Surgical treatment of perianal and rectal fistula
van Koperen, P.J.

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Summary

In the present thesis, several aspects of surgery in the anorectal area are evaluated. The aim of this thesis was to evaluate the surgical treatment options and strategies of perianal fistulas (Part I), to critically appraise the anal fistula plug as a novel method for the definitive closure of complex perianal fistulas (Part II), and to evaluate the treatment of presacral pathology and abscesses after anastomotic leakage resulting from rectal surgery (Part III).

Part I: Surgical treatment of perianal fistulas

A perianal fistula is one of the most frequently encountered anorectal disease in today’s surgical practice. In Chapter 1 the evolution of the classification of perianal fistulas, imaging and surgical treatment options are reviewed. The aim of surgical treatment of perianal fistulas is to cure the perianal fistula with the lowest possible recurrence rate without endangering continence. When patients experience minor complaints surgical treatment is not always necessary and a wait and see policy can be chosen. The Parks’ classification was introduced in 1976 for perianal fistulas. It is an anatomical classification of perianal fistulas based on the relation of the fistula tract and the external sphincter muscle. As a result of developments in the surgical treatment of perianal fistulas it is currently advised to classify perianal fistulas into low and high perianal fistulas as this has implications for the surgical treatment. For imaging of perianal fistulas MR (Magnetic Resonance) is currently the treatment of choice. Anal endosonography is a cheap, easy and suitable alternative readily available. However, the anal endosonography requires expertise and is less useful in patients that have a history of fistula surgery as it is difficult to differentiate between fibrosis and active infection. Hydrogenperoxide can be helpful to differentiate...
between these two. However, this makes the anal endosonography less suitable for patients with a history of fistula surgery.

Low perianal fistulas, situated in the lower 1/3 of the external sphincter muscle can be treated with low recurrence rates by fistulotomy. A fistulotomy is performed by dividing the tissue of the complete fistula tract from the internal to the external opening. The mucosal advancement flap is the treatment of choice for high perianal fistulas. The rationale behind the advancement flap is that the internal opening is the cause of the persisting fistula tract. By closing the internal opening, it is not possible anymore that fecal material is forced into the fistula tract during defecation. In the literature the results of surgical treatment of perianal fistulas are very inconsistent. This is partly caused by heterogeneous research designs. Often patients with fistulas of different etiologies are included, various classifications and treatment protocols were used, and sufficient follow-up is lacking. In the study presented in Chapter 2 the long-term functional outcome and possible risk factors for the development of a recurrent fistula in patients surgically treated according to a standardized treatment protocol are assessed. Between 1995 and 2003, 179 patients with low and high perianal fistulas of cryptoglandular origin were treated by fistulotomy or rectal advancement flap respectively. In these series the observed recurrence rates were 7 and 21% for low and high perianal fistulas respectively at a follow-up of 76 months. No significant risk factors for development of recurrent perianal fistulas were found in both univariate and multivariate analysis. Soiling was reported in 40% of the patients. Overall continence was not significantly different from normal reference patients.

The goal of fistula surgery for patients with Crohn’s disease is to relieve symptoms and to achieve closure in selected cases. Surgical treatment for fistulas in Crohn’s disease consists of abscess drainage, loose-setons drainage, fistulotomy, and mucosal advancement. These fistulas are often refractory to surgery and associated with recurrent sepsis, discomfort, and impaired quality of life. Active Crohn’s disease, especially proctitis, interferes with wound healing and fistula closure. Patients with perianal Crohn’s disease are studied in Chapter 3. Between 1995 and 2006, a consecutive series of patients were primarily treated by surgical drainage by incision and drainage of abscesses and seton drainage in case of insufficiently draining fistulas. Subsequently, optimization by medical therapy was pursued. Only in selected
patients without proctitis or active Crohn’s disease definitive closure by surgical intervention was attempted. In the group in which definitive closure is attempted, low and high fistulas were treated by fistulotomy and advancement flap respectively which resulted in 18% and 56% recurrence rates. There was no difference in continence between patients who were treated by loose seton drainage, fistulotomy or advancement flap. Patients treated surgically for Crohn’s perianal fistulas did worse both in terms of recurrence rates and incontinence compared to patients operated for cryptoglandular disease.

Chapter 4 assesses the use of fibrin glue in the treatment of high perianal fistulas. Fibrin glue has appeared as an alternative treatment for high perianal fistulas. The fibrin glue is injected into the fistula tract. When the glue resolves after a few weeks, fibroblasts, activated by the fibrin glue matrix, enhance fistula tract closure. The initial results were promising, with high success rates being reported. However, with increasing follow-up, the enthusiasm was tempered because of disappointing results. In the current study an attempt was made to decrease the recurrence rate of the surgical treatment of high transsphincteric perianal fistulas of cryptoglandular origin by combining mucosal advancement flap and fibrin glue installation. Between 1995 and 2006, 80 patients were operated for high perianal fistulas with an advancement flap. A consecutive series of 26 patients were treated by an advancement flap combined with obliteration of the fistula tract with fibrin glue. The overall recurrence rate was 26%. Recurrence rates for advancement flap alone and the combination with glue were 17 and 46%. Since the costs of the fibrin glue are considerable and the therapeutic effect very doubtful, it can not be recommended routinely in the adjunct of transanal rectal advancement flap treating high perianal fistulas. The rectal advancement flap remains the treatment of choice for high transsphincteric perianal fistulas of cryptoglandular origin.

