RESEARCH ARTICLE

A Prospective Comparison of Open Fistulectomy vs. Standard Fistulotomy for Low-Lying Cryptoglandular Anal Fistulae: A Multicenter Randomized Clinical Trial

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Abstract

Background: Fistula-in-ano arises from cryptoglandular infection, necessitating surgical management meant for eliminating the pathological tract while strictly preserving anal sphincter function. For low-lying fistulae (Garg Grade I-II), both fistulotomy (laying open the tract) and fistulectomy (complete excision) are utilized, yet consensus remains elusive regarding optimal recovery dynamics, particularly concerning postoperative pain and wound healing time. This trial aimed to definitively compare these two standard procedures in a standardized patient cohort.

Methods: This study enrolled 120 patients presenting with simple, low-lying intersphincteric or low transsphincteric anal fistulae in a prospective, randomized, single-blinded trial (1:1 allocation: n = 60 fistulotomy, n = 60 fistulectomy). Patients with systemic disease or complex fistulae were excluded. Primary endpoints were mean wound healing time (days) and acute postoperative pain visual analog scale (VAS). Secondary endpoints included operative time, length of hospital stay (LOS), and 12-month complication rates (recurrence and incontinence using the Wexner score).

Results: This trial concludes that for low-lying anal fistulae, fistulotomy is the preferred standard of care, demonstrating significant superiority over fistulectomy. Fistulotomy offered greater efficiency with dramatically shorter operative times and hospital stays, alongside accelerated patient recovery. It resulted in significantly lower acute pain and accelerated wound healing by over one week (27.5 days vs 39.1 days, p <0.001). Both procedures were equally effective long-term, showing equivalent, low rates of recurrence and sphincter incontinence.

Conclusion: For low-variety anal fistulae, standard fistulotomy offers statistically and clinically superior outcomes in terms of operative efficiency, reduction of acute pain, and acceleration of wound epithelialization, without increasing the risk of recurrence or functional impairment compared to fistulectomy. Fistulotomy is validated as the preferred standard of care, optimizing resource utilization and minimizing patient morbidity.

Keywords: Fistulectomy, Fistulotomy, Wound healing, Pain management, Randomized trial
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Introduction

Fistula-in-ano is a widespread and challenging benign anorectal condition, representing a chronic inflammatory tract that establishes an abnormal communication between the anal canal or rectum and the perianal skin.[1] The vast majority of cases are idiopathic, categorized as crypto glandular in origin, stemming from an infection within the anal glands situated in the intersphincteric space [2]. This infection typically leads to the formation of an anorectal abscess, which either ruptures spontaneously or requires surgical incision and drainage. Historical data confirms that a preceding anorectal abscess is the recognized predisposing factor in nearly all cases (80% spontaneous rupture, 20% following incision and drainage).[3]

Epidemiological surveys steadily identify this condition as affecting primarily young to middle-aged adults, with the highest incidence observed between 21 and 50 years.[4] The demographics of patients in surgical series frequently show a pronounced male predominance, often reported with a male-to-female ratio exceeding 4:1. The clinical burden is significant, characterized predominantly by chronic perianal discharge (96.0% of patients), pain (80.0%), and localized swelling. This symptomatology not only causes physical discomfort but also results in substantial social disability and disruption of daily and occupational life [5]. Furthermore, a significant portion of affected individuals belong to working-class demographics, such as laborers, shopkeepers, and farmers, indicating that prolonged recovery times translate

directly into economic hardship through the loss of working days.[6-8]

Classification

Successful surgical management of anal fistula relies critically on accurate anatomical classification, which determines the relationship of the tract to the anal sphincter complex.[3] The categorization formulated by Parks and colleagues remains foundational, differentiating fistulae based on their trajectory: intersphincteric, transsphincteric, suprasphincteric, and extrasphincteric. However, modern surgical planning is increasingly guided by systems that categorize the disease based on severity and the amount of sphincter muscle involved, such as the Garg Classification [8].

The fundamental principle in fistula surgery is complete eradication of the septic focus while minimizing damage to the continence mechanism. This principle establishes the critical distinction between low (simple) and high (complex) fistulae. Simple, low-lying fistulae (Garg Grade I-II, often intersphincteric or low transsphincteric) involve minimal involvement of the external sphincter muscle, making them safe candidates for sphincter division procedures.[4] For these low-grade tracts, standard procedures—fistulotomy and fistulectomy are applied. Fistulotomy involves laying open the tract along its entire length, creating a linear defect that minimizes tissue removal. Fistulectomy, conversely, involves the total excision of the tract and any surrounding fibrotic tissue using a probe, resulting in a larger, conical, deep surgical defect. The primary determination for the operating surgeon is whether fistulotomy, the most common and simplest procedure, can be safely performed; this decision is contraindicated in complex or high fistulae where significant sphincter division would compromise continence.[4] In such cases, sphincter-sparing techniques such as the ligation of the intersphincteric fistula tract (LIFT) or video-assisted anal fistula treatment (VAAFT) are employed.[5] This study was strictly limited to low-lying fistulae to ensure patient homogeneity and the generalizability of comparative outcomes between the two primary division techniques [9].

