INPLASY PROTOCOL

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Support: **None.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

A Systematic Review And Meta-Analysis: Botulinum Toxin A Effect on Postoperative Facial Scar Prevention

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Review question / Objective: **P: Patients undergoing facial surgery; I: Botulinum toxin A injection; C: The control group was injected with 0.9% normal saline or without any treatment.; O: The postoperative facial scar will be evaluated by the following items: Vancouver Scar Scale, Visual Analog Scale, Observer Scar Assessment Scale, Patient Scar Assessment Scale, Stony Brook Scar Evaluation Scale, scar width and complications; S: randomized controlled trial.**
Condition being studied: **Several methods, such as lasers, have been used to inhibit scar proliferation and improve the appearance of a facial scar. However, despite the use of such methods, finding a safe and effective method for preventing scars has not yet been realized. Botulinum toxin studies have been encouraging and in recent years, the clinical applicability of botulinum toxin type A (BTA) has been gradually expanded, and it may now be an effective method for anti-scar treatment.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 July 2021 and was last updated on 24 July 2021 (registration number INPLASY202170077).

INTRODUCTION

Review question / Objective: **P: Patients undergoing facial surgery; I: Botulinum toxin A injection; C: The control group was injected with 0.9% normal saline or without any treatment.; O: The postoperative facial scar will be evaluated by the following items: Vancouver Scar Scale, Visual Analog Scale, Observer Scar Assessment Scale, Patient Scar Assessment Scale, Stony Brook Scar Evaluation Scale, scar width**

and complications; S: randomized controlled trial.

Rationale: Postoperative facial scarring can be a significant psychological burden for patients to carry after surgery, often resulting in prolonged mental health dysfunction. Currently, there is no established method to prevent facial scar formation; however, there are several methods to prevent facial scar hyperplasia and improve scar quality. Botulinum toxin A (BTA) has been widely used due to its properties of muscle paralysis and known success in plastic surgery and cosmetology. This meta-analysis is going to evaluate the efficacy of BTA in preventing postoperative facial scar hyperplasia and improving scar quality.

Condition being studied: Several methods, such as lasers, have been used to inhibit scar proliferation and improve the appearance of a facial scar. However, despite the use of such methods, finding a safe and effective method for preventing scars has not yet been realized. Botulinum toxin studies have been encouraging and in recent years, the clinical applicability of botulinum toxin type A (BTA) has been gradually expanded, and it may now be an effective method for anti-scar treatment.

METHODS

Search strategy: Databases will be searched for all randomized controlled trials (published before May 2021) where BTA was used for the treatment of postoperative facial scars. The search terms will be set as "face", "cheek", "chin", "eye", "forehead", "mouth", "nasolabial fold", "nose", "scar", "scars", "scarred", "scarring", "cicatrix", "Botulinum Toxin", "Botulinum Toxin, Type A", "Clostridium Botulinum Toxins", "Toxin, Botulinum", "randomized controlled trial", "controlled clinical trial", "randomized", "placebo", and "randomly".

Participant or population: Patients undergoing facial surgery.

Intervention: Botulinum toxin A injection.

Comparator: The control group was injected with 0.9% normal saline or without any treatment.

Study designs to be included: Randomized controlled trial.

Eligibility criteria: All original published RCTs describing the use of botulinum toxin A in preventing postoperative facial scar will be included.

Information sources: PubMed, MEDLINE, EMBASE, web of science, and Cochrane libraries will be searched for all randomized controlled trials (published before May 2021) where BTA was used for the treatment of postoperative facial scars.

Main outcome(s): The postoperative facial scar will be evaluated by the following items: Vancouver Scar Scale, Visual Analog Scale, Observer Scar Assessment Scale, Patient Scar Assessment Scale, Stony Brook Scar Evaluation Scale, scar width and complications.

Additional outcome(s): None.

Data management: The mean differences (MDs) value or standardized mean differences (Std. MDs) value will be calculated by the inverse variance method for continuous variables, and the Mantel-Haenszel method will be applied for categorical variables. Combined values will be expressed with 95% confidence intervals (CIs), and differences will be considered statistically significant if the result is $p < 0.05$.

Quality assessment / Risk of bias analysis: Two authors will apply the Cochrane Handbook tool to independently perform a quality assessment of the literature of the included studies. In case of disagreement, it will be reassessed by another author. Begg's test and funnel plots will be used to evaluate publication bias in the meta-analysis.

Strategy of data synthesis: Review manager 5.4 will be used to analyze the data and perform the meta-analysis. The

mean differences (MDs) value or standardized mean differences (Std. MDs) value will be calculated by the inverse variance method for continuous variables, and the Mantel-Haenszel method will be applied for categorical variables. Combined values will be expressed with 95% confidence intervals (CIs), and differences will be considered statistically significant if the result is $p < 0.05$.

Subgroup analysis: The effect of botulinum toxin A on postoperative facial scar will be judged by subgroup analysis of various subitems of the Vancouver Scar Scale (VSS). These subitems include pigmentation, vascularity, pliability, and height.

Sensitivity analysis: Sensitivity analysis will be conducted by excluding one study at a time to explore the influence of individual RCTs.

Language: English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Scars, facial, postoperative, Botulinum toxin A.

Dissemination plans: The meta-analysis will be followed by public publication in journals of related fields. It is hoped that some reference can be provided for surgeons who are going to perform the relevant clinical work.

Contributions of each author:

Author 1 - Shuai Yue - The authors will be involved in data collection, analysis as well as in drafting the meta.
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