ORIGINAL ARTICLE

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Drug Eluting Stents versus Bare Metal Stents in ST-Segment Elevation Myocardial Infarction

ABSTRACT

Objective: The aim of this study was to compare the effectiveness and safety of drug eluting stents (DES) with bare metal stents (BMS) in patients presented with ST-segment elevation myocardial infarction (STEMI) in a real world setting.

Methods: One thousand five hundred ninety six STEMI patients treated with primary percutaneous coronary intervention from January 2013 to March 2016 were enrolled to study. One thousand one hundred ninety four of them received BMS while 402 of them received DES. Patients were analyzed for major adverse cardiac events (MACE) and stent thrombosis (ST).

Results: There was no difference at 30 days in relation of MACE, all cause death, re-MI, TVR, TLR and ST. The cumulative incidence of MACE was significantly higher in DES group (9,2% vs. 7,0%, p = 0.02) at 1 year. Stent thrombosis and re-MI incidence were significantly higher in DES group (4,2% vs. 2,6%, p = 0.028, 6,9% vs. 4,8%, p = 0.015) respectively at 1 year. There was no statistically significant difference in relation of all cause death, TVR and TLR at 1 year. The statistically differences between groups vanished at 2 year and the groups looked similar. Male gender (HR, 1.40; 95% CI, 1.00 to 1.94; p = 0.043) and presence of DM (HR, 1.73; 95% CI, 1.29 to 2.32; p<0,001) were found to be independent predictors of 2-year MACE.

Conclusions: Our study showed effectiveness and safety of DES in STEMI. Despite increased incidence of MACE, re-MI and ST in 1-year, DES was found to be non-inferior to BMS at 2-year follow up.

Keywords: Drug-Eluting Stents, Bare-Metal Stents, ST-Segment Elevation Myocardial Infarction

ST Yükselmeli Myokard Enfarktüsünde Çıplak Metal Stentler ve İlaç Kaplı Stentlerin Karşılaştırılması

ÖZET

Amaç: Bu çalışmada ST segment yükselmeli myokard enfarktüsünde ilaç kaplı stentleri ve çıplak metal stentleri karşılaştırmak istedik.

Gereç ve Yöntem: Çalışmamıza merkezimize Ocak 2013 ve Mart 2016 tarihleri arasında başvuran toplam 1596 ST segment yükselmeli myokard enfarktüsü alındı. Katılımcılar çıplak metal stent grubu (n=1194) ve ilaç kaplı stent grubu (n=402) olarak iki gruba ayrıldı. Hastalar major kardiyak sonlanım acısından değerlendirildi.

Bulgular: Gruplar arasında ilk 30 günde major kardiyak sonlanım ve tüm ölüm açısından fark olmamasına rağmen, toplam major kardiyak sonlanım insidansı (9,2% vs. 7,0%, p=0.02), stent thrombozu (4,2% vs. 2,6%, p=0.028) ve tekrar myokard enfarktüsü (6,9% vs. 4,8%, p=0.015) ilaç kaplı stent grubunda yüksek bulundu. Bununla birlikte toplam mortalitede, hedef damar ve lezyon revaskülarizasyonunda istatiksel anlamlı fark bulunmadı. Major kardiyak sonlanım ve toplam mortalite 2 yıllık takipte gruplar arasında benzer bulundu. Erkek cinsiyet (HR, 1.40; 95% CI, 1.00'den 1.94; p = 0.043) ve diyabet varlığı (HR, 1.73; 95% CI, 1.29'den 2.32; p<0,001) major kardiyak sonlanım için bağımsız prediktör olarak saptandı.

Sonuç: Sonuçlarımız St yükselmeli myokard enfarktüsünde ilaç kaplı stentlerin çıplak metal stentler ile karşılaştırıldığında hem etkili hem de güvenli olduğunu gösterdi.

