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SUCCESSFUL INHIBITION OF CORONARY NEO-INTIMAL HYPERPLASIA IN SWINE USING A NOVEL PACLITAXEL-COATED SCORING BALLOON CATHETER

i2 Oral Contributions
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Authors: *Gary Gershony, Bruno Scheller, Ulrich Speck, Bodo Cremers, Klinik für Innere Medizin III, Universitätsklinikum des Saarlandes, Homburg/Saar, Germany, Abteilung für Radiologie, Experimentelle Radiologie, Charité, Universitätsklinikum, Berlin, Germany*

Background: Recent studies with paclitaxel-coated balloons (P-POBA) have demonstrated reduction of late lumen loss (LLL) and TLR in coronary and peripheral lesions. However, POBA is associated with unpredictable acute results requiring bailout stenting. The AngioSculpt Scoring Balloon (ASC) avoids slippage and is associated with improved acute results and a low rate of dissections. We hypothesized that a paclitaxel-coated ASC (P-ASC) might facilitate drug delivery to the vessel wall and minimize the need for stenting.

Methods: Domestic farm pigs (n=30) underwent pre-dilatation of the LAD and LCX (60 vessels) with either an oversized (~1.2:1) bare ASC, a P-POBA or a P-ASC (3 different coatings, paclitaxel ~3µgm/mm2) followed by a bare stent. LV and quantitative coronary angiography (QCA), and histomorphometry (H) was performed at 30 d.

Results: The QCA and H results are summarized in the table. The P-POBA and all 3 P-ASC groups resulted in a highly significant reduction of in-stent LLL, diameter stenosis (DS), and neo-intimal and medial area as compared to the bare ASC group. There was no vessel wall drug/carrier toxicity based on the inflammation scores. The LVEF was unchanged from baseline to 30-d in all treatment groups.

	Bare ASC	P-POBA	P-ASC #1	P-ASC #2	P-ASC #3	P-Value
LLL (mm)	1.43±0.65	0.50±0.35	0.44±0.56	0.27±0.24	0.23±0.22	0.001
DS (%)	43.9±24.9	11.5±15.9	0.6±23.5	-2.1±18.3	-6.6±24.2	0.001
Neointimal Area (mm2)	4.46±1.49	3.26±0.78	2.95±1.22	2.47±0.86	2.80±0.73	0.001
Media Area (mm2)	4.20±2.56	1.77±0.48	1.41±0.75	1.56±0.71	1.44±0.52	0.001
Injury Score	2.53±0.53	2.52±0.30	2.57±0.36	2.52±0.28	2.66±0.26	0.876
Inflammation Score	2.37±0.75	2.55±0.42	2.71±0.32	2.56±0.41	2.60±0.59	0.668

*Negative DS values = persistent overstretch

Conclusions: A P-ASC was at least as successful as a clinically proven P-POBA for inhibiting neo-intimal proliferation in the porcine ISR model. There was no evidence of local toxicity or adverse myocardial effects. A FIM study is being planned.