Integrative Clinical Medicine

Editorial

ISSN: 2515-0219

Biodegradable polymer Evermine 50™ everolimus eluting coronary stent system with ultrathin (50 μm) strut

Suresh V Patted*

Department of Cardiology, KLE Academy of Higher Education and Research Centre, Belgaum, Karnataka, India

Significant development has been made in the field of percutaneous coronary intervention (PCI) from bare metal stents (BMS) to drug-eluting stents (DES). The implantation of BMS was utilized as a minimally persistent treatment for disruptive CAD patients. After the implantation of BMS, few challenges occurred during 6-12 months follow-up, among which stent restenosis or re-narrowing of the treated artery was common in one-third of the patients [1]. It can be resolved using first generation DES with antiproliferative drug. Henceforth, development in stent platform, polymer coating, and drug have revolutionized the approach to treat CAD [2]. Limitation of the first-generation DES is the growing concern for very late stent thrombosis. As a result, second-generation DES with biodegradable polymer coated stent platform was developed from stainless steel to cobalt-chromium (Co-Cr) or platinum-chromium (Pt-Cr) [3]. Thus, the second- generation DES which release everolimus or zotarolimus were associated with lower ST rate. At present, everolimus-eluting stents (EES) are the most frequently used DES.

In the advancement of technology of the DES, the Evermine 50™ (Meril Life Sciences, India) EES with biocompatible and biodegradable polymer poly-L-lactic acid (PLLA) and poly-lactic-co-glycolic acids (PLGA) base has been developed. Evermine 50 is a novel Co-Cr L605 platform with a "hybrid" cell design coronary DES system. It incorporates an advanced ultrathin stent platform with strut thickness of 50 μm coated with a biodegradable polymer and which releases everolimus (1.25 μg/mm^2) as an antiproliferative drug. Evermine 50 EES is approved by Drug Controller General of India (DCGI) and Conformity of European (CE).

EES is associated with a lower rate of cardiac death, myocardial infarction, target lesion revascularization, and also a lower risk of ST, in recent studies after the implantation of EES with Co-Cr platform compared with BMS [4,5]. The Evermine 50 EES is a rapid-exchange delivery percutaneous transluminal coronary angioplasty balloon catheter. The stent is pre-mounted on a balloon catheter and placed between two platinum-iridium radio-opaque markers bands.

Why is second-generation DES Evermine 50 more effective than their older counterparts? They differ from the first-generation stent with respect to the ultrathin strut stent, the polymer used, and the stent design. It is the first thinnest strut stent as compared to Cypher (140 μm), TAXUS Express (132 μm), TAXUS Liberte (96 μm), Resolute Onyx (81 μm), Xience (81 μm), Xience Xpedition (81 μm) and SYNERGY (74 μm) [6-8]. The Evermine 50 EES-KLES is our ongoing study, which observed 171 patients result included 1.81% rate of major adverse cardiac events, and no any stent thrombosis reported at 12 months follow-up period. It is registered at Clinical Trials Registry-India (CTRI) with Number: CTRI/2017/09/009939.

The problems arising due to the durable polymer with thicker metallic stents was resolved using thin biodegradable polymer coated stents with PLLA and/or PLGA [9]. Therefore, many researchers have recently focused their attention on the development of ultrathin strut with biodegradable polymer coated DES. Lower strut thickness might have potential advantages in terms of flow disturbance.

EES are the most frequently used DES. The EES was established as non-inferior to sirolimus-eluting stents in the DESSOLVE III and EXCELLENT trials and superior to paclitaxel-eluting stents in meta-analysis SPIRIT clinical trials [10-12]. Although, DES has significantly reduced the angiographic restenosis rate and has improved clinical outcomes, late lumen loss remains an important subject of ongoing research. At present, in the search for improving the performance of available DES, various developments and clinical studies are ongoing.

The success of the present DES has shifted the focus to further development toward enhancing long-term safety and efficacy of these devices. The new generation DES will probably further improve endothelization and rapid arterial healing and will also provide better safety and performance in CAD patients.

