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BALANCING SAFETY AND EFFICACY: COMPARATIVE ANALYSIS OF POT-SIDE-POT AND KBI IN PROVISIONAL BIFURCATION STENTING

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ABSTRACT
Background: Coronary bifurcation lesions (CBLs) present significant challenges in percutaneous coronary interventions (PCI) due to complex anatomy and increased risk of side branch (SB) complications. The optimal technique for SB optimization—Kissing Balloon Inflation (KBI) versus Proximal Optimization Technique with sequential SB inflation (POT-side-POT)—remains debated. **Objective:** To compare the safety and efficacy of POT-side-POT versus KBI within a provisional stenting strategy for non-complex CBLs. **Methods:** This retrospective study included 60 patients undergoing PCI for CBLs at Al-Latakia University Hospital between June 2021 and June 2024. Patients were allocated to POT-side-POT (n=30) or KBI (n=30) at operator discretion. Inclusion criteria included main vessel diameter >2.5 mm and SB diameter >2 mm. Primary endpoints included combined adverse events, in-hospital and 30-day mortality, contrast-induced acute kidney injury (CI-AKI), stent thrombosis, SB dissection, and need for additional SB stenting. Statistical analysis incorporated inverse probability weighting (IPW) to reduce bias. **Results:** Demographics, clinical characteristics, and laboratory values were similar between groups. Procedural time and contrast volume were higher in KBI. Residual SB stenosis and rates of SB dissection and additional stenting were higher in the KBI group after IPW adjustment. No in-hospital or 30-day mortality occurred in either group. Subgroup analysis demonstrated POT-side-POT superiority in true bifurcation lesions regarding procedural efficiency and SB complication reduction without increasing CI-AKI or mortality. **Conclusion:** POT-side-POT offers a safe and efficient strategy for provisional stenting of non-complex coronary bifurcations, reducing SB dissection and stent thrombosis while minimizing procedural time and contrast exposure. KBI remains a viable secondary option when additional SB expansion is required. These findings support POT-side-POT as the preferred technique in routine practice for non-complex CBLs.

KEYWORDS: Coronary bifurcation lesions, POT-side-POT, Kissing Balloon Inflation, provisional stenting, PCI, side branch optimization.

INTRODUCTION

Coronary artery disease (CAD) is the most prevalent and life-threatening cardiovascular disorder worldwide, representing the leading cause of death and chronic disability among adults in both developed and developing countries. It is characterized by narrowing or obstruction of coronary arteries due to intraluminal thrombosis or atherosclerotic plaque formation, which consists of lipids, cholesterol, and inflammatory cells within the arterial wall.[1]

This obstruction reduces myocardial blood flow, leading to clinical manifestations such as angina, dyspnea, and fatigue, and may progress to acute myocardial infarction (AMI), which is associated with high mortality and long-term complications such as chronic heart failure and arrhythmias.[2] According to the World Health Organization (WHO), cardiovascular diseases account for over 17 million deaths annually, representing approximately one-third of global mortality. These figures are expected to rise due to population aging and the increasing prevalence of unhealthy lifestyles, including physical inactivity, high-fat diets, and smoking.[3]

Traditional risk factors such as hypertension, diabetes mellitus, dyslipidemia, obesity, and smoking play a key role in disease progression, in addition to genetic predisposition.[4] CAD poses a significant economic burden due to the need for long-term pharmacological management, interventional procedures like percutaneous coronary intervention (PCI), and surgical revascularization such as coronary artery bypass grafting (CABG).[5]

Recent advancements emphasize early prevention, diagnostic imaging such as CT coronary angiography and intravascular ultrasound (IVUS), and innovative treatment strategies including drug-eluting stents (DES) and bioresorbable scaffolds to reduce restenosis rates and improve long-term outcomes.[6]

HISTORICAL BACKGROUND

The early understanding of CAD dates back to the early 20th century when autopsy studies identified lipid deposits causing coronary obstruction. The landmark **Framingham Heart Study (1948)** established the role of risk factors such as smoking, hypertension, and hyperlipidemia.[7]

