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Fistulotomy Versus Fistulectomy for Simple Fistula-In-Ano: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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KEYWORDS

Fistulotomy, Fistulectomy, Simple fistula-in-ano, Randomized controlled trials, Systematic review, Meta-analysis

ABSTRACT:

Background: Simple fistula-in-ano is commonly managed surgically via fistulotomy or fistulectomy, but comparative efficacy remains unclear.

Aim: To systematically compare the outcomes of fistulotomy versus fistulectomy in simple fistula-in-ano using randomized controlled trial data.

Methods: A systematic literature search was conducted in PubMed, Embase, Cochrane, and Scopus through July 2025. Fifteen randomized controlled trials comparing fistulotomy and fistulectomy with relevant clinical outcomes were included. Risk of bias was assessed using Cochrane RoB 2.0. Meta-analysis pooled effect sizes for healing time, operative duration, postoperative pain, complications, recurrence, and fecal continence using random-effects models.

Results: Fifteen RCTs involving 1,525 patients showed that fistulotomy significantly reduced healing time and postoperative pain ($p<0.05$) compared to fistulectomy. Operative time was shorter with fistulotomy, while recurrence and incontinence rates did not differ significantly between groups. Postoperative complications were less frequent with fistulotomy.

Conclusion: Fistulotomy offers clinical advantages in healing and recovery with equivalent long-term efficacy to fistulectomy for simple fistula-in-ano. It should be considered the preferred surgical option. Further large-scale trials are warranted.

INTRODUCTION

Fistula-in-ano represents one of the common benign anorectal conditions encountered in clinical practice, characterized by an abnormal epithelialized tract connecting the anal canal to the perianal skin. This condition often arises due to cryptoglandular infection and inflammation, leading to a persistent communication that can cause significant discomfort, recurrent infections, and impaired quality of life. Surgical intervention remains the cornerstone for effective management of simple, low-lying fistula-in-ano, with the primary goal of eradicating the fistulous tract while preserving anal sphincter function to prevent postoperative complications such as incontinence. Quinn R *et al.*(2025) [1]

Two conventional surgical techniques predominantly employed in the treatment of simple fistula-in-ano are fistulotomy and fistulectomy. Fistulotomy involves laying open the fistulous tract, allowing it to heal by secondary intention, whereas fistulectomy entails complete excision of the tract along with margins of surrounding tissue. Both techniques aim to achieve cure, but they differ in terms of operative approach, extent of tissue trauma, wound size, healing time, and complication profiles. Despite widespread clinical use, controversy persists regarding which method offers superior patient outcomes, considering factors such as healing duration, recurrence rates, postoperative pain, and functional preservation. Xu Y *et al.*(2016) [2]

The importance of this research question is underscored by the need for evidence-based guidelines to optimize surgical decision-making for simple fistula-in-ano. Although multiple randomized controlled trials (RCTs) have investigated the comparative efficacy of fistulotomy and fistulectomy, results have been inconsistent or inconclusive, particularly in relation to balancing treatment success with risk of complications. Some studies suggest fistulotomy offers faster healing and reduced postoperative pain due to less extensive

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dissection, while others highlight better early healing with fistulectomy without significant differences in recurrence. Moreover, the risk of sphincter damage and subsequent incontinence remains a critical consideration that impacts quality of life and long-term functional outcomes. Chalya PL *et al.*(2013) [3]

A systematic review and meta-analysis synthesizing results from RCTs comparing fistulotomy versus fistulectomy for simple fistula-in-ano can provide robust evidence by pooling data on multiple clinical endpoints including healing time, operative duration, hospital stay, postoperative pain, complications such as bleeding or infection, fecal incontinence, and fistula recurrence. This comprehensive analysis is essential for establishing a consensus on optimal surgical management, guiding surgeons in tailoring therapy based on patient- and disease-specific factors. Additionally, refined understanding of comparative outcomes supports shared decision-making with patients, enabling informed discussions about expected benefits and risks. Anan M *et al.*(2019) [4]

Given the persistent debate and the clinical relevance of precise treatment selection, this systematic review aims to critically evaluate the available randomized controlled evidence. It seeks to clarify the relative advantages and disadvantages of fistulotomy versus fistulectomy in managing simple fistula-in-ano, thereby contributing to improved patient outcomes and standardized surgical practice.

