



ORIGINAL ARTICLE

What are the outcomes in patients referred to a tertiary referral centre for Crohn's rectovaginal fistula surgery?

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Abstract

Aim: Rectovaginal fistulas in patients with Crohn's disease are challenging to manage, and surgical treatment remains the best option for achieving permanent closure of the fistula. Biologicals are now used routinely for patients with Crohn's disease. The aim of this study was to investigate the surgical procedures used by us to treat rectovaginal fistula in patients with Crohn's disease in the era of biologicals.

Method: Patients with Crohn's disease who underwent surgery for a rectovaginal fistula between 2010 and 2020 were included in this retrospective study and were identified from a prospectively maintained institutional database. Collected variables included demographics, perioperative and operative variables and data regarding medications used. Success of the procedure was defined as no symptoms at least 6 months after definitive repair and/or stoma closure.

Results: Twenty patients (out of 80 referred for evaluation) underwent surgery with intent to close the fistula and had at least 6 months of follow-up. Mean age was 44 ± 12 years with a median follow-up duration of 33 months (range 6–130 months). Forty per cent of the patients had a history of at least two surgeries to close the fistula. The overall healing rate was 70% (14/20). The most performed procedure was a transanal rectal advancement flap (7/20), with a success rate of 85%.

Conclusion: Rectovaginal fistula in Crohn's disease is difficult to cure; according to our results almost half of these patients have multiple surgeries due to recurrence. Multiple procedures may be offered for this challenging problem in motivated patients. Perioperative diversion should be strongly considered.

KEYWORDS

biologicals, Crohn's disease, rectal advancement flap, rectovaginal fistula

INTRODUCTION

Rectovaginal fistula (RVF) is a debilitating result of Crohn's disease, resulting in major symptoms with a significant effect on patients' quality of life [1–3]. It can be found in up to 10% of patients with Crohn's disease, and symptoms include passing stool or air through the vagina, dyspareunia and frequent vaginal discharge [4, 5].

Reported success rates of medical therapy for these fistulas remain low, and surgery is still the best option for achieving permanent closure of the fistula and restoring quality of life [6, 7]. There has been a paradigm shift from the traditional choice of proctectomy to local repairs in surgical treatment of Crohn's-related RVF [1]. Local repairs have become the mainstay of surgical treatment in the past 20 years and various procedures with different success

Authors have no conflicts of interest and no grant support was received for this study.

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rates have been described [3, 8–10]. Fistula location, sphincteric integrity, degree of inflammation in the anal canal and rectum and the general condition of the patient are factors that should be considered in the decision-making process to choose the best surgical method.

Previously reported series on surgical treatment of Crohn's-related RVF are low in numbers, making it relatively difficult to deduce the single best surgical treatment for RVF in Crohn's disease. As a result, there are no clear recommendations for surgical management of RVF in Crohn's disease, especially after the use of biologicals was accepted. In this study, our primary aim was to investigate the surgical procedures used in closure of RVF in patients with Crohn's disease in a tertiary referral centre in the era of biologicals and define the success rate of each procedure.

METHOD

All women who had a diagnosis of Crohn's disease and underwent surgery for RVF between 2010 and 2020 were identified from a prospectively maintained institutional database following Institutional Review Board approval. All included surgeries were performed at our institution. This time frame was chosen because it is when we started ensuring that biologicals were incorporated or considered in a patient's treatment plan prior to proceeding with surgery. Patients with follow-up of less than 6 months were excluded. All patients were preoperatively evaluated with examination under anaesthesia, which included a flexible sigmoidoscopy to examine the rectum and sigmoid; if there was any inflammation present, inflammation control was achieved prior to proceeding with the repair. Severe inflammation categorized by deep ulcers was a contradiction to closure surgery if it persisted after therapy. If there was mild inflammation characterized by granularity and tissue flexibility closure surgery was considered.

The surgeon and primary inflammatory bowel disease gastroenterologist discussed patients with concerning inflammation to optimize therapy. Extensive inflammation control included antibiotics when necessary and seton placement before the repair. No scoring system was used to quantify inflammation. Retrospective data were complemented with chart reviews to collect additional variables. Collected variables included demographics, perioperative and operative outcomes, preoperative medication use, details of medication use, previous repairs and faecal diversion. The decision to use a diverting stoma was made on a case-by-case basis. Final analysis included surgeries that aimed to close the fistula permanently, and examination under anaesthesia and seton placements were excluded. Success of the procedure was defined as no symptoms at least 6 months after definitive repair and/or stoma closure. All patients were given preoperative and postoperative antibiotics (7 days postoperatively) and were directed to limit the lifting of weights to less than 10 lb for 4 weeks after surgery. They were counselled to refrain from sexual activity. Success rates were listed for each procedure and Fisher's exact test was used to compare success rates,

What does this paper add to the literature?

