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International Journal of Current Research
Vol. 10, Issue, 02, pp.65648-65653, February, 2018

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

CLINICAL SAFETY AND PERFORMANCE OF A NOVEL ULTRA-THIN STRUT COBALT-CHROMIUM BARE METAL STENT IMPLANTED IN REAL-WORLD PATIENTS WITH CORONARY ARTERY DISEASE

***[1]Dr. Mahesh Basarge, [2]Dr. Parvindar Singh and [3]Dr. Ashok Thakkar**

[1]Senior Intervetional Cardiologist, Department of Cardiology, Baroda Heart Institute and Research Centre, Vadodara, Gujarat, India
[2]Senior Intervetional Cardiologist, Department of Cardiology, Baroda Heart Institute and Research Centre, Vadodara, Gujarat, India
[3]Department of Clinical Research, Meril life Sciences Pvt. Ltd., Vapi, Gujarat, India

ARTICLE INFO

Article History:
Received 17th November, 2017
Received in revised form
23rd December, 2017
Accepted 13th January, 2018
Published online 28th February, 2018

Key words:
Bare-metal stent,
Chronic total occlusions,
Drug-eluting stents,
Major adverse cardiac events.

ABSTRACT

Background: Despite the prevalent use of drug-eluting stents (DES) in current clinical scenario, many coronary artery disease (CAD) patients are still treated with bare-metal stents (BMS).
Aim: The purpose of this registry was to assess the clinical performance and safety of the ultra-thin (65 μm) strut cobalt-chromium Osum™ BMS for the intervention of CAD patients in real-world clinical practice.
Materials and Methods: This was an observational, non-randomized, retrospective, single-arm registry with a target of evaluating safety and performance of 467 consecutive patients who underwent treatment for CAD by Osum stent implantation from January 2012 to October 2016. The mean follow-up duration of this study was 2 years. The endpoint of the study was to observe major adverse cardiac events (MACE), which includes myocardial infarction (MI), cardiac death, and ischemia-driven target lesion revascularization (ID-TLR).
Results: A total of 512 lesions were treated in 467 enrolled patients (mean age: 56.57 ± 11.02 years) with 28.12 ± 7.89 mm average stent length and average stent diameter of 2.88 ± 0.40 mm. An average of 1.08 ± 0.27 study stent was implanted per patient. Out of 467 patients, 370 (79.23%) were males, 119 (25.48%) were diabetics and 206 (44.11%) had hypertension. At 2.0 ± 1.5 years follow-up, the total incidence of MACE occurred in 36 (7.71%) patients which include 2 (0.43%) MI, 30 (6.42%) cardiac deaths and 4 (0.86%) ID-TLR. There were no cases of stent thrombosis (ST).
Conclusions: This study demonstrated that Osum BMS is associated with a low rate of major adverse cardiac events with an absence of stent thrombosis at a mean follow-up of 2 years in real-world coronary artery disease patients.
Trial registration: This study is registered at clinical trial registry of India with CTRI number: CTRI/2017/11/010531

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Citation: Dr. Mahesh Basarge, Dr. Parvindar Singh and Dr. Ashok Thakkar. 2018. "Clinical safety and performance of a novel ultra-thin strut cobalt-chromium bare metal stent implanted in real-world patients with coronary artery disease", *International Journal of Current Research*, 10, (02), 65648-65653.

INTRODUCTION

Percutaneous coronary intervention (PCI) with stent implantation has become the most conventional coronary revascularization practice. In spite of advancement in polymer and drug coating technology, stent platform remains a key determinant of clinical outcomes. For any interventional cardiologist, the understanding of differences between stent platforms and stent design is of rising value (Menown, 2010).

Corresponding author: **Dr. Mahesh Basarge**
Senior Intervetional Cardiologist, Department of Cardiology, Baroda Heart Institute and Research Centre, Vadodara, Gujarat, India

Drug-eluting stents (DES) have become the first choice of treatment for the patients with coronary artery disease (CAD) and proved to be more effective than bare metal stents (BMS), but their efficacy in comparison to more practical BMS has been queried, particularly in patients with lower risk of restenosis rate or higher risk of thrombosis (Stettler, 2007; Pache, 2005). Although considerable improvements are done in stent platform and alloys, presently existing BMS is still linked with restenosis (Stettler, 2007 and Kaiser, 2009). However, concerning more competitive factors like flexibility, deliverability, and conformability, newer DES is limited. They are more expensive as compare to BMS and increased risk of stent thrombosis (Pfisterer, 2006; Daemen, 2007 and Rubboli,

