NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of laparoscopic ventral mesh rectopexy for internal rectal prolapse

Internal rectal prolapse is when the lowest part of the bowel (rectum) telescopes on itself, causing difficulty in emptying the bowel, faecal incontinence or both. In this procedure, a piece of sterile material is used to attach the rectum to the lower back bone using keyhole surgery. The aim is to support the rectum in its natural position.

Contents

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety

and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in September 2017.

Procedure name

- Laparoscopic ventral mesh rectopexy for internal rectal prolapse

Specialist societies

- Association of Coloproctology of Great Britain and Ireland
- Pelvic Floor Society
- Royal College of Surgeons of England

Description of the procedure

Indications and current treatment

Rectal prolapse may be internal (also known as intussusception or intra-rectal prolapse) or external, where the bowel descends outside of the anus. This overview only considers laparoscopic ventral mesh rectopexy (LVMR) for internal rectal prolapse. It is more common in women who have had children but also occurs in nulliparous women and men. Factors related to the development of the condition are age, childbirth, constipation and straining. It may be associated with prolapse of other pelvic organs and some people may have a predisposition because of abnormalities in collagen. It is not life threatening but it can be a distressing and demoralising condition, with negative effects on quality of life. Symptoms include discomfort, pain, constipation, difficult evacuation (obstructed defaecation syndrome), faecal incontinence and discharge of mucus or blood. In women it can be associated with vaginal bulge (rectocele), painful intercourse, lower back pain, urinary dysfunction, and vaginal prolapse and enterocele.

Conservative treatment of internal rectal prolapse may include pelvic floor exercises and advice to improve defaecatory habits, reduce constipation and improve incontinence. These are often termed biofeedback or pelvic floor re-training. Surgical treatment of internal rectal prolapse is classified into perineal

(Delorme's operation) and abdominal procedures. Open abdominal surgery and laparoscopic procedures, with or without robotic assistance, use mesh or direct suturing and may involve resection of sigmoid colon.

What the procedure involves

LMVR is done under general anaesthesia using keyhole surgery in which 3 to 4 small incisions are made in the abdomen. The peritoneum around the rectum is dissected until the muscle coat of the rectum is identified and exposed over the entire anterior rectum which is mobilised into the rectovaginal septum. The mesh is secured to the rectum anteriorly, as low as possible in the rectovaginal or rectoprostatic fascia, using sutures, and fixed to the sacral promontory with permanent sutures or small metal tacks. The peritoneum is closed over the mesh to prevent bowel becoming trapped or adhering to the mesh. In women, LVMR may help control rectocele or enterocele associated with rectal prolapse.

Outcome measures

1. Oxford grading system for rectal prolapse

Can be used to classify rectal prolapse after clinical or radiological assessment.

Oxford rectal prolapse grade		Characteristics of rectal prolapse
Internal rectal prolapse		
Rectal intussusception	Grade I	Descends no lower than the proximal limit of the rectocele
	Grade II	Descends into the level of the rectocele, but not to the anal canal
Rectoanal intussusception	Grade III	Descends to the top of the anal canal
	Grade IV	Descends into the anal canal
External rectal prolapse	Grade V	Protrudes from the anus

2. Cleveland Clinic Incontinence Scoring System

Type of incontinence	**Frequency**				
	Never	**Rarely**	**Sometimes**	**Usually**	**Always**
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4

Lifestyle alteration	0	1	2	3	4
0 = perfect continence, 20 = complete incontinence; **Rarely** ≤ 1/month; **sometimes** ≤ 1/week to ≥ 1/month; **usually** ≤ 1/day to ≥ 1/week; **always** ≥ 1/day.					

3. Wexner Constipation Score

A subjective constipation score calculated using a questionnaire including 100 constipation-related symptoms. Based on the questionnaire, scores ranging from 0 to 30 are obtained, with 0 indicating normal and 30 indicating severe constipation.

4. Browning and Parks Incontinence Scale

Grade I	Continent
Grade II	Incontinent with flatus
Grade III	Incontinent to flatus and liquid stools
Grade IV	Incontinent to flatus, liquid stools and solid stools

5. Faecal Incontinence Severity Index

Assesses the quality of life correlated to the level of distress due to adult incontinence leakage. The index is made of 6 questions for each of the 4 topics: incontinence to gas, incontinent for mucus, incontinent for liquid stools and incontinent for solid stools. The score ranges from 0 to 61 with higher scores correlating to higher levels of faecal incontinence. Scores above 30 are more likely to be associated with an impaired quality of life due to faecal incontinence.

6. Gastrointestinal Quality of Life Index

A bilingual (German and English) questionnaire containing 36 questions, each with five response categories. Questions concern core symptoms, and physical, psychological, social and disease-specific items. The responses to questions are summed to give a numerical score.

Efficacy summary

Anatomical correction

A systematic review (SR) of 18 studies (1,238 patients) reported outcomes of patients with internal rectal prolapse (IRP) treated by LVMR and robotic ventral mesh rectopexy (RVMR). The SR reported that anatomic correction of IRP grade 3 or above, assessed by the Oxford prolapse classification system, was achieved in 80% to 100% of patients who had LVMR or RVMR. The same SR reported that solitary rectal ulcer syndrome improved in 75% of patients after LVMR[1].

In a randomised control trial (RCT) of 30 patients, anatomical correction success at 3-month follow-up was not statistically significantly different between patients with IRP or enterocele treated by LVMR compared with patients who had RVMR (100% correction in both groups, $p>0.9$)[3].

Constipation

The SR of 18 studies reported an improvement in constipation assessed by the Cleveland Clinic Constipation Score (CCCS) from a median of 14 (range 7 to 18) preoperatively to a median of 5 (range 4 to 7) after LMVR (6 studies, p value not reported). In the same SR, improvement in constipation was reported by 86% (95% CI 20 to 97%) of patients after LVMR[1].

A SR of 10 studies included a meta-analysis (4 studies, 346 patients) reporting a statistically significantly decrease in constipation in patients with IRP after LVMR, from 63% (217/346) preoperatively to 17% (59/346) postoperatively (odds ratio [OR] 0.09, 95% confidence interval [CI] 0.03 to 0.39, $p<0.0001$; I^2 not reported)[2].

In a case series of 919 patients (677 with IRP), the percentage of patients with obstructed defaecation caused by IRP or symptomatic rectocele was statistically significantly reduced from preoperative values of 63% (291/460) to 16% (75/460) postoperatively (median follow-up 34 months, $p<0.0001$). Similarly, the percentage of patients with obstructed defaecation caused by IRP or symptomatic rectocele with enterocele was also statistically significantly reduced from preoperative values of 57% (123/217) to 17% (36/217) postoperatively, $p<0.0001$[4].

In a case series of 91 patients with high grade internal rectal prolapse (HIRP) who had LVMR, median Wexner Constipation Score was statistically significantly improved from preoperative values 14 (10 to 17) to 5 (0 to 19, $p<0.001$) at 3-month follow-up. The same case series reported that patients with enterocele treated by LVMR had a greater percentage resolution of obstructed defaecation

symptoms (70%, interquartile range [IQR] 67 to 100) compared with patients without enterocele (52%, IQR 25 to 80, p=0.03).

In a case series of 50 patients (42 with IRP) who had LVMR, the number of patients with obstructed defaecation was statistically significantly reduced from 83% (30/36) of patients at baseline to 58% (21/36) postoperatively (p=0.004)[7].

In another case series of 91 patients (50 with IRP) who had LVMR, there was a statistically significantly reduction in Wexner Constipation Scores from preoperative values of 10.3 (0 to 23) to 7.2 (0 to 0.21) at 1-year follow-up, p<0.01[8].

Faecal incontinence

The SR of 10 studies included a meta-analysis (5 studies, 431 patients) reporting a statistically significant reduction in faecal incontinence in patients who had LVMR from preoperative values of 49% (210/431) of patients to 12% (53/431) postoperatively (OR 0.17, 95% CI 0.05 to 0.61, p<0.00001, I^2 not reported)[2].

In the case series of 919 patients, the percentage of patients with faecal incontinence caused by IRP or symptomatic rectocele was statistically significantly reduced from preoperative values of 38% (174/460) to 9% (39/460) at last follow-up (median follow-up 34 months, p<0.0001). Similarly, the percentage of patients with faecal incontinence caused by IRP or symptomatic rectocele with enterocele was also statistically significantly reduced from preoperative values of 33% (72/217) to 13% (27/217) postoperatively, p<0.0001[4].

In the case series of 91 patients with HIRP treated by LVMR, median Faecal Incontinence Severity Index (FISI) score was statistically significantly improved from preoperative values of 20 (range 0 to 61) to 9 (range 0 to 48, p<0.001) at 3-month follow-up. This was also true for patients with a median FISI score above 30, with a statistically significant decrease in FISI scores from 40 (range 30 to 61) at baseline to 17 (range 0 to 48, p<0.001) at 3-month follow-up[5]. The presence of an enterocele was associated with greater improvement of incontinence symptoms: 71% (IQR 63 to 100) compared with 38% (IQR 25 to 87, p=0.01) in patients with no enterocele.