This study investigates the success rates of multiple surgical methods for rectovaginal fistula closure in patients with Crohn's disease in the era of biologicals. Rectovaginal fistulas in patients with Crohn's disease are difficult to cure, with at least half of these patients having multiple surgeries due to recurrence. Multiple procedures can be offered in motivated patients.

with $p < 0.05$ being considered significant. Kaplan–Meier plots were constructed for successful closure.

RESULTS

A total of 80 patients underwent surgery for RVF, including examination under anaesthesia and seton placement. Only patients who had surgery with intent to close the fistula, had adequate follow-up and had adequate examination after the surgery that allowed the surgeon to evaluate if the fistula tract was closed were included in the final analysis.

Twenty patients met our inclusion criteria and were included in the final analysis. All these women had surgery with intent to close the fistula and had at least 6 months of follow-up. The mean age of patients was 44 ± 12 years with a median follow-up duration of 33 months (6–130 months). The median body mass index was 27 ± 7 kg/m². Sixteen patients had an American Society of Anesthesiologists score of 2 and four had a score of 3. Six patients were active smokers. Thirteen of 20 patients had previously undergone surgery to close the fistula and the time from last repair to the current repair was 9 months (interquartile range 4–12.5 months). The median number of previous repairs with intent to close the fistula was 2 (range 1–6). Forty per cent of the patients had a history of at least two surgeries to close the fistula. The overall healing rate was 70% (14/20). The most performed procedure was transanal rectal advancement flap (7/20) with a success rate of 85%. This was followed by transanal repair with tissue interposition in three patients (two Martius flap and one gracilis flap; success rate 33%). The success rates of all procedures are given in Table 1. No successful closures were achieved using the fistula plug method. Postoperative complications were seen in 3/20 patients. These were superficial surgical site infection and ileus in the first patient, urinary retention in the second patient and incision dehiscence in the third patient.

When looking at the use of a diverting stoma: A total of eight patients did not have a perioperative stoma performed. Among these, three patients underwent an advancement flap, two underwent a fistula plug procedure (one had stoma performed >30 days after the surgery), two underwent episiotomy and one had a fistulotomy. Seven out of these eight patients had one or zero previous operations and minimal scarring and minimal inflammation. One

TABLE 1 Procedures used to definitively close Crohn's-related rectovaginal fistula (RVF) and success rates.

Procedures done to definitively close RVF	All fistulas (n = 20)	
	Total, n (%)	Successful closure, n (%)
Transanal advancement flap	7 (35%)	6 (85%)
Transanal repair with tissue interposition (Martius or gracilis flap)	3 (15%)	1 (33%)
Episioproctotomy	3 (15%)	3 (100%)
Fistulotomy	3 (15%)	3 (100%)
Coloanal anastomosis	2 (10%)	1 (50%)
Fistula plug	2 (10%)	0 (0)
Perioperative diversion	12 (60%)	7 (58.3%)

patient had six previous operations, and this patient refused a stoma. Six out of eight patients achieved successful closure, only the fistula plug procedures were unsuccessful.

None of the patients received treatment with steroids within 30 days preoperatively. Four patients were treated with immunomodulatory agents (5-aminosalicylic acid) within 30 days preoperatively and fistula closure was successful in 50% (2/4). Eight patients received a biological agent within 3 months of surgery and the success rate in this group was 50% ($p=0.3$). Biological agents were used within 3 months of surgery in eight patients; in this group the success rate was 75% (6/8). The biological agents used were adalimumab, ustekinumab and infliximab. Patients received their last dose of medication 2 weeks before surgery. The success rate was 7/12 in patients who received preoperative diversion and 7/8 in patients without diversion.

Among the patients who were not included in the final analysis, 33 had significant inflammation in their rectum or anus and did not qualify for surgery to close their fistula. They were adequately drained and followed with their local gastroenterologist for optimization of their medication. Thirteen patients had minimal symptoms after seton placement or refused any further intervention. Eight patients remained diverted at their last follow-up. Six patients had a completion proctectomy due to inability to control their fistula symptoms.

