TVR was performed 9 patients (15%). The composite 6-month MACCE was 15%. At 1-year FUP, 1 patient with HIV infection died, 1 patient suffered from stroke. Between 6 and 12 months FUP, 11 patients were lost to follow-up. The composite 1-year MACCE was 35%. Dior balloon angioplasty was repeated in 4 patients, while additional DES implantation was performed in 5 patients.

**Conclusions** This on-going registry reports the successful treatment of ISR with Dior DEB. The 1-year MACCE rate is between the reported MACCE rates of ISR treatment with BMS and DES, but the second generation of Dior DEB might have better results. The DEB use is justified in patients with severe concomitant disease or contra-indication of use of DES of any reason.

**Safety and Efficacy of the 2nd Generation of the Paclitaxel-eluting DIO R-Balloon in Porcine Coronary Arteries**

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**Purpose** The aim of the present study was to investigate the safety and efficacy of the second generation of DIOR paclitaxel-eluting balloon (DEB) in a porcine coronary artery overstretch injury model (1:3:1 balloon/artery ratio).

**Methods** Nineteen domestic pigs were subjected to balloon dilatation with a 1:3:1 balloon to artery ratio overstretch injury. The use of DIOR was optimised by applying 15, 20, 30 and 45 sec inflation time, measuring the coronary arterial tissue concentration of paclitaxel and the remaining paclitaxel amount on the balloon surface post-inflation. Additionally, vessel injury and development of neointimal hyperplasia were compared using 2nd generation of DIOR was optimized by applying 15, 20, 30 and 45 sec inflation time, measuring the coronary arterial tissue concentration of paclitaxel and the remaining paclitaxel amount on the balloon surface post-inflation. Additionally, vessel injury and development of neointimal hyperplasia were compared using 2nd generation of DIOR paclitaxel-derivate (Oregon Green 488) to demonstrate the distribution of the paclitaxel in the vessel wall after use of DEB or DES.

**Results** Depending on balloon inflation time a 2-20-fold tissue drug concentration of the arterial wall could be reached, compared to the 1st generation of DIOR with previous coating technique. The enhanced version of DIOR DEB provided 29 ± 3, 52 ± 6, 196 ± 44 and 202 ± 36 μg paclitaxel to the vessel wall after 15, 20, 30 and 45 sec inflations. The remaining paclitaxel amount on the balloon surface was 182 ± 12, 144 ± 10, 131 ± 12 and 85 ± 4 μg after 15, 20, 30, 45 sec balloon inflations. Two weeks post-overstretch injury, the dilated arterial segment neointimal area (0.19 ± 0.04 vs 0.7 ± 0.66 mm²; p = 0.045) and maximal neointimal thickness (0.13 ± 0.06 vs 0.29 ± 0.19 mm; p = 0.039) were significantly smaller than the usually recommended 1 min DEB inflation time.

**Conclusion** The 2nd generation of the paclitaxel-eluting balloon DIOR is safe and effective in preclinical porcine model of coronary restenosis, providing a higher level of drug-delivery within the therapeutic range. The maximal antiproliferative effect can be achieved after 20 or 30 sec balloon inflation time, which is better tolerated than the usually recommended 1 min DEB inflation time.

**A Case of Complicated Transcatheter Aortic Valve Implantation (TAVI)**

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**Background** Surgical aortic valve replacement is the treatment of choice in severe aortic valve stenosis. However, TAVI is an emerging alternative in the elderly and in patients with limiting comorbidities. Although procedural risk might be lower with transcatheter approach, severe complications can occur anyway. We would like to present a case of TAVI complicated by cardiac arrest, which resulted in complete recovery of the patient.

**Case Presentation**

- 82-year female, symptomatic severe aortic valve stenosis (AVA 0.4 cm²)
- Several episodes of dizziness/day, progressive dyspnea NYHA III
- Patient was not accepted for surgical aortic valve replacement due to high risk, therefore transcatheter treatment was intended (CoreValve® prosthesis)

**Setting of the Procedure**

- Catheterisation laboratory
- Local anaesthesia and analgesic sedation, pat. breathing spontaneously
- Bifemoral percutaneous approach
- Balloon valvuloplasty under rapid pacing (175/min)

Uneventful procedure until balloon deflation: At this time aortic blood flow decreased rapidly. Patient experienced tonic muscle spasm due to lack of cerebral perfusion and lost muscle tone afterwards. Cardio-pulmonary resuscitation (CPR) was initiated immediately. Invasive ventilation was applied. A mechanical chest compression device (Lucas®, Medtronic) was attached and started. Coronary embolism was ruled out by a brief coronary angiography. Since coronary arteries were open, aortic root injection was performed to rule out aortic dissection or perforation. However, aortic root angiogram revealed severe aortic valve regurgitation resulting in functional cardiac arrest. Remaining left ventricular contraction was very poor. At this time we decided to insert the CoreValve® aortic valve prosthesis with ongoing CPR conditions.

- Insertion of the valve with a break of CPR (Lucas® removed for X-ray)
- Two episodes of ventricular fibrillation, terminated by a 200 J shock each
- Epinephrine 1.5 mg bolus and one more minute of CPR finally resulted in return of spontaneous circulation (duration of functional cardiac arrest: 20 min.)

Circulation stabilised and perfusion rates of vasopressors were reduced quickly. Procedure was completed and the patient transferred to the ICU.

- Vasopressors stopped and pacemaker removed after two days
- Ventilation for three days
- Discharge from ICU after five days
- Excellent function of valve prosthesis
- Patient recovered completely without any sequel

**Conclusion** Severe complications including cardiac arrest may occur in TAVI. Therefore, a mechanical chest compression device should be available to improve both, quality of chest compression and patients’ clinical outcome.

**Restenosis Rate and Late-Lumen-Loss: Angiographic Comparison of Paclitaxel-eluting Stents with Bare-metal Stents in Renal Artery Stenosis**

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**Purpose** To compare the angiographically documented incidences of in-stent restenosis (ISR) in patients treated with either paclitaxel-eluting stents (PES) or bare-metal stents (BMS) for hemodynamically relevant renal artery stenosis (RA S).

**Methods** Ninety-five patients (55 women; mean age 71 ± 9 years) with 106 RAS (11 bilateral stenoses) were randomized to either the PES group (implantation of the Taxus stent in 49 [46 %] stenoses) or the BMS group (implantation of the Radix stent in 57 [54 %] lesions). All patients had uncontrolled hypertension, defined by (1) recurrent hypertensive crises despite optimized medical therapy and (2) angiographic findings of unilateral or bilateral significant RAS (≥ 50%). Angiographic follow-up was performed at 6 months, and all angiographic data were evaluated by 2 blinded reviewers using a semi-automated quantitative acquisition technique. Significant