Benha Journal of Applied Sciences (BJAS) **print: ISSN 2356–9751**
Vol.(5) Issue(8) Part (1) (2020), (129-135) **online: ISSN 2356–976x**
http://bjas.journals.ekb.eg

Revascularization Approach in Diabetic Patients with Multivessel Disease or Left Main Coronary Artery Disease

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Abstract

Diabetes melitus is a critical risk factor for coronry artery disease, this is making patients have diffuse, severe and rapidly progressive CAD and is significant accompanied with high rates of ischemic complications and recurrent revascularizton in these patients. The best method of revascularizton for diabetic patients with multivesel CAD is a topic of uncertainty. to evaluate clinical outcome in diabetic patients with three vessel disease who had either PCI (group A) compared to CABG (group B). This study included 120 diabetic patients who were admitted to cardiology department in Benha University hospitals & National heart institute, Egypt during the period from November 2018 to Novrmber 2019 who had three vessel disease or left main coronary artery disease during diagnostic coronary angiography and were divided in to two groups: Group A: underwent PCI with DES and Group B: underwent CABG. Five percent of patients complicated by death after 12 months (2% versus 8% in group A, B respectively, P=0.452), 4% complicated by non-fatal MI after 12 months (0.00% versus 6% in group A, B respectively, P=0.442), 6% was complicated by non-fatal stroke after 12 months (0.00% versus 16% in group A, B respectively, P=0.008). higher incidence of Non-fatal stroke was found in patients who were assigned to CABG compared to PCI. However, the need for revascularization was significantly higher in PCI compared to CABG after 6 months of follow up.

Keywords: Revascularization Strategy, Diabetic patients, Three vessel disease left main coronary artery disease.

1. Introduction

Diabetes Melitus (DM) is a critical risk factor for coronary artery disease (CAD) , making patients prone to diffuse, severe and rapidly progressive CAD [1]**.** About 25% of patients with significant CAD who undergone percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) have DM, and DM is significant with by higher rates of ischemic complications and recurrent revascularizton in these patients [2].

With the more aging population and an increased prevalence of both diabetes and CAD, the number of intervenional coronry and peripheral arterial procedures has surprisingly increased [3]. Morbidity and mortality related to CAD present a very big chalenge in patients with DM. Revascularization of CAD is an important therapeutic intervention owing to its impact on both symptoms and future. In the past 15 years, advancements in both PCI and surgical techniques have been improved. Although there is evidence to suggest that these advancements has been improved results in diabetic patients, this patients still show increased worse outcomes compared with the general population, and the optimal revascularizton strategy in diabetic patients remains unclear [4].

The best way of revascularizton for diabetic patients with multivesel CAD is a topic of uncertainty. Coronary revascularizton can be achieved using either CABG or PCI with stent. Diabetics represent a hard subset for both managements. While PCI is more asociated used in patients affected by single one vessel CAD, the best strategy for patients with multivessel disease (MVD) is still uncertain, due to a higher repeated revascularization rate at 1-year or 2-year follow-up in patients that was treated by PCI with stents [5].

Over the years, percutaneous and surgical revascularizton techniques had very good advances in medical therapies to provide contemporary management of acute coronary syndrome and management of chronic coronary syndrome (CCS) to improve angina, heart failure (HF) symptoms, and quality of life (QoL)**.** In patients with left main disease (LMD) and multivessel disease (MVD), revascularization have been shown to prolong life [6]. Historicaly, CABG was considered the management of choice of MVD and LMD. However, remarkable advances in PCI led to higher operational success rates, decreased procedural myocardial infarction (MI), repeated lesion revascularization (TLR), in-stent thrombosis, and in-stent restenosis numbers. As such PCI became a viable way to CABG in treatment of LMD and MVD [7]. Multiple not so big size randomized and controlled trials comparing both treatment strategies in LMD and MVD interventions shows that an increased in peri-procedural cardiac and cerebro-vascular events with CABG but higher long-term need for repeat revascularization in patients managed with PCI [8].

2. Aim of the work

This study aims to assess clinical outcome in diabetic patients with three vessel disease or left main coronary artery disease who had either coronary intervention via skin or CABG.

3. Patients and methods

This controlled prospective Study included one hundred patients presented to Banha university hospitals and, Egypt during the period from November 2018 to October 2019 for either PCI or CABG. The choice whether the patient will be divided to CABG or PCI with

DES was made on the basis of clinical judgment among cardiologists and cardiac surgeons, patient preferences and patient request. All patients signed an informed consent and the study was approved by local ethics committe.

The study included patients with ages more than or equal 18 years. 2. Diabetic patients who are on medically treated. 3. Angiograpicaly confirmed thre vesel cornary artery disease with greater than or equal to 75% stenotic lesions in major epicardal vessels or left main coronary artery stenosis more than or equal to 50% amenable to either PCI or CABG. 4. Angio-graphic charactristics which are subjected to both PCI/DES and CABG. 5. Indication for revascularization based upon symptoms of chest pain or objective evidence of myocardial ischemia.

Co-morbidity condition that is expected to limit life to less than two years, pregnant women, other structural heart diseases including valvlar, congental, pericrdial and myocardal heart diseases and patients with high surgical risk were excluded from the study.

Methods

All patients were subjected for the following

Full history including

Age, gender and family history of the patient. History of DM (defined as a fasting glucose >126 mg /dl or on pills), high cholesterol (fasting cholesterol > 200 mg /dl or on treatment) and HTN (systolic blood pressure > 140/90 mmHg or on treatment). Special habits (Tobacco use /Alcohol intake) - (current, former or nonsmoker); Full clinical assessment; 12-lead Electrocardiogram (ECG) data analysis. Coronary Angiograpic Details: Include Coronry Angiograpic data before PCI or CABG. PCI Data: included number and types of stents and number of vessels which had been Stented. CABG Data included peroperative complications, types of grafts (venos or arterial) and numbers of grafts used.

Study protocol

After diagnostic coronry angiograpy, patients were subsequently divided into two groups (sixty patients each): The first group underwent PCI with DES. The second group underwent CABG.

Statistical analysis

Data are presented as mean±SD for continuous data and as number (%) for categorical data. Between groups comparson was done using student t-test for continous data and by Chisquare test (or Fisher exact test) for qualitative data. Level of evidence was detected to be significant at P value <0.05. Data were collected and analyzed by SPSS (version 17).

4. Results

I-Baseline characteristics

The mean age was 62 + 8 years (63 ± 7 y versus 58 ± 9 y in group A, B respectively, P = 0.175), 58% were males (52% versus 63% in group A, B respectively, P=0.319). There were no significant diferences between both groups as regard age and gender. P values were 0.175 & 0.319.

All patients are diabetics (DM) while 52% had hypertension (HTN) (54 % versus 47% in group A,B respectively P=0.679), 59 % had high cholesterol (52% versus 47% in group A,B respectively P=0.319), 43 % were smokers (39 % versus 50 % in group A,B respectively P=0.237), 37% had positive family history of CAD (34% versus 38% in group A, B respectively P=0.663) Table (1).

Table (1) Patients' data.

		PCI (n = 50)	CABG (n = 50)	P value
Age (Years)	Mean ±SD	61 ±7	59 ±9	0.175
Gender	Males n (%)	26 (52.0)	32 (62.0)	0.319
	Females n (%)	23 (44.0)	18 (34.0)	
HTN	Yes n (%)	26 (50.0)	24 (44.0)	0.669
DM	Yes n (%)	50 (100.0)	50 (100.0)	-
Smoker	Yes n (%)	19 (36.0)	25 (50.0)	0.237
Dyslipidemia	Yes n (%)	27 (50.0)	32 (62.0)	0.319
positive family history	Yes n (%)	16 (36.0)	18 (36.0)	0.663

Independent t test was used for age. Chi-square test was used for gender

II- Clinical examination of patients

The mean heart rate (HR) was 70+7.5 (72 ±9 versus 70 ±8 in group A,B respectively, P=0.142), mean systolic blood pressure (SBP) was 120±12.5 mmhg (125 ±14 mmhg versus 125 ±11 mmhg in group A,B respectively P=0.147), mean diastolic blood pressure (DBP) was 77.5±11 mmhg (82 ±14 mmhg versus 70 ±8 mmhg in group A,B respectively P=0.65) and all patients presented with Kilip class I Table (2).

Table (2) Clinical examination on admission.

