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Review Article

Medina Classification Modification Proposal. It's Time for a Step Ahead: the Side Branch Lesion Length Matters More (and Changes our Interventions)

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Abstract

The Medina Classification1, extensively employed in clinical practice and scientific literature, delineates bifurcation lesions (BL) treated with percutaneous coronary interventions (PCIs). When initially introduced, the cases addressed by the PCIs were less intricate, with side branch (SB) lesions predominantly featuring less critical involvement in length compared to the procedures routinely conducted in contemporary catheterization laboratories. The absence of precise quantification pertaining to SB involvement induces interpretative ambiguity in discerning the outcomes and the preferred strategies conveyed by randomized controlled trials dedicated to the treatment of BL. Given the inherent affliction of the main branch in true bifurcation lesions, the pivotal determinant in formulating a 1- or 2-stent strategy and, consequently, influencing procedural outcomes lies in discerning the degree and extension of SB disease from the outset. Consequently, we assert that the integration of a more detailed depiction of SB pathology into the original classification is of paramount importance. We believe that the temporal juncture is ripe for progressive refinement, wherein incorporating the original classification with supplementary descriptive parameters and characteristics as already contemplated in Medina's initial publication. Founded on the revised classification, prospective delineation of a 1- or 2-stent strategy becomes feasible from the outset. Furthermore, through nuanced discrimination among distinct bifurcation populations, the classification facilitates more uniform and dependable comparisons across diverse interventions and techniques. This not only holds relevance for future studies but also ensures retrospective applicability to past publications. Importantly, this iteration preserves the inherent simplicity and user-friendly attributes of the original classification.

Keywords: Coronary heart disease; bifurcation lesions; percutaneous coronary intervention; Classification; Main Branch (MB) and Side Branch (SB); 1- or 2-stent techniques.

Introduction and Background

In the realm of Percutaneous Coronary Interventions (PCIs), the term "bifurcation" encompasses a diverse array of angiographic and anatomic morphologies, contingent upon the distribution of plaque within the affected segments. Recognizing the need for a classification system to delineate various bifurcation types, the scientific community has long sought to introduce a common framework. However, these attempts have encountered challenges, including complexity and difficulty in memorization. Numerous definitions of bifurcation stenosis have been proposed in the past. A coronary artery narrowing occurring adjacent to, and/or involving, the origin of a significant side branch [2] (a branch that you do not want to lose in the global context of a particular patient), for symptoms, location of ischemia, branch responsible for symptoms or ischemia, viability, collateralizing vessel, left ventricular

function, and many more. Previously proposed classifications of coronary bifurcation lesions have demanded considerable effort to memorize and proven to be intricate. In 2006, a significant breakthrough occurred with the introduction of the Medina Classification, which was swiftly embraced by interventional cardiologists worldwide. This classification remains the most widely adopted and practical means of categorizing different bifurcation types. The Medina Classification is straightforward and easy to remember, and provides all information contained in the others. It defines all kinds of bifurcations, with the use of the 3 components of the bifurcation, main branch proximal, main branch distal and side branch (MBP, MBD, SB), with binary values (0,1), for not involved or involved. This up to now makes the anatomical description of bifurcation simple and easy to remember. As written in the original paper of Alfonso Medina et al. "likewise it could also facilitate the inclusion of descriptive parameters…". As added in the same paper, "Last, we consider that it allows for homogeneous terminology when comparing different series and techniques". In 2008 the Medina Classification was adopted by the European Bifurcation Club as the official base for the MADS Classification [3], recognizing that it could contain information about the lesion length. Moreover, the angle between the branches was already there and has been recognized to have significant impact on some technique and follow up results. The EBC consensus [4] stated that "however the presence of quantifiable variables would be recorded under "yes" or "no", the addition of these parameters and possibly others (eccentric location of main branch lesion, TIMI Flow, and so on), would negate the simplicity of the Medina Classification". Although it was recognized that "the only parameter which is currently being debated is the lesion length in the side branch, which could have a significant impact at least on the technique used (1 or 2 stent most), and the acute and long-term result". Two major randomized trials (Nordic Bifurcation Study and BBC1) comparing one or two stents in the treatment of coronary bifurcation were at the time of MADS publication completed or ongoing, and, as reported in the original article, "…further trials in such contest appear unnecessary…". Was there recognized that "one difficulty of these types of trials is that the treatment group including two stents is heterogeneous and the techniques used may have very different mid-term outcomes…. Randomized studies and meta-analysis [5-17]. (Table 1) comparing techniques (two by two) display shortcomings in the areas of technique selection, nature of lesions treated, and financial cost of multiple studies. It has been suggested that the Medina Classification also contains information on lesion length…" and "…moreover the angle between the branches has been shown to have a significant impact on certain techniques and on clinical outcome and follow-up... however, apart from the fact that the presence of quantifiable variables would be recorded under "yes" or "no", the addition of these parameters and possibly others (eccentric location of main branch lesion, TIMI flow, and so on would negate the simplicity of the Medina classification…the only parameter which is currently being debated is the lesion length in the SB, which could have a significant impact at least on the technique used and the acute results. But after this publication we had many more studies on bifurcations, all addressing treatment of different populations and so by definition not comparable in a proper way…" At that time, in 2008, most of the bifurcations treated by percutaneous interventions involved only short SB lesions (the examples pictures included at page 178 of the paper of Louvard et al. is emblematic for that). And for this reason, the 1- stent and provisional approach was strongly endorsed by our community and still has a great rationale for this kind of lesion. But nowadays we treat more and more cases involving very long SB severe stenosis, often also suboccluded or occluded, and as also demonstrated by actual literature (DK-Crush V, Definition II), the from beginning 2 stents approach is the way to go in these situations. For all these reasons we think is time now to make a step ahead from the Medina Classification, improving it, but keeping the "original spirit" of it, with also the initial suggestions of Alfonso Medina, not betraying his message and legacy to keep it simple and useful in practical and scientific use.

