Archives of Cardiovascular Disease (2012) **105**, 60—67

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CLINICAL RESEARCH

French Ministry of Health prospective multicentre study using bio-active stents coated with titanium nitride oxide: The EVIDENCE Registry

Étude observationnelle prospective multicentrique requise par le ministère de la Santé français sur une cohorte de patients traités avec le stent coronaire bio-actif Titan2® revêtu d'oxynitrure de titane : registre EVIDENCE

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1875-2136/$ — see front matter
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Received 1st November 2011; received in revised form 2 December 2011; accepted 12 December 2011
Available online 19 February 2012

KEYWORDS
Bioactive stents;
Native coronary arteries;
Outcome

Summary
Background. — Coronary stents have evolved over time, from bare-metal stents to drug-eluting stents, and now to bioactive stents.
Aims. — We sought to explore the immediate outcome of the titanium-nitride-oxide-coated bioactive stent, Titan2®, in real-world practice, and the incidence of major cardiac events at follow-up.
Methods. — Consecutive patients admitted for percutaneous intervention for at least one significant (≥ 50%) lesion in a native coronary artery were treated with Titan2® stent implantation. The primary endpoint was total major adverse cardiac events at 12-month follow-up. Secondary endpoints included target lesion revascularization at 12-month follow-up and the duration of dual antiplatelet therapy.
Results. — Among 356 patients (mean age 67.4 ± 12.1 years), 77.2% were male and 39.3% were treated for myocardial infarction (MI). A total of 546 Titan2® stents were implanted in 420 lesions. Angiographic and clinical procedural success was achieved in all cases. No cases of in-hospital major adverse cardiac events or acute stent thrombosis were reported. Of 335 patients (94.1%) with 12-month clinical follow-up, four (1.2%) died, MI occurred in five (1.5%), target lesion revascularization was performed in 17 (5.1%) and major adverse cardiac events occurred in 24 (7.2%). One patient (0.3%) suffered late stent thrombosis during follow-up, but no cases of acute or subacute stent thrombosis occurred. Dual antiplatelet therapy continued beyond 6 months in 64.5% of patients.
Conclusions. — In real-world practice, Titan2® stent implantation achieves an excellent immediate outcome, with a low incidence of major adverse cardiac events at 12-month follow-up.

MOTS CLÉS
Stents bio-actifs ;
Artères coronaires natives ;
Résultat clinique

Résumé
Contexte. — La sécurité des stents bio-actifs recouverts d'oxynitrure de titane a été démontrée pour des populations non sélectionnées de type « vie réelle ».
Objectifs. — Analyser d'une part les résultats immédiats obtenus après implantation de stents coronaires bio-actifs Titan2® dans une pratique de type « vie réelle » et d'autre part les résultats cliniques à savoir les Major Adverse Cardiac Events (MACE) à 12 mois de suivi.
Méthode. — Trois cent cinquante-six patients consécutifs ont été enrôlés pour suivre un traitement par angioplastie percutanée pour au moins une lésion coronaire significative (50 %). Toutes les lésions ont été traitées par implantation d'un stent Titan2®. L'objectif principal de ce suivi de cohorte était le taux de MACE à 12 mois. Les objectifs secondaires comprenaient le taux de revascularisation de la lésion cible (TLR) à 12 mois et l'analyse de la durée du traitement antiplaquettaire.
Résultats. — L'âge moyen était de 67,4 ± 12,1 ans, 77,2 % étaient des hommes. Un total de 546 Titan2® ont été implantés dans 420 lésions. Le succès angiographique et clinique a été atteint pour toutes les procédures. Aucun évènement cardiaque majeur intrahospitalier n'a été rapporté ni aucune thrombose aiguë. Le suivi clinique à 12 mois a été obtenu pour 335 (94,1 %) patients. Quatre patients sont décédés (1,2 %) et cinq patients ont subi un infarctus (1,5 %). Une revascularisation du vaisseau cible a été effectuée chez 17 (5,1 %) patients. Vingt-quatre (7,2 %) patients ont déploré un évènement cardiaque majeur. Un (0,3 %) patient a souffert d'une thrombose tardive, mais aucun cas de thrombose aiguë ou sub-aiguë n'est arrivé.
Conclusion. — Dans une pratique de type « monde réel », l'implantation du stent Titan2® est associé à d'excellents résultats cliniques, avec un taux d'évènements cardiaques majeurs faible à 12 mois de suivi.

