Analysis of 12 Months Clinical Outcomes Associated with Implantation of Ultrathin (60 µm) Bare Metal Stent in an Unselected Real-world Population with Coronary Artery Disease

ADIKESAVA NAIDU OTIKUNTA[1], UDAY KUMAR HOSAD[2], Y V SUBBA REDDY[3], SRIKANTH ERUVARAM[4], RAVI SRINIVAS[5], RAJEEV GARG[6], LIMMY LORET LOBO[7]

ABSTRACT

Introduction: In the era of drug-eluting stents, Bare Metal Stent (BMS) has worked its way up to be recognized in several indications. Moreover, literature suggests that strut thickness has been directly related to the restenosis rate.

Aim: We intended to evaluate the clinical performance of the ultrathin (60 µm) Flexinnium stent (Sahajanand Medical Technologies Pvt. Ltd. Surat, India) for treatment of a wide range of patients with coronary artery disease in routine clinical practice.

Materials and Methods: This was an observational, non-randomized, retrospective, single-arm study carried out in real-world patients at three clinical centres of India. A total of 419 consecutive patients' data was collected for the study, who underwent treatment for coronary lesions by implantation of Flexinnium stent, between April 2013 and December 2014. The primary endpoint of the study was Major Adverse Cardiac Events (MACE), a conglomerate of cardiac death, Myocardial Infarction (MI) (Q-wave and non-Q-wave), Target Lesion Revascularization (TLR) and Target Vessel Revascularization (TVR). Any incidence of Stent Thrombosis (ST) was also observed as safety endpoint. These endpoints were observed during in-hospital stay, at 30 days, six months and at 12 months follow up. All data were analysed using the Statistical Package for Social Sciences (SPSS; Chicago, IL, USA) program, version 15.

Results: A total of 491 lesions were treated in 419 patients having mean age of 54.1 years. A total of 525 Flexinnium stents were implanted. There were 243 (58.0%) patients with hypertension. At 12 months the total incidences of MACE were 14 (3.5%). These included 9 (2.3%) cardiac deaths, 1 (0.3%) MI, 3 (0.8%) TLRs and 1 (0.3%) TVR. There was one incidence of definite ST at 12 months follow up.

Conclusion: Our results demonstrate that the Flexinnium stent is associated with a low 12 months incidence of MACE in a wide range of real-world population. Long-term follow up would further confirm its clinical performance profile.

Keywords: Myocardial infarction, Percutaneous coronary intervention, Stents

INTRODUCTION

Globally, cardiovascular diseases are the leading cause of death and serious illness accounting for 30% of the deaths annually [1]. Forty years ago, Coronary Artery Bypass Grafting (CABG) surgery was the popular revascularization treatment used in Coronary Artery Diseases (CAD) [2]. Since the dawn of Percutaneous Coronary Intervention (PCI) in 1980s, the number of PCIs performed each year has expanded considerably [1,3]. PCI was initially performed using balloons. Inflating a distensible balloon led to disruption and rearrangement of the plaque that otherwise led to ischaemia; however, in some patients, acute thrombosis, dissection of the artery, or elastic recoil after deflation of the balloon resulted in an inadequate lumen with subsequent symptomatic re-narrowing [4]. This resulted in decreased use of balloon angioplasty and was replaced by BMS.

As the years elapsed, the era budged from use of BMS to durable-polymer coated Drug-Eluting Stents (DES) to biodegradable-polymer coated DES to bioabsorbable stents. However, the BMS has still worked its way up to be recognized in several indications. Various clinical and economic situations of individuals contribute towards the use of BMS over DES. Recent guidelines endorse the use of balloon angioplasty or BMS in patients with high bleeding risk, inability to adhere to 12 months of Dual Antiplatelet Therapy (DAPT), or anticipated invasive procedure or surgery within 12 months,

which would require DAPT interruption [5]. Elderly patients have a higher risk of bleeding as well as comorbidities, which upshots the preference of BMS over DES in such patients. Moreover, DESs have limited flexibility and deliverability [6], with variable penetration rates across the different areas, when compared to the BMSs [7]. Although, DESs have been associated with lower rates of restenosis when compared to BMS, but still pose a risk of late and very late stent thrombosis [8-10].

