

Original Research Article

A comparative study for management of fissure in ano with glycerin-trinitrate and lignocaine ointment: a randomized control trial

Kamlesh J. Galani, Ashwinkumar S. Gadhvi*, Nidhi D. Shah

Department of Surgery, C. U. Shah Medical College, Surendranagar, Gujarat, India

Received: 31 May 2018

Accepted: 28 June 2018

***Correspondence:**

Dr. Ashwinkumar S. Gadhvi,

E-mail: gadhviashwin@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Anal fissure is a very common benign anorectal disorder with significant morbidity among otherwise healthy individuals. Of all the patients coming to our OPD 15-20% have anal fissure. So there arises need to study the best and most compliant conservative treatment modality.

Methods: Study was randomized, prospective, observational and longitudinal including 200 patients of age group 18-60 equally divided in 2 groups. Group A given 0.2% GTN ointment and group B given lignocaine ointment.

Results: Better and early and sustained symptomatic relief was noted with GTN compared to lignocaine. 80% cases showed complete healing by 8 weeks with GTN compared to 52% healing with lignocaine. Headache was main side effect with GTN. Recurrence rate was high with lignocaine.

Conclusions: Topical GTN has a statistically and clinically significant success rate for fissure healing and pain improvement at 8 weeks compared to lignocaine ointment (80% vs. 52%). It came at the cost of clinically acceptable level of morbidity (headache).

Keywords: Anal fissure, Glycerin-trinitrate, Lignocaine

INTRODUCTION

An anal fissure is a split in the anoderm over the hypertrophied band of internal sphincter at the anal verge. The fissure is almost always located close to the midline of the anal canal; in men, 95% are near the posterior midline and 5% near the anterior midline, whereas in women, about 80% will be located posteriorly and 20% anteriorly.

Pathogenesis of Acute anal fissure is associated with increased internal anal sphincter activity, as evidenced by high anal canal resting pressure and ultra-slow waves.¹ This anal hypertonia is most evident in the posterior aspect of the anal canal, a finding confirmed by vector manometry.² The pharmacological medication of the anal sphincter hypertonia has been the subject of much speculation.³ Among the mechanisms postulated are; the lack of endogenous nitric oxide synthase, lack of cyclic

GMP and lack of calcium channel receptors in the internal sphincter. Other theories postulate that anal hypertonia is due to sympathetic over activity, failure of alpha-blockade or beta-adrenergic receptor agonists. The role of the nitric oxide pathway in internal anal sphincter relaxation has received much attention.⁴ GTN is most common drug of this group.⁵ Presenting features of fissure according to common studies are.

In most patients it is possible to make a diagnosis of anal fissure by inspection alone. Patient is made comfortable and explained regarding examinations and made to lie in Sim's position. Despite excessive sphincter activity; it is usually possible to see a small skin tag.

If the patient is reassured, it is usually possible to part the buttocks gently. This manoeuvre may be facilitated by smearing some local anaesthetic jelly around the anal margin. Proctoscopy was avoided in all cases.

Table 1: Anal fissure-presenting features.

	Lock and Thomson (n=188)	Birmingham series [†] (n=355)
Symptoms (%)		
Pain	87	82
Bleeding	82	74
Pruritus	44	14
Anal swelling	29	32
Discharge	7	4
Bowel habit (%)		
Constipation	14	24
Diarrhoea	4	7
Pathogenesis (%)		
Postpartum	3	9
Previous anal disease	26*	32
Duration length of history (weeks)	11	21
[†] Data from clinical trials of treatment		
* Fissure 22%: haemorrhoids 3%: fistula 1%.		

METHODS

In the present study, which was randomized, prospective, observational and longitudinal. Protocol of trial procedure was formed along with proforma, patient information sheet and informed consent. It consisted of 200 cases of symptomatic anal fissure with complaints of bleeding per rectum, pain during defecation, discharge and irritation. A detailed history of each patient was taken with personal history, family history, diet history with systemic examination of respiratory, cardiovascular, per abdominal examination to know any associated disease and to rule out any cause predisposing to bleeding per rectum and local examination was done as per proforma made for the study and the data entered in the proforma. The patients were explained in detail about their disease and the modalities of treatment as conservative and operative. Those cases who were willing were enrolled for study. Patients with Anal spasm due to other cause apart from fissure in ano, patient with internal and external haemorrhoids, Patient on antihypertensive medications, Pregnant females were excluded from study. Randomly the patients were divided into 2 groups and treated with topical preparations.

