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Comparative effectiveness of different surgical procedures for traumatic acute epidural haematoma: study protocol for Prospective, Observational Real-world Treatments of AEDH in Large-scale Surgical Cases (PORTALS-AEDH)

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ABSTRACT

Introduction Controversy and variation exist in surgical management for acute epidural haematoma (AEDH). Although craniotomy for AEDH is conventionally employed, no specific evaluation on the necessity of decompressive craniectomy (DC) followed by AEDH evacuation has been performed.

Methods and analysis This is a multicentre prospective, phase III observational study that evaluates different surgical managements for the AEDH. Patients of both genders, aged 18–65 years, presenting to the emergency room with a clinical and radiological diagnosis of AEDH, complying with other inclusion and exclusion criteria, are enrolled. Clinical information, including diagnosis of AEDH, radiological information, treatment procedures and follow-up data of 1, 3 and 6 months post-injury, is collected on 2000 eligible patients among 263 hospitals in China. Recruitment for the study started in April 2021, and inclusion will be continued until the sample size is obtained, expected is an inclusion period of 24 months. The interventions of concern are surgical treatments for AEDH, including craniotomy and DC. The primary outcome is the Glasgow Outcome Score-Extended 6 months post-injury. Secondary outcomes include the incidence of postoperative cerebral infarction, the incidence of additional craniocerebral surgery and other evaluation indicators within 6 months post-injury.

Ethics and dissemination The study protocol has been approved by the ethics committee and institutional review board of Renji Hospital, School of Medicine, Shanghai Jiao Tong University. All study investigators strictly follow the Declaration of Helsinki and Human Biomedical Research Ethical Issues. Signed written informed consent will be obtained from all enrolled patients. The trial results will be disseminated through academic conferences and published in peer-reviewed journals.

Trial registration number NCT04229966.

Strengths and limitations of this study

- ► This study is the first multicentre, prospective, observational trial to evaluate the benefit of decompressive craniectomy on patients with traumatic acute epidural haematoma (AEDH) based on real-world design.
- ► Multiple distinct covariate information collections and relevant statistical analyses will be performed to control the potential selection and confounding bias.
- ► The multidimensional functional and economic evaluation will be investigated to understand AEDH management better.
- ► Any clinical findings of the trial are helpful for further clarifying the surgical management of AEDH.

INTRODUCTION

Traumatic brain injury (TBI) remains one of the most challenging global public healthcare problems, although developments in TBI management have led to enhanced outcomes over the past decades.[1 2] As a common type of TBI, the incidence of acute epidural haematoma (AEDH) reports in the range of approximately 2%–4%,[3–5] and occurs in 14%–35% of patients with a severe TBI.[6 7] AEDH is caused by blood collection between the skull and dura mater and is mainly attributed to skull fracture with rupture of the middle meningeal artery (MMA) or its branches.[8] AEDH occurs more frequently in young people, with a mean age between 20 and 40 years.[3 6 9] Older adults rarely suffer from AEDH but have significantly higher mortality.[10 11]

Vehicle-related accidents are the most common reasons for AEDH, accounting for 53% (range, 30%–86%) of all AEDH, followed by other causes include falls, assaults, sports injuries and so on.[3] Rapid disease progression may lead to brain herniation, a potentially lethal problem requiring immediate operative management.[3 8 12] Previous studies

indicated mortality of isolated AEDH ranges from 1.2% to 33%.[13 14] Rapidly developed prehospital TBI management and the widespread use of CT examination have caused a decline in mortality of surgically treated epidural haematomas. However, the mortality is still relatively higher in patients with comatose.[5 11 15] AEDH remains a significant cause of morbidity and mortality among TBI.[16]

The Brain Trauma Foundation has produced an informative guideline on the management of AEDH that all patients with an AEDH volume of greater than 30 cm^3 should be surgically evacuated regardless of the Glasgow Coma Scale (GCS).[3] The treatable nature of AEDH has led some authors to suggest that 'toward zero mortality' is an achievable target since the expeditiously surgical evacuation of AEDH is an attainable gold standard and often expects an excellent clinical outcome.[17] However, conflicts exist in the specific management. After an initial craniotomy with AEDH evacuation, some patients suffered from clinical deterioration, such as cerebral infarction (CI), due to a sharp increase in intracranial pressure (ICP) postoperatively. An initial haematoma evacuation with decompressive craniectomy (DC) in these cases may decrease ICP, and prevent or alleviate postoperative CI, and finally, get a better outcome. Nevertheless, relatively low incidence of postoperative CI for AEDH leads to fewer surgeons choosing DC. In addition, lack of high-quality evidence for benefit leads to indefinite indications for adopting DC in AEDH and results in broad practice variation between hospitals, countries, and even between surgeons within a hospital. Besides, key issues such as the association between timing of surgery and outcome, and identification of subgroups that do not benefit from surgery, need further investigation.

