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STUDY THE EFFICACY OF INTRASPHINCTERIC BOTOX INJECTION AND COMPARISON WITH SURGICAL SPHINCTEROTOMY IN CHRONIC ANAL FISSURE.

General Surgery

Dr. Shambhunath Agrawal* Resident, Department of Laparoscopic and General Surgery, Artemis Heath Institute, Gurugram, Haryana, India. *Corresponding Author

Dr. Paritosh Gupta Senior Consultant, Department of Laparoscopic and General Surgery, Artemis Heath Institute, Gurugram, Haryana, India.

Dr. T. K. Thusoo Head of Department, Department of Laparoscopic and General Surgery, Artemis Heath Institute, Gurugram, Haryana, India.

Dr Mayank Manjul Madan Consultant, Department of Laparoscopic and General Surgery, Artemis Heath Institute, Gurugram, Haryana, India.

Dr. Hari S. Mahobia Senior Resident, Department of General Surgery, All India Institute of Medical Science, Raipur (CG), India.

ABSTRACT

Background: Fissure in ano or anal fissure (as it is commonly known as) is a troublesome and painful anal condition that affects a great majority of the population in the world.. The present study comprises the comparative study of intrasphincteric Botox injection and Lateral anal sphincterotomy in the management of chronic fissure in ano

Aim To compare efficacy and complications of intrasphincteric Botox injection and Lateral anal sphincterotomy in management of chronic fissure in ano.

Methodology: All patients attended Surgical OPD or Emergency department with chronic anal fissure were enrolled. After diagnosis patients were explained about the type, method and possible complication of both procedures. If patient opt for any of the procedure than lottery was withdrawn. If patient opt for either of the procedure than that particular procedure was done. After complete evaluation and follow up, two groups were compared with student t test. For pain visual analogue score was used.

Results: Patients treated with intrasphincteric Botox injection in all patients i.e. 100% fissure healed completely within 4 weeks of time. The mean duration of healing was 1.7 weeks and 100% of patients were free from pain after 4 weeks. The mean time for pain relief was 1.5 weeks. In Lateral anal sphincterotomy group, fissure healed in all patients i.e. 100% within 8weeks. Mean duration required for healing was 1.7 weeks and 100 % pateints were pain free by 8 weeks. The mean duration for pain relief was 1.8 weeks.

Conclusion: Botox injection is suitable for treatment of chronic idiopathic anal fissure associated with anal sphincter tone. Botulinum toxin injection is a simple procedure, easy to learn. Surgery should be offered to patients who do not improve with Botulinum toxin injection and to those with complicated anal fissure.

KEYWORDS

Chronic fissure in ano, Lateral anal sphincterotomy, Botulinum toxin injection

INTRODUCTION

Fissure in ano or anal fissure (as it is commonly known as) is a troublesome and painful anal condition that affects a great majority of the population in the world.

An anal fissure is a longitudinal tear or ulcerated area in the distal anal canal starting from anal verge and extending proximally. An acute anal fissure has the appearance of a clean longitudinal tear in the anoderm, with little surrounding inflammation. It is quite clear and much is known about the various predisposing factors and contributing factors that lead to initiation and progression of disease. Commonest site is posterior midline, but can also be seen in anterior midline. Anal fissure affects all age groups, particularly young adults.

A chronic fissure 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 with an irritated skin or sentinel pile at its distal aspect.

Painful fissures are generally associated with spasm of the internal sphincter. The internal sphincter is an involuntary muscle, a continuation of the circular muscle layer of the colon and rectum. Its natural resting tone, along with that of external sphincter complex, maintains continence. Like the involuntary muscle of colon and rectum, the internal sphincter possesses the ability to go into spasm involuntarily. It is this involuntary spasm, in response to trauma of the exposed subcutaneous issue of the fissure that creates the severe pain associated with anal fissure disease.

There has been a lot of progress in the understanding of the anatomy of the anal canal and the mechanism of continence of rectum and anal canal. This has enabled the surgeon to deal with the fissure, keeping the spastic anorectal ring intact, without interfering with continence and eradicating the disease.

Surgical techniques like manual dilatation or lateral internal sphincterotomy, effectively heal most fissures within a few weeks, but may result in permanently impaired anal continence. This has led to the research for alternative non-surgical treatment, and various pharmacological agents have been shown to lower resting anal tone and heal fissures without threatening anal continence.[1]

The present study comprises the comparative study of intrasphincteric Botox injection and Lateral anal sphincterotomy in the management of chronic fissure in ano.

AIMS

Compare efficacy and complications of intrasphincteric Botox injection and Lateral anal sphincterotomy in management of chronic fissure in ano.

METHODOLOGY

The patients were randomly divided into two groups of 25 patients each, depending upon whether they treated with intrasphincteric Botox injection or were submitted to lateral sphincterotomy group respectively.

