Surgical treatment of perianal and rectal fistula
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Chapter 6

The anal fistula plug for closure of difficult anorectal fistula, a prospective study


Diseases of the Colon and Rectum, 2007
ABSTRACT

Background
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. Recently a biologic anal fistula plug was developed to treat these high transsphincteric fistulas. To assess the results of the anal fistula plug in patients with complex high perianal fistulas, a prospective, two-center, clinical study was undertaken.

Methods
Between April 2006 and October 2006, a consecutive series of patients with difficult therapy-resistant high fistulas were enrolled. During surgery, the internal fistula tract opening was identified. A conical shaped collagen plug was pulled through the fistula tract. Any remaining portion of the plug that was not implanted in the tract was removed. The plug was fixed at the internal opening with a deep 3/0 polydioxanone suture.

Results
Seventeen patients with a median age of 45 years (range 27-75) were included. Of these patients, 71% (12/17) were male. At a median length of follow-up of seven months (range 3-9), seven of 17 fistulas had healed (41%). In ten patients the fistula recurred.

Conclusions
In these small series of 17 patients with difficult high perianal fistulas a success rate of 41% is noted. Larger series preferably in trial setting, must be done to establish the efficacy of the anal fistula plug in perianal fistula.
INTRODUCTION

The main objective in fistula surgery is to eradicate the fistula tract by closing the internal opening while preserving continence. Submucosal, intersphincteric, and low transsphincteric fistulas in the lower third of the external sphincter complex are easy to treat by simple fistulotomy, with a favorable success rate and relatively little impact on fecal continence.

High transsphincteric fistulas remain a surgical challenge. Simple division, i.e., fistulotomy will likely result in fecal incontinence.\textsuperscript{1–3} In recent years many options have been explored to successfully treat these difficult perianal fistulas. Surgical procedures suitable for high fistulas include advancement flaps, loose-seton placement, installation of fibrin glue, and diverting ostomy. Unfortunately these techniques have disappointing success rates.\textsuperscript{4–7} Champagne et al.\textsuperscript{8} reported a new biologic anal fistula plug to treat these high transsphincteric fistulas. This plug is biologic absorbable and consists of lyophilized porcine intestinal submucosa. In their series of 46 patients treated with the anal fistula plug, a success rate of 83\% was achieved at a median follow-up of 12 months. Some patients have complex or recurrent therapy-resistant fistulas. Various treatment options have been tried to eradicate the fistula without success. The anal fistula plug might be an attractive alternative in these patients because it is minimally invasive and can be repeated without major consequences. To assess the results of the anal fistula plug in patients with complex high perianal fistulas this prospective, two-center, clinical study was undertaken.

METHODS

Patients

Between April 2006 and October 2006, a consecutive series of patients with difficult and complex therapy-resistant fistulas were enrolled in the Academic Medical Center of Amsterdam, the Netherlands, and in the University Clinics of Leuven, Belgium, and treated with the anal fistula plug. High perianal fistulas were defined as patients with fistulas running through the upper two-thirds of the external sphincter complex, which is confined by the puborectal sling and the end of the anal canal (Figure 6.1) A history for previous fistula surgery, inflammatory bowel disease, and
HIV was obtained. Inclusion criteria included age 18 years and older and informed consent. Patients with submucosal, intersphincteric, and low transsphincteric fistulas were excluded. If the internal opening of the fistula could not be identified under locoregional or general anesthesia, the patient was not included. During surgery, the amount of sphincter involved was judged by palpation of the puborectal sling and the inferior edge of the external sphincter complex. In the Netherlands and Belgium, non-experimental clinical case series such as this do not require approval of the local Medical Ethics Commission.

Figure 6.1 – Low perianal fistulas are fistulas where the fistula tract transverses the lower 1/3 of the external sphincter complex. High fistulas transverse the upper 2/3 of the external sphincter complex.

**Surgical technique**

All patients had an enema on the day of surgery. The complete procedure was done in day-case setting. All procedures were performed under general or locoregional anaesthesia in the lithotomy position. Broad spectrum antibiotics were administered perioperatively.

The introduction of the anal fistula plug (Surgisis, Cook Surgical, Inc., Bloomington, IN) was done as described by Champagne et al. During surgery the internal fistula tract opening was identified. No real surgical debridement of the fistula tract was performed. Only cleaning and chemical debridement was obtained by the use of hydrogen peroxide. A suture was attached to the tail of the plug. A probe was inserted into the external opening and via the fistula tract the internal opening was
The anal fistula plug for closure of difficult anorectal fistula

found. The plug with the suture attached was lead through the fistula tract and pulled in. The suture was drawn into the tract until the plug completely blocked the internal opening. Any remaining portion of the plug that was not implanted in the tract was removed. The plug was fixed at the internal opening with two 3/0 polydioxanone (PDS) sutures. The external side of the plug was fixed to the skin with Vicryl 3/0. The external fistula opening was not completely closed, enabling further drainage from the fistula tract and possible secondary tracts.

Follow-up

Patients were advised to perform no strenuous work during the first two weeks. No specific dietary recommendations were given. Patients were followed-up at two, four, and 12 weeks. Each follow-up visit contained an interview and a physical examination. Fistula closure was defined if the external opening was closed and no discharge and pain were experienced. Otherwise it was considered as a persistent fistula.

Statistical analysis

Continuous data are presented as median values (range) unless otherwise specified. Categorical data are presented as frequencies or percentages. Analysis was performed with SPSS version 12.0.1 for Windows (SPSS Inc, Chicago, IL).

