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A Comparative Study between Subcutaneous Lateral Internal Partial Sphincterotomy versus Open Lateral Internal Partial Sphincterotomy in Management of Chronic Fissure in ANO

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Abstract

Background and objectives: The standard of treatment for chronic anal fissure is lateral internal sphincterotomy, which involves dividing the lower third to half of the internal sphincter thereby reducing the internal sphincter spasm. It may be performed by open or subcutaneous method. This study compares the postoperative outcome of subcutaneous lateral internal sphincterotomy and open lateral internal sphincterotomy with an aim to find an equally effective procedure with fewer complications.

Methods: This was a prospective study conducted in department of general surgery, ESIC MC PGIMSR, Rajajinagar, Bengaluru from January 2018 to June 2019. All patients with chronic fissure were classified into two groups- open LIS and subcutaneous LIS groups. Both procedures were done under local anaesthesia. The sample size was 50 cases in each group.

Results: Majority of the fissures were seen in males (56%) in the age group of 31-40 years. In the open group, 78% attained pain relief in 3-4 weeks and 90% within 1 week in subcutaneous group. Wound healing occurred at 1 week in 90% versus 96% in open and subcutaneous groups respectively. Infection rate was 10% and 4% in open and subcutaneous groups respectively. The time of return to work was 4.7 days versus 1.9 days in the open and subcutaneous groups respectively. Incontinence rate was 8% and 4% in open and subcutaneous groups respectively. Recurrence rate at 6 months was 4% and 2% in open and subcutaneous groups respectively.

Interpretation and conclusion: Lateral internal partial sphincterotomy is the standard of treatment for chronic fissures. Both subcutaneous and open methods are equally effective with the subcutaneous method being better tolerated under local anaesthesia and can be practised as a day care outpatient procedure.

Keywords: Anal fissures; subcutaneous lateral internal sphincterotomy; open lateral internal sphincterotomy; local anaesthesia

Introduction

Diseases of the anorectum are a group of conditions commonly affecting the mankind. They encompass a diverse set of disorders which cause significant discomfort to the patients. Majority of the population (30-40%) suffer from these conditions at least once in their lifetime.

Anal fissure is a common disorder which was first described by Recamier in 1829. It is an ulcer-like tear in the anoderm over the hypertrophied band of internal sphincter at the anal verge, distal to the dentate line. It is seen in all age groups particularly in young adults. It has almost equal gender distribution. The fissure is almost always located close to the midline of the anal canal; in men 95% are near the posterior midline and 5% near the anterior midline, whereas in women about 80% are seen posteriorly and 20% anteriorly. This condition is associated with painful defecation, bleeding per anus and constipation. Most of the anal fissures are acute, resolving spontaneously or with increased dietary fibre intake and stool softeners. Those lesions which fail to heal despite simple lifestyle modifications and persist beyond six weeks are designated as chronic anal fissures.

A chronic fissure is usually deeper and generally has exposed internal sphincter fibres in its base. It is frequently associated with heaped up edges, sentinel pile and occasionally hypertrophied anal papilla. Painful fissures are generally associated with spasm of internal sphincter. This involuntary spasm of the internal sphincter in response to the trauma of the exposed subcutaneous tissue of the fissure causes severe pain, which is a common symptom of anal fissure.

The persistence of a fissure after any initiating event is associated with increased resting anal pressure and hence treatment is directed at eliminating this. The standard algorithm for treatment of anal fissure consists of a trial of fibre supplementation, sitz bath and topical analgesics. Chronic fissures which do not heal by conservative measures can be subjected to chemical sphincterotomy or surgery. Chemical sphincterotomy can be performed with nitrates, calcium channel blockers or botulinum toxin A. Surgical management of chronic fissures includes anal dilatation and internal sphincterotomy. Anal dilatation helps in healing of the fissure by reducing the anal canal pressure. Overstretching is believed to cause permanent damage to the sphincter muscle resulting in incontinence.

In internal sphincterotomy, the internal sphincter is divided partially, away from the fissure either in lateral or posterior position. Lateral internal sphincterotomy is the standard of treatment for chronic fissures. It can be done by subcutaneous/ closed or open methods. Both the methods are equally effective. But, subcutaneous method is associated with fewer complications when compared to open method. Lateral internal sphincterotomy can be done under local/ spinal or general anaesthesia.

This study aims to compare the postoperative outcome of subcutaneous lateral internal sphincterotomy and open lateral internal sphincterotomy, with both the procedures being conducted under local anaesthesia.

Materials and Methods

Source of the data: This study was conducted in department of general surgery, ESIC MC PGIMSR, Rajajinagar, Bangalore-10. All patients with clinical diagnosis of chronic fissure in ano were included in the study.

Study Period: January 2018 to June 2019

Study Design: a prospective randomized study.