		PCI (n = 50)	CABG (n = 50)	P value
HR	Mean ±SD	70 ±9	72 ±8	0.142
SBP	Mean ±SD	120 ±14	128 ±11	0.147
DBP	Mean ±SD	80 ±14	79 ±8	0.64
Killip class	I n (%)	50 (100.0)	50 (100.0)	-

III- Vessels affected

Thirty six percent of patients had Left Main coronry artery (LM) disease (٣٦% versus 45% in group A, B respectively, P=0.687), 98% had Left anterior descening artery disese (٩٦% versus 96% in group A,B respectively, P=1), 90% had left circmflex aretery disease (80% versus 96% in group A,B respectively, P=0.009), 78% had right coronry artery disease (74% versus 80% in group A,B respectively, P=0.639) Table (3).

Table (3) Vessels affected in both groups .

		PCI (n = 50)	CABG (n = 50)	P value
LM	Yes n (%)	19 (36.0)	17 (34.0)	0.677
LAD	Yes n (%)	45 (98.0)	48 (98.0)	1.0
LCX	Yes n (%)	41 (82.0)	48 (98.0)	0.009
RCA	Yes n (%)	38 (76.0)	40 (80.0)	0.639

Ninety one percent of patients presented with stable coronary syndrome (82 % versus 96 % in group A, B respectively, P = 0.032), 4 % presented with unstable angina (6% versus 2% in group A, B respectively, P = 0.627), 10% presented with myocardial infarction (10 % versus 0 % in group A, B respectively, P = 0.056) Table (4)

Table (4) Clinical presentation.

		PCI (n = 50)	CABG (n = 50)	P value
CCS	Yes n (%)	42 (82.0)	49 (96.0)	0.031
UA	Yes n (%)	3 (6.0)	1 (2.0)	0.627
MI	Yes n (%)	5 (10.0)	0 (0.0)	0.056

Fisher's exact test was used, CCS = Chronic coronary syndrome, UA = Unstable angina, MI = Myocardial infarction

V- PCI characteristics

Regarding the type of stents used, all patients had drug eluting stent, regarding number of stents used: 12% had 4 stents, 66% had 3 stents, 14% had 2 stents & 6 % had only 1 stent. Regarding number of vessel stented: 62% had 3 vessels stented, 26% had 2 vessels stented & 16% had only 1 vessel stented Table (5).

Table (5) PCI characteristics.

		N	%
Number of stents	One	3	6.0
	Two	8	16.0
	Three	34	66.0
	Four	5	10.0
Type of stent	DES	50	100.0
Number of vessel stented	One	7	16.0
	Two	12	22.0
	Three	31	60.0

VI- CABG characteristics

Regarding peroperative complications: 64% had no complications, 10% was complicted by postperative Af, 12% was complicated by death, 6% had wound infection, 4% was complicated by MI.

Regarding the sum number of grafts used: 2% had 5 grafts, 74% had 3 grafts, 16% had 2 grafts & only 4% had 1 graft. Arterial grafts were used in 100% of patients (LIMA to LAD), 2% had 4 venous grafts, 76% had 2 venous grafts, 18% had 1 venous grafts & only 4% had no venous grafts Table (6).

Table (6) CABG characteristics.

		N	%
Perioperative complications	AF	6	14.0
	died after first operation	1	2.0
	arrested prebypass	1	2.0
	arrested in ICU	3	6.0
	MI	2	4.0
	wound infection	4	8.0
	No	33	64.0
Arterial grafts	One	50	100.0
Venous grafts	Zero	2	4.0
	One	9	18.0
	Two	38	74.0
	Four	1	2.0
Numbers of grafts	One	2	4.0
	Two	9	18.0
	Three	38	76.0
	Five	1	2.0

VII- One-month outcome

Four percent of patients complicated by death after 1 month (0.00% versus 6% in group A, B respectively, P=0.232), 3% complicted by non-fatal MI after 1 month (0.00% versus 6% in group A, B respectively, P=0.232), 8% complicated by stroke after 1 month (0.00% versus 12% in group A, B respectively, P=0.029), 4% complicated by death after 1 month (0.00% versus 8% in group A, B respectively, P=0.242), 1 month composite endpoints were found in 11% of cases (0.00% versus 22% in group A, B respectively, P<0.001), 1 month need for revascularization was 1% (0.00% versus 2% in group A, B respectively, P=1) Table (7) .

Table (7) One – month outcome.

