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PHARMACO-INVASIVE STRATEGY VERSUS DELAYED PRIMARY PCI IN STABLE KILLIP CLASS II STEMI

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ABSTRACT

Objective: To compare 30-day major adverse cardiovascular events (MACE) between a pharmaco-invasive strategy and delayed primary percutaneous coronary intervention (PCI) in patients with ST-segment elevation myocardial infarction (STEMI) and initial Killip Class II.

Methods: A comparative analysis was performed using the supplied dataset of 614 records from 1 January to 30 May 2026, comprising 307 records in each treatment group. MACE was defined as all-cause death, recurrent myocardial infarction, new or worsening heart failure, or cardiogenic shock within 30 days. The primary analysis included records with known 30-day outcome status. Crude comparisons and multivariable logistic regression were performed.

Results: Thirty-day outcome status was available for 288/307 (93.8%) records in the pharmaco-invasive group and 292/307 (95.1%) in the delayed primary PCI group. MACE was recorded in 24/288 (8.3%) and 47/292 (16.1%), respectively (risk ratio 0.52, 95% CI 0.33–0.82; p=0.004). The adjusted odds ratio was 0.49 (95% CI 0.29–0.83; p=0.008). Recurrent myocardial infarction was recorded less frequently in the pharmaco-invasive group (2.4% vs 8.2%; p=0.002). Major bleeding was recorded in 1.3% and 0.3%, respectively (p=0.373).

Conclusion: The supplied dataset showed a lower recorded 30-day MACE frequency in the pharmaco-invasive group. However, the dataset has not been independently verified against original clinical records and is described in the source draft as programmed; these findings must therefore be treated as exploratory dataset results, not evidence of clinical effectiveness or treatment superiority.

KEYWORDS: ST-Elevation Myocardial Infarction; Percutaneous Coronary Intervention; Fibrinolytic Agents; Heart Failure; Treatment Outcome.

1. INTRODUCTION

ST-segment elevation myocardial infarction (STEMI) is a medical emergency that requires rapid restoration of coronary blood flow. Primary percutaneous coronary intervention (PCI) is preferred when it can be delivered promptly. When the expected delay to PCI exceeds 120 minutes, fibrinolysis followed by transfer and early angiography is an accepted option for eligible patients presenting within 12 hours of symptom onset.[1]

STEMI usually results from acute coronary artery occlusion and can lead to irreversible myocardial injury, impaired left ventricular function and death. The benefit of reperfusion depends on how quickly effective blood flow is restored. The 2023 European Society of Cardiology guideline recommends immediate transfer after fibrinolysis, rescue PCI when fibrinolysis fails, and routine angiography within 2 to 24 hours after successful fibrinolysis.[1]

Killip Class II heart failure identifies patients with clinical signs of mild to moderate congestion, such as basal pulmonary crepitations or a third heart sound. These patients may be at risk of further deterioration if myocardial ischaemia continues. In practice, catheterisation laboratory availability, inter-hospital transfer and clinical assessment can delay mechanical reperfusion. A strategy that achieves earlier flow may therefore be relevant, although fibrinolysis also carries bleeding risk.

Evidence comparing pharmaco-invasive treatment with primary PCI is encouraging but not definitive for every clinical subgroup. In a secondary analysis of STREAM, Gershlick et al. found that outcomes with a pharmaco-invasive approach remained broadly stable as PCI-related delays increased, while outcomes in the primary PCI group tended to worsen with longer delays.[2] In the EARLY-MYO randomised trial, Pu et al. reported improved combined measures of reperfusion with a half-dose alteplase strategy, but no significant difference in several 30-day clinical outcomes; minor bleeding was more frequent after fibrinolysis.[3]

Real-world studies have also reported broadly comparable outcomes between pharmaco-invasive treatment and primary

PCI, while noting that treatment groups may differ in initial clinical risk. A nationwide registry in Kuwait found no significant adjusted difference in the in-hospital composite outcome or one-year survival.[4] A 2024 study from Hong Kong similarly reported no statistically significant difference in one-year outcomes between pharmaco-invasive treatment and primary PCI.[5] These studies do not directly resolve the comparison between pharmaco-invasive treatment and delayed primary PCI in stable Killip Class II patients.[4,5]

