Safety of Fistulotomy and Fistulectomy in Patients with Low Lying Fistulae in Ano: A Randomized Control Trial.

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ABSTRACT

Background: Fistula-in-ano (FIA) is defined as an epithelized abnormal tract connecting two surfaces, usually the rectal mucosa and perianal skin.[1] Different studies have shown different results with recurrence rate upto 18%, while long term incontinence rates can exceed 30%.

Objectives: To compare the safety of fistulotomy and fistulectomy in patients with low lying fistulae in ano.

Material and Methods: This randomized control trial study was carried out over 142(71 in each group) patients in Department of General Surgery, Saidu Teaching Hospital, Swat from Jun 1, 2017 to July 20, 2018. After detecting the high fistula-in-ano, the patients were assigned randomly to each procedure and healing was recorded at 12th week to measure the safety of the procedure.

Results: A total of 142 patients of low fistula in ano were observed, which were divided in two equal groups. Overall Male to female ratio was 1.41:1. The average age of the patients was 40.68 years +14.34SD. Healing of fistula in both the groups shows that fistula in Group A was healed in 65(91.5%) patients while Group B shows healing in 56(78.9%) which shows that effectiveness was significant when both groups were compared (p-value=0.04) .

Conclusion: Fistulotomy yielded better healing rate as compared to fistulectomy for the treatment with low fistula in ano.

Key Words: *Fistula, Fistulotomy, Fistulectomy, wound healing, fistula in ano.*

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INTRODUCTION:

Fistula-in-ano (FIA) is defined as an epithelized abnormal tract connecting two surfaces, usually the rectal mucosa and perianal skin. Low type of fistula accounting for the majority of cases up to 90%.[1] The disease occurs predominantly in the third and fourth decade of life with an incidence of 5.6 per 100.000 in women and 12.3 per 100.000 in men.[2] The majority of anal fistulae are of crypto-glandular origin, following anorectal abscess in 7-40% of cases.[3]

Fistula in ano is a common surgical problem. It is a track lined by granulation tissue, which connects deeply to the anal canal or rectum and superficially to the skin around anus. The incidence of abscesses and fistula is 1-2 per 10,000 populations. It is more common in males than females with a ratio of 2:1.[1] The common age of presentation is between 20-45 years. Different classifications have been used to categorize these fistulae into low or high, simple or complex, or according to their anatomy and relation with the sphincter.[2]

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Anal fistulae are still negatively affecting the patient's quality of life by causing minor pain, social hygienic embarrassment, and in severe cases, frank sepsis.[3]

Although a number of surgical techniques have been proposed to treat this condition, there is still no single ideal technique for the treatment of this disease[4] There are two important problems in the surgical treatment of an anal fistula, recurrence and incontinence, and these two factors greatly affect the surgical outcome.[5] Generally, fistulectomy is an adequate surgical procedure for the treatment of a simple or low trans sphincter fistula while others reported that fistulotomy continues to have excellent results.[6]

In a study a total of 50 patients were clinically diagnosed with fistula in ano. Commonest age of presentation in our series was 20-30 years. Males were more affected as compared to females. Low level fistula were more common and seen in 66% cases where as 34%patients had high level fistula. All patients were subjected to surgical intervention. Follow up of the patients continued up to 1 year. Incidences of pain, bleeding and incontinence were more in those with fistulectomy as compared to fistulotomy. In fistulotomy pain was recorded in 8% patients, bleeding in 8%, and incontinence in no patient. On the other hand in fistulectomy it was 64%,32%and 32 % respectively but recurrences was high, found in 4 (8%) in fistulotomy group.[7]

In a prospective clinical study that included 30 patients suffering from simple perianal fistula; patients were divided into two groups each containing 15 patients: group A was managed by fistulectomy and group B was managed by fistulotomy. Both groups were evaluated according to the operative time, postoperative pain, and time of wound healing, postoperative complication, incontinence, and recurrence. There was a significant decrease in the operative time in group B compared with group A ($P < 0.05$), there was a significant decrease in postoperative pain in group B compared with group A ($P < 0.05$), and there was a significant decrease in the time needed for wound healing in group B compared with group. In fistulotomy group post-operative pain was in 60% patients and in fistulectomy it was 73.3% patients.[8]

Another study consisted of 38 patients in fistulotomy group & 37 patients in fistulectomy group showed that recurrence of fistula developed in 5.3% patients while fistula tract healed in 94.7% patients after fistulotomy. On the other hand 18.9% patients had recurrence of fistula & fistula tract healed in 81.1% patients after fistulectomy.[9]

We conducted this study in order to establish local statistics on outcome of fistulectomy vs fistulotomy, for low fistula in ano in term of healing in our population.