Literature suggests that the stents with thin struts have been associated with improved flexibility and deliverability, faster endothelialization and a lower rate of in-stent restenosis probably due to diminished vascular injury during implantation [11-13]. Flexinnium (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) is one of the new generation BMS with ultrathin struts. The Flexinnium coronary stent system consists of L605 Co-Cr alloy located on balloon catheter in the midst of two radiopaque markers. Flexinnium stent, with ultrathin strut (60 µm), is developed with a highly flexible 'S-link' which allows the stent to be more flexible hence, more deliverable while it travels through vessels at the time of implantation. Thus, we intended to evaluate the clinical performance of the ultrathin (60 µm) Flexinnium stent for treatment of a wide range of unselected patients with CAD in routine clinical practice.

MATERIALS AND METHODS

Study Design and Patient Population

This was an observational, non-randomized, retrospective, single-arm study carried out in real-world patients at three clinical centres of India. A total of 419 consecutive patients' data was collected in the study, who underwent treatment for coronary lesions by implantation of Flexinnium stent, between April 2013 and December 2014. Before the discharge of the patient from the hospital, data release consent was taken from every patient, which is the practise of associated hospitals, irrespective of any study to be conducted in future. Baseline clinical data with procedural outcomes, patients were obtained from medical records and follow up data were recorded prospectively. The study was approved by the Institutional Review Board or Independent Ethics Committee.

The patients were included for analysis if: 1) patient's age was 18 years or above; 2) patients had stable, unstable angina or acute recent myocardial infarction, and 3) were undergoing coronary intervention with the study stent. The patients were excluded if they declined to give consent for data release or if they had any allergy to aspirin, clopidogrel, ticlopidine, heparin and cobalt chromium.

Description of the Study Stent

The Flexinnium coronary stent system comprises L605 Co-Cr alloy positioned on balloon catheter amid two radiopaque markers. High tensile properties of Co-Cr alloy lead to thinner struts without compromising the radial strength. The Co-Cr alloy has been preferred as it retains the properties of biocompatibility, radiopacity, strength, non-ferromagnetism, and high corrosion resistance. Flexinnium has been developed with a very flexible 'S-link' that allows the stent to be more flexible hence, more deliverable as it travels through vessels during implantation. Strut is ultrathin with a thickness of 60 μm. Flexinnium stent is available in different lengths i.e., 8, 12, 16, 20, 24, 28, 32, 36, 40, 44 and 48 mm and different diameters i.e., 2.0, 2.25, 2.5, 2.75, 3.0, 3.5, 4.0, and 4.5 mm.

Interventional Procedure and Adjunctive Medications

All patients were given a loading dose of 300 mg of aspirin and clopidogrel (300 mg) or prasugrel (60 mg) or ticagrelor (two tablets each of 90 mg). The procedural anticoagulation was brought about either with heparin or bivalirudin. The intra-procedural glycoprotein IIb/IIIa- inhibitor was administered based on the investigator's decision. The procedure was performed as per standard treatment guidelines of every participating centre. Dual antiplatelet therapy (aspirin 75-300 mg daily indefinitely and clopidogrel 75 mg daily or prasugrel 10 mg daily or ticagrelor 90 mg twice daily for at least 1 month) was administered to all patients after the procedure.

Endpoints of the Study

Occurrence of any MACE was the primary end-point of the study. The MACE was defined as a miscellany of cardiac death, MI (Q-wave and non-Q-wave), TLR and TVR. The occurrence of ST was also analysed as safety endpoint as per the Academic Research Consortium. These endpoints were observed at in-hospital stay, 30 days, six months and 12 months follow up. The secondary endpoints will be measured at 24 months.

