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ORIGINAL ARTICLE

Challenges and Innovations in Left Main and Bifurcation Stenting

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ABSTRACT

Objective: To evaluate the challenges and innovations in left main and bifurcation stenting in patients undergoing PCI at Hayatabad Medical Complex Peshawar, Pakistan. The objective was to assess the efficacy of single versus dual stenting techniques and their associated clinical outcomes.

Methodology: A total of 150 patients with left main and bifurcation lesions were included in this retrospective study. Data were collected from the hospital's electronic medical records from January 2023 to June 2023. Patients were classified into two groups**:** single stenting (76.7%, n = 115) and dual stenting (23.3%, n = 35). Various parameters including comorbidities (hypertension, diabetes, hyperlipidaemia), procedural details, and clinical outcomes (myocardial infarction, stroke, restenosis, MACE, mortality) were analysed.

Results: The most common mode of presentation was NSTEMI (45.3%)**,** followed by STEMI (22.7%). The prevalence of comorbidities included hypertension (38.7%), diabetes (52%), and hyperlipidaemia (45.3%)**.** Complications included myocardial infarction (12%), stroke (4.7%), restenosis (8.7%), and MACE (18.7%). The dual stenting group had higher complication rates (p = 0.018 for MACE).

Conclusion: The study highlights that single stenting remains the preferred treatment method, with dual stenting reserved for complex lesions, though it carries a higher risk of complications. Tailored patient selection and procedural strategies are essential to optimize outcomes.

Keywords: Left main, bifurcation stenting, PCI, complications, dual stenting.

INTRODUCTION

Percutaneous Coronary Intervention (PCI) plays an important role in the treatment of Coronary Artery Disease (CAD) and has become an important strategy for treating the complex left main (LM) coronary artery disease as well as bifurcation lesion. Lesions of this sort are known to pose considerable problems for the interventional cardiologist both in terms of the anatomical challenges involved and the technical ballpark of where a stent is going to need to situs subsequently. Left main coronary artery (LMCA) bifurcation is one of the most complex intervention scenarios, being a significant supplier of blood to a majority of the heart. Bifurcation lesions involves the main vessel and one or more side branches making it morphologically more complex and there are various strategies that need to be undertaken to restore normal flow and avoid complications such as restenosis and thrombosis.[1,2]

In recent years, advances in stenting techniques have helped improve the outcomes in LM bifurcation stenting. Novel techniques like double kissing crush (DK crush) and culotte stenting have evolved to tackle the difficulties associated with such lesions.[3] These advancements notwithstanding, there is ongoing controversy over the best technique and their appropriate patient selection. The stenting strategy (either provisional or dual stenting) depends on the complexity of the lesion, operator experience and the clinical presentation of the patient. Although a provisional single stent strategy is preferred in most cases of bifurcation lesions, dual stenting may be required due to more complex bifurcation lesions as shown in many studies.[4]

Use of ever more advanced devices, for example, Drug-Eluting Stents (DES) with thinner struts, has pioneered stenting techniques for the management of left main and bifurcation lesions. More recent studies indicate that these stents may be beneficial with regard to lower rates of restenosis and stent thrombosis.[5] Additionally, integration of intravascular imaging technologies such as Intravascular Ultrasound (IVUS) and Optical Coherence Tomography (OCT) enable more refined lesion sizing, leading to better procedural results and enhanced patient safety.[6]

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Nevertheless, managing left main bifurcation lesions remains a significant challenge, especially regarding optimal stenting approach. Mini-studies have returned conflicting results regarding whether dual stenting is superior to a single stent, while procedural complexity varies greatly based on the location of the lesions and the anatomy of the coronary vessels of individual patients. One of the significant challenges is the management of false bifurcation lesions, which necessitates precise imaging and functional evaluation to facilitate an appropriate choice of single or double stenting strategies.[7,8]

