Comparative Study of Lateral Sphincterotomy and Local Application of 2% Diltiazem Gel in Treatment of Chronic Anal Fissure

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Abstract

Background: Fissure-in-ano is one of the most common benign anorectal disorders often encountered in surgical outpatient department. The management of this disorder includes non-operative and operative treatments. Even though the lateral sphincterotomy is the eventual treatment of choice, non-operative treatment has a good role in management of acute and chronic fissure-in-ano. Non-operative treatment has given welcoming results with good healing rate for both acute and chronic fissure-in-ano.

Materials and Methods: This study is based on analysis of 100 patients with fissure-in-ano who underwent treatment in KAPV Government Medical College Hospital, Trichy, from May 2015 to March 2017. These patients were broadly divided into two groups of 50 patients each who were managed by non-operative (medical) and operative (surgical) methods. For all these patients, clinical examinations and routine investigations were done, which also include blood for sugar, urea and serum for creatinine, and electrocardiogram and chest X-ray.

Results: Patients who were treated surgically by open lateral anal sphincterotomy had efficacy of about 94% and failure rate of 6%. Patients treated by operative treatment had a few complications in the perioperative period which subsided after 1 week. Patients who were managed non-operatively by 2% diltiazem have 80% success rate and 20% failure. Complication of topical 2% diltiazem is a headache, perianal itching which occurred in only minority of patients.

Conclusion: Comparison between diltiazem gel application and internal sphincterotomy did not show any significant difference in fissure healing and pain relief. No side effects were seen in diltiazem gel therapy. Topical diltiazem should be the initial treatment in chronic fissure-in-ano. It is better to reserve internal sphincterotomy for patients with relapse or therapeutic failure to prior pharmacological treatment.

Key words: 2% diltiazem, Fissure-in-ano, Lateral sphincterotomy

INTRODUCTION

Anal fissures or anal ulcers are one of the most common causes of severe anal pain. It refers to a longitudinal tear or ulcerated area in the distal anal canal. They are usually located in the posterior or anterior midline and usually extend from

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the level of dentate line out to the anal verge. An acute anal fissure has the appearance of a clean longitudinal tear in the anoderm, with little surrounding inflammation. 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 in its proximal aspect and with a sentinel pile at its distal aspect.¹

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.

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Surgical techniques, such as manual anal dilatation or lateral internal sphincterotomy, effectively heal most fissures within a few weeks but may result in permanently impaired anal continence.² This has led to the research for alternative non-surgical treatment, and various pharmacological agents have been shown to lower resting anal pressure and heal fissures without threatening anal continence. The present study comprises the comparative study of 2% diltiazem gel application and internal sphincterotomy in the treatment of chronic fissure-in-ano.

Aim of the Study

The aim of this study is to compare the effectiveness of topical 2% diltiazem gel with lateral sphincterotomy in the treatment of chronic fissure-in-ano in terms of wound healing, pain relief and complication (Figures 1-3).

MATERALS AND METHODS

Put on 2% diltiazem ointment topically over the perianal region twice daily for 4-6 weeks. They were given syrup cremaffin 2 tablespoon at every night.

They were treated by open lateral anal sphincterotomy. Postoperatively, they were given high-fiber diet and adequate hydration.

Moreover, stool softeners syrup cremaffin, tablet ciprofloxacin 500 mg BD, and tablet metronidazole 500 mg TDs, and they were advised sitz bath twice daily for 7 days in both groups.

They were observed postoperatively for any complications. Patients were discharged on the 4th day. They were followed up in outpatient department (OPD) every 15 days for a month then at 3 months.

ANALYSIS AND RESULTS

This study is based on the analysis of 100 patients, who were treated for fissure-in-ano in KAPV Government Medical College, Trichy, from May 2015 to March 2017.

Age and Sex Distribution

The age and sex distribution of these 100 patients are shown in Tables 1-5. Out of these, 56 were female and 44 were male. Female-to-male ratio is approximately 1.3:1. Lowest age of patients in this study is 21 years. Highest age of patients in this study was 59 years. A maximum number of patients were in the age group.

