Title: Commentary On Packing Vs Non-Packing of Pilonidal Sinus Cavities After Incision and Drainage

Commentary on: Mohamedahmed AYY, Zaman S, Stonelake S, Ahmad AN, Datta U, Hajibandeh S, Incision and drainage of cutaneous abscess with or without cavity packing meta-analysis, and trial sequential analysis of randomised controlled trials. Langenbeck's Archives of Surgery. 2021;406(4):981-991.

Abstract

Pilonidal Sinus Disease (PSD) manifests as an inflammatory skin condition typically emerging within the anal cleft. The prevalence of this disease varies in high income countries. This disease is associated with significant physical and psychosocial distress. Surgery is an option for managing PSD, yet surgical methods vary, and a universally accepted gold standard approach is lacking, leading to current practices that are diverse and subject to ongoing debate. One such point of contention revolves around the decision to use packing or opt for a non-packing approach following surgery. Mohamedahmed et al. (2021) conducted a systematic review to evaluate the comparative outcomes of packing versus non-packing of an abscess cavity following incision and drainage of cutaneous abscess on any part of the body. This commentary aims to critically appraise the methods used within the review by Mohamedahmed et al. (2020) and expand upon the findings in the context of treatment and management of PSD.

Key Points

- Currently there is no evidence of difference for packing versus non-packing after incision and drainage of cutaneous abscess on any part of the body for the outcomes of abscess recurrence and development of Fistula-in-Ano.
- There is low quality, low imprecision, clinically and statistically non-significant evidence that non packing may reduce the risk of intervention during the first 48 hours after incision and drainage of cutaneous abscess on any part of the body.
- Due to this lack of certainty it is difficult to make any direct recommendations regarding the decision of packing versus non-packing for Pilonidal Sinus Disease.
- Due to this notable uncertainty, further large-scale and methodologically robust multi-centred randomised controlled trials are required.

Introduction

Pilonidal Sinus Disease (PSD) is an inflammatory skin condition that usually develops in the anal cleft (de Parades et al. 2013). This is commonly caused by hair follicles that embed in the skin which can lead to a deep sinus or cavitydeveloping (Gupta 2012). The prevalence of PSD varies from 26 cases per 100,000 people (United States of America) (Søndenaa et al. 1995) to 48 cases per 100 000 persons per year (Germany) (Oetzmann von Sochaczewski and Gödeke 2021). PSD is more prevalent in males, with women consistently comprising approximately 20% of patients (Luedi et al. 2021). PSD is linked to notable physical and psychosocial distress (Gil et al. 2023). The psychological impact is attributed to extended periods of inactivity, discomfort, fluctuations in body weight, and delayed healing of wounds (Stewart et al. 2012). The best courses of action will aim to reduce both disease and the side effects associated with treatment (Gil et al. 2023; Harries et al. 2019).

Management of acute PSD may include surgery, regular analgesia and oral antibiotics (Harries et al. 2019; Mahmood et al. 2020). Surgical methods differ, and there is no universally accepted gold standard approach, resulting in current practices being variable and subject to debate (Harries et al. 2019). One such debate is the decision around packing or non-packing for cavity healing after surgery. Whilst an evidence synthesis is lacking specific to cavity packing versus non-packing for PSD, a systematic review was conducted by assessing the effect of packing vs non-packing after incision and drainage of cutaneous abscess on any part of the body (Mohamedahmed et al. 2021).

Aim of commentary

This commentary aims to critically appraise the methods used within the review by Mohamedahmed et al (2020) and expand upon the findings in the context of clinical practice for PSD.

Methods of the review by Mohamedahmed et al. (2021)

A relatively narrow literature search was completed using PubMed, MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials and CINAHL Plus. Only randomised controlled trials which compared incision and drainage of cutaneous abscess on any part of the body with and without post-operative cavity packing were included. Screening and data extraction was carried out by two reviewers independently. The assessment for risk of bias was assessed independently by two authors using the Cochrane risk of bias tool. A random effects meta-analysis was undertaken to assess the relative risk of specific events. Heterogeneity was assessed using the I^2 statistic. A range of subgroup analyses and a trial sequential analysis were also undertaken.

Results of the review by Mohamedahmed et al. (2021)

After duplicate removal, 450 records were identified from the search, of which after screening, eight randomised controlled trials (RCTs) were included in the systematic review. These RCTs were undertaken within the USA (n = 3), Nepal (n = 2), United Kingdom (n = 1), Bangladesh (n = 1) and Australia (n = 1). Three RCTs included only anorectal abscess with the remaining five studies including various types of cutaneous abscesses. The risk of bias assessment demonstrated that one RCT exhibits some concerns regarding bias, while the remaining seven RCTs are deemed to have a high risk of bias overall (Higgins 2021).

