

Procedural and Clinical Outcomes in Management of Left Main Coronary Artery Bifurcational Lesions

Running title: Outcomes of LM Coronary Bifurcational Lesions

Abstract:

Background: Around 20% of percutaneous coronary interventions (PCIs) are used to treat coronary bifurcation syndromes. Technical success was defined as successfully bridging the occluded portion with a wire and balloon and reopening the artery with a 40% residual stenosis in all views. Technical success is defined by the absence of a serious adverse cardiac event throughout the hospital stay (MACE). The purpose of this study was to evaluate the procedural and clinical results associated with LM bifurcational intervention.

Methods: A controlled study was carried out on 100 patients eligible to Left Main bifurcational intervention were included. the patients were divided into two groups according to the stenting technique used, the provisional group (n=70) who managed with one stent strategy, and the non-provisional group (n=30) who managed with a double kissing crush, culotte, T stenting, or TAP technique. This study recorded the incidence of MACE: death, non-fatal myocardial infarction, or target lesion revascularizations were recorded at 6 and 12 months of follow-up.

Results: It is insignificantly different mortality incidence between the 2 groups but non-fatal myocardial infarction, stent thrombosis, re-PTCA, and target lesion revascularizations were significantly increased in the non-provisional group. As regards clinical success in 2 groups,

this study found 68 patients in the provisional group and 24 patients in the non-provisional group fulfilled the characteristics of clinical success.

Conclusions: In LM-bifurcational intervention, there is a significant increase in the incidence of MACE in the non-provisional group and so the clinical outcome is better in the provisional stenting than the non-provisional stenting.

Keywords: Left Main Coronary Artery, Bifurcational Lesions, percutaneous coronary interventions

Introduction

Around 20% of percutaneous coronary interventions (PCIs) are used to treat coronary bifurcation syndromes.^[1] Additionally, coronary, PCIs (PCIs are well-known) interventions in bifurcation are performed due to their technical complexity. Indeed, several factors must be considered when percutaneously treating bifurcation lesions, including the location, size, and angle of bifurcation branches within the coronary tree (e.g., left main versus others), disease extension at the bifurcation (true versus pseudo-bifurcation lesions), stenting technique, and device selection.^[2, 3]

Numerous studies have been published in each of these contexts, although treatment strategies remain highly contextual and operator dependent. The European Bifurcation Club (EBC) has offered the following pragmatic definition of a bifurcation lesion: “A coronary artery narrowing occurring adjacent to, and/or involving the origin of a significant side branch (SB).” and also defines the significant SB as the branch that you do not want to lose during revascularization.^[4]

Although there are presently at least six distinct classifications for bifurcation lesions, the medina classification is the most user-friendly and easy to remember.^[5] Technical success was defined as successfully bridging the occluded portion with a wire and a balloon and opening the artery with residual stenosis of 40% in all views.

A successful operation was defined as one that was technically effective but did not result in an acute coronary syndrome (ACE) in the hospital. A MACE was defined as an event that resulted in death, no-reflow, or STEMI.^[6] Bifurcation lesions could be divided into true True bifurcation lesions (Medina 1.1.1; 1.0.1; 0.1.1) are those in which both the MB and SB are substantially constricted (>50 percent diameter stenosis), whereas non-true bifurcation lesions comprise all other lesions involving a bifurcation.^[7] PCI for complicated lesions,

such as the unprotected left main (ULM) and bifurcations, is assuming a significant role in the treatment of coronary artery disease with favorable results, owing in part to the introduction of next-generation stents. The risk of unfavorable cardiovascular events on a daily basis and **Their** distribution in time following these treatments is unknown. We will examine the procedural and clinical results of left main bifurcational lesions in this study. ^[7] Our study's objective is to evaluate the procedural and clinical results of left main coronary artery bifurcation.

Methods

This interventional observational research included 100 patients who were being prepped for elective Left main bifurcational intervention and stenting at Tanta university hospital's cardiology department. The study was conducted from October 2019 to July 2021. Before enrollment, all patients were informed of the study's exploratory nature and provided signed informed permission. The study was authorized by the ethical committee of Tanta university's connected hospital. Our cardiology department approved the title ethically without code.

