Title page.

Surgical options and trends in treating rectal prolapse.

Long term results in a nineteen-year follow up study.

Dagfinn Gleditsch¹, Wilhelm A Wexels¹, Arild Nesbakken².

Short title: Treatment of rectal prolapse.

Keywords: Rectal prolapse, rectopexy, mesh repair, outcome measures.

1. Department of Gastrointestinal Surgery,

Vestre Viken Health Trust, Drammen Hospital, 3004 Drammen, Norway.

2. Appointments: Professor of Gastrointestinal surgery, University of Oslo.

Consultant, Dept. of Gastrointestinal surgery, Oslo University Hospital.

Affiliations: Department of Gastrointestinal Surgery, Oslo University Hospital.

Institute of Clinical Medicine, University of Oslo.

K.G. Jebsen Colorectal Cancer Research Centre, Oslo University Hospital, Oslo, Norway.

Article type: Original scientific report.

Corresponding author:

Dagfinn Gleditsch

ORCID ID: 0000-0002-0886-9005

Steinsoppgrenda 38,

1352 Kolsaas, Norway.

Tlf. +47 92281611

E-mail: dagledit@online.no

Contribution of author and coauthors:

D. Gleditsch: Initiator of project, substantial involvement in data acquisition, interpretation of data, drafting of article and approval of version to be published. Accountable for all aspects of the work.

W.A. Wexels: Co-initiator of project, substantial involvement in data acquisition, interpretation of data, drafting of article and approval of version to be published. Accountable for all aspects of the work.

A. Nesbakken: Substantial contribution to conception and design, statistical analysis and interpretation of data, structuring of article, critical revision and approval of version to be published. Accountable for all aspects of the work.

Surgical options and trends in treating rectal prolapse.**Long term results in a nineteen-year follow-up study**

D. Gleditsch W.A. Wexels A. Nesbakken

Abstract

Purpose: Many different operations have been proposed for treating rectal prolapse, with varying recurrence rates and functional outcome. The main purpose of this study was to assess long term results of surgery for prolapse of the rectum.

Methods: We carried out a retrospective study to evaluate changing trends in surgical strategies and outcome in patients treated in our hospital over 19 years.

Results: Ninety-three patients were operated and 30 (32%) experienced recurrence of external prolapse during a median (range) follow-up time of 82 (2-231) months. There were 37 reoperations for recurrence, bringing the total number of operations to 130.

From 1998 to 2010 laparoscopic posterior suture rectopexy was the preferred abdominal procedure with Delorme's operation as the perineal alternative. Observed recurrence rates were 15/49 (31%) and 8/15 (53%) during a median observation time of 84 and 9 months respectively.

From 2011 to 2017 these procedures were replaced by ventral mesh rectopexy and Altemeier's rectosigmoidectomy. The observed recurrence rate for ventral mesh rectopexy was 3/22 (14%) during a median observation time of 29 months. The 30-day mortality rate was 3% and complication rate 14%.

Conclusions: The recurrence rates were high after all procedures, with no significant difference between posterior suture rectopexy and ventral mesh rectopexy, but the observation time for the latter procedure was too short to conclude. Both procedures had low complication rates, and ventral mesh rectopexy had no mortality.

Keywords: Rectal prolapse, rectopexy, mesh repair, outcome measures.

Introduction

"When an internal organ persists in an endeavour to become an external organ, it generally causes a great deal of trouble". With this phlegmatic observation W. Ernest Miles starts his presentation on surgical treatment of rectal prolapse in Proceedings of The Royal Society of Medicine in 1933 [1]. Prolapse of the rectum, also referred to as procidentia or external rectal prolapse, involves protrusion of the rectum in all its layers outside the anus. Internal rectal prolapse is a condition of invagination or intussusception of the rectal wall without external protrusion. Anal prolapse involves only the anal mucosa, but this condition can easily be misinterpreted as rectal prolapse by patients and even by referring practitioners. On clinical examination anal prolapse can usually be distinguished by radial folds of mucosa, whereas rectal prolapse is characterised by circular, concentric folds. Only external prolapse is considered in this study.

