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Clinical Anatomy

ROLE OF SECLORISING AGENT SOTRADECOL IN TREATMENT OF ACUTE & CHRONIC ANAL FISSURE

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ABSTRACT **Background/ Aim:** Anal fissure is a tear in the anal canal stretches from just below the dentate line to the anal verge. It is in the long axis of the anal canal which often shows reluctance to recover. The cardinal symptom is pain during defaecation and for minutes to hours following defaecation. Anal fissures are commonly situated in the midline posteriorly (about 90%). The next most common site is midline anteriorly1. Several treatment modalities, conservative as well as surgical have been tried for the cure of anal fissure. In the last decades, the understanding of its pathophysiology has led to a progressive reduction of invasive and potentially invalidating treatments in favor of conservative treatment based on anal sphincter muscle relaxation. This study was designed to establish the Role of Seclorising Agent Sotradecol In Treatment of Acute & Chronic Anal Fissure. **Method:** The present study has been carried out on patients coming to surgery OPD of Guru Nanak Dev Hospital attached to Govt. Medical College, Amritsar. The study cases received a single injection of sodium tetradecyl sulfate under local anesthesia as an OPD procedure in both acute & chronic anal fissure. **Result:** Relief of pain following injection of Sotradecol (sodium tetradecyl sulfate) was observed in 80% of patients within 24 hours and 90% of patients at 12 weeks of follow-up. Healing of fissure was observed in 90% of patients in the present study as a follow-up of 12 weeks. **Conclusion:** injection of sclerosant (sodium tetradecyl sulfate) holds very good promise in the future and can be used as a treatment of choice in patients unfit for surgery.

KEYWORDS : Anal Fissure, Sotradecol (Sodium Tetradecyl Sulfate), Sclerosant.

INTRODUCTION:

In the general surgery clinic, an anal fissure is one of the most common and painful proctologic diseases. Several therapeutic options have been proposed for its treatment. Anal fissure is a tear in the anal canal extending from just below the dentate line to the anal verge. It is in the long axis of the anal canal which often show reluctance to heal. The cardinal symptom is pain during defecation lasting for minutes to an hour following defecation. It is encountered in young adults or middle-aged adults and some time in childhood. Both sexes are equally affected[2]. Anal fissures are commonly situated in the midline posteriorly (about 90%). The next most common site is midline anteriorly[1]**.** Anterior fissures are more common in females than in males and account for some 10% of all anal fissures as compared to 1% in males[3].

The cause of the condition is unclear, but certain factors, responsible for its etiology are that, after child birth approximately 1% of patients develop chronic fissures and the fissure is usually in the anterior midline[4]. The fissure most commonly occurs in the posterior part, because of the stretching of mucosa due to passage of hard stool bolus leading to laceration. Diet low in fiber appears to be a risk factor for the development of anal fissure[5] Another cause is the internal anal sphincter hypertonia. Due to hypertonicity of the internal anal sphincter, the patient with a chronic anal fissure generally has raised resting anal pressure. The maximum resting anal pressure if reduced promotes healing of fissure ulcer. Another theory is that anal fissure may be due to ischemia which is more at the posterior commissure due to paucity of the arterioles, intensified by hypertonicity of the internal anal sphincter[6]**.** It may be attributed to the poorly performed hemorrhoid surgery in which excess skin is removed, leading to stenosis and tearing of scar tissue while passing motion[7]**.** Anti-endothelial cell antibodies identified in the serum of the patient with chronic anal fissure may suggest that it is an autoimmune process[8]**.**

The chronic fissure is characterized by indurated margins & the base consisting of either scar tissue of the lower border of internal anal sphincter muscle or fissure failing to heal within 6 wk. of treatment. Several treatment modalities, conservative as well as surgical have been tried to cure anal fissure.

AETIOLOGY AND PATHOGENESIS

An anal fissure is a common proctological issue about which little physiological knowledge is available and etiopathogenesis is controversial[9]. Spasm is aggressive involuntary contraction of muscle attended by pain and functional interference. It has however been shown that in many patients with an anal fissure, internal and external sphincter pressures function normally, only the resting anal pressure is greater than normal.

