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A Comparative Study between Lateral Sphincterotomy and Diltiazem Application for Anal Fissure Regarding Pain, Bleeding and Healing

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Abstract
Introduction: *Anal fissures are considered one of the commonest causes of severe anal pain. An anal Fissure (synonym: fissure-in-ano) is a longitudinal split in the anoderm of the distal anal canal which extends from the anal verge proximally towards, but not beyond, the dentate line.*
Materials and methods
Prospective Longitudinal Comparative Study including
Patients with anal fissure coming to the outpatient department in Tertiary Care Teaching Hospital during the period of september 2014 to November 2016.
Sample size*: 80 patients(40 each group)*
Inclusion criteria*:*
1) Patients with pain during defecation
2) Patients with frank bleeding during defecation
3) Patients with skin tags { sentinel pile}
Exclusion criteria*:*
1) Patients with signs of haemorrhoids
2) Patients with signs suggestive of fistula
3) Fungating mass or advanced malignancy of anal canal.
4) Patients with rectal prolapsed, fissures secondary to specific diseases like Tuberculosis, Crohn's disease etc., and pregnant women.
Results: *Data From Tertiary Care teaching Hospital Taken and analysed to attain conclusion 40 patients were taken in each group and characteristics of age group, better pain relief hospital stay etc were compared between both the groups. In this study 80 patients were taken, they were divided into 2 groups 40 each. Group 1 were treated with 2% diltiazem gel for twice daily topical application and group 2 underwent lateral spinchterotomy. There were 15 males and 25 females with a male to female ratio of 1:1.6 in group 1 where as in group 2 males are 17 and females are 23 giving the male:female ratio 1:1.35. The study showed that most (42.5%) of the patients were in the age group of 31-40 years in group 1 which included 15% males and 27.5% females in the group. 32.5% of patients were in the 21-30 years age group, 15% in 41-50 years age group and 2.5% in 11-20 years ,5% in 51-60 years age groups,and 2.5% in >60 years.*
Interpretation And Conclusion: *The current study shows results in favor of 2% diltiazem gel local therapy with a healing rate of 92.5% and a faster pain-relief with minimal complications. However, LIS is effective in the treatment of recurrent/ not responding to medical treatment fissure-in-ano . Though there is latency in the clearance of symptoms and lesions when compared to surgical sphincterotomy, this has shown minimal and insignificant adverse effect profile.*
Key Word: *Anal Fissure, Diltiazem, Sphicterotomy, Sentinel Pile*

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I. INTRODUCTION

Anal fissures are considered one of the commonest causes of severe anal pain. An anal Fissure (synonym: fissure-in-ano) is a longitudinal split in the anoderm of the distal anal canal which extends from the anal verge proximally towards, but not beyond, the dentate line.[1] It is usuallylocated in the posterior or anterior midline and extends from the level of dentate line to the anal verge.

Acute fissure is one which presents within 3-6 weeks of symptom onset. It has the appearance of a clean longitudinal tear in the anoderm with little surrounding inflammation. Acute fissure usually heals spontaneously within 6 weeks. A chronic fissure, with more than 6 weeks of symptoms, is usually deeper and generally has exposed internal sphincter fibres in its base. It is frequently associated with a hypertrophic anal papilla at its upper aspect and sentinel pile at its distal aspect.

Based on aetiology it is classified as primary (idiopathic) or secondary. Secondary fissures are those that occur due to some other pathology such as Crohn's disease, anal tuberculosis, AIDS.

Patients usually present with pain during defecation and passage of bright red blood per anus. The precise aetiology of anal fissure is unknown. Fissure is most commonly attributed to trauma from the passage of a large hard stool(constipation), but it is also seen after acute episodes of diarrhea,child birth[2]. Painful fissures are generally associated with involuntary spasm of the internal sphincter with high resting pressure in the anal canal. Normal resting anal pressure 80-160 mm Hg[3]. So it seems that chronic over activity of the internal sphincter may be the cause.

A diagnostic feature of an anal fissure is anal pain after defecation. In chronic cases, the skin at the lower part of the fissure becomes swollen and can be used as a marker of an anal fissure – the 'sentinel pile'.[8]

Reduction of anal sphincter spasm results in improved blood supply and healing of fissure. Surgical techniques like manual anal dilatation or lateral internal sphincterotomy, effectively heal most fissures within a few weeks [4,5], but may result in permanently impaired anal continence.

This has led to the research for alternative non-surgical treatment[6], and various pharmacological agents such as nitrates (glyceryltrinitrate, isosobidedinitrate), calcium channel blockers (nifedepine, diltiazem)[7] have been shown to lower resting anal pressure and heal fissures without threatening anal continence .

II. AIMS and OBJECTIVES

"To study the management follow up and outcome in patients in comparision between lateral sphincterotomy and diltiazem application in anal fissures at Tertiary Care teaching Hospital **"**
With the objective of

1. Assessing pain relief, regression of bleeding per anum.
2. Detecting various side effects of medical and surgical treatment
3. To asses length of hospital stay.
4. To asses best method for acute , chronic and recurrent fissures in ano.

III. PATIENTS AND METHODS

Study design: Prospective Longitudinal Study
Type of study: Comparative Study
Source of data: Patients with anal fissure coming to the outpatient department in Tertiary Care Teaching Hospital during the period of september 2014 to November 2016.
Sample size: 80 patients(40 each group)
Inclusion criteria:
1) Patients with pain during defecation
2) Patients with frank bleeding during defecation
3) Patients with skin tags { sentinel pile}
Exclusion criteria:
1) Patients with signs of haemorrhoids
2) Patients with signs suggestive of fistula
3) Fungating mass or advanced malignancy of anal canal.
4) Patients with rectal prolapsed, fissures secondary to specific diseases like Tuberculosis, Crohn's disease etc., and pregnant women
Procedure
Group 1 :Use of 2% diltiazem gel apply 1.5 to 2 cms length of twice daily at least 1.5 cm into the anus for 6 consecutive weeks.
Group 2 underwent left lateral internal sphincterotomy under spinal anaesthesia
Cases from both Groups were asked to take mild laxatives like cremaffin (milk of magnesia 11.25 ml, liquid paraffin 3.75 ml, per 15 ml of emulsion) three teaspoons at bedtime, high fibre diet and to use warm seitz baths.

