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Laser Sphincterolysis Versus Lateral Internal Sphincterotomy In Treatment Of Anal Fissures In Inflammatory Bowel Conditions

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ABSTRACT

Background: Anal fissure is common with inflammatory bowel diseases. Management of anal fissure in those patients is complex. This study seeks improving the quality of life in patients with inflammatory bowel disease and anal fissures by comparing the outcomes of laser sphincterolysis and lateral internal sphincterotomy in those patients. **Methods:** This is a single-institution comparative randomized clinical study which was done in colorectal unit in surgery department from September 2023 to September 2024. Sixty patients with anal fissures and inflammatory bowel disease were enrolled in the study. Patients were randomly selected in two groups; Group I who had laser sphincterolysis, and Group II who underwent lateral internal sphincterotomy. **Results:** Laser group outformed the lateral internal sphincterotomy group by operative time, pain scale and duration, postoperative anal discharge, time to return to work, and patient satisfaction ($P < 0.001$). **Conclusions:** laser sphincterolysis is better than lateral internal sphincterotomy for anal fissures in inflammatory bowel patients.

Introduction

It is clear that the perianal pathology has a high incidence in Crohn's disease patients [1]. And as anal fissures are very common anal problems, it may be also an association with Crohn's disease, ulcerative colitis, and non-specific colitis.

Pregnancy, vaginal delivery, constipation and low fiber diet are factors electing or aggravating the condition.

Treatment of fissures becomes much more complicated in patients with IBD, who may experience a perianal pathology secondary to chronic inflammation caused by the disease. Because the pathophysiology is distinct and surgical intervention has a higher risk of problems linked to poor wound healing and incontinence, the treatment protocol is therefore very different [2].

Moreover, remission and exacerbation of the primary disease are very possible. The fact that the patient may need extra doses of

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immunosuppressive drugs and corticosteroids, even the patient may need curative enemas.

So, surgeons have favored medical treatment for anal fissures even if surgical intervention is indicated. The fact that inflammatory bowel patient with anal fissures will suffer from anal pain and discharge for most of their life.

Laser was proven to be an effective intervention tool in treatment of hemorrhoids for patients with inflammatory bowel diseases, but the fact that most anal fissure surgeries requires sphincterotomy is questionable in those patients [3].

This study aims to improve the quality of life for patients with inflammatory bowel disease concomitant with anal fissures for whomwhich surgical intervention is indicated by comparing intra and post-operative outcomes between laser sphincterolysis and lateral internal sphincterotomy (LIS). We hypothesize that laser has better results than LIS.

Methods

In this comparative randomized parallel clinical trial, 60 patients with anal fissures and inflammatory bowel diseases such as Crohn's disease, ulcerative colitis, or nonspecific colitis were allocated at a 1:1 ratio. Patients admitted between September 2023 and September 2024 were included.

Blinding and simple randomization in subgroups were used to divide participants into two groups. Group II received LIS treatment, while group I received laser sphincterolysis.

With protocol registration ID: #101080-5-9-2023 and registered at Clinical Trial.gov (NCT06216223), the trial complied with CONSORT 2010 criteria. At 80% power and 95% C, the necessary sample size was calculated to be 60 patients with anal fissure (30 patients in each group). Open epi.

All individuals with anal fissures and IBD either nonspecific colitis, Crohn's disease or ulcerative colitis, between the ages of 18 and 60 were included in the study. Patients with multiple fissures, those eligible for conservative treatment, those with co-existing anal fissures and hemorrhoids, patients with fistulas or abscesses, those under the age of 18 or older, those with a history of malignancy in IBD, those who refused to give informed consent, and patients under the age of 18 or older than 60 were excluded from the study.

Surgery is was recommended when medical treatment failed s and is not followed, when there is persistent pain, anal spasms, and bleeding.

