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ORIGINAL STUDY

Glyceryl trinitrate cream versus lateral sphincterotomy in management of chronic anal fissure: A prospective randomized comparative study

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Abstract

Objective: The aim is to compare complications and long-term outcome of two treatment modalities of chronic anal fissure: chemical sphincterotomy by glyceryl trinitrate (GTN) cream and lateral internal sphincterotomy.

Background: Treatment of chronic anal fissure is achieved by the reduction in the tone of the internal anal sphincter either chemically or surgically.

Patients and methods: In the period from November 2013 to October 2015, all patients who were admitted to the Department of General Surgery in Shebin Elkom Teaching Hospital complaining of chronic anal fissure were included in the study. According to inclusion and exclusion criteria, patients were selected and distributed randomly into two groups: group A had surgical treatment in the form of lateral internal sphincterotomy, and group B received topical treatment in the form of GTN cream. Patients' data such as name, age, sex, history, and examination findings along with the results of investigations were collected. Healing and complications were recorded. All data were then analyzed.

Results: A total of 30 patients were treated and followed up during 3 years. Patients in group A showed higher healing and complication rates than patients in group B.

Conclusion: Lateral sphincterotomy is an effective method in treating chronic anal fissure, whereas GTN is much less effective on long-term outcome.

Keywords: Chronic anal fissure, Glyceryl trinitrate cream, Lateral sphincterotomy

1. Introduction

A nal fissure, either in acute or chronic form is defined as a tear that occurs in the long axis of lower anal canal. In acute fissures, there is little inflammation, indurations, or edema of its edges, whereas there is inflamed indurated margins and scar tissue in chronic fissures. Sometimes, chronic fissures are accompanied by a skin tag and associated with spasm and hypertonicity of anal sphincter muscle [1,2].

The treatment is achieved by reduction of the tone of internal sphincter via chemical and surgical methods. Chemical methods include local anesthetics and glyceryl trinitrate (GTN) cream application, whereas surgical methods include anal dilatation and sphincterotomy [3,4].

Nitric oxide as a chemical messenger of the intrinsic nonadrenergic, noncholinergic pathway mediates relaxation of the sphincter. The blood flow to the skin of the anus is related to the pressure of anal zone. GTN supplies this pathway with nitric oxide to lower the resting pressure of the anus. So, GTN produces chemical sphincterotomy that is used in healing of anal fissure and protects the patient from surgery with its unwanted adverse effect of incontinence [5,6].

On the contrary, lateral sphincterotomy is a simple surgical method that heals anal fissure rapidly with low recurrence rate. It has many disadvantages

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such as incontinence, bleeding, fistula, abscess, and persistent wound pain. Forceful anal dilatation is an another option for anal fissure treatment, but it has unwanted adverse effect of incontinence [7].

This study compared GTN cream and lateral internal sphincterotomy in the treatment of chronic anal fissure in terms of the long-term outcome and occurrence of complications.

2. Patients and methods

This prospective comparative study was conducted in the period from November 2013 to October 2015 in Department of General Surgery, Shebin ElKom Teaching Hospital. All the patients who presented with chronic anal fissure and fulfilled the inclusion criteria were included in this study.

Criteria for chronicity of the condition were the duration (>3 months) and the clinical examination findings (inflammation, edema, and fibrosis). Inclusion criteria were the presence of the chronic anal fissure of more than 3-month duration or the presence of associated features such as sentinel pile, hypertrophied papillae, or exposure of internal sphincter fibers (Fig. 1).

Exclusion criteria included patients who receive nitrates for medical conditions as in cardiac patients, presence of acute anal fissure or other associated pathologies as hemorrhoids or fistula, pregnant women, or immune-compromised patients. Patients with inflammatory bowel disease were also excluded.

Patients' age, sex, and address were recorded. Accurate history and physical examination were assessed. All patients were counseled about their conditions. Informed consent was taken from all patients for their management plan. For treatment, patients were randomized by lottery method into



Fig. 1. Chronic anal fissure with sentinel pile.

two groups: group A for lateral sphincterotomy and group B for home treatment by GTN cream.

In group A, patients were placed in lithotomy position after general or spinal anesthesia, and then a proctoscope was introduced in a closed fashion, and then it was opened completely and pulled to outside to identify the internal anal sphincter.

