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ORIGINAL ARTICLE

DOI: 10.69723/njms.04.02.0616

A PROSPECTIVE COHORT STUDY COMPARING TAILORED AND CONVENTIONAL LATERAL INTERNAL SPHINCTEROTOMY FOR CHRONIC ANAL FISSURES

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Received; 5th Aug '25 Revisions received; 20th Aug '25 Accepted; 9th Sep' 25

ABSTRACT

BACKGROUND: Anal fissure is defined as a superficial tear in the skin distal to the dentate line and is one of the leading causes of hospitalization among proctologic disorders. Anal fissures are initially managed by conservative treatments, but have limited efficacy and may need surgical interventions.

OBJECTIVE: The current study aimed to compare the effectiveness of Conventional lateral internal Sphincterotomy (LIS) versus tailored LIS in terms of pain, bleeding and recurrent symptoms as outcomes.

METHODOLOGY: : The prospective cohort study was carried out at Muhammad Teaching Hospital, Peshawar, including n=196 participants, diagnosed with Chronic anal fissures, over the age of 18 years, through informed consent. Patients were assessed for pain, bleeding, and recurrent symptoms pre-operatively and post-operatively at one-month intervals of follow-up.

RESULTS: The Mean age of the participants was 34.50±11.18 years, including 52 (26.5%) males and 144 (73.5%), operated with Conventional LIS 94 (48%), and tailored LIS 102 (52%). Post-operative pain was significantly reduced, P<0.001 in both groups, with no difference P=0.182, between interventions. For flatus incontinence Significant difference by Fisher's exact test P=0.028 reported between interventions, with a relative risk RR= 0.204 (CI 0.045-0.923), 0.039 for tailored LIS. For faecal incontinence, Fisher's exact test P=0.011 was significant between groups, and RR=0.070 (CI 0.004-1.242), P=0.070 was insignificant. Faecal soiling P=0.108, recurrent symptoms P=0.152, post-operative constipation P=0.124, and pruritus P=0.030 did not report significant differences among treatment groups when conventional LIS was compared with tailored LIS.

CONCLUSION: Conventional LIS and tailored LIS were both effective in post-operative pain and bleeding reduction. Tailored LIS helped reduce post-operative flatus and faecal incontinence. The study was limited by a short follow-up duration and insufficient consideration of patients' medical histories and comorbidities.

KEYWORDS: Anal fissures, Conventional lateral internal Sphincterotomy, Tailored lateral internal Sphincterotomy, LIS, faecal incontinence, flatus incontinence.

HOW TO CITE THIS ARTICLE: Rehman S, Wais M, Khan G Y. A prospective cohort study comparing tailored and conventional lateral internal sphincterotomy for chronic anal fissures. Northwest J Med Sci. 2025;4(3): 29-36

INTRODUCTION

Anal fissure is defined as the superficial tear in the skin distal to the dentate line and is often preceded by a history of hard stools, constipation, a diet low in fibre and anal surgery.1 Chronic Anal Fissures (CAFs) are one of the most common proctologic disorders that present in the outpatient department.2 Anal fissures with a history of more than 6 weeks, having keratinous edges and hypertrophied papillae, are termed as chronic anal fissures.3 It is characterised by a linear breach in the epithelial lining of the anal canal that might extend from the dentate line to the anal verge. 4 While the exact pathogenesis of anal fissure is not clear; however, the suggested etiological factors are hypertonia, local trauma, ischemia, and fibrosis.5 The most common presentation of chronic anal fissures is pain, constipation, and bleeding.6 And the common examination findings are a sentinel tag, hypertrophic anal papilla, and exposed sphincter fibres at the base of the papilla.

