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Original Research Article

Surgical management of anal fissure versus Glyceryl Trinitrate ointment: a comparative prospective study

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ABSTRACT

Background: Anal fissure is common condition in general population which cause severe pain at the anal region while defecation and associated with bleeding. These symptoms cause reduction in quality of life with considerable morbidity. The objective of this study was to compare the difference in outcome between open lateral anal sphincterotomy and application of topical 0.2% nitroglycerin ointment for the treatment of chronic anal fissure and their individual efficacy.
Methods: 68 cases with a clinical diagnosis of anal fissure were recruited in the study. All selected patients met with inclusion criteria. Thus, selected cases were assigned to one of the other groups by odd and even method. Group A was managed conservatively using topical 0.2% nitroglycerin ointment, whereas Group B underwent open lateral anal sphincterotomy. Both groups were followed up at 3 week, 6 weeks, and 12 weeks, after the treatment.
Results: Among all the 68 patients, all patients had come with complaint of pain whereas 31 patients had bleeding per rectum along with pain. On clinical examination, hypertonic anal sphincter elicited in 47 patients, sentinel skin tag was noted in the 23 patients. Group A included 34 patients treated with topical 0.2% nitroglycerin ointment and group B included 34 patients who underwent lateral internal sphincterotomy. In group A, 25 (73.5%) patients treated successfully, 9 (26.4%) patients were uncured who underwent lateral anal sphincterotomy, with no fresh complaints during follow up. By contrast, all patients in group B were successfully treated and only one (0.03%) patient came with unexplained discomfort and one patient suffered from flatus incontinency.
Conclusions: This prospective study, demonstrates that open lateral internal sphincterotomy is superior to topical nitroglycerin application in the treatment of anal fissure with good symptomatic relief, high rate of healing with very low rate of early incontinence. Patients who are not willing to undergo surgery the glycerin trinitrate ointment can be used as medical line for fissure in ano.

Keywords: Anal fissure, Glyceryl trinitrate ointment, Lateral anal sphincterotomy

INTRODUCTION

Anal fissure is one of the most common lesions to be considered in the differential diagnosis of anal pain. It typically causes episodic pain that occurs during defecation and persists for hours afterward.[1] It is a common problem that causes significant morbidity. Majority of fissures are acute and resolve within 6-8 week with conservative treatment. Chronic anal fissures are associated with hypertonia of the anal canal and reduction in mucosal blood flow, with microcirculatory disturbance and a poor healing tendency.[2,3] Knowledge of

the ischemic nature of anal fissures and the high complication rate of surgical treatment were the basis in the search for nonsurgical treatment options, resulting in the topical application of novel agents such as, nitric oxide donors, calcium channel blockers, and local injection of botulinum toxin.[4-6] Few studies quotes causes are still unknown, but predicted that it may be due to increased sphincter pressure which is significantly higher (even at rest) in patients with an anal fissure, in companion with the passage of stiff fecal material.[7,8]

Anal fissure is known as acute type; mostly relieving in one week and chronic; usually lasting for more than 6 weeks, having a hypertrophic papilla of the fissure and a sentinel tubercle and exposure of sphincter muscle fibers on the floor of the wound.[9, 10]

METHODS

This study is a hospital-based prospective observational study in patients with fissure in ano carried out for period of 1 year from January 2017 to January 2018.

Study population

Sample size included 74 patients. Patients were divided into two groups.

- Group A: Topical application of 0.2% nitroglycerin ointment (n = 34)
- Group B: Open partial lateral internal sphincterotomy (n = 34).

Inclusion criteria

Both sexes, with fissure in ano, irrespective of location of the fissure.

Exclusion criteria

- Pregnant women
- Patients with Crohn's disease
- Fissure with complication like abscess or fistula formation
- Patients with recurrent anal fissure, patients with hemorrhoids, and
- Those not willing for treatment.

The study was approved by the Ethical committee of the medical college.