Whether the spasm is the cause or result of an anal fissure is still unknown. High resting anal pressure in patients with chronic anal fissures has been reported by several authors[10-12]**.** Anal resting pressure is primarily caused by internal sphincter activity, but in normal individuals, the external sphincter also contributes a small part of this resting pressure[13]**.**

PHARMACOLOGY OF SODIUM TETRADECYL SULFATE

Sodium tetradecyl sulfate is a colorless, water clear, buffered solution. Its use is associated with minimal local and systemic complications. The chemical formula for sodium tetradecyl sulfate. $C_{14}H_{29}Nao_4S$ (7-Ethyl-2-methyl-4-hendecanol sulfate sodium salt)

Composition

Each ml contains sodium tetradecyl sulfate 30 mg, benzyl alcohol 0.02 ml, and diabasic sodium phosphate, anhydrous 9.0 mg in water for injection.

Pharmacological action

Sodium tetradecyl sulfate is an anionic surface acting agent that has sclerosing properties when injected into the base of the fissure. It acts by denaturation of endothelium with selective removal of proteins. The endothelium becomes sticky, fastens to the neighboring surface, and forms permanent adhesions with a minimum of fibrosis after 6 weeks.

AIM & OBJECTIVE;

The study aims to evaluate the role of sclerosant (sodium tetradecyl sulfate) therapy as a treatment modality in the management of acute & chronic anal fissure.

MATERIAL AND METHODS;

The present study has been carried out on patients coming to surgery OPD of Guru Nanak Dev Hospital attached to Govt. Medical College, Amritsar. The study cases received a single injection of sodium tetradecyl sulfate under local anesthesia as an OPD procedure in both acute & chronic anal fissure. The patients were followed up for 12 weeks & note of the observations made were Pain, Healing of fissure, Anal spasm, Fecal incontinence, Sentinel pile, and Bleeding per rectum.

Equipment:
Light source, Disposable gloves, Proctoscope medium-sized, Xylocaine jelly, Two 5cc disposable syringes, Needle no 26, Povidine iodine solution 10%w/v, Vial of 2% Lidocaine, 1ml of Sodium Tetradecyl Sulphate

inclusion criteria:
- Patient between the age group of 20 to 60 years
- Reported in OPD with a history of symptoms i.e., bleeding per rectum, pain on defecation, and itching.
- Induration of edges of the fissure with no edema/inflammation.
- If the patient chooses sclerotherapy after counseling.
- Each case has been evaluated based on a structured proforma which included; Particulars of the patient (name, age, sex & CR No), A detailed history regarding the nature of symptoms, change in bowel habits, continence, abdominal complaints & any previous illness, General physical examination, Examination of abdomen/ CVS/respiratory system, Local examination.
- As a part of the preoperative workup of the patient Hb, BT, CT, TLC, DLC, Urine C/E, Blood urea, RBS, ECG, HIV (I&II) were done for all patients.

Procedure:
Pre-operatively patient's bowel preparation was done as for other anorectal procedures. PC enema at night was given. The patient was placed in a knee-elbow position & the fissure was exposed. A 26-gauge needle was inserted directly posterior to the fissure. One ml of the local anesthetic agent was infiltrated into the whole base of the fissure. Then 1 ml of sodium tetradecyl sulfate was injected in the same manner.

The patient was observed for one hour after the infiltration of injection sodium tetradecyl sulfate for any immediate complication and then the patient was discharged with appropriate dietary advice.

The patient was placed on a regimen consisting of:
- 2 to 3 sitz bath and one bath after each bowel movement.
- Paraffin to be taken orally
- Normal dietary habits to ensure bulky soft stools with avoidance of constipation.
- The patient was observed in an outpatient clinic for 12 weeks.

RESULT:
In the present study, we found the majority of the subjects were in the age group of 30-50 years (Table 1). This study also showed males (53.30%) were more affected than females (46.70%) (Table 2).

Table no. 1 showing age incidence

Age in years	No of cases	Percentage
21-30	3	10
31-40	12	40
41-50	9	30
51-60	6	20
Total	30	100

Table no. 2 showing sex incidence

Sex	No of cases	Percentage
Male	16	53.30
Female	14	46.70
Total	30	100

Patients suffering from a fissure in ano usually complain of pain on defecation, constipation, pruritus, bleeding per rectum, and the presence of a tag of skin. In the current study half of the patient i.e., 15 (50%) had the pain of 0-3-month duration, the minimum duration of pain was 15 days & maximum for 2 years as shown in table no 4. In this study 28(93.3%) cases complaint of anal irritation and it was absent in 2(6.7%) cases.

