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EFFICACY OF LATERAL INTERNAL SPHINCTEROTOMY VERSUS TOPICAL 0.2% GLYCERYL TRINITRATE OINTMENT IN THE TREATMENT OF CHRONIC ANAL FISSURE

Original Research

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ABSTRACT

Objective: To compare the efficacy of lateral internal sphincterotomy (LIS) and topical 0.2% glyceryl trinitrate (GTN) ointment in the treatment of chronic anal fissure.

Methodology: This randomized controlled trial was conducted at the Department of Surgery, Mercy Teaching Hospital, Peshawar Medical College, Peshawar. One hundred patients with chronic anal fissure were randomly allocated to two groups. Group A patients were treated with LIS and Group B with GTN. Pain during defecation was assessed using the Visual Analog Scale (VAS) at 2 and 6 weeks of follow-up between both groups.

Results: At the 2-week follow-up we found that 90% patients in the LIS group showed notable efficacy in pain relief when compared to 44% in the GTN group (p=0.0001). At six weeks the efficacy in LIS group was 98% while 58% in the GTN group (p=0.0001).

Conclusion: Lateral internal sphincterotomy (LIS) is notably more effective than topical 0.2% glyceryl trinitrate ointment in the treatment of chronic anal fissure.

Keywords: Chronic anal fissure, lateral internal sphincterotomy, internal anal sphincter, glyceryl trinitrate, efficacy, pain relief.

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INTRODUCTION:

Chronic anal fissure (CAF) is characterized by a persistent longitudinal ulcer in the anoderm of the distal anal canal that extends from below the dentate line to the anal verge, lasting beyond 4 to 6 weeks and is often associated with hypertrophied anal papilla, visible internal sphincter fibers or a sentinel tag. Individuals commonly complain of anal discomfort during and shortly after bowel movements, which can persist for several hours, negatively impacting daily activities and overall quality of life. [1, 2] This condition is frequently linked to spasm in internal anal sphincter (IAS), which may result in localized ischemia as well as impede the natural healing process.[2] Relieving the IAS spasm is crucial for achieving pain relief and remission, which can be achieved through either chemical or surgical sphincterotomy. Lateral internal sphincterotomy (LIS) has long been recognized as the main intervention for chronic anal fissure (CAF), which involves the surgical division of the IAS from its distal point to either the proximal end of fissure or dentate line. The overall healing rates following lateral internal sphincterotomy (LIS) are excellently high at 94%. However, it is important to acknowledge the associated risk of anal incontinence, which is reported to be 3.4%-4.4%. This potential complication may have an important impact on the patient's standard of life. [3, 4]

The conventional approaches to managing CAF have consistently focused on alleviating pain, promoting healing, as well as preventing relapses. Non-operative management includes dietary modifications, the use of stool softeners, and topical treatments designed to alleviate sphincter spasm and enhance the flow of blood to fissure site. [5] Glyceryl trinitrate (GTN) ointment acts as a powerful nitric oxide donor, successfully relaxing internal anal sphincter. This action results in reduced resting anal pressure and enhanced blood flow to the anoderm. [6, 7]The effectiveness of GTN, while non-invasive, is frequently constrained by patient compliance issues stemming from its side effects, notably headaches. [8]There is a concern regarding the rates of recurrent disease linked to the management of GTNs. The prevalent surgical methods for anal fissures encompass anal dilation, open lateral sphincterotomy, closed lateral sphincterotomy, midline posterior sphincterotomy, as well as to a lesser extent, dermal flap coverage for fissures. The gold standard therapy to chronic anal fissure is lateral inner sphincterotomy, a procedure that effectively reduces resting anal pressures and effectively resolves the majority of fissures. [9, 10] A study revealed that among 45 patients in the LIS group, 35 patients (78%) experienced healing of anal fissures, whereas 10 patients (22.22%) did not. In contrast, within the GTN group of 45 patients, 23 patients (51.11%) had healed anal fissures, while 22 patients (48.89%) had not achieved healing.[11]

Chronic anal fissure is a common problem, and patients are usually shy to accept the surgical form of treatment, but they readily accept the pharmacological form of treatment. In our setup the efficacy of lateral internal sphincterotomy has not been compared to topical 0.2% glyceryl trinitrate ointment in the treatment of chronic anal fissure. In this study, the researcher wants to compare the efficacy of lateral internal sphincterotomy to topical 0.2% glyceryl trinitrate ointment in order to develop a future scientific/treatment plan for patients suffering from chronic anal fissure, which will guide the surgeons to adapt to the better treatment plan/option based on the results of this study.

