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Percutaneous coronary intervention in bifurcation lesions: independent predictors of in-hospital death

Intervenção coronária percutânea em lesões de bifurcações: preditores independentes de óbito hospitalar

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ABSTRACT – Background: Bifurcation lesions remain a challenge and little is known about the characteristics and outcomes of percutaneous coronary intervention over the last decade with the increasing use of drug-eluting stents. The objective of this study was to identify the patient profile and the in-hospital outcomes as well as the predictors of in-hospital death over time. **Methods:** An observational, retrospective study that evaluated patients undergoing percutaneous coronary intervention for bifurcation lesions between 2006 and 2016. Patients were divided into three groups: 2006-2008 (Group 1), 2009-2011 (Group 2), and 2012-2016 (Group 3). We used multiple logistic regression analysis to identify independent predictors of in-hospital death. **Results:** A total of 36,608 patients were included, and Group 3 patients were older, with a higher number of comorbidities, more stable clinical presentation and lesions treated with longer stent length and smaller stent size. The success of the procedure was higher (96.1% vs. 97.4% vs. 98.1%; $p < 0.0001$) and the mortality lower (1.2% vs. 0.7% vs. 0.6%; $p < 0.0001$) in the most recently treated group. In the multiple logistic regression analysis, female sex, left main coronary artery lesions, primary percutaneous coronary intervention, rescue percutaneous coronary intervention, procedures performed between 2006-2008 and use of glycoprotein IIb/IIIa inhibitors were variables independently associated with in-hospital mortality. **Conclusions:** Female sex, acute clinical presentation, emergency percutaneous coronary intervention, and greater anatomical complexity were associated with in-hospital mortality in patients undergoing coronary bifurcation treatment. Advances in contemporary treatment possibly contributed to the clinical outcome improvement in these patients.

Keywords: Percutaneous coronary intervention; Endovascular procedures; In-hospital mortality

RESUMO – Introdução: Lesões em bifurcações continuam sendo um desafio e pouco se sabe das características e dos resultados da intervenção coronária percutânea ao longo da última década com a utilização crescente dos stents farmacológicos. O objetivo deste estudo foi identificar o perfil do paciente e os desfechos hospitalares, bem como os preditores independentes de morte hospitalar, ao longo do tempo. **Métodos:** Estudo observacional, retrospectivo que avaliou pacientes submetidos à intervenção coronária percutânea em bifurcações entre 2006 e 2016. Os pacientes foram divididos em três grupos: 2006-2008 (Grupo 1), 2009-2011 (Grupo 2) e 2012-2016 (Grupo 3). A análise de regressão logística múltipla buscou identificar preditores independentes de óbito hospitalar. **Resultados:** Foram incluídos 36.608 pacientes, sendo que pacientes do Grupo 3 eram mais idosos, com maior número de comorbidades, quadros clínicos mais estáveis e lesões tratadas com stents de menor calibre e mais longos. O sucesso do procedimento foi maior (96,1% vs. 97,4% vs. 98,1%; $p < 0,0001$) e a mortalidade menor (1,2% vs. 0,7% vs. 0,6%; $p < 0,0001$) no grupo tratado mais recentemente. Na análise de regressão logística múltipla, sexo feminino, lesões envolvendo tronco de coronária esquerda, intervenção coronária percutânea primária, intervenção coronária percutânea de resgate, procedimentos efetivados entre 2006-2008 e uso de inibidores de glicoproteína IIb/IIIa foram variáveis independentemente associadas à mortalidade hospitalar. **Conclusão:** Sexo feminino, quadro clínico agudo, intervenção coronária percutânea em caráter emergencial e maior complexidade anatômica estiveram associados à mortalidade hospitalar em pacientes submetidos ao tratamento de bifurcações coronárias. Avanços no tratamento contemporâneo possivelmente contribuíram para a melhora evolutiva nesse perfil de pacientes.