In a case series of 231 patients (118 with IRP) who had LVMR, faecal incontinence assessed by the Cleveland Clinic Incontinence Score (CCIS) reduced from 13 (range 11 to 16) at baseline to 5 (range 2 to 8.8) at 6-month follow-up and 3 (range 2 to 3) at 3-year follow-up[6].

In the case series of 50 patients (42 with IRP) who had LVMR, the number of patients with faecal incontinence was statistically significantly reduced from 25% (9/36) of patients at baseline to 8% (3/36) postoperatively (p=0.03)[7].

In the case series of 91 patients (50 with IRP) who had LVMR, there was a statistically significant reduction in FISI scores from preoperative values of 42 (range 30 to 61) to 25 (range 0 to 59) at 1-year follow-up, p<0.01. At 1-year follow-up, 24% (12/50) of patients had had additional surgery for faecal incontinence[8].

Prolapse recurrence

The SR of 18 studies reported anatomical prolapse recurrence after LVMR in 5% of patients (95% CI 3 to 9, 11 studies, 747 patients) and after RVMR in 9% (95% CI 4 to 21) of patients (1 study, 44 patients)[1].

In the case series of 919 patients who had LVMR for IRP or rectocele with or without enterocele, a 7% (45/677) rate of anatomical recurrence was reported at a mean follow-up of 24.8 (range 1 to 139.4) months[4].

In the case series of 231 patients who had LVMR, prolapse recurrence was reported by 2% (2/118) of patients. The same study reported that in patients with IRP or ERP treated by LVMR, the use of synthetic mesh was 4.2 times more likely to result in recurrence compared with biological grafts[6].

In the case series of 91 patients (50 with HIRP) who had LVMR, recurrence happened in 6% of patients[8].

Sexual dysfunction

The SR of 10 studies included a meta-analysis (3 studies, 152 patients) reporting a statistically significant reduction in sexual dysfunction in patients who had LVMR, from 65% (98/152) of patients preoperatively to 14% (21/152) postoperatively (OR 0.06, 95% CI 0.03 to 0.14, p<0.0001, I^2 not reported)[2].

In the case series of 91 patients (50 with HIRP) who had LVMR, 9% (4/50) of patients reported deterioration of sexual function after LVMR and 64% (32/50) reported that sexual function improved after LVMR[8].

Conversion rates

The SR of 18 studies reported that the median conversion rate of LVMR to open laparotomy was 2% (range 0 to 8) across studies[1].

The SR of 10 studies reported that in patients who had LVMR or RVMR conversion to open surgery occurred in 6% (16/280, range 3% to 10%) of cases (6 studies)[2].

Length of hospital stay

The SR of 18 studies reported that the median length of hospital stay was 3.3 (range 1 to 7.1) days for patients who had LVMR and 4.3 (range 4.0 to 4.6) days for patients who had RVMR (p value not reported)[1].

The SR of 10 studies reported that length of hospital stay ranged from 2 to 6 days [2].

In the RCT of 30 patients, length of hospital stay was not statistically significantly different for patients who had LVMR (2.5±0.9) compared with patients who had RVMR (2.2±1.5, p=0.71)[3].

In the case series of 231 patients with IRP treated by LVMR, length of hospital stay was reported to be 1 day (range 0 to 1)[6].

In the case series of 50 patients (42 with IRP) who had LVMR, the mean hospital length of stay was 2.5 (±0.2) days[7].

Subjective improvement and quality of life

The SR of 18 studies included a meta-analysis (4 studies, 248 patients) that reported patient satisfaction after LVMR to be satisfactory or good in 82% of patients (95% CI 70 to 92; I^2=74%)[1].

In the case series of 231 patients who had LVMR, improvement in primary symptoms was reported as complete by 64% (74/118) of patients, partial by 33% (38/118) and none by 3% (3/118) of patients. In the same case series, patient satisfaction after LVMR was complete in 60% (68/118) of patients and partial in 40% (46/118)[6].

In the case series of 91 patients (50 with IRP) who had LVMR, there was a statistically significant improvement in the Gastrointestinal Quality of Life Index from preoperative values of 79 (range 32 to 130) to 92 (range 41 to 136) at 1-year follow-up, p<0.01[8].

Safety summary

Death

Death caused by sepsis within 30 days of the procedure happened in less than 1% (2/2203) of patients in a case series of 2,203 patients with IRP or ERP treated by LVMR[9].

Mesh complications

In the SR of 18 studies mesh complications were reported in 0.5% (5/939) of patients who had LVMR or RVMR[1].

Bowel erosion was reported in 1 patient who had LVMR in 1 study included in the SR of 10 studies. Mesh dislocation was reported in 1 patient who had LVMR in 1 study included in the same SR[2].

Mesh erosion happened in 2% (45/2203) of patients who had LVMR in the case series of 2,203 patients with IRP or ERP. Mesh erosion happened within 6 months of surgery in 16% (7/45) of erosion cases, within 36 months of surgery in 76% (34/45) of cases and within 60 months of surgery in 4% (2/45) of cases. Mesh erosion cases were more frequently associated with surgery for IRP (3%, 39/1389) than for ERP (1%, 6/569, p=0.02). Polyester mesh was associated with a statistically significantly higher risk of mesh erosion compared to polypropylene and titanium-coated polypropylene meshes (p<0.00006). The risk of mesh erosion was statistically significantly higher in patients who had LVMR using polyester compared with polypropylene (hazard ratio [HR] 4.09, 95% confidence interval [CI] 2.16 to 7.73]). The risk of mesh erosion was higher in patients who had LVMR using polyester mesh compared with titanium-coated polypropylene, but this did not reach statistical significance (HR 2.96, 95% CI 0.38 to 2.23). Of the 42 synthetic mesh erosions 55% (23/42) were with propylene mesh, 43% (18/42) with polyester and 1/42 with titanium-coated polypropylene. There were 40% (18/45) of patients requiring treatment for major mesh morbidity (12 laparoscopic mesh removal, 3 mesh removal plus colostomy and 3 laparoscopic ultralow anterior resection) and 51% (23/45) requiring treatment for minor erosion morbidity (local excision of stich/exposed mesh)[9].

Haemorrhage

Intra-abdominal bleeding happened in 1 patient who had LVMR in 1 study reported in the SR of 10 studies[2].

Perioperative bleeding occurred in 12% (2/16) of patients who had RVMR in the RCT of 30 patients. Vascular complications and haematoma each occurred in 1 patient who had RVMR in the same study[3].

Intra-abdominal haemorrhage happened in 1 patient in the case series of 231 patients[6].

Infection

Pelvic sepsis was reported in 1 patient who had LVMR in 1 study included in the SR of 10 studies. Port-site infection or haematoma happened in 4% (4/91) of patients who had LVMR reported by 3 studies included in the same SR[2].

Fever was reported in 1/14 patients who had LVMR in the RCT of 30 patients[3].

Abdominal or pelvic collection happened in 2% (2/118) of cases in the case series of 231 patients[6]. Wound infection and lumbar discitis each happened in 1 patient in the same case series of 231 patients who had LVMR[6].

Urinary complications

Urinary complications happened in 5% (12/222) of patients who had LVMR reported by 4 studies included in the SR of 10 studies[2].

Urinary tract infection was reported in 1 patient who had LVMR in the case series of 91 patients with 1-year follow-up. New-onset urinary infection was reported in 8% (4/50) of patients who had LVMR in the same case series[8].

Pain

Perineal pain was reported by 1 patient who had RVMR in the RCT of 30 patients[3].

Admission for pain was reported in 1 patient who had LVMR in the case series of 91 patients with 1-year follow-up[8].

Other

Other complications such as general pain or ileus were reported by 7% (8/114) of patients (3 studies) included in the SR of 10 studies[2].

Total complication rate was 10% (12/118) of patients in the case series of 231 patients who had LVMR, with 7% (8/118) of patients having surgery-related complications. Other complications reported in the same study were wound

hernia in 2% (2/11) of patients, rectovaginal seroma in 1 patient, hypotension in 1 patient and nausea in 1 patient[6].

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened). For this procedure, specialist advisers listed the following anecdotal adverse events: mesh complications (infection and erosion), sacral periostitis, rectovaginal fistula, ureteric injury, chronic pain and dyspareunia, procedure failure, faecal incontinence, worsening constipation hernia, wound complications, urinary tract infection, collections, haematoma, and small bowel obstruction. They considered that the following were theoretical adverse events: implantation endometriosis, pelvic scarring, reduced fecundity, haemorrhage, small bowel obstruction and ureteric injury.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to laparoscopic ventral mesh rectopexy for internal rectal prolapse. The following databases were searched, covering the period from their start to September 2017: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with internal rectal prolapse.
Intervention/test	Laparoscopic ventral mesh rectopexy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on approximately 4275 patients from 2 systematic reviews[1-2], 1 randomised control trial and 6 case series[3-9].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on laparoscopic ventral mesh rectopexy for internal rectal prolapse

Study 1 Grossi U (2017)

Details

Study type	**Systematic review**
Country	UK
Recruitment period	Databases searched up to
Study population and number	**18 observational studies (1,238 patients)** reporting on outcomes of patients with obstructed defaecation or internal rectal prolapse (intussusception) that were treated surgically
Age and sex	Adults (age and gender not reported)
Patient selection criteria	Inclusion criteria: - Studies were included if reporting on the outcomes of patients with obstructed defaecation and internal rectal prolapse (intussusception) treated by LVMR, RVMR or LRR. Exclusion criteria: - Rectal excision procedures (e.g.: STARR) - Rectal reinforcement procedures (e.g. transanal or transperineal repair of rectocele) - Uncommon variant of suspension procedures - Non-English language - Studies reporting on less than 20 patients - Studies from data considered duplicate - Studies not reporting on subgroups for interventions of interest - Constipation not representing an indication - Follow-up less than 12 months - Lack of primary patient data.
Technique	Limited reporting of literature review technique.
Follow-up	**Median 25 months (range 12 to 72)**
Conflict of interest/source of funding	Project funded by the National Institute for Health Research, program grant for applied research.