Definitions of Endpoints and Clinical Events

Any death due to a cardiac cause (such as myocardial infarction, low-output failure, lethal arrhythmia), unwitnessed death and death of unknown reason, and all procedure-related deaths, involving those linked to concomitant treatment, were classified as cardiac death [14]. The MI was defined by rise of cardiac troponin (cTn) values [>5 × 99th percentile upper reference limit (URL)] in patients who have normal baseline values (≤99th percentile URL) or a increase of cTn values >20% when the baseline values are elevated

and are stable or declining [15]. Pathological Q waves are defined as per amplitude, location, and depth if appear in at least two contiguous leads. A TLR was described if restenosis was within the stent or in subsequent 5 mm of distal or proximal segment. A TVR was considered when there was stenosis in any segment of the treated vessel. A ST was considered acute when it occurred within 24 hours, sub-acute when it occurred between 1 and 30 days, and late when it occurred after 30 days. A definite ST was defined by symptoms suggestive of an acute coronary syndrome and angiographic or pathologic confirmation of stent thrombosis. A probable ST was described as unexplained death in 30 days or target vessel MI without angiographic confirmation of ST. A possible ST was described as any unexplained death after 30 day [14].

Follow Up

Clinical follow up or telephonic follow up were scheduled at 30 days, 6 months and 12 months. Follow up data were obtained relating to current clinical status, prior hospitalisation and incidence of any adverse events. Further follow up is scheduled to be taken at 24 months.

STATISTICAL ANALYSIS

Continuous variables were presented as mean ± standard deviation and categorical variables as counts and percentages. The event free survival curve was calculated according to the Kaplan-Meier method. All data were analysed using the Statistical Package for Social Sciences (SPSS; Chicago, IL, USA) program, version 15.

RESULTS

Baseline Demographics and Lesion Characteristics

A total of 419 patients were enrolled in the study. [Table/Fig-1] outlines the basic demographic details of patients. The study population included higher proportion of male (n=317; 75.7%) and average age was 54.1±10.2 years. The rate of hypertension was high in the enrolled patients (n=243; 58.0%). There were 134 (32.0%) diabetic patients in the study. Majority of the patients presented with stable angina (n=153; 36.5%) and non ST-elevation myocardial infarction (n=120; 28.6%). Total 491 lesions were intervened successfully with 525 stents (1.1±0.3 per lesion). The average stent length and diameter were 23.1±8.7 mm and 2.9±0.3 mm, respectively. Type B2 and C lesions accounted for 55 (11.2%) and 200 (40.7%) lesions and there were 88 (17.9%) totally occluded lesions. The lesion and procedural characteristics are detailed in [Table/Fig-2].

Clinical Outcomes

Follow up was completed in 396 (94.5%) patients at the end of 12 months. The occurrence of MACE during in-hospital stay, at 30 days, and 6 months was 5 (1.2%), 5 (1.2%), and 9 (2.2%), respectively. The MACE at 12 months was found to be 14 (3.5%). These included 9 (2.3%) cardiac deaths, 1 (0.3%) MI, 3 (0.8%) TLRs and 1 (0.3%) TVR. There was one incidence of definite ST at 12 months follow-up. [Table/Fig-3] details clinical outcomes of the study. The cumulative event free survival was found to be 96.5% by Kaplan-Meier method [Table/Fig-4].

DISCUSSION

The Flexinnium stent has shown excellent procedural and post-procedural clinical outcomes upto 12 months follow up. The diabetic patients included in the study were 134 (32.0%). More than half (58.0%) of patients were hypertensive. Overall 266 (63.5%) patients presented with acute coronary syndromes. The type of patients included in the study are veracious representative of routine clinical practice for treatment of CAD in India. Type C lesions accounted for 200 (40.7%) lesions. Moreover, the average stent length and diameter were 23.1±8.7 mm and 2.9±0.3 mm, respectively. The primary endpoint, MACE at 12 months was found to be 3.5%. The

Characteristics	Flexinnium (N = 419)
Age (mean ± SD, yrs)	54.1 ± 10.2
Male, n (%)	317 (75.7%)
Diabetes Mellitus, n (%)	134 (32.0%)
Hypertension, n (%)	243 (58.0%)
Left Ventricular Ejection Fraction (mean ± SD, %)	49.3 ± 9.9
Smoker, n (%)	154 (36.8%)
Tobacco User, n (%)	91 (21.7%)
Previous Myocardial Infarction, n (%)	180 (43.0%)
Previous Percutaneous Coronary Intervention, n (%)	7 (1.7%)
Clinical Presentation	
Stable Angina, n (%)	153 (36.5%)
Unstable Angina, n (%)	77 (18.4%)
ST-Elevation Myocardial Infarction, n (%)	69 (16.5%)
Non ST-Elevation Myocardial Infarction, n (%)	120 (28.6%)

[Table/Fig-1]: Baseline demographics characteristics of patients.

