

# Comparison between Fistulotomy vs Fistulotomy with Marsupialization in Simple Low Anal Fistulae: A Randomized Control Trial

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## ABSTRACT

**Objective:** To compare the efficacy of fistulotomy with marsupialization vs fistulotomy alone in the treatment of simple low lying anal fistula in terms of wound healing and postoperative pain.

**Study Design:** Randomized control trial

**Place and Duration:** Department of General Surgery, JPMC Karachi, duration of Study was 6 months from 23rd Aug 2020 to 23rd Feb 2021.

**Methodology:** Sixty patients of either gender having ages 25-60 years presented with low anal fistula were included in this study. Detailed demographics were recorded after taking informed written consent from all the patients. Patients were divided in to two groups. Fistulotomy was performed on 30 patients in group A and fistulotomy with marsupialization was performed on 30 patients in group B. Patients were asked to choose envelop labelled treatment A and treatment B for the randomization. All patients were followed up on 24 hours after surgery and on weekly interval up to 4 weeks to determine the outcomes in terms of wound healing and pain score. Data was analyzed by SPSS 23.0.

**Results:** In group A mean age of patients was 43.633+8.568 years while in group B mean age was 41.800+9.813 years. The mean Pain score after 24 hours in group A was 6.100+0.922 while in group B it was 5.033+0.718 with overall mean Pain score after 24 hours of 5.566+0.980. The mean Pain score after 5<sup>th</sup> day in group A was 4.266+0.639 while in group B it was 2.833+0.698 with overall mean Pain score after 5<sup>th</sup> day of 3.550+0.981. In Group A efficacy was achieved in 4 patients (6.7%) while in Group B efficacy was achieved in 14 (23.3%) patients.

**Conclusion:** Marsupialization of the wound after fistulotomy for low anal fistula results in faster wound healing and less mean post operative pain as compare to fistulotomy alone.

**Keywords:** Low Anal Fistula, Marsupialization, Fistulotomy, Pain, Wound Healing

## INTRODUCTION

Fistula in ano is one of the most common anal benign illnesses treated during routine surgical procedures. It is defined as an abnormal epithelialized tract joining two surfaces, most commonly the perianal skin and the rectal mucosa [1]. Depending on its position relative to the ano-rectal opening, an anal fistula is classified as either a low or high fistula [2]. The tract of a fistula can be classified as intersphincteric, transsphincteric, suprasphincteric, or extrasphincteric, according to the Par'k system [3]. Fistula in ano is characterised by the following symptoms and signs: perianal discharge, pain, swelling, bleeding, diarrhoea, skin excoriation, and an external opening [4].

After an ano-rectal abscess, a fistula may develop in 7-40% of patients.

For the most part, crypto glandular infections are to blame [6]. The most common surgical procedures used to treat fistula are fistulectomy and fistulotomy [7]. During a fistulectomy, the entire fistulous tract is removed, so no collateral tracts are missed and the tissue may be analysed in its entirety on a histological level. With a fistulotomy, the fistulous tract is divided, leaving an incision that is less epithelialized and hence heals more quickly [4]. Traditional fistulotomy is the most common treatment for low anal fistula since it is simple and successful. Although a fistulectomy is a valid therapeutic alternative, it is not as commonly utilised as a standard fistulotomy due to its disadvantages. These include a longer operating time, a bigger surgical wound, a longer recuperation period, and a more than threefold increase in incontinence to flatus [8].

Anal fistula can be treated with or without marsupialization of fistulotomy incisions. Suturing the skin borders together once the fistula has been laid open is the next step [9].

A randomised clinical trial was conducted between January 2008 and December 2012 at Bugando Medical Centre in northwest Tanzania to compare the efficacy of fistulectomy to that of fistulotomy with marsupialization in the treatment of low anal fistula. Patients were randomly assigned to either Group A

(fistulectomy) or Group B (control) ( fistulotomy with marsupialization). In all, 162 people were enrolled and split evenly between groups A and B.

