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A prospective, multicentre registry to assess an everolimus-eluting coronary stent system (PROMUS Element™) for coronary revascularisation in an unrestricted Indian population: the PROMUS Element™ India all-comers registry

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KEYWORDS

- all-comers registry
- Indian population
- PROMUS Element coronary stent system

Abstract

Aims: This registry aims to evaluate the safety and effectiveness of an everolimus-eluting, platinum chromium-based coronary stent system, PROMUS Element™, in an all-comers Indian population.

Methods and results: This prospective, open-label, single-arm study recruited 1,000 patients. The primary endpoint was target vessel failure (TVF) at 12 months post procedure, defined as ischaemia-driven revascularisation of the target vessel (TVR), target vessel myocardial infarction (MI) or cardiac death. Patients were followed up to two years. Mean age was 58.2 (±11.2) years; 83.5% were males. Diabetes mellitus and hypertension were prevalent at 41.1% and 56.5%, respectively. The majority of the patients presented with acute coronary syndrome, of whom 28% had prior STEMI. The primary endpoint occurred in 2.4% at one year. The device-oriented composite endpoint (DoCE), defined as cardiac death, target vessel MI and ischaemia-driven target lesion revascularisation (TLR), was 2.2% at one year and 3.0% at two years. Major adverse cardiac events (MACE), a composite of death, Q-wave MI and TLR, were 2.6% at one year and 3.5% at two years. Cardiac death and all MI were 2.3% and 10.3%, respectively. The definite/probable stent thrombosis rate was low (0.6%). At two years, 91.7% continued to be on dual antiplatelet therapy and the patient follow-up rate was 95.8%.

Conclusions: The primary endpoint and follow-up data up to two years demonstrate the safety and efficacy of the PROMUS Element coronary stent system in an Indian patient population.

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Introduction

India is currently undergoing a rapid epidemiological health transition with a rising burden of non-communicable diseases, such as coronary artery disease (CAD)[1]. In India alone, an estimated 30 million individuals are living with CAD, and 52% of deaths due to CAD occur in people <70 years old[2]. Percutaneous coronary intervention (PCI) is an important way of revascularisation in patients with CAD, including implantation of coronary stents. Drug-eluting stents (DES) provide a controlled localised release of antiproliferative agents over the course of several months, have demonstrated a significant reduction in in-stent restenosis and subsequent repeat revascularisation when compared to bare metal stents (BMS), and have become the standard of care for the treatment of CAD. The PROMUS Element™ everolimus-eluting coronary stent system (Boston Scientific Corporation, Marlborough, MA, USA) is a drug/device combination comprising the following key components: PROMUS Element™ stent composed of a platinum chromium (PtCr) alloy and the drug product (everolimus [40-O-(2-hydroxyethyl)-rapamycin], and two polymers, poly [n-butyl methacrylate] and poly [vinylidene fluoride-co-hexafluoropropylene]). The PROMUS Element uses the same drug and polymer formulation as the PROMUS (Boston Scientific) or XIENCE V (Abbott Vascular, Santa Clara, CA, USA) but combines them with a novel PtCr alloy and flexible stent design, improving deliverability and conformability (88% more conformable), increasing radial strength (136% higher) as well as radiopacity, and reducing recoil (five times lower than cobalt alloy stents) compared with cobalt alloy second-generation stents[3]. Platinum chromium alloys have also shown low thrombogenicity and a high degree of endothelial surface coverage[4]. Several studies have reported the advantages of the PROMUS Element over earlier stents in terms of lower ischaemia-driven target lesion revascularisation (TLR), lower adverse event rates, better safety, and a higher reduction in post-procedure incomplete stent apposition[3,5-7].

We report here the prospective two-year clinical follow-up data of 1,000 Indian patients who underwent coronary revascularisation with the PROMUS Element stent.

