Comparison of Limus- Eluting stents vs. Paclitaxel Eluting Stents in Diabetic & Non-Diabetic Patients: Short Term Results

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Abstract

Background: Diabetes mellitus has been regarded as an independent risk factor for the progression of coronary artery disease. Even with DES, however patients with diabetes had increased rates of restenosis compared with patients who did not have diabetes. This study aimed to examine individual safety and efficacy endpoints. Methods: A total of 287 patients having chronic stable coronary artery disease or ACS were enrolled. To compare PES and LES in the Diabetic and Non-diabetic population, we separated patients in two groups. Results: In present study, there were 287 patients undergoing PTCA in whom 371 lesions were treated using either PES or LES. Out of 371, 169 lesions were treated with PES and 202 were treated with LES. In those treated with PES, 51 were diabetic while those treated with LES, 66 were diabetic. In present study, among all patients cardiac death, MI, ST, ISR and TLR noted in 2.95%, 4.14%, 2.95%, 5.91% and 4.14% patients respectively in those treated with PES. While those treated with LES cardiac death, MI, ST, ISR and TLR noted in 0.99%, 1.48%, 1.48%, 0.49% and 0.99% patients respectively. ISR and overall MACE observed were statistically significant between two groups. Conclusion: Although diabetes remains a significant predictor of adverse clinical outcomes after percutaneous coronary intervention with DES; in present study there was no statistically significant difference for occurrence of MACE among diabetic and nondiabetic patients. The principle end points of interest occurred with statistically significant lower incidence in patients treated with LES as compared to PES.

Keywords: Diabetes; Non-Diabetes; Limus Eluting Stent; Paclitaxel Eluting Stent.

Introduction

Diabetes mellitus is chronic disease which is frequently associated with symptomatic coronary artery disease necessitating percutaneous coronary intervention (PCI) [1]. But, still it is matter of debate about the choice of drug eluting stent in diabetic patients.

People with diabetes mellitus are prone to coronary heart disease, stroke and peripheral vascular disease. Diabetes mellitus has been regarded as an independent risk factor for the progression of coronary artery disease. Several studies have reported that diabetes increased the risk of cardiovascular mortality in both men and women. Moreover, diabetes has been considered to be a

predictor of poor prognosis after coronary artery bypass surgery and percutaneous coronary angioplasty. Long term clinical and angiographic outcomes after PCI with BMS have been shown to be worse in patients with diabetes than in those without diabetes.

With the introduction of DES, the angiographic rates of restenosis have been reduced dramatically in several studies. Even with DES, however, patients with diabetes had increased rates of restenosis and late loss index compared with patients who did not have diabetes [2-4]. Paclitaxel-eluting stents are inferior to limus-eluting stents is well-known in most patients with CAD [5-6]. But on long term large randomized trials have reported that, paclitaxel-eluting stents have safety and efficacy same as limus eluting stents [6].

This study was conducted to evaluate safety and efficacy of Drug Eluting Stents of Limus Eluting stent as compared to Paclitaxel Eluting stent and to study whether an interaction exists between treatment with DES (PES vs. LES) and presence of Diabetes Mellitus.

Method

From October 2014 to June 2015, we recruited 287 patients with chronic stable coronary artery disease or ACS at our institute. The patients were divided into two groups. Patients aged 18 years or older undergoing percutaneous coronary interventions were considered for enrolment and separated patients in diabetic and Non-Diabetic group.

Exclusion Criteria

- 1. Contraindications or expected non-adherence to dual antiplatelet drugs in the 12 months after the procedure.
- 2. Inability or refusal to comply with follow-up procedure.
- 3. Participation in other coronary-device trials; and inability to provide informed consent.
- 4. Patient is receiving chronic anticoagulation therapy.
- 5. Patient has a known hypersensitivity or contraindication to aspirin, paclitaxel, either heparin or bivalirudin, clopidogrel or ticlopidine, everolimus, cobalt, chromium, nickel, tungsten, acrylic and fluoropolymers or contrast sensitivity that cannot be adequately pre-medicated.
- 6. Elective surgery is planned within the first 9 months & 14 days after the procedure that will require discontinuing either aspirin or clopidogrel.
- Patient has a platelet count <100,000 cells/mm3 or >700,000 cells/mm3, a WBC of <3,000 cells/ mm3, or documented or suspected liver disease (including laboratory evidence of hepatitis) or malignancy.
- 8. Patient has a history of bleeding diathesis or coagulopathy or will refuse blood transfusions.
- 9. A target lesion in saphenous vein graft.
- 10. Known immunologic or autoimmune disease or prescribed immunosuppressive medication.

