Chapter 1

Bowel Function after Laparoscopic Posterior Sutured Rectopexy versus Ventral Mesh Rectopexy for Rectal Prolapse: A Double-Blind, Randomised Single-Centre Study

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Reviewed by Thomas M. Ward and Liliana G. Bordeianou

Research Question/Objective Myriad procedures have been proposed to treat full-thickness rectal prolapse. This study sought to compare functional symptoms in patients with rectal prolapse who were treated with either laparoscopic posterior sutured rectopexy or laparoscopic ventral mesh rectopexy.

Study Design The study was a single-center, double-blind, randomized trial performed at the Department of Surgery in Aarhus University Hospital in Denmark. It enrolled patients with full-thickness rectal prolapse and randomized them to treatment with either laparoscopic posterior sutured rectopexy or laparoscopic ventral mesh rectopexy. The primary outcome was change in preoperative obstructed defecation syndrome (ODS) score at 1-year postoperative follow-up. Secondary outcomes included the change in patients' preoperative baselines compared to 1-year postoperative follow-up in their Cleveland Clinic constipation scores, Cleveland Clinic fecal incontinence scores, and their colon transit time as measured by ingested radio-opaque markers.

Sample Size A total of 176 patients were assessed for eligibility with 75 patients enrolled from the years 2006 to 2014. Thirty-eight patients were randomized to ventral mesh rectopexy, while the 37 other patients were randomized to posterior suture rectopexy. Thirty-three patients in the ventral mesh rectopexy arm, and 34 in the posterior suture rectopexy arm completed 12-month follow-up.

Follow-Up Study follow-up occurred at 1-year postoperatively, at which time, ODS score, Cleveland Clinic constipation score, Cleveland Clinical fecal incontinence score, and colon transit time were assessed. Additional assessment at 1-year included a clinical examination and defecography.

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Inclusion/Exclusion Criteria Patients were enrolled in the study if they had full-thickness rectal prolapse, as determined by inducible prolapse while straining on a toilet chair in clinic and were deemed suitable for a transabdominal procedure. Exclusion criteria included being a pediatric patient (under 18 years of age), pregnancy or breast-feeding, dementia, psychiatric diseases that would preclude the ability to give informed consent, recurrent rectal prolapse, and the inability to speak or read Danish.

Intervention or Treatment Received Patients underwent either a laparoscopic posterior suture rectopexy or a laparoscopic ventral mesh rectopexy. The laparoscopic posterior suture rectopexy technique included division of the lateral rectal attachments, full posterior mobilization of the rectum, and suturing of the rectum to the sacral promontory with nonabsorbable sutures. The laparoscopic ventral mesh rectopexy included dissection of the anterior aspect of the rectum, incising the peritoneum to the right of the rectum, suturing of a polypropylene mesh to the distal ventral aspect of the rectum, securing this mesh to the sacral promontory with tacks, and closure of the incised peritoneum to cover the mesh.

Results

Primary Outcome The ventral mesh rectopexy arm had a mean preoperative ODS score of 9.3, which decreased by 1.97 [95% confidence interval (CI) 0.01 to 3.93] at 1-year follow-up. In comparison, the posterior suture rectopexy arm had a mean preoperative ODS score of 10.8, which decreased by 2.18 (95% CI −0.14 to 4.49) at 1-year follow-up. There was no difference in the ODS score decrease between the two groups (−0.21, 95% CI −3.19 to 2.78).

Secondary Outcomes In both arms, the Cleveland Clinic constipation score and fecal incontinence score decreased (functional improvement) at 1-year follow-up. There was no difference in the decrease in either score between the two groups. Colon transit time was affected significantly more in the suture rectopexy group. The ventral mesh rectopexy group preoperatively took a mean of 2.8 days [standard deviation (SD) 1.5] to pass the radio-opaque markers. Their transit time did not increase when measured at 1-year follow-up. This contrasted with the laparoscopic suture posterior rectopexy, when preoperatively the markers took 2.5 days (SD 1.6) to pass, which increased by 1.39 days (95% CI 0.05 to 2.74) at 1-year follow-up. The suture rectopexy group therefore had 1.11 days (95% CI 0.33 to 1.89) added to their transit timed at 1-year in comparison to the ventral mesh rectopexy.

Defecography was also obtained at 1-year follow-up. The posterior suture rectopexy group had more occurrences of internal intussusception (53% vs. 28%, $p = 0.04$). There was no difference between patients in each arm when comparing incomplete evacuation (48% in the ventral mesh rectopexy, 43% in the posterior suture rectopexy) at 1 year.

