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Case Report

Provisional Technique for Bifurcation Left Main In-Stent Restenosis Lesion: A Case Report

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ABSTRACT

Background: Percutaneous coronary intervention for bifurcation lesions remains challenging because of its complexity and the lack of trials to guide decision-making. It also comes with several debatable issues, including the requirement for kissing balloon inflation as the post-dilation produces.
Case Illustration: A 64-year-old male with some coronary risk factors of hypertension, passive smoker, and family history of CAD presented with recurring exertional chest pain for the last 4 months. He was hospitalized to undergo DCA-Adhoc after the ECG stress test revealed a positive result. The coronary angiography revealed a 95% ISR in the osteal LAD and 20% ISR of the proximal LCx. Since the patient refused to undergo coronary bypass surgery, the team decided to perform catheter intervention to the LM bifurcation of LAD-LCx. The procedure begins with the insertion of IABP through the access of the left femoral artery. We performed a provisional approach with the main vessel stenting of LM-LAD. At the end of the procedure, we performed simultaneous kissing balloon inflation of LAD-LCx followed by POT in LM stent as the post-dilation produces.
Discussion: When considering intervention on a bifurcation lesion, there are two general strategies i.e the more conservative or provisional technique that intent to only use one stent and the two-stent approach. The provisional technique is considered to offer advantages in terms of reducing procedure complexity, reducing fluoroscopic time, requiring less contrast volume, and reducing resource (stent) use compared by 2 stent strategy.
Conclusion: Coronary bifurcation lesions are fairly frequent, and their management is associated with an increased risk of MACE, increased complexity, and prolonged treatment times.

1. Introduction

Coronary artery intervention for bifurcation lesions continues to be an issue of contention. Regardless of traditional cardiovascular risk factors, high turbulence and shear stress leads to a high prevalence of stenosis in the bifurcation of about 10-15% from all percutaneous coronary intervention (PCI). The heterogeneity of bifurcation lesions anatomy and the paucity of large randomized trials make decision making need certain consideration.[20] As the clinical outcomes following PCI have notably improved due to improvements in drug-eluting stent (DES) technologies, there still several debatable issues including the techniques to approach the bifurcation lesion. The requirement for post-dilatation was one issue that has been making PCI for bifurcation lesions remains challenging.

Even while provisional procedure can treat most patients with bifurcation lesions, a small percentage of them have different bifurcation architecture, making provisional technique risky in the event of side branch occlusion.[5]

The complexity of performing PCI in coronary bifurcation lesions is simply due to the operator efforts to maintain optimal patency of the side branch (SB) while optimally treating the main vessel (MV). From several trials there is no disadvantage to a provisional approach in terms of clinical outcomes. This case report tried to explain the provisional stenting approach in patients with LM bifurcation lesion.

2. Case Illustration

A 64-year-old male was diagnosed with coronary artery disease (CAD) in 2013. Hypertension, being a passive smoker, and having a family history of CAD were both risk factors for atherosclerosis in this patient. In the last three years, the patient has undergone PCI treatments. It is also known that patients experience incidents of in-stent restenosis (ISR) despite having good medication adherence and having followed a healthy lifestyle. In May 2018, he undergo PCI in LM bifurcation since the CAG revealed 70% distal LM stenosis, 90% ostial

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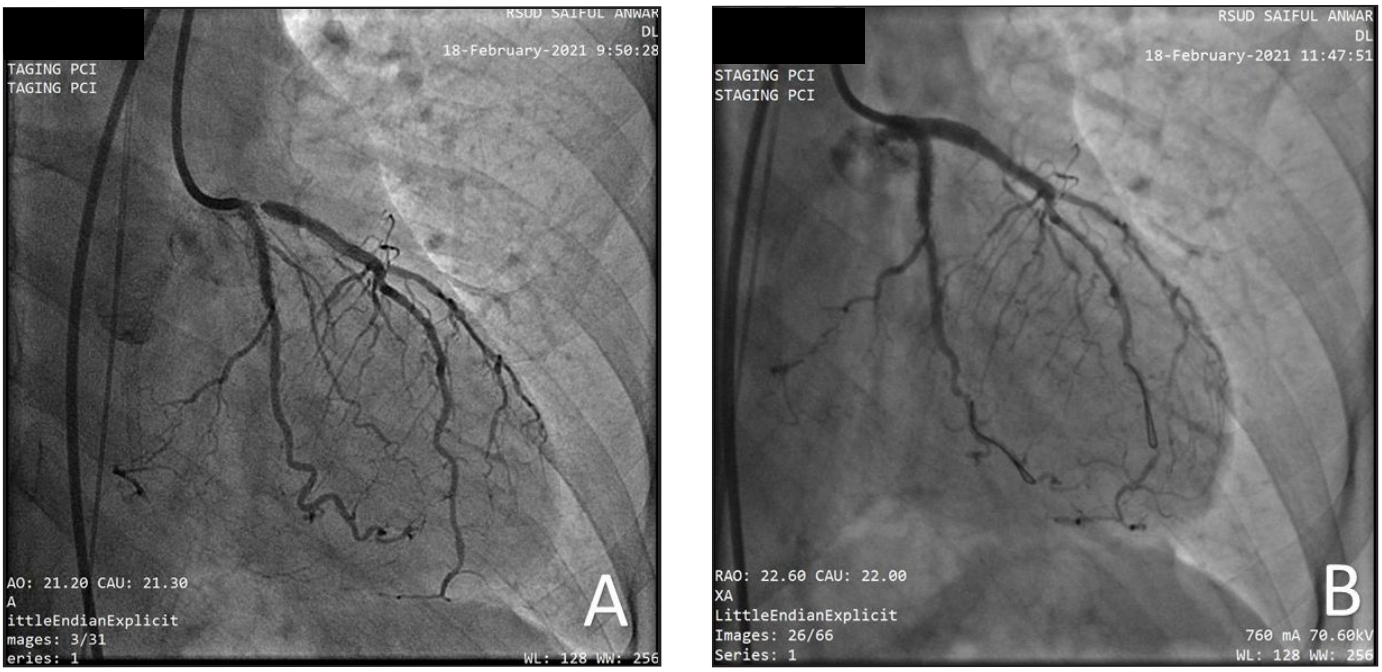

