Tissue selecting technique for adult women with low rectovaginal fistula

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ABSTRACT

Background: This study aimed to assess the effect of tissue selecting technique (TST) on low rectovaginal fistula (RVF) repair.

Methods: Patients with low RVF were included in the prospective study from August 2009 and January 2013 in xx hospital. Patients assigned to the TST or control groups based on the different surgical methods. Surgical success, complications, and quality of life were evaluated. Patients were followed up for 1–3 years.

Results: A total of 81 patients were included in the study. Foutry-one were in the TST group, and 40 were in the control group. Surgery was successful in 100% of patients who underwent TST, and in 95% of patients who underwent the classical perineal approach. Less patients experienced pain (72% vs 90%, $p = 0.04$) and edema (6% vs 25%, $p < 0.001$) in the TST group compared with the control group. In addition, the QOL score was significantly higher in the TST group (122 ± 21 vs 111 ± 12, $p = 0.02$).

Conclusion: The TST stapler approach appears to be appropriate for the treatment of low RVF in adults.

Keywords: Adults; Ectovaginal fistula; Surgery; Tissue-selecting therapy stapler

1. INTRODUCTION

Rectovaginal fistula (RVF) is a pathological channel between the front rectal wall and the rear vaginal wall. Patients mainly complain of gas, feces, or thick liquid defecating through the vagina. Trauma during vaginal delivery is the main cause of RVF, accounting for about 88% of all cases.[1,2] RVF can also be secondary to fecal impaction, vaginal expansion after radiotherapy, and sexual violence.[3,4] According to its location, RVF can be classified into lower fistula (located at or above the dentate line, at the vaginal opening of the labial frenulum), higher fistula (located at one-third part of rectum and posterior vaginal fornix, near the cervix), and middle fistula (located between the lower and higher fistulas).[2,5]

Once a RVF is formed, no surgical treatment can guarantee a cure even if most RVF must be operated.[6] Many different techniques are available to perform this repair, but they are all associated with certain drawbacks. Previous studies reported many ways of repairing low RVF: (1) rectovaginal operation; (2) anal sphincter operation (Mason); (3) perineum operation; and (4) anal rectal pushing flap technique.[5,7,8] The key to repairing RVF lies in the reconstruction of the anterior wall of the rectum. Regardless of the selected technique, the basic condition for successful repair is cutting off the fusion between the rectum and vagina epithelium, removing partial stale tissue, and leaving no tension suture.[5,7,8]

Tissue-selecting therapy (TST) stapler is an open-ring device for minimally invasive hemorrhoid mucosa resection, prolapsing hemorrhoids, and anastomosis.[9–11] TST uses a special single-, double-, or ternary-hole anus mirror suture device that resects alternatively the scar lying in the stoma of the intestinal wall mucosa of lower rectal and partial submucosal tissue. The aseptic inflammation caused by the titanium rivet can cause the rectal mucosa to adjoin with the muscular layer of the rectal wall.[9,10]

The present study aimed to assess the use of TST in the surgical treatment of RVF, compared with the classical perineum operation.

2. METHODS

2.1. Patients

Adult female patients with low RVF were recruited in the prospective study between August 2009 and January 2013 in xx department xx hospital. Inclusion criteria were as follows: (1) vaginal exhaust and defecation; (2) complete fistula between the vagina and rectum revealed by physical examination; and (3) definite methylenum coeruleum staining diagnosis. Exclusion criteria were as follows: (1) severe cardiovascular disease, hepatopathy, nephropathy, or hematopoietic diseases; (2) hyperemia, dropsy, or inflammation pathology of the rectum perineum; (3) psychiatric disease; (4) inflammation enteropathy and RVF after radiotherapy; (5) ongoing menstruations; or (6) pregnancy.

Patients underwent TST operation (n = 41) and transperineal surgery (n = 40). The present study was approved by the Ethics

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Committee of our hospital (IRB approval identification code: 2020033). Each patient provided a written informed consent.