Device Description

In LES, we have included everolimus eluting stents

(Xience V, Xience-Prime) and Zotarolimus eluting stents (endeavour sprint, resolute integrity stents).

Everolimus-eluting stents (Xience V) were available in diameters of 2.25 mm, 2.50 mm, 2.75 mm, 3.00 mm, 3.50 mm and 4.00 mm, and in lengths of 8 mm, 12 mm, 15 mm, 18 mm, 23 mm and 28 mm.

Everolimus-eluting stents (Xience prime) were available in diameters of 2.50 mm, 2.75 mm, 3 mm, 3.50 mm and 4 mm and in lengths of 33 mm, 38 mm.

Zotarolimus-eluting stents (Endeavor sprint) were available in diameters of 2.50 mm, 2.75 mm and in lengths of 8 mm, 12 mm, 14 mm, 18 mm, 24 mm, 30 mm and in diameters of 3 mm, 3.5 mm, 4 mm and in lengths of 9 mm, 12 mm, 15 mm, 18 mm, 24 mm and 30 mm.

Paclitaxel-eluting stents (Taxus) were available in diameters of 2.25 mm, 2.50 mm, 3.00 mm, 3.5 mm, and 4 mm, and in lengths of 8 mm, 12 mm, 16 mm, 20 mm, 24 mm, 28 mm 32 mm, 38 mm.

Procedure

Percutaneous coronary intervention was done according to standard techniques through femoral or radial approach. Technical details, such as the decision to stent without balloon pre-dilatation, use of adjunctive techniques and decision to post dilate the stent, were at the discretion of the operator. Quantitative coronary angiography analysis for the baseline data was done.

All patients not on dual antiplatelet drugs were given aspirin (300 mg) and clopidogrel (600 mg) before the procedure. An initial bolus of unfractionated heparin (70–100 IU/kg) was given to all patients, and additional boluses were given to achieve and maintain an activated clotting time of more than 250 s. The use of bivaluridin or low molecular-weight heparin was not allowed. The use of glycoprotein IIb/IIIa antagonists was at the discretion of the operator. A 12-lead electrocardiograph was done before and after the procedure; before discharge.

Selected Post procedural measurements of cardiac biomarkers were obtained only in patients with complications, such as side-branch closure, residual dissection, or no reflow or when patients had chest pain or electrocardiographic changes after the procedure.

At the time of discharge all patients were treated with 2 antiplatelet agents (i.e., acetylsalicylic acid with clopidogrel or prasugrel or ticagrelor). Ecosprin 150 mg once a day was used with clopidogrel 75mg

twice a day regimen and dose of ecosprin was reduced to 75mg once a day if given along with ticagrelor. Dose of ticagrelor used was 90 mg twice a day and dose of prasugrel used was 10 mg once a day.

Follow-Up

Clinical follow-up was performed at 6 & 12 months hospital visit. Relevant data were collected and entered into a computerized database. Post procedure symptomatic patients were requested for follow-up angiogram.

Statistical Analysis

All statistical analyses were performed with commercially available software (SPSS version 20.0, SPSS, Inc., Chicago, Illinois). Continuous variables are expressed as mean ±SD and categorical data as percentages.

Study End Points

The primary end point was target vessel failure or in stent restenosis. Target-vessel failure was defined as a composite of cardiac death, target-vessel myocardial infarction. Secondary end point was the ischemia driven target lesion revascularization, target vessel revascularization, composite of cardiac death, target vessel myocardial infarction, Noncardiac death, myocardial infarction, and Academic Research Consortium-defined stent thrombosis.9 The procedural end points were the rate of technical success and the rate of clinical procedural success.

Results

Two hundred eighty seven patients underwent PTCA during period from October 2014 to June 2015 in whom 371 lesions were treated using either Paclitaxel Eluting Stents or Limus Eluting Stents. Out of 371 lesions, 169 lesions were treated with PES and 202 lesions were treated with LES. In those treated with PES, 51 were diabetic while those treated with LES 66 were diabetic.

Table. 1 represents the Demographic characteristic of the patients treated with PES and LES. Mean age in patients treated with PES was 56.98±10.15 and that of patients with LES was 56.85±10. In patients treated with PES 159 (94.08%) were male while patients treated with LES 165 (81.68%) were male in patients treated with LES. Among the Patients treated

with PES 67 (39.64%) were hypertensive, 82 (48.52%) had dyslipidemia, 44 (26.03%) were smokers and 1 had CKD while patients treated with LES 80 (39.60%) were hypertensive, 66 (32.67%) had dyslipidemia, 48 (23.76%) were smokers and 1 had CKD. On coronary angiography, patients who were treated with PES, SVD was found in 80 (47.33%) patients, 64 (37.86%) patients had DVD, 25 (14.79%) patients had TVD while Patients treated with LES, 107 (52.97%) patients had SVD, 76 (37.62%) patients had DVD, 19 (9.40%) patients had TVD.