Study	Arms	SB lesion length (mm)	SB stenosis (%)	SB Ca (%)	SB Tortuosity (%)	SB angle >60%	SB stent length (mm)	ACS %
CACTUS	**Crush**	**5.9**	**63**	**N/A**	**N/A**	**N/A**	**17.9**	**44**
	Provisional	5.7	61	N/A	N/A	N/A	18.1	47.4
BBC 1	**Culotte/Crush**	**N/A**	**68**	**11**	**11**	**13#**	**16**	**16**
	Provisional	N/A	63	8	10	15	N/A	16
BBK II	**Culotte**	**13.8**	**N/A**	**22.6**	**N/A**	**57.8***	**21.6**	**21.3**
	TAP	15.5	N/A	31.3	N/A	51.5	18.5	19.3
Nordic	**Two stent**	**6.4**	**N/A**	**N/A**	**N/A**	**N/A**	**10.3**	**33**
	Simple	6.0	N/A	N/A	N/A	N/A	2.8	31
EBC Main	**Provisional**	**5.8**	**TIMI 3 pre 99%**	**44**	**19**	**N/A (>95%?)**	**17.6**	**33**
	2-stents (Culotte 53%, Crush 5%)	**7.9**	**TIMI 3 pre 77%**	**54**	**24**	**NA (>95%?)**	**19.3**	**40**
EBC II	**Culotte**	**10.8**	**58.4**	**17**	**15**	**N/A**	**20.7**	**32**
	Provisional	9.7	54.1	19	10	N/A	19.9	31
PERFECT	**Crush**	**10.3**	**57.2**	**2.4**	**0**	**N/A**	**21.4**	**34.9**
	Provisional	8.3	53.3	2.0	0.5	N/A	21.5	31.7
Nordic-Baltic Bif V	**Two stent**	**7.7**	**47.3**	**43.6**	**7.0**	**49.3***	**9**	**16**
	Provisional	6.4	44.3	48.4	2.8	48.9	13	12.9
Smart-Strategy	**Aggressive**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**17.7**	**41**
	Conservative	N/A	N/A	N/A	N/A	N/A	18.4	35
Definition II	**DK/Culotte**	**>10 "**	**96##**	**17.7**	**N/A**	**64.9§**	**25.6**	**48.8**
	Provisional	>10	93	18.2	N/A	67.1	26.4	50.5
DKCrush V	**DK**	**32.4**	**N/A**	**15.4**	**N/A**	**N/A**	**N/A**	**70.0**
	Provisional	28.3	N/A	14.0	N/A	N/A	N/A	74.4

BBC trial- bifurcation angle > 60 was found in 15% provisional and 13% Culotte/Crush

* BBK II trial- the mean bifurcation angle in Culotte arm was 57.8 degrees and 51.5 in TAP

* Nordic Baltic Bifurcation V Trial- the mean bifurcation angle 49.3 and 48.9 respectively

Definition II Trial SB % stenosis >70% to 90% was found in 96% and 93% of population respectively