An outpatient with anal fissures was examined to evaluate the sphincter tone, the number of fissures and the presence anal spasm. Fasting for six hours was recommended and patients admitted for one day surgery without bowel preparation. Saddle anesthesia was used and the patients were placed in the lithotomy position. Group I underwent laser treatment for anal fissures as lateral sphincterolysis (Lasotronix SMARTMSG-3-1470nm (15W) 1470 nm wavelength, Poland). Group II underwent LIS.

The laser sphincterolysis procedure involved lateral closed sphincterolysis was carried out by inserting the left index finger into the anal canal and the right index finger palpating the inter-sphincteric groove from outside. Subsequently, a curved laser probe was introduced into the inter-sphincteric space externally at 3 o’clock and advanced in a closed technique to cut the internal anal sphincter fibers at different levels using a pulsatile mode guided by the left index from inside [4, 5]. A range of 170-200 joules was provided. Application of ice cubes inside, which had a cooling effect, resulting in reduced pain and edema.

The lateral internal sphincterotomy (LIS) group underwent open lateral internal sphincterotomy by a small incision at 3 o’clock and a punch of internal sphincter fibres was hanged as a sling and cut at the same level using a classic energy source such as monopolar diathermy.

Intraoperatively, patients received a dose of corticosteroids. Postoperative corticosteroids along with immunosuppressive drugs were resumed.

Patients were monitored as outpatients twice a week for a month after hospital discharge, and then once a month for six months, or more frequently if difficulties arose in between visits. Data were collected prior to, during, and after surgery.

Age, gender, and he the category of inflammatory bowel confirmed by colonoscopy and biopsy were gatheredwhich performed a long time prior to surgery. Both groups' surgical times (measured in minutes) from skin incision to dressing were noted. Intraoperative bleeding was measured in milliliters (mL) using the gravimetric technique. Surgical gauze and blood-soaked dressings were

weighed, and dry weight was subtracted. Following surgery, the same technique was applied, gathering the patients' pads or dressings and noting their weight and quantity each day for two weeks. Additionally, patients had daily direct interaction with the doctor to visually estimate the quantity of blood loss. A conversion of 1 g = 1 ml was used to compute the blood loss [6]. According to the Advanced Trauma Life Support (ATLS) hemorrhagic shock categorization established by the American College of Surgeons, all patients were classified as class I (having < 750 ml of blood loss) [67].

A visual analog score with a low limit of 0 to a high limit of10 was used to assess the pain score. A maximum score of 10 denotes extreme agony, while a score of 0 shows no discomfort at all. The mean score was determined after the pain was assessed on the first, second, third, seventh, and fourteenth days. The duration of analgesic intake in days was estimated for two weeks postoperatively. Over the course of two weeks following surgery, the presence of postoperative anal discharge was assessed.

Furthermore, the time to return to work was evaluated from one day to two months after surgery, the duration for full healing in days was recorded from the first day to three months postoperatively and verified by digital rectal examination and proctoscopy, and patient satisfaction scores were examined for three months postoperatively using the customer satisfaction score, where a score of one indicates that the patient is very dissatisfied and a score of ten indicates that the patient is very satisfied.

A three to six months duration occurrence of recurrence was followed up.

Statistics

The acquired data was tabulated, summarized, and statistically analyzed with SPSS version 17. We compared the two groups using standard deviation (SD), Independent t-test, and Chi-square test ($\chi 2$).

Results

A total number of 60 inflammatory bowel patients (nonspecific colitis, Crohn’s disease, or ulcerative colitis) with anal fissures that needed intervention were randomized into two groups. Group I (30 patients) underwent laser sphincterolysis, whereas Group II (30 patients) underwent LIS. The study concluded upon reaching the estimated sample size.

Demographic, clinical, operative, and postoperative data of patients with anal fissure are depicted in Table 1. There were no significant differences in age, sex, presentation of inflammatory disease, site, postoperative bleeding, and recurrence of fissures between the two groups. However, there was a significant difference in operative time, pain sensation, analgesia requirements, time for healing, return to work, and patient satisfaction, with the laser group demonstrating better outcomes (p-value <0.001). In addition, anal discharge was lower in the laser group, with a p-value of 0.04.