Abbreviations

BAS	bioactive stents
DES	drug-eluting stents
LAD	left anterior descending
LCx	left circumflex
MACE	major adverse cardiac event
MI	myocardial infarction
PCI	percutaneous coronary intervention
RCA	right coronary artery
TIMI	thrombolysis in myocardial infarction
TLR	target lesion revascularization

Background

Coronary stent implantation has become the standard-of-care percutaneous coronary intervention (PCI), providing a safer approach and a better outcome than balloon angioplasty [1,2]. Nevertheless, since the introduction of coronary stents, in-stent restenosis has been the 'stumbling block' of this technology, resulting in repeat revascularization with increased total costs [3,4]. The restenosis rate following bare-metal stent implantation may approach 30% in some patient subgroups, such as those with diabetes, small coronary vessels or long lesions [5,6].

The introduction of drug-eluting stents (DES) has revolutionized the field of interventional cardiology, as it has reduced the incidence of restenosis by 50—70% [7,8]. However, recent worrisome data from registries and meta-analyses have raised concern about the long-term safety of DES, highlighting higher rates of late and very late stent thrombosis, a potentially life-threatening complication [9—11].

Stent technology has evolved recently, with the invention of bioactive stents (BAS). The safety of titanium-nitride-oxide-coated bioactive stents (Titan2®) has been established in several reports from real-life unselected populations [12—16]. Interestingly, some randomized trials have demonstrated a better outcome with BAS compared with paclitaxel-eluting stents in high-risk patients with complex (type B and C) coronary lesions [17,18] and in those with myocardial infarction (MI) [19,20].

The current registry was a post-approval registry performed at the request of, and under the control of, the French High Authority of Health (Haute Autorité de santé, Saint-Denis La Plaine, France). The aims were to confirm the safety and efficacy of Titan2® BAS in 'on-label' indications in real-world practice (with no exclusion criteria) and estimate the duration and average cost per patient of dual antiplatelet therapy.

Methods

Study protocol

The registry protocol was designed under the control of the French High Authority of Health, and through collaboration between the main investigator, an independent contract research organization and the manufacturer, Hexacath. It was officially validated and accepted on 12 June 2007 by the French High Authority of Health. No financial compensation was given to any of the participating centres to conduct the registry, as dictated by the French High Authority of Health. The current registry was executed under complete data monitoring and surveillance by an independent contract research organization company (MAPI NAXIS, Lyon, France). The current registry was conducted according to the 'Standard Medical Practice' (les bonnes pratiques en épidémiologie 1998 version), and law No. 78-17 dated 06 January 1978 referring to private freedom, and following the article L.4113-6 of the French Public National Health Code.

Study design and population

The EVIDENCE Registry is a prospective multicentre non-randomized observational registry performed in 21 French medical centres, with the chief aim to confirm the safety and efficacy of the Titan2® BAS stent in real-world practice. Before the launch of the registry, a scientific main investigator was nominated (Prof. J.-M. Lablanche, Cardiology Department, University Hospital of Lille, France) and assigned the task of selecting the participating centres, as well as validating the process of data collection and statistical analysis. Participating centres were selected on the basis of their high annual volume of PCI performance and their capability to execute the procedures and undertake the necessary follow-up. Recruitment of the participating centres and attendant cardiologists started in June 2007. Participating centres were representative of the French national figures regarding the volume of angioplasties executed per year.

From October 2007 to March 2008, 356 consecutive patients with symptomatic coronary artery disease amenable for PCI were enrolled, provided that they were 18 years or over, with at least one significant coronary lesion (defined as $\geq$ 50% diameter stenosis by visual estimation) in a native coronary artery. Treatment of more than one vessel was permissible, but only the Titan2® stent was allowed, as dictated by the registry. Before inclusion, a written informed consent was obtained from each patient after full explanation of the study protocol, the type of data collected, the method of data processing and the scope of data collection. Collected data were given a code number for the centre and another for the patient, to ensure patient anonymity.

Device

A commercially available stainless steel tubular stent with the unique helicoidal design was used. The Titan2® (Hexacath, Paris, France) stent is a thin-strut (0.07—0.09 mm) balloon-expandable stent made of stainless steel and coated with titanium-nitride-oxide, which prevents discharge of nickel, chromium and molybdenum ions. The coating process is performed by plasma-enhanced vapour deposition of titanium in a pre-specified gas mixture of nitrogen and oxygen in a vacuum chamber. Stents were available in lengths of 7, 10, 13, 16, 19 and 22 mm and in diameters of 2.5, 2.75, 3.0, 3.5 and 4.0 mm.