		PCI (n = 50)	CABG (n = 50)	P value
Death	Yes n (%)	0 (0.0)	3 (6.0)	0.232
Non-fatal MI	Yes n (%)	0 (0.0)	3 (6.0)	0.232
Stroke	Yes n (%)	0 (0.0)	6 (12.0)	0.029
1ry endpoints	Yes n (%)	0 (0.0)	11 (22.0)	<0.001
Need for revascularization	Yes n (%)	0 (0.0)	1 (2.0)	1.0

Five percent of patients complicated by death after 6 months (2% versus 8% in group A, B respectively, P=0.352), 3% complicated by non-fatal MI after 6 months (0.00% versus 6% in group A, B respectively, P=0.252), 8% was complicated by non-fatal stroke after 6 months (0.00% versus 16% in group A, B respectively, P=0.007).

Seventeen percent of patients had the need for revascularization (26% versus 8% in group A, B respectively, P=0.017) Table (8).

Table (8) Twelve – month outcome

		PCI (n = 50)	CABG (n = 50)	P value
Death	Yes n (%)	1 (2.0)	4 (8.0)	0.342
Nonfatal MI	Yes n (%)	0 (0.0)	3 (6.0)	0.232
Nonfatal stroke	Yes n (%)	0 (0.0)	8 (16.0)	0.007
Need for revascularization	Yes n (%)	13 (26.0)	4 (8.0)	0.018

Stepwise logistic regression analysis was done for prediction of 12 months need for re-vascularization. It was found that there was significant differnces between the 2 groups regarding MACE and need for revascularization. (OR = 4.041 & 95% CI from 1.225 to 13.443). P value was 0.023 Table (9).

Table (9) Multivariate logistic regression analysis for prediction of 6 months need for revascularization.

	B	S.E.	Wald	OR	95% C.I. for OR	P value
PCI	1.376	0.613	5.19	4.041	1.225 - 13.443	0.025

5. Discussion

A fifth of myocardal revascularizton procedures are performed in patients with DM. Revascularizton in these patients is challenged by a more diffuse atherosclertic involvement of epicardial vessels, higher propensty to develop re-occlusion after PCI and saphenous graft occlusion after CABG and unrepeated atherosclerotic progresion causing new stenosis [9]. This results in a higher risk, including long-term mortality, than seen in patients with no DM, irespective of revascularizton modality **(10).**

Evidence on the effect of myocardal revascularizton in patients with DM has been obtained in the shifted context of a contined development of PCI, CABG and pharmacolgical treatments, making it hard to establish good comparisons **(11).**

In our study, we aimed to assess clinical outcome in diabetic patients with three vessel disease coronry artery disease who had either PCI or CABG.

This study was made on one hundred and twenty patients presented to Banha university hospitals and NHI for either PCI or CABG. The study population was divided into two groups (sixty patients each). The first group undergone PCI with DES, the second group undergone CABG. The choic whether the patient will perform CABG or PCI with DES was made on the concept of clinical judgment among cardiologists and cardiac surgeons, patient preferences and their request. Then follow up was done after twelve months looking for the primary outcome included combined major adverse cardiovascular and cerbero-vascular events (death from any cause, nonfatal MI and nonfatal stroke) and the secondary outcomes included need for revascularizton.

In the present study we reported that there were no significant differences between both groups as regard 1 month death, non-fatal MI, need for revascularization.

Our results are the same with Kim et al. [12] who reported that six hundred and five patients were treated: three hundred fifty six by CABG and three hundred fifty one by PCI and after two years follow up, there was no statistically significant difference between the PCI and CABG groups regarding the complete of death or Q-wave MI, (8.0% in CABG versus 10.6% in PCI) (p value=0.45).

But our results are not the same with the long-term Future Revascularizton Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivesel Disease trial which had 1900 patients with diabetes and multivessel CAD who were randomly divided to perform either CABG or PCI with drug-eluting stents (mainly first-generation PES or SES) **(13).** After 4 years of follow-up, the 957 patients assigned to undergo CABG had significntly lower mortality (10.9% vs. 16.3%) and fewer myocardial infarctions (8.0% vs. 13.0%) than the 963 patients assigned to undergo PCI.

In our study 1 month and 12 months nonfatal stroke was significantly higher in CABG (12.0% and 14.0% respectively) compared to PCI (0.0% and 0.0%). P value was 0.006.

In opposite to our study, Serruys, et al. [14] reported that after one year follow up, there was statistically significant difference between the PCI and CABG (p value=0.003) as in CABG group 0.04 % of the patients had cerebro-vascular stroke but in PCI group 2.4% had cerebrovasclar stroke. However, opposite to our results in the FREDOM trial patients in the CABG group had signifcantly more stroke (5% vs. 2.2%), mostly those that occured within 30 days after revascularizton.

