Journal of
Transcatheter Interventions
e-ISSN e-2595-4350

Time profile of percutaneous coronary interventions in calcified lesions

Perfil temporal das intervenções coronárias percutâneas em lesões calcificadas

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DOI: 10.31160/JOTCI2019;27A0002

ABSTRACT – **Background:** Calcified coronary lesions are a complex angiographic scenario in the practice of percutaneous coronary intervention. The objective of this article was to present the temporal trends of the clinical and angiographic profile, and in-hospital outcomes of patients with calcified lesions. **Methods:** A retrospective study of 35,897 patients with coronary calcification included in the *Central Nacional de Intervenções Cardiovasculares* (CENIC) registry, from January 2006 to January 2016. The temporal trends of clinical, angiographic and procedural variables, as well as severe in-hospital clinical events were assessed. **Results:** There was an increase in mean age in this period, with a drop in the number of smokers and of patients with a history of infarction. The use of drug-eluting stents has grown significantly throughout the years. Between 2012 and 2016, the rate of successful procedures was greater than in other periods, accounting for 96.6% of cases. Moreover, there was a temporal reduction in mortality and periprocedural infarction. **Conclusion:** Over one decade, the percutaneous coronary interventions in calcified lesions registered at CENIC presented increasing success rates, rise in the use of drug-eluting stents, and a significant drop in deaths and periprocedural infarction.

Keywords: Percutaneous coronary intervention; Vascular calcification; Coronary artery disease; Stents

RESUMO – **Introdução:** Lesões coronárias calcificadas representam um cenário angiográfico complexo na prática da intervenção coronária percutânea. O objetivo deste trabalho foi apresentar as tendências temporais do perfil clínico, angiográfico e desfechos intra-hospitalares de pacientes com lesões calcificadas. **Métodos:** Estudo retrospectivo com 35.897 pacientes portadores de calcificação coronária inseridos no registro da Central Nacional de Intervenções Cardiovasculares (CENIC) entre janeiro de 2006 a janeiro de 2016. Foram avaliadas as tendências temporais das variáveis clínicas, angiográficas e dos procedimentos, bem como dos eventos clínicos graves intra-hospitalares. **Resultados:** Houve aumento da média de idade entre os períodos, com declínio de tabagistas e de pacientes com histórico prévio de infarto. O uso de stents farmacológicos foi significativamente crescente ao longo dos anos. Entre 2012 e 2016, a proporção de procedimentos com sucesso foi maior do que em outros períodos, alcançando 96,6% dos casos. Ainda, constatou-se redução temporal de mortalidade e de infarto periprocedimento. **Conclusão:** As intervenções coronárias percutâneas em lesões calcificadas da CENIC apresentaram, ao longo de uma década, taxas de sucesso crescentes, aumento no uso de stents farmacológicos e redução significativa de óbitos e infarto periprocedimento.

Descritores: Intervenção coronária percutânea; Calcificação vascular; Doença da artéria coronária; Stents

How to cite this article:
Nascimento GA, Castro MA, Castro PP. Time profile of percutaneous coronary interventions in calcified lesions. J Transcat Interven. 2019;27:eA0002. https://doi.org/10.31160/JOTCI2019;27:A0002

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Received on:
Mar 14, 2017

Accepted on:
Oct 25, 2018

INTRODUCTION

The aging world population, due to health-related and socioeconomic advances achieved throughout the last decades, brings new challenges, especially in the field of health and cardiovascular diseases. In this context, coronary atherosclerosis stands out, and vascular calcification is one of its most advanced presentations. It has been demonstrated that calcification of the atherosclerotic plaque is associated to the degree of vascular inflammation, with expression and activation of osteoblastic cells on

the arterial wall, in addition to calcium deposition.[1] As a result, reduced vascular compliance, abnormal vasomotor responses, and decreased flow in affected myocardial territories are observed.[2]

