



Comparative Study Between Diclofenac Suppository And Combined Oral Diclofenac With Local Anaesthetic Agent In Pain Management In Acute Fissure In Ano In Out Patient Department Care

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Abstract

Introduction: Anal fissure is a common problem that causes significant morbidity in a young and otherwise healthy population. Acute fissure in ano is a very common problem faced by Indian population. Though it is a very common problem still the pain relief has always been an unsolved issue. There are various pain management modalities for fissure in ano. The objectives of this study is to evaluate and compare the efficacy of diclofenac suppository versus combined oral diclofenac with local anaesthetic agent in prevention of pain in acute fissure in ano and to achieve an effective, cheaper and an easy method to relieve pain in patients with acute fissure in ano in Out patient department care. Diclofenac suppositories are opted as they are easily available and patient could insert it without anyone's assistance and hence not hospitalized for intravenous administration of analgesics.

Methods: A study was conducted over 100 cases over a span of 1 year in a tertiary health care centre. Group A patients were treated with Diclofenac suppository 100 mg twice a day for 5 days with glycerine for lubrication at anal verge and Group B patients were treated with Oral Diclofenac 75 mg twice a day for 5 days plus Lignocaine Jelly for local anaesthetic. The pain score was noted in both the groups. All acute fissure in ano cases were included in the study.

Results: The pain score of Group A cases was significantly lower than Group B cases.

Conclusion: It was noted that the pain relief was significant in patients in Diclofenac suppository alone compared to combined Oral Diclofenac and Lignocaine jelly and thus we can achieve significant pain reduction on Out Patient Department basis with Diclofenac suppositories alone within seven days. Thus an effective, safe, cheap and an easy modality for pain relief in acute fissure in ano with good results could be achieved.

Keywords: Diclofenac suppository, Acute fissure in ano, Pain

Introduction

Anal fissure is a common problem that causes significant morbidity in a young and otherwise healthy population.

Acute fissure in ano is a very common problem faced by Indian population.

Though it is a very common problem still the pain relief has always been an unsolved issue.

An anal fissure is a longitudinal tear or defect in the skin of the anal canal distal to the dentate line¹.

Anal fissure can be acute (lasting less than six weeks) or chronic (lasting more than six weeks)¹.

Symptoms associated with acute fissures include anal pain, spasm, or bleeding with defecation.

The majority of anal fissures occur at either the posterior or anterior midline.

Anal fissure are common in those with a history of constipation, low fibre diet, trauma or previous anal surgery.

1.9 Chronic constipation is the most common cause of acute fissure in ano².

1.10 It is commonly seen in young adults and middle aged people.

The objectives of this study is to evaluate and compare the efficacy of diclofenac suppository versus combined oral diclofenac with local anaesthetic agent in prevention of pain in acute fissure in ano and to achieve an effective, cheaper and an easy method to relieve pain in patients with acute fissure in ano in Out patient department care.

Aims And Objectives

Aim-

To compare the efficacy of diclofenac suppository versus combined oral diclofenac with local anaesthetic agent in prevention of pain in acute fissure in ano in Out patient department care.

Objectives-

To evaluate the efficacy of diclofenac suppository in prevention of pain in acute fissure in ano.

To evaluate the efficacy of combined oral diclofenac with local anaesthetic agent in prevention of pain in acute fissure in ano.

To compare the efficacy of diclofenac suppository versus combined oral diclofenac with local anaesthetic agent in prevention of pain in acute fissure in ano.

Materials And Methods

Type of Study: Prospective Randomized Comparative Study

Place of Study: MGM Medical College and Hospital, Navi Mumbai

Period of Study: May 2021 to May 2022

Institute Ethics Committee approval and consent will be obtained before the start of the study.

Sampling type- Simple random sampling technique.

Sampling method- Convenient sampling.

Statistical analysis plan and data will be collected by using standard tool and stored in MS excel. Basic descriptive statistics like frequency, percentage, mean, mode, median, standard deviation and graphs will be prepared by using MS excel.

