

Percutaneous Coronary Intervention in Brazil. Results from the Brazilian Public Health System

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Abstract

Background: The Brazilian Public Health System (SUS) holds approximately 80% of percutaneous coronary interventions (PCI) in Brazil. Being aware of these data will enable to design a proper plan for the treatment of coronary artery disease (CAD).

Objective: To review and discuss the results of PCIs performed by the SUS.

Methods: We reviewed data from SIH/DATASUS available for public consultation.

Results: From 2005 to 2008, 166,514 procedures were performed in 180 hospitals. Average hospital mortality was 2.33%, ranging from 0% to 11.35%, being lower in the Southeast, 2.03% and higher in the northern region, 3.64% ($p < 0.001$). The mortality rate was 2.33% in 45 (25%) higher-volume hospitals, accounting for 101,218 (60.8%) of the PCIs, 2.29% in 90 (50%) medium-volume hospitals with 50,067 (34.9%) PCIs and 2.52% in 45 (25%) small-volume hospitals with 7,229 (4.3%) PCIs ($p > 0.05$). Mortality was higher in females ($p < 0.0001$) and at ages ≥ 65 to = ($p \leq 0.001$). In the diagnosis of angina (79,324, 47.64%) mortality was 1.03%, and AMI (33,286, 32.30%) 6.35% ($p < 0.0000001$). In the single stent implantation, the most common (102,165, 61.36%), mortality was 1.20%, and Primary PCI (27,125, 16.29%), 6.96%.

Conclusion: Although it is growing, the number of PCIs in Brazil is still low. High-volume hospitals, in smaller numbers, accounted for most procedures. Single stent implantation through hospital admission was reported to be most commonly used procedure. Mortality rates were highly variable among the hospitals. Primary PCI was responsible for the highest mortality rate. (Arq Bras Cardiol 2011;96(4):317-324)

Keywords: Angioplasty transluminal percutaneous coronary; Single Health System; angina pectoris.

Introduction

The introduction of percutaneous coronary intervention (PCI) using a balloon catheter, by Andreas Gruentzig¹ in 1977 revolutionized the treatment of coronary artery disease (CAD). Coronary lesions hitherto only covered by a surgical procedure involving thoracotomy began to be treated with a balloon catheter taken to the coronary system by a simple peripheral arterial puncture. Coronary restenosis, a common complication in the early years, was reduced with the implantation of coronary stents used from 1986², a procedure that became standard. In 2001, uncoated stents, initially employed, were replaced with drug-eluting stents, first eluted with sirolimus³, followed by paclitaxel⁴, and subsequently by other different drugs^{5,6} which, if have failed to abolish restenosis and the need for reintervention, have made it less frequent.

It is currently estimated that each year 2 to 3 stents are implanted around the world. Out of these, around 70% are drug eluting stents. The limitation for its use is the cost, especially in countries with economic difficulties to maintain their health systems. In Brazil, until now, this type of stent is not reimbursed by the Brazilian Public Health System (SUS). Non-pharmacological stents are reimbursable, however distribution is controlled according to the number of stents assigned to each patient. It is allowed to implant two stents in 20% of all procedures.

Many studies related to the implantation of stents are published abroad and in Brazil, but in our country isolated statistics from some institutions are little comprehensive and generally come from leading services with higher experience.

Conventional stents were added to the treatments provided by the SUS in December 1999. Until then, the main procedure available was coronary artery bypass grafting.

A unique opportunity to get acquainted with the national numbers is analyzing the DATASUS⁷, accessible through the Internet and under public domain. DATASUS is the information technology department of the SUS. It reports to the Executive Office of the Ministry of Health. It is responsible for collecting, processing and disseminating health

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information. This database is fed by the hospital information system (SIH). Despite the limitations inherent in administrative characteristics, and the fact that it is not universal, because it includes only the admissions paid by SUS, the SIH/SUS has several advantages: routine collections in a large number of hospitals, it is available to those interested in a short time, it covers approximately 80% of hospital admissions in Brazil and has important epidemiological information, which allow analyzing the situation of hospital morbidity and assessment of services. This database serves as a record, with a very special feature: all procedures performed within the SUS are necessarily written down, otherwise there would be no reimbursement for the costs of the treatment.