Place of Study: The present study will be conducted in the Department of General surgery, ESIC MC&PGIMSR, Rajajinagar and Bengaluru – 10

Sample Size: The sample size for the present study has been calculated by considering the proportion of complications in closed technique and in open technique as 18% and 58% respectively from the previously published literature. The minimum sample size has been calculated to be 50 cases in each group with 0.4 as effect size at 5% level of significance, which gives at least 95% power assuming two-tailed hypothesis. Therefore, the total sample size of the study will be 100 cases.

Following formula has been used to calculate the sample size:

$$n = \frac{\left[Z_{\alpha/2}\sqrt{2*\overline{P}(1-\overline{P})} + Z_{\beta}\sqrt{P_0(1-P_0)+P_1(1-P_1)}\right]^2}{(P_0 - P_1)\text{^}2}$$

Where, $Z_{\alpha/2}$ = 1.96, Z_{β} = 1.64, P_0=.58, P_1= 0.18 and $\overline{P} = \frac{P_0 + P_1}{2}$

Inclusion Criteria

Participants aged above 18 years of age of both genders, with chronic fissure in ano undergoing surgery and willing to participate in the study. Fissures with following features will be included in the study:

1. Fissures failing to heal in 6 weeks with conservative measures
2. Fissures with indurated margins
3. Fissures lacking granulation tissue
4. Fissures with sentinel pile

Exclusion Criteria: Patients with

1. Haemorrhoids.
2. Fissures associated with inflammatory bowel diseases
3. Comorbidities like malignancy and immunosuppressive diseases.
4. Fissures in atypical locations and multiple fissures.

Methodology

- After thorough history taking, clinical examination and routine blood investigations, those patients meeting the above criteria and consenting for the study will be included in the study. All patients will be classified into two groups with first group undergoing subcutaneous (closed) lateral internal sphincterotomy and second group undergoing open lateral internal sphincterotomy.
- Patients will be asked to undergo only liquid diet the previous day and to prepare parts by themselves. Both the procedures will be carried out in minor operation theatre, under local anaesthesia with an intravenous line. Patient will be discharged after one hour of observation.
- Local anaesthetic that will be used is 1% lignocaine. Local infiltration will be given below the dentate line to block the sensation of pain below the dentate line. Using a 21-gauge needle the local anaesthetic is injected deep into the intersphincteric space on both right and left side. The total volume of 1% lignocaine solution that may be used is 20 ml.
- Patient is put in lithotomy position. Parts painted and draped. In closed lateral internal partial sphincterotomy, the index finger of the left hand is inserted into the anal canal. Keeping this finger in place, the intersphincteric groove and internal sphincter is felt. Using 11-no blade 5mm stab incision is given on the anal verge on left or right lateral side and the blade is inserted in the submucous plane. The internal sphincter is cut with see-saw movements in the distal 1/3 only. The defect can be felt with the index finger. The anal canal packed with roll gauze which exerts counter pressure and achieves haemostasis. The stab incision is left open.
- In open method, a radial incision is made laterally at the lower border of the internal sphincter into the intersphincter groove. The distal internal sphincter is grasped with allis forceps and bluntly freed. The lower one third to one half is divided. The incision is left open. Sentinel pile is excised only if it is troublesome for the patient.
- Parameters that will be studied include:
  1. Postoperative pain assessed by verbal rating scale
  2. wound healing
  3. Infection
  4. Time of return to work
  5. Alteration in anal continence
  6. Recurrence.

Statistical Analysis

All characteristics were summarized descriptively. For continuous variables, the summary statistics of mean± standard deviation (SD) were used. For categorical data, the number and percentage were used in the data summaries and diagrammatic presentation. Chi-square ($\chi 2$) test was used for association between two categorical variables.

The formula for the chi-square statistic used in the chi square test is:

$$\chi_c^2 = \sum \frac{(O_i - E_i)^2}{E_i}$$

The subscript "c" is the degrees of freedom. "O" is observed value and E is expected value. The difference of the means of analysis variables between two independent groups was tested by unpaired t test.

The t statistic to test whether the means are different can be calculated as follows:

$$t = \frac{(\overline{x_1} - \overline{x_2}) - (\mu_1 - \mu_2)}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}}$$

where $\bar{x}_1$ = mean of sample 1

$\bar{x}_2$ = mean of sample 2

n_1 = number of subjects in sample 1

n_2 = number of subjects in sample 2

s_1^2 = variance of sample 1 = $\frac{\Sigma(x_1 - \bar{x}_1)^2}{n_1}$

s_2^2 = variance of sample 2 = $\frac{\Sigma(x_2 - \bar{x}_2)^2}{n_2}$

If the p-value was < 0.05, then the results were considered to be statistically significant otherwise it was considered as not statistically significant. Data were analyzed using SPSS software v.23.0 and Microsoft office 2007.