To test the significance 0.01 or 0.05 in the level of significance will be used for parametric and non-parametric tests.

To test the test of significance statistical package SPSS24 will be used.

Size= 100 cases

Plan Of Study: All acute fissure in ano cases in Out patient department will be included in the study.

Inclusion Criteria-

1. All patients with acute fissure in ano in Out patient department.
2. Age group- 18 to 60 years.

Exclusion Criteria-

1. All chronic fissure in ano cases.
2. All other per anal pathologies.
3. Patients below 18 years and above 60 years of age.
4. Patients having contraindications to Diclofenac.
5. Patient not willing to take part in the study.

All patients coming to Out patient department were examined thoroughly and diagnosed based on history taking and clinically per rectal examination if and when possible.

Patients selection will be based on a Lottery system:

A box containing chits each enclosed within a sealed envelope is prepared. On the chit its written whether Diclofenac suppository with glycerine for lubrication at the

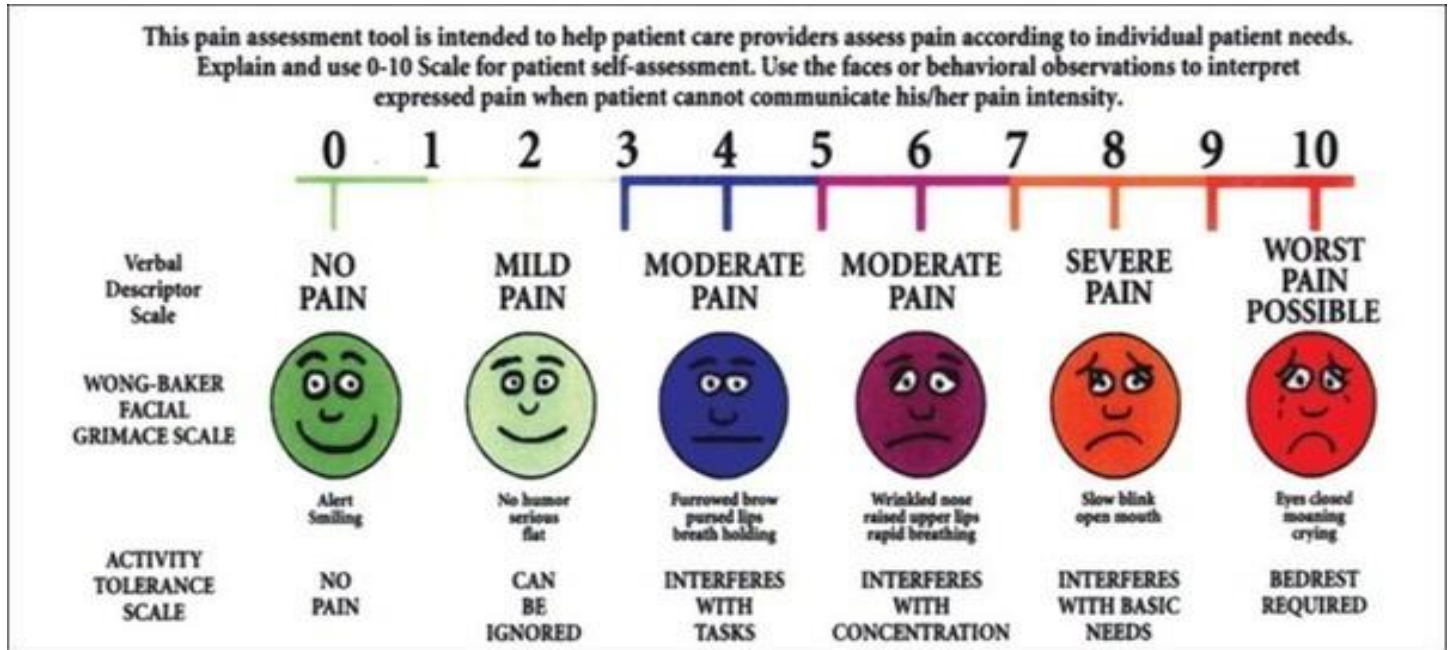
anal verge (Group A) or combined oral tablet Diclofenac 75mg twice a day for 5 days with lignocaine jelly for local anaesthetic (Group B) will be given to the patient. Depending on the chit drawn, patient will be treated with either Diclofenac suppository 100 mg twice a day for 5 days with glycerine for anal verge lubrication or combined oral

Diclofenac 75 mg twice a day for 5 days with lignocaine jelly for local anaesthetic.