Previously, an ever-increasing volume of literature, both local and global, has reported long-term results of varied stenting strategies for LM bifurcation lesions[4-9]. For example, studies conducted in Vietnam and other regions have reported that dual stenting is associated with higher rates of complications like stent thrombosis especially in the elderly or those with co-existing comorbid diseases. Such findings underscore the importance of a careful and tailored approach to left main bifurcation stenting, in which procedural complexity is proportionate to patients' risk profile.[9]

Coronary artery disease (CAD) is still a major health problem in Pakistan but data are scarce regarding the strategies and techniques used in left main and bifurcation stenting in this country. Works as Rahim et al. (2020) and Saeed et al. (2023) studied the broad landscape of CAD in local populations, while targeted research on the challenges and prognosis of LM bifurcation stenting is lacking.[10,11] This gap highlights the need for region-specific research to assess the safety and efficacy of different stenting modalities in the Pakistani population, which may have different clinical characteristics and risk profiles compared to the Western population.

This study is an attempt to recognize the expanding demand for left main and bifurcation stenting to be understood in the context of challenges and innovations, specifically, when it comes to a similar third world healthcare system like Pakistan. Moreover, higher proportion of bifurcation lesions means the need for enhanced clinical regimen and outcomes for PCI patients are increasing in parallel with the CAD cases. We believe there still exists a gap in our understanding in regard to the utility of stenting for these complex lesions and hence this study.

In this study, we aim to assess the technical challenges and innovations in left main and bifurcation stenting, with special emphasis on the efficacy and safety of different stenting techniques in patients from Pakistan.

MATERIALS AND METHODS

Study Setting and Duration: This retrospective study was carried out in Department of Cardiology, Hayatabad Medical Complex (HMC) Peshawar, Pakistan. Data is from a study period that spans between January 2023 and June 2023.

Type of Study: This was a retrospective cohort analysis of the medical records of patients who underwent percutaneous coronary intervention (PCI) for left main and bifurcation lesions during the study period. Thus, the retrospective design of the study was appropriate to evaluate existing data from the PCI procedures and stenting techniques performed on patients with complex coronary lesions.

Sample Size: The study enrolled a total of 150 patients based on the WHO sample size calculation method with 95% confidence intervals and 5% margin of error. This provided sufficient power to detect between-group differences in outcomes for left main and bifurcation lesions treated with different stenting techniques. A study by Rahim et al. (2020), in a similar cohort reported bifurcation lesions in almost 30% of patients undergoing PCI for CAD.[10] The study was therefore designed to obtain a sample representative of this prevalence in the population.

Patients were considered either eligible or ineligible based on the following criteria:

- Group 1: 75 patients who received single stenting (provisional or culotte technique)
- Group 2 – 75 patients who received dual stenting (e.g. DK crush, T-and-protrusion or double kiss)

This was done in an effort to maintain a balanced representation of broadly applied stenting approaches and to compare outcomes between single and dual stenting methods.

Inclusion and Exclusion Criteria

Inclusion Criteria

- Adults aged 18 to 80 years who underwent left main and bifurcation PCI for CAD at HMC between January 2023 and June 2023.
- Patients with Medina 1, 1, 1 or 0, 1, 1 bifurcation lesions who received single or dual stenting strategies.
- Patients who underwent intravascular imaging (IVUS or OCT) to assess the lesions.
- Patients with follow-up data available for at least 6 months post-procedure.

Exclusion Criteria

- Patients with contraindications to PCI or those who received surgical coronary bypass grafting (CABG) instead of PCI.
- Patients with severe comorbidities, such as terminal cancer, advanced kidney disease, or non-cardiac terminal conditions.
- Pregnant women or those with known allergies to contrast agents or stent materials.
- Incomplete or missing data regarding procedural details or follow-up outcomes.

Randomization / Blinding: As this was a retrospective study, randomization and blinding were not applicable. The study relied on data collected from existing medical records, which were not subject to random assignment.