Investigations Required For Study

- Haemogram: Haemoglobin, total count, differential count and platelet count
- Random blood Sugar
- Coagulation profile
- HIV, HBsAg and HCV

Result

One hundred patients with chronic anal fissure were chosen for this study from those who were presented in surgical out patients department of ESIC-MC & PGIMSR, between anuary 2018 and June 2019.

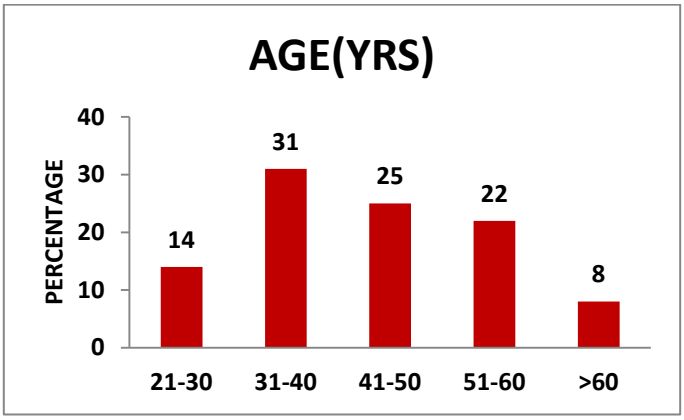
Among the 100 who had chronic fissure, their age ranged from 21- 72 years, with the mean age being 45.6 with SD of 11.4. The peak incidence was noted in the age group of 31- 40 years (31%) and the lowest incidence was recorded in the age group of >60 years (8%).

Table-1: Distribution of Cases According To Age

AGE(YRS)	N	%
21-30	14	14
31-40	31	31
41-50	25	25
51-60	22	22
>60	8	8
Total	100	100

Descriptive Statistics	Range	Mean	SD
AGE(YRS)	26-72	45.6	11.4

Figure- 1: Distribution of Cases According To Age



In this study, there were 56 male patients (56%) and 44 female patients (44%) with a male to female ratio of 1.3:1.0

Table-2: Distribution of Cases According To Sex

Sex	N	%
Male	56	56
Female	44	44
Total	100	100

Male to Female Ratio Is 1.3:1.0

Figure 2: Distribution of Cases According To Sex

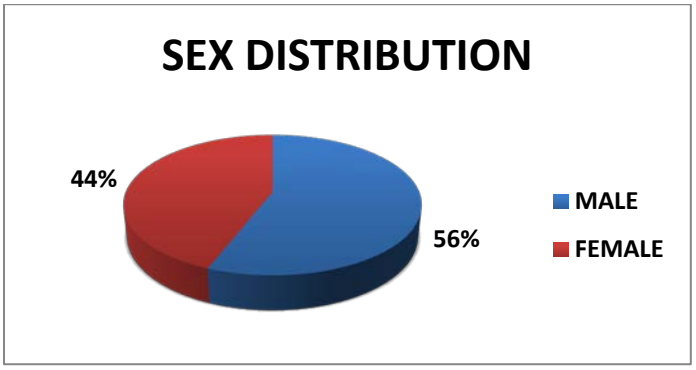
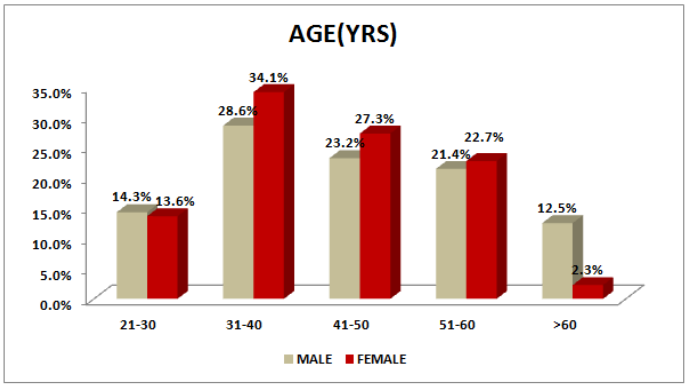


Table-3: Association of Age and Sex

Age(Yrs)	Male		Female		P Value
	N	%	N	%	
21-30	8	14.3%	6	13.6%	0.455
31-40	16	28.6%	15	34.1%	
41-50	13	23.2%	12	27.3%	
51-60	12	21.4%	10	22.7%	
>60	7	12.5%	1	2.3%	
Total	56	100.0%	44	100.0%	

