

## ORIGINAL ARTICLE

### STUDY TO ASSESS THE EFFECTIVENESS AND SIDE EFFECT OF DILTIAZEM 2% GEL IN THE MANAGEMENT OF CHRONIC FISSURE-IN-ANO

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**ABSTRACT: OBJECTIVE:** To know the effectiveness and side effect of diltiazem 2% gel in the management of chronic fissure-in-ano. **MATERIALS AND METHODS:** Prospective study was undertaken at Department of general surgery, Gold Field Medical College and Research Centre, Chhainsa, Ballabgarh, Haryana from January 2012 to January 2014. 84 patients with only primary fissure-in-ano and in which fissure symptoms not relieved in 8 weeks were treated in this study. **RESULT:** Study shows male predominance. 60.7% were males 39.3% were females. 76% patients were in age group between 25 to 35 yrs. posterior fissure was in 82.1% of cases and anterior in 17.9% of cases. Fissure healing with pain relief was in 90.4% cases. In 9.6% cases fissure symptoms were not relieved, such patients were treated surgically using lateral internal sphincterotomy with sentinel tag excision. In 2.3% cases had headache and palpitation in 0%cases. **CONCLUSION:** After doing this study we conclude that one should initially manage the cases of chronic fissure-in-ano with, diltiazem 2% gel before opting any surgical procedure for it.

**KEYWORDS:** Fissure-In-Ano, 2% Diltiazem Gel, Lateral Internal Sphincterotomy.

**INTRODUCTION<sup>1,2,3</sup>:** Anal fissures are commonly encountered problem in surgery clinic. Anal fissures are cracks or tears in the anus and anal canal. It is usually located in the posterior or anterior midline and extends from the level of dentate line to the anal verge. It can occur after constipation, after passage of hard stool, after repeated diarrhea or after child birth. The primary symptom of anal fissures is pain during and following bowel movement. Other symptoms that may occur are bleeding, itching, and a malodorous discharge.

They may be acute or chronic <sup>4,5</sup> Anal fissure that hasn't healed after 8 to 12 weeks is considered as a long-term (Chronic) fissure. Chronic fissure is frequently associated with a hypertrophic anal papilla at its upper aspect and sentinel pile at its distal aspect. Painful fissures are generally associated with involuntary spasm of the internal sphincter with high resting pressure in the anal canal.

Short-term (Acute) anal fissures heals with home treatment after a few days or weeks. A chronic fissure need medical treatment and in few cases surgery is required. Developments in the pharmacological understanding of the internal anal sphincter have resulted in more conservative approaches towards treatment. Simple measures are often effective for early fissures. Topical Calcium channel blockers are well established first-line pharmacological therapy.

Surgery has a defined role and should not be discounted completely. Surgical techniques like <sup>6</sup> manual anal dilatation or <sup>7,8,9</sup> lateral internal sphincterotomy, effectively heal most fissures within a few weeks, but may result in permanently impaired anal continence. The present study assess the effectiveness and side effects of topical application of 2%.<sup>10,11,12</sup> Diltiazem gel.

**MATERIALS AND METHODS:** This prospective study was undertaken at Department of general surgery, Gold field medical college and research Centre, Chhainsa, Ballabgarh, Haryana from January 2012 to January 2014. 84 patients were treated in this study. Patients with symptoms not relieved in

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8 weeks were considered as chronic fissure-in-ano and were included in this study. Patient with age between 18 to 65 yrs. of both sex were included in this study.

They were further divided into 18 to 25yrs, 26 to 35yrs, 36 to 45yrs, 46 to 55yrs and 56 to 65 yrs. Patients with only primary fissure-in-ano were included in this study. Paediatric, pregnant and mentally challenged patient were excluded. Patient with secondary fissure-in-ano, with haemorrhoids or fistula were excluded. Patient with anorectal malignancy were also not included in this study. All Patients were explained about proper and hygienic application of diltiazem 2% gel.

They are advised to apply 1.5cm gel inside the anal canal around 2.5cm from anal verge. They all were instructed to use gloves during application of gel. It was advised to them to apply it twice a day and apply 10 minutes before going for defecation.

They were advised to continue this treatment for 6 weeks. With this treatment they were advised to take plenty of fluids and high fiber diet. Laxative was advised to all patients. Patients reviewed weekly for 6 weeks and then after 3, 6, 9 and 12 months. They were assessed for fissure healing, pain relief, anal incontinence, headache and palpitation. Patient not relieved of fissure symptom or recurrence was surgically treated using<sup>7,8</sup> lateral internal sphincterotomy with sentinel tag excision.

