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PROTOCOL

Effectiveness of antimicrobial dressings in surgical site infection prophylaxis in surgical wounds healing by secondary intentions (SWHSI): a systematic review protocol

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Plain English Summary

Why we are undertaking this work: Open surgical wounds are commonly left to heal from the bottom up but this usually takes a long time and they often get infected. Many different types of dressings are used to manage these wounds including dressings with antimicrobial properties which aim to reduce the risk of infection. Small studies have suggested these antimicrobial dressings may reduce infection but the data are not clear.

What we will do: To investigate the effect of antimicrobial dressings on infection rates in open surgical wounds, we are going to do a systematic review. A systematic review is a way of bringing together the results from existing studies to decide if an intervention is effective or not. This paper describes how we are going to bring all the existing studies on antimicrobial dressings and infection rates together to decide if they should be used in routine practice. We are going to search databases for published and unpublished studies that study the use of antimicrobial dressings to prevent infection in patients with open surgical wounds.

What this means: The results from the systematic review will tell us if antimicrobial dressings should be used in routine practice or if more research is needed. It will also allow other researchers to repeat the systematic review if they wish.

Abstract

Background: Surgical wounds healing by secondary intentions (SWHSI) refers to wounds left open after surgical procedures. SWHSI is challenging to manage and presents a significant burden to both individual and healthcare services. They require more nursing and healthcare support, such as continuous district nurse involvement, recurrent hospitalisations and surgical re-interventions. These wounds also negatively impact functional status, body image and psychological well-being. There are various treatment modalities offered for SWHSI ranging from negative wound pressure therapy to various dressings and implantable topical antibiotics. However, there is a lack of formalised guidance and decisions are highly variable by care provider. This study aims to systematically evaluate data on the effectiveness of antimicrobial dressings in preventing surgical site infections in SWHSI.

Methods: This is a protocol for the systematic review and meta-analysis of studies investigating the efficacy of antimicrobial dressings in preventing surgical site infections in SWHSI. It has been registered in PROSPERO with the registration number CRD42024608611. A comprehensive literature search will be conducted in EMBASE, MEDLINE, CINAHL and CENTRAL to identify relevant studies. Randomised controlled trials, cohort studies and cross-sectional studies will be reported. Data will be extracted, synthesised and a meta-analysis performed to determine the overall association of antimicrobial dressings with surgical site infections. Subgroup analysis will be conducted to elicit the influence of confounders on pooled data. If meta-analysis is unable to be carried out due to insufficient studies or high data heterogeneity, the results will be expressed narratively instead. A risk-of-bias tool appropriate for each study design will be used to ensure high quality studies are selected. The systematic review will be reported as per PRISMA guidelines.

Discussion: The findings from this systematic review will provide a comprehensive assessment of the available evidence. As there is a lack of high-quality clinical evidence exploring the benefits and drawbacks of this treatment, this review will be able to evaluate the quality of evidence and potentially produce a meta-analysis to further guide clinical decision-making.

Key words: antimicrobial dressings, surgical wounds healing by secondary intentions, surgical site infections

Prospero registration number: CRD42024608611

Introduction

Healing by primary intention occurs when the incision edges are approximated with physical means (sutures, staples, etc) after surgery. Surgical wounds healing by secondary intention (SWHSI) refers to surgical wounds left open after a surgical procedure. The general definition of SWHSI is a wound left open arising from any surgical specialty and occurring on any part of the body. This includes cases where wound closure was not planned (eg, due to infection, tissue loss or undue tension when wound edges are approximated),[1] initially closed wounds have dehiscence or experience a post-surgical breakdown and existing wounds that underwent debridement.[2] Secondary intention aims to heal by the formation of granulation tissue in the tissue defect.

The point prevalence of SWHSI has been found to be 4.1 per 1000 population.[3] Colorectal and vascular surgery are the most common surgical specialties with SWHSI, with SWHSI being most located in the abdomen and foot.[3] This is supported by Chetter *et al* who showed that the common operations leading to SWHSI are surgery for pilonidal sinuses, lower limb amputations and laparotomy with bowel resections.[4]

