

# Secondary branch patency in coronary angioplasty of bifurcation lesions with the provisional stent technique: clinical and angiographic follow-up

Permeabilidad del ramo secundario en angioplastia coronaria de lesiones en bifurcación con la técnica Stent Provisional: seguimiento clínico y angiográfico

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## ABSTRACT

Coronary bifurcation lesions account for 15% to 20% of all percutaneous coronary interventions (PCI). Treating these lesions remains a significant challenge for interventional cardiologists due to higher procedural costs, higher complication rates, and poorer outcomes compared to PCI for simple coronary lesions. In the era of drug-eluting stents (DES), several trials have compared provisional stenting (PS), a simple strategy, with complex 2-stent strategies; however, the optimal technique remains a controversial issue. Regardless of the strategy chosen, the initial procedural success regarding these lesions has been low due to its association with a risk of side branch occlusion. This study aims to analyze the characteristics of bifurcation lesions treated with provisional stenting, identify predictors of secondary branch patency related to various technical aspects or steps during the intervention, and assess, through angiographic follow-up, the incidence of lesion restenosis and the need for revascularization.

**Keywords:** (MeSH): angioplasty, stents, bifurcation, DES.

## RESUMEN

Las lesiones coronarias en bifurcación representan del 15% al 20% de las intervenciones coronarias percutáneas (ICP). El tratamiento de estas lesiones sigue siendo un desafío considerable para los cardiólogos intervencionistas debido a que se asocian con mayores costos del procedimiento, mayores tasas de complicaciones y peores resultados en comparación con la ICP de lesiones coronarias simples. En la era de los stents liberadores de fármacos (DES), se han publicado varios ensayos que comparan una estrategia simple como la técnica Stent Provisional (SP) con estrategias complejas de 2 stents; sin embargo, persisten las controversias sobre la elección correcta de la técnica e, independientemente de la estrategia, el éxito inicial del procedimiento en este tipo de lesiones ha sido más bajo, asociado con el riesgo de oclusión de la rama lateral. A partir de este estudio se pretenden analizar las características de las lesiones en bifurcación tratadas con técnica Stent Provisional, determinar predictores de permeabilidad del ramo secundario referidos a diferentes aspectos técnicos o pasos durante la intervención y evaluar con seguimiento angiográfico la incidencia de reestenosis de la lesión y la necesidad de nueva revascularización.

**Palabras clave:** (MeSH): angioplastia, stents, bifurcación, DES.

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## INTRODUCTION

Coronary bifurcation lesions account for 15% to 20% of all percutaneous coronary interventions (PCI)<sup>1</sup>. By definition, these lesions involve the exit of a secondary branch whose patency must be preserved due to its impact on clinical outcomes, given its size and the extent of its irrigation to the myocardium<sup>2</sup>. These lesions take on various forms of presentation, depending on plaque distribution and the number of bifurcation components involved. The Medina classification is currently the most widely accepted categorization in the field of interventional cardiology, due to its simplicity and practical utility. It is based on the identification of three bifurcation components: the proximal main vessel (PMV), distal main vessel (DMV), and the side branch (SB). Following this sequence, the classification assigns a binary value (1, 0) depending on whether the aforementioned bifurcation segments are involved or not. Accordingly, there are seven possible morphologies, including a subgroup termed “true bifurcations,” where significant disease is present in at least one component of

the main vessel (MV) and in the SB. These are {1,1,1}, {1,0,1}, {0,1,1}<sup>2</sup>. However, beyond the Medina classification, there are other characteristics that define a bifurcation lesion and make each case unique. The first aspect is the significance of the SB (its size in relation to the main vessel). Another aspect to consider, with technical implications, is lesion length at the SB level, which can be focal—only affecting the ostium—or extend over a greater length. Also relevant is the angle between the SB and the MV, and so are the ultrasound characteristics of the bifurcation (plaque distribution and carina morphology). After stenting in the MV, depending on all these features, the SB may experience dynamic changes leading to greater stenosis than before or even complete vessel occlusion<sup>3-5</sup>.

