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INFLUENCE OF 20-YEAR REDUCTION IN DOOR-TO-BALLOON TIMES ON OUTCOMES OF PATIENTS WITH ANTERIOR ST-ELEVATION MYOCARDIAL INFARCTION UNDERGOING PRIMARY PERCUTANEOUS CORONARY INTERVENTION: A PROSPECTIVE COHORT STUDY.

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ABSTRACT

Background

The study aims to investigate the relationship between shortened DTB times and long-term clinical outcomes in ST-Elevation Myocardial Infraction (STEMI) patients receiving Primary Percutaneous Coronary Intervention (PPCI).

Methods

This 20-year study at the tertiary care center examined how reduced door-to-balloon timings (DBT) affected outcomes for anterior STEMI patients from 2003 to 2022. The study examined 829 anterior STEMI patients who received PPCI within 12 hours of presentation. Patient data were divided into four five-year quartiles (2003-2007, 2008-2012, 2013-2017, and 2018-2022). Analyses included demographic, clinical, and mortality data. Age, hypertension, smoking status, obesity, hospital stay, diabetes, and DBT were important. The multivariate analysis accounted for gender, age, comorbidities, clinical shock, ejection fraction, and mitral regurgitation.

Results

The study found a substantial drop in patient age (63.4 to 60 yrs, $p<0.01$), with hypertension, smoking, and obesity prevalence increasing across all quartiles. Diabetes prevalence remained unchanged. Median hospital stays decreased (7 to 4.6 days, $p<0.01$), and median DBT fell significantly (216 to 37 minutes, $p<0.01$). Both 30-day and 1-year mortality improved ($p=0.01$), from 13.4% to 6.8% and 19.5% to 12.9%, respectively. Three-year mortality fell from 24.3% to 15.5% ($p=0.02$). Compared to DBT < 60 minutes, shorter DBT was related to reduced mortality over time after controlling for numerous variables.

Conclusion

The long-term prognosis for anterior STEMI patients at our center has improved over the previous two decades. DBT decreased with these changes. This study emphasizes the need to optimize door-to-balloon timeframes for anterior STEMI care and prompt intervention.

Recommendation

Healthcare providers should target anterior STEMI door-to-balloon time reduction based on this study. To improve results in this patient population, smoking, hypertension, and obesity should be addressed. Additional research is needed to improve anterior STEMI patient treatment and care.

Keywords: *Outcomes, Primary Percutaneous Coronary Intervention, Anterior ST- Elevation Myocardial Infraction, Ischemic heart disease*
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INTRODUCTION

Significant alterations have been made to the way people who have ST-segment elevation myocardial infarction (STEMI) are managed within the last 20 years. The therapy landscape for patients with STEMI has changed due to innovations including glycoprotein IIB/IIIA inhibitors, drug-eluting stents, mechanical thrombectomy, and new anti-platelets. Simultaneously, changes in individual risk profiles, as seen by the rising incidence of hypertension and type II diabetes, have complicated the clinical picture [1-3].

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Moreover, the implementation and strengthening of quality metrics principles in 2002 by oversight authorities like the Centers for Medicare and Medicaid Services and the Joint Commission has significantly altered the way myocardial infarction patients are treated in American hospitals [4]. Notably, one of the most significant changes has been the marked decrease in time from door to balloon (DTB) for patients with STEMI, reflecting a concerted effort to improve the timeliness of care [5].

The effect of shorter DTB time on mortality in these individuals has been a subject of debate, with some studies indicating improved outcomes, while others report no clear correlation [6]. Understanding these dynamics is crucial in optimizing the care of anterior wall STEMI patients undergoing primary percutaneous coronary intervention (PPCI).

In a similar vein, PPCI has become a successful therapeutic option for acute STEMI, and acute coronary syndrome (ACS) continues to be a major cause of death globally. The possibility of dying in a hospital for STEMI patients is strongly correlated with the amount of time they receive therapy with PPCI, as previous studies have repeatedly shown [7, 8]. In comparison to patients with shorter DTB timings, patients with DTB times more than 90 minutes have demonstrated higher in-hospital mortality.

Guidelines have emphasized the importance of shortening DTB times as much as possible, with recommendations that PPCI hospitals strive for a DTB duration of under 60 minutes [9]. In Japan, a DTB time of 90 minutes is the standard for STEMI patients [10]. Still up for debate, though, is how short DTB times affect long-term prognosis, and the long-term effects of shorter DTB times have not yet been fully evaluated.

In STEMI patients receiving PPCI, the study aims to look into the association between reduced DTB times and long-term clinical results. By analyzing outcome trends over the past two decades in anterior wall STEMI patients treated at our tertiary care center, we seek to shed light on the intricate interplay between evolving treatment strategies and their impact on patient survival and well-being.

METHODOLOGY

Study Design

This study employed a prospective cohort observational design.

Study Setting

The study was conducted at the Department of Cardiology, J.V.N. Heart Hospital, Patna, Bihar, India, between January 2003 and December 2022.

Study Size

All consecutive patients who had PPCI within the allotted period were included in the research.

Inclusion Criteria

The individuals who exhibited symptoms consistent with anterior STEMI. Individuals who went through PPCI within a time frame of 12 hrs from the onset of symptoms.

Exclusion Criteria

Patients who received thrombolytic therapy before arriving at the hospital, individuals with a history of severe allergic reactions to contrast media, unless pre-medication protocols are followed, and participants with previous coronary artery bypass graft surgery were excluded from the study.

Bias

Potential bias was reduced by implementing a prospective enrollment strategy, wherein consecutive patients were included based on predefined criteria for inclusion and exclusion.

Data Collection and Analysis

Data regarding the fundamental demographic characteristics, presence of concurrent medical conditions, clinical conditions, echocardiographic measurements, and specific procedural information were systematically gathered. The follow-up data were acquired via retrospective examination of patient charts, while the mortality data were extracted from the patient's medical records.

Variables

-Primary Outcome: All-cause 30-day and 1-year mortality.
-Secondary Outcomes: 3- and 5-year mortality.

Statistical Analysis

For abnormal distributions, continuous variables were expressed as mean ± SD. The percentages were used to illustrate the categorical data. Using a significance level of $p<0.05$, The study employed Cox proportional hazards analysis to evaluate the independent determinants of the outcome. A thorough analysis was carried out to assess the correlation between mortality and changes in door-to-balloon time. First, multivariate Cox proportional analysis was conducted, then logistic regression. The statistical analysis was carried out using version 10.0 of JMP Pro.

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Ethical Considerations

The study was undertaken with the appropriate ethical approval and oversight from the Institutional Review Board. Data collection and analysis were conducted by institutional guidelines, thereby waiving the requirement for individual informed consent.

RESULTS

This study had 829 patients in all. They were allocated into four groups: the first group contained 156 patients, the second group contained 204 patients, the third group contained 214 patients, and the fourth group contained 255 patients. Table 1 presents the basic characteristics of these patient groupings, while Table 2 offers the clinical details of their presentations.

Table 1: Baseline attributes of the research group.

Variables	2003-2007	2008-2012	2013-2017	2018-2022	P value
	N= 156	N= 204	N= 214	N= 255	
Age (Mean ± SD) (yrs)	63.4 ± 12.6	61 ± 13.3	59.3 ± 12.2	59.7 ± 12.1	<0.01
Men	65%	64%	66%	64%	0.9
Hypertension	57%	66%	67%	42%	<0.01
Diabetes mellitus	26%	26%	27%	29%	0.6
Insulin treatment	13%	5%	10%	12%	0.008
Hyperlipidemia	23%	23%	21%	26%	0.1
Smoker	24%	29%	41%	24%	<0.01
Kidney impairment	5%	3%	5%	6%	0.3
Peripheral arterial disease	4%	6%	6%	7%	0.6
COPD	3%	7%	9%	10%	0.005
BMI (Kg/m^2)	26.7	27.4	27.5	27.5	0.05
BMI ≥ 30 Kg/m^2	29%	37%	38%	39%	<0.01
Prior stroke	8%	6%	8%	5%	0.4
Family history of CAD	19%	27%	21%	24%	0.04
Prior myocardial infarction	27%	30%	32%	28%	0.5
Prior coronary artery bypass graft surgery	6%	5%	4%	1%	0.007

Table 2: The study population's clinical characteristics.

Variables	2003-2007	2008-2012	2013-2017	2018-2022	P value
Heart rate (bpm)	80	79	81	83	0.001
Systolic blood pressure (mm Hg)	116	115	126	130	<0.01
New York Heart Association (NYHA) functional class					
I	92%	90%	73%	78%	<0.01
II	2%	1%	12%	9%	
III	1%	1%	5%	6%	
IV	2%	5%	6%	3%	
Shock	13%	9%	13%	11%	0.1
Intra-aortic balloon pump	34%	22%	18%	14%	<0.01
Ejection fraction	39.3 ± 12.6	37.4 ± 12.2	36.6 ± 12.5	41.3 ± 11.5	<0.01
Ejection fraction <0.4	42%	46%	49%	37%	0.005
Anemia (serum hemoglobin <12 g/dl)	18%	16%	16%	16%	0.8
Creatine kinase-MB fraction	212	135	123	117	0.002

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All four groups saw a significant reduction in the time it took to travel from the door to the balloon (DBT), with median DBT timings of 216, 193, 134, and 37 minutes ($p<0.001$). The measure of procedural success, which is determined by the post-intervention TIMI III flow, showed an upward trend with time ($p=0.03$), although the duration of hospital stay showed a downward trend (median 7, 5.4, 5.2, and 4.6 days, $p<0.001$).

Prescription of prescribed drugs following STEMI elevated significantly with time in the remaining three groups; unfortunately, data on medications used for discharge were not available for the first group. A follow-up time of 5.4±1.5 years was averaged.

Both 30-day and 1-year mortality rates showed improvement over time (19.5%, 15.4%, 14.9%, and 12.9%, $p<0.01$) and 13.4%, 10.8%, 7.4%, and 6.8%, respectively. There was a significant improvement in the three-year mortality rate for each of the four groups ($p=0.02$, 24.3%, 20.6%, 20.3%, and 15.5%).

Table 3: Mortality rate and hospital duration during the study period

Period	2003-2007	2008-2012	2013-2017	2018-2022
30-Day Mortality	19.5%	15.4%	14.9%	12.9%
1-Year Mortality	13.4%	10.8%	7.4%	6.8%
3-Year Mortality	24.3%	20.6%	20.3%	15.5%
Hospitalization Duration (Days)	7	5.4	5.2	4.6

The DBT time was split into four groups for the trial's duration: less than 60 min., 60-90 min., 90-120 min., and more than 120 min. The 30-day mortality rate did not differ among the groups (log-rank $p=0.14$).

A DBT duration of <60 minutes ($p< 0.001$) was linked to better results than longer DBT periods, according to a logistic regression analysis. Even after controlling for several variables, including gender, age, comorbidities, clinical shock, mitral regurgitation, and acute renal injury in multivariate Cox analysis, shorter DBT durations were still substantially linked to lower long-term mortality.

DISCUSSION

In the present study, over 20 years, patients presenting with anterior STEMI demonstrated a significant reduction in 30-day, 1-year, and 3-year mortality rates. During the same period, door-to-balloon time (DBT) also significantly improved and was associated with decreased mortality over the short and long terms. Shorter DBT was linked to significantly lower 30-day mortality but significantly lower 1-, 3-, and 5-year mortality rates, according to the study.

Pressure from regulatory agencies and the development of quality indicators in the late 1990s and early 2000s probably played a part in the notable improvement in DBT in the study's latter quartiles [4]. The rise in anterior STEMI instances could be attributed to better transportation options, such as helicopter transportation, and wider coverage.

The results of the study indicate that shorter DBT, which results in faster intervention, improves long-term outcomes by reducing total ischemia time, infarction size, and post-infarction remodeling. Crucially, the study refutes the notion that DBT should be restricted to a set amount of time (such as 90 minutes), as shorter DBT sessions consistently produced superior results, independent of the target time. This study differs from others that included a variety of STEMI types and did not account for total ischemia time by concentrating on anterior STEMI patients undergoing PPCI during the first 12 hours [11].

Shorter DBT may be associated with lower peak levels of creatinine kinase MB fraction (CK-MB), which would lead to fewer infarctions and better long-term results [12]. After 2004, the number of drug-eluting stents (DES) used in coronary procedures rose, which probably had a major effect on long-term mortality and the necessity of target artery revascularization [13].

