

Comparative Study of 0.2%GlycerylTrinitrate Ointment versus LateralInternal Sphincterotomy for Chronic Anal Fissure

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ABSTRACT

Objective: To compare the efficacy in terms of Pain relief in 0.2% Glyceryl Trinitrate ointment versus fissurectomy with lateral internal sphincterotomy in the management of chronic anal fissure.

Study Design: Randomized controlled trial

Place and Duration: This study was conducted at Surgical Unit, DHQ Teaching Hospital, Rawalpindi over a period of 06 months starting from April 2015 to September 2015.

Methodology: 100 patients of chronic anal fissure were included in the study. Patients were divided equally into two treatment groups A & B. Group 'A' was treated with 0.2% Glyceryl Trinitrate and Group 'B' was treated by Lateral Internal Sphincterotomy. Efficacy regarding pain relief was assessed by visual analogue scale (VAS). Patients were followed for 2 weeks. Data was analyzed by SPSS 27.0.

Results: 64 patients (64%) were male and 36 patients (36%) were female (n=36). Mean age of patients was 31.36±9.68 years. Mean duration of symptoms was 14.83±7.01 weeks. 75% patients had posterior anal fissure while 25% had anterior anal fissure. At the end of 02 weeks of treatment, follow up Overall pain free outcome was seen in 35 (70 %) patients (n=50) in group A and 48 (96%) patients (n=50) in group B and on statistical basis there was significant difference in pain free outcome between the two groups (p-value <0.05).

Conclusion: Lateral internal sphincterotomy is safe and effective in the management of chronic anal fissure. 0.2% GTN ointment could be used as an alternate to the fissurectomy.

Keywords: Chronic Anal Fissure, 0.2% GTN, Lateral Internal Sphincterotomy, Pain (VAS).

INTRODUCTION

Anal fissure is one of the most common, painful diseases of the proctology[1]. Anal fissure consists mainly of a fracture in the cutaneous portion of the anal canal that is sometimes reticent to heal[2]. Around 90% of anal fissures occur later in the middle line in both men and women. Previous fissures occur more often in women in 10 percent of the patients[3].

Anal fissuring is considered acute if it is shallow and has well-marked edges for less than six weeks. They are regarded as chronic, instead, if there is a sentinel knot and hypertrophied anal papillas, or if the fibers of the anal internal sphincter are present more than 6 weeks, and if they have keratinous edges [4]. The widespread perineal disease and well known painful entity of chronic anal fissure (CAF). His treatment was debated for a long time and various therapeutic approaches were suggested. The most popular operating techniques in fissure anus include: anal stretch, lateral sphincterotomy open, lateral sphincterotomy closed, midline posture sphincterotomy, and in a smaller degree the fissure dermal flap[5] coverage. Chronic anal fissure gold standard therapy is lateral inner sphincterotomy, which decreases resting anal pressures and cures the majority of fissures effectively[6]. Lateral internal sphincterotomy is nevertheless still a preferential surgical procedure for refractory anal fissures and can be given by the American Society of Colon and Rectal Surgeons without a pharmacologic treatment failure in accordance with the practice parameters[7]. A Cochrane review of seven randomized controlled trials, contrasting anal and inner sphincterotomy to a substantially preferred anal-efficacy stretch (OR = 3.35, 95% IC = 1.55–7.26), and flatus and feces (OR = 4.03, 95% IC = 2.04–7.46,

respectively)[8]. [4]. Standard surgery can require long hospital stays, even though it is not costly and often has troubling complications like anal incontinence. There is also a great need for no operational therapy for this ailment[2]. After the recent showing of nitrogen oxide as the most effective biological broker for recto anal reflexes, it was demonstrated that topics such as GlycerylTrinitrate can lower sphincter pressure and heal anal fissures through the use of nitric oxide. A successful therapy for chronic anal fissures was shown to be the glyceryl trinitrate. It decreases the anal tone and heals anal fissure[2] in the final analysis. Cost-effective first-line therapy approach for chronic anal fissures is GlycerylTrinitrate [2]. The current research is therefore trying, with lateral internal sphincterotomy, to know the effectiveness of a 0.2 percent glyceryltrinitrate ointment versus fissurectomy. To improve mammation, patient management can be improved.

MATERIALS AND METHODS

This randomized controlled trial was conducted at Surgical Unit, DHQ Teaching Hospital, Rawalpindi over a period of 06 months starting from April 2015 to September 2015. 100 patients of both genders presented with chronic anal fissure were included in the study. Patients ages were ranging between 18 to 70 years. Patients on nitrates for medical conditions like IHD, pregnant women, inflammatory Bowel Disease and Crohn's disease, and patients with immunocompromised state were excluded.

