

A comparative study of wound opening versus primary closure after fistulectomy in the lower anal fistula

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ABSTRACT



Objectives. The aim of the study is to investigate the outcome of primary wound closure versus non-wound closure after fistulectomy in terms of postoperative pain and wound healing time. **Materials and Methods.** A prospective comparative randomized study was performed on patients admitted to the General Surgery Department of our Institute (Dec.1, 2019-Nov.31, 2021), with a diagnosis of low anal fistula and undergoing fistulectomy. 54 patients were included in the study and were assigned alternately and equally in group A (fistulectomy with laying open of wound) and group B (fistulectomy with primary closure), with 27 patients in each group. On day 1 postoperatively, the pain score was assessed by analog visual scale. Patients were followed for 6 weeks, and healing was assessed by visual examination of epithelialization at each follow-up visit. **Results.** In our study, the average healing time in group A was 20.77 days and in group B 14.07 days (the average healing time in group B is significantly longer than in group A, with P value of <0.00001). In our study, the average pain score among the participants in group A is 4, and among the participants in group B it is 2.148, with the value P <0.00001, which is statistically significant. **Conclusion.** Primary closure fistulectomy is a better method for treating low anal fistula due to the fact that it causes less pain, accelerated healing compared to wound opening fistulectomy. However, further studies are needed to compare other methods of treating low anal fistula.

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Introduction

Fistula-in-ano is a chronic abnormal communication, usually lined to some degree by granulation tissue, which runs outwards from anorectal lumen (internal opening) to an external opening on the skin of perineum or buttock (or rarely in women, to vagina) [1]. Fistula-in-ano is the most common malady and an intriguing problem of the anorectal region in general population. The prevalence in men is 12.3 cases per 100,000 population, while in women it is 5.6 cases per 100,000 population [2]. The location of the disease makes the patient refrain from early consultation. The common pathogenesis is the bursting open of an acute or inadequately treated anorectal abscess into the perianal skin.

A low anal fistula is defined as one that has the internal opening below the anorectal ring [2]. Various procedures are included in the surgical management of the fistula-in-

ano, such as fistulotomy, fistulectomy either with laying open o wound or primary closure, use of setons, LIFT procedure, anal advancement of flaps, use of biological agents and VAAFT procedure [3]. The two conventional standard procedures used are represented by fistulotomy and fistulectomy. Fistulotomy involves laying open of fistulous tract wherein the fistulous tunnel is laid open, which allows the fistula to heal from below upwards. Fistulectomy on the other hand aims at complete removal of the fistulous tract which is supposed to eliminate the risk of missing secondary tracts. Both these conventional methods are associated with delayed wound healing and prolonged hospital stay and have concerns regarding pain, high recurrence rates and the risk of postoperative wound infection and incontinence [4]. Recurrence is defined as clinical reappearance of the fistula after complete healing of the surgical wound, occurring within one year after the procedure [5].

Thus, the need for the study is to compare the outcome of open fistulectomy and fistulectomy with primary closure to determine the best procedure for the treatment of low anal fistula (better wound healing, short hospitalization, lower postoperative pain and lower costs), but without compromising safety compared to standard procedures.

Materials and Methods

A randomized comparative prospective study was conducted from 1st December 2019 to 30th November 2021, among 54 patients who got admitted as inpatient at our institute with diagnosis of low-level fistula-in-ano and undergone fistulectomy.

Inclusion criteria:

- The patients aged above 18 years with diagnosis of low anal fistulas including: trans sphincteric, inter sphincteric and subcutaneous fistula.

Exclusion criteria:

- recurrent fistula
- patients with associated conditions such as anal fissure, hemorrhoids, carcinoma, irradiation.
- the fistula with multiple secondary branching tracts or multiple external openings
- patients with suspected high anal fistula
- Crohn's disease, tuberculosis
- active sepsis
- fistulous abscess
- patients not willing to participate in study

Study methodology:

All patients who got admitted as inpatient in Department of General Surgery at our Institute with diagnosis of low-level fistula-in-ano and undergoing fistulectomy were included in the study. Patients were alternately included in group A and group B. Detail clinical history, thorough clinical examination including per rectal examination was done in all the cases. All patients undergone routine blood investigations, chest X-Ray, and EKG prior to surgery. In suspected case of high anal fistula or complex fistula, a fistulogram and MRI were done. Patients of group A underwent fistulectomy with laying open of wound, which means excision of entire fistulous tract and leaving wound open to heal by secondary time. Patients of group B underwent fistulectomy with primary closure of wound, which means excision of fistulous tract with primary closure of wound following surgery. Pain score measured on postoperative day 1 and all the patients were followed up for 06 weeks. On each visit, healing was assessed by visual examination of epithelialization.