Figure 1. A. The diagnostic angiography revealed an ISR of 95% in the osteal LAD and an ISR of 20% in the proximal LCx (RAO 20, CAU 20 view); B. Successful provisional stenting with final KBI shows remarkable result of bifurcational intervention.

LAD stenosis, and 80% proximal LCx ISR. There was a complex procedure using 2 stents strategy of culotte technique with implantation of DES in LM-LAD and LM-LCx.

Patients receive 1x100mg CardioAspirin, 1x40mg Atorvastatin, 1x10mg Ramipril, 1x2.5mg bisoprolol, and 3x5mg ISDN in cardiac outpatient clinic. The patient reported that he already had diminished symptoms of chest pain since receiving this treatment. He also was able to carry out his everyday household chores without difficulties.

Unfortunately since last 4 months, the patient has had complaints of angina triggered by moderate activity. Angina is felt more frequently with lesser triggers despite it still relieved by rest. The patient has never experienced an episode of acute coronary syndrome or hospitalization due to other causes of an acute cardiac event. The ECG stress test was came with the result a positive ischemic response. We saw a horizontal ST depression in leads II, III, aVF, and episodes of PVC trigeminy. The patient then underwent coronary angiography and obtained an ISR of 95% in the osteal LAD and an ISR of 20% in the proximal LCx. The patient was planned to undergo a PCI procedure on the LM bifurcation with several preparations to achieve optimal results. Action will be taken with IABP backups followed by provisional technique approach.

Pre-procedural preparation showed that the patient was hemodynamically stable. He was fully alert, the BP was 125/65 mmHg, HR 69 x / min, RR 20 x / min, and the peripheral oxygen saturation was 96% on room air. The procedure begins with the insertion of the IABP through the access of the left femoral artery. The 40 cc IABP balloon was inserted and set 1: 1, with an ECG trigger.

We used right femoral artery access using a 7F sheath with a JL 3.5 6F and JR 3.5 6F diagnostic catheter. Coronary artery diagnostic revealed a CAD Three Vessel Disease + LM disease with ISR 95% in osteal LAD, ISR 100% proximal to RCA, ISR 20% proximal to LCx. The target lesion was the ostial LAD. The procedure started by administration of a 5000 IU IV heparin bolus and continued by intravenous infusion 2000 IU / hour. The guiding catheter (GC) BL 3.5 7F was engaged in ostial LMCA. We delivered the first Guiding Wire (GW) Runthrough NS Floppy to distal LAD. Then followed by the Asahi Sion GW as a protection wire to the distal LCx. The 3.0 x 10 mm NC Saphire II balloon was entered through the GW Runthrough NS Floppy towards the LM-proximal LAD. We inflated the Balloon several times with a maximum pressure of 14 atm for 9 seconds. Pull out the balloon then we performed a sine-angiographic evaluation.

The Stent Combo Plus 4.0x18 mm was delivered through the first GW towards LM - proximal LAD. Inflate the stent with a pressure of 9 atm for 8 seconds. Post dilation at the distal to the stent was performed with a pressure of 10 atm for 7 seconds. Proximal optimalization was performed with a pressure of 12 atm for 6 seconds precisely at the proximal of the carina. Asahi Sion GW became jailed wire afterwards. Pull out balloon ex-stent then cine-angiographic evaluation performed. We deliver the third GW, by recrossing to distal LCx using GW Runthrough Hypercoat, but failed. We directed the GW Runthrough Hypercoat to distal LAD followed by pulling the GW Runthrough NS Floppy from the distal LAD then directed towards the distal LCx through the strout stent at the LM-proximal LAD. GW Runthrough NS Floppy made it to distal LCx, followed by delivering the NC Sapphire II Balloon 3.5x15 mm towards LM - proximal LCx. Inflate the balloon several times with a maximum pressure of 12 atm for 8 seconds. The Balloon NC Sapphire II 4.5x12 mm entered via GW Runtrough Hypercoat towards LM - proximal LAD. We inflate the NC Saphhire 3.5x12 mm balloon in LM - proximal LCx several times with maximum pressure of 20 atm for 10 seconds. The NC Saphhire balloon 4.5x12 mm was inflated at LM - proximal LAD with a maximum pressure of 14 atm for 8 seconds. We repeated the inflation of the NC Saphhire 3.5x12 mm balloon at LM - LCx several times with a maximum pressure of 20 atm for 5 seconds.

