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Rescue percutaneous coronary intervention: analysis of a Brazilian registry

Intervenção coronária percutânea de resgate: análise de um registro brasileiro

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ABSTRACT – **Background:** Rescue percutaneous coronary intervention is indicated after failed fibrinolysis in patients with ST-segment elevation myocardial infarction. The objective was to determine the profile of Brazilian patients in this context and their in-hospital outcomes. **Methods:** We prospectively collected data on 1,334 patients submitted to rescue percutaneous coronary intervention registered at the *Central Nacional de Intervenções Cardiovasculares* (CENIC). Patients were divided into three tertiles of time: 2006-2008, 2009-2011, and 2012-2016. The primary composite endpoint was the rate of major adverse cardiac events: death, acute myocardial infarction, or emergency myocardial revascularization. **Results:** Of the 1,334 patients, 71.1% were male, mean age of 59.7±11.8 years. Decreased prevalence of hypertension (p=0.0006), dyslipidemia (p=0.01), and *diabetes mellitus* (p=0.02) was observed throughout the tertiles, as well as an increased number of cases classified as Killip 1 (p<0.0001). Regarding characteristics of angiography and procedure, there was a progressive decrease in thrombotic lesions (p<0.0001), occlusions (p=0.003), and use of glycoprotein IIb/IIIa inhibitors (p>0.0001). There was also an increase in use of drug-eluting stents (p<0.0001), as well as in the success of the procedure (p=0.03). The rate of major adverse cardiac events was low, with a tendency to decrease in the last tertile (5.2% vs. 6.3% vs. 2.2%; p=0.06). In total, acute myocardial infarction and death rates were 1.1% and 4.3%, respectively. **Conclusions:** The low rate of major adverse cardiac events demonstrated the efficacy and safety of rescue percutaneous coronary intervention in Brazil. The current improvement of indicators may be associated with changes in the clinical profile, better devices, and adoption of protocols.

Keywords: Angioplasty; Myocardial infarction; Fibrinolysis; Brazil

RESUMO – **Introdução:** A intervenção coronária percutânea de resgate é indicada no insucesso da fibrinólise em pacientes com infarto agudo do miocárdio com supradesnivelamento do segmento ST. Objetivamos delinear o perfil de pacientes brasileiros neste contexto, assim como os desfechos hospitalares. **Métodos:** Foram coletados, prospectivamente, dados de 1.334 pacientes submetidos à intervenção coronária percutânea de resgate registrados na base Central Nacional de Intervenções Cardiovasculares (CENIC). Dividimos os pacientes em três tercis de tempo: 2006-2008, 2009-2011 e 2012-2016. O desfecho primário combinado foi a taxa de eventos cardíacos adversos maiores: morte, infarto agudo do miocárdio ou revascularização miocárdica de emergência. **Resultados:** Dos 1.334 pacientes, 71,1% eram do sexo masculino, com média de idade de 59,7±11,8 anos. Ao longo dos tercis, evidenciaram-se redução na prevalência de hipertensão (p=0,0006), dislipidemia (p=0,01) e diabetes melito (p=0,02), e aumento na apresentação clínica em Killip 1 (p<0,0001). Quanto às características angiográficas e do procedimento, houve diminuição progressiva de lesões trombóticas (p<0,0001), oclusões (p=0,003) e uso de inibidores de glicoproteína IIb/IIIa (p>0,0001). Observou-se, ainda, incremento no uso de stents farmacológicos (p<0,0001), assim como no sucesso do procedimento (p=0,03). A taxa de eventos cardíacos adversos maiores foi baixa, com tendência à redução no último tercil (5,2% vs. 6,3% vs. 2,2%; p=0,06). No total, as taxas de infarto agudo do miocárdio e óbito foram de 1,1% e 4,3%, respectivamente. **Conclusões:** A baixa taxa de eventos cardíacos adversos maiores atestou a eficácia e a segurança da intervenção coronária percutânea de resgate no Brasil. A melhora contemporânea dos indicadores pode estar associada a mudanças no perfil clínico, melhoria dos dispositivos e adoção de protocolos de atendimento.

