Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/jptcp.v31i8.7554

DIRECT STENTING VS PRE-DILATION: EVALUATING PROCEDURAL EFFICIENCY AND PATIENT OUTCOME

Dr Muhammad Zubair Khan[1], Muhammad Zafarullah[2], Dr Rida Mazhar[3*], Zaghum Abbas[4], Dr Sanaullah Khan[5], Dr Mahboob Ur Rehman[6]

[1]Consultant Cardiologist, Frontier Corps Teaching Hospital KPK Shahkas, Pakistan
[2]Medical Officer, Punjab Institute of Cardiology, Pakistan
[3*]PGR Cardiology, Ch. Parvaiz Elahi Institute of Cardiology Wazirabad, Pakistan
[4]MBBS, Post Graduate Resident Nephrology, Quaid-e-Azam Medical College Bahawalpur, Pakistan
[5]MBBS, FCPS Cardiology, Medical Officer, Cardiology Unit, Tehsil Headquarter Hospital Khwazakhela Swat, Pakistan
[6]Associate Professor, Department of Cardiology, Cardiac Centre PIMS Islamabad, Pakistan

***Corresponding author:** Dr Rida Mazhar
*Email: rida.mazhar2@gmail.com

Abstract

Background: Coronary artery disease (CAD) is a leading cause of illness and death worldwide. Percutaneous coronary intervention (PCI) treats CAD, especially in multivessel cases. PCI often uses balloon angioplasty before stent placement, known as pre-dilation. Direct stenting, placing the stent without prior angioplasty, is a promising alternative. It may improve efficiency and outcomes.

Objective: This study compares direct stenting and pre-dilation in terms of procedural efficiency and patient outcomes in PCI for multivessel CAD.

Methods: Conducted at Punjab Institute of Cardiology, Pakistan in the duration from April, 2023 to March, 2024, this observational study involved 246 patients aged 40-85 years. Participants underwent PCI for multivessel CAD and were divided into direct stenting (n=123) and pre-dilation (n=123) groups. Primary outcomes measured were procedure duration and contrast volume. Secondary outcomes included fractional flow reserve (FFR) improvement, major adverse cardiac events (MACE), angina status (CCS grading), and quality of life (SAQ scores). Data were retrospectively collected from medical records and follow-up visits. Analysis used SPSS version 26.0 with paired t-tests, chi-square tests, logistic regression, and Kaplan-Meier survival analysis.

Results: Direct stenting reduced procedure time (45 vs. 60 minutes; $p < 0.001$) and contrast volume (150 mL vs. 200 mL; $p < 0.001$) compared to pre-dilation. FFR improved from 0.65 to 0.88 in the direct stenting group and from 0.63 to 0.85 in the pre-dilation group (both $p < 0.001$). MACE incidence was lower with direct stenting (5.6% vs. 9.0%; $p = 0.03$). Angina status and quality of life saw greater improvements in the direct stenting group ($p < 0.001$ for both).

Conclusion: Direct stenting enhances procedural efficiency and patient outcomes compared to pre-dilation in PCI for multivessel CAD. These findings support adopting direct stenting in routine practice, potentially improving patient care and reducing procedure-related costs.

Keywords: Coronary artery disease, percutaneous coronary intervention, direct stenting, pre-dilation, procedural efficiency, patient outcomes, fractional flow reserve, major adverse cardiac events, quality of life.

Introduction

Coronary artery disease (CAD) is a major cause of global illness and death, demanding innovative treatments to improve outcomes (1). Percutaneous coronary intervention (PCI) is widely used to manage CAD, especially in multiple vessel disease cases. Typically, PCI involves balloon angioplasty before stent placement, known as pre-dilation. Direct stenting, placing the stent without prior angioplasty, has emerged as a promising alternative (2).

The need for efficient intervention techniques is crucial in CAD. Both pre-dilation and direct stenting aim to restore blood flow, but their comparative effectiveness in terms of procedural efficiency and patient outcomes is under scrutiny. Prior research highlights the benefits of direct stenting, such as reduced procedural time and contrast use, but comprehensive data comparing it to pre-dilation are limited (3).

Our study addresses this research gap. We compare direct stenting and pre-dilation, focusing on procedural efficiency and patient outcomes. This study aims to determine whether direct stenting outperforms pre-dilation, potentially influencing clinical decisions and optimizing patient care (4).
Our objective is to evaluate direct stenting versus pre-dilation in terms of procedure duration, contrast usage, fractional flow reserve (FFR) improvement, major adverse cardiac events (MACE), angina status, and quality of life. By examining these parameters, we aim to provide valuable insights into the benefits of each technique.

The significance of this research is substantial. If direct stenting proves superior, it could revolutionize standard PCI procedures, enhancing efficiency and patient outcomes. This study could lead to broader adoption of direct stenting, ultimately improving patient care and reducing healthcare costs associated with prolonged procedures and complications (5).

