Percutaneous coronary intervention in octogenarians in Brazil. Data from the last decade

Intervenção coronária percutânea em octogenários no Brasil.
Dados da última década

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ABSTRACT – Background: As the population ages, the prevalence of diseases has increased, particularly that of coronary artery disease requiring treatment. The objective of this study was to assess the temporal evolution of percutaneous coronary intervention in octogenarians in Brazil. **Methods:** Based on data from the *Central Nacional de Intervenções Cardiovasculares* (CENIC), we analyzed procedures carried out in patients aged 80 years and over, from June 2006 to March 2016, classified into three time ranges: 2006-2008, 2009-2011 and 2012-2016. We assessed clinical and angiographic parameters, characteristics of the procedure and their in-hospital outcomes. **Results:** Of the 176,780 percutaneous coronary interventions that took place during the study period, 14,148 were performed in 13,256 patients aged 80 years and older. The mean age was 83.6 years, and 52% were men. We observed greater prevalence of male, asymptomatic patients, with a history of acute myocardial infarction, prior percutaneous coronary intervention and Killip class 1. Concomitantly, there was a decrease in smoking, left main coronary artery interventions and multi-vessel disease patients. There was a progressive increase in the use of drug-eluting stents, thrombus aspiration devices, and stent length. The success rate of the procedures was high, and increased over the time periods (93.9% vs. 96.1% vs. 96.3%; $p < 0.0001$), associated with a decrease in major adverse cardiac events (3.9% vs. 2.1% vs. 2.3%; $p < 0.0001$). **Conclusions:** Although more challenging, the treatment of octogenarian patients has become more frequent, with good outcomes and safety over the years.

Keywords: Percutaneous coronary intervention; Coronary angiography; Aged, 80 and over; Coronary artery disease; Brazil

RESUMO – Introdução: Com o envelhecimento populacional, a prevalência de doenças tem aumentado, principalmente da coronariopatia com necessidade de tratamento. O objetivo do estudo foi avaliar a evolução temporal da intervenção coronária percutânea em octogenários no Brasil. **Métodos:** Com base nos dados da Central Nacional de Intervenções Cardiovasculares (CENIC), foram avaliados procedimentos em pacientes com mais de 80 anos, entre junho de 2006 a março de 2016, classificados temporalmente em três grupos: 2006-2008, 2009-2011 e 2012-2016. Avaliamos características clínicas, angiográficas, dos procedimentos e seus desfechos hospitalares. **Resultados:** Das 176.780 intervenções coronárias percutâneas realizadas no período, 14.148 foram realizadas em 13.256 pacientes com mais de 80 anos. A média de idade foi de 83,6 anos, com 52% do sexo masculino. Notou-se aumento da prevalência de pacientes do sexo masculino, assintomáticos, com antecedentes de infarto agudo do miocárdio, intervenção coronária percutânea prévia e em Killip 1. Concomitantemente, houve queda de tabagismo, intervenções em tronco de coronária esquerda e pacientes multarteriais. Houve aumento progressivo do uso de stents farmacológicos, de dispositivos de tromboaspiração e do comprimento dos stents. O sucesso dos procedimentos foi alto, com incremento ao longo dos períodos (93,9% vs. 96,1% vs. 96,3%; $p < 0,0001$), associado à redução de eventos cardíacos adversos maiores (3,9% vs. 2,1% vs. 2,3%; $p < 0,0001$). **Conclusões:** O tratamento de pacientes octogenários, apesar de mais desafiador, tornou-se mais frequente, com bons resultados e segurança ao longo dos anos.

Descritores: Intervenção coronária percutânea; Angiografia coronária; Idoso de 80 anos ou mais; Doença da artéria coronariana; Brasil

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INTRODUCTION

The Brazilian population pyramid has been changing. According to the Information Technology Department of the Unified Healthcare System (DATASUS), we have moved from an age profile with a broad base and a narrow top, with a population predominantly under 60 years of age, to a model with a wider top. This means that, proportionally, we have more people in older age cohorts in our society than we did a few decades ago, due to the longer life expectancy of the population. This change is likely to persist over the next decade. Estimates suggest that the number of octogenarians will increase from 2.9 million in 2012 to about 6 million in 2030.¹

