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A meta-analysis of randomized trials on clinical outcomes of paclitaxel-eluting stents versus bare-metal stents in ST-segment elevation myocardial infarction patients

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Abstract: A meta-analysis was performed to address the efficacy and safety of paclitaxel-eluting stent (PES) in ST-segment elevation myocardial infarction (STEMI) patients. A systematic literature search was conducted to identify all randomized clinical trials in mortality, recurrent myocardial infarction (rMI), repeat revascularization (RR), and stent thrombosis (ST). A total of 4190 STEMI patients were enrolled in six randomized trials comparing PES with bare-metal stent (BMS). The pooled repeat revascularization rate was 5.7% in PES group, significantly lower than 10.0% in BMS group with an odds ratio (OR) of 0.56, 95% confidence interval (CI) [0.44, 0.72] (P<0.00001). No significant difference was found between PES and BMS groups in mortality at one year after the indexing procedure (3.9% vs. 5.1%, OR 0.88, 95% CI [0.63, 1.21], P=0.42). Similarly, rMI rate did not differ significantly between the two groups (3.4% vs. 4.1%, OR 0.80, 95% CI [0.56, 1.13], P=0.21). PES was also associated with the comparable pooled rate of definite stent thrombosis with BMS (2.3% vs. 2.4%, OR 0.81, 95% CI [0.52, 1.26], P=0.35). The results show that PES improved clinical outcomes in STEMI patients with a decreased need for repeat revascularization and no concerns for safety.

Key words: Myocardial infarction, Paclitaxel-eluting stent, Bare-metal stent, Meta-analysis
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1 Introduction

Primary percutaneous coronary intervention (PCI) has currently been established as an optimal treatment strategy for ST-segment elevation myocardial infarction (STEMI) patients (Silber *et al.*, 2005; Smith *et al*., 2006). Though implantation of bare-metal stent (BMS) could effectively improve outcomes by decreasing the risk of reintervention, the development of in-stent restenosis remains a major reason for the limit of its use (Chen *et al*., 2006).

Since the introduction of drug-eluting stent (DES), registry studies and randomized trials have tried to evaluate the efficacy and safety of DES in STEMI cases (Spaulding *et al*., 2006; Daemen *et al*., 2007; Brodie *et al*., 2008; van der Hoeven *et al*., 2008). Compared to BMS, DES could be potentially good for reducing the risk of restenosis, but there is a concern that it may increase the incidence of thrombosis. A meta-analysis of 3605 STEMI patients demonstrated that DES was associated with a decreased risk in repeat revascularization (RR) in STEMI patients in comparison with BMS. No increased incidence of stent thrombosis (ST) was found (de Luca *et al*., 2009a).

Paclitaxel-eluting stent (PES), another widely-used DES, was also used in STEMI patients in recent trials (Di Lorenzo *et al*., 2005; Ilkka *et al*., 2006; Laarman *et al*., 2006; Pittl *et al*., 2006; Chechi *et al*., 2007; Stone *et al*., 2009). We performed a meta-analysis to address the long-term clinical efficacy of PES in STEMI patients, applying the definition for clinical endpoints in coronary stent trials set

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by the Academic Research Consortium (ARC) (Cutlip *et al*., 2007).

2 Materials and methods

In this study, we compared PES with BMS in STEMI patients in this study, as described in our previous analyses on the comparison between sirolimus-eluting stent (SES) and BMS (Pan *et al*., 2009). There is no conflict of interest statement declared.

2.1 Criteria for trial inclusion

The meta-analysis included randomized clinical trials that compared PES with BMS in STEMI patients followed up for more than six months.

