INDIAN HEART JOURNAL 66 (2014) 345–349

Available online at www.sciencedirect.com

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Safety and efficacy of the Yukon Choice Flex sirolimus-eluting coronary stent in an all-comers population cohort

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Keywords:
Percutaneous coronary intervention
Bioresorbable-polymer drug-eluting stent
Stent thrombosis

ABSTRACT

Aims: The use of biodegradable-polymer drug-eluting stents has been shown to provide favorable results when compared with durable polymer drug-eluting stents and long-term follow up data have recently shown significant reductions in terms of very late stent thrombosis.

Aim of the present study was to assess the safety and efficacy profile of a novel biodegradable polymer DES, the Yukon Choice Flex sirolimus-eluting stent.

Methods: We report here the one-year clinical outcomes associated with the use of the Yukon Choice Flex sirolimus-eluting stent in an all-comers patient population. The present stent represents a further refinement of the stent platform tested in the ISAR TEST 3 and 4 randomized clinical trials. A total of 778 consecutive patients undergoing implantation of this stent were enrolled in the present observational study and prospectively followed for one year.

Results: The use of the Yukon Choice Flex stent in a patient population with complex coronary lesion morphology was associated with optimal immediate angiographic results. At one year follow up the rates of death, myocardial infarction, definite stent thrombosis and ischemia-driven target lesion revascularization were respectively 2.4%, 1.9%, 0.3% and 11.3%.

Conclusions: The use of the sirolimus-eluting biodegradable polymer Yukon Choice Flex stent in an all-comers population of patients with complex coronary artery disease is associated with a favorable safety and efficacy profile up to one year follow up.

1. Introduction

The introduction of drug-eluting stents (DES) in clinical practice has led to a drastic reduction in the rates of restenosis and the need for repeat revascularization procedures.[1–3] However, an increase in the incidence of very late stent thrombosis associated with the use of early generation DES compared with BMS has been reported,[4,5] particularly among patients with off-label indications.[6,7] Despite the increase in the

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http://dx.doi.org/10.1016/j.ihj.2014.05.003

occurrence of very late thrombotic events seems relatively limited in absolute terms, owing to the poor outcomes associated with this clinical entity, considerable efforts have been directed to clarify its underlying pathobiological mechanisms and to reduce its incidence. Animal experiments and human autopsy studies have shown that very late stent thrombosis is related to delayed arterial healing and remodeling of the stented vessel owing to ongoing inflammation.[8–11] Particularly, the persistence of the polymer coating on the stent surface after completion of the drug-elution process, has been shown to act as a trigger for a chronic inflammatory response, which delays the process of stent coverage and predisposes to late thrombotic events.[12,13] Since the function of the polymer coating is limited to that of a reservoir which allows for drug loading and modification of the release kinetics of the antiproliferative drug, the use of biodegradable polymer coatings, which undergo a process of absorption once their role has been served, seems particularly attractive, since it would eliminate the stimulus for the chronic inflammatory response, leading to a more favorable tissue healing profile and potentially reducing the rates of very late stent thrombosis.

Accordingly, biodegradable polymer DES have been developed and compared with durable polymer DES in randomized clinical settings and the favorable outcomes associated with their use have provided support to the initially hypothesized advantages associated with their use.[14–16] Owing to these favorable results, great interest and hope has been associated with this new generation of stents, which could further improve the safety and efficacy of percutaneous coronary interventions (PCI).

We report here the one-year outcomes associated with the use of a novel biodegradable polymer DES, the Yukon Choice Flex sirolimus-eluting stent (Translumina Therapeutics), in an unselected population cohort.

2. Methods

Patients presenting with ischemic symptoms or signs of myocardial ischemia in the presence of ≥50% coronary stenosis were considered eligible, provided that written, informed consent by the patient or her/his legally authorized representative was obtained. Besides age ≥18 years, there were no adjunctive exclusion criteria to patient enrollment in this prospective observational study.

The Yukon Choice Flex stent is a new generation stent consisting of a cobalt–chromium backbone (79 μm thickness) and a biodegradable polymer (polylactic acid) applied on the stent surface, which allows a controlled release of the antiproliferative drug followed by a bioresorption process of the polymer coating over a period of 6–9 weeks. The eluted drug is represented by sirolimus, a highly effective and widely tested agent with immunosuppressive and antimitotic properties, which has consistently shown superior outcomes compared with the paclitaxel-eluting stent platforms in terms of neointimal proliferation inhibition and repeat revascularization procedures.[17,18]

During the procedure, patients were given intravenous aspirin, heparin or bivalirudin; glycoprotein IIb/IIIa inhibitors were used at the discretion of the operator. After the intervention, all patients received aspirin indefinitely, clopidogrel, prasugrel or ticagrelor for at least 12 months and other cardiac medications according to the judgment of the patient's physician [β-blockers, ACE (angiotensin-converting enzyme)-inhibitors, statins etc.]. Patients remained in the hospital for at least 48 h. Blood samples were drawn every 8 h for the first 24 h and daily afterward for the determination of cardiac markers (CK, CK-MB, Troponin T) and blood cell counts (hemoglobin, hematocrit, platelet count, white blood cell count). Daily recording of ECG was also performed until discharge.

Relevant data were collected and entered into a computer database by specialized personnel of the Clinical Data Management Center. Baseline and post-procedural cineangiograms were forwarded to the Quantitative Angiographic Core Laboratory (DeutschesHerzzentrum, Munich, Germany) for assessment by experienced operators. Angiographic image acquisition of the target lesion was done after intracoronary administration of nitroglycerin and the measurements were performed in the same single worst view projection. The offline quantitative coronary angiographic analysis was performed with an automated edge-detection system (QAngio XA 7,1; Medis, Medical Imaging Systems). The contrast filled, nontapered catheter tip was used for calibration. The reference diameter was measured by interpolation. Minimal lumen diameter was measured within the stent and within the 5 mm proximal and distal edges of the stent. Quantitative analysis was performed in the in-stent area (in-stent analysis) and in the in-segment area including the stented segment, as well as both 5 mm margins proximal and distal to the stent (in-segment analysis). Qualitative morphological lesion characteristics were characterized by standard criteria.[19]

2.1. *Statistical analysis*

Categorical variables are summarized as counts or proportions (%) whereas continuous variables are expressed as mean ± SD or median with 25th and 75th percentiles. Data distribution was tested for normality using the Kolmogorov–Smirnov test. Survival was assessed using the Kaplan–Meier method.

3. Results

3.1. *Baseline characteristics and procedural results*

A total of 778 consecutive patients undergoing coronary implantation of the Yukon Choice Flex sirolimus-eluting stent in our center were enrolled in the present study and considered for the present analysis.

Baseline clinical characteristics of the patient population are shown in Table 1. Overall, there is a high prevalence of coronary risk factors and 26.1% of patients had diabetes mellitus. Moreover, a high percentage of patients (40.9%) displayed unstable coronary syndromes and multivessel disease was present in 83% of the patient population.

A total of 1440 lesions were treated (1.85 lesions/patient). Baseline angiographic characteristics are displayed in Table 2 and are notable for a high prevalence of complex lesion