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Effectiveness of Flexyrap® Cobalt-Chromium Rapamycineluting Stents with Biodegradable Polymer in Coronary Artery Disease

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Abstract

Background: Data supporting effectiveness and safety of indigenously developed Drug-Eluting Stents (DES) for treatment of Indian patients with de novo Coronary Artery Disease (CAD) remain scarce. In this Postmarketing Surveillance (PMS) study, we evaluated effectiveness and safety of an indigenously developed DES, FlexyRap®, for treatment of Indian patients with obstructive native artery.

Methods: We enrolled 100 patients with obstructive native artery who underwent Percutaneous Coronary Intervention (PCI) using DES technology called FlexyRap®. The primary efficacy endpoint was Target Vessel Revascularization (TVR) at 1-year follow-up. The primary safety outcome was incidence of a Major Adverse Cardiac Event (MACE), defined as a composite of cardiac death, myocardial infarction, target lesion revascularization, and TVR at 12 months. Secondary efficacy endpoints included procedural and device success. Additional safety endpoints were incidences of any device-related Serious Adverse Events (SAEs) and stent thrombosis.

Results: In this study, of the 100 patients treated with FlexyRap®, data was available for 96 patients at the end of the 24-month surveillance period. Device and procedural success was observed in 100% of patients. At 12 months after implantation of FlexyRap®, 6.25% of patients developed MACE; the incidence of MACE remained at 6.25% at completion of the 24-month PMS period. The primary endpoint of TLR developed in 5% of patients. The MACE-free survival rate was 93.78%. No SAE leading to death was reported throughout the 24-month surveillance period. No patient experienced AEs that led to major bleeding, permanent disability, or death.

Conclusion: FlexyRap® was safe and effective in Indian patients with CAD. Results of the study are encouraging and support clinical benefits of the indigenously developed FlexyRap® DES for treating Indian patients with CAD in a real-world scenario.

Keywords: Coronary artery disease • Drug-eluting stent • Percutaneous coronary intervention • Rapamycin • Myocardial infarction • Hrombosis Myocardial revascularization

Abbreviations: BMS: Bare-Metal Stents • DES: Drug-Eluting Stents • BD-DES: Biodegradable Drug-Eluting Stents • PCI: Percutaneous Coronary Intervention • DP-DES: Durable Polymer Drug-Eluting Stents • TVR: Target Vessel Revascularization • CAD: Coronary Artery Disease • PMS: Postmarketing Survey • MI: Myocardial Infarction • LVEF: Left Ventricular Ejection Fraction • QCA: Quantitative Coronary Angiography • MACE: Major Adverse Cardiac Event • TLR: Target Lesion Revascularization • SAE: Serious Adverse Event • TIMI: Hrombolysis In Myocardial Infarction • CABG: Coronary Artery Bypass grafting

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