For the outcomes of abscess recurrence at maximum follow-up period (6 RCTs) and development of Fistula-in-Ano (3 RCTs), there was no evidence of difference between the packing and non-packing

groups after incision and drainage of cutaneous abscess on any part of the body. There was a borderline statistically non- significant reduction for the need of a secondary intervention during the first 48 hours when comparing non-packing and packing (4 RCTs, 33.7% vs 52%, RR O.70, 95% CI:0.49 to 0.99, P = 0.05). However, there existed modest non-statistically significant heterogeneity (I^2 = 38%, P = 0.19).

Two outcomes were unable to be meta synthesised, post-operative pain and healing time. Four of five studies demonstrated no statistically significant difference for post-operative pain and one study demonstrated a statistically significant improvement favouring non-packing. For healing time there was a statistically significant improvement for 2/3 studies favouring non-packing and one study reported no significant difference.

There was no statistically significant difference for the subgroup analyses for RCTs which included only anorectal abscess, paediatric patients, adult patients and antibiotic use for risk of abscess recurrence. The sequential analysis revealed the necessity for additional studies, as the results for abscess recurrence were susceptible to type II error regarding the primary outcome during the maximum follow-up period.

Commentary

Using the AMSTAR-2 (A MeaSurement Tool to Assess systematic Reviews) (Shea et al. 2017), eight out of the 16 criteria were achieved. The main areas of concern included the lack of protocol registration prior to commencing the systematic review. This could result in adaptations to key methodological processes occurring during the undertaking of the review,leading to such issues as reporting bias, and non-reporting of outcomes due to lack of data (dos Santos et al. 2020). Without a pre-registered protocol these issues are difficult to verify.

Furthermore, there were also concerns regarding the search strategy of the review where key methodological processes, such as citation screening of included studies and consultation with experts, were not described as part of the search strategy. This omission of additional search strategy methods may have resulted in the exclusion of potentially pertinent studies from the review. Additionally, there was no indication for reasons of exclusion for studies at full paper screening. This lack of transparency makes it difficult to replicate this phase of the systematic review, thus, reducing the repeatability of the review. Finally, there was no assessment of the impact the risk of bias may have had on the estimates presented in the review. However, this may have been difficult due to the lack of number of studies within the main analysis.

Though not a criterion within the AMSTAR-2, there were some concerns regarding reporting errors within the review. For example, within the PRISMA table it is indicated that six studies were included in the meta-analysis, where in total eight studies were included. Where it is unlikely that these reporting errors would make a substantial impact to the overall findings of the review, it does raise some concerns regarding unperceived errors. Due to these methodological and reporting issues, some caution should be given to interpreting the findings of this review.

Table 1.Critical appraisal using the AMSTAR 2 tool for assessing systematic reviews.

	AMSTAR 2 items	Responses
1.	Did the research questions and inclusion criteria for the review include the components of PICO?	Yes - all key variables were identified as inclusion criteria.
2.	Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	No - Despite being indicated within the PRISMA checklist there was no link to a pre-published protocol.
3.	Did the review authors explain their selection of the study designs for inclusion in the review?	No - there is no indication of why only randomised controlled trials were included.
4.	Did the review authors use a comprehensive literature search strategy?	No - no indication of citation screening or trial registries searching.
5.	Did the review authors perform the study selection in duplicate?	Yes - study selection was undertaken in duplicate independently.
6.	Did the review authors perform data extraction in duplicate?	Yes - data extraction was undertaken by two reviewers independently.
7.	Did the review authors provide a list of excluded studies and justify the exclusions?	No - the PRISMA table was given which gives global reasons for exclusion, but no specific supplement file was provided regarding individual studies.
8.	Did the review authors describe the included studies in adequate details?	Yes - a comprehensive study characteristic table was provided.
9.	Did the review authors use a satisfactory technique for assessing the risk of bias in the individual studies that were included in the review?	Yes - the Cochrane risk of bias assessment tool was used.
10.	Did the review authors report on the sources of funding for the studies included in the review?	No - the review did not indicate where the funding for the included studies came from.
11.	If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes - a random effects model was used.
12.	If meta-analysis was performed did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	No – no subgroup analysis for meta-regression were undertaken to assess the impact of particular data items of risk of bias.
13.	Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	No - there was no discussion of the effects of risk of bias in regard to interpretation of the findings of the review. Outside the possible issue of small study publication bias and type II error.
14.	Did the review authors provide a satisfactory explanation for, and discussion of any heterogeneity observed in the results of the review?	Yes - there was no substantial heterogeneity in the results therefore no discussion was undertaken.
15.	If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small	No – no assessment of publication bias was undertaken due to the small number of studies.

study bias) and discuss its likely impact on the results of the review?	
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes - there was a conflicts of interest statement indicating that there are no conflicts in undertaking the review.

