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Original Article

In-hospital and mid-term clinical outcomes after percutaneous coronary intervention with drug eluting stents

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ABSTRACT

Background and objective-Sirolimus-eluting (SES) and paclitaxel-eluting (PES) stents are first generation drug-eluting stents (DES) used to treat patients with ischemic heart disease. Drug-eluting stents (DES) have reduced the occurrence of restenosis and major adverse cardiac events (MACE) when compared with bare metal stents. Our aim was to assess the safety and mid-term clinical outcomes of stenting with Sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) for the treatment of coronary artery disease in our routine practice. Material and methods- The study population consisted of 100 patients who had undergone drug eluting stent implantation. Patients were eligible for enrollment if they had symptomatic coronary artery disease or positive exercise testing, and angiographic evidence of single or multivessel disease with a target lesion stenosis of ≥ 70%. Patients were followed-up for 6 months. The efficacy and safety of the procedure, in-hospital clinical outcome and the occurrence of major adverse cardiac events in the first 6 months were assessed. Statistical analysis was done. Results-All patients survived after stent implantation.1 (1%) patient experienced acute ST elevation myocardial infarction during follow up. Recurrent angina pectoris was observed in 5 (5%) patients (2 stable angina pectoris and 3 unstable angina pectoris).The 6month rate of MACE in our study was 1%. Conclusion-The results of the present study indicate that drug eluting stents could be implanted with a very high success rate and have encouraging mid-term clinical results.

1. Introduction

Percutaneous transluminal coronary angioplasty (PTCA) is one of the main procedures used to treat coronary artery disease. Drug-eluting stents (DES) have brought a revolution in the field of PTCA by significantly reducing the occurrence of restenosis and major adverse cardiac events (MACE) compared with bare metal stents in short-term and long-term follow-up [1-2] . Sirolimus-eluting (SES) and paclitaxel-eluting (PES) stents are first generation DES. Everolimus-eluting (EES) and zotarolimus-eluting (ZES) are second generation stents.

Several head-to-head analyses of the SES and the PES have been published from the West. The REALITY trial [3] did not demonstrate a difference in clinical outcomes between patients who received the SES and those who received the PES. In meta-analyses of studies comparing the 2 stent types, authors have confirmed a clinical advantage for those who receive the SES [4–5]. Uncertainty still remains regarding whether a true difference in clinical outcomes exists. The safety and midterm clinical outcomes of Indian patients treated with the SES and the PES is not well reported.

Our aim was to assess the safety and mid-term clinical outcomes of stenting with Sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) for the treatment of coronary artery lesions in our routine practice.

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2. Materials and Methods :

Study population

This study group consisted of 100 consecutive patients who had coronary artery disease and were treated either with Sirolimus eluting stent (SES) or Paclitaxel eluting stent (PES) according to stent availability and discretion of the cardiologist at a tertiary care center. The type, length and number of coronary lesions did not influence the choice of stent. Patients were eligible for enrollment if they had symptomatic coronary artery disease or positive exercise testing, and angiographic evidence of single or multivessel disease with a target lesion stenosis of ≥ 70%.Patients with contraindication to antithrombotic therapy were excluded from the study .The follow-up period was 6 months.

Baseline clinical, angiographic, and procedural characteristics and in-hospital outcomes were obtained by research physicians. Clinical outcomes, most importantly major adverse cardiac events (MACE) were obtained at 6 months. In our study, only patients treated exclusively either with Sirolimus eluting stent (SES) or Paclitaxel eluting stent (PES) were included. This study was approved by the Institutional Ethics Committee and written informed consent was obtained from all patients for enrolment in the study.

Angioplasty procedure

Balloon angioplasty and stenting were performed according to standard clinical practice by femoral approach. Elective stenting was done in all patients. All patients were pretreated with aspirin 325 mg daily, Clopidogrel 75 mg once daily and ticlopidine 250 mg twice daily for at least 48 hours or more. The use of glycoprotein IIb/IIIa inhibitors was allowed at physician discretion. During the procedure heparin was administered in boluses to reach and maintain an activated clotting time of more than 300 s. After stent implantation, aspirin 325 mg daily, Clopidogrel 75 mg once daily and ticlopidine 250 mg twice daily was given for twelve weeks. Aspirin and Clopidogrel were continued for duration of 9 months.

Study endpoints and Definitions

The primary endpoint was the rate of major adverse cardiac event (MACE) at 6months. As a secondary aim, we studied the in hospital outcomes after stent implantation.

Anginal symptoms were defined according to the classification of the Canadian Cardiovascular Society [6].A Q wave MI was defined as the presence of new Q waves in at least 2 contiguous leads with increase in MB fraction of creatine kinase. A non-Q wave MI was defined as a 2-fold increase in MB fraction of creatinine kinase without the development of new Q waves .Angiographic success was defined as 20% reduction in the stenosis of lesion treated resulting in < 50% residual lumen diameter stenosis. Procedural success was defined as angiographic success without major complications (death, MI, emergency bypass surgery, or PCI) during hospitalization.Major adverse cardiac events were defined as cardiac death or acute MI.

