

Outcome and quality of life following gracilis muscle transposition flap in management of recurrent and complex rectovaginal fistulas

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Background

Treatment of complex and recurrent rectovaginal fistulas (RVF) is a challenge, with high recurrence rates. Gracilis muscle transposition (GMT) is an option for management of such cases. The aim of this study was to evaluate the outcome of GMT in management of patients with recurrent or complex RVF and the effect of this procedure on the quality of life (QoL) and the sexual function.

Patients and methods

The current study included 23 female patients presented with recurrent and complex RVF who were eligible to undergo GMT. Early postoperative complications were reported. Follow-up was extended up to 24 months to detect recurrence. QoL and sexual function were evaluated using Colorectal-Anal Impact Questionnaire-7 scale from Pelvic Floor Impact Questionnaire-short form 7 and the Female Sexual Function Index, respectively.

Result

The mean age of the included patients was 43.6±10.16 years. Early postoperative follow-up reported surgical site infection and functional lower limb problem in 13%, and hematoma, deep vein thrombosis, and hypoesthesia in only 4% of cases for each. Recurrence was reported in 21.5% of cases, with fistula-free time of 7.6±2.3 months. There was a statistically significant difference in Female Sexual Function Index in patients with preoperative sexual problem ($P=0.001$) and in Colorectal-Anal Impact Questionnaire-7 scale before and after graciloplasty ($P=0.0001$).

Conclusion

GMT is assumed to be an optimal option for recurrent and complex RVFs, with minimal postoperative complications and high success rates. Patients who underwent GMT showed significant improvement of the female sexual function and the overall QoL.

Keywords:

complex rectovaginal fistula, graciloplasty, quality of life

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Background

Rectovaginal fistula (RVF) is an uncommon condition, not exceeding 5% of the perianal fistulas with major physiological and psychological effect [1,2]. RVF has multiple etiological factors including obstetric trauma followed by Crohn's disease, irradiation to the pelvis such in cases of cervical and endometrial carcinomas, malignancy, and postoperative complications [3]. RVF could be classified into the following: (a) simple fistulas, including small (<2.5 cm) and low fistulas secondary to trauma or infection with characteristic surrounding well-vascularized and healthy tissue, and (b) complex fistulas, including large (>2.5 cm), high, or fistulas complicating inflammatory bowel disease. Recurrent fistulas are also complex owing to their association with poor blood supply and tissue scarring [4].

Several surgical techniques were developed for treatment of RVFs. Transvaginal or perineal approaches including

fibrin glue, biomesch, or even local advancement muscle flaps like Martius flaps can be used with satisfactory outcome in treatment of simple low and middle fistulas [5]. Repair of complex fistulas is a challenge; therefore, many complex procedures including Sartorius muscle flap and gracilis muscle transposition (GMT) were developed. High fistulas can be approached through abdominal operations that may include proctectomy or diversion colostomy [2].

There is very high incidence of recurrence after treatment of RVF, and this may be attributed to chronic inflammation, infection, repeated trauma, pressure necrosis, and previous irradiation and

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associated comorbidities such as diabetes and smoking [5]. Recurrent RVFs are more complex due to poor vascularity, tissue scarring and absence of the rectovaginal septum. The success rates decrease with each additional attempt [6]. More than 50% of the recurrences take place within 5–7 months [7].

GMT flap creates a muscle layer between the rectum and vagina replacing the lost rectovaginal septum and provides a good blood supply by interposing the vascularized muscle that allows healing of the wall defects and directs closure of the direct fistula [8]. GMT flaps are associated with many postoperative complications such as prolonged sexual dysfunction. Short-term functional impairment of the corresponding lower limb has been reported in 26% of the patients for ~6 months and long-term difficulties occurred in 6% of patients [7].

The debates about the efficacy and the cost benefit of GMT for management of complex RVF and its effect on the patient quality of life (QoL) have motivated the authors to conduct this study to evaluate both short-term and long-term outcomes of the gracilis flap transposition in cases with complex and recurrent RVF.

Patients and methods

Study design and patients

The current prospective clinical study was conducted at the General Surgery Department, Tanta University and Colorectal Surgery Unit, Benha University, throughout the period from June 2015 till May 2020. Approval to conduct the research was obtained from local ethical and research committees Benha University. A written informed consent was obtained from all participants included in this study.