" Definition II Trial SB lesion length >10 mm was found in 93.9 % of DK arm and in 94.8% of provisional arm

§ Definition II Trial Bifurcation angulation <45 and >70 was found in 64.9% and 67.1% population respective

Table 1: Relevant Literature about SB Characteristics

Methods

Medina Modification Proposal

We have concentrated solely on side branch (SB) lesions, recognizing that adding complexity for main branch proximal (MBP) and main branch distal (MBD) may not significantly alter intervention strategies or the choice between a 1- or 2-stent approach. We introduced a visual assessment of the length of the SB lesion by adding a letter (A, B, or C) to the third digit of the original Medina Classification, emphasizing the importance of SB involvement in true bifurcations. Specifically, we assigned "A" if the SB length was up to 5 mm, indicating a visually "short" lesion, "B" if the length fell between 6 and 10 mm, considered as "intermediate," and "C" if the length exceeded 10 mm, categorized as "long." In cases of Chronic Total Occlusion (CTO), the length of the SB was determined through collateral flow. If this was not possible during the diagnostic procedure (always after double injection angiography), it was assessed after the first pass of the occlusion with the wire or microcatheter, or after the inflation of the first smallest balloon during the PCI intervention (as soon as possible to define). Only for intermediate lesions (denoted by "B"), we further distinguished complexity by adding a subscript digit (1 or 2) to this letter. This additional digit indicated the absence (0), presence of one (1), or presence of more than one (2) characteristic of complexity in the SB lesions (refer to Figure 1). To facilitate memory, we utilized the acronym CADATO, outlined in (Table 2) (Calcium, Angle, Difficult Access or DAngerous, and TOrtuosity), to enumerate the specific characteristics considered.

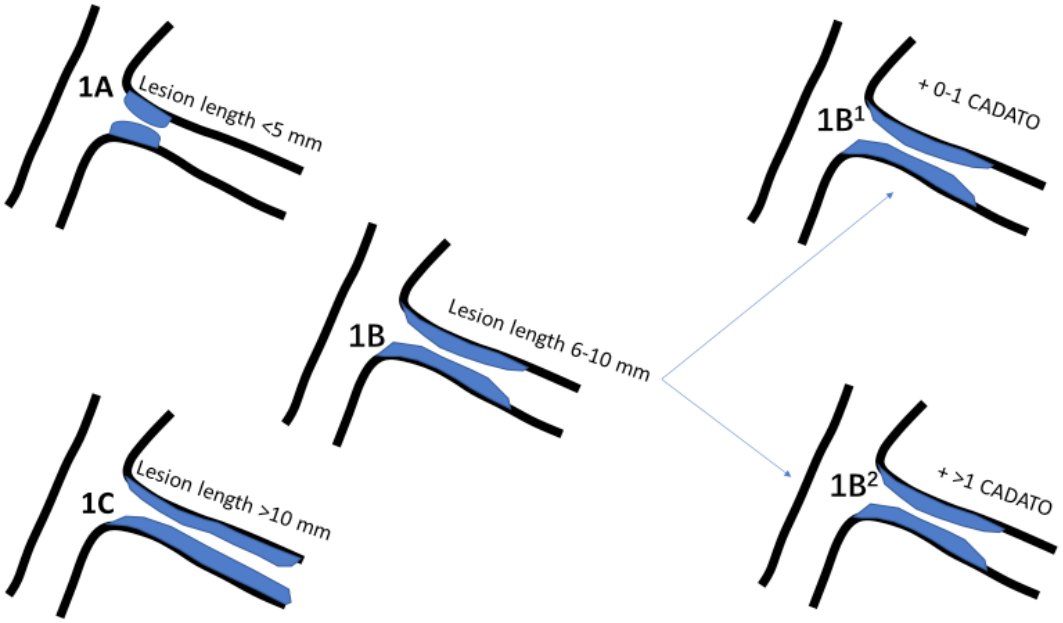

Figure 1: Graphical illustration of CADATO characteristics

1. Significant **C**alcification
2. Difficult **A**ngle of origin (< 45 or > 75 degrees) between MB and SB
3. High possibility of wire (or balloon) **D**ifficult **A**ccess for any reason or "**DA**ngerous" SB stenosis (extreme eccentricity of the plaque or subocclusion, thrombus, TIMI<3, severe plaque burden in MB opposite /near the SB, …). Every clearly immediate evident anatomic characteristics of complexity. Each of these characteristics counts one if present! If 2 or more count 2 as index.
4. Significant **TO**rtuosity of SB (> 70 degrees) in bended segment involved
5. MB: Main Branch; SB: Side Branch

Table 2: CADATO Characteristics of Complexity for Side Branch lesions length intermediate (B)

Descriptive characteristics of complexity considered in intermediate length (6-10 mm, classified as B) side branch lesions (CADATO)

Calcification: Presence of significant calcification in the lesion.

