

# Short-Term Clinical Outcomes of Complex Percutaneous Coronary Intervention in Patients Declined for Coronary Artery Bypass Grafting: A Contemporary Real-World Registry

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## Abstract

**Background:** Coronary artery bypass grafting (CABG) is recommended as the optimal revascularization strategy in preference to PCI in patients with multivessel disease and intermediate to high SYNTAX scores. However, PCI seems appropriate for patients deemed surgically ineligible or refused the operation.

**Aim of Study:** This study aimed to the short-term major adverse cardiac and cerebrovascular events (MACCE) in patients with multivessel complex coronary anatomy, defined as SYNTAX score above 22, undergoing non-emergent PCI who were indicated for CABG but either they were rejected by the surgeons, or they refused it.

**Patients and Methods:** Our registry was conducted on 193 patients throughout a 6-month recruitment period and subsequently followed-up for in-hospital and 6-month mortality and MACCE.

**Results:** Regarding the in-Hospital study outcomes, the mortality was 3%, and the MACCE occurred in 7%, while in the 6-month outcomes, the mortality was 4.5%, and the MACCE occurred in 17.5%. When comparing the intermediate to high SYNTAX score groups, there was a statistically significant increase in both in-hospital and short-term mortality and MACCE in the high SYNTAX score group but no significant difference regarding the incidence of contrast-induced nephropathy. SYNTAX II score  $\geq 41$  (OR 3.9, 95% CI 1.7-9.1,  $p=0.001$ ) and incomplete revascularization (OR 5.4, 95% CI 2.1-13.7,  $p<0.001$ ) were independent predictors for short-term MACCE.

**Conclusions:** Patients with high SYNTAX scores portend a significantly higher in-hospital and 6-month MACCE and mortality. When considering complex multivessel PCI, one should consider the benefits of achievement of complete revascularization and the risks in patients with higher SYNTAX II scores.

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**Key Words:** SYNTAX score – SYNTAX II score – Percutaneous coronary intervention – MACCE – Complex coronary anatomy – Complete revascularization.

## Introduction

**ALTHOUGH** there has been a significant reduction in mortality rates from cardiovascular diseases (CVD), they remain the leading cause of global mortality among non-communicable diseases, principally coronary artery disease (CAD) and stroke [1,2]. CAD could affect single or multiple vessels. The prevalence of multivessel disease is high, especially among diabetic individuals. Kesani et al., found that in patients with significant CAD, significant 2-4-vessel CAD was present in 80% of patients with diabetes and 57% without diabetes [3].

### List of Abbreviations:

ACS	: Acute coronary syndrome.
BMS	: Bare metal stent.
CVD	: Cardiovascular disease.
CCS	: Chronic coronary syndrome.
CKD	: Chronic kidney disease.
CTO	: Chronic total occlusion.
CIN	: Contrast-induced nephropathy.
CABG	: Coronary artery bypass graft.
CAD	: Coronary artery disease.
CHD	: Coronary heart disease.
DBP	: Diastolic blood pressure.
DES	: Drug-eluting stent.
DAPT	: Dual antiplatelet therapy.
ESC	: European Society of Cardiology.
H.F.	: Heart failure.
IVUS	: Intravascular ultrasound.
L.M.	: Left main.
LVEF	: Left ventricular Ejection fraction.
MACCE	: Major adverse cardiac and cerebrovascular events.
NSTEMI	: Non-ST elevation myocardial infarction.
PCI	: Percutaneous coronary intervention.
STEMI	: ST-elevation myocardial infarction.
SBP	: Systolic blood pressure.

Coronary revascularization could be achieved either percutaneously or surgically. Coronary artery bypass grafting (CABG) has been principally used to revascularize complex coronary artery disease (CAD) since 1968. When percutaneous intervention (PCI) was preliminarily introduced in 1977, it was initially regarded as a treatment option for patients with single-vessel disease. Although recent technological and technical advancement in PCI techniques has broadened the treatment scope to include patients with multivessel disease, the debate about the benefits and risks of each strategy is still ongoing. Although PCI offers favorable short-term outcomes related to its minimal invasiveness, CABG is superior in terms of long-term freedom from myocardial infarction and target vessel revascularization (TVR) and myocardial infarction (MI) [4-6].

The SYNTAX trial is a landmark study comparing CABG with PCI (using first-generation drug-eluting stents) in all-comer patients with a de-novo three-vessel disease, left main coronary artery disease, or both. Following the results of the SYNTAX trial and subgroup analyses, the European Society of Cardiology and European Association for Cardio-Thoracic Surgery (ESC/EACTS) guidelines on myocardial revascularization adopted an algorithm based on the type (three-vessel disease or left main coronary artery disease), extent, and severity of coronary artery disease, as assessed by the anatomical SYNTAX score. In the SYNTAX trial, terciles of SYNTAX scores with low, intermediate, and high anatomical complexity stratified patients into those with similar outcomes with both PCI and CABG and those who derived significant benefits from CABG. In patients with the three-vessel disease (whether diabetic or non-diabetic) and intermediate or high anatomical complexity (i.e., SYNTAX >22), CABG is recommended as the optimal revascularization strategy in preference to PCI [4,7,8]. However, as noted in the guidelines, these subgroup analyses merely provide the heart team with an anatomical stratification of treatment recommendations. Besides, they do not consider major clinical characteristics and comorbidities [9]. In addition, occasionally, CABG wouldn't be the appropriate option because patients are deemed surgically ineligible (high surgical risk or poor distal target vessels) or refused the operation [10].