Postoperatively, open surgical wounds can require continuous intensive treatment. Acute wounds typically heal in a predictable fashion following the four defined stages of haemostasis, inflammation, proliferation and remodelling while chronic wounds do not progress through these phrases in the expected timeframe. While acute closed surgical wounds normally heal in 4 weeks, SWHSI take longer to heal with a median time to healing of 86 days.[3] In a study by Saramago *et al* of the cost-effectiveness of negative wound pressure therapy (NWPT), statistical modelling estimated that patients with SWHSI will take 181 days to heal compared with 42 days for patients without SWHSI when both were treated with NWPT.[5]

A burden of wounds study by Guest *et al* conducted in 2017/20186 showed that the annual prevalence of wounds increased by 71% between 2012/2013 and 2017/2018. SWHSI have explicit and implicit costs for individuals and healthcare services. Explicit costs include prolonged or recurrent hospitalisations with costs for laboratory investigations, radiological tests, treatment costs such as wound management therapies, antibiotic therapies, further surgical intervention and continuing community support requirement for district nursing. The annual cost of NHS wound management (closed and open wounds) was estimated at £8.3 billion, with 81% being incurred in community care.[5,6] The social and personal costs of living with a SWHSI can include unemployment and significant psychosocial impacts.

Current recommendations by the National Institute for Health and Care Excellence (NICE)[7] for infection prevention in SWHSI is to avoid Eusol, gauze, moist cotton gauze or mercuric antiseptic and to use an appropriate interactive dressing. This guideline lacks clarity on specific dressings and therapies to be used. Two therapies that are frequently implemented are wound dressings and NWPT. One of the fundamental tenets of wound healing involves establishing an optimal microenvironment. This is where advanced wound dressings are of critical importance as they have been proven to improve the microenvironment by facilitating cell migration and reducing the risk of infection from the bacterial microenvironment.[8]

A cross-sectional survey shows that most patients were receiving dressings in the community setting.[9] Given the lack of research in this area, decision-making regarding the choice of dressing is often made based on clinical or patient preference without a rigorous underpinning of evidence available to guide this choice. The lack of formalised guidance leads to a discrepancy in decision-making with potential implications for time to healing, wound infections and antimicrobial stewardship. The categories of dressings currently available as per the British National Formulary (BNF) are listed below:[10]

- Gauze
- Films
- Foams
- Hydrogels
- Hydrocolloids
- Alginate
- Antimicrobial

Antimicrobial dressings can be further divided into:[10]

- Silver
- Iodine
- Polyhexamethylene biguanide (PHMB)/polyhexanide
- Honey
- Chlorhexidine gauze
- Dialkylcarbamoyl chloride
- Alginate dressings with silver
- Octenidine dihydrochloride

There is a gap in evidence-based treatment for SWHSI. This is especially true for the selection of dressings, which are often the mainstay of SWHSI treatment.[9] Current guidelines do not precisely define dressing type, so the purpose of this systematic review is to help identify healthcare gaps and develop more comprehensive guidance for care providers in terms of dressing selection.

The aim of this study is to identify and establish the effectiveness of antimicrobial dressing usage in SWHSI in the context of surgical site infection. Currently, there is no formalised guidance on the benefits or disadvantages of antimicrobial dressings. A systematic review would help to consolidate our understanding and support decision-making to help fulfil current healthcare needs.

This systematic review also aims to assess variability in outcome reporting of surgical site infection if sufficient data could be collected.

Objectives

To investigate if antimicrobial dressings are effective in reducing surgical site infections in SWHSI.

Methods

Outcomes

The primary outcome measure will be the binary outcome of surgical site infection in SWHSI as defined by the individual studies. This could be diagnosed by any surgical site infection scoring system such as the ASEPSIS score, which is an acronym for Additional treatment, Serous discharge, Erythema, Purulent exudate, Separation of deep tissue, Isolation of bacteria and Stay as inpatient prolonged over 14 days. Alternatively, we also accept surgical site infection as diagnosed by predefined Centre of Disease Control (CDC) criteria and the Southampton score,[11] or by any other methods.

Secondary outcomes would be:

- Patient-reported quality of life measures
- Time to heal
- Mean length of hospital stays
- Reoperation within 30 days
- Amputation of affected body part
- Hospital re-admissions related to wound complications
- 30-day mortality

Eligibility criteria

Studies will be eligible for inclusion if they meet the following criteria:

- *Population*: Adult human patients with SWHSI (all surgery types will be included). This will include wounds where healing by secondary intention was planned, initial wounds closed with primary intentions that have dehiscence or experience a post-surgical breakdown. Wounds healing by primary closure or delayed primary closure and surgical procedures such as stomas, skin grafts and dental extractions will be excluded.
- *Intervention/comparator*: Studies with antimicrobial dressings as part of the intervention or standard treatment will be included. The comparator could be no treatment, systematic antibiotics, other dressings, adjuvant therapies (eg, NWPT, local application of antimicrobial implants, topical antibiotics or antimicrobial coated sutures). Antiseptic skin preparation used preoperatively will be excluded.
- *Outcomes*: Surgical site infections. Diagnosis could be made via any scoring system or method.
- *Study design*: Randomised controlled trials, cohort studies or cross-sectional studies.

