Conclusions:

Coronary segments than in distal tissue samples. Drug levels in remote tissues were
7 days (n = 30), 7 (n = 7) and 28 days (n = 9) and detected to determine Sirolimus systemic distribution
following local drug delivery.

Results:
The Sirolimus levels found immediately after balloon delivery were 422.6 ± 110
ng/ml. Subsequent tissue levels were at 400 (13.8 ± 40.4 ng/ml) and 7 (49.8 ± 17.1 ng/ml) and 21 (32.7 ± 13.6 ng/ml) at last follow up (n = 28).

Sirolimus tissue levels were still above the target therapeutic levels (18.5
/h11006 24). Rates of target lesion revascularization (TLR) were significantly lower with DCB versus POBA for non-diabetics (15.2% vs.
36.0%; p = 0.107) Overall rates of

Conclusions:
The local arterial delivery of Sirolimus nanoparticles using a novel porous
balloon delivery system was safe and capable of achieving long term intra-arterial
drugs without significant systemic residual exposure in a porcine model.

Background:

The PEPCAD-DES Study showed a significantly lower late loss with the use of a drug
coated balloon in comparison to balloon angioplasty alone in the treatment of
insent-restenosis of drug-eluting stents (DES). In the presence of diabetes there are higher
rates of ISR reported in comparison to a healthy population. Purpose of this study was to
investigate the impact of diabetes mellitus on late lumen loss and angiographic restenosis
in patients, who were treated with a drug-coated balloon (DCB) in comparison to balloon
angioplasty alone (POBA) for in-stent-restenosis (ISR) of drug-eluting stents (DES).

Methods:

110 patients with an ISR of either Cypher®, Taxus®- or XienceV®-stent in a native
coronary artery with indication for percutaneous coronary intervention were included
in six centers in Germany. Exclusion criteria were: acute myocardial infarction, chronic total
occlusion, lesion in grafts, bifurcation lesion, left main lesion, restenosis and in-stent
restenosis, contraindication for acetylsalicylic acid or clopidogrel. All patients were
scheduled for control angiography at 6 months.

Results:

38 patients were randomized to POBA and 72 patients to DCB. Of these 26
(36.1%) pts. of the DCB-group and 13 (34.2%) were diabetics. DCB as compared with
POBA significantly reduced late loss in diabetics and non-diabetics, respectively. At
angiographic 6 month follow-up late lumen loss (LLL) in patients treated with a DCB
(0.31 ± 0.72 mm in diabetics, and 0.39 ± 0.58 mm in non-diabetics (n = 42). In
patients treated with POBA LLL was 1.45 ± 0.85 mm in the diabetic subgroup and
0.91 ± 0.71 mm in non-diabetics (n = 24). Rates of target lesion revascularization(TLR)
rates were significantly lower with DCB versus POBA for non-diabetics (15.2% vs.
36.0%; p = 0.045), but not for diabetics (15.4% vs. 38.5%; p = 0.107) Overall rates of
major adverse cardiac events (MACE) were significantly lower.

Conclusions:

Paclitaxel coated balloon angioplasty was superior to POBA for treatment of
DES-ISR and reduced significantly MACE-rates in diabetics and non-diabetics. DCB
effect on late loss was more effective in patients without diabetes.

TCT-598

Luminal Fibrin as a Key Component in Mechanism of Action in Drug Coated Balloon Technologies
Armando Tellez1, Taylor Palmieri1, Maxwell Afari1, William Rate1, Samantha Stone1, Piotr Baszmann1, Greg Kaluza1, Juan Granada1
1Cardiovascular Research Foundation, Orangeburg, NY

Background:
The mechanism of action of Drug Coated Balloons (DCB) is not fully understood. It’s suggested that following balloon dilatation, Paclitaxel is deposited on the vascular luminal surface and serves as a natural drug delivery system. We hypothesize that fibrin acts as a biological glue covering Paclitaxel deposits following balloon delivery. In this study, we aimed to evaluate the effect of the number of balloon inflations on luminal fibrin deposits over time.

Methods:

A total of 22 porcine femoral arterial segments were randomized to 1x (n = 4), 2x (n = 7) and 6x (n = 11) PCB inflations (Covatane, Medrad, Inc. Indianola, PA) and followed for 7 days. Additional 7 arterial segments received 6x PCB inflations and were followed for 14 (n = 2) and 30 days (n = 5). Vessels were harvested for the evaluation of luminal fibrin deposition using a semi-quantitative score.

Results:

A total of 148 vessel segments were analyzed in the 7 day study (1x, n = 35; 2x, n = 37; 6x, n = 76) and 40 slides in the long term study (14 days, n = 11; 30 days, n = 29). Fibrin deposits when present, were found to be deposited on the luminal surface of the vessel and covering crystalline material. At 7 days following PCB inflation, fibrin scores significantly increased according to the number of inflations. Single PCB inflation showed the highest fibrin score (0.2 ± 0.5) followed by double PCB inflation (0.43 ± 0.55). Six inflations showed a significantly increase in fibrin score (1.88 ± 0.71, p < 0.001). In the analysis of PCB over time, a peak in fibrin deposition was seen at 14 days (2.45 ± 1.04) before it decreases at 30 days (1.66 ± 0.90).

Conclusions:

Our study suggests that fibrin gets deposited on the surface of the vessel in a dose dependent fashion following PCB delivery and may play a major role in the creation of drug reservoirs and long term intra-vessel drug delivery. The course of the luminal fibrin deposition overtime suggests that this process peaks at 14 days and starts to resorb thereafter.

TCT-597

Angiographic and clinical outcome in the treatment of Restenosis of Drug Eluting Stents with drug coated balloons in diabetics: Insights from the PEPCAD-DES study
Harald Ritter1, Johannes Brachmann2, Matthias Waliszewski3, Ralf Birkmeyer3, Christoph Garlicht3, Jochen Wöhle3
1Universitätsklinikum Erlangen, Medizinische Klinik 2, Erlangen, Germany, 2Klinikum Coburg, Medizinische Klinik 2, Coburg, Germany, 3B. Braun Vascular Systems, Melsungen, Germany, 4Klinik für Kardiologie, Universitätsklinikum Rostock, Rostock, Germany, 5Dept. of Cardiology, University of Ulm, Ulm, Germany, 6Germany, Ulm, Germany

Background:
The PEPCAD-DES Study showed a significantly lower late loss with the use of a drug coated balloon in comparison to SeQuent Please balloon catheter (B.Braun Melsungen AG, Germany) in comparison to balloon angioplasty alone in the treatment of

Results:

The lowest inflammatory dose of double PCB delivery was 0.1 (13.8 ± 40.4 ng/ml) and 7 (49.8 ± 17.1 ng/ml) and 21 (32.7 ± 13.6 ng/ml) at last follow up (n = 28).

Conclusions:
The local arterial delivery of Sirolimus nanoparticles using a novel porous
balloon delivery system was safe and capable of achieving long term intra-arterial
drugs levels without significant systemic residual exposure in a porcine model.