

Treatment with Wound Edges Marsupialization of Simple Anal Fistula: A Randomized Controlled Trial

Rahman MM¹, Rahman MM², Chowdhury SA³, Kabir R⁴DOI: <https://doi.org/10.3329/jafmc.v19i1.68356>**Abstract**

Introduction: Simple anal fistula, a common anorectal disease, can be treated with various surgical techniques, including fistulectomy and fistulotomy. Wound edge marsupialization, a procedure that involves everting the fistula tract onto the skin surface, has been proposed as a potential adjunct to improve healing outcomes.

Objective: To evaluate the efficacy and safety of wound edge marsupialization in the treatment of simple anal fistula.

Methods: A prospective randomized controlled trial was conducted, involving 60 consecutive patients with simple anal fistula. Patients were randomly allocated into two groups: Group A underwent fistulotomy alone (n=30), while Group B underwent fistulotomy with marsupialization (n=30). The primary outcome measure was wound healing time. Secondary outcome measures included operating time, postoperative wound size, pain score, bleeding, infection, incontinence, recurrence and patient satisfaction.

Results: The mean operating time was significantly shorter in Group A compared to Group B (21.00±6.35 minutes vs. 28.20±6.57 minutes, p=0.0001). Postoperative wound size was significantly larger in Group A than Group B (2.07±0.90cm² vs. 1.03±0.87cm², p<0.0001). Postoperative bleeding was less frequent in Group B (10%) than in Group A (53.33%, p=0.0003). Wound discharge duration was significantly longer in Group A (4.10±1.8 weeks) compared to Group B (2.05±1.71 weeks, p<0.0001). Postoperative wound healing time was significantly faster in Group B compared to Group A (3.85±1.19 weeks vs. 6.55±1.3 weeks, p<0.0001). Visual analogue scale (VAS) scores for postoperative pain on the first day post-surgery were lower in Group B compared to Group A (4.05±1.47 vs. 5.15±1.32, p=0.0035).

Conclusion: This study demonstrates that wound edge marsupialization as an adjunct to fistulotomy significantly reduces wound healing time, post-operative bleeding risk, and wound size without increasing the risk of postoperative anal incontinence, recurrence or sepsis.

Key words: Anal Fistula, Fistulotomy, Marsupialization.

Introduction

Anal fistula stands as one of the prevalent benign conditions observed in general surgery. It involves an abnormal epithelized tract linking two surfaces, often the rectal mucosa and perianal skin.¹ Typically stemming from an anorectal abscess that either ruptures spontaneously or arises due to inadequate surgery,^{2,3} an anal fistula emerges from an acute infection of the anal crypt. This infection, when chronic, leads to the formation of a persistent anal fistula. Traditionally, two surgical options have been prevalent for addressing a simple anal fistula: fistulotomy and fistulectomy.⁴ The former involves complete excision of the fistulous tract, while the latter keeps the tract open, resulting in unepithelized wounds that may necessitate hospitalization for irrigation and dressing. Moreover, there exists a risk of bleeding and recurrent sepsis. Although a recent colorectal textbook deems post-fistulotomy marsupialization as 'optional',⁵ it remains the most commonly practiced procedure in certain specialized centers.⁶⁻⁸ The objective of this randomized prospective study is to compare the postoperative outcomes between marsupialized and open wounds in patients who underwent fistulotomy or fistulectomy for a simple anal fistula.

Materials and Methods

This prospective randomized single blind clinical trial took place between January 2018 and December 2019 in the general surgical wards of BNS PATENGA hospital in New Mooring, Chittagong. The study included all adult patients of both sexes admitted to surgical wards with a clinical diagnosis of a low anal fistula. The following were the inclusion criteria: A single internal and external opening; no secondary tract and a low fistula-in-ano. Patients with recurrent fistulas, as well as those with associated comorbid conditions such as anal fissures, haemorrhoids, chronic colitis, diabetes mellitus, and those who did not give consent to participate in this study, were excluded. All patients included in the study were interviewed to ascertain their clinical histories including presenting symptoms; duration of symptoms; history of anorectal sepsis, previous anorectal surgery and chronic illness.