Informed consent will be taken before starting this study demographic data will be collected .50 patients treated with 0.2%GTN and 50 patients treated with surgicallywith lateral internal sphincterotomy selected for study by lottery method

A single brand of 0.2% GlycerylTrinitrate ointment (Nitrogescic) will be used for trial arm. Dose of administration will be 1.5 cm to 2 cm in the anal canal with device provided by manufacturers of the proprietary preparation and applied twice daily for 02 weeks by patient him/her self while in case of lateral internelsphincteromy patients will be admitted in wards from OPD and procedure will be performed by consultants . Patients of both groups will be followed up for 02 weeks .for follow up contact number will be taken. Observations will be recorded at 2 weeks of follow up period, regarding pain relief. Data will be collected in proforma by researcher.

Statistical analysis will be performed using statistical package for social sciences (SPSS version 24.0). Mean and standard deviations will be presented for numerical values i.e., age. Frequency and percentages will be presented for categorical data like gender. Chi-square test will be used to find possible associations between categorical data. Data will be presented in the form of tables and graphs. A P value of less than 0.05% will be considered statistically significant.

RESULTS

In our study, 64 patients (64%) were male and 36 patients (34%) were female (n=76).There were 30 male and 20 female patients in the group A.On the other hand there were 34 male and 16 female patients in group B. Mean age of patients in group A was 30.26±8.76 years and in group B it was 31.48±8.88 years. Mean duration of symptoms in group A was 13.48±6.22 weeks and in group B it was 14.82±6.96 weeks. In group A 37 (74%) patients had posterior and in group B 38 (76%) had posterior anal fissure. (Table 1)

Table No 1: Baseline details of all the patients

| Variables | Group A | Group B |
|-----------------------|------------|------------|
| Mean age (yrs) | 30.26±8.76 | 31.48±8.88 |
| Gender | | |
| Male | 30 (60%) | 34 (68%) |
| Female | 20 (40%) | 16 (32%) |
| Mean Duration (weeks) | 13.48±6.22 | 14.82±6.96 |
| Site | | |
| Posterior | 37 (74%) | 38 (76%) |
| Anterior | 13 (26%) | 12 (24%) |

P-value >0.05

Table No 2: Outcome of Treatment

| Treatment Group | Complete Pain Free | Incomplete / Pain Free | % of Pain Free |
|------------------------------------|--------------------|------------------------|----------------|
| GTN (A) | 35 | 15 | 70 |
| lateral internalsphincterotomy (B) | 48 | 2 | 96 |
| Total | 83 | 17 | 83 |

P-value <0.05

All the 100 patients who included in the study had completed the follow up after 12 weeks of treatment in either group. Three patients from Group B experienced intractable headache and were managed by analgesics accordingly but they went on to complete the treatment. None of the patient in group A had any significant side effects causing any adjustments in the treatment. Thus

total 100 patients in the study of both the groups were available for follow up .

At the end of 02 weeks of treatment, follow up Overall pain free outcome was seen in 35 (70 %) patients (n=50) in group A and 48 (96%) patients (n=50) in group B and on statistical basis there was significant difference in pain free outcome between the two groups (p=0.021

DISCUSSION

Topical GTN is also most often used in chronic anal fission[9-10] non-surgical treatment. The GTN remains still the reference agent for the effectiveness and conformity of the other newer agents. Experimental studies have shown that Nifedipine has a LA and modulates microcirculations[11]. Local anti-inflammatory activity. Several studies have shown that nifedipine with a healing rate of up to 95% has a higher efficacy compared to 67% diltiazem[12, 13]. The aim of the study was to compare the effectiveness of Nifedipine treatment for chronic anal fissure treatment with glyceryl trinitrate.

Anal fissures are found in young and otherwise healthy adults, in particular, according to literature. The majority of patients fell in a category of age 31 to 35 years in a local study conducted in Pakistan, and the male to female ratios were 1:3[14]. In a study carried out by Usman et al. locally in Pakistan, most patients 25-35 years of age with a mean age of 37 years (n=60) have compared their care with surgical rather than non-chirurgical chronic anal fissures[15], respectively. The mean age of 40,1 years was recently compared to GTN in Masood et al. for fissure care, the age of topical diltiazem was 21 - 50 years[16]. [16]. The mean age of 33,71 years ranging from 18 to 60 years[17] was recently conducted by Golfam et al in Iran. The mean age of most patients was 31,36 years in our sample, with a 20-40-year age group (n=76). These all studies correspond to the published literature on the popular age for cracks.

