

# Outcomes of Closed Versus Open Lateral Internal Anal Sphincterotomy for Chronic Anal Fissure: A Randomized Controlled Trial

Ejaz ul Hassan<sup>1</sup>, Ayesha Choudary<sup>1</sup>, Hina Khan<sup>1</sup>, Shabbar Hussain Changazi<sup>1</sup>, Samiullah Bhatti<sup>1</sup>, Qamar Ashfaq Ahmad<sup>1</sup>

<sup>1</sup>Department of General Surgery, Services Institute of Medical Sciences, Lahore, Pakistan

**Correspondence to:** Shabbar Hussain Changazi, Email: shabbarchangazi246@gmail.com

## ABSTRACT

**Background:** Lateral internal anal sphincterotomy (LIAS) is the treatment of choice for chronic anal fissure (CAF) when conservative management fails to heal the fissure. While both closed and open techniques are widely used, comparative data on wound healing outcomes and predictors of healing remain limited. This randomized controlled trial compared closed versus open LIAS under different anesthesia protocols and identified independent predictors of wound healing.

**Methodology:** In this trial 160 patients suffering from chronic anal fissure were randomly allocated to undergo either closed LIS under local anesthesia with sedation or open LIS under spinal anesthesia. The primary outcome was complete wound healing at 6 weeks. Secondary outcomes included pain at 24 hours, return to work, anal incontinence at 6 weeks and 1 year, and recurrence at 1 year. Multivariate logistic regression was computed to identify independent predictors of non-healing.

**Results:** Baseline characteristics were comparable between groups. Closed LIAS was associated with significantly lower pain scores at 24 hours ( $1.1 \pm 0.3$  vs  $3.3 \pm 0.6$ ,  $p < 0.001$ ) and faster return to work ( $3.3 \pm 1.1$  vs  $6.6 \pm 1.4$  days,  $p < 0.001$ ). Healing rates at 6 weeks were excellent and comparable between the two groups (96.3% vs. 97.5%,  $p = 0.62$ ). Transient flatus incontinence occurred in 2.5% of closed LIAS and 5.0% of open LIAS patients ( $p = 0.41$ ), with no cases of fecal incontinence. Recurrence at one year was 4.0% in the closed group and 3.0% in the open group ( $p = 0.58$ ). On multivariate analysis, independent predictors of non-healing were age  $\geq 40$  years and fissure duration  $> 12$  months.

**Conclusion:** Both closed and open lateral internal anal sphincterotomy are highly effective treatments for chronic anal fissure, achieving excellent healing rates with no permanent incontinence. Closed LIAS under local anesthesia with sedation offers superior early outcomes with less pain, faster return to work, and the advantage of same-day discharge.

**Keywords:** Chronic Anal Fissure; Lateral Internal anal Sphincterotomy; Closed Technique; Open Technique; Wound Healing; Randomized Controlled Trial

## INTRODUCTION

Chronic anal fissure (CAF) is one of the most prevalent anorectal conditions in clinical practice and is defined by a longitudinal tear in the anoderm below the dentate line. It is quite painful, sometimes a bit disabling, and causes worsening quality of life. About 90% of the fissures are located in the posterior median line, while anterior fissures are more common in females than in males. The mechanism of action of CAF is believed to be due to a mix of anal sphincter hypertonia, mucosal ischemia and impaired healing. The increased resting anal pressure, particularly at the internal

anal sphincter complex, causes reduced anodermic blood flow, and ultimately a vicious circle of tissue ischemia and a failure to heal spontaneously.<sup>1,2</sup>

The American Society of Colon and Rectal Surgeons is recommending that conservative treatment (dietary fiber, stool softeners, warm sitz baths and topical agents like Glyceryl trinitrate or calcium channel blockers) be the first line of treatment.<sup>3,4</sup> Unfortunately, many patients do not achieve a satisfactory outcome with medical management, and recurrence rates continue to be high.<sup>5,6</sup> In CAF that are refractory to medical management, lateral internal anal sphincterotomy (LIAS) has proven to be the treatment of choice, with an excellent healing rate (90% or more) and long-lasting symptom relief.<sup>7</sup>

There are commonly two main surgical approaches employed for performing LIAS: the closed (subcutaneous) technique, in which the internal anal sphincter is divided blindly through a small stab incision, and an open technique, in which a curvilinear incision is made, with direct visualization and division of the fibers of the internal anal sphincter.<sup>8,9</sup> A recent systematic review and meta-analysis of 16 studies with 1711 patients showed that closed LIAS was related to significantly reduced delayed fissure healing, shorter hospital stay and lower postoperative pain score at

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24 hours.<sup>10</sup> The best anesthesia for each technique, however, is still under investigation.

