

Randomized Clinical Trial Comparing Topical Nitroglycerin And Posterior Perineal Support With Topical Nitroglycerin Only for Chronic Anal Fissure

Chung Ming Chen*

Francis Seow-Choen†

*chung_ming_chen@cgh.com.sg

†

Randomized Clinical Trial Comparing Topical Nitroglycerin And Posterior Perineal Support With Topical Nitroglycerin Only for Chronic Anal Fissure

Chung Ming Chen and Francis Seow-Choen

Abstract

Abstract

Background: In recent years medical therapy has largely replaced surgery as first line treatment for chronic anal fissure. Although it is effective, its use has not been widespread because of its side effects. A recent novel innovation using a specially designed toilet seat device has been reported to have encouraging results for the treatment of chronic anal fissure. This device provides posterior perineal support and thus easing defaecation, preventing overstretching and reducing trauma to the anal canal.

Methods: We conducted a randomized study involving 42 patients between Dec 2007 to May 2008 to test the hypothesis that combination use topical nitroglycerin 0.2% and toilet seat device during defaecation is superior to topical nitroglycerin 0.2% alone in the treatment of chronic anal fissure.

Results: In both groups there was a reduction in pain score after 2 weeks of treatment but the difference is not significant. At the end of 6 weeks, 14(63.6%) patients receiving topical nitroglycerin 0.2% only had their fissures healed compared to 16(84.2%) patients receiving both topical nitroglycerin 0.2% and the toilet seat device (p=.138)

Conclusion: Combination use of topical nitroglycerin 0.2% and toilet seat device have a tendency towards a better healing rate for chronic anal fissure than topical nitroglycerin 0.2% alone but this difference is not significant due to our small sample size.

KEYWORDS: Posterior perineal support, anal fissure, topical nitroglycerin

Randomized Clinical Trial Comparing Topical Nitroglycerin And Posterior Perineal Support With Topical Nitroglycerin Only for Chronic Anal Fissure

Abstract

Background: In recent years medical therapy has largely replaced surgery as first line treatment for chronic anal fissure. Although it is effective, its use has not been widespread because of its side effects. A recent novel innovation using a specially designed toilet seat device has been reported to have encouraging results for the treatment of chronic anal fissure. This device provides posterior perineal support and thus easing defaecation, preventing overstretching and reducing trauma to the anal canal.

Methods: We conducted a randomized study involving 42 patients between Dec 2007 to May 2008 to test the hypothesis that combination use topical nitroglycerin 0.2% and toilet seat device during defaecation is superior to topical nitroglycerin 0.2% alone in the treatment of chronic anal fissure.

Results: In both groups there was a reduction in pain score after 2 weeks of treatment but the difference is not significant. At the end of 6 weeks, 14(63.6%) patients receiving topical nitroglycerin 0.2% only had their fissures healed compared to 16(84.2%) patients receiving both topical nitroglycerin 0.2% and the toilet seat device (p=.138)

Conclusion: Combination use of topical nitroglycerin 0.2% and toilet seat device have a tendency towards a better healing rate for chronic anal fissure than topical nitroglycerin 0.2% alone but this difference is not significant due to our small sample size.

Introduction

Anal fissure is a common and debilitating condition that is usually seen in young and otherwise healthy patients. It causes significant pain, discomfort and disability far exceeding that which might be expected from the size of the lesion. Pathologically anal fissure develops following a linear tear in the squamous epithelium of the cutaneous anal canal located distal to the muco-cutaneous junction and usually in the posterior midline of distal anal canal.

Classically it had been thought that acute anal fissure develops following the passage of a large hard faecal mass or recurrent bouts of diarrhea [1]. Under these circumstances, the tear results in pain and spasm of the underlying anal sphincters. This causes anal hypertonia. Anal hypertonia then in turn results in a decreased ano-dermal blood flow. The decreased ano-dermal blood flow results in non-healing and chronicity of the anal fissure. Therefore anal sphincter spasm had been shown to influence blood flow to the mid-line of the anal verge and hence resulting in chronicity of the fissure [2,3]. Nonetheless, it does not quite explain how the fissure is caused in the first place. Studying the physical structure of the anal canal had led us to believe that during the act of defaecation, whilst the puborectalis is lax, there is a general lack of support to the perineum (Fig1). The exiting faecal bolus therefore extends the length of the anal canal and stretches the lip of the anal verge (Fig 1). This action initiates the tear as well as perpetuates the chronicity of the fissure [3]. In

our initial experience with the perineal support device [4], we have found that usage of the device facilitates defaecation as well as enabling the healing of anal fissures. This tearing of the anoderm causing significant acute pain and spasm of the internal anal sphincter (IAS). The IAS tone starts to elevate and overtime it remains persistently elevated as demonstrated by anal manometric studies showing a high resting anal canal pressure [5,6].