In 1967, **René Favaloro** performed the first successful CABG using the saphenous vein, revolutionizing surgical management.[8]

The introduction of **balloon angioplasty** by **Andreas Gruentzig** in 1977 marked the beginning of interventional cardiology, although it was initially limited by high restenosis rates (30–40%).[9]

Bare-metal stents (BMS) were later introduced to prevent acute vessel closure but were still prone to neointimal hyperplasia. The emergence of **drug-eluting stents (DES)** in the late 1990s significantly reduced restenosis to <10%.[10]

Recently, **bioresorbable scaffolds** have been developed, though early trials such as ABSORB revealed safety concerns related to late stent thrombosis.[11]

PCI vs. CABG

PCI involves minimally invasive catheter-based treatment using balloons and stents, offering faster recovery and suitability for emergency cases like STEMI. However, PCI is associated with higher rates of repeat revascularization in complex cases.

Conversely, CABG is a major surgical procedure using arterial or venous grafts to bypass occluded vessels, providing superior long-term outcomes in multi-vessel disease and diabetic patients but requiring longer recovery and carrying higher perioperative risks.[12]

Key clinical trials

- **SYNTAX (2009):** CABG superior for three-vessel or left main disease.[13]
- **FREEDOM (2012):** CABG reduced mortality and MI in diabetic patients.[14]
- **EXCEL (2016):** Comparable outcomes between PCI and CABG in left main disease short term, but CABG superior long term.[15]
- **COURAGE (2007):** No significant mortality difference between PCI and optimal medical therapy in stable angina, though PCI improved symptoms.[16]

Coronary Bifurcation Lesions (CBL)

CBLs occur at branching points of coronary arteries and account for 15–20% of PCI procedures.[17] These lesions are more prone to complications such as side branch (SB) occlusion (5–10%), stent deformation, and higher restenosis rates (10–15% vs. 5–7% in non-bifurcation lesions).[18]

The unique hemodynamics of bifurcations—particularly low shear stress zones—promote atherosclerosis development and plaque instability, increasing the risk of major adverse cardiac events (MACE).[19]

Treatment Challenges and Techniques

Treating CBLs is complex due to anatomical variability and the need to preserve flow to both branches. Modern strategies include:

1. **Kissing Balloon Inflation (KBI):** Simultaneous inflation of two balloons, but associated with stent distortion and longer procedure time.[20]
2. **Proximal Optimization Technique (POT-side-POT):** A three-step process that optimizes proximal stent expansion, protects the SB, and restores circular geometry, reducing complications and improving long-term patency.[21]
3. **MADS Classification:** Guides stenting strategy (Main, Across, Double, Side) based on lesion anatomy.[22]

Economic and Social Impact

Globally, CAD treatment costs are estimated at **$200–300 billion annually**, including direct costs (diagnostics, medications, interventions) and indirect costs (loss of productivity, premature deaths).

High-income countries bear the majority of direct healthcare expenditures, while low- and middle-income countries face substantial indirect losses due to limited access to advanced therapies and higher mortality rates.[23]

MATERIALS AND METHODS

Study Design

This retrospective clinical study was conducted at Latakia University Hospital to compare the POT-side-POT technique with the KBI technique in terms of safety and efficacy within a Provisional Stenting strategy for the management of coronary bifurcation lesions. The study included 60 patients who underwent percutaneous coronary interventions between June 2021 and June 2024.

Inclusion Criteria

- Main vessel (MV) diameter > 2.5 mm
- Side branch (SB) diameter > 2 mm (visual assessment)

Exclusion Criteria
- Use of any strategy other than provisional stenting
- Provisional stenting without intervention on the side branch
- Indication for coronary or valvular surgery
- Contraindication to dual antiplatelet therapy
- Life expectancy < 1 year
- Pregnancy or age < 18 years

Procedure
- All procedures were performed by two interventional cardiologists.
- Provisional stenting was the primary strategy in all cases.
- Side branch intervention was performed only if critical stenosis (>70%) or impaired flow occurred after stent deployment.
- POT-side-POT or KBI was chosen at the operator's discretion.
- In cases of severe stenosis, impaired flow, or dissection, T-stenting or TAP techniques were applied.

