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Title

Wound Cleansing and Care in Treating Leg Ulcers: A Commentary on a Cochrane Systematic Review

Abstract

Leg ulcers pose a significant challenge to healthcare services, requiring effective wound cleansing strategies to promote healing and prevent complications. Large amounts of nursing time is spent managing patients with venous leg ulcers (VLU), with an average appointment time of approximately 30 minutes. Yet, there is a lack of clear guidance for the treatment of VLU's with nurses adopting a wide range of cleansing practices. This commentary provides an overview of existing evidence on wound cleansing and care in treating leg ulcers, for the benefit of healthcare professionals working within clinical practice.

Keywords

Nursing; Wound healing; Leg ulcer; Evidence-based practise; Healthcare; Practise guideline

Key Points (4 points)

1. Further high-quality research is needed to establish the effectiveness of different wound cleansing methods for patients with leg ulcers.
2. Due to the very low certainty of evidence, it is not yet possible to make recommendations for the adoption of any standardised wound cleansing approach within clinical practice.
3. In the absence of an evidence based VLU cleansing approach, clinicians should be guided by up-to-date national guidelines and key clinical guidance documents.
4. To strengthen non evidence-based approaches to cleansing VLU's, regular evaluations should be conducted to establish the effectiveness, acceptability and tolerability of the treatment.

INTRODUCTION

Leg ulcers pose a significant challenge to healthcare services, requiring effective wound cleansing strategies to promote healing and prevent complications (Raffetto et al. 2020). A venous leg ulcer (VLU) is classified as a break to the skin, below the knee which has been present for a minimum of 2 weeks (NICE. 2021). Leg ulcers are often caused by arterial insufficiency, mixed arterio-venous disease, sustained venous hypertension, deep vein occlusions or carcinoma (De Maeseneer et al. 2022; Raffetto et al. 2020; VascularSociety 2021). In addition, leg ulcers can also originate from conditions such as oedema (lymph/lipid), vascular disease and obesity (De Maeseneer et al. 2022; Gordon et al. 2015; Nyamekye 2022). It is estimated that 1 in every 170 adults experience a leg ulcer at any one given time, however, this is a conservative estimate with the total number of VLU's likely to be much higher (Julian et al. 2015). The estimated economic burden of VLU's has increased by 101% over a five year period, with substantial increases in the use of resources and cost to services (Guest et al. 2020). The mean cost associated with managing leg ulcers is estimated to be £7600 per patient (NHS, over 12 months), however the cost of managing an unhealed ulcer is 4.5 times higher; highlighting the importance of effective management to improve patient outcomes (Guest et al. 2018). There are several treatment options including dressings, topical agents, therapeutic ultrasound, electromagnetic therapy, negative pressure wound therapy and therapeutic compression (De Maeseneer et al. 2022). However, most treatments (i.e., therapeutic ultrasound, electromagnetic therapy, negative pressure wound therapy) have little to no evidence of effectiveness for improving wound healing (Aziz and Cullum 2015; Cullum and Liu 2017; De Maeseneer et al. 2022).

The main effective treatment for venous leg ulcers is therapeutic compression which delivers at least 40mmHg at the ankle (Lim et al. 2018; Nair 2014; WoundsUK 2022). This should be supported by effective management of the skin (Guest et al. 2018), involving a good skin care regime of washing of the lower limb, removal of hyperkeratosis, and promoting skin hydration with emollients (WoundsUK 2022). That said, some evidence suggests that routine washing of legs does not frequently or consistently happen, leading to inequalities in patient care (Franks et al. 2016). This is a particular concern in community settings whereby variances in practices occur with patients not receiving the

best possible care (Franks et al. 2016). There is a range of practises that occur in these settings including, legs being washed in a bucket using warm water and emollients, leg ulcers being cleansed with normal saline, legs being washed with an octenidine wash mitts, patient being asked to remove bandages and shower prior to nurse visits, no leg washing, and a wide variety of emollients being applied to hydrate skin (Grace 2002). The reasons for the variance in practice is likely due to availability of equipment (buckets, bowls etc), but could also be a consequence of a lack of clear national policy guidelines relating to cleansing and care (of leg ulcers) (Franks et al. 2016; Grace 2002). With clear guidance through an evidence-based strategy, leg ulcer care could be improved to support practitioners deliver the most effective care (Phillips et al. 2018). This commentary article aims to review and expand upon the existing evidence from a recent Cochrane systematic review, to determine the most effective method of cleansing for the management of leg ulcers to support healthcare professionals within clinical practice.

