


Effect of intraoperative pressure ulcer preventive nursing on inflammatory markers in patients with high-risk pressure ulcers

A protocol of systematic review and meta-analysis

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Abstract

Background: This study will be designed to appraise the effects of intraoperative pressure ulcer preventive nursing (IPUPN) on inflammatory markers (IMs) in patients with high-risk pressure ulcers (HRPU) based on high quality randomized controlled trials (RCTs).

Methods: In this study, we will perform a rigorous literature search from the following electronic databases: Cochrane Library, MEDLINE, Embase, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, and Chinese Biomedical Literature Database. All electronic databases will be retrieved from their initial time to March 1, 2020 without limitations of language and publication status. We will only consider high quality RCTs that explored the effects of IPUPN on IMs in patients with HRPU. Two investigators will identify relevant trials, extract data, and appraise risk of bias in each eligible trial. Data will be pooled by either a fixed-effects model or a random-effects model according to the results of heterogeneity identification. The primary outcomes include IMs, and incidence of new pressure ulcers. The secondary outcomes are time to ulcer development, quality of life, length of hospital stay, and adverse events. Statistical analysis will be undertaken using RevMan 5.3 software.

Results: This study will summarize high quality clinical evidence of RCTs to evaluate the effects of IPUPN on IMs in patients with HRPU.

Conclusion: The expected findings may provide helpful evidence to determine whether IPUPN is an effective intervention on IMs in patients with HRPU.

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Abbreviations: CIs = confidence intervals, HRPU = high-risk pressure ulcers, IMs = inflammatory markers, IPUPN = intraoperative pressure ulcer preventive nursing, RCTs = randomized controlled trials.

Keywords: effects, inflammatory markers, pressure ulcer, preventive nursing

1. Introduction

Pressure ulcers (PUs) are very common public health issue.^[1,2] They occur when the skin is exposed to pressure and shear,^[3–5] especially in patients under conditions of long-term mobility or immobility, poor nutrition status, compromised blood flow, and

neuropathy sensation.^[6–9] Published study has reported that the prevalence of PUs ranges from 0.3% to 46%, and its incidence varies between 0.8% and 34%.^[10] Thus, it is very important to prevent PUs in patients with high-risk PUs (HRPUs),^[6,11–13] which is associated with inflammatory markers (IMs).^[14–17]

F J and Y-J F contributed equally to the study.

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The authors have no conflicts of interest to disclose.

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

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Table 1
Search strategy utilized in Cochrane library.

Number	Search terms
1	Mesh descriptor: (pressure ulcer) explode all trees
2	(inflammatory markers) explode all trees
3	((pressure*) or (ulcer*) or (sore*) or (bedsore*) or (decubitus*) or (high risk*) or (inflammation*) or (maker*) or (factor*)):ti, ab, kw
4	Or 1-3
5	MeSH descriptor: (nursing) explode all trees
6	((intraoperative*) or (preventive*) or (nursing*) or (care*)):ti, ab, kw
7	Or 5-6
8	MeSH descriptor: (randomized controlled trial) explode all trees
9	((controlled trial*) or (clinical trial*) or (randomly*) or (randomized*) or (control*) or (placebo*) or (sham*) or (study*) or (trial*)):ti, ab, kw
10	Or 8-9
11	4 and 7 and 10

Fortunately, intraoperative PU preventive nursing (IPUPN) has found to be effectively preventing PUs and impacting IMs in patients with HRPU.^[18–26] However, no study has investigated the effects of IPUPN on IMs in patients with HRPU. Therefore, this study will systematically and comprehensively explore the effects of IPUPN on IMs in patients with HRPU.

2. Methods

2.1. PROSPERO registration

This protocol has been reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocol (PRISMA-P) statement guidelines,^[27] and it has been registered in the INPLASY202040029.

2.2. Ethics and dissemination

No ethical approval is required in this study, because it will only analyze published data. It is supposed to be published on a peer-reviewed journal or presented in a conference meeting.

2.3. Inclusion criteria for study selection

2.3.1. Type of studies. This study will only include high quality randomized controlled trials (RCTs) that assessed the effects of IPUPN on IMs in patients with HRPU. We will exclude other types of studies, such as non-RCTs, quasi-RCTs, case studies, reviews, and animal studies.

2.3.2. Type of participants. Any participants (18 years old or over) who have been diagnosed as HRPU and received IPUPN will be included in spite of race, nationality, and sex.

2.3.3. Type of interventions. All patients in the experimental group were treated with any types of IPUPN.

Comparison interventions could be placebo, sham intervention, conventional pharmacological treatments, and any other management. In addition, patients who also received IPUPN in the control group will be excluded.

