparotomische versus laparoscopische resectie rectopexie voor interne rectum prolaps

De enige geïnccludeerde studie laat duidelijk geen verschil in complicaties en postoperatieve obstipatie klachten zien tussen laparotomische en laparoscopische resectie rectopexie²². Hierbij is het belangrijk dat, in zowel open als laparoscopisch, het

rectum zowel ventraal als posterieur gemobiliseerd was. Er wordt beschreven dat de 'meeste' laterale ligamenten behouden worden. Hoewel de vergelijking laparotomische versus laparoscopische resectie rectopexie voor een IRP maar in één studie is onderzocht, is de uitslag bemoedigend en in lijn met de vergelijking laparotomische versus laparoscopische benadering voor ERP. Ook hier zal gelden dat de laparoscopische benadering goedkoper zal zijn, vooral door de kortere opnameduur. Ook zal de patiënt de voorkeur geven aan de minder invasieve benadering via laparoscopie die tevens een mooier cosmetisch resultaat oplevert. Een laparoscopische benadering geniet dan ook de voorkeur. Mits de techniek goed wordt beheerst door de operator uiteraard.

STARR versus conservatieve behandeling

Wanneer een rectocele en/of IRP symptomatisch wordt kan chirurgie overwogen worden. STARR is een veel gebruikte operatie bij een rectocele en/of IRP in combinatie met ODS klachten. De studie geeft weer dat zowel STARR als bekkenfysiotherapie nuttig zijn bij deze groep patiënten²⁵. De STARR geeft echter betere resultaten in ODS klachten reductie. Dat bij STARR meer adverse events plaatsvonden was te verwachten. De morbiditeit viel echter mee, maar 1 ernstige complicatie waarvoor re-interventie (nabloeding) nodig was. Desalniettemin moet de behandelaar rekening houden met de mogelijke adverse events van de STARR in de keuze voor de behandeling. De werkgroep vindt het dan ook aan te bevelen bij patiënten met een kleine rectocele en/of een laaggradige IRP en ODS klachten eerst te beginnen met bekken-fysiotherapie. Wanneer de patiënt hiermee niet uit komt kan een operatie worden overwogen. Dit zou ook voor oudere patiënten met veel comorbiditeit een goede strategie zijn.

Double-stapling (PPH) STARR versus Countour Transtar

Hoewel de resultaten van de Double-stapling (PPH) STARR en de Countour Transtar (CT) staplers voor de behandeling van patiënten met ODS klachten in combinatie met een rectocele en/of IRP niet veel verschillen lijkt het er op dat de CT op de lange termijn superieur is¹⁶. De onderzoeken van Isbert en Renzi laten geen verschillen in functionele

uitkomst zien na 12 maanden^{21,26}. Renzi et al. beschrijft een minieme verbetering ten faveure van de CT na 24 maanden. In het cohort van Boccasanta, met een follow-up duur van 36 maanden, worden minimale functionele verschillen beschreven¹⁶. In dit zelfde cohort komen klachten van fecale drang echter wel meer dan twee keer zo vaak voor in de STARR groep. Hierbij kampt van de STARR groep 12% na 3 jaar met een recidief, wat veel is in vergelijking met de 0% van de CT groep. Het lijkt alsof er vanaf 12 maanden een verschil gemaakt wordt^{16,26}. Hieruit kan men concluderen dat het lijkt alsof de CT een voordelig effect heeft ten opzichte van de STARR wanneer men kijkt naar de lange termijn. Postoperatieve complicaties waren in alle drie de studies nagenoeg gelijk. Naast het functionele aspect heeft de CT een aantal technische voordelen. Het heeft een groter reservoir dan de STARR zodoende kan er meer weefsel worden geresceerd. Hierbij kan de CT een volledige circumferentiële resectie in een shot uitvoeren, in tegenstelling tot de PPH stapler waarbij het apparaat één maal voor de anterieure en één maal voor de posterieure zijde moet worden afgevuurd. Bij de PPH techniek blijven er vaak laterale flapjes weefsel over welke een bloeding, pijn of een partiële obstructie kunnen veroorzaken. Hiernaast heeft de CT als voordeel dat het zicht op het te reseceren weefsel veel beter is. In de literatuur wordt ook wel beschreven dat het afvuren van de PPH stapler blind gebeurt met het risico op een perforatie. Als laatste moet rekening worden gehouden met het feit dat de CT duurder is dan de conventionele STARR. Concluderend stelt de werkgroep dat door de minimale voordelen op functioneel gebied, het lagere recidief percentage en de technische voordelen de CT de voorkeur geniet boven de conventionele double stapling (PPH) STARR.

Beschrijvende studies behandeling interne rectum prolaps of rectocele (met of zonder enterocele)

Laparoscopische ventrale rectopexie voor interne rectum prolaps

De twee geselecteerde studies beschrijven een positief effect van de LVR op de functionele uitkomst en goede complicatie en recidief percentages worden gerapporteerd^{18,29}. Na studies waarin LVR zich bewees als een goede chirurgische behandeling voor ERP

volgden er steeds meer studies die hetzelfde bewijzen voor een IRP. De LVR is vooral geïndiceerd bij patiënten met een symptomatische *high-grade* IRP (graad 3 of 4 volgens de Oxford classificatie). Dit wordt bevestigd door een panel van experts in een recent ‘consensus’ artikel³⁷. Het panel stelt ook dat de LVR een goede chirurgische behandeling is voor de symptomatische complexe rectocele van meer dan 3-4 centimeter, doorgaans vergezeld door een hooggradige IRP en een enterocele. Bij patiënten met dergelijke problematiek kan altijd eerst biofeedback therapie geprobeerd worden, zo stelt ook het panel³⁷.

Hoewel de LVR als indicatie voor IRP niet in vergelijkende studies is uitgezocht acht de werkgroep de LVR adequaat om patiënten die lijden aan een symptomatische IRP te helpen. Meer vergelijkend onderzoek is echter nodig om deze stelling te onderbouwen.

TRREMS (transanal repair of rectocele and rectal mucosectomy with a single circular stapler)

TRREMS is een techniek specifiek toepasbaar op patiënten met ODS klachten ten gevolge van een rectocele en een mucosa prolaps. Over deze techniek is enkel beschrijvend en geen vergelijkend onderzoek te vinden. In de enige beschrijvende studie opgenomen in deze richtlijn wordt een positief resultaat op de obstipatie en incontinentie gemeten middels gevalideerde scores²⁴. Tezamen met een acceptabel complicatie percentage lijkt het alsof deze techniek veilig en effectief is voor deze specifieke patiëntengroep. Echter het bewijs is marginaal. Meer bij voorkeur vergelijkende studies zouden moeten volgen om deze stelling kracht bij te zetten.

Algemeen

Alvorens de werkgroep haar aanbevelingen over de uitgangsvragen in dit hoofdstuk doet is het onderstaande van belang. Gedurende de zoektocht naar geschikt bewijs om beide uitgangsvragen te beantwoorden bleek al snel dat er weinig kwalitatief goed vergelijkend onderzoek beschikbaar was. Hierbij bleek het vergelijkende onderzoek vooral patiënten te betreffen die geopereerd waren middels een laparotomische rectopexie. Aangezien heden ten dage de laparotomische rectopexie nagenoeg niet meer in Nederland wordt uitgevoerd gaat het hier om zeer gedateerde onderzoeken.

Tegenwoordig worden vrijwel alleen de laparoscopische benaderingen voor het opheffen van een RP uitgevoerd. De beweegredenen hiervoor zijn te vinden in de resultaten van de laparotomische onderzoeken die, ondersteund door losse laparoscopische series, geëxtrapoleerd worden naar de laparoscopische benadering. Zo werd het *behoud versus klieven van de laterale ligamenten* in de laparotomische setting onderzocht waaruit naar voren kwam dat behoud van de ligamenten de voorkeur geniet¹⁵. Het review van Samaranayake laat hetzelfde resultaat zien wanneer losse laparoscopische series vergeleken worden²⁷. Hierbij werd er al lang geleden in meerdere vergelijkende studies bewezen dat de laparoscopische techniek superieur was aan de laparotomische benadering¹⁵. Dit was vooral vanwege de mindere postoperatieve complicaties, lagere kosten en een verschil in het cosmetische effect. De aanbevelingen zullen daarom vooral voortkomen uit de uitkomsten van de laparotomische onderzoeken geëxtrapoleerd naar de laparoscopische benadering, op basis van losse beschrijvende series en de expert opinion van de werkgroep. Daarom raadt de werkgroep aan bij een ERP of IRP de LVR toe te passen. Eventueel kan de operateur bij een ERP voor een LRR kiezen, voornamelijk als preoperatief de obstipatie op de voorgrond staat. De LRR wordt echter nauwelijks uitgevoerd in Nederland. Het is algemeen bekend dat perineale procedures voor de behandeling van ERP inferieur zijn aan de abdominale benaderingen en dit is vooral te wijten aan het hogere recidief percentage^{1,13,15}. Er zijn voldoende aanwijzingen dat de abdominale technieken een betere functionele uitkomst hebben in vergelijking met de perineale benaderingen. Deze uitspraken zijn voornamelijk gebaseerd op losse, niet vergelijkende series. Een perineale ingreep onder loco-regionale anesthesie bij voorkeur gecombineerd met een levatorplastiek kan worden gekozen wanneer een laparoscopische benadering gecontra-indiceerd is^{9,17}. Over de STARR procedure zijn veel goede recente vergelijkende onderzoeken beschikbaar. Voor rectocele met ODS klachten is vanuit chirurgisch perspectief een STARR of een LVR aangewezen. Helaas is er geen vergelijkend onderzoek tussen de twee behandelingen en op basis van ervaring kan de werkgroep geen voorkeur uitspreken. De werkgroep acht beide behandelingen adequaat voor patiënten met een symptomatische rectocele. De kundigheid en ervaring van de chirurg zullen bij de keuze voor een van de twee behandelingen leidend zijn.

Aanbevelingen

Een laparoscopische ventrale rectopexie (LVR) is de eerste keus voor behandeling van een externe of interne rectum prolaps

Als een laparoscopische benadering gecontra-indiceerd is verdient de perineale benadering (de Delorme of Altemeier procedure met levatorplastiek) onder loco-regionale anesthesie de voorkeur.

Het verdient aanbeveling een patiënt met een anterieure rectocèle in combinatie met obstructief defecatie syndroom klachten te behandelen met een STARR of een LVR.

Zoekverantwoording

Onderwerp:	Database	Zoekstrategie	Aantal ref.
Chirurgie van een rectum prolaps	Medline (OVID), 1946-mei 2013 Engels, Nederlands Embase (Elsevier)	<p>1 Rectal Prolapse/ or Rectocele/ or ((rectal or anal) adj5 prolapse*).tw. or enteroc?ele*.tw. or proctoc?ele*.tw. or sigmoidoc?ele*.tw. or Intussusception/ or Intussusception*.tw. or "rectal invagination".tw. (11378)</p> <p>10 (LVR or LRR or STARR or delorme* or alteimeier* or rectopex* or mucosectom* or proctosigmoidectom*).tw. (4595)</p> <p>11 ((stapled adj7 transanal) or (stapled adj7 trans-anal)).tw. (148)</p> <p>12 Rectocele/su or "Rectal Diseases"/su or Rectal Prolapse/su or "Digestive System Surgical Procedures"/ or "Laparoscopy"/ (66501)</p> <p>13 10 or 11 or 12 (70451)</p> <p>14 1 and 13 (2139)</p> <p>15 Rectocele/su or "Rectal Diseases"/su or *Rectocele/su or *"Rectal Diseases"/su or *Rectal Prolapse/su or *"Digestive System Surgical Procedures"/ (8339)</p> <p>16 9 and 14 (3)</p> <p>17 15 and (10 or 11) (581)</p> <p>18 14 or 17 (2195)</p> <p>19 limit 18 to (dutch or english) (1659)</p> <p>20 (meta-analysis/ or meta-analysis as topic/ or (meta adj analy\$).tw. or (systematic* adj review\$1).tw. or (systematic adj overview\$1).tw. or exp "Review Literature as Topic"/ or cochrane.ab. or cochrane.jw. or embase.ab. or medline.ab. or (psychlit or psyclit).ab. or (cinahl or cinhal).ab. or cancerlit.ab. or ((selection criteria or data extraction).ab. and "review"/)) not (Comment/ or Editorial/ or Letter/ or (animals/ not humans/)) (127085)</p> <p>21 19 and 20 (31)</p> <p>22 (exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti.ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind\$3 or mask\$3)).tw. or Placebos/ or placebo*.tw.) not (animals/ not humans/) (1271329)</p> <p>23 19 and 22 (170)</p> <p>24 21 or 23 (182)</p> <p>((rectal OR anal) NEAR/5 prolapse*):ab,ti OR rectocele*:ab,ti OR enterocele*:ab,ti OR proctocele*:ab,ti OR sigmoidocele*:ab,ti OR intussusception*:ab,ti OR (rectal NEAR/2 invagination*):ab,ti OR 'rectum prolapse'/exp/mj AND (lvr:ab,ti OR lrr:ab,ti OR starr:ab,ti OR delorme*:ab,ti OR alteimeier*:ab,ti OR rectopex*:ab,ti OR mucosectom*:ab,ti OR proctosigmoidectom*:ab,ti OR (stapled NEAR/7 transanal):ab,ti OR (stapled NEAR/7 'trans-anal'):ab,ti OR 'rectocele'/exp/mj/dm_su OR 'rectum disease'/exp/mj/dm_su OR 'rectum prolapse'/exp/mj/dm_su OR 'laparoscopy'/exp/mj) OR ('rectocele'/exp/mj/dm_su OR 'rectum disease'/exp/mj/dm_su OR 'rectum prolapse'/exp/mj/dm_su AND (lvr:ab,ti OR lrr:ab,ti OR starr:ab,ti OR delorme*:ab,ti OR alteimeier*:ab,ti OR rectopex*:ab,ti OR mucosectom*:ab,ti OR proctosigmoidectom*:ab,ti OR (stapled NEAR/7 transanal):ab,ti OR (stapled NEAR/7 'trans-anal'):ab,ti))) AND ([dutch]/lim OR [english]/lim) AND [embase]/lim</p>	315

Evidencetabellen

De evidencetabellen zijn te vinden in de officiële richtlijn (o.a. op Heelkunde, NVOG, NHG, richtlijnendatabase en kwaliteitskoepel.nl).

English summary Dutch national prolapse guideline

The Dutch pelvic floor prolapse guideline was initiated by the Dutch Society of Obstetrics and Gynaecology in collaboration with the Dutch Society for Surgery. This summary is about the optimal surgical treatment of external rectal prolapse (ERP, circumferential full-thickness protrusion of the rectal wall through the anus) and internal rectal prolapse (IRP, telescopic infolding of the rectal wall).

Rectal prolapse is rare (420 per 100.000 persons) and occurs mainly in women (80-90%) aged 60 to 70 years old¹. The occurrence of a rectal prolapse has a multifactorial origin, but known risk factors are an abnormal deep pouch of Douglas, a mobile mesorectum, laxity of the lateral ligaments and pelvic floor muscles and weakness of the internal and external anal sphincter, often combined with a pudendal neuropathy³. A radiological examination, divided in functional and imaging studies, to diagnose rectal prolapse can be needed. A comprehensive assessment of anorectal function consists of measuring at a minimum each of the following parameters: (1) anal sphincter function, (2) rectoanal reflex activity, (3) rectal sensation, (4) changes in anal and rectal pressures during attempted defecation, (5) rectal compliance and (6) performance of a balloon expulsion test⁵. In addition, the pudendal nerve terminal motor latency may be tested. Imaging studies are subdivided in conventional defecography and dynamic MR defecography (see chapter 4 of thesis). The most used classification for rectal prolapse is the Oxford rectal prolapse grade system (see achtergrond informatie, Tabel 1⁷). Commonly, a symptomatic rectal prolapse (obstructed defecation and/or faecal incontinence) grade 1-2 is treated with pelvic floor physiotherapy. A symptomatic rectal prolapse grade ≥ 3 is considered an indication for surgery. An additional rectocele or enterocele may be present. In the past more than 300 operations are described and because of heterogeneity between studies it is difficult to determine the optimal procedure¹⁴. Comparative studies are scarce, and common practice is primarily based on observational studies. In this summary the available comparative and observational studies on the different surgical procedures are described per indication.

Comparative studies for ERP

Laparoscopic vs. open rectopexy

Both the meta-analysis by Cadeddu et al. (275 open, 192 laparoscopic procedures) and the cochrane by Tou et al. (2 comparative studies) demonstrated no difference between the groups in recurrent prolapse or difference in functional outcome^{13,15}. De Hoog et al. showed a significant higher recurrence for robot-assisted rectopexy as compared with the open technique¹⁹. However, in this study different rectopexy techniques (according to Wells and to D'Hoore) and materials were used and a low number of patients were included. The cochrane described a lower postoperative complication rate and lower costs in the laparoscopic groups¹⁵. For these reasons a laparoscopic approach is preferred nowadays.

Open vs. perineal approach

The cochrane of Tou et al. described one randomised control trial (RCT, abdominal resection rectopexy n=10 vs. perineal rectosigmoidectomy n=10), that showed more recurrences (1 vs. 0) and a higher postoperative faecal incontinence rate (60% vs. 10%) in the perineal group¹⁵. There was no difference in postoperative morbidity. A cohort study comparing abdominal rectopexy (n=569) with a perineal approach (n=706) demonstrated the latter is associated with less postoperative morbidity (major morbidity OR 0.46, p=0.0038 and minor morbidity OR 0.35, p=0.0002)²⁰. Over the past decades, a perineal approach was preferred for older patients with co- morbidities. Recent research, however, showed that an abdominal approach is safe in elderly patients³³⁻³⁶. Since perineal approaches are associated with a higher recurrence rate, commonly an abdominal procedure is preferred.

Preservation vs. division of the lateral ligaments during open mesh rectopexy

The cochrane of Tou et al. included two trials addressing this issue¹⁵. Rectal prolapse recurred in 4/21 (19%) participants following preservation of the lateral ligaments and 0/23 participants following division of the ligaments (OR 15.35, 95% CI 0.73 to 321.58).

Four of the 21 included patients (19%) developed constipation after rectopexy with preservation of the lateral ligaments compared with 10/23 (43%) with division (OR 0.32 CI 0.08 to 1.23). There were no complications in either group. A recent systematic review presenting non-comparative observational studies, reported comparable recurrence rates between different laparoscopic procedures with different rectal mobilisations¹³. Since division of the lateral ligaments is an irreversible process and because preservation is associated with less postoperative new-onset constipation, preservation of the lateral stalks is advised by the guideline committee.

Resection vs. no resection during open rectopexy

Two small trials investigated this comparison (total n=48)¹⁵. In the resection group of one trial (n=30), more major complications were described (2/15 vs. 3/15). A small advantage in postoperative faecal incontinence was observed in the non-resection group (21 vs. 33%), but this was not significant. However, a significant better improvement of constipation in the resection group was reported (8 vs. 50%). A large cohort study comparing rectopexy techniques, showed significant more major complications in the resection group (OR 2.15, 95% CI 1.10-4.41)²⁰. If constipation is the main complaint pre-operatively, a resection rectopexy may be chosen. The technique is, however, associated with a higher incidence of postoperative morbidity. In addition, the length of hospital stay and the costs are higher following a resection rectopexy.

Abdominal rectopexy vs. mobilisation of rectum and no rectopexy

In a multicentre RCT by Karas et al., rectopexy (suture or mesh, n=136, 45 laparoscopic, 91 open) was compared with a group of patients (n=116, 48 laparoscopic, 68 open) who only underwent rectal mobilisation²³. The degree of mobilisation (ventral, ventral and posterior or circumferential) was determined intraoperatively by the surgeon. Patients with constipation pre-operatively underwent a sigmoid resection, regardless of what group they were in. There were two recurrences in the rectopexy group and 10 in the no rectopexy group, and the difference was significant (8.6% vs. 1.5%, p=0.003). There was no difference in postoperative morbidity. Considering these results, it is recommended to perform a rectopexy in addition to the mobilisation of the rectum.

Delorme's procedure vs. Delorme's procedure with levatorplasty

Adding a levatorplasty to Delorme's procedure results in a lower recurrence rate (14.3% vs 2.4%, $p = 0.048$) as compared to a Delorme's procedure alone⁹. An additional levatorplasty also showed a significant better improvement in constipation and faecal incontinence. No difference in complications was observed.

Perineal rectosigmoidectomy (Altemeier's procedure) vs. perineal rectosigmoidectomy with levatorplasty

A cohort of 120 patients (52 without, 68 with levatorplasty) showed that perineal rectosigmoidectomy with levatorplasty is associated with a lower recurrence rate (20.6 vs. 7.7%) and a longer time to recurrence than perineal rectosigmoidectomy alone¹⁷. A greater improvement of incontinence scores (Wexner) was observed in the levatorplasty group (12.9 pre-operative to 5.8 postoperative) as compared to the conventional perineal rectosigmoidectomy group (11.1 to 7.7). Levatorplasty should be offered to patients when a perineal approach for rectal prolapse is selected.

Comparative studies for IRP or rectocele (with or without enterocele)*Open resection rectopexy vs. laparoscopic resection rectopexy*

An observational cohort study of 48 patients with IRP who had ligament-preserving suture resection rectopexy by laparoscopic ($n=25$) or open ($n=23$) technique showed comparable major postoperative morbidity and functional outcome²². Because of abovementioned reasons, a laparoscopic approach is preferred.

Stapled transanal rectal resection (STARR) vs. conservative treatment

Lehur et al. randomised 119 patients who suffered from obstructed defecation syndrome (ODS) with rectocele and IRP to STARR ($n=59$) or biofeedback training ($n=60$)²⁵. Scores of obstructed defecation improved significantly in both groups as did quality of life (both $p < 0.0001$). Adverse events occurred in 8 (15%) women undergoing STARR and 1 (2%) patient who underwent biofeedback training.

Successful treatment was observed in 44 (81.5%) STARR vs. 13 (33.3%) evaluable biofeedback training patients ($p < 0.0001$). STARR is more effective than biofeedback training for the resolution of obstructed defecation symptoms, with minimal risk of impaired continence. Therefore, it could be offered after failure of conservative measures.

Double-stapling (PPH) STARR vs. Countour Transtar

Three RCT's address this issue for patients with ODS and an IRP and/or rectocele^{16,21,26}. Postoperative morbidity and functional outcome after 12 months were comparable between the two staplers. Longer follow-up (24-36 months), however, showed a minimal advantage for the countour transtar^{16,26}. Boccasanta et al. described a significant difference in recurrence rate in favour of the countour transtar (0 vs. 12%, $p = 0.035$)¹⁶. Because of the above mentioned reasons, and due to technical motives (bigger reservoir, a full circumferential resection in one shot, better view of the tissue), the countour transtar is preferred over double-stapling.

Observational studies for ERP

Laparoscopic rectopexy

A systematic review on ventral mesh rectopexy (VMR) compared patients with (12 studies, 476 open, 29 laparoscopic) and without (7 studies, 6 open, 217 laparoscopic) posterior mobilisation (Tabel 2)²⁷. Functional improvement was measured as the difference in incidence pre- and postoperatively. VMR without posterior rectal mobilisation showed an improvement from 15.4% to 83.3%, and a mean decrease of 40.3% for constipation. VMR with posterior mobilisation noted a change in constipation complaints from -13.6% to 28.8%, with an overall weighted difference of 6.1% (5/7 studies). New-onset constipation was described from 5.5 to 10.5% for VMR without posterior mobilisation and from 2.7 to 58.3% with posterior mobilisation. Faecal incontinence was improved from 13.6% to 77.3% with an overall weighted mean decrease of 44.9% for the total group. Recurrences and postoperative complications were comparable between the two techniques.

Cadeddu et al. performed a meta-analysis of literature and reports of two additional abdominal procedures; posterior mesh and the laparoscopic Orr-Loygue technique (Tabel 3)¹³. The functional improvement in this review is the ratio between pre- and postoperative values. The three studies concerning posterior mesh reported an average improvement of faecal incontinence of 59% with a mean improvement of constipation of 0% and an average recurrence rate of 1.7% (2 studies) after a mean of 24 months of follow-up. In two of the three studies a deterioration in constipation (21-38%) was noted. The five Orr-Loygue articles showed a mean improvement of 65% (4 studies) for faecal incontinence and of 33% for constipation (4 studies). The mean recurrence rate was 4.2% (mean follow-up 46 months). Three of the five studies reported a deterioration in constipation (27-58%). On the basis of the available observational studies, VMR without posterior mobilisation is preferred over VMR with posterior mobilisation, the Orr-Loygue technique and abdominal procedures with posterior mesh because of a better result on postoperative constipation.

Laparoscopic resection rectopexy (LRR)

Cadeddu et al. also includes six studies (n=244) on LRR (Tabel 4)¹³. Mean improvement of faecal incontinence of 71% (4 studies) and constipation of 44.8% (4 studies) were reported. New-onset faecal incontinence and constipation of 8% was described in one study. The average postoperative morbidity was 15.4% (1.6% anastomotic leakages in total). The recurrence was 0% (5 studies, mean follow-up 28.5 months). Comparing the available observational evidence on resection rectopexy and VMR, LRR shows better results on incontinence and recurrence rate. A comparable improvement in constipation between the two techniques is noted. However, the mean follow-up of LRR studies was shorter (28.5 vs. 46 months). In addition, LRR contains the risks of an anastomosis. The risks of LRR should be weighed against the benefits of the procedure. Since no high-quality comparative evidence exists, local experience of each technique should be decisive in rectal prolapse surgery. The guideline committee prefers laparoscopic VMR (LVMR, expert opinion).

Delorme's procedure

Schiedeck et al. described 8 studies (n=323) with an average recurrence percentage of 14.4 and a mean postoperative morbidity of 22.4% (Tabel 5)²⁸. A single cohort study noted a significant improvement from 11.5 to 6 in the Wexner incontinence score³⁰.

Perineal rectosigmoidectomy (Altemeier's procedure)

A review reported on 972 patients (18 studies) who underwent an Altemeier's procedure and noted a mean recurrence of 14.3% (Tabel 6, 17 studies)³¹. A mean decrease in faecal incontinence from 59.3% to 29.2% (8 studies) was described. Because of the high recurrence rate of the Delorme's and Altemeier's procedure, an abdominal procedure is preferred. However, a perineal procedure is a good option if general anaesthesia is contraindicated.

Observational studies for IRP or rectocele (with or without enterocele)

Laparoscopic ventral mesh rectopexy

LVMR for IRP showed similar results as for ERP with an improvement in constipation and faecal incontinence of 86% and 85%, respectively^{18,29}. Recurrence rates vary from 1.5 to 5%^{18,29}. Level one evidence for VMR for IRP is lacking. The procedure is, however, recommended for a symptomatic IRP grade 3-4 by an expert panel³⁷. Although more high-quality research is needed, the guideline committee considers the LVMR adequate to treat symptomatic high-grade IRP.

TRREMS (transanal repair of rectocele and rectal mucosectomy with a single circular stapler)

Leal et al. reported on 35 women with a rectocele and a mucosal prolapse accompanied with ODS complaints. The study observed a significant decrease in Wexner scores (constipation 15.2 vs. 4.5, faecal incontinence 2.8 vs. 1.7)²⁴. The TRREMS technique appears adequate for this specific group of patients.

Comment

The lack of high-quality comparative evidence on the different techniques, together with the small sample size of included studies and their methodological weaknesses, severely limit the usefulness of this guideline. The majority of the comparative studies concern an open procedure and are thus outdated. It is very difficult to identify clinically important differences between the variety of procedures. Therefore, the majority of the below mentioned conclusions and recommendations are from the older, comparative, open studies that are supported by single observational laparoscopic series and the expert opinions of the guideline committee. For this reason a LVMR is recommended for ERP and IRP. If a patient mainly suffers from constipation pre-operatively, a LRR may be chosen. However, LRR is rarely performed in the Netherlands. A perineal approach seems inferior to an abdominal procedure, mainly due to the high recurrence rate^{1,13,15}. In addition, several studies show a better functional outcome following an abdominal repair as compared to a perineal approach^{1,13,15}. If an abdominal procedure is contraindicated, the perineal procedure should be combined with a levatorplasty^{9,17}. For patients with a rectocele and ODS, either a STARR or LVMR seems indicated. Unfortunately no studies comparing the two techniques exist. Therefore, both operations are considered adequate by the guideline committee. The local experience and skill of the surgeon of each technique will be decisive in the choice of one of the two treatments. Longer follow-up with current studies and larger rigorous trials are needed to improve the evidence base and to define the optimal surgical treatment for rectal prolapse.

Conclusions from the literature

Question 1: What is the optimal treatment for an external rectal prolapse?

<p>Quality of evidence: HIGH</p>	<p><i>Laparoscopic vs. open rectopexy</i></p> <p>Generally, there is no difference in recurrence or improvement in functional outcome between the two techniques to treat ERP. A laparoscopic approach is associated with less complications and lower costs.</p> <p><i>Cadeddu 2012¹³, De Hoog 2009¹⁹ Tou 2008¹⁵</i></p>
<p>Quality of evidence: MODERATE</p>	<p><i>Open vs. perineal approach</i></p> <p>A perineal approach to treat ERP is associated with less postoperative complications. Evidence suggests that a perineal approach causes more recurrences and has a higher incidence of postoperative faecal incontinence as compared to an open procedure.</p> <p><i>Fleming 2012²⁰, Tou 2008¹⁵</i></p>
<p>Quality of evidence: MODERATE</p>	<p><i>Preservation vs. division of the lateral ligaments during open mesh rectopexy</i></p> <p>Division, rather than preservation, of the lateral ligaments was associated with less recurrent prolapse but more postoperative constipation in the treatment of ERP.</p> <p><i>Tou 2008¹⁵</i></p>
<p>Quality of evidence: MODERATE</p>	<p><i>Resection versus no resection during open rectopexy</i></p> <p>Evidence suggests that an open resection rectopexy is better to reduce postoperative constipation than an open rectopexy without resection in the treatment of ERP. An open resection rectopexy is, however, associated with a higher postoperative (major) complication rate and a higher postoperative faecal incontinence percentage as compared to an open rectopexy without resection.</p> <p><i>Fleming 2012²⁰, Tou 2008¹⁵</i></p>
<p>Quality of evidence: MODERATE</p>	<p><i>Abdominal rectopexy vs. mobilisation of rectum and no rectopexy</i></p> <p>The addition of a rectopexy to the mobilisation of the rectum, reduces the recurrence rate.</p> <p><i>Karas 2011²³</i></p>

Quality of evidence: MODERATE	<i>Delorme's procedure vs. Delorme's procedure with levatorplasty</i> Evidence suggests that the addition of a levatorplasty to a Delorme's procedure to treat ERP reduces the recurrence rate and generates a better functional improvement as compared to a Delorme's procedure without levatorplasty. <i>Youssef 2013</i> ⁹
Quality of evidence: VERY LOW	<i>Perineal rectosigmoidectomy (Altemeier's procedure) vs. Perineal rectosigmoidectomy with levatorplasty</i> Evidence suggests that the addition of a levatorplasty to an Altemeier's procedure to treat ERP generates a better functional outcome, fewer complications and less recurrences as compared to an Altemeier's procedure without levatorplasty. <i>Chun 2004</i> ¹⁷
Quality of evidence: MODERATE	<i>Laparoscopic rectopexy</i> Based on non-comparative observational studies, LVMR without posterior mobilisation might be superior to LVMR with posterior mobilisation, laparoscopic Orr-Loygue rectopexy and abdominal procedures with posterior mesh in terms of functional outcomes. <i>Cadeddu 2012</i> ¹³ , <i>Samaranayake 2010</i> ²⁷
Quality of evidence: VERY LOW	<i>Laparoscopic resection rectopexy</i> LRR is a safe and effective technique to treat ERP, providing a low recurrence rate, good symptomatic relief with acceptable morbidity. <i>Cadeddu 2012</i> ¹³
Quality of evidence: LOW	<i>Delorme's and Altemeier's procedure</i> Both the Delorme's and Altemeier's procedures provide good symptomatic relief and an acceptable postoperative complication rate. However, recurrences rates following a perineal repair are higher than compared to an abdominal approach. A perineal procedure could be a good option if general anaesthesia is contraindicated. <i>Schiedeck 2005</i> ²⁸ , <i>Tsunoda 2003</i> ³⁰ , <i>Zbar 2002</i> ³¹

Question 2: What is the optimal treatment for an internal rectal prolapse?

<p>Quality of evidence: VERY LOW</p>	<p><i>Open resection rectopexy vs. laparoscopic resection rectopexy</i></p> <p>No difference between an open and a laparoscopic resection rectopexy for the treatment of IRP in terms of postoperative morbidity and constipation was observed.</p> <p><i>Johnson 2012²²</i></p>
<p>Quality of evidence: MODERATE</p>	<p><i>STARR vs. conservative treatment</i></p> <p>Both treatments reduce obstructed defecation symptoms in patients with an IRP and/or rectocele, but STARR is more effective than biofeedback training.</p> <p>STARR is, however, associated with a higher postoperative morbidity.</p> <p><i>Lehur 2008²⁵</i></p>
<p>Quality of evidence: HIGH</p>	<p><i>Double-stapling (PPH) STARR vs. Countour Transtar</i></p> <p>For the treatment of patients with ODS and an IRP and/or rectocele, the countour transtar generates a better functional outcome and a lower recurrence rate on the long-term as compared to double-stapling.</p> <p><i>Boccasanta 2011¹⁶, Isbert 2010²¹, Renzi 2011²⁶</i></p>
<p>Quality of evidence: VERY LOW</p>	<p><i>Laparoscopic ventral mesh rectopexy</i></p> <p>LVMR is a safe and effective technique to treat IRP, providing an acceptable recurrence rate, good symptomatic relief with minimal morbidity.</p> <p><i>Collinson 2010¹⁸, Sileri 2012²⁹</i></p>
<p>Quality of evidence: VERY LOW</p>	<p><i>TRREMS</i></p> <p>TRREMS appears to be an effective technique to treat rectocele in combination with a mucosal prolapse, providing a good functional outcome.</p> <p><i>Leal 2010²⁴</i></p>

Recommendations

Laparoscopic ventral mesh rectopexy (LVMR) is the first choice to treat an external rectal prolapse or an internal rectal prolapse.

