Transanal Opening of the Intersphincteric Space to Treat Anal Fistula: A Systematic Review and Meta-Analysis

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AIM: Transanal opening of the intersphincteric space (TROPIS) is a minimally invasive surgical treatment for anal fistula that not only eliminates the source of infection but also protects anal function to the greatest extent. This systematic review and meta-analysis aims to evaluate the efficacy of TROPIS in the treatment of anal fistula.

METHODS: We searched PubMed, EMBASE, Web of Science, and the Cochrane Library for information on TROPIS surgery for anal fistulas performed between the inception of each database and 1 November 2024. We used the single-arm studies for analysis, with a total of 918 subjects and a follow-up period ranging from 3 months to 36 months. The analysis focused on the cure rate of different types of anal fistula, postoperative bleeding, infection, and adverse reactions.

RESULTS: This systematic review included six single-arm studies involving a total of 918 patients with anal fistula who underwent TROPIS surgery, with follow-up durations ranging from 3 to 36 months. Among the included studies, all were classified as high quality (score $\geq$7). This study demonstrated an 80% success rate for the initial operation (95% confidence interval (CI): 0.77–0.83), as well as an 80% success rate specifically for high fistulas (95% CI: 0.77–0.83). The success rate for second operations was 73% (95% CI: 0.47–0.99). For patients with high fistulas who underwent a second procedure, the success rate was 78% (95% CI: 0.40–1.00). The cure rate for anal fistulas accompanied by abscesses was 88%, while the cure rate for anal fistulas without abscesses is the same. For horseshoe fistulas, the cure rate was 87%, whereas it was 88% for non-horseshoe fistulas. The overall cure rate in this study was 88% (95% CI: 0.86–0.90). The rate of intraoperative bleeding was 3%, the postoperative infection rate was 5%, and the overall incidence of adverse reactions was 3%.

CONCLUSIONS: This study demonstrates that TROPIS holds significant potential in the treatment of anal fistulas, particularly for high fistulas, fistulas with associated abscesses, and horseshoe-shaped fistulas, whilst exhibiting a relatively low incidence of incontinence.

Keywords: anal fistula; transanal opening of intersphincteric space; sphincter-preserving procedure; meta-analysis

Introduction

An anal fistula is an abnormal connection between the anal canal and perianal skin, and its clinical manifestations include perianal swelling, pain, and pus discharge. The ideal treatment for anal fistulas is to achieve complete healing without causing anal incontinence. Low anal fistulas, which span less muscle tissue, can be treated with anal fistulectomy or fistulotomy. However, when the fistula extends through the sphincter, surgical methods must be chosen carefully to ensure the preservation of anal function. Currently, surgical techniques aimed at protecting the sphincter include anal fistula plugs, mucosal advancement flaps, and the ligation of the intersphincteric fistula tract (LIFT) procedure. Although minimally invasive surgeries can reduce postoperative injury to the anal sphincter to varying degrees, the cure rates are not high, particularly for patients with high anal fistulas. There remains no satisfactory treatment, and the risk of incontinence is significant [1].

Therefore, a new procedure, transanal opening of the intersphincteric space (TROPIS), first described in 2017, completely preserves the external anal sphincter (EAS) space. TROPIS is a transanal approach that involves opening the sphincter space through internal opening and drainage, ensuring wound healing. It emphasizes the role of infection in the Deep Posterior Intersphincteric Space (DPIS) in the formation of complex anal fistulas, especially posterior horseshoe anal fistulas, while excluding the posterior deep postanal space (DPAS) as a contributing factor [2]. The shift in understanding the source of infection has led to a change in surgical method. In Hanley's procedure [3], the internal and external sphincters were removed through a posterior median incision, which transitioned from clear-

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ing DPAS lesions to targeting intersphincteric lesions. Currently, TROPIS has been shown to have promising results in the treatment of complex high anal fistulas, but the success rate varies widely across different studies, ranging from 85% to 94% [2,4,5]. However, robust evidence-based medical data supporting its effectiveness are lacking.

Therefore, the primary aim of this study is to explore the safety and effectiveness of TROPIS in the treatment of complex anal fistulas using evidence-based medicine methods to provide reliable evidence for improving the prognosis of inpatients.

Methods

Inclusion and Exclusion Criteria

The inclusion criteria were as follows: (1) use of TROPIS to treat patients with anal fistula; and (2) complete literature and experimental procedures. The exclusion criteria were as follows: (1) animal experiments; (2) reviews and case reports; (3) inability to obtain valid data; and (4) duplicated published papers.

Search Strategy

The PubMed, Web of Science, Embase, and Cochrane Library databases were searched from inception to 1 November 2024, using the following key terms: "transanal opening of intersphincteric space", "transanal surgery", "colorectal surgery", "anal fistula", "intersphincteric fistula", and "fistula tract" combined with Boolean operators AND or OR. The detailed search strategies are presented in **Supplementary Table 1**.

Data Extraction and Quality Assessments

Two researchers independently screened the literature and extracted data on the basis of established inclusion and exclusion benchmarks. The literature was initially screened by reading titles and abstracts, and those articles not meeting the inclusion criteria were excluded. The remaining articles were read in whole to determine the final inclusion criteria. If there was disagreement, decisions were made through discussion with all the researchers. For the quality assessment of the literature, the quality of the articles was scored using the Newcastle–Ottawa Scale (NOS). The quality assessment criteria for the studies were based on the NOS score. High-quality studies (NOS score $\geq$7) were defined using the following criteria. As the standard NOS is not applicable to non-comparative studies, a modified version of NOS was employed to assess the methodological quality of single-arm studies. The modified tool comprised the following items: clear research objectives (1 point), consistency in patient inclusion (1 point), representativeness of the cohort (1 point), adequate sample size (1 point), complete data collection (1 point), objectivity of evaluation (1 point), sufficient follow-up duration or a low loss-to-follow-up rate ($<$20%) (1 point), clearly defined outcome measures (1 point), and appropriate and reproducible outcome assessment (1 point). The total possible score was 9 points, with higher scores indicating better methodological quality. Details of the NOS assessment criteria are available on the official website: http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp. The completed PRISMA checklist is provided in the **Supplementary Material**.