The mean recovery period for Group A was significantly greater than that of Group B (36+ 12.8 days vs. 28+ 16.3 days;  $p = 0.002$ ). There was no statistically significant difference ( $p > 0.05$ ) between groups A and B, despite the fact that group B had a higher mean post-operative visual analogue scale score than group A at different follow-up intervals. [1].

Despite the fact that marsupialization for anal fistulotomy has been shown in recent studies to be safe and helpful in improving postoperative outcomes, there is a lack of data comparing fistulotomy with and without marsupialization, which is why I would like to conduct this study to determine its benefits in terms of wound healing and postoperative outcomes. If my research demonstrates that marsupialization is effective, the method will be recommended for use in the future.

## METHODOLOGY

This randomized control trial was conducted at Department of General Surgery, JPMC Karachi, during from 23rd Aug 2020 to 23rd Feb 2021. Sixty patients of either gender having ages 25-60 years presented with low anal fistula were included in this study. Patient with high anal fistula, patient with systemic immunocompromised states like diabetes mellitus, malignancy etc, patient on steroids and anaemic patients (affect wound healing), patient with associated co-morbid like anal fissure, haemorrhoids, recurrent fistula and chronic colitis, and patient refused consent for the procedure were excluded.

**Data Collection Procedures:** The patients who fulfill the inclusion criteria were included in our study. The study was conducted after the approval from the College of Physicians And Surgeon and hospital ethical review committee. 60 patients were enrolled and admitted through OPD of Department of surgery Jinnah Postgraduate Medical Centre and Ziauddin university and hospital

Karachi and were operated after taking anesthesia fitness, ethical approval, informed and written consent.

Patients were divided in to two groups. Fistulotomy was performed on 30 patients in group A and fistulotomy with marsupialization was performed on 30 patients in group B. Patients were asked to choose envelop labelled treatment A and treatment B for the randomization.

Procedure was done under general or spinal anesthesia in lithotomy position by single experience general surgeon fellow of CPSP and was assessed by researcher itself. All above mentioned information was recorded in the predesigned performa,

Follow up was done in OPD and the researcher followed the patient by himself. If on examination complete epithelization and reduction in pain scores found then this was considered efficacy positive. All patients were followed up on 24 hours after surgery and on weekly interval up to 4 weeks to determine the outcomes in terms of wound healing and pain score.

A data base was developed on SPSS 23 through performa filled in. Mean and standard deviation was calculated for age, duration of low anal fistula, mean pain scores. Frequency and percentage was calculated for gender, socioeconomic status (lower class/middle class/upper class), co-morbidis like hypertension and outcome variables i.e. wound healing (yes/no), and grade of pain (mild/moderate/severe). Both groups were compare in terms of efficacy using Chi square test. P value <0.05 was taken as significant.

## RESULT

Group 'A' included 30 subjects of which 13(21.7%) were male while 17(28.3%) were female, with mean age of 43.633+8.568 years, while group 'B' also included 30 patients of which 14(23.3%) were male while 16(26.7%) were female, with mean age 41.800+9.813 years,(as shown in table:1 and Table-2). The overall mean age came out to be 42.716+9.180 years (as shown in table-1)

In Group A socio-economic status was lower class in 18(30%) & middle class was in 12(20%) patients, while in Group B socio-economic status was lower class in 14(23.3%) & middle class was in 16(26.7%) patients, as shown in table-3.

The mean duration of low anal fistula in group A was 6.133+3.126 while in group B it was 6.700+2.215 m with overall mean duration of low anal fistula of 6.416+2.701 as shown in table-4.

In Group A hypertension was seen in 7(11.7%) while in Group B hypertension was seen in 8(13.3%) patients, as shown in table-5.

The mean Pain score after 24 hours in group A was 6.100+0.922 while in group B it was 5.033+0.718 with overall mean Pain score after 24 hours of 5.566+0.980. (as shown in table:6). The mean Pain score after 5<sup>th</sup> day in group A was 4.266+0.639 while in group B it was 2.833+0.698 with overall mean Pain score after 5<sup>th</sup> day of 3.550+0.981. (as shown in table:6).