Patients were explained the Pain Visual Analogue Scale (VAS) and asked to note the VAS score for next 5 days which patient would come and show in the follow-up visit in the Out patient department on 5th day and a record was maintained.

The study will involve the use of following variables to compare the efficacy of diclofenac suppository versus combined oral diclofenac with local anaesthetic agent in prevention of pain in acute fissure in ano in Out patient department care-

A) Pain based on Visual Analogue Scale



Results

Statistics:

Table 1: Sex distribution

	Groups			
	Diclofenac suppository		Oral Diclofenac+Lignocaine jelly	
	Count	Column N %	Count	Column N %
Male	21	42.0%	16	32.0%
Female	29	58.0%	34	68.0%

Graph 1: Sex distribution

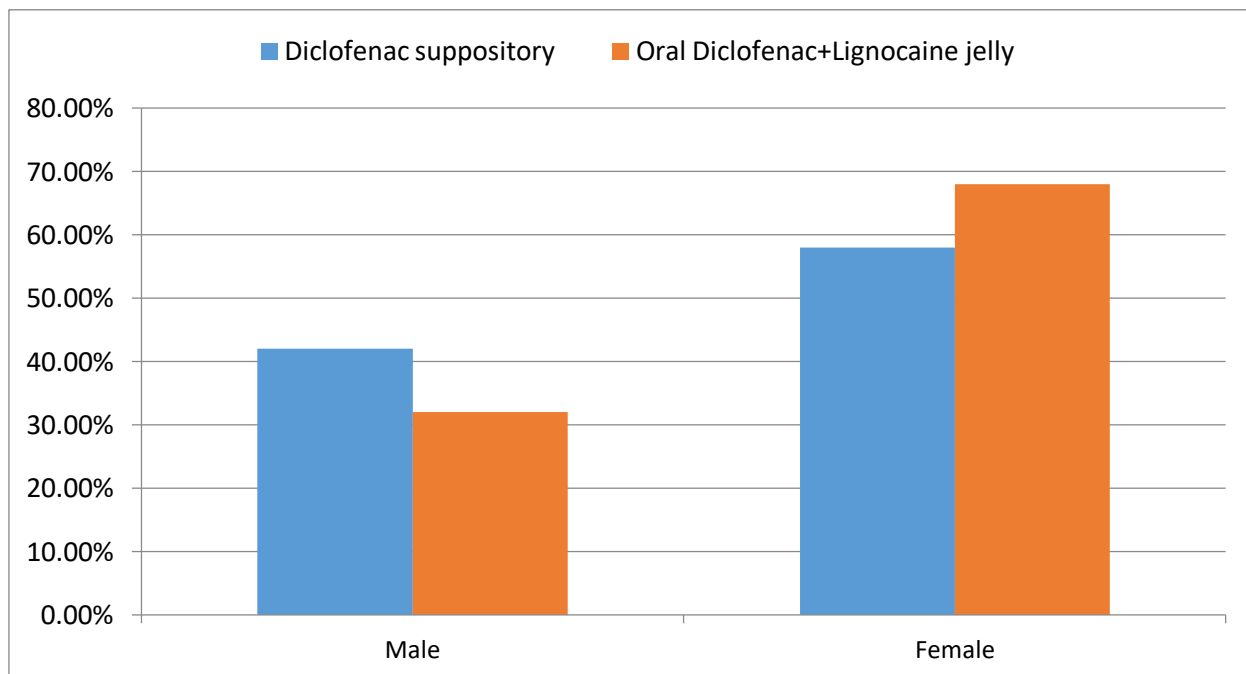


Table 2: Age distribution

	Groups			
	Diclofenac suppository		Oral Diclofenac+Lignocaine jelly	
	Count	Column N %	Count	Column N %
30 & Less	32	64.0%	40	80.0%
31 to 40	11	22.0%	10	20.0%
41 to 50	4	8.0%	0	.0%
51 to 60	3	6.0%	0	.0%

