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Safety and efficacy of everolimus-eluting stent versus zotarolimus-eluting stent: A meta-analysis of randomized controlled clinical trials and observational studies☆

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ABSTRACT

Background: The safety and efficacy of everolimus-eluting stent (EES) versus zotarolimus-eluting stent (ZES) are controversial both in randomized controlled clinical trials (RCTs) and observational studies. The aim of this study was to assess the safety and efficacy of EES versus ZES.
Methods: Pubmed, Embase, Cochrane database and www.clinicaltrials.gov updated to Mar 2014 with safety [major adverse cardiac events (MACE)], all-cause mortality, non-fatal myocardial infarction (MI), stent thrombosis (ST) and efficacy [target vessel revascularization (TVR), target lesion revascularization (TLR), target vessel failure (TVF), target lesion failure (TLF)] endpoints and follow-up of ≥12 months were identified.
Results: Data from 11,778 patients in 8 RCTs and 34,850 patients in 26 observational studies were included. In RCT studies, no evidence indicating that EES was safer or more efficacious than ZES. In observational studies, EES associated with a significantly lower risk for MACE (RR: 0.56, 95% CI: 0.46–0.69), ST (RR: 0.59, 95% CI: 0.45–0.78), TVR (RR: 0.61, 95% CI: 0.47–0.79), TLR (RR: 0.57, 95% CI: 0.38–0.83) and TLF (RR: 0.69, 95% CI: 0.50–0.93). The pooled data of RCTs and observational studies showed that compared to ZES, EES associated with a significant lower risk for MACE (RR: 0.65, 95% CI: 0.54–0.78), ST (RR: 0.66, 95% CI: 0.52–0.83), TVR (RR: 0.72, 95% CI: 0.58–0.89), TLR (RR: 0.63, 95% CI: 0.49–0.82) and TLF (RR: 078, 95% CI: 0.62–1.00).
Conclusions: In RCTs, EES and ZES showed comparable safety and efficacy, while in observational studies or pooled data, EES was safer and more efficacious than ZES.

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1. Introduction

Second generation drug-eluting stents (DES) have become the standard of care for patients undergoing percutaneous coronary intervention (PCI) in current clinical practice, and provide non-inferior safety and efficacy compared with first generation DES and bare metal stents [1]. Everolimus-eluting stents (EES) and zotarolimus-eluting stents (ZES) are the mainstay second generation DES initially approved by Food and Drug Administration. To date, numerous randomized controlled clinical trials and head-to-head comparative observational studies have been conducted to compare EES and ZES with respect to safety and efficacy both in short or long-term follow-up. However, the relative results still remain controversial [2–7]. Therefore, we performed a comprehensive meta-analysis of both randomized controlled clinical trials (RCTs) and observational studies to compare the safety and efficacy of EES with ZES in patients undergoing PCI.

2. Methods

2.1. Eligibility criteria

We searched several sources for published/presented studies, including Pubmed, Embase, the Cochrane database and www.clinicaltrials.gov updated to Mar 7, 2014. A broad search strategy was used to search for studies we need. The keywords were "everolimus-eluting stent" or "everolimus", "zotarolimus-eluting stent" or "zotarolimus" with slight modifications based on the source. We also checked the reference lists of review articles, meta-analyses, and

Abbreviations: EES, everolimus-eluting stent; ZES, zotarolimus-eluting stent; RCTs, randomized controlled clinical trials; MACE, major adverse cardiac events; MI, myocardial infarction; ST, stent thrombosis; TVR, target vessel revascularization; TLR, target lesion revascularization; TVF, target vessel failure; TLF, target lesion failure; DES, drug-eluting stents; ARC, academic research consortium; RR, risk ratio; CI, confidence interval

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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original studies identified by the electronic searches to find other eligible trials. There was no language restriction for the search.

Eligible trials had to fulfill the following criteria: (1) randomized clinical trials or observational studies comparing the outcome of the above stents (ZES vs EES); (2) at least 12 month follow-up period; and (3) ability to report the outcomes of interest (below).

2.2. Study endpoints

The safety endpoints chosen for this analysis including major adverse cardiac events (MACE), all-cause mortality, non-fatal myocardial infarction (MI), and stent thrombosis (ST). The efficacy endpoints chosen for this analysis were included target vessel revascularization (TVR), target lesion revascularization (TLR), and target vessel failure (TVF) and target lesion failure (TLF).

2.3. Selection and quality assessment

Two authors (GHQ, HK) independently assessed study eligibility, bias risk and extracted data. Discrepancies were discussed with a third researcher (WY) to get a mutual agreement. For RCT studies, the bias risk of trials was assessed with the components recommended by the Cochrane Collaboration: Sequence generation of the allocation; allocation concealment; blinding of participants, personnel, and outcome assessors; incomplete outcome data; selective outcome reporting; and other sources of bias.