Table no. 4 showing a history of pain

Duration	No of cases	Percentage
0-3 months	15	50.00
3-6 months	6	20.00
6-9 months	3	10.00
9-12 months	5	16.70
>1 year	1	3.30
Total	30	100

Majority of patients in study group complained of bleeding per rectum which was either in form of fresh blood with stools or passage of few drops of fresh bright blood after stools. In the present study, 86.7% of patients presented in OPD with a history of bleeding per rectum, as shown in table no 5. In 29 (96.7%) patients, Constipation also complained and sentinel piles were present in 19 (63.3%) of total patients.

Table no. 5 showing the incidence of bleeding per rectum

Bleeding per rectum	No of cases	Percentage
Present	26	86.70
Absent	4	13.30
Total	30	100

In the present study, 73.30% of a total number of patients had posterior midline fissure, 20% had anterior midline fissure & 6.7% had both anterior and posterior midline fissure (Table no 6) and table no 6a showing different authors comparing the location of the fissure.

Table no. 6 showing Fissure Location

Location of fissure	No of cases	Percentage
Anterior	6	20
Posterior	22	73.30
Both	2	6.70
Multiple	-	-
Total	30	100

Table no. 6a showing the comparison of Fissure Location

Name of Author	Posterior	Anterior	Anterior & posterior	Multiple
Notras[19]	89.0	11.0	-	-
Lock& Thomson[16]	75.6	13.8	8.0	2.6
Hsu et al[22]	70.2	20.0	8.1	1.6
Study group	73.3	20.0	6.7	-

The spasm of the anal sphincter was subdivided into mild, moderate, and severe depending upon whether the patient permitted the rectal examination with mild or severe pain. The cases with mild spasms allowed rectal examination. Others who had pain on per rectal examination but allowed it after the liberal application of xylocaine jelly were categorized as having a moderate spasm, still, others who didn't allow per rectal examination at all were categorized as having severe spasm as shown in table no 7. Out of 30 patients, 83.3% (25) had induration of edges and in 16.7% (5) of patients induration of edges was absent.

Table no7 incidence of the degree of sphincter spasm

Degree of sphincter spasm	No of cases	Percentage
No spasm	1	3.30
Mild	2	6.70
Moderate	3	10.00
Severe	24	80.00
Total	30	100

All patients were examined after 24 hours, 1 week, 4 weeks, 8 weeks, and 12 weeks & notes were made regarding the relief of pain, bleeding per rectum, anal sphincter spasm, healing of fissure, sentinel pile, complications, hospital stay, and cost of treatment.

Relief of pain following injection of Sotradecol (sodium tetradecyl sulfate) was observed in 80% of patients within 24 hours and in 90% of patients at 12 weeks of follow-up. The incidence of bleeding per rectum at 24 hours was 40% and was 10% at 12 weeks. In the present study, 2 (6.7%) patients had no spasm, 4(13.3%) had a mild spasm, 9 (30%) had a moderate spasm and 15 (50%) had severe spasms after 24 hours. The patient followed up after 1 week, 4 weeks, 8 weeks & 12 weeks. By the 12th week, 27 (90.30%) patients had no spasm, 1 (3.30) patient had a mild spasm and only 2 patients (6.70%) had a moderate spasm.

Table no. 8 showing follow-up relief of pain, bleeding per rectum & incidence of the degree of anal sphincter spasm

		After 24 hrs		After 1 week		After 4 weeks		After 8 weeks		After 12 weeks	
		No.	%age	No.	%age	No.	%age	No.	%age	no.	%age
Relief of pain	Complete	24	80	26	86.70	27	90.00	28	93.30	28	93.30

	Partial	3	10	1	3.30	1	3.30	-	-	-	-
	No relief	3	10	3	10.00	2	6.70	2	6.70	2	6.70
	Total	30	100	30	100	30	100	30	100	30	100
Bleeding per rectum	Positive	12	40.00	8	26.70	3	10	3	10	3	10
	Negative	18	60.00	22	73.30	27	90	27	90	27	90
	Total	30	100	30	100	30	100	30	100	30	100
Degree of sphinct-er spasm	No spasm	2	6.7	27	90.00	28	93.30	28	93.30	27	90.30
	Mild	4	13.30	1	3.30	-	-	-	-	1	3.30
	Moderate	9	30.00	2	6.70	2	6.70	2	6.70	2	6.70
	Sever	15	50.00	-	-	-	-	-	-	-	-
	Total	30	100	30	100	30	100	30	100	30	100

Healing of fissure was observed in 90% (27) patients at the end of 8 weeks, but the failure of fissure healing was noticed in 10% (3) cases by the end of 8th week. In 6.7% (2) cases no relief was seen which persisted at 12th week follow up.