METHODOLOGY:

This study, which was designed as a randomized controlled trail (RCT), was conducted at the Department of Surgery, Mercy Teaching Hospital, Peshawar Medical College, Peshawar from 11th March,2024 to 11th September,2024. A randomized controlled trial (RCT) design was employed with non-probability consecutive sampling technique used to select participants. We included one hundred patients with primary idiopathic chronic anal fissure lasting more than six weeks. The sample was determined using previous frequency of efficacy of lateral internal sphincterotomy (LIS) group as 78%[11] and glyceryl trinitrate (GTN) group as 51%[11], keeping the 95% confidence level and 80% power. Inclusion criteria were patients aged 18 to 60 years of both genders. Patients with co-morbidities such as tuberculosis, hypertension, diabetes and ischemic heart disease as well as pregnant patients and those previously treated with nitrates or who had undergone LIS surgery were screened out. All participants were first assessed with a comprehensive history and clinical assessment followed by a diagnosis of chronic anal fissure.

After taking consent, patients were randomly allocated into two groups using blocked randomization. Group A received treatment by lateral internal sphincterotomy under general or spinal anesthesia while Group B received topical 0.2% glyceryl trinitrate ointment

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applied three times daily for six weeks. Follow-up visits were then scheduled at two and six weeks for assessment of the efficacy of treatment based on improvements in pain defined by a visual analogue scale (VAS) score.
The data analysis was conducted with SPSS 20, the quantitative variables were displayed as means ± standard deviations and categorical variables as frequencies and percentages. Chi-square and T-test were used to compare the efficacy of both treatments considering a significant level of $p \leq 0.05$.

RESULTS:

In this study two treatment groups were compared: Group A which was treated with lateral internal sphincterotomy (LIS) and Group B which received a topical 0.2% glyceryl trinitrate (GTN) ointment. Mean age for Group A was 39.88±14.50 years while Group B had mean age 40.10±12.37 years. Mean monthly income in Group A was 53571.02±17367 rupees compared to 64666.80±21479.59 rupees in Group B. In terms of body mass index (BMI) Group A had mean of 25.27±1.78 kg/m² while Group B 24.88±1.94 kg/m².

Regarding the gender, thirty-two (64%) males and 18 (36%) females were in Group A while Group B had 26 (52%) males and 24 (48%) females (Table 1).
The site of the fissure was posterior in 35 (70%) cases in Group A and 41 (82%) in Group B. Regarding bleeding during defecation 30 (60%) participants in Group A and 34 (68%) participants in Group B reported bleeding (Table 2).

We assessed the pain scores on visual analogue scale (VAS) during defecation at two and six weeks. At two weeks Group A had a mean pain score of 3.22±1.75 which decreased to 2.94±1.45 at six weeks. In Group B mean pain score was 4.80±2.02 at two weeks which improved to 4.30±1.99 at six weeks (Table 3).
Regarding the efficacy Group A showed notably better results. At two weeks, about 45 (90%) patients in Group A reported efficacy compared to only 22 (44%) in Group B (p=0.0001). At six weeks 49 (98%) patients in Group A reported efficacy while 29 (58%) in Group B (p=0.0001) (Table 4). Stratification of efficacy of both procedures with demographics can be seen from table no 5 to 10.