Figure 3: Association of Age and Sex

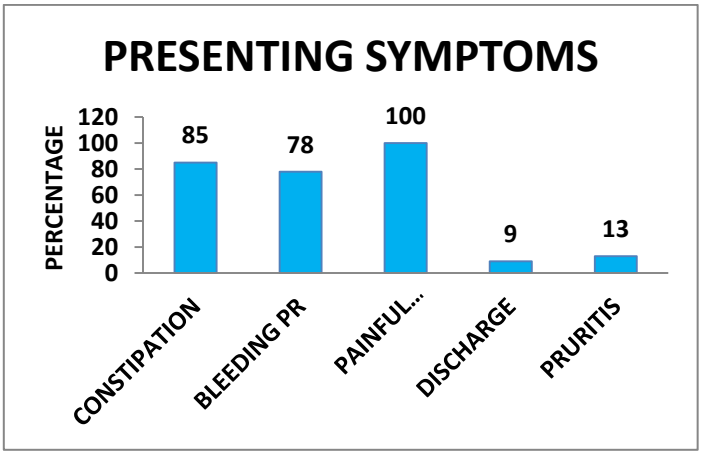


Most of the patients in this study complained of painful defaecation, with the symptom being present in all the 100 patients (100%). Next most common symptom was constipation (85%) followed by bleeding per rectum (78%). 13% of them complained of pruritis in the perianal region and 9% had discharge per rectum.

Table 4: Distribution of Cases According To Presenting Symptoms

Presenting Symptoms	N	%
Constipation	85	85
Bleeding Pr	78	78
Painful Defaecation	100	100
Discharge	9	9
Pruritis	13	13

Figure 4: Distribution of Cases According To Presenting Symptoms

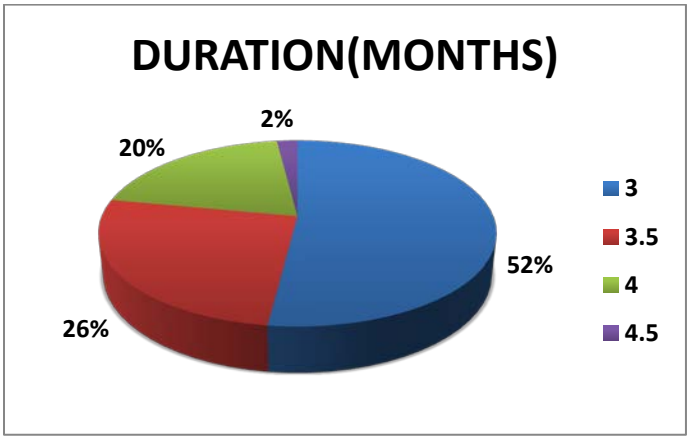


The duration of symptoms ranged from 3-4.5 months with a mean duration of 3.4 months and a SD of 0.4. Of the 100 patients, 52% of them had the symptoms for 3 months, 26% for 3.5 months, 20% for 4 months and 2% for 4.5 months.

Table 5: Distribution of Cases According To Duration (Months)

Duration(Months)	N		%
3	52		52
3.5	26		26
4	20		20
4.5	2		2
Total	100		100
Descriptive Statistics	Range	Mean	Sd
Duration(Months)	3-4.5	3.4	0.4

Figure 5: Distribution of Cases According To Duration (Months)

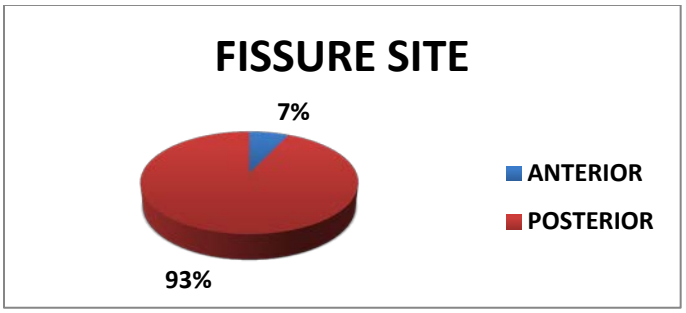


In all 100 patients included in the study, the position of anal fissure was noted. Ninety three patients (93%) were having posterior fissure and 7 patients (7%) were having anterior fissure.

Table 6: Distribution of Cases According To Fissure Site

Fissure Site	N	%
Anterior	7	7
Posterior	93	93
Total	100	100

Figure 6: Distribution of Cases According To Fissure Site

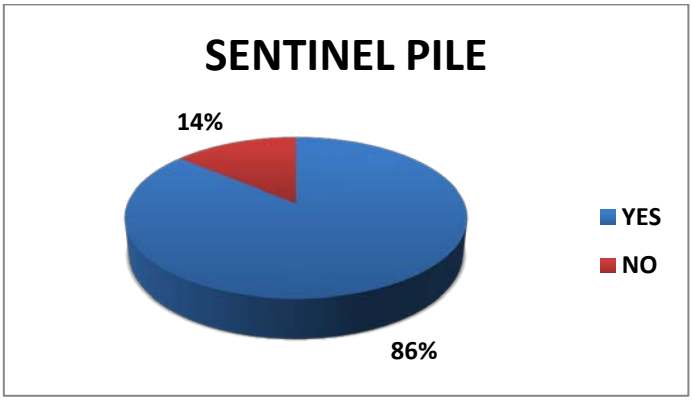


In our study population, 86% of them had sentinel pile.

