A COMPARATIVE STUDY OF TOPICAL 2% DILTIAZEM WITH LATERAL SPHINCTEROTOMY IN THE TREATMENT OF CHRONIC FISSURE IN-ANO

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ABSTRACT

Anal fissure also known as Fissure in-ano is a common anorectal condition. It can be a very distressing condition if acute. The severity of patient discomfort and extent of disability far exceed that which would be expected from a lesion which seems to be trivial. Anal fissure or Fissure in-ano is considered as one of the most common causes of severe pain in the anal canal. 52 patients were broadly divided into two groups with 26 patients in each group who were managed by medical or surgical treatment.

RESULTS

The average age of patients was around 36-40 years. On an average, surgical group patients had to spend around 13038 rupees for surgery while medical group patients had to spend around 11135 rupees. There was a statistically significant difference among medical group patients and surgical group patients with respect to the duration to return to work after surgery/treatment. No difference was noticed in the cost for treatment/surgery among the groups (P>0.05).

KEY WORDS: anal fissure, anoderm, sphincterotomy


INTRODUCTION

Anal fissure also known as Fissure in-ano is a common anorectal condition. It can be a very distressing condition if acute. The severity of patient discomfort and extent of disability far exceed that which would be expected from a
lesion which seems to be trivial. Anal fissure or Fissure in-ano is considered as one of the most common causes of severe pain in the anal canal. Fissure generally occurs in the posterior or anterior midline and can extend anywhere from the level of dentate line to the anal verge. An acute anal fissure has the appearance of a clean longitudinal tear in the anoderm. A chronic fissure is generally deeper and is frequently associated with a hypertrophic anal papilla at its upper aspect and with a skin tag at its distal aspect. It affects 1 in 10 people.

An anal fissure is a linear ulcer of the lower half of the anal canal, usually located in the posterior commissure in the midline. Often misnamed as rectal fissures, in fact, these lesions truly involve just the anal tissues and are typically best seen by visually inspecting the anal verge with gentle separation of the gluteal cleft. Location may vary, and an anterior midline fissure is seen more often in women, although most fissures in women and men reside in the posterior midline. Characteristic associated findings include a sentinel pile or tag externally and an enlarged anal papilla internally. Fissures away from these two locations should raise the possibility of associated diseases especially Crohn's disease, Hidradenitis suppurativa or Sexually Transmitted Diseases. Because it involves the highly sensitive squamous epithelium, fissure in-ano is often a painful condition. With defecation, the ulcer is stretched, causing pain and mild bleeding.

Persistent Hypertonia of the anal sphincter is thought to be the most probable cause. Fissure in-ano is a painful condition which is generally associated with spasm of the internal sphincter. The internal sphincter which is a continuation of the circular muscle layer of the colon and rectum is an involuntary muscle. Its natural resting tone, along with that of external sphincter maintains continence. It is the involuntary spasm which causes the severe pain associated with fissure in-ano. The treatment options target at relieving the spasm of the internal anal sphincter with surgical or chemical methods.

Different modes of treatment exist in the treatment of Fissure in-ano though it is an old entity. Surgical techniques such as Lateral Sphincterotomy effectively heal most fissures within a few weeks but may result in permanent anal incontinence. Hence alternative non-surgical treatment and various pharmacological agents have been adopted to lower the resting anal pressure and heal fissures without causing anal incontinence (1).

A fissure in ano is a tear in the anoderm distal to the dentate line. Anal fissure is a linear ulcer or a tear in the squamous epithelium of the anal canal that may extend from the mucocutaneous junction to the Dentate line. It can be acute or chronic. It may occur at any age though usually a condition of young adults. Both sexes are affected equally.
The pathophysiology of anal fissure is thought to be related to trauma from either the passage of hard stool or prolonged diarrhea. A tear in the anoderm causes spasm of the internal anal sphincter, which results in pain, increased tearing, and decreased blood supply to the anoderm. This cycle of pain, spasm, and ischemia contributes to development of a poorly healing wound that becomes a chronic fissure. The vast majority of anal fissures occur in the posterior midline. Ten to 15% occur in the anterior midline. Less than 1% of fissures occur off midline.

METHODOLOGY

Patients admitted in Department of General Surgery and patients presenting to the Out-Patient Department of General Surgery in Chettinad Hospital and Research Institute, Kelambakkam, Tamil Nadu with symptoms of chronic fissure in-ano over a period of 1 year from February 2019.

