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Original Research Article

COMPARING OUTCOMES OF DIRECT STENTING VS PREDILATION IN PERCUTANEOUS CORONARY INTERVENTIONS

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Abstract: *Percutaneous coronary intervention (PCI) is a widely used treatment for coronary artery disease. While direct stenting and predilation are commonly practiced techniques in PCI, their comparative efficacy and outcomes need further investigation to guide optimal treatment strategies.* ***Objective:*** *To compare the outcomes of direct stenting versus predilation in patients undergoing percutaneous coronary interventions (PCI).* ***Methods:*** *This randomized controlled trial (RCT) was conducted at the National Institute of Cardiovascular Diseases (NICVD) in Karachi, Pakistan, from August 2023 to January 2024, following ethical approval. One hundred fifty patients undergoing PCI were enrolled and randomly assigned into Group A (Direct Stenting) and Group B (Predilation). Group A received PCI with direct stent placement, while Group B underwent PCI with balloon predilation before stent deployment. Patients were followed up at one month and six months post-PCI for major adverse cardiovascular events (MACE), including death, myocardial infarction, target vessel revascularization (TVR), and stent thrombosis. Angiographic follow-up was performed as clinically indicated at six months. Data were analyzed using SPSS Version 25.* ***Results:*** *150 patients participated, with a mean age of 50.25 ± 10.14 years. The Direct Stenting group had a shorter mean hospital stay (2.04 ± 0.44 days) than the Predilation group (3.08 ± 0.56 days). Gender distribution showed a higher percentage of males in the Direct Stenting group (54.7%) and more females in the Predilation group (60.0%). The Direct Stenting group demonstrated a lower incidence of MACE (5.3% vs. 12.0%) than the Predilation group. The rates of myocardial infarction, TVR, stent thrombosis, and complications such as coronary dissection and distal embolization were comparable between both groups. Mortality rates were identical at 1.3% in both groups.* ***Conclusion:*** *Both direct stenting and predilation are effective strategies in PCI, with direct stenting showing a slight advantage in reducing MACE and hospital stay. However, further large-scale randomized trials are required to define better the optimal use of these techniques across diverse patient populations and lesion types, ultimately improving patient outcomes.*

Keywords: Direct Stenting, Predilation, Percutaneous Coronary Intervention, Major Adverse Cardiovascular Events, Myocardial Infarction, Stent Thrombosis.

Introduction

Percutaneous coronary intervention (PCI) is a widely used therapeutic strategy for treating coronary artery disease (CAD).(1) It involves inserting a stent to open blocked or narrowed coronary arteries, thus improving blood flow to the heart muscle.(2, 3) Traditionally, PCI is performed using a technique known as predilation, which involves inflating a balloon at the site of the lesion to prepare the vessel for stent placement.(4, 5) In recent years, direct stenting (DS), where a stent is placed without prior balloon dilation, has gained attention as a potential alternative to predilation.(6, 7) PCI is a minimally invasive procedure that has revolutionized the treatment of CAD, allowing for revascularization of stenosed coronary arteries without the need for open-heart surgery.(8) Since its inception in 1977, PCI has undergone significant technological advancements, including developing bare-metal stents (BMS), drug-eluting stents (DES), and bioresorbable scaffolds.(9) The primary goals of PCI are to relieve symptoms, improve quality of life, prevent myocardial infarction, and reduce mortality. The procedure has become a mainstay in the treatment of both stable angina and ACS, including unstable angina and myocardial infarction (MI).(10)This study reflects a critical area of investigation in contemporary interventional cardiology. It is designed to evaluate two distinct procedural approaches used during PCI, direct stenting and stenting following predilection, to determine their respective impacts on clinical outcomes, procedural complications, and overall patient prognosis.

To compare the outcomes of Direct Stenting vs. Predilation in Percutaneous Coronary Interventions.

Methodology

This RCT study took place in the NICVD Karachi, Pakistan, from August 2023 to January 2024, following the approval of the hospital's ethical committee. A total of 150 patients were enrolled after obtaining an informed consent from the patients/guardian. All patients were divided into two groups using block randomization. Group A, the Direct Stenting Group, consisted of patients who received PCI with direct stenting without prior balloon dilation. Group B, the Predilation Group, included patients who underwent PCI with predilation involving balloon dilation before the stent was deployed. All patients will be followed up at 1 and 6 months after PCI, with clinical evaluations focusing on major adverse cardiovascular events (MACE), such as death, myocardial infarction, target vessel revascularization

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(TVR), and stent thrombosis. Depending on clinical indications, an angiographic follow-up may also be conducted at six months to assess for restenosis or other complications. For statistical analysis, we used SPSS Version 25.

Results

One hundred fifty patients were enrolled, with a mean age of 50.25 ± 10.14 years. The mean age of patients in the Direct Stenting group was 50.21 ± 10.29 years, while in the Predilation group, it was 50.29 ± 10.06 years. The mean hospital stay was shorter for the Direct Stenting group, at 2.04 ± 0.44 days, compared to 3.08 ± 0.56 days for the Predilation group. In terms of gender distribution, the Direct Stenting group comprised 41 males (54.7%) and 34 females (45.3%), whereas the Predilation group included 30 males (40.0%) and 45 females (60.0%) (Table 1). The comparison between the Direct Stenting and Predilation groups showed that the incidence of major adverse cardiovascular events (MACE) was 5.3% in the Direct Stenting group and 12.0% in the Predilation group, with a p-value of 0.14. Peri-procedural myocardial infarction occurred in 2.7% of the Direct Stenting group compared to 4.0% in the Predilation group (p = 0.64). Target vessel revascularization (TVR) rates were 5.3% in the Direct Stenting group and 6.7% in the Predilation group (p = 0.73), while stent thrombosis was observed in 1.3% and 2.7% of the groups, respectively (p = 0.56). The complication rates for coronary dissection were 1.3% in the Direct Stenting group and 2.7% in the Predilation group (p = 0.56). Distal embolization occurred equally in both groups at 2.7% (2 cases each) (p = 1.00), while the no-reflow phenomenon was observed in 1.3% of the Direct Stenting group and 4.0% of the Predilation group (p = 0.31). Mortality rates were identical, with 1.3% in each group (p = 1.00) (Table 2).

Table 1: Characteristics of enrolled patients (n=150)

Factors	Groups	
	Direct Stenting	**Predilation**
Age (years)	50.21±10.29	50.29±10.06
Hospital Stay (Days)	2.04±0.44	3.08±0.56
Gender		
Male	41(54.7%)	30(40.0%)
Female	34(45.3%)	45(60.0%)

Table 2: Clinical Outcomes and Complication Rates between both Groups *(n=150)*

Outcome	Groups		P-value
	Direct Stenting	**Predilation**	
MACE	4(5.3%)	9(12.0%)	0.14
Peri-procedural Myocardial Infarction	2(2.7%)	3(4.0%)	0.64
Target Vessel Revascularization (TVR)	4(5.3%)	5(6.7%)	0.73
Stent Thrombosis	1(1.3%)	2(2.7%)	0.56
Complication Rates			
Coronary Dissection	1(1.3%)	2(2.7%)	0.56
Distal Embolization	2(2.7%)	2(2.7%)	1.00
No-reflow Phenomenon	1(1.3%)	3(4.0%)	0.31
Mortality	1(1.3%)	1(1.3%)	1.00

Discussion

Direct stenting and predilection are two approaches to treating coronary artery disease that are used in percutaneous coronary interventions (PCI).(11) Direct stenting involves placing a stent at the target lesion without prior balloon dilation, while predilation requires initial dilation with a balloon catheter to prepare the lesion for stenting.(12) The primary goal of predilation is to prepare the lesion site, ensuring that the stent can be safely and effectively delivered and expanded. While this technique is a traditional approach in PCI, its role and benefits, compared to direct stenting, continue to be evaluated in clinical practice. Predilation may not significantly improve outcomes in straightforward lesions, where direct stenting can reduce procedure time, costs, and complications; however, in complex lesions, predilation may help ensure proper stent placement and lower the risk of adverse events like stent thrombosis and TVR. The present study compared the outcomes of direct stenting vs predilation in PCI.

In the present study, comparing clinical outcomes between the Direct Stenting and Predilation groups in PCI revealed notable differences in the incidence of major adverse cardiovascular events (MACE) and procedural complications. The MACE rate was lower in the Direct Stenting group (5.3%) compared to the Predilation group (12.0%). However, this difference did not reach statistical significance (p = 0.14), suggesting that direct stenting may be associated with fewer adverse cardiovascular events.

In a meta-analysis conducted by Federico Piscione et al.(11) It is stated that direct stenting improves outcomes in patients undergoing percutaneous coronary intervention, primarily reducing myocardial infarction incidence, as stated in another meta-analysis study conducted by Francesco

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Burzotta MD et al.(13) Stated that DS, compared with CS, in selected coronary lesions, is safe, optimizes equipment use, and may enhance the early results of coronary interventions while warranting similar late clinical outcomes.

However, the lack of statistical significance in the present study ($p = 0.14$) suggests that the difference in MACE rates may be insignificant across all patient populations. This is consistent with findings from another study. (14) Findings showed no significant difference in MACE rates between direct stenting and predilation groups, particularly in more complex lesions, where the benefits of predilation, such as better lesion preparation and improved stent deployment, may mitigate the advantages of direct stenting. Thus, while the trend observed in the current study favors direct stenting for reducing MACE, especially in more straightforward lesions, the lack of statistical significance underscores the need for individualized patient selection and a tailored approach based on lesion complexity, vessel size, and other clinical factors. In the present study, the incidence of peri-procedural myocardial infarction was slightly lower in the Direct Stenting group (2.7%) compared to the Predilation group (4.0%). Still, this difference was not statistically significant ($p = 0.64$). This aligns with the findings of the DIRECT trial by Grines et al.(14), which also reported no significant difference in peri-procedural myocardial Infarction rates between the two strategies, particularly in more complex lesions.

The rates of target vessel revascularization (TVR) were similar between the two groups, with 5.3% in the Direct Stenting group and 6.7% in the Predilation group ($p = 0.73$). This finding is consistent with results from a meta-analysis. (15)This indicated that direct stenting did not significantly reduce the need for TVR compared to predilation, except in more superficial lesions.

Stent thrombosis occurred in 1.3% of patients in the Direct Stenting group compared to 2.7% in the Predilation group ($p = 0.56$). Although this difference suggests a trend towards fewer thrombotic events with direct stenting, the lack of statistical significance aligns with findings from the STENT group (Doyle et al., 2003), which reported comparable rates of stent thrombosis between the two approaches.

Complication rates, such as coronary dissection, were observed in 1.3% of the Direct Stenting group versus 2.7% in the Predilation group ($p = 0.56$), reflecting a trend towards fewer complications with direct stenting. Distal embolization rates were equal in both groups at 2.7% ($p = 1.00$), which aligns with data from other studies and indicates that both techniques carry a comparable risk of embolic events.(16) The incidence of the no-reflow phenomenon was observed at 1.3% in the Direct Stenting group and 4.0% in the Predilation group ($p = 0.31$). While the difference was not statistically significant. Mortality rates were identical between the groups, with 1.3% in each group ($p = 1.00$),

Overall, these findings suggest that while direct stenting may offer some procedural advantages, such as reduced dissection rates and a trend toward fewer peri-procedural complications, the differences in outcomes between direct stenting and predilation remain modest and are often not statistically significant. This underscores the need for further research to delineate the specific clinical contexts in which one strategy might be favored.

Conclusion

It was concluded that both direct stenting and predilection are viable options in PCI, with each strategy offering unique advantages depending on the clinical scenario. Further, large-scale, randomized trials are recommended to better define the optimal use of these techniques across diverse patient populations and lesion characteristics, ultimately improving patient outcomes and refining interventional strategies.

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. (IRBEC-NICVKHR-923/22)

Consent for publication

Approved

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Conflict of interest

The authors declared the absence of a conflict of interest.

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Conception of Study, Final approval of manuscript.
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