A perineal procedure (Delorme's or Altemeier's procedure with levatorplasty) with regional anaesthesia is preferred if a laparoscopic procedure is contraindicated.

It is advisable to treat a patient with an anterior rectocele in combination with obstructive defecation syndrome complaints with STARR or LVMR.

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Chapter 4

Current status of laparoscopic and robotic ventral mesh rectopexy for external and internal rectal prolapse

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World Journal of Gastroenterology 2016 Jun; 22(21): 4977-4987.

Abstract

External and internal rectal prolapse with their affiliated rectocele and enterocele, are associated with debilitating symptoms such as obstructed defecation, pelvic pain and faecal incontinence. Since perineal procedures are associated with a higher recurrence rate, an abdominal approach is commonly preferred. Despite the description of greater than three hundred different procedures, thus far no clear superiority of one surgical technique has been demonstrated. Ventral mesh rectopexy (VMR) is a relatively new and promising technique to correct rectal prolapse. In contrast to the abdominal procedures of past decades, VMR avoids posterolateral rectal mobilisation and thereby minimizes the risk of postoperative constipation. Because of a perceived acceptable recurrence rate, good functional results and low mesh-related morbidity in the short to medium term, VMR has been popularized in the past decade. Laparoscopic or robotic-assisted VMR is now being progressively performed internationally and several articles and guidelines propose the procedure as the treatment of choice for rectal prolapse. In this article, an outline of the current status of laparoscopic and robotic ventral mesh rectopexy for the treatment of internal and external rectal prolapse is presented.

Selection of used literature

Studies presenting a homogeneous group of patients with rectal prolapse syndromes treated with VMR (laparoscopic or robotic) as described by D'Hoore et al.⁶, avoiding posterolateral mobilization and using a synthetic mesh were selected. Laparoscopic and robotic outcomes had to be displayed separately. Studies describing a heterogeneous group were excluded. Articles using a biological mesh are described separately.

Complications

Laparoscopic

Since the introduction of laparoscopic surgery, complications following rectopexy have reduced significantly¹¹. Over the years, many studies have been published investigating surgical complications after LVMR. Most were small case series, but recently a large cohort of 919 patients with a median follow-up of 33.9 months was published¹². For this topic highlight, we have included 24 studies showing postoperative complication rates from 0 to 23.5% (Table 1). This extensive variation can be explained by the different ways in scoring morbidity between studies, especially for minor complications. Therefore, we have divided complications in minor and major groups according to the Clavien-Dindo (CD) classification¹³. Major complications, requiring surgical intervention (CD ≥ 3), are more relevant and in most cases directly ascribed to the VMR. Such complications were demonstrated from 0 to 7.7% of patients, which is acceptable and comparable to other minimal-invasive abdominal pelvic floor procedures¹⁴. Perioperative mortality is very low and occurred from 0 to 1.1%. Conversion is rare and was described from 0 to 5.9% with one study reporting a rate of ten percent. The majority of the conversions were due to extensive intra-abdominal adhesions.

Table 1. Conversion, intra- and postoperative complications following LVMR and RVMR with synthetic mesh

Laparoscopic studies	n	Median FU (months)	Intra-operative complications	Conversion	Postoperative complications			
					Total	Minor (CD 1-2)	Major (CD 3-4)	Mortality (CD 5)
D'Hooere <i>et al</i> ¹⁶ , 2004	42	61	0	2 (4.8%)	2 (4.8%)	0	0	
D'Hooere <i>et al</i> ^{16a} , 2006	109	-	0	4 (3.7%)	8 (7.3%)	0	0	
Slawik <i>et al</i> ^{16b} , 2008	80	54	-	1 (1.3%)	7 (8.8%)	0	0	
van den Esschert <i>et al</i> ^{15d} , 2008	17	38 ^a	0	1 (5.9%)	4 (23.5%)	3 (17.6%)	0	
Boons <i>et al</i> ¹⁴ , 2010	65	19	-	1 (1.5%)	11 (16.9%)	6 (9.2%)	0	
Collinson <i>et al</i> ¹⁵ⁱ , 2010	75	12	0	1 (1.3%)	4 (5.3%)	3 (4%)	0	
Wijffels <i>et al</i> ^{15j} , 2011	80	23	-	1 (1.3%)	10 (12.5%)	9 (11.3%)	0	
Wong <i>et al</i> ¹⁶ , 2011	40	6	0	4 (10)	5 (12.5%)	5 (12.5%)	0	
Wong <i>et al</i> ^{15j} , 2011	84	29	4 (4.8%)	3 (3.6%)	3 (3.6%)	2 (2.4%)	0	
Lauretta <i>et al</i> ¹⁴ , 2012	30	13.9 ^a	-	0	2 (7.7%)	0	0	
Faucheron <i>et al</i> ^{16k} , 2012	175	74/60 ^b	0	3 (1.7%)	8 (4.6%)	5 (2.9%)	0	
Formijne Jonkers <i>et al</i> ¹²³ , 2013	233	30	0	6 (2.6%)	11 (4.7%)	7 (3%)	0	
Badrek-Amoudi <i>et al</i> ¹²⁵ , 2013	48	33	-	0	9 (18.8%)	8 (16.7%)	0	
Maggiori <i>et al</i> ¹²⁶ , 2013	33	42a	0	1 (3%)	0	0	0	
Mantoo <i>et al</i> ¹³⁸ , 2013	74	16 [*]	0	3 (4.1%)	15 (20%)	15 (20%)	0	
Mäkelä-Kaikkonen <i>et al</i> ¹²⁷ , 2014 ^c	20	3	0	0	1 (5%)	0	0	
Mackenzie <i>et al</i> ¹³² , 2014	953	21	-	8 (1.3%)	63 (6.6%)	53 (5.6%)	2 (0.2%)	
Ogilvie <i>et al</i> ¹³⁰ , 2014	29	15.4	1 (3.4%)	0	3 (10.3%)	2 (6.9%)	0	
Randall <i>et al</i> ¹³¹ , 2014	190	29	1 (0.5%)	5 (2.6%)	22 (11.6%)	11 (5.7%)	2 (1.1%)	
Owais <i>et al</i> ¹³³ , 2014	68	42	0	0	11 (16.2%)	10 (14.7%)	0	
Gosselink <i>et al</i> ¹³⁹ , 2015	91	12	0	0	5 (5%)	4 (4.4%)	0	
Tsunoda <i>et al</i> ¹³³ , 2015	26	16	0	0	2 (7.7%)	2 (7.7%)	0	
Consten/van Iersel <i>et al</i> ¹² , 2015	919	33.9/120 ^b	3 (0.3%)	20 (2.2%)	203 (23.4%)	153 (19.3%)	1 (0.1%)	
Tsunoda <i>et al</i> ¹³⁴ , 2016	31	25	0	0	2 (6.5%)	2 (6.5%)	0	
Robotic studies								
Wong <i>et al</i> ¹³⁶ , 2011	23	6	0	1 (4.3%)	1 (4.3%)	0	0	
Mantoo <i>et al</i> ¹³⁸ , 2013	74	16 ^d	0	1 (2.3%)	5 (11%)	5 (11%)	0	
Mäkelä-Kaikkonen <i>et al</i> ¹³⁷ , 2014 ^c	20	3	1 (5%)	0	1 (5%)	1 (5%)	0	

^a Mean instead of median; ^b Percentages are Kaplan-Meier estimates at 60 and 120 months of follow-up; ^c The results of Wong, Mantoo and Mäkelä-Kaikkonen *et al.* are displayed per technique; d not specified whether mean of median was used. n: no. of patients, FU: follow-up; -: not specified of not applicable.

Robotic

Three studies using synthetic mesh discussed the complication rate following RVMR (Table 1). Robotic surgery showed a non-significant minimal advantage in terms of intra- and postoperative complications compared to LVMR, described in a meta-analysis of these three studies¹⁵. However, studies were small and follow-up was short. Very recently, a randomised controlled trial (RCT) comparing the two techniques demonstrated a non-significant equality in complication rates¹⁶.

Synthetic mesh-related complications*Laparoscopic*

The use of mesh in pelvic floor surgery has been subject for debate in recent years. Considerable commotion arose in response to the US Food and Drug Administration (FDA) report in 2011 where a high number of mesh-related adverse events associated with transvaginal pelvic organ prolapse repair were described¹⁷. The systematic review of Abed et al., showing a mesh erosion rate of 10.3% (110 studies, range 0 – 29.7%) within 12 months after transvaginal pelvic organ prolapse repair, confirmed these concerns¹⁸. The contemporary literature present a low incidence of mesh-related morbidity following VMR, but studies discussing this issue are limited. A pooled analysis of 11 observational studies (n=767) demonstrated a 0.7% rate for mesh-related complications after LVMR in 2012¹⁹. Recently a multicentre study, including 2203 patients from databases of five hospitals over a 14-year period, described 45 patients (2%) developing mesh erosion (42 synthetic, 3 biologic) after a median of 23 months²⁰. However, underestimation is probable because of the retrospective character and a lack of systematic follow-up of this study. In general, mesh complication rates from 0 to 6.7% with mesh erosion percentages between 0 and 3.7% are described^{12,19–34}. Most articles report vaginal mesh erosions, but intrarectal mesh migration following LVMR is not uncommon. The study of Evans et al. showed approximately half of the mesh erosions were rectal (17/45, 0.8%) and a similar percentage was described in other articles^{20,27,31,35}. Recognized risk factors for developing mesh erosion are smoking, steroids, poorly regulated diabetes mellitus,

pelvic hematoma, pelvic infection and a history of pelvic irradiation or pelvic surgery^{19,35}.

The multicentre study also suggested that mesh erosions were more frequently associated with LVMR for IRP ($p=0.02$) and polyester mesh ($p=0.00006$)²⁰.

Robotic

Only four studies mentioned examination for synthetic mesh-related complications following RVMR and all reported a rate of zero percent^{36–39}. The follow-up, however, was short varying from 3 to 23 months.

Functional outcome

Laparoscopic - ERP

LVMR, with a limited anterior dissection, was introduced to avoid rectal denervation associated with damage to the parasympathetic fibres of the inferior hypogastric plexus. The RCT of Speakman et al. showed that preservation, rather than division, of the lateral ligaments is associated with less postoperative constipation⁴⁰. Meta-analyses confirmed this specific finding and demonstrate that VMR seems to be related to less constipation postoperatively as compared with other abdominal techniques (posterior mesh rectopexy, Ripstein, Orr-Loygue)^{5,41}. An ERP is a circumferential full-thickness protrusion of the rectum through the anal verge. A recent consensus report, by a panel of international experts, considers ERP a definitive indication for VMR⁹. LVMR showed improvement of obstructed defecation complaints from 52 to 84.2% ($p<0.01$ - $p<0.0001$)^{6,12,21,23,33,42–44} with a median gain of the Cleveland Clinic Constipation Score (CCCS)⁴⁵ between 4.8 and 7 points ($p<0.01$ - $p<0.0001$, Table 2)^{29,33,34,43,44}. Obstructed defecation *de novo* was noted in 4.8 to 17.6% of patients^{6,21}. Improvement of faecal incontinence was described in 50 to 93% of patients ($p<0.01$ - $p<0.0001$)^{6,12,21,23,29,31,33,42–44}. There was a median gain of the Cleveland Clinic Incontinence Score (CCIS)⁴⁶ of 8 to 13 ($p<0.001$ - $p<0.0001$)^{6,31} and one study reports a mean CCIS gain of 5.8 points²¹. The median Faecal Incontinence Severity Index (FISI)⁴⁷ benefit varied from 12 to 36 points ($p<0.01$ - $p<0.0001$)^{29,33,34,43,44}. Two studies demonstrated new-onset faecal incontinence with an incidence of 1.5 and 3.2% in patients^{43,44}.

Laparoscopic – ERP and/or IRP and/or rectocele

An IRP is a telescopic infolding of the rectal wall during defecation. IRP is most commonly classified by the Oxford rectal prolapse grade differentiating between an intrarectal (grade 1 and 2) and intra-anal (grade 3 and 4) intussusception⁴⁸. An Oxford grade 3 or 4 IRP, in combination with significant functional complaints failing to conservative therapy, is considered an indication for VMR^{9,10}. The expert panel stated that VMR could also be performed for a complex rectocele of more than 3-4 cm⁹. However, a rectocele frequently exists with an IRP (80%) and, therefore, an isolated rectocele is rare (10%)⁴⁹. LVMR for IRP and/or rectocele showed improvement of obstructed defecation complaints from 55 to 86% ($p < 0.001$ - $p < 0.0001$)^{12,23,33,50-52} with a median CCCS decrease between 3.1 and 9 points ($p < 0.01$ - $p < 0.0001$, Table 2)^{28,29,33,34,50,51}. Improvement of faecal incontinence with 20 to 92% of patients ($p > 0.05$ - $p < 0.0001$)^{12,23,29,33,50-52} and a median gain of FISI of 16 to 25 points ($p < 0.01$ - $p < 0.0001$) was observed in multiple cohorts^{28,29,33,34,50,51}. None of the studies performing LVMR for IRP and/or rectocele described new-onset functional complaints. Studies including both ERP and IRP and/or rectocele as indication for surgery showed 56.7 to 92.8% ($p = 0.119$ - $p < 0.0001$)^{24-26,32,53} improvement for obstructed defecation complaints with a median advantage of 9.1 to 17 points in obstructed defecation syndrome (ODS) score ($p < 0.05$ - $p < 0.0001$, Table 2)^{24-26,32,53}. One report described a non-significant deterioration in ODS score postoperatively⁵⁴. A decrease in faecal incontinence complaints is reported from 82 to 90% of patients^{24,26,32,53} with a median CCIS gain of 4 to 8 points ($p < 0.05$ - $p < 0.0001$)^{24-26,32,53}. Literature demonstrated new-onset complaints of obstructed defecation between 1.4 and 7% of patients, with one report showing a *de novo* faecal incontinence rate of one percent^{26,32}.

Robotic

To date, only two studies using synthetic mesh discuss functional outcomes following RVMR (Table 2)^{38,39}. The laparoscopic cohort of De Hoog et al. included various mobilizations and was excluded³⁹. The RVMR series of this study showed a median CCCS gain of 3.2 points, which was lower than other studies performing LVMR for ERP (Table 2).

Table 2. Functional results following LVMR and RVMR with synthetic mesh

Laparoscopic studies		n	Median FU (months)	Improvement OD	P value	Improvement FI	P value	Median gain CCCS	P value	Median gain CCCS	P value
Indication ERP											
D'Hoore <i>et al</i> ⁸ , 2004		42	61	84.2%. De novo 4.8%	-	90.3%	-	-	-	13	<0.001
Auguste <i>et al</i> ²¹ , 2006		54	12	70%. De novo 17.6%	-	72.4%	-	-	-	5.8 ^a	-
Verdaasdonk <i>et al</i> ⁴² , 2006 ^b		13	7	66%	-	69%	-	-	-	-	-
Cristaldi <i>et al</i> ⁴³ , 2007		63	18	78%	-	90%. De novo 3.2%	-	5	<0.0001	32 (FIS)	<0.0001
Boons <i>et al</i> ⁴⁴ , 2010		58c	19	72%	-	83%. De novo 1.5%	-	5	<0.0001	36 (FIS)	<0.0001
Formijne Jonkers <i>et al</i> ²³ , 2013 ^d		36	30	57.9%	0.01	76.2%	<0.001	-	-	-	-
Randall <i>et al</i> ³¹ , 2014		190	29	-	-	93%	-	-	-	8	<0.0001
Gosselink <i>et al</i> ²⁹ , 2015 ^d		41	12	-	-	50%	<0.01	4.8	<0.01	12 (FIS)	<0.01
Tsunoda <i>et al</i> ³³ , 2015 ^{d,e}		19	12	52%	-	62%	-	7	<0.0001	23 (FIS)	<0.0001
Consten/van Iersel <i>et al</i> ¹² , 2015 ^d		242	33.9	63.3%	<0.0001	73.2%	<0.0001	-	-	-	-
Tsunoda <i>et al</i> ³⁴ , 2016		31	12	-	-	-	-	5	0.005	22 (FIS)	<0.0001
Indication IRP and/or rectocele											
Collinson <i>et al</i> ³⁰ , 2007		30	3	83%	-	92%	-	9	<0.0001	25 (FIS)	<0.0001
Collinson <i>et al</i> ³¹ , 2010		75	12	86%	-	85%	-	7	<0.0001	20 (FIS)	<0.0001
Wong <i>et al</i> ³² , 2011		84	29	45%	<0.001	20%	>0.05	-	-	-	-
Formijne Jonkers <i>et al</i> ²³ , 2013 ^d		197	30	76.9%	<0.001	65.4%	<0.001	-	-	-	-
Gosselink <i>et al</i> ²⁹ , 2013		72	12	-	-	-	-	5	<0.001	16 (FIS)	<0.01
Gosselink <i>et al</i> ²⁹ , 2015 ^d		50	12	-	-	48%	<0.01	3.1	<0.01	17 (FIS)	<0.01
Tsunoda <i>et al</i> ³³ , 2015 ^{d,e}		25	12	55%	-	63%	-	6	<0.0001	22 (FIS)	<0.0001
Tsunoda <i>et al</i> ³⁷ , 2015		26	16	-	-	-	-	7	<0.01	24 (FIS)	<0.01
Consten/van Iersel <i>et al</i> ¹² , 2015 ^d		242	33.9	61%	<0.0001	73.2%	<0.0001	-	-	-	-
Indication both ERP and IRP and/or rectocele											
van den Esschert <i>et al</i> ⁵⁴ , 2008		1 ERP, 16 IRP	38 ^a	-	-	-	-	+2.7g (ODS)	0.091	-	-
Lauretta <i>et al</i> ⁵⁴ , 2012		2 ERP, 28 IRP	13.9 ^a	92.8%	-	85.7%	-	9.1 (ODS) ^{ab}	<0.05	7.1 ^a	<0.05
Badre-Ammoudi <i>et al</i> ²⁵ , 2013		11 ERP, 37 IRP	33	68%	<0.0001	-	-	17 (ODS) ^{ab}	<0.0001	4	<0.0001
Maggiori <i>et al</i> ²⁶ , 2013		33 ⁱ	42 ^a	72%. De novo 7%	-	90%	-	-	-	8	0.002
Mackenzie <i>et al</i> ³² , 2014		149 ERP, 487 IRP	21	56.7%. De novo 1.4%	0.119	89.7%. De novo 1%	0.040	12 (ODS) ^{ab}	-	8	-
Owais <i>et al</i> ⁵³ , 2014 ^j		18 ERP, 50 IRP	42	82%	-	82%	-	12.5 (ODS) ^{ab}	<0.001	4	<0.001
Robotic vs. Laparoscopic studies - various indications											
De Hoog <i>et al</i> ³⁹ , 2009 ^a		20 ERP R	23.4	-	-	-	-	3.2 ^a	-	-	-
Mantoo <i>et al</i> ³⁹ , 2013 ^m		23 ERP, 51 IRP L	16 ⁿ	-	-	-	-	6 (ODS) ^o	0.004	4 ^o	0.604
		12 ERP, 32 IRP R						14 (ODS) ^o	0.004	4 ^o	0.604

^a Mean instead of median; ^b One patient was excluded from further analysis, therefore n=13 instead of n=14 was used; ^c functional data were complete in 58 of 65 patients; ^d The results of Formijne Jonkers *et al*, Gosselink *et al*, Tsunoda and Consten and van Iersel *et al* are displayed per indication; ^e Postoperative functional data were fulfilled in 44 of 59 patients; ^f preoperatively the mean CCIS is given, postoperatively the median; ^g Mean ODS score was 2.7 higher after surgery meaning function deteriorated postoperatively; ^h Pre- and postoperative ODS scores were available for 36 patients; ⁱ Of the 33 patients (ERP n = 20, n = 13 IRP) 3 lost to follow-up. For the remainder of patients the surgical indication was not given; ^j Based on 602 patients; ^k Based on 276 patients; ^l Only men included; ^m A modified version of the D'Hoore rectopexy used; ⁿ not specified whether mean of median was used; ^o estimation based on bar chart. OD: obstructed defecation, FI: faecal incontinence, ODS: obstructed defecation syndrome score, L: laparoscopic, R: robot.

Mantoo et al., performing LVMR and RVMR for various indications, noted a significantly greater improvement for obstructed defecation after RVMR³⁸. Median gain of CCIS was non-significantly equivalent between the two techniques. Both improvement of obstructed defecation and faecal incontinence was in line with the literature on LVMR for various indications (Table 2). Functional outcome was not described in the recent RCT of Mäkelä-Kaikkonen et al¹⁶. However, this RCT did show a non-significant difference in postoperative residual rectoceles on MRI in favour of the robot compared with laparoscopy (8 vs 33%, $p=0.26$). This may result in a better functional outcome for patients suffering obstructed defecation, but these outcome measures need to be evaluated at a longer follow-up.

Recurrence

Laparoscopic – ERP

With the introduction of minimally invasive surgery, recurrence rates with rectal prolapse surgery remained low and equivalent to those of open surgery^{55,56}. In the nineties, three small trials suggested that preservation of the lateral ligaments might result in a higher recurrence rate¹¹. Tou et al. speculated this was due to the limited mobilization of the rectum¹¹. Nonetheless, to date, numerous non-randomised observational studies, with increasing follow-up, quote acceptable recurrence rates following VMR. From 2004 until presently, recurrence percentages following LVMR for ERP range between 1.5 to 9.7%, with one small cohort ($n=13$) reporting a rate of 15.4% (Table 3). Several reviews demonstrate comparable recurrence rates with various rectal mobilisations and abdominal techniques^{5,22,41}. In addition, a multicentre, pooled analysis of 643 patients from 15 centres undergoing abdominal surgery for ERP, showed that the method of rectopexy did not influence the recurrence rate⁵⁷. Variation in recurrence usually reflects differences of follow-up between studies. Articles reporting on LVMR for ERP described a time interval to presentation of recurrence between 10 and 91 months after surgery. Most recurrences developed within the first 36 months, but not all studies reported this time interval (Table 3). Little is known about risk factors for developing a recurrence following VMR. Mackenzie et al. found the only predictor of recurrence was the use of polyester mesh which generated a twofold increase in recurrence rate, with an odds ratio of 1.96 ($p=0.017$), as compared with the most commonly used polypropylene graft³².

Laparoscopic – ERP and/or IRP and/or rectocele

Three studies, performing LVMR for IRP and/or rectocele, quoted recurrence rates between 5.3 and 7.1 percent. Literature, including all rectal prolapse syndromes, reported recurrence percentages between 2.6 to 14.3%. The time interval between LVMR for various indications and recurrence varied from 10 to 139 months (Table 3).

Robotic

The contemporary literature comparing LVMR with RVMR show similar recurrence rates between the two techniques (Table 3). Recurrence percentages vary from 0 to 7 for the robotic and 0 to 8 for the laparoscopic inclusions and were comparable to observational LVMR studies. One additional study from the Hoog et al. noted a recurrence rate of 20% for the robotic, and 26.7% for the laparoscopic cohort³⁸. The laparoscopic series also included Well's procedures and therefore these results were excluded for analysis (Table 3).

Table 3. Recurrence rates following LVMR and RVMR with synthetic mesh

Laparoscopic studies	n	FU (median)	Recurrence	Type of recurrence	Presentation of recurrence (months)
Indication ERP					
D'Hoore <i>et al</i> ⁶ , 2004	42	61	2 (4.8%)	2 ERP	54, 91
Verdaasdonk <i>et al</i> ⁴² , 2006 ^a	13	7	2 (15.4%)	2 ERP	-
Auguste <i>et al</i> ²¹ , 2006	54	12	4 (7.4%)	3 ERP, 1 IRP	26 (7-54) ^b
D'Hoore <i>et al</i> ⁸⁴ , 2006	109	-	5 (4.6%)	4 ERP, 1 enterocele	-
Cristaldi <i>et al</i> ⁴² , 2007	63	18	1 (1.7%)	ERP	-
Boons <i>et al</i> ⁴⁴ , 2010	65	19	1 (1.5%)	ERP	12
Wijffels <i>et al</i> ⁸⁵ , 2011	80	23	2 (2.5%)	2 ERP	6, 16
Faucheron <i>et al</i> ⁸⁶ , 2012	175	74/60 ^c	2 (3%) ^c	2 ERP	6, 24
Randall <i>et al</i> ³¹ , 2014 ^e	190	29	9 (4.7%)	1 ERP, 8 IRP	25, 30, 31, 60 ^f
Gosselink <i>et al</i> ²⁹ , 2015 ^c	41	12	1 (2.3%)	ERP	12
Tsunoda <i>et al</i> ³⁴ , 2016	31	25	3 (9.7%)	3 IRP	10, 17, 31
Indication IRP and/or rectocele					
Collinson <i>et al</i> ⁵¹ , 2010	75	12	4 (5.3%)	4 IRP	-
Wong <i>et al</i> ⁵² , 2011	84	29	6 (7.1%)	6 rectocele	-
Gosselink <i>et al</i> ²⁹ , 2015 ^d	50	12	3 (5.8%)	3 IRP	-
Indication both ERP and IRP and/or rectocele					
Lauretta <i>et al</i> ²⁴ , 2012	2 ERP, 28 IRP	13.9 ^g	1 (3.3%)	1 IRP	19
Formijne Jonkers <i>et al</i> ²³ , 2013	36 ERP, 197 IRP	30	6 (2.6%)	-	-
Badrek-Amoudi <i>et al</i> ²⁵ , 2013	11 ERP, 37 IRP	33	4 (8.3%)	4 IRP	22 (median)
Maggiore <i>et al</i> ²⁶ , 2013	33 ^h	42 ^g	2 (6.7%)	2 rectocele	11, 14
Mackenzie <i>et al</i> ³² , 2014	149 ERP, 487 IRP	21	60 (9.4%)	-	-
Owais <i>et al</i> ⁵³ , 2014 ⁱ	18 ERP, 60 IRP	42	2 (2.9%)	2 IRP	-
Consten/van Iersel <i>et al</i> ¹² , 2015	242 ERP, 677 IRP	33.9/120 ^c	68 (14.3%) ^c	15 ERP, 53 IRP	24.1 (1-139.4) ^b
Tsunoda <i>et al</i> ³³ , 2015	19 ERP, 25 IRP	26	2 (3.4%)	2 IRP	10, 15
Robotic vs. Laparoscopic – various indications					
De Hoog <i>et al</i> ³⁹ , 2009	20 ERP robot	23.4	4 (20%)	-	-
Wong <i>et al</i> ⁹² , 2011	23 IRP lap	12	1 (4.3%)	Rectocele	3
	15 IRP robot		1 (6.7%)	Rectocele	7
Wong <i>et al</i> ³⁶ , 2011	40 IRP lap	6	0 (0%)	-	-
	23 IRP robot		0 (0%)	-	-
Mantoo <i>et al</i> ³⁸ , 2013 ^j	23 ERP, 51 IRP lap	16 ^k	6 (8%)	-	-
	12 ERP, 32 IRP robot		3 (7%)	-	-
Mäkelä-Kaikonen <i>et al</i> ³⁷ , 2014	14 ERP, 6 IRP lap	3	1 (5%)	-	-
	13 ERP, 7 IRP robot		0 (0%)	-	-

^a One patient was excluded from further analysis, therefore n=13 instead of n=14 is used; ^b mean (range); ^c Recurrence percentage is KM estimate at 60 and 120 months of follow-up; ^d The results of Gosselink *et al.* is displayed per indication; ^e Study group included the first 44 cases from Slawik *et al.* 62; ^f Only 4 time intervals are described; ^g Mean instead of median; ^h Of the 33 patients (ERP n = 20, n = 13 IRR) 3 lost to follow-up. For the remainder of patients the surgical indication was not given; ⁱ Only men included; ^j A modified version of the D'Hoore rectopexy used; ^k not specified whether mean of median was used. Lap: laparoscopic.

Multi-compartment prolapse

Pelvic floor dysfunction is regularly characterised by multi-visceral pelvic organ prolapse⁵⁸. With an ageing population, the prevalence of uni- and multi-visceral pelvic organ prolapse will increase^{59–61}. A growing number of articles discuss a multidisciplinary approach for multi-compartment prolapse, but only two studies avoid posterolateral rectal mobilization^{62,63}. The first report, describing an open recto-vagino-vesicopexy, presented an improvement with constipation in 77% ($p=0.001$), faecal incontinence in 69% ($p=0.005$) and urinary incontinence in 50% ($p=0.18$) of all patients respectively after 12 months⁶³. Two (8%) patients developed new-onset urinary incontinence. Slawik et al., performing a laparoscopic sacro-colpo-rectopexy, described an improvement in 91% of patients with faecal incontinence and a reduction in median CCIS of 10 points after six months⁶². Obstructed defecation resolved in 80% of patients, but 7% of these underwent an additional bowel resection. New-onset obstructed defecation occurred in 3.8%, and urinary incontinence in 2.5% of patients respectively. No patient developed a recurrence after a median follow-up of 54 months. Thus far, no robotic studies describing a multi-compartmental approach with a limited anterior rectal dissection are published.

Biological mesh

Concerns over synthetic mesh-related complications such as erosion, dyspareunia, fistulation and stricturing have led to the introduction of a more expensive biological equivalent. The biological mesh is characterised by degradation of the graft and regeneration of host tissue⁶⁴. In theory, this degradation could decrease the chance of erosion and chronic infection. Conversely, the partial resolution of the material may lead to a higher recurrence rate. In 2013, a systematic review by Smart et al. was published comparing 11 studies (767 patients) receiving synthetic mesh with two studies (99 patients) using a biologic graft¹⁹. An erosion rate of less than one percent, with no difference identified between synthetic and biological mesh (0.7% vs 0%, $p=1.0\%$) was described. There was no significant difference in other mesh-related complications or short-term recurrence (3.7 vs 4.0%, $p=0.78$). The multicentre study of Evans et al. and

two recent biological mesh studies (4 and 20 months follow-up) showed similar rates of mesh erosion^{20,65,66}. However, Franceschilli et al. reported a much higher percentage prolapse recurrence rate of 14% after a mean follow-up of 20 months⁶⁶. Improvement with obstructed defecation was described from 82 to 92% with a mean gain of CCCS between 9 and 13 points ($p=0.02$ – $P<0.0001$)^{65–68}. Reduction in faecal incontinence complaints occurred in 73 and 85% of patients with a mean gain in FISI score between four and 6 points ($p=0.01$ – $p=0.001$)^{65–68}. One report demonstrated a median gain in CCIS of approximately 10 points ($P=0.0002$)^{65–68}. Wahed et al. was the only study describing new-onset complaints (4.6% with constipation and 3.1% with faecal incontinence)⁶⁷. Only one study comparing and matching biological and synthetic mesh for LVMR (29 vs. 29) exists, demonstrating no significant difference in mesh-related complications, recurrence or functional outcome after a median follow-up of 15.4 months³⁰. Mehmood et al., comparing 34 LVMR with 17 RVMR patients using biological mesh, demonstrated a minor significant advantage in median CCIS gain for LVMR (10 vs. 9.5, $p=0.02$)⁶⁹. Conversely, a non-significant benefit in favour of the robot was seen in a reduction of the FISI (32 vs. 35, $p=0.3$). Both the functional outcomes of the robotic and the laparoscopic cohort compared favourably to other studies describing LVMR for ERP (Table 2). No recurrences or mesh-related complications were seen in either cohort after 12 months. There is a lack of high-level comparative evidence with long-term follow-up for biological mesh, which demonstrates any significant difference in graft-related morbidity and recurrence rates. When more data becomes available, the choice of the mesh may be influenced by cost or possible comorbidity. In a recent publication a panel of experts suggested that biological grafts may be a better option in the following circumstances: young patients, women of reproductive age, diabetics, smokers, patients with a history of previous pelvic radiation or sepsis, inflammatory bowel disease, and in cases of intraoperative breach of the rectum or vagina⁹.

Discussion

LVMR has become popularised in the past decade and is the preferred technique for treating rectal prolapse syndromes by many surgeons, especially in Europe. The procedure is becoming increasingly applied with robotic assistance. The robot enhances visualisation and manoeuvrability to improve complicated procedures in the deep pelvis, such as dissection and intracorporeal suturing⁷⁰. Robotic surgery has proven to be more expensive in the short-term, but may lead to an overall reduction of costs due to enhanced ergonomics for the surgeon^{11,71,72}. However, a long-term cost-effectiveness analysis of LVMR vs. RVMR has not been performed. The current evidence shows that LVMR and RVMR are safe procedures in terms of intraoperative, postoperative and mesh-related complications. Both LVMR and RVMR generate an acceptable recurrence rate and satisfactory improvement of functional outcome, with only one small laparoscopic cohort reporting an overall non-significant deterioration with obstructed defecation after surgery⁵⁴. There may be a trend towards a better outcome for obstructed defecation following RVMR as compared with LVMR, but the level of evidence is low^{16,38}. LVMR and RVMR show similar good results for improvement of faecal incontinence. Based on the currently available data, no superiority for either technique can be determined. As compared with other observational studies describing an abdominal approach to treat rectal prolapse syndromes, VMR shows similar recurrence rates and less constipation postoperatively^{5,22,41}. Circumspection is required interpreting these results, however. Heterogeneity between the articles in patient selection and outcomes measured makes it difficult to draw conclusions from the current literature. In addition, follow-up has been relatively short and lacks a systematic approach for the majority of studies, especially the robotic series. Since pelvic floor dysfunction increases with age, long-term follow-up is required to assess functional outcome and recurrence. The true mesh erosion rate can only be obtained with adequately powered, long term studies incorporating a vaginal and anorectal examination for every patient. Thus far, only level 3 evidence exists with a paucity of RCT's and case controlled trials. There are no results of comparative studies including VMR available. In a recent critical appraisal, Lundby and Laurberg expressed

their concerns about the rapid implementation of LVMR for obstructed defecation syndrome based on the contemporary evidence⁷³. High-level comparative evidence is necessary to overcome these doubts and to determine the value of VMR in the definitive treatment of rectal prolapse syndromes.

