IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 22, Issue 7 Ser.7 (July. 2023), PP 21-33
www.iosrjournals.org

"Effectiveness of Calcium Channel Blockers as Local Ointment Vs Lateral Sphincterotomy in the Treatment of Chronic Fissure in Ano"

Dr. P. Manikandan, M.S., Dr. R. Karthikeyan,M.S.,
1(Assistant Professor of General Surgery, Government Medical College Hospital, Karur /The T.N.M.G.R University India)
2(Assistant Professor of General Surgery, Government Medical College Hospital, Karur /The T.N.M.G.R University India)

Abstract:
An anal fissure is a linear ulcer of the lower half of the anal canal.
It is classified into two types :
1. Acute fissure in ano
2. Chronic fissure in ano
Acute fissures are those presenting within three to six weeks of onset of symptoms. Chronic fissures are those presenting after six weeks of onset of symptoms. Acute fissure usually presents with tearing or burning discomfort during defecation. They are usually self healing. Chronic fissures are more persistent and relapsing compared to acute fissures. Acute fissures are usually managed medically. Most effective drugs are calcium channel blockers, either orally or topically . Chronic fissures are managed either medically or surgically, by means of lateral sphincterotomy. The present study has compared the effectiveness of calcium channel blockers as local ointments (2% Diltiazem cream) and lateral sphincterotomy in the treatment of chronic fissure in ano. The percentage of symptomatic relief in patients suffering from chronic fissure in ano after the usage of 2% diltiazem cream and lateral sphincterotomy were analysed at first , second and third month after initiation of therapy.
With results we conclude that Lateral sphincterotomy is more effective than using calcium channel blockers as local ointments in the treatment of chronic fissure in ano

Background:
A fissure in ano is a tear in the anoderm distal to the dentate line. It is one of the most common painful condition of perianal region. It occurs following trauma, passage of hard stools or prolonged diarrhea. It is classified into acute and chronic fissure depending upon the duration of symptoms. 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 the development of a poorly healing wound that becomes a chronic fissure.
Therapy focuses on breaking the cycle of pain, spasm and ischemia thought to be responsible for development of fissure in ano. It can be either medical or surgical. There are various chemical agents used for relaxing the tone of internal anal sphincter. Of these, calcium channel blockers (2% Diltiazem) as local ointments are used in this study because of its better healing rate and least side effects. Gold standard surgical treatment for chronic fissure in ano is lateral internal sphincterotomy. Many patients prefer a conservative approach to this condition by using 2% Diltiazem cream when compared to surgical approach by lateral internal sphincterotomy. Hence, the present study has been designed keenly taking into consideration the percentage of symptomatic relief after both the techniques as the primary objective.

Materials and Methods:
This study has been conducted in Government Karur Medical College & Hospital , Karur with the patients suffering from chronic fissure in ano attending the surgical OPD. Ethical committee approval was obtained prior as per protocol. Present study includes 50 Patients of chronic fissure in ano treated during January 2022 to January 2023.

Results:
This study compares the effectiveness of calcium channel blockers as local ointments and lateral sphincterotomy in the treatment of chronic fissure in ano. In this study it was observed that Lateral internal sphincterotomy in comparison with calcium channel blocker ointments is superior in relieving symptoms like pain , constipation , bleeding perrectum , Itching and has improved fissure healing . Thus this study concludes that Lateral internal sphincterotomy is more effective in the treatment of chronic fissure in ano than local alcium channel blocker ointments (2%Diltiazem) . Hence, Lateral sphincterotomy can be offered as a permanent cure for the patients diagnosed with chronic fissure in ano than the conservative approach using medical therapy.

Conclusion:
Fissure in ano is a common problem today, due to unhealthy sedentary life style and decreased consumption of fiber. Most patients present with chronicity of symptoms. Two main treatment approach for this conditions include calcium channel blockers used as local ointments (2% Diltiazem cream) or surgical treatment with Lateral internal sphincterotomy.This study compares the effectiveness of calcium channel blockers as local ointments and lateral sphincterotomy in the treatment of chronic fissure in ano. In this study it was observed that Lateral internal sphincterotomy in comparison with calcium channel blocker ointments is superior in relieving symptoms like pain , constipation , bleeding per rectum , Itching and has improved fissure healing .Thus this study concludes that Lateral internal sphincterotomy is more effective in the treatment of chronic fissure in ano than local alcium channel blocker ointments (2%Diltiazem) . Hence, Lateral sphincterotomy can be offered as a permanent cure for the patients diagnosed with chronic fissure in ano than the conservative approach using medical therapy

---

Date of Submission: 08-07-2023 Date of Acceptance: 18-07-2023

I. Introduction :

A fissure in ano is a tear in the anoderm distal to the dentate line. It is one of the most common painful condition of perianal region. It occurs following trauma, passage of hard stools or prolonged diarrhea. It is classified into acute and chronic fissure depending upon the duration of symptoms. A tear in the anoderm causes spasm of the internal an al sphincter, which results in pain, increased tearing and decreased blood supply to the anoderm. This cycle of pain, spasm and ischemia contributes to the development of a poorly healing wound that becomes a chronic fissure.