Methods

STUDY DESIGN AND PATIENTS

PROMUS Element™ India is a prospective, open-label, observational, multicentre, single-arm registry designed to evaluate the safety and effectiveness of the PROMUS Element stent in 1,000 patients with CAD undergoing revascularisation in a real-world setting. Ethics committee approval was obtained from each participating institution before commencing the study. All consecutive patients who underwent PCI with the PROMUS Element stent from July 2012 to April 2013 from 30 centres across India were enrolled. Patients willing to provide informed consent, who had received the PROMUS Element stent (up to three stents per patient with two stents per artery), and who were willing to comply with all protocol-required follow-up evaluations were included in the study. Patients with a known allergy to the PROMUS Element stent or protocol-required concomitant medications, and any other serious medical illness that may reduce life expectancy below 12 months, were excluded from the study. The study was conducted in compliance with the approved protocol and guidelines. The PROMUS Element received CE mark approval on 30 October 2009 and DCGI approval on 13 April 2010. Stents are available in diameter sizes of 2.25-4.0 mm and lengths of 12-38 mm. The study was registered with the Clinical Trials Registry of India: CTRI/2012/06/003734.

STUDY PROCEDURE

The PCI strategy, procedure and adjuvant medication were determined solely by the investigator according to conventional clinical practice. However, it was suggested that all investigators be familiar with the recommendations in the protocol. Post procedure, all the patients were recommended to be on dual antiplatelet therapy, aspirin for an indefinite duration and either clopidogrel or prasugrel or ticagrelor for at least six months at recommended dosages. The usage of statins and other medication was noted meticulously.

FOLLOW-UP

Clinical follow-up was scheduled for 30 days (±7 days), 180 days (±30 days), 12 months (±30 days) and two years (±30 days), where an office visit was essential for the 12-month follow-up period and the remaining follow-ups were either by telephone contact or by office visit. Patients who were enrolled but who did not receive the PROMUS Element stent were followed for 12 months. At each follow-up, collection of data was carried out regarding any adverse events, angina assessment, laboratory tests performed by the treating physician and medication details. **Figure 1** provides the details of the study flow.

STUDY ENDPOINTS

The safety event dossier and all important clinical endpoints, including serious adverse events (SAE), stent thrombosis (ST), target vessel revascularisation (TVR), myocardial infarction (MI) and death were adjudicated by an independent data safety monitoring committee (DSMC), which also reviewed the cumulative safety data on a regular basis. The steering committee was responsible for the overall study procedures and ensured appropriate actions as per DSMC recommendations, if required.

The primary endpoint was target vessel failure (TVF) of the PROMUS Element at 12 months post procedure, defined as ischaemia-driven TVR, target vessel MI or cardiac death. The secondary endpoints were the TVR rate, the TLR rate, the composite of cardiac death or target vessel MI, all MI (Q-wave and non-Q-wave) rate, cardiac death rate, non-cardiac death rate, all death rate, and major adverse cardiac events (MACE) which is the composite of death, Q-wave MI and TLR. The device-oriented composite endpoint (DoCE) was defined as cardiac death, target vessel MI and ischaemia-driven TLR. Stent thrombosis (ST) was defined using the Academic Research Consortium (ARC) definition and categorised into definite, probable and possible ST and also as