Study Limitations The first and main study limitation is the patient population. It describes a relatively small sample size, with only 75 patients randomized in the trial with 67 following up at 1 year. Comparison between outcomes is therefore limited due to the lack of power in the trial. It was especially not powered to detect nonfunctional outcomes such as prolapse recurrence. The study's outcomes also describe the functional outcomes for patients at a single institution in Northern Europe, which may not extrapolate to other patient populations. This study is also limited in follow-up, with only 1 year of postoperative outcomes reported.

The study also has limitations regarding surgical technique. The authors do not fully describe their posterior rectopexy technique with respect to the lateral rectal attachments. They do not comment on whether they took one or both stalks and whether they closed the peritoneum after their anchoring sutures.

A last group of limitations involves the surgeons. The results speak to the work of three surgeons, but a closer look at the data shows that one surgeon performed two-thirds of the operations. Another limitation is the experience of the three study surgeons in ventral mesh rectopexy. The three surgeons' combined experience prior to the study was 10 ventral mesh rectopexies. This contrasts with learning curves for laparoscopic ventral mesh rectopexy published in literature, where approximately 25–50 cases were needed until operative proficiency (1, 2).

Relevant Studies Treatment of rectal prolapse continues to remain an area with no definitive evidence to guide surgeons on the best operative treatment. Prior to this study, additional randomized trials had been done. One was the PROSPER trial, which compared abdominal (posterior suture rectopexy versus sigmoid resection with posterior suture rectopexy) and perineal (Altemeier vs. Delorme) approaches. Ventral mesh rectopexy was not a treatment option in the trial design. The study found no differences in recurrence, bowel function, or quality of life between the treatments (3). This study was also limited by statistical power due to a low sample size and limited follow-up. The Swedish Rectal Prolapse Trial, conducted from 2000 to 2009 with results just published in 2022, similarly showed no difference in recurrence (measured at 3 years in the study) but did show that for all procedures, quality of life improved for patients (4). Like the PROSPER trial, ventral mesh rectopexy was not included as a treatment option in the trial design.

Meta-analyses have also been published looking at the best procedure for treating rectal prolapse. A Cochrane review in 2015, which did not include ventral mesh rectopexy, concluded that recurrence rates between abdominal and perineal procedures were similar but acknowledged a large need for trials with long-term follow-up and adequate power (5). A more recent systemic review and meta-analysis in 2021, which did include ventral mesh rectopexy, showed that the difference between recurrence in suture rectopexy versus ventral mesh rectopexy was not significant (6).

Mesh concerns arise when discussing ventral mesh rectopexy. There have been two larger studies looking at long-term mesh outcomes. One observational study that followed 919 patients found mesh-related complications to occur in 4.6% of patients (7). An additional retrospective review looked at over 2000 patients who had undergone ventral mesh rectopexy and found that 2% of the patients had mesh erosion. Of these patients, 51% needed treatment for minor erosion morbidity (such as local excision of a stitch or mesh), and 40% had major erosion morbidity necessitating an operation for mesh explantation (8).

Lastly, long-term follow-up for the main study was limited. This limited follow-up was partially addressed with a recent publication from the same group, where they published their 6-year follow-up outcomes (9). Recurrence of rectal prolapse did not differ, though the study was not powered to detect such a difference. When looking at functional outcomes, the ventral mesh rectopexy group had a significantly lower mean ODS score (6.52) versus the posterior suture rectopexy group (9.5), $p = 0.01$. They also sent out an additional patient survey that they had not measured preoperatively, the Patient Assessment of Quality of Life (PAC-QoL), where the ventral mesh rectopexy group had a significantly lower (better quality of life) score compared to the suture rectopexy group [mean (95% CI) 0.26 (0.14–0.84) vs. 0.93 (0.32–1.61), $p = 0.01$].

Despite many efforts at both observational and randomized trials, there still exists a lack of quality data to help guide surgeons in treatment of rectal prolapse. This lack of data is not due to a lack of trying. Time and time again, adequate patient accruement in these trials has proven difficult, leading to underpowered studies. An alternative method for studying this pathology is needed, such as a large quality improvement registry that tracks patients' functional outcomes. We have had successful initial efforts at such a registry (10), and we encourage others to enroll their patients in similar efforts, so that we can start to provide the evidence-based treatment to our patients that they deserve.

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