Methods of Collection of Data: Patients with symptoms of chronic fissure in-ano i.e. more than 6 weeks have been taken up for comparative study on randomized trial. History of the patients was noted. Clinical examination was done to confirm chronic fissure in ano.

MATERIALS AND METHODS

The study was based on an analysis of 52 patients with chronic fissure in-ano who underwent treatment in Chettinad Hospital and Research Institute, Kelambakkam. These patients were broadly divided into two groups with 26 patients in each group who were managed by medical or surgical treatment. Clinical examination and routine investigations were done for all patients which included Chest X-ray and ECG.

 Patients who were advised medical treatment was put on topical 2% Diltiazem. Informed consent was taken prior to the study. Patients were instructed to apply 1.5 to 2cm length of gel twice a day for at least 1.5cm into the anus. Patients were advised to wash their hands before and after the use of gel. Patients were also advised high fibre diet, adequate hydration. These patients were advised sit bath thrice a day. These patients were followed up at the end of 2 weeks, 6 weeks and 12 weeks.

 Patients who had been advised surgical management were treated by lateral anal sphincterotomy. Post-operatively these patients were advised high fibre diet, adequate hydration, Sit bath twice daily, syrup Cremaffin 15ml at bedtime. These patients were followed up at the end of 2 weeks, 6 weeks and 12 weeks.

At each visit, patients were evaluated based on

1. Pain relief

2. Bleeding per rectum

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3. Healing of fissure

4. Duration to return to work.

**Internal Sphincterotomy**

Under spinal anaesthesia, Internal Sphincterotomy was carried out with patient in Lithotomy position. Post-operatively on the day of surgery, patients were kept nil per oral till evening followed by liquid diet. Intravenous fluids were administered. Adequate analgesia was given. Antibiotics were given for one week. High fibre diet was advised from post-operative day 1. All patients were advised three teaspoons of syrup Cremaffin (milk of magnesia 11.25 ml, liquid paraffin 3.75 ml, per 15 ml of emulsion) at bedtime from post-operative day 1 onwards. Warm Sitz bath was started from post-operative day 1. Digital examination was done to assess the relaxation of sphincter. Patients were followed up at the end of 2 weeks, 6 weeks and 12 weeks.

**RESULTS**

Patients’ data was entered in MS-Excel and then it was imported in STATA software to analyze. Descriptive statistics was calculated to nominal data. Inferential statistics like Chi-square test, Fisher’s exact test, Mann-Whitney U test and independent sample t-test were used in the data analysis. Chi-square test / Fisher’s exact test is used to find the difference between two group proportions. Mann-Whitney U test is used to compare two groups data on the basis of mean rank value. Independent sample t- test is used to compare two groups data on the basis of average value. 5% level of significance is considered statistically significant.

From the findings of results, it was concluded that male-female ratio was similar in medical group and surgical group. The average age of patients was around 36-40 years. On an average, surgical group patients had to spend around 13038 rupees for surgery while medical group patients had to spend around 11135 rupees. There was a statistically significant difference among medical group patients and surgical group patients with respect to the duration to return to work after surgery/treatment. No difference was noticed in the cost for treatment/surgery among the groups (P>0.05). The majority of the medical group patients and surgical group patients did not experience bleeding per rectum after two weeks follow-up. There was a significant difference in the healing state between medical group patients and surgical group patients after two weeks follow-up. The majority of the surgical group patients did not experience pain while the majority of the medical group patients experienced severe pain after two weeks follow-up. The majority of the surgical group patients (n=23) completely healed after six weeks follow-up while only 10 medical group patients were completely healed. Around 84% of the surgical group patients did not
experience pain after six weeks follow up while only 42% of the medical group patients did not experience pain. The majority of the medical group patients and surgical group patients completed healed and did not experience pain after twelve weeks follow-up.

**DISCUSSION**

Fissure in-ano is a very common ailment across the world. It causes considerable morbidity and adversely affects the quality of life. Hence apt treatment is compulsory.

Surgery is the most effective modality of reducing the spasm of the internal anal sphincter. Lateral Sphincterotomy is the gold standard in the treatment of chronic anal fissure. It involves partial division of the internal anal sphincter away from the fissure.

