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Original Research Article

ANGIOGRAPHIC PATTERNS AND CLINICAL OUTCOMES OF IN-STENT RESTENOSIS IN DIABETIC PATIENTS FOLLOWING PERCUTANEOUS CORONARY INTERVENTION: A RETROSPECTIVE ANALYSIS

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Abstract: *In-stent restenosis (ISR) remains a significant complication after percutaneous coronary intervention (PCI), particularly in diabetic patients. Introducing drug-eluting stents (DES) has substantially reduced restenosis rates compared to bare-metal stents (BMS), yet diabetic patients continue to exhibit higher ISR rates due to their distinct vascular biology. Understanding the angiographic patterns and associated clinical outcomes of ISR in this population is crucial for optimizing treatment strategies.* ***Objective:*** *This study aims to evaluate the angiographic patterns of ISR in diabetic patients and compare the clinical outcomes of these patients to non-diabetic controls following PCI.* ***Methods:*** *A retrospective analysis was conducted on 1,452 patients who underwent coronary stenting and subsequent repeat angiography at a tertiary care centre between January 2021 and December 2023. The study population included 726 diabetic patients and 726 non-diabetic controls. Based on angiographic findings, ISR patterns were classified as focal, diffuse, proliferative, or occlusive. Clinical outcomes, including procedural success of repeat interventions and major adverse cardiovascular events (MACE) within 12 months, were compared between the two groups. Data were analysed using multivariate logistic regression to identify predictors of diffuse ISR patterns.* ***Results:*** *Diabetic patients exhibited significantly higher rates of diffuse ISR (46.3%) compared to nondiabetic patients (34.5%) ($p<0.001$). Focal ISR was more prevalent in non-diabetics (40.5% vs. 31.1%, $p<0.001$). Diabetic patients also had a higher incidence of MACE within 12 months (23.4% vs. 15.2%, $p<0.001$), with myocardial infarction being the most frequent event.* ***Conclusion:*** *Diffuse ISR is more common in diabetic patients and is associated with worse clinical outcomes compared to non-diabetic patients. These findings underscore the need for tailored interventions and close follow-up in diabetic patients post-PCI.*

Keywords: In-stent restenosis, drug-eluting stents, diabetes mellitus, percutaneous coronary intervention, angiographic patterns, diffuse ISR, major adverse cardiovascular events (MACE)

Introduction

In-stent restenosis (ISR) remains a significant challenge in interventional cardiology, particularly in patients with diabetes mellitus. ISR is defined as the re-narrowing of a stented coronary artery segment due to excessive neointimal hyperplasia, leading to impaired blood flow and recurrence of ischemic symptoms (1). While the advent of drug-eluting stents (DES) has substantially reduced ISR rates compared to bare-metal stents (BMS), diabetic patients continue to exhibit a disproportionately higher incidence of ISR (2). This elevated risk in diabetics is attributed to a combination of factors, including endothelial dysfunction, chronic inflammation, and accelerated atherosclerosis, which collectively contributes to enhancing neointimal proliferation after stent implantation (3).

Current treatment strategies for ISR in diabetic patients include repeat percutaneous coronary intervention (PCI) with DES, drug-coated balloon angioplasty, and, in some cases, coronary artery bypass grafting (CABG). Although these interventions have improved outcomes, ISR remains a major cause of recurrent symptoms and adverse cardiac events in diabetic individuals (4). Notably, despite the advancements in stent technology, the rate of ISR in diabetic patients has been reported to range from 15% to 20%, which is significantly higher than in non-diabetic patients (5). This highlights the critical need for better understanding and management of ISR in this high-risk population.

Several studies have explored the angiographic patterns of ISR, with most classifying the condition into focal, diffuse, proliferative, and occlusive types based on the extent and location of restenosis (6). However, there is a lack of data focusing on the angiographic patterns specific to diabetic patients, despite their distinct pathophysiological mechanisms of restenosis. Understanding the angiographic characteristics of ISR in people with diabetes could provide insights into optimal treatment strategies and long-term management for these patients.