Graph 2: Age distribution

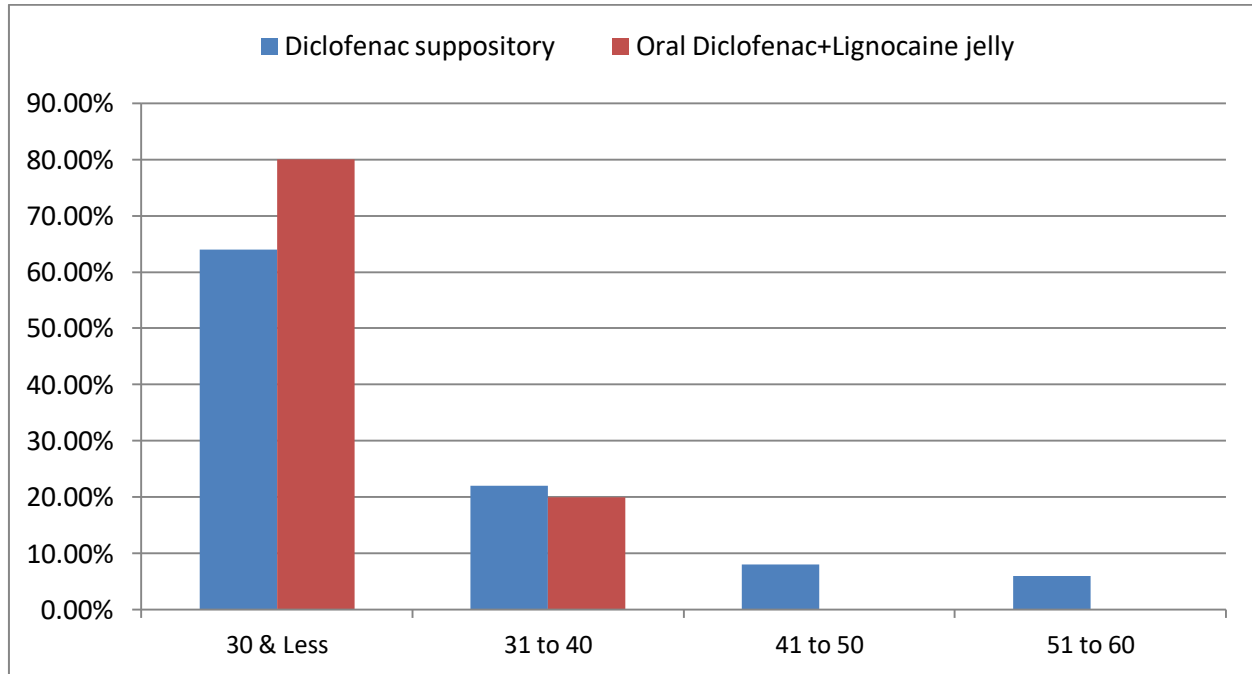


Table 3: VAS score in Diclofenac suppository

	Day 1		Day 2		Day 3		Day 4		Day 5	
	Count	%	Count	%	Count	%	Count	%	Count	%
1									3	6.0%
2					6	12.0%	3	100.0%	47	94.0%
3					44	88.0%				
4										
5			10	20.0%						
6	1	50.0%	40	80.0%						
7	1	50.0%								
8										
9										
10										

