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Original Artical

Primary Fistulotomy with Drainage Alone in Perianal Abscess: A Randomized Controlled Trial

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ABSTRACT

Background: Perianal abscess is a clinical condition frequently encountered in daily surgical practice and recurrences may occur despite treatment with adequate incision and drainage. Most perianal abscess originates from an infected anal gland. Obstruction of these glands leads to stasis, bacterial overgrowth, and ultimately abscesses that are located in the intersphincteric groove. Primary fistulotomy may be advantageous for perianal abscesses because unlike ischiorectal abscesses, fistulas are more commonly found and can be laid open with full preservation of the external anal sphincters. Primary fistulotomy at the time of drainage for perianal abscesses results in fewer persistent fistulas and no added risk of fecal incontinence. Little clinical study has been performed in this issue. The aim of this study was to evaluate the early outcome of Primary Fistulotomy in case of Perianal Abscess at a tertiary level hospital.

Study design: Randomized controlled trial.

Study setting and period: Department of Surgery, Dhaka Medical College Hospital from 29th September 2018 to 28th September 2019.

Methods: Randomized controlled trial.

Result: It was observed that majority, e.g., 29.0% patients belonged to age 18-30 years. The mean age was found 35.4±8.5 years in Group-A and 35.1±9.2 years in Group-B. Male and female ratio was 3.87:1. Large numbers of respondents came from urban area (70.0%). It was evident from this study that, total 17 patients developed Abscess recurrence or purulent discharge from the site with group A predominance (14.0% vs. 3.0% in group-A and group -B respectively). Fistula formation was found in 12 patients in group A and 2 patients in group B. In this study 79 cases in group A while 96 cases in group B had detected healthy wound with good healing. Findings suggested that postoperative outcome was better in group B patients, the difference was statistically significant ($p<0.05$) between groups. In this study, it was observed that mean duration of surgery was 24.7±4.31 minute in group-A and 25.9±4.78 minute in group B patients. Similarly mean duration of healing was 27.5±5.23 days in group-A and 28.2±5.65 days in group B patients. Although operation time and healing duration was prolonged in group-B, but the difference was statistically non-significant ($p>0.05$) between groups. Present study demonstrated that, frequency of recurrence and fistular formation was 21% versus 4% in group-A and group-B respectively. Therefore perianal abscess surgery through the combined maneuver of incision – drainage with fistulotomy is associated with better outcome.

Conclusions: Although both procedures are simple and easy to perform, drainage & fistulotomy appears to produce the better postoperative outcome, healing rate, with the fewest complications.

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Introduction:

Perianal abscess is one of the most common general surgical emergencies encountered in clinical practice and the initial treatment is simple incision and drainage, other surgical procedures as fistulotomy may be required as a definitive measure for treating fistula because about 40% of patients present with a fistula after simple incision and drainage of their perianal abscesses[1]. The classical signs of acute anorectal abscesses include pain, swelling and occasionally fever. A thorough understanding of the anatomy and pathophysiology of the disease process is critical for optimal diagnosis and management. Abscess management is fairly straight forward, with incision and drainage being the hallmark of therapy[2].

Among anorectal abscesses, 90% develop as a result of non-specific cryptoglandular infection and nearly one third of anorectal abscesses are accompanied by anal fistula[3], which increases the abscess recurrence, repeated need for drainage and may result in life-threatening conditions such as perianal sepsis. This situation is worrisome for both the patient and the surgeon, and the repeated intervention requirements may prolong hospital stay and increase the cost. There is a close relationship of abscess and fistula in etiology, anatomy, pathophysiology, therapy, complications and morbidity, it is appropriate to consider them as one entity[4].

Perianal abscesses arise from anal glands which have a predisposition to get obstructed and suppurated leading to abscess formation. Perianal abscesses and anal fistula are often found together[5]. While the initial treatment of perianal abscess is simple incision and drainage, other surgical procedures as fistulotomy may be required as a definitive measure for treating fistula because about 40% of patients present with a fistula after simple incision and drainage of their perianal abscesses6,[7]. Surgical intervention is recommended in case of spontaneous perforation since insufficient drainage may cause abscess recurrence or fistula formation. Conservative treatment options, particularly antibiotic treatment, are unlikely successful and are not considered appropriate[8]. In a Randomized controlled trial between primary fistulotomy with incision and drainage alone revealed, persistent fistulas developing after surgery were significantly more common after incision and drainage than after fistulotomy. The anal pressures after incision and drainage and fistulotomy were not significantly different. Primary fistulotomy may be advantageous for perianal abscesses because unlike ischiorectal abscesses, fistulas are more commonly found and can be laid open with full preservation of the external anal sphincters[14].