After this, in group 1 each patient was assigned to a 6-week course of medical therapy with topical calcium channel blocker after a Warm Seitz bath three times a day. The amount of crème to be applied was shown during the outpatient visit. If patients experienced side effects, he/she was instructed to reduce the amount to be applied. On follow up visits twice monthly, patients were examined for fissure healing, symptoms, complications and adverse effects prospectively. Secondary endpoints were symptomatic improvement, need for

surgery, side effects [9] and surgical complications and patients' satisfaction. Improvement was defined as absence of pain or bleeding. Healing was defined as complete epithelization of the fissure base. Those patients in group 2 were subjected to surgery in form of lateral internal sphincterotomy. Before surgery, all patients had a limited bowel preparation with warm water enema. An open lateral internal sphincterotomy [10] was performed with patient in lithotomy position under regional anaesthesia. A circumanal incision of 1 cm was made just distal to the intersphincteric grove in the lateral position with subsequent partial division of the internal anal sphincter using coagulation diathermy. The distal internal sphincter was divided under direct vision for a length up to the fissure apex. Patients were discharged home.

Criteria for comparison included were pain, bleeding, healing and other side effects. Wexner incontinence score [11] was used to assess continence after the procedures. Cases were reviewed in Outpatient Department weekly for 6 consecutive weeks and biweekly for subsequent 3 months.

Data Analysis:
Statistical analysis done using Microsoft Excel software and SPSS computer program .

IV. OBSERVATIONS AND RESULTS

A total of 80 patients have been included in the study and the following criteria were analysed. 40 patients were analysed using 2% diltiazem gel application, 40 patients were observed on lateral spinchterotomy under spinal anaesthesia results have been formulated by using Microsoft excel and SPSS software