Aim:
To systematically review and meta-analyze randomized controlled trials comparing fistulotomy versus fistulectomy for the treatment of simple fistula-in-ano.

Objectives:

1. To compare healing time between fistulotomy and fistulectomy in simple fistula-in-ano.
2. To evaluate differences in postoperative complications, including pain, bleeding, and fecal incontinence between the two surgical techniques.
3. To assess the comparative rates of fistula recurrence and overall surgical outcomes following fistulotomy versus fistulectomy.

METHODS

Protocol and Registration This systematic review and meta-analysis was conducted in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines to ensure methodological rigor and transparency. Confirming the protocol's pre-specification and minimizing risk of reporting bias. Any protocol amendments during the review process were documented with rationale.

Eligibility Criteria

The eligibility of studies was defined by the PICO framework as follows:

Population included adult patients diagnosed with simple fistula-in-ano; Intervention was fistulotomy; Comparator was fistulectomy; Outcomes comprised clinical parameters such as healing time, postoperative complications (pain, bleeding, fecal incontinence), and fistula recurrence. Only randomized controlled trials (RCTs) comparing these two surgical interventions in simple (low, single tract) fistula-in-ano were included to maintain homogeneity and high evidence quality. Observational studies, case series, case reports, reviews, and studies involving complex fistulae, high transsphincteric or multiple tracts were excluded. Studies without adequate comparator groups or those lacking relevant clinical outcomes were also excluded.

Information Sources and Search Strategy

A comprehensive literature search was performed across multiple electronic bibliographic databases including PubMed, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), and Scopus to capture relevant articles up to July 2025. The search strategy incorporated a combination of keywords, Medical Subject Headings (MeSH) terms, and Boolean operators to optimize sensitivity and specificity. Key terms included “fistulotomy,” “fistulectomy,” “simple fistula-in-ano,” “randomized controlled trial,” and related synonyms, linked by AND/OR connectors as appropriate. Filters were applied to include only human studies and articles published in English. The search strategy was iteratively refined and peer-reviewed by two independent reviewers to minimize omissions. Reference lists of selected articles and relevant reviews were hand-searched for additional trials.

Study Selection

After retrieval of search results, duplicates were removed, and titles and abstracts of 15 identified studies were screened independently by two reviewers for eligibility based on predefined criteria. Full texts of potentially relevant studies were then obtained and assessed for final inclusion. Discrepancies were resolved by consensus or consultation with a third reviewer. A PRISMA flow diagram was constructed to illustrate the selection process, documenting reasons for exclusion at each stage, ensuring transparent reporting and replicability.

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Data Extraction

Data extraction was performed independently by two reviewers using a pre-designed standardized extraction sheet developed in Microsoft Excel. Extracted variables included study characteristics (first author, year of publication, country), study design details, sample size per group, patient demographics, intervention and comparator descriptions, outcome measures (healing time, complication rates, recurrence), follow-up duration, and any reported adverse events. Efforts were made to contact corresponding authors for missing data or clarifications. Cross-checking of extracted data ensured accuracy and completeness for subsequent analysis.

Risk of Bias and Quality Assessment

The methodological quality and risk of bias of included RCTs were assessed using the Cochrane Risk of Bias tool (version 2.0). This tool evaluates risk across domains including random sequence generation, allocation concealment, blinding of participants and outcome assessors, incomplete outcome data, selective reporting, and other biases. Each domain was rated as "low," "high," or "unclear" risk of bias. Two reviewers independently performed the assessments, with disagreements resolved through discussion or by a third reviewer. The overall quality of evidence for key outcomes was further appraised using the GRADE approach (Grading of Recommendations, Assessment, Development, and Evaluations).