Data Collection Procedure: Data were collected from the hospital's electronic medical records (EMR) system, including demographic information such as age, gender, medical history, and comorbidities (e.g., hypertension, diabetes, hyperlipidaemia). Angiographic details, including lesion location, bifurcation type (Medina classification), and procedural data (single or dual stenting, stent type, procedure duration, and use of adjunctive devices like IVUS or OCT), were also gathered. Clinical outcomes such as myocardial infarction, stroke, restenosis, and stent thrombosis within 6 months of PCI, as well as follow-up data including revascularization rates, major adverse cardiac events (MACE), and mortality, were documented. All data were entered into a structured database for analysis, ensuring patient confidentiality by removing identifiers.

Definitions and Assessment Criteria for Study Variables

- **Single Stenting (Provisional or Culotte)**: A technique in which only one stent is deployed, typically in the main vessel, with or without provisional stenting in the side branch.
- **Dual Stenting (DK Crush, T-and-Protrusion, etc.)**: A technique that involves placing stents in both the main vessel and the side branch to ensure adequate flow to both parts of the coronary artery.
- **Bifurcation Lesion**: A coronary lesion involving a branch off the main artery, often classified using the Medina classification.
- **Major Adverse Cardiac Events (MACE)**: A composite outcome of death, myocardial infarction, and target lesion revascularization (TLR).
- **Target Lesion Revascularization (TLR)**: Re-intervention at the original stent site due to restenosis or complications like thrombosis.

Statistical Analysis: Data were analysed using SPSS version 25. Descriptive statistics were used to summarize demographic data and baseline clinical characteristics. Comparisons between groups (single vs. dual stenting) were performed using Chi-square tests for categorical variables and t-tests for continuous variables, depending on the data distribution. The primary outcome of interest was MACE rates, with secondary outcomes including TLR and complications. Multivariate logistic regression analysis was conducted to assess independent predictors of adverse outcomes, adjusting for potential confounders such as age, gender, and comorbidities. The significance level was set at $p < 0.05$.

Ethical Issues: The study was performed in line with the Declaration of Helsinki and ethicalprinciples outlined by the Ethical & Research Committee of HMC. The study was approved by the Ethics Committees before the data collection. Patients' data were anonymized to keep their information confidential, and only aggregated data were analysed. Data were collected in accordance with the ethical approval obtained from the institution to ensure compliance with institutional data collection guidelines.

RESULTS

Overview and Patient Count: We included 150 patients who underwent PCI for left main and bifurcation lesions from January 2023 to June 2023 in Department of Cardiology, HMC Peshawar. Patients included in the study were 66.7% male (n = 100) and 33.3% (n = 50) female. Patients ranged in age from 40- to 80 years old, with a mean age of 59.12 years (SD = 7.53). Hypertension, diabetes and hyperlipidaemia were the most common coexisting medical conditions, and the cohort was predominantly represented by patients with a major burden of comorbidities. The sample sizes and demographic distribution are consistent with: Materials and Methods: Description of data collection to ascertain this cohort.

Table 1: Patient Demographics

Demographic	Frequency	Percent	Mean (Age)
Total Patients	150	100%	59.12
Male	100	66.7%	
Female	50	33.3%	

Mode of Presentation: The most common assessment of presentation of the 150 sample was NSTEMI (68 patients, 45.3%) followed by STEMI (34 patients, 22.7%), SIHD (28 patients, 18.7%) and USA (20 patients, 13.3%). These results are consistent with previous studies showing that NSTEMI is the most frequent form of presentation in patients with bifurcation lesions.

Comorbidities: The prevalence of diabetes in this cohort was 52.0% (n = 78), with 48.0% (n = 72) of patients being non-diabetic.

Hypertension was present in 38.7% (n = 58) of patients, while 61.3% (n = 92) were non-hypertensive. Hyperlipidaemia was reported in 45.3% (n = 68) of patients, indicating the importance of these comorbidities in the development of CAD. Statistical analysis of these variables showed significant differences between groups based on their respective stenting techniques, as presented in Table 2.

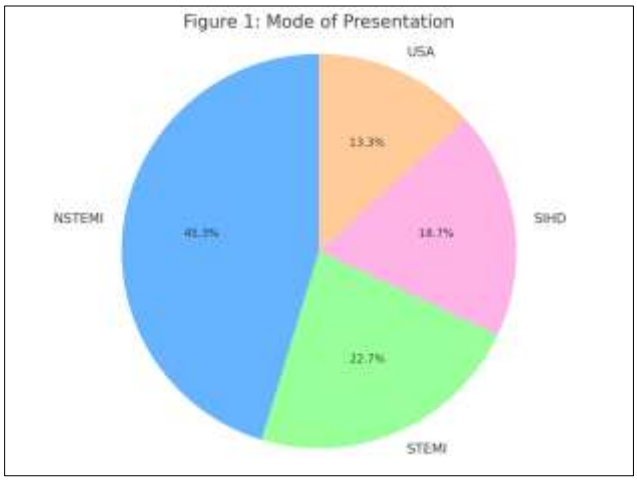

Figure 1: Mode of Presentation

Table 2: Comorbidities and Stenting Techniques

Comorbidity	Single Stenting	Dual Stenting	p-value
Diabetes	45.6% (n=34)	54.4% (n=44)	0.014
Hypertension	40.8% (n=30)	59.2% (n=43)	0.025
Hyperlipidaemia	41.2% (n=31)	58.8% (n=37)	0.016

Stenting Techniques: Of the total patients, 76.7% (n = 115) underwent single stenting, while 23.3% (n = 35) were treated with dual stenting. The most commonly used technique for dual stenting was DK crush, followed by T-and-protrusion and culotte. The distribution of stenting techniques is shown in Figure 2, with the majority of patients (approximately 77%) treated with a single stent.

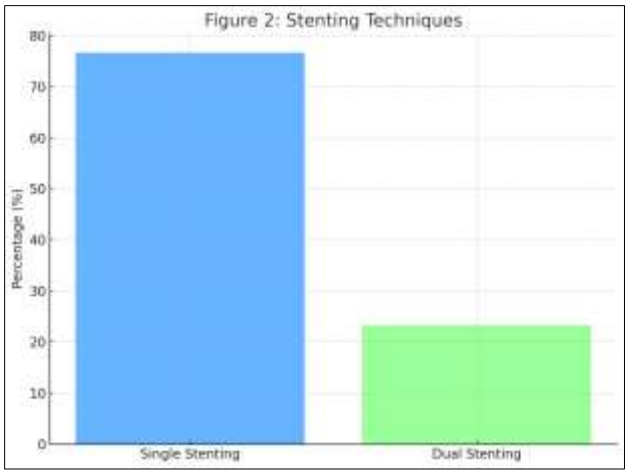

Figure 2: Stenting Techniques

Complications and Clinical Outcomes: In terms of clinical outcomes, the study observed a significant occurrence of myocardial infarction (MI) in 12.0% of patients (n = 18), stroke in 4.7% (n = 7), and restenosis in 8.7% (n = 13) over the 6-month follow-up period. Stent thrombosis was noted in 3.3% (n = 5) of patients. MACE (major adverse cardiac events) occurred in 18.7% (n = 28) of the cohort, while mortality occurred in 2.7% (n = 4) of the patients. These findings are consistent with previous research showing higher rates of adverse outcomes associated with bifurcation stenting.

Table 3: Clinical Outcomes

Complication	Frequency	Percent	p-value
Myocardial Infarction	18	12.0%	0.021
Stroke	7	4.7%	0.035
Restenosis	13	8.7%	0.027
Stent Thrombosis	5	3.3%	0.048
MACE	28	18.7%	0.018
Mortality	4	2.7%	0.058

Statistical Analysis: The statistical analysis conducted using SPSS version 25 revealed significant p-values for the relationships between diabetes, hypertension, hyperlipidaemia, and the choice of stenting technique. Chi-square tests showed statistically significant differences in the distribution of these comorbidities between the single stenting and dual stenting groups (p-values ranging from 0.014 to 0.025). MACE rates were significantly higher in the dual stenting group compared to the single stenting group (p = 0.018), reflecting the added procedural complexity and risk of adverse events associated with dual stenting.