RESULTS OF GROUP 1 :Use of 2% diltiazem gel twice daily

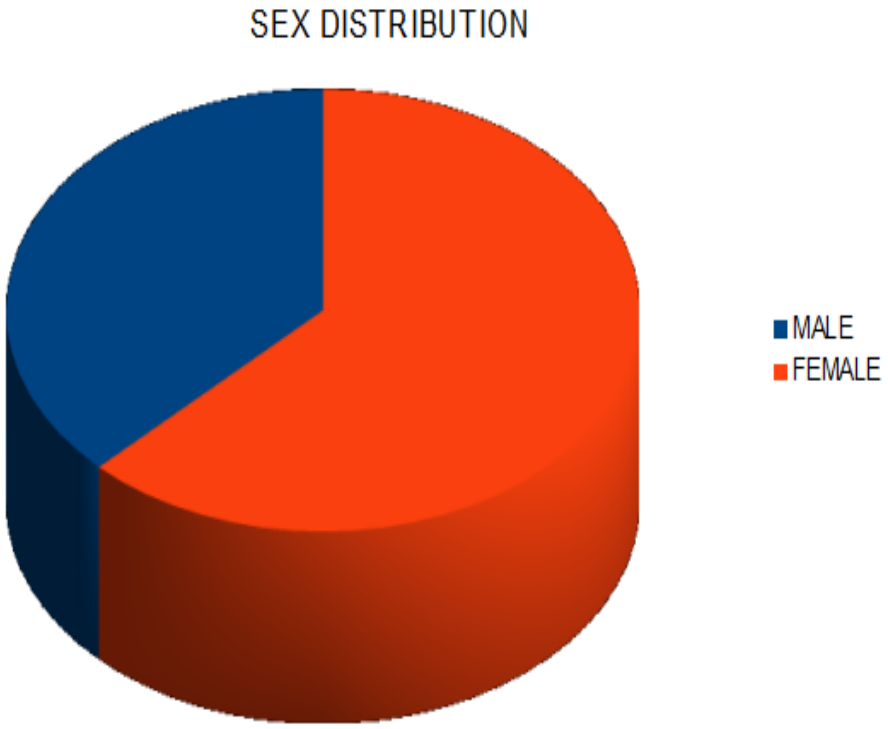

TABLE 1 : SEX DISTRIBUTION

SEX	NO OF PATIENTS
MALE	15
FEMALE	25

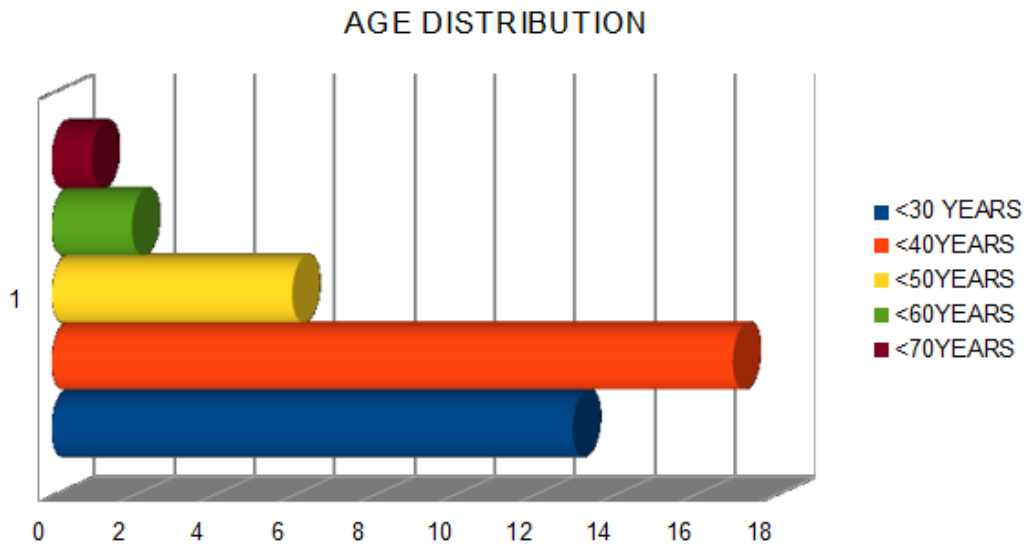

TABLE 2: AGE DISTRIBUTION

<20YEARS	21-30 YEARS	31-40YEARS	41-50YEARS	51-60YEARS	61-70YEARS
1	13	17	6	2	1

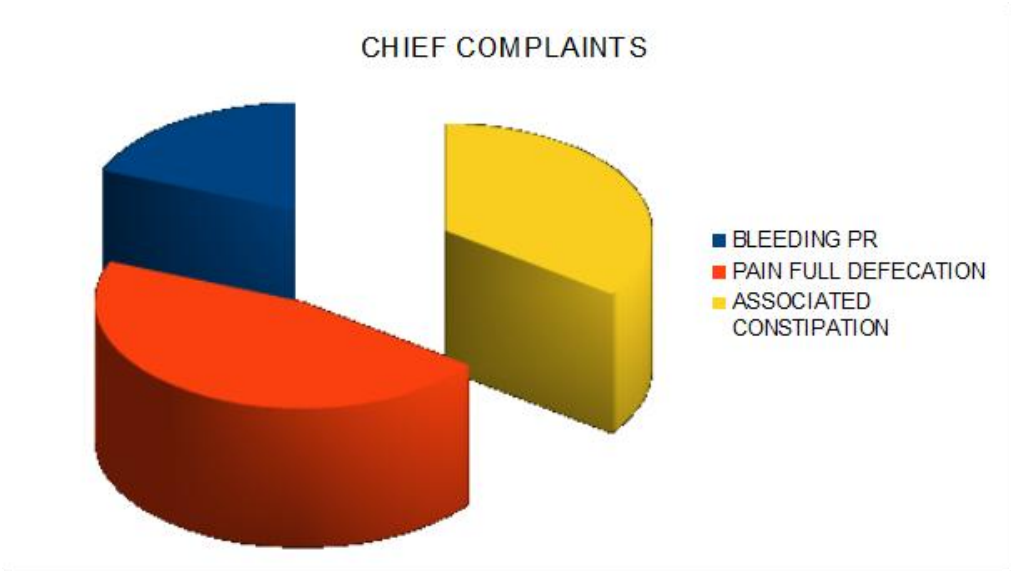

TABLE 3: CHIEF/ PRESENTING COMPLAINTS

CHIEF COMPLAINT	NO OF PATIENTS
BLEEDING PR	14
PAIN FULL DEFECATION	34
ASSOCIATED CONSTIPATION	26

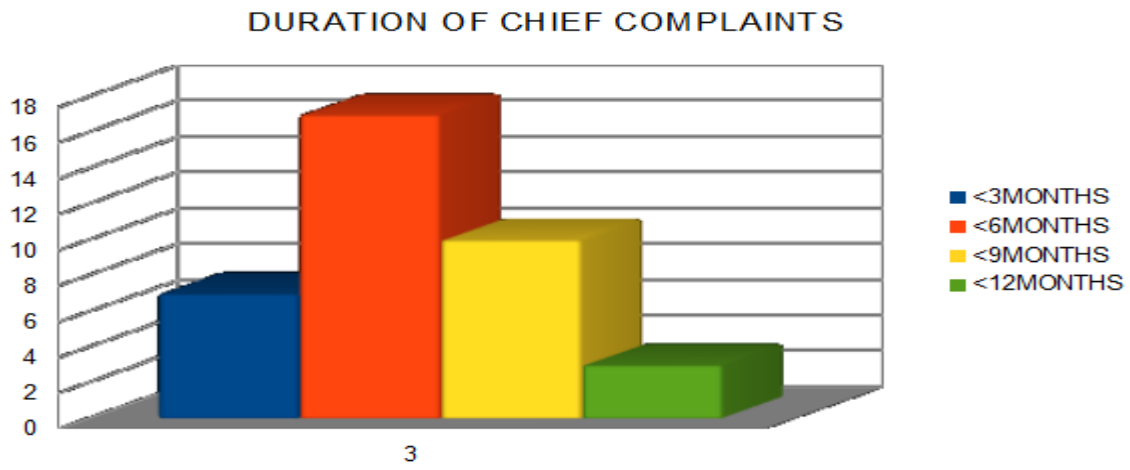

TABLE 4: DURATION OF COMPLAINTS

<1MONTH	<3MONTHS	<6MONTHS	<9MONTHS	<12MONTHS
3	**7**	**17**	**10**	**3**