The current study included 23 patients presented with recurrent and complex RVF, with exclusion of surgically unfit patients, as well as simple or malignant fistulas. Patients who did not complete 24-month follow-up were excluded. Before consideration of enrollment of eligible patients, all included patients underwent detailed history taking about age, duration of the complaint, possible cause, presence of comorbidities, and duration and severity of incontinence if present.

Physical examination was performed to assess presence, location of the fistulous openings, and the function of the anal sphincter. Presence of local inflammatory manifestations suggests Crohn's disease, radiation

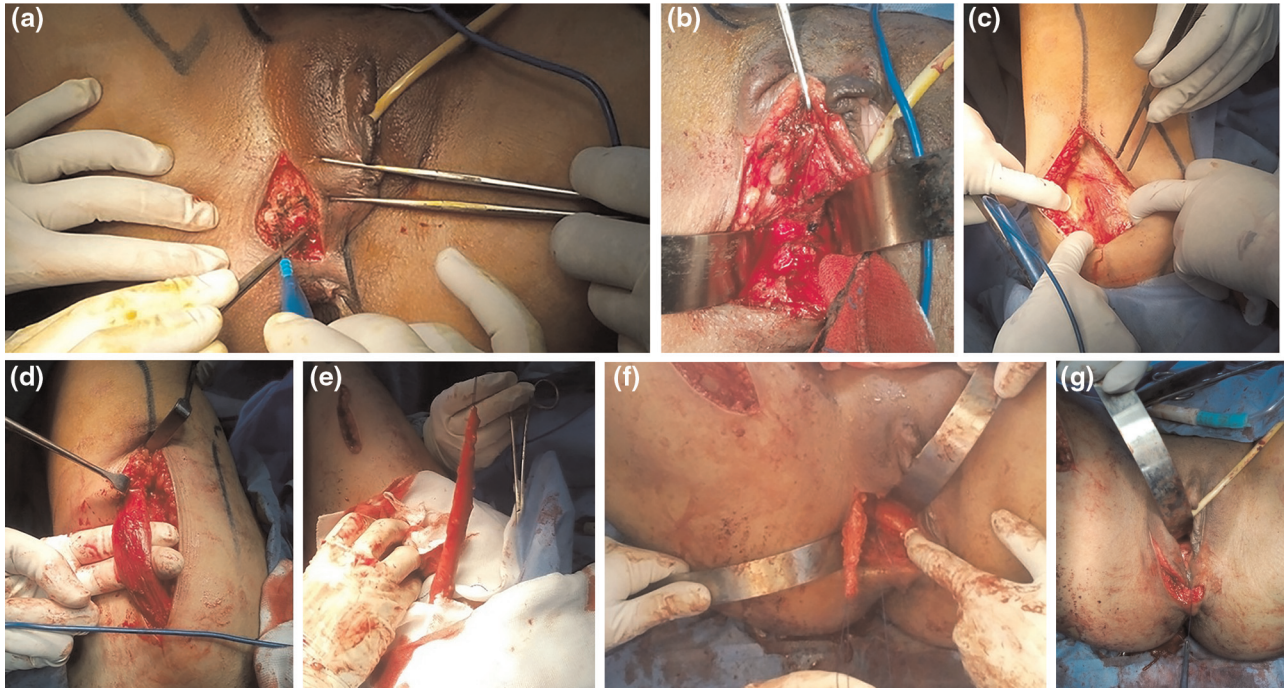
injury, or uncontrolled local sepsis. Bidigital examination was done for assessment of tissue induration, and integrity of the anterior perineal body. In the presence of associated incontinence, a baseline of Vaizey incontinence score [9] was applied to detect its degree. Two-dimensional and three-dimensional transanal ultrasonography using BK Medical Flex Focus 400 (Denmark), was performed to confirm the site of the fistula and to evaluate any sphincteric defects. MRI was performed if the transanal ultrasonography was inconclusive. Colonoscopy was done in suspected cases of inflammatory bowel. Examination under anesthesia with biopsies was performed in patients with past history of malignancy.

