

Chemical Sphincterotomy with 2% Diltiazem Gel Local Application in the Treatment of Chronic Anal Fissure: A Prospective Study.

Arun Chandra¹, Mishra R P², Shrivastava S K³, Singh H P³, Singh A K³, Gupta S³, Vishal B⁴, Alok⁴, Ahmad Imran⁴, Tiwari J P⁵, Mishra Vishal⁶, Chovatiya Pooja⁶, Mangal Mohit⁶.

^{1,3} MS General Surgery

² JR3 DNB, General Surgery

⁴ JR2 DNB, General Surgery

⁵ DNB Anaesthesia

⁶ JR2 DNB, Anaesthesia

Department of General Surgery & Department of Anaesthesia Dr. RML Combined Hospital Vibhuti Khand, Gomti Nagar Lucknow UP

Abstract:

Aims: To assess the efficacy of topical 2% Diltiazem gel in the treatment of chronic anal fissure.

Materials and Methods: In this prospective study we included 92 General surgery out patients with chronic anal fissure & patients were advised to apply 1.5 to 2 cms length of gel twice daily at least 1.5 cm into the anus with finger for 6 consecutive weeks. Patients were followed up weekly for six consecutive weeks and fortnightly for subsequent 3 months. Laxatives and high fiber diet was given for all the patients & hot sitz bath with povidone iodine was advised.

Results: Fissure was completely healed in 88.46% of patients. The mean duration required for healing of fissure was 5.04 weeks. 78.26% patients were free from pain. No patient had any side effect.

Conclusion: Topical Diltiazem should be considered as first line treatment in chronic anal fissure. Topical diltiazem is a good alternative mode of therapy for patients who refuse surgery or unfit for surgery and prefer medical line of treatment.

Keywords: Anal fissure, Chemical sphincterotomy

I. Introduction

Anal fissure is a common problem that causes significant morbidity. It is characterized by a linear ulcer of the anoderm, mostly in the distal one third of the anal canal, and can cause pain during defecation and for three to four hours afterwards[1]. Majority of fissures is acute and resolve within 6-8 wk of conservative treatment. However, a significant minority of fissures becomes chronic and remains a continuing problem for months or even years. Chronic anal fissures are associated with hypertonia of the anal canal[2] and a reduction in mucosal blood flow, with microcirculatory disturbance and a poor healing tendency[3]. Acute fissure usually heals spontaneously within 6 weeks. A chronic fissure, with more than 6 weeks of symptoms, is usually deeper and generally has exposed internal sphincter fibers in its base. It is frequently associated with a hypertrophic anal papilla at its upper aspect and sentinel pile at its distal. Fissures may be classified as primary (idiopathic) or secondary. Secondary fissures are those that occur due to some other pathology such as inflammatory bowel disease (Crohn's disease), anal tuberculosis, AIDS. Patients usually present with pain during defecation and passage of bright red blood during defecation. The exact etiology of anal fissure is unknown. Fissure is most commonly attributed to trauma to anal canal while passing of hard stool, but it is also seen after acute episodes of diarrhea. Painful fissures are usually associated with involuntary spasm of the internal sphincter with high resting pressure in the anal canal. So it seems that etiology of fissure may be chronic over activity of the internal sphincter. Reduction of anal sphincter spasm leads to improved blood supply and healing of fissure. Surgical techniques like manual anal dilatation or lateral internal sphincterotomy, effectively heal most fissures within a few weeks [4,5], but may result in permanently impaired anal continence. This has led to the research for alternative non-surgical treatment, and various pharmacological agents such as nitrates (glyceryl trinitrate, isosbide dinitrate), calcium channel blockers (nifedepine, diltiazem) have been shown to lower resting anal pressure and heal fissures without threatening anal continence. These treatments can create a reversible chemical reduction of sphincter pressure until the fissure has healed. [6]. The present study we are assessing efficacy and side effects of 2% Diltiazem gel local application in the treatment of chronic anal fissure.

