Original Article

LONG-TERM CLINICAL OUTCOME AFTER IMPLANTATION OF SECOND-GENERATION BARE-METAL STENTS

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ABSTRACT

Objective: Many clinical studies have been performed to determine the long-term outcome of coronary Stenting, most of them were based on first-generation bare-metal Stents. This study evaluated long-term (24 $\pm$ 6.4 month) result of second-generation bare metal stents (BMS).

Methodology: A consecutive series of 128 patients with symptomatic coronary artery disease (CAD) treated electively with second generation bare metal stents between august 2004 and September 2006 was included. Clinical outcome were analyzed after (24±6.4) months. The Primary end point was based on the occurrence of major adverse cardiac events of MACE (MI, Death, and Repeat Revascularization).

Results: One hundred and forty four bare metal stent were implanted in 134 Vessels. The Mean age of patients was (57±10.4) years, 72% of patients were male and 35.2% were diabetic with 98.4% in-hospital success rate. Thirteen (10.3%) patients had MACE during Follow-Up Period (4MI, 3CABG, 2Death and 4R-PCI). Independent Predictor of MACE was Unstable Angina.

Conclusion: Our study showed second generation bare-metal stents is superior to the first one due to better survival rate and lower incidence of MACE.

KEY WORDS: Bare metal stent, Angioplasty, Coronary artery disease (CAD).

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INTRODUCTION

The first case of percutaneous trans-femoral coronary angioplasty (PTCA) was performed in 1977 and since then different techniques of balloon angioplasty have been developed with little influence on clinical outcomes. Using coronary stenting has dramatically improved outcomes.[1,2] Rapid acceptance and widespread use of coronary stenting is based on two randomized clinical trials, STRESS and BENSTENT, comparing balloon angioplasty with elective palmaz-schatz stent which showed reduced clinical and angiographic restenosis.[1-4]

The long-term benefit of coronary angioplasty and stenting as a treatment strategy for coronary artery disease is based on its ability to reduce subsequent ischemic events including repeat revascularization procedure, myocardial infarction and death.[4] Since first successful coronary stent implantation in 1988 many

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clinical trials were performed to evaluate its outcomes.[5] Rankin et al reported a better results for coronary angioplasty using stent. Drug-eluting stents have been shown to reduce restenosis, with no significant difference in clinical outcome.[2] In addition, available long-term data for BMS are based on first-generation and specific ones,[5] so we designed this study to compare long-term benefit of second-generation Bare Metal Stents (BMS) alongside with a new anti-platelet drug (Clopidogrel) one.

METHODOLOGY

Patient selection: One hundred and twenty eight consecutive patients with elective placement of second-generation bare metal stents from August 2004 to September 2006 were enrolled in this study. Stent type is listed in Table-I, all of them were balloon expandable. The procedures were unsuccessful in two cases. In 126 patients 144 BMS were inserted in 134 vessels. Demographic parameters including age, gender, risk factors for coronary artery disease (hypertension, hyperlipidemia, diabetes mellitus, cigarette smoking and positive family history of ischemic heart disease) and patient history for angioplasty (MI or UA), angioplasty site, number of vessels, stents per patient, stent size and dose of plavix before angioplasty were collected from the hospital records.

Stent placement and medication: Stent implantation was performed using balloon-expandable bare-metal coronary stent. The procedure was performed via femoral artery using right and left judkins delivery system and Ebu or Amplatz catheter and using standard seldinger technique. Stent deployment was considered to be successful when a residual stenosis of less than 30% was achieved by visual estimation. Prior to stent placement, patients received a mean dose of plavix 562.5mg (7.5 tablets) and Aspirin (325mg and then 80mg/daily). All patients received unfractionated Heparin intravenously and nitroglycerin if necessary during the procedure. They were discharged on lifetime Aspirin (80mg) and plavix (75mg or 150mg) daily for one month.

Clinical follow-up: Clinical follow-up data were obtained from the hospital records or telephone contact and/or reviewing them in the out-patient clinic. All patients were followed for 24 6.4 month (12 to 36month); the end point was MACE (major adverse cardiac event).MACE was defined as Death, MI, Coronary revascularization (CABG or PCI).

