

Early Laparoscopic Colostomy in Advanced Cancer Patients with Rectovaginal Fistula: Results of Seven Patients

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A rectovaginal fistula (RVF) is an abnormal tract between the rectum and vagina, which requires surgical intervention in many cases. Although there are many different therapeutic approaches for RVF depending on the patients' condition, there are no established guidelines for the care of RVF. This study aimed to evaluate the results of laparoscopic colostomy in advanced cancer patients with RVF, and the safety and efficacy of this surgery. In this study, seven female advanced cancer patients with RVF were hospitalized and successfully treated with laparoscopic colostomy from 2015 to 2018 at our university hospital. Their data were retrospectively evaluated from their medical records. The early use of diverting stomas facilitated timely resumption of cancer treatment and enabled early treatment with chemotherapy or radiotherapy. Although vaginal stool leakage affected three patients, all patients recovered, experiencing neither pain nor infection during their cancer treatment. While colostomy was physically and mentally taxing for the patients, it improved the infection and pain caused by the RVF. We conclude that the early use of diverting stomas had two effects: a significant improvement in infection management and facilitation of the rapid resumption of cancer treatment.

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Key words: rectovaginal fistula, laparoscopic early colostomy, advanced cancer

Introduction

A rectovaginal fistula (RVF) is an abnormal tract between the rectum and vagina that is usually caused by obstetric injury, Crohn's disease, trauma, infection, neoplasm or radiation injury¹. The most common symptoms are passage of stool, gas, and pus through the vagina, which are difficult to manage, as well as being painful and irritating to the vaginal mucosa. RVF is a distressing condition that significantly impairs the patient's quality of life.

Currently, surgical treatment is the major approach for this condition and is crucial in many cases of RVF. There are various surgical techniques to treat RVF, such as transvaginal, transanal, and laparoscopic or open transabdominal repair. For low RVFs between the lower

third of the rectum and lower half of the vagina, transvaginal repair is the best approach. High RVFs occur between the middle third of the rectum and posterior vaginal fornix. A transabdominal approach is the preferred surgical approach for high RVFs with large defects². Laparoscopic repair, also referred to as minimally invasive surgery, is advantageous in terms of postoperative pain reduction and rapid recovery, and is associated with reduced complication rates and improved blood loss. However, reports of laparoscopic repair of high RVFs are scarce³. Additionally, although there are many different therapeutic approaches for RVF depending on the patient's condition, there are no established guidelines for the care of RVFs.

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Ostomy, which involves diversion of feces away from the fistula site, is a treatment option for preventing infection until complete healing, allowing tissue regeneration and healing. Whereas ostomy is infrequently required in anal fistula surgery, its usage rate is far higher in RVF⁴. An ostomy is sometimes created to regulate bowel movements. The decision to create an ostomy in cases of RVF is based on patient characteristics. While making this decision is particularly difficult, it can allow effective management of the patients. Prophylactic ostomy might also be needed in some patients with RVF.

Tumor invasion and progression can cause intractable RVF. In such cases, repair of the RVF is generally thought to be impossible because of severe tissue destruction, and a defunctioning stoma is considered favorable to allow for healing of the injured tissue. In this study, we evaluated the results of laparoscopic colostomy in advanced cancer patients with RVF, as well as the safety and effectiveness of this surgery.

Methods

From 2015 to 2018, seven female patients with advanced cancer and RVF were hospitalized and successfully treated with laparoscopic colostomy at our university hospital. Their data were retrospectively evaluated from their medical records.

The mean age of the patients was 61.9 ± 11.2 years. Laparoscopic colostomy was performed 20.9 ± 12.1 days after RVF formation. RVFs were confirmed by computed tomography, magnetic resonance imaging and colonoscopy. All patients were operated on under general anesthesia and in the lithotomy position. Surgical antibiotic prophylaxis was administered in all patients. During the surgery, one 12-mm and three 5-mm trocars were inserted into the upper and lower abdomen. After careful inspection of the abdominal cavity, intra-abdominal adhesions were meticulously dissected. Laparoscopic colostomy was performed and a diverting stoma was created at the preselected site. The average surgical time was 140.9 ± 61.8 minutes (range, 75-240 minutes). All the operations were performed by experienced surgeons.