2.2. Surgery

Surgery was performed at least 5 days after menstruation. Routine examinations, including laboratory testing, liver, and kidney function tests, were performed to ensure that there was no vaginal or intestinal infection. Before operation, the patient received oral metronidazole (0.5 g tid) and amoxicillin (0.5 g every 8 hours).

All TST operations were performed under lumbar anesthesia, and all patients were in the chest-knee position and fixed with wide straps. Fig. 1 summarize the TST surgery process. The anus was exposed, disinfected and enlarged with 4–6 fingers. The anal margin was clamped with three Allis' forceps and pulled toward the left, right, and front. A single-hole transparent anus mirror was inserted under the guidance of an anus dilator and sutured for fixation, to expose the internal fistula opening; the anterior wall of the rectum was then exposed adequately. For small openings, a hemostat was passed through the fistula and opened; the opening distance of the hemostat was measured as the fistula opening size. For large openings, the index finger was used as a reference. About 2–3 cm of tissue close to the rectal mucosa in the rectovaginal septum was separated with shears to fully free the fistula and anterior wall of the rectum. Scar tissues were trimmed around the fistula. The knot was tightened to close the fistula. After sufficient hemostasis, 3–4 suture points (7-0 suture) were made from the fistula upper and lower edges, through the mucosa layer to the contralateral mucosa. The type HYG-34 stapler was selected according to the single-hole transparent anus mirror. The stapler is manufactured by Haida Medical Instrument Ltd. in Changzhou City, China (Registration No.: China Food and Drug Administration, 2008, no. 2080462nd).

All patients in the control group were treated with routine perineal transanal endorectal advancement flap surgery; closure of internal sphincter and rectal advancement flap comprised the mucosa, submucosa, and circular muscle layer sutured 1 cm below the level of internal opening.[8,12,13] The patients were placed in the prone position, with a urinary catheter inserted. Skin preparation was performed as per the approved guidelines before surgery. After successful administration of subarachnoid anesthesia, the patient was moved to the chest-knee position to fully expose the anus, perineum, and vagina. The surgical wound was locally disinfected, with the anus as the center, and the surrounding area of about 15 cm in diameter. After disinfection, as a first step, the rectal fistula was separated from the surrounding tissues through the anus. The anus was expanded with fingers (4–6 fingers of both left and right hands were used to expand the anus), then the rectal fistula was exposed and 1:20,000 adrenaline was injected around the rectal fistula. Normal saline was used to elevate the mucosa and incise the rectal fistula. Around 2–3 cm full-thickness rectal mucosa tissue around the rectal fistula was incised. Tissue snips were used to close the rectal mucosa and the surrounding free area. Using a 3-0 absorbable thread, the pruned fistula was sutured with a purse string and homeostasis was achieved.

Nutrition was individualized according to each patient's condition, nutritional status, and gastrointestinal functions.

2.3. Demography Characteristics

Patients' data were recorded including age, etiology of RVF, duration, symptoms, bimanual examination, methylenum coeruleum enema examination, and imaging, as well as the location and size of the RVF.

2.4. Outcomes

Success was determined as fistula closure on the anal side, as evaluated based on the complete absence of vaginal exhaust, defecating, gas leakage, or feces leakage.

Follow-up was carried out by outpatient visits, and telephone or letter interviews, once a month for the first 3 months and at 3-month intervals afterwards. Patients were followed up for 1–3

