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ORIGINAL ARTICLE

Behavior of percutaneous coronary intervention in bifurcation lesions

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ABSTRACT

Introduction: bifurcation lesions, as a manifestation of coronary atherosclerosis, represent one of the greatest challenges in percutaneous coronary intervention.
Objectives: to characterize the outcomes of percutaneous coronary intervention in patients with bifurcation lesions treated at the Hermanos Ameijeiras Clinical Surgical Hospital between January 2016 and December 2017.
Methods: a prospective, longitudinal observational study was conducted in a series of patients diagnosed with coronary artery disease involving bifurcation lesions treated with percutaneous coronary intervention. A probabilistic simple random sampling was performed, selecting 143 patients. Data were obtained through document review, and descriptive and inferential statistical methods were applied.
Results: the mean age was 61,9 years, with a predominance of men (78,3 %) and hypertensive patients (81,1%). Lesions were mostly longer than 20 mm (76,2 %), severely calcified (72,7 %), thrombotic (45,5 %), located in the anterior descending–diagonal bifurcation (57,3 %), and classified as Medina 1-1-0 (40,6 %). The simple strategy was predominantly used (88,2 %), with drug-eluting stents implanted in 55,2 %. During follow-up, the most frequent adverse events were stent thrombosis (4,8 %), restenosis (4,1 %), and cardiac death (3,4 %), with no statistically significant associations identified due to the low number of complications.
Conclusions: patients with cardiovascular risk factors and stable ischemic heart disease predominated among those treated with percutaneous coronary intervention, with stent thrombosis and restenosis being the most frequent adverse events.

Keywords: Angioplasty, Balloon, Coronary; Coronary Artery Disease; Percutaneous Coronary Intervention; Stents.

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INTRODUCTION

In the last decade, cardiovascular diseases (CVD) have become the leading cause of death worldwide, responsible for 16 million annual deaths, resulting in the loss of 293 million disability-adjusted life years (DALYs), which represents nearly 30 % of all deaths and 11 % of the total years lost.[1]

In Cuba, heart diseases have been the main cause of death among the population aged over 60 for more than four decades. In the years 2011 and 2012, a total of 22,237 and 22,234 deaths were reported, corresponding to mortality rates of 198,0 and 197,6 deaths per 100,000 inhabitants, respectively. Within this group, ischemic heart disease is the most prevalent and accounts for one in every four deaths, representing almost 80 % of all cardiac-related deaths in both sexes. The mortality rate from this condition has increased by 5 %, with the number of deaths from ischemic heart disease rising from 9,748 in 1970 (rate of 114,0 per 100,000 inhabitants) to 15,429 in 2013 (rate of 138,2 per 100,000 inhabitants), primarily affecting males, while the female mortality rate has remained stable at 127 per 100,000 women.[2,3]

Coronary artery disease is the single most common cause of death globally. Over seven million people die each year due to ischemic heart disease, accounting for 12,8 % of all deaths.[4] Among men, prevalence increases with age—from 7 % between ages 40–49, to 13% between 50–59, 16 % between 60–69, and 22 % between 70–79 years. In women, prevalence is somewhat lower (5 %, 8 %, 11 %, and 14 %, respectively).[5]

This disease is the leading cause of morbidity and mortality in patients with Diabetes Mellitus (DM). In the United States, approximately 1,5 million coronary interventions are performed annually, including Coronary Artery Bypass Grafting (CABG) and Percutaneous Coronary Interventions (PCI), of which an estimated 25 % involve diabetic patients. Technological advances have continuously refined diagnostic methods, enabling early treatment with optimal outcomes; however, experts remain concerned about the high incidence, mortality, and lethality rates.[6,7]

In this context, bifurcation lesions (BL)—a common manifestation of ischemic heart disease—represent one of the greatest challenges in percutaneous coronary intervention and are regarded by many authors as its final frontier. These lesions occur at arterial bifurcations, areas of high endothelial stress due to turbulent blood flow, which promotes atherosclerosis. Although multiple definitions exist, a true bifurcation lesion is generally accepted as involving stenosis greater than 50 % within 3 millimeters of the carina, affecting segments such as the proximal main vessel, distal main vessel, and the side branch.[8,9]