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Inquiries were made to assess anal continence in each patient. The trial was single blinded as patients were aware of the nature of the study, but not of the type of procedure what the operating surgeon was aware of. The patients were operated on under spinal anaesthesia by the surgeons of the department of the hospital. Under anaesthesia, an anorectal examination was performed to verify the findings of the clinical examination.

Group A: In the fistulectomy, a keyhole skin incision was made encircled the external opening and over the fistulous tract. The incision was deepened through the subcutaneous tissue and the whole tract was excised from the surrounding tissues. Towards the anal verge, fibres of the anal sphincters overlying the tract were divided.⁹ While the tract was being removed, also sought for any secondary tracts. Haemostasis was achieved.

Group B: In the fistulectomy/fistulotomy with marsupialisation, wound edges were sutured with the edge of fistula tract by using interrupted 3-0 chromic catgut sutures to marsupialize the operative wound from distal to proximal. Apex of the wound proximally at ano-rectal mucosa was sutured to avoid stretching and tear during defecation.

The procedure's operating time was calculated from the start of the dye test to the start of postoperative wound dressing. Patients in both groups were given ciprofloxacin and metronidazole as perioperative antibiotics for three days. Analgesics included intramuscular Pethidine (75-100mg 8 hourly for 24 hours) followed by Ketorolac (10mg thrice a day) for a total of three days. Within a week of surgery, the patients were discharged. The first post-operative evaluation was performed twenty-four hours after surgery. The severity of postoperative pain was graded on a scale of 0 to 10 using VAS. The three-point Lickert scale (0, never; 1, sometimes; 2, always) was used to assess the development of incontinence based on the inability to distinguish between gas and stool, difficulty holding gas and soiling of undergarments.

Statistical data analysis was performed using the SPSS v.17. Qualitative data from the two groups were compared using the Chi-square test or Fischer's exact test while quantitative data were compared using the Mann-Whitney U test. P-values less than 0.05 were considered significant. Ethical approval to conduct the study was obtained from the Ethic Review Committee before the commencement of the study. An informed written consent was sought from patients or relatives.

Results

Sixty five patients clinically diagnosed to be suffering from simple anal fistula were enrolled in this study. Five patients were excluded as they were subsequently found

to have a complex anal fistula. The mean age of the patients in group A was 34.40±1.96 years with a male-to-female ratio of 10:1 while the mean age of the patients in group B was 35.11±2.03 years with a male to-female ratio of 8:1. The mean radial distances of the external opening from the anal verge were 2.17±0.98 cm and 1.96±0.86 cm in groups A and B, respectively (Table-I).

Table-I: Pre-operative Characteristics

Characteristics	Group A	Group B
Age (year)	34.40	35.11
Sex ratio (male:female)	10:1	8:1
Duration of symptoms (mo)	8.12	9.96
Radial distance of external opening from anal verge (cm)	2.17	1.96

The operating times was noted between the two groups (A=21.00±6.35 vs B=28.20±6.56, P<0.05). Though wound size was smaller in group B (1.03±0.87 cm²) than in group A (2.07±0.90 cm²), this difference reached statistical significance (P<0.05). Bleeding occurred less frequently in group B than in group A (10% vs 53.33%, P<0.05) and Postoperative wounds ceased to ooze earlier in group B than in group A (2.05±1.71 weeks vs. 4.10±1.8 weeks, P<0.05). Postoperative wounds healed earlier in group B (3.85±1.19 weeks) than in group A (6.55±1.3 weeks). This difference in healing time reached statistical significance with a P-value of <0.05 (Table-II).

