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Angioplasty in coronary bifurcation: provisional stent technique

Angioplastia em bifurcação coronária: técnica de stent provisional

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ABSTRACT – Bifurcation lesions are present in one out of every five percutaneous coronary interventions. Despite the progress of techniques, materials, and imaging technologies, the bifurcation approach remains challenging, and its percutaneous treatment results in higher rates of adverse cardiac events when compared to treatment of lesions with no bifurcation involvement. The best technique to treat bifurcation lesions is still a subject of debate. For most cases, the provisional technique is preferred, since it is simpler, easier, faster, less expensive, and presents better clinical results in several studies analyzed. The two-stent technique, especially the double kissing crush, has shown better results than the provisional method in complex coronary anatomies. This review aimed to discuss the rationale for using the provisional approach, describing the planning of its various stages, and establishing its main indications.

Keywords: Coronary artery disease; Percutaneous coronary intervention; Stents

RESUMO – As lesões de bifurcação estão presentes em uma a cada cinco intervenções coronárias percutâneas. Apesar da evolução das técnicas, dos materiais e das tecnologias de imagem, a abordagem em bifurcação continua desafiadora, e seu tratamento percutâneo resulta em maiores taxas de eventos cardíacos adversos, quando comparada ao tratamento de lesões sem envolvimento de bifurcação. A melhor técnica para tratar as lesões de bifurcação ainda é tema de debate, sendo a técnica provisional preferencial para a maioria dos casos, por ser mais simples, fácil, rápida, ter menor custo e apresentar melhores resultados clínicos em vários estudos analisados. A técnica com dois stents, em especial a de *double kissing crush*, tem apresentado melhores resultados que a provisional em anatomias coronárias complexas. Esta revisão teve o objetivo de discutir o racional do uso da abordagem provisional, descrevendo o planejamento de suas diversas etapas e estabelecendo suas principais indicações.

Descritores: Doença da artéria coronária; Intervenção coronária percutânea; Stents

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INTRODUCTION

Bifurcation lesions are involved in approximately 20% of percutaneous coronary interventions.[1] Coronary bifurcations present a characteristic geometric conformation that makes them more susceptible to atherogenesis and thrombogenesis, which can be explained by the low and oscillating shear stress on the walls opposite the carina, caused by blood flow.[2]

Percutaneous interventions in coronary bifurcations are associated with procedures that are more complex, and their results are often suboptimal. There are more immediate complications, such as occlusion, dissection, flow disorder and severe residual stenosis, as well as late complications, such as restenosis, thrombosis and the need for further revascularization.[3,4]

Several randomized clinical trials investigated the best intervention strategy for bifurcation lesions, and the provisional stent technique[5] is currently recommended as the standard for most of these lesions.[6] The European Bifurcation Club (EBC) also recommends it because it is simple, safe, and respects the original anatomy of the bifurcation.[7]

In this article, we review concepts, planning, and steps of the procedure, as well as the main clinical trials that evaluated the provisional strategy in the treatment of bifurcations.

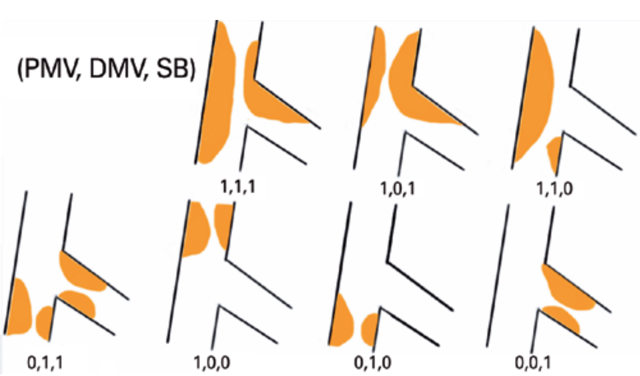
CONCEPTS

The EBC defines coronary bifurcation lesions as narrowing ≥50% adjacent to and/or involving the origin of a significant side branch (SB).[7] If one significant SB is lost, it will bring consequences to the patient, such as symptoms, myocardial ischemia, periprocedural infarction, impairment of the collateral circulation source, and ventricular function impairment.[8]

