Albanian Journal of Trauma and Emergency Surgery (2025) 9/2:1765 - 1775
DOI: **10.32391/ajtes.v9i2.466**

ORIGINAL ARTICLES

Comparative Meta-Analysis of Recurrence Rates in Classical vs. Modified Limberg Flap Techniques for Pilonidal Sinus Disease Surgery: Evidence for Enhanced Efficacy

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Received: 19 May 2025 / *Accepted:* 30 May 2025 / *Published online:* 20 July 2025
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Abstract

Aim: In the surgery of pilonidal sinus disease (PSD), positioning any incision away from the central axis of the crenae is expected to yield a reduced recurrence rate. If so, it can be anticipated that the modified Limberg flap (MLF) exhibits a lower recurrence rate than the Limberg flap (LF).

Material and Methods: To perform a comparative meta-analysis of the recurrence rates, 1,338 studies encompassing 153,098 patients were identified. Out of these, 210 studies (both randomized controlled and nonrandomized controlled trials) with n=16,588 patients who had undergone either LF or MLF were included in the Kaplan-Meier Survival analysis.

Results: In non-RCT analysis, the LF group exhibited a 5-year recurrence rate of 7.1% (CI 6.3-8.0), while the MLF group showed a 5-year recurrence rate of 4.9% (CI 3.7-6.1) ($p<0.0001$). After 8 years, which represents the most extended observation period for the MLF group, the recurrence rate was 10.9% (CI 9.6-12.1) for LF and 7.3% (CI 5.4-9.1) for MLF ($p<0.0001$).
In the RCT analysis, the curves differ as a trend but not significantly, as PT numbers are scarce beyond year 2. The RCT-versus-nonRCT analysis of LF shows significantly higher RR for RCT studies, which is the same for MLF.

Conclusion: This meta-analysis, which focused on recurrence rates associated with Limberg flap variants and analyzed data from 16,588 patients, shows that the modified Limberg flap technique effectively reduces the risk of recurrence compared to the already low recurrence rate associated with the classical Limberg flap. The presence of a scar in the caudal midline, as observed in the classical Limberg variant but not in the modified Limberg, is strongly correlated with a higher recurrence rate. Therefore, the modified Limberg flap variant is recommended in future surgical procedures.

What does this paper add to the literature? This paper contributes significantly to the existing literature by providing robust evidence supporting the modified variant of the Limberg flap technique. While the Limberg flap's recurrence rate is already low, its modification notably diminishes recurrence rates even further. Consequently, the modified Limberg plasty may be considered the emerging gold standard.

Keywords: Pilonidal Sinus, Therapy, long-term Recurrence Rate, Incidence, Observation bias, Limberg flap, modified Limberg flap.

Original article, no submission or publication in advance or in parallel

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** *Members of the PiloNerds Group are provided in the Acknowledgment.*

Introduction

Surgery for pilonidal sinus disease (PSD) is primarily focused on achieving surgical efficiency while mitigating patient discomfort, and both these facets have been subjects of extensive debate. [1]

Some define surgical efficacy as the accomplishment of swift and uncomplicated surgical procedures with early, cost-effective patient discharge. In contrast, others emphasize the importance of reliability, particularly in achieving a recurrence-free outcome. [2]

Patient discomfort can manifest as prolonged hospitalization, protracted recovery periods, diminished sexual functionality [3, 4], the necessity for multiple dressings, or the need for repeated surgical interventions.[5]

Asymmetric and flap techniques have consistently emerged as the most dependable surgical methods for preventing recurrences, substantiated by numerous studies and meta-analyses spanning the past few decades. [6, 7, 8]

Their supposed drawback has been identified as the complexity of acquiring proficiency, the significant time required in the surgical operating room, and the generation of numerous wound complications.

Notably, Wysocki has demonstrated that below 10 flaps, learning has just begun, but a mere 24 procedures are adequate for mastering the Karydakis [9] flap technique.[10]

Several colleagues worldwide concur with this assertion, extending its applicability to other advancement flaps such as the cleft lift and rhomboid plastics, exemplified by Limberg [11] and Dufourmentel [12].

Becoming proficient in these techniques is a matter of experience, with surgical operating room times typically ranging from 28 to 45 minutes.· [13, 14]

Wound complications associated with flaps for PSD are most frequently observed in the distal portion of the wound. [15] Kaplan et al. have elegantly shown, through a case-control study, that the distance of the wound from the midline predicts uneventful healing and a reduction in wound complications.

Their findings suggest that maintaining a distance of at least 2 cm from the midline is advisable. [16]

Furthermore, there is a proposition that sharp hair fragments originating from the scalp can become embedded in the glabella sacralis and the upper third of the intergluteal fold.

Consequently, ensuring that the lower part of the wound avoids the midline should result in a lower recurrence rate, as scar tissue in the midline is thought to be less resilient to hair penetration.

If this hypothesis holds, it implies that the modified Limberg Flap (MLF) should yield a lower recurrence rate than the classical Limberg flap (LF) as, in the classical LF, the rhomboid-shaped excision is on the midline whereas as the MLF places the inferior tip of the rhomboid excision 1–2 cm lateral to the midline onto the side of the recipient area.

To explore this possibility, we investigated the recurrence rates associated with the LF and MLF techniques as documented in the global literature.

Materials and Methods

The study was registered in the PROSPERO study register as "The efficacy of the commonest surgical procedures in pilonidal sinus patients—a meta-analysis comparing the recurrence rates over time using long-term follow-up data" at PROSPERO 2016 CRD42016051588.

The data retrieval process adhered to the Stauffer methodology and yielded results in the *Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (PRISMA) flow diagram (Figure 1) [17].