The global prevalence of anal fissures is hard to pin down due to a higher proportion of patients not reporting the cases. Thus, no international epidemiological database exists, although individual studies have reported the incidence with variations from different regions and countries of the world. In the Pakistani population, the prevalence cannot be determined due to underreporting and the large number of acute cases being treated with traditional methods7 . In United States, the estimated annual incidence of anal fissures is 235,000 cases, altough underreporting has been a key issue. '' 8 CAFs have a negative and significant impact on Quality of Life (QoL) in patients, simultaneously leading to anxiety and symptoms of depression. 9,10

The initial management of CAFs is conservative with stool softeners, a high-fibre diet, sitz baths, and topical healing agents

in the form of Glyceryl triturate and Diltiazem as per the recommendation of the American Society of Colon and Rectal Surgeons (ASCRS).11,12 However, outcomes of conservative management are not effective for most of the patients and ultimately need surgical intervention. 13 The first line of surgical intervention is lateral internal Sphincterotomy (LIS), which is considered the gold standard. 11,13 In the conventional method, the internal anal sphincter is incised up to the dentate line. Conversely, tailored LIS involves a more limited incision, extending only up to the base of the anal fissure.14 The available literature demonstrates a higher risk of incontinence in conventional LIS and a higher recurrence rate in tailored LIS.11,14 Although findings from different studies vary and lack consistency related to clinical effectiveness and outcomes of different surgical interventions. The main purpose of this study is to look for the comparative efficacy, recurrence rate and complications in tailored LIS and conventional LIS for the treatment of chronic anal fissures.

METHODOLOGY:

The prospective cohort study was conducted at Muhammad Teaching Hospital (MTH), Peshawar, from September 2021 to September 2024. The study was approved by the Ethical committee, MTH Peshawar. Informed consent was obtained from the patient. The minimum age of the patients to enrol in the study was more than 18 years, with a history of anal fissure for more than six weeks. Patients were assessed by a consultant surgeon, and if patients had exposed fibres of internal anal sphincter, sentinel tag, hypertrophied anal papilla, and a failed attempt at conservative management, they were included in the study. Patients with concomitant anal fistula, haemorrhoids, perianal abscess, inflammatory bowel disease, pregnancy, and previous surgical intervention for anal fissure were excluded from the study.

During the study duration, n=196 patients reported with CAFs in the study settings, patients were non-randomly assigned to conventional LIS or tailored LIS upon the patients' clinical condition and the surgeon's understanding of the favourable intervention based on the patient's history and medical records. During the study duration, n=102 patients presented in the Tailored LIS and n=94 patients in the Conventional LIS group. Post-hoc power analysis with G-power, for Related-Samples Wilcoxon Signed Rank Test, and Fisher's Exact tests was performed to check the adequacy of the studied sample size. With Effect size dz =0.5, DF= 186 and the reported Power (1-β err prob) =0.99, affirmed that the current sample size was justified for evaluating the difference between the two interventions. All the studied participants were followed over time up to the end of the study, and there was no missing data or dropouts.

Pre-operative examination of the lower rectum and the anal canal was done by using a proctoscope. All the patients were operated in the lithotomy position either under general or regional anaesthesia (spinal or saddle). For tailored LIS, a vertical incision was made in the pit between the internal and external anal sphincter with a 15-size surgical blade. The internal anal sphincter was held with the help of artery clips and cut with cautery. Postoperatively, all the patients were given intravenous metronidazole for 24 hours along with analgesics. Patients were discharged from the hospital with oral medications including Metronidazole, Non-steroidal anti-inflammatory drugs, and laxatives. All the patients were advised to have a sitz bath for 10 days.

Patients' sociodemographic characteristics were recorded from the hospital files upon consent of the patient and caregivers. Patient's age, gender, type of LIS performed, pre-operative and post-operative pain, presence and absence of bleeding in the post-operative stage were recorded. At one month, patients were assessed for flatus incontinence, faecal incontinence, faecal soiling, recurrent symptoms, constipation, pruritus and the operated region was assessed to look for signs of any local active infection. Pain was recorded on the visual Analogue scale (VAS) as a continuous scale and was categorised as mild (<3 on VAS), moderate (4-7 VAS) and severe pain (>7 VAS). Both the conventional and tailored LIS were performed according to the standard procedure protocols.

