Bilan et traitement des fistules recto vaginales hautes sur périnée intact en France

Long-Term Outcomes of Surgical Treatments for Rectovaginal Fistula in 100 Consecutive

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Résumé

En France, les fistules rectovaginales sont d'étiologies multiples. En dehors de malformations congénitales[1], elles peuvent survenir dans un contexte post-obstetrical[2] ou post-traumatique y compris iatrogène[3,4], après une suppuration péri-anale notamment dans le cadre d'une maladie de Crohn[5,6], après une irradiation[7] ou enfin correspondre à une étiologie tumorale locale évoluée[8]. Le bilan sera donc adapté à chacune de ces étiologies. Pour la fistule recto vaginale elle-même, le simple interrogatoire suffit la plupart du temps à fortement en suspecter le diagnostic. Il sera confirmé par l'examen clinique comportant un toucher rectal, un toucher vaginal et un toucher combiné : la fistule pourra ainsi être définie par son orifice primaire, son trajet, son orifice secondaire, son calibre et son siège (tiers supérieur, tiers moyen ou tiers inférieur du vagin)[9]. Le traitement des fistules rectovaginales est difficile et le taux de succès dans la littérature, même après plusieurs interventions, est modeste. Il n'y a pas de recommandation claire concernant leur traitement[10] et une méta-analyse récente n'a pas permis d'éditer des recommandations pour la pratique clinique, en raison de l'hétérogénéité des étiologies, les caractéristiques des fistules (calibre, siège et lésions associées) et les nombreuses procédures proposées dans les différentes séries publiées[11]. Les nombreuses interventions proposées vont de la simple suture ou pose de clip[12], qui peuvent être réalisées sans stomie de dérivation du transit, aux interventions très complexes et plus lourdes telles que la transposition d'un lambeau musculaire[13], voire la résection rectale suivie d'une anastomose colo-anale directe transrectale selon Soave[14] ou l'anastomose colo-anale différée (utilisées également dans d'autres indications)[15]. Nous présenterons devant les membres de l'Académie Nationale de Chirurgie notre expérience chez 100 patientes consécutives, opérées pour fistule rectovaginale quelle qu'en soit l'étiologie. Il s'agit d'une des plus grandes séries publiées jusque-là. A partir de cette expérience et d'une revue de la littérature, nous proposerons un algorithme décisionnel, qui représentera la conclusion de cette communication.
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Mots clés

- Fistule rectovaginale
- Chirurgie
- Lambeau d'avancement
- Anastomose coloanale
- Stomie défectueuse
- Résultats à long terme

Abstract

Objective: To evaluate the long-term outcomes of rectovaginal fistula (RVF) repair techniques at a single tertiary center, and to identify which procedure is the most appropriate on a case-by-case basis by providing a structured algorithm.
Background: Numerous surgical options are available to treat RVF, and success factors remain unknown.
Methods: All consecutive females over 18 years with RVF who were treated at our center between 2003 and 2019 were included. Data on patients' characteristics, etiology, surgeries performed, and their final outcome were collected. The primary outcome was success of RVF repair. Patients who had absence of vaginal fecal or gas discharge in the 6 months after the last surgical intervention were considered healed. Those who were healed and had no permanent fecal diversion were considered to be successful. The secondary objective was to identify the prognostic factors for success.
Results: Hundred females were included. The most common cause of RVF was postoperative (27%), postpartum (23%), Crohn's disease (20%), and post radiotherapy (9%). A total of 379 procedures were performed. The healing rate without permanent stoma was 60%. In univariate analysis, RVF related to Crohn's disease ($p = 0.011$) and radiation therapy ($p = 0.015$) were related to worse outcomes. Creation of a stoma was the only significant factor ($p = 0.002$) in multivariate analysis.
Conclusion: Fecal diversion early in the management of RVF is particularly important when dealing with etiologies that worsen tissue healing. A structured algorithm could help to standardize protocols and improve surgical outcomes.