Search Strategy and Study Selection Criteria

A pre-study investigation began in 1986, and the German Bundeswehr Medical Archives (WEHRMEDSTATINST Bw Remagen) were searched under the guidance of the archivists. [18]

Applying pinpoint searching, it was found that all diseases except non-PSD diseases were wrongfully classified as PSD. More PSD patients were found misclassified as other diseases, so previously unknown PSD results could be added to the PSD population as soon as broader search terms were applied (not relying on ICD or OPS codes, but on "pilonidal*" and "dermoid*" AND "cyst."

This resulted in an increased workload to sift through thousands of findings that were later dismissed, but it also added more than 5% of previously non-PSD labeled reports to our database. This is the reason why we opted to use a small meshed fishing net for the following research to build up the PSD world literature database.

A systematic search of the existing world literature using the NCBI Medical Subject Heading (MeSH) term "pilonidal*" and a combination of "dermoid" AND "cyst" was conducted across all databases available, including MEDLINE, PubMed, PubMed Central, Scopus, Ovid, EMBASE, and the Cochrane Central Register of Controlled Trials (CENTRAL).

In addition, these terms were searched using Google, Google Scholar, and ResearchGate. Furthermore, references cited in national and international guidelines, such as the S3 guidelines of the Association of the Scientific Medical Societies in Germany about PSD treatment, were scrutinized.

We also examined the references in the bibliographies of all documents obtained from these searches. The collected documents encompassed various types of studies, including randomized and non-randomized trials, prospective and retrospective studies, as well as observational studies such as cohort studies, case-control studies, cross-sectional studies, and case reports. These documents covered the period from 1833 to 2023.

Three authors (TH, HH, DD) meticulously reviewed the retrieved documents to ensure compliance with the inclusion criteria. These criteria required information on definitive treatment, recurrence, gender composition, and follow-up duration. Reports published in English, French, German, Italian, and Spanish were considered, and publications in other languages were included if they provided an English abstract detailing definitive treatment, recurrence, and follow-up time.

In cases where translations were necessary, authors were contacted via email or ResearchGate. Alternatively, two different translation software programs were used to translate text passages of interest. The exclusion criteria included PSD occurrences in locations other than the presacral region, involvement of neoplastic conditions, and duplicate publication of data by the same author.

Studies that lacked any component of the minimal data set, which includes information on the definitive treatment strategy, recurrence, and follow-up time, were also excluded. While previous meta-analyses and review articles were excluded, their reference lists were examined for potential additions to the evidence. Furthermore, unpublished data presented in review articles were taken into account.

Data Collection, Extraction, and Quality Assessment

All identified studies underwent thorough analysis and documentation. The transcribed data were then entered into a Microsoft Excel spreadsheet (Version 2016, Microsoft Corp., Redmond, WA, USA) and verified to ensure accuracy.

Each distinct therapeutic strategy detailed in a study was assigned a separate line, with columns covering citation details, the number of included patients, therapeutic procedures, reported follow-up times, study particulars, and recurrence data. Given the variation in statistical measures used to report follow-up times across studies, we considered mean and median reports as equivalent due to the concentration of disease incidence among young adults. These values were included as reported for cases where minimum follow-up times were provided.

Individual studies were systematically scrutinized for methodological consistency, and their reported results were examined to mitigate potential bias during data synthesis. A subgroup analysis was conducted for prospective randomized controlled trials (RCTs) to ensure alignment with the broader set of studies.

The recurrence rates reported in each study were associated with the corresponding follow-up time, defined as the mean, median, center of the range, or minimum. To enable uniform comparison across all studies, individual patients were statistically simulated, with each study participant represented as a data sample that included recurrence status, follow-up time, and therapeutic procedure. For example, if a study included 500 patients and recorded a recurrence rate of 20% for a specific therapeutic procedure, we designated 100 individual samples as having recurrent disease. In contrast, the remaining 400 samples were classified as recurrence-free. Certain information, such as gender ratios, was excluded since it was primarily available in aggregate form in most studies.

In cases where an article discussed multiple therapeutic strategies, data about each treatment strategy were analyzed separately. Since pediatric pilonidal sinus disease exhibits a significantly different recurrence rate dynamic, as recently shown, only cohorts with a mean age of 18 years and older were included in this analysis. Given that return-on-recurrence (ROR) studies are subject to significant observation bias, which also affects PSD studies with ROR follow-up, these studies have been excluded (see PRISMA schedule, Figure 1).

As an expert group of statisticians advised, case reports and case series excluded 10 patients. A meta-regression analysis conducted beforehand on a cohort of 89,583 patients, which examined established RR modifying factors (choice of treatment, follow-up duration, age, Methylene Blue use) and potentially influential variables (year of therapy, country of treatment, annual caseload) on recurrence rates, confirmed the impact and ranking of these known factors.

Other potential influences, such as family history and recurrence status (primary versus recurrent disease), were reported inconsistently in the global literature and were too sparse to be analyzed meaningfully. Cardiovascular comorbidities are rare in patients with PSD, who typically fall within the at-risk age range of 15 to 25. Previous co-interventions were also limited and, therefore, were not investigated.

Grouping of Therapeutic Procedures, Gender Cohorts, and Statistical Analyses

Therapeutic procedures were analyzed for RCT and non-RCT and were subcategorized into therapeutic categories. Variants of therapeutic procedures were grouped with the originating procedures, as outlined in Table 1 in [20].

Statistical analysis and visualization were performed using the R statistical software package (version 4.3.2) within the R-Studio framework (version 2023.6.1.524). Statistical significance was set at $p < 0.05$, and all tests were conducted in a two-tailed configuration.

Kaplan-Meier survival analysis was used to evaluate the recurrence-free outcome over time, along with pointwise 95% confidence intervals (CI), implemented using the R package ‘survival’ (version 3.5-7).