Descritores: Intervenção coronária percutânea; Procedimentos endovasculares; Mortalidade hospitalar

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INTRODUCTION

Coronary bifurcation lesions are frequent in interventional cardiology, accounting for 10 to 20% of percutaneous coronary interventions (PCI). However, they remain one of the most challenging coronary lesions in terms of success, and early and mostly late adverse cardiovascular events.¹ A bifurcation stenosis is a type of lesion involving a main branch, usually larger, and a smaller side branch. True bifurcation lesions are those in which both the main branch and the side branch are affected by obstructive atherosclerotic disease, whereas non-true or pseudo bifurcation lesions are those with no stenosis in the side branches.²

Some classifications are used to define the best strategy to be used in the procedure, and Medina classification is widely used in contemporary practice.³ The optimal treatment of bifurcation lesions, as to the technique to be adopted, has been a subject of debate over the years and is still not fully established and has undergone important modifications.⁴ An understanding of the anatomical and functional relation of coronary bifurcations with atherosclerosis is necessary to understand the distribution of the atheroma plaque, and also to restore structure and function after PCI.⁵ The diameter and length of the side branch, which estimate the amount of myocardium at risk, are part of the criteria for defining the percutaneous treatment strategy. However, the functional significance of the branch should be based not only on these aspects, but also on the diameter of the main vessel, which estimates the distribution of blood flow and the myocardial mass involved.^{5,6}

Currently, stent implantation in the main vessel and balloon dilation in the side branch, when necessary (provisional stenting technique), has been the strategy recommended in most procedures. When there is no severe stenosis, or when unfavorable calcifications or angulations are present, the side branch may be left untreated and, after implanting the stent in the main branch, the side branch is reassessed as to whether a treatment is still necessary. In the provisional stenting technique, the stent is sized to the distal reference diameter of the main vessel. After stent implantation, the proximal optimization technique is performed in the vessel. Afterwards, a kissing balloon inflation can be performed. In the double-stent technique, the angle of the origin of the side branch is evaluated, and the culotte or double-kissing crush (DK crush) stenting technique is recommended when the angle is $<70^\circ$. When the angle is $\geq 70^\circ$, the T-stenting or the T-stenting with small protrusion (TAP) technique is used. In the double-stent strategy, the final kissing balloon is mandatory, followed by proximal optimization.⁷

Knowledge of the clinical and angiographic characteristics of patients with bifurcation lesions undergoing PCI, as well as the in-hospital outcomes of a large national

registry, may contribute to the improvement of management strategies, revealing part of the reality of PCI in our country.

The objective of this study was to identify the patient profile and the in-hospital outcomes as well as the predictors of in-hospital death over time of patients with bifurcation lesions undergoing percutaneous coronary intervention.

METHODS

This was a study conducted with data from a national real-world registry on PCI. It is an observational, retrospective and analytical study that evaluated patients undergoing PCI for lesions at bifurcations between 2006 and 2016. This information was extracted from the *Central Nacional de Intervenções Cardiovasculares* (CENIC; <http://www.corehemo.net/>) from the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* (SBHCI), created with the spontaneous contribution of the members of this society. Centers from all regions participated by entering patient data. A structured electronic questionnaire was developed by the SBHCI to collect data, including patient clinical profile, angiographic and procedural characteristics, as well as cardiovascular events in the in-hospital phase.

The major adverse cardiovascular events (MACE) included death, acute myocardial infarction (MI), and coronary artery bypass grafting (CABG). The MACE rate was considered a composite primary outcome, and each component was analyzed as a secondary outcome. The definition of the PCI treatment strategies was at the discretion of the professionals who performed the procedures.

Patients were divided into three groups according to the time of the percutaneous treatment: 2006-2008 (Group 1), 2009-2011 (Group 2), and 2012-2016 (Group 3).

The categorical variables were presented as absolute frequency and percentage, whereas the numerical variables were presented as mean and standard deviation, for they were normal according to the Shapiro-Wilk test. For the comparison of the categorical variables, the Chi-square test was used. When necessary, the likelihood ratio test was used. For comparison of continuous variables, the analysis of variance (ANOVA) was used. In multiple comparisons, the Bonferroni correction was applied. To explore the influence of variables of interest on mortality, the simple and multiple logistic regression model was employed. All analyses considered a significance level of 5% ($p < 0.05$).

This study was evaluated and approved by the Research Ethics Committee of Hospital Leforte, in São Paulo (SP), under CAEE 07804919.5.0000.5485.