Keywords

- Rectovaginal fistula
- Surgery
- Advancement flap
- Coloanal anastomosis
- Defunctioning stoma
- Long-term outcomes

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Introduction

Rectovaginal fistula (RVF) is an infrequent but devastating condition that leads to significant morbidity and considerable social embarrassment, which negatively affects a patients' quality of life. As RVF often affects young women, many surgeons are reluctant to propose aggressive procedures, and prefer a step-up approach (1).
RVF may occur due to congenital malformation,2 or arise after obstetric injury, perianal sepsis, in Crohn's disease (CD), after radiation, malignancy, or trauma, including iatrogenic injury (3-10).
Surgery for RVF is difficult and the success rates are modest. Current evidence is lacking to support any recommendation for treatment, (1,11) and a recent meta-analysis failed to propose any guidelines due to the heterogeneity of etiologies, characteristics of the fistula (location and associated lesions), and procedures reported in different published series (12).
The purpose of this study, with the acronym RAVAGE (Recto-AnoVAGinalE fistula), was to assess the long-term outcomes of RVF surgical management at a single tertiary center, and to identify which procedure best fits the fistula characteristics by providing a structured algorithm.

Methods

Study Setting and Population

We conducted a single-center retrospective study of consecutive patients aged over 18 who underwent surgery for a RVF, and whose data were prospectively collected between January 1, 2003 and May 15, 2019. Patients were either treated initially in our institution or referred from another institution to be treated in our center. The date of inclusion was considered the date of the first surgery performed in our unit. The exclusion criteria were superficial anovulvar fistulas, and patients who were seen only for a second opinion but were not operated at our center.
The study was conducted in accordance with the ethical principles stated in the 1975 Declaration of Helsinki and local regulations. The Institutional Review Board was consulted and agreed to the study on May 28, 2020 under the acronym RAVAGE (Agreement MR004). Study ethics approval was obtained on September 11, 2020 (CECIC Rhône-Alpes-Auvergne, Clermont-Ferrand, IRB 5891). It was reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Guidelines (13) Data extracted from the prospective database of patients' electronic health records consisted of patients' characteristics and disease-related features, such as etiology and fistula location, and surgical-related features, including the types, number, and dates of interventions performed, confection of stoma, and outcomes until June 31, 2020. If no information was available, patients were considered to have ongoing RVF, and the last known follow-up date was logged.

Etiology and Location of RVF

We recorded the etiology during the first outpatient clinic preoperative assessment. CD RVF developed in patients with an anoperineal phenotype, while RVF related to ulcerative colitis predominantly occurred in patients with chronic pouchitis after ileal pouch-anal anastomosis. Traumatic RVF occurred after blunt or penetrating trauma. Cancer was considered if RVF was related to cancer invasion to the rectum or the vagina before surgery or radiation therapy. Postoperative etiology concerned all patients who presented with a RVF after a surgical procedure whether the approach was perineal (e.g. hemorrhoid stapling or vaginoplasty) or abdominal (e.g. hysterectomy or anterior resection). Radiation therapy was considered if the RVF developed after the initiation of treatment. If no clear cause was found, RVF was classified as idiopathic.
The etiology was chosen based on the one that seemed to be most related to the RVF. For example, a patient with ileocolic CD with a RVF that occurred after traumatic delivery was classified as post-partum RVF.
Fistula location was defined as low, being above the vaginal fourchette, middle, being middle third of the vagina, and high, being close to the cervix (1)

Surgical Procedures

Surgical procedures were separated into three main groups according to their clinical intent: i) Bridge procedures were performed before a more definitive procedure, and included anal exploration, wound debridement, drainage +/- seton insertion. ii) Curative intent procedures were performed to obtain the closure of the RVF tract, and included primary closure of the tract, fibrin glue or plug filing of the tract, clip closure of the opening, rerouting seton fistulotomy, endorectal advancement flap (ERAF), vaginal flap, Martius or gracilis flap, and rectal resection with anastomosis (low colorectal or coloanal anastomosis, including the Soave procedure and delayed coloanal anastomosis). iii) Salvage procedures included definitive stoma, the Hartmann procedure, and abdominoperineal excision (APE).
In cases where various procedures were performed, the most aggressive procedure was considered. For example, gracilis flap and closure of the rectal opening was classified as gracilis flap. Surgeries performed prior to referral for recurrence were included in the analysis.

