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**Efficacy and Safety of Bariatric** 

Intracranial Hypertension: a

**Surgery in Patients with Idiopathic** 

# **INPLASY** PROTOCOL

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## INTRODUCTION

**Review question / Objective: (1)** Participants: obese patients with IIH; (2) Intervention: underwent bariatric surgery, no matter laparoscopic or open surgeries were used (including Roux-en-Y gastric bypass, sleeve gastrectomy, adjustable gastric banding); (3) Comparison: obese patients with IIH who got non-surgical treatment (diet, behavior therapy, weight reducing drugs, or any combination thereof); (4) Outcomes: the primary symptoms include ICP, IIH related symptoms (the number of patients with headache and visual defect). Other

detail information of patients.

outcomes include weights, body mass index(BMI), and ophthalmological examination, complication or mortality at the final of follow-up. (5)Study design: randomised controlled trials (RCT) or observational studies(including prospective and retrospective studies) or case report studies that show the detail information of patients.

**Condition being studied: Idiopathic** intracranial hypertension (IIH) is a debilitating disorder characterized by elevated intracranial pressure (ICP) that causes the swelling of optic disc, which is also called papilledema, leading to the risk of permanent vision loss and chronic headaches, resulting in decreased quality of life.1, 2 Although the details of the pathogenesis of IIH is still unclear, there are several risk factors that have already been recognized.3 IIH is more common in obese women of reproductive age.4 At least 90% of patients are female, and the obesity rates ranged from 70.5 to 94%5-7. Recent weight gain is also a significant risk factor in the further development of IIH.8 The burden of IIH continues to increase globally, with a recent estimated annual incidence of up to 21 cases per 100,000 in young obese women per year.9 High missed diagnosis rate existed because the comprehension of doctors to IIH wasn't deep enough. This increase comes against the backdrop of concurrent increases in obesity rates, which defined as body mass index (BMI) within the range of 25-30 kg/ m2.

## **METHODS**

Search strategy: Two independent researchers conducted a systematic literature search in the National Library of Medicine (PubMed/MEDLINE), the Cochrane Library, and EMBASE databases to identify articles published up to September 30th, 2022 using the keywords of (bariatric surgery OR weight loss surgery OR metabolic surgery OR Roux-en-Y gastric bypass OR sleeve gastrectomy OR gastric banding) AND (idiopathic intracranial hypertension OR pseudotumor cerebri). Participant or population: Obese patients with IIH.

Intervention: Underwent bariatric surgery, no matter laparoscopic or open surgeries were used (including Roux-en-Y gastric bypass, sleeve gastrectomy, adjustable gastric banding).

**Comparator:** Obese patients with IIH who got non-surgical treatment (diet, behavior therapy, weight reducing drugs, or any combination thereof).

Study designs to be included: Randomised controlled trials (RCT) or observational studies(including prospective and retrospective studies) or case report studies that show the detail information of patients.

**Eligibility criteria:** The exclusion criteria were: (1) the study was a review, letter or comment; (2) the study was not in English.

Information sources: The National Library of Medicine (PubMed/MEDLINE), the Cochrane Library, and EMBASE databases.

Main outcome(s): The outcomes included author, year of publication, journal of publication, title, weights, BMI, complication, mortality rate, ICP, IIH related symptoms (headache and visual defect) and ophthalmological examination.

Quality assessment / Risk of bias analysis: Methodological Index for Non-randomized Studies (MINORS) tool was used to assess the risk of bias of the included studies. MINORS contains 12 methodological points, the top eight points apply to both comparative and noncomparative studies, and the remaining four points are associated with studies with two or more than two groups. Each item gets a score from 0 to 2, thus overall scores range from 0 to 24. Two investigators independently performed the assessment.

Strategy of data synthesis: The analysis was performed using RevMan 5.3 (freeware from the Cochrane Collaboration).

Outcomes from included studies were analysed to assess the risk ratios (RR) or mean difference (MD) with 95 % confidence intervals (CI) favoring the bariatric surgery over non-bariatric surgery treatment. Statistical heterogeneity and inconsistency were tested by the Cochran's Q tests and I2. Statistical significance was detected with two-tailed P <0.05 level.

Subgroup analysis: No subgroup analysis has been made.

Sensitivity analysis: Sensitivity analysis has been made using the Revman software.

Language restriction: English.

Country(ies) involved: China.

**Keywords:** Bariatric surgery, Idiopathic intracranial hypertension, Systematic review and meta-analysis.

#### **Contributions of each author:**

Author 1 - Haiying Teng - Author 1 drafted the manuscript and analyze the data. Email: 814382250@qq.com Author 2 - Zilan Wang. Author 3 - Dongwei Wang. Author 3 - Dongwei Wang. Author 4 - Huiru Chen. Author 5 - Hanyu Ni. Author 6 - Tong Hu. Author 7 - Zhong Wang.