Adjunctive pharmacological therapy

All included patients were pretreated with aspirin (100 mg daily). Oral clopidogrel was initiated at a loading dose of 300 mg before the procedure. The protocol gave no specific recommendations regarding the duration of clopidogrel maintenance therapy, since one of the objectives of this registry was to investigate the routine medical practice concerning the duration of dual antiplatelet therapy following PCI with BAS. During the procedure, intravenous heparin was given to maintain an activated clotting time of 200—300 seconds. Use of periprocedural glycoprotein IIb/IIIa inhibitors was left up to the operator's discretion. The medical treatment of coronary artery disease was optimized according to the contemporary guidelines.

Quantitative coronary analysis

Coronary angiograms were obtained in multiple views after intracoronary injection of nitrates. Quantitative analysis of angiographic data before the procedure was performed in each participating centre according to the standards of care, using validated edge-detection techniques. Visual assessment included thrombolysis in myocardial infarction (TIMI) flow, calcification, thrombus, lesion length, lesion classification, dissection grade and aneurysm. A contrast-filled non-tapered catheter was used for calibration. Interpolated reference vessel diameter, lesion length and percent initial diameter stenosis were measured before the procedure as well as residual stenosis following stent implantation.

Angioplasty procedure

Lesions were treated according to contemporary interventional techniques. The investigators used similar materials and techniques throughout the study to maintain consistency and standardization of care. Predilatation was left to the operator's discretion. The operator decided the appropriate diameter to be implanted, aiming at a stent: vessel ratio of 1.1:1 prior to stent placement (using nominal pressure). Stents were expanded by adjusting the balloon inflation pressure to achieve an angiographic appearance of the expanded stent slightly larger than the reference vessel segment. After stent deployment, post-dilatation was allowed. An additional Titan2® stent could be deployed in overlap with the first in case of edge dissection, incomplete lesion coverage or otherwise suboptimal result (at the operator's discretion).

Follow-up protocol

The total follow-up period extended from June 2007 to March 2009. All patients were observed during hospital stay for the occurrence of the clinical endpoints prespecified by the study protocol (as described below). Patients were prospectively followed up for a period of 12 months by means of clinic visits or telephone contacts by the attendant cardiologists to obtain information concerning their clinical status, hospitalization, invasive procedures and medications. Follow-up contacts were performed at 3 and 12 months following stent implantation. Follow-up coronary angiography was performed for patients who developed recurrent symptoms during the follow-up period. The decision to perform further revascularization for the target lesion at follow-up coronary angiography was based on clinical justification (as described below). A specialized independent Contract Research Organization (MAPI NAXIS) performed additional telephone contacts with patients at 3 and 12 months following stent implantation. Beforehand, all attendant cardiologists had faxed a signed formal agreement of participation to MAPI NAXIS. All patient data available from hospital records or attendant cardiologists were collected in the EVIDENCE Registry case report forms in each of the participating centres, which were provided by MAPI NAXIS. At the end of follow-up, all case report forms were sent to MAPI NAXIS and carefully reviewed to ensure quality control of the registered data.

Study endpoints and definitions

The primary endpoint of the study was the occurrence of major adverse cardiac events (MACE) at 12-month follow-up. Secondary endpoints included target lesion revascularization (TLR) at 12-month follow-up and the duration and average cost per patient of dual antiplatelet therapy. MACE were defined as a composite of cardiac death, non-fatal MI (including Q-wave and non-Q-wave MI) and TLR. MI was diagnosed by persistent ischaemic-type chest pain with a rise in the creatine kinase-MB fraction of more than three times the upper limit of normal, according to the guidelines for PCI [21]. Q-wave MI was distinguished by the development of new abnormal Q waves, while their absence identified non-Q-wave MI. TLR was defined as a repeat intervention (surgical or percutaneous) to treat significant luminal stenosis (defined as $\geq$ 50% diameter stenosis by visual estimation) within the stent or in the 5-mm distal or proximal segments adjacent to the stent. Revascularization was regarded as 'clinically driven' if it was motivated by angina symptoms and/or proven myocardial ischaemia in the target vessel territory by non-invasive testing. Angiographic success was defined as successful implantation of the assigned study stent into the target lesion with residual stenosis less than 20% and TIMI 3 flow at the conclusion of the procedure, in the absence of dissection or thrombosis. Clinical success was defined as angiographic success in the absence of in-hospital MACE. Stent thrombosis was diagnosed by the occurrence of acute coronary syndrome with angiographic evidence of either index vessel occlusion or thrombus within the study stent, according to the 'definite category' definition of the Academic Research Consortium [22]. Stent thrombosis was classified into: acute (occurring within 24 hours of the index procedure), subacute (> 24 hours but < 30 days) and late (> 30 days).