Pre-op preparation:

- liquid diet 1 day prior to surgery
- enema 4 hours prior to surgery
- nothing by mouth 2 hours prior to surgery

- IV fluid 2 hours before surgery
- IV Antibiotics – Inj. Ciprofloxacin 500mg 1-0-1, Inj. Metronidazole 500mg 1-1-1
- IV Antibiotics started one hour before shifting to OT
- other supportive medications – PPI'S and Anti emetics [6].

Procedure details:

- Anaesthesia: spinal anaesthesia
- Position: lithotomy position
- Painting and draping
- Per rectal and proctoscopic examination
- Delineation of fistulous tract; probing of the fistulous tract - methylene blue dye injection.
- Elliptical incision around external opening, incision deepened through subcutaneous tissue.
- Fistulous tract separated from surrounding tissue using sharp and blunt dissection till 3-5mm from the internal opening.
- Tranfixation of fistulous tract done 3-5mm from its internal opening and cut.
- Hemostasis ensured throughout the procedure
- Fistulectomy with laying wound open; following fistulectomy wound was kept open to granulate and heal. Lignocaine lubricated pack kept in anal canal and sterile dressing applied (group A).
- Fistulectomy with primary closure; following fistulectomy, cavity of wound obliterated using vicryl 2-0 intermittent sutures, skin and subcutaneous tissue approximated using Ethilon 2-0 mattress sutures. Lignocaine lubricated pack kept in anal canal and sterile dressing applied (Group B).

Post op care:

- nothing by mouth for 6 hours
- IV fluids
- IV antibiotics – inj. ciprofloxacin 500mg 1-0-1 and inj. metronidazole 500mg 1-1-1 for 2 days followed by oral medications.
- IV analgesic – Inj. Paracetamol 1-0-1 on the day of surgery followed by tab. paracetamol 1-1-1
- pain score assessed on postoperative day 1 with visual analogue score [7].
- anal pack removed on postoperative day 1, Seitz bath started 4-5 times daily for 5-10 min each time. Continued 3 times daily till the wound healing.
- patients were discharged on postoperative day 3 or 4 and advised to be monitored once in a week for 6 weeks or till the wound heals.

Follow up:

Patients were followed up every week for a minimum period of 6 weeks or till the wound healing. For the patients who underwent fistulectomy with primary closure sutures removed between 8-10 POD. At every visit wound healing assessed by visual examination of epithelialization.

Statistical Analysis: The collected data was entered into Microsoft excel data sheet and was analyzed using SPSS software with appropriate statistical tests. **Sample size:** 54 patients who diagnosed as low anal fistula undergone fistulectomy with primary closure and fistulectomy alone, 27 in each group being included in the study. **Ethical clearance:** Obtained from the Institutional Ethical Board.