Simultaneous double kissing of balloons was performed at the LM - LAD and LM-LCx. We inflate both NC balloons simultaneously

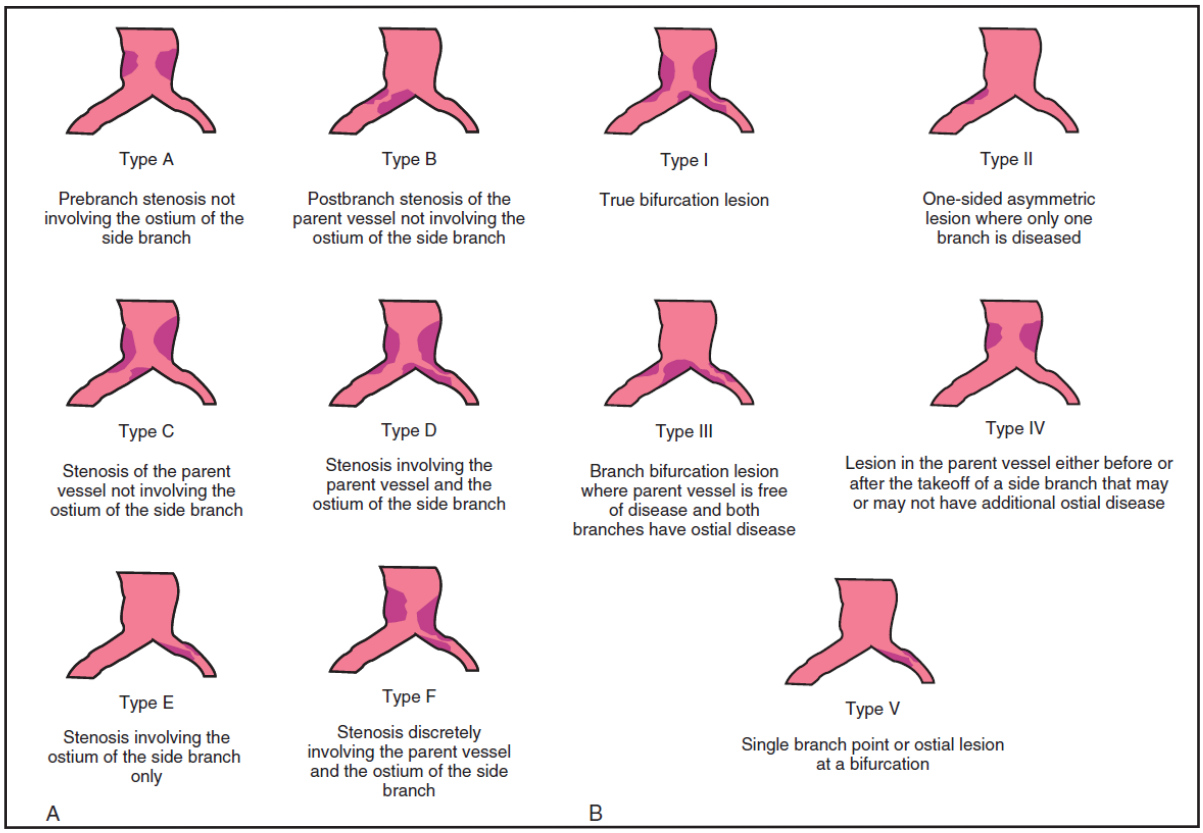

Figure 2. Various classifications of bifurcations according to plaque distribution. A, Duke. B, Sanborn.[4]

several times with a maximum pressure of 14 atm in LM-LAD and 20 atm in LM-LCx for 8 seconds. Final kissing balloon was performed with a pressure of 14 atm in LM-LAD and 20 atm in LM-LCx for 7 seconds. Finally, the NC Saphhire 4.5x12 mm balloon was inflated in LM - LAD carina several times with maximum pressure of 26 for 6 seconds, followed by proximal optimization with a pressure of 26 atm for 7 seconds. Pull out both balloons, followed by sine-angiography evaluation. We sought a TIMI Flow 3 without residual stenosis (figure 1). The procedure is complete, then the patient was transferred to the recovery room. For further observation in the CVCU room, we still maintain the IABP support for the next 24 hours. During the observation there were no complications, the IABP was weaned and removed on the second day of treatment. The patient was discharged on day 5 of treatment, with continued therapy and control as an outpatient clinic.

