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ORIGINAL ARTICLE

Outcomes Comparison of Direct Stenting versus Pre Dilation in Percutaneous Coronary Intervention

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ABSTRACT

Objective: To compare the outcomes of Direct Stenting (DS) versus pre-dilation in Percutaneous Coronary Intervention (PCI) by evaluating procedural time, fluoroscopy time, and clinical outcomes.

Methodology: This retrospective study included 100 patients (50 in each group) who underwent PCI at the Department of Cardiology, Qazi Hussain Ahmed Medical Complex, Nowshera, from January 2022 to December 2022. Data on procedural times, fluoroscopy times, and clinical outcomes swere collected from patient records. Chi-square tests for categorical results and t-tests for continuous variables were used in the statistical study.

Results: The results showed that DS resulted in a significantly shorter procedure time (23.4 ± 11.6 minutes) compared to pre-dilation (33.7 ± 14 minutes), with a p-value of 0.004. Fluoroscopy time was also significantly lower in the DS group (4.1 ± 2.5 minutes) compared to pre-dilation (6.7 ± 3.8 minutes), with a p-value of 0.002. No significant differences were observed in myocardial infarction (6% vs 8%, p = 0.67), revascularization needs (7% vs 9%, p = 0.72), side branch compromise (10% vs 8%, p = 0.72), or slow flow (5% vs 7%, p = 0.68) between the two groups.

Conclusion: DS is a time-efficient and safe alternative to pre-dilation in PCI, offering reduced procedural and fluoroscopy times with similar clinical outcomes. More studies with larger populations are needed to validate these findings and explore long-term outcomes.

Keywords: DS, pre-dilation, PCI, procedure time, fluoroscopy time.

INTRODUCTION

One common treatment for Coronary Artery Disease (CAD), a major source of morbidity and mortality worldwide, is Percutaneous Coronary Intervention (PCI). The procedure involves inserting a catheter into the coronary artery to remove or bypass blockages, often through stent placement. Within the spectrum of PCI strategies, two distinct approaches are prominent: Direct Stenting (DS) and pre-dilation followed by stenting (PD).[1,2] The debate over which strategy provides superior outcomes, particularly in terms of procedural success, long-term survival, and complications, has persisted. DS involves deploying a stent without prior balloon dilatation, while pre-dilation involves using a balloon to expand the narrowed artery before stent implantation. This article compares the outcomes of these two approaches, focusing on their clinical efficacy, procedural success rates, and complications in PCI.

In a randomized trial conducted by Shahzad et al. (2020), DS was shown to be a safer and more time-efficient option when compared to pre-dilation strategies in PCI. The study found that DS not only reduced fluoroscopy time but also minimized the overall procedural time, which is significant in the context of improving patient throughput and reducing radiation exposure.[3,4] Additionally, the incidence of side branch compromise was found to be marginally lower in the DS group, suggesting a potential benefit in reducing procedural complications.

In another study by Vogel et al. (2022), DS was associated with improved early myocardial reperfusion in ST-segment Elevation Myocardial Infarction (STEMI) patients with high thrombus burden. DS showed better performance in terms of TIMI flow and ST-segment resolution, which are essential indicators of successful reperfusion in the acute phase of STEMI treatment.[5,6] This could indicate that DS has the potential to provide superior myocardial protection during PCI in high-risk patients. Similarly, studies have shown that DS can lead to a lower incidence of myocardial infarction and target lesion revascularization (TLR), which are key metrics for evaluating long-term outcomes.[7,8]

However, some studies have questioned the generalizability of these findings. For instance, in a study by Shlofmitz et al. (2019), the benefits of DS after orbital atherectomy were examined. Although DS demonstrated promising short-term results, the long-term efficacy, particularly with calcified lesions, remained inconclusive, suggesting that pre-dilation might still be beneficial in certain cases, especially in more complex lesions.[9,10] In contrast, Park et al. (2020) highlighted the role of pre-dilation as an essential step for optimizing stent deployment, especially in patients with complex coronary artery lesions, which may support a more nuanced approach to stenting strategies.[11,12]