These analyses were conducted for RCT and non-RCT cohorts, as well as LF and mLF. The results were presented as percentages of recurrence-free outcomes along with their corresponding 95% confidence intervals. The ‘survminer’ package (version 0.4.9) was utilized for graphical display.

A two-tailed log-rank test was conducted, and a student’s t-test was performed for the two-group comparison. The horizontal axes on the plots represented the number of patients within a specific follow-up period, measured in months.

In cases where specific data were unavailable for an interval, linear interpolation was applied to estimate recurrence-free outcomes based on the two nearest observed follow-up times.

The horizontal axes on the plots represented the number of patients within a specific follow-up, given in months. The time frame was truncated to 10 years postoperatively.

To provide a comprehensive assessment of recurrence and a robust foundation for selecting treatment procedures, we evaluated the data in a manner consistent with a classical meta-analysis of randomized controlled trials (RCTs) and conducted an analysis that incorporated non-randomized controlled trials (non-RCTs). Due to the incremental nature of the Kaplan-Meier curves, minor discrepancies between the plotted and tabulated values may arise.

Bias Assessment for Randomized Controlled Trials (RCTs)

The risk of bias (RoB) in RCTs was assessed using the Cochrane RoB1[21, 22], instrument (Figure 1). The low RoB (green) is seen in performance and detection bias due to blinding, as regular unblinding carries a low risk of strategy or quality changes in surgery.

The highest risk RoB (red) is associated with incomplete outcome data, as a shorter follow-up < 2 years is prone to miss recurrences happening later. The most significant amount of unclear RoB (yellow) is attributed to the unknown bias section.

Bias Assessment for Nonrandomized Studies

Nonrandomized studies were evaluated for bias using the Newcastle-Ottawa Scale (Figure 2). [21-23]

For RoB assessment, a follow-up period of two years and a follow-up rate of at least 66% of enrolled patients were required to achieve a low RoB status. Cohort studies scored between 4 and 8 stars (median 6) on the Newcastle-Ottawa Scale, while return-on-recurrence observational studies (excluded) ranged from 3 to 7 stars (median 5).

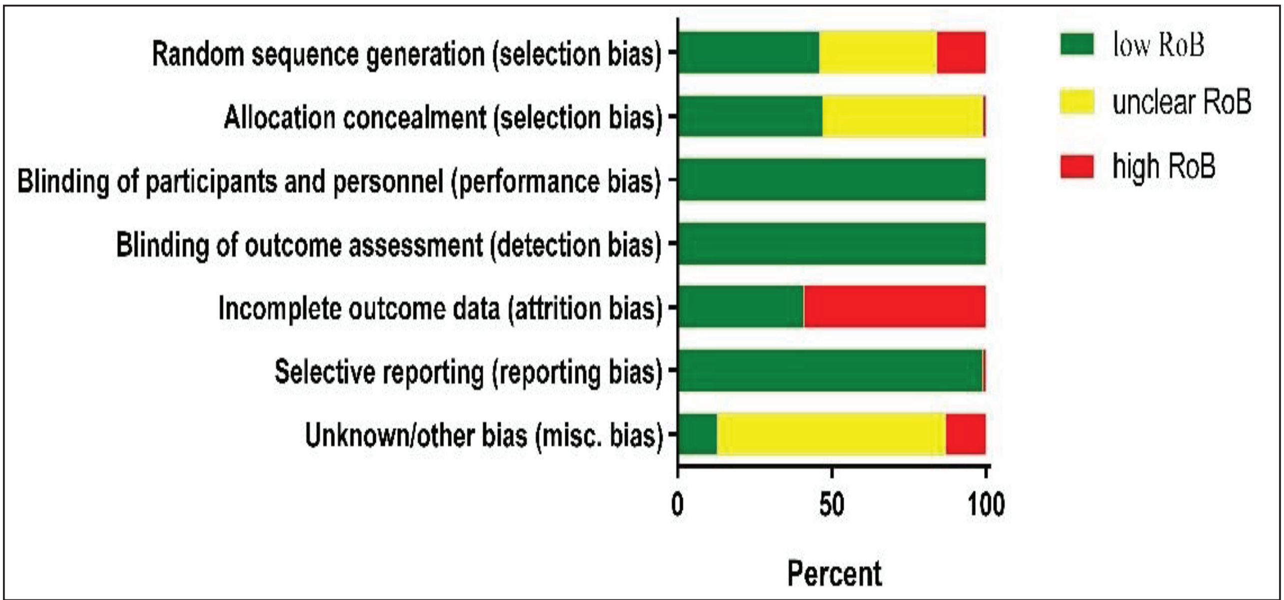

Figure 1Risk of bias analysis for RCT studies characterised by the Cochrane RoB1 instrument.[4]

