Drug Eluting Stents Versus Coronary Artery Bypass Graft Surgery for Patients with Diabetes Mellitus and Multivessel Disease

Abstract

Background: through coronary artery bypass graft (CABG) or through utilization of percutaneous coronary intervention (PCI) with stenting, coronary revascularization can be achieved. Diabetics represents a particularly challenging group for both treatments. This work aimed to estimate clinical outcome in diabetic individuals with multiple vessels disease (MVD) who had either PCI or CABG over 30 days.

Methods: This prospective research was conducted on 200 diabetic individuals with MVD established as severe stenosis. Into 2 equal groups, individuals were divided: Group (A) [underwent CABG], and group (B) [performed Drug Eluting Stents (DES) PCI]. All individuals underwent full history taking, resting twelve-leads electrocardiogram, complete clinical examination, transthoracic echocardiography, coronary angiographic, SYNTAX score and Euro score.

Results: In CABG group, age, statin, ACE-I/ARB, β- -blocker and dual antiplatelet therapy was significantly higher than PCI group. PCI group had significantly higher PCI, MI and repeated revascularization than the group of CABG. In PCI group, stroke and MI, death, myocardial infarction (MI), were significantly higher than in group of CABGS.

Conclusions: DES have developed for the coronary artery disease (CAD) treatment and are increasingly being utilized for complex CAD treatment, such as multivessel or left main CAD. PCI is preferred over CABG in high surgical risk individuals due to the shorter hospital stay, faster time of recovery, and potentially decreased stroke rate.

Keywords: Diabetes Mellitus, DES, CABG Surgery, PCI, Multivessel Disease

Introduction:

A major risk factor for coronary artery disease (CAD) is diabetes Mellitus (DM), increasing the susceptibility of individuals to develop rapid progressing ,diffuse and complex CAD [1].

Around 25% of individuals with severe CAD who receive percutaneous coronary intervention (PCI) or coronary artery bypass graft surgery (CABG) have DM. In these individuals, DM is significantly related with ischemic complications and recurrent revascularization procedures increased rate [2].

Advancements of cardiovascular surgical procedures and PCI have continued to enhance approaches of coronary revascularization over the last decade. Despite there is indication suppose that these developments have enhanced the consequences for diabetics, this group continues to have much significant worse outcomes than the general population, and the ideal approach of revascularization for diabetic patients still unclear [3].

The ideal revascularization technique for diabetics with multivessel CAD is a point of argument. For Coronary revascularization, CABG or PCI with stenting might be used. Diabetics are a particularly challenging subgroup for both treatments. While in individuals with single vessel CAD, PCI is more often utilised, the ideal method for multivessel disease individuals is still undetermined, as found in patients received PCI with stenting a greater rate of revascularization repeat at 1-year follow-up [4].

In 1960, CABG surgery utilizing the internal mammary artery (IMA) was performed on humans for the first time [5]. Following that, in 1977, Transluminal balloon angioplasty PCI was established as an substitute approach of revascularization of coronary artery [6].

Over the years, surgical and percutaneous revascularization techniques have evolved to complement medical advances in order to provide stable coronary artery disease (SCAD) and acute coronary syndromes (ACS) efficient therapy, and hence overall quality of life (QoL) and angina improving [7]. In multi vessel disease (MVD) and left main disease (LMD)

individuals, coronary revascularization has been proven to provide survival prolongation [7]. Historically, CABG was regarded as the ideal option for MVD and LMD treatment. Although significant PCI advancements have resulted in procedural success rates increase and decreased in-stent thrombosis, in-stent restenosis, target lesion revascularization (TLR), and procedural myocardial infarction (MI) rates. As a result, PCI has established itself as a valuable option to CABG in MVD and LMD treatment [8].

Numerous randomised controlled studies of moderate size comparing the two treatment options for treatment of MVD and LMD found that in CABG there is an elevated risk of periprocedural cerebrovascular and cardiac events while in patients received PCI found a higher long-term requirement for revascularization repeat [9].