Inadequate blood supply also plays an important role in the development of chronicity of the anal fissure [7]. The distal anal canal is supplied by the inferior rectal arteries which are branches of the internal pudendal artery. The end arterioles pass through the anal sphincter to reach the submucosa of the anal canal. It is postulated that in chronic anal fissures, the elevated internal sphincter pressure reduces the perfusion in the terminal vessels as they traverse the sphincter [8]. Although the exact mechanism is not yet completely understood, the hypertonia and ischaemia theories play a pivotal role in the pathophysiology of chronic anal fissure.

For more than a century, surgery has been the treatment of choice for the management of chronic anal fissure and lateral internal sphincterotomy is the recommended procedure [9]. However, faecal soilage is a major concern and the rate of faecal incontinence has been reported to be as high as 30% [10]. This has prompted the development of chemical sphincterotomy such as topical nitroglycerin, calcium channel blocker, or botulinum toxin [11]. These noninvasive medical therapies have shown promising results and have largely replaced surgery as the first line treatment for chronic anal fissure [3]. But the initial success of these pharmacological agents have not led to their widespread use due to concerns regarding their efficacy as well

as their side effects [3]. A noninvasive, non-pharmacological novel concept based on the stretching of the posterior anal area and the anal verge as outlined above and demonstrating the effectiveness of a posterior perineal support in facilitating the healing of chronic anal fissure is being published [4]. Colorec (Trademark) (Fig 2) is a specially designed toilet seat device with a posterior anal support. It holds up the anococcygeal region just behind the posterior anus. This will help to prevent overstretching of the anus especially at the posterior area by exerting a counter pressure as the faeces traverse the anal canal (Fig 3). This study was designed to test the hypothesis that the combination of 0.2% topical nitroglycerin and a specially designed toilet seat that provided a posterior perineal support is superior to that of topical nitroglycerin alone in the healing of chronic anal fissure.

Methods

All patients with symptomatic chronic anal fissure referred to the senior author (F.S-C) between Dec 2007 and May 2008 were eligible for the study. Chronicity is defined as either having symptoms for at least 6 months or the presence of sentinel skin tag or an intra-anal firoepithelial polyp on physical examination. Exclusion criteria were atypical anal fissures, previous anorectal surgery or history of inflammatory bowel disease.

Once the diagnosis is confirmed, the patients were randomly assigned (by computer sequential method) to either receiving Rectogesic ointment (0.2% topical nitroglycerin) three times a day or Rectogesic ointment and Colorec (Trademark) (Mecha-Medic Solution Sdn Bhd Plot 92 , Hala Kampung Jawa 1, Kawasan Perindustrian Bayan Lepas (Fasa 3), 11900 Bayan Lepas, Penang, Malaysia). The

latter is a specially designed toilet seat that provided support to the posterior perineum during defaecation. Patients receiving this device were also taught and demonstrated on how to fit the device on to their toilet and how to position themselves whilst sitting on the device during defaecation.

The patients were assessed on the pain score (using the visual analog scale from 0 to 10) before and 2 weeks after the commencement of treatment. They were reviewed in the clinic at 2, 4 and 6 weeks after treatment to determine healing of the fissure. Patients whose fissures were not healed by 6 weeks or who were unable to tolerate the symptoms after starting the treatment were offered lateral internal sphincterotomy.

Statistical analysis

Statistical analysis were conducted using SPSS version 12.0. Difference in the reduction of pain score between the treatment groups was compared by use of Mann-Whitney U test and the percentage of healing of the anal fissure was compared by Chi-square test.

Results

A total of 42 patients were recruited into the study. One patient who received the 0.2% topical nitroglycerin and toilet seat device was lost to follow up after the first consultation and this was excluded in the statistical analysis. Table 1 shows the mean age and sex distribution in both groups.

