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Total Versus Culprit Artery Revascularization in Patients with ST-Segment Elevation Myocardial Infarction Undergoing Primary PCI.

Running Head: Primary PCI in ST segment myocardial infarction patients

Mahmoud Hanafy Kappary (MSc)*, Abdalla Mostafa Kamal (MD)*, Wessam Eldin Hadad El Shafey (MD)*

***Cardiology Department, Faculty of medicine, Menoufia University, Menoufia, Egypt**

Name: Mahmoud Hanafy Kappary (Corresponding author)

Address: Palm City, Mokatam, Cairo, Egypt

Telephone: 01069198936

Email: mahmoud.kappary@gmail.com

Name: Abdalla Mostafa Kamal

Address: Shebin Elkom, Menoufia, Egypt

Telephone: 01000079160

Email: abdthallium2@gmail.com

Name: Wessam Eldin Hadad El Shafey

Address: Shebin Elkom, Menoufia, Egypt

Telephone: 01006420955

Email: wassamelshafey@gmail.com

Abstract

Background: Cases with STEMI may present with multivessel disease in forty percent to sixty-five percent of the patients. Guidelines guide earlier reopening of the Infarct-Related Artery (IRA) by primary PCI, but plaque's instability may develop in many forms leading to many unstable coronary plaques in anatomically far sites.

Objective: to compare 30 days follow-up of complete revascularization Vs. Culprit only in STEMI patients who underwent primaryPCI regarding MACE.

Patients and methods: 70 cases presented with STEMI were categorized into 2 groups; ***Culprit only group*** was thirty-five in number consisting of primary PCI within the guidelines directed time fram of the infarct-related artery via femoral or radial approach according to operator decision. ***Complete Revascularization group*** was thirty-five in number consisting of primary PCI within the guidelines directed time fram of any significant coronary artery stenosis (more than or equal seventy percent luminal narrowing) via femoral or radial approach according to

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operator decision. We compared death rates and outcomes between the 2 groups in hospital and at 30 days.

Results: The results showed 35 patients out of 70 developed MACE, 22 patients belong to Culprit only group, and 13 patients belong to Complete Revascularization Group, as there was statistically significant higher MACE in Culprit Only Group when compared to Complete Revascularization group with p-value (p=0.031).

Conclusions: The total revascularization PCI appears to be safe as culprit artery PCI with effective reduction of refractory angina and repeated hospital admissions and revascularization but no benefit on mortality or recurrent MI.

Keywords: Culprit, infarct-related artery, complete revascularization, Preventive PCI.

Background

Coronary heart disease (CAD) is the leading cause of death worldwide. More than 7 million people die from CAD each year, accounting for 12.8% of deaths. In Europe, one in six men and one in seven women die of myocardial infarction (MI). The hospital death of STEMI cases in the national registries of ESC countries differs between six and fourteen percent **[1].**

Fifty percent of cases with STEMI and having primary PCI have MVD; (known as equal or more than fifty percent stenosis in equal or more than one non-infarct related artery) **[2].**

Patients with MVD and STEMI have the worst thirty-day outcome, mainly related to disease, heart ischemia, or vulnerable plaques **[3].**

Management of those patients has been a matter of debate. Earlier, observational data showed no benefit in performing multivessel PCI (MV-PCI) in those patients due to their critical condition, longer procedure time, and a large amount of contrast being used **[4,5].**

Recent trials have revived the debate and provided data suggesting that MV-PCI in STEMI patients may improve patient outcomes **[6].**

Due to different study selection criteria, PCI timing, procedural techniques, and study endpoints, there is a shortage of consensus on the optimal treatment for these patients **[7]**.

Earlier, American College of Cardiology and American Heart Association guidelines voted against complete revascularization, gave it Class III (harmful) evidence, and only recommended the consideration of multivessel PCI in hemodynamically unstable patients **[8].**

Then recently has been updated considering the increase in data supporting the procedure, and the classification has been upgraded to Class IIb **[7].**

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Meanwhile, the ESC / EACTS Revascularization Guidelines stated that routine pre-discharge revascularization of non-IRA lesions in patients with multivessel disease should be considered (Class IIa) **[9]**.