MATERIAL AND METHODS:

This randomized control trial study was carried in Department of General Surgery, Saidu Teaching Hospital, Swat from Jun 1, 2017 to July 20, 2018 including follow up. A sample of 142 patients was included in study. Using proportion of healing in fistulotomy, it was 94.7 % & proportion of healing in fistulectomy was 81.1 % based on previous study.[9] Significance level was 5% and power was 80% under WHO sample size calculation formula. All patients were randomized to two groups i.e group A and B by block method, 71 patients in each group. Patients in Group A were managed by fistulotomy and another Group B, patients were going through fistulectomy.

After taking informed consent of patients for inclusion in the study and the specific procedure, Clinical history was obtained for all the patients. Relevant initial information including perianal pain, perianal discharge, duration of symptoms, position of fistula, granulation tissue at external opening, type of discharge, induration of tract, and internal opening were observed. All patients have proctoscopy preoperatively to assess the internal opening and any other anal abnormality. Patients were operated in lithotomy position under general or spinal anesthesia with preoperative preparation by enema and antibiotics. Injection of hydrogen peroxide were used to localize internal opening. In fistulectomy procedure the fistulous tract was excised completely while in fistulotomy the fistulous tract was laid open to heal. Patients were discharged on first postoperative day with advice of antibiotic (metronidazole 400mg three times daily) and analgesic (diclofenic sodium 50 mg twice daily) for five days and sitz bath. Patients were followed for a period of 12 weeks for postoperative complications like pain, perianal discharge, any granulation tissue, incontinence and recurrence. Safety of procedur was measured in term of healing while Healing was considered if the patients have pain score of less than 4 on VAS (Visual analogue scale) and no Purulent discharge from the wound confirmed by culture in the laboratory through expert mircrobilogist after 12 weeks of operation.

Patients with previous history of anal incontinence, high fistulae with complex type, inflammatory bowel disease, tuberculosis, co-morbid conditions like diabetes mellitus confirmed by blood test, patients with ischemic heart disease and malignancy were excluded as these were the confounders and make the study results biased. All the data were analyzed in SPSS version 16.

RESULTS:

Gender wise distribution shows that 40(56.3%) were male and 31(43.7%) were female in Group A with male to female ratio was 1.29:1 while Group B contains 43(60.6%) were male and 28(39.4%) were female with male to female ratio was 1.53:1. Overall Male to female ratio was 1.41:1. Sex distribution among the groups was insignificant with p-value=0.367. Detail given in table:1.

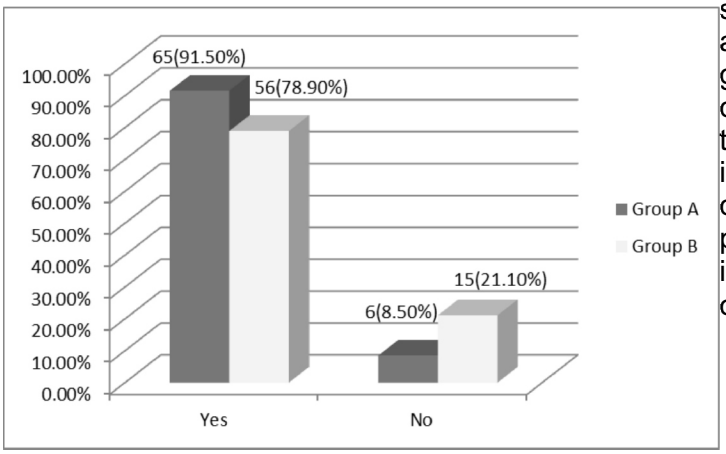
Table no: 1. Gender and Duration of Symptoms wise Distribution of Healing in Both the Groups

		Groups				p-value
		Group A		Group B		
		Fistula Tract Healed		Fistula Tract Healed		
		Yes	No	Yes	No	
Gender	Male	36	4	32	11	0.1166
		90.0%	10.0%	74.4%	25.6%	
	Female	29	2	24	4	0.5746
		93.5%	6.5%	85.7%	14.3%	
Duration of Symptoms (in days)	<= 5.00	5	1	2	4	0.2424
		83.3%	16.7%	33.3%	66.7%	
	6.00+	60	5	54	11	0.1807
		92.3%	7.7%	83.1%	16.9%	

Average age was 40.29 ±14.57 years in Group A and contains 16(22.5%) patients having less than 25 years, 19(26.8%) patients 26-40 years, 21(29.6%) patients 41-55 years and 15(21.1%) patients having age more than 56 years. While Group B have average age of 41.07 ±14.19 years and contains 18(25.4%) patients in less than or equal to 25 years, 13(18.3%) in 26-40 years, 21(29.6%) in 41-55 years and 9(12.7%) patients have age more than 55 years of age. The overall average of the patients was 40.68 ±14.34 years. The age distribution among the group was also insignificant with p-value 0.198.

Healing of fistula in both the groups shows that fistula in Group A was healed in 65(91.5%) patients and 6(8.5%) patients have not showed the healing of fistula while Group B shows healing in 56(78.9%) patients and no healing in 15(21.1%) patients which shows that fistula tract healing was significant in both the group with p-value=0.02. (Fig : 1).