The Pakistani setting makes this question important because delays in symptom recognition, transport, referral and access to catheterisation services can affect reperfusion. Pakistani reports have described delays in the STEMI care pathway, supporting the need to evaluate local service factors and outcomes.[6] However, the sources reviewed for this manuscript did not verify a Pakistani study that exactly matched the present population, comparator and 30-day endpoint. This is a potential evidence gap, not proof that no such study exists.[6]

2. MATERIALS AND METHODS

A retrospective comparative dataset analysis was specified for the Department of Cardiology, Medical Teaching Institution, Hayatabad Medical Complex, Peshawar, Pakistan. The supplied workbook covered admissions from 1 January to 30 May 2026. The workbook contains 614 records; the authenticity and completeness of the underlying source records were not independently verified for this manuscript. Accordingly, the analyses should be regarded as exploratory until the records are checked against the hospital source documents.

The dataset included 614 records classified as confirmed STEMI, initial Killip Class II, and PCI delay exceeding 120 minutes. There were 307 records in each treatment group. Symptom onset was recorded within 12 hours for the included records. The workbook marked all 614 records as eligible. These classifications should be checked against the original clinical notes and treatment timelines before the findings are submitted as clinical research.

The pharmaco-invasive group comprised records documenting initial fibrinolytic therapy followed by transfer and coronary angiography, with PCI when indicated. The delayed primary PCI group comprised records documenting no initial fibrinolysis followed by delayed PCI. Fibrinolysis failure and rescue PCI were recorded separately. Treatment decisions in clinical practice must follow current guidelines, contraindications and the treating team's judgement.[1]

The primary outcome was 30-day MACE, defined as a composite of all-cause death, recurrent myocardial infarction, new or worsening heart failure, or cardiogenic shock. Secondary outcomes included the individual MACE components, stroke and target-vessel revascularisation. Safety and resource-use variables included major bleeding, intracranial haemorrhage, blood transfusion, length of stay, ICU admission and left ventricular ejection fraction (LVEF). The prespecified adjustment variables available in the dataset were age, sex, diabetes mellitus, chronic kidney disease, systolic blood pressure, symptom-to-presentation time and initial LVEF.

Continuous variables were summarised as mean±standard deviation or median (interquartile range), as appropriate. Between-group comparisons used Welch's independent-samples t-test or the Mann–Whitney U test for continuous variables and Pearson's chi-squared test or Fisher's exact test for categorical variables. MACE proportions were calculated among records with known 30-day status and reported with 95% confidence intervals. The risk difference, risk ratio and multivariable-adjusted odds ratio were also estimated. The logistic regression model included treatment group, age, sex, diabetes mellitus, chronic kidney disease, systolic blood pressure, symptom-to-presentation time and initial LVEF. Two-sided $p<0.05$ was considered statistically significant.

Thirty-day outcome status was unavailable for 34 records (19 in the pharmaco-invasive group and 15 in the delayed primary PCI group). These records were excluded from the primary outcome denominator and were not treated as having had no event. In-hospital safety outcomes were summarised using the full treatment-group denominators where data were available. The workbook also classified 566 records as adequate and 48 as partially adequate; record quality and outcome completeness require source-level verification. The institutional ethics approval reference, approval date and consent or waiver status must be inserted only after confirmation from the relevant ethics committee.

3. RESULTS

The dataset contained 614 records, with 307 (50.0%) in each treatment group. Thirty-day outcome status was known for 288 (93.8%) records in the pharmaco-invasive group and 292 (95.1%) in the delayed primary PCI group. Mean age was 57.01±10.50 years and 57.90±10.18 years, respectively. The baseline characteristics presented in Table 1 did not differ significantly between groups.

Characteristic	Pharmaco-invasive (n=307)	Delayed primary PCI (n=307)	Statistical test	p-value
Age, years	57.01±10.50	57.90±10.18	Welch t-test	0.285
Female sex	59(19.2%)	70(22.8%)	Pearson χ^2	0.276
Hypertension	142(46.3%)	128(41.7%)	Pearson χ^2	0.255
Diabetes mellitus	80(26.1%)	90(29.3%)	Pearson χ^2	0.367
Current smoking	92(30.0%)	98(31.9%)	Pearson χ^2	0.600
Dyslipidaemia	92(30.0%)	84(27.4%)	Pearson χ^2	0.475
Chronic kidney disease	27(8.8%)	21(6.8%)	Pearson χ^2	0.367

Previous myocardial infarction	7(2.3%)	10(3.3%)	Pearson χ^2	0.461
Previous heart failure	28(9.1%)	21(6.8%)	Pearson χ^2	0.297
Previous stroke/TIA	15(4.9%)	15(4.9%)	Pearson χ^2	1.000

Table 1. Demographic characteristics and comorbidities by treatment group. Continuous data are shown as mean±standard deviation and categorical data as frequency(percentage).