METHODS OF MCLAIN et al, 2021

A comprehensive search strategy was conducted, including five electronic databases and two clinical trials registries (i.e., Cochrane Wounds Specialised Register, the Cochrane Central Register of Controlled Trials, Ovid MEDLINE, Ovid Embase, EBSCO CINAHL Plus, ClinicalTrials.gov and the World Health Organization International Clinical Trials Registry Platform). Searches were conducted from conception to September 2019 with no publication or language restrictions. RCT's with adults diagnosed venous leg ulcer comparing wound cleansing with no wound cleansing, comparing different wound cleansing solutions, and comparing different wound cleansing techniques were considered for inclusion. The review excluded studies whereby they included mixed wound populations and did not provide separate outcome data for participants with venous leg ulcer(s).

Two reviewers independently screened titles, abstracts, and full texts to determine eligible studies. Data extraction was conducted independently by one reviewer and checked by a second reviewer. Two reviewers independently assessed the risk of bias of included studies using the Cochrane tool for

assessing Risk of Bias (RoB). Any disagreements during study selection, data extraction or risk of bias assessment were resolved through discussion with a third reviewer. The primary outcomes of interest included complete wound healing and time to wound healing (specific time period). Secondary outcomes included patient preference, procedural pain, ease of use of the method of cleansing, cost, health-related quality of life, and adverse events. A narrative synthesis was undertaken to summarise the findings of the included studies.

RESULTS OF MCLAIN et al, 2021

Effectiveness of interventions in adults diagnosed with venous ulcers

Following the study selection process, a total of 4 studies were eligible for inclusion. All 4 included studies were deemed to be high risk of bias due to selective reporting or incomplete outcome data.

Aqueous oxygen peroxide treatment versus sterile water

Very low certainty evidence indicated that adults who received aqueous oxygen peroxide had significantly increased number of wounds completely healed compared to those who received sterile water at 12 months follow-up (RR 1.88, 95% CI, 1.10 to 3.20: 1 study, 34 participants, GRADE: Very low) (see table 1).

There was no evidence of difference in change of ulcer size (at eight weeks follow-up) in adults who received aqueous oxygen peroxide compared with those receiving sterile water (GRADE: Very low). Similarly, there was also no evidence of difference in pain reduction (at eight weeks follow-up) in adults who received aqueous oxygen peroxide compared to sterile water (GRADE: Very low).

Table 1. Aqueous oxygen peroxide treatment versus sterile water

Outcome	Relative effect / mean difference (95% CI)	No. of studies (no. of participants)	Grade (certainty of evidence)
Number of wounds completely healed	RR of 1.88, 95% CI 1.10 to 3.20	1 study (n= 34)	Very low
Change in ulcer size	Mean wound size reduction in the intervention group was 1.38 cm^2 Lower (-4.35 lower to 1.59 higher)	1 study (n= 61)	Very low
Pain reduction	Mean pain reduction in the intervention group was 3.80 higher (-10.83 lower to 18.43 higher)	1 study (n= 61)	Very low

Octenidine dihydrochloride/phenoxyethanol (OHP) versus Ringer's solution

Very low certainty evidence showed that there was a greater decrease in mean wound surface area between baseline and the end of the observation period in adults who received octenidine dihydrochloride/phenoxyethanol (decreased 37 to 90%: −2·53 cm^2) compared to those receiving Ringer's solution (decreased 30 to 40%: −2·81cm^2) (1 study, 99 participants, GRADE: Very low). However, there was a lack of data to determine if the difference was significant between these comparators at 12 weeks follow up (see table 2).

There was no evidence of difference in the number of wounds healed at 12 weeks of follow up in adults who received octenidine dihydrochloride phenoxyethanol compared to those who received Ringer's solution (GRADE: Very low). Similarly, there was no evidence of difference in adverse events (12 weeks follow up) in adults who received octenidine dihydrochloride phenoxyethanol compared to those who received Ringer's solution (GRADE: Very low).