Fig No: 1. healing wise distribution in both the groups



Age wise distribution in both the groups shows that healing was greater in younger age group and decreases with the increase of age. The patients having less than or equal to 25 years of age have showed healing in 15(93.3%) in Group A while 15(83.3%) in Group B. We can see that effectiveness in both the group when stratified among the age, it shows insignificant.

When healing was stratified among the gender in both the groups it showed that female have better healing as that of males although insignificant in both the groups. While duration of symptoms shows that healing was greater in proportion in patients with less duration of symptoms. Moreover when fecal incontinence was compares between two groups none of the patient in either group had develop incontinence so in terms of incontinence there was no significant difference between fistulectomy and fistulotomy.

DISCUSSION: A fistula is an abnormal communication between two epithelialized surfaces. For years, it has been accepted that the abnormal communication of the lower gastrointestinal system with the perianal region is due to a cryptoglandular infection. It is believed that the anal crypts become blocked by inspissated debris or stool. As a result, an infection develops at the anal glands, which extends in a path of least resistance, forming an abscess in the intersphincteric space leading to the development of a fistula in about one third of patients.[10]

In our series of cases, we included a total sample size of 142 cases of fistula in ano. The study was predominated by male gender with a total of 83 cases (58.5%) and 59 were female (41.5%) with a male to female ratio of 1.41:1. The same male to female ratio was reported in a study by Qureshi S et al.[11] with a ratio of 1.4:1 and nearly same Dholia KR et al. [12] with a male to female ratio of 1.7:1 however a different ratio was reported by Khan S with a male to female ratio of 0.6:1. [13]

The mean age group of the patients in our study was 40.68 years +14.34SD years with a age range 18-65 years. The age range reported in our study was closer to the study conducted by Gondal KM et al who reported the range in their study to be 16-65 years[14] and a range of 18-62 years by Dholia KR et al[12] however a different age range was reported by Khan S et al with 39-75 years[13]. The mean age group reported by other studies were 40years[12], 36years[11] little different from our study and 33.9[15] years which has close approximation to the mean age group of our study.

The treatment of anal fistula has challenged physicians and healers for millennia. References to fistulous disease and use of both fistulotomy and setons can be found in the writings of Hippocrates, dating from 400 BC[16].

Current demographic data for fistula-in-ano in the United States are difficult to ascertain, as the Health Care Utilization Project (HCUP), since 1979, has recorded only inpatient procedures through its discharge data from the National Inpatient Sample. Data from a 1979 Ambulatory Care Survey of the National Center of Health Statistics listed 24 000 individuals with the diagnosis of fistula-in-ano[17]. This corresponds to the incidence of 8.6 per hundred thousand per year reported by Sainio in 1984 in the city of Helskini[18]. Another similarity seen in these studies is the 2:1 ratio of men to women in both the US and Finland[17,18]. A more current analysis of data from Europe has been performed by Zanotti in 2007, where queries of databases in the UK, Spain, Germany and Italy showed an incidence ranging from 1.04 per 10 000 in Spain to 2.32 per 10 000 in Italy[19].

For a long time, fistulotomy was the definite choice for management of anal fistula because of the best results of success healing rate which was between 74% and 100%, but in many literatures, the high risk of recurrence and fecal incontinence in the treatment of complex anal fistulas Visscher et al. was reported. In 2015, an evaluation on 141 patients with simple and complex perianal fistula who underwent fistulotomy was performed. The median follow-up was 7.8 years. 34% of the patients experienced fecal incontinence, which was worse in patients with complex fistula in comparison with simple fistula.[20] Both the American and European guidelines suggest using this procedure only for low, “simple” fistulas.[21,22]

Wound discharge was observed being significantly of shorter duration in fistulotomy group than in fistulectomy group in the present study and in similar works of same interest[23,24]. The mean healing time was statistically significantly longer in fistulotomy group than in fistulectomy group which similar to findings from other randomized clinical trials[24-26]. This finding can be explained by the fact that the mean operation wound size in these studies was smaller in fistulotomy group than in fistulectomy group[24]. The healing times in days and weeks were nearly similar in our study and others of same interest [23,27-29]. In fistulectomy the whole track and adjacent tissue is removed resulting in larger wound followed by longer healing time[30]. In fistulotomy, lesser amount of tissue is excised resulting in earlier healing time as compared to fistulectomy [31].

CONCLUSION: In conclusion, our study is the first and only to provide prospective 12weeks follow-up of fistula-in-ano. We showed that fistulotomy was technically advantageous than traditional fistulectomy and had marked difference in the incidence of wound healing. There were fewer who have problems with fistulotomy which had shorter duration of symptom as compared to long term duration, less post operative pain and less morbidity than fistulectomy.

CONFLICT OF INTEREST: No conflict of interest among authors.

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