INPLASY PROTOCOL

To cite: Li et al. Different materials of cranioplasty for patients undergoing decompressive craniectomy: A protocol for systematic review and network meta-analysis. Inplasy protocol 202110001. doi: 10.37766/inplasy2021.1.0001

Received: 01 January 2021

Published: 01 January 2021

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Support: **2020YFQ0009, ZY2016102.**

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

Conflicts of interest:
None.

Different materials of cranioplasty for patients undergoing decompressive craniectomy: A protocol for systematic review and network meta-analysis

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Review question / Objective: Participants: The current study will include adult patients undergoing cranioplasty after depression craniectomy. The included patients who undergone cranioplasty because of refractory intracranial hypertension resulting of traumatic brain injury, cerebrovascular diseases, and space occupying lesions. Intervention: We will include studies assessing the efficacy and safety of 2 or more of the following material for cranioplasty. Comparator: The interventions include: 1) autologous bone, 2) allografts, 3) titanium mesh, 4) hydroxyapatite, 5) methylmethacrylate (MMA), 6) alumina ceramics, 7) polyetheretherketone (PEEK), and 8) combination of synthetic and biological grafts. Outcome: The primary outcomes are early mortality and implant failure, which mainly results from implant rejection, early severe infection. In view of the short interval between operation and adverse events, there is no time restrictions applied on implant failure. Secondary outcomes will include presence of postoperative infection, implant resorption, intracranial hemorrhage, extra-axial fluid collection, hydrocephalus, neurological dysfunction, and seizures. Reoperation, cosmetic evaluation, and patients' satisfaction will also be included, which are evaluated by both subjective and objective tests. Study design: A systematic review and network meta-analysis will be conducted with principles and methods of Cochrane Handbook. This protocol has been reported in accordance with the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) guidelines.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 January 2021 and was last updated on 01 January 2021 (registration number INPLASY202110001).

INTRODUCTION

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resulting of traumatic brain injury, cerebrovascular diseases, and space occupying lesions. Intervention: We will include studies assessing the efficacy and safety of 2 or more of the following material for cranioplasty. Comparator: The interventions include: 1) autologous bone, 2) allografts, 3) titanium mesh, 4) hydroxyapatite, 5) methylmethacrylate (MMA), 6) alumina ceramics, 7) polyetheretherketone (PEEK), and 8) combination of synthetic and biological grafts. Outcome: The primary outcomes are early mortality and implant failure, which mainly results from implant rejection, early severe infection. In view of the short interval between operation and adverse events, there is no time restrictions applied on implant failure. Secondary outcomes will include presence of postoperative infection, implant resorption, intracranial hemorrhage, extra-axial fluid collection, hydrocephalus, neurological dysfunction, and seizures. Reoperation, cosmetic evaluation, and patients' satisfaction will also be included, which are evaluated by both subjective and objective tests. Study design: A systematic review and network meta-analysis will be conducted with principles and methods of Cochrane Handbook. This protocol has been reported in accordance with the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) guidelines.

Rationale: Cranioplasty is widely applied on patients who has undergone decompress craniectomy (DC) due to intractable increased intracranial pressure and the cranioplasty materials represent an ever-changing frontier of biomolecular and material science advancement. This systematic review and network meta-analysis (NMA) will be conducted to comprehensively evaluate the safety and efficacy of different cranial implants for patients with cranial defects due to various reasons.

Condition being studied: To our knowledge, this will be the first network meta-analysis (NMA) to comprehensively compare the safety and efficacy of different materials for cranial repairing in patients undergoing decompression craniectomy.

METHODS

Search strategy: We will comprehensively search objective studies in the following electronic databases: PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), VIP, and Wanfang. We will also screen ClinicalTrials.gov to include relevant trials in progress. Manual searching of reference lists from relevant articles will also be necessary. Search terms: #1: (((((((((Autografts[MeSH Terms]) OR (Autografts)) OR (autologous bone)) OR ((Allografts[MeSH Terms]) OR (Allografts))) OR ((Titanium[MeSH Terms]) OR (Titanium))) OR ((hydroxyapatite[MeSH Terms]) OR (hydroxyapatite))) OR ((Methylmethacrylate[MeSH Terms]) OR (Methylmethacrylate))) OR (((Ceramics[MeSH Terms]) OR (Ceramics)) OR (alumina ceramics))) OR (((polyetheretherketone [Supplementary Concept]) OR (polyetheretherketone)) OR (PEEK))) OR (synthetic grafts) #2: (((cranial defect) OR (skull defect)) OR (cranioplasty)) OR (cranial repair) #3: (((((((Clinical Trials, Randomized) OR (Trials, Randomized Clinical)) OR (Controlled Clinical Trials, Randomized)) OR (Randomized Controlled Trials[MeSH Terms])) OR ((Controlled Clinical Trial[MeSH Terms]) OR (Controlled Clinical Trial))) OR ((prospective study[MeSH Terms]) OR (prospective study))) OR ((double blind method[MeSH Terms]) OR (double blind method))) OR ((single blind method[MeSH Terms]) OR (single blind method)) #4: #1 AND #2 AND #3.

Participant or population: The current study will include adult patients undergoing cranioplasty after depression craniectomy. The included patients who undergone cranioplasty because of refractory intracranial hypertension resulting of traumatic brain injury, cerebrovascular diseases, and space occupying lesions.

