Temporal analysis of percutaneous coronary intervention in diabetic patients. Data from a national registry

Análise temporal da intervenção coronária percutânea em diabéticos. Dados de um registro nacional

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ABSTRACT – Background: Few publications have evaluated temporal trends and outcomes of percutaneous coronary intervention in diabetic patients in the contemporary era. Our objective was to verify characteristics, procedural results and mortality of percutaneous coronary intervention in diabetic subjects in Brazil in the last 10 years. **Methods:** We analyzed the percutaneous coronary interventions registered in the Brazilian National Registry of Cardiovascular Interventions (CENIC) of the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista*, from 2006 to 2016, comparing three timeframes: 2006-2008, 2009-2011, and 2012-2016. Clinical, angiographic, and procedure characteristics were analyzed, in addition to clinical outcomes and predictors of in-hospital mortality. **Results:** The sample consisted of 38,938 patients, mean age of 63.8±10.5 years, with higher prevalence of male patients (58.9%), and hypertension was the most frequent risk factor (88.6%). During this period, there was an increase in percutaneous coronary interventions in older individuals, with a past history of this procedure, in the presence of acute coronary syndrome, involving a single vessel, and with complex lesions. The use of drug-eluting stents increased, as well as use of longer and small caliber devices. There was a significant increase in procedural success, with decreased mortality rates and major adverse cardiovascular events. The mortality predictors were age, previous infarction, smoking, extent of coronary disease, left main coronary artery lesion, and clinical presentation of myocardial infarction. **Conclusion:** In a 10-year analysis, percutaneous coronary intervention in diabetics patients in Brazil showed a progressive improvement in its results, with reduced in-hospital mortality, in spite of the increasing clinical and angiographic complexity of this population.

Keywords: Chronology as topic; Percutaneous coronary intervention; Diabetes mellitus; Coronary artery disease; Stents; Atherosclerosis

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RESUMO – Introdução: Poucas publicações avaliaram a evolução temporal dos resultados da intervenção coronária percutânea em pacientes diabéticos na era contemporânea. Nosso objetivo foi verificar a evolução do resultado e da mortalidade da intervenção coronária percutânea em diabéticos no Brasil nos últimos 10 anos. **Métodos:** Analisamos as intervenções coronárias percutâneas cadastradas na Central Nacional de Intervenções Cardiovasculares (CENIC) da Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista de 2006 a 2016, sendo comparados três intervalos de tempo: 2006-2008, 2009-2011 e 2012-2016. Foram verificadas as características clínicas, angiográficas e dos procedimentos, além de desfechos clínicos e preditores de mortalidade hospitalar. **Resultados:** A amostra foi composta por 38.938 pacientes, com idade de 63,8±10,5 anos e maior prevalência do sexo masculino (58,9%), sendo a hipertensão o fator de risco mais frequente (88,6%). Nesse período, houve crescimento das intervenções coronárias percutâneas entre os pacientes mais idosos, com antecedentes desse procedimento anteriormente, na vigência de síndrome coronária aguda, com acometimento uniarterial e portadores de lesões complexas. O uso de stents farmacológicos também foi crescente, assim como de dispositivos mais longos e menos calibrosos. Houve aumento significativo das taxas de sucesso do procedimento, com redução da mortalidade e de eventos cardíacos adversos maiores. Foram preditores de mortalidade: idade, infarto prévio, tabagismo, extensão da doença coronária, acometimento do tronco de coronária esquerda e quadro clínico de infarto. **Conclusões:** Evolutivamente, em análise de 10 anos, a intervenção coronária percutânea em diabéticos no Brasil apresentou melhora progressiva de seu resultado, com redução da mortalidade hospitalar, a despeito da crescente complexidade clínica e angiográfica dessa população.

Descritores: Cronologia como assunto; Intervenção coronária percutânea; Diabetes mellitus; Doença da artéria coronariana; Stents; Aterosclerose

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INTRODUCTION

Diabetes mellitus is a known risk factor for the development of atherosclerosis, which is the major cause of mortality in diabetics.¹ The incidence of type 2 diabetes mellitus has doubled in the last 30 years and is estimated to affect 366 million people by 2030.² Following the global trend, Brazil is among the ten countries with the highest absolute number of diabetic individuals.^{3,4}

