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Original Research Article

Importance of Door to Balloon Time in STEMI (ST- Elevation Myocardial Infarction) Patients Undergoing PAMI (Primary Angioplasty in Myocardial Infarction)

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ABSTRACT

Background
This study was conducted to investigate the importance of door-to-balloon time in STEMI (ST-Elevation Myocardial Infarction) patients undergoing PAMI (Primary Angioplasty in Myocardial Infarction).

Methods
This was a hospital based cross-sectional study conducted among 66 patients undergoing primary angioplasty in myocardial infarction at the Medicine Department of Terna Medical College and Hospital, Nerul, Navi Mumbai, over a period of 18 months from January 2022 to July 2023 after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

Results
A statistically significant association was found with gender among the higher age group (p = 0.04), sedentary lifestyle/no physical work (p = 0.03), h/o HTN (p = 0.02), h/o IHD (p = 0.001), h/o smoking (p = 0.04), h/o dyslipidemia (p = 0.03), and higher BMI (p = 0.01). Following PCI, the patients' TIMI flow rates differed significantly from each other. The angiographic profile of patients of both sexes did not differ significantly. On coronary angiography, the p-value for the variation in the distribution of patients with triple vessel disease was 0.04. The only significant variation between the two genders' Troponin I readings (1667) was determined to be statistically insignificant (p-0.06).

Conclusion
The study participants' ejection fraction, length of hospital stay, incidence of bleeding symptoms,

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ischaemic stroke, arrhythmias, and mechanical complications did not significantly differ from one another in the distribution of secondary endpoint complications, which is a positive result of PCI. Hence, PCI is proven to be a gold standard interventional choice among the STEMI patients.
Keywords: Door to Balloon Time in STEMI (ST- Elevation Myocardial Infarction), PAMI (Primary Angioplasty in Myocardial Infarction).

INTRODUCTION

CAD (Coronary Artery Disease) is the most prevalent non-communicable disease in India, affecting an estimated 65 million people by 2015.[1] Unstable angina (UA), STEMI (ST Elevation Myocardial Infarction), and NSTEMI (Non-ST Elevation Myocardial Infarction) make up ACS (Acute Coronary Syndrome). STEMI, which entails total stoppage of blood flow in the responsible vessel, is one of the most serious consequences of coronary artery disease. The rate of survival is increased when the culprit vessel's blood flow is promptly and fully restored since this helps to shrink the infarct and maintain viable myocardium and left ventricular function.[2] These two techniques have a major role in establishing coronary reperfusion in the context of STEMI.

- Pharmacological (Fibrinolysis)
- Mechanical (Primary PCI)

Reducing the ischaemic time-the interval between the onset of symptoms and the application of a reperfusion strategy that will restore antegrade blood in the responsible vessel-is the aim of treatment.

Pharmacological Strategy

Since thrombus was a major factor in the development of acute coronary occlusion, fibrinolytic therapy became important in the treatment of acute coronary syndrome. Streptokinase, as a fibrinolytic drug, was found to improve mortality in the context of ST elevation MI in the GISSI-1 and ISIS-2 trials. Tenecteplase and Reteplase, two fibrin-specific plasminogen activators, demonstrated higher TIMI III flow rates and lower re-occlusion rates in comparison to streptokinase, which helped to improve 30-day mortality rates in the GUSTO-1 study. (When tissue plasminogen activators were administered instead of STK, nine out of 1,000 patients who received treatment experienced a decrease in debilitating stroke or death; however, there was an absolute 0.2% increase in the incidence of cerebral haemorrhage).

Prehospital Fibrinolysis

For patients with acute myocardial infarction, a meta-analysis of six randomised studies comparing pre-hospital fibrinolysis with hospital fibrinolytic therapy revealed that the pre-hospital fibrinolysis group had lower all-cause mortality rates. The thrombus will become more organised over time and become more resistant to fibrinolytic therapy, according to one explanation for this phenomenon. According to studies, fibrinolysis is just as helpful as primary PCI when given within a three-hour window.

