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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 4 November 2024 and was last updated on 4 November 2024.

INTRODUCTION

Review question / Objective Study subjects (P) : Patients with Recurrent Aphthous Ulcer. Interventions (I): Diode Laser Therapy. Control (C): conventional treatment method or placebo. Outcome measures (O): pain relief, ulcer healing (ulcer size, healing time). Study design (S): After searching and screening the randomized controlled trial of Diode Laser Therapy for Recurrent Aphthous Ulcer, relevant data were extracted for meta-analysis.

Condition being studied Recurrent oral ulcer (RAU) is a common oral mucosal disease, also known as recurrent stomatitis, affecting at least 10% to 25% of the population, with a high prevalence (50%). In clinical practice, RAU can be divided into three subtypes: mild, severe and herpetic. Mild RAU is present in about 80% of RAU clinical cases, with a diameter of less than 5

mm. The primary RAU is a more severe form of RAU that affects about 10% of patients with RAU, usually exceeding 1 cm in diameter. Herpetic ulcers of 2 – 3mm in diameter are present in about 1-10% of patients with RAU.

RAU is known to be very painful and has terrible effects on the quality of life, including nutritional intake, communication, and other daily activities. Currently, the pathogenesis of RAU is uncertain. RAU is a multifactorial disease, including immune disorders, endocrine imbalance, vitamin deficiency, local trauma, as well as several systemic diseases, which is widely accepted. Based on the complex etiology of RAU, pain relief and promoting healing remain the main targets of RAU treatment.

The management of RAU mainly includes topical drugs (such as dexamethasone ointment, amicol, hyaluronic acid, etc.), systemic drugs (such as prednisone, levamisole, dapsone, etc.), traditional Chinese medicine (acupuncture and herbal therapy) and physical therapy. Although drug

treatment regimens are commonly used in clinical practice. There are some limitations in achieving the desired treatment effect, including uniform incidence frequency, saliva wash, and unclear side effects. Therefore, physical therapy RAU is becoming increasingly popular, one of which is laser therapy. Laser treatment equipment application most for Diode Laser(DL) , but the lack of DL treatment of RAU meta-analysis. What's more, Clinically, there are differences in the selection of DL parameters for RAU. Therefore, this study is proposed to conduct a meta-analysis of DL treatment for RAU, aiming to provide evidence-based reference for clinical DL treatment of RAU.

METHODS

Participant or population Patients with Recurrent Aphthous Ulcer.

Intervention Diode Laser Therapy.

Comparator Conventional treatment method or placebo.

Study designs to be included The randomized controlled trial of Diode Laser Therapy for Recurrent Aphthous Ulcer.

Eligibility criteria Inclusion Criteria: (1) They must focus on human subjects. (2) They must involve patients diagnosed with RAU. (3) The intervention must be DL. (4) They must be randomized controlled trials (RCTs) with random group allocation. (5) The sample size (n) must be greater than 10. (6) The data must be readily extractable from the articles.

Exclusion Criteria: (1) RAU is secondary to systemic diseases. (2) No a control group in the RCTs, such as a placebo or medicine (3) No specific laser parameters. (4) No available outcomes for this review.

Information sources Studies from PubMed, Embase, Web of Science, Cochrane, CNKI, VIP, and Wanfang Data.

Main outcome(s) Pain relief, ulcer healing (ulcer size, healing time).

Quality assessment / Risk of bias analysis The Review Manager 5.4 software (RevMan 5.4, provided by Cochrane Collaboration) was used to evaluate the Risk of Biases (RoBs). This evaluation encompassed various domains such as random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data,

selective reporting, and other bias. Distinct colors were employed to signify varying levels of risk. WANG & HE were tasked with independently conducting the aforementioned process and compiling all data. In the event of any disagreements, ZHAO would participate in the deliberations to render the ultimate decision.

Strategy of data synthesis RevMan 5.4 was used for data processing in this review. An inspection level of 0.05 was utilized. A fixed-effect model (FEM) was applied for the meta-analysis in the absence of statistical heterogeneity among the articles (I^2 0.05). Conversely, if I^2 was greater than or equal to 50% and P was less than or equal to 0.05, it signified statistical heterogeneity among the articles. In such instances, the article-by-article elimination method and subgroup analysis were employed to pinpoint the sources of heterogeneity. Should these approaches fail to identify the sources, a random-effects model (REM) was then used for the meta-analysis. The mean difference value and its 95% confidence interval (CI) were adopted as the combined effect size of the two sets of evaluation index data. The research conclusions were presented in forest plot, which were based on the integrated system evaluation results. Additionally, publication bias was assessed using the funnel plot method and the Egger's test when there were ten or more articles included in the analysis.

Subgroup analysis Time point of pain relief after DL treatment (24 hours, 48 hours, 7 days); clinical parameters of DL for affecting pain relief (number of irradiation, energy density); clinical parameters of DL affecting ulcer healing (number of irradiation, energy density).

Sensitivity analysis Sensitivity analysis of data related to Visual Analogue Scale (VAS) and ulcer healing time was performed with Stata18 after extracting literature data.

Country(ies) involved China.

Keywords Recurrent aphthous ulcer, diode laser, systematic review, meta-analysis.

Contributions of each author

Author 1 - hongyu wang.

Author 2 - xiaohan he.

Author 3 - danyang wang.

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