All patients attended Surgical OPD or Emergency department with anal pain with or without bleeding were examined to confirm the diagnosis of chronic anal fissure on the basis of following finding

- Anal pain > 4 weeks.
- Pain aggravated on defecation.
- Per rectal examination showing posterior and/or anterior anal fissure. The chronicity of which may suggested by
- Mild indurated margins
- Whitish floor of the fissure
- With/without sentinel pileWith mild to moderate anal spasm

After diagnosis patients were explained about the type, method and possible complication of both procedures. If patient opt for any of the procedure than lottery was withdrawn. If patient opt for either of the procedure than that particular procedure was done. After complete evaluation and follow up, two groups were compared with student t test. For pain visual analogue score was used.

EXCLUSION CRITERIA

1. Children and mentally handicapped patients
2. Fissures with hemorrhoids and fistula
3. Fissure associated with local malignancies
4. Fissure secondary to specific diseases such as Tuberculosis, Crohn's disease etc.
6. Pregnant women

Method of Intrasphincteric Botox Injection

Technique

Patients were prepared preoperatively, and shifted to OT. Placed in lithotomy position. Intrasphincteric BOTOX injection was given in Internal sphincter under General Anesthesia (GA) using Laryngeal mask airway (LMA) or under Spinal Anesthesia (SA). Sphincter was identified or palpated at the anal verge between two fingers. Most of the time internal sphincter was hypertrophied. Total 40 unit of Botox was given, 20 units at 6 o clock and 10 units each at 3 and 9 o clocks positon. If patient having sentinel tag that was excised. Hemostasis achieved and small anal pack placed for 1 hr.

BOTOX available as freeze dried form in 50/100 units vial. 50 unit vial was taken and mixed with 5ml of saline. Each ml contains 10units of Botox. Botox solution taken in insulin syringe and injected at all 3 sites as directed above.

Post operatively patient kept NPO for 2 hrs. Anal pack removed after 1 hr. Patients were discharged on same day or next day. Patients were advised for sitz bath and Lox ointment for next 1 week and stool softener for 15days. Then patients were followed up for 6 month.

Method of Lateral anal sphincterotomy

Patients were prepared preoperatively, and shifted to OT. Placed in lithotomy position. Under general anesthesia (GA) or spinal anesthesia (SA) the distal internal sphincter was palpated with a bivalved speculum at the intersphincteric groove. Small longitudinal incision was made over this and the sub mucosal and intersphincteric planes were carefully developed to allow precise division of the internal sphincter with a knife or a scissor on lateral side i.e. at 3 or 9 o clock. Pressure was applied to the wound for a few minutes to avoid hematoma formation. The wound was then closed with a single absorbable suture. If patient having sentinel tag that was excised. Hemostasis achieved and small anal pack placed.

Post operatively patient kept NPO for 2 hrs. Anal pack removed after 12hrs. Patients were discharged on next day. Patients were advised for sitz bath and Lox ointment for next 1 week and stool softener for 15days. Then patients were followed up for 6 month.

RESULTS

Age incidence

In our study 21 patients out of 50 belonged to age group 30-39yrs (42%), 10 patients between the age group 50-59yrs (20%), 7 (14%) in the age group 40-49yrs and 20-29yrs each and 5 patients were more than 60yrs of age (10%).

Table-1- Age incidence

Age	N. of patient	Percentage
20-29yrs	7	14
30-39yrs	21	42
40-49yrs	7	14
50-59yrs	10	20
60-69yrs	3	6
70-79yrs	2	4

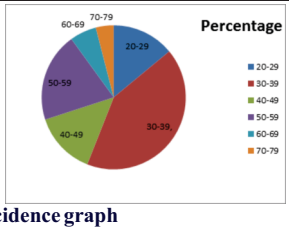

Figure – 1 Age incidence graph

Sex Incidence

In our study out of 50 patients, 28 (56%) patients were males and 22 (44%) patients were females. Male - female ratio being 1.2:1.

Table-2- Sex incidence

Sex	N. Of patient	Percentage
Male	28	56
Female	22	44

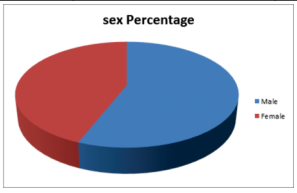

Figure –2 Sex incidence graph

Site of Fissure

In our study of 50 cases, anterior fissure was seen in 6 patients (12%) and posterior fissure in 42 (84%) patients and 2 patients were having fissure at both sites i.e. anterior and posterior.