Studies will be limited to those published in English from the year 1974. Studies with no full text but an abstract in English would be eligible for inclusion provided the primary outcome could be extracted.

Search strategy

In accordance with the recommendation from the Cochrane Handbook for Systematic Reviews of Interventions,[12] the following electronic databases will be searched: Medline, Embase, CINAHL and Cochrane Group. The following keywords would be used "anti- bacterial agents", "surgical site infection", "SSI", "open wound", "secondary intention" in combinations. An information search specialist was consulted for conducting the literature search (see Appendix 1 online at www.jvsgbi.com for a full search strategy). All published full-text articles will be included. For incomplete or restricted articles, the authors will be contacted to obtain the completed texts.

Data management

Selection process

All studies for potential inclusion will be imported into Covidence and de-duplicated prior to blind screening. Two reviewers (MCL/MS) will independently review and screen the remaining texts according to the inclusion/exclusion criteria. Where a full-text article is not available, we will attempt to contact the corresponding author for information. If this is unsuccessful, the studies will be excluded. Any difference in opinions between the two reviewers will be resolved with the input of a third reviewer (CA).

Data extraction

Data will be extracted from relevant studies into a pre-piloted Microsoft Excel spreadsheet. Data will be collected on:

- characteristics of each study (study design, sample size, publication year, funding source);
- demographic factors of participants (age, gender, ethnicity, comorbidities, smoking);
- wound-related information (number, duration, previous SWHSI, location, size, tissue involvement, originally intended secondary intention);
- surgery-related information (type, date, indication);
- associated treatment strategies (no treatment, systematic antibiotics, adjuvant therapies);

- primary outcome of surgical site infection and severity (including scoring system used to diagnose and stratify);
- secondary outcome measures.

Assessment of methodological quality

Different quality assessment tools will be used and tailored to the specific study design to enable rigorous appraisal of methodological quality. For randomised controlled trials, the Cochrane risk-of-bias tool (RoB 2)[13] will be used to systematically assess for risk of bias. For non-randomised studies, the Risk of Bias In Non-randomised Studies of Intervention (ROBINS-I)[13] will be used.

The Grading of Recommendations, Assessment, Development and Evaluations (GRADE) system will be used to assess the certainty of evidence for each outcome.

Data synthesis

Data extracted will be input into a standardised Excel table with any analysis being conducted with Stata. The primary outcome measure of surgical site infection will be expressed as odds ratios (ORs) with 95% confidence intervals (CIs) where clinical and methodological heterogeneity allows. This will quantify the strength of the association between the use of antimicrobial dressings and surgical site infections. A meta-analysis is planned to be conducted by using the inverse variance method. Studies reporting different effect measures will be converted to ORs to allow for consistency. This would be performed by either using raw data or the Generalised Linear Mixed Model.

Log-transformation of all ORs and standard errors will be calculated before proceeding with the meta-analysis. This will stabilise variance and allow additive calculations to be performed. A pooled OR will be calculated from transformed ORs and the results will be back-transformed and reported as OR and 95% CI for the likelihood of surgical site infection when antimicrobial dressings are used. The results of the pooled ORs and study weighting will be visualised with a forest plot. Sensitivity analysis will be conducted to assess the robustness of the results. If pooling is not feasible due to significant heterogeneity or lack of eligible studies, the results will be synthesised narratively.

Heterogeneity between studies will be assessed using Cochran's Q test and I^2 statistics. If substantial heterogeneity (I^2 >50%) as per Cochrane's Handbook for Systematic Review of Interventions[12,14] is found and sample size is adequate, potential sources of heterogeneity will be explored using subgroup analysis. The subgroups will include design (randomised controlled trials vs observational studies), type of SWHSI (planned vs unplanned), patient demographics (eg, age, sex, body mass index, presence of comorbidities), SWHSI location (abdomen vs limbs), therapies (dressings vs adjuvant therapies), surgery performed (elective vs emergency) and operation duration.

