DRUG-ELUTING STENT STUDIES - BIODEGRADABLE POLYMERS

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1-Year Clinical Outcomes After Percutaneous Coronary Intervention With Biodegradable Polymer Ultra-Thin Strut Everolimus-Eluting Coronary Stent System

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BACKGROUND First-generation drug-eluting stents had thicker struts and were associated with a higher rate of stent thrombosis. Hence, newer generation biodegradable polymer-coated drug-eluting stents are developed with thinner struts to improve clinical outcomes. This study aims to demonstrate the safety and performance of a newer-generation ultrathin (50-μm) strut Evermine 50 everolimus-eluting coronary stent (EES) system (Meril Life Sciences Pvt. Ltd., India) in patients with de novo coronary artery lesions.

METHODS Evermine 50 EES-1 BGM was a prospective, single-arm, single-center, real-world study conducted at tertiary care center in India. Patients with de novo coronary artery lesions (length <44 mm) were enrolled. All the enrolled patients had at least 1 de novo coronary artery lesion (length <44 mm) and successfully underwent implantation with Evermine 50 EES. The safety endpoint was major adverse cardiac events, composite of cardiac death, myocardial infarction attributed to the target vessel, and clinically driven target lesion revascularization, at 12-month follow-up. Stent thrombosis was classified according to the definitions of the Academic Research Consortium. The performance endpoints were procedural as well as device success. (CTRI Number: CTRI/2017/03/008173)

RESULTS Between March 2017 and April 2018, a total of 251 patients (mean age 58.20 ± 9.92 years) was enrolled. Of this cohort, 76.9% patients were male. Among these, 48.6% patients were diabetic, and 45.4% had hypertension. Of 343 lesions treated with EES, 337 (98.2%) were de novo lesions. Multiple vessel disease was present in 50.6% of the patients, and 50.4% of the lesions were located in the left anterior descending artery. The device success and procedure success rate were achieved in 100% of the patients. At 12-month follow-up, 1.2% for major adverse cardiac events (0.8% cardiac death and 0.4% clinically driven target lesion revascularization) was reported. There was no stent thrombosis or myocardial infarction up to 12-month follow-up.

Lesion Characteristics (343 Lesions)		Procedural Characteristics (343 Lesions)			
American College of Cardiology/ American Heart Association Classification		TIMI (Thrombolysis In Myocardial Infarction) Flow Grade			
Lesion Class	n (%)	Pre-Procedure	n (%)	Post-Procedure	n (%)
A	108 (31.5)	0	38 (11.1)	0	4 (1.2)
B1	160 (46.6)	1	29 (8.5)	1	0 (0.0)
B2	21 (6.1)	2	35 (10.2)	2	3 (0.9)
C	54 (15.7)	3	241 (70.3)	3	336 (98)

CONCLUSION The present study demonstrates the favorable safety and performance of ultrathin strut EES system in the treatment of de novo coronary artery lesion, as demonstrated by the low incidence of major adverse cardiac events at 12-month follow-up.

CATEGORIES CORONARY: Stents: Drug-Eluting