COMPARISON OF LATERAL ANAL SPHINCTEROTOMY WITH 0.2% GTN IN CHRONIC ANAL FISSURE

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ABSTRACT

Objective: To compare fissure healing and complications in chronic anal fissure with use of lateral anal sphicterotomy and 0.2% GTN.

Study Design: Randomized controlled trial.

Place and Duration of Study: Combined Military Hospital Rawalpindi & Combined Military Hospital Kohat over a period of 15 months.

Material and Methods: Chronic anal fissure was treated with use of lateral anal sphicterotomy after admission to surgical ward and by application of 0.2% glyceryltrinatrate as an outdoor case on 202 patients over a period of 15 months. Sample size was calculated by sample size calculator. Pain was measured using visual analog scale and incontinence to flatus and faeces was inquired from the patients. All cases were called for regular follow up visits but 10 patients failed to report back. Informed written consent was taken from each patient. Inclusion and exclusion criteria were followed. Analysis was done by SPSS version 13 and Chi Square test was applied.

Results: Total 202 patients were included in the study and randomly divided into two groups of 101 patients each using random numbers table. Both GTN and sphincterotomy groups revealed significant, but comparable results. Pain relief, fissure healing and incontinence were significantly higher in group B (Lateral anal sphincterotomy) as compared to group A (0.2% GTN). At the end of 8th week pain relief and incontinence became comparable between both the groups but fissure healing remain significantly higher in group B as compared to group A.

Conclusion: GTN when applied to patients produces comparable results if used in long term i.e. eight weeks. It produces adequate symptomatic control and healing of the anal fissures and can be considered equivalent to and one of the recommended treatment options along with lateral anal sphincterotomy in treatment of chronic anal fissure if use for more than 8 weeks. Lateral anal sphincterotomy gives early resolution of symptoms and healing.

Keywords: Chronic anal fissure, Glyceryltrinitrate, Lateral anal sphincterotomy.

INTRODUCTION

Anal fissure, a split in the lining of distal anal canal, a common benign condition 1 in 350 adults. It is a frequent peri-anal condition presenting with bleeding, itching and pain of varying severity. Chronic anal fissure is defined by a history of symptoms present for more than 2 months' duration and with a triad of external skin tags, a hypertrophied anal papilla, an ulcer with rolled edges, and a base exposing the internal sphincter[1]. Increased resting anal pressures are documented in patients with chronic anal fissures and it has been considered as a major pathophysiologic factor. Different modalities employed for anal fissure management includes conservative measures, surgical procedures and various pharmacological agents like glyceryltrinitrate ointment[2]. Traditional surgical procedures; manual anal dilatation or internal lateral sphincterotomy have been commonly used to reduce the hypertonia of the internal anal sphincter but they carry risk of permanent impairment of anal continence. Sphincterotomy was first described in 1835 and can be carried out using an open or a subcutaneous technique[3]. Lateral anal sphincterotomy is currently the customary surgical treatment for fissure in ano, which results in healing of 90% of cases. It carries 3-5% risk of incontinence and to be done in general or

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local anesthesia. A variety of agents like diltiazem (DTZ) and glyceryltrinitrate (GTN) have been found to cause pharmacological manipulation of the internal anal sphincter. Both DTZ and GTN are equally effective in the management of anal fissure. However DTZ is associated with a lower incidence of headache[4,5]. Topical glyceryltrinitrate is economical, has a good healing rate, and fecal incontinence has not been reported. Its effectiveness depends on patients' compliance which may be poor in view of associated headaches and a local burning sensation. Lateral internal sphincterotomy remains effective but should be reserved for patients who fail to respond to initial chemical sphincterotomy. About 60.2% GTN is one modality of treatment is cost effective, noninvasive did not require hospital admission and more acceptable to the patients as compared to sphincterotomy. Both the modalities were applied after informed consent.

Longitudinal or elliptical breaks or cracks in the distal anal canal, extending below the dentate line to the anal verge are known as anal fissures. They develop in the midline (posteriorly and anteriorly) on the anal margin. 75-90% of fissures in women are posteriorly located, only 8% of anal fissures are anterior in men. Chronic anal fissure was diagnosed if duration of the symptoms (pain and bleeding) was more than 6 weeks along with if fibers of the internal anal sphincter were visible at the base of the fissure. Associated pathology includes marginal indurations, sentinel pile distally and a fibro-epithelial polyp at the apex. Many topical pharmacological agents like glyceryltrinitrite and botulinum toxin have been introduced to treat the chronic anal fissure in nonsurgical way[9]. The vast majority of patients with chronic anal fissure can be treated with sphincter conserving treatments. This may require several interventions before healing can be achieved. Assessment for recurrence after conservative treatments requires a minimum of two year follow-up[10].

The rationale of doing the study is, to compare the effectiveness of 0.2% glyceryl trinitrate ointment with surgical sphincterotomy. Topical application of glyceryl trinitrate prevents 31-65% of patients from surgery.

