

Management of Chronic Anal Fissure: A Randomized Study of Operative vs Conservative Approach

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Abstract

Background: The treatment of chronic anal fissure, in recent years, has seen inclusion of various non surgical modalities to the gold standard i.e. lateral sphincterotomy. It was the attempt of this research to objectively ascertain the roles of various modes of therapy in treatment of chronic anal fissure and also to find correlation between decrease in sphincter pressures and decrease in pain with treatment, if any.

Methods: A total of 102 patients were included in the study and randomized to receive medical or surgical treatment. 52 patients were managed with Glyceryl trinitrate ointment (0.2%) while 50 patients underwent lateral internal sphincterotomy. Objective assessment of the pain was recorded as per the Visual Analog Score before and after treatment. Mean basal anal sphincter pressures were recorded before and after treatment. All patients were assessed for fissure healing at 4 and 6 weeks after completion of treatment.

Results: The reduction in pain score was significantly higher in the patients treated surgically ($p=0.037$). The reduction in sphincter pressure was also significantly higher in the surgical group at 25.10, while in the medical group it was 6.56 ($p < 0.001$). Fissure healing rates were significantly higher in surgical treatment group at 92 per cent versus 55.76 per cent. The correlation between reduction in pain in anal canal and reduction in the MASP was found to be significant ($p=0.00$; $r=0.488$).

Conclusion: This is the largest study in Indian patients comparing chemical with surgical sphincterotomy using reduction in anal pressures and pain along with fissure healing as outcomes. It showed that the reduction in pain and anal sphincter pressure as well as fissure healing is significantly better in patients undergoing surgery.

Keywords: Anal fissure; Anal sphincter pressure; Sphincterotomy.

Introduction

Anal fissure is a very common and painful disorder.[1] An anal fissure is a linear tear or ulcer of the lower half of the anal canal and in the skin around the anus. It is usually located in the posterior commissure in the midline.[2] Numerous studies have documented higher than normal resting anal canal pressures and reduced anal blood flow in the posterior midline.[3] It is therefore believed that anal fissures are the result of anal sphincter hypertonia and subsequent mucosal ischemia. [4] The pain of the fissure leads to sphincteric spasm, which in turn aggravates the pain, and thus, it becomes a vicious cycle. Increases in resting anal pressure is documented in patients with chronic anal fissures (CAF) and it has been considered as a major pathophysiologic factor.[5] Recent work has suggested that anal sphincter spasm and subsequent ischemia are important factors in the development and persistence of an acute fissure.[6] Evidence to support this includes the observation that

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reducing anal sphincter pressure, surgically or pharmacologically, results in healing of both acute and chronic fissures.[5] Patients with acute anal fissures are managed with warm sitz baths, bran or bulking agents and symptomatic pain relief. Patients with CAF should be started on the acute fissure regimen but are typically also started on other therapies simultaneously, including nitroglycerin or isosorbide dinitrate, theoretically producing "reversible chemical sphincterotomy". Medical management in the form of calcium channel blockers which decrease the anal sphincter tone have been related to the decrease of symptoms of anal fissure. Other newer agents such as Botulinum toxin A have also shown a promising role in the management of anal fissures. Research data suggests that lateral internal sphincterotomy causes a significant decline in the resting anal pressure which has been related to the relief of symptoms as in pain.[1] The best mode of management, therefore, is not clear. The objective of this study was to compare patients with single CAF treated either by lateral internal sphincterotomy(LIS) or with local application of Glyceryl Trinitrate (GTN) ointment (0.2%), in terms of rate of healing, pain control, lowering of basal sphincter pressures and complications at 6 weeks of follow-up. The primary objective of the study was fissure healing while pain control, decrease in mean basal anal sphincter pressures (MASP), complications and correlation between pain and pressure in cases of CAFs were secondary objectives.

Patients and Methods

It was a prospective study on all patients with symptomatic anal fissure at a tertiary care hospital reporting between August 2006 and July 2008. The diagnosis of a CAF was based on symptoms of pain during defecation with evidence of a linear ulcer in the lower half of the anal canal along with indurated edges, hypertrophied anal papilla or a sentinel tag lasting for more than 6 weeks. Inclusion criteria included all consenting patients of either sex

