

Original Article

Percutaneous coronary intervention in large vessels

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ABSTRACT

Background: Percutaneous coronary intervention (PCI) in large vessels has peculiarities that have been little explored in studies. Our objective was to evaluate temporal trends over the last 10 years and in-hospital outcomes for this population.

Methods: Using data from the National Center for Cardiovascular Interventions (CENIC), procedures performed between June 2006 and March 2016 were analyzed. The data were divided into three periods (2006-2008, 2009-2011 and 2012-2016). Clinical, angiographic, therapeutic and in-hospital outcome data were considered.

Results: The sample comprised 35,065 patients and 35,837 procedures. The mean age was 61.7 years. In addition, 72.1% of patients were male, and 19.6% had diabetes mellitus. The success rate was high (98.7%) with increased use over time for drug-eluting stents, the radial access route and approaches to lesions in the left main coronary artery. A significant reduction in in-hospital mortality was observed, favoring contemporary interventions. The main variables correlating with death in a multiple logistic regression model included ST-segment elevation myocardial infarction, left main coronary artery lesions and left ventricular dysfunction.

Conclusions: A reduction in mortality associated with percutaneous treatment of large vessels was noted. The effect of adopting measures capable of favorably influencing outcomes, such as the increased use of drug-eluting stents and radial approach, requires confirmation by studies methodologically directed to this investigational hypothesis.

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Intervenção coronária percutânea em vasos de grande calibre

RESUMO

Introdução: A intervenção coronária percutânea (ICP) em vasos calibrosos possui particularidades pouco exploradas nos estudos. Nosso objetivo foi avaliar as tendências temporais nos últimos 10 anos e desfechos intra-hospitalares nesta população.

Métodos: Utilizando dados da Central Nacional de Intervenções Cardiovasculares (CENIC), foram analisados os procedimentos realizados entre junho de 2006 e março de 2016, divididos em três períodos (2006-2008; 2009-2011 e 2012-2016). Contemplaram-se dados clínicos, angiográficos, terapêuticos e desfechos intra-hospitalares.

Resultados: A amostra foi composta por 35.065 pacientes e 35.837 procedimentos. A média de idade foi 61,7 anos, sendo 72,1% do sexo masculino e 19,6% portadores de diabetes melito. A taxa de sucesso foi elevada (98,7%), com maior utilização ao longo do tempo de stents farmacológicos, da via de acesso radial e da abordagem de lesões no tronco de coronária esquerda. Observou-se redução significativa da mortalidade hospitalar, favorecendo as intervenções contemporâneas. As principais variáveis correlacionadas ao óbito em modelo de regressão logística múltiplo foram infarto agudo do miocárdio com supradesnivelamento de ST, lesão de tronco e disfunção ventricular esquerda.

Conclusões: Houve redução de mortalidade no tratamento percutâneo de vasos calibrosos. O impacto da adoção de medidas capazes de influenciar favoravelmente nos resultados, como maior utilização de stents farmacológicos e do acesso radial, requer confirmação por estudos metodologicamente dirigidos a esta hipótese investigacional.

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Introduction

The treatment approach to lesions in large coronary vessels is a controversial topic given that all available forms of treatment (medication, percutaneous or surgical) have demonstrated significant progress in recent decades. Its importance is justified by the typical involvement of a large area of at-risk myocardium with consequent prognostic impact.

For patients with lesions in larger vessels, i.e., coronary arteries or bypass grafts with a diameter greater than or equal to 3.5 mm, there is no consensus regarding percutaneous treatment using drug-eluting stents (DES). First, the reduction in restenosis rate is relatively reduced in these vessels compared with lesions in small-caliber vessels.¹ Furthermore, acute thrombotic occlusion in large vessels correlates with increased risk of sudden death or extensive myocardial infarction.²

The increased use of DES in percutaneous coronary intervention (PCI) is noticeable given that these devices are proven effective in reducing restenosis compared with bare metal stents.³ The reduced vessel diameter, long lesions and diabetes are well-known predictors of this complication with clear benefits favoring indication of the former.^{4,5} However, previous studies have associated DES with increased risk of late thrombosis, particularly first generation DES, which represents a limiting factor to their widespread indication in procedures involving large vessels.⁶

Numerous and consistent evidence suggests that the use of DES is favorable in small vessels; however, there has been minimal research exploring the population undergoing PCI in large vessels, especially in Brazil.⁷ In this context, the present study sought to analyze the clinical and angiographic profile, DES utilization rate and clinical outcomes of a national cohort of patients undergoing PCI in lesions involving large-caliber vessels in over 10 years.