Statistical analysis

The collected data was analyzed using SPSS version 11.5.

3. Results

100 patients who had completed 6 month follow up were included for analysis.

Baseline characteristics of study population

The mean age of our study population was 54.08± 7.82 years. Out of the total of 100 patients, 89 were males and the rest were females. The commonest risk factor for ischemic heart disease was hypertension followed by diabetes mellitus in our study. In our study myocardial infarction (52%) was the commonest indication for stenting. 31 patients had Anterior wall MI and 21 patients had Inferior wall MI(Table 1).Paclitaxel eluting stent (PES) was used in 75(75%) patients and Sirolimus eluting stent (SES) was used in 25(25%) patients. Left anterior descending artery (LAD) was the commonest vessel (65%) for which stenting was done.

In-hospital outcomes

The immediate procedural success was 100 %. There were no deaths following intervention during the hospital stay. None of the patients required rescue PTCA or urgent CABG (Coronary artery bypass graft)(Table 2).

Table 1. Demographic and clinical characteristics of patients treated with Sirolimus-eluting stents (SES)and paclitaxel eluting stents (PES)(n = 100)

PARAMETERS	PATIENT CHARACTERISTICS	NO. OF PATIENTS(n)
GENDER	MALE	89
	FEMALE	11
COMORBIDITY	DIABETES	26
	HYPERTENSION	40
INDICATIONS FOR STENTING	CHRONIC STABLE ANGINA	30
	UNSTABLE ANGINA	18
	ANTERIOR WALL MI	31
	INFERIOR WALL MI	21

Table 2: In-hospital clinical outcomes in patients treated with SES and PES

EVENT	NUMBER OF PATIENTS(n)
ACUTE STENT THROMBOSIS	NIL
DEATH	NIL
URGENT	NIL
ACUTE MI POST PTCA	NIL
PROCEDURAL SUCCESS	100

Mid-term outcomes

During the follow up period, there were no deaths. Three patients had unstable angina and two had stable angina (Table 3). One patient who had chronic stable angina before PTCA presented

with acute Anterior wall MI and was thrombolysed with injection Streptokinase. Subsequent angiography done revealed patent stent and no residual stenosis. The 6-month rate of MACE was 1%.

Table 3. Clinical outcomes during the follow up period

EVENT	NUMBER OF PATIENTS(n)
MYOCARDIAL INFARCTION	1
UNSTABLE ANGINA	3
STABLE ANGINA	2
DEATH	NIL
MACE	1

MACE – Major adverse cardiac events

4. Discussion

In our study DES stent was associated with an excellent acute procedural success rate of 100 % which is comparable with the procedural success rate observed in a study conducted by Mohammed et al (97.5% for SES and 99.1% for PES) [7].The procedural and technical success rate was 100% in the TAXUS-I trial were PES stent was used.

At 6 months the rate of MACE in the 100 patients available for follow-up remained low at 1%. The 6 month rates of MACE in our study was comparable with the 6-month rates of MACE observed in previous studies of drug eluting stents. The 6-month MACE rate was 0% (0 of 31 patients) in the TAXUSI trial.

In our study recurrent angina pectoris was observed in 5 (5%) patients (2 stable angina pectoris and 3 unstable angina pectoris) during the follow up period. There was no death in our study during the follow up period. In a 6 month follow up study of 5084 patients who were treated with SES there were 32 cardiac deaths and 48 non-fatal MI (15 Q-wave MI and 33 non-Q-wave MI)during the follow up period [8].Doven et al [9] conducted a study to determine clinical and angiographic outcome of patients treated with PES stents. In their study patients were followed up for 16.7 ± 7.4 months. All patients survived after stent implantation. 2 (1.3%) patients experienced acute myocardial infarction after 3 and 9 months following angioplasty and recurrent angina pectoris was observed in 3 patients. The results of our study suggest that the performance of the drug eluting stent seen in various clinical trials is mirrored in clinical practice.

Sirolimus is an immunosuppressive drug which produces cell-cycle arrest in the G1/S phase transition, while paclitaxel is an antineoplastic drug that causes cell-cycle arrest in the G2/M phase transition and is considered as a cytotoxic agent [10-11].Drug-eluting stents reduce intimal hyperplasia, the main cause of in-stent restenosis. RAVEL study, Sirolimus-Eluting Balloon-Expandable Stent in the Treatment of Patients with De Novo Native Coronary-Artery Lesions(SIRIUS), and the smaller European and Latin American (E-SIRIUS)trials[12-14]are some of the trials were benefits of SES was demonstrated when compared to bare metal stents. Similarly benefits of PES has been demonstrated in TAXUS-I, TAXUS-IV and TAXUS-V[15-17] trials.

Our study had some limitations. The patients were not randomly assigned to PES or SES and it was a single centre study.

5. Conclusion

Our findings demonstrate that drug eluting stents can be implanted with a very high success rate and have good mid-term clinical outcomes. Longer follow-up studies are needed which will provide further insight into the safety and performance of drug eluting stents in the Indian population.

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