The follow-up, which was carried out 2 months after the procedure, found that the patient had returned complaint-free and was able to carry out his daily activities properly. The patient continues to live a healthy lifestyle and adheres to the routine therapy given, namely 1x80mg aspilet, 2x90mg brilinta, 1x40mg atorvastatin, 1x10mg Ramipril, 1x5mg bisoprolol, and ISDN 3x5mg.

3. Discusion

A coronary bifurcation lesion is a lesion that occurs at or adjacent to a significant division of a major epicardial coronary artery.[3] Functionally, coronary bifurcation lesions are defined as angiographically significant lesions which involve a branch point or the immediate vicinity of a branch point between two coronary arteries larger than 2 mm in diameter. Consensus societies have simplified this definition to “a coronary artery narrowing adjacent to and/or involving a significant side branch.” The larger of the two vessels (either in size or territory supplied) is referred to as the parent or main branch, while the smaller vessel is designated as the side branch.

Various techniques involving complex angioplasty plus one or more stents can be employed for treating bifurcation lesions, making the development of a standardized approach difficult. High complexity and lesion variability, high rates of restenosis and thrombosis, and a myriad of approaches to treating bifurcation lesions have left the field with many unanswered questions. Small trials, case series, and registries have reported on specialized techniques including dedicated bifurcation-specific stents, but for now interventional cardiologists are left choosing an approach based on personal preference and anecdotal experience rather than rigorous randomized data.

On the LM bifurcation lesion, our patient was approached using the provisional technique. It is expected that by preparing mechanical circulatory support with IABP before the high risk PCI procedure, the outcome would be optimal, regarding the complexity of the patient's lesion. There was an unprotected left coronary artery in this patient, due to the existing 100% ISR in the RCA. Previous studies have proven the benefits of IABP in complex PCI procedures, it is in line with the procedures performed in these patients.[13,14]

Patients with ISR, as our patient, commonly present with a current presentation of recurrent angina. Following the 2018 ESC guidelines regarding myocardial revascularization, repeat PCI is a procedure that should be performed in patients with ISR with clinical presentation of progressive or recurrent angina. DES are shown to be superior compared with balloon angioplasty, BMS implantation or brachytherapy. New-generation DES (everolimus, zotarolimus) are recommended as 1st line treatment of ISR of BMS/DES.[14]

Although DES significantly reduces the incidence of ISR, the multifactorial etiology of ISR still makes ISR a challenge in the world of interventional cardiology.[10]

3.1 Classification of Bifurcation Lession

Currently, six different classifications of bifurcation lesions have been defined. The most important distinction to make is to divide bifurcation lesions into true bifurcations, in which the main branch (MB) and the side branch (SB) are both significantly narrowed (>50% diameter stenosis), and non-true bifurcations, which include all the other lesions that involve a bifurcation.

In routine practice, the Medina classification is still the most simple and widely used approach to classify distribution of atherosclerotic plaque at a bifurcation site.

With the Medina classification system, lesions can be easily characterized using a three-number designation system where the first number represents the presence or absence of disease in the proximal main branch, the second number represents the presence or absence of disease in the distal main branch, and the third number represents the presence or absence of disease in the side branch. For each of the three locations, a zero (0) is designated for less than 50 % stenosis, and a one (1) is designated for a greater than or equal to a 50 % stenosis. Each of the three numbers is then listed in order separated by a comma to create a classification schema for the lesion.