No specific evaluation on the necessity of DC in AEDH was performed in prospective clinical trials. Several sporadic and retrospective studies on AEDH in China indicated the incomplete status of surgical management of AEDH during past decades, but specialised, extensive sample size studies remain absent. Therefore, we present a multicentre prospective, observational study of surgical strategies for AEDH, based on a real-world design called Prospective, Observational Real-world Treatments of AEDH in Large-scale Surgical Cases (PORTALS-AEDH).

METHODS AND ANALYSIS

Study objectives

We aim to evaluate the outcomes of different surgical managements for patients with AEDH, mainly DC and craniotomy. Furthermore, incidence, cost-effectiveness, complications and management variation of surgical treated AEDH in China are concerned.

Study design

This is a multicentre prospective observational cohort study using a real-world comparative effectiveness research design. Two hundred and sixty-three centres from 30 provinces in China will participate, ensuring the required number of patients with different surgical treatments for AEDH. Before patients formally enrolled, we performed a set of questionnaires about the hospital's scales and the amount of surgical patients with AEDH in the last years among centres. According to an incomplete data set, more than 2000 patients who presented AEDH as the leading cause of operation received surgical treatments. All centres will conduct recruitment for two straight years to fully reflect the population. Each participant will be followed up for half a year by researchers. Follow-up data and clinical information relating to the participants, including diagnosis of AEDH, radiological information and treatment procedures, are collected in detail. The data are then analysed statistically. The study flowchart is provided in figure 1. Moreover, table 1 summarises the study assessment schedules.

Study population

Recruitment was started in April 2021 and anticipates to be completed by May 2023, with an anticipated sample size of 2000 patients. The last half a year follow-up assessment will anticipate to stop on November 2023. Patients of both genders presenting to the emergency room of participating centres with a clinical and radiological diagnosis of AEDH are eligible for inclusion. Only eligible patients, determined by participating senior neurosurgeons of the centre, can be recruited. The inclusion and exclusion criteria are as follows.

Inclusion criteria

- Patients aged from 18 to 65 years.
- Clear medical history of TBI.
- Within 12 hours after injury.
- Supratentorial unilateral AEDH on first head CT scan examination.
- The admitting neurosurgeon considers that the epidural haematoma must be evacuated with surgical treatment.
- With informed consent to surgery and trial participation.

Exclusion criteria

- Previous intracranial surgery prior to the trauma.
- Patients with a score of 3 on the GCS, with bilateral fixed and dilated pupils, bleeding diathesis or defective coagulation, or an injury that was deemed to be unsurvivable.
- CT demonstrates associated other intracranial haematomas for example, subdural, intracerebral haemorrhage or large size infarction, which are the leading causes of operation.
- Patients who had injury of the oculomotor nerve.
- Severe pre-existing disability or severe comorbidity would lead to a poor outcome even if the patient is supposed to a good recovery from the TBI.
- Pregnant female.