Table 7: Distribution of Cases According To Sentinel Pile

Sentinel Pile	N	%
Yes	86	86
No	14	14
Total	100	100

Figure 7: Distribution of Cases According To Sentinel Pile



Out of the 100 patients, 50 underwent open lateral internal partial sphincterotomy and the other 50 underwent subcutaneous (closed) lateral internal partial sphincterotomy.

On the first postoperative day, pain was assessed using the Verbal Rating Scale.

In the group that underwent open LIS, 32 patients (64%) had a score of 5-6, which is classified as severe pain under the verbal rating scale. The remaining 18 patients (36%) had a score of 7-8, which is classified as very severe pain.

In the group that underwent subcutaneous (closed) LIS, 38 patients (76%) had a score of 3-4, which is classified as moderate pain and the rest 12 patients (24%) had a score of 5-6.

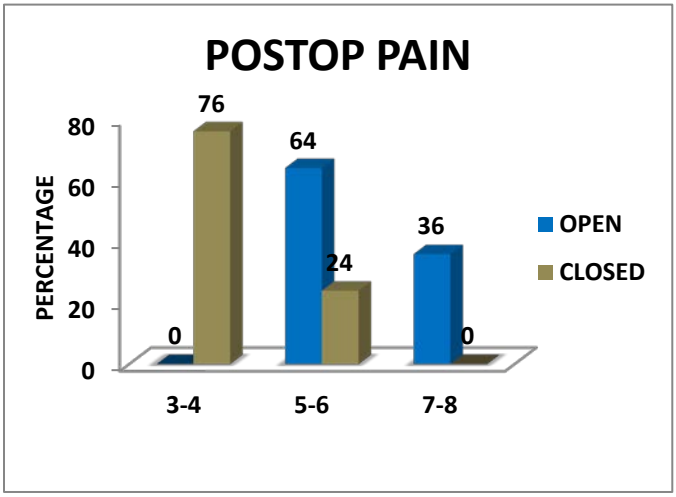
P value is <0.001, which is statistically significant.

Table 8: Distribution of Postop Pain between Study Groups

Postop Pain (Verbal Rating Scale)-Pod1	Open		Subcutaneous/ Closed		P Value
	N	%	N	%	
3-4	0	0	38	76	<0.001*
5-6	32	64	12	24	
7-8	18	36	0	0	
Total	50	100	50	100	

Note: * significant at 5% level of significance (p<0.05)

Figure 8: Distribution of Postop Pain between Study Groups



In the first group (open LIS), no patient had pain relief in the first week. 1 patient (2%) obtained pain relief in 1-2week, 39 patients (78%) in 3-4weeks and 10 patients (20%) required >4 weeks for pain relief.

In the second group (subcutaneous/closed LIS), 45 patients (90%) had pain relief in the first week with remaining 5 patients (10%) achieving the same in 1-2 weeks.

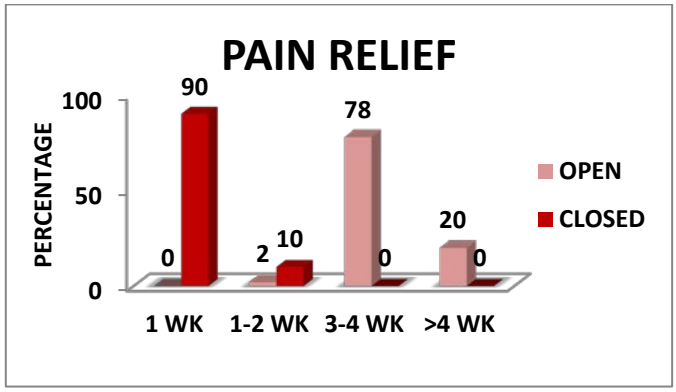
P value was <0.001 which is statistically significant.

Table 9: Distribution of Pain Relief Between Study Groups

Pain Relief	Open		Subcutaneous/Closed		P Value
	N	%	N	%	
1 Wk	0	0	45	90	<0.001*
1-2 Wk	1	2	5	10	
3-4 Wk	39	78	0	0	
>4 Wk	10	20	0	0	
Total	50	100	50	100	

Note: * significant at 5% level of significance (p<0.05)

Figure 9: Distribution of Pain Relief between Study Groups



In the first group (open LIS), wound healed within the first week in 45 patients (90%) and healed at 2 weeks in the rest 5 patients (10%).

In the second group (subcutaneous LIS), wound healed within the first week in 48 patients (96%) and at 2 weeks in the remaining 2 patients (4%).