Fistulotomy performed at the same sitting as incision and drainage of a perianal abscess is termed a “primary” or “synchronous” fistulotomy. Proponents of this technique purport that, if at the time of abscess drainage, a superficial fistula tract and internal opening are readily identified, a fistulotomy performed at the same sitting may be curative and avoid the need for subsequent fistula surgery. Opponents, on the other hand, believe that two thirds of abscesses never progress to fistulas and that a primary fistulotomy with its potential complications is usually unnecessary. In addition, the patients who are ideal candidates for primary fistulotomy are also the easiest to treat with delayed fistulotomy with subsequent low morbidity. Because there is inadequate evidence from which to draw a clear consensus, the prudent policy would be to defer fistulotomy until the fistula becomes manifest[2]. Primary fistulotomy may be attempted when it is identified and superficial9. One can suspect development of fistula later on when there is a prolonged drainage from an incision site beyond 2–3 months and abscess heals and recurs at the same first location10. Study shows that in case of perianal abscess, one stage abscess and fistula treatment by identification of fistula’s tract minimizes the risk of recurrence, thus leading to safe and definite treatment[11].

The incidence of fistula following an abscess incision and drainage is 26% and incidence of recurrent abscess 37%[12,13]. If a fistula is identified and is quite superficial, primary fistulotomy may be attempted using a loose seton of braided, nonabsorbable suture that inserted into the fistula tract, tied loosely to act as a drain4. This is termed a “primary” or “synchronous” fistulotomy which is curative and avoid the need for subsequent fistula surgery[9,10]. Another comparative study showed that treatment of perianal abscess through the combined maneuver of incision drainage with fistulotomy at the same time significantly reduced the likelihood of persistent abscess, recurrence and need for repeat surgery[15]. The aim of this study is to assess and compare the outcome of primary fistulotomy at the time of incision-drainage with incision and drainage alone in perianal abscess surgery.

Study design:
Prospective Randomized controlled trial.

Place of study:
Department of Surgery, Dhaka Medical College Hospital, Dhaka.

Study periods:
Study was conducted from 29th September 2018 to 28th September 2019.

Study Population:
Patients with perianal abscess attended in surgery department of Dhaka Medical College and Hospital, Dhaka for surgical treatment were enrolled after careful history taking, thorough general and local examination and appropriate investigations fulfilling inclusion and exclusion criteria.

Sample size:
The following standard formula is widely used in determining sample size:

$$n = \frac{z^2 pq}{d^2}$$

n= the desired sample size
z= Standard normal deviate usually set at 1.96
p= Proportion in the population will be 0.5 (0.01-0.99), due to unknown prevalence.
q= 1-p
d= Degree of accuracy which is considered as 0.05

According to this formula the targeted sample is 384. This study period was 12 months. Due to time and resourced constrain total 200 patients were selected, 100 in each group.

Sampling:
Purposive sampling was applied for sampling.

Data collection procedure:
This Randomized controlled trial was conducted in Department of surgery, DMCH for 12 months. Patients admitted to surgery department and scheduled for surgical management of perianal abscess were included in the study. However, patients refuse to participate in study, pregnancy cases or breast feeding mother, patient with ongoing infection or sepsis, , etc were excluded. Ethical approval was obtained from the DMCH ethical review board. A total 200 consecutive, simple random sample were assessed by the investigator. Diagnosis was made on the basis of patient's medical record, statement of the witness, characteristic features of manifestation, clinical examination and available medical records. After fulfilling the inclusion and exclusion criteria, patients were enrolled with unique ID. Patients and legal guardians of selected patients were approached to take participation in the study and risk and benefits, freedom for participation were briefed. Informed consent was obtained accordingly. Patient was managed according to the feature of corresponding aetiology.