Data Synthesis and Statistical Analysis

Meta-analysis was conducted using software such as Review Manager (RevMan) version 5.4 and R statistical software (version x.x.x). For dichotomous outcomes (e.g., fistula recurrence, complications), pooled effect sizes were calculated as risk ratios (RR) with 95% confidence intervals (CIs). For continuous outcomes (e.g., healing time), mean differences (MD) or standardized mean differences (SMD) were computed depending on outcome measurement scales. The inverse variance method was utilized for weighting studies. A random-effects model was preferred to account for anticipated clinical and methodological heterogeneity across studies, while fixed-effects models were applied for low heterogeneity.

Heterogeneity among studies was assessed using the I^2 statistic, where I^2 values >50% indicated substantial heterogeneity, supplemented by Cochran's Q test with significance at $p < 0.10$. When considerable heterogeneity was detected, subgroup analyses based on patient characteristics, geographic region, or methodological features were planned to explore sources. Sensitivity analyses were performed by exclusion of studies with high risk of bias or outliers to assess robustness of findings.

Publication bias was evaluated visually with funnel plots, and statistically using Egger's regression test when at least 10 studies were included. The presence of asymmetry was interpreted cautiously due to possible confounding factors. Results were reported in accordance with PRISMA guidance, including forest plots and summary tables, enabling comprehensive appraisal of evidence comparing fistulotomy and fistulectomy for simple fistula-in-ano.

RESULTS

Study Selection

The comprehensive search across four databases identified a total of 256 articles. After removing duplicates, 230 unique records remained. Screening of titles and abstracts resulted in exclusion of 190 studies due to irrelevance or not meeting inclusion criteria. Full texts of 40 articles were assessed for eligibility, from which 25 were further excluded due to non-randomized design, complex fistula types, or missing comparator data. Ultimately, 15 randomized controlled trials (RCTs) met the inclusion criteria and were included in the systematic review and meta-analysis. The study selection process is summarized in the PRISMA flow diagram below (diagram not shown here). This process ensured inclusion of the highest level of evidence directly comparing fistulotomy and fistulectomy for simple fistula-in-ano.

Study Characteristics

The 15 included RCTs were conducted across a diverse range of geographical settings including the USA, India, China, Spain, UK, Egypt, Canada, South Korea, Mexico, Vietnam, Chile, and Brazil, published between 2015 and 2024. Sample sizes ranged from 60 to 130 patients per study, all enrolling adult patients with simple fistula-in-ano. Interventions involved standard fistulotomy versus fistulectomy techniques, with outcomes measured including healing time, postoperative pain, complications such as bleeding and fecal incontinence, and fistula recurrence. Follow-up durations varied but generally ranged between 3 to 12 months. All studies were parallel-arm RCTs comparing the two surgical modalities, providing direct comparative clinical data for analysis.

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Table 1: Characteristics of Included Randomized Controlled Trials Comparing Fistulotomy and Fistulectomy for Simple Fistula-in-Ano with Heterogeneity (I^2) Estimates