**RESULT:** Study shows male predominance. Out of 84 patients 51(60.7%) were males and 33(39.3%) were females. 64(76%) patients were in age group between 25 to 35 yrs. Posterior fissure was in 69(82.1%) of cases and anterior in 15(17.9%) of cases. Fissure healing with pain relief was in 76 (90.4%) cases. In 8(9.6%) cases fissure symptoms were not relieved, such patients were treated surgically using lateral internal sphincterotomy with sentinel tag excision. In 2(2.3%) cases they had headache and palpitation in 0%cases.

### Statistical Analysis:

Sl. No.	Sex	No. of Patients	Percentage (%)
1	Male	51	60.71
2	Female	33	39.29
	<b>Total</b>	<b>84</b>	<b>100.00</b>

Table 1: Sex wise distribution of the patients

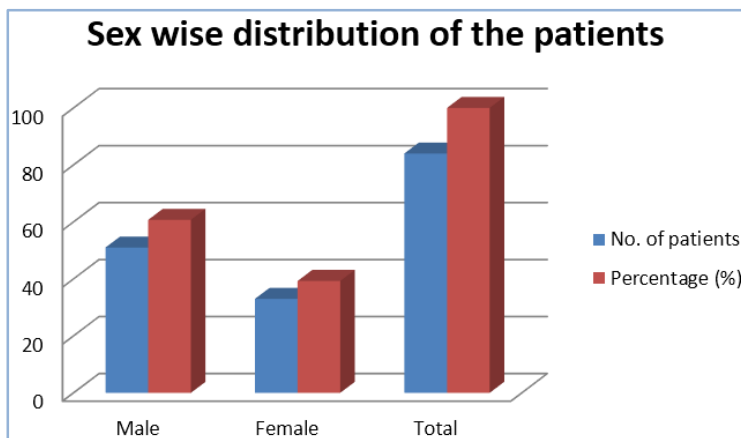


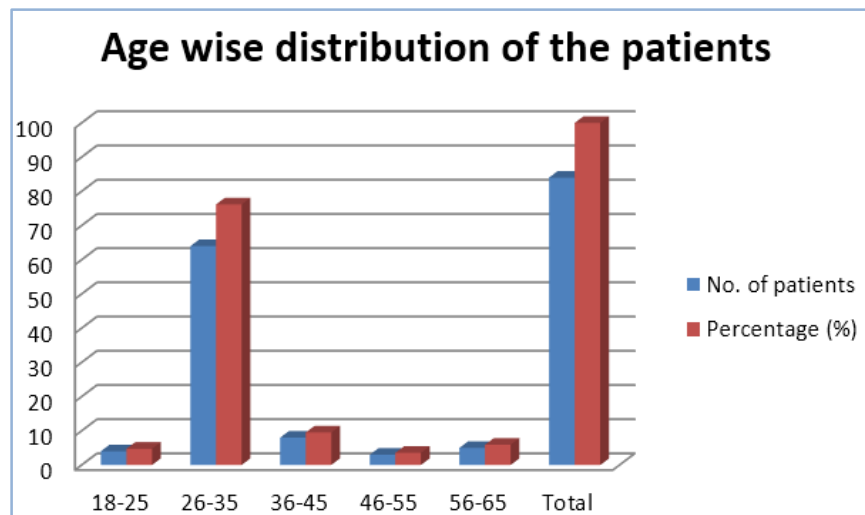
Figure 1

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Sl. No.	Age Group (in years)	No. of Patients	Percentage (%)
1	18-25	4	4.76
2	26-35	64	76.19
3	36-45	8	9.52
4	46-55	3	3.57
5	56-65	5	5.95
	<b>Total</b>	<b>84</b>	<b>100.00</b>

**Table 2: Age wise Distribution of the Patients**

Age mean±sd value is 33.58±9.13 and range 18-65.



**Figure 2**

Sl. No.	Age Group (in years)	Male	Female	Total Patients	Percentage (%)
1	18-25	1	3	4	4.76
2	26-35	43	21	64	76.19
3	36-45	2	6	8	9.52
4	46-55	2	1	3	3.57
5	56-65	3	2	5	5.95
	<b>Total</b>	<b>51</b>	<b>33</b>	<b>84</b>	<b>100.00</b>

**Table 3: Age wise Distribution of the Patients**

Sl. No.	Site of the Diseases	No. of Patients	Percentage (%)
1	Posterior Fissure	69	82.14
2	Anterior	15	17.85
	<b>Total</b>	<b>84</b>	<b>100.00</b>

