

INPLASY PROTOCOL

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Corresponding author:
Mingfei Yang

iloveyoucmu@163.com

Author Affiliation:
Qinghai Provincial People's Hospital

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There was no potential conflict of interest relevant to this meta-analysis.

The value of goreisan on recurrence after surgery for chronic subdural hematoma: A systematic review and meta-analysis

Guo, Y¹; Du, C²; Zhao, K³; Yang, M⁴.

Review question / Objective: P: chronic subdural hematoma undergoing burr-hole surgery; I: oral administration of goreisan; C: placebo or blank control; O: hematoma recurrence; S: comparative studies.

Condition being studied: Chronic subdural hematoma (CSDH) is a widespread neurosurgical disease. According to the incidence statistics of a related study, each year from 1.72 to 20.6 of every 100,000 people developed CSDH, but was more prevalent in the aged. And with the world's aging population, the incidence of this disease was expected to rise. Fortunately, however, with advances in diagnosis and surgical techniques, gone were the days when CSDH caused severe complications and mortality. Most cases of CSDH were treated by burr-hole surgery with irrigation and drainage, and more than 80% could obtain a favorable prognosis. Nevertheless, about 5-30% rate of postoperative recurrence remained an urgent worldwide problem need to be solved urgently. Goreisan, a traditional Chinese medicine, has been widely used in East-Asian. In some states, this Chinese herb was used to prevent postoperative recurrence of CSDH and to treat asymptomatic CSDH because it could inhibit the expression of aquaporins (AQPs) on the hematoma membrane. But, there is no consensus on its efficacy. To clarify whether goreisan was valuable in reducing CSDH recurrence, we undertook a systematic review and meta-analysis compared CSDH outcomes in those allocated goreisan versus those who were not.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 May 2020 and was last updated on 09 May 2020 (registration number INPLASY202050034).

INTRODUCTION

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METHODS

Search strategy: Two independent investigators (Y.G., C.N.D.) searched three electronic databases (PubMed, EMBASE and The Cochrane Library) using free and MeSH (Medical Subjective Headings) and combination of key words related to goreisan and CSDH, without language and publication restrictions from initial until May 1, 2020. At the same time, to avoid missing additional studies, we had screened and searched the list of references of the final included citations and relevant reviews by the electronic.

Participant or population: Patients with chronic subdural hematoma as the primary diagnosis and underwent burr-hole surgery treatment.

Intervention: Oral administration of goreisan.

Comparator: Placebo or blank control.

Study designs to be included: Randomized controlled trials (RCT), quasi-RCT, prospective and retrospective controlled studies.

Eligibility criteria: (1) Types of design: randomized controlled trials (RCT), quasi-RCT, prospective and retrospective controlled studies; (2) Objects of study: patients with CSDH as the primary diagnosis and underwent burr-hole surgery treatment; (3) Medical interventions: the control group treated with surgery alone, the intervention group received surgery with adjuvant goreisan therapy; (4) Outcome assessment indexes: including hematoma recurrence rate; (4) At least 15 patients were included in the goreisan and control groups.

Information sources: We conducted a comprehensive search of 3 electronic databases, PubMed, EMBASE and The Cochrane Library, including relevant controlled trials study whether goreisan was effective in recurrence after burr-hole surgery of CSDH, and manually searched the list of included studies references to ensure no relevant literature was omitted.

Main outcome(s): Primary outcome variable was hematoma recurrence.

Additional outcome(s): Complications were also taken as outcome measures.

Quality assessment / Risk of bias analysis: The methodological quality of RCT was assessed using the Cochrane risk of bias tool, and the Newcastle–Ottawa scale (NOS) was adopted for cohort studies.

Strategy of data synthesis: The detailed to be obtained for each study were as follows: (1) Study ID: the first author and year of publication of article; (2) Study design types (retrospective, prospective or RCT) and quality assessment index. (3) Characteristics of the population under study (number of patients, age, intervention methods, etc.); (4) Follow-up time, outcome indicators and outcome measurement data. RevMan 5.3, a special software provided by the international Cochrane

collaboration for workers of the systematic review, was used for statistical analyses of this meta-analysis. The effect size was expressed by the odds ratio (OR) and its 95% confidence interval (CI) using a random-effects.

Subgroup analysis: N/A.

Sensibility analysis: If $T^2 > 0$ or I^2 was greater than 30% or in case of a p value < 0.10 in the chi-square test for heterogeneity, the impact of these studies in the overall assessment of results was analyzed by a sensitivity analysis.

Language: Without language restrictions.

Country(ies) involved: China.

Keywords: chronic subdural hematoma; burr-hole surgery; recurrence; goreisan; meta-analysis.

Contributions of each author:

Author 1 - Yu Guo.

Author 2 - Chaonan Du.

Author 3 - Kai Zhao.

Author 4 - Mingfei Yang.