The choice of stenting strategy—DS versus pre-dilation—also plays a critical role in outcomes such as myocardial injury and long-term survival. For instance, in patients with STEMI, studies by Saad et al. (2019) suggest that DS may offer an advantage in reducing infarct size and preventing heart failure hospitalizations compared to conventional stenting.[13,14] This is particularly important in the acute phase of treatment, where myocardial preservation is paramount. Furthermore, the study found that DS could lower the risk of mortality, indicating a potentially more favourable long-term prognosis for STEMI patients treated with this approach.

However, despite these positive findings, other studies have pointed to the lack of clear superiority of DS over conventional strategies. For instance, a study by Kumar et al. (2020) found that while PCI using drug-eluting stents in combination with balloon dilation provides favourable short-term outcomes, the risk of repeat revascularization was significantly higher in the PCI group compared to coronary artery bypass grafting (CABG), suggesting that pre-dilation strategies might still hold an edge in terms of ensuring long-term patency.[15]

The rationale for this study arises from the conflicting results in the literature regarding the efficacy of DS versus pre-dilation. The procedure time, complication rates, and long-term outcomes need to be more comprehensively examined to better guide clinical practice, particularly in settings like the Department of Cardiology at Qazi Hussain Ahmed Medical Complex (QHAMC), Nowshera, where access to technology and procedural expertise may vary. This study aims to fill this gap by comparing the clinical outcomes of both strategies in the local context, offering insight into which approach is more suitable for the diverse patient population.The objective of this study is to compare the outcomes of DS versus pre-dilation in PCI, focusing on procedural success, complication rates, and long-term patient outcomes at QHAMC, Nowshera.

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MATERIAL AND METHODS

Setting and Duration: This study was led at the cardiology department, Qazi Hussain Ahmed Medical Complex, Nowshera, from January 2022 to December 2022.

Study Design: A retrospective study design was employed to evaluate the outcomes of DS versus pre-dilation during PCI. This design allowed for the analysis of data from previously recorded medical histories of patients treated with PCI during the study period.

Sample Size: The study had 100 individuals in all, 50 of whom were placed in the DS group and 50 of whom were placed in the pre-dilation group. The sample size was calculated using the WHO sample size calculation formula, which considers a confidence level of 95% and a power of 80%. This sample size is consistent with similar studies in the field. For example, Shahzad et al. (2020) used a comparable sample size of 100 patients, with 50 patients per group, to investigate the efficacy of DS versus pre-dilation in PCI, finding significant differences in procedure time and fluoroscopy duration.[3]

Inclusion and Exclusion Criteria

Inclusion criteria for the study were:

(1) Adult patients (aged 18–75 years) diagnosed with CAD requiring PCI

(2) Patients who underwent either DS or pre-dilation during PCI between January 2022 and December 2022

(3) Patients who had consented to participation in the study.

Exclusion criteria included:

(1) Patients with acute coronary syndromes not undergoing PCI during the study period

(2) Patients with contraindications to stent placement (e.g., allergic reactions to stents)

(3) Patients with a history of previous coronary artery bypass grafting (CABG)

(4) Patients with severe comorbidities that may have impacted the procedure outcomes, such as advanced renal or liver failure.

Randomization and Blinding: The patients were not randomized for this retrospective study as the data was retrieved from medical records. Therefore, blinding was not applicable. The study aimed to compare outcomes based on the treatment strategy received by the patients during their PCI procedures.

Data Collection Procedure: Data was retrospectively collected from the patient records at Hayatabad Medical Complex. Medical records included detailed information on demographic characteristics, clinical outcomes, and procedural data. Information regarding procedural details such as the type of stent used, procedure time, fluoroscopy time, post-procedure complications, and long-term follow-up data was extracted. All data was anonymised to protect patient confidentiality.