Characteristics	Patients = 419 / Lesions = 491
Target Coronary Artery	
Left main artery, n (%)	1 (0.2%)
Left anterior descending artery, n (%)	257 (52.3%)
Right coronary artery, n (%)	156 (31.8%)
Left circumflex artery, n (%)	77 (15.7%)
ACC/AHA Lesion Classification	
A, n (%)	57 (11.6%)
B1, n (%)	179 (36.5%)
B2, n (%)	55 (11.2%)
C, n (%)	200 (40.7%)
No. of Diseased Vessels	
Single vessel disease, n (%)	281 (67.1%)
Double vessel disease, n (%)	126 (30.1%)
Triple vessel disease, n (%)	12 (2.9%)
Total occlusion, n (%)	88 (17.9%)
Total no. of stents, n	525
No. of stents per patient, (mean ± SD, mm)	1.3 ± 0.5
No. of stents per lesion, (mean ± SD, mm)	1.1 ± 0.3
Average stent length, (mean ± SD, mm)	23.1 ± 8.7
Average stent diameter, (mean ± SD, mm)	2.9 ± 0.3

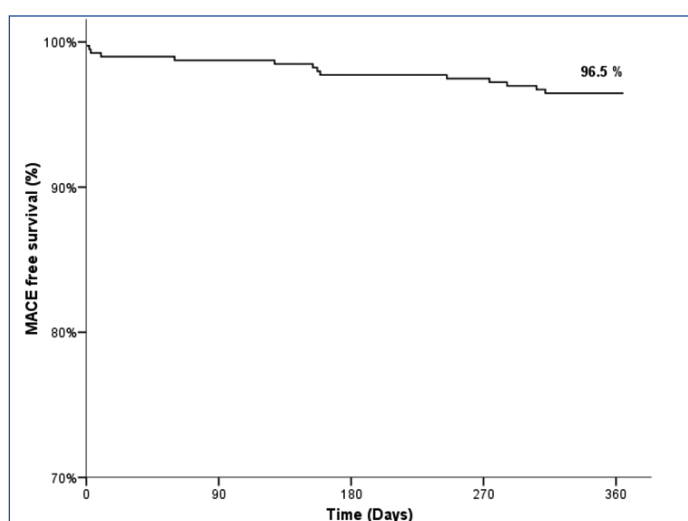**[Table/Fig-2]:** Lesion and procedural characteristics of patients.
ACC/AHA = American College of Cardiology/American Historical Association

Variables	In-hospital N = 419; 100%	30 days N = 419; 100%	6 months N = 410; 97.9%	12 months N = 396; 94.5%
Death	5 (1.2%)	5 (1.2%)	7 (1.7%)	11 (2.8%)
Cardiac, n (%)	5 (1.2%)	5 (1.2%)	7 (1.7%)	9 (2.3%)
Non-cardiac, n (%)	0 (0%)	0 (0%)	0 (0%)	2 (0.5%)
Myocardial Infarction	0 (0%)	0 (0%)	0 (0%)	1 (0.3%)
Q-wave, n (%)	0 (0%)	0 (0%)	0 (0%)	1 (0.3%)
Non Q-wave, n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Target Lesion Revascularization, n (%)	0 (0%)	0 (0%)	1 (0.2%)	3 (0.8%)
Target Vessel Revascularization, n (%)	0 (0%)	0 (0%)	1 (0.2%)	1 (0.3%)
Stent Thrombosis, n (%)	0 (0%)	0 (0%)	0 (0%)	1 (0.3%)
Definite, n (%)	0 (0%)	0 (0%)	0 (0%)	1 (0.3%)
Probable, n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Possible, n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Total MACE, n (%)	5 (1.2%)	5 (1.2%)	9 (2.2%)	14 (3.5%)

[Table/Fig-3]: Cumulative clinical outcomes upto 12 months.

