Plasmonic Photothermal Therapy of Atherosclerosis and Preparation of Target Lesion in Patients with Arterial Remodeling Subanalysis of NANOM-FIM Trial NCT01270139

Dr Alexander Kharlamov, MD, FESC, FACC, De Haar Research Foundation, Amsterdam-Rotterdam, The Netherlands, www.dhrfpro.com

Background and Aims:

To evaluate the role of lesion preparation for long-term clinical outcomes and patterns of arterial remodeling in patients with plasmonic photothermal therapy (PPTT) of atherosclerosis.

Methods:

This is a subanalysis of the 5-year long-term clinical outcomes in three subsets of the intention-to-treat population (n=180) of NANOM-FIM trial (NCT01270139). The first subset was pre-treated with stenting proximal to the site of nano-intervention (n=13). Subjects in the second subset have undergone drug-coated balloon pre-dilation (n=20). Lesions of the third subset were not prepared (n=147).

Results:

A 5-year major adverse cardiovascular events (MACE)-free survival achieved 39/60 (65.0%), 32/60 (53.3%), and 34/60 (56.7%) in groups respectively (p<0.05). Non-inferiority of patient-oriented composite endpoint (POCE) with the clinical benefits of the proximal stenting was demonstrated if compared with no preparation (38.5% vs 77.0%; OR, 0.19, 95%CI: 0.05, 0.63, p=0.006). The similar trend of POCE was confirmed for proximal stenting and nano-intervention vs conventional stenting (38.5% vs 83.3%; OR, 0.13, 95%CI: 0.03, 0.46, p=0.002), pre-dilation vs no preparation (50.0% vs 77.0%; OR, 0.3, 95%CI: 0.11, 0.82, p=0.01), pre-dilation vs conventional stenting (50.0% vs 83.3%; OR, 0.2, 95%CI: 0.07, 0.61, p=0.004). Target lesion failure achieved 30.8%, 45.0%, and 32.2% in subsets respectively (p>0.05) if compare with 43.3% in stenting (p>0.05). The adjusted linear regression analysis (if plaque burden was between 37.8% and 70.8%) revealed moderate direct positive correlation (R2=0.5868) between plaque burden and MACE.

Conclusions:

Strategy with the lesion preparation proves acceptable survival profile at the long-term follow-up in patients who underwent PPTT.

Figure 1. Patterns of the publishing activity in the field of nanomedicine for the management of atherosclerosis in a systems biomedicine approach.

Figure 2. The hype cycle of the emerging technologies in interventional cardiovascular biomedicine with a focus on the management of coronary atherosclerosis.

Figure 3. Flow-chart of NANOM-FIM trial.

Figure 4. Schematic representation of the intravascular strategies in subsets.

Figure 6. Results of the 1-year imaging follow-up: reduction of the total atheroma volume.

Figure 5. Clinical cases with different intravascular approaches in NANOM-FIM trial.

Figure 7. Glagov phenomenon at NANOM-FIM trial.

Figure 8. Plaque burden versus MACE in NANOM-FIM Trial