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**Original Article** 

# Complications after elective percutaneous coronary interventions: A comparison between public and private hospitals



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#### ABSTRACT

*Objective:* Complications after percutaneous coronary interventions (PCI) are associated with significant morbidity and mortality, although institutional discrepancies can occur when public and private hospitals coexist within the healthcare system. The aim of this study was to compare the in-hospital complication rates and mortality in addition to long-term survival following elective PCI in two reference public and private cardiology hospitals in Rio de Janeiro, Brazil. *Methods:* From January 1st 2013 to December 31st 2014, a total of 440 procedures were identified in both hospitals (public: 328 vs. private: 112) and retrospectively analyzed by chart review. *Results:* There were no significant differences between the two hospitals regarding the total number of procedures with at least one complication (public: 23.8 vs. private: 17.9%, p = 0.2) or in-hospital mortality rates (public: 0.6% vs. private: 0%, p = 0.5). Post-procedural renal insufficiency was more frequent in the private hospital, whereas coronary-related complications were more prevalent in the public hospital. After a mean follow up of 30.3 months (SD  $\pm$  9.2), the survival rate was also similar. *Conclusions:* Clinical complications after elective PCI are common both in public and private hospitals. Meticulous pre-procedural clinical assessment and patient selection as well as adherence to guideline-based practices could minimize the risk of PCI-related adverse events.

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## 1. Introduction

Over the last decade, the number of percutaneous coronary interventions (PCI) performed in developing countries such as Brazil and India has steadily risen. 1,2 An in-hospital mortality rate as high as 3.64% and an overall complication rate of 6.0% have been previously reported, even after elective angioplasties. 1,3 However, in healthcare systems where private and public providers coexist, encountering institutional discrepancies is to be expected. Previous data suggest that major in-hospital complications and mortality are generally similar between public and private institutions.4 Nevertheless, little is known about the performance of these procedures in highly referenced private and public hospitals within a healthcare system that includes both types of providers. As such, the aim of this study was to determine the prevalence of clinically relevant in-hospital complications and mortality, in addition to long-term survival after elective PCI, in two highly specialized public and private hospitals in Rio de Janeiro, Brazil.

# 2. Methods

Consecutive patients submitted to PCI were screened between January 2013 and December 2014 in two reference cardiology hospitals, one in the public and one in the private health system, in Rio de Janeiro, Brazil. The public hospital that was selected specializes in high-complexity cardiovascular procedures and was responsible for over 60% of the PCIs that were performed by this type of provider in Rio de Janeiro State between 2013 and 2014. Conversely, the private hospital that was analyzed is considered a leading institution in terms of medical technology in the state. As such, both hospitals were representative of the highest quality of medical assistance that is available in Rio de Janeiro, although access to the private hospital is restricted to patients with higher income.

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Only elective procedures were included, and they were defined by the absence of myocardial infarction (MI) in the two weeks preceding the intervention. Hospitalization for more than seven days before the procedure, sepsis, and active cancer were further exclusion criteria. Additionally, only patients with post-procedural troponin I (TnI) measurements were considered, in order to accurately estimate the prevalence of PCI-related myocardial injury, Troponin I (Abbot Laboratories, Architect STAT Troponin I or Architect High Sensitive STAT Troponin I) elevation was assessed by measurements performed between six and 24h after the intervention. Data regarding clinical, angiographic, and procedural characteristics were collected retrospectively by chart review and correlated to post-procedural complications. All in-hospital complications related to the procedure that were reported in the medical charts during the same hospitalization period were considered relevant. The prevalence and the total rates of each complication were compared between the two hospitals. Besides aspirin, a clopidogrel loading dose between 300 and 600 mg was routinely administered to all patients during or immediately after the intervention, along with an intravenous bolus dose of unfractionated heparin.

All complications were assessed considering the number of patient-procedures in each hospital. However, mortality rates and long-term survival were evaluated by including only the most recent procedure among those with multiple interventions. The follow-up period began on the day of the procedure. Mortality was established by consulting a public regional online database of births and deaths in Rio de Janeiro State, and an 18-month minimum follow-up was available for all included patients. In accordance with the Declaration of Helsinki, the study was approved by both hospitals' human research committees and obtaining informed consent was not necessary since the data collection was based on retrospective chart review.

Stata<sup>®</sup> 11.0 software was used for statistical analysis. Categorical variables were analyzed with Pearson's  $\chi^2$ , Fisher's exact test, and the two-sample test of proportions. Continuous normally distributed variables were expressed as mean  $\pm$  standard deviation (SD) and assessed by two-sample t tests. Non-normal distributions were represented by the median associated with the 25th to 75th percentile interguartile range (IQR) and analyzed by the Wilcoxon-Mann-Whitney test. The associations between continuous variables and the probability of any post-PCI complication were assessed by fractional polynomial plots. Survival curves were constructed from Kaplan Meier survival estimates with follow-up being censored at 30 months. Differences between the curves were analyzed using the Cox proportional hazards model. A p value <0.05 was considered significant.

