

Objective

We performed a meta-analysis to assess whether amphilimus eluting stent superseded the permanent-polymer second-generation drug-eluting stents in terms of clinical outcomes.

Introduction

The polymer-free amphilimus-eluting stent (PF-AES) is a novel stent technology developed with the intent to further reduce the risk of stent thrombosis and restenosis that comes with the commonly used second-generation permanent-polymer drug-eluting stents (PP-DES). The PF-AES platform is made of a thin-strut (80 μ m) cobalt-chromium alloy, coated with an ultrathin (<0.3 mm) passive layer (Bio-inducer Surface) to accelerate endothelialization. It has abluminal laser dug-wells that are filled with a mixture of sirolimus and long-chain fatty acids (Amphilimus formulation) which allow sustained and homogenous drug release along with enhanced drug-penetration and bioavailability directly to the vessel wall. The PF-AES has been shown to reduce late stenosis when studied against 1st generation PP-DES. Data on comparison between the two stent technologies is extremely limited.

Methods and Materials

We searched PubMed, Cochrane Library and Google Scholar databases and a total of 4 studies (2 prospective randomized trials, 1 prospective propensity-score adjusted study and 1 retrospective study) totaling 2502 patients were included. The data was analyzed using RevMan 5.3 software.

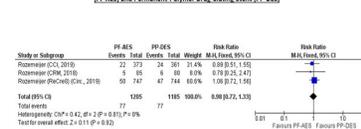
Results

No difference was seen in the analysed outcomes at 1-year between PF-AES and PP-DES, i.e. target-lesion failure (RR 0.98, 95% CI 0.72-1.33), probable/definite stent thrombosis (RR 1.30, 95% CI 0.62-2.69), cardiac death (RR 1.12, 95% CI 0.62-2.02), target-vessel MI (RR 0.90, 95% CI 0.51-1.61), target-lesion revascularization (TLR) (RR 0.93, 95% CI 0.60-1.45), all-cause death (RR 1.20, 95% CI 0.78-1.86), any MI (RR 1.07, 95% CI 0.68-1.68) and major bleeding (RR 0.69, 95% CI 0.37-1.29). Subgroup analysis for TLR in diabetics between PF-AES and PP-DES also did not reveal significant difference (RR 0.88, 95% CI 0.46-1.68). Analysis of early (RR 2.24, 95% CI 0.69-7.26) and late (RR 0.45, 95% CI 0.10-2.01) probable/definite stent thrombosis between the PF-AES and PP-DES also failed to show difference.

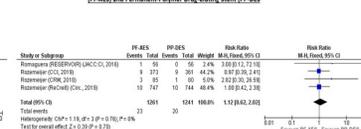
Conclusions

Despite the technological advancement, clinical outcomes with PF-AES and PP DES are similar.

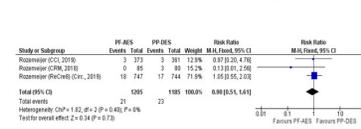
Target Lesion Failure Between Polymer-free Amphilimus-eluting Stent (PF-AES) and Permanent-Polymer Drug-eluting Stent (PP-DES)



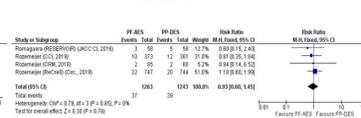
Cardiac Death Between Polymer-free Amphilimus-eluting Stent (PF-AES) and Permanent-Polymer Drug-eluting Stent (PP-DES)



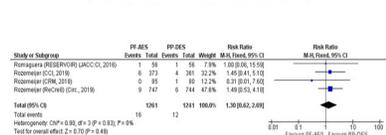
Target-vessel Myocardial Infarction Between Polymer-free Amphilimus-eluting Stent (PF-AES) and Permanent-Polymer Drug-eluting Stent (PP-DES)



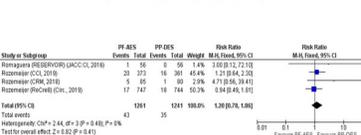
Target Lesion Revascularization Between Polymer-free Amphilimus-eluting Stent (PF-AES) and Permanent-polymer Drug-eluting Stent (PP-DES)



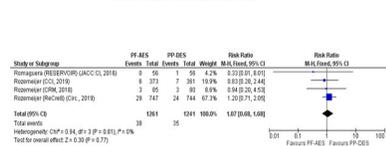
Probable or Definite Stent Thrombosis Between Polymer-free Amphilimus-eluting Stent (PF-AES) and Permanent-polymer Drug-eluting Stent (PP-DES)



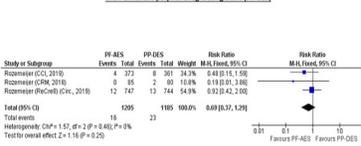
All-cause Death Between Polymer-free Amphilimus-eluting Stent (PF-AES) and Permanent-polymer Drug-eluting Stent (PP-DES)



Myocardial Infarction Between Polymer-free Amphilimus-eluting Stent (PF-AES) and Permanent-Polymer Drug-eluting Stent (PP-DES)



Major Bleeding Between Polymer-free Amphilimus-eluting Stent (PF-AES) and Permanent-polymer Drug-eluting Stent (PP-DES)



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