Original Article

Real-World Experience with a 60-mm-Long Stent in the Setting of Primary Percutaneous Coronary Intervention

Babu Thevan, Abdulkarim Abdulrahman, Suddharsan Subbramaniyam, Tarique Shahzad Chachar, Nooraldaem Yousif, Husam A. Noor, Haitham Amin, Fuad Abdulqader, Sadananda Shivappa
Mohammed Bin Khalifa Specialist Cardiac Centre, Awali, Kingdom of Bahrain

ABSTRACT

Introduction: Primary percutaneous coronary intervention (PPCI) represents a timely procedure that requires speedy revascularization. Moreover, PPCI in diffuse coronary lesions remains to be challenging even in the hands of experienced operators as the use of a long stent may increase the difficulty of the procedure in terms of stent delivery, deployment, and optimization. However, the practicability and clinical outcomes of deployment of a 60-mm-long stent in the setting of PPCI remain to be determined.

Methods: The study is a retrospective observational analysis in a prospective cohort. The prospectively gathered data of consecutive patients from June 2016 to December 2019, who underwent PPCI with BioMime sirolimus-eluting stents 2.5–3.0/60 mm or 3.0–3.5/60 mm were analyzed at 1 year regarding the primary outcome of major adverse cardiovascular and cerebrovascular events (MACCE) and target lesion revascularization (TLR).

Results: A total of 88 cases were included in the study; 23 cases underwent PPCI, whereas 65 underwent nonPPCI. The PPCI group had a mean age of 65.7 ± 10.9 years compared with 63.3 ± 9.6 years (P = 0.34) in the nonPPCI group. Eighty-three percentage of PPCI were males compared with 94% of their nonPPCI counterparts (P = 0.20). In addition, the prevalence of hypertension was more common in the PPCI group (87% vs. 63%, P = 0.03). There was no statistically significant difference between the two groups regarding other comorbidities. The most common culprit vessel was the left anterior descending artery (57%) in the PPCI group and the right coronary artery (58%) in the nonPPCI. The use of a stent with a diameter of 2.5–3.0 mm was more common in both groups (61% in PPCI vs. 66% in nonPPCI, P = 0.8). MACCE occurred in four patients during a year of follow-up. One occurred in the PPCI group (4%) compared with three in the nonPPCI group (5%) (P = 1.00). TLR was required in two cases, one in each group (4% vs. 2%, P = 0.46).

Conclusion: The use of a 60-mm-long stent in the setting of PPCI has an excellent 12-month outcome in procedural success, MACCE, and TLR. Large randomized studies are required to confirm these results.

Key words: BioMime, coronary artery disease, drug-eluting stent, full metal jacket, primary percutaneous coronary intervention, sirolimus, ST-elevation myocardial infarction

INTRODUCTION

Diffuse long segment coronary lesions, when there is vessel size discrepancy between the proximal and distal segments may demand the use of the "multiple stent strategy." In these cases, multiple short stents with variable diameters are implanted

Address for correspondence: Dr. Sadananda Shivappa,
Mohammed Bin Khalifa Specialist Cardiac Centre, Awali, Kingdom of Bahrain.
E-mail: sadajhansi@gmail.com

Received: 05-01-2022 **Published Online:** 22-10-2022
Accepted: 08-09-2022

Access this article online
Quick Response Code:
Website: www.heartviews.org
DOI: 10.4103/heartviews.heartviews_2_22

How to cite this article: Thevan B, Abdulrahman A, Subbramaniyam S, Chachar TS, Yousif N, Noor HA, *et al*. Real-world experience with a 60-mm-long stent in the setting of primary percutaneous coronary intervention. Heart Views 2022;23:133-7.

overlapping each other to fit the size of the coronary arteries. Stent overlap interferes with the two major goals of placement optimization, which are reduction in disruption of luminal flow and minimization of mural injury.[1]

Stacking of stents creates regions of stagnation, separation, and recirculation, and it is difficult to have complete apposition without exacerbating vascular injury and alteration in arterial hemodynamics.[1,2] Overlapping struts or multiple struts nearby may increase the risk of local cytotoxicity, persistent inflammation, and amplification of thrombogenic effects. These effects may result in wide variations in mural drug concentration with areas of depletion and excessive concentration.[3]

All these factors increase the risk of complications, mainly stent thrombosis and in-stent restenosis. In addition, deployment of multiple overlapping stents increases treatment cost, prolongs procedural time including radiation exposure, and often requires a prolonged duration of dual antiplatelet therapy.[4]

Zubaid *et al*. studied the significance of angiographic tapering by calculating the tapering index. They found that the proximal and distal left anterior descending (LAD) arteries showed a decremental ratio of 7.7% and the right coronary artery (RCA) showed 5.1% between the proximal and distal ends.[5] Hence, its herculean task is to decide on optimal stent strategy and stent sizing during the procedure, particularly for long segment lesions in the setting of the primary percutaneous coronary intervention (PPCI).