Publication bias will be assessed by construction of a funnel-plot of log-transformed ORs against standard error if at least 10 studies are included in the meta-analysis.

KEY MESSAGES

- Surgical wounds healing by secondary intentions (SWHSI) are surgical wounds that are left open after the procedure. These wounds are common in colorectal, plastic and vascular surgery.
- They require long healing times and more intensive care efforts, generating a significant economic and personal burden.
- There are various wound care options available, of which dressings are frequently used. Antimicrobial dressings are one such option.
- However, there is a lack of clear evidence-based guidelines regarding their effectiveness in reducing surgical site infections.
- This systematic review aims to assess the effectiveness of antimicrobial dressings in managing SWHSI and explores the variability in outcomes of surgical site infections reported in the current literature.
- The results of this study will help guide evidence-based decision-making and improve consistency in clinical practice and antimicrobial stewardship.

Meta-bias(es)

No meta-biases are expected to occur for this review.

Discussion

SWHSI is a significant clinical challenge with far-reaching impacts on both patients and healthcare services. This protocol is designed to systematically evaluate the current available medical literature on antimicrobial dressings. This planned review includes a comprehensive search strategy, independent dual assessor screening and data extraction in line with the Preferred Reporting items for Systematic Review and Meta- Analyses Protocols (PRISMA-P) guidelines and checklist. This ensures a maximal identification of relevant studies and reduction of selection and extraction biases. Validated methodological review tools will be implemented to enhance the internal and external validity of evidence.

Despite the planned methodological rigour, several challenges in interpreting the results of studies on SWHSI are anticipated. A key limitation is the presence of multiple confounders, including heterogeneity of the study population due to the variety of underlying comorbidities and clinical heterogeneity in wound aetiology. The lack of standardised surgical site infection diagnostic criteria is expected to lead to variability in outcome measures, complicating comparisons and data synthesis. Additionally, inconsistencies in treatment duration and wound healing outcome reporting (time to healing vs wound size reduction vs clinical judgement) might limit feasibility of a quantitative meta-analysis and may necessitate narrative synthesis.

While this review will address an important clinical question with a robust methodological framework, careful consideration of limitations is essential during the interpretation of the findings. These anticipated inconsistencies highlight the need for this review as well as the need for standardised trials in this field.

Conclusion

The findings of this systematic review will focus on the use of antimicrobial dressings and the effect on SWHSI, especially its efficacy in preventing surgical site infections. Based on the results of this systematic review, potential avenues for further research will be identified, including the potential need for extra research to address gaps in current evidence.

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Appendix 1

Embase <1974 to 2024 October 18>

1	Anti-Bacterial Agent*.mp.	1936
2	*antiinfective agent/	91174
3	Anti-Infective Agent*.mp.	2214
4	*antimicrobial dressing/	150
5	antimicrobial.mp.	347685
6	(dressing* or bandage*).mp.	77462
7	5 and 6	5056
8	1 or 2 or 3 or 4 or 7	98879
9	Surgical Wound Infection*.mp.	3792
10	*surgical infection/	18629
11	surgical site infection*.mp.	27325
12	SSI.mp.	16340
13	9 or 10 or 11 or 12	43847
14	SWHSI.mp.	10
15	secondary intention*.mp.	1776
16	Open surgical wound*.mp.	70
17	open wound*.mp.	3640
18	14 or 15 or 16 or 17	5399
19	8 and 13 and 18	15

Ovid MEDLINE(R) ALL <1946 to November 05, 2024>

Appendix 1

1	Anti-Bacterial Agent*.mp.	428111
2	*antiinfective agent/	0
3	Anti-Infective Agent*.mp.	88377
4	*antimicrobial dressing/	0
5	antimicrobial.mp.	249524
6	(dressing* or bandage*).mp.	53716
7	5 and 6	3310
8	1 or 2 or 3 or 4 or 7	502223
9	Surgical Wound Infection*.mp.	42875
10	*surgical infection/	0
11	surgical site infection*.mp.	18444
12	SSI.mp.	10560
13	9 or 10 or 11 or 12	54648
14	SWHSI.mp.	11
15	secondary intention*.mp.	1353
16	Open surgical wound*.mp.	51
17	open wound*.mp.	2728
18	14 or 15 or 16 or 17	4063
19	8 and 13 and 18	62