In the current study, the QoL was assessed using Colorectal-Anal Impact Questionnaire (CRAIQ-7) scale from Pelvic Floor Impact Questionnaire-short form 7 [10]. The score is calculated using the mean value for the answered items within the scale (value 0–3) and then multiply by 100/3 to obtain the final score (range, 0–100). Zero score means no effect of symptoms in the last 3 months on the QoL, whereas 100 score means the maximum effect. Moreover, the female sexual function was assessed through the Female Sexual Function Index (FSFI) [11], in which the maximum score is 36, and the minimum is 2, whereas 0 means no sexual relation in the past month.

Operative steps

While the patient in lithotomy position, a perineal incision was done, and dissection was processed till complete separation of the rectum from the vaginal wall to remove the fistulous tract completely (Fig. 1a, b). Debridement of both vaginal and rectal fistulous openings and separate repair of the rectal wall and the vaginal wall with interrupted 3/0 Vicryl sutures were performed. The gracilis muscle was palpated, then through a 10-cm incision in the medial aspect of the upper part of the thigh and another small incision in the lower part of the medial side of the thigh over its tendon was done (Fig. 1c, d). Then the muscle was cut at its tendon. Mobilization of the gracilis muscle with intact neurovascular pedicle was done (Fig. 1e). Through subcutaneous tunnel, the muscle flap was transferred to the perineal incision after proper mobilization to ensure that the muscle flap was not under tension (Fig. 1f). The gracilis flap was then embedded between the rectum and vagina and was secured to the apex of dissection with interrupted sutures to hold the muscle in place. Proper attention was given to avoid kinking of the muscle. The gracilis flap was then covered by soft tissue of the perineal wound, and finally, closure of all incisions was done.

Figure 1



Gracilis muscle flap transposition. (a) Perineal dissection. (b) Identification and dissection of the fistulous tract. (c) Identification and dissection over the gracilis muscle. (d) Dissection of the gracilis muscle. (e) Full mobilization of the gracilis muscle. (f) Transposition and inset of the gracilis muscle flap. (g) Closure of the perineal wound.

Ileostomy was done routinely for all cases, and restoration of GIT continuity was done 12 weeks later after ensuring healing of the perineal wound.

Evaluation and follow-up

Follow-up was aimed to detect any postoperative complications, recurrence, improvement in the incontinence (if present) though Vaizey incontinence score, or any significant sexual or functional effect on the patient's life. Follow-up took place in the outpatient clinic after 1 week, and then 1 month, 3 months, 1 year, and 2 years after discharge. To assess cases of recurrence, an enema using water-soluble contrast with complementary endoanal ultrasonography were performed 3 months, 1 year and 2 years after the operation to detect any recurrence. Stoma reversal was planned after closure of a fistula tract.

The primary outcome measure was successful closure of the fistula with minimal early postoperative complications. Secondary outcomes included improvement of QoL of the patient.

Statistical analysis

Statistical analysis was done using SPSS, version 25. Numerical variables were expressed as mean and SD. Paired samples *t* test was used for testing statistically significant difference between the means of the same

group at before and after test, where *P* value less than 0.05 was considered statistically significant. Contingency coefficients were used to estimate the extent of the relationship between two variables, or to show the strength of a relationship. The contingency coefficient (*C*) values were described as less than or equal to 0.4 low associations, 0.4–0.7 middle association, whereas more than or equal to 0.7 described as high association.

Results

The current study included 23 women patients presented with recurrent and complex RVF, with mean age of 43.6 ± 10.16 years. Overall, 21% of them were hypertensive and 17.5% were diabetics (Table 1). Fistula characteristics are shown in Table 1, where the main cause was obstetric trauma (78.5%) followed by inflammatory bowel disease (17.5%). The mean operative time was 131 ± 21.5 min, and mean hospital stay was 6.7 ± 1.2 days.

Recurrence was reported in 21.5% of cases with fistula-free time of 7.6 ± 2.3 months. Other postoperative complications are shown in Table 2, where SSI and functional lower limb problem were reported in 13% of cases, tender scar in 8.7% of cases, whereas hematoma, deep vein thrombosis, and hypoesthesia in only 4% of cases each.