RESULTS

In the study period, data were collected from 176,780 patients, and 191,127 procedures were performed in 255,222 vessels. In the final sample, 36,608 patients with coronary stenoses in bifurcations were included, and 37,878 pro-

cedures were performed (mean of 1.03 procedure per patient), and 45,865 stents were implanted.

The comparison of the clinical characteristics of patients among Groups 1, 2 and 3 indicated, respectively, prevalence of hypertension 82.0% vs. 81.1% vs. 71.6% ($p<0.0001$); dyslipidemia 62.1% vs. 63.1% vs. 52.8% ($p<0.0001$); smoking 28.4% vs. 25.3% vs. 20.3% ($p<0.0001$); and prior CABG 6.7% vs. 6.5% vs. 5.1% ($p<0.0001$). Table 1 shows the clinical characteristics of the population.

Regarding the angiographic characteristics, the comparative analyzes among the groups showed, respectively, prevalence of three-vessel disease patients 16.5% vs. 16.3% vs. 13.5% ($p<0.001$), two-vessel disease patients 31.0% vs. 33.8% vs. 27.5% ($p<0.0001$), thrombotic lesions 19.1% vs. 19.7% vs. 15.3% ($p<0.0001$), long lesions (≥ 20 mm) 35.6% vs. 31.2% vs. 27.4% ($p<0.0001$), calcified lesions 33.8% vs. 33.4% vs. 29.9% ($p<0.0001$), and occlusions 16.5% vs. 15.2% vs. 14.3% ($p<0.0001$). Tables 2 and 3 show the comparisons of the angiographic and procedure characteristics.

Table 4 shows the comparative analysis of the MACE composite outcome, as well as occurrence of death, acute MI and CABG in the in-hospital phase. The results of the simple logistic regression analysis are presented in table 5. In the multiple logistic regression analysis, with death as a dependent variable, the variables age, female sex, hypertension, multi-vessel coronary artery disease, acute clinical presentation, emergency procedures, procedures performed between 2006-2008, and use of glycoprotein IIb/IIIa inhibitors were independently associated with in-hospital mortality (Table 6).

DISCUSSION

In this study, patients with bifurcation lesions treated with PCI between 2012 and 2016 had a lower prevalence of hypertension, dyslipidemia, smoking and CABG, but had higher prevalence of prior MI and PCI, angina pectoris, and Killip functional class 1. Lower mean age, less use of glycoprotein IIb/IIIa inhibitors, higher percentage of left ventricular dysfunction, use of devices for thrombus aspiration, and implantation of drug-eluting stents were observed. The occurrence of in-hospital death, acute MI, and MACE was lower in patients treated in Group 3. Although there was reduction of up to 50% in these events, in absolute numbers the reduction was less than 1%.

Patients with bifurcation lesions undergoing PCI demonstrate a prevalence of comorbidities of 25 to 34% for diabetes mellitus, 55 to 89% for hypertension, 62 to 82% for dyslipidemia, and 4 to 40% for previous infarction.^{8,9} The clinical profile of patients of our study was similar to that in the literature, revealing that patients with bifurcation lesions are at high risk for MACE regardless of the treatment strategy.

The clinical profile of patients was more severe in the group treated in Group 3, reflecting the current practice in interventional cardiology supported by advances in knowledge and treatment techniques.^{2,7} Bifurcation lesions are considered complex, and the angiographic analysis has revealed presence of calcifications, severe atherosclerotic disease in side branches, unfavorable angles of origin of the side branches, greater extent and severity of coronary artery disease.⁷⁻¹⁰ Consistently to these data, the coronary

Table 1. Clinical characteristics

Characteristic	Group 1 (n=12,724 patients)	Group 2 (n=12,824 patients)	Group 3 (n=11,060 patients)	p-value
Age, years	62.2±11.4	62.9±11.5	63.0±11.4	<0.0001
Male sex	8,457 (66.5)	8,550 (66.7)	7,467 (67.5)	0.199
Diabetes mellitus	2,868 (22.5)	2,710 (22.2)	2,314 (23.2)	0.239
Prior acute MI	2,332 (18.3)	2,013 (16.5)	2,689 (27.0)	<0.0001
Prior PCI	2,365 (18.6)	2,273 (17.7)	2,970 (26.9)	<0.0001
Clinical presentation				<0.0001
Stable angina	5,255 (41.3)	4,972 (38.8)	4,914 (44.4)	
Silent ischemia	979 (7.7)	1,171 (9.1)	888 (8.0)	
Acute MI	2,799 (22.0)	2,699 (21.0)	1,808 (16.3)	
NSTE-ACS	3,691 (29.0)	3,982 (31.1)	3,450 (31.2)	
Killip				<0.0001
1	1,994 (71.2)	2,039 (75.6)	1,396 (77.2)	
2	497 (17.8)	403 (14.9)	250 (13.8)	
3	156 (5.6)	95 (3.5)	65 (3.6)	
4	152 (5.4)	161 (6.0)	97 (5.4)	