The mechanism of the underlying the increased risk of stroke with surgery is likely multiple. Firstly, most CABG operations are performed on-pumping with canlation and clambing of the aortaa; even if they are performed on-pump, the aorta is often manipulated for construction of the proxmal anastomosis [15,16,17]. Secondly, approaches to reduce post-operative bleeding that are often required after CABG (but not after PCI), such as usage of tranexmic acid, lead to a hypercagulable state that may increase the risk of stroke [18]. Third, post-operative atrial fibrilation is frequently after CABG and increases the risk of stroke in the early post-operative period [19,20**]**. Fourth, times of hypoperfusion during surgery and early postoperative low cardiac output syndrome may impair brain perfusion, leading to ischemia and watershed strokes [21].

Another hypothesis is that strokes may be minimum after PCI due to the use of SAPT after stent implanttion [22].

In our study when the primary endpoints of the major adverse cardio-vascular and cerbero-vascular events (death from any cause, nonfatal MI and nonfatal stroke) were combined in a composite endpoint, there were significantly higher 1 month and 6 months rates of primary endpoints in CABG compared to PCI. This may be explained by technological advances over the past 20 years in PCI (delivery systems, stents, and adjunctive pharmcotherapy), there may have been wilingness on the part of the interventional cardiolgists to make more chalenging anatomic patients, thereby contributing to the differences that was observed in favor of PCI over CABG regarding primary results.

These results are not similar with the Bypass Angioplasty Revascularizton Investigation study which compared multivesel angioplasty to CABG in patients with medically treated DM and found a near doubling of

mortality at 6-years with PCI (32% vs. 18%, P=0.004). The survival benefit of CABG in patients with diabetes persisted at 11 years (PTCA 46.5% vs. CABG 58.8%, P=0.035). Our results also are inconsistent with an analysis based on pooled individual patient data from 10 randomized trials comparing CABG with PCI (median follow-up of 5.9 years), mortality among patients with DM was 32% lower in the CABG group than in the PCI group [10].

Also not similar with our study, Kurlansky et al. [23] studied improved long term survival for diabetic patients with surgical versus interventional revascularizton. This study reported that one thousand eighty three patients was treated: three hundred forty four by CABG and six hundred forty eight by PCI and after five to eight years follow up there was statisticaly significant difference between the PCI and CABG groups (p value less than 0.001) regarding the primary outcome including major adverse cardic events (MACE) as in CABG group 31.08 % of the patients had combined MACE but not in PCI group 44.92 % had composite MACE.

The differences in both 1 month and 12 months results between the previous mentioned studies may be explained with the differences in study populations, their numbers, associated co morbidities, left and right ventricular functions, lesions complexty, and skills of the operators, and the post CABG ICU care.

Bangalore et al. [24] showed indirect comparisons of patients underwent CABG with PCI specifically with DM and showed similar mortality rates with either strategy. Such analyses continue to rise the important question whether advancing PCI approches technology will make a different result from what has been watched thus near in comparative revascularizton trials.

The FAME 4 (A Comparison of Fractional Flow Reserve-Guided Percutaneos Coronry Intervention and Coronry Artery Bypass Graft Surgery in Patients With Multivesel Coronry Artery Disease) trial seeks to address this hypothsis in patients with 2-vessel disease, by using a newer-generations stents platforms in similar with fractional flow reserve guidance [25].

The factors that determined to undergo add hoc PCI are likely alot and complicated and include patients' and physicians' choice, upfront use of triple antiplatelet therapy, delayed availability of CABG, anatomy or comorbidties not suited for CABG, and other specific local institutonal factors.

In our study twelve months need for revascularizton was significantly higher in PCI (24.0%) compared to CABG (10.0%). P value was 0.017.

Our results are consistent with the pre-specified DM-subgroup analysis (n=462) of SYNTAX (SYNrgy Between PCI With TAXs and Cardic Surgery) [26] which showed that an increased risk of repeated revascularizton in PCI group (PCI: 35.3% vs CABG: 15.6%; P< 0.001) [27].

Similar with the our study Serruys, et al. [14] showed that there was statisticaly significant diference between the PCI and CABG (p value less than 0.001^{*}) as in CABG group 5.7 % of the patients underwent repeated revascularizton but in PCI group 12.5% undergone repeated revascularization.

6. Conclusion

Our study showed no significant differences in patients who were assigned to CABG compared to PCI regarding MACE and need for revascularization after 12 months of follow up.

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