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Original Research Article

Combined mucosal advancement and lateral internal sphincterotomy in treatment of chronic anal fissure: could be an effective alternative procedure?

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ABSTRACT

Background: Chronic Anal Fissure (CAF) is a common anal problem. Lateral Internal Sphincterotomy (LIS) is the recommended treatment when conservative treatment fails, however it has its drawbacks. On the other hand, Anal Advancement Flap (AAF) may help in some cases. In this study, we tried to combine both techniques to evaluate the outcome of this dual procedure.
Methods: This prospective study was conducted on one hundred patients with chronic anal fissure who were divided randomly into two groups group (A) LIS, group (B) the combined technique. Both groups were compared regarding, pain and constipation prior to treatment and at 1, 2, 4, 6 weeks post-operative using Visual Analogue Scale (VAS) and Wexner constipation score at 6weeks in addition to timing of complete fissure healing.
Results: Both groups were comparable preoperatively regarding demographic data, pain score, constipation score but post-operative group B has achieved an earlier significant decrease in pain score, (1.7±0.65 vs 4.4±1.1) at 1st week (P<0.001) and (1.5±0.55 vs 3.3±1.04) at 2nd week also (P<0.001). In addition to a superior healing rate (96% vs 76%) at 4th week (P=0.009) with non-significantly longer operative time or complication rate.
Conclusions: The combined technique of mucosal advancement and LIS can achieve a superior outcome compared to the traditional LIS in the treatment of CAF regarding faster healing rates with marked decrease in early post-operative pain and by far earlier return to normal life habits.

Keywords: CAF, Combined technique, LIS, Mucosal advancement

INTRODUCTION

Anal fissure is defined as a superficial linear tear in the anoderm distal to the dentate line it is a well- known cause of anal pain.[1] It may be acute or chronic the period after which we could say that it has become a chronic one, differs and there is no universal agreement. Some say that it is after 6 weeks of initial symptoms, some after 8 weeks others may prolong the period to 3 months, with an annual incidence of about 1.1 per 1000 person-years, with a peak incidence in females during adolescence and young adulthood and during middle age in men, most commonly caused by the passage of hard stool but also with acute diarrhea, pregnancy and other medical conditions. Typically, it causes cyclical pain that occurs during defecation and persists for one to two hours afterwards.[2-4] It may be associated with fresh bleeding per rectum, on examination chronic anal fissure presents with anal skin tags or namely sentinel piles, ulcer with rolled indurated edges and exposed internal anal sphincter.[3] They are usually associated with spasm of the Internal Anal Sphincter (IAS), which may lead to local ischaemia

and impaired healing.[5] Guidelines from the American Society of Colon and Rectal Surgeons (ASCRS) recommend non-operative management of anal fissures as first line therapy, specifically with pharmacological agents such as nitric oxide donors (e.g. nitroglycerin) and calcium channel blockers (CCB) (e.g. nifedipine, diltiazem).[6] Acute fissures usually heal with conservative measures taken to relieve constipation and the associated pain. CAFs and fissures due to underlying diseases are unlikely to resolve with conservative management. The principal aim of treatment for a CAF was to reduce the tone of the internal sphincter and hence, increase the blood flow with subsequent tissue healing. Lateral sphincterotomy has been regarded as the gold standard for the treatment of CAFs. Various studies have shown the superiority of lateral sphincterotomy over posterior sphincterotomy.[7,8] Due to the adverse effects of this procedure in the form of incontinence even if it is temporary. Some wes start to advocate local flaps such as V-Y advancement flaps and rotation flaps particularly in recurrent cases and in patients with impaired continence preoperatively.[9,10] This study assessed the benefit of combination between mucosal advancement flap and lateral sphincterotomy for treatment of CAFs.

METHODS

This was a prospective randomized study that was conducted at General Surgery Department in the period between December 2016 till January 2018. Ethical approval was obtained from the Institutional Review Board (No. 36-12-2016).

The study included 100 patients with CAFs. Symptoms persisting more than 6weeks with failed conservative treatment in the form of bulking agents, sitz baths and topical lignocaine and glyceryl trinitrate therapy (GTN 0.2% ointment).

