Outcome and quality of life following gracilis muscle transposition flap in management of recurrent and complex rectovaginal fistulas
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\begin{abstract}
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 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, biomesh, 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
\end{abstract}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{Graphic representation of complexity in RVF management.}
\end{figure}

\textbf{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, graciplasty, quality of life

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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
date 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.
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.
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 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
Graciloplasty in complex rectovaginal fistula Kharoub et al. 5

Table 3 Preoperative and postoperative findings

<table>
<thead>
<tr>
<th>Variables</th>
<th>Before graciloplasty [n (%)]</th>
<th>After graciloplasty [n (%)]</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexual problem</td>
<td>5 (21.5)</td>
<td>3 (13)</td>
<td>0.426</td>
</tr>
<tr>
<td>Mean and SD</td>
<td></td>
<td>Mean and SD</td>
<td></td>
</tr>
<tr>
<td>Incontinence score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>1.26±2.36</td>
<td>0.17±0.39</td>
<td>0.017</td>
</tr>
<tr>
<td>In incontinent patients</td>
<td>4.67±3.21</td>
<td>0.67±0.58</td>
<td>0.12</td>
</tr>
<tr>
<td>FSFI</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>28.0±9.5</td>
<td>29.4±9.43</td>
<td>0.015</td>
</tr>
<tr>
<td>In patients with preoperative sexual problems</td>
<td>25±1</td>
<td>30.4±1.14</td>
<td>0.001*</td>
</tr>
<tr>
<td>CRAIQ-7 scale</td>
<td>52.5±8.78</td>
<td>16.1±6.7</td>
<td>0.0001*</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Number of recurrence/number of patients (%)</th>
<th>C value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>4/16 (25)</td>
</tr>
<tr>
<td>≤50</td>
<td>1/7 (14.3)</td>
</tr>
<tr>
<td>Cause</td>
<td></td>
</tr>
<tr>
<td>Obstetric trauma</td>
<td>2/18 (11)</td>
</tr>
<tr>
<td>Crohn’s disease</td>
<td>2/4 (50)</td>
</tr>
<tr>
<td>Radiation</td>
<td>1/1 (100)</td>
</tr>
<tr>
<td>Type</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>2/10 (20)</td>
</tr>
<tr>
<td>Recurrent</td>
<td>2/13 (15)</td>
</tr>
<tr>
<td>Level</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>2/3 (66)</td>
</tr>
<tr>
<td>Middle</td>
<td>2/12 (17)</td>
</tr>
<tr>
<td>Low</td>
<td>1/8 (12.5)</td>
</tr>
</tbody>
</table>

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, Labwani 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, Knieri 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 \((52.5±8.78)\) \((P=0.0001)\). 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.

**Financial support and sponsorship**
Nil.

**Conflicts of interest**
There are no conflicts of interest.

**References**
AQ3: Please check the edits made in the sentence “RVF could ... bowel disease.” and correct if necessary.

AQ4: Please check the edits made in the sentence “GMT flap ... direct fistula” and correct if necessary.

AQ5: Please provide city location for BK Medical Flex Focus 400.

AQ6: Please provide manufacturing information for SPSS: company name, town, state (if USA), and country.

AQ7: Please check the edits made in the sentence “Paired samples ... statistically significant.” and correct if necessary.