Total 100 (59.17%) patients had STEMI, 17 (10.05%) had NSTEMI, 18(10.69%) had UA and 34 (20.11%) had CSA in patients treated with PES. while 111 (54.95%) patients had STEMI, 26 (12.87%) had NSTEMI, 15 (7.42%) had UA and 50 (24.75%) had CSA in Patients treated with LES. The mean LVEF in PES group is 41.96±12.14 and in LES group is 43.46±9.81.

Patients treated with PES, LAD were stented in 84 (49.70%) patients, LCX were stented in 25 (14.79%) patients, RCA was stented in 59 (34.91%) patients, LMCA was stented in 1 (0.59%) patients while Patients treated with LES, LAD were stented in 116 (57.42%) patients, LCX were stented in 38 (18.81%) patients, RCA were stented in 42 (20.79%) patients, LMCA were stented in 6 (2.97%) patients.

Table 2. shows the Lesion characteristics of patients. In patients treated with PES, 72 (42.60%) patients had type A, 74 (43.78%) patients had type B1, 10 (5.91%) patients had type B2, 13 (7.69%) patients had type C lesion while Patients treated with LES, 112 (55.44%) patients had type A, 67 (33.16) patients had type B1, 19 (9.40%) patients had type B2, 4 (1.98%) patients had type C lesion.

Quantitative Coronary Angiography Parameters are presented in Table.3 In PES group, QCA parameters like mean Pre procedural RVD, MLD, DS was 2.97± 0.25mm, 0.26±0.15mm and 90.22±8.08% respectively while mean post procedural MLD, DS, acute gain was2.95±0.27, mm, 0.83±0.70% and 2.67±0.31 mm respectively. Patients treated with LES; QCA parameters were mean Pre procedural RVD, MLD, DS were 3.04±0.34mm, 0.34±0.31mm and 89.25±5.66% respectively while mean post procedural MLD, DS, acute gain was 4.51±19.20mm, 0.93±0.73% and 2.71±0.32 mm respectively

In PES group, tirofiban was used in 73 (43.19%) patients while in LES group, tirofiban was used in 56 (27.72%) patients. Patients treated with PES mean stent diameter was 2.98±0.30 mm and mean stent length was 27.94±13.20mm while Patients treated with LES mean stent diameter was 2.99±0.30mm and mean stent length was 27.43±13.07mm.

Table 1: Comparison of study

Variables	Lesions Treated with PES			Lesions Treated with LES			P Value
	DM (N=51)	NON-DM (N=118)	Total (N=169)	DM (N=66)	NON-DM (N=136)	Total (N=202)	between PES & LES
Age	56.88±9.94	55.85±10.64	56.36±10.29	57.78±8.43	55.26±10.37	56.52±9.4	0.8758
Male	47(92.2%)	112(94.9%)	159(94.08%)	47 (71.2%)	118(86.8%)	165(81.68%)	0.0006
Female	04(7.8%)	06(5.1%)	10(5.91%)	19(28.8%)	18 (13.2%)	37(18.31)	0.0006
HTN	28 (54.9%)	39(33.1%)	67(39.64%)	42(63.6%)	38(27.9%)	80(39.60%)	0.9215
Smoking	06(11.8%)	38(32.2%)	44(26.03%)	19(28.8%)	29(21.3%)	48(23.76%)	0.7008
CKD	00	01	01(0.59%)	01(1.5%)	00	01(0.04%)	0.5584
STEMI	29 (56.9%)	71 (60.2%)	100(59.1%)	28 (42.4%)	83 (61%)	111(54.95%)	0.4763
NSTEMI	04(7.8%)	13(11%)	17(10.05%)	07(10.6%)	19 (14%)	26(12.87%)	0.4966
UA	07(13.7%)	11(9.3%)	18(10.69%)	10 (15.2%)	05 (3.7%)	15(7.42%)	0.3662
CSA	11(21.6%)	23(19.5%)	34(20.11%)	21 (31.8%)	29 (21.3%)	50(24.75%)	0.3484
LVEF	42.60±14.63	41.32±9.66	41.96±12.14	43.89±10.22	43.03±9.40	43.46±9.81	0.1889
SVD	19(37.3%)	61(51.7%)	80(47.33%)	31(47.0%)	76(55.9%)	107(52.97%)	0.6013
DVD	22(43.1%)	42(35.6%)	64(37.86%)	29(43.9%)	47(34.6%)	76(37.62%)	0.9531
TVD	10(19.6%)	15(12.7%)	25(14.79%)	06(9.1%)	13(9.6%)	19(9.40%)	0.1507