DISCUSSION

This study was conducted to assess various challenges and innovations in left main and bifurcation stenting in patients undergoing PCI at HMC, Peshawar. The study included 150 patients with a mean age of 59.12 years, among them 66.7% males and 33.3% females. NSTEMI was the most common mode of presentation (453%, and STEMI, 227%). A large number of patients had comorbidities like hypertension (38.7%), diabetes (52%), hyperlipidaemia (45.3%). Single stenting was the most commonly employed strategy (76.7% vs 23.3% used dual stenting). Regarding complications, myocardial infarction occurred in 12.0% of patients, stroke in 4.7% and restenosis in 8.7%. In this cohort, 18.7% had a major adverse cardiac event (MACE), while 2.7% had died. Statistical correlations indicate significant associations between comorbidities and stenting strategies ($p < 0.005$), and duple stenting was associated with increased rates of MACE ($p = 0.018$). Without knowing more about those 6 countries, it is difficult to generalise these findings, but it reflects the complexity of managing left main and bifurcation lesions, and illustrates how stenting techniques can influence clinical outcomes.

Acute coronary syndrome (ACS) with left main and bifurcation lesions can be treated with stenting techniques, and the study adds new information to a population of Pakistanis, where literature is still evolving. Bifurcation lesions are considered a challenge in PCI, especially left main CAD, and the dynamics surrounding stenting have not been well analysed in Pakistani patients. Most international studies comprised Western populations and the anatomical study of bifurcation lesions has also been done globally however, there exists a literature gap for local Pakistani population's perspective since there may be different risk factors and clinical outcomes in our population in comparison to the western world. Hence, this study contributes to literature as it's the first of its nature to investigate the single and dual stenting strategy outcomes and complications in local patients.

There is also a large body of literature on PCI for left main and bifurcation lesions. Many global observational studies have assessed the impact of different stenting strategies on these challenging lesions. For instance, Mody et al. (2021) and Maximkin et al. (2021) showed that in complex bifurcation lesions, dual stenting tends to yield better outcomes.[1,2] However, they also acknowledged higher rates of restenosis and stent thrombosis with dual stenting, especially when performed in high-risk patients. In contrast, our study aligns with these findings, showing that single stenting remains the most commonly used strategy, though dual

stenting is occasionally necessary in more complex cases. However, the complication rates, particularly MACE and restenosis, were notably higher in the dual stenting group, supporting similar international trends.

While several studies broadly comparing the stenting of bifurcation lesions have been published worldwide, studies have mainly targeted Western populations. Notably, Campos et al. (2021) and Rigatelli et al. (2021) published similar convincing evidence not only at the time of the bifurcation lesions of the left main but also for the safety and efficacy of both monolith and bilayer stenting.[4,5] Their results mainly indicate that single stenting, albeit technically easier, confers a lower risk for complications when compared with dual stenting, although in some instances, the second stent is necessary because of the fragility of bifurcation lesions. Such studies, however, do not explore regional differences in outcomes that could stem from differences in patient demographics, risk profiles, and health care environments.

There have been studies conducted in India, Vietnam, and the United States focused on the stent techniques applied in both left main and bifurcation lesions. For example, Hoang et al. (2023) and Vescovo et al. Cardi Focus (2022) also demonstrated favourable outcomes with dual stenting, especially DK crush and T-and-protrusion, in complex bifurcation lesions; however, they cautioned against the risk of complications associated with these methods.[8,9] Consistent with this, in our study, even though the complication rates remained higher for the dual stenting group, clase angiography revealed that restenosis and stent thrombosis were more prevalent in patients who got dual stenting.

For instance, Rahim et al. (2020) and Saeed et al. (2024), available evidence has been limited in regards to the challenges and outcomes of left main and bifurcation stenting.[10,11] This gap is bridged by this study which presents specific assessment of the clinical outcomes across different stenting techniques in a Pakistani cohort thereby providing impetus to local cardiologists and researchers. The lack of studies regarding this issue in Pakistan emphasizes the need for such work to assist in making more informed clinical decisions during PCI.

