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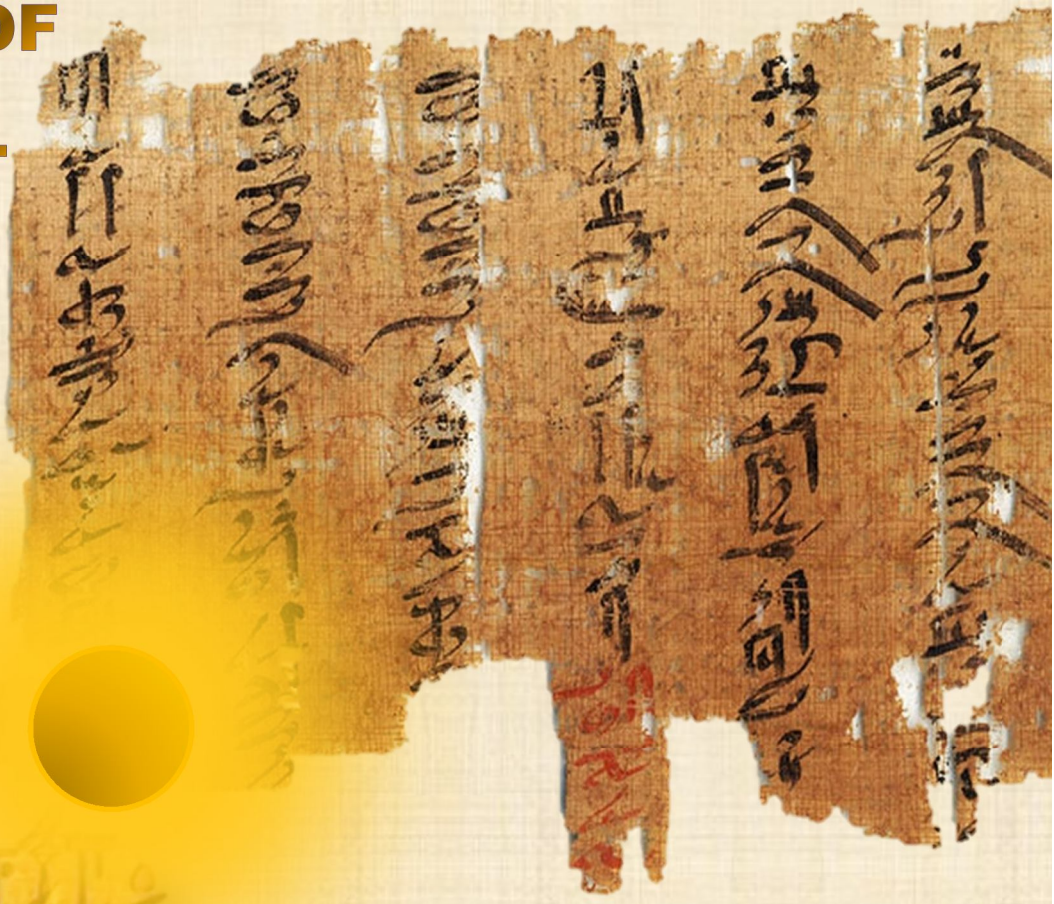

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Original article

Comparison between a Bare–Metal Stents and Drug Eluting Stents in Patients Undergoing Percutaneous Coronary Intervention

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ABSTRACT

Background: little researches have directly compared second-generation drug-eluting stents with each other or with bare-metal stents.

Aim of the work: To compare between outcomes after implantation of bare-metal stents [BMS] and two kinds of 2nd generation drug eluting stents [DES] [Zotarolimus-Eluting Stents [ZES], and A Everolimus-Eluting Stents [EES]] in patients undergoing percutaneous coronary intervention.

Patients and Methods: 160 Ischemic Heart Disease [IHD] patients undergoing PCI with 2nd generation DES implantation [80 ZES and 80 EES] were analyzed against 50 IHD patients undergoing PCI with BMS implantation. Each patients group received up to 6 [in BMS group] or 24 months [in ZES and EES groups] of clopidogrel therapy. The key efficacy endpoint was the 24 months major adverse cardiac event [MACE] [death, myocardial infarction, or target lesion revascularization], whereas stent thrombosis [ST] was the safety endpoint.