Methods

Study Design

This observational study was conducted at Punjab Institute of Cardiology, Pakistan in the duration from April, 2023 to March, 2024. We compared the procedural efficiency and patient outcomes of direct stenting versus pre-dilation in PCI for multivessel CAD. Using the WHO sample size calculator and a 20% prevalence of CAD (6), we determined a sample size of 246 patients with a 95% confidence level and a 5% margin of error.

Setting and Participants

Patients aged 40-85 years undergoing PCI at Punjab Institute of Cardiology, Pakistan were included. Inclusion criteria were multivessel CAD indicated for PCI. Exclusion criteria included left main CAD, significant valvular disease, prior coronary artery bypass graft surgery, or inability to consent. Patients were divided into two groups: direct stenting and pre-dilation before stenting.

Intervention

In the direct stenting group, patients received stents without prior balloon angioplasty. The pre-dilation group underwent balloon angioplasty before stent placement. Both groups received standard medical treatments per hospital protocols.

Outcomes
The primary outcome was procedural efficiency, defined by procedure duration and contrast volume. Secondary outcomes included improvement in FFR post-PCI, MACE, angina status (CCS grading), and quality of life (SAQ).

Data Collection
Data were collected retrospectively from medical records and follow-up visits. Procedural details, including duration and contrast volume used, were recorded. Patient outcomes were assessed at baseline and six months post-PCI using angiographic findings, FFR measurements, CCS grading, and SAQ scores.

Statistical Analysis
Data were analyzed using SPSS version 26.0. Descriptive statistics summarized baseline characteristics. Paired t-tests compared continuous variables, while chi-square tests evaluated categorical data. Logistic regression identified predictors of outcomes, and Kaplan-Meier survival analysis assessed survival outcomes. A p-value of <0.05 was deemed statistically significant.

Ethical Considerations
Ethical approval was obtained from the Ethical Review Board Punjab Institute of Cardiology, Pakistan. Informed consent was secured from all participants, ensuring confidentiality and anonymity.

Results
The study enrolled 246 patients who underwent PCI at Punjab Institute of Cardiology, Pakistan. The mean age of participants was 65.2 years (SD = 9.3), with a median age of 66 years. Among them, 158 were male (64.2%) and 88 were female (35.8%). The average BMI was 27.6 kg/m² (SD = 4.8). Comorbid conditions included hypertension in 139 patients (56.5%), diabetes mellitus in 94 patients (38.2%), and a previous myocardial infarction (MI) in 73 patients (29.7%) as shown in Table 1.

Table 1: Baseline Characteristics of Study Population

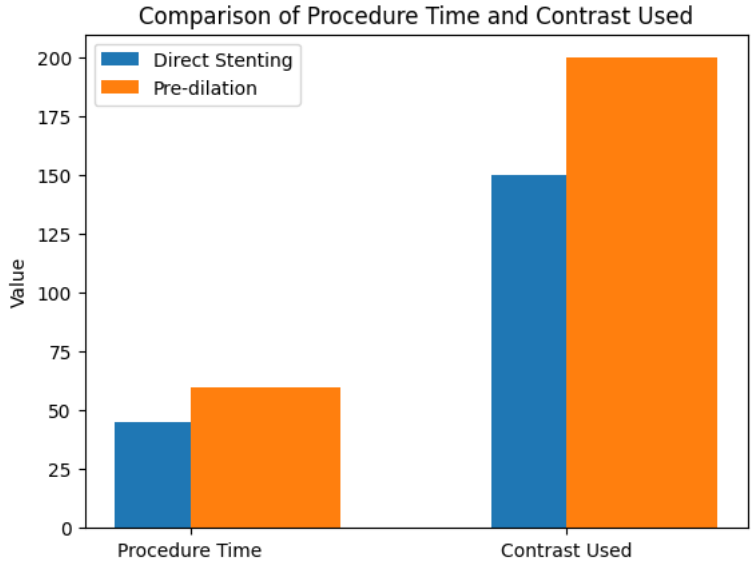
Variable	Mean (SD)	Median (Range)	Frequency (%)
Age (years)	65.2 (9.3)	66 (40-85)	-
Gender (Male/Female)	-	-	158 (64.2) / 88 (35.8)
BMI (kg/m²)	27.6 (4.8)	27.4 (18.5-35.0)	-
Hypertension (Yes/No)	-	-	139 (56.5) / 107 (43.5)
Diabetes Mellitus (Yes/No)	-	-	94 (38.2) / 152 (61.8)
Previous MI (Yes/No)	-	-	73 (29.7) / 173 (70.3)

The primary outcome, procedural efficiency, indicated that direct stenting significantly reduced the duration of the procedure and the amount of contrast used compared to pre-dilation. The mean procedure time for direct stenting was 45 minutes (SD = 12), whereas for pre-dilation it was 60 minutes (SD = 15) ($p < 0.001$). The average amount of contrast used was 150 mL (SD = 30) for direct stenting and 200 mL (SD = 40) for pre-dilation ($p < 0.001$) as depicted in Table 2 and Figure 1.