2.4. Data extraction and synthesis

Long-term (≥12 month) efficacy and safety outcomes were evaluated. Safety outcomes including MACE, all-cause mortality, MI, and ST. Three types of stent thrombosis were evaluated: "Any" stent thrombosis (based on trial stent thrombosis definition), Academic Research Consortium (ARC)-defined "definite" or "probable" stent thrombosis, and ARC-defined "definite" stent thrombosis. Efficacy outcomes including TVR, TLR, TVF and TLF.

2.5. Statistical analyses

Risk ratio (RR) and 95% confidence interval (CI) were employed as the metric of choice for all outcomes. Cochrane test was used to assess heterogeneity across studies. Also, we calculated the I^2 statistic to measure the consistency between trials with values of 25%, 50%, and 75% representing low, moderate, and high degrees of heterogeneity,

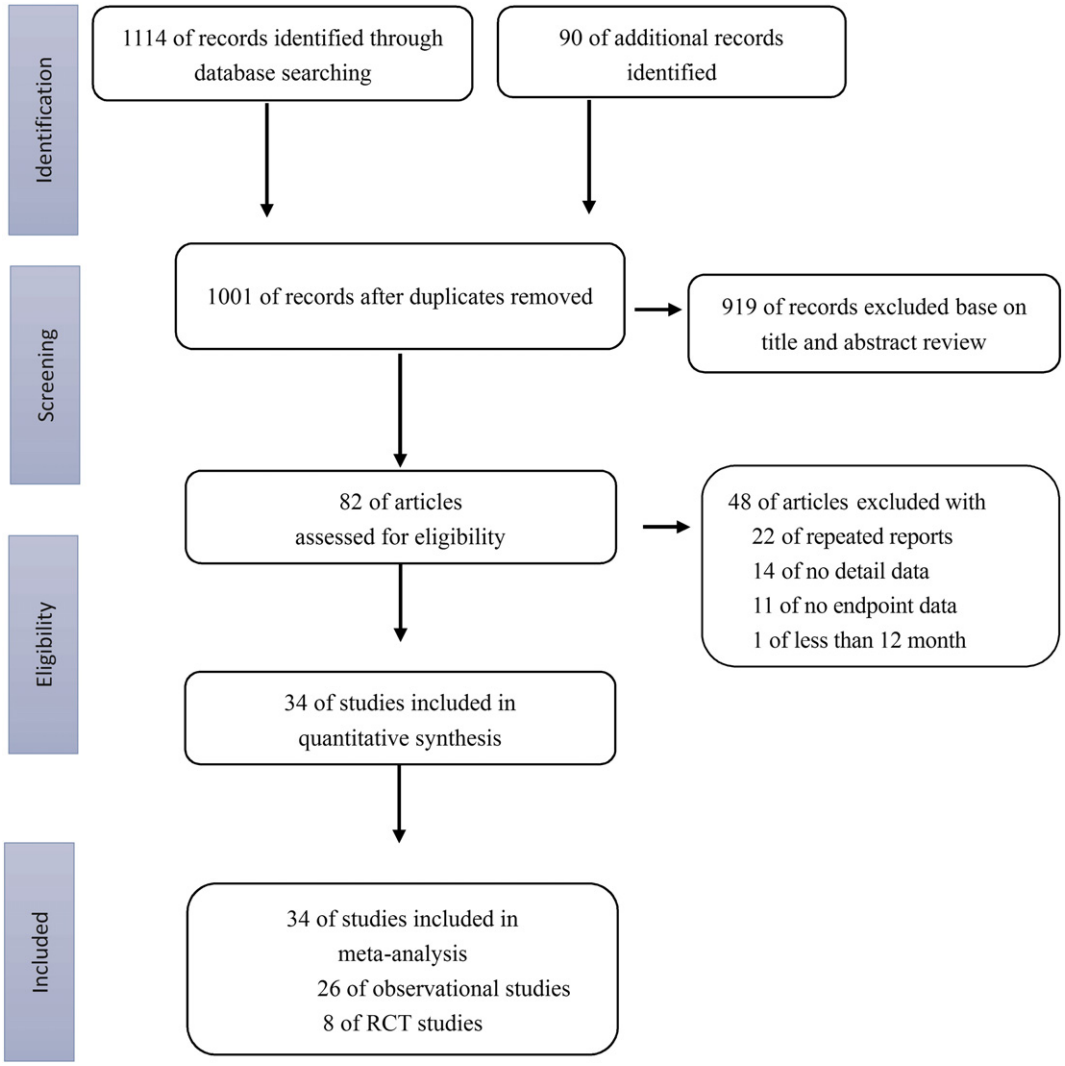

Fig. 1. Flow chart showing the reference searches of articles included in meta-analysis.

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