ORIGINAL ARTICLE

COMPARISON OF EFFICACY OF LATERAL INTERNAL SPHINCTEROTOMY (LIS) VERSUS GLYCERYL TRINITRATE (GTN) IN THE TREATMENT OF CHRONIC ANAL FISSURE

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ABSTRACT

Objectives: To determine the effectiveness of Glyceryl Trinitratepaste (GTN) versus Lateral Internal Sphincterotomy (LIS) in treatment of chronic anal fissure in terms of pain relief and cessation of bleeding per rectum.

Material and Methods: This randomized control study was carried out in Surgical A Unit, Khyber Teaching Hospital, Peshawar, Pakistan from May 2013 to April 2015. On the basis of convenient purposive sampling consecutive 110 patients with chronic anal fissure were selected from those came through outpatient department for anal pain and bleeding per rectum. The patients were divided into 2 groups A (LIS) and B (GTN), by simple random sampling to which either topical GTN treatment or surgery i.e. LIS were offered respectively, and were advised to follow up at 2nd and 6th weeks. Patient's symptoms were noted in proforma at each follow up.

Results: In group A in 98% patients the bleeding had stopped by 2 weeks and in 100% patients by 6 weeks postoperatively, whereas in group B, the bleeding had stopped in 78% and 90% at 2 and 6 weeks respectively. The difference in both groups was statistically significant. The mean pain scores in group A was 1.51±0.29(95% CI) compared to group B as 3.93±0.38(95% CI) at 2 weeks; and pain scores of group A was 0.35±0.16(95% CI) as compared to group B as 2.11±0.37(95% CI). The difference in both groups was statistically significant.

Conclusion: Lateral Internal Sphincterotomy is the quick and effective method of management for chronic anal fissure regarding improvement of symptoms as compared to medical treatment with Glyceryl Trinitrate treatment.

Key Words: Glyceryl trinitrate, lateral, internal sphincterotomy, chronic, anal fissure.

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INTRODUCTION

Anal fissure a common proctologic problem that occurs in either gender with slightly increased frequency in females and it commonly affects young and middle aged people who are in most productive part of their lives.[1,2] Anal fissures are of two varieties, acute and chronic. Acute is a deep tear through the skin of the anal margin extending into the anal canal with surrounding oedema and inflammatory induration. It is always associated with the spasm of the anal sphincters. It often heals spontaneously. When it fails to heal, it will gradually develop into a deep undermined ulcer with continuing infection and oedema known as chronic fissure. This ulcer stops above at the dentate line, below there is hypertrophied papilla and skin tag. There is usually spasm of the involuntary musculature of the internal sphincter.[3,4] The majority of fissures are situated posteriorly in midline with approximately 10% in anterior midline in female patients compared with 1% in male patients.[1,3,5]

After excluding other pathologies that can cause anal fissure secondarily, majority of these are treated by some form of surgery and the simplest procedure among these is gentle dilatation of sphincter. Despite healing rates over 90% of fissures, this technique is no longer recommended in view of the high rates of incontinence.[1] The second method of Lateral Internal Sphincterotomy is much favourable option with complete healing rates approaching up to 97 to 100%. It has

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been adopted by most of the surgeons, because it offers long lasting relief in sphincter spasm.[6] Although complications may arise like haemorrhage, perianal abscess, fistula and most important of all anal incontinence.[5,7,8]

With better understanding of pathophysiology of chronic anal fissure, certain pharmacological products have been used with success for treatment of chronic anal fissure. Their aim is to reduce smooth muscle spasm, to increase local blood flow and thus promote healing.[5,8] Among these, Nitroglycerine, Nifedipine, Diltiazem and Botox are noteworthy.[3,9] Nitroglycerine is of special interest as it can be manufactured easily in pharmacy and economical as compared to others. It is applied locally as 0.2% cream.[4] High success rates have been reported with its use in addition to acceptability of this form of treatment to patient and low incidence of post treatment incontinence. However, its use is limited by its side effects like headache, hypotension and dizziness etc.[10]

Chronic anal fissure is a common problem and patients are usually shy to accept the surgical form of treatment. They readily accept the pharmacological form. In our setup, efficacy of Glyceryl Trinitrate (GTN) paste in treating anal fissure has been studied scarcely and limited studies are available regarding its comparison to the surgical treatment. In this study, the effectiveness of GTN paste is compared to LIS in order to develop a scientific plan for future for the treatment of patients with anal fissure.