Future research

This review focusses solely on VMR, but more than three hundred different procedures to treat rectal prolapse syndromes have been described. Thus far, no technique has been shown to be superior. This was confirmed by an international survey in 2012, showing no uniformity of surgical procedure⁷⁴. The survey demonstrated, *inter alia*, that more than 20% of the surgeons preferred stapled transanal resection of the rectum (STARR) for the treatment of IRP. Festen et al. suggested an IRP associated with fecal incontinence should be treated with LVR and an IRP in combination with obstructed defecation with STARR or LVR⁷⁵. At present, one Italian trial is comparing LVMR with STARR for obstructed defecation syndrome⁷⁶. In addition, there are eight ongoing surgical trials, of which five are mentioned by the cochrane study of Tou et al¹¹; two comparing LVMR with Delorme's procedure for ERP^{77,78}, one investigating the outcomes of LVMR versus laparoscopic posterior rectopexy without mesh⁷⁹, one comparing laparoscopic resection rectopexy (RR) with laparoscopic fixation rectopexy⁸⁰, one assessing the difference between standard mesh rectopexy with ventral rectopexy⁸¹, one studying the efficacy of LVMR for the treatment of chronic constipation⁸² and two examining LVMR versus RVMR^{16,83}. The trial by Mäkelä-Kaikkonen et al. has presented its short-term results, but long-term outcomes are awaited¹⁶. The survey also shows VMR and RR are the two most common abdominal procedures for RP⁷⁴. RR was developed to reverse the symptoms of rectal denervation inertia which is associated with traditional posterolateral rectal mobilization, but introduces the risks of a pelvic anastomosis. Three trials, comparing (predominantly open) abdominal rectopexy with and without sigmoid resection, described that RR was associated with less postoperative constipation but with a higher

complication rate ($p>0.05$)¹¹. There is a need for a well-designed and adequately powered RCT comparing these two techniques laparoscopically or robotic-assisted. Lastly, high-quality evidence for the choice of a specific mesh type, either synthetic or biological, is required. The authors do acknowledge the slow recruitment and logistical difficulties of performing such trials, however.

Conclusion

Ventral mesh rectopexy (laparoscopic and robotic) appears a safe and effective procedure to correct different rectal prolapse syndromes with a low morbidity rate, acceptable long-term recurrence rates and a good functional outcome.

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Chapter 5

Long-term outcome after laparoscopic ventral mesh rectopexy: an observational study of 919 consecutive patients

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Annals of Surgery 2015 Nov;262(5):742-7; discussion 747-8.

Abstract

Objective

This multicentre study aims to assess long-term functional outcome, early and late (mesh-related) complications and recurrences after Laparoscopic Ventral Rectopexy (LVR) for rectal prolapse syndromes in a large cohort of consecutive patients.

Background data

Long-term outcome data for prolapse repair are rare. A high incidence of mesh-related problems has been noted after transvaginal approaches using nonresorbable meshes

Methods

All patients treated with LVR at the Meander Medical Centre, Amersfoort, the Netherlands and the University Hospital Leuven, Belgium between January 1999 and March 2013 were enrolled in this study. All data were retrieved from a prospectively maintained database. Kaplan-Meier estimates were calculated for recurrences and mesh-related problems.

Results

919 consecutive patients (869 women; 50 men) underwent LVR. A 10-year recurrence rate of 8.2% (95% confidence interval 3.7 - 12.7) for external rectal prolapse repair was noted. Mesh-related complications were recorded in 18 patients (4.6%), of which mesh erosion to the vagina occurred in 7 patients (1.3%). In five of these patients, LVR was combined with a perineotomy. Both rates of fecal incontinence and obstructed defecation decreased significantly ($p < 0.0001$) after LVR compared to the preoperative incidence (11.1% *versus* 37.5% for incontinence and 15.6% *versus* 54.0% for constipation)

Conclusions

LVR is safe and effective for the treatment of different rectal prolapse syndromes. Long-term recurrence rates are in line with classic types of mesh rectopexy and occurrence of mesh-related complications is rare.

Introduction

Rectal prolapse (RP) and concomitant rectocele and enterocele can be associated with pelvic discomfort and a varying degree of symptoms such as obstructed defecation, and/or fecal incontinence¹⁻⁴. Throughout the past century, more than 100 different surgical techniques have been described to repair RP^{5,6}. Heterogeneity of studies makes it difficult to determine the optimal surgical technique⁷. Laparoscopic ventral mesh rectopexy (LVR), as described by D'Hoore et al., has gained increasing acceptance to correct RP⁸⁻¹¹. The technique corrects the descent of the posterior and middle pelvic compartment and reinforces the rectovaginal septum. Dissection is limited to the anterior aspect of the distal rectum followed by a mesh suspension to the sacral promontory. Avoidance of extensive rectal mobilization minimizes the risk for autonomic nerve damage and related new-onset constipation. A recent systematic review of 760 patients (15 studies) provides support for the safety and short-term efficacy of the procedure¹². In 2008 and again in 2011, the US Food and Drug Administration (FDA) expressed its concern about the high rate of mesh-related complications in pelvic organ prolapse (POP) surgery¹³. Although this warning was primarily intended for transvaginal procedures, also considerable uncertainty was created about the safety of abdominally placed meshes. Therefore, the aim of this study was to further assess safety and effectiveness of LVR and report in detail on mesh-related morbidity in a large cohort of patients with substantial follow-up.

Patients and methods

Study design

This observational cohort study is a retrospective analysis based on two prospectively maintained databases and was performed in a large teaching hospital in the Netherlands and a university hospital in Belgium. All consecutive patients older than 18 years who underwent LVR between January 1999 and April 2013 were included. The study was approved by the medical ethics committees of both centres. Patients were seen in the outpatient clinic at 6 weeks and 3 months post-operative. The majority of patients received longer follow-up in accordance with two previous studies^{19,21}. All patients were instructed to return in the event of symptoms of recurrence.

Patients and evaluation

All patients suffered from an external rectal prolapse (ERP) or an Oxford grade III/IV internal rectal prolapse (IRP) with symptoms of fecal incontinence or obstructed defecation. In addition a descent of the middle pelvic compartment (rectocele, enterocele) could be present. The extent of the anatomical defect was assessed by dynamic MRI or colpo-cysto-defecography¹⁴. Fecal continence was graded as proposed by Browning and Parks¹⁵ (grade 1, continent; grade 2, incontinent to flatus; grade 3, incontinent to flatus and liquid stools; grade 4, incontinent to flatus, liquid and solid stools). Grade 1 and 2 were graded as 'continent', grade 3 and 4 as 'incontinent'. Incontinent patients had further sphincter evaluation. In case of fecal incontinence combined with an insufficient sphincter function the prolaps was corrected first. Rome II criteria were used to assess constipation and to arbitrarily differentiate between obstructed defecation and slow transit constipation in accordance to D'Hoore et al^{10,16}. A radiopaque marker test was performed if patients revealed a pattern of low frequency constipation. The functional outcome was measured at the moment of last follow-up. In patients where a re-intervention was indicated, the functional outcome was noted at the last follow-up before the intervention. Postoperative morbidity was classified according to the Clavien-Dindo (CD) classification^{17,18}. Grade I and II were assigned as minor, grade $\geq$ III as major. Mesh related morbidity was recorded separately.

Surgical technique

The surgical technique of LVR was performed according to the technique as described in detail by D'Hoore et al.⁹ In Belgium a Marlex (Bard, Crawley, UK) mesh was used. In the Netherlands either a Hi-TEC mesh (Textiles Hi-Tec, Labastide-Rouairoux, France) (until mid2007) or a Prolene (Ethicon Inc., Johnson & Johnson, Hamburg, Germany) mesh (from mid2007 and onwards) was inserted. The change of mesh was due to a new policy in stock acquisition, not on any surgical grounds¹⁹. The mesh was attached to the sacral promontory using titanium tacks (Autosuture Protack 5mm, Covidien, USA), a stapler (Endopath EMS; Ethicon Endosurgery, Norderstedt, Germany) and/or non-resorbable sutures. The mesh was sutured to the ventral aspect of the distal rectum. In patients with a concomitant symptomatic low rectocele (level III, perineocele), a small perineotomy was performed to complete the rectovaginal septum dissection to the level of the perineal body. The mesh was sutured on top of the anal sphincters to obtain complete rectovaginal septum reinforcement. Technical details were highlighted elsewhere^{20,21}.

Statistical Analysis

Statistical Package for the Social Science, version 20.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Data are presented as percentage, mean $\pm$ S.D, median and range. Because of difference in follow-up between patients the Kaplan-Meier method was used to estimate the complication and recurrence rate at various timepoints. In the text, the risk estimates after a period of 10 years are presented. To evaluate differences in functional outcome, McNemar tests were used. $P < 0.05$ was considered statistically significant.

Results

Patients characteristics and operative data

A total of 919 patients (869 females; 50 males) underwent LVR (Table 1). One hundred six patients (11.5%) had an additional perineotomy to correct a level III perineocele^{20,21}. Five hundred twenty one (56.7%) patients had previous pelvic or abdominal surgery; 338 (36.8%) received hysterectomy, 85 (9.2%) cystopexy, 96 (10.4 %) posterior colporrhaphia and 12 (1.3%) various sphincter operations. In twenty (2.2%) patients conversion to laparotomy was required. The reasons for conversion were extensive intra-abdominal adhesions in 13 patients, bleeding from the left iliac vein (n=4), poor visibility (n=1), small bowel perforation (n=1) and an anesthesia-related cause (n=1). In addition, intra-operative complications occurred in three patients (0.3%). In two patients a posterior vaginal wall perforation occurred and in one patient the rectum was perforated. All perforations were sutured during surgery. In both patients with vaginal lacerations LVR was continued. The procedure complicated by a rectal perforation was aborted and performed uneventful at an interval of 4 months. No mesh-related complications occurred after these intra-operative complications.

Early postoperative course

Postoperative in-hospital mortality occurred in one (0.1%) 85 -year-old ASA IV patient as a result of urosepsis. Mean overall length of hospital (LOS) stay was 4.4 days (range 1 – 30, SD 2.45) with a median of 4 days. Mean LOS stay decreased from 5.92 days (first 50 patients per hospital) to 3.86 (last 50 patients per hospital). Early postoperative (< 30 days) complications were observed in 110 (12.0%) patients. Only 1.6% of these patients had a major complication (Table 1).

Table 1. Patient characteristics, operative data, early postoperative course and functional outcome per hospital

	Total n = 919 (%)	Leuven n=498 (%)	Amersfoort n=421 (%)
Women/men [mean age]	869/50 [55.8]	463/34 [50.7]	405/16 [61.8]
Diagnosis – <i>ERP</i>	242 (26.3)	186 (37.3)	56 (13.3)
<i>IRP or/and symp. rectocele*</i>	460 (50.1)	194 (39.0)	266 (63.2)
<i>* with enterocele</i>	217 (23.6)	118 (23.7)	99 (23.5)
Conversion	20 (2.2)	10 (2.0)	10 (2.4)
Postoperative in-hospital mortality	1 (0.1)	0	1 (0.2)
Length of hospital stay (mean)	4.4	4.4	4.5
Early postoperative complications	114 (12.4)	82 (16.5)	32 (7.6)
<i>Major</i>	15 (1.6)	7 (1.4)	8 (1.9)
<i>Minor</i>	99 (10.8)	75 (15.1)	24 (5.7)
Pre-op fecal incontinence	344 (37.5)	121 (24.3)	223 (53.0)
<i>Grade 3 B&P</i>	18 (2.0)	3 (0.6)	15 (3.6)
<i>Grade 4 B&P</i>	326 (35.5)	118 (23.7)	208 (49.4)
Post-op fecal incontinence	102 (11.1)	50 (10.0)	52 (12.4)
<i>Grade 3 B&P</i>	27 (2.9)	17 (3.4)	10 (2.4)
<i>Grade 4 B&P</i>	75 (8.2)	33 (6.6)	42 (10.0)
Pre-op obstructed defecation	496 (54.0)	269 (54.0)	227 (53.9)
Post-op obstructed defecation	143 (15.6)	73 (14.7)	70 (16.6)
	12 ST (1.3)	11 (2.2)	1 (0.2)

ERP: external rectal prolapse, IRP: internal rectal prolapse, symp.: symptomatic, B&P: grading system as proposed by Browning and Parks, ST: slow transit.

Long-term outcome

Late postoperative complications

Median follow-up after LVR was 33.9 months (range 0.4 - 143.6). Seven hundred and ninety patients (86.0%) were available for follow-up after 3 months. During follow-up, 23 patients (2.5%) died of a cause unrelated to LVR. Seventy-eight patients suffered from 89 late complications (> 30 days, table 2). Three patients developed a septic spondylodiscitis. This was treated by antibiotics in one patient (early complication). The second patient required extensive orthopaedic surgery and has, despite control of the sepsis, chronic invalidating lumbosacral pain. In the third patient the discitis was due to a rectal perforation for which the mesh was removed and a deviating colostomy was created (Table 2).

Table 2. Late and mesh complications after LVR – treatment^a

	Total (%^b)	CD Classification^{17, 18}	Months^c
Late complication			
<i>Minor</i>			
Dyspareunia	21 (3.3)	21 I	8.2 [1.1 – 60.3]
Proctalgia fugax	17 (2.5)	17 II	5.4 [1.1 – 38.8]
Anal fissure	14 (2.4)	14 I	5.2 [1.3 – 70.9]
Chronic pelvic pain	1 (0.1)	I	1.1
SRUS/rectitis	1 (0.2)	II	13.5
Total minor late complications >30 days n=54 (8.5%)			
<i>Major</i>			
Perianal fistula – fistulectomy	4 (0.6)	4 IIIa	11.5 [3.2 – 13.5]
Incisional hernia – primary closure	5 (0.9)	5 IIIb	12.0 [5.1 – 52.3]
Anal fissure – LIS	2 (0.3)	2 IIIa	6.4 [4.4 – 13.6]
Chronic pain – adhesiolysis/cleaving mesh	3 (0.4)	3 IIIb	11.0 [4.3 – 14.4]
Neurinoma scar – excision	1 (0.1)	IIIa	7.5
Spondylodiscitis – prolonged AB/orthopaedic surgery (spondylodesis, stabilization titanium cage)	1 (0.1)	IIIb	2.8
Rectal perforation/spondylodiscitis/sepsis – mesh removal/ double-barrel colostomy	1 (0.1)	IIIb	1.5
Total major late complications n=17 (2.5%)			
<i>Mesh complication</i>			
Mesh detachment – re-do rectopexy	9 (2.7)	IIIb	45.6 [5.0 – 99.3]
Mesh erosion – resection	7 (1.3)	IIIb	8.9 [1.7 – 47.9]
Obstruction/pre-sacral adhesions mesh – adhesiolysis/partial enterectomy	1 (0.4)	IIIb	69.6
(Chronic) mesh infection and fistula - low anterior side to end coloanal anastomosis	1 (0.2)	IIIb	18.2
Total mesh complications n=18 (4.6%)			

LIS: Lateral internal sphincterotomy. SRUS: solitary rectal ulcer syndrome, AB: antibiotics. ^a All minor late complications were treated conservative. ^b All percentages are Kaplan-Meier (KM) estimates at 10 years of follow-up. ^c Median [minimum - maximum] duration in months between surgery and complication of the observed events (hence not based on the KM curve).

Mesh-related complications

Eventually 18 patients developed a mesh-related complication. The estimated percentages (Kaplan Meier) were 1.5% after 3, 2.9% after 5 and 4.6% after 10 years (95% confidence interval (CI) 2.1 - 7.1, see figure 1 for Kaplan Meier curve). Erosion of the mesh to the vagina occurred in 7 (1.3%) patients (Table 2, all percentages are Kaplan-Meier estimates at 10 years). Five of these patients had received a perineotomy in addition to the standard LVR^{20,21}. In all erosions debridement of the mesh was performed and the vagina was closed over the defect. Most patients had pre-treatment with topical estrogen. Two patients needed a second procedure and one patient underwent 3 interventions due to erosion, but at the end of follow-up all defects were closed without residual localized sepsis. In addition, one patient developed a complex fistula to the rectum and vagina. In this patient a restorative resection with a low colorectal anastomosis was performed 18.2 months after LVR. Dehiscence of the cranial side of the mesh (sacral promontory) was the reason for RP recurrence requiring refixation in 9 patients.

Figure 1. Kaplan-Meier curve for mesh related complications for the total cohort (continuous line, n=919) and the confidence interval (dotted line). The duration of event-free survival was measured from date of surgery to the time of the event (complete) or the last follow-up (censored). At the bottom of the figure a table with the number of patients left for analysis at each time point is presented.

Functional outcome - Fecal incontinence

Pre-operatively, 344 patients (37.5%) suffered from fecal incontinence and at final follow-up a postoperative improvement of 80.2% (n=276) was reported. Two hundred and forty-seven patients went from grade 4 to 1/2, 16 from grade 3 to 1/2 and 13 from grade 4 to 3 and the remaining 68 sixty-eight patients (66 grade 4, 2 grade 3) did not change. ERP showed a decrease of fecal incontinence complaints from 40.5% to 14.8%, IRP and/or symptomatic rectocele from 37.8% to 8.5% and IRP and/or symptomatic rectocele combined with enterocele from 32.2% to 12.5% ($p<0.0001$, Table 3). New onset incontinence was documented in 21 patients (2.3%).

Table 3. Functional outcome and recurrence

Functional outcome	Total n (%)	ERP (n=242)	IRP and/or symptomatic rectocele (n=460)	IRP and/or symptomatic rectocele with enterocele (n=217)
<i>Fecal incontinence</i>				
Pre-op	344 (37.5)	98 (40.5)	174 (37.8)	72 (33.2)
<i>Grade 3</i>	18	3	8	7
<i>Grade 4</i>	326	95	166	65
Last FU	102 (11.1)	36 (14.8)	39 (8.5)	27 (12.5)
<i>Grade 3</i>	27	10	9	8
<i>Grade 4</i>	75	26	30	19
<i>p</i> value	<i>p</i> <0.0001	<i>p</i> <0.0001	<i>p</i> <0.0001	<i>p</i> <0.0001
<i>Obstructed defecation</i>				
Pre-op	496 (54.0)	82 (33.9)	291 (63.3)	123 (56.7)
Last FU	143 (15.6)	32 (13.2)	75 (16.3)	36 (16.6)
<i>ST</i>	12 (1.3) <i>ST</i>	4 (1.7) <i>ST</i>	7 (1.5) <i>ST</i>	1 (0.5) <i>ST</i>
<i>p</i> value	<i>p</i> <0.0001	<i>p</i> <0.0001	<i>p</i> <0.0001	<i>p</i> <0.0001
Recurrence				
	Total	ERP (n=242)	IRP and/or symptomatic rectocele with or without enterocele (n=677)	
Duration ^a between surgery and recurrence	24.1 (1.0 – 139.4)	22.0 (3.8 – 64.6)	24.8 (1.0 – 139.4)	
<i>Initial diagnosis</i>				
ERP	21	13	8	
IRP and/or symp. rectocele with/without enterocele	47	2	45	
Total recurrences	68	15	53	

ERP: external rectal prolapse, IRP: internal rectal prolapse, pre-op: pre-operative, FU: follow-up, ST: slow transit constipation, symp.: symptomatic. ^a Median [minimum - maximum] duration in months between surgery and recurrence of the observed events (hence not based on the Kaplan Meier curve).

Functional outcome - Obstructed defecation, constipation

Twenty-two (2.4%) patients developed new onset constipation and 12 patients with slow transit colonic constipation did not improve after LVR. The pre-operative presence of outlet obstruction (n= 496, 54%) declined significantly after surgery (n=143, 15.6%, $p<0.0001$). In patients with IRP and/or symptomatic rectocele, symptoms of obstructed defecation resolved in 74.2%. This was the case in 70.7% of patients with IRP and/or symptomatic rectocele combined with enterocele and in 61.0% of those with ERP ($p<0.0001$, table 3). Overall functional differences between the two hospitals are shown in Table 1.

Recurrence

A total of 68 patients developed a recurrence (Table 3). The estimated recurrence percentages for the whole cohort according to the Kaplan Meier method were 7.0% after 3, 10.7% after 5 and 14.3% after 10 years (95% CI 10.6 – 18.0).

Recurrence after LVR for ERP

Thirteen patients with ERP (13/242) developed a clinical full-thickness external prolapse recurrence generating a recurrence percentage (Kaplan-Meier estimates) of 4.2%, 7.2% and 8.2% (95% CI 3.7 - 12.7) after 3, 5 and 10 years (Figure 2). In addition 8 patients developed a symptomatic IRP with/without enterocele recurrence requiring surgical correction.

Recurrence after LVR for IRP

Forty-five patients were diagnosed with recurrent IRP with/without enterocele (45/677) and two patients developed an ERP (2/677, Table 3). The Kaplan-Meier estimates for recurrence for patients initially diagnosed with IRP was 7.5% after 3, 11.1% after 5 and 14.2% after 10 years.

Figure 2. Kaplan-Meier curve patients with an ERP recurrence within the ERP group (continuous line, n=242) and the confidence interval (dotted line). The duration of recurrence-free survival was measured from date of surgery to the time of recurrence (complete) or the last follow-up (censored). At the bottom of the figure a table with the number of patients left for analysis at each time point is presented.

Discussion

Surgery for rectal prolapse not only aims to correct the anatomical defect but should also improve anorectal function and avoid postoperative functional sequelae. LVR is rapidly becoming the procedure of choice to correct rectal prolapse syndromes¹¹. In our cohort half of the patients had previous abdominal or pelvic surgery, which is high compared to similar smaller studies^{9,10}. Nonetheless a low conversion rate (2.2%) was found, comparable to recent literature⁸⁻¹⁰. During the dissection of the sacral promontory it should be noted that the left iliac vein is at risk. Inadvertent vaginal or rectal perforation should be treated with meticulous suture closure and delayed mesh rectopexy. Most postoperative morbidity is minor and underscores the safety and reproducibility of the technique²²⁻²⁴. Sacral discitis is a rare complication; prompt diagnosis should prevent long-term sequelae^{12, 25}. Considering the low perioperative and postoperative complication rate, LVR can be considered safe. Over time the risk for recurrence increases. The actuarial 10-year ERP recurrence rate in our study is 8.2% (CI 3.7-12.7). In a multicentre pooled analysis of 643 individual patients, data on different abdominal surgical techniques to treat RP showed a five- and ten-year recurrence of 6.61 and 28.9 percent, regardless of the technique being used²⁶. Foppa et al. reported a crude 5-year recurrence rate of 6% but an actuarial 10-year recurrence rate of 20% (CI 10.8-20.1) in 179 patients after laparoscopic suture rectopexy²⁷. LVR studies with shorter follow-up consequently show lower ERP recurrences rates varying from 1.6% to 5.6%^{9, 10, 28-32}, with one small report with a percentage of 15.4%³³. These studies reflect the need to have long-term follow-up data to evaluate ultimate efficacy of rectopexy. In total (ERP/IRP), 68 recurrences were seen generating a 10yrs KM of 14.3%. This number is high compared to recurrence rates in recent studies including both ERP and IRP and describing recurrences of both entities (0% to 9.4%^{19, 34-38}). However, these are small studies with large differences in follow-up. The study of Mackenzie and Dixon compares best to our series (9.4% total recurrence ERP/IRP)³⁸. Recurrence rates in our cohort are comparable with other rectopexy techniques that require more extensive rectal mobilization^{22, 39, 40}. Most recurrences occur after dehiscence of the mesh from the sacral

promontory. However, we reinforce the mechanical fixation with one or two additional non-resorbable sutures. The risk for mesh related complications is key importance. The FDA warning is based on data from 110 studies including 11,785 women, where approximately 10 percent of women undergoing transvaginal POP repair with mesh will experience mesh erosion within 12 months⁴¹. A large systematic review (21 studies, n=1,869) on sacral colpopexy showed an erosion rate of 4.7% (median 4.0%) for non-absorbable synthetic mesh thus showing that abdominal POP surgery using mesh generates lower rates of mesh complications compared to transvaginal POP surgery with mesh⁴². The laparoscopic route for rectovaginal septum reinforcement using synthetic mesh is more safe with an actuarial 10-year risk for erosion of only 1.3% in this series. Furthermore this risk can be reduced by avoiding an additional perineotomy to correct low rectoceles, considering the incidence of erosion in the perineotomy group (5/106, 10yrs KM 6.2%). A review comparing multiple techniques for RP using mesh, reported 2% to 16% of patients with prosthetic rectopexy developing significant pelvic sepsis⁴⁰. However, specific literature on mesh-related complications following LVR is limited. Mesh complication rates from 0% to 6.7% with mesh erosion percentages between 0% and 3.7% are described^{19, 22, 24, 31, 32, 35-38, 43, 44}. Although there are serious concerns about mesh complications in POP surgery, based on this study and the literature it seems this is less of an issue regarding LVR. The use of biologicals is still under debate and more data is needed to balance between the risk for recurrence and graft-related morbidity. The behaviour and tissue incorporation of the available biological grafts differ which makes outcome comparison difficult. Recent literature shows no statistical difference between biologic and non-absorbable mesh, but follow-up is short for studies concerning biologicals^{43, 44}. Surgical prolapse repair also aims to improve anorectal function. We observed a significant decrease in symptoms of obstructed defecation and a significant improvement of fecal continence. These findings correlate with literature on LVR without posterior rectal mobilization showing rates from 15.4% to 83.3% and a mean decrease of 40.3% for constipation and 13.6% to 77.3% with an overall weighted mean decrease of 44.9% for fecal incontinence²². In our cohort, new-onset constipation was only noted

in 22 (2.4%) patients. A systemic review on functional outcome of different rectopexy techniques reported new-onset constipation in 5.5% to 10.5% for LVR without posterior rectal mobilization²². The most important limitation of this study are the differences in follow-up between patients due to the retrospective character. Although the Kaplan-Meier method yield appropriate estimates for recurrence and complication rates at various points in time, underestimation remains possible. In the evaluation of functional scores, differences in follow-up were even ignored. Therefore selection bias may have occurred, since the probability of a revisit might be related to the degree of complaints. Furthermore, we cannot draw any conclusion on the within-patient evolution of the functional score, because these dates are cross-sectional. These limitations should be taken into account interpreting the long-term outcomes.

Conclusion

Laparoscopic ventral rectopexy is a safe and reliable technique to repair different rectal prolapse syndromes. It results in acceptable long-term recurrence rates while functional improvement is significant. Mesh-related problems are rare.

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Chapter 6

Robot-Assisted Ventral Mesh Rectopexy for rectal prolapse: a 5-year experience at a tertiary referral centre

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Accepted Diseases of the Colon & Rectum

Abstract**Background**

Laparoscopic ventral mesh rectopexy is being increasingly performed internationally to treat rectal prolapse syndromes. Robotic assistance appears advantageous for this procedure, but literature regarding robot-assisted ventral mesh rectopexy is limited

Objective

The primary objective of this study is to assess the safety and effectiveness of robot-assisted ventral mesh rectopexy in the largest consecutive series of patients to date

Design

This study is a retrospective cross-sectional analysis of prospectively collected data

Settings

The study was conducted in a tertiary referral centre.

Patients

All patients undergoing robot-assisted ventral mesh rectopexy for rectal prolapse syndromes between 2010 and 2015 were evaluated.

Intervention

Robot-assisted ventral mesh rectopexy.

Main Outcome Measures

Pre- and postoperative (mesh and nonmesh) morbidity and functional outcome were analysed. The actuarial recurrence rates were calculated using the Kaplan-Meier method.

Results

A total of 258 patients underwent robot-assisted ventral mesh rectopexy (mean follow-up 23.5 months, range 0.2 – 65.1, SD $\pm$ 21.8). There were no conversions and only five (1.9%) intra-operative complications. Mortality (0.4%), major (1.9%) and minor early (<30 days) morbidity (7%) were acceptably low. Only one (1.3%) mesh-

related complication (asymptomatic vaginal mesh erosion) was observed. A significant improvement in obstructed defecation in 78.6% of patients and fecal incontinence of 63.7% was achieved (both $p < 0.0005$). At final follow-up, new-onset of fecal incontinence and obstructed defecation were induced or worsened in 3.9% and 0.4%. The actuarial 5-year ERP and IRP recurrence rates were 12.9% and 10.4%, respectively.

Limitations

This was a retrospective study including patients with minimal follow-up. No validated scores were used to assess function. The study was monocentric and there was no control group.

Conclusions

Robot-assisted ventral mesh rectopexy is a safe and effective technique to treat rectal prolapse syndromes, providing an acceptable recurrence rate, good symptomatic relief with minimal morbidity.

Introduction

Surgical robots were introduced in the late 1990s to expand the benefits of minimally invasive surgery¹. The enhanced visualization, dexterity and precision make the use of surgical robotics particularly suitable for confined spaces, such as the pelvis. Currently, conventional laparoscopic ventral mesh rectopexy (LVMR) appears to be the treatment of choice for external rectal prolapse (ERP) for the majority of surgeons in Europe and an increasing number of surgeons in the U.S.²⁻⁴. Growing evidence on safety and improved functional outcome has contributed to this growth in popularity⁵. In recent years, the indication for LVMR became wider as it also successfully treats large symptomatic rectoceles and internal rectal prolapse (IRP)^{4,6-10}. Dissection of the rectovaginal septum down to the pelvic floor and suturing a mesh to the ventral aspect of the rectum as distally as possible, are crucial steps during ventral mesh rectopexy. Especially for these steps, robotic assistance has been found advantageous. The literature regarding robotic ventral mesh rectopexy (RVMR) is quite limited. To date, less than 200 RVMR procedures have been described^{1,11-19}. The aim of this article was thus to further assess the safety and effectiveness of RVMR in the largest consecutive series of patients thus far described.

Methods

Study design

This observational cohort study is a retrospective cross-sectional analysis of a prospectively maintained database and was undertaken in a tertiary referral centre for pelvic floor disorder in the Netherlands. All consecutive patients referred between February 2010 and October 2015 who underwent RVMR for rectal prolapse syndromes were analysed. All of the procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments. Informed consent was obtained for all of the patients.

Evaluation

Indication for surgery was an ERP or an Oxford grade III/IV (recto-anal) IRP with symptoms of fecal incontinence or obstructed defecation failing to respond to conservative therapy²⁰. An additional enterocele or rectocele may be present. The diagnosis was suggested on history of functional symptoms and clinical examination and confirmed radiologically by a dynamic MRI and/or a entero-colpo defecography²¹. Prior to surgery, all patients were discussed in a multidisciplinary meeting by specialist gynaecologists, urologists, radiologists, pelvic floor physical therapists and pelvic floor surgeons. The majority of patients with an IRP were treated with biofeedback therapy first. Perioperative, postoperative early (< 30 days) and late complications were classified using the Clavien-Dindo Classification (CD)²². CD grade 1 and 2 were classified as minor, CD grade ≥ 3 as major. Rome III criteria were used to diagnose and differentiate between constipation and obstructed defecation according to D'Hoore et al^{23,24}. Based on this classification, patients were divided into three groups: no complaints, obstructed defecation and a combination of obstructed defecation and slow-transit constipation (ST). If ST was suspected, a colonic transit study was performed. Fecal continence was graded according to Browning and Parks into four categories; grade 1, continent; grade 2, incontinent to flatus; grade 3, incontinent to flatus and liquid stools; grade 4, incontinent

to flatus, liquid and solid stools²⁵. Grade 1 and 2 were classified as “continent”, grade 3 and 4 as “incontinent”. A patient was declared incontinent if grade 3 or 4 complaints occurred at least once a month. In patients with an additional ST or an insufficient sphincter function, RVMR was performed before surgery for ST or for a sphincter defect was offered. Before and 6 weeks after surgery all patients completed an institutional questionnaire including constipation questions based on the Rome III criteria and the Browning and Parks incontinence score^{24,25}. Functional outcome was measured at the time of last RVMR follow-up, or just before a re-intervention to improve function was performed. Recurrence was defined as complaints of persistent or new symptoms, together with an anatomical prolapse (Oxford grade ≥ 2) diagnosed by proctoscopy and dynamic MRI. All patients were followed up in the outpatient clinic at 6 weeks for an assessment of morbidity, function and recurrence and thereafter on demand. All patients were asked to return in the event of anorectal complaints. Ninety-five cases (36.8%) received longer follow-up (6 weeks postoperatively and annually thereafter), as part of a still ongoing study.