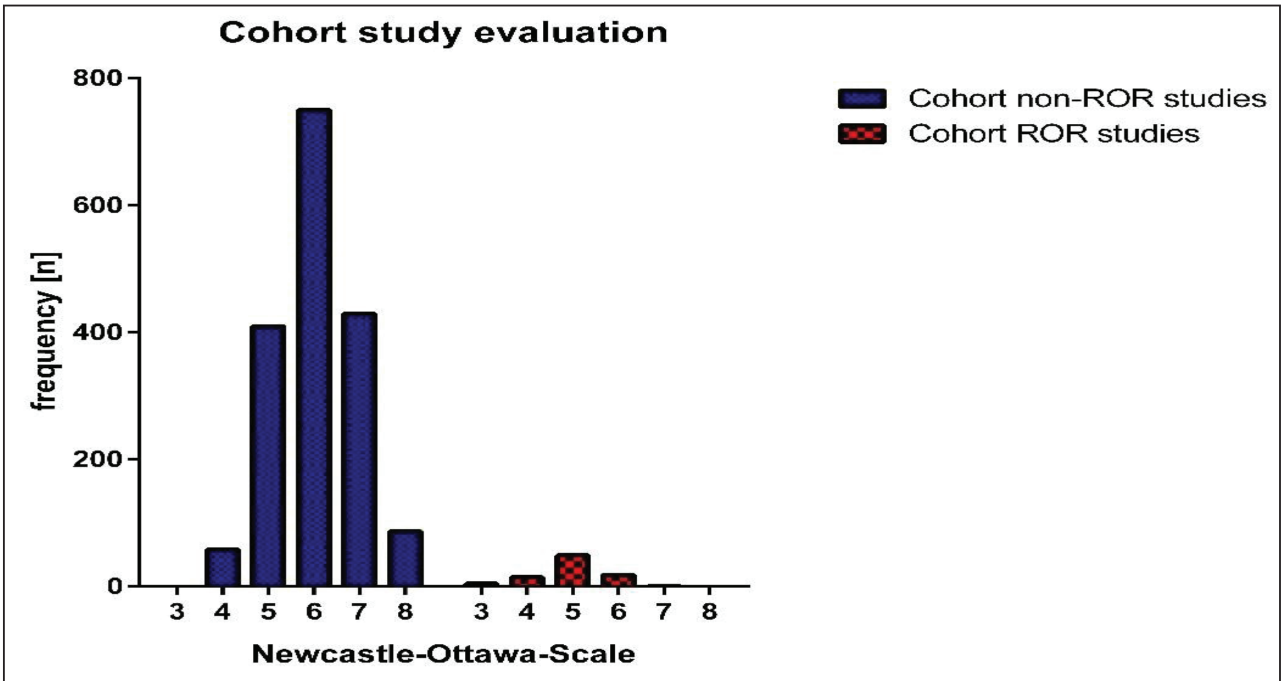

Figure 2: Newcastle-Ottawa Scale ranking of non-RCT cohort and ROR studies. [23] ROR studies are also shown for reasons of curiosity, though excluded from the analysis.[23]

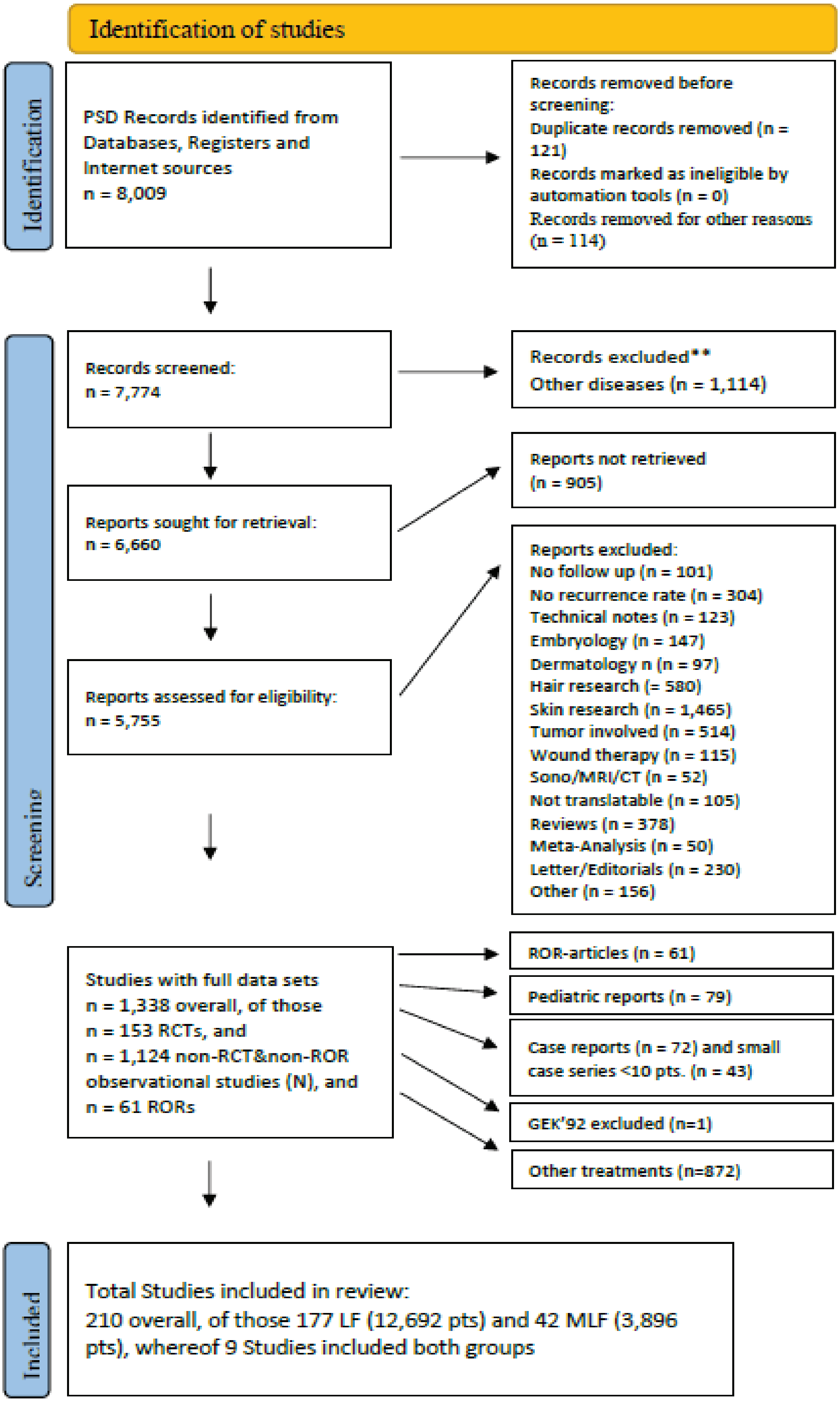

Figure 3 PRISMA flow chart of study harvest and qualification steps [17]

Results

Our analysis included 1,338 studies involving 153,098 patients from 1833 to 2023. Of these, 210 studies reported outcomes on LF or MLF, with n=16,588 patients available for comparative analysis (Figure 1).