Two groups of patients, 100 patients in each group were allocated by purposively. The group-A had given incision and drainage and group-B patients were given drainage & primary fistulotomy. Both groups were studied for postoperative surgical outcome. The primary end points were abscess recurrence, fistula formation and incontinence. The secondary end points were time off from work, wound discharge, wound healing and patients' satisfaction. The case definitions of operational variable were described. Patient data such as age, sex, clinical presentation, etc were noted. This questionnaire was used for collection of information by interviewing patients. All the collected data questionnaire were checked very carefully to identify errors in collecting data. Data processing work consisted of registration of schedules, editing, coding and computerization, preparation of dummy tables, analysis and matching data. Categorical variables were summarized as percentages. Quantitative variables were summarized as mean standard deviation. Test for association between groups and categorical variables was perform using chisquare test. For quantitative variable means will compare by student t test. P<0.05 was accepted as statistical significant.

Data analysis:
Keeping the research topic in concern, a preset questionnaire was set for data collection. Data for socio-demographic and clinical variables were obtained from all participants using a pre-designed and easily understandable questionnaire. After collection of all information, these data were checked, verified for consistency and edited for finalized result. Data processing work will consist of registration schedules, editing computerization, preparation of dummy table, analyzing and matching of data. After editing and coding, the coded data directly entered into the computer by using SPSS latest version. Data cleaning validation and analysis was performed using the SPSS/PC

software and graph and chart by MS excel. The result was presented in tables in proportion. A "P" value <0.05 considered as significant.

Ethical measures:

- Prior to the commencement of this study, the thesis protocol was approved by the Ethical Review Committee, DMCH.
- Informed written consent was obtained from the patients' authorized guardians after explaining every ethical issue regarding the study. They were clearly informed in easily understandable local language about the nature and purpose of the study, procedures, risk associated with it and benefits, expected outcome of this research and their probable welfare implications.

They were informed about the right to participate or to withdraw from the study at any time. They assured that data obtained from the study will be used only for the research purpose and there is minimum physical, psychological, social and legal risk during collection of data. Patients' basic human rights would not be violated in any way. Every precaution will be taken so that this study will not cause any harm or delay in treatment of cases. It will also be mentioned that the subject will not gain financial benefit from this study.

Methodology Proper:

1) This study was done in Department of Surgery, Dhaka Medical College Hospital, Dhaka
2) Pretesting of questionnaire
3) Finalization of questionnaire
4) Consecutive sampling
5) Consent taking
6) Detailed history
7) Physical examination
8) Investigation
9) Filling the questionnaire by data collected from patients

RESULTS:

This Prospective Randomized controlled trial was carried out to compare the outcome of primary fistulotomy with incision & drainage alone in case of perianal abscess. This study included total 200 patients admitted to surgery department of DMCH and scheduled for perianal abscess surgery, allocated in two groups. Among them in group-A there were 100 patients (incision and drainage) and group-B, 100 patients (drainage & fistulotomy). All patient in both arm completed treatment. No drop out was noticed during treatment.