Statistical Analysis

Meta-analysis was performed using Stata 18.0 software (StataCorp, College Station, TX, USA). Statistical heterogeneity of the included studies was assessed using the Q test and I^2 statistic. Heterogeneity was considered low when $I^2 < 50\%$ and $p > 0.1$ and high when $I^2 \geq 50\%$ and $p \leq 0.1$. A two-sided $p < 0.05$ was regarded as statistically significant for all the other analyses. If there was no statistical heterogeneity among the study results, a fixed-effects model was used; otherwise, a random-effects model was used. This study planned to employ Egger's test to assess publication bias when at least ten studies were included. However, as statistical tests for funnel plot asymmetry are unreliable when fewer than ten studies are included, no formal publication bias analysis was conducted in this systematic review.

Results

A total of 1881 records were initially retrieved. After 178 duplicates were removed, 1703 studies remained for screening. Of these, 318 were excluded because they were reviews, systematic evaluations, or basic research literature. After screening the titles and abstracts, 1375 studies were excluded, and 10 studies remained for full-text review. Following the full-text assessment, 4 studies were excluded, and 6 studies were ultimately included in the meta-analysis (Fig. 1).

The characterization table in this study summarizes extracted basic information such as the author of the article, year, region, age, and gender, and incorporates information such as the proportion of high fistulas, associated abscesses, and horseshoe fistulas, etc., as shown in Table 1 (Ref. [2,4–8]).

In this study, the quality of all six included articles was assessed using the modified NOS. The evaluation criteria included the following aspects: clear research objective, consistency in patient enrolment, representativeness of the cohort, adequate sample size, completeness of data collection, objectivity of assessment, sufficient follow-up duration or a loss-to-follow-up rate below 20%, well-defined outcome measures, and appropriate and reproducible outcome assessment methods. Each criterion meeting the standard was scored 1 point, with a maximum score of 9. The results demonstrated that all six studies were of high quality (score $\geq$7, including three studies scoring 8 and three scoring 7). No low-quality studies were included in this analysis. These findings indicate that the overall quality of the literature included in this meta-analysis is high

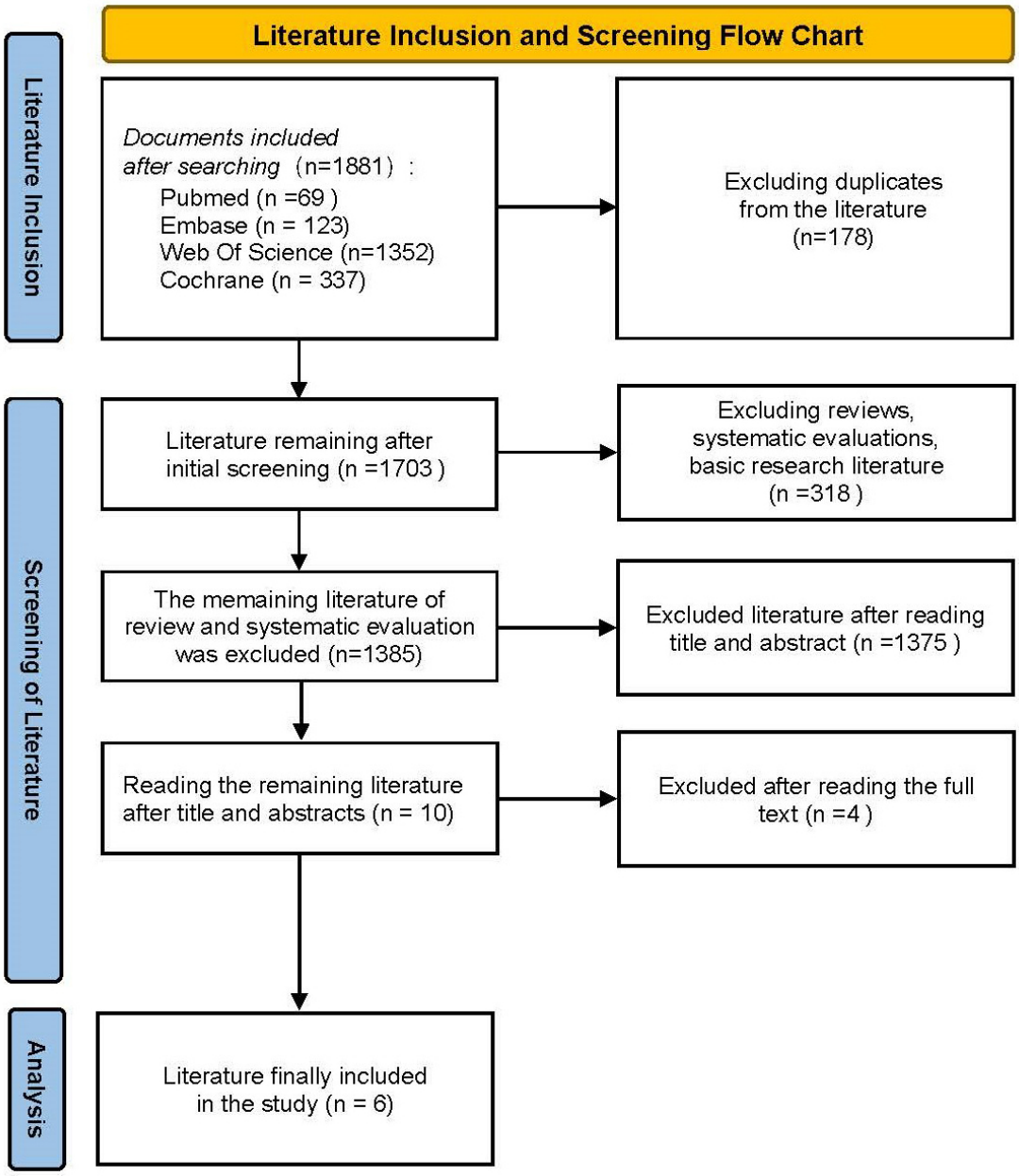

Fig. 1. Screening flow chart.

and that the results exhibit good reliability and robustness (**Supplementary Table 2**).

A total of 5 studies conducted meta-analyses of the success rate of the first cure, with a heterogeneity of 14.26%. A fixed effects model was used for analysis, and the success rate of the first cure was 80% (95% confidence interval (CI): 0.77, 0.83) (Fig. 2).