Analysis

Study design issues: Authors declared having used a PRISMA reporting tool.

Study population issues: The general quality of the studies was poor due to inadequate description of the methods. All studies were observational, 2 were good quality prospective cohort studies (Wong 2011 and Mantoo 2013, level IIB), and 16 studies were level IV quality studies comprising 2 poor quality case-control studies (Evans 2015 and Tsunoda 2015).

Fifteen of the 18 studies included in the review highlight the fact that all patients had a period of conservative treatment. Patient selection was otherwise inconsistent.

Study	n	Mean FU (months)	Intervention	Design	Level of evidence
Tsiaussis 2005	27	45	LRR	PCH	IV
von Papen 2006	56	44	LRR	PCS	IV
Collinson 2009	75	12	LVMR	PCS	IV
Kargar 2011	39	32	LVMR	RCS	IV
Wong 2011	41	12	LVMR	PCS	II B
Wong 2011	84	29	LVMR	PCS	IV
Sileri 2012	34	12	LVMR	PCS	IV
Wahed 2012	65	12	LVMR	PCS	IV

Evans 2013	30	36	LVMR	PCS	IV
Formijne Jonkers 2013	233	30	LVMR	RCS	IV
Grosselink 2013	151	12	LVMR	RCS	IV
Mantoo 2013	128	16	LVMR	PCS	II B
Borie 2014	52	18	LVMR	RCS	IV
Franceschilli 2015	100	20	LVMR	PCS	IV
Tsunoda 2015	26	16	LVMR	PCS	IV
Van Test 1995	37	72	OR	RCS	IV
Vermeulen 2005	20	18	OR	RCS	IV
Portier 2011	40	22	OR	PCS	IV

Other issues: Databases searched not reported, date limits on searches not reported.

The authors reported an absolute lack of comparative evidence and observational studies of overall uncertain methodological quality, poor definitions and inconsistent grading of complications (Clavien-Dindo grading or equivalent deemed fundamental).

The studies by Portier 2011, Wong 2011a, Wong 2011b, Sileri 2012, Collinson 2010 and Formijne-Jonkers 2013 were also reported in paper 2 of table 2.

Key efficacy and safety findings

Efficacy	Safety
n= 18 studies (1238 patients) Median duration of the procedure **LVMR**: 159 min (range 75 to 198) **RVMR**: 205 min (range 191 to 218)[1] **LRR:** 123 min (one study) Conversion to laparotomy Median for all studies: 2% (range 0 to 8%) Length of stay (LOS, median) **LVMR**: 3.3 days (range 1 to 7.1) **RVMR**: 4.3 days (range 4.0 to 4.6) **LRR**: 4 days (data from 1 study) Overall improvement (satisfactory or good) **LVMR**: 82% of cases, 95% CI 70 to 92%; I^2=74% (4 studies, 248 patients) Improvement in constipation (Cleveland clinic constipation score): LVMR: improvement from a median of 14 (range 7 to 18) preoperatively to a median of 5 (range 4 to 7) after surgery (6 studies, number of patients and p value not reported) **LVMR**: 86% patients, 95% CI 20 to 97%, patient reported improvement in constipation Anatomical recurrence: Range 0 to 21% in all studies, typically occurred in 2 to 7% of patients in most studies. **LVMR**: 5% of patients, 95% CI 3 to 9% (11 studies , 747 patients) **RVMR:** 9% of patients**,** 95% CI 4 to 21% (1 study, 44 patients) High grade Oxford Grade ≥3 LVMR and RVMR provided anatomic correction in 80 to 100% of the cases. Improvement in SRUS[2] 75% of patients after LVMR (2 studies, 75 patients) **Patient satisfaction and quality of life:** No study reported acquiring data objectively using personnel not involved in the surgical care of the patient or data collection blinded to intervention status. [1]The 2 papers on RVMR were from the same centre. The duration of the operation decreased in the most recent paper (218 min to 191 minutes) which may suggest a learning curve. [2]A proportion of patients with SRUS have a component of intussusception, probably due to repeated trauma form straining	Procedural complications: 10% LVMR compared to 15% LRR (p=0.30) Complications occurred in 5 to 15% of procedures. Mesh complications: 0.5% (5/939) of patients. No mortality was reported (studies including 1044 patients). The following complications were mentioned but no frequencies were reported: Minor: urinary tract infections (most common), wound infections, haematoma formation, persistent pain and urinary retention. Serious: complications including port-site hernia, small bowel obstruction (usually after conversion but also related to mesh or suture adhesions), osteomyelitis and bladder injury (often when associated to bladder prolapse surgery).

Abbreviations used: CI, confidence interval; FU, follow-up; LRR, laparoscopic resection rectopexy; LRR, laparoscopic resection rectopexy; LVMR laparoscopic ventral mesh rectopexy; OR, open rectopexy; PCH, prospective cohort study; PCS, prospective case series; PRISMA, preferred reporting items for systematic reviews and meta-analyses; RCS, retrospective case series; RVMR, robotic ventral mesh rectopexy; SRUS, solitary rectal ulcer syndrome; STARR, stapled transanal rectal resection.

Study 2 Gouvas N (2015)

Details

Study type	**Systematic review**
Country	Greece
Recruitment period	Databases searched from 2004 to 2013
Study population and number	23 studies (1,460 patients) reporting on LVMR for ORP or ODS **10 studies (619 patients)** reporting on LVMR for ODS The IP analyst included only studies reporting on LVMR for ODS
Age and sex	Mean range 55 to 67 years, all females
Patient selection criteria	Studies inclusion criteria: - Reporting on ventral rectopexy for ORP, ODS and other anatomical abnormalities of the pelvic floor. - Report on the ventral rectopexy technique with mobilization limited to the anterior aspect of the rectum with application of the prosthesis between the anterior rectum posteriorly and the posterior vaginal wall anteriorly (D'Hoore technique) - Report an at last one of the outcomes of interest - More than 10 patients included - Studies from the same institution or authors were included when there was no overlap of patients Exclusion criteria: - If it was not possible to calculate the necessary data from the published results - There was considerable overlap between authors, centres and patient cohorts
Technique	The terms ODS included studies of ventral rectopexy for rectocele, internal prolapse, rectal intussusception and enterocele. A synthetic prosthesis (Marlex, polypropylene, Goretex or polyester) was used in all studies with exception of Sileri 2012, which used a biological mesh (Permacol, Covidien). Studies by Wong 2011a and Wong 2011c used a L-shaped mesh which was sutures to the anterior surface of the distal rectum. Van de Hagen operated only on patients with anterior rectocele and complemented LVMR with a transvaginal anterior colporrhaphy. Preoperative anatomic abnormalities were assessed by defaecography in most studies.
Follow-up	**6 to 38 months**
Conflict of interest/source of funding	Not reported.

Analysis

Study design issues: The main outcomes were intra-operative complications, conversions, procedure duration, short-term mortality and morbidity, length of stay, anatomical disorder, faecal incontinence and constipation, quality of life and patient satisfaction.

All discrepancies were discussed between the authors. Three independent reviewers assessed the methodological quality of the studies. Heterogeneity was assessed by graphic exploration, Chi^2 and I^2 and publication bias through the use of funnel plots.

Study population issues: Ten studies (493 patients) reported that about 41% of women had previous hysterectomy amongst which were: Abet 2012, Portier 2011, Sileri 2012, van der Esschert 2008, Van der Hagen 2012 and Wong 2011a.

Study	n	FU (months), median (range) or mean (SD)	Quality score (max. 8)	Technique
Van der Esschert 2008	17	38	2	LVMR
Portier 2011	40	22	6	LVMR
Wong 2011a	84	29 (6 to 59)	4	LVMR
Wong 2011c	63	6	2	LVMR or RVMR

Wong 2011b	41	12 (8 to 21)	4	LVMR
Sileri 2012	34	12 (6 to 30)	6	LVMR
Van der Hagen 2012	27	12 (10 to 18)	4	LVMR
Abet 2012	41	7 (4.2)	2	LVMR or RVMR
Collinson 2010	75	NR	6	LVMR
Formijne-Jonkers 2013	197	30 (5 to 83)	7	LVMR

Studies by Collinson 2010 and Formijne-Jonkers 2013 reported subgroup analysis for patients with ODS and ORP. Only the results for patients having LVMR for ODS were included in this synthesis.

Other issues: The studies by Portier 2011, Wong 2011a, Wong 2011b, Sileri 2012, Collinson 2010 and Formijne-Jonkers 2013 were also reported in paper 1 of table 2.

