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**PACLITAXEL-COATED BALLOON STUDY:  
QUANTITATIVE CORONARY ANGIOGRAPHY AND  
OPTICAL COHERENCE TOMOGRAPHY EVALUATION  
IN A SWINE IN-STENT STENOSIS MODEL**

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**Background** Drug coated balloons (DCBs) have shown efficacy for treatment of coronary artery disease. In PEPCAD II ISR trial, paclitaxel-coated balloon (PCB) reduced in-stent restenosis (ISR) compared with paclitaxel-eluting stent (PES). Here we evaluated the efficacy of PCB in porcine ISR model.

**Materials and methods** 32 coronary arteries (LAD: n=12, LCX: n=11, RCA: n=9) of 12 Yorkshire pigs were assigned to two (2) groups randomly. PCB (SeQuent, length 20 mm, n=16) or non-coating balloon (NCB, length 20 mm n=16) were inflated for 60 s with B:A 1.2:1 followed by BMS (length 12 mm) implantation (S/A 1.5:1) within the target region. At 28 days, animals underwent restudy for the assessment of quantitative coronary angiography (QCA) and optical coherence tomography (OCT).

**Results** There were no differences between groups among all of the parameters measured by QCA and OCT. QCA late luminal loss was  $1.27 \pm 0.57$  mm for PCB and  $1.11 \pm 0.52$  mm for NCB (p=NS). Similarly, the percent of in-stent stenosis was  $34.5 \pm 15.0\%$  for PCB and  $36.2 \pm 13.6\%$  for NCB (p=NS). OCT image analysis, showed that the mean thickness of neointimal hyperplasia (NIH) on stent strut was  $585 \pm 219$   $\mu$ m for PCB compared to  $661 \pm 183$   $\mu$ m for NCB (p=NS), and the percent of in-stent area stenosis was  $43.2 \pm 14.9\%$  for PCB, and  $49.5 \pm 11.5\%$  for NCB (p=NS).

**Conclusions** In the current experimental setting, we didn't observed inhibition of neointimal formation response to PCB therapy as determined by both QCA and OCT measurement.