This means that in hemodynamically stable patients, multivessel PCI is considered and can be performed during the index procedure or in a stepwise staged approach **[7].**

The aim of this work is to compare 30 days follow-up of complete revascularization Vs. Culprit only in STEMI patients who underwent primary PCI regarding MACE.

Methods

A total of 70 patients presented with STEMI at Nasr city insurance and Menofia university hospitals had been prospectively selected for this study Between January 2020 and November 2021. The cases were categorized into 2 groups, *Culprit only group were thirty-five in number,* consisting of primary PCI within the guidelines directed time fram of the infarct-related artery via femoral or radial method according to operator opinion, and *Complete Revascularization group were thirty-five in number* consisting of primary PCI within the guidelines directed time fram of any significant coronary artery stenosis (≥70%luminal narrowing) via femoral or radial method according to operator opinion. Then, we compared complications (CIN, Major bleeding, Cardiogenic shock, stroke, need for urgent CABG and cardiac mortality) between the 2 groups in hospital and after thirty days.

Ethical consideration :All cases signed a written informed consent with explaining the aim of study before the study initiation. Approval of the study protocol was obtained by Ethical Scientific Committee of Menoufia University Hospital.

Cases with STEMI and multivessel CAD were selected for this study according to the following criteria:

Inclusion criteria were Patients presented with STEMI and 18 years old or older and had symptoms within 12 hours.

Exclusion criteria were cases who had previous pci, previous CABG, recent thrombolysis, left main disease, single vessel disease, diffuse calcified or severe abnormality lesion side branch more than two mm needing a stent, valvular disease, cardiogenic shock, mechanical cardiac complication requiring surgical intervention, and unsuccessful procedures.

All patients were evaluated by history taking regarding demographic data, past history, previous IHD and Analysis of chest pain , Complete general and local cardiac examination, 12-lead ECG, Laboratory investigations were done including Cardiac markers, total CK , CK-MB and Troponin –I on admission and then serially every 8 years for 24 hours, then daily till normalization, , serum creatinine , ALT, AST, Complete blood picture, random blood sugar.

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Echocardiography to assess ejection fraction (EF), assessment of rest segmental wall motion abnormalities (SWMA) and any valvular lesions.

Results

No difference was detected in clinical manifestations between the two groups (table 1).

Although the complete revascularization group took significantly more contrast amount (236.29±31.44 vs. 157.43±16.33, P<0.001) and no significant difference in periprocedural safety outcomes of significant bleeding and CIN rates (5.7% vs. 2.9%, p=0.555) (table 2).

The study did not show any significant statistical difference between the 2 groups regarding total mortality (5.7% vs 0%, P= 0.151), stroke (0 %in both groups), STEMI (5.7% vs 2.9%, P=0.555), CHF (20.0% vs 8.6%, P=0.172), CABG (5.7% vs 2.9%, P=0.555) (table 3).

However there was an increase in CCU stay (4.11±0.99 vs 5.43±1.84, P <0.001), refractory angina and rsehospitalization for cardiac cause in Culprit only group vs Complete Revascularization group (table 4)

The results also showed 35 cases out of 70 having major adverse cardiac events (MACE), with percent 50%, 22 cases belong to Culprit only group, and 13 cases belong to the Complete Revascularization group, as there was a statistically significant higher MACE in Culprit Only group compared to complete revascularization group with p-value (p=0.031) (Figure 1).

DISCUSSION

PCI is recently the treatment of choice for cases with STEMI. CAD is a diffuse process, and cases with coronary artery syndrome have many significant coronary artery lesions in twenty to forty percent of cases and are at risk of cardiovascular morbidity and mortality **[10].**

New studies suggest that acute coronary syndromes, including AMI, may result from a systemic inflammatory process, leading to many unstable, vulnerable plaques. So, PCI at a specific time may be useful in improving the results of primary revascularization **[11].**

Such attempts at complete revascularization prevent repeated ischemia from " non-infarct-related " lesions; avoid the need for recurrent interventions, and decrease ischemic stress after myocardial damage. It may also improve the late outcomes **[12].**

With the advancement in technology, recent antiplatelet drugs and results from four major randomized trials-**PRAMI [13], CvLPRIT [14], DANAMI-3-PRIMULTI [15],** and **Compare-Acute [9]** the benefit of complete revascularization (performed immediately or staged) have been confirmed when compared to culprit-only PCI in patients presenting with STEMI and multivessel disease.

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A recent meta-analysis has proved that MV-PCI in STEMI patients was associated with a lower risk of MACE, due to a lower risk of urgent revascularization, with no significant difference in mortality **[16].**

However, as in previous trials, the benefits of MV-PCI in STEMI patients over the IRA-only revascularization seen in Compare-Acute were emphasized by the reduced need for repeated revascularization, but death and recurrence. The incidence of death and myocardial infarction were similar between both strategies **[9].**

Based on these results, the latest 2018 ESC Guidelines for Revascularization considered complete revascularization in patients with multivessel disease pre-discharge is (Class IIa), while IRA-only PCI is the default strategy in patients with STEMI and cardiogenic shock **[17].**

This study was designed to compare the clinical outcomes of the complete revascularization group (Culprit and non-Culprit artery PCI) with Culprit only group in hemodynamically stable patients presenting with STEMI and multivessel CAD.

This study demonstrated that total revascularization PCI for STEMI and MVD significantly reduced MACE, rehospitalization for cardiac cause, and refractory angina, with no benefit on mortality or recurrent MI at 30 days follow up than when only the culprit artery was treated. Concerning periprocedural safety outcomes of stroke, major bleeding, and CIN rates, we demonstrated no significant difference in patients undergoing complete versus Culprit only PCI.

In the current study, no statistically significant differences were found between preventive PCI and Culprit artery PCI regarding age and sex. The mean age of the total revascularization PCI group was (56.40±9.43) years, and the female subject represented (28.6%). In the Culprit artery PCI group, the mean age was (55.14±9.29) years, and female subjects represented (22.9%). This is in agreement with other studies comparing culprit artery versus MVR strategies. **In *Wald DS et al. 2013[13]***, the mean age of both groups was sixty-two years, and female subjects represented 24% in the preventive PCI group while 19% in the non-preventive PCI group. **In *Gershlick et al. 2015[14],*** the mean age of the complete revascularization group was 64.6 ±11.2 years, and the female subject represented 14.7% while the IRA-only revascularization group was 65.3±11years and female subject represented 23.3%. Also, no statistically significant differences were found between total revascularization PCI and culprit artery PCI regarding hypertension, hyperlipidemia, and family history of CAD; 29% vs. 20%, 29% vs. 22%, and 13%vs 9%, respectively. This is concordant with other studies as ***Dahud Q et al. 2014*****[18]** that found no statistically significant difference between complete revascularization and Culprit only PCI as regard hypertension, hyperlipidemia, and diabetes; 45.7%vs 40.0%, 40.0% vs. 42.9%, and 22.9 %vs. 25.7% respectively.

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In addition, there was no significant difference regarding the anterior and non-anterior infarct location between the two groups, but inferior infarction represented 47 % in both groups. This contradiction may be due to bias in patient selection. This disagreed with ***Dahud Q et al. 2014*** **[18],** where rates of anterior wall infarction were 51.3% in the two groups (p=0.16). Nevertheless, in ***Wald DS et al. 2013*****[13],** there were significantly less anterior and more non-anterior infarction in the total revascularization PCI compared to culprit artery PCI

In our study, MVD with STEMI was defined as angiographic diameter stenosis ≥ 70 % in ≥ 1coronary arteries other than IRA, this agreed most studies, but ***Wald DS et al. 2013[13]***, ***Barringhaus et al. 2010*****[19]**; reported that the non-culprit artery stenosis was ≥ 50%. In ***Engstrøm et al. 2015*****[15],** patients with more than fifty percent angiographic diameter stenosis in ≥ 1 non-IRA participated in their study because they found that FFR-guided revascularization before discharge the complexity of CAD was the same in the 2 groups, and the LM disease was excluded. The incidence of 2 or 3 vessel disease was not statistically significant between the two studied cohorts (89 %vs. 86%, 11% vs. 14% respectively P=0.721), which was discordant with ***A.R.Santos et al. 2014*****[20]** that revealed patients with culprit artery PCI had a higher prevalence of three-vessel disease (27.3% vs. 31.8%; p<0.001), also the two groups were comparable in preprocedural TIMI flow in the culprit artery, (p= 0.755). This is agreed with ***Hyun Su Jo et al. 2011*****[21]** who reported similar preprocedural TIMI flow in the culprit artery among the studied groups (p=0.131).

In our study, there was a higher rate of contrast dye used in the preventive PCI (236.29±31.44 vs. 157.43±16.33, p=0.044). In contrary with ***Gershlick et al. 2015*** who demonstrated a higher rate of contrast dye used in the complete revascularization (190–330 ml vs. 150–250 ml, p<0.0001) and discordant with ***Khattab AA et al. 2008*****[22],** who reported no significant difference in the rate of contrast dye use between MV-PCI and culprit-only PCI (p=0.16), this may be explained by the smaller number of MV- PCI (28 patients) as compared by (45 patients) in culprit-only PCI in his study.

In the hospital, mortality was 2.9% **(**2 patients in Culprit only group). In ***A.R. Santos et al. 2014***, overall mortality was 5.2%, with a non-significant difference of 7.8% vs. 2.6% between the two groups. This may be explained by a small number of our studied patients (70) vs. (257) in ***A.R. Santos et al. 2014***.

Complete revascularization has been shown to increase contrast agent usage, longer procedure time, and more radiation exposure, mainly when performed simultaneously with the index primary PCI of the causative lesion **[14]**

Pooled analysis of **CVLPRIT**, **PRAMI,** and **Politi et al. [23]** showed no increase in CVA, hemorrhage, or contrast-induced nephropathy. Therefore, it was suggested that while complete revascularization may increase procedure time and contrast consumption, this does not lead to an increased risk of adverse events. Similarly, in the DANAMI3 and PRIMULTI studies, there was no significant

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incidence of perioperative myocardial infarction, stroke, contrast-enhanced nephropathy, or bleeding between the two revascularization strategies [**24**].

Our results were concordant with the previous data; (CIN 5.7% vs 2.9% p=0.555), and (Major bleeding 0% vs 2.9%p=0.314).

In contrast, Zhang D et al. 2014 **[25]** multivessel-PCI was associated with a short-term increase in mortality. In the hospital or 30 days, 4.83% of culprit PCI died compared to 6.93% who received MV-PCI (OR: 0.50, 95% CI: 0.32-0.77, p = 0.002). In addition, MVPCI may increase the risk of renal impairment due to high doses of contrast agents (CIN).

In our study, cardiogenic shock was more in the culprit artery cohort 8.6% vs. 2.9%, but a statistically insignificant value(p=0.303). ***A.R. Santos et al.* 2014[20]** showed that HF was the most common side effect in 2 cohorts and was higher in the culprit artery group, 30% vs. 19.5%, but this was of no statistically significant value, ***Qarawani et al.* 2008 [26]** reported a higher rate of acute left heart failure in 32% of the Culprit only PCI cohort when compared to 9.4% in the multi-vascular PCI cohort (P = 0.02).

In our study, the 30 days follow up showed that cardiac mortality was less in the complete Revascularization cohort in spite of insignificant factor 0.0% vs. 5.7%, p=0.151. while There was no non-cardiac mortality in both groups. Also, there was no increase in reinfarction in both groups (STEMI; 2.9% vs. 5.7% p=0.555). refractory angina was significantly less in the complete revascularization group (8.6% vs. 34.3% p= 0.009), which led to a significant decrease of rehospitalization for cardiac cause in the complete Revascularization group (20.0% vs. 42.9 %p<0.039).

As with ***CvLPRIT and PRAMI, DANAMI3-PRIMULTI*** study also showed the benefits of supporting complete revascularization (HR = 0.56, 95% CI = 0.38-0.83, P = 0.004). However, there was no significant difference in all-cause mortality or non-fatal myocardial infarction between the two groups, and the reduction in composite endpoints was primarily due to the decreased numbers of ischemia-related revascularization in the FFR-controlled complete revascularization cohort (HR = 0, 31, 95% CI = 0.18-0.53, P <0.001). It should be noted that the two trials comparing the Culprit only with the primary MV-PCI involved patients with staged PCI, and the results were often reported as primary multivessel-PCI **[14, 23]**.

Proper treatment of these patients was also a topic repeatedly discussed in the meta-analysis. **El Hayek et al. In 2015 [24],** an RCT meta-analysis of 1044 patients showed beneficial results in an MV-PCI strategy compared to Culprit vessel-only revascularization, that showed a statistically significant decrease in recurrent myocardial infarction, all-cause mortality, and the need for repeated interventions without an increased risk of complications (including contrast-induced nephropathy, stroke or major bleeding).

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In contrast, **Baney and others. 2014 [27]** confirmed an increased risk of death from MV-PCI performed in this primary PCI setting but stagged MV-PCI is better than IRA only revascularization. It is associated with decreased in-hospital and long-term mortality with staged MV-PCI compared to increased hospital mortality in multivessel PCI during the index procedure.

The 2015 ACC / AHA / SCAI-focused update recommendations did not differentiate between primary multivessel-PCI and staged PCI but instead gave (class IIb) recommendations for multivessel PCI **[7].** However, the studies included did not meet this limitation of current evidence because the timing of complete revascularization was different **[28].**

In complete trial 2019, with a follow-up period of 3 years, the first co-primary outcome was 158 (7.8%) of the 2016 patients in the complete revascularization group compared to 213 (10.5%) of 2025 patients in the culprit-lesion-only PCI group (hazard ratio, 0.74; 95% confidence interval [CI], 0.60 to 0.91; p= 0.004). The second major outcome occurred in 179 patients (8.9%) in the complete revascularization group, compared with 339 patients (16.7%) in the culprit-lesion-only PCI group (hazard ratio 0.51; 95% CI). 0.43 to 0.61, P <0.001) **[29].**

From the previous data, based on individual and careful patient and lesion assessments, preventive PCI can be done safely with less need for further revascularization and reduced risk of refractory angina in STEMI with MVD.

Conclusions

The total revascularization PCI appears to be safe as culprit artery PCI at 30 days follow up with effective reduction of refractory angina and repeated hospital admissions and revascularization but no benefit on mortality or recurrent MI in certain hemodynamically stable STEMI patients with multivessel disease.

Decisions regarding PCI for non-infarcted vessel(s) must be made case by case and We Recommend Larger RCTs with longer follow-up periods that can help solve this dilemma.

List of abbreviations

ACS: acute coronary syndrome

CAD: coronary artery disease

CIN: Contrast induced nephropathy

CR: complete revascularization

CP2B: Chest pain to ballon time

CVD: Cardiovascular disease

EF: Ejection fraction

FFR: Fractional Flow Reserve

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IRA: infarct-related artery

MACE: major adverse cardiac events

MV- PCI: Multivessel PCI

MVD: Multivessel disease

MVR: Multivessel Revascularization

PCI: percutaneous coronary intervention

STEMI: ST elevation myocardial infarction

TIMI: Thrombolysis in Myocardial Infarction

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Figure (1): Comparison between both groups according to major adverse cardiac events (MACE).