Symptomatology (Figure 4)

The symptomatology of these patients are shown in the table. Majority of these patients had history of pain during

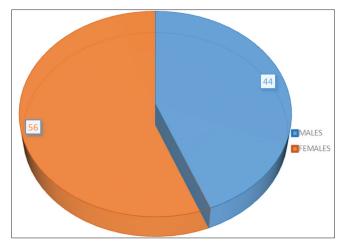


Figure 1: Age and sex distribution

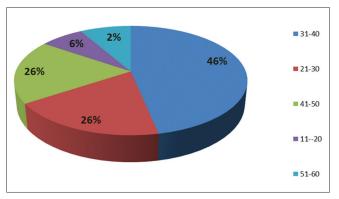


Figure 2: Age group distribution - non-operative management

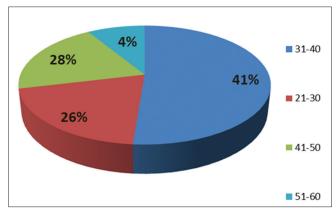


Figure 3: Age group distribution - operative management

defecation and bleeding per rectum (defecation). Other symptoms were, skin tag or both pain / skin tag, pain/bleeding per rectum.

Predisposing Factors and Aetiology (Figure 5)

Most of these patients had constipation as the major predisposing factor. Other coexsisting factors include were haemorrids post-pregnancy, tuberculosis, inflammatory bowel disease and immunocompromised state.

Location of Fissure

Almost all of the patients were subjected to proctoscopy/ digital rectal examination and found out that most of them had posterior fissure-in-ano. Some of the patients had anterior fissure which is prevalent among females. Lateral fissure was seen in 3 patients; the details are shown in Table 6 and Figure 6.

Management Medical

Totally, 50 patients out of 100 were managed by medical and conservative method of treatment. All patients were advised high-fiber diet and adequate hydration and oral antibiotics. All patients were put on 2% diltiazem ointment twice daily topically after sitz bath. All patients were followed weekly in OPD for 1 month. Results were inferred by relief of pain and healing of fissure. A total of 34 out of 50 patients had relief of symptoms, which accounts to patients who were treated medically. Other patients had persistent pain and complications such as a headache (Tables 7 and 8).

Table 1: Age group males/females total %

| Age group | Male | Female | Total | Percentage |
|-----------|------|--------|-------|------------|
| 11-20 | | 1 | 1 | 1 |
| 21-30 | 9 | 17 | 26 | 26 |
| 31-40 | 21 | 20 | 42 | 42 |
| 41-50 | 11 | 16 | 27 | 27 |
| 51-60 | 3 | 3 | 3 | 3 |

Table 2: Age group distribution – non-operative management

| Age group | Male | Female | Total | Percentage |
|-----------|------|--------|-------|------------|
| 11-20 | | 1 | 1 | 2 |
| 21-30 | 4 | 9 | 13 | 26 |
| 31-40 | 11 | 9 | 20 | 40 |
| 41-50 | 5 | 8 | 13 | 26 |

Table 3: Age group distribution - operative management

| Age group | Male | Female | Total | Percentage |
|-----------|------|--------|-------|------------|
| 11-20 | | | | |
| 21-30 | 5 | 8 | 13 | 26 |
| 31-40 | 10 | 11 | 21 | 41 |
| 41-50 | 6 | 8 | 14 | 28 |
| 51-60 | 2 | | 2 | 4 |

Table 4: Symptomatology

| Symptom | Number of cases (%) | | |
|---------------------|---------------------|--|--|
| Pain | 66 (66) | | |
| Bleeding per rectum | 9 (9) | | |
| Pain and bleeding | 10 (10) | | |
| Skin tag | 9 (9) | | |
| Pain and skin tag | 6 (6) | | |

Surgical Management

Totally, 50 patients out of 100 were treated by surgical line of management. All patients were treated by open lateral anal sphincterotomy under spinal anesthesia. Duration of surgery was approximately 15-20 min. A total of 47 out of 50 patients had relief of pain and healing of fissure, which corresponds to 94%. Some of the patients had complications as shown in Tables 9 and 10.