#### 3. Results

A total of 1078 elective patient-procedures were initially identified in both hospitals during the study period, according to the predefined inclusion and exclusion criteria. Thereafter, an additional 638 procedures without post-PCI TnI measurements were excluded from the study. Hence, the remaining 440 patientprocedures, performed in 414 individual patients, were included in the analysis. In the public hospital, 328 interventions were performed in 322 patients; in the private hospital, 112 procedures were performed in 92 patients. In order to verify the possibility of selection bias, the one-year mortality of the cohort of patients without enzyme measurements was compared to that of the patients included in the study. Since the mortality difference was not statistically significant (without TnI: 4.3% vs. with TnI: 5.6%. p = 0.4), the possibility of selection bias was minimized.

Clinical, angiographic, and procedural characteristics according to each healthcare provider are listed in Table 1. In the private

Table 1

Clinical, angiographic, and procedural characteristics according to each healthcare provider.

Characteristics	Total (%)	Public (%)	Private (%)
Total patient-procedures ( <i>n</i> )	440	328	112
Mean age, years $(SD\pm)$	64.6 (11)	62.5 (10.1)	70.7 (11.3)
Male gender	71.8	66.8	86.6
Hypertension	89.3	88.4	92
Diabetes	31.6	30.2	35.7
Hyperlipidemia	69.6	63.1	88.4
$BMI \ge 30 \text{ kg/m}^2$	12	8.2	23.2
Current or prior tobacco use	24.8	22	33
Mean baseline hemoglobin, mg/dL (SD $\pm$ )	13.5 (1.5)	13.6 (1.5)	13.1 (1.5)
Median baseline creatinine, mg/dL (IQR)	0.97 (0.8-1.2)	0.92 (0.9–1.1)	1.03 (0.9-1.2)
Heart failure or LVD	10.7	8.8	16.1
Symptomatic CAD	57.7	52.4	73.2
Prior PCI	32.3	26.2	50
Prior CABG	12.3	9.5	20.5
Pre-procedural medications <sup>a</sup>			
Aspirin	49.1	40.9	73.2
Clopidogrel	27.5	21.7	44.6
ß-blockers	54.8	58.2	44.6
ACEi or ARB	59.6	60.7	56.3
CCB	23.9	22.3	28.6
Statins	59.1	54.3	73.2
Angiographic and procedural aspects			
Multivessel disease <sup>b</sup>	31.1	28.1	40.2
Multivessel angioplasty <sup>c</sup>	27.1	27.7	25
Multistenting <sup>d</sup>	43.9	45.1	40.2

SD - standard deviation; IQR - interquartile range; BMI - body mass index; CAD - coronary artery disease; LVD - left ventricular dysfunction; PCI - percutaneous coronary intervention; CABG - coronary artery bypass grafting; ACEi - angiotensin converting enzyme inhibitors; ARB - angiotensin receptor blockers; CCB - calcium channel blockers. Medication usage at hospital admission.

b  $\geq$ 70% obstruction in  $\geq$ 2 vessels.

с Intervention in  $\geq 2$  vessels.

 $^{d}\,$  Implantation of  ${\geq}2$  stents.

hospital, patients were older with a male predominance and the prevalence of major cardiovascular risk factors was greater. Although most patients had single-vessel disease, defined by only one coronary obstruction  $\geq$ 70%, there was also a greater prevalence of multivessel disease in the private hospital.

The total in-hospital mortality in both institutions was low (0.5%). However, periprocedural and post-PCI complications were reported in 98 interventions (22.3%), with more than one event occurring in some procedures. Clinically relevant complications included bleeding leading to a diagnostic or therapeutic intervention, acute coronary syndrome, renal insufficiency, hypotension, coronary dissection, occlusion or perforation, symptomatic arrhythmias, and cardiac tamponade. Other reported adverse events were acute respiratory distress, seizures, hypertensive crisis, urinary retention, and unsuccessful PCI. There were no significant differences between the two hospitals in the total number of procedures with at least one complication. Among the specific adverse events, there was a higher frequency of coronary dissection, occlusion, and perforation in the public hospital, whereas renal insufficiency was significantly more prevalent in the private hospital (Table 2).

When all patients were considered, age, baseline creatinine, and TnI were directly related to post-PCI complications. In contrast, baseline hemoglobin (HGB) was inversely associated with the occurrence of any complication. These associations are shown in Fig. 1. In addition, mean baseline HGB was significantly lower among patients who suffered any complication (13.0 mg/dL SD  $\pm$  1.6 vs. 13.6 mg/dL SD  $\pm$  1.46, p = 0.003), and the overall post-PCI mean HGB was lower than the baseline value (12.4 mg/dL SD  $\pm$  1.57 vs. 13.3 mg/dL SD  $\pm$  1.54, p < 0.001). Nevertheless, no significant difference was observed in the post-procedural HGB values between the public and private hospitals (public: 12.5 mg/dL SD  $\pm$  1.6 vs. private: 12.3 mg/dL SD  $\pm$  1.6, p = 0.176).