Gender distribution was approximately balanced across these groups, with a ratio of 5.7:1 (males to females) in the Limberg group and 6.3:1 in the modified Limberg group. Furthermore, the age distribution exhibited a similar balance, with the Limberg group having a mean age of 26 years and the modified Limberg group having a mean age of 25.6 years.

A Kaplan-Meier survival analysis was performed to illustrate the recurrence-free outcomes across both study flap type groups and for RCT versus non-RCT studies. Beginning with the latter (Figure 2The recurrence-free outcome in the MLF group is significantly superior to that of the LF group (p<0.0001).

The Kaplan-Meier curve for the LF group extends for more than ten years, whereas the MLF curve spans eight years. Although both curves appear identical in the initial years following surgery, they gradually diverge, as do their associated confidence intervals.

At three years (36 months) post-surgery, the recurrence rate in the LF group is 3.5% (95% CI 3.0-4.0), compared to 1.7% (95% CI 1.2-2.2) in the MLF group (p<0.0001; log-rank test). At 60 months, the recurrence rate is 7.1% (95% CI 6.3-8.0) in the LF group and 4.9% (95% CI 3.7-6.1) in the MLF group. At eight years (96 months), the recurrence rate is 10.9% (95% CI 9.6-12.1) in the Limberg flap group and 7.3% (95% CI 5.4-9.1) in the modified Limberg flap group. Consequently, the risk of recurrence following MLF surgery remains lower than that of LF surgery within a study period of up to 100 months (eight years). However, the numbers at risk, particularly in the MLF group, are small.

As Figure 3 Shows, the RR of unmodified Limberg flaps in RCT studies is 7.3% (95% CI 5.2-9.3) at 36 months, whereas that of modified Limberg flaps is 4.9% (95% CI 2.3-7.4). Although this follows the trend in Figure 2A significant difference between the two curves cannot be elucidated due to the small patient numbers already present at 2 years (p = 0.64).

Analysing the flap types separately for both study types (Figure 6The 36-month RR in Limberg (non-RCT study) is 3.5% (95% CI 3.0-4.0), and in the RCT studies analysis, 7.3% (95% CI 5.2-9.3). At 5 years, RR for non-RCT Limberg studies is 7.1% (95% CI 6.3-8.0) and 10-year RR 14.3% (95% CI 12.4-16.1), while longer LF follow-up is unavailable in RCTs beyond 4 years. Despite minor differences in RR, log-rank testing reveals a highly significant difference.

In Figure 7MLF results from RCT and non-RCT studies are compared. At 36 months, RR from non-RCT amounts to 1.7% (95% CI 1.2-2.2), while 4.9% (95% CI 2.3-7.4) is to be recognized in RCT analysis. The 5-year RR for non-RCTs is 4.9% (95% CI 3.7-6.1). Both curves differ significantly with p<0.0001.

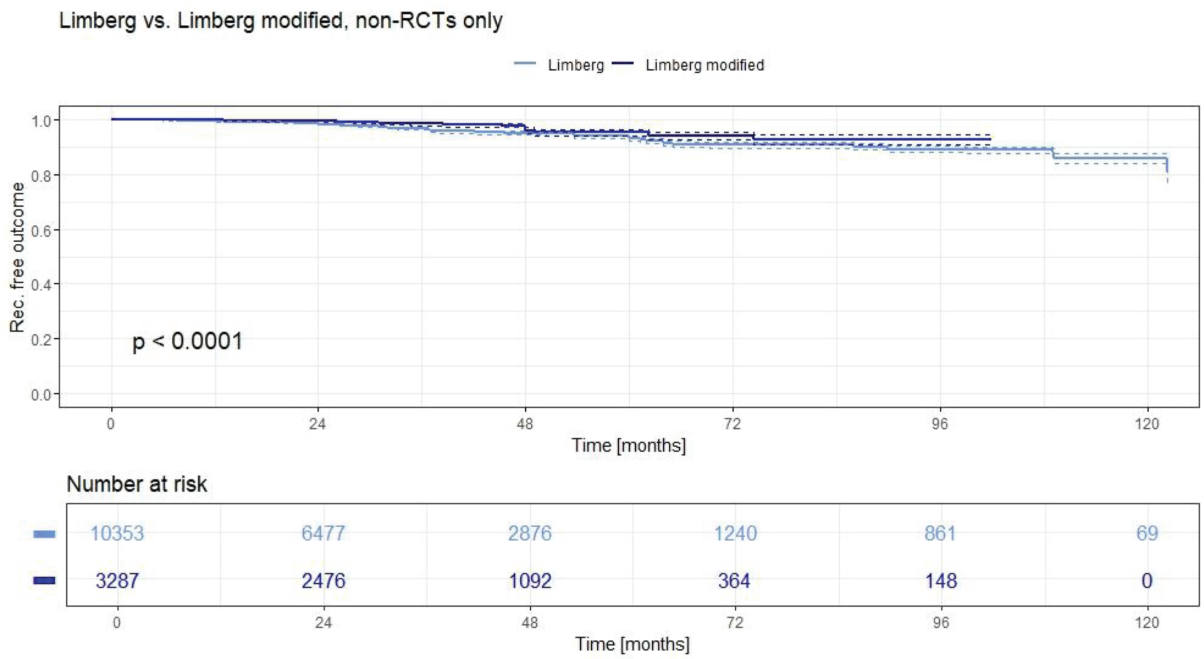

Figure 4 Recurrence-free outcome in classical Limberg flap (light blue) versus modified Limberg flap (dark blue) for non-RCTs only. The horizontal axes on the plots represented the number of patients within the follow-up intervals. The vertical axis on the plot represents the percentage of recurrence-free outcomes. Below the graph, the at-risk patients are listed separately, with the number decreasing over time.