Therapy focuses on breaking the cycle of pain, spasm and ischemia thought to be responsible for development of fissure in ano. It can be either medical or surgical. There are various chemical agents used for relaxing the tone of internal anal sphincter. Of these, calcium channel blockers (2% Diltiazem) as local ointments are used in this study becauseof its better healing rate and least side effects. Gold standard surgical treatment for chronic fissure in ano is lateral internal sphincterotomy. Many patients prefer a conservative approach to this condition byusing 2% Diltiazem cream when compared to surgical approach by later alinternal sphincterotomy. Hence, the present study has been designed keenly taking into consideration the percentage of symptomatic relief after both the techniques as the primary objective.

II. Material And Methods :

This study has been conducted in Government Karur Medical College & Hospital , Karur with the patients suffering from chronic fissure inano attending the surgical OPD. Ethical committee approval was obtained prior as per protocol. Present study includes 50 Patients of chronic fissurein ano treated during January 2022 to January 2023.

Study Design:
Prospective study
Study Location:
Government Karur Medical College & Hospital, Karur.
Study Duration:
January 2022 to January 2023
Sample size:
50 cases

Sample size calculation:
50 Patients included in the study are divided into two groups .
1. Group A (25 patients)
2. Group B (25 patients)

Subjects & selection method:
1. Group A (25 patients) - were subjected to use Calcium channel blocker ointment locally for treating chronic fissure in ano.
2. Group B (25 patients) - were subjected for surgical procedure, Lateral internal Sphincterotomy for treating chronic fissure in ano. All patients were followed at First , Second and Third month
respectively after both procedures. All patients were analyzed for % of symptomatic relief during each month.

Inclusion criteria:
The patients admitted to various surgical wards in Government Karur Medical College & Hospital as

CHRNIC FISSURE IN ANO (Symptoms more than 6 weeks) .

Exclusion criteria:

1. Patients not willing to use local calcium channel blocker ointments
2. Patients not willing for surgery (Lateral sphincterotomy)
3. Patients not fit for surgery .

Procedure methodology :

All patients were analyzed for % of symptomatic relief during each month. It can be split up as follows :

1. Relief from pain - 20%
2. Relief from constipation - 20%
3. Relief from Bleeding PR - 20%
4. Relief from Itching / others - 20%
5. Amount of fissure healing - 20 %

out of 100 is calculated for all Patients in both the groups during first, second and third months. Results were analyzed. For pain assessment , all Patients were given with a pain scoring chart and instructed to mark the level of pain in it daily . Average is taken during each month. Scoring given for No pain - 20% . Mild pain - 15% . Moderate pain - 10% . Severe pain - 5% . Worst pain - 0% Relief from Bleeding PR can be assessed as Nil bleed-20% ,streaks of blood with stool occasionally- 15% , Obvious blood in stools occasionally- 10%, obvious blood in stools most of the time- 5%, Blood alone passed- 0%. Amount of Fissure Healing is assessed visually .All collected data will be analyzed and conclusions derived .

Statistical analysis :

The collected data were analyzed with IBM. SPSS statistics software 23.0 Version. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in Independent groups the Unpaired sample t-test was used. For the multivariate analysis of repeated measures the Repeated measures of ANOVA was used with Bonferroni correction to control the type I error on multiple comparison. In all the above statistical tools the probability value .05 is considered as significant level.

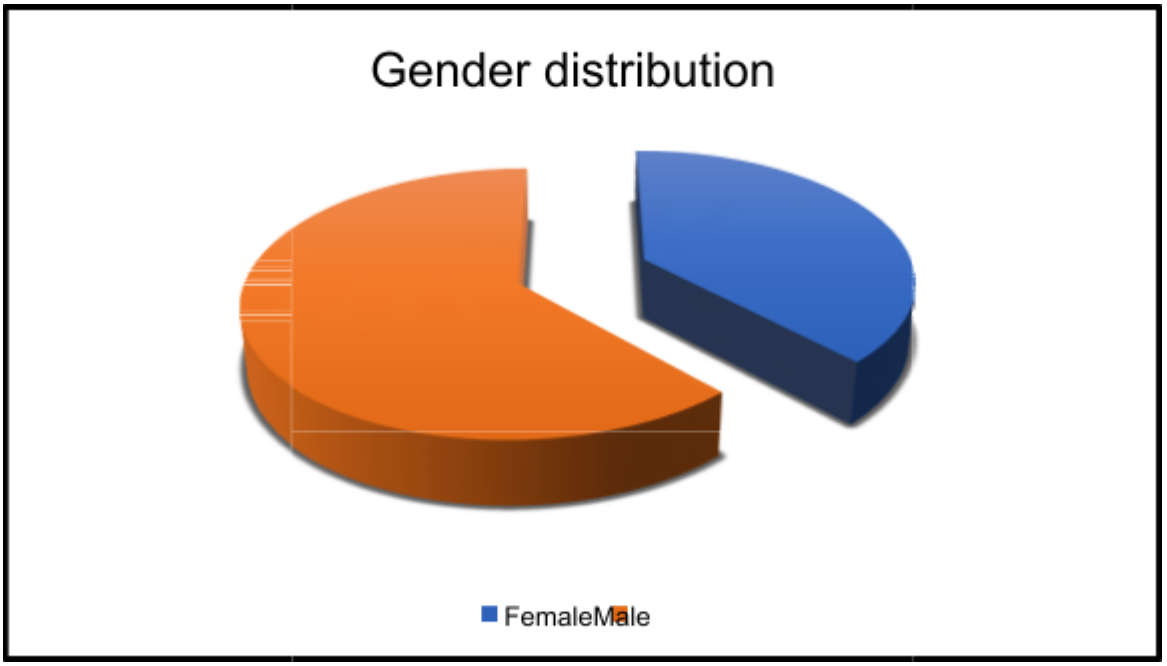
P-Vlue	**HighlySignificantatP≤.01

AGE

		Frequency	Percent
Valid	Upto30yrs	8	16.0
	31 -40yrs	23	46.0
	41 -50yrs	15	30.0
	Above50yrs	4	8.0
	Total	50	100.0

