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ORIGINAL ARTICLE

EFFICACY OF LATERAL INTERNAL SPHINCTEROTOMY VERSUS 0.2% GTN OINTMENT IN HEALING OF CHRONIC ANAL FISSURE IN POPULATION OF MUZAFFARABAD DIVISION, AZAD KASHMIR

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ABSTRACT

Background: Anal fissure is a longitudinal or oval tear in the anal mucosa in distal anal canal. Chronic anal fissure can be treated conservatively with medications, including 0.2% glyceryl trinitrate (GTN) rectal ointment or surgically by internal lateral sphincterotomy (ILS). The objective of this study was to compare the efficacy of LIS vs. 0.2% GTN rectal ointment in healing of anal fissure in population of Muzaffarabad division, Azad Kashmir.

Materials & Methods: This randomized controlled trial was carried out in Department of Surgery, Abbas Institute of Medical Sciences, Muzzafarabad, Azad Kashmir from June 2021 to Feb 2022. Ninety patients were equally randomly allocated by toss to control group using medical treatment by 0.2% GTN rectal ointment and experimental group for surgical intervention by lateral internal sphincterotomy. Sex (men/women) and age groups (≤40 years/>40 years) were two matching variables, while healing of anal fissure was research variable, all being nominal. McNemar chi-square test was used for hypothesis testing.

Results: Out of 45 patients in control/GTN group, 23 (51.11%) had healed anal fissures and 22 (48.89%) had not. Out of 45 patients in experimental/LIS group, 35 (77.78%) patients had healed anal fissures and 10 (22.22%) patients had not. Mc-Nemar chi-square test rejected null hypothesis (p=.0139), showing that LIS has significantly higher efficacy than 0.2% GTN in healing of chronic anal fissure.

Conclusion: In our population, lateral internal sphincterotomy showed significantly higher efficacy than 0.2% GTN rectal ointment in healing of chronic anal fissure.

KEYWORDS: Lateral Internal Sphincterotomy; Anal Canal; Rectum; Defecation.

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1. INTRODUCTION

1.1 Background: Anal fissure is a longitudinal or oval tear in the anal mucosa in distal anal canal. It is one of the most common conditions for surgical consultation and generally affects young adults.[1] Life time risk to develop anal fissure is approximately 11% in adults.[2] Anal fissure commonly presents with pain during defecation, itching, discharge & bleeding per rectum.[3] Pain persists for 1-2 hours after defection and is thought to be due to loss of blood supply and spasm of internal anal sphincter.[4] Acute anal fissure generally heals spontaneously. It is labeled as chronic anal fissure when it persists for more than 6-8 weeks.[5]

About 80-90% fissures are found in the posterior midline of the anus and 10-20% are found in the anterior midline.[5,6] Blood supply to posterior commissure is by end arteries which is further worsened by hypertonic internal sphincter leading to high frequency, chronicity and non-healing fissure in this region.[3] The risk factors that lead to anal fissure formation

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are constipation, low fiber diet, obesity, pregnancy, hard stools and hypothyroidism.[7] Additional factors described in literature are labor pains for >20 minutes, birth weight >3800 grams, and previous history of perianal diseases and bacterial, viral and inflammatory diseases.[8]

Chronic anal fissure can be treated conservatively with medications, including 0.2% glyceryl trinitrate (GTN) rectal ointment or surgically by internal lateral sphincterotomy (ILS).[1]The purpose of conservative or surgical treatment is to reduce the tone of internal anal sphincter and to improve the anodermal blood supply at the affected region to let the fissure heal.

Evans et al.[9] from Queen Elizabeth Hospital, Woodville, South Australia for the period from February 1998 to June 1999 in a randomized controlled trial found that 96.3% (26*100/27=96.3) lateral internal sphincterotomy (LIS) patients had healed fissures, while GTN patients had 60.6% (20*100/33=60.6) healed fissures.

Boland et al.[10] from Department of Colorectal Surgery, St James Hospital, Ireland for the period from January 2000 to February 8, 2020 conducted randomized controlled trials, comparing treatment options for anal fissure. Healing at eight weeks was 95.1% (332*100/349=95.1) in LIS group, while it was 63.6% (131*100/206=63.6) in GTN group.

Libertiny, et al.[11] from the Department of Colorectal Surgery, Royal Berkshire & Battle Hospitals, England for the period from January 1, 1998 to December 31, 1998 conducted randomized controlled trials to compare the efficacy of GTN ointment with LIS for treatment of anal fissure. Healing at eight weeks was 97.14% (34*100/35=97.14) for LIS and 54.29% (19*100/35=54.29) for GTN patients.