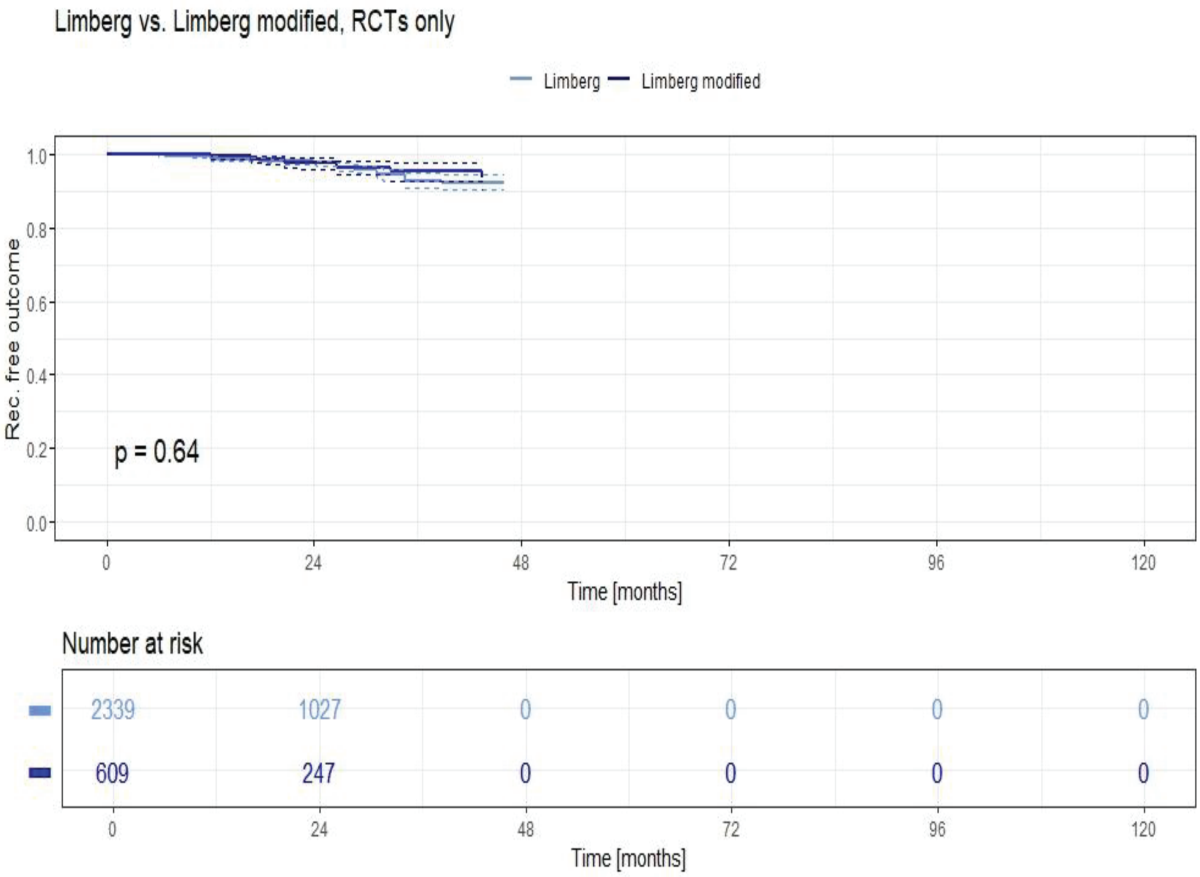

Figure 5: Recurrence-free outcome in classical Limberg flap (light blue) versus modified Limberg flap (dark blue) for RCTs only. The horizontal axes on the plots represented the number of patients within the follow-up intervals. The vertical axis on the plot represents the percentage of recurrence-free outcomes. Below the graph, the at-risk patients are listed separately, with the number decreasing over time.