Treating these lesions remains a significant challenge for interventional cardiologists due to higher procedural costs, higher complication rates, and poorer outcomes compared to PCI for simple coronary lesions. When deciding on the treatment of bifurcation lesions, there are numerous techniques available, categorized as either simple or complex, with varying degrees of difference and levels of adoption (provisional stenting, Culotte, Crush, Minicrush, T-stenting with minimal protrusion, etc.)<sup>6</sup>. In the era of drug-eluting stents (DES), several published trials have compared provisional stenting (PS), a simple technique, with complex systematic 2-stent strategies; however, the optimal technique remains a controversial issue. Regardless of the strategy chosen, the initial procedural success regarding these lesions has been low, due to its association with a risk of side

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branch occlusion. Furthermore, long-term outcomes are linked to a high rate of reintervention<sup>7,8</sup>.

The term “simple” applied to a technique or strategy refers to techniques where a stent is placed in the MV, and SB stenting happens only after an unsuccessful outcome of the initial approach. This technique is called provisional stenting, stepwise technique, or stepwise approach. Similarly, we can define as “complex” a strategy where two stents are the initial consideration (two-stent technique) or cases of PS that derive in SB stenting. All published randomized studies show superiority of the simple or stepwise strategy over complex techniques<sup>9,10</sup>.

As mentioned earlier, in a simple or SP strategy, the SB is treated in case of significant stenosis and antegrade flow involvement, as opposed to systematically. Regarding the technique, an angioplasty guidewire is used towards the MV. Recommendations then suggest the use of a second guidewire towards the SB, even without significant lesion in this vessel, since its origin may be compromised by plaque and/or carina displacement during MV treatment. If necessary, balloon predilation of the MV may be considered. In some studies, SB predilation has been proven counterproductive because it may cause a proximal dissection that subsequently complicates the crossover. However, there is controversy on this point, and some teams predilate the SB without any subsequent major crossover difficulties. Regarding the choice of stent for the MV, an attempt should be made to adjust it to the diameter of the distal MV. Additionally, the chosen stent must be long enough to cover the bifurcation correctly. If there is a marked difference in diameter between the proximal and distal segments, it may be necessary to perform post-dilation with a larger-diameter balloon at the proximal segment of the stent (POT: proximal optimization technique) to correct malapposition. Once the stent is implanted in the MV, if the SB result is acceptable, the treatment is completed. If the SB result is suboptimal, a new angioplasty guidewire should be used to cross towards that branch, and angioplasty should be performed on the SB ostium. While performing such SB dilation using the kissing balloon technique (simultaneously using a balloon in the MV and a balloon in the SB) has been considered essential, various studies have shown that systematic use of kissing balloon (KB) in these cases, regardless of the result in the SB, does not provide any advantage. If balloon dilation of the SB results in an acceptable outcome, treatment can be concluded. If a good SB result is not achieved, SB stenting will be considered. Experts have described that, with the single-stent technique, final KB dilation does not seem to provide any benefit. In the case two-stent implantation, the recommendation is to always conclude treatment with simultaneous dilation in both branches<sup>12-14</sup>.

Based on this study, our aim is to analyze the characteristics of bifurcation lesions treated with the SP technique, determine predictors of SB patency related to various technical aspects or procedural steps, and evaluate the incidence of lesion restenosis and need for repeat revascularization through angiographic follow-up.

## MATERIALS AND METHODS

This observational and retrospective study included 45 patients who underwent bifurcation angioplasty with PS at the Department of Hemodynamics and Catheterization Interventions of Sanatorio Allende, Cerro branch, from July 1, 2017, to July 1, 2022.

Clinical data were collected from the digitalized medical records system, and angiographic and procedural data were obtained from the Department’s electronic database.

