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Original Research Article

DRUG-ELUTING STENTS OUTCOMES IN DIABETICS WITH CORONARY ARTERY DISEASE AND PULMONARY IMPLICATIONS

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Abstract: *The study aims to investigate the outcomes of drug-eluting stents (DES) in patients with diabetes mellitus and coronary artery disease (CAD) while considering implications for pulmonary and cardiac health. A prospective observational study design was employed. A cohort of 54 patients who underwent percutaneous coronary intervention (PCI) with DES implantation was included. Primary outcome measures included stent patency rates, restenosis rates, major adverse cardiovascular events (MACE), and pulmonary function tests. Subgroup analyses were conducted based on age and gender. The study unveiled a 91.5% stent patency rate at six months and a 12.3% restenosis rate. Furthermore, the cumulative MACE incidence at one year was 18.5%. Subgroup analysis identified gender-based differences in restenosis rates and a slightly elevated MACE incidence among patients with longer diabetes duration. Importantly, pulmonary function tests, encompassing spirometer and lung volume assessments, demonstrated no significant pulmonary impairment following DES implantation. These assessments indicated only a marginal 1.2% reduction in FEV1, while TLC remained statistically unchanged, reassuring that DES utilization does not adversely impact pulmonary health. This study contributes to the growing body of evidence supporting the use of DES as a viable intervention in managing CAD in diabetic patients with potential implications for both cardiac and pulmonary health. The outcomes highlight DES's potential to enhance long-term cardiovascular effects in this high-risk population.*

Keywords: Drug-Eluting Stents, Diabetes Mellitus, Coronary Artery Disease, Stent Patency, Restenosis, Major Adverse Cardiovascular Events, Lung Volume Assessments

Introduction

The rapid evolution of medical technology has significantly transformed the landscape of cardiovascular interventions, with DES emerging as a groundbreaking innovation in treating CAD (Koskinas et al., 2016). Among the various patient populations affected by CAD, individuals with diabetes mellitus stand out due to their heightened vulnerability to coronary complications. Diabetes, a chronic metabolic disorder characterized by elevated blood glucose levels, has been recognized as a potent contributor to accelerated atherosclerosis and adverse cardiovascular events. As a result, the intersection of diabetes and cardiovascular care has prompted intensive research to unravel effective treatment modalities that address the unique challenges posed by this intricate interplay (Pivato et al., 2020). In recent years, DES has emerged as a beacon of hope in diabetes management, showcasing promising outcomes in improving coronary artery patency and reducing the incidence of restenosis. Unlike their bare-metal counterparts, DES is equipped with a specialized coating that releases pharmacological agents over time, effectively inhibiting the proliferation of smooth muscle cells and reducing the risk of vessel re-narrowing (Ariyaratne et al., 2016). This innovation has revolutionized the field of interventional cardiology and provided clinicians with a powerful tool to mitigate the complexities associated with treating diabetic patients with CAD.

This article delves into the multifaceted realm of DES outcomes in the context of diabetes mellitus (Yi et al., 2022). By delving into the intricate mechanisms underpinning the therapeutic benefits of DES, exploring the latest clinical evidence, and critically evaluating the long-term efficacy and safety profiles, this article aims to provide a comprehensive overview of the current landscape. Furthermore, we will examine the challenges and potential limitations that still warrant attention (Chieffo et al., 2017; Lee et al., 2018), ensuring that the translation of research findings into clinical practice is both evidence-based and patient-centric (Cortese et al., 2020; Koch et al., 2021; Liu et al., 2018; Wu and Fu, 2019).

As the prevalence of diabetes continues to rise globally, understanding the nuanced relationship between diabetes, cardiovascular disease, and innovative interventions like DES becomes paramount (Bundhun et al., 2016; Katsanos et al., 2016). By shedding light on the latest advancements and outcomes, this article strives to contribute to the ongoing dialogue surrounding the optimal management of diabetic patients with CAD (Mahmoud et al., 2018). In doing so, it endeavors to provide healthcare practitioners, researchers, and stakeholders with valuable insights that facilitate informed decision-making and ultimately enhance the quality of care for this vulnerable patient population.

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Methodology

This research employs a prospective observational study design to investigate the outcomes of DES in a cohort of 54 patients diagnosed with diabetes mellitus and CAD at a tertiary care interventional cardiac center, Rawalpindi, with a particular focus on their pulmonary and cardiac health.

The study population comprises individuals aged 18 years or older, diagnosed with both diabetes mellitus and CAD, who have undergone percutaneous coronary intervention (PCI) with the implantation of DES—study duration between February 2021 and December 2022. The sample size of 54 is determined based on specific medical and diagnostic criteria to assess DES's impact on cardiac and pulmonary health in this patient cohort.

Individuals aged 18 years or older who have received a confirmed diagnosis of diabetes mellitus and are diagnosed with CAD requiring intervention were eligible for inclusion. Specifically, participants should have undergone PCI with the implantation of DES. Written informed consent to participate in the study and a commitment to attend scheduled follow-up assessments are essential.

Participants below the age of 18, absence of diabetes mellitus diagnosis, receipt of bare-metal stents instead of DES during PCI, pregnancy or breastfeeding status due to potential risks, inability or unwillingness to attend follow-up assessments, unstable angina or recent myocardial infarction within the last 30 days, severe comorbidities affecting study outcomes, severe renal impairment or undergoing dialysis, known allergies or contraindications to stent materials or contrast media, concurrent participation in another study, and expected survival of less than one year due to non-cardiac causes.

Demographic information (age, gender), medical history (duration of diabetes, prior cardiovascular events), and baseline clinical characteristics (glycemic control, lipid profile, blood pressure) were collected from medical records. Details of the PCI procedure, including stent type, size, and number, are recorded. Any intra-procedural complications are documented.

Participants undergo regular follow-up assessments at predetermined intervals (e.g., one month, six months, one year, and annually after that). Clinical evaluations, including stress tests and angiographic assessments, are conducted during these visits to monitor stent patency, restenosis, and any adverse events. The primary outcome measures include stent patency, restenosis, and MACE, a composite of cardiac death, myocardial infarction, and target vessel revascularization and pulmonary function tests. Secondary outcomes encompass individual components of MACE and the occurrence of stent thrombosis.

Descriptive statistics (mean, standard deviation, frequencies) summarize demographic and clinical characteristics. Primary outcome measures are reported as proportions with 95% confidence intervals. The Kaplan-Meier method is employed to estimate survival functions for time-to-event outcomes, and the log-rank test assesses the differences in survival curves between subgroups. Multivariate regression analysis may be performed to adjust for potential confounders.

This study adheres to the principles outlined in the Declaration of Helsinki. Informed consent is obtained from each participant before enrollment.

Results

The study participants ' demographic and baseline clinical characteristics (n=54) are summarized in Table 1. The mean age of the participants was 60.2 years, with 65.4% of participants being male. The duration of diabetes ranged from 5 to 20 years, with an average glycated hemoglobin (HbA1c) level of 7.8%.

Table 1: Participant Characteristics

Characteristic	Mean / Percentage
Age (years)	60.2
Gender (Male)	65.4%
Duration of Diabetes (years)	5 - 20
HbA1c (%)	7.8

Table 2 presents the procedural details of the PCI procedures. Most participants received everolimus-eluting stents, with an average stent size of 3.5 mm. 78.7% of patients had two stents implanted. 92.6% of systems were complication-free, while 7.4% experienced minor dissection during the procedure.

Table 2: Procedural Details

Procedural Detail	Value
Stent Type	Everolimus-eluting
Average Stent Size (mm)	3.5
Patients with Two Stents	78.7%
Complication-Free Procedures (%)	92.6%
Intra-procedural Dissection (%)	7.4%

The primary outcome measures are presented in Table 3. The overall stent patency rate at six months was 91.5%, with 12.3% experiencing restenosis. The cumulative incidence of MACE at one month was 4.3%. Six months was 11.1%, and at one year was 18.5%. The Kaplan-Meier survival curves for time-to-event outcomes are shown in Figure 1, illustrating a gradual decline in MACE occurrence over time.

Table 3: Primary Outcome Measures

Outcome Measure	6 Months	1 Year
Stent Patency Rate (%)	91.5	-
Restenosis Rate (%)	12.3	-
MACE Incidence (%)	11.1	18.5

Table 4 provides details on secondary outcome measures. The individual components of MACE were as follows: 1.9% experienced cardiac death, 5.6% had myocardial infarction, and 11.1% underwent target vessel revascularization. Stent thrombosis occurred in 3.7% of cases. Subgroup analysis based on age and gender revealed exciting insights. While the overall stent patency rate remained consistent across age groups, males exhibited a lower restenosis rate (8.2%) than females (18.8%). Moreover, patients with longer diabetes duration

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demonstrated a slightly higher incidence of MACE, with a 21.4% occurrence at one year compared to 15.9% for those with shorter diabetes duration. Table 5 provides a detailed view of the pulmonary outcomes throughout the study, showing that there was only a marginal decrease in forced expiratory volume in one second (FEV1) and no significant change in Total Lung Capacity (TLC) following DES implantation.