Written informed consent was obtained from all patients for the publication of their case reports. The institutional review board of Ehime University Hospital waived the need for ethical approval for this study.

Results

Our experience with the seven patients is reported below.

Case 1: A 63-year-old female patient underwent total

abdominal hysterectomy and bilateral salpingo-oophorectomy due to ovarian cancer. She received paclitaxel plus carboplatin, topotecan and doxorubicin (liposomal), followed by gemcitabine plus bevacizumab. During the second cycle of chemotherapy, she noticed fecal discharge from the vagina and was diagnosed with simple high RVF. Consequently, a laparoscopic transverse colostomy was performed. She subsequently reported leakage of loose stool into the vagina and developed a fever. After the symptoms subsided, chemotherapy was performed. Nine months later, the patient died of ovarian cancer despite treatment with chemotherapeutic drugs. She remained in good general health without systemic signs of infection until the end of her life.

Case 2: A 70-year-old female patient underwent rectal cancer resection and D3 lymphadenectomy. XELOX (capecitabine plus oxaliplatin) was administered as first line treatment after surgery due to peritoneal dissemination, followed by double chemotherapy with FOLFIRI/mFOLFOX6 (oxaliplatin or irinotecan plus fluorouracil and folinic acid) plus bevacizumab, and then by regorafenib and TAS-102. During the course of the chemotherapy treatment, she developed a fever and complained of fecal discharge from the vagina, and was diagnosed with simple high RVF. A laparoscopic transverse colostomy was performed. She subsequently reported leakage of loose stool into the vagina and developed a fever. After the symptoms subsided, chemotherapy was performed. The patient died of rectal cancer with peritoneal dissemination after about 2 years. She was in good general health without systemic signs of infection until the end of her life.

Case 3: A 69-year-old female patient with a chief complaint of atypical genital bleeding was referred to our hospital for suspected cervical cancer. The patient was diagnosed with simple high RVF secondary to stage IVA cervical cancer. Magnetic resonance imaging showed air bubbles in the uterus and revealed RVF (Fig. 1). A laparoscopic sigmoid colostomy was performed, after which the patient underwent radiotherapy. She died of cervical cancer about 20 months after surgery, having remained in good general health without systemic signs of infection until the end of her time.

Case 4: A 58-year-old female patient with cervical cancer stage IVB was treated with concurrent chemoradiation therapy (45 Gy) along with paclitaxel and carboplatin. The patient presented with fecal discharge from her vagina and was diagnosed with simple high RVF. A laparoscopic transverse colostomy was performed. The

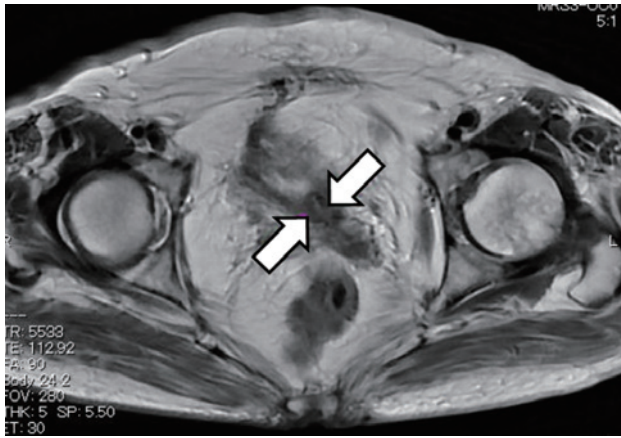


Fig. 1 Magnetic resonance imaging findings
Magnetic resonance imaging showed air bubbles in the uterus and revealed rectovaginal fistula (arrows).

patient died from cervical cancer after about 3 months. Her postoperative course was mostly uneventful, and her discomfort improved.

Case 5: A 59-year-old female patient underwent radical hysterectomy and received adjuvant radiation therapy (45 Gy) for cervical cancer. Subsequently, she was found to have recurrent cervical cancer and received chemotherapy. The patient complained of fecal discharge from her vagina and was diagnosed with simple high RVF. A laparoscopic transverse colostomy was performed. The patient died of cervical cancer more than 5 months after surgery. Her postoperative course was mostly uneventful, and her discomfort improved.