A procedure often performed following fistulotomy and advancement flap is curettage of the fistula tract after fistulotomy or after closing the internal opening. Epithelialization of the fistula tract might prevent closure of the fistula tract. The aim of the study presented in Chapter 5 is to assess the incidence and origin of epithelialization of the fistula tract in patients with perianal fistulas undergoing fistulotomy. Eighteen patients with low perianal fistulas that were surgically treated by fistulotomy were included. Surgical biopsies were taken from the fistula tract from three
different locations; on the proximal side at the internal opening, in the middle of the fistula tract and near the distal end close to the external opening. In 15 of the 18 patients, squamous epithelium was found at least in one of the biopsies taken from the fistula tract. Epithelium was predominantly found near the internal opening. There was no relation between the duration of fistula complaints and the amount of epithelialization. The study demonstrated epithelialization in the fistula tract in the majority of the patients surgically treated by fistulotomy for low perianal fistulas. Curettage of perianal fistulas must therefore be considered an essential step in the surgical treatment of perianal fistulas.

Part II: Novel techniques in fistula surgery

Complex high and recurrent fistulas remain a surgical challenge. Simple division, i.e. fistulotomy, will likely result in fecal incontinence. Various surgical treatment options for these fistulas have shown disappointing results. The standard treatment for high fistulas is the mucosal advancement flap. However, this technique does not result invariably in high success rates. The anal fistula plug is developed to treat these perianal fistulas. The plug is a bioabsorbable xenograft, made of lyophilized porcine intestinal submucosa. The material has inherent resistance to infection. Furthermore, it does not produce a foreign body reaction, and becomes repopulated by own tissue in a period of about three months. The plug is designed to close the fistula tract from the internal to the external opening. The plug is easy to use and could provide a solution for perianal fistulas. Moreover, the anal fistula plug may reduce the recurrence rate, postoperative pain and incontinence. To assess the results of the anal fistula plug in patients with complex high perianal fistulas, a prospective, two-center, clinical study (PLUG trial) was undertaken which is described in Chapter 6. Between April 2006 and October 2006, a consecutive series of 17 patients with difficult therapy-resistant high fistulas were enrolled. For some of these patients, the only remaining treatment option was chronic seton drainage or a diverting ostomy. At a follow-up of seven months, 41% of the fistulas healed. In seven patients, the reason for the recurrence was the falling out of the plug. In this group of “last resort” patients, an acceptable healing rate was achieved. In Chapter 7 a randomized controlled multicenter trial is proposed. The objective of this study is to compare, in a prospective randomized way, the anal fistula plug with
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the mucosal advancement flap in the treatment of high transsphincteric perianal fistulas in terms of fistula closure rate, continence, morbidity, postoperative pain, and quality of life. Patients with high perianal fistulas of cryptoglandular origin are randomized to either the fistula plug or the mucosal advancement flap. Patients will be blinded for the type of intervention i.e. anal fistula plug or mucosal advancement flap. At the final follow-up closure rate is determined by clinical examination. Follow-up is done by a colorectal surgeon, who is blinded for the type of intervention. Inclusion criteria are; age above 18 years, high anorectal fistula of cryptoglandular origin (transsphincteric, upper 2/3 of the sphinctercomplex which is confined by the puborectal sling and the end of the anal canal), and informed consent. Exclusion criteria are; no internal opening found during surgery, HIV-positive patients and Crohn’s disease. The primary endpoints of the PLUG trial are fistula closure rate and continence. Secondary endpoints are morbidity, postoperative pain, and quality of life.

The results of this double blinded multicenter trial are described in Chapter 8. Between October 2006 and 2008, 104 patients were eligible for this study. Sixty patients were randomized during surgery after fulfilling the in- and exclusion criteria. Thirty-one patients were randomized to the anal fistula plug, and 29 to the mucosal advancement flap. Four of the 31 patients (13%) reported that the plug had fallen out, all within 10 days after surgery. At a follow-up of 11 months the recurrence rates were 71% (n=22) in the anal fistula plug group and 52% (n=15) in the mucosal advancement group, which was not significantly different. The continence was not significantly different pre- and postoperatively. Postoperatively soiling was reported in the plug group and the advancement group in 29% and 48% respectively which was not significantly different. Quality of life was assessed by SF-36 and EQ-5D before surgery and after 16 weeks. The results were equal pre- and postoperative in both groups. The price of the anal fistula plug is 690 euro. As a result, the cost of the placement of the plug is 690 euro more than the mucosal advancement flap. As the plug is technically simple to install and minimally invasive, it can be considered to use as initial treatment option for high transsphincteric fistulas despite of the high costs.
Part III: Presacral pathology and anastomotic leakage

Anastomotic leakage is a feared complication following colorectal surgery. It is associated with considerable morbidity and mortality. Particularly, (low) anterior resections are associated with a high leakage rate ranging from 1-24%. In case of significant anastomotic leakages a presacral abscess can develop in the pelvic area.