2.2 Data sources and search strategy

We searched PubMed, EMBASE, ISI Web of Science, and the Cochrane Central Register of Controlled Trials for randomized trials comparing PES with BMS for the management of STEMI. Trials published only in abstract form and conference proceedings from the European Society of Cardiology (ESC), the American College of Cardiology (ACC), and the American Heart Association (AHA) were also searched and included. Relevant information of internet-based sources in cardiology (http://www.cardiosource.com, http://www.clincaltrials.gov, http://www.clinicaltrialresults.org, http://www.tctmd.com, and http://www.theheart.org) was identified and assessed for possible information on trials of interest. The assessment of pexelizumab in acute myocardial infarction (APEX-AMI), drug elution and distal protection in ST-segment-elevation myocardial infarction (DEDICATION), and facilitated intervention with enhanced reperfusion speed to stop events (FINESSE) trials were excluded because of no randomization assignment between PES and other DESs, such as SES and zotarolimus-eluting stent (Ad J van Boven *et al*., 2007; Kelbaek *et al*., 2008; Patel *et al*., 2009). The meta-analysis was fulfilled according to the standard protocol recommended by the Quality of Reporting of Meta-analyses Group (QUOROM) and the guidelines of Cochrane Handbook of Systematic Reviews of Interventions 4.2.6 (http://www.cochrane.org/resources/handbook/).

Searches covered publicly available studies until May 10th, 2009. Two reviewers were responsible for the extract of studies independently. Disagreements were resolved by consensus.

2.3 Clinical outcomes and definitions

Mortality, recurrent myocardial infarction (rMI), repeat revascularization (RR), and stent thrombosis (ST) were evaluated as clinical endpoints. RR referred to target lesion revascularization (TLR) and target vessel revascularization (TVR). TLR was defined as repeated PCI or bypass grafting of the target lesion and 5-mm segments immediately proximal and distal to the stent. TVR was defined as percutaneous or surgical revascularisation of the stented vessel. Definite ST was taken as ST in this meta-analysis. More specifically, the presence of an ischemic clinical symptom together with an angiographically confirmed thrombus involving the study stent was defined as ST in this meta-analysis (Cutlip *et al*., 2007; Pan *et al*., 2009).

2.4 Statistical analysis

RevMan software Version 4.2.8 (the Nordic Cochrane Centre, the Cochrane Collabration, Copenhagen, Denmark) was used for statistical analyses. The outcomes were summarized and compared as odds ratios (ORs) with 95% confidence intervals (CIs). Publication bias was assessed with funnel plots as well as the adjusted rank correlation test. Heterogeneity across studies was assessed by the Cochrane test. In the presence of significant heterogeneity, the pooled ORs were calculated with the DerSimonian and Laird random-effect models. Otherwise, Mantel-Haenszel method with a fixed-effect model was adopted for statistics. All P values were two-sided, and $P<0.05$ was considered significant.

3 Results

3.1 Eligible trials

Overall six randomized clinical trials comparing PES with BMS in STEMI patients were included. A total of 4190 patients were involved: 1344 for the BMS group and 2846 for the PES group (Di Lorenzo *et al*., 2005; Ilkka *et al*., 2006; Laarman *et al*., 2006; Pittl *et al*., 2006; Chechi *et al*., 2007; Stone *et al*., 2009). The main characteristics were summarized in Table 1.

Table 1 Main characteristics of the study trials

Trial	Design	Stent type	No. of patients			Facilitation	Medication of thienopyridine (month)
			BMS	PES	Total		
BASKET-AMI	R, SC	Taxus vs. Vision	74	67	141	The use of glycoprotein IIb/IIIa inhibitors was at the discretion of the physician	≥6
HAAMU-STENT	R, SC	Taxus Express vs. Liberté	82	82	164	All patients randomly received thrombolytic or abciximab previously	12
HORIZONS-AMI	R, MC	Taxus Express vs. Express	749	2257	3006	All patients randomly received heparin plus glycoprotein IIb/IIIa inhibitors or bivaludin alone	≥6
PASEO	R, SC	PES vs. BMS	90	90	180	All patients received glycoprotein IIb/IIIa inhibitors previously	12
PASSION	R, BC	Taxus Express2 vs. Express2/Liberté	309	310	619	The use of glycoprotein IIb/IIIa inhibitors was at the discretion of the operator	≥6
SELECTION	R, SC	Taxus vs. Express	40	40	80	All patients received abciximab	9