The research also observed a gradual decline in puncture site problems and retroperitoneal bleeding, which may have been brought on by a rise in the usage of radial access and vascular closure devices (VCD) [13]. Better results and lower transfusion rates may have been attributable to restrictive blood transfusion procedures with lower hemoglobin limits. It was found that patients with STEMI having PPCI who had blood transfusions also had lower outcomes, indicating that blood transfusions themselves have a deleterious effect on outcomes [14]. Procedural success rates rose and complication rates did not change despite the rise in high-risk procedures; this may be because these treatments were necessary in some cases.

Enhancing outcomes were probably aided by improved prescription rates of mortality-benefit drugs at discharge, among them are angiotensin-converting enzyme drugs, beta-blockers, and statins.

Consistent with the results of this trial, a number of other investigations have shown reduced fatality rates in STEMI patients receiving PPCI when DBT is shortened [12]. This research is particularly specific to the patient population of anterior STEMI patients who received PPCI within the

initial 12 hours, in contrast to certain previous studies. The study challenges the accepted 90-minute recommendation by highlighting the significance of customized DBT targets based on the idea that shorter DBT leads to better outcomes. The results of previous trials are in line with the reduction in peak CK-MB levels, the increase in DES use, and the decrease in puncture site problems [14]. The study's conclusions about the effects of blood transfusions, the usage of VCDs, and the advantages of radial access are consistent with previous studies on these subjects [15]. The steady complication rates despite high-risk procedures and the rise in overall procedural success are consistent with earlier findings [16].

Overall, this study highlights the value of ongoing quality improvement initiatives in enhancing outcomes for anterior STEMI patients receiving PPCI and contributes to the body of research demonstrating the advantages of shorter DBT.

Generalizability

The study's findings over a 20-year observation of anterior STEMI patients emphasize the critical impact of reduced door-to-balloon time (DBT) on lowering mortality rates and improving long-term outcomes. Highlighting the importance of timely interventions, the study showcases advancements in treatment, such as the use of drug-eluting stents, radial access, and restrictive transfusion practices, contributing to the enhanced care of STEMI patients. By focusing specifically on anterior STEMI patients treated with PPCI within the first 12 hours, this research adds to the body of evidence supporting quicker DBT for better patient results. Furthermore, the study's challenge to the traditional 90-minute DBT target underscores the need for tailored treatment approaches. These insights not only align with previous research on STEMI care but also advocate for continuous quality improvement in clinical practices to optimize outcomes for patients undergoing PPCI.

CONCLUSION

This 20-year study reveals significant improvements in outcomes for anterior STEMI patients undergoing PPCI. Shorter door-to-balloon times (DBT) were associated with decreased chances of both short- and long-term death, challenging conventional DBT thresholds. Regulatory initiatives and improved transportation methods played a role, highlighting the value of ongoing quality improvement in cardiovascular care.

Limitations

This research was subject to several drawbacks. It was an observational study, to start with, which introduced bias in selection and had a limited capacity to establish causality as opposed to association. Second, as this study only involved one center, greater caution had to be used when extrapolating results to the population at large or to other smaller centers. Third, the use of DES and pharmaceutical use were two significant variables that the logistic regression did not account for. It was decided to exclude from the model any variable with more than 10% missing values.

Recommendations

Based on the findings of this study, healthcare providers should continue to prioritize the reduction of door-to-balloon times in anterior STEMI patients. Additionally, efforts to address modifiable risk factors such as smoking, hypertension, and obesity should be reinforced to further improve outcomes in this patient population. Further research is warranted to explore additional strategies for enhancing the management and care of anterior STEMI patients.

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List of abbreviations

STEMI- ST-Elevation Myocardial Infarction
DBT- Door-To-Balloon
PPCI- Primary Percutaneous Coronary Intervention
ACS- Acute Coronary Syndrome
SD- Standard Deviation
NYHA- New York Heart Association
CAD- Coronary Artery Disease
COPD- Chronic Obstructive Pulmonary Disease
CK-MB- Creatinine Kinase MB Fraction
DES- Drug-Eluting Stents
VCD- Vascular Closure Devices

Source of funding

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Conflict of interest

The authors have no competing interests to declare.

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