[Table/Fig-4]: Cumulative event-free survival rate upto 12 months.

study included real-world patients with relatively complex lesions and characteristics; still it demonstrated low MACE rates. Thus, it can be postulated that the remarkable ultrathin stent struts (60 μm); the exceptional 'S-link' design and the illustrious Co–Cr alloy have contributed to the splendid clinical performance.

Thinner struts have been associated with lower rates of restenosis, which has been depicted by the ISAR STEREO and ISAR STEREO II trials [16,17]. Thin struts have manifested improved stent crossing, superior trackability, and reduced periprocedural MI [18]. Additionally, the Co-Cr stents can be designed with thinner struts when compared to Stainless Steel (SS) stents owing to its high tensile properties leading to thinner struts without compromising radial strength. Previously a study had reported higher cumulative survival at six months for patients treated with Co-Cr stents than those with SS stents (log-rank p=0.03) [19]. Literature suggests that stent designs have also been responsible for the clinical outcomes. The rigid stents have resulted into development of thicker neointima at follow up when compared to flexible stents [20]. Thicker neointima consecutively results into augmented in-stent restenosis. Thus, the flexible 'S-link' design also contributes towards the lower MACE rates after the implantation of Flexinnium stents.

[Table/Fig-5] represents comparison of patient characteristics and clinical outcome data of some previously published studies and the present study. This study includes greater number of diabetic patients (32.0%) and longer stent length (23.1±8.7 mm) than most studies. Despite the definition of MACE was not uniform in all these studies, our comparison demonstrated favourable MACE rate in the Flexinnium study when compared to most other studies. The MACE in other studies with 12 months follow-up [7, 21-24] was higher than the present study; OMEGA study (12.8%), Polish NexGen Registry (25.2%), KARE study (8.2%), Arthos Pico Austrian Multicenter Registry (15.0%), MULTIBENE (14.5%). Moreover, Flexinnium has the lowest strut thickness among all the compared stents; this represents role of strut thickness towards the clinical outcomes after stent implantation. Based on this comparative data, it could be reasonable to infer that Flexinnium stent had depicted propitious clinical performance at 12 months follow up. In addition, recently a study had also depicted favourable outcomes after implantation of Flexinnium in unselected real-life patients with simple and complex coronary lesions [25].

Currently, the DESs have been extensively used with favourable outcomes in terms of lower rates of restenosis when compared with BMS. Nevertheless, DESs suffer a major drawback of late stent thrombosis which has been associated with a mortality rate of around 45% [26]. Moreover, the BASKET-LATE study emphasizes that DES have been allied with augmented rate of late, apparently thrombosis-related, death or non fatal MI when compared to BMS [8]. There was low rate of restenosis-related TVR after DES (4.5%)

when compared to BMS (6.7%), on the other hand the rates of cardiac death (1.2% vs. 0%) and non fatal MI (4.1% vs. 1.3%) were higher after DES implantation than BMS at 7 to 18 months follow up. Likewise, the DEDICATION trial determined that long term cardiac death, presumably due to stent thrombosis, was higher in DES than in BMS (7.7% vs. 3.2%; p =0.02) [27]. Similarly, Vogt A et al., had reported that on multivariate analysis at long term follow-

Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. 2011;58(24):e44-122.

[6] Suttorp M, Stella P, Dens J, McKenzie J, Park K, Frambach P. Ultra-thin strut cobalt chromium bare metal stent usage in a complex real-world setting (SOLSTICE registry). Neth Heart J. 2015;23(2):124-29.

[7] Carrie D, Schaechinger V, Danzi GB, Macaya C, Zeymer U, Putnikovic B, et al. Cobalt–Chromium KAname™ coRonary stEnt system in the treatment of patients with coronary artery disease (KARE Study). J Interv Cardiol. 2014;27(5):491-99.

