



## Original Research

## Use of an antiepileptic drug to control epileptic seizures associated with cranioplasty: A randomized controlled trial



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## HIGHLIGHTS

- The incidence of epilepsy associated with the cranioplasty is 28.6%.
- Early use of anti-epileptic drugs can effectively reduce the occurrence of seizures to 5.9%.
- Early use of anti-epileptic drugs shows few side effects.

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## ABSTRACT

**Background:** Epilepsy is a common complication of cranioplasty. The present study was designed to explore the clinical effect of prophylactic anti-epilepsy drugs (AED) to control epileptic seizures associated with cranioplasty.

**Methods:** and design: This trial was a prospective, randomized, open-label, single-centre, active controlled study designed to investigate the use of antiepileptic drug to control epileptic seizures associated with cranioplasty. We tested the necessity and methods of drug use. Three hundred twenty epilepsy patients who underwent cranioplasty were included in this study. The patients were randomly divided into the control group (160 cases) and the experimental group (160 cases). AED were administered to experimental group from 4 days before the surgery until 1 month after the surgery. The incidence of early and late epileptic seizures after cranioplasty was analyzed. The liver function, abnormal blood test 1 month after surgery were compared between these two groups.

**Results:** The incidence of seizures in the Control group was 28.6% (43 cases in 149 cases) while in the experimental group was only 5.9% (9 cases in 151 cases), which had statistical significance. The incidence of epileptic seizure was significantly higher in patients who received no AED treatment than in those who received AED treatment. Besides, the abnormal liver function and blood routine examination in both control and experimental group had no significant differences.

**Conclusion:** The incidence of epilepsy associated with the cranioplasty is high and early use of anti-epileptic drugs can effectively reduce the occurrence of seizures.

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## 1. Introduction

Cranioplasty or replacement of bone flap or prosthesis is a

surgical procedure usually performed to fill in, or replace a defect in the skull following a decompressive craniotomy (DC) or removal of a bone flap. DC may be performed in patients with acutely raised intracranial pressure due to traumatic brain injury or stroke. It is later followed by a cranioplasty procedure (CP) in the surviving patients. This procedure (cranioplasty) is associated with a high frequency of post-operative complications. Among the several complications of cranioplasty, epilepsy is a common complication

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with an incidence of 14.8–33.0% [1,2]. In order to prevent from different levels of psychological barriers and physical damage, we applied antiepileptic drug (AED) to control seizures before and after cranioplasty by selecting patients from March 2014 to March 2016 with cranioplasty. This study was a prospective, randomized, open-label, single-centre, active controlled study with two parallel study groups. We tested the hypothesis that the use of AED can control epileptic seizures associated with cranioplasty. Compared with the patients without AED during the same period time, the application of AED received good effects. Now the report is as follows:

## 2. Material and methods

### 2.1. Trial design

The work is fully compliant with the CONSORT criteria [3]. The patients with preoperative basic self-care were included in the study from March 2014 to March 2016 in our department. Before the experiments, we obtained approval for our study from the Ethics Committee and written informed consent from all participants involved in our study. The cases were divided into the experimental group and control group according to random number table method (Table 1). Randomization was performed by an individual not involved in the study and kept concealed. Potential attrition bias was mitigated by only including patients who were motivated to receive treatment.

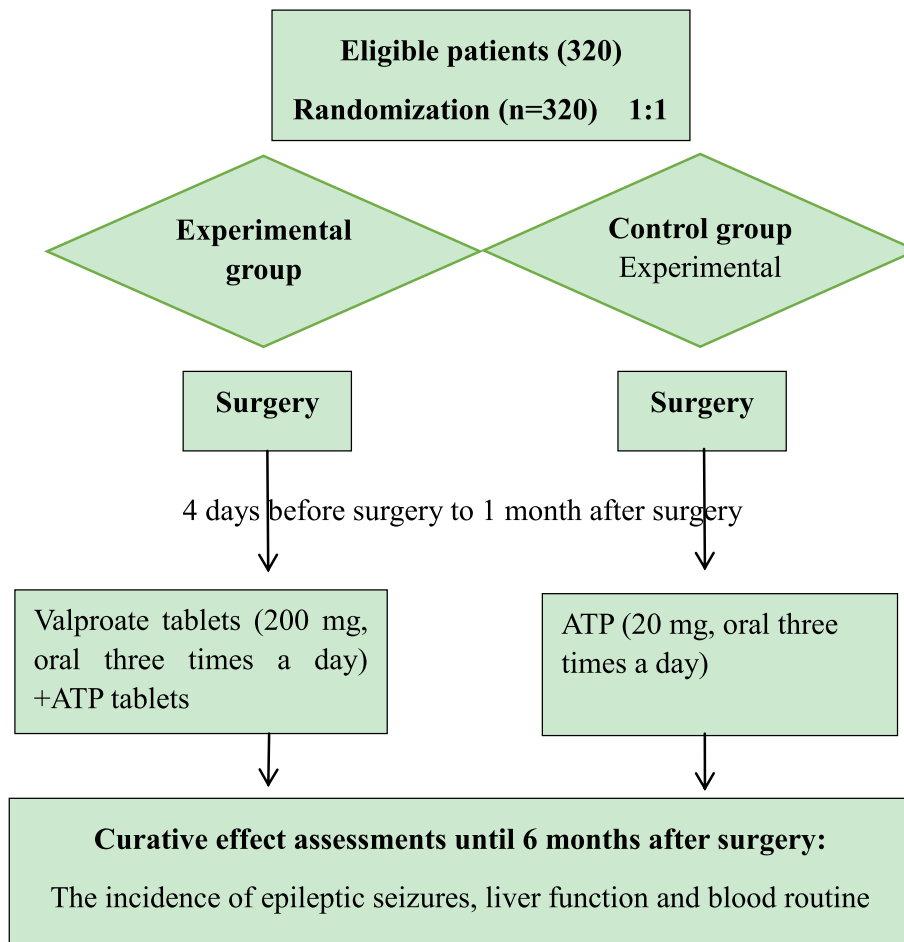
### 2.2. Participants

Inclusion criteria: Patients with 177 male and 143 female of 17–72 years old (average  $36.2 \pm 2.6$  years old) were chosen according to the previous reported incidence of epileptic seizures. Among them, epidural hematoma drainage and bone disc decompression were carried out in 179 cases of craniocerebral trauma (or brain) and 141 cases of spontaneous intracranial hemorrhage. The time from a surgical operation to cranioplasty was  $4.5 \pm 0.8$  months.

Exclusion criteria: Patients needed hydrocephalus bypass in an anesthesia; Patients had been found epilepsy before being hospitalized for cranioplasty; Patients needed extra surgery because of infection or rejection after cranioplasty; Patients had serious abnormalities in heart, kidney or blood routine test before surgery.

### 2.3. Interventions

All participants carried out basic relevant examinations after admission including liver and kidney function, blood routine, cranial CT, customized titanium plate. Under general anesthesia, an incision was made along the original surgical incision. Scalp was stripped carefully to open duramater, and then the bone window was fully opened and covered with custom titanium plate with number of titanium nails to fix it. External drainage pipe connected to negative pressure was placed until 48 h.



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