We excluded patients with associated anorectal pathology such as hemorrhoids, fistula or abscess, patients with Crohn's disease, malignancy, pregnant females, patients unfit for surgery with bleeding tendency or those who refused to enter in the study.

Complete history was taken and detailed physical examination was conducted for all patients before the start of conservative treatment. Patients were interviewed about the relevant present history including the type, onset and duration of complaint, degree of pain and its score, presence of constipation and scoring of it, rectal bleeding, previous treatments received and associated medical conditions.

Patients were divided into two groups each was 50 patients. The sample size calculation was based on historic data of this center of postoperative pain and rate of fissure healing (control group-38%) and an expected reduction of this rate to 20% in patients undergoing the combined technique of mucosal advancement and lateral internal sphincterotomy (experimental group). At 80% power and a significance level of p=0.05, it was calculated that 50 patients were required in each arm of the study.

Patients were randomized using a computerized simple randomization scheme in a 1:1 ratio into 2 groups: those patients undergoing lateral internal sphincterotomy alone (group A) and those patients undergoing the combined technique of mucosal advancement and lateral internal sphincterotomy (group B). In order to have objective assessment, we used standardized methods for evaluation as visual analogue scale (VAS) from 0 to 10 for assessment of pain during and after defecation where zero means absence of pain and 10 represents the worst possible pain with grading degrees between both. Wexner constipation score was employed for evaluation of constipation. Patients were examined in the left lateral position to inspect the type and position of the anal fissure and to exclude the presence of associated anal pathology as hemorrhoids or anal fistula. Chronicity of anal fissure was indicated by the presence of indurated fibrotic edges and sentinel piles.[11]

Procedure

In group A using regional (saddle or spinal) or general anesthesia with lithotomy position open LS was performed for IAS muscles in which 5mm incision was done starting from left side of the anal canal into the perianal skin through the intersphincteric groove. The lateral side of IAS was dissected and a segment of which was withdrawn to outside using artery forceps and then divided completely with electro-diathermy.

The wound was left open to heal by secondary intention and to avoid closing the space that may result in haematoma. Meanwhile freshening of fissure edges and bed with excision of sentinel skin tags was done a layered gauze packed with lignocaine 5% and panthenol cream was inserted in the anal canal and in the space of sphincterotomy. This will be removed in the next day after 24hours of surgery this we used routinely in this technique. This may help in decreasing post-operative pain and facilitates removal of the layered gauze.

In group B, first we examined the anal canal using the proctoscope to exclude other anal pathology (Figure 1) then freshening of fissure edges then elevation of part of mucosal covering sufficient to cover the fissured area without tension (Figure 2). Later on we sutured the elevated mucosal flap using interrupted sutures of vicryl 3/0 on rounded needle and we adopted starting from the skin side first then the mucosa second to facilitate manipulation of the needle as the limited space in anal canal makes it difficult to start from inside to outside (Figure 3) and finally we performed open lateral internal sphincterotomy as in group A (Figure 4). The operation was performed as a one-day case surgery.

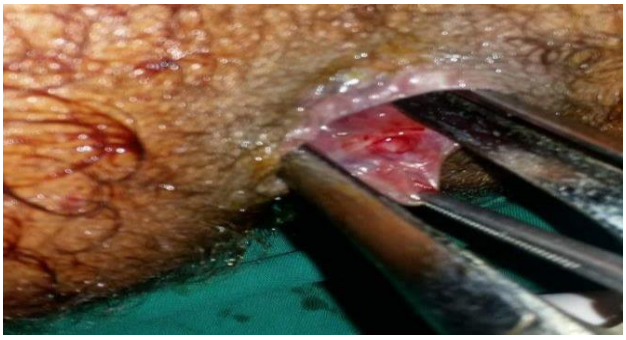

Figure 1: Proctoscopy examination of CAF.

