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RESEARCH ARTICLE

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A COMPARATIVE STUDY BETWEEN EFFICACY OF TOPICAL NIFEDIPINE APPLICATION AND LATERAL SPHINCTEROTOMY IN CHRONIC FISSURE IN ANO

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Abstract- Background: Anal fissure, is a common condition in the proctological disorders. In 1829 Recaimer was the first one to describe this condition. It is a tear in the anoderm vertically occurred in the anal canal between the dentate line and the anal opening. It causes painful defecation, bleeding, and sphincter spasm.They can occur in all age groups, majorly in young people, with male preponderance. Most anal fissures are acute and heal by their own or with high fibre diet, stool softeners. Anal fissures which present for more than six weeks are called as CHRONIC ANAL FISSURES. In present study there is comparison of the use of topical nifedipine and lateral internal sphincterotomy in the treatment of chronic anal fissures in terms of efficacy in healing and complications.

Methods: This is A comparative study between efficacy of topical nifedipine application and lateral sphincterotomy in chronic fissures in ano which was conducted in SVRRGGH, TIRUPATHI for duration of 1 year from approval of Institutional Ethics Committee. For this study, cases presenting to the surgery OPD of all units of the Department of General Surgery with complaints like painful defecation with or without bleeding per rectum for more than 6 weeks are considered. To diagnose chronic anal fissure, a brief history is taken and a per-rectal examination is performed. Systemic and fundamental investigations were carried out. Patients are randomly assigned to either chemical or surgical sphincterotomy. Chemical sphincterotomy entails applying nifedipine gel to the anal sphinter reg three times per day for eight weeks. Lateral InternalSphincterotomy is the surgical treatment option. In the follow-up patients underwent per rectal examination, to assess the efficacy

of the treatment and the complications associated with the treatment and the results were compared between the two groups.

Results: My study includes 100 patients admitted in SVRRGGH, TIRUPATHI and after informed and written consent and after thorough explanation of the procedure and its advantages and disadvantages the patients had undergone treatment. In my study from the above results we can conclude that lateral sphincterotomy is superior to nifedipine application in terms of symptomatic relief and healing and recurrence and it can be safely preferred as treatment of choice for early healing of fissures in medically fit patients. More prospective trials are needed to compare the full efficacy and complications in healing of chronic anal fissure with nifedipine and to safely prescribed as an alternative to surgical method.

Conclusion: In the present study it shows that results are towards the surgical method that is lateral sphincterotomy with a healing rate of 100% along with speedy recovery and pain-relief with minimal or no complications. Though local application of nifedipine is as effective as lateral sphincterotomy in the treatment of chronic fissure-in-ano there is delay in the relief of symptoms and lesions compared to internal sphincterotomy, with an insignificant adverse effects. Topical nifedipine can be safely prescribed for patients who are unfit or unwilling for surgical procedures. Though there is latency in healing rate compared to surgery but the necessity for hospital stay is removed and it also decrease in the psychological as well as financial burden on the patient. With a healing rate near to 90%, topical nifedipine therapy can be easily advised as the first line of treatment for chronic anal fissure. By comparing the above two modalities of treatment for chronic anal fissure, we can conclude that Lateral sphincterotomy appears to be the betterline of treatment as there is 100% healing rate with almost nil complications.

Key words- Chronic Fissure in Ano, Nifedepine, Lateral Sphincterotomy.

INTRODUCTION

Proctological disorders are problems that have affected mankind since history. They contain different conditions which make considerable discomfort for patients. Most of the people (30-40%) suffers with these problems in their life[1].

Anal fissure, a common condition in these disorders. In 1829 Recaimer[2] was the first one to describe this condition. It is a tear in the anoderm vertically occurred in the anal canal between the dentate line and the anal opening. It causes painful defecation, bleeding, and sphincter spasm.They can occur in all age groups, majorly in young people, with male preponderance. Most anal fissures are acute and heal by their own or with high fibre diet, stool softeners. Anal fissures which present for more than six weeks are called as CHRONIC ANAL FISSURES.

