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Original Research Article

COMPARISON OF DIRECT STENTING VERSUS PRE-DILATION OUTCOMES IN PRIMARY PCI AT A MAJOR HOSPITAL

SHIREEN F[1], MASOUD M[*2]

[1]Department of Cardiology, Hayatabad Medical Complex, Pakistan
[2]Department of Cardiology, Peshawar Institute of Cardiology Peshawar, Pakistan
**Corresponding author`s email address:* maryum.masoud@gmail.com

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Abstract: *Stents are utilized in over 95% of percutaneous coronary interventions (PCIs), and advancements in balloon and stent technologies have fostered the development of direct stent (DS) delivery. This approach, which bypasses pre-dilatation, may offer distinct advantages over conventional stenting (CS), which includes balloon dilation before stenting.* ***Objective:*** *To evaluate the angiographic and short-term clinical outcomes of direct stent placement compared to traditional stenting following balloon dilation in patients undergoing primary percutaneous coronary interventions.* ***Methods:*** *This cross-sectional study was conducted from December 2023 to May 2024 at Hayatabad Medical Complex, Pakistan. One hundred patients undergoing primary PCI were randomly assigned to two groups: Group A (n=50) received direct stent placement, and Group B (n=50) underwent stenting following balloon dilation. Data collection included demographic details, coronary intervention details, and procedural outcomes from medical records. Statistical analyses were performed using SPSS software, with Independent samples t-tests used to compare fluoroscopy times, procedure durations, and contrast usage, considering a P-value < 0.05 as significant.* ***Results:*** *The study enrolled 100 patients, with a mean age of 52.8 ± 11.0 years; 76% were male. The most commonly treated vessel was the left anterior descending artery. Group A demonstrated a significantly shorter fluoroscopy time (4.6 ± 2.9 minutes vs. 6.9 ± 4.1 minutes, P=0.001) and total procedure duration (24.4 ± 12.4 minutes vs. 34.6 ± 13.5 minutes, P=0.008) compared to Group B. Furthermore, Group A used less contrast material than Group B.* ***Conclusion:*** *Direct stenting offers a safer, quicker, and more cost-effective alternative to conventional stenting with balloon dilation in primary PCI. This method reduces radiation exposure, procedural costs, and operational time, potentially enhancing outcomes for patients and healthcare teams.*

Keywords: Balloon Dilation; Coronary Artery Disease; Direct Stenting; Percutaneous Coronary Intervention; Stents

Introduction

Stents are currently employed in approximately 95% of PCI procedures. (1). Advancements in stent and balloon technology have led to the introduction of direct stent strategies (DS) that deliver stents without previous dilation, as opposed to conventional stenting (CS), which involves balloon pre-dilation (2). Research indicates that this treatment is safe and viable in certain situations, leading to lower costs, shorter process times, and less radiation exposure. (3).In randomized studies, the DS procedure achieved similar long-term clinical outcomes as the traditional CS (4, 5). Two recent studies found that direct stents (DS) are more effective than stents after pre-dilation (5, 6).Ormiston et al. found that using Taxus Liberte Paclitaxel eluting stents (PES) in properly chosen defects resulted in much lower procedural complications and restenosis (7). Cuisset et al. employed a guidewire with an intracoronary pressure sensor tip to detect microcirculatory resistance. They found that direct stent implantation in unstable angina patients improved microcirculatory malfunction compared to traditional placement. (8). This approach reduces fluoroscopy time, the amount of contrast material used, and fewer balloons during the procedure. (9).One potential drawback of this method is reduced visualization due to decreased distal contrast leaking through unilateral lesions, which may hamper proper stent placement and sizing (10).This cross-sectional study aimed to evaluate the angiographic and short-term clinical outcomes of direct stent placement with stenting following Balloon dilation.

Methods

This cross-sectional study was conducted at the Hayatabad Medical Complex, Pakistan, from December 2023 to May 2024. One hundred individuals getting primary percutaneous coronary intervention were randomly assigned to two groups. Group A included 50 patients receiving direct stent placement, whereas Group B included 50 patients undergoing stenting following balloon dilation. All patients who had undergone primary PCI were included in the research. Only those individuals who had incomplete medical records were left out of the study. The Hayatabad Medical Complex approved the study, Pakistan review board, and hospital ethical committee. Due to the retrospective nature of the study, consent was not required. This approach follows international standards, assuring the reliability and consistency of the study findings.