Bifurcated lesions were defined according to the previously described Medina classification.

The single-stent bifurcation lesion angioplasty technique, also referred to as PS, was defined as treating the main branch with a stent and then treating the side branch only in cases of significant stenosis and flow difficulty, as opposed to systematically.

The kissing balloon technique was defined as simultaneously inflating a balloon in the MV and another at the SB origin.

The POT technique was defined as post-dilation with a larger-diameter balloon in the proximal segment of the stent to correct malapposition. It is used when there is a significant difference in diameter between the proximal and distal segments of the vessel.

Researchers assessed various technical aspects of angioplasty, correlating them with side branch patency, percentage of restenosis, and need for treated vessel repeat revascularization through angiographic follow-up three months after the initial intervention.

## Statistical methodology

Data collected from medical records and angiographic studies were used to create an Excel database that was then used for statistical processing. For quantitative variables, measures of central tendency and dispersion (mean and standard deviation [SD]) were calculated. For categorical variables, absolute and percentage distributions were calculated. The chi-square test was applied to correlate categorical variables. In all cases, the significance level used was 0.05. The software used for statistical processing was InfoStat (v.2020). Results are presented as graphs or tables as appropriate.

## Inclusion criteria:

- Patients of both sexes.
- Angioplasty of *de novo* coronary bifurcation lesions using the PS technique.
- Bifurcation lesions with a SB diameter greater than 2 mm.
- PCI for silent ischemia, stable/unstable angina, or myocardial infarction.

## Exclusion criteria:

- Intended use of 2 or more stents.
- Left main coronary artery bifurcation lesions.
- Need to discontinue antiplatelet therapy before 6 months have passed.
- Patients without angiographic follow-up after 3 months post-intervention.

## RESULTS

During the study period, a total of 2107 coronary angiographies were conducted; 998 of them were performed on angioplasties and, of those, 159 were performed on bifurcation lesion angioplasties. Finally, 45 of those were performed on bifurcation lesions treated using the PS technique. That was the analyzed patient sample (**Figure 1**).

Most of these patients were men, about 82% of the total. Regarding age, the mean was 60.1 years (SD = 12.6), with ages ranging from 39 to 92 years. As for comorbidities, 51% of patients were hypertensive, 44% were smokers, and 33% were diabetic (**Table 1**).

**TABLE 1.** General characteristics of the sample (n = 45).

Variables	Values
Age (in years) - mean (SD)	60,1 (12.6)
Sex - n (%)	
Women	8 (18%)
Men	37 (82%)
Comorbidities - n (%)	
Hypertension	23 (51%)
Smoking	20 (44%)
Prior MI	12 (27%)
Diabetes	15 (33%)
Prior PCI	12 (27%)

The most frequent clinical presentations were ST-segment elevation acute coronary syndrome (STEACS), 38%, and exertional angina, 27%. The access sites were, in similar proportions, the transradial and transfemoral: 49% and 51%, respectively. In the vast majority of patients (80%), the bifurcation lesion was located in the left anterior descending artery with the diagonal branch.

According to the Medina classification of coronary bifurcation lesions, 67% were type 1,1,1 and 24% were type 1,1,0 (Figure 2).

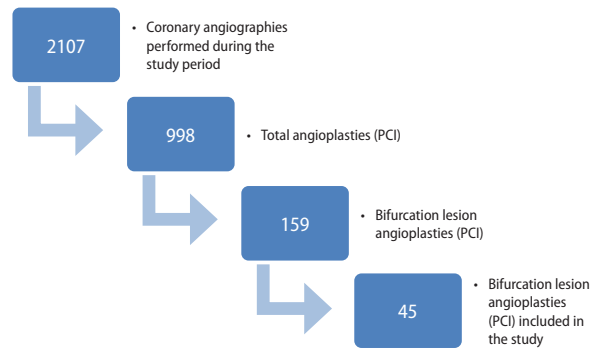
Twenty percent (9) of patients had their SB protected with a guidewire. When correlating SB protection with a guidewire with vessel patency at the end of the procedure and at follow-up, there was a significant difference in SB patency at the end of the procedure (Table 2). All patients without guidewire protection had SB patency, while, among those who received protection, the patency rate was 89% (11% experienced SB occlusion).