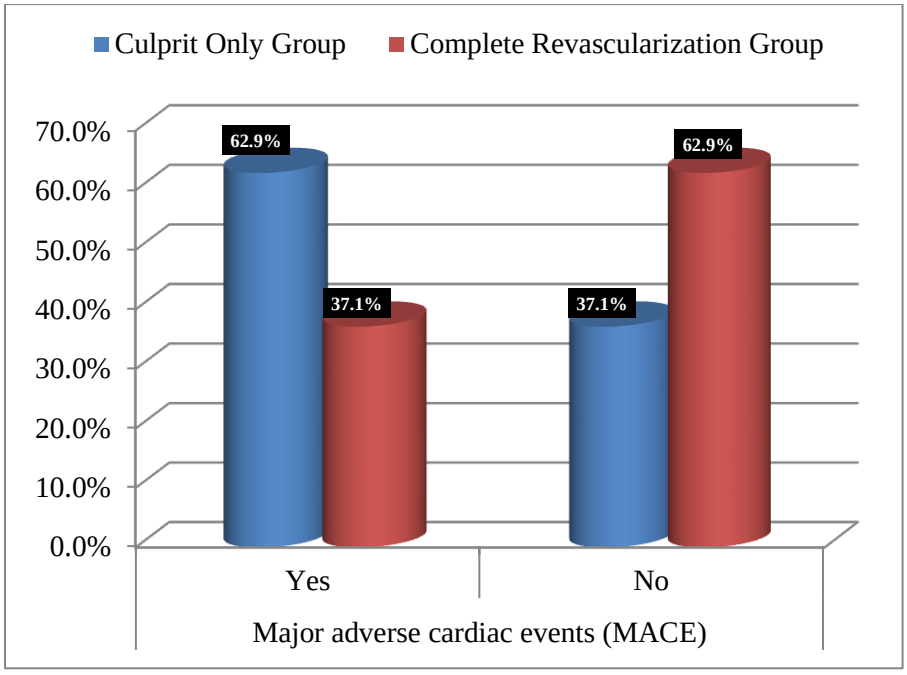

Figure (2): Hazard ratio curves of cumulative event rate for both groups.

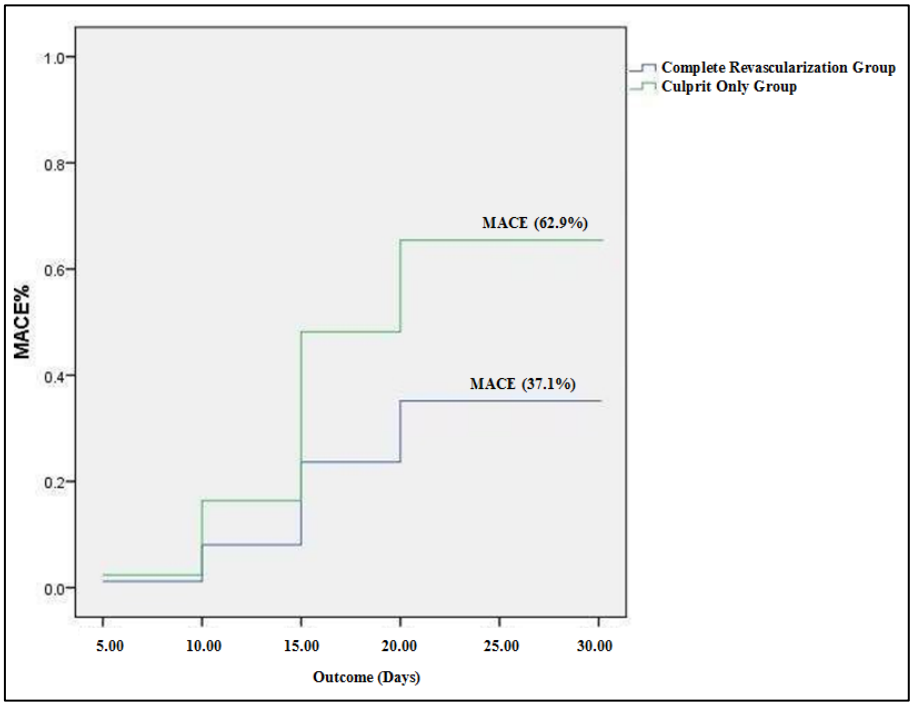

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Table (1): Comparison between both groups according to demographic data and Risk factors