Results: The MACE rate was lowest in EES [19%; $\chi 2$= 7.661], highest in BMS [41.7%; $\chi 2$ =7.661], and intermediate in ZES [28.2%; $\chi 2$= 7.661] group with significant P Value =0.002.The 2-year incidence of ST in the EES group [1.3%] was similar to that in the ZES-S group [2.2%], whereas it was lower in contrast with BMS [7.5%] groups, with significant P value= 0.004].

Conclusion: DES have more efficacy and safety than BMS as EES have lowest MACE and ST rate while BMS have the highest rate and ZES have intermediate rate while the three stent groups have similar rate of mortality at 2 years follow up.

Keywords: Bare Metal; Zotarolimus; Eluting Stents; Major Adverse Cardiac Events; In Stent Restenosis; Stent Thrombosis.

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* Main subject and any subcategories have been classified according to research topic.

INTRODUCTION

Coronary artery disease is the most common cause of dying in cardiovascular disease. The rate of morbidity and mortality is high, the charges incurred for the treatment manner are also very high, thus giving a bad impact on the welfare and quality of life both in patients, families, and health costs borne by the state. The perfect management can limit the number of losses[1]. Percutaneous coronary intervention [PCI] additionally regarded as coronary angioplasty, is a nonsurgical method for treating obstructive coronary artery disease, consisting of unstable angina, acute myocardial infarction [MI], and Multivessel coronary artery disorder [CAD][2]. A coronary stent is a wire mesh tube-shaped device expanded along with balloon catheter when the balloon is inflated in the stenotic part of coronary arteries that furnish blood to the heart, to preserve the arteries open in the therapy of coronary artery disease. It is used in a PCI process in greater than 90% of PCI procedures. The stent may be included with a drug known as Drug Eluting Stents[3]. Coronary stents improved procedural safety and efficacy and eradicated the need for surgical standby, Arterial injury by stent produces neo intimal hyperplasia, that causes in-stent restenosis in 20-35% after implantation of bare-metal stents [BMS] whereas it's further decreased to 5%–10% after DES implantation[4]. Drug-eluting stents with managed regional release of anti-proliferative agents have persistently decreased the risk of repeat revascularization, as contrast with bare metal stents[5-6].

AIM OF THE WORK

The present research was designed to compare between outcomes after implantation of BMS and two types of 2nd generation drug eluting stents [DES] [Zotarolimus-Eluting Stents [ZES], and A Everolimus-Eluting Stents [EES] in patients undergoing percutaneous coronary intervention

PATIENTS AND METHODS

This prospective research included 210 IHD patients undergoing PCI who fulfill inclusion criteria at cardiology department of Al-Azhar Assiut University hospital Between October 2016 and January 2020. Patients with primary PCI [STEMI], implantable stent over saphenous vein graft, Left Main coronary artery lesion, Previous CABG, a BMS implantation While it's candidate for DES but shifted to BMS as it's waiting non-cardiac surgery all through the first year after stent implantation that causing interruption of dual anti platelet administration, Those with left ventricular failure [ejection fraction < 35%], known allergy to clopidogrel, planned surgery not beyond two years of PCI excepting that the dual antiplatelet therapy could be maintained during the peri surgical period, Active bleeding or previous stroke in the last 6 months, Life expectancy <2 years, Serum creatinine ≥2 mg/dl were excluded from the research where Diabetic patient, Small caliber vessel less than 2.5mm in diameter, Bifurcation and Ostial lesions were additionally excluded from BMS group[7-9]. Those patients were classified into three groups based on type of implanted stent: **Group I:** Included 50 patients subjected to a Bare Metal Stent implantation, **Group II:** Included 80 patients submitted to implantation of Zotarolimus–Eluting Stents [ZES] [second generation DES] and **Group III:** Included 80 patients subjected to implantation of Everolimus –Eluting Stents [EES] [second generation DES]. All subjects gave written informed consent. All study subjects underwent complete history taking, physical examination, routine lab investigations, resting ECG, echocardiography and Coronary angiography that indicate needing for PCI. All PCI procedures have been done based on cutting-edge standard guidelines of the interventional strategy, including glycoprotein IIb/IIIa inhibitors administration, pre- or post-dilation, or the use of intravascular imaging techniques, was left absolutely to the discretion of the operator, except for the stent use. Angiographic successes have been considered if residual stenosis <30% by visual analysis with Thrombolysis in Myocardial Infarction flow grade III.

