INPLASY PROTOCOL

To cite: Li et al. Comparison of the efficacy and safety of preinjury use of new oral anticoagulants with traditional oral antithrombotics in patients with TBI: A Systematic Review and Meta-analysis. Inplasy protocol 202250107. doi: 10.37766/inplasy2022.5.0107

Received: 16 May 2022

Published: 16 May 2022

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Support: **2019Y9045.**

Review Stage at time of this submission: **Piloting of the study selection process.**

Conflicts of interest:
None declared.

Comparison of the efficacy and safety of preinjury use of new oral anticoagulants with traditional oral antithrombotics in patients with TBI: A Systematic Review and Meta-analysis

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Review question / Objective: **P:traumatic brain injury patients with preinjury use of all kinds of anticoagulants; I:preinjury use of new oral anticoagulants (NOAs); C:preinjury use of traditional oral antithrombotics (OATs); O:the outcomes of traumatic brain injury patients; S:observational studies.**
Condition being studied: **More than half of the current TBI patients are older than 50 years old, most of these patients have been taking anticoagulants before injury, previous studies have reported traditional oral antithrombotics (OATs) can cause the ICH expansion, with the release of several novel oral anticoagulants (NOAs). different types of anticoagulant prognosis has not been systematically evaluated.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 May 2022 and was last updated on 16 May 2022 (registration number INPLASY202250107).

INTRODUCTION

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METHODS

Participant or population: Traumatic brain injury patients with preinjury use of all kinds of anticoagulants.

Intervention: Preinjury use of new oral anticoagulants（NOAs）.

Comparator: preinjury use of traditional oral antithrombotics（OATs）.

Study designs to be included: Studies were included if they compared the prognostic outcomes of TBI(head abbreviated injury score (AIS) ≥ 3, and all other AIS < 3) patients who took novel anticoagulants(NOAs) or traditional oral antithrombotics（OATs）,New anticoagulants include: Rivaroxaban or Dabigatran, Traditional anticoagulants include warfarin and clopidogrel, The review did not include studies without prognostic analysis or treatment with anticoagulant drugs after injury or non-brain injury patients or pediatric patients,Case reports and letters were also excluded.

Eligibility criteria: Studies were included if they compared the prognostic outcomes of TBI(head abbreviated injury score (AIS) ≥ 3, and all other AIS < 3) patients who took novel anticoagulants(NOAs) or traditional oral antithrombotics（OATs）,New anticoagulants include: Rivaroxaban or Dabigatran,Traditional anticoagulants include warfarin and clopidogrel,The review did not include studies without prognostic analysis or treatment with anticoagulant drugs after injury or non-brain injury patients or pediatric patients,Case reports and letters were also excluded.This review will be grouped with different prognostic outcomes, Drug efficacy and safety were also analyzed according to their different outcomes, Finally, a subgroup analysis was performed according to the primary outcome.

Information sources: We conducted a search of the MEDLINE and EMBASE databases, and the Cochrane Central Register of Controlled Trials (Central), covering the periods from their inception to June 2022.

Main outcome(s): We grouped according to different prognosis,such as Progression of ICH, Reversed or death

Quality assessment / Risk of bias analysis: We used the criteria for reporting observational studies proposed in the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement to complete a methodological evaluation of the included observational studies.Although all the studies noted the inclusion criteria and outcome definition, still some studies lack of adjustment for confounders, also indicating a risk of bias. Therefore, the high quality studies that meet all the items of the STROBE criteria and have large sample size will be required.

Strategy of data synthesis: According to our pre-established eligibility criteria, 2 reviewers (L.Z. and M.S.) independently reviewed all citations and selected eligible studies using a standardized data abstraction form. Disagreements were resolved by consensus. The data extracted from studies meeting the inclusion criteria included the name of the first author, year of publication, study design, demographic data of the patients, severity of injury (such as injury severity score (ISS)),Glasgow Coma Scale (GCS), outcomes of the prognosis (such as Progression of ICH, Reversed or death) In instances of duplicate reporting, we used data from the study that included the largest number of patients, or, when available, individual patient data from each study. We contacted authors for clarification on study samples or for missing data.

Subgroup analysis: This review will be grouped with different prognostic outcomes, Drug efficacy and safety were also analyzed according to their different

outcomes, Finally, a subgroup analysis was performed according to the primary outcome.

Sensitivity analysis: If significant heterogeneity is found, change the analysis model by one, exclude the literature and use stata software to perform trim and filling method.

Country(ies) involved: China.

Keywords: TBI, traumatic brain injury, brain injury, intracerebral hemorrhage, intracerebral hematoma,Hematoma expansion, Glasgow outcome scale, Novel oral anticoagulants , Anticoagulants, Warfarin.

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