Albaidany, et al.[12] from four hospitals in Sanaa City, Yemen for the period from October 2019 to April 2021 conducted randomized controlled trials to assess treatment options for anal fissure. Healing at six weeks was 96.67% (29*100/30=96.67) in LIS group, while it was 86.67% (26*100/30=86.67) in GTN patients.

Kumar, et al.[13] from Department of Surgery, Adichunchanagiri Institute of Medical Sciences, B.G. Nagara, India for the period from January 2019 to December 2020 conducted a prospective cohort study to assess medical and surgical management options for the treatment of anal fissure. Healing at two weeks was 90% (45*100/50=90) in LIS group, while it was 64% (32*100/50=64) in GTN patients.

Siddique, et al.[14] from the Department of Surgery, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh for the period from February 2006 to February 2007 conducted randomized clinical trial and found that after six weeks of treatment for anal fissure, healing was 84.85% (28*100/33=84.85) in LIS group, while it was 35.48% (11*100/31=35.48) in GTN group.

1.2 Research problem (RP), Knowledge Gap (KG) & Research Questions (RQ): Unawareness about the efficacy of LIS vs. 0.2% GTN ointment in healing of chronic anal fissure in population of Muzaffarabad division, Azad Kashmir was our research problem. Unavailability of data about this problem was our knowledge gap and to see if there is any difference in efficacy of these two in healing of chronic anal fissure was our research question.

Research Objective: The objective of this study was to compare the efficacy of LIS vs. 0.2% GTN rectal ointment in healing of anal fissure in population of Muzaffarabad division, Azad Kashmir.

1.4 Research (Null) Hypotheses: There is no statistically significant difference in the efficacy of LIS vs. 0.2% GTN rectal ointment in healing of anal fissure in population of Muzaffarabad division, Azad Kashmir.

1.5 Significance: This study will provide an important data regarding efficacy of LIS vs. 0.2% GTN ointment in healing of anal fissure. It will guide and help surgeons in the initial medical management of anal fissure as well as definitive treatment option for the management of anal fissure.

2. MATERIALS & METHODS

2.1 Design, Setting & Duration: This randomized controlled trial was carried out in the Department of Surgery, Abbas Institute of Medical Sciences, Muzzafarabad, Azad Kashmir from June 2021 to Feb 2022 after approval from Hospital Ethical Committee. Informed consent was taken from patients.

2.2 Sampling & Randomization: All patients with chronic anal fissure were included. Patients having inflammatory bowel disease, HIV infection, previous sphincter injury or surgery or having fecal incontinence were excluded from the study. Ninety patients were equally randomly allocated by toss to two groups; control group using medical treatment by 0.2% GTN rectal ointment and other experimental group for surgical intervention by lateral internal sphincterotomy (LIS).

2.3 Procedure, intervention & follow up: Patients in control group were advised to apply small amount of 0.2 % GTN rectal ointment to perianal skin three times a day for two months, while patients in experimental group were booked on the next available list for LIS.

Under spinal or general anesthesia, 1-2 cm circumferential incision was given at the anal verge at 5 O' clock position at the free edge of internal anal sphincter. Using scissor or diathermy, lower edge of the sphincter was grasped and divided equally to the length of the fissure below the dentate line. Any associated polyp at the inner end or sentinel skin tag was also excised if present. The wounds were left opened & patients were advised to take sitz baths and high fiber diet.

All patients were followed till the end of eight weeks. Fissure was labeled as healed, when there was complete absence of pain & no visual lesion in anoderm.

2.4 Data collection & Analysis plan: Sex (men/ women) and age groups (≤40 years/ >40 years) were our two matching variables, while healing of anal fissure was our research variable, all on nominal scale. The sample data were described by count & percentages. McNemar chi-square test was used for hypothesis testing to compare the efficacy of LIS vs. 0.2% GTN for healing of anal fissure at alpha .05 with Yates continuity correction. Online statistical calculator was used for the analysis of data.[15]

2.5 Marwat Logical Trajectory of Research Process: We have adopted eight steps "Marwat's Logical Trajectory of Research Process" model for our research project as devised by Dr. Muhammad Marwat.[16-17]

3. RESULTS

The 45 patients in control/ GTN group included 22 (48.89%) men and 23 (51.11%) women, while 45 patients of the experimental/ LIS group included 24 (53.33%) men and 21 (46.67%) women; almost with similar proportion.