Surgical technique

All of the procedures are performed by 3 experienced pelvic floor surgeons using the four-armed da Vinci® Si HD surgical system (Intuitive Surgical Inc., Sunnyvale, CA). The patients are positioned in a steep Trendelenburg position using adaptable leg supports with swing stirrups. The robotic procedures are performed according to the laparoscopic technique described by D’Hoore et al.²³ The camera trocar is introduced through the upper margin of the umbilicus. Three 8-mm ports, for robotic arms number 1 to 3, and an additional 8-mm trocar is placed between the camera trocar and the robotic trocar for robotic arm 1 assistance (Figure 1). The robotic cart is positioned at the lower left side of the OR table. The rectosigmoid junction is retracted to the left and a peritoneal incision is made over the right side of the sacral promontory and extended to an inverted J-form along the rectum. Care is taken to avoid damage to the presacral nerve plexus during dissection of the sacral promontory, as well as to the right hypogastric nerve, while opening the rectovaginal septum in females or Denonvillier’s fascia in

male patients. The septum is opened down to the level of the anal sphincter and pelvic floor muscles. No lateral mobilization or lateral dissection of the rectum is performed. Subsequently, a 3 cm x 15 cm strip of polypropylene (Prolene, Ethicon Inc., Johnson & Johnson, Hamburg, Germany) is fixed to the ventral aspect of the distal rectum using Ethibond sutures (Ethicon, Figure 2). The proximal end of the mesh is fixed to the sacral promontory using titanium tacks (Autosuture Protack 5 mm, Covidien, Minneapolis, MN). The posterior vaginal fornix is elevated and sutured to the anterior aspect of the mesh in female patients, closing the rectovaginal septum. Finally, the peritoneum is approximated using a 23-cm V-Loc suture (Covidien). The cut end of the V-Loc suture was buried in the peritoneum. The operative time from incision to wound closure was measured.

Figure 1. Port placement. Robotic trocars R1, R2 and R3, camera port C and the assistant port AP.

Figure 2. Opening the rectovaginal septum (A), suturing the mesh to the ventral aspect of the rectum (B), tacking to the sacral promontory (C) and closure of the peritoneum over the mesh (D).

Statistical Analysis

Statistical Package for the Social Science, version 20.0 (IBM Corp, Armonk, NY) was used for statistical analysis. Data are presented as percentage, mean $\pm$ S.D, median, and range. Because of a large range in follow-up, long-term complication and actuarial recurrence rates were calculated at various time points using the Kaplan-Meier method. In the text, the risk estimates after a period of 5 years are presented. McNemar's test was used for the presence/absence of constipation and fecal incontinence before and after RVMR. P values <0.05 were considered significant.

Results

Patient demographics and follow-up

A total of 258 patients (248 female) underwent RVMR for ERP (n=48, 18.6%), IRP and/or symptomatic rectocele (n=139, 53.9%) or IRP and/or symptomatic rectocele with an enterocele (n=71, 27.5%, Table 1). Mean age at the time of surgery was 60.3 years (range 22.3 – 95.7, SD $\pm$ 13.7). Mean follow-up was 23.5 months (range 0.2 – 65.1, SD $\pm$ 21.8). Two hundred and twenty-seven patients (88%) were available for follow-up after the postoperative control of 6 weeks.

Table 1. Patient characteristics and admission details

		Total n = 258
Women/men (mean age, range, SD)		248/10 (60.3, 22.3 – 95.7, $\pm$ 13.7)
Mean ASA classification (range, SD) [mean BMI, SD]		1.69 (1-3, $\pm$ 0.6) [26.0, $\pm$ 4.7]
Mean parity (range, SD) [episiotomy, %]		2.39 (0 – 7, $\pm$ 1.3) [62, 24.0]
Primary/re-do rectopexy		248/10
History (%)	Hysterectomy	90 (34.9)
	Sacrocolpopexy	4 (1.6)
	Cystopexy	20 (7.8)
	Colporrhaphia anterior	26 (10.1)
	Colporrhaphia posterior	27 (10.5)
	TVT	9 (3.5)
	Perineal procedure	1 (0.4)
	Sphincter procedure	4 (1.6)
	Hemorrhoidectomy	21 ^a (8.1)
	Other abdominal surgery	90 (34.9)
Diagnosis (%)	ERP	48 (18.6)
	IRP or/and symp. rectocele*	139 (53.9)
	* with enterocele	71 (27.5)
Mean total operation time^b, minutes (range, SD)		85 (52 – 127, $\pm$ 18)
Conversion		0
Intra-operative complications (%)		5 (1.9)
Mean length of hospital stay, nights (range, SD)		3.4 (1 – 12, $\pm$ 1.4)

^a Two patients underwent 2 hemorrhoidectomies pre-operatively; ^b time from incision until closure of the incisions; ASA indicates American society of anaesthesiologists; BMI body mass index; TVT: Tension-Free Vaginal Tape; symp.: symptomatic.

Surgical details and perioperative morbidity

The mean total operation time was 87.2 minutes (range 55.0 – 218.2 , SD ± 18.8). In three patients with an extensive pelvic floor history, the procedure was aborted because of a frozen pelvis. One of those patients underwent a robotic resection rectopexy several months later; one was treated with sacral nerve stimulation and one decided against further treatment. One further procedure was cancelled for cardiopulmonary reasons. There were no conversions and the estimated blood loss was less than 300 mL in all cases. Intra-operative complications occurred in five (1.9%) patients; two small posterior vaginal wall perforations, one minor bladder perforation and two mild haemorrhages. All perforations and haemorrhages were over-sewn and all procedures were continued with placement of the mesh. One of the patients with a posterior vaginal wall perforation, developed an abscess in the rectovaginal septum for which surgical drainage (Pfannenstiel incision) was required. This procedure was complicated by a bladder perforation and eventually a colovesical fistula, requiring a temporary colostomy. This case accounted for two of the five (1.9%) major early (<30 days) postoperative complications (Table 2). The majority of the early postoperative morbidity was minor (7%, Table 2). One of those minor complications was a spondylodiscitis of L5-S1 which was treated with antibiotics (2 weeks intravenous, 4 weeks oral).

Late nonmesh and synthetic mesh-related morbidity

Six (2.3%) patients died from unrelated causes during follow-up. Fifteen patients developed 16 late complications (Table 3). One patient (91-year-old female, ERP, ASA II) was readmitted six weeks after an uncomplicated RVMR with severe septic shock based on bowel ischemia. Palliative care was started (CD grade 5). Whether RVMR was directly related to this event could not be determined. There was only one (1.3%) a symptomatic mesh erosion of the posterior wall of the vagina for which oestrogen cream was sufficient (Table 3).

Table 2. Early (<30 days) complications – *treatment* **Total (%)** **CD class.²²**

<i>Minor</i>		
UTI - <i>antibiotics</i>	3 (1.2)	II
Urinary retention - <i>catheter</i>	3 (1.2)	II
Bladder spasms with catheter - <i>oxybutynin</i>	2 (0.8)	II
Pneumonia - <i>antibiotics</i>	1 (0.4)	II
Hypertension - <i>antihypertensive</i>	1 (0.4)	II
Pulmonary edema - <i>diuretic</i>	1 (0.4)	II
Constipation – <i>enema</i>	1 (0.4)	II
Spondylodiscitis - <i>antibiotics</i>	1 (0.4)	II
Paralytic ileus – <i>conservative</i>	1 (0.4)	I
Gastroenteritis – <i>conservative</i>	1 (0.4)	I
Wound infection – <i>conservative</i>	1 (0.4)	I
Electrolyte imbalance – <i>electrolytes</i>	1 (0.4)	I
Paresthesia genitofemoral nerves bilateral - <i>conservative</i>	1 (0.4)	I
Total minor early complications n=18 (7.0)		
<i>Major</i>		
Bowel obstruction – <i>adhesiolysis</i>	3 (1.2)	IIIb
Abscess rectovaginal septum - <i>surgical drainage</i>	1 (0.4)	IIIb
Colovesical fistula - <i>temporary colostomy</i>	1 (0.4)	IIIb
Total major early complications n=5 (1.9)		

UTI: urinary tract infection

Obstructed Defecation

An overall improvement of obstructed defecation was achieved in 78.6% of patients (Table 4, $p<0.0005$). Functioning did not improve following RVMR in four patients (1.6%) with slow transit constipation in combination with obstructed defecation syndrome (ODS). A decrease in obstructed defecation was seen in 85% of patients with an ERP ($p<0.0005$). No new-onset obstructed defecation occurred in ERP patients. Obstructed defecation improved in 81.2% (82/101) of patients with IRP and/or symptomatic rectocele and 19 patients (18.8%) experienced persistent complaints ($p<0.0005$). One patient (2.9%) developed *de novo* obstructed defecation in this subgroup of patients. Obstructed defecation resolved in 72.3% of patients with an enterocele ($p<0.0005$). Thirteen patients (27.7%) with an enterocele continued to have complaints and no patient developed new-onset symptoms (Table 4).

Table 3. Late and mesh complications - treatment

	Total (%^a)	CD class.²²	Months
<i>Late complication</i>	<i>Minor</i>		
New-onset pain posterior side both legs eci – <i>conservative</i>	1 (1)	I	26.5
New-onset lower back pain eci – <i>conservative</i>	1 (0.8)	I	13.6
Chronic pelvic pain – <i>conservative</i>	1 (0.7)	I	10.9
Anal fissure – <i>diltiazem cream</i>	2 (1.0)	I	1.9, 3.9
Total minor late complications >30 days n=5 (3.5)			
<i>Late complication</i>	<i>Major</i>		
Chronic pain coccyx – <i>botox injection</i>	1 (0.7)	IIIa	12
Perianal fistula – <i>fistulectomy</i>	1 (0.6)	IIIa	6.1
Anal fissure – <i>LIS</i>	2 (1.5)	IIIa	1.6, 36.7
Proctalgia fugax – <i>TENS</i>	1 (0.4)	IIIa	1.2
Vaginal pain and obstructed micturition – <i>adhesiolysis, vaginal mesh release, cleaving TVT</i>	1 (0.5)	IIIb	3.8
Chronic pelvic pain – <i>robotic cleaving mesh</i>	1 (0.8)	IIIb	14.4
Incisional hernia – <i>primary closure</i>	2 (2.2)	IIIb	35.9, 40.1
Bowel ischemia with septic shock – <i>palliative care</i>	1 (0.4)	V	1.4
Total major late complications n=10 (7.1)			
<i>Mesh complication</i>			
Mesh erosion posterior wall of the vagina – <i>estrogen cream</i>	1 (1.3)	II	42.7
Total mesh complications n=1 (1.3)			

Eci: e causa ignota; LIS: Lateral internal sphincterotomy. TENS: Transcutaneous electrical nerve stimulation, TVT: Tension-Free Vaginal Tape.^a All percentages are Kaplan-Meier estimates at 5 years of follow-up.

Fecal incontinence

In total 113 patients (43.8%) complained of fecal incontinence before surgery. At final follow-up, an overall improvement of 63.7% was reported (Table 4, $p<0.0005$). Of the 26 patients with an ERP and grade 4 fecal incontinence, symptoms were reduced to grade 1 or 2 in 21 patients (80.7%), in two patients (7.7%) symptoms were reduced to grade 3 and three patients (11.5%) remained at the same level of fecal incontinence ($p<0.0005$). One patient (3.8%) with an EPR developed new-onset incontinence grade 4. Forty-three (75.4%) of the 57 patients with an IRP and/or symptomatic rectocele and grade 4 fecal

Table 4. Functional outcome

	Total n (%)	ERP (n=48)	IRP and/or symptomatic rectocele (n=139)	IRP and/or symptomatic rectocele with enterocele (n=71)
<i>Obstructed defecation</i>				
Pre-op	168 (65.1)	20 (41.7)	101 (72.7)	47 (66.2)
ST	4 (1.6)	-	3 (2.2)	1 (1.4)
Last FU	36 (14.0)	3 (6.3)	20 (14.4)	13 (18.3)
ST	4 (1.6)	-	3 (2.2)	1 (1.4)
p value	$p<0.0005$	$p<0.0005$	$p<0.0005$	$p<0.0005$
<i>Fecal incontinence</i>				
Pre-op	113 (43.8)	26 (54.2)	59 (42.4)	28 (39.4)
Grade 3	3	1	2	1
Grade 4	110	25	57	27
Last FU	41 (15.9)	6 (12.5)	21 (15.1)	14 (19.7)
Grade 3	11	2	4	5
Grade 4	30	4	17	9
p value	$p<0.0005$	$p<0.0005$	$p<0.0005$	$p<0.0005$

Pre-op: pre-operative, FU: follow-up, ST: slow transit constipation, symp.: symptomatic.

incontinence showed an improvement down to grade 1 or 2, one patient (1.8%) to grade 3 and thirteen patients (22.8%) had persistent complaints (grade 4, $p<0.0005$). Of the two patients suffering from soiling (grade 3) pre-operatively, one continued to have symptoms and one became asymptomatic ($p<0.0005$). New onset incontinence grade 4 was documented in four patients (2.9%) and grade 3 in 2 patients (1.4%). Grade 4 fecal incontinence in patients with an additional enterocele ($n=27$) was reduced to grade 1 or 2 for 17 patients (63.0%) and to grade 3 for two patients (11.1%, $p<0.0005$). Eight patients (29.6%) remained incontinent. The only patient with grade 3 fecal incontinence preoperatively, continued to experience soiling. One patient (1.4%) suffered from *de novo* complaints grade 4, and 2 patients (2.8%) from grade 3 in this subgroup of patients (Table 4).

Recurrence

A total of twelve patients developed a recurrence during follow-up (Table 5).

Recurrence following RVMR for ERP

Two patients who underwent RVMR for an ERP (2/48) developed a full-thickness recurrence generating actuarial recurrence rates of 4.2% after 1 and 12.9% (95% CI, 0–30.7) after 3 and 5 years (Figure 3, Table 5). One of these patients underwent robot-assisted sacrocolporectopexy because of a concomitant uterine prolapse and cystocele (both grade 2). One patient with an ERP pre-operatively, developed an IRP and an asymptomatic cystocele (grade 3) postoperatively. This patient refrained from further treatment.

Table 5. Recurrence

	ERP (n=48)	IRP and/or symptomatic rectocele with or without enterocele (n=210)
Duration ^a between surgery and recurrence (range)	29.4 (3.8 – 37.9)	10.9 (2.7 – 56.5)
ERP recurrence (%) ^b	2 (12.9)	-
IRP recurrence (%) ^b	1 (10.0)	9 (10.4) ^c

^a Median (minimum - maximum) duration in months between surgery and recurrence of the observed events (not based on the Kaplan Meier curve); ^b All percentages are Kaplan-Meier (KM) estimates at 5 years of follow-up; ^c Two of these patients had an additional enterocele recurrence.

Recurrence following RVMR for IRP

Nine patients (9/210) were diagnosed with recurrent IRP (two with recurrent enteroceles, Table 5). The corresponding actuarial IRP recurrence rates for patients initially diagnosed with IRP were 2.6% after 1, 6.3% after 3, and 10.4% after 5 years (95% CI, 1.6–19.2, figure 3). Two of these patients underwent robot-assisted sacrocolporectopexy because of a multi-compartment prolapse and one patient developed a uterine prolapse after the RVMR procedure and before the IRP recurrence. An additional three patients required a stoma; two because of disabling fecal incontinence and an extensive sphincter dysfunction without any other curative options, and one for therapy-resistant ODS. No anatomical recurrence was diagnosed in these three patients. Seventeen patients (17/258, actuarial 5-year rate 10.6%) required a stapled hemorrhoidectomy because of a recurrent/residual mucosal prolapse.

Years	0	1	2	3	4	5
Number at risk for ERP	48	16	12	11	2	0
Number at risk for IRP	210	120	93	85	52	529

Figure 3. Blue: Actuarial ERP recurrence rate after RVMR for ERP (Kaplan-Meier method). Green: Actuarial IRP recurrence rate after RVMR for IRP (Kaplan-Meier method). The duration of recurrence-free survival was measured from date of surgery to the time of recurrence (complete) or the last follow-up (censored). At the bottom of the figure, a table with the number of patients left for analysis at each time point is presented.

Discussion

Laparoscopic or robotic-assisted ventral mesh rectopexy is being increasingly performed internationally to treat rectal prolapse syndromes. The limiting literature regarding RVMR suggests a possible added value of robotic assistance in this procedure. The current study analyses the largest published case series of RVMR to date.

One of the reasons for the popularity of LVMR is the low complication rate. A recent multicentre study by Evans et al., including 2203 LVMR patients, showed an overall nonmesh morbidity rate of 11.1%²⁶. Our complication rate was low (8.9%) and in line with the multicentre study and comparable observational RVMR cohorts^{1,11,12,26}. The incidence of postoperative spondylodiscitis (0.4 vs. 0.1%), pain (4.5% vs. 2.8%) and incisional hernia (2.2 vs. 1.4%) in our cohort was comparable to the study by Evans et al.²⁶. The only available randomized control trial (RCT) by Mäkelä-Kaikkonen et al., comparing LVMR with RVMR, shows no significant difference in morbidity¹³. Only one (1.3%) mesh-related complication (asymptomatic mesh erosion) was observed in our series, which is comparable to literature on LVMR^{5,26}. Mortality after LVMR and RVMR is rare (0-1.1%)^{5,26}. The one dead (bowel ischemia) in the current study occurred within 60 days following RVMR. Whether this fatality was related to the RVMR is uncertain as no permission for autopsy was obtained. There has only been one other dead out of almost 700 LVMR and RVMR procedures in our institution since 2004⁶.

A significant decrease in obstructed defecation of 78.6% and fecal incontinence of 63.7% was observed. There are no observational RVMR series to compare with, but literature on LVMR for all rectal prolapse syndromes demonstrates similar rates of improvement for obstructed defecation (range 57 – 93%) and fecal incontinence (range 77 – 90%)^{5,7}. The RCT by Mäkelä-Kaikkonen et al. describes a significant improvement in functional outcome (Colorectal-Anal Distress Inventory, incorporating both ODS and fecal incontinence) of 85.7 % after 3 months for the total cohort¹⁴. The best outcome was in the RVMR cohort, but this was not statistically different. A non-randomized, comparative (LVMR vs. RVMR) study shows a significantly greater improvement for obstructed defecation following RVMR with no significant difference in fecal incontinence¹¹.

Mehmood et al., comparing 34 LVMR with 17 RVMR patients using biological mesh, failed to confirm the advantage of using robotic assistance¹⁹.

The actuarial 5-year recurrence rate in this series is 12.9% for ERP and 10.4% for IRP. A single-centre observational study, describing 77 patients who underwent different robotic rectopexies for ERP, shows a recurrence rate of 12.8% at a mean follow-up of 52.5 months²⁷. Recurrence rates following LVMR for ERP vary from 1.5 to 15.4% (median follow-up range 7 – 74 months) and for IRP from 5.3 – 7.1 (median follow-up range 12 – 29)⁵. The robotic series of the available comparative (LVMR vs. RVMR) studies, present a recurrence rate between 0 and 20% with a maximum follow-up of 23 months⁵.

Meta-analysis comparing the two techniques did not demonstrate a statistically significant difference in recurrence with an odds ratio of 0.91 ($p=0.87$)²⁸. Other abdominal techniques requiring a more extensive rectal mobilization show similar recurrence rates^{29–31}.

In 2015 we published an identical analysis of a large cohort of consecutive LVMR patients⁶. Overall, the results of that study correlate well with the current RVMR series. Based on the literature, no superiority for robotic assistance in this procedure can be determined^{1,11–17,19}. MR defecography demonstrates an equal effect on ERP, IRP and enterocele for both techniques¹³. However, given the nature of pelvic floor surgery, robotic assistance could be advantageous with benefits such as 3-dimensional magnification, obliteration of hand tremor, enhanced dexterity and superior precision^{1,28,32}. In our experience, a more distal fixation of the mesh appears possible with RVMR, which could be especially beneficial for patients with ODS. For these reasons, all abdominal pelvic reconstructive surgeries are performed with robotic assistance in our centre since 2010. Our experience is supported by Mantoo et al. describing a significant higher improvement in ODS score for RVMR as compared to LVMR¹¹. In addition, level one evidence shows a lower incidence and a smaller size of residual rectoceles following RVMR, but the difference was not statistically significant¹³.

Ventral mesh rectopexy is technically demanding, but the procedure is easier to learn with robotic assistance. Recent data on LVMR shows a learning curve of 82 to 105 cases for relevant clinical and quality of life outcomes, and of 54 cases with respect to the operating time³³. The learning curve for RVMR is very steep, reaching the plateau phase before 20 robot-assisted procedures^{13,27}. Furthermore, the conversion rate following RVMR (0% in our series) appears lower as compared to LVMR⁵. Robotic assistance is, however, associated with higher costs. One report comparing the two techniques, quotes a difference of €557.29 ($p=0.01$) in favour of a laparoscopic approach, without including the purchase and servicing of the robot¹⁷. Nonetheless, the robot might lead to a reduction in costs on the long-term because of ergonomic reasons³⁴. As well as others describing RVMR, we strongly feel that robotic assistance is beneficial in this procedure^{1,3,11,19}. However, the higher costs cannot be justified yet with the results of this current study and the literature. The major limitation of this study are the differences in follow-up between patients because of its retrospective character. No systematically follow-up was performed in patients without complaints. This is partly obviated by using the Kaplan-Meier method, presenting appropriate estimates for recurrence and complication rates at various points in time. However, underestimation of these rates remains possible. In addition, selection bias may have occurred in evaluating functional outcome since the probability of a revisit might correlate to the severity of complaints. Moreover, because the functional data were cross-sectional, outcome for a single patient cannot be predicted. In addition, data was retrieved from a single tertiary referral hospital, therefore limiting the generalizability of the results.

Conclusion

Robot-Assisted Ventral Mesh Rectopexy is safe and effective technique to treat rectal prolapse syndromes, providing an acceptable recurrence rate, good symptomatic relief with minimal morbidity.

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Chapter 7

Robot-assisted sacrocolporectopexy for multi-compartment prolapse of the pelvic floor; a prospective cohort study evaluating functional and sexual outcome

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Diseases of the Colon & Rectum 2016 Oct;59(10):968-74.

Abstract**Background**

Pelvic floor disorders are a major public health issue. For female genital prolapse sacrocolpopexy is the gold standard. Laparoscopic ventral mesh rectopexy is a relatively new and promising technique correcting rectal prolapse. There is no literature combining the two techniques robotically assisted.

Objective

This study was designed to evaluate the safety, quality of life, functional and sexual outcomes of robot-assisted sacrocolporectomy for multi-compartment prolapse of the pelvic floor.

Design

This was a prospective, observational cohort study.

Settings

The study was conducted in a tertiary care setting.

Patients

All sexually active patients undergoing robot-assisted sacrocolporectomy between 2012 and 2014 were included.

Intervention

Robot-assisted sacrocolporectomy.

Outcome Measures

Pre- and postoperative (12 months) questionnaires using the Urinary Distress Inventory, Pescatori Incontinence Scale, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire and Pelvic Floor Impact Questionnaire were completed. In addition Wexner and Vaizey Incontinence scores and the Wexner Constipation score were recorded postoperatively.

Results

Fifty-one patients underwent robot-assisted sacrocolporectopexy (median follow-up 12.5 months). The simplified Pelvic Organ Prolapse Quantification improved significantly ($p<0.0005$) for all four anatomic landmarks. Both median fecal (pre- and postoperative Pescatori 4 vs 3, $p=0.002$) and urinary incontinence (Urinary Distress Inventory 27.8 vs 22.2, $p<0.0005$) scores improved significantly at 12 months. Postoperatively median Wexner (3) and Vaizey incontinence (6) and Wexner Constipation (7) scores were noted. A positive effect on sexual function (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire score 31.8 vs 35.9, $p=0.002$) and quality of life for each compartment ($p<0.0005$) was observed. One (2%) patient developed mesh erosion. No multi-compartment recurrences were detected.

Limitations

This was an observational study with a limited follow-up, no control group and no validated constipation score preoperatively.

Conclusions

Robot-assisted sacrocolporectopexy is a safe and effective technique for multi-compartment prolapse in terms of functional outcome, quality of life and sexual function.

Introduction

The treatment of pelvic floor disorders (PFD) has become an increasingly important part of women's health care. Such disorders, including urinary and fecal incontinence, obstructed defecation, pelvic organ prolapse (POP) and sexual dysfunction are associated with considerable morbidity and a serious impact on quality of life.¹⁻³ With a current prevalence of 23.7% and the expectation of the percentage to rise twice the rate of annual growth of the population, PFD are a major public health issue.^{4,5}

Traditionally, surgical treatment for POP is performed per compartment by the relevant specialty. However, POP is often multi-compartmental, commonly a combination of urogenital and rectal prolapse.^{6,7} A multidisciplinary procedure for multi-compartment POP is increasingly applied and the limited available data show outcomes comparable to rectal prolapse (RP) surgery.^{1,3,7-16} The gold standard for female genital prolapse is abdominal sacrocolpopexy, which is superior to a vaginal approach and is used in almost all studies describing multi-compartmental procedures.^{1,17}

The optimal procedure for RP remains undecided. Laparoscopic ventral mesh rectopexy (LVMR) has gained increasing acceptance for RP. LVMR mobilises just the anterior aspect of the rectum and thereby the risk for autonomic nerve damage and associated dysmotility with impaired evacuation is minimised. Thus far, sacrocolporectopexy with a limited anterior mobilization of the rectum is described in two studies, but neither were robot-assisted.^{8,11} In addition, none of the articles evaluating a multi-compartmental approach explored postoperative sexual functioning in detail.^{1,3,7-14} For pelvic floor surgery, robotic assistance appears advantageous because of a better-controlled and deeper dissection of the rectovaginal septum, easier intracorporeal suturing and optimal visualization.

This study aims to assess safety, quality of life, functional and sexual outcome of robot-assisted sacrocolporectopexy (RSCR) for multi-compartment prolapse of the pelvic floor.

Materials and Methods

Study design

All consecutive patients undergoing RSCR for multi-compartment pelvic floor prolapse between January 2012 and November 2014 at the Meander Medical Center, Amersfoort, the Netherlands were prospectively enrolled. To evaluate the effect of RSCR on sexual functioning, only sexually active patients were included. All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments. For all patients informed consent was obtained.

Patients and evaluation

Preoperatively patients were examined by a colorectal surgeon and urogynaecologist in the standing and lithotomy position using leg supports, both at rest and during straining. In addition, proctoscopy and a speculum examination were performed. All patients underwent a dynamic MRI defaecography and/or an entero-colpo-cysto-defaecography. Indication for surgery was a combination of prolapse of the posterior and the middle/ anterior compartment, accompanied by a disabling multi-compartment problem (i.e. fecal incontinence, obstructed defecation, sensation of prolapse, dyspareunia, micturition symptoms). Prior to surgery every patient was discussed in a multidisciplinary setting, including colorectal surgeons, urogynaecologists, urologists, radiologists, and pelvic floor physical therapists. Preoperatively, the following questionnaires were completed; the Urinary Distress Inventory (UDI-6, translated and validated in Dutch^{18,19}) assessing urinary symptoms, the Pescatori Incontinence Scale²⁰ assessing fecal incontinence, the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12, translated and validated in Dutch²¹) assessing sexual functioning and the Pelvic Floor Impact Questionnaire (PFIQ-7, translated and validated in Dutch²²) assessing quality of life. The PFIQ-7 includes the Urinary Impact Questionnaire (UIQ-7), Colorectal-Anal Impact questionnaire (CRAIQ-7) and the Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7). The UDI-6 score was converted to a 0–100 scale as described by the original

developer.¹⁹ To improve our pelvic floor questionnaire, the Wexner Incontinence Score, Vaizey Incontinence Score and the Wexner Constipation Score were added in 2014.^{23–25} Worsening of fecal incontinence was defined as a deterioration of Pescatori incontinence score and a postoperative Wexner Incontinence Score greater than 4. The genital prolapse was measured using the simplified Pelvic Organ Prolapse Quantification (POP-Q).²⁶ Complications were assessed using the Clavien-Dindo (CD) classification.²⁷ Grade I and II were considered minor, grade III or higher as major. Mesh erosion was graded according to the International Urogynaecological Association (IUGA) and the International Continence Society (ICS) joint terminology and category, time and site (CTS) classification.²⁸

Surgical technique

Surgery was performed under general anesthesia, jointly by an experienced colorectal and urogynaecological surgeon. All procedures were performed with robotic assistance of the da Vinci Si-HD® (Intuitive Surgical, Inc., Sunnyvale, CA, USA). The pneumoperitoneum was created through a Veress needle or Hasson open entry followed by the placement of two 12 mm and three 8 mm robotic trocars. Intra-abdominal pressure was set at 14 mm Hg. The patients were placed in lithotomy and Trendelenburg position using adaptable leg supports with swing stirrups. The colorectal surgeon started the procedures performing a ventral mesh rectopexy according to D'Hoore et al.²⁹ No posterolateral rectal mobilization or lateral ligament dissection was performed. The mesh (Prolene, Ethicon Inc., Johnson & Johnson, Hamburg, Germany, weight 80-85g/m²) was distally attached by sutures (Ethibond, Ethicon Inc., Johnson & Johnson, Hamburg, Germany) to the ventral aspect of the rectum and proximally to the sacral promontory using titanium tacks (Autosuture Protack 5mm, Covidien, USA). The urogynaecological surgeon, if the uterus was in situ, performed a supravaginal hysterectomy in standard fashion. The posterior vaginal wall was deperitonised, and the mesh was sutured to the posterior vaginal wall. The bladder was dissected from the anterior vaginal wall to the trigone, creating a vesicovaginal space anteriorly. In patients who already had a hysterectomy, a standard sacrocolpopexy dissection was performed. Once dissection was completed,

the mesh, cut to the appropriate length and width, was attached to the anterior vaginal wall and cervix with non- absorbable sutures. Both meshes were then connected with non-absorbable sutures to the vaginal top or cervix to create a Y-shaped suspension. The peritoneum was then closed to cover the graft using a 23 cm V-Loc suture (Covidien, Mansfield, MA, USA). At the end of the procedure, a vaginal examination was performed by the urogynaecological surgeon to evaluate the correction of the prolapse and to exclude a possible (needle) perforation of the vaginal wall. Postoperatively, all patients were prescribed a laxative (Macrogol 3350/electrolytes, Movicolon®, Norgine Limited, Mid Glamorgan, UK). Patients were advised to refrain from heavy lifting and sexual intercourse for six weeks after surgery.

Follow-up

All patients were reviewed in the outpatient clinic at 6 weeks and 12 months postoperatively. All patients underwent a speculum examination on both occasions. At the discretion of the surgeon proctoscopy was performed. At the 12 months follow-up, all questionnaires were repeated. Patients visiting the hospital for the 1-year evaluation in 2014 filled in the extended questionnaire containing the Wexner and Vaizey Incontinence Score and the Wexner Constipation score additionally.

Statistical Analysis

Statistical Package for the Social Science, version 20.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Data are presented as percentage, mean, median and range. POP-Q, UDI-6, Pescatori incontinence, PISQ-12 and PFIQ-7 scores before and after surgery were compared using the Wilcoxon signed-ranks test. McNemar's test was used for the presence/absence of constipation and fecal incontinence before and after RSCR. $P < 0.05$ was considered statistically significant.

Results

Patient demographics and operative data

Fifty-one sexually active patients (mean age 56.2 years) with multi-compartment prolapse underwent RSCR (Table 1). Median follow-up was 12.5 months. No patient was lost to follow-up. The majority of patients (n=37, 72.5%) had a history of pelvic or abdominal surgery. Mean total operation time was 179 minutes with an average blood loss of 49 ml. Robot related problems occurred in two cases (3.9%). In one (2%) patient conversion to laparotomy was required because of a ventilation problem in the extreme Trendelenburg position. Extensive endometriosis resulted in a perforation of the anterior side of the vagina in one (2%) patient. The defect was closed with sutures and the procedure was continued with placement of the mesh.

Table 1. Patient demographics and surgical details

		Total n = 51
Mean age (range)		56.2 (33.9 – 75.0)
Mean ASA classification (range) [mean BMI]		1.65 (1-3) [27.4]
Mean para (range) [episiotomy/rupture]		2.75 (0 – 6) [27/21] ^a
Postmenopausal		36 (70.6%)
History	<i>Hysterectomy [oophorectomy]</i>	21 (41.2%) [2] (3.9%)
	<i>Rectal prolapse surgery</i>	6 (11.8%)
	<i>Cystopexy</i>	12 (23.5%)
	<i>Colporrhaphia anterior or posterior</i>	22 (43.1%)
	<i>Hemorrhoidectomy</i>	8 (15.7%)
	<i>Other abdominal surgery</i>	18 (35.3%)
RSCR combined with hysterectomy		30 (58.8%)
Mean docking time, minutes (range)		7 (3 – 15)
Total operation time, minutes (range)		179.3 (76 – 250)
Mean blood loss, milliliters (range)		49.3 (5-200)
Conversion		1 (2%)
Intra-operative complications		1 (2%)
Mean length of hospital stay, nights (range)		2.4 (1 – 8)

BMI indicates body mass index, ASA: American society of anesthesiologists.

^a 15 patients had an episiotomy and a rupture.

Morbidity

No postoperative mortality occurred. Seven (13.7%) early (<30 days) minor postoperative complications occurred in six patients. Six (11.8%) late complications were recorded after a median of 4.7 months (1.4 – 12.3). One of these complications was mesh-related. This patient developed mesh erosion to the posterior wall of the vagina, categorised as IUGA/ICS CTS classification 2B/T3/S1. A partial resection of the mesh was vaginally executed after 14.8 months (Table 2). No recurrence of erosion was observed after 24 months of follow-up.