In the early days of PCI, bifurcation lesions were primarily an indication for coronary artery bypass surgery, as results obtained with balloon angioplasty and subsequent volume-reduction techniques proved unsatisfactory. With the introduction of new stent generations in the 1990s, PCI became a viable surgical alternative, leading to the development of novel treatment techniques.[10,11]

From the interventional cardiologist's perspective, these lesions have posed special difficulties, yielding inferior immediate and mid-term outcomes. Thus, they remain a subject of ongoing debate—motivating the present study, which aimed to characterize the results of percutaneous coronary intervention in patients with bifurcation lesions treated at Hermanos Ameijeiras Clinical and Surgical Hospital between January 2016 and December 2017.

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METHODS

An observational, descriptive, prospective longitudinal study was conducted on a series of patients diagnosed with coronary artery disease and bifurcation lesions treated with percutaneous coronary intervention at "Hermanos Ameijeiras" Clinical and Surgical Hospital from January 2016 to December 2017.

The study population consisted of all patients with coronary artery disease presenting bifurcation lesions who met the inclusion criteria (patients undergoing percutaneous coronary intervention, with proper informed consent obtained from their families) and exclusion criteria (patients with left main coronary bifurcation lesions, as this represents a different clinical scenario compared to other coronary bifurcations, as well as those unable to attend follow-up appointments). Using simple random probabilistic sampling, a sample of 143 patients was selected.

Documentary review of individual medical records, coronary angiography request forms, Percutaneous Transluminal Coronary Angioplasty (PTCA) reports, and outpatient follow-up records allowed collection of data for the analyzed variables: age, sex, presence of cardiovascular risk factors (hypertension, diabetes mellitus, dyslipidemia, smoking, obesity), prior restenosis, prior myocardial infarction, clinical diagnosis, lesion location, main vessel lesion length >20 mm, Medina classification, lesion angulation, severe calcification, thrombus presence, procedural technique used, side branch pre-dilation, main vessel pre-dilation, proximal optimization technique (POT), final kissing balloon, sequential inflation, stent type used, and occurrence of major adverse cardiac events.

PCI was considered effective when, upon procedure completion, residual stenosis in the treated vessel was ≤20 %, epicardial artery flow was TIMI grade III, and no major complications occurred during the procedure. Following intervention, patients were monitored after hospital discharge: evaluated at one week, then monthly for the first six months, and subsequently every three months until completing one year of follow-up.

At each visit, clinical status was assessed (presence of angina or angina-equivalent symptoms), prompting exercise stress testing and/or invasive coronary angiography as clinically indicated. The exercise stress test was deemed positive if any of the following occurred: inability to complete stage II of the Bruce protocol due to dyspnea or angina; ischemic ST-segment depression >2 mm before completing stage II of the Bruce protocol; early onset (stage 1) or prolonged duration of ST-segment depression after exercise cessation; ST depression in five or more ECG leads; flat or decreased systolic blood pressure response with increased workload; angina during testing necessitating exercise termination; or heart rate <120 beats/minute at symptom-limited effort.

Patients presenting with Canadian Cardiovascular Society (CCS) functional class III or IV angina underwent coronary angiography. Asymptomatic patients were followed as per the previously described protocol.

Throughout the follow-up period, patients and their families were instructed to contact a member of the research team immediately if any symptoms or adverse events recurred, who would then provide guidance on appropriate management.

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Data processing and analysis

Descriptive statistical analysis was performed using the SPSS statistical software package, version 13,0 based on simple randomized sampling. Summary measures (percentages), means, and standard deviations were used for quantitative and qualitative variables. The Chi-square test for comparison of proportions was applied to qualitative variables. Where statistical test limitations existed, Fisher's exact probability test was used. For quantitative variables, hypothesis tests comparing means in independent samples were conducted using Student's t-statistic, as well as the Mann-Whitney U test. A p-value <0,05 was considered statistically significant in all cases. Results are presented in tables.

Ethical considerations

This study adhered to the ethical principles for medical research involving human subjects as outlined in the Declaration of Helsinki. Patient confidentiality was respected, and all data were handled appropriately and used exclusively for research purposes. The study protocol was submitted to and subsequently approved by the scientific committee of "Hermanos Ameijeiras" Clinical and Surgical Hospital.