Method of collection of data

Total 68 patients with fissure in ano were enrolled for the study. Patients were subjected to the detailed inquiry regarding the mode of presentation, clinical examination and routine investigations preoperatively. Informed consent was obtained from the patients.

Patients were divided into following groups by odd and even method.

- Group A (nitro-glycerine ointment): (n = 34; odd numbers)
- Group B (lateral internal sphincterotomy) (n = 34; even numbers)

All patients in both groups were followed up at 3 weeks, 6 weeks and 12 weeks after the treatment with consideration to pain relief, spasm, bleeding, healing of fissure, and side effects of treatment. Those patients on NTG, who were not cured after 12 weeks, have considered for lateral anal sphincterotomy. The pain severity was recorded as mild, moderate, and severe. Regular conservative approach was initiated i.e., Analgesics, sitz bath, and laxatives were standard options to treat pain. The patient is considered to be successfully healed when the breach in mucosa was completely treated and the patient had not experienced pain during defecation.

Statistical analysis

- Data were entered into Microsoft excel data sheet and was analyzed using SPSS 22 version software. Independent t-test was used as the test of significance to identify the mean difference between two quantitative variables.
- Categorical data was represented in the form of Frequencies and proportions. Chi-square test was used as the test of significance for qualitative data.
- Continuous data were represented as the mean and standard deviation. Graphical representation of data: MS Excel and MS Word were used to obtain various types of graphs such as bar diagram.
- *p*-value (Probability that the result is true) of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.
- Statistical software: MS Excel, SPSS version 22 (IBM SPSS Statistics, Somers NY, USA) was used to analyze data.

RESULTS

In a period of one year, 68 patients were followed in two different groups (Table 1). In Group A, the minimum age of the participants was 19 years and the maximum age was 64 years (mean age: 38.23) (Table 1).

In Group B, the minimum age of the participants was 17 years and the maximum age of the participants was 59 years (mean age: 40.52) (Table 1). A total of 19 participants were female and 55 were male (Table 1).

Table 1: Demographic data.

Demographic Data	Age				Sex		
	Minimum	Maximum	Mean	p value	Male	Female	p value
Group A (GTN) (n= 34)	19	64	38.23	>0.05	23	11	>0.05
Group B (LIS) (n= 34)	17	59	40.52		26	08	

All 68 patients complained of pain (100%). However, intensity of pain varied from mild, moderate and severe. After the patient detailed history, we obtained the following parameters. A total of 40 patients recorded pain as moderate (54.05%), whereas 10 (13.5%) patients recorded it as severe. Constipation was found in 39 (52.70%) cases and 31(41.89%) individuals presented with bleeding per rectum (Table 2).

Table 2: Symptomatology of patients.

	Pain			Constipation	Bleeding
	Mild	Moderate	Severe		
Group A (0.2% nitroglycerin) (n = 34)	7	21	6	21	14
Group B (LIS) (n = 34)	11	19	4	18	17

Per rectal examination reveals, 24 patients had sentinel skin tag, 47 patients have hypertonic anal sphincter. (Table 3). When come to the location of fissure most of the patients, fissure was situated posteriorly, between 5 to 7 o clock positions. Patients with anterior fissure were 3 and rest all had posterior fissure (Table 3).

Table 3: Clinical examination findings.

Clinical examination findings	Sentinel skin tag	Sphincter spasm	Situation of fissure	
			Anterior	Posterior
Group A (0.2% Nitroglycerin) n = 34	14	23	2	32
Group B (LIS) n = 34	9	24	1	33

Table 4: Outcome of therapy in both groups during follow up period.