2012). There are various clinical settings in which DES has better results than BMS for restenosis; like long lesions, small vessels, chronic total occlusions (CTO), in-stent restenosis, and unprotected left main artery disease [Rubartelli 2010, Patti 2008 and Pandya 2010]. Bare metal stents may be considered effective in the condition of long duration antiplatelet therapy and remain a precious option in large vessels or patients with ST-segment elevation myocardial infarction (STEMI) and saphenous vein graft (SVG) stenosis. Hence, it is essential to modify stent designs by employing established new materials or material modifications and lessen strut thickness. An ideal stent has characteristics like high deliverability with a thin-strut, low profile, flexible design but with high radiopacity, high radial strength, and minimal recoil. Newer BMS are characterized by ultrathin struts - a factor that improves their flexibility and deliverability. During implantation, it also diminishes vessel wall injury, which leads to quick endothelialization and reduced restenosis rate (Kastrati, 2001 and Pache, 2003). The primary intent of this real-world, single-centre, retrospective study was to determine the safety and performance of an ultra-thin strut L605 cobalt-chromium Osum BMS in a real-world setting.

MATERIALS AND METHODS

Study design and patient population

A total of 467 successive patients who underwent treatment of coronary artery disease with the use of Osum BMS (Meril Life Sciences Pvt. Ltd., Vapi, India) from January 2012 to October 2016 at Baroda Heart Institute and Research Centre, Vadodara, India. It was a retrospective, single-arm, observational, non-randomized, real-world study which was conducted in accordance with Good Clinical Practices guidelines, Declaration of Helsinki, and local Ethics Committee requirements. The trial is registered at Clinical Trials Registry-India (CTRI/2017/11/010531). Patients of at least 18 years of age and have been treated with Osum BMS, were enrolled for the study. The patients were excluded if they had contraindications to long-term duration of dual antiplatelet therapy, or if they had any hypersensitivity to cobalt-chromium.

Device description

The polyamide balloon expandable Osum BMS is an L605 cobalt-chromium platform with 65 µm strut thickness, mounted on rapid exchange balloon catheter between two platinum-iridium radio-opaque marker bands. Cobalt-chromium platform have high tensile strength and the alloy has properties like non-ferromagnetism, radiopacity, strength, biocompatibility and high corrosion resistance. Osum BMS is available in different lengths i.e., 8 mm to 40 mm and different diameters i.e., 2.5 mm to 4.5 mm. It is indicated for improving coronary luminal diameter in patients with symptomatic ischemic heart disease (IHD) in de novo coronary artery lesion in patients eligible for percutaneous transluminal coronary angioplasty (PTCA).

Interventional procedure and adjunctive medications

The PCI procedures were performed as per the current standard guidelines (Levine, 2016). All patients received both aspirin 75-150 mg and clopidogrel 75 mg once daily for six months, followed by aspirin alone after that. Pre-dilatation was not essential and depended on the operator's preferences.

Definitions and endpoints

The primary endpoint of the study was a rate of major adverse cardiac events (MACE), defined as a composite of cardiac death, myocardial infarction (MI) and ischemia-driven target lesion revascularization (ID-TLR). Cardiac death was defined as any death resulting from an acute MI, sudden cardiac death, due to heart failure or stroke. MI was defined as development of new pathological Q-waves on electrocardiogram, or elevation of creatinine kinase (CK) ≥2-fold the upper limit of normal with elevated CK-MB in the absence of new pathological Q waves or new ischemic symptoms (e.g., chest pain or shortness of breath). ID-TLR was defined as revascularization performed on a patient who returns with clinical symptoms such as unstable angina, that is, chest pain that increases in frequency, intensity or duration. Stent thrombosis (ST) was defined according to Academic Research Consortium (ARC) definitions (Cutlip, 2007).

Follow-up

Clinical/telephonic follow-up was performed for a mean follow-up period of 2 years.

Statistical analysis

All data were analyzed using the statistical package for social sciences (SPSS; Chicago, IL, USA) program, version 15. Continuous variables are presented as mean ± standard deviation (SD) and categorical variables as count and percentage. Time-to-event curve was calculated according to the Kaplan-Meier method.

