Clinical endpoint was composed of cardiac death, myocardial infarction attributed to the target vessel or TLR.

Results: There was no difference in patient baseline characteristics. Lesion length was 11.2±6.5mm in the DCB- and 12.2±8.2mm in the POBA-group (p=ns). Post PCI, for the stented segment and the total segment minimal lumen diameter and diameter stenosis were not different. Clinical follow-up after 12 months was 100%. Treatment with DCB was superior to balloon angioplasty alone with an in-stent late loss of 0.43±0.61mm vs. 1.03±0.77mm (p<0.001). Minimal lumen diameter was significantly larger and percent diameter stenosis significantly lower with use of the DCB for both the stented and total segment. Restenosis rate was reduced from 58.1% to 17.2% (p<0.001) and the clinical endpoint at 6 months was reduced from 50% to 16.7% (p<0.001), respectively. After 12 months the effect of DCB persisted (clinical endpoint 52.6% vs. 16.7%; p=0.001 and TLR 36.8% vs. 15.3%; p=0.005), respectively. There was one probable stent thrombosis in the POBA group. Clinical follow-up after 3 years will be completed in June 2014 and presented.

Conclusions: Paclitaxel coated balloon angioplasty was superior to balloon angioplasty alone for the treatment of in-stent-restenosis of drug-eluting stents. Longterm effects of the DCB-therapy after 3 years will be presented.

TCT-267
Lower Mortality of Paclitaxel-Coated Balloon Compared with Paclitaxel-Eluting Stent for the Treatment of DES In-Stent Restenosis: Two-Year Follow-Up of the PEPCAD China ISR Trial
Yelin Zhao1, Bo Xu2, Junbo Ge2, Yuejin Yang1, Jian’an Wang3, Shao Liang Chen1, Bin Liu1, Fang Chen1, Run-Lin Gao1
1Fu Wai Hospital, National Center for Cardiovascular Diseases, Beijing, China, 2Fudan University Zhongshan Hospital, Shanghai, China, 3The Second Affiliated Hospital of Zhejiang University School of Medicine, Hangzhou, China, 4Nanjing First Hospital, Nanjing Medical University, Nanjing, China, 5Jilin University the Second Hospital, Changchun, China, 6Affiliated Anzhen Hospital of Capital Medical University, Beijing, China

Background: Previous studies demonstrated that angioplasty with a paclitaxel-coated balloon (PCB) was non-inferior to paclitaxel-eluting stent (PES) implantation when used for the treatment of instent-restenosis of drug-eluting stents. The latest interim results of the Freeway Stent Study show that PCB might significantly lower the in-stent-restenosis rate in the treatment of PAD patients.

Methods: The Freeway Stent Study is a prospective, randomized, international trial started in 15 centers in Germany and Austria. 200 patients will be enrolled and randomized equally to primary nitinol stenting followed by either DCB (Freeway™) or plain balloon postdilatation. Primary endpoint is clinically driven target lesion revascularization (TLR) at 6 months, secondary endpoints include further clinical and safety evaluations like shift in Rutherford classification and ABI, LLL, patency rate and MAE. Conclusions: The use of PCB as postdilatation device is investigated in a new approach to decrease the restenosis rate after nitinol stenting in the SFA and PI segment. The latest interim results of the Freeway Stent Study show that PCB might significantly lower the in-stent-restenosis rate in the treatment of PAD patients.

TCT-268
Randomized clinical trial favors the use of drug-coated balloons over plain balloons for the posttialization of nitinol stents in the SFA and PI segment to lower restenosis rate
Josef Tacke1, Dominik Kieselbach2, Schulte Karl-Ludwig2
1Klinikum Passau, Passau, Germany, 2Eurocor GmbH, Bonn, Germany, 3Charité Berlin, Vascular Center Berlin, Ev. Hospital Königin Elisabeth Herzberge, Berlin, Germany

Background: Stents are needed in up to 50 % of all peripheral interventions where PTA with plain or drug-coated balloons alone will not reopen the vessel sufficiently. Nevertheless, the restenosis rate of stents is still a major limitation of peripheral arterial interventions. Drug-coated balloons potentially overcome the problem of in-stent restenosis when used for posttialization after primary nitinol stenting in the SFA and PI segment.

Methods: The Freeway Stent Study is a prospective, randomized, international trial started in 15 centers in Germany and Austria. 200 patients will be enrolled and randomized equally to primary nitinol stenting followed by either DCB (Freeway™) or plain balloon postdilatation. Primary endpoint is clinically driven target lesion revascularization (TLR) at 6 months, secondary endpoints include further clinical and safety evaluations like shift in Rutherford classification and ABI, LLL, patency rate and MAE. Conclusions: The use of PCB as postdilatation device is investigated in a new approach to decrease the restenosis rate after nitinol stenting in the SFA and PI segment. The latest interim results of the Freeway Stent Study show that PCB might significantly lower the in-stent-restenosis rate in the treatment of PAD patients.

TCT-269
Drug-coated balloon vs. standard balloon for the PTA treatment of lesions in the SFA and popliteal artery – First interim results of the FREERIDE study
Schulte Karl-Ludwig1, Elisabeth Graef2, Rembert Pogge von Strandmann2, Ralf Langhoff2
1Vascular Center Berlin, Ev. Hospital Königin Elisabeth Herzberge/Charité, Berlin, Germany, 2Eurocor GmbH, Bonn, Germany, 3Dept Internal Medicine, St Gertrauden Hospital, Berlin, Germany

Background: Drug coated balloons (DCB) have provided a new option in the treatment of peripheral artery disease, because they allow elution of an anti-proliferative agent into the vessel wall. With the standard methods like the plain old balloon angioplasty (POBA) the effort to restore the normal flow often fails due to restenosis. The FREERIDE study investigates the inhibition of restenosis by the (Paclitaxel) DCB Freeway (Eurocor GmbH, Bonn, Germany) versus standard balloon angioplasty. All treatment of target lesion revascularization (TLR) was performed in femoral reoccluded lesions in peripheral arteries (SFA and popliteal/PI segment).

Methods: Controlled multicenter trial conducted in 23 centers worldwide with 280 PAD patients randomized either to Freeway DCB or to POBA. The primary endpoint is the rate of target lesion revascularization (TLR) at 6 months. Further, several secondary endpoints like late lumen loss and patency rate at 6 months, TLR at 12, 24 months follow up (FU), change in the Ankle-Brachial index (ABI) and Rutherford classification at FU, and MAE are investigated.

Results: Until the date 84 patients have been enrolled, 62 completed the 6 months FU. There are no adverse ischemic events occurred between 1 to 2 years in PCB group except 1 non-Q wave MI and 1 non-target vessel revascularization. However, the rate of all-cause death was statistically significant lower in the PCB group (0% vs. 4.9%, p=0.03) compared with PES group at 2 years.

Conclusions: The interim results indicate that the (Paclitaxel)-coated balloon Freeway might provide an advantage for PTA in SFA lesions and PI segment. The drug coated balloons could result in better outcomes overcoming the existing limitations in peripheral artery disease treatment.