between 18 and 75 years of age with a single, CAF defined as above. Exclusion criteria were acute fissures, multiple fissures, previous anal surgery and anal fissures due to some underlying condition (including inflammatory bowel disease, hemorrhoids, fistula-in-ano or anal canal cancer). All patients were randomized to one of the two treatment groups - medical or surgical using computer generated randomly allocated numbers. Ethical committee approval was obtained before commencing the study. 94 patients had a posterior anal fissure at 6 o' clock position and remaining eight patients had a fissure at 12 o' clock position(including two male patients). The duration of symptoms ranged from 6 weeks to 15 years with a mean of 12 weeks and 86 patients reported bleeding per rectum as an associated symptom ranging from one episode of bleed to daily bleeding during defecation. Constipation at some time during the illness was also reported by 91 patients. Difficulty in sitting was a complaint of as many as 63 patients while 36 patients also reported associated peri-anal itching. Medical management was offered in the form of warm sitz baths, stool softeners, symptomatic pain relief and GTN. GTN used was Glyceryl trinitrate ointment 0.2% w/w, available as Nitrogesic ointment marketed by the company Troikkaa. GTN was applied three times daily for a period of 8 weeks. Surgical management was the standard open LIS. The surgical procedure was done under spinal or regional anesthesia with the patient in lithotomy position. A stab incision is made at 3 o'clock with one finger inside the anal canal to prevent incision extending into anal mucosa. The lower fibers of the internal sphincter are separated at the inter-sphincteric groove and brought out and divided. Closure of stab wound is not required. Objective assessment of the pain as experienced by the patient was recorded as per the Visual Analog Score (VAS) before and after completion of treatment. MASP were recorded with a saline-perfused single channel anorectal manometer before commencement of treatment and after completion of treatment. The instrument used is a portable microprocessor based anorectal manometry

system mounted on a comprehensive platform. It has been developed by researchers at the All India Institute of Medical Sciences, New Delhi, and has undergone extensive clinical trials at that institution. The recording was done after defecation and three readings were taken for all patients and the average of readings were considered for analysis. Intention to treat principle was adhered to. All patients were assessed for fissure healing at 4 and 6 weeks after completion of treatment by another clinician blinded to the study. The end point of fissure healing was considered to be complete healing with epithelial cover over the lesion.

Statistical analysis

Analysis was conducted using SPSS 14 for Windows. Differences in VAS and MASP were compared with Z test. Pearson correlation was used to correlate reduction in pain in anal canal with reduction in MASP. P value of less than 0.05 was considered to be significant.

Results

A total of 102 patients were included in the study. Medical group consisted of 52 patients and 50 patients underwent surgery. The mean age was 38.24yrs. Before treatment, MASP was 71.65 +/- 15.17cm H₂O while mean VAS was 8.46 +/- 0.9. The groups were similar with regard to age, sex and resting anal canal

pressures. MASP post therapy was 56 +/- 15.2 cm H₂O while mean VAS post therapy was 2.08 +/-1.45. There were no drop outs or loss to follow-up in the study group and no drop outs or non-compliers were shifted to the surgical group. The comparison results are shown in the Table. The pre treatment VAS was comparable in both groups (p = 0.451). The pre treatment MASP was higher in the surgical group (p = 0.08) though it did not reach statistical significance. The post treatment VAS was lower in the patients treated surgically at 1.30 as compared to patients treated medically who had a post treatment VAS of 2.83. The post treatment MASP was also lower in the surgical group at 49.16 cm H₂O, while in the medical group it was 62.58 cm H₂O. The reduction in pain following treatment was significantly higher in the surgical group at 7.16, while in the medical group it was 5.63 (p = 0.037). The reduction in MASP after treatment was significantly higher in the patients undergoing lateral internal sphincterotomy (pressure difference = 25.10) as compared to the medical management group (pressure difference = 6.56) (p < 0.001). Fissure healing rate was significantly higher in the surgical group where 92% of the fissures healed as compared to 55.76% in the medical group (p < 0.001). The correlation between reduction in pain in anal canal and reduction in the MASP was found to be significant (p=0.00; r=0.488). There were complications in the form of headache in the

Table: Comparison of results of medical and surgical treatment

	Medical Group (n=52)	Surgical Group (n=50)	P value
Pre treatment pain	8.46 (+/-0.93)	8.46 (+/-0.86)	0.451
Pre treatment anal pressure	69.13(+/-17.24)	74.26 (+/-12.31)	0.08
Post treatment pain	2.83 (+/-1.63)	1.30 (+/-0.61)	-
Post treatment anal pressure	62.58 (+/-15.75)	49.16 (+/-11.17)	-
Reduction in pain	5.63 (+/-1.59)	7.16 (+/-1.13)	0.037
Reduction in anal pressure	6.56 (+/-5.39)	25.10 (+/-11.08)	<0.001
Fissure healing	29 (55.76*)	46 (92*)	<0.001

Figures in parentheses are 95 per cent confidence intervals.

* Figures are percentages.

medical group (n=34) while in the surgical group one patient experienced transient incontinence to flatus which resolved over 3 weeks.