RESULTS

Baseline demographics and lesion characteristics

A total of 467 patients were enrolled in the study. The basic demographic details of the patients are outlined in (Table 1). The mean age was found to be 56.57 ± 11.02 years. Out of total patients, 370 (79.23%) were male, 119 (25.48%) had a history of diabetes mellitus, and 206 (44.11%) had the history of hypertension.

Table 1. Baseline Data of the Patients with Osum Stent Implantation

Baseline and demographic characteristics	n = 467
Age, years (mean ± SD)	56.57 ± 11.02
Male, n (%)	370 (79.23)
Medical history, n (%)	
Diabetes mellitus	119 (25.48)
Hypertension	206 (44.11)
History of PCI	10 (2.14)
History of CABG	7 (1.50)
History of CAD	56 (11.99)
Cardiac status, n (%)	
Stable angina	162 (34.69)
Unstable angina	15 (3.21)
STEMI	287 (61.46)
NSTEMI	3 (0.64)
Thrombolysis, n (%)	32 (6.85)
LVEF % (mean ± SD)	44.25 ± 8.60

CABG= coronary artery bypass graft; LVEF= left ventricular ejection fraction; NSTEMI= non-ST segment elevation myocardial infarction; PCI= percutaneous coronary intervention; STEMI= ST segment elevation myocardial infarction.

Table 2. Lesion and Procedural Characteristics

Variables	Patients (n=467)
No. of diseased vessels, n (%)	
Single vessel disease	332 (71.09)
Double vessel disease	91 (19.49)
Triple vessel disease	44 (9.42)
Target vessel location, n (%)	
LMCA	3 (0.59)
LAD	192 (37.50)
LCx	96 (18.75)
RCA	221 (43.16)
Procedure characteristics	
Total number of lesions, n	646
Total number of lesions treated with study stent, n	512
Lesion per patient	1.08 ± 0.27
% Occlusion, (mean±SD, mm)	92.33 ± 9.08
Average stent length, (mean±SD, mm)	28.12 ± 7.89
Average stent diameter, (mean±SD, mm)	2.88 ± 0.40

LAD= left anterior descending artery; LCx= left circumflex artery; LMCA= left main coronary artery; RCA= right coronary artery.

Table 3. Cumulative Clinical Events for Mean Follow-up of 2 Years for Patients Receiving Osum

Events	Mean follow-up
All cause death, n (%)	41 (8.78)
Cardiac death	30 (6.42)
Non-cardiac death	11 (2.36)
Myocardial infarction, n (%)	2 (0.43)
ID-TLR, n (%)	4 (0.86)
ID-TVR, n (%)	6 (1.28)
Non-TVR, n (%)	1 (0.21)
ST, n (%)	0 (0)
MACE, n (%)	36 (7.71)

MACE= major adverse cardiac events; ID-TLR= ischemia-driven target lesion revascularization; ID-TVR= ischemia-driven target vessel revascularization; ST= Stent thrombosis.

Table 4. Comparison of Previously Published Studies and the Present Study

Registry/ Study	Stent name	Material	Strut thickness (µm)	No. of Patients	Average stent length (mm)	Average stent diameter (mm)	Mean follow up (months)	MACE (%)	TLR (%)
CLASS **(Legrand, 2006)**	Driver	MP35N Co-Cr	91	202	12 ± 3.0	-	6	12.4	9.4
RISICO Italian Registry **(Brambilla, 2009)**	Vision	L605 Co-Cr	81	138	17.01 ± 3.9	2.41 ± 0.14	6	11.6	5.8
CoroFlex Blue Registry **(Bocksch, 2010)**	CoroFlex Blue	L605 Co-Cr	65	2315	15.6 ± 4.4	3.03 ± 0.43	6	9.2	5.5
VISION Registry **(Kereiakes, 2003)**	Vision	L605 Co-Cr	81	267	17.2 ± 6.3	3.5 ± 0.5	6	6.2	4.3
Driver Registry **(Sketch, 2005)**	Driver	MP35N Co-Cr	91	298	-	-	9	8.4	7
Polish NexGen Registry **(Milewski, 2016)**	NexGen	L605 Co-Cr	65	365	29.50 (19.0-40.0)	3.12 (2.75-3.50)	12	25.2*	13.7
OMEGA Study **(Wang, 2015)**	Omega/ Rebel	Pt-Cr	81	328	18.12 ± 6.54	3.12 ± 0.6	12	12.8	8.4
MULTIBENE **(Vermeersch, 2012)**	PRO-Kinetic	SiC-coated L605	60-120	179	15.7 ± 3.5	3.21 ± 0.45	12	14.5	11.2
MILES Study **(Giordano, 2012)**	Skylor	L605 Co-Cr	70-95	1020	19.5 ± 10.3	3.03 ± 0.43	16	9.9	5
Integrity Study **(Lee, 2011)**	S9 (Integrity)	Co-Cr	91	15	22.23 ± 5.82	2.82 ± 0.30	16	21.4	14.3
OSUM Registry	Osum	L605 Co-Cr	65	467	28.12 ± 7.89	2.88 ± 0.40	24	7.71	0.86