Methods

The National Center for Cardiovascular Interventions (CENIC, acronym from Portuguese *Central Nacional de Intervenções Cardiovasculares*) database was used, which belongs to the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* (SBHCI). This registry is voluntary and contains entries from 323 reference centers representing the national situation. The study population consisted of 35,065 patients undergoing 35,837 PCIs on large vessels between June 2006 and March 2016. Clinical, angiographic and procedure-related characteristics were analyzed along with in-hospital adverse cardiac outcomes. Data referring to procedures that did not fulfill the target vessel diameter criterion of ≥ 3.5 mm or did not include all the variables of interest were excluded.

To evaluate the temporal influence on demographic and angiographic characteristics and the occurrence of clinical events, defined as death, acute myocardial infarction (AMI) and emergency coronary arterial bypass graft (CABG), patients were grouped into consecutive time intervals as follows: 2006-2008, 2009-2011 and 2012-2016.

The Chi-squared test and, when necessary, the likelihood ratio test were used to compare continuous variables in relation to the three periods. Analysis of variance (ANOVA) was used to compare categorical variables. In the case of multiple comparisons, Bonferroni correction was applied. The effects of variables on the in-hospital death outcome were assessed using simple and multiple logistic regression models. A significance level of 5% (p -value of <0.05) was adopted.

Results

The mean age was 61.7 years. In total, 72.1% of patients were male, and 19.6% had diabetes mellitus. A reduction over time was observed

in the prevalence of risk factors, such as hypertension, smoking and prior CABG, with an increase in diabetes mellitus cases and acute clinical presentations (Table 1).

Regarding angiographic characteristics (Table 2), there was a predominance of single-vessel patients, and the right coronary artery was the most commonly treated vessel. An increased frequency of complex lesions was noted over time, involving 90.0% of cases in the period from 2012-2016. Regarding procedure characteristics, a progressive and significant increase in DES utilization rates, radial access and final success and a decrease in the prescription of glycoprotein IIb/IIIa inhibitors were noted (Table 3).

The overall rate of severe adverse cardiac events was low ($< 1\%$) with a significant reduction favoring contemporary procedures, leading to a lower incidence of in-hospital death and AMI (Table 4). In the univariate analysis (Table 5), independent predictors of death

Table 1
Clinical characteristics

| Characteristics | 2006-2008 (n = 12,206) | 2009-2011 (n = 12,337) | 2012-2016 (n = 10,522) | p-value |
|------------------------------|---------------------------|---------------------------|---------------------------|-----------|
| Age, years | 61.5 \pm 11.3 | 61.9 \pm 11.3 | 61.7 \pm 11.4 | 0.01 |
| Male gender, n (%) | 8,777 (71.9) | 8,862 (71.8) | 7,640 (72.6) | 0.36 |
| Smoking, n (%) | 3,847 (31.5) | 3,344 (27.1) | 2,367 (22.5) | < 0.001 |
| Hypertension, n (%) | 9,718 (79.6) | 9,806 (79.5) | 8,014 (76.2) | < 0.001 |
| Dyslipidemia, n (%) | 6,951 (56.9) | 7,180 (58.2) | 6,049 (57.5) | 0.13 |
| Diabetes mellitus, n (%) | 2,401 (19.7) | 2,312 (18.7) | 2,148 (20.4) | 0.006 |
| Prior AMI, n (%) | 2,120 (17.4) | 1,985 (16.1) | 1,592 (15.1) | < 0.001 |
| Prior PCI, n (%) | 1,875 (15.6) | 2,075 (17.3) | 2,559 (24.7) | < 0.001 |
| Prior CABG, n (%) | 1,004 (8.2) | 890 (7.2) | 520 (4.9) | < 0.001 |
| Clinical presentation, n (%) | | | | < 0.001 |
| Asymptomatic | 987 (8.1) | 1014 (8.2) | 952 (9.0) | |
| Stable angina | 4,988 (40.9) | 4,969 (40.3) | 3,718 (35.3) | |
| NSTEMI-ACS | 3,261 (26.7) | 3,611 (29.3) | 3,524 (33.5) | |
| STEMI | 2,970 (24.3) | 2,743 (22.2) | 2,328 (22.1) | |