Table 2. Octenidine dihydrochloride/phenoxyethanol (OHP) versus Ringer's solution

Outcome	Relative effect / mean difference (95% CI)	No. of studies (no. of participants)	Grade (certainty of evidence)
Mean wound surface	Ringer - 37·90% (−2·53 cm2) reduction OHP - 40·30% (−2·81 cm^2)	1 study (n= 99)	Very low

Wounds healed at 12 weeks	RR of 0.96, 95% CI 0.53 to 1.72	1 study (n= 99)	Very low
Adverse events	RR of 0.58, 95% CI 0.29 to 1.14	1 study (n= 126)	Very low

Propyl betaine and polihexanide versus saline solution

Although one study (n= 40 participants, RoB: high risk of bias) did compare propyl betaine and polihexanide versus saline solution, there was insufficient data to determine differences in pain, change in ulcer size over time or adverse events. Furthermore, the study did not report on time to complete wound healing or number of wounds completely healed. The evidence was judged to be of very low certainty according to the GRADE criteria.

Polyhexamethylene biguanide (PHMB) versus 0.9% saline solution

One study (n= 27 participants, RoB: high risk of bias) compared polyhexamethylene biguanide (PHMB) to 0.9% saline solution in adults diagnosed with venous ulcers but did not report any primary or secondary outcomes of interest.

Different cleansing techniques and cleansing compared with no cleansing

The review did not identify any studies that compared different cleansing techniques or cleansing with no cleansing.

COMMENTARY

Using the AMSTAR-2 critical appraisal tool for systematic reviews, 14 criteria were judged to be satisfactory (seen in Table 3) and the remaining two criteria were deemed to be not applicable (Shea

et al. 2017). Based on this appraisal, it could be judged that the systematic review provides a comprehensive synthesis of relevant studies associated with the research question of interest.

Table 3. Critical appraisal of the review by McLain et al, 2021.

AMSTAR-2 items	Responses
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes – The study stated the PICO's within the methods section.
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? Yes	Yes – The protocol was registered on the Cochrane Database of Systematic Reviews.
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes – The authors provided a detailed rationale on the criteria for considering studies.
4. Did the review authors use a comprehensive literature search strategy?	Yes - Electronic searches of five databases, the Cochrane Wounds Specialised Register, Cochrane Central Register of Controlled Trials, MEDLINE, Embase and CINAHL.
5. Did the review authors perform the study selection in duplicate?	Yes – Studies selection was conducted independently by two reviewers.
6. Did the review authors perform data extraction in duplicate?	Yes - Data extraction was conducted independently by one reviewer and checked by two other review authors.
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Yes - The author provided a list of reasons for excluding studies.
8. Did the review authors describe the included studies in adequate details?	Yes – A characteristics of included studies table was presented in the appendix.
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 - two reviewers independently assessed the risk of bias using the Cochrane RoB tool.
10. Did the review authors report on the sources of funding for the studies included in the review?	Yes – The authors reported funding sources for studies in the in the characteristics in included studies table.
11. If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	Yes – Authors used mean difference (MD) and risk ratios (RR) where appropriate. Meta-analysis was not conducted.
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?	Yes - A sensitivity analysis was not conducted as a meta-analyses were not conducted. However, GRADE assessments were conducted.
13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes – the authors outlined the risk of bias when discussing the results in the discussion section of the review.

14. Did the review authors provide a satisfactory explanation for and discussion of, any heterogeneity observed in the results of the review?	N/A – The authors did not provide explanation for heterogeneity because it was not computed.
15. If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	N/A – Publication bias was not investigated because there was not enough evidence to assess it.
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes - The authors declared a conflict of interest in that one author received an honorarium for speaking at professional meetings for Smith & Nephew and Molnlycke.

*RoB = Risk of Bias, GRADE = Grading of Recommendations, Assessment, Development, and Evaluations.

The findings of the review suggest that adults who received aqueous oxygen peroxide had significantly higher number of completely healed wounds compared to those who received sterile water (very-low certainty evidence) (McLain et al. 2021). However, there was no evidence of a difference in ulcer size change or pain reduction between the two groups (McLain et al. 2021). The review also indicates that adults who received octenidine dihydrochloride/phenoxyethanol experienced a greater decrease in mean wound surface area compared to those receiving Ringer's solution (very-low certainty evidence). However, there was no evidence of a difference in the number of healed wounds or adverse events between the two groups (McLain et al. 2021).

