

# COMPARATIVE STUDY OF LOCAL CALCIUM CHANNEL BLOCKER APPLICATION AND LATERAL INTERNAL SPHINCTEROTOMY IN THE TREATMENT OF CHRONIC ANAL FISSURE: STUDY OF 50 CASES

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## ABSTRACT

**Background:** The treatment of chronic anal fissure has changed greatly during the past two decades with ongoing research directed at lowering the internal anal sphincter tone and avoiding the risk of fecal continence disturbance. Glycerin trinitrate, topical calcium channel blockers and anal dilators and botulinum toxin injection alone are all known to be able to lower the internal anal sphincter tone but results have been disappointing in curing chronic anal fissure, often marginally better than to placebo. The surgical treatment in the form of lateral internal sphincterotomy is the gold standard for chronic anal fissure.

**Aims & Objective:** The aim of this prospective study was to assess the efficacy of medical treatment in form of topical calcium channel blocker and surgery in the management of chronic anal fissure. The objective is to compare the efficacy with regard to complete healing, recurrence, incontinence and other complications after treatment with topical calcium channel blocker and lateral anal sphincterotomy.

**Material and Methods:** From October 2010 to October 2012, 50 patients with typical chronic anal fissure completed the study. 25 patients were initially treated with topical calcium channel blocker for 8 weeks and rests 25 were treated with lateral anal sphincterotomy. During the follow-up healing rates, symptoms, incontinence scores, and therapy adverse effects were recorded.

**Results:** Overall healing rates were 60% after 8 weeks therapy with topical calcium channel blocker. Whereas overall healing after lateral internal sphincterotomy group was 88% with no recurrence.

**Conclusion:** Lateral internal sphincterotomy is far more effective than medical treatment, with significantly increased healing rates while avoiding risk of incontinence.

**KEY-WORDS:** Chronic Anal Fissure; Lateral Internal Sphincterotomy; Topical Calcium Channel Blocker

## Introduction

The treatment of chronic anal fissure has changed greatly during the past two decades with ongoing research directed at lowering the internal anal sphincter tone and avoiding the risk of fecal continence disturbance. Glycerin trinitrate<sup>[1]</sup>, topical calcium channel blockers<sup>[2]</sup> and anal dilators<sup>[3]</sup> and botulinum toxin injection<sup>[4]</sup> alone are all known to be able to lower the internal anal sphincter tone but results have been disappointing in curing chronic anal fissure, often marginally better than to placebo. In recent meta-analysis of randomized clinical trials comparing medical treatments to placebo or surgery have shown that topical agents calcium channel blockers and surgery have overall response rates of about 55% and 85%, respectively, whereas the placebo healing rate is about 35% across all the studies.<sup>[5]</sup> This evidence points out that surgery in

the form of sphincterotomy is markedly superior to chemical sphincterotomy and is more effective treatment for fissure at present.<sup>[6]</sup> Lateral internal sphincterotomy<sup>[7]</sup> allows prompt healing in more than 85% of the patients with a low recurrence risk of 3%. However, it may cause minor but permanent incontinence. According to a systematic review of randomized surgical trials, the overall risk of continence disturbance after surgery is about 10% but can be as high as 35%.<sup>[8]</sup> Obviously these findings augment the fear of incontinence and reluctance toward surgery for both the patient and the surgeon with the continuing call for changes to safer medical alternatives. Medical treatment seems therefore a reasonable first line therapy for most patients with chronic anal fissure. It is likely that the fibrotic nature of chronic fissures resistant to topical calcium channel blocker and is not resolved by chemical sphincterotomy alone. We

have demonstrated in this study that surgical treatment with lateral anal sphincterotomy is safe and associated with the highest likelihood of chronic anal fissure healing compared to medical treatment. We present in our study, longer results in a prospective study of patients with chronic anal fissure assessing the efficacy of conservative treatment (including topical calcium channel blocker) and surgery (including lateral anal sphincterotomy). The aim of this prospective study was to assess the efficacy of medical treatment in form of topical calcium channel blocker and surgery in the management of chronic anal fissure. The objective is to compare the efficacy with regard to complete healing, recurrence, incontinence and other complications after treatment with topical calcium channel blocker and lateral anal sphincterotomy.