II. Materials and Methods

In this prospective study we included 98 patients who presented to General Surgery out patient department at Dr R M L Combined Hospital from April 2014 to Dec 2015 with symptoms of anal fissure for more than 2 months were labeled as having chronic anal fissure and were enrolled in this study after obtaining an informed written consent and ethical approval clearance. Six cases did not turn up for follow up so excluded from study our study was confined to 92 patients only.

Inclusion Criteria

1. All the cases of anal fissure of more than 2 months duration.
2. Anal fissures with associated sentinel pile, hypertrophied papillae, and exposure of internal sphincter fibers.

Exclusion Criteria

1. Fissures with presumed or confirm pregnancy .
2. Anal fissures secondary to Inflammatory Bowel Disease, tuberculosis & malignancy
3. Patients with immunocompromised state.
4. Fissure with associated complications like abscess, fistula and cancer.
5. allergy to diltiazem.

Patients were advised to squeeze 2 cm of the diltiazem gel onto a finger and to apply this 1 cm inside the anus and to the anal margin. Each patient was given a 6-week course of the diltiazem gel for twice-daily application, as close to every 12 h as possible. Patients were followed up at weekly intervals for six consecutive weeks and biweekly for subsequent 3 months. Laxatives and high fiber diet was given for all the patients & hot sitz bath with povidone iodine was advised.

Cases were reviewed in Outpatient Department weekly for 6 consecutive weeks and fortnightly for subsequent 3 months. At each visit questions were asked regarding pain relief, leakage of flatus/feces, and any side effects. Healing was assessed by inspecting area and defined as complete disappearance of fissure. Pain was assessed using a pain score chart graded from 0 (almost pain free) to IV (severe pain)

III. Results

In our study most of the cases belonged to age Group 20-30 years 71 out of 92 (77.1%) with slight male preponderance 62 out of 92 (67.3%). Majority of the fissures were posterior in location 78 out of 92 (84.8%) with sentinel pile present in 44 out of 92 (47.8%) of cases. Cases were followed up at weekly intervals for 6 consecutive weeks and fortnightly for subsequent 3 months. 80 out of 92 (86.9%) of patients had completely healed fissures at the end of 4 weeks. There were eleven patients whose fissures did not heal after 6 weeks of Diltiazem application and remained symptomatic, subsequently underwent internal sphincterotomy and fissures healed in 4 weeks after surgery. The mean duration of healing was 5.01 weeks.

The first application of diltiazem was uneventful in all patients, but 12 out of 92 (13%) developed side effects subsequently. Ten patients reported perianal itching; two patient discontinued diltiazem because of delayed onset of headache after 5 wk. No other side effects were reported.

IV. Discussion

Anal fissure is a very common problem across the world. It causes considerable morbidity and adversely affects the quality of life. Anal fissure is usually encountered in young or middle aged adults [7,8] and is equally common in both sexes [7]. It is commonly found in the posterior position, although anterior fissure is comparatively common in females [9].

Therapy focuses on breaking the cycle of pain, spasm, and ischemia thought to be responsible for the development of fissure in ano. Operative management includes anal dilatation and lateral internal sphincterotomy. Lateral sphincterotomy is perhaps the operation of choice to perform in patients with chronic anal fissure needing surgical treatment. Postoperative management is simple and rate of healing is faster. However complication such as permanent anal incontinence is associated with the surgery.

Chemical sphincterotomy is now the first line of treatment in many centers [10,11,12]. Calcium channel blockers like nifedipine and diltiazem have been shown to lower resting anal pressure [13], promote fissure healing and are associated with good healing rate [10,14]. They are associated with side effects such as headache and perianal dermatitis [10]. Healing rates of chronic anal fissure in various studies ranged from 47% - 80% [6,13,14,16], while that seen in our study is 88.46%. Side effects due to Diltiazem ranged from 0%-10% [6,13,16] in various studies while no patient developed side effect in our study. In contrast to surgery, chemical sphincterotomy with Diltiazem is reversible and therefore unlikely to have adverse effects on continence.