Most of the surgical complications subsided within 2 weeks, and the patient had complete relief of symptoms. A total of 6 out of 50 patients treated surgically did not turn up for follow-up.

DISCUSSION

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

Table 5: Etiology and predisposing/coexisting factors

| Etiology | Number of cases (%) |
|-----------------------|---------------------|
| Constipation | 85 (85) |
| Tuberculosis | 1 (1) |
| Post pregnancy | 3 (3) |
| Fistula | 2 (2) |
| Hemorrhoids | 3 (3) |
| HIV | 1 (1) |
| Previous anal disease | 4 (4) |
| Laxative abuse | 1 (1) |
| Total | 100 |

Table 6: Location of fissure

| Location | Male | Female | Total |
|-----------|------|--------|-------|
| Posterior | 42 | 47 | 89 |
| Anterior | 1 | 7 | 8 |
| Lateral | 2 | 1 | 3 |

Table 7: Medical management (non-operative)

| Results | Number of patients | Male | Female | Percentage |
|--------------------|--------------------|------|--------|------------|
| Symptomatic relief | 40 | 17 | 23 | 80 |
| Failure | 10 | 6 | 10 | 20 |

Table 8: Complications of non-operative management

| Complications | Total number of cases (%) |
|------------------|---------------------------|
| Headache | 9 (18) |
| Perianal itching | 7 (14) |
| No complaints | 34 (68) |

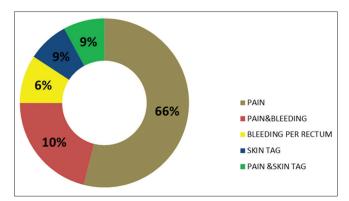


Figure 4: Symptom distribution

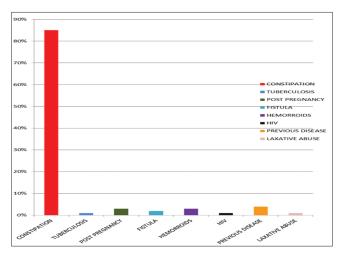


Figure 5: Etiology and predisposing/coexisting factors

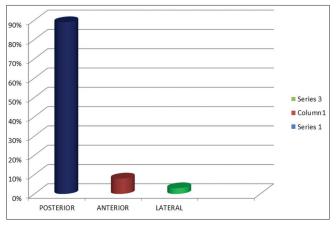


Figure 6: Location of fissure

simplest and most effective way of reducing internal anal sphincter tone is surgery. Lateral internal sphincterotomy is the golden standard in the treatment of chronic anal fissures. ¹⁻³ It involves partial division of the internal anal sphincter away from the fissure. Calcium channel blockers have been shown to lower resting anal pressure and promote fissure healing. ^{4,5} In the present study, a comparative evaluation of topical 2% diltiazem gel

Table 9: Operative management of 50 cases

| Results | Number of cases (%) |
|---------|---------------------|
| Treated | 47 (94) |
| Failure | 3 (6) |

Table 10: Complications of surgery

| Complications | Number of patients (%) |
|-------------------------------|------------------------|
| Post-operative pain | 8 (16) |
| Transient flatus incontinence | 4 (8) |
| Retention of urine | 3 (6) |
| No complications | 29 (58) |

and internal sphincterotomy has been done to examine the effectiveness, complications, and side effects in the treatment of chronic anal fissure.