The geometric relations in the bifurcations for determination of the diameters between the main vessel (MV), proximal main vessel (PMV), distal main vessel (DMV), and SB can be determined by Finet's formula and constant: PMV = (DMV + SB) x 0.678.[9]

Routine use in clinical practice of the Medina classification is recommended by EBC (Figure 1). It is a simple and commonly used classification. It gives each segment of the bifurcation (PMV, DMV, and SB) the binary values 1 or 0, representing presence or absence of stenosis ≥50%, respectively. True bifurcations are those with involvement of the MV (PMV and/or DMV) and SB, represented by Medina types 1-1-1, 1-0-1, and 0-1-1.[10]

The SNuH (size, number, and highest) is a scoring system that predicts the importance of the diagonal branch involved in a bifurcation for the estimation of the myocardial mass at risk. For its calculation, the size and number of diagonal branches are used, as well as their distribution (Chart 1). Only branches >1.5mm in diameter are evaluated. The SNuH score is calculated by the sum of each factor. It varies between zero and three points, and the higher the score, the greater the myocardial mass at risk.[11]



Source: adapted from Medina A, Suárez de Lezo J, Pan M. [A new classification of coronary bifurcation lesions]. Rev Esp Cardiol. 2006;59(2):183-4. Spanish. Figure, A new classification of coronary bifurcation lesions; p. 183.[10]
PMV: proximal main vessel; DMV: distal main vessel; SB: side branch.

Figure 1. Classification of the lesions in coronary bifurcation.

Chart 1. SNuH Score. Scoring system for the diagonal branch

Variables	Description	Score
Size (S)	Vessel diameter ≥2.5mm	1
Number (Nu)	Number of diagonal branches ≤2	1
Highest (H)	Absence of a branch below the target branch	1

Source: adapted from Koo BK, Lee SP, Lee JH, Park KW, Suh JW, Cho YS, et al. Assessment of clinical, electrocardiographic, and physiological relevance of diagonal branch in left anterior descending coronary artery bifurcation lesions. JACC Cardiovasc Interv. 2012;5(11):1126-32. Table 1, A diagonal branch scoring system (SNuh Score); p. 1128.[11]

PLANNING

Adequate visualization of all segments involving a bifurcation is fundamental both for the definition of severity of the lesion and for planning the treatment strategy, taking into consideration the distribution of the atherosclerotic plaque, the angle of the bifurcation, and the involvement or not of the SB. One should opt for the projection that allows the best visualization of the origin of the SB and that has the smallest foreshortening of vessels. However, the correct evaluation of a bifurcation lesion is not always possible only by angiography and requires the use of complementary methods.

Preprocedural coronary computed tomography angiography can be used to define the best angiographic projection and to measure the importance of the SB. Notably, SB with length >73mm is associated with irrigation of, at least, 10% of myocardial mass.[12]

Fractional flow reserve (FFR) evaluation in the SB can be used prior to the procedure to assist in planning, as well as during the intervention, to define the need for additional treatment, including stent implantation in this branch.[12,13]

Intravascular ultrasound (IVUS) allows visualization of the morphology and extension of the atherosclerotic plaque, the degree of involvement of the main and lateral branches, the correct measurement of vessel dimensions, and the evaluation of negative remodeling (particularly in the ostium of the SB), and can identify some prognostic factors of SB impairment after stent implantation in the MV.[14,15]

