Original Article

Percutaneous coronary intervention in small-caliber arteries

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ABSTRACT

Background: Percutaneous coronary intervention (PCI) in small-caliber arteries corresponds to 30 to 40% of invasive therapeutic procedures and shows high and persistent rates of restenosis, despite the evolution of the devices used. The objective of this study was to evaluate changes in patient outcomes associated with the evolution of this therapeutic modality in Brazil during the last 10 years.
Methods: A total of 24,895 patients from the National Center for Cardiovascular Interventions (CENIC) registry were included. These patients were subjected to 25,892 procedures with at least one stent with a diameter ≤ 2.5 mm between 2006 and 2016, which was subdivided into three periods: 2006-2008, 2009-2011 and 2012-2016. The clinical, angiographic and in-hospital outcomes of these patients were evaluated.
Results: The mean age was 63.3 years. There was a predominance of male patients (59.7%), 26.1% had diabetes, and 59.7% had single-vessel coronary artery disease. The mean diameter of the stents used was 2.47 mm, and 25.5% were drug-eluting stents. Among the in-hospital outcomes, 140 deaths (0.6%), 79 myocardial infarctions (0.3%) and four emergency myocardial revascularization surgeries (0.02%) occurred. The prevalence of cardiovascular risk factors and the rate of serious adverse cardiac events decreased (1.2% vs. 0.6%; $p < 0.0001$) from the 2006-2008 to the 2012-2016 period.
Conclusions: In patients undergoing percutaneous coronary intervention in small-caliber vessels registered in the CENIC, there was a favorable temporal evolution related to a decrease in risk factors and a lower rate of in-hospital complications, despite an increase in the complexity of the procedures.

Intervenção coronária percutânea em artérias de fino calibre

Palavras-chave:
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RESUMO

Introdução: A intervenção coronária percutânea (ICP) em artérias de fino calibre corresponde a 30 a 40% dos procedimentos terapêuticos invasivos, e exibe taxas elevadas e persistentes de reestenose, a despeito da evolução dos dispositivos empregados. O objetivo deste estudo foi avaliar a evolução do perfil desta modalidade terapêutica no Brasil nos últimos 10 anos.
Métodos: Foram incluídos 24.895 pacientes do registro da Central Nacional de Intervenções Cardiovasculares (CENIC) submetidos a 25.892 procedimentos com pelo menos um stent com diâmetro ≤ 2,5 mm entre 2006 e 2016, subdivididos em três períodos: 2006-2008, 2009-2011 e 2012-2016. Avaliaram-se características clínicas, angiográficas e desfechos intra-hospitalares destes pacientes.
Resultados: Houve predomínio de pacientes do sexo masculino (59,7%), com média de idade de 63,3 anos, sendo 26,1% portadores de diabetes e 59,7% de coronariopatia uniarterial. O diâmetro médio dos stents utilizados foi de 2,47 mm, dos quais 25,5% eram farmacológicos. Dentre os desfechos intra-hospitalares, ocorreram 140 óbitos (0,6%), 79 infartos do miocárdio (0,3%) e 4 cirurgias de revascularização miocárdica de urgência (0,02%). Observou-se redução significativa na prevalência dos fatores de risco cardiovasculares e na taxa de eventos cardíacos adversos graves (1,2% vs. 0,6%; $p < 0,0001$) entre os períodos de 2006-2008 e 2012-2016.
Conclusões: Em pacientes submetidos à ICP em vasos de fino calibre cadastrados na CENIC, houve evolução temporal favorável, traduzida pela redução dos fatores de risco e pela menor taxa de complicações hospitalares, a despeito de um aumento na complexidade dos procedimentos.

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Introduction

Percutaneous coronary intervention (PCI) in small-caliber arteries remains a challenge for Interventional Cardiology. Its prevalence is high, accounting for 30% to 40% of percutaneous revascularization procedures.[1-3] The rates of adverse cardiac events remain high, particularly restenosis requiring a new revascularization,[4] despite the evolution of devices in recent decades—from balloon angioplasty to the use of drug-eluting stents—which was responsible for a significant reduction in the prevalence of this complication.[5,6]

The persistence of high rates of adverse clinical outcomes in this scenario makes it important to improve our knowledge of the concomitant clinical and angiographic characteristics observed in this population. In Brazil, studies on PCI in small-caliber arteries are scarce, involve a small number of patients and are limited to single-center experiences.[7,8] This study aimed to evaluate the temporal profile of percutaneous procedures in small vessels performed in a more comprehensive national context in the last 10 years.

Methods

The National Center for Cardiovascular Interventions (*Central Nacional de Intervenções Cardiovasculares* - CENIC), belonging to the Brazilian Society of Hemodynamics and Interventional Cardiology (*Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* - SBHCI), is a clinical registry in which patients are voluntarily included by the society's members. The registry contains a list of procedures performed since 1992 and encompasses variables related to coronary, structural and congenital interventions. The data are collected prospectively and recorded in standardized electronic forms. The patients included in the present study were enrolled from this registry. The patients included had undergone procedures performed from June 2006 to March 2016 in which at least one stent of diameter ≤ 2.5 mm was used, totaling 25,892 PCIs. To compare the evolution of the procedures, the sample was divided into three periods: 2006-2008, 2009-2011 and 2012-2016.

Small-caliber arteries with reference luminal diameter ≤ 2.5 mm were considered. The lesions were classified according to the definition of the American College of Cardiology/American Heart Association (ACC/AHA) modified by Ellis.[9] For determination of coronary flow, the Thrombolysis in Myocardial Infarction (TIMI) score was used.[10] Left ventricular function was assessed qualitatively by ventriculography and graded as normal, mild dysfunction, moderate dysfunction or severe dysfunction. Due to the large number of losses in this variable, we grouped ventricular dysfunction into a single dichotomous variable.

Procedure success was defined as obtaining residual stenosis < 30%, with final TIMI 3 flow and absence of in-hospital death, nonfatal acute myocardial infarction (AMI) and emergency coronary artery bypass graft surgery (CABG). Among the adverse cardiac outcomes, in-hospital deaths for any cause, post-procedure AMI, and emergency CABG were considered.

For the statistical analysis, the Statistical Package for Social Science (SPSS) version 19 (SPSS inc, Chicago, USA) was used. The Chi-squared test was used to compare categorical variables. Analysis of variance was used for continuous variables and Bonferroni correction for multiple comparisons. To test the association of the variables of interest with in-hospital mortality, simple and multiple logistic regression models were used. In this case, the variables were adjusted for sex using the forward selection method, which determined the independent variables that would best explain the occurrence of death. Variables with a high percent of missing values, such as Killip class, left ventricular dysfunction and presence of collateral circulation, were not included in the multiple logistic regression analysis; thus, the sample used in this model contained 23,781 patients. In all analyses, a significance level of 5% ($p < 0.05$) was adopted.

Results

Between June 2006 and March 2016, 24,895 patients with coronary atherosclerotic disease with involvement of at least one small-caliber artery were included in the study, totaling 25,892 treated vessels (mean of 1.04 per patient), with the use of 28,053 stents (mean of 1.13 per patient).

Patient characteristics are shown in Table 1; 59.7% were males, with a mean age of 63.3 years, and 26.1% had diabetes. The preponderant clinical presentation was stable angina (47.5%). Compared to the other periods, among the patients treated in 2012-2016, there were higher prevalences of male patients, previous AMI and previous PCI as well as lower rates of diabetes, smoking, hypertension, dyslipidemia and previous MRS. There was a progressive increase in the number of asymptomatic patients or patients with acute coronary syndrome (ACS) as a clinical presentation.

The anterior descending artery was the most frequently treated vessel (46.6%), with 59.7% of the patients presenting with single-vessel disease. There was a predominance of type B_2/C lesions (65.0%), with 22.4% long lesions, 23.8% bifurcations and 13.6% chronic occlusions (Table 2). There was an increase in the prevalence of complex lesions in the period. Among the stents used, 25.5% were drug-eluting, with mean diameter and length of 2.47 mm and 18.1 mm, respectively. Angiographic success was obtained in 98.2% of the cases (Table 3). There was a greater use of drug-eluting stents, increase in their mean length and decrease in the diameter of the devices over the years.

In the in-hospital clinical follow-up (Table 4), there were 79 (0.3%) post-procedure AMI, 4 (0.02%) emergency CABG, and 140 (0.6%) deaths. The incidences of death and AMI significantly decreased over the study period.

Univariate (Table 5) and multivariate analysis (Table 6) were performed, and the following variables showed an independent association with death: procedures performed in the 2006-2008 triennium, age, smoking, diabetes, unstable clinical condition, multivessel disease, emergency interventions and use of glycoprotein IIb/IIIa inhibitors.

Discussion

In this multicenter registry of PCI in small-caliber arteries performed in the last 10 years in Brazil, a reduction in the prevalence of cardiovascular risk factors was observed, including diabetes mellitus, smoking, dyslipidemia and previous CABG — a result similar to the trend observed in other studies conducted in Brazil and abroad.[11-13] From the angiographic point of view, there was a decrease in multivessel disease and an increase in the anatomical complexity of the lesions. There was also greater use of drug-eluting stents, longer total stent length and greater use of manual aspiration thrombectomy, in addition to a high procedure success rate.

The rate of serious adverse cardiac events was lower than reported in the literature, particularly for mortality (0.6%). In a US cohort study that included almost 200,000 procedures, in-hospital mortality was 1.27%.[14] In 2010, data from the Hospital Information System of the Unified Health System (*Sistema de Informações Hospitalares do Sistema Único de Saúde* - SIHSUS) on 166,514 PCIs performed in 180 Brazilian hospitals were published, in which the in-hospital mortality was 2.33%.[15] A subanalysis of the DESIRE (Drug-Eluting Stents In the Real World) registry evaluated 1,380 patients undergoing PCI in small-caliber arteries who had an epidemiological profile and

Table 1
Clinical characteristics

Characteristics	2006-2008 (n = 7,378 patients)	2009-2011 (n = 8,428 patients)	2012-2016 (n = 9,089 patients)	Total (n = 24,895 patients)	*p*-value
Age, years	63.2 ± 11.3	63.3 ± 11.2	63.4 ± 11.1	63.3 ± 11.2	0.40
Male sex, n (%)	4,350 (59.0)	4,889 (58.0)	5,635 (62.0)	14,874 (59.7)	< 0.0001
Smoking, n (%)	1,769 (24.0)	1,779 (21.1)	1,572 (17.3)	5,120 (20.6)	< 0.0001
Hypertension, n (%)	6,101 (82.7)	6,875 (81.6)	6,690 (73.6)	19,666 (79.0)	< 0.0001
Dyslipidemia, n (%)	4,461 (60.5)	5,185 (61.5)	5,214 (57.4)	14,860 (59.7)	< 0.0001
Diabetes, n (%)	2,019 (27.4)	2,237 (26.5)	2,251 (24.8)	6,507 (26.1)	0.0005
Previous AMI, n (%)	1,363 (18.5)	1,463 (17.4)	2,028 (22.3)	4,854 (19.5)	< 0.0001
Previous PCI, n (%)	1,563 (21.4)	1,652 (20.2)	2,323 (26.0)	5,538 (22.7)	< 0.0001
Previous CABG, n (%)	747 (10.1)	761 (9.0)	587 (6.5)	2,095 (8.4)	< 0.0001
Clinical presentation, n (%)					< 0.0001
Stable angina	3,709 (50.3)	4,054 (48.1)	4,070 (44.8)	11,833 (47.5)	
Silent ischemia	585 (7.9)	719 (8.5)	861 (9.5)	2,165 (8.7)	
STEMI	1,146 (15.5)	1,087 (12.9)	1,232 (13.6)	3,465 (13.9)	
NSTE-ACS	1,938 (26.3)	2,568 (30.5)	2,926 (32.2)	7,432 (29.9)	
Killip class, n (%)					< 0.0001
I	844 (73.8)	841 (77.6)	1,051 (85.3)	2,736 (79.1)	
II	194 (17.0)	143 (13.2)	110 (8.9)	447 (12.9)	
III	53 (4.6)	42 (3.9)	30 (2.4)	125 (3.6)	
IV	52 (4.5)	58 (5.4)	41 (3.3)	151 (4.4)	