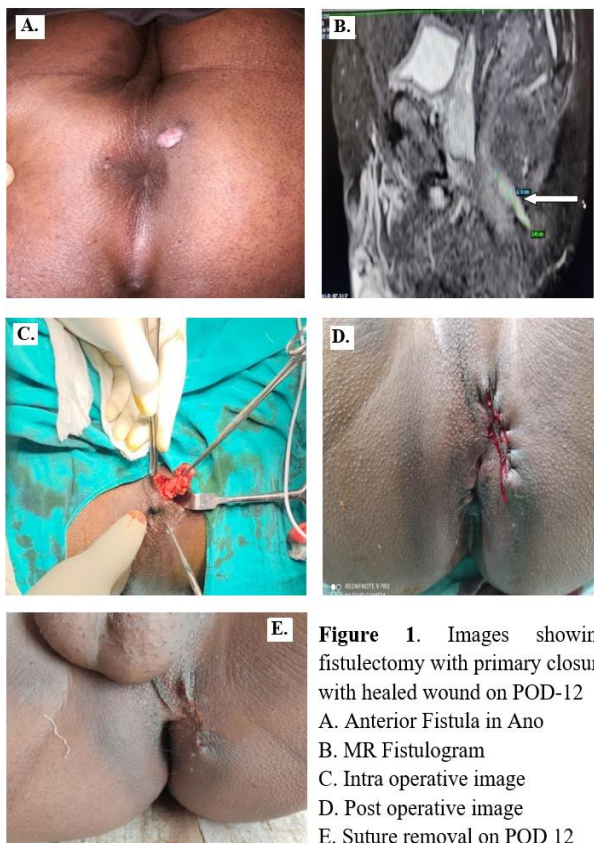


Figure 1. Images showing fistulectomy with primary closure with healed wound on POD-12
 A. Anterior Fistula in Ano
 B. MR Fistulogram
 C. Intra operative image
 D. Post operative image
 E. Suture removal on POD 12

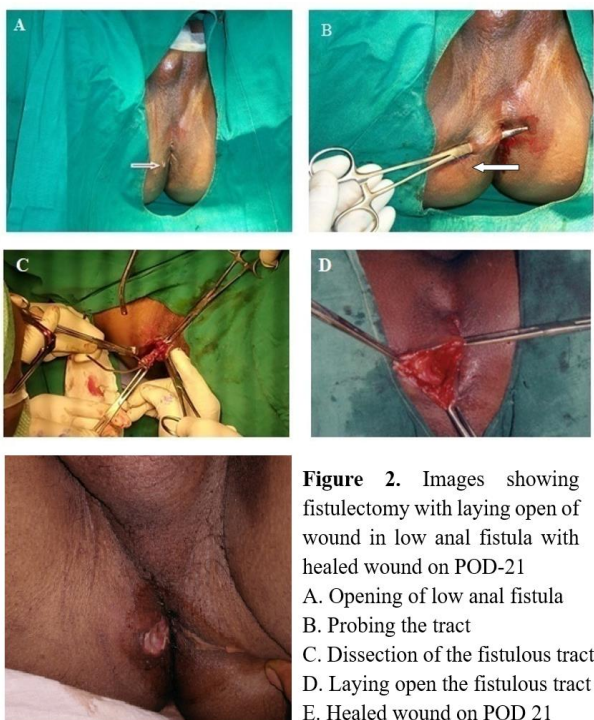


Figure 2. Images showing fistulectomy with laying open of wound in low anal fistula with healed wound on POD-21
 A. Opening of low anal fistula
 B. Probing the tract
 C. Dissection of the fistulous tract
 D. Laying open the fistulous tract
 E. Healed wound on POD 21

Results

The 54 patients admitted for the study were divided into two equal and comparable groups by allotting alternatively to group A and group B. Patients in group A underwent open fistulectomy and patients in group B underwent fistulectomy with primary closure (Figures 1-2). After appropriate statistical analysis, observations and results were tabulated as follows.

Table 1. Number of study participants in group A and group B

Groups	Number	Frequency
Group A	27	50
Group B	27	50
Total	54	100

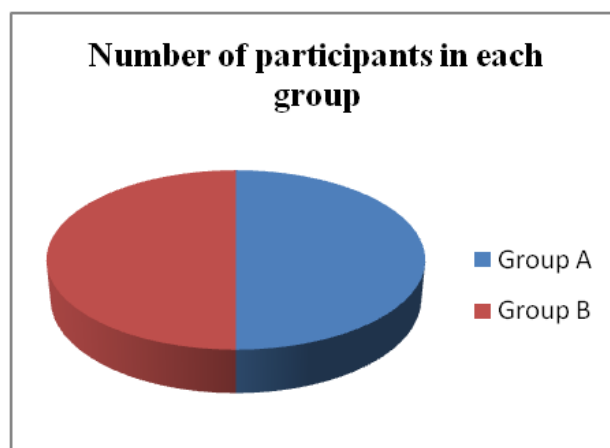


Figure 3. Graphical representation of study participants in Group A and Group B

The number of participants in Group A was 27 and in Group B 27, with equal distribution of participants in both the groups.

Table 2. Age distribution of the participants in group A and group B

Age (years)	Group A		Group B		Total percentage
	N	percentage	N	percentage	
18-20	0	0.00%	2	7.41%	3.27%
21-30	6	22.22%	8	29.63%	25.92
31-40	14	51.85%	11	40.74%	46.29
41-50	6	22.22%	5	18.52%	20.37
51-60	0	0.00%	0	0.00%	0.00%
61-70	1	3.70%	1	3.70%	3.27%
Total	27	100.00%	27	100.00%	100.00%

The chi-square statistic with Yates correction was 1.231. The p-value was 0.97532, not significant at $p < .05$.

