Original Research Article

Percutaneous Coronary Intervention withEverolimus-Eluting Versus Sirolimus-Eluting Stents inDiabetic Patientspresented with Acute Coronary Syndromes:A short-termcomparative clinical outcome study

ABSTRACT:

Background:The use of drug-eluting stents (DES) resulted in innovative progress in the field of interventional Cardiology. Nowadays, the most common indication for coronary stenting is acute coronary syndromes (ACS) due to the better clinical consequences of PCI compared with conservative management. However, in diabetic patients, there is a large debate in the literature regarding the selection of an optimal drug-eluting stent.

Aim:This work aimed to compare short term clinical outcome post-Percutaneous Coronary intervention with Everolimus-eluting stents (EES) versus Sirolimus-eluting stents (SES) in diabetic patients presented with acute coronary syndromes.

Methods:The present study was carried out on 120 diabetic patients presented with acute coronary syndromes (Non-STEMI, Unstable angina) and divided into 2 groups; group 1 included patients treated with PCI with Everolimus eluting stenting(EES), and group 2 included patients treated with PCI with Sirolimus-eluting stenting (SES).

***Results*:**After 6 months of follow-up, the percentages of treated patients who were complicated with sudden cardiac death, congestive heart failure, and planned further PCIwere 5%, 6.7%, and 6.7%,respectively in group 1, and were 3.3%, 8.3%, and 10% respectively in group 2.While no acute coronary syndrome or repeated coronary angiography was reported in both groups. In the current study,there was no statistically significant difference between the EES group and the SES group in diabetic patients either during implantation or during6months follow up (P-value >0.05).

Conclusion: In this current study, both EES and SES are comparable to each other regarding the treatment of acute coronary syndrome in diabetic patients.

Abbreviations:PCI: Percutaneous Coronary Intervention, **DES:** drug-eluting stenting, **EES:**Everolimus eluting stenting, **SES:**Sirolimus-eluting stenting, **PES:**paclitaxel-eluting stents **LL:**In-stent late loss, **BMS:** Bare-metal stents, **CABG:** Coronary artery bypass grafting, **ACS:** Acute coronary syndrome, **MACE:** Major adverse cardiac effect.

Keywords: Everolimus eluting stenting, Sirolimus-eluting stenting, diabeticpatients.

1.INTRODUCTION

Nowadays, the use of Drug-eluting stents (DES) in interventional cardiology makes a great revolution in this field. Therefore, the development of newer stents is continuous as well as many trials are performed to improve the efficacy and safety of different stents[(1)]The Sirolimus-eluting stents (SES) is the most widely used first-generation DES due to fewer post stenting complications such as chest pain and dyspnea, cardiac death, fatal or non-fatal myocardial infarction[(2-6)].Everolimus eluting stents (EES) are second-generation DES where the stent platformis used accompanied by a polymer coating containing Everolimus[(1)].Another difference between the SES and the EES rather than the polymer coating which contains Sirolimus or Everolimus, respectively, is that the stent and the polymer platform thickness of the EES are considered the thinnest among the all available DES[(7)].

Diabetes Mellitus (DM) which is a common metabolic disease all over the world is usually accompanied by symptomatic coronary artery disease requiring treatment[(8)].All the published randomized clinical trials performed on diabetic patients to compare the medium- to long-term outcome of PCI to that of CABG in multivessel coronary disease revealed the superiority of the surgical option particularly concerning the new revascularizations and death. However, the decision of DES for multivessel disease in diabetic patients is still controversial[(9)].

In fact, the Sirolimus, Everolimus, or Zotarolimus-eluting stents whichare known as Limus-eluting stents are superior to paclitaxel-eluting stents (PES) in the treatment of coronary artery disease. However, this is not typical in diabetic patients as it was proven from large randomized trials, meta-analyses, pooled analyses, and registries where the diabetics were represented as small subgroups that both stents have the same efficacy and safety in the diabetics[(10-12)].

