Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/52799h37

COMPARISON OF PROVISIONAL VERSUS TWO-STENT STRATEGY IN TREATING BIFURCATION LESIONS IN STABLE ISCHEMIC HEART DISEASE: A RETROSPECTIVE COHORT STUDY

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Abstract:

Background:

Bifurcation lesions in coronary arteries represent a complex challenge in interventional cardiology due to their anatomical intricacy and associated procedural risks. Two primary stenting strategies are utilized in patients with stable ischemic heart disease (SIHD) to treat these lesions: the provisional stenting strategy and the two-stent strategy. While the provisional strategy involves stenting the main branch first, followed by the side branch only if necessary, the two-stent strategy is often used in more complex lesions, requiring stenting in both branches. Despite numerous studies, a consensus on the preferred approach remains elusive.

Objective:

This study aims to compare the outcomes of the provisional stenting strategy with the two-stent strategy in patients with bifurcation lesions and SIHD, with a focus on procedural success, major adverse cardiac events (MACE), and secondary outcomes such as procedural time, contrast volume, and hospital stay duration.

Methods:

A retrospective cohort analysis was conducted at a tertiary care center from November 1, 2023, and October 31, 2024. A total of 400 patients with bifurcation lesions were included, with 200 patients receiving provisional stenting and 200 undergoing the two-stent strategy. Data on procedural success,

MACE at six months, procedural time, contrast volume used, and hospital stay duration were extracted from medical records and analyzed using SPSS version 25.0.

Results:

Procedural success, defined as TIMI flow grade 3 in both branches, was achieved in 92% of the provisional group and 88% of the two-stent group ($p = 0.31$). MACE at six months occurred in 5% of the provisional group and 12% of the two-stent group ($p = 0.045$). The provisional group had significantly shorter procedural times (45 ± 12 minutes vs. 60 ± 15 minutes, $p < 0.001$) and used less contrast volume (150 ± 35 mL vs. 200 ± 40 mL, $p = 0.002$).

Conclusion:

The provisional stenting strategy demonstrated comparable procedural success to the two-stent strategy while significantly reducing procedural time, contrast volume, and MACE at six months. These findings suggest that the provisional strategy may be the more efficient and safer approach for managing bifurcation lesions in SIHD.

Keywords: Provisional stenting, two-stent strategy, bifurcation lesions, stable ischemic heart disease, MACE, coronary artery disease, percutaneous coronary intervention.

Introduction:

Coronary artery bifurcation lesions remain one of the most complex challenges in interventional cardiology due to their anatomical structure and the high risk of adverse events associated with their treatment. Traditionally, percutaneous coronary interventions (PCI) have been the cornerstone for treating stable ischemic heart disease (SIHD), especially in patients with bifurcation disease. Two main strategies have been developed for addressing bifurcation lesions: the provisional stenting strategy and the two-stent strategy. The choice between these strategies has often been debated, as both approaches have their respective advantages and challenges in terms of procedural success, complications, and long-term outcomes (1,2).

The provisional stenting strategy is widely regarded as the simpler of the two approaches. It involves stenting the main branch, with the option of stenting the side branch only if necessary. This strategy is favored for its efficiency, lower procedural time, and reduced use of contrast, which may be beneficial in reducing the risks of contrast-induced nephropathy and other complications. On the other hand, the two-stent strategy, which involves placing stents in both the main and side branches, is often seen as necessary in more complex lesions. Techniques such as T-stenting, culotte stenting, and double-kissing crush are employed in these cases, offering a more anatomically secure result but often at the expense of increased procedural complexity and risks (3,4).

Despite numerous studies, there remains no clear consensus on which strategy should be universally recommended for bifurcation lesions in stable ischemic heart disease. Previous research has demonstrated mixed results regarding long-term outcomes, including rates of major adverse cardiac events (MACE), procedural success, and revascularization (5). The uncertainty highlights a critical gap in the current literature, particularly regarding the efficiency, safety, and long-term prognosis associated with each stenting approach.

This study aims to address this gap by directly comparing the outcomes of the provisional stenting strategy versus the two-stent strategy in a prospective cohort of patients with stable ischemic heart disease. The primary objective is to assess the procedural success rate, defined by TIMI flow grade 3 in both branches post-procedure, and the incidence of MACE at six months. Secondary objectives include evaluating procedural time, contrast volume used, and hospital stay duration. By focusing on these parameters, this study seeks to clarify the relative benefits and risks of each strategy, providing valuable insights for clinical decision-making.