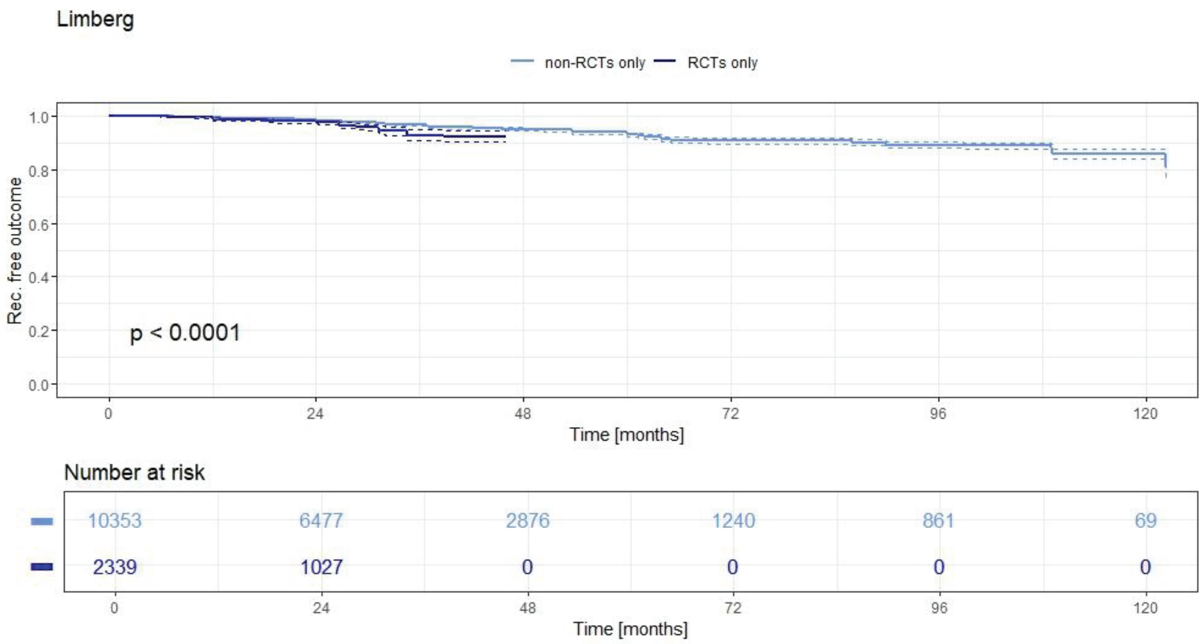

Figure 6 Recurrence-free outcome in LF studies, given for RCT (dark blue) and non-RCT studies (light blue).

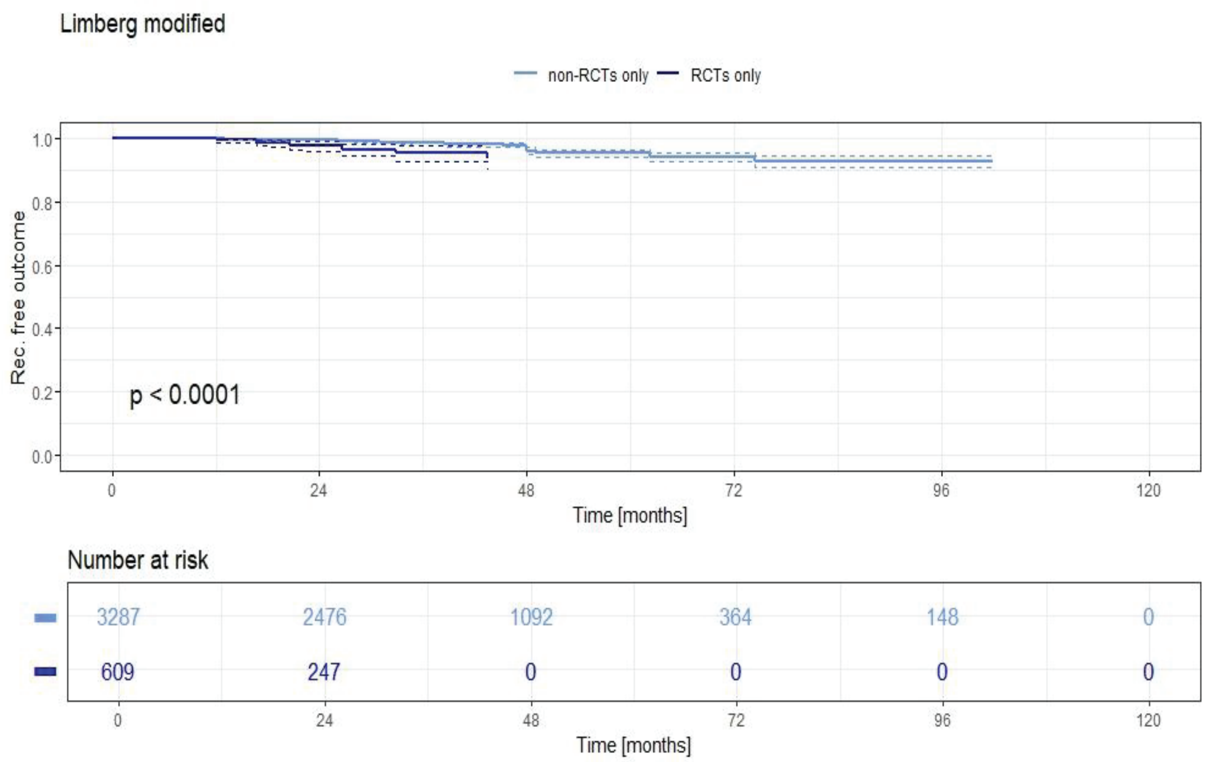

Figure 7 Recurrence-free outcome of MLF studies, given for RCT (dark blue) and non-RCT studies (light blue).

As evident in the detailed analysis for LF RCT versus non-RCT (Figure *6*) and MLF RCT versus non-RCT (Figure *7*) RCTs generally detect a higher recurrence rate than studies conducted in the non-RCT design.

Discussion

To our knowledge, this is the most comprehensive meta-analysis comparing the modified Limberg Flap with the classical Limberg Flap technique and its outcomes in 16,588 patients with PSD. We found that despite the already favorable recurrence rate after Limberg flap surgery, modifying the method significantly reduced recurrence rates.

Among the various surgical approaches used to treat PSD, the asymmetric and flap techniques have consistently proven to be the most effective methods for preventing recurrences. [6, 8].

From a pathophysiological point of view, this may be due to the journey of loose scalp hair fragments: It has been proposed that pointed fragments of hair originating from the scalp tend to embed in the upper third of the intergluteal fold and that – being less resilient to hair penetration - scar tissue in the intergluteal midline therefore is associated with (much) higher recurrence rates. Thus, positioning any incision away from the central axis of the crena would be expected to yield a reduced recurrence rate.

With the distal proportion of the distal rhomboid excision relocated away from the midline in the MFL technique compared to the classic LF, with the rhomboid excision placed with the proximal and distal proportions within the midline, we are observing exactly what would be expected with a decrease in recurrence rates.

As suggested by previous analyses, studies conducted in the RCT framework tend to reveal a higher recurrence rate compared to non-RCT studies, a finding also observed in the recent research. [20, 24]

RCTs tend to detect a slightly, albeit significantly different, higher recurrence rate more accurately than the non-RCT studies.

