Abstract: P2798

Final 5-year outcomes of the TRIAS High Risk of Restenosis; a multi-centre, randomized trial comparing endothelial progenitor cell capturing stent with drug-eluting stents

Authors:
L S M Kerkmeijer¹, P Woudstra¹, M Klomp¹, DN Kalkman¹, C Varma², JJ Koolen³, E Teiger⁴, B Florian⁵, NJ Verouden⁶, JG Tijssen¹, MA Beijk¹, RJ De Winter¹, ¹Academic Medical Center of Amsterdam, Cardiology - Amsterdam - Netherlands (The), ²Sandwell and West Birmingham Hospitals NHS Trust - West Bromwich - United Kingdom of Great Britain & Northern Ireland, ³St Antonius Hospital - Nieuwegein - Netherlands (The), ⁴Mondor Biomedical Research Institute - Creteil - France, ⁵Krankenhäuser Landkreis , Cardiology - Freudenstadt - Germany, ⁶VU University Medical Center - Amsterdam - Netherlands (The),

Topic(s):
Coronary Intervention: Stents

Citation:
OrbusNeich

Background: One of the major long-term disadvantages of percutaneous coronary intervention (PCI) remains in-stent restenosis and need for repeat revascularisation. The polymer-regulated delivery of cytotoxic or cytostatic drugs, on drug-eluting stents (DES), impede the natural healing response of the damaged vessel wall. In animals, endothelial progenitor cells (EPCs) beneficially influence the repair of the coronary vessel wall after damage by stent placement. It is hypothesized that after immobilisation the EPCs differentiate into a functional endothelial layer and that this layer will prevent neointimal proliferation and thrombus formation. Anti-CD34+ antibodies are able to capture the EPCs. The Genous stent consist of a bare-metal stent with anti-CD34+ antibody coating.

Purpose: Demonstrating long-term performance of Genous EPC capturing stent (ECS) relative to DES regarding target lesion failure (TLF); the composite of cardiac death, myocardial infarction (MI) and any target lesion revascularisation (TLR) within 5 years.

Methods: We undertook an international, clinical trial in 26 centres planning to randomise 1300 patients with stable coronary artery disease and with a high risk of restenosis between treatment with either ECS or DES. After a routine review with 50% of the patients enrolled, early cessation of the trial was recommended by the data and safety monitoring board when TLF in the ECS population was substantially higher and treatment of new patients with an ECS would be unreasonable. The trial was terminated for safety reasons.

Results: A total of 622 were randomly assigned to receive either Genous ECS (304 patients, 367 lesions) or DES (318 patients, 388 lesions). Five year follow-up data was obtained in 95.5 % of patients. TLF occurred in 29.1% of the ECS-treated patients and in 16.0% of the DES-treated patients (p<0.001)(Figure 1). This difference was driven by higher rates of TLR (22.9% vs. 10.7%, p<0.001), but not by cardiac death (6.5% vs. 4.5%, p=0.268), or MI (5.8% vs. 3.6%, p=0.175). Definite or probable stent thrombosis was seen in 8 ECS-treated patients (2.7%) and in 3 DES-treated patients (1%), p=0.11.

Conclusion: The Genous ECS is not sufficiently strong to compete with DES in terms of restenosis prevention in patients/lesions with a high risk of restenosis. If the addition of a EPCs capturing layer on a DES, like the COMBO stent, provides a lower risk of restenosis compared to DES will be tested in the ongoing SORT-OUT X trial.
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1 Academic Medical Center of Amsterdam, Cardiology - Amsterdam - Netherlands (The), 2 Sandwell and West Birmingham Hospitals NHS Trust - West Bromwich - United Kingdom of Great Britain & Northern Ireland, 3 St Antonius Hospital - Nieuwegein - Netherlands (The), 4 Mondor Biomedical Research Institute - Creteil - France, 5 Krankenhäuser Landkreis, Cardiology - Freudenstadt - Germany, 6 VU University Medical Center - Amsterdam - Netherlands (The)

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