The inclusion criteria: 100 patients with LM bifurcational lesions eligible for PCI. The exclusion criteria: Patient refusal, patients with marked renal impairment eGFR less than 30 ml/min, presence of any significant co-morbid condition that severely limits patient's life span, known allergy to iodine contrast media, severe LV dysfunction < 30%.

All patients had a comprehensive history taking, clinical examination, and laboratory investigations, which included serum creatinine, blood urea, liver function tests, lipid profile, complete blood count, prothrombin time, and **INR**. All patients underwent electrocardiograms and were evaluated by echocardiography.

Procedure: Coronary angiograms were done **transradially or transfemorally.** All operations were carried out in accordance with the most recent PCI guidelines.

During the operation, unfractionated heparin was used in proportion to the patient's weight.

All patients should receive a loading dose of aspirin (300 mg) and clopidogrel 600 mg (or ticagrelor 180 mg). Following PCI, all patients were administered aspirin 100 mg daily for an indeterminate period of time and clopidogrel 75 mg daily (or ticagrelor 90 mg twice daily) for at least six months. Following coronary angiography, individuals who do not meet any exclusion criteria are split into two groups: The first group (70 patients) received provisional stenting (one stent), whereas the second group (30 patients) did not get provisional stenting.

All were between the ages of 6 and 12 and were eligible for the LM bifurcational intervention isional (two stents) group.

In all patients, **The intervention approach** was chosen in accordance with the lesion's location. Stent diameter and length were determined visually, with a stent/vessel diameter ratio of 1.1:1.0. Post-dilation with a non-compliant balloon was not routine and was carried performed according to operator experience; the stents' outcomes were evaluated angiographically.

Strategy and technique of Left Main PCI

Stenting of the left main should be conducted by highly trained and experienced operators. Our treatment strategy of LM bifurcational stenting is the approach suggested by Rab et al, which has been illustrated in the following diagram (figure 1).

Our strategy started with the preparation of the lesion by balloon predilatation then stenting with appropriate stent caliber and lastly evaluation of good stent struts expansion, if there was sub-optimal stent struts expansion, non-compliant balloon post dilatation was done.

Provisional stenting using a stent crossover method with a single stent ^[8]:

This technique includes 3 crucial steps:

- (1) Wiring of LAD and CX
- (2) Main vessel stenting almost from LAD back to the LM with diameter selected according to distal LAD reference.
- (3) With a balloon diameter defined by the LM diameter and the balloon's distal tip in front of the carina, the proximal optimization method (POT) is utilized. (option1).

After assessing the side branch ostium in the preceding three phases, two alternatives are possible. POT-KISS-POT (option 2) is performed following guidewire exchange and distal SB rewiring. Kissing balloon inflation (KBI) is then performed followed by Re-POT.

POT-SIDE-POT (option 3), POT After guidewire exchange and distal rewiring of the SB, SB opening using a short noncompliant balloon followed by Re-POT. Figure 2

Although a single stent technique is almost always sufficient, bailout side branch stenting may be performed following main branch stenting using one of three SB stenting techniques (T stenting, T and small protrusion (TAP), or culotte procedures). as shown in figure 2.

Two-stent strategy

When there is a high risk of SB compromisation like long or ostial SB lesion, especially with difficult access to the SB, so planned two-stent technique is preferred as the first strategy. ^[9]

T- or TAP-stenting, culotte, and mini- or **double kissing** crush methods are all examples of two-stent tactics. Kissing balloon and proximal optimization should be used in conjunction with all of these methods.^[8]

Culotte Technique^[10]

After the Wiring of both branches, the first stent is deployed to the main vessel almost from LAD back to the LM with a diameter selected according to distal LAD reference. Followed by the First proximal optimization technique (POT) (preferred after the removal of the jailed SB wire). Following rewiring of the SB, the stent struts are dilated into the side branch (SB). A second stent with a diameter defined by the distal SB reference is subsequently placed from the SB into the main branch.

Second POT (recommended following the removal of the imprisoned main vessel wire), followed by main vessel rewiring and final Inflation of a kissing balloon.

