Original Article

One-Year Clinical Outcomes of Ultra Long Apollo Polymer-Based Paclitaxel-Eluting Stents in Patients with Complex, Long Coronary Artery Lesions

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Abstract

Background: *For all the wealth of research comparing the efficacy of the different types of the drug-eluting stent (DES) such as sirolimus- , paclitaxel- , and zotarolimus-eluting stents, there is still a dearth of data on the different brands of each DES type. We aimed to investigate the one-year clinical outcomes, including major adverse cardiac events (MACE), of the use of the ultra long Apollo paclitaxel-eluting stent in patients with long atherosclerotic coronary artery lesions.*

Methods: *According to a retrospective review of the Tehran Heart Center Registry of Interventional Cardiology, a single-center nonrandomized computerized data registry in which all adult patients who undergo single or multi-vessel percutaneous coronary intervention (PCI) are enrolled without any specific exclusion criteria, the mixed use of long Apollo paclitaxel-eluting stents and other types of the DES as well as myocardial infarction within forty-eight hours prior to the procedure was excluded. In total, 122 patients were enrolled in the study, and their baseline clinical, angiographic, and procedural characteristics were obtained. In addition, the patients' follow-up data and, most importantly, MACE during a one-year period after intervention were recorded.*

Results: *The mean follow-up duration was 14.1 ± 3.8 months. The one-year clinical follow-up data were obtained in 95.9 % of all the patients. The incidence of MACE was 5.7% during the entire study period. There was 1 death, which occurred during the initial days after PCI. The incidence of non-fatal myocardial infarction was 2.5% (3 cases), including one patient who underwent target vessel revascularization seven months later. Also, 3 patients with single-vessel disease and in-stent restenosis underwent coronary artery bypass grafting between five to ten months later.*

Conclusion: *Our results showed that the Apollo paclitaxel-eluting stent might be regarded as a safe and effective treatment for long coronary lesions.*

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Introduction

Percutaneous coronary intervention (PCI), especially stenting, has become the most common method for coronary revascularization.[1] The recent widespread use of coronary stenting, new antiplatelet drugs, and increased skills of operators have decreased the incidence of urgent coronary artery bypass grafting (CABG) after unsuccessful PCI.[2] Drug-eluting stents (DES) such as paclitaxel-eluting stents have been shown not only to markedly improve clinical and angiographic outcomes compared to bare-metal stents but also to be effective in reducing the rate of major adverse cardiac events (MACE).[3-5] However, in-stent restenosis remains a limitation of PCI, not least in high-risk patients such as those with diabetes or longer lesions.[3]

Despite the fact that the existing literature abounds with data comparing the efficacy and safety of the different types of the DES like sirolimus-, paclitaxel-, and zotarolimus-eluting stents, to the best of our knowledge there is currently a paucity of information on the different brands of each DES type.[6-11] This study was designed to investigate the one-year clinical outcomes, including MACE, of the use of the ultra long Apollo paclitaxel-eluting stent in patients with long atherosclerotic coronary artery lesions.

Methods

The data were extracted from the Tehran Heart Center Registry of Interventional Cardiology (THCRIC), a single-center nonrandomized computerized data registry in which all adult patients who undergo single- or multi-vessel PCI are enrolled without any specific exclusion criteria. Detailed data on the demographic and clinical characteristics such as previous medical status and history of risk factors in conjunction with procedural data, including lesions characteristics, type of procedure and stent used, complications, discharge disposition and destination, medication, and clinical follow-up data are documented in our registry. The follow-up data, first and foremost amongst them MACE, are obtained through organized clinical visits or telephone contacts by trained research physicians and nurses at hospital discharge one, six, and twelve months after PCI. All the data are recorded in formal datasheets before being fed into a computerized data bank.

Amongst the patients with a history of coronary artery disease who underwent PCI between October 2006 and August 2008 in THC (Tehran University of Medical Sciences), 180 patients received Apollo paclitaxel-eluting long stents (stent length = 38 mm) at least in one vessel. The mixed use of Apollo paclitaxel-eluting stents and other types of the DES as well as myocardial infarction within forty-eight hours prior to the procedure was the exclusion criterion. In total, 122 patients were enrolled in the study and their baseline clinical, angiographic, and procedural characteristics were obtained. Moreover, the patients' follow-up data and, most significantly, MACE during a one-year period after intervention were recorded.