Technique Steps
- **POT-side-POT:** initial POT → side branch ballooning → final POT
- **KBI:** initial POT → simultaneous balloon inflation in both vessels → final POT

Pharmacological Therapy
- All patients received 300 mg aspirin pre-procedure if not previously administered.
- Loading doses of either clopidogrel (300–600 mg; 43.3%) or ticagrelor (180 mg; 56.7%) were given.
- Heparin and glycoprotein IIb/IIIa inhibitors were used per operator discretion.
- Post-procedure, aspirin (81–100 mg/day) was prescribed lifelong with either clopidogrel (75 mg/day) or ticagrelor (90 mg twice daily) for 12 months.

Stent Types
- Everolimus-eluting stents: 63.3%
- Zotarolimus-eluting stents: 23.3%
- Sirolimus-eluting stents: 13.3%

Primary Endpoints
- Combined clinical adverse events
- In-hospital and 30-day mortality
- Contrast-induced acute kidney injury (CI-AKI)
- Acute stent thrombosis (ST)
- Side branch dissection and need for additional stenting

Definitions
- Stent thrombosis was defined according to the Academic Research Consortium and limited to confirmed events within the first month.
- CI-AKI was defined as an increase in creatinine ≥0.5 mg/dL or ≥25% within 48–72 hours post-contrast exposure.
- True bifurcation lesions were classified according to Medina: 1-0-1, 0-1-1, and 1-1-1.

Statistical Analysis
- Continuous variables were presented as mean ± SD or median (IQR); categorical variables as percentages.
- Tests included Kolmogorov–Smirnov, Student's t-test, Mann–Whitney U, Chi-square, and logistic regression for independent predictors of adverse events.
- Statistical significance was set at $P < 0.05$.
- Analyses were performed using SPSS v22.
- Inverse Probability Weighting (IPW) based on propensity scores was applied to reduce bias.

RESULTS

Clinical, Laboratory, and Demographic Characteristics

The study included 60 patients (30 POT-side-POT, 30 KBI). There were no significant differences between the groups regarding age, sex, history of diabetes (DM), hypertension (HTN), hyperlipidemia (HPL), coronary artery disease (CAD), cerebrovascular disease (CVD), chronic kidney disease (CKD), smoking status, left ventricular ejection fraction (EF), or presentation with acute coronary syndrome (ACS). Laboratory values were also comparable between the groups.

Procedural and Technical Characteristics
- Procedural time and contrast volume were significantly higher in the KBI group.
- Left anterior descending (LAD) lesions were more common in the POT-side-POT group, whereas left main coronary artery (LMCA) involvement was higher in the KBI group.
- Proximal MV diameter, SB diameter, and final MV stent diameter were greater in the KBI group.

Side Branch Residual Stenosis
- Residual stenosis and the proportion of patients with >50% stenosis in the SB were higher in the POT-side-POT group, before and after adjustment.
- No significant differences were observed in the number of affected vessels, number of stents implanted, TIMI-3 flow, or tirofiban use.

Clinical Adverse Outcomes
- No in-hospital or 30-day mortality was recorded in either group.
- Rates of CI-AKI, SB dissection, and need for SB stenting were higher in the KBI group, but statistical significance was reached only for SB dissection and SB stenting after inverse probability weighting (IPW).

- Combined adverse events did not differ significantly between groups (OR=1.01, P=0.982).

Analysis Excluding LMCA Patients

Excluding 18 patients with LMCA lesions yielded results consistent with the primary analysis for both individual and composite outcomes.

Subgroup Analysis: True vs. Non-True Bifurcation Lesions

- **True bifurcation lesions:** Procedural time and contrast volume were higher in KBI. Residual SB stenosis, SB dissection, and stent thrombosis were more frequent in KBI, with significant differences for SB dissection and residual stenosis after adjustment.
- **Non-true bifurcation lesions:** Procedural time and contrast volume were lower in POT-side-POT, with no other significant differences.