Age distribution of the patients in both groups

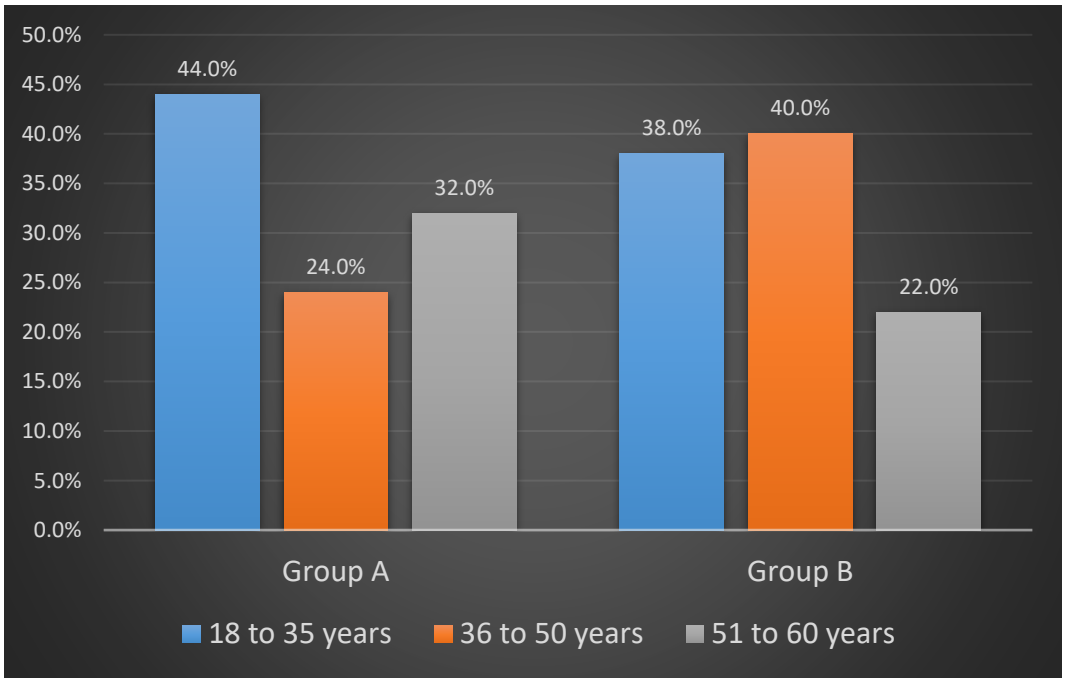


Figure 1 Age distribution of the patients in both groups

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Table 1: Demographics of the patients

Demographics		Groups			
		Group A (LIS)		Group B (GTN)	
		Frequency	Percentage	Frequency	Percentage
Gender	Male	32	64.0%	26	52.0%
	Female	18	36.0%	24	48.0%
Residence	Urban	23	46.0%	28	56.0%
	Rural	27	54.0%	22	44.0%
Education	Educated	26	52.0%	28	56.0%
	Uneducated	24	48.0%	22	44.0%

Table 2: Clinical parameters

Clinical parameters		Groups			
		Group A (LIS)		Group B (GTN)	
		Frequency	Percentage	Frequency	Percentage
Site of fissure	Anterior	5	10.0%	3	6.0%
	Posterior	35	70.0%	41	82.0%
	Both	10	20.0%	6	12.0%
Bleeding during defecation	Yes	30	60.0%	34	68.0%
	No	20	40.0%	16	32.0%

Table 3: Pain score on VAS in both groups

Groups		Pain score on VAS during defecation at two weeks	Pain score on VAS during defecation at six weeks	P value
Group A (LIS)	Mean	3.22	2.94	0.0001
	N	50	50	
	Std. Deviation	1.753	1.449	
Group B (GTN)	Mean	4.80	4.30	0.0001
	N	50	50	
	Std. Deviation	2.020	1.992	

Table 4: Comparison of efficacy between both groups at two weeks and six weeks

Efficacy		Groups				P value
		Group A (LIS)		Group B (GTN)		
		Frequency	Percentage	Frequency	Percentage	
Efficacy at two weeks	Yes	45	90.0%	22	44.0%	0.0001
	No	5	10.0%	28	56.0%	
Efficacy at six weeks	Yes	49	98.0%	29	58.0%	0.0001
	No	1	2.0%	21	42.0%	

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Table 5 Comparison of efficacy between both groups at two weeks and six weeks w.r.t age

