Original research article

A Comparative Study on Manual Anal Dilatation Versus Lateral Internal Sphincterotomy in the Treatment of Fissure in Ano

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Abstract

Introduction: Anorectal disorders including fissure and haemorrhoids are among the most common afflictions of this region which negatively impact the 'quality of life' of the patient and incur a massive financial burden on both the patient. Most of the patients hesitate to seek medical care unless the symptoms become too bothersome. The present study was conducted in our proctology unit to compare the outcome of Manual anal dilatation and lateral internal sphincterotomy in the management of fissure in ano.

Materials & Methods: The present study was conducted in the Department of General Surgery, Kamalnayan Bajaj hospital, Aurangabad from September 2020 to August 2021 on total of 110 patients admitted for evaluation of Fissure in ano. Patients were randomized in two groups; group A was treated with Manual anal dilatation and group B was treated with lateral internal sphincterotomy under general anesthesia.

Results: In our present study 92 % of cases showed posterior location of fissure. One fissure in ano was seen in 108 (97%) and Sentinel piles were seen in 48 (43%) cases. While spasm was present in 110 (99%) study cases. There was a significant difference between the MAD and LIS group for postoperative pain VAS score at 06 hours (P < 0.0001). We have done monthly follow-up assessment of all patients up to 3 months for detecting complications and development of recurrence.

Conclusion: It can be concluded that that there was no significant difference in post operative pain between MAD group compared to LIS group. Both MAD and LIS provide early pain relief and high ulcer healing rate and both the procedures are equally effective under experienced hands.

Keywords: Anorectal, haemorrhoids, fissure, sphincterotomy, Sentinel piles **Introduction**

Anal fissure is a distinct clinic pathological condition of the lower anal canal. It can be defined as a ulcer in the anoderm usually in the posterior midline, less frequently in the anterior midline, and rarely in the lateral position of the anal canal.[1] Atypical ulcer or fissures may be multiple or off the midline or be large and irregular.[2] Incidence of anal fissure is slightly higher in females (especially in postpartum) than males.[3]

Causative factors may be ischemia due to high anal pressure or trauma to the anal canal e.g. constipation, diarrhea, childbirth, surgery, banding.[4] Rarely, it may be manifestation of underlying disease e.g., AIDs, tuberculosis, neoplasms, Crohn's disease and ulcerative colitis. Anal fissure is also commonly found in homosexuals, local or systemic malignancy. Symptoms usually consist of painful defecation, post defecation pain and sparse bleeding. Diagnosis is based on history and clinical examination. [5]

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Treatment of anal fissure focuses on breaking the cycle of pain, spasm, and ischemia. [6] First-line therapy to minimize anal trauma includes bulk agents, stool softeners, and warm sitz baths. [7] Those who do not achieve a relief from first line conservative management or those who have a recurrence, second line therapy is advocated with botulinum toxin injections or the topical application of ointments such as calcium blockers (nifedipine, diltiazem), or nitric oxide donors (glyceryl trinitrate). Surgical techniques, such as manual anal dilatation or lateral internal sphincterotomy, effectively heal most fissures within a few weeks but may result in permanently impaired anal continence. [8] Anal dilatation has been criticized for recurrence varying from 2% to 80%, and incontinence up to 51%. But proponents of Anal dilatation advocate that when performed in properly controlled manner, it results in significant success rates safely. [9]

The present study was conducted in our proctology unit to compare the outcome of Manual anal dilatation and lateral internal sphincterotomy in the management of fissure in ano.

Material & Methods:

The present single blinded randomized control study was conducted in the Department of General surgery, Kamalnayan Bajaj hospital, MMRI, Aurangabad, Maharashtra. Amongst 110 patients those who were clinically diagnosed as Fissure-in-ano from September 2020 to August 2021 after taking proper permission from Institutional Ethics committee.

Inclusion Criteria:

Patients of age above 18 years and below 60 years with diagnosis of Fissure-in-ano with typical presentation and symptoms and those gave consent.