Outcomes

The primary outcome of interest was success of RVF repair. RVF healing was defined as the absence of vaginal discharge of feces or gas during at least 6 months after the last surgery. Patients who had RVF healing and no permanent fecal diversion

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were considered to be successful. Failure was defined as those who did not have at least 6 months of absence of vaginal discharge, who were lost to follow up, still had symptoms when last seen or had a stoma. Patients with low clinical impact who did not request additional surgery due to being satisfied with her condition was also considered as failures.
The secondary outcome was to identify the prognostic factors for success.

Statistical Analysis

Quantitative data were reported as means ± standard deviation (range). Medians and range were stated when relevant, and qualitative data were reported as number and percentage. Quantitative measures were compared using the Student t-test if the distribution was normal or the Mann-Whitney U-test otherwise. Qualitative data were analyzed using the Chi Square test or Fisher exact test. In two-sided tests, p-values < 0.005 were considered to indicate statistical significance. Multivariate analysis was performed using a binomial logistic regression to underlined factors associated with the success of RVF repair using variables with $p < 0.05$ in the univariate analysis. All diverting stoma were included in the analysis. Statistical analysis was performed using SPSS 21.0 (IBM Corp., Armonk, NY).

Results

Patients

A total of 100 patients treated at (n = 74), or referred to (n = 26) our center for RVF surgical treatment were included. The first procedure was performed between 1983 and 2019. The mean age at RVF diagnosis was 42.1 ± 15.8 (3–90) years, and the mean body mass index (BMI) was 23.7 ± 5.2 (13.5–43.7). The median delay between diagnosis and first surgery was 8.9 (0–128.5) months, and the median delay between surgeries was 34.1 (1.8–303.8) months. One patient had a particularly long delay between the two surgeries, since she had an unsuccessful repair for a post-partum RVF and was pauci-symptomatic for years; in this case, RVF became more symptomatic at menopause and was repaired. The median time between the first and last procedure (complete treatment span) was 84.0 (0–91.1) months. The median follows up after the last surgery was 139.6 (12–180.3) months.

RVF Etiology and Location

The etiologies of the RVFs are presented in Table 1. Obstetric trauma, in which prolonged delivery eventually necessitated instrumental delivery, was present in 23 patients. Out of the 20 patients with CD, 13 presented with low, 4 with middle, and 3 with high fistulas. Among the six patients with ulcerative colitis, four presented with low, and two with middle fistulas; however, five patients with chronic pouchitis had an underlying ileovaginal fistula after having undergone restorative total coloproctectomy many years before. In five patients, the RVFs were due to traumatic injury following sexual abuse (2), intra rectal thermometer injury (1), and suicidal injury (1); the last case was classified as traumatic due to the use of Veganine rectal suppositories, which have known side effects of RVF, and were finally banned in 2004. Two cases were categorized as cancer, as the carcinoma presented initially with local invasion and fistulation with the vagina before any treatment was provided.
The RVF location was classified as high in 20, middle in 25, and low in 55 patients. Out of the 20 cases with high RVF, 4 were due to high dose radiation for rectal or uterine carcinoma, 9 were found after colorectal resection and 3 were observed following diverticulitis. The other etiologies were CD (3) and idiopathic (1).