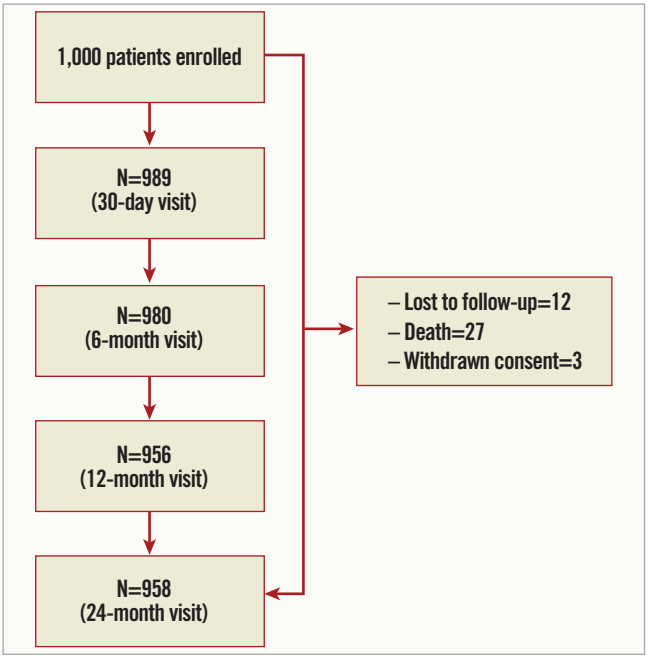

Figure 1. *Patient flow and follow-up of the PROMUS Element registry up to two years.*

Table 1. Baseline patient characteristics and risk factors.

Baseline characteristics & risk factors	ITT population (N=1,000)
Age, years (mean±SD)	58.2±11.23
Male, n (%)	835 (83.5%)
Body mass index, kg/m^2 (mean±SD)	25.8±3.90
Current smoker, n (%)	142 (14.2%)
Family history of CVD, n (%)	127 (12.7%)
Hypertension, n (%)	565 (56.5%)
Dyslipidaemia, n (%)	430 (43.0%)
Diabetes, n (%)	412 (41.2%)
Insulin requiring, n (%)	198 (19.8%)
Previous PCI, n (%)	90 (9.0%)
Previous CABG, n (%)	37 (3.7%)
Left ventricular ejection fraction (mean±SD)	49.9±11.54
Left ventricular ejection fraction <40%, n (%)	302 (30.2%)
Clinical presentation at admission, n (%)	
Acute coronary syndrome	595 (59.5%)
Chronic stable angina	214 (21.4%)
Post-STEMI, n (%)	160 (16.0%)
Asymptomatic ischaemia, n (%)	31 (3.1%)

CABG: coronary artery bypass surgery; CVD: cardiovascular disease; ITT: intention-to-treat; PCI: percutaneous coronary intervention; SD: standard deviation; STEMI: ST-elevation myocardial infarction

acute, subacute and late ST based on the time elapsed since stent implantation. The procedural endpoints were the technical success rate and clinical procedural success rate. All study-related definitions are given in the **Appendix**.

STATISTICAL ANALYSIS

No formal sample size calculations were performed as this study was a post-market registry meant for descriptive analyses. One thousand patients who were enrolled in the study after meeting the eligibility criteria constituted the intention-to-treat (ITT) population and safety population. Nine hundred and fifty-eight (95.8%) patients did not have major protocol deviations and completed two-year follow-up and hence constituted the per-protocol (PP) population. Categorical variables were compared with the use of the chi-square test or Fisher's exact test; the Student's t-test was used for comparison of continuous variables. Adverse events (AE) were coded using the Medical Dictionary for Regulatory Affairs, version 17.0.

Results

A total of 1,000 patients were enrolled in the study (the first patient first visit was on 26 July 2012 and the last patient last visit was on 26 June 2015). All the results are presented for the ITT population. Forty-two (4.2%) patients did not complete two-year follow-up, among whom 27 (2.7%) patients died, three (0.3%) withdrew consent, and 12 (1.2%) patients were lost to follow-up at two years. Detailed patient follow-up is illustrated in **Figure 1**.

Baseline demographics and patient characteristics are summarised in **Table 1**. Male patients accounted for 83.5% (835) of the study population and the mean age was 58.2±11.2 years. Diabetes and hypertension were highly prevalent at 41.2% and 56.5%, respectively. The majority of patients presented either with acute coronary syndrome (59.5%) or post STEMI (16%), 30.2% had an ejection fraction (EF) ≤40%. Baseline procedural characteristics are summarised in **Table 2**. The total number of target lesions treated was 1,264. The left anterior descending (LAD) artery was the most commonly involved, LMCA interventions were 0.2%, and 22% of patients had more than one target lesion treated.