Patients with diabetes have a higher risk of cardiovascular events and death as compared to non-diabetics. Surgical or percutaneous myocardial revascularization are important strategies in the treatment of coronary artery disease, impacting on quality of life and survival of these patients. Diabetics account for approximately one-third of patients undergoing percutaneous coronary intervention (PCI) in the United States.⁵ Recent data from the National Cardiovascular Data Registry® (NCDR®) have reported an increase from 45% to 48.9% in PCI conducted in multivessel diabetic patients with non-ST segment elevation acute coronary syndrome (NSTEMI-ACS), from 2008 to 2014.⁶ The results of PCI among diabetic subjects are, however, less striking, with higher incidence of repeat revascularizations in the late follow-up, especially in multivessel patients. The complexity of coronary lesions, rapid progression of atherosclerotic disease, and higher rates of restenosis, even with the use of drug-eluting stents, are some reasons for these results.⁷⁻⁹

On the other hand, the progress of PCI techniques and devices in recent years has been outstanding, and few publications are available regarding the impact of this development on in-hospital outcomes of PCI in diabetic patients in our country. Our objective was to verify characteristics, procedural results and mortality of PCI in diabetic patients in Brazil in the last 10 years.

METHODS

This study was evaluated by the Research Ethics Committee of the *Hospital Leforte* and registered at *Plataforma Brasil*, approval under CAAE: 92420918.7.0000.5485. The *Central Nacional de Intervenções Cardiovasculares* (CENIC, <http://www.corehemo.net/>), an official body of the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* (SBHCI), was established in 1991 and is a database fed by voluntary contribution, through standardized files stored in an automated registry; the success and failure criteria are included by SBHCI members from several Brazilian interventional centers.¹⁰

This study did a retrospective analysis of data related to PCI performed in diabetic patients between 2006 and 2016. For the evolutionary analysis, the study population was divided into three periods: 2006-2008, 2009-2011, and 2012-2016. The following criteria were adopted, as established by CENIC, but appraised by the operators: procedural success, defined as the achievement of a residual

stenosis <30%; and incidence of in-hospital major adverse cardiac events (MACE) was defined as death, reinfarction or emergency surgery, when performed as a result of acute or subacute occlusion of the target vessel, or triggered by other reasons of PCI failure, followed by acute myocardial ischemia. Diagnosis and management of patients were carried out according to the specific routines of each collaborating center associated with SBHCI.

Categorical variables were expressed as absolute numbers and percentages, and compared using the Chi-square test. Fisher's exact test or likelihood ratio test were used whenever necessary. Continuous variables were expressed as mean and standard deviation, and compared by analysis of variance (ANOVA). For multiple comparisons, the Bonferroni correction was used. To verify the influence of variables of interest in relation to mortality, the simple and multiple logistic regression model was used. In all analyzes, the significance was set at 5% (p-value <0.05).

RESULTS

During the study period, from 2006 to 2016, a total of 191,716 patients were included in CENIC, and 38,938 (20.3%) were diabetics who comprised our sample for analysis. The clinical characteristics are depicted in table 1. The number of patients with acute myocardial infarction (MI) was small in relation to the total sample size. Over time, the number of subjects with ST-segment elevation acute MI (STEMI) tended to decrease. Considering the Killip classification, Killip 1 was found in the following rates per period: 69% in 2006-2008, 74.6% in 2009-2011, and 77.8% in 2012-2016 (p<0.0001), demonstrating an

Table 1. Clinical characteristics

Characteristic	2006-2008 (n=13,173)	2009-2011 (n=13,758)	2012-2016 (n=12,007)	p-value
Age, years	63.8±10.5	63.8±10.5	64.3±10.7	0.001
Male sex	7,647 (58.1)	8,138 (59.2)	7,154 (59.6)	0.037
Smoking	2,754 (20.9)	2,699 (19.6)	2,299 (19.1)	0.001
Hypertension	11,671 (88.6)	12,232 (88.9)	10,605 (88.3)	0.335
Dyslipidemia	8,689 (66)	9,141 (66.4)	7,633 (63.6)	<0.0001
Prior acute MI	2,424 (18.4)	2,732 (19.9)	2,260 (18.8)	0.007
Prior PCI	2,563 (19.9)	2,718 (20.8)	2,511 (21.6)	0.006
Prior CABG	1,433 (10.9)	1,587 (11.5)	1,226 (10.2)	0.003
Clinical presentation				<0.0001
Stable angina	5,902 (44.8)	5,977 (43.4)	4,419 (36.8)	
Silent ischemia	1,241 (9.4)	1,481 (10.8)	1,205 (10.0)	
STEMI	2,224 (16.9)	1,998 (14.5)	1,662 (13.8)	
NSTEMI-ACS	3,806 (28.9)	4,302 (31.3)	4,721 (39.3)	

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

increasing pattern, with a concurrent decrease in Killip IV patients.

