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Brazilian registry of percutaneous coronary intervention in chronic total occlusions

Registro brasileiro de intervenção coronária percutânea em oclusões crônicas

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ABSTRACT – Background: Coronary chronic total occlusion is present in approximately one third of patients with coronary artery disease, and its management is challenging. Brazilian reports on percutaneous coronary intervention in this scenario are scarce. The objective of this study was to present contemporary data on percutaneous coronary intervention in chronic total occlusions. **Methods:** We analyzed the clinical, angiographic and procedural characteristics of all coronary interventions in chronic total occlusions of the *Central Nacional de Intervenções Cardiovasculares* (CENIC) performed between June 2006 and March 2016. In-hospital clinical events were also considered. For time trend analysis, the data were divided into periods/groups: 2006-2008 (Group 1), 2009-2011 (Group 2) and 2012-2016 (Group 3). **Results:** A total of 2,018 procedures were performed in 2,009 patients with chronic total occlusions. The mean age was 60.4±10.8 years, with an increase from the first to the third period (59.6±11.0 and 61.2±10.6 years, respectively; $p<0.05$), 21.9% of patients were diabetic, and 62.8% had single-vessel disease. There was an increase in the use of drug-eluting stents between the first and third periods (19.4% and 35.7%; $p<0.0001$). In the multivariate analysis, females (OR: 13.77; 95%CI 1.55-122.39; $p=0.01$) and use of glycoprotein IIb/IIIa inhibitors (OR: 32.29; 95%CI 6.03-172.75; $p<0.0001$) were associated with an increased risk of death. **Conclusion:** There was a temporal increase in the use of drug-eluting stents in the management of chronic total occlusions. Furthermore, female sex and the need for glycoprotein IIb/IIIa inhibitors were associated with a higher risk of death.

Keywords: Coronary artery disease; Coronary occlusion; Angioplasty; Myocardial ischemia

RESUMO – Introdução: A oclusão coronária crônica está presente em aproximadamente um terço dos pacientes com doença arterial coronária, sendo sua abordagem desafiadora. Resultados da intervenção coronária percutânea nesse cenário no Brasil são escassos. Este estudo teve como objetivo apresentar dados contemporâneos da intervenção coronária percutânea em oclusões coronárias crônicas. **Métodos:** Analisamos características clínicas, angiográficas e dos procedimentos de todas as intervenções coronárias em oclusões crônicas da Central Nacional de Intervenções Cardiovasculares (CENIC) realizadas entre junho de 2006 e março de 2016. Eventos clínicos intra-hospitalares também foram analisados. A fim de analisar tendências temporais, os dados foram divididos por períodos/grupos: 2006-2008 (Grupo 1), 2009-2011 (Grupo 2) e 2012-2016 (Grupo 3). **Resultados:** Foram realizados 2.018 procedimentos em oclusões crônicas em 2.009 pacientes. A média de idade foi 60,4±10,8 anos, com aumento do primeiro para o terceiro período (59,6±11,0 e 61,2±10,6 anos, respectivamente; $p<0,05$), 21,9% eram diabéticos e 62,8% uniarteriais. Houve aumento no uso de stents farmacológicos entre o primeiro e o terceiro períodos (19,4% e 35,7%; $p<0,0001$). Na análise multivariada, sexo feminino (RC: 13,77; IC95% 1,55-122,39; $p=0,01$) e uso de inibidores de glicoproteína IIb/IIIa (RC: 32,29; IC95% 6,03-172,75; $p<0,0001$) foram associados a maior risco de óbito. **Conclusão:** Houve incremento temporal no uso de stent farmacológico na abordagem de oclusões crônicas. Ainda, sexo feminino e necessidade de inibidores de glicoproteína IIb/IIIa foram associados a maior risco de óbito.

Descritores: Doença da artéria coronariana; Oclusão coronária; Angioplastia; Isquemia miocárdica

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INTRODUCTION

Chronic coronary occlusion is described in approximately one-third of patients with coronary artery disease (CAD), with records of up to 20% occurrence in patients

undergoing coronary angiography for CAD investigation.^{1,2} Improvements in revascularization strategies and techniques have increased the success rates of percutaneous coronary intervention (PCI) in these cases.³⁻⁶

Registries are a good source for analyzing real-life results. In 1991, the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* (SBHCI) prepared a database for all PCI procedures performed in the country. This is the *Central Nacional de Intervenções Cardiovasculares* (CENIC; <http://www.corehemo.net/>).⁷

Very little is known about the Brazilian experience on the management of chronic total occlusions. This study aimed to present the temporal profile of patients with this condition and the results of the procedures performed in a period of 10 years.⁸⁻¹¹

METHODS

Data were obtained from CENIC. Patient characteristics and procedural data are voluntarily sent by registered members, and detailed information is collected on coronary interventions performed in approximately 200 interventional cardiology centers in the country. This study was approved by the Research Ethics Committee of Hospital Leforte and was registered in Plataforma Brasil, CAAE: 07801419.9.0000.5485.