Optical coherence tomography (OCT) also allows evaluating atherosclerotic plaque distribution at the bifurcation, as well as its characterization between lipid-rich and calcified, which has great importance in planning the stent implantation strategy. Moreover, it enables choosing the appropriate stent size, including, at least, 6mm to 8mm in the portion proximal to the carina. This is the minimum distance necessary to perform the proximal optimization technique (POT) with the balloon catheter commonly used in daily practice, in the proximal segment of the bifurcation, after stent implantation in the PMV. Another tool available in OCT is the three-dimensional reconstruction, which can be used to facilitate understanding of the anatomical complexity of the bifurcation, as well as to evaluate the position of the guidewire, during the procedure, when recrossing the stent into the SB, excluding the accidental positioning by the abluminal face, and the ideal positioning by the most distal cell.[16]

The treatment of bifurcation involving the left main coronary artery (LMCA) presents some particularities. It is estimated that the LMCA irrigates >75% of left ventricle myocardium in cases of right dominance. In general, revascularization is indicated in angiographic stenosis >50% in LMCA, associated with documentation of myocardial ischemia; however, in clinical practice, these definitions may fail. The limitation of adequate angiographic projections, the absence of proximal reference, its short path, diffuse distribution of the disease, and the impairment of angiographic visualization due to inadequate positioning of the guiding catheter during the acquisition of the angiographic image impair its analysis by the two-dimensional method. Therefore, assessment by intravascular imaging methods and physiological evaluation by FFR are recommended. Minimum luminal area >6mm^2 by IVUS and FFR >0.80 are acceptable criteria for postponing revascularization in LMCA.[17-19] However, evaluation with invasive physiology may be impaired by the presence of significant stenosis in the distal “branches”, such as the left anterior descending and left circumflex arteries.[20]

STEPS OF THE PROCEDURE

Access route and catheter

The use of a 6F guide catheter allows adequate treatment in most bifurcations. Catheters with better passive support (extra backup) are recommended in situations where it may be difficult to advance the stent and recross balloons through the stent structures towards the SB (presence of significant tortuosity and/or calcification). The use of a larger caliber guiding catheter, such as 7F, is recommended in cases of elective implantation of two stents, performing a rotational atherectomy with olive-shaped burrs larger than 1.75mm, or the need for post-dilation using three simultaneous balloons.[21]

Radial access is safe and adequate for treatment of most bifurcations including LMCA,[22,23] and can offer the same benefits in relation to early deambulation and greater comfort for the patient, in addition to reducing complications associated to the access route.

Guidewire positioning

The positioning of the guidewire in the SB before stent implantation in the MV is recommended as a strategy for patency maintenance and as a guide for recrossing, and is especially important in cases in which SB is considered significant and/or in true bifurcations. Specifically, the guidewire in the SB has as functions to mark the ostium in case of occlusion, and improve the angle of the bifurcation, facilitating access of other guidewires and balloons through the struts of the MV stent. It can also be used as an anchoring technique, enhancing support for balloon crossing.[24] In emergency situations, when all attempts to recross the SB fail, passing a small caliber balloon through the wire trapped between the stent and the vessel wall can be performed to restore the flow in the SB.[25]

In general, the recommendation is to advance and position the guidewire first in the most difficult to access vessel (due to angulation and/or injury), in such a way that the second guidewire is positioned with minimal manipulation, to avoid twisting and intertwining of wires.

When it is necessary to approach the SB after delivering the stent in the MV, it is possible to pull the guidewire from the MV to the carina, and reposition it in the SB, through the stent struts (switch technique). In this case, the use of a third guidewire can be avoided. Therefore, before introducing the guidewire into the MV, it is recommended to mold its tip in a manner favorable to recrossing. Even so, a third guidewire can be used for this purpose, if the MV guidewire has to remain in the same position.[24]

It is important to carefully remove the entrapped guidewire to avoid injury to the vessel wall or damage to the stent structure, caused by anterograde traction of the guiding catheter, especially in case of LMCA treatment.

Predilation

Predilation of the MV is encouraged in cases of severe stenosis, since it enables proper stent positioning and implantation, and can optimize long-term results.