Angle: Difficult angle of origin (<45° or >70°) between the main branch (MB) and side branch (SB).

Difficult Access or DAngerous: Possibility of difficulty accessing the wire (or balloon) for any reason or "dangerous" sb stenosis (extreme eccentricity of plaque, thrombus, TIMI flow <3, severe plaque burden in mb opposite/near the sb). Each of these characteristics is counted as 1 if present.

TOrtuosity: Presence of significant tortuosity of the SB (>70°) in the bended diseased segment.

This modification aims to provide a more nuanced classification, particularly for intermediate-length SB lesions, while maintaining simplicity and ease of application. By introducing a complexity index only for B lesions, we align with our belief that SB length is the primary determinant of bifurcation complexity. This refined approach results in Categories: X, X, 0 or 1A or 1B1 or 1B2 or 1C, where X can be 0 or 1, and adds a layer of detail for intermediate-length SB lesions without introducing unnecessary complexity for shorter or longer lesions.

Discussion

Clinical Considerations

We introduced a small subscript index (1 or 2) exclusively for letter B (denoting intermediate-length side branch lesions) in the Medina Modification Proposal. This decision stems from our belief that the length of the side branch (SB) is the dominant characteristic for describing bifurcations and making decisions about the 1- or 2-stent technique (for A-one stent upfront, for C-two stents upfront, see below). Consequently, only for intermediate-length lesions do we consider the additional complexity characteristics.

Implementation and Application

Our Modified Medina Classification results in classes: X, X, 0 or 1A or 1B1 or 1B2 or 1C, where X can be 0 or 1. This approach maintains simplicity and ease of remembrance while providing a more useful prediction of the technique (direct 2 stents or provisional) used and the potential outcomes. By introducing letters and complexity indices, we provide interventional cardiologists with a more granular classification that aids in decision-making regarding intervention strategies and the choice between a 1- or 2-stent approaches (Table 3). Below we present an example of utility in predicting techniques and outcomes:

Sb Lesions Length	Suggestion Of Predilatation Sb	First Treatment	Alternative Treatments As Bail Out If First Choice Provisional And Problems On Sb After Mb Stenting
Third Letter 1 (Side Branch Involved)			
A	**No**	**Provisional/Deb On Sb**	**Tap Or Culotte ++; Exceptionally T +/-**
B_1	**No**	**Provisional +++/- Deb On Sb**	**Tap Or Culotte**
B_2	**No/Yes -**	**Provisional +/-** **Deb On Sb T/Tap/Reverse Culotte/Crush**	**Culotte++/ Tap+/ Internal (Reverse) Crush**
C	**Yes**	**Crush/Culotte**	
SB (SIDE BRANCH); TAP (T And Protrusion); DEB (Drug Eluting Balloon).			

Table 3: Sb Lengths, Strategy and First Recommended Treatment

For A (up to 5 mm length SB), a provisional technique with MB stenting (1-stent technique) is preferred in most cases.

For B, the approach depends on complexity. For less complex cases (B1), provisional with MB stent and DEB on SB is often suitable. For more complex cases (B2), the decision is made after predilatation, potentially involving techniques like TAP, Reverse Culotte, or Internal/Reverse Crush if needed.

For C (>10 mm length), a 2-stent approach from the beginning is recommended, with extensive pretreatment of SB often DK Crush or Culotte.

Future Research

We underscore the critical importance of side branch (SB) lesion length in scientific literature. Different outcomes observed across studies often stem from the treatment of dissimilar populations, particularly in relation to SB lesion length. Establishing a common and reliable tool is imperative for comparing similar subpopulations in diverse studies, encompassing registries, randomized trials, and meta-analyses.

When contemplating all studies and accounting for SB lesion length, the calculated means can be unduly influenced by extreme values. For instance, a mean derived from one patient with an SB lesion length of 30mm and nine patients with an SB lesion length of 2mm yields a result of 4.8mm. However, this figure fails to accurately represent both sets of patients—those with shorter and longer SB lesion lengths. While the inclusion of the Standard Deviation in presented data aids in defining the range, it does not completely mitigate the risk of an incomplete characterization and inclusion of heterogeneous studied population.

