



ORIGINAL ARTICLE

## Fistulotomy versus fistulotomy with marsupialization, a randomized controlled trial.

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**ABSTRACT... Objective:** To compare the efficacy of fistulotomy and fistulotomy with marsupialization in the management of simple anal fistula. **Study Design:** Randomized Controlled study. **Setting:** Department of Surgery, District Head Quarter Hospital, Mardan, Pakistan. **Period:** 1<sup>st</sup> September 2021 to 31<sup>st</sup> August 2022. **Methods:** A total of 60 Patients coming to hospital with simple anal fistula were randomized into two equal groups. In group A, 30 patients were treated with fistulotomy, while in group B, 30 patients were treated with fistulotomy with marsupialization. The primary outcome was set as time required for complete wound healing. Secondary outcomes were operation time, postoperative pain, anal incontinence, incidence of recurrence and patient satisfaction. **Results:** The mean wound healing time after 6 weeks was shorter in group B in comparison to group A ( $4.7 \pm 0.74$  versus  $6.4 \pm 0.85$  weeks;  $p=0.0001$ ). There was no significant difference in mean operation time between Group B and Group A. The difference in mean pain score was also not statistically significant. There was no significant difference in the incidence of anal incontinence, incidence of recurrence and patient's satisfaction among two groups. **Conclusion:** Fistulotomy with marsupialization is more effective procedure than fistulectomy alone in shape of early wound healing without increase in operation time and therefore can be taken as surgical procedure of choice for the simple anal fistula.

**Key words:** Fistulotomy, Fistula-in- ano, Marsupialization.

### INTRODUCTION

Perianal fistula is an ailment that has been reported since the ancient Greek times and this still remains the common benign conditions that are presented by patients in colorectal outpatient departments. This perianal fistula, also called as Fistula-in- ano or simple anal fistula, is an abnormal tract that is lined by granulation tissues between anorectal mucosa and perianal skin. These tissues are deeply connected to the rectum or anal canal and also to the skin superficially encircling the anus. This is a surgical problem, found twice more in male gender than female gender.<sup>1</sup> Patients presenting with the problem are commonly between the age of 20-45 years. Classifications is done to label them as low, high, simple and complex or in accordance with their connection to sphincter as inter-sphincter, suprasphincter, trans-sphincter and or extra-sphincter.<sup>2,3</sup> The more commonly reported

fistulae is low fistulae compared to the high fistulae. The difference between the two is that low fistula is opened below the anorectal ring in to the anal canal while high fistula is opened at/ above the anorectal ring.

The more commonly reported low fistulae (both inter-sphincter and trans-sphincter) accounts for approximately 90% of the cases.<sup>4,5</sup> Anal fistulas is mostly due to perianal abscess resulted from infections of crypt glands or may be associated with other disease processes.<sup>6</sup> The treatment procedure is greatly based on understanding the anatomy and etiology of fistula. Treatment is focused to eradicate the sepsis and preserve the anorectal functions. Reducing the recurrence rate is yet another important goal.<sup>4,5,7,8</sup>

Conventionally fistulectomy and fistulotomy are the two processes opted for this surgery.

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In fistulotomy, fistulous tract is laid open which leaves small epithelialized wounds, this may hasten the healing process of wound.<sup>9</sup> Fistulotomy is an easy treatment for low fistulae.<sup>10</sup>

As per a meta-analysis conducted in 2016 on the topic, fistulotomy provides early healing of the wound within 4-6 weeks and low incidence of recurrence. The USA guideline also describes fistulotomy as the optimal treatment for simple anal fistula.<sup>11,12</sup>

While determining the superiority of techniques, the duration to achieve a complete healing of the postoperative wound remains important factor in treating anal fistula. This quicker healing helps in reducing the days required for dressing and lesser wound care, resulting in reduced inconvenience and the cutting associated costs. Discussion relating to attempts made for achieving early wound healing after surgery is shared in medical literature. Alvandipour et al studied the sucralfate ointment for this wound healing and reported that its topical application helps to reduce pain in patients where fistulotomy was performed.<sup>13</sup>