Results expressed as as mean±standard deviation or n (%). MI: myocardial infarction; PCI: percutaneous coronary intervention; NSTE-ACS: non-ST segment elevation acute coronary syndrome.

angiography of patients in our study showed the complexity of the bifurcation stenoses treated. Although the occurrence of calcified thrombotic lesions decreased in the last period of time, other characteristics were noted, such

as the prevalence of Thrombolysis in Myocardial Infarction (TIMI) flow 0/1 and larger mean length of the stents, whereas their diameter was smaller, corroborating complexity of the lesions.

Table 2. Angiographic characteristics

Characteristic	Group 1 (n=13,192 procedures/ n=15,816 vessels)	Group 2 (n=13,286 procedures/ n=16,077 vessels)	Group 3 (n=11,400 procedures/ n=13,465 vessels)	p-value
Coronary disease extension				<0.001
Single vessel	6,749 (52.1)	6,494 (49.8)	6,510 (58.9)	
LMCA	47 (0.4)	15 (0.1)	6 (0.1)	
Multi-vessel + LMCA	0 (0.0)	2 (0.03)	7 (0.1)	
Treated vessels				<0.0001
RCA	2,672 (16.9)	3,058 (19.0)	2,459 (18.3)	
LCx	3,439 (21.7)	3,423 (21.3)	3,003 (22.3)	
LAD	9,352 (59.1)	9,204 (57.2)	7,601 (56.5)	
Venous graft	139 (0.9)	116 (0.7)	107 (0.8)	
LMCA	214 (1.4)	276 (1.7)	295 (2.2)	
Type B ₂ /C lesions	12,431 (78.6)	13,247 (82.4)	12,239 (90.9)	0.414
TIMI flow pre				<0.0001
0/1	3,276 (20.7)	3,136 (19.5)	3,315 (24.6)	
2/3	12,540 (79.3)	12,941 (80.5)	10,150 (75.4)	
Left ventricular dysfunction	6,043 (53.1)	5,221 (53.5)	3,988 (46.3)	<0.0001
Collateral circulation	1,863 (14.3)	1,172 (14.7)	1,239 (15.4)	0.083

Results expressed as n (%). LMCA: left main coronary artery; RCA: right coronary artery; LCx: left circumflex artery; LAD: left anterior descending artery; TIMI: Thrombolysis in Myocardial Infarction.

Table 3. Characteristics of procedures

Characteristic	Group 1 (n=12,724 patients/ n=13,192 procedures/ n=15,496 stents)	Group 2 (n=12,824 patients/ n=13,286 procedures/ n=16,281 stents)	Group 3 (n=11,060 patients/ n=11,400 procedures/ n=14,088 stents)	p-value
Treated vessels/patient	1.2±0.5	1.3±0.5	1.2±0.5	<0.0001
Use of stent	12,202 (95.9)	12,435 (97.0)	10,782 (97.5)	<0.0001
Stent/patient ratio	1.3±0.6	1.3±0.6	1.3±0.6	0.414
Drug-eluting stents	3,264 (21.1)	4,915 (30.2)	5,918 (42.0)	<0.0001
Stent diameter, mm	3.01±0.44	3.01±0.46	2.95±0.49	<0.0001
Stent length, mm	19.9 (7.0)	20.1 (7.3)	20.4 (7.9)	<0.0001
Types of intervention				<0.0001
Primary PCI	1,611 (12.2)	1,695 (12.8)	1,081 (9.5)	
Rescue PCI	248 (1.9)	65 (0.5)	65 (0.6)	
Glycoprotein IIb/IIIa inhibitors	1,174 (8.9)	543 (4.1)	245 (2.1)	<0.0001
Thromboaspiration	32 (0.2)	123 (0.8)	717 (5.1)	<0.0001
TIMI flow post				<0.0001
0/1	596 (3.8)	433 (2.7)	1,515 (10.8)	
2/3	14,890 (96.2)	15,835 (97.3)	12,570 (89.2)	
Diameter stenosis				
Pre	87 (13.1)	87 (12.6)	87.6 (13.9)	0.0001
Post	2.5 (10.5)	3.2 (9.2)	7.2 (7.8)	<0.0001
Success of procedure	12,674 (96.1)	12,944 (97.4)	11,182 (98.1)	<0.0001