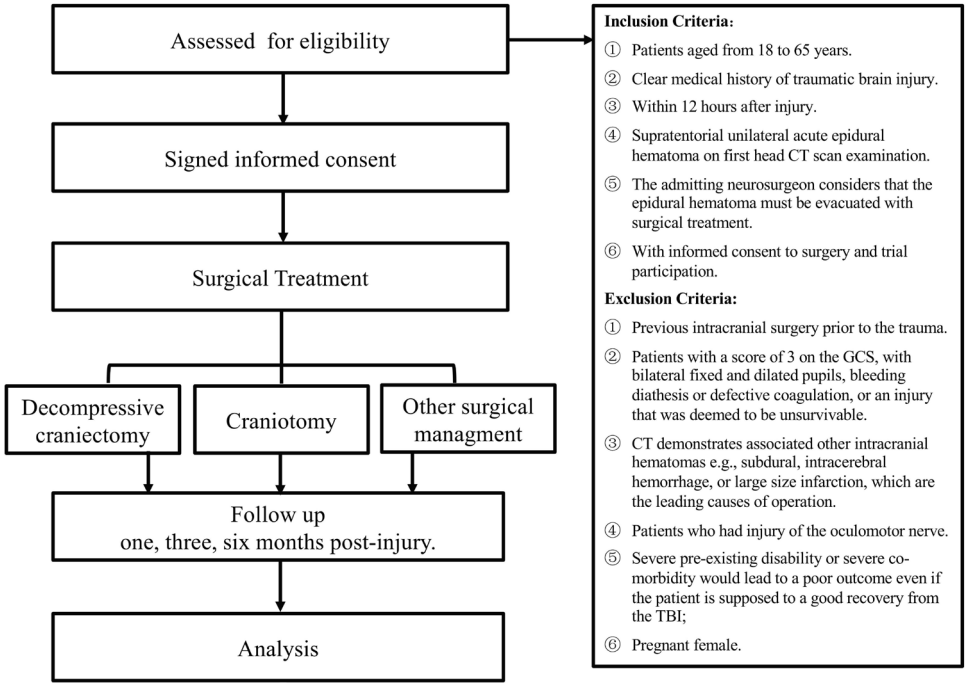

Figure 1 Study flow chart. GCS, Glasgow Coma Scale; TBI, traumatic brain injury.

Treatment strategies

All management strategies should proceed according to local emergency and intensive care protocols or the surgeon's expertise. According to guidelines for the surgical management of TBI and AEDH, conventional strategies consist of evacuating the haematoma using craniotomy, with or without DC.[3 18] A DC can be undertaken in patients with comatose with substantial mass effect, and this can manifest as midline shift with or without herniation. Significantly, DC is mainly related to elevated ICP and possibly increasing brain swelling in patients with comatose with an AEDH. DC refers to removing a large bone flap and opening the underlying dura to control brain swelling and raised ICP. The incision begins from the point below the upper edge of the zygoma and just anterior to the tragus as described above,

Table 1 Time and events table of the study procedure

	Enrollment	Operation	Discharge	Follow-up			Adverse effects and other operation
Timepoints	**Day 0**	**Day 0**	**At discharge**	**1 month post-injury**	**3 months post-injury**	**6 months post-injury**	**Within 6 months post-injury**
Informed consent	X						
Eligibility	X						
Information of enrollment	X						
Patient information	X						
Medical history	X						
Surgery notes		X					X
Physical and neurological examination	X	X	X	X	X	X	
Imaging	X	X	X	X	X	X	X
ICP management		X					
GOSE			X	X	X	X	
LOS			X	X	X	X	
Treatment cost			X	X	X	X	
MMSE				X	X	X	
EQ-5D-5L				X	X	X	

EQ-5D-5L, 5-level EuroQol five dimensions questionnaire; GOSE, Glasgow Outcome Score-Extended; ICP, intracranial pressure; LOS, length of stay; MMSE, mini-mental state examination.

but follows a 'question mark' shape curving around the upper edge of the pinna and extending backward and upwards before returning to the frontal area, with a short extension towards the contralateral side, staying behind the hairline. The standard 'question mark' incision provides adequate access for hemispheric decompression in most patients.[19] The operation will be performed by qualified senior neurosurgeons with sufficient surgical skills from each participating centre.

The postoperative care and examination, for example, the radiographic or biochemical examination, is generally approached according to local management protocol. Treatment for complications of primary injury or initial surgery will differ considerably between patients. Commonly, cranioplasty is recommended to reconstruct the skull for patients who adopted DC before. Early complications, for example, epilepsy or CI, and late complications, for example, hydrocephalus, will accept appropriate treatment. In a word, an objectively real-world treatment situation of AEDH is fully reflected as far as possible. Participants' normal management process and medical decisions will not be affected by being recruited into the PORTALS study.

Outcome measures

The primary outcome is the Glasgow Outcome Score-Extended (GOSE) at 6 months post-injury, indicated by the long-term functional outcomes, including overall mortality and morbidity rates.[20 21]

Additionally, the following secondary outcomes are investigated as supplementary functional and cognitive measures:

1. The incidence of traumatic AEDH postoperative CI within 6 months post-injury, which independent radiologists primarily diagnose with CT or MRI examination.
2. The incidence of additional craniocerebral surgery within 6 months post-injury, related to clinical deterioration after initial surgical treatment of AEDH.
3. The incidence of serious adverse events (SAEs) within 6 months post-injury.
4. The duration of hospitalisation after initial surgery within 6 months post-injury, including intensive care unit (ICU) and hospital stays.
5. Total medical expense related to the treatment of AEDH, including the costs of operations, hospitalisation and rehabilitation within 6 months post-injury.
6. Quality of life at 6 months post-injury with the score of 5-level EuroQol five dimensions questionnaire (EQ-5D-5L), which is a generic instrument for describing and valuing health in terms of five dimensions: mobility, self-care, usual activities, discomfort and anxiety.
7. Mini-mental state examination (MMSE) scores 6 months post-injury.