RESULTS

The sample had a mean age of 61,9 ± 9,3 years (95 % CI: 60,3–63,4), with a male predominance (78,3 %). The most frequent comorbidities were hypertension (81,1 %), dyslipidemia (74,1 %), smoking (37,1 %), and obesity (36,4 %), while diabetes mellitus was present in 18,9 %. Previous restenosis was recorded in 15,4 % of cases, and prior myocardial infarction in 28 %. Regarding clinical diagnosis, most patients presented stable ischemic heart disease (56,6 %), followed by non-ST-elevation acute coronary syndrome (30,1 %) and ST-elevation acute coronary syndrome (13,3 %).

In the analyzed cohort, angiographic characteristics (Table 1) showed a predominance of main vessel lesions longer than 20 mm (76,2 %) and severe calcification (72,7 %). Nearly half of cases exhibited thrombus (45,5 %) and side branch angulation greater than 70 degrees (44,1 %). According to Medina classification, the most common variant was 1-1-0 (40,6 %), followed by 1-1-1 (23,3 %) and 1-0-1 (14,7 %). Regarding lesion location, the anterior descending–diagonal bifurcation was most frequent (57,3 %), followed by circumflex–obtuse marginal (30,1 %), while other locations were less common.

Table 1. Angiographic characteristics.

Variable		No.	%
Lesion > 20 mm in main vessel		109	76,2
Side branch angulation > 70°		63	44,1
Severe calcification		104	72,7
Presence of thrombus		65	45,5
Medina classification	0-0-1	7	4,9
	0-1-0	11	7,7
	0-1-1	9	6,3
	1-1-1	34	23,3
	1-1-0	58	40,6
	1-0-1	21	14,7

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	1-0-0	3	2,1
Lesion location	Right coronary artery – acute marginal	2	1,4
	Right coronary artery – posterior descending	6	4,2
	Right coronary artery – posterolateral	8	5,6
	Circumflex – obtuse marginal	43	30,1
	Left anterior descending – diagonal	82	57,3
	Left anterior descending – first septal	2	1,4

The table 2 shows the technical variables of the procedures performed, with the simple technique being predominant, applied in 126 patients (88,2 %), while the complex strategy was used in 11,8 %. Among the associated procedures, vascular predilatation of the main vessel was performed in 60,8 % of cases and the proximal optimization technique in 44,8 %. The use of predilatation in the secondary vessel was observed in 28,0 % the final kissing balloon in 18,2 %, and sequential inflation in 8,4 %. Regarding the type of stent implanted, drug-eluting stents were the most employed (55,2 %), compared to conventional metallic stents (44,8 %).

Table 2. Technical variables of the procedures performed.

Variable		No.	%
Strategy used	Simple Strategy	126	88,2
	Complex Strategy	17	11,8
Associated procedures	Secondary vessel predilatation	40	28,0
	Main vessel predilatation	87	60,8
	Proximal optimization technique	64	44,8
	Final Kissing Balloon	26	18,2
	Sequential inflation	12	8,4
Stent type	Metallic stent	64	44,8
	Drug-eluting stent	79	55,2

When analyzing the incidence of adverse cardiac events during follow-up, it can be observed that stent thrombosis was the adverse event that occurred most frequently (4,8 %), followed by stent restenosis and death from cardiac causes at 4,1 % and 3,4 %, respectively.

In Table 3, the relationship between clinical, angiographic, and procedural technique variables and the occurrence of stent thrombosis is shown, with no statistically significant relationship identified. These patients had a lower mean age (54,4 years) compared to those who did not develop thrombosis (62,2 years). All cases were male, the majority with arterial hypertension (85,7 %) and dyslipidemia (71,4 %). Stable ischemic heart disease was the predominant clinical context (57,1 %), and the most frequent lesion topography was the left anterior descending with a diagonal branch (71,4 %). In 100 % of cases, lesions longer than 20 mm in the main vessel were observed, and the most common Medina anatomical variant was 1-1-1 (57,1 %). From a technical standpoint, all were treated with a simple strategy; none of the patients who underwent final "kissing balloon" experienced thrombosis. Regarding the type of stent, drug-eluting stents were associated with 57,7 % of cases. Overall, no statistically significant association was found between the studied variables and stent thrombosis, a finding that was probably influenced by the small number of affected patients.