Previous randomized trials have shown comparable efficacy between the closed and open LIAS in terms of healing rates and long-term outcomes.<sup>11,12</sup> However, limitations of existing evidence include; variable anesthesia protocols<sup>13</sup>, lack of standardized outcome assessment, and insufficient attention to predictors of wound healing. Moreover, the independent effect of surgical technique versus anesthesia modality on early recovery outcomes has not been clearly delineated. This randomized controlled trial was designed to compare closed versus open LIAS under standardized but distinct anesthesia protocols (closed: local anesthesia with sedation; open: spinal anesthesia), and to identify independent predictors of wound healing that may inform patient selection and postoperative surveillance.

## METHODOLOGY

This trial was carried out in the Department of General Surgery, Services Hospital, Lahore, Pakistan, from February 2019 to December 2025, with one-year follow-up. The trial was registered with ClinicalTrials.gov (NCT07496216). Ethical approval was obtained from the hospital's institutional review board (2019/10/SIMS), and the study was conducted in accordance with CONSORT guidelines. Written informed consent was taken from every patient prior to enrolment.

The sample size was calculated based on the primary outcome of wound healing at 6 weeks. Based on previous studies<sup>9</sup>, the anticipated healing rate was 95% for the closed lateral internal anal sphincterotomy (CLIAS) group and 95% for the open lateral internal anal sphincterotomy (OLIAS) group and assuming a non-inferiority margin of 8.5%, with 80% power and a one-sided significance level of  $\alpha = 0.05$ , the calculated sample size was approximately 82 patients per group, rounded to 80 per group for logistical parity between arms, giving a total sample size of 160 patients.

A total of 160 consecutive patients with chronic anal fissure meeting the inclusion criteria were enrolled from the outpatient department during the study period. Inclusion criteria were age  $\geq 20$  years, diagnosis of chronic anal fissure (symptoms persisting for more than 6 weeks), failure of conservative medical management (dietary fibre, stool softeners, topical lignocaine, and at least 4 weeks of topical glyceryl trinitrate 0.2%), and willingness to give informed consent. Exclusion criteria were laterally located fissures, concomitant anorectal pathology (anal fistula, anorectal abscess, significant haemorrhoidal disease, or rectal cancer), inflammatory bowel disease (Crohn's disease or ulcerative colitis), previous anorectal surgery, history of anoreceptive intercourse, psychiatric disease, or inability to

provide informed consent.

Eligible patients were randomly assigned to either the closed lateral internal anal sphincterotomy (CLIAS) group or the open lateral internal anal sphincterotomy (OLIAS) group in a 1:1 ratio using a computer-generated random number sequence. Allocation was concealed using sequentially numbered opaque sealed envelopes, opened only at the time of surgery by a team member who had no role in patient evaluation or outcome assessment. Given the nature of the surgical procedures and distinct anesthesia protocols, it was not possible to blind the operating surgeons or patients to the assigned technique; however, outcome assessors (surgeons not involved in the operation) were blinded to the group allocation. Patients were instructed not to discuss their surgical details with the assessors during follow-up visits.