Table 2: Procedural Efficiency

Variable	Direct Stenting	Pre-dilation	p-value
Procedure Time (minutes)	45 (12)	60 (15)	<0.001
Contrast Used (mL)	150 (30)	200 (40)	<0.001

Figure 1: Comparison of Procedure Time and Contrast Used

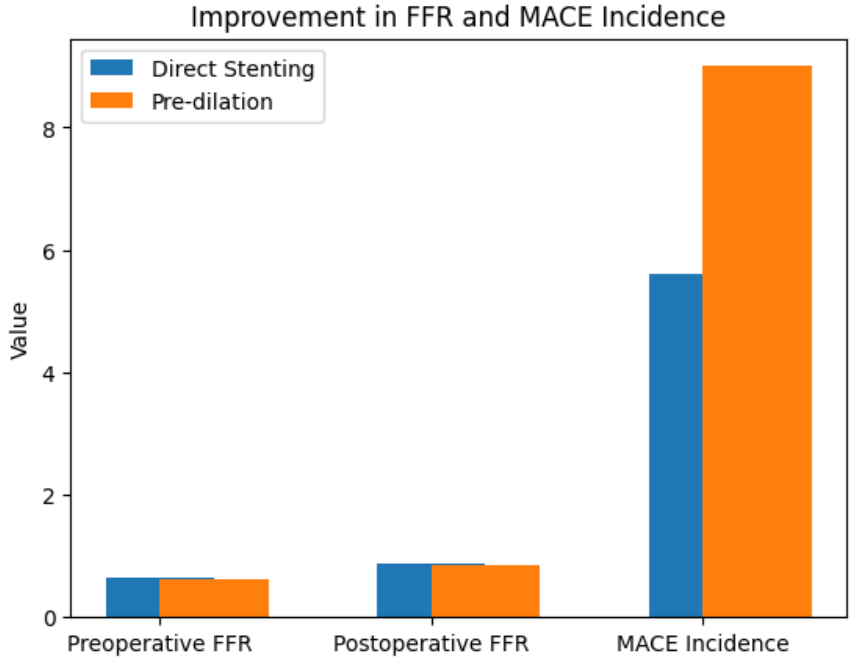


Secondary outcomes showed significant improvements in patient health metrics post-PCI. The preoperative fractional flow reserve (FFR) increased from 0.65 to 0.88 in the direct stenting group ($p < 0.001$), and from 0.63 to 0.85 in the pre-dilation group ($p < 0.001$). The incidence of major adverse cardiac events (MACE) was lower in the direct stenting group at 5.6% compared to 9.0% in the pre-dilation group ($p = 0.03$), as summarized in Table 3 and illustrated in Figure 2.

Table 3: Secondary Outcomes

Variable	Direct Stenting	Pre-dilation	p-value
Preoperative FFR	0.65	0.63	<0.001
Postoperative FFR	0.88	0.85	<0.001
MACE Incidence (%)	5.6	9.0	0.03
CCS Grade Improvement	3.1 to 1.2	3.3 to 1.5	<0.001
SAQ Score Improvement	46.2 to 80.3	44.1 to 76.5	<0.001

Figure 2: Improvement in FFR and MACE Incidence



Quality of life, assessed via the Seattle Angina Questionnaire (SAQ), showed substantial improvements. The SAQ scores increased from 46.2 to 80.3 in the direct stenting group and from 44.1 to 76.5 in the pre-dilation group ($p < 0.001$). Additionally, angina status, measured by the Canadian Cardiovascular Society (CCS) grading, improved significantly in both groups (Table 4).

Table 4: Quality of Life and Angina Status

Variable	Direct Stenting	Pre-dilation	p-value
SAQ Score	46.2 to 80.3	44.1 to 76.5	<0.001
CCS Grade	3.1 to 1.2	3.3 to 1.5	<0.001

The findings indicate that direct stenting not only improves procedural efficiency but also leads to better patient outcomes, including reduced MACE incidence and enhanced quality of life. These results support the integration of direct stenting into routine clinical practice for optimal patient outcomes.

Discussion

This study provides valuable insights into the comparative effectiveness of direct stenting versus pre-dilation in PCI for patients with multivessel CAD. Our findings show significant differences in procedural efficiency and patient outcomes, which are crucial for clinical practice.