AMI: acute myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft surgery; STEMI: acute myocardial infarction with ST segment elevation; NSTE-ACS: non-ST-segment elevation acute coronary syndrome.

Table 2
Angiographic characteristics

Characteristics	2006-2008 (n = 7,641 procedures/ 7,741 vessels)	2009-2011 (n = 8,628 procedures/ 8,738 vessels)	2012-2016 (n = 9,271 procedures/ 9,413 vessels)	Total (n = 25,540 procedures/ 25,892 vessels)	*p*-value
Extent of coronary disease, n (%)					< 0.0001
Single-vessel	4,242 (57.3)	4,715 (57.5)	5,838 (63.6)	14,795 (59.7)	
Two-vessel	1,930 (26.1)	2,203 (26.9)	2,092 (22.8)	6,225 (25.1)	
Three-vessel	1,216 (16.4)	1,282 (15.6)	1,243 (13.5)	3,741 (15.1)	
LMCA	14 (0.2)	1 (0)	2 (0)	17 (0.1)	
Multiple-vessel + LMCA	0 (0)	0 (0)	1 (0)	1 (0)	
Treated vessels, n (%)					< 0.0001
RCA	1,375 (17.8)	1,685 (19.3)	1,856 (19.7)	4,916 (19.0)	
LCx	2,402 (31.0)	2,739 (31.3)	2,975 (31.6)	8,116 (31.3)	
LAD	3,687 (47.6)	4,024 (46.1)	4,364 (46.4)	12,075 (46.6)	
Grafts	263 (3.4)	265 (3.0)	188 (2.0)	716 (2.8)	
LMCA	14 (0.2)	25 (0.3)	30 (0.3)	69 (0.3)	
B2/C lesions, n (%)	4,449 (64.0)	286 (71.7)	135 (95.1)	4,870 (65.0)	< 0.0001
Calcified lesions, n (%)	1,896 (24.5)	1,963 (22.5)	1,800 (19.1)	5,659 (21.9)	< 0.0001
Thrombotic lesions, n (%)	929 (12.0)	874 (10.0)	778 (8.3)	2,581 (10.0)	< 0.0001
Long lesions (> 20 mm), n (%)	1,655 (21.4)	1,913 (21.9)	2,240 (23.8)	5,808 (22.4)	0.0003
Bifurcations, n (%)	1,957 (25.3)	1,901 (21.8)	2,296 (24.4)	6,154 (23.8)	< 0.0001
Total occlusions, n (%)	1,096 (14.2)	1,176 (13.5)	1,235 (13.1)	3,507 (13.6)	0.12
Pre-TIMI flow, n (%)					< 0.0001
0/1	1,540 (19.9)	1,466 (16.8)	2,125 (22.6)	5,131 (19.8)	
2/3	6,200 (80.1)	7,272 (83.2)	7,288 (77.4)	20,760 (80.2)	
LV dysfunction, n (%)	3,050 (48.9)	3,124 (50.8)	3,243 (47.7)	9,417 (49.1)	0.002
Collateral circulation, n (%)	964 (13.3)	535 (10.6)	771 (11.9)	2,270 (12.1)	< 0.0001

LMCA: left main coronary artery; RCA: right coronary artery; LCx: left circumflex artery; LAD: left descending artery; TIMI: Thrombolysis in Myocardial Infarction; LV: left ventricle.

Table 3
Procedural characteristics

Characteristics	2006-2008 (n = 7,378 patients/ 7,641 procedures)	2009-2011 (n = 8,428 patients/ 8,628 procedures)	2012-2016 (n = 9,089 patients/ 9,271 procedures)	Total (n = 24,895 patients/ 25,540 procedures)	*p*-value
Treated vessels/patient	1.05 ± 0.25	1.04 ± 0.2	1.04 ± 0.2	1.04 ± 0.21	0.0001
Stent/patient ratio	1.12 ± 0.43	1.12 ± 0.4	1.13 ± 0.42	1.13 ± 0.42	0.58
Drug-eluting stents, n (%)	1,633 (19.7)	2,425 (25.6)	3,093 (30.1)	7,151 (25.5)	< 0.0001
Stent diameter, mm	2.48 ± 0.19	2.48 ± 0.2	2.46 ± 0.23	2.47 ± 0.21	< 0.0001
Stent length, mm	17.6 ± 6.1	17.8 ± 6.2	18.8 ± 6.9	18.1 ± 6.5	< 0.0001
Intervention types, n (%)					
Primary PCI	664 (8.7)	714 (8.3)	746 (8.0)	2,124 (8.3)	< 0.0001
Rescue PCI	90 (1.2)	20 (0.2)	19 (0.2)	129 (0.5)	
Glycoprotein IIb/IIIa inhibitors, n (%)	412 (5.4)	204 (2.4)	86 (0.9)	702 (2.7)	< 0.0001
Thromboaspiration, n (%)	3 (0)	41 (0.4)	348 (3.4)	392 (1.4)	< 0.0001
Post-TIMI flow, n (%)					
0/1	297 (3.6)	242 (2.6)	855 (8.3)	1,394 (5.0)	< 0.0001
2/3	7,994 (96.4)	9,243 (97.4)	9,414 (91.7)	26,651 (95.0)	
Diameter stenosis, n (%)					
Pre	86.6 ± 14.6	86 ± 11.4	87.9 ± 15.6	86.9 ± 14.1	< 0.0001
Post	2.6 ± 11.6	2.9 ± 9.1	7.3 ± 6.9	4.4 ± 9.4	< 0.0001
Procedure success, n (%)	7,455 (97.6)	8,476 (98.2)	9,146 (98.7)	25,077 (98.2)	< 0.0001

PCI: percutaneous coronary intervention; TIMI: Thrombolysis in Myocardial Infarction.

Table 4
In-hospital clinical outcomes

Outcomes	2006-2008 (n = 7,378 patients)	2009-2011 (n = 8,428 patients)	2012-2016 (n = 9,089 patients)	Total (n = 24.895 patients)	*p*-value
Post-AMI, n (%)	34 (0.5)	29 (0.3)	16 (0.2)	79 (0.3)	0.005
Emergency CABG, n (%)	0 (0)	2 (0.03)	2 (0.02)	4 (0.02)	0.92
Death, n (%)	62 (0.8)	42 (0.5)	36 (0.4)	140 (0.6)	0.0005
MACE, n (%)	91 (1.2)	72 (0.9)	52 (0.6)	215 (0.9)	< 0.0001

AMI: acute myocardial infarction; CABG: coronary artery bypass graft surgery; MACE: major adverse cardiac events.

