Original Research Article

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Effect of marsupialization on the healing of fistulotomy wounds of simple anal fistula: a randomized control trial

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ABSTRACT

Background: An anal fistula is traditionally treated by fistulotomy, adding marsupialization of fistulotomy wounds is optional. The aim of the current study was to compare the outcomes of fistulotomy with marsupialization and fistulotomy alone for simple anal fistula on healing rates and post-operative complications

Methods: 50 patients with simple anal fistula randomly allocated to two groups fistulotomy alone group (F)and fistulotomy with marsupialization group(FM). The primary outcome was the healing time secondary outcomes included postoperative pain, operating time, incontinence and recurrence.

Results: Mean age of group (F) patients was 37.55 ± 1.96 years with a male: female ratio of 19:6 while the mean age of group (FM) patients was 36.30 ± 3.03 years with a male: female ratio of 21:4. Mean operative time in the group (F) was 23.5 ± 3.3 minutes while in the group (FM) It was 29.00 ± 4.595 minutes difference is statistically significant. Mean time for complete healing in group (F) was 6.9 ± 0.73 weeks while in group (FM) was 4.80 ± 0.96 weeks difference is significant statistically. Mean postoperative pain score by visual analogue scale in the group (F) was 3.4 ± 1.2 while in the group (FM) it was 3.3 ± 1.3 this difference is statistically non-significant. No recurrences or incontinence.

Conclusions: Study demonstrated faster-wound healing when adding marsupialization to fistulotomy compared to fistulotomy alone. There is an increase operative time with marsupialization. This effect is minimal when compared with the benefits of enhanced healing. Limitations are mainly the inadequate sample size and inadequate follow-up period.

Keywords: Anal fistula, Fistulotomy Marsupialization

INTRODUCTION

Anal abscesses and fistulae are common surgical problems. Management of the most of fistulae is straightforward. It is based on excellent knowledge of the anatomy of the sphincter complex and adherence to established surgical principles. An anal fistula is traditionally treated by fistulotomy. It is still used by the majority of surgeons as the "gold standard" for treatment of fistula-in-ano.¹

Although recurrence rates are low with such procedure. Fistulotomy leaves a raw area with the unepithelialized

wound. Such a wound may need hospital admission for irrigation and frequent dressing also there are chances of bleeding from the raw area and chances for recurrence of sepsis.^{2,3} Adding marsupialization of fistulotomy wounds is an optional treatment for anal fistula.⁴

It involves suturing of the skin edges to the laid opened fistula. There are insufficient randomized controlled data to compare the lay open technique with or without adding marsupialization. The aim of the current study was to compare the outcomes of fistulotomy with marsupialization and fistulotomy alone for simple anal fistula.

METHODS

This study is a randomized control trial where 50 patients with simple anal fistula randomly divided into two groups each is twenty-five patients by computer-generated randomization. The Present study was performed at the colorectal unit of the general surgery department. Cairo University from November 2014 to November 2016

After being approved by the committee of research ethics. All patients signed informed detailed consents and agreed to have the treatment and to participate in the study.

Inclusion criteria were low trans-sphincteric fistula, intersphincteric fistula, and subcutaneous fistula. fistula should have only a single internal and a single external opening without any secondary tracts.

Exclusion criteria were as follows, patients having recurrent or complex fistulae, associated anorectal comorbidities (piles, anal fissure etc.,), patients receiving drugs that negatively affect wound healing (such as steroids or chemotherapy), or patients refusing consent for participation in the study.

All patients were subjected to detailed history taking for their presenting symptoms, associated chronic illness, and any previous surgeries. Continence was evaluated by Wexner incontinence score.⁵ preoperative and postoperative. Preoperative digital rectal examination and 10-MHz anal endosonography (BK Medical US Scanner 1202; BK Medical, Herlev, Denmark) were done in all patients to confirm the diagnosis of simple anal fistula.

Patients were divided into two groups the fistulotomy group (F) and the fistulotomy with marsupialization group (FM).