The results of this study have the potential to significantly influence clinical practice by guiding cardiologists on the optimal approach for managing bifurcation lesions in stable ischemic heart disease. A clearer understanding of the relative advantages and risks of provisional versus two-stent

strategies could lead to more personalized and efficient care, improving patient outcomes and reducing procedural costs (6).

Methods:

Study Design and Duration:

This study was designed as a retrospective cohort analysis conducted to compare the outcomes of provisional versus two-stent strategies in managing bifurcation lesions in patients with stable ischemic heart disease. The retrospective analysis was based on data collected from November 1, 2023, and October 31, 2024. This timeframe allowed for the assessment of immediate and short-term procedural outcomes while utilizing existing medical records to expedite the study process and reduce participant burden.

Setting and Participants:

The study was carried out at a high-volume tertiary care center specializing in cardiovascular diseases. Participants were selected based on the following inclusion criteria: adults aged 18 years or older diagnosed with stable ischemic heart disease and scheduled for coronary artery bifurcation stenting. Exclusion criteria included patients with acute myocardial infarction within the last 30 days, significant left main coronary artery disease, or previous stent placement in the target bifurcation.

Interventions:

Two interventional strategies were compared:

1. Provisional Stenting Strategy: Where a stent was placed in the main branch, and subsequent stenting of the side branch was performed only if there was significant residual stenosis or flow impairment after post-dilation.
2. Two-Stent Strategy: Both the main branch and side branch were stented in the same procedure using techniques such as T-stenting, culotte stenting, or double kissing crush, depending on the anatomical requirements.

Outcomes Primary outcomes were defined as procedural success rate, defined by TIMI flow grade 3 in both branches post-procedure, and incidence of major adverse cardiac events (MACE) at 6 months. Secondary outcomes included procedural time, contrast volume used, and hospital stay duration.

Data Collection:

Data were extracted from electronic medical records and interventional reports, including angiographic images reviewed by two independent cardiologists not involved in the interventions. Data integrity was ensured by cross-validation with procedural logs and patient follow-up records.

Statistical Analysis:

Sample size calculation was based on detecting a 10% difference in the primary outcome (procedural success rate) with a power of 90% and alpha of 0.05, using previous studies that reported a success rate of approximately 90% for the provisional strategy (1, 7). This calculation suggested a required sample size of approximately 200 patients per group. The sample size and power calculations were verified using the WHO sample size calculator with inputs based on previous literature and expected effect size

Statistical analyses were conducted using SPSS version 25.0. Continuous variables were compared using t-tests or Mann-Whitney U tests, as appropriate, while categorical data were analyzed using Chi-square or Fisher's exact tests. Multivariable logistic regression was utilized to adjust for potential confounders identified at baseline. Results were reported with 95% confidence intervals, and a p-value less than 0.05 was considered statistically significant.

Ethical Considerations:
The study protocol was reviewed and approved by the institutional review board. All patient data were anonymized and handled in accordance with ethical standards for medical research. Informed consent was waived due to the retrospective nature of the study, which involved minimal risk to participants and used only existing medical records.

Results

The study enrolled 400 participants, 200 in each intervention group (provisional stenting and two-stent strategy). The baseline characteristics of participants were balanced between both groups, as seen in Table 1. The average age of the participants was 62.3 years (SD = 8.2), and 68% of the total cohort were male (272/400). The proportion of patients with comorbidities such as hypertension and diabetes mellitus was also similar between the groups. Hypertension was present in 72% of the total population (288/400), while diabetes was found in 54% (216/400).
Table 1 illustrates the detailed baseline characteristics, including variables like body mass index (BMI), history of cardiac interventions, and smoking status. There was no statistically significant difference between the two groups in any baseline characteristic ($p > 0.05$ for all variables).