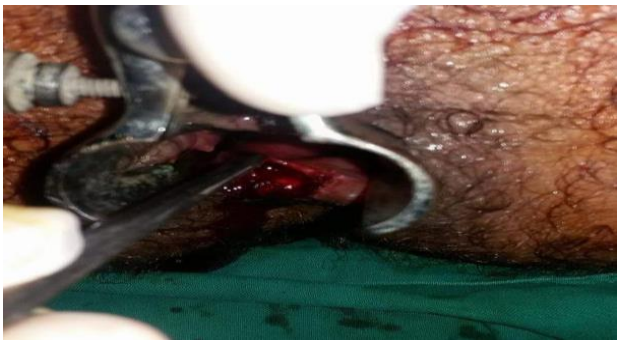

Figure 2: Creation of mucosal flap.

Figure 3: Suturing of mucosal flap to perianal skin.

Figure 4: Lateral internal sphincterotomy.

Prophylactic antibiotics in the form of metronidazole and a third-generation cephalosporin were administered intravenously on induction and for 48hours postoperatively and then oral second generation cephalosporins were used for another one week. A single dose of a non-steroidal anti-inflammatory drug was injected intramuscular on recovery and was repeated if additional analgesia was needed. Analgesic drugs given by mouth were also used as needed, the dose and duration of which was recorded for both groups. The patients resumed oral feeding in the form of drinking 3-4hours postoperatively while eating a high fiber diet by mouth started by the end of the day of the operation. Laxatives or stool softeners were given for 2-3weeks. The wound and perianal area were inspected for bruising or hematoma 8-12hours after the operation. Patients were followed up at 1, 2, 4 and 6weeks after the operation to monitor fissure healing. They were subsequently followed up monthly by telephone call for 6months. If the patients developed any related complications, they were called in for a consultation and evaluated. At every visit, patients were interviewed by an independent specialist nurse to eliminate the risk of investigator bias the degree of anal pain according to VAS, constipation symptoms as evaluated by Wexner constipation score. The presence or absence of rectal bleeding or discharge then patients were examined to assess and record the extent of healing of anal fissure by wes. The patient was considered to be successfully healed when the breach in mucosa was completely treated and the patient had not experienced pain during defecation. The primary outcome of the study was the degree of healing of anal fissure observed by clinical examination during follow up. Healing was defined as complete epithelialization of the site of anal fissure with no residual cracks or ulcers. Secondary outcomes included reduction in pain score, improvement in constipation and other symptoms and the incidence of post-operative complications e.g. (infection or abscess formation, incontinence or recurrence). Data were collected and analyzed with SPSS Software, version 20 for Microsoft Windows and were expressed as median and normal range or mean±standard deviation (SD). The variables were compared with student t-test for continuous parametric data and Chi-square, Fisher's exact or Mann Whitney tests for categorical data. P value less than 0.05 was considered significant.

RESULTS

Patients were 38 males and 62 females with a mean age of 42.8±5.9 (range, 19-69) years. All patients complained of anal pain during and persisting after defecation for about 1-2hours. Fourty-five patients reported slight fresh bleeding per rectum during defecation, and 60% of patients reported history of constipation.

The duration of complaint for all patients ranged from 8weeks-6months. 94% of patients had posterior anal fissure, five (5%) had anterior anal fissure 3 in group A and two in group B and one (1%) had combined anterior and posterior anal fissures it was in group A. Sentinel skin tag was detected in ninety patients from the whole patients. 85% of patients had tried conservative treatment

while 15 patients had refused and preferred surgery after they had known that there was liability by 50% for failure of conservative therapy. There were no significant differences in the demographic data of patients in both groups as shown in Table 1.

Table 1: Demographic data of both groups.

Variable	Group A	Group B	Total	P value
Number	50	50	100	-
Mean age (years)	42.7±5.9	42.8±6.1	42.8±5.9 (19-69)	0.35
Range	(22-67)	(19-69)		
Gender (male/female)	18/32	20/30	38/62	0.84
Pain (%)	50 (100%)	50 (100%)	100	-
Bleeding (%)	21 (42%)	24 (48%)	45 (45%)	0.69
Constipation (%)	28 (56%)	32 (64%)	60 (60%)	0.54
Median duration of complaint in months (range)	3.2 (2.2-5.4)	4.1 (2.5-6)	3.5 (2-6)	-
Position of anal fissure				
Anterior (%)	3 (6%)	2 (4%)	5 (5%)	0.54
Posterior (%)	46 (92%)	48 (96%)	94 (94%)	
Combined (%)	1 (2%)	0 (0%)	1 (1%)	
Sentinel skin tags	43 (86%)	47 (94%)	90 (90%)	0.32

Table 2: Difference in pain score in both groups.