Table no. 9 showing the incidence of healing of fissure

Healing of fissure	After 1 week		After 4 weeks		After 8 weeks		After 12 weeks	
	No.	%age	No.	%age	No.	%age	No.	%age
Complete	24	80	26	86.70	27	90.00	28	93.30
Partial	3	10	1	3.30	1	3.30	-	-
No relief	3	10	3	10.00	2	6.70	2	6.70
Total	30	100	30	100	30	100	30	100

Table no 10. comparison in the healing of fissure

Name of Author	Treatment modality	%age of fissure healed
Antebi et al[10]	Sotradecol	80.2
Jost et al[29]	BTX-A-5U	82.0
Study group	Sotradecol	93.3

There was no increase or decrease in the incidence of sentinel pile after injection therapy. At 12 week follow up it was observed that none of the patients had fecal/flatus incontinence and fistula formation as a complication of the procedure. 2 (6.7%) patients had perianal thrombosis. The duration of hospital stay was 2 hours after the procedure and the patient was advised to follow up in OPD after one day.

DISCUSSION:

An anal fissure is a remarkably painful condition in an otherwise healthy population. The patient asks for relief but is reluctant to accept a treatment that demands absence from day-to-day activities for a prolonged duration of time. Generally, the precipitating factor considered for anal fissure is trauma to anal mucosa caused by hard stools. One factor that is important in causing anal fissure is chronic constipation. Once the fissure has been established, the spasm of the internal sphincter prevents drainage & subsequent healing[14] and is the basic cause of persistent pain thus decreasing or inhibiting the contraction of the internal anal sphincter should be the mainstay of any treatment of anal fissure.

Over the past 50 years, anal fissure has undergone a continuous evolution. Conservative management of anal fissure has always been the initial treatment of choice and consists of stool softeners, sitz bath, high fiber diet, and local anesthetic or analgesic ointments. This therapy, however, is hardly documented in medical literature but research on the effectiveness of conservative therapy of anal fissure have been performed. **Fries and Rietz (1964)[15]** found that on the conservative side, 54.2% of patients were successfully treated. A healing rate of 56.9% was seen by **Lock and Thomsom (1977)[16]**.

Surgery has played an important role in the treatment of anal fissure. Since 1969 there had been several studies on the lateral subcutaneous internal sphincterotomy e.g. **Hawely (1969)[17], Hoffmann and Goligher (1970)[18], Notaras (1971)[19], Miller (1971)[20], Bailey et al (1978)[21], Hsu et al (1984)[22], Pegnikoff et al (1994)[23].** They all have attested the superiority of this procedure over all other forms of surgery of anal fissure. Anal dilatation was probably originated with **Recamier (1938)**[24]. It was recommended at the end of century by **Goodshall (1892)[25]** and later by **Gabriel (1929)[26]**. The key criticism of this approach, however, has also been the relatively high incidence of bruising, hematoma formation and the problem of anal incontinence.

In the past, attempts have been made to formulate some form of therapy that does not necessitate surgical care, anesthesia, or hospitalization but significantly alleviates symptoms related to anal fissure. Local injection into the internal anal sphincter of purified botulinum toxin has been suggested by various authors as a treatment modality in simple uncomplicated chronic anal fissure **(Gui et al (1994)[27], Mason et al (1996)[28], Jost (1997)[29]. Antebi et al (1985)[10]** injected 96 patients of anal fissure with sotradecol sclerosant in to the base of the fissure and reported that 80.2% of patients were symptoms free 12 weeks after receiving 1 ml of Sotradecol injection at the base of the fissure. He also observed a 4.2 % incidence of perianal abscess in treated patients with sotradecol.

CONCLUSION:

It was concluded from the analysis that sclerotherapy has an exceptional role in the conservative management of anal fissure. It contributes to a greater occurrence of a good outcome as compared to results obtained with routine types of local treatment. Furthermore, in cases treated by injection of 1 ml of sotradecol, no sanatorium stay was required. The complication rate was nearly non-existent and in no instance led to any everlasting effect. Since it is an outpatient procedure, it can be performed with a minimal amount of equipment, technical capacity, and experience, resulting in immediate relief. Thus, injection of sclerosant (sodium tetradecyl sulfate) holds very good promise in the future and can be used as a remedy of choice in patients unfit for surgery or patients having a high risk of anesthetic complication or if the patient chooses sclerotherapy after counselling. Hence sclerosant therapy can be used as routine remedial procedure, due to its cost effectiveness and less hospital stay, thereby maximizing the provision of appropriate effective health care to patients with anal fissure.