Registry/Study	Stent name	Material	Strut Thickness (µm)	No. of Patients/Lesions	Diabetic Patients (%)	Average Stent Length (mm)	Follow up (months)	MACE (%)	TLR (%)
Flexinnium Study	Flexinnium	L605 Co-Cr	60	419/491	32.0	23.1±8.7	12	3.5	0.3
Integrity Study [28]	S9 (Integrity)	Co-Cr	91	15/30	53.0	22.2±5.8	16	21.4	14.3
MILES Study [29]	Skylor	L605 Co-Cr	70–95	1020/-	27.1	19.5±10.3	16	9.9	5.0
OMEGA Study [21]	Omega/ Rebel	Pt-Cr	81	328/328	17.4	18.1±6.5	12	12.8	8.4
Polish NexGen Registry [22]	NexGen	L605 Co-Cr	65	383/-	30.3	29.0 (19.0-40.0)	12	25.2	13.7
KARE Study [7]	Kaname	Co-Cr	80	282/284	22.7	-	12	8.2	6.4
Arthos Pico Austrian Multicenter Registry [23]	Arthos Pico	Phynox Co-Cr	65	203/203	27.0	16.2±6.5	12	15.0	-
MULTIBENE [24]	PRO-Kinetic	SiC-coated L605	60–120	198	10.2	15.7±3.5	12	14.5	11.2
Driver Registry [30]	Driver	MP35N Co-Cr	91	298/298	27.6	-	9	8.4	7.0
MATSURI Registry [31]	Tsunami	316L SS	80	1437/1792	24.9	-	6	7.3	4.5
VISION registry [32]	Vision	L605 Co-Cr	81	267/267	23.0	17.2±6.3	6	6.2	4.3
CoroFlex Blue registry [33]	CoroFlex Blue	L605 Co-Cr	65	2315/2315	19.8	15.6±4.4	6	9.2	5.5
SOLSTICE Registry [6]	SolarFlex	L605 Co-Cr	65	240/292	29.0	17.5±4.8	6	5.8	5.0

[Table/Fig-5]: Comparison of patient characteristics and clinical outcome data of some previously published studies and the present study.

up in STEMI patients after the implantation of DES and BMS, DES was not found to be superior to BMS [26]. The differences in clinical outcomes of DES and BMS are now being diminished through versatile mechanical characteristics and improved deliverability of BMS. Thus, it can be proposed that as the BMS are being improved with better designs and breakthrough engineering, they have been used in parallel with DES under myriad situations.

LIMITATION

The present study is limited by the fact that it was an observational, non-randomized, retrospective, single-arm study without any direct concurrent comparator. In this era of drug eluting stents, the extraction of sizeable clinical data of BMS becomes difficult and takes longer time. Nevertheless, these unselected consecutive patients represent real-world practice; whereas, patients enrolled in clinical trials are carefully selected. We did not have any information on bleeding complications or antiplatelet therapy during follow-up. Despite these limitations, this study demonstrates favourable clinical outcomes that are representative of the real-world situation.

CONCLUSION

Our results demonstrate that the Flexinnium stent is associated with a low 12 months incidence of MACE in a wide range of real-world population. The remarkable ultrathin stent struts (60 µm); the exceptional 'S-link' design and the illustrious Co-Cr alloy have also contributed to the favourable clinical performance of Flexinnium. Long-term follow up would further confirm its clinical performance profile.

REFERENCES

[1] Mathers CD, Boerma T, Ma Fat D. Global and regional causes of death. British Medical Bulletin. 2009;92:7-32.

[2] Garg S, Serruys PW. Coronary stents: current status. J Am Coll Cardiol. 2010;56(10 Suppl):S1-42.

[3] Whittaker DR, Fillinger MF. The engineering of endovascular stent technology: a review. Vasc Endovascular Surg. 2006;40(2):85-94.

[4] King III SB. Why have stents replaced balloons? Underwhelming evidence. Ann Intern Med. 2003;138(10):842-43.

[5] Levine GN, Bates ER, Blankenship JC, Bailey SR, Bittl JA, Cercek B, et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention: a report of the American College of Cardiology Foundation/American Heart Association Task

[8] Pfisterer M, Brunner-La Rocca HP, Buser PT, Rickenbacher P, Hunziker P, Mueller C, et al. Late clinical events after clopidogrel discontinuation may limit the benefit of drug-eluting stents: an observational study of drug-eluting versus bare-metal stents. J Am Coll Cardiol. 2006;48(12):2584-91.

