

INPLASY PROTOCOL

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submission:** Preliminary
searches.

Conflicts of interest:
None declared.

INTRODUCTION

Review question / Objective: The subjects were patients who met the diagnostic criteria for stage II - IV pressure ulcers. Interventional factors include various acupuncture treatments, including ordinary acupuncture, peripheral acupuncture, electroacupuncture or fire

The Meta-analysis of efficacy and safety of acupuncture in the treatment of stage II-IV pressure ulcers

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Review question / Objective: The subjects were patients who met the diagnostic criteria for stage II - IV pressure ulcers. Interventional factors include various acupuncture treatments, including ordinary acupuncture, peripheral acupuncture, electroacupuncture or fire acupuncture. The course of treatment is more than 10 days. The control group was treated with conventional western medicine for more than 1 days. The main results included the time of complete healing, the time of granulation growth, and percentage of ulcer healed (PUHTP) in the trial period. The main results included the complete healing time, granulation growth time and percentage of ulcer healing (PUHTP), and the total effective rate and average healing time were calculated. The type of study was a randomized controlled trial.

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Condition being studied: Pressure ulcer refers to the skin and/or deep soft tissue damage caused by local strong and/or long-term pressure, or pressure combined with shear force, which is more common in the bone protuberance, and is more common in the caudal and sacral region in clinical practice. The treatment of clinical pressure ulcers has always been a key and difficult point in clinical practice. Paralytic patients are already faced with muscle atrophy and poor nutritional status. Pressure ulcers increase the risk of serious infection and affect the prognosis of the disease, undoubtedly making their health worse and increasing their economic burden. With the development of acupuncture and moxibustion, more and more clinical studies have shown that acupuncture can improve the local blood flow state and promote the healing of pressure ulcers, which has far-reaching application and promotion prospects. However, there is a lack of evidence based evidence. Therefore, this paper evaluates the clinical efficacy and safety of acupuncture in the treatment of pressure ulcers through meta-analysis, with a view to providing more evidence based basis for clinical treatment of pressure ulcers in the future.

METHODS

Participant or population: The subjects were patients who met the diagnostic criteria for stage II - IV pressure ulcers. There were no restrictions on disease stage, age, sex, race, education or economic status.

Intervention: Intervention factors were various acupuncture treatments, including general acupuncture, peripheral acupuncture, electroacupuncture, or fire acupuncture.

Comparator: The control group was treated with conventional western medicine for more than 10 days.

Study designs to be included: All randomized controlled trials (RCTs) do not restrict the language of publication and do not include cohort studies and case reports.

Eligibility criteria: Diagnostic criteria for stage II-IV pressure ulcers: Stage II local epidermal detachment or partial dermal defect, wound bed (pink) red, or complete or ruptured serous blisters, but no exposure of adipose layer and deep tissue, no granulation tissue, carrion, and eschar; Stage III full thickness skin damage, with subcutaneous adipose tissue, granulation tissue, carrion, eschar, or hidden cavities and sinuses on the ulcer surface, but no exposure of fascia, muscles, or bones; Stage IV full thickness skin damage, necrotic tissue and eschar visible on the ulcer surface, epithelial involution, common infiltrating cavities or sinuses, accompanied by exposure of fascia, muscles, and bones.

Information sources: The English databases includes PubMed, Embase, The Cochrane Library and Web of Science, the Chinese databases includes CNKI, Wanfang, VIP and CBM Database.

Main outcome(s): The main results included total effective rate, cure rate, time to complete healing, pressure ulcer area and PUSH score of pressure ulcer. The total effective rate, cure rate and average healing time were measured after treatment. The pressure ulcer area is measured before and after treatment, and the wound area is measured by "weighing method". Take the paper quality of a standard area as the standard, use transparent film to trace the size of the wound contour, draw the contour on the paper with the same material as the standard paper, compare the quality of the paper drawing the contour with the quality of the standard paper, and calculate the wound area according to the proportional relationship. PUSH score of pressure ulcer

was measured before and after treatment, which is between 0 and 17. The higher the score, the more serious the wound.

Quality assessment / Risk of bias analysis: The quality of the study will be assessed according to Cochrane's risk of bias.

Strategy of data synthesis: The risk of bias will be used to assess the quality of the methods included in the RCTs. The relative risk of 95% CI will use the collaboration software (Review Manager 5.4.1) to calculate the binary data in each measurement., For each trial, we will calculate the risk ratio (RR) of classification results, such as the total effective rate of pressure ulcer healing, PUSH score, etc., with a 95% confidence interval (95% CI). The results will be charted and individual study details will be displayed in the characteristics of the included studies. If multiple tests are compared with similar equipment, I^2 will be used to evaluate statistical heterogeneity, and χ^2 Test significance. I^2 values greater than 50% will indicate significant heterogeneity, which is considered significant when $P < 0.05$. In the absence of significant statistical heterogeneity, a similar comparison will be made using a random effects model. In the absence of significant statistical heterogeneity, fixed effect models will be used to aggregate trials with similar comparisons. If centralized testing is not appropriate, the results will be reported in a narrative manner. For the purpose of meta analysis, we will assume to analyze the total effective rate of pressure ulcer healing and summarize the studies. All statistical analysis will be conducted on RevMan 5.4.1.

Subgroup analysis: If the heterogeneity is caused by the above clinical trials, grouping analysis will be conducted and detailed grouping will be classified according to the results of data synthesis.

Sensitivity analysis: Sensitivity analysis was carried out through Review Manager 5.4.1.. After deleting one piece of paper, the change of effect size can reflect the sensitivity of it.

Language restriction: No language restrictions.

Country(ies) involved: China.

Keywords: Pressure ulcer; Acupuncture and Moxibustion; Meta analysis; Randomized Controlled Trial.

Contributions of each author:

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