SEX

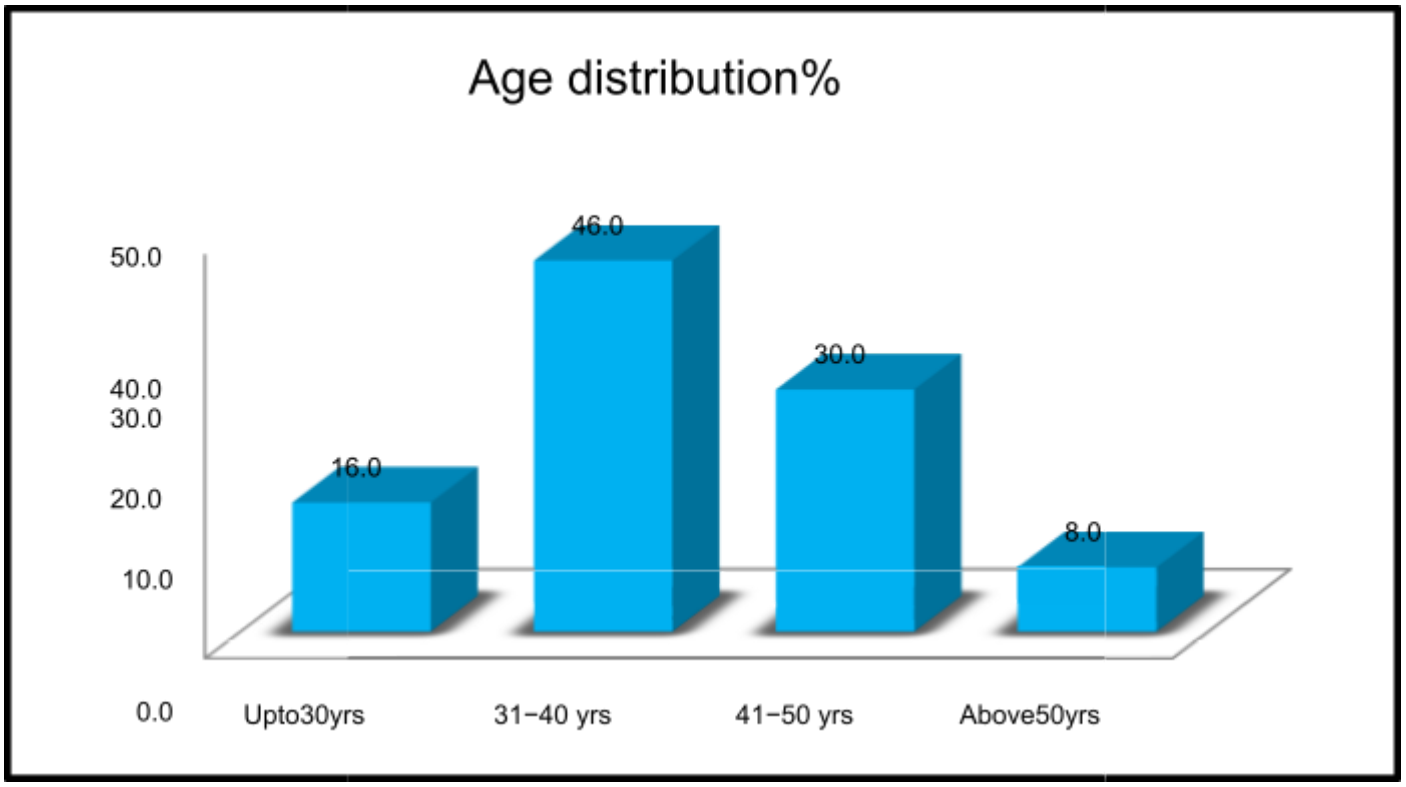
	Frequency	Percent
Female	**19**	**38.0**
Male	**31**	**62.0**
Total	**50**	**100.0**



50 Patients included in the study are divided into to groups.

GroupA (25patients)-were subjected to use **Calcium channel blocker** ointment topically for treating chronic fissure in ano.