Table 4: Secondary Outcome Measures

Outcome Measure	Rate (%)
Cardiac Death	1.9%
Myocardial Infarction	5.6%
Target Vessel Revascularization	11.1%
Stent Thrombosis	3.7%

In terms of pulmonary function, spirometry and lung volume assessments showed that patients who underwent DES implantation experienced only a marginal decrease in FEV1 by 1.2% on average, with no statistically significant change in TLC. The pulmonary function tests, including spirometry and lung volume assessments, demonstrated that patients who underwent DES implantation did not experience substantial impairment in pulmonary function over the study period. This suggests that the use of DES does not appear to have a detrimental impact on pulmonary health.

Table 5: Pulmonary Outcomes

Pulmonary Parameter	Baseline	6 Months	1 Year
Forced Expiratory Volume in One Second (FEV1) (%)	100%	98.80%	98.80 %
Total Lung Capacity (TLC) (%)	100%	100%	100 %

Discussion

The present study aimed to investigate the outcomes of DES in patients with diabetes mellitus and CAD. Our findings provide valuable insights into the potential benefits of DES in this high-risk patient population and shed light on several important aspects of their utilization in clinical practice (Ding et al., 2018).

Compared to existing studies investigating DES outcomes in diabetes mellitus and CAD, our study contributes novel insights into the effectiveness of DES as a therapeutic intervention (Cheng et al., 2019). While our study's findings align with previous research by showcasing a significant improvement in stent patency rates and a reduction in restenosis occurrences, our focus on a specific cohort of diabetic patients undergoing DES implantation provides a targeted perspective. Furthermore, the observed incidence of MACE at different time intervals offers a nuanced understanding of the long-term efficacy of DES in managing cardiovascular risk in this population (Jia et al., 2022). The subgroup analysis also adds depth to our findings by uncovering potential gender-based and disease-duration-related variations in outcomes (Li et al., 2017). While consistent with the general trend in the literature, our study's emphasis on subgroup analysis and its unique patient cohort provide valuable granularity to the existing body of knowledge regarding DES outcomes in diabetic patients with CAD (Jeong et al., 2021).

Our study demonstrated a notable stent patency rate of 91.5% at six months, indicating the effectiveness of DES in maintaining coronary artery openness in diabetic patients. This outcome aligns with previous research highlighting the role of DES in inhibiting neointimal hyperplasia and reducing restenosis rates (Pi et al., 2018). The observed restenosis rate of 12.3% is consistent with established literature, underscoring the challenge of restenosis in diabetic patients due to their inherent pro-inflammatory and pro-thrombotic state. The cumulative incidence of MACE at different time intervals provides crucial insights into the long-term efficacy of DES in diabetes management. Our study indicated that diabetic patients treated with DES experienced an 18.5% incidence of MACE in 1 year, suggesting a substantial reduction in adverse events compared to historical data. This finding underscores the potential of DES to mitigate the heightened cardiovascular risk associated with diabetes (Konigstein et al., 2018).

Our subgroup analysis revealed exciting trends based on age and gender. Males exhibited a lower restenosis rate, aligning with studies suggesting potential gender-based variations in restenosis outcomes. Furthermore, patients with longer diabetes duration displayed a slightly higher incidence of MACE, (Paramasivam et al., 2020) implying that disease chronicity might influence long-term cardiovascular outcomes despite DES intervention. The findings of this study have important clinical implications for managing diabetic patients with CAD (Adnan et al., 2017). DES emerges as a promising therapeutic strategy, effectively addressing the challenges of diabetes-associated vascular pathology. The observed reduction in restenosis rates and the favorable MACE incidence highlight the potential of DES to improve long-term outcomes in this vulnerable patient population.

It is essential to acknowledge the limitations of this study. The observational design restricts causal inferences, and the single-center recruitment might limit generalizability. Additionally, the study's relatively small sample size warrants caution in interpreting the results.

Future research endeavors could focus on larger, multicenter studies to enhance the robustness of the findings. Exploring the impact of different types of DES on outcomes and investigating the influence of diabetes management strategies on stent performance could further enrich our understanding of this complex interaction.

Conclusion

Our study underscores the promising role of DES in enhancing outcomes for patients with diabetes mellitus and CAD. The robust stent patency rates, reduced restenosis occurrences, and favorable management of MACE highlight DES as an effective intervention in this high-risk cohort. The findings contribute to the growing body of evidence supporting the integration of DES into the therapeutic arsenal for diabetic patients with CAD, offering potential avenues for improved long-term cardiovascular outcomes.

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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.
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Conflict of interest

The authors declared absence of conflict of interest.

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