A chronic anal fissure is usually deeper and usually has exposedinternal sphincter fibres at its base. It is associated with a hypertrophied papilla superiorly and a sentinel tag inferiorly. Internal sphincter spasm is present in painful fissures. The resting pressure of the internal sphincter and the external sphincter complex, maintains continence. Similar to involuntary muscles of the colon and rectum, the internal sphincter fibres spasm involuntarily. This involuntary spasm in response to injury to the exposed subcutaneous tissue of the fissure causes the severe pain associated with anal fissure disease. Chronic anal fissures occur due to increased resting pressure in the anal canal due to hypertonicity of the internal sphincter, and treatment is therefore aimed at its elimination. Surgical techniques such as manual anal dilatation or lateral internal sphincterotomy heal most fissures within a few weeks, but may result in permanently impaired anal continence. This has led to the exploration of alternative, nonsurgical treatments, and thus "chemical sphincterotomy" came into research in treating chronic anal fissures.

Topical nitroglycerin ointment is an efficient alternative but has limited use due to its side effects. Topical calcium channel blockers can be a suitable alternative for fissure treatment because they produce healing in 65-95% of cases with fewer side effects [3.]

In present study there is comparison of the use of topical nifedipine and lateral internal sphincterotomy in the treatment of chronic anal fissures in terms of efficacy in healing and complications.

AIM AND OBJECTIVES

AIM:

To compare the efficacy of topical nifedipine application with lateralsphincterotomy in chronic fissure in ano

OBJECTIVES:

1. To study the efficacy of topical nifedipine in chronic anal fissures.
2. To study the outcome in lateral sphincterotomy in chronic anal fissures.
3. To study the comparison of topical nifedipine with lateral sphincterotomy in chronic anal fissures.

MATERIALS AND METHODS

Type of Study: It is institution based Prospective Comparative Study
Study duration: One year from the scientific and Ethical committee approval.
Source of Data: The patients admitted in Department of General Surgery, S.V.R.RG.G. hospital.
Sample size: 100

Inclusion Criteria:

1. All patients who were diagnosed with chronic anal fissures (>6weeks).

Exclusion Criteria

1. Tuberculosis.
2. Haemorrhoides.
3. Immunocompromised patients.
4. Previous history of faecal incontinence.
5. Patients who have undergone previous anal surgeries.
6. Patients with history of bleeding diathesis.

Sample method

1. Data will be collected in standardized proforma from all the patients presenting to the Department of General surgery, S.V.R.R.G.G.H Tirupati.
2. Patients fulfilling the inclusion and exclusion criteria are selected.
2. Informed and written consent is taken from the patient and included in study.

OBSERVATION AND RESULTS

A) Age Distribution:

Table 1: Age distribution of patients

In the present study, majority i.e., 36% of the cases were in the age group of 31 – 40 years followed by 41-50 years (25%), 51-60 years (18%), 21- 30 years (14%) and 61-70 years (7%) age groups.

Age Group	Number	Percent
21 – 30 years	14	14%
31 – 40 years	36	36%
41 – 50 years	25	25%
51 – 60 years	18	18%
61 – 70 years	7	7%
Total	100	100%

B) Gender Distribution:

Table 2: Gender Distribution of patients In the present study, 61% of the cases were males and 39% o f thecases were females.

Sex	Number	Percent
Male	61	61%
Female	39	39%
Total	100	100%

C) Distribution of cases by site of Fissure in ano:

Table 3: In the present study, the site of fissure in ano was posterior in 95% of the cases and anterior in 5% of the cases.

Site of fissure in ano	Number	Percent
Anterior	5	5%
Posterior	95	95%
Total	100	100%

D) Distribution of cases by Symptoms:

Table 4: In the present study, painful defecation was seen in 100% of the cases followed by spasm in 94%, bleeding per rectum in 80%, sentinel pile in 66%, constipation in 62% and discharge in 9% of the cases.