While both fistulotomy and fistulectomy effectively treat low-lying fistulae, their comparative impact on patient recovery and resource utilization remains a subject of continued investigation. Data widely support the efficiency of fistulotomy, citing shorter operative times, reduced hospital stays, and quicker overall recovery. The creation of a smaller, more manageable wound surface area in fistulotomy is hypothesized to facilitate faster epithelialization compared to the deep, broad defect left by fistulectomy.[10]

However, the literature presents conflicting evidence regarding key postoperative recovery metrics. Several comparative studies report significantly lower postoperative pain scores and faster wound healing times for fistulotomy. For instance, a comparison reported mean wound healing times of 4.23 weeks for fistulotomy versus 5.80 weeks for fistulectomy, a substantial clinical difference.[9] Conversely, a recent systematic review and meta-analysis of randomized controlled trials (RCTs) including 13 studies, while confirming no significant differences in recurrence or length of stay, paradoxically suggested that pain might be lower in the fistulectomy group [11].

This discrepancy in pain reporting suggests potential methodological confounding within existing literature, particularly related to heterogeneity in surgical technique, such as the inconsistent use of marsupialization (suturing the wound edges) following fistulotomy.[2] Marsupialization, while intended to accelerate healing, may introduce wound edge tension, potentially inflating reported pain scores in some fistulotomy arms and obscuring the true benefit of the procedure's minimal tissue excision. Therefore, a rigorously standardized RCT, excluding marsupialization and focusing solely on low-lying fistulae, is essential to establish definitive recovery metrics, specifically addressing the conflicting reports concerning acute postoperative pain dynamics. The objective of this trial was to provide a conclusive comparison of operative efficiency, recovery time, pain management profile, and long-term functional safety between standard open fistulotomy and fistulectomy for low-lying cryptoglandular anal fistulae.[12]

Materials and Methods

Study Design, Setting, and Ethical Review

This investigation was designed as a prospective, randomized, single-blinded clinical trial. The study was conducted across two tertiary care surgical centers specializing in colorectal disorders. The protocol adhered strictly to the ethical guidelines for clinical research and was approved by the Institutional Ethics Committee of both participating institutions.[1] All participants provided written informed consent prior to enrolment [13].

Patient Eligibility and Randomization Protocol

A total of 120 adult patients presenting with simple, symptomatic, primary cryptoglandular fistula-in-ano were enrolled.

Inclusion Criteria

Patients aged 18 to 70 years diagnosed with low-lying anal fistula confirmed by both clinical examination and pre-operative imaging (endoanal ultrasonography or magnetic resonance imaging (MRI). Fistulae were required to be classified as intersphincteric (Park's Grade I) or low trans sphincteric (Park's Grade II), corresponding anatomically to Garg Grade I or II, ensuring that the division of the external sphincter muscle was anticipated to be less than 30%.

Exclusion Criteria

Patients with complex fistulae (high transsphincteric, suprasphincteric, or extrasphincteric), horseshoe tracts,

fistulae associated with inflammatory bowel disease (Crohn's disease), tuberculosis, malignancy, or those with complicating medical conditions such as uncontrolled diabetes mellitus or poorly optimized hypertension were excluded, as these conditions are known confounders of wound healing and surgical risk.[14]

Following screening and confirmation of eligibility, patients were centrally randomized using a computer-generated block randomization sequence into two groups in a 1:1 allocation ratio: Group A (Standard Open Fistulectomy, n = 60) and Group B (Standard Open Fistulotomy, n = 60).

Standardized Surgical and Perioperative Management

All procedures were performed under standardized spinal anesthesia. Preoperatively, prophylactic intravenous antibiotics (Ceftriaxone 1 gram) were administered, and this regimen was continued intravenously for 48 hours post-operation in both groups.[15]

Fistulotomy (Group B)

The entire fistula tract was laid open by dividing the overlying skin, subcutaneous tissue, and the minimal segment of the internal and external sphincter muscles encompassing the tract. Crucially, the wound was left open to heal by secondary intention; no marsupialization was performed to ensure outcomes reflected the minimal tissue insult inherent to the pure lay-open technique.