Table 1: (Age Distribution with respect to groups)

Age groups	Group-A	Group-B	Overall
25-43 years	15(25%)	15(25%)	30(50%)
44-60 years	15(25%)	15(25%)	30(50%)
Total	30(50%)	30(50%)	60(100%)
Mean+SD	43.633+8.568	41.800+9.813	42.716+9.180

Table-2: Gender-wise distribution with respect to groups

Distribution of gender :(n=60)				
Gender	Group-A	Group-B	Total	P-value
Male	13(21.7%)	14(23.3%)	27(45%)	0.431
Female	17(28.3%)	16(26.7%)	33(55%)	
Total	30(50%)	30(50%)	60(100%)	

In Group A Wound healing on 28<sup>th</sup> day was seen in 4(6.7%) while in Group B Wound healing on 28<sup>th</sup> day was seen in 14(23.3%) patients, as shown in table-7.

In Group A efficacy was achieved in 4 patients (6.7%) while in Group B efficacy was achieved in 14 (23.3%) patients, as shown in table-8.

Table-3: Socio-economic status distribution with respect to groups

Distribution of gender :(n=60)				
Socio-economic status	Group-A	Group-B	Total	P-value
over class	18(30%)	14(23.3%)	32(53.3%)	0.296
Middle class	12(20%)	16(26.7%)	28(46.7%)	
Upper class	0(0%)	0(0%)	0(0%)	
Total	30(50%)	30(50%)	60(100%)	

Table-4: Duration of low anal fistula distribution with respect to groups

Duration of low anal fistula groups	Group-A	Group-B	Overall
1-7	20(33.3%)	18(30%)	38(63.3%)
8-15	10(16.7%)	12(20%)	22(36.7%)
Total	30(50%)	30(50%)	60(100%)
Mean+SD	6.133+3.126	6.700+2.215	6.416+2.701

Table-5: Hypertension distribution with respect to groups

Distribution of gender :(n=60)				
Hypertension status	Group-A	Group-B	Total	P-value
Yes	7(11.7%)	8(13.3%)	15(25%)	0.269
No	23(38.3%)	22(36.7%)	45(75%)	
Total	30(50%)	30(50%)	60(100%)	

Table-6: Pain score after 24 hours & Pain score after 5<sup>th</sup> day distribution with respect to groups

Pain score after 24 hours groups	Group-A	Group-B	Overall
2-5	20(33.3%)	22(36.7%)	42(70%)
6-8	10(16.7%)	8(13.3%)	18(30%)
Total	30(50%)	30(50%)	60(100%)
Mean+SD	6.100+0.922	5.033+0.718	5.566+0.980
Pain score after 5 <sup>th</sup> day groups	Group-A	Group-B	Overall
2-5	29(48.3%)	30(50%)	59(98.3%)
6-8	1(1.7%)	0(0%)	1(1.7%)
Total	30(50%)	30(50%)	60(100%)
Mean+SD	4.266+0.639	2.833+0.698	3.550+0.981

Table-7: Wound healing on 28<sup>th</sup> day distribution with respect to groups

Wound healing on	Group-A	Group-B	Total	P-value
28th day				
Yes	4(6.7%)	14(23.3%)	18(30%)	0.351
No	26(43.3%)	16(26.7%)	42(70%)	

Table-8: Efficacy achieved distribution with respect to groups

Distribution of wound healing on 28 <sup>th</sup> day:(n=60)				
Efficacy achieved	G-A	G-B	Total	P-value
Yes	4(6.7%)	14(23.3%)	18(30%)	0.351
No	26(43.3%)	16(26.7%)	42(70%)	
Total	30(50%)	30(50%)	60(100%)	