The Apollo paclitaxel-eluting stent is a polymer-based drug-eluting stent with biostable, hemocompatible polymer coating. The uniform biocompatible elastomeric polymer provides controlled drug release and homogeneous drug coverage along the stent but it also prevents drug loss during implantation and drug overdose because of the immediate burst release of the total loaded dose. Paclitaxel concentration in the polymer is 1 μg/mm.[2] These characteristics provide the optimal release of low concentrations of paclitaxel over a short period of time. Coating dimensions include one layer of asymmetric coating; the drug-releasing outer matrix is 5-7 μm and the inner matrix is 2 μm.

Apollo paclitaxel-eluting stents are available in a wide array of diameters (range = 2.0 to 4.0 mm) and length (range = 10 to 38 mm), enabling the interventionist to fit the stent precisely within a lesion.

All our angioplasty procedures were carried out with a 6 or 7 French guiding catheter and a femoral approach. The patients received 600 mg of clopidogrel and 325 mg of aspirin before and 7500-10000 IU of heparin at the commencement of the procedure. Clopidogrel (75 mg once daily) and aspirin were administered routinely for six to twelve months upon stent placement.

Lesion types were noted according to the American College of Cardiology/American Heart Association (ACC/AHA) lesion characteristics classification. The study end-point was the occurrence of MACE during the follow-up, defined as cardiac death, myocardial infarction, target lesion revascularization, and target vessel revascularization. All deaths were considered cardiac unless a definite non-cardiac cause could be established. Myocardial infarction was defined as elevated cardiac enzymes (troponin or CK-MB) more than three times the normal upper limit.[12] Target vessel revascularization was defined as the ischemia-driven repeat PCI or bypass surgery of the target vessel, and target lesion revascularization was defined as the ischemia-driven repeat PCI of the target lesion.[5]

The continuous variables are presented as mean ± standard deviation (SD), and the categorical variables are presented as count and percentages. The statistical analyses were conducted with SPSS 13.0 for Windows.

Results

Of the 180 patients, who underwent PCI between October 2006 and August 2008 in Tehran Heart Center and received the Apollo paclitaxel-eluting stent, 122 patients fulfilled the inclusion criteria. The mixed use of Apollo stents and other types of the DES was excluded. Three of the 122 selected

patients were treated with the Apollo stent in two different vessels, and the remaining 119 patients had single-vessel lesions. The baseline demographic and clinical characteristics of the study population are depicted in Table 1.

Table 1. Baseline characteristics*

Age (y)	57.6±10.3
Gender	
Male	73 (59.8)
Female	49 (40.2)
Hypertension	55 (45.1)
Diabetes mellitus	25 (20.5)
Hyperlipidemia	87 (71.3)
Current smoker	21 (17.2)
Positive family history	35 (28.7)
History of angina	
Stable	48 (39.3)
Unstable	38 (31.1)
History of MI	
STEMI	41 (33.6)
NSTEMI	22 (18)
History of CVA	0 (0)
History of renal failure	1 (0.8)
Previous CABG	2 (1.6)
Previous PCI	10 (8.2)
LVEF, (%)	50±9.6

*Data are presented as mean±SD or n (%)

MI, Myocardial infarction; STEMI, ST segment elevation myocardial infarction; NSTEMI, Non-ST segment elevation myocardial infarction; CVA, Cerebrovascular accident; CABG, Coronary artery bypass grafting; PCI, Percutaneous coronary intervention; LVEF, Left ventricular ejection fraction

Table 2. Angiographic and procedural characteristics*

Site of PCI	
LAD	89 (73)
LCX	2 (1.6)
RCA	31 (25.4)
Type of lesion (AHA Grade)**	
A	0
B1/B2	0
C	122 (100)
Lesion length (mm)	35.97±6.3
RVD	3.17±0.37
Stent (mm)	
Length	38.00
Stent diameter	3.03±0.32

*Data are presented as mean±SD or n (%)
**According to American College of Cardiology/American Heart Association classification
PCI, Percutaneous coronary intervention; LAD, Left anterior descending artery; LCX, Left circumflex artery; RCA, Right coronary artery; RVD, Reference vessel diameter

Most patients were men (73 = 59.8%)**.** Sixty-three patients (51.6%) had a history of ST-elevation or non-ST-elevation myocardial infarction. The angiographic and procedural outcomes are represented in Table 2. The left anterior descending artery was the prominent intervention site (73%). All the lesions were type C according to the American College of Cardiology/American Heart Association classification (ACC/AHA type C stenosis) and categorized as long lesions (mean lesion length = 35.97 ± 6.3 mm). Therefore, in order to treat such types of lesions, long Apollo paclitaxel-eluting stents were used for all the patients (stent length = 38 mm).