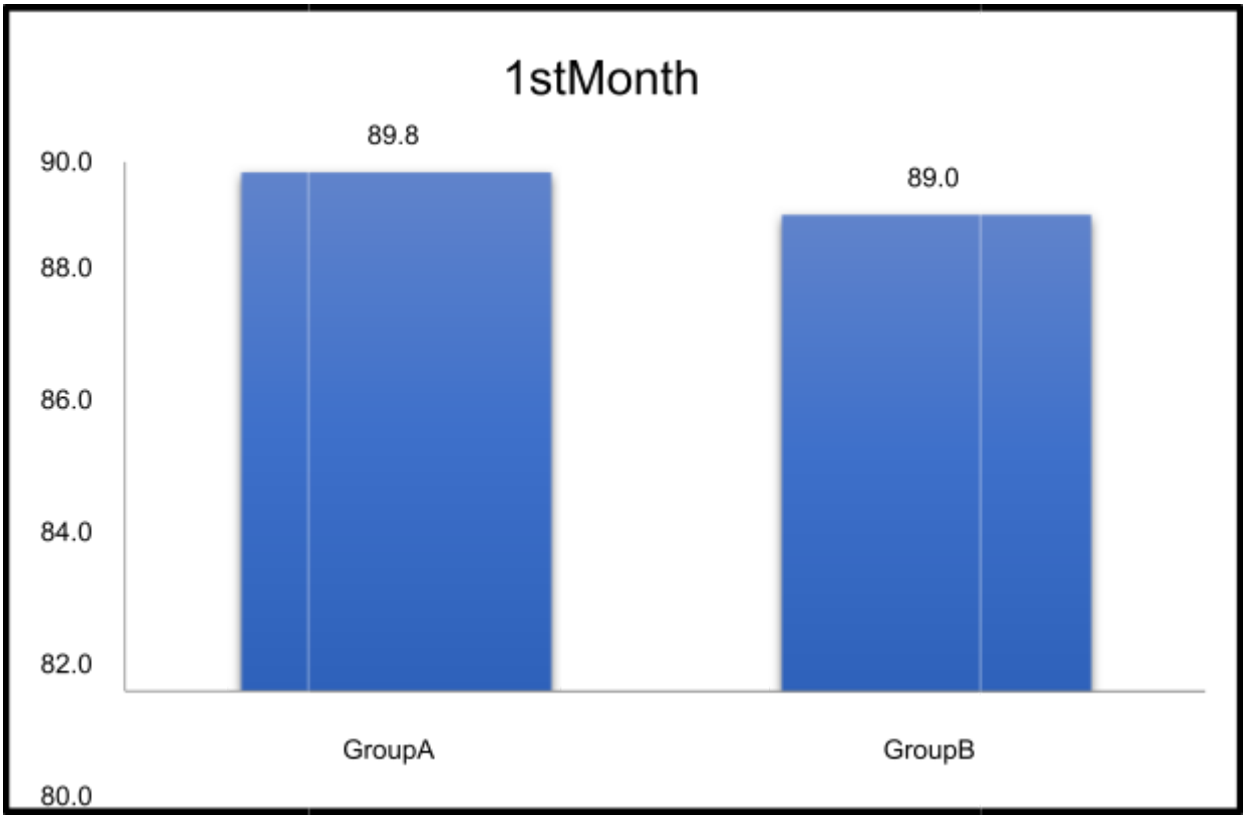
GroupB (25patents)-were subjected for surgical procedure,**Lateral internal Sphincterotomy** for treating chronic fissure in ano.