## DISCUSSION

The fistula in ano is a common surgical problem that has been around at least since Hippocrates' time. Fistulotomy, fistulectomy, seton, and more complex sphincter-preserving surgeries like fibrin glue injection and fistula plug insertion are presently used as surgical therapy, depending on the type of fistula and the patient's continence [10]. Low fistula-in-ano was formerly treated often with fistulectomy and fistulotomy [11]. Recent studies have shown that marsupialization following fistulotomy results in less raw, unepithelialized tissue in the fistulotomy wound, which in turn results in less postoperative blood loss and faster wound healing [12]. Even though marsupialization has been shown to hasten the healing process, many surgeons are hesitant to perform the procedure [12]. So, it's up to the discretion of the surgeon to decide whether marsupialization or fistulotomy is best. Factors

such as length of hospital stay, postoperative pain and bleeding, ability to return to normal activities, wound care, wound healing time, interference with anal continence, and recurrence of the disease all contribute to patient satisfaction following surgical treatment for anal fistula [13]. Lay open fistulotomy versus fistulotomy with marsupialization for the treatment of low fistula-in-ano has been the subject of a number of randomised clinical trials [14, 15].

In our study the mean Pain score after 24 hours in group A was 6.100±0.922 while in group B it was 5.033±0.718. The mean Pain score after 5<sup>th</sup> day in group A was 4.266±0.639 while in group B it was 2.833±0.698. In Group A Wound healing on 28<sup>th</sup> day was seen in 4(6.7%) while in Group B Wound healing on 28<sup>th</sup> day was seen in 14(23.3%) patients. In Group A efficacy was achieved in 4 patients (6.7%) while in Group B efficacy was achieved in 14 (23.3%) patients, as compare to the prospective interventional study by Ali et al [4] was conducted in omdurwan teaching hospital in the period from 2014 july to 2015 july. Total number of 80 patients were include with simple anal fistula. Forty patients were involved in each group. The mean healing time was longer in fistulotomy group than in marsupialization group (8.4±1.3 vs 5.9±1.1 week;p<0.001). Post-operative pain had no statistically significant difference in first 24 hours (P value 0.330) and second post-operative day (P value 0.120). In Ali et al [6] study efficacy in terms of wound healing of fistula in ano (FIA) was achieved in forty five percent of the patients, 05.0% in lay open (LO) technique and 40.0% in marsupialization (MS).

Although the mean postoperative VAS score for the fistulotomy with marsupialization group was higher, there was no statistically significant difference in pain scores between the groups in the Sandhya et al [14] study. The pain scores were evaluated and compared at various follow-up intervals to see if there were any statistically significant differences. There was no statistically significant difference between the two groups. Both groups experienced a significant reduction in pain after three weeks (VAS score 1). Pescatori et al. found similar results, finding that the mean pain score at 12 hours after surgery was 3.41.6 in the non-marsupialized group and 3.51.5 in the marsupialized group, respectively. The difference between the two groups, however, was statistically insignificant (p > 0.05).

In the study by Sandhya et al. [14], the wounds from fistulotomy with marsupialization were smaller than the wounds from fistulectomy (1.23±0.87 cm<sup>2</sup> vs. 2.06±1.90 cm<sup>2</sup>), but this difference was not statistically significant. Also, in the fistulotomy with marsupialization, the floor of the wound was made up of the fistula tract, which could have been covered with skin in different ways. This is why the wounds in the fistulotomy-with-marsupialization group healed faster than those in the fistulectomy group. Kronborg did a study that showed that fistulectomy wounds took 5.85 weeks to heal, while fistulotomy wounds took 4.55 weeks (p 0.02) [15]. In a study by Ho et al., wounds that had been "marsupialized" healed much faster than wounds that had not been "marsupialized" (6.0 0.4 weeks vs. 10.0 0.5 weeks, p 0.001) [16].

The limitation of our study was single center study, smaller sample size. Further studies with larger sample sizes are required.

## CONCLUSION

Marsupialization of the wound after fistulotomy for low anal fistula results in faster wound healing and less mean post operative pain as compare to fistulotomy alone.

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