RESULTS

The current study included n=102 (52.0%) participants in tailored LIS and n=94 (48%) in conventional LIS. Participants included 52 (26.5%) males and 144 (73.5%) females. The mean age of the participants was 34.50 years±11.18 years. With a minimum age of 18 years, and a maximum was 64 years. Pre-operative pain was reported as mild in n=112 (57.1%), moderate pain in 67 (34.2%) and severe pain in 17 (8.7%) of participants. In the post-operative assessment, no pain was reported in n=182 (92.9%), mild pain in 9 (4.6%) and moderate pain was reported in 5 (2.6%) participants, as reported in Table 1.

Table 1: Sociodemographic and clinical characteristics of the study participants

Variables	Frequency, percentage and standard deviations			
Age	34.50±11.18			
Gender	Male		Female	
	Freq	%	Freq	%
	52	26.5%	144	73.5%
Procedure of Lateral Internal Sphincterotomy	Conventional		Tailored	
	Freq	%	Freq	%
	94	48%	102	52%

Pre-operative pain	No Pain		Mild		Moderate		Severe	
	Frequency	%	Frequency	%	Frequency	%	Frequency	%
	0	0	112	57.1	67	34.2	17	8.7
Post-operative Pain	No pain		Mild		Moderate		Severe	
	182	92.9	9	4.6	5	2.6	0	0

Bleeding Status	**Present**		**Absent**	
	Frequency	%	Frequency	%
Pre-operative	61	31.1	135	68.9
Post-operative	16	8.2	180	91.8
Post-operative assessment	**Present**		**Absent**	
Flatus incontinence	11	5.6	185	94.4
Faecal incontinence	6	3.1	190	96.9
Faecal soiling	3	1.5	193	98.5
Recurrent Symptoms	13	6.6	183	93.4
Local infection	0	0	196	100
Constipation	19	9.7	177	90.3
Pruritus	6	3.1	190	96.9

Significant difference reported on the Related-Samples Wilcoxon Signed Rank Test, P<0.001 for pre- and post-operative pain. As Figure 1 illustrates in the post-operative pain assessment, pain reduction was reported in n=188 participants, n=4 participants reported no pain difference, and n=4 participants reported an increase in pain.