Table 2. Early (< 30 days), late and mesh complications

Total n = 51		N (%)	CD²⁷	Treatment
Early complications	<i>Constipation</i>	3 (5.9)	Gr. 2	Laxatives ^a
	<i>UTI</i>	1 (2)	Gr. 2	Antibiotics
	<i>Hematoma</i>	1 (2)	Gr. 2	2 packed cells
	<i>Abscess proximal of bladder^b</i>	1 (2)	Gr. 2	Antibiotics
	<i>Hypokalemia</i>	1 (2)	Gr. 1	Oral potassium
Total early complications		7 (13.7)		
Late complications	<i>ACNES</i>	2 (3.9)	Gr. 2, 3b	TENS, neurectomy
	<i>Perforating vaginal suture</i>	1 (2)	Gr. 3a	Removal ^c
	<i>UTI</i>	2 (3.9)	Gr. 2	Antibiotics
Total late complications		5 (9.8)		
Mesh complication	<i>Erosion</i>	1 (2)	Gr. 3b	Partial resection
Total mesh complications		1 (2)		

UTI indicates urinary tract infection, ACNES: anterior cutaneous nerve entrapment syndrome,

TENS: transcutaneous electrical nerve stimulation. ^a one patient was admitted and treated with enemas,

^b this patient also suffered from constipation, ^c removal in outpatient clinic without anesthesia.

Post-interventions

During follow-up ten patients required 11 (21.6%) post-interventions after a median interval of 6.4 months (2.9 – 16.6). Seven (13.7%) patients received treatment for hemorrhoids; four stapled hemorrhoidectomies and three rubber band ligations. Three patients underwent a Tension free Vaginal Tape Obturator (TVT-O) for stress urinary incontinence complaints after a mean of 8.7 months (6.6 – 11.5). All three patients had

pre-existing micturition problems (UDI score 22.2, 38.8 and 72.2) and were seen by a urologist before surgery. One patient suffered from an overactive bladder syndrome preoperatively and received additional percutaneous tibial nerve stimulation.

Functional outcome

Preoperatively 30 patients (58.8%) complained of constipation. After 12 months, 22 of these patients (73.3%) reported an improvement while eight (26.7%) experienced persistent constipation ($p<0.0005$). No patient reported new-onset constipation. The median Wexner Constipation Score was 7 (0-16) after one year (Table 3). Thirty-three patients (64.7%) had complained of fecal incontinence before surgery. At 1 year postoperatively this percentage was reduced significantly to 27.5% ($n=14$, $p<0.0005$). Five patients (9.8%) experienced worsening of fecal incontinence. Two patients (3.9%) reported new-onset fecal incontinence, be it infrequently (<1 /month). The median Pescatori incontinence scale improved significantly from 4 (0-6) to 3 (0-5, $p=0.002$). At 1 year postoperative, the median Wexner and Vaizey Incontinence Score were 3 (0-17) and 6 (0-21, Table 3). The impact on urinary symptoms was reflected in a significant median reduction of irritative (33.3 vs. 16.7, $p=0.03$), stress (33.3 vs. 16.7, $p=0.03$) and obstructive/discomfort symptoms (33.3 vs. 16.7, $p<0.0005$). The total median UDI-6 score improved from 27.8 (0-88.9) to 22.2 (0-61.1, $p<0.0005$, Table 3). Eight patients (15.7%) experienced a deterioration in UDI score and one patient (2%) developed urine incontinence complains *de novo* (UDI score 27.8).

Quality of life

RSCR significantly improved all three scales included in the PFIQ-7 score (UIQ-7, CRAIQ-7 and POPIQ-7, all three $p<0.0005$), which was reflected in a significant decrease in the median summary score from 47.6 (0-276.2) to 14.3 (0-133.3, $p<0.0005$, Table 3).

Table 3. Anatomical, functional and quality of life results

	Pre-operative	12 months	P value
	Mean (range)	Mean (range)	
<i>Anatomical</i>			
POP-Q - A	2.29 (1-4)	1.15 (1-3)	<0.0005
POP-Q - B	2.33 (1-4)	1.06 (1-2)	<0.0005
POP-Q - C	2.10 (1-4)	1.00 (1-1)	<0.0005
POP-Q - D	1.69 (1-4)	1.00 (1-1)	<0.0005
	Median (range)	Median (range)	
<i>Functional</i>			
UDI-6 total	27.8 (0-88.9)	22.2 (0-61.1)	<0.0005
Irritative	33.3 (0-100)	16.7 (0-66.7)	0.03
Stress	33.3 (0-100)	16.7 (0-100)	0.03
Obstructive/discomfort	33.3 (0-100)	16.7 (0-83.3)	<0.0005
Pescatori incontinence score	4 (0-6)	3 (0-5)	0.002
Wexner incontinence score	-	3 (0-17)	n/a
Vaizey incontinence score	-	6 (0-21)	n/a
Wexner constipation score	-	7 (0-16)	n/a
<i>Quality of Life</i>			
UIQ-7	16.67 (0-100)	0 (0-80.95)	<0.0005
CRAIQ-7	23.81 (0-100)	4.76 (0-57.14)	<0.0005
POPIQ-7	16.67 (0-76.19)	0 (0-76.19)	<0.0005
PFIQ-7	47.62 (0-276.19)	14.29 (0-133.33)	<0.0005

n/a indicates not applicable.

Sexual function

Preoperatively all included patients were sexually active, but three PISQ-12 questionnaires were incomplete. At 12-months follow-up, three out of 48 (6.3%) patients were no longer sexually active because of partner related factors. Sexual function for the remainder of patients had improved on each item of the PISQ-12 with a significant increase in mean PISQ-12 score from 31.8 (range 7-44, median 32) to 35.9 (range 16-46, median 37, $p=0.002$, Table 4). Significantly fewer women reported pain (PISQ-12 question #5, 61.6 vs 40%, $p=0.02$) and fear of fecal or urinary incontinence (#7, 40.4

Table 4. Sexual outcome according to the PISQ-12 score

	Pre-operative	12 months	P value
	Mean (range)	Mean (range)	
Q1 (sexual desire)	1.83 (0-3)	2.20 (0-3)	0.02
Q2 (orgasm)	2.21 (0-4)	2.40 (0-4)	0.80
Q3 (sexual excitement)	2.49 (0-4)	2.78 (0-4)	0.51
Q4 (satisfaction variety activities)	2.30 (0-4)	2.60 (0-4)	0.34
Q5 (pain)	2.04 (0-4)	2.58 (0-4)	0.02
Q6 (urinary incontinence during sex)	3.28 (0-4)	3.64 (0-4)	0.05
Q7 (fear of fecal or urinary incontinence)	2.89 (0-4)	3.53 (0-4)	0.001
Q8 (avoid sex due to bulging)	2.53 (0-4)	3.67 (0-4)	<0.0005
Q9 (negative emotions)	2.94 (0-4)	3.38 (0-4)	0.07
Q10 (erection problem partner)	3.32 (0-4)	3.36 (0-4)	0.55
Q11 (premature ejaculation partner)	3.66 (0-4)	3.82 (0-4)	0.12
Q12 (change in orgasm intensity)	1.68 (0-4)	1.67 (0-4)	0.64
PISQ-12 total	31.8 (7-44)	35.9 (16-46)	0.002

Q indicates question.

vs. 14%, $p=0.001$) during intercourse. There was a significant reduction in patients avoiding sexual intercourse because of bulging in vagina (#8, 42.6 vs 8.8%, $P<0.0005$).

Recurrence

No recurrence of multi-compartment prolapse was seen. One (2%) patient developed a rectocele distally from the mesh with obstructed defecation after 12 months. This resolved after a transanal mucosectomy and plication. Because of persistent fecal obstruction, a stoma was created in one (2%) patient in the absence of a curative surgical option. In another patient (2%) a recurrence of an asymptomatic cystocele (grade 3) was noted after 12.2 months for which no further treatment was needed. In all other patients anatomical reconstruction was achieved in all compartments as assessed by the simplified POP-Q ($p<0.0005$, Table 3).

Discussion

Dysfunction of the pelvic floor is frequently characterised by multi-compartment prolapse. The literature quotes a high prevalence of concomitant rectal intussusception (55%), rectal prolapse (38%), rectocele (53%) and enterocele (14%) in patients with urogynaecological complaints and/or prolapse of the middle compartment.^{6,30} A prevalence of constipation of 32-67% and fecal incontinence of 13-20% in combination with urinary incontinence and/or POP is described.^{14,30,31} A prolapse in an adjacent compartment is easily missed unless each compartment has been examined specifically. Multi-compartmental assessment is therefore essential before planning surgical repair.⁶ Several studies have shown that a uni-compartmental approach could aggravate or even provoke complaints of the non-treated compartment. New-onset fecal incontinence of 16.5% and an increased prevalence of constipation, rectal emptying difficulties and digitally assisted rectal emptying following a genital prolapse repair are reported.³²⁻³⁴ These data reflect the need of a standard multi-compartment procedure for multi-compartment prolapse. Our study showed a significant improvement in quality of life, constipation, fecal and urinary incontinence, sexual function and anatomical repair after RSCR. To our knowledge, this study is the first to describe the outcomes of a robot- assisted combined approach, and the first study including assessment of sexual functioning. A significant improvement of 73.3% for constipation and 57.6% for fecal incontinence was observed. No patients developed constipation, but new-onset fecal incontinence (3.9%) was noted. These results are in keeping with previously published rates of functional outcome after sacrocolporectomy (with various rectal mobilizations) which vary between 33 and 82% for constipation and between 69 and 91% for fecal incontinence.^{3,8,10,11} New-onset constipation is described between 0 to 3.8%, one report even quotes a percentage of 20%.^{3,8,10,11} Several studies report worsening of fecal incontinence, but new-onset complaints have not been described.^{3,9} Urinary function improved in 73%, reflected by a significant reduction of the median UDI-6 score. This compares favorably with other studies quoting an improvement of around 50%.^{8,10}

A reduction in UDI score after similar procedures is mentioned in recent literature.^{7,35} New-onset urinary incontinence is described between 2.5 and 20% with a deterioration in urinary function of 9.1%.^{8,10,11} These figures are in line with our results. RSCR proved to be safe and effective. Morbidity was low as compared to the literature, with the majority of complications being minor and three major complications (5.9%).^{1,3,11,13} Only one mesh-related complication (2%, erosion) occurred. Similar mesh erosion rates (2.8 to 5%) are reported after a comparable combined operation and after LVRM.^{1,7,9,36} These figures are in contrast to the mesh erosion rates of the transvaginal approach described in the report of the American Food and Drug Administration (FDA) quoting an overall rate, by meta-analysis, of 10.3% (110 studies, range 0 – 29.7%).³⁷ The data in the FDA report also suggests that graft erosions tend to occur within twelve months after surgery, implying our 2% could be representative of the true erosion rate. To test this hypothesis we aim to review all patients five years postoperatively. No patient developed a multi-compartment recurrence, but one recurrent rectocele (2%) and one asymptomatic cystocele (2%) were observed. Cronje et al. quotes an overall recurrence rate of 10.3%, but the exact pathology of recurrence was not given.¹² None of the other studies describing a combined approach report multi-compartmental recurrence.^{3,7,9–11,14} However, recurrence of a single compartment is not uncommon. Sullivan et al. noted a re-operation rate of the anterior and posterior compartment of 36% and 28%.⁹ Other articles quote a recurrence percentage of 6.9% for prolapse of the middle compartment and 2.2% of the anterior compartment.^{7,14} The prevalence of TVT-O after multi-compartment prolapse surgery ranges from 2.5 to 12.8%, which is in keeping with our data (5.9%).^{11,12} Walters et al. recommends an abdominal prolapse repair with apical suspension for sexually active patients as the procedure restores normal pelvic anatomy and maintains vaginal length.³⁸ Our study supports this statement with a significant improvement of overall sexual function (PISQ-12 score 31.8 vs 35.9, $p=0.002$). Data on sexual function after sacrocolporectopexy are not available, but our sexual results are comparable with laparoscopic sacrocolpopexy.³⁹ Robotic assistance was added to our procedure to enhance visualization and maneuverability required for the complex

maneuvers deep in the narrow pelvis. In our experience, robot assistance is superior to laparoscopy for intracorporeal suturing and a better-controlled and deeper dissection in the rectovaginal septum seems possible. A more distal fixation of the mesh is possible which is especially favorable for patients with obstructed defecation syndrome.

In addition, robotic assistance is preferable for ergonomic reasons and provides optimal visualization. The facile dissection with the robot results in a shorter operation time compared to laparoscopy.⁴⁰ The safety of the robotic procedure has been described and is further emphasised by a low rate of intra-operative complications, conversions and a low mean blood loss of <50 ml. Several limitations should be taken into account. Follow-up was limited to one year and there was no control group. Furthermore, the Pescatori incontinence score is considered of limited value since it only contains six scoring points and it does not account for alteration in lifestyle. However, a study by Vaizey et al. showed similar outcomes between the Pescatori and Wexner incontinence scales.²⁵ In addition, no validated constipation score was recorded preoperatively. From 2014 this is, however, obviated by adding the Wexner Constipation score to the pelvic questionnaire.

In conclusion, the results of the present study show RSCR is a safe and effective technique for multi-compartment prolapse in terms of functional outcome, quality of life and sexual function.

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Chapter 8

High-grade hemorrhoids requiring surgical treatment are common after laparoscopic ventral mesh rectopexy

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Techniques in Coloproctology 2016 Apr;20(4):235-42.

Abstract

Purpose

To describe patients developing grade III and IV hemorrhoids requiring surgery after Laparoscopic Ventral Mesh Rectopexy (LVMR) and to explore the relationship between developing such hemorrhoids and recurrence of rectal prolapse after LVMR.

Methods

All consecutive patients receiving LVMR at the Meander Medical Centre, Amersfoort, the Netherlands, between 2004 and 2013 were analysed. Kaplan-Meier estimates were calculated for recurrences.

Results

420 patients underwent LVMR. Sixty-five of these patients (actuarial 5-year incidence 24.3%, 95% confidence interval (CI) 18.6–30.0) developed symptomatic grade III/IV hemorrhoids requiring stapled or excisional hemorrhoidectomy. Re-do surgery for recurrent grade III/IV hemorrhoids was required for 15 of the 65 patients (actuarial 5-year recurrence rate 40.6%, 95% CI 23.2–58.0) after the primary hemorrhoidectomy. Three of the 65 patients developed an external rectal prolapse (ERP) recurrence and eight an internal rectal prolapse (IRP) recurrence. This generated a 5-year recurrence rate of 25.3% (95% CI 0 - 53.9) for ERP recurrence and 24.4% (95% CI 9.1 - 39.7) for IRP recurrence. The rest of the LVMR cohort not receiving additional surgery for hemorrhoids (n= 355) showed significantly lower actuarial 5-year ERP (0.8%, $p=0.011$) and IRP (11%, $p=0.020$) recurrence rates.

Conclusions

High-grade hemorrhoids requiring surgery may be common after LVMR. The development of high-grade hemorrhoids after LVMR might be considered a predictor of rectal prolapse recurrence.

Introduction

Disorders of the pelvic floor, including urinary and fecal incontinence, pelvic organ prolapse, obstructed defecation and chronic pelvic pain, are socially disabling conditions. In the western world, this pathology is common, affecting more than 40% of the middle-aged and older women, with a lifetime risk of undergoing surgery of 10-20%^{1,2}. The rectum is often involved in this multi-organ problem³. Various conditions including rectoceles, internal and external rectal prolapse may cause fecal incontinence and the obstructed defecation syndrome (ODS)⁴. Laparoscopic ventral mesh rectopexy (LVMR) is increasingly applied for the treatment of external rectal prolapse (ERP) and internal rectal prolapse (IRP). This technique proved to be safe and effective in terms of functional results in large cohorts of patients⁵⁻⁸. For prolapse surgery, the recurrence rate is a key indicator of success. ERP recurrence is easily assessed, but diagnosing IRP recurrence remains challenging. One hypothesis is that IRP could be the cause of high-grade hemorrhoids (III and IV), but the development of such hemorrhoids after LVMR is not well known⁹. In the past 25 years, the incidence of high-grade hemorrhoids has been quoted as up to 18% after different types of rectopexy¹⁰⁻²⁵, but specific literature regarding LVMR is scarce. Only a handful of relatively small series mention the incidence^{5,26-28}, but none of these discuss the issue in depth. The aim of this study therefore, was to identify patients developing high-grade hemorrhoids requiring surgical treatment after LVMR and to explore the relationship between such hemorrhoids and the recurrence of rectal prolapse following LVMR.

Materials and methods

Study design

This observational cohort study was a retrospective analysis of a prospectively maintained database and was undertaken in a large teaching hospital in the Netherlands. All consecutive patients undergoing LVMR for rectal prolapse syndromes (Table 1) between March 2004 and May 2013 were analysed. All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments. Formal consent is not required for this type of study.

Table 1. Patient characteristics, medical history and initial indications for LVMR.

Patient characteristics	LVMR N = 420 (%)	Hemorrhoidectomy group N = 65 (%)
Woman/men [mean age]	404/16 [61.8]	61/4 [60.4]
History		
Mean para (range) [episiotomy]	2.4 (0-10) [37] ^a	2.6 (0-5) [12] ^b
Hysterectomy	139 (33.1)	47 (72.3)
Cystopexy	39 (9.3)	4 (6.2)
Anterior colporrhaphy	56 (13.3)	13 (20.0)
Sphincter operation	6 (1.4)	0
Other abdominal surgery	137 (32.6)	23 (35.4)
Rubber band ligation before LVMR [second session]	28 (6.7) [7] ^c	3 (3.1) [2] ^d
Pre-hemorrhoidectomy - <i>before initial LVMR</i>	20 (4.8)	2 (3.1)
RBL between LVMR & hemorrhoidectomy [second RBL]	39 (9.3) [13]	4 (6.2) [1]
Indication for initial LVMR		
ERP	55 (13.1)	5 (7.7)
IRP ^e and/or symptomatic rectocele	266 (63.3)	44 (67.7)
IRP ^e and/or symptomatic rectocele with enterocele	99 (23.6)	16 (24.6)

LVMR: laparoscopic ventral mesh rectopexy, ERP: external rectal prolapse, IRP: internal rectal prolapse. RBL: rubber band ligation. ^a In 25 patients, ^b In 7 patients, ^c 2 patients underwent a 3rd and a 4th session, ^d 1 patient underwent a 3rd and a 4th session, ^e Oxford rectal prolapse grade III/IV.

Patients and evaluation

Postoperatively all patients were prescribed a laxative (Macrogol 3350/ electrolytes, Movicolon®, Norgine Limited, Mid Glamorgan, U.K.). Follow-up after LVMR was carried out according to a standardized protocol and performed at 6 weeks after surgery by one of the three participating experienced pelvic floor surgeons (P.V., E.C. and I.B.). At the 6 weeks follow-up, the presence of hemorrhoids, recurrence of rectal prolapse, incontinence and constipation was assessed. All patients were asked to return in the event of anorectal complaints. Patients were examined for hemorrhoids in the standing and lithomy position using leg supports, both in rest and during straining. In addition, proctoscopy was performed. Hemorrhoids were graded using the Goligher classification²⁹. Patients with grade II and III hemorrhoids were treated with rubber band ligation (RBL) first. Persisting symptomatic grade III/IV hemorrhoids ('high-grade') were considered an indication for surgery, but results of LVMR were awaited for at least 10 weeks. Lower grades of hemorrhoids were not operated on. ERP recurrence was clinically assessed. IRP recurrence was defined as Oxford rectal prolapse grade III/IV IRP with symptoms of obstructed defecation or fecal incontinence. Most of these patients had a coexisting rectocele or enterocele. A dynamic MRI of the pelvic floor was done on all patients suspected of an IRP recurrence. A large part of the study cohort (most patients operated from 2004 to 2011) had participated in a previous study about the outcomes of LVMR and therefore a longer follow-up period was available for these patients⁷. For those patients not included in this previous study no additional effort was made to systematically follow them up. Kaplan-Meier curves were used to establish whether there was a difference in outcome between the two groups.

Surgical technique

All laparoscopic ventral mesh rectopexies were performed according to the technique described by D'Hoore et al.⁶ All meshes used were synthetic. Either a stapled hemorrhoidectomy (SH) or a traditional excisional hemorrhoidectomy (TEH) was performed. Where a SH was not technically possible, a TEH was done. Surgery was

performed by, or under direct supervision of, one of the three pelvic floor surgeons (P.V., E.C. and I.B.). Operations were performed under general or spinal anaesthesia. The patients were placed in the lithomy position using adaptive leg supports with swing stirrups. The PPH 03 stapler produced by Ethicon (EndoSurgery, Cincinnati, Ohio, USA) was used for SH. The stapled procedure had been previously standardized and was performed according to the technique described by Singer et al.³⁰. Excisional hemorrhoidectomy was performed according to standard protocol³¹.

Statistical analysis

Statistical Package for the Social Science Advanced, version 20.0 (IBM Corp., Armonk, NY) was used for statistical analysis. Data are presented as percentage, median and range. Because of differences in follow-up between patients, the Kaplan-Meier method was used to estimate the incidence of postoperative high-grade hemorrhoids and recurrence rates at various points in time. The risk estimates after a period of 5 years are shown in the text. $P < 0.05$ was considered statistically significant.

Results

Patients characteristics

Before LVMR, twenty-eight patients (6.7%) underwent RBL for grade II hemorrhoids and 20 patients (4.8%) underwent a hemorrhoidectomy for grade III / IV hemorrhoids. A total of 420 patients (16 men; 404 women) underwent LVMR. Indications for surgery were ERP (n=55, 13.1%), IRP (Oxford rectal prolapse grade III/IV) and/or symptomatic rectocele (n=266, 63.3%) and IRP and/or symptomatic rectocele combined with enterocele (n=99, 23.6%). General patient characteristics are presented in table 1.

Follow-up

The median follow-up after LVMR was 16.0 months (range 0.4 - 93.7). Three hundred and ninety-one patients (93.1%) were available for follow-up after the standardized outpatient visit at 6 weeks postoperatively. Nine patients (2.1%) died of causes unrelated to the LVMR within the study period. During follow-up after LVMR, 89 patients required treatment for haemorrhoids, of which 24 were treated sufficiently by RBL. The remaining 65 patients (Kaplan-Meier estimate of 24.3% at 5 years, 95% confidence interval (CI) 18.6 – 30.0, table 2) received surgical treatment for symptomatic grade III / IV haemorrhoids and are referred to as the 'hemorrhoidectomy group' (63 SH, 2 TEH). Four of the hemorrhoidectomy group (6.2%) received RBL between LVMR and the hemorrhoidectomy without sufficient result (flowchart figure 1). The median duration between LVMR and hemorrhoid surgery was 6.2 months (2.5 – 45.3).

Figure 1 Flowchart

LVMR: laparoscopic ventral mesh rectopexy; RBL: rubber band ligation; SH: stapled hemorrhoidectomy; TEH: traditional excisional hemorrhoidectomy; RP: rectal prolapse; Gr.: grade. ERP: external rectal prolapse; IRP: internal rectal prolapse. ^a 4 of these patients received a re-SH first.

High-grade hemorrhoids recurrence

Fifteen patients of the hemorrhoidectomy group (15/65) needed re-do surgery (n=13 SH) for recurrent grade III / IV hemorrhoids after a median of 8.3 months (1.5 – 40.5) after the primary hemorrhoidectomy. The estimated percentages (Kaplan Meier) were 31.2% after 1, 35.2% after 3 and 40.6% after 5 years (95% CI 23.2 – 58.0, table 2). One patient received an excisional hemorrhoidectomy after twice a SH in a period of 8.9 months. This was the only patient receiving more than two hemorrhoidectomies after LVMR.

Rectal prolapse recurrence - ERP

In the hemorrhoidectomy group, three patients (3/65) developed a clinical full-thickness external prolapse generating a recurrence percentage (Kaplan-Meier estimates) 0% after 1, 2.0% after 3 and 25.3% after 5 years (95% CI 0 - 53.9). Two of these patients underwent re-do LVMR and the third patient declined surgery. The ERP recurrence rate (Kaplan Meier estimates) in the group of patients who did not received additional surgery for hemorrhoids after LVMR ('non-hemorrhoidectomy group', n=355) was 0.8% after 5 years (95% CI 0 - 2.0). This is significantly (p=0.011) lower compared to the hemorrhoidectomy group (n=65, figure 2a and table 2).

Table 2. Kaplan-Meier estimates (%) for incidence and recurrence of gr. III/IV hemorrhoids and recurrence of rectal prolapse in the hemorrhoidectomy group (n=65) and the non-hemorrhoidectomy group (n=355) at various time points.

Kaplan-Meier estimates % [CI]	Years		
	1	3	5
Gr. III / IV hemorrhoids after LVMR	16.5 [CI 12.4–20.6]	22.2 [CI 17.1–27.3]	24.3 [CI 18.6–30.0]
<i>Recurrence high-grade hemorrhoids</i>			
Hemorrhoidectomy group (n=65)	31.2 [CI 16.9–45.5]	35.2 [CI 19.7–50.7]	40.6 [CI 23.2–58.0]
<i>External rectal prolapse recurrence</i>			
Hemorrhoidectomy group (n=65)	0	2.0 [CI 0–5.9]	25.3 [CI 0 - 53.9]
Non-hemorrhoidectomy group (n=355) ^a	0.8 [CI 0–2.0]	0.8 [CI 0–2.0]	0.8 ^b [CI 0–2.0]
<i>Internal rectal prolapse recurrence</i>			
Hemorrhoidectomy group (n=65)	1.9 [CI 0–5.6]	20.2 [CI 6.5–33.9]	24.4 [CI 9.1–39.7]
Non-hemorrhoidectomy group (n=355) ^a	2.1 [CI 0.3–3.7]	5.7 [CI 2.0–9.4]	11.0 [CI 4.3–17.7]

CI: 95% confidence interval, LVMR: laparoscopic ventral mesh rectopexy; gr.: grade. ^a This cohort contains the 420 patients receiving a LVMR minus the patients developing postoperative high-grade hemorrhoids; 420-65=355; ^b One ERP recurrence after 64.6 months.

Figure 2a. Kaplan-Meier curve for ERP recurrence (cohort n=420). The green line represents the cohort developing high-grade hemorrhoids after LVMR ('hemorrhoidectomy group', n=65), the blue line represents the rest of the LVMR cohort not developing high-grade hemorrhoids after LVMR ('non-hemorrhoidectomy group', n=355, p=0.011)

Figure 2b. Kaplan-Meier curve for IRP recurrence (cohort n=420). The green line represents the cohort developing high-grade hemorrhoids after LVMR ('hemorrhoidectomy group', n=65), the blue line represents the rest of the LVMR cohort not developing high-grade hemorrhoids after LVMR ('non-hemorrhoidectomy group', n=355, p=0.020). The duration of event-free survival was measured from date of LVMR to the time of the event (complete) or the last follow-up (censored) for both curves. At the bottom of the figure a table with the number of patients left for analysis per year is presented

Rectal prolapse recurrence – IRP

Additionally, eight patients of the hemorrhoidectomy group (8/65) were diagnosed with an IRP recurrence. The Kaplan-Meier estimates for IRP recurrence were 1.9%, 20.2% and 24.4% after 1, 3 and 5 years (95% CI 9.1 - 39.7). One patient decided against surgery and the rest received re-do rectopexy. One patient required a SH 9 months after the re-do rectopexy. Due to persistent faecal incontinence without curative surgical options, a stoma was created in a further three patients. The estimated IRP recurrence percentage after 5 years was significantly lower (11%, $p=0.020$, 95% CI 4.3 – 17.7) in the non-hemorrhoidectomy group ($n=355$) compared to the hemorrhoidectomy group ($n=65$, figure 2b and table 2).

Discussion

The exact incidence of high-grade hemorrhoids following LVMR is not known. Our study found a high actuarial 5-year incidence of 24.3%. In the literature only four articles report on this issue, quoting a lower incidence varying from 1.6 to 5% (table 3)^{5,26–28}.

However, these studies describe the outcome of LVMR rather than focus on the development of postoperative high-grade hemorrhoids. Of the two studies with substantial follow-up, the study of D'Hoore et al. only followed up the patients by telephone and Slawik et al. did not perform an anorectal examination after 3 years^{5,27}. In the other two studies, the follow up period was substantial shorter^{26,28}. As a result, in these studies the occurrence of high-grade hemorrhoids after LVMR may have been underestimated. Furthermore, in the reported studies the main indication for LVMR was ERP, whereas in our study 86.9% of the patients presented with IRP. Also, two studies combined the LVMR with other procedures (e.g. STARR or resection rectopexy)^{27,28}. This heterogeneity amongst studies might explain the differences in reported percentages of high-grade hemorrhoids after LVMR.

Table 3. Available literature concerning high-grade hemorrhoids requiring surgery after LVMR.

First author	No. of patients	Indication LVMR	Follow-up in months (median)	High-grade hemorrhoids after LVMR	Treatment
D'Hoore 2004 ⁵	42	ERP	61	1 (2.4%)	SH
Slawik 2007 ^{a 27}	80	44 ERP 36 IRP	54	4 (5%)	3 SH, 1 TEH
Wijffels 2011 ²⁶	80	ERP	23	2 (2.5%)	1 SH, 1 STARR
Randall 2014 ^{b 28}	190	ERP	29	3 (1.6%)	3 SH

LVMR: laparoscopic ventral mesh rectopexy, SH: stapled hemorrhoidectomy, STARR: stapled transanal rectal resection. ^a 7 patients underwent a laparoscopic resection rectopexy, 74 females underwent concurrent posterior colporrhaphy and vaginal sacrocolpopexy, ^b LVMR was combined with Orr–Loygue (n=3), anterior colporrhaphy (n=7), posterior STARR (n=10) and SH (n=2).

In our study, 53.8% of the hemorrhoidectomy group (35/65) suffered from ODS complaints before LVMR and most of them had a long history of straining and incomplete evacuation. After LVMR, still 15 patients of the hemorrhoidectomy group (15/65, 23.1%. $p=0.004$)

reported persisting ODS complaints. Other studies quote a slightly lower figure (up to 19%) of patients suffering from persisting ODS after LVMR⁵⁻⁸. The high incidence of grade III / IV hemorrhoids after LVMR and the high recurrence rate of grade III / IV hemorrhoids after hemorrhoidectomy might be the result of persistent straining. The actuarial 5-year recurrence rate of 40.6% for grade III / IV hemorrhoids after hemorrhoidectomy was very high compared to several randomized controlled trials showing recurrence rates from 0 to 5% for both excisional as stapled hemorrhoidectomy³²⁻³⁵. It is also possible that some of the patients in the hemorrhoidectomy group were not properly assessed before LVMR. Possibly, some patients underwent LVMR for symptomatic IRP combined with a rectocele, whereas retrospectively the symptoms might have been caused mostly by a mucosal prolapse. Consequently, it could be that high-grade hemorrhoids following LVMR might be attributed to residual mucosal prolapse in some cases. In these patients, it seems LVMR repairs the rectal prolapse, but fails to correct the mucosal prolapse. If so, a different operation instead of LVMR (e.g. STARR) might have been more appropriate. Because of the retrospective character of this study, it is unfortunately not possible to verify if mucosal prolapses were missed before LVMR. The role of mucosal prolapse in hemorrhoidal disease is in debate. Gaj et al. showed 40% of the proctologists do not consider mucosal prolapse as independent from hemorrhoidal disease in a national survey³⁶.

We believe that mucosal prolapse is an integral part of the hemorrhoidal disease. However, whether mucosal prolapse is a completely different entity or not, with excising a circumferential band of excessive rectal mucosa and submucosa and interrupting the blood supply of the superior hemorrhoidal artery proximal to the hemorrhoidal tissue the clinical condition is treated either way. In addition, it is worth noting that the hemorrhoidectomy group includes more patients with a history of hysterectomy (72.3% vs. 33.1), re-do of the initial LVMR (12.3% vs. 8.8%) and number of past episiotomies (8.8% vs. 18.5%) than the non-hemorrhoidectomy group. All these variables might constitute an increased risk of developing high-grade hemorrhoids after LVMR. No

other differences worth mentioning were found between the groups. The incidence of recurrence of rectal prolapse in the hemorrhoidectomy group was also high, with an actuarial 5-year ERP recurrence rate of 25.3% and an actuarial 5-year IRP recurrence rate of 24.4%. In contrast, the non-hemorrhoidectomy group ($n = 355$) showed significantly lower actuarial 5-year ERP (0.8%, $p=0.011$) and IRP (11%, $p=0.020$) recurrence rates (figure 2a/b and table 2). The literature quotes similar incidences to our non-hemorrhoidectomy group with rates varying from 1.6% to 4.8%^{5,6,28,36} for ERP and from 0 to 15% for IRP^{8,37}. This could suggest that patients with high-grade hemorrhoids after rectopexy are susceptible to developing a rectal prolapse recurrence after LVMR. The hemorrhoidectomy group seems to contain a cohort of patients with persisting symptoms possibly not well responding to the standard therapy. Both high recurrence rates of rectal prolapse and grade III / IV hemorrhoids are indicative.

The three patients requiring a stoma due to persistent faecal incontinence support this impression. It may be that high-grade hemorrhoids after LVMR are a sign of laxity of (a part of) the posterior compartment and represent the first stage of a continuum, eventually developing into rectal prolapse. Consequently, the findings of this study could suggest that the development of high-grade hemorrhoids following LVMR might be considered predictive of a rectal prolapse recurrence. In order to exclude a rectal prolapse recurrence, additional radiological imaging should be considered when a patient presents with grade III / IV hemorrhoids following LVMR. Unfortunately, our data did not offer a clear explanation for the relationship between post-LVMR high-grade hemorrhoids and rectal prolapse recurrence. As there is no literature available on this potential relationship, it would be an interesting topic for future studies. LVMR has been performed in our hospital since 2004. Analysis shows that the occurrence of post-LVMR hemorrhoidectomy is fairly stable over the years. This indicates that there is probably no learning curve problem, or sign of insufficient repair. This is supported by the rates for ERP and IRP recurrence in the non-hemorrhoidectomy group which are comparable to the contemporary literature. A limitation of this paper are the differences in follow-up between patients. Although the Kaplan-Meier method yields appropriate estimates for recurrence rates at various points in time, underestimation remains possible.