As highlighted previously, there is no gold standard approach for surgical management of PSD (Harries et al. 2019). Regarding the decision of packing or non-packing after incision and drainage of cutaneous abscess, the findings from this review suggest that there is currently no evidence of difference between the two approaches for recurrence of abscess at last point of observation. However, it is important to acknowledge that this review examined the procedures for both packed and non-packed cutaneous abscesses located anywhere on the body. This aspect may limit its generalizability, particularly about PSD. However, we believe that these findings hold relevance when considering the fundamental principles of wound healing. Furthermore, this review does indicate that data is collected for the primary aim of assessing the recurrence of abscess at the last reported clinical point, but specific time points for the studies are not provided, making it difficult to interpret the long-term effects of the primary outcome reported. Additionally, as demonstrated within the sequential analysis there is still significant uncertainty surrounding this presented estimate, underscoring the need for additional research before specific clinical recommendations can be made. Finally, for all RCTs used in the analysis there were notable issues of risk of bias and issues of imprecision regarding the estimates presented which would warrant caution when interpreting the findings in context to clinical practice (Balshem et al. 2011). Hence, when interpreting these findings in the context of deciding whether to pack or not after incision and drainage of PSD, one should exercise caution.

Concerning the development of a Fistula-in-Ano, the review found there was no evidence of difference between packing and non-packing. However, there was a borderline statistically non-significant reduction in risk of intervention during the first 48 hours after surgery favouring non-packing. For the other secondary outcomes, a meta-analysis was unable to be undertaken due to heterogeneity in reporting. The findings suggest that there was no evidence of difference for the outcome of post-operative pain. There was some evidence to suggest that healing times were improved with non-packing with two thirds of the studies reporting a statistically significant finding. However, it is important to note that typically when undertaking a vote counting method of analysis, directional improvement should be counted rather than number of statistical significance studies as this can be misleading (Higgins 2023). Thus, these findings may be subject to questioning, especially in the absence of proper vote counting methods. Even when such methods are applied, there remains a considerable level of uncertainty in the results (Higgins 2023). Subsequently, as with the previous estimation of effect, extreme caution is required when interpreting these results due to these factors and as highlighted previously, reduced external validity of the population being assessed.

The review conducted a variety of subgroup analyses on studies including only anorectal abscess, paediatric patients, adult patients, and antibiotic use. However, like other estimates in the review, there is significant uncertainty in these analyses, due to the limited number of studies per group. In summary, there appears to be limited and uncertain evidence to support either approach which makes it difficult to make any recommendations for practice. Despite this lack of certainty, typically surgeons will opt to pack the wound despite the notable lack of evidence regarding its benefits (Nyandoro et al. 2023). It is important to ensure that whatever decision is made regarding the post-operative care for PNS, patients are presented with both options and are provided with the current best evidence regarding the treatment's success (Wickramasekera et al. 2023).

Given the sequential analysis indicating a risk of a type II error in these results, it is crucial for upcoming studies to further examine the key outcome of abscess recurrencewhen assessing packing versus non-packing after incision and drainage of cutaneous abscess. Moreover, as highlighted in this review, most of the included studies had relatively small sample sizes. Therefore, it is crucial that future research endeavours to enrol a larger and more diverse population. This approach is essential to mitigate the potential impact of publication bias stemming from small-scale studies in the future iterations of this review (Sterne et al. 2000).

As previously highlighted there has been no specific systematic review, to the best of our knowledge, which has looked at packing versus non-packing after incision and drainage of PSD specifically. However, regarding this review there are certain principles which may help to inform future research in this domain With such high frequencies of re-occurrence, it is important that a post-operative long-term follow-up is provided (Milone et al. 2018). Considering that earlier studies have proposed that this duration could potentially extend up to 5 years (Milone et al. 2018), it becomes crucial for future RCTs and clinical practices to scrutinize longer-term outcomes to assess the success of surgery. Additionally, it is vital to address specific methodological issues, such as the absence of blinding for both assessors and patients, wherever feasible. As identified in the review, a meta-analysis could not be conducted concerning post-operative pain due to the heterogeneity in reporting. Consequently, it is essential to establish a standardized pain assessment tool in future research, possibly as part of a core patient outcome set for this condition. Furthermore, in conjunction with reporting pain levels, future studies should also document the use of pain medications. Beyond these outcomes, it is equally important to evaluate the cost implications of this approach. Therefore, future research should not only assess the effectiveness but also the economic impact of the intervention or treatment being studied. This comprehensive approach will provide a more robust foundation for evidence-based decision-making in the management of post-operative care.

