#### **Original** Article

# Outcomes of a Two-stage Operation Strategy for Rectovaginal Fistulas Following Minimally Invasive Colorectal Resection: A Single Center Experience

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#### Key Words

Rectovaginal fistula; Transvaginal repair; Minimally invasive colorectal surgery **Purpose.** To investigate the incidence of rectovaginal fistulas following minimally invasive colorectal surgeries and the outcomes of treating these fistulas with two-stage operations in our institute.

*Methods.* We retrospectively reviewed patients experiencing rectovaginal fistulas as complications from minimally invasive colorectal surgeries for rectal cancer from 2010 to 2021. The patients' demographic, histopathological, and perioperative data were collected from electronic medical records. All patients with rectovaginal fistulas underwent a two-stage operation, that is, a routine diversion stoma followed by a definite repair if the rectovaginal fistula persisted. Surgical outcomes were analyzed according to each repair method.

**Results.** Seventeen patients with rectovaginal fistulas were recruited, representing an incidence of 4.3% (N = 17/400) in our institute. The mean age was 58.7 years. The fistulas were complications from laparoscopic surgeries and robotic surgeries for rectal cancer in 11 and 6 patients respectively. Fourteen patients (82.4%) were successfully treated with the proposed two-stage operation. Six patients received only diversion stoma without definite repair, and five had resolution of the fistulas. Eight patients underwent subsequent transvaginal repair, and six had no recurrence. Three patients who underwent either a transanal or transabdominal repair had no recurrent rectovaginal fistulas.

*Conclusions.* The two-stage surgical strategy for rectovaginal fistulas, had an excellent success rate of 82.4%. A substantial proportion of patients may benefit from stoma alone. However, a subsequent definite repair is required in most patients.

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A rectovaginal fistula (RVF) is an abnormal epithelial connection between the rectum and vagina. An RVF may present with flatus passage from the vagina, fecal incontinence, irritation of the vulva, and urinary incontinence. Only a minority of the patients are asymptomatic. An RVF usually results from diverticular disease, inflammatory bowel disease (IBD), surgery, or injury. Although the most common cause of RVFs is reported to be related to obstetric injuries,<sup>1</sup> the incidence in modernized countries has de-

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creased to only 0.2 per 1,000 deliveries.<sup>2</sup> Nonetheless, this condition also occurs after colorectal surgeries. The reported incidence of RVFs after colorectal resection is reported at 1.6-9.9%.<sup>3-6</sup> RVFs are a debilitating condition as they affect the patients' quality of life, sexual activity, and psychological condition.<sup>7-9</sup>

Treating RVFs is a challenge for surgeons because the procedures are complex, and the results may vary according to the location, size, etiology, condition of the surrounding tissue, and patients' comorbidities.<sup>10</sup> There are several repair methods for RVFs. The main three categories are the local repair, muscle transposition, and transabdominal approach.<sup>11</sup> The local repair strategy has three major approaches: transanal, transvaginal, and transsphincteric. Among these options, the transanal advancement flap (TRAF) is endorsed by most surgeons, has a relatively good initial success rate,<sup>10-12</sup> and is supported by the American Society of Colon and Rectal Surgeons (ASCRS).<sup>13</sup> The transvaginal approach is also a feasible method that shows overall good results comparable to the transanal approach.<sup>10,11,14</sup> The muscle transposition is used in more complex or recurrent RVFs. Finally, the transabdominal approach is typically used for proximally located RVFs.

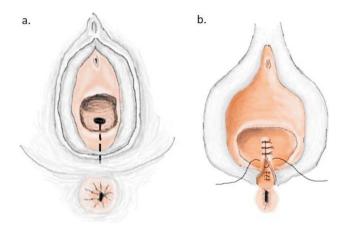
Another issue for RVF repair is whether a diversion stoma should be performed. Some studies have shown that a diversion stoma did not improve RVF resolution.<sup>15</sup> Others have described a possibility of spontaneous RVF closure of after stoma creation.<sup>3,11,16</sup> RVFs occurring after colorectal surgery are often caused by anastomotic leakage and inadvertent injury to the rectovaginal septum. Thus, diversion stoma is frequently performed for RVFs in our hospital to enable patients to return to oral feeding as soon as possible. Definitive repair would be performed later if spontaneous closure of the fistula did not occur. To date, the operative strategies for rectovaginal fistulas are based on the fistula size, location, presence of sphincteric defect, and etiology.<sup>17</sup> In the era of minimally invasive colorectal surgeries, we aimed to examine the incidence of RVFs following these operations and the outcomes of our two-stage operation.