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Table 3. Relationship between clinical, angiographic, and procedural variables and the occurrence of stent thrombosis.

Variable		Reestenosis del stent		p Valor
		Si [n=6] No. (%)	No [n=137] No. (%)	
Age		55,8±8,9	62,1±9,2	0,148[b]
Sex	Male	6 (100)	106 (77,4)	0,340[b]
	Female	0 (0)	31 (22,6)	
Hypertension		4 (66,7)	112 (81,8)	0,317[b]
Diabetes Mellitus		0 (0)	27 (19,7)	0,594[b]
Dyslipidemia		6 (100)	107 (78,1)	0,343[b]
Smoking		3 (50,0)	50 (36,5)	0,670[b]
Stable Ischemic Heart Disease		5 (83,3)	76 (55,5)	0,234[a]
Anterior Descending - Diagonal		4 (66,7)	79 (57,7)	1,000[a]
Lesion > 20 mm en RP		5 (83,3)	104 (75,9)	1,000[b]
Medina classification1-1-1		3 (50,0)	31 (22,6)	0,146[a]
Severe Calcification		3 (50,0)	101 (73,7)	0,345[b]
Presence of Thrombi		4 (66,7)	61 (44,5)	0,411[b]
Strategy used	Simple strategy	6 (100)	120 (87,6)	O,624[b]
	Complex Strategy	0 (0)	17 (12,4)	
Proximal Optimization Technique		2 (33,3)	62 (45,3)	0,691[b]
Final Baloon Kissing		0 (0)	26 (19,0)	0,592[b]
Type of stent used	Metalic Stent	1 (16,7)	63 (46,7)	0,225[b]
	Drug-Eluting Stent	5 (83,3)	74 (54,0)	

Notes: SD (standard deviation); a (Mann - Whitney U test); b (Fisher's exact test)

In Table 5, it can be seen that in the 5 cases (3,5 %) that presented cardiac - related death, the mean age was lower (54,8 years) compared to those who did not die from this cause (62,0 years). All were hypertensive men, without diabetes mellitus, and with lesions greater than 20 mm in the main vessel, characterized by a high thrombus burden. The most frequent location of the lesion corresponded to the left anterior descending artery and a diagonal branch (80,0 %), while the predominant Medina anatomic variant was 1 - 1 - 1 (60,0 %). From a technical standpoint, all were treated with a simple stent implantation strategy; none of the patients who underwent a "kissing balloon" procedure experienced this complication. Regarding the type of stent, drug - eluting stents were associated with 60,0 % of the cases. Overall, no statistically significant association was found between clinical, angiographic, or procedural variables and cardiac - related mortality, a finding that was probably conditioned by the small number of affected patients.

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Table 5. Relationship between clinical, angiographic, and procedural variables and cardiac - related death.

Variable		Death by heart attack		p Valor
		Si [n=5] No. (%)	No [n=138] No. (%)	
Age		54,8±13,9años	62,05±9,0años	0,222[b]
Sex	Male	5 (100)	107 (77,5)	0,585[b]
	Female	0 (0)	31 (22,4)	
Hypertension		5 (100)	111 (80,4)	0,584[b]
Diabetes Mellitus		0 (0)	27 (19,5)	0,584[b]
Dyslipidemia		2 (40,0)	111 (80,4)	0,062[b]
Smoking		3 (60,0)	50 (36,2)	0,360[b]
Stable Ischemic Heart Disease		3 (60,0)	40 (28,9)	0,653[a]
Anterior Descending - Diagonal		4 (80,0)	79 (57,2)	0,399[a]
Lesion > 20 mm en RP		5 (100)	104 (75,3)	0,339[b]
Medina classification1-1-1		3 (60,0)	31 (22,4)	0,087[a]
Severe Calcification		2 (40,0)	102 (73,9)	0,125[b]
Presence of Thrombi		5 (100)	60 (43,4)	0,118[b]
Strategy used	Simple strategy	5 (100)	121 (87,6)	0,526[b]
	Complex Strategy	0 (0)	17 (12,3)	
Proximal Optimization Technique			63 (45,6)	0,380[b]
Final Baloon Kissing			26 (18,4)	0,585[b]
Type of stent used	Metalic Stent	2 (40,0)	62 (44,9)	0,599[b]
	Drug-Eluting Stent	3 (60,0)	76 (55,0)	

DISCUSSION

ICP has become the first - line treatment for addressing a coronary artery bifurcation over time, which was one of the reasons that motivated the present study. In our series, the mean age was 61,9±9,3 years, and the results corresponded to those published by other authors, such as Arrieta and colleagues,[12] who reported a mean age of 55,8 years in a six - month follow - up of patients with bifurcation lesions treated with stent placement.