A useful technique to hasten healing process following fistulotomy is the marsupialization of the edges of wound. This technique is reported to decrease postoperative bleeding and reduce wound healing time.<sup>4,14,15</sup> Anan M et al., in their study compared the efficacy of fistulotomy versus fistulotomy with marsupialization and shared results in favor of marsupialization after fistulotomy.<sup>16</sup> So, in addition to traditional fistulotomy commonly employed, studies have suggested marsupialization leaves lesser raw unepithelialized tissue in the postoperative wound which causes lesser blood loss therefore early healing.<sup>17</sup>

Marsupialization is, however, is still not considered essential so this is left on the choice of surgeon to perform it or not.<sup>18,19</sup>

Recommendation of Italian Society of Colorectal Surgery is also in favor of marsupialization after the fistulotomy however the data available is small

and more work is needed to further study the outcomes.<sup>20</sup> In view of above scenario this study was planned to compare the efficacy of fistulotomy versus fistulotomy with marsupialization in the treatment of a simple anal fistula in reducing mean wound healing time, operation time, postoperative pain, anal incontinence, incidence of recurrence and adverse effects of patient's daily life activities. The outcome of the study will add up to data to set clear guidelines for surgeons regarding treatment of a simple anal fistula.

## METHODS

This was a randomized controlled study conducted at department of surgery, District Head Quarter Hospital, Mardan, Pakistan over a period of 12 months from 1<sup>st</sup> of September 2021 to 31<sup>st</sup> of August 2022.

Sample size was calculated with power = 80% and  $\alpha = 5\%$  (two sided) By using expected Mean  $\pm$  SD of healing time of  $6.7 \pm 1.7$  weeks with Fistulotomy as compare to  $5.1 \pm 1$  weeks with Fistulotomy with marsupialisation.<sup>8</sup> Calculated sample size was 24 but I used 60 patients (30 in each group).<sup>16</sup>

A total of 60 Patients coming to hospital with anal fistula were randomized into two equal groups. In group A, 30 patients were treated with fistulotomy, while in group B, 30 patients were treated with fistulotomy with marsupialization. Inclusion criteria were set as all the patients above the age of 18 years presenting with a low anal fistula with 3 months duration.

Exclusion criteria were those patients having high fistula, complex fistula and with comorbidities like Crohn disease, tuberculosis and malignancies. Patients with associated abnormalities like anal fissures, hemorrhoids and anal masses were also excluded. Randomization was done by computer generated number list. A written consent was taken from all the patients for the study. The primary outcome was set as wound healing time. Secondary outcomes were operation time, postoperative pain, anal incontinence, patient satisfaction and incidence of recurrence. These clinical observations were noted at 24 hours and patients were asked for follow up visits at the

completion of 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup>, 6<sup>th</sup> weeks and then at the end of 3 months.

History of patients was taken including duration of these symptoms like perianal discharge, painful defecation, incontinence and any previous surgery for related comorbidities.

In addition to detailed related clinical assessment, proctoscopy and digital rectal examination were done. All surgical procedures were carried out by a consultant. Patients were operated under spinal anesthesia. Verification of clinical findings was also done through anorectal examination under anesthesia. Patency of fistulous tracts was found through methylene blue test.

While performing fistulotomy, probe was inserted through the external opening till it came out through the internal opening. The tract was laid open over the probe. After that fistulous tract was curetted and further examination was done to look for any secondary extension.

While performing fistulotomy with marsupialization, to marsupialize the operated wound, fistula track was undertaken from the distal to the proximal end and the edges were then sutured with the use of interrupted 3-0 chromic catgut.

Patients were prescribed ciprofloxacin, diclofenac sodium 50mg BID and metronidazole for 5 days. For avoiding constipation, laxatives were suggested during the days of wound healing. Sitz baths after bowel movements, guidance for local hygiene and dressings was given. Schedule of follow-up visit was advised.

Wound healing was assessed on follow up visits at weekly and then fortnightly basis thorough clinical examination. Complete epithelialization with no external fistula opening or any discharge was taken as complete wound healing.

The calculation of operation time was made from the injection of povidone iodine up to the dressing of wound postoperatively.

Postoperative pain was evaluated with the help

of visual analogue scale after 24 hours and then on follow up visits. The patients were asked and assessed for recurrence and anal incontinence during these visits. Questions were asked in shape of yes or no from patients about anal incontinence in shape of soiling of undergarments, distinguishing ability between gas and stool, difficulty to hold gas. Report was also taken from the patients to assess the effects of surgical procedure on daily life activities. Assessment was made by use of the scale (0, never; 1, sometimes; 2, always).

