

A Prospective Randomized Study of Comparision between Lateral Internal Sphincterotomy versus Lord’s Anal Dilation In Chronic Anal Fissure

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Abstract

Background: Anal fissure is a common proctological problem, which presents with pain in the anal region during and after defecation. Anal fissure is a linear tear at the anal verge. It usually presents in 3rd & 4th decade of life.

Methods: A prospective, randomized, single blinded trial of 60 patients was done in department of General Surgery at the JLN Medical College & Hospital Ajmer. The patients were evaluated and followed up according to protocol.

Results: There was minor postoperative bleeding present in both the groups at 24 hours and at discharge, one patient have bleeding per rectum at 1st week also which get relived in follow up. There was only transient incontinence present in both groups. Some patients were having incontinence till 1st week which get corrected in follow-up by perineal and urethral exercises.

Conclusion: Closed lateral internal sphincterotomy is effective and safe procedure as compared to Lord’s anal dilation as surgical treatment in cases of

chronic anal fissure. Closed lateral internal sphincterotomy has many benefits.

Keywords: CLIS, LAD, Complication.

Introduction

Anal fissure is a common proctological problem, which presents with pain in the anal region during and after defecation. Anal fissure is a linear tear at the anal verge. It usually presents in 3rd & 4th decade of life. It is very distressing condition associated with spasm of internal anal sphincter⁽¹⁾. It is common in both sexes and can be found in infants and elderly people. It is more in female than male. It can be seen either in the anterior or the posterior midline just distal to the dentate line. In female 89% of fissures occur posteriorly and only 10% of the fissures are seen in the anterior midline. While in male 98% of fissures are posterior and 1% is anterior. Less than 1% of patients have a fissure in lateral position in both sex^(2,3,4,5). Women of child bearing age have more chances of getting anterior anal fissure specially soon after pregnancy or vaginal delivery⁽⁶⁾. It is, most probably, result of damage and weakening of the

pelvic floor muscles and attenuation of perineal body.

Material and Method

Study Design: Prospective study

Study Place: surgery department of JLN Medical College and hospital, Ajmer

Study Period: AUGUST 2018 TO JULY 2019

Method of Data Collection

A prospective, randomized, single blinded trial of 60 patients was done in department of General Surgery at the JLN Medical College & Hospital Ajmer. The patients were evaluated and followed up according to Detailed history of patient was entered in protocol. After admission they underwent through pre-proforma were. Patients who were fit operative investigation its advantage and explained the procedure. A written and informed risk involved disadvantage. Consent was taken preoperatively.

All those patients undergoing surgery were divided into two groups. Group-CLIS (C group) included all patients undergoing surgery by closed lateral internal sphincterotomy and group-LAD (L group) included all patients undergoing surgery with Lord's Anal dilation. At surgical room randomly each patient were given 2 card, one of them written Closed lateral internal sphincterotomy and another Lord's Anal dilation and patients asked to select one of them. Closed lateral internal sphincterotomy (C group) was done in 30 (50%) of patients and 30 (50%) patients by Lord's Anal dilation (L group).

Inclusion Criteria

- Age between 18-60 years.
- Having Chronic Anal Fissure (All patients with anal pain for ≤ 6 weeks with induration of the edges of the fissure and exposure of the fibers of the internal sphincter in the floor of the

fissure with sentinel tag were defined as having Chronic Anal Fissure)

- Failed medical management (Not responded to medical management of Chronic Anal Fissure for ≥ 6 weeks).

Exclusion Criteria

- Patients with inflammatory bowel disease, AIDS, tuberculosis, sexually transmitted diseases
- Pregnancy/ Puerperium
- Patients on anticoagulation/immunosuppression medications
- Patients with other conditions affecting anal canal (tumours, Incontinence, abscess, fistulas, hemorrhoids, stenosis)
- Any previous anorectal surgery
- Obstetric trauma.
- Critically ill or moribund patient
- Consent not obtained

Statistical Analysis

The data was coded and entered into Microsoft Excel spreadsheet. Analysis was done using SPSS version 20 (IBM SPSS Statistics Inc., Chicago, Illinois, USA) Windows software program. Descriptive statistics included computation of percentages, means and standard deviations. Nonparametric data were analyzed by using Mann-Whitney U-test. Chi-square test and fisher exact test were used for qualitative data whenever two or more than two groups were used to compare. Level of significance was set at $P \leq 0.05$.