Graph 3: VAS score in Diclofenac suppository

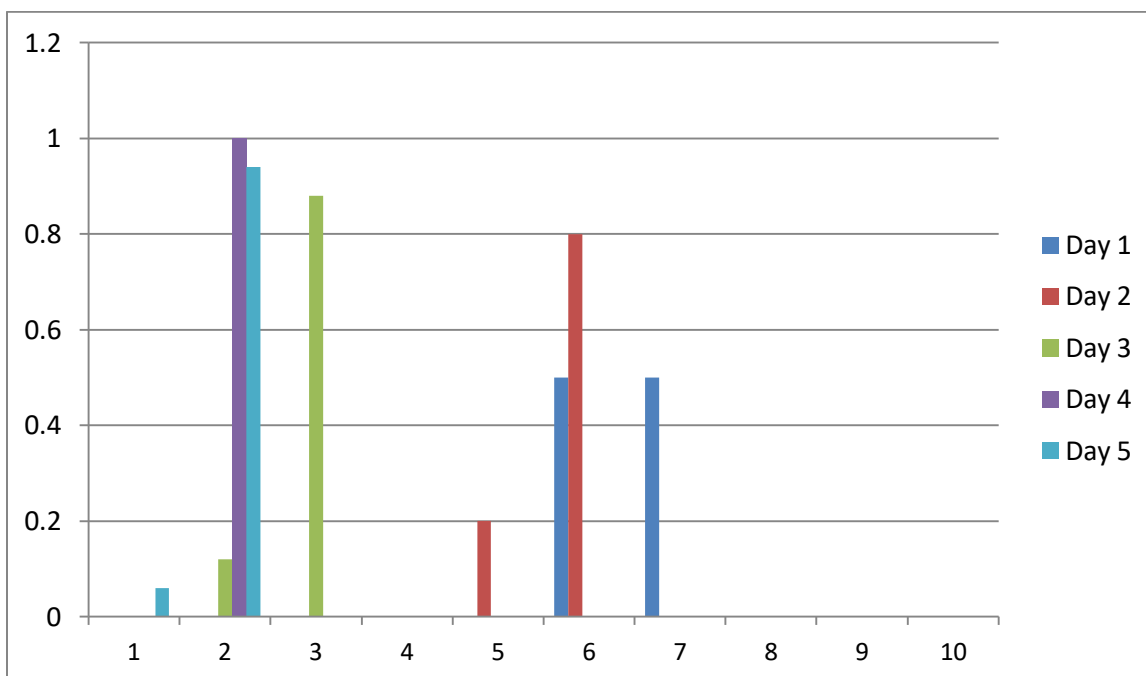
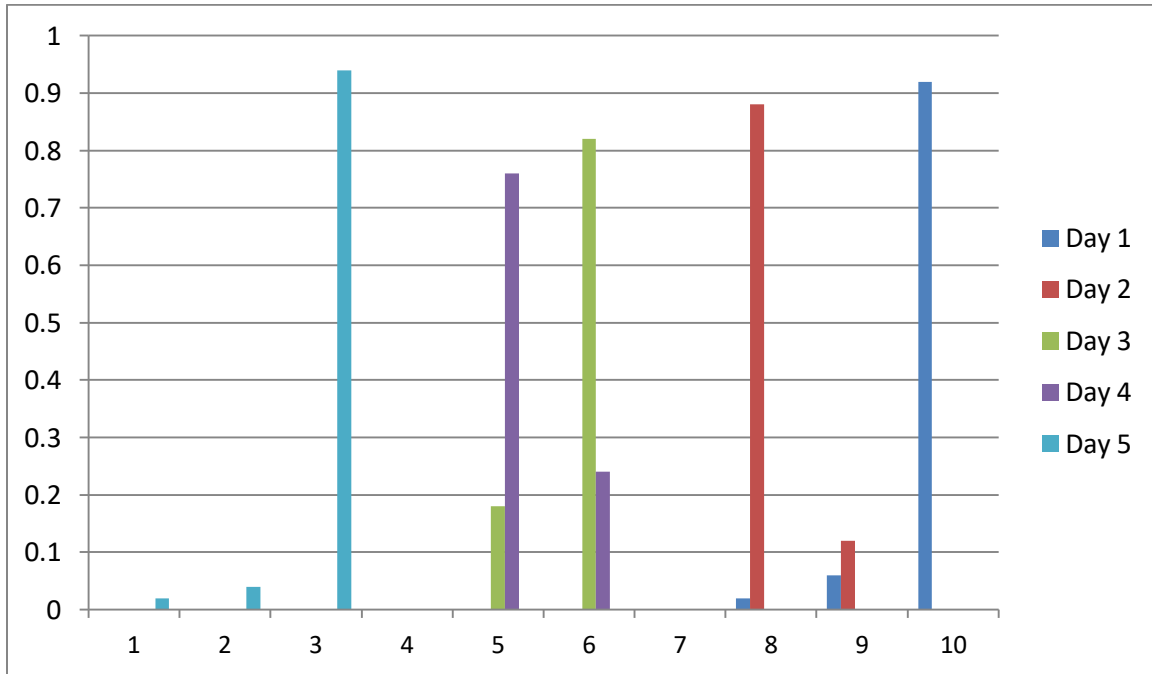


