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Comparative outcomes of MACE after Drug eluting balloon Vs. Drug Eluting Stent in treatment of in-stent restenosis (ISR) patients presented with acute coronary syndrome.

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Abstract

Background: Currently, patients with coronary artery disease are advised to use coronary stenting as their primary revascularization method. This study aims to compare outcome of MACE after DEB Vs DES in treatment of patients within stent restenosis (ISR) presented with chest pain.

Methodology: The current study was Quasi experimental study carried out at the Department of Cardiology, MTI-HMC Peshawar for duration of six months from 21 April 2021 to 21 Nov 2021. In this study, 94 patients in DEB group and 94 patients in DES group were followed for 06 months to look for development of MACE. All data was collected through a well-defined proforma. Data was entered on computer software SPSS version 22.

Results: In DEB group, 52 (55.3%) male patients and 42 (44.7%) female patients were recorded whereas in DES group, 57 (60.6%) male patients while 37 (39.4%) female patients were recorded. In DEB group, 15 (16.0%) patients were recorded with MACE whereas in DES group, 38 (40.4%) patients were recorded with MACE.

Conclusion: Our study showed that DEB is superior to DES in the management of in-stent restenosis and results in fewer major adverse cardiovascular events (MACE), so DEB may be considered as a treatment option for CAD patients admitted to our setting in in order to reduce mortality and morbidity associated to restenosis in such patients.

Keywords

Coronary Artery Disease, Drug-Eluting Stents, Drug Eluting Balloon, Restenosis.

Introduction

Presently, coronary artery disease patients are advised to use coronary stenting as their main revascularization approach[1]. One of the problems with PCI (percutaneous coronary intervention) is ISR (in-stent restenosis). Despite the fact that drug-eluting stents (DES) have decreased the prevalence of ISR, it still affects 5%–10% of patients having PCI and is a serious issue[2]. One of the clinical problems that are yet unsolved and stubborn is restenosis. Patients with DES-ISR need more difficult treatment[3].

Drug eluting stents ISR is characterized by delayed vessel healing as a result of the stent materials, like the durable polymer, which generally manifests after two years as opposed to bare metal stent ISR, which normally takes between six and eight months to manifest. Vascular damage and the ensuing intima inflammation function as the first stimulus for multiplication and stimulation of vascular smooth muscle. As a result, myofibroblast move to create neointimal layer and extracellular matrix that is coated by endothelial cells above the stented section, leading to restenosis of the stent[4]. Additionally, a previous study identified the stent under-expansion as a significant possible ISR mechanism[5].

Individuals diagnosed with recurrent ISR have been treated with a variety of therapeutic modalities, including drug eluting balloon (DEB) dilation, DES repeated implantation, brachytherapy and excimer laser angioplasty.

The best course of action for recurring DES-ISR is currently unknown. According to prediction, redeployment of new stents with multi-metallic layers would itself contribute to lumen loss at lesions, particularly in vessels with a small diameter[6]. 30.8% and 24.2% of recurrent DES-ISR patients handled with new generation DES repeat deployment experienced serious adverse cardiovascular events within one year and ischemia-driven target lesion revascularization, respectively, according to a study by Varghese et al.[7]. Drug-eluting balloon angioplasty is a novel approach to treating ISR. A unique therapy option for ISR is DEB, which does not require to employ supplementary layers of metal stents and may administer anti-proliferative drugs to a restenotic artery part[8].

Outcome of these treatment modalities is not widely known. In previous study MACE (major adverse cardiovascular event) was present in 32.9% patients treated with reimplanted DES and 17.2% patients treated with DEB[6].

The rationale of this study is to compare outcome of DEB and DES in patients of in-stent restenosis. Finding a long-term outcome helped us in determining the efficacy of treatment modality and reduced mortality and morbidity associated with restenosis.

Methodology

The current study was Quasi experimental study carried out at the Department of Cardiology, MTI-HMC Peshawar for duration of six months from 21 April 2021 to 21 Nov 2021. Using open epi software, sample size was determined with a 95% confidence level, 80% power of the study, 32.9% MACE in the DES group, and 17.2% in the DEB group[6]. Sample size was n=188 patients, n_1=94 and n_2=94 patients in each group. Non-probability, consecutive sampling method was employed. The inclusion criteria of our study were patients of age between 17-60 years, patients of both gender, patients with previously done DEB and DES after in stent restenosis and patient on optimal medical therapy with compliance whereas criteria for exclusion were patient on optimal medical therapy with non-compliance and patients with coronary arterial bypass graft CABG.