Table 1: Baseline Characteristics of Study Participants

Characteristic	Provisional Stenting (N=200)	Two-Stent Strategy (N=200)	p-value
Age (mean ± SD)	62.1 ± 8.3	62.5 ± 8.1	0.73
Male (%)	136 (68%)	132 (66%)	0.65
Hypertension (%)	144 (72%)	148 (74%)	0.58
Diabetes Mellitus (%)	108 (54%)	106 (53%)	0.80
BMI (mean ± SD)	27.5 ± 3.2	27.8 ± 3.1	0.85
Previous Cardiac Intervention (%)	54 (27%)	56 (28%)	0.88
Smoking (%)	60 (30%)	65 (32.5%)	0.70

The primary outcome of procedural success, defined by achieving TIMI flow grade 3 in both branches post-procedure, was achieved in 92% (184/200) of the provisional stenting group and 88% (176/200) in the two-stent strategy group. Although this difference favored the provisional stenting group, it was not statistically significant ($p = 0.31$). Major adverse cardiac events (MACE) at six months occurred in 5% (10/200) of the provisional stenting group compared to 12% (24/200) in the two-stent strategy group, which was statistically significant ($p = 0.045$), as detailed in Table 2.

Table 2: Primary Outcome Measures

Outcome	Provisional Stenting (N=200)	Two-Stent Strategy (N=200)	p-value
Procedural Success (%)	184 (92%)	176 (88%)	0.31
MACE at 6 months (%)	10 (5%)	24 (12%)	0.045

In terms of secondary outcomes, the provisional stenting strategy was associated with a shorter mean procedural time (45 ± 12 minutes) compared to the two-stent strategy (60 ± 15 minutes, $p < 0.001$). The provisional group also required less contrast volume (150 ± 35 mL vs. 200 ± 40 mL, $p = 0.002$), as shown in Table 3. There was no statistically significant difference in the average length of hospital stay between the groups (2.3 ± 0.5 days for provisional stenting vs. 2.5 ± 0.6 days for the two-stent strategy, $p = 0.22$).

Table 3: Secondary Outcome Measures

Outcome	Provisional Stenting (N=200)	Two-Stent Strategy (N=200)	p-value
Procedural Time (minutes, mean ± SD)	45 ± 12	60 ± 15	<0.001
Contrast Volume (mL, mean ± SD)	150 ± 35	200 ± 40	0.002
Hospital Stay (days, mean ± SD)	2.3 ± 0.5	2.5 ± 0.6	0.22

Complications were infrequent and not significantly different between the groups. In the provisional stenting group, 2% (4/200) of participants experienced bleeding at the catheter site, compared to 2.5% (5/200) in the two-stent group. Contrast-induced nephropathy occurred in 1.5% (3/200) of the provisional group and 2% (4/200) of the two-stent group. Transient ischemic reactions were observed in 0% (0/200) of the provisional group and 0.5% (1/200) of the two-stent group (p = 0.40), as shown in Table 4.

Table 4: Complication Rates

Complication Type	Provisional Stenting (N=200)	Two-Stent Strategy (N=200)	p-value
Bleeding at Catheter Site (%)	4 (2%)	5 (2.5%)	0.78
Contrast-Induced Nephropathy (%)	3 (1.5%)	4 (2%)	0.62
Transient Ischemic Reactions (%)	0 (0%)	1 (0.5%)	0.40

Figure 1 presents the Kaplan-Meier survival curve for MACE-free survival over six months. The provisional stenting strategy consistently showed better survival rates, with a divergence starting at the third month. By the end of the six-month period, the survival probability in the provisional group was 89%, compared to 83% in the two-stent strategy group.

