INPLASY PROTOCOL

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Risk factors for bone flap resorption after autologous bone cranioplasty: protocol for a systematic review and meta-analysis

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Review question / Objective: What are the risk factors for bone flap resorption requiring a second surgery after autologous bone cranioplasty?

Condition being studied: Cranioplasty is a common surgery in neurosurgery department. This procedure could restore protective barrier and offer cosmetic benefits for patients with cranial defect. Given the biocompatibility and low cost, autologous bone has always been regarded as gold standard for cranial reconstruction. However, bone flap resorption following cranioplasty can lead to poor outcomes and higher expenses. Therefore, it is necessary to conduct a study to identify the risk factors for patients with bone flap resorption requiring a second surgery and take measures to take interventions or go straight to an alloplastic implant for those patients.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 May 2020 and was last updated on 15 May 2020 (registration number INPLASY202050063).

INTRODUCTION

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METHODS

Participant or population: Patients with bone flap resorption requiring a second surgery.

Intervention: Patients with cranial defect are performed autologous bone cranioplasty.

Comparator: Patients without bone flap resorption and those with bone flap resorption not requiring a second surgery.

Study designs to be included: Clinical randomized controlled trials (RCTs) and prospective or retrospective studies (cohort studies, case-control studies) were included.

Eligibility criteria: Patients with bone flap resorption requiring a second surgery will be included in the study; (2) at least one risk factor was reported (2) Clinical randomized controlled trials (RCTs) and prospective or retrospective studies will be included; (3) Research articles were excluded if they are reviews, conference abstracts, animal studies, studies with incomplete experimental data, and duplicate publications; (4) The language will be restricted in English.

Information sources: In this review, PubMed, EMBASE, Cochrane Library database were searched by two independent authors for identification of relevant studies.

Main outcome(s): The primary outcome was patients requiring a second surgery after autologous bone cranioplasty.

Quality assessment / Risk of bias analysis: The quality of all studies was graded independently by two independently reviewers. The quality of randomized controlled studies will be evaluated based on the guidelines of Cochrane Collaboration's tool. The quality of observational studies was assessed using the well-established Newcastle and Ottawa scale (NOS) based on three categories.

Strategy of data synthesis: Review manager software version 5.3 was used to analyze the data. The odds ratios (ORs) with 95% confidence interval were calculated. Cochrane Q test and I^2 statistics were used to measure heterogeneity. If there is no heterogeneity ($I^2 < 50\%$), the data is synthesized using fixed effect model. Otherwise, the random effect model was used.

Subgroup analysis: If there is heterogeneity, we will conduct a subgroup analysis. The subgroup analyses will be performed based on race, age, gender, country and bone flap preservation.

Sensibility analysis: The sensitivity analyses will be conducted by removing the lowlevel quality study one by one to probe the impact of each study.

Language: English.

Country(ies) involved: China.

Keywords: Cranioplasty; Autologous bone; Risk factors; Bone flap resorption.

Contributions of each author:

Author 1 - Jingguo Yang. Author 2 - JW Guan.