Diltiazem which is a Calcium channel blocker have been shown to lower resting anal pressure and promote fissure healing. In many centres, Chemical Sphincterotomy is currently considered as the first line of treatment.\(^{2,3,4}\)

The present study was done to compare the efficacy of topical 2% Diltiazem gel and Lateral Sphincterotomy in the treatment of Chronic Fissure in-Ano. To compare the efficacy, patients were evaluated based on:-

1. Symptomatic relief (pain relief and bleeding per rectum)
2. Healing of fissure
3. Length of hospital stay
4. Duration to return to work
5. Cost factor / expenditure .The study was based on an analysis of 52 patients with chronic fissure in- ano who underwent treatment in Chettinad Hospital and Research Institute, Kelambakkam. These patients were broadly divided into two groups with 26 patients in each group who were managed by medical or surgical treatment. Patients with symptoms of chronic fissure in-ano i.e. more than 6 weeks have been taken up for comparative study on randomized trial.

In this study, there were 25 male patients and 27 female patients from both groups. The mean age of the patients in the medical group were 36.08 and 39.88 years in the surgical group respectively.

According to J.C. Goligher\(^{(5)}\) in 1984, the disease is generally prevalent in young or middle-aged adults. In Udwadia T.E.35 series maximum incidence was seen in 31-40 years age group. In my study, there was no significant difference in male-female ratio among medical group and surgical group. It is confirmed from a study done by Bennett and Goligher\(^{(5)}\) in 1962 which said anal fissure is common in both sexes equally.
In this study it was observed that the majority of the subjects (75%) had a posterior anal fissure while 25% had an anterior anal fissure. It has been observed that posterior fissure is more common in both sexes, although anterior fissure is common in females comparatively. This was confirmed from a study done by Boulous P.B. and Araujo J.G.C.\(^{(6)}\) in 1984 which said posterior fissure (85.7%) is more common than anterior fissure (14.2%).

Patients in the medical group using Diltiazem gel underwent domiciliary treatment and were followed up at the end of 2 weeks, 6 weeks and 12 weeks.

There was a significant difference in the healing state between medical group patients and surgical group patients at the end of 2nd week. There was a significant difference in the healing state between medical group patients and surgical group patients after six weeks follow-up with fissure healing only in 10 out of the 26 patients. Of the 26 patients undergoing treatment with Diltiazem gel, fissure had completely healed in 23 patients at the end of 12 weeks.

In the Lateral Sphincterotomy group, fissure completely healed in 16 out of 26 patients at the end of 2nd week, 23 out of 26 patients at the end of 6 weeks and in all 26 patients at the end of 12 weeks. There was a significant difference in the healing state between medical group patients and surgical group patients after six weeks follow-up with fissure healing only in 10 out of the 26 patients. However there was no difference in the healing state among both the groups after twelve weeks follow-up.

Study conducted by J. S. Knight\(^{(2)}\) et al. in 2001 reported a healing rate of 75% after 8-12 weeks treatment with Diltiazem gel. U. K. Shrivastava\(^{(7)}\) in 2007 reported a healing rate of 80% with Diltiazem gel in 12 weeks.

The healing rates with Surgical method was constantly high (>95%) in all the above trials including the present study which was 100%. In this study, 7 out of 26 patients in the medical group were pain free at the end of 2 weeks. 11 out of 26 patients in the medical group were free from pain at the end of 6 weeks and 22 out of the 26 patients had no pain on follow up after 12 weeks.

In this study, 16 out of 26 patients in the surgical group did not have experience pain at the end of 2 weeks. 22 out of 26 patients in the surgical group were free from pain at the end of 6 weeks and none of the 26 patients had pain on follow up after 12 weeks.

Medical group patients and surgical group patients experienced different level of pain after two weeks follow-up. It clearly depicted that the majority of the surgical group patients did not experience pain while the majority of the medical group patients experienced severe pain after two weeks follow-up. 84% of the surgical group patients did
not experience pain after six weeks follow-up while only 42% of the medical group patients did not experience pain. There was no difference in the level of pain among medical group patients and surgical group patients after twelve weeks follow-up.

Scouten W.R. et al.\(^\text{8}\) reported pain relief in 98% of cases after undergoing Lateral Sphincterotomy. Adriano Tocchhi et al.\(^\text{9}\) in 2004 reported a healing rate of 100% with internal sphincterotomy at the end of 6 weeks post Sphincterotomy review. Pain and bleeding per rectum are the most common presentations of chronic fissure in-ano. Pain relief, bleeding per rectum, and healing of fissure are faster with LIS compared to topical 2% Diltiazem ointment. Surgical treatment with LIS has an upper hand over topical 2% Diltiazem gel in the management of chronic fissure inano.