## Materials and Methods

Between October 2010 to October 2012, 50 patients with CAF were enrolled in the study. Diagnosis was made according to history and physical exam. Chronic anal fissure<sup>[9]</sup> was defined by duration of symptoms longer than 3 months and the presence of a skin tag, a sentinel pile or fibrosis at the margins of the fissure. Exclusion criteria included atypical CAF associated with grade III/IV hemorrhoids, previous anal surgery, incontinence, inflammatory bowel disease, infection, or cancer, Patients with coexisting medical conditions requiring calcium channel blockers and oral, sublingual or transdermal nitrates were also considered ineligible for this study. Patients with incomplete follow-up were also excluded. Patients were randomly selected for group 1- topical calcium channel blocker and group 2- lateral internal sphincterotomy. After this, in group 1 each patient was assigned to an 8-week course of medical therapy with topical calcium channel blocker after a Warm Seitz bath three times a day. The amount of crème to be applied was shown during the outpatient visit. If patients experienced side effects, he/she was instructed to reduce the amount to be applied. On follow up visits twice monthly, patients were examined for fissure healing, symptoms, complications and adverse effects prospectively. Secondary end-points were symptomatic improvement, need for surgery, side effects<sup>[10]</sup> and

surgical complications and patients' satisfaction. Improvement was defined as absence of pain or bleeding. Healing was defined as complete epithelialization of the fissure base. Those patients in group 2 were subjected to surgery in form of lateral internal sphincterotomy. Before surgery, all patients had a limited bowel preparation with warm water enema. An open lateral internal sphincterotomy<sup>[11]</sup> was performed with patient in lithotomy position under regional anesthesia. A circumanal incision of 1 cm was made just distal to the intersphincteric groove in the lateral position with subsequent partial division of the internal anal sphincter using coagulation diathermy. The distal internal sphincter was divided under direct vision for a length up to the fissure apex. Patients were discharged home on the same day and stayed on a high residue diet and stool softener for 7 days. A non-narcotic analgesic was also prescribed as needed and patients were advised to take regular warm Seitz baths. Patients were seen in outpatient clinic after 1 week and therefore at a 1, 2, and 3 month intervals. Patients were examined for fissure healing, symptoms, complications and adverse effects prospectively. Wexner incontinence score<sup>[12]</sup> was used to assess continence after the procedures.

## Results

**Table-1: Age Distribution**

Age Groups (in years)	No. of Patients
≤ 20	2
21-40	18
41-60	21
≥ 60	9

**Table-2: Clinical Features**

Clinical Features	No. of Patients
Pain while defecation	50
Bleeding per rectum	8
Constipation	45
Anal spasm	12
Sentinel pile	48

**Table-3: Complications**

Complications	No. of Patients	
	Group 1	Group 2
Local Hematoma	0	0
Infection	6	1
Incontinence to Flatus	0	5
Incontinence to Stool	0	0

Most of patients were from middle age group. Pain while defecation was the most common symptom.

Constipation was present in almost all patients. During the follow up, infection was more common in group 1.

**Table-4: Outcome**

Outcome	No. of Patients	
	Group 1	Group 2
Healing	15	22
Non healing	5	3
Recurrence	5	0

Chi squared equals 42.193 with 5 degrees of freedom. The two-tailed P value is less than 0.0001. By conventional criteria, this difference is considered to be extremely statistically significant. The total recovered patients were 60% in group 1 and 88% in group 2.

**Table-5: Days of Time off Work**

Days	No. of Patients	
	Group 1	Group 2
≤ 7	0	22
8-14	4	3
15-21	3	0
22-28	9	0
≥ 29	9	0

Chi squared equals 56.200 with 9 degrees of freedom. The two-tailed P value is less than 0.000. By conventional criteria, this difference is considered to be extremely statistically significant. 72% of patients in group 1 had time off work about 3 to 4 weeks.