Statistical analysis

To estimate the number of patients that would give an adequately powered sample size, we hypothesized a MACE toll of 11% at 12-month follow-up. This figure was based on prior studies employing the Titan2® stent in unselected populations, that reported 10.4% and 10.9% MACE at 9 and 12 months' follow-up, respectively [17,23]. Given the above assumption, the number of patients necessary to achieve

such a proportion, with a 95% confidence interval, was calculated by means of the following formula:

$$n = p \times (1 - p) \times \left(\frac{1,96}{e}\right)^2$$

where p is the proportion to estimate and e is the absolute precision of estimation. To estimate a proportion of 11%, with an alpha risk of 5% and an absolute precision of 4%, a minimum of 235 patients needed to be included. Taking into account a proportion of patients lost to follow-up or excluded from the analysis (25—30%), the number of patients to be enrolled was predetermined to be 300.

Double data entry was carried out. Source data verification was implemented to detect any data discordance. An independent organization body (MAPI NAXIS) performed additional telephone contacts with patients at 3 and 12 months following stent implantation to collect data about MACE.

Continuous variables are expressed as mean ± SD, while categorical variables are described with their absolute and relative (percentage) frequencies. Analyses were performed with SPSS version 14.0 statistical package (SPSS Inc., Chicago, IL, USA).

Results

Baseline clinical and angiographic characteristics

From October 2007 to March 2008, 356 consecutive patients were enrolled with symptomatic coronary artery disease amenable for PCI who received at least one Titan2® stent in native coronary arteries. Baseline clinical characteristics of the study population are shown in Table 1. The majority of patients were males (77.2%) and had dyslipidaemia (62.6%), and 39.3% were treated for acute coronary syndrome. Angiographic and procedural characteristics are shown in Table 2. Most of the treated lesions (75.0%) were type B according to the American Heart Association/American College of Cardiology classification.

Table 1 Baseline clinical characteristics of the study population.

	All patients ($n = 356$)
Age (years)	67.4 ± 12.1
Men	275 (77.2)
Diabetes mellitus	65 (18.3)
Dyslipidaemia	223 (62.6)
Current smoking	136 (38.2)
Myocardial infarction	140 (39.3)
Q wave	65 (18.3)
Non-Q wave	75 (21.1)
Prior cerebrovascular stroke	12 (3.4)
Peripheral arterial disease	40 (11.2)
TIMI risk score	3.1 ± 1.1
Beta blocker[a]	272 (76.4)
Statin[a]	315 (88.5)
Glycoprotein IIb/IIIa inhibitor	36 (10.1)

Data are mean ± standard deviation or number (%). TIMI: thrombolysis in myocardial infarction.
[a] On hospital discharge.

Table 2 Angiographic and procedural characteristics of the lesions.

Variable	All lesions ($n = 420$)
Lesion type	
A	71 (16.9)
B	315 (75.0)
C	34 (8.1)
Lesion location	
LAD	201 (47.9)
LCx	101 (24.0)
RCA	118 (28.1)
Reference diameter (mm)	3.0 ± 0.5
Lesion length (mm)	11.8 ± 3.6
Initial stenosis (%)	83.2 ± 10.7
Stent diameter (mm)	3.0 ± 0.4
Stent length (mm)	14.4 ± 4.5
Residual stenosis (%)	2.4 ± 0.4

Data are presented as mean ± standard deviation or number (%). LAD: left anterior descending; LCx: left circumflex; RCA: right coronary artery.

Procedural data

A total of 546 Titan2® stents were implanted in 420 lesions during the index procedures. The mean stent diameter was 3.0 ± 0.4 mm, while the mean stent length was 14.4 ± 4.5 mm (Table 2). Stenosis improved from 83.2 ± 10.7 to 2.4 ± 0.4% following stent implantation (Table 2). Glycoprotein IIb/IIIa inhibitors were used in 36 patients (10.1%). Angiographic and clinical success was achieved in all cases (no cases of in-hospital MACE), and no cases of acute stent thrombosis were reported during the hospital stay.

Twelve-month follow-up

Clinical follow-up for 12 months was completed in 335 patients (94.1%). Table 3 summarizes the 12-month clinical

Table 3 Clinical outcome at 12-month follow-up.