The debut of the new BioMime Morph (Meril Life Sciences, Vapi, Gujarat, India) sirolimus-eluting coronary stent introduced the concept of placing a long tapered stent (up to 60 mm in length) that conforms to the physiological tapering of coronary arteries, avoiding overlapping of drug-eluting stent (DES), and geographical miss and decreasing overall procedure-related DES costs.[6]

There are limited data regarding the use of these long stents, especially in the context of ST-elevation myocardial infarction (STEMI). In the present study, we evaluated the safety and feasibility of using a 60-mm-long stent in the PPCI versus nonPPCI settings concerning 1-year clinical outcomes.

METHODS

Setting

The current study was a retrospective observational analysis in a prospective cohort (88 patients enrolled in our "BioMime Registry" from June 2016 to December 2019). The study took place at Mohammed Bin Khalifa Bin Salman Al Khalifa Specialist Cardiac Centre (MKCC), Riffa, Kingdom of Bahrain.

Study population and data sources

All patients who underwent percutaneous coronary intervention (PCI) with BioMime sirolimus-eluting stents (SES) 2.5–3.0/60 mm and 3.0–3.5/60 mm were included in the study. Exclusion criteria were patients' refusal of informed consent to participate in the registry or lack of capacity to consent and high probability of nonadherence to follow-up requirements. Any patient who underwent PCI with any other type of stent at the same target vessel was excluded from the analysis. Patients' data were extracted from the electronic medical records. The data gathered included patients' demographic details, medical history, angiographic details, and events until 1 year of follow-up. Patients were stratified into two groups: PPCI and nonPPCI. Outcomes were compared between these two groups at 1 year of follow-up.

Definition of the studied groups

Primary percutaneous coronary intervention

PCI is a primary revascularization method for acute STEMI.

Nonprimary percutaneous coronary intervention

PCI as an elective or emergency procedure (other than acute STEMI) including rescue PCI after failed thrombolysis.

Clinical outcomes

Target lesion revascularization during 1 year of follow-up

It is defined as any repeat percutaneous or surgical revascularization of the target lesion within 1 year from the index procedure.

Major adverse cardiovascular and cerebrovascular events during 1 year of follow-up

It is defined as a composite outcome of all cardiovascular mortality, nonfatal stroke, or nonfatal myocardial infarction (MI) within 1 year from the index procedure. A stroke is defined as an acute episode of focal or global neurological dysfunction caused by the brain, spinal cord, or retinal vascular injury as a result of hemorrhage or infarction. MI was defined based on the universal definition including periprocedural MI in patients with unstable angina.

Statistical analysis

The distribution of groups was summarized. Bivariate associations were analyzed using Chi-square tests for categorical variables and *t*-tests for continuous variables. We assessed endpoints and their associations with both groups. A two-sided $P = 0.05$ was considered statistically significant. The STATA software, version 15.1, was used to execute the statistical analyses (StataCorp. 2017, Stata Statistical Software: Release 15; StataCorp LLC., College Station, TX, USA).

Ethical approval

The protocol of this study was submitted to MKCC Ethical and Research Committee before the study initiation. The manuscript was also reviewed and approved by the MKCC research committee. All methods and retrospective analysis of data were carried out by the local guideline and ethical guidelines of the Declaration of Helsinki 1975. The Research and Ethics Committee waived the informed consent for this study due to its retrospective and observational nature and the absence of any patient-identifying information.

RESULTS

Baseline characteristics

A total of 88 cases were included in the study; 23 cases underwent PPCI, whereas 65 underwent nonPPCI. Patients undergoing PPCI had a mean age of 65.7 ± 10.9 years compared with 63.3 ± 9.6 years (P = 0.34). Males represented the majority of cases in both groups. Moreover, 83% of PPCI were males compared with 94% of nonPPCI (P = 0.20). In addition, 30% of cases undergoing PPCI were smokers with no significant difference between the two groups. The median number of comorbidities per person was higher in the PPCI group (4 interquartile range (IQR) 2–4 vs. 3 IQR 2–4, P = 0.18).