If, on one hand, aging of the population is a direct reflection of the level of development of a country, on the other, this entails an increase in the prevalence and severity of chronic diseases, such as diabetes and cardiovascular disease, and the latter is the major cause of death in Brazil and developed countries.^{2,3} Some studies showed the mortality rate due to major adverse cardiac events (MACE) was 11.5% in patients aged 80 years and over, 4.1% between 60 and 80 years, and only 1% in patients under 60 years.⁴⁻⁷

The number of octogenarian patients undergoing coronary angiography, percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) is ever increasing. Studies from the year 2000 with octogenarians undergoing PCI showed that these patients had higher mortality and more complications after the procedure. However, with improved techniques, better therapeutic armamentarium and adjuvant therapies, and more experienced operators, there was a decrease in complications and, therefore, lower mortality rates.⁵⁻⁸

The objective of this study was to describe the clinical profile of octogenarian patients undergoing PCI; characteristics of the procedures; clinical outcomes and how this evolved over the course of a decade, from June 2006 to March 2016, based on data from the *Central Nacional de Intervenções Cardiovasculares* (CENIC).

METHODS

We analyzed a historic cohort of PCI patients logged into the CENIC database (<http://www.corehemo.net/>) of the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* (SBHCI), from June 2006 to March 2016, for a total of 176,780 procedures. CENIC, founded in 1991, is a central database voluntarily maintained and updated by full members of the SBHCI. For comparison purposes, the DATASUS registry had, from 2005 to 2008, 166,514 procedures recorded⁹ and, in the period corresponding to this study, it had 589,360 authorizations for hospital ad-

mission for PCI across Brazil.¹⁰ This study was approved by the Institutional Review Board of Hospital Leforte (CAAE: 92420718.9.0000.5485).

We analyzed the data from octogenarian patients concerning demographics, indication for PCI, angiographic features, use of drug-eluting stents and glycoprotein IIb/IIIa inhibitors, success of the procedure and incidence of MACE, defined as all-cause mortality, urgency CABG and acute myocardial infarction (MI) events combined.

For comparison, patients were divided into three groups according to when the PCI took place, considering the possibility of this influencing the progress along the learning curve, as well as the emergence of new technologies: 2006-2008 (Group 1), 2009-2011 (Group 2) and 2012-2016 (Group 3).

STATISTICAL ANALYSIS

For comparison of continuous variables, we used the analysis of variance (ANOVA). For multiple comparisons, we used the Bonferroni correction. To compare the categorical variables, the Chi-square test was used. To verify the influence of the variables of interest on mortality, we used a logistic regression model and calculated the odds ratio, with a 95% confidence interval. In all analyses, significance was set at 5% (p-value < 0.05). In the simple logistic regression model, the influence of each independent variable was analyzed (time tertile, age, sex, smoking status, systemic arterial hypertension, dyslipidemia, diabetes mellitus, prior MI, prior PCI, prior CABG, clinical presentation, Killip class, extent of the coronary artery disease, left ventricular dysfunction, collateral circulation, types of PCI, and use of glycoprotein IIb/IIIa inhibitors) regarding the endpoint death. For this analysis, we used random selection, to ensure that each patient would have had only one procedure.

RESULTS

During the study period, 176,780 procedures were recorded with CENIC, of which 14,148 were performed in 13,256 patients aged 80 years and over, with an average of 1.07 procedure per patient. A total of 19,879 vessels were treated, in that, 96.5% using stent (1.01 stent per vessel).

A total of 3,707 patients were assigned to Group 1, 4,822 to Group 2 and 4,727 to Group 3. The number of octogenarian patients treated increased over the years. Also, there was an increase in procedures performed in male, asymptomatic, older patients with past history of MI or PCI (Table 1). There was a decrease in the number of smokers, as well as patients with ST-elevation myocardial infarction (STEMI), and Killip class 4.

