Novel Stent Surface Coating Inhibits Thrombus Formation in a Baboon Ex-Vivo Model

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Background: Thrombogenicity of permanent polymers used on existing drug-eluting stents (DES) is implicated in late stent thrombosis; novel polymers that are thromboresistant may be advantageous. The non-human primate *ex-vivo* arteriovenous shunt is a valid, reliable, and relevant model to assess stent thrombogenicity.

Objectives: To compare thrombogenicity of stents coated with a novel bioabsorbable salicylate-based polymer without (polymer-only) or with sirolimus (polymer+sirolimus), to that of bare metal stents (BMS).

Methods: Stents (n=21, 7 of each type) were assessed for accumulation of ^{111}In-oxine labeled platelets and ^{125}I labeled fibrinogen during a 2hr exposure to 100ml/min flowing blood in *ex vivo* shunts of conscious, non-anticoagulated baboons. Subsequently stents were examined macroscopically and by scanning electron microscopy (SEM).

Results: Polymer-only coated stents accumulated fewer platelets (graph) during the 2hr shunt exposure than either BMS (P=0.017) or polymer+sirolimus (P=0.025). There was also a trend for polymer+sirolimus to have reduced platelet thrombus compared to BMS (P=0.05). Fibrin deposition was similar among stent types. Thrombus accumulation was notable for all stent types by macroscopy and SEM, but somewhat more pronounced in BMS. No marked differences in thrombic components between groups were revealed by SEM.

Conclusions: Salicylate polymer coating reduces thrombogenicity of metal stents in arterial blood flow conditions, even when the drug sirolimus is included. This novel, fully bioabsorbable salicylate-based polymer may be advantageous for reducing DES thrombotic complications.