Data collection

The local investigators will collect and record demographic and clinical information, including hospital admission, treatment process and follow-up. Detailed information includes the timing of injury (also the arrival in emergency room, initial CT and surgical operation), cause and mechanism of injury, neurological condition, radiographic abnormalities, operation, postoperative care management. Postoperative CT scan is performed routinely based on local management protocol. CI is initially detected on a postoperative CT image depicting a low-dense area. The blood supply of involved lobes is further detected by transcranial doppler sonography or MRI. Related radiographic data and neurological conditions will be recorded, and independent radiologists will diagnose CI. Follow-up visits in the outpatient department are scheduled at 1, 3 and 6 months after injury. The information recorded on case report form (CRF) will enter into an electronic data collection (EDC) database by a designated person at each participating centre. EDC is developed and maintained by an investigator independent of study in the Clinical Research Institute, Shanghai Jiao Tong University School of Medicine. Follow-up assessments mainly perform outpatient follow-up or telephone interviews, including clinical data such as GOSE, EQ-5D-5L, MMSE and imaging information.

Data management

All investigators participating in this study will comply with the requirements of the Data Protection Act 1998 about the collection, storage, processing and disclosure of personal information. Access to collated participant data will be restricted to approved individuals involved in the treating process and representatives of regulatory authorities. Computers used to input the data will set up user names and passwords with limited-access measures. Published results will not contain any personal data that could allow the identification of individual participants.

All data will be collected using CRFs and the EDC. The PORTALS will establish a data management committee (located at Renji Hospital) to supervise data quality. Clinical research associates (CRA) will regularly visit each participating centre to ensure that all programme contents are strictly followed. If not, the CRA promptly submits information to the investigators. All staff will try to avoid errors and data loss as much as possible to control information bias adequately. Every 6 months, this study holds a summary meeting to discuss and solve research questions and outcome measures informed by patients' priorities, experiences and preferences.

Limitation

The study's main limitation is the lack of a randomised surgical treatment assignment mechanism, which characterises how patient-level, physician-level and system-level characteristics influence the decision-making process regarding which treatment any given patient is assigned. Another limitation of the study is the absence of blinding of surgeons and participants to the treatment allocation. Moreover, this may bias the results due to differences in preference and expectations between the treatment

groups. Additionally, variation in management between different hospitals or surgeons will also bias the results.

Potential bias and data analysis

Relevant covariate information collection and statistical analyses have been designed to control potential selection, confounding and information bias. Precisely, to adequately control confounding bias, data collection must include factors related to both surgical treatment choice and the outcome of interest. Essential demographic characteristics of the patient, information on the scene of injury, emergency settings, physical examination, imaging examination and re-examination, including the haematoma location, volume, the largest thickness and midline shift, basal cisterns compression, traumatic subarachnoid haemorrhage, pupil dilatation, preoperative GCS score and vital signs in a different time, and intraoperative ICP are all recorded in CRF and EDC. To adequately control selection bias, data collection includes factors related to why certain patients participate in the analysis of the study and others do not, specifically, to record the relevant question of why some patients have complete data and others do not. All factors, which characterise patient-level, physician-level and system-level characteristics that influence the decision-making process are recorded.

Regression adjustment and propensity score analyses will be performed for statistical control of confounding bias. In addition, stratified analysis, sensitivity analyses and instrumental variable analysis will be performed depending on the situation. For statistical control of selection bias, the patients with missing data in the study population will be viewed, and multiple imputations may be applied. If necessary, inverse-probability weighting in which patients observed in the study analysis subsample may also be reweighted to reconstruct the original study population.

Patient characteristics, treatment and outcome variation will be described using descriptive statistics. Continuous variables were described as mean and SD or median and IQR. Appropriate tests will be employed according to distribution and scale of measurement to assess differences between cohorts. Student's t-tests or Mann-Whitney U tests are used for continuous variables, χ^2 tests or Fisher's exact test is used for categorical variables. The analyses for better characterisation of AEDH will be exploratory, aiming to understand the disease's complexity better and discover new associations. In addition to standard statistical descriptive, multivariable regression models or other analyses and subgroup analyses will be used as appropriate. A p value <0.05 (two-sided tests) will be taken as a threshold of statistical significance.