BASKET-AMI: Basel stent Kosten-Effektivitäts in acute myocardial infarction trial; HAAMU-STENT: Helsinki area acute myocardial infarction treatment re-evaluation—should the patient get a drug-eluting or a normal stent; HORIZONS-AMI: harmonizing outcomes with revascularization and stents in acute myocardial infarction; PASEO: paclitaxel- or sirolimus-eluting stent versus bare-metal stent in primary angioplasty; PASSION: paclitaxel-eluting stent versus conventional stent in myocardial infarction with ST-segment elevation; SELECTION: single-center randomized evaluation of paclitaxel-eluting versus conventional stent in acute myocardial infarction; R: randomized; SC: single-center; MC: multicenter; BC: bi-center; PES: paclitaxel-eluting stent; BMS: bare-metal stent

Four trials, including Helsinki area acute myocardial infarction treatment re-evaluation—should the patient get a drug-eluting or a normal stent (HAAMU-STENT), harmonizing outcomes with revascularization and stents in acute myocardial infarction (HORIZONS-AMI), the paclitaxel-eluting stent versus conventional stent in myocardial infarction with ST-segment elevation (PASSION), and single-center randomized evaluation of paclitaxel-eluting versus conventional stent in acute myocardial infarction (SELECTION), were two-arm designed studies. The other two trials, namely, Basel stent Kosten-Effektivitäts in acute myocardial infarction trial (BASKET-AMI) and paclitaxel- or sirolimus-eluting stent versus bare-metal stent in primary angioplasty (PASEO) trials, were three-arm designed studies (Di Lorenzo *et al*., 2005; 2009; Pittl *et al*., 2006). STEMI patients received implantation of PES, SES, or BMS randomly at a 1:1:1 ratio. HAAMU-STENT and HORIZONS-AMI trials both incorporated two-factorial randomized phases (Ilkka *et al*., 2006; Stone *et al.*, 2009). Before PCI procedure, all patients in HAAMU-STENT trial randomly received thrombolytic or abciximab, and all patients in HORIZONS-AMI trial randomly received heparin plus glycoprotein IIb/IIIa inhibitors or bivaludin alone. Glycoprotein IIb/IIIa inhibitors were medicated at the discretion of the doctor in BASKET-AMI and PASSION trials. All patients received glycoprotein IIb/IIIa inhibitors in PASEO and SELECTION trials (Laarman *et al*., 2006; Pittl *et al*., 2006; Chechi *et al*., 2007). In five trials which described the details of stents, Taxus serial products (Boston Scientific, Natick, MA, USA) were applied as PES (Ilkka *et al*., 2006; Laarman *et al*., 2006; Pittl *et al*., 2006; Chechi *et al*., 2007; Stone *et al.*, 2009). Four trials, including HAAMU-STENT, HORIZONS-AMI, PASSION, and SELECTION, took Express, Express2 or Liberté stents of the same platform as the control group (Ilkka *et al*., 2006; Laarman *et al.*, 2006; Chechi *et al.*, 2007; Stone *et al.*, 2009). Antiplatelet therapy with thienopyridine and indefinite aspirin was recommended after the indexing procedure. All patients were followed up for at least one year, except for the SELECTION trial with seven-month follow-up. Clinical follow-up was completed for 4071 (97.2%) patients.

3.2 Mortality

Fig. 1 shows the number of patients who died during the long-term clinical follow-up with the OR for each trial. None of the individual trials showed significant difference between patients who received PES or BMS. The overall mortalities in the PES and DES groups were 3.9% and 5.1%, respectively. No

statistical difference between the two groups was observed (OR 0.88, 95% CI [0.63, 1.21], P=0.42).

3.3 Recurrent myocardial infarction rate

The pooled rMI rates with PES and BMS were 3.4% and 4.1%, respectively. Our pooled estimates did not demonstrate significant difference (OR 0.80, 95% CI [0.56, 1.13], P=0.21) (Fig. 2).

3.4 Repeat revascularization rate

The available five TVR rates and one TLR rate resulted in 5.7% of pooled RR rate in the PES group. In comparison with 10.1% of RR rate in the BMS group, patients in the PES group were associated with a significant reduction in the risk of revascularization with an OR of 0.56 (95% CI [0.44, 0.72], P<0.00001) (Fig. 3).