Table 4: VAS score in Oral Diclofenac plus lignocaine jelly

	Day 1		Day 2		Day 3		Day 4		Day 5	
	Count	%	Count	%	Count	%	Count	%	Count	%
1									1	2.0%
2									2	4.0%
3									47	94.0%
4										
5					9	18.0%	38	76.0%		
6					41	82.0%	12	24.0%		
7										
8	1	2.0%	44	88.0%						
9	3	6.0%	6	12.0%						
10	46	92.0%								

Graph 4: VAS score in Oral Diclofenac plus lignocaine jelly



Comparison of pain Score on Day 5:

Mann-Whitney U test result:

Table 5: Comparison of VAS score on day 5

		Groups		Mann-Whitney U test p-value
		Mean	Standard Deviation	
Day 5	Diclofenac suppository	1.94	.24	0.000
	Oral Diclofenac+Lignocaine jelly	2.92	.34	

Interpretation: As p-value for Mann-Whitney U test is less than that of 0.05 indicates that the average pain score for Diclofenac suppository is significantly less than Oral Diclofenac + Lignocaine jelly.

Graph 5: Comparison of VAS score on day 5

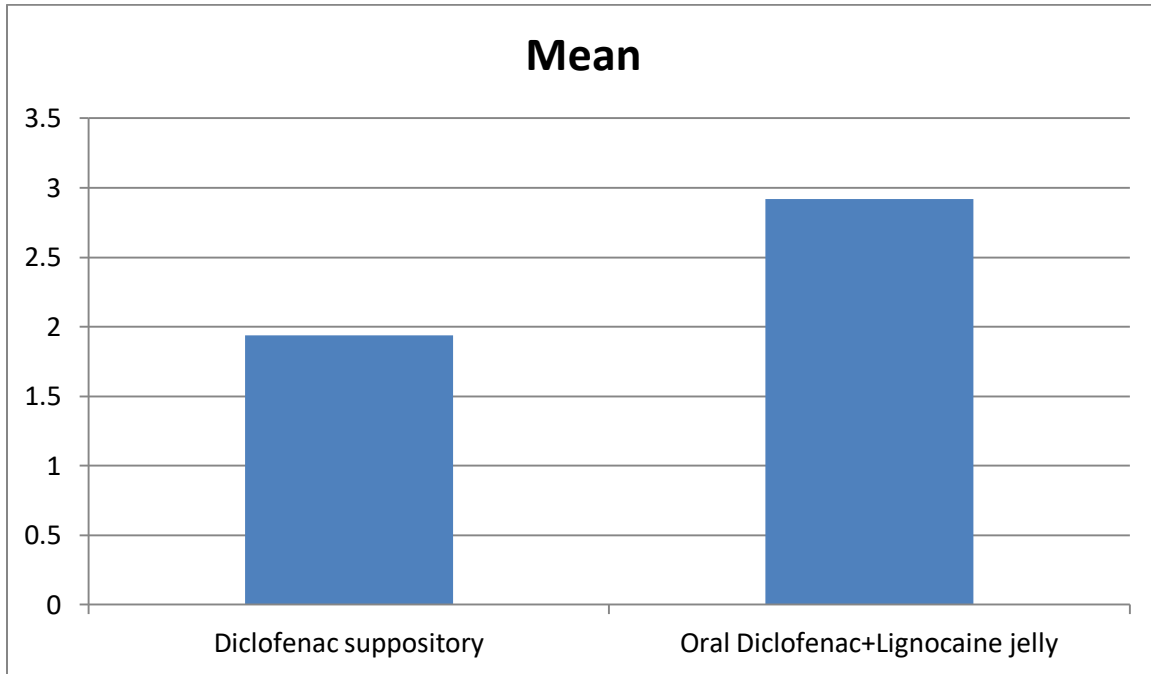


Table 1 and Graph 1 shows that female patients were more affected with acute fissure in ano compared to males in our study.

Table 2 and Graph 2 shows that maximum number of patients were seen in the younger age group between 18-30 years followed by 31-40 years and the least were seen in the old age group between 50-60 years in our study.

Table 3 and Graph 3 shows that by day 3 around 88% had pain score 3 and by day 5 around 94% had pain score 2.

Table 4 and Graph 4 shows that by day 3 around 82% had pain score 6 and by day 5 around 94% had pain score 3.

Table 5 and Graph 5 shows comparison of pain score on day 5 and indicates that the average pain score of Diclofenac suppository is less than that of combined oral Diclofenac and Lignocaine jelly.

Discussion

An anal fissure is a small break or tear in the skin of the anal canal, which typically runs from below the dentate line to the anal verge, and is usually situated in the posterior midline³.

It causes severe pain and bleeding with bowel movements, and is associated with spasm of the

internal anal sphincter which may lead to reduction of blood flow and delayed healing³.

The incidence of anal fissures is around 1 in 350 adults⁴.

The incidence is equal in men and women, however in our study shows that females were more affected than males.