However, despite the preceding trials, they are not sufficient to evaluate the clinical consequences of stenting in diabetic patients. However, to the best of our knowledge, no comparison has been carried out between the SES and the EES. Therefore, we carried out a prospective, randomized trial to compare SES with ESE in diabetic patients.

2.PATIENTS AND METHODS:

This study was carried out on 120 diabetic patients presented with acute coronary syndromes (Non-STEMI, Unstable angina) during the period from October 2018 to September 2020at the Cardiology department at Tanta University Hospital.This study was encompassed, two groups; group 1, included patients treated with PCI with Everolimus eluting stenting (EES), and group 2, included patients treated with PCI with Sirolimus-eluting stenting (SES).Clinical follow-up post-PCI for both groups for 6months' duration was done for major adverse cardiac events (MACE) including sudden cardiac death, acute coronary syndromes, Congestive heart failure, coronary angiography, and revascularization (PCI or CABG).

All the patients in the study were subjected to the following:full history taking, full clinical examination, standard supine 12- lead ECG, laboratory investigations,Transthoracic Echocardiography (TTE), diagnostic coronary angiography, PCI with stenting with either EES or SES, and clinical follow up for 6months' post PCI.In the present study, all the included patients were with eligible coronary anatomy for PCI and successfully deployed either Sirolimus or Everolimus stents.

Statistical analysis of the data. Data were collected, coded, revised, and entered into the Statistical Package for Social Science (Rstudio) version 2.3.2. The data were presented as numbers and percentages for the qualitative data, mean, standard deviations, and ranges for the quantitative data with parametric distribution and median with interquartile range (IQR) for the quantitative data with the non-parametric distribution.

3.RESULTS

Demographic personal dataare demonstrated in Table 1**.** There was a statistically significant difference between both groups only as regards BMI (P-value=0.003).

Table 2 illustrates all studied risk factors.There was a statistically significant difference between the two groupsonly as regards the LDL level.All patients in both groups are overweight.

No statistically significant difference was recorded between both groups as regards the laboratory results. (Table 3)

Regarding Echocardiographic findings,the mean ejection fraction (EF) was 59.4% ± 11.3 while in group 2 was 58.2±12.2.Concerning the ***clinical indication***, there was no statistical difference between both groups. (Table 4)

Table 5 demonstrated ***the angiographic variables*** in both studied groups. Single vessel disease was more common in both groups than the Multivessel disease. The total stent length

was shorter in group 1 compared to group 2 (37.1 ± 24.4 vs 41.5 ± 26.2 with a p-value of 0.28). Also, the lesion length was shorter in group 1 than group 2(35.3 ± 23.3 vs38.9 ± 24.7 with a p-value of 0.98). Theprior ballon inflation was more common in both groups than the direct stenting with no recorded statistical difference. The inflation pressure of stents was higher in group 1 than group 2(13.2±7.1 ATMOS vs 12.±1.4 ATMOS). In group 1, we put 1 stent in 50 cases, 2 stents in 6 patients,and 3 stents in 4 cases, while in group 2, we put 1 stent in 46 patients and 2 stents in 8 cases, and 3 stents in 6 cases.Stenosis was 70% in 46 patients (76.7%) in group 1 while it was 70 % in 42 patients (70 %) in group 2. Stenosis was 90 % in group 1 in 14 patients (23.3%) and in group 2 in 18 patients (30%).Regarding the complexity of the lesions,in both groups, the simple lesions were more common than the tortuous lesions.

In the present study, radial access was used more than femoral access in both groups with no access complications.The left anterior descending artery (LAD) was the commestsite of stents in both groups.(Table 6)

All medications are demonstrated in Table 7. There was no statistically significant difference between both groups as regardsthe medication of DM,in-hospital medications,or the discharge medications (P-value > 0.05 for all).