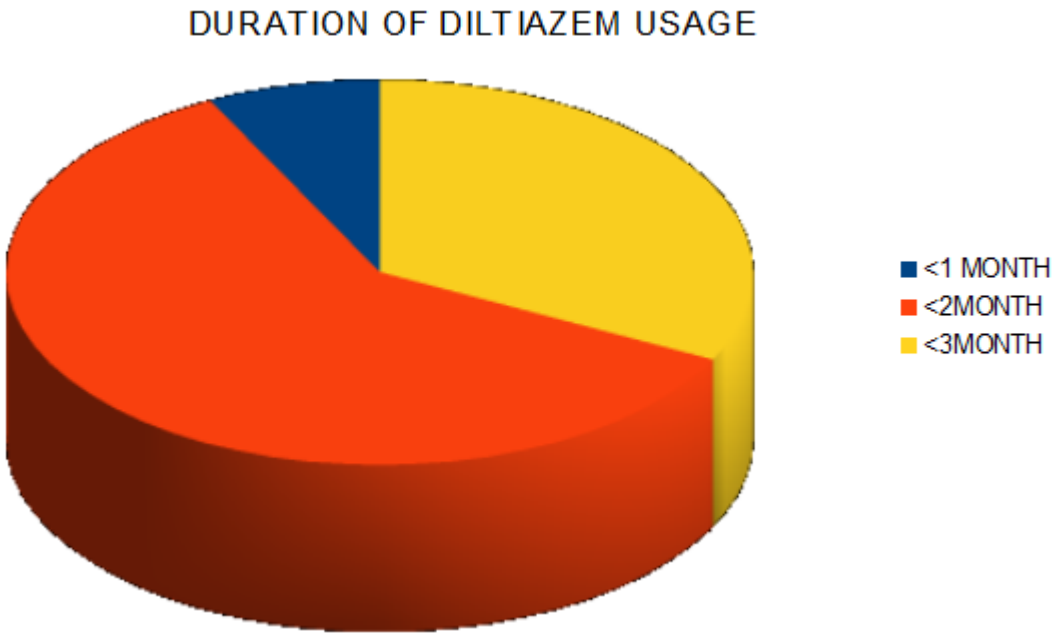

TABLE 5: DURATION OF DILTIAZEM USAGE

DURATION IN MONTHS	NO OF PATIENTS
<1 MONTH	**3**
<2MONTH	**24**
<3MONTH	**13**

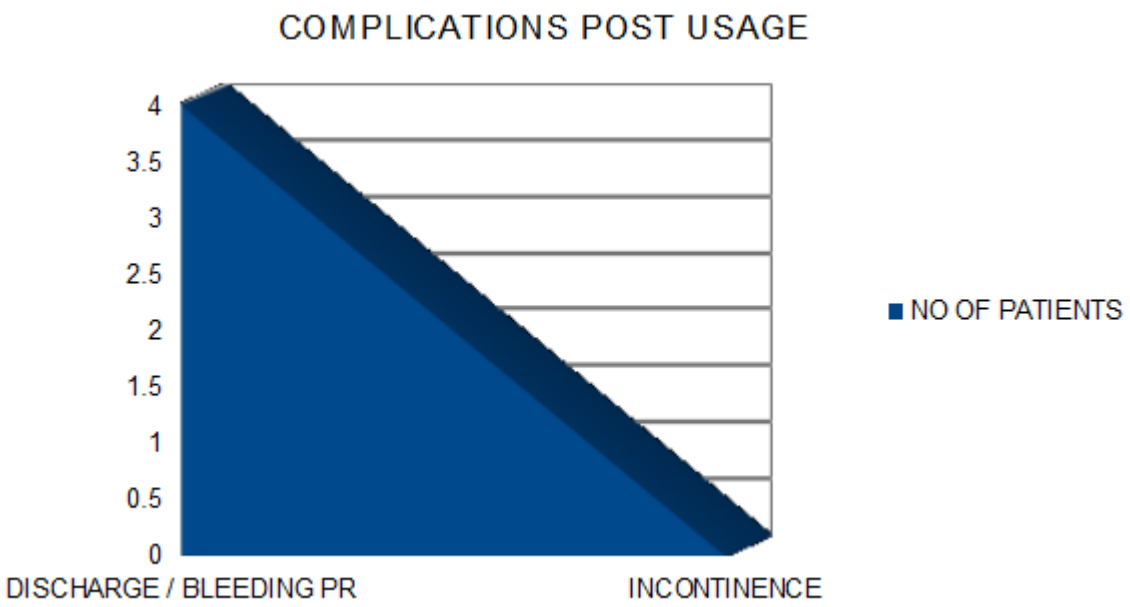

TABLE 6: COMPLICATIONS POST DILTIAZEM USAGE

COMPLICATIONS	NO OF PATIENTS
DISCHARGE / BLEEDING PR	4
INCONTINENCE	0

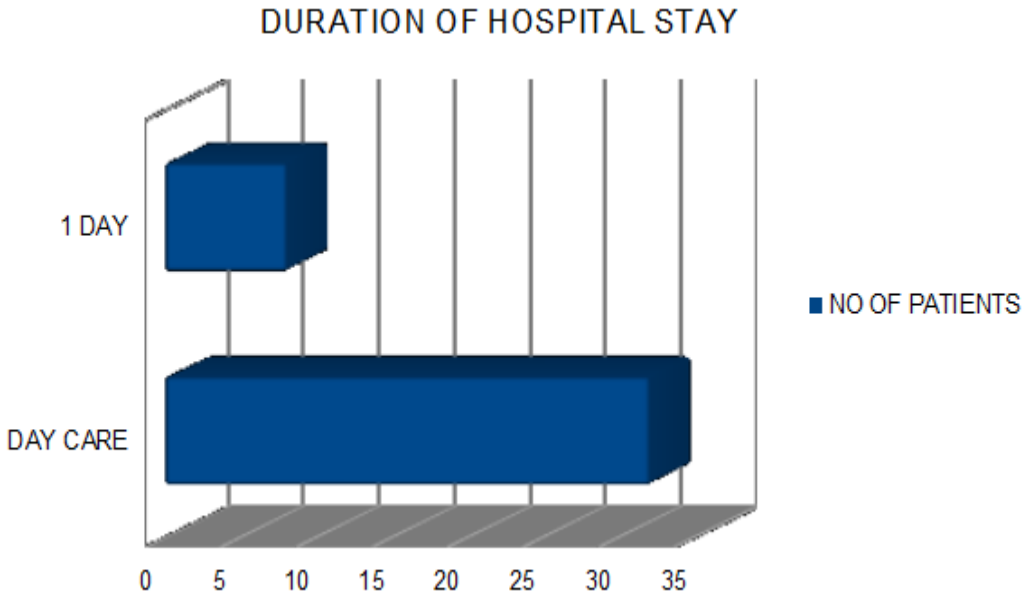

TABLE 7: DURATION OF HOSPITAL STAY

DURATION IN DAYS	NO OF PATIENTS
DAY CARE	32
1 DAY	8

RESULTS OF GROUP 2 : LATERAL SPINCHTEROTOMY

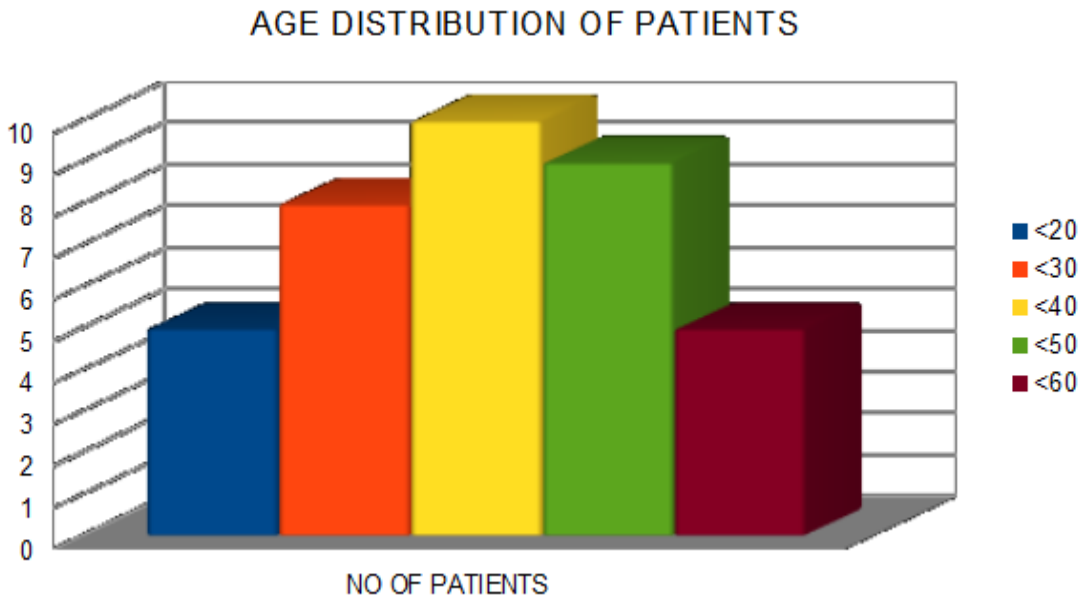

TABLE 8: AGE DISTRIBUTION OF PATIENTS

AGE IN YEARS	<20	21-30	31-40	41-50	51-60
NO OF PATIENTS	5	8	10	9	5

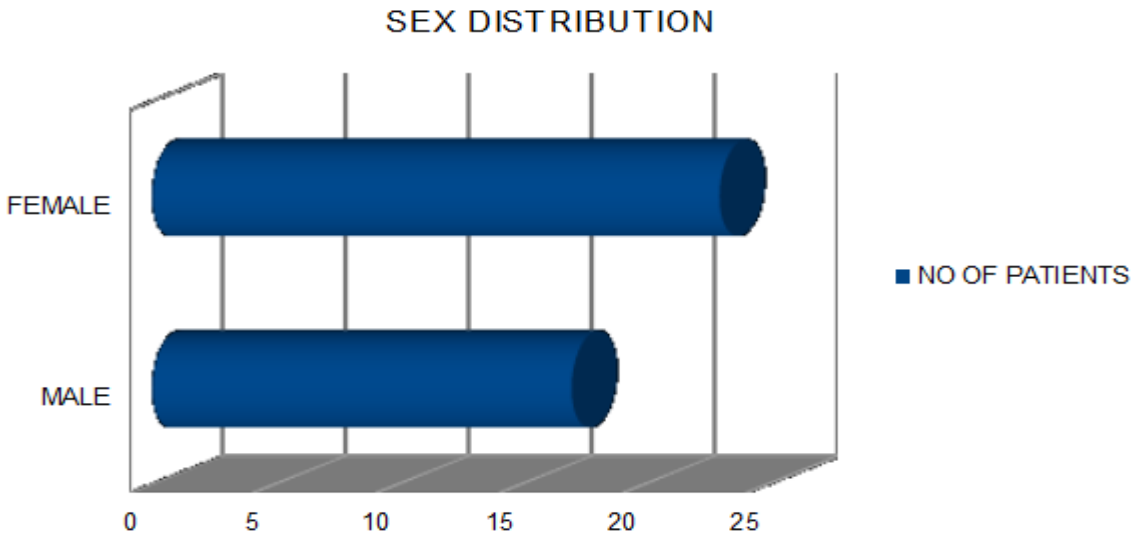

