



A COMPARATIVE STUDY BETWEEN CHEMICAL SPHINCTEROTOMY WITH BOTULINUM TOXIN VERSUS LATERAL SPHINCTEROTOMY IN THE MANAGEMENT OF CHRONIC FISSURE IN ANO

General Surgery

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ABSTRACT

Background - Anal fissure is a crack or split in the vertical axis of the Squamous lining of the anal canal. There are so many surgical and nonsurgical management to treat chronic anal fissure by reducing hypertonia of internal anal sphincter. In this study a surgical procedure lateral anal sphincterotomy is compared with a nonsurgical procedure injection of botulinum toxin into internal sphincter.

Methods - This is a prospective comparative study conducted in Medical College Kolkata. Total 100 were randomized into two groups. One group of 50 patients randomly assigned for Lateral Anal Sphincterotomy another 50 patients underwent 20 IU Botulinum toxin injection into internal sphincter and two groups advised for follow up at 2 weeks, 6 weeks and 6 months.

Results - 98% of botulinum toxin group satisfied regarding complete relieved of pain but 84 % in case of LS group after 6 months ($p=0.036$). After 6 months no patient complaints about incontinence in BT group but 16% in case of LS group ($p=0.036$). 2% of BT group complains about recurrence but 15% cases came with recurrence in case LS group.

Conclusion - Local infiltration of botulinum toxin into internal sphincter (single dose 20 IU) is as good as first line treatment option in cases of chronic anal fissure.

KEYWORDS

BT -Botulinum toxin, LS- Lateral anal sphincterotomy, CFA- Chronic Anal Fissure.

1) INTRODUCTION -

Anal fissure is a crack or split in the vertical axis of the Squamous lining of the anal canal between the anal verge and the dentate line over the hypertrophied band of internal sphincter. The pathophysiology of anal fissure is thought to be related to trauma from either passage of hard stool or prolonged diarrhea.

An initial traumatic event leads to tearing of the pecten and pain. A constipated stool is often implicated, but there can be many other causes. The pain leads to associated anal spasm and it is this that then impedes the local blood supply, interfering with healing. Over time the fissure becomes an ischemic ulcer².

There are so many surgical and nonsurgical management to treat chronic anal fissure by reducing hypertonia of internal anal sphincter and increasing blood supply towards affected areas. In this study a surgical procedure lateral anal sphincterotomy is compared with a nonsurgical procedure injection of botulinum toxin into internal sphincter.

2) AIM OF THE STUDY -

To compare the results of botulinum toxin and conventional lateral sphincterotomy in the management of chronic anal fissure.

3) OBJECTIVES -

- Compare anal pressure before and after each procedure
- Compare patients acceptance with botox over Lateral anal sphincterotomy
- Compare pain score
- Compare the time taken to return to normal activities
- Compare complication bt two techniques
- Compare overall cost benefit bt two procedures

4) MATERIALS AND METHODS

INCUSION CRITERIA -

- Age group of 15-65 yrs
- Symptomatic chronic anal fissure patients

EXCLUSION CRITERIA -

- Acute anal fissure
- patients with associated comorbid conditionss like fistula in ano,
- anal abscess, haemorrhoids, IBD, DM, HIV
- pt who has undergone anal surgical procedure previously
- Chronically debilitated pts like paraplegia, bedridden patients
- Pregnant patients

STUDY DESIGN - It is a prospective comparative study

STUDY AREA - Medical college Kolkata

STUDY PERIOD - 1st March 2009 to 31st August 2010

SAMPLE SIZE -

Total 100 patients were randomized into two groups, each groups comprise of 50 patients. One groups undergone chemical sphincterotomy by botulinum toxin injections and another group undergone lateral anal sphincterotomy.

METHOD OF DATA COLLECTION -

Patient attending SOPD with chronic anal fissure are examined clinically and included into the study according to inclusion and exclusion criteria. Inform consent taken from the patient after explaining about study and procedure to be performed. Willing patient was randomized into two groups, each group consist of 50 patients. One group was entitled for chemical sphincterotomy by botulinum toxin. Total 20 units of botulinum injection are injected into three region of anal sphincter. 7 units each for 3 'o' clock and 9 'o' clock positions and 6 units for anterior part. Another group was entitled for Lateral Sphincterotomy. Pre-Procedure Anal Manometry was performed in left lateral position by using precalibrated closed water filled micro balloon (2.5mm), nondistensible polyethylene tube (1.5mm), Pressure transducer. Patients were advised for follow up after 2 weeks, 6 weeks and 6 months. In each follow up patient were undergone anal manometry, detailed history regarding pain which was measured according to visual analogue scale, and incontinence, clinical examination of perianal region regarding ecchymosis, perianal hematoma, fistula, abscess, stenosis, recurrence

5) DATA ANALYSIS -

Two groups were compared in relation to the outcome of treatment using T test and Chi-Square test.