MATERIAL AND METHODS

This randomized control study was conducted in surgical department of Khyber Teaching Hospital (KTH), Peshawar, Pakistan from May 2013 to April 2015. One hundred and ten patients with chronic anal fissure were selected randomly from those who came through OPD to seek treatment for anal fissure. The patients were divided into 2 groups by simple random sampling to either group A or B; to whom either medical treatment with topical GTN or surgery i.e. lateral internal sphincterotomy (LIS) was done respectively.

All the patients with primary idiopathic symptomatic chronic anal fissure (lasting for more than 6 weeks), of age more than or equal to 18 years, and of both gender were included in the study. Patients who had secondary anal fissures, with comorbidities (TB, hypertension, diabetes, malignancies and ischemic heart diseases etc) and pregnancy were excluded. The study design was approved by the ethical committee of Khyber Teaching Hospital.

Patients with symptoms of chronic anal fissure were registered in OPD, followed by a complete history and thorough examination including local examination of the anal region. When the diagnosis of chronic anal fissure was established they were included in the study after merits and demerits of both treatment options been explained and fully informed consent taken. The patients were allocated to either group A or B using table of random numbers. Group A were treated with Lateral Internal Sphincterotomy, and Group B treated with topical Glyceryl Trinitrate (GTN). The appropriate treatment to each group was offered at the out door department for GTN paste group and the Lateral internal sphincterotomy group were admitted and surgery was done the next day. After treatment the patients were asked for follow up at 2 and 6 weeks. Complete examination was done at the follow up visits. All the data was recorded on a standard proforma. For patients of each group, the variables of pain, bleeding per rectum were recorded at 2 weeks and 6 weeks intervals.

Statistical analysis was done with the help of computer software SPSS ® for windows version 11.0. Age was presented with range, mean and standard deviation. Gender distribution was described in percentage. Post- operative pain scores, assessed by visual analogue scale were analyzed with student T-test to compare both the procedures. The nominal data variable i.e. pain and bleeding per rectum was analyzed by chi square test. The data is presented in tabular form. P value of ≤ 0.05 is considered significant.

RESULTS

During this study period, a total of 110 (n =110) patients were included, 55 were prescribed GTN ointment (Group A) and 55 underwent lateral internal sphincterotomy under general anesthesia (Group B). All the patients showed up at 2 & 6th weeks for follow up. Mean age in group A was 30.65 years ± 12.84 SD while in group B it was 32.54 years±14.56 SD. There were 15 (27%) males and 40 (73%) females in Group A; and 17(31%) males and 38 (69%) females in Group B. There was no statistically significant difference between the two groups regarding age and gender distribution.

There was complete cessation of bleeding in 45 (81.81%) patients in Group A and in 54 (98.18%) patients in Group B at 2 weeks follow up with statis-

Table 1: Post operative persistent bleeding per rectum

Follow up in weeks	Group A n (%)	Group B n (%)	$\chi^{2[1]}$	df	P value
2	1(1.81)	12(21.81)	8.723	1	0.0031
6	0(0.00)	05(9.09)	3.352	1	0.0671

Table 2: Post operative mean pain scores[3]

Follow up	Group A Mean VAS	Group B Mean VAS	T test	df	P value
2 weeks	1.51	3.93	5.063	108	<0.0001
6 weeks	0.35	2.11	4.3608	108	<0.0001

tically significant difference between the two groups. At 6 weeks there was persistent bleeding in 5 cases in group A while there was no case of persistent bleeding in group B (Table 1). The mean pain scores were statistically significantly lower in the Group B as compared to Group A, both at 2 and 6 weekly intervals as shown in Table 2. Due to persistent pain in 8 (14.54%) patients in Group A at 6 weeks, all of them opted for the alternative treatment i.e. Lateral Internal Sphincterotomy.