References

1. Poder TG, Erraji J, Coulibaly LP, Koffi K (2017) Percutaneous coronary intervention with second-generation drug-eluting stent versus bare-metal stent: Systematic review and cost–benefit analysis. *PLoS ONE* 12: p. e0177476. [Crossref]

2. Katz GB, Harchandani, Shah B (2015) Drug-eluting stents: the past, present, and future. *Curr Atheroscler Rep* 17: p. 485. [Crossref]

3. Dehghani P (2017) Bioresorbable Polymers and Stent Devices. *Curr Treat Options Cardiovasc Med* 19: p. 12. [Crossref]

4. Valgimigli M (2014) Effects of cobalt-chromium everolimus eluting stents or bare metal stent on fatal and non-fatal cardiovascular events: patient level meta-analysis. *British Medical Journal* 349.

5. Aoki J, Kozuma K, Awata M, Nanasato M, Shiode N, et al. (2016) Three-Year Clinical Outcomes of Everolimus-Eluting Stents From the Post-Marketing Surveillance Study of Cobalt-Chromium Everolimus-Eluting Stent (XIENCE V/PROMUS) in Japan. *Circulation* 80: p. 906-912. [Crossref]

Correspondence to: Suresh V Patted, Department of Cardiology, KLE Academy of Higher Education & Research Centre, Belgaum, Karnataka, India, E-mail: drpatted@yahoo.com

Key words: *biodegradable polymer, coronary artery disease, Everolimus, ultra-thin strut*

Received: June 25, 2018; **Accepted:** July 20, 2018; **Published:** July 24, 2018

6. Kastrati A, Mehilli J, Dirschinger J, Dotzer F, Schuhlen H, et al. (2001) Intracoronary stenting and angiographic results: strut thickness effect on restenosis outcome (ISAR-STEREO) trial. *Circulation* 103: p. 2816-2821. [Crossref]

7. Simon C, Palmaz JC, Sprague EA (2000) Influence of topography on endothelialization of stents: clues for new designs. *J Long Term Eff Med Implants* 10: 143-151. [Crossref]

8. Panoulas VF, Mastoris I, Konstantinou K, Tespili M, Ielasi A (2015) Everolimus-eluting stent platforms in percutaneous coronary intervention: comparative effectiveness and outcomes. *Med Devices (Auckl)* 8: 317-329. [Crossref]

9. Zhang F, Yang J, Qian J, Ge L, Zhou J, et al. (2016) Comparison of long-term clinical outcomes after the second-generation cobalt-chromium sirolimus-eluting stents implantation in diabetic versus non-diabetic patients: a subgroup analysis from the prospective FOCUS registry. *Ann Med* 48: 202-10. [Crossref]

10. Dangas GD, Serruys PW, Kereiakes DJ, Hermiller J, Rizvi A, et al. (2013) Meta-analysis of everolimus-eluting versus paclitaxel-eluting stents in coronary artery disease: final 3-year results of the SPIRIT clinical trials program (Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions). *JACC Cardiovasc Interv* 6: 914-922. [Crossref]

11. Park KW, Chae IH, Lim DS, Han KR, Yang HM, et al. (2011) Everolimus-eluting versus sirolimus-eluting stents in patients undergoing percutaneous coronary intervention: the EXCELLENT (Efficacy of Xience/Promus Versus Cypher to Reduce Late Loss After Stenting) randomized trial. *J Am Coll Cardiol* 58: 1844-54. [Crossref]

12. de Winter RJ, Katagiri Y, Asano T, Milewski KP, Lurz P, Buszman P, et al. (2018) A sirolimus-eluting bioabsorbable polymer-coated stent (MiStent) versus an everolimus-eluting durable polymer stent (Xience) after percutaneous coronary intervention (DESSOLVE III): a randomised, single-blind, multicentre, non-inferiority, phase 3 trial. *Lancet* 391: 431-440. [Crossref]