Results expressed as mean±standard deviation or n (%). PCI: Percutaneous coronary intervention; TIMI: Thrombolysis in Myocardial Infarction.

Table 4. Clinical outcomes in the in-hospital phase

Outcome	Group 1 (n=12,724 patients)	Group 2 (n=12,824 patients)	Group 3 (n=11,060 patients)	p-value
Acute MI	50 (0.4)	13 (0.1)	14 (0.1)	<0.0001
Emergency CABG	0	11 (0.09)	4 (0.04)	0.235
Death	154 (1.2)	90 (0.7)	67 (0.6)	<0.0001
MACE	193 (1.5)	110 (0.9)	79 (0.7)	<0.0001

Results expressed as n (%).MI: myocardial infarction; CABG: coronary artery bypass graft; MACE: major adverse cardiovascular events.

Tabela 5. Simple logistic regression

	Estimate	p-value	OR	95%CI
Group 2 vs. Group 1	-0.50	0.0002	0.61	0.47-0.79
Group 3 vs. Group 1	-0.63	<0.0001	0.53	0.40-0.71
Age, years	0.06	<0.0001	1.06	1.05-1.07
Sex, female vs. male	0.33	0.0041	1.39	1.11-1.75
Smoking, no vs. yes	0.01	0.9134	1.01	0.78-1.31
HTN, no vs. yes	0.05	0.6889	1.06	0.81-1.38
Dyslipidemia, no vs. yes	0.21	0.0719	1.23	0.98-1.54
Diabetes mellitus, yes vs. no	0.35	0.0067	1.42	1.10-1.83
Prior acute MI, yes vs. no	0.10	0.4926	1.10	0.83-1.46
Previous PCI, no vs. yes	0.67	0.0001	1.96	1.39-2.77
Previous CABG, no vs. yes	0.19	0.4684	1.21	0.73-2.00
Clinical presentation, angina vs. acute MI	-3.10	<0.0001	0.05	0.03-0.07
Clinical presentation, silent ischemia vs. acute MI	-2.65	<0.0001	0.07	0.03-0.16
Clinical presentation, NSTEMI-ACS vs. acute MI	-1.53	<0.0001	0.22	0.17-0.28
Killip, 1 vs. 4	-4.01	<0.0001	0.02	0.01-0.03
Killip, 2 vs. 4	-2.88	<0.0001	0.06	0.04-0.09
Killip, 3 vs. 4	-1.19	<0.0001	0.30	0.20-0.46
Extension of coronary disease, two-vessel vs. single-vessel	0.73	<0.0001	2.08	1.53-2.82
Extension of coronary disease, three-vessel vs. single-vessel	1.84	<0.0001	6.29	4.74-8.35
Extension of coronary disease, multi-vessel + LMCA vs. single-vessel	2.07	0.9995	7.89	0.01-4304.60
Extension of coronary disease, LMCA vs. single-vessel	3.75	<0.0001	42.62	19.46-93.33
Left ventricular dysfunction, yes vs. no	2.43	<0.0001	11.32	6.79-18.86
Collateral circulation, yes vs. no	0.91	<0.0001	2.48	1.90-3.23
Types of intervention, primary vs. others	2.42	<0.0001	11.19	8.86-14.14
Types of intervention, rescue vs. others	2.24	<0.0001	9.40	5.25-16.81
Glycoprotein IIb/IIIa inhibitors, yes vs. no	1.66	<0.0001	5.24	4.00-6.87

OR: odds ratio; 95%CI: 95% confidence interval; HTN: hypertension; MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; NSTEMI-ACS: non-ST segment elevation acute coronary syndrome; LMCA: left main coronary artery.