Table 2 shows the mean pain score before and 2 weeks after treatment. There was a reduction of pain score in both groups. The mean reduction in pain score in patients

receiving Rectogesic ointment only and Rectogesic ointment and Colorec (trademark) was 5.00 (sd 4.05) and 5.26 (sd 3.02) respectively. The median reduction was 5.50 (range -4 to 10) and 5.00 (range 0 to 10) respectively. However, when comparing the difference in the improvement of pain score in both groups using the Mann-Whitney U test, this is not statistically significant.(Table 3)

Table 4 shows the percentage of patients with healed fissure at the end of 6 weeks. Fourteen(63.6%) of patients with Rectogesic ointment only had their fissures healed and 16(84.2%) patients with Rectogesic ointment and Colorec (trademark) had their fissures healed. However, this was also not statistically significant using the Chi-Square test. Eight(36.4%) patients treated with Rectogesic ointment only failed treatment and underwent lateral internal sphincterotomy compared to 3 (15.8%) patients in the other group. All patients who underwent lateral internal sphincterotomy had their anal fissures healed.

Discussion

Lateral internal sphincterotomy has long been seen as the treatment of choice for the management of chronic anal fissure [9]. Even though this is a simple procedure, it is not without complications such as varying degrees of flatus or stool incontinence as well as IAS deformity. In recent years, medical sphincterotomy has been a promising replacement as a first line therapy for such fissures; it is non-invasive and effective, and the side effects are reversible. However, unlike surgery, it may take quite some time to see any improvement in symptoms and the side effects may affect its compliance [3].

Following an initial tear in the anoderm, subsequent defaecation process is painful and can become difficult. During defaecation, the unsupported pelvic floor descends and the downward stretching of the anal verge as faeces traverse the anal canal further aggravates the hypertonia-fissure cycle. The use of dietary fibres and laxatives have no effect on the defaecatory mechanism. However, an earlier study by Tan et al [4]. showed encouraging results of a non randomized prospective study on the use of a specially designed toilet seat device that can provide perineal support during defaecation for patients with anal fissure [4]. Our theory is in line with a recent published study showing that lay open of a subcutaneous tract and fissurotomy healed fissures as the subcutaneous tract was also said to be due to stretching of the posterior midline [12].

Our randomized study showed that the healing rates for chronic anal fissure treated with Rectogesic ointment only and Rectogesic ointment and Colorec (trademark) were 63.6% and 84.2% respectively. This seemed to favour the use of the toilet seat device, however, the difference was not statistically significant. The improvement in the pain scores in both groups also did not differ significantly from each other. The small sample size in this study limited the possible detection of any statistical difference.

In a conventional toilet seat there is no support to the posterior anal area during defaecation. We believe that this innovative toilet seat device supports the anococcygeal region and the lax puborectalis just posterior to the anus. This acts as a counter pressure exerted by the faecal mass in the anal canal thereby preventing overstretching of the anus (Fig 3). As a result the stimulus to evacuation is enhanced and this in turn improves the defaecatory mechanism and reduces excessive straining. This device facilitates the defaecatory process and may help in improving healing of

chronic anal fissure. However although we have not provided data from defaecography as objective evidence to support our theory, the change in the length of the anal canal during defaecation is obvious to most practitioners of defaecography. We are currently setting up a protocol to determine and measure this sort of change on normal defaecation as well as during defaecation using our posterior perineal support device. Although not conclusive, our study showed that there is a tendency towards a better healing rate with the addition of the toilet seat device in the management of chronic anal fissure when compared to topical nitroglycerin alone. However this difference did not reach significant level because of our small sample size.