As to the angiographic characteristics, more patients had single-vessel disease and the left anterior descending artery was the vessel treated more often over time, as well as more complex lesions. B₂/C lesions were progressively more treated, as well as longer lesions. On the other hand, calcified, thrombotic, bifurcation or chronic total occlusion lesions occurred in slightly smaller numbers in the evolution (Table 2).

Coronary stents were placed in over 95% of procedures, at a ratio of 1.5 stent per patient, in the 10-year period. The use of drug-eluting stents increased, as well as employment of longer and small caliber devices. Glycoprotein IIb/IIIa inhibitors were progressively less prescribed, unlike manual thrombus aspiration which increased in the period. Final TIMI 2/3 flow was achieved at a progressively higher frequency, and the procedural success rate that was high during the study period, had significant improvement throughout time. The procedural data are presented in table 3.

Table 2. Angiographic characteristics

Characteristic	2006-2008 (n=13,173 patients/n=14,174 procedures/n=19,614 vessels)	2009-2011 (n=13,758 patients/n=14,636 procedures/n=20,401 vessels)	2012-2016 (n=12,007 patients/n=12,594 procedures/n=17,338 vessels)	p-value
Coronary disease extension				<0.0001
LMCA	51 (0.4)	17 (0.1)	22 (0.2)	
Single vessel	5,802 (42.3)	5,806 (41.8)	5,739 (46.5)	
Two-vessel	4,671 (34.0)	4,780 (34.4)	3,785 (30.7)	
Three-vessel	3,201 (23.3)	3,291 (23.7)	2,790 (22.6)	
Treated vessels				<0.0001
RCA	5,604 (28.6)	6,073 (29.8)	5,039 (29.1)	
LCx	4,899 (25.0)	5,043 (24.7)	4,394 (25.3)	
LAD	8,221 (41.9)	8,331 (40.8)	7,140 (41.2)	
Grafts	698 (3.6)	744 (3.6)	524 (3.0)	
LMCA	192 (1.0)	210 (1.0)	241 (1.4)	
Calcified lesions	5,568 (28.4)	5,863 (28.7)	4,379 (25.3)	<0.0001
Thrombotic lesions	2,192 (11.2)	2,100 (10.3)	1,497 (8.6)	<0.0001
Lesions >20mm	5,280 (26.9)	5,980 (29.3)	5,108 (29.5)	<0.0001
Bifurcations	5,046 (25.7)	4,657 (22.8)	3,821 (22.0)	<0.0001
Chronic total occlusions	2,114 (10.9)	2,084 (10.2)	1,722 (9.9)	0.010
TIMI flow pre				<0.0001
0/1	3,186 (16.2)	2,815 (13.8)	2,091 (12.1)	
2/3	16,425 (83.8)	17,581 (86.2)	15,241 (87.9)	
Collateral circulation	1,951 (14.6)	1,103 (12.4)	1,114 (12.1)	<0.0001

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	2006-2008 (n=13,173 patients/n=14,174 procedures/n=18,746 stents)	2009-2011 (n=13,758 patients/n=14,636 procedures/n=19,831 stents)	2012-2016 (n=12,007 patients/n=12,594 procedures/n=16,963 stents)	p-value
Treated vessels/patient	1.5±0.8	1.5±0.8	1.4±0.8	<0.0001
Use of stent	12,573 (95.4)	13,128 (95.4)	11,491 (95.7)	0.492
Number of stents/patient	1.5±0.8	1.5±0.8	1.5±0.8	0.999
Drug-eluting stents	5,622 (30.1)	7,695 (38.8)	6,786 (40.0)	<0.0001
Stent diameter, mm	2.97±0.47	2.95±0.48	2.92±0.48	<0.0001
Stent length, mm	19.3±7.0	19.6±7.1	19.9±7.2	<0.0001
Types of intervention				<0.0001
Primary PCI	1,323 (9.3)	1,218 (8.3)	1,072 (8.5)	
Rescue PCI	206 (1.5)	55 (0.4)	36 (0.3)	
Glycoprotein IIb/IIIa inhibitors	1,175 (8.3)	585 (4.0)	222 (1.8)	<0.0001
Thromboaspiration	44 (0.2)	143 (0.7)	177 (1.0)	<0.0001
TIMI flow post				<0.0001
0/1	681 (3.6)	433 (2.2)	167 (1.0)	
2/3	18,043 (96.4)	19,392 (97.8)	16,796 (99.0)	
Diameter stenosis				<0.0001
Pre	85.1±13.7	84.4±14.5	85.0±11.7	
Post	2.4±10.6	2.7±7.7	5.6±4.3	
Procedural success	13,597 (95.9)	14,193 (97.0)	12,276 (97.5)	<0.0001

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

In-hospital clinical outcomes had a significant reduction over time in the rate of major adverse cardiac events and mortality, as presented in table 4. In the univariate analysis, age, smoking, previous acute MI, clinical presentation of ACS, Killip 4, extension of coronary disease, left main coronary artery lesion, left ventricular dysfunction, use of glycoprotein IIb/IIIa inhibitors, primary and salvage PCI, and the procedures conducted between 2006-2008 were the variables most related to the event of death. In the multivariate analysis, age, smoking, previous AMI, clinical presentation of the ACS, extent of coronary disease, left main coronary artery lesion, primary and salvage PCI, use of glycoprotein IIb/IIIa inhibitors, and procedures conducted between 2006-2008, remained as the variables that best explained the occurrence of death (Table 5).

Table 4. Clinical outcomes in the in-hospital phase

Outcome	2006-2008 (n=13,173 patients)	2009-2011 (n=13,758 patients)	2012-2016 (n=12,007 patients)	p-value
MI	55 (0.4)	68 (0.5)	37 (0.3)	0.066
Emergency CABG	2 (0.18)	7 (0.06)	4 (0.03)	0.134
Death	186 (1.4)	114 (0.8)	92 (0.8)	<0.0001
MACE	225 (1.7)	183 (1.3)	125 (1.0)	<0.0001

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

Table 5. Logistic regression analysis for the outcome mortality

Variables	Estimate	p-value	OR	95%CI
2009-2011 vs. 2006-2008	-0.41	0.0027	0.67	0.51-0.87
2012-2016 vs. 2006-2008	-0.48	0.0010	0.62	0.46-0.82
Age, years	0.04	<0.0001	1.04	1.03-1.05
Smoking, yes vs. no	0.35	0.0074	1.41	1.10-1.82
Prior acute MI, yes vs. no	0.53	0.0001	1.69	1.31-2.19
Two-vessel vs. single-vessel	0.66	0.0001	1.93	1.40-2.66
Three-vessel vs. single-vessel	1.27	<0.0001	3.56	2.63-4.82
Multivessel + LMCA vs. single-vessel	15.02	0.9997	23.68	0.04-15.41
LMCA vs. single-vessel	3.44	<0.0001	31.22	14.33-68.03
GP IIb/IIIa inhibitors, yes vs. no	0.61	<0.0001	1.84	1.38-2.46
Silent ischemia vs. stable angina	0.33	0.4491	1.39	0.6-3.22
STEMI vs. stable angina	2.20	<0.0001	9.02	5.22-15.57
NTSE-ACS vs. stable angina	1.39	<0.0001	4.03	2.56-6.34
Primary PCI vs. others	1.09	<0.0001	2.99	1.98-4.50
Rescue PCI vs. others	1.44	<0.0001	4.24	2.26-7.93

MI: myocardial infarction; LMCA: left main coronary artery; GP: glycoprotein; STEMI: ST-segment elevation myocardial infarction; NTSE-ACS: non-ST segment elevation acute coronary syndrome; PCI: percutaneous coronary intervention.

DISCUSSION

In the last 10 years, there has been a progressive improvement in clinical results with significant reduction in mor-

talidity of diabetic patients submitted to PCI and included in CENIC. This improvement occurred even in a scenario in which PCI is increasingly more indicated in ACS, in older patients with more complex lesions. This fact may be explained by the constant evolution of techniques and materials used in PCI and the appropriate indication, respecting the guidelines for coronary artery bypass grafting. Singh et al., in an evolutionary 30-year analysis (1978 to 2008) of PCI conducted at the Mayo Clinic, also found significant improvement in procedural success (from 27.5% to 92.5%) and reduced hospital mortality (from 4.9% to 2.5%) in diabetics over time, in an increasingly elderly population.¹¹ A registry with national data of PCI in diabetics in Spain, from 2001 to 2011, showed no change in in-hospital mortality (1.9% to 2.5%).¹² This fact was also found in a large, more recent (2011 to 2015) Korean registry, with 37% diabetic patients, and a mean mortality of 2.6%.¹³