It is estimated that the SUS accounts for 80% of the PCIs performed in Brazil, which are registered for the purposes of reimbursement of costs by hospitals, either state, private or philanthropic, which provide this service. The accounts are audited and the values of the Authorization for Hospitalization (AIH), hospital stay and mortality, among other information, are integrated into the SIH, and are available for public consultation in the DATASUS. Data on PCIs performed by private health insurance are very few, or none. According to information from the *Agência Nacional de Saúde Suplementar* (Brazilian Supplementary Health Office), the government agency that regulates private health insurance, in 2009, only 42,310,415 Brazilians had some kind of private health care. This translates into a coverage rate of health insurance of 21.3% (expressed as percentage ratio between the number of beneficiaries and the Brazilian population)⁸. Rather than providing an overview of all the procedures performed, this information gives us an overview of the total population served by the system, which is over three quarters of the Brazilian population.

Methods

The PCI data analyzed were obtained through the SIH/DATASUS⁷. We considered the data for the years 2005, 2006, 2007 and 2008, since these are the most recent data available and express the indications and techniques currently practiced in Brazil.

The procedures were classified using codes from the SUS table, maintaining the original nomenclature of the following procedures: 48030066 - coronary angioplasty; 48030074 - coronary angioplasty with intraluminal prosthesis; 48030082 - coronary angioplasty with dual intraluminal prosthesis; 48030090 - angioplasty in coronary graft; 48030104 - coronary angioplasty in coronary grafts with prosthesis; 48030112 - primary coronary angioplasty (including catheterization). In 2008, these codes have been given new numbers: 0406030014 - coronary angioplasty; 0406030022 - coronary angioplasty with dual intraluminal prosthesis; 0406030030 - coronary angioplasty with intraluminal arterial prosthesis; 0406030049 - primary coronary angioplasty (includes catheterization); 0406030065 - angioplasty in coronary graft; 0406030073 - angioplasty in coronary graft (with prosthesis).

We used the codes for the clinical picture, by grouping them as Angina, Acute Myocardial Infarction and Other Angina

(in a few cases with incomplete data, it was not possible to establish the diagnosis, so the classification was Unknown):

Angina - unstable angina, angina pectoris with documented spasm, other forms of acute ischemic heart disease; unspecified acute ischemic heart disease.

AMI - acute transmural anterior wall myocardial infarction; acute transmural inferior wall myocardial infarction; acute transmural myocardial infarction at other locations; acute transmural myocardial infarction with unspecified location; acute subendocardial myocardial infarction; unspecified acute myocardial infarction; recurrent anterior wall myocardial infarction; recurrent inferior wall myocardial infarction; recurrent myocardial infarction at other locations; recurrent myocardial infarction at an unspecified location

Other anginas - other forms of angina pectoris; unspecified angina pectoris; coronary thrombosis not resulting in myocardial infarction; atherosclerotic cardiovascular disease, so described; atherosclerotic heart disease; old myocardial infarction; cardiac aneurysm; coronary artery aneurysm; ischemic cardiomyopathy; silent myocardial ischemia; other forms of ischemic heart disease; unspecific chronic ischemic heart disease.

Indication for the procedure was classified as elective, urgency/emergency and others, according to the classification used for filling the AIH source form from which the information is extracted to supply the database.

The SUS table classifies the various procedures as: isolated PCI, PCI + double stent, PCI + one stent, primary PCI, PCI in coronary grafts, PCI + coronary graft stent.

This study excluded those hospitals that performed 48 or fewer angioplasties in the period of 4 years, that is, those which did not perform at least one procedure per month.

To analyze the data, according to the volume of PCIs, we calculated the 25th and 75th percentiles of the distribution of the number of procedures performed by these hospitals from 2005 to 2008, finding the values $P_{25} = 331$ and $P_{75} = 1,064$. Those hospitals that served 331 patients or fewer patients for PCIs were then classified as low-volume hospitals; medium-volume hospitals were those serving 332 to 1,063 patients; high-volume hospitals were those serving 1,064 patients or more.

Statistical analysis

The qualitative variables are presented in percentages and the comparisons were performed by the χ^2 test (chi-square). The quantitative variables are presented as means, standard deviations, minimum and maximum and mean comparisons by Student t test and analysis of variance. The level of significance was $p < 0.05$.

Results

From 2005 to 2008, 166,514 PCIs were performed in the 180 hospitals that performed more than one procedure per month in average. Hence, 23 small-volume hospitals, which held a total of 437 interventions, were excluded. In 2005, there were 35,717 (21.4%) procedures; in 2006, 41,693 (25.0%); in 2007, 43,124 (25.9%); and in 2008, 45,980

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(27.6%). Based on 2007, when the system admitted 1,157,509 patients due to circulatory diseases, the PCI accounted for 3.73% of admissions.

Overall hospital mortality was 2.33% and remained stable over the period [(2.22% in 2005, 2.29% in 2006, 2.46% in 2007 and 2.32% in 2008 ($p > 0.05$)]. The lowest mortality rate was found in the Southeast, 2.03%, and the highest in the North, 3.64%, and there was a significant difference among the five physiographic regions of Brazil ($p < 0.001$) (Table 1).

Hospital mortality according to hospital production volume is shown in Table 2. All of the 45 hospitals (25%) considered of small volume accounted for 7,229 (4.3%) of the PCIs; 90 (50%) medium-volume hospitals accounted for 58,067 (34.9%) and 45 (25%) large-volume hospitals accounted for 101,218 (60.8%). The mortality rates were respectively 2.52%, 2.29% and 2.33% ($p > 0.05$).

Mortality by gender and age is shown in Table 3. It was lower among males and patients aged 0-64 years.

Mortality in the 180 hospitals studied ranged from 0% to 11.35% with an average of 2.33% and a median of 2.15% (Figure 1).

Mortality in 22 hospitals, producing more than 400 procedures per year, or 1,600 over this period, ranged from 0.37% to 7.83% (Figure 2). Altogether, these hospitals held 71,412 (43%) procedures, with an individual production ranging from 1,605 to 8,638 procedures.

Mortality according to the clinical picture was 1.03% for angina, 6.35% for AMI and 1.75% for other angina ($p < 0.0000001$) (Table 4). Mortality also varied according to the

indication, elective, 0.86%, emergency, 3.25% and others (cases not characterized), 0.79% ($p < 0.0000001$) (Table 5). The procedures employed have influenced the mortality as shown in Table 6, with the highest mortality rates in primary PCI, 6.97% and in the Isolated PCI in coronary graft, 17.65% ($p < 0.0000001$).

Although in this study the total volume of procedures did not influence mortality, in elective procedures in small, medium and large-volume hospitals, we have found differences resulting in mortality rates of 1.51%, 0.84% and 0.82%, respectively ($p < 0.001$).

Average hospital stay, according to the PCI volume, did not vary, and was 4.15 days in small-volume hospitals, 3.84 days in medium-volume hospitals, and 4.01 in high-volume hospitals.

Discussion

The PCI has become a treatment commonly used in CAD, relieving angina, improving quality of life, and even reducing mortality in acute cases. In recent years, it has been the method most commonly used for coronary grafting, outnumbering surgeries⁹⁻¹¹.

As with any procedure that begins, the number of complications and deaths is reduced as experiences accumulate. The decision for treatment by both patients and the doctors take into account the experience and results obtained, preferably local. Despite the tremendous development achieved by this technique in recent years, the severity of patients usually submitted to it is still a concern due to the ever-present risk of mortality associated. From the standpoint of public health, it is important to know information about hospital stay, costs involved and the outcomes in different regions, hospitals and even teams, if possible. In Brazil, it is necessary to be aware of the efficiency and effectiveness of the procedures performed in order to make the most accurate possible decisions, both individually and collectively. In our country, much of these data, though available, had not yet been evaluated.

The PCI data analyzed were obtained through the SIH/DATASUS. Worldwide, the SUS is one of the largest public health care systems, accounting for 11,107,155 admissions in 2008¹² for a population of 189,335,191 individuals, resulting in an annual percentage of admissions of 6% of the population not covered by private health insurance. It is estimated to be responsible for 80% of the interventions

Table 1 - Total in-hospital mortality rate in PCIs within the SUS, from 2005 to 2008 per physiographic region

Region	No. of patients	%	No. of patients	%
Southeast	79,709	47.9	1,619	2.03
South	53,319	32.0	1,282	2.0
Northeast	23,277	14.0	692	2.97
North	3,272	1.9	119	3.64
Center west	6,937	4.2	162	2.34
Total	166,514	100.0	3,874	2.33

* $p < 0.001$.

Table 2 - Total in-hospital mortality rate in PCIs within the SUS, from 2005 to 2008 according to hospital volume

Volume	No. of hospitals	%	No. of PCIs	%	No. of deaths	%*
Small	45	25	7,229	4.3	182	2.52
Medium	90	50	58,067	34.9	1,330	2.29
Large	45	25	101,218	60.8	2,362	2.33
Total	180	100	166,514	100	3,874	2.33

* $p > 0.05$.

Table 3 - In-hospital mortality rate in PCIs within the SUS, from 2005 to 2008 according to gender and age

		No. of Patients	%	No. of deaths	%
Gender	Male	107,473	64.5	2,253	2.10*
	Female	59,041	35.5	1,621	2.75
Age	0 to 64 years	100,840	60.6	1,407	1.39*
	65 or more	65,674	39.4	2,467	3.76

* $p < 0.0001$.

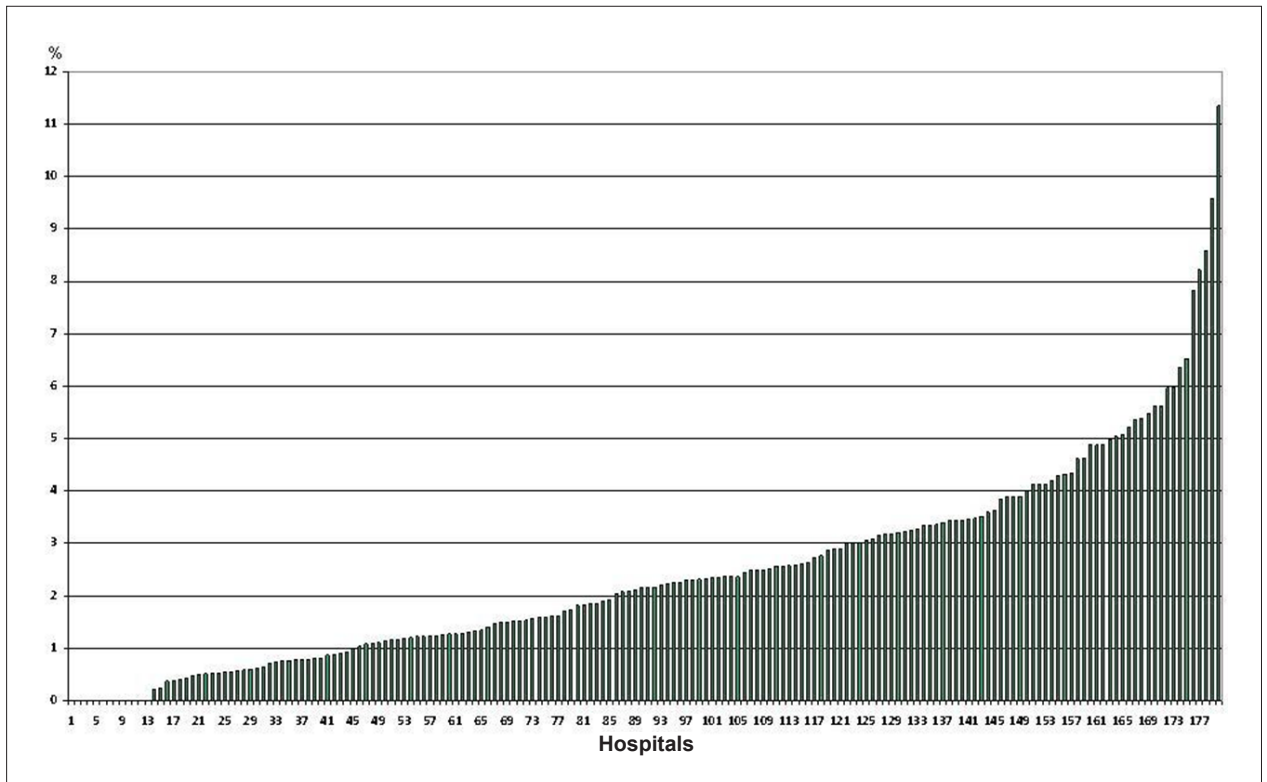


Figure 1 - Average in-hospital mortality rate over the period, in PCIs, in each of the 180 hospitals that performed this procedure for the SUS from 2005 to 2008.

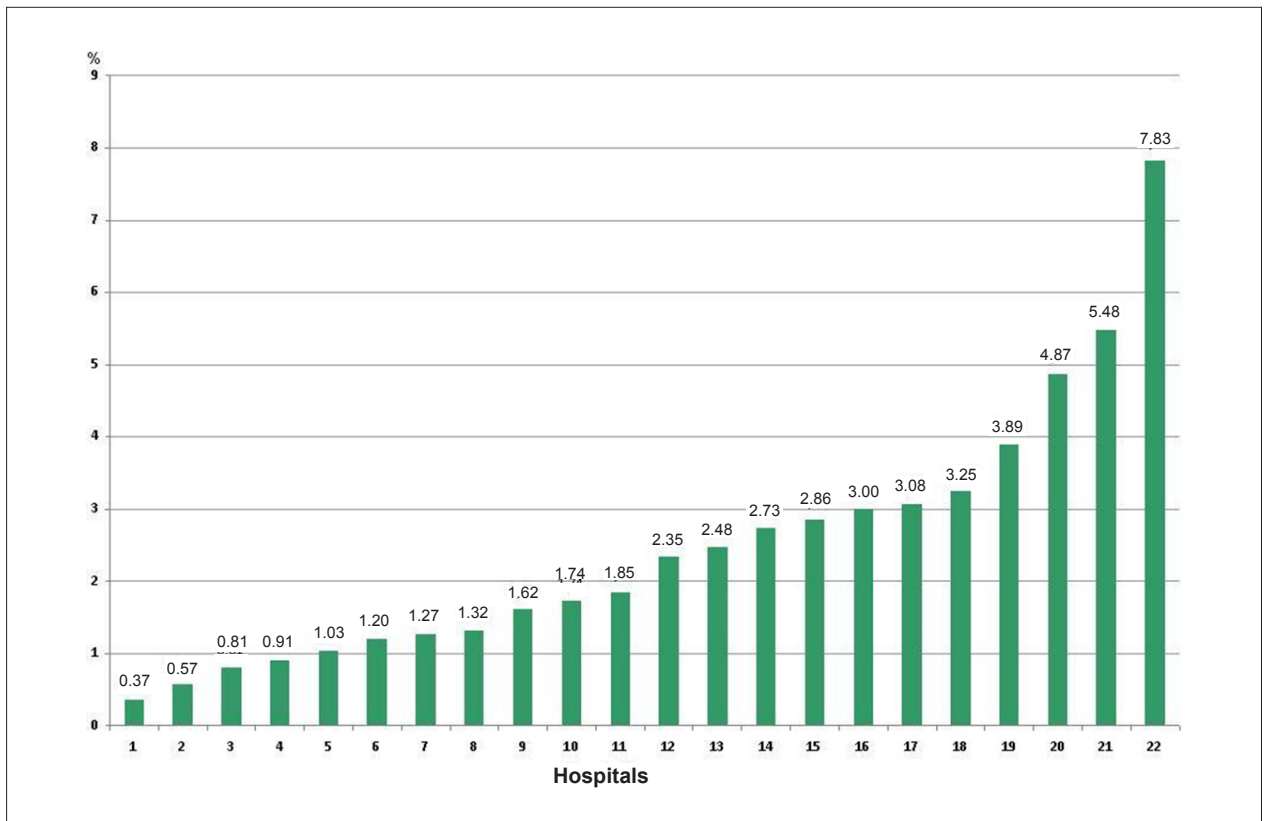


Figure 2 - Average in-hospital mortality rate, in PCIs, in each of the 22 hospitals that performed over 400 procedures/year for the SUS from 2005 to 2008.

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Table 4 - Clinical picture and in-hospital mortality in PCIs in the SUS from 2005 to 2008

Clinical picture	No.	%	Deaths	%	p value
Angina	79,324	47.64	814	1.03	<0.0000001
AMI	33,286	19.99	2,113	6.35	
Other Anginas	53,787	32.30	943	1.75	
Unknown	117	0.07	4	3.42	

Table 5 - Indications for PCI in the SUS from 2005 to 2008

Indiction	No.	%	Deaths	%	p value
Elective	62,607	37.60	537	0.86	<0.0000001
Emergency	102,513	61.56	3,326	3.24	
Others	1,394	0.84	11	0.79	

performed annually, considering that in Brazil, private health insurance accounted for 20.61% of health coverage in 2008¹³ and in 2009 for 21.38⁸.

During the period analyzed, there were 166,514 PCIs, resulting in an annual average of 41,628 procedures or 22/100,000 inhabitants. An increase of 29% compared to 2005. It should be noted that 25% of the hospitals (large volume) performed 61% of the procedures and 25% (small volume), only 4%. It is difficult to estimate the number of scheduled readmissions to have a new stent implanted, as it was not authorized by the SUS on the first admission, because the system sets the limit of 20% per hospital implantation of two stents. In Scotland¹⁴, in 2009, 99.4 procedures were done for each group of 100,000 inhabitants, while in the UK, according to the British Cardiovascular Intervention Society¹⁵, in 2007 there were 73,692 interventions or 121.6 per 100,000 inhabitants. In Canada, the recommendation of the Cardiac Care Network of Ontario¹⁶ was reaching a minimum of 221 interventions in 2005/6, increasing to 260/100,000 inhabitants in 2008/9. The latest statistics available, covering the year 2008 in Canada, records 168/100,000 inhabitants¹⁷. In the United States, the American Heart Association¹⁸ estimated that in 2006 there were 1,313,000 PCIs, i.e. 440/100,000 inhabitants. Comparing our figures with those from other countries, it appears that fewer interventions are carried out

here, knowing that the SUS figures do not include SUS 20% of those interventions estimated to be performed out of the SUS.

Average mortality rate of 2.33% varied in different regions of the country. It was higher in the northern region, accounting for less than 4% of the procedures, and lower in the Southeast, accounting for nearly half of the procedures performed. It is assumed that these differences are explained by the greater experience of the regions with a higher volume of interventions. These data are consistent with those provided by the medical literature. The greater the experience the better the results¹⁹. In 8,735 coronary angioplasties (7.5-15.5/100,000 inhabitants in the period) performed by the SUS in the state of Rio de Janeiro, from 1999 to 2003, mortality was 1.9%, noting variations from 0 to 6.5% in 14 hospitals (12 with more than 200 procedures in the period) that performed this intervention²⁰.

The National Cardiovascular Data Registry in the United States, a registry sponsored by the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions, seeking a model of contemporary risk, analyzed data on 588,398 PCI procedures performed from 2004 to 2007 and reported a hospital mortality rate of 1.27%, ranging from 0.65% for elective cases to 4.81% for the cases of AMI with ST-segment elevation²¹.

As opposed to the findings related to physiographic regions, there was no difference in the mortality rate in large, medium and small-volume hospitals, although in absolute numbers, the latter had the highest percentage of deaths. For a long time, the literature has shown an inverse relationship between the volume and the development of different forms of treatments employing procedures and the PCI is within this paradigm²². The most plausible explanation is supposedly the experience. More experienced groups, who probably went through a learning curve, have a team that is more capable of succeeding, lower complication rates and lower mortality rates. Admittedly, the selection of patients and the severity of these cases may also affect the results.

Mortality rates were higher in the elderly^{21,23}, and in women^{21,24}. As with the CAD, mortalities in PCI relate to age, increasing according to the age²⁵ and gender. A recent review of 588,398 procedures from the National Cardiovascular Data Registry, a database organized by the American societies, the American College of Cardiology and the Society for Cardiovascular Angiography and Intervention, confirm these findings. Elderly *versus* nonelderly, 2.25% *versus* 0.76%, female *versus* male, 1.63% *versus* 1.04%²¹. The literature reports that

Table 6 - PCI procedures in the SUS from 2005 to 2008

Procedures	No.	%	Deaths	%	p value
Isolated PCI	8,457	5.08	295	3.49	<0.0000001
PCI + double stent	28,241	16.96	443	1.57	
PCI + one stent	102,165	61.36	1,230	1.20	
PCI primary	27,125	16.29	1,889	6.96	
PCI in coronary graft	17	0.01	3	17.65	
PCI + stent in coronary graft coronary	509	0,31	14	2,75	

out of 1.3 million procedures performed in the United States in 2006, only 35% were in women despite the known benefits of this treatment, particularly in acute coronary syndromes with or without ST-segment elevation²⁶.

We observed a large disparity in mortality rates between hospitals. Even those with more than 400 PCIs per year, a minimum experience required by each center, as recommended by the guidelines, there is still, in some hospitals, mortality rates higher than expected when compared with other hospitals in Brazil. The literature ranks mortality in PCI at around 2%. In Canada, in 23 hospitals, the unadjusted mortality rate in 127,103 PCIs was 1.4%²⁷. In a Canadian registry, collected in the Canadian province of British Columbia, which compared the outcomes of 32,899 PCIs, of which 26,350 were performed in 2000 to 2004 and 6,549 in 2005, overall mortality in 30 days was 1.5%, 1.5% in the first period analyzed, and 1.4% in the second period²⁸. Data from the New York's Percutaneous Coronary Interventions Reporting System for the period 1998 to 2000 with 107,713 cases, reported a mortality rate of 0.79%, of which 1.23% were from 2,435 patients treated in hospitals that had a volume smaller than 400 procedures per year and 0.78% in 105,278 patients in hospitals with volumes exceeding 400 cases/year¹⁹.

Although the information available for analysis in the DATASUS does not include clinical variables, we have data relating to the clinical picture and indication for treatment, which can be elective or emergency treatment. Mortality is low when the indication is for angina, whereas in cases categorized as infarction (primary angioplasty) is about six times larger. The SOLACI Registry, a spontaneous and non-mandatory registry of the Latin American Society of Interventional Cardiology, reported in 2007 to 2008, 13,925 interventions of primary angioplasty with a hospital mortality of 4.5%²⁹. Data from the New York State PCI Registry, a mandatory controlled registry of this American state, show an interaction between hospital volume and physician experience. In this study, we compared the mortality rates of 7,321 patients undergoing primary angioplasty in high-volume hospitals for this procedure (> 50 cases/year) and small-volume hospitals, and large-volume physicians (> 10 cases/year) and small-volume physicians, showing that the group of larger volume (hospitals and physicians) the results are better than in a small volume (3.2% versus 6.7%, $p = 0.03$, unadjusted; 3.8% versus 8.4%, $p = 0.09$, adjusted)³⁰. The National Cardiovascular Data Registry CathPCI, a U.S. voluntary program concerned with quality improvement sponsored by the American College of Cardiology, reports in the first half of 2009 an adjusted hospital mortality rate of 2% for acute coronary syndrome and 0.5% for non acute coronary syndrome³¹.

The performance of the procedure in emergency situations brings higher mortality rates than in elective situations, which is expected due to the severity of patients seen in emergency situations, usually admitted with a clinical picture of acute coronary syndrome.

The most commonly used PCI was stent implantation, and 60% of patients were treated that way. Not surprisingly, the use of a single stent has been the procedure most frequently used because the system does not allow multiple stents in more than 20% of the cases that perform this kind of treatment. In

the group that received a single stent, a lower mortality was observed. In this database, it is not possible to identify patients who were electively readmitted to receive a second stent which was not authorized at the first admission.

Isolated angioplasty without stenting was used in a minority of cases, as well as interventions in coronary grafts with or without stenting.

According to this database, the intervention cataloged as primary PCI, which by definition is characterized by PCI in treating acute infarction, was frequent and mortality rate was high, about six times the one found stenting in patients without infarction. Although it is possible to report other forms of ACS in this diagnosis than infarction with ST-segment elevation, post thrombolytic rescue cases, erroneously reported as primary PCI, lengthy delays or cases complicated with cardiogenic shock, mortality was still high.

Average hospital stay per procedure was around 4 days, slightly below the overall average hospital stay in SUS, which is 5.9 days⁷.

The average cost per admission was R\$ 5,135.15, which was much higher than the amounts paid by AIH in the system, which is R\$ 672.35⁷. It should be noted that this amount includes the cost of the prosthesis, which accounts for more than half of the final amount.

Limitations

The main limitation of this study is the fact that the SIH/DATASUS does not provide clinical information on patients undergoing PCI. Not only age, gender, admission diagnosis and the ability to perform the procedure are responsible for the hospital outcome. The lack of such information prevents an adjustment of mortality according to the severity of patients among different hospitals, although it is expected that, at least in high-volume hospitals, any differences that may exist are standardized according to the large volume of patients served and do not have any substantial clinical impact. Also, the performance of various teams in some hospitals, not always with similar results, is another factor that may influence local outcomes.

Conclusions

Compared with more industrialized countries and those with more resources available for health, the number of PCIs performed in Brazil is still low. High-volume hospitals, in smaller numbers, are responsible for most of the production, what makes we think that better management of public funds, prioritizing these hospitals, and a regionalization system, could make the system more efficient. Mortality rates are highly variable and in average are higher than those found in other countries, although in many centers, the results delivered are comparable to the best results published in the international literature. Although higher-volume hospitals have a lower average mortality rate, we could not find any difference comparing to lower-volume hospitals, perhaps because there is no adjustment of clinical variables. These differences appear when we consider the group of elective indication. The procedures performed in emergency situations, which are more frequent, and primary PCI, had the highest mortality rates. The procedure accounts for the greatest

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number of cases was the single stent implantation, although, as said before, the SUS sets a 20% limit on the number of two stents per intervention.

The PCI is a procedure that delivers excellent results, and in each year is more and more employed, although it is less often employed than in other countries. In our country, the results still differ widely among hospitals, even among high-volume hospitals, calling for a better quality control in order to standardize future results. It is necessary to discuss the situation of small-volume hospitals, since this is a costly procedure which requires better equipment and specialized personnel which are often underused.

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Potential Conflict of Interest

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Study Association

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