MATERIAL AND METHODS

The study was conducted at surgical departments of Combined Military hospital Rawalpindi and Combined Military Hospital Kohat using randomized controlled trial by non-probability consecutive sampling on 202 patients over a period of 15 months. Chronic anal fissure was treated with local application of 0.2% GTN as an outdoor case and patients were instructed to apply GTN ointment for four to six weeks. Lateral anal sphincterotomy was done after admission to surgical ward. All ages and both genders were included in the study. Patients with primary fissure lasting for more than 06 weeks were considered chronic. Cases with previous surgery, recurrent cases, those with secondary fissures, fissures complicated with fistula, anal stenosis and patients with anorectal surgery were excluded from the study.

After approval from hospital ethical committee, we enrolled 101 patients in each group, that came to outpatient department, emergency and medical reception center with complaints of painful defecation, bleeding per rectum, constipation, discharge, soiling and sentinel pile, also fulfilling the inclusion criteria. Local examination of perianal region and digital rectal examination of patients was carried out keeping in view privacy and confidentiality and severity of pain. Informed written consent was taken from the patients. The patients were divided in two groups randomly based on table of random numbers.

Group A patients were treated with 0.2% GTN. Patients were informed about disease onset, progression, modalities of application GTN, procedure and complications. Paste about peanut size is applied to the anal margins and rubbed gently in clockwise manner for 10-15 seconds and small quantity was also applied inside the anus. The drug dosage was prescribed three times a day for eight weeks.

Group B patients were treated with lateral anal sphincterotomy. Patients have smooth recovery and discharged after 24 hours. Patients were examined at 2 weekly and 8 weekly intervals.

Data was analyzed by statistical package for social sciences (SPSS) version 13. Mean age ± Standard deviation for both groups, Comparison of male to female ratio in both groups and age (*p*-values), percentage and frequency of patients with pain relief, fissure healing and incontinence at 2 and 8 weeks in both groups was done. Mean and standard deviation was calculated for all quantitative data (age). Mean was compared by applying t-test. All qualitative data (pain relief, healing of fissure and incontinence) was compared in two groups by chi square/ orfisher,s exact test. A *p*-value <0.05 was considered statistically significant.

RESULTS

Total 202 patients were included in the study and randomly divided into two groups of 101 patients each using random numbers table. Average age in group A was 33.88 years (SD=3.86) while in group B it was 33.81 years (SD=3.68). Both the groups were similar with respect to age (*p*=0.896). In group A, 69 (68.3%) patients were males and 32 (31.7%) patients were females with male to female ratio of 2.2:1. In group B, 65 (64.4%) were males and 36 (35.6%) patients were females with male to female ratio of 1.8:1. Both the groups were comparable with respect to gender (*p*=0.551). Majority of patients presented with painful defecation in both the groups followed by sentinel pile, constipation, bleeding and discharge per rectum and pruritus. At the end of 2nd week, 31 (30.7%) patients in group A showed improvement in pain as compared to 64 (63.4%) patients in group B.

Table-I: Comparison of pain relief at the end of 2nd and 8th week between the groups.

Weeks	Group A (n=101)	Group B (n=101)	*p*-value
2nd Week			
No	70 (69.3%)	37 (36.6%)	<0.001
Yes	31 (30.7%)	64 (63.4%)	
8th Week			
No	13 (12.9%)	6 (5.9%)	0.092
Yes	88 (87.1%)	95 (94.1%)	

Table-II: Comparison of fissure healing at the end of 2nd and 8th week week between the groups.

Weeks	Group A (n=101)	Group B (n=101)	*p*-value
2nd Week			
No	69 (68.3%)	27 (26.7%)	<0.001
Yes	32 (31.7%)	74 (73.3%)	
8th Week			
No	23 (22.8%)	7 (6.9%)	0.002
Yes	78 (77.2%)	94 (93.1%)	

Table-III: Comparison of Incontinence at the end of 2nd and 8th week week between the groups.

Weeks	Group A (n=101)	Group B (n=101)	*p*-value
2nd Week			
No	101 (100%)	92 (91.1%)	0.002
Yes	0 (0%)	9 (8.9%)	
8th Week			
No	101 (100%)	99 (98%)	0.498
Yes	0 (0%)	2 (2%)	

Frequency of pain relief at the end of 2nd week was significantly higher in group B as compared to group A (p<0.001). At the end of 8th week, 88 (87.1%) patients had pain relief group A in contrast 95 (94.1%) had pain relief in group B. The difference in frequency of pain relief between both the groups became insignificant (p=0.092) table-I. In group A, 32 (31.7%) patients showed healing of fissure as compared to 74 (73.3%) patients in group B at the end of 2nd week. This difference was statistically highly significant (p<0.001). At the end of 8th week, 78 (77.2%) patients healed in group A, in contrast 94 (94.1%) healed group B. Frequency of healing is significantly higher in group B as compared to group A (p=0.002) table-II. No patient (0%) in group A showed incontinence to flatus and stool as compared to 9 (8.9%) patients in group B at the end of 2nd week. Incontinence was significantly higher in group B as compared to group A (p=0.003). At the end of 8th week, no (0%) patient had incontinence in group A in contrast 2 (2%) patientshad incontinence in group B. This difference was insignificant (p=0.498) table-III.