Table-3- Site incidence

Site	N. Of patient	Percentage
Anterior	6	12
Posterior	42	84
Both site	2	4

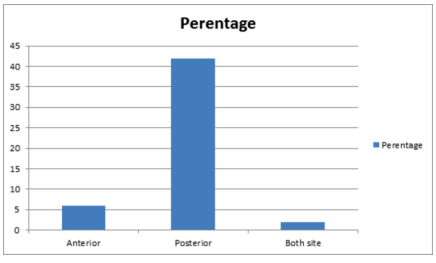

Figure – 3 Site of fissure

Duration for healing and postoperative follow-up

A. Intrasphincteric Botox Injection group

Out of 25 patients underwent treatment with Intrasphincteric Botox Injection fissure healed in 100% of patients completely within 4 weeks.

B. Internal Sphincterotomy Group

Out of 25 patients who underwent internal sphincterotomy, fissure healed in all patients (100%) completely within 8 weeks and healing was complete in 24 out of 25 patients by the end of 4 weeks.

Follow-up

1. Pain Relief and Healing

A. Intrasphincteric Botox Injection group
All patients whose fissures had healed were free from pain at the end of 4weeks. Mean duration for pain relief was 1.5 week and that for healing was 1.7 weeks

B. Internal Sphincterotomy Group
Out of 25 patients 24 (96%) patients whose fissures had healed were free from pain at the end of 4weeks. And healing and pain relief was seen in all patients by the end of 8weeks. Mean duration for pain relief was 1.8weeks and that for healing was 1.7 weeks.

Table-4- fissure healing and pain relief

Types of procedure	Completely healed at 4 weeks	Percentage	Completely pain relieved at 4 weeks	Percentage
LAS	24	96	24	96
Botox injection	25	100	25	100

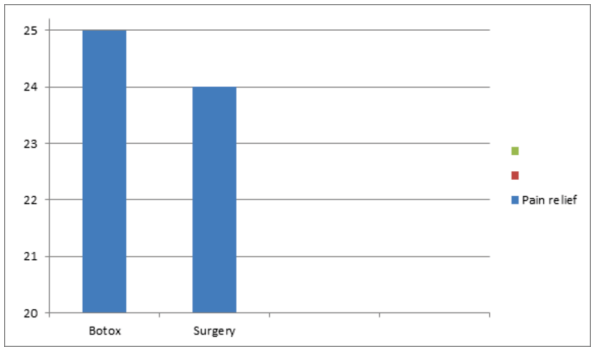

Figure –4 Pain relief by 4 weeks

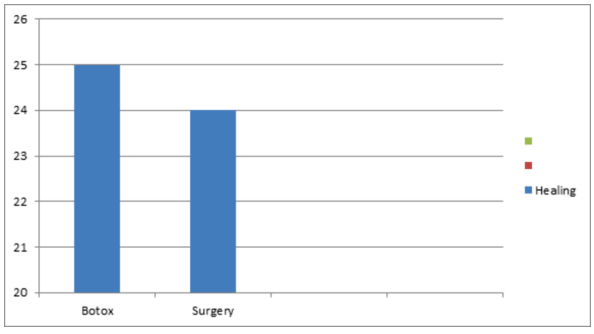

Figure – 5 Healing by 4 weeks

Complications

A. Intrasphincteric Botox injection group
Out of 25 patient 1 patient had developed incontinence to flatus which was reversed by 4weeks time. And 1 patient shows inflammation at the injection site which was improved in next 7days. No recurrence was seen in patients treated with intrasphincteric Botox Injection in 6 month follow up.

B. Internal Sphincterotomy Group
No complications and recurrence were reported after follow up of patients for 6 month.

DISCUSSION

Anal fissure is a very common problem across the world. It causes considerable morbidity and adversely affects the quality of life. Therefore appropriate treatment is mandatory.

The simplest and most effective way of reducing internal anal sphincter tone is surgery. Lateral anal sphincterotomy is the gold standard in the treatment of chronic anal fissures. It involves partial division of the internal anal sphincter away from the fissure. Calcium channel blockers have been shown to lower resting anal tone and promote fissure healing. Intrasphincteric Botox Injection has been shown to decrease resting anal tone without cutting anal sphincter with complete cure and so chemical sphincterotomy is now the first line of treatment in many centers.

The study has shown that Lateral Anal Sphincterotomy (LAS) and intrasphincteric Botox injection treatment modalities had similar effects in healing rates and no recurrence in long-term follow-up. We can suggest that LAS and Botox injection treatment were equally effective in the treatment of chronic anal fissure patients.

In this study the commonest age group only with fissure in ano affected were 30-39 years of age (42%) and least affected were more than 60 years of age (10%). According to J.C. Goligher[2] the disease is usually encountered in young or middle aged adults. In Udwadia T.E.[3] series maximum incidence was seen in 31-40 years of age group. The incidence of fissure in males was slightly greater than females. Male-female ratio being 1.2: 1. It is confirmed with study from Bennett and Goligher[2] which says anal fissure is equally common in the two sexes. In our study incidence of fissure is slightly higher than female.