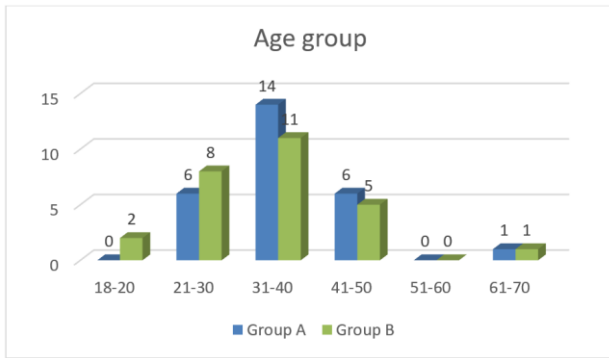


Figure 4. Graphical representation of age distribution of the participants in Group A and Group B

In our study over all incidence of fistula in ano found maximum that was 46.29% in 31-40 years age group and 25.92%, 20.37% in 21-30 years and 41-50 years age group respectively, with range of 22 to 70 years in Group A and 20 to 70 years in Group B. There was no significant statistical difference in the age distribution between two groups as the p value is 0.97 and was not significant.

Table 3. Sex incidence of fistula in ano in Group A and Group B

	Group A		Group B	
	Number	Percentage	Number	Percentage
Male	24	88.89%	20	74.07%
Female	3	11.11%	7	25.92%
Total	27	100.00%	27	100.00%

The chi-square statistic with Yates correction is 1.1045. The p-value is 0.293271. Not significant at $p < .05$.

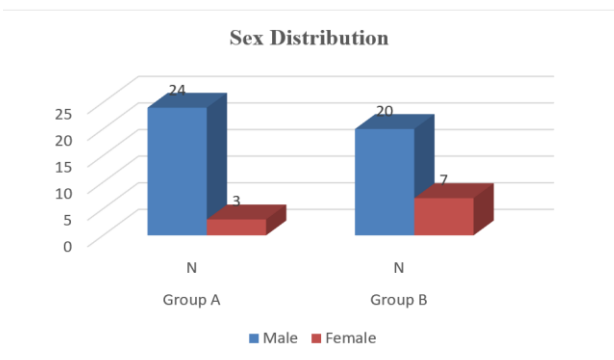


Figure 5. Graphical representation of sex incidence of Fistula in Ano in Group A and Group B

In our study incidence of Fistula in Ano in Group A was 24 (88.89%) males, 3(11.11%) females, and in Group B 20 (74.07%) males and 7 (25.92%) females, with overall incidence among males and females was 44 and 10 respectively, which amounts to overall sex incidence of 82% in males and 18% female, with no statistical difference in sex distribution among two groups as the p value is 0.293271 (not statistically significant).

Table 4. Various symptoms of presentation of Fistula in Ano in Group A and Group B.

Symptoms	Group A		Group B		Total
Discharge	26	96.29%	23	85.18%	49 (90.74%)
Swelling	18	66.66%	13	48.14%	31 (57.40%)
Itching	2	4.40%	1	3.70%	3 (5.55%)
Pain	5	18.51%	7	25.92%	12 (22.22%)

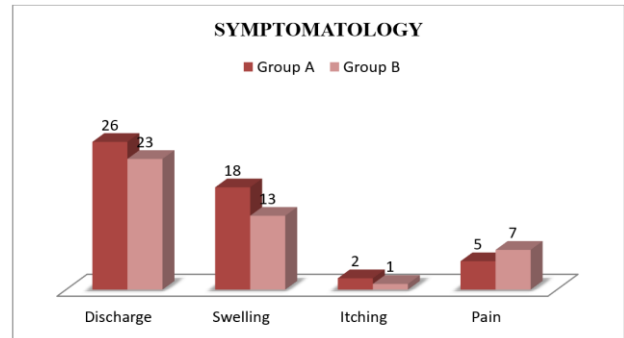


Figure 6. Graphical representation of Various symptoms of presentation of Fistula in Ano in Group A and Group B.

In our study the predominant symptom in both groups was perianal discharge 26 in group A and 23 in Group B with other symptoms being perianal swelling 18,23%, pain 5,7% and itching 2,1% in Group A and Group B respectively.