TABLE 9: SEX DISTRIBUTION

SEX DISTRIBUTION	NO OF PATIENTS
MALE	17
FEMALE	23

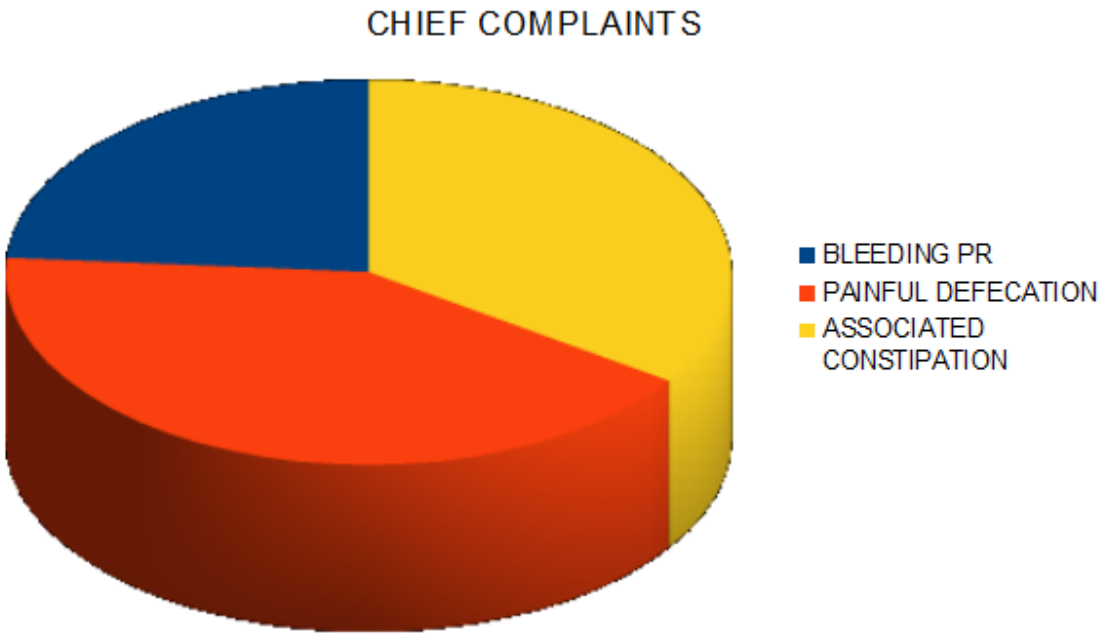

TABLE 10: CHIEF PRESENTING COMPLAINTS

CHIEF PRESENTING COMPLAINTS	NO OF PATIENTS
BLEEDING PR	20
PAINFUL DEFECATION	35
ASSOCIATED CONSTIPATION	29

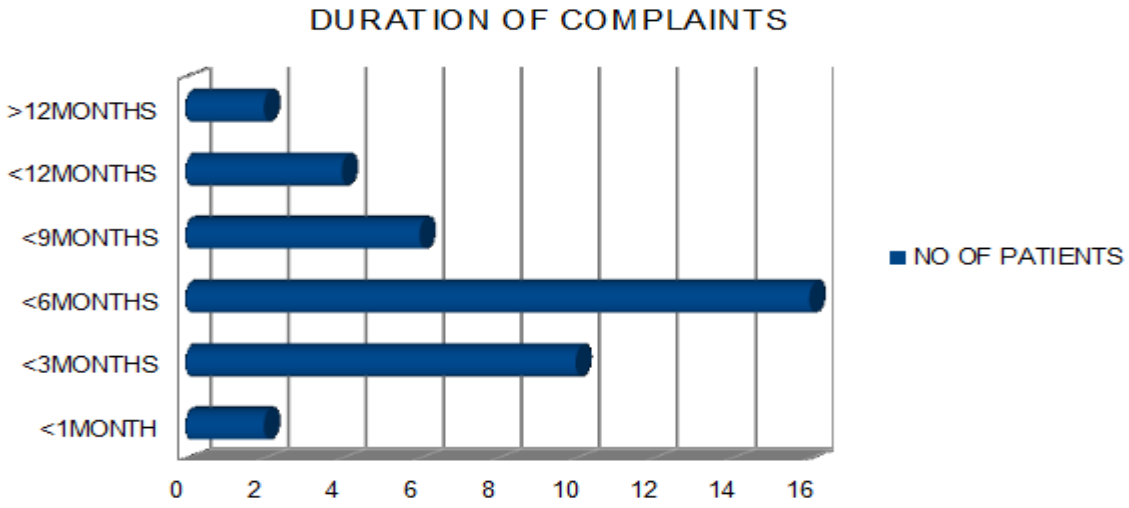

TABLE 11: DURATION OF COMPLAINTS

DURATION IN MONTHS	NO OF PATIENTS
<1MONTH	2
<3MONTHS	10
<6MONTHS	16
<9MONTHS	6
<12MONTHS	4
>12MONTHS	2

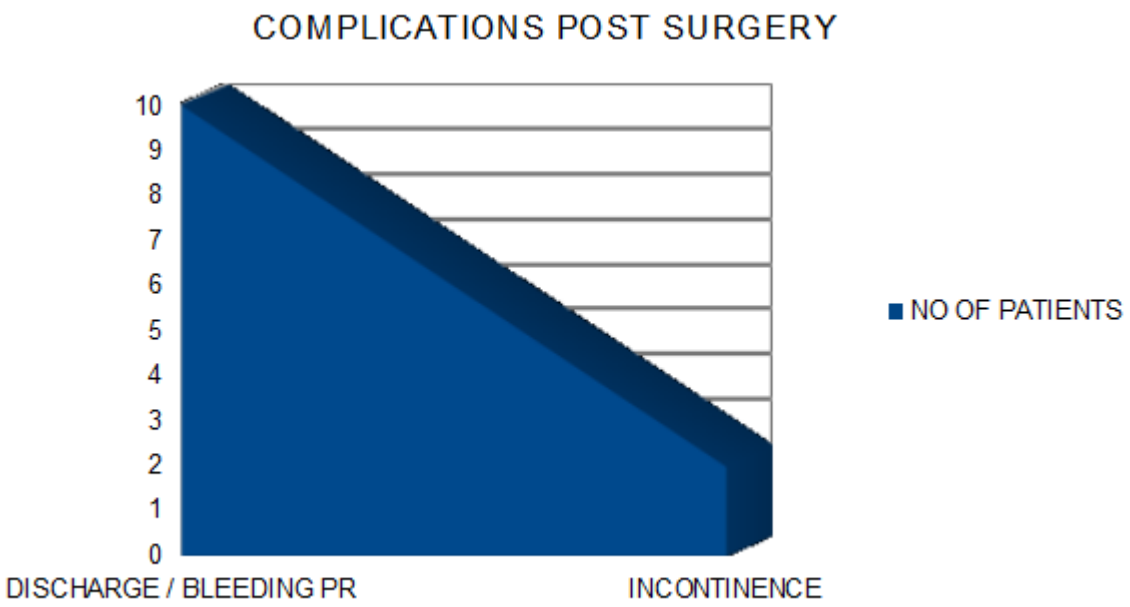

TABLE 12: COMPLICATIONS POST SURGERY

COMPLICATIONS	**NO OF PATIENTS**
DISCHARGE / BLEEDING PR	**10**
INCONTINENCE	**2**

V. RESULTS

In this study 80 patients were taken, they were divided into 2 groups 40 each. Group 1 were treated with 2% diltiazem gel for twice daily topical application and group 2 underwent lateral spinchterotomy. There were 15 males and 25 females with a male to female ratio of 1:1.6 in group 1 where as in group 2 males are 17 and females are 23 giving the male:female ratio 1:1.35. The study showed that most (42.5%) of the patients were in the age group of 31-40 years in group 1 which included 15% males and 27.5% females in the group. 32.5% of patients were in the 21-30 years age group, 15% in 41-50 years age group and 2.5% in 11-20 years ,5% in 51-60 years age groups,and 2.5% in >60 years.