Exclusion Criteria:

- 1. All anal fissures in patients who are known cases of ulcerative colitis, Crohn's disease, carcinoma of rectum, active abdominal tuberculosis, radiation therapy.
- 2. Patients below 18 years age, not willing to participate in the study, surgically unfit and refused for surgery are excluded.
- 3. Patients with previous dilatation of anus OR with previous perianal surgery OR with atypical fissures

Details Recorded:

In this study, data was collected about the demographic details of patients, detailed clinical history, previous treatment if any, Digital rectal examination and Laboratory investigations, Operative findings and postoperative consequences and Complications if any noted. Patient was followed up in outpatient department basis for one month or longer period 3 months whenever necessary after discharge for evaluating outcomes and late complications.

Visual Analogue Score (VAS):

The concept of visual analogue score was explained to each patient in the post operative period with maximal imaginable pain as 10 and least as 1. The patients were assessed for pain by VAS post operatively at 06hrs 12 hours,24hrs.

Evaluation of incontinence: Wexner score [10] was used to evaluate incontinence.

A total of 110 patients divided in two groups based; Group A patients were treated with Manual anal dilatation and Group B were treated with lateral internal sphincterotomy. All patients were operated in left lateral position (Sims) under general anesthesia.

PRE - OPERATIVE WORK UP:

The patients with no other co-morbid condition were admitted directly on the day before surgery; patients with any co morbidities are admitted to the hospital preferably 1 days prior to operation for necessary evaluation. The patient was prepared with proctoclysis enema previous night and on the morning of the day of surgery. At the time induction, injection Ceftriaxone + Tazobactam 1.125 gm I/V and injection Metronidazole 500 mg I/V were injected for prophylactic antibiotic coverage.

SURGICAL TREATMENT: -

Surgical treatment (Manual anal dilatation or Lateral internal anal sphincterotomy) was done by senior consultant under general anesthesia.

Operative techniques:

Lord's anal dilatation - First digital rectal examination, and proctoscopy was performed to confirm clinical findings, and to rule out other causes of bleeding. Thereafter fully lubricated index finger of right hand was introduced, and constriction band was palpated which corresponds to anorectal line. After palpating the constriction band, fully lubricated index finger of each hand was introduced in the anal canal and continuous gentle outward pressure was applied, till the constriction overcame. During this procedure hand repeatedly moved all around in order to relax all the segment. The procedure was stopped till the anal canal was relaxed enough to accept four fingers (two of each hand) at a time without much force.

In lateral sphincterotomy, a 0.5- to 1-cm incision is made in the inter-sphincteric plane. The internal sphincter is then looped on a right angle and brought up into the incision. The internal sphincter is then cut under direct visualization. The two ends are allowed to fall back after being cut. A gap can then be palpated in the internal sphincter through the anal mucosa, as in the closed technique. The incision was left open to heal.

POST OPERATIVE CARE

- 1) Diluted Injection Tramadol 100 mg IV stat as needed.
- 2) The patient was allowed fully orally after 3 hours of surgery. P/R diclofenac suppository was kept to reduce the post operative pain.

Then the patient was put on standard post operative care including antibiotics, analgesics, Bromelain+trypsin+rutoside and sucralfate + lignocaine cream(local application). The patient was advised as follows, soft and fat free diet, Syrup Lactulose 15ml at bedtime, Plenty of fluids orally and twice daily sitz bath.

The patients were discharged when there was no requirement for IV analgesia in the last 12 hours. The criteria of passage of first motion after surgery was not considered necessary for discharge.

The patients were advised to follow up after 15 days and one month and 3rd month.

Success Rate: Success rate is the fraction or percentage of success among a number of attempts.

Failure rate: It can be defined as the anticipated number of times that a surgical attempt fails in a specified period of time.

Statistical Methods: Data collected and entered in windows excel format. by computing percentage, mean and standard deviation. Frequency tables and measures of central tendency (mean) and measures of dispersion (Standard deviation) were obtained by using the statistical package SPSS. At the end of study, the results were compared, and chi-square test was applied as these are qualitative variables, the p value was calculated and a value of less than 0.05 was considered to be statistically significant.

The research hypothesis and statistical methods formed in consultation with Biostatistician.

Results:

In the present study we evaluated 110 patients of fissure in ano with reference to manual anal dilatation and lateral internal sphincterotomy.

Table 1: Distribution of patients according to their occupation.