In the context of the provisional technique, routine predilation of the SB should be avoided since it can cause dissection, hindering repositioning of the guidewire and the approach of the SB.[21] In complex coronary bifurcations with significant ostial lesions in the SB, predilation of the SB can be considered before the implantation of a stent in the MV, because it favors the patency of the SB and reduces the need for its subsequent treatment.[26]

Stent implantation in the main vessel

The stent diameter should be chosen according to the DMV reference to prevent displacement of the carina to the SB, as well as possible dissections in the DMV. The stent in the PMV should extend, at least, 6mm to 8mm proximal to the carina, to avoid trauma of the balloon at the proximal edge of the stent during the POT.[21,24]

The use of a drug-eluting stent is recommended, preferably for those with a lower profile.[27] It is paramount to know the characteristics of the stent regarding its maximum expansion capacity, to adapt the proximal reference of the MV during the POT, respecting the natural distal thinning of the vessel and avoiding distortions and fractures.[28]

Proximal optimization technique

POT should be routinely performed after stent implantation in the MV to correct poor expansion and frequent stent malapposition, as well as to restore the vessel geometry.[17] It should be done before repositioning the guidewire in the SB, because it facilitates its movement and prevents the wire from passing between the stent and the PMV wall.

The use of a short non-compliant balloon is recommended for performing POT, according to the extension of the stent in the proximal segment of the bifurcation, with a ratio of 1:1 considering the balloon diameter and the PMV reference. Proper balloon positioning is essential, with its distal mark adjacent to the flow divider at the carina level, to avoid displacement of the carina towards the SB ostium, and its proximal mark within the stent, thus preventing proximal edge injury.[29] The use of the best angiographic projection and tools to enhance stent imaging can contribute to a successful technique.

After this stage of the provisional technique, it is possible to conclude the procedure if the SB is smaller than 2mm in diameter or clinically irrelevant, and is patent ("keep it open" strategy).

Side branch approach

The routine use of the kissing balloon (KB) in the provisional technique did not show any improvement in clinical results.[30-32] Its performance is recommended in clinically relevant territories when, after the POT, there is impairment of the SB flow, dissection, severe residual stenosis, or FFR <0.80. In bifurcations involving the LMCA, besides the situations described, KB should be considered in young patients when there is a future possibility of percutaneous coronary intervention in SB territory, or the left anterior descending artery was considered as SB (stent implanted from the LMCA to the left circumflex artery).[33]

To approach the SB after POT, the MV guidewire or a third wire is recrossed to the SB through the cell (of the MV stent) that is closest to the flow divider in the carina (distal cell). This is done to promote greater coverage of the SB ostium (scaffold) with the protrusion of the PMV stent strut on the roof of the SB ostium. Next, the SB wire is repositioned in the DMV. Two balloons, preferably non-compliant, according to the respective DMV and SB references, are then positioned with overlap proximal to the bifurcation. The balloons are inflated sequentially, first in the SB with nominal pressure, and then in the MV with high pressure, followed by concomitant inflation with low pressure and simultaneous deflation. After the KB, the stent in the portion of the PMV assumes an oval conformation, repeating the POT is recommended. However, unlike the first POT, the re-POT technique aims to restore the circumferential shape of the stent,[21] and should be performed with proximal positioning to the flow divider in the carina.

An alternative that requires fewer resources than KB is performing the POT-side-POT technique. After the first POT, the guidewires are recrossed as described in the KB. A balloon is then inflated into the SB and then a second POT is performed to correct the area of malapposition on the wall opposite to the origin of the SB.[21,24] The preferential technique recommended by the EBC is the POT-KB-POT, especially for true bifurcations, although a conclusive clinical benefit is still awaited.[7]

In the provisional technique, a strategy that presents an attractive rationale is the use of pharmacological balloon in the SB. Studies have compared a drug-eluting stent strategy in MB and a drug-eluting balloon or conventional balloon in SB, and have shown that the drug-eluting balloon strategy presented better angiographic results in the long-term follow-up.[34,35]

In situations of difficult access to the SB with a balloon, one should consider untwisting the guidewires; repositioning the guidewire in the SB by another, more distal cell; performing a new POT, for greater opening of the stent mesh; using smaller caliber balloons, and performing an anchoring technique, inflating an intrastent balloon in the DMV.