It could be identified as a circular band at the mucocutaneous junction. Small lateral incision about 0.5–1 cm was done at 3o'clock position. Submucous dissection between the sphincter and the mucous membrane of anal canal was then done to about the dentate line only. A thin scissors then could be introduced to cut a part of the sphincter, which was dissected on both sides. Bleeding could be controlled with either compression with a towel tight plaster over it or more secure 8-shaped suture with 3/0 proline at the wound and removed as early as possible after 48 h. All complications were then recorded.

In group B, a single brand of 0.5% GTN ointment was used. Dose of administration was 2 cm that was applied to the anal canal with device provided by manufacturers of the preparation and applied twice daily for 8 weeks. In this maneuver, patient compliance was an important factor for success [6].

Short-term follow-up of these patients was done for 12 weeks. Observations were recorded at second, fourth, sixth, eighth, and 12th postoperative weeks. Follow-up of the symptoms like pain, bleeding, and healing and also adverse effects such as incontinence in group A and headache in group B was done. After 3 months, effect of treatment was assessed by the relief of symptoms and also fissure healing that was identified by clinical examination.

Long-term follow-up for all patients was carried out through outpatient department every 3 months for 2 years to assess complications like persistence of symptoms, incontinence, and other complications.

2.1. Statistical analysis

Data were analyzed by Statistical Package for Social Science (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp) program, version 26. Descriptive statistics were expressed as percentage, frequency, and χ^2 test in qualitative data. P value was considered significant if it was less than 0.05.

3. Results

A total of 30 patients were included during the study period. They were distributed equally into the two groups. They were eight male and 22 female (Fig. 2).

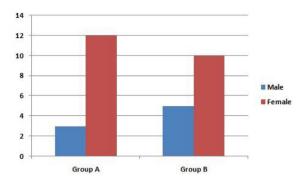


Fig. 2. Sex distribution among the study groups.

Regarding complications, 4 patients in group A complained of some degree of incontinence compared with no patients in group B (P = 0.032). Overall, six patients complained of postoperative bleeding in group A, whereas no patient complained of bleeding in group B (P = 0.006). Infection occurred in four patients in group A and two patients in group B, whereas itching occurred in one patient group A and nine patients in group B (P = 0.002). Moreover, two patients complained of headache in group A, whereas eight patients complained of it in group B (P = 0.002) (Table 1).

After a period of 3 months, 14 patients in group A showed complete healing of anal fissure, whereas 12 patients in group B still complained of painful defecation with episodes of severe inflammations and with no complete healing (P < 0.001). Overall, two of four patients in group A still complained of incontinence after 3 months (Table 2).

4. Discussion

The purpose of this study was to assess the effectiveness of lateral internal sphincterotomy as

Table 1. Complications among patients included in the study.

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Complications	Group A	Group B $(N = 15) [n (\%)]$	P value
	(N = 15) [n (%)]	(N = 15) [n (%)]	
Incontinence			
Yes	4 (26.67)	0	0.032
No	11 (73.33)	15 (100)	
Bleeding			
Yes	6 (40)	0	0.006
No	9 (60)	15 (100)	
Infection			
Yes	4 (26.67)	2 (13.33)	0.361
No	11 (73.33)	13 (86.67)	
Itching sensatio	n		
Yes	1 (6.67)	9 (60)	0.002
No	14 (93.33)	6 (40)	
Headache			
Yes	2 (13.33)	8 (53.33)	0.02
No	13 (86.67)	7 (46.67)	

Table 2. Follow-up after 3 months among patients included in the study.

Follow-up	Group A $(N = 15) [n (\%)]$	Group B (N = 15) [n (%)]	P value
Yes	1 (6.67)	12 (80)	< 0.001
No	14 (93.33)	3 (20)	
Incontinence	!		
Yes	2 (13.33)	0	0.143
No	13 (86.67)	15 (100)	

compared with GTN cream and to find out the longterm outcome and complication rate of both modalities of treatment of chronic anal fissure.