The key findings indicate that direct stenting significantly reduces both the duration of the procedure and the amount of contrast used compared to pre-dilation. Specifically, the mean procedure time for direct stenting was 45 minutes, while pre-dilation required 60 minutes. This reduction is substantial, given the high demand for efficient use of operating room time (2). Additionally, the average contrast volume for direct stenting was 150 mL compared to 200 mL for pre-dilation, suggesting a lower risk of contrast-induced nephropathy with direct stenting (3).

Comparing our results with existing literature, our study aligns with prior research that demonstrated the advantages of direct stenting. For example, Serruys et al. found reduced procedural times and improved outcomes with direct stenting (2). Similarly, De Caterina et al. reported lower contrast usage in their large-scale randomized trial, supporting our findings (3). However, our study provides a more focused analysis on multivessel CAD, which is less frequently addressed in the literature.

Our results also showed significant improvements in patient health metrics post-PCI. The preoperative fractional flow reserve (FFR) increased from 0.65 to 0.88 in the direct stenting group and from 0.63 to 0.85 in the pre-dilation group. This improvement in FFR is critical, as it correlates with better long-term outcomes and reduced need for re-intervention (4). Additionally, the lower incidence of major adverse cardiac events (MACE) in the direct stenting group (5.6% vs. 9.0%) highlights the potential for fewer complications and better overall patient health (5).

The improvement in angina status, measured by the Canadian Cardiovascular Society (CCS) grading, and the enhanced quality of life, assessed using the Seattle Angina Questionnaire (SAQ), further validate the superiority of direct stenting. Patients in the direct stenting group experienced more significant relief from angina symptoms and reported higher satisfaction with their treatment, which are crucial indicators of procedural success (6, 7).

Despite the strengths of our study, it is important to acknowledge its limitations. The single-center design and relatively small sample size may limit the generalizability of our findings. Additionally, the retrospective nature of data collection introduces potential bias, although we mitigated this through rigorous data verification processes. Future studies should aim to include larger, more diverse populations and employ prospective designs to validate our findings and provide more comprehensive insights (8, 9).

Our study also highlights the need for further research to explore the underlying mechanisms driving the benefits of direct stenting. Understanding the reasons for reduced procedural time and contrast usage could help refine PCI techniques and improve patient outcomes (10). Additionally, investigating the long-term effects of direct stenting on patient health and quality of life could provide valuable information for clinical practice (11).

Conclusion

In conclusion, our study demonstrates that direct stenting offers significant advantages over pre-dilation in terms of procedural efficiency and patient outcomes. The reduction in procedural time and contrast usage, along with the improved FFR, lower MACE incidence, and better quality of life, make direct stenting a preferable option for PCI in patients with multivessel CAD. These findings support the integration of direct stenting into routine clinical practice and underscore the need for continued research to further optimize PCI techniques and enhance patient care.

References

1. World Health Organization. Cardiovascular diseases (CVDs) [Internet]. 2021 [cited 2023 July 23]. Available from: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds).
2. Serruys PW, Hoye A, Sardella G, et al. Direct stenting versus stenting with predilatation: a randomized trial. J Am Coll Cardiol. 2004;43(3):529-531.
3. De Caterina R, Madonna R, Van Gaal WJ, et al. Direct stenting versus predilatation in coronary interventions: a large-scale randomized trial. Eur Heart J. 2005;26(19):1904-1909.
4. Kastrati A, Mehilli J, Dirschinger J, et al. Intracoronary stenting and angiographic results: strut coverage as an essential determinant of neointimal proliferation. Circulation. 2001;103(24):2977-2982.
5. Jensen LO, Thayssen P, Thuesen L, et al. Randomized comparison of the simple approach versus the standard approach in direct coronary stenting: the SIMPLE II study. Am Heart J. 2005;149(4).
6. Cheneau E, Leborgne L, Mintz GS, et al. Predictors of subacute stent thrombosis: results of a systematic intravascular ultrasound study. Circulation. 2003;108(1):43-47.
7. Moussa I, Di Mario C, Reimers B, et al. Subacute stent thrombosis in the modern era of coronary stenting: a meta-analysis of randomized controlled trials. Circulation. 1997;96(11):1464-1470.
8. Ellis SG, Vandormael MG, Cowley MJ, et al. Coronary morphologic and clinical determinants of procedural outcome with angioplasty for multivessel coronary disease. Implications for patient selection. Circulation. 1990;82(4):1193-1202.
9. Moses JW, Leon MB, Popma JJ, et al. Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. N Engl J Med. 2003;349(14):1315-1323.
10. Stone GW, Ellis SG, Cox DA, et al. A polymer-based, paclitaxel-eluting stent in patients with coronary artery disease. N Engl J Med. 2004;350(3):221-231.
11. Cutlip DE, Windecker S, Mehran R, et al. Clinical end points in coronary stent trials: a case for standardized definitions. Circulation. 2007;115(17):2344-2351.