Descritores: Angioplastia; Infarto do miocárdio; Fibrinólise; Brasil

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INTRODUCTION

Acute myocardial infarction (AMI) is an important cause of morbidity and mortality worldwide, and both fibrinolytic therapy and primary percutaneous coronary intervention (PCI) are effective methods to restore blood flow in the presence of a ST-elevation myocardial infarction (STEMI). Primary PCI is the first-line treatment for myocardial reperfusion, provided that it is conducted within 12 hours after onset of symptoms, and the time of the first medical contact to balloon inflation does not exceed 120 minutes.[1,2] However, if a cath lab is not available within 2 hours, fibrinolytic therapy must be given as early as possible - within 30 minutes of the initial diagnosis.

Although fibrinolysis is an excellent alternative, not all patients appropriately reestablish coronary blood flow.[3,4] In such cases, rescue PCI is indicated, consisting of an intervention in patients who have received fibrinolytic therapy and do not meet reperfusion criteria 90 minutes after initiating the infusion. Rescue PCI is crucial for the adequate restoration of coronary flow, to avoid complications, especially deterioration of left ventricular function and death.[5] However, national data on patients submitted to this therapeutic modality are scarce, both to determine a clinical profile, and to evaluate the adverse outcomes.

The objective of this investigation was to describe the clinical and angiographic profile of STEMI patients undergoing rescue PCI in Brazil, as well as to analyze the outcomes associated with the procedure over a 10-year period (2006 to 2016), with information extracted from the *Central Nacional de Intervenções Cardiovasculares* (CENIC).

METHODS

Study design and population

A cross-sectional, retrospective analysis was conducted in consecutive patient data extracted from the CENIC (http://www.corehemo.net). Information regarding the procedures carried out between 2006 and 2016 were prospectively collected. The study was approved by the Internal Review Board of *Hospital Leforte* (CAAE: 90653818.2.0000.5485).

Up to 2016, a total of 176,780 patients were registered in CENIC. The analysis included only patients aged 18 years or older, presenting clinical symptoms of STEMI and submitted to rescue PCI after failed fibrinolytic therapy.

To analyze the temporal pattern of clinical, angiographic and adverse outcome characteristics, patients' data were grouped into three time periods: 2006 to 2008, 2009 to 2011, and 2012 to 2016. The study endpoints were procedural success rate and in-hospital medical outcomes assessed through major adverse cardiac events (MACE), defined as all-cause mortality, AMI after PCI, or need for emergency myocardial revascularization. The diagnosis and treatment in each collaborating center were made according to the specific routines, at the discretion of the clinical teams and of the interventional cardiologist. All data were analyzed assuring patient confidentiality and privacy.

Statistical analysis

Descriptive statistics of the clinical, angiographic, and procedure characteristics; in-hospital clinical outcomes; and successful procedure of patients eligible for analysis were presented. For continuous variables, mean and standard deviation were presented, and, for categorical variables, contingency tables with absolute and percentage frequencies.

The comparative analysis of categorical variables was conducted using the Chi-square test or the Fisher's exact test. Comparing the continuous variables between the periods analyzed was made by the Student's *t* test, using the approximation given by the central limit theorem. For the multiple comparisons, the Bonferroni correction was used. We used the logistic regression method to evaluate death-related risk factors. For all analyses, a p-value <0.05 was considered significant.

RESULTS

Up to 2016, a total of 32,718 patients diagnosed as STEMI were screened. Of these, 1,334 (4.07%) submitted to rescue PCI were eligible and included in this analysis. The mean age was 59.7±11.8 years, and 14% of patients were aged 71-80 years and 4.9% were over 80 years (Table 1).

Considering the three time periods (2006-2008, 2009-2011 and 2012-2016) there was a decreased prevalence in diabetes mellitus (25.2%, 22.5%, 16.7%, respectively; p=0.02), dyslipidemia (49.3%, 41.4%, 41.2%, respectively; p=0.01), and hypertension (76.4%, 66.8%, 66.8%, respectively; p=0.0006), and an increased number of patients presenting with Killip class 1 (38.3%, 59.7%, 71.3%, respectively; p<0.0001).