When we compared patients receiving extended follow-up in the context of a previous study (n=149)⁷ with those followed-up according to the standardized postoperative protocol (n=271), the risk of high-grade hemorrhoids was somewhat higher with the standardized postoperative follow-up. However, estimates were unstable and the difference was not statistically significant (p=0.149). In the standardized follow-up protocol, the probability of the patient presenting at the outpatient clinic after the standard 6-week postoperative control might be related to the degree of postoperative complaints and therefore selection bias may have occurred.

Conclusion

High-grade hemorrhoids requiring surgery may be common after LVMR. The development of high-grade hemorrhoids after LVMR might be considered a predictor of rectal prolapse recurrence.

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Chapter 9

Long-term mesh erosion rate following abdominal robotic pelvic floor surgery

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Abstract

Objective

To determine the long-term vaginal and rectal erosion rate following abdominal pelvic reconstructive surgery.

Summary Background Data

The use of synthetic mesh in transvaginal pelvic floor surgery has been subject to debate internationally and led to two US Food and Drug Administration warnings in 2008 and 2011. Although mesh erosion appears less associated with an abdominal approach, long-term outcome has not been studied intensively.

Methods

All consecutive patients who underwent Robot-Assisted Laparoscopic Ventral Mesh Rectopexy (LVMR), Robot-Assisted Laparoscopic Sacrocolpopexy (LSC) and Robot-Assisted Laparoscopic Sacrocolporectopexy (LSCR) in 2011 and 2012 were prospectively included. Patients with a minimum of 36 months of follow-up were invited to the outpatient clinic. Long-term evaluation included a digital rectal and vaginal examination, proctoscopy and a vaginal speculum examination to assess mesh-related complications. Patients who were either unable or declined to attend clinic, were asked to participate in a standardized telephone and paper questionnaire. Kaplan-Meier estimates were calculated for erosions.

Results

171 of the 196 included patients actively participated. Of those cases, 141 patients (45 LVMR, 50 LSC, 46 LSCR) with a median follow-up of 49.2 months (range 36.0-62.1) were clinically examined. Three (2.8%, 95% confidence interval 0–5.9) mesh erosions were diagnosed; one bladder erosion for which a resection and an omental patch interposition was performed, and two asymptomatic vaginal erosions (42.7 and 42.3 months) treated with estrogen cream in one. None of the additional 30 patients assessed with a telephone and paper questionnaire reported mesh-related complaints.

Conclusions

Concerns relating to transvaginal mesh placement may not be extrapolated to abdominal procedures because mesh erosion following an abdominally placed synthetic graft is low on the long-term.

Introduction

The use of synthetic mesh in pelvic floor surgery has been subject to debate in the past two decades. In 2008 and 2011, the US Food and Drug Administration (FDA) warned about the high rate of mesh-related complications following a transvaginal pelvic organ prolapse repair¹. The FDA warnings were underlined by a systematic review suggesting a summary incidence of mesh erosion following transvaginal pelvic organ prolapse repair as high as 10.3% (range 0 – 29.7%, n=11,785) in the first postoperative year². Recent literature on a transvaginal repair has confirmed this high incidence³. Transabdominal approaches for pelvic reconstructive surgery are increasingly performed as an alternative to transvaginal repair. Minimally invasive sacrocolpopexy with mesh is currently the gold standard for a middle compartment prolapse, and minimally invasive ventral mesh rectopexy has gained increasing worldwide acceptance for rectal prolapse^{4,5}.

More recently, the two abdominal procedures have been combined to treat multi-compartment prolapse^{6,7}. However, the safety of an abdominally placed synthetic mesh remains uncertain. Since the FDA warnings, several articles describing the two techniques reported mesh erosion^{5,8}. Most of the reported studies are, however, retrospective or uncontrolled series with short-term follow-up. Research focusing specifically on mesh-related morbidity following a minimally invasive abdominal approach with long-term follow-up is lacking. In addition, the literature might underestimate the incidence of mesh-related morbidity since mesh erosion also occurs asymptotically^{2,9}.

It is against this backdrop that we designed a study to evaluate the true long-term mesh erosion rate following Robot-Assisted Laparoscopic Ventral Mesh Rectopexy (LVMR), Robot-Assisted Laparoscopic Sacrocolpopexy (LSC) and Robot-Assisted Laparoscopic Sacrocolpoporectomy (LSCR). In addition, we performed an extensive literature search on mesh-related morbidity following a minimally invasive abdominal pelvic floor repair.

Methods

Study design

All consecutive patients who underwent LVMR, LSC or LSCR at a tertiary referral centre for pelvic floor disorders in the Netherlands in 2011 and 2012, were prospectively included. Prolapse of the posterior compartment was diagnosed using the Oxford Grading System by proctoscopy and dynamic MRI¹⁰. The simplified Pelvic Organ Prolapse Quantification (POP-Q) was used for determining prolapse in the LSC and LSCR groups¹¹. Patients were reviewed at 6 weeks postoperatively and annually thereafter. In 2016, all patients with a minimum of 36 months of follow-up were invited to a clinical assessment at the outpatient clinic. The general practitioner was contacted in cases of incorrect address details. Patients who were either unable or declined to attend clinic, were asked to participate in a standardized telephone and paper questionnaire to evaluate mesh-related complications. This study was carried out in accordance with the ethical standards of the institutional research committee and with the Declaration of Helsinki. All patients gave informed consent before inclusion in this study.

Surgical techniques

All operations were performed with the da Vinci robot (Intuitive Surgical, Inc., Sunnyvale, CA, USA) by surgeons and gynaecologist with ≥ 10 years' experience. Every patient received prophylactic intravenous antibiotics (1000 mg. cefazolin and 500 mg. metronidazole) 15 minutes prior to incision. The LVMR procedures were performed exactly according to the laparoscopic technique firstly described by D'Hoore and Penninckx¹². Posterolateral rectal mobilization or lateral ligament dissection were avoided. The LSC procedures, with or without supravaginal hysterectomy, were performed according to the technique described by Clifton et al.¹³. The technique of LSCR, performed jointly by a colorectal and a urogynaecological surgeon, has been previously described by our study group⁶.

All meshes (type 1, macroporous polypropylene, Prolene, Ethicon Inc., Johnson & Johnson, Hamburg, Germany, weight 80-85g/m²) were distally attached using non-absorbable sutures (Ethibond, Ethicon Inc., Johnson & Johnson, Hamburg, Germany)

and anchored proximally to the sacral promontory using titanium tacks (Autosuture Protack 5mm, Covidien, USA). Two meshes, connected to each other to create a Y-shaped suspension, were used in the LSCR procedures. In all operations the peritoneum was approximated to cover the implant using a 23 cm V-Loc suture (Covidien, Mansfield, MA, USA). The surgeon performed a vaginal and/or rectal examination at the end of each procedure to exclude a possible (needle) perforation of the vaginal and/or rectal wall and to determine the correct position of the mesh.

Clinical evaluation

The long-term postoperative evaluation at the outpatient clinic included a standardized structured surgical and urogynaecological history, especially focused on mesh-related morbidity. All patients underwent a digital rectal and vaginal examination, a proctoscopy and a vaginal speculum examination to assess mesh-related complications. Both the proctoscope and the speculum were transparent. Patients were examined in the supine lithotomy position using leg supports, both in rest and during maximal Valsalva. Clinical examination was performed by an objective researcher. If mesh-related morbidity was suspected, a second examination by a gynaecologist was performed to confirm the diagnosis. Mesh erosion was graded according to the International Urogynaecological Association (IUGA) and the International Continence Society (ICS) joint terminology and category, time and site (CTS) classification¹⁴.

Statistical Analysis

Statistical Package for the Social Science, version 20.0 (IBM Corp, Armonk, NY) was used for statistical analysis. Data are presented as percentage, mean $\pm$ standard deviation (SD), median and range. Because of difference in follow-up between patients, the Kaplan-Meier method was used to estimate the erosion rate at various time points.

Selection of literature

To compare our mesh erosion rates with the literature, three Pubmed and Medline searches were performed using the terms “ventral OR anterior AND rectopex*”, “sacrocolpopex* OR sacral colpopex*” and “(rectopex* AND sacr*) OR (rectopex* AND colp*) OR sacrocolporectopex* OR colporectopex* OR rectovaginopex* OR sacrocolpoperineopex* OR colpoperineopex*” for English-language articles until September 1, 2016. References of the eligible studies were searched to identify other potential relevant articles. Only articles describing a minimally invasive procedure with a duration of follow-up of at least 12 months were included for ventral mesh rectopexy and sacrocolpopexy studies. Paediatric articles were excluded.

Results

Patients

In total 196 patients were included (Flowchart Fig. 1). One LSC patient was converted because of a pre-sacral bleeding due to manipulation of the promontory by the assistant in order to keep the small intestine in position in an obese patient. Instead of LSC an anterior colporrhaphy was performed in this patient. Six patients (3.1%) died of natural causes and four patients suffered from cognitive impairment. During follow-up, two patients received a stoma (one because of therapy-resistant faecal incontinence and extensive sphincter dysfunction and one due to disabling obstructed defecation) and declined participation. Two patients refused involvement because of the absence of any complaints. Ten further patients were lost to follow-up, including three emigrations. Of the remaining 171 cases, 143 (83.6%) patients visited the outpatient clinic. Two of those patients (with no complaints or symptoms) declined a physical examination, leaving 141 (82.5%) patients who underwent a full clinical evaluation with questionnaires. The rest of the patients were unable to attend the clinic and were assessed with a standardized telephone and a paper questionnaire (n=19, 11.1%), or just a telephone questionnaire (n=9, 5.3%).

Figure 1. Flowchart.

Demographics and operative data

Of the 141 included cases, 45 (31.9%) patients (including 2 men) underwent LVMR, 50 (35.5%) women received a LSC and 46 (32.6%) women underwent LSCR (Table 1).

Table 1. Patient demographics and operative data

	Total n=141	LVMR n=45^a	LSC n=50^b	LSCR n=46
Women/men (mean age)	139/2 (61.9)	43/2 (61.0)	50/0 (62.4)	46/0 (62.2)
Mean ASA classification (SD)	1.8 (0.5)	1.9 (0.6)	1.7 (0.5)	1.9 (0.5)
Mean parity (SD)	2.7 (1.1)	2.5 (1.1)	2.8 (1.1)	2.8 (1.0)
Mean BMI (SD)	26.0 (4.3)	25.9 (4.6)	25.9 (3.7)	26.3 (4.7)
Episiotomy (%)	78 (55.3)	27 (60.0)	29 (58.0)	22 (47.8)
Prolapse 1 st degree relative (%)	48 (34.0)	13 (28.9)	20 (40.0)	15 (32.6)
History				
(%) <i>TVT</i>	8 (5.7)	3 (6.7)	1 (2.0)	4 (8.7)
<i>Burch colposuspension</i>	4 (2.8)	3 (6.7)	1 (2.0)	-
<i>Hysterectomy</i>	50 (35.5)	16 (35.6)	14 (28.0)	20 (43.5)
<i>Sacrocolpopexy</i>	1 (0.7)	-	1 (2.0)	-
<i>Anterior colporrhaphy</i>	28 (19.9)	8 (17.8)	9 (18.0)	11 (23.9)
<i>Posterior colporrhaphy</i>	30 (21.3)	11 (24.4)	8 (16.0)	11 (23.9)
<i>Rectopexy</i>	2 (1.4)	-	1 (2.0)	1 (2.2)
<i>Perineal procedure</i>	4 (2.8)	2 (4.4)	-	2 (4.3)
<i>Sphincter procedure</i>	1 (0.7)	1 (2.2)	-	-
<i>Hemorrhoidectomy</i>	9 (6.4)	7 (15.6)	-	2 (4.3)
<i>Other abdominal surgery</i>	46 (32.6)	14 (31.1)	15 (30.0)	17 (37.0)
Posterior compartment (%)				
<i>ERP</i>	7 (5.0)	3 (6.7)	-	4 (8.7)
<i>IRP or/and symp. rectocele*</i>	81 (57.4)	32 (71.1)	21 (42.0)	28 (60.9)
<i>* with enterocele</i>	25 (17.7)	10 (22.2)	3 (6.0)	12 (26.1)
Middle/ant. Compartment (mean, range)				
<i>POP-Q A</i>	2.4 (1-4)	1.6 (1-4)	2.6 (1-4)	2.4 (1-4)
<i>POP-Q B</i>	2.0 (1-4)	1.9 (1-4)	1.9 (1-4)	2.2 (1-4)
<i>POP-Q C</i>	2.4 (1-4)	1.2 (1-4)	2.9 (1-4)	2.2 (1-4)
<i>POP-Q D</i>	1.5 (1-4)	1.3 (1-4)	1.8 (1-4)	1.3 (1-4)
Concomitant hysterectomy (%)	61 (43.3)	-	36 (72.0)	25 (54.3)
Conversion (%)	2 (1.4)	-	1 (2.0)	1 (2.2)
Intra-operative complications (%)	3 (2.1)	-	-	3 (6.5)
Mean LOS, nights (SD)	2.9 (1.2)	3.1 (1.0)	2.3 (0.9)	3.4 (1.2)
Early postoperative complications (%)				
<i>Minor</i>	3 (2.1)	1 (2.2)	2 (4.0)	-
<i>Major</i>	1 (0.7)	-	1 (2.0)	-
Mesh erosion (%)	3 (2.1)	-	2 (4.0)	1 (2.2)
Postoperative in-hospital mortality	-	-	-	-

Mo. indicates months; ERP: external rectal prolapse; PP: polypropylene; - : missing; n/d: not described; PE: polyester; R: robot; L: laparoscopic. ^a Follow-up (FU) was carried out with a telephonic interview;

^b Percentages are Kaplan-Meier estimates at 60 and 120 months of FU; ^c mean instead of median; ^d one patient lost to FU; ^e 3 of the 33 patients (ERP n=20, n=13 IRP) lost to FU. Of the lost to FU patients initial diagnosis was not given; ^f Only patients with recurrent symptoms were examined. ^g Data is i.a. a collection of previously described studies. Only procedures with synthetic meshes selected. Indications for surgery were not given;

^h Percentages are Kaplan-Meier estimates at 10 years of follow-up.

LSC and LSCR were combined with a concomitant supravaginal hysterectomy in 36 (72%) and in 25 (54.3%) cases. Mean age and body mass index of all patients were 61.9 ± 10.5 years and 26.0 ± 4.3 kg/m², respectively. Overall, 2% of LSC cases (1/50) and 2.2% of LSCR (1/46) cases were converted to an open procedure, in one case because of extensive intra-abdominal adhesions and in another case due to anaesthesia-related issues. Intra-operative complications occurred in three (2.1%) patients; two small bladder perforations in the bladder dome and one minor serosal lesion. All lesions were over-sewn and the operations were continued by placement of the mesh. No (mesh-related) postoperative complications were observed in these patients. Median follow-up was 49.2 months (range 36.0 – 62.1).

Mesh-related complications

Three patients developed mesh erosion during follow-up (Table 2). The accompanying actuarial erosion rates for the total cohort were 0% after 1, 0% after 3, and 2.8% after 5 years (95% confidence interval (CI) 0–5.9, Fig. 2). The first patient presented with pain, dysfunctional voiding and recurrent urinary tract infections 45 months after LSC with hysterectomy. A small defect of the posterior wall of the bladder with mesh exposure was observed with cystoscopy. The mesh was resected and an omental patch interposition was performed by a Pfannenstiel incision. The second mesh erosion was discovered at a regular control 42.7 months following LSCR with supravaginal hysterectomy. An asymptomatic erosion was found in the posterior wall of the vagina for which vaginal oestrogen cream was prescribed. The third mesh erosion was also asymptomatic and was found in the posterior wall of the vagina at 42.3 months after LSC. Since the mesh exposure was so small, expectant management was chosen. All three patients who developed a mesh erosion had an extensive surgical pelvic floor history (Table 2). Two of the three women were post-menopausal.

Five (3.5%) other post-menopausal patients (mean age 69 ± 7.2 years), all with vaginal atrophy, experienced vaginal discomfort examining the distal side of the mesh. No mesh erosion or other mucosal abnormalities were observed. One of these patients

Table 2. Mesh erosions current study

Age, y (ASA)	Previous surgery	Procedure	Location, symptoms	CTS ¹⁴	Defect	Delay, mo.	Treatment
50 (2)	Cervical amputation, ventral mesh rectopexy, ant. and post. colpor- rhaply	LSC with hysterectomy	Bladder, posterior wall, symptomatic	4B/T4/S3	< 1cm	45.0	Pfannenstiel: mesh resection and omental patch interposition
77 (2)	Unknown prolapse surgery, ant. and post. colporrhaphy	LSCR with hysterectomy	Vagina, posterior wall, asymptomatic	2A/T4/S1	1 cm	42.7	Vaginal oestrogen cream 2x/week
74 (2)	Hysterectomy, post. col- porrhaphy and McCall	LSC	Vagina, posterior wall, asymptomatic	2A/T4/S1	< 1cm	42.3	Expectant manage- ment

y indicates years; ASA: American society of anaesthesiologists; mo.: months; ant.: anterior; post.: posterior.

Figure 2. Kaplan-Meier curve for mesh erosion for the total cohort (n=141).

developed postoperative new-onset dyspareunia, but refused vaginal oestrogen cream because of the sporadic occurrence of complaints. All five patients were offered vaginal oestrogen cream, but only two (both sexually active) patients accepted the prescription.

No other mesh-related morbidity was observed in the total cohort. Telephone and paper questionnaire None of the 30 patients assessed by telephone questionnaire reported mesh-related complaints. The paper pelvic floor questionnaires filled in by 21 of these patients, did not generate additional information.

Discussion

Synthetic meshes are used to reinforce weak or defective supportive tissues since 1959 in pelvic reconstructive surgery¹⁵. The use of synthetic mesh potentially adds to the complication profile and mesh-related morbidity can have a considerable impact on the quality of life¹⁶. The introduction of transvaginal procedures highlighted the risk of mesh-related complications, which have since been reported in high numbers¹. This current study proves that mesh-related morbidity following a minimally invasive abdominal pelvic floor repair is rare in the long-term. The three patients with erosions had some of the characteristics and recognized risk factors for mesh erosion including history of pelvic floor surgery (n=3), smoking (n=1), sexual activity (n=1) and age >70 years (n=2)^{3,16-18}. During the vaginal examination directly postoperatively a perforating suture was removed in one of these patients which is a risk factor for mesh erosion¹⁷. Two of the three patients underwent a concomitant supravaginal hysterectomy. A total hysterectomy concomitant to a sacrocolpopexy is associated with a four times higher risk of mesh erosion as compared to sacrocolpopexy without hysterectomy¹⁹. A subtotal hysterectomy, however, appears to generate comparable mesh erosions rates to sacrocolpopexy without hysterectomy¹⁹. Other known predictors of mesh erosion include the use of steroids, diabetes, level of surgeon experience, intra-abdominal adhesions and postoperative pelvic hematoma^{3,16-18}. In this study a monofilament and macroporous (>75 µm, type I) mesh, allowing host cell colonization with collagen deposition, angiogenesis and infiltration of leukocytes, resulting in good support and a reduced risk for infection was used²⁰. Research shows that synthetic meshes with smaller pores (type II and III) are associated with a higher erosion rate^{9,16}. It has been suggested that light-weight meshes may be less prone to erosion, but may have a higher recurrence rate than heavy-weight grafts^{21,22}. Three studies on sacrocolpopexy using a light-weight mesh show an erosion percentage of 0% after 12 months of follow-up²¹⁻²³. Studies with longer follow-up or comparative studies for an abdominal prolapse repair, however, do not exist. Data on hernia repair suggests an impact of the weight of the mesh, but the optimal balance between weight and porosity is unknown²⁴. In the contemporary literature on

LVMR and sacrocolpopexy no significant difference is observed between synthetic and biological mesh in mesh-related complications^{9,25-28}. Evidence suggests, however, that recurrence rates are higher following a repair with biological mesh as compared to synthetic mesh^{5,27-29}. To reduce the risk of mesh erosion, we administered preoperative antibiotics, dissected meticulously with a strict monitoring on haemostasis to prevent a hematoma, attached the (type I) mesh and closed the incised peritoneum over the mesh. Considering the numerous risk factors and prevention strategies, the occurrence of mesh erosion presumably has a multifactorial origin. A further five (3.5%) patients in this study experienced vaginal discomfort during speculum examination. Only two of the five patients (both sexually active) occasionally experience vaginal discomfort in daily life. The possibility of vaginal discomfort, probably due to vaginal atrophy, should be considered in the decision to offer pelvic reconstructive surgery using mesh in older sexually active females. Both the rectum and the vagina were examined in this study, but only vaginal erosions were diagnosed. The most probable explanation for this difference is vaginal atrophy, increasing with age. In order to obviate this, surgeons could consider to prescribe vaginal oestrogen cream. Articles on laparoscopic and robotic ventral mesh rectopexy report a mesh erosion rate between 0 and 3.7% (median range of follow-up 12 - 74 months, Table 3). The median erosion rate of the studies is zero with more than 90% of the articles showing an erosion rate <2.5% (Fig. 3). There are two outliers; Randall et al. (3.7%) partially used polyester mesh which is associated with a higher risk of mesh erosion^{30,31}. Laurretta et al. (3.3%) reported only one suture erosion in a small study including only 30 patients³². The contemporary literature on laparoscopic and robotic sacrocolpopexy shows erosion rates between 0 and 13.3% (median range of follow-up 12 - 72 months, Table 4). More than 85% of the articles report an erosion percentage of ≤5% with an overall median erosion rate of 1.9% (Fig. 3). The only outlier in the boxplot (Geller et al., 13%) could be attributed to a low sample size³³. The figures in the literature are in line with the erosion rates of our LVMR (0%) and LSC (Kaplan-Meier estimate 5.3% after 5 years, 95% CI 0-12.4) subgroups. However, the majority of the studies in the literature were retrospective and lacked a systematic follow-up with a

rectal and vaginal examination. In particular, mesh erosion rates following ventral mesh rectopexy studies are unreliable due to the study design. Furthermore, our study proves mesh erosion also occurs asymptotically. None of the ventral mesh rectopexy studies and only one sacrocolpopexy article mentions asymptomatic mesh erosion³⁴. Because of a lack of a systematic follow-up with adequate physical examination, poor methodology and the lack of mentioning of asymptomatic erosions, it is likely that erosion rates are underestimated in current literature. We believe this study approaches the true

Table 3. Mesh erosion following minimally invasive ventral mesh rectopexy with synthetic mesh (≥12 mo. of follow-up)

First author	No. of patients	Material and type of mesh	Vaginal/rectal examination mesh	Follow-up mo. (median)	Mesh complication (%)	Mesh erosion (%)
Indication ERP						
D'Hoore ³⁷ 2004	42	PP, 1	No, tel. FU ^a	61	0	0
Auguste ³⁸ 2006	54	-	n/d	12	0	0
D'Hoore ¹² 2006	109	PP, 1	n/d	-	0	0
Boons ³⁹ 2010	65	PP, 1	No, tel. FU ^a	19	0	0
Wijffels ⁴⁰ 2011	80	PP, 1/PE, 3	n/d	23	0	0
Faucheron ⁴¹ 2012	175	PE, 3	n/d	74/60 ^b	1 (0.6)	1 (0.6)
Tranchart ⁴² 2013	312	PE, 3	n/d	-	-	6 (1.9)
Randall ³⁰ 2014	190	PP, 1/PE, 3	No	29	7 (3.7)	7 (3.7)
Tsunoda ⁴³ 2016	31	PP, 1	Only rectal	25	2 (6.5)	0 (0)
Emile ⁴⁴ 2016	25	PP, 1	Only rectal	18 ^c	0	0
Chandra ⁴⁵ 2016	15	PP, 1	No, tel. FU ^a	22	0	0
Indication IRP and/or rectocele						
van den Esschert ⁴⁶ 2008	17 ^d	PP, 1	No, tel. FU ^a	38 ^c	1 (6.3)	0
Slawik ⁴⁷ 2008	80	PP, 1	n/d	54	0	0
Collinson ⁴⁸ 2010	75	PP, 1	Only rectal	12	0	0
Wong ⁴⁹ 2011	84	PE, 3	Yes, both	29	1 (1.2)	1 (1.2)
Gosselink ⁵⁰ 2013	72	PP, 1	n/d	12	1 (1.4)	1 (1.4)
Indication both ERP and IRP and/or rectocele						
Formijne Jonkers ⁵¹ 2012	36 ERP, 197 IRP	PP, 1	No, tel. FU ^a	30	2 (0.8)	0
Lauretta ³² 2012	2 ERP, 28 IRP	PP, 1	n/d	13.9 ^c	1 (3.3)	1 (3.3)
Badrek-Amoudi ⁵² 2012	11 ERP, 37 IRP	PP, 1	n/d	33	1 (2.1)	1 (2.1)
Maggiori ⁵³ 2013	33 ^e	PP, 1	No, tel. FU ^a	42 ^d	2 (6.7)	0 (0)
Gosselink ⁵⁴ 2014	41 ERP, 50 IRP	PP, 1	Only rectal	12	0	0
Ogilvie ²⁶ 2014	19 ERP, 10 IRP	PP, 1	No ^f	15.4	0	0
Mackenzie ³¹ 2014	149 ERP, 487 IRP	PP, 1/PE, 3	n/d	21	20 (3.1)	7 (1.1)
Evans ⁹ 2015 ^g	1764 ^g	PP, 1/PE, 3	n/d	38	42 (2.4)	42 (2.4)
Consten/van Iersel ⁵⁵ 2015	242 ERP, 677 IRP	PP, 1	No	33.9/120 ^b	18 (4.6) ^h	7 (1.3) ^h
Tsunoda ⁵⁶ 2015	19 ERP, 25 IRP	PP, 1	n/d	26	1 (1.7)	0
Horisberger ⁵⁷ 2016	12 ERP, 15 IRP	-	n/d	22	1 (3.7)	0
Robotic vs Laparoscopic studies - various indications						
De Hoog ⁵⁸ 2009	20 ERP R	-	n/d	23.4	0	0
Wong ⁵⁹ 2011	15 IRP R, 23 IRP L	PE, 3	Yes, both	12	0	0
Mantoo ⁶⁰ 2013	12 ERP, 32 IRP R 23 ERP, 51 IRP L	-	No	16 ^c	0	0

Mo. indicates months; ERP: external rectal prolapse; PP: polypropylene; - : missing; n/d: not described; PE: polyester; R: robot; L: laparoscopic. ^a Follow-up (FU) was carried out with a telephonic interview; ^b Percentages are Kaplan-Meier estimates at 60 and 120 months of FU; ^c mean instead of median; ^d one patient lost to FU; ^e 3 of the 33 patients (ERP n=20, n=13 IRP) lost to FU. Of the lost to FU patients initial diagnosis was not given; ^f Only patients with recurrent symptoms were examined. ^g Data is i.a. a collection of previously described studies. Only procedures with synthetic meshes selected. Indications for surgery were not given; ^h Percentages are Kaplan-Meier estimates at 10 years of follow-up.

Table 4. Mesh erosion following minimally invasive sacrocolpopexy with synthetic mesh (≥ 12 mo. of follow-up)

First author	No. of patients	Material and type of mesh	Vaginal/rectal exam. mesh	Follow-up mo. (median)	Mesh complication (%)	Mesh erosion (%)
Laparoscopic and Robotic						
Paraiso ⁴ 2011	38 L, 40 R	PP, 1	Only vag.	12	0 L, 2 (5.3) R	0 L, 2 (5.3) R
Chan ⁶¹ 2011	20 L, 16 R	PP, 1	Only vag.	39 L, 16 R	0 L, 0 R	0 L, 0 R
Tan-Kim ⁶² 2011	58 L, 42 R	PP, 1	Only vag.	19 L, 12 R	2 (3.6) L, 2 (5.0) R	2 (3.6) L, 2 (5.0) R
Seror ⁶³ 2012	47 L, 20 R	PP, 1	Only vag.	18 L, 15 R	1 (2.1) L, 0 R	1 (2.1) L, 0 R
Joubert ⁶⁴ 2014	39 L, 17 R	PP, 1/PE, 3	Only vag.	12 L, 14.9 R	2 (5.1) L, 0 R	2 (5.1) L, 0 R
Tan-Kim ⁶⁵ 2015	32 L, 32 R	PP, 1	Only vag.	12	1 (3.1) L, 2 (6.3) R	1 (3.1) L, 1 (3.1) R
Kenton ⁶⁶ 2016	33 L, 33R	PP, 1	Only vag.	12	0	0
Laparoscopic						
Gadonneix ⁶⁷ 2004	46	PE, 3	Only vag.	24	0	0
Antiphon ⁶⁸ 2004	104	PE, 3	Only vag.	17	1 (1.0)	0
Paraiso ⁶⁹ 2005	56	PP, 1	n/d	13.5 ^a	2 (3.6)	2 (3.6)
Ross ⁷⁰ 2005	51	PP, 1	Only vag.	60	8 (18.6)	4 (7.8)
Rozet ⁷¹ 2005	363	PE, 3	Only vag.	14.5 ^a	8 ^b (2.2)	3 (0.8)
Agarwala ⁷² 2007	49	PP, 1	Only vag.	24	1 (2.0)	0
Rivoire ⁷³ 2007	108	PP, 1	Only vag.	33.7 ^a	9 (8.3)	7 (6.5)
Stepanian ²⁰ 2008	402	PP, 1	n/d	12	12 (3.0)	5 (1.2)
North ⁷⁴ 2009	22	PP, 1	Only vag.	27.5 ^a	1 (4.5)	1 (4.5)
Granese ⁷⁵ 2009	165	PP, 1	Yes, both	43	9 (5.5)	1 (0.6)
Loffeld ⁷⁶ 2009	20	PP, 1	Only vag.	45 ^a	1 (5.0)	1 (5.0)
Deprest ²⁹ 2009	104 ^c	PP, 1	Only vag.	33 ^a	12 (11.5)	8 (7.7) ^d
Sabbagh ⁷⁷ 2010	132	PP, 1	Only vag.	60	6 (4.5)	5 (3.8)
Akladios ⁷⁸ 2010	48	PP, 1	Only vag.	15.8 ^a	1 (2.2)	1 (2.2)
Maher ⁷⁹ 2011	53	PP, 1	Only vag.	24 ^a	1 (1.9)	1 (1.9)
Sergeant ⁸⁰ 2011	116	PE, 3	Only vag.	34.2	5 (4.3)	4 (3.4)
Perez ⁸¹ 2011	85	PE, 3	Only vag.	12	5 (5.9)	3 (3.5)
Price ⁸² 2011	84	PP, 1	Only vag.	24 ^a	5 (6.0)	5 (6.0) ^e
Chan ⁸³ 2011	31	PP, 1	Only vag.	32	0	0
Freeman ⁸⁴ 2013	23	PP, 1	Only vag.	12	0	0
Leruth ⁸⁵ 2013	55	PE, 3	Only vag.	25 ^a	0	0
Culligan ²¹ 2014	143	PP, 1	Only vag.	12	0	0
Sarlos ⁸⁶ 2014	68	PP, 1	Only vag.	60 ^a	2 (2.9)	2 (2.9)
Liu ²² 2014	39	PP, 1	Only vag.	12	0	0
Estrade ⁸⁷ 2015	35	PE, 3	Only vag.	13.2	1 (2.9)	1 (2.9)
El Hamamsy ⁸⁸ 2015	220	PP, 1	Only vag.	12	2 (0.9)	2 (0.9)
Vieillefosse ⁸⁹ 2015	100	PP, 1/PE, 3	Only vag.	23.6	2 (2.0)	2 (2.0)
Dandolu ³ 2016	4552	n/d	n/a	24	52 (1.7)	52 (1.7)
Lizee ⁹⁰ 2016	60	PE, 3	Only vag.	27	1 (1.7)	1 (1.7)
Vandendriessche ⁹¹ 2016	391 ^f	PP, 1/PE, 3	No, tel. FU ^g	53.3	11 (2.8)	7 (1.8)
Zebede ⁹² 2016	144	PP, 1	Only vag.	21	4 (2.8)	0
Liang ⁹³ 2016	30	PP, 1	Only vag.	36	3 (10)	3 (10)
Costatini ⁹⁴ 2016	60	PP, 1	Only vag.	41.7 ^a	3 (5.0)	3 (5.0)
Pan ⁹⁵ 2016	99	PP, 1	Only vag.	33 ^a	0	0
Robotic						
Elliott ⁹⁶ 2007	42	PP, 1	Only vag.	36 ^a	3 (7.1)	2 (4.8)
Benson ⁹⁷ 2010	43	PP, 1	n/d	20.7-38.4 ^h	0	0
Xylinas ⁹⁸ 2010	12	PP, 1	n/d	19.1	0	0
Shveiky ⁹⁹ 2010	17	PP, 1	Only vag.	12.3	0	0
Moreno-Sierra ¹⁰⁰ 2011	31	PP, 1	Only vag.	24.5 ^a	1 (3.2)	0
Shimko ¹⁰¹ 2011	40	PP, 1	Only vag.	62	2 (5.0)	2 (5.0)
Geller ³³ 2011	15	PP, 1	Only vag.	14.8 ^a	2 (13.3)	2 (13.3)
Geller ³⁴ 2012	23	PP, 1	Only vag.	44.2 ^a	2 (8.7)	2 (8.7)
Mourik ¹⁰² 2012	50	PP, 1	Only vag.	16	1 (2.0)	0
Siddiqui ¹⁰³ 2012	70	PP, 1	Only vag.	18.3 ^a	3 (4.3)	3 (4.3)
Göçmen ¹⁰⁴ 2012	12	PP, 1	n/d	12	0	0
Louis-Sylvestre ¹⁰⁵ 2013	90	PE, 3	n/d	15.6 ^a	1 (1.1)	1 (1.1)
Belsante ¹⁰⁶ 2013	35	PP, 1	Only vag.	28	1 (2.9)	1 (2.9)
Salamon ²³ 2013	118	PP, 1	Only vag.	12	2 (0.8)	0
Borahay ¹⁰⁷ 2014	20	PP, 1	Only vag.	17.3 ^a	0	0
Barboglio ¹⁰⁸ 2014	127	PP, 1	Only vag.	12	3 (2.4)	3 (2.4)
Ploumidis ¹⁰⁹ 2014	95	PP, 1	Only vag.	34	1 (1.1)	1 (1.1)
Linder ¹¹⁰ 2015	70	PP, 1	n/d	72	2 (2.7)	2 (2.7)
Myers ¹¹¹ 2015	83	PP, 1	Only vag.	12.8	4 (4.8)	4 (4.8)
Jambusaria ¹¹² 2015	30	PP, 1	Only vag.	12	1 (3.3)	1 (3.3)
Prendergast ¹¹³ 2016	33	PP, 1	Only vag.	12	2 (6.1)	2 (6.1)

Mo. indicates months; R: robot; L: laparoscopic; PP: polypropylene; PE: polyester; vag.: vaginal; n/d: not described; n/a: not applicable. ^a mean instead of median; ^b 2 patients underwent an additional TVT; ^c 39 with porcine dermis, 65 with PP; ^d 2 after SCP with a xenograft, 6 after SCP with PP; ^e 4 of the 5 were suture erosions; ^f Long-term follow-up performed with a telephone or a postal questionnaire; ^g Follow-up (FU) was carried out with a telephonic interview; ^h Patients with a LSC: mean FU 20.7 mo., patients with a LSC + hysterectomy: mean FU 38.4.