In Chapter 9 the incidence, the natural course and outcome of the persisting presacral sinuses resulting from anastomotic leakage were studied. Between 1997 and 2007, 25 patients were identified out of a group of 1063 patients having low anterior resection or a restorative proctocolectomy which was complicated by anastomatic leakage resulting in a chronic presacral sinus. Primary outcome parameters were the incidence of persistent presacral sinuses, the closure rate of these sinuses, the average time to closure and the rate of successful closure of the ostomy. Definitive resolution of the sinus occurred in 12 patients (48%). This was achieved in a median of 340 days (range 23-731). At final follow-up, 9 of the 25 analyzed patients had permanent fecal diversion due to recurrent abscesses or a persistent sinus. The persisting sinuses were the main cause of a permanent ostomy in these patients. Since treatment of the persistent sinus is difficult, all effort should be directed to the prevention of the development of the sinus once the anastomotic leakage has been established. In the treatment of various wounds the vacuum-assisted therapy is often used to achieve wound closure. Recently, the application of local vacuum sponge treatment has shown to be effective to treat locally contained anastomotic leakage after low anterior anastomosis in rectal cancer patients. In Chapter 10, two patients with anastomotic leakage after restorative proctocolectomy are described. The material used for the sponge is an open-pored polyurethane sponge (B. Braun Medical B.V., Melsungen, Germany). The sponge was installed transanally after examination and rinsing (saline 0.9%) of the abscess cavity using a small calibre flexible gastroscope (GIF-100 Video Gastroscope, Olympus, 9.8mm in diameter). Next, the sponge was connected to a low vacuum suction bottle (Redyon TRANS PLUS suction device), creating a constant negative pressure in the sponge. The endo-sponge was changed every 3-4 days to prevent the tissue from growing into the sponge causing painful sponge exchanges. Two patients (1 male, 18 years; 1 female 40 years) who underwent proctocolectomy because of ulcerative colitis with ileo-anal J-pouch (reservoir) reconstruction developed a localized anastomotic leakage
without general peritonitis. This was endoscopically managed by transanal placement of an endo-sponge after a diverting ileostomy was constructed. The sponge was frequently replaced until resolution of the sinus was obtained in respectively 35 and 56 days. The use of the endo-sponge in the treatment of anastomotic leakage after ileoanal pouch anastomosis resulted in quick resolution of the presacral abscess cavity and finally healing of the anastomosis. In Chapter 11 a series of patients is described with presacral cavities associated with anastomotic leakage in the Netherlands that were treated with the endo-sponge. Between July 2006 and April 2008, 16 patients who underwent surgery for rectal cancer (n=13), or ulcerative colitis (n=3) were treated with the endo-sponge treatment after anastomotic leakage. Of the 16 patients, eight patients started with the endo-sponge treatment within six weeks after the initial surgery. In the remaining eight patients the endo-sponge treatment was started later than six weeks after the initial surgery. The cavity closed in six out of eight patients (75%) in the group that started with the endo-sponge treatment within six weeks of surgery, compared to 3 out of 8 patients (38%) in the group that started later. Closure was achieved in a median of 40 (range 28-90) days with a median amount of 13 sponge replacements (range 8-17). Endo-sponge placement can be helpful in the treatment of anastomotic leakage after colorectal surgery and might prevent a chronic presacral sinus. Starting early with endo-sponge treatment is probably more effective than late initiation of treatment of the presacral sinus. The long-term follow-up and functional outcome of the neorectum must be awaited.

The presacral region is the space between the mesorectum and the sacrum, also referred to as the retrorectal region. It is an area of embryologic fusion of the hindgut, proctodeum, neural elements and bone. Congenital presacral tumours are seen in children and adults. The exact risk of malignancy rising in presacral lesions remains unclear and estimates differ for specific types of masses. The aim of the study presented in Chapter 12 is to survey the spectrum of these masses in both groups focusing on the type of presentation, origin of the tumour and the development of malignant tumours. The vast majority of children presented with constipation. Pain in the sacral region and urological problems were also seen. All adult patients initially presented with complaints of pain, mainly sacral, perianal or lower abdominal pain. In children mature teratomas (n=8) were mostly observed
and three malignancies were diagnosed, all in patients over the age of one year. In the adult group mainly developmental cysts (n=5) were observed, one malignancy had developed in a tailgut cyst. The Currarino syndrome was diagnosed in nine children. Bony sacral defects typical for Currarino syndrome were present in one adult patient. This series showed that congenital presacral tumours in children and adults differ in type of presentation and origin. The Currarino syndrome is almost exclusively seen in the pediatric patient because of early manifestation of functional symptoms. There is a risk of malignancy in patients older than one year, both in the pediatric as well as the adult patient, which mandates early surgical resection.