CLINICAL EXPERIENCE WITH A SIROLIMUS-ELUTING NITINOL STENT IN A BIODEGRADABLE POLYMER MATRIX USING THE CARDIOMIND® 0.014" SPARROW® STENT SYSTEM

i2 Poster Contributions
Georgia World Congress Center, Hall B5
Monday, March 16, 2009, 9:30 a.m.-10:30 a.m.

Session Title: Endovascular and New Technologies
Abstract Category: New Technologies/Innovations
Presentation Number: 2505-524

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Background: Lower plaque trauma may result in favorable late outcomes after coronary stenting. The Sparrow® Coronary Stent System (CardioMind, Inc. Sunnyvale, CA) is a 0.014" guidewire-based stent delivery platform combining the Sirolimus drug in a fully biodegradable SynBiosys polymer matrix on CardioMind’s nitinol stent platform. Stent release is achieved with a novel release mechanism which utilizes a principle of electrochemical dissolution. Both the Bare metal (BMS) and sirolimus eluting (DES) versions are under evaluation in the CARE II randomized clinical study.

Methods: CARE II is a prospective, multicenter and multinational (Asia, Australia/NZ, Brazil and Europe) randomized 3-arm clinical study. CARE II was designed to demonstrate the safety, efficacy and performance of the CardioMind Coronary DES Stent in the treatment of single de novo native coronary artery lesions < 20 mm long and 2.0 - 2.75 mm in reference diameter when compared to the Bare Metal Sparrow and Driver/MicroDriver (MDT) stents. The primary endpoint is 8 mo in-stent LLL with IVUS follow-up in a subset of the patients.

Results: The mean age of the CARE II patients (n=100) was 63 yr with 33% diabetic and 88% with history of hyperlipidemia. Procedural success with the BMS or DES versions was 94.9% (75/79) with lesion success at 100% (79/79). Lesion access with either the BM or DES Sparrow System as a front line guidewire was in >70% of patients. The mean vessel size and lesion length were 2.32 mm and 14.47 mm. Post-procedure residual in-stent stenosis was 10.3 %. Preliminary follow-up data will be presented comparing the DES to BMS and MDT arms.

Conclusions: CARE II clinical experience with the Sparrow’s electrically activated stent release system demonstrates the feasibility and safety of this platform in small coronary arteries with guidewire-like deliverability and good stent expansion. The tailored design of the fully biodegradable polymer platform on the ultra-thin nitinol struts of the Sparrow may provide improved outcomes in small vessels by enabling atraumatic stenting.