6) RESULT AND ANALYSIS -

Total 100 patients was included in this study and result of analysis are-

- Sex ratio - Among 100 patients 52 patients was male and 48 patients was female.
- Age distributions - Most patients are from 31 to 40 years age group.
- Comparison of symptoms in different follow-up visit -
 - Ecchymosis - Was more in botulinum toxin group in first follow up (30%), in comparison to lateral anal sphincterotomy (20%). But it was disappeared in subsequent follow up visit in both groups.
 - Perianal hematoma noted 10% of patients of Lateral

sphincterotomy groups and 4% in chemical sphincterotomy groups after 2 weeks. But it was disappeared in both groups in subsequent follow-up.

- Abscess formation noted in 10% of surgical sphincterotomy groups and 2% in case of Botulinum groups in first follow up, but disappeared in next two follow-up.
- Patients complained about similar pain 20% in case of chemical sphincterotomy groups and 30% in case of surgical sphincterotomy groups after 2 weeks. But it became 10% in case of chemical sphincterotomy and 20% in case of surgical sphincterotomy group. Similar pain disappeared in case chemical sphincterotomy group but it persists in 10% of surgical sphincterotomy group after 6 months.
- 98% of botulinum group patients was satisfied regarding complete relieved of pain but 84% in case of Lateral Sphincterotomy group after 6 months of procedures. ($p=0.036$)
- Incontinence – After 6 months no patients complaints about incontinence in botulinum toxin injection group, but 16 % patients complained about incontinence in lateral internal sphincterotomy group ($p=0.0360$).
- Recurrence – 2 % of botulinum toxin group came for follow-up with features of recurrence, but 15% of lateral sphincterotomy group patients came with features of recurrence.

d) Comparison of Anal pressure –

- Pre-operative anal pressure is high in case of chronic anal fissure compared to control (90 cm of H_2O).
- Postoperative resting anal pressure below or equal to control 22% in botulinum toxin group and 20% in Lateral anal sphincterotomy group.
- Maximum voluntary contraction pressure >170 cm of H_2O in both groups (control 140 – 160 cm of H_2O)

e) Comparison of duration of hospital stay and return to work –

- Average time of hospital stay 2 hours in case of botulinum toxin group and 48 hours in lateral anal sphincterotomy group.
- Average time to return in normal activity was 6 hours in botulinum toxin group, 120 hours in case of lateral anal sphincterotomy group.

TABLES AND FIGURES

FIGURE NO 1- Sex distribution

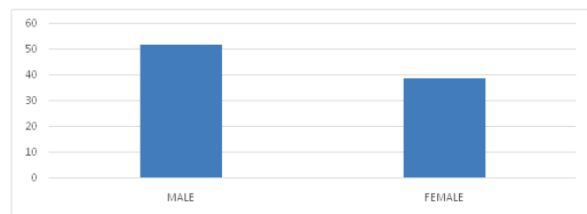


FIGURE NO 2 – Age distributions of patients

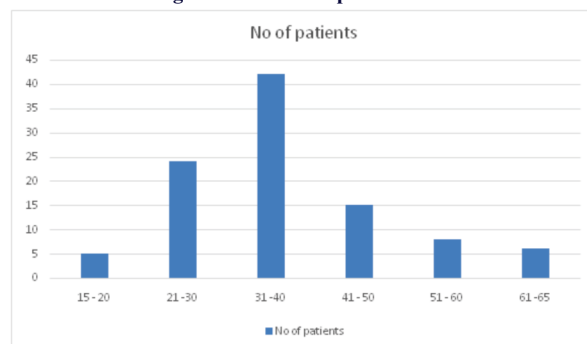


TABLE NO 1 – Comparison of symptoms in different follow up

Parameter	2 wees		6weeks		6months	
	BT	LS	BT	LS	BT	LS
Echymosis	30%	20%	0	0	0	0
PerianalHaematoma	4 %	10%	0	0	0	0
Abscess	2%	10%	0	0	0	0
Similar pain	20%	30%	10%	20%	0	10%
Improved pain	80%	75%	40%	75%	98%	90%
No pain	0	80%	50%	60%	98%	90%

Incontinence	10%	20%	0	15%	0	15%
Recurrence	0	0	0	0	2%	15%

BT- BOTULINUM TOXIN GROUP ; LS – LATERAL ANAL SPHINCTEROTOMY

TABLE NO 2 – Comparison of Anal pressure

PARAMETERS	2 WEEKS		6 WEEKS		6 MONTHS	
	BT	LS	BT	LS	BT	LS
RAP (CONTROL 90 CM OF H_2O)	100	98	90	88	88 (22%)	90(20%)
MVCP (CONTROL 140 -160 CM OF H_2O)	174	170	172	172	170	174