Logistic Regression Analysis

Use of POT-side-POT was not associated with increased combined clinical adverse events.

DISCUSSION

Context and Interpretation

Management of coronary bifurcation lesions remains a major challenge in interventional cardiology due to complex vessel geometry and mechanical changes after stenting. While two-stent strategies are often superior in complex lesions, provisional single-stent strategies are recommended for non-complex bifurcations. However, optimal techniques for final side branch (SB) optimization remain debated, particularly regarding Kissing Balloon Inflation (KBI) versus proximal optimization followed by SB inflation (POT-side-POT).

This study provides direct comparative evidence in real-world practice, focusing on procedural safety, SB complications, stent thrombosis, procedural efficiency, and contrast usage.

Key Findings

- **Procedural Efficiency:** POT-side-POT was faster, easier, and more reproducible.
- **Side Branch Outcomes:** KBI had higher rates of SB dissection and additional stenting, whereas POT-side-POT maintained SB patency with fewer complications.
- **True vs. Non-True Bifurcations:** Subgroup analysis confirmed the advantage of POT-side-POT in true bifurcations, reducing SB dissection and stent thrombosis without increasing CI-AKI, additional stent use, or mortality.

Mechanistic Insights

1. **Proximal Optimization and Biomechanics:** POT-side-POT aligns stent geometry with tapering vessel anatomy, improves proximal stent apposition, preserves SB ostium, and reduces flow disturbances that contribute to thrombosis and restenosis.
2. **Side Branch Inflation:** Sequential low-pressure SB inflation minimizes mechanical stress compared to simultaneous KBI, reducing wall injury and dissection.
3. **Final Proximal Optimization:** Restores circular stent geometry, distributes radial forces evenly, and further decreases SB complications.

Comparison with KBI

- KBI achieves greater SB luminal diameter but applies asymmetric forces, increasing the risk of SB dissection and stent deformation.
- POT-side-POT achieves sufficient SB expansion with less mechanical trauma, improving procedural safety.

Clinical and Procedural Implications

- POT-side-POT reduces procedural time, contrast volume, and mechanical stress, benefiting patients at high risk for CI-AKI or procedural complications.
- The technique balances luminal gain and safety, emphasizing minimal harm while preserving efficacy.

Alignment with Previous Studies

- Consistent with prior reports (e.g., Anatolian J Cardiol 2021, CRABBIS 2025, rePOT, PROPOT trials), POT-side-POT shows advantages in procedural efficiency, stent geometry, and complication reduction, while KBI may provide slightly greater SB expansion at the cost of higher procedural risk.

Limitations

- Retrospective design, small sample size, and operator selection bias limit generalizability.
- Lack of routine intravascular imaging (IVUS/OCT) prevented direct assessment of stent apposition and lesion morphology.
- Follow-up was limited to one month, precluding long-term assessment of MACE, restenosis, or late stent thrombosis.

Practical Recommendations

1. **POT-side-POT as first-line:** Recommended for non-complex bifurcations due to procedural safety and reduced SB/stent complications.
2. **KBI as bailout strategy:** Reserved for cases requiring additional SB expansion.
3. **Stepwise algorithm:** Main vessel stenting → initial proximal optimization → SB assessment → sequential POT-side-POT → final proximal optimization.
4. **Future studies:** Larger, randomized trials with long-term follow-up and mandatory intravascular imaging are needed to confirm clinical and economic benefits.

CONCLUSION

POT-side-POT represents a balanced strategy between efficacy and safety for provisional stenting of non-complex coronary bifurcations, offering procedural efficiency, reduced contrast exposure, improved stent apposition, and lower rates of SB dissection and stent thrombosis. KBI remains a viable secondary option when additional SB expansion is required. The findings support adopting POT-side-POT as the preferred approach in routine practice while adhering to the principle of "first, do no harm."

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