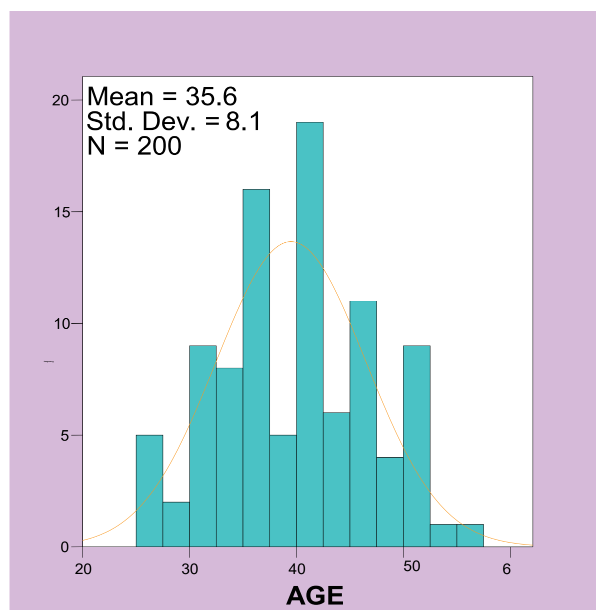

Figure- 1: Histogram showing age distribution of the patients

Figure depicts the age distribution of the patients. Mean age was 35.6 (SD±8.172) years. Age distribution resembles normal distribution where the numbers of middle to younger aged patients were high in contrast to extreme or older age groups. About 80% patient's age was between 25 to 35 years. Least numbers of patients was present from other age groups. Sample 't test' were done to find whether any significant difference does exist or not. The T-value was 0.747815. The P-Value was 0.2282. The result was not significant at $p < 0.05$.

Table- 1: Demographic characteristics of the patients (n=200)

Age (years)	Frequency and percentage		Total (%)
	Group A (n = 100) No. (%)	Group B (n = 100) No. (%)	
18-30	32(32.0%)	24(24.0%)	58
31-40	22(22.0%)	30(30.0%)	52
41-50	26(26.0%)	24(24.0%)	50
51-60	16(16.0%)	14(14.0%)	30
61-70	4(4.0)	8(8.0%)	12
Mean ± S.D.	**35.4±8.5**	**35.1±9.2**	

Table shows the demographic characteristics of the patients. It was observed that majority, e.g., 29.0% patients belonged to age 18-30 years, followed by 26.0% patients belonged to age 31-40 years. The mean age was found 35.4±8.5 years in Group-A and 35.1±9.2 years in Group-B. There was no significant difference between two groups.

Table- 2: Gender distribution of study subject (n=200)

Gender distribution	Frequency and percentage		P value
	Group A (n = 100) No. (%)	Group B (n = 100) No. (%)	
Male	73(73.0%)	86(86.0%)	0.361ns
Female	27(27.0%)	14(14.0%)	0.361ns

Table shows gender of the patients. Out of 200 cases 159(79.5%) cases were male and 41(20.5%) were female. Male and female ratio was 3.87:1.

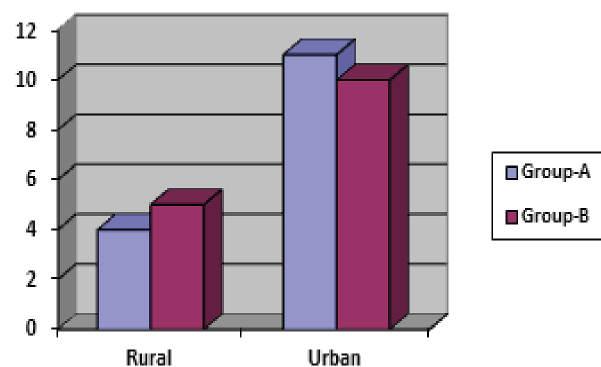

Figure- 2: Distribution of patients according to residence (n=200)

Table showed area of residence of the patients. Large numbers of respondents came from urban area (70.0%), followed by rural area (30.0%).

Table- 3: Occupational distribution of the study patients (n=200)

Occupational status	Frequency and Percentage				P value
	Group A (n = 100) No. (%)		Group B (n = 100) No. (%)		
	No.	%	No.	%	
Business	28	28.0	30	30.0	0.158ns
House wife	26	26.0	12	12.0	
Service & Worker	46	46.0	58	58.0	
Total	100	100.0	100	100.0	

Regarding occupational status of the patients, it was observed that maximum patients e.g., 47.0% were service holder & worker, 46.0% in group A and 48.0% in group A. House wife was 26.0% in group A and 12.0% in group B patients. The difference was not statistically significant (p>0.05) between two groups.

