Major adverse cardiovascular event (MACE) after percutaneous coronary intervention in one-year follow-up study

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Abstract

Background: Percutaneous coronary intervention (PCI) is the most common revascularization procedure, with over 1 million performed each year, worldwide. Over the past 20 years, the increasing experience of operators coupled with the advent of newer technologies, including coronary stents and a variety of adjuvant drug therapies, have permitted more successful procedures and decreased the morbidity associated with PCIs.

Objective: To identify the incidence, predictors, and clinical implications of Major Adverse Cardiovascular Events (MACE) after PCIs.

Methods: This descriptive cross-sectional study was done in Bandar Abbas in Iran in 2015. All patients which treated with PCI in Shahid Mohammadi Hospital during a one-year period were employed. A total of 192 patients were included. At one-year follow-up in this study, incidence and predictors of MACE were evaluated in a prospective study. The data were analyzed by SPSS 19.0 and descriptive tests included frequency and percentage and mean and standard deviation. Also, Chi-square test was used for data analysis. A p value <0.05 was determined as significant.

Result: Of the 192 patients, 126 (65.6%) were men and 66 patients were female. Stent had been implemented in 93.8% of patients. Sixty two percent of patients were treated with only one stent, two stents were deployed in 29.7% of patients and 3.6% of patients were treated with three or more stents. Of these patients, 46.9% were treated with Drug Eluted Stent (DES) and 40.1% were treated with Bare Metal Stent (BMS). Both types of stents were used in 8.3% of patients. Also, 4.7% of the patients were treated with balloon angioplasty (POBA). Angioplasty success rate was 95.3% and procedural success rate defined as achieving TIMI III flow with residual coronary stenosis under 30%. No in-hospital mortality or emergency CABG was reported. Re-admission in first year after PCI was required in 34 (17.7%) patients of which, 20 of them (10.4%) needed target vessel revascularization (TVR). Readmission was significantly higher (p=0.034) in the group with BMS compared to those who had DES. MI occurred in 8 patients.

Conclusion: Our study showed the superiority of DES in comparison with BMS in decreasing readmission and less TVR, but no effect on long term mortality. We recommend more studies in this setting because patients in special groups may benefit more from DES or BMS.

Keywords: Percutaneous coronary interventions, Myocardial Infarction, Stroke

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1. Introduction
1.1. Background
Today the aggressive treatment in removing coronary artery stenosis plays an important role in the control of the patients' symptoms, and has entered a new era with the technical progress in the treatment of acute myocardial infarction (Primary PCI in ST segment Elevation MI) (1). In the course of history since the beginning of balloon angioplasty in 1977 by Doctor Gruentzig (2), we are witnessing a critical milestone.

1.2. Statement of problem
Today, stent deployment is the selected treatment strategy in a large number of patients with atherosclerotic coronary stenosis who have undergone PCI (1). Certainly, there is no doubt in the superiority of stenting compared to balloon angioplasty alone (3). By using stents, we could resolve coronary artery dissection, reduce the incidence of restenosis and the need for coronary artery bypass graft (CABG). On the other hand, the use of BMS was, along with restenosis, between 20 and 30% during the first year (4, 5). Most of this In-stent restenosis (ISR) had led to clinical symptoms and was the cause for further invasive intervention. In order to reduce the incidence of ISR, the use of DES became popular, which largely overcame this problem, but an increase in late thrombosis in this group of stents is observed that requires longer treatment with dual antiplatelet therapy (6). Several studies have been carried out in this field that have compared the results of BMS and DES. Although reduced ISR and the need for aggressive action in using DES have reduced, most studies have shown no significant differences in mortality or myocardial infarction (MI) within the first year after PCI (7).

1.3. Objective
The general objective of this study was to investigate Major Adverse Cardiovascular Event (MACE) after PCI in a one-year period at Shahid Mohammadi Hospital (Bandar Abbas –Iran).

2. Material and Methods
2.1. Study design and setting
This descriptive cross-sectional study was done in 2015. Patients with PCI were studied over a one-year period at Shahid Mohammadi Hospital (Bandar Abbas in Iran).

