INPLASY PROTOCOL

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None declared.

Posterior fossa decompression with or without duraplasty in patients with Chiari type I malformation: systematic review and meta-analysis

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Review question / Objective: **The clinical symptoms of CMI patients are most common in the early stage of head and neck pain, followed by limb movement, sensory disorders and other symptoms. At present, the surgery for the patients with CMI combined with syringomyelia is still an effective method in clinical treatment. PFD and PFDD are the common surgical methods for the treatment of CMI. PFD usually only needs to perform simple bone decompression through the posterior median straight incision, while PFDD needs to use artificial dura or myofascial membrane to repair the dura and expand the formation after the incision of the dura on the basis of simple bone decompression in the posterior cranial fossa. Therefore, PFD is popular with clinicians for its relatively simple surgical method and small trauma, but some studies have pointed out that PFDD has better efficacy in treating CMI patients. We therefore performed a systematic review and meta-analysis of available evidence from observational studies to evaluate the effectiveness and safety of the two surgical methods.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 04 June 2023 and was last updated on 04 June 2023 (registration number INPLASY202360013).

INTRODUCTION

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Condition being studied: Chiari malformations (CM) generally have four types, of which type I (CMI) is the most common. It was first proposed by Austrian pathologist Hans Chiari in 1891. CMI is mainly due to the abnormal development of the midline structure of the posterior cranial fossa in the embryonic period, which causes the cerebellar tonsil to herniate into the spinal canal, resulting in the compression and traction of the brainstem, cerebellum and posterior cranial nerves, and further causes the expansion of the central spinal canal, forming a series of syndromes, most of which are combined with syringomyelia.

METHODS

Search strategy: (Arnold-Chiari Malformation or Arnold Chiari Malformation or Malformation, Arnold-Chiari or Malformation, Arnold Chiari or Arnold-Chiari Deformity or Arnold Chiari Deformity or Deformity, Arnold-Chiari or Arnold-Chiari Syndrome or Arnold Chiari Syndrome or Syndrome, Arnold-Chiari or Arnold-Chiari Malformation, Type I or Arnold Chiari Malformation, Type I or Chiari Malformation Type I or Type I Arnold-Chiari Malformation or Type I Arnold Chiari Malformation or Arnold-Chiari Malformation, Type 1 or Arnold Chiari Malformation, Type 1) and (Posterior Fossa Decompression or Duraplasty).

Participant or population: Patients with Chiari malformation type I.

Intervention: Posterior fossa decompression (PFD).

Comparator: Posterior fossa decompression with duraplasty(PFDD).

Study designs to be included: Cohort study.

Eligibility criteria: We considered studies eligible for inclusion if they: were randomized trials or observational studies with a retrospective or prospective cohort; compared PFD and PFDD, and operated on Arnold-Chiari Malformation patients; compared the efficacy and prognosis of PFD and PFDD, and gave detailed data. Studies were excluded if there was no qualified surgical method or PFD was not compared with PFDD. We also excluded publications without original data, such as reviews, editorials, and comments. Translate non-English potential research with the help of translation software or translators, if necessary. Two review authors independently evaluated eligibility. The research selection was conducted in two stages: the preliminary screening of titles and abstracts, and then the full text review of articles that might meet the criteria. Finally, if there are discrepancies, the third investigator will solve them.

Information sources: PubMed, Embase, and the Cochrane Library from inception to 21 March 2023.

Main outcome(s): Fifteen studies were finally included. Among 5613 Chiari malformation type I patients, 2783 patients were treated with PFD and 2830 patients were treated with PFDD. Compared with patients who have undergone PFD surgery, patients who have undergone PFDD surgery have a higher rate of improvement of clinical symptoms (risk ratio 0.93, 95% confidence interval 0.87 to 0.99), but also have a higher incidence of overall complications (0.67, 0.59 to 0.77).Patients in the PFDD group were more prone to meningitis (0.28, 0.14 to 0.59),cerebrospinal fluid leakage(0.28, 0.17 to 0.47) and pseudomeningocele (0.55, 0.40 to 0.76),but the treatment effect of syringomyelia(0.65,

0.54 to 0.78) was better and there was a lower reoperation rate(1.73, 1.25 to 2.38).Subgroup analysis of overall complication outcome stratified by study characteristics showed significant differences by sample size(P=0.01), publication time(P=0.01), and region (P=0.01).

Additional outcome(s): Specific types of complications and reoperation, as well as relief of syringomyelia.

Quality assessment / Risk of bias analysis: We used the risk of bias in nonandomised studies of interventions (ROBINS-I) tool to assess the quality of the studies. The detailed scoring criteria have been explained in the tool. This tool consists of seven domains, with bias assessed as due to: selective reporting of the results, measurement of the outcome, missing data, misclassification during follow-up, exposure assessment, selection of participants, confounding. Two raters independently assessed the risk of bias, rating the risk of each domain as low, moderate, severe, serious, or uninformative. One senior investigator was responsible for discrepancies resolution.

Strategy of data synthesis: Data extraction and meta-analysis were analyzed using the R statistical language r version 4.2.3. P values are two-sided and 0.05 alpha levels were considered significant. A fixed effects model was used for all outcomes to calculate the pooled risk ratios with 95% confidence intervals between both surgery and each postoperative indicator of PFD versus PFDD. Heterogeneity between studies was quantified using the I2 statistic, with 0-25% considered low heterogeneity, 25-50% considered moderate heterogeneity, 50-75% considered significant heterogeneity, and 75-100% considered high heterogeneity. To assess the robustness of the pooled results, we performed sensitivity analyses. Potential publication bias was assessed by asymmetric visualization of funnel plots combined with egger's test and Begg's test.

Subgroup analysis: To identify potential sources of observed heterogeneity and subgroup differences, we performed subgroup analyses including: patient age (mean age < 18 years vs mean age > 18 years), median year of publication (before 2016 vs after 2016), study site (Americas vs Asia), duration of follow-up (> 2 years vs ≤ 2 years), sample size (< 100 vs ≥ 100), and Study quality (low risk of bias vs moderate risk of bias vs severe risk of bias).

Sensitivity analysis: To assess the robustness of the pooled results, we performed sensitivity analyses.

Country(ies) involved: China.

Keywords: Posterior fossa decompression (PFD), Posterior fossa decompression with duraplasty (PFDD), Chiari malformation type I, meta-analysis.

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