Final 5-year results of the TRIAS-LR: a multi-centre, randomized trial comparing the Genous endothelial progenitor cell capturing stent with bare metal stents in patients with low risk for restenosis

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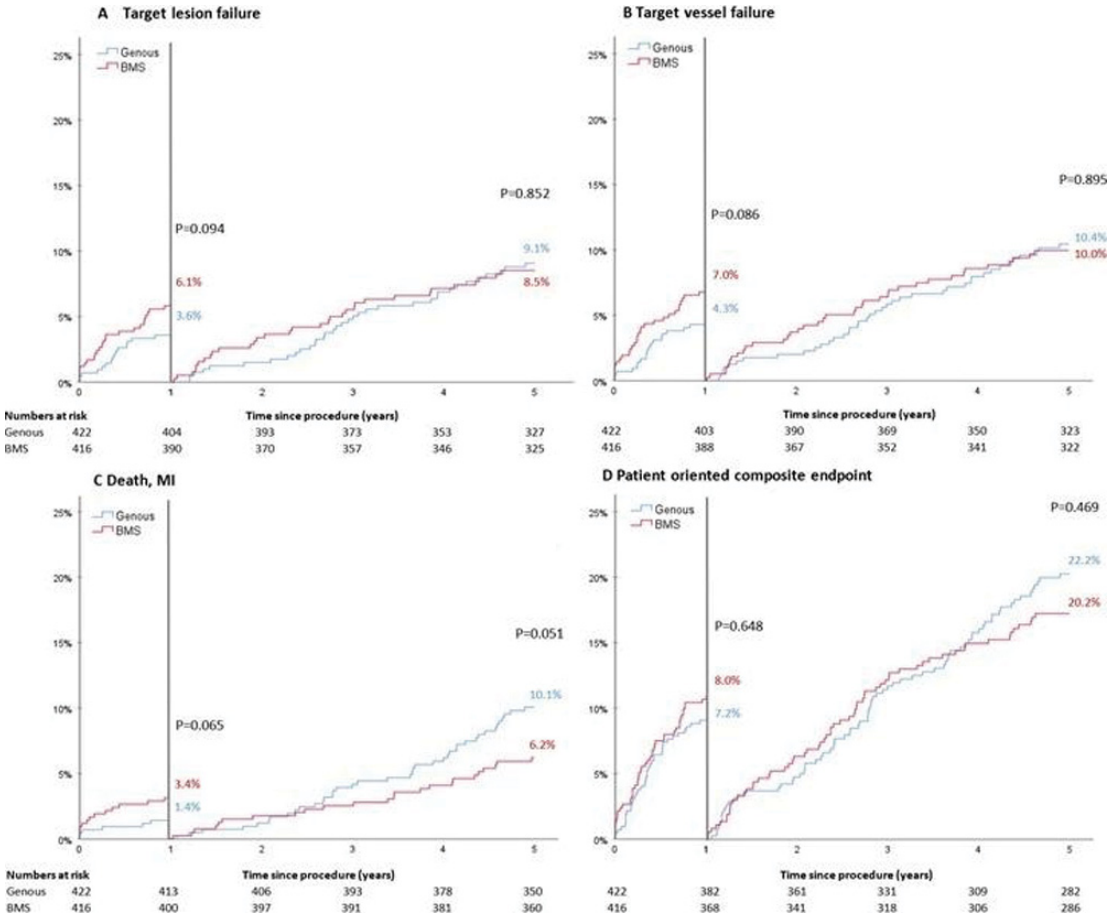
Introduction: The Genous stent is a bare metal stent (BMS) together with a technique of capturing endothelial progenitor cells. The successor of the Genous endothelial progenitor cell capturing (EPC) stent, the COMBO stent, combines this technique with the drug eluting polymer. The current studies showed promising results of the COMBO stent, however the additional value of EPC technique in overcoming neointimal hyperplasia has yet to be proven.

Purpose: This study sought to evaluate the efficacy and safety of the Genous EPC stent compared to BMS in a patient population with low risk for restenosis.

Methods: TRIAS-LR was an investigator-initiated, prospective, multicentre, single blind trial randomizing patients with low risk of restenosis 1:1 to Genous ECS or BMS. Patients were recruited between 2007 and 2014 at 31 sites across Europe. The study enrolment was terminated at 70% of the planned inclusion due to slow enrolment and change of guidelines. Patients or lesions were considered low risk if all of the following criteria were met: 1) reference vessel diameter >2.8mm, 2) lesion length <20mm, 3) no thrombolysis in myocardial infarction (TIMI) flow of 0, and 4) patient without diabetes mellitus. Clinical follow-up was obtained yearly. The trial was monitored and independent clinical event committee adjudicated serious adverse clinical events. The primary endpoint was target lesion failure (TLF), composite of cardiac death, target-vessel myocardial infarction (TV-MI) or target lesion revascularization (TLR) at 1 year. Secondary endpoint included the composite of death or MI at 5-year follow-up.

Results: In total, 838 patients were enrolled of whom 422 patients with 476 lesions were randomly assigned to Genous EPC stent and 416 patients with 480 lesions to BMS. The mean age was 64 years, 74% were males and in 76% patients were treated in elective setting. At 1 year TLF had occurred in 3.6% (n=15) of the Genous arm and in 6.1% (n=25) of the BMS arm (p=0.094; risk difference of –2.5%). However, this difference disappeared, at 5-years of follow-up; TLF rate was 12.6% (n=51) in the Genous arm versus 14.3% (n=58) in the BMS arm (p=0.385; risk difference of –1.7%). The secondary objective of the composite death or MI at 5 years occurred in 11.6% (n=47) in the Genous arm and 9.9% (n=40) in the BMS arm (p=0.479; risk difference of 1.7%). At 5 years definite stent thrombosis (ST) occurred in 0.5% (n=2) of the Genous arm, no definite ST had occurred in the BMS arm (p=0.162).

Conclusion: TRIAS-LR trial showed no differences between Genous EPC and BMS throughout 5-year follow-up in patients considered as low risk of restenosis.



Kaplan-Meier plot of composite endpoints