References

1. Lund JN, Scholefield JH. Aetiology and treatment of anal fissure. *Br J Surg* 1996;83(10): 1335-1344
2. Kua KB, Kocher HM, Kelkar A, Patel AG. Effect of topical glyceryl trinitrate on anodermal blood flow in patients with chronic anal fissures. *ANZ J Surg* 2001; 71: 548-550
3. Acheson AG, Scholefield JH. Anal fissure: the changing management of a surgical condition. *Arch Surg* 2005; 390: 1-7
4. Tan KY, Seow-Choen F, Chew HH, Gan KT. Posterior perineal support as treatment for anal fissure – Preliminary results of a new toilet seat device.
5. Hancock BD. The internal sphincter and anal fissure. *Br J Surg* 1997; 64: 92-5
6. Lin JK. Anal manometric studies in haemorrhoids and anal fissures. *Dis Colon Rectum* 1989; 32: 839-42

7. Lund JN, Binch C, McGrath J, Sparrow RA, Scholefield JH. Topographical distribution of blood supply to the anal canal. *Br J Surg* 1999; 86: 496-8
8. Klosterhalfen B, Vogel P, Rixen H, Mittermayer C. Topography of the inferior rectal artery: a possible cause of chronic, primary anal fissure. *Dis Colon Rectum* 1989; 32: 43-52
9. Nelson R (2005) Operative procedures for fissure in ano. *Cochrane Database Syst Rev*:CD002199
10. Lindsey I, Jones OM, Cunningham C, McC.Mortensen NJ. Chronic anal fissure. *Br J Surg* 2004; 91: 270-279
11. Collins EE, Lund JN. A review of chronic anal fissure management. *Tech Coloproctol* 2007; 11: 209-223
12. Pelta AE, Davis KG, Armstrong DN. Subcutaneous fissurotomy: a novel procedure for chronic fissure-in-ano. A review of 109 cases. *Dis Colon Rectum* 2007 Oct; 50(10): 1662-7

Table 1

	Rectogesic ointment (n = 22)	Colorec (trademark) with Rectogesic Ointment (n = 20)
Mean age	33.05 (s.d 13.20)	31.05 (s.d 14.58)
Sex ratio (M : F)	12 : 10	14 : 6

Table 2 –Mean pain score

	Before Treatment	2 Weeks after Treatment
Rectogesic ointment	6.86 (s.d 3.07)	1.86 (s.d 3.01)
Colorec (trademark) with Rectogesic ointment	6.50 (s.d 2.81)	1.21 (s.d 2.12)

Table 3 – Reduction in Pain Score

	Maximum	Mean	Median	Minimum	Std Deviation
Rectogesic ointment	10.00	5.00	5.50	-4.00	4.05
Colorec (trademark) with Rectogesic ointment	10.00	5.26	5.00	.00	3.02

P = 1.0

Table 4 – No. of patients with healed anal fissure at the end of six weeks

	Healed	Not Healed
Rectogesic ointment	14 (63.6 %)	8 (36.4 %)
Colorec (trademark) with Rectogesic Oint	16 (84.2 %)	3 (15.8 %)

P = .138

Figure 1. Without posterior anal support.