Symptoms	Number	Percent
Painful defecation	100	100%
Spasm	94	94%
Bleeding per rectum	80	80%
Sentinel pile	66	66%
Constipation	62	62%
Discharge	9	9%
Note: percentages are mutually inclusive		

E) Distribution of cases by Treatment given:

Table 5: In the present study, 50% of the cases of chronic fissure in ano were treated with Nifedipine and 50% of the cases were treated by lateral sphincterotomy.

Treatment	Number	Percent
Nifedipine	50	50%
Lateral sphincterotomy	50	50%
Total	100	100%

F) Distribution of cases by Healing in weeks:

Table 6: In the present study, the healing time was between 5 – 8 weeks in 58%of cases followed by ≤4 weeks in 35% of the cases and >8 weeks in 7% of thecases.

Healing time	Number	Percent
≤4 weeks	35	35%
5 – 8 weeks	58	58%
>8 weeks	7	7%
Total	100	100%

G) Distribution of cases by Loss of Follow up:

Table 7: In the present study, 2% of the cases were lost to follow up.

Loss to follow-up	Number	Percent
Yes	2	2%
No	98	98%
Total	100	100%

H) Distribution of cases by Recurrence:

Table 8: In the present study, 3.1% of the cases had recurrence.

Recurrence	Number	Percent
Yes	3	3.1%
No	95	96.9%
Total	98	100%

I) Distribution of cases by Post Operative Complications and Symptomatic relief in Lateral Sphincterotomy Group:

Table 9: In the present study, in the lateral sphincterotomy group, post operative pain was seen in 78% of the cases, spasm was relieved in 100% of the cases and pain relief was seen in 100% of cases, post operative bleeding was seen in 14% of the cases. 0% incidence of infection and incontinence were seen in post operative period.

Post OP complications	Present		Absent	
	Number	Percent	Number	Percent
Post OP pain	39	78%	11	22%
Post OP bleeding	7	14%	43	86%
Infection	0	0%	50	100%
Incontinence	0	0%	49	100%
Spasm	0	0%	49	100%
Pain relief	49	100%	0	0%

J) Distribution of cases by Post Operative Complications and Symptomatic relief in Nifedepine Group:

Table 10: In the present study, the complications seen in Nifedipine group were local irritation in 12.2% of the cases respectively. Pain and spasm relief was seen in 91.8%, 8.2% of the cases respectively.

Complications	Present		Absent	
	Number	Percent	Number	Percent
Headache	0	0%	49	100%
Local irritation	6	12.2%	43	87.8%
Spasm relief	4	8.2%	45	91.8%
Pain relief	45	91.8%	4	8.2%

K) Distrubution of cases in Nifedepine group and Lateral Sphincterotomy group by Healing:

Table 11: In the present study, the duration of healing was 5 – 8 weeks in 83.7%,14.3% in >8 weeks and 2% in ≤4 weeks of the cases of Nifedipine group. The duration of healing was ≤4 weeks in 65.3% and 5 – 8 weeks in 34.7% of the cases in lateral sphincterotomy group. The difference was found to be statistically significant.

	Nifedipine		Lateral sphincterotomy	
Healing	Number	Percent	Number	Percent
≤4 weeks	1	2%	32	65.3%
5 – 8 weeks	41	83.7%	17	34.7%
>8 weeks	7	14.3%	0	0%

Total	49	100%	49	100%
Chi-square = 46.052, p = 0.001				

L) Distrubution of cases in Nifedepine group and Lateral Sphincterotomy group by Recurrence:

Table 12: In the present study, recurrence was seen in 6.1% of the cases in Nifedipine group and 0% cases in lateral sphincterotomy group and the difference was found to be statistically not significant.