				Groups				P value
				Group A (LIS)		Group B (GTN)		
				N	%	N	%	
Age distribution (Years)	18 to 35	Efficacy at two weeks	Yes	20	90.9%	8	42.1%	0.001
			No	2	9.1%	11	57.9%	
		Efficacy at six weeks	Yes	22	100.0%	12	63.2%	0.002
			No	0	0.0%	7	36.8%	
	36 to 50	Efficacy at two weeks	Yes	11	91.7%	9	45.0%	0.008
			No	1	8.3%	11	55.0%	
		Efficacy at six weeks	Yes	12	100.0%	10	50.0%	0.003
			No	0	0.0%	10	50.0%	
	51 to 60	Efficacy at two weeks	Yes	14	87.5%	5	45.5%	0.01
			No	2	12.5%	6	54.5%	
		Efficacy at six weeks	Yes	15	93.8%	7	63.6%	0.04
			No	1	6.2%	4	36.4%	

Table 6 Comparison of efficacy between both groups at two weeks and six weeks w.r.t gender

				Groups				P value
				Group A (LIS)		Group B (GTN)		
				N	%	N	%	
Gender	Male	Efficacy at two weeks	Yes	29	90.6%	10	38.5%	0.0001
			No	3	9.4%	16	61.5%	
		Efficacy at six weeks	Yes	32	100.0%	12	46.2%	0.0001
			No	0	0.0%	14	53.8%	
	Female	Efficacy at two weeks	Yes	16	88.9%	12	50.0%	0.008
			No	2	11.1%	12	50.0%	
		Efficacy at six weeks	Yes	17	94.4%	17	70.8%	0.05
			No	1	5.6%	7	29.2%	

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Table 7 Comparison of efficacy between both groups at two weeks and six weeks w.r.t residence

				Groups				P value
				Group A (LIS)		Group B (GTN)		
				N	%	N	%	
Residence	Urban	Efficacy at two weeks	Yes	22	95.7%	11	39.3%	0.0001
			No	1	4.3%	17	60.7%	
		Efficacy at six weeks	Yes	23	100.0%	14	50.0%	0.0001
			No	0	0.0%	14	50.0%	
	Rural	Efficacy at two weeks	Yes	23	85.2%	11	50.0%	0.008
			No	4	14.8%	11	50.0%	
		Efficacy at six weeks	Yes	26	96.3%	15	68.2%	0.008
			No	1	3.7%	7	31.8%	

Table 8 Comparison of efficacy between both groups at two weeks and six weeks w.r.t education

				Groups				P value
				Group A (LIS)		Group B (GTN)		
				N	%	N	%	
Education	Educated	Efficacy at two weeks	Yes	23	88.5%	13	46.4%	0.001
			No	3	11.5%	15	53.6%	
		Efficacy at six weeks	Yes	26	100.0%	15	53.6%	0.0001
			No	0	0.0%	13	46.4%	
	Uneducated	Efficacy at two weeks	Yes	22	91.7%	9	40.9%	0.0001
			No	2	8.3%	13	59.1%	
		Efficacy at six weeks	Yes	23	95.8%	14	63.6%	0.006
			No	1	4.2%	8	36.4%	

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Table 9 Comparison of efficacy between both groups at two weeks and six weeks w.r.t monthly income

				Groups				P value
				Group A (LIS)		Group B (GTN)		
				N	%	N	%	
Monthly income (Rs)	< 50K	Efficacy at two weeks	Yes	11	100.0%	2	28.6%	0.001
			No	0	0.0%	5	71.4%	
		Efficacy at six weeks	Yes	11	100.0%	2	28.6%	0.001
			No	0	0.0%	5	71.4%	
	50K to 100K	Efficacy at two weeks	Yes	25	86.2%	16	47.1%	0.001
			No	4	13.8%	18	52.9%	
		Efficacy at six weeks	Yes	28	96.6%	18	52.9%	0.0001
			No	1	3.4%	16	47.1%	
	> 100K	Efficacy at two weeks	Yes	8	88.9%	4	50.0%	0.07
			No	1	11.1%	4	50.0%	
		Efficacy at six weeks	Yes	9	100.0%	8	100.0%	Not applicable
			No	0	0.0%	0	0.0%	

Table 10 Comparison of efficacy between both groups at two weeks and six weeks w.r.t BMI