Operative and postoperative data of patients with nonspecific colitis for both groups are presented in Table 2.

The laser group demonstrated significant improvements in terms of operative time, pain score, analgesia duration, healing duration, and return to work, with a p-value <0.001. However, there were no differences observed between the two groups in terms of postoperative bleeding, postoperative anal discharge, or recurrence.

Table 3 presents the results of intra and postoperative outcomes for fissure instances in patients with Crohn's disease. The data indicates that the laser group had considerably better outcomes in terms of operation time, duration of analgesia, and patient satisfaction score, with a p-value <0.001. Pain score, healing duration, and return to work were significantly better in the group I with a P value <0.05, while there was no statistical difference between the two groups in bleeding time, anal discharge, or recurrence.

The laser group demonstrated significantly improved outcomes regarding ulcerative colitis patients, operation time, pain score, anal discharge, and patient satisfaction score, with a p-value <0.05. Moreover, the laser group had an earlier return to work, with a p-value <0.001. There was no difference between the two groups regarding bleeding, analgesia duration, healing duration, or recurrence. These results are depicted in Table 4.

Table 1. Demographic, clinical and operative data of anal fissure cases:

Variable		Group I (Laser) (*n*=30)		Group II (Surgery) (n=30)		Test	P
		No	**%**	**No**	**%**		
Age: (years)	*Mean ± Sd* *Range*	40.47±6.98 29-53		38.77±7.43 29-54		t 0.91	0.36 NS
Sex:	*Female* *Male*	18 12	60 40	21 9	70 30	χ^2 0.66	0.42 NS
Disease:	*Colitis* *Crohn's* *Ulcerative*	15 10 5	50 33.3 16.7	15 10 5	50 33.3 16.7	χ^2 0	1 NS
Site:	*Anterior* *Posterior* *Lateral* *Ant & post*	3 9 6 12	10 30 20 40	5 10 6 9	16.7 33.3 20 30	χ^2 0.98	0.81 NS
Operation time: (min)	*Mean ± Sd* *Range*	11.77±1.65 10-15		18.57±5.52 13-40		**t** **6.46**	**<0.001****
Bleeding post operation:	*No* *Yes*	25 5	83.3 16.7	26 4	86.7 13.3	χ^2 0.13	0.72 NS
Anal Discharge:	*No* *Yes*	28 2	93.3 6.7	22 8	73.3 26.7	**χ^2** **4.32**	**0.04***
Pain score:	*Mean ± Sd* *Range*	4.2±1.35 1-7		7.27±1.23 5-10		**t** **9.20**	**<0.001****
Pain duration (day):	*Mean ± Sd* *Range*	2.6±1 1-5		5.13±1.20 2-7		**t** **8.89**	**<0.001****
Healing duration: (day)	*Mean ± Sd* *Range*	42.57±6.85 30-54		53.5±8.27 38-70		**t** **5.57**	**<0.001****
Return to work: (day)	*Mean ± Sd* *Range*	15.47±3.44 10-25		23.3±4.57 15-31		**t** **7.50**	**<0.001****
Patient satisfaction score:	*Mean ± Sd* *Range*	8.2±0.93 7-10		6.27±1.23 3-8		**t** **6.88**	**<0.001****
Recurrence:	*No* *Yes*	26 4	86.7 13.3	21 9	70 30	χ^2 2.46	0.12 NS

SD: Standard deviation**;** t: Independent t test; χ^2:Chi square test; NS: Non significant (P>0.05); *:Significant (P<0.05); **: Highly significant (P<0.001)

Table (2): Operative data of colitis anal fissure cases.