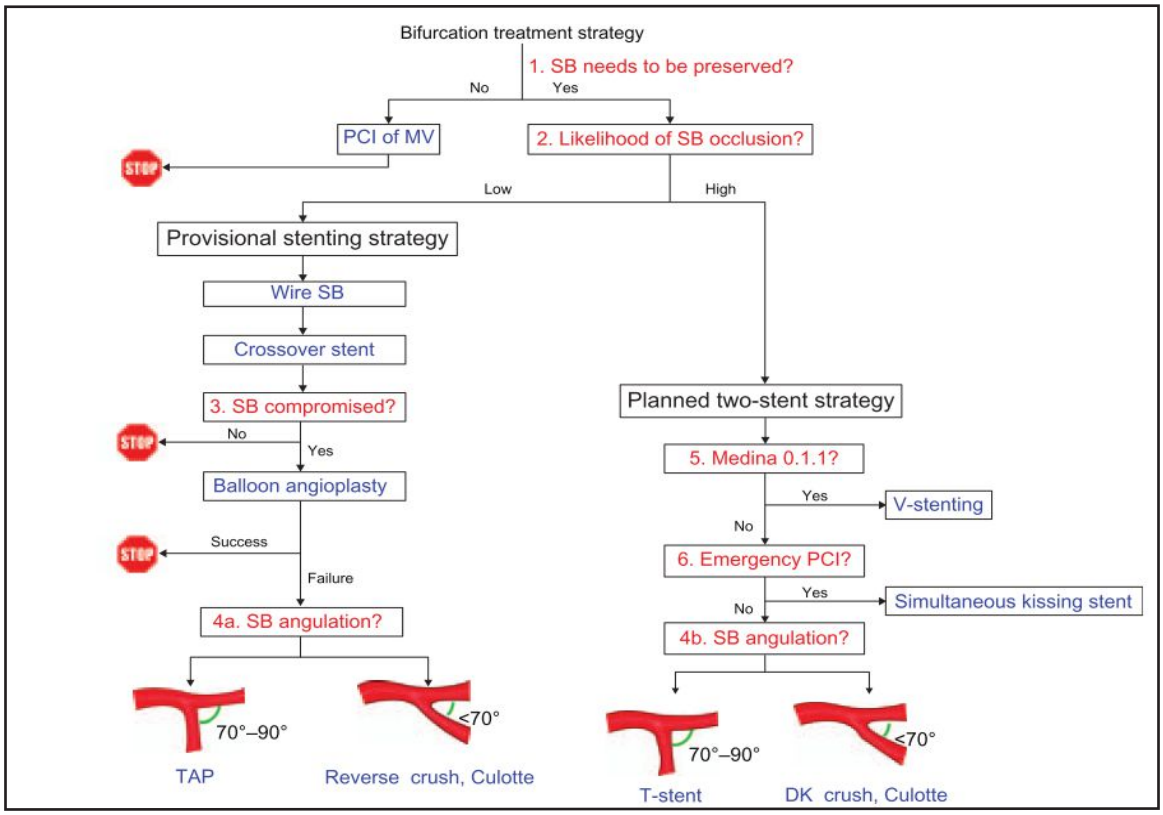

Figure 3. Algorithm for Bifurcation Lesion (modified from Rai et al., 2015).

In practice, the Medina system is both easy to calculate and has been shown to have excellent inter- observer agreement for classification of lesion subtypes. Despite its strengths, the Medina system has several weaknesses, including that it does not account for the side branch angle or side branch size, two factors which may impact an interventional approach and the number of stents which are utilized. Additionally, it does not quantify the percent stenosis, but uses a binary "present or not present" approach, which can lead to the same classification for a 50 % stenosis as a 99 % stenosis in a main vessel or side branch, despite the difference in interventional risks which may be present with these disparate lesions. Nevertheless, the trade-off in ease of use may be justified, especially when considering that complex lesion subsets are easily identified with the Medina classification despite its simplistic formulation.

3.2 Current Treatment Options for Bifurcation Lesions

When considering intervention on a bifurcation lesion, there are two general tactics that can be employed. The more conservative, or provisional, approach involves the intent to only use one stent to treat the stenosis (typically the main branch is stented).

Frequently, balloon angioplasty is used to "bail-out" the side branch using a KBI, which involves simultaneous inflation of two balloons in the coronary which are touching ("kissing"), with one in the main branch and one in the side branch. The operator can elect to use a second stent, but usually this would only be performed if there was significant compromise to the side branch (residual high-grade stenosis, dissection, or reduced distal flow) which could not be rectified with additional balloon angioplasty. The goal of the provisional approach is to minimize the complexity of the procedure, reduce the fluoroscopic time and contrast volume required, and reduce the resource (stent) utilization. In contradistinction to a provisional approach, a dedicated approach implies the planned use of two stents, one in the main branch and one in the side branch.[12,20] An algorithm may simplified decision making for bifurcation lesion as seen in figure 3.[11]

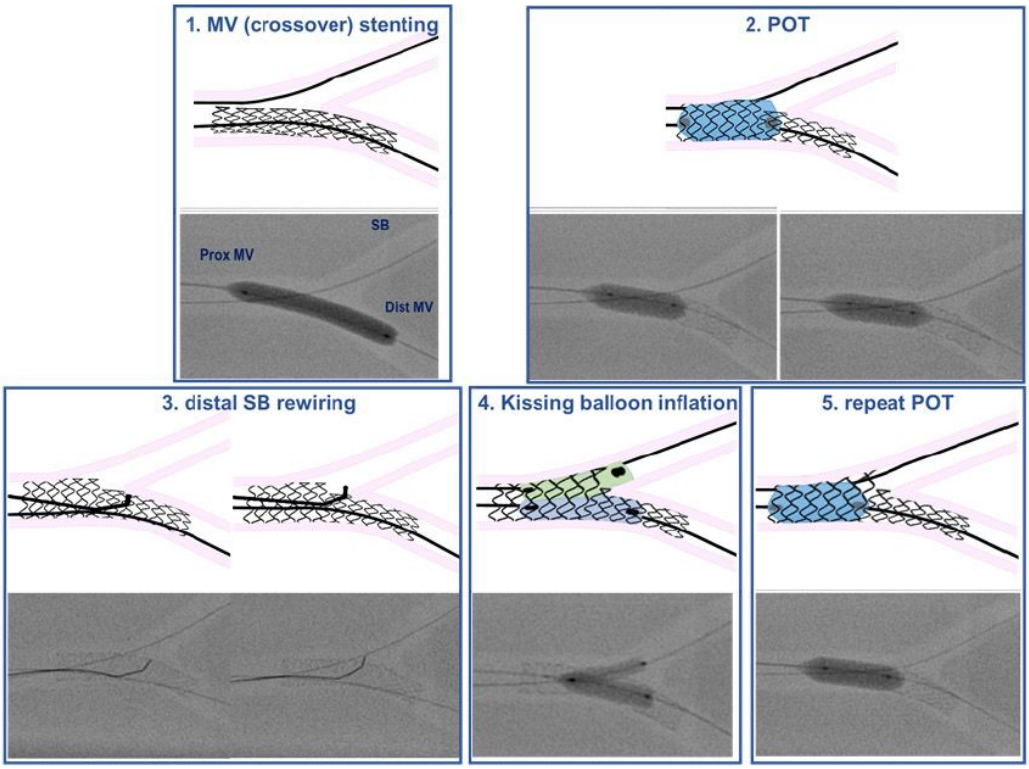

Figure 4. Sequential step for provisional technique.[2]