	Patients with 12-month follow-up ($n = 335$)
Cardiac death	4 (1.2)
Myocardial infarction	5 (1.5)
TLR	17 (5.1)
Stent thrombosis	1 (0.3)
MACE	24 (7.2)

Data are number (%). MACE: major adverse cardiac events; TLR: target lesion revascularization.

Table 4 Clinical outcome of registries and trials employing bioactive stents at long-term follow-up.

	Follow-up (months)	MACE (%)	Death (%)	MI (%)	TLR (%)
EVIDENCE Registry	12	7.2	1.2	1.5	5.1
Mosseri et al. [14]	6	7.6	0.7	0.6	5.4
Pori Registry [17]	12	10.9	0.5	4.5	5.2
TIBET Registry [26]	6	10.3	1.9	1.3	7.1
TITAX AMI Trial [19]	12	10.3	0.5	4.2	9.3

MACE: major adverse cardiac events; MI: myocardial infarction; TLR: target lesion revascularization.

follow-up data. During follow-up, four patients (1.2%) died of a cardiac cause, MI occurred in five patients (1.5%) (one ended in cardiac death and the other underwent TLR) and TLR was performed in 17 patients (5.1%) (all clinically driven). MACE at 12-month follow-up occurred in 24 patients (7.2%), i.e. the overall event-free survival rate at 12-month follow-up was 92.8%. The number of patients who completed 12-month follow-up allowed the estimation of MACE (7.2%) with an absolute precision of 2.8% (alpha risk of 5%), that reasonably respects the prespecified requirement of the protocol.

Only one patient suffered late stent thrombosis (2 months and 18 days after stent implantation), according to the per-protocol definition. This was a diabetic woman aged 85 years with acute coronary syndrome treated for a type C lesion. Surprisingly, this patient was prescribed clopidogrel for only 1 month after the procedure. No case of acute or subacute stent thrombosis occurred during follow-up.

Dual antiplatelet therapy was prescribed for 1 month in 55.5% of patients, 1—3 months in 6.8% and more than 3 months in 37.7%. Interestingly, despite these initial prescriptions, 64.5% of patients received dual antiplatelet therapy for more than 6 months. The cost of the dual antiplatelet therapy was estimated based on the public price of clopidogrel in the French market (€55.50 for 28 tablets of 75 mg clopidogrel) at the time of the study. The average cost per patient (in most centres, for stable patients) was estimated to be €55.50 (for 4 weeks) for patients treated for stable angina or silent ischaemia, and more than €333 (for > 24 weeks) for patients treated for an acute coronary syndrome.

Discussion

The current EVIDENCE Registry of the unrestricted use of the titanium-nitride-oxide-coated BAS in an unselected patient population demonstrated an excellent immediate angiographic and clinical outcome, with a low incidence of MACE (7.2%) at 12-month follow-up. The low incidence of MACE at 12-month follow-up is similar to that reported for DES, and is better than that reported for bare-metal stents. This confirms the favourable safety/efficacy profile of BAS in a 'real-world' population with no exclusion criteria.

Titanium-nitride-oxide-coated BAS

Titanium-nitride-oxide-coated stents are a new generation of biologically active stents. Titanium exhibits a far superior biocompatibility than stainless steel, cobalt-chromium, gold or other surface-coating materials, and therefore minimizes stent-induced inflammation [24]. Titanium oxides have proven efficacy for inhibiting platelet aggregation and fibrin growth compared with carbon oxides, which are known to be highly biocompatible [25]. Moreover, metallic sheaths coated with titanium nitride or titanium oxide can promote endothelial cell growth on their surfaces, suggesting that the use of stents covered with these coatings may accomplish earlier complete endothelialization [25].

BAS outcome in real-world practice

The EVIDENCE Registry has demonstrated an excellent immediate outcome of BAS, with 100% angiographic and clinical success. Although the study population was a high-risk one (62.6% dyslipidaemic, 39.3% with acute coronary syndrome) with rather complex lesion characteristics (83.1% type B or C), no in-hospital MACE were encountered, and only one case of 'definite' late stent thrombosis occurred. The absence of in-hospital MACE, considering the reasonably high prevalence of acute coronary syndrome might be attributed to selection bias. This is liable to occur with observational registries, especially when the number of patients enrolled in each individual centre is not adequately high. At 12-month follow-up, the overall rate of MACE, as well as that of its individual components (death, non-fatal MI and TLR), was similar to previous registries employing the stent in unselected populations (Table 4) [14,17]. Outcomes were also similar to the use of the stent in a population of diabetic patients in the Titanium-nitride-oxide-coated stents multicenter registry in diabetic patients (TIBET) (Table 4) [26], although it should be noted that these patients were generally more stable with less complex lesion criteria than in the current study.