The treatment available for this condition has evolved. Percutaneous coronary intervention (PCI) stands out in this scenario, despite the inherent limitations. PCI of calcified lesions demonstrates greater rates of coronary restenosis, dissections and perforations, possible damage to stent polymer, need for new interventions, and more failure, associated to difficulty in crossing the lesion with balloons or stents, since reduced distensibility of the vessel predisposes to poor expansion and malapposition of the stent struts.[3] Complementary techniques have been developed for adequate preparation of the plaque and lower failure rates. The current options include the use of some tools, such as the cutting balloon, rotational atherectomy and excimer laser, associated with implant of drug-eluting stents.

This study aimed to analyze the clinical and angiographic profile and the PCI characteristics in patients with coronary calcifications, considering the influence of these variables in hospital mortality.

METHODS

The *Central Nacional de Intervenções Cardiovasculares* (CENIC; http://www.corehemo.net/) is an official agency of the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* (SBHCI), established in 1991 to document the performance and progression of the specialty in the country. It is a database of voluntary contributions of full and candidate members of this society, who are authorized to perform PCI, and covers the Brazilian territory.

Out of 176,780 patients registered, we retrospectively included 35,897 (20.3%) individuals with calcified lesions from 2006 to 2016, divided into three phases: 2006-2008, 2009-2011, and 2012-2016. The clinical, angiographic and procedure characteristics were evaluated, as well as the severe adverse clinical events (death, periprocedural infarction and urgent coronary artery bypass surgery). This study was approved by the Research Ethics Committee of Hospital Bandeirantes, São Paulo (SP), protocol 058162/2018 (CAEE 90669218.4.0000.5485).

Definitions

The Killip-Kimball classification[4] was used to define the functional class. Blood flow before the procedure was defined according to the Thrombolysis in Myocardial Infarction (TIMI) group.[5] The acute patients were classified as ST-segment elevation myocardial infarction (STEMI) or non-ST segment elevation acute coronary syndrome (NTSE-ACS). Multivessel coronary artery disease was defined as presence of stenosis ≥50% in more than one coronary artery. Thrombotic lesions were defined as those presenting images suggesting thrombi in angiography. The definition of left ventricle dysfunction was ventricular ejection fraction <50%.

The procedure success was visually defined, including residual stenosis <20%, with no clinical events, such as death (cardiac or non-cardiac), myocardial infarction (MI) or urgent coronary artery bypass surgery (CABG). Death was defined as any cardiac death, excluding the cases that a non-cardiac cause was identified as the reason for the fatal event.

Statistical analysis

The Chi-square test or likelihood ratio test was used to compare the continuous variables. For the categorical variables, we used the analysis of variance (ANOVA), and for multiple comparisons, the Bonferroni correction. To assess the influence of variables of interest on mortality, the simple logistic regression model was used. The level of significance was set at 5% ($p<0.05$) in all analyses. In the logistic regression analysis, only patients with data for all variables analyzed were validated. Those with many incomplete data, such as Killip classification, left ventricle dysfunction and collateral circulation, were not included. Patients with complete information made up the sample of 32,520 individuals, which was used to analyze mortality. When patients underwent more than one procedure, the random selection was used to analyze the variables associated to the outcome death, so that each patient would represent only one procedure.

RESULTS

The sample comprised 35,897 patients undergoing PCI in calcified lesions, and assessed in the in-hospital period. A total of 47,113 vessels were treated and stents were used in 44,772 (95%) of them, totaling up 47,173 devices. Since one patient could undergo PCI in more than one artery, the rate was 1.04 procedure per patient, totaling up 37,425 cases.