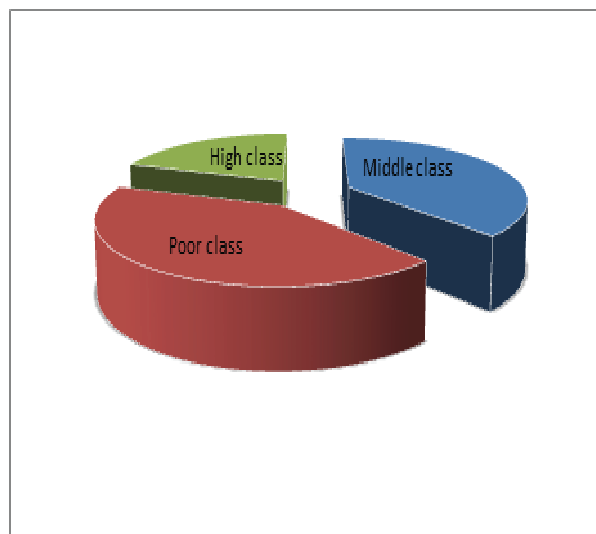

Figure- 3: Socioeconomic status of the study population (n=200)

Socioeconomically patients are grouped into three classes. Among the patients the poor class 42% comprising the major percentage of the patients, which is followed by middle class 38% and remaining are upper class 20%.

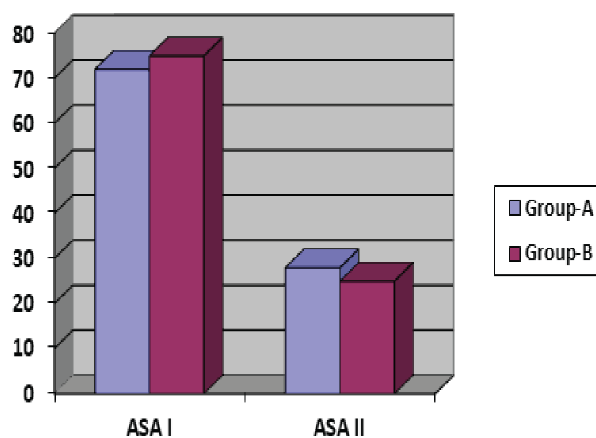

Figure- 4: American Society of Anesthesiologist (ASA) physical status (n=200)

Patient distribution as regard to ASA status. There were no significant difference between the groups (p=0.950). Comparison was done by Chi-Square ($\chi 2$) test.

Table- 4: Assessment and follow-up of surgical site at postoperative period (n=200)

Characteristics of wound site	Number of patients		Total (%)	P value
	Group A (n = 100) No. (%)	Group B (n = 100) No. (%)		
Healthy wound with good healing	79	96		0.0003
Purulent discharge from the site (Abscess recurrence)	14	3	17	0.0054
Fistula formation	12	2	14	0.0057

Multiple respondents

It is evident from the table that, total 17 patients developed Abscess recurrence or purulent discharge from the site with group A predominance (14.0% vs. 3.0% in group-A and group -B respectively). Fistula formation was found in 12 patients in group A and 2 patients in group B. In this study 79 cases in group A while 96 cases in group B had detected healthy wound with good healing. Findings suggested that postoperative outcome was better in group B patients, the difference was statistically significant ($p<0.05$) between groups.

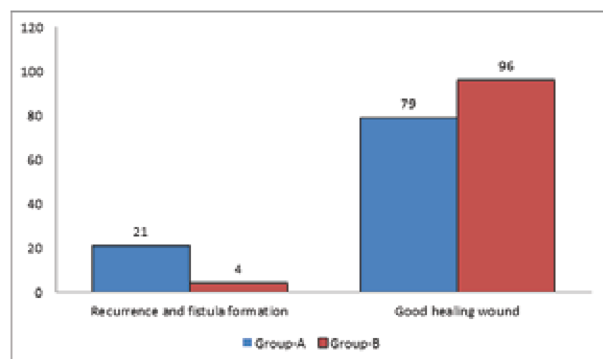

Figure- 5: Comparison of postoperative outcome between groups (n=200)

Present study demonstrated that, frequency of recurrence and fistular formation was 21% versus 4% in group-A and group-B respectively. Therefore perianal abscess surgery through the combined maneuver of incision – drainage with fistulotomy is associated with better outcome.

Table- 5: Comparison of duration of surgery and healing between two groups (n=200)

Variable	Mean duration		P value
	Group A (n = 100) No. (%)	Group B (n = 100) No. (%)	
Mean duration of surgery (minute)	24.7±4.31	25.9±4.78	0.063
Wound to heal completely (Mean duration of healing) in days	27.5±5.23	28.2±5.65	0.364

Table shows comparison of duration of wound healing and mean duration of surgery between two groups. It was observed that mean duration of surgery was 24.7±4.31 minute in group-A and 25.9±4.78 minute in group B patients. similarly mean duration of healing was 27.5±5.23 days in group-A and 28.2±5.65 days in group B patients. Although operation time and healing duration was prolonged in group-B, but the difference was statistically non-significant ($p>0.05$) between groups.