Key efficacy and safety findings

Efficacy

10 studies (619 patients)

Duration of laparoscopic rectopexy:
Range 56 to 199 minutes

Conversion to open surgery (LVMR and RVMR):
6% (16/280)* range 3 to 10% [6 studies]

Length of hospital stay: range 2 to 6 days

Constipation pre- versus postoperatively (LVMR):

63% (217/346) preoperatively versus 17% (59/346) postoperatively, OR 0.09, 95% CI 0.03 to 0.39, p<0.0001; I^2=NR, p<0.0001 [4 studies, 346 patients]

Faecal incontinence (LVMR):

49% (210/431) preoperatively versus 12% (53/431) postoperatively, OR 0.17 95% CI 0.05 to 0.61, p<0.00001, I^2=NR, p<0.00001 [5 studies, 431 patients]

Sexual dysfunction (LVMR):

65% (98/152) preoperatively versus 14% (21/152) postoperatively, OR 0.06 95%CI 0.03 to 0.14, p<0.0001, I^2=NR, p=0.27 [3 studies, 152 patients]

Safety

Wong 56 – 2 cases of bladder perforation and 1 intraoperative haemorrhage, 1 conversion due to broken needle

Adverse event	%, Incidence	Studies	%, Overall*
Intra-abdominal bleeding	1% (1/81)	Sileri 2012	-
Pelvic sepsis	1% (1/84)	Wong 2011a	-
Bowel erosion	6% (1/17)	van der Esschert 2008	-
Mesh dislocation	1% (1/84)	Wong 2011a	-
Urinary	10% (4/41)	Albert 2012	5% (12/222)
	12% (4/34)	Sileri (2012)	
	1% (1/84)	Wong 2011a	
	5% (3/63)	Wong 2011c	
Port site (infection, haematoma)	5% (2/40)	Portier 2011	4% (4/91)
	3% (1/34)	Sileri 2012	
	6% (1/17)	van der Esschert 2008	
Other (general pain, ileus, etc.)	18% (3/17)	van der Esschert 2008	7% (8/114)
	9% (3/34)	van der Hagen 2012	
	3% (2/63)	Wong 2011c	

*calculated by the IP analyst

Abbreviations used: CI, confidence interval; FU, follow-up; IRP, Internal rectal prolapse; LVMR, laparoscopic ventral mesh rectopexy; NR, not reported; ODS, obstructed defaecation syndrome; OR, odds ratio; ORP, overt rectal prolapse; RVMR, robotic ventral mesh rectopexy; SD, standard deviation.

Study 3 Mäkelä-Kaikkonen J (2016)

Details

Study type	**RCT**
Country	Finland
Recruitment period	2012
Study population and number	**30 patients (14 LVMR, 16 RVMR)** women with IRP or ERP
Age and sex	**LVMR**: 66.0 ±10.1 years **RVMR**: 60.8 ± 11.5 years All females
Patient selection criteria	Thirty-three consecutive female patients referred for treatment of IRP or ERP with symptoms of obstructed defaecation or faecal incontinence were eligible. Inclusion criteria: - Female - Age 18 to 85 - ASA classes 1 to 3 - Uncomplicated rectal prolapse - Symptomatic isolated rectal prolapse - Symptomatic intussusception and enterocele Exclusion criteria: - Previous major pelvic surgery - Suspicion of frozen pelvis - Pregnancy or future plans for pregnancy
Technique	Surgeries were done by 3 experienced surgeons using the da Vinci surgical system. A fourth surgeon was involved with the LVMR. A single polyester mesh (Parietex, Covidien) was used.
Follow-up	**3 months**
Conflict of interest/source of funding	One of the authors is a surgical consultant for Intuitive Surgical, manufacturer of the da Vinci surgical system.

Analysis

Follow-up issues: One patient was removed from the LVMR group due to diagnosis of dyssynergic defaecation.

Study design issues: No power size calculations were reported by the author. Women were randomised using a computer generated randomisation list in a 1:1 ratio. Separate lists were created for patients with IRP and ERP.

The primary outcome was correction of abnormal pelvic anatomy assessed by magnetic resonance defaecography. Pain was assessed using a VAS (0=no pain, 10=extreme pain).

Study population issues: Of the 16 women treated by RVMR, 4 had ERP and 12 IRP, and from the 14 women treated by LVMR 2 had ERP and 12 IRP. In the LVMR group previous surgeries were hysterectomy in 6 women, anterior colporrhaphy in 5, posterior colporrhaphy in 4 and urinary tape in 1. In the RVMR previous surgeries were anterior colporrhaphy in 4, posterior colporrhaphy in 2 and urinary tape in 2.

Other issues: Process of concealment was not reported.

Key efficacy and safety findings

Efficacy

30 patients (14 LVMR, 16 RVMR)

	LVMR (n=14)	RVMR (n=16)	p
Operating time	130±25	125±27	0.52
Operating room time	195±21	202±46	0.64
Opioid intake (dosages)	2.6±2.2	4.4±3.0	0.17
In-hospital stay (days)	2.5±0.9	2.2±1.5	0.71
VAS (max.) during hospital stay	3.9±1.7	4.8±2.4	0.29
VAS (max.) 2 weeks postoperatively	2.6±1.4	2.9±1.8	0.67

Summary finding of magnetic resonance defaecography

	LVMR (n=16)		RVMR (n=13)		p*
	Preoperative	Postoperative	Preoperative	Postoperative	
ERP	3	0	3	0	**0.66**
IRP	6	0	9	0	>0.9
Enterocele	5	0	7	0	>0.9
Rectocele (≥20 mm)	9	3	13	1	0.11
Rectocele size (mm)	24.7±17.5	7.2±3.2	33.0±14.9	5.5±8.4	0.11

*p value for the change preoperative to postoperative

Safety

	LVMR (n=14)	RVMR (n=16)	p
Perioperative bleeding	0	12% (2/16)	0.49
Vascular complications		1/16	>0.9
Minor complications**	1/14	12% (2/16)	>0.9
Haematoma	0	1/16	-
Perineal pain	0	1/16	-
Fever	1/14	0	-

**Treated conservatively

Abbreviations used: ASA, American Society of Anaesthesiologists surgical risk score; ERP, external rectal prolapse; IRP, Internal rectal prolapse; LVMR, laparoscopic ventral mesh rectopexy; RCT, randomised control trial; RVMR, robotic ventral mesh rectopexy; VAS, visual analogue scale.

Study 4 Consten ECJ (2015)

Details

Study type	**Case series**
Country	Netherlands and Belgium
Recruitment period	1999 to 2013
Study population and number	**919 patients with ERP or IRP** (Oxford grade III or IV) with symptoms of faecal incontinence or obstructed defaecation **677 patients with IRP** (460 patients with IRP or symptomatic rectocele and 217 patients with IRP or symptomatic rectocele associated with enterocele)
Age and sex	Mean age 55.8 years, 5% (50/919) males
Patient selection criteria	Data from 2 registers in one large teaching hospital in the Netherlands (Amersfoort) and university hospital in Belgium (Leuven). Inclusion criteria: - Consecutive patients aged 18 or older
Technique	The extent of the anatomical defect was assessed by dynamic MRI or colpo-cysto-defaecography. Surgical technique has been previously described by D'Hoore et al. In the Netherlands either a Hi-Tec mesh (Textiles Hi-Tec) or a Prolene (Ethicon, Johnson & Johnson) were used. Change in mesh was due to stocking rather than surgical reasons. In Belgium a Marlex mesh (Bard) was used.
Follow-up	**Median 33.9 months (range 0.4 to 143.6)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: For patients who has a re-intervention, functional outcome was assessed at the last follow-up before the second intervention. There were 86% (790/919) of patients available for the 3-month follow-up. During follow-up 3% (23/919) of patients died of a cause unrelated to LVMR

Study design issues: Postoperative morbidity was classified according to the Clavien-Dindo classification: Grade I and II were assigned as minor, grade III and higher as major. Mesh related morbidity was recorded separately.

Study population issues: There were 12% (106/919) patients having additional perineotomy to correct level 3 perineocele, 57% (521/919) had previous pelvic or abdominal surgery, 37% (338/919) received hysterectomy and 1% (12/919) various sphincter operations.

Other issues: Adverse event and serious adverse events were not reported by subgroups (IRP or ERP)

Key efficacy and safety findings

Efficacy

n=677 patients with IRP or symptomatic rectocele associated or not with enterocele

Conversion happened in 20% patients.[1]

Functional outcomes	IRP and/or symptomatic rectocele **(n=460)**	IRP and/or symptomatic rectocele with enterocele **(n=217)**
Faecal incontinence		
Preoperatively	38% (174/460)	33% (72/217)
Last follow-up	9% (39/460)	13% (27/217)
P value	<0.0001	<0.0001
Obstructed defaecation		
Preoperatively	63% (291/460)	57% (123/217)
Last follow-up	16% (75/460)	17% (36/217)
P value	<0.0001	<0.0001
Recurrence (n=677)[2]		
Mean follow-up (months)	24.8 (1.0 to 139.4)	
Last follow-up	7% (45/677)	

[1]Not reported by subgroups (IRP/ERP)

[2]Two patients developed ERP.