Post PCI follow up: All study subjects were evaluated at 1, 6, 12, 18, & 24 months and when complaining via clinical visits and also telephone interview for assessment of stent outcome via follow up presence or absence of MACE [including re-hospitalization, death, nonfatal MI, In stent Restenosis [ISR] [Angiographic ISR is defined as the ≥ 50% narrowing of the diameter the of the implanted stent, or 5mm proximal or distal to its edges].[4] or target lesion revascularization [TLR]] and stent

thrombosis. On the elapsed time since stenting, stent thrombosis can be classified as: **Early** [0-30 days post stent implantation], **Late** [between 30 days and 1 year] and **Very late** [>1 year]. Often, early stent thrombosis is further subdivided into **acute** [<24 hours] and **sub-acute** [1-30 days] events. Based on evidence of stent thrombosis, It is categorized into **Definite:** presence of angiographic affirmation of stent thrombosis [thrombus inside the stent or 5mm segment proximal or distal to it] in association with at least one of the following standards inside 48-hour window: acute onset of resting symptoms of ischemia, new ECG changes that indicate acute ischemia or traditional rise and fall in cardiac biomarkers; or presence of pathological affirmation of stent thrombosis. **Probable** [unexplained dying inside 30 days after stent implantation or target vessel myocardial infarction without angiographic affirmation of stent thrombosis and in the absence of any-of-a-kind apparent cause, irrespective of the time after the index procedure]. **Possible** [any unexplained death after 30 days until the end of follow up]. [10]

During follow-up visits, patients had been examined, assessed for adverse cardiac events via History taking, Clinical Assessment which include general and local examination. Resting 12 lead Electrocardiography complete Tran Thoracic Echocardiographic examination and Coronary angiography if indicated with or without TLR. Adherence to dual antiplatlet therapy all through the path of the study [24 months] was once excessive and did no longer range throughout stent groups, whereas BMS-treated patients received a shorter [6 months] period of clopidogrel therapy. Secondary prevention medications, including angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, beta-blockers, and statins did not differ among the 3 groups during follow-up.

Statistical methods: Data have been collected and coded prior to analysis using the professional statistical Package for Social Science [SPSS 12]. All statistics had been expressed as mean and standard deviation [SD], Frequency tables for all categorical data. Student *t*-test [unpaired] after checking normality for all continuous data. Mann Whitney test was once used when the normality of the sample was violated. Chi-square test for all categorical data to test for the presence of an association. For small sample size fisher exact test was calculated. P value < 0.05 was once considered significant.

RESULTS

Demographic & clinical characteristics:

Three stent groups were well-matched with regard to demographic characteristics, risk factors, clinical presentation, angiographic and PCI characteristics with only two exceptions, diabetes being absent in BMS group and stent length that used to be smaller in group I [BMS] in contrast with other two stent groups [Tables 1,2]. Clinical follow-up all through 2 years was completed with overall 2, 2 and 1 patients being lost to follow-up through non-cardiac Cause [travelling and motor traffic accident [MTA]] in groups I, II and III, respectively.

Comparison between three groups regarding MACE cumulative rate:

Regarding MACE cumulative rate there was statistically difference among the three groups [highest [41.7%] in group I, intermediate [28.2%] in group II and lowest [19%] in group III, P value < 0.002]. As regard 2 years mortality and non-fatal MI rates among all stent groups there was no statistically difference [2.1% death for BMS group and similar 1.3% death for other two groups, P value = 0.920]. Whereas [8.3% non-fatal MI in group I, 3.8% in group II and 1.3% in group III, P value 0.137]. As regard ISR and TLR by PCI there was statistically significant difference among the three groups [highest [18.9 %] in group I, intermediate [10.9%] in group II and lowest [5.6%] in group III, P value = 0.004]. [Table 3] & [figure 1]

Comparison between three groups as regard stent thrombosis:

Regarding stent thrombosis cumulative rate that was [7.5%] in group I, [2.2%] in group II and [1.1%] in group III with significant P value 0.004 between BMS and DES while statistical difference between both DES [ZES and EES] was not significant. All ST was definite early and late [at 15, 25 days 2nd and 3rd month] in BMS group whereas late and very late [at 5 and 13 months] in ZES group and late [at 9th month] in EES group.