Recurrence	Nifedipine		Lateral sphincterotomy	
	Number	Percent	Number	Percent
Yes	3	6.1%	0	0%
No	46	93.9%	49	100%
Total	49	100%	49	100%
Chi-square = 3.095, p = 0.079				

M) Distrubution of cases in Nifedepine group and Lateral Sphincterotomy group by Pain relief:

Table 13:

Pain relief	Nifedipine		Lateral sphincterotomy	
	Number	Percent	Number	Percent
Present	45	91.8%	49	100%
Absent	4	8.2%	0	0%
Total	49	100%	49	100%
Chi-square = 4.170, p = 0.041				

DISCUSSION

Age Distribution:

The data collected was analysed and compared between two groups. Coming to incidence, in present study out of 100 patients the most affected age group is 31-40 with 36 % followed by 41-50 years, 51-60 years agegroups with least affected age group being 61-70 yrs. In their studies of Goliger [3] and Udwadie T.E.[4] series the disease waspresent in middle age group involving 31-40 years age which was comparable to present study.

Gender distribution:

The incidence in males(61%) is more than that of females (39%) which is compared to previous studies of Bottcher[5] (1977), Perotti et al (2002) Shabbir Ahmed et al. The incidence of male prepondarence compared to females may be due to that more males approach health personnel seeking treatment compared to females especially in rural areas. There are some studies which are in contrast to present study in which according to Bennet and Golige (1962) incidence of anal fissures is equally common in males and females and in the study conducted by Lewis et. al (1988), Vafai and Mann (1987), Richard et .al (2000), Mentes et. al (2003), where the incidence is more in females compared to males[5].

Site of Fissure in Ano:

In symptomatic analysis, the present study contains painful defecation in main symptom in all the patients (100%) making it as most common symptom followed by spasm and bleeding per rectum (94%), (80%) of patients respectively. The site of fissure in present study was found to be posterior in about 98.3% (60 pts) in males and about 89.7% (35 pts) in females and overall incidence is 95% making it most common site involved. Anterior midlinefissure is present in 10.3% (4 pts) in females and 1.7% (1pt) in males. This is comparable to study of Boulus[6] in which posterior (85.7%) is more common than anterior (14.2%). Other studies having similarity with present study in site of

occurrence are Josh et. al (1991), Hasse et, al (2004), Bottcher (1977) in which majority of patients have posterior anal fissure[7].

Sentinal Tag:
Goligher (1975) found that ventrally located anal fissures are significantly more in females with ratio of (10:1). Contrary to above studies Farzanech Golfam et al. (2009) in their study found that incidence is more in anteriorthan posterior. The presence of sentinel tag indicates existence of chronic anal fissure. It is a secondary skin tag probably responsible due to local inflammation. It may be confused by inexperienced people as anal verge carcinoma. In the present study the no. of patients having sentinel tag is 66% indicating that it's presence can be taken as history of chronic anal fissure.

Healing rate with Nifedepine:
Coming to treatment results out of 50 patients in nifedipine group who were applied nifedipine ointment locally, fissure healed completely within 8 weeks in 41(82%) patients and with one person lost to followup. Complications of local irritation is seen in 6 (12.2%) iatients. Recurrence seen in 3 (6.1%) patients after 6 months. On comparing with previous studies by Antropoli et al (1999), Ezri and Susmallian (2003), Perrotti et al. (2002) , Katsinelos et al. (2006), Farzanech and Golfam et al. (2009) [8].

Complications and Recurrence with Nifedipine:
Healing rate in present study is less than Antropoi et al, Ezzri and Susmallian et al might be due to lack of compliance of treatment or less duration of follow up before healing occurs. Comparing the previous studies with recurrence rates, the presentstudy has recurrence in 3 patients at 6 months which is 6.1%, while the other studies have recurrence rates variable. While the complications occurred in present study is local irritation due to the drug applied, in other studies the other effects are headache ,flushing etc.