This work aimed to estimate clinical outcome in diabetics with multiple vessels disease who had either CABG or PCI over 30 days.

Patients and Methods:

This prospective research was applied on 200 diabetic individuals with MVD determined as in at least 2 major epicardial coronary arteries with severe stenosis (≥ 70%), CABG with complete revascularization in one section and angiographic characteristics adaptable to both PCI/DES and patients received CABG or those received PCI with DES implantation.

The research was carried out at The Department of Cardiology, Tanta University Hospitals and National Heart Institute through 6 months from April 2020 to September 2020. A written informed consent was obtained from all the patients included and the study was approved by the Ethics Committee of Faculty of Medicine, Tanta University.

Exclusion criteria included severe left main coronary artery disease CAD (degree of stenosis ≥50%), MI within 24 hours of the index procedure, revascularization within 1 year before the index procedure, prior PCI, and prior cardiac surgery (valve surgery or CABG), as these

patients are in cardiogenic shock or preferentially treated with PCI; and unstable hemodynamic.

Included individuals were classified into two equal number groups: group (A) [underwent CABG] and Group (B) [underwent PCI with DES].

All patients were undergoing full history taking, complete clinical examination, resting twelve-leads electrocardiogram, transthoracic echocardiography and coronary angiographic.

PCI: include number and types of stents and number of vessels which had been stented.

CABG: include types of grafts (venous or arterial) and numbers of grafts used.

Syntax score: SYNTAX is a sponsored-manufacturer study with a primary endpoint of mortality. Patients were randomized to drug-eluting stent (the Boston Scientific TAXUS paclitaxel-eluting stent) or CABG surgery. It discovered that both techniques are comparable for hard endpoints (MI and death). While individuals getting PCI need more repeat revascularization (so PCI was not shown to be non-inferior in the primary endpoint analysis), those receiving CABG had considerably higher strokes either pre- or postoperatively. The SYNTAX risk score is being examined as a means of determining individuals with MVD who may benefit from PCI vs those for whom CABG still the favored technique.

Euro score: Euro SCORE (European System for Cardiac Operative Risk Evaluation) is a model of risk that enables the mortality risk following a cardiac surgery to be determined. The model takes 17 pieces of information on the patient, the planned procedure and the heart's state, and then uses logistic regression to compute the mortality risk.

All-cause death was the primary outcome, while stroke, MI and repeat revascularization tabulated separately were the secondary outcomes.

Statistical analysis

SPSS v25 was used to do statistical analysis (IBM Inc., Chicago, IL, USA). Numbers and percentages expressed qualitative data, while quantitative data were expressed as ranges,

mean and standard deviations when they are of parametric distribution. When the predicted count in any cell was less than 5, To compare the two groups with qualitative data, the Chi-square and/or Fisher exact tests were used. To compare two independent groups with quantitative data and a parametric distribution, the independent t-test was utilised. A two-tailed P value < 0.05 was considered significant.

Results:

Age was significantly higher in CABG than PCI groups, there was insignificant different between CABG and PCI groups regarding Sex, smoker, DM, oral medications, require insulin, HTN, hypercholesterolemia and clinical presentation. **Table 1**

HbA1c (NGSP), % was significantly lower in CABG compared to PCI group while LVEF, %, triglyceride, mg/dL and HDL-C, mg/dL. was significantly higher in PCI compared to CABG groups. Diseased vessel, SYNTAX score, Euro SCORE, follow-up (30 days), total cholesterol, mg/dL, LDL-C, mg/dL, were insignificantly different between both groups. **Table 2**.

Death, MI, stroke and MI were significantly higher in PCI than CABG groups, there was insignificant different between two groups regarding repeat revascularization, Stroke, death from cardiac cause and death from any cause. **Table 3**

β- -blocker, Statin, ACE-I/ARB and Dual antiplatelet therapy were significantly higher in CABG compared to PCI group, while PCI was significantly lower in CABG compared to PCI group. CABG and Aspirin were insignificantly different between both groups regarding. **Table 4**

Repeated revascularization and MI were significantly higher in PCI compared to CABG group. Stroke and death were insignificant different between groups. **Table 5**

Discussion

In 1960 CABG surgery was first performed in humans utilising the IMA [5]. Following that, in 1977, PCI with transluminal balloon angioplasty was established as an alternate approach of coronary artery revascularization [6]. Over the years, developments in medicinal therapy have complemented percutaneous and surgical revascularization approaches to give effective treatment of SCAD and ACS, therefore improving angina and QoL [7].