In this study posterior midline fissure (84%) was more common than anterior midline fissure (12%). It has been observed that posterior fissure is more common in both sexes, although anterior fissure is common in females comparatively. Both anterior and posterior fissures are common in female sex. This was confirmed by study from Boulous P.B. and Araujo J.G.C.[4] which says posterior fissure (85.7%) is more common than anterior fissure (14.2%).

Patients treated with Intrasphincteric Botox Injection were injected Botulinum injection in internal sphincter in operating room under GA/Spinal anesthesia. Out of 25 patients treated with intrasphincteric Botox injection in all patients i.e. 100% fissure healed completely within 4 weeks of time. The mean duration of healing was 1.7 weeks. In our study 100% of patients were free from pain after 4 weeks in intrasphincteric Botox injection group. The mean time for pain relief was 1.5 weeks. Out of 25 patients treated with intrasphincteric Botox injection, 1 patient had developed incontinence to flatus which was temporary and reversed by 4weeks time. And 1 patient showed inflammation at the injection site which was resolved within one week. Patients in Lateral anal sphincterotomy group underwent surgery under spinal Anaesthesia or general anesthesia. Post operative hospital stay was between 1-2 days. In Lateral anal sphincterotomy group, fissure healed in all patients i.e. 100% within 8weeks. Mean duration required for healing was 1.7 weeks. All patients after Lateral anal sphincterotomy were pain free by 8 weeks. The mean duration for pain relief was 1.8 weeks. Out of 25 patient 24 were pain free within 4 weeks. Similarly healing was complete in 24, out of 25patients within 4 weeks of time. No complication was noted in any of the patients treated with Lateral anal sphincterotomy.

On comparison of both the group treated with Intrasphincteric Botox Injection and Lateral Anal sphincterotomy, Fissure healing was 100 %. And mean duration of healing was 1.7 for both the group. Study conducted by Adnan Giral et.al.[5] showed that fissures were healed in 70 percent of patients in the Intrasphincteric Botox injection group and 82 percent in the Lateral anal sphincterotomy group. In both the group pain relief was 100%. But mean duration for pain relief was 1.5 weeks for Intrasphincteric Botox Injection group and 1.8 weeks for Lateral Anal Sphincterotomy group. Scouten W.R. et. al.[6] reported pain relief in 98% of cases after undergoing internal sphincterotomy. Adriano Tocchhiet al. (2004) reported a healing rate of 100% with internal sphincterotomy at the end of 6 weeks of post-sphincterotomy. Our study has shown minimum side effect in patients treated with Intrasphincteric Botox Injection and no complications were reported in patients underwent Lateral anal sphincterotomy after follow up for 6 month. Adriano Tocchhi et al.[7] report no long-term complication after Lateral anal sphincterotomy. Patient satisfaction was 96%.

Intrasphincteric Botox injection was given to a patient with diagnosed CML, in whom surgery was contraindicated due to persistent thrombocytopenia. Patient was on chemotherapy and was complaining of fissure in ano for last 1 month. Conservative treatment was given, but he did not improve. After Intrasphincteric Botox injection patient was free of pain in 2 days post injection and fissure healed in 1 week of time. Post injection no complication was seen. Thus Intrasphincteric Botox injection can be the first choice of treatment in patients with coagulopathy, thrombocytopenia, or cardiac patient on blood thinning agents.

Comparison between Intrasphincteric Botox injection and Lateral anal sphincterotomy did not show any statistically significant difference in pain relief (P value = 0.1761) or fissure healing (P value = 0.5000).

CONCLUSION

The conclusion from this study is though internal sphincterotomy is the current standard treatment; intrasphincteric Botox injection can also be the 1st choice in the treatment for chronic anal fissure. Side effects of intrasphincteric Botox injection are minimal and which are reversible. In contrast with surgery, chemical sphincterotomy with intrasphincteric Botox is unlikely to damage the sphincter. In patients where bleeding tendency is high such as patients with thrombocytopenia, patients in coagulopathy, or cardiac patients on blood thinning agents, Intrasphincteric Botox injection can be the 1st choice of treatment, which can avoid bleeding complications of surgery. Botox injection may become the treatment of choice though Botox injection itself is costly, yet it needs to be seen if it can be given under local anesthesia as OPD procedure to offset the cost of admission and proper regional or general anesthesia. If so it may become to be both cost-effective and efficient in the treatment of chronic anal fissure. It also can be the treatment of choice in patients who are unwilling for surgery.

Botox injection is suitable for treatment of chronic idiopathic anal fissure associated with anal sphincter tone and not associated or complicated by other anal diseases which require surgical treatment such as fistula in ano or hemorrhoids. BTX injection is a simple procedure, easy to learn. Surgery should be offered to patients who do not improve with Botulinum toxin injection and to those with complicated anal fissure.

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