#### **Materials and Methods**

In this retrospective study, we reviewed the electronic medical records of patients who underwent surgeries for RVFs at the National Taiwan University Hospital, a tertiary center in Taiwan, from January 2010 to December 2021. We included patients whose RVFs were considered complications from previous laparoscopy or robot-assisted minimally invasive colorectal surgeries. Patients with inflammatory bowel disease, diverticulitis, or other causes of RVF were excluded.

Patient demographic data, such as age, BMI, Charlson comorbidity index (CCI), smoking, perioperative chemotherapy, radiotherapy, receiving immunosuppressants, histology, TNM staging, location of the tumor, lymphovascular space invasion (LVSI), perineural invasion (PNI), size and location of the fistula, postoperative anal tube use, and the operation method were retrieved. The size of a fistula is considered small if the diameter was < 2 cm, and large if the diameter was > 2 cm.<sup>18</sup> The location of a fistula is high if it was located just next to the cervix, low if it was located just above the dentate line and the vaginal opening inside the vaginal fourchette, and medium if it was between these landmarks.<sup>19</sup>

In our institute, the management process for patients with RVFs was as follows. A patient presenting with symptoms compatible with RVFs such as stool or flatus from vagina would be evaluated for surgery. A digital rectal examination would be performed in the clinic. If the RVF was considered complex or in a high location, computed tomography (CT) of the fistulogram or lower GI series would be performed. In the CT fistulogram, water-soluble contrast medium with a 1:10 dilution was injected via the anus until the entire rectum was filled before the CT was performed. In the lower GI series, barium contrast medium was used before the radiography was performed. Prophylactic antibiotics to cover anaerobic pathogens were administered after the diagnosis of RVF was made and continued until the operation for stoma creation. Either ileostomy or colostomy was performed for diversion. After several months, the patient would undergo another imaging evaluation. If the RVF had spontaneously closed, then stoma closure would be performed. Otherwise, a fistula repair would be performed. Based on the characteristics of the fistula, the surgical approach was selected at the discretion of the surgeon. The transvaginal approach was usually the first to be considered for low- and medium-positioned RVFs. A vaginal flap would be created to expose the rectal opening. Primary closure with interrupted suture of the rectal opening and closing of the vaginal mucosa after trimming the vaginal opening would be performed. The surgical procedure is illustrated in Fig. 1. Stoma closure would be performed if there was no residual



**Fig. 1.** Transvaginal approach repair of a rectovaginal fistula. (a) A malleable probe is passed through the fistula tract for identification of the openings. (b) The rectovaginal septum is closed with interrupted suture followed by closing the vaginal mucosa. RVF on imaging at a follow-up several months later. After the two-stage operation, any occurrence of typical RVF symptoms was considered recurrence. If no recurrence was documented, RVF repair would be considered resolved, and the resolution rate would be analyzed according to each repair method. SPSS software ver.26 (IBM, Armonk, NY, USA) was used for statistical analysis and calculation.

#### Results

Between 2010 and 2021, 20 patients underwent surgeries for treating RVFs. Among them, one had an RVF that was related to diverticular disease and was excluded. The other 19 patients underwent colorectal surgeries before symptoms of rectovaginal fistulas were noticed. Seventeen of them underwent either laparoscopy or robot-assisted minimally invasive surgeries. During this study period, there were 400 female patients who underwent rectal surgeries. Thus, the estimated incidence of RVFs after minimally invasive rectal surgery was 4.3% (N = 17/400). Among the 400 patients, 277 patients received laparoscopic surgery and 123 patients received robotic assisted surgery. The patient selection process is shown in Fig. 2.

The mean age was 58.7-year-old and BMI was  $23.8 \text{ kg/m}^2$ . The median CCI, used to evaluate the severity of comorbidities, was 4. Most of the tumors

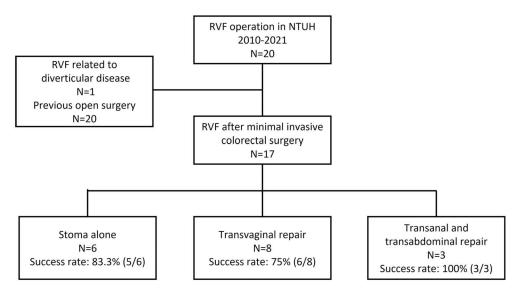


Fig. 2. Patient selection flowchart. NTUH, National Taiwan University Hospital; RVF, rectovaginal fistula.

were located in the middle rectum, and the mean distance above the anal verge (AAV) was 6.4 cm. Of the six patients who received chemotherapy, two received concurrent chemoradiotherapy (CCRT) before the surgery, while the other four received adjuvant chemotherapy during the follow-up period. Most patients received laparoscopic surgeries. The adenocarcinoma was the most common histological diagnosis. Only one patient had high-risk features, that is, LVSI and PNI. The tumors were mostly in stage I (56.3%). The RVFs were mostly small (82.3%) and in the medium location. The patients' characteristics are shown in Table 1.