Coronary revascularization has been shown to prolong survival in patients with MVD and LMS [7].

Our study found no statistically significant difference in primary, secondary, or 30-day follow-up outcomes between the two groups (PCI and CABG).

Lee et al. [10]. conducted a meta-analysis where CABG and PCI were compared in individuals with MVD and DM, revealed no significant difference in MI or mortality was seen between both treatments.

Large-scale randomized research by Farkouh et al. [11]. in contrast, with 1900 individuals with MVD and DM revealed that MI and mortality rates were superior with the CABG method than PCI.

A comparison of CABG with PCI in individuals with multivessel CAD was conducted by Several researches Foundation and Serruys [12, 13] . previous researches revealed equivalent long-term clinical results in individuals who received CABG or PCI, however the PCI group experienced a much greater risk of subsequent revascularization.

Regarding the bare metal stent era, for multivessel CAD, CABG and balloon angioplasty or bare metal stent PCI revealed comparable mortality rates and a complex of mortality or MI; CABG, on the other hand, indicated a survival benefit in diabetic patients or older [14].

In the DES era, the advantage of CABG over DES- PCI was demonstrated by Farkouh et al. [11] FREEDOM trial, which was due to lowering MI and mortality rates in diabetics individuals and multivessel CAD.

Similarly Chang et al. [15] reported significant decrease in the long-term risk of mortality in nondiabetics had multivessel CAD in CABG when compared to DES- PCI. Thus, despite advancements in stent technology during the DES era, CABG revealed improvement of mortality clinical outcomes in multivessel CAD individuals when compared to PCI, [11] [15, 16] corroborating the hypothesis that in most of patients had multivessel CAD, CABG is the preferred technique.

Thus, despite advancements in stent technique throughout the DES era, CABG revealed superior in mortality clinical outcomes in multivessel CAD patients when compared to PCI, corroborating the hypothesis that CABG is the optimal method for the majority of multivessel CAD individuals.

CARDia was the first research to assess CAD therapy in a subset of diabetics, demonstrating the CABG superiority with combined incidence of stroke, MI, death, and revascularization recurrence of 19.3 % in the PCI and 11.3 % in the CABG at one year [17].

In 1,900 complex MVD and diabetic individuals, research of FREEDOM corroborated these results, relatively revealing 5-year worse rates of a compound outcome in the PCI group, which involved mortality from any cause, nonfatal stroke or nonfatal MI (26.6 % vs. 18.7 % in the CABG group). However, the fact that a stroke higher incidence in CABG cohort and significantly higher MI and mortality rate in the PCI cohort, resulting in the conclusion that the diabetics would advantage most from CABG rather than PCI [11].

The VA-CARDS investigators then published the findings of a randomised study comparing treatments entirely with surgery and drug-eluting stents in high-complex CAD and diabetic individuals. Despite being underpowered, CABG had a 5% all-cause mortality rate, whereas

PCI had a 21% rate after follow-up of 2 years, while CABG has a risk of nonfatal MI 15% and PCI has 6.2% [18]..

Sipahi and colleagues [19]. also conducted another review involving 6 randomised trials involved 6,055 individuals, and their meta-analysis demonstrating that in CABG, a significant decrease in MI, overall mortality, and repeat revascularization compared to PCI. Unlike earlier trials, these researchers discovered that with CABG there is a tendency toward more strokes, although it was not statistically significant. The findings demonstrate the superiority of CABG as the therapeutic choice for MVD patients when compared to PCI, owing to the undeniable decrease in MIs, long-term mortality and revascularizations recurrence, regardless of diabetes.