The incidence of major adverse cardiac and cerebrovascular events (MACCE) is considered a clinical endpoint in revascularization trials. It is usually defined as cardiac death, recurrent acute coronary syndrome (ACS), recurrent coronary revascularization (PCI or CABG, urgent or nonurgent), and stroke. Cardiac death includes any death with a cardiac cause (e.g., myocardial infarction, congestive heart failure, low-output failure, and fatal arrhythmia), unwitnessed death, and sudden cardiac death [11].

## Patients and Methods

This registry aimed to study the short-term MACCE after non-emergent PCI in patients with multivessel complex coronary anatomy and intermediate to high SYNTAX scores indicated for CABG, but either they were rejected by the surgeons, or they refused it. Our registry comprised patients with coronary angiograms showing multivessel involvement with complex anatomy based on a calculated SYNTAX score of 23 or more. All eligible patients underwent non-emergent PCI in our university Cath lab and were followed-up for six months for MACCE.

*Ethical approval and consent to participate:* The approval was obtained from the university ethical committee under registration number (MS. 661/2021). All participants had informed written consent with consideration of adequate privacy and confidentiality in accordance with the seventh revision of the Declaration of Helsinki in 2013.

*Study population:* The study included patients with multivessel disease, defined as significant luminal stenosis of at least 70% in two or more major coronary arteries of at least 2.5 mm diameter or a single coronary artery plus a 50% or greater luminal stenosis of the left main coronary artery [12,13], with a calculated SYNTAX score above 22. Patients either rejected the option of surgical revascularization after informed consent or were deemed surgically ineligible or extremely high risk for CABG and subsequently underwent successful non-emergent PCI with drug-eluting stents (DES) were included in the study. Patients who underwent emergent revascularization for cardiac arrest, cardiogenic shock, or ST-segment-elevation myocardial infarction and patients with prior CABG were excluded from the study. In addition, patients with severe valvular (mitral or aortic) stenosis or regurgitation were excluded from the study.

### *Study tools:*

After written informed consent and before the revascularization procedure, all patients were assessed for the type of presentation, either acute coronary syndrome or chronic coronary syndrome. Relevant history was taken from all cases with particular emphasis on patient demographics, risk factors for coronary artery disease (diabetes mellitus, hypertension, dyslipidemia, smoking, family history of coronary heart disease), relevant medical history (stroke, heart failure, peripheral vascular disease, chronic lung disease, chronic kidney disease, prior myocardial infarction, or prior PCI).

Relevant laboratory investigations were documented, including hemoglobin, renal function tests, glycated H.B. (HbA1C), and lipid profile (LDL-cholesterol). The calculated left ventricular ejection fraction (LVEF) was documented in the baseline transthoracic two-dimensional echocardiography

data. All the echocardiographic studies were done in the Echocardiography unit of the Cardiology Department at Aim Shams University Hospital, using Echo machines GE VIVID S5 or GE VIVID E9, as per the recommendations of the ASE (American Society of Echocardiography) and EACVI (European Association of Cardiovascular Imaging) [14].

Angiographic characteristics were documented for the presence of individual complexity (left main disease, CTO, bifurcation, or severe calcification) or collectively (SYNTAX score, PCI SYNTAX II), in addition to operative scores (EURO score and Euro score II). Scores for complexity and risk for intervention were calculated using online calculators ([www.syntaxscore.org](http://www.syntaxscore.org), [www.euroscore.org](http://www.euroscore.org)) [15,16].

Indication for PCI, in preference to CABG, was documented whether rejection by surgery or patient refusal. The type of periprocedural P2Y12 inhibitor was also documented, whether clopidogrel or ticagrelor. The technical aspects of PCI were observed concerning the procedural staging, radial access use, IVUS guidance, LM PCI, bifurcation PCI, CTO PCI, rotational atherectomy, and eventual completeness of revascularization. Complete revascularization was defined as the successful treatment of all lesions of anatomical significance, most commonly specified as those with diameter stenosis of more than 70% in vessels with a reference diameter of  $\geq 2.0$  mm, during the index procedure (and, if necessary, a planned staged procedure) [17,18].

**Follow-up:** The patients were followed-up in-hospital and six months post-intervention regarding contrast-induced nephropathy (CIN) and MACCE. Contrast induced nephropathy (CIN) was defined as the impairment of kidney function measured as either a 25% increase in serum creatinine from baseline or a 0.5mg/dl increase in absolute serum creatinine value within 48-72 hours after intravenous contrast administration [19]. MACCE was defined as all-cause death, recurrent acute coronary syndrome, recurrent revascularization, and cerebrovascular stroke.