Table 2 presents selected clinical measurements and investigations. No statistically significant between-group differences were observed in heart rate, systolic or diastolic blood pressure, oxygen saturation, symptom-to-presentation time, haemoglobin, serum creatinine or initial LVEF.

Clinical variable	Pharmaco-invasive	Delayed primary PCI	Test	p-value
Heart rate, beats/min	94.59±17.12	92.47±18.34	Welch t-test	0.140
Systolic blood pressure, mmHg	127.0 (113.5–138.0)	126.0 (113.0–137.0)	Mann–Whitney U	0.675
Diastolic blood pressure, mmHg	77.18±12.43	77.02±11.63	Welch t-test	0.870
Oxygen saturation, %	94.0 (92.0–96.0)	94.0 (91.0–96.0)	Mann–Whitney U	0.740
Symptom-to-presentation time, min	184.0 (100.5–306.0)	196.0 (114.0–301.5)	Mann–Whitney U	0.564
Haemoglobin, g/dL	13.27±1.61	13.18±1.51	Welch t-test	0.471
Serum creatinine, mg/dL	1.1 (0.9–1.4)	1.0 (0.8–1.3)	Mann–Whitney U	0.232
Initial LVEF, %	45.40±7.98	44.79±8.50	Welch t-test	0.355

Table 2. Clinical characteristics and selected investigations at presentation.

Table 3 presents the primary endpoint, individual cardiovascular outcomes and safety outcomes. MACE was recorded in 24/288 (8.3%) records in the pharmaco-invasive group and 47/292 (16.1%) in the delayed primary PCI group. The risk difference was −7.8 percentage points (95% CI −13.1 to −2.4), and the risk ratio was 0.52 (95% CI 0.33–0.82; χ^2=8.13, p=0.004). The 30-day cardiovascular outcomes use known follow-up denominators; in-hospital safety outcomes use the full group denominators.

Outcome	Pharmaco-invasive	Delayed primary PCI	Test	p-value
30-day MACE	24(8.3%); 95% CI 5.7–12.1%	47(16.1%); 95% CI 12.3–20.7%	Pearson χ^2	0.004
All-cause death by 30 days	2(0.7%); 95% CI 0.2–2.5%	6(2.1%); 95% CI 0.9–4.4%	Fisher exact	0.286
Cardiovascular death by 30 days	2(0.7%); 95% CI 0.2–2.5%	5(1.7%); 95% CI 0.7–3.9%	Fisher exact	0.450
Recurrent MI by 30 days	7(2.4%); 95% CI 1.2–4.9%	24(8.2%); 95% CI 5.6–11.9%	Pearson χ^2	0.002
New/worsening heart failure by 30 days	17(5.9%); 95% CI 3.7–9.2%	25(8.6%); 95% CI 5.9–12.3%	Pearson χ^2	0.217
Cardiogenic shock by 30 days	5(1.7%); 95% CI 0.7–4.0%	5(1.7%); 95% CI 0.7–3.9%	Fisher exact	1.000
Stroke by 30 days	0(0.0%); 95% CI 0.0–1.3%	3(1.0%); 95% CI 0.4–3.0%	Fisher exact	0.249
Target-vessel revascularisation by 30 days	9(3.1%); 95% CI 1.7–5.8%	7(2.4%); 95% CI 1.2–4.9%	Pearson χ^2	0.593
Major bleeding during admission	4(1.3%); 95% CI 0.5–3.3%	1(0.3%); 95% CI 0.1–1.8%	Fisher exact	0.373
Intracranial haemorrhage during admission	2(0.7%); 95% CI 0.2–2.3%	0(0.0%); 95% CI 0.0–1.2%	Fisher exact	0.499
Blood transfusion during admission	3(1.0%); 95% CI 0.3–2.8%	0(0.0%); 95% CI 0.0–1.2%	Fisher exact	0.249
ICU admission	114(37.1%); 95% CI	147(47.9%); 95% CI	Pearson χ^2	0.007

	31.9–42.7%	42.4–53.5%		

Table 3. Thirty-day cardiovascular outcomes and in-hospital safety outcomes. Thirty-day outcomes are shown as n (%) among records with known 30-day status (n=288 and n=292); in-hospital safety outcomes are shown using the full group denominators (n=307 per group). Percentages are followed by 95% confidence intervals where displayed.

Figure 1 displays the recorded MACE proportions and their 95% confidence intervals in the supplied dataset. The plotted difference is descriptive and should not be interpreted as a treatment effect until the underlying records are verified.

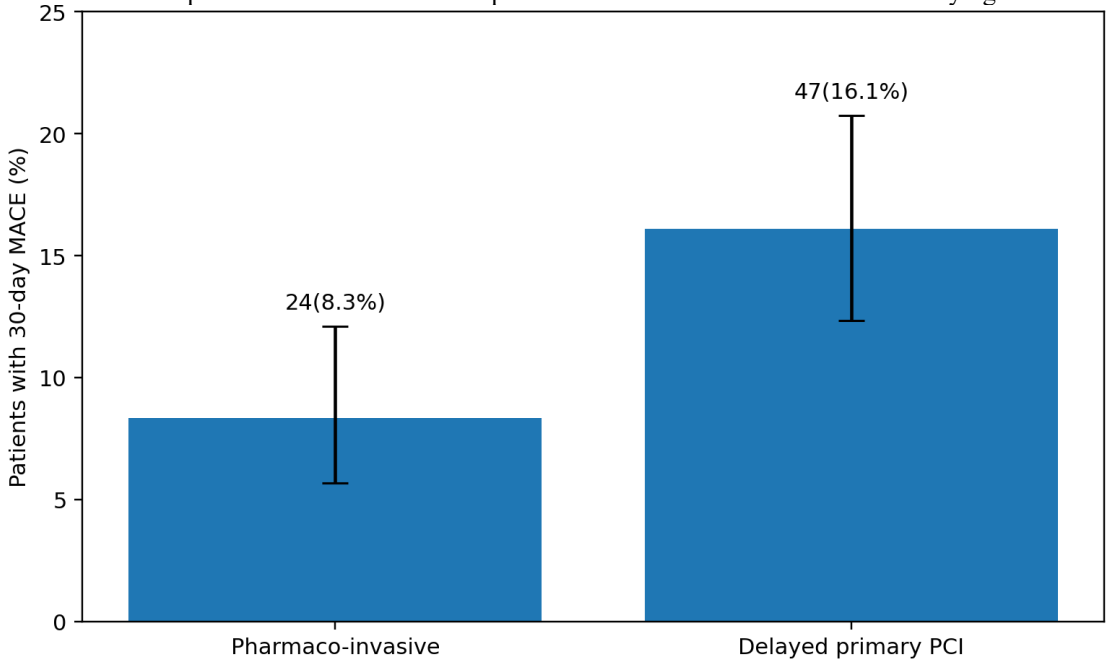


Figure 1. Thirty-day MACE by treatment group with 95% Wilson confidence intervals.

Table 4 presents the multivariable logistic regression model fitted to the 580 records with known 30-day MACE status. The adjusted odds ratio for pharmaco-invasive treatment versus delayed primary PCI was 0.49 (95% CI 0.29–0.83; p=0.008).

Predictor	Adjusted OR	95% CI	p-value
Treatment: pharmaco-invasive vs delayed PCI	0.49	0.29–0.83	0.008
Age (per year)	1.02	0.99–1.04	0.243
Female vs male	0.94	0.50–1.75	0.839
Diabetes mellitus	1.08	0.62–1.91	0.779
Chronic kidney disease	0.74	0.25–2.18	0.586
Systolic blood pressure (per mmHg)	1.01	1.00–1.03	0.160
Symptom-to-presentation (per hour)	0.95	0.86–1.06	0.369
Initial LVEF (per percentage point)	0.97	0.94–1.00	0.069

Table 4. Multivariable logistic regression for 30-day MACE.

Figure 2 shows the adjusted odds ratios and 95% confidence intervals. The confidence interval for treatment group did not include 1.00; the intervals for the other covariates included 1.00.