In a contemporary analysis, Burzotta and colleagues,[13] within the framework of the European Bifurcation Club, reported in their consensus on percutaneous coronary intervention in bifurcation lesions that the mean age of patients was 65 years, very close to that of our cohort. This finding reinforces the role of aging on the coronary arterial system, characterized by progressive fibrosis, vascular remodeling, and endothelial degeneration that favor accelerated atherogenesis. Regarding sex, the same document describes that approximately 78 % of patients were men, a proportion that coincides with the male predominance observed in our study (78,3 %). These results align with those previously published by other national and international research groups, consolidating the evidence on the demographic profile of patients with bifurcated coronary artery disease treated with complex stent techniques.

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In an updated analysis, the ESC Atlas of Cardiovascular Disease Statistics 2023 reports that hypertension continues to be the most prevalent risk factor in patients with coronary artery disease, with figures ranging from 60 % to 70 % in European cohorts, which is close to the results of our series (81,1 %). This high proportion is explained by the intimate association between hypertension and coronary artery disease, where elevated pressure favors vascular remodeling and accelerates atherosclerotic progression. Regarding clinical diagnosis, it is confirmed that stable ischemic heart disease remains the most frequent reason for percutaneous coronary intervention, in line with what was observed in our group (56,6 %) and with what was published by Arrieta Maturino and colleagues, who reported a predominance of 79,3 % of cases with this condition. This finding is justified because patients with stable ischemic heart disease remain in a stable state for long periods, interrupted by episodes of instability, and may also be conditioned by the organizational characteristics of each healthcare center, such as the availability of emergency services for chest pain.[14]

The angiographic characteristics of bifurcation lesions continue to be determinants of short - and long - term outcomes of percutaneous coronary intervention. In our cohort, the length of the lesion in the main vessel greater than 20 mm was present in 76,2 % of patients. Similar data were reported by Kojima and colleagues,[15] in Japan, who observed that most patients with bifurcation lesions had lengths greater than 20 mm in the main vessel, which was associated with greater technical complexity and risk of adverse events during follow - up. In contrast, recent studies such as that of Khan and colleagues,[16] in the United Kingdom, in patients treated with the latest generation of stents, described an average lesion length in the main vessel close to 18 mm, which was linked to better clinical and angiographic outcomes. These findings reinforce the importance of lesion length as a prognostic factor in coronary bifurcation intervention.

Lesion calcification continues to be a critical variable that can complicate the evolution of any interventional coronary procedure. In our series, lesions with severe calcification predominated, a finding that coincides with what was reported by Ali and colleagues,[17] in the international ROTA - DES registry, where it was documented that more than 60 % of patients undergoing percutaneous coronary intervention had moderate to severe calcification. This degree of calcification was associated with greater technical complexity, the need for plaque modification devices, and an increase in adverse events during follow - up. Similarly, Yamamoto and colleagues,[18] in Japan confirmed that the presence of severe calcification in bifurcated coronary lesions conditions less favorable outcomes, reinforcing the importance of this variable as a prognostic determinant in contemporary clinical practice.

In our cohort, the most affected bifurcation was the left anterior descending - diagonal. This finding coincides with what was reported by Burzotta and colleagues,[19] who describe that the most frequently compromised anatomic location in percutaneous coronary interventions of bifurcations is the left anterior descending artery and one of its diagonal branches. As explained in that document, this predilection is due to the high endothelial stress and shear forces that characterize the left anterior descending artery and its bifurcations, factors that favor the acceleration of the atherosclerotic process and condition the need for complex stent techniques in this region.