DISCUSSION

Surgery is the best option for definitive closure for RVF in Crohn's disease, and we report a success rate of 70% in 14/20 patients in a tertiary referral centre. Our study also highlights that almost half of the patients undergoing repair had previous failed attempts to close the fistula. In addition, complication rates were low in our series, which can be ascribed to the increasing experience in our group with these procedures.

Success rates reported in our study are similar to those in the literature [5, 10, 11]. Tozer et al. reported a success rate of 67% in patients with Crohn's disease that is comparable to the current study and an early previous report from our group [10, 12]. In one of the

largest series in the literature on Crohn's-related RVF, El-Gazzaz et al. from our unit most recently reported a success rate of 46% in 65 patients, and the most commonly performed procedure was an advancement flap with a success rate of 42% [5]. Corte et al. reported a success rate of 72% in all RVFs and 40% for Crohn's-related RVF [13]. In that study, however, they did not find Crohn's disease to be a poor prognostic factor, which they attributed to their management strategy of controlling inflammation before attempting surgery. At our institution we are adamant that inflammation must be controlled before proceeding with surgery. The moderately higher success rates of the current study may be attributed to increased experience, better patient selection and patient education. A flow-chart outlining the decision-making process is included in Figure 1.

We found that the most often used procedure was rectal advancement flap, with a success rate of 85% in the current study. Kodner et al. reported a success rate of 71% using a primary advancement flap repair [14]. Ruffolo et al. reported 56% success in closure of RVF from Crohn's disease, which is similar to our series [15]. Advancement flaps are advantageous due to their relatively noninvasive technique and the lower risk of faecal incontinence or exacerbating patient symptoms [2]. When considering successful closure rates, varying success rates may be due to differences in technique and the diverse perioperative management of the patients. In our centre, the decision to close the fistula with rectal advancement flap versus tissue interposition was made based on patients' prior repairs and the current state of the tissues. If there was extensive scarring in the anterior rectum, an interposition was chosen.

Tissue transposition may be successfully employed in selected patients, especially in patients with previous failed repairs [2]. Similar to previous studies, all three of the patients in our study who underwent tissue interposition with Martius or gracilis flaps had failed previous repairs. In our study one out of the three patients achieved successful closure. The success rate with this technique reported by Zmora et al. for Crohn's-related RVF was 50% and only included two patients [8]. It is important to note that these procedures require distinct technical skills and may require a collaborative approach with plastic surgery (for gracilis flap) or gynaecology when appropriate. At our institution the gracilis muscle is harvested by one plastic surgeon who works with our department, but the actual placement and

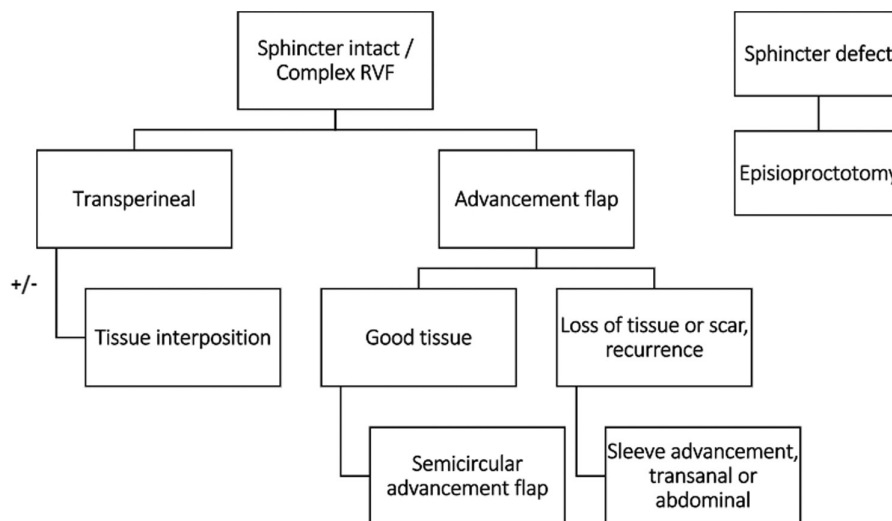


FIGURE 1 Flowchart of the decision-making process.

suturing on the wall of the rectum is done by both the colorectal and plastic surgeon. Harvesting of the Martius graft is done by the colorectal surgeon at our institution.