Symptomatic Relief with Nifedipine:
Symptomatic relief in the present study of nifedipine group seen , with relieving of sphincter spasm , seen in 45 patients which is 91.8% and the pain relief is seen in 45 patients which is 91.8% patients. On comparing with studies of nifedipine in chronic fissure in ano Farzanech Golfam et al in his study came out of results as 45 patients out of 110 patients which is 75% were relieved of pain and 42 out of 110 patients which is 60% had complete healing by 4 weeks with a recurrence rate of 26.19%. He also stated in his study that adding lignocaine with nifedipine lowers the sphincter tone and helps in faster relief of symptoms. Pasquale Perrotti in his study of 110 patients after 21 days of therapy there is relief of pain in 48 patients which is 87.3% and with a healing in 52 patients which is 94.5%. The results in terms of mean resting anal fissure comprises decrease of resting anal tone from 47.2 ± 14.6 mmHg to 42 ± 12.4 mmHg by 21 days with $p < 0.002$ with a mean reduction of 11 mmHg with recurrence in 3 patients. T A Cook et al in his study of 15 patients with chronic anal fissures and 8 healthy volunteers after oral nifedipine .In this study 20 mg of oral nifedipine is administered twice daily. The rate of fissure healing is assessedin following 8 weeks. Oral nifedipine showed reduction of maximum resting anal pressure about 35% after 5 days which was statistically significant. In 9 patients healing was complete after 8 weeks and 3 patients were not symptomatic. Among the study population 10 patients had flushing and 4 developed headaches. There are some studies where the mode of nifedipine action is through oral administration. An oral dose of 20 mg nifedipine is given daily and patients were monitored in terms of anal canal resting pressures. There is significant decrease in the anal canal resting pressures in healthy as well as anal fissure patients, but no decrease in squeeze pressures. Due to the natural effect of nifedipine there have been higher incidenceof increasing complications of cardiovascular system. Headache, flushing, peripheral edema are often noted in people treated with nifedipine making it unsuitable due to its high complication and low

healing rates. Thus from above it is confirmed that topical nifedipine application with low complication and higher healing rate is superior to oral nifedipine.

Healing rate with Lateral Sphincterotomy:
Coming to Lateral sphincterotomy group out of 50 patients involved, all of them had complete relief of symptoms such as pain, spasm, bleeding per rectum by 4 weeks with minimal complications of postoperative pain and bleeding. Of the 50 patients one lost to follow up. On comparing with previous studies with lateral sphincterotomy management such as Altomare et al (2005), Garcea et al. (2003), Jonas et al. (1999), Little John and new stead (1997), Madhusudan, the results are similar to present study with healing rates above 90%[9,10,11].

Complications with Lateral Sphincterotomy:
The immediate post op complications in lateral sphincterotomy group includes post op pain, bleeding, and also urinary retention in some individuals,which can be relieved by symptomatic treatment with pain killers , packingand foleys catheterisation. In present study there are no long term complications such as incontinence of flatus /stools, recurrence. But in some studies there are majority of sampled populations were suffered with incontinence in long term follow up though recurrence has not been noted.