Variable		Group I (Laser) (*n*=15)		Group II (Surgery) (n=15)		Test	P
		No	**%**	**No**	**%**		
Operation time: (min)	*Mean ± Sd* *Range*	11.8±1.78 10-15		16.2±2.18 13-20		**t** **6.06**	**<0.001****
Bleeding post operation:	*No* *Yes*	13 2	86.7 13.3	13 2	86.7 13.3	**χ^2** 0	1 NS
Anal Discharge:	*No* *Yes*	15 0	100 0	13 2	86.7 13.3	χ^2 2.14	0.14 NS
Pain score:	*Mean ± Sd* *Range*	4.4±1.24 2-7		7.93±1.1 6-10		**t** **8.25**	**<0.001****
Pain duration (day):	*Mean ± Sd* *Range*	2±0.76 1-3		5.07±0.88 4-7		**t** **10.21**	**<0.001****
Healing duration: (day)	*Mean ± Sd* *Range*	39.53±5.76 30-48		54.73±6.41 44-65		**t** **6.84**	**<0.001****
Return to work: (day)	*Mean ± Sd* *Range*	16.27±2.79 12-21		21.6±4.27 15-30		**t** **4.05**	**<0.001****
Patient satisfaction score:	*Mean ± Sd* *Range*	8.4±0.91 7-10		7±0.85 6-8		**t** **4.37**	**<0.001****
Recurrence:	*No* *Yes*	14 1	93.3 6.7	10 5	66.7 33.3	**χ^2** 3.33	0.07 NS

SD: Standard deviation t: Independent t test χ^2:Chi square test NS: Non significant (P>0.05) *:Significant (P<0.05) **: Highly significant (P<0.001)

Table (3): *Operative data of crohn's anal fissure cases:*

Variable		Group I (Laser) (*n*=10)		Group II (Surgery) (n=10)		Test	P
		No	**%**	**No**	**%**		
Operation time: (min)	*Mean ± Sd* *Range*	11.9±1.73 10-15		23.4±7.07 15-40		**t** **4.99**	**<0.001****
Bleeding post operation:	*No* *Yes*	7 3	70 30	8 2	80 20	χ^2 0.27	0.61 NS
Anal Discharge:	*No* *Yes*	9 1	90 10	8 2	80 20	χ^2 0.39	0.53 NS
Pain score:	*Mean ± Sd* *Range*	4±1.76 1-6		6.6±0.97 5-8		**t** **4.09**	**0.001***
Pain duration (day):	*Mean ± Sd* *Range*	3.4±0.84 2-5		6±0.82 5-7		**t** **7.01**	**<0.001****
Healing duration: (day)	*Mean ± Sd* *Range*	47.6±6.67 30-54		56.5±8.78 44-70		**t** **2.55**	**0.02***
Return to work: (day)	*Mean ± Sd* *Range*	15.4±4.58 10-25		23.1±3.84 15-30		**t** **4.08**	**0.001***
Patient satisfaction score:	*Mean ± Sd* *Range*	7.7±0.68 7-9		5.5±0.85 4-7		**t** **6.41**	**<0.001****
Recurrence:	*No* *Yes*	7 3	70 30	6 4	60 40	χ^2 0.22	0.64 NS

SD: Standard deviation t: Independent t test χ^2:Chi square test

NS: Non significant (P>0.05) *:Significant (P<0.05) **: Highly significant (P<0.001)

Table (4): *Operative data of ulcerative anal fissure cases:*

Variable		Group I (Laser) (*n*=5)		Group II (Surgery) (n=5)		Test	P
		No	**%**	**No**	**%**		
Operation time: (min)	*Mean ± Sd* *Range*	11.4±1.34 10-13		16±2 13-18		**t** **4.27**	**0.003***
Bleeding post operation:	*No* *Yes*	5 0	100 0	5 0	100 0	χ^2 ---	----
Anal Discharge:	*No* *Yes*	4 1	80 20	1 4	20 80	χ^2 **3.6**	**0.05***
Pain score:	*Mean ± Sd* *Range*	4±0.71 3-5		6.6±1.14 5-8		**t** **4.33**	**0.003***
Pain duration (day):	*Mean ± Sd* *Range*	2.8±0.84 2-4		3.6±1.14 2-5		t 1.27	0.24 NS
Healing duration: (day)	*Mean ± Sd* *Range*	41.6±5.03 35-48		43.8±5.76 38-50		t 0.64	0.54 NS
Return to work: (day)	*Mean ± Sd* *Range*	13.2±1.64 11-15		28.8±2.39 25-31		**t** **12.04**	**<0.001****
Patient satisfaction score:	*Mean ± Sd* *Range*	8.6±1.14 7-10		5.6±1.67 3-7		**t** **3.31**	**0.01***
Recurrence:	*No* *Yes*	5 0	100 0	5 0	100 0	χ^2 ---	----