Episioproctotomy was chosen if there was an anterior sphincter defect. This repair resulted in successful closure in all six patients and should be considered in appropriate patients with an anterior sphincter defect. Previously, El-Gazzaz et al. reported a successful healing rate of 71% with episioproctotomy for Crohn's-related RVF [5].

The effects of immunomodulators, and especially biological agents, on postoperative outcomes in Crohn's disease is a popular subject, and increased postoperative complications have been reported [16]. Narang et al. investigated this effect specifically for patients with Crohn's disease undergoing RVF repairs. They found that preoperative use of immunomodulators did not adversely affect healing rates [17]. Our current study reports similar results with no difference in healing rates related to the use of biologicals. In the patient group that used biologicals before surgery, success rates were 75%, showing that timely use of biologicals may possibly increase the success rates in selected patients. In 2010 our group specifically started to emphasize use of biological agents before repair of RVF in Crohn's disease. We were surprised to note that only eight patients received a biological agent within 3 months of definitive repair.

Another interesting finding of our study is that 40% of the patients had undergone a previous surgical repair and the majority had at least two prior operations that failed to close the fistula. Waiting between repairs for tissue to become pliable is crucial, and this time period can typically be 3 or more months [17]. Recognizing the impact of previous repairs is especially important, since most of the patients are likely to have normal tissue fibrosis/scarring. Hyperbaric oxygen therapy can be considered prior to surgery in selected patients to obtain optimal tissue conditions [18].

Although reports are not uniform regarding the benefit of faecal diversion as an aid to successful repair it is strongly encouraged for certain groups of patients [12, 19]. Diversion should be strongly considered in patients undergoing tissue interposition with muscle

flaps [1, 3, 18]. Its ability to eliminate the loose stools commonly seen in patients with Crohn's disease, from traversing a fresh repair may confer an added benefit to success. We liberally employ a diverting stoma prior to repair in patients who have failed more than one repair or have diarrhoea. In patients who are having their first or second local repair, and have minimal scarring and inflammation, we discuss perioperative diversion. However, under these conditions we are more liberal in proceeding without diversion in this group.

When selecting the individualized approach, patients should be given realistic treatment goals. It is imperative to control any sepsis and consider perioperative diversion prior to surgery [3, 20]. The time frame varies, but some patients require months after diversion to achieve optimal tissue pliability for repair and some never achieve this. As seen in this study of 80 patients who were seen in our unit, only 20 met the criteria for closure. When optimal circumstances are achieved, success with local repair is possible.

Limitations of our study are the low number of patients in this series, limited long-term follow-up data and single-institution data. In addition, the current study does not address the quality-of-life aspect of these repairs and future studies are needed to clearly describe the effect on patients. Furthermore, the reported success rate is arguably short term and longer follow-up is necessary to clearly define the curative effect, adding to the heterogeneity in outcome measurement in RVF repair. The inclusion of patient-reported outcomes in further studies would be beneficial.

CONCLUSION

Rectovaginal fistulas in patients with Crohn's disease are difficult to cure, with our results showing that at least half of these patients have multiple surgeries due to recurrence. Multiple procedures can be offered for this challenging problem in motivated patients with acceptable anatomy (i.e. sphincter integrity, position of the internal opening from the anal verge, minimal previous scarring), lack of

sepsis and minimal inflammation. Perioperative diversion should be strongly considered based on specific patient characteristics.

AUTHOR CONTRIBUTIONS

Ipek Sapci: conceptualization, design of the study and acquisition, analysis and interpretation of data. Drafting and revising the article for important intellectual content. Final approval of the version to be published. Massarat Zutshi: conceptualization, design of the study, acquisition of data. Revising the article for important intellectual content. Final approval of the version to be published. Nouf Akeel: conceptualization, design of the study, analysis and interpretation of data. Drafting the article and revising the article for important intellectual content. Final approval of the version to be published. Tracy L. Hull: conceptualization and design of the study, analysis, and interpretation of data. Drafting and revising the article for important intellectual content. Final approval of the version to be published.

CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest and no grant support was received for this study.

DATA AVAILABILITY STATEMENT

Data not available for sharing.

ETHICS STATEMENT

This study was approved by the Institutional Review Board of the Cleveland Clinic (#17-644) and conducted in accordance with the Declaration of Helsinki.

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How to cite this article: Sapci I, Zutshi M, Akeel N, Hull T.

What are the outcomes in patients referred to a tertiary referral centre for Crohn's rectovaginal fistula surgery? *Colorectal Dis.* 2023;25:1653–1657. <https://doi.org/10.1111/codi.16660>