Fanari and colleagues [20], just published an interesting study in which they conducted a meta-analysis of 6 RCTs and examined the findings of the trials' follow-up over long-term.

Although there is a possibility of bias due to the inclusion of an additional RCT with unprotected LM disease [21], this research revealed that, when compared to CABG, PCI was related with no difference in MI or mortality, an increased incidence rate of target vessel revascularization and a significantly lower stroke incidence rate at 1 year. However, at five years, PCI was associated with higher mortality and MI elevated incidence rate. Increased mortality was seen in the PCI group mostly among diabetics [20].

In a meta-regression study utilising incidence rates as a dependent variable to investigate an choice of revascularization and baseline clinical features (i.e., age, gender, ejection fraction , DM and previous MI) interaction, D'Ascenzo et al. [22] found that when compared to CABG , PCI significantly reduces the incidence of stroke especially in women , the risk of revascularization is raised with PCI, in women particularly and those who are diabetics.

A point of interest has been reported on CAD in systematic reviews and meta-analyses with regard to the outcome’s comparison in revascularization either incomplete or complete. Large

preliminary research involving 35 investigations and 89,883 individuals established that in CABG complete revascularization is more frequently accomplished than with PCI and that incomplete revascularization is related to repeated revascularization and elevated mortality regardless of the treatment method [23].

An individual patient-level data of the randomized BEST and SYNTAX trials in a pooled research, Cavalcante et al [24] analysed the 1,166 patients outcomes, 577 of whom received PCI and 589 received CABG., CABG was observed to have a significantly decreased risk of MI, cardiac mortality, and all-cause revascularization in MVD patients involving the proximal left anterior descending artery (LAD) when compared to DES-PCI . Despite, there was no difference in stroke and all-cause mortality across the groups were regarded, CABG was preferred in the combined outcome of significant unfavourable cerebrovascular and cardiovascular events (i.e., revascularization, stroke, MI, or all-cause mortality,). The authors found that CABG was better than drug-eluting stents due to cardiovascular events and survival in MVD cases after a follow-up period of 5-year.

Additionally, a systematic review published by Head et al. [25] and published in The Lancet found that the long-term safety results for revascularization techniques with unprotected LM disease were equivalent. 11 randomised studies involving 11,518 individuals. On the other hand, the advantage of CABG was restricted to diabetic patients and those with complex MVD, as evidenced by.

Finally, our research has limitations because it was conducted at a single centre with a small sample size.

Conclusions:

CABG and DES -PCI are both effective in the CAD treatment, whether multivessel or left main. DES have revolutionised the treatment of CAD and are increasingly being used to treat complex CAD involving multivessel or the left main. Patients with a high surgical risk prefer

PCI over CABG because it results in a faster recovery time, a shorter hospital stay, and maybe a lower stroke incidence rate.

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Conflict of Interest: Nil

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Table 1: Comparison between CABG and PCI regarding age, sex, BMI, smoker, DM, oral medications, require insulin, HTN, hypercholesterolemia and clinical presentation

		CABG (n= 100)	PCI (n= 100)	P-value
Age(years)		46.56 ± 6.97	42.52 ± 10.73	**0.002***
Sex	**Female**	40 (40.0%)	48 (48.0%)	0.254
	Male	60 (60.0%)	52 (52.0%)	
BMI		28.75 ± 2.90	29.46 ± 2.91	0.089
Smoker		16 (16.0%)	8 (8.0%)	0.082
DM		100 (100.0%)	100 (100.0%)	NA
Oral medications		56 (56.0%)	68 (68.0%)	0.080
Require insulin		44 (44.0%)	32 (32.0%)	0.080
HTN		68 (68.0%)	64 (64.0%)	0.550
Hypercholesterolemia		60 (60.0%)	64 (64.0%)	0.560
Clinical presentation	**Stable angina**	40(40%)	44(44%)	0.567
	Acute coronary syndrome	64(64%)	60(60%)	0.560
	Prior myocardial infarction	40(40%)	36(36%)	0.560
	Prior stroke	8(8%)	12(12%)	0.346
	Peripheral artery disease	20(20%)	16(16%)	0.462
	Chronic pulmonary disease	12(12%)	16(16%)	0.415
	Chronic kidney disease	8(8%)	12(12%)	0.346
	Left ventricular dysfunction	12(12%)	8(8%)	0.346

Data are presented as mean ± SD or frequency (%), BMI: Body mass index, HTN: hypertension, DM: diabetes mellitus, *: significant difference at $p<0.05$.