After following up in 6 months regarding MACE,**3** patients had ***sudden cardiac death*** in group 1 (5%)while 2 patients had sudden cardiac death in group 2 (3.3%).No ***acute coronary syndrome*** was encountered or coronary angiography was done in the follow-up period. 4 patients had ***congestive heart failure*** symptoms in group 1 (6.7%)while 5 patients had congestive heart failure symptoms in group 2 (8.3).***Planned further PCI*** for other lesions in the multivessel disease cases was done in 4 cases in group 1 (6.7). And in 6 cases in group 2 (10%). No patients got needed ***repeated coronary angiography*** with further revascularization in both groups.All reported MACE after 6 months follow up are simplified in figure 1.

4.DISCUSSION

Diabetes mellitus is considered a significant independent risk factor resulting in adverse consequences of PCI irrespective of the type of used stent[13]. The incidence of coronary artery disease is increased from 2-4 times with diabetes Mellitus[14].Unfortunately, diabetic patients had the worst major adverse cardiac effect (MACE) after PCI. So, the complete management, including medications plus interventional and surgical procedures, of diabetic patients with CAD is not a simple matter.Despite the reduction of repeated revascularization need after using DES in diabetics, the risk of MACE with diabetic patients undergoing PCI remains high[15-17].

The SPIRIT II (Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients With de novo Native Coronary Artery Lesions)[18] and SPIRIT III[19] randomized trials proved the superiority of EES compared to Paclitaxel-eluting stents (PES) concerning the in-stent late loss (LL) within 180 days.In addition, the SPIRIT IV[20] and COMPARE (Comparison of the Everolimus eluting Xience V stent with the paclitaxel-eluting TaxusLiberte stent in all-comers: A randomized open-label trial)[21] trials reported that regarding the reduction in the clinical consequences, the EES is more preferred than the PES which represented by 38% and 31%, respectively.

Regarding the cardiovascular complications, the ZEST (Comparison of the Efficacy and Safety of Zotarolimus-Eluting Stent with Sirolimus-Eluting and Paclitaxel-Eluting Stent for Coronary Lesions)[22] and SORTOUT III (Danish Organization for Randomized Trials with Clinical Outcome)[23] randomized trials compared between both SES and Zotarolimus-eluting stents ZES. Both trials found rates of MACE were lower in cases treated with SES than cases treated with ZES.

In the present study, we tried to compare short term clinical outcome post-Percutaneous Coronary intervention with Everolimus-eluting stents (EES) versus Sirolimus-eluting stents (SES) in diabetic patients presented with acute coronary syndromes.

Regarding the baseline characters, our study showed no significant differences between the two groups as regards age and gender. Also; the possible risk factors of the two studied groups showed no statistical difference between the two groups as regard hypertension, smoking, and positive family history of coronary artery disease. It also showed no statistical difference between the two groups as regard left ventricular ejection fraction.

On the other hand, the EXCELLENT registry[13] reported that hypertension and smoking were higher in the EES group. In addition, the mean age was higher in the non-diabetic patients treated with EES, and although the patients of this group had a lower rate of preceding MI, they reported a higher rate of congestive heart failure.

As for the clinical indications (unstable angina, and Non-ST-elevation myocardial infarction), there was no statistically significant difference between the two studied groups where the p-value was 0.16. Besides, the angiographic variables, with the exclusion of previously stented or CABG, our study showed no statistical difference between the two groups, although, the single vessels disease was relatively higher in the Everolimus groupthan the Sirolimusgroup (73.3% vs 63.3% with p-value 0.33) and the Multivessel Disease was relatively lower in group 1 than group 2 (26.7% vs 36.7% with p-value 0.33), and the total stent length was shorter in the Everolimus group compared to the Sirolimus group (37.1 ± 24.4