				Groups				P value
				Group A (LIS)		Group B (GTN)		
				N	%	N	%	
BMI (Kg/m2)	18 to 24.9	Efficacy at two weeks	Yes	22	100.0%	13	44.8%	0.0001
			No	0	0.0%	16	55.2%	
		Efficacy at six weeks	Yes	22	100.0%	17	58.6%	0.001
			No	0	0.0%	12	41.4%	
	> 24.9	Efficacy at two weeks	Yes	23	82.1%	9	42.9%	0.004
			No	5	17.9%	12	57.1%	
		Efficacy at six weeks	Yes	27	96.4%	12	57.1%	0.001
			No	1	3.6%	9	42.9%	

DISCUSSION:

The demographic characteristics of our patients, including their gender, age and clinical presentation were similar to those found in previous literature allowing for a broader contextual understanding of our results. In terms of patient demographics, we found that the mean age in our study for the LIS group was 39.88±14.50 years and 40.10±12.37 years for the GTN group, which resonates with the findings of Tauro et al., they reported that the mean age in their study was found to be around 34.14 years.[12] This age range is common for chronic anal fissures which mostly affect adults in the 20–40 years age group. Gender distribution in our study exhibited a slight male predominance in both groups, which fits well with the findings of Qureshi et al., where they reported 53.3% of patients in the GTN group and 50% in the LIS group were male patients.[7] This aligns with the literature as chronic anal fissures are more commonly reported in males.

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Regarding clinical features both groups in our study exhibited pain and bleeding as the most prominent symptoms which is a hallmark of chronic anal fissures. The majority of patients in both the LIS and GTN groups in our study reported posterior fissures which is in agreement with previous study which also reported a higher frequency of anal fissures to occur in the posterior area.[13]

When analyzing the efficacy of the two treatments our findings found a noteworthy reduction in pain in the LIS group when compared to the GTN group. At the two-week follow-up pain relief was more marked in the LIS group with a mean pain score of 3.22±1.75 decreasing to 2.94±1.45 by sixth week. In the GTN group, patients exhibited a higher initial pain score of 4.80±2.02 which decreased to 4.30±1.99 by sixth week.

We defined efficacy as reduction in the pain at 2nd week and 6th week assessment, we found that LIS group showed higher efficacy when compared to the GTN group. This is consistent with Qureshi et al., where they reported 95% of patients treated with LIS had relief of pain at six weeks compared to 86.7% in the GTN group.[7] These results are also similar to those reported by Tauro et al., where they demonstrated that pain relief was better in the surgical group, though they also found that GTN group showed improvement as well. In a study by Memon et al., the pain relief with GTN was less effective when they compared it to surgical treatments like LIS.[14] The slower pain relief in the GTN group is likely due to the nature of the treatment which works by relaxing the sphincter and increasing blood flow processes that take time to manifest.

Memon et al., noted that none of the patients in their surgical group had an incidence of recurrence of fissure while 69.95% cases had recurrence in the GTN group.[14] These findings further affirm that LIS is has superior efficacy than GTN.

Although both treatment options are effective for managing chronic anal fissures but lateral internal sphincterotomy remains the more definitive treatment due to its higher healing rate along with faster pain relief and lower recurrence incidents. However, for patients who are not willing to undergo surgery, topical GTN ointment may serve as a reasonable alternative in relieving the pain but its effectiveness is slower and it is associated with more side effects such as headache and recurrence. Given the remarkable advantages of LIS in terms of long-term pain relief and reduced recurrence it is recommended as the first-line treatment for patients with chronic anal fissures.

CONCLUSION:

In conclusion, lateral internal sphincterotomy proved to be more effective than 0.2% glyceryl trinitrate ointment in treating chronic anal fissure in terms of pain relief at two and six weeks follow up. GTN can be considered as a viable alternative for patients not willing to undergo surgery.

AUTHOR CONTRIBUTION

Author	Contribution
Muhammad Owais Ali*	Substantial Contribution to study design, acquisition, analysis, and interpretation of Data Manuscript Writing Has given Final Approval of the version to be published
Muzafaruddin Sadiq	Substantial Contribution to study design, interpretation of Data Critical Review Has given Final Approval of the version to be published

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