Although some of these findings appear to favour some wound cleansing approaches, the certainty of evidence relating to these estimates is very low due to the limited and low-quality of existing evidence (McLain et al. 2021). This suggests that the estimates presented in this review may be markedly different from the true effect (Guyatt et al. 2011). As a consequence, it is not yet possible to make recommendations for the adoption of any of these approaches into clinical practice. These findings are consistent with current policy, national guidance and best practice statements which provide generic advice on ways of VLU cleansing, but do not provide a specific method of cleansing (RCN 2006; Todd 2022). The findings which highlight a dearth of evidence, may explain why there are so many variances in clinical practice regarding cleansing and care of leg ulcers (McLain et al. 2021).

Implications for practice

There are several implications for practice that could be considered by healthcare professionals. With very low certainty of evidence, it is unclear which approach to cleansing leg ulcers is the most effective strategy (McLain et al. 2021). In the absence of an evidence-based cleansing and care approach, clinicians may need to rely on expert consensus, traditional approaches, and clinical experience when making treatment decisions for patients with leg ulcers (Kahle et al. 2011). Clinicians should also be guided by up-to-date national guidelines and clinical guidance documents from key organisations that report on the treatment and management of VLU's (VascularSociety 2021). Given the lack of high-quality evidence, it is likely that the best approach would be one that considers all patient factors, wound characteristics, and treatment preferences (Kahle et al. 2011). To strengthen this approach, regular evaluations should be conducted to establish the effectiveness, acceptability and tolerability of the treatment based on patient response (Saunders et al. 2019). To ensure and monitor the safety of this approach, healthcare professionals should be aware of potential adverse events associated with the different wound cleansing and care interventions (Samra et al. 2016). Furthermore, practitioners should closely monitor the leg ulcer wound site and evaluate the treatment response to ensure adverse events are identified and managed promptly (Charles 1998).

Although a dearth of research exists to support an evidence-based approach, existing literature suggests several components of wound cleansing that may be beneficial to leg ulcer management (NHS 2022; RCN 2006; Todd 2022). Several articles provide best practice guidelines that outline the key steps for healthcare professionals when cleansing leg ulcers (Grace 2002; NHS 2022; NICE. 2021; Todd 2022). Initially, the whole of the affected leg should be prepared for washing (irrigating or swabbing) with a particular focus on the area around the wound (leg ulcer) (NICE 2023). The leg should be immersed in warm water using a bucket lined with plastic and washed by irrigating or swabbing the area (Todd 2022). This step allows for a more thorough observation of the limb, removes bacteria, soften dry skin, and separates any hyperkeratosis, while also minimizing damage to healthy granulated tissue (Murphy et al. 2020; Todd 2022). Following immersion, emollients and topical treatments may be applied to help restore the barrier function of the skin, reduce irritation, and

increase hydration (NHS 2022; Rajhathy et al. 2023; Woo et al. 2021). Finally, the limb should be dried with special care placed on drying of the joints (e.g., toes and ankles) to minimise the risk of any infection (mitigating the risk of cellulitis) (PHE 2020). These steps may be useful for healthcare professionals as a guide to best practise in the absence of an evidence-based standardisation of care for wound cleansing in the treatment of leg ulcers.

Implications for further research

Further high-quality research is needed to establish the effectiveness of different wound cleansing and care approaches for patients with leg ulcers. Given current practice traditions of cleansing venous leg ulcers with potable water, further research is needed to establish the effectiveness of cleansing with water compared with no cleansing. Further research should also focus on comparisons between different types of cleansing solutions (e.g., saline, antiseptics, potable water etc), and comparisons between different cleansing techniques (i.e., irrigation, swabbing, soaking, immersion etc).

Further to establishing effective solutions and techniques, future research should explore the cost effectiveness of different solutions to determine if clinical effectiveness is at an acceptable level of increased cost for healthcare services.

CPD reflective questions

- What other factors should you take in consideration when washing a patient wound?
- How do the findings contribute to our understanding of wound cleansing for treating venous leg ulcers?
- What evidence do you used to inform your leg washing technique?

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