If the result after the SB approach is satisfactory (no significant residual lesion in the SB, dissection, flow impairment, or ischemia), the procedure can be concluded. If any of these situations occur, implantation of a stent in the SB is recommended.

Stent implantation in the side branch

Several case series demonstrated the use of a second stent for treating the SB may be necessary in approximately 20% of cases approached with the provisional technique. Its indication usually occurs when, after the SB approach (POT-KB-POT or POT-side-POT), there is a suboptimal result due to flow impairment, significant residual lesion, dissection, or ischemia.[24]

T and small protrusion technique

The T and small protrusion (TAP) technique is the simplest to perform. It is preferably used in bifurcations with angles greater than 70°.

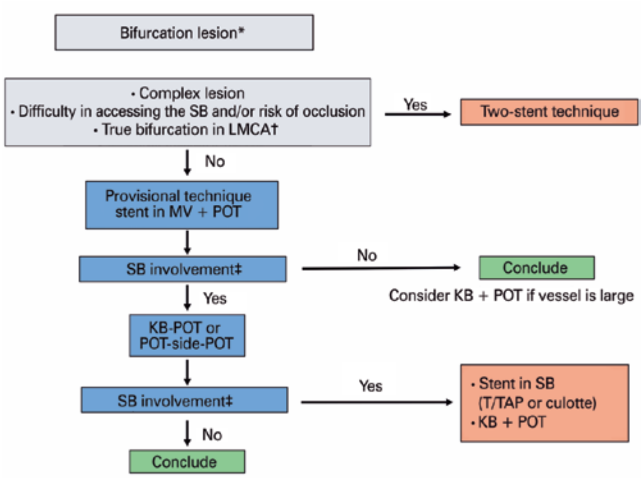
T-stenting can be used if the bifurcation angle is favorable (near 90°) and there is coverage of the roof of the SB ostium by the MV stent (detected by image enhancement techniques or OCT), resulting from recrossing of the guidewire in a more distal cell near the carina.

The second SB stent is implanted with minimal protrusion into the interior of the MV, with a deflated balloon positioned in the MV. After the implantation, the SB stent balloon is pulled a few millimeters and the SB and MV are sequentially inflated with high pressure, followed by KB. Finally, a new POT can be performed to restore the circumferential geometry of the stent, taking care to position the non-compliant balloon more proximally to the formed metallic neo-carina, in order not to compromise the result in the SB ostium.[21,24]

Culotte

This technique can be used in bifurcations with angulations less than 70°, when the diameters of the DMV and SB are similar. Three POTs are recommended. After the first POT, the inversion of the guidewires and the opening of the stent cell from the MV to the SB with a balloon are performed. The second stent is then implanted from the MV to the SB, with minimal overlap of the MV stent in its entire circumference, followed by the second POT. The MV wire trapped by the overlapping part of the SB stent in the MV is repositioned in the MV by the stent mesh, in the cell closest to the carina. Non-compliant high-pressure balloons are recommended in the SB, followed by the MV, to achieve complete expansion in both ostia. The procedure is concluded after KB and the third POT.[21]

The steps of the procedure are summarized in figure 2.



Source: adapted from Sawaya FJ, Lefèvre T, Chevalier B, Garot P, Hovasse T, Morice MC, et al. Contemporary approach to coronary bifurcation lesion treatment. JACC Cardiovasc Interv. 2016;9(18):1861-78. Central Illustration, Simplified approach to treatment of bifurcation lesions; p. 1875.[21]

* Recommend use of imaging tests, especially in LMCA; † the double kissing crush technique is preferred, if performed by experienced operators; ‡ significant stenosis, dissection, ischemia or flow <Thrombolysis in Myocardial Infarction III.