All patients underwent stoma creation. Eleven of them received definite repair of fistula. Six patients did not receive definite repair because the subsequent fistulography showed RVF resolution. The mean time from stoma creation to definite repair was 6.5 months. Three patients did not undergo stoma closure, and none of them showed residual RVFs on imaging. One patient still had anastomotic leakage without RVF. Another patient had end-stage Parkinsonism and was bedridden; thus, stoma closure was not deemed appropriate. Another patient had an anastomotic stricture; therefore, stoma closure was not recommended. The mean time from definite repair to stoma closure was 7.43 months. RVF recurrence was still noticed in three patients (17.6%). Among these, one did not receive definite repair of the fistula. Other two patients received transvaginal repair. Three patients who underwent either transanal or transabdominal repair showed no recurrence of RVF. The mean time to recurrence is shown to be 14 months. The outcomes of two-staged RVF repair strategy are shown in Table 2. The clinical details of the three patients with recurrent RVFs are presented in Table 3.

#### Discussion

An RVF after colorectal surgery is a challenge for surgeons. The patient may suffer from poor quality of life and impaired social activity.<sup>7-9</sup> However, the inconvenience of living with RVFs could be reversed by surgical management, reducing stool incontinence and

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Table 1. Patients' characteristics

	Number (percentage)/	
	Mean $\pm$ SD	
Demographic data		
Age (year)	$58.7\pm7.5$	
BMI $(kg/m^2)$	$23.8 \pm 5.0$	
CCI <sup>a</sup>	$4 \pm 1$	
Tumor location (AAV <sup>b</sup> cm)	$6.4 \pm 3.1$	
Chemotherapy		
Yes	6 (35.3%)	
No	11 (64.7%)	
Radiation		
Yes	2 (11.8%)	
No	15 (88.2%)	
Histopathological characteristics		
Histology		
Adenocarcinoma	15 (88.2%)	
Squamous cell carcinoma	1 (5.9%)	
Gastrointestinal stromal tumor	1 (5.9%)	
Pathology T stage <sup>c</sup>	1 (3.570)	
T1	3 (18.8%)	
T2	10 (62.5%)	
T3	3 (18.8%)	
Pathology N stage <sup>c</sup>	5 (10.070)	
N0	9 (56.3%)	
Nla	1 (6.3%)	
N1c	1 (6.3%)	
N2a	5 (31.3%)	
TNM stage <sup>c</sup>	5 (51.570)	
I	9 (56.3%)	
IIA	1 (6.3%)	
IIIA	1 (6.3%)	
IIIB	5 (31.3%)	
LVSI <sup>d</sup>	5 (51.570)	
Yes	1 (7 7%)	
No	1 (7.7%) 12 (92.3%)	
PNI <sup>e</sup>	12 (92.370)	
Yes	1(7.70/)	
No	1 (7.7%) 12 (92.3%)	
Rectal operation details	12 (92.370)	
Operation method		
Laparoscopic (N = 277)	11/277(2.00/)	
Robot assisted (N = $123$ )	11/277 (3.9%) 6/123 (4.8%)	
Blood loss (ml) $(N - 125)$	$163.3 \pm 75.2$	
	$103.5 \pm 73.2$ $317.6 \pm 64.6$	
Operation time (min)	$51/.0 \pm 04.0$	
Rectovaginal fistula characteristics Location		
	0(00/)	
High Medium	0(0%)	
	10(58.8%)	
Low	7 (41.2%)	
Size of fistula	14 (02 20/)	
Small	14 (82.3%)	
Large	3 (17.7%)	

<sup>a</sup> Charlson comorbidity index, <sup>b</sup> Above anal verge, <sup>c</sup> AJCC 7<sup>th</sup> edition, <sup>d</sup> Lymphovascular space invasion, <sup>e</sup> Perineural invasion.