Table 2: Comparison between CABG and PCI regarding diseased vessel, SYNTAX score, Euro SCORE, follow-up (30 days), total cholesterol, mg/dL, LDL-C, mg/dL, HDL-C, mg/dL, triglyceride, mg/dL, HbA1c (NGSP), % and LVEF, %.

		CABG (n= 100)	PCI (n= 100)	P-value
Diseased vessel	**Proximal LAD disease**	60 (60.0%)	52 (52.0%)	0.254
	Left main disease	36 (36.0%)	40 (40.0%)	0.560
	Multivessel disease	64 (64.0%)	60 (60.0%)	0.560
SYNTAX score		29.80 ± 7.72	28.53 ± 6.26	0.205
Euro SCORE		7.58 ± 1.36	7.56 ± 1.40	0.886
Follow-up (30 days)		4.24 ± 1.72	4.30 ± 1.74	0.807
Total cholesterol, mg/dL		183.16 ± 38.42	179.83 ± 36.50	0.530
LDL-C, mg/dL		111.74 ± 23.74	106.74 ± 34.12	0.231
HDL-C, mg/dL		44.92 ± 11.50	46.44 ± 10.43	0.330
Triglyceride, mg/dL		134.02 ± 62.04	133.47 ± 54.48	0.947
HbA1c (NGSP), %		7.03 ± 1.36	7.99 ± 1.47	**< 0.001***
LVEF, %		64.17 ± 9.99	51.50 ± 16.87	**< 0.001***

Data are presented as mean ± SD or frequency (%), LAD: Left anterior descending artery. *: significant difference at $p < 0.05$.

Table 3: Comparison between CABG and PCI regarding primary outcome and secondary outcome.

	CABG (n= 100)	PCI (n= 100)	P-value
Death, MI, Stroke	28(28%)	44(44%)	**0.018***
Secondary outcome			
Death from any cause	20(20%)	24(24%)	0.495
Death from cardiac cause	12(12%)	16(16%)	0.415
Myocardial infarction	4(4%)	12(12%)	**0.037***
Stroke	8(8%)	4(4%)	0.234
Repeat revascularization	28(28%)	28(28%)	1.000

Data are presented as mean ± SD or frequency (%), LAD: Left anterior descending artery. *: significant difference at $p < 0.05$.

Table 4: Comparison between CABG and PCI regarding medication and PCI and CABG

Medication	CABG (n= 100)	PCI (n= 100)	P-value
Aspirin	96(96%)	16(16%)	0.234
Dual antiplatelet therapy	96(96%)	16(16%)	**< 0.001***
Statin	68(68%)	24(24%)	**< 0.001***
ACE-I/ARB	52(52%)	24(24%)	**< 0.001***
β-blocker	56(56%)	28(28%)	**< 0.001***
PCI	8 (8.0%)	52 (52.0%)	**< 0.001***
CABG	16 (16.0%)	20 (20.0%)	0.462

Data are presented as frequency (%), PCI: percutaneous coronary intervention, CABG: coronary artery bypass grafting surgery, *: significant difference at p <0.05. ACE-I: angiotensin converting enzyme inhibitors, ARBs: angiotensin-receptor blockers

Table 5: Comparison between CABG and PCI regarding 30-days Outcome

30-days Outcome	CABG (n= 100)	PCI (n= 100)	P-value
MI	4(4%)	16(16%)	**0.005***
Repeated revascularization	4(4%)	12(12%)	**0.037***
Stroke	4(4%)	4(4%)	1.000
Death	8(8%)	16(16%)	0.082

Data are presented as frequency (%), *: significant difference at p <0.05.MI: myocardial infarction,