3.5 Stent thrombosis rate

The ST rates were 2.3% in the PES group and 2.4% in the BMS group. No significant difference was found between the two groups (OR 0.81, 95% CI [0.52, 1.26], P=0.35) (Fig. 4).

3.6 Heterogeneity test and funnel plot analysis

No significant results were found in the heterogeneity test for all pooled analyses (all P>0.05). As shown by the funnel plot analyses, there was no significant evidence of publication bias (data not shown).

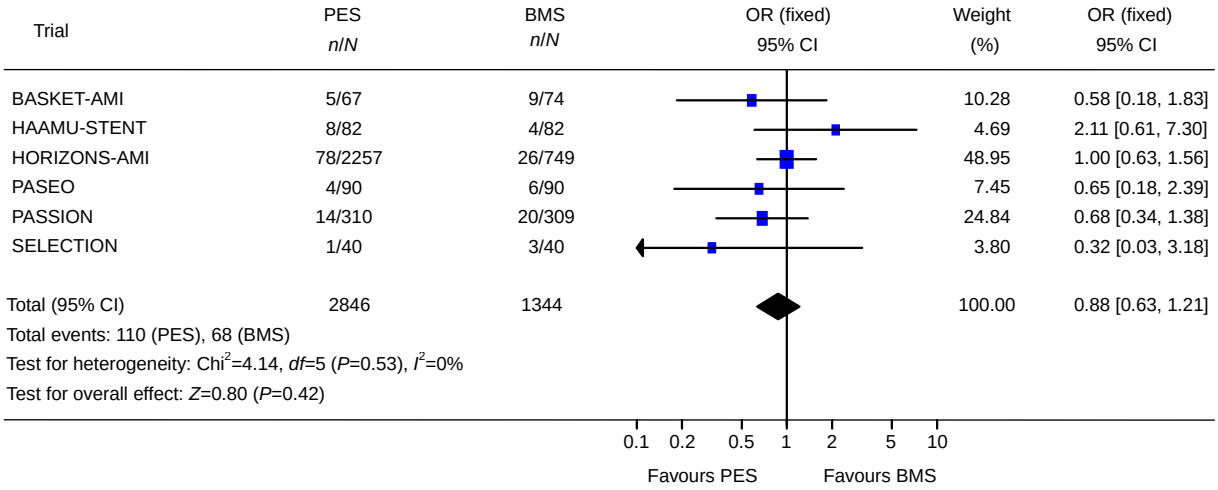

Fig. 1 Forest plot for the comparison of PES and BMS in mortality

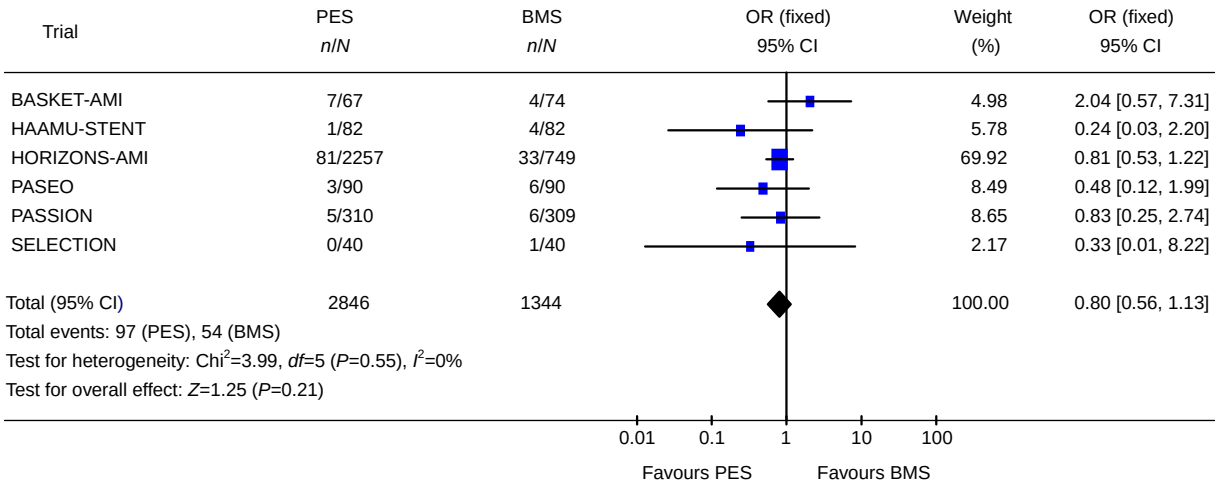

Fig. 2 Forest plot for the comparison of PES and BMS in recurrent myocardial infarction

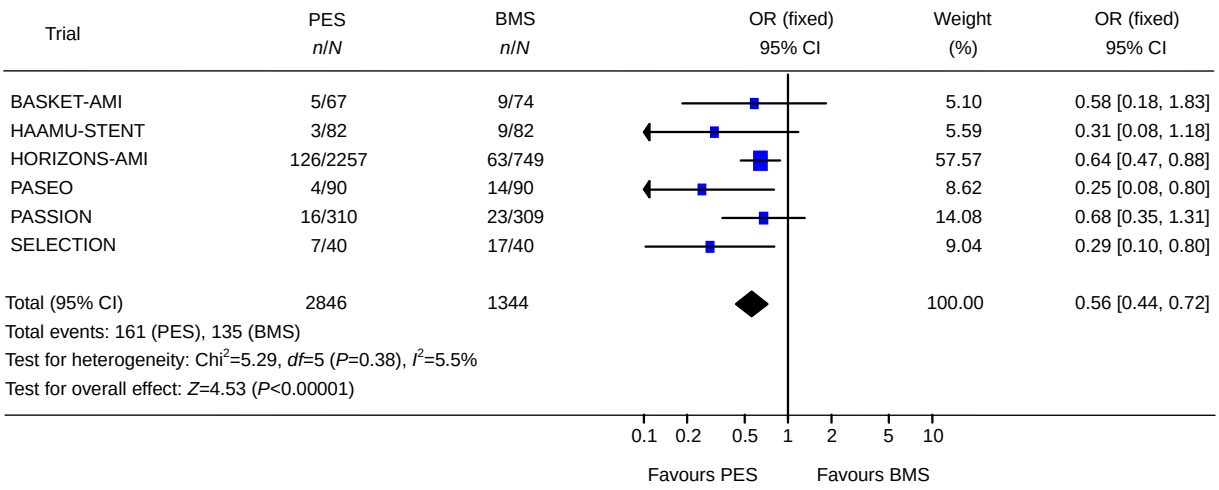

Fig. 3 Forest plot for the comparison of PES and BMS in repeat revascularization

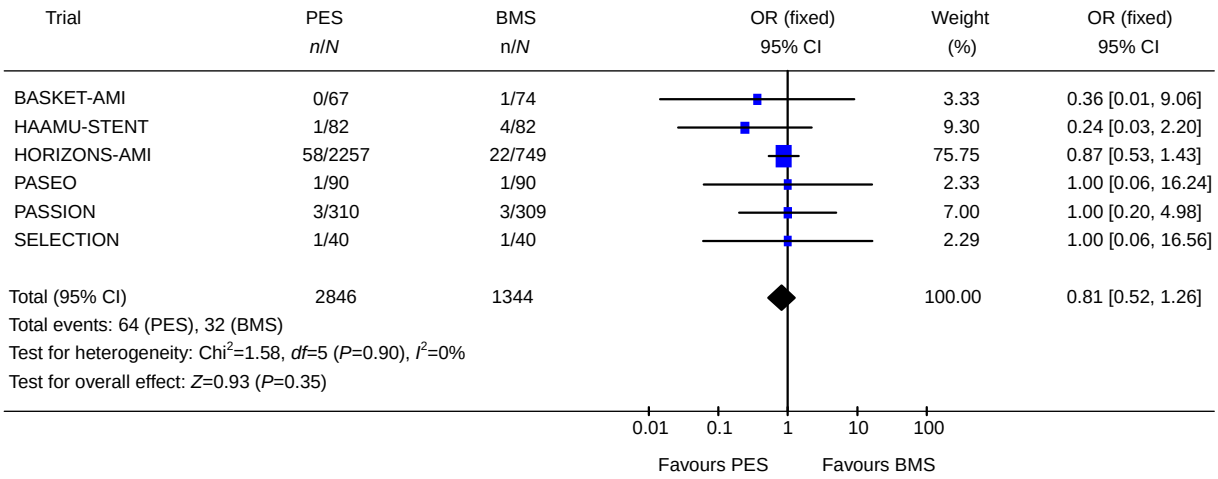

Fig. 4 Forest plot for the comparison of PES and BMS in definite stent thrombosis

4 Discussion

A meta-analysis of six randomized trials was performed in this study to evaluate the clinical efficacy and safety of PES in acute STEMI patients in comparison with BMS. The main finding is that implantation of PES significantly reduced the risk of RR without safety concerns.

Previous published meta-analysis papers have compared PES versus BMS at six months with three trials, SES versus BMS at one year or longer, and DES versus BMS at one year or longer (Moreno *et al.*, 2007; de Luca *et al.*, 2009a; 2009b; Iijima *et al.*, 2009; Pan *et al.*, 2009). The results of our meta-analysis confirmed and expanded the previous studies on the effect of DES on STEMI patients. DES was associated with a remarkable decrease of the need for RR and no significant change was found in mortality, rMI, or ST rates when compared with BMS in STEMI patients. No individual randomized trial or meta-analysis comparing PES and BMS involving a considerable number of STEMI patients at various clinical risks reported a significant difference in mortality and rMI rates up to one year.

Clinical follow-ups of STEMI patients were prolonged to find out whether lower RR rate needs to be translated into lower morbidity and rMI rates, which is very important. Benefits of DES over BMS in decreasing rates of the two-year mortality and RR were reported in 3379 STEMI patients (Mauri *et al.*, 2008).

On the contrary, investigators of the global registry of acute coronary events (GRACE) found increased mortality in DES compared to BMS from six months to two years in 5093 STEMI patients (Steg *et al*., 2009). PASSION is currently the only randomized trial publishing two-year follow-up after primary PCI with PES versus BMS in STEMI patients. No evidence of further improvement or attenuation in clinical outcomes was found (Dirksen *et al*., 2008). The Taxus stent evaluated at Rotterdam cardiology hospital (T-RESEARCH) demonstrated no association of PES with significantly lower rates of major adverse cardiac events and TVR in 136 patients when the follow-up time was prolonged from one year to three years (Daemen *et al*., 2007). However, in the Freiburg stent registry (FRIST), DES including PES caused fewer cardiac and non-cardiac deaths than BMS after a four-year clinical follow-up in STEMI patients (Grumann *et al*., 2008). Further investigations of randomized trials are necessary to address the long-term outcomes of PES in STEMI patients.

The concerns about safety of PES in STEMI patients were mostly focused on ST. This catastrophic complication could happen rapidly within 24 h after the indexing procedure (defined as acute ST), or could be delayed to more than one year later (very late ST), especially in cases of dual antiplatelet drug therapy discontinuation (Jaffe and Strauss, 2007). Very late ST cases were reported even more than three years later after PES implantation (Flores-Ríos *et al*., 2007). The present analysis included only definite ST cases requiring angiographic confirmation with high specificity to avoid heterogeneity. PES in STEMI patients were not associated with increased ST rate up to nearly one year. Actually, no significant difference in definite ST between PES and BMS groups was found at two years in PASSION trial (Dirksen *et al*., 2008).

The limitations of the present meta-analysis were as follows. Use of aggregate data from published trials instead of individual patient data to lump study outcomes is an inherent limitation. The restrictive definition of ST as being angiographically proven inevitably leads to the underestimation of the real ST events. The patients included in all the trials are STEMI patients, so it would be inappropriate to apply the conclusion of this meta-analysis to all acute coronary syndrome patients. The conclusion may not also be applied to everyday practice in the real world, since the patients in the trials likely received closer medical supervision and probably better adhered to advised medication, especially the continuation of long-term oral dual antiplatelet therapy.

5 Conclusions

PES improved clinical outcomes in STEMI patients with a decreased need for RR and no concerns for safety.

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