Permission for conducting study was taken from ethical committee (183-40/30-2-2022) of District Head Quarter Hospital, Mardan, Pakistan.

All the data like age and gender was recorded in performa designed for the study. Pain score and wound healing time were also noted in the performa. Data was entered and analyzed using SPSS version 25. Comparison of intraoperative findings and post-operative complications between two groups was done by applying independent t-test & Chi-square test. ( $p \leq 0.05$  as significant).

## RESULTS

The mean age in our study was  $36.8 \pm 10.03$  years with a range of 18 to 60 years. Duration of symptoms was from 1 to 6 months with mean duration of  $3.666 \pm 1.60$  months. Radial distance of the external opening from the anal verge was from 1.85 to 2.6 cm with mean distance of  $2.206 \pm 0.27$  (cm). Male gender was dominant (86.66%) in overall study population. These details for group-A and group-B are shown in Table-I.

The mean wound healing time was significantly less in group-B as compared to group-A.

There was no significant difference in mean operation time between the 2 groups and post-operative pain was also comparable between the 2 groups.

Moreover, there was no statistically significant difference among the 2 groups regarding number of patients reporting post-operative anal

incontinence at follow up visit at the end of 6 weeks. The details of results are given in Table-II.

No difference was found among patients of these two group regarding adverse effects of surgeries on their daily life activities as shown in Table-III.

## DISCUSSION

The possible surgical treatments suggested in various literatures are fistulectomy, fistulotomy and seton. Another complex one procedure is sphincter-preserving which includes fistula plug insertion and fibrin glue injection.

All these procedures suggested are used depending on the etiology and anatomy and thereby type of fistula and condition of patient's anal continence.<sup>14</sup>

Besides this, comorbidities and experience of surgeons also counts in this selection. So the primary objective of the treatment of these low fistulas is to remove this internal opening and the fistulous tract with preservation of anal sphincter functions. Despite all these suggested procedures there remains the reports of morbidity and recurrence in these patients.<sup>8</sup>

Demographics	Group-A Mean±SD (n=30)		Group-B Mean±SD (n=30)	
	Age (years)	35.933±9.68		37.666±10.46
Duration of Symptoms (months)	3.633±1.65		3.7±1.57	
Radial distances of the external opening (cm)	2.218±0.27		2.194±0.26	
Gender	Male n (%)	Female n (%)	Male n (%)	Female n (%)
	27 (90%)	3 (10%)	25 (83.33%)	5 (16.66%)

**Table-I. Details of demographics in both groups. N=60**

	Group-A n=30	Group-B n=30	P-Value <sup>*,**</sup>
Wound Healing time week (Mean±SD)	6.4± 0.85	4.7± 0.74	0.0001
Operation time Minutes (Mean±SD)	16.5±1.45	17.066±0.98	0.0818
Postoperative pain on VAS 1-10 (Mean±SD)	1.2±0.88	0.866± 0.62	0.0946
Report of anal incontinence n (%)	3 (10)	1 (3.33)	0.612

**Table-II. Details of mean duration of wound healing, mean operation time, mean post-operative pain score and anal incontinence in both groups. n=60**

\*Independent t-test applied to calculate the significance between the Mean±SD

\*\* Chi-square test was used calculate the significance between n(%)

Adverse Effect on Daily Life Activities	Group-A n=30	Group-B n=30	P-Value
<b>Physical</b>			
Not at All n (%)	26 (86.66)	27 (90)	0.68
To Some Extent n (%)	4 (13.33)	3 (10)	0.68
Greatly n (%)	0 (0)	0 (0)	1
<b>Social</b>			
Not at All n (%)	28 (93.33)	29 (96.66)	0.55
To Some Extent n (%)	2 (6.66)	1 (3.33)	0.55
Greatly n (%)	0 (0)	0 (0)	1
<b>Sexual</b>			
Not at All n(%)	0 (0)	0 (0)	1
To Some Extent n(%)	1 (3.33)	0 (0)	0.31
Greatly n(%)	0 (0)	0 (0)	1

**Table-III. Adverse effects on patient's daily life activities in both groups. n=60**

\*Chi-square test was applied to calculate the significance between 2 groups.