Double Kissing Crush or DK Crush Technique^[10]

In this technique, we start to stent the SB while the main vessel wire is usually in place and we rewire twice the side branch,

DK crush technique includes the following steps:

Stenting the side branch (SB) with a little protrusion of 2–3 mm into the main vessel and maintaining the balloon across the SB ostium, followed by crushing the SB stent with the main vessel balloon following removal of the SB wire.

First, the SB is rewired, and then the stent struts are opened into the side branch (SB) through modest balloon dilatation followed by first kissing balloon inflation.

After removing the SB wire, the main branch is stented across the SB and then POT.

Second SB rewires, followed by a second kissing balloon, and lastly, Re-POT.

Simultaneous kissing stents may also be explored for hemodynamically unstable patients, however, this technique has gone out of favor due to the formation of a new carina and complications with side branch access.

^[10]

FOLLOW-UP. After hospital discharge, clinical follow-up was performed with office visits (preferred) at 6 and 12 months, careful inquiring about symptoms and events or hospital admission due to any cause were done, full clinical examination and 12 leads ECG and echocardiography were done at each visit, Angiographic follow up was repeated for some cases with recurrence of symptoms.

In both groups, we assessed the procedural and clinical outcomes of percutaneous coronary intervention.

A-Angiographic success: PCI success: reduction <10% to 0% minimum diameter stenosis +TIMI 3flow + no side branch (SB) loss + no flow limiting dissection or angiographic thrombus.

B-Procedural success: Angiographic success without significant complications such as mortality, MI, stroke, or emergency CABG during the hospital stay.

C-Clinical success: Clinical success: angiographic and procedural success +relief of ischemia-related symptoms.

Statistical analysis

The present study was statistically presented and analyzed utilizing the mean, standard deviation, and chi-square test in SPSS V.22. The Chi-square test is used to test the hypothesis that the row and column variables are independent but do not indicate the degree or direction of the link. Pearson chi-square and likelihood-ratio chi-square are two types of chi-square. For 2x2 tables, Fisher's exact test and Yates' corrected chi-square are computed.

Results:

Regarding demographic data, there were no significant differences between groups. Table 1

Regarding Serum creatinine and E\G >55%, There were no statistically significant differences in the groups.

Table 2

Regarding the incidence of major risk factors, pre dilatation and post dilatation in both groups, there was no significant difference between groups as regards the incidence of diabetes mellitus, hypertension, dyslipidemia, smoking, and pre dilatation, and post dilatation. Table 3

Regarding the incidence of MACE in provisional and non-provisional groups after 6 months follows up, there were no significant differences between both groups as regards mortality and stent thrombosis at 6 months, while there was a significant increase in the incidence of re-infarction, incidence of re-PTCA, TLR and incidence of referral for CABG in the non-provisional group at 6 months. Table 4

Regarding the incidence of MACE in provisional and non-provisional groups after 12 months follows up, there were no significant differences between both groups as regards mortality and referral for CABG at 12 months while there was a significant increase in the incidence of re-infarction, re-PTCA, TLR at 12 months in the non-provisional group. Table 5

As regards clinical success in provisional and non-provisional groups, there was a significant increase in clinical success in the provisional group. Table 6