Data was collected from medical records. Data collected included a history, a comprehensive physical and systemic assessment, and details on the primary percutaneous coronary intervention technique. Baseline factors, including diabetes, hypertension, smoking, dyslipidemia, and a family history of ischaemic heart disease, were recorded. In the

Department of Coronary Angiography and Interventional Cardiology, standard images were acquired using multiple angiographic projections of the stenosis. Intracoronary nitro-glycerine was used to achieve maximum coronary vasodilation. A contrast catheter was a calibration source for a validated quantitative coronary angiography algorithm (Cardiovascular Angiography Analysis System, CAAS II, Medical Imaging. We opted for angiographic projections with minimal vessel overlap and a tighter view of the stenotic lesion. Patients were given 300 mg of clopidogrel, followed by 75 mg every day, along with 150 mg of aspirin. The others were treated using standard approaches. In Group A, patients got a direct stent, but in Group B, a 2×15 mm mercury balloon dilatation was required before stent implantation. All of the patients underwent therapy with either a single eluting drug or bare metal stents. An additional dilatation with the same stent balloon was done to optimize angiographic deployment, mainly if the first deployment was unsatisfactory. Throughout the procedure, intravenous heparin boluses were provided. The PCI vessel was designated as either LAD, LCx, or RCA. The administration of intravenous IIb/IIIa glycoprotein inhibitors was at the physician's discretion, and they were monitored if administered. Medical records were utilized to record parameters such as posterior dilation, fluoroscopy time, operation time, contrast quantity, procedure success, lateral branch involvement, and slow flow. SPSS Software 21 was employed for the analysis. Quantitative variables (e.g., age, fluoroscopy duration, procedure duration, contrast amount) were presented as Mean±SD (Standard Deviation). At the same time, qualitative parameters (e.g., diabetes mellitus, hypertension, smoking, dyslipidemia, family history of IHD, PCI vessel, GP IIb/IIIa used, DES, BMS, post dilatation) were stated as frequency and percentages. Quality characteristics were analyzed using the Chi-square test, whereas quantitative variables were analyzed using the student t-test. A p-value of <0.05 was considered statistically significant.

Results

A total of 100 patients were enrolled in the study. The mean age of individuals in group A was 52.4 ±11.2 years, while in group B, it was 53.2 ± 10.8 years. Males were predominant in the study sample, up to 76% of the study population (Figure 1). In group A, diabetes was present in 40% of the participants, while in group B, it was 52% (Figure 2). Only 8% of the participants in Group A had a history of dyslipidemia, while it was 12% in Group B (table 1).

Table 1: Demographics of the study population

Variable	Group A	Group B	Total	P value
Age (years)	52.4±11.2	53.2±10.8	52.9±10.9	0.64
Gender				
Male	40(80)	36(72)	76(76)	0.43
Female	10(20)	14(28)	24(24)	0.78
Diabetes	20(40)	26(52)	46(46)	0.23
Smoking	21(42)	23(46)	44(44)	0.11
Dyslipedimia	4(8)	6(12)	10(20)	0.54
Family history of IHD	23(46)	19(38)	42(42)	0.75

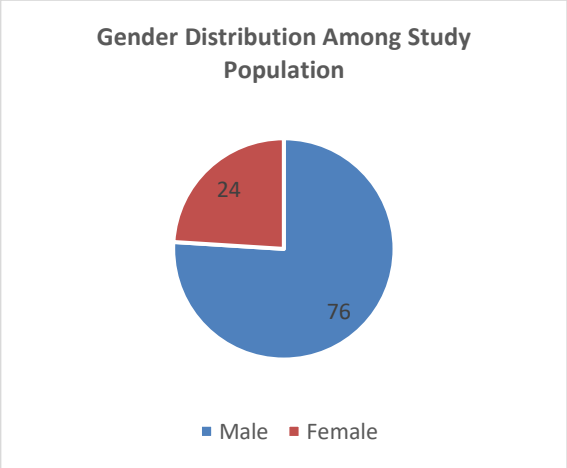

Fig 1: Showing the gender distribution of the study population.

Both groups were comparable in terms of demographics, as indicated by their p-values. Table 1 above shows other details of the patient's demographics. In group A, the PCI vessel was LAD in 32 patients, LCX in 6 patients, and RCA in 12 patients (Figure 3). In group B, the PCI vessel was LAD in 23 patients, LCX in 14 patients, and RCA in 13. Post-dilatation was done in 3 patients in group A and four patients in group B (Table 2)

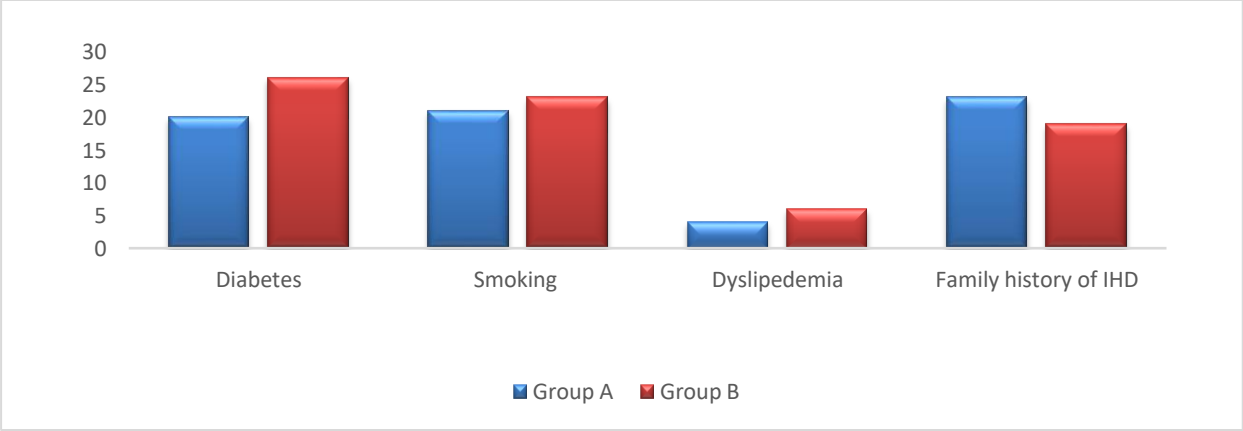

Fig 2: Showing the comorbidity status among both groups.

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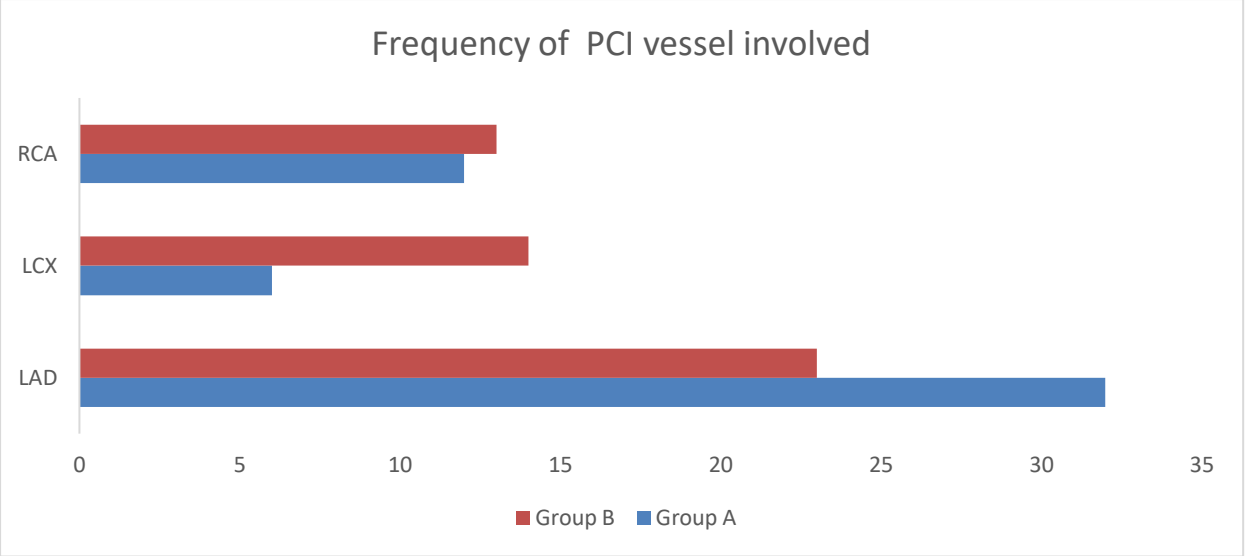