A total of 4 studies conducted meta-analyses of the success rate of the first cure in the high fistula subgroup, with a heterogeneity of 32.24%. The fixed model was used for analysis, and the success rate of the first cure was 80% (95% CI: 0.77, 0.83) (Fig. 3).

A total of 4 studies conducted meta-analyses of the success rate of reoperation, with a heterogeneity of 90.82%. A random effects model was used for analysis, and the success rate of the second operation was 73% (95% CI: 0.47, 0.99) (Fig. 4).

Three studies were included in the meta-analysis of reoperation success rates, but heterogeneity was substantial (I^2 = 98.18%). Consequently, a random-effects model was employed for analysis. The combined success rate for the second operation was 78% (95% CI: 0.40–1.00). (Fig. 5).

A total of 6 studies performed a meta-analysis of the overall cure rate of surgery, with a heterogeneity of 0.83%. A fixed effects model was used for analysis, and the overall cure rate was 88% (95% CI: 0.86, 0.90) (Fig. 6).

A meta-analysis was conducted on the overall cure rates for the high-level fistula subgroup across five studies, revealing

Table 1. Characteristics of the included trials.

First author	Countries	Year	n	Age (years)	M/F	High fistula (%)	Recurrent (%)	Associated abscess (%)	Horseshoe fistulas (%)	Follow-up time	NOS score
Pankaj Garg [6]	India	2021	325	39.9 ± 10.9	292/33	100	67.4	37.5	36.3	36 months	8
Baolei Huang [4]	China	2021	48	40.0 ± 11.7	41/7	100	45.8	60.4	29.2	12 months	7
Yu-Bo Li [5]	China	2022	41	38.6 ± 13.2	35/6	90.2	22.0	14.6	29.3	22.2 months	8
Pankaj Garg [7]	India	2021	408	40.5 ± 11.1	372/36	100	14.0	NA	NA	30 months	8
Shrivats Mishra [8]	India	2024	35	33.3 ± 10.5	30/5	NA	11.4	NA	8.6	3 months	7
Pankaj Garg [2]	India	2017	61	42.3 ± 9.5	59/2	100	85.2	26.2	36.1	9 months	7

NA, not applicable; NOS, Newcastle–Ottawa Scale; M, male; F, female.

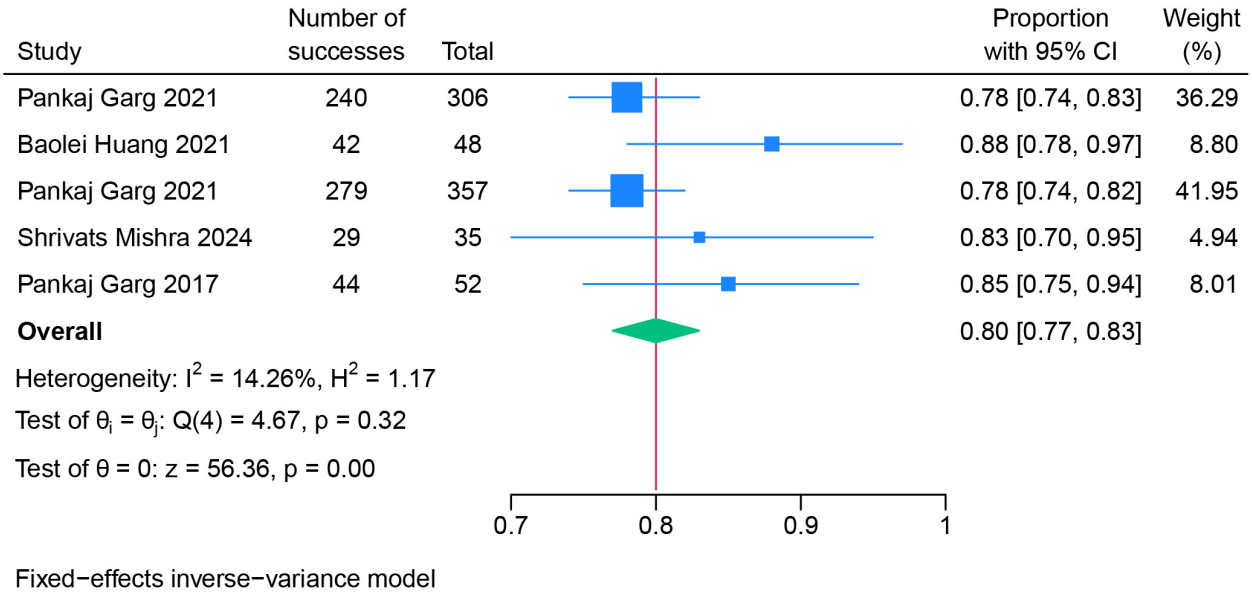

Fig. 2. Success rate of the first operation. CI, confidence interval.

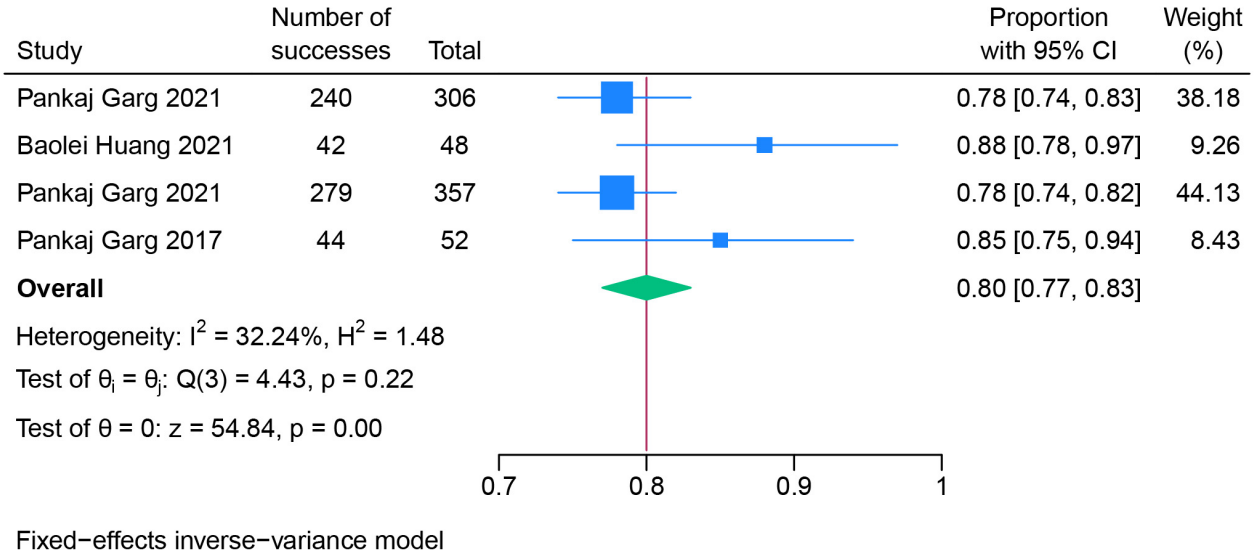

Fig. 3. Success rate of the first operation in the high fistula subgroup.

low heterogeneity (I^2 = 7.71%). Consequently, employing a fixed-effects model yielded a pooled cure rate of 88% (95% CI: 0.86, 0.90) (Fig. 7).