2.3.4. Type of outcomes. The primary outcomes include IMs (such as C-reactive protein, white blood cell count, and body temperature), and incidence of new PUs (the proportion of participants developing any new PUs of any grade).

The secondary outcomes consist of time to ulcer development, quality of life as assessed by a validated tool, patient length of hospital stay (days or weeks), and adverse events.

2.4. Search strategy

We will carry out a rigorous literature search from Cochrane Library, MEDLINE, Embase, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, and Chinese Biomedical Literature Database. We will search all those electronic databases from inception to the March 1, 2020 with no restrictions of language and publication status. The search strategy sample for Cochrane library is created in Table 1. We will also build similar search strategies for other electronic databases.

In addition to the electronic databases, we will also examine clinical trial registries, dissertations, informal publication, and reference lists of all relevant reviews.

2.5. Data collection and management

2.5.1. Study selection. All titles/abstracts of potential studies will be scanned by 2 independent investigators. After removing irrelevant studies, such as duplicates and nonclinical trials, full papers of the remaining trials will be read carefully against all inclusion criteria. Once any divergences occur between 2 investigators, a decision will be made through discussion or will be judged with the help of a 3rd investigator. Details of entire study selection will be summarized in a flowchart.

2.5.2. Data collection. After study selection, data will be extracted based on the predefined standard data extraction form. Two investigators will independently extract the data from all included trials. Any disagreements between 2 investigators will be solved through discussion or consultation by a 3rd investigator. The extracted information includes study demographic information (such as 1st author, publication time, and country), patient characteristics (such as gender, age, and number of patients), study methods (such as study setting, randomization, and blind), interventions and comparators (such as types of therapies, dosage, and duration), outcomes (such as primary, secondary, and harm measurements), and other information (such as funding information).

2.5.3. Missing data dealing with. If missing or insufficient information occurs, we will contact primary authors to obtain it by email or fax. We will analyze obtainable data if we cannot receive that information.

2.5.4. Risk of bias assessment. Two investigators will appraise the risk of bias for each included trial using Cochrane risk of bias tool, which consists of 7 different items. Each one is judged as low

risk of bias, unclear risk of bias, and high risk of bias. Any opposition between 2 investigators will be settled down by a 3rd investigator through discussion.

2.6. Data synthesis and analysis

We will use RevMan 5.3 Software to perform statistical analysis in this study.

2.6.1. Measurement of treatment effect. For continuous data, it will be calculated using mean difference or standardized mean difference and 95% confidence intervals. For dichotomous data, it will be presented using risk ratio and 95% confidence intervals.

2.6.2. Assessment of heterogeneity. Statistical heterogeneity among trial results will be identified using I^2 index. $I^2 \leq 50\%$ will be regarded as not having statistical heterogeneity and a fixed-effects model will be exerted. On the contrary, $I^2 > 50\%$ will be considered as having statistical heterogeneity, and a random-effects model will be employed.

2.6.3. Data synthesis. If $I^2 \leq 50\%$ and sufficient data are collected on the same outcome measurement, we will carry out a meta-analysis if necessary. Otherwise, if $I^2 > 50\%$, subgroup analysis will be conducted, and data will be synthesized more cautiously. If there is still substantial heterogeneity after subgroup analysis, the outcome data will not be suitable for pooling quantitative synthesis. Under such situation, we will report a narrative description with the information in the text to summarize and elaborate the characteristics and finding of individual trials.

2.6.4. Subgroup analysis. Subgroup analysis will be carried out to explore the causes of significant heterogeneity based on the different study or patient characteristics, treatment and control types, and outcome measurements.

2.6.5. Sensitivity analysis. When there are adequate trials, we will conduct sensitivity analysis to check the robustness and stability of conclusions by excluding low quality studies.

2.6.6. Reporting bias. If adequate number of qualified trials is included, a funnel plot and Egger regression test will be performed to detect if there are any reporting biases.

2.7. Grading the quality of evidence

The quality of evidence and confidence for each outcome will be rated by 2 independent investigators according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines.^[28] Any differences between 2 investigators will be solved by a 3rd investigator through discussion.

3. Discussion

The PUs often occurs in patients with HRP, especially when they are under long-term mobility or immobility, poor nutrition status, compromised blood flow, and neuropathy sensation. A variety of studies have reported that IPUPN can help to prevent HRP and significantly affect IMs. However, no systematic review has conducted to explore the effects of IPUPN on IMs in patients with HRP. Thus, it is very necessary to carry out this systematic review to examine the effects of IPUPN on IMs in patients with HRP. The results of this study may provide

informative evidence for both patients with HRP and clinical practice.

Author contributions

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