The clinical characteristics are presented in table 1. The mean age of patients was 65.4 years, and patients were noted to be older when comparing the 2006-2008 and 2012-2016 periods. There were more male patients (64%). Throughout the years, patients were more likely to present with dyslipidemia, diabetes mellitus, hypertension and history of PCI. On the other hand, smoking, previous history of acute MI or CABG demonstrated a significant drop, when comparing the periods 2006-2008 and 2012-2016. The clinical picture upon admission also showed statistically significant difference in the period assessed, with a decreased number of patients admitted with stable disease and more presenting acute manifestations.

Table 2 displays the angiographic characteristics of the procedures. Single-vessel coronary disease was more frequent, accounting for 45.6% of cases, and showed a significant increase in the last period. Patients with ventricular dysfunction were more prevalent in the period 2012-2016. Table 3 displays the characteristics of proce-

Table 1. Clinical characteristics

Characteristic	2006-2008 (n=12,549 patients)	2009-2011 (n=13,505 patients)	2012-2016 (n=9,843 patients)	p-value
Age, years	65.1±11.3	65.5±11.2	65.6±11.3	0.001
Male sex	8,076 (64.4)	8,584 (63.6)	6,327 (64.3)	0.35
Smoking	3,465 (27.6)	3,390 (25.1)	2,169 (22.0)	<0.0001
HTN	10,652 (84.9)	1,395 (84.4)	8,565 (87.0)	<0.0001
Dyslipidemia	8,026 (64.0)	8,763 (64.9)	6,876 (69.9)	<0.0001
Diabetes mellitus	3,370 (26.9)	3,599 (26.6)	2,744 (27.9)	0.0008
Prior acute MI	2,783 (22.2)	2,834 (21.0)	1,805 (18.3)	<0.0001
Prior PCI	2,393 (19.1)	2,365 (17.5)	2,474 (25.1)	<0.0001
Prior CABG	1,228 (9.8)	1,302 (9.6)	801 (8.10)	<0.0001
Clinical presentation				<0.0001
Stable angina	5,431 (43.3)	5,383 (39.9)	3,407 (34.6)	
Silent ischemia	1,104 (8.8)	1,433 (10.6)	1,147 (11.7)	
Acute MI	2,355 (18.8)	2,235 (16.5)	1,453 (14.8)	
NSTE-ACS	3.659 (29.2)	4,454 (33.0)	3,836 (39.0)	
Killip classification				<0.0001
1	1,609 (12.8)	1,579 (11.7)	1,062 (10.8)	
2	464 (3.7)	396 (2.9)	240 (2.4)	
3	114 (0.9)	92 (0.7)	50 (0.5)	
4	141 (1.1)	167 (1.2)	101 (1.0)	

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

dures. There was a significant increase in use of drug-eluting stents (Figure 1), accounting for 31.9% of PCI in the period 2012-2016. The use of glycoprotein IIb/IIIa inhibitors dropped throughout the years and is limited to 1.8% of the current procedures. Likewise, thromboaspiration was more often used in 2009-2011, and less employed in the last years analyzed. Procedural success significantly increased when comparing recent to prior rates (Figure 2) and was approximately 97%.

As to clinical outcomes during the in-hospital phase, there was lower mortality in 2012-2016, and less periprocedural acute MI (Table 4). The logistic regression analysis showed higher probability of death in patients from the periods 2006-2008 and 2009-2011, as compared to those seen in 2012-2016 (Table 5). Advanced age increased the risk of death (6%), as well as female sex, diabetes mellitus, dyslipidemia, previous infarction, greater extension of coronary involvement, Killip class IV, and left ventricular dysfunction.

DISCUSSION

We analyzed the clinical and angiographic profile, and the characteristics of the PCI procedures in patients with coronary calcification using the CENIC database. This evaluation is relevant considering the increasing number of percutaneous procedures performed in Brazil and other countries, and the impact of significant calcifications on

Table 2. Angiographic characteristics

Characteristic	2006-2008 (n=13,140 procedures/ n=16,568 vessels)	2009-2011 (n=14,086 procedures/ n=17,799 vessels)	2012-2016 (n=10,199 procedures/ n=12,746 vessels)	p-value
Coronary disease extension				<0.0001
Single vessel	5,519 (42.0)	5,853 (41.6)	4,963 (48.7)	
Two-vessel	4,289 (32.6)	4,389 (31.2)	3,037 (29.8)	
Three-vessel	2,716 (20.7)	2,949 (20.9)	2,025 (19.9)	
Multi-vessel + LMCA	0	0	8 (0.1)	
Isolated LMCA	63 (0.5)	24 (0.2)	21 (0.2)	
Treated vessels				0.0007
RCA	4,962 (37.8)	5,477 (38.9)	3,846 (37.7)	
LCx	3,525 (26.8)	3,854 (27.4)	2,661 (26.1)	
LAD	7,582 (57.8)	7,891 (56.0)	5,856 (57.4)	
Venous graft	268 (2.0)	324 (2.3)	167 (1.6)	
LMCA	231 (1.8)	253 (1.8)	216 (2.1)	
Type B2/C lesions	12,155 (92.5)	1,058 (7.5)	402 (3.9)	0.0001
Thrombotic lesions	2,590 (19.7)	2,784 (19.8)	1,635 (16.0)	<0.0001
Lesions >20mm	5,544 (42.2)	6,193 (44.0)	4,347 (42.6)	0.03
Bifurcations	5,806 (44.2)	5,883 (41.8)	4,366 (42.8)	0.0005
Occlusions	2,215 (16.9)	2,241 (15.9)	1,617 (15.9)	0.02

Results expressed as n (%). LMCA: left main coronary artery; RCA: right coronary artery; LCx: circumflex; LDA: left anterior descending artery.

Table 3. Characteristics of procedures

Characteristic	2006-2008 (n=13,140 procedures/ n=16,262 stents)	2009-2011 (n=14,086 procedures/ n=17,716 stents)	2012-2016 (n=10,199 procedures/ n=13,195 stents)	p-value
Treated vessels/patient	1.3±0.5	1.3±0.5	1.3±0.5	0.25
Use of stent	11,153 (93.8)	12,141 (93.7)	8,973 (94.6)	0.009
Stent/patient ratio	1.3±0.6	1.3±0.6	1.4±0.6	<0.0001
Stent diameter, mm	3.02±0.47	3.01±0.47	2.97±0.48	<0.0001
Stent length, mm	19.6±6.9	20.0±7.2	20.1±7.5	<0.0001
Types of intervention				<0.0001
Primary PCI	1,259 (9.6)	1,356 (9.6)	960 (9.4)	
Rescue PCI	125 (1.0)	54 (0.4)	31 (0.3)	
Glycoprotein IIb/IIa inhibitors	799 (6.1)	523 (3.7)	182 (1.8)	<0.0001
Thromboaspiration	25 (0.2)	83 (0.5)	80 (0.6)	<0.0001
TIMI flow post				<0.0001
0/1	402 (2.5)	312 (1.8)	145 (1.1)	
2/3	15,830 (97.5)	17,394 (98.2)	13,047 (98.9)	
Stenosis grade				
Pre	86.4 (14.0)	86 (13.2)	87.1 (17.7)	<0.0001
Post	3.2 (11.6)	2.8 (8.9)	5.8 (5.2)	<0.0001

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

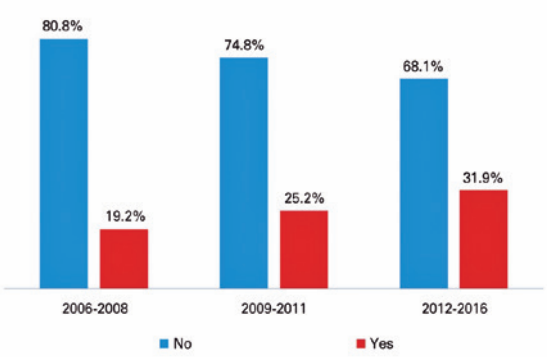

Figure 1. Increased use of drug-eluting stents along time.

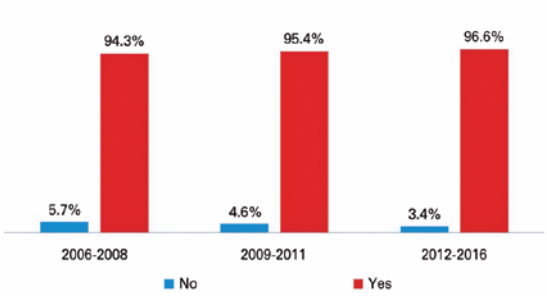

Figure 2. Procedure success.

Table 4. Clinical outcomes in the in-hospital phase

Outcome	2006-2008 (n=12,549 patients)	2009-2011 (n=13,505 patients)	2012-2016 (n=9,843 patients)	Total (n=35,897 patients)	p value
Periprocedural acute MI	93 (0.7)	99 (0.7)	33 (0.3)	225 (0.6)	0.0002
Emergency CABG	0	11 (0.1)	7 (0.1)	18 (0.1)	0.68
Death	184 (1.5)	153 (1.1)	79 (0.8)	416 (1.2)	0.0001

Results expressed as n (%). Acute MI: Acute myocardial infarction; CABG: coronary artery bypass surgery.

Table 5. Simple logistic regression

	Estimate	p-value	OR	95%CI
2006-2008 vs. 2012-2016	0.63	<0.0001	1.88	1.43-2.46
2009-2011 vs. 2012-2016	0.41	0.003	1.51	1.15-1.99
Age, years	0.06	<0.0001	1.06	1.05-1.07
Sex, female vs. male	0.35	0.0004	1.43	1.17-1.73
Smoking, no vs. yes	0.22	0.075	1.24	0.98-1.57
HTN, no vs. yes	0.20	0.131	1.22	0.94-1.58
Dyslipidemia, no vs. yes	0.37	0.0002	1.45	1.19-1.76
Diabetes mellitus, yes vs. no	0.55	<0.0001	1.74	1.42-2.13
Prior acute MI, yes vs. no	0.34	0.003	1.41	1.13-1.76
Previous PCI, no vs. ye	0.32	0.029	1.38	1.03-1.85
Prior CABG, yes vs. no	-0.15	0.396	0.86	0.6-1.22
Clinical presentation, stable angina vs. acute MI	-3.27	<0.0001	0.04	0.02-0.06
Clinical presentation, silent ischemia vs. acute MI	-2.53	<0.0001	0.08	0.04-0.14
Clinical presentation, NSTE-ACS vs. acute MI	-1.40	<0.0001	0.25	0.2-0.31
Killip, 1 vs. 4	-3.82	<0.0001	0.02	0.02-0.03
Killip, 2 vs. 4	-2.54	<0.0001	0.08	0.05-0.12
Killip, 3 vs. 4	-1.15	<0.0001	0.32	0.21-0.48
Two-vessel vs. single-vessel	0.73	<0.0001	2.08	1.54-2.79
Three-vessel vs. single-vessel	1.81	<0.0001	6.09	4.66-7.95
Multivessel + LMCA vs. single-vessel	-15.90	<0.0001	28.32	3.44-233.01
LMCA vs. single-vessel	3.74	<0.0001	42.16	23.84-74.55
Left ventricular dysfunction, yes vs. no	1.72	<0.0001	5.58	3.71-8.39
Collateral circulation, yes vs. no	1.13	<0.0001	3.08	2.41-3.94
Primary PCI vs. others	2.31	<0.0001	10.06	8.23-12.3
Rescue PCI vs. others	2.76	<0.0001	15.83	9.56-26.24
Glycoprotein llb/IIIa inhibitors, yes vs. no	1.81	<0.0001	6.08	4.74-7.8
Procedure success, no vs. yes	6.61	<0.0001	741.87	434.08-1267.91