Many anal fissure studies indicate that females have a higher prevalence as a result of their interaction with obstetrician history[15]. The majority of patients were female (70% and 57percent respectively in Group A and B) in a local study carried out by Usman et al in Pakistan [15]. The Golfam et al research also included high-level female patients (60 percent) in both groups[17]. The topical Nifedipine was compared with placebo in this study. In our sample, 69 (N=76) percent of the patients were women, with a 1:3 ratio of men to women. This is almost the same as Usman et al[15] figures.

Fissures are preferable to the midline (90%), but can also be found in the midline or lateral anterior. Anatomic as well as practical are the reasons of this phenomenon. Most (68%) of the fissures were subsequently located in a local analysis conducted in Pakistan [15]. Masood et al trails have performed 90,1% of post-fissure patients (n=73)[16]. 75% of patients in our sample were subsequently fissured. This distinction may be because of the increased number of women who appear to have a prior fissure due to obstetric trauma in our research. 65.4% of patients with anterior fissure[17] were recorded for Golfam et al.

Many controlled clinical trials demonstrated diverse outcomes for the topical GTN (45-80 percent) of fissure healing [18-19]. As a consequence, nearly 40% of people using this agent report headaches[17], as a significant side

effect of topical GTN therapy for anal fissure treatment. Following topical application low side effects (headache, flushing) and higher healing rate in comparison with oral use [20-21] were observed.

Masood et al showed that 82% of the patients who used topical GTN had an anal fissure cure. However, 67% of the GTN patients experienced headache as their main side effect[22]. The high recurrence rate is another well-known significant disadvantage of GTN treatment[15]. Lack of compliance with medication recommended also results in low results. The research in recent years has focused on the function of calcium channel blockers such as nifedipine and diltiazem in fissure control. Cook et al. showed reduced anal resting tone, inhibited smooth muscle contractions in IAS, decreased MRAP, and anal fissure healing using oral nifedipine[20].

The healing rates with topical nifedipine have been higher than GTN in the case of anal fissures, Ezri and Susmalliam [23]. In the Group of the GTN, the group of nifedipines had more side effects[23]. In 85.2 percent of patients with 0.5 percent nifedipine after topical therapy, Katsinelos P et al showed a full remission of anal fissure as indicated for resolution of symptoms and cure for fissure for 08 weeks[24]. In only 7.4% of patients (n=27) headache has been identified as a significant side effect[24]. Katsinelos P et al. compared 0.5% topical nifedipine to lateral internal sphincterotomy in another study conducted in Greece. After 08 weeks of therapy, the healing rate was 96.7% for the nifedipine community in comparison with the 100% for the group of sphincterotomies[25]. In 50% of patients who used nifedipine, however, headache was registered. In 88.2 percent of patients who used diltiazem relative to GTN, Sanei et al have demonstrated reduced anal fissure symptoms[14].

In our research, healing in the GTN Community was 65%, which is similar to other efficacy studies. After 06 weeks of GTN topical therapy, Usman et al showed healing of anal fissure in 88% of patients [15]. They compared topical GTN with chronic anal fissure anal internal anal sphincterotomy[15]. However, 40% of the patients reported headache of variable intensity[15]. Sanei et al demonstrated the decrease of anal fissure symptoms in 70 percent of patients (n = 36) with GTN topical in a randomized trail in a tertiary-care hospital in the city of Isfahan, Iran [14].

In comparison with GTN in the topical management of an anal fissures, our research was exceptional in the way a very few randomized trials in the literature were available. In a randomized study of 52 patients, Ezri et al. compared topical nifedipine and GTN. They observed that nifedipine healing was higher (89% versus 58%) with lower side effects (5% versus 40%) [23]. Although the profile of side effects was not part of the analysis, the number of headaches in our study identified in the nifedipine community was still significantly lower than GTN. In several previous studies [15, 23] this was demonstrated.

Our theory was impossible to confirm. While nifedipin has not demonstrated a statistically significant difference in efficacy over GTN, it is still comparable with other studies that have demonstrated its efficacy.

CONCLUSION

It is concluded that 2% nifedipine paste is as effective as 0.5% GTN ointment in terms of efficacy in management of chronic anal fissure. However, the study was conducted on a limited number of patients and many aspects of nifedipine, e.g., side effects were not compared with GTN, it is suggested that further research could help in adapting the nifedipine as a first line treatment in chronic anal fissure.

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