**Statistical analysis:** The collected data was revised, coded, tabulated, and introduced to a P.C. using the Statistical Package for Social Science (SPSS 25). Data were presented and analyzed according to the type of data obtained for each parameter. Mean, and standard deviation were used for parametric numerical data, whereas percentage and frequency were used to present non-numerical data. Student *t*-test was used to statistically examine the difference between the study group's parametric variables. The Chi-Square test examined the statistical relationship between two qualitative variables. A *p*-value of less than .05 was regarded as significant. Since the study was nonrandomized, a logistic regression model for analysis of patients with and without MACCE at six months. The variables used in this model were: Serum creatinine, hemoglobin, LVEF, SYNTAX

score, PCI SYNTAX II, and incomplete revascularization. Univariate and multivariate analyses were performed to determine the predictors of 6-month MACCE. Receiver-operating characteristic (ROC) curve graphics were used to determine the cutoff values of SYNTAX and SYNTAX II for the prediction of 6-month MACCE.

## Results

Our registry comprised 193 patients presented during the six-month recruitment period from the first of June 2021 till the end of November 2021 in Ain Shams University Hospitals. The study population had multivessel involvement with coronary angiograms deemed complex anatomy based on a calculated SYNTAX score of 23 or more. The decision for PCI for each patient was made individually after a heart team discussion and discussion with the patient. The patients were declined for CABG due to either surgeon rejection in 65.3% of patients or refusal by the patient in 34.7%.

### Descriptive data:

Our registry's mean SYNTAX score was  $32.8 \pm 8.4$  (range 23-68). Based on the SYNTAX score, the study population was dichotomized into an intermediate SYNTAX group with a SYNTAX score of 23-32 (111 patients; 57.5%) and a high SYNTAX group with a SYNTAX score above 32 (82 patients; 42.5%). The mean age of the study population was  $60.5 \pm 9.6$  years, with 69% males and the predominant presentation being chronic coronary syndrome (56%). The distribution of relevant risk factors and comorbidities and relevant laboratory results are shown in Table (1). No significant statistical difference was found between both SYNTAX groups regarding patient demographics, presentation, relevant risk factors, comorbidities, and laboratory results (Table 1).

Regarding relevant echocardiographic findings, the mean LVEF in the whole population was  $46 \pm 12\%$  ( $47 \pm 13\%$  in the intermediate SYNTAX vs.  $43 \pm 11\%$  in the high SYNTAX group,  $p=.028$ ) (Table 1).

Regarding angiographic complexity, coronary bifurcation was present in 38.3%, CTO in 37.8%, severe calcification in 9.3%, and significant left main disease in 31.1%. Only LM disease was significantly higher in the high SYNTAX group ( $p=0.018$ ). Regarding angiographic scores, the mean SYNTAX score was  $32.8 \pm 8.4$ , and the PCI SYNTAX II scored  $37.6 \pm 10.1$ . Regarding operative scores, the Euro SCORE was  $4.6 \pm 2.5$ , and the Euro SCORE II was  $2.3 \pm 2.3$ .

The periprocedural P2Y12 inhibitor was predominantly clopidogrel (72.5%), with ticagrelor used in 27.5% of patients. Regarding the technical aspects of PCI, staging of the PCI was planned in 17.6% of patients, radial access was used in 16.6%

of patients, and IVUS guidance was used in 11.9% of patients. The CTO PCI was done in 28% of patients, rotational atherectomy in 2.6%, bifurcation PCI in 34.7%, and LM PCI in 29%. The median number of used DES was 3 (range 1-7). Comparing

both SYNTAX groups, the high SYNTAX group has significantly higher LM PCI (29% vs. 24.3%,  $p=0.009$ ) and a higher incidence of eventual incomplete revascularization (52.4% vs. 40.4%,  $p=0.022$ ) as shown in Table (1).

Table (1): Descriptive data of the whole study population and comparison between intermediate and high SYNTAX groups.

	All patients (n=193)	Intermediate SYNTAX (n=111)	High SYNTAX (n=82)	<i>p</i> - values
Age (years)	60.5±9.6	59.5±9.2	61.8±10.1	0.103
Male sex (%)	133 (68.9%)	78 (70.3%)	55 (67.1%)	0.635
<i>Presentation:</i>				
ACS	84 (43.52%)	51 (45.95%)	33 (40.24%)	0.430
CCS	109 (56.48%)	60 (54.05%)	49 (59.76%)	
<i>Relevant risk factors and comorbidities:</i>				
Hypertension	122 (63.2%)	74 (66.7%)	48 (58.5%)	0.247
Diabetes mellitus	118 (61.4%)	68 (61.3%)	50 (61%)	0.868
Smoking	87 (45.1%)	49 (44.14%)	38 (46.34%)	0.762
Dyslipidemia	145 (75.1%)	81 (72.97%)	64 (78.05%)	0.420
Positive family history of CAD	12 (6.2%)	5 (4.50%)	7 (8.54%)	0.252
Prior myocardial infarction	23 (11.9%)	15 (13.51%)	8 (9.76%)	0.426
Prior PCI	42 (21.8%)	28 (25.23%)	14 (17.07%)	0.175
Prior heart failure	16 (8.3%)	9 (8.11%)	7 (8.54%)	0.915
Stroke	40 (20.7%)	24 (21.62%)	16 (19.51%)	0.721
PAD	14 (7.3%)	8 (7.21%)	6 (7.32%)	0.977
Chronic lung disease	7 (3.6%)	4 (3.60%)	3 (3.66%)	0.984
Chronic kidney disease	37 (19.2%)	16(14.4%)	21(25.6%)	0.051
<i>Relevant laboratory results:</i>				
Hemoglobin (g/dl)	12.6±2	12.5±2	12.7±2.1	0.523
Creatinine (mg/dl)	1.1±0.4	1.1±0.5	1.1±0.4	0.817
HbA1C (%)	7.5±2.4	7.5±2.4	7.6±2.5	0.884
LDL-C (mg/dl)	112.7±34.8	113.4±34.3	111.7±35.6	0.733
<i>Relevant echocardiographic data:</i>				
LVEF (%)	45.6±12.4	47.3±13.3	43.3±10.7	0.028
<i>Angiographic characteristics and scores:</i>				
Left main disease	60 (31.1%)	27 (24.3%)	33 (40.2%)	0.018
Chronic total occlusion	73 (37.8%)	39 (35.1%)	34 (41.5%)	0.252
Bifurcation	74 (38.3%)	36 (32.4%)	38 (46.3%)	0.054
Severe Calcification	18 (9.3%)	9 (8.1%)	9 (11%)	0.648
PCI SYNTAX II	37.6±10.1	34.3±8.7	41.9±10.2	<0.001
Euro SCORE	4.6±2.5	4.6±2.4	4.6±2.6	0.918
Euro SCORE II	2.3±2.3	2.3± 2.3	2.3±2.3	0.597
<i>Indications of PCI:</i>				
Rejection by surgery	126 (65.3%)	70 (63.06%)	56 (68.29%)	0.098
Patient refusal	67 (34.7%)	41 (36.94%)	26 (31.71%)	
<i>Type of periprocedural P2Y12 inhibitor:</i>				
Clopidogrel	140 (72.5%)	82 (73.9%)	58 (70.7%)	0.484
Ticagrelor	53 (27.5%)	29 (26.1%)	24 (29.3%)	
<i>Technical aspects of PCI:</i>				
Staged PCI	34 (17.6%)	19 (17.12%)	15 (18.29%)	0.161
Radial access	32 (16.6%)	19 (17.1%)	13 (15.9%)	0.816
IVUS guided PCI	23 (11.9%)	11 (9.9%)	12 (14.6%)	0.317
Left main PCI	56 (29%)	27 (24.32%)	29 (35.37%)	0.009
Bifurcation PCI	67 (34.7%)	32 (28.83%)	35 (42.68%)	0.082
CTO PCI	54 (28%)	31 (27.93%)	23 (28.05%)	0.161
Rotational atherectomy	5 (2.6%)	2 (1.80%)	3 (3.66%)	0.553
Incomplete Revascularization	78 (40.4%)	35 (31.53%)	43 (52.44%)	0.022

ACS: Acute coronary syndrome.  
CCS: Chronic coronary syndrome.  
CTO: Chronic total occlusion.

IVUS: Intravascular ultrasound.  
LVEF: Left ventricular ejection fraction.  
PAD : Peripheral arterial disease.

*Study outcomes:*

Out of 193 patients regarding the in-hospital follow-up, CIN occurred in 15.5% of patients, whereas MACCE occurred in 14 patients (7.3%), including six patients (3.1%) with cardiac death, eight patients (4.2%) who experienced recurrent acute coronary syndrome (4.15%), five patients (2.5%) who necessitated repeat revascularization and only one patient (0.5%) who developed cerebrovascular stroke.

Regarding the occurrence of MACCE during the 6-month follow-up, a total of 34 patients (17.6%) developed MACCE, including nine cardiac deaths (4.67%), 23 patients (11.9%) who developed recurrent ACS, six patients (3.1%) who necessitated repeat revascularization and only one patient (0.5%) who developed stroke. Occurrence of MACCE was significantly higher in the high SYNTAX group compared to the intermediate SYNTAX group whether in-hospital (12.2% vs. 3.6%,  $p=0.023$ ) or during the 6-month follow-up (26.8% vs. 10.8%,  $p=0.004$ ), mainly driven by the significantly higher incidence of cardiac deaths during the in-hospital and 6-month follow-up respectively (Table 2).

We dichotomized the whole study population according to the occurrence of MACCE during the 6-month follow-up into two groups: MACCE group (34 patients, 17.6%) and MACCE-free group (159 patients, 82.4%). Regarding demographics, presentation, and relevant risk factors and comorbidities, there was no significant difference between MACCE and MACCE-free groups. Regarding relevant laboratory results, the MACCE group had significantly lower hemoglobin levels ( $p=0.045$ ) and significantly higher serum creatinine ( $p=0.013$ ). However, no significant difference existed regard-

ing HbA1C or LDL-cholesterol. Regarding relevant echocardiographic findings, the MACCE group had substantially lower LVEF at baseline ( $41.5\pm 12.2\%$  vs.  $46.5\pm 12.3\%$ ,  $p=0.032$ ); however no significant difference for the presence of concomitant severe AS or severe M.R. (Table 3).

As regards angiographic characteristics and scores, although there were no significant differences between both groups for individual complexity, the MACCE group had a significantly higher SYNTAX score ( $p=0.01$ ) and PCI SYNTAX II score ( $p=0.001$ ) (Table 3).

ROC curve analysis was performed for SYNTAX and PCI SYNTAX II scores. A cutoff value of SYNTAX of 32.5 yielded an accuracy of 73.8% with a negative predictive value of 89.9%. A PCI SYNTAX II cutoff value of 41 yielded an accuracy of 82.1% with a negative predictive value of 89.9%. (Table 4 and Fig. 1).

There was no significant difference between both groups regarding indications of PCI, type of periprocedural P2Y12 inhibitor, use of radial access, procedural staging, IVUS guidance, use of rotational atherectomy or PCI complexity (CTO, bifurcation or left main). However, the MACCE group had a significantly higher incidence of incomplete revascularization (76.5% vs. 32.7%,  $p<0.001$ ).

Logistic regression analysis revealed that PCI SYNTAX II score  $\geq 41$  (OR 3.9, 95% CI 1.7-9.1,  $p=.001$ ) and incomplete revascularization (OR 5.4, 95% CI 2.1-13.7,  $p<.001$ ) were the only independent predictors for the occurrence of 6-month MACCE (Table 5).

Table (2): In-hospital and short-term outcomes.

	All patients	Intermediate SYNTAX	High SYNTAX	<i>p</i> -values
<i>In-hospital outcomes:</i>				
CIN	30 (15.5%)	16 (14.6%)	14 (17.1%)	0.614
MACCE	14 (7.3%)	4 (3.6%)	10 (12.2%)	0.023
All-cause death	6 (3.1%)	1 (0.9%)	5 (6.1%)	0.04
Recurrent ACS	8 (4.2%)	3 (2.7%)	5 (6.1%)	0.242
Repeat revascularization	5 (2.6%)	2 (1.8%)	3 (3.7%)	0.422
Stroke	1 (0.5%)	0 (0%)	1 (1.2%)	0.243
<i>Six-month (short-term) outcomes:</i>				
MACCE	34 (17.6%)	12 (10.8%)	22 (26.8%)	0.004
All-cause death	9 (4.7%)	2 (1.8%)	7 (8.5%)	0.028
Recurrent ACS	23 (11.9%)	9 (8.1%)	14 (17.1%)	0.057
Repeat revascularization	6 (3.1%)	3 (2.7%)	3 (2.7%)	0.705
Stroke	1 (0.5%)	0 (0%)	1 (1.2%)	0.243

ACS: Acute coronary syndrome.

CIN : Contrast-induced nephropathy.

MACCE: Major adverse cardiac and cerebrovascular events.

Table (3): Comparison of MACCE and MACCE-free groups regarding demographic data, cardiovascular risk factors, and comorbidities.

	MACCE-group (n=34)	MACCE-free group (n=159)	p-values
Age (years)	60.91±9.8	60.40±9.5	0.780
Male sex (%)	19 (58.82%)	114 (71.07%)	0.070
<i>Presentation:</i>			
ACS	15 (44.12%)	69 (43.4%)	0.938
CCS	19 (55.88%)	90 (56.6%)	
<i>Relevant risk factors and comorbidities:</i>			
Hypertension	21 (61.76%)	101 (63.52%)	0.847
Diabetes mellitus	19 (55.88%)	99 (62.26%)	0.488
Smoking	16 (47.06%)	71 (44.65%)	0.798
Dyslipidemia	26 (76.47%)	119 (74.84%)	0.841
Positive family history of CAD	2 (5.88%)	10 (6.29%)	0.929
Prior myocardial infarction	4 (11.76%)	19 (11.95%)	0.975
Prior PCI	6 (17.65%)	36 (22.64%)	0.522
Prior heart failure	5 (14.71%)	11 (6.92%)	0.135
Stroke	7 (20.59%)	33 (20.75%)	0.983
PAD	2 (2.94%)	12 (7.55%)	0.827
Chronic lung disease	2 (5.88%)	5 (3.14%)	0.438
Chronic kidney disease	9 (26.47%)	28 (17.61%)	0.234
<i>Relevant laboratory results:</i>			
Hemoglobin (g/dl)	12±2	12.7±2	0.045
Creatinine (mg/dl)	1.3±0.8	1.1±0.3	0.013
HbA1C (%)	12±2	12.7±2	0.192
LDL-C (mg/dl)	110.12±26.7	113.2±36.2	0.646
<i>Relevant echocardiographic data:</i>			
LVEF (%)	41.47±12.2	46.51±12.26	0.032
<i>Angiographic characteristics and scores:</i>			
Left main disease	7 (20.6%)	53 (33.3%)	0.145
CTO	10 (29.4%)	63 (39.6%)	0.298
Bifurcation	8 (23.5%)	66 (41.5%)	0.136
Severe Calcification	3 (8.8%)	15 (9.4%)	0.704
SYNTAX score	36.57±9.68	32.03±7.87	0.010
PCI SYNTAX II	43.33±12.82	36.32±8.97	0.001
Euro SCORE	4.88±2.21	4.54±2.49	0.342
Euro SCORE II	2.38±1.79	2.3±2.36	0.263
<i>Indications of PCI:</i>			
Rejection by surgery	23 (67.6%)	103 (64.8%)	0.749
Patient refusal	11 (32.4%)	56 (35.2%)	
<i>Type of periprocedural P2Y12 inhibitor:</i>			
Clopidogrel	21 (61.8%)	119 (74.8%)	0.121
Ticagrelor	13 (38.2%)	40 (25.2%)	
<i>Technical aspects of PCI:</i>			
Radial access	5 (14.7%)	27 (16.98%)	0.75
IVUS guided PCI	11 (9.9%)	12 (14.6%)	0.317
Left main PCI	7 (20.6%)	49 (30.8%)	0.233
Bifurcation PCI	8 (23.53%)	59 (37.1%)	0.131
CTO PCI	5 (14.7%)	49 (30.8%)	0.058
Rotational atherectomy	0 (0.00%)	5 (3.1%)	0.295
Staged PCI	5 (14.7%)	29 (18.2%)	0.623
Incomplete	26 (76.5%)	52 (32.7%)	<0.001
Revascularization			

ACS: Acute coronary syndrome.

CCS: Chronic coronary syndrome.

CTO: Chronic total occlusion.

IVUS: Intravascular ultrasound.

LVEF: Left ventricular ejection fraction.

PAD: Peripheral arterial disease.

Table (4): ROC curve analysis of SYNTAX and SYNTAX II scores for occurrence of six-month MACCE.

ROC curve between MACCE free and MACCE groups							
	Cutoff	Sens.	Spec.	PPV	NPV	Accuracy	AUC
SYNTAX	≥32.5	67.6	61.6	27.4	89.9	73.8%	0.6560
PCI SYNTAX II	≥41	64.7	73	33.8	90.6	82.1%	0.6749

Table (5): Logistic regression analysis for factors associated with MACCE.

	Univariate				Multivariate			
	Odds ratio (OR)	95% C.I. for OR		p-value	Odds ratio (OR)	95% C.I. for OR		p value
		Lower	Upper			Lower	Upper	
Creatinine >1.1 mg/dl	1.400	0.656	2.989	0.346	-	-	-	-
Hemoglobin <12.5 g/dl	1.531	0.726	3.226	0.263	-	-	-	-
LVEF ≤40%	2.013	0.949	4.271	0.068	-	-	-	-
SYNTAX score ≥32.5	3.359	1.530	7.375	0.003	1.929	0.823	4.521	0.131
PCI SYNTAX II ≥41	4.649	2.136	10.118	<0.001	3.941	1.702	9.124	0.001
Incomplete revascularization	6.688	2.833	15.786	<0.001	5.361	2.104	13.661	<.001

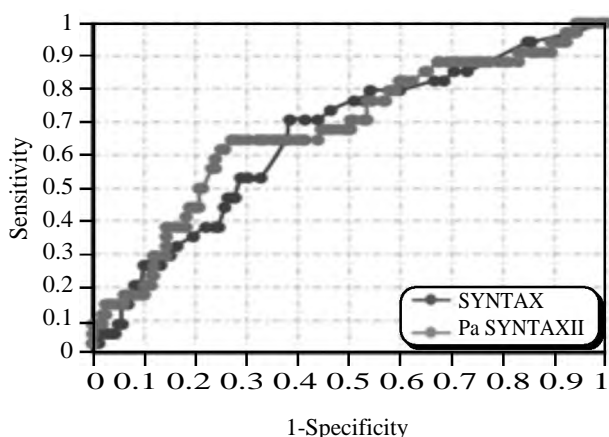


Fig. (1): ROC curve of SYNTAX and SYNTAX II scores for occurrence of six-month MACCE.

**Discussion**

Myocardial revascularization is one of the most extensively studied fields in cardiovascular medicine. More than 20 randomized controlled trials were conducted to test the efficacy and safety of CABG versus PCI in approximately 15 000 patients to cut the Gordian knot of revascularization [20]. Nevertheless, the optimal revascularization strategy for patients with complex CAD is still debated. Although CABG is recommended as the optimal revascularization strategy in preference to PCI in patients with multivessel disease and intermediate to high SYNTAX, PCI is appropriate for patients deemed surgically ineligible or who declined the operation [10].

This registry comprised 193 eligible patients who represent a relatively high-risk population for both patient comorbidities and anatomical com-

plexity. We aimed to study in-hospital and 6-month MACCE in patients with intermediate to high SYNTAX scores percutaneously revascularized due to surgical ineligibility or patient decline. Our study included patients with a mean age of 61 years, comorbidities (20% with previous stroke, 7% PAD, 19% CKD), and impaired LV systolic function with a mean LVEF of 46%. It is also worth mentioning that 43.5% of patients presenting with ACS and 65% were surgically ineligible. Regarding anatomical complexity, the mean SYNTAX score was 32.8±8.4 (31% with L.M. involvement, 38% with CTO, 38% with bifurcation lesions, and 9% with heavily calcified vessels).

We find our results comparable to previously published studies, considering the anatomical complexity and patient comorbidities of the patients assigned to our registry. Regarding the in-hospital study outcomes, the mortality was 3%, MACCE occurred in 7%, while in the 6-month outcomes, the mortality was 4.5%, and MACCE occurred in 17.5%. These results are concordant with the PCI registry in the SYNTAX study, which was conducted more than a decade ago, and included a similar number of patients (192 patients) with a mean SYNTAX score of 31.6±12.3. The PCI registry in the SYNTAX study was analyzed in an intention-to-treat manner, revealing an in-hospital MACCE was 5.7% and a 6-month MACCE was 14.1%.

The incidence of contrast-induced nephropathy (CIN) in the study population was 15.5%, similar to Azzalini et al., who found that CIN developed in 12.1% of the complex PCI group [21]. It is worth mentioning that there was no significant difference in CIN incidence between both intermediate and high SYNTAX groups.

In line with the ESC 2018 revascularization guidelines to consider the anticipated achievement of complete revascularization, 60% of patients achieved complete revascularization in our registry, with a median number of three stents implanted per patient in the whole study. In the SYNTAX PCI registry, complete revascularization was achieved in 36.5% only, albeit with a mean number of stents of 3.1. This discrepancy in the percentage of complete revascularization may be attributed to the different definitions adopted for complete revascularization, which was defined in the SYNTAX study as the treatment of any lesion with more than 50% diameter stenosis in at least one angiographic view in vessels  $>1.5\text{mm}$  as estimated on the diagnostic angiogram during the local Heart Team conference. However, our registry adopted complete revascularization to treat any lesion with more than 70% diameter stenosis in vessels  $>2\text{mm}$  [7].

Our study showed that incomplete revascularization is a strong independent predictor of short-term MACCE. Although no prospective randomized studies compare planned complete versus incomplete revascularization, our study is concordant with several observational studies that have concluded that patients who undergo revascularization with either CABG or PCI have worse outcomes if major epicardial vessels with significant stenoses are not revascularized during the index procedure. In a systematic review and meta-analysis done by Nagaraja et al., including 38 publications and 156240 patients, the occurrence of MACCE was significantly lower in patients who underwent complete revascularization regardless of the definition of complete revascularization and regardless of the complexity of the vessels, even with CTO intervention [22]. Another meta-analysis of 89883 patients by Garcia et al., concluded that MACCE decreases significantly after complete revascularization. Relative to incomplete revascularization, complete revascularization was associated with lower long-term mortality, myocardial infarction, and repeat coronary revascularization [23]. In the ACUITY trial ( $n=13,819$ ), incomplete revascularization after PCI in patients with NSTEMI-ACS with residual one or more untreated lesions with diameter stenosis  $>50\%$  was an independent predictor of MACCE at one year [24]. Our study emphasized the evidence in previous studies by demonstrating the benefit of complete revascularization over incomplete revascularization for MACCE as early as six months.

When considering the patients' anatomical complexity, comparing both intermediate and high SYNTAX score patients, it was found that the high SYNTAX group has a significantly higher in-hospital and 6-month MACCE compared to the intermediate SYNTAX group. These findings concord with the SYNTAX trial, where the one-year MACCE rates, in either the PCI registry or randomized

arm, were significantly higher in the high SYNTAX group compared to the intermediate SYNTAX group [7]. In addition, a retrospective analysis of three-vessel disease in ARTS-II (Arterial Revascularization Therapies Study part II) showed an almost linear increase in 30-day MACCE for patients with an increasing SYNTAX score from low ( $\leq 18$ ) to intermediate (19–26) to high ( $>26$ ), 3% vs. 5% vs. 12% ( $p=0.03$ ) [25]. Therefore, our study adds to the current data that the MACCE rates in intermediate and high SYNTAX groups significantly divert earlier in the in-hospital setting and at six months. This adds weight to the discriminative clinical value of the SYNTAX score. Thus, higher SYNTAX scores that cipher more angiographic complexity portend a worse prognosis.

In our study, the SYNTAX II score (not the SYNTAX score) is an independent predictor of 6-month MACCE. Compared to the SYNTAX score, the SYNTAX score II has two additional anatomical (unprotected left main coronary artery disease and anatomical SYNTAX score) and six clinical variables (age, sex, creatinine clearance, left ventricular ejection fraction, peripheral vascular disease, and chronic obstructive pulmonary disease). Combining clinical and anatomical variables, rather than solely depending on angiographic complexity, has possibly contributed to the predictive value. This agrees with Farooq et al., who showed that SYNTAX II outperformed SYNTAX score in predicting 4-year mortality to support more evidence-based decision-making by the heart team [26]. Besides, Salvatore et al., showed its predictive potential of one-year MACCE in patients with acute coronary syndrome and severe CAD undergoing PCI [27].

#### *Study limitations:*

Although the current study provides information about the contemporary percutaneous treatment of complex coronary artery disease declined for CABG, it is a single-center registry with a six-month follow-up period only. Thus, a large-scale multicenter study in patients who were declined for CABG, with long-term follow-up comparing high-risk PCI against conservative management, is warranted.

#### *Conclusions:*

In conclusion, patients with high SYNTAX scores portend a significantly higher in-hospital and 6-month MACCE and all-cause mortality. In addition, in patients with multivessel disease and SYNTAX score above 22, both incomplete revascularization and clinical SYNTAX II score are independent predictors of short-term (6-month) occurrence of MACCE after PCI. When considering complex multivessel PCI, one should consider the benefits of achievement of complete revascularization and the risks in patients with higher SYNTAX II scores.



**Ethical Statement:****Ethical Approval and Consent to Participate:**

The approval was obtained from the ethical committee at the Faculty of Medicine, Ain Shams University, under registration number (MS. 661/2021). All participants had informed written consent with consideration of adequate privacy and confidentiality in accordance with the seventh revision of the Declaration of Helsinki in 2013.