Discussion

The LM bifurcation is the biggest of the coronary tree's bifurcations, supplying blood to more than 50% of the total myocardial mass. The SB, which is the Cx, has a wide reference diameter and is angulated, which makes access with guide wires problematic. As mentioned by **Song et al., 2016**,^[11] Acute Cx blockage often causes significant ischemia and may result in acute ischemic mitral regurgitation. Additionally, the LM's T-shaped bifurcation angle may alter the implantation method, and a strongly angulated Cx take-off may have an effect on prognosis following LM stenting. PCI for bifurcation lesions, particularly those in the left main (LM) coronary artery, involves the risk of acute blockage of side branches (SB) and increased rates of in-stent restenosis. Only at the LM does the proximal MB originate directly from the aorta. This adds difficulty due to the interaction with the guide catheter and the possibility of guide wires passing between LM stent struts or causing stent longitudinal compression. According to **Park et al., 2016**,^[12] the proximal reference diameter may surpass 5 mm, which is close to the maximum dilation of many coronary stents. Trifurcations of the left main occur in around 10% of LM instances and may need specialized treatment approaches. In agreement with **Stone et al., 2016**^[13] PCI is a class 1B indication in patients with a low SYNTAX score and severe LM disease, according to the European Society of Cardiology/European Association for Cardio-Thoracic Surgery guidelines for myocardial revascularization. PCI for LM disease has a class IIa level of evidence in persons with a SYNTAX score of 22-33. A SYNTAX score of 33 is suggested for Class III. EXCEL & NOBLE EXCEL & NOBLE^[14] ^[15]^[16] trials, the comparison of PCI to coronary artery bypass grafting [CABG] in the treatment of LM disease has reinforced the argument for PCI with latest-generation DES. Notably, CABG showed no prognostic benefit over PCI in terms of mortality or stroke in either trial, indicating that a growing proportion of patients, particularly those with a low or intermediate complexity score or those at high surgical risk, may have PCI for LM disease therapy. Patient selection and PCI in high-risk surgical patients may now result in an increase in the volume of LM PCI.^[14, 15, 17]

In agreement with **Darremont et al., 2015**^[18] now the strategy of provisional side branch (SB) stenting is currently considered the "standard" approach for the treatment of most bifurcation lesions according to the European bifurcation club. **De Luca, 2016**^[19] said that provisional SB stenting is a treatment philosophy rather than a technique. Once the MB is identified, it should be stented first after wiring both branches of the bifurcation. In agreement with Koo et al., 2005^[20] After optimization of MB treatment using the POT, the SB is evaluated and if its flow is compromised, it should be treated. If the SB requires attention, the guide wires are switched, and kissing balloon inflation or POT/side/POT (re-POT) procedure is done. In agreement with **Park**

et al., 2016 ^[12] In the majority of patients, LM therapy should begin with a preliminary SB stenting technique. Occasionally, however, a two-stent technique is necessary from the start of the LM process. The SB should be wired first, and because of the variations in vascular diameter proximal and distal to the LM bifurcation, a cautious single stent approach with POT is necessary. PCI in the LM should be viewed as a difficult operation at all times. Operators and their teams must be trained and skilled in swiftly responding to unexpected deterioration of the situation necessitating the use of bail-out stenting techniques. Two stents are typically required only in highly complicated lesions with substantial calcified side branches, an ostial disease that extends >5 mm beyond the carina, and bifurcations with extremely difficult-to-access side branches that should be stented once accessible. As a result, two technical elements are critical for patients requiring elective double stenting to achieve clinical success: 1) Prior to bifurcation stenting, the lesion is prepared. 2) Inflating a kissing balloon and administering POT. Stent extension to its maximum length enables optimum scaffolding of atherosclerotic lesions, resulting in the greatest possible increase in the acute vascular lumen. In agreement with **Chen et al., 2008** ^[21] The method developed by **Colombo et al.** has gained popularity since it permits stenting of both the MB and SB without rewiring via the stent struts. However, due to the poor success rate of KBI-assisted procedures and the dismal long-term outcome without KBI, this surgery is no longer recommended.

Chen and colleagues modified the original crush technique to produce the DK-crush strategy, which has been proven in studies to dramatically reduce the risk of kissing balloon inflating failures while being clinically effective and safe over the long term. by **Lassen and Stankovic, 2015.** ^[17] Contrary to **Kervinen et al., 2013** and **Louvard and Medina, 2015** [22, 23]. While culotte stenting is widely used and has been evaluated in numerous studies, it does have one limitation: the requirement for two stents to address any diameter mismatch between the SB and proximal MB. In the multicenter randomized trial (DKCRUSH-V) mentioned by **Chen et al., 2019** ^[22], PCI of real distal LM bifurcation lesions using a planned DK crush 2-stent method resulted in a significantly lower probability of target lesion failure (TLF) at 1 year when compared to a provisional stenting strategy. (Double Kissing and Double Crush Versus Temporary T Stenting for Unprotected Distal Left Main True Bifurcation Lesions. In the DKCRUSH-V trial, there was no significant difference in demographic data or the prevalence of major risk factors between the preliminary strategy and the DKCRUSH-V strategy groups, and this was also true in our analyses. Within one year of enrollment in the DKCRUSH-V trial, TLF developed in 26 patients (10.7 percent) assigned to the preliminary approach and 12 patients (5.0 percent) assigned to DK crush (hazard ratio: 0.42; 95 percent confidence interval: 0.21 to 0.85; p 14 0.02). Additionally, DK crushing