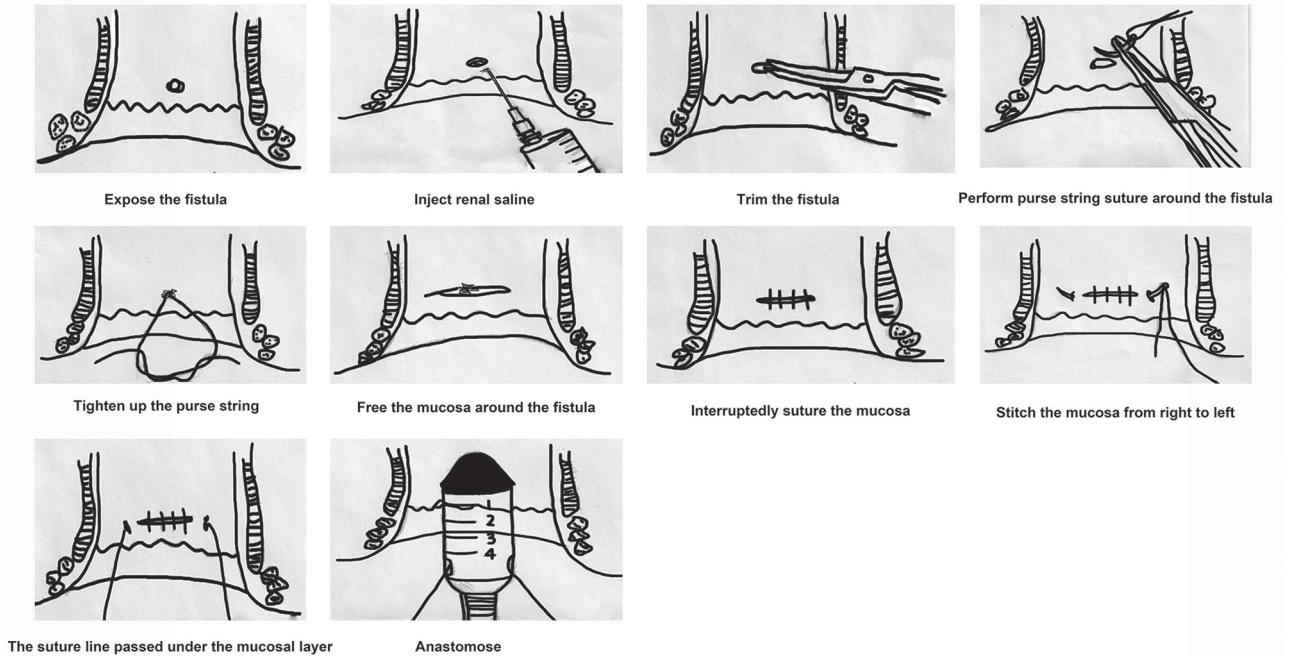

Fig. 1 Schematic diagram of the surgical procedure using TST for the treatment of rectovaginal fistula. (1) Fistula exposure. (2) Epinephrine/saline 1:20,000 injection. (3) Fistula trimming. (4) Purse string suture around the fistula. (5) Purse string tightening up. (6) Freeing the mucosa around the fistula. (7) Interrupted suture of the mucosa. (8) Stitching the mucosa from right to left. (9) The suture line passed under the mucosal layer. (10) Anastomosis.

years. At the 1-year follow-up, edema, pain, and quality of life were assessed. Edema was classified into three levels: mild or no edema with daily activities not affected, moderate edema with daily activities affected but bearable, and severe edema with unbearable pain were classified as levels 1, 2, and 3, respectively. In this study, level 2 or 3 was considered to represent "edema." The visual analog scale (VAS) was used to assess pain, with a score ≥4 defined as "with pain." The RVF Quality of Life Evaluation Scale (RVF-QOL) was used for quality of life measurement. The RVF-QOL includes three aspects: avoidance and restrictive behavior, psychosocial influence, and self-distress, with a total of 22 items graded by five-level four-point method (score of 0-4 points). The higher the score, the higher the QoL. Individuals with a total score of >44 were considered to have a poor QoL.

2.5. Statistical Analysis

Continuous data were presented as mean ± SD and analyzed with the Student's t-test. Categorical data were presented as proportions and analyzed using chi-square test or Fisher's exact test, as appropriate. Statistical analysis was performed using SPSS 17.0 (SPSS Inc., Chicago, IL). Two-sided $p < 0.05$ was considered statistically significant.