	At 3 weeks			At 6 weeks			At 12 weeks		
	Group A (0.2% GTN) (n = 34)	Group B (LIS) (n = 34)	P value	Group A (0.2% GTN) (n = 34)	Group B (LIS) (n= 34)	P value	Group A (0.2% GTN) (n= 34)	Group B (LIS) (n = 34)	P value
Bleeding	11 (78.57%)	13 (76.47%)	0.47	12 (85.71%)	15 (88%)	0.15	12 (85.71%)	17 (100%)	0.074
Reduced pain	26 (76.47%)	28 (82.5%)	0.052	23 (67.64%)	33 (97.05%)	0.019	29 (85.29%)	33 (97.05%)	0.046
Reduced spasm	16 (69.56%)	21 (87.5%)	0.038	21 (91.30%)	24 (100%)	0.32	21 (91.30%)	24 (100%)	0.08
Healing	8 (38.23%)	25 (73.5%)	0.0142	22 (64.70%)	33 (97.05%)	0.022	25 (73.52%)	34 (100%)	0.029

Patients were subjected to 0.2% Nitroglycerin and lateral internal sphincterotomy, on odd and even method.

The results were compared among two groups, in respect to the decreased in pain, bleeding, spasm, healing of fissure and complications of the treatment. These parameters as mentioned in Table 4.

Side effects and complications

The common side effects of GTN are Headache, flushing and dizziness: in the present study 4 out of 34 patients, have developed headache in GTN. None of the patients in GTN group showed flushing and dizziness.

Complications in surgical group: One patient out of 34 showed flatus incontinence, no patient had fecal incontinency.

DISCUSSION

Treatment of fissure in general are aimed at pain-free symptomatic control with as little disruption to the sphincter mechanism as possible. The chief factors which have been implicated have been increased sphincter tone and passage of hard stools. Thus, dietary manipulation as well as use of laxatives contributes to rapid healing of the acute fissure. However, in case of chronic fissures the treatment strategies are wider. These treatment options mainly focus on the reduction of the sphincter pressure.

In the present study there were 49 (66.2%) male patients and 25 (33.7%) female patients found in study group. The male: female ratio was 3:1.5. Which is in accordance with study conducted by Schouten et al and Divino et al.[11,12] This may be due to the higher incidence of male patients presenting for medical help. But in contrarily female patients were found more in study conducted by Christie et al and Richard et al.[13,14] This explains the golden concept of a large iceberg phenomenon of patients within the population who are not willing to report to surgeon.

Present study, Majority of the patients was found in between 21 to 40 years of age in both groups. The mean duration of age was 34.14 in both groups. This in accordance with study conducted by Schouten et al, Divino et al, Christie et al, Richard et al, Lund et al and where mean age was 39, 39, 35, 34.7 and 44 years respectively, which implies, this age group seems to have higher predilection for development of chronic fissure in ano.[11-14,4]

From the clinical data, found that the mean duration of symptoms was ranges between 3.5 to 4.5 months. This is in accordance with study conducted by Christie et al and Schouten et al.[13,11] This explains the delayed presentation. Delay in presentation and diagnosis is primarily due to the nature of the disease. This late presentation also associated with a disagreeable mode of treatment. In those patients from a rural background, the notion of anal surgeries being painful is deep-set in the mind set of many patients especially.

The presentations of symptoms were found similar in both groups. Majority of patients 95.9% had posterior anal fissure, which is the commonest site of occurrence of fissure in ano which is due to decreased ano dermal flow at the posterior midline compared to another segment of the anal canal. The rarer presentation of anterior fissure was encountered in 4% of patients. These finding were in accordance with study conducted by Lund et al and Schouten et al.[4,11] The presenting symptoms and the duration of presenting symptoms have been found to be similar in both arms of study.

The indicators used for analysis have been mentioned below:[21]

- Pain assessed by a visual analogue scale (ranging from 1 to 10, 10 for worst pain experienced by patient)
- Presence of bleeding per rectum (reported as streaking of formed stools. Frank bleeding per rectum was infrequently observed)
- Sphincter tone as assessed by the surgeon
- Healing of the fissure
- Side effects: headache, dizziness and flushing in GTN group
- Complications of Lateral Internal Sphincterotomy.

The above factors were found to have correlation with the disease process and have good correlation with overall outcome of the disease.

