includes cardiogenic shock in 18 patients (38%) and postcardiotomy cardiogenic shock in 29 patients (62%). Thirty-eight patients of the 47 total patients (80%) were supported withImpella 5.0/LD and with Impella 2.5 for the remaining 9 (19%) patients. . The 30-day survival rate was 75% (35/47) and of those 97% (34/35) recovered their native heart function and 1 (3%) was bridged to long term ventricular assist device Complications occurred in 14 (30%) patients and consisted of device malfunction (11%), high purge pressures (6%), catheter fracture (2%), and groin hematoma (2%).

**Conclusions:** The outcomes from our study were very favorable; myocardial recovery was accomplished in the majority of the patients with acceptable complication rate in these critically ill patients. These benefits encourage the use of a less invasive circulatory support with Impella in the setting of cardiogenic shock.

**TCT-391**

**Selected CD133+ endothelial progenitor cells to create angiogenesis in no-option patients. Preliminary results of Safety and feasibility**

*Pilar Jimenez-Quevedo[1], Juan Jose Gonzalez-ferrer[1], Manel Sabate[2], Xavier Garcia-Moll[3], Fernando Alfonso[4], Rosana Hernandez-Antolin[1], Nieves Gonzalo[5], Camino Banuelos[1], Javier Escaned[6], Antonio Fernandez-Ortiz[1], Carlos Macaya[7]*

*[1]Hospital Clinico San Carlos, Madrid, Spain, [2]University of Barcelona, Barcelona, Spain, [3]Hospital Sant Pau, Barcelona, Spain, [4]Clinico San Carlos. Madrid, Madrid, Spain, [5]Hospital Clinico San Carlos, Madrid, Madrid, [6]Cardiovascular Institute, Hospital Clinico San Carlos, Madrid, Spain, [7]Clinico San Carlos Hospital, Madrid, Spain*

**Background:** CD133+ progenitor cells are considered an inmature 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 transendocardial 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 II-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 electromechanical 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 transendocardial 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.

POSTERS

## Vascular Access

## *Hall D*

## Tuesday, October 23, 2012, 8:00 AM–10:00 AM

Abstract nos: 392-428

**TCT-392**

**Silent Cerebral Infarcts Following Cardiac Catheterization: A Randomized Comparison Of Radial And Femoral Approaches**

*Michele Hamon[1], Guillaume Coutance[1], Janusz Lipiecki[2], Didier Carrié[3], Francesco Burzotta[4], Nicolas Durel[2], Nicolas Boudou[3], Cesare Colosimo[4], Carlo Trani[4], Nicolas Dumonteil[3], Rémy Morello[1], Fausto Viader[1], Béatrice Clais[2], Martial Hamon[1]*

*[1]University Hospital, Caen, FRANCE, [2]University Hospital, Clermond-Ferrand, FRANCE, [3]University Hospital, Toulouse, FRANCE, [4]The Policlinica, Catholica University Hospital, Roma, ITALY*

**Background:** Single center studies, using serial cerebral diffusion-weighted magnetic resonance imaging in patients having cardiac catheterization have suggested that cerebral microembolism might be responsible for silent cerebral infarct as high as 15 to 22%. We evaluated in a multicenter trial the incidence of silent cerebral infarcts after cardiac catheterization and whether or not the choice of the arterial access site might impact this phenomenon.

**Methods:** Patients were randomized to have cardiac catheterization either by Radial (n=83) or Femoral (n=77) arterial approaches by experimented operators. The main outcome measure was the occurrence of new cerebral infarct on serial diffusion-weighted magnetic resonance imaging.

**Results:** Patient and catheterization characteristics, including duration of catheterization, were similar in both groups. The risk of silent cerebral infarct did not differ significantly between the Femoral and Radial groups (incidence of 11.7% versus 17.5%; odds ratio [OR], 0.85; 95% confidence interval [CI], 0.62-1.16; p = 0.31). At multivariable analysis, the independent predictors of silent cerebral infarct were the patient's higher height and lower transvalvular gradient.

**Conclusions:** The high rate of silent cerebral infarct after cardiac catheterization of patients with aortic stenosis was confirmed, but its occurrence was not affected by the selection of Radial and Femoral access.

**TCT-393**

**A randomized trial comparing two vascular closure devices: PROGLIDE and the novel EXOSEAL after percutaneous femoral procedures**

*Madjid Hattab[1], Maher Hakim[1], Virginie Brandao Carreira[1], Simon Elhadad[1]*

*[1]hopital, lagny sur marne, France*

**Background:** Obtaining safe and effective closure of the femoral access site following percutaneous coronary interventions (PCI) can sometimes be challenging, especially in patients on anti-coagulation or anti-platelet therapy. Vascular closure devices (VSC) have been shown to shorten hemostasis time, reduce the discomfort of manual or mechanical compression, and allow for earlier ambulation after percutaneous invasive procedures without increasing vascular complications compared with conventional compression techniques. The 6 French EXOSEAL, a new vascular closure device, is composed of a bioabsorbable plug and a Plug Delivery System which positions and releases the bioabsorbable plug to the extravascular surface of the femoral artery. The objective of this prospective randomized study was to compare the efficacy and safety of the 6 French EXOSEAL (Cordis) versus the PERCLOSE PROGLIDE in patients undergoing PCI and endovascular peripheral procedures via a retrograde femoral artery access.

**Methods:** From January 2011 to November 2011, 100 Patients were enrolled in this single-center trial. Immediately after the coronary or peripheral procedure, they were randomly assigned to PROGLIDE (n:50) versus EXOSEAL (n:50). The end points were the immediate total hemostasis and the incidence of vascular complication.

**Results:** There were no significant differences in baseline characteristics between the 2 treatment groups. Immediate total hemostasis was achieved with the EXOSEAL device in 46 patients (92%) versus 44 patients with the PROGLIDE device (88%) (p: 0,74). 4 patients needed additional action (manual or mechanical compression) in the EXOSEAL group versus 6 in the PROGLIDE group (8% versus 12%, p: 0,74). 2 patients experienced a minor complication (hematoma < 5cm) in the EXOSEAL group versus 3 in the PROGLIDE group (4% vs 6%, p:0,54). . No other vascular complication occurred and no transfusion were necessary.

**Conclusions:** After percutaneous invasive procedures, the difference between the EXOSEAL and the PROGLIDE devices concerning the incidence of immediate total hemostasis, and vascular complication did not reach statistical significance.