Moreover, the fairly low incidence of MACE in the current registry was similar to those reported in many registries and randomized trials performed with DES [7,8,27,28]. It is well known that most early randomized trials of DES were 'restrained' by extensive lists of exclusion criteria, e.g. recent MI, visible thrombus and bifurcation lesion. In contrast, the EVIDENCE Registry was deliberately designed with no exclusion criteria, to reflect 'real-world practice', and involved a rather 'high-risk' cohort, with quite complex lesion characteristics. We can therefore speculate that the performance of the BAS would have been 'superior' to DES should it have been employed in a 'low-risk' population analogous to those of the aforementioned randomized trials. Ultimately, several clinical trials showed an even better

outcome with BAS versus paclitaxel-eluting stents in high-risk patients with complex (type B and C) lesions [17,18] and in patients presenting with acute MI [19,20].

Duration of antiplatelet therapy

Our data demonstrate that dual antiplatelet therapy was prescribed by interventional cardiologists for more than 3 months in 62.3% of patients, most commonly for only 1 month. In reality, the proportion of patients prescribed dual antiplatelet therapy for short periods by the interventional cardiologists (62.3%) matched the prevalence of patients presenting with stable angina or silent ischaemia (60.7%). Similarly, the proportion prescribed dual antiplatelet therapy for long periods (37.7%) matched the prevalence of those presenting with an acute coronary syndrome (39.3%). In fact, the most recent update of the European Guidelines do recommend continuing dual antiplatelet therapy in patients presenting with acute coronary syndrome for 12 months unless there is an excessive risk of bleeding (class I-A) [29].

Interestingly, however, despite the initial prescription, dual antiplatelet therapy was extended beyond 6 months in 64.5% of patients. Considering that only 39.3% of the registry patients were treated for acute coronary syndrome, dual antiplatelet therapy was, therefore, unduly prolonged by attendant cardiologists in 25.2% of patients. Despite the clear recommendations for the optimum duration of dual antiplatelet therapy after stent implantation, there is a universal tendency to 'keep on' this regimen for longer periods, both in patients receiving bare-metal stents and in those receiving DES [30]. However, a similar cohort (matching the EVIDENCE population) receiving DES would have been 'appropriately' prescribed dual antiplatelet therapy for at least 12 months, for all patients. A recent report from the Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients with de novo Native Coronary Artery Lesions (SPIRIT) III trial comparing two DES demonstrated that the proportion of patients receiving dual antiplatelet therapy at 24-month follow-up was 59.4% and 63.9% for everolimus-eluting and paclitaxel-eluting stents, respectively [31].

Clinical implications

Achievement of the goal of reducing TLR following PCI, without the risk of developing the unpredictable life-threatening 'hard' endpoint of stent thrombosis, and at an almost similar cost, would be an attractive strategy in combating in-stent restenosis. Furthermore, unlike DES, which need maintenance clopidogrel therapy for 12 months (sometimes for even more extended periods), BAS require no more than 1 month of dual antiplatelet therapy. In the modern era of escalating healthcare costs, physicians could do both the patients and the 'Healthcare Systems' a great favour by resorting to safer and less costly means of maintaining coronary patency. In this context, BAS may appear to open a new horizon for revascularization of coronary atherosclerosis.

Study limitations

The EVIDENCE registry was not randomized, and hence is liable to selection bias. Additionally, it bears an inherent limitation of any registry, namely, non-blinded outcome assessment. Moreover, although the sample size was formally calculated, the number of patients is quite small. The rather high prevalence of patients presenting with an acute coronary syndrome (39.3%) is another limitation of a registry designed, a priori, to reflect real-world practice. Furthermore, longer-term follow-up is still needed before we can reach solid conclusions on the long-term safety of this 'novel' approach. Finally, TLR was clinically driven, and this may underestimate the actual incidence of angiographic restenosis. However, it would avoid unnecessary interventions in borderline lesions due to the 'oculostenotic reflex' and undue patient anxiety.

Conclusions

BAS implantation in 'real-world' practice, in native coronary arteries, achieves an excellent immediate clinical and angiographic outcome, with a low incidence of MACE at 12-month follow-up.

Disclosure of interest

The authors declare that they have no conflicts of interest concerning this article.

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