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Colorectal-vaginal fistula after rectal cancer resection: international comparative cohort study of characteristics and treatment

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Lay summary

A colorectal-vaginal fistula (CRVF) can occur as a complication of rectal cancer surgery. They can cause discomfort, repeated infection, need for treatment/further surgery, and a permanent stoma (an opening in the abdomen to collect bowel contents). This study looked at how often CRVF happened after surgery complicated by a leak where bowels ends have been joined together, how they were treated, and how likely patients were to live without a stoma 1 year after surgery. Researchers collected data on women from around the world who had rectal cancer surgery between 2014 and 2018 and developed a bowel leak (called anastomotic leakage). They compared those with and without a CRVF. A total of 88 out of 694 patients (12.7%) developed a CRVF. These patients more often had major surgery involving removal of nearby organs, including part of the vagina. They were more likely to have ongoing problems and needed more surgeries to manage them. Most had a temporary stoma, but only 29.5% could live without it after 1 year, compared with 48.7% of women without CRVF. CRVF is a serious complication that makes recovery harder. These patients are less likely to live without a stoma and usually need more surgery. However, if the leak is small, the chances of recovery without a permanent stoma are better.

Introduction

Colorectal-vaginal fistula (CRVF) is a challenging complication of rectal cancer resection, characterized by a leaking anastomosis in combination with vaginal discharge. Recent studies report incidences of CRVF after low anterior resection for rectal cancer between 1.6% and 5.1%, depending on the definition and the observation interval[1–3]. Clinically, CRVF can present with (recurrent) vaginitis, faecal incontinence, and/or foul-smelling vaginal discharge due to passage of flatus or stool through the vagina[1]. CRVF can lead to chronic infections, multiple operations, sexual dysfunction, delayed adjuvant therapy, and a substantial reduction in quality of life[1,2]. Therefore, adequate

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management of CRVF is important to mitigate the negative consequences.

Management of CRVF is challenging due to the fact that the fistula remains a route of least resistance, prohibiting spontaneous healing in the presence of a competent internal sphincter. Management options for CRVF include conservative treatment (for example antibiotics), local endoscopic intervention (for example clipping, endosponge), local closure, and more invasive approaches, such as redo colorectal anastomosis, or dismantling or intersphincteric resection of the anastomosis with construction of an end colostomy[1,2,4–9]. In clinical practice, treatment decision-making is often influenced by several factors, such as clinical presentation, location and size of the fistula, and the quality of the colorectal anastomosis and surrounding tissue[1,4] . Most studies reporting treatment of CRVF are limited by small cohorts and/or heterogeneity of the study population (for example also including patients after gynaecological resection)[1,10].

Hence, the aim of this study was to examine the characteristics and treatment of patients with CRVF after rectal cancer resection in a large, international, multicentre database of patients with anastomotic leakage (AL), and to compare treatment and outcomes after AL in female patients without CRVF[11].

Methods

Study design

The TENTACLE–Rectum study (TreatmENT of AnastomotiC LeakagE after rectal cancer resection) was an international, multicentre, retrospective cohort study involving 216 centres from 45 countries that included 2470 patients with AL after rectal cancer resection[4,12]. The TENTACLE–Rectum study was approved by the institutional review board of the Radboud University Medical Centre Nijmegen (file number 2009-5849)[4]. All collaborating centres adhered to the regulations of their national ethical committees. The study was registered at ClinicalTrials.gov (NCT04127734) and was conducted in agreement with the STROBE guidelines for reporting of observational studies[4,11,13].

Patient selection

Patients with rectal cancer operated between 1 January 2014 and 31 December 2018 were eligible for the TENTACLE–Rectum study if they were diagnosed with AL within 1 year after surgery. AL was defined, in accordance with an international consensus definition, as 'a defect of the intestinal wall at the anastomotic site (including suture and staple lines of neorectal reservoirs) leading to a communication between the intra- and extraluminal compartments'[14]. Inclusion criteria were an age of ≥18 years, having an adenocarcinoma with its lower border below the level of the sigmoid take-off, and having undergone surgical resection with the creation of a primary anastomosis. The indication could be primary cancer, salvage resection for regrowth, or completion surgery after local excision[4] . Exclusion criteria were benign disease, locally recurrent rectal cancer, or emergency surgery[4]. For the present analysis, all female patients with AL were selected and those with a CRVF were compared with those without a CRVF. CRVF was defined as a connection between a defect in the anastomosis and a defect in the vaginal wall. A reactivation AL was defined as AL diagnosed after the reversal of a primary or secondary diverting stoma to restore bowel continuity, due to failed healing of the anastomosis by primary or secondary intention[15].