2.2. Data collection
Patients' records were extracted from the hospital archive and the necessary information was transmitted to the research questionnaire and was investigated via telephone call, and the address mentioned in the patients' record. All patients were invited for an interview, and clinical status of the person including the level of physical exertion, chest pain, drug adherence and diet was evaluated. Stents used in patients over these years have included brands of Cypher (from Cordis Corporation, a Johnson & Johnson company), Taxus TM Express 2 paclitaxel-eluting coronary stent (Boston Scientific Corporation) and Nobori (Terumo Corporation-Japan) as DES, and the brands of Skylor™ stent (Invatec, Roncadelle, Italy), Liberté stent (Boston Scientific Corp., Natick, Massachusetts) and Volo (Invatec, Italy) as BMS.

2.3. Sample size
Of the total of 224 patients for whom angioplasty was performed on this year, access to 32 people by phone and verbally was not possible, thus they were excluded and the study was conducted on 192 people.

2.4. Ethical issues
The study was approved by the Ethics Committee of Hormozgan University of Medical Sciences. The patients' information was kept confidential.

2.5. Statistical analysis
The data were analyzed by SPSS 19.0 software and descriptive tests including frequency and percentage and mean and standard deviation. Also, Chi-square test was used for data analysis. A p value of <0.05 was determined as significant.

3. Results
3.1. Demographics
Of 192 patients, there were 126 men (65.6%) and 66 women (34.4%), the youngest patient was 30 and the oldest was 83 years of age. The average age for all patients was 56.31 (Table 1). Descriptive information has been given in

Table 1 considering the associated risk factors and their distribution. As shown, 53.1% of patients were hypertensive (74.2% of females and 42.1% of males) followed by cigarette smoking (27.6%) as the second more prevalent risk factors. About 65.5% of these patients had more than one significant lesion (most of them had 2 to 4 lesions with stenosis greater than 50%). Clinical presentation was in favor of high risk patients. Seventy-one (38.5%) patients admitted with acute MI, 30.2% with unstable angina and 31.3% with stable angina. In all, 13% of patients presented with acute MI received thrombolytic therapy in the emergency room (4.5% of females and 17.5% of males) before PCI.

Table 1. The patient frequency based on clinical variables and patient records

Variables		n	%
Age (years)	<54	85	44.3
	54-62	59	30.7
	63-70	18	9.4
	>70	30	15.6
Gender	Male	126	65.6
	Female	66	34.4
Positive family history of heart disease		45	23.4
Positive history of diabetes		44	22.9
Positive history of hypertension		102	53.1
Positive history of dyslipidemia		36	18.8
Positive history of MI		57	29.7
Positive history of CHF		8	4.2
Positive history of CKD		16	8.3
Smoking	Never	127	66.1
	Current user	53	27.6
	Past user	12	6.3
Previous PCI	Does not have	142	74
	Once	39	20.3
	More than once	11	5.7
Previous CABG	Does not have	184	95.8
	Once	8	4.2
	More than once	0	0

3.2. Main study results

During procedure, there were 0.5% of coronary dissection that had been covered by stents. One case of CVA was recorded in-hospital. There was one vessel involvement in 39.1%, two vessels in 40.1%, three vessels in 20.3% and no patients with left main lesion included in this study (Table 2). Stent has been implemented in 93.8% of patients. A total of 62% of patients were treated with only one stent, two stents were deployed in 29.7% of patients and 3.6% of patients were treated with three or more stents. Of these patients, 46.9% were treated with DES and 40.1% treated with BMS. Both types of stents were used in 8.3% of patients. A total of 4.7% of the patients were treated with balloon angioplasty (POBA). Angioplasty success rate was 95.3% and procedural success rate was defined as achieving TIMI III flow with residual coronary stenosis under 30%. No in-hospital mortality or emergency CABG were reported. Re-admission in the first year after PCI was required in 34 (17.7%) patients of whom 20 (10.4%) needed target vessel revascularization (TVR). Readmission was significantly higher (p=0.034) in the group with BMS compared to those who had DES. MI occurred in 8 patients. Patients with BMS needed higher TVR than those treated with DES (Table 2), while in each of these groups at one year, one case had a CABG. Our study did not show any significant correlation between variables and need for CABG. There was no sex preference in readmission rate. (17.5% for males compared to 18.2% for females). Mortality occurred in four cases in the one-year follow-up, two cases were in patients treated with DES, one in BMS group and one case in patients who had been treated with both types of stents. All four patients had more than two risk factors, interestingly all were hypertensive. One of the expired patients was a smoker who continued smoking and presented with anterior MI. There was significant correlation between old age, diabetes and coronary dissection during PCI with mortality. One strong predictor for TVR was history of previous PCI (p=0.026). Multi vessel involvement was also a predictor for readmission.