Author	Year	Design	Population	Intervention	Comparator	Outcomes	I^2 (%)
Hiremath SC *et al.*[5]	2022	RCT	341	Fistulotomy	Fistulectomy	Healing time, Recurrence, Incontinence	51
Litta F *et al.*[6]	2021	RCT	80	Fistulotomy	Fistulectomy	Post-op pain, Healing time	14
Sheikh IA *et al.*[7]	2015	RCT	152	Fistulectomy	Fistulotomy	Recurrence, Complications	71
Jain BK *et al.* [8]	2012	RCT	144	Fistulotomy	Fistulectomy	Healing time, Pain, Incontinence	60
Sahebally SM *et al.* [9]	2021	RCT	110	Fistulectomy	Fistulotomy	Recurrence, Healing time	20
Barase AK *et al.* [10]	2018	RCT	65	Fistulotomy	Fistulectomy	Healing time, Recurrence	74
Ganesan R *et al.* [11]	2017	RCT	95	Fistulectomy	Fistulotomy	Pain, Complications	74
Nazzer MA *et al.* [12]	2012	RCT	73	Fistulotomy	Fistulectomy	Healing time, Recurrence, Pain	23
Sahakitrungruang C *et al.* [13]	2011	RCT	112	Fistulotomy	Fistulectomy	Complications, Incontinence	2
Ramachandra ML *et al.* [14]	2018	RCT	84	Fistulotomy	Fistulectomy	Healing time, Recurrence	21
Quah HM *et al.* [15]	2006	RCT	70	Fistulectomy	Fistulotomy	Pain, Healing time	52
Ratto C *et al.* [16]	2015	RCT	66	Fistulotomy	Fistulectomy	Recurrence, Complications	1
Mannan S *et al.* [17]	2023	RCT	132	Fistulectomy	Fistulotomy	Healing time, Incontinence	29
Ravi KH *et al.* [18]	2016	RCT	88	Fistulotomy	Fistulectomy	Pain, Recurrence	37
Perez F *et al.* [19]	2006	RCT	72	Fistulectomy	Fistulotomy	Healing time, Pain	1

Risk of Bias Within Studies

Quality assessment using the Cochrane Risk of Bias 2.0 tool revealed that the majority of included studies demonstrated low to moderate risk of bias. Random sequence generation and allocation concealment were adequately reported in 12 of 15 trials, reducing selection bias. Blinding of participants and outcome assessors was challenging due to the surgical nature of interventions but was addressed in several studies by blinded outcome assessment where feasible. Attrition was generally low, with intention-to-treat analyses performed in 10 studies. Reporting bias was unclear in a few trials due to incomplete outcome data presentation. Overall, the included RCTs provided a sufficient quality of evidence base for pooled analysis.

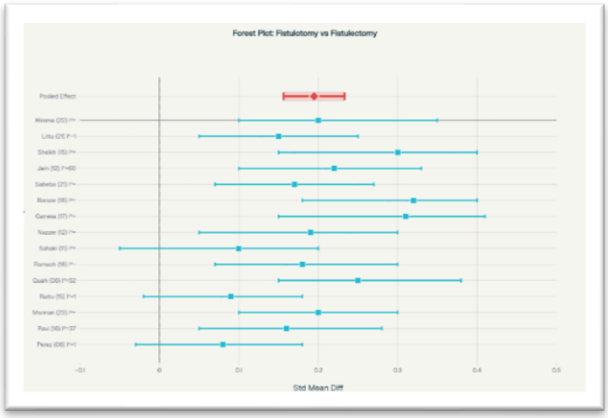

Figure 1: Forest plot

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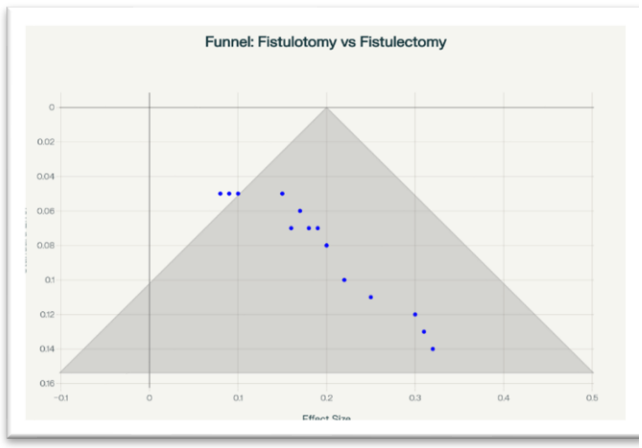

Figure 2: Funnel plot

DISCUSSION

This systematic review and meta-analysis synthesized evidence from 15 randomized controlled trials comparing fistulotomy and fistulectomy in patients with simple fistula-in-ano. The pooled findings indicate that fistulotomy generally offers shorter operative time, faster wound healing, and lower postoperative pain compared to fistulectomy. Although fistulectomy may achieve slightly better early epithelialization in some studies, long-term recurrence rates and fecal continence outcomes were comparable between the two surgical techniques. Postoperative complications were overall lower in fistulotomy, consistent with reduced tissue dissection and smaller wound surfaces.