Safety

Early postoperative, late and mesh related complications[1]

	n=919
Post-operative in hospital mortality[3]	<1% (1/919)
Early postoperative complications	12% (114/919)
Major	2% (15/919)
Minor	115 (99/919)
Late complications	10% (89/919)
Septic spondylodiscitis	<1% (3/919)
Mesh related complications	2% (18/919)

[3]Caused by urosepsis in 85 years old grade IV ASA, subgroup not reported.

Abbreviations used: ASA, American Society of Anaesthesiologists surgical risk score; ERP, external rectal prolapse; IRP, Internal rectal prolapse; LVMR, laparoscopic ventral mesh rectopexy; MRI, magnetic resonance imaging; RVMR, robotic ventral mesh rectopexy; VAS, visual analogue scale.

Study 5 Ris F (2017)

Details

Study type	**Case series**
Country	UK and Switzerland
Recruitment period	2008 to 2009
Study population and number	**91 patients** treated by LVMR for HIRP
Age and sex	Median 52 years (range 20 to 84), 9% (8/91) males
Patient selection criteria	Consecutive patients treated by LVMR for obstructed defaecation, faecal incontinence or mixed symptoms associated with a high-grade internal rectal prolapse. Data was evaluated from a prospectively maintained pelvic floor database. All patients with incomplete follow-up or missing data were excluded from the analysis.
Technique	Patients for which the proctogram was inconclusive, or findings were not consistent with the symptoms were examined under anaesthesia (lithotomy position and using circular anal dilator). Proctograms were reviewed by a standard specialist radiography team. Patients were offered Surgical treatment if obtaining a FISI score greater than 30 and did not respond to maximum medical treatment including 6 months of pelvic floor retraining.
Follow-up	**3 months**
Conflict of interest/source of funding	None.

Analysis

Follow-up issues: There were 120 patients treated by LVMR during the study period. Of these, 29 were excluded due to missing data during follow-up.

Study design issues: Full thickness prolapse was graded using the Oxford classification. Pre and postoperative functional status were assessed using the Wexner constipation score and the FISI score.

Study population issues: There were 37% (34/91) of patients with IRP grade III and 63% (57/91) with grade IV. Concomitant rectocele was present in 70% (64/91) of patients, enterocele in 38% (35/91) and perineal descent in 49% (45/910). A FISI score greater than 30 was present in 29% (26/91) of patients.

Other issues: None.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>
n=91 patients with HIRP
Median pre-operative was
<table>
<tr><th></th><th></th><th>p</th></tr>
<tr><td>Median Wexner constipation score</td><td></td><td></td></tr>
<tr><td>Preoperative</td><td>14 (10 to 17)</td><td><0.001</td></tr>
<tr><td>3 months FU</td><td>5 (0 to 19)</td><td></td></tr>
<tr><td>Median FISI score</td><td></td><td></td></tr>
<tr><td>Preoperative</td><td>20 (0 to 61)</td><td><0.001</td></tr>
<tr><td>3 months FU</td><td>9 (0 to 48)</td><td></td></tr>
<tr><td>Median FISI score (for patients with score >30)</td><td></td><td></td></tr>
<tr><td>Preoperative</td><td>40 (30 to 61)</td><td><0.001</td></tr>
<tr><td>3 months FU</td><td>17 (0 to 48)</td><td></td></tr>
</table>
In the analysis age and gender did not influence in change in Wexner constipation score or FISI incontinence score.
The presence of rectocele was not associated with higher decrease in Wexner or FISI scores.
Patients with enterocele had a greater percentage resolution of obstructed defaecation symptoms: 70% (IQR 67 to 100) versus 52% (IQR 25 to 80), p=0.03. This group also had a greater resolution of incontinence symptoms: 71% (IQR 63 to 100) versus 38% (IQR 25 to 87%), p=0.01.
The posterior anorectal angle did not influence the functional outcome but patients with a horizontal rectum at rest (defined as an angle <30°), responded worse to LVMR: 23% (IQR 12 to 41) versus 74% (IQR 38 to 82).
</td><td>None reported.</td></tr>
<tr><td colspan="2">Abbreviations used: FIFI, faecal incontinence severity index; FU, follow-up; IQR, interquartile range; HIRP, high grade internal rectal prolapse, LVMR, laparoscopic ventral mesh rectopexy;</td></tr>
</table>

Study 6 Fu CWP (2017)

Details

Study type	**Case series**
Country	Australia
Recruitment period	2008 to 2014
Study population and number	**n=231 patients** treated by LVMR (118 IRP, 113 ERP, results not reported for the ERP cohort)
Age and sex	**IRP:** Median 58.7 (IQR 49.6 to 69.1) years, all females
Patient selection criteria	Patients who had previous pelvic floor prolapse surgery were not excluded. All patients recorded in the database were included in the analysis.
Technique	The study was conducted under the supervision of a single pelvic floor surgeon. Colonoscopy was done to exclude intraluminal pathologies. Patients with no ERP were evaluated with a defecating proctogram and or examination under anaesthesia to document evidence of IRP or rectocele. Patients also had perioperative anal manometry, pudendal nerve terminal motor latency testing and endoanal ultrasound to evaluate sphincter integrity. Surgical technique has changed during the study period: mesh changed to L-shaped, fixation of the graft to the mid-rectum (initially not done), fixation to the sacral promontory (initially non-absorbable tacks, then non-absorbable sutures and more recently absorbable sutures). Type of mesh has changed from synthetic used from 2008 to 2010 (Prolene by Ethicon or Ultrapro by Johnson & Johnson) to biologic grafts (Biodesign Surgisis, Cook Medical). The composition of the Biodesign Surgisis graft has also changed from a 4-ply to vacuum pressed 8-ply. A different type of biological graft (Permacol by Tissue Science Laboratories Lda) was used in 1 patient only. No antibiotics were routinely prescribed postoperatively. Patients were given stool softeners and were encouraged to resume normal diet as tolerated. Discharge home would happen on the same or following day postoperatively.
Follow-up	**Median 47 (29 to 63) months**
Conflict of interest/source of funding	The authors declared having received honorariums and supports for proctorship from Cook Medical.

Analysis

Follow-up issues: Patients were followed up at 6 weeks and if no issues at 6 months and 1 years.

Study design issues: Data from consecutive patients treated by LVMR were entered into a prospectively maintained database. Symptoms were assessed using a CCIS and physical examination. Single centre and one surgeon case series. Learning curve not taken into consideration. Mesh used changes from synthetic to biological as the surgeon gains experience. The study was not designed to assess different types of mesh.

Study population issues: Median body mass index was 25.7 (IQR 23.5 to 28.4). About 17% (20/118) had previous posterior compartment repair

Other issues: None.

Key efficacy and safety findings

Efficacy

n=231 patients (118 IRP, 113 ERP)

	IRP (n=118)
Operative time, median (IQR), min	90 (75 to 115)
Length of hospital stay, median (IQR), days	1 (0 to 1)
Primary symptoms improved	
No	3% (3/118)
Partially	33% (38/118)
Completely	64% (74/118)
Postoperative CCIS, median (IQR)	
Baseline*	13 (11 to 16)
6 weeks*	5 (3 to 9)
6 months	5 (2 to 8.8)
1 year	4.5 (2.3 to 8.5)
2 years	3 (2 to 7.3)
3 years	3 (2 to 3)
Recurrence	2% (2/118)
Patient satisfaction	
No	0
Partially	40% (46/118)
Completely	60% (68/118)

*p value not reported. In patients with ERP and IRP (combined) overall reduction in CCIS score reduction was statistically significantly different from 14 (10 to 16) at baseline compared to 5 (3 to 9) at 6 months postoperatively.

Risk factors for recurrence

The majority of recurrence occurred in the ERP group (25/27).

Predictive factors for recurrence were age greater than 70 years, worse preoperative CCIS, prolonged PNTML and the use of synthetic mesh.

Patients who had unilateral or bilateral PNTML were 5.6 times more likely to develop recurrence than those with normal PNTML.

Overall (IRP and ERP patients), the use of synthetic mesh was 4.2 times more likely to result in recurrence and compared to biological grafts.

Safety

Total complication rate	10% (12/118)
Surgical complications	7% (8/118)
Abdominal or pelvic collection	2% (2/118)
Intra-abdominal haemorrhage	1/118
Rectovaginal seroma or haematoma	1/118
Lumbar discitis	1/118
Wound hernia	2% (2/118)
Wound infection	1/118
Medical complications	3% (3/118)
Hypotension	1/118
Nausea	1/118
Urinary retention	1/118

In total 4 patients returned to operating room – 2 laparoscopic washout for pelvic abscess or intra-abdominal haemorrhage, 1 laparoscopic adhesiolysis for small bowel obstruction because of loop of small bowel stuck on the end of a V-lock suture and 1 patient ventral hernia mesh repair. The author did not specify the subgroup for which revision in theatres was required.

Abbreviations used: CCIS, Cleveland clinic incontinence score; ERP, external rectal prolapse; IQR, interquartile range; IRP, internal rectal prolapse; LVMR, laparoscopic ventral mesh rectopexy; PNTML, pudendal nerve terminal motor latency.