The inference drawn from these observations is that:-

- Though Chemical Sphincterotomy takes a longer time to heal, it can be advised as the initial treatment as there was no significant difference between the two groups at the end of 12 weeks
- By using topical 2% Diltiazem, it takes 12 weeks to be pain-free for majority of the patients belonging to the Medical group. Hence it can be advised as the initial treatment as there was no significant difference between the two groups at the end of 12 weeks
- Comparing pain relief in both the groups at 2 weeks and 6 weeks follow up, definitely surgery is a better modality. Since 85% of the medical group patients had relief from pain completely at the end of 12 weeks, topical 2% Diltiazem application can be advised to the patient who present with pain as the chief complaint.
- Based on 2nd week and 6th week follow up of patients who had bleeding per rectum as the main complaint, topical 2% Diltiazem can be advised as the initial treatment.
- With respect to duration to return to work after treatment, Surgery is considered as the gold standard treatment for Chronic Fissure in-Ano

CONCLUSION

In conclusion, though healing of fissure is comparatively slower with topical 2% Diltiazem gel therapy, patients can be avoided from the trauma of surgery and they can take treatment at home. Therefore, topical 2% Diltiazem gel therapy should be advocated as the first line of treatment and surgery should be reserved for patients with relapse and therapeutic failure of prior pharmacological treatment.

The conclusion from this study is that though Lateral Internal Sphincterotomy is the gold standard treatment at present for Chronic Fissure in-ano; most of the chronic fissures heal with topical 2% Diltiazem therapy. Complications or side effects of Diltiazem gel are minimal. In contrast to surgery, Chemical Sphincterotomy with Diltiazem is reversible and therefore unlikely to have adverse effects on fecal continence. Patients who are hypertensive, diabetic and medically unfit for surgery can be recommended with Diltiazem. Though fissure healing rate is comparatively slower with Diltiazem, patients can be avoided from the trauma caused by surgery. Hospital stay is not required too.

Considering all these parameters it could be recommended that Topical 2% Diltiazem gel is the best available alternative for surgical method in the treatment of chronic fissure in-ano and Lateral Sphincterotomy can be reserved for nonresponders alone. Topical 2% Diltiazem should be advocated as the first option of treatment for chronic anal fissure. Lateral Internal sphincterotomy should be offered to patients with relapse and therapeutic failure of prior pharmacological treatment.

The study was based on an analysis of 52 patients with Chronic Fissure in-ano who underwent treatment in Chettinad Hospital and Research Institute, Kelambakkam. These patients were broadly divided into two groups with 26 patients in each group who were managed by medical or surgical treatment.

- Diagnosis was made on the basis of thorough history and clinical examination.
- The commonest age group affected was 31-40 years age group (18 cases) and least affected was 51-60 years age group (4 cases). The average age of patients was around 36-40 years.
- The incidence of male-female ratio was similar in medical group and surgical group.
- Posterior midline fissure (39 cases) was more common than anterior midline fissure (13 cases). Majority of the subjects (75%) had a posterior anal fissure while 25% had an anterior anal fissure.
- Majority of the patients presented with pain during defecation.
- The length of hospital stay was 8.54 +/- 4.8 days for the surgical group.
- The majority of the medical group patients and surgical group patients did not experience bleeding per rectum after two weeks follow-up.
- In Diltiazem gel group, 22 out of 26 patients were free from pain and 4 had pain after follow-up for 12 weeks.
• In Lateral Internal Sphincterotomy group, 22 out of 26 patients were free from pain at the end of 6 weeks and all 26 patients were pain-free at the end of 12 weeks. 79

• The majority of the medical group and surgical group patients completely healed and did not experience pain after twelve weeks follow-up. (p-value : 0.235)

• The average duration to return to work after treatment was high (17 days) in medical group patients whereas the duration to return to work after surgery was very less (5 days) in surgical group. There was a statistically significant difference among medical group patients and surgical group patients with respect to the duration to return to work after surgery/treatment.

• On an average, surgical group patients had to spend around 13038 rupees for surgery while medical group patients had to spend around 11135 rupees. No difference was noticed in the cost for treatment/surgery among the groups(p>0.05)

REFERENCES