We analyzed all cases included in the registry from June 2006 to March 2016. Inclusion criteria were patients with total obstructive coronary lesions (100% luminal diameter stenosis), with pre-PCI Thrombolysis in Myocardial Infarction (TIMI) flow 0, with at least 3 months of occlusion. Exclusion criteria were patients with acute coronary syndromes (with or without ST segment elevation), presence of thrombotic lesions, and thromboaspiration. The analysis was conducted according to the period in which PCI

was performed. The patients were divided into three time groups: 2006-2008 corresponded to Group 1; 2009-2011 to Group 2; and 2012-2016 to Group 3.

Clinical, angiographic and procedure characteristics, and in-hospital clinical outcomes were analyzed: death, emergency coronary artery bypass graft (CABG), and periprocedural infarction, either alone or associated with other major adverse cardiac events (MACE).¹² For the analysis of variables, each patient was considered as a sampling unit. Some patients underwent more than one procedure. In these cases, the procedure considered was randomly selected.

For comparison of categorical variables, the Chi-square test was used. When necessary, the likelihood ratio test was used. For comparison of continuous variables in the 2006-2016 period, 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 logistic regression model was used. All analyses considered a significance level of 5% ($p < 0.05$).

RESULTS

The sample consisted of 2,018 procedures performed in 2,009 patients. A total of 2,153 vessels were treated using 2,695 stents. Table 1 shows the clinical characteristics of the patients. There was a significant difference in mean age among the periods analyzed. In Group 1, the proportion of smokers was greater than in the two following periods. In Group 3, the proportion of patients with prior PCI was higher than in Groups 1 and 2. In Group 1, the proportion of patients with angina was greater than in other groups.

Table 2 shows the angiographic characteristics. In Group 3, the proportion of single-vessel procedures was greater than in other groups. In Group 1, the proportion of vessels with calcified lesions was greater than in the other groups.

Table 1. Clinical characteristics

Characteristic	Group 1 (n=591 patients)	Group 2 (n=759 patients)	Group 3 (n=659 patients)	Total (n=2,009 patients)	p-value
Age, years	59.6±11.0	60.3±10.8	61.2±10.6	60.4±10.8	0.03
Male sex	66.3	68.1	67.5	67.4	0.78
Smoking	27.6	21.1	12.4	20.2	<0.0001
Hypertension	77.0	77.5	80.9	78.4	0.18
Dyslipidemia	59.9	61.4	56.1	59.2	0.12
Diabetes mellitus	23.9	21.3	19.3	21.9	0.22
Prior MI	34.5	33.2	27.6	32.4	0.07
Prior PCI	11.7	13.6	22.4	15.9	<0.0001
Prior CABG	4.2	2.5	3.3	3.3	0.21
Clinical presentation					<0.0001
Stable angina	84.4	76.0	74.7	78.0	
Silent ischemia	15.6	24.0	25.3	22.0	

Results expressed as mean±standard deviation or (%). MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass surgery.

There was also a difference in the number of bifurcation lesions and long lesions among the years observed.

Regarding the procedure characteristics, which are shown in table 3, differences were observed in the number of vessels treated per patient, in the number of stents per patient, in the use of drug-eluting stents, in stent length, in the use of glycoprotein IIb/IIIa inhibitors, in post-procedure TIMI flow, in the diameter of stenosis at the end of the procedure, and in the angiographic success rates among the years analyzed. There was no statistically significant difference in clinical outcomes among the groups during the in-hospital phase (Table 4).

In univariate analysis (Table 5), the following variables demonstrated a significant correlation with a higher risk of death: age (OR: 1.11; 95%CI 1.04-1.19; $p<0.01$), female sex (OR: 16.88; 95%CI 2.11-135.34; $p<0.01$), left main coronary artery lesions (these patients had a 149.8-fold greater risk of death than those with single-vessel disease; 95%CI 10.54-2130.54; $p=0.001$) and use of glycoprotein IIb/IIIa inhibitors (OR: 12.22; 95%CI 2.99-50.03; $p=0.001$).