improving quality of life.<sup>20</sup> Therefore, surgeons should endeavor to help patients solve this complication. The incidence of RVFs after colorectal surgeries has been

Table 2. Outcomes of two-staged RVF repair strategy

	Number (percentage)/ Mean ± SD	
Repair method		
Transvaginal	8 (47.1%)	
Transanal	1 (5.9%)	
Transabdominal	2 (11.7%)	
No definite repair	6 (35.3%)	
Recurrence		
Yes	3 (17.6%)	
Transvaginal repair	2	
No definite repair	1	
No	14 (82.4%)	
Closure stoma		
Yes	14 (82.4%)	
No	3 (17.6%)	
Resolution rate by repair method		
Transvaginal	6/8 (75%)	
Transanal	1/1 (100%)	
Transabdominal	2/2 (100%)	
Time to RVF recurrence (month)	$14.0\pm9.2$	

Table 3. Summary of patients with recurrent rectovaginal fistulas

reported at 1.6-9.9%. In our hospital, 400 female patients underwent minimally invasive surgeries for rectal cancer between 2010 and 2021. The incidence of RVFs as complications of these procedures was 4.3%. Several risk factors are related to the incidence of RVF, including larger tumor size, neoadjuvant therapy, intraoperative blood loss > 200 ml, and concomitant hysterectomy or oophorectomy. In our study, only two patients had received neoadjuvant therapy. In addition, most of our patients only had stage I malignancy, suggesting that RVFs are not limited to advancedstage colorectal cancer. Thus, an intraoperative technique for preserving the rectovaginal septum is crucial. The double stapling technique (DST), frequently used in rectal cancer surgery in modern days, is also associated with RVFs.<sup>21-23</sup> In our hospital, the DST is routinely used for low anterior resection. Considering the possibility of RVFs, we kept the distal rectal stump away from the posterior vaginal wall as far as possible and made sure the entire circumference of the DST device was visible before firing. The stapler pin was better passed through the posterior transection line, as previously suggested.24

	Case		
	1	2	3
Age	45	67	61
Chemotherapy	Yes	No	Yes
Radiotherapy	No	No	No
Rectal operation method	Laparoscopic	Robotic	Robotic
Repair method	Transvaginal	Transvaginal	No definite repair
Tumor location (AAV cm)	6	8	5
Histology	Adenocarcinoma	GIST	Adenocarcinoma
Tumor stage (TNM staging)	IIIB	NA	IIIB
Rectovaginal fistula location	Medium	Medium	Medium
Rectovaginal fistula size	Small	Small	Small
Stoma closure	Yes	Yes	Yes
Time to recurrence (month)	35	4	3
Management after recurrence	Loop stoma and transvaginal repair. Stoma was closed after 2 years, and no RVF was observed.	Loop stoma and transvaginal repair. Stoma was closed after 5 months, and no RVF was observed.	The patient tolerated the symptoms.
Others	Patient had synchronous colon cancer, and right hemicolectomy was performed in the first operation. Local recurrence occurred after 6 years.		

In recent years, robotic surgery for rectal cancer has become popular because of its advantages in dissecting deep pelvic tissue.<sup>25</sup> In our study, we observed several RVF cases in the robotic surgery group, though there is no significant difference in occurrence of RVF between laparoscopic group and robotic group (3.9% vs. 4.8%, p > 0.05). Although several randomized controlled trials have compared laparoscopy and robotic surgeries for rectal cancer, RVFs as a complication were usually not explored. In a retrospective cohort study, the occurrence of RVFs did not differ between the laparoscopic (0.5%) and robotic groups (0.3%).<sup>26</sup> We speculate that robotic surgery enables surgeons to have a better view of pelvic anatomy. Thus, more aggressive dissection is achievable, unfortunately, results in RVFs.

Diversion stoma is routinely performed at our hospital. However, a literature review showed that fecal diversion did not increase the rectovaginal fistula closure rate.<sup>10,27,28</sup> Nonetheless, these articles are retrospective in nature, and bias could not be avoided. Patients with larger and more complex fistulas are more likely to undergo stoma creation. In contrast, Komori et al. proposed a particular type of RVFs that could be treated with diversion alone with a success rate of 71.4%.<sup>29</sup> Zheng et al. also found that 15 of 21 patients recovered from stomas alone without additional surgery. Our study also showed that 5 of 17 (29.4%) patients with stomas alone had RVF resolution. Fu et al. proposed that diversion stoma should be advised if the fistula is large and high, related to low anterior resection, or if the first repair attempt has failed.<sup>27</sup> Lohsiriwat et al. also provided a treatment algorithm for the management of RVFs after colorectal cancer surgeries and the conditions of diversion stoma. In our opinion, creation of stomas enables patients to return to normal daily activities. Controlled stool passage into the stoma bag may also increase the patients' willingness to consume food. A proportion of patients may require adjuvant chemotherapy after surgery. Hence, nutritional status is critical in these patients.

