TCT-391
Selected CD133+ endothelial progenitor cells to create angiogenesis in no-option patients. Preliminary results of Safety and feasibility
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Background: CD133+ progenitor cells are considered an immature population of haematopoietic stem cells with the capacity to differentiate into endothelial cells. The aim of this study was to assess the safety and the feasibility of transcatheter injection of selected CD133+ cells in patients (pts) with refractory angina without any option of revascularization.
Methods: The PROGENITOR trial is a randomized, blinded, multicenter controlled trial.Pts with class IIb-IV angina and with ischemic/viable zone demonstrated with SPECT without any option of revascularization were included. All pts were treated for 4-days with G-CSF and undergo apheresis to isolate the cells from the peripheral blood. CD133+ cells were selected with CliniMacs system (Miltenyi Biotec). The cells were injected transendocardially, guided by electromagnetic mapping with the NOGA system.
Results: 28 pts were included. The mean age 64±9, 85% were male, 53% were diabetics and 85% had previous surgery. The dose of injected cells was 30 millions with >85% of CD133+ purity. One pt allocated to the placebo group suffered ventricular fibrillation 24-hours after the baseline procedure and an ICD was implanted. This pt died at 3.5 months of follow-up due to a cardiovascular cause. One pt from the treatment group presented VT during the injection that was successfully cardioverted. One pt from the treatment group had a cardiac tamponade during mapping that was revolved, but the pt died due to cardiogenic shock. No more events were recorded.
Conclusions: this is the first-in-man trial with transcatheter injection of selected CD133+ cells in no-option pts. To date, these results suggest the safety and feasibility of the procedure. Three-months efficacy results will be presented at the congress.