In the multivariate analysis, female sex (OR: 13.77; 95%CI 1.55-122.39; $p=0.01$) and use of glycoprotein IIb/IIIa inhibitors (OR: 32.29; 95%CI 6.03-172.75; $p<0.0001$) were associated with an increased risk of death.

Table 2. Angiographic characteristics

Characteristic	Group 1 (n=594 procedures/ n=649 vessels)	Group 2 (n=760 procedures/ n=810 vessels)	Group 3 (n=664 procedures/ n=694 vessels)	Total (n=2,018 procedures/ n=2,153 vessels)	p-value
Coronary disease extension					0.01
Single vessel	64.7	62.4	61.3	62.8	
Two-vessel	25.2	21.7	26.4	24.2	
Three-vessel	10.0	14.8	12.1	12.5	
LMCA	0.2	1.0	0.2	0.5	
Treated vessels					0.46
RCA	37.3	35.1	34.0	35.4	
Cx	22.3	24.1	20.2	22.3	
LAD	39.4	39.4	44.5	41.1	
LMCA	0.2	0.2	0.3	0.2	
Calcified lesions	27.9	20.8	16.3	21.5	<0.0001
Lesions >20 mm	44.5	34.0	21.5	33.1	<0.0001
Bifurcations	19.6	13.2	15.7	15.9	0.004
Left ventricular dysfunction	48.4	54.5	52.0	51.3	0.32
Collateral circulation	44.7	37.7	40.1	41.6	0.10

Results expressed as %. LMCA: left main coronary artery; RCA: right coronary artery; Cx: circumflex; LDA: left anterior descending artery.

Table 3. Characteristics of procedures

Characteristic	Group 1 (n=594 procedures/ n=740 stents)	Group 2 (n=760 procedures/ n=1,018 stents)	Group 3 (n=664 procedures/ n=937 stents)	Total (n=2,018 procedures/ n=2,695 stents)	p-value
Treated vessels/patient	1.12±0.36	1.08±0.29	1.07±0.28	1.09±0.31	0,005
Stent/patient ratio	1.27±0.50	1.35±0.62	1.44±0.67	1.36±0.61	<0,0001
Drug-eluting stents	19.4	19.8	35.7	25.3	<0,0001
Stent diameter, mm	2.91±0.40	2.90±0.43	2.88±0.47	2.9±0.43	0,38
Stent length, mm	22.7±6.8	23.2±8.9	23.9±9.6	23.3±8.6	0,01
Glycoprotein IIb/IIIa inhibitors	4.5	4.3	0.9	3.3	0,0002
Diameter stenosis post	23.7	15.9	12.3	17.4	0,0008
Angiographic success rate	92.9	97.1	98.0	96.2	<0,0001

Results expressed as mean±standard deviation or %.

Table 4. In-hospital clinical outcomes

Outcome	Group 1 (n=591 patients)	Group 2 (n=759 patients)	Group 3 (n=659 patients)	Total (n=2,009 patients)	p-value
Periprocedural acute MI	3 (0.5)	3 (0.6)	1 (0.3)	7 (0.5)	0.82
Emergency CABG	0 (0)	0 (0)	0 (0)	0 (0)	NA
Death	3 (0.5)	4 (0.7)	2 (0.5)	9 (0.6)	0.83
MACE	6 (1.0)	7 (0.9)	3 (0.5)	16 (0.8)	0.48

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

Table 5. Univariate analysis of the outcome hospital death

Variables	OR	95%CI	p-value
Group 1 vs. Group 3	1.44	0.32-6.48	0.63
Group 2 vs. Group 3	0.92	0.15-5.53	0.92
Age, years	1.11	1.04-1.19	0.002
Female sex	16.88	2.11-135.34	0.007
Smoking	5.85	0.34-100.72	0.99
Hypertension	0.43	0.05-3.43	0.42
Dyslipidemia	0.84	0.21-3.38	0.80
Diabetes mellitus	1.19	0.24-5.94	0.82
Prior MI	1.26	0.3-5.28	0.75
Prior PCI	2.88	0.16-50.54	0.99
Prior CABG	0.27	0.03-2.18	0.21
Clinical presentation	3.22	0.86-12.05	0.08
Two-vessel vs. single-vessel	4.91	0.9-26.94	0.06
Three-vessel vs. single-vessel	4.89	0.68-34.91	0.11
LMCA vs. single-vessel	149.83	10.54-2,130.54	0.0002
Left ventricular dysfunction	3.22	0.137-9.32	0.99
Collateral circulation	0.47	0.05-4.52	0.51
Glycoprotein IIb/IIIa inhibitors	12.22	2.99-50.03	0.0005

OR: odds ratio; 95%CI: 95% confidence interval; MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass surgery; LMCA: left main coronary artery.