The incidence of rectal prolapse is difficult to establish. Certainly many cases are untreated. It most commonly occurs in elderly women, with 50% of patients being over 70 years. Although multiparity is said to increase the risk of developing prolapse, the fact that a third of women with this condition are nulliparous indicates that this is tenuous [2,3]. The cause of rectal prolapse is unclear, but some common, contributing factors have been noted. Laxity of the pelvic floor muscles and perirectal connective tissue is common in elderly women, and concomitant genital prolapse is often observed. The angulation of the rectoanal junction may be decreased and the anal sphincters dilated. There is often a deep rectovaginal pouch which may contribute to an enterocoele, increasing the bulk of the prolapse, thus further dilating the anal sphincters. The sigmoid colon is commonly described as long and “redundant,” though the significance is unclear, the sigmoid normally being a mobile part of the large bowel. In males and younger patients the anal sphincter may be normal, unless the prolapse has remained untreated for a long time.

Associated disturbances of bowel function often add to the malady, constipation, evacuation problems or faecal incontinence being common [4]. Outlet obstruction is most often associated with internal rectal prolapse or intussusception. Urinary incontinence is frequently present.

In cases of pelvic insufficiency and a lax anal sphincter, a prolapsed rectum is easily reduced. In younger patients, particularly males, a preserved sphincter may cause strangulation, constituting a surgical emergency. Reduction of the prolapse under anaesthesia should be performed without delay, definitive surgery being performed later [5].

Although non-surgical therapies have been proposed, amongst others the use of anal plug [6], they have not met with success, and only surgery can significantly alleviate the condition.

A large number of surgical strategies have been developed, signifying that to date no universally accepted optimal treatment exists [7]. Operations for rectal prolapse are generally divided into perineal and abdominal procedures. Traditionally perineal operations were preferred in frail patients where abdominal surgery was thought to involve too great a risk,

while abdominal procedures were preferred in fit patients. The introduction of atraumatic laparoscopic techniques has shifted preferences in favour of abdominal approaches, also in elderly and frail patients [8-11].

The aim of surgery is primarily a lasting reduction of the prolapse. Secondary aims are improvement of functional disturbances, such as anal and urinary incontinence, constipation or problems of evacuation [12].

Drammen Hospital is the largest of four hospitals in a health trust serving a population of 490 000 in south-eastern Norway. Laparoscopic repair of rectal prolapse using the posterior suture fixation technique was introduced as the preferred abdominal method in our unit in 1998. Delorme's procedure was reserved for patients thought to be unfit for abdominal surgery. Treatment strategies have evolved over the last two decades, with the increasing use of laparoscopic repairs and growing popularity of the ventral mesh technique. After nineteen years' experience of laparoscopic prolapse surgery we wished to review our results, particularly with respect to recurrences in the long term perspective.

Materials and methods

A retrospective, single-centre study was carried out collecting data from the health trust database and computerised patient records. All operations performed for external rectal prolapse from 1998 to January 2017 were recorded. Follow-up data were collected, ending as of April 2017. Patients were routinely examined prior to admission in a consultant outpatient clinic, involving a thorough patient history, as well as assessment of the patient's general health. Genitourinary problems were noted, and previous psychiatric history was recorded, with particular emphasis on eating disorders. Anoproctoscopy was routinely performed and anal sphincter function was evaluated with digital anorectal examination. A more comprehensive preoperative work up was initiated in cases deemed suitable for surgery (Table 1). Patients complaining of constipation were routinely referred to an examination of colonic transit time using radiological markers, and X-ray defecography was carried out in

patients with symptoms of obstructed defecation syndrome. Anal physiology was investigated in patients with unclear anorectal symptoms. Barium enema examination, CT colonography or colonoscopy were reserved for cases of suspected large bowel pathology.

At completion of the work-up, patients underwent a final assessment and were informed about surgical recommendations, risks and expected outcome.

From 1998 through 2010 the preferred abdominal operation was a laparoscopic posterior suture rectopexy, involving mobilisation of the rectum to the pelvic floor on the right side with division of the lateral ligament. Non-resorbable sutures were used for posterior fixation.