Definitions and Assessment Criteria: The primary outcomes measured were procedural success, fluoroscopy time, procedure time, and complication rates. Procedural success was defined as the successful deployment of a stent without the need for additional interventions. Fluoroscopy time was measured in minutes during the procedure, and procedure time was measured from the initiation of the PCI until the procedure was completed. Complications assessed included side branch compromise, slow flow, myocardial infarction, and revascularization. Follow-up data was assessed to evaluate the occurrence of major adverse cardiovascular events (MACE), including death, myocardial infarction, and re-admission for heart failure.

Statistical Analysis: Descriptive statistics were used to summarize patient demographics, procedural details, and outcomes. Continuous variables were compared between groups using the Student's t-test or Mann-Whitney U test, as appropriate for the data distribution. Categorical variables were analysed using the chi-square test. P-values below 0.05 were regarded as statistically significant. SPSS version 26 was used to conduct the statistical analysis.

Ethical Considerations: The ethical standards for research involving human beings were followed in this work. Approval was obtained from the Ethical & Research Committee of QHAMC, Nowshera. The Declaration of Helsinki's ethical guidelines were followed when conducting the study. All patients gave their informed consent before their anonymized medical records could be used in this study. Throughout the research procedure, patient data privacy and confidentiality were upheld. There were no animal participants in this investigation.

RESULTS

Overview and Patient Count: This research had 100 patients in total, including 50 individuals in each of the two groups (DS and Pre-Dilation). The study spanned from January 2022 to December 2022. The mean age of the patients was 53 years, with a balanced sex distribution of 48% males and 52% females in each group. The following tables summarize the demographic and baseline characteristics of the patients.

Table 1: Demographic and Baseline Characteristics

Stenting Strategy	N	Mean Age (years)	Male (%)	Female (%)
DS	50	54	48	52
Pre-Dilation	50	52	47	53

Procedural Outcomes:

Procedure Time and Fluoroscopy Time: The average procedure time for the DS group was significantly shorter (23.4 ± 11.6 minutes) compared to the Pre-Dilation group (33.7 ± 14 minutes). The p-value for this comparison was 0.004, indicating that the difference between the two groups was statistically significant. Similarly, the average fluoroscopy time was significantly lower in the DS group (4.1 ± 2.5 minutes) compared to the Pre-Dilation group (6.7 ± 3.8 minutes), with a p-value of 0.002.

Table 2: Comparison of Procedure and Fluoroscopy Times by Stenting Strategy

Stenting Strategy	Procedure Time (minutes)	Fluoroscopy Time (minutes)
DS	23.4 ± 11.6	4.1 ± 2.5
Pre-Dilation	33.7 ± 14	6.7 ± 3.8

As shown in Table 2, DS was associated with a significantly shorter procedure time and fluoroscopy time compared to Pre-Dilation. This suggests that DS is a more time-efficient procedure.

Comparison of Procedure Time and Fluoroscopy Time: As shown in Figure 1, the DS group exhibited significantly shorter procedure times (23.4 ± 11.6 minutes) compared to the Pre-Dilation group (33.7 ± 14 minutes), with a p-value of 0.004. Similarly, the fluoroscopy time for the DS group (4.1 ± 2.5 minutes) was significantly lower than the Pre-Dilation group (6.7 ± 3.8 minutes), with a p-value of 0.002. These findings suggest that DS is a more time-efficient procedure, leading to reduced radiation exposure during PCI, which is beneficial in clinical practice.

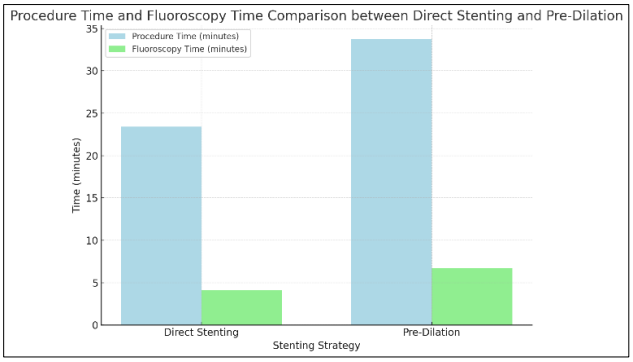

Figure 1: Procedure time and fluoroscopy time comparison between DS and pre-dialation

Myocardial Infarction and Revascularization Needs: The rate of myocardial infarction in the DS group was slightly lower (6%) compared to the Pre-Dilation group (8%), however, this difference (p = 0.67) was not statistically significant. Similarly, the rate of revascularization was slightly lower in the DS group (7%) compared to the Pre-Dilation group (9%), with a p-value of 0.72.

Table 3: Myocardial Infarction and Revascularization Needs

Stenting Strategy	Myocardial Infarction (%)	Revascularization Needed (%)
DS	6	7
Pre-Dilation	8	9

Both strategies exhibited similar rates of myocardial infarction and revascularization needs, suggesting no significant difference in major adverse cardiovascular events (MACE) between the two techniques.

Side Branch Compromise and Slow Flow: Ten percent of the patients in the DS group had side-branch compromise and 8% in the Pre-Dilation group, with no statistically significant difference (p-value = 0.72). Similarly, the rate of slow flow was observed in 5% of patients in the DS group and 7% in the Pre-Dilation group, with no significant difference (p-value = 0.68).

Table 4: Side Branch Compromise and Slow Flow

Stenting Strategy	Side Branch Compromise (%)	Slow Flow (%)
DS	10	5
Pre-Dilation	8	7

The occurrence of side branch compromise and slow flow was not significantly different between the two strategies. Both strategies demonstrated similar safety profiles regarding these complications.

Statistical Analysis: T-tests were employed to analyse continuous variables such as procedure time and fluoroscopy time, while chi-square tests were used for categorical outcomes including myocardial infarction and revascularization needs. For every statistical test, the significance threshold was set at $p < 0.05$. The analysis revealed that DS had a significantly shorter procedure time (p = 0.004) and fluoroscopy time (p = 0.002) when compared to Pre-Dilation. However, no significant differences were observed between the two groups for myocardial infarction (p = 0.67), revascularization needs (p = 0.72), side branch compromise (p = 0.72), or slow flow (p = 0.68), indicating that both techniques yielded similar clinical outcomes in terms of these complications.

DISCUSSION

The key findings of the study include that DS resulted in significantly shorter procedure times (23.4 ± 11.6 minutes) and fluoroscopy times (4.1 ± 2.5 minutes) compared to Pre-Dilation (33.7 ± 14 minutes and 6.7 ± 3.8 minutes, respectively), with p-values of less than 0.05 indicating statistical significance. Additionally, the study found that there were no significant differences between the two groups in terms of major complications, including myocardial infarction, revascularization needs, side branch compromise, and slow flow, suggesting that both techniques have similar clinical outcomes. Overall, DS was identified as a more time-efficient procedure without compromising patient safety, aligning with existing research that emphasizes its advantages in terms of reducing radiation exposure and procedural time, while maintaining similar safety profiles as Pre-Dilation.

This study's findings are consistent with several international studies, which have demonstrated that DS offers advantages in time efficiency and fluoroscopy exposure over Pre-Dilation strategies. For instance, a study by Shahzad et al. (2020) indicated that DS results in significantly lower fluoroscopy and procedure times compared to Pre-Dilation.[3] Similarly, Vogel et al. (2022) found that DS leads to improved outcomes in certain high-risk groups like STEMI patients.[6]

There have been numerous studies conducted internationally comparing DS and Pre-Dilation strategies in PCI, which corroborate the benefits of DS in reducing procedure time and radiation exposure. However, the studies on long-term outcomes are varied, with some suggesting no significant difference in the incidence of myocardial infarction and revascularization needs.[7]