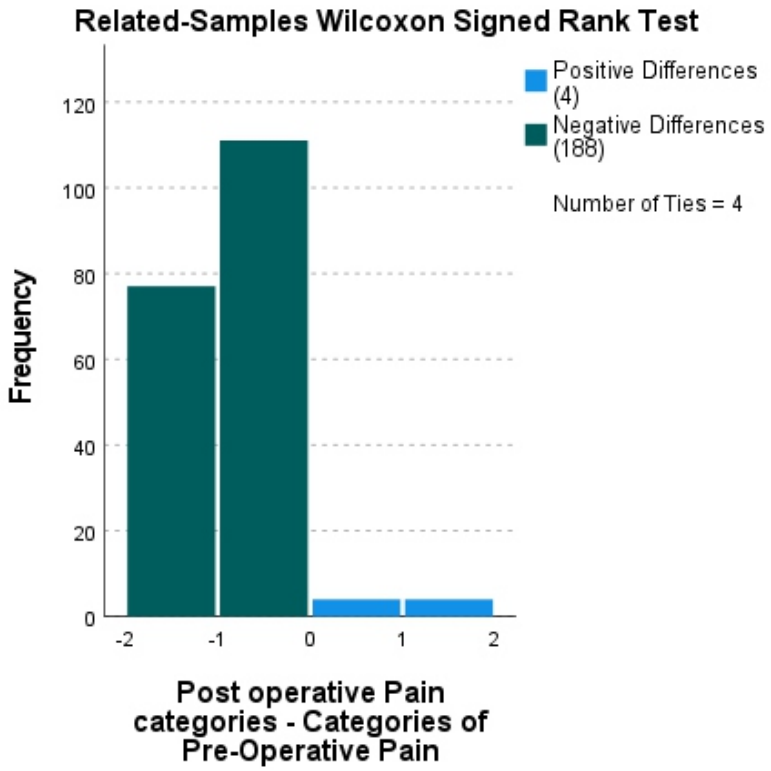


Figure 1: Pre and Post-Operative Pain comparison of the Wilcoxon Signed rank test

When both groups were compared, through the Mann-Whitney U Test, the Conventional LIS group showed somewhat higher post-operative pain, although there was no statistically significant difference, P=0.182 between conventional LIS and tailored LIS in pain reduction, as illustrated in Figure 2.

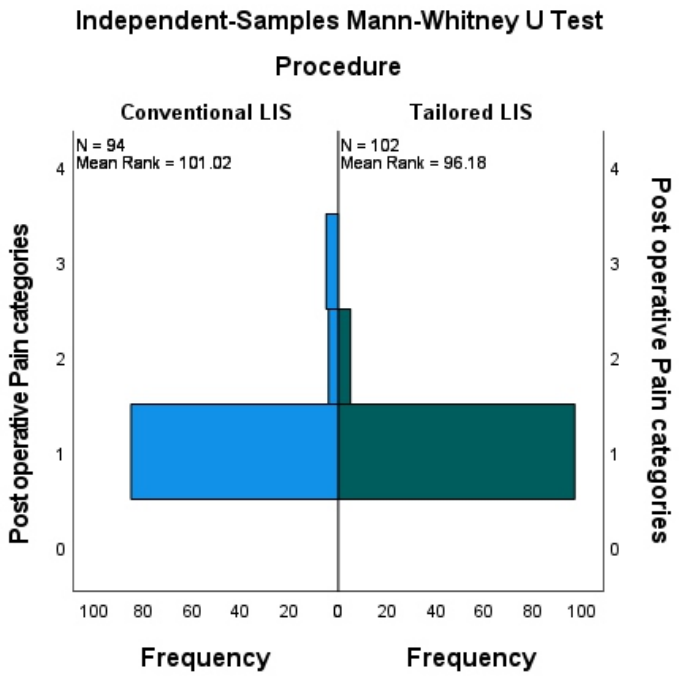


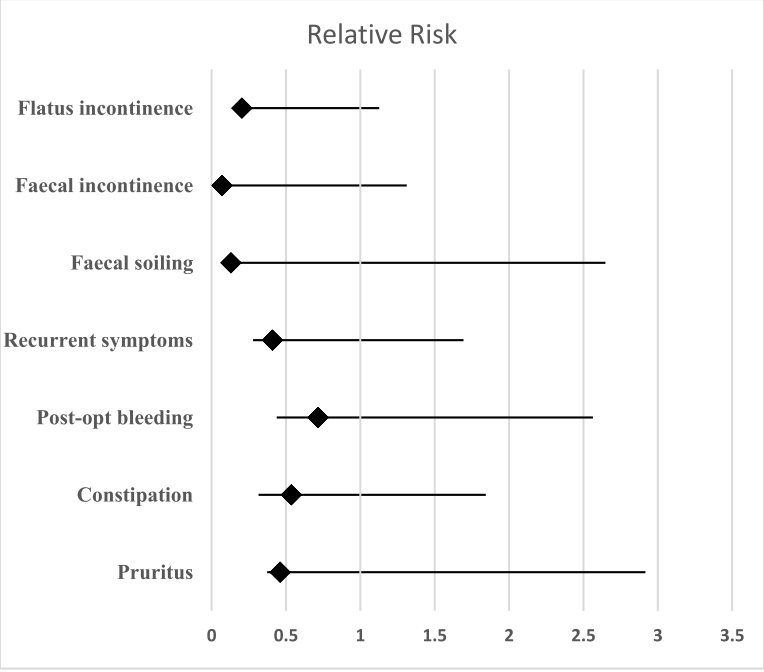
Figure 2: Mann-Whitney U Test for comparison of Post-operative Pain in tailored LIS versus Conventional LIS