Anahtar Kelimeler: İlaç Kaplı Stentler, Çıplak Metal Stentler, ST Yükselmeli Myokard Enfarktüsü

INTRODUCTION

Primary percutaneous coronary intervention (pPCI) is the gold reperfusion strategy for patients presenting with ST-segment elevation myocardial infarction (STEMI)[1]. In this setting bare-metal stent (BMS) has been showed to reduces the risk of re-occlusion of the ischemia related artery and need for repeat revascularization compared to balloon angioplasty alone[2]. Superiority of first generation DES over BMS in reducing clinical and angiographic restenosis has been shown in patients with both stable angina pectoris and STEMI[3,4]. However, there are concerns about DESs' safety in STEMI regarding reduced endothelialization and healing of the vessel leading stent thrombosis (ST). Due to these concerns DESs are not universally implanted in STEMI patients. Reciprocal pros and cons of DES and BMS confuse interventional cardiologists' preference especially in STEMI setting.

The purpose of this study was to compare the effectiveness and safety of DES with BMS in patients undergoing pPCI for STEMI in a real world setting.

MATERIAL AND METHODS

Patient Selection: This is a retrospective, single center study included 402 DES and1194 BMS implanted patients presented with STEMI in tertiary heart hospital (From January 2013 to March 2016). Patients treated with balloon dilatation without stent implantation, medical therapy alone and a combination of DES and BMS was excluded from the study. All the interventions were performed via femoral route according to the current guidelines. All patients received acetylsalicylic acid 300 mg, clopidogrel 300 mg and un-fractioned heparin (100 IU/kg) at the beginning of the intervention. An activated clotting time of 250 to 300 provided in prolonged intervention with additive dose of heparin. Pre-dilation with a balloon angioplasty was performed whenever needed before stent deployment. The interventional cardiologists decided the type of coronary stent according to the national and international guidelines and recommendations. Glycoprotein IIb/IIa inhibitor usage was also up to the interventional cardiologists' preference. The patients were followed with acetylsalicylic acid 100 mg for indefinitely and a P2Y12 inhibitor daily for a minimum duration of 12 months.

Definitions and End Points: ST-segment elevation myocardial infarction (STEMI) was defined as an electrocardiographic ST-segment elevation ≥ 1mm in ≥ 2 contiguous leads or new left bundle branch block with symptoms of angina < 12 hours duration.

All the patients' data were analyzed for major avers cardiac events (MACE) and ST from the database of the hospital. MACE was defined as all cause death, repeated myocardial infarction (unstable angina, non ST-segment myocardial infarction and STEMI), repeat target vessel revascularization and repeat target lesion revascularization. Target lesion revascularization was defined to have a repeat intervention to previous stent or proximal and distal 5 mm edge segments. Target vessel revascularization was defined to have any revascularization to previously treated vessel. ST was defined as angiographic confirmation of thrombus within the stent causing partial or total occlusion of the vessel according to Academic Research Consortium criteria[5]. Left ventricular ejection fraction (LVEF) was measured by echocardiography.

Statistical Analysis: Statistical analyses were performed using SPSS 15.0 (SPSS Inc., Chicago, IL, USA) software. Continuous variables were defined as mean± SD or median; categorical variables were defined as percentages. The Student *t*-test was used for continuous variables between groups. The chi-square test was used in categorical variables comparison. Pearson or Spearman correlation tests were used in correlation single variables. P values less than 0.05 was accepted as statistical significance level. In addition, univariate and multivariate binary logistic regression analysis was performed to detect independent factors affecting MACE. All p values were two-sided in the tests and p values less than 0.05 were considered to be statistically significant.

RESULTS

The study included 402 (25%) DES and 1194 (75%) BMS implanted patients presented with STEMI. Clinical and demographic properties of the groups are summarized in the Table-1. DES received group was older than BMS received group was (60,18±12,21 vs. 57,50±11,89, p=0.01). The frequency of cardiovascular risk factors; DM, HT, hyperlipidemia, smoking, coronary artery disease anamnesis did not differ between groups. DES implanted patients had a higher frequency of chronic kidney disease (15,3% vs. 9,1%, p=0.01) and stroke (4,7% vs. 2,4%, p=0.01). The frequency of patients received thrombolytic therapy before intervention and the proportion of patients received resuscitation was similar. The admission LVEF, electrocardiographic presentation of STEMI and KILLIP score were similar between groups.

Table 1. Demographic characteristics and risk factors identification of patients.