Outcomes

The primary outcome was one-year stoma-free survival, defined as being alive without a temporary or permanent ileostomy or colostomy 1 year after rectal cancer resection. Secondary outcome measures were the number of reinterventions (endoscopic, radiological, surgical), postoperative day of first surgical intervention, total duration of hospital stay, intensive care unit (ICU) admission, total duration of ICU stay, and time to healing of AL. Treatment strategy and associated one-year stoma-free survival was separately analysed for patients who had a primary diverting stoma and those who did not.

Statistical analysis

Dichotomous data were presented as *n* (%) and continuous data were presented as mean (s.d.) or median (interquartile range (i.q.r.)), as appropriate. The Pearson chi-squared test was used for the analysis of categorical variables and the Mann–Whitney *U* test was used for the analysis of continuous variables. $P < 0.050$ was considered statistically significant. Statistical analysis was performed using SPSS® (IBM, Armonk, NY, USA; version 29).

Results

Baseline characteristics

Of 2470 patients with AL, 694 female patients were included, of whom a total of 88 (12.7%) presented with CRVF and 606 (87.3%) patients did not. No significant differences in age, ASA grade, BMI, and proportions of neoadjuvant therapy were found between the patients with CRVF and the patients without CRVF (*Table S1*).

Patients with CRVF more often had a lower tumour border from the anorectal junction (ARJ) (median of 43 mm *versus* 55 mm; $P = 0.013$). They more often underwent a multivisceral resection (MVR) (19.5% *versus* 10.3%; $P = 0.011$), especially vaginal resection (11 of 17 (6.5%) *versus* 6 of 61 (9.8%); $P < 0.001$), and they more often had a primary diverting stoma (72.7% *versus* 59.1%; $P = 0.014$). In the CRVF group, median time to AL diagnosis was longer (18 (i.q.r. 8–55) days *versus* 7 (i.q.r. 4–15) days; $P < 0.001$), abdominal contamination was less frequent (20.0% *versus* 42.5%; $P < 0.001$), and reactivation leakages were more often observed after reversal of a diverting stoma (32.1% *versus* 9.9%; $P < 0.001$) compared with patients without CRVF.

Differences in treatment depending on the presence of CRVF

Treatment of AL in patients with (or without) CRVF is outlined in *Table S2* and *Fig. 1*. Management in patients with CRVF was more often surgical compared with patients without CRVF (73.9% *versus* 54.3%; $P < 0.001$). The proportion of patients who underwent endoscopic interventions was similar in the CRVF group and the non-CRVF group (10.2% *versus* 10.7% respectively; $P = 0.887$), and radiological interventions were less common in the CRVF group (3.4% *versus* 12.0%; $P = 0.015$). The median time to the first surgical intervention was 22 (i.q.r. 10–166) days in patients with CRVF compared with 7 (i.q.r. 4–16) days in patients without CRVF ($P < 0.001$). In 88 patients with CRVF, the median total number of reinterventions was 148 and the median total number of surgical interventions was 136. The median total duration of hospital stay was shorter for patients with CRVF (10 days *versus* 15 days; $P = 0.013$).