Table 5. Distribution of types of anal fistula among Group A and Group B

Type of fistula	Group A	Group B	Total
Anterior	10 (37.03%)	11 (40.74%)	21 (38.88%)
Posterior	17 (62.96%)	16 (59.25%)	33 (61.11%)
Total	27 (100%)	27 (100%)	54 (100%)

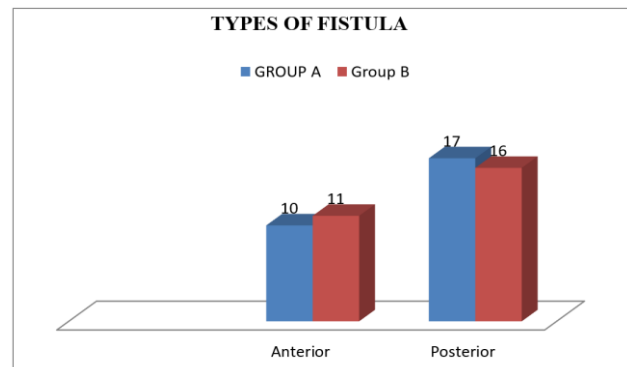


Figure 7. Graphical representation of distribution of Types of anal fistula among Group A and Group B.

In our study the incidence of posterior anal fistulas was common, with 17 cases in Group A and 16 in Group B, compared to anterior fistulas with 10 and 11 cases in Group A and Group B, respectively; there was no significant statistical difference between both groups. Overall, the incidence of posterior anal fistula was more than anterior.

Table 6. Various blood parameters among participants in Group A and Group B

Blood parameters	Group A	Group B
Mean haemoglobin	12.18g%	12.98g%
Mean total protein	6.41g/dl	6.9g/dl
Mean albumin	3.64g/dl	3.88g/dl

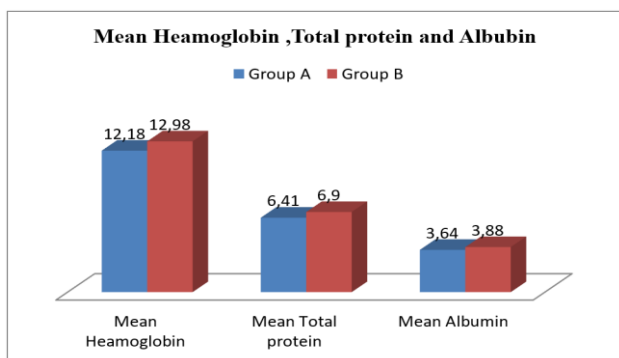


Figure 8. Graphical representation of various blood parameters among participants in Group A and Group B

In our study the mean of hemoglobin among participants in Group A is 12.18 g% and 12.98 g% in Group B, mean total protein is 6.41g/dl in Group A and 6.9g/dl in Group B, mean Albumin is 3.64g/dl in Group A and 3.88g/dl in Group B, which are similar and comparable in both groups.

Table 7. Pain score among participants in Group A and Group B

	Pain Scores		U Value	Z Score	P value
	Mean	SD			
Group A	4	0.8164	42.5	-5.5619	<0.00001
Group B	2.1481	0.7046			

In our study, mean Pain score among participants of Group A was 4 and among participants of Group B was 2.148 with P value of < 0.00001 which was statistically significant.

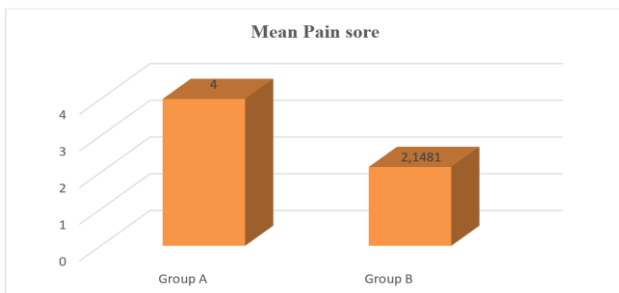


Figure 9. Graphical representation of pain score among participants in Group A and Group B

Table 8. Mean duration healing among participants in Group A and Group B

	Healing time		U Value	Z Score	P value
	Mean	SD			
Group A	20.777	5.6455	97.5	-4.61044	<0.00001
Group B	14.074	8.1142			