Several repair methods for treating RVFs have been proposed. They can be categorized into local repair, muscle transposition repair, and transabdominal repair. An appropriate repair method depends on the size and location of the fistula.<sup>27,30</sup> When the fistula is low, repair could be performed locally using either a transvaginal or transanal approach. The transabdominal approach is suitable for a higher RVF. Some studies have reported a better initial success rate for muscle repair.<sup>30</sup> Other studies reported similar outcomes.<sup>10,27</sup> In a systemic review, local repair has the success rate of 70-80%.<sup>31</sup> However, in these studies, the etiologies of RVFs were diverse or related to Crohn's disease. Treatment outcomes focusing on RVFs after rectal cancer surgeries are limited. Woo et al. reported a 30% success rate of primary repair and a 50% success rate when combined with a diversion stoma. However, this repair method was not documented in that study.<sup>32</sup> In the definite repair group of our study, 9 out of 11 patients (81.8%) had resolution of RVFs. Specifically, in the local repair group, 7 of 9 patients (77.8%) no longer suffered from RVFs within the follow-up period. From the literature, the initial success rate of local repair is around 33-66.7%.<sup>10,27,33</sup>

If the rectovaginal fistula is low or medium, the transvaginal approach is preferred in our hospital. Although the transvaginal approach is more used in gynecological procedures, it has advantages in exposing the fistula tract. In our study, eight patients received the transvaginal two-layer suture, and six of those (75%) achieved resolution of RVFs. Rahman et al. described transvaginal purse string repair for obstetric injury-related RVFs, and the cure rate reached 100% in 39 patients.<sup>14</sup> Bhome et al. proposed a flapless transvaginal repair that only requires less operative time, with a healing rate of 67%.<sup>34</sup> Thayalan et al. suggested that RVFs were cured by transvaginal primary closure in 38 of 41 patients (92.7%) with minimal complications.35 These studies have verified that the transvaginal approach is safe and effective.

#### Conclusion

In this study, the incidence of rectovaginal fistulas after minimally invasive colorectal surgeries was 4.3%. Stoma creation alone led to a resolution rate of 29.4%. Subsequent repair, including the transvaginal, transanal, or transabdominal approaches, resulted in an overall good success rate (82.4%). In our view, the transvaginal approach — demonstrating 75% RVFs resolution rate — should be advocated in low- or medium-positioned RVFs due to its excellent exposure to the fistula.

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None.

## **Declarations of Interest**

None.

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#### <u>原 著</u>

## 兩階段手術修補於微創直腸手術併發直腸陰道 廣管之成果:單一中心的經驗

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**目的** 了解本院進行微創直腸手術後發生直腸陰道廔管的發生率,及檢視使用兩階段手術修補直腸陰道廔管之成果。

**方法**回溯性統計本院於 2010 至 2021 年於微創直腸手術後發生直腸陰道廔管之病患。 病患之基本特徵,病理組織學,手術近期資訊由電子病歷中取得。此族群病患均接受兩 階段修補手術策略,即第一階段施行分流造口,如病人仍持續有直腸陰道廔管之問題, 再於第二階段進行修補手術。依據各種修補方式分析手術的成果。

**結果** 自 2010 至 2021,共有 17 位微創直腸手術後併發之直腸陰道廔管,根據本院統計此併發症發生率約 4.3%。平均年齡為 58.7 歲。11 個接受腹腔鏡手術,而 6 個接受機器手臂輔助手術。14 位病患沒有再出現直腸陰道廔管,兩階段修補手術的策略成功率約 82.4%。6 個只接受造口手術的病患,其中 5 個沒有再有直腸陰道廔管。8 個接受經陰道修補術,6 個治療成功。另外 3 個接受經腹部或經肛門修補手術,均無復發狀況。

結論 此二階段修補手術的策略適合用於治療直腸陰道廔管,其成功率可高達 82.4%。一部分的人可以單靠造口即得到治療效果,然而大多數病患仍需第二階段的修補手術。

關鍵詞 直腸陰道廔管、經陰道修補手術、微創直腸手術。