Surgery was done under general or spinal anesthesia. The first step was a digital examination under anesthesia to confirm the diagnosis and exclude any patient that does not the inclusion criteria, followed by Injection of about 2 mL of methylene blue through the external fistula Opening then using proctoscope the internal opening is visualized. Gentle manipulation of the probe to avoid false tract creation will allow it to pass in the correct tract from external opening to reach the internal opening safely. In the fistulotomy group (F) the fistula tract was laid open over the probe then curetted and inspected carefully in order not to miss any secondary branches. In the fistulotomy with marsupialization group (FM), Wound edges were sutured to the edge of fistula tract by using interrupted 3-0 polyglactin 910 sutures to marsupialize the wound starting from distal to proximal. Marsupialization was not an easy task proximally at the friable anorectal mucosa then hemostasis was achieved.

Operative time was calculated starting from examination under anesthesia till hemostasis is achieved. All patients receive perioperative antibiotics (Ciprofloxacin and metronidazole) and postoperative analgesia for three days (Diclofenac sodium 50 mg twice daily). All patients were discharged on a postoperative day one with instructions to maintain local hygiene, sitz bath following defecation, dressings, and regular follow-ups.

The pain was assessed on day one and in every follow-up visit by visual analogue scale(VAS). Follow up duration of 12 weeks. The visits were weekly in the first four weeks then at two weeks interval thereafter till the end of the 12 weeks. Follow up visits includes assessment of pain by the visual analog scale score, incontinence by Wexner incontinence score, recurrence, and infection which was defined as erythema induration and fever. Time for complete healing was calculated where it was defined as the time needed for complete epithelialization of the wound.

The primary outcome was the healing time secondary outcomes included postoperative pain, operating time, incontinence and recurrence

Statistical analysis was performed using the SPSS ver. 17.0 (SPSSInc., Chicago, IL, USA). Chi-square test was used for comparison of Qualitative data while t-test was used to compare quantitative data from both groups.

RESULTS

Fifty patients with the clinical and radiological diagnosis of simple anal fistula were enrolled in the current study. The mean age of group (F) patients was 37.55 ± 1.96 years with a male: female ratio of 19:6 while the mean age of group (FM) patients was 36.30 ± 3.03 years with a male: female ratio of 21:4.

Group	Mean age	Male /female	Subcutaneous fistula	Intersphincteric fistula	Transsphicteric fistula
Fistulotomy (F)	37.55±1.96	19:6	9	9	7
Marsupialialization (FM)	36.30±3.03	21:4	7	8	10

Table 1: Preoperative characteristics of two groups.

Group		Operative Time	Healing Duration	Post- Operative Pain Score	Bleeding N=3	Sepsis N=4	Recurrence	Incontinence
Fistulotomy (F)	Mean	23.50	6.9	3.4	12%	16%	None	None
	SD	3.375	0.73	1.2				
Marsupialialization (FM)	Mean	29.00	4.80	3.3	0	12% (N=3)	None	None
	SD	4.595	0.96	1.3				

Table 2: Postoperative outcome in two groups

In group (F) there were nine patients with subcutaneous fistulae, nine patients with intersphincetric fistulae and seven patients with low trans-sphincteric fistula, In group (FM) there were seven patients with subcutaneous fistulae, eight patients with intersphincetric fistulae and ten patients with low trans-sphincteric fistula Table 1.

The mean operative time in the group (F) was 23.5 ± 3.3 minutes while in the group (FM) It was 29.00 ± 4.595 minutes with a P value equals 0.0060 this difference is considered statistically significant.

The mean time for complete healing in the group F was 6.9 ± 0.73 weeks while in the group (FM) it was 4.80 ± 0.96 weeks with a P value equals 0.001 which is considered to be very significant statistically.