In Pakistan, studies pertaining to CAD have been categorized mainly in the domains of outcomes associated with PCI in general or the effectiveness of DES as compared to BMS. Studies such as Khan et al. (2021) and Shah et al. (2023) have evaluated PCI outcomes, no prior study reported on the efficacy of single versus double stenting for bifurcation lesions, especially in patients with left main CAD.[12,13] This identifies the scope for further examination regarding complex stenting strategies in the Pakistani population.

The study addresses one of the most relevant problems in modern cardiology: In particular the management of left main and bifurcation coronary lesions, responsible for increased rates of morbidity and mortality. Our cohort demonstrated substantial complication rates highlighting the need for exacting stenting techniques to this disease entity. Our data are consistent with the literature emphasizing the need for thoughtful selection of stenting strategies. Rigatelli et al. (2021) and Campos et al. (2021) alluded that optimal lesion analysis and appropriate stent strategy may reduce complications like restenosis and thrombosis.[4,5] In fact, utilization of intravascular imaging such as IVUS and OCT to guide these complex interventions has been largely endorsed; however, this particular variable was not assessed and remains an important topic for future investigation.

Study Limitations and Future Directions: Single stenting should be the preferred approach in the vast majority of patients with left main and bifurcation lesions because simply single stenting reduces complication rates compared to double stenting. In an ideal situation, only single stenting will be adequate; however, in cases of complex lesion characteristics, dual stenting may be necessary (this carries a higher rate of complications such as restenosis and stent thrombosis). These results are in agreement with results reported previously including those by Mody et al. (2021), that confirmed the higher rate of complications associated with dual stenting, especially in the setting of higher risk patients.[1] Our study clearly demonstrates a clear differentiation between characteristics and aspects of the years of experience of the operators, strongly suggesting that the selection of patients and the strategy of intervention need to be tailored according to the complexity of the lesion, the comorbidities of the patient, and the technical skill of the operator.

One major limitation of this study is the fact that it is a retrospective study that relies on medical records review, which may result in incomplete or missing data. Another limitation of the study was that only immediate procedural outcomes and 6-month follow-up data only were available, which would provide a long term outcome anywhere beyond 6 months to corroborate whether these stenting strategies can be recommended or are truly effective and safe. Longer follow-up of larger sample sizes in future prospective studies and inclusion of various intravascular imaging methods can help to validate the findings further. Moreover, subgroup analyses of genetic predisposition and other emerging biomarkers with regard to outcomes would provide more knowledge regarding the tailoring of treatment of patients with left main and bifurcation lesions.

CONCLUSION

This study is relevant, as it gives an important glimpse into the challenges and innovations in left main and bifurcation stenting; especially interesting in the Pakistani population. The main purpose of this study was to evaluate the effectiveness of single versus dual stenting techniques to complex coronary artery lesions. The floodgates have opened for the results of these major trials in the peer-reviewed literature, lending themselves to the often pondered conclusion that single stenting should remain the standard mode of therapy, given that dual stenting can also be applied in the most complex of lesions where a segment cannot be optimized, but acceptance of this approach requires a willingness to accept a higher complication rate in the form of restenosis and stent thrombosis. The results are consistent with earlier international data, highlighting the need for careful patient selection and integrated procedural strategies.

This is proof for the role of comorbidities such as hypertension and diabetes in the determination of stenting method and outcomes assessment; including the fact that dual stenting carries a higher rate of damage for high-risk patients

Future Recommendations: Future studies should incorporate larger cohorts with long-term follow-up data to evaluate the durability of these findings. Advanced imaging techniques (eg, IVUS and OCT) should be evaluated further to guide stenting. And, more specifically, regional differences in outcomes suggest a need for more tailored research in Pakistan to understand how PCI strategies can be refined for the local Pakistani population to get the best possible short- and long-term outcomes.

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