Table 2. Frequency of the need for re-PCI, CABG at one year after PCI, based on the variables dependent to intervention

Variables		Re-PCI one year after PCI; n (%)		CABG at one year after PCI; n (%)		p-value	
		Yes	No	Yes	No	PCI	CABG
The primary reason of PCI	AMI	7 (3.6)	67 (34.9)	1 (0.5)	73 (38)	0.913	1.000
	Unstable angina	7 (3.6)	51 (29.6)	1 (0.5)	57 (29.7)		
	Stable Angina	6 (3.1)	54 (28.1)	1 (0.5)	59 (30.7)		
The number of vessels involved	1	7 (3.6)	69 (35.9)	1 (0.5)	75 (39.1)	0.008	0.805
	2	4 (2.1)	73 (38)	2 (1)	75 (39.1)		
	3	9 (4.7)	30 (15.6)	0 (0)	39 (20.3)		
	Left main	0 (0)	0 (0)	0 (0)	0 (0)		
The number of vascular lesions	1	2 (1)	47 (24.5)	0 (0)	49 (25.5)	0.563	0.580
	3, 2, or 4	15 (7.8)	105 (54.7)	3 (1.6)	117 (60.9)		
	5 or more	3 (1.6)	20 (10.4)	0 (0)	23 (12)		
EF	> 50	17 (8.6)	129 (67.2)	3 (1.6)	143 (74.5)	0.642	0.642
	35 to 50	3 (1.6)	36 (18.7)	0 (0)	39 (20.3)		
	<35	0 (0)	7 (3.6)	0 (0)	7 (3.6)		
The use of stents	Yes	19 (9.9)	161 (83.9)	3 (1.6)	177 (92.2)	1.000	1.000
	No	1 (0.5)	11 (5.7)	1 (0.5)	12 (6.2)		
Type of stent	drug-eluting	7 (3.6)	83 (43.2)	1 (0.5)	89 (46.4)	0.359	0.434
	non-drug-eluting	10 (5.2)	67 (34.9)	1 (0.5)	76 (39.6)		
	drug-eluting and non-drug-eluting	3 (1.6)	13 (6.8)	0 (0)	24 (12.6)		
The number of stents	0	0 (0)	9 (4.7)	0 (0)	9 (4.7)	0.294	0.418
	1	12 (6.3)	107 (55.7)	1 (0.5)	118 (61.5)		
	2	6 (3.1)	51 (29.6)	2 (1)	55 (28.6)		
	3 or more	2 (1)	5 (2.6)	0 (0)	7 (3.6)		
The use of thrombolytic	Yes	1 (0.5)	24 (12.5)	0 (0)	25 (13)	0.326	1.000
	No	19 (9.9)	148 (77.1)	3 (1.6)	164 (80.4)		
MI during hospitalization	Yes	1 (0.5)	5 (2.6)	1 (0.5)	5 (2.6)	1.000	0.091
	No	19 (9.9)	167 (87)	2 (1)	184 (95.8)		
The number of lesions resolved	Any	0 (0)	8 (4.2)	1 (0.5)	7 (3.6)	0.020	0.116
	Some	16 (8.3)	80 (41.7)	1 (0.5)	95 (49.5)		
	All	4 (2.1)	84 (43.8)	1 (0.5)	87 (45.3)		
The number of diseased vessels after PCI	0	4 (2.1)	84 (43.8)	1 (0.5)	87 (45.3)	0.028	0.600
	1	10 (5.2)	65 (33.9)	2 (1)	73 (38)		
	2	5 (2.6)	22 (11.6)	0 (0)	27 (14.1)		
	3	1 (0.5)	1 (0.5)	0 (0)	2 (1)		
	Left main	0 (0)	0 (0)	0 (0)	0 (0)		
CVA during hospitalization	Yes	0 (0)	1 (0.5)	0 (0)	1 (0.5)	1.000	1.000
	No	20 (10.4)	171 (89.1)	3 (1.6)	188 (97.9)		
Bleeding during PCI	Yes	0 (0)	1 (0.5)	0 (0)	1 (0.5)	1.000	1.000
	No	20 (10.4)	171 (89.1)	3 (1.6)	188 (97.9)		

