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Original article

Evaluation and efficacy of long length Pronova XR Bioabsorbable Polymer stent in the treatment of long coronary lesions

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ABSTRACT

Aim: The study aims an observational registry of the long and extra-long length (>33 mm) Pronova XR stents in patients with long coronary lesions (>30 mm) in a prospective real world study.

Methods and results: Current study was conducted at Ruby Hall Clinic Pune, between July 2012 and July 2013 including 30 patients who underwent PTCA using long and extra-long Pronova XR stents. Among the stents used, one stent - 33 mm, 2 stents - 38 mm, 5 stents - 43 mm and 25 stents were of 48 mm in length. In particular average stent length for the study was 46.03 mm and the average stent diameter was 3.09 ± 0.41 mm.

For this study coronary angioplasty was performed using femoral approach and standard practice. Lesions were predilated using undersized balloons and study stent was deployed at pressure 7–26 atm. (12.8 ± 3.2 atm.) The successful delivery of stent at the intended lesion with visual residual stenosis less than 50% was defined as Procedural success. Follow up studies were conducted for all the patients at 30 days, 3 months and 6 months intervals. The predefined QCA parameters were calculated using Sanders Data System QCA plus software (Palo Alto, CA, USA).

No procedural complication was observed during the whole study. 100% successful stent placement was achieved in all patients. Six months clinical follow-up was available for all patients. No adverse events (Acute closure, angina, REPCI, MI, death, sub acute stent thrombosis) or hospitalization was reported for any of the patients except one. The Quantative Coronary Core Lab analysis post 6 months showed well-flowing stent with average late lumen loss 0.10 mm ± 0.26.

Conclusion: In patients with long coronary lesions and very long length stent implantation series, Pronova XR showed excellent in 6 months results. This is for the first time reported that use of long length Pronova XR stents has shown so low restenosis rate and absent of mortality in six month period. These results offer a new opportunity to single long length stenting.

1. Background

In spite of a steep development of percutaneous coronary angioplasty, long coronary lesions are still a formidable challenge for the coronary stenting. It is known that, the excessive neointimal proliferation around and within the stented segment causes the in-stent restenosis. Therefore, a return of coronary symptoms is observed in 20–50% of cases, according to complexity and size of the stenosis.[1,2] Consequently, the lesion length is known as the independent predictor of in-stent restenosis.[3,4] Patients in India annually spent about 2500 crore for stenting, which is a three times import price for stents. In order to save money it is more expedient to go for single stenting. However, the stent length has been shown to correlate with the occurrence of restenosis.[5,6]

Nevertheless, the significant development of drug-eluting stents has improved treatment efficiency in patients with long coronary lesions.[7] Also, sirolimus eluting coronary stents have shown to be substantially higher to the bare metal stents (BMS) in reducing restenosis and target vessel revascularization, as examined in various randomized trials.[8–10]

The Pronova XR stent represent this new generation of Bioabsorbable Polymer sirolimus-eluting stents (SES). In this device, a pharmaceutical excipient is used for the timed release of sirolimus from the XR stent platform instead of a polymeric coating.[11] The longer configurations of Pronova XR stents (33 mm–48 mm) are expected to provide physicians with greater flexibility and higher efficiency in long coronary lesions treatment. However, this matter requires further investigation.

Abbreviations: SES, sirolimus-eluting stents; BMS, bare metal stents; PTCA, percutaneous trasluminal coronary angioplasty; QCA, Quantitative Coronary Angiography; TVF, Target Vessel Failure.

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2. Methods

2.1. Study population

Our study had included 30 patients who underwent PTCA using long and extra-long Pronova XR stents. Among the stents used in the study, one stent - 33 mm, 2 stents - 38 mm, 5 stents - 43 mm and 25 stents were 48 mm in length. In particular average stent length was 46.03 mm and the average stent diameter was 3.09 ± 0.41 mm. (Table 1). In all cases, general clinical examinations were performed, including blood pressure and heart beat monitoring. Additionally, coronary lesions were classed in morphological type by American College of Cardiology/American Heart Association (ACC/AHA).12

Patients undergoing elective or urgent percutaneous trasluminal coronary angioplasty (PTCA) were enrolled consecutively after obtaining informed consent. The study was conducted in accordance with the Declaration of Helsinki and the study protocol was approved by Local Ethical Committee of Poona Heart Hospital and Research Foundation.

Inclusion Criteria were age more than 18 years old, coronary lesion length more than 30 mm, one or multiple vessels of 2.5 mm–4.00 mm in diameter and patients with signs of ischemia were eligible for PCI. Exclusion Criteria were patients who have major bleeding and hematological problems, patients who are non-compliant to the dual antiplatelet therapy (DAPT) protocol and exposure to any other investigational device or drug in the recent past.

