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The Role of Dual Antiplatelet Therapy with Indobufen as Background Therapy in Coronary artery disease: a meta-analysis

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ADMINISTRATIVE INFORMATION

Support - NA.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120009

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 December 2023 and was last updated on 02 December 2023.

INTRODUCTION

Review question / Objective Population: Dual antiplatelet therapy (DAPT) with aspirin in combination with a platelet P2Y12 receptor inhibitor is a cornerstone in the prevention of cardiac and systemic ischaemic events in patients with coronary artery disease. Although indobufen is recommended as an alternative to aspirin intolerance, the safety and efficacy of DAPT with Indobufen as background therapy in the prevention of cardiac and systemic ischaemic events in patients with coronary artery disease remain unclear.

Intervention: This meta-analysis aimed to investigate the safety and efficacy of DAPT with indobufen in combination with a platelet P2Y12 receptor inhibitor in the prevention of cardiac and systemic ischaemic events in patients with coronary artery disease.

Comparison: DAPT with indobufen in combination with a platelet P2Y12 receptor inhibitor compared with DAPT with asiprin in combination with a platelet P2Y12 receptor inhibitor.

Outcome: randomized trials comparing oral antiplatelet agents in patients with coronary artery disease. Results that will be combined show for all adverse events, ischaemic events, haemorrhagic events and gastrointestinal adverse events.

Study design: randomized trials comparing oral antiplatelet agents in patients with coronary artery disease.

Rationale This study assessed the safety of dual antiplatelet therapy with indobufen as background therapy by pooling the results of existing randomized controlled trials. The results are expected to provide additional references and evidence for clinical application. As coronary artery disease continues to increase, the search for more

effective and safe treatment options is important to reduce patient risk and improve patient quality of life.

Condition being studied Dual antiplatelet therapy (DAPT) with aspirin in combination with a platelet P2Y12 receptor inhibitor is a cornerstone in the prevention of cardiac and systemic ischaemic events in patients with coronary artery disease. Although indobufen is recommended as an alternative to aspirin intolerance, the safety and efficacy of DAPT with Indobufen as background therapy in the prevention of cardiac and systemic ischaemic events in patients with coronary artery disease remains unclear. This meta-analysis aimed to investigate the safety and efficacy of DAPT with indobufen in combination with a platelet P2Y12 receptor inhibitor in the prevention of cardiac and systemic ischaemic events in patients with coronary artery disease.

METHODS

Search strategy A search strategy for the entire study was developed by Ke Xiao, and two authors (Yi Ming and Lu Wu) independently searched the PubMed, Web of Science, Embase, and Cochrane databases to identify relevant studies that had been published as of Oct, 2023. The search keywords were "Indobufen", "Ibostrin", and "K-3920". Post-search literature was screened, and references to included studies were manually searched for additional relevant publications.

Participant or population Coronary artery disease patients oral antiplatelet agents.

Intervention Dual antiplatelet therapy with indobufen as background therapy.

Comparator DAPT with indobufen in combination with a platelet P2Y12 receptor inhibitor compared with DAPT with asiprin in combination with a platelet P2Y12 receptor inhibitor.

Study designs to be included Randomized trials comparing oral antiplatelet agents in patients with coronary artery disease.

Eligibility criteria The aim of this review was to include only randomised controlled trials. Patients with Coronary artery disease who oral antiplatelet agents were recruited in randomised controlled trials. Studies were included if they met the following criteria: Inclusion criteria (1) Study design: randomized controlled trial (RCT); (2) Study population: all diagnosed with coronary artery disease (Pathological conditions involving the CARDIOVASCULAR SYSTEM including the HEART; the BLOOD VESSELS; or the PERICARDIUM), patients were of any gender and age; (3) Interventions: the trial group was given indobufen combination with P2Y12 receptor inhibitors, the control group was given clopidogrel monotherapy, aspirin monotherapy, aspirin combination with P2Y12 receptor inhibitors therapy. studies were excluded if they met the following criteria: (1) literature using other indicators of efficacy evaluation; (2) healthy volunteers in the control group (3) incomplete data from the experimental sample; (3) duplicate published literature (4) Pharmacokinetic studies; (5) Meta-analyses, reviews (7) Not reveal the random control details.

Information sources PubMed, Embase, Cochrane Library, Web of Science, Clinical Trials.gov, and CNKI were searched systematically, all from the time of database creation to 10, 2023.

Main outcome(s) Incidence of endpoint events such as death of cardiovascular origin, non-fatal myocardial infarction, non-fatal stroke, restenosis, thromboembolism, haemorrhagic and gastrointestinal reactions.

Additional outcome(s) NA.

Data management Yi Ming and Lu Wu extracted data from the included articles independently using electronically extracted files based on predefined standardizations. The following information was extracted from each of the articles used in the final review: investigator, year of study, study design, number of participants, mean age, type of treatment, duration of follow-up, RR, and concomitant 95% confidence intervals, and information on the cases reported in the intervention group and the case–control group. We contacted the corresponding authors when the univariate or multivariate HR was not reported. Studies were excluded if additional information could not be provided.

Quality assessment / Risk of bias analysis The Revman tool was used to assess the study quality of all of the included full-text articles. We looked at 1) random sequence generation, 2) allocation concealment, 3) participant and personnel blinding, 4) outcome assessment blinding, 5) incomplete outcome data, 6) selective reporting, and 7) other potential sources of bias.

Strategy of data synthesis RR or case data from the intervention and control groups were used to analyze dichotomous data. Heterogeneity among

studies was assessed using the Cochrane Q test and I2 test. When I2 > 30% or P<0.05 indicated considerable heterogeneity, sensitivity and subgroup analyses were performed to determine the effect of each study on the overall outcome. A random effects model was used to obtain pooled estimates. A funnel plot and Egger's test were used to assess potential publication bias. There are various analytical methods for estimating the accuracy of the comprehensive tests. Statistical analysis was performed using Stata software version 16 (StataCorp LLC, 4905 Lakeway Drive, College Station, Texas), and p 0.05 was considered statistically significant.

Subgroup analysis We conducted a subgroup analysis according to two dual antiplatelet regimens (indobufen combination with clopidogrel VS aspirin combination with clopidogrel therapy).

Sensitivity analysis Heterogeneity among studies was assessed using the Cochrane Q test and I2 test. When I2 > 30% or P<0.05 indicated considerable heterogeneity, sensitivity and subgroup analyses were performed to determine the effect of each study on the overall outcome.

Language restriction NA.

Country(ies) involved China.

Keywords Dual Antiplatelet Therapy; Indobufen ;Coronary artery disease.

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