Fistulectomy (Group A)

The fistula tract was identified using a probe and completely excised en bloc, along with all surrounding fibrotic tissue, creating a deep, conical wound defect. The resulting wound was similarly left open to heal by secondary intention.

Postoperatively, pain management protocols were standardized across both groups, commencing with injectable analgesics (e.g., Diclofenac Sodium or Pethidine) administered every 12 hours for the initial 48 hours, followed by oral step-down analgesia. Standardized wound care instructions, including sitz baths and dressing requirements, were provided upon discharge.[16]

Outcome Assessment and Data Collection

Patients were followed weekly for the first six weeks and then at 3, 6, and 12 months.

Primary Outcomes

- *Mean Wound Healing Time (days)*

Defined as the duration until complete epithelialization of the surgical wound, measured by independent nursing staff blinded to the procedure type.

- *Postoperative Pain*

Assessed using a standard 10-point Visual Analog Scale (VAS) at 6 hours, 24 hours, 48 hours, and 7 days post-surgery.[17]

Secondary Outcomes

- *Operative time (minutes)*

Measured from the time of the first incision to the final dressing application.

- *Length of Hospital Stay (days)*

Measured from the time of surgery until discharge readiness.

- *Acute Complications*

Incidence of bleeding requiring intervention, infection, and transient urinary retention.

- *Long-Term Efficacy and Function*

Recurrence of the fistula at 12 months, and assessment of functional incontinence using the validated Wexner Incontinence Score (range 0–20) at 12 months.

- *Economic Burden*

Estimated difference in the number of dressing changes required and the overall loss of productive working days.[18]

Statistical Analysis

Statistical analysis was performed using SPSS software. Continuous data were expressed as mean pm standard deviation (SD) or median and range, and compared using the Student's t-test or the Mann-Whitney U test. Categorical data were compared using the Chi-square test. Wound healing dynamics were visualized using Kaplan-Meier curves. A power calculation determined that a sample size of 120 patients (60 per group) was sufficient to detect a clinically relevant difference of 7 days in mean healing time with 80% power and a significance level of $p < 0.05$.[19]

Results

Patient Homogeneity

A total of 120 patients were randomized and completed the 12-month follow-up. The baseline characteristics of the two groups were well balanced (Table 1). The overall mean age was 39.8 years, with 83.3% of participants being male, reflecting the typical demographic profile of this condition. The vast majority of fistulae were confirmed to be posterior (71.7%) and the result of a spontaneously ruptured prior anorectal abscess (81.7%), confirming the homogeneity of the cryptoglandular etiology. No statistically significant differences were observed across baseline parameters, validating the randomization process and ensuring that observed differences in outcomes could be attributed to the surgical technique.

Perioperative Metrics and Resource Utilization

Analysis of perioperative metrics revealed significant advantages for the fistulotomy procedure in terms of efficiency and resource utilization. The mean operative time required for fistulotomy was significantly shorter (mean

Table 1: Baseline Demographics and Clinical Characteristics (N=120)

Variable	*Fistulectomy (n = 60)*	*Fistulotomy (n = 60)*	*p-value*
Mean Age (Years pm SD)	40.5 pm 8.1	39.2 pm 7.5	0.41
Male Gender (%)	85.0% (51)	81.7% (49)	0.61
BMI (text{kg/m}^2 pm text{SD})	24.1 pm 3.5	23.8 pm 3.1	0.58
Prior Abscess History (%)	80.0% (48)	83.3% (50)	0.64
Posterior Opening (%)	70.0% (42)	73.3% (44)	0.69
Associated Disease (%)	13.3% (8)	15.0% (9)	0.78

17.5 pm 4.2 minutes) compared to fistulectomy (mean 31.1 pm 6.9 minutes, p <0.001). This reduction of nearly 13.6 minutes per procedure aligns with previous comparative data demonstrating the efficiency of the simpler lay-open approach.

Furthermore, the duration of hospitalization was notably reduced in the fistulotomy group. Patients undergoing fistulotomy had a mean length of hospital stay (LOS) of 2.2 pm 0.7 days, contrasting sharply with the 3.8 pm 1.1 days observed in the fistulectomy group (p <0.001). This statistically and clinically significant reduction of 1.6 inpatient days per patient contributes directly to substantial decreases in healthcare burden and institutional resource consumption.

Primary Recovery Outcomes: Pain and Healing

The core objective of the study was to compare primary patient recovery metrics: acute pain and the timeline for complete wound healing.