Results

C group - CLIS group

L group - LAD group

Table 1: Socio-demographic variable

Variable	Group		P-value
	L	C	
Age	36.60±10.05	36.96±10.48	0.89
Sex (M:F)	19:11	18:12	0.78

In this study 18-60 year age group patient with chronic anal fissure were enrolled. Above table shows mean age of cases. In L group mean age is 36.6 year and in C group mean age is 36.96. There is statically insignificant (p=0.89) difference between two. In study total 38.3% (23 out of 60) were female and 61.7% (37 out of 60) were male. In group C female were 36.7% (11 out of 30) and male were 63.3% (19 out of 30). In group L total female were 40% (12 out of 30) and male were 60% (18 out of 30). Sex difference between these two group in statically insignificant (p=0.79).

Table 2: VAS

	Groups	Mean	Std. Deviation	P VALUE
At 24 hrs	L	3.00	1.894	0.01 (S)
	C	1.83	1.840	
At discharge	L	.63	.809	0.24
	C	.40	.724	
At 1 st week	L	.30	.596	0.33
	C	.17	.461	
At 1 st month	L	.17	.461	0.3
	C	.07	.254	
At 6 th month	L	.20	.610	0.07
	C	.00	.000	

Above table shows comparison of postoperative pain assessment between C and L group according to VAS (visual analogue scale) score. At 24 hour after surgery difference in pain score between two groups is statically significant (p=0.01). At discharge difference is statically insignificant (p=0.24). At 1st week difference is insignificant (p=0.33). At 1st month

difference is insignificant (p=0.3). At 6th month difference is insignificant (p=0.07).

Table 3: Bleeding

Time	Group		P-value
	L	C	
At discharge (present)	3(10.00%)	2(6.67%)	0.64
At 1 st week(present)	1(3.33%)	0(0.00%)	0.31

Above table shows comparison of postoperative bleeding assessment at discharge, between C and L group. In C group 93.3% (28 out of 30) patients were not having any bleeding and 6.7% (02 out of 30) patients were having mild bleeding in the form of soakage. In L group 90% (27 out of 30) patients were not having bleeding and 10% (03 out of 30) patients were having mild bleeding (mild soakage). Difference between two group were statically insignificant (p=0.64). Comparison of postoperative bleeding assessment at 1st week, between C and L group. In C group 100% patients were not having any bleeding. In L group 96.7% (29 out of 30) patients were not having bleeding and 3.3% (01 out of 30) patients were having mild bleeding. Difference between two group were statically insignificant (p=0.31).

Table 4: Incontinence

Time	Group		P-value
	L	C	
At discharge (present)	4(13.33%)	1(3.33%)	0.16
At 24 hours (present)	4(13.33%)	3(10.00%)	0.27
At 1 weeks (present)	1(3.33%)	0(0.00%)	0.31

Above table shows comparison of postoperative incontinence assessment at discharge, between C and L group. In C group 3.3% (01 out of 30) patients were having incontinence to flatus only. In L group 13.3% patients were having incontinence to flatus only. Difference between two group were statically insignificant (p=0.16). Comparison of postoperative incontinence assessment at 24hour, between C and L group. In C group 10% (03 out of 30) patients were having incontinence to flatus only. In L group 20% (06 out of 30) (13.3%-incontinence to flatus, 6.3%- soiling of clothes) patients were having some incontinence. Difference between two group were statically insignificant (p=0.27). Comparison of postoperative incontinence assessment at 1st week, between C and L group. In C group no patients were having incontinence. In L group 3.3% (1 Patient) patients were having incontinence to flatus only. Difference between two group were statically insignificant (p=0.31).

Table 5: Complete Wound Healing

Time	Group		P-value
	L	C	
At 1 weeks (present)	24(80.00%)	25(83.33%)	0.73
At 1 month (present)	27(90.00%)	30(100.00%)	0.07
At 6 months (present)	27(90.00%)	30(100.00%)	0.07

Above table shows comparison of postoperative wound healing assessment at 1st week, between C and L group. In C group 83.3% patients (25 out of 30) were having complete healing while 16.7% patients (5 out of 30) were healed incompletely. In L group 80% patients (24 out of 30) were healed completely and 20% (6 out of

30) were not healed completely. Difference between these two group was statically insignificant (p=0.73). Comparison of postoperative wound healing assessment at 1st month, between C and L group. In C group 100% patients (30 out of 30) were healed completely. In L group 90% patients (27 out of 30) were healed completely and 10% (3 out of 30) were not healed completely. Difference between these two group was statically insignificant (p=0.07).

Table 6: Hospital stay

Groups	Mean	Std. Deviation	P value
L	3.2333	.50401	0.22
C	3.1000	.30513	

Above table shows comparison of postoperative hospital stay between C and L group. In C group mean hospital stay was 3.10 days while in group L mean hospital stay was 3.233 days. Difference between these two group was statically insignificant (p=0.22).

Table 7: Recurrence

			Recurrence		Total
			Absent	Present	
Groups	C	N	30	0	30
		%	100.0%	0.0%	100.0%
	L	N	27	3	30
		%	90.0%	10.0%	100.0%
Total		N	57	3	60
		%	95.0%	5.0%	100.0%

P value=0.07. OD=1.11, 95% CI=0.98-1.25

Above table shows comparison of Recurrence, between C and L group. In C group there was no recurrence. In L group 10% patients (03 out of 30) were presents with recurrence. Difference between these two group was statically insignificant(p=0.07).

Discussion

Anal fissure is a common proctological problem, which presents with pain in the anal region during and after

defecation. Anal fissure is a linear tear at the anal verge.

It is more in female than male. It can be seen either in the anterior or the posterior midline just distal to the dentate line but more common posteriorly. Most of the ulcers are primary and cause is thought to be ischemia of lower anal canal secondary to spasm of internal sphincter as blood vessels traverse through it. Constipation predisposes to the development of anal fissure because of its pressure effect on anal mucosa.

Sexually transmitted diseases, tuberculosis, Crohn's disease, and local or systemic malignancies are other causes of anal fissure.

The most commonly observed abnormalities are hypertonicity and hypertrophy of the internal anal sphincter, leading to elevated anal canal and sphincter resting pressures. Most patients with anal fissures have an elevated resting pressure, and this resting pressure returns to normal levels after surgical sphincterotomy.

There are many surgical techniques to decrease the anal tone. Most popular are Lord's Anal Dilation and Lateral Internal Sphincterotomy.

In our study postoperative pain was assessed by VAS score. And assessed at 24 hours, at discharge, 1st week, 1st month and at 6th month. Pain in anal fissure due to spasm of anal sphincter muscles. In CLIS internal sphincter is cut while in LAD both external and internal sphincters stretched. So after both these procedures patients get relieved. Effective pain control in both groups may be related to temporary loss of muscle tone. In Closed lateral internal sphincterotomy, the tone of internal sphincter is decreased while in LAD, tone of both internal & external sphincter is decreased.

At 24 hours in CLIS group 40% (12 out of 30) patients were not having any pain and 60% (18 out of 30) patients were having mild to moderate pain. In LAD group 20% (06 out of 30) patients were not having pain and 80% (24 out of 30) patients were having mild to moderate pain. Analgesics were used for pain. Difference between two groups was statistically significant ($p=0.03$).

But at discharge in CLIS group 73.3% (22 out of 30) patients get relieved of pain and 27.7% (08 out of 30) patients were having mild to moderate pain. While in LAD group only 56.7% (17 out of 30) patients get pain free and 43.3% (13 out of 30) patients were having mild to moderate pain. Difference between two groups was statistically insignificant ($p=0.17$).

After 1st week in CLIS group 86.7% (26 out of 30) patients were not having any pain and 13.3% (04 out of 30) patients were having mild pain. In LAD group 76.7% (23 out of 30) patients were not having pain and 23.3% (07 out of 30) patients were having mild pain. Difference between two groups was statistically insignificant ($p=0.6$).

After 1 month in CLIS group 93.3% patients do not have any pain while in LAD group 86.3% patients get pain free. After 6 months 100% patients in CLIS group became pain free while in LAD 90% patients get pain free. So in our study CLIS group patients get more pain relief than LAD group but statistically significant only at 24 hours and remaining time it was statistically insignificant.

In a study done by Kumar D. et al (2018)⁷, pain score in first 24 hours was significantly higher in LAD group as compared to LIS group reason might be due to inter-individual difference in the application of force in anal dilation, intra-operatively. This difference was negated

in subsequent days and difference at the time of discharge was non-significant.

In a study done by **J. I. Khan et al(2017)**⁸, there was complete pain relief in 29 (96%) cases in lateral internal sphincterotomy group. In Lord's anal dilation group, there was complete pain relief in 17 (56%) and partial pain relief in 12 (40%) patients. So it seems that, both procedures are good for pain relief but pain did not completely go off in 12 patients in manual anal dilation]. However, pain relief was quick in L.I.S (lateral internal sphincterotomy) group as compared to Lord's anal dilation group in present study Effective pain controlled in both groups may be related to temporary loss of muscle tone.

In a study done by **Alok Chandra et al (2017)**⁸ in which Altogether 60 patients were treated by lateral Internal sphincterotomy and 56 by anal dilation. All 60 patients treated by sphincterotomy gets pain relief while 54 patients out of 56 treated by manual dilation gets pain relief

In present study postoperative bleeding was assessed. There was only minor bleeding no major bleeding present in any case. At 24hours in CLIS group 70% (21 out of 30) patients were not having any bleeding and 30% (09 out of 30) patients were having mild bleeding in the form of soakage. In LAD group 66.7% (20 out of 30) patients were not having bleeding and 33.3% (10 out of 30) patients were having mild bleeding (mild soakage). At 24 hours difference between two group were statistically insignificant ($p=0.78$). At discharge in CLIS group 93.3% (28 out of 30) patients were not having any bleeding and 6.7% (02 out of 30) patients were having mild bleeding in the form of soakage. In LAD group 90% (27 out of 30) patients were not having bleeding and 10% (03 out of 30) patients were

having mild bleeding (mild soakage). Difference between two group were statistically insignificant ($p=0.64$) at discharge.at 1st week in C group 100% patients were not having any bleeding. In L group 96.7% (29 out of 30) patients were not having bleeding and 3.3% (01 out of 30) patients were having mild bleeding. At 1st week difference between two group were statistically insignificant ($p=0.31$). After that at 1st month and 6th month no patient have bleeding per rectum.

In our study there was mild bleeding per rectum was present in both group in till 1st week post-operatively but after that there was no bleeding per rectum and difference between two group in view of postoperative bleeding per rectum was insignificant ($p>0.05$)

In a study done by **Kumar D. et al**⁷ Thirty-seven patients (74%) in LAD and 41 (82%) in LIS group observed bleeding in first 24 hours post operatively, which was clinically not bothering and subsided in subsequent days and were not found to be statistically significant (p value 0.3364).

In LAD group flatus incontinence in 4 (13.3%), 4 (13.3%) and 1(3.3%) patients at 24 hour, at discharge and at 1st week but they gradually recovered and no flatus/faecal incontinence was present after 1week in Lord's anal dilation group also. This can be explained with the fact that initial trauma to external sphincter decreased its tone and voluntary control, but healing took place as time passed. Similarly voluntary control over the passage of faeces also improved along with the help of other perianal and pelvic floor muscles.

Flatus incontinence in CLIS group was only 6.7% (2 patients out of 30) and 3.3% (1patients out of 30) at 24 hour and at discharge respectively.so incontinence was also transient in CLIS group.

Difference between two group was statistically insignificant p value ($p > 0.05$).

In one study done by **Khalid M et al (2004)**⁹ faecal and flatus incontinence was reported to be found in 59.6% in Manual anal dilation and only 6.6% cases in lateral internal sphincterotomy group.

A study from Israel, done by **Ram E et al (2005)**¹⁰ where manometric pressure was measured before and after surgery, also proved that Lateral internal sphincterotomy does not cause any incontinence.

In our study, in CLIS group there is 100% **healing** while in LAD group there is 90% healing rate. 3 patients in LAD group disease remain persist and they did not get healed completely even after 6month.

So healing rate is high in CLIS group compared to LAD group but difference is statistically insignificant ($p=0.07$).

Results of our study supported by **Javed Khan et al**⁽⁸⁾ in which there was 93% healing rate in CLIS group and 60% healing rate was present in LAD group.

In our study, mean **hospital stay** in CLIS group mean hospital stay was 3.10 days while in group LAD mean hospital stay was 3.233 days. Difference between these two group was statistically insignificant ($p=0.22$).

In LAD group 5 patients have hospital stay of 4 days and one patient have 5 days hospital stay because of pain, while in CLIS group three patients have hospital stay of 4 days because of pain.

In a study done by **Hareesh GSR et al**¹¹ in the MAD (Manual anal dilation) group, the maximum 28 (93.3%) patients are staying less than four days in hospital and 2 (6.7%) patients are staying more than four days, whereas all 30 (100.0%) patients are staying less than four days in hospital the LIS (Lateral internal sphincterotomy) group.

In a study done by **Uttam A. K.**¹² **et al** post-operative hospital stay in LAD group is comparable to LIS group i.e. mean 3.4 ± 0.6701 days (minimum 3 days and maximum 5 days) and mean 3.5 days (minimum 3 and maximum 5 days) respectively.

CONCLUSION

Closed lateral internal sphincterotomy is effective and safe procedure as compared to Lord's anal dilation as surgical treatment in cases of Chronic anal fissure. Closed lateral internal sphincterotomy has many benefits. It has excellent success rate (100%) regarding healing of fissure and pain relief. While in Lord's anal dilation there is 10% failure rate and more postoperative pain. Furthermore Closed lateral internal sphincterotomy has low complication rate and repeated surgery is avoided because of very low recurrence rate. This also reduces the cost of treatment in long term. Lord's anal dilation has high recurrence rate (10%). Lord's anal dilation has low success rate with high complication rates. Lord's anal dilation has high rate of incontinence compared to closed lateral internal sphincterotomy (transient, which gets treated with perineal exercise). However long-term follow-up and large sample size is needed to proper evaluation of recurrence and incontinence. So it can be recommended that patients of anal fissure who do not respond to conservative methods of treatment should undergo Closed lateral internal sphincterotomy. This is best for patients in terms of cost, recurrence and recovery from disease.

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