[9] Daemen J, Wenaweser P, Tsuchida K, Abrecht L, Vaina S, Morger C, et al. Early and late coronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study. Lancet. 2007;369(9562):667-78.

[10] Rubboli A, Dewilde W, Huber K, Eeckhout E, Herzfeld I, Valencia J, et al. The management of patients on oral anticoagulation undergoing coronary stent implantation: a survey among interventional cardiologists from eight European countries. J Interv Cardiol. 2012;25(2):163-69.

[11] Simon C, Palmaz JC, Sprague EA. Influence of topography on endothelialization of stents: clues for new designs. J Long Term Eff Med Implants. 2000;10(1):143-51.

[12] Briguori C, Sarais C, Pagnotta P, Liistro F, Montorfano M, Chieffo A, et al. In-stent restenosis in small coronary arteries: impact of strut thickness. J Am Coll Cardiol. 2002;40(3):403-09.

[13] Rittersma SZ, De Winter RJ, Koch KT, Bax M, Schotborgh CE, Mulder KJ, et al. Impact of strut thickness on late luminal loss after coronary artery stent placement. Am J Cardiol. 2004;93(4):477-80.

[14] Cutlip DE, Windecker S, Mehran R, Boam A, Cohen DJ, Van Es GA, et al. Clinical end points in coronary stent trials: A case for standardized definitions. Circulation. 2007;115(17):2344-51.

[15] Thygesen K, Alpert JS, Jaffe AS, Simoons ML, Chaitman BR, White HD. Third universal definition of myocardial infarction. Circulation. 2012;60(16):1581-98.

[16] Kastrati A, Mehilli J, Dirschinger J, Dotzer F, Schühlen H, Neumann F-J, et al. Intracoronary stenting and angiographic results strut thickness effect on restenosis outcome (ISAR-STEREO) trial. Circulation. 2001;103(23):2816-21.

[17] Ürgen Pache J, Kastrati A, Mehilli J, Schühlen H, Dotzer F, Örg Hausleiter J, et al. Intracoronary stenting and angiographic results: strut thickness effect on restenosis outcome (ISAR-STEREO-2) trial. J Am Coll Cardiol. 2003;41(8):1283-88.

[18] Jorge C, Dubois C. Clinical utility of platinum chromium bare-metal stents in coronary heart disease. Med Devices (Auckl). 2015;8:359.

[19] Koh AS, Choi L, Sim L, Tan JW, Khin L, Chua TS, et al. Comparing the use of cobalt chromium stents to stainless steel stents in primary percutaneous coronary intervention for acute myocardial infarction: a prospective registry. Acute Card Care. 2011;13(4):219-22.

[20] Fontaine AB, Spigos DG, Eaton G, Dos Passos S, Christoforidis G, Khabiri H, et al. Stent-induced intimal hyperplasia: are there fundamental differences between flexible and rigid stent designs? J Vasc Interv Radiol. 1994;5(5):739-44.

[21] Wang JC, Carrié D, Masotti M, Erglis A, Mego D, Watkins MW, et al. Primary endpoint results of the OMEGA Study: One-year clinical outcomes after implantation of a novel platinum chromium bare metal stent. Cardiovasc Revasc Med. 2015;16(2):65-69.

[22] Milewski K, Gąsior P, Samborski S, Buszman PP, Błachut A, Wojtaszczyk A, et al. Evaluation of safety and efficacy of NexGen–an ultrathin strut and hybrid cell design cobalt-chromium bare metal stent implanted in a real life patient population–the Polish NexGen Registry. Advances in Interventional Cardiology. 2016;12(3):45.

[23] Strehblow C, Gyöngyösi M, Zenker G, Wallner H, Heigert M, Siostrzonek P, et al. Small vessel stenting with cobalt–chromium stents (Arthos Pico) in a real world setting. Coron Artery Dis. 2007;18(4):305-11.