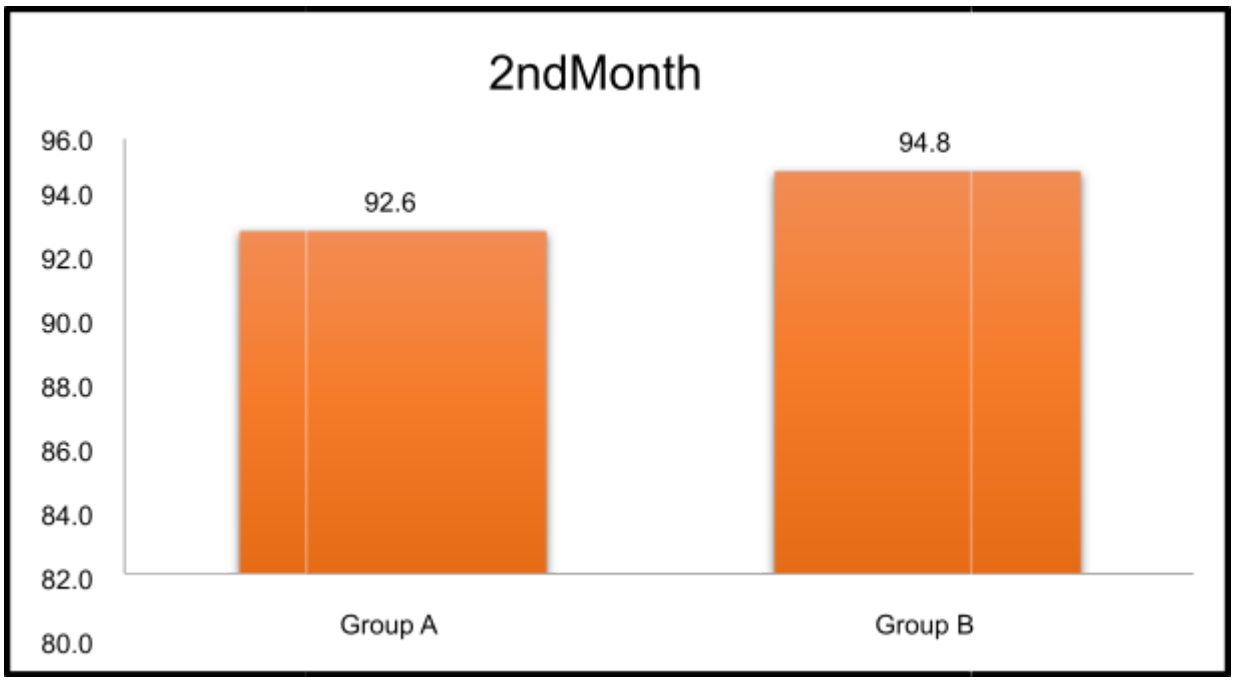


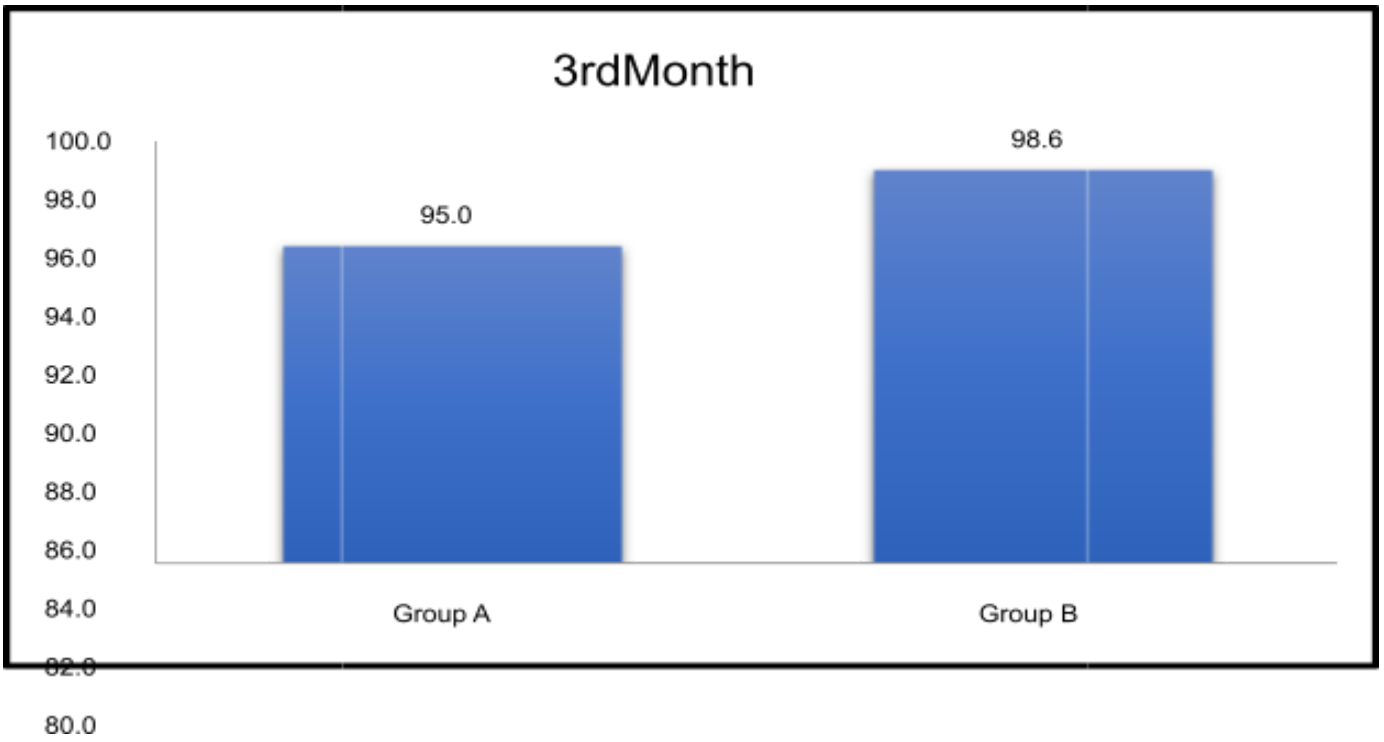
T TEST

Group Statistics

Groups		N	Mean	Std. Deviation	Std. Error Mean
1st Month	GroupA	25	89.8	4.203	.841
	GroupB	25	89.0	4.787	.957
2nd Month	GroupA	25	92.6	4.592	.918
	GroupB	25	94.8	3.055	.611
3rd Month	GroupA	25	95.0	4.330	.866
	GroupB	25	98.6	2.291	.458


1stMonth
89.8
89.0
90.0
88.0
86.0
84.0
82.0
80.0
GroupA
GroupB


2ndMonth
92.6
94.8
96.0
94.0
92.0
90.0
88.0
86.0
84.0
82.0
80.0
Group A
Group B



Descriptives

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
AGE	50	26	55	38.08	7.480
ValidN (list wise)	50				

GENERAL LINEAR MODEL

Within-Subjects Factors Measure: MEASURE_1

Groups	Dependent Variable
1	M1
2	M2
3	M3

Independent Samples Test										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std .Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
1st Month	Equal variances assumed	1.490	.228	.628	48	.533	.800	1.274	-1.762	3.362
	Equal variances not assumed			.628	47.210	.533	.800	1.274	-1.763	3.363
2nd Month	Equal variances assumed	6.210	.016	-1.995	48	.052	-2.200	1.103	-4.418	.018
	Equal variances not assumed			-1.995	41.767	.050	-2.200	1.103	-4.426	.026
3rd Month	Equal variances assumed	3.851	.056	-3.674	48	.001	-3.600	.980	-5.570	-1.630
	Equal variances not assumed			-3.674	36.463	.001	-3.600	.980	-5.586	-1.614