RESULTS

Patient characteristics

During the study period, 17 patients with a median age of 45 (range, 27-75) years were included in the prospective study. Patient characteristics are presented in Table 6.1. The study group consisted of one patient with Crohn’s disease, two patients had human immunodeficiency virus (HIV). The patient with Crohn’s disease used azathioprine and mesalamine at the time of surgery. The remaining 14 patients had perianal fistulas of cryptoglandular origin. Twelve patients had a history of perianal fistula surgery. The remaining patients had, among other things, anal stenosis, anal fibrosis, and problems with haemorrhoidal tissue. All patients had a single internal
and external opening except for one patient that had three external openings. The median number of previous procedures was one (range, 0-6). Various treatment modalities had been tried to close the perianal fistula. Treatment options that were used consisted of seton drainage and subsequent mucosal advancement flap, bioglue installation and performing a colostomy in one patient.

Table 6.1 – Patient characteristics.

<table>
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<tr>
<th>Patient</th>
<th>Gender</th>
<th>Age</th>
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<th>Previous surgery (n)</th>
<th>Result</th>
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M=Male, F=Female, Crypto=Cryptoglandular

Clinical outcome

All patients were operated in day-case setting. The median duration of surgery was 25 (range, 10-50) minutes. No complications were encountered during the postoperative course. No readmissions were encountered. At a median length of follow-up of seven (range, 3-9) months, seven of the 17 fistulas had healed (41%). The results in both clinics were comparable in terms of amount of patients and recurrence rate. Ten patients had a persistent fistula. Although a significant improvement of one patient’s symptoms had occurred, it was considered as a persistent fistula. In all three patients with HIV or Crohn’s disease, the fistula had healed. In seven patients, the reason for the recurrence was the falling out of the plug. In two patients this was because of a very wide fistula tract. During primary surgery, only one plug had been
inserted. One patient underwent a reoperation in which two plugs were inserted. No other modifications were performed during surgery to avoid plug fallouts. In 12 patients with a history of fistula surgery, five had closed. In the group without previous fistula surgery, two out of five fistulas had closed.

DISCUSSION

A mucosal advancement flap seems to be the standard approach in complex, recurrent high fistulas. This results in an overall healing rate between 60 and 80% for fistulas of cryptoglandular origin and in a healing rate between 50 to 60% for patients with fistulas caused by Crohn’s disease. In recurrent fistulas, after previous surgery, healing rates are reduced. Therefore, the use of an anal fistula plug, a minimally invasive procedure, could be an attractive alternative and avoid more complex surgery in those patients. As a consequence, this prospective, two-center, clinical study was started to assess the fistula closure rate in patients with complex and therapy-resistant high perianal fistulas. In some of these patients, the only remaining treatment option was chronic seton drainage or a diverting ostomy.

Champagne et al. recently reported on 46 patients treated with the anal fistula plug. A conical-shaped, bioprosthetic plug made from porcine small intestinal submucosa was used. Patients with high anorectal fistulas (high transsphincteric or deeper) were included. Excluded were patients with Crohn’s disease or superficial fistulas (low transsphincteric or more superficial). At a median follow-up of 12 (range, 6-24) months, a fistula closure rate of 83% was achieved. The same research group reported on the treatment of 20 patients with Crohn’s disease treated with the anal fistula plug. Patients with superficial fistulas, which could be safely treated by fistulotomy, were excluded. Of the 20 patients 16 had closed (80%). In both series the presence of multiple fistula tracts was significantly associated with failure. Their results seem to be very encouraging; however, the fact that they do not define high and low transsphincteric fistula could be criticized.

In our series of 17 patients, a closure rate of only 41% was found after a median follow-up of seven months. Most of the patients operated on were patients with complex and therapy-resistant perianal fistulas. Of the total of 17 patients in this study, 12 had a history of fistula surgery. In that perspective, these short-term re-
sults can be interpreted as relatively good. Patients with Crohn’s disease and HIV infection showed more favorable results than those observed in patients with fistulas of cryptoglandular origin. In the subset of patients with cryptoglandular fistulas, better results were obtained in patients who had not been previously operated on compared with patients who had undergone multiple surgical procedures. In the majority of persistent fistulas, the reason of recurrence was falling out of the plug. This could be considered as a technical failure. Possibly there is a learning curve to be overcome. It is important to assure adequate fixation of the plug during surgery to prevent plug extrusion.

In the series from Champagne et al., high transsphincteric fistulas were selected for surgery. Unfortunately, no information is presented on the previous surgery undergone before using the anal fistula plug and the exact definition of high transsphincteric fistula. In these series high perianal fistulas were defined as patients with fistulas containing the upper two-thirds of the external sphincter complex, which is confined by the puborectal sling and the end of the anal canal.

Although not objectified by questionnaires, patients treated with the anal fistula plug in our series seemed to report less postoperative pain compared to patients treated with the mucosal advancement flap.

The principal effect of the anal fistula plug as stated by Johnson et al. is to close the internal opening by using the plug-shaped device. This is the same principle that is used when performing the mucosal advancement flap. Theoretically, the fistula tract also can close as the result of incorporation of the plug.

The anal fistula plug is fabricated from porcine collagen, which stimulates tissue remodelling to eventually fully close the fistula tract. Furthermore, the advantage of the plug is that it can be used repeatedly, without risk of damaging the anal sphincter. Another advantage is that installing the plug is minimally invasive with probably less postoperative pain.

The anal fistula plug seems to be a promising alternative for high perianal fistula of various origins. In a group of “last resort” patients, an acceptable healing rate was achieved. However, the present study consists of a small series of patients with a limited follow-up, which makes it difficult to draw firm conclusions. Because most of the failures are caused by plug fallout, which we consider to be a technical failure, the true efficacy is not yet known. To assess the value of the anal fistula plug,
randomized, controlled trials should be awaited before broader implementation.

REFERENCES


Chapter 6