Despite the complexity of these patients and the low mortality rate, the beginning of the period studied demonstrates a bias in patient selection, that is, the multivessel patients with greater angiographic complexity were referred for surgical treatment.¹⁴⁻¹⁶ This management is corroborated by the non-availability of drug-eluting stents for patients of the Brazilian Public Health System (SUS) in the period studied, justifying the low rate of use of these devices in this population, despite the growth of their use from 30% to 40% within 10 years. This progress is less than expected, since the guidelines' recommendation to use drug-eluting stents is supported by indication Class 1 and Level of Evidence A, being diabetes a marker of worse prognosis in the mid- and long run after PCI, with higher incidence of clinical and angiographic events, especially coronary restenosis, due to exacerbated neointimal hyperplasia.¹⁷⁻²⁰ Some studies analyzed the influence of using drug-eluting stents on selection of diabetic patients treated by PCI, and demonstrated the greater availability of such stents increases the indications for more complex cases and enables achieving more complete myocardial revascularization.⁷⁻⁹

Two temporal trends demonstrated in this study with diabetic patients show what occurred with the Brazilian population in the past 10 years: aging, with older individuals having access to the healthcare system, and reduction in smoking, as a consequence of policies and laws restricting this habit. Another result that may find an answer in the organization of health policies in our country, instead of representing improvement of cardiovascular prevention actions, was the progressive reduction of patients with STEMI and, consequently, of primary PCI during the course of the study. A drop in PCI in acute MI patients was also described in the registry by Han et al.¹³

Angiographic complexity, with more type B₂/C lesions, was greater in the period analyzed, and was mostly due to increasingly longer lesions, reflecting the progressive use of longer and small caliber stents. It is worth mentioning that longer stents have become more available in Brazil in

recent years. Poddar et al., in a study analyzing the evolutionary trend of PCI in young patients, during a 20-year period (1992 to 2012), reported the same results, with an increasing number of type B₂/C and long lesions, which were addressed when drug-eluting stents were launched.²¹ However, the reduction in interventions in chronic total occlusions, despite improved techniques and materials used, may be related to the more frequent evaluation of myocardial viability.^{22,23} In addition, drug-eluting stents were not provided by the SUS in the first periods, and patients were referred for coronary artery bypass graft.

The use of glycoprotein IIb/IIIa inhibitors in PCI was recommended in diabetic patients with angiographic complexity in the past decade in studies demonstrating a reduction in MACE. Nonetheless, the use of these drugs was not frequent in this registry.²⁴ The efficacy and safety of pre-treatment with clopidogrel and new antiplatelet agents, such as prasugrel and ticagrelor, associated with acetylsalicylic acid in the dual antiplatelet therapy, have restricted the current use of glycoprotein IIb/IIIa inhibitors in ACS patients, who presented a high thrombus burden or as bail-out therapy in vessel occlusions during the procedure.¹⁷ These pieces of evidence justify the significant drop in use of this drug class over the studied period.

In our analysis, age, smoking, prior acute MI, clinical status of ACS, extent of coronary artery disease, left main coronary artery lesion, primary or rescue PCI, use of glycoprotein IIb/IIIa inhibitors, and procedures conducted between 2006-2008 were the variables that best explained the occurrence of death. Age was the only factor also found in a model developed with 588,398 procedures included at the National Cardiovascular data Registry (NCDR) to predict intrahospital mortality, in which cardiogenic shock was the strongest predictor, followed by renal failure and age.²⁵

We considered some limitations of this study, including its observational, retrospective nature and the analysis of non-adjudicated data, which are contributed on a voluntary basis. Since data are provided by operators, there may be a trend towards valuing successes, besides reporting less complex procedures, not including all procedures conducted in the country in the period. We are aware that information was provided by several organizations, spread throughout Brazil, and data related to MACE and mortality may be suppressed by operators, thus avoiding reporting of negative outcomes from their respective organizations. It is also important to emphasize the decrease in clinical outcomes found in the results of this study could be associated with a lower prevalence of lesions that are calcified, thrombotic, at bifurcations, and chronic occlusions, as well as single-vessel involvement, progressively more frequent in our results. In spite of the limitations here presented, the large number of patients, might be the largest population with national data on the topic published to this day, which gives merit to this analysis.

CONCLUSION

Throughout time, percutaneous coronary intervention in diabetic patients in Brazil has presented increasingly better results, with decreased in-hospital mortality, despite the growing clinical and angiographic complexity of this population.

SOURCE OF FINANCING

None.

CONFLICTS OF INTEREST

The authors declare they have no conflicts of interest.

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