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RESEARCH ARTICLE
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ANALYSIS OF INTRACORONARY IMAGING-GUIDED PERCUTANEOUS CORONARY STENTING VERSUS DRUG-COATED BALLOONS IN IMPROVING RECANALIZATION IN RESTENOSIS VESSELS

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Abstract:

Objectives:

To compare the efficacy of intracoronary imaging-guided percutaneous coronary stenting (PCI) versus drug-coated balloons (DCBs) in improving Recanalization in Restenosis Vessels.

Materials and Methods: This RCT, approved by the hospital's ethical committee, involved 130 patients who provided informed consent. They were randomly assigned in a 1:1Muhammad hasnain iqbal

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Hbs medical and dental college islamabad ratio to either Group A (imaging-guided PCI) or Group B (DCB). Group A underwent PCI with stent placement guided by intracoronary imaging (IVUS or OCT) to ensure optimal stent placement, while Group B received angioplasty with a drug-coated balloon (paclitaxel or sirolimus) to minimize vessel injury. Statistical analysis was performed using SPSS Version 25.

Results: In this study of 130 patients (mean age 55.27±9.13 years), Group A had 52.3% males, while Group B had 55.4% males. Group A showed a lower target lesion revascularization rate (10.8% vs. 15.4%, p=0.43) and major adverse cardiac events rate (15.4% vs. 20.0%, p=0.49) compared to Group B. Group A also had significantly less late lumen loss (0.29±0.03 mm vs. 0.33±0.04 mm, p=0.00) and a lower rate of in-stent thrombosis (1.5% vs. 3.1%, p=0.55). Procedural success rates were 96.9% for Group A and 93.8% for Group B (p=0.40).

Conclusion: It was concluded that both intracoronary imaging-guided PCI and DCBs have distinct benefits in treating restenosis: imaging-guided PCI may be more effective for immediate recanalization, while DCBs are favorable for long-term restenosis prevention with a reduced risk of thrombotic complications. The choice between these strategies should be tailored to the patient's

clinical profile, lesion characteristics, and the specific risks and benefits. Future research should include long-term randomized trials to further compare these approaches and enhance treatment guidelines.

Key words: Intracoronary imaging-guided PCI, Restenosis, Recanalization

INTRODUCTION:

Coronary artery disease (CAD) often necessitates interventional procedures to restore patency in stenosed coronary vessels.(1, 2) Percutaneous coronary intervention (PCI) with stent placement and drug-coated balloons (DCB) are two prevalent strategies employed to address restenosis, a condition where the treated vessel narrows again over time.(3-5) Intracoronary imaging-guided PCI utilizes advanced imaging techniques such as intravascular ultrasound (IVUS) or optical coherence tomography (OCT) to optimize stent selection, sizing, and deployment, potentially reducing complications and improving outcomes.(6) In contrast, DCB therapy involves angioplasty with a balloon coated with antiproliferative drugs such as paclitaxel or sirolimus, designed to minimize neointimal hyperplasia and restenosis without the need for permanent stent implantation.(4, 7)

The choice between imaging-guided PCI and DCB therapy for treating restenosis in coronary vessels remains a subject of ongoing debate.(8) Both approaches aim to enhance recanalization and long-term vessel patency,(9)but their relative effectiveness in achieving these goals warrants thorough evaluation. This analysis seeks to compare the clinical outcomes and success rates of intracoronary imaging-guided PCI versus DCB therapy in improving recanalization in restenosis vessels. Restenosis was defined as a residual stenosis exceeding 50% of the luminal diameter at the time of follow-up angiography.(10, 11) By examining key metrics such as target lesion revascularization (TLR) rates, major adverse cardiac events (MACE), late lumen loss, in-stent thrombosis rates, and procedural success rates, this study aims to elucidate the advantages of each approach, thereby providing valuable insights for optimizing treatment strategies in CAD management.

Objective:

To compare the efficacy of intracoronary imaging-guided percutaneous coronary stenting (PCI) versus drug-coated balloons (DCBs) in improving Recanalization in Restenosis Vessels.

MATERIALS AND METHODS:

Study Design: Randomized, controlled trial (RCT).

Study setting: Frontier Corps Teaching Hospital KPK Shahkas, Pakistan.

Inclusion Criteria:

- Patients with coronary artery disease (CAD).
- Patients with restenosis (≥50% diameter stenosis) in a previously treated coronary artery.
- Patients of both gender of age ranging from 18 years to 70 years.
- Patients eligible for either PCI with stent implantation or DCB therapy.

Exclusion Criteria:

- Patients with Acute myocardial infarction (MI) within the last 48 hours..
- Patients presenting with severe left ventricular dysfunction (ejection fraction <30%).

Methods:

This RCT study took place Frontier Corps Teaching Hospital KPK Shahkas, Pakistan in the duration from November, 2023 to May, 2024, following the approval of the hospital's ethical committee. A total of 130 patients were enrolled in the study, with informed consent obtained before enrollment following a thorough explanation of the study's purpose. All enrolled patients were randomly assigned

to one of two groups in a 1:1 ratio: Group A (imaging-guided PCI) or Group B (DCB). In the intervention groups, participants in the intracoronary imaging-guided PCI group underwent PCI with stent placement, guided by intracoronary imaging techniques such as IVUS or OCT to optimize stent selection, sizing, and deployment. This imaging helped ensure the stent was placed correctly, with minimal residual stenosis and no complications like malapposition or edge dissection. In contrast, participants in the drug-coated balloon (DCB) group received angioplasty using a balloon coated with either paclitaxel or sirolimus at the target lesion. The balloon was inflated at low pressure to deliver the drug effectively to the vessel wall while minimizing the risk of significant vessel injury. For statistical analysis we used SPSS Version 25.

RESULTS:

A total of 130 patients were enrolled, with a mean age of 55.27±9.13 years (Table 1). In Group A, the gender distribution consisted of 52.3% male (34 patients) and 47.7% female (31 patients). In Group B, 55.4% of the patients were male (36 patients), while 44.6% were female (29 patients). The comparison of clinical outcomes and success rates between the two groups (n=130) revealed that Group A had a target lesion revascularization (TLR) rate of 10.8% (7 patients) compared to 15.4% (10 patients) in Group B (p=0.43). The rate of major adverse cardiac events (MACE) was 15.4% (10 patients) in Group A and 20.0% (13 patients) in Group B (p=0.49). Group A also demonstrated a lower late lumen loss of 0.29±0.03 mm versus 0.33±0.04 mm in Group B, with this difference being statistically significant (p=0.00). The in-stent thrombosis rate was lower in Group A at 1.5% (1 patient) compared to 3.1% (2 patients) in Group B (p=0.55). Procedural success rates were 96.9% (63 patients) in Group A and 93.8% (61 patients) in Group B (p=0.40).

Table 1: Mean age of all enrolled Patient *(n=150)*

Variables	Mean±SD
Age (Years)	55.27±9.13

Fig 1: Frequency of gender of both group

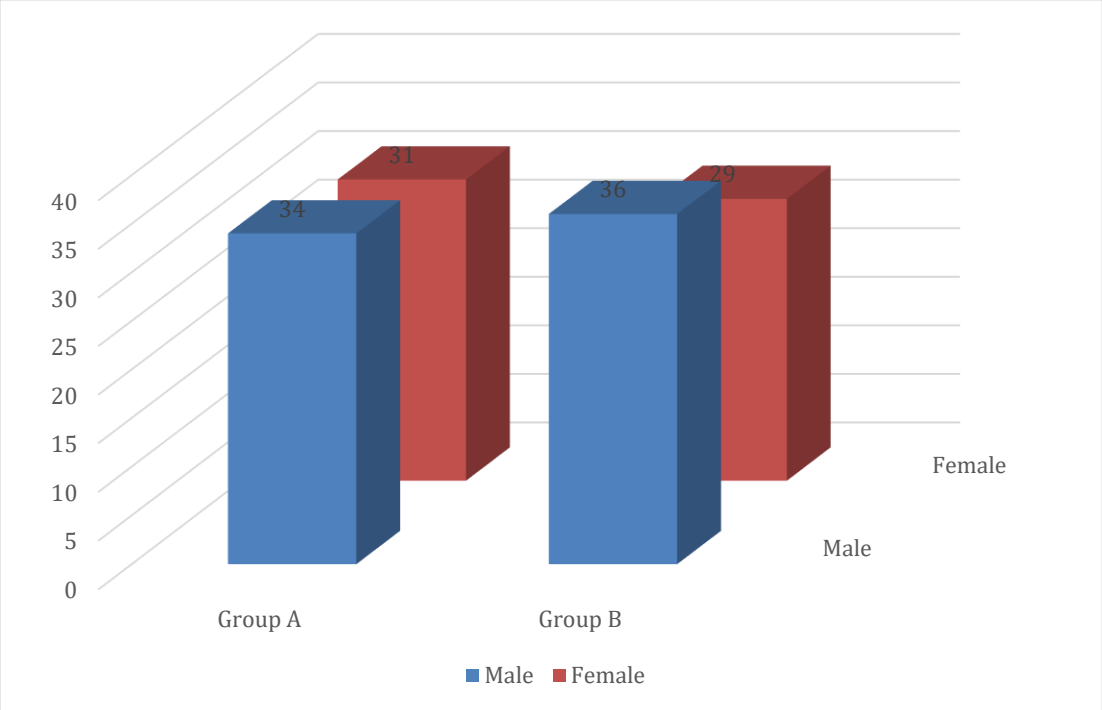
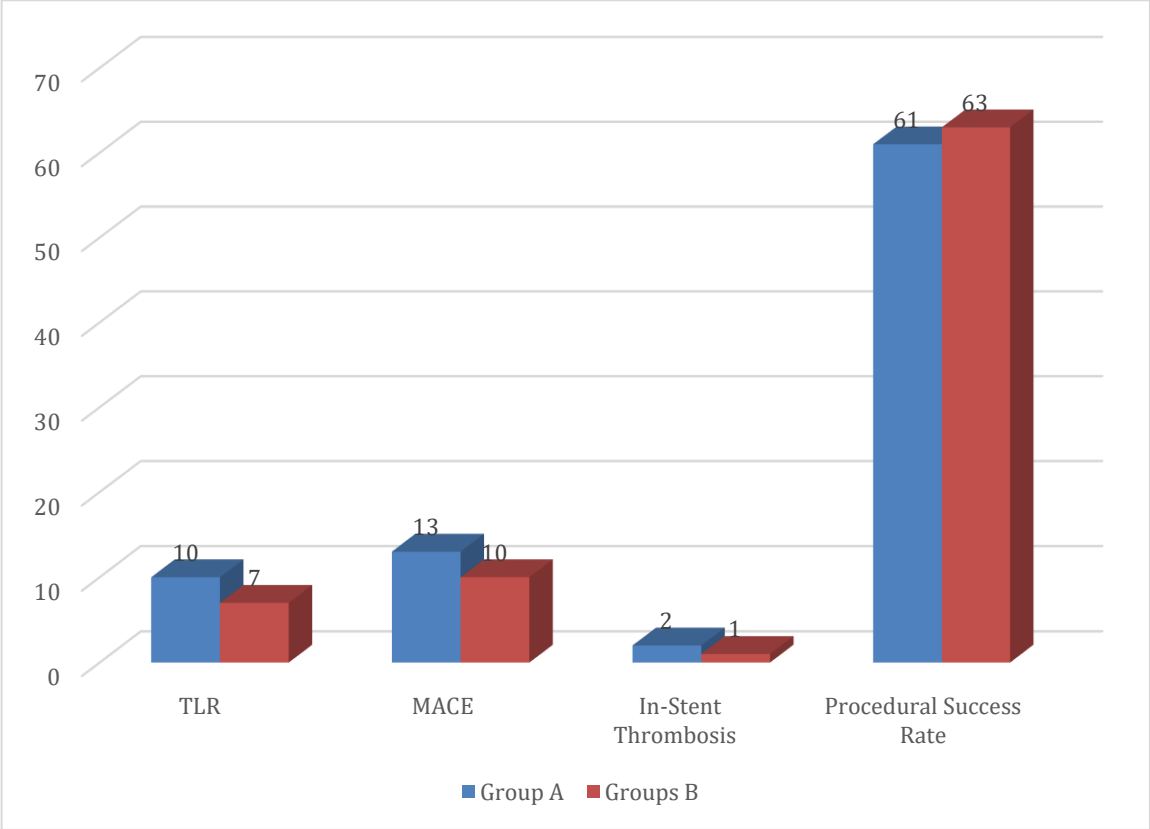