FIGURE NO 3-COMPARISON OF HOSPITAL STAY

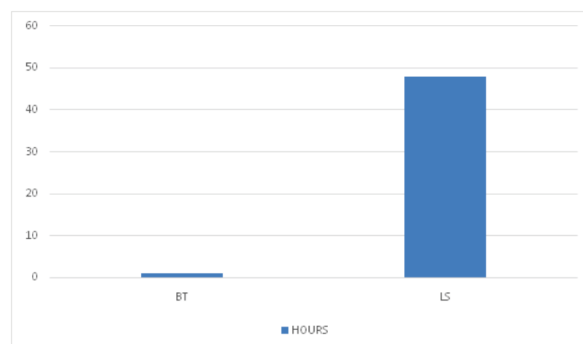
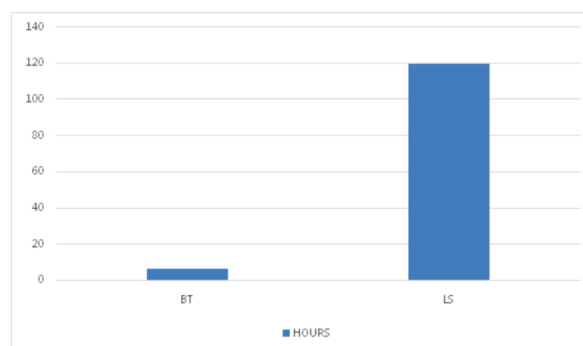


FIGURE NO 4 – COMPARISON OF DURATION TO RETURN NORMAL WORK



DISCUSSION

Our randomized prospective control study was carried out among 100 patients divided into two groups. Group 1 consist of 50 patients who were treated by infiltration of botulinum toxin into internal anal sphincter. Group 2 consisted of 50 patients who treated with lateral sphincterotomy.

In our study Most patients are from 31 to 40 years age group. A study conducted by Lock and Thompson in 1977 also found mean age of 38 years³.

The sex distribution of our study shows male female ratio 1.08. Similar study conducted by Macdonald et al (1983) has noted higher incidence in female⁴, 51 %.

In our study at 2 weeks, ecchymosis found 30% in BT group and 20 % in LS group. But after 6 weeks and 6 months of follow up no ecchymosis was found in both groups.

Similarly, perianal hematoma and abscess formation were not noted in both group after 6 months follow up. Some study shows abscess formation that is 13% in lateral sphincterotomy patient. JOST et al reported a single case of perianal thrombosis after BOTOX injection into external sphincter muscle⁵.

Healing of fissure indicate pain improvement or no pain and no recurrence. Our study shows after 6 months follow up healing in

BOTOX group was 98% and 84% healing rate in LS group. Study of Saudi medical journal 2008 shows about 100 patients the healing rate was 100% in surgical (LS) group with no recurrence in the period of 3 years follow up. while in chemical group the healing rate was 86% with 40 IU Botox⁶ ($p=0.006$).

By reducing the sphincter hypertonia, lateral internal sphincterotomy improves the perfusion of the distal anal mucosa and leads to healing of the chronic anal fissure in 90 – 95% of cases^{7,8}. in spite of high healing rate, internal anal sphincterotomy has drawbacks, like incontinence, complication related to wound healing, and anaesthesia related complications.

In a study patient underwent lateral sphincterotomy has shown that incontinence to flatus can reach up to 35%. In another study, endo anal ultrasound has demonstrated extensive sphincter defects in patients underwent sphincterotomy⁹.

BOTOX has a direct analgesic effect causing relief before the healing of the fissure.

BOTOX injection (20 IU) is suitable for treatment of chronic idiopathic anal fissure. BOTOX injection is a simple procedure, easy to learn, and can be done in the outpatient clinic without the need for sedation or local anaesthesia. It is cost effective and leads to healing of the fissure avoiding surgery with potential risk of incontinence.

Another study conducted by G Brisinda et al shows at 2 months follow up, 59 patients (74%) had a healing scar and anorectal manometry at 1 month demonstrated a significant reduction in both resting anal pressure and maximum voluntary squeeze pressure ($p < 0.001$). There was no relapse during a mean value of 57.9 months of follow up¹⁰.

Our study shows at 2 weeks 10% (5/50) cases of incontinence to flatus was found in BOTOX group and 20% (10/50) cases of incontinence to flatus was noted in lateral sphincterotomy group but after 6 months follow up no incontinence in BOTOX group but in 15 % (7/50) cases shows incontinence to flatus ($p = .0187$). Radwan et al reported 2 patients with temporary faecal soiling after BOTOX injection into internal sphincter¹⁰.

Our study shows duration of hospital stay 1 hour in case of BOTOX group and 48 hours in case of lateral sphincterotomy group. Return to normal activity occurred within 6 hours in case of BOTOX group and within 5 days in case of lateral sphincterotomy group. So local infiltration of Botulinum toxin (single 20 IU) into internal sphincter is more cost effective than lateral internal sphincterotomy.

CONCLUSION –

Local infiltration of Botulinum toxin into internal sphincter is an effective, less expensive, easier to perform treatment modality indicated particularly in patients at risk of incontinence, recurrence after surgery and when surgery is contraindicated.

Local infiltration of botulinum toxin into internal sphincter (single dose 20 IU) is as good as first line treatment option in cases of chronic anal fissure.

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