The prevalence of hypertension was more common in the PPCI group (87% vs. 63%), and this was significantly different across both groups (P = 0.03). There was no statistically significant difference between the two groups regarding other comorbidities. Details of the baseline characteristics between the two groups are shown in Table 1.

Procedural details

The most common vessel involved in the PPCI was the LAD artery (57%), followed by RCA (39%). The nonPPCI group had more RCA lesions (58%), followed by LAD lesions (37%). The left circumflex artery lesions represented the minority of lesions within both groups. The use of a stent with a diameter of 2.5–3.0 mm was more common in both groups (61% in PPCI vs. 66% in nonPPCI).

Bifurcation stenting occurred in three cases, and all were within the PPCI group (13% vs. 0%, P = 0.016). The use of predilatation and postdilatation techniques was similar between the two groups. In addition, 52% of the cases required GuideLiner catheter to ensure safe and successful stent delivery, with no significant difference between the two groups.

Finally, intravascular imaging was performed more frequently in the nonPPCI group compared to their PPCI counterparts (26% vs. 13%, P = 0.03). Procedural success occurred in all cases except one case in the PPCI. Table 2 summarizes the procedural details.

Outcomes

Major adverse cardiovascular and cerebrovascular events (MACCE) occurred in four patients during a year of follow-up. One occurred in the PPCI group (4%) compared with three in the nonPPCI group (5%) (P = 1.00). Cardiovascular mortality occurred in two cases, one in each group (4% in PPCI vs. 2% in nonPPCI, P = 0.46).

Nonfatal MI and nonfatal stroke occurred only in nonPPCI in two and one cases, respectively (P = 1.0 for both). Target lesion revascularization (TLR) was required in two cases, one in each group (4% vs. 2%,

Table 1: Baseline characteristics of the entire study population

Variables	Non-PPCI (n=65), n (%)	PPCI (n=23),n (%)	P
Age, mean±SD	63.3±9.6	65.7±10.9	0.34
Male	61 (94)	19 (83)	0.20
Smoking	29 (45)	7 (30)	0.32
Hypertension	41 (63)	20 (87)	0.03
Diabetes mellitus	47 (72)	20 (87)	0.25
Dyslipidemia	51 (78)	17 (74)	0.77
Coronary artery disease	31 (48)	12 (52)	0.81
Stroke	4 (6)	1 (4)	1.00
Chronic kidney disease	14 (22)	5 (22)	1.00
Peripheral vascular disease	3 (5)	2 (9)	0.60
Number of comorbidities per person, median (IQR)	3.0 (2.0-4.0)	4.0 (2.0-4.0)	0.18
Ejection fraction (%), mean±SD	44.3±15.2	43.0±11.9	0.72

SD: Standard deviation, IQR: interquartile range, PPCI: Primary percutaneous coronary intervention

Table 2: Procedural details

Variables	Non-PPCI (n=65), n (%)	PPCI (n=23),n (%)	P
Culprit vessel			
LAD	24 (37)	13 (57)	0.22
LCX	3 (5)	1 (4)	
RCA	38 (58)	9 (39)	
Left main stenting	0	1 (4)	0.18
Stent diameter (mm)			
2.5-3.0	43 (66)	14 (61)	0.80
3.0-3.5	22 (34)	9 (39)	
Bifurcation	0	3 (13)	0.01
Intravascular imaging	17 (26.1)	3 (13)	0.03
GuideLiner catheter	36 (55)	10 (44)	0.09
Predilatation	56 (86)	20 (87)	1.00
Postdilatation	60 (92)	20 (87)	0.43
Procedural success	65 (100)	22 (96)	0.26

LAD: Left anterior descending artery, LCX: Left circumflex, RCA: Right coronary artery, PPCI: Primary percutaneous coronary intervention

