Safety and Effectiveness of Long Paclitaxel-Eluting Stents in patients with de novo coronary disease in Shaheed Rajaee Cardiovascular Medical and Research Center

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Abstract

Background- A great revolution happened in coronary intervention after the invention of drug eluting stents (DES). Different types of DES have been made. Stents with biocompatible polysulfone polymer and paclitaxel drug is newly introduced. In this study we aimed to evaluate the efficacy of this new drug eluting stent.

Methods- All consecutive patients underwent coronary angioplasty with paclitaxel eluting stents from January to March 2009 were enrolled. Data was collected in answer sheath and analyzed with SPSS 18.

Results- One hundred patients were included in this study, with mean age of 55.21±10.00. Most of the patients were male (70%). The most common risk factor was hyperlipidemia (47%). Most of the lesions undergone angioplasty was in B2/C ACC/AHA class, and LAD was the most common vessel. In this study the rate of technical and procedural success was 100%. There was not any early or late thrombosis, and death, myocardial infarction and stroke (major adverse cardiovascular events, MACE) was similar to other drug eluting stents.

Discussion- Stenting with paclitaxel eluting stents is safe. Regarding its biocompatible polymer it doesn't have any added hazard compared to bare metal stents. Further studies needed for other aspects ***(Iranian Heart Journal 2012; 13 (1):6 -10*)**.

Keywords: Drug Eluting Stent■ Restenosis■ MACE

Drug-eluting stents (DESs) have significantly reduced the rates of restenosis and target lesion revascularization (TLR) over bare metal stents (BMSs) in patients with symptomatic coronary artery disease.[1-3] The use of the Paclitaxel-eluting stent for treating single de novo lesions in patients with symptomatic coronary artery disease has been examined previously.[4,5] However, the late clinical outcome of these stents in unselected patients treated in daily practice remains controversial and the long-term safety of DESs remains in question.

Despite the results of meta-analyses of randomized studies refuting these concerns [6], late stent thrombosis remains a limitation of DES technology. The late stent thrombosis is depending on stent size. The long term outcomes of Iranian patients treated with Paclitaxel-eluting stent in "real world" practice are not well reported. Therefore, we report the one-year outcomes of unselected patients with coronary artery disease treated with long Paclitaxel-eluting stent.

In this study we decided to determine the rate of stent thrombosis and restenosis of long

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Paclitaxel-eluting stents that were used in Rajaee Cardiovascular Medical and Research Center from January 2009 to December 2009.

Materials and Methods

The study designed as prospective and descriptive. We select the patients who were candidate for coronary angioplasty and Paclitaxel-eluting stent were used from January 2009 to December 2009. Demographic data, coronary artery disease risk factors, and stents data were collected. Clinical follow-up was performed at 1, 6 and 12 months after the procedure. Angiography was performed in cases with symptoms or positive non invasive tests. Major Adverse Cardiac Events (MACE) were defined as cardiac death, MI, early stent thrombosis and late stent thrombosis. Myocardial infarction and stent thrombosis definitions used in this study were consistent with the newest consensus of the Academic Research Consortium (7). We also evaluate target lesion revascularization (TLR) and target vessel revascularization (TVR) either by PCI or CABG during clinical follow up. Data were collected and then were analyzed with SPSS 18.

Results

In this study since January 2009, 100 consecutive patients who underwent coronary angioplasty were included. Enrollment was completed by December 2009.Most of our patients were male (70%).Mean age of the patients was 55/21± 10year. Baseline characteristics of the patients are listed in Table I.

The prevalence of diabetes mellitus in our patients was about 27% and the most common risk factor in this population was hyperlipidemia (47%).

Table I. Baseline characteristics of study population

Baseline characteristics	Percentage
Male (%)	70%
Age(Years)	55.21± 10.00
Previous PCI (%)	10%
Previous CABG (%)	8%
Diabetes Mellitus (%)	27%
Hypertension (%)	45%
Hyperlipidemia (%)	47%
Family History of CAD (%)	16%
Chronic Kidney Disease (%)	4%
Smoking (%)	31%
ACS/UA (%)	81%
STEMI (%)	53%
Stable CAD (%)	19%

Most of our patients were admitted with acute coronary syndrome (ACS). Lesion characteristics are listed in Table II.

There were 166 lesions and most of the lesions were in B2/C ACC/AHA group which means that most lesions had high risk characteristics (92%). LAD was the most common vessel. After that RCA, LCX and Diagonal were common (62%, 21%, 16% and 1% respectively). Most of our patients had significant stenosis in one or two coronary vessels. Ostial lesions were 7% of cases.

Table II. Characteristics of the lesions which undergone PCI

PCI Results	Percentage
Stent number/Patient	1.54
Direct Stenting (%)	28%
Maximal pressure of stent deployment (Kpa)	13.28±2.18
Stent Length (mm)	36.72±4.64
Stent Diameter (mm)	2.86±0.28
Perforation (%)	0%
Dissection (%)	0%
Technical success (%)	100%
Procedural success (%)	100%

Our technical and procedural success was 100% and there were no complications (perforation, dissection or etc). PCI results are listed in table 3 and 4.