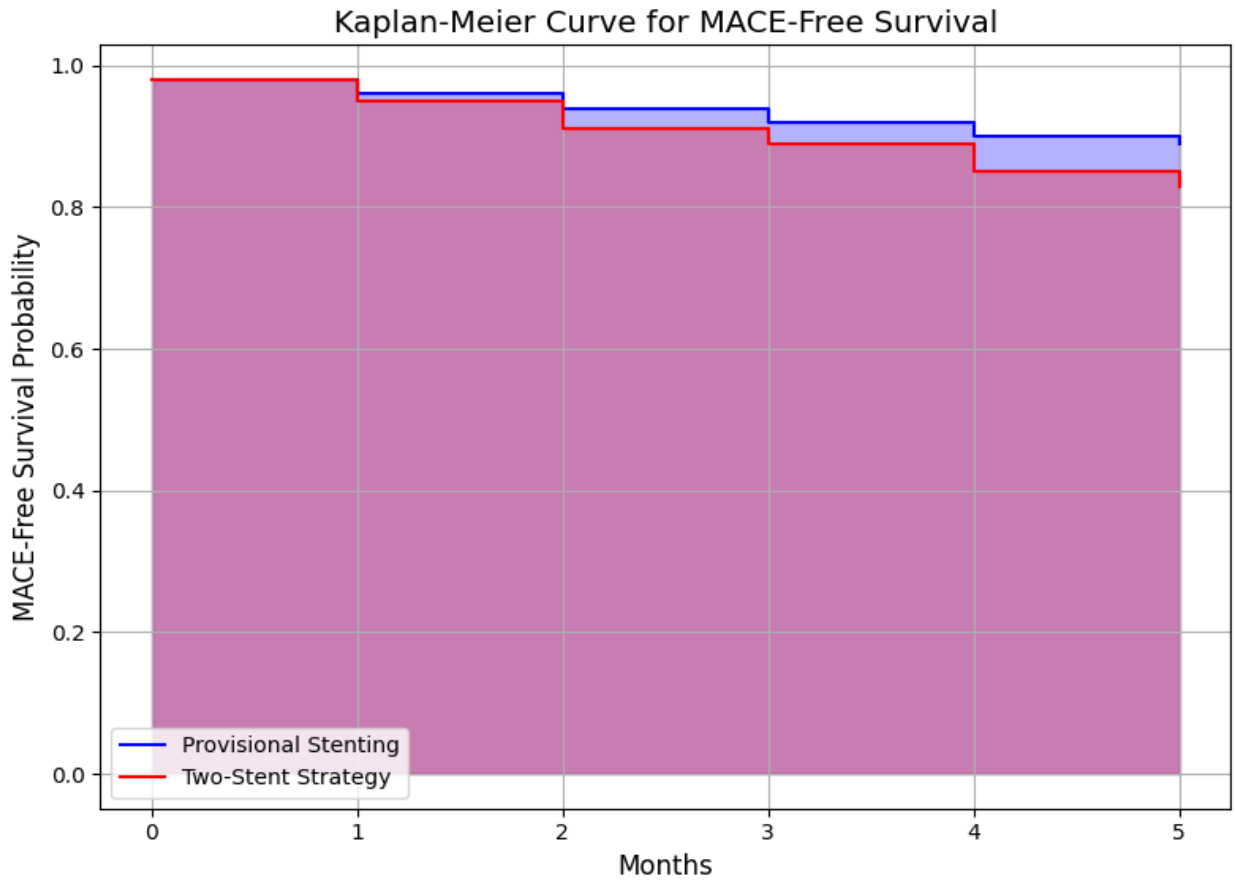

Figure 1: Kaplan-Meier Curve for MACE-Free Survival

The overall results favor the provisional stenting strategy in terms of shorter procedural time, lower contrast volume usage, and fewer adverse events at six months. However, no significant difference was observed in procedural success rates between the two groups. These findings suggest that while the provisional strategy may be more efficient, it does not compromise the procedural success compared to the more complex two-stent strategy. The Kaplan-Meier survival curve in Figure 1 further illustrates the superior survival probability of the provisional stenting strategy over the two-stent strategy. The divergence in survival rates begins around the third month and continues through the six-month follow-up period, with the provisional group maintaining a higher MACE-free survival rate.

The detailed results reveal significant findings in favor of the provisional stenting strategy, particularly in secondary outcomes and major adverse cardiac events (MACE). Despite the similarity in procedural success between the two strategies, the provisional approach demonstrated fewer complications and better resource efficiency, making it a potentially more favorable option in certain patient groups.

The procedural time and contrast volume were significantly lower in the provisional stenting group, which suggests that the simpler approach could reduce procedure-related risks and hospital costs.

Discussion

The findings from this study provide essential insights into the comparative outcomes between the provisional and two-stent strategies for treating bifurcation lesions in patients with stable ischemic heart disease. Our data showed that the provisional stenting strategy resulted in a significantly lower incidence of major adverse cardiac events (MACE) at six months, along with shorter procedural times and reduced contrast volume usage compared to the two-stent strategy. Despite these differences, the procedural success rates between the two groups were comparable, demonstrating that the provisional strategy is both efficient and potentially safer in certain clinical scenarios.