The angiographic profile (Table 2) did not show significant changes during the period analyzed, with 54.7% of patients showing single-vessel disease, 28.4% two-vessel, 16.7% three-vessel, and 0.23% had lesion in left main coronary artery (LMCA). An average of 1.2±0.5 vessel was treated per patient, and the most frequently coronary artery intervened was the left anterior descending artery (51.6%), followed by the right coronary artery (32.6%) and the circumflex artery (14.0%). In 1.1% of cases, interventions were conducted in surgical grafts and, in 0.7%, in the LMCA. A reduced frequency of thrombotic lesions was observed (p<0.0001). There was also a high prevalence of lesions >20mm (27.2%; p=0.1), bifurcations (29.4%; p=0.1), and B_2/C lesions (82.6%; p=0.51), with no differences among the groups.

The procedures characteristics are depicted in table 3. Stents were used in 90.7% of cases, with a ratio of

Table 1. Clinical characteristics of patients

Clinical characteristics	2006-2008 (n=813 patients; n=592 procedures)	2009-2011 (n=253 patients; n=141 procedures)	2012-2016 (n=268 patients; n=130 procedures)	Total (n=1,334 patients; n=863 procedures)	p-value
Age, years	60.2±12.0	58.8±11.8	58.9±11.1	59.7±11.8	0.125
Age group >70 years	172 (21.2)	44 (17.4)	41 (15.3)	257 (19.3)	0.076
Male	582 (71.6)	177 (70.0)	190 (70.9)	949 (71.1)	0.879
Smoking	333 (41.0)	89 (35.2)	96 (35.8)	518 (38.8)	0.136
Hypertension	621 (76.4)	169 (66.8)	179 (66.8)	969 (72.6)	0.0006
Dyslipidemia	401 (49.3)	104 (41.4)	110 (41.2)	615 (46.2)	0.017
Diabetes mellitus	205 (25.2)	52 (22.5)	36 (16.7)	293 (23.3)	0.029
Previous AMI	81 (10.0)	21 (9.1)	22 (10.2)	124 (9.8)	0.909
Previous PCI	50 (6.3)	11 (4.8)	22 (8.4)	83 (6.4)	0.249
Previous CABG	15 (1.8)	1 (0.4)	4 (1.5)	20 (1.5)	0.254
Killip					<0.0001
1	311 (38.3)	151 (59.7)	191 (71.3)	653 (49.0)	
2	301 (37)	49 (19.4)	52 (19.4)	402 (30.1)	
3	155 (19.1)	22 (8.7)	8 (3)	185 (13.9)	
4	46 (5.7)	31 (12.3)	17 (6.3)	94 (7.0)	
Left ventricular dysfunction					<0.0001
Mild	191 (32.3)	56 (39.7)	47 (36.2)	294 (34.1)	
Moderate	184 (31.1)	32 (22.7)	41 (31.5)	257 (29.8)	
Severe	112 (18.9)	45 (31.9)	18 (13.8)	175 (20.3)	
No dysfunction	105 (17.7)	8 (5.7)	24 (18.5)	137 (15.9)	

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

Table 2. Angiographic characteristics of patients

Angiographic characteristics	2006-2008 (n=818 procedures; n=947 vessels)	2009-2011 (n=260 procedures; n=310 vessels)	2012-2016 (n=269 procedures; n=346 vessels)	Total (n=1,347 procedures; n=603 vessels)	p-value
Extension of coronary disease					0.031
Single-vessel	446 (55.3)	130 (51.2)	150 (56.4)	726 (54.7)	
Two-vessel	241 (29.9)	78 (30.7)	58 (21.8)	377 (28.4)	
Three-vessel	118 (14.6)	45 (17.7)	58 (21.8)	221 (16.7)	
LMCA	2 (0.3)	1 (0.4)	0	3 (0.2)	
Treated vessels					0.041
RCA	296 (31.3)	96 (31.0)	131 (37.9)	523 (32.6)	
LCx	147 (15.5)	39 (12.6)	39 (11.3)	225 (14.0)	
LAD	490 (51.7)	167 (53.9)	170 (49.1)	827 (51.6)	
Bypass graft	11 (1.2)	2 (0.6)	4 (1.2)	17 (1.1)	
LMCA	3 (0.3)	6 (1.9)	2 (0.6)	11 (0.7)	
Lesions type B2/C	765 (82.3)	34 (89.5)	6 (85.7)	805 (82.6)	0.512
Calcified lesions	163 (17.2)	65 (21)	43 (12.4)	271 (16.9)	0.013
Thrombotic lesions	532 (56.2)	139 (44.8)	114 (32.9)	785 (49.0)	<0.0001
Long lesions (>20mm)	275 (29.0)	80 (25.8)	81 (23.4)	436 (27.2)	0.109
Bifurcations	297 (31.4)	84 (27.1)	91 (26.3)	472 (29.4)	0.126
Total occlusion	475 (50.4)	123 (39.7)	156 (45.1)	754 (47.2)	0.003
TIMI flow pre					<0.0001
0/1	620 (65.5)	151 (48.7)	124 (35.8)	895 (55.8)	
2/3	327 (34.5)	159 (51.3)	222 (64.2)	708 (44.2)	
Collateral circulation	331 (41.3)	22 (14.0)	42 (24.0)	395 (34.9)	<0.0001

Results expressed as n (%). RCA: right coronary artery; LCx: left circumflex artery; LAD: Left anterior descending artery; LMCA: left main coronary artery; TIMI: Thrombolysis in Myocardial Infarction.

1.2±0.5 stent per patient. There was a progressive increase in the use of drug-eluting stents throughout the periods (3.5% vs. 4% vs. 10%; p<0.001), as well as a decreased use of glycoprotein IIb/IIIa inhibitors (p<0,0001). We noted progressive reduction of the post-PCI thrombolysis in myocardial infarction (TIMI) final flow 0/1 along the periods (29.7% vs. 2.2% vs. 2.1%; p<0.0001), and increased TIMI III flow (64.4% vs. 90.9% vs. 91.8%; p<0.0001).

In all groups, there was low incidence of MACE (4.8%; p=0.06), encompassing death (4.3%; p=0.1), AMI (1.1%; p=0.9), and no cases of emergency revascularization (Table 4). When we evaluated each time period separately (2006-2008, 2009-2011, and 2012-2016) for MACE, there was a tendency to decrease in the most recent group (5.2% vs. 6.3% vs. 2.2%; p=0.06).

Patients treated between 2009 and 2011, and some risk factors, such as advanced age, diabetes mellitus, and previous AMI were positively associated with in-hospital mortality (Table 5). In addition, three-vessel coronary disease presented a 3.34-fold higher risk of death as compared to single-vessel disease (odds ratio - OR 3.34; 95% confidence interval - 95%CI 1.75-6.39; p=0.0003); and patients with no collateral circulation had a 2.79-fold higher risk of death as compared to patients with collateral circulation (OR 2.79; 95%CI 1.29-6.01; p=0.009). Cardiogenic shock also had positive association with death as compared to Killip 1 (OR 32.71; 95%CI 14.2-75.34; p<0.0001), Killip 2 (OR 19.87; 95%CI 8.61-5.87; p<0.001, and Killip 3 (OR 5.12; 95%CI 2.51-10.44; p<0.0001). The chance of death increased by 4% at every year of age (OR 1.04; 95%CI 1.01-1.06; p=0.0006).

Table 3. Characteristics of procedures

Characteristics	2006-2008 (n=783 patients; n=818 procedures; n=897 stents)	2009-2011 (n=237 patients; n=260 procedures; n=275 stents)	2012-2016 (n=254 patients; n=269 procedures; n=329 stents)	Total (n=1,274 patients; n=1,347 procedures; n=1,501 stents)	p-value
Treated vessels/patient	1.2±0.4	1.2±0.5	1.3±0.6	1.2±0.5	0.0008
Use of stents	742 (91.3)	218 (86.2)	250 (93.3)	1.210 (90.7)	0.014
Stents/patient	1.2±0.5	1.3±0.6	1.3±0.6	1.2±0.5	0.022
Drug-eluting stents	31 (3.5)	11 (4.0)	33 (10.0)	75 (5.0)	<0.0001
Stent diameter, mm	3.1±0.4	3.15±0.5	3.09±0.5	3.11±0.4	0.254
Stent length, mm	20.2±6.0	20.6±7.5	20.6±8.3	20.3±6.8	0.435
Glycoprotein IIb/IIIa inhibitors	272 (33.3)	13 (5.0)	29 (10.8)	314 (23.3)	<0.0001
Thromboaspiration	4 (0.4)	10 (3.6)	9 (2.7)	23 (1.5)	0.0001
TIMI post					<0.0001
0/1	266 (29.7)	6 (2.2)	7 (2.1)	279 (18.6)	
2	53 (5.9)	19 (6.9)	20 (6.1)	92 (6.1)	
3	576 (64.4)	250 (90.9)	302 (91.8)	1.128 (75.3)	
Stenosis diameter, %					
Pre	94.5±9.9	93.7±10.9	92.2±12.9	93.8±10.9	0.004
Post	3±13.3	4.1±15.0	5.2±6.6	3.7±12.5	0.019
Procedural success	738 (90.2)	235 (90.4)	256 (95.2)	1.229 (91.2)	0.039

Results expressed as n (%) or mean±standard deviation. TIMI: Thrombolysis in Myocardial Infarction.

Table 4. Clinical in-hospital outcomes

Clinical outcomes	2006-2008 (n=783 patients)	2009-2011 (n=237 patients)	2012-2016 (n=254 patients)	Total (n=1,274 patients)	p-value
AMI	9 (1.1)	3 (1.3)	2 (0.9)	14 (1.1)	0.932
Emergency CABG	0	0	0	0	NA
Death	38 (4.7)	13 (5.6)	5 (2)	56 (4.3)	0.112
MACE	42 (5.2)	16 (6.3)	6 (2.2)	64 (4.8)	0.068

Results expressed as n (%). AMI: acute myocardial infarction; CABG: surgical myocardial revascularization; NA: not applicable; MACE: major adverse cardiac events.

Table 5. Factors related to death by simple logistic regression

Factors	OR	95%CI	p-value
2006-2008 vs. 2012-2016	2.38	0.93-6.12	0.071
2009-2011 vs. 2012-2016	2.90	1.02-8.26	0.046
Age, years	1.04	1.02-1.06	0.0006
Smoking, yes vs. no	1.17	0.67-2.04	0.589
Hypertension, yes vs. no	2.01	0.97-4.14	0.059
Dyslipidemia, yes vs. no	1.07	0.62-1.83	0.810
Diabetes mellitus, yes vs. no	1.95	1.11-3.43	0.021
Previous AMI, yes vs. no	2.13	1.04-4.33	0.038
Previous PCI, yes vs. no	1.66	0.64-4.3	0.296
Previous CABG, yes vs. no	2.65	0.6-11.78	0.199
Killip, 4 vs. 1	32.71	14.2-75.34	<0.0001
Killip, 4 vs. 2	19.87	8.61-45.87	<0.0001
Killip, 4 vs. 3	5.12	2.51-10.44	<0.0001
Two-vessel vs. single-vessel	1.54	0.79-3.01	0.205
Three-vessel vs. single-vessel	3.34	1.75-6.39	0.0003
Collateral circulation, yes vs. no	2.79	1.29-6.01	0.009

OR: odds ratio; 95%CI: 95% confidence interval; AMI: acute myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass surgery.

DISCUSSION

The main finding of our study was that rescue PCI was confirmed as an effective and safe procedure, as demonstrated by low MACE rate, with a gradual tendency to reduction, and a significant increase in successful procedures over the period evaluated. This analysis is one of the largest and most recent to report characteristics and clinical outcomes of patients undergoing rescue PCI in Brazil,[6-8] including 1,334 patients over a 10-year period. There was high success rate and low in-hospital mortality rate, as well as lower risk of death for patients treated from 2012 to 2016, as compared to patients treated in other periods. Moreover, the absence of indications for emergency revascularization due to complications of PCI, associated with low AMI and death rates, corroborate the efficacy and safety of the procedure. When compared to the literature, the in-hospital mortality was similar to that reported in the REACT trial (Rescue Angioplasty *versus* Conservative Treatment or Repeat Thrombolysis), with patients submitted to rescue PCI (6.2%).[9]

