EP3_57

Atheroregression Below Glagov Threshold Using Noble-metal Nanoparticles: Results of NANOM-PCI Trial

Alexander Kharlamov[1,2], Jan Gabinsky[1]
[1]*Department of Science, Ural Institute of Cardiology, Russia*
[2]*Department of Interventional Cardiology, Rotterdam University Medical Center (Erasmus MC), Netherlands*

Background:
Our previous bench studies PLASMONICS and NANOM First-in-Man trial documented TAV reduction up to unprecedented 79.4 and 60.3 mm3 respectively with high level of safety and feasibility.

Methods:
The completed randomized two arm (1:1) study (NANOM-PCI) with parallel assignment (n=62) assessed (NCT01436123) the safety and feasibility of the delivery technique for nanoparticles (NP) using micro-injection catheter (with intravascular intramural injection of allogenious stem cells carring NP after MSCT-, IVUS- and OCT-guided mapping of the vessel), and plasmonicphotothermal therapy of atherosclerosis combined with stenting (Nano group, n=32) versus stenting with Xience V cage (Stenting group, n=30). The primary outcome was TAV at 12 months.

Results:
The mean reduction of TAV at 12 months in Nano group was -84.1 mm3 (95% CI: SD 28.3; min -52.4 mm3, max -99.1 mm3; p0.05) versus +12.4 mm3 in case of stenting (p0.05 between groups). 42/62 patients (68%) in Nano group passed the Glagov threshold of a 40% plaque burden with mean plaque burden (PB) 36.2% (95% CI: SD 9.3%, min 30.9%, max 44.5%). We have documented 2 vs 3 cases of the definite thrombosis and 3 vs 5 cases of target lesion revascularization in groups respectively. The analysis of the event-free survival of the ongoing clinical follow-up shows the significantly lower risk of cardiovascular death in Nano group if compare with stenting (93.4% vs 86.7%; p0.05).

Conclusions:
Plasmonic resonance-mediated therapy using noble-metal NP associated with significant regression of coronary atherosclerosis. Tested delivery approach has acceptable safety and efficacy for atheroregression below a 40% PB.