Occupation	MAD	LIS	P value
	(Manual anal dilatation)	(lateral internal sphincterotomy)	
Housewife	6	6	
	(5%)	(8%)	
Carpenter	3	2	
	(3%)	(2%)	
Driver	6	4	
	(5%)	(4%)	
Businessman	9	11	1.000
	(8%)	(10%)	
Agriculturist	11	10	
	(10%)	(9%)	
Labour	20	22	
	(18%)	(20%)	
Total	55	55	

Table no. 1 shows the occupational distribution of patients, majority of patients were agriculturist 21(19%) and labour 42(38%). The p-value is 1. The result is not significant at p < .05. These groups are non-comparable.

Table 2: Distribution of patients according to their symptoms.

Table 2. Distribution of patients according to their symptoms.				
Clinical Features	MAD	LIS	P value	
	Number of cases (%)	Number of cases (%)		
Pain	55	55		
	(50%)	(50%)		
Bleeding	40	45	0.9702	
	(36%)	(41%)		

Constipation	47	48	
	(42%)	(43%)	
Discharge	5	2	
	(5%)	(2%)	
Pruritus	8	2	
	(7%)	(2%)	

Table no. 2 shows the distribution of patients according to their symptoms, we observed that pain was seen in 55 (50%) MAD cases and in 55 (50%) cases of LIS relates to acute throbbing ischemic pain of fissure, bleeding was seen in 40 (36%) cases while 45 (41%) cases of LIS, constipation was seen in 47 (42%) cases of MAD and 48 (43%) cases of LIS. Discharge was observed in 5 (5%) MAD cases and 2 (2%) LIS cases. Pruritus was seen in 8 (7%) MAD cases and 2 (2%) LIS cases. Discharge and pruritus were seen in patients of sentinel pile. Pain, constipation, and bleeding was commonly seen in both MAD and LIS study groups. The p-value is 0.9702. The result is not significant at p < .05. These groups are non-comparable.

Table 3: Distribution of patients according to their per rectal findings.

Parameters	S	MAD	LIS	P value
Position	Anterior	3	3	
		(3%)	(3%)	
	Posterior	50	52	0.3607
		(55%)	(57%)	
	Both	2	0	
		(2%)		
Number	One	53	55	
		(58%)	(61%)	0.4954
	Two	2	0	
		(2%)		
Sentinel	Present	28	20	
Pile		(31%)	(22%)	0.1781
	Absent	27	35	
		(30%)	(39%)	
Spasm	Present	55	55	
		(61%)	(61%)	
	Absent	0	0	

Table no. 3 shows per rectal findings, we found that position of fissure in ano was anterior side in 6 (5%) cases, posterior in 102 (92%) and 2 (2%) were on both side. Anterior side fissure in ano was seen commonly in females. One fissure in ano seen in 108 (97%) while two seen in 2 (2%) study cases. Sentinel piles were seen in 48 (43%) cases. While spasm was present in 110 (99%) study cases attributes contraction of sphincter complex due to pain. Among study cases fissure in ano shown non significance for its position, number sentinel

pile in between MAD and LIS study groups. These groups are non-comparable at p < .05 regarding all parameters.

Table 4: Distribution patients according to mean VAS score at different time points.

Duration	Type of Surgery	MAD	LIS	P value
06 Hrs	Mean	3.891	2.691	0.0001
	Std. Deviation	0.3146	0.4664	0.0001
12 Hrs	Mean	0.60	0.5273	0.1981
	Std. Deviation	0.4944	0.5039	0.1961
24 Hrs	Mean	0.1091	0.0545	
	Std. Deviation	0.3146	0.2292	0.1505

Table no. 4 shows VAS score at different time points. The mean \pm SD postoperative pain vas score at 6 hours of MAD group [3.981 \pm 0.3146] is higher than LIS group [2.691 \pm 0.4664]. There is a significant difference between the MAD and LIS group for postoperative pain vas score at 06 hours (P < 0.0001). The mean \pm SD postoperative pain vas score at 12 hours of MAD group [0.6 \pm 0.49] is higher than LIS group [0.5273 \pm 0.5]. However, there is no significant difference between the MAD and LIS group for postoperative pain vas score at 12 hours (P = 0.1981). The mean \pm SD postoperative pain vas score at 24 hours for MAD and LIS group is 0.1091 \pm 0.31 and 0.05 \pm 0.22. However, there is no significant difference between the MAD and LIS group for postoperative pain VAS score at 24 hours (P = 0.1505). The mean VAS score was slightly high at 6 hrs,12 hrs. 24 hrs for MAD group than LIS group. The p value of 6 hrs VAS score is significant p value 0.0001. While p value at 12 hrs and 24 hrs VAS score was non-significant. So, the groups are non- comparable at this duration.