3. RESULTS

3.1. Baseline Characteristics of the Patients

A total of 81 patients with low RVF were included in the study. Table 1 presents the patients' baseline characteristics. Age ranged from 21 to 41 years, with means of 29 ± 8 versus 32 ± 9 years in the TST and control groups, respectively ($p = 0.67$). There were no differences between the two groups for stool consistency, diameter of internal opening, course of disease, cause of disease, and proportion of patients undergoing RVF surgery for the first time.

3.2. Surgical Outcomes

At the last follow-up for each patient, surgery was successful in 100% and 95% of patients who underwent TST and the classical perineal approach, respectively. Two patients in the control group had recurrence after 1 and 2 years, respectively. These recurrences were successfully treated.

As shown in Table 2, less patients experienced pain (72% vs 90%, p = 0.04) and edema (6% vs 25%, p < 0.001) on the first day after surgery in the TST group compared with the control group. Pain and edema disappeared by 12 months in all patients. Finally, QOL scores were significantly higher in the TST group (122 ± 21 vs 111 ± 12, p = 0.02) compared with the control group.

Table 1

Baseline characteristics of the patients

	TST group (n = 41)	Control group (n = 40)	*p*
Age (years)	29 ± 8	32 ± 9	0.67
Stool consistency, n (%)			
Loose	24 (58.5)	24 (60.0)	0.93
Formed	17 (41.5)	16 (40.0)	
Diameter of internal opening (cm)	0.8 ± 0.6	0.8 ± 0.3	0.91
Course of disease (months)	36.1 ± 13.2	34.2 ± 11.9	0.60
Cause of disease, n			0.76
Childbirth	18 (43.9)	15 (37.5)	
Perianal abscess	4 (9.8)	6 (15.0)	
Treatment of internal pile	10 (24.4)	10 (25.0)	
Other	9 (22.0)	9 (22.5)	
Primary surgery, %	(89)	(91)	0.89

Table 2

Postoperative outcomes

	Postoperative period	Control (n = 40)	TST (n = 41)	*p*
Pain	1 day	36 (90%)	29 (72%)	0.04
	7 days	14 (35%)	11 (27%)	0.43
	3 months	0	0	–
	12 months	0	0	–
Edema	1 day	10 (25%)	2 (6%)	<0.001
	7 days	10 (25%)	2 (6%)	<0.001
	3 months	10 (25%)	2 (6%)	<0.001
	12 months	0	0	–
Quality of life	1 year	111 ± 12	122 ± 21	0.02

3.3. Safety

Two patients in control group had recurrence. In patient 1, gas and feces were defecating through the vagina 12 months after surgery. After discussion with the patient, the reason of recurrence was mainly considered to be frequent and forceful motions during coitus. In patient 2, the same signs of recurrence were observed 24 months after surgery, which was 2 months after adjuvant radiotherapy for a cervical cancer. Therefore, the cause was considered to be radiation proctitis.

4. DISCUSSION

The present study showed that surgery was successful in all patients treated with TST; meanwhile, 95% of patients who underwent the classical perineal approach had successful outcome. Less patients experienced pain and edema in the TST group compared with the control group; quality of life was significantly higher in the TST group.

The perineal approach is the most commonly used, allowing the repair of the RVF with an easier operation, incision, and separation of the rectal and vaginal walls, and closing of the rectal wall involved in the RVF.[14] The key to surgical success is to achieve sutures without tension or ischemia, and the mucosal muscle flap must have sufficient blood supply.[15] However, early studies using the perineal approach reported high recurrence rates of 30–84%.[16–19]

Transvaginal repair of RVF is not recommended, because of the existence of the high-pressure zone in the rectum.[20] If the repairing of the fistula is successful on the rectal side, there will be no need to manage the vaginal cavity. On the contrary, if the opening on the rectal end fails to be safely closed, then failure is inevitable, irrespective of vaginal repair.[15]