Group s= Group A

Descriptive Statistics [a]

	Mean	Std. Deviation	N
1st Month	89.8	4.203	25
2nd Month	92.6	4.592	25
3rd Month	95.0	4.330	25

a. Groups = Group

Mauchly'sTest of Sphericity[a,]

Measure:MEASURE_1

Within Subjects Effect	Mauchly'sW	Approx. Chi-Square	df	Sig.	Epsilon[c]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
Groups	.933	1.591	2	.451	.937	1.000	.500

Tests the null hypothesis that the error covariance matrix of theorthonormalized transformed dependent variables is proportional to an identitymatrix.

a. Groups= Group A

b. Design: Intercept
Within Subjects Design: Groups

c. May be used to adjust the degrees of freedom for the averaged tests of significance. Corrected tests are displayed in the Tests of Within-Subjects Effects table.

Tests of Within- Subjects Effects [a]						
Measure:MEASURE_1						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Groups	SphericityAssumed	338.667	2	169.333	45.663	.000
	Greenhouse-Geisser	338.667	1.875	180.649	45.663	.000
	Huynh-Feldt	338.667	2.000	169.333	45.663	.0005
	Lower-bound	338.667	1.000	338.667	45.663	.000
Error(Groups)	SphericityAssumed	178.000	48	3.708		
	Greenhouse-Geisser	178.000	44.993	3.956		
	Huynh-Feldt	178.000	48.000	3.708		
	Lower-bound	178.000	24.000	7.417		
a.Groups= GroupA						

Estimated Marginal Means

Groups

Estimates [a]

Measure:MEASURE_1

Groups	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
1	89.800	.841	88.065	91.535
2	92.600	.918	90.705	94.495
3	95.000	.866	93.213	96.787

a. Groups= Group A

Pair wise Comparisons[a]

Measure: MEASURE_1

(I) Groups		Mean Difference(I-J)	Std. Error	Sig.[c]	95% Confidence Interval for Difference[c]	
					Lower Bound	Upper Bound
1	2	-2.800*	.507	.0005	-4.104	-1.496
	3	-5.200*	.611	.0005	-6.773	-3.627
2	1	2.800*	.507	.000	1.496	4.104
	3	-2.400*	.510	.0005	-3.712	-1.088
3	1	5.200*	.611	.000	3.627	6.773
	2	2.400*	.510	.000	1.088	3.712

Based on estimated marginal means

*.Themeandifferenceissignificantatthe.05level.

a. Groups= Group A

c. Adjustment for multiple comparisons : Bonferroni.

Groups= Group B

Descriptive Statistics[a]

	Mean	Std. Deviation	N
1st Month	89.0	4.787	25
2nd Month	94.8	3.055	25
3rd Month	98.6	2.291	25

a. Groups = Group B

Mauchly's Test of

Sphericity[a,b]Measure:MEASURE_1

Within Subjects Effect	Mauchly'sW	Approx. Chi-Square	df	Sig.	Epsilon[c]		
					Greenhouse-Geisser	Huynh-Feldt	Lower-98.6
Groups	.752	6.547	2	.038	.801	.850	.500