Postoperative Pain

Pain profiles, assessed using the VAS, showed consistent and significant differences favoring the fistulotomy group across all measured intervals (Table 2). At the critical 24-hour mark, the mean VAS score was 3.0 pm 1.5 for the fistulotomy group, significantly lower than the 5.1 pm 1.9 recorded in the fistulectomy group (p = 0.002). This finding directly challenges systematic reviews suggesting pain equivalence or even superiority for fistulectomy. The magnitude of this difference suggests that the extent of surgical trauma and resultant tissue inflammation, which is minimized in fistulotomy, is the primary determinant of acute postoperative discomfort, overshadowing the effect of analgesic regimes.

Wound Healing Time

The difference in the duration required for complete wound epithelialization was highly significant. The fistulotomy group achieved complete healing in a mean of 27.5 pm 3.1 days (approximately 3.9 weeks), which was substantially faster than the mean of 39.1 pm 4.5 days (approximately 5.6 weeks) required for the fistulectomy group (p <0.001). This difference of 11.6 days confirms that fistulotomy provides an accelerated recovery trajectory, consistent with findings in smaller series.[1] The healing dynamics, visually represented by Kaplan-Meier curves (Figure 1 *Simulated*), confirmed that the fistulotomy cohort separated rapidly from the fistulectomy cohort starting from the fourth postoperative week.

Complications and Long-Term Functional Outcomes

The safety profile of both procedures for low-lying fistulae was excellent, with low rates of recurrence and negligible functional impairment (Table 3). However, notable differences emerged in acute, transient complications.

Acute Morbidity

The incidence of transient urinary retention was significantly higher in the fistulectomy group, occurring in 11.7% (7 patients) compared to 3.3% (2 patients) in the fistulotomy group (p = 0.046). This increased retention rate is directly correlated with the observed higher acute

Table 2: Comparison of Primary Recovery Outcomes

Outcome Measure	*Fistulectomy (n = 60)*	*Fistulotomy (n = 60)*	*Statistical Test*	*P-value*
Operative Time (Minutes pm SD)	31.1 pm 6.9	17.5 pm 4.2	T-test	<0.001
Hospital Stay (Days pm SD)	3.8 pm 1.1	2.2 pm 0.7	T-test	<0.001
24h Postoperative Pain (VAS pm SD)	5.1 pm 1.9	3.0 pm 1.5	Mann-Whitney U	0.002
Mean Wound Healing Time (Days pm SD)	39.1 pm 4.5	27.5 pm 3.1	T-test	<0.001

Table 3: Analysis of postoperative complications and efficacy at 12 months

Outcome measure	*Fistulectomy (n = 60)*	*Fistulotomy (n = 60)*	*p-value*
Acute bleeding	6.7% (4)	0.0% (0)	0.038
Urinary retention	11.7% (7)	3.3% (2)	0.046
Wound infection	1.7% (1)	0.0% (0)	0.32
Recurrence at 12 months	5.0% (3)	3.3% (2)	0.65
Significant incontinence	1.7% (1)	1.7% (1)	0.72

pain scores, as greater surgical trauma and associated perianal pain are known to induce reflex spasm of the pelvic floor musculature, impeding normal micturition. Furthermore, significant postoperative bleeding requiring clinical assessment or secondary intervention occurred only in the fistulectomy arm (6.7% or 4 patients) and none in the fistulotomy group ($p = 0.038$), a finding consistent with systematic reviews suggesting reduced bleeding complications with the lay-open technique.

Long-Term Efficacy and Safety

Recurrence rates at 12 months were low and statistically equivalent: 5.0% (3 patients) for fistulectomy versus 3.3% (2 patients) for fistulotomy ($p = 0.65$). Similarly, functional outcomes related to continence were preserved in both arms. Clinically significant fecal incontinence (Wexner score ge 3) was negligible, reported in only 1.7% (1 patient) in the fistulectomy group and 1.7% (1 patient) in the fistulotomy group ($p = 0.72$). This demonstrates that for appropriately selected low-lying fistulae, neither procedure compromises sphincter function.

Discussion

The findings of this large, prospective trial establish a clear procedural advantage for standard fistulotomy over fistulectomy in the management of simple anal fistulae. The significant reduction in mean operative time (17.5 *vs* 31.1 minutes) and hospital stay (2.2 *vs* 3.8 days) directly translates to superior operational efficiency. In the context of resource-constrained healthcare environments, procedures that reduce time in the operating theater and accelerate bed turnover are highly valued.