The mean postoperative pain score by visual analogue scale (VAS) in the group (F) was 3.4 ± 1.2 while in the group (FM) it was 3.3 ± 1.3 with a P value equals 0.77 this difference is considered statistically non-significant. Pain scores during follow-up visits were evaluated and compared. There was no significant difference seen between the two groups. The pain disappeared (VAS score less than 1) at about the third week of follow up in both groups Table 2.

All patients had smooth postoperative recovery except for three patients in the fistulotomy alone group had bleeding from the wound. However, its level was marginal significance (P-value= 0.0501). Wound inflammation was found in four patients in (F) group compared to three patients in the (FM) group but statistically was of no significant value.

No cases of recurrence or incontinence were reported in this study.

DISCUSSION

An anal fistula can be treated with different methods. These include either excision, lay open or curettage of fistula tract and placement of skin or mucosal flaps. It may also include coring out of the tract, placement of setons and injection of fibrin glue. Despite the variation of such methods the majority of surgeons still trust the conventional lay open technique [fistulotomy], as the 'gold standard' for treatment of anal fistula.^{1,6}

On one hand, the mean operative time actually was longer with adding marsupialization technique the difference between two groups was of statistical significance. In group (F) it was 23.5 ± 3.3 minutes while in the group (FM) It was 29.00 ± 4.595). This seems to be logic as adding more steps will add to the operative time. In a study of 103 fistula patients for whom a fistulotomy or a fistulotomy with adding marsupialization was done, a longer operating time was required for the marsupialization step.⁷

A study included fourty patients, the operating time was nearly the same and the difference between the two groups was not statistically significant. Yet it was comparing fistulectomy that usually consumes more time to fistulotomy and marsupialization.⁸

On the other hand, the healing time showed a statistically significant difference that was observed between the two groups, while the mean healing time was in the group (F) (6.9 ± 0.73 weeks) it was in the group (FM) (4.80 ± 0.96 weeks). The difference in healing rates with marsupialization was found to be statistically significant (P value = 0.003).

Thus, marsupialization when added to fistulotomy wounds, enhances healing. In group (FM) wounds were smaller after marsupialization with less infection.⁹ A study by Kronborg pointed out that median healing time was 5.85 weeks in fistulectomy wounds in comparison to 4.55 weeks for fistulotomy wounds.¹⁰ Thus fistulotomy heals faster than fistulectomy.

Ho et al., showed in their study that marsupialized wounds heal faster than non-marsupialized wounds.⁸ Though the mean VAS score was high for the marsupialized group statistically no significant difference noted between both groups.

Similar results were obtained by Pescatori et al., They found that the mean pain score postoperatively was

higher in the marsupialized group. But was also statistically insignificant (P > 0.05).⁹

Recurrent infections are an important issue. One may argue that marsupialization of a post-fistulotomy wound may favor an earlier skin healing thus leading to a nonhealed deep cavity which in turns increases the risk of infection and recurrence.

The author found neither increase in infection rates nor recurrences in the marsupialization group.

The risk of wound bleeding was reduced by marsupialization this may be related to decreasing the raw area and suturing of the skin edges which has a hemostatic effect. The risk of bleeding is lower when adding marsupialization.⁹

Anal incontinence was not present in any patient in both groups. No recurrences in any patient of the study population during the follow-up period.

Although The duration of observation in the current study was not sufficient, yet all complex and high fistula was initially excluded which in fact have the highest incidence of recurrence and incontinence problems.^{11,12}

The small sample size, short follow up period is of the limitations of the current study. Another limitation is the subcutaneous fistulae number in both groups of patients. Treatment of such fistulae is unlikely to affect continence.

CONCLUSION

This study demonstrated faster-wound healing time when adding marsupialization to fistulotomy if compared to fistulotomy alone. Although there is an increase operative time consumed with marsupialization.

This effect is minimal when compared with the benefits of enhanced healing gained by applying this technique.

Limitations are mainly the inadequate sample size and inadequate follow-up period. These findings need to be substantiated with further studies avoiding the previously mentioned limitations.

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