The effectiveness of cleansing solutions for wound treatment: a systematic review protocol

Paulo Queirós RN, PhD¹
Eduardo Santos RN¹
João Apóstolo RN, PhD¹
Daniela Cardoso RN¹
Madalena Cunha RN, PhD²
Manuel Rodrigues RN, PhD, Agregation¹

1. The Portugal Centre for Evidence-Based Practice: an Affiliate Centre of the Joanna Briggs Institute
2. Center of Studies in Education, Health and Technology – Research and Development Unit

Corresponding Author
Paulo Queirós
Email pauloq@esenfc.pt

Review question/objective

The objective of this review is to identify and synthesize the best available evidence on the effectiveness of cleansing solutions for wound treatment in clinical practice and compare the effectiveness of different cleansing solutions in infection and wound healing rates.

More specifically, the review will focus on the following questions:

- Does the effectiveness of different cleansing solutions influence the infection and wound healing rates?
- Which cleansing solution is more effective for reducing wounds infection rates?
- Which cleansing solution is more effective for increasing wounds healing rates?
- What if the effectiveness of cleansing solutions is affected by the wound etiology?

Background

The management of chronic and acute wounds has changed significantly in the last decade. The practice of wound cleansing or antiseptic management has a dichotomous history anchored in tradition and science.¹ It is an integral part of the management of acute wounds as well as chronic wounds.²,³
Although there is a consensus that wound cleansing reduces infection rates\textsuperscript{2} there is, however, a debate in clinical circles about the potential advantages and disadvantages of cleansing wounds because the exudate itself may contain growth elements and chemokines which contribute to wound healing and for that reason it is not always necessary.\textsuperscript{3,4} Until further research has established its demerits, cleansing will continue to remain an integral part of the wound management process although there is an absence of strong evidence to indicate that cleansing wounds per se increases healing or reduces infection.\textsuperscript{5,6}

This reality is also intensified by the lack of a diagnostic test that would allow healthcare professionals to identify the bacterial load in the wound that is capable of causing wound infections. In addition, the situation is further complicated by studies showing that bacterial colonization of the wound does not necessarily indicate infection and that there is no need to remove the bacteria in the absence of clinical signs of infection.\textsuperscript{2}

Yet amongst scientific literature, several studies have recommended various cleansing agents for their supposed therapeutic value. It has also been suggested that wound cleansing helps to optimize the healing environment and decrease the potential for infection.\textsuperscript{7,8} It loosens and washes away cellular debris such as bacteria, exudate, purulent material and residual topical agents from previous dressings.\textsuperscript{9,10} However, in practice, the decisions on which cleansing solutions to use have been based on experience, service policy and personal preference.

In general, the characteristics of an ideal wound cleansing solution are: non-toxic to human tissues; remains effective in the presence of organic material; reduces the number of micro-organisms; does not cause sensitivity reactions; is widely available; is cost-effective; and is stable with a long shelf life.\textsuperscript{11}

Normal saline fulfills all the criteria given above. Normal saline (0.9\%) is the favored wound cleansing solution because it is an isotonic solution and does not interfere with the normal healing process, damage tissue, cause sensitization or allergies or alter the normal bacterial flora of the skin (which would possibly allow the growth of more virulent organisms).\textsuperscript{5,10,12,13,14,15}

Tap water is also recommended and has the advantages of being efficient, cost effective and accessible.\textsuperscript{5,16} There is now increasing recognition of the safe use of tap water for wound irrigation, especially in chronic wounds\textsuperscript{15} and it is worth considering as an acceptable alternative to other products. Indeed, Flanagan\textsuperscript{11} argues that water has been used for centuries to treat wounds without any reported detrimental effects. Although the two most commonly cited concerns regarding tap water are possible infection risk and the fact that it is not an isotonic solution.

In this matter, several studies have found that there was no significant difference between the infection and healing rates in wounds irrigated with normal saline or tap water.\textsuperscript{8,16,17} Indeed, Angeras et al.\textsuperscript{16} found a higher rate of infection in those wounds irrigated with saline. However, clinicians have been cautioned against using tap water to cleanse wounds that have exposed bone or tendon, in which case normal saline is recommended.\textsuperscript{5,18}

On the other hand, there is no agreement amongst wound care authorities on the advantages of using sterile solutions over non-sterile solutions.