Table-II: Post-operative Characteristics

Characteristics	Group A	Group B	P-value
Operating time	21.00	28.20	0.0001
Wound size	2.07	1.03	0.00001
Wound Oozing	4.10	2.05	0.0001
Wound Bleeding	53.33	10	0.0003
Wound healed up	6.55	3.85	0.0001
Pain VAS score (24hrs)	4.05	4.15	0.0035

None of each group had infection, recurrence or incontinence. No differences in the extents of adverse effects of surgery on the physical, social and sexual lives of the patients in the two groups (Table-III).

Table-III: Adverse effects on the lifestyles of Lay open (group A) and wound with marsupialization (group B)

Activity	Group A (n = 30)	Group B (n = 30)
Physical	Not at all	27
	To some extent	3
	Greatly	0
Sexual	Not at all	29
	To some extent	1
	Greatly	0
Social	Not at all	30
	To some extent	0
	Greatly	0

Discussion

The operating times between the two groups exhibited a significant difference (21.00±6.35 minutes vs. 28.20±6.56 minutes, P<0.05). Notably, a significant amount of time was allotted during fistulotomy with marsupialization to

suture the borders of the laid-open fistula tract to the skin incision and stabilize the wound apex. In their analysis of 103 patients who had comparable operations, Ho et al also discovered a lengthier operating time for marsupialization (8.0 ± 0.5 minutes vs. 10.0 ± 0.7 minutes, $P < 0.05$).⁸ Following surgery, measurements of the postoperative wound size revealed that group A had a larger wound size (2.07 ± 0.90 cm²) compared to group B (1.03 ± 0.87 cm², $P < 0.05$). Pescatori et al observed a mean wound size of 1.17 ± 0.31 cm² for patients undergoing laying open or excision of the fistula, contrasting with 0.81 ± 0.38 cm² for marsupialized wounds.¹⁰ Analyzing the mean postoperative VAS score, fistulotomy with marsupialization resulted in higher pain levels. Nonetheless, Pescatori et al found no statistically significant difference in pain scores at 12 hours postoperatively between non-marsupialized and marsupialized groups.¹⁰ Interestingly, neither group exhibited anal incontinence, likely due to the internal openings being situated in the lower anal canal, potentially prevented by marsupialization from causing anal deformity and fecal incontinence. However, Ho et al. discovered transitory anal incontinence in 2% of marsupialized individuals vs 12% of non-marsupialized patients.⁸ Throughout the postoperative period, none of the patients reported fever or increased pain. Persistent wound discharge was more notable in the lay open group, suggesting a longer wound duration compared to the marsupialization group. Conversely, Pescatori et al. noted a 14% postoperative sepsis rate in the marsupialized group versus 21% in the non-marsupialized group.¹⁰ Wound bleeding was less prevalent in group B than in group A (10% vs. 53.33%, $P < 0.05$), with gauze tamponade with adrenaline and saline being the common treatment. Marsupialization significantly reduced the risk of wound bleeding, and continuous sutures were found to be more hemostatic than interrupted stitches.¹⁰ Healing times varied significantly between the two groups, with group A (6.55 ± 1.3 weeks) showing a longer mean healing time than group B (3.85 ± 1.19 weeks), a difference that was statistically significant ($P < 0.05$). Similarly, Kronborg found differing median healing times for fistulectomy and fistulotomy wounds.⁴ Interestingly, no recurrences were reported during the 12-week follow-up in either group. However, incomplete marsupialization of a postfistulectomy wound might hinder premature skin healing, leaving a nonhealed cavity prone to infection and recurrence. Patient dissatisfaction, observed in 12% of cases, was primarily linked to recurrence and anal incontinence after surgery.^{10,11}

Conclusion

This study demonstrated that shorter wound healing time and shorter duration of postoperative wound discharge following a fistulotomy or fistulectomy with marsupialization and in comparison to lay open. The findings of the present study need to be substantiated further with studies involving larger sample sizes and longer follow-ups. A randomized prospective trial of different methods might also be useful to clarify which is the most effective suture for marsupialization.

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