One-year clinical follow-up and major adverse cardiac events

The mean follow-up duration was 14.1 ± 3.8 months. The one-year follow-up data were obtained in 95.9% of the patients via clinical visits or telephone contacts. One case was excluded from the follow-up because of unsuccessful PCI results due to failure to pass the guide wire and 4 cases failed to complete their follow-up; however, for as long as they were under observation (approximately six months), there were no new post-PCI events such as MACE, myocardial infarction, or target vessel revascularization.

The incidence of MACE was 5.7% during the entire study period. There was one death: a 54-year-old woman with a history of hyperlipidemia and prior ST-segment-elevation myocardial infarction and staged PCI for the right coronary artery and left anterior descending artery performed one month apart. The latter procedure for the proximal end of the left anterior descending artery (lesion diameter = 3.5 mm and length = 34 mm) was treated with the Apollo stent (stent diameter = 3 mm and length = 38 mm) successfully without apparent complications. The day after the PCI procedure, however, the patient complained of dyspnea and chest pain. Echocardiography showed cardiac tamponade, for which pericardial window surgery was performed successfully; but twelve hours later, she developed bradyarrhythmia (although coronary angiography demonstrated patent stents and arteries) unresponsive to the temporary pacemaker and expired.

The incidence of non-fatal myocardial infarction was 2.5% (3 cases): One case underwent target vessel revascularization seven months later, another patient had total occlusion in the first branch of the left circumflex artery, and the third patient was admitted to the cardiac care unit of another hospital one year later without any additional data being collected through telephone follow-up. Also, 3 patients underwent CABG for single vessel disease (SVD) and in-stent restenosis between five to ten months later (Table 3).

Table 3. Major adverse cardiac events at 14.1±3.8 months of follow up*, **

MACE	7 (5.7)
TVR	4 (3.3)
TLR	0 (0)
MI	3 (2.5)
CABG	3 (2.5)
Cardiac death	1 (0.8)

*Data are presented as mean±SD or n (%)
**Follow- up rate was 95.9 %, and 117 patients completed their follow-up
MACE, Major adverse cardiac events; TVR, Target vessel revascularization; TLR, Target lesion revascularization; MI, Myocardial infarction; CABG, Coronary artery bypass grafting

Discussion

There are a number of predictors of restenosis such as lesion length and complexity, vessel diameter, and history of myocardial infarction. The patients enrolled in our study represented a high-risk profile for restenosis in that they all had type C lesions according to the ACC/AHA classification and an average lesion length of 35.97 ± 6.3 mm. In addition, 63% of our patients had a previous history of myocardial infarction ST segment elevation myocardial infarction (STEMI) and Non-ST segment elevation myocardial infarction (NSTEMI) and 17.2% were current smokers.

Major published studies on long coronary lesions have compared bare metal stents with long sirolimus-eluting stents. The rate of MACE in the E-SIRIUS study, which compared sirolimus-eluting stents with bare metal stents for the treatment of patients with long lesions (15 - 32 mm) in small coronary arteries (diameter = 2.5 - 3.0 mm), was 8% with 4% target lesion revascularization in 175 patients.[13]

The C-SIRIUS was a randomized double-blind trial study conducted in Canada after E-SIRIUS with a similar design. In this study on 50 patients treated with sirolimus-eluting stents, both the MACE and target lesion revascularization rates were 4%.[14]

The TAXUS VI was a prospective double-blind randomized trial designed by Keith D Dawkins and her colleagues to assess the clinical and angiographic outcomes of the Taxus polymer-based moderate release paclitaxel-eluting stent in the treatment of long, complex coronary artery lesions by comparison with the Taxus uncoated express control stent. The incidence of nine-month MACE was 16.4% amongst 219 patients and the target lesion revascularization rate was 6.8%.[15] It is deserving of note, however, that data both on paclitaxel-eluting stents in these types of lesions and on comparisons between sirolimus-eluting stents with other DES types are limited in the existing literature.

By contrast, there was no need for repeat target lesion revascularization (as a major contributor to the overall MACE rate) amongst the patients who received Apollo paclitaxel-eluting stents in our study. The overall MACE rate was 5.7%, which is acceptable as a good one-year outcome after PCI for a long type C coronary de novo lesion.

First and foremost amongst the limitations of the present study is the absence of a comparative control group. In addition, angiographic follow-up information could not be obtained in our set up.

Conclusion

In light of our results, it can be concluded that the Apollo paclitaxel-eluting stent may be considered a safe and effective treatment for ultra long coronary lesions. Nevertheless, further studies are required to assess the effectiveness of this stent in comparison with other types of the DES over long-term follow-up periods and in other high-risk subsets of patients.

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