[24] Vermeersch P, Appelman Y, Horstkotte D, Richardt G, Boland J, Lalmand J, et al. Safety and efficacy of the cobalt chromium PRO-Kinetik coronary stent system: results of the MULTIBENE study. Cardiovasc Revasc Med. 2012;13(6):316-20.

[25] Rajasekhar D, Vanajakshamma V, Reddy GO, Vamsidhar A, Latheef K, Reddy PS. Twelve months clinical outcomes after percutaneous coronary intervention with bare metal stents in unselected real-life patients with coronary artery disease: results from FLEXUS Study. World Journal of Cardiovascular Diseases. 2016;6(10):342-51.

[26] Vogt A, Schoelmerich A, Pollner F, Schlitt M, Raaz U, Maegdefessel L, et al. Comparison of outcome in 1809 patients treated with drug-eluting stents or bare-metal stents in a real-world setting. Vasc Health Risk Manag. 2011;7:693-99.

[27] Holmvang L, Kelbæk H, Kaltoft A, Thuesen L, Lassen JF, Clemmensen P, et al. Long-term outcome after drug-eluting versus bare-metal stent implantation in patients with ST-segment elevation myocardial infarction: 5 years follow-up from the randomized DEDICATION trial (Drug Elution and Distal Protection in Acute Myocardial Infarction). JACC Cardiovasc Interv. 2013;6(6):548-53.

[28] Lee SWL, Chan MP, Chan KK. Acute and 16 month outcomes of a new stent: the first in man evaluation of the medtronic S9 (integrity) stent. Catheter Cardiovasc Interv. 2011;78(6):898-908.

[29] Giordano A, Polimeno M, Corcione N, Fattore L, Di Lorenzo L, Biondi-Zoccai G, et al. Synergy between direct coronary stenting technique and use of the novel thin strut cobalt chromium Skylor™ stent: the mace in follow up patients treated with skylor stent [MILES Study]. Curr Cardiol Rev. 2012;8(1):6-13.

[30] Sketch MH, Ball M, Rutherford B, Popma JJ, Russell C, Kereiakes DJ, et al. Evaluation of the Medtronic (Driver) cobalt-chromium alloy coronary stent system. Am J Cardiol. 2005;95(1):8-12.

[31] Blanchard D, Danzi GB, Urban P, Moseri M, Juergens C, Guyon P, et al. A novel ultra-thin bare metal stent (BMS): results from a worldwide registry. Euro Intervention. 2007;3(2):249-55.

[32] Kereiakes DJ, Cox DA, Hermiller JB, Midei MG, Bachinsky WB, Nukta ED, et al. Usefulness of a cobalt chromium coronary stent alloy. Am J Cardiol. 2003;92(4):463-66.

[33] Bocksch W, Pomar F, Dziarmaga M, Tresukosol D, Ismail O, Janek B, et al. Clinical safety and efficacy of a novel thin strut cobalt–chromium coronary stent system: results of the real world Coroflex Blue Registry. Catheter Cardiovasc Interv. 2010;75(1):78-85.

PARTICULARS OF CONTRIBUTORS:
1. Associate Professor, Department of Cardiology, Osmania General Hospital, Hyderabad, Telangana, India.
2. Senior Consultant Interventional Cardiologist, Department of Cardiology, Yashoda Hospital, Secunderabad, Telangana, India.
3. Professor and Head, Department of Cardiology, Osmania General Hospital, Hyderabad, Telangana, India.
4. Senior Resident, Department of Cardiology, Osmania General Hospital, Hyderabad, Telangana, India.
5. Assistant Professor, Department of Cardiology, Osmania General Hospital, Hyderabad, Telangana, India.
6. Senior Interventional Cardiologist, Department of Cardiology, Yashoda Hospital, Malakpet, Hyderabad, Telangana, India.
7. Clinical Researcher, Department of Cardiology, Yashoda Hospital, Secunderabad, Telangana, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Adikesava Naidu Otikunta,
Associate Professor, Department of Cardiology, Osmania General Hospital, Hyderabad-500012, Telangana, India.
E-mail: oadikesavanaidu@gmail.com