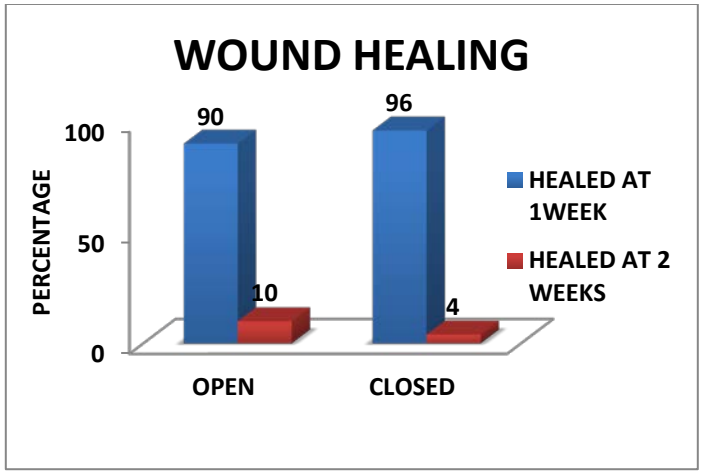
P value is 0.240 which is statistically insignificant.

Table 10: Distribution of Wound Healing Between Study Groups

Wound Healing	Open		Subcutaneous/Closed		P Value
	N	%	N	%	
Healed At 1week	45	90	48	96	0.240
Healed At 2 Weeks	5	10	2	4	
Total	50	100	50	100	

Note: * significant at 5% level of significance (p<0.05)

Figure 10: Distribution Of Wound Healing Between Study Groups

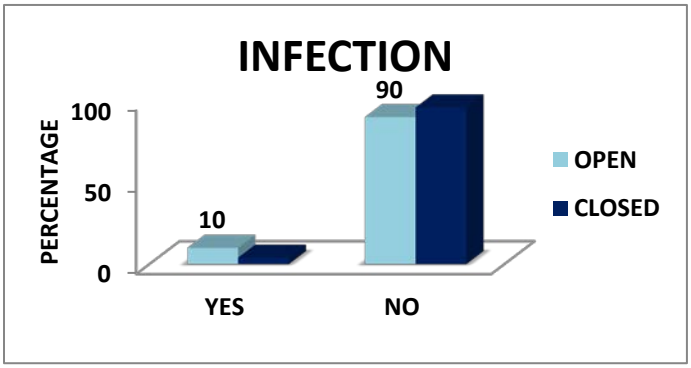


Among the patients who underwent open LIS, 5 (10%) of them developed infection at the surgical site, whereas only 2 patients (4%) in the closed group developed infection. P value is 0.240 which is statistically insignificant.

Table 11: Distribution of Infection between Study Groups

Infection	Open		Subcutaneous/Closed		P Value
	N	%	N	%	
Yes	5	10	2	4	
No	45	90	48	96	0.240
Total	50	100	50	100	

Figure 11: Distribution of Infection between Study Groups



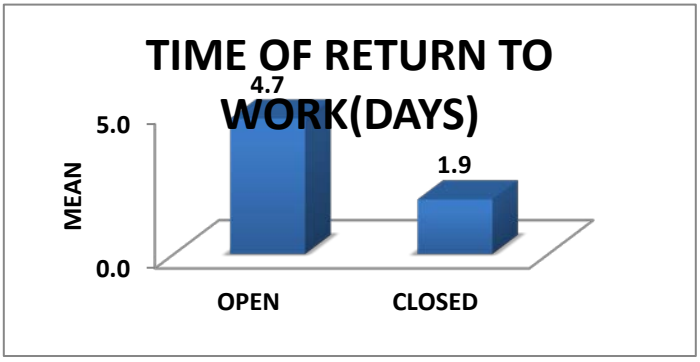
The mean duration of time required to return to work was 4.7 days with SD of 1.8 for the patients who underwent open LIS, when compared to 1.9 days with SD of 0.9 for those underwent subcutaneous/closed LIS. P value is <0.001 which is statistically significant.

Table 12: Time of Return To Work Between Study Groups

Parameters	Open		Subcutaneous /Closed		P Value
	Mean	SD	Mean	SD	
Time Of Return To Work(Days)	4.7	1.8	1.9	0.9	<0.001 *

Note: * significant at 5% level of significance (p<0.05)