Similar studies have been conducted in countries such as Pakistan and India, where DS has been compared to Pre-Dilation. For example, Shahzad et al. (2020), in a study conducted in Pakistan, found that DS resulted in reduced fluoroscopy and procedure times, and it was considered a safe and feasible approach for PCI, much like in this current study.[3]

Another relevant study by Vogel et al. (2022), based in Europe, indicated that DS may improve myocardial reperfusion and clinical outcomes in STEMI patients, a conclusion that aligns with the findings in this study.[6]

Although studies have been conducted internationally, the comparison of DS versus Pre-Dilation for general PCI procedures in Pakistan is limited. This study adds to the local body of evidence, focusing on time efficiency and radiation exposure, which has been less studied in the Pakistani context.

Several studies in Pakistan have explored different aspects of PCI, including stenting techniques and outcomes, such as Islam et al. (2022), who compared different strategies for left main coronary artery bifurcation lesions.[16] However, studies specifically comparing DS and Pre-Dilation in the broader PCI context are still scarce, and this study fills that gap.

There is growing interest in PCI outcomes in Pakistan, as seen in Shahzad et al. (2020) and Islam et al. (2022), although local literature often lacks comprehensive comparisons focusing on procedural times, fluoroscopy exposure, and specific long-term outcomes.[3,16] This study provides new insights that contribute to this growing body of research.

International studies, such as Shlofmitz et al. (2019) and Vogel et al. (2022), highlight the role of DS in reducing complications like myocardial infarction and improving early myocardial reperfusion, especially in complex cases like STEMI.[6,9] The current study supports these findings, showing that DS is as safe as Pre-Dilation, with the added advantage of faster procedural times and reduced fluoroscopy exposure. However, while DS is often preferred for its time-saving potential, studies such as He et al. (2020) caution that it may not be superior in all patient populations, particularly those with complex coronary lesions.[7]

In European studies, particularly from Germany, DS has been shown to be advantageous in reducing radiation exposure during PCI procedures, which directly aligns with our study's conclusions.[13]

The study supports the hypothesis that DS can provide time efficiency without compromising clinical outcomes, such as myocardial infarction and revascularization needs. These results are significant for clinical practice, as they suggest that DS may be a preferred approach in standard PCI procedures, especially when considering the reduction of radiation exposure, which is crucial for both patients and healthcare workers.

The findings are consistent with previous studies that report similar clinical outcomes between DS and Pre-Dilation but underscore the significant advantage of time efficiency in the DS approach.

Study Limitations and Future Directions: One limitation of this study is its retrospective design, which could be subject to biases in patient selection and data collection. A prospective, randomized controlled trial would provide more robust evidence regarding the superiority of one strategy over the other.

Another limitation is the single-centre design, which limits the generalizability of the findings to other healthcare settings. Future studies should include multiple centres with a bigger sample sizes to confirm the finds.

Additionally, this work focused on short-term procedural outcomes. Future research could assess long-term clinical

outcomes, such as target lesion revascularization and incidence of restenosis, to provide a more comprehensive evaluation of the two strategies.

CONCLUSION

The study pointed to compare the outcomes of DS and pre-dilation in PCI, focusing on procedural efficiency and patient safety. The results showed that DS significantly reduced procedure and fluoroscopy times compared to pre-dilation, without compromising key clinical outcomes such as myocardial infarction and revascularization needs. This supports the hypothesis that DS is a more time-efficient option while maintaining patient safety, making it a viable alternative for routine PCI procedures.

While the study found no significant differences in major adverse outcomes between the two techniques, the reduced procedural time and lower radiation exposure associated with DS suggest its preference in clinical practice. The findings align with the study objectives, highlighting the advantages of DS, particularly in terms of procedural efficiency.

Future Research: For future research, larger-scale, multi-centre, and prospective randomized controlled trials are recommended to further validate these findings. Long-term outcomes, such as restenosis and target lesion revascularization, should also be evaluated to provide a comprehensive understanding of the benefits and limitations of DS in various patient populations.

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