**Table 4: Site of fissure in ano**

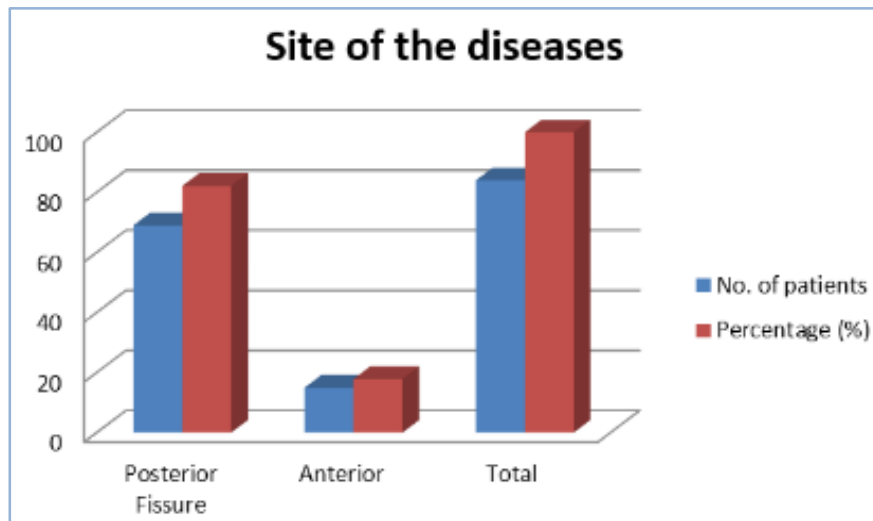


Figure 3

Sl. No.	Response of Patients	No. of Patients	Percentage (%)
1	Fissure Pain Relief	76	90.48
2	Fissure Not Relief	8	9.52
	<b>Total</b>	<b>84</b>	<b>100.00</b>

Table 5: Response of the treatment of the patients

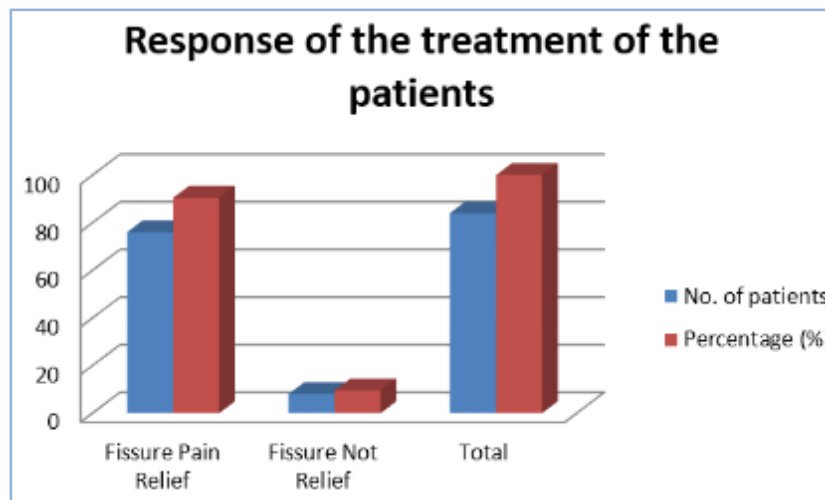


Figure 4

**DISCUSSION:** Chronic fissure-in-ano is a painful disease. It is mainly associated with abnormal bowel habit. Patient gives history of chronic constipation with passage of hard stools. Common in both sex with slight predominance in male. Lock & Thombson et al (1977) the Birmingham series noted a slightly male preponderance. In our study also there is slight male predominance, Out of 84 patients 51(60.7%) were males and 33(39.3%) were females. Study conducted by.

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Lock & Thombsen et al (1977) the posterior fissure was in 75% of cases, anterior and lateral in 14% and 3% respectively. In our study posterior fissure was in 82% of cases and anterior in 18% of cases. As it is associated with perianal pain and discomfort, quality of life is seriously affected. Persistent pain is because of non-healing ulcer in anal canal region and spasm of anal sphincter muscle.

Principal treatment is to reduce anal tone. Both operative and non-operative methods are available. Operative procedures like anal dilatation, lateral internal sphincterotomy are effective method to treat fissure-in-ano.<sup>7</sup>Hananel and Gordon reported a healing rate of 84% in 4 weeks raised to 94.4% in 8 weeks. But these procedures are sometime associated with permanent anal incontinence.

Non-operative methods using<sup>9</sup> botulinum toxin, Ca<sup>2+</sup> channel blocker like<sup>10</sup> nitroglycerine and diltiazem have good results. Occasionally Botulinum toxin has got serious side effects. Mild temporary incontinence of flatus and abscess formation is also noted after botulinum toxin.<sup>10</sup> Topical nitroglycerin is associated with headache and palpitation.<sup>10,11,12</sup> Diltiazem 2% gel has a good effect on reducing anal tone and healing of fissure. In our study also there is 90.4% success rate in healing of fissure and relief of pain. Only 2.3% cases had headache with palpitation in 0%cases.

**CONCLUSION:** After doing this study we conclude that one should initially manage chronic fissure-in-ano with diltiazem 2% gel before opting any surgical procedure for it.

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