- Group A- 0.2% glycerin-trinitrate ointment
- Group B- 5% lignocaine ointment.

Patients were taught how and when to apply ointment. They were explained regarding maintaining local hygiene. Follow-up was arranged after end of each week upto 8 weeks. Assessment was purely based on symptomatic and clinical evaluation.

RESULTS

In the present study, conducted over period from 1/1/16 to 30/9/17, 200 cases of anal fissure were included of which 100 were treated with topical glycerin-trinitrate

and rest 100 treated with topical lignocaine ointment. Following observations were made during the study.

In this study, cases were distributed according to age and sex criteria in which 62 male and 38 female patients were treated with GTN ointment while 63 male and 37 female patients were treated with lignocaine. Patients were randomly assigned into two groups. They were then divided into age groups which included 49 patients in age group 21-30years. 74 patients in age group of 31-40 years. 55 patients in age group 41-50 years and 22 patients in 51-60years age group. Henceforth, It was observed that anal fissure was more common in age group of 31-40 with maximum number of patients (74) and there was male preponderance as there were 125 male patients and 75 female patients (ratio M:F=1.7:1) (Table 2).

Table 2: Case distribution according to age and sex.

Age groups	Total cases	GTN		Lignocaine	
		Male	Female	Male	Female
21-30	49	18	5	15	11
31-40	74	20	15	25	14
41-50	55	20	12	16	7
51-60	22	4	6	7	5

After examination of all the patients those who were included in study it was noted that common sites of anal fissure were posterior and anterior and less commonly lateral aspect. It was observed that the most common site for anal fissure was posterior (88%) followed by anterior aspect (6%) then lateral aspect and mixed 3% each. In 94% cases patient presented with single fissure (posterior in majority of cases) (Table 3).

Table 3: Incidence according to site of anal fissure.

Site	Incidence
Anterior	6%
Posterior	88%
Lateral	3%
Anterior and posterior	3%

In 100 patients who were treated with GTN ointment in the study were called for regular examination at end of each week till 8th week and clinically examined and assessed for pain, bleeding PR, discharge, pruritis. At the end of 1st week only 5% had pain and 6% had bleeding PR and no complains of discharge or pruritis.

At end of 2nd week only 2% had complain of discharge and no other complains. At end of 3rd week 4% had pain again and 2% had bleeding PR. At end of 4th week 4% had discharge and 5% had pruritis. At end of 8th week in 12% patients fissure had recurred. It was observed that better and early symptomatic relief was obtained (Table 4).

Table 4: Observations made on follow-up after starting treatment, residual symptoms with GTN.

Symptoms	1 st week	2 nd week	3 rd week	4 th week	8 th week
Pain	5%	-	4%	-	10%
Bleeding	6%	-	2%	-	3%
Discharge	-	-	-	4%	-
Pruritis	-	2%	-	5%	-
Recurrence	-	-	-	-	12%

Similarly, other 100 patients who were treated with Lignocaine ointment in the study were called for regular examination at end of each week till 8th week and clinically examined and assessed for pain, bleeding PR, discharge, pruritis. At the end of 1st week 6% had pain and 8% had bleeding PR and no complains of discharge or pruritis. At end of 2nd week 3% had complain of bleeding PR. At end of 3rd week 8% had pain again and 2% had discharge. At end of 4th week 15% had pain, 4% had bleeding and 3% had discharge. At end of 8th week in 20% patients fissure had recurred (Table 5).

Table 5: Observations made on follow-up after starting treatment residual symptoms with lignocaine.

Symptoms	1 st week	2 nd week	3 rd week	4 th week	8 th week
Pain	6%	-	8%	15%	20%
Bleeding	8%	3%	-	4%	9%
Discharge	-	-	2%	3%	-
Pruritis	-	-	-	-	5%
Recurrence	-	-	-	-	20%

In the following study, some common side effects that were noted are headache, pruritis ani, postural hypotension. Among the two groups treated with GTN and lignocaine headache was found in 42% and 5% respectively, pruritis ani was 5% and 14% respectively and postural hypotension 2% was found only in GTN treated patients (Table 6).

Table 6: Common side effects observed.