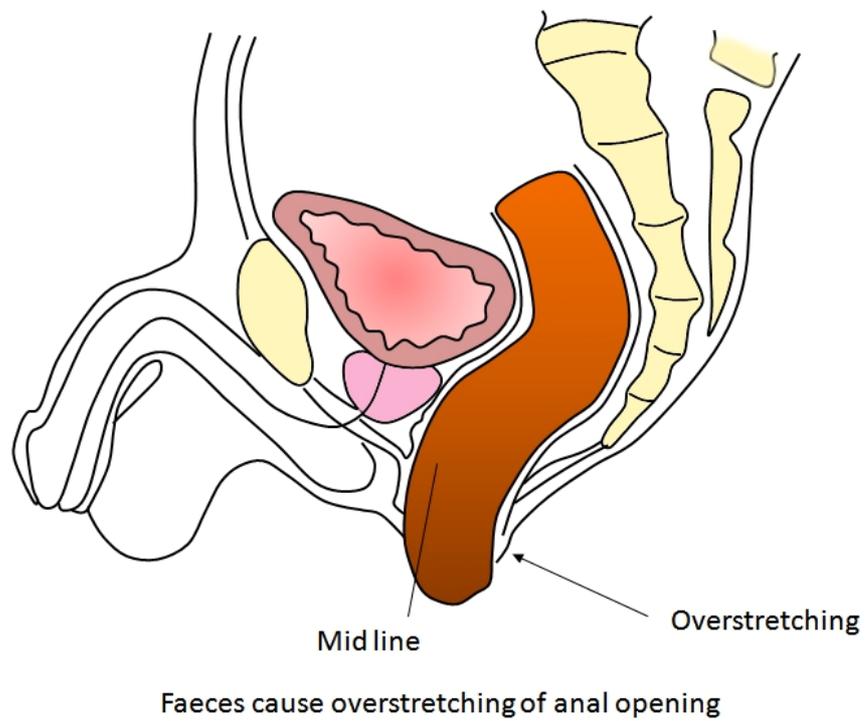
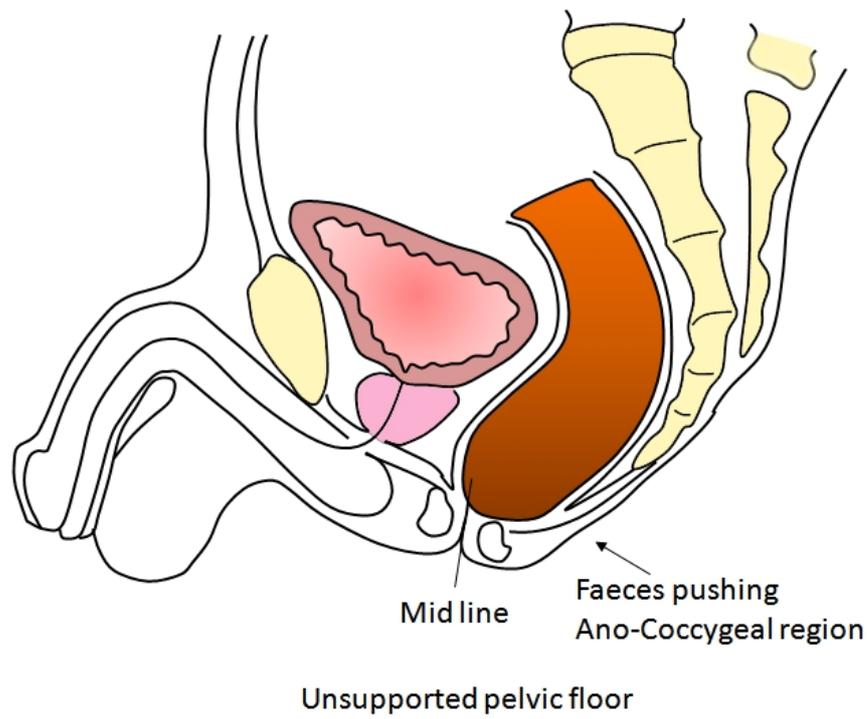
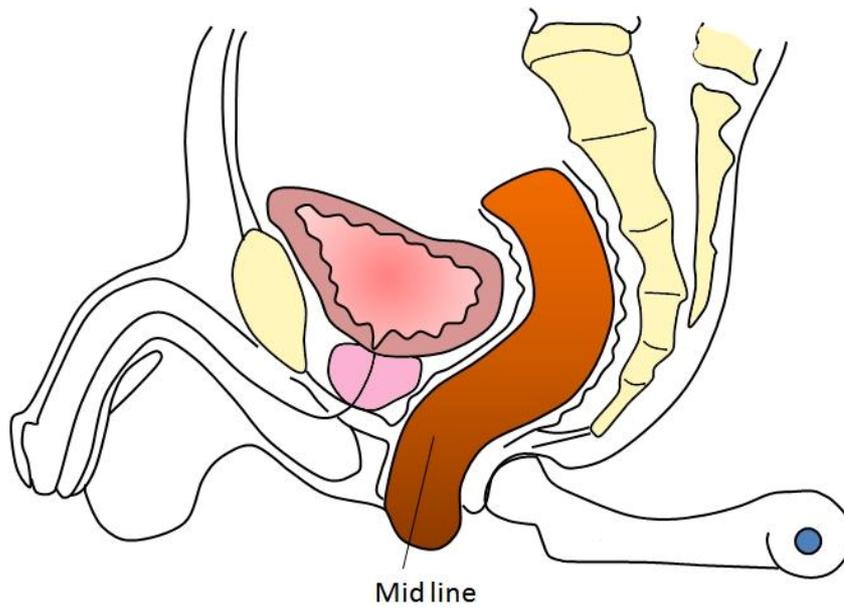


Figure 2 Colorec (Trademark)



Figure 3 With posterior anal support.



**Colorec (Trademark) supports posterior anal area
preventing overstretching of anal canal**