After approval from hospital ethical committee, 188 patients fulfilling inclusion / exclusion criteria with the diagnosis of in-stent restenosis were enrolled from emergency department of HMC Peshawar. Written informed consent was taken. Demographic data regarding age, gender, residence, duration of symptoms, smoking (at least for last 6 months), diabetes (RBS more than 200mg/dl), hypertension

(systolic BP more than 130mmHg at rest), hyperlipidemia (fasting serum cholesterol more than 200mg/dl) obesity (> 25Kg/m^2) and family history of coronary disease was noted. Patients was admitted and treated for chest pain as per hospital protocol. For six months, 94 patients in the DEB group and 94 patients in the DES group were monitored for the emergence of MACE. Patients developing MACE was managed as per hospital protocols. All data was collected through a well-defined proforma. Data was entered on computer software SPSS version 22. Age and the length of the symptoms were quantitative data given for both groups using the mean and standard deviation. Qualitative data like gender, diabetes, hypertension, smoking, obesity, hyperlipidemia, family history and MACE was presented by frequency and percentages for both groups. Both groups were compared for presence of MACE by employing chi square test and p-value of ≤ 0.05 was considered significant statistically

Results

This study was conducted on 188 patients (94 patients in each group) admitted at the Department of Cardiology, Hayatabad Medical Complex, Peshawar.

In DEB group, the mean (±SD) age, duration of symptoms, BMI was 51.43 (±5.104) years, 3.52 (±1.233) months and 25.39 (±0.88) kg/m2 respectively while in DES group, the mean (±SD) age, duration of symptoms, BMI was 51.49 (±5.299), 3.56 (±1.205) and 25.364 (±0.885) respectively. In DEB group, 52 (55.3%) male patients and 42 (44.7%) female patients were recorded whereas in DES group, 57 (60.6%) male patients while 37 (39.4%) female patients were recorded. In DEB group, 35 (37.2%) patients were recorded with diabetes. In DES group, 27 (28.7%) patients were recorded with diabetes in DES group. In DEB group, 33 (35.1%) patients were recorded with hypertension. In DES group, 25 (26.6%) patients were recorded with hypertension. In DEB group, 26 (27.7%) patients were recorded with smoking history whereas in DES group, 30 (31.9%) patients were recorded with smoking history. In DEB group, 39 (41.5%) patients were recorded with obesity while in DES group, 35 (37.2%) patients were recorded with obesity. In DEB group, 35 (37.2%) patients were recorded with hyperlipidemia while in DES group, 36 (38.3%) patients were recorded with DES group. In DEB group, 41 (43.6%) patients were recorded with family history of coronary disease. In DES group, 29 (30.9%) patients were recorded with family history of coronary disease (Table 1).

Table 1: Clinical and sociodemographic characteristics of the enrolled patients

Parameter	Subcategory	DEB group	DES group	P value
		n(%)		
Gender	Male	52(55.3%)	57(60.6%)	0.460
	Female	42(44.70%)	37(39.4%)	
Age	≤ 50 Years	21(22.3%)	23(24.5%)	0.730
	> 50 Years	73(77.7%)	71(75.5%)	
Diabetes	Yes	35(37.2%)	27(28.7%)	0.215
	No	59(62.8%)	67(71.3%)	
Hypertension	Yes	33(35.1%)	25(26.6%)	0.207
	No	61(64.9%)	69(73.4%)	
Smoking status	Yes	26(27.7%)	30(31.9%)	0.524
	No	68(72.3%)	64(68.1%)	
Obesity	Yes	39(41.5%)	35(37.2%)	0.550
	No	55(58.5%)	59(62.8%)	
Hyperlipidemia	Yes	35(37.2%)	36(38.3%)	0.880
	No	59(62.8%)	58(61.7%)	

Family History of Coronary Disease	Yes	41(43.6%)	29(30.9%)	0.070
	No	53(56.4%)	65(69.1%)	

As per frequencies and percentages for MACE in both groups, in DEB group, 15 (16.0%) patients were recorded with MACE. In DES group, 38 (40.4%) patients were recorded with MACE (Table 2).