Table 2: Lesion characteristics (ACC/AHA lesion type)

Variables	Lesion Treated with PES (N=169)			Lesion Treated with LES (N=202)		
	DM (N=51)	NON-DM (N=118)		DM (N=66)	NON-DM (N=136)	
А	18(35.3%)	54(45.8)	72(42.60%)	35(53%)	77(56.6%)	112(55.44%)
B1	22(43.13%)	52(44.1%)	74(43.78%)	23(34.8%)	44(32.35%)	67(33.16%)
B2 C	04(7.8%) 07(13.7%)	06(5.1%) 06(5.1%)	10(5.91%) 13(7.69%)	07(10.6%) 01(1.5%)	12(8.8%) 03(2.2%)	19(9.40%) 4(1.98%)

Table 3: Quantitative Coronary Angiography Parameters

OCA Parameters	Lesi	on Treated with PF	ES.	Les	ions Treated with	LES
	DM (N=51)	NON-DM (N=118)	significance	DM (N=66)	NON-DM (N=136)	significance
PRE RVD	2.90±0.20	2.99±0.27	0.018	3.04±0.32	3.04±0.34	0.975
PRE MLD	0.25±0.15	0.27±0.15	0.48	0.36±0.49	0.32 ± 0.17	0.546
PRE DS	90.36±5.71	86.53±18.33	0.14	89.7±6.89	87.53±12.13	0.251
POST MLD	2.88±0.20	2.97±0.29	0.014	3.01±0.32	5.24±23.39	0.269
POST DS	0.89 ± 0.69	0.81 ± 0.71	0.492	0.87±0.65	0.93±0.77	0.554
POST ACUTE GAIN	2.62±0.23	2.98±0.34	0.151	2.74±0.36	2.69±0.35	0.382

Table 4: Clinical outcome of patients treated with PES

Clinical Outcome	Lesions Treated with PES			
	DM (N=51)	NON-DM (N=118)	P Value	
Cardiac Death	02(3.9%)	03(2.5%)	0.97	
MI	01(2%)	06(5.1%)	0.62	
Stent Thrombosis	01(2.1%)	04(3.4%)	0.99	
ISR	05(9.8%)	05(4.2%)	0.34	
TLR	04(7.8%)	03(2.5%)	0.28	
Non Cardiac Death	00	02(1.7%)		

Table 5: Clinical outcome of patients treated with LES

Clinical Outcome	Lesions Treated with LES			
	DM (N=51)	NON-DM (N=118)	P Value	
Cardiac Death	02(3%)	00	0.20	
MI	02(3%)	01(0.7%)	0.53	
Stent Thrombosis	02(3%)	01(0.7%)	0.53	
ISR	01(1.5%)	00	0.71	
TLR	02(3%)	00	0.20	
Non Cardiac Death	03(4.5%)	05(3.7%)		

Table 6: Clinical Outcome Between PES & LES

Clinical outcome	Lesions treated with PES (N=169)	Lesions treated with LES (N=202)	P Value	P Value
Cardiac Death	05(2.95%)	02(0.99%)	0.32	0.006
MI	07(4.14%)	03(1.48%)	0.22	
Stent Thrombosis	05(2.95%)	03(1.48%)	0.55	
ISR	10(5.91%)	01(0.49%)	0.007	
TLR	07(4.14%)	02(0.99%)	0.11	

Out of total 371 stents were used, Taxus, Xience V, Xience prime, Endeavor sprint and Resolute integrity were used in 169 (45.55%), 146 (39.35%), 39 (10.51%), 13 (3.50%) and 4 (1.07%) patients respectively.

Table. 4 presents the clinical outcomes of the patients treated with PES at follow up. Among Major Adverse Cardiac Events in patients treated with PES; cardiac death, MI, ST, ISR, TLR noted in 05(2.95%), 07(4.14%), 05(2.95%), 10(5.91%) and 07(4.14%) patients respectively while in patients treated with LES; cardiac death, MI, ST, ISR, TLR noted in 02 (0.99%), 03 (1.48%), 03 (1.48%), 01 (0.49%) and 02 (0.99%)patients respectively which were found to be statistically significant. (P value 0.006) showed in Table 5.

Table 6 shows the clinical outcome between PES and LES. MACE rate was statistically significant lower in LES group (P value 0.006) as compared to PES group.