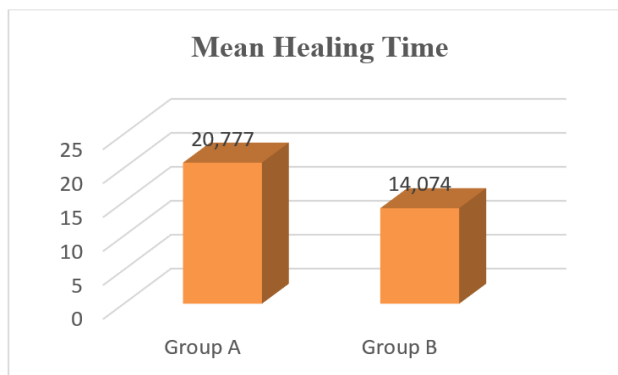


Figure 10. Graphical representation of Mean duration healing among participants in Group A and Group B

In our study the mean healing time in Group A was 20.77, with minimum 13 days to maximum of 42 days, and in Group B 14.074 days with minimum 8 days to maximum of 40 days. The mean healing time in Group B was significantly higher than Group A, with P value of <0.00001.

Discussion

In our study the distribution of number of participants in Group A (27) who underwent fistulectomy with laying open of wound and in Group B (27) who underwent fistulectomy with primary closure was equal. In our study the two groups were comparable and similar with respect to sample size, age, sex, presenting symptoms, location of external opening, and the blood parameters like haemoglobin, total protein and albumin levels which may influence the healing.

In our study, the overall incidence of fistula in ano found maximum between age group of 21-40 years, that is 39 participants (71.16%), with age group range from 20-70 years, which is in par with other studies. There is no significant statistical difference in the age distribution between two groups as the p value is 0.97 and was not statistically significant.

In our study, the incidence of Fistula in Ano among males and females is 44 (82%) and 10 (18%), respectively, which implied that the incidence of Fistula in Ano is more common in males and the results were consistent with other studies. There is no statistical difference in sex distribution among the two groups, as the p value was 0.293271 and was not significant.

In our study, the predominant symptom in both groups was discharge 26 in group A and 23 in Group B, with other symptoms being swelling 18/23, pain 5/7 and itching 2/1 in Group A / Group B, respectively. Overall predominant symptom was discharge in 49 participants (90.74%), followed by swelling (57.40%), pain (22.22%), itching (5.55%).

In our study, 19 males and 2 females had anterior anal fistula, 25 males and 8 females had posterior anal fistula; thus, the incidence of posterior anal fistula was more common in both the sexes.

The mean of hemoglobin among participants in Group A was 12.18g% and 12.98 g% in Group B, mean total protein was 6.41g/dl in Group A and 6.9g/dl in Group B, mean Albumin was 3.64g/dl in Group A and 3.88g/dl in Group B, which were similar and comparable in both groups.

In our study, the mean pain score among participants of Group A was 4 and among participants of Group B was 2.148, with P value of < 0.00001 which was statistically significant and was in accordance with other studies.

In a study published in 2019 by Nangare et al., the mean pain score among patients who underwent Fistulectomy with laying open of wound was 7.4, while it was 3.36 in patients who underwent Fistulectomy with primary closure [8]. In a study published in 2002 by Shahbaz et al., the mean pain score among patients who underwent Fistulectomy with laying open of wound was severe while it was mild in patients who underwent Fistulectomy with primary closure [9]. In a study published in 2013 by Damor et al., the mean pain score among patients who underwent Fistulectomy with laying open of wound was 4.42, while it was 2.77 in patients who underwent Fistulectomy with primary closure [10]. In a study published in 2014 by Prakash et al., the mean pain score among patients who underwent Fistulectomy with laying open of wound was 9.8, while it was 3.3 in patients who underwent Fistulectomy with primary closure [11]. In a study by More et al., the mean pain score among patients who underwent Fistulectomy with laying open of wound was 9.8, while it was 3.3 in patients who underwent Fistulectomy with primary closure [12].

The results of our study are partly similar to the studies mentioned above. In our study, the mean duration of hospital stay among participants in Group A was 4.81 days which was same as mean duration of hospital stay among participants of Group B, with P value of 0.20054 which was statistically insignificant. There were no any changes in the duration hospital stay in both the groups. The mean healing time in Group A was 20.77 days, with minimum 13 days to maximum of 42 days, and in Group B 14.074 days, with minimum 8 days to maximum of 40 days. The mean healing time in Group B was significantly higher than Group A, with P value of <0.00001.