SD: Standard deviation t: Independent t test χ^2:Chi square test

NS: Non significant (P>0.05) *:Significant (P<0.05) **: Highly significant (P<0.001)

Discussion

Hemorrhoids and anal fissures are frequent problems in inflammatory bowel sufferers. The effectiveness of laser hemorrhoidoplasty has been the subject of numerous research, although LaFiP laser sphincterolysis has received less attention. Nevertheless, no research or studies have evaluated laser ablation for inflammatory bowel disease patients. It is challenging to treat anal diseases in these patients since surgery might exacerbate the burden of the condition and result in complications.

Conservatively treating non-indicated cases, however, exacerbates the condition.

Diode lasers, carbon dioxide, argon, and Nd:YAG are the most common types of laser energy used in the health care sector. Laser causes tissue shrinkage and degeneration to variable degrees, depending on the laser strength and length of the laser light exposure. Recently, diode laser therapy has emerged as a painless and minimally invasive substitute for surgery. It is linked with an early recovery, decreased bleeding, and less post-operative pain [78].

A total of 60 patients with anal fissures were admitted. There were 30 patients in each group (15 had nonspecific colitis, 10 had Crohn's disease, and five had ulcerative colitis). Group I was treated with laser, whereas Group II underwent surgery. All patients were on immunosuppressive and corticosteroids therapy. No statistically significant differences were observed among the patients treated with laser and those treated with surgery in terms of age, sex distribution, pathology, or site of fissure.

There are various laser methods for treating anal fissures. According to Talaat et al., the lateral internal sphincterotomy using a closed laser technique was effective. They used bare fibers at a wavelength of 1470 nm. The total number of joules ranged between 70 and 100. Hussein et al. used a diode laser in anal fissures. The technique they used for anal fissures was the open method of lateral internal sphincterotomy (LIS). They used a laser probe to cut the internal anal sphincter fibers. Esfahani et al. conducted internal sphincterotomy and fissuroplasty using a carbon dioxide laser [89].

In our study, we used a diode laser with a wavelength of 1470 nm (15 w) in a pusatile mode to undergo closed lateral sphincterolysis. The energy delivered was about 170-200 joules. Patients with inflammatory bowel disease often develop fibrosis and necrotic tissue. And because LIS is known to be the most minimally invasiveand the most effective method to treat anal fissure rather than fissurectomy, open LIS was done in group II and closed laser lateral internal sphincterolysis. This is more favorable than the open method due to its smaller wound size and decreased pain. Sphincterolysis was equally effective or superior to sphincterotomy in maintaining continence. However, it provides longer-lasting relief from anal spasms [910].

The fact that anal fissure is mostly associated with hypertonia and anal spasm makes sphincterotomy alone or associated with fissurectomy is the routine treatment for anal fissure. It is also known that sphincterotomy is contraindicated in inflammatory bowel disease for increased risk of incontinence. This contraindication is absolute in ulcerative colitis being has muscle pathogy.

Cracco and Zinicola have discussed in their study the risk of sphincterotomy in Crohn's disease and their results demonstrated that none experienced impairment of continence occurred in their study on the effect sphincterotomy in Crohn's patient [1011].