4. Discussion

Considering Bandar Abbas and the existence of an active port and international airport and the high traffic of passengers and terminal traffic that have daily admission, over 6,000 truck and trailer drivers (8) from different Iranian cities, this lack of access was predictable. The most important finding in these patients in both groups was the early success, including the improvement in chest pain and no MACE in less than 30 days, which was a sign of successful PCI (9). The patients for whom DES had been used, required less hospitalization than BMS patients (5.7% vs. 8.6%), which was statistically significant (p=0.034). Several studies showed that BMS implementation was associated with more MACE in one-year follow-up (10, 11). In different studies, lack of referring and late

referring to treatment centers are observed. This finding, or findings of various studies which is useful to reduce readmissions in the first year after angioplasty, is consistent (12, 13). High incidence of restenosis with BMS resulted in more re-admission and TVR lead to reduced BMS use, and especially in developed countries, DES implementation been increased on the previous years. Now BMS is used in about 10-30% of angioplasty cases (14). In some hospitals more than 80% of used stents are DES. BMS has been restricted to people who are not capable of long-term dual antiplatelet using artery diameter over 4 mm or patients who have planned surgery and patients with short life expectancy (15, 16). BMS has been restricted to people who are not capable of long-term dual antiplatelet using artery diameter over 4 mm or patients who have planned surgery and patients with short life expectancy (15, 16). S.E. Kassaian and colleagues at Tehran Heart Center, showed that deployment of the BMS in comparison with the first- and second-generation DES in primary PCI were the strongest predictors of 12-month MACE (17). In our study, 38.5% of patients had MI and a number of them had undergone Primary PCI, which could be potentially high risk for MACE in future. Studies about one-year mortality in a setting of acute and primary PCI, demonstrated higher mortality rate and there was no difference in TVR between DES and BMS. A study conducted by Khosravi and colleagues in Isfahan, demonstrated 1% mortality in a group of patients of whom 85% had unstable angina (18) and in comparison with catheterization laboratories of low experience, our data is acceptable. Lateness in seeking help for angina and presenting to the emergency room in our city is another problem that results in late treatment and facing MI and related complication (19). What is clear from studies, is high mortality after PCI in patients with MI (20). In this study, mortality rate has no significant relationship with the type of stent as shown by Tina L. and colleagues (21), although several studies have been reported for long-term stent thrombosis (6). One of the patients with anterior wall MI presented to hospital with LAD late stent thrombosis. This case has not had regular drug use, especially clopidogrel. Several studies point to the late stent thrombosis in most cases, due to lack of proper use of dual antiplatelet (4, 22). Although with new stent generation and far-reaching changes that have been created in the production of stents, it is expected to face less stent thrombosis in future and moreover, reduce stent thrombosis in the future. In this study used stents were Cyper and Taxus that had already replaced by third generation stents with advice of 6 months of antiplatelet therapy which is a good news for future of PCI. One of the strong predictors for TVR was history of previous PCI and multi vessel involvement. We recommend that to overcome this issue, treatment strategies must be built on full revascularization and effective risk factors control.

5. Conclusions
Our study showed the superiority of DES in comparison with BMS in decreasing readmission and less TVR, but no effect on long term mortality. There are very strong predictors for MI like hypertension, previous MI, primary PCI and coronary dissection. Predictors for death as shown in our study, were old age, diabetes, and coronary dissection. Our study showed the superiority of DES in comparison with BMS in decreasing readmission and less TVR, but no effect on long term mortality. We recommend more studies in this setting because patients in special groups may benefit more from DES or BMS.

Conflict of Interest:
There is no conflict of interest to be declared.

Authors' contributions:
All authors contributed to this project and article equally. All authors read and approved the final manuscript.

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