Statistical analysis: Statistical analysis was performed using SPSS 11.5. Results were expressed as (mean value ± SD)or proportion (%). Differences were assessed by chi-square test. Uni and multivariate logistic regression analysis were carried out to identify independent correlates for MACE. Death free and Event Free survival distribution were estimated by using the Kaplan-Meier method. Statistical significance was accepted with $P < 0.05$.

RESULTS

From 128 patients, 126 (98.43%) had a successful elective stent deployment. One hundred forty four BMS were implanted in 134 vessels. Demographic data and stented vessels are listed in Table-II.

Table-I: Stents make and model

Stent's Name	*No. Implanted*	*%*
Driver RX	33	22.9
AVE S660	4	2.8
Medtronic AVE	13	9
Biodivysio OC	9	6.3
Multilink Tetra	8	5.6
Multilink Zeta	14	9.7
Libertte monorail	11	7.6
Micro Driver RX	15	10.4
Occam	1	0.7
ExpressII Monorial	19	13.2
AVE S667	1	0.7
Multilink Vision	11	7.6
Arthus	4	2.8
Abott	1	0.7
Total No.	144	100

Table-II: Patients demographic and stented vessels data

Patient date	*No. of patients (%)*
Age	57.15±0.4
Sex (male)	72 (56.3)
Diabetes	45 (35.2)
HTN	70 (54.7)
HLP	83 (64.8)
Prior MI	47(36.7)
Prior PCI	8 (6.3)
Prior CABG	3 (2.3)
Smoking	33 (25.7)
PCI for UA	52 (40.6)
PCI for MI	19 (14.8)
SVD	43 (33.6)
2VD	60 (46.9)
3VD	23 (18)
MVD	2 (1.5)
LAD	79 (59)
RCA	32 (23)
LCX	22 (16.4)
SVG	1 (0.7)

Mean hospital stay was (4.13±3.1) days and they were discharged home (1.12±0.04) days after stent implantation. They received a mean dose of plavix 562.5mg (7.5 tablets) before stenting and were discharged on 75mg for one up to six month. 16 patients (12.7%) had two and one (0.8%) received three stents. 80 (63.5%) patients had pre-dilation using a mean of (9.3±1.9) and 6-14 Atmosphere pressure. All stents were balloon expandable. The mean pressure for expanding stents was (13.1±2Atm) for a mean of (2.96±0.37) mm sized stents. The length of coronary stent was (16.334.4) mm for 60% up to 100% (89.84±8.14%) coronary narrowing.

Clinical Outcome: During hospital stay, there was no death or repeat revascularization. Three patients (2.4%) had coronary artery dissection; out of them one (0.8%) had Q-wave myocardial infarction. Three stents were overlapped to manage dissection. Stent did not pass the lesion in one case in spite of pre-dilatation. Only two patients (1.5%) needed to stay more than three days in the hospital.

Seven days after discharge one patient (0.8%) had MI one (0.8%) had sepsis and one patient (0.8%) had sub-acute instent thrombosis, a second attempt for deploying another stent was unsuccessful. He underwent an uneventful CABG. After a mean follow-up of (24 ± 6.4 month), 13(10.3%) patients had MACE [4MI (3.2%), 3 CABG (2.4%), four Repeat-PCI (3.2%) and two cardiac death(1.6%)] (Table-III). One and two year event free survival was 92.06% and 87.53% respectively. Two out of four patients with MI had CABG (1.6%) three month later. MI free survival for one and two years was 96.85%. One and two year death- free survival rate was 99.2% & 97.4% respectively. Four patients had repeat PCI and one of them died four month later. We found unstable angina (P value 0.02) as an independent predictor of MACE in our patients.