Superficial fissures can be cured conservatively by following methods such as warm water sitz bath with or without boric powder or potassium permanganate, adequate analgesia, stool softening agents, high fibre diet and laxatives with reassurance and encouragement⁵.

Other modalities like local application of nifedipine also shown good results but have been proven more effective in increasing the blood supply thus promoting in healing of fissure⁵⁻⁶.

However for relief of pain local anaesthetic agent such as lignocaine jelly and sometimes oral with local analgesics were needed.

Diclofenac is easily available across the counter and is safe and easy to use hence widely used in many other perineal cases.

Our study showed good results on using Diclofenac suppository in on the Visual Analogue Scale with a score of 2 in 94% cases.

We emphasize on the pain relief of the patient which was the most important from the patient's point of view and thus instead of multiple modalities of treatment a simple and easy treatment with Diclofenac suppository of 100mg twice a day gave good results in just 5 days to an extent of pain score 2 in comparison to Oral Diclofenac plus Lignocaine Jelly that achieved a pain score 3.

Hence, our study advocates the practice of these suppositories in pain management in acute fissure in ano in Out patient department care on routine basis along with dietary modification, laxatives and reassurance to combat constipation which acts as the most common cause of fissure in ano.

Conclusion

Our study concludes that female patients are more affected by fissure in ano than males and also the younger age group more commonly affected than the old age.

It was also noted that the pain relief was significant in patients in Diclofenac suppository alone compared to combined Oral Diclofenac and Lignocaine jelly and thus we can achieve significant pain reduction on Out Patient Department basis with Diclofenac suppositories alone within seven days.

Thus an effective, safe, cheap and an easy modality for pain relief in acute fissure in ano with good results could be achieved.

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