DISCUSSION

This study presented the profile of patients with chronic total occlusion and the outcomes of the procedures performed and recorded in the CENIC database, in a period of 10 years. Previous studies have been published using information from this registry.⁷⁻¹¹ However, no report on the reality of Brazilian centers concerning procedures for chronic total occlusion had been published.

Although PCI for chronic total occlusions renders the treatment more expensive, benefits have been demonstrated in cases appropriately indicated for this procedure, such as situations in which the vessel involved is definitely responsible for ischemic symptoms, or in some patients with silent ischemia and a large myocardial area at risk, in whom the intervention has a good chance of success.¹³⁻¹⁵ With the development of new strategies, in addition to the techno-

logical evolution of the various devices, the success rate in high-volume centers with high experience reaches approximately 90%.¹⁶ However, many definitions still need to be established and ascertained, and further studies in the area are needed.¹⁷

With a little more than 2,000 patients in this registry, we observed an increase in mean age over time, which is consistent with the worldwide epidemiology of chronic total occlusion in the middle-aged and elderly population.¹⁸ The currently increased use of drug-eluting stents, indicating a preferential use of this procedure in such cases, may explain the greater device length in the later range of the period evaluated.¹⁹

The high success rate observed in this study (96.2%) is consistent with the results of more recently published registries, particularly the OPEN-CTO (Outcomes, Patient Health Status, and Efficiency in Chronic Total Occlusion Hybrid Procedures), which reported a 86% success rate. It may be due to low complexity of the lesions, although no data were available to assess difficulty of the procedures, such as the Japanese CTO score (J-CTO), or to underreporting of therapeutic failures.²⁰⁻²⁴ The in-hospital mortality rate observed in the registry assessed in this study was 0.6% (9 out of 2,009 patients included in the analysis), whereas in the OPEN-CTO registry, the mortality rate was 0.9% (9 out of 1,000 patients included in the analysis). Evaluating the clinical characteristics of patients from both studies, a higher prevalence of patients with multiple comorbidities was observed in the OPEN-CTO registry. In this registry, the mean age was 65.4±10.3 years, the proportion of diabetics was 41.2%, and 65.7% of patients had previously undergone PCI. In our study, the mean age was 60.4±10.8 years, the percentage of diabetics was 21.9%, and only 15.9% of patients underwent PCI.

It is noteworthy that, in our registry, there have been a greater number of procedures in the left anterior descending artery. Usually, the right coronary artery is the most commonly treated vessel, but it was demonstrated that the only subgroup in which there may be a reduction in mortality is the one with involvement of the left anterior descending artery (possibly because it is associated with a larger myocardial area at risk), a factor that may have influenced the local referrals for PCI.²⁵

In the multivariate analysis, the need for glycoprotein IIb/IIIa inhibitors during the procedure was associated with a higher mortality. Probably, this was due to higher procedure failures or complications, which ended up demanding triple antiplatelet therapy in an attempt to improve the outcome, as in cases of slow-flow or no-reflow. Another aspect observed was the fact that the female sex was one of the variables most highly associated with the risk of death. This data aspect, which is presented in a conflicting way in the literature,²⁶⁻³⁰ though most of the studies have been on acute procedures, is not supported by results of more recent studies, which compare the success rate of the PCI and the number of patients.³¹

This study presents the typical limitations of registry-based studies. CENIC contains information voluntarily sent to SBHCI by registered members and therefore some procedures may have not been included. No data are available on the complexity of the procedures or lesions. However, complexity scores were not yet available at the beginning of the study data collection. Recently, a registry on chronic total occlusions has been developed in the country, providing more precise data in this context.³²

It is noteworthy that, in Brazil, the use of drug-eluting stents became available for the patients of the Unified Health System only recently, and most procedures in interventional cardiology in the country are performed in this setting. This explains the large use of bare metal stents in this study and, consequently, some of the population and procedure characteristics.

CONCLUSION

Coronary chronic total occlusion is a major therapeutic challenge. In this Brazilian registry, we present the profiles of patients with this condition and the outcomes of the procedures performed and recorded in CENIC. The data showed a temporal increase in the use of drug-eluting stents, and the variables female sex and use of glycoprotein IIb/IIIa inhibitors were associated with a higher risk of death. The creation of a specific registry for chronic total occlusions will provide a more detailed knowledge about this procedure in the country.

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None.

CONFLICTS OF INTEREST

Luiz Fernando Ybarra is a proctor, speaker and consultant for Boston Scientific (Canada/Portugal).

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