In this study 28% of lesion underwent direct stenting and most stents were used are long (36.72±4.64).

Mean diameter of stents in our study is 2.86±0.28.

Table III. Procedural and stent data

Lesion characteristics	Percentage
Number of lesions	166
Lesion Length (mm)	35.16±3.56
Diameter Stenosis	90%± 5.48%
ACC/AHA Type B2/C Lesion	92%
Reference Vessel Diameter	2.86±0.28
Ostial Lesion (%)	7%
LAD (%)	62%
RCA (%)	21%
LCX (%)	16%
Diagonal (%)	1%
SVD (%)	49%
2VD (%)	36%
3VD (%)	15%

Clinical follow-up is summarized in Fig.1.

Clinical follow-up was done 1, 6, and 12 months after PCI. 79% of cases were symptom free, 9% of them had typical chest pain and about 12% had positive noninvasive test. Coronary angiography was done for patients with chest pain or positive noninvasive test (21%). For patients with in-stent restenosis (2%), revascularization was done (TLR=3%)

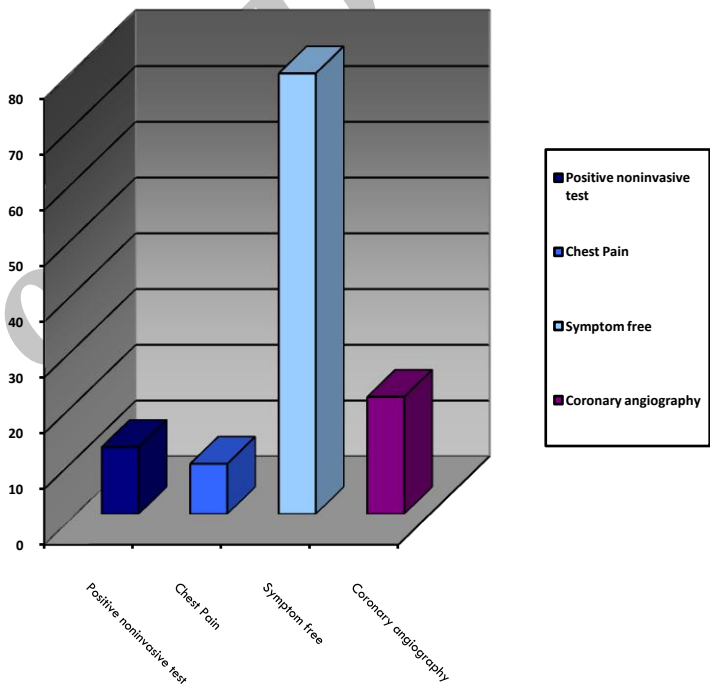

Fig. 1. Data of Clinical follow-up during 1 year

Table IV shows 12 month outcome and primary events. Myocardial infarction was seen in one patient who underwent LAD stenting and had Infero-RV MI; unfortunately we lost this patient due to cardiogenic shock secondary to RV MI.

Table V. Data of Primary events and 1 year out come

Events	Percentage
In hospital MACE (%)	4%
One year MACE (%)	6%
Early Thrombosis (%)	0%
Late Thrombosis (%)	0%
Cardiac Death (%)	1%
MI (%)	1%
Target Lesion Revascularization (%)	2%
Target Vessel Revascularization (%)	3%
Instent Restenosis (%)	2%

Discussion

Currently approved paclitaxel drug-eluting stents have become the predominant percutaneous treatment strategy for patients with CAD. We performed a descriptive study on paclitaxel eluting stent receiving patient to assess the clinical efficacy and possible complications. The outcome of our study showed MACE of 6%. Previous studies on these stents had MACE ranged from 3% to 29%.[8,9] Interestingly the TAXUS VI trial designed to show whether the benefit will be reproducible in subsets of the patient population with complex and long lesion lengths[10] registered a MACE rate of 21.3%. Previous studies have shown that a potential problem with the DES is late in-stent thrombosis.[11] It is proven that the use of antiplatelet agents decreases the risk of in-stent thrombosis in DES treated patients and has been used in most of the trials described earlier. Moreover, the rate of late stent thrombosis ranges from 0.5% to 0.6% in different trials. It is comparable to our result with no case of stent thrombosis. Target vessel revascularization in previous study ranged from 8% to 10%. In our study this was only 3% that may be due to technical improvement of interventionalists.

When we compare these results with earlier studies paclitaxel eluting stent is as safe as others drug eluting stents and it hasn't further risk of early or late stent thrombosis, cardiac death or MI.

This stent also reduces the rate of TLR, TVR and in stent restenosis at 12 month after implantation in complex lesions in comparison to other stents.

Conclusion

The Paclitaxel drug and biocompatible polysulfone polymer has not any inferiority in comparison of other drug eluting stents and it can be used safely without complications.

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