Fig 3: Showing the PCI vessel involvement frequency

The fluoroscopy time was 4.6±2.9 minutes in group A, while it was 6.9±4.1 minutes in group B (P=0.001). The total duration of the procedure in group A was 24.4±12.4 minutes, while in group B, it was 34.6±13.5 minutes (P=0.008).In group A, the amount of contrast used was less than in group B (Table 2)

Table 2: Technique variables of the study population

Variable	Group A	Group B	Total	P value
PCI vessel				
LAD	32(64)	23(46)	55(55)	0.23
LCX	6(12)	14(28)	20(20)	0.41
RCA	12(24)	13(26)	25(26)	0.67
GP llb/la blockers used	32(64)	38(76)	70(70)	0.87
DES	35(70)	34(68)	69(69)	0.14
BMS	15(30)	16(32)	31(31)	0.52
Post dilatation	3(6)	4(8)	7(14)	0.25
Fluoroscopy time (min)	4.6±2.9	6.9±4.1	5.5±3.7	0.001
Procedure duration (min)	24.4±12.4	34.6±13.5	29.6±14.9	0.008
Amount of contrast used	91±33.7	120.3±52.9	105.6±46.5	0.16

Discussion

The direct stent approach (DS) offers an alternative to traditional stents, with a preference for balloons (11). Regular stent usage in CAD therapy promotes the idea of DS. This study confirmed the safety of coronary stenting without balloon pre-dilation, with comparable success rates in both groups, consistent with earlier investigations (4, 12). This study found similar complication patterns to earlier research, including lateral branch involvement, reduced flow, and dissection (4, 13). Cuisset et al. found that in some cases, the DS is as secure and prosperous as the midterm clinical result (13). Group A experienced less fluoroscopy time in our study and used less contrast than group B. These findings are in line with the findings of the previous research. Bendary et al. found that using the DS approach resulted in less fluoroscopy, shorter procedures, fewer guiding catheters, and lesser contrast (12). In a trial of 128 patients, Stys and colleagues found a 99% success rate with the direct stent method, with no procedural severe problems (14). These results are in line with the findings of our study. Several investigations found a significant decrease in procedure duration, contrast quantity, and fluoroscopy time in direct stenting in primary PCI. (15). These results are the findings of our study. The less fluoroscopy exposure time is beneficial for both the patient and the staff performing the procedure (16). The operator's proximity to the radiation source makes them liable for mistakes and grave consequences (17). Reduced radio contrast usage has several benefits, particularly for patients with impaired renal function (18). Direct stents are economical compared with pre-dilation stenting, with studies demonstrating comparable financial benefits. Thus, in our country, it is beneficial to go for DS as it is cost-effective and provides similar success rates and fewer adverse effects owing to the reduced fluoroscopy time, procedure length, and amount of

contrast used. Our study had many limitations that should be considered while interpreting these results. First, the small sample size limits the generalization of the findings. Second, the limited sample size reduces the research's statistical significance. The research also has other limitations, including a lack of consideration for different complications that occurred in the study population.

Conclusion

Direct stenting is a more effective and safer percutaneous therapy for CAD compared to balloon dilation. It can reduce radiation exposure, procedure costs, and duration, leading to improved outcomes for patients and the operating team.

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-TCHA-2424/23)
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

FARHAT SHIREEN (Fellow Interventional Cardiology)
Coordination of collaborative efforts. Study Design, Review of Literature. Manuscript revisions, critical input. Data acquisition and analysis. Manuscript drafting.
***MARYUM MASOUD* (*Registrar of Cardiology*)**
Conception of Study, Development of Research Methodology Design, Study Design, Review of manuscript, final approval of manuscript. Conception of Study, Final approval of manuscript.

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