As underlined already from many colleagues we agree that can look unfair not to stent very long lesions in SB, as in some recent study (DEFINITION II, DK CRUSH V also more than 20 mm), but in the same way we consider wrong to include in a randomized trial with 2 stents techniques patients with SB lesions short (for example in EBC MAIN SB lesion length in mm of 5.8 and 7.9 mm stented with stent length of 17.9, SD 6.9, and 19.3, SD 6.7). This was recently demonstrated also by the met analysis of Di Gioia et al. [18] that found that for SB lesions less than 10 mm there is no advantage of 2-stent technique, but this is present and significant for longer lesions, and by the paper of Bujak et al [19]. On Euro intervention, that shows advantage of 2-stents techniques only in SB lesions length >10.1 mm. For long SB lesions we suggest from beginning a 2-stent approach, without the fears of an adequate aggressive predilatation/pre-treatment. For short SB lesions the provisional approach is the preferred one, without the drawbacks of the 2-stents technique without any advantage added by the complexity. Finally for intermediate length SB lesions we suggest a more tailored and stepwise treatment, most depending on complexity characteristics and the result after predilatation and kissing. This approach seems also supported by the results of the already cited recent met analysis, showing that the value of 10 mm length of the SB lesion can be the watershed between 1- and 2-stent best results on bifurcation trials. It is obvious now that all the presented studies addressed treatment in different populations, making comparisons challenging. It is needed to do "consistent" studies and to compare different studies in a proper way (apples with apples, pears with pears!). Our categorization overcomes this problem, allowing for more homogeneous comparisons among similar lesion lengths. For example we can say that in a study X there is a distribution of SB lesions of 30% A, 20% B1, 20% B2, and 30% C, and in a study Y the distribution is completely different, like 10% A, 10% B1, 30%B2 and 50% C, so the comparison of the different results is now more really deeply and clearly understandable, and we still can properly compare subgroups of patients with the same length lesions of different studies and also different techniques. The exigence to further define lesions is a real need in clinical and scientific interventional work and was already recently applied also to CTO lesions [20]. This can clearly be useful also for more homogeneous and better meta-analyses.

Limitations

As with any modification, further research and validation studies are essential to assess the clinical utility and impact of this refined classification in real-world scenarios. Prospective trials and analyses of individual patient data could provide valuable insights into the effectiveness of this modification in guiding treatment decisions and optimizing outcomes. The Medina Modification shares some limitations with the original Medina, such as being a simple, "first-seen" evaluation rather than a comprehensive 3D assessment of bifurcations. The visual evaluation of SB length may be imperfect, but the primary aim of this classification is to categorize short, intermediate, and long lesions at first sight, guiding PCI toward a rational and planned approach. The B1 class can have 0 or 1 characteristic of complexity CADATO, covering different kinds of lesions. B1 and B2 lesions still will be evidently different population (simple vs complex) in intermediate length SB lesions, driving to different kind of approach/ interventions, with different probability of complications. The analysis at posteriori of the original individual patient data of some important original papers, most of which present some bias, although very difficult to obtain, will further prove the pros and cons of this proposed classification change. And new more uniform comparisons between studies will have less bias vs the old ones done up to now and will also improve quality of next studies on this field. About other limitations we remember that in most of published trials the "difficult" characteristics that we could recognize as CADATO are mostly reported as not mutually exclusive, so one patient could have more than one and so the cataloging of patients in one class or other could not be univocal if only imported by the tables on the original papers and not derived by true rough original data. But this should not preclude the identification of more complex cases, and for sure will not have any impact on SB lesions length, the determinant parameter to consider.

Conclusions

Our proposed Medina Modified classification aligns with the characteristics of an ideal classification system. It is simple, easy to remember, descriptive of relevant differences, and useful in predicting treatment techniques, outcomes, and complications. The need for consistent studies and proper comparisons between different studies is highlighted, ensuring that comparisons are made between similar subpopulations. This classification could prove valuable in prospective trials and contribute to more consistent and appropriate study comparisons. While we acknowledge certain limitations, we maintain that SB characteristics, particularly length, are the most crucial determinants of bifurcation complexity, influencing treatment techniques and patient outcomes. The actual and future more frequent use of Drug Eluting Balloons [21] instead

of the Drug Eluting Stents doesn't make less useful or needed this classification iteration.

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