Case 6: A 40-year-old female patient consulted her local doctor with a chief complaint of atypical genital bleeding. The patient was subsequently diagnosed with stage IIB cervical cancer and received chemoradiation (50 Gy to the pelvis and 24 Gy to the vagina, along with docetaxel) as curative treatment. The patient developed bilateral hydronephrosis and radiation-induced hemorrhagic cystitis, and was referred to our hospital for percutaneous nephrostomy due to urine leakage. She was postoperatively found to have high RVF, so laparoscopic transverse colostomy was performed. The patient received supportive care at home and died of cervical cancer about 9 months postoperatively. Her postoperative course was mostly uneventful, and her discomfort improved.

Case 7: A 73-year-old female patient with vaginal cancer received total pelvic radiation therapy of 50 Gy. The patient was later found to have recurrent vaginal cancer, for which she received tegafur-uracil followed by paclitaxel plus carboplatin. She had previously undergone in-

ferior vena cava filter placement. The patient complained of fecal discharge from her vagina. She was diagnosed with simple high RVF, and a laparoscopic transverse colostomy was performed. She subsequently reported leakage of loose stool into the vagina and developed a fever. After the symptoms subsided, chemotherapy was performed. The patient died of vaginal cancer more than 2 years later, but she was in good general health without systemic signs of infection until the end of her life.

The patients' characteristics and treatment outcomes are shown in **Table 1**. Chemotherapy was postponed in cases 1, 2 and 7 due to the year end and New Year holidays. Patients' blood biochemistry and body temperature were measured 1 week before and 1-3 weeks after ostomy surgery to check for the presence of infection (**Fig. 2**). None of our patients had severe complications during follow-up. A colostomy reversal may be required after they have fully recovered.

Discussion

This study describes our experience of seven cases of laparoscopic colostomy for unresectable RVF in advanced cancer patients with poor prognosis. The most frequently reported cause of RVF in the developing world is obstetric vaginal trauma⁵. In developed countries, on the other hand, RVF occurs as a result of tumor invasion or as a consequence of radiation and chemotherapy⁶. In this study, all the patients developed RVF because of tumor progression, and repair of RVF was very difficult. In general, a period of healing for a few years might be necessary before RVF reconstruction. During this period, it is important to maintain the tumor in a retracted state, and appropriate clinical care should be provided to each patient based on their clinical condition.

At this time, there is no established standard treatment for any kind of RVF. RVF is typically managed with surgery or conservative treatment. Various surgical procedures, including flap advancement, muscle interposition and fistula excision, have been reported, with success rates ranging from 30% to 90%⁷. For recurrent RVF or large RVF repair, gracilis muscle interposition is an excellent option. Pinto et al.⁸ reported success rates of 79.2% with surgical procedures (e.g. gracilis muscle interposition). However, the optimal surgical technique is still a subject of debate.

Full consensus on the advantages of diverting stomas in the management of RVF has not yet been reached, so diverting stomas are ordinarily only attempted after other treatments have failed. However, early use of di-

Table 1 Patients' characteristics and treatment outcomes in the present case series

Case No.	Age (years)	Etiology of RVF	Primary tumor site	Distant metastases	Location of RVF	Comorbidities	Ostomy type	Time from RVF formation to surgery (days)	Time from surgery to the initiation of chemotherapy or radiotherapy (days)	Symptom improvement	Death (Y/N)	Time from surgery to death (days)
1	63	Ovarian cancer	Ovary	Y	High	Asthma	Transverse colostomy	37	39 (chemotherapy)	Improved	Y	266
2	70	Rectal cancer	Rectum	Y	High	None	Transverse colostomy	6	56 (chemotherapy)	Improved	Y	715
3	69	Cervical cancer	Uterine cervix	Y	High	Cataract	Sigmoid colostomy	13	7 (radiotherapy)	Improved	Y	603
4	58	Cervical cancer	Uterine cervix	Y	High	None	Transverse colostomy	27	N.A.	Improved	Y	91
5	59	Cervical cancer	Uterine cervix	Y	High	None	Transverse colostomy	26	N.A.	Improved	Y	155
6	40	Cervical cancer	Uterine cervix	Y	High	None	Transverse colostomy	7	N.A.	Improved	Y	258
7	73	Vaginal cancer	Vagina	N	High	None	Transverse colostomy	30	31 (chemotherapy)	Improved	Y	793