Table- 6: Distribution of the patients according to minor pattern incontinence to liquid & flatus (n=200)

Incontinence	Number of patients		P value
	Group A (n = 100) No. (%)	Group B (n = 100) No. (%)	
Present	0	3	
Absent	100	97	0.081

Table shows minor pattern incontinence to liquid & flatus of study subject. It was observed that anal incontinence rate was higher in group B patients (e.g., 3.0%) compared with group A. But the difference was statistically non-significant ($p>0.05$) between groups.

Table- 3.7: Satisfaction Following perianal abscess treatment (n=50)

Impression	Satisfaction grade (Likert Scale)	Number of patients		P value
		Group A (n = 100) No. (%)	Group B (n = 100) No. (%)	
Very satisfied	5	27	35	
Somewhat satisfied	4	52	61	
Undecided/ neutral	3	0	0	
Somewhat dissatisfied	2	6	0	
Very dissatisfied	1	15	4	
mean±SD		3.71±0.8	4.23±1.5	0.002

In this study 5(five) point Likert Scale was used to assess the patients satisfaction. The Likert Scale is a rating scale that's often used assessing the patients/ subject/ patron regarding experiences and overall effectiveness with the sort or service. Total 175(87.5%) patients experienced/ satisfaction of grades 4 and 5 after perianal abscess treatment. The mean±SD of score was 3.71±0.8 in group-A and 4.23±1.5 in group-B. So, surgical operation of drainage & fistulotomy is associated with better technique in the means of patient's satisfaction. The difference was statistically significant ($p<0.05$) between groups.

Discussion:

This randomized controlled trial was conducted in department of surgery, Dhaka medical college hospital over a period of 12 month to compare the outcome of primary fistulotomy with incision & drainage alone in case of perianal abscess. It was observed that majority, e.g., 29.0% patients belonged to age 18-30 years. The mean age was found 35.4±8.5 years in Group-A and 35.1±9.2 years in Group-B. There was no significant difference between two groups. Out of 200 cases 159(79.5%) cases were male and 41(20.5%) were female. Male and female ratio was 3.87:1. Large numbers of respondents came from urban area (70.0%).

Findings consistent with result of other studies. in a study group comprised of 68 (92.64%) patients with perianal abscess with a median age of 39 years (range 20-68 years). Males (63/68) (92.64%) were more than females (5/68) (7.35%)[14]. The prevalence of perianal abscesses and anorectal abscesses, in general, are underestimated, since most patients do not seek medical attention, or are dismissed as symptomatic hemorrhoids. It is estimated that there are approximately 100,000 cases of the benign anorectal disease in general. The mean age at presentation is 40 years old, and adult males are twice as likely to develop with abscess than females[3].

The peak incidence of anorectal abscesses is in the third and fourth decades of life. The exact mechanism is poorly understood but does not appear to be related to constipation. Men are affected more frequently than women, with a male-to-female predominance of 2:1 to 3:1. The age of most patients with anorectal suppuration is between 20 and 60 years, with a mean of 40 years and an incidence twice as high in men, reaching up to 83.9% of cases6. Saber et al reported concerning the demographic data, there was no statistical significant difference between the two groups regarding age, sex, body mass index (BMI) and diabetes. 79% of our patients were gentlemen, 38% were ≥50 years old[11].

It was evident from this study that, total 17 patients developed Abscess recurrence or purulent discharge from the site with group A predominance (14.0% vs. 3.0% in group-A and group -B respectively). Fistula formation was found in 12 patients in group A and 2 patients in group B. In this study 79 cases in group A while 96 cases in group B had detected healthy wound with good healing. Findings suggested that postoperative outcome was better in group B patients, the difference was statistically significant ($p<0.05$) between groups.