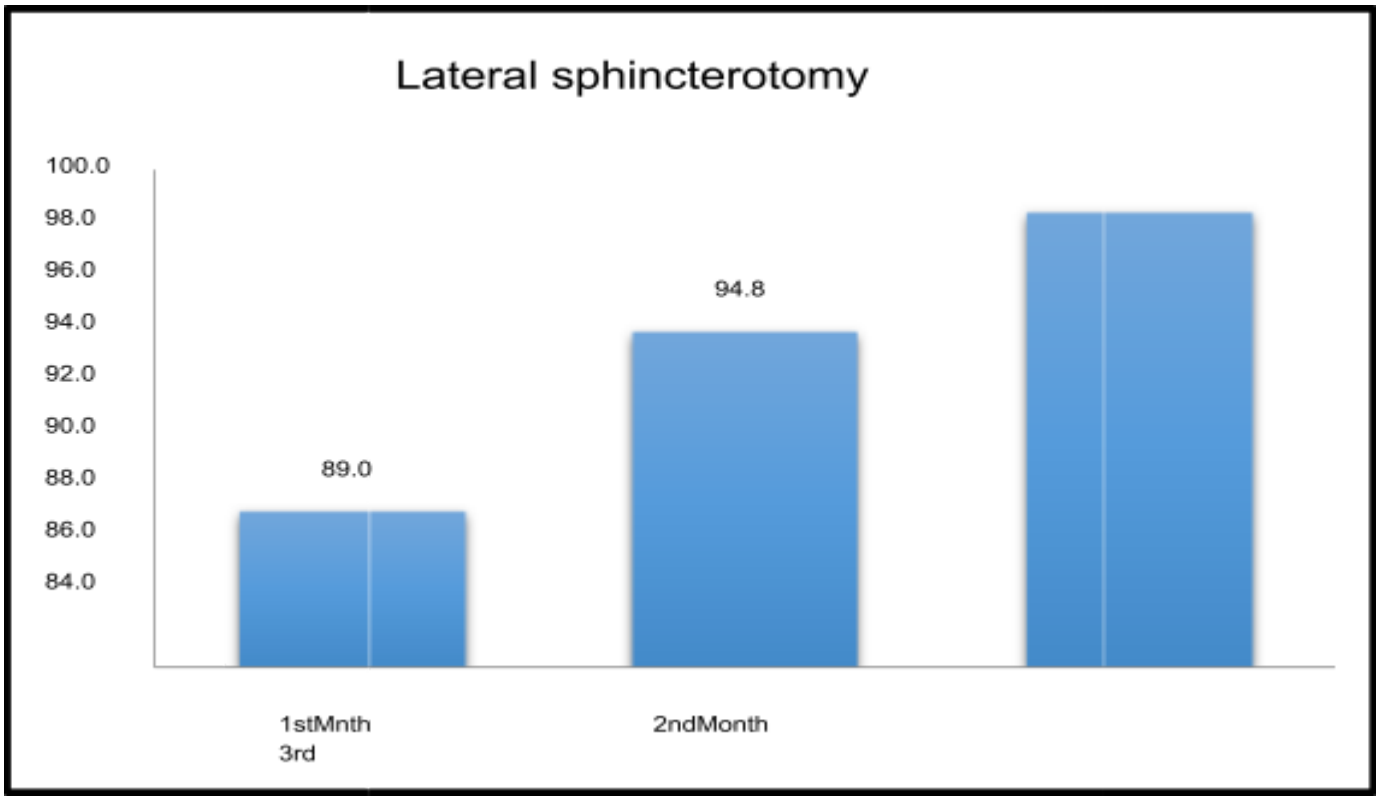
Tests the null hypothesis that the error covariance matrix of theorthonormalized transformed dependent variables is proportional to an identity matrix.

a. Groups=Group B

b. Design: Intercept
Within Subjects Design : Groups

c. May be used to adjust the degrees of freedom for the averaged tests of significance.

Corrected tests are displayed in the Tests of Within-Subject Effects table.



Tests of Within- Subjects Effects [a]						
Measure:MEASURE_1						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Groups	Sphericity Assumed	1168.667	2	584.333	130.658	.000
	Green house-Geisser	1168.667	1.603	729.081	130.658	.000
	Huynh-Feldt	1168.667	1.700	687.482	130.658	.0005
	Lower-bound	1168.667	1.000	1168.667	130.658	.000
Error(Groups)	Sphericity Assumed	214.667	48	4.472		
	Green house-Geisser	214.667	38.470	5.580		
	Huynh-Feldt	214.667	40.798	5.262		
	Lower-bound	214.667	24.000	8.944		
a. Groups =Group B						

III. Result :

The collected data were analyzed with IBM. SPSS statistics software 23.0 Version. To describe about the data descriptive statistics frequency analysis, percentage analysis were used for categorical variables and the mean & S.D were used for continuous variables. To find the significant difference between the bivariate samples in Independent groups the Unpaired sample t-test was used. For the multivariate analysis of repeated measures the Repeated measures of ANOVA was used with Bonferroni correction to control the type I error on multiple comparison. In all the above statistical tools the probability value .05 is considered as significant level.

IV. Discussion :

This study compares the effectiveness of calcium channel blockers as local ointments and lateral sphincterotomy in the treatment of chronic fissure in ano. In this study it was observed that Lateral internal sphincterotomy in comparison with calcium channel blocker ointments is superior in relieving symptoms like pain , constipation , bleeding perrectum , Itching and has improved fissure healing .Thus this study concludes that Lateral internal sphincterotomy is more effective in the treatment of chronic fissure in ano than local alciumchannel blocker ointments (2%Diltiazem) .Hence, Lateral sphincterotomy can be offered as a permanent cure for the patients diagnosed with chronic fissure in ano than the conservative approach using medical therapy.

V. Conclusion :

Fissure in ano is a common problem today, due to unhealthy sedentary life style and decreased consumption of fiber. Most patients present with chronicity of symptoms. Two main treatment approach for this conditions include calcium channel blockers used as local ointments (2% Diltiazem cream) or surgical treatment with Lateral internal sphincterotomy. This study compares the effectiveness of calcium channel blockers as local ointments and lateral sphincterotomy in the treatment of chronic fissure in ano. In this study it was observed that Lateral internal sphincterotomy in comparison with calcium channel blocker ointments is superior in relieving symptoms like pain , constipation , bleeding per rectum , Itching and has improved fissure healing.Thus this study concludes that Lateral internal sphincterotomy is more effective in the treatment of chronic fissure in ano than local calcium channel blocker ointments (2%Diltiazem) .Hence, Lateral sphincterotomy can be offered as a permanent cure for the patients diagnosed with chronic fissure in ano than the conservative approach using medical therapy

References :

[1]. Dykes SL, Madoff RD. Benign Anorectal: Anal Fissure. In: Wolff BG, Fleshman JW, Beck DE, Pemberton JH, Wexner SD, et al.,editors. The ASCRS textbook of colon and rectal surgery. New York: Springer Science and Business Media LLC; 2007. pp. 178–191.