In 11% (5) of patients, the SB was predilated with a balloon. When correlating SB predilation with patency, there was a significant difference at the end of the procedure, where all patients without SB predilation had patency, while, among those with predilation, the patency rate was 80% (Table 3). As regards guidewire crossover to the SB, it was observed in 38% (28) of the total patients. Ninety-four percent of patients who underwent guidewire crossover to the SB had SB patency both at the end of the procedure and at follow-up. The difference with patients who did not undergo crossover was not significant.

Additionally, the kissing balloon technique was used at the end of the procedure on 36% (29) of patients. There was no significant correlation between the final use of the kissing balloon technique and SB patency, neither at the end of the procedure nor at follow-up. Forty-nine percent of patients were reassessed because they experienced chest pain. Eighteen percent of cases underwent target lesion revascularization, and 16% had STEACS (Figure 3).

The average time elapsed until the follow-up study was 11.2 months (SD = 9.8), ranging from 3 months to a maximum of 38 months.

Finally, during the angiographic follow-up, out of all the patients, only one had restenosis with total intrastent occlusion of the main vessel, and another one had moderate neointimal proliferation. The first patient underwent myocardial revascularization surgery. The remaining patients did not experience significant MV restenosis. Regarding the SB, only 4% (2) patients had complete SB occlusion. Of the

**Figure 1.** Number of bifurcation lesion angioplasties according to the inclusion criteria.

96% who had SB patency, 44% (19) patients had severe involvement (equal to or greater than 70%). None of them required repeat target-lesion revascularization.

## DISCUSSION

Coronary bifurcation lesions vary widely, with a wide range of bifurcation angles and MV and SB diameters. As a philosophy, “simplifying the complex” has been supported by several clinical trials demonstrating that the PS technique is associated with better clinical outcomes compared with a routine two-stent approach. However, for the first time ever, the DKCRUSH II trial reported a reduced restenosis rate using the DK-CRUSH (double kissing-crush) technique with two stents in true bifurcations (Medina 1,1,1 or Medina 0,1,1), compared with the PS technique<sup>15</sup>.

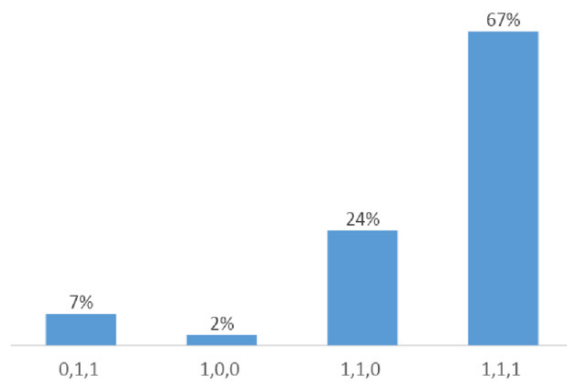
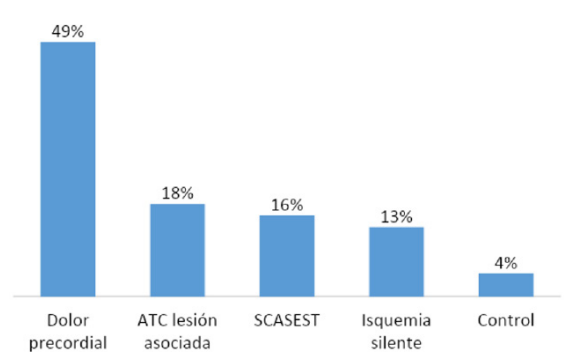
Among patients in whom the PS technique was used, the optimal SB treatment remains uncertain. An unresolved issue is whether final KB dilation should be performed. In the Nordic-Baltic Bifurcation Study III, patients with bifurcation lesions in whom the PS technique was used were randomized to final KB dilation or not. At the 8-month follow-up, there were no significant differences in terms of restenosis and major adverse cardiac events<sup>14</sup>. In our study, there were no significant differences either in terms of BS patency with and without final KB dilation. Another question regarding the technique is whether SB balloon angioplasty is necessary, especially in less complex bifurcation lesions. The COBIS III study analyzed 2194 patients with bifurcation lesions who underwent PCI using the PS technique. Of them, 23.2% underwent SB balloon angioplasty; these patients had more complex lesions, mostly true bifurcations (Medina 1,1,1 or 0,1,1). In this group, the percentage of SB stenosis was lower after the procedure. However, there were no significant differences in the primary endpoint of target-lesion failure at the 5-year follow-up compared with those who did not undergo SB balloon angioplasty<sup>16</sup>. After analyzing this point in our work, we found a significant difference regarding the SB patency at the end of the procedure: there was SB patency in all patients who underwent SB balloon dilation compared with 20% occlusion in those who underwent balloon angioplasty. This could be due to the fact that the patients who underwent SB balloon angio-

