Effect of topical nifedipine in treatment of chronic anal fissure

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Abstract
Chronic anal fissure is the most common cause of anal pain associated with internal anal sphincter hypertonia. Reduction of hypertonia is a special treatment for fissure healing. For this purpose chronic anal fissure were conventionally treated by anal dilatation or by lateral sphincterotomy. However, both of these methods may cause a degree of incontinence in some patients. The uptake of medical therapies that create a reversible chemical sphincterotomy has recently become widespread. The aim of this study is to assess the effectiveness of nifedipine in healing anal fissure, a calcium channel blocker that reduces sphincter pressure. An observational study conducted with 100 patients of chronic anal fissures treated with 0.3% nifedipine and 1.5% lignocaine. A net 52(52%) patients got their fissure healed with nifedipine. Remaining 48(48%) patients underwent surgery and there fissure healed with out complication. 4(4%) patients reported mild head ache with nifedipine use. Even though significant number of fissures heal with nifedipine recurrence is common. Another finding is low complication rate with nifedipine.

Keywords: Fissure in ano, nifedipine, calcium channel blockers, sphincterotomy

Introduction
Pathologies of anal canal- acute and chronic fissures and hemorrhoids are extremely common. About 30 to 40% of population suffers from proctologic pathologies at least once in their lives. The resulting disorders are generally more annoying than dangerous. A fissure is an oval ulcer like lesion in the anoderm, distal to dentate line usually in the posterior midline and rarely in the anterior midline. Its principle symptom is pain. Bleeding is the next common symptom and sphincter spasm. Acute anal fissure causes acute stabbing and burning pain in anal canal during and after defecation, lasting even hours. Chronic fissure is subsequent to the formation of an inflammatory infiltrate that leads to continuous hypertonicity of the internal sphincter, a microcirculatory disturbance and poor healing tendency. This vicious cycle leads to anal fissure recurrence and formation of a deep ulcer, or a pouch sinus. Acute anal fissures usually heal spontaneously or by conservative treatment with stool softeners and local anesthetic agents but chronic anal fissures do not respond to such measures and treatment is aimed at reducing the anal internal sphincter pressure with minimal complication. In some recent studies with long term follow up it seems that lateral internal sphincterotomy is a long lasting treatment for chronic anal fissure compared to topical agents and does not compromise long term fecal continence [2]. On the other hand there were some reports that traditional surgical techniques such as partial division of the internal sphincter or manual dilatation of the anal canal cause the risk of permanent anal incontinence. Chemical sphincterotomy by local application of agents that reduce the sphincter pressure until the fissure has healed, has gained acceptance in treatment of chronic anal fissure at first line. These agents include local injection of Botulinum Toxin, Topical Glyceryl Trinitrate, Diltiazem and Nifedipine. The purpose of the present study is to obtain information on the efficacy and safety of topical application Nifedipine cream (0.3%) as an effective therapeutic modality in healing chronic anal fissure.

Patients and Methods
Selected 100 patients with definite diagnosis of chronic anal fissure who presented in Chamarajanagar are taken for the study. Study period is from April 2016 to August 2018. Inclusion criteria includes, patients with chronic anal fissure who have symptoms lasting for
more than six weeks and ulcer with induration at the edges and skin tag. Exclusion criteria are any reaction to topical agents, associated diseases like Cancer, Tuberculosis, Fistula, Abscess, Crohn’s disease, HIV related anal ulcer, Third and Fourth degree Hemorrhoids and patients who did not present for follow up. All patients were advised to apply Nifedipine 0.3% and Lignocaine 1.5% ointment two to three times daily. Patients were advised to take treatment for one to one and half month. Patients are followed up at 15 days, one month, and after one and half month. Treatment is considered successful if the fissure has healed and pain subsided in 6 weeks. Ointment is applied inside the anus with the help of applicator. It is applied for six weeks. Stool softeners and Sitz bath are also given. The healing of the fissure and side effects were recorded. If the healing occurred after 6 weeks period, the patients were consequently followed up in clinic at 2, 6, and 12 months or earlier if symptoms has relapsed.

Results
Among 100 patients, 20 patients refused medical line of treatment and opted for surgical treatment. Among remaining 80 patients 58 patients have no pain and fissure healed in 6 weeks. In remaining 22 patients, 8 patients offered surgery. Other 12 patients continued chemical treatment. Among these 6 fissures healed with continued treatment for another 4 weeks.

Fissurectomy + Posteriorlateral Sphincterotomy (in 7 o clock) was done as surgery in long standing fissures with sentinal tag. Only lateral sphincterotomy was done for fissures without sentinal tag. All of them were symptom free and wound healed after 6 weeks of surgery.

Gender distribution
In our study 48 males and 52 females were found.

Position of fissure
In our study 80 fissures were posterior, 10 fissures were anterior, 6 were both anterior and posterior fissures and 4 fissures were lateral.

Mean age was 30 years, ranging from 15 years to 72 years. On long term follow up, 6 patients had recurrent pain those were operated and symptom free. Net healed fissures with chemical treatment are 52 only, remaining 48 patients went for surgery. All fissures healed after surgery without any recurrence after 6 months follow up. No patient had long term incontinence.

4 patients have reported mild headache after Nifedipine application, which was relieved with Paracetamol. 96% of patients had no side effects.

Discussion
Number of studies have shown that topical ointments containing smooth muscle relaxants promote the healing of chronic anal fissures [1, 2]. These agents produce chemical sphincterotomy without the complication of irreversible incontinence. Earlier days topical Glyceryltriminitrate (GTN) was the most widely used non-surgical treatment for anal fissure. Main adverse effect is headache and tachyphylaxis seen in 40% of the patients. Another known considerable drawback to GTN drugs is high recurrence rate [3].

Calcium channel blockers such as Nifedipine and Diltiazem had same success in treating anal fissure by both oral and topical use. Lower adverse effects (headache, flushing) and a higher rate of healing have been observed after topical application compared with oral use [4, 5]. The transport of calcium through calcium channels are important for maintenance of internal anal sphincter tone [6], a calcium channel blocker reduces the tone and spontaneous activity of sphincter by decreasing the intracellular availability of calcium [6-8]. Experimental studies designate that Nifedipine has local anti-inflammatory effect and produces modulating effect on the microcirculation too. A number of studies have shown that topical Nifedipine with a healing rate of up to 95% has a higher effectiveness compared to Diltiazem with a 67% healing rate [9, 10, 11].

This study showed that the topical use of 0.3% Nifedipine with 1.5% lignocaine could achieve complete healing in 52% of the patients after 6wks. This finding is lower than the similar studies reported by Perrotti et al. [10].

The advantage of Nifedipine is lower side effect, better compliance and better healing rate. One of obvious failures of non-surgical treatment in anal fissure is recurrence. This should be informed to the patient.

Few studies have shown higher concentration of Nifedipine (0.5% and 0.7%) have higher healing rates and with similar adverse effects [11].

References