MACE= major adverse cardiac events; TLR= target lesion revascularization; Co-Cr= cobalt-chromium; Pt-Cr= platinum chromium; Sic= silicon carbide; *Major adverse cardiac events includes all cause death, myocardial infarction, target lesion revascularization, stent thrombosis and stroke.

Lesions and procedural characteristics of the patients

A total of 646 lesions were intervened successfully with 512 stents (1.08 ± 0.27 lesion per patient). A total of 512 lesions were treated with the Osum BMS with an average diameter and total stent length of 2.88 ± 0.40 mm and 28.12 ± 7.89 mm, respectively. Patients with single, two and three diseased vessels were 332 (71.09%), 91 (19.49%), and 44 (9.42%) respectively. The target lesion was most commonly located in the right coronary artery 221 (43.16%), followed by the left anterior descending artery 192 (37.50%), and the left circumflex 96 (18.75%). Details of the lesion and procedural characteristics are outlined in Table 2.

Clinical outcomes

The primary endpoint was MACE at 2.0 ± 1.5 years mean follow-up, occurred in 36 (7.71%) patients consisting of 30 (6.42%) cardiac death, 4 (0.86%) ID-TLR and 2 (0.43%) MI was reported. The rates of non-cardiac death, ischemia-driven target vessel revascularization (ID-TVR), non-TVR, ST were 11 (2.36%), 6 (1.28%), 1 (0.21%) and 0 (0%) respectively. All ST were documented as per the ARC definition. The time-to-event analysis performed by Kaplan-Meier method was found to be 92.29% (Figure 1). The summary of MACE is presented in Table 3.