The results revealed that the cure rate of anal fistula combined with abscess was 88%. The cure rate of no abscess was 88%. The cure rate of horseshoe fistula was 87%, and

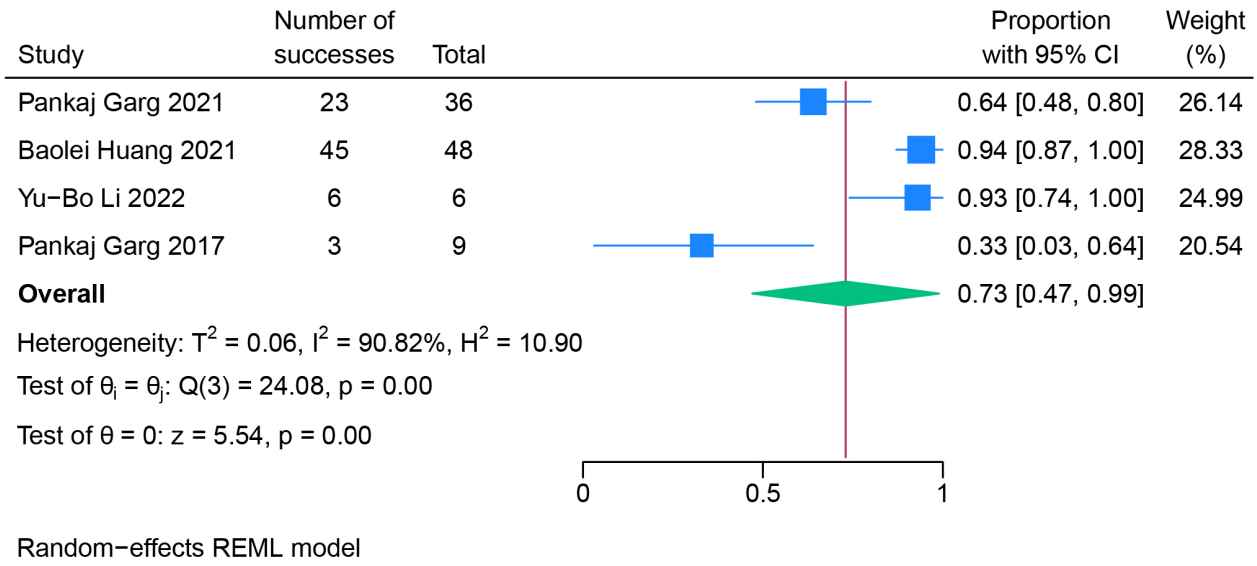

Fig. 4. Success rate of reoperation.

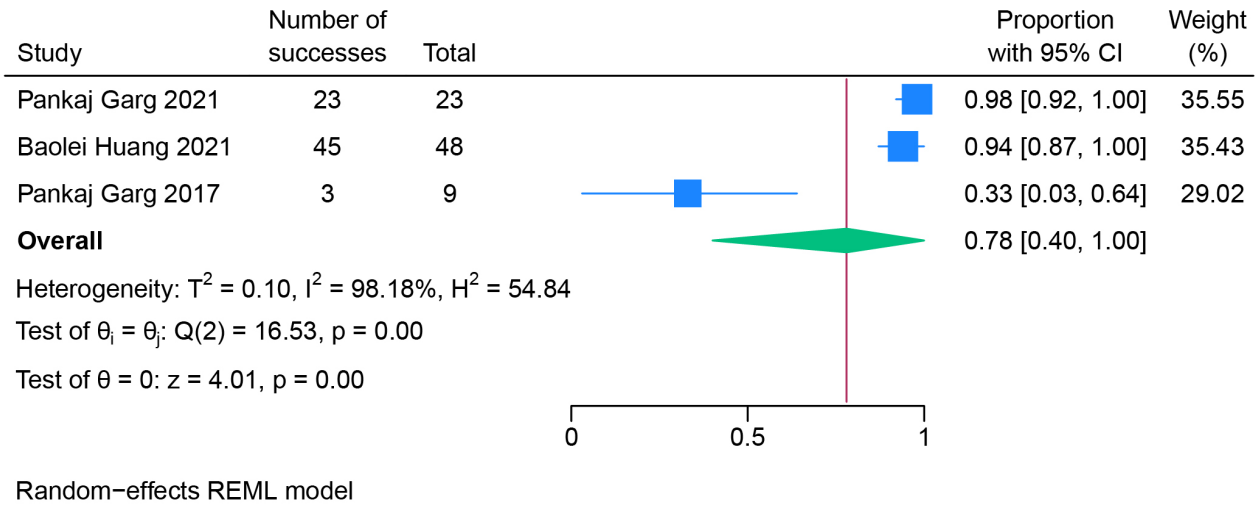

Fig. 5. Success rate of reoperation in the high fistula subgroup.

the cure rate of non-horseshoe fistula was 88%, with no significant statistical difference between the two conditions (Fig. 8).

A total of 6 articles were included to analyze the recurrence rate of patients. A random effects model revealed that the recurrence rate of patients was 26% (95% CI: 0.02, 0.50). However, considerable heterogeneity was observed, and therefore the results should be interpreted with caution (Fig. 9).

A total of 3 studies conducted meta-analyses on Incontinence scores, with a heterogeneity of 0.00%. A fixed effects model was used for analysis, and surgery had no significant effect on the incontinence score (Weighted Mean Difference (WMD) 0.04, 95% CI (–0.02, 0.11)) (Fig. 10).