In our patient, the provisional technique approach was chosen regarding the existing risk and benefit considerations. The patient has borderline serum creatinine so that optimizing the procedure by calculating an efficient contrast agent to prevent worsening of the renal function is one of the considerations. In addition, as previously mentioned, the provisional technique allows a shorter procedural time so that radiation exposure for the operator is also minimal.

Recommended steps for provisional technique were described as follow in figure 4. (1) MV stenting across SB take-off with DES sized 1:1 according to distal MV diameter. (2) POT with balloon sized 1:1 to proximal MV. Note that, due to long stented area in the proximal MV, two inflations were needed to appropriately post-dilate the entire proximal MV stent segment. (3) Distal SB rewiring according to the pullback technique. Note the double bended guidewire tip shape that allows entering easily the distal part of SB ostium. (4) Simultaneous kissing balloon inflation with MV balloon sized 1:1 according to distal MV and SB balloon sized 1:1 according to SB diameter. (5) Repeat POT with balloon sized 1:1 to proximal MV.[5]

3.3 A General Outline when Treating a Bifurcation Lesion – SB protection

An important aspect when stenting bifurcations is the protection of the SB by insertion of a wire to be left until the stenting procedure on the MB has been completed, which includes high-pressure stent deployment or post dilation. These temporary “jailed” wires can be retrieved provided attention is paid to avoid any trauma to the ostium of the proximal coronary with the guiding catheter, which tends to be pulled in as the guidewire is withdrawn. In the provisional technique, wire crossing through the distal strut (the “carina strut”) following MB stenting is strongly suggested because it creates better SB scaffolding than proximal crossing.

To optimize SB access through the carina strut, the proximal optimization technique (POT) is proposed. Optimization of the stent deployment proximal to the carina using a short, bigger balloon may help to access the most distal strut during wire exchange. If the result remains unsatisfactory after MB stenting (>75% residual stenosis, dissection, TIMI flow grade <3 in an SB ≥2.5 mm, or FFR <0.75), SB stenting should be performed. SB stenting can be performed with T stenting or with T-and-protrusion (TAP) stenting, reverse/internal crush and culotte, followed by FKBI.[3] It is important to perform SB assessment after the MV stenting as seen in figure 5.

3.4 The Role of Final Kissing Balloon Inflation

Stenting only the main vessel (MV) in a bifurcation without further post-dilation produces incomplete stent apposition proximal to the side branch (SB), leaving stent struts malapposed at the SB ostium that disturb flow and increase the risk of stent thrombosis. Post-dilation is necessary to ensure full apposition of the stent. In bifurcation stenting practice, it is still controversial how post-dilation should be performed and whether the final kissing balloon inflation (FKBI) is mandatory when only the main vessel (MV) receives a stent.

Final kissing balloon inflation (FKBI) is proposed if the SB is dilated through the MB stent struts to correct MB stent distortion and proximal expansion and to provide better scaffolding of the SB ostium and facilitate future access to the SB. The long-term clinical benefit of FKBI, in cases of MV stenting alone, is still unproven. The Nordic-Baltic Bifurcation Study (Nordic III) and the Cordoba & Las Palmas (CORPAL-KISS) trial demonstrated that no systematic clinical advantage exists with a routine kissing strategy when a single stent treatment is used, and retrospective analysis of the COBIS registry showed that FKBI may even increase long-term TLR rate in the MV. However, angiographic follow-up at 8 months in the NORDIC III study showed a lower SB restenosis rate in patients with true bifurcation lesions when

FKBI was performed (7.6% vs. 20.0%, P = .024), and a study by Koo and colleagues showed that FKBI restores normal FFR in the SB in the majority of patients. Several criteria have been proposed to define lesions in which FKBI is required: these include greater than 75% residual stenosis at the SB, TIMI flow grade less than 3, or FFR below 0.75. Therefore two appropriate strategies are to use either a pressure wire to interrogate the significance of the SB lesion and treat or not accordingly or to simply do FKBI on all angiographically significant ostial SB lesions, which reduces the proportion of these lesions that are physiologically significant; in light of the information from Nordic III, there appears to be no penalty for doing so. A two-step sequential strategy has also been proposed as a simpler and more efficient alternative to an FKBI technique; this accomplishes SB dilation with a balloon at least the diameter of the SB, and final optimization of the MV stent is with a balloon sized per the proximal MV with the distal marker at the carina site. As a general approach, we favor performance of FKBI.[3,9]

Final KBI has been recommended repeatedly based on bench experiments and observational studies. From the study of Bondi-Zoccai et al., KBI appears beneficial in reducing the risk of side-branch repeat revascularization after using a two-stent strategy.[1] However, after provisional bifurcation stenting, sequential post-dilation of the SB and MV may offer a simpler alternative to final KBI. A multicentre study by Watanabe et al., PROPOT Trial, comparing proximal optimization technique (POT) versus KBI found that POT was not superior to KBI in terms of stent apposition.

