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Three-year follow-up outcomes of SES and PES in a randomized controlled study stratified by the presence of diabetes mellitus: J-DEsSERT trial

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ABSTRACT

Background: Three-year clinical follow-up of patients with diabetes mellitus (DM) in the Japan-Drug Eluting Stents Evaluation; a Randomized Trial (J-DESsERT) using 2 different drug eluting stents (DES). A recent study demonstrated that efficacy of sirolimus eluting stents (SES) attenuated over time in diabetic patients.
Methods: In the largest trial of its kind, 1724 DM patients out of 3533 enrolled patients were randomized to either SES or paclitaxel eluting stents (PES).
Results: There were no significant differences in baseline clinical characteristics aside from hypertension. Incidence of major adverse cardiac cerebrovascular events (MACCE) mainly due to higher target vessel failure (TVF) initially indicated a benefit in SES (MACCE rate at 1 year: SES 9.4%, PES 12.2%, $p = 0.08$); however this had attenuated by the time of the 3-year follow-up (MACCE rate from 1 to 3 years: SES 8.4%, PES 6.1%, $p = 0.10$). A similar pattern was observed in insulin-treated patients: MACCE rate from 1 to 3 years was 10.5% in SES and 6.4% in PES ($p = 0.25$). Angiographic follow-up also resulted in higher major adverse cardiac event (MACE) rates at 1 year (presence 11.5%, absence 8.3%, $p = 0.04$); however by 3 years rates were similar regardless of the presence of angiographic follow-up (MACE rate at 3 years: presence 16.0%, absence 14.5%, $p = 0.35$).

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[1] This author takes responsibility for all aspects of reliability and declares freedom from bias of the data presented and discussed interpretations thereof.
[2] The investigators, institution, and research organization participating in J-DESsERT are listed in Appendix A.

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Conclusions: The superiority of SES over PES in MACCE at 1 year had attenuated by 3-year follow-up. Eventually, the 3-year safety and efficacy profiles were similar regardless of insulin treatment.

1. Introduction

Coronary artery lesions in diabetes mellitus (DM) patients are typically small and diffuse, making them unsuitable for percutaneous coronary intervention (PCI) and leading to exaggerated intimal hyperplasia if PCI is performed. As a result, post-PCI restenosis has been troublesome in the era of bare metal stents (BMS). Drug eluting stent (DES) technology has succeeded in controlling the development of intimal hyperplasia following stent deployment. Compared with BMS, the use of DES in diabetic patients is associated with a lower risk of target lesion revascularization (TLR) without any increase in death or myocardial infarction (MI) [1,2]. Nonetheless, there is still uncertainty regarding the effectiveness of various DES. Randomized controlled studies revealed the superiority of sirolimus eluting stents (SES) compared with paclitaxel eluting stents (PES) in terms of restenosis in DM patients [3–6]. Although late luminal loss has been proposed as a robust marker for evaluating DES in the overall population [7], clinically-driven TLR is considered to be a more reasonable index to evaluate the true impact of DES outcomes in DM patients. Additionally, major drawbacks of previous studies have been a lack of adequate sample sizes to show the superiority of one DES over another, as well as a short follow-up period to demonstrate the durability of DES in DM patients. Recently, Lee et al. demonstrated that the superiority of SES over PES during the first 2 years attenuated between 2 and 4 years in diabetic patients [8]. A large 5-year observational study demonstrated that PES and SES were equally safe and efficacious in DM patients undergoing PCI in clinical practice [9]. However, long-term follow-up data of large randomized controlled studies examining DES in DM patients was still limited. The Japan-Drug Eluting Stents Evaluation; a Randomized Trial (J-DEsSERT) was a randomized controlled trial which was stratified by the presence of DM and compared the difference in SES and PES efficacy [10]. Here we report the 3-year clinical follow-up of this trial, the largest randomized controlled trial of its kind. We endeavored to clarify the long-term safety and efficacy of SES and PES for DM patients in Japan.