Mean VAS				
		Group A	**Group B**	**Test of significance and P value**
Before operation		5.8±1.04	5.6±1.05	Mann Whitney U= 1.6, P =0. 12 (>0.05)
After operation	1st week	4.4±1.1	1.7±0.65	Mann Whitney U= 8.4, P =0.00** (<0.001)
	2nd week	3.3±1.04	1.5±0.55	Mann Whitney U= 7.4, P =0.00** (<0.001)
	4th week	1.2±0.51	1.1±0.49	Mann Whitney U= 1.1, P =0.26 (>0.05)
	6th week	0.5±0.25	0.54±0.29	Mann Whitney U= 0.69, P =0.49 (>0.05)

During the follow up period and according the VAS, we found that patients in group B had achieved a significantly lower pain score P= (<0.001) at the 1st week and 2nd week with non-significant difference at the 4th and 6th week (Table 2).Also, patients in group B although they achieved a final healing of all patients by the 6th week. As in group A. They had a faster healing rate which can be noticed in Table 3 at the 2nd and 4th week.

Table 3: Rate of fissure healing in both groups.

Variable	Number of patients with complete fissure healing							
	After 1st week	**P value**	**After 2nd week**	**P value and test of sig.**	**After 4th week**	**P value and test of sig.**	**After 6th week**	**P value**
Group A	0	-	0	Fisher's Exact=22.5	38	Fisher's Exact=6.7	50	-
Group B	0		20	P =0.00** (≤0.001)	48	P =0.009* (≤0.05)	50	

Table 4: Post-operative improvement in bleeding and constipation score after 6weeks.

Variable	No. of patients with bleeding		P value	Mean Constipation Score		P value
	Before operation	**After 6 weeks**		**Before operation**	**After 6 weeks**	
Group A	21 (42%)	0	-	16.3±1.5	1.6±0.89	Mann Whitney U= 0.86 P =0.38 (>0.05)
Group B	24 (48%)	0		16.8±0.79	1.55±0.89	

Post-operative follow up of both groups had demonstrated improvement in bleeding per-rectum and constipation score with non-significant difference Table 4. Also, there was non-significant difference between both groups regarding post-operative complications (incontinence and wound infection) as in Table 5.

Table 5: Difference in operative time and post-operative complications.

Variable	Mean time of operation(min)±SD	P value and test of significance	Post- operative incontinence	P value	Wound infection	P value and test of significance
Group A	24.2±2.8	Mann Whitney U= 0.35	1	-	0	Fisher's Exact= 0.5
Group B	24.4±3.2	P =0.73 (>0.05)	1		2	P =0.47 (> 0.05)

DISCUSSION

Chronic anal fissure is one of the most common anal problems that is associated with both sphincter spasm and a degree of hypertrophy and secondary fibrosis with multiple alternative procedures for its treatment without universe consensus on the best way. However, LIS remains the procedure that takes the upper hand worldwide. Although it has its adverse effects as complete sphincterotomy is associated with increased incidence of incontinence compared with incomplete sphincterotomy, a more conservative approach dividing less than half of the internal sphincter length is recommended.[12]

LIS routinely does not include wound closure. This may lead to complications of secondary wound healing with the risk of anal stenosis or even keyhole deformity as a late complication.[13] Therefore, symptoms of minor incontinence after LIS may not only result from sphincter damage but also from unevenly healed anal skin with impaired anal closure. Certain patients seem to be at higher risk of continence disturbance such as age ≥50, multiparous women with prior repeated vaginal delivery and patients having a second anorectal procedure carried out in addition to LIS (such as haemorrhoidectomy). These patients may be better served with a 'sphincter-preserving' procedure.

The procedure of LIS postulates that it reduces anal sphincter hypertonia with concomitant increase in the received blood supply to the fissured area this in turn will improve healing and this agrees with the theory postulated by Schouten and colleagues that states that CAF is considered ischemic ulcer however still an incidence of recurrence that rates about 5% also, the process of inflammation and pain that associates anal fissure preoperative and even postoperative will share in the vicious circle of impaired healing with more pain and more inflammation due to persistent reflex hypertonia of anal sphincter.[14,15,16]

So, we developed in this study the technique of combining both LIS and mucosal advancement for coverage of the fissured area by this we supposed that the benefit of LIS by decreasing the anal sphincter hypertonia in addition to covering the raw area this will cover the exposed nerve endings with resultant decreasing postoperative pain and by that we disrupted the vicious circle of (pain and hypertonia) another benefit of this technique is the change of the process of healing of the fissured area from secondary intention to primary intention so rapid rate of healing will be achieved and by that hospital stay will be decreased and early return to work and normal life activity. Also, theoretically improving blood supply by two options (LIS and mucosal coverage) will decrease the incidence of failure of healing or recurrence. In addition to avoiding the potential risk of anal stricture associated with healing by secondary intention.

We reported a healing rate of 100% of all cases in both groups after 6weeks of follow up the difference between both groups was at time of complete healing which reached 40% by the 2nd week then 96% in group B by the end of the 4th week in comparison to 0% and 76% respectively in group A. In the study by Gupta PJ et al, he reported a healing rate exceeding 90% of the cases by the end of the 4th week.[17] Another study published at 2018, it reported similar results comparing AAF and LIS regarding healing rates of anal fissure but anal incontinence was higher with LIS taking in mind that they have randomized only patients with elevated resting anal manometric pressure only excluding normo or hypotonic sphincters but in this study we combined both techniques in one group and compared it with LIS because we noticed that patients suffer from pain for long period post-operative with consequently delayed fissure healing with traditional LIS.[18] By that "combined technique" we achieved the benefit of both techniques but we haven't reported any case of permanent incontinence in any group and this may be due to small number in the study and that during LIS we don't cut more than 50% of the sphincter and this had been recognized by experience in our center. The results match with that of Magdy A et al, had reported in one arm of their study that tailored LIS combined with AAF was associated with superior fissure healing rates and less recurrence.[19]

Again, Magdy A et al, in their study they reported cases of recurrent fissures after one year of follow up in patients who had simply V-Y anocutaneous flap to cover the fissured area without fissurectomy but in our study we implied fissurectomy as a step in both groups and we didn't experience any recurrent fissures during this follow up period.[19] Studies on AAF alone reported higher rates of unhealed fissures reaching 15-19% although, this is surprising as flaps involves implication of vascularized tissues but the fact that anal sphincter spasm and fibrosis that associates CAF may be involved and this limits the uptake of the new flap, this supports our technique that combines both and so it will decrease the incidence of non-uptake of the flap.[20,21]

In this study, both groups were comparable regarding age, gender and the presenting symptoms e.g. (pain, bleeding and constipation). VAS scores for both were not different at the start of the study but postoperative there was significant difference between them at two and four weeks of follow up in favor of patients with the combined technique group (B) but the difference was not significant later on (at 6 weeks). In the same way Wexner constipation scores showed marked improvement in both groups but the difference was not significant at (6weeks) although it appears that both groups achieve finally comparable results, but the combined technique has reached that earlier with the benefit of better patient satisfaction, earlier return to work and normal life habits. Following the study of Theodoropoulos GE et al, they reported similar results that the combined technique strategy showed significantly less post-operative pain.[22] On the other hand, wound complications are more commonly encountered with anoplasty techniques as they involve more tissue dissection and mobilization as well as a longer operative time and this matches with present study as we reported more incidence of wound infection and longer operative time however, this has not reached to a significant level.

Finally, the present study was limited by the small number of patients in each group and the lack of long period of follow-up of the patients to exclude long-term recurrence of the anal fissure. However, the assessment of pain and constipation improvement was objective using well-defined scales in addition to concomitant complete healing of anal fissure with promising results that may favor this technique on larger scale and longer period of follow up.

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