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

the clinical progression of this group of patients.[6,7] Treated lesions are also more complex. Data obtained from the SYNTAX study showed 32.7% of patients undergoing coronary artery bypass surgery presented significant calcification in these arteries.[8] The prevalence of patients who were elderly, diabetic, hypertensive, male and smoker found in our analysis confirms the risk factors closely related to pathogenesis of coronary calcification.[2,9]

The analysis of the ACUITY and HORIZONS-AMI studies performed by Généreux et al.[10] demonstrated that culprit lesions in cases of NSTE-ACS and acute MI were often moderately to severely calcified. Moreover, they were associated with suboptimal angiographic result and periprocedural complications, hindering stent deployment, leading to less expansion and malapposition of the struts, dissection of the edges and even rupture of the vessel due to post-dilation at high pressure.[11] The presence of significant calcification can also cause damage to the drug-eluting stent polymers,[12,13] contributing to less efficacy of the devices in these lesions.[14] As a result, greater thrombosis and restenosis rates are reported in this patient group, as compared to lesions with little or no calcification.[10]

Some tools, such as intracoronary ultrasound and optical coherence tomography (OCT), have been employed for more accurate diagnosis, better characterization of the calcified plaque and optimization of the stent implantation.[15-18] With better knowledge about the lesion characteristics, some strategies were developed to improve the success rate in this adverse scenario.[10] New technologies and evolution of the previously employed methods have gained importance when preparing the calcified artery. The current options include rotational atherectomy that modifies the plaque;[3,19,20] use of cutting/scoring balloon - proven as superior to conventional balloons[21] as it can cause fracture, compression and redistribution of the calcified plaque, increasing local elasticity of the vessel;[22] orbital atherectomy using centrifugal force;[23] excimer laser, which causes small erosions and dissections in the plaque;[24] besides conventional, semi-compliant or non-compliant balloons. Within this context, the use of complementary tools to properly prepare the lesions was the most efficient and safe method to obtain successful and sustained late results in interventions in calcified arteries.[10]

The increased number of PCI after approval of drug-eluting stents in the United States reflects in Brazil[25,26] and coincides with the data found in our analysis, primarily in more severe patients who initially presented with acute manifestation. Some studies demonstrated drug-eluting stents are able to reduce revascularization of the target lesion in up to 56% of patients with calcified lesions, with good safety results in the long run.[27-29] These data can be improved with new generation stents that have enhanced mesh and polymers.[29-30]

These findings, associated with the recommendations of the guidelines,[31] justify the marked increase in drug-eluting stents throughout the years, as described in our analysis. However, as compared to the international statistics, the use of these stents in Brazil is still low.[10,23,32] The main reason for this difference is that few centers in the country used this technology in patients reliant on the National Public Health System (SUS, acronym in Portuguese) during the period analyzed in this study. Use of new technologies could justify the temporal differences found, such as increased rate of implanted stents, greater immediate intraluminal expansion, and success rates similar to those described in procedures performed in lower risk subgroups.[23,26,33,34] This improvement may result in decreased number of deaths and periprocedural infarctions.

Among the limitations of the study, we highlight the voluntary contribution of data to the CENIC registry and the absence of detailed information about the tools used to prepare the atheromatous plaque, complicated by calcification, and to enhance stent implantation. Furthermore, we only have in-hospital data and no information on late results to corroborate the maintenance of these early outcomes. Better quality of life and longer survival are important factors to include in a risk stratification model required to make decisions, considering the cost-benefit ratio of treatment strategies for this profile of patients.

CONCLUSION

Over one decade, percutaneous coronary interventions in calcified lesions registered at CENIC presented increasing success rates, rise in use of drug-eluting stents, and a significant drop in deaths and periprocedural infarction.

FUNDING SOURCE

None.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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