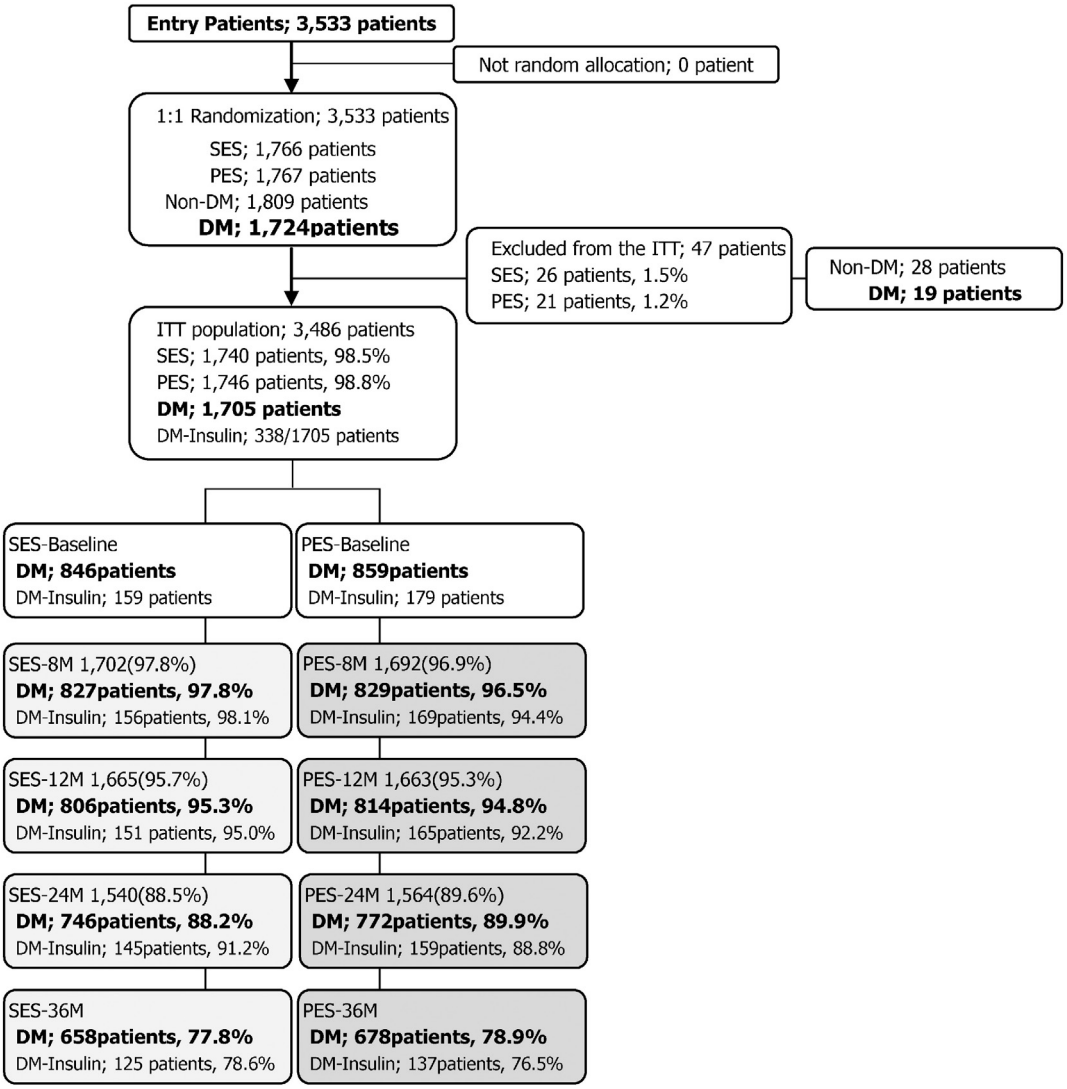

Fig. 1. Trial flow chart. DM = diabetes mellitus; ITT = intention to treat; M = month; PES = paclitaxel-eluting stent(s); SES = sirolimus-eluting stent(s).