Side effects	Glycerin-trinitrate	Lignocaine
Headache	42%	5%
Pruritis ani	5%	14%
Postural hypotension	2%	0%

DISCUSSION

In the present study of conservative management of fissure in ano with topical glyceryl-trinitrate (GTN) versus lignocaine we observed 200 cases over period of 1st January 2016 to 30th September 2017, of which 100 were treated with GTN and 100 with lignocaine.

In patients with anal fissure, it was seen more in males (62%) compared to female (38%) patients. The incidence

was anal fissure in various age groups was-21-30: 24.5%, 31-40: 37%, 41-50: 27.5%, 51-60: 11%. Main complaint was found to be pain while and after defecation in 90% cases and bleeding per rectally in 80% cases (of which 72% cases had blood streaked stool).

In 88% of cases; single posterior fissure was observed, with 6% cases having anterior fissure and 3% cases had lateral and 3% cases had anterior plus posterior fissure. In 94% cases patient presented with single fissure (posterior in majority of cases) and 3% with 2 fissures and multiple fissure were observed in around 3% cases.

Most common side effect encountered with GTN was headache. Other side effects did not increase morbidity. There was no significant side effect of lignocaine that increased the morbidity.

On follow-up visits patient were assessed for symptomatic relief and clinical improvement and those patients having persistent complains were given further symptomatic treatment and those who didn't respond to these symptomatic treatments were advised regarding surgical management (lateral spinterotomy).⁷

Better and early symptomatic relief was noted with GTN compared to lignocaine.⁸⁻¹² It came at the cost of clinically acceptable level of morbidity (headache). 80% cases showed complete healing by 8 weeks compared to 52% healing with lignocaine. The relapse rate was independent of either treatment modality as observed in various studies conducted worldwide depending on patient compliance.

CONCLUSION

Hence, we can say that compared to lignocaine, glyceryl-trinitrate ointment offers faster symptomatic relief with more complete healing by 8 weeks in compliant patients.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

- Keighley M, Williams N. Surgery of the anus, rectum and colon. Elsevier Pub. 3rd edition. 2008;1:383.
- Schouten WR, Briel JW, Auwerda JJ, De Graaf EJ. Ischemic nature of anal fissure. Br J Surg. 1996;83(1):63-5.
- Nelson R. Non-surgical therapy for anal fissure. Cochrane database Syst Rev. 2006;18(4):CD003431.
- Tøttrup A, Glavind EB, Svane D. Involvement of the L-arginine-nitric oxide pathway in internal anal sphincter relaxation. Gastroenterology. 1992 Feb 1;102(2):409-15.

5. Kennedy ML, Sowter S, Nguyen H, Lobowski DZ. Glyceryl trinitrate ointment for the treatment of chronic anal fissure: results of a randomized placebo controlled trial. *Dis Colon Rectum.* 1999;42:1000-6.
6. Haq Z, Rahman M, Chowdhury RA, Baten MA, Khatun M. Chemical sphincterotomy first line of treatment for chronic anal fissure. *Mymensingh Med J.* 2005 Jan;14(1):88-90.
7. Lund JN, Scholefield JH. A randomized, prospective, double blind, placebo-controlled trial of glyceryl trinitrate ointment in treatment of anal fissure. *Lancet.* 1997;349(9044):11-4.
8. Wemyss H, Haslam P, Hemingway D. The efficacy of glyceryl trinitrate ointment for anal fissure in clinical practice. *Br J Surg.* 1999;86(Suppl. 1):104.
9. Novell F, Novell-Costa F, Novell J. Topical glyceryl trinitrate in the treatment of anal fissure. *Rev Esp Enferm Dig.* 2004 Apr; 96(4):255-8.
10. Mustafa NA, Cengiz S, Turkyilmaz S, Yucel Y. Comparison of topical glyceryl trinitrate ointment and oral nifedipine in the treatment of chronic anal fissure. *Acta Chir Belg.* 2006;106(1):55-8.
11. Mann MS, Mishra R, Thomas S, Hadke NS. Randomized, double blind trial comparing topical nitroglycerine with xylocaine and proctosedyl in primary idiopathic chronic anal fissure. *Ind J Gastroenterol.* 2004;23(3):91-3.

Cite this article as: Galani KJ, Gadhvi AS, Shah ND. A comparative study for management of fissure in ano with glycerin-trinitrate and lignocaine ointment: a randomized control trial. *Int J Res Med Sci* 2018;6:2644-7.