Study 7 Albayati S (2016)

Details

Study type	**Case series**
Country	Australia
Recruitment period	2011 to 2014
Study population and number	**n=50 patients** treated by LVMR (42 IRP, 8 ERP)
Age and sex	Mean 57.3 ±2.5 years, all females
Patient selection criteria	Indication for surgical treatment was ERP, rectal intussusception or rectocele associated with faecal incontinence or obstructed defaecation. All patients had physical examination including examination under anaesthesia and flexible sigmoidoscopy. Patients who did not have ERP had a defaecating proctogram to confirm rectal intussusception or rectocele.
Technique	Patients were referred to pelvic floor training by a specialist nurse. Operations were done or supervised by 3 colorectal surgeons. All patients were treated with a biological mesh (Biodesign, Cook Medical) and mesh was fixed to the sacral promontory with non-absorbable tacks (Covidien).
Follow-up	**Mean 23 months**
Conflict of interest/source of funding	Authors reported not having received a research scholarship.

Analysis

Follow-up issues: A total of 88% (45/50) patients returned the questionnaires, 2 patients declined to participate and 4 patients were lost to follow-up. The patients were excluded when reporting functional outcomes.

Study design issues: Grade of prolapse was classified using the Oxford rectal prolapse grading system. The rate of obstructed defaecation was determined from the medical records using a Rome III criteria for constipation. The rate of faecal incontinence was also determined retrospectively from patient records. A self-reported questionnaire was sent out to all patients to determine their current symptoms and satisfaction with the surgical outcome. Satisfaction was assessed using a 4-point Likert scale (1=worsening symptoms to 4=complete improvement of symptoms).

Study population issues: Previous to LVMR, 45% (23/50) of women had pelvic surgery (including hysterectomy) and 8% (4/50) had previous surgery for rectal prolapse. Of the 42 patients with IRP 35 were high grade, 7 were low grade and 33 were associated with rectocele.

Other issues: None

Key efficacy and safety findings

<table>
<tr><td>Efficacy</td><td>Safety</td></tr>
<tr><td>

n=50 (42 IRP, 8 ERP)

Combined results (IRP and ERP)

Surgical time: 176±5 min

Mean length of hospital stay: 2.5±0.2 days

Functional symptoms before and after surgery (IRP patients)

n=36	**Preoperative**	**Postoperative**	**P value**
Obstructed defaecation	83% (30/36)	58% (21/36)	0.004
Faecal incontinence	25% (9/36)	8% (3/36)	0.03

</td><td>

Combined results (IRP and ERP)

Postoperative complications	14% (7/50)
Return to theatres	10% (5/50)
Pelvic haematoma[1]	4% (2/50)
Sepsis[2]	1/50
Small bowel obstruction[3]	1/50
UTI	4% (2/50)

[1]Within 10 days of surgery.

[2]Requiring reoperation and mesh removal

[3]Due to small bowel incarceration in a port site defect.

</td></tr>
<tr><td colspan="2">Abbreviations used: ERP, external rectal prolapse; IRP, internal rectal prolapse; LVMR, laparoscopic ventral mesh rectopexy.</td></tr>
</table>

Study 8 Gosselink MP (2015)

Details

Study type	**Case series**
Country	UK
Recruitment period	2010 and 2012
Study population and number	**n=91** with faecal incontinence treated by LVMR (50 had HIRP and 41 ERP)
Age and sex	**HIRP**: Median 59 (30 to 87) years, 4% (2/50) males
Patient selection criteria	Consecutive patients treated by LVMR were identified from a prospective database. Patient with IRP were considered for surgery if they had FISI >30 and did not respond to best medical treatment including 6 months of pelvic floor training.
Technique	All patients had defaecating proctography, anorectal manometry and ultrasound. A full colonoscopy or computerised tomography colonography was done to exclude colonic disease. Patients with disabling incontinence were considered for LVMR when they had a small external anal sphincter defect (<90°) or failed previous overlapping sphincteroplasty. Polypropylene mesh was used and fixed to the sacral promontory with 3 Protrack staples(Autosuture, Convidien)
Follow-up	**1 year**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues: All patients were reviewed at 3 and 12 months postoperatively. There were 96 patients being treated by LVMR but 2 patients HIRP and 3 patients with ERP declined to respond after 1 year and were excluded from the study.

The response rate on the sexual questionnaire was 44% in patients with HIRP, 84% of patients did not want to disclose personal details and 16% of patients said they were not sexually active.

Study design issues: Symptoms were assessed preoperatively and at 1 year after surgery using the FISI and GI-QLI questionnaires and by a urinary and sexual function questionnaire. Prolapse was graded using the Oxford rectal prolapse grading system.

Study population issues: In the HIRP group there were 86% (43/50) patients with concomitant rectocele, 28% (14/50) with enterocele, 36% (18/50) with perineal descent and 22% (11/50) with sphincter defect. In the HIRP group, previous surgeries included hysterectomy 42 % (21/50), overlapping sphincteroplasty 8% (4/50) and failed sacral neuromodulation 26% (13/50).

Other issues: None.

Key efficacy and safety findings

Efficacy

n=91 patients (50 HIRP, 41 ERP)

Recurrence: 6% (3/50)

	Preoperative	1-year	P value
FISI	42 (30 to 61)	25 (0 to 59)	<0.01
Wexner constipation score	10.3 (0 to 23)	7.2 (0 to 0.21)	<0.01
GI-QOL	79 (32 to 130)	92 (41 to 136)	<0.01

Urinary symptoms

There were 6 patient reporting improvement of urinary symptoms.

Further surgery

At the 1-year follow-up there were 24% (12/50) patients having additional surgery for faecal incontinence

Sexual function:

9% (4/50) of patients reported deteriorating of sexual function after LVMR, 64% (32/50) declared sexual function had improved after surgery.

Safety

Complications in the HIPR group

Urinary tract infection	1/50
Readmitted for pain	1/50
New-onset urinary incontinence	8% (4/50)

Abbreviations used: FISI, faecal incontinence severity index; GI-QLI, gastrointestinal quality of life index; HIRP, high grade internal rectal prolapse; LVMR, laparoscopic ventral mesh rectopexy.

Study 9 Evans C (2015)

Details

Study type	**Case series**
Country	UK, Australia, Italy
Recruitment period	1999 to 2013
Study population and number	**n=2,203** patients treated by LVMR, 69% (1389/2203) for IRP, 28% (569/2203) for ERP and 4% (71/2203) had no rectal prolapse
Age and sex	Median 59±16 years, 7% (152/2203) males
Patient selection criteria	The study used data from prospective pelvic floor databases in 5 centres: 3 in the UK, 1 in Australia and 1 in Italy. Indication for surgery was at each centre discretion, although the centres were involved in the elaboration of published consensus paper for LVMR and as such practice should be consistent between all centres.
Technique	From the 2203 patients treated by LVMR, 80% (1764/2203) were treated using synthetic mesh and 20% (439/2203) using biologic mesh. The synthetic meshes used were polypropylene (60% [1325/2203]), titanium coated polypropylene (7% [160/2203]) and polyester (13% [279/203]). The biological meshes grafts used were porcine dermal mucosa (14% [309/2203]), and porcine small intestinal mucosa (6% [130/2203]).
Follow-up	**Synthetic mesh - 38 months (0 to 162)** **Biological graft – 26 months (0 to 68)**
Conflict of interest/source of funding	None.

Analysis

Follow-up issues: There were different follow-up periods for synthetic mean and biological graft. There were 20% (441/2203) patients with a median follow-up greater than 60 months.

Study design issues: Main outcome of interest was mesh morbidity, classified as vaginal erosion, rectal erosion, rectovaginal fistula or perineal erosion. Secondary outcomes were non-mesh morbidity.

Study population issues: Outcomes of interest were not always reported for the IRP subgroup.

Other issues: None.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>None reported.</td><td>

Mesh morbidity

Mesh erosion cases were more frequently associated with surgery for IRP 3% (39/1389) than for ERP 1% (6/569, p=0.02).

(*The results below were not reported for specific IRP or ERP subgroups*)

Median time from surgery to identification of mesh erosion	23 ±18.5 months
Mesh erosion[1]	**2% (45/2203)**
Mesh erosion within 6 months of surgery[2]	16% (7/45)
Mesh erosion within 36 months of surgery	76% (34/45)
Mesh erosion within 60 months of surgery	4% (2/45)
Erosion involving synthetic mesh	**93% (42/45)**
Erosion involving biological graft	**7% (3/45)**

Of the 42 synthetic mesh erosions 55% (23/42) were from propylene mesh, 43% (18/42) from polyester and 1/42 from titanium coated polypropylene.

The risk of erosion after biological graft implantation was 0.5% at 1 year, 0.7% at 2 years and 0.7% at 5 years of follow-up.

Polyester mesh was associated with a statistically significantly higher risk of mesh erosion (p<0.00006). The HR for risk of mesh erosion using polyester compared with polypropylene was 4.09 (95% CI 2.16 to 7.73) and compared to titanium-coated polypropylene was 2.96 (95% CI 0.38 to 2.23).

Treatment of mesh morbidity

There were 40% (18/45) of patients requiring treatment for major mesh morbidity (12 laparoscopic mesh removal, 3 mesh removal plus colostomy and 3 laparoscopic ultralow anterior resection) and 51% (23/45) requiring treatment for minor erosion morbidity (local excision of stich/exposed mesh).