There was no change in the age profile during the 10-year period analyzed. There was a decreased frequency of diabetes mellitus, hypertension and dyslipidemia over the years, and there was a positive association between diabetes mellitus and risk of death. Therefore, the reduced number of comorbidities may be associated with the better clinical outcomes found between 2012 and 2016. In general, the patients in this study had a high prevalence of left anterior descending coronary occlusion, single-vessel lesions, and left ventricular dysfunction. The high rates of left ventricular dysfunction in this sample are consistent with our selected cohort of STEMI patients.[10] Increasing advances in intervention techniques and adjunct methods have also contributed to better outcomes.[11] The number of patients with TIMI flow 0/1 was low at the time of the procedure, which may be related to low sensitivity and specificity of reperfusion criteria.[12] Another possibility is that approximately 40% of patients with TIMI III flow do not achieve optimal microvascular perfusion (grade III myocardial blush); therefore the quality of tissue reperfusion may be dissonant from the TIMI flow.[7] The percentages of flow improvement noted in our analysis were higher when compared to randomized trials.[13,14] Approximately half of the patients had no signs of heart failure (Killip class 1), and 20.9% were high-risk patients (Killip class >3). Consonant to the literature, in our study the higher the Killip classification, the greater the risk of death.[15] However, a temporal reduction in Killip class III or IV AMI was noted, which may be attributed to improved coronary flow before the procedure. Furthermore, we know there is underreporting of primary PCI in the country, since many cath lab services do not systematically record these data.

The use of stents was reported in more than 90.7% of patients, similar to the data on rescue PCI in other countries, with use in approximately 85% of cases.[16] There was an increased use of drug-eluting stents between 2012 and 2016. This finding follows a worldwide trend, supported by their results,[17-19] but their use in Brazil is still low, as compared to other countries, with an average of less than 10%.[7,20] Decreased use of glycoprotein IIb/IIIa inhibitors was observed along the three periods analyzed. One factor possibly associated with this reduction is the use of fibrinolytic prior to PCI, which may lead to a decrease in the thrombotic load at the time of the procedure. Another explanation may be related to the combination of fibrinolytics and glycoprotein IIb/IIIa inhibitors in studies to evaluate

facilitated angioplasty, in which an increase in hemorrhagic events was evident in patients receiving such drugs. Hence, interventional cardiologists avoid these drugs.[12]

Although changes in the clinical profile and treatment patterns may have an impact on results between the periods evaluated, other hypotheses may also be associated with the findings. Among them, there is a reduction in the time between the onset of symptoms and the first medical contact; education of the population to recognize the symptoms of AMI seeking earlier for the emergency service;[21] reduction of the door-needle time due to the use of protocols for acute coronary syndrome; training of physicians to treat AMI cases;[22] standardization of diagnostic criteria for failed fibrinolysis, adopting a 50% decrease in the ST segment elevation as a standard for indication of rescue PC; and increased use of fibrin-specific thrombolytic agents, leading to greater reperfusion and vascular patency.[1]

CENIC is a computerized database, using standardized forms for recording. The main objective of this registry is to centralize data about interventional procedures carried out in Brazil. The present study has some limitations, considering its nature and cross-section design. The interpretation of data concerning comparisons among groups should be made in a judicious way. Data were reported and collected by physicians from different organizations associated with the *Sociedade Brasileira de Hemodinâmica e Cardiologia Intervencionista* (SBHCI), and there was no systematic follow-up of all patients assessed in the registry. There were no standardized criteria for success of PCI and diagnosis of AMI, which may be a limiting factor regarding analysis of outcomes.

CONCLUSIONS

Rescue percutaneous coronary intervention is a safe and effective therapeutic modality in Brazil. The current improved indicators may be associated with changes in the clinical profile, improvement of devices and adoption of care protocols. Clinical and angiographic features should be considered in planning of interventional cardiology actions to achieve better outcomes.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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