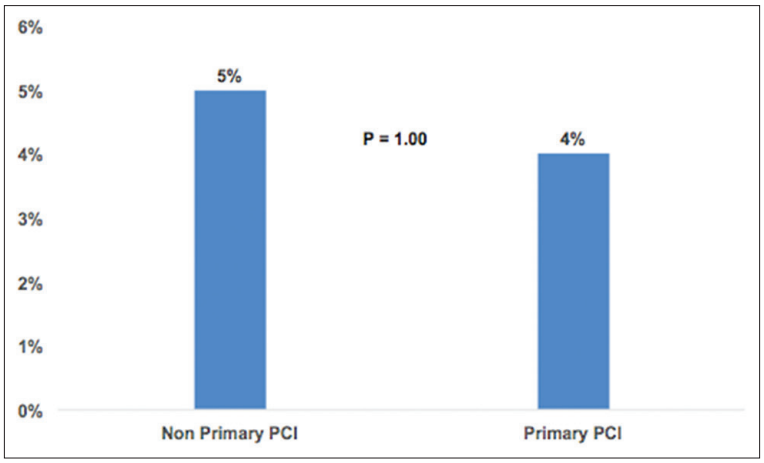

Figure 1: MACCE at 1 year. MACCE: Major adverse cardiovascular and cerebrovascular events. PCI: Percutaneous coronary intervention

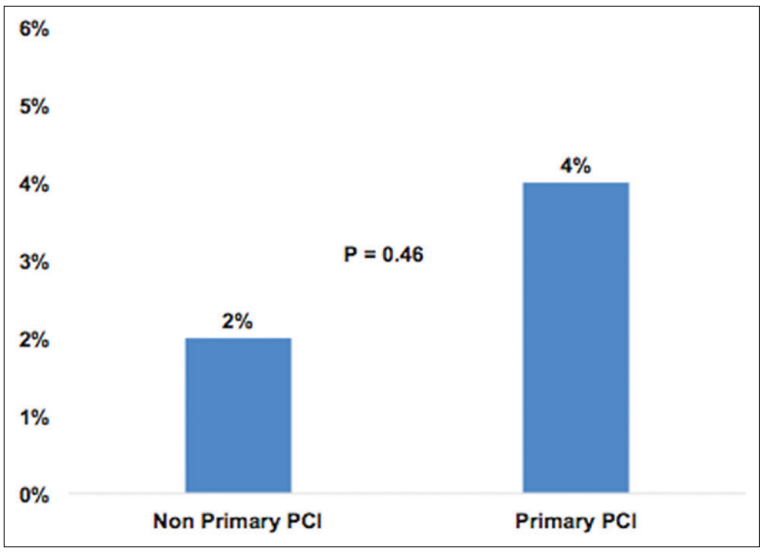

Figure 2: TLR at 1 year. TLR: Target lesion revascularization, PCI: Percutaneous coronary intervention

Table 3: 1-year outcomes in primary percutaneous coronary intervention versus nonprimary percutaneous coronary intervention

Variables	Non-PPCI (*n*=65), *n* (%)	PPCI (*n*=23),*n* (%)	*P*
MACCE	3 (5)	1 (4)	1.00
Cardiovascular mortality	1 (2)	1 (4)	0.46
Nonfatal MI	2 (3)	0	1.00
Nonfatal stroke	1 (2)	0	1.00
Target vessel revascularization	1 (2)	1 (4)	0.46

PPCI: Primary percutaneous coronary intervention, MACCE: Major adverse cardiovascular and cerebrovascular events, MI: Myocardial infarction

P = 0.46). Table 3 and Figures 1 and 2 summarizes the clinical outcomes at 1 year of follow-up.

DISCUSSION

In the present study, we evaluated the safety and feasibility of BioMime Morph SES System tapered stent in the setting of acute STEMI PPCI compared with a nonPPCI setting. There were no significant differences observed in TLR and MACCE at 1 year of follow-up. Despite more advanced DES technology and techniques, the management of very long lesions of more than 40 mm remains a challenge, and overlapping stenting is the norm.[7]

Not many studies have directly compared very long lesions requiring a single stent in the setting of PPCI. Various studies have reported adverse outcomes after overlapping long stents. The increased MACCE with overlapping stents is probably due to increasing neointimal proliferation, variation in the mural drug concentration, rigid overlapped portions with excessive metal areas, and higher vascular injury leading to restenosis and an unfavorable geometry of the overlapped part.[8]