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

Table 2
Angiographic characteristics

| Characteristics | 2006-2008 (n=12,545) | 2009-2011 (n=12,597) | 2012-2016 (n=10,695) | p-value |
|-------------------------------------|-------------------------|-------------------------|-------------------------|-----------|
| Extent of CAD, n (%) | | | | < 0.001 |
| Single-vessel | 7,301 (58.2) | 7,492 (59.5) | 7,067 (67.9) | |
| Multivessel | 5,244 (41.8) | 5,105 (40.5) | 3,628 (32.1) | |
| Treated vessels, n (%) | | | | < 0.001 |
| RCA | 5,092 (40.6) | 5,155 (40.9) | 4,357 (40.7) | |
| LCx | 1,820 (14.5) | 1,896 (15.1) | 1,636 (15.3) | |
| LAD | 4,909 (39.1) | 4,845 (38.5) | 4,206 (39.3) | |
| LMCA | 195 (1.6) | 229 (1.8) | 199 (1.9) | |
| Bypass graft | 529 (4.2) | 472 (3.7) | 297 (2.8) | |
| B2/C lesions, n (%) | 7,648 (61.0) | 9,460 (75.1) | 9,625 (90.0) | < 0.001 |
| Lesions > 20 mm, n (%) | 2,986 (23.8) | 3,020 (24.0) | 2,518 (23.5) | < 0.001 |
| Bifurcations, n (%) | 2,960 (23.6) | 2,801 (22.2) | 2,120 (19.8) | < 0.001 |
| Total occlusions, n (%) | 1,958 (15.6) | 1,848 (14.7) | 1,569 (14.7) | 0.71 |
| Pre-TIMI 0/1, n (%) | 2,556 (20.4) | 2,319 (18.4) | 2,059 (19.3) | < 0.001 |
| Left ventricular dysfunction, n (%) | 5,172 (41.2) | 4,719 (37.5) | 4,277 (40.0) | < 0.001 |

CAD: coronary artery disease; RCA: right coronary artery; LCx: left circumflex artery; LAD: left anterior descending artery; LMCA: left main coronary artery; TIMI: Thrombolysis in Myocardial Infarction.

included procedures performed between 2006-2008, age, bare-metal stent implantation, left main coronary artery (LMCA) lesion, ST-segment elevation myocardial infarction (STEMI) and left ventricular dysfunction. The latter three variables were retained in the multiple logistic regression model.

Discussion

The present study allowed percutaneous coronary interventions performed on large vessels to be characterized based on a national representative sample extracted from the CENIC registry. Given the longevity of the data acquisition period (10 years), the measured changes are noteworthy. One of these changes was the reduction in the prevalence of hypertension and smoking, corroborating the

global trend.⁸ Similarly, there was a reduction in prior coronary artery disease and procedures performed on patients with prior CABG and a concomitant increase in those with prior PCI, suggesting the greater penetration of the percutaneous treatment as the preferred strategy for revascularization.⁹⁻¹¹

In the analyzed decade, a significant reduction in the in-hospital death rate was identified in the CENIC registry. Variables that correlated with the event (lesions involving the LMCA, presence of left ventricular dysfunction and STEMI) represent a broad domain.¹²⁻¹⁵ Although these variables were not featured in the logistic regression models applied in this study, we can suggest some explanations for the reduction in mortality. First, lifestyle changes were noted with a reduction in the prevalence of major risk factors, such as hypertension and smoking, as previously mentioned. Second, increased adherence to drug treatment and the use of more powerful and beneficial drugs that were not evaluated on the database were observed. Furthermore, a growing number of interventions with DES implantation were observed, especially in the second period. These factors coincided with studies attesting to its safety and effectiveness in this scenario.¹⁶⁻²⁰ Finally, the preference for radial access compared with femoral access was adopted in one-third of the procedures, and this strategy also validated by recent studies.^{21,22}

The study has some limitations. The SYNTAX score was not calculated. The score can demonstrate the extent and complexity of the lesions treated with better accuracy and provide an analysis of severity and prognosis after PCI. Despite the use of an adjusted model when analyzing the results, there is a clear selection bias given that participation in the CENIC registry is voluntary. The lack of information on operator's experience and resource availability at the centers can influence the outcomes and characteristics of the procedures performed given that they include public, private and university services with distinctive characteristics, including the availability of DES.²³

The strengths of the analysis include the sample size and scope of the data collection period relating to PCI on large vessels. Given the study's retrospective nature, it was not possible to establish the exact causal relationship between in-hospital death or other outcomes and the studied variables, but it was possible to demonstrate changes in the demographic characteristics studied over the course of a decade.