Conflict Of Interest: Nil

REFERENCES:

1. Bailey and Love. Short Practice of Surgery. 22nd edition, 1995.
2. Bennett RC and Goligher JC. Results of internal sphincterotomy for anal fissure. Br Med J 1962;2: 1500-3.
3. Goligher JC, Leacock AG and Brossy JJ. The surgical anatomy of anal canal. Br J Surg 1962; 43:51-61.
4. Martin JD. Postpartum anal fissure. Lancet 1953: 271-73.
5. Jensen SL. Diet and other risk factors for fissure in ano. Prospective case-control study. Dis Colo Rectum 1988; 31: 770-73.
6. Lund JN and Scholefield JH. Aetiology and treatment of anal fissure. Br J Surg 1996; 83: 1335-44.
7. Rains AJH and Richie HDR. Bailey and Love's Short Practice of Surgery. 17th ed. 1997: 1291-95.
8. Maria G, Brisindo D, Ruggien MP, GrettoIM, Brisinda G. identification of antiendothelial cell antibodies in patients with chronic anal fissure. Surgery 1999; 126(3): 535-40.
9. Kuypers HC. Is there really a sphincter spasm in anal fissure? Dis Colon Rectum 1983; 26: 493-94.
10. Antebi Y, Alexander WJ, Keighley MRB. Anal pressure in hemorrhoids and anal fissure. Am J Surg 1977; 134: 608.
11. Hancook BD. The internal sphincter and anal fissure. Br Jour Surg 1977; 65: 92-5.
12. Cerdan JF, Michowitz M, BawnikJB. Sodium tetradecyl sulphate as alternative conservative treatment for acute anal fissure: a controlled clinical study. Am J Surg 1982; 58(11): 705-09.
13. Duthie HL and Watts JM. Anal sphincter pressure in fissure in ano. Gynecol Obstet 1964: 19.
14. Allan A and May R. anal fissure. Br J Hosp Med 1985: 41-43.
15. Fries B and Reitz KA. Treatment of fissure in ano. Acta chirurgica Scandinavica 1964; 128: 312-15.
16. Lock MR,and Thomson JPS. Fissure in ano the initial management and prognosis. Br J Surg 1977; 64: 355.
17. Hawley PR, the treatment of chronic fissure in ano, a trial method. Br J Surg 1969; 56: 915. Cited by Hoffmann and Goligher. Br J 1969; 3: 673-75.
18. Hoffmann DC and Goligher JC. Lateral subcutaneous internal sphincterotomy in treatment of anal fissure. Br Med J 1970; 3: 673-75.
19. Notaras MJ. The treatment of anal fissure by lateral subcutaneous internal sphincterotomy- A technique and results. Br J Surg 1971; 58: 96-100.
20. Miller DM. subcutaneous lateral internal sphinctrotomy of anal fissure. Br J Surg 1971;

58: 737.
21. Bailey RV, Ribin RJ and Salvati EP. Lateral internal spincterotomy. Dis colon Rectum 1978; 21: 584-86.
22. Hsu TC and Mackeigan JM. Surgical treatment of chronic anal fissutre- A retrospective study of 1753 cases. Dis Colon Rectum 1984; 27: 475-78.
23. Pernikoff BJ, Eisenstat TE, Rubin RJ, OliverGC and Salvati EP. Reappraisal of partial lateral internal spincterotomy. Dis Colon Rectum1994; 37: 1291-95.
24. Recamier JC. Extension, massage et percussion cadancee dans le des contractures muscularis. Revue Medicine Francois et Estranger 1838; 1:74. Cited by Watts et al. Br Med J 1964:342-43.
25. Goodsall DH. Fissure, on syphilitic and syphilitic of rectum anus. St Bartholonew Hosp Rep 1892, 28:205. Cited by rudd Dis Colon Rectum 18:319-23.
26. Gabriel WB. Treatment of pruritis ani and anal fissure.: the use of anesthetic solutions in oil. Br Med J 1929; 1: 1070.
27. Gui D, Cassetta E, Anastasio G, Bentivoglio AR, Maria G and Albanese A. ABotulinumtoxin for chronic anal fissure. Lancet 1994; 64: 92-95.
28. Mason F, Watkin MJG, Hall HS and Hall AW. The management of chronic fissure in ano with botulinum toxin. Royal College Surg Edinb 1996; 41: 235-38.
29. Jost WH. One hundred cases of anal fissure treated with botulin toxin. Dis Colon Rectum 1997: 1029.