The mean age of occurrence of fissure is 34.92years ,in males was 36.93 years and in females33.8 years with a standard deviation of 11.8and 8.9respectively.

Table 13 showing standard deviation and mean of males of group 1

Sample Standard Deviation males, s	11.822899491282
Variance (Sample Standard), s^2	139.78095238095
Population Standard Deviation, σ	11.4220060507
Variance (Population Standard), σ^2	130.46222222222
Total Numbers, N	15
Sum:	554
Mean (Average):	36.933333333333

Table 14 showing standard deviation and mean of females of group 1

sample Standard Deviation females, s	8.9256185593306
Variance (Sample Standard), s^2	79.666666666667
Population Standard Deviation, σ	8.7452844436302
Variance (Population Standard), σ^2	76.48
Total Numbers, N	25
Sum:	845
Mean (Average):	33.8

All the patients included in the study group had painful defecation which was the most common symptom 86.25%. This was followed by constipation and bleeding per anum in 68.75% and 42.5% of the patients respectively.

The occurrence of posterior anal fissure was noted to be 88.75%Anterior anal fissure was noted in 2.5% of male and 8.75% of female patients. Sentinel pile was present in 37.5% of the patients.

Out of the 40 patients who underwent treatment with 2% Diltiazem gel (Group 1), fissures in 37 patients (92.5%) healed completely between 4-8weeks. Of the 40 patients who underwent LIS (Group 2), 40 patients (100%) had complete resolution at the end of 4 weeks.

As noted in Table 3, in Group 1 , 14 (35%) patients were pain-free at the end of 2 weeks. An additional of 19 (47.5%) patients were free of pain by 4 weeks and 4 (10%) more patients by 6 weeks. 3 patients (7.5%) were not relieved of pain even at the end of 6 weeks. In Group 2, 24 patients were relieved of pain by 2 weeks and all the patients were relieved of pain by 6weeks time.

Table 15:

Pain relief	Diltiazem group		LIS group	
	No.	%	No.	%
At the end of 2 weeks	14	35	24	60
At the end of 4 weeks	19	47.5	12	30
At the end of 6 weeks	04	10	4	10
No relief	03	7.5	-	-
Table 15: Pain relief				

The chi-square statistic is 5.0125.
The p-value is 0.025164. This result is significant at $p < .05$.

Table 16:

Healing	Diltiazem group		LIS group	
	No.	%	No.	%
At the end of 2 weeks	12	30	8	20
At the end of 4 weeks	18	45	12	30
At the end of 6 weeks	07	17.5	19	47.5
No healing	03	7.5	1	2.5
Table 16: Healing				

The chi-square statistic is 5.3333.
The p-value is 0.020921. This result is significant at $p < .05$.

Table 17:

Bleeding	Diltiazem group		LIS group	
	No.	%	No.	%
At the end of 2 weeks	15	37.5	18	45
At the end of 4 weeks	16	40	16	40
At the end of 6 weeks	09	22.5	6	15
Persistant bleeding	00	0	00	0
Table 17: Bleeding				

The chi-square statistic is 0.7385.
The p-value is 0.390154. This result is not significant at $p < .05$.

Of the 40 patients that were followed up in the Diltiazem group, 3(7.5%) patients experienced mild headache and local irritation was present in 5 (12.5%) patients (Table 4).Out of the 40 patients that were followed up in the LIS group, 14(35%) patients experienced post-operative pain and transient incontinence for flatus was present in 2 (5%) patient ,Bleeding (n=3, 7.5%).

Recurrence was seen in 3(7.5%) patient in the Diltiazem group and none in the LIS group.

GROUP 1 - Diltiazem gel (n=40)	GROUP 2 – LIS (n=40)
Headache (n=3, 7.5%)	Post-operative pain (n=14, 35%)
Local irritation (n=5, 12.5%)	Incontinence for flatus (n=2, 5%)
giddiness (n=0)	Bleeding (n=3, 7.5%)
	Discharge (n=6 , 15%)
Table 18: Complications in individual study groups	

Comparison between Diltiazem gel therapy and internal sphincterotomy showed a difference in pain relief ($P<0.025$) and fissure healing ($P= 0.020$) which is statistically significant.but there was no significance regarding bleeding ($p=0.39$) as both are showing similar results**.**

VI. DISCUSSION

Fissure-in-ano is a very common problem across the world which causes considerable morbidity and affects the patient's quality of life to a great extent. This warrants prompt treatment of the condition with appropriate methods.

The rationale of treating this condition lies in reducing the internal anal sphincter tone, relieving the spasm and thereby improving the circulation. Of the surgical modalities available, the gold standard procedure is lateral internal sphincterotomy (LIS) wherein there is partial division of the internal anal sphincter away from the fissure site.

Chemical sphincterotomy, which is a medical line of treatment, has now been accepted as the first line of treatment of anal fissures at various centers. As per various previous studies, diltiazem has been found efficacious in the treatment of chronic anal fissure. Studies showed that oral intake and topical applications of diltiazem reduced the anal pressure significantly.

In the present study, a comparative analysis of topical application of 2% diltiazem gel and LIS was done with regards to efficacy, adverse effects and complications in patients with anal fissure.

The current study included a total of 80 patients of anal fissure who presented to the surgery OPD at Tertiary Care Teaching Hospital between september 2014 and november 2016. The patients were randomly allocated into two groups of chemical (Group 1) and surgical (Group 2) sphincterotomy, comprising 40 patients each.

Patients with complaints of painful defecation with or without bleeding per rectum were labelled as fissure-in-ano and considered for this study. Patients were advised local application of 2% diltiazem gel twice a day, for a period of 6 weeks in group 1 and taken up for lateral internal sphincterotomy in group 2. They were adequately followed up at regular intervals and the final data was analyzed according to the proforma sheets.