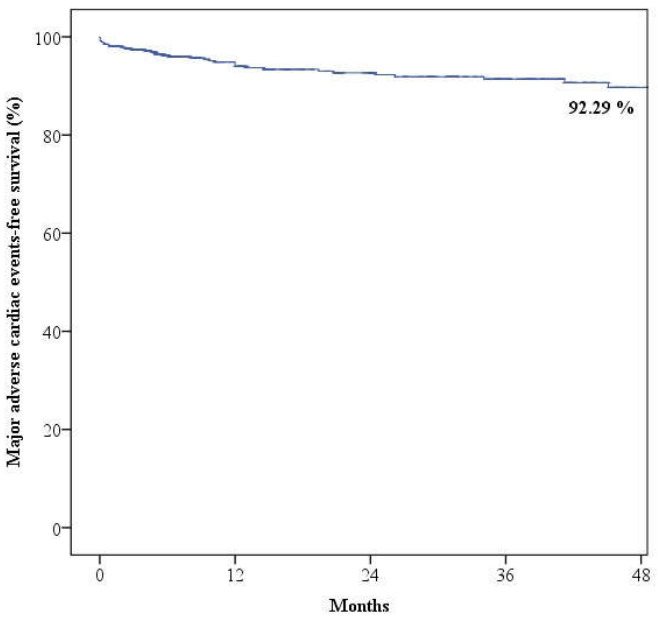

Figure 1. Time-to-event Curve by Kaplan–Meier Method

DISCUSSION

The Osum BMS has shown favourable clinical outcomes at a mean follow-up of 2 years. Several patients treated with Osum BMS had one or more risk factors like diabetes (25.48%) and hypertension (44.11%). Also, the average stent length and diameter were 28.12 ± 7.89 mm and 2.88 ± 0.40 mm, respectively. The primary endpoint, MACE at 2 years mean follow-up was found to be 7.71%. The primary objective of this registry was to assess safety and performance of Osum BMS, and compare its results with other existing BMS stents results such as Driver, Vision, CoroFlex Blue, NexGen, Omega/Rebel, PRO-Kinetic, Skylor, S9 (Integrity). Thus, it can be suggested that the ultrathin stent struts (65 µm) recognized Co-Cr alloy have impressive clinical performance in real-world clinical practice with complex lesions. BMS results have been documented in various indications like large vessel diameter, ST-segment elevation myocardial infarction, higher age, with oral anticoagulant treatment, cancer, or anaemia, intended non-cardiac surgery within the next year (Morice, 2013). Even though the use of DES in preferred in clinical practice, a majority of patients with CAD are still treated with BMS. While DES continue to be more efficient than BMS, patients treated with BMS on basis like insufficient financial resources or contraindication to long-term duration of dual antiplatelet therapy and still have favourable outcomes in the current clinical scenario (Yong, 2013). There are various clinical scenarios for choosing BMS over DES. These include poor conformity with dual-antiplatelet therapy, intolerance/ sensitivity to aspirin or clopidogrel, very elderly people, large coronary artery size (more than 3.5 mm diameter vessel), acute MI and acute coronary syndromes with heavy thrombus burden, venous graft disease, and risk of bleeding, long-term anticoagulation contradiction, those who will need a surgical procedure within 1-2 years (Ben-Dor, 2011). In this study, we tested polyamide balloon expandable Osum BMS, which is based on an L605 cobalt-chromium platform and utilizes open to close cell design allowing for morphology mediated growth from middle to the edges of arteries. Such structure should allow fast healing of patients and favourable procedural results. The use of thinner struts facilitated lower blood flow perturbance and affect endothelialization, neointimal hyperplasia, and possibly stent thrombosis by influencing endothelial shear stress (Kastrati, 2001; Simon, 2000). In the current study, we have presented a comparison of clinical outcomes of previously published studies and current study (Table 4).

The MACE in previous studies between 6 and 12 months was higher to the current study; CLASS (12.4%), RISICO Italian Registry (11.6%), CoroFlex Blue Registry (9.2%), VISION Registry (6.2%), Driver Registry (8.4%), Polish NexGen Registry (25.2%), OMEGA study (12.8%), MULTIBENE (14.5%), MILES study (9.9%), and Integrity study (21.4%). Based on this relative data, it could be concluded that Osum BMS stent had shown favourable clinical performance at 2 years mean follow-up. After Osum BMS implantation, MACE incidence at 2 years was (7.7%) in the 467 patients, and it is comparative with earlier study of various BMS stent-like Bard XT [(Bard Ireland, Galway, Ireland) - balloon-expandable stent], Wiktor [(Medtronic, Interventional Vascular, Netherlands) balloon-expandable tantalum coil], Nir [(Boston Scientific Corp.) - stainless steel stent] or Tenax [(Biotronik, Berlin, Germany) - 316 L stainless steel stent of tubular slotted design] stents (10.4%) and S670 stent (13.5%) (Konig, 2002 and Elbaz, 2002; Legrand, 2001). The event of TLR for Osum BMS at 2-year was (1.28%) was low compared with meta-analysis of ten randomized trials (10.0%) and the earlier stated study of the Wiktor, Nir, Bard XT and Tenax stents (6.1% at 6 months) (Burzotta, 2003). Reduced strut thickness and large vessels are mainly two factors for such lower adverse event rates in the current study (Legrand, 2006). Several previously published studies have recognized that thinner strut stents considerably decrease the prevalence of restenosis rate by ≤40% comparative to other thicker strut devices (Pache, 2003; Briguori, 2002 and Kastrati, 2012). Another study reported that patients treated for smaller vessel disease have a higher restenosis rate following implantation of the (Elezi, 1998). In current study, large vessels were included with stent implantation of large diameter, which lead to low adverse event incidence. Drug-eluting stents have constantly reduced the rate of restenosis compared to BMS and can be the choice of treatment for patients who are at high restenosis risk, whereas BMS remains a precious option for patients with large vessels and clinical contraindication to prolonged dual-antiplatelet therapy.

Limitations of the study

The present study is limited by the fact that it was an observational, non-randomized, retrospective, single-arm study without any direct concurrent comparator. Despite these potential limitations, the large numbers of patients and long duration follow-up associated with our results confirmed the safety and performance of Osum BMS in real-world setting.

Conclusions

In the current study, ultra-thin strut Osum bare metal stent demonstrated the low rate of major adverse cardiac events and provided evidence about favourable safety and performance at 2 years mean follow-up in a wide range of real-world patients.

Conflicts of Interest

Dr. Ashok Thakkar is an employee of Meril Life Sciences Pvt. Ltd., Vapi, India. All authors declare that they have no conflicts of interest.

Funding: None.

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