Table 1 Sociodemographic data and clinical characteristics

Patient	
Age	Mean=43.6, SD=10.16
HTN [n (%)]	5 (21.5)
DM [n (%)]	4 (17.5)
Smoking [n (%)]	1 (4)
Fistula characteristics [n (%)]	
Duration (months)	
≤ 6	7 (30)
6–12	6 (26)
12–24	8 (35)
>24	2 (9)
Type	
Primary	10 (43)
Recurrent	13 (57)
Cause	
Obstetric trauma	18 (78.5)
Inflammatory bowel	4 (17.5)
Others	1 (4)
Level	
Low	8 (35)
Middle	12 (52)
High	3 (13)
Incontinence	3 (13)
Mean operative time	131±21.5 min
Mean hospital stay	6.7±1.2 days

DM, diabetes mellitus; HTN, hypertension.

Table 3 shows clinically improvement of sexual problems presented before graciloplasty, but this was not statistically significant ($P=0.426$) and the same for incontinence score ($P=0.017$). There was a statistically significant difference in FSFI in patients with preoperative sexual problem ($P=0.001$). Moreover, there was a statistically significant difference in QoL before and after graciloplasty assessed by CRAIQ-7 scale ($P=0.0001$).

There was Low Contingency coefficients (C) correlation between the incidence of postoperative recurrence and type and level of fistula where C values were 0.293 and 0.353 respectively. Strong contingency coefficients (C) correlation was reported between recurrence and cause of fistula ($C=0.855$) (Table 4).

Discussion

RVFs are often worrisome to the patient and therefore to the surgeon because of their irritating symptoms, high recurrence rate, and psychological effect [4]. Successful treatment requires proper understanding and analysis of the many variables including etiology, type, location of the fistula, and tissue quality [3]. Tissue interposition is considered the option of choice in treatment of complex and recurrent cases [4]. GMT does not close the existing

Table 2 Postoperative complications

Variables	n (%)
Recurrence	5 (21.5)
Fistula-free time	Mean=7.6, SD=2.3
No complications [n (%)]	16 (69.5)
SSI	3 (13)
Hematoma	1 (4)
Tender scar	2 (8.7)
Hypoesthesia	1 (4)
DVT	1 (4)
Functional LL problem	3 (13)

DVT, deep vein thrombosis.

fistulas itself as was first described since 1930s, but its main value is in reduction of the dead space in the perineum and improvement of vascularity in the healing areas with impaired blood supply owing to soft tissue loss in the previous operations [12].

In the current study, 23 female patients underwent GMT, with mean operative time of 131 ± 21.5 min, and mean hospital stay of 6.7 ± 1.2 days. Overall, 18 (78.5%) of them were caused by obstetric trauma. This was less than Ommer *et al.* [13], who reported that ~88% of cases were owing to obstetric trauma.

All the patients underwent temporary covering fecal diversion following the recommendation of Fu *et al.* [1] and Das and Snyder [3], who recommended it routinely in all complex cases.

Patients in the current study were followed in the outpatient clinic for 24 months. This follow-up period was longer than Maeda *et al.* [14] and Chen *et al.* [15], who followed their patients for 10 and 18 months, respectively, but still a bit shorter than Lefevre *et al.* [16], in which their average follow-up period extended up to 28 months.

In the current study, 30% of the patients had developed early postoperative complication, and most of them were mild and treated conservatively in the form of surgical site infection, hematoma, thigh hypoesthesia, and tender scar. This percentage is higher than what was reported by Wexner *et al.* [17], who described 14% postoperative complication rate. The most common early postoperative complication was the surgical site infection (13%). This percentage is comparable with Fu *et al.* [1] (10%) but still less than Kalra *et al.* [18] (20%).

Lower limb functional complications were 13%, and all of them were reversible. This is less than what reported by Kniery *et al.* [7], who found 26% short-term lower

Table 3 Preoperative and postoperative findings

Variables	Before graciloplasty [n (%)]	After graciloplasty [n (%)]	P value
Sexual problem	5 (21.5)	3 (13)	0.426
	Mean and SD	Mean and SD	
Incontinence score			
Total	1.26±2.36	0.17±0.39	0.017
In incontinent patients	4.67±3.21	0.67±0.58	0.12
FSFI			
Total	28.04±9.5	29.43±9.43	0.015
In patients with preoperative sexual problems	25±1	30.4±1.14	0.001*
CRAIQ-7 scale	52.54±8.78	16.15±6.7	0.0001*

Paired samples *t* test. CRAIQ-7, Colorectal-Anal Impact Questionnaire; FSFI, Female Sexual Function Index. *Statistically significant.