**TABLE 2.** SB occlusion and patency according to SB protection.

Variables	Categories	SB guidewire				p-value
		No (n = 36)		Yes (n = 9)		
		Number of patients	Percentage	Number of patients	Percentage	
SB occlusion after MV stenting	No	35	97%	8	89%	0.278
	Yes	1	3%	1	11%	
SB patency at the end of the procedure	No	0	0%	1	11%	<b>0.043</b>
	Yes	36	100%	8	89%	
SB patency at follow-up	No	1	3%	1	11%	0.278
	Yes	35	97%	8	89%	

**TABLE 3.** SB occlusion and patency according to SB predilation.

Variables	Categories	SB predilation				p-value
		No (n = 40)		Yes (n = 5)		
		Number of patients	Percentage	Number of patients	Percentage	
SB occlusion after MV stenting	No	39	98%	4	80%	0.073
	Yes	1	3%	1	20%	
SB patency at the end of the procedure	No	0	0%	1	20%	<b>0.004</b>
	Yes	40	100%	4	80%	
SB patency at follow-up	No	1	3%	1	20%	0.073
	Yes	39	98%	4	80%	

**Figure 2.** Distribution of the sample according to lesion type (n = 45).**Figure 3.** Distribution of the sample according to reason for reassessment (n = 45).

plasty had more complex bifurcated lesions that were true bifurcations according to the Medina classification.

Regarding POT, it is particularly important in those patients who undergo final KB dilation to avoid geometric distortion of the proximal segment of the stent in the MV<sup>17</sup>. Currently, the vast majority of studies recommend routine POT after MV stenting to correct stent underdeployment and malapposition<sup>18</sup>. In our study, POT was performed in 48% of patients; however, there were no differences in terms of SB patency or lesion restenosis at follow-up compared with patients who did not undergo POT.

Even though it still is subject to great debate, the provisional stenting technique continues to be the preferred strategy in most cases of bifurcation lesion. This technique allows for a flexible start to the procedure, i.e., it is based on the results.

While some studies have shown less restenosis with the two-stent strategy, this method was not superior to the PS technique in terms of adverse cardiovascular events and it increased procedure time, contrast use, radiation dose, and costs<sup>15</sup>.

## CONCLUSION

Based on our site's experience with coronary angioplasty in bifurcation lesions using the PS technique, patients who underwent some kind of intervention in the SB (protection with guidewire, predilation, or crossover), experienced a higher rate of occlusion. Most patients were reassessed with angiography after reporting chest pain; however, the rates of restenosis were minimal, and none of them required repeat target-lesion revascularization.

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