	BMS (n=1194, 75%)	DES (n=402, 25%)	P
Age, years	57.50±11.89	60.18±12.21	**0.01**
Male sex, (%)	990(83%)	320(80%)	0.15
Hypertension, (%)	407/810(50,2%)	160/317(50,5%)	0.94
Diabetes mellitus, (%)	397/1122(35,4%)	141/391(36,1%)	0.80
Hyperlipidemia, (%)	433/1089(39,8%)	149/387(39,4)	0.90
Smoking, (%)	399/593(67,3%)	140/206(68%)	0.85
Chronic kidney disease, (%)	108/1187(9,1%)	61/400(15,3%)	**0.01**
Anemia, (%)	164/1189(13,8%)	72/400(18%)	**0.04**
Stroke, (%)	23/951(2,4%)	17/363(4,7%)	**0.01**
Coronary artery disease, (%)	145/1194(12,1%)	50/402(12,4%)	0.87
Thrombolytic	4 (0,3%)	4 (1,0%)	0.116
Cardio pulmonary Resusitation, (%)	86/1194(7,2%)	32/402(7,9%)	0.6
Ejection Fraction, (%)			
10-20%	2/995()	0()	
20-30%	29/995(2,9%)	12/343(3,4%)	0.86
30-40%	197/995(19,7%)	68/343(19,8%)	
40-50%	290/995(29%)	101/343(29,4%)	
Over 50%	477/995(47,7%)	162/343(47,2%)	
Myocardial infarction ECG, %			
Anterior MI, (%)	549(46%)	187(46,5%)	
High Lateral MI, (%)	19(1,5%)	9(2,2%)	0.84
Inferior MI, (%)	604(50,5%)	199(49,5%)	
Posterior MI (%)	22(1,8%)	7(1,7%)	
Killip, %			
I, %	1145(96%)	376(93,5%)	
II, %	2(0.1%)	4(1%)	0.47
III, %	11(1%)	7(1,7%)	
IV, %	36(3%)	15(3,7%)	

BMS: bare metal stent, DES: drug eluting stent, ECG: electrocardiography, MI: myocardial infarction

Procedural characteristics of the study are presented in Table-2. There were no statistically significant differences in relation of door to balloon time, balloon size, pre-procedural TIMI flow and the number of diseased vessels between the groups. Implanted stents were wider and shorter in BMS group than DES group [(3.08±0.52 vs. 2.6±0.35, p=0.01), (21.73±6.30 vs. 22.9±7.08, p=0.01), respectively].

Table 2. Procedural characteristics of the study.

	BMS(n=1194)	DES (n=402)	P
Door to balloon time, min	18.06±7.32	19.07±7.40	0.13
Balloon size, mm	1.23±1.14	1.23±1.04	0.98
Stent diameter, mm	3.08±0.52	2.6±0.35	**0.01**
Stent length, mm	21.73±6.30	22.9±7.08	**0.01**
Pre-procedural TIMI flow-no (%)			
Grade 0	970/1194(81,2%)	327/402(81,3%)	
Grade 1	54/1194(4,5%)	27/402(6,7%)	0.15
Grade 2	87/1194(7,2%)	29/402(7,2%)	
Grade 3	83/1194(6,9%)	19/402(4,7%)	
Post-procedural TIMI flow-n (%)			
Grade 0	16/1194(1,3%)	5/402(1,2%)	
Grade 1	3/1194(0,2%)	8/402(1,9%)	
Grade 2	43/1194(3,6%)	35/402(8,7%)	**0.01**
Grade 3	1132/1194(95%)	354/402(88%)	
Thrombus aspiration	79/1115(7%)	12/390(3%)	**0.01**
Glycoprotein IIb/IIIa inhibitor, %)	629/1194(52,7%)	186/402(46,3%)	**0.02**
Diseased vessel			
One-vessel	699/1194(58,5%)	219/402(54,5%)	
Two-vessel	314/1194(26%)	109/402(27%)	0.09
Three-vessel	181/1194(15%)	73/402(18%)	

Successful blood flow restoration with post-procedural grade 3 TIMI flow was more prominent in BMS received group than DES received group [(1132/1194 (95%) vs. 354/402 (88%), p=0.01]. Glycoprotein IIb/IIIa inhibitor usage and thrombus aspiration catheter usage during procedure also were more prominent in BMS received group than DES received group 629/1194(52,7%) vs. 186/402(46,3%), p=0.02), (79/1115(7%) vs. 12/390(3%), p=0.01) respectively.

