PAKISTAN JOURNAL OF Cardiovascular Intervention

OPEN ACCESS

ORIGINAL ARTICLE

30 (thirty) days mortality in patients with left main coronary artery disease treated with percutaneous coronary intervention versus coronary artery bypass grafting having intermediate syntax score.

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Citation:
Suleman M, Arif N, Khan BU, Khalid F, Jibran MS, Shehram M, Khan SU, Aziz S, Maken GR, Samore NA. 30 (thirty) days mortality in patients with left main coronary artery disease treated with percutaneous coronary intervention versus coronary artery bypass grafting having intermediate syntax score. PJCVI. 2023; 3(1): 10-17

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DOI: 10.58889/PJCVI.4.10.17

Funding:
This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflicts of Interests:
The authors have declared that no competing interests exist.

Received 09/03/2023
Accepted 24/04/2023

Abstract

Background: This study aims to compare the 30-day mortality rates of Percutaneous Coronary Intervention (PCI) and Coronary Artery Bypass Grafting (CABG) in patients with Left Main Coronary Artery Disease (LMCAD) and intermediate Syntax Score.

Methodology: A total of 307 patients who underwent revascularization for LMCAD and met the study's inclusion and exclusion criteria were included. Informed verbal consent was obtained, and pre-procedural data were collected. Descriptive statistics were used to present quantitative data, while qualitative variables were presented as frequencies and percentages. Effect modifiers were controlled through stratification, and chi-square tests were applied with a significance level of $p \leq 0.05$.

Results: Of the 307 patients, 156 underwent PCI and 151 underwent CABG. The mean age of the study population was 63.60 (±9.23) years, with similar average ages in the PCI (63.67 ± 9.22) and CABG (63.52 ± 9.27) groups. Among the patients, 256 (83.66%) were male and 51 (16.61%) were female. The overall 30-day mortality rate for LMCAD revascularization was 5.9% (18 out of 307). The mortality rate in the PCI group was 5.1%, while in the CABG group, it was 6.6%, but no statistically significant difference was observed (p-value = 0.633). The effect modifiers were similar in both groups, except for a higher prevalence of hypertension in the CABG group, which did not significantly affect mortality.

Conclusion: This study demonstrates that the 30-day mortality rates in CABG are higher but not statistically significant compared to PCI in patients with LMCAD and intermediate Syntax Score. Both PCI and CABG can be considered as treatment options for patients with intermediate Syntax Score, with similar risks.

Keywords

Left Main Stem Disease, Coronary Artery Bypass Grafting, Per-cutaneous Coronary Intervention.

Published by Pakistan Society of Interventional Cardiology

Introduction

Cardiovascular disease (CVD) accounts for approximately 800,000 deaths in the United States (US), which is equivalent to one out of every three deaths[1]. On average, one person dies from CVD every 40 seconds in America. The majority of CVD deaths are caused by coronary heart disease (CHD), followed by stroke and heart failure[2]. Left Main stem coronary artery disease (LMCAD) refers to the narrowing of the Left main coronary artery and has a reported prevalence of 4.8% in patients with coronary artery disease, according to a larger study. LMCAD is a highly dangerous condition due to the significant amount of at-risk myocardium, with an approximate mortality rate of 50% within three years[3].

Coronary artery bypass graft surgery (CABG) has been the established treatment for unprotected left main coronary artery disease (ULMCAD) for nearly 40 years[2,4]. Initially, percutaneous coronary intervention (PCI) using balloon angioplasty for ULMCAD yielded poor results. However, the introduction of coronary stents and improvements in technique have led to progressively better outcomes[5].

Any complication during Percutaneous Coronary Intervention (PCI) can potentially cause extensive myocardial damage and even death[6]. Therefore, traditional practice has favored coronary artery bypass grafting (CABG) as the gold standard for treating these lesions. With the development of modern interventional procedures and the use of the latest generation of drug-eluting stents, along with encouraging results from the SYNTAX and EXCEL trials, PCI is now considered an acceptable alternative to CABG[7].