Table 4 Correlation between age, fistula characteristics, and postgraciloplasty recurrence

	Number of recurrence/number of patients (%)	C value
Age (years)		0.574
<50	4/16 (25)	
≤50	1/7 (14.3)	
Cause		0.855
Obstetric trauma	2/18 (11)	
Crohn's disease	2/4 (50)	
Radiation	1/1 (100)	
Type		0.293
Primary	2/10 (20)	
Recurrent	2/13 (15)	
Level		0.353
High	2/3 (66)	
Middle	2/12 (17)	
Low	1/8 (12.5)	

C, contingency coefficient.

limb functional affection (<6 months) and 6% long-term affection.

There was no mortality in the current study. Similarly, Picciariello *et al.* [19] also mentioned that no mortality was reported in their study.

In the current study, the success rate of GMT was 79.5%. and this is comparable to Rottoli *et al.* [20] and Picciariello *et al.* [19], who reported success rates of 75 and 78%, respectively. However, it is better than Wexner *et al.* [17] who reported success rate of 44%. This success rate reported in the current study was less than Korsun *et al.* [12], Fürst *et al.* [21], and Crestani and Dal Moro [22], who described success rate of 88, 90, and 94%, respectively, and this is assumed to be owing to inclusion of simple RVFs in their studies.

Gracilis muscle transfer achieved superior results when compared with other techniques, like Martius flap

(65% success rate) [23], and endorectal advancement flap (45%) [24].

The average fistula-free time was found to be 7.6±2.3 months. This was shorter than what was mentioned by Korsun *et al.* [12] (17 months) but was still longer than what was reported by Rottoli *et al.* [20] (3.5 months).

The incidence of recurrence was found to be higher in cases with Crohn's disease in comparison with obstetric trauma (50 and 11%, respectively). This result agreed with Pinto *et al.* [25]. Moreover, the risk of recurrence increases with the higher levels of the fistula (high fistula was associated with 66% recurrence rate), and this is also in agreement with Ryoo *et al.* [2], who stated that high RVF is associated with poor outcome and high recurrence rate.

In the current study, it was found that the history of previous repair and the age of the patient did not affect the outcome of GMT. The same was mentioned by Pinto *et al.* [25]. On the contrary, Lalwani *et al.* [26] mentioned that recurrent cases give poor results, and each attempt of repair causes more damage and devascularization that impair the subsequent healing process. RVF regularly involves the sphincteric apparatus affecting the continence mechanism [8]. In the current study, 13% of the patients had some degree of fecal incontinence. The degree of incontinence assessed by Vaizey score showed postoperative improvement in the complaining patients from 4.67±3.21 to 0.67±0.58. This agreed with Picciariello *et al.* [19] who found ~50% improvement of the continence after GMT assessed by Wexner score.

Khalil *et al.* [27] stated that RVF causes significant sexual morbidity in the sexually active females. In the current study, the sexual function was assessed with FSFI questionnaire, which is a valid and reliable questionnaire [11]. Overall, 21% of the sexually

active patients were found to have sexual problems. However, a statistically significant improvement of FSFI score was noticed postoperatively (30.4 ± 1.14) compared with preoperatively (25 ± 1) ($P=0.001$). The same conclusion was approached by Picciariello *et al.* [19], who demonstrated 14% improvement in the Change of Sexual Function Questionnaire. On the contrary, these results disagreed with Ommer *et al.* [13] who stated that 25% of the female subjected to graciloplasty developed sexual complaints postoperatively mainly related to pain. Moreover, Kniery *et al.* [7] concluded that 57% of the operated patient developed dyspareunia, and this significantly affected the sexual desire.

There was a statistically significant improvement in the patient QoL collectively assessed through CRAIQ-7 scale postoperatively (16.15 ± 6.7) compared with preoperatively (52.54 ± 8.78) ($P=0.0001$). The same was reported by Picciariello *et al.* [19] Moreover, Kalra *et al.* [18] concluded that GMT significantly improves the QoL in patients presented with fecal incontinence.

Conclusion

According to our results, GMT is assumed to be an optimal option for recurrent and complex RVFs with minimal postoperative complications and high success rates. Patients who underwent GMT showed significant improvement of the sexual function and the overall QoL.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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