RVF: rectovaginal fistula

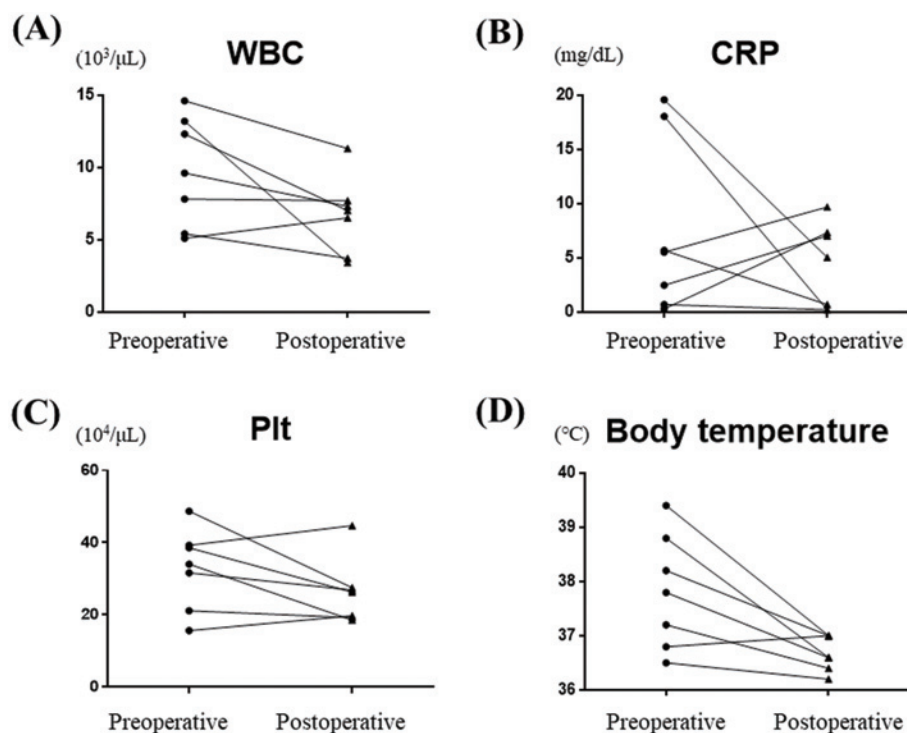


Fig. 2 Preoperative and postoperative levels of biochemical parameters and body temperature

(A) WBC, (B) CRP, (C) Plt, (D) Body temperature

Normal WBC count: $<9 \times 10^3/\mu\text{L}$; Normal CRP value: $<0.20 \text{ mg/dL}$; Normal Plt value: $<40 \times 10^4/\mu\text{L}$

WBC: white blood cells, CRP: C-reactive protein, Plt: platelets

verting stomas has also been advocated⁹. Corte et al.⁹ showed that aggressive use of diverting stomas and major surgical procedures (e.g. gracilis muscle interposition) leads to an increased success rate of RVF repair. On the other hand, early use of diverting stomas can lead to mild rectal mucosal inflammation¹⁰. After treatment with radiation therapy, a period of healing of one to three years is necessary before RVF reconstruction¹¹. In our seven cases, major surgical procedures were only considered after mucosal inflammation had subsided. Gracilis muscle interposition might be required for definitive RVF repair.