Clinical outcomes at 30 days, 1 and 2 years of study are described in Table-3. There was no difference at 30 days in relation of MACE, all cause death, re-MI, TVR, TLR and ST. The cumulative incidence of MACE was significantly higher in DES group (9,2% vs. 7,0%, p = 0.02) at 1 year.

Stent thrombosis and re-MI incidence were significantly higher in DES group (4,2% vs. 2,6%, p = 0.028, 6,9% vs. 4,8%, p = 0.015) respectively at 1 year. There was no statistically significance difference in relation of all cause death, TVR and TLR at 1 year. The statistically differences between groups vanish at 2 year and the groups look similar.

Independent predictors of 2-year MACE are presented at Table-4. On univariate analysis male gender and presence of DM were associated with 2-year MACE. After adjustment for these parameters, male gender (HR, 1.40; 95% CI, 1.00 to 1.94; p = 0.043) and presence of diabetes mellitus (HR, 1.73; 95% CI, 1.29 to 2.32; p<0,001) were found to be independent predictors of 2-year MACE.

Table 3. Clinical outcomes at 30 days, 1 and 2 years.

	BMS (n=1194)	DES (n=402)	P
30-Day outcomes			
MACE	46(3,8)	20(4,9)	0.096
All cause death	24(2,0)	9(2,2)	0.654
MI(re-infarction)	24(2,0)	11(2,7)	0.199
Target lesion revascularization	18(1,5)	8(2,0)	0.368
Target vessel revascularization	19(1,6)	8(2,0)	0.468
Stent thrombosis	18(1,5)	9(2,2)	0.259
1-Year outcomes			
MACE	84(7,0)	37 (9,2)	**0.020**
All cause death	28(2,3)	11(2,7)	0.489
MI(re-infarction)	58(4,8)	28(6,9)	**0.015**
Target lesion revascularization	35(2,9)	15(3,7)	0.168
Target vessel revascularization	38(3,2)	16(3,9)	0.204
Stent thrombosis	32(2,6)	17(4,2)	**0.028**
2-Year outcomes			
MACE	96(8,0)	39(9,7)	0.062
All cause death	30(2,5)	12(2,9)	0.312
MI(re-infarction)	77(6,4)	31(7,7)	0.089
Target lesion revascularization	41(3,4)	16(3,9)	0.489
Target vessel revascularization	45(3,7)	17(4,2)	0.472
Stent thrombosis	36(3,0)	17(4,2)	0.099

Values are presented as number (%).
BMS: bare metal stent; DES: drug-eluting stent; MACE: major adverse cardiac event; MI: myocardial infarction.

Table 4. Independent predictors of 2-year major adverse cardiac event.

	Univariate		Multivariate	
	HR (95% CI)	p value	HR (95% CI)	p value
Age, years	1,24 (0,89-1,73)	0.199		
Male gender	1,40 (1,00-1,95)	**0.048**	1,40 (1,00-1,94)	**0.043**
DM	1,56 (1,14-2,13)	**0.005**	1,73 (1,29-2,32)	**<0.001**
HT	1,15 (0,84-1,57)	0.385		
HL	1,22 (0,90-1,66)	0.202		
Thrombus aspiration	1,20 (0,64-2,25)	0.565		
Tirofiban usage	1,06 (0,78-1,43)	0.713		
Stent type, DES	1,12 (0,78-1,63)	0.535		
Stent Width	1,20 (0,85-1,68)	0.304		
Stent Length	1,31 (0,97-1,77)	0.080	1,30 (0,97-1,75)	0.083

HR: hazard ratio, CI: confidence interval, DM: diabetes mellitus, HT: hypertension, HL: hyperlipidemia, DES: drug-eluting stent.