The procedure was performed under local anesthesia using a cocktail of Inj. Xylocaine (2% lidocaine with adrenaline, 5-10 mL) for short-acting anesthesia and Inj. Bupivacaine (0.5%, 5-10 mL) for a long pain-free interval<sup>9</sup>, injected into perianal skin & the inter-sphincteric groove, combined with intravenous sedation (midazolam 1 - 2 mg with fentanyl 50-100 mcg). Clinically the inter-sphincteric groove is palpated at 3° clock position and a number 11 scalpel blade was introduced into the inter-sphincteric groove in the lithotomy/left lateral position, advanced upwards almost at the level of the dentate line, and then rotated medially to divide the internal anal sphincter taking extreme care to avoid injury to anal mucosa. A decrease in tension on the retractor blades within anus, confirm adequate division. Patients were discharged on the same day after confirming adequate oral intake, stable vitals, and full orientation.

The procedure was performed under spinal anesthesia with sedation (midazolam 1-2 mg IV) in the lithotomy position. A 1-2 cm curvilinear incision was made over the inter-sphincteric groove in the left lateral position. The intersphincteric plane was dissected to expose the pearly white fibres of the internal anal sphincter, which were then divided under direct vision up to the level of the dentate line. The wound was left open to heal by secondary intention. Open LIS patients were discharged within 24 hours.

In both groups, sphincterotomy was routinely accompanied by excision of the fissure and removal of any associated sentinel tag or hypertrophied anal papilla (anal fissure complex) when present. All patients received preoperative antibiotics (cefazolin 1g IV) and postoperative analgesics (diclofenac sodium 75mg IM PRN). Closed LIAS patients received instructions for sitz baths twice daily and oral analgesics as needed, with discharge on the same day. Open LIS patients were discharged within 24 hours with similar instructions.

Follow-up was conducted at 2, 4, 6 weeks, and 1 year

postoperatively by assessors unaware of treatment allocation. The primary outcome was complete wound healing at 6 weeks (the presence of scarring at the fissure site). Secondary outcomes were: Pain at 24 hours using a 10-point pain Visual Analog Scale (VAS); return to work – defined as the number of days until the patient returned to normal working activities; anal incontinence – assessed by the Wexner Continence Grading Scale<sup>14</sup>; and reoccurrence of an ulcer or a tear in the previously healed scar at one year.

Data were analyzed with SPSS version 24.0 (IBM Corp., Armonk, NY, USA). The continuous variables (age, BMI, pain scores, return to work) were discussed in terms of mean  $\pm$  standard deviation and compared by independent t-test after checking the normality assumptions. Categorical variables including sex, fissure location, history of constipation, presence of anal fissure complex, fissure duration >12 months, age  $\geq$ 40 years, and complete healing at 6 weeks were compared using the chi-square test. Fisher's exact test was applied for outcomes with expected cell frequencies <5, specifically for: non-healing at 6 weeks, flatus incontinence at 6 weeks, fecal incontinence at 1 year, and recurrence at 1 year. Subgroup analyses by age and sex were performed using the chi-square test. Multivariate logistic regression was performed with non-healing at 6 weeks as the dependent variable. Independent variables entered the model, were pre specified based on clinical importance: age  $\geq$ 40 years, fissure duration >12 months, and surgical technique (closed vs open LIS). Variables with univariate  $p < 0.20$  were considered for inclusion; surgical technique was forced into the model regardless of significance. Adjusted odds ratios with 95% confidence intervals were reported. All analyses followed intention-to-treat principles, with statistical significance set at  $p < 0.05$ .

## RESULTS

A total of 160 patients were enrolled in the study, with 80 patients randomized to the closed LIAS group and 80 to the open LIAS group. The demographic and clinical baseline data were similar in the two groups (Table 1). Across the

cohort, the mean age was  $38.9 \pm 11.2$  years (range: 20–75 years), with 118 (73.8%) male patients and 42 (26.2%) female patients. Mean BMI was  $24.3 \pm 3.1$  kg/m<sup>2</sup>. Posterior midline fissures were the most common location, observed in 139 patients (86.9%), followed by anterior midline in 17 patients (10.6%), and combined anterior and posterior in 4 patients (2.5%). A history of constipation was present in 138 patients (86.3%), and fissure duration exceeding 12 months was noted in 68 patients (42.5%). A typical anal fissure complex (sentinel tag, hypertrophied anal papilla) was present in 96 patients (60.0%).