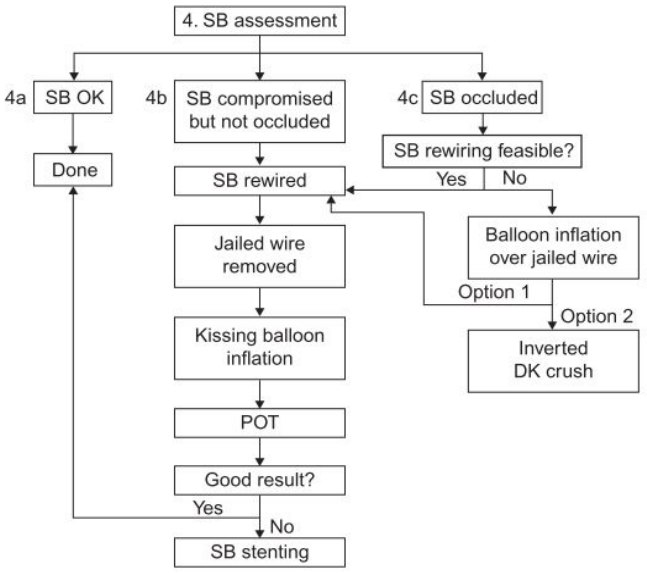

Figure 5. Algorithm for SB Assessment after Provisional Stenting.[11]

3.5 Randomized Data for Bifurcation Approaches

Studies and randomized trials have been conducted since the introduction of DES to determine the best treatment for bifurcation stenosis, especially comparing provisional and dedicated two-stent strategies. There is considerable variation in trial end points, stenting procedures, lesion characteristics, and side branch bailout approaches; nonetheless, for most bifurcations, a provisional approach has no detriment in terms of clinical results (fig. 6, table 1). The provisional approach of implanting one stent on the MV should be the default approach in most bifurcation lesions.[3]

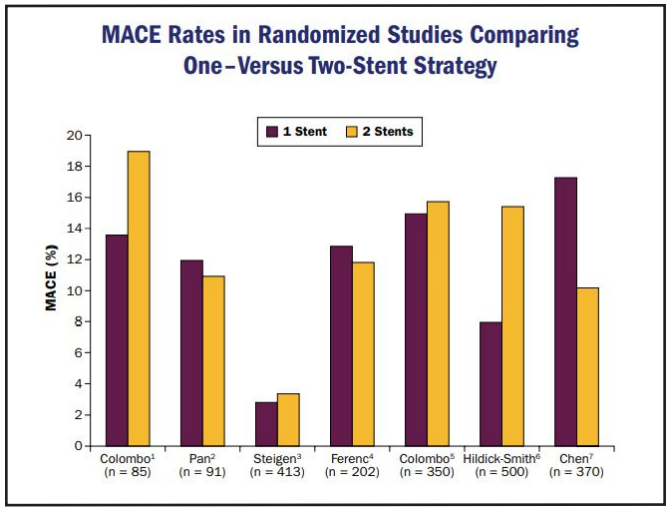

Figure 6. MACE Rates in Randomized Studies Comparing One- Versus Two-Stent Strategy.[3]

The Nordic trial enrolled 413 patients with bifurcation lesions were randomly assigned to either a two-stent technique or a dedicated approach in the first randomized trial comparing the two therapies. Patients assigned to a two-stent strategy underwent either culotte or crush stenting at the operator's choice. Cardiac mortality and stent thrombosis were the major outcomes after six months of follow-up in this study. No difference was found between the two groups at six months, with the provisional group reporting 2.9 percent and the dedicated group reporting 3.4 percent. An important "cost" of a dedicated method was a higher rate of biomarker elevation, as well as increased contrast volume, fluoroscopy time, and operation time in the group using a dedicated two-stent technique. Overall, the authors concluded that the data support a de facto provisional approach.[13,20]

Shortly after the publication of the Nordic and BBK trials, the Cactus trial was reported. In this randomized trial, 350 patients with bifurcation lesions were assigned to a dedicated crush-stenting approach or to a provisional strategy using sirolimus-eluting stents. The primary angiographic outcome measure was in-segment restenosis at 6 months, and the primary clinical outcome was MACE defined as cardiac death, myocardial infarction, or target vessel revascularization at 6 months. The results demonstrated a statistically identical, but numerically lower, rate of restenosis in the side branch of 13.2 % in patients who received the dedicated crush versus 14.7 % in those with provisional stenting. Clinical outcomes as measured by MACE at 6 months were also identical between the two approaches.[4,20]

