

EFFICACY AND SAFETY OF DRUG-ELUTING BALLOONS (DEB) IN THE TREATMENT OF PATIENTS PRESENTED WITH ACUTE STEMI

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Abstract: Drug-eluting balloons (DEB) have emerged as a promising strategy for coronary revascularization, offering the capability to deliver anti-proliferative medicines directly to coronary arteries. Nevertheless, the exploration of their role in the acute STEMI context is now underway. Objective: To assess the efficacy of DEB in mitigating major adverse cardiac events (MACE) among individuals diagnosed with Acute ST-segment elevation myocardial infarction (STEMI) at the Peshawar Institute of Cardiology. The present study employed various methodologies to investigate the research question. A prospective cohort study was undertaken during a period spanning from September 2022 to June 2023, encompassing a sample size of 100 eligible participants. The study gathered data on the baseline characteristics of the participants, as well as the details of the DEB intervention. Additionally, safety outcomes were assessed and recorded. The study included statistical analyses to evaluate alterations in troponin and CK-MB levels following DEB intervention. During the follow-up period, many patient outcomes were documented, including MACE, occurrences of bleeding episodes, and instances of restenosis. The study's findings demonstrated noteworthy decreases in troponin and CK-MB levels following the DEB intervention, suggesting effective restoration of blood flow to the heart muscle. The study observed a significant decrease in troponin levels, from an initial mean of 12.7 ng/mL (± 4.6) to a final mean of 5.3 ng/mL (± 2.1) ($p < 0.001$). Similarly, CK-MB levels showed a significant reduction, with an initial mean of 42.3 U/L (± 12.8) decreasing to a final mean of 20.5 U/L (± 8.3) ($p < 0.001$). Nevertheless, there was a notable rise in MACE rates after the DEB intervention, as 38% of the individuals observed encountered MACE throughout the follow-up period. The safety concerns encompass hemorrhagic episodes, occurring in 10% of cases, and restenosis observed in 14% of cases. In conclusion, DEB has shown effectiveness in attaining myocardial reperfusion. However, the observed rise in MACE rates and safety concerns emphasize the intricate nature of DEB utilization in cases of acute STEMI. Additional investigation is required to enhance the process of selecting patients and refining procedure approaches within this particular environment.

Keywords: DEBs, Acute STEMI, Percutaneous Coronary Intervention (PCI), MACE, Troponin, Creatine Kinase-MB, Cardiovascular Intervention, Myocardial Reperfusion, Cardiac Biomarkers

Introduction

Acute STEMI remains a formidable challenge in cardiology, representing a critical medical emergency with potentially devastating consequences (Hirshon et al., 2014; Mehta et al., 2018). Prompt and effective reperfusion therapy is paramount in reducing morbidity and mortality in these patients. Over the years, PCI has emerged as the gold standard for revascularization in STEMI cases, significantly improving outcomes and reducing ischemic injury to the myocardium (Lopes et al., 2019; Ozaki et al., 2018). The drug-eluting stents (DES) have become the cornerstone of PCI in coronary artery disease. However, another interventional strategy has gained prominence in recent years—DEBs (Subban et al., 2018). DEBs have shown promise as an alternative or adjunctive therapy in treating coronary artery disease, owing to their ability to deliver anti-proliferative drugs directly to the vessel wall, inhibiting neointimal hyperplasia and reducing restenosis rates (Ramakrishna et al., 2017).

However, the application of DEBs in acute STEMI management is a topic that warrants further exploration. The acute setting poses unique challenges, including rapid lesion preparation, thrombus management, and optimal stent choice (Martin et al., 2013). Consequently, the efficacy and

safety of DEBs in this specific patient population remains a subject of investigation and debate (Ayyub et al., 2023).

This research seeks to bridge this knowledge gap by conducting a prospective cohort study at the Peshawar Institute of Cardiology, focusing on the efficacy and safety of DEB intervention in patients presenting with acute STEMI. The study aims to provide insights into whether DEBs can offer favorable outcomes, reducing MACE and minimizing complications such as bleeding and restenosis. Given the ongoing evolution of interventional cardiology, evaluating the prospective advantages and drawbacks of novel technology and procedures, such as DEBs, is crucial. This assessment is necessary to maximize patient care and expand the range of alternatives accessible to doctors. This study aims to assess the efficacy of DEB in reducing MACE among patients diagnosed with Acute STEMI at the Peshawar Institute of Cardiology.

Methodology

This study used a prospective cohort design to evaluate the effectiveness and safety of Drug-Eluting Balloons (DEBs) in treating Acute ST-Elevation Myocardial Infarction (STEMI) patients at Peshawar Institute of Cardiology from

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September 2022 to June 2023. Peshawar Institute of Cardiology is a well-known tertiary care center for cardiovascular diseases.

The study included 100 adults aged 18-75 years who were diagnosed with acute STEMI based on clinical symptoms, ECG results, and cardiac biomarkers. They were eligible for Percutaneous Coronary Intervention (PCI). The exclusion criteria were severe allergies to DEB components, pregnancy, severe renal or hepatic dysfunction, severe medical conditions, and inability to provide informed consent.

Data collection included baseline data, intervention details, and follow-up assessments. Baseline data included demographic information, clinical history, risk factors, medication history, initial ECG findings, and cardiac biomarker levels. Intervention details included DEB type, dosage, procedure duration, stent implantation, and complications that occurred during the procedure. Follow-up assessments included cardiac functional status using the New York Heart Association (NYHA) class, repeat ECG and troponin level measurements at predefined intervals, and tracking Major Adverse Cardiovascular Events (MACE) such as cardiac death, non-fatal myocardial infarction (MI), and target vessel revascularization. Safety outcomes included bleeding events, restenosis, and allergic reactions. This comprehensive dataset allowed for a thorough evaluation of the efficacy and safety of DEB for acute STEMI treatment at Peshawar Institute of Cardiology. Data analysis included descriptive statistics to summarize the baseline characteristics of the participants, comparisons between outcomes before and after DEB intervention, and safety outcomes to identify any adverse events related to the treatment. Appropriate tests were used to analyze continuous and categorical variables. A multivariate analysis was performed to account for potential confounding factors, and survival analysis techniques were used to examine time-to-event outcomes such as MACE. This comprehensive analytical approach allowed for a robust evaluation of the efficacy and safety of DEB in managing acute STEMI patients at the Peshawar Institute of Cardiology.

Ethical considerations were adhered to, and ethical approval was obtained from the Institutional Review Board (IRB). Informed consent was secured from all participants, and privacy and data confidentiality were maintained throughout the study to safeguard participant information.

Results

This study aims to provide valuable insights into the efficacy and safety of DEB in treating patients with acute STEMI at the Peshawar Institute of Cardiology. The results will contribute to the evidence base for using DEB in this patient population. Table 1 presents a summary of the baseline characteristics of the 100 participants who were enrolled in this study. These characteristics provide crucial insights into the demographics and health profiles of the individuals involved. The mean age of the participants was 58.4 years, with a standard deviation (SD) of 9.2 years, indicating a relatively middle-aged to older study population. The gender distribution was predominantly male, accounting for 68% of the participants.

Additionally, comorbidities such as hypertension, diabetes mellitus, and smoking were prevalent among the cohort, with 52%, 36%, and 24% of participants, respectively, having these conditions. Furthermore, 20% of the participants had a previous myocardial infarction (MI) history. All participants' initial electrocardiogram (ECG) findings showed ST-segment elevation, a hallmark sign of acute STEMI. Troponin levels, a critical cardiac biomarker, had a mean value of 12.7 ng/mL with an SD of 4.6 ng/mL, while creatine kinase-MB (CK-MB) levels had a mean of 42.3 U/L with an SD of 12.8 U/L, indicating cardiac injury in these patients.

Moving to Table 2, this table provides an overview of the patient outcomes observed after the DEB intervention. The primary outcome measure assessed was MACE, which includes cardiac death, non-fatal MI, and Target Vessel Revascularization (TVR). The results show that 8% of the participants experienced cardiac death, 12% had a non-fatal MI, and 18% required TVR during the study period. Safety outcomes were also evaluated, encompassing bleeding events, restenosis, and allergic reactions. Among the participants, 10% experienced bleeding events, 14% had restenosis, and 4% had allergic reactions following the DEB intervention.

Table 3 presents the results of statistical tests comparing baseline and outcome variables. The primary focus here is the changes in troponin and CK-MB levels before and after DEB intervention. The data reveal significant reductions in both troponin and CK-MB levels post-intervention. Specifically, troponin levels decreased from a mean of 12.7 ng/mL before the intervention to 5.3 ng/mL afterward, with $p < 0.001$, indicating successful myocardial reperfusion. Similarly, CK-MB levels showed a substantial reduction from a mean of 42.3 U/L to 20.5 U/L after DEB treatment, also with a p -value < 0.001 , further supporting the efficacy of the intervention.

Table 1: Baseline characteristics of the 50 participants.

Characteristic	Mean ± SD or N (%)
Age (years)	58.4 ± 9.2
Male gender	34 (68%)
Hypertension	26 (52%)
Diabetes mellitus	18 (36%)
Smoking	12 (24%)
Previous MI	10 (20%)
Initial ECG findings	ST-segment elevation
Troponin levels (ng/mL)	12.7 ± 4.6
Creatine kinase-MB (U/L)	42.3 ± 12.8

Table 2: An overview of patient outcomes after DEB intervention

Outcome Measure	N (%)
MACE	
Cardiac death	4 (8%)
Non-fatal MI	6 (12%)
TVR	9 (18%)
Safety Outcomes	
Bleeding events	5 (10%)
Restenosis	7 (14%)
Allergic reactions	2 (4%)

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Furthermore, the table includes data on the occurrence of MACE, bleeding events, and restenosis. The proportion of participants experiencing MACE increased significantly post-DEB, with 38% affected. Additionally, 10% of participants experienced bleeding and 14% developed restenosis after DEB treatment.

These findings collectively provide valuable insights into the effectiveness and safety of DEB intervention in patients with acute STEMI, highlighting the positive outcomes and potential adverse events associated with this treatment approach.

Table 3: Results of statistical tests comparing baseline and outcome variables.

Variable	Pre-DEB Mean (\pm SD)	Post-DEB Mean (\pm SD)	p-value
Troponin levels (ng/mL)	12.7 \pm 4.6	5.3 \pm 2.1	<0.001
Creatine kinase-MB (U/L)	42.3 \pm 12.8	20.5 \pm 8.3	<0.001
MACE (Any)	-	19 (38%)	-
Bleeding Events	-	5 (10%)	-
Restenosis	-	7 (14%)	-

Discussion

The findings of this research provide significant contributions to understanding the effectiveness and safety of DEBs as an interventional approach for individuals with Acute STEMI at the Peshawar Institute of Cardiology. These findings must be considered within the existing literature on DEB use in acute STEMI management.

Our study demonstrated a significant reduction in troponin levels and creatine kinase-MB (CK-MB) levels post-DEB intervention. This observation aligns with previous research highlighting the ability of DEBs to achieve effective myocardial reperfusion (Garcia-Garcia et al., 2019; Indermuehle et al., 2013). The reduced troponin and CK-MB levels post-intervention signify successful restoration of coronary blood flow and mitigation of myocardial damage, which are critical objectives in managing acute STEMI (Stătescu et al., 2022).

However, it is noteworthy that the study also revealed an increased incidence of MACE post-DEB intervention, with 38% of participants experiencing MACE during the follow-up period. This outcome warrants careful consideration in light of prior studies. The literature has shown mixed results regarding the impact of DEBs on MACE in STEMI patients (Tan et al., 2021; Wei et al., 2023; Yang et al., 2023). Some studies have reported favorable outcomes with lower MACE rates (Murnaghan et al., 2022), while others have indicated higher MACE rates, similar to our findings (Wei et al., 2023). These discrepancies in MACE rates may be attributed to variations in study populations, DEB types, or procedural techniques.

Furthermore, the safety outcomes in our study indicated that 10% of participants experienced bleeding events, and 14% developed restenosis after DEB treatment. These safety concerns echo concerns raised in previous research (Spaulding et al., 2023). The risk of bleeding events associated with DEB use in STEMI patients, often receiving dual antiplatelet therapy, necessitates careful patient selection and management.

This study has certain limitations that should be considered when interpreting the findings. Firstly, the sample size is relatively limited, which may affect the generalizability of the results. Additionally, this research is conducted as a single-center study, potentially limiting the broader applicability of the findings to other healthcare settings. Lastly, the possibility of selection bias should be

acknowledged, as the study participants were drawn from a specific population seeking treatment at the Peshawar Institute of Cardiology, which may not fully represent the diversity of STEMI cases. These limitations emphasize the need for cautious interpretation and suggest avenues for future research to corroborate and expand upon the current findings.

Conclusion

Our findings suggest that DEB intervention in acute STEMI patients can effectively achieve myocardial reperfusion, as evidenced by reductions in troponin and CK-MB levels. However, the increased occurrence of MACE and safety concerns such as bleeding events and restenosis highlight the complexity of using DEBs in this context. These results emphasize the importance of further research to elucidate the optimal patient selection criteria, procedural techniques, and DEB types in acute STEMI management.

Declarations

Data Availability statement

All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned.

Consent for publication

Approved

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Not applicable

Conflict of interest

The authors declared absence of conflict of interest.

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