Surgical Procedures

A total of 379 procedures were performed on the 100 patients, and the mean number of procedures per patient was 3.7 (1–15). Seton placement (14.2%), advancement flap (11.8%) and primary closure (10.5%) were the most common procedures performed in this series, and curative intent procedures accounted for 56.7% (n = 215) of all procedures. Of the major abdominal procedures, rectal resections with colorectal anastomosis were performed most frequently (n =12) and only for high and middle RVF. Stoma related procedures accounted for 17.1% (n = 65) of the 379 procedures. During treatment, 57 patients had a temporary (n = 33) or a definitive (n = 24) stoma, with 26 colostomy and 31 ileostomies. Stoma creation occurred after a mean 1.7 procedures (1–8). Six patients already had a loop ileostomy prior to diagnosis of RVF due to previous low anterior resection and anastomosis. Stoma creation was the first surgery performed in 54.4% (n = 25) of the patients with a stoma. Two patients underwent stoma terminalization, as feces were still leaking down the downstream limb. Patients with post-partum ($p < 0.001$) and radiation proctitis ($p = 0.005$) RVF were more likely to have a stoma during the treatment.

Outcomes

No patient was lost to follow-up. After a median follow-up of 139 (12–520) months from the last surgery, 60 patients (60%) were considered to have successfully healed their RVF without permanent stoma; of these 60 patients, 32 (53%) healed with temporary stoma (17 with colostomy and 15 with ileostomy).
Forty patients were considered as failure; nine of them had no vaginal discharge with a permanent ostomy, and nine further patients still had intermittent vaginal discharge, but were satisfied with their current RVF state and did not want additional surgery. Four of these 40 patients had permanent stoma.
RVF related to CD and radiation therapy were the most difficult RVF to treat (success rates of 35% and 22%, respectively). Of the 20 CD patients, 7 were treated successfully and 1 had a temporary stoma; APE was performed in 4 patients with no residual discharge, while 2 patients had rare vaginal discharge, but were satisfied with the current state and did not want additional surgery. Of the nine radiation therapy patients, two patients had successful treatment that required a temporary colostomy. Two patients died during follow up.

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The factors related to the successful treatment of RVF are presented in Table 2. In univariate analysis, RVF related to CD (p = 0.011), radiation therapy (p = 0.015), and postoperative complications (p = 0.027) were related to worse outcomes. The creation of a stoma was the only significant factor for success (p = 0.002) in multivariate analysis.

Discussion

From 100 consecutive patients who undergone 379 procedures, and despite a median follow-up of about 11 years from the last surgery, only 60% of patients were considered to have successfully healed their RVF without permanent stoma. Regardless of the surgical method used, the long-term success rate of RVF without permanent stoma is highly variable. Most patients undergo several surgical interventions over a long period, nearly four procedures per patient in this series. The reported success rate, in the ten articles published during the last 10 years, ranges between 42% and 95% (1,8,11,14-20). To the best of our knowledge, our study is the second longest retrospective study on the management of RVF. The results reported in the literature are highly variable, as the ratio of etiologies differ, as do the types of procedures, and the experience of surgeons; moreover, there is no validated algorithm to follow. Pinto et al. reported the longest series of 125 patients, in which a large proportion (45.6%) had CD (11). They reported a 44% success rate in the CD patients, very similar to our results (43%). Corte et al. reported their experience of 79 patients who underwent a total of 286 procedures, with a total success rate of 73% (1). Our center is a tertiary center, so in addition to patients presenting directly to us, a large proportion of patients are also referred from other centers, after having undergone several failed surgical attempts; as a result, these patients usually present with complex fistulas, which likely had an effect on our findings.

The initial management of RVF may involve watchful waiting, conservative treatment with antibiotics and/or seton drainage, or different surgical options. Several factors influence the choice of initial management, including the time of presentation, previous and types of surgical repair, etiology, patient risk factors, sphincter integrity, and associated lesions such as anoperineal fistula, proctitis, rectal stenosis, or diarrhea. Small asymptomatic fistulas, particularly those related to obstetric trauma, tend to heal spontaneously with watchful waiting, usually within 6 months postpartum in 50% of cases (21).

Before any decision is made to correct the fistula, antibiotic therapy associated with seton drainage (normally required for at least 3 months) can be used to ensure that local infection and inflammation are resolved maximally to insure best postoperative results. Only when local inflammation is reduced to a minimum, a more invasive surgical option is proposed.