Closed LIAS was associated with significantly lower pain scores at 24 hours compared to open LIAS (mean VAS:  $1.1 \pm 0.3$  vs  $3.3 \pm 0.6$ ,  $p < 0.001$ ). Return to work was significantly faster in the closed LIAS group (mean  $3.3 \pm 1.1$  days' vs  $6.6 \pm 1.4$  days,  $p < 0.001$ ). Complete wound healing at 6 weeks was achieved in 77 patients (96.3%) in the closed LIAS group and 78 patients (97.5%) in the open LIAS group, with no statistically significant difference between groups ( $p = 0.62$ ). Transient flatus incontinence at 6 weeks developed in 2 patients (2.5%) in the closed LIAS group and 4 patients (5.0%) in the open LIAS group ( $p = 0.41$ ), with all cases resolving spontaneously by 10 weeks. No patient in either group experienced fecal incontinence at 6 weeks or at one-year follow-up. Recurrence at one year was seen in 3 patients (4.0%) in the closed LIS group and 2 patients (3.0%) in the open LIAS group, without a statistically significant difference between groups ( $p = 0.58$ ). A summary of postoperative outcomes is presented in Table 2. Among the 160 patients, 94 were aged < 40 years and 66 were aged  $\geq$  40 years. The distribution of surgical technique was balanced within each age subgroup: among patients aged < 40 years, 48 underwent closed LIAS and 46 underwent open LIAS; among patients aged  $\geq$  40 years, 32 underwent closed LIAS and 34 underwent open LIAS. Non-healing at 6 weeks occurred in 1 patient (1.1%) aged < 40 years compared with 4 patients (6.1%) aged  $\geq$  40 years ( $p = 0.02$ ), and recurrence at 1 year occurred in 2 patients (2.1%) aged < 40 years compared with 3 patients (4.5%) aged  $\geq$  40 years ( $p = 0.03$ ).

**Table 1: Baseline demographic and clinical characteristics**

| Characteristics                         | Closed LIAS<br>(n = 80) | Open LIAS<br>(n = 80) | Total<br>(n = 160) | p-value |
|-----------------------------------------|-------------------------|-----------------------|--------------------|---------|
| Age (years), mean $\pm$ SD              | 38.5 $\pm$ 11.4         | 39.3 $\pm$ 11.0       | 38.9 $\pm$ 11.2    | 0.65    |
| Age $\geq$ 40 years, n (%)              | 32 (40.0)               | 34 (42.5)             | 66 (41.3)          | 0.75    |
| Male sex, n (%)                         | 58 (72.5)               | 60 (75.0)             | 118 (73.8)         | 0.72    |
| Female sex, n (%)                       | 22 (27.5)               | 20 (25.0)             | 42 (26.2)          | 0.72    |
| BMI (kg/m <sup>2</sup> ), mean $\pm$ SD | 24.2 $\pm$ 3.2          | 24.4 $\pm$ 3.0        | 24.3 $\pm$ 3.1     | 0.68    |
| Fissure duration >12 months, n (%)      | 35 (43.8)               | 33 (41.3)             | 68 (42.5)          | 0.75    |
| History of constipation, n (%)          | 68 (85.0)               | 70 (87.5)             | 138 (86.3)         | 0.64    |
| Fissure location, n (%)                 |                         |                       |                    | 0.88    |
| - Posterior                             | 69 (86.3)               | 70 (87.5)             | 139 (86.9)         |         |
| - Anterior                              | 9 (11.3)                | 8 (10.0)              | 17 (10.6)          |         |
| - Combined                              | 2 (2.5)                 | 2 (2.5)               | 4 (2.5)            |         |
| Anal fissure complex present, n (%)     | 48 (60.0)               | 48 (60.0)             | 96 (60.0)          | 1.00    |

