

INPLASY PROTOCOL

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None declared.

Efficacy and Safety of Oxymetazoline for the Treatment : a Meta-analysis of Rosacea

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Review question / Objective: This meta-analysis attempts to explore its efficacy and adverse events, so as to provide guidance for clinical medication.

Condition being studied: Rosacea is a chronic skin disease characterized by persistent facial erythema, flushing, telangiectasia, and inflammatory papules or pustules, and it is estimated to affect 16 million adults in the United States¹. Rosacea has four main subtypes: erythematotelangiectatic, papulopustular, phymatous, and ocular rosacea. The most common sign of rosacea is persistent erythema, which is usually related to social embarrassment and psychological distress. The pathophysiology of rosacea is not yet fully understood, but it is believed to be due to an inflammatory process caused by multiple etiologies. Although most topical pharmacological agents can reduce the inflammatory lesions of rosacea and erythema around the lesion, they are less effective for persistent erythema, which makes the treatment options for rosacea persistent facial erythema limited. It is reported that activating the α 1- and α 2-adrenergic receptors on vascular smooth muscle can promote vasoconstriction, which may help to improve the persistent erythema associated with rosacea.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 February 2023 and was last updated on 02 February 2023 (registration number INPLASY202320008).

INTRODUCTION

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METHODS

Participant or population: Patients who have been diagnosed with Rosacea.

Intervention: Oxymetazoline.

Comparator: Vehicle.

Study designs to be included: The inclusion criteria were as follows: the study type is randomized controlled trial (RCT); eligible patients were randomly assigned to receive oxymetazoline or vehicle; the language is limited to English.

Eligibility criteria: Exclusion criteria: duplicate publication; research without full text, incomplete information or inability to conduct data extraction; animal experiments; reviews and systematic reviews.

Information sources: We searched PubMed, Embase, and Cochrane Library from the establishment of the database to May 2021. We included studies that patients were randomly assigned to receive oxymetazoline or vehicle, and we excluded duplicate publications, research without full text, incomplete information or inability to conduct data extraction, animal

experiments, reviews, and systematic reviews. STATA 15.1 was used to analyze the data.

Main outcome(s): The pooled results show that the 3 (RR=1.76, 95%CI: 1.53-2.03), 6 (RR=1.71, 95%CI: 1.47-2.00), 9 (RR=1.63, 95%CI: 1.40-1.90), 12 (RR=1.41, 95%CI: 1.18-1.67) -hours CEA success rate and the 3 (RR=1.65, 95%CI: 1.34-2.03), 6 (RR=1.75, 95%CI: 1.43-2.14), 9 (RR=1.63, 95%CI: 1.33-2.00), 12 (RR=1.78, 95%CI: 1.45-2.18) -hours SSA success rate after oxymetazoline treatment for rosacea is significantly higher than that of vehicle. Additionally, the pooled results show that the incidence of TEAEs after treatment with oxymetazoline is significantly higher than that of vehicle (RR=1.34, 95%CI: 1.10-1.2). However, our analysis of specific adverse events found that the oxymetazoline group was only significantly higher than the vehicle group in the incidence of application-site dermatitis (RR=8.91, 95%CI: 1.76-45.23), and there was no statistical significance in the difference in the incidence of other adverse events.

Quality assessment / Risk of bias analysis: Two researchers independently conducted literature quality evaluation, using Review manager 5.3 software risk assessment tool, according to Cochrane risk assessment scale, according to random sequence generation, allocation concealment, blind method, whether the research results were blindly evaluated, and the completeness of the result data Evaluation of the included literature. When the opinions are inconsistent, it is decided through discussion or consultation with the third person. The meta-analysis was performed based on the related items of Preferred Reporting Items for Systematic Reviews and Meta-analysis statement (PRISMA statement).

Strategy of data synthesis: STATA 15.1 was used to analyze the data. RR (ratio rate) (95%CI) was used to evaluate the difference in CEA success rate, SSA success rate, satisfaction rate, TEAEs rate. I² is used to evaluate heterogeneity. If the heterogeneity test is $P \geq 0.1$ and $I^2 \leq 50\%$, it

indicates that there is heterogeneity between studies, and the fixed effects model is used for combined analysis; if $P \geq 50\%$, it indicates that the study If there is heterogeneity, use sensitivity analysis to find the source of heterogeneity. If the heterogeneity is still large, use the random effects model or give up the combination of results and use descriptive analysis. Funnel plot and Egger's test was used to analyze publication bias.

Subgroup analysis: Not applicable.

Sensitivity analysis: If the heterogeneity test is $P \geq 0.1$ and $I^2 \leq 50\%$, it indicates that there is heterogeneity between studies, and the fixed effects model is used for combined analysis; if $P \geq 50\%$, it indicates that the study If there is heterogeneity, use sensitivity analysis to find the source of heterogeneity. If the heterogeneity is still large, use the random effects model or give up the combination of results and use descriptive analysis.

Country(ies) involved: China.

Keywords: Oxymetazoline; Rosacea; Efficacy; Safety; Meta-analysis.

Contributions of each author:

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