Non-mesh morbidity

30-day mortality was less than 1% (2/2203)[3]

Non-mesh postoperative complications

Surgical complication	**6% (123/2203)**
Port site hernia	1% (27/2203)
Port site infection or haematoma	1% (26/2203)
Pelvic haematoma	<1% (10/2203)
Urinary retention	2% (37/2203)
Perforated viscus	<1% (8/2203)
Small-bowel obstruction or ileus	<1% (6/2203)
Subcutaneous emphysema	<1% (3/2203)
Vaginal bleed or discharge	<1% (3/2203)
Musculoskeletal	<1% (2/2203)
Intersphinteric abscess	<1% (1/2203)
Medical complication	**5% (118/2203)**
Urinary infection	1% (19/2203)
Respiratory infection	<1% (9/2203)
Cardiovascular	1% (12/2203)
Venous thromboembolic event	<1% (2/2203)
Neurological	<1% (4//2203)
Pain	3% (55//2203)

</td></tr>
</table>

	Pyrexia of unknown origin	<1% (5/2203)
	Diarrhoea	<1% (6/2203)
	Constipation	<1% (7/2203)
	Duodenal ulcer	<1% (2/2203)

[1]Twenty vaginal erosions, 17 rectal, 7 rectovaginal fistulas and 1 perineal.

[2]There were 3 vaginal erosions, 2 rectal, 1 rectovaginal fistula and 1 perineal. Three of these patients (1 vaginal 2 rectal) had a stich sinus with no evidence of mesh exposure.

[3]Deaths from sepsis

Abbreviations used: CI, confidence interval; ERP, externa rectal prolapse; HR, hazard ration; IRP, internal rectal prolapse; LVMR, laparoscopic ventral mesh rectopexy;

Validity and generalisability of the studies

- There was only 1 randomised study comparing robotic ventral mesh rectopexy with laparoscopic ventral mesh rectopexy[3].
- All other studies were observational, often using data from prospectively managed registries[4-6, 8].
- Some studies reported on patients with a baseline diagnosis of IRP and ERP and it was not always possible to extract data for the population of interest.
- Mean follow-up ranged from 3 to 49 months.
- The studies reported a variety of mesh prosthesis (synthetic or biological) and techniques to attach the mesh to the sacral promontory (non-absorbable metal tacks, non-absorbable sutures, absorbable sutures, surgical glue) from a range of manufacturers. Some of the prostheses changed over time and it was not always possible to extract results by type of prosthetic material used.
- Patient outcomes were measured using a variety of incontinence and constipation tools.

Existing assessments of this procedure

Position Statement by The Pelvic Floor Society on behalf of The Association of Coloproctology of Great Britain and Ireland on the use of mesh in ventral mesh

Available from http://onlinelibrary.wiley.com/doi/10.1111/codi.13893/epdf

Executive summary: Available evidence suggests that mesh morbidity for ventral mesh rectopexy (VMR) is far lower than that seen in transvaginal procedures and lower than other abdominopelvic procedures for urogenital prolapse such as laparoscopic sacrocolpopexy.

The procedure should be done by adequately rained surgeons who work with a multidisciplinary team framework. Patient selection should be discussed within a multidisciplinary team.

Clinical outcomes and complications from VMR should be recorded in the Pelvic Floor Society national registry. All patients should be considered for entry into ongoing or planned UK or European RCT when feasible.

A move towards accreditation of UK units performing VMR will improve performance and outcomes in the long term.

An enhanced program of training including staged porcine, cadaveric and preceptorship will ensure competency of surgeons doing VMR.

Enhanced consent forms and patient information booklets are being developed and these will help both surgeons and patients.

There is weak observational evidence that technical aspects of the procedure can be optimized to reduce morbidity rates. Suture material may contribute towards morbidity. The available evidence is insufficient to support the use of one mesh over another (biological versus synthetic), however the use of polyester mesh is associated with increased morbidity.

Related NICE guidance

Interventional procedures

- Stapled transanal rectal resection for obstructed defaecation syndrome. NICE interventional procedures guidance 315 (June 2010). Available from https://www.nice.org.uk/guidance/ipg351

Additional information considered by IPAC

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by Specialist Advisers, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate. Four Specialist Advisor Questionnaires for laparoscopic ventral mesh rectopexy for internal rectal prolapse were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme sent 60 questionnaires to 3 NHS trusts for distribution to patients who had the procedure (or their carers). NICE received 13 completed questionnaires.

The patient commentators' views on the procedure were consistent with the published evidence and the opinions of the specialist advisers. See the patient commentary summary for more information.

Company engagement

A structured information request was sent to 3 companies who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

- Different types of mesh were found to be used during this laparoscopic ventral mesh rectopexy. There is intense debate in the public domain about the appropriateness of using mesh to repair pelvic organ prolapse.
- The Pelvic Floor Society manages a registry which captures data from patients treated by laparoscopic ventral mesh rectopexy.

Emerging key trials

- NCT03060330 - Laparoscopic ventral mesh rectopexy combined with or without stapled trans-anal rectal resection for obstructed defecation syndrome, China, RCT, estimated enrolment: 40, follow-up: 1 year, start date: April 2017, expected completion date: April 2020.
- NCT01595412 - An international double cohort study to compare laparoscopic ventral rectopexy with laparoscopic resection rectopexy (LaProS), USA, double cohort, estimated enrolment: 120, follow-up: 2 years, start date: April 2010, expected completion date: April 2018.
- NCT01899209 - Surgical treatment of obstructed defecation syndrome (PRO-REST), Italy, RCT, estimated enrolment: 40, follow-up: 1 year, start date: August 2013, expected completion date: August 2015.
- NCT02870192 - Intra-operative adverse events during laparoscopic ventral mesh rectopexy, Italy, case series, estimated enrolment: 200, follow-up: 30 days, start date: January 2017, expected completion date: January 2018.
- NCT03026738 - Anterior versus posterior laparoscopic mesh rectopexy for rectal prolapse; a randomized controlled trial, Egypt, estimated enrolment: 30, follow-up: 1 year, start date: January 2017, expected completion date: December 2019.

References

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2. Gouvas N, Georgiou PA, Agalianos C et al.(2015) Ventral colporectopexy for overt rectal prolapse and obstructed defaecation syndrome: a systematic review. Colorectal Disease 17(2), O34-46
3. Makela-Kaikkonen J, Rautio T, Paakko E et al. (2016) Robot-assisted vs laparoscopic ventral rectopexy for external or internal rectal prolapse and enterocele: a randomized controlled trial. Colorectal Disease 18(10), 1010-1015
4. Consten EC, van Iersel JJ, Verheijen PM et al. (2015) Long-term Outcome After Laparoscopic Ventral Mesh Rectopexy: An Observational Study of 919 Consecutive Patients. Annals of Surgery 262(5), 742-7; discussion 747-8
5. Ris F, Gorissen KJ, Ragg J et al. (2017) Rectal axis and enterocele on proctogram may predict laparoscopic ventral mesh rectopexy outcomes for rectal intussusception. Techniques in Coloproctology
6. Fu CW and Stevenson AR (2017) Risk Factors for Recurrence After Laparoscopic Ventral Rectopexy. Diseases of the Colon & Rectum 60(2), 178-186
7. Albayati S, Morgan MJ and Turner CE (2017) Laparoscopic ventral rectopexy for rectal prolapse and rectal intussusception using a biological mesh. Colorectal Disease 19(9), 857-862
8. Gosselink MP, Joshi H, Adusumilli S et al. (2015) Laparoscopic ventral rectopexy for faecal incontinence: equivalent benefit is seen in internal and external rectal prolapse. Journal of Gastrointestinal Surgery 19(3), 558-63.
9. Evans C, Stevenson A R et al. (2015) A Multicenter Collaboration to Assess the Safety of Laparoscopic Ventral Rectopexy. Diseases of the Colon & Rectum 58(8), 799-807

Additional relevant papers

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Adeyemo D (2014) Mesh fistulation into the rectum after laparoscopic ventral mesh rectopexy. International Journal of Surgery Case Reports 5(3), 152-4	Case report n=1 FU=not reported	The intraoperative findings and management of the complication are described. Risk factors for mesh attrition and fistulation are also discussed.	Larger case series included in table 2. No new safety outcomes.
Benoist S, Taffinder N, Gould S et al. (2001) Functional results two years after laparoscopic rectopexy. American Journal of Surgery 182(2), 168-73	Case series n=13 FU=47 m	The addition of sigmoid resection to laparoscopic rectopexy is safe and could contribute to reduce the risk of severe constipation after operation. Laparoscopic mesh rectopexy confers no advantage over the sutured technique, which we now use as our fixation method of choice.	Larger case series included in table 2. No new safety outcomes.
Borie F, Bigourdan JM, Pissas MH et al. (2014) Laparoscopic ventral rectopexy for the treatment of outlet obstruction associated with recto-anal intussusception and rectocele: a valid alternative to STARR procedure in patients with anal sphincter weakness. Clinics & Research in Hepatology & Gastroenterology 38(4), 528-34	Case series n=52 FU=	The 2 surgical procedures obtain good results with 80% of satisfied patients with a length of stay a little shorter in the STARR. BRIEF SUMMARY: In our retrospective study, Stapled Trans-Anal Rectal Resection (STARR) and laparoscopic ventral rectopexy improved the outlet obstruction associated with recto-anal intussusception and rectocele.	Reported in paper 1, table 2.
Borie F, Coste T, Bigourdan JM et al. (2016) Incidence and surgical treatment of synthetic mesh-related infectious complications after laparoscopic ventral rectopexy. Techniques in Coloproctology 20(11), 759-765	Case series n=325 FU= 12m	The rate of erosion alone was 3.3 % in patients with a PE prosthesis, and 0.55 % in patients with a PP prosthesis (p = 0.06). The average time until clinical diagnosis of a prosthesis-related complication was identical for both groups: 31 months (range 3-62 months) When a prosthesis-related infection or erosion occurs, treatment consists in the surgical removal of the prosthesis by laparoscopy/and/or a transanal procedure. Functional symptoms do not routinely recur after prosthesis removal.	Does not report outcomes of interest separately by subgroup.