The main objective of ostomy is to prevent the development of chronic infection, since the infection might spread rapidly and widely, leading to sepsis. Uncontrolled sepsis causes irreparable damage to the patient's health. In our patients, ostomy had a favorable effect on inflammatory markers (**Fig. 2**), except in cases 4, 5 and 7. These three patients had serious medical conditions that made cancer treatment very risky, leading to high inflammatory marker levels. The decision to create diverting stomas should be carefully considered in each patient with malignant RVF due to invasive cancer. On the other hand, since early use of diverting stomas might support optimal chemotherapy procedures by stabilizing the patients' condition, palliative stoma formation might increase the life expectancy of such patients. In our seven patients, the average time from RVF formation to laparoscopic colostomy surgery was 20.9 days (range: 6-37 days), and the time from surgery to the initiation of adjuvant chemotherapy or radiotherapy was 33.3 days (range: 7-56 days), excluding patients who did not resume treatment. Of our seven patients, cases 4, 5 and 6 did not resume their cancer treatment because their medical condition was life-threatening, and they were considered unable to tolerate the treatment. Due to recent improvements in cancer treatment, Japan's cancer survival rates have improved¹², and early postoperative chemotherapy has become very beneficial and important for the improvement of survival prognosis. Delayed resumption of chemotherapy postoperatively is associated with significant morbidity, and a longer time interval between colostomy and resumption of chemotherapy is associated with an excessive risk of death. Therefore, it is preferable to resume chemotherapy or radiotherapy as soon as possible after RVF treatment. In our case series, the early use of diverting stomas facilitated timely resumption of cancer treatment and enabled early treatment with chemotherapy or radiotherapy. Although vaginal stool leakage

affected three of our patients, all patients recovered, experiencing neither pain nor infection during their cancer treatment. While colostomy was physically and mentally taxing for the patients, it improved the infection and pain caused by the RVF. There were no postoperative complications of Clavien-Dindo classification Grade 3 or above in any of the patients. Locally advanced colorectal and cervical carcinomas are the most common indications for pelvic exenteration (PE). The 5-year survival rate following PE for advanced pelvic cancer ranges from 20% to 60%¹³. Despite being a procedure with high morbidity, PE has shown improved survival rates when performed with curative intent¹³. In stark contrast, the 5-year survival rate for patients who do not undergo PE is very low¹⁴. A study by Ishiguro et al.¹⁵ found that surgery-related complications occurred in 41% of their patients who underwent PE. Perineal wound dehiscence was the most frequent complication (20.3%), followed by urinary tract infection (10.8%) and pelvic sepsis (8.4%)¹⁵. Although PE is a promising treatment option for patients with locally advanced cancer, potentially improving their survival rates, it also raises serious concerns about quality of life. PE, which removes the uterus, ovaries, bladder, rectum, and potentially the vagina, significantly alters patients' physical and emotional well-being. In our seven cases, inoperable distant solid organ or lymph node metastases and an inability to attain a clear resection margin hindered curative PE. Therefore, laparoscopic colostomy was performed in seven cases, and all patients remained in good general health without systemic signs of infection until the end of their lives. We conclude that the early use of diverting stomas had two effects: a significant improvement in infection control and facilitation of the rapid resumption of cancer treatment.

So far, there has been no reliable evidence regarding RVF treatment with diverting stomas. This report suggests that RVF treatment with the early use of diverting stomas improves chronic inflammation of the rectum and the patient's general well-being, and enables early treatment with chemotherapy. To the best of our knowledge, this is the first case series on laparoscopic colostomy for RVF in advanced cancer patients. Of note in this study, all patients had advanced cancer, so major surgical procedures (e.g. gracilis muscle interposition) would have been difficult because of prolonged mucosal inflammation. As for limitations, this study lacked an objective assessment of patients' quality of life, and comparing PE and colostomy outcomes is challenging due to variations in patient selection, techniques used, and care provided.

Additionally, this study involved a relatively small patient population. This report can, however, help increase awareness among gastrointestinal surgeons of the utility of early use of diverting stomas for RVF. We believe that this report will be useful to clinical staff involved in the treatment of RVF in cancer patients. However, a larger study is needed to confirm the effects of early laparoscopic colostomy for RVF in advanced cancer patients.

Author contributions: SA and KI performed the surgery and collected the data for this case report. KW, HS, YO, JK, KT, SK, HM, MY, SK, and TO reviewed the manuscript. MS is the corresponding author, contributed to data analysis and interpretation, reviewed the literature, and wrote the manuscript. All authors read and approved the final manuscript.

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