Table 5: Mean difference among MAD and LIS group for Wexner score.

Duration	Type of Surgery	MAD	LIS	P value
24 Hrs	Mean	0.4545	0.3091	0.4088
	Std. Deviation	0.9392	0.9001	0.4088
15 days	Mean	0.0363	0.0363	
	Std. Deviation	0.1889	0.1889	1
One Month	Mean	0	0	
	Std. Deviation	0	0	
Three Month	Mean	0	0	
	Std. Deviation	0	0	

Table no. 5 shows the distribution of MAD and LIS group according to Wexner score Wexner scoring for incontinence. The mean Wexner score was slightly high or equal at 24 hrs,15 days, one month and three months for MAD group than LIS group. The p value is non-significant for 24 hrs and 15 Days. These groups are non-comparable.

Table 6: Showing association between complications and type of Surgery performed.

Complications	MAD	LIS	P value
	Number of cases (%)	Number of cases (%)	
Haematoma	3	1	

Abscess	1	0	
Nocturnal Soiling	0	0	0.3588
Incontinence	0	0	
Fistula in Ano	0	0	

Table no. 6 shows the association between complications and type of surgery. In the MAD group hematoma seen in 3 patients, abscess seen in 1 patient and recurrence seen in 2 patients while in the LIS group recurrence seen in 1 patient. The p value is not significant (p value 0.3588). These groups are non-comparable

Discussion:

A total of 110 patients of fissure in ano those who presented to surgery OPD and / or admitted were divided into MAD and LIS groups on randomized basis.

In the present study we observed that this condition is very common in the second to fifth decade. The mean age of patients underwent MAD was 41.09 ± 11.83 years while for LIS patients mean age was 37.58 ± 11.81 years which was comparable with studies Muhammad AR et al [5] and Hanaa AK et al. [11] This might be due to adult age group engaged in sitting activity. In our study There was a definite male preponderance to developing fissure -in-ano with most of our patients being male. In our study $40 \ (36\%)$ male and $15 \ (14\%)$ female among 55 patients underwent MAD while $28 \ (26\%)$ male and $27 \ (24\%)$ female underwent LIS were included. The p value was 1.000 which was non-significant. This might be due males are more prone to consume alcohol and non-veg food than female. These findings are consistent with previous similar studies done by Shantha MN et al [6], Rakesh KP et al [12].

In the present study we observed that pain constipation bleeding most common symptoms. Pain was seen in 55 (50%) MAD cases and in 55 (50%) cases of LIS, bleeding was seen in 40(36%) cases while 45 (41%) cases of LIS, constipation was seen in 47 (42%) cases of MAD and 48 (43%) cases of LIS. Pruritus was seen in 8 (7%) MAD cases and 2 (2%) LIS cases. Rakesh KP et al [12] and Tayfun Y et al [4] in their studies mentioned similar findings.

In the present study in the per rectal findings, we found that position of fissure in ano was, posterior in 102 (92%) anterior side in6 (5%) cases and 2 (2%) were on both side. Anterior side fissure in ano was seen commonly in females. One fissure in ano seen in 108 (97%) while two seen in 2 (2%) study cases. Sentinel pile were seen in 48 (43%) cases. While spasm was present in 110 (99%) study cases. The fissure in ano was found more commonly at posterior site this might be due to the posterior wall of the rectum curves forward from the hollow of the rectum to join the anal canal, which then turns sharply backwards. During defecation, the pressure of a hard faecal mass is mainly on the posterior anal tissues, in which event the overlying epithelium is greatly stretched resulting in trauma. Trauma to the anal canal during the passage of large hard fecal matter is responsible for this condition. Muhammad AR et al [5] and Arunkumar U et al [14] in their study observed similar findings.

One of the aspects of our study was to compare pain in two groups All patients were explained visual analogue score (VAS) in the pre-operative period itself. Scoring initiated following surgery at 06 hours, 12 hours, 24 hours was compared with the aid of visual analogue scale (VAS). The mean \pm SD postoperative pain vas score at 6 hours of MAD group [3.981 \pm 0.3146] is higher than LIS group [2.691 \pm 0.4664]. There is a significant difference between the MAD and LIS group for postoperative pain vas score at 06 hours (P < 0.0001).