CPD reflective questions

1. What are the main methodological issues within this systematic review?
2. What additional evidence are you aware of from your own practice which may help you inform the effectiveness of packing versus non-packing for patients with PSD?
3. What additional factors should be taken into consideration when making this decision regarding packing and non-packing?

Funding statement (*must be included in the published article)

This research was partly-funded by the National Institute for Health and Care Research Applied Research Collaboration North West Coast (NIHR ARC NWC). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health and Social Care.

References

Balshem H, Helfand M, Schünemann HJ, Oxman AD, Kunz R, Brozek J, Vist GE, Falck-Ytter Y, Meerpohl J, Norris S et al. 2011. Grade guidelines: 3. Rating the quality of evidence. J Clin Epidemiol. 64(4):401-406.

de Parades V, Bouchard D, Janier M, Berger A. 2013. Pilonidal sinus disease. J Visc Surg. 150(4):237-247.

dos Santos MBF, Agostini BA, Bassani R, Pereira GKR, Sarkis-Onofre R. 2020. Protocol registration improves reporting quality of systematic reviews in dentistry. BMC Medical Research Methodology. 20(1):57.

Gil LA, Deans KJ, Minneci PC. 2023. Management of pilonidal disease: A review. JAMA Surg. 158(8):875-883.

Gupta PJ. 2012. Pilonidal sinus disease and tuberculosis. Eur Rev Med Pharmacol Sci. 16(1):19-24.

Harries RL, Alqallaf A, Torkington J, Harding KG. 2019. Management of sacrococcygeal pilonidal sinus disease. Int Wound J. 16(2):370-378.

Cochrane handbook for systematic reviews of interventions version 6.2 (updated february 2021). 2021. Cochrane; [accessed]. training.cochrane.org/handbook.

Higgins TJ, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). 2023. Cochrane handbook for systematic reviews of interventions version 6.4 (updated august 2023). Cochrane.

Luedi MM, Schober P, Stauffer VK, Diekmann M, Andereggen L, Doll D. 2021. Gender-specific prevalence of pilonidal sinus disease over time: A systematic review and meta-analysis. ANZ J Surg. 91(7-8):1582-1587.

Mahmood F, Hussain A, Akingboye A. 2020. Pilonidal sinus disease: Review of current practice and prospects for endoscopic treatment. Ann Med Surg (Lond). 57:212-217.

Milone M, Velotti N, Manigrasso M, Anoldo P, Milone F, De Palma GD. 2018. Long-term follow-up for pilonidal sinus surgery: A review of literature with metanalysis. Surgeon. 16(5):315-320.

Mohamedahmed AYY, Zaman S, Stonelake S, Ahmad AN, Datta U, Hajibandeh S, Hajibandeh S. 2021. Incision and drainage of cutaneous abscess with or without cavity packing: A systematic review, meta-analysis, and trial sequential analysis of randomised controlled trials. Langenbeck's Archives of Surgery. 406(4):981-991.

Nyandoro MG, Teoh M, Thompson A, Fletcher D. 2023. Surgical practice parameters for the definitive management of sacrococcygeal pilonidal sinus disease: Surgeons' perspective. Cureus. 15(5):e39480.

Oetzmann von Sochaczewski C, Gödeke J. 2021. Pilonidal sinus disease on the rise: A one-third incidence increase in inpatients in 13 years with substantial regional variation in germany. Int J Colorectal Dis. 36(10):2135-2145.

Søndenaa K, Andersen E, Nesvik I, Søreide JA. 1995. Patient characteristics and symptoms in chronic pilonidal sinus disease. Int J Colorectal Dis. 10(1):39-42.

Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, Moher D, Tugwell P, Welch V, Kristjansson E, Henry DA. 2017. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. Sep 21;358:j4008.

Sterne JA, Gavaghan D, Egger M. 2000. Publication and related bias in meta-analysis: Power of statistical tests and prevalence in the literature. J Clin Epidemiol. 53(11):1119-1129.

Stewart AM, Baker JD, Elliott D. 2012. The psychological wellbeing of patients following excision of a pilonidal sinus. J Wound Care. 21(12):595-596, 598-600.

Wickramasekera N, Strong E, Shackley P, Callaghan T, Lee M, Hind D, Brown S. 2023. Patient preferences for pilonidal sinus treatments: A discrete choice experiment survey. Colorectal Dis.