The study revealed that the probability of bleeding was 3%, the probability of infection was 5%, and the overall incidence of adverse reactions was 3%. The pooled estimate of overall adverse reactions is derived from studies reporting composite adverse events, whereas infections were reported separately and not consistently across all studies (Fig. 11).

As fewer than ten studies were included in each meta-analysis, no tests for publication bias (including Begg's test and Egger's test) or funnel plots were conducted in accordance with the Cochrane Handbook recommendations.

Discussion

TROPIS surgery demonstrates promising efficacy in treating complex and high anal fistulas, with a high initial

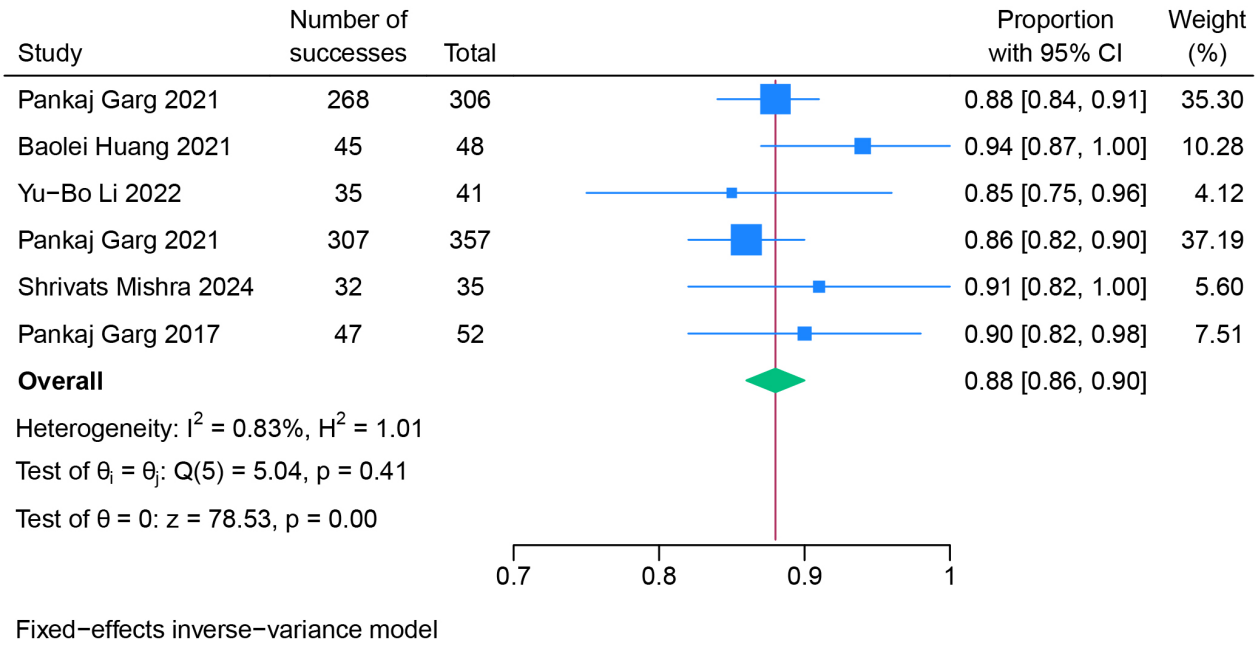

Fig. 6. Overall cure rate.

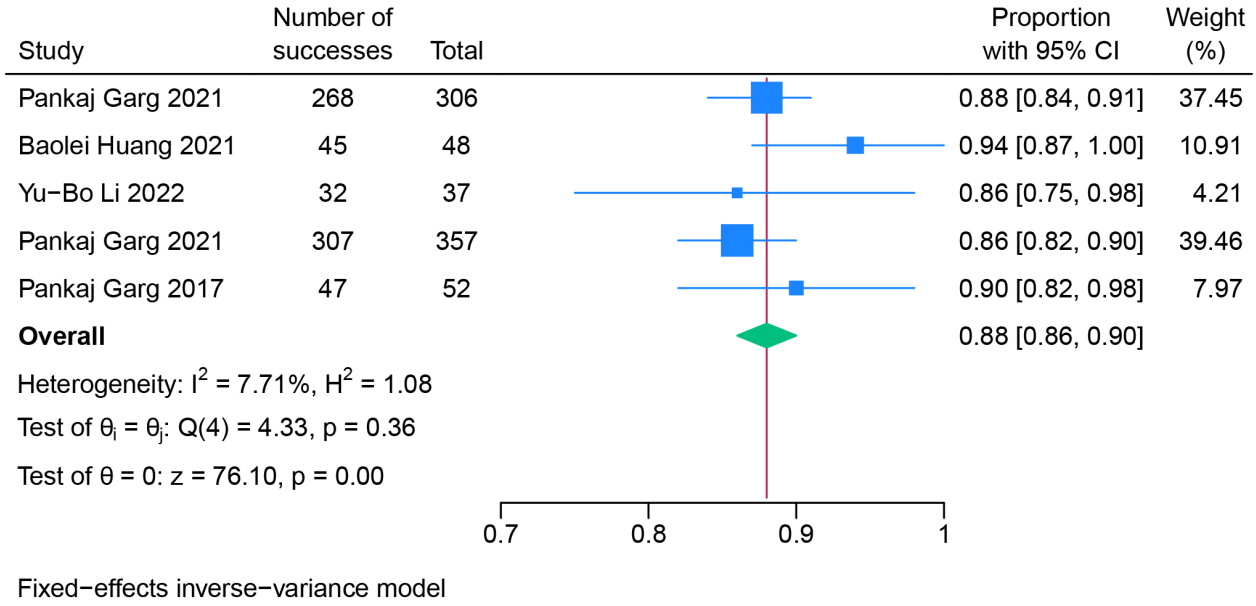

Fig. 7. Overall cure rate in the high fistula subgroup.

success rate. Our analysis revealed consistent outcomes between patients with complex fistulas overall and those with high fistulas specifically. Additionally, the procedure yields favorable cure rates for challenging subtypes such as horseshoe fistulas and those accompanied by abscesses. Postoperative adverse events, including bleeding and infection, were infrequent, suggesting a favorable safety profile.