Table 2: Frequencies and percentages for major adverse cardiovascular event (mace) in both groups

Group	MACE	n(%)	P Value
DEB (n=94)	Yes	15(16.0)	0.000
	No	79(84.0)	
	Total	94(100.0)	
DES (n=94)	Yes	38(40.4)	
	No	56(59.6)	
	Total	94(100.0)	

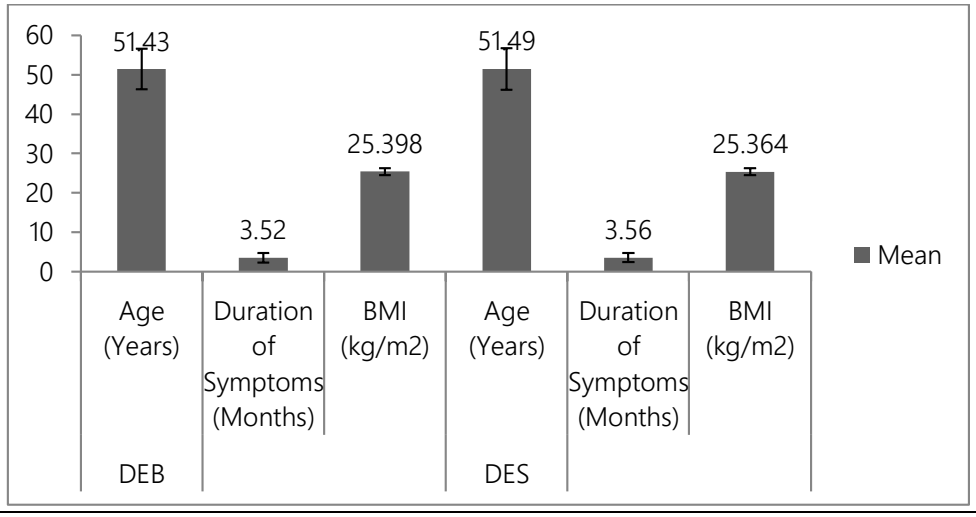

Figure 1: Mean age, duration of symptoms and BMI in both the group (Drug Eluting Balloon (DEB) Drug-Eluting Stents (DES)

Based on age distribution, in DEB group 21 (22.3%) patients were observed in age group < 50 years while 73 (77.7%) patients were observed in age group > 50 years whereas in DES group, 23 (24.5%) patients were observed in age group < 50 years whereas 71 (75.5%) patients were observed in age group > 50 years (Figure 1).

Discussion

Drug-eluting stents (DES) are still considered to be the best option for percutaneous coronary intervention (PCI) since they significantly lower the risk of in-stent restenosis (ISR) when compared to bare metal stents (BMS)[9,10]. Regardless of the increasing use of newer generation DES, DES-ISR still manifests in 5–10% of patients following DES deployment[11,12], and it has now become a prevalent therapeutic problem[13,14]. Additionally, DES-ISR therapy is linked to poorer long-term results when compared to BMS ISR; recent data indicate that 10 to 20% of these individuals will go on to get recurrent ISR after many stentings[15,16]. DEB angioplasty is a novel therapeutic approach for BMS-ISR and DES-ISR; studies have shown that it is

linked with better results when compared to other traditional treatment techniques[16,17]. Because it may prevent new metal layers and prolonged dual anti-platelet treatment, DEB is a desirable option for recurrent DES-ISR (DAPT). Recurrent DES-ISR managed with DEB has only been the subject of a small number of trials, and the outcomes are debatable[18-20].

This study was conducted on 188 patients (94 patients in each group) admitted at the Department of Cardiology, MTI-Hayatabad Medical Complex, Peshawar. In DEB group, the mean (±SD) age, duration of symptoms, BMI was 51.43 (±5.104) years, 3.52 (±1.233) months and 25.39 (±0.88) kg/m2 respectively while in DES group, the mean (±SD) age, duration of symptoms, BMI was 51.49 (±5.299), 3.56 (±1.205) and 25.364 (±0.885) respectively. Other previous studies carried out by Ferri LA et al. and Wang G et al. reported comparable findings to our study[5,6].

As per main outcome variable of our study, in DEB group, 15 (16.0%) patients were recorded with MACE. In DES group, 38 (40.4%) patients were recorded with MACE. Previous studies carried out by MJ et al. and Gao L et al. reported almost similar findings[7,8]. In accordance with our study another study carried out by Varghese et al. shows that cardiovascular events were observed in 30.8% while ischemia-driven target lesion revascularization were observed in 24.2% patients of recurrent DES-ISR managed by new-generation DES repeat deployment[21].

A new strategy for ISR treatment is drug-eluting balloon angioplasty. Outcome of these treatment modalities is not widely known. Similar with our findings, in previous study MACE (major adverse cardiovascular event) was observed in 32.9% patients treated with reimplanted DES and in 17.2% patients treated with DEB[6]. Our study's primary limitations were its single-center design and small sample size. It is necessary to conduct a larger prospective, randomized study to evaluate both therapy options for recurrent DES-ISR.

Conclusion

Our results demonstrated that DEB is superior to DES in the management of in-stent restenosis and results in fewer major adverse cardiovascular events (MACE), so DEB may be considered as a treatment option for CAD patients admitted to our setting in in order to reduce mortality and morbidity associated to restenosis in such patients.

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