The DK-Crush-II trial is the most recent randomized trial comparing a double kissing crush technique with provisional stenting. In this trial, 370 patients were assigned to either the double kissing crush technique or the provisional technique. Of the patients assigned to the provisional technique, about 28 % crossed over to a 2-stent technique. Double kissing crush technique involves deploying the side branch stent, balloon crushing that stent, then performing a kissing balloon inflation in the side branch and main vessel. Next, the main vessel stent is deployed and a final kissing balloon angioplasty is performed. In the DK-Crush trial, the primary end point was MACE at 12 months and the secondary end point was angiographic restenosis at 8 months. Results of the study demonstrated a lower rate of target-lesion revascularization in the two-stent group (4.3 % vs. 13.0 %, p = 0.005) and lower target-vessel revascularization in the two-stent

Table 1. Baseline characteristic of research partisipants.

Study	NORDIC [7] Elective (N = 206)	NORDIC [7] Provisional (N = 207)	BBK [8] Elective (N = 101)	BBK [8] Provisional (N = 101)	CACTUS [9] Elective (N = 177)	CACTUS [9] Provisional (N = 173)	BBC-ONE [10] Elective (N = 250)	BBC-ONE [10] Provisional (N = 250)
Clinical Outcome	6 months		1 year		6 months		9 months	
Primary end point	Death, MI, TVR, or Stent thrombosis		% DS of the SB		Death, MI, TVR		Death, MI, TVF	
	3.4 %	2.9 %	27.7 ± 24.8 1	23.0 ± 20.2 2	15.8 %	15 %	15.2 %*	8 %*
Death (%)	1.5	1	1	1	0.0	0.5	0.8	0.4
Non- fatal MI (%)	0.5	0.0	2	NA	10.7	8.6	11.2*	3.6*
Peri-procedure	18	8	NA	10.9	8.5	6.9	6.8	1.6
TVR (%)	1.9	1.9	8.9	1	7.9	7.5	6.8	5.6
Stent thrombosis (%)	0.0	0.5	2		1.7	1.1	2.4	0.4
Angiographic outcome	8 months		9 months		6 months		NA	
Re stenosis (%)								
MV	5.1	4.6	3.1	7.3	4.6	6.7	NA	NA
SB		19.2	12.5	9.4	13.2	14.7	NA	NA
%DS in SB	24 ± 21*	31 ± 22*	27.7 ± 24.8	23.0 ± 20.2	30 ± 19	31 ± 22	NA	NA

From Moussa [15], with permission
The CACTUS trial: Peri-procedural and non-Q-wave MI was defined as an elevation of postprocedural CK levels >2 times normal levels with elevated CK-MB in the absence of pathological Q waves.
The NORDIC trial: Peri-procedural cardiac biomarker elevation was defined as a CK-MB or troponin increase to ≥3 times the upper limit of nor- mal with or without clinical manifestations.
BBC ONE: Peri-procedure non-Q-wave myocardial infarction was defined as a CK-MB or troponin increase to ≥3 times the upper limit of normal.
BBK: Peri-procedure Non-Q-wave myocardial infarction was defined as. an elevation of creatine kinase or its MB isoenzyme to at least three times the upper limit of normal in two samples during hospitalization.
*$p < 0.05$

approach (6.5 % vs .14.6 %, p = 0.017). Moreover, the restenosis in the side branch was 4.9 vs. 22.2 % (p = 0.001) when comparing the two stent approach to the provisional approach, respectively.[3]

4. Conslusions

Coronary bifurcation lesions are fairly frequent, and their management is associated with an increased risk of MACE, increased complexity, and prolonged treatment times. Cardiologists have gotten more active in their treatment of these tough lesions over the last decade, with the introduction of drug-eluting stents. With the exception of the DKCRUSH trial, the majority of randomized studies have indicated equality in outcomes employing a provisional technique to bifurcation treatment. Nonetheless, there are several circumstances in which a two-stent technique appears to be appropriate, including big side branch, severe stenosis in either branch of the bifurcation, and strongly angulated lesions. More information regarding the newer bifurcation-specific stent designs and their performance in comparison to current choices will become accessible in the future years. Until that happens, interventional cardiologists must rely on common sense and clinical expertise judgment to guide decision making about the treatment of bifurcation lesions.

5. Declarations

5.1. Ethics Approval and Consent to participate
This study was approved by local Institutional Review Board, and all participants have provided written informed consent prior to involvement in the study.

5.2. Consent for publication
Not applicable.

5.3. Availability of data and materials
Data used in our study were presented in the main text.

5.4. Competing interests
Not applicable.

5.5. Funding source
Not applicable.

5.6. Authors contributions
Idea/concept: KAN, SW. Design: KAN, SW. Control/supervision: SW, BS, NK. Literature search: KAN, SW. Data extraction: KAN, AW. Statistical analysis: KAN SW. Results interpretation: KAN, W, BS, NK. Critical review/discussion: W, BS, NK. Writing the article: KAN, SW. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

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