EFFECTIVE NEOINTIMAL REDUCTION WITH TWO NOVEL DRUG-ELUTING STENTS COATED WITH BIODEGRADABLE POLYMER - AN INTRAVASCULAR ULTRASOUND ANALYSIS FROM THE PAINT RANDOMIZED TRIAL

i2 Poster Contributions
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Background: Sirolimus and Paclitaxel are well known anti-restenosis agents; they have been tested in different stents with different platforms and polymers.

Methods: We aim to compare the neointimal inhibition efficacy of two drug eluting stents with identical platforms and biodegradable polymers, but with different drugs (Sirolimus or Paclitaxel) against bare metal stents (BMS) by intravascular ultrasound (IVUS). From the 274 patient (pts) randomized in the PAINT trial, who had a stent implanted in a de novo lesion in a native vessel, a pre-defined subset of 110 patients underwent 9-month IVUS follow-up. Patients were randomly allocated at a 2:2:1 ratio for sirolimus-eluting stent (SES; n=45), paclitaxel-eluting stent (PES; n=45), or BMS (n=20). All IVUS analyses were performed by a technician blinded to the study group.

Results: There were no differences in the stent length or stent area among the three groups. Incomplete apposition was found in 2 pts (1 in the BMS and 1 in the SES group). The average neointimal hyperplasia (NIH) area was 0.8 ± 0.9 mm2, 1.0 ± 1.2 mm2, and 1.8 ± 1.3 mm2, for the SES, PES, and BMS groups respectively (p = 0.004 for the overall comparison). Also, the NIH obstruction was 12.0 ± 11.9%, 12.9 ± 13.3%, and 24.9 ± 15.8% respectively (p = 0.002). There were no differences in the NIH parameters for the comparison of SES vs. PES. There were no differences in the analysis of the stent edge portions.

Conclusions: Both sirolimus- and paclitaxel-eluting stents coated with a novel biodegradable polymer carrier were effective in inhibiting neointimal hyperplasia, in comparison to bare stents. The efficacy of both formulations of drug-eluting stents, releasing either sirolimus or paclitaxel, did not appear to be different when compared in a head-to-head analysis by IVUS.