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ORIGINAL ARTICLE

Biodegradable Polymer DES Versus Durable Polymer Everolimus-eluting Stents for Patients Undergoing PCI: A Meta-analysis

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Background Everolimus-eluting stents are associated with low risk of stent thrombosis and stent restenosis, and the new generation of stents with biodegradable polymer were designed to reduce that risk. However, the benefits have been variable.

Methods and results Four RCTs with a total of 8282 patients were included. Overall, BP-DES was not inferior to EES with equivalent risk of TVR (relative risk [RR], 1.07; 95% confidence interval [CI], 0.91–1.27; $P = 0.414$; $I^2 = 0.0\%$) and ARC definite and/or probable ST (RR, 1.06; 95% CI, 0.66–1.70; $P = 0.810$; $I^2 = 4.8\%$). Furthermore, there was no difference in all-cause mortality (RR, 1.06; 95% CI, 0.84–1.33; $P = 0.651$; $I^2 = 0.0\%$), myocardial infarction (RR, 1.12; 95% CI, 0.88–1.44; $P = 0.360$; $I^2 = 0.0\%$), and MACE (RR, 1.00; 95% CI, 0.87–1.15; $P = 0.975$; $I^2 = 0.0\%$) between the two groups.

Conclusions The new generation of biodegradable polymer stents were not inferior to EES for equivalent risk of MACE and ST.

Keywords Biodegradable polymer • Everolimus-eluting stent • Target vessel revascularisation • Stent thrombosis • Percutaneous coronary intervention

Introduction

Everolimus-eluting stents, which utilise a thinner cobalt chromium alloy and a thinner and more biocompatible polymer layer, were associated with significantly lower rates of definite ST than BMS (OR 0.35, 95% CI 0.17–0.69) and PES (OR 0.34, 95% CI 0.19–0.62) [1], and marked reduction in the risk of repeat revascularisation (OR 0.85, 95% CI 0.71–1.00) and ST (OR 0.68, 95% CI 0.45–1.02) compared to SES [2]. Despite these improvements, there are still limitations, particularly in regards to prolonged dual-antiplatelet therapy (DAPT) and increased incidence of Academic Research Consortium (ARC) definite very late (≥1 year) ST [3], which is related to the pathological effects of delayed healing, impaired endothelialisation, allergy, inflammation and the presence of polymers that do not erode [4].

The next generation of DES with biodegradable polymer, which can biodegrade after the conclusion of drug elution, may reduce the risk of in-stent restenosis and stent thrombosis [5]. Previous studies have found that biodegradable polymer DES had equivalent in-stent late loss at six months (0.10 ± 0.25 mm vs. 0.15 ± 0.34 mm, $P = 0.19$) and comparable risk of MACE when compared with EES at six months [6] and three years [7]. With recently accumulating evidence [8,9], we conducted this meta-analysis to evaluate the risk of ST, TVR and MACE for patients with coronary artery disease.

Methods

Data Sources and Searches Strategy

We searched MEDLINE (source, PubMed, 2005–May 2013), EMBASE (2005–May 2013), the Cochrane Controlled Clinical

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Trials Register Database (through May 2013), and the ClinicalTrials.gov Website (through May 2013) using the terms ''biodegradable polymer'', ''everolimus-eluting stent'', ''coronary artery disease'', ''stent thrombosis'', ''target vessel revascularization'', and ''percutaneous coronary intervention''. Manual reference checking of the bibliographies of all relevant articles was performed. No restrictions were applied.

Study Selection

We first conducted an initial screening of titles and abstracts. A second evaluation was based on full-text review. Trials were considered eligible if they met these criteria: (1) Study was a prospective RCT and conducted in patients undergoing PCI; (2) Intervention consisted of biodegradable polymer DES and EES therapy; (3) Outcome interests were ST, TVR, cardiac death, MI and MACE.

Data Extraction

Data extraction was performed by two independent reviewers (L.-X. S. and J. Z.) using a standard data-collection form, and disagreements were resolved by discussion. The details extracted were patient's characteristics, biodegradable polymer, study quality, clinical outcomes included Academic Research Consortium (ARC) definite and/or probable ST [10] and MACE (i.e., cardiac death, MI, TVR).

Quality Assessment

The principal components used for quality assessment were generation of random sequence, allocation concealment, blinding of outcome assessment, loss of follow-up, and selective outcome reporting. Quality assessment was undertaken independently by two reviewers (L.-X. S. and J. Z.).

Data Synthesis and Analysis

Results were analysed with STATA (version 12.0, Stata Corp., College Station, TX, USA) using the DerSimonian and Laird random-effects model [11]. On the intent-to treat basis, we calculated pooled relative risk (RR) for dichotomous outcomes with 95% confidence interval.

Heterogeneity was examined by the I^2 statistic and the chi-squared test. The value of $I^2 > 50\%$ was considered as a substantial level of heterogeneity. Statistical significance was set at the 0.05 level for both I^2 test for heterogeneity and Z-test for RR.

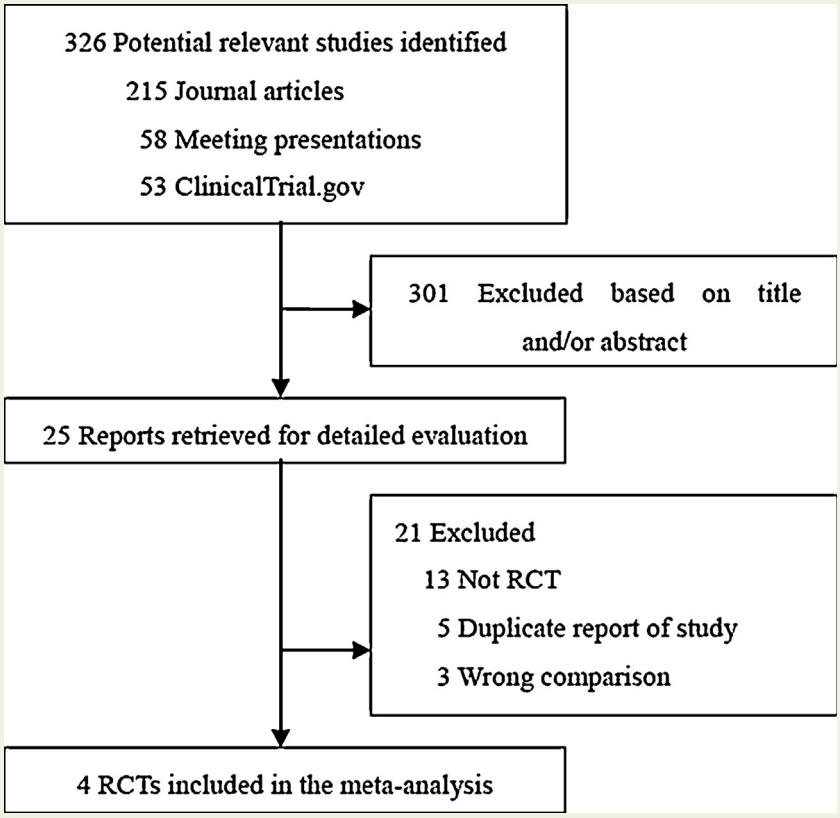

Figure 1 Flow chart of study selection. Flow chart shows the literature search for RCTs of biodegradable polymer DES versus durable polymer EES therapy for CAD. RCT = randomised controlled trial; DES = drug-eluting stent; EES = everolimus-eluting stent; CAD = coronary artery disease.