vs 41.5 ± 26.2 with p-value 0.28). This was in agreement with ESSENCE-DIABETES randomized trial conducted by Kim et al.,[24] who reported that both Everolimus andSirolimus did not differ notably regarding angiographic outcomes. In addition, a sub-study of the SORT OUT IV trial[25] compared between EES and SES in diabetic or non-diabetic patients. The study reported the insignificant difference between both stents as regards the clinical outcomes. Also, Kufner et al.,[26] in the ISAR-TEST-4 trial found similar outcomes between the EES and the SES in diabetics. However, the results of these previous studies ignored the EES problem of attenuated efficacy.However, this was in disagreement with the EXCELLENT registry[13]which reported the significance of the clinical and angiographic factors in PCI patients. However, the diabetic patients in the EXCELLENT registry were represented 36.8% of all cases, but in our study, all the patients were diabetics[13].

Concerning the discharge medications, all patients in both groups were maintained on aspirin, statin, and antidiabetic drugs and our statistical results were mostly comparable between the two groups.

In the present study, it was notable that there was no significant difference between the EES and the SES regarding the risk of device-specific clinical events (i.e., TLR, TVR, and ST). This result was similar to a pooled analysis of RESOLUTE programs[27] that concerning the risk of device-specific clinical events found no statistically significant difference between both stents either in diabetic or nondiabetic patients. However, in real life, the incidence of these events remains statistically high and the risk ratio did not show any improvement as the TLR, and TVR relative risk remains between 1.2-1.5 and of ST remains approximately 1,5[27].

Future Prospective Although, it is well noticed that there is a great revolution in the field of interventional cardiology, however, this study showed that the treatment of coronary artery disease with PCI in diabetic patients remains to represent some sort of difficulty. We hope further development of the technology of the used stents may overcome these problems.We recommended that future trials should solve the debate regarding the strict glycemic control would obviously result in advances in the PCI outcome in diabetic patients or not.

The limitation of this study was that all the included patients were had DM type 2, while patients with insulin-dependent DM were not involved in the current study. Another concern was that the late stent problems such as stent thrombosis and stent restenosis which is considered the main reflection of DES safety were not captured in the present study.As the main concern of our study was restricted to clinical follow-up within 6 months.Also, the angiographic follow-up was not mandatory in this study, despite the high rate of silent

ischemia in diabetics. Besides, the rates of post-DES events were lower than expected, accordingly, we cannot exclude that the study was underpowered.Also, all the used Everolimus stents in our study were Xience Expedition. This was due to the unavailability of other brands of Everolimus stents. Finally, the study did not include a nondiabetic control group. So, the statistical significance of the study may be negatively affected.

5.CONCLUSION

In this study, we found that using either Everolimus or Sirolimus-eluting stents in patients with diabetes mellitus presented by unstable angina/Non-STEMI were with no statistically significant difference either duringthe in-hospital stay or in 6months follow up. Both EES and SES are comparable to each other regarding the treatment of acute coronary syndrome in diabetic patients.

6.REFERENCES

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Tables and figures:

Table 1: Demographic and personal data of the studied groups:

	Group 1 EES (n = 60)		Group 2 SES (n = 60)		Student t. test	
					t- sig	p-value
Age Mean ± SD	64.3 ± 9.7		63.9 ± 9.6		0.184	0.85
Gender	**No.**	**%**	**No.**	**%**	**Chi-square test**	
Male	48	80%	48	80%	X^2	**p-value**
Female	12	20%	12	20%	0	1
BMI Mean ± SD	25.6 ± 0.4		26.2 ± 0.7		**Student t. test**	
					t-sig	**p-value**
					-3.04	0.003*
Duration of DM Mean± SD	10.6 ± 2.1		10.9 ± 1.9		Student t. test	
					t-value	p-value
					0.4	0.69

Table 2: Risk factors distribution of the studied groups:

	Group 1 EES (n = 60)		Group 2 SES (n = 60)		Chi-square test	
Smoking	**No.**	**(%)**	**No.**	**(%)**	X^2	**p-value**
Current Smoking	42	70%	46	76.7%	0.526	0.47
Non smoking	18	30%	14	23.3%		
Hypertension					X^2	**p-value**
Present	46	76.7%	41	68.1%	0.669	0.41
No hypertension	14	23.3%	19	31.7%		
Family history						
Present	7	11.7%	11	18.3%	0.588	0.44
Absent	53	88.3%	49	81.7%		
LDL	112 ± 2.7		117 ± 1.1		**Student t. test**	

Mean ± SD					t-sig	p-value
					-13.7	<0.0001*
Over weight(>25)	60	100%	60	100%	1	

Table 3: Laboratory results of the studied groups

	Group 1 EES (n =60) Mean ± SD		Group 2 SES (n =60) Mean ± SD		Student t. test	
					t-sig	P-value
Creatinine	1.1 ± 0.1		1.2 ± 0.2		1.06	0.113
HbA1c	8.4 ± 1.6		8.6 ± 1.4		-2.014	0.05
	Group 1 EES (n = 60)		**Group 2 SES (n = 60)**		**Chi-square test**	
Troponin & CKMB	**No.**	**(%)**	**No.**	**(%)**	**X^2**	**p-value**
Positive	14	23.3%	22	36.7%	1.94	0.16
Negative	46	76.7%	38	63.3%		

Table 4: Distribution of the studied groups according to clinical manifestation

EF	Group 1 (EES) (n =60)		Group 2 (SES) (n =60)		Student t. test	P-value
Mean ± SD	59.4 ± 11.3%		58.2 ± 12.2%		1.013	0.31
	No.	**(%)**	**No.**	**(%)**	**Chi-square test**	**P-value**
Unstable angina	46	76.7%	38	63.3%	1.94	0.16
Non-ST-elevation myocardial infraction	14	23.3%	22	36.7%		

Table 5: Comparison between the studied groups according to angiographic variables, prior balloon, direct stent, number of stents.

	Group 1 EES n =60		Group 2 SES n =60		Chi-square test	
	No.	**(%)**	**No.**	**(%)**	**X^2**	**P-value**
Single vessel disease	44	73.3%	38	63.3%	0.96	0.33
Multi vessel disease	16	26.7%	22	36.7%		
stent length Mean± SD	37.1 ± 24.4		41.5 ± 26.2		**Student t. test**	
					t-value	**p-value**
					-1.08	0.28
Lesion length Mean ± SD	35.3 ± 23.3		38.9 ± 24.7		0.03	0.98
Prior balloon inflation	**No.**	**%**	**No.**	**%**	**Chi-square test**	
	53	88.3%	52	86.7%	**X^2**	**p-value**
Direct stenting	7	11.7%	8	13.3%	0	1
Inflation pressure of stent Mean ± SD	13.2 ± 7.1		12.9 ± 1.4		**Student t. test**	
					t-sig	**p-value**
					-0.16	0.87
Number of stent	**No.**	**%**	**No.**	**%**	**Chi-square test/fisher test**	
1 stent	50	83.3%	46	76.7%	**X^2**	**p-value**
2 stent	6	10%	8	13.3%	0.85	0.65
3 stent	4	6.7%	6	10%		
Percent of stenosis	**No.**	**%**	**No.**	**%**	**Chi-square test**	
70%	46	76.7%	42	70%	**X^2**	**P-value**
90%	14	23.3%	18	30%	0.38	0.54
Complexity	**No.**	**%**	**No.**	**%**	**Chi-square test**	
Tortuous	19	31.7%	12	20%	**X^2**	**P-value**
Simple	41	68.3%	48	80%	1.57	0.21

Table 6: Comparison between the studied groups according to access and site of stents