In our study, procedural success was 96% in the PPCI group (22 of 23) and 100% (65 of 65) in the nonPPCI group. This procedural success is to most

published studies in the literature of very long stents more than 40 mm. There was one procedural failure in the PPCI group due to stent delivery failure in the setting of anterior wall STEMI. In this challenging case by Yousif and Noor, the long stent failed to cross a heavily calcified LAD lesion, and an attempt to pull back the undeployed stent into the guiding catheter resulted in eversion of the stent partially stripping it off the stent balloon and rendering the stent irretrievable. Retrieval of the stent at all costs might have led to major complications; hence, stent deployment in the radial artery bailed us out of this precarious situation.[9]

MACCE occurred in four patients during the 12 months of follow-up. One patient (4%) in the PPCI group and three patients (5%) in the nonPPCI groups had MACCE; the difference was not statistically significant (P = 1.00). The Morpheus Global Registry, which evaluated the safety and performance of the BioMime Morph SES system in very long coronary lesions, showed 4% MACCE and 98% procedural success with 2% TLR at 6 months, in which 13% of the patients in this registry were STEMI, and 25% of the patients were with lesions more than 50 mm.[10]

In our study, all patients in both groups had lesions of more than 50 mm in length, and all patients were treated with a 60-mm BioMime Morph stent with no statistically significant correlation between the utilization of a single long stent in PPCI and adverse clinical outcomes at 1 year of follow-up.

CONCLUSION

The use of a 60-mm-long stent in the setting of PPCI has an excellent 12-month outcome for MACCE and TLR. In addition, such long stents frequently require GuideLiner catheter assistance to ensure safe and successful stent delivery, despite that; it can reduce the number of stents per patient and may be associated with lower duration of the procedure, fluoroscopy time, and contrast volumes in appropriately selected patients.

Limitations

The study limitations stem mainly from the design and the sample size. This is an observational retrospective single-center study, and hence it is possible to have unmeasured confounding factors. Furthermore, the sample size is relatively small, and hence the lack of significant difference observed could be due to an underpowered study, which made it difficult to draw any definitive conclusion. Large randomized studies are required to confirm these results.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Timmins LH, Meyer CA, Moreno MR, Moore JE Jr. Mechanical modeling of stents deployed in tapered arteries. Ann Biomed Eng 2008;36:2042-50.
2. Räber L, Jüni P, Löffel L, Wandel S, Cook S, Wenaweser P, *et al*. Impact of stent overlap on angiographic and long-term clinical outcome in patients undergoing drug-eluting stent implantation. J Am Coll Cardiol 2010;55:1178-88.
3. Roach MR, MacLean NF. The importance of taper proximal and distal to Y-bifurcations in arteries. Front Med Biol Eng 1993;5:127-33.
4. Lupi A, Ugo F, De Martino L, Infantino V, Iannaccone M, Iorio S, *et al*. Real-world experience with a tapered biodegradable polymer-coated sirolimus-eluting stent in patients with long coronary artery stenoses. Cardiol Res 2020;11:219-25.
5. Zubaid M, Buller C, Mancini GB. Normal angiographic tapering of the coronary arteries. Can J Cardiol 2002;18:973-80.
6. Tan CK, Tin ZL, Arshad MK, Loh JK, Jafary FH, Ho HH, *et al*. Treatment with 48-mm everolimus-eluting stents: Procedural safety and 12-month patient outcome. Herz 2019;44:419-24.
7. Valero E, Consuegra-Sánchez L, Miñana G, García-Blas S, Rodríguez JC, Moyano P, *et al*. Initial experience with the novel BioMime 60 mm-long sirolimus-eluting tapered stent system in long coronary lesions. EuroIntervention 2018;13:1591-4.
8. Sgueglia GA, Belloni F, Summaria F, Conte M, Cortese B, Silva PL, *et al*. One-year follow-up of patients treated with new-generation polymer-based 38 mm everolimus-eluting stent: The P38 study. Catheter Cardiovasc Interv 2015;85:218-24.
9. Yousif N, Noor HA. Entrapment of a partially degloved stent in the radial artery: Is there any way out? J Saudi Heart Assoc 2020;32:458-61.
10. Patted SV, Jain RK, Jiwani PA, Suryavanshi S, Raghu TR, Raveesh H, *et al*. Clinical outcomes of novel long-tapered sirolimus-eluting coronary stent system in real-world patients with long diffused *de novo* coronary lesions. Cardiol Res 2018;9:350-7.