The primary endpoint, TVF, was 2.4% at 12 months post procedure and it was 3.3% at two years. At two years, the ST rate was 0.8%, and the definite/probable ST rates were 0.4% and 0.2%, respectively. There were no acute STs reported in the study but subacute and late ST rates were 0.3% and 0.5%, respectively. The timelines of the ST rate are given in **Figure 2**. Regarding secondary endpoints, the death rate was 2.7% (cardiac death: 2.3%; non-cardiac: 0.4%), the TVR rate was 1.1%, and the MACE rate was 3.5%. All revascularisations were considered clinically indicated, and the TLR rate was low at 0.8% at two years. DoCE was 2.2% at one year and 3.0% at two years. **Table 3** lists all the important outcomes of the study. Patients were treated according to standard interventional techniques with high device (post-procedure diameter stenosis <30%, no device malfunction) and procedure success rates of 100% and 99.9%, respectively.

The percentage of patients who remained on dual antiplatelet therapy at one and two years was 98.6% and 91.7%, respectively. More patients were on clopidogrel (69%) than prasugrel or ticagrelor

Table 2. Baseline coronary lesion characteristics.

Baseline lesion characteristics	ITT population (N=1,000)
Total no. of target lesions	1,264
Location of lesions - no. of lesions (%)	
LMCA	3 (0.2%)
LAD	702 (55.5%)
LCX	257 (20.3%)
RCA	300 (23.7%)
Target lesions treated, no. of lesions (%)	
One lesion	780 (78.0%)
Two lesions	195 (19.5%)
Three or more lesions	25 (2.5%)
Target lesions per patient, mm (mean±SD)	1.2±0.48
Reference vessel diameter[a], mm (mean±SD)	2.93±0.398
Diameter stenosis, mm (mean±SD)	88.67±9.167
Lesion length (visual estimate), mm (mean±SD)	21.53±7.652

[a]Visual assessment by the investigator. LAD: left anterior descending artery; LCX: left circumflex artery; LMCA: left main coronary artery; RCA: right coronary artery

Table 3. Clinical outcomes at 2 years - ITT population.

Outcome	12 months (N=1,000)	24 months (N=1,000)
TVF	24 (2.4%)	33 (3.3%)
All death	19 (1.9%)	27 (2.7%)
Cardiac death	15 (1.5%)	23 (2.3%)
Non-cardiac death	4 (0.4%)	4 (0.4%)
Myocardial infarction (MI)	97 (9.7%)	98 (9.8%)
Q-wave MI	2 (0.2%)	3 (0.3%)
Non-Q-wave MI	95 (9.5%)	95 (9.5%)
Stent thrombosis (ST)		
Acute ST (<24 hrs after procedure)	–	–
Subacute ST (24 hrs to 30 days after procedure)	3 (0.3%)	3 (0.3%)
Late ST >30 days after procedure	5 (0.5%)	5 (0.5%)
Definite ST	4 (0.4%)	4 (0.4%)
Probable ST	2 (0.2%)	2 (0.2%)
Possible ST	2 (0.2%)	2 (0.2%)
Cardiac death or target vessel MI	21 (2.1%)	29 (2.9%)
TVR	9 (0.9%)	11 (1.1%)
TLR	7 (0.7%)	8 (0.8%)
Major adverse cardiac events (MACE)	26 (2.6%)	35 (3.5%)
Device-oriented composite endpoint (DoCE)	22 (2.2%)	30 (3.0%)
Device success	1,000 (100%)	1,000 (100%)
Procedure success	997 (99.7%)	997 (99.7%)

TLR: target lesion revascularisation; TVR: target vessel revascularisation

(Table 4). Other details of medication are given in the **Appendix**. Subgroup analysis for the primary endpoint is given in **Table 5**.