The discrepancy in the proportion of RCT studies between groups suggests that the disparity between MLF and LF in recurrence rate may be even more pronounced than our analysis revealed in the non-RCT group.

While our study cannot definitively conclude whether the presence of the scar causes recurrence due to increased friction, making it easier for hair to penetrate the elevated scar, or if the scar represents less resilient tissue that facilitates hair penetration, this intriguing question will be investigated in due course.

Our findings, however, may encourage surgeons already employing rhomboid plastic flaps to relocate the lower portion of the future scar away from the midline, ideally at least 11 mm or more, if technically feasible.[16]

It is a compelling argument for surgeons who have hesitated to try flaps to treat PSD. The primary flaps used in PSD surgery, such as the Karydakis or Bascom variant and the Limberg / Dufourmentel or even other flaps, can be acquired with relative ease. [10, 25]By opting for the modified variant, one can minimize the risk of healing complications and recurrence rates. This, in turn, enhances patient comfort and surgical efficiency, while maintaining the duration of surgery unchanged and keeping costs consistent.

The overall outcome is improved.

Several authors have hinted that a modified variant of Karydakis or Limberg Flaps may reduce healing complications and recurrence rates.

In a Turkish study involving 61 patients and 194 control patients followed up for more than 5 years post-surgery, Kaplan and colleagues observed that prolonged healing time was associated with an increased likelihood of recurrence.[16] Conversely, higher age was associated with a reduced likelihood of recurrent disease.

This highlights the crucial role of the local wound condition in both healing and recurrence. In Turkey, Demiryas and Donmez investigated the potential association between recurrence and wound infection and dehiscence.[14]

In a retrospective comparison of 840 patients who underwent two different flaps (Karydakis flap and MLF flap) using the same technique and surgeon, the authors found that dehiscence and wound infection significantly correlated with recurrence in both groups ($p < 0.001$).

Limitations

Our retrospective study is subject to inherent limitations associated with its study type. We included primary and secondary PSD patients who had undergone unknown initial therapies from studies conducted globally. Both randomized controlled trials (RCTs) and non-RCT studies were included, excluding return-on-recurrence studies due to their inherent observational bias.[24]

Most authors reported mean recurrence rates at various time points; thus, long-term Kaplan-Meier data were limited. Consequently, heterogeneity exists within these data, and we have adjusted our statistical methods accordingly. We did not control for the application of drains at the flap site, which may reduce the risk of wound hematoma.[26]

Methylene Blue application may reduce infection in PSD surgery, as Sahin et al. [27] found, which we did not investigate. Other authors attribute an unjustified, too small excision of diseased tissue.[28] To use Methylene blue, which others deny.[29-31]

We did not investigate the impact of smoking, despite the controversy surrounding this topic, as it has been suggested to increase the rate of wound complications.. [32, 33]

However, it appears not to affect the recurrence rate.[18] The Modified Limberg Flap (MLF) technique is defined by maintaining the lower part of the wound or scar away from the midline. Kaplan demonstrated in 2017 that maintaining a scar-to-midline distance of 11 mm is advantageous in achieving a lower recurrence rate.[16] However, the MLF studies analysed provided limited information regarding the intraoperative distance from the wound to the midline and the postoperative wound-to-midline distance.

These factors may have influenced our findings, but given the large cohort size of patients undergoing the Limberg Flap and (to a lesser extent) the Modified Limberg Flap procedures, we anticipate that the impact of these factors is limited due to their random distribution. The comparison of RCT studies on LF versus MLF was insignificant, despite showing the same course as in non-RCT studies. This may be due to the limited number of available RCT studies, necessitating the analysis of RCT and non-RCT studies together without differentiation.

The key distinction between MLF and LF is the absence of a scar in the distal midline. This disparity is associated with a lower recurrence rate. Hence, the treating surgeon must avoid a midline scar - an iatrogenic *locus minoris resistentiae*. Maintaining the distal scar at a minimum of 11 millimeters from the midline is feasible in most cases and may further decrease the recurrence rate.

This approach also minimizes wound healing problems. Since changing from classical to modified Limberg does not require additional costs or increased operating room time, there are no valid arguments against adopting this practice. Reducing the recurrence rate of Pilonidal Sinus with a single incision has never been as straightforward.

Conclusion

In conclusion, our meta-analysis of 16,588 patients has demonstrated that the modified Limberg flap technique offers additional protection against recurrence compared to the classical Limberg flap's already low recurrence rate.

This highlights the correlation between the presence of scars in the midline and a higher recurrence rate. The modified Limberg flap technique should be preferred over the classical Limberg flap to reduce the disease burden regarding wound healing and lower recurrence rates.

This simple adjustment can be made without additional costs or extended operating room time. It is now easier than ever to reduce the recurrence rate of PSD with a single incision.

Abbreviations: *FUP follow-up period; LF Limberg flap; MLF modified Limberg Flap; nonRCT non-randomised controlled trial, PSD Pilonidal Sinus Disease; pt patient; RCT randomised controlled trial, ROR return on recurrence; RR Recurrence rate; tx treatment; yr year*

Acknowledgement:

This work is a brainchild of discussions from the **PiloNERDs** International Group (The Pilonidal Network for Expertise, Research and Development); members are as follows:

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Ethics: This review does not contain any personal data or interventions that could potentially cause harm to human participants. Nevertheless, according to the Declaration of Helsinki, ethical standards were strictly adhered to.[34]

COI: All authors declare that they have no conflicts of interest. No relevant or minor financial relationships exist between relatives or next of kin and external companies.

Funding: No funding or grants were received from any public, commercial, or not-for-profit sectors.

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