DISCUSSION

The reason underlying the non-healing of chronic anal fissures is thought to be due to ischaemia of the affected area, secondary to spasm of the internal sphincter. Various studies have demonstrated increased resting tone in the internal anal sphincter in patients with chronic anal fissures, which is thought to decrease the perfusion to the fissure lesion and delay healing[11]. Treatment of anal fissure is therefore directed towards reducing the sphincter resting tone and consequently increasing perfusion. This relaxation can be achieved via pharmacological or surgical means. The recognition that nitric oxide was an inhibitory neurotransmitter regulating sphincter tone lead to the development of Glyceryl Trinitrate (GTN) ointment which can achieve healing in 70-80% of chronic anal fissures. Other pharmacological agents are also used such as calcium channel blockers17 and Botulin toxin.[19,20]

The major advantage of 'chemical' sphincterotomy is that the risk of incontinence is avoided, however, those fissures failing to heal after pharmacological intervention will still require surgery to achieve a mechanical dilatation of the internal anal sphincter[19]. In this study 110 patients were randomized into two groups, although about 70% of each group population was female (Table 2). The reason for the preponderance of females is suspected to be constipation which is more prevalent among females; also obstetrical reasons have been implicated.

According to our study LIS showed better result regarding early symptomatic improvement and fewer side effects than topical GTN which closely coincides with RCT published by Richard et al[14] in which 90 patients were assigned to either GTN or LIS, he demonstrated that LIS is superior to topical GTN with early relief of symptoms, according to him topical GTN may be effective in short term for providing symptom relief but does not seem to be effective in eradicating symptoms in the long term.

In our study the pain was completely relieved in 98% of the patients at 2nd week post-operative using visual analogue scale (VAS) for pain measurement and at the end of study i.e. 6 weeks, all patients who underwent LIS were completely pain free. This study thus closely with another study performed in Lahore.[12]

The figures are different in GTN group where pain relief is much slower and by end of 6 week 8 patients (4.4%) were still complaining of pain. Various local and international studies support these findings.[7,8,14,15] Due to persistent pain in GTN group, those patients were counselled and offered LIS as alternative form of treatment.

Although at 2nd week followup, there has been a significant difference between bleeding episodes after defecation between the two groups with less bleeding with GTN treatment as compared with LIS but at 6th week follow up bleeding in almost all the study subjects improved with no significant difference between the two groups. In the early follow up visit, it was probably the local sphincterotomy wound infection that was responsible for some cases of persistent bleeding in the LIS group.

In most of the studies the usual end point variable is “Patients’ Satisfaction”, measured differently taking into account one or more of the variables viz cessation of bleeding per rectum, improvement in pain, improvement in quality of life, incontinence etc. Although LIS achieves a high rate of healing (35%) yet incontinence to either flatus or feces (5.3%) is a well-known complication.[13,20] Normal weakening of sphincter with age and possibility of future anorectal procedures, obstetrical trauma or radiation may contribute to an even higher rate of incontinence later in life on an already compromised sphincter. A more recent study[14] demonstrated less improvement at 6 weeks with topical GTN. Its efficacy is limited by its side effects of which headache occurring in 72% of patients but no such thing seen in our study. Only 2 (1.81%) patient were complaining of headache which was not that severe to force patients to stop it.

CONCLUSION

Lateral internal sphincterotomy is superior to topical GTN in terms of symptomatic improvement in

the treatment of chronic anal fissure. Medical treatment with GTN may be a good option for initial control of symptoms and patients who are not willing for surgery or in whom surgery might be contraindicated.

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AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

Ahmed N:	Study Design , data Collection and manuscript Writing.
Muslim M:	Data Collection , Review of manuscript
Maroof SA:	Data Collection ,Statistical analysis
Aurangzeb M:	Revision of manuscript
Ahmad M:	Revision of manuscript ,Literature review

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.