Discussion

The results presented show that the PROMUS Element stent is safe and efficacious when used in a real-world patient population in India. The major findings of this study are as follows: 1) the PROMUS Element demonstrated a good performance with lower rates of TVF, DoCE and stent thrombosis in an enriched PCI population of all-comers in India; 2) with the PROMUS Element, the ischaemia-driven revascularisation within two years occurred infrequently, with low two-year rates of cardiac death and MI; 3) there was no reported case of ST after one year, indicating the long-term safety of the PROMUS Element stent in the study population.

The overall results with the PROMUS Element are consistent with the primary endpoint of the PLATINUM study, which demonstrated low rates of cardiac death or MI, TLR, and stent thrombosis with an everolimus-eluting platinum-chromium stent[3]. The PROMUS Element stent was also associated with a significant improvement in two-year event-free survival when the broader composite measures of TVF (3.3%), DoCE (3.0%) and MACE (3.5%) were considered. These benefits were due largely to reductions in MI and ischaemia-driven TLR and TVR, confirming the positive clinical performance of the PROMUS Element, despite the fact that the Indian population is considered to have high rates of restenosis because of a high prevalence of risk factors such as diabetes. TLR estimates the impact of restenosis while TVR clarifies the dispute whether a re-PCI was caused by a stenosis at the stent edge or by a more distally, newly developed stenosis[8]. The two-year TLR rate was 0.8%, and the TVR rate was 1.1%, which were both appreciably lower than the TLR and TVR rates reported elsewhere with similar patient populations[9,10]. This finding may in part be attributed to the higher threshold for repeat revascularisation (TLR/TVR) for Indian patients due to various socioeconomic constraints. Several studies have reported the advantages of the

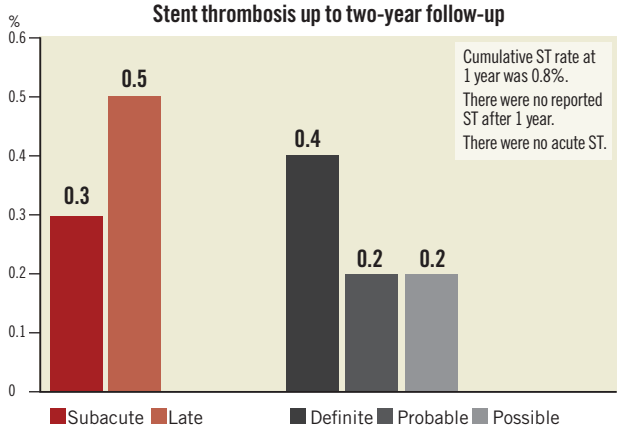

Figure 2. *Stent thrombosis rates in the PROMUS Element™ India all-comers registry up to two-year follow-up.*

Table 4. Summary of antiplatelet therapy up to 2-year follow-up.

Generic name	Pre hospital discharge (N=1,000)	30 days (N=989)	Month 6 (N=980)	Month 12 (N=960)	Month 24 (N=958)
Aspirin	981 (98.1%)	976 (98.7%)	968 (98.8%)	947 (98.6%)	941 (98.2%)
Clopidogrel	649 (64.9%)	637 (64.4%)	638 (65.1%)	663 (69.1%)	661 (69.0%)
Prasugrel	246 (24.6%)	249 (25.2%)	247 (25.2%)	220 (23.0%)	190 (19.8%)
Ticagrelor	105 (10.5%)	95 (9.6%)	86 (8.8%)	77 (8.0%)	65 (6.8%)

PROMUS Element over earlier stents in terms of lower ischaemia-driven TLR: the PLATINUM study reported numerically lower ischaemia-driven TLR (3.5% vs. 4.9%, p=0.21) at three years when compared to the XIENCE V stent[6].

The composite endpoint of cardiac death and target vessel MI was low at 2.9% at two years in this real-world Indian population with CAD. The outcomes of the present study were consistent with the two-year event rates in the XIENCE V® INDIA Study[9]. The low rates of death and target vessel MI were suggested to be due to very few ST reported in this study[11]. DoCE or TLF, the endpoint that supports the characterisation of device effectiveness and safety, was also low in this study at two years (3.0%) and is similar to the reported TLF rates with the XIENCE V stent in an Indian population[9].