In present study with respect to pain control in 28 patients (82.3%), 33 patients (97.06%) and 33 patients (97.06%) pain relief were seen at 3, 6 and 12 weeks respectively in lateral sphincterotomy group and Pain relief was in 26 patients (76.47%), 29 patients (85.29%), 29 patients (85.29%) at 3, 6 and 12 weeks of interval in GTN group. So, pain relief was significantly reduced after LIS when compared to GTN group at different interval of time. Freidman test showed significant pain relief in all 3 groups as duration progresses from 2 to 12 weeks.

These results comparable with study conducted by Mishra et al.[15] But Palazzo et al showed pain relief in 33%, 51% and 62% of patients at 2, 6 and 12 weeks respectively.[16] This pain relief is due to reduction in the mean anal resting pressure.

Control of bleeding was found in 13 patients (76.47%), 15 patients (88.71%) and 17 patients (100%) in surgical group at 3, 6 and 12 weeks of duration respectively. Though 'P' is significant at 12 weeks, a better result was also obtained with GTN group: 11 patients (78.57%), 12 patients (85.71%) and 13 patients (92.8%) at 3, 6 and 12 weeks of duration respectively. This is again due to reduction in the mean anal resting pressure.

Healing was seen in 73.5%, 97.05% and 100% of patients at 2, 6 and 12 weeks in lateral sphincterotomy group respectively. Healing rate was found in 38.23%, 64.70% and 73.52% of patients at 2, 6 and 12 weeks in GTN arm. Freidman test showed significant healing of fissure in lateral sphincterotomy group as duration progresses from 3 to 12 weeks.

Lateral sphincterotomy had excellent healing of fissure and near normal sphincter tone at 6 and 12 weeks, good chances of healing were also present in treatment with GTN therapy at 12 weeks. This is in accordance with study conducted by Oettle et al[17] and Mishra et al[15] where healing rates were 80% and 92.5% respectively.

The most important and common side effect of GTN treatment was occurrence of headache, In our study headache was found in 4 patients (11%). Headache was mild degree and was controlled with using simple paracetamol. No other side effects like cardiac effects, flushing, and dizziness were observed in present study group. This was in accordance with study conducted by Lund et al, Oettle et al and Bacher et al.[4,17,18]

In the literature, the common complications in patients who underwent lateral internal sphincterotomy surgery, were faecal incontinence on straining, flatus incontinence, anal seepage or soiling of under clothes. Hence patients were followed up. The occurrences of the said complications were elicited by history.

Out of 34 patients one patient (3%) showed flatus incontinence and no patient revealed history of anal seepage, fecal incontinency on straining. However, none of the patient who underwent surgery developed the fecal incontinence during 12 weeks of post-surgery follow up. Utzig et al in their study showed incontinence of flatus and anal seepage up to 12% of the patients.[19]

The studies quoted earlier had longer duration of follow up which might explain the reason for less incidence of incontinence in the present study. The absence of recurrence is also attributed to same reason. Libertiny et al[20] in their study showed 3% recurrence at 8 months in LIS group and 15% recurrence at 6 months in GTN group. However dietary modification, intake of high fiber diet and prescriptions of laxative in patients suffering from constipation could also be contributory. Longer follow ups are required for proper assessment of recurrence.

Patients could not be followed up for longer duration. Recurrence has been noted following the stoppage of GTN therapy. The role of GTN ointment in recurrence cases was not studied. Long term use of GTN may result in its cardiac side effects. In the LIS group long term follow requires for eliciting the developing fecal or flatus incontinence.

CONCLUSION

This prospective study demonstrates that open lateral internal sphincterotomy is superior to topical Nitroglycerin application in the treatment of anal fissure with good symptomatic relief, high rate of healing with very low rate of early incontinence. Glyceryl trinitrate to be considered as chemical sphincterotomy. The chemical sphincterotomy induced by GTN is reversible and therefore avoids permanent division of part of the sphincter and the consequent disturbance of continence mechanism. Glyceryl Trinitrate ointment showed pain relief, no bleeding and healing during the study period. Patients who are not willing to undergo surgery the glycirine trinitrate ointment can be used as medical line for fissure in ano.

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