Demographic data	Total (n=70)	Culprit Only Group (n=35)	Complete Revascularization Group (n=35)	Test value	p-value
Age (year)					
Mean±SD	55.77±9.31	55.14±9.29	56.40±9.43	t=-0.562	0.576
Range	37–77	39–74	37–77		
Sex					
Female	18 (25.7%)	8 (22.9%)	10 (28.6%)	x2=0.299	0.584
Male	52 (74.3%)	27 (77.1%)	25 (71.4%)		
Risk Factors					
DM	17 (24.3%)	9 (25.7%)	8 (22.9%)	0.078	0.780
Current smoker	47 (67.1%)	23 (65.7%)	24 (68.6%)	0.065	0.799
HTN	30 (42.9%)	14 (40.0%)	16 (45.7%)	0.233	0.629
Dyslipidemia	29 (41.4%)	15 (42.9%)	14 (40.0%)	0.059	0.808
Family history of CAD	15 (21.4%)	8 (22.9%)	7 (20.0%)	0.085	0.771

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Table (2): Comparison between both groups according to PCI strategy.

PCI strategy	Total (n=70)	Culprit Only Group (n=35)	Complete Revascularization Group (n=35)	Test value	p-value
Thrombectomy devise use	5 (7.1%)	1 (2.9%)	4 (11.4%)	x^2=1.938	0.164
GPIIb/IIIa use	13 (18.6%)	7 (20.0%)	6 (17.1%)	x^2=0.094	0.759
Procedure success	67 (95.7%)	34 (97.1%)	33 (94.3%)	x^2=0.348	0.555
Contrast amount (ml)					
Mean±SD	196.86±46.86	157.43±16.33	236.29±31.44	z=-13.167	<0.001**
Range	130–310	130–190	200–310		
CP2B duration (hrs.)					
Mean±SD	5.43±2.33	5.66±2.67	5.20±1.94	z=-0.794	0.427
Range	1–11	1–11	1–10		

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Table (3): Comparison between both groups according to in hospital complications.

Inhospital complications	**Total (n=70)**	**Culprit Only Group (n=35)**	**Complete Revascularization Group (n=35)**	**x^2-test**	**p-value**
Cardiac death	2 (2.9%)	2 (5.7%)	0 (0.0%)	2.059	0.151
CIN	3 (4.3%)	1 (2.9%)	2 (5.7%)	0.348	0.555
Major bleeding	1 (1.4%)	1 (2.9%)	0 (0.0%)	1.014	0.314
Card. Shock	4 (5.7%)	3 (8.6%)	1 (2.9%)	1.061	0.303
Stroke	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.000	1.000
Urgent CABG	0 (0.0%)	0 (0.0%)	0 (0.0%)	0.000	1.000

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Table (4): Comparison between both groups according to the one-month outcomes after hospital discharge.

One month outcome after Hospital Discharge	Total (n=70)	Culprit Only Group (n=35)	Complete Revascularization Group (n=35)	Test value	p-value
CCU stay (days) Mean±SD Range	4.77±1.61 3–12	4.11±0.99 3–7	5.43±1.84 4–12	z=-3.665	<0.001**
Cardiac death	2 (2.9%)	2 (5.7%)	0 (0.0%)	*FE*	0.151
STEMI	3 (4.3%)	2 (5.7%)	1 (2.9%)	*FE*	0.555
CHF	10 (14.3%)	7 (20.0%)	3 (8.6%)	*FE*	0.172
Refractory Angina	15 (21.4%)	12 (34.3%)	3 (8.6%)	*FE*	0.009*
CABG	3 (4.3%)	2 (5.7%)	1 (2.9%)	*FE*	0.555
Stroke	0 (0.0%)	0 (0.0%)	0 (0.0%)	*FE*	1.000
Rehospitalization for cardiac cause	22 (31.4%)	15 (42.9%)	7 (20.0%)	x^2=4.242	0.039*