From 2011 the standard procedure was a ventral mesh repair, using biological mesh (Permacol Biological Implant® Covidien), or synthetic mesh (Ultrapro® Ethicon Inc, Johnson & Johnson). We used the anterior single-mesh modification of the Orr-Loygue technique, described by D'Hoore in 2004. The dissection was carried to the bottom of the rectovaginal pouch. The mesh was sutured to the anterior rectal wall and the posterior vaginal wall, then tacked to the sacral promontory. In male patients Denonvillier's fascia and the lower limit of the prostate gland were dissection landmarks. The mesh was covered with peritoneum using continuous knotless sutures (V-lock® Covidien). Delorme's operation was the preferred perineal procedure till 2010, thereafter it was replaced by Altemeier's rectosigmoidectomy.

In atypical cases other abdominal operations were performed. Open surgery was chosen in cases of extensive pelvic adhesions, and colostomy was chosen in agreement with patients suffering from severe fecal incontinence. Large bowel resection was offered in addition to rectopexy to patients with intractable constipation. All operations were performed by consultant surgeons with subspecialist accreditation in gastrointestinal surgery, or by senior registrars with consultants assisting. All surgeons involved had considerable experience in laparoscopy.

General anaesthesia was used for all abdominal surgery. Perineal procedures were performed in spinal, epidural or general anaesthesia. Antibiotic prophylaxis was administered in cases of

planned bowel resection.

We have excluded 18 patients who underwent rectopexy for internal prolapse in the same period, because this is regarded as a distinct disorder. It has a different clinical presentation, and the objective assessment of recurrence poses special problems.

At follow-up patients were questioned on bowel function, genitourinary symptoms and general satisfaction. Anoproctoscopy was routinely performed. In cases of recurrence or persisting functional problems, examinations of large bowel and anorectal function were performed as deemed necessary.

The primary endpoint was recurrence of prolapse. Recurrence was defined as a full thickness rectal prolapse verified by a surgeon, or an operation for rectal prolapse performed in our unit or another surgical department. Secondary endpoints were perioperative outcomes recorded as morbidity and mortality.

Statistics

Observation time was calculated from time of operation to recurrence, death or termination of study. Estimated 10-year recurrence rates were calculated by the Kaplan-Meier method.

Clinical sign of recurrent external prolapse was defined as event. Patients were censored at death, loss to follow-up or end of study. Log-rank test was applied to test significance of differences in recurrence rates. A p-value less than 0.05 was considered significant. IBM SPSS Statistics 21 was used to compute the statistics.

Results

Ninety three patients were treated for full thickness external prolapse from 1998 to 2017, none of whom had been treated for this condition previously. There were 77 (83%) females and 16 men, median (range 26-97) age was 72 years,

Thirty patients (32%) had undergone pelvic surgery previously. Genital prolapse was present in 18 women (23%), and ten had undergone previous surgery for this condition.

A history of psychiatric problems or mental retardation was recorded in 15 patients (16%).

Four women had suffered from eating disorders.

Seventy three (78%) underwent abdominal surgery, 65 by laparoscopy, 5 by laparotomy, and 3 laparoscopy converted to open procedure. Twenty had perineal procedures.

Complications: 30-day mortality was 3/93. One 89 year old patient died following a surgical complication, and another 89 year old patient succumbed after medical complications related to general frailty. A third male patient, age 63, with cirrhosis of the liver and a Body Mass Index of 34, underwent an open sigmoidostomy for a second recurrence of prolapse. He developed abdominal compartment syndrome with multiorgan failure, and died 14 days postoperatively.

A total of 13 patients (14%) experienced complications (Table 2). Eight of 65 (12%) who underwent a laparoscopic procedure developed complications.

According to the Clavien-Dindo classification [13], there were 2 grade I, 6 grade III, 2 grade IV and 3 grade V (death) complications.

Half of the patients who survived complications developed a later recurrence of prolapse.