resulted in a decrease in the incidence of target vascular myocardial infarction I (2.9 percent vs. 0.4 percent; p 14.0.03) and definite or probable stent thrombosis (3.3 percent vs. 0.4 percent; p 14.0.02). Clinically caused target lesion revascularization (7.9 percent vs. 3.8 percent; p 14.06) and angiographic LM complex restenosis (14.6 percent vs. 7.1 percent; p 14.10) were also significantly less prevalent with DK crush than with PS. There was no significant difference in cardiac death rates across the groups.

The results of DKCRUSH-V trial was the same as our results as regards cardiac death but differ from our results in TLF, re-AMI, and stent thrombosis which were more evident in the provisional group and that gives the advantage of DK crush strategy over provisional stenting which against our results as in our study, Provisional strategies are related with a decrease in the prevalence of TLF, re-PTCA, re-AMI, and stent thrombosis compared with non-provisional strategies and also against the recommendations of European bifurcation club.

The difference between the DKCRUSH-V trial and this study may be a result of our study's limited sample size and also may be due to our comparison between provisional versus all non-provisional (two stents) strategies and not versus DK crush alone.

In a recent study by Chen et al., 2017 ^[23] which is, Bifurcation validation criteria for definition and comparison of stenting strategies in actually left main bifurcational lesions The purpose of this study was to determine whether the definition criteria (true left main bifurcation lesions in LM or with a large SB, severe SB plaque burden, moderate to severe calcification and multiple lesions, and longer or diffuse main vessel lesions indicate complex bifurcation lesions) were capable of accurately identifying true left main bifurcation lesions. As was the case in our research, the demographic features and prevalence of major risk factors were identified in the provisional (one stent) and non-provisional (two stents) groups.

The main limitations of our investigation are the small number of patients involved and the fact that it was conducted in a single site; thus, larger sample size and a multicenter study are required to confirm the results. According to the results of the present study, we recommend the provisional technique over the non-provisional technique as the clinical outcome is better in the patients managed by such technique than the patients managed by the non-provisional techniques.

Conclusion

In LM-bifurcational intervention, there has been a noticeable increase in the prevalence of MACE in the non-provisional group and so the clinical outcome is better in the provisional stenting than the non-provisional stenting.

Ethical Approval:

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

Consent

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

UNDER PEER REVIEW

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Figure legend

1. Figure 1: Proposed algorithm for method selection in percutaneous coronary intervention of the left main coronary artery, as suggested by Rab et al., 2017
2. Figure 2: Provisional stenting using a stent crossover method with a single stent

Tables:

Table 1: Demographic data of provisional group versus non provisional group

			Provisional	Non-Provisional	Test	P-value
Age	Range		50 – 84	55 – 83	t: 1.280	0.203
	Mean ± SD		63.80 ± 6.94	65.70 ± 6.46		
Height	Range		150 – 185	164 – 178	t: 1.099	0.275
	Mean ± SD		171.09 ± 4.93	170.00 ± 3.37		
Weight	Range		60 – 105	62 – 100	t: 0.331	0.742
	Mean ± SD		87.86 ± 8.86	87.23 ± 8.11		
Sex	Male	N	57	22	X ² : 0.830	0.362
		%	81.4%	73.3%		
	Female	N	13	8		
		%	18.6%	26.7%		

Table 2: Serum creatinine and EF >55% of provisional versus non provisional group

			Provisional	Non-Provisional	Test	P-value
Creatinine	Range		0.6 – 1.6	0.8 – 1.6	t: 0.240	0.675
	Mean \pm SD		1.16 \pm 0.22	1.14 \pm 0.21		
EF > 55%	No	N	51	19	X²: 0.907	0.341
		%	72.9%	63.3%		
	Yes	N	19	11		
		%	27.1%	36.7%		

Table 3: Major risk factors of provisional versus non provisional group.