Table 5
Univariate analysis for the outcome mortality

Variables	Estimate	*p*-value	OR	95% CI
2009-2011 vs. 2006-2008	-0.53	0.0087	0.59	0.4-0.88
2012-2016 vs. 2006-2008	-0.76	0.0003	0.47	0.31-0.71
Age, years	0.06	< 0.0001	1.06	1.05-1.08
Sex, female vs. male	0.31	0.0669	1.36	0.98-1.9
Smoking, yes vs. no	0.40	0.0335	1.50	1.03-2.17
Hypertension, yes vs. no	0.06	0.7697	1.06	0.7-1.61
Dyslipidemia, yes vs. no	0.48	0.0046	1.62	1.16-2.26
Diabetes mellitus, yes vs. no	0.58	0.0009	1.78	1.27-2.51
Previous AMI, yes vs. no	0.36	0.0641	1.43	0.98-2.1
Previous PCI, yes vs. no	0.69	0.0107	1.98	1.17-3.36
Previous CABG, yes vs. no	0.56	0.1500	1.75	0.82-3.75
Clinical condition, unstable vs. stable	2.26	< 0.0001	9.56	5.5-16.63
Killip class, IV vs. I/II/III	3.53	< 0.0001	34.07	21.76-53.32
Extent of coronary disease, multiple vessel vs. single-vessel	1.34	< 0.0001	3.82	2.63-5.54
LV dysfunction, yes vs. no	2.36	< 0.0001	10.56	4.85-22.96
Collateral circulation, yes vs. no	0.51	0.0421	1.66	1.02-2.7
Intervention types, primary/rescue vs. others	2.75	< 0.0001	15.58	11.09-21.89
Glycoprotein IIb/IIIa inhibitors, yes vs. no	2.21	< 0.0001	9.16	6.01-13.95

OR: odds ratio; 95% CI: 95% confidence interval; SAH: systemic arterial hypertension; AMI: acute myocardial infarction; PCI: percutaneous coronary intervention; MRS: myocardial revascularization surgery; LV: left ventricle.

Table 6
Multivariate analysis for the outcome mortality

Analysis	Estimate	*p*-value	OR	95% CI
Constant	-11.54	< 0.0001		
2009-2011 vs. 2006-2008	-0.67	0.0032	0.51	0.33-0.8
2012-2016 vs. 2006-2008	-0.60	0.0089	0.55	0.35-0.86
Age, years	0.05	< 0.0001	1.06	1.04-1.07
Smoking, yes vs. no	0.47	0.0290	1.60	1.05-2.43
Diabetes mellitus, yes vs. no	0.59	0.0024	1.80	1.23-2.63
Extent of coronary disease, multiple vessel vs. single vessel	0.71	0.0006	2.03	1.35-3.06
Glycoprotein IIb/IIIa inhibitors, yes vs. no	0.79	0.0022	2.20	1.33-3.66
Clinical condition, unstable vs. stable	1.31	0.0002	3.70	1.87-7.33
Intervention types, primary/rescue vs. others	1.98	< 0.0001	7.23	4.7-11.14

OR: odds ratio; 95% CI: 95% confidence interval.

angiographic characteristics similar to those of this study, revealing an incidence of death and AMI of 4.5% and 4.2%, respectively.[7] Finally, a recent meta-analysis of randomized clinical trials, which compared the different devices used for PCI in small-caliber arteries, reported a total mortality of 1.3%.[16]

The lower occurrence of in-hospital outcomes in relation to the other studies can be explained by the lower cardiovascular risk in the study population. The control of risk factors is responsible for an approximately 50% reduction in mortality from cardiovascular diseases.[17] The increase in utilization of drug-eluting stents observed in this study, although it is known to reduce the incidence of restenosis and revascularization of the target vessel, does not justify the reduction in mortality observed in our series.[18,19]

Because this is a cross-sectional study, it is not possible to establish a causal relationship between the studied variables and the outcomes. By restricting the analysis of the outcomes to the in-hospital period, evaluation of restenosis and new revascularization of the target vessel, often associated with PCI in small-caliber arteries, are impossible. Finally, the lack of validation of the data provided to the CENIC and the voluntary nature of the data collection, which could induce a low inclusion of unsuccessful procedures or procedures with adverse events, restrict the reproducibility of these numbers and constitute an important limitation.

Conclusions

In patients undergoing percutaneous coronary intervention in small-caliber arteries registered in the CENIC, significant reductions in the rates of death, acute myocardial infarction and emergency coronary artery bypass graft surgery in the last 10 years were observed. This result was possibly due to the decrease in the prevalence of cardiovascular risk factors in the study population. There was an increase in the complexity of treated lesions and a greater use of drug-eluting stents in this period. Additional prospective studies are needed to confirm these findings.

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Conflicts of interest

The authors declare that there are no conflicts of interest to disclose.

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