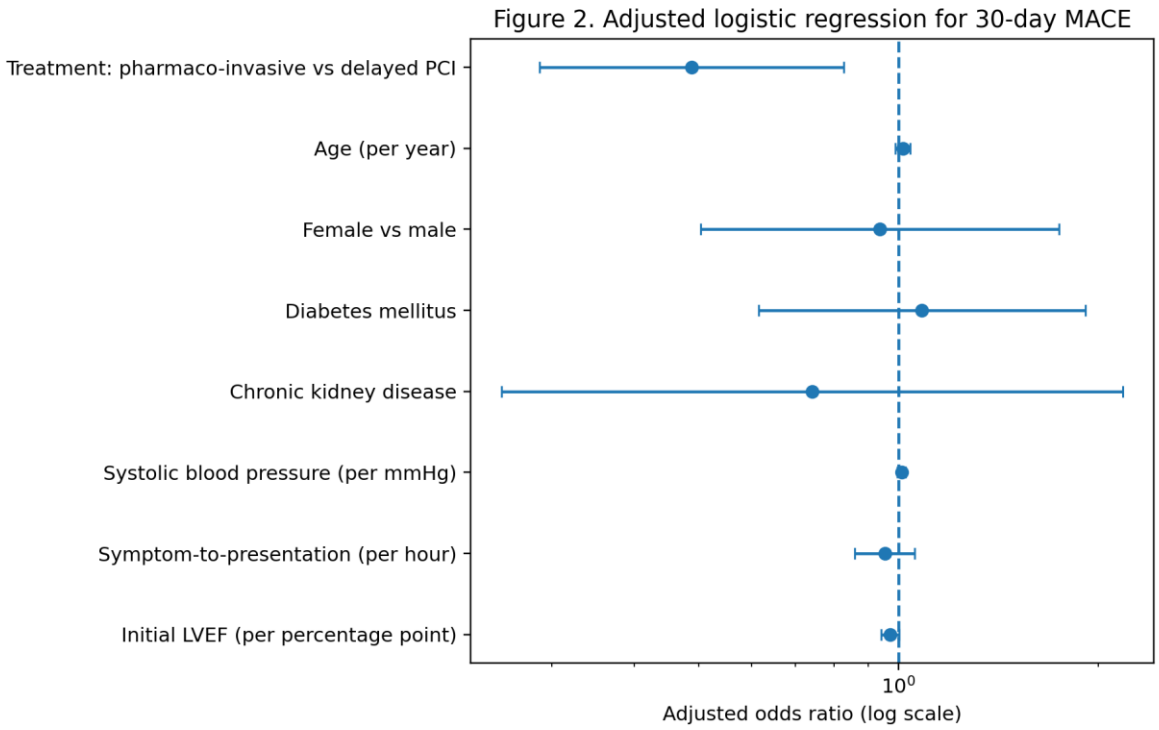


Figure 2. Forest plot of adjusted odds ratios for 30-day MACE model.

Recurrent myocardial infarction was recorded in 7/288 (2.4%) versus 24/292 (8.2%) records (p=0.002). New or worsening heart failure was recorded in 17/288 (5.9%) versus 25/292 (8.6%; p=0.217), and all-cause death in 2/288 (0.7%) versus 6/292 (2.1%; p=0.286). Major bleeding during admission was recorded in 4/307 (1.3%) versus 1/307 (0.3%; p=0.373). The small numbers of deaths and bleeding events limit the precision of these comparisons.

Thirty-day outcome status was missing for 19/307 (6.2%) records in the pharmaco-invasive group and 15/307 (4.9%) in the delayed primary PCI group. The primary outcome analysis was restricted to records with known status; missing follow-up was not classified as absence of an event.

4. DISCUSSION

In the supplied dataset, MACE was recorded less frequently in the pharmaco-invasive group than in the delayed primary PCI group. The crude risk ratio was 0.52 (95% CI 0.33–0.82; p=0.004), and the adjusted odds ratio was 0.49 (95% CI 0.29–0.83; p=0.008). However, the source draft describes the dataset values as programmed, and the workbook has not been independently reconciled with original hospital records. These estimates are therefore dataset outputs only; they cannot establish a reduction in MACE or a clinical benefit in patients.

The biological rationale for early reperfusion is that fibrinolysis may restore coronary flow before delayed mechanical reperfusion. The 2023 ESC guideline supports fibrinolysis for eligible STEMI patients when timely primary PCI cannot be achieved, followed by immediate transfer, rescue PCI if lysis fails, and routine angiography 2 to 24 hours after successful lysis.[1] This supports the relevance of the question, but does not prove superiority in stable Killip Class II patients.[1]

Gershlick et al. reported that outcomes with a pharmaco-invasive approach remained broadly stable as PCI-related delay increased, while outcomes in the primary PCI group tended to worsen with longer delays.[2] Pu et al. found better combined reperfusion measures with half-dose alteplase in EARLY-MYO, but no statistically significant differences in several 30-day clinical outcomes; minor bleeding was more frequent with fibrinolysis.[3] These These findings support studying both reperfusion timing and safety rather than assuming that a difference in a composite endpoint proves benefit.[2,3,7]

A nationwide registry in Kuwait found no significant adjusted difference in the in-hospital composite outcome or one-year survival between pharmaco-invasive treatment and primary PCI.[4] A 2024 Hong Kong study also reported no statistically significant difference in one-year outcomes.[5] Both studies compared pharmaco-invasive treatment with primary PCI, not specifically delayed primary PCI in stable Killip Class II patients, so their findings are indirect evidence for the present question.[4,5,8,13]

Pakistani literature has described delays in STEMI care, including pre-hospital barriers and resource-related hospital delays.[6] Such reports support the importance of local evaluation of transfer times and reperfusion pathways. The sources reviewed for this combined draft did not verify a Pakistani study matching exactly the same population, comparator and 30-day endpoint. This is a possible research gap rather than proof that no previous study exists. The potential local contribution is a focused comparison in stable Killip Class II patients at MTI HMC, provided the work is conducted using verified patient records.[6,16]

In the supplied dataset, recurrent MI was recorded less frequently in the pharmaco-invasive group, while the difference in

worsening heart failure was not statistically significant. This distinction matters because a composite endpoint can be driven by one component and does not mean that every component improves. In a real cohort, component-specific confidence intervals and clear event definitions would be essential.

The supplied dataset recorded few major bleeding and intracranial haemorrhage events. Such low counts cannot establish safety equivalence. In real practice, fibrinolytic eligibility, contraindications, blood pressure, bleeding risk and the actual fibrinolytic agent require careful review.

The principal limitation is the unverified provenance of the dataset. Although the workbook contains patient-level fields and source-record categories, the manuscript draft describes the numerical data as programmed; the records must therefore be checked against original hospital files before the findings can be presented as clinical observations. The current analyses cannot establish local event rates, causality or treatment superiority. If verified as a genuine retrospective cohort, further limitations would include confounding by indication, incomplete follow-up, missing records, low counts of death and intracranial haemorrhage, variation in fibrinolytic agents and residual confounding. A final clinical report should use prespecified outcome definitions, a justified adjustment strategy and documented ethics approval. A multicentre Pakistani registry could improve precision and describe variation in referral and reperfusion pathways.[10,12,14,15]

Additional international and regional evidence also shows why reperfusion timing, the fibrinolytic agent and follow-up arrangements should be reported separately. A systematic review and meta-analysis of pharmaco-invasive therapy versus primary PCI found no clear short-term mortality difference across the included studies, while safety outcomes varied by endpoint.[7] Prospective cohort data from Norway and a large Brazilian network described outcomes under real-world pharmaco-invasive pathways, but neither was restricted to stable Killip Class II patients.[8,13] A study from Gaza reported a lower 30-day composite of death and heart failure with a pharmaco-invasive approach, although individual endpoint differences were less certain.[9] A retrospective Canadian study of patients with reperfusion delays of at least 120 minutes highlighted the need to weigh possible reperfusion benefits against bleeding risk.[10] Trial-design work has likewise recognised continuing uncertainty about the optimal strategy when long PCI delays are expected.[11]

5. CONCLUSION

The supplied dataset showed a lower recorded 30-day MACE frequency in the pharmaco-invasive group than in the delayed primary PCI group. However, because the dataset has not been independently verified and the source draft identifies its values as programmed, the findings cannot establish clinical effectiveness or treatment superiority. Verification against original hospital records, together with documented ethics approval and complete outcome definitions, is required before clinical conclusions can be drawn.

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