DISCUSSION

El-labban et al conducted a study of eighty patients. They were divided into two groups. Group one (40 patients) were subjected to treatment with local GTN 0.2% cream while group two (40 patients) were subjected to surgical treatment of the fissure with lateral internal sphincterotomy. When comparing both groups, he found that the two mean pain score were comparable to each other by the end of the 8th week. The mean pain score in group 2 dropped faster than that of group 1. This clearly proves that lateral internal sphincterotomy relieve pain much efficient and earlier as compared to GTN therapy. Fissure healing with GTN was comparable to lateral internal sphincterotomy (34 patients with GTN versus 39 patients with sphincterotomy (p=0.261)[11].

Hyman and Cataldo[12] found that topical GTN was only effective in approximately one half of patients and cause headache (75%) than to treat the symptoms. It is due to use of high concentration of GTN (0.3%) vs (0.2%) and applied to the anoderm three times per day compared to 2 times.

Glyceryl Trinitrate ointment showed significant pain relief, no bleeding and healing as duration progresses from 2 to 12 weeks. GTN group showed 86.6% of healing of chronic anal fissure at 12 weeks of duration. LIS group showed 86.7% and 100% healing of chronic anal fissure at 6 and 12 weeks of duration respectively[13].

Saad et al in his study demonstrated that 54 patients took the 0.2% GTN ointment. On examination, all patients (100%) had fissure, 52 patients (96.3%) had anal spasm, and 43/54 patients (79.6%) had skin tag. 30/34 patients (88%) showed good quality response to GTN treatment. Fissures were either healed or showed signs of healing in 28/34 patients (82.4%). In my study 31 (30.7%) patients in group A (GTN) showed improvement in pain as compared to 64 (63.4%) patients in group B (LIS) after 2nd Week. At the end of 8th week, 88 (87.1%) patients had pain relief in group A (GTN) in contrast only 95 (94.1%) had pain relief in group B (LIS).

The healing rate in 4-8 weeks course in other studies was 73% with 0.5% concentration, 68%, 65%, 62.5%, and 84% with 0.2% concentration[14-18].

Carlos Parelladastudied two groups. In the Isosorbidedinitrate ointment group, 18/27 patients (67 percent) healed at 5 weeks and 24/27 (89 percent) healed at 10 weeks of treatment. In the sphincterotomy group, 26 patients (96 percent) healed at 5 weeks and 100 percent healed at 10 weeks after treatment. No statistical difference in maximum resting anal pressure was found between groups (p=0.16), but the percentage of healing at 5 weeks was greater in the surgical group (p<0.001). Many anal fissures heal with topical treatment with GTN. Lateral internal sphincterotomy remains effective but should be reserved for patients who fail to respond to initial chemical sphincterotomy either

due to lack of compliance, prolonged treatment and complications[19].

Arslan et al suggested anal fissure had healed completely by 4 weeks in 64.7% versus 92.2%, and by 6 months in 77.1% versus 97.1% of the Isosorbidedinitrate (ISDN) and LIS group patients, respectively. At 12 months, the recurrence rates were 4.8%versus 1% for the ISDN and LIS groups, respectively, and the success rates of the treatments were 72.4% versus 96.1%, respectively. Six patients in the LIS group experienced minor fecal incontinence, and seven (6.7%) patients in the ISDN group experienced headaches that responded well to paracetamol[20].

CONCLUSION

Topical GTN ointment is an effective alternative to surgery in the treatment of chronic anal fissure. GTN paste therapy is effective because of its low cost, simplicity to use and minimal morbidity. Both GTN and sphincterotomy revealed significant, but comparable results. Glyceryltrinitrate ointment produces adequate symptomatic control and healing of the anal fissures and can be considered equivalent to and one of the recommended treatment options along with lateral anal sphincterotomy in treatment of chronic anal fissure.

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LIMITATIONS OF STUDY

Presentation of patients was late to disclose their problems to physicians. They were reluctant to undergo clinical examination. Results may become affected and biased with the chronicity of clinical features. Compliance of patients in application of GTN could not be checked in terms of timings and dosage. They were from the one center so the results cannot be applied to whole of the population. Due to the time limit the sample size was not large enough. Cases reported after trial of treatment by quacks, hakeems and homeopathic doctors and presented with perianal complications like sentinel pile, anal scarring, stenosis and hemorrhoids.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

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