In a study published in July 2019 by Nitin R. Nangare et al., a prospective interventional study that was done with 30 randomly selected patients subjected to the open fistulectomy and 30 to the fistulectomy with the primary closure, the authors proved that the primary closure after fistulectomy showed better results in terms of patient's compliance, lesser pain management and short hospital stay as compare to the open fistulectomy. The mean duration of wound healing among patients who underwent Fistulectomy with laying open of wound was 11.46 days, while it was 7.93 days in patients who underwent Fistulectomy with primary closure [8].

In a study published in 2002 by CM Shahbaz A. et al., a prospective study with 50 patients in department of surgery Mayo Hospital Lahore, they concluded that the healing time is much shorter with fistulectomy with primary closure. The mean duration of wound healing among patients who underwent Fistulectomy with laying open of wound was 31.82 days, while it was 8.0 days in patients who underwent Fistulectomy with primary closure, with the p-value of 1.13×10^7 So, they can safely recommend fistulectomy with primary closure as a better choice than fistulectomy alone [9].

In a study published in 2013 by Sushil Damor et al., a prospective study including a total of 50 cases of fistula in ano treated by Fistulectomy, was carried out on patients who were admitted in surgical ward in Medical College and S.S.G. Hospital, Vadodara. This study showed that the primary closure method of fistulectomy is safe, feasible and equally effective. The post operative pain is much less, early discharge from the hospital, healing of wound is faster, decreased morbidity, as compared to open method of fistulectomy. The mean duration of wound healing among patients who underwent Fistulectomy with laying open of wound was 21.24 days while it was 8.24 days in patients who underwent Fistulectomy with primary closure [10].

In a study published in Sep 2014 by Sundar et al., a randomized comparative prospective study of 52 cases of fistula-in-ano (presented at the surgical OPD of Meenakshi Medical College and Research Institute during the period of March 2012 to February 2014), the primary closure was a better alternative in the surgical management of fistula in ano considering the benefits of lesser postoperative pain, early healing, early discharge, early return to normal activity, cost effective and lesser recurrence rate above the open fistulectomy. The mean duration of wound healing among patients who underwent Fistulectomy with laying open of wound was 3-4 weeks while it was 1-3 weeks in patients who underwent Fistulectomy with primary closure [11].

In a study by Manoj N. More et al., a randomized comparative prospective study of 41 cases of fistula in ano presented at the surgical OPD of tertiary care center, during

the period of December 2011 to June 2014, it is showed that the Primary closure is better alternative in the surgical management of fistula in ano, considering the benefits of less post op pain, early healing, early discharge, early return to normal activity, cost effective and less recurrence above the non-closure. The mean duration of wound healing among patients who underwent Fistulectomy with laying open of wound was 3-6 weeks, while it was 1-3 weeks in patients who underwent Fistulectomy with primary closure [12].

In a study published in July 2019 by Sushila Garag et al., a randomized comparative prospective study of 30 cases of fistula-in-ano presented at the surgical OPD of Almeen Medical College and Research Institute, they were found that the primary closure method of fistulectomy is a safe and feasible method and more effective in the management of fistula-in-ano. The mean duration of wound healing among patients who underwent Fistulectomy with laying open of wound was 4 weeks, while it was 1.9 weeks in patients who underwent Fistulectomy with primary closure [2].

The results of our study were consistent with the studies mentioned above and others similar [13-15].

Limitation of our study:

The duration of follow up in our study was not enough to assess the recurrence rate associated with these procedures, which stands as one of the most important determinants of the outcome following the low anal fistula surgery.

Highlights

- ✓ Fistulectomy with primary closure in low anal fistula has less mean healing time compare to laying wound open.
- ✓ Fistulectomy with primary closure in low anal fistula has less post operative pain compare to laying wound open.

Conclusions

In conclusion, the post operative pain and mean duration of wound healing was significantly less in patients who underwent Fistulectomy with primary closure compare to Fistulectomy with laying open of wound. Fistulectomy with primary closure is a better method for treating Low anal Fistula owing to fact that it had less pain, accelerated healing compare to Fistulectomy with laying open of wound without compromising the safety. However, the studies are required to compare other methods of treating Low Anal Fistula.

Conflict of interest disclosure

There are no known conflicts of interest in the publication of this article. The manuscript was read and approved by all authors.

Compliance with ethical standards

Any aspect of the work covered in this manuscript has been conducted with the ethical approval of all relevant bodies and that such approvals are acknowledged within the manuscript.

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