## Discussion

The most recent theories on etiopathogenesis of anal fissures have focused on increased tonicity of internal anal sphincterotomy, which induces ischemia of the anodermis mainly of the posterior commissure. Since the introduction of the posterior internal sphincterotomy by Eisenhammer<sup>[13]</sup> in 1951, chronic anal fissure has been managed with surgery once conservative measures failed. The more safe lateral sphincterotomy popularized by Notaras<sup>[14]</sup> in 1969 has, until recently, been the mainstay of treatment. Despite surgery is highly efficacious and succeeds in curing chronic anal fissure in more than 90% of patients (often exceeds 95% with high patient satisfaction); postoperative impairment of continence is not uncommon. The incidence varies between 0% and 35% for flatus incontinence, 0% and 21% for liquid, and 0% and 5% for solid stool. According to a recent

systematic review<sup>[15]</sup>, the overall risk of incontinence is about 10%, mostly to flatus. We used topical calcium channel blocker in addition to conservative approaches (fibers and Seitz bath) as first line treatment because of its safety, convenience, and cost. The dosage and number of applications previously reported ranges from twice to four per day. The principal side effect is headache and less commonly anal pruritus. Compliance issues are observed in up to 24% of patients.<sup>[16]</sup> Medical treatment alone for chronic, well-established fissures might be inappropriate, merely delaying definitive fissure healing.<sup>[17]</sup> Failure of medical therapy or recurrence indicates the need of lateral internal sphincterotomy. Lateral internal sphincterotomy represents the most effective approach to chronic anal fissure with minor morbidity and minimal recurrence rate.<sup>[18]</sup> Although transitory postoperative incontinence can be observed in 20% of patients.<sup>[19]</sup> Nonetheless, we did not observe any permanent incontinence. Our general complication rate after lateral internal sphincterotomy was approximately 3.3% within the range reported from the literature.<sup>[20]</sup> Although the proximal extent of the lateral internal sphincterotomy continues to be a topic of debate, in our experience, by “tailoring” the amount of sphincter to be divided to the length of the fissure, the risk of incontinence is minimized as well as the fissure healing achieved. The proximal extent of lateral internal sphincterotomy up to the apex of fissure, although associated with a delayed healing, minimizes the risk of continence disturbance.<sup>[21]</sup> Proximal extent of lateral internal sphincterotomy is particularly important in female patients because of the shorter length of the internal sphincter and vaginal deliveries that have been found to be a significant risk factor of incontinence after lateral internal sphincterotomy.<sup>[22]</sup> A review of patients who had undergone lateral internal sphincterotomy revealed incontinence to stool and gas of 2.8% and 4.4%, respectively. The surgeons may significantly underestimate the scale of postoperative continence impairment after lateral internal sphincterotomy. Nonetheless, the normal weakening of the sphincters with age or other insults (anorectal surgeries, radiation, or obstetrical trauma) may influence the continence during the life.<sup>[23]</sup> Besides endoanal ultrasound

reports demonstrate extensive permanent sphincter defects after lateral internal sphincterotomy even if patient remains continent.<sup>[24]</sup> Incontinent patients after lateral internal sphincterotomy seem to have a thinner external sphincter than those who remain continent postoperatively. In order to minimize this risk, several authors have tried a more limited division of internal sphincter, a tailored or controlled sphincterotomy. In addition to continence disturbance, general surgical complication rates range from 7% to 42% mostly related to haemorrhage, abscess, fistula, fecal impaction, and urinary retention.<sup>[25]</sup>

## Conclusion

Although lateral internal sphincterotomy is far more effective than medical treatments, topical calcium channel blocker remains as the first line treatment may significantly increase the healing rate compared to standard conservative treatment. Moreover, this approach as first line treatment allows a faster healing while avoiding any risk of incontinence compared to lateral internal sphincterotomy.

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