SB: side branch; LMCA: left main coronary artery; MV: main vessel; POT: proximal optimization technique; KB: kissing balloon; TAP: T and small protrusion technique.

Figure 2. Simplified approach to treat coronary bifurcations lesions.

WHY CHOOSE THE PROVISIONAL STENT TECHNIQUE?

Despite still being a subject of great debate, the provisional technique is preferred for most cases of bifurcation lesions, because it is simpler, easier, and faster; it is less expensive and presents better clinical results in several studies analyzed.[36-39] This choice allows the procedure to be initiated in a flexible manner, that is, according to the results obtained. It is the decision to follow the next steps gradually, avoiding the more complex approach from the beginning, as occurs in the two-stent technique.

The main characteristics and results of large randomized studies comparing the bifurcation treatment strategies with the provisional technique (stent in the SB) *versus* two-stent technique in the drug-eluting stent era are shown in chart 2. Although some studies have shown less angiographic restenosis with the two-stent strategy,[40-41] this method was not superior to the provisional technique as to adverse cardiovascular events, besides increasing the procedural time, use of contrast, radiation dose, and cost.[36,38,39]

For true bifurcations specifically involving LMCA, the provisional strategy was compared to the double kissing (DK) crush technique in the DK CRUSH-V[42] study. In the provisional strategy, the second stent was necessary in almost half of the patients, indicated if stenosis >75%, dissection > type A or Thrombolysis in Myocardial Infarction (TIMI) flow <3. The primary outcome, composed of cardiovascular death, MI related to the target vessel, and target lesion revascularization (TLR) at the end of one year was higher in the provisional strategy when compared to DK crush (10.7% *versus* 5.0%; p=0.02), as well as MI (2.9% *versus* 0.4%; p=0.03), and stent thrombosis (3.3% *versus* 0.4%; p=0.02). In the 3-year follow-up, the DK crush technique still maintained better results, compared to the provisional procedure, regarding the primary outcome (8.3% *versus* 16.9%; p=0.005), MI (1.7% *versus* 5.8%; p=0.017), TLR (5.0% *versus* 10.3%; p=0.029), and stent thrombosis (0.4% *versus* 4.1%; p=0.006).[43]

Based on these studies, the treatment of bifurcation with a provisional strategy presents with a class IIa recommendation, Level of Evidence A, whereas with the initial strategy of two stents as class IIb, Level of Evidence B, according to the Brazilian guideline of percutaneous coronary intervention.[27] In the European guideline on coronary artery bypass grafting,[6] the provisional technique presents recommendation I, Evidence Level A, for bifurcation lesions; for true LMCA bifurcation lesions, the DK crush technique should be preferred over the provisional strategy with T-stenting, recommendation IIb, Evidence Level B.

Recently, the DEFINITION II study randomized 653 patients for the provisional technique *versus* two stents in complex bifurcation lesions, also including LMCA lesions (approximately 30% of cases). Complexity was defined in the presence of one major criterion (SB with lesion ≥10mm and stenosis ≥70% in LMCA lesions or ≥90% in other locations), and two minor criteria (moderate or major calcification, multiple lesions, bifurcation angle <45° or >70°, MV with diameter <2.5mm or lesion extension ≥25mm and presence of thrombus). In the two-stent technique, DK crush was used in 78% and, in culotte, in 18%. At the end of 1-year follow-up, the primary outcome, composed of cardiovascular death, MI related to the target vessel, and TLR, was higher in the provisional strategy, when compared to the two-stent technique (11.4% *versus* 6.1%; p=0.019). This was mainly at the cost of periprocedural MI (5.8% *versus* 2.1%; p=0.022) and TLR (5.5% *versus* 2.4%; p=0.049), with no differences in cardiovascular death and stent thrombosis.[44]