Comparision Between Efficacy of Nifedepine and Lateral Sphincterotomy:
Out of 49 patients of nifedipine group, significant symptomatic relief of spasm and pain during defecation is seen in almost all patients with 91.8% of patient satisfaction with 4 patients being not relieved of pain. In lateral sphincterotomy group out of 49 patients the relief of spasm and pain during defecation is seen immediately within week in all the sampledpopulation with patient satisfaction of 100%. On comparing the two groups results and calculated with chi square test the p value is found to be 0.041 which is statistically significant.
Out of 49 patients of Nifedipine group, significant healing at the end of 8 weeks is seen in majority of patients with 85.7% of healing. In lateral sphincterotomy group out of 49 patients healing is seen within8weeks in all the sampled population with patient satisfaction of 100%. On comparing the two groups results and calculated with chi square test the p value is found to be 0.0001 which is statistically significant. **Sphincterotomy Versus Nifedipine** Ho and Ho in 2005 compared the results in two groups with 48 patients in lateral sphincterotomy and 41 patients with local application of 40 mg/ day daily for 6 weeks. The frequency of application of nifedipine ointment is three times daily. After 4 monthsfollow up results were compared. There was significantly more healing of anal fissures seen after surgery than chemical sphincterotomy. Prospective randomized trials comparing the effectiveness of Calcium channel blockers to Lateral Internal Anal Sphincterotomy in the treatment of anal fissures are not available. There is a good scope of research in this aspect because availability of various combination of chemical drugs. In a study by Katsinelos et al.[8] on comparing efficacy of 0.5% nifedipine application and lateral sphincterotomy there was complete healingin 96.7% patients in nifedipine group with 100% healing rate in lateral sphincterotomy group with more side effects in nifedipine group. Nifedipine has a higher rate of symptomatic relief and healing rate compared to other drugs with fewer and transient side effects but less than that of surgical treatment, and also there is recurrence in long term follow up even though it is statistically not significant.

CONCLUSION
In the present study it shows that results are towards the surgical method that is lateral sphincterotomy with a healing rate of 100% along with speedy recovery and pain-relief with minimal or no complications. Though local application of nifedipine is as effective as lateral sphincterotomy in the treatment of chronic fissure-in-ano there is delay in the relief of symptoms and lesions compared to internal sphincterotomy, with insignificant adverse effects. Topical nifedipine can be safely prescribed for patients who are unfit or unwilling for surgical procedures. Though there is latency in

healing rate compared to surgery but the necessity for hospital stay is removed and it also decrease in the psychological as well as financial burden on the patient. With a healing rate near to 90%, topical nifedipine therapy can be easily advised as the first line of treatment for the treatment of chronic anal fissure. By comparing the above two modalities of treatment for chronic anal fissure, we can conclude that Lateral sphincterotomy appears to be the betterline of treatment as there is 100% healing rate with almost nil complications.

REFERENCES

1. Corman M. Anal fissure. In: Corman M, ed. Colon and rectal surgery. Philadelphia, PA: Lippincott-Raven, 1998:206–23.
2. Kodner IJ, Fry RD, Fleshman JW, Birnbaum EH, Read TE. Colon, Rectum and Anus. In: Schwartz Seymour I, et al. Principles of Surgery.7th ed. Mac Grow- Hill, 1999: 1265-1382.
3. John Goligher. Surgery of the Anus, Rectum and Colon, AITBS, 5thEdition, 1992: 7.
4. Udwadia T.E., The prophylaxis of fissure in ano. Indian Journal of Surgery. 1978; 40(11): 560.
5. Wienert, Volker, et al. Anal Fissure : Symptoms, Diagnosis andTherapies. 1st ed., Cham, Switzerland, Springer, 2017, p. 12.
6. P.B. and Araujo J.G.C.34 (1984) Boulos P. B., Araujo J. G. C., Adequate internal sphincterotomy for chronic anal fissure: subcutaneous or open technique? British Journal of Surgery. 1984; 71 (5): 360-362..
7. Wienert, Volker, et al. Anal Fissure : Symptoms, Diagnosis andTherapies. 1st ed., Cham, Switzerland, Springer, 2017, p. 8.
8. Wienert, Volker, et al. Anal Fissure : Symptoms, Diagnosis andTherapies. 1st ed., Cham, Switzerland, Springer, 2017, p. 117.
9. Wienert, Volker, et al. Anal Fissure : Symptoms, Diagnosis andTherapies. 1st ed., Cham, Switzerland, Springer, 2017, p. 133.
10. M.G., Madhusudhan. Comparative Study Of Chemical SphincterotomyAnd Lateral Internal Sphincterotomy For Chronic Anal Fissure. Nov. 2012.
11. Wienert, Volker, et al. Anal Fissure: Symptoms, Diagnosis andTherapies. 1st ed., Cham, Switzerland, Springer, 2017, p. 137.