Recurrences: During an observation time of 0.4 to 19 years (median 6.8 years) 30/91 patients (33% percent of those who survived the operation) were diagnosed with recurrent external prolapse. Details of recurrence, reoperations and re-recurrence are shown in Fig 2. The estimated 10-year recurrence rate according to Kaplan Meier was 39%. Details of recurrence, reoperations and re-recurrence are shown in Fig 1.

The observed (and 10-year estimated) recurrence rates after Delorme's operation, posterior suture (PSR) and ventral mesh rectopexy (VMR) was 53% (60%), 31% (32%) and 14% respectively. For the VMR group 10 year estimates could not be calculated due to short observation time. The difference between PSR and VMR was not statistically significant ($p=0.95$).

Median time from operation to recurrence after Delorme, PSR and VMR was 4, 48 and 3 months respectively. Details of observation times and time from operation to failure are summarised in Table 3.

Two patients underwent Altemeier's operation and two patients Longo's operation (on wrong indication) as the primary procedure, both suffered recurrence.

Twenty six of 31 patients went on to further surgery. Table 4 shows the distribution of procedures performed as first, second, third or fourth operation. The recurrence rate after secondary procedures was 13/26 (50%). The recurrence rates after abdominal procedures was higher after secondary than after primary operations: PSR observed rates were 7/14 (50%) and 15/48 (31%), $p=0.045$. After VMR the observed rates were 1/4 (25%) and 3/22 (14%), respectively;

A total of 46 recurrences were recorded, 37 of these were operated, bringing the total number of operations to 130. Nine recurrences were not reoperated because the patients declined further treatment or were regarded as unsuitable due to comorbidity.

Discussion

Recurrence rates following rectopexy must be related to the duration of follow up, low recurrence rates often being attained in short-term studies [14]. Numerous publications report increasing rates of recurrence with time, but studies exceeding a fifteen-year time span are rare [15].

The present study revealed a recurrence rate of 31% after posterior suture rectopexy, which is high, but should be seen in the light of a median follow up time of 7 years. The median delay of recurrence in this group was 4 years, indicating an adequate observation time in this study, and suggests that that a follow-up time of less than 4 years will give a skewed impression of recurrence rate.

In the ventral mesh group the recurrence rate was lower at 14%, but with a median observation time of only 2 1/2 years, conclusions should be drawn with care. However, all

recurrences in this group occurred within 4 months of the primary operation, which may indicate that improper surgical technique was the cause of recurrence. This was evident at the reoperation in one patient, whereas faulty surgical technique could not be identified as a cause during reoperation in the other three patients. The first recurrence occurred in the eighth patient, more than two years after the method was introduced in the department.

For the purpose of comparing recurrence rates, there are few prospective, randomised studies of adequate size with long-term follow-up. Following PSR in 179 patients Foppa et al. [15] reported a crude recurrence rate of 6% at 5-year follow-up, with an actuarial 10-year recurrence rate of 20%. D'Hoore et al. [22] had a recurrence rate of 4,8% after VMR in a study of 42 patients with a median follow-up of 61 months. Auguste et al. [24] published a VMR series of 54 patients operated by a single surgeon using two 15 cm wide anterolateral bands, observing a recurrence rate of 7,4%, with an average (range) delay of 26 months (7-54). In a larger single-centre study of 175 patients treated with VMR, Faucheron et al. [23] reported a recurrence rate of 3% at 5 years, with a median follow-up of 74 months.

Although perineal operations have been associated with higher recurrence rates than abdominal procedures, it is possible that the difference expresses a bias in patient selection [16]. We initially resorted to the Delorme procedure in patients believed to be unsuited for abdominal surgery due to general frailty, or predicted obstacles in pelvic anatomy. Life expectancy was taken into consideration, as is reflected in the median observation time of only 9 months, although it is noteworthy that 1 patient lived for over 8 years after surgery without recurrence. The recurrence rate was very high (53%), but similar recurrence rates have been published [17]. The short median time to recurrence (4 months) underlines that this method did not work well in our hands. Delorme's procedure should probably be reserved for patients with short life expectancy [18], or replaced with alternative operations [19]. Since the Delorme procedure was abandoned in 2011 in favour of Altemeier's operation [20], only four perineal operations have been performed in our department, mostly without success.