There were 25 (55.56%) patients in age group ≤40 years and 20 (44.44%) in age group >40 years in control/ GTN group, while there were 26 (57.78%) patients in age group ≤ 40 years and 19 (42.22) in age group >40 years in experimental/ LIS group with almost equivalent proportion.

Out of 45 patients in control/ GTN group, 23 (51.11%) had healed anal fissures and 22 (48.89%) had not healed fissures. Out of 45 patients in experimental/ LIS group, 35 (77.78%) patients had healed anal fissures and 10 (22.22%) patients had not healed fissures. The rate of healing/ efficacy was significantly higher in experimental/ LIS group than control/ GTN group.

Mc-Nemar chi-square test revealed p-value of .0139 (less than alpha). So, the null hypothesis was rejected, which revealed significant difference between LIS and 0.2% GTN in the healing of chronic anal fissure.

4. DISCUSSION

Increased anal sphincter tone and ischemia of the anal canal are the factors suggested for the pathogenesis of anal fissure.[11] The normal anal sphincter pressure is about 69 mm Hg which is increased to about 121 mmHg in anal fissure patients that causes decreased blood supply to the affected area and results in ischemia and insufficient healing.[18] Non-surgical management for chronic anal fissure includes use of fiber diet, sitz baths and use of 0.2% GTN or 2% Diltiazem ointment or Botulinum toxin injection. The surgical management for chronic anal fissure includes lateral internal sphincterotomy.

The American Society of Colon and Rectal Surgeon guidelines recommend LIS (lateral internal sphincterotomy) as better treatment option as compared to long term conservative therapy.[19]

Our study showed higher efficacy in healing of anal fissure in LIS group 35 (77.78%) patients as compared to 0.2% GTN rectal ointment group in which 23 (51.11%) patients had healed anal fissure and 22 (48.89%) had non-healed fissures at eight weeks of follow up.

Six following studies have similar results to our study.

Siddique, et al.[14] from Dhaka, Bangladesh found that after six weeks of treatment for anal fissure, healing was 84.85% (28*100/33=84.85) in LIS group, while it was 35.48% (11*100/31=35.48) in GTN group patients.

Kumar, et al.[13] from B.G. Nagara, India found that healing at two weeks was 90% (45*100/50=90) in LIS group patients, while it was 64% (32*100/50=64) in GTN patients. Albaidany, et al.[12] from four hospitals in Sanaa City, Yemen found that healing at six weeks was 96.67% (29*100/30=96.67) in LIS group patients, while it was 86.67% (26*100/30=86.67) in GTN patients. Libertiny, et al.[11] from England found that healing at eight weeks was 97.14% (34*100/35=97.14) for LIS and 54.29% (19*100/35=54.29) for 0.2% GTN patients.

Boland, et al.[10] from Ireland found that healing at eight weeks was 95.1% (332*100/349=95.1) in LIS group, while it was 63.6% (131*100/206=63.6) in 0.2%GTN group. Evans, et al.[9] from Woodville, South Australia found that 96.3% (26*100/27=96.3) LIS patients had healed fissures, while 0.2% GTN patients had 60.6% (20*100/33=60.6) healed fissures.

In literature no study was revealed with same or higher efficacy for 0.2% GTN as compared to LIS in the treatment of chronic anal fissure.

Table 1: Efficacy of lateral internal sphincterotomy vs. 0.2% GTN in healing of anal fissure in population of Muzaffarabad division, Azad Kashmir

Groups		Lateral Internal Sphincterotomy		Columns Total	χ^2 value	d.f.	p-value
		Healed	Unhealed				
0.2% GTN	Healed	19	4	23	6.050	1	.0139
	Unhealed	16	6	22			
Rows Total		35	10	45 pairs	H_0 rejected at alpha .05		

CONCLUSION

In our population, lateral internal sphincterotomy showed significantly higher efficacy than 0.2% GTN rectal ointment in healing of chronic anal fissure.

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CONFLICT OF INTEREST
Authors declare no conflict of interest.
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AUTHORS' CONTRIBUTION

The following authors have made substantial contributions to the manuscript as under:

Conception or Design:	HUH, ZAK, MA
Acquisition, Analysis or Interpretation of Data:	HUH, ZAK, MA, MSR, IG
Manuscript Writing & Approval:	HUH, ZAK, MA, MSR, IG

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.