Comparison of two iterations of the zotarolimus-eluting stents: an analysis of all-comer patients from two consecutive randomised clinical trials

R.A. Buiten¹, E.H. Ploumen¹, P. Zocca¹, G.A.J. Jessurun², C.E. Schotborgh³, A. Roguin⁴, P.W. Danse⁵, E. Benit⁶, A. Aminian⁷, M. Scholte⁸, M. Hartmann¹, K.G. Van Houwelingen¹, C.J.M. Doggen⁹, G.C.M. Linssen¹⁰, C. Von Birgelen¹

¹Thorax Centre in Medisch Spectrum Twente (MST), Enschede, Netherlands (The); ²Treant Zorggroep Scheper Hospital, Emmen, Netherlands (The); ³Haga Hospital, Den Haag, Netherlands (The); ⁴Rambam Health Care Campus, Rambam, Israel; ⁵Rijnstate Hospital, Arnhem, Netherlands (The); ⁶Jessa clinic Hasselt, Hasselt, Belgium; ⁷University Hospital Charleroi, Charleroi, Belgium; ⁸Albert Schweitzer Hospital, Dordrecht, Netherlands (The); ⁹University of Twente, Enschede, Netherlands (The); ¹⁰Twente Hospital Group, Almelo, Netherlands (The) Funding Acknowledgement: Type of funding source: Other. Main funding source(s): Thoraxcentrum Twente has received institutional research grants provided by Abbott Vascular, Biotronik, Boston Scientific and Medtronic. The present analysis received no funding.

Background: The newest iteration of the durable polymer zotarolimuseluting stents (ZES) is designed with thin swaged shape composite-wire struts (inner platinum-iridium core and outer cobalt-chromium layer). It is of interest to compare the clinical performance of this novel device with its predecessor in all-comers.

Purpose: The purpose of the present study is to assess 2-year clinical outcome in all-comer patients who were treated with the novel ZES versus the previous iteration ZES.

Methods: We did a post-hoc analysis of clinical outcome data of 2374 patients who were treated with the novel or the previous generation ZES (only nominal stent diameters that were available for both devices) in two consecutive large-scale randomised all-comer trials. A total of 1201 trial participants were treated with the novel ZES, and 1173 were treated with the previous generation ZES. The main outcome parameter target vessel failure is a composite of safety (cardiac death, target vessel myocardial infarction) and efficacy (target vessel revascularisation). Clinical outcome data were analysed with Kaplan-Meier methods and hazard ratios were computed with Cox regression analysis. An additional analysis was done in a subgroup of patients who presented with chronic coronary syndromes.

Results: The mean age of the study population was 63.9 ± 10.9 years, 611 (25.7%) were female and 1669 (70.3%) presented with acute coronary syndromes. Two-year follow-up was available in 2346 (98.8%) participants. After 2 years, there was no significant difference between stent-groups in the rates of target vessel failure (7.2% vs. 8.3%, HR 0.85, 95% CI 0.64-1.14, plogrank = 0.28; Figure 1) or its individual components. Peri-procedural myocardial infarction occurred less often in patients treated with the novel ZES (0.7% vs. 2.1%, p-logrank <0.01), and definite-or-probable stent thrombosis rates were low in both ZES groups (0.3% vs. 0.8%, p-logrank = 0.15). In a subgroup of 705 patients with chronic coronary syndromes, the rate of target vessel myocardial infarction tended to be lower with novel ZES (1.8% vs. 4.2%, p-logrank = 0.05).

Conclusions: The novel ZES showed similar 2-year clinical outcomes as compared to its predecessor. Furthermore, there was a positive safety signal regarding the incidence of target vessel myocardial infarction and a particularly low stent thrombosis rates with the novel ZES.