Regarding the Medina classification, the present study shows a predominance of the 1 - 1 - 0 variety. In contemporary multicenter registries such as that of Kojima and colleagues,[15] in Japan, it was evidenced that the most commonly treated variety was the 1-1-1, with a proportion close to 35 %. These modalities of the Medina classification are recognized as high - complexity anatomic scenarios, which condition the intervention strategy and can significantly influence short - and long - term clinical and angiographic outcomes.

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The simple strategy is considered the best interventional option for addressing most lesions that affect a coronary bifurcation. As we observed earlier, it was the one that predominated in our study with 88,2 %. We can say that these results coincide with those exposed by Chen and colleagues.[20] Another study reports this strategy as the choice, demonstrating better short - and long - term outcomes.[21]

Predilatation of the main vessel before releasing the stent conditions a favorable vascular architecture for better stent adaptation to the vascular tree, although it is known that it can increase the risk of vessel dissection by over - inflation. In our study, as previously expressed, it was performed on 87 patients for 60,8 %, a figure that does not differ from what was recently published in the PROGRESS - BIFURCATION registry, where it is reported that predilatation of the main vessel was carried out in 59,2 % of cases, with favorable results in terms of correct stent expansion and low incidence of major complications.[22]

In our work, stent thrombosis, stent restenosis, and cardiac - related death were found as major adverse cardiac events. As previously exposed, they occurred in 4,8 %, 4,1 %, and 3,4 %, respectively. These are serious short - and long - term complications of the interventional procedure, both in lesions that affect a coronary bifurcation and in those that are outside of these. Similar results have recently been published in a national Swedish study, which included patients treated with percutaneous coronary intervention in LAD - D1 bifurcation lesions.[23] In that work, stent thrombosis was reported in 5,1 %, restenosis in 4,6 %, and cardiac - related mortality in 3,2 %, confirming that these complications continue to be relevant in contemporary clinical practice and comparable to the figures previously described in the international literature. These findings reinforce what was observed in previous studies, such as that of Liang and colleagues,[24] who found thrombosis and restenosis in 5,4 % and 4,8 % of their patients, respectively, and that of Galassi and colleagues,[25] where cardiac - related mortality occurred in 3,5 % and 3,4 % of the lesions treated with the Mini - Crush and T - Provisional techniques.

Stent thrombosis continues to be an infrequent but feared complication in patients treated with percutaneous coronary intervention, occurring more frequently in patients with bifurcation lesions since these are areas of high anatomic complexity, where sometimes complete stent apposition to the vascular wall cannot be achieved, areas where endothelial dissections at the bifurcation margin expose residual thrombus that protrudes into the vascular lumen constituting a highly thrombogenic substrate.[24]

Although there have been multiple variables related to a higher incidence of stent restenosis, such as clinical, genetic, angiographic, and procedural factors, only some have been more consistently identified in different published studies. Among these are diabetes mellitus, smaller reference vessel diameter, the restenotic nature of the lesion, ostial location, the number, total length, and type of stents implanted per lesion, implantation in the left anterior descending artery, and the presence of greater residual stenosis. These findings were recently corroborated in a meta - analysis by Rohman and colleagues,[26] which included more than 20 contemporary studies on drug - eluting stents. In that work, the presence of diabetes mellitus, smaller treated vessel diameter, accumulated length of implanted stents, and ostial lesion location were identified as independent predictors of restenosis, confirming that these factors maintain their clinical relevance in the modern era of coronary intervention.

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Cardiac - related death is the most feared episode when evaluating the outcomes of a given interventional procedure. It is also a variable that is frequently used as an endpoint in most clinical research in Cardiology and other specialties. In our study, it was one of the major adverse events that occurred during follow - up, with an incidence of 3,4 % of the total patients. Similar results have been reported in a national Swedish study, where cardiac - related mortality after percutaneous coronary intervention in bifurcation lesions occurred in 3,2 % of patients during prolonged follow - up.[23]

CONCLUSIONS

In the study, male patients predominated with a history of hypertension and diabetes mellitus, in addition to presenting atherosclerotic disease in the bifurcation that compromised the left anterior descending artery and one of its diagonal branches, with stable ischemic heart disease being the clinical diagnosis that motivated the percutaneous coronary intervention; during follow - up, stent thrombosis was the most frequent adverse event, followed by restenosis and cardiac - related death, with no statistically significant relationship found between clinical, angiographic, and procedural variables and the observed adverse cardiac events.

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