Table 2: Clinical outcomes and success rate comparison between both groups (n=130)

	Groups		P-Value
	Group A	Groups B	
TLR	7(10.8%)	10(15.4%)	0.43
MACE	10(15.4%)	13(20.0%)	0.49
Late Lumen Loss (mm)	0.29±0.03	0.33±0.04	0.00
In-Stent Thrombosis	1(1.5%)	2(3.1%)	0.55
Procedural Success Rate	63(96.9%)	61(93.8%)	0.40

TLR: Target Lesion Revascularization,
MACE: Major Adverse Cardiac Events

Fig 2: Frequency of clinical outcomes and success rate comparison between both groups



Discussion: The present study compares the effectiveness of intracoronary imaging-guided percutaneous coronary stenting (PCI) versus drug-coated balloons (DCB) in improving recanalization in restenosis vessels. The findings provide valuable insights into the relative advantages of these two interventional strategies for managing coronary artery disease (CAD) and addressing the challenge of restenosis. The choice between intracoronary imaging-guided PCI and DCBs should be individualized based on patient characteristics, lesion complexity, and clinical judgment. Combining both strategies might also be considered in specific cases to maximize the benefits of each approach. In our study we have found that Procedural success rates were 96.9% (63 patients) in Group A and 93.8% (61 patients) in Group B (p=0.40). This indicates that both approaches are equally effective in achieving procedural success, and the choice between them may be guided by considerations other than the minor difference in success rates observed in this study. Intracoronary Imaging-Guided PCI is generally favored in cases involving complex lesions, such as those with significant calcification, bifurcations, or tortuous anatomy, where achieving optimal stent placement is challenging.(12)

It allows for precise visualization of the lesion, accurate measurement of vessel dimensions, and assessment of stent expansion and apposition, which are crucial for reducing the risk of future restenosis.(13) On the other hand, Drug-Coated Balloons are typically more suitable for treating in-stent restenosis, particularly when there is a need to avoid placing additional stents to minimize the risk of stent thrombosis.(14) They are also preferred in patients with a high risk of bleeding, as they often require a shorter duration of dual antiplatelet therapy, making them a safer option in these circumstances.(15, 16)

The comparison of clinical outcomes and success rates between the two groups (n=130) reveals that Group A generally showed slightly better results across several key parameters, although most differences did not reach statistical significance. Group A had a Target Lesion Revascularization (TLR) rate of 10.8% compared to 15.4% in Group B (p=0.43), suggesting a lower need for repeat procedures in Group A, although the difference was not statistically significant and may have occurred by chance. The rate of Major Adverse Cardiac Events (MACE), which includes events such as myocardial infarction, revascularization, or death, was also lower in Group A at 15.4% compared to 20.0% in Group B (p=0.49), further indicating that both groups had a relatively similar risk profile for major complications. However, Group A demonstrated a significantly lower late lumen loss (0.29±0.03 mm) compared to Group B (0.33±0.04 mm, p=0.00). This finding suggests that Group A achieved better long-term vessel patency, which could potentially translate into a reduced risk of restenosis and need for future interventions. Additionally, the rate of in-stent thrombosis, a serious complication associated with stent placement, was lower in Group A (1.5%) than in Group B (3.1%), although this difference was not statistically significant (p=0.55), indicating that both groups had a similarly low risk of this complication. Overall, while Group A showed some trends toward improved clinical outcomes, such as lower rates of TLR, MACE, and in-stent thrombosis, the only statistically significant difference was in late lumen loss. This suggests that the two treatment strategies are generally comparable in effectiveness, and the decision between them should consider other factors, such as individual patient characteristics, clinical context, and physician preference, rather than the marginal differences observed in the study outcomes.

Conclusion: It was concluded that both intracoronary imaging-guided PCI and DCBs offer unique advantages in treating restenosis. Imaging-guided PCI may be more effective for immediate recanalization, while DCBs provide a promising option for long-term restenosis prevention with a lower risk of thrombotic complications. The decision between these two strategies should be individualized, considering the patient's clinical profile, lesion characteristics, and the potential risks and benefits of each approach. Future research should focus on long-term randomized trials comparing these strategies to refine treatment guidelines and optimize patient outcomes.

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