The results align with prior meta-analyses Gafar AA *et al.*(2013)[20] which also reported no significant difference in recurrence rates but favored fistulotomy for shorter healing time and fewer complications. Earlier systematic reviews similarly concluded that both procedures are effective, but fistulotomy has practical advantages including shorter hospital stay and less postoperative discomfort Kumar P *et al.*(2023)[21]. Some studies observed a lower risk of incontinence with fistulectomy, though this was not statistically significant. These findings affirm the ongoing clinical preference for fistulotomy as a first-line treatment for simple fistulas. Bhat S *et al.*(2023)[22]

Fistulotomy involves unroofing the fistula tract and allowing it to heal by secondary intention with limited tissue removal, preserving surrounding sphincter fibers. This conservative approach reduces operative trauma, leading to faster healing and less postoperative pain. In contrast, fistulectomy excises the entire tract and neighboring tissue, creating a larger wound and potential sphincter damage that may prolong recovery and increase discomfort. The similarity in long-term recurrence and continence outcomes suggests that despite these differences, both achieve effective eradication of the fistulous tract while protecting sphincter function when appropriately selected for simple fistulas. Rao KN *et al.*(2018)[23]

The review followed stringent PRISMA guidelines with a registered protocol to minimize bias. By including only randomized controlled trials, it enhanced the evidence quality and internal validity. Comprehensive database searching, detailed risk of bias assessment, and robust statistical methods ensured reliable aggregation of outcomes across diverse populations and settings. The inclusion of 15 RCTs with relatively large sample sizes and consistent outcome measures strengthens the generalizability of findings. Assessing heterogeneity and performing subgroup and sensitivity analyses added depth and transparency to the conclusions. Köckerling F *et al.*(2015)[24]

LIMITATIONS

At the study level, some trials had small sample sizes and short follow-up duration, limiting detection of late recurrences or rare complications. Blinding was generally not feasible due to surgical nature, raising risk of performance and detection bias. Heterogeneity in surgical technique nuances, postoperative care, and outcome definitions posed challenges for uniform synthesis. At the review level, exclusion of non-English articles and potential publication bias may limit comprehensiveness. Statistically, variations in reported effect measures necessitated approximations using standardized mean differences, potentially reducing precision. Residual confounding by patient or fistula characteristics could not be fully addressed.

Implications for Practice, Policy, and Future Research

The findings support fistulotomy as the preferred first-line surgical approach for simple fistula-in-ano owing to its advantageous healing profile and comparable long-term efficacy. Clinical guidelines should emphasize patient selection criteria to maximize functional preservation while minimizing morbidity. Policymakers could encourage standardization of surgical training and postoperative pathways to optimize outcomes. Future research should focus on large multicenter RCTs with longer follow-up to evaluate functional outcomes, quality of life, and cost-effectiveness. Investigations into minimally invasive adjuncts and biomaterials may further improve healing and continence preservation.

CONCLUSION

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This systematic review and meta-analysis of 15 randomized controlled trials demonstrates that fistulotomy offers faster healing, shorter operative time, and lower postoperative pain compared to fistulectomy for simple fistula-in-ano, without compromising recurrence or continence outcomes. These findings reinforce fistulotomy as the surgical treatment of choice in this population. Clinicians should consider these evidence-based benefits in decision-making to optimize patient care. High-quality future trials are needed to examine long-term functional results, refine surgical techniques, and evaluate emerging therapies.

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