A recent meta-analysis[45] used a network methodology to compare 21 randomized clinical trials, involving 5,711 patients treated with five different bifurcation techniques (provisional, T/TAP, culotte, crushing, and DK crush). The mean follow-up was 12 months. There were no differences in cardiac death, myocardial infarction, or stent thrombosis

Chart 2. Characteristics and results of randomized studies

Study	Year	Technique	n	Follow-up	Stent used	Primary outcome	Results	Stent indication in the SB (provisional)	Use of stent in the SB (provisional) (%)	Notes
NORDIC[36]	2006	Provisional *versus* crush, *culotte* or T	413	6 months	Cypher®	CV death + MI + TVR + ST	2.9% *versus* 3.4% (p=NS)	TIMI Flow 0	4.3	
Cactus[37]	2009	Provisional *versus* crush	350	6 months	Cypher®	Clinical: CV death + MI + Angiographic TVR: restenosis	Clinical: 15.0% *versus* 15.8% (p=NS) Angiographic: • MB: 6.7% *versus* 4.6% (p=NS) • SB: 14.7% *versus* 13.2% (p=NS)	Lesion ≥50% TIMI Flow <3 Dissection >A	31.0	
EBC TWO[38]	2016	Provisional *versus culotte*	200	12 months	Nobori®	CV death + MI + TVR	7.7% *versus* 10.3% (p=NS)	Lesion ≥90% TIMI Flow <3 Dissection >A	15.5	SB ≥2.5mm with lesion ≥5mm in length
BBC ONE[39]	2010	Provisional *versus* crush or *culotte*	500	9 months	Taxus™	Death + MI + target vessel failure	8.0% *versus* 15.2% (p=0.009)	Lesion ≥70% TIMI Flow <3 Dissection >A	2.8	
NORDIC IV[40]	2020	Provisional *versus* culotte, mini-crush or T	450	6 and 24 months	Cypher® and Xience	CV death + AMI* + TLR	5.5% *versus* 2.2% (p=0.07) 12.9% versus 8.4% (p=0.12)	TIMI Flow <3	3.7	SB ≥2.75mm with lesion ≤15mm in length
DK Crush II[41]	2011	Provisional *versus* DK crush	370	12 months	Excel	CV death + MI + TVR	17.3% *versus* 10.3% (p=0.07)	Lesion ≥50% TIMI Flow <3 Dissection ≥B	28.1	TVR 14.6% versus 6.5% (p=0.017)
DEFINITION II[44]	2020	Provisional versus DK crush or culotte	653	12 months	Firebird™ 2 Excel BuMA™ Xience Endeavor™	CV death + MI in target vessel + TLR	11.4% *versus* 6.1% (p=0.019)	Severe lesion TIMI Flow <3 Dissection >A	22	

* MI not related to the procedure.
SB: side branch; CV: cardiovascular; MI: myocardial infarction; TVR: target vessel revascularization; ST: stent thrombosis; NS: not significant; TIMI: Thrombolysis in Myocardial Infarction; MB: main branch; DK: double kissing.

among the percutaneous coronary intervention techniques analyzed. Considering all techniques, DK crush reduced major cardiovascular events when compared to the provisional technique, with a lower rate of TLR (odds ratio of 0.36; 95%CI 0.22-0.57). There was a clinical benefit of the technique with two stents over the provisional, when the length of the lesion in the SB was greater than 10mm.

FINAL REMARKS

The provisional strategy should be the technique of choice for most bifurcations. The two-stent technique should be reserved for lesions of greater complexity, or when a difficulty in accessing the significant lateral branch is predicted, after implantation of the stent in the main vessel.

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None.

DECLARATION OF CONFLICTS OF INTEREST

The authors declare there are no conflicts of interests.

CONTRIBUTION OF AUTHORS

Conception and design of the study: RAF, GG and FAP; data collection: RAF, GG and FAP; data interpretation: RAF, GG and FAP; text writing: RAF, GG and FAP; approval of the final version to be published: RAF, GG, FAP and RAC.

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