The major concerns following DES implantation are non-compliance to antiplatelet therapy and late stent thrombosis. The two-year rate of ST was found to be 0.8%, and ARC definite or probable ST in the present study was 0.6%, consistent with the low thrombosis rates reported in the PLATINUM trial[3]. Late ST was very low at 0.5%, and there were no ST reported after one-year follow-up. The low rates of ST with current-generation DES are reported to be probably due to an optimal combination of a thin fracture-resistant alloy, a low dose of everolimus elution, and the thrombus-resistant non-inflammatory properties of the polymer[12]. This registry also demonstrates that 91.7% of patients continued to be on dual antiplatelet therapy, even at two years. While this practice is not in line with current international guidelines, it is a common practice in India and could possibly be associated with the low ST rates reported in the study.

Table 5. Subgroup analysis for the primary endpoint (target vessel failure) – ITT population.

Category	Subgroup	PROMUS Element (N=1,000)	
		12 months, n (%)	24 months, n (%)
Overall		24/1,000 (2.4)	33/1,000 (3.3)
Age	<65 years	10/720 (1.4)	15/720 (2.1)
	≥65 years	14/280 (5.0)	18/280 (6.4)
Sex	Male	21/835 (2.5)	28/835 (3.4)
	Female	3/165 (1.8)	5/165 (3.0)
eGFR	≤60 mL/min/1.73 m²	7/200 (3.5)	12/200 (6.0)
	>60 mL/min/1.73 m²	17/784 (2.2)	21/784 (2.7)
Angina status	Stable angina	5/342 (1.5)	11/342 (3.2)
	Unstable angina	15/549 (2.7)	18/549 (3.3)
	No angina	4/109 (3.7)	4/109 (3.7)
No. of treated lesions	1	16/780 (2.1)	25/780 (3.2)
	≥2	8/220 (3.6)	8/220 (3.6)
Lesion type	A	–	–
	B	11/489 (2.2)	15/489 (3.1)
	C	24/741 (3.2)	29/741 (3.9)
Reference vessel diameter	≤2.75 mm	21/568 (3.7)	26/568 (4.6)
	>2.75 mm	14/696 (2.0)	18/696 (2.6)
Target vessel	LAD	23/702 (3.2)	29/702 (4.1)
	Non-LAD	12/562 (2.1)	15/562 (2.6)

Conclusions

In conclusion, in this real-world population of Indian patients undergoing coronary revascularisation, PROMUS Element implantation resulted in low two-year rates of TVF, TLR, MI, death, TVR, DoCE, MACE and late ST, suggesting long-term safety and efficacy of the PROMUS Element stent.

Impact on daily practice

This registry of 1,000 patients demonstrated the safety and efficacy of the PROMUS Element™ coronary stent system in an all-comers Indian population. Diabetes and hypertension were highly prevalent at 41.1% and 56.5%, respectively. The majority of the patients presented with ACS, of whom 28% had STEMI. The primary endpoint TVF occurred in 2.4% at one year and in 3.3% at two years. The definite/probable stent thrombosis rate was low at 0.6%. The study was completed by 95.8% of patients, representing a trend towards an improved follow-up rate in Indian patients. Nearly 92% were on DAPT at two years; while this is not in compliance with the current guidelines, it is a common practice in India and could possibly be linked to the low ST rates reported in this study.