Tabela 6. Multiple logistic regression (dependent variable in-hospital death)

	Estimate	p value	OR	95%CI
Constant				
Group 2 vs. Group 1	-0.43	0.0021	0.65	0.49-0.86
Group 3 vs. Group 1	-0.57	0.0008	0.57	0.41-0.79
Female vs. male	0.26	0.0409	1.30	1.01-1.66
Prior acute MI, yes vs. no	0.54	0.0003	1.72	1.28-2.32
Extension of coronary disease, multi-vessel + LMCA vs. single-vessel	3.16	0.9997	23.58	0.04-15,343.18
Extension of coronary disease, LMCA vs. single-vessel	3.17	<0.0001	23.85	9.79-58.08
Glycoprotein IIb/IIIa inhibitors, yes vs. no	0.72	<0.0001	2.06	1.52-2.79
Clinical presentation, angina vs. acute MI	-1.95	<0.0001	0.14	0.07-0.27
Clinical presentation, silent ischemia vs. acute MI	-1.30	0.0053	0.27	0.11-0.68
Clinical presentation, NSTEMI-ACS vs. acute MI	-0.48	0.0640	0.62	0.37-1.03
Types of intervention, primary vs. others	1.38	<0.0001	3.97	2.46-6.41
Types of intervention, rescue vs. others	1.34	0.0003	3.82	1.84-7.92

OR: odds ratio; 95%CI: 95% confidence interval; MI: myocardial infarction; LMCA: left main coronary artery; NSTEMI-ACS: non-ST segment elevation acute coronary syndrome.

The literature does not consistently present the main predictors of in-hospital mortality after PCI in bifurcation lesions. Our study sought to bring the subject to debate. We observed that, except for the location of the stenosis in the distal left main coronary artery (LMCA), no other independent angiographic predictor was a determinant of poor prognosis. LMCA bifurcation stenosis is different from other bifurcation lesions, and there are specific recommendations for its treatment, such as the use of intravascular imaging.⁷

In current practice, successful in-hospital outcomes and MACE prevalence are satisfactory. The success rate of PCI in bifurcation lesions is over 90%, and the occurrence of cardiovascular events does not exceed 2%. The prevalence of death is less than 1%.^{11,12} These numbers are similar to the results of our study. Therefore, the limitations of the different strategies for PCI treatment in bifurcations are not related to the early outcomes, but to late outcomes.^{13,14} However, it is possible that some subgroups of patients with bifurcation stenosis have a higher risk of in-hospital death, and that we should consider improving the technical approach and management for these patients.

Drug-eluting stents have shown superiority over bare metal stents, but there are still unmet needs in this scenario.^{8,15} Late outcomes still need to improve and, in this aspect, there are some treatment strategies that depend on the individual characteristics of each patient and aim to reduce the occurrence of late MACE.^{16,17} The most used techniques for PCI in bifurcation lesions are provisional stenting, culotte, mini-crush, step-crush, DK crush, T-stenting, TAP, V-stenting, and simultaneous kissing stents.^{7,18,19} Current recommendations suggest a preference for the use of T-stenting, TAP, DK crush, or culotte techniques.

The dedicated stents specifically designed for bifurcation have also been or are being evaluated in clinical studies. Some have shown promising results and for many investigators may represent the device of choice for future treatment of bifurcation stenoses.²⁰⁻²³ Although there are promising studies on the role of intravascular ultrasound, optical coherence tomography, and fractional flow reserve in the context of percutaneous treatment of bifurcations, these modalities have not been routinely incorporated into clinical practice yet.²⁴

The main limitations of the study were its retrospective nature, inclusion of patients conditioned to the decision of the operator, with potential selection bias, non-identification of the PCI techniques used, and the adjunct pharmacotherapy in use by the patients.

CONCLUSIONS

The independent predictors of in-hospital mortality in patients undergoing percutaneous bifurcation treatment at CENIC were left main coronary artery involvement, age, hypertension, female sex, previous acute myocardial infarction, use of glycoprotein IIb/IIIa inhibitor, multi-ves-

sel coronary artery disease, and emergency procedures. Advances in current treatment contributed to the clinical improvement in patients with this profile.

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None.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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