Patients who are hypertensive, diabetic and medically unfit for surgery can be recommended treatment with Diltiazem. Though fissure healing rate is comparatively slower with Diltiazem, the trauma caused by surgery can be avoided and hospital stay is not required. Treatment works out to be very cost effective.

V. Conclusion

Chemical Sphincterotomy with Topical 2% Diltiazem should be advocated as the first option of treatment for chronic anal fissure. Topical diltiazem is a good alternative mode of therapy for patients who refuse surgery or unfit for surgery and prefer medical line of treatment.

References

- [1]. Goligher JC. Surgery of the anus, rectum, and colon. 5th ed. London: Balliere Tindall; 1984.
- [2]. Farouk R, Duthie GS, MacGregor AB, Bartolo DC. Sustained internal sphincter hypertonia in patients with chronic anal fissure. *Dis Colon Rectum*. 1994;37:424–429. [PubMed]
- [3]. Schouten WR, Briel JW, Auwerda JJ, De Graaf EJ. Ischaemic nature of anal fissure. *Br J Surg*.1996;83:63–65. [PubMed]
- [4]. Scouten WR, et al. Ischemic nature of anal fissure. *British Journal of Surgery*. 1996;83:63–65. [PubMed]
- [5]. Tocchi Adriano, Mazzoni Gianluca, Miccini Michelangelo, Cassini Diletta, Bettelli Elia, Brozzetti Stefania. Total lateral sphincterotomy for anal fissure. *International Journal of Colorectal Disease*.2004;19(3):245–49. [PubMed]
- [6]. Jonas Marion, Scholefield JH. Taylor I, Johnson CD. Recent advances in Surgery. 24th Edition. Churchill Livingstone; 2001. Anal fissure and chemical sphincterotomy; p. 115.
- [7]. Goligher John, Anal Fissure, John Goligher. *Surgery of the Anus, Rectum & Colon*. AITBS. (5th Edition) 1992:150.
- [8]. Udhwadia T.E. The prophylaxis of fissure in ano. *Indian Journal of Surgery*. 1978;40(11):560.
- [9]. Boulos PB, Araujo JGC. Adequate internal sphincterotomy for chronic anal fissure: subcutaneous or open technique? *British Journal of Surgery*. 1984;71(5):360–62. [PubMed]
- [10]. Knight J. S, Birks M, Farouk R. Topical Diltiazem ointment in the treatment of chronic anal fissure.*British Journal of Surgery*. 2001;88(4):553–56. [PubMed]
- [11]. Bhardwaj R, Parker M. C. Modern perspectives in the treatment of chronic anal fissures. *Annals of the Royal College of Surgeons of England*. 2007;89(5):472–78. [PMC free article] [PubMed]
- [12]. Haq Z, Rahman M, Chowdhury RA, Baten MA, Khatun M. Chemical sphincterotomy – first line of treatment for chronic anal fissure. *Mymensingh Medical Journal*. 2005;14(1):88–90. [PubMed]
- [13]. Carapeti E, Kamm M, Evans B, Phillips R. Topical Diltiazem and Bethanechol decrease anal sphincter pressure and heal anal fissures without side effects. *Diseases of the Colon and Rectum*. 1999;43(10):1359–62. [PubMed]
- [14]. Srivastava UK, Jain BK, Kumar Praveen, Saifee Yusuf. A comparison of the effects of Diltiazem and Glyceryl trinitrate ointment in the treatment of chronic anal fissure: a randomized clinical trial. *Surgery Today*.2007;37(6):482–85. [PubMed]
- [15]. Nash GF, Kapoor K, Saeb-Parsy K, Kunanadam T, Dawson PM. The long term results of Diltiazem treatment for anal fissure. *International Journal of Clinical Practice*. 2006;60(11):1411–13. [PubMed]
- [16]. Dasgupta R, Franklin I, Pitt J, Dawson PM. Successful treatment of chronic anal fissure with Diltiazem gel. *Colorectal Disease*. 4:20–22. [PubMed]