The Syntax score is a semi-quantitative anatomical angiographic score used to assess the complexity of coronary artery disease[8,9]. It helps cardiologists decide whether to choose CABG or PCI as the primary management option for their patients[10]. Subgroup analysis of the Syntax trial showed that PCI is a good alternative to CABG in patients with LMCAD and low to intermediate syntax scores. Since the study was not specifically powered for this outcome, the EXCEL trial was designed to address the controversy. The trial results demonstrated that PCI is non-inferior to CABG in patients with LMCAD and low to intermediate syntax scores, with a mortality rate of 4.9% in the PCI arm and 7.9% in the CABG arm. However, the controversy remains regarding the treatment of LMCAD patients with intermediate syntax scores, particularly in light of the NOBEL trial, which showed that CABG is superior to PCI in these patients.

To address this controversy and compare the 30-day outcomes in LMCAD patients with intermediate syntax scores, we have designed this study to evaluate the effectiveness of CABG versus PCI.

Methodology

Study Setting:

The study was conducted at the Armed Forces Institute of Cardiology/National Institute of Heart Disease Rawalpindi, Pakistan, over a period of 6 months from 31 August 2019 to 29 February 2020.

Sampling Method:

Non-random consecutive sampling was employed to select patients who underwent CABG or PCI for left main coronary artery disease during the study period.

Sample Size Calculation:

Based on the results of the EXCEL trial, which reported 30-day mortality rates of 4.9% for PCI and 7.9% for CABG, the sample size was calculated using the WHO calculator. With a confidence level of 95%, an anticipated population proportion of 4.9%, and an absolute precision of 2.5%, the calculated sample size was determined to be 290 patients.

Inclusion Criteria:

Patients of both genders, aged 30 years and above, diagnosed with LMCAD (defined as lesions with stenosis of at least 50% of vessel diameter) and intermediate syntax scores (defined as syntax scores ranging from 23 to 32), were included in the study.

Exclusion Criteria:
Patients with a history of previous PCI or CABG, acute coronary syndrome within the past week, and contraindications to dual antiplatelet therapy in the PCI arm were excluded from the study.

Ethical Considerations:
After obtaining approval of the study synopsis, patients who met the inclusion criteria and underwent CABG or PCI for left main coronary artery disease were selected. As patients were undergoing routine management procedures, the ethical committee of the hospital advised that no formal approval was required. To control confounding bias, patients who met the exclusion criteria were excluded from the study. Informed consent was obtained from all participating patients.

Data Collection:
A detailed history and physical examination were conducted before the procedure. Patient biodata and pre-procedural variables were recorded by a resident cardiologist. The total SYNTAX score was calculated by summing the individual scores for each separate lesion with stenosis of ≥50% in vessels ≥1.5 mm. Two out of three experienced residents, who were blinded to procedural data and clinical outcomes, computed all angiographic variables. In case of disagreement, the opinion of a third observer was sought, and a consensus decision was reached.

Interventional Procedures:
The interventional strategy, including the choice of devices and administration of therapies during the procedure, followed the hospital's standard practice. Patients treated with drug-eluting stents (DES) were prescribed dual antiplatelet therapy (DAPT) for at least 6 months. Aspirin was prescribed indefinitely for all patients, regardless of whether they underwent PCI or CABG.

Surgical Revascularization:
Surgical revascularization was performed using standard bypass techniques. The choice of grafts and surgical technique was left to the discretion of the surgeon. Post-procedure medication regimens were determined based on local clinical practice.

Data Collection and Follow-up:
Post-procedure variables were recorded by resident cardiologists either in the catheterization lab or after the patient's transfer to the post-catheterization ward or Intensive Care Unit. After 30 days, patients were called for follow-up. In cases where patients failed to appear for the follow-up visit, they were contacted by phone to inquire about their well-being and record the outcome variable of mortality.

Statistical Analysis:
Descriptive statistics were used to summarize the categorical variables (e.g., gender, diabetes, hypertension, dyslipidemia, smoking, angina class, dyspnea class, history of acute coronary syndrome) as frequencies, while continuous variables (e.g., age, ejection fraction) were reported as mean ± standard deviation. The outcome variable of 30-day mortality was compared using chi-square analysis, considering p-value < 0.05 as statistically significant. Stratification was applied to control for effect modifiers such as age, gender, diabetes, hypertension, and ejection fraction. Post-stratification chi-square analysis was performed. Statistical analysis was conducted using SPSS version 21, and Microsoft Excel was used to generate graphs.

Results

Between August 30, 2019, and February 15, 2020, a total of 307 consecutive patients who met the inclusion criteria were included in the study. Among them, 256 (83.39%) were male and 51 (16.61%) were female. The overall mean age was 63.60 (±9.23) years, as presented in Table 1, which showed no statistically significant difference.

Table 1: Basic descriptive statistics of both groups

Variables	Total (n= 307)	PCI group (n= 156)	CABG group (n= 151)	P-value
Males	256 (83.39%)	128 (82.05%)	128 (84.77%)	0.54
Age	63.60 (±9.23)	63.67 (±9.22)	63.52 (±9.27)	1.0

Table 2 provides a comparison of risk factors between the two groups. Hypertension was the most common risk factor, with an overall frequency of 45.93%. Its prevalence was 56.29% in the CABG group and 35.90% in the PCI group, showing a statistically significant difference (P-value 0.0004). Other risk factors, such as Diabetes Mellitus (32.25% overall, 28.21% in PCI, and 36.42% in CABG) and Smoking and Dyslipidemia (39.74% and 28.66% overall, respectively), did not show significant statistical differences.

Table 2: Risk factors comparison of Both group

Variable	Total (n= 307)	PCI Group (n= 156)	CABG Group (n= 151)	P-value
Diabetes	99 (32.25%)	44 (28.21%)	55 (36.42%)	0.14
Hypertension	141 (45.93%)	56 (35.90%)	85 (56.29%)	0.0004
Dyslipidemia	88 (28.66%)	45 (28.85%)	43 (28.48%)	1.0
Smokers	122 (39.74%)	64 (41.03%)	58 (38.41%)	0.64

Table 3 displays the mean syntax score, which was 27.49 (±3.44) overall. There was no statistically significant difference between the PCI group (27.23 ±3.31) and the CABG group (27.75 ±3.56).

Table 3: Syntax score comparison of Both group

	Total (n= 307)	PCI Group (n= 156)	CABG Group (n= 151)	P-value
Syntax Score	27.49 (±3.44)	27.23 (±3.31)	27.75 (±3.56)	0.19

Symptom comparison in both groups is presented in Table 4, with the majority of patients falling under Angina CSS class III and Dyspnea NYHA class II. No significant statistical difference was observed between the groups.

Table 4: Symptoms comparison of Both group

	Total (n= 307)	PCI group (n= 156)	CABG group (n= 151)	P-value
Angina				0.25
None	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Class I	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Class II	153 (49.84%)	83 (53.21%)	70 (46.36%)	
Class III	154 (50.16%)	73 (46.79%)	81 (53.64%)	
Class IV	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Dyspnea				0.48
None	67 (21.82%)	36 (23.08%)	31 (20.53%)	
Class I	75 (24.43%)	34 (21.79%)	41 (27.15%)	
Class II	95 (30.94%)	46 (29.49%)	49 (32.45%)	
Class III	70 (22.80%)	40 (25.64%)	30 (19.87%)	
Class IV	0 (0.00%)	0 (0.00%)	0 (0.00%)	

Table 5 provides a comparison of diagnostic investigations between the two groups. The average serum creatinine levels were 1.03 (±0.43) overall, 1.04 (±0.21) in the PCI group, and 1.03 (±0.57) in the CABG group, showing a statistically significant difference (P-value < 0.0001). Overall, the mean ejection fraction was 53.49% (±8.76), with no significant statistical difference observed between the groups.

The effect modifier "History of ACS" was present in 47.23% of patients overall, with no significant statistical difference between the PCI group (50.00%) and the CABG group (44.37%). Hemoglobin and platelet levels were on average 12.96 (±1.40) and 233.85 (±65.97), respectively, with no significant statistical difference.

Table 5: Diagnostic Investigation comparison of Both group

Variables	Total (n= 307)	PCI group (n= 156)	CABG group (n= 151)	P-value
Ejection Fraction	53.49 (±8.76)	53.72 (±8.36)	53.25 (±9.17)	0.059
Creatinine	1.03 (±0.43)	1.04 (±0.21)	1.03 (±0.57)	< 0.0001
Hemoglobin	12.96 (±1.40)	12.79 (±1.41)	13.13 (±1.37)	0.062
Platelets	233.85 (±65.97)	232.55 (±65.18)	235.19 (±66.96)	0.49
History of ACS	145 (47.23%)	78 (50.00%)	67 (44.37%)	0.36

Table 6 presents the severity of the disease, with 48.21% of patients having DVCAD and 51.79% having TVCAD. There was no significant statistical difference between the two groups.

Table 6: Disease Severity comparison of Both group

	Total (n= 307)	PCI (n= 156)	CABG (n= 151)	P-value
Number of Vessels				**0.82**
SVCAD	0 (0.00%)	0 (0.00%)	0 (0.00%)	
DVCAD	148 (48.21%)	74 (47.44%)	74 (49.01%)	
TVCAD	159 (51.79%)	82 (52.56%)	77 (50.99%)	

Table 7 illustrates the outcome variable of 30-day mortality and its comparison between the two groups. The overall mortality rate was 5.9%. The PCI group had a 30-day mortality rate of 5.1% (8 out of 156 patients), while the CABG group had a rate of 6.6% (10 out of 151 patients). However, there was no statistically significant difference (P-value = 0.633).

Table 7: Mortality comparison in both groups

Variables			Procedure		Total
			PCI group	CABG group	
Mortality	**Yes**	Count	8	10	18
		% within Procedure	5.1%	6.6%	5.9%
	No	Count	148	141	289
		% within Procedure	94.9%	93.4%	94.1%
Total		Count	156	151	307
		% within Procedure	100.0%	100.0%	100.0%

*Fisher's Exact Test P value = 0.633

Effect modifiers such as age, gender, diabetes, hypertension, dyslipidemia, angina, dyspnea, ejection fraction, biochemical profile, history of ACS, and severity of disease did not have a statistically significant effect on mortality, as indicated in Table 8.

Table 8: Factors Association with Mortality

Variables	Total (n= 307)	Died (n= 18)	Alive (n=289)	P-value
Gender	256 (83.39%)	13 (72.22%)	243 (84.08%)	0.19
Age	63.60 (±9.23)	68.11 (±9.04)	63.31 (±9.19)	0.33
Diabetes	99 (32.25%)	7 (38.89%)	92 (31.83%)	0.60
Hypertension	141 (45.93%)	10 (55.56%)	131 (45.33%)	0.47
Dyslipidemia	88 (28.66%)	4 (22.22%)	84 (29.07%)	0.79
Smokers	122 (39.74%)	9 (50.00%)	113 (39.10%)	0.46
Syntax Score	27.49 (±3.44)	27.06 (±2.71)	27.52 (±3.48)	0.47
Angina				0.34
None	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Class I	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Class II	153 (49.84%)	11 (61.11%)	142 (49.13%)	
Class III	154 (50.16%)	7 (38.89%)	147 (50.87%)	
Class IV	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Dyspnea				0.25
None	67 (21.82%)	4 (22.22%)	63 (21.80%)	
Class I	75 (24.43%)	1 (5.56%)	74 (25.61%)	
Class II	95 (30.94%)	7 (38.89%)	88 (30.45%)	
Class III	70 (22.80%)	6 (33.33%)	64 (22.15%)	
Class IV	0 (0.00%)	0 (0.00%)	0 (0.00%)	
Ejection Fraction	53.49 (±8.76)	50.83 (±10.33)	53.65 (±8.64)	0.25
Creatinine	1.03 (±0.43)	1.00 (±0.24)	1.04 (±0.44)	0.3
Hemaglobin	12.96 (±1.40)	13.06 (±1.26)	12.96 (±1.41)	0.44
Platelets	233.85 (±65.97)	222.22 (±57.63)	234.57 (±66.47)	0.12
History of ACS	145 (47.23%)	7 (38.89%)	138 (47.75%)	0.63
Number of Vessels				0.81
SVCAD	0 (0.00%)	0 (0.00%)	0 (0.00%)	
DVCAD	148 (48.21%)	8 (44.44%)	140 (48.44%)	
TVCAD	159 (51.79%)	10 (55.56%)	149 (51.56%)	

Discussion

The findings of our study contribute to the ongoing discussion regarding the optimal revascularization strategy for patients with intermediate syntax scores in LMCAD. The 30-day mortality rates observed in the PCI and CABG groups were 5.1% and 6.6% respectively, with no statistically significant difference. These results are consistent with the NOBEL trial, which also did not find a significant disparity in mortality rates between the two treatment approaches[11].

In contrast, the EXCEL trial reported a statistically significant difference in 30-day mortality, with rates

of 4.9% in the PCI group and 7.9% in the CABG group. However, it's important to note that both the NOBEL and EXCEL trials included patients across all syntax score ranges, while our study specifically focused on those with intermediate syntax scores[12]. This discrepancy in patient selection may contribute to the differences observed in mortality outcomes[13].

Our study revealed a higher proportion of males undergoing revascularization for LMCAD, with 83.39% being male and 16.6% female. This finding aligns with a similar study by Patrick et al., which reported a male predominance of 76.9% in their comparison of PCI and CABG for LMCAD. The higher prevalence of coronary artery disease in males may explain this gender imbalance[14].

The mean age of patients in both the PCI and CABG groups in our study was 63.67 years, consistent with the EXCEL trial, which reported average ages of 66.0 years in the PCI group and 65 years in the CABG group. These findings indicate that LMCAD predominantly affects individuals in their early to mid-sixties, highlighting the significance of effective treatment options for this age group.

Regarding comorbidities, our study found a lower prevalence of diabetes mellitus in the PCI group (28.21%) compared to the CABG group (36.42%)[15]. Similar results were reported in the EXCEL trial, with prevalence rates of 30.2% in the PCI group and 28% in the CABG group. This suggests that patients with diabetes mellitus may have a slight preference for CABG over PCI as a revascularization strategy.

Hypertension was more prevalent in the CABG group (56.29%) than in the PCI group (35.90%) in our study. This difference may be attributed to our center's referral pattern, as patients with multiple comorbid conditions were more likely to be recommended for CABG. The selection bias in patient referrals could influence the distribution of risk factors between the two treatment groups[16].

Presenting symptoms did not significantly differ between the PCI and CABG groups in our study. This is likely due to our center's policy of performing angiography and revascularization primarily on symptomatic patients, rather than those with asymptomatic LMCAD[17,18].

It is worth noting that our study has limitations, including its single-center design and lack of randomization. Unmeasured variables and selection bias on the part of operators may have influenced the results. Therefore, dedicated randomized controlled trials are needed to assess the true outcome of PCI versus CABG for revascularization in LMCAD patients.

Conclusion

In our study, we observed that the 30-day mortality rate in patients with intermediate syntax scores undergoing revascularization for left main coronary artery disease (LMCAD) was slightly higher in the CABG group compared to the PCI group, although this difference was not statistically significant. These findings suggest that both PCI and CABG can be considered as viable treatment options for patients with intermediate syntax scores, with comparable risk profiles.

Limitation

Our results are consistent with international studies that have investigated the outcomes of PCI and CABG in LMCAD patients. However, it is important to note that our study is limited by its single-center design and the potential for selection bias. Therefore, it is crucial to conduct large-scale, multicenter, randomized controlled trials to validate these findings and provide more robust evidence regarding the optimal revascularization strategy for patients with intermediate syntax scores in LMCAD.

Recommendation

Further research is needed to explore other important outcomes such as long-term mortality, major adverse cardiac events, and quality of life measures. Additionally, the cost-effectiveness and individual patient factors should be taken into consideration when making treatment decisions.

Acknowledgment

We would like to express our sincere gratitude to all individuals and institutions who contributed to the successful completion of this study.

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