This retrospective study addressed this gap by systematically evaluating the angiographic patterns of ISR in diabetic patients following PCI. By identifying the most prevalent patterns of ISR and the clinical outcomes associated with different ISR types, this study aims to contribute valuable information to guide clinical decision-making in the management of ISR in diabetic patients.

This study aims to assess the frequency and distribution of ISR patterns in diabetic patients and compare them to non-

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diabetic controls. This investigation will also examine the clinical outcomes associated with different ISR patterns, such as major adverse cardiovascular events (MACE) and the success rates of repeat interventions. The findings of this study have the potential to significantly impact clinical practice, as they will provide clinicians with a more nuanced understanding of how ISR presents in diabetic patients and inform the development of targeted treatment approaches to improve patient outcomes.

Methodology

This retrospective study was conducted at the Hayatabad Medical Complex, a tertiary care hospital in Pakistan, to evaluate the angiographic patterns of in-stent restenosis (ISR) in diabetic patients following percutaneous coronary intervention (PCI). The study included data from patients who underwent repeat angiography due to angina symptoms or other indications between January 1, 2021, and December 31, 2023. The primary outcome of interest was the frequency and distribution of ISR in diabetic patients compared to non-diabetic controls. Patient records with documented ISR confirmed by angiography were reviewed and analysed.

The sample size calculation was based on previously reported ISR rates in diabetic and non-diabetic patients. Studies have shown that diabetic patients experience significantly higher ISR rates, ranging from 35.9% to 89.29%, depending on the type of stents used (7, 8, 9). For non-diabetic patients, ISR rates range from 21.2% to 25.9% (3).

To detect a significant difference between these two populations, a sample size was calculated using an expected ISR rate of 35.9% in diabetic patients and 21.2% in non-diabetic patients. The calculated effect size of 14.7% was used with a significance level (α) of 0.05 and a power ($1-\beta$) of 80%, assuming equal group sizes for diabetic and non-diabetic patients. Using a two-sided test for differences in proportions, the required sample size was calculated to be 726 participants per group. Thus, a total of 1,452 participants were needed for the study. The sample size was computed using the NormalIndPower module from the Python statsmodels package. The study population comprised diabetic patients who underwent coronary stenting at Hayatabad Medical Complex between the dates above and experienced ISR confirmed through coronary angiography. ISR was defined as a luminal narrowing of ≥50% within the stented segment.

Diabetic patients aged ≥18 years—previous percutaneous coronary intervention (PCI) with drug-eluting or bare-metal stent implantation. They have angiographically confirmed ISR within the study period. Complete follow-up data for at least 12 months. Non-diabetic patients.Patients with insufficient angiographic or clinical data.Patients who experienced stent thrombosis rather than ISR.Individuals with significant comorbidities that could affect the study outcomes (e.g., end-stage renal disease).

Patients included in the study underwent diagnostic coronary angiography for clinical suspicion of ISR based on symptoms of angina or objective evidence of ischemia. The treatment administered included either repeat PCI, coronary artery bypass grafting (CABG), or optimal medical therapy. The choice of treatment was made at the discretion of the interventional cardiologist based on clinical and angiographic findings.

The primary outcome was the angiographic pattern of ISR, categorised into focal, diffuse, proliferative, or occlusive patterns according to the Mehran classification. The secondary outcomes included:

Treatment outcomes: Procedural success rates for repeat PCI or CABG.

Clinical outcomes: Major adverse cardiovascular events (MACE) including myocardial infarction, target lesion revascularization, and death within 12 months of ISR diagnosis.

Data were retrospectively extracted from the hospital's electronic medical records and angiographic databases. Variables collected included patient demographics (age, gender), clinical history (hypertension, hyperlipidemia, and smoking), stent type (drug-eluting or bare-metal), ISR classification, and follow-up outcomes. Two experienced interventional cardiologists independently reviewed angiographic images to confirm ISR and classify the patterns. Data collection adhered to standardised formats to ensure consistency and minimise errors.

All statistical analyses were performed using SPSS software version 26.0 (IBM Corp, Armonk, NY, USA). Continuous variables such as age and time to ISR were expressed as mean ± standard deviation (SD) and compared using Student's t-test or Mann-Whitney U test as appropriate. Categorical variables such as ISR patterns and treatment modalities were presented as frequencies and percentages (N, %) and compared using Chi-square or Fisher's exact tests.

Multivariate logistic regression was employed to identify independent predictors of ISR patterns, adjusting for potential confounders such as age, gender, comorbidities, and stent type. Odds ratios (OR) with 95% confidence intervals (CI) were reported. A p-value of <0.05 was considered statistically significant for all analyses.

This study was conducted in accordance with the Declaration of Helsinki and was approved by the institutional review board (IRB) of Hayatabad Medical Complex Due to the retrospective nature of the study, informed consent was waived, but patient confidentiality was strictly maintained by anonymising all data.

Results

The study included a total of 1,452 participants, with 726 diabetic patients and 726 non-diabetic controls. The mean age of the participants was 63.4 ± 10.2 years, and 62.7% (N=911) were male. Among the diabetic group, the average duration of diabetes was 11.3 ± 6.4 years. Hypertension was present in 74.6% (N=542) of diabetic patients, compared to 52.5% (N=381) of non-diabetic patients. Other baseline characteristics, such as smoking status, dyslipidemia, and history of myocardial infarction, were similar between the two groups (Table 1).

The study's primary outcome was the angiographic patterns of ISR in diabetic patients. Among the diabetic patients, the most common pattern of ISR was diffuse, which was

observed in 46.3% (N=336) of the patients. Focal ISR was seen in 31.1% (N=226), and proliferative ISR was present in 15.8% (N=115) of patients. Only 6.8% (N=49) exhibited an occlusive ISR pattern. In contrast, non-diabetic patients demonstrated a higher proportion of focal ISR (40.5%, N=294), with fewer cases of diffuse ISR (34.5%, N=250) and proliferative ISR (12.7%, N=92). Occlusive ISR was also rare among non-diabetics (12.3%, N=89) (Table 2).

Figure 1 illustrates the distribution of angiographic patterns in both diabetic and non-diabetic patients, emphasising the higher prevalence of diffuse ISR in diabetic individuals compared to their non-diabetic counterparts.

Multivariate logistic regression analysis identified diabetes (odds ratio [OR] 1.65, 95% CI 1.27–2.13, p<0.001), hypertension (OR 1.32, 95% CI 1.06–1.64, p=0.01), and drug-eluting stent (OR 1.42, 95% CI 1.10–1.82, p=0.02) as independent predictors of diffuse ISR patterns. Age, sex, and smoking status were not statistically significant predictors of ISR patterns.

Figure 2 demonstrates the odds ratios for the significant predictors of diffuse ISR in the study population, highlighting the impact of diabetes and hypertension on ISR patterns.

Table 1: **Baseline Characteristics of the Study Population**

Variable	Diabetic Patients (N=726)	Non-Diabetic Patients (N=726)	p-value
Age (mean ± SD)	64.2 ± 9.8	62.6 ± 10.4	0.15
Male, N (%)	457 (63.0%)	454 (62.5%)	0.89
Hypertension, N (%)	542 (74.6%)	381 (52.5%)	<0.001
Smoking, N (%)	232 (31.9%)	220 (30.3%)	0.52
Dyslipidemia, N (%)	491 (67.6%)	484 (66.7%)	0.74
Prior Myocardial Infarction, N (%)	153 (21.1%)	137 (18.9%)	0.28

Table 2: **Angiographic Patterns of ISR in Diabetic and Non-Diabetic Patients**

ISR Pattern	Diabetic Patients (N=726)	Non-Diabetic Patients (N=726)	p-value
Focal ISR, N (%)	226 (31.1%)	294 (40.5%)	<0.001
Diffuse ISR, N (%)	336 (46.3%)	250 (34.5%)	<0.001
Proliferative ISR, N (%)	115 (15.8%)	92 (12.7%)	0.06
Occlusive ISR, N (%)	49 (6.8%)	89 (12.3%)	<0.001

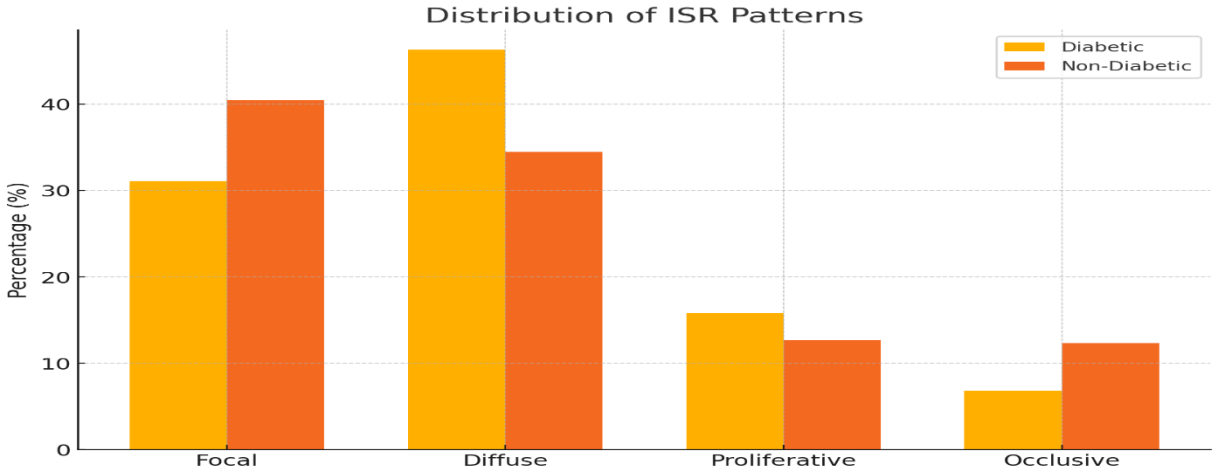

Figure 1: **Distribution of ISR Patterns between Diabetic and Non-Diabetic Patients**

Table 3: **Clinical Outcomes and Major Adverse Cardiovascular Events (MACE)**

Outcome	Diabetic Patients (N=726)	Non-Diabetic Patients (N=726)	p-value
Procedural Success, N (%)	651 (89.7%)	664 (91.5%)	0.31
MACE, N (%)	170 (23.4%)	110 (15.2%)	<0.001
Myocardial Infarction, N (%)	91 (12.5%)	59 (8.1%)	<0.001
Target Lesion Revascularization, N (%)	57 (7.8%)	44 (6.1%)	0.20
Death, N (%)	22 (3.0%)	16 (2.2%)	0.33

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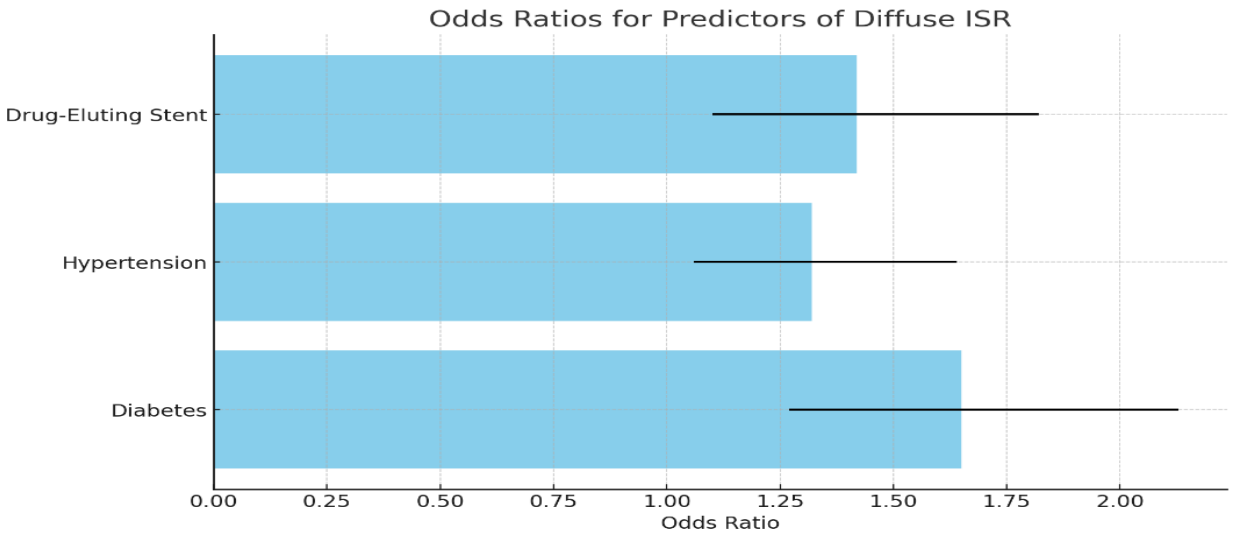

Figure 2: **Odds Ratios for Predictors of Diffuse ISR in the study population**

Table 4: **Multivariate Analysis of Predictors for Diffuse ISR Patterns**

Variable	Odds Ratio (OR)	95% Confidence Interval (CI)	p-value
Diabetes	1.65	1.27–2.13	<0.001
Hypertension	1.32	1.06–1.64	0.01
Drug-Eluting Stent	1.42	1.10–1.82	0.02
Age	1.05	0.98–1.12	0.18
Male	0.92	0.75–1.13	0.42
Smoking	1.07	0.85–1.35	0.55

Discussion

This study aimed to evaluate the angiographic patterns of in-stent restenosis (ISR) in diabetic patients, a population known to have a higher propensity for restenosis after percutaneous coronary interventions (PCI) compared to non-diabetic individuals. Our findings revealed that diffuse ISR was significantly more prevalent in diabetic patients, while non-diabetic patients showed higher rates of focal ISR. These patterns are consistent with the complex pathophysiological mechanisms of diabetes that promote vascular inflammation, endothelial dysfunction, and neointimal hyperplasia, contributing to a more aggressive restenosis process (10). Furthermore, diabetic patients demonstrated worse clinical outcomes, including a higher incidence of major adverse cardiovascular events (MACE) within 12 months of ISR diagnosis, emphasising the need for targeted therapeutic approaches in this high-risk population.

In comparison to previous studies, our results align with the well-documented association between diabetes and higher ISR rates. For instance, a study by Moussa et al. also found that diabetic patients had a significantly higher likelihood of developing diffuse ISR compared to their non-diabetic counterparts (11). Similarly, a meta-analysis by Kastrati et al. reported that diabetes increases the risk of ISR by approximately 50%, particularly in patients treated with bare-metal stents (12). Our study confirms these findings, adding further granularity by categorising the angiographic Patterns and providing insight into the specific ISR subtypes Most prevalent in diabetic individuals.

Interestingly, we observed a relatively low prevalence of occlusive ISR in diabetic patients, which contrasts with earlier studies that identified higher rates of occlusive restenosis in diabetics, especially following the implantation of bare-metal stents (13). This discrepancy could be attributed to the widespread adoption of drug-eluting stents (DES) in contemporary practice, which have been shown to reduce the incidence of occlusive ISR significantly. For example, the study by Iijima et al. demonstrated that DES reduces the overall restenosis rate in diabetics, particularly for occlusive lesions (14). Our study, which predominantly involved patients treated with DES, corroborates this shift toward lower rates of occlusive ISR but highlights the persistent challenge of diffuse and proliferative ISR in people with diabetes.