Our data reported that higher abscess recurrence and fistula formation after the treatment modalities using incision & drainage of perianal abscess and this finding was in concordance with other published data that reported abscess recurrence rate of 29% incision/drainage group as compared with 5% of the fistulotomy group[25], [26]. Other studies of same interest reported that acute abscess recurrences occur in 10% and development of chronic fistula-in-ano occurs in up to 50% of patients[27] while another stated that 31% of patients developed fistula-in-ano following incision and drainage[28].

The decision of whether or not to perform a fistulotomy during the original incision and drainage of perianal abscess has been debated in the literature[1], [29]. In a randomized clinical trial done by

Oliver and colleagues compared simple drainage abscess drainage with and without fistula track treatment to evaluate the effectiveness and morbidity of both operations in the management of acute anal sepsis. They found that drainage of the abscess with fistulotomy can be safely performed in cases of subcutaneous, intersphincteric, or low transsphincteric fistula with a minimal recurrence rate as 5% compared with 29% recurrence rate in patients treated with drainage alone[26].

In this study it was observed that anal incontinence rate was higher in group B patients (e.g., 3.0%) compared with group A. But the difference was statistically non-significant ($p>0.05$) between groups.

Previous studies were similar result. Incontinence rates following fistulotomy depends on both the amount of muscle divided at the time of operation as well as any preexisting previous sphincter damage causing scarring of the anal canal[29, 30, 31]. Incontinence rates have been reported in previous reports to range from 18% to 52%[29, 32, 33]. Oliver and his colleagues found zero % incontinence in drainage only and 6% in drainage with fistulotomy[26].

In this study, it was observed that mean duration of surgery was 24.7±4.31 minute in group-A and 25.9±4.78 minute in group B patients. Similarly mean duration of healing was 27.5±5.23 days in group-A and 28.2±5.65 days in group B patients. Although operation time and healing duration was prolonged in group-B, but the difference was statistically non-significant ($p>0.05$) between groups.

Similar observation reported that the mean operative time in patients of group A was 23±5.21 minutes and that for patients of group B was 25±4.68 minutes with statistically insignificant distribution {P≥0.0996}1. Regarding the time to complete healing, the mean time was 18 (range 10-53) days and 26 (range 18-40) days after drainage alone versus fistulotomy respectively[1, 34].

In this study 5(five) point Likert Scale was used to assess the patients satisfaction. The Likert Scale is a rating scale that's often used assessing the patients/ subject/ patron regarding experiences and overall effectiveness with the sort or service. Total 175(87.5%) patients experienced/ satisfaction of grades 4 and 5 after perianal abscess treatment. The mean±SD of score was 3.71±0.8 in group-A and 4.23±1.5 in group-B. So, surgical operation of drainage & fistulotomy is associated with better technique in the means of patient's satisfaction. The difference was statistically significant ($p<0.05$) between groups.

Patient satisfaction after surgery for anal diseases depends on factors like period of hospitalization, postoperative pain and bleeding, return to routine activity, wound care, wound healing time, interference with the anal continence and recurrence. The majority of patients subjected to surgery for anal problems attributed their dissatisfaction to recurrence and anal incontinence following surgery25. In other study, satisfaction was much more in patients treated with abscess drainage and fistulotomy than those treated as drainage only as a result of less recurrence, less wound discharge and lower incidence of fistula formation1. Present study demonstrated that, frequency of recurrence and fistular formation was 21% versus 4% in group-A and group-B respectively. Therefore perianal abscess surgery through the combined maneuver of incision – drainage with fistulotomy is associated with better outcome.

Conclusion:

Perianal abscess is one of the most common general surgical emergencies encountered in clinical practice and its surgical management is one of the most common surgical emergency procedures performed by the surgical team. Proper evaluation and meticulous surgical technique reduced the burden of Perianal abscess. The present study showed that treatment of perianal abscess through the combined maneuver of incision – drainage with fistulotomy at the same time significantly reduced the likelihood of persistent abscess, recurrence and need for repeat surgery. Patient's satisfaction after treatment with this combined method showed a significant value than incision – drainage only as regard disease recurrence, time of wound discharge and the incidence of fistula formation.

Recommendations:

- Considering easy availability and use in practice, combined drainage & fistulotomy surgical approach can be used routinely

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