Flatus incontinence was present in n=11 (5.6%) and absent in n=185 (94.4%) of the studied participants, post-operatively. Chi-square test showed significant difference, P=0.028 in both groups for presence/absence of flatus incontinence. Further analysis was done through risk assessment, calculated through Medcalc version 23.3.2. The flatus incontinence development (Relative Risk) RR=0.2014 (CI 0.045-0.923) P=0.039 was reported 80% lower in tailored LIS as compared to conventional LIS, and reported in Table 2.

Fisher-exact test for faecal incontinence reported P=0.011 significant difference between tailored and conventional LIS, Although further analysis showed that RR=0.070 (CI 0.004-1.242) with P=0.070, did not report a significant difference on the basis of positive cases of faecal incontinence, which were reported 6/94 in conventional LIS and 0/102 in tailored LIS. There was no difference reported between the treatment groups for faecal soiling with Fisher's exact test P=0.108 and RR=0.131 (CI 0.006-2.517), P=0.178 as non-significant, reported in Table 2.

Table 2: Chi-Square and Risk estimation of clinical characteristics

Variable	Relative Risk	95% Confidence interval	Level of Significance	Positive events	
				Conventional n=94	Tailored n=102
Flatus incontinence	0.204	0.045-0.923	**0.039**	9	2
Faecal incontinence	0.070	0.004-1.242	0.070	6	0
Faecal soiling	0.131	0.006-2.517	0.178	3	0
Recurrent symptoms	0.409	0.130-1.285	0.126	9	4
Post-op bleeding	0.716	0.278-1.848	0.490	9	7
Constipation	0.537	0.221-1.307	0.171	12	7
Pruritus	0.460	0.086-2.457	0.364	4	2[1]



Recurrence of symptoms was reported in n=13 (6.6%) and absent in n=183 (93.4%) of the participants, with no significant difference on Fisher's exact test, P=0.152 and RR=0.409 (CI 0.130-1.285), P=0.126. Bleeding was reported pre-operatively in 61 (31.1%) and post-operatively in 16 (8.2%) participants, as reported in Table 1. The McNemar

[1] Relative risk was calculated with Medcalc online RR calculator.

test reported a significant difference, P <0.001, in the treatment groups, while the RR=0.716 (CI 0.278-1.849)P=0.490 did not significantly contribute to changes within bleeding status. Post-operative local Infection was not reported in any of the participants.

The complaint of post-operative constipation in n=19 (9.7%) and pruritus was reported in n=6 (3.1%) participants, as reported in Table 1. The Chi-square results for Fisher's exact test reported post-operative constipation P=0.124 and post-operative pruritus, P=0.429 no significant difference within treatment groups. The RR= 0.537 (CI 0.221-1.307) P=0.171 for constipation and pruritis, RR= 0.460 (CI 0.086-2.457) P=0.364 did not report a significant difference among the intervention groups.

DISCUSSION

The current study aimed to compare the effectiveness of Conventional lateral internal Sphincterotomy versus tailored lateral internal Sphincterotomy in patients with chronic anal fissures. The mean age of participants was 34.50±11.18 years, 52 (26.5%) of the participants were male, and n=144 (73.5%) were female. Conventional LIS was carried out in 94 (48%) and tailored LIS in 102 (52%) of participants. In the pre-operative assessment, all the patients reported pain ranging from mild to severe, while in the post-assessment, pain was absent in 92.9% of the study participants. Descriptive statistics showed prominent differences in the pre- and post-clinical parameters of pain and bleeding. The current study reported significant improvement in pain P<0.001) in the pre- and post-intervention; however, there was no significant difference in post-operative pain between the treatment groups. Flatus incontinence RR=0.204 (CI 0.045-0.923), P=0.039 was significantly lower in Tailored LIS, while faecal incontinence RR=0.070 (CI 0.004-1.242), P=0.070 did not report a significant difference. Significant difference, P<0.001, was reported between the pre- and post-operative bleeding assessments, while post-operative constipation, P=0.124 and pruritus, P=0.429, were not significant.