Figure 3. Boxplot of mesh erosion rates in the literature on minimally invasive ventral mesh rectopexy, minimally invasive sacrocolpopexy and multi-compartment procedures.

erosion rate. The clinical significance of an asymptomatic mesh erosion is unclear. Only the patient with a symptomatic mesh erosion underwent a surgical intervention in our series. Practically all erosions reported in the literature were symptomatic and the majority of those erosions required surgery (94% for ventral mesh rectopexy, 87% for sacrocolpopexy, Table 1 and 2). The LSCR subcohort of our study noted an actuarial mesh erosion percentage of 3.0 (95% CI 0-8.9). To date, four studies describing a multi-compartment approach mention mesh erosion, varying from 2.0 to 5.4% (median range of follow-up 195 days - 64 months, Fig. 3)^{6,7,35,36}. Only one of the four studies performed a rectal and vaginal examination after 12 months of follow-up and noted a 2% erosion rate⁶. The most important limitation of this study is that all patients were treated in a single tertiary referral hospital for pelvic floor disorders, therefore limiting the generalizability of the results. In addition, 17.5% of the invited patients did not undergo a physical examination due to various reasons and therefore bias may have occurred. Mesh-related morbidity is an important issue because of the potential impact on the quality of life, the widespread use of mesh and the global attention to the topic. In recent years the public opinion has turned against synthetic grafts. Fear of mesh-related morbidity is resulting

in under-treatment of serious, disabling pelvic floor disorders. The results of this study demonstrate that abdominal placed synthetic meshes for pelvic reconstructive surgery are safe on the long-term. This is an encouraging finding for patients and doctors, in a field marked by a lack of adequate evidence. Surgeons using synthetic mesh for pelvic floor repair are encouraged to perform focused and meticulous examination looking for mesh erosion on the long-term to confirm these results.

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Chapter 10

Summary

The findings of the studies are summarised per section in this chapter. The results of the studies are further discussed in the **chapter eleven**.

SECTION ONE: DIAGNOSTICS AND CURRENT PRACTISE

The two most used radiological imaging techniques for the diagnosis of a pelvic floor prolapse, conventional dynamic defecography (CD, gold standard) and dynamic magnetic resonance imaging (MR defecography, D-MRI), were compared in **chapter two**. D-MRI underreported rectocele formation with a difference in prevalence (CD 77.8 vs. D-MRI 55.6%), mean protrusion (26.4 vs. 22.7 mm, $p=0.039$) and 11 false negative results. For the diagnosis of enterocele, D-MRI was inferior to CD with five false negative results. D-MRI, however, appears superior to CD in identifying intussusception with nine false positive results and only two missed IRPs (one symptomatic). It may therefore be concluded that CD and D-MRI are complementary imaging techniques for the diagnosis of a prolapse of the posterior compartment.

Numerous surgical techniques for rectal prolapse have been described. Despite the high number of procedures in the literature, there are only a few actually routinely performed and the majority has historical interest only. In **chapter three** an overview of procedures in common practice and routinely reported on in the literature are given in the context of the Dutch prolapse guideline. The conclusions from comparative studies on external rectal prolapse (ERP) were that a laparoscopic approach is preferred over an open procedure (also applicable for internal rectal prolapse (IRP)); an open abdominal procedure is favoured over a perineal approach; preservation, rather than division, of the lateral ligaments is preferred; resection of the redundant colon is associated with less postoperative constipation but with a higher postoperative (major) complication rate and a higher postoperative faecal incontinence percentage; the addition of a rectopexy to rectal mobilisation reduces the recurrence rate; and that an additional levatorplasty to either a Delorme's or Altemeier's procedure is preferred. Non-comparative observational studies on ERP show that laparoscopic resection rectopexy is a safe and effective technique; a perineal procedure could be a good option if general anaesthesia

is contraindicated and suggest an advantage in functional outcome of laparoscopic ventral mesh rectopexy (LVMR) without posterolateral rectal mobilisation compared to abdominal procedures with a more extensive mobilisation. The available comparative evidence on IRP shows stapled transanal resection of the rectum (STARR) is more effective than biofeedback training and that Countour Transtar is preferred over double-stapling STARR on the long-term. Non-comparative observational studies demonstrate LVMR and LRR are safe and effective to treat IRP. The accompanying recommendations of the guideline committee, based on older, comparative, open studies supported by single observational laparoscopic series and expert opinion, were as follows:

- LVMR is the first choice to treat ERP or IRP.
- A perineal procedure (Delorme's or Altemeier's procedure with levatorplasty) with regional anaesthesia is preferred if a laparoscopic procedure is contraindicated.
- It is advisable to treat a patient with a rectocele in combination with obstructive defecation syndrome complaints with STARR or LVMR.

Chapter four contains a review on (laparoscopic and robot-assisted) ventral mesh rectopexy, currently the most popular surgical technique in Europe for the treatment of ERP and IRP. Observational studies on ventral mesh rectopexy reported postoperative complication rates from 0 to 23.5%, mesh morbidity percentages from 0 to 6.7% with mesh erosion rates between 0 and 3.7%. Obstructed defecation improved from 52 to 84.2% of patients following LVMR for ERP, from 55 to 86% after LVMR for IRP and between 56.7 and 92.8% following LVMR for all rectal prolapse syndromes. A decrease in faecal incontinence complaints following LVMR is reported from 50 to 93% of patients for ERP, between 20 and 92% for IRP and from 82 to 90% for all rectal prolapse syndromes. Recurrence percentages following LVMR for ERP range between 1.5 to 9.7%, with one small cohort reporting a rate of 15.4%. Studies, performing LVMR for IRP, quoted recurrence rates between 5.3 and 7.1%. Literature, including all rectal prolapse syndromes, reported recurrence percentages from 2.6 to 14.3%. The robotic series showed comparable rates on morbidity, functional outcomes and recurrence. However, the follow-up of the robotic studies was relatively short.

SECTION TWO: SURGICAL TECHNIQUES

In **chapter five** the results of 919 patients undergoing LVMR are described. A 10-year recurrence rate of 8.2% for ERP repair was noted. Mesh-related complications were recorded in 18 patients (4.6%), of which mesh erosion to the vagina occurred in 7 patients (1.3%). Both rates of fecal incontinence and obstructed defecation decreased significantly ($P<0.0001$) following LVMR compared to the preoperative incidence (11.1% vs 37.5% for incontinence and 15.6% vs 54.0% for constipation). New onset incontinence and constipation were documented in 2.3 and 2.4% of patients, respectively.

Chapter six analyses 258 patients who underwent RVMR. Mortality (0.4%), major (1.9%) and minor early (<30 days) morbidity (7%) were acceptably low. Only one (1.3%) mesh-related complication (asymptomatic vaginal mesh erosion) was observed. A significant improvement in obstructed defecation in 78.6% of patients and fecal incontinence of 63.7% was achieved (both $p<0.0005$). At final follow-up, new-onset of fecal incontinence and obstructed defecation were induced or worsened in 3.9% and 0.4%. The actuarial 5-year ERP and IRP recurrence rates were 12.9% and 10.4%, respectively. **Chapter five and six** show LVMR and RVMR are safe and effective procedures to treat rectal prolapse syndromes in the long-term, as indeed supported by observational studies (**chapter four**).

In **chapter seven** the first prospective cohort reporting on a robot-assisted multi-compartment procedure is described. Fifty-one sexually active patients (median follow-up 12.5 months) with a multi-compartment prolapse underwent robot-assisted sacrocolpoporectomy (RSCR), a combination of abdominal sacrocolpopexy and ventral mesh rectopexy. The simplified Pelvic Organ Prolapse Quantification improved significantly ($p<0.0005$) for all four anatomical landmarks. Both median fecal (pre- and postoperative Pescatori 4 vs 3, $p=0.002$) and urinary incontinence (Urinary Distress Inventory 27.8 vs 22.2, $p<0.0005$) scores improved significantly at 12 months. Postoperatively median Wexner (3) and Vaizey incontinence (6) and Wexner

Constipation (7) scores were noted. A positive effect on sexual function (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire score 31.8 vs 35.9, $p=0.002$) and quality of life for each compartment ($p<0.0005$) was observed. One (2%) patient developed mesh erosion. No multi-compartment recurrences were detected. These results show that RSCR treats multi-compartment prolapse effectively, providing good symptomatic relief with minimal morbidity.

SECTION THREE: SEQUELAE AND EFFECTS OF SURGERY

The incidence of patients developing grade III and IV hemorrhoids requiring surgery following LVMR and to explore the relationship between developing such hemorrhoids and recurrence of rectal prolapse after LVMR is studied in **chapter eight**. Sixty-five of the 420 patients undergoing LVMR (actuarial 5-year incidence 24.3%) developed symptomatic grade III/IV hemorrhoids requiring hemorrhoidectomy. Re-do surgery for recurrent grade III/IV hemorrhoids was required for 15 of the 65 patients (actuarial 5-year recurrence rate 40.6%) after the primary hemorrhoidectomy. Three of the 65 patients developed an ERP recurrence and eight an IRP recurrence, providing 5-year recurrence rates of 25.3% and 24.4%, respectively. The rest of the LVMR cohort not receiving additional surgery for hemorrhoids ($n=355$) showed significantly lower actuarial 5-year ERP (0.8%, $p=0.011$) and IRP (11%, $p=0.020$) recurrence rates. This study shows high-grade hemorrhoids requiring surgery may be common after LVMR and that the development of such hemorrhoids might be predictor of a rectal prolapse recurrence. In order to exclude a rectal prolapse recurrence, additional radiological imaging may be considered when a patient presents with grade III/IV hemorrhoids following LVMR.

Chapter nine reports on the long-term vaginal and rectal mesh erosion rate following abdominal robotic pelvic floor surgery. Among 141 patients (45 following LVMR, 46 robot-assisted sacrocolpopexy, 46 RSCR) evaluated clinically with a proctoscopy and

a speculum examination, three (2.8%) mesh erosions were diagnosed after a median follow-up of 49.2 months (range, 36.0-62.1). One of those patients (bladder erosion after 45 months) required a resection and an omental patch interposition. The other two patients had an asymptomatic vaginal erosion (42.7 and 42.3 months) treated with oestrogen cream in one. Thirty patients were either unable or declined to attend clinic, but agreed to participate in a standardized telephone and/or paper questionnaire. None of these patients reported mesh-related complaints. Concerns relating to transvaginal mesh placement may not be extrapolated to abdominal procedures because mesh erosion following an abdominally placed synthetic graft is rare on the long-term.

Chapter 11

General discussion and future perspectives

GENERAL DISCUSSION

This thesis aims to address several aspects in the decision-making around rectal prolapse by describing the diagnostics and current practise, reporting on the most used minimally invasive surgical procedures and illustrating the benefits and disadvantages of surgery. Clinical implications and limitations of the findings of this thesis are discussed here by answering the research questions formulated in the introduction.

Which imaging technique is the best to diagnose a prolapse of the posterior compartment of the pelvic floor?

Rectal prolapse surgery is only recommended in the presence of an anatomical defect accompanied by corresponding symptoms. Physical examination has its limitations and therefore dynamic imaging plays an important role in the diagnosis of a prolapse. Both in our study (**chapter two**) and in the literature there were substantial differences between the two most commonly used techniques, conventional dynamic defecography (CD) and dynamic magnetic resonance imaging (D-MRI). We found that the ability to detect a rectocele and enterocele using D-MRI is less than with CD, but D-MRI appears to be superior in identifying intussusception. A difference in diagnosing intussusceptions of that order has not been previously described. Based on the findings of our study and the literature, no superiority was found of either technique and it appears that CD and D-MRI are complementary imaging modalities in the evaluation of patients with symptoms of prolapse of the posterior compartment. Because of additional advantages, such as a multi-compartment overview with soft tissue details and the lack of ionising radiation, D-MRI is preferred in our clinic. Surgeons could consider additional imaging in symptomatic patients without defects on either D-MRI or CD.

What is, based on the available evidence, the optimal surgical treatment for IRP and ERP?

The lack of high-quality comparative evidence on the different techniques, together with the small sample size of included studies and their methodological weaknesses,

limits the usefulness of the Dutch prolapse guideline (**chapter three**). The majority of level one evidence on rectal prolapse surgery is severely outdated¹. In addition, the heterogeneity of studies and the lack of superiority of any procedure makes it difficult to determine the optimal surgical technique. Recommendations were therefore largely based on observational series and expert opinion, in accordance with common practise in the Netherlands. Based on the currently available evidence the guideline committee recommends LVMR as the first choice to treat external or internal rectal prolapse (ERP/IRP). If a laparoscopic procedure is contraindicated, a perineal procedure (with levatorplasty) is preferred. Patients with a rectocele in combination with obstructive defecation can be treated with stapled transanal rectal resection (STARR) or LVMR. Randomised controlled trials (RCT) of minimally invasive abdominal rectal prolapse surgery are much needed. Unfortunately, efforts of our study group to produce level one evidence (comparing LVMR with laparoscopic resection rectopexy for ERP) have thus far been unsuccessful. Most trials (including ours) seem to either not reach completion, or fail to show a significant difference between groups, for reasons such as patient demographics, logistical challenges, geographical differences, and slow recruitment. Added to that is the constantly moving field of rectal prolapse surgery research, yielding almost every decade different insights into the optimal technique and the design of adequate trials. The recently published PROSPER trial showcased the difficulty in recruitment, with a study period of more than 12 years yet unable to achieve the target number of participants².

Is ventral mesh rectopexy a safe and effective technique to treat ERP and IRP in a large cohort of patients?

LVMR has gained increasing worldwide acceptance for ERP and high-grade IRP (**chapter four**). The technique avoids posterolateral rectal mobilization and the risks of an anastomosis, corrects the middle compartment and can be combined with a vaginal prolapse procedure, such as sacrocolpopexy³. However, LVMR exposes patients

to a synthetic mesh and should therefore be carefully considered before application. Although long-term prospective research shows that overall, abdominally placed meshes are safe (**chapter nine**), the mesh-related morbidity rate is never zero. LVMR has a high post-operative incidence of high-grade hemorrhoids requiring surgery (**chapter eight**). It seems that LVMR repairs the rectal prolapse, but fails to correct the mucosal prolapse in some patients. However, other (open and laparoscopic) types of rectopexy also quote a high incidence of postoperative high-grade hemorrhoids (up to 18 %, chapter eight). Residual high-grade hemorrhoids following STARR occur in 3.6–5.9%^{4–6}. A stapled hemorrhoidectomy following LVMR has proven to be safe. The large LVMR and robotic ventral mesh rectopexy (RVMR) cohorts we investigated both show an erosion rate of 1.3%; with an ERP recurrence of 8.2 and 12.9%; a significant improvement of obstructed defecation of 71.2 and 78.6%; and a significant improvement of fecal incontinence of 80.2 and 63.7%, respectively (**chapter five and six**). These results are in line with other reports on ventral mesh rectopexy (**chapter four**) and represent a good outcome compared to other rectal prolapse surgery techniques^{1,7–12}. Although the use of ventral mesh rectopexy has increased over a short period of time because of these perceived positive outcomes, this is in the absence of high-quality comparative research evidencing the superiority of this procedure. After the publication of chapter four, the first two RCTs incorporating LVMR have been published^{13,14}. Emile et al. compared LVMR with Delorme's procedure for ERP (n= 25 vs. 25, mean follow-up of 18 months), and found no difference in recurrent prolapse between the two groups (8% in the LVMR group vs. 16% in the Delorme group; p=0.66) or in change in postoperative continence or constipation scores¹³. The other trial, comparing LVMR (n=38) with laparoscopic posterior sutured rectopexy (n=37) for ERP, also suggested no difference between the groups with regards to recurrence of prolapse (0% LVMR vs. 5% posterior rectopexy, p=0.3) or change in continence or constipation scores 12 months post-operatively¹⁴. Considering the relatively fast uptake of LVMR, these results should serve as a reminder of the need to critically analyse the available evidence on LVMR before drawing conclusions. However, LVMR did show some advantages in these trials. Significantly more intussusceptions

(53 vs. 28%, $p=0.037$) were seen in the posterior rectopexy group at the postoperative defecography at 12 months. In addition, virtually all outcomes of both trials were in favour of LVMR, although the differences were not significant. Still, this may suggest a trend towards superiority of LVMR, as indeed supported by observational studies. The popularity of LVMR is understandable considering this trend together with the safety and reproducibility of the procedure. Future research, however, should determine whether LVMR will stand the test of time.

What is the effect of a multi-compartment pre-operative assessment and what are the results of a robot-assisted multi-compartment procedure?

Rectal prolapse is frequently observed with prolapses in other compartments, but the relationship is complex¹⁵. All pelvic floor prolapses share many common risk factors. Furthermore, also a prolapse itself or its treatment may be a risk factor for the development of another¹⁶. Several studies have shown that a prolapse repair of one compartment could aggravate or even provoke symptoms and/or prolapses of the non-treated compartment^{16–26}. The new-onset complaints and/or prolapses of the patients in these studies may have resulted from the initial operation, or developed *de novo* due to other pathophysiological factors in the follow up period. The question therefore arises whether a multi-compartment procedure is required for every prolapse patient merely to avoid potential future problems in an adjacent compartment. We do not think such a approach is necessary, but we do believe it is essential to perform a multi-compartment assessment of the pelvic floor before planning surgical repair in every patient with a prolapse to avoid possible under-treatment. In our pelvic floor clinic every patient suspected of a prolapse receives a multi-compartment questionnaire before attending hospital. At the outpatient clinic, this questionnaire is reviewed and symptoms of all compartments are assessed by the specialist. Research revealed that patients under-report complaints related to other compartments and therefore a thorough multi-compartment evaluation is required²². Patients presenting to the surgeon with multi-compartment symptoms are also referred to the urogynaecologist. In cases of complaints

in just one compartment, a D-MRI is performed. Patients with a multi-compartment prolapse on D-MRI are assessed both by the surgeon and the urogynaecologist. Before surgery, every patient is discussed in a multidisciplinary setting, including colorectal surgeons, urogynaecologists, urologists, radiologists, and pelvic floor physical therapists. A uni-compartment approach is chosen in cases of prolapse in just one compartment on D-MRI accompanied by corresponding symptoms. The indication for a multi-compartment procedure is a combination of prolapse of the posterior and the middle/ anterior compartment, accompanied by a disabling multi-compartment problem (i.e., fecal incontinence, obstructed defecation, sensation of prolapse, dyspareunia, and micturition symptoms). The number of patients developing an anterior or middle compartment prolapse following our uni-compartment procedures (**chapter five and six**) was acceptable with an actuarial 5-year rate of 4.2% for the RVMR cohort (5/258) and an actuarial 10-year rate of 1.3% for the LVMR cohort (7/919). In our opinion these numbers confirm the adequate pre-operative assessment of these cohorts and justify our above mentioned method. In addition, we show a significant improvement of quality of life, functional and sexual outcomes following robot-assisted sacrocolporectopexy (RSCR) for multi-compartment prolapse (**chapter seven**).

What are the sexual outcomes following a multi-compartment procedure with synthetic mesh?

Sexual function significantly improved following RSCR. An increase in the mean Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire score from 31.8 to 35.9 (PISQ-12, $p=0.002$) was noted, comparable to the PISQ-12 score for the general population²⁷. Significantly fewer women reported pain and fear of fecal or urinary incontinence during intercourse. In addition, there was a significant reduction in patients avoiding sexual intercourse because of bulging in the vagina. There is no literature describing sexual outcome following a multi-compartment procedure thus far, but our results

are comparable to several studies describing gynaecological procedures²⁸⁻³⁰. Recent research in our centre found a similar postoperative PISQ-12 score following LVMR³¹, indicating an acceptable sexual outcome after a minimally invasive pelvic floor repair.

Does robotic assistance influence the morbidity and the outcomes of pelvic reconstructive surgery?

Since 2010 in our centre the majority of all abdominal pelvic reconstructive surgeries are performed with robotic assistance (**chapter six and seven**). Improved dexterity, obliteration of hand tremor and motion scaling, three-dimensional visualization and instruments with a wide range of movements has been found advantageous in confined spaces, such as the pelvis^{32,33}. In our experience, a more distal attachment of the mesh appears possible with RVMR, which could be especially beneficial for patients with ODS. In the past few years in our clinic, several patients presented with recurrent ODS complaints following LVMR. Recently, we re-operated selected cases with a recurrent rectocele and ODS complaints using robot-assistance and effectuated a deeper placement of the mesh. Symptomatic relief was achieved, but at the moment without the scientific underpinnings. Mantoo et al. confirmed our hypothesis by reporting a significant higher improvement in ODS score for RVMR as compared to LVMR³⁴, but another report showed no difference in functional outcome³⁵. The only RCT available comparing RVMR with LVMR found no significant difference in morbidity and functional outcome after 3 months of follow-up^{36,37}. This RCT did show a lower incidence and a smaller size of residual rectoceles following RVMR, but the difference was not statistically significant³⁷. Observational RVMR studies, including our cohort (**chapter six**), show comparable morbidity and recurrence rates and improvement of function comparable to our and other observational LVMR series (**chapter four and six**). The outcomes of our RSCR cohort are also similar to the results of laparoscopic multi-compartment procedures in the literature (**chapter seven**).

In theory it is possible that mesh erosion is higher following a robotic repair because of lack of haptic feedback³⁸. There is no level one evidence comparing LVMR with RVMR

with regards to mesh erosion. The only 3 RVMR studies mentioning mesh erosion all reported a rate of 0%, but the follow-up was short varying from 12 to 23.4 months^{34,39,40}. Level one evidence comparing laparoscopic with robotic sacrocolpopexy is conflicting, but erosion rates for both techniques are acceptably low^{41–47}. Observational laparoscopic sacrocolpopexy studies show a similar combined estimated median erosion rate (2.0%) as compared to its robotic equivalent (1.8%, **chapter nine**). In our prospective cohort, we found a mesh erosion rate of 2.8% after a median follow-up of 49.2 months following abdominal robotic pelvic floor surgery (**chapter nine**).

Generally, robotic assistance appears to be at least as safe and effective as laparoscopy in rectal prolapse surgery. However, this is not yet supported by level one evidence. Robot-assistance is considerably more expensive than its laparoscopic equivalent^{32,39}. Based on the currently available data, these higher costs cannot yet be justified. Some believe that robot-assistance may result in a cost reduction if more procedures can be performed by each surgeon in a lifetime due to improved ergonomics^{32,48}. In addition, the much steeper learning curve with the robot (18 vs. 54 procedures with respect to the operating time), especially interesting for low-incidence operations as RVMR, may lead to cost savings^{37,49,50}. Laparoscopic techniques were globally implemented long before high-quality evidence confirmed its superiority over an open approach⁵¹. One would expect outcomes of robotic surgery to improve with advances in the technology. We feel that robotic assistance is beneficial in this procedure and this is supported by is supported by other authors describing RVMR^{34,35,52,53}. However, only future research will determine whether robotic assistance has a permanent role in the surgical armamentarium for the treatment of rectal prolapse.

Are abdominally placed synthetic meshes safe?

Mesh-related morbidity is an important issue because of the potential impact on the quality of life. In recent years the public opinion has turned against synthetic grafts based on high mesh erosion rates following *transvaginal repair*^{54,55}. Because of this negative publicity many patients refuse a mesh, regardless of the indication or approach.

We showed that synthetic meshes for abdominal pelvic reconstructive surgery are safe in the long-term (**chapter nine**). The result of this study is supported by the different cohorts of this thesis (**chapter five, six and seven**). In these studies simple, cheap type I macroporous (>75 microns), monofilament polypropylene meshes were used. The pore size influences cellular infiltration and mesh density and flexibility. Macropores allow infiltration of macrophages and natural killer cells, fibroblast and blood vessels resulting in proper tissue integration and a lower risk of infection^{56,57}. In addition, the mesh retains its flexibility because the pores of a macroporous mesh are large enough to prevent bridging of scar tissue throughout the entire pore ('scare plate')⁵⁸. Although type I meshes are preferred by most surgeons because of these characteristics, the superiority of one mesh over another has not yet been clearly demonstrated⁵⁹. Synthetic meshes with smaller pores (type II and III) are, however, associated with a higher rate of mesh erosion and are rarely used in pelvic floor reconstruction^{56,60}. The contemporary literature on abdominally placed type I meshes shows low erosion rates in line with our prospective cohort (**chapter nine**). Concerns over synthetic mesh morbidity have led to the introduction of a more expensive biological equivalent. The biological mesh is characterised by degradation of the graft and regeneration of host tissue⁶¹. Theoretically, this degeneration reduces the chance of infection, but the partial dissolution of the mesh could also result in a higher recurrence rate. Level four evidence shows no significant difference in mesh-related morbidity and recurrence between biological and synthetic mesh for LVMR^{62,63}. High-quality evidence on sacrocolpopexy shows a significant higher rate of recurrent disease following a repair with biological graft than compared to a synthetic mesh^{64–66}.

This thesis proves that the concerns relating to transvaginal mesh placement should not be extrapolated to abdominal procedures. There is no need to switch to biological mesh or to avoid robotic assistance based on the literature and our data. These are encouraging findings for patients and doctors faced with all the currently existing concerns around the safety of the mesh in pelvic reconstructive surgery.

FUTURE PERSPECTIVES

Although this thesis has given more insight on the management of rectal prolapse, many questions remain unanswered. The lack of high-quality evidence for rectal prolapse surgery in general and for ventral mesh rectopexy in particular, should encourage surgeons to initiate larger (randomised controlled) trials with long-term outcomes. It will be interesting to compare LVMR with laparoscopic resection rectopexy for ERP or IRP and LVMR with STARR for IRP. The author does acknowledge the difficulties of performing such trials, however. In addition, long term results for the recently published randomised controlled trials (LVMR vs. Delorme, LVMR vs. posterior suture rectopexy, and LVMR vs. RVMR) are awaited. In our centre we are testing our hypothesis that robot-assistance enables a deeper placement of the mesh. Currently, we are using a new 'MRI-visible' mesh (DynaMesh Visible™, FEG Textiltechnik, Aachen, Germany) in the context of a study to investigate the depth of a robotically placed graft and the relationship of this depth to the improvement of functional outcome as compared to LVMR. One could question the feasibility of large clinical trials. In addition to the difficulties described in the general discussion, the PROSPER trial showed that surgeons are reluctant to change personal practice². This hampers subject recruitment and affects surgical outcome. Although not ideal, an international prospective register for rectal prolapse, but also for mesh morbidity, may be a more pragmatic approach. Universal subscription to a robustly validated diagnostic questionnaire would be fundamental to such a register. The clinical significance of an IRP observed on imaging studies remains partially unknown. We found that D-MRI appears superior to CD in identifying intussusceptions and it would be interesting to investigate the morphology, accompanying symptoms, possible treatment and its benefits on thus identified intussusceptions in future studies. There is a growing body of evidence showing that a uni-compartment approach potentially aggravates or induces symptoms and/or prolapses in the adjacent compartments. However, none of these studies investigated whether the complaints of the previously untreated compartment could be explained through another cause. Although difficult, it would be interesting to study this. Furthermore, prospective studies into a uni-

compartment approach ought to include a thorough pre-operative assessment of all pelvic compartments through meticulous history taking and physical examination and at post-operative follow up, examination of the untreated compartments for prolapse, preferably applying additional diagnostics. An adequately long-term assessment of mesh morbidity is required to confirm our results. A comparison between biological and synthetic mesh may be considered, but we believe the use of a biological mesh should be limited to specific circumstances only (e.g. inflammatory bowel disease). The present thesis did not focus on the identification of risk factors predicting a poor outcome following surgery. This is, however, highly relevant and should be addressed in future research.

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Chapter 12

Appendices

Summary and future perspectives in Dutch

Review committee

List of publications

Curriculum vitae

Acknowledgements

SUMMARY AND FUTURE PERSPECTIVES IN DUTCH

Symptomatische bekkenbodempandoeningen komen vaak voor met een prevalentie van 23.7% in de algehele vrouwelijke populatie en van bijna 50% voor vrouwen ouder dan 80 jaar¹. In Nederland is het risico op een operatieve behandeling van een aandoening aan de bekkenbodem gedurende het leven rond de 20%². Met de alsmaar groeiende bevolking en vergrijzing bestaat de verwachting dat deze prevalenties zullen verdubbelen in de komende decennia³⁻⁵. Aangezien met deze aandoeningen hoge kosten gepaard gaan en ze een grote impact op de kwaliteit van leven hebben, is er sprake van een serieus maatschappelijk gezondheidsprobleem^{6,7}. Van deze bekkenbodempandoeningen maken verzakkingen van het posterieure compartiment van de een groot deel uit¹. De rectum prolaps kan op basis van anatomie worden onderverdeeld in een interne en een externe variant. De externe rectum prolaps (ERP) is een circumferentiële ('full-thickness') intussusceptie van de gehele rectumwand, die zich uitstrekt voorbij het anale kanaal. Van een interne rectum prolaps (IRP, ook wel intussusceptie genoemd) wordt gesproken wanneer deze intussusceptie zich boven het niveau van de anus (recto-recto of recto-anaal, zie **hoofdstuk 3** voor gradaties) bevindt. Rectum prolaps, en in het bijzonder de interne variant, gaat vaak gepaard met andere verzakkingen van het posterieure compartiment zoals een rectocèle of enterocele. Een prolaps van het posterieure compartiment van de bekkenbodem is geassocieerd met invaliderende klachten als obstipatie (obstructed defecation), fecale incontinentie en (chronische) pijn.

Dit proefschrift richt zich op enkele belangrijke aspecten over de besluitvorming van de aandoening rectum prolaps door het beschrijven van de diagnostiek, de hedendaagse minimaal invasieve chirurgische technieken en de rapportage van de voor- en nadelen van chirurgie. De klinische implicaties en de limitaties van de bevindingen van dit proefschrift worden hieronder samengevat en besproken aan de hand van de onderzoeksvragen zoals geformuleerd in de introductie.

Welk radiologisch onderzoek is het beste om een prolaps van het posterieure compartiment van de bekkenbodem te diagnosticeren?

Chirurgie voor rectum prolaps wordt alleen aanbevolen wanneer een anatomisch defect gepaard gaat met daaruit voortkomende invaliderende symptomen. Dynamisch radiologisch onderzoek speelt een belangrijke rol in de diagnose van verzakkingen van het posterieure compartiment aangezien het lichamelijk onderzoek zijn beperkingen kent. Zowel in onze studie (**hoofdstuk twee**) als in de literatuur worden substantiële verschillen tussen de twee meest gebruikte radiologische technieken, conventionele röntgen defecografie (CD, gouden standaard) en dynamic magnetic resonance imaging (D-MRI), gevonden. **Hoofdstuk twee** zien dat rectocèles en enterocèles minder worden gedetecteerd door de D-MRI vergeleken met CD, maar de D-MRI lijkt wel superieur in het diagnosticeren van intussuscepties. Een dergelijke superioriteit in detectie van intussuscepties was niet eerder beschreven. Op basis van de resultaten en de literatuur is het niet mogelijk een duidelijke voorkeur voor een van de technieken uit te spreken. Het lijkt er op dat beide radiologische modaliteiten complementair aan elkaar zijn in het diagnosticeren van een prolaps van het posterieure compartiment. De D-MRI krijgt in het Meander Medisch Centrum de voorkeur vanwege additionele voordelen zoals een multi-compartimenteel overzicht in hetzelfde frame, goede weke delen resolutie en het gebrek aan stralingsbelasting. Aanvullend radiologisch onderzoek kan overwogen worden bij symptomatische patiënten zonder afwijkingen op D-MRI dan wel CD.

Wat is, gebaseerd op de huidige literatuur, de optimale chirurgische correctie van een externe en een interne rectale prolaps?