Table-III: Adverse cardiac event

MACE	*In hospital (%)*	*After 1 month (%)*	*After 6 month (%)*	*After 1 year (%)*	*at the end of follow up(%)*
MI	1(0.8)	1(0.8)	3(2.4)	4(3.2)	4(3.2)
CABG	0	0	1(0.8)	2(1.6)	3(2.4)
Death	0	0	1(0.8)	1(0.8)	2(1.6)
Re-PCI	0	1(0.8)	2(1.6)	3(2.4)	4(3.2)
Total	1(0.8)	2(1.6)	7(5.6)	10(8)	13(10.3)

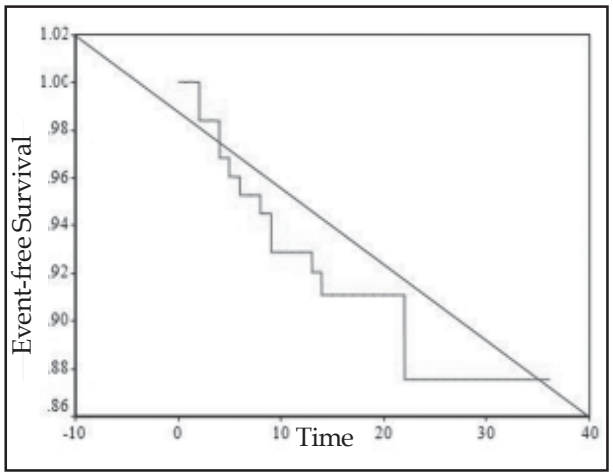

Fig-1: Event-free survival

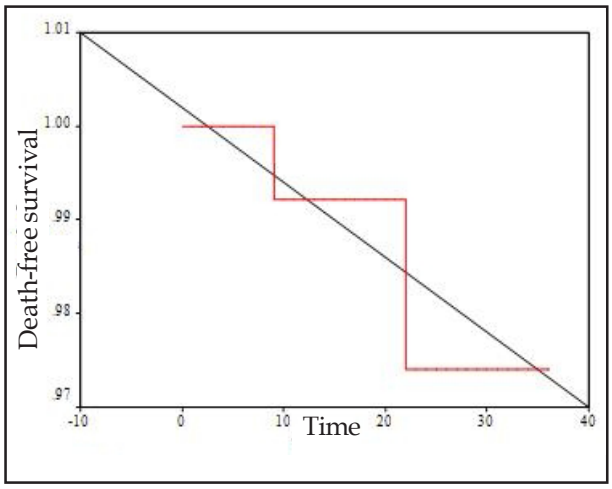

Fig-2: Death-free survival

DISCUSSION

The major findings of the present study are that improved stent design, stent implantation technique, and antiplatelet regimen result in a change of traditional restenosis paradigm and of predictor factors of MACE. The present study analyzed different models of second generation of Bare-metal stents and new anticoagulant regimen and implantation techniques in the time period of 2004-2006.

In-hospital and long-term clinical outcome: The rate of in-hospital major cardiac events in our study was (0.8%) which is comparable with other similar stent studies.[6,8-11] The event free survival rates at the end of one and two year were 92.06% and 87.53% respectively. The Death free survival rates were 99.2% and 97.4% at the same time. These results are in aggrement with those reported with the second generation BMS[8-17] and is better than the first generations.[12-16, 18-24]

The event-free survival at the end of follow-up in HAMON et al and FINESSII trials were 91.3% and 83% respectively.[8,10] The event-free survival at the end of three years in Choussat et al and Klugherz et al trials were 75% and 56%.[14,15]

In the present study, rate of MACE at the end of follow-up in order to baseline characteristics of our patients and vessels are low (40.6% with unstable angina and 35.2% with diabetes and 59% of vessels with LAD stenosis). The comparison of our study with first generation BMS[12-16,19] showed that event-free survival rate and major cardiac event rates are improved with use of second-generation Bare-metal stents , new anticoagulant regimen (like clopidogrel) and new techniques.[7,11-12,14,18,25-30]

Clinical predictors of outcome: In our study with Uni and multivariate logistic regression analysis, only unstable angina was found to be independent predictor of MACE. A number of risk factors for coronary stent restenosis and MACE have been revealed.[6-16] Fujiwara et al reported major coronary risk factors (especially diabetes mellitus) are predictors of MACE but Hamon et al found patient's sex, history of CABG, unstable angina were these predictors.[8,22] In this study major coronary risk factors (diabetes, hypertension, and hyperlipidemia) were not predictors for MACE. This was thought to be the reason that appropriate medical intervention had been performed for the established risk factors. Also Ghoussat et al reported that only insulin-treated diabetic patients had a higher risk for MACE.[14]

Limitations: The present study was based on clinical observation instead of angiographic follow-up. But the prevalence of death and myocardial infarction in the present study is similar to the same studies.

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