Minimal LIS and tailored LIS have been reported as safe procedures as compared to other treatments for anal fissures, with fewer cases of recurrence.14 However, in the current findings, there was no significant difference in conventional versus tailored LIS for symptom recurrence; four recurrent cases were reported in tailored LIS and nine cases in conventional LIS. Evidence has shown that modifications in the conventional LIS have improved clinical outcomes, with significant improvement in healing P<0.001) and in reduced episodes of soiling P<0.05.15 In the current study, only three cases of faecal soiling were reported post-operatively, all in the conventional LIS, with statistically no significant difference RR=0.131 (CI 0.006-2.517) P=0.178 between the treatment groups.

Other than the surgical intervention, several other factors have been recognised in the literature which affect the occurrence of flatus incontinence, like younger age (P=0.001), harder stool formation (P=0.02), as well as adverse obstetric history and impaired anorectal physiology.16 In the current study, n=11 cases of flatus incontinence were reported, n=9 in conventional and n-2 in tailored LIS. Incontinence associated with Sphincterotomy has been reported in earlier studies as well, specifically in cases when Sphincterotomy is performed for hemorrhoidectomy.17 Findings of the current study reported n=6 cases of faecal incontinence, all in the conventional LIS group.

For pain and blood loss reduction, both the conventional and tailored LIS were helpful, without significant differences between the interventions. In terms of flatus incontinence, tailored LIS is more helpful, while more cases of faecal incontinence are being observed in the conventional LIS. There was no significant difference noted between the treatment groups for symptom recurrence, post-operative constipation and pruritus. The current study has helped report the comparative effectiveness of tailored LIS versus conventional LIS. Besides the significant findings, the study had a few limitations, including the limited history and information about patients' medical history, limited duration of follow up and one-time follow-up at a one-month interval. The study was conducted in a single centre, patients were assigned to treatment groups based on the surgeon's understanding, and patients were followed for short intervals. The pre-operated data was collected only for bleeding and pain, thus the study was unable to report pre and post-operative difference in outcomes of faecal incontinence, faecal soiling, flatus incontinence, constipation and puritis. The study can be repeated by focusing on the past medical history of patients, looking for the confounding factors, following patients for a longer duration, and follow-up and assessment at multiple intervals post-operatively will help gain deeper insights about the study variables.

CONCLUSION

The current study found that both the procedures, conventional LIS and tailored LIS, were helpful in reducing pain and post-operative bleeding. Flatus incontinence was significantly reduced in tailored LIS, while higher faecal incontinence was associated with conventional LIS. There was no difference in both interventions for recurrence of symptoms, post-operative constipation and pruritus. Faecal soiling, recurrent symptoms, constipation and pruritus showed no difference between the treatment groups. Patients were followed for a shorter duration, and confounding factors, comorbidities of the patients were not assessed, which may have an impact on patient outcomes. Due to fewer positive events in post-operative complications, the relative risk was limited in reporting the precise effect size estimation. Future studies should be conducted with larger sample sizes to overcome the limitation.

SOURCE OF FUNDING: No financial support or external funding

was received for the completion of this work.

CONFLICT OF INTEREST STATEMENT: The authors declare no conflict of interest related to this publication.

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A.Conception or Design
B.Acquisition, Analysis, or Interpretation of Data
C.Manuscript writing
D.Critical Review and approval
All the authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved