

ORIGINAL ARTICLE

An Overview of Care Changes in the Last 6 Year in Primary PCI in ST-Elevation Myocardial Infarction in a Tertiary University Brazilian Hospital

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Abstract

Background: Although new studies and guidelines can be considered useful tools, it does not necessarily mean they are put into clinical practice.

Objective: The aim of the current analysis was to assess the changes in primary percutaneous coronary intervention (PCI) and mortality in a tertiary university hospital in southern Brazil during a six-year period.

Methods: We have included consecutive patients with ST-elevation myocardial infarction (STEMI) who underwent primary PCI between March 2011 and February 2017. Previous clinical history, characteristics of the procedure, and reperfusion strategies were collected. In-hospital, short and long-term mortalities were also evaluated. The significance level adopted for all tests was 5%.

Results: There was an increase in the use of radial access in patients from 20.0% in 2011 to 62.7% in 2016 ($p_{\text{trend}} < 0.0001$). Moreover, thrombus aspiration decreased significantly from 66.7% in 2011 to less than 3.0% in 2016 ($p_{\text{trend}} < 0.0001$). In-hospital, short and long-term mortalities remained reasonably stable from 2011 to 2016 ($p_{\text{trend}} > 0.05$). However, a lower in-hospital mortality was observed in patients treated through radial access ($p < 0.001$). Cardiogenic shock occurred in 11.1%, without statistical differences in the period ($p_{\text{trend}} = 0.39$), while long-term mortality rate decreased from 80.0% in 2011 to 27.3% in 2016 in this patient group ($p_{\text{trend}} = 0.29$).

Conclusions: During a 6-year follow-up period, primary PCI characteristics underwent important modifications. Radial access became widely used, with a decrease in mortality with the use of this route, while aspiration thrombectomy became a rare procedure. The incidence of cardiogenic shock remained stable, but has shown a reduction in its mortality. (Int J Cardiovasc Sci. 2018; [online].ahead print, PP.0-0)

Keywords: Myocardial Infarction/ mortality; Percutaneous Coronary Intervention; Mortality; Shock, Cardiogenic.

Introduction

Coronary artery disease remains the main cause of death worldwide.¹ Among its clinical spectrum, acute myocardial infarction (AMI) is a major cause of higher mortality, despite continuous therapeutic advances in the recent decades.

It is known that early and effective reperfusion therapy of ST-elevation myocardial infarction (STEMI)

is the most important component of the treatment, being responsible for the infarct size reduction, ventricular function preservation and a significant decrease in morbidity and mortality. Furthermore, the benefit of any type of treatment decreases as the time to symptom onset increases.²

Recent evidence from large randomized trials and meta-analyses has changed the clinical practice, suggesting that primary percutaneous coronary

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intervention (PCI) performed via radial access is associated with a significant reduction in mortality rate and a lower incidence of adverse cardiac events in patients with a STEMI diagnosis. Moreover, it has been shown that performing routine aspiration thrombectomy shows no benefit in terms of reduction of mortality and major adverse cardiac and cerebrovascular events.³⁻⁶

There have been few registries documenting clinical practice in Brazilian patients treated through the Brazilian national health system, *Sistema Único de Saúde* (SUS). Despite its many accomplishments, the Brazilian health system faces serious financial and organizational challenges and, thus, high-end treatments are not always available, leading to different results from those seen in clinical trials in developed countries. Therefore, the aim of the current analysis was to assess the care changes in primary PCI, in addition to its mortality, in a tertiary university hospital in southern Brazil over a six-year period.

Methods

Patients

This was a prospective single-center cohort study, which included consecutive patients with STEMI who underwent primary PCI in a tertiary university hospital with 24-hour primary PCI service in southern Brazil, between March 2011 and February 2017. Patients were stratified according to the year of admission. Each 1-year period was considered from March to February of the next year. Temporal trends in baseline characteristics, in-hospital treatment, and clinical events in the follow-up period were assessed.

STEMI was defined as typical chest pain at rest associated with ST-segment elevation of at least 1 mm in two contiguous leads in the frontal plane or 2 mm in the horizontal plane, or typical pain at rest in patients with a new, or presumably new, left bundle-branch block. This study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki, as reflected in a previous approval by the Institutional Research and Ethics Committee and written informed consent was obtained from all individual participants included in the study.

Study protocol

Data from medical records were transferred into standardized case report forms (CRFs). Data collected included: baseline clinical characteristics, medical history, procedure characteristics, reperfusion strategy, initial

and final thrombolysis in myocardial infarction (TIMI) flow grade, and discharge therapies. In-hospital and 30-day mortality rates were also recorded in the CRF. Thirty-day and 1-year follow-up were ascertained by clinical visit or telephone contact with patients or their families. When follow-up was conducted by telephone contact, a standardized questionnaire was used to guide the conversation with the patients or their families.

Blood samples were collected by venipuncture before the procedure as part of routine patient care. Blood parameters were analyzed with the XE 5000 system (Sysmex®, Norderstedt, Germany). All patients were pre-treated with a loading dose of acetylsalicylic acid (300 mg) and clopidogrel (600 mg), and unfractionated heparin was used during the procedure (70-100 UI/kg). Use of IIb/IIIa glycoprotein, aspiration thrombectomy and PCI technical strategies (i.e. pre-dilation, direct stenting, post-dilation) were performed according to the operator's choice. Coronary epicardial blood flow before and after the procedure was assessed and described according to TIMI criteria. Anticoagulants were suspended after the end of the procedure, and dual antiplatelet therapy was recommended for 12 months after the event. Creatinine was measured at baseline and 48-72 hours post-procedure.

Clinical definitions

Major adverse cardiac and cerebrovascular events (MACCE) were defined as death from any cause, new myocardial infarction (MI), stroke, Canadian Cardiovascular Society (CCS) class III/IV angina or re-hospitalization for heart failure 30 days after primary PCI. New MI was defined as recurrent chest pain with ST-segment elevation or new Q waves and increase in serum biomarkers after their initial decrease. Stroke was defined as a new, sudden-onset focal neurological deficit, of presumably cerebrovascular cause, irreversible (or resulting in death) and not caused by other readily identifiable causes. Cardiogenic shock at admission was defined as a systolic BP < 90 mmHg for \geq 30 minutes, clinical signs of pulmonary congestion, and end-organ hypoperfusion (cool extremities, altered mental status, or urine output < 30 mL/h). Contrast-induced nephropathy (CIN) was considered when there was an increase of 0.3 mg/dL or 50.0% in post-procedure (24-72 h) creatinine compared to baseline, as proposed by the Acute Kidney Injury Network (AKIN) as a standardized definition of acute kidney injury.

Statistical analysis

Continuous variables were expressed as mean (\pm standard deviation) or median (interquartile range [IQR]) based on the presence of symmetrical and asymmetrical distribution, respectively. The normality of the distribution of each variable was assessed by the Shapiro-Wilk test. Categorical variables were represented by their relative and absolute frequencies. Temporal trends were tested using the chi-square test for binary variables and we performed either the Kruskal-Wallis one-way analysis of variance by rank for non-normally distributed values or one-way analysis of variance for normally-distributed values. All hypothesis tests had a two-sided significance level of 0.05. All statistical analyses were conducted using IBM *Statistical Package* for the Social Sciences (SPSS) Statistics, version 21.0.

Results

Between March 2011 and February 2017, 541 consecutive patients presenting with STEMI were enrolled in our registry. Baseline characteristics are shown in Table 1. The incidence of diabetes increased significantly during the study period (from 20.0% in 2011 to 32.4% in 2016 ($p_{\text{trend}} = 0.005$)). Incidences of hypertension (63.3%), previous history of MI (9.6%), history of stroke (5.9%), chronic obstructive pulmonary disease (COPD, 4.1%), current smoking (50.9%) and obesity (23.6%) remained stable. There was no significant change over the 6-year period regarding the proportion of Killip III-IV patients.

There was an important increase in the use of radial access in patients, from 20.0% in 2011 to 62.7% in 2016 ($p_{\text{trend}} < 0.0001$). Additionally, thrombus aspiration decreased significantly, from 66.7% in 2011 to less than 3.0% in 2016 ($p_{\text{trend}} < 0.0001$), as seen in Figure 1. Furthermore, the use of bare metal stents (BMS) decreased from 97.6% (in 2011) to 75.0% (in 2016) due to the increment of use of drug-eluting stents (DES, $p_{\text{trend}} < 0.0001$). Another important decrease was observed regarding the dose of radiation and contrast volume during procedures ($p_{\text{trend}} < 0.0001$). Other procedural characteristics and initial and final TIMI flow grades are detailed in Table 2.

In-hospital short and long-term mortalities remained reasonably stable from 2011 to 2016 ($p_{\text{trend}} > 0.05$) as the incidence of in-hospital MACCE and 30-day MACCE ($p_{\text{trend}} > 0.05$). These data are detailed in Figure 2 and

Table 3. Patients with femoral access had significantly higher rates of in-hospital mortality (19.8%) and in-hospital MACCE (20.7%) and long-term mortality (24.9%), when compared to patients treated via radial access (5.3%, 8.84%, 11.4% respectively; $p < 0.0001$ for both comparisons). However, patients treated through femoral access more often had Killip class III or IV (24.9% vs 5.0%), cardiac arrest (20.5% vs 6.5%), hypotension at admission (26.6% vs 4.1%) intra-aortic balloon use (8.5% vs 0.9%; $p < 0.0001$ for all comparisons).

There was a significant reduction in the door-to-balloon median time from 80.0 minutes in 2011, to 67.0 minutes in 2016 ($p_{\text{trend}} = 0.002$). In addition, there was an increase in the use of public emergency medical services (SAMU) from 13.3% in 2011, to 33.1% in 2016 ($p_{\text{trend}} = 0.01$), with a significant reduction in hospital admissions through the emergency department from 40.0% in 2012, to 23.0% in 2016 ($p_{\text{trend}} = 0.004$). There was no significant reduction in hospital length of stay during the study period ($p = 0.56$).

Discussion

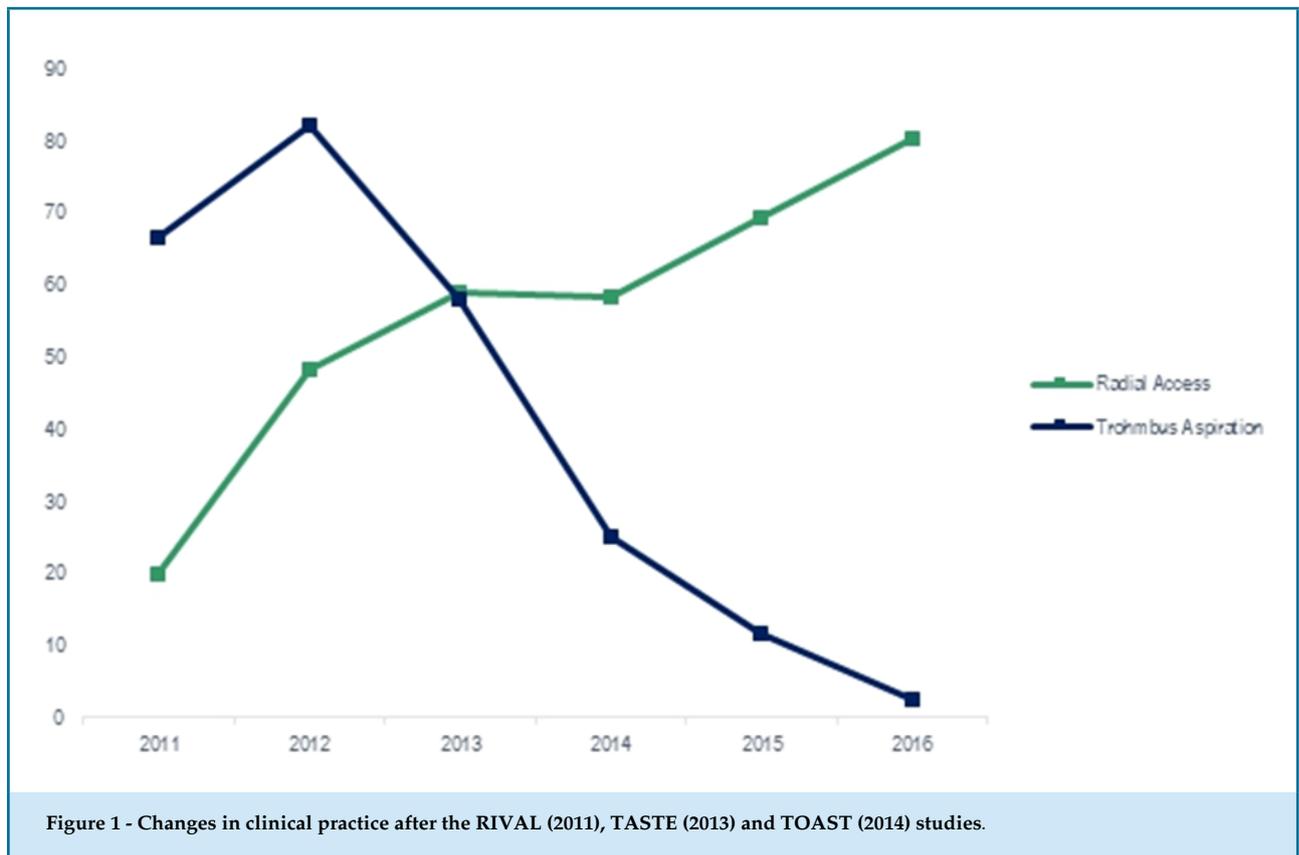
During the period of analysis of our cohort of STEMI patients who underwent primary PCI, a rise in STEMI patients assisted in our service was observed, with changes in patient's profile, reflected by a higher incidence of diabetes, and the increase in the number of patients admitted via SAMU. Nevertheless, there was a significant reduction in door-to-balloon time. Procedural characteristics also underwent modifications, such as the preference for radial access and the disuse of aspiration thrombectomy, in conformation with the changes in guidelines.

The increased incidence of diabetes worldwide has been associated to changes in lifestyle and the environment brought on by industrialization. These changes have led to obesity, lack of physical activity and consumption of a diet rich in fats and calories.⁷ The prevalence of diabetes in patients with AMI in the present study (24.9%) seems to be similar to that observed in the Brazilian population in general, which in this age group over 60 years is around 25%.^{8,9} However, its increase from 20.0% in 2011, to 33.1% in 2016, agrees with an expected increase in the incidence found in other national prevalence studies. VIGITEL data – a national survey of chronic disease carried out through telephone contact – also detected a national increase from 6.3% to 8.9% from 2011 to 2016 in adults over 18

Table 1 - Baseline characteristics

Variable	All (n = 542)	2011 (n = 45)	2012 (n = 56)	2013 (n = 88)	2014 (n = 84)	2015 (n = 121)	2016 (n = 148)	P _{trend}
Age	60.4 ± 12.1	58.5 ± 13.7	59.1 ± 11.5	61.5 ± 12.4	60.8 ± 13.0	58.9 ± 11.1	61.9 ± 11.8	0.16
Male gender	349 (64.4)	28 (62.2)	32 (57.1)	57 (64.8)	57 (67.9)	80 (66.1)	95 (64.2)	0.49
Caucasian	474 (87.5)	40 (88.9)	51 (91.2)	79 (89.8)	76 (90.5)	105 (86.8)	123 (83.1)	0.08
Risk factors								
Hypertension	344 (63.5)	22 (48.9)	38 (67.9)	57 (64.8)	54 (64.3)	77 (63.6)	96 (64.9)	0.14
Diabetes	135 (24.9)	9 (20)	11 (19.6)	14 (15.9)	19 (22.6)	33 (27.3)	48 (33.1)	0.005
Current smoking	276 (50.9)	23 (51.1)	27 (48.2)	51 (58)	42 (51.2)	63 (52.1)	70 (47.3)	0.49
Obesity								
(BMI ≥ 30 kg/m ²)	103 (23.6)	3 (11.5)	11 (36.7)	13 (19.1)	12 (16.0)	27 (24.5)	37 (29.1)	0.13
COPD	22 (4.1)	0 (0)	1 (1.8)	5 (5.7)	6 (7.1)	4 (3.3)	6 (4.1)	0.44
CKD	20 (3.7)	3 (6.7)	0 (0)	3 (3.4)	1 (1.2)	5 (4.1)	8 (5.4)	0.40
Cardiovascular history								
MI	52 (9.6)	2 (4.4)	7 (12.5)	8 (9.1)	3 (3.6)	13 (10.7)	19 (12.8)	0.17
Stroke	32 (5.9)	3 (6.7)	3 (5.4)	7 (8)	4 (4.8)	7 (5.8)	8 (5.4)	0.66
Clinical status								
Heart rate (bpm)	79.1 (18.2)	78.24 (16.76)	80.18 (16.30)	78.28 (17.54)	77.24 (18.08)	78.7 (20.91)	80.75 (17.5)	0.71
SBP < 80 mmHg	67 (12.4)	8 (17.8)	4 (7.1)	9 (10.2)	10 (11.9)	22 (12.8)	14 (9.7)	0.97
Killip								
I	368 (67.9)	34 (75.6)	45 (80.4)	64 (72.7)	58 (69)	69 (57)	98 (66.2)	0.01
II	105 (19.4)	6 (13.3)	7 (12.5)	13 (14.8)	16 (19)	28 (23.1)	35 (23.8)	0.01
III	8 (1.7)	0 (0)	2 (3.6)	2 (2.3)	0 (0)	3 (2.5)	1 (0.7)	0.63
IV	60 (11.1)	5 (11.1)	2 (3.6)	9 (10.2)	10 (11.9)	21 (17.4)	13 (8.8)	0.39
TIMI score	4.16 (2.42)	4.11 (2.66)	3.44 (1.79)	4.23 (2.29)	4.18 (2.55)	4.41 (2.66)	4.61 (2.68)	0.18
Anterior wall MI	239 (44.1)	24 (53.3)	25 (44.6)	41 (46.6)	35 (41.7)	48 (39.7)	66 (44.6)	0.30
Inferior wall MI	261 (48.2)	20 (44.4)	24 (42.9)	43 (48.9)	26 (46.4)	69 (57)	79 (53.4)	0.06
Pain-to-door (hours)	4 (2.5-6)	4.25 (3-7.25)	4 (2-6)	4 (3-6)	4 (3-7)	4.4 (2.86-7.95)	3.3 (1.5-5.1)	0.001
Door-to-balloon (min)	68 (55-90)	80 (60-120)	72 (60-90)	60 (44.25-83.75)	63.5 (46.75-73.25)	68 (57.75-90.25)	67 (56.5-91.5)	0.002
Admission								
ED	172 (31.7)	9 (20)	22 (39.9)	40 (45.5)	35 (41.7)	31 (25.6)	35 (23.6)	0.04
EMS	146 (26.9)	6 (13.3)	11 (19.6)	17 (19.3)	25 (29.8)	38 (31.4)	49 (33.1)	0.01
Hospital length of stay	5 (4-8)	5 (3-9)	4 (3-6)	5 (4-8)	5 (4-7.75)	6 (4-8)	5 (4-9)	0.56

Values are expressed as mean ± standard deviation, median (interquartile range) or number (%). BMI: body mass index; COPD: chronic obstructive pulmonary disease; CKD: chronic kidney disease; MI: myocardial infarction; SBP: systolic blood pressure; ED: Emergency department; EMS: Emergency medical service



years of age.^{10,11} Other comorbidities remained stable during the study period.

Recently, new evidence suggests that primary PCI should be performed through radial access due to a significant mortality reduction and lower occurrence of adverse cardiac events. In the largest comparative study between the access routes, the randomized and multicenter trial RIVAL⁴ (Radial Versus Femoral Access for Coronary Intervention), patients with STEMI who underwent primary PCI through radial access had lower mortality rates (1.3 versus 3.2%, $p = 0.006$) and lower rates of death, infarction and stroke (2.7 versus 4.6%, $p = 0.03$) at 30 days when compared to those who underwent primary PCI through femoral access. In fact, due to the consistency of these findings, international guidelines^{12,13} recommend that the radial access be preferred in situations of STEMI. The data found in our study confirm the changes observed in clinical practice after the publications and highlight a consistency of practice with the current guidelines changes by a significant replacement of the radial access by the femoral access. When compared in the present study, the radial access showed lower mortality and adverse events in relation to the femoral access, corroborating the literature

data, although a significant mortality reduction over the 6-year period was not demonstrated in our service ($p_{\text{trend}} < 0.001$ for all comparisons).

Another important data from the analysis was the significant reduction in the performance of aspiration thrombectomy. The rates, which were 82.1% in 2012 decreased progressively after the publication of the TASTE⁶ study, which suggested the non-effectiveness of the device as an adjunct treatment to primary PCI. After these data were published, routine aspiration thrombectomy reached rates of less than 3.0% in 2016. In 2014, the TOTAL³ study was published, which showed an increase in stroke rates (0.7 vs. 0.3%, $p = 0.02$) without reducing other outcomes, leading to changes in the current guidelines regarding indications for routine aspiration thrombectomy¹⁴ and corroborating the discontinuity of this technique as a routine procedure in our service.

The use of DES increased after their selective reimbursement by the Brazilian public healthcare system, which occurred in August 2014. Thus, there was a significant increase in their use in our registry, reaching 25.0% in 2016. The use of DES is associated with a decrease in repeated target vessel revascularization

Table 2 - Procedural characteristics

Variable	All (n = 542)	2011 (n = 45)	2012 (n = 56)	2013 (n = 88)	2014 (n = 84)	2015 (n = 121)	2016 (n = 148)	P _{trend}
Arterial access								
Radial	340 (62.7)	9 (20)	27 (48.2)	52 (59.1)	49 (58.3)	84 (69.2)	119 (80.4)	<0.0001
Femoral	202 (37.3)	36 (80)	29 (51.8)	36 (40.9)	35 (41.7)	37 (30.8)	29 (19.6)	<0.0001
Angioplasty								
BMS	483 (90.3)	41 (97.6)	56 (100)	88 (100)	81 (97.6)	108 (90)	111 (75)	<0.0001
Thrombus aspiration	166 (30.6)	30 (66.7)	46 (82.1)	51 (58)	21 (25)	14 (11.76)	4 (2.7)	<0.0001
Initial TIMI flow 0-1	422 (80.1)	40 (88.9)	45 (80.4)	66 (75.9)	61 (72.6)	94 (81)	116 (83.5)	0.72
Final TIMI flow 2-3	511 (95)	44 (97.8)	55 (98.2)	78 (88.6)	78 (92.9)	115 (95.8)	141 (97.2)	0.48
Culprit artery								
ADA	222 (41.4)	22 (48.9)	21 (38.9)	40 (46.0)	32 (38.6)	44 (36.7)	63 (42.9)	0.53
RCA	212 (39.6)	17 (37.8)	22 (40.7)	30 (34.5)	35 (42.2)	49 (40.8)	59 (40.1)	0.58
No reflow	32 (6.2)	2 (4.4)	0 (0)	5 (5.8)	1 (1.2)	13 (10.8)	11 (8.5)	0.01
Distal embolization	21 (4.1)	1 (2.2)	0 (0)	1 (1.2)	1 (1.2)	11 (9.2)	7 (5.4)	0.008
CIN	70 (12.9)	6 (13.3)	6 (10.7)	12 (13.6)	16 (19)	16 (13.2)	14 (9.5)	0.49
Radiation (Gy)	2,112 (1,215-3,192)	2,581 (518-3,697)	2,883 (1,404-3,412)	2,107 (1,476-3,370)	2,613 (1,608-3,582)	2,548 (1,650-3,379)	1,511 (902-2,491)	<0.001
Contrast volume (mL)	180 (140-230)	180 (150-250)	200 (150-230)	177 (150-232)	200 (150-280)	180 (142-227)	150 (120-200)	<0.001

Values are expressed as median (interquartile range) or number (%). BMS: bare metal stent; ADA: anterior descendente artery; RCA: right coronary artery; CIN contrast-induced nephropathy.

and lower stent thrombosis rates.¹⁵ Despite the lower rates and their delay in being routinely applied, it is an example of more people having access to new therapies.

Another example of in healthcare assistance improvement, i.e., the use of SAMU, has been increasing in recent years in our cohort. One might suggest the population acknowledges that such care is one of the fastest and most efficient means of having access to different technologies, either for providing assistance or removal to a health service. The percentage of heart disease (angina, cardiac arrest, hypertensive crisis, AMI) in the population treated by the emergency medical services (EMS) is 17.4%¹⁶ and the response time, one of the quality markers of the provided service, was reduced from 21 minutes to 15 minutes in 2016, according to Porto Alegre's Health Agency.¹⁷ The reduction in time

demonstrates an improvement in the care of the patients who use the emergency services.

We found a significant reduction in the door-to-balloon time, in agreement with the current guidelines that recommend a door-to-balloon time < 90 minutes; however, the delay should be shorter, preferably within 60 min, in patients presenting early, with a large amount of myocardium at risk.^{12,13} Despite these favorable changes in the service routine, the observed mortality has remained constant, with an approximate rate of 10.0 to 11.0%. When compared to the ACCEPT study,¹⁸ a Brazilian national-based registry, which showed a mortality rate of 3.4%, the mortality found in our service is high; however, these data can be justified due to the disease severity observed in our patients, of which approximately 13.0% presented with Killip class III/IV,

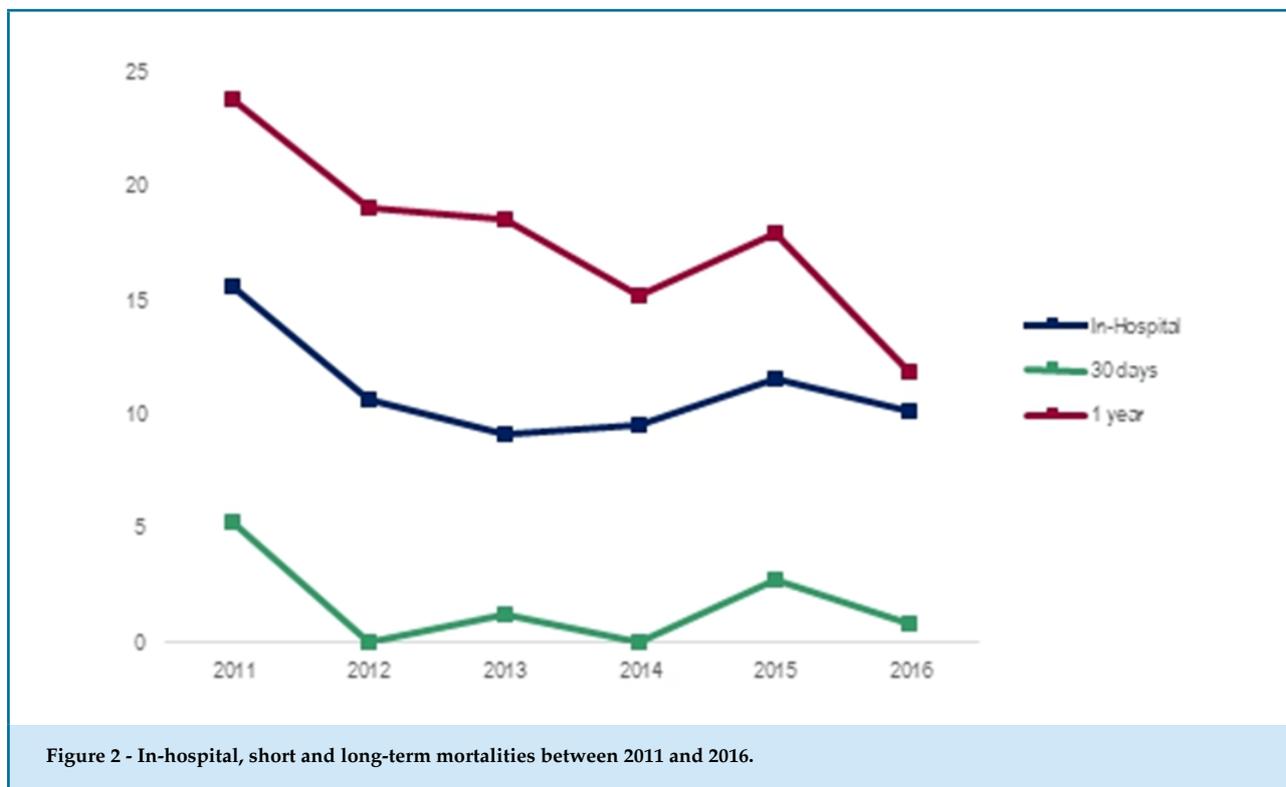


Table 3 - Mortality and major adverse cardiac and cerebrovascular event (MACCE)

Variable	All (n = 542)	2011 (n = 45)	2012 (n = 56)	2013 (n = 88)	2014 (n = 84)	2015 (n = 121)	2016 (n = 148)	P _{trend}
In-hospital outcomes								
Death	58 (10.7)	7 (15.6)	6 (10.7)	8 (9.1)	8 (9.1)	15 (11.6)	15 (10.1)	0.62
AMI	4 (0.70)	1 (2.2)	0 (0)	1 (1.1)	1 (1.2)	1 (0.8)	0 (0)	0.26
Stroke	6 (1.1)	0 (0)	0 (0)	4 (4.5)	0 (0)	0 (0)	2 (1.4)	0.81
In-hospital MACCE	72 (13.3)	9 (20)	6 (10.7)	11 (13.6)	11 (13.1)	18 (14.9)	16 (10.8)	0.35
Short and long term outcomes								
30-day death	7 (1.5)	2 (5.3)	0 (0)	1 (1.3)	0 (0)	3 (2.8)	1 (0.8)	0.47
30-day stroke	4 (0.8)	0 (0)	0 (0)	1 (1.3)	0 (0)	3 (2.8)	0 (0)	0.66
30-day AMI	8 (1.7)	0 (0)	1 (2)	2 (2.3)	2 (2.7)	2 (2)	3 (2.3)	0.28
30-day MACCE	69 (14.6)	5 (13.2)	3 (6.1)	6 (7.5)	10 (13.2)	30 (29.4)	15 (11.6)	0.06
1-year mortality	81 (16.6)	10 (23.8)	9 (19.1)	15 (18.5)	12 (15.2)	20 (17.9)	15 (11.9)	0.07

Values are expressed as number (%). AMI: acute myocardial infarction; MACCE: major adverse cardiac and cerebrovascular events (death, new MI, stroke, angina class III/IV, re-hospitalization for heart failure).

representing a very high baseline risk and with higher morbidity and mortality.

In our analysis, some strengths and limitations deserve to be highlighted. This study has limitations that are

inherent to observational studies, such as the lack of follow-up, which in our case was 10%. Some data were obtained retrospectively and others through telephone calls, which can determine less reliable information. However, this study is a registry of consecutive and unselected patients coming from a tertiary referral hospital, submitted to the treatment of acute coronary syndromes, so the data shown herein are highly applicable to daily clinical practice.

Conclusions

In conclusion, our registry illustrates the care changes in clinical practice in line with current guidelines. From 2011 to 2016, the patient's profiles, amount and characteristics of the procedures have undergone important modifications. Radial access became more widely used with a decrease in mortality through this route, and aspiration thrombectomy became a rare procedure.

Author contributions

Conception and design of the research: Machado GP, Wainstein R, Araujo GN, Carpes CK, Valle FH, Gonçalves SC. Acquisition of data: Carpes CK, Lech MC, Bergoli LCC, Gonçalves SC. Analysis and interpretation of the data: Machado GP, Wainstein R, Araujo GN, Valle FH,

Gonçalves SC. Statistical analysis: Machado GP, Araujo GN, Valle FH, Bergoli LCC. Writing of the manuscript: Machado GP, Pivatto Junior F, Araujo GN, Carpes CK, Lech MC, Valle FH, Wainstein MV. Critical revision of the manuscript for intellectual content: Machado GP, Pivatto Junior F, Wainstein R, Bergoli LCC, Wainstein MV. Supervision / as the major investigador: Wainstein MV.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

This study is not associated with any thesis or dissertation work.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the Hospital de Clínicas de Porto Alegre under the protocol number 1.438.645. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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