Table [1]: Shows Comparison between three groups as regard demographic, risk factors, clinical presentation, angiographic and PCI characteristics.

	Group-I		Group-II		Group-III		χ^2	P
	N	%	N	%	NO	%		
Male	34	68%	53	66.3%	56	70%	0.259	0.878
Female	16	32%	27	33.8%	24	30%		
DM	0	0%	39	48.8%	48	60%	48.504	<0.001
HTN	25	50%	41	51.3%	42	52.5%	0.079	0.961
Dyslipidemia	26	52%	38	47.5%	42	52.5%	0.461	0.794
Current smoking	23	46%	36	45%	38	47.5%	0.102	0.950
+ ve FH of IHD	17	34%	25	31.3%	24	30%	0.230	0.891
UA	22	44%	38	47.5%	43	53.8%	1.808	0.771
NSTEMI	19	38%	26	32.5%	22	27.5%		
SA	9	18%	16	20%	15	18.8%		
LAD	23	41.1%	39	41.1%	35	38.5%	0.622	0.961
LCX	15	26.8%	26	27.4%	29	31.9%		
RCA	18	32.1%	30	31.6%	27	29.7%		
Single vessel	44	88%	65	81.3%	69	86.3%	1.307	0.520
Two vessels	6	12%	16	18.8%	11	13.8%	1.307	0.520

DM [diabetes mellitus], HTN [hypertension], UA [unstable angina], NSTEMI [non-ST segment elevated myocardial infarction], SA [stable angina], LAD [left ant. descending], LCX [left circumflex] & RCA [right coronary artery].

Table [2]: shows comparison between the three groups as regard age, BMI and stents size.

	Group I		Group II		Group III		F	P Value
Age [years]	58.38	±4.94	56.95	±7.49	58.79	±6.06	1.759	0.175
BMI	26.18	±3.47	25.28	±2.76	26.30	±2.66	2.797	0.063
S. creatine [mg/dl]	0.98	±0.16	0.97	±0.16	0.97	±0.16	0.146	0.864
LVEF%	55.56	± 5.33	54.01	± 6.29	54.41	± 5.78	1.093	0.337
Stent width	3.06	± 0.27	3.14	±0.41	3.19	± 0.43	1.968	0.142
Stent Length	14.75	± 2.18	25.68	± 6.66	27.96	± 6.46	94.707	<0.001
Number of implanted stents	56		95		91			

BMI [body mass index], LV EF [left ventricular ejection fraction].

Table [3]: shows comparison between three groups as regard MACE cumulative rate.

	Group-I		Group-II		Group-III		χ2	P value
	N	%	N	%	N	%		
MACE cumulative rate	20	41.7%	22	28.2%	15	19%	7.661	0.002*
Rehospetalization. Rate of CA at follow up	20	41.7%	22	28.2%	15	19%	7.661	0.002*
Deth rate	1	2.1%	1	1.3%	1	1.3%	0.167	0.920
Non-fatal MI	4	8.3%	3	3.8%	1	1.3%	3.978	0.137
STEMI	5	10.4%	3	3.8%	2	2.5%	4.290	0.117
NSTEMI	2	4.2%	4	5.1%	2	2.5%	0.717	0.699
UA	8	16.7%	7	9%	4	5.1%	4.793	0.091
ISR and TLR by PCI	10	18.9%	10	10.9%	5	5.6%	6.227	0.004*
New vessel lesion while patent stents.	2	4.2%	3	3.9%	3	3.75%	0.033	0.983