Lord's anal dilatation was the earliest method of treatment of fissure-in-ano, first described in 1838. Since then, numerous treatment options have been used including sclerotherapy⁶ (using sodium tetradecyl sulfate), lateral internal sphincterotomy, and chemical sphincterotomy using calcium channel blockers such as glyceryl trinitrate (GTN), is isosorbide dinitrate, and use of botulinum toxin. 9

Diltiazem, another calcium channel blocker was also gradually introduced. A study by Medhi *et al.*¹⁰ described diltiazem to be efficacious in the treatment of chronic fissure-in-ano. Study showed that oral intake and topical applications of diltiazem reduced the anal pressure significantly with better healing rates. Another review by Bhardwaj and Parker¹¹ showed that diltiazem was a valid alternative to GTN with improved healing rates and lower rates of recurrence.

A study on the different methods by Gupta¹² showed that medical manipulation of the internal sphincter should be the first line of treatment and that only if this fails or if the fissure recurs then subcutaneous lateral internal sphincterotomy should be done.

Diltiazem, a non-dihydropyridine calcium channel blocker, induces vascular smooth muscle relaxation and dilatation. Topical 2% diltiazem reduces maximum resting pressure by approximately 28%, and this effect lasts 3-5 h after application. Side effects are minimal with diltiazem and include perianal itching and dermatitis.

The most common age group affected in this study was 31-40 years (42%), which coincides with the data by goligher *et al.*¹³ in whom, the most common age group affected was 31-40 years. Although the incidence of chronic fissure is equal in both sexes, ¹³ in our study, we found a higher incidence in females compared to males.

Approximately, 90% of anal fissures in both men and women are located posteriorly in the midline. Anterior fissures occur in 10% of patients, more commonly in women. ¹⁴ In this study, we found the incidence of anterior fissure to be around 8% and posterior fissure 89%.

In this study, 61.5% of the patients treated with diltiazem were pain-free at the end of 4 weeks. Patients who did not have symptomatic relief were subjected to lateral sphincterotomy.

Previously, the favored primary treatment of fissure is a nitric oxide donor of choice (0.2% or 0.4% GTN). Moreover, only if the patient cannot tolerate the GTN ointment or is still symptomatic after 8 weeks therapy, topical 2% diltiazem treatment was to be tried. However, from my study, since the side effects of topical 2% diltiazem are low compared to topical GTN, it can be offered as a first line of treatment for anal fissure. If this fails, operative (sphincterotomy) can be recommended. However, sphincterotomy is indicated only if the patient has not had a third-degree tear or previous sphincterotomy. It is our view that the role of pharmacological agents is likely to assume greater prominence in the future and that more effective agents and modes of delivery will be developed. Non-operative treatment of chronic anal fissure may be applied with a chance of cure that is only marginally better but far less effective than surgery.

CONCLUSION

- A total of 100 patients were studied during the study (May 2015 to March 2017). These patients were broadly divided into two groups of 50 each who were treated by non-operative and operative methods, respectively, by non-randomized control study
- In this study, females were commonly affected than males in the ratio 1.3:1
- The most common age group affected are 31-40yrs. (3rd decade).
- Fissure-in-ano is rare in children and old age
- Most of the patients presented with pain during defecation as their main complaint about 66% and pain with bleeding per rectum 10%
- Constipation was the major predisposing factor among all cases 85%
- Most of the fissures were located in the posterior midline 89%
- Anterior fissures were slightly more common in females. Although posterior fissure is common in females

- Patients who were treated surgically by open lateral anal sphincterotomy had efficacy of about 94% and failure rate of 6%
- Patients treated by operative treatment had a few complications in the perioperative period which subsided after 1 week
- Patients who were managed non-operatively by 2% diltiazem have 80% success rate at the end of 4-6 weeks and 20% failure. A total of 10 patients, who did not have relief of symptoms after 1 month of treatment, required operative treatment
- Complication of topical 2% diltiazem is headache, perianal itching which occurred in only minority of patients
- It is our view that the role of pharmacological agents is likely to assume greater prominence in the future and that more effective agents and modes of delivery will be developed.

Non-operative treatment of chronic anal fissure may be applied as the initial choice of treatment with a chance of cure that is better but less effective than surgery.

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