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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Data analysis.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120053

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 December 2023 and was last updated on 13 December 2023.

INTRODUCTION

Review question / Objective We conducted a systematic review and network meta-analysis to evaluate the comparative efficacy of potassium-competitive acid blockers (P-CABs) and proton-pump inhibitors (PPIs) for healing erosive esophagitis (EE) patients. A subgroup analysis of patients with different baseline erosive grades would be also conducted, given that P-CABs could be more effective in patients with severe EE who could not benefit from PPIs. We ranked the efficacy on the 4- and 8-week healing rate of each treatment to help establish evidence-based hierarchies. In addition, the pooled 4- and 8-week healing rates were compared, in order to determine the optimal main outcome as well as the appropriate treatment course.

Condition being studied Proton-pump inhibitors (PPIs) and potassium-competitive acid blockers (P-CABs) are recommended for Erosive esophagitis (EE), with good safety and tolerance. The confirmed safety and tolerance of PPIs and P-CABs has been demonstrated in clinical practice. However, the comparative efficacy of P-CABs and PPIs for healing EE patients are not determined.

METHODS

Participant or population Patients with Erosive esophagitis (EE). Exclude refractory EE or resistance to previous PPIs treatment.

Intervention Placebo, and drugs included either Proton-pump inhibitors (PPIs) or potassium-competitive acid blockers (P-CABs) PPIs or P-CABs administered with the standard or double-dose.

Comparator Placebo, and drugs included either PPIs or P-CABs administered with the usual dosage.

Study designs to be included Randomized controlled trials.

Eligibility criteria (1) Patients: patients with EE. Exclude refractory EE or resistance to previous PPIs treatment. (2) Interventions and comparisons: placebo, and drugs included either PPIs or P-CABs administered with the usual dosage. (3) Outcomes: 4- or 8-weeks healing rate. (4) Study design: only RCTs published in English. Studies were excluded if unpublished clinical trials or patients received combined therapy for EE, such as two types of PPIs.

Information sources PubMed, Embase, Web of Science, Cochrane Library, and Medline were searched for all years up to May 31, 2023.

Main outcome(s) 4- or 8-weeks healing rate.

Quality assessment / Risk of bias analysis The risk of bias was assessed using the Cochrane Risk of Bias Tool for randomized clinical trials.

Strategy of data synthesis The network meta-analyses were performed under the frequentist framework using Stata 13 software (StataCorp, College Station, TX, United States).

Inconsistency was assessed by global Wald χ^2 , with a P-value > 0.05 defined as no inconsistency, and the fixed-effects model was used; otherwise, a random-effects model with restricted maximum likelihood variance estimation was used. Pairwise odds ratios (ORs) and the 95% confidence interval (95% CI) were calculated to compare the efficacy of treatments. The surface under the cumulative ranking curve (SUCRA) was used to rank the efficacy of the treatments, and the larger SUCRA indicated the better efficacy of the treatment regimen. The funnel plot and Egger's test of the intercept were employed to assess indications of publication bias.

To control the impact of the proportion of severe EE at baseline on the outcomes, studies were included into the main analysis if: (1) they were originally conducted for both patients with and without severe EE at baseline; and (2) the proportion of severe EE at baseline included in the study was >10%. Sensitivity analysis was also conducted to examine the validity and robustness of the main analysis by using all studies which were originally conducted for both patients with and without severe EE at baseline. Subgroup analysis was conducted on the data of patients

with or without a severe EE baseline grade, which was defined as grade 3 or higher on the Hetzel-Dent or Savary-Miller scales, or grade C or D on the Los Angeles scale. If the study was originally conducted only for patients with or without severe EE at baseline, the data was only used in the subgroup analysis. The pooled 4- and 8-week healing rates were compared based on each treatment arm, via calculating OR and 95% CI.

Subgroup analysis Subgroup analysis was conducted on the data of patients with or without a severe EE baseline grade, which was defined as grade 3 or higher on the Hetzel-Dent or Savary-Miller scales, or grade C or D on the Los Angeles scale.

Sensitivity analysis Sensitivity analysis was also conducted to examine the validity and robustness of the main analysis by using all studies which were originally conducted for both patients with and without severe EE at baseline.

Language restriction English.

Country(ies) involved China.

Keywords erosive esophagitis, proton-pump inhibitors, potassium-competitive acid blockers.

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