Research has also established that the use of antiseptic solutions may compromise the healing process\textsuperscript{19} and, as a result, the use of normal saline as a cleansing solution is widely recommended.\textsuperscript{15}
In fact and since the earliest times, preparations with antiseptic properties have also been traditionally used; however published research has suggested that antiseptic solutions may hinder the healing process. For this reason several guidelines and various studies discourage the use of antiseptic solutions such as povidone iodine, hydrogen peroxide, or sodium hypochlorite because in most instances, they do not effectively promote good wound healing; in contrast, most studies showed either impaired wound healing, reduced wound strength, or infection.\textsuperscript{14,20}

The controversy surrounding the use of antiseptics prompted the development of guidelines for the use of antiseptics by wound care experts. These guidelines have also resulted in changes in hospital practice.\textsuperscript{5} Concerns are also mounting relating to the use of these products, and the development of bacterial resistance and the possible systemic absorption of antiseptics. In most cases, the selection of these products does not have a solid scientific basis.

Still, new cleansing solutions are appearing. Most recently, the new cleansing solution based on polyhexanide and betaine has recently emerged as a credible alternative to currently available products.\textsuperscript{21,22,23} This particular solution is effective for treating colonized/infected wounds, providing optimal conditions for wound healing, reducing healing time, signs of inflammation and/or infection/colonization, provides greater odor control, has a painless application and is especially indicated for the treatment of chronic wounds and those which are difficult to heal.\textsuperscript{21,23,24,25}

An extensive review of literature identified several systematic reviews and best practice guidelines. However despite the presence of these publications, rigorous research is still needed to support the identified recommendations.\textsuperscript{5,14,23}

Remarkable advances have been made in the science of wound care and treatment. Despite this, numerous factors impact on this science, and managing wounds will continue to be a healthcare concern. Increasing life expectancy, frequency of wound development in the aged care community, increased prevalence of diabetes, and considerable monetary and lifestyle costs make the appropriate cost-effective management of wounds an international healthcare imperative. Nurses, both acute care and community-based, are in a unique position to provide evidence based education and interventions to their colleagues and consumers. Thus, the purpose of this systematic review is to investigate the effectiveness of cleansing solutions for wound treatment in clinical practice.

**Keywords**

Water; sodium chloride; polihexanide; clean*; wound*; heal*; infect*; detergents; povidone-iodine; chlorhexidine; hydrotherapy; shower; bath; irrigate

**Inclusion criteria**

**Types of participants**

This review will consider studies that include patients with chronic and acute wounds (of any etiology) with the exception of obstetric wounds. It will be include patients of 18 or more years, in any setting (hospital, community and general practice) with the exception of patients with very poor nutrition.
**Types of intervention(s)/phenomena of interest**

This review will consider studies that use any cleansing solution or chemicals as cleansing solutions other than antiseptic solutions in wound treatment.

For this purpose we will compare the effects on rates of healing and infection in acute and chronic wounds with the following cleansing solutions (may include, but not be limited to):

- Tap water compared with normal saline;
- Water (distilled and/or cooled boiled water) compared with sterile normal saline;
- Tap water compared with cooled boiled tap water;
- Tap water compared with polyhexanide/betaine solution;
- Tap water compared with any other solution;
- Sterile normal saline compared with polyhexanide/betaine solution;
- 0.5% or 2% Chlorhexidine Gluconate (CG);
- 70% Alcohol;
- Povidone-iodine; and
- Any other comparable solution that appears in scientific papers.

**Types of outcomes**

This review will consider studies that include the outcome “infection rate” and “healing rate”.

In this regard, this review will focus in two types of outcomes:

1) Primary outcome (infection rate);
2) Secondary outcome (healing rate).

Both analyses will be divided in three groups:

1) Acute wounds;
2) Chronic wounds; and
3) Wounds with specific aetiology.

**Types of study**

This review will only consider experimental study designs including randomised controlled trials, non-randomised controlled trials, or other quasi-experimental studies, including before and after studies for inclusion.

**Search strategy**

The search strategy incorporates published and unpublished studies. A three-step search strategy will be used in this review. An initial limited search of MEDLINE and CINAHL will be undertaken, followed by an analysis of text words in the titles and abstracts, and of the index terms used to describe the article. A second search using all identified keywords and index terms will then be undertaken across all databases included. Thirdly, the reference list of all identified reports and articles will be searched for additional studies. Studies published in English, Spanish and Portuguese will be considered for
inclusion in this review. In this regard, all studies in other languages will be excluded. The search strategy per database will encompass the period January 2000 to January 2013.

The databases to be searched will include:

CiNAHL Plus with Full Text, MedicLatina, Academic Search Complete, MEDLINE with Full Text, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Nursing & Allied Health Collection: Comprehensive (via EBSCO);

LILACS;

Elsevier - Science Direct (via b-on – Online Knowledge Library);

Embase;

Scopus;

JBI Library;

ACP online;

BioMed Central;

Health Technology Assessment database;

Scielo - Scientific Electronic Library Online.