Discussion

Surgery in the form of LIS has been considered to be the gold standard in the treatment of CAF. This was so without the objective evidence of effect on anal sphincter pressures and pain score. There is an undercurrent of change in the management of anal fissures with various new modalities as GTN and Botulinum toxin entering the spectrum of treatment. As per various studies, LIS results in a healing rate of 90-95 per cent [1,7] which is higher than GTN and Botulinum toxin. [8] Our study also shows that rate of fissure healing is much higher with LIS and is comparable with earlier studies.

It has also been observed that reducing MASP, surgically or pharmacologically, results in healing of both acute and chronic fissures. [5] Thornton MJ *et al* studied fifty-seven patients of CAF and injected botulinum toxin into the intersphincteric groove. Although MASP fell by 17 percent (range 0-71), the pressure reduction did not correlate with clinical outcome assessed with a linear analog pain score ($P > 0.2$). [9] Our study shows that following treatment, reduction in pain in anal canal is associated with a reduction in the MASP ($p=0.00$; $r=0.488$). This study differs in the fact that it does show a good correlation between the reduction in pain and reduction in MASP after treatment, while other studies have not shown the same [9]. This correlation suggests that the decrease in pain is brought about by the decrease in MASP and may also be due to the limited number of patients.

A randomized study was conducted by Mishra R *et al* who randomized 40 consecutive patients with CAF for treatment with either topical GTN or internal sphincterotomy (20 in each group). [10] Both GTN and sphincterotomy brought about a highly significant, but comparable drop in the MASP

after treatment ($P < 0.0001$ in both groups). Sphincterotomy relieved pain much earlier compared to GTN (70% vs 40% at 2 weeks, $P = 0.0032$); but after 4 weeks of treatment, pain relief in both groups was comparable. They concluded that topical GTN should be the initial treatment in CAF. Lateral sphincterotomy should be reserved for patients with severe disabling pain (because pain relief is much faster), and for patients not responding to at least 4 weeks of GTN therapy. The pain relief was not only faster but higher in magnitude in our study ($p = 0.037$). The study proves the efficacy of surgery over GTN therapy.

In the present study, surgical treatment was found to be significantly better than GTN ointment for objective and symptomatic relief. This is the largest study, at least in the Indian population, that *objectively* compares medical mode of therapy and surgery for symptomatic relief in patients with chronic anal fissure. The low patient number in this study is a weakness and therefore, more randomized studies on larger groups of Indian population are required. Though, a sample size calculation was not done a priori, the significant results of the study still remain valid in spite of small sample size. This study has not assessed the dose response curve of GTN therapy as literature suggests that the effect of GTN is maximum after an hour of application and then slowly decreases to have no long lasting effect on sphincter pressure. This study has not compared other medical modalities of treatment available, eg. Botulinum toxin injections, which could have led to different findings and a better comparison could have been made between medical and surgical management. A longer follow-up period could have led to identification of recurrences in the study, more so for the medical treatment group. Pain was the subjective outcome assessed in the study being the commonest and most worrisome symptom. Other subjective outcomes like bowel habits, bleeding per rectum were not assessed which could be a weakness of the present study.

LIS carries a significant risk of minor,

persistence disturbances in anal continence. The incidence has been poorly documented but varies between 0 and 36 per cent for incontinence to flatus, 0 and 21 per cent for incontinence to liquid stool, and 0 to 5 per cent for incontinence to solid stool [11]. GTN ointment is fraught with a common side effect of headaches and rarely, postural hypotension. In our study, one patient in surgical group suffered from transient incontinence to flatus and there was a high incidence of headaches in the medical group.

It could be suggested that surgery in the form of LIS be offered to all patients with chronic anal fissure, in view of the low complication rate, fast relief from pain and high rate of fissure healing. Patients who suffer mild symptoms, or those not willing to undergo surgery with the attendant complications, however low, should be offered medical management.

Conclusion

The study showed that the reduction in pain and anal sphincter pressure is significantly more in the patients undergoing surgery as compared to the patients undergoing medical management. Lateral internal sphincterotomy causes a reduction in the pain as well as pressures in patients with anal fissure more efficiently than medical methods in the form of GTN ointment in addition to the fissure healing. This reduction in pain following therapy is probably due to a decrease in the anal sphincter pressure, which forms the basis for fissure healing. It could be suggested that surgery in the form of LIS be offered to all patients with chronic anal fissure, except the ones with the mildest of symptoms, which might respond to medical management. Further research should be concentrated on making the surgical gold standard safer so as to decrease the complication of incontinence. Surgery should be considered the treatment of choice after failure of conservative management.

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