		Group 1 EES n =60		Group 2 SES n =60		Chi-square test/ Fisher test	
		No.	(%)	No.	(%)	X^2	P-value
Access							
Femoral access		50	83.3%	47	78.3%	0.215	0.64
Radial access		10	16.7%	13	21.7%		
Site of stents							
1 stent	**LAD**	23	38.3%	19	76.7%	0.53	0.77
	RCA	18	30%	16	26.7%		
	LCX	9	15%	11	18.3%		
2 stents	**LAD**	4	6.7%	4	6.7%	-	0.37
	LAD D1	2	3.3%	1	1.7%		
	RCA	0	0%	3	5%		
3 stents	**LAD**	4	6.7%	6	10%	-	1
	RCA	4	6.7%	6	10%		
	LCX	4	6.7%	6	10%		

LAD: Left anterior descending artery.
RCA: Right coronary artery.
LCX: Left circumflex artery.
D1: Ostial diagonal.

Table 7: Comparison between the studied groups according to medications.

	Group 1 EES n =60		Group 2 SES n =60		Chi-square test/ Fisher test	
	No.	(%)	No.	(%)	X^2	P-value
Diabetic Medications						
Oral medication	48	80%	53	88.3%	1.005	0.32
Insulin	12	20%	7	11.7%		
Inhospital Medications						
Enoxaparin	48	80%	46	76.7%	0.83	
Unfractionated heparin	12	12%	14	23.3%		
Glycoprotein IIB IIIA	0	0%	0	0%		
Discharge medications						
Aspirin	60	100%	60	100%	0	1
Clopidogrel	53	88.3%	48	80%	1.0005	0.31
Ticagrelor	7	11.7%	12	20%	1.0005	0.31
β- blockers	37	61.7%	40	66.7%	0.145	0.7
ACE inhibitor	42	70%	47	78.3%	0.696	0.41
Angiotensin receptor antagonist	14	23.3%	9	15%	0.861	0.35
Statins	60	100%	60	100%	0	1
Anti-hyperglycemic agents	60	100%	60	100%	0	1

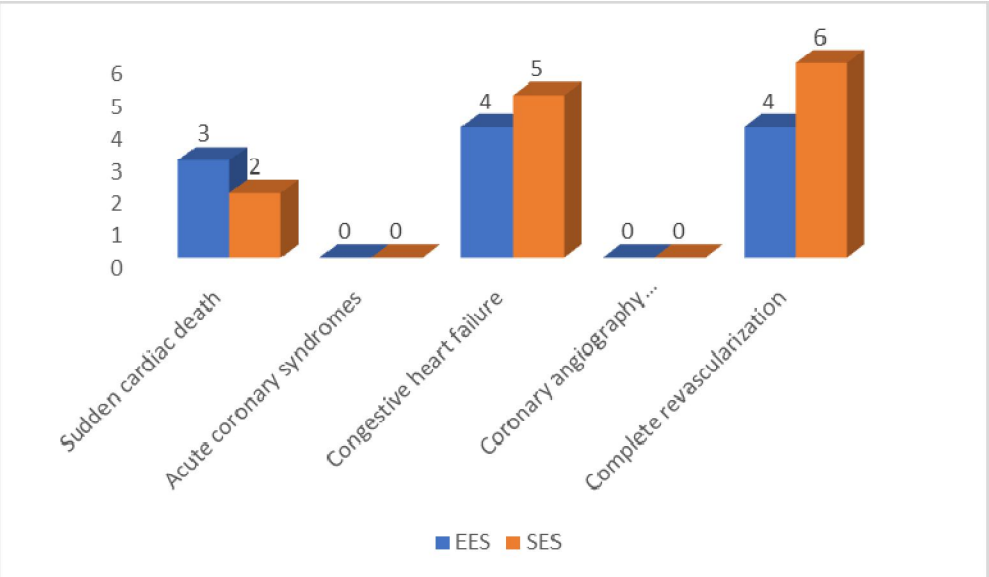

Figure 1. MACE after 6 months Follow up