Figure 12: Time of Return To Work Between Study Groups

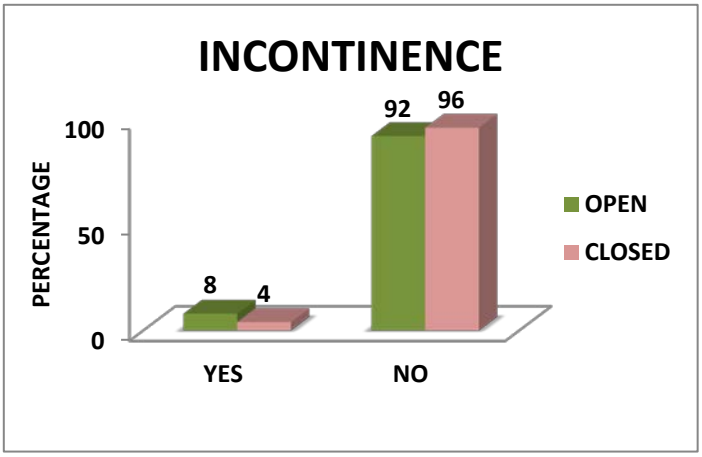


Among the 50 patients who underwent open LIS, 4 (8%) developed incontinence postoperatively, whereas only 2 (4%) patients in the second group developed incontinence. P value is 0.400, which is statistically insignificant.

Table 13: Distribution of Incontinence between Study Groups

Incontinence	Open		Subcutaneous/ Closed		P Value
	N	%	N	%	
YES	4	8	2	4	
NO	46	92	48	96	0.400
Total	50	100	50	100	

Figure 13: Distribution of Incontinence between Study Groups

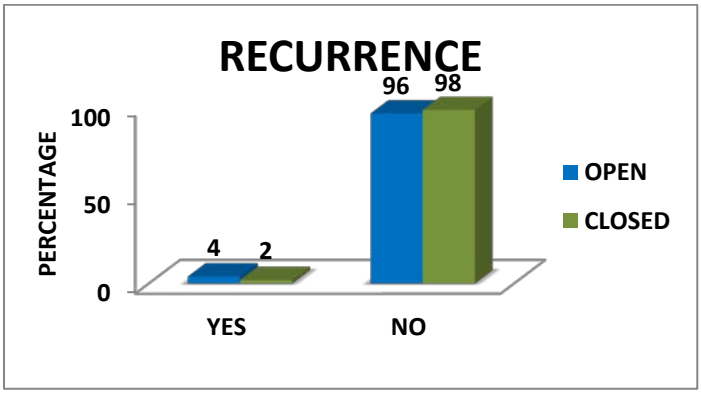


Recurrence was assessed till 6 months postoperatively. It recurred in 2 patients (4%) in the open LIS group and in 1 patient (2%) in the subcutaneous LIS group. P value is 0.954, which is statistically insignificant.

Table 14: Distribution of Recurrence between Study Groups

Recurrence	Open		Subcutaneous/Closed		P Value
	N	%	N	%	
Yes	2	4	1	2	0.954
No	48	96	49	98	
Total	50	100	50	100	

Figure 14: Distribution of Recurrence between Study Groups



Discussion

Most of the fissures were found in middle age group. 31% of the patients were between 31-40 years and mean age in present study was 45.6 years. Mean age reported in different studies range from 30 - 45 years which is nearly the same as in our study. In our study 56% of patients were males, and 44% of patients were females with a sex ratio of 1.3:1 respectively. In the study done by Nahas, 70% were males and 30% were females with a ratio of 2.3:1. 55.2% males and 47.8% females with a ratio of 1.15:1 presented with chronic anal fissure in the study done by Melange.

The patients suffering from anal fissure complain of pain during defaecation, constipation, bleeding per rectum, discharge and pruritis ani. 100% patients presented with pain defaecation, 85% patients presented with constipation and 78% with bleeding per rectum. In the study by Hananel and Gordon, 90.8% presented with pain and 71.4% with bleeding.

In our study 93 patients (93%) presented with posterior midline fissures and 7 patients (7%) presented with anterior anal fissure. In a study by Mazier et al it was found that 84% of anal fissures were posterior. Nahas reported in his study that 86.1% of fissures were in posterior midline and 13.9% were anterior fissures. Shafiq Ullah reported that 88% of patients had fissures posterior midline, 10% in anterior midline and 2% in other sites (lateral). This could be due to hypovascularization and hypoperfusion occuring in the posterior anal commissure. Combination of these factors with internal anal sphincter hypertonia cause ischemia, which can explain the poor wound healing and also the pain, which is ischemic in nature occurs only during and for a certain period after defecation. Patients may try to avoid defecation because of the pain.

In the patients undergoing open lateral internal sphincterotomy, 64% of the patients had a score of 5-6 on the verbal rating scale for pain on the first postoperative day, which translates to severe pain. Whereas in patients undergoing subcutaneous/ closed lateral internal sphincterotomy, about 76% of them had a score of 3-4 on the first postoperative day which translates to moderate pain. Shafiq Ullah described similar results in the case of lateral internal sphincterotomy in his study.