The mean \pm SD postoperative pain vas score at 12 hours of MAD group [0.6 \pm 0.49] is higher than LIS group [0.5273 \pm 0.5]. However, there is no significant difference between the MAD and LIS group for postoperative pain vas score at 12 hours (P = 0.1981). The mean \pm SD postoperative pain vas score at 24 hours for MAD and LIS group is 0.1091 \pm 0.31 and 0.05 \pm 0.22. However, there is no significant difference between the MAD and LIS group for postoperative pain VAS score at 24 hours (P = 0.1505). These findings are comparable with the similar study done by Hareesh GSR et al [15], Rakesh KP et al [12] and Tayfun y et al [13].

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The incontinence following surgery at 24 hours, 15 days and 1 month 3 month was compared with the aid of Wexner score. The mean \pm SD of Wexner score at 24 hours of MAD group [0.4545 \pm 0.9392] is higher than LIS group [0.3091 \pm 0.9001]. There is no significant difference between the MAD and LIS group for Wexner score at 15 days one month and 3 months none of our study subjects had incontinence.

The calculation of the hospital stay was made from day of surgery and from the day of admission thus excluding the duration in hospital for getting pre-anaesthetic fitness. In this study duration of hospital stay was 1 day for 44 (40%) MAD underwent patients and 48 (44%) LIS underwent patients. It was 2 days for 11 (10%) and 7 (6%) MAD and LIS patients respectively. Longer duration was stay seen in comorbid patients. There was no statistical significance found in duration of hospital stay regarding MAD and LIS underwent patients (p value 0.6299). The mean and standard deviation for MAD was 1.2 ± 0.4037 days while mean and standard deviation for LIS was 1.127 ± 0.3364 days. P value 0.3070. The results are comparable with similar study done by Hareesh GS et al [15], Muhammad AR et al [5]. While discharging each patient was educated about the disease, and the study. All the patients were requested to attend the outpatient department for follow up for a period of 3 months.

In our study, all the patients were given post operatively daily sitz bath and appropriate intravenous antibiotics, analgesics, and other supportive care. Post operative sitz bath helps to relieve pain and minimize local edema. None of our study subjects had an adverse event immediate post operative period. All the patients are called up for follow up to check for late post-operative complications like recurrence, abscess formation, fecal or flatus incontinence. In the present study postoperative complications seen in the MAD group, hematoma seen in 3 patients, abscess seen in 1 patient and recurrence seen in 2 patients while in the LIS group recurrence seen in 1 patient. These results are comparable with the studies of Hanaa AK et al [11] and Ritesh M et al [16].

In our study 110 patients who underwent MAD hematoma seen in 3 patients, abscess seen in 1 patient and recurrence seen in 2 patients while in the LIS group recurrence seen in 1 patient in the 3rd month of follow up. Permanent fecal or flatus incontinence and nocturnal soiling was not reported in any patient of both groups.

Conclusion:

Fissures were commonly seen in middle aged males and lower socio-economic status.

Most of the patients were labelled to have haemorrhoids this is because of the old belief that any pain and bleeding around the anal opening are due to haemorrhoids

Most common clinical feature seen was pain followed by constipation & bleeding pain.

The most common position of fissure in ano was posterior followed by anterior on both sides. Anterior side fissure in ano was seen commonly in females.

Complications and recurrences were seen to be more with manual anal dilatation.

However, difference between success rate of both groups was statistically not significant as p value is 0.0954. Based on the results of our study, The results are not statistically significant to recommend one procedure as superior to other. Both MAD and LIS provide early pain relief and high ulcer healing rate and both the procedures are equally effective under experienced hands. No significant difference in post operative pain scores and duration of hospital stay in both the groups. However, LIS appears to be safer regarding hematoma, abscess formation and the chance of recurrence is also lower compared to MAD.

LIMITATIONS OF STUDY

1. The data collection was confined to only particular limited area of country.

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- 2. The present study has relied largely on quantitative methodology of data collection (through qualitative methodology was used to a limited extent) and is therefore restrictive.
- 3. This sample is only a very small proportion and hence generalization of data result is difficult.

Appendix:

MAD- Manual Anal Dilatation

LIS – Lateral internal anal sphincterotomy

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