No patient suffered recurrence in any of the group at 12 weeks follow up visit.

Patient's satisfaction perspective includes postoperative bleeding, wound healing time, hospitalization after surgery, postoperative pain, anal incontinence, recurrence of the disease and restoration of daily life activities.<sup>4,5</sup>

Healing can proceed faster with appreciable functional results by adopting staged procedures without cutting and damaging anal sphincter.<sup>18</sup>

Ho YH and Pescatori M supported the benefits of marsupialization after fistulotomy in comparison of fistulotomy alone in the surgical procedure for anal fistula.<sup>14,15</sup>

Chalya PL et al reported in their study in 2013 that fistulotomy with marsupialization results in faster wound healing compared to only fistulectomy. They, therefore recommend it as surgical procedure taken as standard while treating low fistula-in-ano.<sup>21</sup> Jain BK and coworkers published a study in 2012 and favored fistulotomy with marsupialization versus fistulectomy for earlier wound healing. Postoperative pain score assessed on visual analogue scale between two groups was also comparable. There were no reports of anal incontinence and recurrences at the follow up of 12 weeks.<sup>4</sup>

Anan M et al. in their study with 60 patients published in 2019 shared that the group treated with fistulotomy with marsupialization for their simple anal fistula leads to complete wound healing in shorter duration of time compared the group treated with fistulotomy alone (5.1 vs 6.7 weeks) They therefore concluded that marsupialization of the edges of the laid open fistula track provides faster healing of the wound compared to fistulotomy alone.<sup>16</sup>

The results of our study are also in line with the studies mentioned above on this topic.

The mean age in our study was also less than 40 years as was present in studies previously conducted on anal fistula and male gender was dominant with this disease.

The wound healing time was significantly less

in group-B (fistulotomy with marsupialization ) as compared to group-A (fistulotomy alone), with a duration of  $4.7 \pm 0.74$  Vs  $6.4 \pm 0.85$  weeks respectively ( $p=0.0001$ ) as shown in Table-III, which is line as reported by Anan M et al. previously.<sup>16</sup>

This reduced time in complete wound healing can be due to the marsupialization of postoperative anal wound after fistulotomy that reduces the size of the wound. Pescatori et al has already mentioned in their study that the process of marsupialization resulted the wound size to be half as compared to patients where only marsupialization was performed.<sup>14</sup>

Marsupialization of the edges of the wound performed after fistulotomy do not significantly increase the operation time, as mentioned in previous studies.<sup>4,14,15,16</sup> In our study as well, the mean operation time was comparable between the group-B and group-A,  $17.066 \pm 0.98$  Vs  $16.5 \pm 1.45$  minutes respectively ( $p=0.0818$ ).

Sahakitrunguang C and Anan M in their studies mentioned that fistulotomy with marsupialization does not increase postoperative pain.<sup>16,22</sup> The findings of our study are same regarding postoperative pain assessed through VAS between two groups as shown in Table-IV. There was no statistical difference in the incidence of anal incontinence between these groups as shown in Table-V. There was no adverse effect on patient's daily social and sexual activities and no recurrence reported in both the groups as also previously reported by Anan M.<sup>16</sup>

So this study demonstrates that fistulotomy with marsupialization in comparison to a fistulotomy alone provides shorter healing time without any increase in operation time in patients with perianal fistula or simple anal fistula. The postoperative pain, anal incontinence, incidence of recurrence and patient satisfaction to the patients remains the same.

Limitations of our study are that all patients selected in our study had a simple fistula and complications are mostly observed in patients



with complex and high tract fistula. This may also be the reason that our patients expressed better functional outcome in both groups. The small sample size and shorter follow up are other limitations. Therefore the finding of our study need to be evaluated with larger sample size and longer follow ups.

## CONCLUSION

Fistulotomy with marsupialization is more effective procedure than fistulotomy alone in shape of early wound healing without increase in operation time and therefore can be taken as surgical procedure of choice for the simple anal fistula.





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2	Faheem Khan	Data collection & Analysis.	
3	Saman Hafeez	Writing & References analysis.	
4	Mian Tauseef	Overall supervision, Results, Interpretation.	
5	Muhammad Usman	Data collection	