Appendix

STUDY DEFINITIONS

INCLUSION CRITERIA

1. Patients receiving PROMUS Element stents
2. Up to:
   3 PROMUS stents per patient
   2 stents per artery
3. Patient (or legal guardian) understood the trial requirements and the treatment procedures and provided written informed consent before any trial-specific tests or procedures were performed

4. Patient was eligible for PCI
5. Patient was willing to comply with all protocol-required follow-up evaluations

EXCLUSION CRITERIA

1. Patient had known allergy to the study stent system or protocol-required concomitant medications (e.g., stainless steel, platinum, chromium, nickel, iron, thienopyridines, aspirin, contrast) that cannot be adequately pre-medicated
2. Patient had any other serious medical illness (e.g., cancer, congestive heart failure - NYHA Class III and IV) that may reduce life expectancy to less than 12 months
3. Patients with a mixture of other drug-eluting stents
4. Pregnant and lactating females or females who had positive pregnancy test (urine or serum)
5. Known/suspected case of Human Immunodeficiency Virus infection
6. Cardiac death
7. Cardiac death was defined as death due to any of the following reasons: acute MI, cardiac perforation/pericardial tamponade, arrhythmia or conduction abnormality, cerebrovascular accident (CVA) through hospital discharge or CVA suspected of being related to the procedure, death due to complication of the procedure, including bleeding, vascular repair, transfusion reaction, or bypass surgery or any death in which a cardiac cause cannot be excluded. Death not due to cardiac causes is defined as a non-cardiac death.

TARGET VESSEL

The target vessel is any coronary vessel (e.g., left main coronary artery, left anterior descending artery [LAD], left circumflex artery [LCX], or right circumflex artery [RCX]) containing a target lesion. Side branches of a target vessel such as the LAD are also considered part of the target vessel. In this study, the ramus was considered as a branch of the LCX for the purposes of determining eligibility and for determining TVR.

TARGET VESSEL FAILURE

Target vessel failure is any ischaemia-driven revascularisation (TVR), target vessel MI or cardiac death. For the purposes of this protocol, TVF was considered if it could not be determined with certainty whether the MI was related to the target vessel.

TARGET LESION REVASCULARISATION

Target lesion revascularisation is any ischaemia-driven repeat percutaneous intervention, to improve blood flow, of the successfully treated target lesion or bypass surgery of the target vessel with a graft distal to the successfully treated target lesion. A TLR was considered as ischaemia-driven if the target lesion diameter stenosis was ≥50% by quantitative coronary angiography (QCA) in addition to clinical or functional ischaemia which cannot be explained by other coronary or graft lesions. A TLR was considered as ischaemia-driven if the lesion diameter stenosis was ≥70% by QCA even in the absence of clinical or functional ischaemia.

TARGET VESSEL REVASCULARISATION

Target vessel revascularisation is any ischaemia-driven repeat percutaneous intervention, to improve blood flow, or bypass surgery of not previously existing lesions, diameter stenosis ≥50% by QCA in the target vessel, excluding the target lesion. A TVR was considered ischaemia-driven if the target vessel diameter stenosis was ≥50% by QCA and if any of the following were present in the patient: 1) positive functional study corresponding to the area served by the target vessel, 2) ischaemic ECG changes at rest in a distribution consistent with the target vessel, 3) ischaemic symptoms referable to the target vessel. A TVR was also considered as ischaemia-driven if the lesion diameter stenosis was ≥70% even in the absence of clinical or functional ischaemia.

STENT THROMBOSIS

Stent thrombosis was categorised as acute (<1 day), subacute (>24 hours to 30 days), late (>30 days) and very late (>1 year) and was defined as confirmed/definite (acute coronary syndrome and angiographic or pathologic confirmation of ST), probable (unexplained death ≤30 days or TVMI without angiographic information) and possible (unexplained death >30 days after stent placement) as per the Academic Research Consortium guidelines (2007).

TECHNICAL SUCCESS

Technical success is the successful delivery and deployment of the study stent to the target vessel, without balloon rupture or stent embolisation.

CLINICAL PROCEDURE SUCCESS

Clinical procedural success is a mean lesion diameter stenosis <10% in two near-orthogonal projections with TIMI 3 flow, as visually assessed by the physician, without the occurrence of in-hospital MI, TVR, or cardiac death (MACE).

Conflict of interest statement

The authors have no conflicts of interest to declare.

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