Novel Bioabsorbable Salicylate-Based Polymer as a Drug-Eluting Stent Coating

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Background: Permanent polymers used in current DES can trigger chronic inflammation and hypersensitivity reactions which may contribute to increased risk of late thrombosis and rebound restenosis. Therefore, optimal polymer selection and the use of completely absorbable but biocompatible polymers are expected to minimize these risks.
Objectives: We sought to evaluate a novel, potentially innately anti-inflammatory, bioabsorbable salicylate-based polymer as a drug-eluting stent coating, in a clinically relevant animal model.
Methods: Four types of stents were implanted in pig coronary arteries using QCA to optimize stent apposition: bare metal stents (BMS); salicylic acid/adipic acid bioabsorbable polymer-only coated metal stents (SA/AA); biostable polymeric sirolimus-eluting stents (Cypher); and metal stents coated with salicylic acid/adipic acid bioabsorbable polymer containing sirolimus (SA/AA + S). The dose density of sirolimus was 8.3 μg/mm of stent length (similar to Cypher) with *in-vitro* studies demonstrating elution over 30 days and complete polymer degradation in 37 days. Animals underwent angiographic restudy and were terminated at 1 month for complete histopathologic and histomorphometric analyses.
Results: Both SA/AA + S and Cypher stents had significantly lower angiographic % stenosis compared to BMS and SA/AA polymer-only groups (6±4% and 5±4% vs. 15±7% and 16±5%, respectively, $P<0.001$). Intimal thickness was lower for SA/AA + S and Cypher, than for BMS (0.14±0.06mm and 0.13±0.04mm vs. 0.23±0.05mm, respectively, $P<0.001$). Histologic % area stenosis was also lower for SA/AA + S and Cypher, compared to BMS (22±7% and 23±6% vs. 33±5%, respectively, $P<0.001$). There was a strong trend towards reduced inflammatory response in the SA/AA and SA/AA + S compared to BMS and Cypher groups ($P=0.072$).
Conclusions: This study shows favorable vascular compatibility and efficacy for a novel bioabsorbable salicylate-based polymer as a DES coating, and supports further research and development of this unique class of polymer materials for applications in cardiovascular devices.