Table 1. Clinical characteristics

Characteristic	Group 1 (n=3,707 patients)	Group 2 (n=4,822 patients)	Group 3 (n=4,727 patients)	p-value
Age, years	83.4±3.4	83.6±3.4	83.7±3.5	0.0004
Male	1,876 (50.6)	2,492 (51.7)	2,527 (53.5)	0.03
Smoking	433 (11.7)	494 (10.2)	466 (9.9)	0.02
HTN	3,118 (84.1)	4,058 (84.2)	3,899 (82.8)	0.12
Dyslipidemia	2,055 (55.4)	2,761 (58.2)	2,656 (56.7)	0.04
Diabetes mellitus	854 (23.2)	937 (21.6)	952 (25.0)	0.001
Previous acute MI	525 (14.3)	665 (15.3)	623 (16.4)	0.04
Previous PCI	599 (16.4)	823 (17.6)	1,019 (22.2)	<0.0001
Previous CABG	329 (8.9)	473 (9.8)	365 (7.8)	0.002
Clinical presentation				<0.0001
Stable angina	1,320 (35.6)	1,749 (36.3)	1,668 (35.3)	
Silent ischemia	286 (7.7)	500 (10.4)	597 (12.6)	
STEMI	754 (20.3)	766 (15.9)	717 (15.2)	
NTSE-ACS	1,347 (36.3)	1,807 (37.5)	1,745 (36.9)	
Killip, n (%)				<0.0001
1	468 (62.2)	493 (64.6)	507 (71.1)	
2	136 (18.1)	133 (17.4)	102 (14.3)	
3	62 (8.2)	59 (7.7)	38 (5.3)	
4	86 (11.4)	78 (10.2)	66 (9.3)	

Results expressed as mean ± standard deviation and n (%). HTN: systemic arterial hypertension; MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; STEMI: ST-elevation myocardial infarction; NTSE-ACS: non-ST segment elevation acute coronary syndrome.

In Group 3, there was a greater prevalence of single-vessel disease patients. The number of B₂/C and left main coronary artery (LMCA) lesions treated increased, while the number of calcified, thrombotic and long lesions, and bifurcations, decreased (Table 2). The use of drug-eluting stents has increased in recent years. We also observed a decrease in stent diameters, use of glycoprotein IIb/IIIa inhibitors, and Thrombolysis in Myocardial Infarction (TIMI) flow grade 0/1 lesions post PCI, and an increase in the use of thrombus aspiration (Table 3).

Over time, there was a decrease in the number of deaths and MACE, but no statistically significant difference was observed in the incidence of emergency CABG or post-procedure acute MI (Table 4).

Patients who underwent PCI from 2009 to 2011 had a 51% reduction in the odds of dying when compared to the 2006-2008 period, whereas those treated between 2012 and 2016 had a 32% reduction. Each 1-year increment in age produced an increase by 8% in mortality. Finally, female patients had a 38% higher odds of dying than males. Compared to acute clinical presentation, a stable clinical condition was associated with a reduction by 98% in odds of dying, and LMCA lesions were a strong predictor of adverse outcomes (Table 5).

Table 2. Angiographic characteristics

Characteristic	Group 1 (n=3,972 procedures/ n=5,542 vessels)	Group 2 (n=5,135 procedures/ n=7,166 vessels)	Group 3 (n=5,041 procedures/ n=7,171 vessels)	p-value
Extent of coronary artery disease				<0.0001
Single vessel	1,574 (41.0)	2,025 (41.5)	2,167 (47.5)	
Two-vessel	1,254 (32.7)	1,616 (33.1)	1,362 (29.9)	
Three-vessel	975 (25.4)	1,230 (25.2)	1,010 (22.2)	
Multivessel + LMCA	0 (0)	1 (0)	4 (0.1)	
LMCA	33 (0.9)	11 (0.2)	15 (0.3)	
Treated vessels				<0.0001
RCA	1,548 (27.9)	2,055 (28.7)	1,954 (27.2)	
LCx	1,157 (20.9)	1,480 (20.7)	1,593 (22.2)	
LAD	2,563 (46.2)	3,250 (45.4)	3,206 (44.7)	
Venous graft	182 (3.3)	256 (3.6)	220 (3.1)	
LMCA	92 (1.7)	125 (1.7)	198 (2.8)	
Type B ₂ /C lesions	3,636 (72.5)	242 (79.6)	148 (84.1)	0.0001
Calcified lesions	2,089 (38.1)	2,443 (34.4)	1,898 (29.1)	<0.0001
Thrombotic lesions	724 (13.1)	768 (10.7)	620 (8.6)	<0.0001
Long lesions (>20 mm)	1,415 (25.5)	1,683 (23.5)	1,556 (21.7)	<0.0001
Bifurcations	1,522 (27.5)	1,751 (24.4)	1,445 (20.2)	<0.0001
Occlusions	649 (11.7)	688 (9.6)	756 (10.5)	0.0005
TIMI flow pre				<0.0001
0/1	933 (16.8)	1,005 (14.0)	1,048 (14.6)	
2/3	4,608 (83.2)	6,161 (86.0)	6,117 (85.4)	
Left ventricular dysfunction	1,777 (58.7)	1,832 (58.8)	1,624 (57.5)	0.54
Collateral circulation	550 (14.6)	317 (11.9)	352 (12.6)	0.003