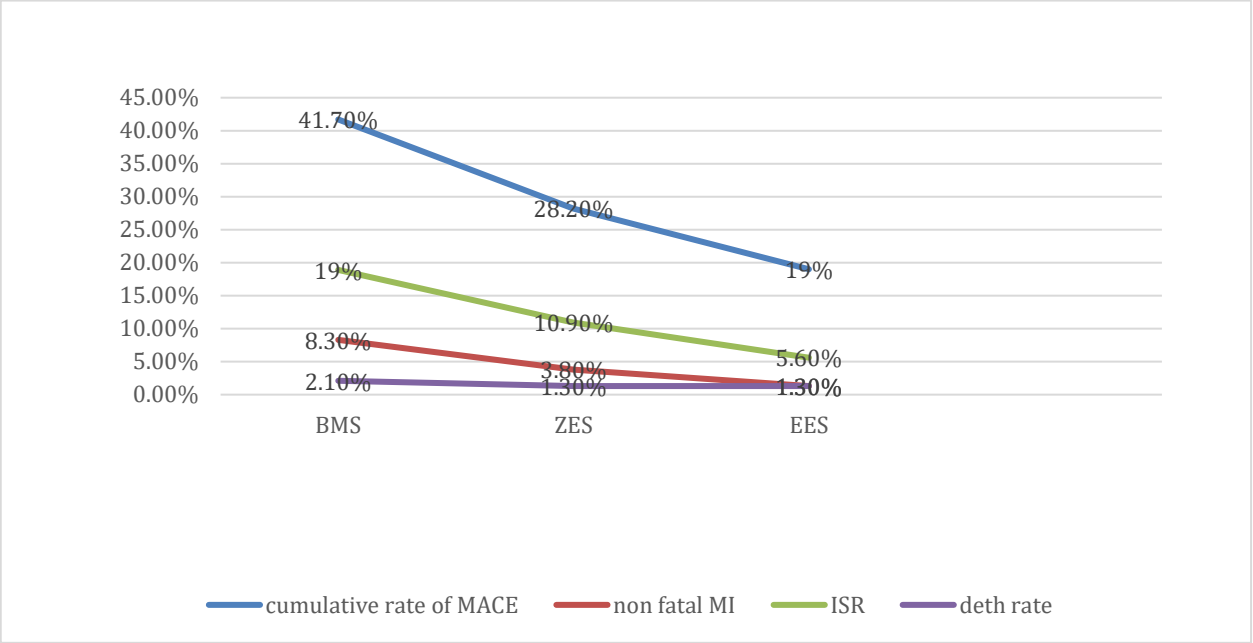

Figure [1]: shows comparison between the three groups a regarding MACE [MACE [Major Adverse Cardiac Events], non-fatal MI [non-fatal Myocardial infarction] ISR [in stent restenosis].

DISUCSSION

Result of this study groups had been matched in age, sex, BMI, hypertension, dyslipidemia, current smoking, family history of IHD, and serum creatinine This results show agreement with **Valgimigli et al.**[11] as regard group I [BMS group] not diabetic and have smaller stent length than group- II [ZES] and group-III [EES] with statistically significant difference, this our study differences were planned to match protocols of BMS or DES selection based on American College Cardiology/American Heart Association 2005 guideline] and Victorian Department of Human Services[7], Whilst some cardiologists argue that all subjects get hold of DES, it is additionally acceptable that shorter lesions [<15 mm] in wide vessels [>3 mm diameter] in non-diabetic patients may be used BMS. Diabetic patients, longer lesions [>15 mm], small diameter vessels [<3 mm] must be treated with DES, unless DAPT is contraindicated[8-9].

As regard cumulative MACE among patients groups showing statistically significant difference [highest [41.7%] for group I, intermediate [28.2%] for group II and lowest [19%] for group III, P value < 0.002] in agree with **Garg S., et al.**[12], **Garg P, et al.**[13] and **Bangalore, et al.**[14] and disagreement with **Di Mario et al.**[15] that compared long-term outcomes of STEMI patients subjected to primary angioplasty who used to be randomized to R-ZES [n=122] or everolimus eluting stent [EES, n=158] had similar five year TLF, cardiac dying, and MI in contrast with those receiving EES these findings have been confirmed by larger cohort of patients, demonstrating the long-term efficacy and safety of current-generation DES for management of patients with STEMI. The five-year cumulative incidence of target lesion revascularization [TLR, 2.5% versus 2.0%, adjusted p=0.766] and cardiac death/target vessel MI [5.1% versus 9.1%, adjusted p=0.123].