DISCUSSION

Complete occlusion of coronary arteries with thrombus is the major underlying mechanism for STEMI. Early benefit of balloon angioplasty over thrombolytic therapy is decreased with extended follow-up and reduction in rates of death and nonfatal MI at 30 days had lost statistical significance at 6 months[6]. Restenosis gave rise to this loss of beneficial effect of balloon angioplasty, and this has been decreased with coronary stents in elective PCI patients. However, it was once believed stents should not be implanted acute MI patients due to high thrombotic milieu. Stent underdeployment and late stent malapposition leading restenosis and stent thrombosis were the concerns in high thrombus-burden lesion of acute MI[7]. But clinical trials with adequate antiplatelet therapy showed statistically significant reduction in need TVR[8] and restenosis[9] at 6 months with stent placement in patients with acute MI.

The beneficial effect of PCI using BMS over balloon angioplasty alone in reduction restenosis without increase in death and re-MI made it first line treatment in acute MI and STEMI. The first two study comparing DES with BMS in STEMI patients showed no benefit of DES in reducing restenosis[10,11] but increase of ST[12]. But several meta-analyses showed no differences in terms of mortality, MI and risk of stent thrombosis[12-14]. More, HORIZONS-AMI showed decreased rate of ischemia-driven TVR and TLR[15] with DES usage. In 2009 ACC/AHA guidelines advise DES as an alternative to BMS in patients undergoing primary PCI for STEMI after this progress[16]. According to the guidelines, our tertiary cardiovascular hospital uses both DES and BMS in pPCI. In this study we aimed to compare mortality and safety in an unselected patient population undergoing pPCI with DES versus BMS implantation.

As described in the results section, the two groups differed significantly in cardiovascular risk factors. Patients with anemia, chronic kidney disease and stroke anamnesis received more DES than BMS and DES received group was older. The difference continued in procedural characteristic of study too. Longer and narrower stents were used in DES group and post-procedural TIMI flow was worse in DES group. Thrombus aspiration and tirofiban usage were less in DES group.

Clinical outcomes of the study showed unfavorable incidence of MACE, re-MI and ST in DES group at 1-year which disappears at 2-year follow up. TVR, TLR and all cause death incidence were similar. It was suggested that DES implantation during pPCI could be associated with an increased risk for ST, which is associated with high-morbidity and -mortality rates[17,18]. However, subsequently conducted studies showed DES usage with favorable outcomes in various clinical and angiographic characteristics[19,20]. Acute MI leads an increased platelet activation[21] and stent placement in this setting is associated with more intense platelet activation than balloon angioplasty alone[22]. Lack of endothelialization, exposure of proinflammatory and prothrombogenic environment of the necrotic core could be explanation of increased risk of ST with DES in acute MI[23]. Acute and subacute ST was found to be associated with sirolimus-eluting or paclitaxel-eluting stents in acute MI setting[18]. In our study, acute and subacute ST was similar between groups, interestingly late ST was found to be higher in DES. We suppose this difference comes from cardiovascular risk difference and procedural disadvantage of DES group. Extended dual anti-platelet therapy necessity and harmony with it could be another pitfall. Re-MI and MACE also found to be increased but we do not have convincing suggestion. At the same time we remind that this study is a real-world patients study and results of study could vary.

On univariate analysis male gender and presence of DM were associated with 2- year MACE and after adjustment for these parameters they were found to be independent predictors of 2-year MACE. A registry including patients from 2007 to 2011 with a total of 243,861 patients showed an increased adjusted risk of in-hospital mortality in the DM group in both the NSTEMI (n=53,094) and STEMI (n=21,507) population[24]. As a previously counted risk factor for development of cardiovascular disease DM was found to be an independent predictor with male gender in our study. This was attributed do microvascular degeneration of endothelium of coronary vessels.

CONCLUSION

Our study shows increased incidence of MACE, re- MI and ST in DES received group in patients presenting with STEMI at 1-year follow up. However, this difference vanished at 2-year follow up and there is no statistically significant difference of MACE, all cause death, re-MI, TVR, TLR and ST between groups. In this study; male gender and presence of DM were found to be independent predictors of 2-year MACE. These results could be interpreted as safety and effectiveness of DES in STEMI in long term.

Limitation

This study reflects the result of a ‘real-life experience’ of pPCI of a tertiary cardiovascular center. Naturally, interventional cardiologists chose the stent type according to national and international guidelines and recommendations and more patients received BMS than DES. Relatively small sample size of patients treated with DES. This could be a limitation.

Conflict Of Interest

None for any authors

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