**Table 2: Postoperative outcomes**

| Outcome                               | Closed LIAS (n=80) | Open LIAS (n=80) | p-value |
|---------------------------------------|--------------------|------------------|---------|
| Pain at 24 hours (VAS), mean $\pm$ SD | 1.1 $\pm$ 0.3      | 3.3 $\pm$ 0.6    | <0.001  |
| Return to work (days), mean $\pm$ SD  | 3.3 $\pm$ 1.1      | 6.6 $\pm$ 1.4    | <0.001  |
| Complete healing at 6 weeks, n (%)    | 77 (96.3)          | 78 (97.5)        | 0.62    |
| Non-healing at 6 weeks, n (%)         | 3 (3.8)            | 2 (2.5)          | 0.62    |
| Flatus incontinence at 6 weeks, n (%) | 2 (2.5)            | 4 (5.0)          | 0.41    |
| Fecal incontinence at 1 year, n (%)   | 0 (0)              | 0 (0)            | 1.00    |
| Recurrence at 1 year, n (%)           | 3 (4.0)            | 2 (3.0)          | 0.58    |

**Table 3: Multivariate analysis of predictors of non-healing at 6 weeks**

| Variable                     | Adjusted Odds Ratio | 95% Confidence Interval | p-value |
|------------------------------|---------------------|-------------------------|---------|
| Age $\geq$ 40 years          | 3.42                | 1.21 – 9.67             | 0.02    |
| Fissure duration > 12 months | 2.89                | 1.05 – 7.95             | 0.04    |
| Closed LIAS vs Open LIAS     | 1.38                | 0.52 – 3.66             | 0.53    |

Among the 160 patients, 118 were male, and 42 were female. The distribution of surgical technique was balanced within each sex subgroup: among male patients, 58 underwent closed LIAS and 60 underwent open LIAS; among female patients, 22 underwent closed LIAS and 20 underwent open LIAS. Non-healing at 6 weeks occurred in 4 male patients (3.4%) compared with 1 female patient (2.4%) ( $p = 0.03$ ), and recurrence at 1 year occurred in 3 male patients (2.5%) compared with 2 female patients (4.8%) ( $p = 0.29$ ). Multivariate logistic regression analysis was performed to identify independent predictors of non-healing at 6 weeks. Due to the limited number of non-healing events (5 total: 3 in closed LIS, 2 in open LIS), the model was restricted to include only three pre-specified clinically important variables (age  $\geq$  40 years, fissure duration > 12 months, and surgical technique) to maintain statistical stability. The events-per-variable ratio was 1.7, which is acknowledged as a limitation.

Independent predictors of non-healing at 6 weeks were age  $\geq$  40 years (adjusted OR: 3.42, 95% CI: 1.21–9.67,  $p = 0.02$ ) and fissure duration > 12 months (adjusted OR: 2.89, 95% CI: 1.05–7.95,  $p = 0.04$ ). Surgical technique (closed LIAS vs open LIAS) was not a significant independent predictor of healing (adjusted OR: 1.38, 95% CI: 0.52–3.66,  $p = 0.53$ ). Full results of this model appear in Table 3.

## DISCUSSION

Our findings established that both closed and open lateral internal anal sphincterotomy have excellent healing rates (more than 96%) and no permanent incontinence, thus confirming the high efficacy of the surgery in the treatment of chronic anal fissure. Notably, closed LIAS was done with local anesthesia and sedation, and the patient was discharged the same day when the oral intake was achieved and the patient was oriented, while open LIAS required spinal anesthesia and night housing. Similar effectiveness of the techniques is consistent with previous randomized trials and meta-analyses.<sup>10-12</sup> The high healing rates are based on the fundamental pathophysiological principle of LIAS,

which involves controlled division of the internal anal sphincter (IAS) and, thereby, decreasing the resting anal pressure, improving anodermal perfusion, and providing a healing environment.<sup>2</sup> These were excellent, especially in concomitant excision of fissure tissue in all cases, with 60% of patients having an associated anal fissure complex, probably played a role in these results by removing fibrotic, poorly vascularized tissue that hinders healing.

The early benefits of closed LIAS included improved pain scores at 24 hours (1.1 vs 3.3) and a shorter time to return to work (3.3 vs 6.6 days). This is consistent with the closed technique, which only makes a small stab wound, compared to a 1- 2 cm open wound. Moreover, the local anesthesia and sedation techniques, do not involve the risks and recovery period from spinal anesthesia, including post-dural puncture headache, urinary retention or prolonged motor blockade, which allow for same day discharge and add to the rapid recovery to normal activities. The benefit of the reduced soft tissue trauma is directly reflected in the reduced nociceptive input and in a more rapid functional recovery. Closed LIAS is a treatment option preferred by patients who want to get back to their normal routine as quickly as possible, especially for those living in resource-limited areas where work absenteeism has major socio-economic consequences.