Composite Major Adverse Cardiac Events including cardiac death, MI, ST, TLR in patients treated with PES noted in 24 patients while in patients treated with LES, they were noted in 10 patients which was statistically significant. (P value 0.008).

Discussion

In present study, there were 287 patients who underwent PTCA in whom 371 lesions were treated using either Paclitaxel Eluting Stents or Limus Eluting Stents. Out of 371, 169 lesions were treated with PES and 202 were treated with LES. In those treated with PES, 51 were diabetic while those treated

Table 7: Comparison of study

Present Study **Parameters** Kereiakes et al Kaul et al PES LES (EES+ZES) Diabetics PES LES(EES) **PES** LES(EES) Diabetics Diabetics Diabetics Diabetics Diabetics Clinical Outcome Cardiac Death 3.9% 3% 0.9% 0.3% 1.8% 1.7% MI 2% 3% 3.7% 2.6% 3.2% 1.2% ST2.1% 3% 1.33% 0.53% 2.1% 0.4%ISR 9.8% 1.5% TLR 7.8% 3% 4.7% 4.2% 3.4% 1.2%

with LES 66 were diabetic.

Study by stone et al [7] reported that the rates of stent thrombosis and myocardial infarction are reduced with everolimus-eluting stents but, composite outcomes among patients with diabetes were not significantly improved with everolimus-eluting stents, as compared to paclitaxel-eluting stents.

The results from the meta-analysis from three similarly performed, prospective randomized trials with 3-year follow-up after the index coronary implantation of EES compared with PES demonstrate significantly reduced rates of all-cause mortality, MI, ischemia-driven TLR, stent thrombosis, TLF, target vessel failure, and MACE with EES [8].

Study by Onuma et. al [9] reported that largest cohort with the longest follow-up of patients treated with the EES, compared with the PES reduces the rates of MI and TLR, with lower overall TVF and MACE. MACE rates were 7.1% in EES vs. 12.3% in PES, without late increase in TLR. Our study found greater MACE rate in PES group as compared to LES group. Our study found higher ISR rate in patients with PES (9.8%) than in patients treated with LES (1.5%).

In present study, mean age in patients treated with PES was 56.98±10.15 and mean age in patients treated with LES was 56.85±10. the study conducted in diabetic population by Kaul et al [10] reported mean age in patients treated with PES was 58.40±9.21 and mean age in patients treated with LES was 58.34±9.12. Another study by Kereiakes et al [11] reported among diabetic mean age in patients treated with PES was 63.48±10.15 and mean age in patients

treated with LES was 63.06±10.05. The results of both studies by Kaul et al and Kereiakes et al are comparable to the our study. The comparision is given in Table 1.

Kaul et al [10] reported cardiac death, MI, ST, TLR in 1.8%, 3.2%, 2.1% and 3.4% patients respectively in PES group and cardiac death, MI, ST, TLR in 1.7%, 1.2%, 0.4% and 1.2% patients respectively in EES group.

Kereiakes et al [11] reported among diabetic cardiac death, MI, ST, TLR in 0.3%, 3.7%, 1.33% and 4.7% patients respectively in PES group and cardiac death, MI, ST, TLR in 0.9%, 2.6%, 0.53% and 4.2% patients respectively in EES group.

In present study among all patients cardiac death, MI, ST, ISR and TLR noted in 2.95%, 4.14%, 2.95%, 5.91% and 4.14% patients respectively in those treated with PES. While those treated with LES cardiac death, MI, ST, ISR and TLR noted in 0.99%, 1.48%, 1.48%, 0.49% and 0.99% patients respectively. ISR and overall MACE observed were statistically significant between two groups. Thus patients treated with LES found to have lower incidence of MACE as compared to those treated with PES.

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Conflicting Interest: None declared

Conclusion

The principal end points of interest including the safety parameters, principally cardiac death, myocardial infarction and stent thrombosis and efficacy parameters; including ischemia driven TLR and MACE; a composite measure of safety and efficacy consisting of cardiac death, MI, ischemia driven TLR occurred with statistically significant lower incidence in patients treated with LES as compared to PES.

Thus in patients undergoing percutaneous intervention treatment with LES provides considerable benefit over PES with respect to freedom from death, MI, stent thrombosis, recurrent ischemia and TLR procedures. Our study highlights

that short term ISR are statistically significantly lower with LES group compared to PES group. the present study reported higher incidence of adverse clinical outcome especially ISR and TLR as comparable to above mentioned studies. Although diabetes remains a significant predictor of adverse clinical outcomes after percutaneous coronary intervention with DES; in present study there was no statistically significant difference for occurrence of MACE among diabetic and non-diabetic patients.

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