TROPIS, as a new surgical method for protecting the sphincter, has attracted increasing attention in recent years. From the perspective of the pathogenesis of glandular anal fistulas, intersphincteric infection plays an important role in the development of most complex anal fistulas [5,7–9]. TROPIS is a transanal approach that involves opening the sphincter space through internal opening and drainage to ensure wound healing [6]. Parks described a surgical technique that involves a limited incision of the lower half of the internal anal sphincter (IAS) to drain the infected anal gland, in addition to removing or scraping the outer por-

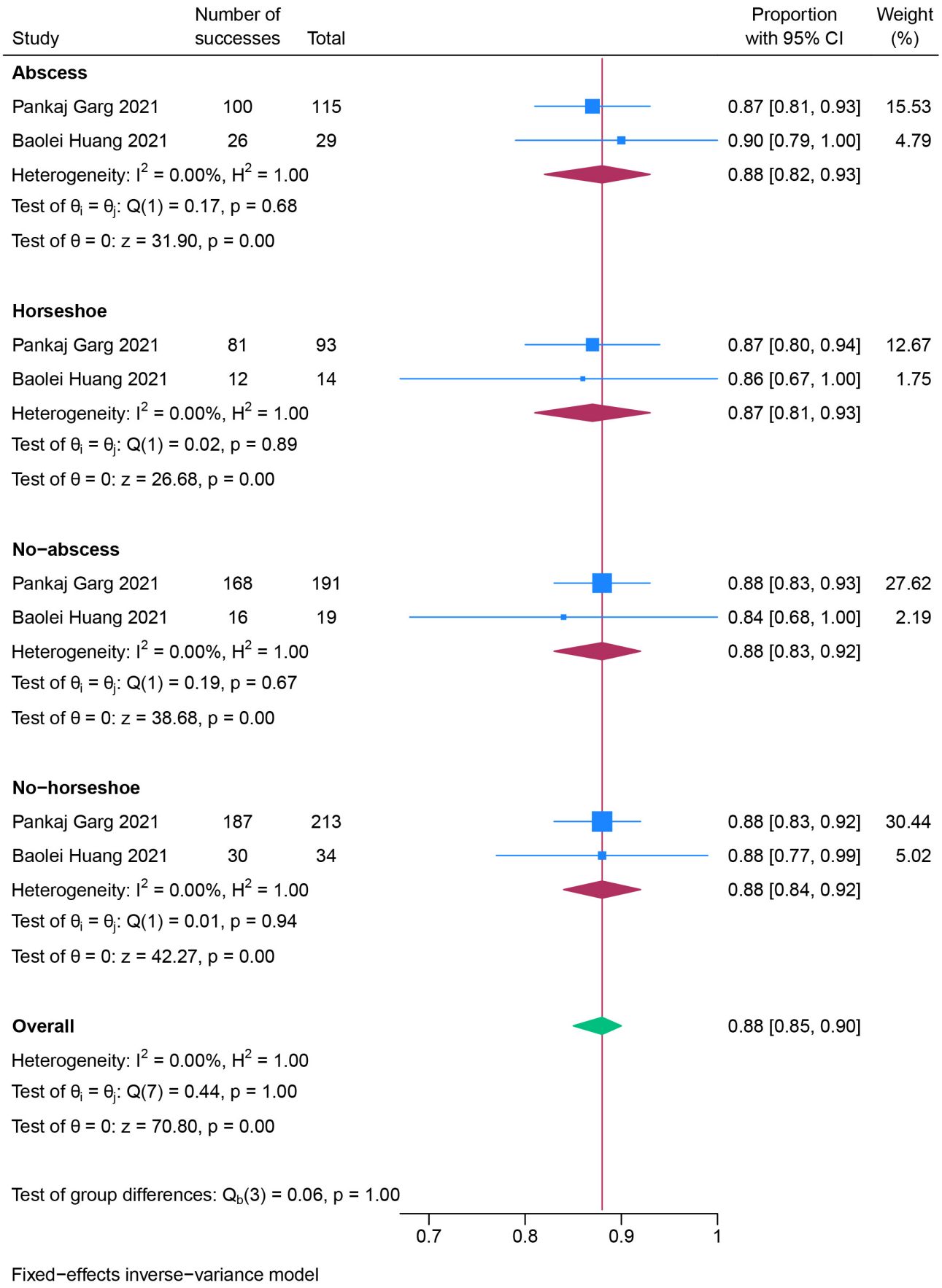

Fig. 8. Overall cure rate with analysis of other conditions.