In our study, the results of open and subcutaneous/closed techniques were compared respectively under the following parameters

- Postoperative pain relief- open group: 78% attained relief from pain in 3-4 weeks, 20% required >4 weeks and 2 % in 1-2 weeks; subcutaneous group: 90% had relief from pain within 1 week and the rest 10% in 1-2 weeks
- Wound healing- At 1 week, operated wounds of 90% of open LIS group and 96% of subcutaneous LIS

group had healed, while the remaining healed at 2 weeks.

- Infection- 10% of open LIS and 4% of subcutaneous LIS developed infection.
- Time of return to work- 4.7 days with SD of 1.8 in open LIS group and 1.9 days with SD of 0.9 in subcutaneous LIS group.
- Incontinence- 8% of open LIS group and 4% of subcutaneous LIS group developed incontinence
- Recurrence- 4% of open LIS and 2% of subcutaneous LIS group recurred when followed up postoperatively for 6 months.

It was noted that both techniques of lateral sphincterotomy are effective in the treatment of a chronic anal fissure. However, this study showed that subcutaneous/ closed lateral sphincterotomy is significantly better than the open technique ($p<0.001$). Pernikoff et al and Shafiq Ullah also reported that the complications rate is relatively higher in the open technique than the closed technique. Kortbeek et al and Shafiq Ullah reported that closed lateral internal sphincterotomy for a chronic anal fissure is effective and may result in less postoperative discomfort, shorter postoperative length of stay and a comparable rate of complications compared with open lateral internal sphincterotomy.

Comparison of Results of This Study with Previous Studies:

(Open versus subcutaneous/closed methods)

	Sanniyasi S et al, 2016	Anandaravi BN et al, 2017	Hamid H, 2012	Our study, 2019
Pain	29% vs 6%	12% vs 2%	8% vs 4%	64% had severe pain vs 76% who had moderate pain
Infection	8% vs 0%	6% vs 2%	8% vs 2%	10% vs 4%
incontinence	32% vs 10%	20% vs 9%	20% vs 8%	8% vs 4%
recurrence	5.8% vs 10%	4% vs 4%	12% vs 8%	4% vs 2%

Conclusion

- Subcutaneous/ closed lateral internal partial sphincterotomy and open lateral internal partial sphincterotomy are both equally effective in management of chronic anal fissure.
- The rate of complications in subcutaneous/ closed lateral internal partial sphincterotomy is lesser than open lateral internal partial sphincterotomy, especially with regard to postoperative pain and early return to work.
- The rates of infection, wound healing, incontinence and recurrence are statistically insignificant between the two groups.
- Subcutaneous/ closed lateral internal partial sphincterotomy is better tolerated than open lateral internal partial sphincterotomy under local anesthesia and can be better practiced as a day care out-patient procedure, thereby reducing the in-patient burden in the hospital.
- Thus, subcutaneous/ closed lateral internal partial sphincterotomy is a better procedure compared to open lateral internal partial sphincterotomy for the working class or laborers who were the main subjects of this study, as they are able to return to work early, thereby reducing their loss of man hour days and economic strain on the family.

Summary

1. One hundred patients with chronic anal fissure were chosen for this study from those who were presented in surgical out patients department of ESIC-MC & PGIMSR, between January 2018 and June 2019.
2. The peak incidence was noted in the age group of 31- 40 years (31%) with the mean age being 45.6 years and a SD of 11.4. 56% were males and 44% were females.
3. 93% had posterior midline fissures and 7% had anterior anal fissure.
4. 50 patients underwent open lateral internal partial sphincterotomy and the other 50 underwent subcutaneous lateral internal partial sphincterotomy.
5. Postoperatively, the two groups were compared with respect to the following parameters:

- Postoperative pain relief- open group: 78% attained relief from pain in 3-4 weeks, 20% required >4 weeks and 2 % in 1-2 weeks; subcutaneous group: 90% had relief from pain within 1 week and the rest 10% in 1-2 weeks
- Wound healing- At 1 week, operated wounds of 90% of open LIS group and 96% of subcutaneous LIS group had healed, while the remaining healed at 2 weeks.
- Infection- 10% of open LIS and 4% of subcutaneous LIS developed infection.
- Time of return to work- 4.7 days with SD of 1.8 in open LIS group and 1.9 days with SD of 0.9 in subcutaneous LIS group.
- Incontinence- 8% of open LIS group and 4% of subcutaneous LIS group developed incontinence
- Recurrence- 4% of open LIS and 2% of subcutaneous LIS group recurred when followed up postoperatively for 6 months.

6. Subcutaneous/ closed lateral internal sphincterotomy and open lateral internal sphincterotomy are both equally effective in management of chronic anal fissure. But, subcutaneous/ closed lateral internal sphincterotomy is better tolerated than open lateral internal sphincterotomy under local anaesthesia and can be better practised as a day care out-patient procedure, thereby reducing the in-patient burden in the hospital and reducing the loss of man hour days and economic strain on the family.

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