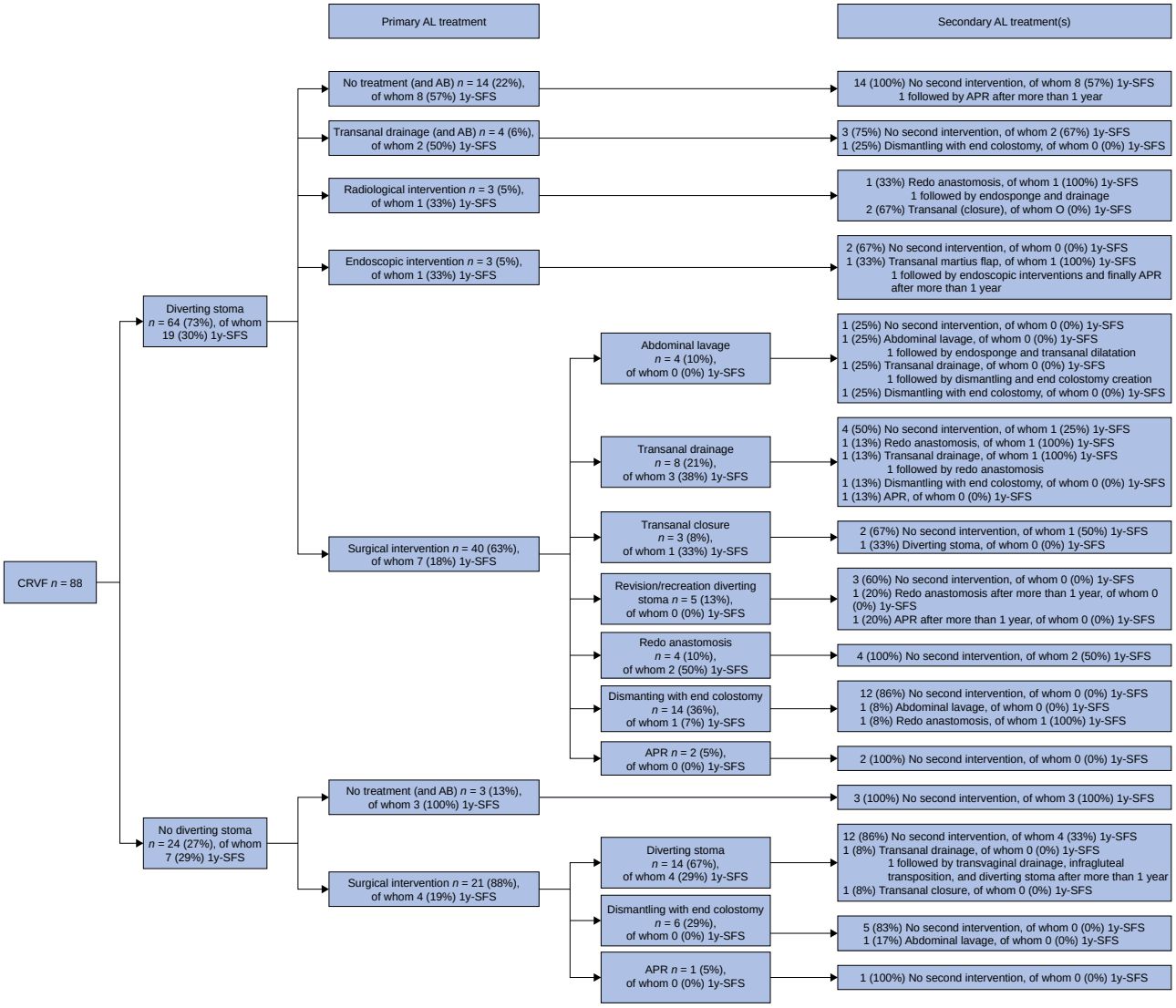

Fig. 1 Patient flow diagram for treatment of CRVF

Values are presented as frequency with corresponding percentage. Stoma interventions are not included and only primary-treatment endoscopic/radiological interventions are presented. CRVF, colorectal-vaginal fistula; 1y-SFS, 1-year stoma-free survival; AL, anastomotic leakage; AB, antibiotics; APR, abdominoperineal resection with proctectomy, resection of the anastomosis and end-colostomy.

One-year stoma-free survival

One-year stoma-free survival was significantly lower in patients with CRVF compared with patients without CRVF (29.5% *versus* 48.7%; $P = 0.002$) (*Table S2*). A total of 64 (72.7%) patients with CRVF underwent a primary diverting stoma procedure (*Fig. 1*). Among those 64 patients with a diverted leak, conservative treatment of AL was initiated in 18 (28.1%) patients, with only antibiotics (14 patients) or transanal drainage on the ward (4 patients). One of those 18 patients underwent dismantling of the anastomosis and, eventually, 10 of 18 patients were without a stoma at 1 year. In the other 46 (71.9%) patients, initial treatment was surgical in 40 patients, endoscopic in 3 patients, and radiological in 3 patients. A redo anastomosis procedure was performed at some stage during treatment in 9 patients and 6 of those were without a stoma at 1 year. Eventually, the anastomosis was dismantled in 17 patients and a proctectomy with resection of the anastomosis (that is abdominoperineal resection (APR)) was performed in 5 patients.