The MACE incidence appears to be high even in the best results group that was due to increased number of Rehospitalization and coronary angiography during follow up that some of which were done when the patient complaining of recurrent attack of chest pain in absence of new ECG or Echocardiographic ischemic changes related to target vessel and show patent stents.

As regard the two-years mortality and non-fatal MI rates among all stent groups there was no statistically difference [2.1% death for BMS group and similar 1.3% death for other two groups, P value = 0.920]. Whereas [8.3% non-fatal MI in group I, 3.8% in group II and 1.3% in group III, P value 0.137]. This results show agreement with **Bangalore et al.**[14], **Valgimigli et al.**[11], **and Chen et al.**[16] that showing no mortality rate and non-fatal MI differences between the subjected groups in

various situation. While disagreement with **Mauri et al.**[17] that show off that DES was associated with lower mortality, myo-cardial infarction, and target vessel revascularization contrasted with BMS treatment in similar subjects in a matched groups and also in disagreement with **Garg S, et al.**[12] and **Garg P, et al.**[13] who concluded that there was significant decline in rates of death, AMI and repeat revascularization among DES treated subjects contrasted to BMS treated subjects.

As regard ISR and TLR difference among the subjects' group, there was statistically significant [highest [18.9 %] for group I, intermediate [10.9%] for group II and lowest [5.6%] for group III, P value = 0.004]. in agreement with **Valgimigli et al.**[11] and disagreement with **Di Mario et al.**[15] that show similar frequency of ISR and TVR between ZES and EES group where the five-year cumulative frequency of target lesion revascularization [TLR, 2.5% versus 2.0%, adjusted p=0.766].Our findings need to be interpreted as confirmatory of preceding observations in terms of both cumulative TVR rates and distribution pattern of events over time [18-20].

As regard cumulative rate of stent thrombosis was 7.5% in group I, 2.2% in group II and 1.1% in group III with significant P value 0.004 between BMS and DES whereas no statistically significant difference among both DES [ZES and EES].this results in agreement with **Di Mario et al.**[15] that show five-years cumulative frequencies of stent thrombosis was 0.8% for R-ZES patients versus 1.3% for EES patients [adjusted p=0.868].

In our study we found that all of ST were definite, with early & late [at 15, 25 days 2nd and 3rd month] in BMS group [I], late and very late [at 5 and 13 month] in ZES group [II] while it late at 9th month in EES group [III].The particularly higher risk of very late ST with the second-generation DES tested in the cutting edge learn about no longer new and is steady with many previous observations [20-21]. This finding reinforces the idea that DES safety is particularly heterogeneous all through DES types. In particular, we even determined an elevated safety profile for EES, with admiration to particular or in all possibility ST, compared with BMS. In this regard, the examination [Evaluation of the Xience-V stent in Acute Myocardial Infarction] trial was the first rather sized study of second-generation DES and BMS and reported significantly decrease rates of ST with EES than with BMS at one-year follow-up [22]. Therefore, our data, although preliminary, suggest that stent safety may also additionally no longer be always disconnected from efficacy, which has most important scientific and pathophysio-logical implications.

Study limitations: This study included small number of patients. Also, that study didn't include the severe and complex diseased coronary arteries [left main coronary artery, chronic total occlusion, bifurcation lesions, and SYNTAX score], the clinical variables were not involved [e.g., left ventricular ejection fraction, STEMI and primary PCI], and a different operator included as MACE that may be operator dependent. Further, the open label layout can also have added the viable for bias.

Conclusion: DES have more safety and efficacy than BMS. Our findings showed that DES and BMS have the equal mortality rate. Whereas EES have lowest rate of MACE, ST and ISR while BMS have the highest rate and ZES have intermediate rate. Prolonged use of dual antiplatelet therapy is indicated to decrease stent thrombosis incidence especially in DES.

Financial and Non-Financial Relationships and Activities of Interest

None

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