So, we tried to find if laser sphincterolysis can be safely done in those patients as an alternative for sphincterotomy and if it is effective or not. We found that all cases preserved their continence. This may be due to cutting the sphincter at different levels, the cutting also can be adjusted to be very few millimeters by the very thin laser prob.

Consistent with our findings Hussein and his colleagues [1112], who conducted a study on patients without inflammatory bowel disease, found that the duration of anal fissure surgery ranged from 12 to 17 minutes with a mean time of 15 minutes. In addition, the duration of laser surgery ranged from 8 to 13 minutes, with a mean time of 9 minutes. They also found no significant difference in bleeding between the two groups.

In our study, the range of operative time for traditional surgery was (13-40) minutes, while that for the laser group was (10–15) minutes, with a mean time of 18.57 vs. 11.77 minutes. Operation time was shorter in group I as the laser delivered high energy in a shorter time compared to surgery. However, there was no difference in the frequency of bleeding between the two groups, possibly due to extensive fibrosis in those patients.

According to Maurice et al. [1213], LaFiP laser sphincterolysis had less postoperative pain than surgery. In our study, we assessed postoperative pain on a visual analog scale, which showed that the laser group had a markedly lower pain score. This may be because the burnt area in the laser group was smaller, and the laser decreased inflammation by decreasing the release of inflammatory mediators such as TNF-α and IFN-γ [14]. The weaning time from analgesia was also markedly shorter in the laser group.

While postoperative anal discharge following fissure procedures is relatively infrequent, it can be bothersome. The laser group had a significantly decreased incidence of postoperative anal discharge, particularly among patients with ulcerative colitis. This could be attributed to the reduction of itching through the application of ice cubes, which decreased the itching.

Maurice et al. [1213] also stated that the healing duration was shorter in the laser group than

in traditional surgery. This finding aligns with our study, as the mean time for complete healing was 42.57 days in the laser group vs. 53.5 in the surgery group. The shortest duration was among nonspecific colitis patients and the longest among Crohn's disease patients. Moreover, we found that patients in the laser group resume their work significantly earlier than those in the surgery group. This finding can be attributed to the stimulation of regeneration and collagen formation by laser and decreasing inflammation.

One of the most annoying known complications of closed sphincterolysis is perforation of the mucosa causing perianal fistula. We did not experience any occurrence of fistula. If it occurs intraoperative, it should be managed by opening the tract from outside to the mucosa making fistulotomy. If it occurs postoperative, we recommend conservative management if the patient is not medically controlled and fistulotomy if he is controlled as fistula is usually low intersphincteric.

Finally, patient satisfaction was assessed after three months by using the patient satisfaction score. The results indicated that patients in the laser group, particularly those with Crohn's disease, exhibited higher satisfaction levels. No statistically significant difference in recurrence rates was detected between the two groups over the 6-month follow-up period.

Conclusion

Laser sphincterolysis demonstrated better outcomes compared to LIS in treating anal fissures in inflammatory bowel conditions as nonspecific colitis, Crohn's disease, and ulcerative colitis.

Trial limitations and recommendations

We suggest that future studies extend the follow-up period and the sample size to evaluate long-term results, including the likelihood of long-term recurrence and short-term complications of sphincterolysis especially occurrence of perianal fistula. It is also essential to study the effect of sphincterolysis on a larger number of ulcerative colitis patients or to make a multicentre studies to collect a larger sample size.

Funding

No funding was received for conducting this study.

Conflict of interest

The authors declare that they have no conflict of interest.

Data availability

No datasets were generated or analysed during the current study.

Ethics declarations

Ethical approval

This study was conducted following the ethical principles of the Declaration of Helsinki (Edinburgh 2000) and the approval of the Institutional Review Board. An exemption for informed consent was given by the Institutional Review Board.

Ethical approval and consent to participate

-Informed written consent was taken from all participants.

-This study was approved by institutional research board (IRB) in our University with ethics approval number #101080 in 5-9-2023

Consent for publication

Informed written consent was taken from all participants to publish their data.

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