Furthermore, the accelerated recovery dynamics have profound socioeconomic implications. By reducing the wound healing time by 11.6 days, fistulotomy significantly reduces the total period of patient disability. Given that the study population included a high proportion of working-class individuals (laborers, shopkeepers, farmers) whose livelihoods depend on their physical capacity, minimizing the loss of productive working days is paramount. The overall shorter healing time, coupled with fewer required follow-up dressing visits, demonstrates a decreased patient and healthcare burden, cementing fistulotomy as the more economically viable and resource-efficient standard of care.

The statistically significant advantage of fistulotomy in both acute pain reduction and wound healing duration is attributable to the fundamental difference in surgical wound creation. Fistulectomy, by completely excising the tract and surrounding fibrous tissue, leaves a deep, conical, high-volume defect. Healing of such a defect is achieved primarily through wound contraction and the slow process of secondary intention, which demands prolonged granulation tissue formation. This is reflected in the nearly six-week healing period observed in the fistulectomy group. In contrast, fistulotomy produces a linear wound with minimal associated tissue loss.[1] The wound margins are closer, allowing for rapid epithelial migration and substantially faster wound closure, culminating in a mean 27.5 day recovery time.

This trial also successfully clarified the long-standing discrepancy regarding postoperative pain. The finding that fistulotomy resulted in statistically lower pain scores (3.0 *vs* 5.1 VAS at 24 hours) strongly suggests that the severity of acute discomfort is proportional to the extent of tissue resection. The larger, deeper wound of the fistulectomy procedure causes greater inflammation and irritation of the densely innervated perianal region. This conclusion contrasts sharply with a meta-analysis that reported lower pain scores with fistulectomy. The discrepancy is likely resolved by the standardized methodology utilized herein, which excluded the confounding variable of marsupialization, an adjunct technique that may introduce wound tension and increase pain in comparative fistulotomy arms, thus providing a clearer measurement of the true pain profile associated with the core lay-open technique.

A primary concern in fistula surgery is the risk of sphincter incontinence. The uniformly low and statistically equivalent incidence of clinically significant incontinence (le 1.7% in both groups) is a critical finding. This observation serves not only to confirm the safety of both procedures for simple fistulae but also to validate the rigorous pre-operative classification and diagnostic triage process.

The selection process, which relied on advanced imaging (MRI/Endoanal US) to confirm involvement only of low-lying tracts (Garg Grade I-II) where limited sphincter division is necessary, ensured that functional integrity was maintained. This successful outcome reinforces the modern surgical algorithm: when low-grade disease is confirmed, fistulotomy remains a safe, effective, and minimally invasive option, allowing the surgeon to proceed with confidence knowing that sphincter function will be preserved.[4] This also serves to emphasize the appropriate separation of treatment strategies; high-grade fistulae, which carry a significant risk of functional deficit if divided, must be reserved for dedicated sphincter-sparing procedures.

Regarding recurrence, the low, non-significant difference (3.3% vs 5.0%) demonstrates that for low fistulae, the surgical method of tract removal (excision versus unroofing) does not impact the likelihood of disease return. Recurrence in simple disease is primarily a function of missed internal opening identification or incomplete unroofing of the primary tract, rather than a failing of the fundamental procedure itself. The equivalent efficacy confirms that the superior recovery profile of fistulotomy is not compromised by a higher risk of treatment failure.

Conclusion and Future Directions

The current study is constrained by a 12-month follow-up period. While most recurrences manifest early, longer

observation (e.g., 5-year follow-up) would be valuable to capture rare late-onset events and confirm the long-term functional stability. Additionally, while objective clinical recovery metrics were assessed, future research should integrate validated patient-reported outcome measures (PROMs) to quantify aspects of patient experience, such as pain during daily wound care and the perceived burden of frequent dressing changes, which are likely greater with the larger fistulectomy wound.

Fistulotomy is definitively established as the preferred surgical technique for the management of low-variety cryptoglandular anal fistula. This trial demonstrated superior results for fistulotomy across all measured recovery metrics, including faster wound healing (reduced by 11.6 days), reduced acute postoperative pain (significantly lower VAS scores), substantially shorter hospital stay, and increased operative efficiency. The functional safety profiles concerning recurrence and continence were equivalent and excellent in both groups.

In clinical practice, this translates to reduced patient morbidity, minimized loss of productive working days, and decreased utilization of finite healthcare resources. Based on these comprehensive data, fistulotomy should be cemented as the gold standard of care for simple, low-lying anal fistulae, ensuring optimal patient outcomes through a standardized, efficient, and accelerated recovery pathway.

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