A total of 24 patients with CRVF did not undergo a primary diverting stoma procedure (*Fig. 1*). Three patients were managed conservatively and all three were alive without a stoma at 1 year. Twenty-one patients were treated surgically, of whom 14 patients underwent a secondary diverting stoma procedure. None of those 21 patients underwent a redo anastomosis procedure at some stage during treatment. The anastomosis was dismantled in 6 patients and an APR was performed in 1 patient. Eventually, 4 of the surgically treated patients were alive without a stoma after 1 year and all of them underwent a secondary diverting stoma procedure.

Stoma-free survival in CRVF patients

When comparing patients with CRVF who were stoma-free or not at 1 year, anastomotic defect circumference was smaller in patients with restored bowel continuity (0–25% of circumference in 12 of 15 (80.0%) *versus* 11 of 28 (39.3%); $P = 0.011$) (*Table S3*). The proportion of reactivation leakages was lower in stoma-free patients (4 of 24 (16.7%) *versus* 14 of 32 (43.8%); $P = 0.032$). Age, ASA, BMI, proportions of neoadjuvant therapy, abdominal approach, MVR, and the presence of a diverting stoma during rectal cancer resection were similar.

Discussion

This large, international, multicentre, retrospective cohort study investigated characteristics, treatment, and outcomes of patients with CRVF after restorative rectal cancer resection. Index surgery in patients who developed CRVF more often included MVR (especially vaginal resection). CRVF patients more often had a primary diverting stoma, had a longer median time to AL diagnosis, less often had abdominal contamination, and more often had reactivation leakages. At 1 year after surgery, only three of ten were stoma-free compared with almost half of the patients without a CRVF. Twelve of 15 patients with CRVF who were stoma-free at 1 year had a small defect size (0–25% of circumference), while this was much lower in patients with a stoma at 1 year. Remarkably, several patient factors (for example age, ASA), neoadjuvant radiotherapy, and the presence of a diverting stoma did not seem to be associated with stoma-free survival among patients with CRVF.

What are the potential explanations for the worse prognosis of CRVF? If compared with female patients with AL but without CRVF, there were no differences in age, ASA, or BMI, while these were predictive factors in the previously published STOMA score[12]. Therefore, it seems that the low one-year stoma-free survival rate cannot be attributed to patient factors. Regarding index surgery, there was even a slightly higher proportion of full splenic flexure mobilization in the CRVF group, corresponding with a mean shorter distance of the anastomosis to the ARJ. This makes tension on the anastomosis an unlikely explanation. However, significantly more MVR was performed, which might have contributed to the lower stoma-free survival. The anastomosis was more often in a side-to-end configuration in CRVF patients, although this is not a known risk factor. The proportion of patients with a primary diverting stoma was higher in the CRVF group, while it is often stated that defunctioning can help in preservation of the anastomosis. Similarly, a contradictory trend was observed regarding quick sequential organ failure assessment (qSOFA) scores, showing that patients with CRVF seemed to be even less sick.

Among patients with CRVF, patient factors (age, ASA, BMI) and the proportion of primary diversion were also not different between those with or without a stoma at 1 year. Remarkably, the proportions of neoadjuvant radiotherapy were also not different. The only clear difference was the defect circumference, with the smallest defects (0–25% of circumference) being significantly over-represented in the patients who were stoma-free afterat 1 year, which is in line with the literature[6]. None of the patients with a defect circumference beyond 50% was stoma-free after 1 year.

The low stoma-free survival rate in patients who develop CRVF is most likely related to pathophysiology. If an anastomotic leak is draining to the vagina, this is a route of least resistance compared with a competent anal sphincter. With such a drainage route, there will be less pus accumulation under pressure in the perianastomotic abscess, which likely explains the relatively low qSOFA scores and the lower rate of abdominal contamination. While this has an initial advantage, the vaginal drainage likely prohibits healing of the leak afterwards. Without surgical repair, a fistula tract with a short distance between the bowel and the vagina becomes epithelialized and is unlikely to heal spontaneously. After repair of the bowel and vagina, the competent anal sphincter can again cause a recurrent fistula. Even when repair seemed to be successful with subsequent stoma reversal, there was a high proportion of reactivation leakage in the CRVF group. Restoration of bowel continuity puts pressure on a fragile healed anastomosis, with seemingly a high risk of recurrent fistula.