ETHICS AND DISSEMINATION

Ethics approval

The study protocol has been approved by the ethics committee and institutional review board of Renji Hospital, School of Medicine, Shanghai Jiao Tong University, research sponsored centre (No: Renji Lunshen KY2020-13). The majority of participating centres (n=247, 94%) have an independent department of medical ethics or committee approving the study, the remains (n=16, 6%) agree to accept the conclusion of the ethical review of the sponsored centre (Renji Hospital) and involve in the study based on the local administrative regulations.

The study investigators will strictly follow the Declaration of Helsinki and Human Biomedical Research Ethical Issues during the process. Any protocol modifications will be first submitted to the review board that might approve them before practice. Besides, if suppose participant dies or SAEs occur, the detailed record will be reported to the ethics committee and institutional review board of sponsored centres or participating centres and be investigated.

All enrolled participants are asked to provide signed informed consent to produce documentary evidence that they have received enough information about the clinical trial, the study interventions, participants' rights and voluntary wishes of participation. For patients, who could not be physically or mentally capable of consenting themselves, the legal representative usually refers to one of the family members or the closest relatives who can decide on behalf of the patient, is to be approached for the assent of participation in the trial or not. An independent staff from the local ethics committee and institutional review board will be asked for approval when no legal representative is available in due time. Meanwhile, participants are also informed that they could withdraw consent and quit at any moment during trial, without affecting their treatment process, only by communicating this decision with investigators first. However, all data collected up to the dropout point, including withdrawal, will be retained for use within analyses to adequately control selection bias.

Patient and public involvement

All patients or the public were not directly involved in the design or conduct of the study. The patient and their caregivers will be told that this study will take about 4 years to complete, and the developments of the study will be informed. The trial results will be disseminated through academic conferences and published in peer-reviewed journals. After the study results are published, investigators will inform patients and their caregivers by telephone or email immediately.

DISCUSSION

The PORTALS-AEDH study is the largest project exploring surgical managements of AEDH nationwide in terms of the epidemiological characteristic and analysis of the differences in management with the outcome, and so on. In particular, this study compares the effectiveness of two surgical treatments for AEDH, craniotomy and DC.

There is controversy concerning the initial neurosurgical management of AEDH.[4 22 23] Neurosurgeons are confronted by the decision to evacuate the haematoma with or without a DC in some cases, especially for

patients with brain herniation.[24 25] More interestingly, for possible delayed haematoma development, in addition to surgery, MMA endovascular coil embolisation has the potential role.[26–28] This suggests that management of AEDH deserves further investigation under complex disease conditions. The incidence of post-traumatic CI secondary to AEDH was reported to be 18.2%, which was even higher among patients with high-risk factors, for example, transtemporal location, preoperative shock for longer than 30 min.[3 25 29] Factors associated with outcome and the incidence of post-traumatic CI of surgically treated patients with AEDH need further exploration and confirmation. DC has shown potential in controlling raised ICP, which is recommended as soon as possible in post-traumatic severe CI secondary to AEDH.[25 29–33] However, previous clinical practice indicates that the removal of the bone flap is not always essential in many patients with AEDH.[5 10] DC performed inappropriately with initial haematoma-evacuation might lead to unavoidable complications, such as abnormal haemodynamics, subsequent cerebral necrosis and infarction, as well as a need for cranioplasty.[30 34]

Although there is no consensus on if and when to proceed with DC in the management of AEDH, concerns regarding the application of DC deserve more investigation.[31] As of now, there is no available data in the literature about cost, mortality and management variation for surgically treated patients with AEDH in China. The advantage of different surgical management remains unproven. Managements variability between centres is far from clear. China is a large country with broad population distribution and general primary hospitals. Fastly accurate diagnosis, correct and effective management of AEDH is principal for medical workers of primary hospitals. Therefore, there is a clinical rationale to investigating variation in management of AEDH in current surgical practice patterns to improve the current situation of lack of available evidence.

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Contributors JF and JJ are the primary investigators, proposed and initiated PORTALS-AEDH, defined the research strategy. CY, LX and JF contributed substantially to conception and design of the study, and drafting of the manuscript. JH helped to draft the manuscript and revised the manuscript for important intellectual content.

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Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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