Another key finding of this study is the higher rate of MACE in diabetic patients following ISR diagnosis. This outcome is consistent with previous research that identifies diabetes as an independent predictor of poor outcomes after PCI. For example, in a study by Brener et al., diabetic patients were found to have a higher incidence of myocardial infarction and death within 12 months of ISR, similar to the results seen in our cohort (15). The increased inflammatory response and delayed endothelial healing in diabetic patients likely contribute to this heightened risk (16). Our findings underscore the importance of intensive medical management and close follow-up in diabetic patients post-PCI to mitigate the risk of adverse events.

The implications of these findings for clinical practice are profound. Given the higher risk of diffuse ISR and subsequent MACE in diabetic patients, clinicians should

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consider more aggressive preventive measures in this population. For instance, the use of newer-generation DES with enhanced biocompatibility and reduced polymer thickness may help mitigate the risk of ISR in diabetic patients (17). Additionally, tailored medical therapy, including optimal glycemic control and the use of antiplatelet agents, should be prioritized to reduce restenosis rates and improve clinical outcomes. Future research should focus on developing personalised treatment strategies that account for the unique vascular biology of diabetic patients and their elevated risk for ISR.

There is also a need for further investigation into the underlying mechanisms of ISR in diabetic patients. While our study provides valuable insight into the angiographic patterns of ISR, additional research is required to explore the molecular and cellular pathways that drive restenosis in this population. Studies utilising intravascular imaging techniques, such as optical coherence tomography (OCT), could provide more detailed information on neointimal thickness and stent apposition in diabetic patients, potentially revealing new therapeutic targets (18). Moreover, long-term follow-up studies are essential to assess the durability of treatment strategies for ISR in diabetic patients, particularly with the advent of bioresorbable stents and other novel technologies (19).

This study has several limitations that should be acknowledged. First, the retrospective design may introduce selection bias, as only patients who underwent repeat angiography were included in the analysis. This could result in an overrepresentation of patients with clinically significant ISR. Additionally, our study was conducted at a single tertiary care centre, which may limit the generalizability of the findings to other populations. Despite these limitations, the large sample size and comprehensive angiographic data provide robust evidence to support our conclusions. Future studies with prospective designs and multi-centre collaboration are necessary to confirm these findings and explore the long-term outcomes of ISR in diabetic patients.

Conclusion

This study highlights the higher prevalence of diffuse in-stent restenosis (ISR) in diabetic patients compared to non-diabetic individuals following percutaneous coronary intervention (PCI). Diabetic patients also faced a greater risk of adverse events within 12 months, emphasising the complex and aggressive nature of ISR in this population. These findings reinforce the role of diabetes as a significant factor in ISR development, requiring focused management strategies.

These results suggest that more aggressive preventive measures, including newer-generation drug-eluting stents (DES) and optimal medical therapy, should be considered for diabetic patients. Ensuring close follow-up and proactive treatment planning can help mitigate the risk of restenosis and improve outcomes in this high-risk group.

In summary, personalised approaches to treating ISR in diabetic patients are essential. Future studies should investigate novel stent technologies and long-term management strategies to better address the unique challenges posed by diabetes in coronary interventions.

Declarations

Data Availability statement

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

Ethics approval and consent to participate

Approved by the department concerned. (IRBEC-CAG-004/22)

Consent for publication

Approved

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Not applicable

Conflict of interest

The authors declared the absence of a conflict of interest.

Author Contribution

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Coordination of collaborative efforts.
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ABDUL QADEER (Resident Cardiologist)
Conception of Study, Development of Research Methodology Design, Study Design, Manuscript Review, and final approval of manuscript.
IRUM HUSSAIN (Cardiologist)
Manuscript revisions, critical input.
Coordination of collaborative efforts.
KAINAT MOMIN KHAN (House Officer)
Data acquisition and analysis.
Manuscript drafting.
PARKHA SETHI (House Officer)
Data entry and data analysis, as well as drafting the article.
HABIBA DURRANI (House Officer)
Data acquisition and analysis.
Coordination of collaborative efforts.

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