**Consent for publication:** The patient informed consent form included approval to publish anonymized clinical data.

**Availability of data and material:** The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

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## النتائج السريرية قصيرة الأمد للتدخل التاجي المعقد عن طريق القسطرة في المرضى الذين تم رفضهم جراحياً: سجل معاصر للتدخلات التاجية المعقدة في العالم الواقعي

التدخل التاجي عن طريق القسطرة للشرايين التاجية المعقدة هو مجال سريع التطور. في السنوات الأخيرة ، أدى تطوير تقنيات ومعدات جديدة ، وكذلك تدريب الأطباء المتخصصين، إلى زيادة معدلات نجاحها. على الرغم من أن ترقيع الشريان التاجي قد استخدم في المقام الأول لإعادة السريان الدموي لمرض الشريان التاجي المعقد، ولكن لسوء الحظ في بعض الأحيان لن يكون ترقيع الشرايين خياراً مناسباً.

هدفت هذه الدراسة إلى تطوير سجل إلكتروني لجميع المرضى الذين خضعوا للتدخل التاجي عن طريق الجلد مع وجود معدل SYNTAX متوسط إلى عالي وكانوا في الأصل مؤهلين للجراحة لعمل ترقيع للشرايين التاجية ولكن إما رفض الجراحون العملية أو المريض نفسه قام برفض عمل عملية الترقيع في مستشفيات جامعة عين شمس على مدى ثمانية أشهر. لجمع البيانات حول استراتيجيات العلاج التي تهدف إلى تحليل عوامل الخطر المحتملة وتأثيرها على استراتيجيات العلاج المختلفة والتنبؤ بالنتائج المتعلقة بالنجاح الفنى والإجرائى أثناء الإقامة في المستشفى والمتابعة قصيرة الأجل (٦ أشهر).

شملت دراستنا ١٩٢ مريضاً وتم رفض حوالي ثلثي المرضى من قبل الجراحة ١٢٦ (٦٥٪) ، في حين رفض ٦٧ مريضاً (٣٥٪) الجراحة.

وفيما يتعلق بالتعقيد التشريحي، كان لدى ٦٠ مريضاً (٣١٪) مشاركة في الشريان الأيسر الرئيسي، مع ٥٦ مريضاً (٢٩٪) تم التدخل في الشريان الأيسر الرئيسي، و٧٣ مريضاً (٣٨٪) لديهم انسداد مزمن كلي، مع ٥٤ (٢٨٪) تم التدخل في الانسداد المزمّن الكلي، و ٧٤ مريضاً (٣٨٪) لديهم انسداد متشعب، مع ٦٧ (٣٥٪) تم التدخل في الانسداد المتشعب، ١٨ مريضاً (٩٪) لديهم أوعية متكسدة بشدة، مع استخدام الشنتور الشرياني في ٥ مرضى (٢,٥٪). متوسط معدل SYNTAX هو  $32,8 \pm 8,4$  ، متوسط معدل PCI SYNTAX II هو  $37,5 \pm 10$  ، متوسط معدل EuroSCORE II هو  $2,3 \pm 2,2$  ، متوسط معدل EuorSCORE هو  $4,6 \pm 2,4$  ، متوسط معدل EuroSCORE II هو  $2,3 \pm 2,2$

ومن بين ١٩٢ مريضاً، حقق ١١٥ مريضاً (٦٠ في المائة) إعادة السريان الدموي الكامل، في حين حقق ٧٨ (٤٠ في المائة) إعادة سريان دموى غير مكتمل، حيث بلغ متوسط عدد الدعامات المستخدمة  $2,8 \pm 1$ .

من خلال متابعة المرضى بعد التدخل التاجي المعقد عن طريق الجلد، توفي ٦ مرضى (٣٪) في المستشفى، بينما توفي ٩ مرضى (٤,٥٪) في فترة المتابعة لمدة ٦ أشهر.

معدل الأحداث القلبية والدماغية السلبية الكبرى في المستشفى كان ١٤ مريضاً (٧٪)، في حين أن ٣٤ مريضاً (١٧,٥٪) قد أصابهم حدث أو أكثر من الأحداث القلبية والدماغية السلبية الكبرى في فترة المتابعة قصيرة الأجل لمدة ٦ أشهر.

من خلال مقارنة كل من مجموعات معدل SYNTAX المتوسطة والعالية ، كان لدى مجموعة SYNTAX العالية زيادة كبيرة في انتشار مرض الكلى المزمّن ، وضعف بكفاءة عضلة القلب، ونسبة مشاركة الشريان الأيسر الرئيسي، ومشاركة الانسداد المتشعب، والموت القلبي والأحداث القلبية والدماغية السلبية الكبرى في المستشفى وخلال المتابعة قصيرة الأجل (٦ أشهر).

أثناء مقارنة كل من المجموعات التي أصابها أو لم يصيبها أحد الأحداث القلبية والدماغية السلبية الكبرى، وجد أن الأحداث القلبية والدماغية السلبية الكبرى ترتبط بشكل كبير بانخفاض الهيموغلوبين، وزيادة الكرياتينين، وانخفاض كفاءة عضلة القلب، والمنفذ الفردي، وإعادة السريان الدموى غير المكتمل ، وارتفاع كل من معدلات SYNTAX و SYNTAX II.

في حين تبين أن إعادة السريان الدموى غير المكتمل ومعدل SYNTAX II هي تنبؤات مستقلة بحدوث الأحداث القلبية والدماغية السلبية الكبرى على المدى القصير (٦ أشهر).