The search for unpublished studies will include:

Agency for Healthcare Research and Quality (AHRQ);

‘Grey Literature Report’ from New York Academy of Medicine;

Mednar;

Scirus.com website;

National Library of Australia’s Trove service;

ProQuest – Nursing and Allied Health Source Dissertations;

Banco de teses da CAPES (www.capes.gov.br);

RCAAP – Repositório Científico de Acesso Aberto de Portugal.

Initial English language keywords to be used will be:

Water, sodium chloride, polihexanide, clean*, wound*, heal*, infect*, detergents, povidone-iodine, chlorhexidine, hydrotherapy, shower, bath, irrigate

Assessment of methodological quality

Papers selected for retrieval will be assessed by two independent reviewers for methodological validity prior to inclusion in the review using standardized critical appraisal instruments from the Joanna Briggs Institute System for the Unified Management, Assessment and Review of Information package (SUMARI). Any disagreements that arise between the reviewers will be resolved through discussion
with a third reviewer (Appendix I). Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

**Data collection**

Data will be extracted from papers included in the review independently by two reviewers, using standardized data extraction tools from the Joanna Briggs Institute Meta Analysis of Statistics Assessment and Review Instrument JBI-MAStARI (Appendix II). The data extracted will include specific details about the interventions, populations, study methods and outcomes of significance to the review question and specific objectives. For missing information or data that needs clarification, the authors of primary studies will be contacted. Any disagreements that arise between the reviewers will be resolved through discussion, or with a third reviewer.

**Data synthesis**

Quantitative data will, where possible, be pooled in statistical meta-analysis using JBI-MAStARI. All results will be subject to double data entry. Effect sizes expressed as odds ratio (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated. Heterogeneity will be assessed statistically using the standard Chi-square. Plausible explanations for variations in treatment effects will be explored using subgroup analyses, where possible, to specify population and intervention differences and quality of studies. Where statistical pooling is not possible, the findings will be presented in narrative form including tables and figures to aid in data presentation where appropriate.

*Conflicts of interest*

There are no conflicts of interest.

**Acknowledgements**

The authors thank the support provided by Health Sciences Research Unit – Nursing (UICISA-E), hosted by the Nursing School of Coimbra (ESEnFC).
References


Appendix I: Appraisal instruments

SUMARI Appraisal instrument

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer ___________________________ Date ___________________________

Author ___________________________ Year _______ Record Number _______

1. Was the assignment to treatment groups truly random?
   Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

2. Were participants blinded to treatment allocation?
   Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

3. Was allocation to treatment groups concealed from the allocator?
   Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

4. Were the outcomes of people who withdrew described and included in the analysis?
   Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

5. Were those assessing outcomes blind to the treatment allocation?
   Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

6. Were the control and treatment groups comparable at entry?
   Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

7. Were groups treated identically other than for the named interventions?
   Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

8. Were outcomes measured in the same way for all groups?
   Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

9. Were outcomes measured in a reliable way?
   Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

10. Was appropriate statistical analysis used?
    Yes ☐ No ☐ Unclear ☐ Not Applicable ☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)
____________________________________________________________________
____________________________________________________________________

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JBI Critical Appraisal Checklist for Descriptive / Case Series

Reviewer __________________________ Date __________________________
Author __________________________ Year __________ Record Number __________

1. Was study based on a random or pseudo-random sample?  
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<th>Yes</th>
<th>No</th>
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<th>Not Applicable</th>
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2. Were the criteria for inclusion in the sample clearly defined?  
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3. Were confounding factors identified and strategies to deal with them stated?  
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<th>Yes</th>
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4. Were outcomes assessed using objective criteria?  
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5. If comparisons are being made, was there sufficient descriptions of the groups?  
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6. Was follow up carried out over a sufficient time period?  
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7. Were the outcomes of people who withdrew described and included in the analysis?  
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8. Were outcomes measured in a reliable way?  
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9. Was appropriate statistical analysis used?  
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Overall appraisal:  Include ☐ Exclude ☐ Seek further info ☐

Comments (Including reason for exclusion)
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# JBI Critical Appraisal Checklist for Comparable Cohort/ Case Control

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**Overall appraisal:**  Include □  Exclude □  Seek further info. □

**Comments (Including reason for exclusion)**

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Appendix II: Data extraction instruments

MAStARI data extraction instrument

**JBI Data Extraction Form for Experimental / Observational Studies**

Reviewer: ___________________________ Date: ___________________________

Author: ___________________________ Year: ___________________________

Journal: ___________________________ Record Number: ___________________________

**Study Method**

RCT ☐ Quasi-RCT ☐ Longitudinal ☐

Retrospective ☐ Observational ☐ Other ☐

**Participants**

Setting

Population

**Sample size**

Group A: __________ Group B: __________

**Interventions**

Intervention A

Intervention B

Authors Conclusions:

Reviewers Conclusions:
### Study results

#### Dichotomous data

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#### Continuous data

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