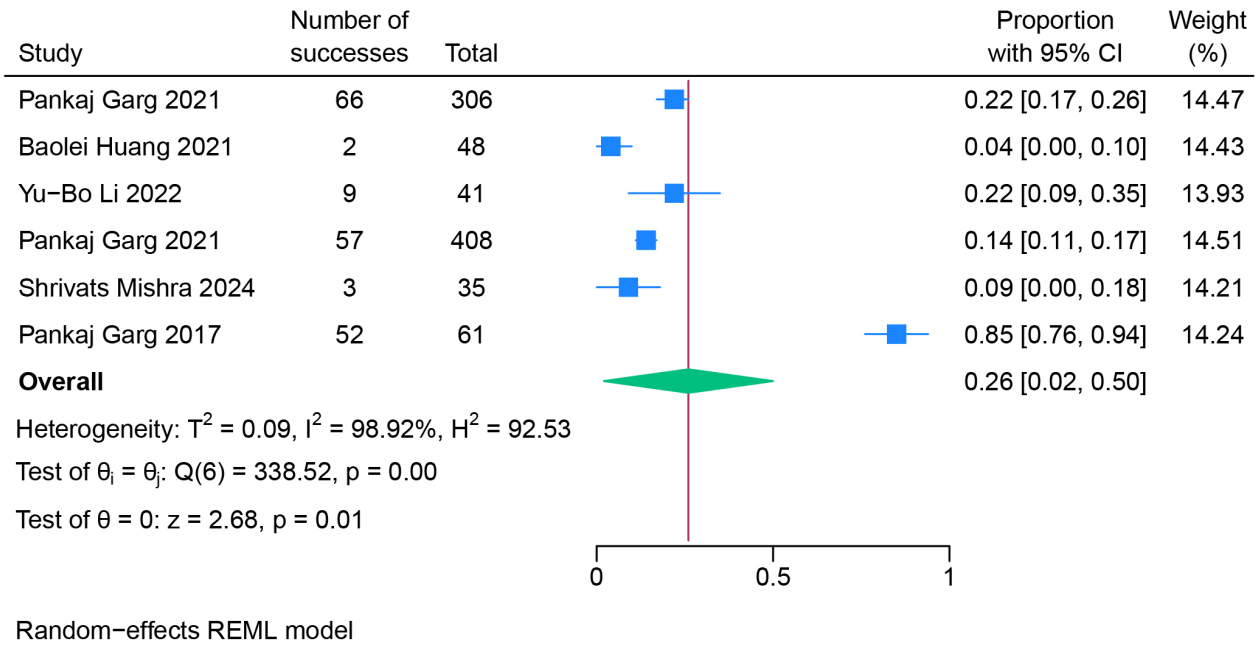

Fig. 9. Forest plot of the recurrence rate.

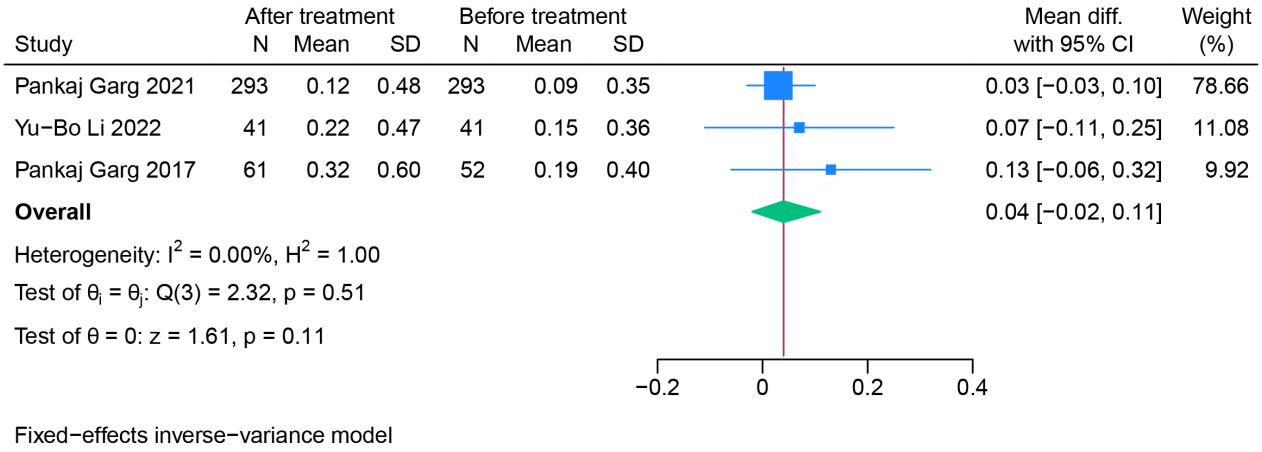

Fig. 10. Incontinence scores.

tion of the excluded fistula. However, Parks' surgery limits the internal sphincterotomy to below the dentate line [10]. Cases in which the infected anal gland or part of its catheter is located in a higher plane of the sphincter space may be missed, leading to a high risk of recurrence. In TROPIS surgery, internal anal sphincterotomy is extended to the height of the sphincter space to ensure complete elimination of the infection source [2]. Additionally, TROPIS surgery removes the infected anal gland and simultaneously opens the fistula in the sphincter space, emphasizing the role of DPIS infection in the formation of complex anal fistulas, especially for complex high anal fistulas, and remains a safe and effective method [6]. In Parks' surgery, the infected lesions in the sphincter space are not completely eradicated, as seen in the case of intersphincteric horseshoe fistulas. Residual pus-infected lesions increase the chance of recurrence. In terms of current surgical treatments, although LIFT addresses the infected anal gland and sepsis in the intersphincteric space, one study reported a 76.4% success rate for the treatment of complex anal fistulas, which is lower than that of the TROPIS procedure. LIFT preserves the IAS and therefore poses no risk of incontinence [11,12]; however, LIFT is technically challenging, has a long learning curve, and is difficult to perform in high intersphincteric, suprasphincteric, and intersphincteric horseshoe fistulas [13]. TROPIS has a relatively low incidence rate of 3%, despite the risk of incontinence, and the incontinence score did not differ significantly before and after the pro-