In the present study, the age group most affected was 31-40 years (42.5%) and least affected was 11-20 and >60 years (2.5%). According to J.C. Goligher[12] the disease is usually encountered in middle aged adults. In UdwadiaT.E[13] series maximum incidence was seen in 31-40 years age group. There was female preponderance (60%) compared to males (40%) in our study.

In our analysis, painful defecation was a universal and the most common symptom (86.25%). This was followed by constipation and bleeding per anum in 68.75% and 42.5% of the patients respectively. Local pruritis was present in 10% of the patients and discharge per anum noted in 7.5% of the study group.

The presence of posterior anal fissure was noted to be 93.75% (30 out of 32 patients) in males and 83.3% (40 out of 48 patients) in females. The overall incidence of posterior anal fissure was found to be 87.5 % making it the most common site involved. Anterior anal fissure was noted in 6.25% of male and 16.6% of female patients. The incidence of concomitant anterior and posterior fissure-in-ano was seen in 4.34% and 4.16% of males and females respectively. This is in conjunction with the study from Boulos[14] which says posterior fissure (85.7%) is more common than anterior fissure (14.2%).

Another observation made in the study was regarding the sentinel pile which was present in 37.5% of the patients**.**

Out of 40 patients who underwent treatment with 2% Diltiazem gel, 37 (92.75%) fissures healed completely between 4-6 weeks, while 3 patients had recurrance.

In group 2, out of 40 patients who underwent internal sphincterotomy, 40 (100%) patients healed completely at the end of 4-6 weeks

In the diltiazem group, 14(35 %) patients were pain-free at the end of 2 weeks, 19 (47.5%) by 4 weeks and 4(10%) were pain free by 6 weeks. 3 patients (7.5%) were not relieved of pain even at the end of 6 weeks. Fissure was completely healed in 37 (92.5%) out of 40 patients by 6 weeks. Study (Table III) conducted by J. S. Knight[15] et al (2001) reported a healing rate of 75% after 8-12 weeks treatment with Diltiazem gel. U. K. Srivastava[16] (2007) reported a healing rate of 80% with Diltiazem gel in 12 weeks.

Studies	Number of patients	Healing rate (%)
Knight et al [15] (2001)	66	89.4
Bharadwaj et al [17](2000)	27	73
Kocher et al [18](2002)	31	67
Srivastava et al [16](2007)	90	80
Present study	37	92.5
Table 19: Comparison of results with Diltiazem		

In the LIS group, 24 patients were pain-free by 2 weeks and all the patients were free of pain by 6weeks time. Fissure was completely healed in 40 (100%) out of 40 patients by 6 weeks. Scouten W.R. et al[19] reported pain relief in 98% of cases after undergoing internal sphincterotomy. Adriano Tocchhi et al[5] (2004) reported a healing rate of 100% with internal sphincterotomy at the end of 6 weeks post-sphincterotomy review.

In our study, out of the 40 patients that were followed up in the Diltiazem group, 3(7.5%) patients experienced mild headache and local irritation was present in 5(12.5 %) patients. Study conducted by U. K. Srivastava reports no side effects in patients treated with Diltiazem gel.[16]

In a study conducted by G. F. Nash et al [20] 112 patients were treated with 2% Diltiazem gel for 6 weeks and were followed up over 2 years. The success rate and satisfaction of topical Diltiazem were each over two thirds. Nearly 80% of patients reported no adverse effects.

Of the 40 patients that were followed up in the LIS group 14(35%) patients experienced post-operative pain and transient incontinence for flatus was present in 2(5%) patient. Adriano Tocchhi et al. report no long-term complication after internal sphincterotomy and patient satisfaction was 96%.[5]

Recurrence was seen in 3(7.5%) patient in the Diltiazem group and none in the LIS group.

Comparison between Diltiazem gel therapy and internal sphincterotomy showed a difference in pain relief ($P<0.025$) and fissure healing ($P= 0.020$) which is statistically significant.but there was no significance regarding bleeding ($p=0.39$) as both are showing similar results.

The follow up period available after successful treatment with Diltiazem gel was short and therefore no long term conclusions could be drawn. Long term follow up is needed to assess the risk of recurrence after initial healing with Diltiazem gel therapy.

Studies	Number of patients	Healing rate
Jensen et al [21] (1984)	--	100
Evans et al [22] (2001)	65	97
Wiley et al [23] (2004)	79	97
Present study	37	92.5

Table 20 : Comparison of results with LIS

VII. CONCLUSION

The current study shows results in favor of 2% diltiazem gel local therapy with a healing rate of 92.5% and a faster pain-relief with minimal complications. However, LIS is effective in the treatment of recurrent/ not responding to medical treatment fissure-in-ano. Though there is latency in the clearance of symptoms and lesions when compared to surgical sphincterotomy, this has shown minimal and insignificant adverse effect profile. Topical diltiazem can be safely prescribed for patients having contraindications for surgical procedures. The healing rate of the fissure is much slower compared to surgery but the need for hospital stay is abolished and it also reduces the psychological as well as financial burden on the patient. With a healing rate close to 92.5 %, topical 2% Diltiazem therapy can be easily advised as the first line of treatment for anal fissure

Anal fissure is a common problem. The pathophysiology is based on high sphincter pressures and management is generally aimed toward reducing anal pressures. Anal fissures can generally be treated with conservative management/ pharmacologic management with topical calcium channel blockers, with minimal side effects and good cure rates. Lateral internal sphincterotomy remains the gold standard for definitive management of anal fissures, but comes with a risk of incontinence. Open or closed techniques can be used with similar healing and complication rates. Anal stretch should be abandoned in the management of anal fissure. Particular attention must be paid to anterior anal fissures as they are typically associated with low anal pressures. These patients should undergo anorectalmanometery testing preoperatively. Those patients with sphincter hypotonia who fail conservative management should undergo advancement anoplasty. However, recent data suggests that lateral internal sphincterotomy may be tolerated well in these patients when conservative management fails**.**

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