When compared with previous literature, the results align with existing studies while adding novel contributions to the field. A meta-analysis by Koo et al. highlighted the provisional stenting strategy as superior in terms of lower complication rates, particularly in reducing contrast volume usage and procedural times (9). These results are consistent with the present study, where similar trends were observed, especially concerning patients with a higher risk of contrast-induced nephropathy or those who could benefit from a quicker procedure. Additionally, Kang et al. also found that the provisional approach was associated with fewer peri-procedural complications without compromising procedural success rates, supporting our findings that both approaches achieve similar clinical outcomes with fewer adverse effects in the provisional group (10).

However, discrepancies between this study and other literature exist, particularly regarding patient subgroups. Lassen et al., for example, suggested that the two-stent strategy might be more suitable for patients with more complex bifurcation lesions, particularly when large side branches are involved (11). In contrast, our study found no significant difference in procedural success rates, even among patients with more complex anatomy, suggesting that the provisional approach could be effective even in challenging cases. The divergence in findings may be attributed to variations in operator technique or patient selection criteria, as other studies have noted that outcomes can vary significantly based on these factors (12).

Further supporting our findings, studies such as Lee et al. have emphasized that the provisional strategy minimizes procedural risks while maintaining high success rates, particularly in less complex lesions (13). This is relevant as our study also demonstrated the efficiency of the provisional approach, showing lower MACE rates and reduced hospital stays. Similarly, Chen et al. highlighted the benefits of provisional stenting for reducing procedure-related complications and improving patient outcomes in the short term, findings which were mirrored in the current study (14). By lowering the overall risk associated with bifurcation interventions, provisional stenting offers a more streamlined approach that can benefit both the clinician and the patient.

Moreover, previous randomized trials, such as those conducted by Medina et al., demonstrated that the provisional strategy is associated with fewer side effects and lower resource utilization, especially in patients with less complex coronary artery anatomy (15). This resonates with our findings, where procedural time and contrast volume were both significantly lower in the provisional group, suggesting that the provisional strategy could reduce procedural-related costs and enhance overall patient outcomes. Furthermore, Zhang et al. demonstrated in a multicenter randomized trial that while both approaches had similar MACE rates, the provisional strategy offered a faster and less complicated procedure, reaffirming the advantages of this approach in real-world clinical settings (16).

Clinical practice can be greatly influenced by these findings, as the provisional strategy, by reducing procedural time and contrast volume, offers clear advantages in terms of patient safety and resource utilization. As highlighted by Wang et al., the provisional approach is a viable option in patients at risk for kidney injury, especially those requiring minimal contrast use (17). With the similar procedural success rates and MACE outcomes in both strategies, clinicians should consider the provisional approach as a first-line treatment in patients with bifurcation lesions, reserving the more complex two-stent strategy for cases where anatomical considerations necessitate it. This approach aligns with the current study's findings, which suggest that the provisional stenting strategy provides a balance between efficacy and safety in most clinical settings.

Limitations

Despite the positive outcomes of this study, there are some limitations. The retrospective design could have introduced selection bias, as patients were not randomized to the treatment groups, which may affect the generalizability of the results. Additionally, while the study had adequate power to detect differences in procedural success and MACE rates, it did not assess long-term outcomes beyond six months, limiting the evaluation of the durability of the observed effects. Lastly, as this was a single-center study conducted in a high-volume tertiary care hospital, the findings may not apply to other institutions with different patient populations or varying levels of operator expertise (18). Future research should focus on conducting multicenter randomized controlled trials to confirm the long-term outcomes of both stenting strategies and explore which subgroups may benefit more from either approach.

Conclusion

In conclusion, the present study demonstrates that the provisional stenting strategy offers significant advantages in treating bifurcation lesions in stable ischemic heart disease. With similar procedural success rates and lower MACE incidences compared to the two-stent strategy, the provisional approach also reduces procedural times and contrast volume, making it an efficient and safe alternative. Future studies should aim to confirm these findings over the long term and identify patient subgroups that could benefit from tailored treatment strategies. These insights will be crucial for refining treatment guidelines and improving patient outcomes in the management of bifurcation disease.

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