2.2. Study procedures and medications

Coronary angioplasty was performed using femoral approach and standard practice. Lesions were predilated using undersized balloons and study stent was deployed at pressure 7–26 atm. (12.8 ± 3.2 atm.) Post dilatation of the stents was performed using a noncompliant balloon for suboptimal deployment assessed visually. Procedural success was defined as the successful delivery of stent at the intended lesion with visual residual stenosis less than 50%.

The angiograms were sent to the Quantitative Coronary Angiography (QCA) core lab to Krakow Cardiovascular Research Institute Poland for further analysis. QCA parameters included lesion length, percent diameter stenosis, stent length, and stent diameter.

2.3. Data collection and core laboratory analysis

All patients were clinically followed at 30 days, 3 months and 6 months intervals. 26 of these underwent check angiography after six months of the implant and three also underwent IVUS during the follow-up angiography. The remaining 4 patients who could not undergo check angiography were followed up telephonically through a clinical follow-up a questionnaire and were asymptomatic. The predefined QCA parameters were calculated using Sanders Data System QCA plus software (Palo Alto, CA, USA)

2.4. Study endpoints

The primary endpoint was late lumen loss and death. The secondary endpoint was major adverse cardiac events (MACE) such as death, myocardial infarct or TVF (Target Vessel Failure), Stent Thrombosis (as per ARC definition), and Peri stent Stenosis.

2.5. Statistical analysis

Continuous variables were presented as mean and standard deviation. A probability < 0.05 was considered to be statistically significant. For angiographic parameters one-sided-test or Wilcoxon signed-rank test (depending on normality) was used, because measurements were dependent, and direction of the difference was known; only the significance of observed differences was investigated.

3. Results

30 patients undergoing elective or urgent PTCA at our center were included in the study. The patient population was predominantly male (26 males and 4 females). The mean age of the enrolled patients was 60.5 ± 9 years. 53% patients had hypertension and 56% suffered from diabetes mellitus. Hypertension was defined as blood pressure of 140 mm Hg and greater systolic or 90 mm Hg or greater diastolic pressure. Of the total population, no one was a smoker and only one patient (3.3%) had a family history of premature coronary artery disease. In 53.3% of patients, Acute Coronary Syndrome was the indication for urgent PTCA. Accordingly, in 46.6% of cases the indication for PTCA was the stable angina. In the study population, average left ventricular ejection fraction (LVEF) was $52.9 \pm 13.8\%$. In particular the 16.7% (5 patients) of all cases had LVEF less than 45%. It was significant to note that one patient with the positive outcome has been with 25% LVEF. The resting heart rate varied in the range of $61 - 102$ beats per minute. The details of angina status and LV ejection fraction are summarized in Table 2.

Of the total population, 70% (21 patients) had single vessel disease and double vessel disease was present in 30% (9 patients). Accordingly, 20 patients (66.7%) underwent PTCA to single artery only while double vessel PTCA was performed on 9 patients (30%). One patient (3.3%) underwent triple vessel stenting. A total of 39 lesions were treated with 41 stent implantations. The average stent diameter was 3.09 ± 0.41 mm and average stent length was 46.03 mm (Table 1). One stent was 33 mm in length, 2 stents - 38 mm, 5 stents – 43 mm and 25 stents were 48 mm in length. The other 8 stents had a length less than 33 mm and were not included in the study.

In most of the cases, treated vessels were Right Coronary Artery (RCA) (33.3%) and Left Anterior Descending Artery (LAD) (30%). Details of the stented vessels are shown in Fig. 1.

Maximum of cases in the study, the regions of lesion were proximal and middle-proximal parts of coronary vessels in 13 patients (43.3%) and 6 patients (20%) approximately. Four patients (13.3%) had lesion in middle region of artery, and 2 patients (6.7%) had lesions in distal, ostial and middle-distal regions. It should be

Table 1
Lesions and stents parameters.

Lesion length (mm)	40.03 ± 7.49
Stenosis (%)	89.33 ± 5.83
Stent Length (mm)	46.03
Stent Diameter (mm)	3.09 ± 0.41

Table 2
Angina status among different types of patients.

Type of patients	Percentage of total population	Number of patients
Diabetic Patients	56%	n = 17
Acute Coronary Syndrome	53.3%	n = 16
Stable angina	46.6%	n = 14
LV ejection fraction	$52.9 \pm 13.8\%$	
Patient with LVEF <45%	16.7%	n = 5

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