Remarkably, the time to AL diagnosis was significantly longer in the CRVF group. It seems that patients do not easily relate vaginal discharge to a leak. Furthermore, 72.7% of these leaks were defunctioned, which minimizes discharge and symptoms. Surgeons should probably be more proactive in diagnosing leaks in patients with CRVF, especially in patients undergoing MVR including the posterior vaginal wall, although it remains unknown if early surgical repair can improve success rates.

What can be learned from this observational cohort data? First, patients with ‘limited’ leaks with CRVF who are candidates for conservative management have a relatively high chance of ultimately having bowel continuity restored. Accurate assessment of defect size is difficult, but a registered defect size ≤25% likely corresponds to a ‘pinhole’ leak in most patients. A redo anastomosis procedure in selected patients can be successful in a similar proportion. This has been recently demonstrated in video presentations with various techniques such as single stapled anastomosis or a pull-through technique[16–18]. Other techniques, such as the use of bioprosthetics, are uncommonly used in patients after rectal cancer surgery, so these do not seem to play an important role[19]. Defect circumference seems to be the main driver for becoming stoma-free. Therefore, surgeons should probably be reserved in their attempts to restore bowel continuity in patients with an a priori low likelihood of success based on this leakage characteristic. Dismantling can then be a good option, although the rectal stump might still maintain an active fistula to the vagina, with significant discharge and compromised quality of life. Therefore, proctectomy and filling of the pelvis (using, for example, omentoplasty), although not effective in primary APR, should be considered as an alternative in these patients[20].

The major strength of this study is the robust and detailed data of a large multicentre and international population, while other studies were impeded by small sample sizes and heterogeneous populations (for example also benign disease) and relatively short follow-up[10,21–23]. Limitations are related to the retrospective design, which could have contributed to data inconsistencies and missing data, but intensive data cleaning, verification, and validation was performed to mitigate this limitation[4]. Furthermore, the TENTACLE–Rectum study was not specifically designed to analyse CRVF and CRVF was not defined according to a generally accepted definition, as this remains lacking. However, the current definition was in line with how data were consistently entered into the database, thereby promoting validity and homogeneity in the reporting of CRVF.

The female patients who are collected in this study were all patients who were entered into the TENTACLE–Rectum AL database[11]. This means that patients might have been missed, such as patients with a CRVF documented as ‘fistula’ in the electronic patient file rather than ‘AL’, patients with only a minor CRVF without septic symptoms, or those who develop CRVF beyond 1 year after index resection (for example after late stoma closure). This might have influenced the observed low stoma-free survival in this study, as some patients with potentially better outcomes were not included. Unfortunately, specific characteristics of the vaginal fistula (for example exact location, defect size, extent of discharge) were not collected, but the reliability of assessing such criteria in daily practice and their clinical relevance can be questioned. Furthermore, data

regarding the (potential) aetiology of CRVF were lacking, for instance whether the posterior vaginal wall was included in the anastomosis during circular stapling. Moreover, reconstruction techniques as described in CRVF not related to rectal cancer were not specifically scored in the database and only recorded in free-text remarks. These techniques, such as Martius plasty, gracilis muscle interposition, and pull-through coloanal anastomosis, are all described in expert centres with higher success rates[24,25]. However, only a minority of patients have undergone rectal cancer surgery as the reason for CRVF in these expert series. This is probably due to the fact that the rectum, including the mesorectum, is (nearly) completely removed, making such reconstructions more difficult compared with CRVF after trauma or post-partum. Finally, the proportion of APR as definitive treatment might be underestimated, as this was based on free-text remarks in the database and some patients even underwent APR after 1 year and, as such, the stoma-free survival was perhaps even lower than reported.

In conclusion, female patients developing AL with CRVF after rectal cancer resection are unlikely to become stoma-free, and the majority require surgical reintervention(s), even in the presence of a primary diverting stoma. These data from a large international database can be used for adequate patient counseling in women who present with CRVF. Patients with small leaks that can be managed conservatively, and those being candidates for a redo anastomosis have a reasonable chance for ultimate bowel continuity.

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The authors declare no conflict of interest.

Supplementary material

Supplementary material is available at *BJS* online.

Data availability

Data may be available upon reasonable request.

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