In this study, it was found that GTN is not effective in healing of chronic anal fissure. Many authors have studied the effectiveness of GTN in the management of anal fissure. Shaukat et al. [8] stated that topical GTN can be used to produce chemical sphincterotomy, and they concluded that GTN not only helps in relieving symptoms of patient but also promotes healing of fissure.

Muhammad et al. [9] stated that hope for treatment of patients with anal fissure has increased with the introduction of GTN, as it has revolutionized the non-surgical treatment because it is safe and effective in cure of both acute and chronic anal fissures and it is also economical.

In our opinion, these mentioned studies were limited regarding duration of follow-up, the frequency of relapse, and recurrence. Recurrences following GTN therapy were noted to occur several months following the stoppage of therapy. Moreover, the effect of GTN on the hypertonicity of the anal sphincter muscle was found to be not durable.

The effect of GTN, a nitric oxide donor, on anal tone was examined by Khan and colleagues. They reported that nitric oxide has emerged as one of the most important neurotransmitters that mediate internal anal sphincter relaxation. They found a 27% decrease in sphincter pressure 20 min after 0.5% GTN ointment application, but they found that it is a reversible effect, what is so-called reversible chemical sphincterotomy.

So, they concluded that the spasm of the sphincter can recur at any time after cessation of chemical relaxant topical treatment [10]. So accordingly, noncompliance could be a significant factor of failure of GTN modality. So, the high failure rate in group B in our study may be owing to the temporary effect of GTN itself plus the noncompliance of some patients.

Samad et al. [11] observed that the initial use of GTN before sphincterotomy rather than the use of sphincterotomy alone in primary treatment for chronic anal fissure is cost-effective and provides

substantial momentary benefit, as lateral internal sphincterotomy leads to permanent termination of the pathological hypertonicity state of internal anal sphincter.

Rather et al. [12] stated that internal lateral sphincterotomy is curative, easy, and safe procedure in the hands of beginners as well as experienced surgeons with high patient satisfaction. They recommended lateral internal sphincterotomy as a first line of therapy in all types of anal fissures.

Memon et al. [13] concluded that lateral internal sphincterotomy is superior than chemical sphincterotomy. It is an effective and curative procedure even if the latter is a noninvasive, cost-effective, and first line of treatment for anal fissure.

Qureshi et al. [14] noted that GTN proved to be good first-line treatment for most of the patients with anal fissure. A small group of patients experienced recurrence of symptoms; moreover, most of them responded to prolong duration of treatment.

Malik et al. [15] stated that lateral internal sphincterotomy is the most effective method of management for acute anal fissure regarding post-operative complications, loss of work hours, and pain relief.

Tauro et al. [6] observed that lateral sphincterotomy is effective but should be considered after failure of initial chemical sphincterotomy or GTN therapy.

In our study, patients required frequent follow-up, and the duration of treatment varied from the studies, supported the superiority of GTN over lateral sphincterotomy. Khan et al. [10] stated that GTN brought a highly significant drop in complication in terms of incontinence of feces and flatus, but sphincterotomy is better than GTN, as healing in the sphincterotomy group was also earlier than GTN, despite that sphincterotomy is more expensive and requires hospital stay, such as seen in our study.

A rationale approach was suggested in the treatment of chronic anal fissure. It started by the use of debulking agents and stool softeners, in the form of topical agents such as 0.5% GTN. If patients do not respond within 4 weeks, lateral internal anal sphincterotomy should then be offered. Surgery is also beneficial in cases of relapse or failure to respond to medical therapy. GTN is good alternative mode of therapy for patients who refuse surgery and prefer medical line of treatment [14].

Abd Elhady et al. [16] concluded that lateral sphincterotomy is an easy way with satisfactory results, low recurrence rate, and minimal complications, but also chemical sphincterotomy is safe and easy with mild complications but it is reversible, and relapse usually occurs even after a while.

Our study has shown that medical sphincterotomy can be tried in patients who are unable or unwilling to undergo surgery and has a good compliance to medical treatment.

4.1. Conclusion

Although complications on short term are more common with the surgical management of chronic anal fissure, but long-term follow-up is more satisfactory regarding the persistence of pain and occurrence of stenosis.

Ethical approval statement

The institutional committee's ethical criteria were followed during all proceedings. The Ethics Committee approved the study.

Conflicts of interest

There are no conflicts of interest.

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