PRECLINICAL RESULTS WITH A NOVEL INTERNALLY LOADED DRUG-FILLED CORONARY STENT

Poster Contributions
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Background: A non-polymeric drug-eluting stent (DES) offers theoretical safety and efficacy advantages. However, controlled drug release in the absence of a polymer carrier vehicle has proven challenging.

Methods: The internally loaded drug-filled stent (DFS, Medtronic, Santa Rosa, CA) has a hollow lumen containing sirolimus (1.1 ug/mm2) and laser cut abluminal fenestrations (average 5/strut, average minimal bore diameter 20 um) for controlled drug release. 559 DFS were implanted in porcine coronary pharmacokinetic and histology studies to evaluate the performance of this device.

Results: 67.5% ± 6.9% and 93.2% ± 2.1% of drug were released at 28 days and 90 days, respectively (Figure left). In vivo tissue drug levels peaked at 1.6 ± 0.5 ng/mg at 24 hours and remained ≥0.5 ng/mg through 90 days (Figure right). Histology demonstrated effective suppression of neointimal hyperplasia at 28 days (diameter stenosis 13.2% ± 3.4% vs. 21.0% ± 7.5% with BMS, P<0.0001). Fibrin scores demonstrated drug effect through 90 days, then fell to control levels. Inflammation was minimal at all time periods.

Conclusion: The internally loaded DFS is a unique DES platform which provides therapeutic sirolimus delivery to the arterial wall in the absence of a polymer carrier. On the basis of these data, the first-in-human clinical trial with DFS is projected to begin in mid-2015.