A thorough work up is essential for deciding on the most suitable operation with a focus on bowel function. In our experience investigations of large bowel morphology are of limited value. None of the colonoscopies performed in our study revealed significant new pathology, and none had impact on patient management.

Some complications should be avoidable with precautionary measures, such as brachial plexus palsy, reported in many studies, in our study afflicting one patient. Two patients developed port site herniation, which is probably a result of inadequate surgical closure. Two patients suffered large bowel perforation, one of whom died 19 days postoperatively, after Hartmann's resection and colostomy. Needless to say cautious operative technique is mandatory, particularly in cases of difficult dissection.

Most of our complications occurred following primary operations. One would expect a higher risk of complications following secondary and tertiary operations, due to postoperative changes in pelvic anatomy. In the majority of reoperations however, the pelvis was found to be safely accessible to surgery, perhaps a testimony to the atraumatic nature of laparoscopic surgery.

Anterior mesh repair allows for concomitant correction of middle pelvic compartment descent, as well as reinforcement of the rectovaginal septum [21]. It also avoids division of lateral ligaments, thus minimising the risk of autonomic nerve damage. The method has become increasingly popular in Europe [22-25], but there have been reports of mesh related complications [26], and studies have focused on mesh erosion [27]. One study suggests that mesh should be avoided if a vaginal perforation occurs intraoperatively [28]. We have employed both biological and synthetic meshes over the past 6 years, and have not experienced any complications related to mesh erosion in the 29 mesh repairs performed since 2011.

One of the limitations of our study is the retrospective nature. We also acknowledge that our study makes it difficult to compare the efficacy of different operations, as patients were selected for each procedure on the basis of patient characteristics. We cannot rule out that

recurrences have gone undetected, particularly in nursing home patients who may have declined further treatment on grounds of age and debility. Despite the established routines of our surgical unit regarding choice of operation in the time periods 1998-2010 and 2011-2017, there were some deviations from department guidelines, notably the use of the Longo procedure and one Thiersch operation. The latter may be explained by the patient being 97 years old, surviving for 14 months without recurrence. The use of the Longo technique was not in accordance with department guidelines, and these operations were unsuccessful. Our study gives limited information regarding functional disorders and general satisfaction. Preoperatively 12 patients reported urinary incontinence and 39 reported anal incontinence. Unfortunately there were too many missing data for meaningful analysis of postoperative function or the assessment of general satisfaction after surgery.

Our practice reflects the changing trends in treating rectal prolapse in Europe over the past two decades, the most obvious developments being the introduction of laparoscopic operations, the shift from perineal operations to abdominal procedures, and the move from posterior rectal fixation to anterior elevation combined with repair of genital descent [29,30]. Numerous operations for rectal prolapse have been described, but a Cochrane Review in 2015 could not conclude on the best surgical option [31]. The prospective PROSPER trial did not demonstrate superiority of any one method [32]. It has been commented that a relatively small proportion of patients in the PROSPER trial were subject to actual randomisation between abdominal or perineal surgery. The German DeloRes trial, which closed recruitment in 2016, aimed at randomising eligible patients between Delorme's procedure and resection rectopexy [33]. Hopefully prospective long-term studies focused on recurrence and function will yield more information regarding the long term efficacy of different techniques.

Conclusion

There was a high recurrence rate after all procedures, highest after perineal operations and after reoperations for recurrence. We could not demonstrate a significant difference between

posterior suture rectopexy and ventral single mesh rectopexy performed by the technique of D'Hoore, but the observation time for the latter procedure was too short for conclusion. VMR seemed to be associated with fewer complications.

Laparoscopic surgery is feasible in most cases, making perineal operations necessary in only a small proportion of patients.

Compliance with Ethical Standards.

The study received no external funding.

D. Gleditsch declares that he has no conflict of interest.

W.A. Wexels declares that he has no conflict of interest.

A. Nesbakken declares that he has no conflict of interest.

All procedures were performed in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

Approval of ethics and study protocol was obtained from the Hospital Research Committee and the Data Protection Official for Research.

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