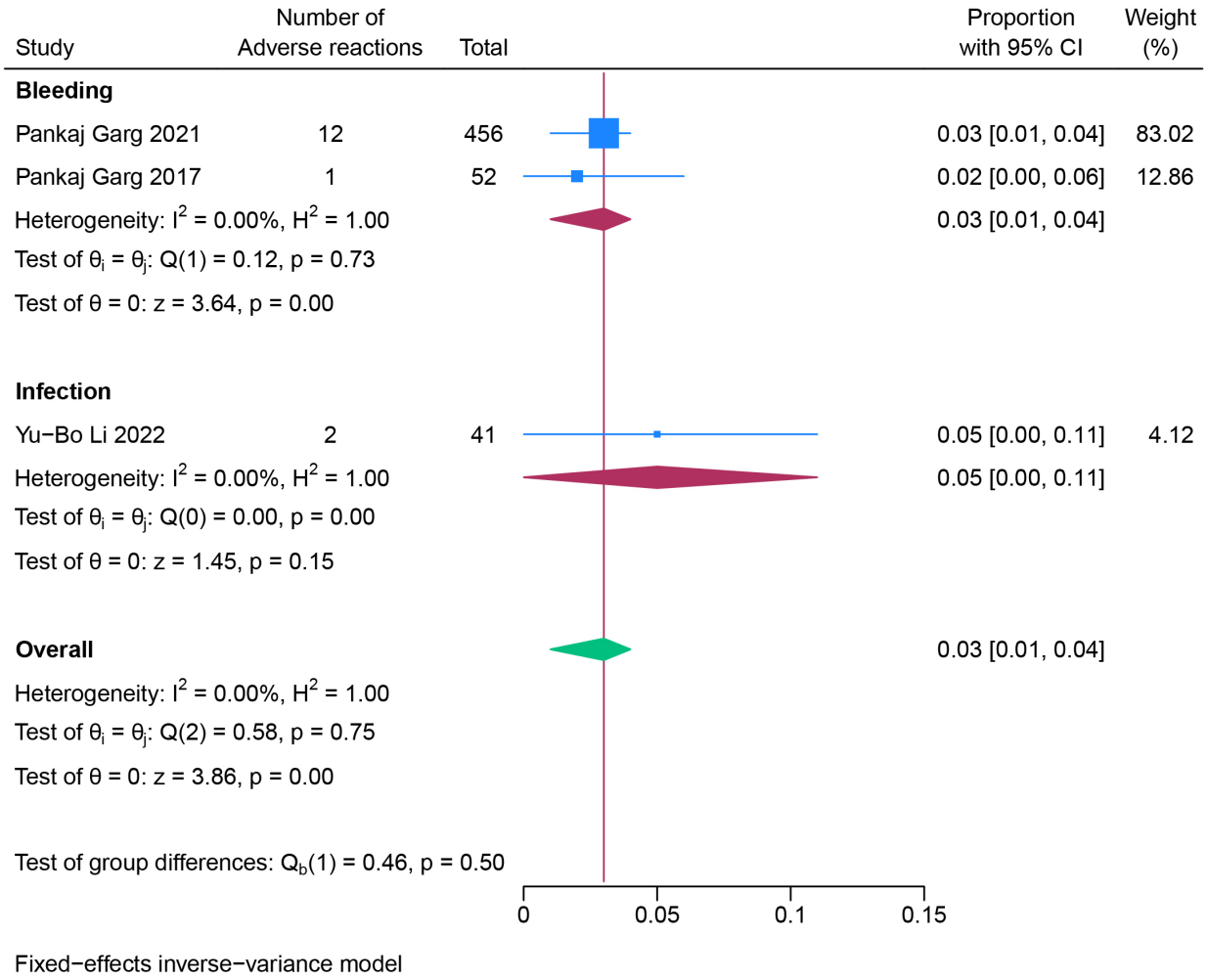

Fig. 11. Adverse reactions.

cedure. This may be because the IAS is responsible for maintaining resting anal pressure, whereas the external anal sphincter (EAS) contributes mainly to squeezing or peak anal pressure. A slight reduction in resting anal pressure caused by partial internal sphincter injury may be functionally alleviated by strengthening the external sphincter through Kegel exercises, thereby improving faecal control rather than restoring resting pressure itself [14]. Notably, the pooled success rates for the two analyses—the first operation success rate and the success rate specifically for high fistulas—were nearly identical. This consistency is largely attributable to the significant overlap in the studies contributing to both estimates, with the results being heavily influenced by the larger, high-weight studies common to both analyses.

In a mesh meta-analysis conducted by Hua Huang *et al.* [15], TROPIS was found to be the best treatment plan, but the evidence-based level of the mesh meta-analysis was lower, and the small amount of data in the article may also cause bias in the superposition results. Therefore, it is necessary to include randomized controlled studies for direct comparison in the future to further improve the level of evidence-based medicine. A systematic review of single-arm studies conducted by Nusrat Iqbal *et al.* [16] revealed that fistulotomy with immediate sphincter reconstruction (FISR) is an effective way to preserve sphincter function for the treatment of high anal fistula, with a success rate of 92%, which is higher than that of TROPIS, but the degree of incontinence associated with this surgical protocol is 16%. The percentage of adverse reactions is also much greater than 3% for TROPIS. Therefore, the selection of surgery may be based on the individual treatment of patients. Current studies have shown that there is no significant difference between the use of an anal fistula plug and a mucosa advancement flap in the treatment of complicated anal fistula [17], and there is no direct evidence to show the advantages and disadvantages of TROPIS and these two surgeries. However, circumstantial evidence suggests that TROPIS may be more effective in treating complex anal fistulas. A systematic review and meta-analysis of six recent studies from European countries revealed that the primary healing rate of fistula laser closure (FiLaC™) in the

treatment of anal fistulas was 68% (95% CI: 53.0–84.0%) [18], which was much lower than that of TROPIS. Hui Zhang *et al*. [19] conducted a network meta-analysis and reported that incision thread-drawing counterdrainage procedures increased the effective rates and cure rates. Reducing the recurrence rate is advantageous for reducing the incidence of anal canal injuries. However, this research method uses a network meta-analysis with a low evidence-based level and lacks direct comparisons and incidence statistics. However, there are several limitations in this study: (1) All included studies were single-arm observational studies, and our analysis was based solely on the outcomes reported in the TROPIS surgery groups, which may be influenced by other confounding factors. In addition, high-quality randomized controlled trials should be included in future research. (2) The total sample size was small, and some indicators showed high heterogeneity, which could be attributed to the varying surgical skills of different surgeons. Further relevant studies should be included in the future to conduct subgroup analyses, explore the sources of heterogeneity, and further refine and guide the selection of clinical surgical methods. (3) A significant portion of the included studies, particularly those with the largest sample sizes that heavily weighted our meta-analysis, originated from a single country, India. This geographic concentration may introduce selection bias and limit the generalizability of our findings. Factors such as genetic predispositions, dietary habits, specific surgical training, and health care system characteristics can vary across different populations and may influence treatment outcomes. Therefore, the high success rates reported in this review should be interpreted with some caution, and we strongly recommend that future large-scale, multicentre trials be conducted across more geographically diverse regions to validate these results and enhance their external validity.

Conclusions

This study demonstrates that TROPIS holds significant potential in the treatment of anal fistulas, particularly for high fistulas, fistulas complicated by abscesses, and horseshoe-shaped fistulas, whilst exhibiting a relatively low incidence of incontinence.

Availability of Data and Materials

The data that support the findings of this study are available from PubMed, EMBASE, Web of Science, and the Cochrane Library.

Author Contributions

Conceptualization: CC, WJ, JW and ZW. Data curation: CC, HY, LJ, YL. Formal analysis: CH, HY. Methodology: CC, WJ, JW, CH, HY, ZW. Project administration: CC, ZW. Visualization: CC, YL, LJ. CC drafted the manuscript. All authors contributed to the critical revision of the manuscript for important intellectual content. All authors read and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work.

Ethics Approval and Consent to Participate

Not applicable.

Acknowledgment

Not applicable.

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Conflict of Interest

The authors declare no conflict of interest.

Supplementary Material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.62713/aic.4148.

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