Due to the characteristics of RVF's local anatomy, commonly used methods for repair surgery easily fail, leading to a high recurrence rate, even after multiple attempts, with a reported success rate of only 55% after three attempts.[21] There are three reasons that may influence the success or failure of the repair. First, the tension at the site of the anastomosis is important. Indeed, adult RVF operation success depends on whether there is a tension at the anastomosis site. If the tension is too high, tissue blood perfusion is poor, and more prone to cracking. Second, the internal pressure may cause anastomotic leakage, with the associated complications and failure. Finally, local infections appear in 90% of patients without appropriate preparation.[4,7] Therefore, an appropriate pressure must be achieved at the anastomosis site, and all measures must be implemented to control infection.

Nevertheless, new surgical approaches could help to further decrease the risk of recurrence. We previously used TST for hemorrhoidectomy,[10] and observed that after placing a single-hole

transparent anus mirror, exposure of the rectum anterior wall was improved compared with the use of a rectum pushing flap. Moreover, removing the stale local tissues can avoid tension of mucosal resection, which is suitable for lower adult rectum anterior wall reconstruction. Therefore, we attempted to use the TST to treat low RVF. This approach protects the integrity of the mucosa around the anorectal dentate line and anal cushion, holding the normal mucosal bridge, and maximizing the maintenance of functional fine feeling and contraction of the anus. The advantages of the TST stapler are clear operation visual field, ease of operation, no damage to the perianal body and anal sphincter, small operation wound, and no or low recurrence.

The present study suggests a number of means that can be used to decrease the occurrence of complications after RVF repair. First, proper intestinal and vaginal preparation is necessary, including no defecation before postoperative day 5, avoiding any postoperative intestinal content that could increase the intestinal wall pressure, causing postoperative infection. In addition, the use of mannitol to thoroughly clean the intestinal tract and iodine gauze in the vagina can help decrease the occurrence of infections. Second, achieving tension-free anastomosis while adequately separating the rectum from the vagina may help decrease anastomosis leakage and wall perforation. Third, scar tissues surrounding the fistula resection should be removed to facilitate healing. Suture should be half-made before completing it, to ensure that the suture fistula does not lift the surrounding tissue fistula. Fifth, 4–6 sutures should be made through the fistula, to tighten the tissue surrounding the fistula completely into the inner stapler. Finally, appropriate drainage should be placed, if needed, reducing the pressure inside the anus. However, additional studies might be needed to improve this approach.

In the present study, the success rate was 100% after 1–3 years using the TST approach, compared with 95% using the perineal approach. Although the sample size was small, these findings suggest a success rate that could be better for the TST approach than for other approaches. Nevertheless, specific events were due to treatment failure in the control group and additional studies are necessary and with a longer follow-up. In addition, the TST approach had some advantages over transanal endorectal advancement flap, such as small trauma, easy operation, high quality of anastomosis, and high safety. The Martius flap technique is associated with a success rate of 65–100%.[22] Gracilis muscle interposition is associated with a success rate of 33–100%.[23] The use of collagen matrix biomesh showed promising initial results, but 25% of patients showed recurrence.[24] Other and older methods are available, and all are associated with moderate to high recurrence rates.[5,7] A previous study using another type of stapler also showed promising results, with a success rate of 100%.[25]

This is the first study using the TST for the treatment of rectovaginal fistula and the exact complications are unknown. Nevertheless, based on the literature about the use of the TST for hemorrhoids, we could expect some complications such as urine retention, difficult bowel movement, intractable pain, and anal discharge, but these complications have been shown to be less frequent with the use of the TST compared with conventional hemorrhoid surgery.[26] No such complications were observed in the present study, irrespective of the group.

The present study is not without limitations. Indeed, the sample size was small and from a single center. Additional studies are required to adequately assess the efficacy of this approach.

In conclusion, TST appears to be appropriate for the candidate treatment of low RVF in adults.

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