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. Procedure characteristics

Characteristic	Group 1 (n=3,707 patients/n=3,972 procedures/n=5,364 stents)	Group 2 (n=4,822 patients/n=5,135 procedures/n=7,095 stents)	Group 3 (n=4,727 patients/n=5,041 procedures/n=6,938 stents)	p-value
Treated vessels/patient	1.5 (0.8)	1.5 (0.8)	1.5 (1.0)	0.15
Use of stent	3,563 (96.1)	4,616 (95.7)	4,519 (95.6)	0.49
Stent/patient ratio	1.5 (0.8)	1.5 (0.8)	1.5 (0.8)	0.07
Drug-eluting stents	1,041 (19.4)	2,016 (28.4)	2,390 (34.5)	<0.0001
Stent diameter, mm	3.00±0.46	2.98±0.48	2.93±0.49	<0.0001
Stent length, mm	18.9±6.8	19.6±7.8	20.8±8.6	<0.0001
Types of intervention				<0.0001
Primary PCI	551 (13.9)	577 (11.2)	466 (9.2)	
Rescue PCI	55 (1.4)	15 (0.3)	14 (0.3)	
Glycoprotein IIb/IIIa inhibitors	317 (8.0)	171 (3.3)	51 (1.0)	<0.0001
Thrombus aspiration	8 (0.1)	33 (0.5)	78 (1.1)	<0.0001
TIMI post				<0.0001
0/1	212 (4.0)	143 (2.0)	195 (2.8)	
2/3	5,147 (96.0)	6,946 (98)	6,735 (97.2)	
Stenosis grade				<0.0001
Pre	86.1 (11.1)	85.7 (16.4)	86.2 (10.9)	
Post	3.1 (13.7)	2.7 (7.8)	5 (6.2)	
Procedural success	3,729 (93.9)	4,933 (96.1)	4,856 (96.3)	<0.0001

Results expressed as n (%) and mean ± standard deviation. PCI: percutaneous coronary intervention; TIMI: thrombolysis in myocardial infarction.

Table 4. Clinical outcomes in in-hospital phase

Outcome	Group 1 (n=3,707 patients)	Group 2 (n=4,822 patients)	Group 3 (n=4,727 patients)	p-value
Post-procedure acute MI	21 (0.6)	22 (0.5)	16 (0.4)	0.65
Emergency CABG	0 (0)	3 (0.07)	0 (0)	0.23
Death	131 (3.6)	77 (1.8)	97 (2.4)	<0.0001
MACE	145 (3.9)	100 (2.1)	111 (2.3)	<0.0001

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

Table 5. Simple logistic regression

Variables	OR	95%CI	p-value
2009-2011 vs. 2006-2008	0.49	0.37-0.65	<0.0001
2012-2016 vs. 2006-2008	0.68	0.52-0.88	0.004
Age, years	1.08	1.05-1.11	<0.0001
Female vs. male	1.38	1.1-1.74	0.006
Smoking, no vs. yes	1.36	0.9-2.04	0.14
HTN, no vs. yes	1.31	0.99-1.73	0.06
Dyslipidemia, no vs. yes	1.82	1.45-2.29	<0.0001
Diabetes mellitus, yes vs. no	1.18	0.9-1.55	0.22
Previous acute MI, yes vs. no	1.02	0.74-1.42	0.89
Previous PCI, no vs. ye	1.60	1.11-2.29	0.011
Previous CABG, no vs. ye	1.17	0.76-1.8	0.47
Clinical presentation, angina vs. acute MI	0.02	0.01-0.05	<0.0001
Clinical presentation, asymptomatic vs. acute MI	0.17	0.1-0.29	<0.0001
Clinical presentation, NTSE-ACS vs. STEMI	0.22	0.17-0.29	<0.0001
Killip 1 vs. 4	0.06	0.04-0.09	<0.0001
Killip 2 vs. 4	0.14	0.08-0.22	<0.0001
Killip 3 vs. 4	0.29	0.17-0.48	<0.0001
Extent of coronary artery disease, two-vessel vs. single vessel	1.50	1.08-2.07	0.015
Extent of coronary artery disease, three-vessel vs. single vessel	3.55	2.65-4.74	<0.0001
Extent of coronary artery disease, multivessel + LMCA vs. single vessel	6.40	0.01-4164.4	0.99
Extent of coronary artery disease, LMCA vs. single vessel	24.77	12.63-48.6	<0.0001
Left ventricular dysfunction, yes vs. no	7.72	4.36-13.65	<0.0001
Collateral circulation, yes vs. no	2.51	1.86-3.41	<0.0001
Types of intervention, primary vs. others	8.88	7.03-11.22	<0.0001
Types of intervention, rescue vs. others	4.82	1.92-12.09	0.0008
Glycoprotein IIb/IIIa inhibitors, yes vs. no	4.58	3.32-6.32	<0.0001