			Provisional	Non provisional	X ²	P-value
Smoking	+ve	N	37	17	0.123	0.726
		%	52.9%	56.7%		
	-ve	N	33	13		
		%	47.1%	43.3%		
HTN	+ve	N	47	20	0.002	0.963
		%	67.1%	66.7%		
	-ve	N	23	10		
		%	32.9%	33.3%		
Dyslipidemia	+ve	N	29	13	0.031	0.860
		%	41.4%	43.3%		
	-ve	N	41	17		
		%	58.6%	56.7%		
DM	+ve	N	42	19	0.098	0.754
		%	60.0%	63.3%		
	-ve	N	28	11		
		%	40.0%	36.7%		
Pre dilation	No	N	3	0	1.325	0.250

	Yes	%	4.3%	.0%		
		N	67	30		
		%	95.7%	100.0%		
Post dilation	No	N	2	1	0.016	0.898
		%	2.9%	3.3%		
	Yes	N	68	29		
		%	97.1%	96.7%		

Table 4: Death, re AMI, Incidence of MACE of provisional versus non provisional group in 6 months.

			Provisional	Non-Provisional	X ²	P-value
Death	No	N	70	29	2.357	0.125
		%	100.0%	96.7%		
	Yes	N	0	1		
		%	.0%	3.3%		
Re_AMI	No	N	70	28	4.762	0.029*
		%	100.0%	93.3%		
	Yes	N	0	2		
		%	.0%	6.7%		
Re-PTCA	No	N	68	26	4.086	0.043*
		%	97.1%	86.7%		
	Yes	N	2	4		
		%	2.9%	13.3%		
TLR	No	N	68	26	4.086	0.043*
		%	97.1%	86.7%		
	Yes	N	2	4		
		%	2.9%	13.3%		
CABG	No	N	68	28	0.794	0.373
		%	97.1%	93.3%		
	Yes	N	2	2		
		%	2.9%	6.7%		
Stent _ thrombosis	No	N	69	28	1.980	0.159
		%	98.6%	93.3%		
	Yes	N	1	2		
		%	1.4%	6.7%		

Table 5: Incidence of MACE in provisional versus non-provisional group at 12 months.

			Provisional	Non-Provisional	X ²	P-value
Death12	No	N	69	29	0.389	0.533
		%	98.6%	96.7%		
	Yes	N	1	1		
		%	1.4%	3.3%		
Reinfarction12	No	N	69	27	0.016	0.045*
		%	98.6%	90%		
	Yes	N	1	3		
		%	1.4%	10%		
PTCA12	No	N	68	25	6.152	0.013*
		%	97.1%	83.3%		
	Yes	N	2	5		
		%	2.9%	16.7%		
TLR12	No	N	68	25	6.152	0.013*
		%	97.1%	83.3%		
	Yes	N	2	5		
		%	2.9%	16.7%		
CABG12	No	N	68	28	0.794	0.373
		%	97.1%	93.3%		
	Yes	N	2	2		
		%	2.9%	6.7%		

Table 6: Clinical success of provisional versus non provisional group

Clinical success		Provisional	Non-Provisional	Total
Yes	N	68	24	92
	%	97.1%	80.0%	92.0%
No	N	2	6	8
	%	2.9%	20.0%	8.0%
Total	N	70	30	100
	%	100.0%	100.0%	100.0%
Chi-square	X ²	8.385		
	P-value	0.004*		

Figures:

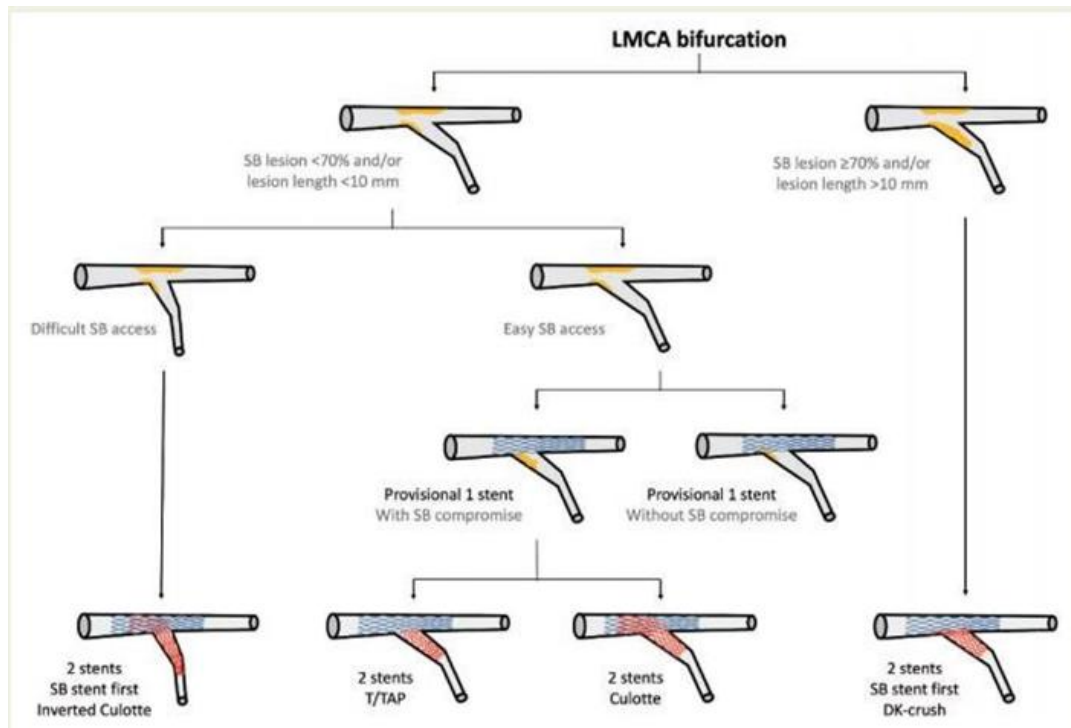


Figure 3: Proposed algorithm for method selection in percutaneous coronary intervention of the left main coronary artery, as suggested by Rab et al., 2017 ^[8]

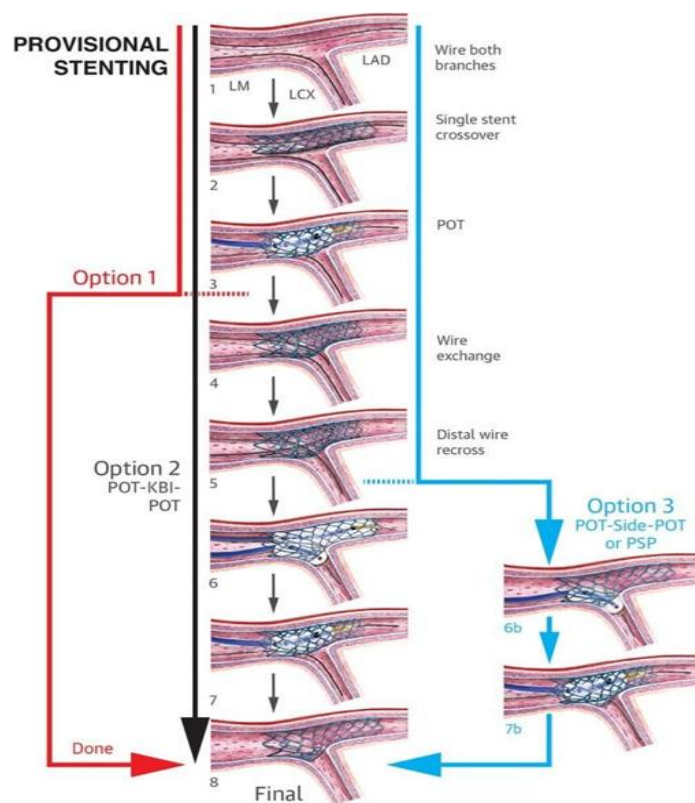


Figure 4: Provisional stenting using a stent crossover method with a single stent ^[10]