[2]. Nyam DC, Pemberton JH. Long-term results of lateral internal sphincterotomy for chronic anal fissure with particular reference toIncidence of fecal incontinence. Dis Colon Rectum. 1999; 42:1306–1310.

[3]. Hyman N. Incontinence after lateral internal sphincterotomy: a prospective study and quality of life assessment. Dis Colon Rectum. 2004;47:35–38.

[4]. Nelson RL. Epidemiology of fecal incontinence. Gastroenterology. 2004;126:S3–S7

[5]. Brown CJ, Dubreuil D, Santoro L, Liu M, O'Connor BI, McLeod RS.Lateral internal sphincterotomy is superior to topical nitroglycerin for healing chronic anal fissure and does not compromise long-term fecalcontinence: six-year follow-up of a multicenter, randomized, controlled trial. Dis Colon Rectum. 2007;50:442–448.

[6]. Barton J. Nitroglycerin and Lidocaine topical treatment for anal fissure. Nat ClinPract Gastroenterol Hepatol. 2002:April.

[7]. Lund JN, Scholefield JH. Aetiology and treatment of anal fissure. Br J Surg. 1996;83:1335–1344.

[8]. Soybel DI. What causes anal fissure? Gastroenterology. 1996;111:1154–1155.

[9]. Farouk R, Duthie GS, MacGregor AB, Bartolo DC. Sustained internal sphincter hypertonia in patients with chronic anal fissure. Dis Colon Rectum. 1994;37:424–429.

[10]. Littlejohn DR, Newstead GL. Tailored lateral sphincterotomy for anal fissure. Dis Colon Rectum. 1997;40:1439–1442.

[11]. Pitt J, Dawson PM, Hallan RI, Boulos PB. A double-blind randomizedplacebo-controlled trial of oral indoramin to treat chronic anal fissure.Colorectal Dis. 2001;3:165–168.

[12]. Ho KS, Ho YH. Randomized clinical trial comparing oral nifedipinewith lateral anal sphincterotomy and tailored sphincterotomy in the Treatment of chronic anal fissure. Br J Surg. 2005;92:403–408.

[13]. Nelson R. Non surgical therapy for anal fissure. Cochrane Database Syst Rev. 2006;18:CD003431.

[14]. Carapeti EA, Kamm MA, McDonald PJ, Chadwick SJ, Melville D,Phillips RK. Randomised controlled trial shows that glyceryl trinitrate heals anal fissures, higher doses are not more effective, and there is a high recurrence rate. Gut. 1999;44:727–

[15]. Sileri P, Stolfi VM, Franceschilli L, Grande M, Di Giorgio A, D'UgoS, Attina' G, D'Eletto M, Gaspari AL. Conservative and surgical treatment of chronic anal fissure: prospective longer term results. J Gastrointest Surg. 2010;14:773–780.

[16]. Schubert MC, Sridhar S, Schade RR, Wexner SD. What every gastroenterologist needs to know about common anorectal disorders.World J Gastroenterol. 2009;15:3201–3209

[17]. Madalinski M. To predict and understand anal fissure healing. Int JColorectal Dis. 2011;26:263.

[18]. Madalinski M, Chodorowski Z. Our view on fissure healing should be verified. Dis Colon Rectum. 2006;49:414–415.

[19]. Bassenge E. Endothelial function in different organs. Prog Cardiovasc
Dis. 1996;39:209–228.

[20]. Patel CA, Rattan S. Cellular regulation of basal tone in internal analsphincter smooth muscle by RhoA/ROCK. Am J PhysiolGastrointest Liver Physiol. 2007;292:G1747–G1756.

[21]. Essler M, Linder S, Schell B, Hüfner K, Wiedemann A, Randhahn K,Staddon JM, Aepfelbacher M. Cytotoxic necrotizing factor 1 of Escherichia coli stimulates Rho/Rho-kinase-dependent myosin lightchain phosphorylation without inactivating myosin light-chain phosphatase in endothelial cells. Infect Immun. 2003;71:5188–5193.15.Sileri P, Stolfi VM, Franceschilli L, Grande M, Di Giorgio A, D'UgoS, Attina' G, D'Eletto M, Gaspari AL. Conservative and surgicaltreatment of chronic anal fissure: prospective longer term results. J Gastrointest Surg. 2010;14:773–780

[22]. Watts EJ, Rose MT. Platelet-derived growth factor acts via both theRho-kinase and p38 signaling enzymes to stimulate contraction in an in vitro model of equine wound healing. DomestAnim Endocrinol.2010;38:253–259.

[23]. Martinez-Ramos D, Nomdedeu-Guinot J, Artero-Sempere R, EscrigSos J, Gibert-Gerez J, Alcalde-Sanchez M, Salvador-Sanchis JL.
Prospective study to evaluate diagnostic accuracy in benign analdiseases in primary care. Aten Primaria. 2009;41:207–212.

[24]. Grucela A, Salinas H, Khaitov S, Steinhagen RM, Gorfine SR,Chessin DB. Prospective analysis of clinician accuracy in the diagnosis of benign anal pathology: comparison across specialties andyears of experience. Dis Colon Rectum. 2010;53:47.

.