Intervention: We will include studies assessing the efficacy and safety of 2 or

more of the following material for cranioplasty. The interventions include: 1) autologous bone, 2) allografts, 3) titanium mesh, 4) hydroxyapatite, 5) methylmethacrylate (MMA), 6) alumina ceramics, 7) polyetheretherketone (PEEK), and 8) combination of synthetic and biological grafts.

Comparator: 1) autologous bone, 2) allografts, 3) titanium mesh, 4) hydroxyapatite, 5) methylmethacrylate (MMA), 6) alumina ceramics, 7) polyetheretherketone (PEEK), and 8) combination of synthetic and biological grafts.

Study designs to be included: A systematic review and network meta-analysis will be conducted with principles and methods of Cochrane Handbook. This protocol has been reported in accordance with the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) guidelines.

Eligibility criteria: Eligibility criteria 1 Types of studies This study will include randomized control trials (RCTs) and non-randomized prospective studies, which should be available in full papers and peer-reviewed. Retrospective studies, case reports, case series or reviews will not be eligible. No language restrictions will be applied. 2 Types of participants The current study will include adult patients undergoing cranioplasty after depression craniectomy. The included patients who undergone cranioplasty because of refractory intracranial hypertension resulting of traumatic brain injury, cerebrovascular diseases, and space occupying lesions. 3 Types of interventions We will include studies assessing the efficacy and safety of 2 or more of the following material for cranioplasty. The interventions include: 1) autologous bone, 2) allografts, 3) titanium mesh, 4) hydroxyapatite, 5) methylmethacrylate (MMA), 6) alumina ceramics, 7) polyetheretherketone (PEEK), and 8) combination of synthetic and biological grafts. 4 Outcome measures The primary outcomes are early mortality and implant failure, which mainly results from implant rejection, early severe infection. In view of the short interval between operation and adverse events, there is no time restrictions applied on implant failure. Secondary outcomes will include presence of postoperative infection, implant resorption, intracranial hemorrhage, extra-axial fluid collection, hydrocephalus, neurological dysfunction, and seizures. Reoperation, cosmetic evaluation, and patients' satisfaction will also be included, which are evaluated by both subjective and objective tests. The time point for outcomes will be the longest follow-up time in each study.

Information sources: We will comprehensively search objective studies in the following electronic databases: PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), VIP, and Wanfang. We will also screen ClinicalTrials.gov to include relevant trials in progress. Manual searching of reference lists from relevant articles will also be necessary. If some data cannot be obtained from the articles directly, we will attempt to contact the authors by corresponding e-mail to acquire those data.

Main outcome(s): The primary outcomes are early mortality and implant failure, which mainly results from implant rejection, early severe infection. In view of the short interval between operation and adverse events, there is no time restrictions applied on implant failure.

Additional outcome(s): Secondary outcomes will include presence of postoperative infection, implant resorption, intracranial hemorrhage, extra-axial fluid collection, hydrocephalus, neurological dysfunction, and seizures. Reoperation, cosmetic evaluation, and patients' satisfaction will also be included, which are evaluated by both subjective and objective tests.

Quality assessment / Risk of bias analysis: We will assess the quality of the evidence using the Grading of Recommendations Assessment, Development, and Evaluation

(GRADE) framework. This approach contains four major steps including presenting direct and indirect treatment estimates for each comparison of the evidence network, rating the quality of each direct and indirect effect estimate, presenting the NMA estimate for each comparison of the evidence network, and rating the quality of each NMA effect estimate, which can provide ratings for the confidence in the estimates of effect for a specific comparison for all outcomes of importance to patients.

Strategy of data synthesis: We will assess the quality of the evidence using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework. This approach contains four major steps including presenting direct and indirect treatment estimates for each comparison of the evidence network, rating the quality of each direct and indirect effect estimate, presenting the NMA estimate for each comparison of the evidence network, and rating the quality of each NMA effect estimate, which can provide ratings for the confidence in the estimates of effect for a specific comparison for all outcomes of importance to patients. Two independent authors will assess risk of bias for every single included studies in accordance with the Cochrane Collaboration tool for RCTs. 7 specific domains including sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias and detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other bias and the risk of bias of all included RCTs will be estimated. As regard to bias evaluating of non-randomized trials, risk of bias in nonrandomized studies of interventions (ROBINS-I) will be used, which also contains 7 domains including bias due to confounding, bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported result. In the same way, two independent reviewers will finish this job.

Subgroup analysis: Subgroup analyses are conducted based on the following factors: 1) age at operation, 2) gender, 3) race, 4) region, 5) size of cranial defects, 6) location of cranial defects, 7) primary disease before DC, 8) interval to cranioplasty after DC. abbreviation: DC, decompress craniectomy.

Sensibility analysis: Subgroup analysis and meta-regression analysis will be performed in consideration of potential evident heterogeneity or inconsistency.

Language: There will be no language limits.

Country(ies) involved: China.

Keywords: Cranioplasty, cranial implant, systematic review, network meta-analysis.

Dissemination plans: We are planning to publish this systematic review and network meta-analysis in a peer-reviewed scientific journal and disseminate it widely through the Internet.

Contributions of each author:

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