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

DISCUSSION

Elderly patients are challenging in interventional cardiology, from both the diagnostic and treatment standpoints, due to atypical clinical presentations, higher prevalence of risk factors and comorbidities, more complex coronary artery disease and a higher procedure-related complication rate.^{11,12} A significant number of patients with acute coronary syndrome is octogenarian, however only a small portion of subjects in randomized studies fall into this age group. Nonetheless, the randomized octogenarians had fewer comorbidities than commonly seen in daily clinical practice.¹³

Besides comorbidities, another variable that can explain why octogenarians are excluded from trials is frailty.^{14,15} Ridda et al.¹⁶ demonstrated that frail elderly patients are usually excluded from trials. Frailty is a risk factor for mortality and prolonged length of stay in elderly patients after PCI.¹⁷

When compared to younger patients, elderly individuals with cardiovascular disease have an up to four-fold higher risk for complications and mortality.¹⁸ However, in more recent studies, evidence shows that, due to more severe coronary artery disease, the benefits of CABG tend to be greater than in younger patients, including a reduction in mortality.¹⁹⁻²¹ In this study we observed decreased mortality and MACE over time, which may be due to improvement of the techniques and operator experience, and the emergence of new technologies, although no intracoronary ultrasound, optical coherence tomography or fractional flow reserve data were available. The number of procedures increased progressively, particularly between the first and second periods, as well as the use of drug-eluting stents, as supported by recent evidence.²²

In our study, as well as in the literature,¹⁸⁻²⁰ an increase in successful procedure rates was observed over time, even for more complex lesions. We also detected a higher proportion of patients with stable coronary artery disease and silent ischemia, which may be due to increased functional evaluation using different methods.^{23,24} As supported by current evidence, we have seen a less frequent use of glycoprotein IIb/IIIa inhibitors in Brazil (being indicated for selected cases), which may contribute to reduce bleeding and, thus, mortality.^{25,26} Several publications have shown a decrease in post-PCI MACE-related mortality, with an increase in non-cardiovascular mortality, coinciding with an increase in non-cardiac comorbidities.²⁷

Among the limitations of this study, we highlight that the analysis was based on a database updated by volunteers in a non-monitored, non-consecutive fashion, with the possibility of submitting incomplete data or excluding patients with worse clinical outcomes and complications. In addition, this study did not look into any long-term follow-up of patients, which may lead to faulty hypotheses that would have to be validated by further studies. Since this is a registry analysis, there is no control group evaluation or comparisons with patients in other age groups, patients

on medical treatment, or those undergoing CABG. Besides these limitations, due to missing data on entry forms, we could not analyze some relevant variables, such as stroke, vascular and hemorrhagic complications, antiplatelet therapies used, the reason for percutaneous treatment being chosen over other options, the level of angina, the prevalence of patients with high surgical risk, or the SYNTAX score.^{28,29}

CONCLUSION

In the last decade, percutaneous coronary intervention has been offered to an increasing number of octogenarian patients in Brazil. Despite the increased prevalence of comorbidities in these patients over the years, the efficacy and safety of the procedure have clearly improved, with a lower rate of adverse cardiac events and mortality.

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CONFLICTS OF INTEREST

The authors declare there are no conflicts of interest.

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