Transient incontinence was assessed in this study using the Wexner Continence Grading Scale<sup>14</sup> and was found to be at 2.5% in closed and 5.0% in open techniques, which is similar to the literature.<sup>15</sup> Importantly, all cases resolved spontaneously over 10 weeks, with no patient being incontinent at long-term follow-up. These results highlight the safety of both techniques, when the procedures are performed in a controlled manner by an experienced surgeon and good patient selection. The slightly higher transient incontinence rate in the open group could be attributed to more surgical dissection of the tissues and direct visualization, but this was not statistically significant.

In this study, age  $\geq$  40 years and duration of fissure > 12 months were independent factors associated with

impaired wound healing. The results have clinical implications for risk stratification and postoperative monitoring. As with many other relationships, this correlation between advanced age and delayed healing would be consistent with the already known age-related alterations in tissue repair mechanisms such as decreased fibroblast proliferation, decreased collagen synthesis, and impaired angiogenesis.<sup>16</sup> Similarly, longer fissure duration may reflect more advanced fibrosis, increased ischemia and more severe sphincter hypertonia, and these factors may require more intense treatment and/or more frequent follow-up. These will enable the clinician to look for those at a greater risk for poor healing and may warrant more frequent follow-up or other therapies for them.

Several limitations warrant mention. Being conducted at a single center, the trial's findings may not generalize readily to other populations or care settings. Second, because closed LIAS was uniformly performed with local anesthesia and sedation while open LIAS was performed with spinal anesthesia, the anesthesia protocol and surgical technique are confounded. Consequently, the observed differences in early outcomes (pain, return to work) cannot be attributed solely to the surgical technique; the anesthesia modality likely contributes substantially to these differences. This should be considered in the interpretation of results and in future research designs that might consider standardizing anesthesia across groups. Third, the number of non-healing events was relatively small (5 total), limiting the statistical stability of the multivariate model and precluding inclusion of additional predictor variables. Fourth, patient blinding was not feasible given the distinct nature of the anesthesia protocols, which represents a potential source of bias in subjective outcome assessment. Finally, the non-inferiority analysis would be strengthened by reporting the confidence interval for the between-group difference in healing rates relative to the pre-specified margin, rather than relying solely on conventional p-values.

Future research should focus on standardizing anesthesia protocols across surgical techniques to isolate the independent effect of the surgical approach on outcomes. Longer follow-up studies are needed to assess the durability of healing and late recurrence rates. Additionally, investigation of patient-reported outcomes and quality of life measures would provide a more comprehensive assessment of treatment success. The role of adjunctive therapies in high-risk patients with identified predictors of non-healing warrants further exploration.

## CONCLUSIONS

Both closed and open lateral internal sphincterotomy are highly effective treatments for chronic anal fissure, achieving excellent healing rates with no permanent

incontinence. Closed LIAS under local anesthesia with sedation offers superior early outcomes with less pain, faster return to work, and the advantage of same-day discharge after oral intake and orientation. Patients who are older than 40 years and fissure duration exceeding 12 months independently predict impaired wound healing and warrant closer postoperative surveillance. These findings should guide patient counselling and perioperative management to optimize outcomes.

## Author Contributions

**IUH:** Conception and design, analysis and interpretation of data, drafting the article, critical revision for important intellectual content, final approval.

**AC:** Conception and design, analysis and interpretation of data.

**HK:** Analysis and interpretation of data, drafting the article.

**SHC:** Acquisition of data, conception and design, analysis and interpretation.

**SB:** Analysis and interpretation of data, proofreading.

**QAA:** Conception and design, drafting the article.

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The AI tool was not used in the preparation or modification of the manuscript's scientific content, research data, statistical analyses, or scientific conclusions. The authors reviewed and approved the final cover letter and remain fully responsible for its content.

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