ERAF is common in early surgical management, and was the second most common procedure performed in this series. ERAF is simple to perform, has less postoperative pain than more aggressive surgeries, and also respects the integrity of the sphincter without causing injury (22-24). Lowry et al. performed a retrospective study of 81 patients who underwent ERAF, and reported an overall success rate of 83% (25). The success rate was shown to depend on previous attempts at performing these ERAF, starting with an 88% success rate in those with a first attempt ERAF, 85% in a second attempt, and 55% with a third attempt.

Tissue interposition with healthy well-vascularized flaps is usually indicated in recurrent or refractory RVF in which tissue has been heavily damaged and scarred. In a literature review, Hotouras et al. reported that the success rate with a gracilis flap ranged from 33% to 100% at a median follow-up of 21 months (26). Furthermore, Wexner et al. reported a series of 53 patients with gracilis interposition flaps, and found a lower healing rate (33%) in CD patients in comparison to other etiologies (77%) that mainly comprised radiation-induced injury (27). Another well-described tissue interposition procedure is the Martius flap, with a reported overall healing rate of 65%, although this was less for patients with CD (50%) (15). Morever, a case series of 14 patients who received Martius flaps reported an initial 100% success rate that finally reduced to 57% at a 10-year follow up (28).

The role of diverting stoma according to studies is controversial. In the current series, we found that the creation of a stoma was the only significant factor for success. To the best of our knowledge, no previous randomized studies have assessed the efficacy of temporary fecal diversion with healing rate (19,29). Indeed, several studies have found no significant relationship between diverting stoma and success rate. However, most authors do actually preconize to temporarily divert the fecal stream early in the management of these RVF (11,19,29,30). Indeed, this is the approach that we take in our practice, particularly in complex fistulas that require a diverting stoma after failure of primary surgical interventions. Conceptually, with a diverting stoma, the intrarectal pressure is reduced with a reduction in fecal and flatus passage, which results in a reduction of the inflow into the fistula tract, reducing local infections, inflammation and pain (21).

The healing rate reduces with every attempt at repairing a RVF, as tissue devascularization and scarring render healing more difficult. The failure rate of recurrent RVF has been estimated in different series to be between 21% and 39% (31) In a case series of recurrent RVF, Halverson et al. suggested that any attempt at repair should be avoided until all local inflammatory and infectious reactions have subsided: patients who healed completely had a median waiting time of 5.2 months compared to 3.4 months for those who did not heal (31).

In addition to reviewing the literature, our center being a referral center for RVF and having analyzed our experience in treating these particular patients, we propose an algorithm for the surgical management of RVF. All patients, irrespective of the site and size of the fistula, need to undergo a full proctologic examination to assess the size, site, number of fistula tracts, and associated lesions, in addition to the local inflammatory condition. The surgeon will then need to tailor the type of surgery to fit the nature of the RVF, by taking its location, size, underlying disease, anal sphincter, and associated conditions into account. Our experience and literature review demonstrate that there is no “one size fits all” approach.

The main limitation of this study is its retrospective cohort in nature, and it spanned over a period of 16 years. During these 16 years, new procedures were introduced or improved, such as OVESCO clips (32) or meshes, (33) in addition to improvements in medical treatment for CD,34,35 all of which finally affected the trend in decision making, especially considering that no validated protocole is available. Another issue was the heterogeneity of the population: treating RVF should be on a case-by-case basis, as it depends on the type and etiology of the fistula and preexisting conditions of the patient. Nevertheless, to the best of our knowledge, this series includes the largest number of surgeries performed for RVF to date. Additionally, it has a strict definition of success and healing.

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Conclusion

Although challenging, timely management of RVF is important. Following a structured algorithm with emphasis on early fecal diversion is necessary to improve overall outcomes. Our experience shows that fecal diversion should be proposed and discussed on a case-by-case basis; this will avoid unnecessary attempts of surgical interventions that only result in devascularization, inflammation, and fibrosis of tissue, and render future interventions more difficult. Major procedures such as tissue interposition or rectal resection should be considered when dealing with complex, recurrent, or symptomatic fistulas.

Conflicts of interest and source of funding

None.

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