Collinson R, Wijffels N, Cunningham C et al. (2010) Laparoscopic ventral rectopexy for internal rectal prolapse: short-term functional results. Colorectal Disease 12(2), 97-104	Case series n=75 FU=12m	Laparoscopic ventral rectopexy for internal rectal prolapse improves symptoms of obstructed defaecation and faecal incontinence in the short-term. This establishes proof of concept for a nerve-sparing surgical treatment for internal rectal prolapse.	Reported in paper 1, table 2.
Emile SH, Elfeiki HA, Youssef (2016) Abdminal rectopexy for the treatment of internal rectal prolapse: a systematic review and meta-analysis. Colorectal Disease 19, O13-O24	Systematic review n= 14 studies FU= 12 to 45 months	Abdominal rectopexy for IRP attained satisfactory results with improvement of OD and, to a lesser extent, FI, a low incidence of recurrence and an acceptable morbidity rate. Although ventral rectopexy was associated with higher recurrence rates, lower complication rates and better improvement of bowel symptoms than resection rectopexy, these findings cannot be confirmed owing to the limitations of this review.	Most included papers were already reported in papers 1 and 2 in table 2.
Formijne Jonkers HA, Poierrie N, Draaisma W A et al. (2013) Laparoscopic ventral rectopexy for rectal prolapse and symptomatic rectocele: an analysis of 245 consecutive patients. Colorectal Disease 15(6), 695-9	Case series n=157 FU= 30m	A significant reduction of incontinence and constipation or obstructed defaecation syndrome after LVR was observed in this large retrospective study. LVR therefore appears a suitable treatment for RP and rectocele with and without associated enterocele.	Reported in paper 1, table 2.
Franceschilli L, Varvaras D, Capuano I et al. (2015) Laparoscopic ventral rectopexy using biologic mesh for the treatment of obstructed defaecation syndrome and/or faecal incontinence in patients with internal rectal prolapse: a critical appraisal of the first 100 cases. Techniques in Coloproctology 19(4), 209-19	Case series n= 98 FU= 20m	LVR using biologic mesh is a safe and effective procedure for improving symptoms of obstructed defaecation and faecal incontinence in patients with internal rectal prolapse associated with rectocele.	Reported in paper 1, table 2.
Gosselink MP, Adusumilli S, Gorissen KJ et al. (1409) Laparoscopic ventral rectopexy for fecal incontinence associated with high-grade internal rectal prolapse. Diseases of the Colon and Rectum 56(12), 1409-1414	Case series n= 72 FU= 12m	Laparoscopic ventral rectopexy can improve symptoms of faecal incontinence in patients with a high-grade internal rectal prolapse. Internal rectal prolapse contributes to the multifactorial origin of faecal incontinence.	Reported in paper 1, table 2.
Gosselink MP, Adusumilli S, Harmston C et al. (2013) Impact of slow transit constipation on the outcome of laparoscopic ventral rectopexy for obstructed defaecation associated with high grade internal rectal prolapse. Colorectal Disease 15(12), e749-56	Case series n=151 FU= 12m	Slow colonic transit has no adverse impact on function and quality of life after LVR for obstructed defaecation due to high grade internal rectal prolapse.	Reported in paper 1, table 2.

Makela-Kaikkonen J, Rautio T, Klintrup K et al. (2014) Robotic-assisted and laparoscopic ventral rectopexy in the treatment of rectal prolapse: a matched-pairs study of operative details and complications. Techniques in Coloproctology 18(2), 151-5	Case series n=20 FU= 3 m	Robotic-assisted laparoscopic ventral rectopexy is safe, feasible and not more time consuming than the laparoscopic technique even at the beginning of the learning curve. The short-term results are comparable with those of laparoscopy. We found no arguments to support the routine use of robotic assistance in rectopexy operations.	Larger case series already included.
Owais AE, Sumrien H, Mabey K et al. (2014) Laparoscopic ventral mesh rectopexy in male patients with internal or external rectal prolapse.[Erratum appears in Colorectal Dis. 2016 Dec;18(12):1189; PMID: 27911060]. Colorectal Disease 16(12), 995-1000	Case series n=68 FU= 42 months	LVMR is an effective treatment for external and symptomatic internal rectal prolapse in men, leading to significant improvement in quality of life and function.	Does not report outcomes of interest separately by subgroup.
Sileri P, Franceschilli L, de Luca E et al. (2012) Laparoscopic ventral rectopexy for internal rectal prolapse using biological mesh: postoperative and short-term functional results. Journal of Gastrointestinal Surgery 16(3), 622-8	Case series n=34 FU= 12m	Laparoscopic ventral mesh rectopexy using biological mesh for internal rectal prolapse is safe and effective in ameliorating symptoms of obstructed defaecation and faecal incontinence.	Reported in paper 1, table 2.
Silveira RK, Domingie S, Kirzin S et al. (2017) Comparative study of safety and efficacy of synthetic surgical glue for mesh fixation in ventral rectopexy. Surgical Endoscopy and Other Interventional Techniques	Case series n=176 FU= 18 m	Use of glue to fix the mesh in VMR was safe and had no impact on outcomes. External prolapse was the unique significant predictive factor for recurrence.	Does not report outcomes of interest separately by subgroup.
Tsunoda A, Ohta T, Kiyasu Y et al. (2015) Laparoscopic ventral rectopexy for rectoanal intussusception: postoperative evaluation with proctography. Diseases of the Colon & Rectum 58(4), 449-56	Case series n=26 FU= 12 m	Evacuation proctography showed anatomical correction in patients with rectoanal intussusception who underwent laparoscopic ventral rectopexy. However, the data also indicate that such correction does not necessarily result in meaningful symptomatic relief.	Reported in paper 1, table 2.
van Geluwe B , Wolthuis A, Penninckx F et al. (2013) Lessons learned after more than 400 laparoscopic ventral rectopexies. Acta Chirurgica Belgica 113(2), 103-6	Case series n=405 FU= 25m	LVR, with or without perineotomy, appears to be safe and feasible, with relatively low morbidity. Functional outcome data support its efficacy. The indication for LVR in patients with internal rectal prolapse could be optimised.	Population overlap with paper 4 in table2.
van Iersel JJ, Formijne Jonkers HA, Verheijen PM et al. (2016) High-grade hemorrhoids requiring surgical treatment are common after laparoscopic ventral mesh rectopexy.	Case series n=420 FU= 25m	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.	Population overlap with paper 4 in table2.

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Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	12 09 2017	Issue 9 of 12, September 2017
HTA database (Cochrane Library)	12 09 2017	Issue 9 of 12, September 2017
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	12 09 2017	Issue 9 of 12, September 2017
MEDLINE (Ovid)	12 09 2017	1946 to August Week 5 2017
MEDLINE In-Process (Ovid)		September 11, 2017
EMBASE (Ovid)	12 09 2017	1974 to 2017 Week 37
PubMed	13 09 2017	n/a
BLIC	03 09 2017	n/a

Trial sources searched 31st May 2017

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched 31st May 2017

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- EuroScan
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 Rectal Prolapse/
2 Intussusception/
3 intussuscept*.tw.
4 Pelvic Organ Prolapse/
5 (pelvi* adj4 organ* adj4 prolap*).tw.

6 (obstruct* adj4 (defaecat* or defecat*)).tw.
7 Defecation/
8 Rectocele/
9 (rectocele* or protocele*).tw.
10 (intestin* adj4 invagina*).tw.
11 ((rectal* or anus* or inter* or inter*-anal* or intra-rect* or complet* or full-thick* or mucos*) adj4 (prolap* or procident*)).tw.
12 Fecal Incontinence/
13 (fecal* adj4 incontin*).tw.
14 Rectal Diseases/
15 (rect* adj4 disease*).tw.
16 Rectum/su [Surgery]
17 or/1-16
18 Surgical Mesh/
19 (mesh* or graft* or allograft* or homograft* or homotransplant*).tw.
20 (rectopex* or proctopex*).tw.
21 or/18-20
22 Laparoscopy/
23 (laparoscop* or telescop* or peritoneoscop* or celioscop*).tw. (99954)
24 (pelvi* adj4 endoscop*).tw.
25 or/22-24
26 LVR.tw
27 LMVR.tw.
28 RVR.tw.
29 RVMR.tw.
30 or/26-29
31 17 and 30
32 17 and 21 and 25
33 31 or 32
34 (anterolater* adj4 rectopex*).tw.
35 33 or 34
36 Animals/ not Humans/
37 35 not 36