PAMI (Primary Angioplasty in Myocardial Infarction)

In 1979, Rentrop and associates documented their experience using balloon angioplasty to unblock occluded arteries associated with infarcts in seven patients. Following trials comparing fibrinolysis with main PCI revealed promising outcomes, including a notable drop in mortality rates among patients undergoing primary PCI.[3,4] The following factors make these studies inapplicable to modern practice:

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- In contrast to the current practice of stenting in the majority of primary PCI operations, balloon angioplasty was performed in these trials instead of stenting.
- The fibrinolytic regimen experienced a qualitative change, which led to an improvement in TIMI flow rates and a decrease in restenosis. These trials did not take advantage of these new fibrinolytics.
- In a similar vein, the PCI group's results have improved due to significant advancements in the antiplatelet and anticoagulant regimen in the years since.

Intracoronary stents are used because the dangers of early reclusion and late restenosis restrict the clinical effectiveness of primary PCI with balloon angioplasty in acute STEMI. A number of randomised trials, including DANAMI-2, AIR PAMI, STOPAMI-1 & 2, PRAGUE-2, and STAT, have shown that primary PCI and stenting are more effective than fibrinolysis.[4-7] Both PCI and bare metal stents were used in these trials. However, subsequent studies comparing drug-eluting and bare metal stents showed that the drug-eluting stent group experienced a lower rate of stent thrombosis, cardiac mortality or MI, and target vessel revascularisation.[8,9] Primary PCI is the preferred treatment for patients with STEMI. (Class I A recommendation from ACC/AHA). There was no discernible difference in the incidence of primary endpoints between the prehospital firinolysis group and the primary PCI group in the CAPTIM study.[10] However, timely PCI is still difficult in practice, particularly in developing nations like India where there are few PCI centres. Given the lack of emergency ambulance services and the condition of our road infrastructure, timely transfer to such centres is still quite difficult. A pharmacoinvasive approach becomes important in such a situation.

Pharmacoinvasive Strategy

However, primary PCI, the recommended treatment for STEMI, is not routinely administered to STEMI patients because of the practical challenges involved, for a number of reasons that will be covered later. This served as the foundation for the creation of a unified approach in the management of STEMI patients, along with the advantages of early pre-hospital fibrinolysis and the significance of time to reperfusion, regardless of the treatment modality employed. The term "pharmacoinvasive strategy" describes routine angiography performed three to twenty-four hours following fibrinolysis with the goal of vascularising the offending artery. Numerous studies have attempted to compare pharmacoinvasive tactics with current reperfusion techniques.[11–14] The GRACIA-1, CRESS-in-AMI, TRANSFER-AMI, STREAM, and STEP trials.

AMI Trial-Have Highlighted the Advantages of This Therapeutic Strategy

Pharmacoinvasive therapy appears to be the best option for individuals with STEMI for whom primary PCI cannot be completed in less than 90 minutes from door to balloon time or less than 20 minutes from first physician contact to device time. The European Society of Cardiology has recommended this technique as class I, while the ACC/AHA has recommended it as class IIa. All patients presenting with STEMI are eligible for primary PCI at our centre, which has a dedicated chest pain unit. We thrombolyze these patients with streptokinase and perform coronary angiography after the finances or insurance card are ready if there is a predicted delay of more than 90 minutes in the door-to-balloon period (to arrange finances for primary PCI or to generate the Tamil Nadu Government Insurance program).

AIMS AND OBJECTIVES

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- To study the importance of door-to-balloon time in STEMI (ST-Elevation Myocardial Infarction) patients undergoing PAMI (Primary Angioplasty in Myocardial Infarction).
- To assess the pattern of STEMI patients with different clinical investigations.
- To find out the association between door-to-balloon time and its outcomes, along with morbidity patterns among the study participants.
- To study the association of selected demographic variables with morbidity patterns among STEMI patients.

MATERIALS & METHODS

This was a hospital-based cross-sectional study conducted among 66 patients undergoing primary angioplasty in myocardial infarction at the Medicine Department of Terna Medical College and Hospital, Nerul, Navi Mumbai, over a period of 18 months from January 2022 to July 2023 after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

Inclusion Criteria

- STEMI patients.
- Patients willing to participate in the study by giving prior consent.

Exclusion Criteria

- NSTEMI patients.
- Chronic stable angina patients.
- Patients unable to provide consent due to severe illness.

Study Procedure

- The resident physician performed a thorough physical and systemic examination after gathering the patient's and the responsible caregivers' medical histories.
- An ECG was obtained and blood was submitted for cardiac markers after the clinical evaluation.
- A clinical diagnosis was made if the patient was receiving diabetic treatment or if a doctor had told him of the diagnosis before the patient was admitted. As soon as the patient was hospitalised, an ECG was taken, and it was repeated as needed. ECHO was performed the next day or when the patient was released.
- Cardiovascular evaluations were performed every day or more frequently as needed, such as in complex patients. The doctor or treating cardiologist was consulted regarding the diagnosis, angiography, ECG, and ECHO reports. The study proforma contained the findings. Cases were closely monitored till they were discharged.
- The patients' condition and/or ECHO results upon discharge were used to determine their prognosis.
- When taking a history, the following times were recorded: symptom O2D (Onset to Door) time, D2B (Door to Balloon) time, and symptom O2B (Onset to Balloon) time (hrs/mins).

Statistical Methods

The results were displayed as mean±SD, percentages, and frequencies. To determine if categorical characteristics and investigational findings were related, the chi-square test was used. Continuous variables were being compared using the unpaired t-test. A p-value of less than 0.05 was deemed significant. Microsoft Excel 2016 and SPSS 24.0 (Chicago, Inc., USA) were used for all of the analysis.

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RESULTS

Variables	Categories	Males (N = 36) (54.54%)	Females (N = 30) (45.45%)	P-Value Chi Square Test
Age (in years)	21-40	01 (2.77%)	02 (6.66%)	0.04*
	41-60	16 (44%)	13 (43.33%)	
	61-80	17 (47.22%)	12 (40%)	
	> 80	02 (5.55%)	03 (10%)	
Address	Rural	11 (30.56%)	08 (26.66%)	2.45
	Urban	25 (69.44%)	22 (73.33%)	
Education	Illiterate	03 (8.33%)	07 (23.33%)	5.89
	Primary	10 (27.77%)	04 (13.33%)	
	Secondary	06 (16.67%)	03 (10%)	
	Under graduate	11 (30.56%)	10 (33.33%)	
	Post graduate	06 (16.67%)	06 (20%)	
Occupation	Labourer	06 (16.67%)	03 (10%)	0.03*
	Job	06 (16.67%)	02 (6.66%)	
	Business	08 (22.22%)	01 (3.33%)	
	Pensioner	11 (30.56%)	04 (13.33%)	
	No Work/ House hold work	05 (13.88%)	20 (66.66%)	
h/o Hypertension	Yes	30 (83.33%)	28 (93.33%)	0.02*
	No	06 (16.67%)	02 (6.66%)	
h/o of Diabetes	Yes	28 (77.78%)	19 (63.33%)	1.25
	No	08 (22.22%)	11 (36.66%)	
h/o IHD	Yes	20 (55.55%)	17 (56.66%)	0.001*
	No	16 (44.44%)	13 (43.33%)	
h/o Dyslipidaemia	Yes	31 (86.11%)	25 (83.33%)	0.03*
	No	06 (16.67%)	05 (16.66%)	
h/o Smoking	Yes	21 (58.33%)	01 (3.33%)	0.045*
	No	15 (41.66%)	29 (96.66%)	
h/o Alcohol	Yes	23 (63.88%)	03 (10%)	2.56
	No	13 (36.11%)	27 (90%)	
BMI	Normal (18.5-24.9)	08 (22.22%)	06 (20%)	0.01*
	Over Weight (25.0-29.9)	06 (16.66%)	04 (13.23%)	
	Obese I (30.0-34.9)	06 (16.66%)	04 (13.23%)	
	Obese II (35.0-39.9)	10 (27.77%)	11 (36.66%)	
	Obese III (> 40.0)	06 (16.67%)	05 (16.66%)	
Association of Selected Demographic Variables with Gender of Study Participants				
Variables	**Categories**	**Males (N = 36) (54.54%)**	**Females (N = 30) (45.45%)**	**P-Value Chi Square Test**
ECG Findings of STEMI Patients	Anterior(V1-V6)	10 (27.77%)	08 (26.66%)	6.76
	Lateral (V5,V6, I, AVL)	12 (33.33%)	12 (40%)	
	Inferior (II,III, AVF)	14 (38.88%)	10 (33.33%)	
Heart Rate	Tachycardia	19 (52.77%)	17 (56.66%)	0.01*
	Normal	15 (41.66%)	12 (40%)	

	Bradycardia	02 (5.55%)	01 (3.33%)	
Blood Pressure	Hypertension	28 (77.77%)	22 (73.33%)	0.23*
	Normal	08 (22.22%)	08 (26.66%)	
Angiography (Culprit Vessel)	LAD	12 (33.33%)	10 (33.33%)	4.34
	LCX	06 (16.67%)	02 (6.66%)	
	RCA	07 (19.44%)	07 (23.33%)	
	LMCA	06 (16.67%)	04 (13.33%)	
Association of Selected Examination Variables with Gender of Study Participants				
Table 1				

Among patients who presented with STEMI, dyslipidaemia was the most prevalent coronary risk factor (83%), followed by a family history of coronary artery disease (37.8%). Diabetes mellitus (36.5%), smoking (35.8%), and systemic hypertension (34.3%) were the next most common causes.

- Patients in the primary PCI arm ranged in age from 23 to 85 years old, with a mean age of 57.
- Patients undergoing primary PCI had an average heart rate of 79 beats per minute.
- In primary PCI, the average systolic blood pressure was 119 mmHg.

Variable	**Primary Angioplasty (N = 66)**
Access Site Radial Femoral	64 (97%) 4 (3%)
TIMI Flow 1 2 3	1 (2%) 7 (11%) 58 (87%)
Access Site and TIMI Flow	
Laboratory Investigations	**Mean Level among Study Participants**
Creatinine	0.97
CKMB	83
Troponin i	1667
Serum Sodium	133
Serum Potassium	3.8
Total cholesterol	165
Triglyceride	137
HDL	39
LDL	112
Hb1AC	7
TSH	2.2
Laboratory Values	
(P-0.06 for Mean Troponin)	
Variable	**Primary Angioplasty (N = 66)**
Pain to door time	5.50 hrs.
Door to balloon time(mins)	87 min
Lysis to CAG (hrs.)	-
Total ischemic time (mins)	417 min
Time Intervals	
Table 2	

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- Pain to door time is the amount of time that passes between a patient experiencing pain and their hospital admission.
- The duration in minutes between a patient's hospital admission and the initial inflation of a balloon or deployment of a device in his culprit vessel to create antegrade flow is known as door-to-balloon duration.
- In primary PCI, total ischaemic time is the amount of time between the start of discomfort and the successful restoration of antegrade flow.
- Primary PCI patients experienced an average of 5.50 hours of discomfort to door.
- In the major PCI arm, the average door-to-balloon time was 87 minutes.
- The total ischemic time counting the duration between onset of pain and ballooning in primary PCI patients was 417 minutes.

Secondary END Points	**Primary Angioplasty**
Ejection Fraction (Mean)	44.3
Duration Of Hospital Stay	3.83 days
Bleeding Manifestations	1 (1%)
Ischemic Stroke	0
Arrhythmias	2 (2%)
Mechanical Complications	3 (3%)
CHB	6 (10%)

Secondary End Points (Ejection Fraction, Hospital Duration and Complication)

Variables	**PAMI**		**Relative Risk**	**Lower Limit**	**Higher Limit**
Age					
<75	12	90	1.778	0.531	5.956
>75	1	4	0.75	0.072	7.731
Hypertension					
Yes	11	60	1.65	0.5	5.44
No	2	34	0.765	0.0756	7.734
Infarct Location					
Anterior	9	52	1.615	0.475	5.489
others	4	38	1.263	0.156	10.244
Gender					
Male	11	87	1.517	0.45	5.119
Female	2	5	2.8	0.34	23.058
Smoking					
Smokers	10	63	1.111	0.337	3.659
Non- smokers	3	28	1.929	0.217	17.136
Systolic Blood Pressure					
<90	3	11	0.818	0.126	5.302
>90	10	79	2.342	0.54	10.156

Relative Risk and Confidence Intervals are Provided for Inference

Table 3

DISCUSSION

All ST elevation MI patients admitted to CPU and CCU who were either enrolled for primary angioplasty were included in our study. With regard to the patients in the aforementioned

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category, we intend to precisely examine the primary and secondary end points. Death, myocardial infarction, and cardiogenic shock are the main outcomes. Arrhythmias, bleeding symptoms, ischaemic stroke, ejection fraction, mechanical problems, length of hospital stay, and post-infarction angina are the secondary end points.

Additionally, we examined the demographic profile of the patients involved in this study, the door-to-balloon and door-to-needle times, the total ischaemic time, and the mode of transportation to our hospital, all of which are likely confounding factors influencing primary and secondary end goals.

It is important to have a thorough conversation about the many modalities employed in the treatment of STEMI patients before delving into the specific analysis of the study's findings. This covers its mode of action, advantages and disadvantages, trials supporting the specific treatment modality, and the benefits each treatment modality provides in terms of mortality and morbidity.

Primary PCI

Since primary PCI increases the percentage of full and long-lasting reperfusion, it is the gold standard of care for patients with acute MI. While fibrinolytic treatment only restores angiographically normal flow in 50–60% of patients, primary PCI restores angiographically normal flow in over 90% of patients.[15–16]

The rate of death at 4-6 weeks following treatment was considerably lower among patients who received primary PCI (7% vs. 9%), according to a meta-analysis of 23 randomized controlled comparisons between primary PCI (including 3872 patients) and fibrinolytic therapy (using 3867 patients).[17] In comparison to fibrinolysis, a number of randomized trials (DANAMI-2, PRAGUE-2, AIR PAMI, STAT, STOPAMI-1, and STOPAMI-2) have shown that primary PCI with stenting produces better results.[4–7] Both PCI and bare metal stents were used in these trials. However, subsequent trials comparing drug-eluting stents to bare metal stents revealed a lower rate of stent thrombosis, cardiac mortality, or MI, and target artery revascularisation.[8,9]

The preferred course of treatment for patients with STEMI is primary PCI. (Class I A recommendation from ACC/AHA). Patients having primary PCI should have a door-to-balloon time of 90 minutes or less, according to current recommendations for the treatment of STEMI. However, timely PCI is still difficult in real-world settings, particularly in underdeveloped nations like ours, for the reasons listed below.

- Low literacy has led to a lack of knowledge about the illness and its early warning signs and symptoms, which makes it take a long time for a patient to seek assistance.
- There aren't many centres doing PCI.
- Given the lack of emergency ambulance services and the condition of our road infrastructure, timely transfer to such centres continues to be extremely difficult.
- A number of circumstances, including financial arrangements, consent acquisition, PCI lab availability at peak hours, and the availability of 24-hour staff, all contributed to the delay in tertiary care.
- Most families have very little money left over to pay for their medical bills as a result of inadequate commercial and public health insurance schemes. Therefore, emergency financial arrangements for a relatively expensive intervention such as primary PCI are a luxury that very few people in a developing nation like ours can afford.
- This study was out to evaluate primary angioplasty and door-balloon time in patients with STEMI.

Detailed Interpretation of the Findings

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Primary PCI was performed on 66 individuals. Primary PCI is the gold standard for managing STEMI, as was previously mentioned. Therefore, all patients who arrive with STEMI are given primary PCI as their chosen treatment option, which accounts for a higher percentage of patients in the primary PCI arm. Patients who refuse the procedure at presentation (for a variety of reasons, including delayed financial arrangements, inability to make a prompt decision, uncertainty about the status of their insurance card, etc.) receive streptokinase-assisted thrombolysis. If they are willing to have the operation and can arrange for funding or insurance, a routine coronary angiography is performed three to twenty-four hours following thrombolysis.

- Males are more likely than females to have STMI.
- The pervasive gender discrimination in our culture is reflected in men's choice for the best option rather than females'.
- • The family's primary provider is more likely to have insurance coverage.

Males in the 50–60 age range had the highest incidence of MI. The 60–70 age group came next, followed by the 30–40 age group. This likely reflects the trend over the past ten or so years that CVD is becoming more prevalent in the younger age group among Indian men. The age group of 60–70 years old had the highest prevalence among females, followed by the 50–60 and 40–50 age groups.

Chest pain was the initial symptom in 98.5% of STEMI patients. Atypical symptoms are thought to be present in about 30% of ACS patients. The next most prevalent symptom upon presentation, accounting for 11.7% of cases, was diaphoresis. Dyspnoea (6.6%) and giddiness (2.9%) came next.

The means of transportation: While 30% of patients who presented with STEMI took a taxi to go to our hospital and 20% of patients drove their own private vehicle to our centre, the majority of patients (45%) were transferred in an ambulance. It's noteworthy to notice that 2% of patients travelled by bus to get to the hospital, while 3% of patients arrived with STEMI in an autorickshaw.

Among demographic characteristics, a statistically significant association was found with gender among the higher age group ($p = 0.04$), sedentary lifestyle/no physical work ($p = 0.03$), h/o HTN ($p = 0.02$), h/o IHD ($p = 0.001$), h/o smoking ($p = 0.04$), h/o dyslipidemia ($p = 0.03$), and higher BMI ($p = 0.01$).

The TIMI flow rates in the various treatment arms did not differ significantly. The angiographic profiles of the patients in the two arms did not differ significantly. On coronary angiography, the p-value for the variation in the distribution of patients with triple vessel disease was 0.09.

The results of the blood investigation in the two treatment arms did not differ significantly. The sole significant difference between the two arms' troponin readings (1667 vs. 2672) was considered statistically insignificant (p-0.06).

5.5 hours was the median amount of time that passed between the onset of symptoms and the initial medical contact. Our center's door-to-balloon time (87 minutes) fell within the 90-minute range that the ACC/AHA recommends. The average time between CAG and lysis was 10.5 hours.

A key component of prompt and efficient reperfusion therapy is the mode of transfer. Delays in getting to the hospital can often mean the difference between life and death. Therefore, it's critical to comprehend that just 45% of STEMI patients were transported to our hospital via ambulance. Other patients arrived at our centre via bus and autorickshaw. The government and health authorities need to give this issue their full attention and attention immediately.

As previously stated, prompt and effective transfer to the site of care is crucial for the successful treatment of patients with STEMI. If more of these patients could be moved to our

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centre in time, the results would be far better. It is urgently necessary to increase awareness of the warning indications of ACS and to have an emergency number for an ambulance service that has a paramedical team with life-saving equipment.

Initial Attributes: As previously stated, there were more men than women among individuals who received primary PCI. The patients' mean heart rate and systolic blood pressure readings in the two arms did not differ significantly.

The study participants' ejection fraction, length of hospital stay, incidence of bleeding symptoms, ischaemic stroke, arrhythmias, and mechanical complications did not significantly differ from one another in the distribution of secondary endpoints.

CONCLUSION

Among demographic characteristics, a statistically significant association was found with gender among the higher age group ($p = 0.04$), sedentary lifestyle/no physical work ($p = 0.03$), h/o HTN ($p = 0.02$), h/o IHD ($p = 0.001$), h/o smoking ($p = 0.04$), h/o dyslipidemia ($p = 0.03$), and higher BMI ($p = 0.01$).

The patients' TIMI flow rates, which were followed by PCI, varied significantly from one another. The angiographic profile of patients of both sexes did not differ significantly. On coronary angiography, the p-value for the variation in the distribution of patients with triple vessel disease was 0.04. The only significant variation between the two genders' Troponin I readings (1667) was determined to be statistically insignificant (p-0.06). 5.5 hours was the median amount of time that passed between the onset of symptoms and the initial medical contact. Our center's door-to-balloon time (87 minutes) fell within the 90-minute range that the ACC/AHA recommends. An excellent result of PCI was that there was no significant difference in the distribution of secondary endpoint complications between the study participants' ejection fraction, length of hospital stay, incidence of bleeding manifestations, ischaemic stroke, arrhythmias, or mechanical complications.

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