Table 3
Procedural characteristics

| Characteristics | 2006-2008 (n=12,545) | 2009-2011 (n=12,597) | 2012-2016 (n=10,695) | p-value |
|-------------------------------|-------------------------|-------------------------|-------------------------|---------|
| Vessels treated/patient | 1.04 ± 0.2 | 1.03 ± 0.17 | 1.03 ± 0.17 | < 0.001 |
| Stents/patient | 1.08 ± 0.33 | 1.07 ± 0.32 | 1.09 ± 0.35 | < 0.001 |
| Drug-eluting stent, n (%) | 1,449 (11.6) | 2,133 (16.9) | 2,247 (21.0) | < 0.001 |
| Stent diameter, mm | 3.61 ± 0.32 | 3.61 ± 0.34 | 3.59 ± 0.34 | < 0.001 |
| Stent length, mm | 19.0 ± 6.4 | 19.2 ± 6.5 | 19.7 ± 6.9 | < 0.001 |
| IIB/IIIa GPI, n (%) | 1,183 (9.4) | 657 (5.2) | 297 (2.8) | < 0.001 |
| Thromboaspiration, n (%) | 72 (0.5) | 225 (1.7) | 339 (2.9) | < 0.001 |
| Post-TIMI 2/3, n (%) | 12,068 (96.2) | 12,282 (97.5) | 10,331 (96.6) | < 0.001 |
| Diameter stenosis pre, (%) | 86.2 | 86.1 | 87.4 | < 0.001 |
| Unsuccessful procedure, n (%) | 213 (1.7) | 164 (1.3) | 75 (0.7) | < 0.001 |
| Radial access, n (%) | 1,738 (13.9) | 2,771 (22.0) | 3,665 (34.3) | < 0.001 |

GPI: glycoprotein inhibitor; TIMI: Thrombolysis in Myocardial Infarction.

Table 4
In-hospital clinical outcomes

| Outcome | 2006-2008 (n=12,206) | 2009-2011 (n=12,337) | 2012-2016 (n=10,522) | p-value |
|-----------------------|-------------------------|-------------------------|-------------------------|---------|
| AMI, n (%) | 36 (0.3) | 38 (0.3) | 16 (0.2) | 0.04 |
| Emergency CABG, n (%) | 0 (0) | 2 (0.02) | 2 (0.02) | 0.90 |
| Death, n (%) | 79 (0.6) | 60 (0.5) | 26 (0.2) | 0.001 |
| MACE, n (%) | 115 (0.9) | 100 (0.8) | 44 (0.4) | < 0.001 |

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

Table 5
Simple logistic regression related to in-hospital death

| | OR | 95% CI | p-value |
|--|-------|-------------|---------|
| 2006-2008 vs. 2012-2016 | 2,63 | 1,69-4,1 | < 0,001 |
| Age, years | 1,05 | 1,04-1,06 | < 0,001 |
| Smoking, yes vs. no | 0,94 | 0,67-1,32 | 0,72 |
| Hypertension, yes vs. no | 1,25 | 0,88-1,78 | 0,21 |
| Dyslipidemia, yes vs. no | 1,94 | 1,42-2,65 | < 0,001 |
| Diabetes mellitus, yes vs. no | 1,27 | 0,89-1,83 | 0,18 |
| Extent of CAD, LMCA vs. single-vessel | 58,68 | 26,6-129,48 | < 0,001 |
| Clinical presentation, STEMI vs. stable angina | 20,53 | 39,16-10,76 | < 0,001 |
| LV dysfunction, yes vs. no | 11,01 | 5,1-23,79 | < 0,001 |
| Drug-eluting stent, no vs. yes | 2,78 | 1,47-5,27 | 0,002 |

OR: odds ratio; 95% CI: 95% confidence interval; CAD: coronary artery disease; LMCA: left main coronary artery; STEMI: ST-segment elevation myocardial infarction; LV: left ventricle.

Conclusions

A reduction in mortality was observed in the percutaneous treatment of large vessels allied to a reduced prevalence of risk factors, such as smoking, hypertension and previous coronary atherosclerotic disease. The effect of adopting measures capable of favorably influencing the outcome of procedures, such as the increased use of drug-eluting stents and radial approach, requires confirmation by studies methodologically directed to this investigational hypothesis.

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Conflicts of interest

The authors declare no conflicts of interest.

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