De bruikbaarheid van de Nederlandse richtlijn Prolaps (**hoofdstuk drie**) is beperkt vanwege het gebrek aan vergelijkende studies van goede kwaliteit over de verschillende technieken, de kleine patiënt aantallen en de methodologische gebreken van de geïncludeerde studies. Het gros van het niveau één bewijs (level one evidence) over rectum prolaps is zeer verouderd⁸. Het bepalen van een optimale chirurgische techniek wordt hiernaast bemoeilijkt door een grote heterogeniteit tussen studies en het en het

gebrek aan een evident superieure procedure. De aanbevelingen van de richtlijn werden derhalve met name geformuleerd aan de hand van observationele studies gecombineerd met expert opinion, overeenkomstig met de huidige praktijk in Nederland. Op basis van het huidige bewijs wordt de laparoscopische ventrale mesh rectopexie (LVMR) aangeraden als eerste keus voor het behandelen van een IRP en een ERP. Wanneer er een contra-indicatie voor laparoscopische chirurgie bestaat, wordt een perineale procedure -in combinatie met een levatorplastiek- aangeraden. Voor patiënten met obstructieve defecatie door een rectocèle wordt een stapled transanal rectal resection (STARR) of LVMR geadviseerd. Er is een urgentie tot Randomised controlled trials (RCT) over dit onderwerp. Helaas is de poging van onze studie groep om niveau één bewijs te produceren tot nu toe onsuccesvol gebleken, waarin de LVMR en laparoscopische resectie rectopexie voor ERP werd vergeleken. Het merendeel van de opgestarte trials wordt vroegtijdig gestaakt of laat geen statistisch significant verschil zien vanwege bepaalde patiënten karakteristieken, logistieke moeilijkheden, geografische verschillen en langzame inclusie. Daarnaast wordt het ontwerp van adequate trials bemoeilijkt door de het dynamische karakter van het wetenschappelijk onderzoek naar rectum prolaps, waarin bij benadering elk decennium een andere chirurgische techniek de voorkeur geniet. De recent gepubliceerde PROSPER trial geldt als voorbeeld van een moeizame studie, met een inclusie-periode van meer dan 12 jaar zonder dat het beoogde aantal patiënten bereikt is⁹.

Is ventrale mesh rectopexie een veilige en effectieve techniek voor de behandeling van ERP en IRP?

De LVMR wordt wereldwijd in toenemende mate toegepast voor de behandeling van ERP en hooggradige IRP (**hoofdstuk vier**). De techniek vermijdt posterolaterale rectale mobilisatie en het risico van een anastomose, corrigeert het middelste compartiment en kan worden gecombineerd met gynaecologische ingrepen zoals een sacrocolpopexie¹⁰. Het uitvoeren van de procedure moet echter van te voren goed overwogen worden aangezien er een synthetische mesh aan de ventrale zijde van het rectum wordt

geïmplant. Prospectief onderzoek met een lange follow-up laat zien dat abdominale meshes veilig zijn (**hoofdstuk negen**), maar het risico op mat gerelateerde complicaties is nooit helemaal nul. Hiernaast wordt er een hoge post-operatieve incidentie van hooggradige hemorroïden na LVMR gezien (**hoofdstuk acht**).

De LVMR lijkt wel de rectum prolaps, maar niet de mucosa prolaps te corrigeren. Andere -open en laparoscopische- abdominale technieken laten echter ook hoge incidenties van postoperatieve hooggradige hemorroïden zien (tot 18%, **hoofdstuk acht**). Na een STARR worden in 3.6-5.9% van de gevallen resterende hooggradige hemorroïden beschreven¹¹⁻¹³. Een stapled hemorrhoidectomy na LVMR blijkt veilig ondanks de aanwezigheid van een mesh in het rectovaginale septum. De grote LVMR en robotgeassisteerde ventrale mesh rectopexie (RVMR) cohorten (**hoofdstuk vijf en zes**) lieten beide een erosie percentage van 1.3% zien met een ERP recidief percentage van 8.2 en 12.9%; een significante verbetering in obstructieve defecatie van 71.2 en 78.6%; en een significante verbetering in fecale incontinentie van 80.2 en 63.7%, respectievelijk. De resultaten van deze studies zijn vergelijkbaar met literatuur over ventrale mesh rectopexie en superieur aan andere technieken^{8,14-18}.

Hoewel de toepassing van de ventral mesh rectopexie de laatste jaren een vlucht heeft genomen, is er tot op heden weinig vergelijkend kwalitatief onderzoek uitgevoerd naar deze techniek. Na de publicatie van **hoofdstuk vier** van dit proefschrift zijn de eerste twee RCTs over LVMR uitgekomen^{19,20}. Emile et al. vergelijkt LVMR met de procedure van Delorme voor ERP (n= 25 vs. 25, gemiddelde follow-up 18 maanden) en beschrijft geen verschil in recidief percentage (8% in de LVMR groep vs. 16% in de Delorme groep; p=0.66) of in functionele uitkomsten¹⁹. Lundby et al. vergelijken de LVMR (n=38) met de laparoscopische posterieure suture rectopexie (n=37) voor ERP en beschrijft geen verschil in recidief percentage (0% LVMR vs. 5% posterieure rectopexie, p=0.3) of in functionele uitkomst na 12 maanden²⁰. Deze resultaten herinneren ons eraan dat we kritisch moeten zijn op de relatieve snelle implementatie van de LVMR. In deze trials kwamen echter ook voordelen van de LVMR naar voren. Zo werden er op het defecogram 12 maanden postoperatief significant meer intussuscepties gezien in de groep die een

posterieure rectopexie onderging (53 vs. 28%, $p=0.037$). Hiernaast waren alle andere uitkomsten van beide trails in het voordeel van de LVMR, maar waren deze verschillen niet significant. Deze trend, ondersteund door observationele series, tezamen met de theoretische voordelen, de veiligheid en de reproduceerbaarheid van de ingreep, verklaren de populariteit van de techniek. Toekomstig kwalitatief onderzoek zal echter moeten uitwijzen of LVMR de tand des tijds zal doorstaan.

Wat is het effect van een pre-operatieve multi-compartmentele evaluatie en wat zijn de resultaten van een robot-geassisteerde multi-compartmentele procedure?

Rectum prolaps komt vaak voor met verzakkingen van andere compartimenten, maar de relatie tussen de compartimenten is complex²¹. Een uni-compartmentele prolaps of de uni-compartmentele behandeling hiervan is een risicofactor voor verzakking in een aangrenzend compartiment²²⁻³². Het is echter onduidelijk of nieuw ontstane klachten en verzakkingen in een aangrenzend compartiment het resultaat zijn van de uni-compartmentele operatie of dat ze *de novo* zijn ontstaan door andere pathofysiologische factoren gedurende de follow-up. Derhalve rijst de vraag of elke patiënt met een prolaps een multi-compartmentele procedure moet ondergaan om potentiële toekomstige klachten van een aangrenzend compartiment te voorkomen. Wij zijn niet van mening dat een dergelijke aanpak vereist is, maar we geloven wel dat het essentieel is om een adequate multi-compartmentele evaluatie uit te voeren voordat chirurgisch herstel wordt gepland. Met een multi-compartmentele pre-operatieve evaluatie zal onderbehandeling voorkomen kunnen worden. Elke patiënt die wordt verdacht van een prolaps ontvangt thuis een multi-compartmentele vragenlijst voor presentatie in ons ziekenhuis. Op de polikliniek wordt de vragenlijst geëvalueerd en worden symptomen van alle compartimenten bevraagd. Bij uni-compartmentele problematiek wordt er een D-MRI gemaakt. Patiënten met multi-compartmentele problematiek of een multi-compartmentele prolaps op de D-MRI worden zowel door de chirurg als de gynaecoloog gezien. Wekelijks is er een multi-disciplinair overleg waarin

alle patiënten met een indicatie tot chirurgie besproken worden. Patiënten met een uni-compartmentele prolaps op D-MRI in combinatie met invaliderende symptomen ondergaan een operatieve correctie van het aangedane compartiment. De indicatie voor een multi-compartmentele procedure is een verzakking van het posterieure en het middel/voorste compartiment in combinatie met invaliderende multi-compartmentele symptomen (fecale incontinentie, obstructieve defecatie, prolaps gevoel, dyspareunie en mictie problemen). Het aantal recidieven van het anterieure en middelste compartiment na onze uni-compartmentele procedures (**hoofdstuk vijf en zes**) wars acceptabel met een 5-jaars percentage van 4.2% in het RVMR cohort (5/258) en een 10-jaar percentage van 1.3% in het LVMR cohort (7/919). Dit toont aan dat pre-operatieve evaluatie adequaat was en rechtvaardigt het gebruik van bovenstaande methode. In **hoofdstuk zeven** is een significante verbetering in kwaliteit van leven in functionele en seksuele uitkomsten na een robot-geassisteerde sacrocolporectopexie (RSCR) beschreven.

Wat zijn de seksuele uitkomsten na een multi-compartmentele procedure met een synthetische mesh?

De seksuele functie verbeterde significant na RSCR. In **hoofdstuk zeven** wordt een significante verbetering in de gemiddelde Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire score van 31.8 tot 35.9 (PISQ-12, $p=0.002$) beschreven. De postoperatieve PISQ-12 score is vergelijkbaar met vrouwen van dezelfde leeftijd uit de algemene populatie³³. Significant minder vrouwen rapporteerden pijn en angst voor verlies van ontlasting of urine tijdens gemeenschap. Daarnaast was er een significante vermindering in het aantal patiënten dat gemeenschap mijdt vanwege een prolaps in de vagina. De resultaten van deze studie zijn vergelijkbaar met data uit de gynaecologische literatuur; een artikel aangaande seksuele uitkomst na een multi-compartmentele ingreep werd tot dusver niet eerder gepubliceerd (**hoofdstuk zeven**)³⁴⁻³⁶. Recent onderzoek uit ons ziekenhuis toonde een gelijkwaardige postoperatieve PISQ-12 score na LVMR waarmee geconcludeerd kan worden dat de seksuele functie na een minimaal invasieve bekkenbodem ingreep acceptabel is³⁷.

Beïnvloedt robotische assistentie de morbiditeit en de uitkomsten van reconstructieve bekkenbodembodem chirurgie?

Vanaf 2010 wordt het merendeel van alle abdominale bekkenbodembodem operaties uitgevoerd met robotische assistentie (**hoofdstuk zes en zeven**). Met name in de nauwe bekkenbodembodem heeft de robot een aantal theoretische voordelen, zoals een driedimensionaal beeld, een verbeterde bewegelijkheid van de arm van de robot en het uitsluiten van tremor van de hand^{38,39}. Met robotische assistentie lijkt een meer distale verankering van de mesh op het rectum mogelijk, hetgeen met name voor patiënten met het obstructive defecation syndrome (ODS) van toegevoegde waarde zou kunnen zijn. In ons ziekenhuis zijn er meerdere patiënten met een recidief rectocèle na een LVMR met robotische assistentie geopereerd, waarbij er een diepere plaatsing van de nieuwe mesh mogelijk bleek. Al deze patiënten rapporteerden postoperatief een verbeterde functie (unpublished data). Mantoo et al. beschrijven een significante verbetering van ODS score na RVMR vergeleken met LVMR en bevestigde zo onze hypothese⁴⁰. Een andere studie liet echter geen verschil in functionele uitkomst tussen de twee technieken zien⁴¹. De enige beschikbare RCT waarbij RVMR met LVMR wordt vergeleken toont geen verschil in morbiditeit en functionele uitkomst na 3 maanden follow-up^{42,43}. In deze RCT werd wel een lagere incidentie en een kleinere grootte van de resterende rectocèles vermeld, maar het verschil was niet significant. In observationele RVMR studies, inclusief ons cohort (**hoofdstuk zes**), wordt een vergelijkbare morbiditeit, recidief percentage en verbetering in functie beschreven in vergelijking met onze eerdere observationele LVMR series (**hoofdstuk vier en vijf**). De resultaten van ons RSCR cohort zijn ook vergelijkbaar met de resultaten van laparoscopische multi-compartmentele procedures in de literatuur (**hoofdstuk zeven**). Theoretisch zou er een hogere kans kunnen zijn op mesh erosie na een robotische ingreep vanwege het ontbreken van tactiele feedback⁴⁴. Er bestaat heden ten dage geen niveau één studies die LVMR met RVMR vergelijken en mesh erosie rapporteren. Slechts drie RVMR studies beschrijven mesh erosie (allen 0%), maar de follow-up is kort (12-23.4 maanden)^{40,45,46}. Getallen aangaande mesh erosie na niveau één bewijs voor laparoscopische en robotische sacrocolpopexie zijn tegenstrijdig,

maar percentages voor beide technieken zijn laag en acceptabel⁴⁷⁻⁵³. Het gecombineerde mediane mesh erosie percentage na observationele laparoscopische sacrocolpopexie studies (2.0%) is vergelijkbaar met haar robotische equivalent (1.8%, **hoofdstuk negen**). Het prospectieve cohort van **hoofdstuk negen** beschrijft een mediaan mesh erosie percentage van 2.8% na een mediane follow-up van 49.2 maanden na een abdominale robotische bekkenbodem ingreep. Robotische-assistentie lijkt derhalve op zijn minst even veilig en effectief als laparoscopie, maar bewijs van niveau één ontbreekt tot dusver. Robotisch geassisteerde chirurgie is aanzienlijk duurder dan laparoscopie^{38,45} en gezien de huidige literatuur kunnen deze hogere kosten nog niet gerechtvaardigd worden. Er bestaat echter ook een theorie dat robotische-assistentie uiteindelijk tot een kostenreductie zal leiden als chirurgen door verbeterde ergonomische omstandigheden langer door kunnen werken^{38,54}. Hiernaast is de leercurve van de robot aanzienlijk korter dan van laparoscopie (18 vs. 54 procedures), hetgeen ook tot een kostenbesparing kan leiden^{42,55,56}. Laparoscopische technieken werden wereldwijd geïmplementeerd lang voordat hoogwaardig kwalitatief onderzoek de superioriteit over de open benadering was bewezen⁵⁷. De verwachting bestaat dat de uitkomsten van robotische chirurgie zullen verbeteren al naar gelang de technologie zich ontwikkelt. In ons centrum zijn we van mening dat de robot van additionele waarde is in de bekkenbodem chirurgie en deze mening wordt gedeeld door vele andere auteurs die RVMR beschreven hebben^{40,41,58,59}. Toekomstig onderzoek zal uitwijzen of robotische-assistentie een vaste rol krijgt in het chirurgische armamentarium voor de behandeling van rectale prolaps.

Zijn abdominaal geplaatste synthetische meshes veilig?

Mesh gerelateerde complicaties kunnen een zeer grote impact op de kwaliteit van leven hebben. In de afgelopen jaren heeft de publieke opinie zich gekeerd tegen het gebruik van synthetische mesh in de bekkenbodem op basis van hoog percentage mesh gerelateerde complicaties na een transvaginale ingreep^{60,61}. Vanwege de negatieve publiciteit over de transvaginale repair, onder andere via het televisie programma Radar, weigeren veel patiënten het gebruik van een synthetische mesh, ongeacht de indicatie

of wijze van implantatie. We hebben laten zien dat abdominaal ingebrachte synthetische meshes in de bekkenbodem chirurgie op de lange termijn veilig zijn (**hoofdstuk negen**). Het resultaat van deze studie wordt ondersteund door de andere cohorten van dit proefschrift (**hoofdstuk vijf, zes en zeven**).

TOEKOMSTPERSPECTIEVEN

Hoewel dit proefschrift meer inzicht over de hedendaagse behandeling van rectum prolaps geeft, blijven er veel vragen onbeantwoord. Het gebrek aan bewijs van hoge kwaliteit in de rectum prolaps chirurgie in het algemeen en voor laparoscopische ventrale mesh rectopexie in het bijzonder zou chirurgen moeten aanmoedigen om grotere en gerandomiseerde trials met lange termijn uitkomsten te initiëren. Het zou van waarde zijn om de LVMR met de laparoscopische resectie rectopexie voor ERP of IRP of de LVMR met de STARR voor IRP te vergelijken. De moeilijkheden van de uitvoering van dergelijke trials worden echter door onze studie groep erkend. De lange termijn resultaten van de recent gepubliceerde RCTs (LVMR vs. Delorme, LVMR vs. posterior suture rectopexie en LVMR vs. RVMR) worden afgewacht. Deze onderzoeksgroep toetst momenteel de hypothese dat met robotische assistentie een diepere verankering van de mesh op de ventrale zijde van het rectum mogelijk is. Hiervoor gebruiken we een nieuwe 'MRI-visible' mesh (DynaMesh Visible™, FEG Textiltechnik, Aachen, Duitsland). Hierbij zal ook worden onderzocht of een diepere verankering van de mesh tot betere functionele resultaten leidt in vergelijking met de LVMR. De haalbaarheid van grote klinische trials kan in twijfel worden getrokken. De PROSPER trial liet namelijk zien dat, zoals reeds genoemd in de algemene discussie, chirurgen terughoudend zijn om van techniek te wisselen⁹. Dit belemmert het recruterende van patiënten en het beïnvloedt de chirurgische uitkomsten van trials. Hoewel het niet een ideale oplossing is, zou een internationale prospectieve database voor rectum prolaps en mesh gerelateerde morbiditeit wellicht een meer pragmatische aanpak zijn. Een universeel gevalideerde en wijd gebruikte diagnostische vragenlijst is echter essentieel voor een dergelijke database. Tot nu toe bestaat er geen vragenlijst die voldoet aan deze criteria. De klinische significantie van radiologisch gediagnosticeerde IRP blijft deels onbekend. In onze studie vonden we dat de D-MRI superieur leek te zijn aan CD voor het identificeren van intussuscepties en het zou interessant zijn om in toekomstige studies de morfologie, symptomatologie, de behandeling en de uitkomst van op beeldvorming waargenomen intussuscepties te bestuderen. Er is een groeiende hoeveelheid literatuur die laat zien dat een uni-

compartimentele ingreep mogelijk symptomen en/of verzakkingen van een aangrenzend compartiment kan verergeren of zelfs kan uitlokken. Er zijn echter tot op heden geen studies waarin is onderzocht of de klachten van het initieel onbehandelde compartiment te verklaren zijn voor een andere oorzaak. Het zou van waarde zijn dit te onderzoeken, al zal dit in de praktijk lastig zijn. In prospectieve studies naar een uni-compartimentele ingreep zou pre-operatief een multi-compartimentele evaluatie uitgevoerd moeten worden. Dit zal en herhaald moeten worden tijdens het post-operatieve follow-up onderzoek, waarin bij voorkeur ook radiologisch onderzoek plaats vindt ter uitsluiting van verzakkingen in de onbehandelde compartimenten. Meer lange termijn data over mesh gerelateerde morbiditeit is nodig om onze resultaten te bevestigen. Een vergelijking tussen biologische en synthetische mesh kan worden overwogen, maar wij geloven dat de biologische mesh alleen toepasbaar is in specifieke omstandigheden (bijvoorbeeld bij inflammatoire darm ziekten). In dit proefschrift ligt de focus niet op de identificatie van risico factoren die een slechte uitkomst voorspellen; dergelijk onderzoek is echter wel relevant en zou een plaats moeten krijgen op de onderzoeksagenda.

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International guideline of the 6th International Consultation on Incontinence

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Schraffordt Koops SE

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CURRICULUM VITAE

Jan van Iersel was born on December the 7th 1986 in Leiden, the Netherlands. In May 2005 he graduated from the Rijnlands Lyceum in Oegstgeest. The same year he commenced his medical training at the University of Utrecht. From June 2009 to September 2010 Jan interrupted his studies to participate in the board of a student association. His interest in surgery emerged during his junior internships. During his second rotation in general surgery he was asked by Dr. Henk Formijne Jonkers, Dr. Esther Consten and Prof. Dr. Ivo Broeders to join their surgical research group in the Meander Medical Centre, Amersfoort. After participating in two diverticulitis studies, he initiated several studies in the field of rectal prolapse surgery as the successor of Dr. Henk Formijne Jonkers. After obtaining his medical degree from the University of Utrecht in December 2013 he combined his research activities with working as a surgical resident (ANIOS) at the department of surgery at the Meander Medical Centre. In 2016 he received a full-time PhD scholarship of the University of Twente to finish his thesis. Between 2013 and 2016 Jan participated in one national and one international guideline on rectal prolapse and published in multiple peer reviewed journals. The majority of his studies were presented at national and international conferences. In January 2017 he started his surgical training at the University Medical Centre Utrecht under supervision of Prof. Dr. Menno Vriens. From January 2018 on, he will continue his residency at the Jeroen Bosch Hospital in Den Bosch under supervision of Dr. Koop Bosscha.

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ACKNOWLEDGEMENTS - DANKWOORD

Prof. dr. I.A.M.J. Broeders. Beste Ivo, ik ben trots onder jouw hoede te mogen promoveren. In het soms wat chaotische MeanderMC was jij altijd, als ik je te pakken had gekregen, een baken van rust. Je hebt een duidelijke, kritische en rechtlijnige visie op onderzoek en het was dan ook zeer interessant en leerzaam om met je te sparren. Veel dank voor je begeleiding de afgelopen jaren! Daarbij wil ik je danken voor het faciliteren van het laatste fulltime jaar aan de Universiteit van Twente. Een dergelijk jaar had ik echt nodig om het proefschrift netjes af te maken, dus dank daarvoor. Achter de rustige, welbespraakte, deftige professor gaat echter ook iemand anders schuil die hierboven niet wordt beschreven. Die Ivo heb ik met name leren kennen tijdens de ski vakanties en de laatste maanden ook via de WhatsApp. Ik zal er via dit medium niet verder over uitweiden, maar ik geloof dat we qua humor meer gemeen hebben dan we denken. Wellicht kunnen we het daar op het promotie feest nog even over hebben!

Dr. E.C.J. Consten. Beste Esther, 'Zeg Jan, als jij nou even..... gewoon even hakkie takkie.... als een razende Roeland!.....als JIJ begrijpt wat IK bedoel!'. Als the *Queen of Surgery* van het MeanderMC woorden van deze strekking met een licht Brabantse tongval uitsprak, dan wist je dat je aan de bak moest. Of het nou ging om het instellen van de printer op het operatie complex, kleine Timmetje ophalen op het station of participeren in een internationale richtlijn; the *Queen* kreeg altijd alles voor elkaar. Zo werd ik, als volgende choco prins in de successie, de afgelopen jaren onder de vleugels genomen van Esther en werd ik geïntroduceerd in de wondere wereld van de proctologie. En met wat een resultaat! Inmiddels ben ik in opleiding tot chirurg en staan we samen op een paar aardige publicaties. Beste Esther, ik heb de afgelopen jaren ontzettend fijn met je samen gewerkt en heel veel van je geleerd. Ik wil je hartelijk bedanken voor de afgelopen jaren, ik heb een fantastische tijd gehad!

Dr. P.M. Verheijen. Beste Paul, als een speedy gonzales met immer een goed humeur begeef jij je door de gangen van het Meander. Je enthousiasme, positivisme, werklust en humor heb aanstekelijk gewerkt op mijn wetenschappelijke prestaties. Je was altijd bereid voor overleg, keek de manuscripten razend snel na en had altijd goede adviezen. Daarnaast ben je met je enthousiasme een zeer fijn persoon om samen te werken. Heel veel dank voor al je inzet de afgelopen jaren!

Dr. W.A. Draaisma. Beste Werner, ik weet dat je diep in je hart toch ook een bekkenbodem man bent, zoals je gappies stoma Henkie en ik, en dus moet het slechts een kwestie van tijd zijn voordat je je weer op de pelviene organen stort. Naast onze gezamenlijke voorliefde voor de bekkenbodem hebben we natuurlijk meer gemeen; het zal vandaag immers niet de laatste keer zijn dat we samen op de prachtsite Jezuswatslecht.nl (voor de oplettende lezers ook echt een aanrader) een fijn hitje van de Stoopjes of van Ben en Ruurd luisteren. Werrrnor, in het begin was je mijn co-promotor en voor die tijd wil ik je uiteraard hartelijk danken! Gedurende mijn hele promotie stond je altijd klaar voor goede adviezen, hetgeen ik altijd zeer kon waarderen, dank!

Geachte leden van de beoordelingscommissie: **Prof. dr. ir. Stramigioli, Prof. dr. Geelkerken, Prof. dr. D'Hoore, Prof. dr. Roovers, Dr. Schraffordt Koops en Dr. Wijffels.** Hartelijk dank voor uw bereidheid om dit proefschrift te beoordelen en plaats te nemen in de oppositie. Hiernaast wil ik **Prof. dr. Apers** hartelijk danken voor het voorzitten van de promotie.

Prof. dr. Vriens, mijn opleider in het UMC Utrecht. Beste Menno, ik wil je danken voor je vertrouwen de afgelopen periode. Hoewel ik nog maar kort in het UMCU werk, zie ik met wat voor een enorme energie en toewijding jij werkt. Dit maakt je toch een geweldige opleider en ik ben blij onder jouw hoede opgeleid te worden!

Chirurgen Meander Medisch Centrum. Allen dank voor de begeleiding en interesse de afgelopen 3 jaar. Ik heb een geweldige tijd in het Meander gehad!

Chirurgen UMC Utrecht. Nog maar kort ben ik in jullie midden, maar ik merk nu al het prettige opleidingsklimaat en de relaxte sfeer in het UMCU. Ik ben blij dat ik in de regio Utrecht opgeleid mag worden. Dank voor het vertrouwen, ik hoop nog veel van jullie te leren!

Arts-assistenten Meander Medisch Centrum en UMC Utrecht. Jaaa, jullie zijn top!

Paranimf, drs. Jan-Paul Briët. JP, vriend, de gehele opleiding geneeskunde hebben we zijde aan zijde opgetrokken met Zuid-Afrika als (en dan met name in de the 31) hoogtepunt. Gedurende al die jaren zijn we goede maten geworden en toen ik een paranimf moest kiezen was er eigenlijk maar één keuze. Ik ben er trots op dat jij vandaag mijn paranimf bent!

Paranimf drs. Tim Paulides a.k.a. Paul Timmiedes a.k.a. Tim the Police a.k.a. Techno Tim. Timmie, de laatste jaren hebben we veel gedeeld: huis, problemen, the silver bullit met blauwe kap, een WhatsApp relatie met Anne, onderzoek en werk. Door dit intensieve contact zijn we goede maten geworden en die vriendschap waardeer ik zeer. Het beeld van jou met een knalletje peukie in de Praagse straten krijg ik denk ik nooit meer van mijn netvlies! Ik ben blij dat je mijn paranimf bent en ik weet zeker dat we later samen ergens staan te opereren!

Dr. Steven Schraffordt Koops. Beste Steven, afgelopen jaren heb ik jou leren kennen als een bevlogen gynaecoloog en onderzoeker. Samen hebben we twee projecten opgepakt met een zeer goed resultaat. Bij deze studies was je zeer betrokken, enthousiast en altijd bereid tot overleg. Veel dank voor je hulp en begeleiding hierbij! Daarnaast ben je een

prettig persoon om mee samen te werken en kon ik je uitnodiging om een keer uit eten te gaan om de promotie te bespreken zeer waarderen. Dank!

Drs. Chris de Witte en drs. Femke van Zanten. Beste Chris en Femke, veel dank voor jullie inzet en bijdrage aan onze studies!

Priscilla, de papier vrouw. Beste Priscilla, nog bedankt voor het bijvullen van de printer, die ene keer.

Dr. Bryan van de Wall. Brrrrryyyyyyyaaaaaan! Los van het feit dat ik het leuk vind je naam zo op te schrijven moet ik je ook danken. Jij was de man die mijn introduceerde in het onderzoek en in het Meander, dank daarvoor! Helaas lopen we elkaar net mis in den Bosch, maar we drinken vast ergens anders nog wel en keer een biertje!

Corinne Verduijn-Staal, Sonja Veerman en Ebelien van Wieren - Numan. Waar is een onderzoeker zonder de hulp van de dames van de poli? Helemaal nergens natuurlijk. Beste Corinne, Sonja en Ebelien, duizendmaal dank voor jullie tomeloze inzet de afgelopen jaren! Jullie zijn nu officieel van me af!). Hopelijk tot snel een keer!

Dr. Fütterer, Drs. Heggelman, Drs. Somers en Drs. van der Leest, radiologen. Beste Jurgen, Ben, Inne en Marloes, hartelijk dank voor jullie inzet voor het radiologische stuk. Hiernaast een speciale dank aan Ben, voor de begeleiding rondom deze studie en het lopende MRI visible project!

Prof. dr. D'Hoore. Beste Andre, dank voor de mogelijkheid om onderzoek te komen doen in Leuven. Het was een zeer leerzame tijd en er is een fantastische publicatie uit gekomen!

Anja, Marja en Henriëtte. Wat ik ook nodig had, jullie hielpen me op weg. Veel dank daarvoor.

Dr. Pieternel Pasker. Beste Pieternel, hartelijk dank voor al je statistiek begeleiding van de afgelopen jaren! Zoals je gemerkt hebt ligt mijn talent niet bij de statistiek en dus kon ik je hulp goed gebruiken, dank!

Drs. Femke Amelung a.k.a. Femmie, Hendrike Bolkenstein, Rob Tolboom a.k.a. Robbie T, Paul Wijsman a.k.a. Paulus. Beste mede onderzoekers, dank dat ik tegen jullie mocht zeiken, klagen, janken en schelden, want god, wat kan onderzoek toch verschrikkelijk zijn. Toch was het een super tijd, en dat kwam niet in de laatste plaats door jullie aanwezigheid. Heel veel succes met het afronden van jullie promotie en we keep in touch! P.S. Hendrike, zou je je panterpakkie aan kunnen doen naar mijn promotie feest? Robbie, jij niet alsjeblieft. Thanks!

Dr. Marguerite Gorter-Stam. Beste Marguerite, hartelijk dank voor al je goede adviezen en hulp rondom mijn sollicitatie procedure en promotie. Ik waardeer het zeer!

Willem van der Vossen a.k.a. Party. God, Willem, waar moet ik beginnen? Voor mij ben jij de basis van alles. Mits je je trui niet aan hebt dan. Als ik bij jou ben, dan denk ik 'wat hebben we weinig geld, maar god, wat zijn we rijk'. Daar wil ik het bij laten eigenlijk.

Gerrit, de koffieman. Bedankt voor de koffie Gerrit, hij was lekker.

Lieve familie, schoonfamilie, vrienden en vriendinnen van het MOG, SV, jaarclub, de Biltstraat, het voetbalteam, uit Leiden, Oegstgeest, Utrecht en Amsterdam; ik hoop dat mijn proefschrift een mooi plekje bij jullie op de plee krijgt;))!

Henk, gast! Wat kon er eigenlijk misgaan met een waanzinnige voorganger zoals jij? Met een onovertroffen begeleiding, steengoede grappen en een feilloos gevoel voor de pathologie heb je mij kennis laten maken met de mysterieuze wereld van de prolaps. Tegenwoordig behandel jij de rectum prolapsen met een gamma nail, maar diep in je hart blijf je toch een bekkenbodem man. Ik ken immers weinig mensen die zo veel weten van de Willospon© als jij. Ik kijk met smart uit naar ons eerste bekkenbodemweekend; ik koop alvast het landbouwplastic in!

Jansie! Poeh, wat was er terecht gekomen van dit proefschrift zonder my personal English reviewer Jansie? Ik denk niet ver! Wat een werk heb jij ook in dit boekje zitten. Duizendmaal dank voor al je revisies en Engelse grammatica aanpassingen! Zodoende ben je waarschijnlijk een van de weinige Engelse psychiaters met een special interest in de proctologie! Het was leuk je wat vaker te spreken, zullen we dat er in houden;)?

Lieve **Saskia**, een van mijn grootste dankwoorden gaat naar jou. Ik geloof dat je niet helemaal beseftte waarin je toestemde toen je vertelde dat je lay-out van dit proefschrift wilde doen. Van wijken wilde je echter niks weten en dat verdient veel respect, lof en een dikke knuffel uiteraard! Heel erg lief dat je deze zware taak als nieuw lid van onze familie op je wilde nemen en daar wil ik je bij dezen ook heel erg voor bedanken! In de toekomst (mag nu ook al, maar dat kan ik je niet aanraden) mag je een chirurgische behandeling naar keuze uitkiezen!

Lieve **Thijs**, grote broer, ook een speciaal dankwoord naar jou. Je bent de ontwerper van de omslag, maar gedurende mijn promotie (en daarvoor ook al) heb je veel meer voor mij gedaan. Ik hou van je gabber (en van jou natuurlijk ook Markie, maar jij hebt geen bal aan het proefschrift gedaan).

Lieve **Pap en Mam**, ook aan jullie een speciaal dankwoord. Niet alleen in de laatste jaren maar gedurende mijn hele leven ervaar ik onvoorwaardelijk steun en betrokkenheid van jullie. Ik vermoed dat jullie toen ik op 7 jarige leeftijd een gitaar op het hoofd van Wilbert kapot sloeg niet direct hadden vermoed dat ik later een doctorale graad zou halen. Het is echter gelukkig toch nog goed gekomen en niet in de laatste plaats door jullie! Mijn dank aan jullie is niet uit te drukken op papier. Ik hou van jullie.

Lieve **Anne-Sophie**, lieve Fietje, mijn vingers jeuken om allerlei spelfouten in dit stukje te zetten, omdat ik weet dat je dat niet kan uitstaan en me dan heeeeel dom vindt, maar ik houd me in omdat ik zo gek op je ben. Voor mijn dankwoord aan jou heb ik gelukkig voldoende inspiratie, gezien het feit dat je je eigen dankwoord al meerdere keren aan mij gedicteerd hebt. Aangezien je, naar eigen zeggen, lijdt aan het extreme humor syndroom, zal het in ieder geval een grappig stukje worden. Zonder grap ben je echter degene die ik het meeste moet danken voor de realisatie van dit proefschrift. Meerdere avonden en weekenden heb ik aan onderzoek moeten werken, met name tijdens mijn ANIOS periode. Gedurende deze tijd was je (bijna;) altijd begripvol, geduldig, lief en stimuleerde je me om verder te gaan. Ik durf te stellen dat ik het zonder jou niet voltooid had en daar ben ik je zeer dankbaar voor! Ik hou van je en kijk uit naar al onze toekomstige avonturen!