In spite of similar bleeding rates, the median post-intervention creatinine level was significantly higher in the private hospital (0.97 mg/dL, IQR: 0.86–1.13 vs. 0.84 mg/dL, IQR: 0.73–0.99, p < 0.001). In contrast, asymptomatic post-PCI TnI elevation at levels  $\geq 5$  times higher than the 99th percentile was observed more frequently in the public hospital (44.2% vs. 32.1%, p = 0.025). When all patients were considered, the median post-intervention TnI level was also higher among those who suffered a complication (0.16 ng/mL, IQR: 0.04–1.4 vs. 0.09 ng/mL, IQR: 0.03–0.32, p = 0.001). After a mean follow up of 30.3 months (SD ± 9.2), survival was similar among patients from both institutions (Fig. 2).

#### 4. Discussion

According to our results and in light of other studies, the total complication rates after elective PCI during the study period were high, irrespective of the type of healthcare provider.3,4 Even though it is believed that physicians have greater access to medical supplies and more optimal working conditions in the private sector, the complication rates were found to be similar between the public and private hospitals that were studied. Access to the private hospital was restricted to patients with higher income and more favorable social conditions, which was reflected by an elevated percentage of individuals with a college degree (60%). Consequently, these patients tended to be older, with a greater prevalence of cardiovascular risk factors and more advanced coronary disease.

However, it should be noted that the public hospital had an active residency program during the study period, which resulted in some procedures being performed by trainees. Conversely, all of the procedures in the private hospital were performed by certified interventional cardiologists. Moreover, although patients from the private hospital had a greater prevalence of multivessel disease, the multivessel angioplasty rate was similar between the two hospitals, whereas multistenting occurred more frequently in the public hospital. These observations might explain the greater frequency of coronary-related complications in the public hospital, despite the predominance of less complex disease. In any case, an accurate estimation of procedural complication rates based on earlier studies remains elusive, as only 23% of previous clinical trials involving coronary stents provided details as to the occurrence of complications directly related to the interventions.5

Length of stay was one day shorter in the public hospital, which could reflect a greater procedural demand in the public sector and the fact that this hospital performed more interventions during the study period. Most of the diagnosed complications, such as bleeding, are knowingly associated with adverse long-term clinical outcomes. The significant post-procedural HGB decline that was observed must be appreciated, as it was equivalent to the loss of one unit of packed red blood cells per procedure. Accordingly, Lindsey et al. previously reported that post-PCI one-year mortality was four times greater in the presence of periprocedural bleeding. 6 In addition, Reinecke et al. observed a 10% mortality increase after PCI when the post-procedural creatinine level was >1.3 mg/ dL.7 This value was frequently observed in our study (10.3% of all

Table 2

In-hospital incidence of reported complications in the public and private hospitals according to the total number of procedures performed in each hospital.

Complication	Total, <i>n</i> (%) ( <i>n</i> = 440)	Public, <i>n</i> (%) ( <i>n</i> = 328)	Private, <i>n</i> (%) ( <i>n</i> = 112)	p value
Acute coronary syndrome	24 (5.5)	19 (5.8)	5 (4.5)	0.6
Clinically relevant bleeding <sup>a</sup>	22 (5)	14 (4.3)	8 (7.1)	0.24
Hypotension	16 (3.6)	15 (4.6)	1 (0.9)	0.07
Coronary complications <sup>b</sup>	14 (3.2)	14 (4.3)	0	0.03
Symptomatic arrhythmias	7 (1.6)	7 (2.1)	0	0.12
Cardiac tamponade	4 (0.9)	3 (0.9)	1 (0.9)	1
Renal insufficiency	4 (0.9)	1 (0.3)	3 (2.7)	0.02
Other complications <sup>c</sup>	19 (5.8)	17 (5.2)	2 (1.8)	0.12
Procedures with complications	98 (22.3)	78 (23.8)	20 (17.9)	0.2
In-hospital death	$2 (0.5)^{d}$	2 (0.6) <sup>e</sup>	0	0.5
Mean length of stay, days (SD $\pm$ )	2.9 (7.7)	2.6 (8.5)	3.8 (3.8)	0.08

Bold values are <0.05.

<sup>a</sup> Resulting in a diagnostic or therapeutic intervention.

<sup>b</sup> Dissection, occlusion or perforation.

<sup>c</sup> Hypertensive crisis, respiratory distress, urinary retention, seizures, unsuccessful angioplasty.

<sup>d</sup> n = 414.

<sup>e</sup> n=322.



Fig. 1. Risk factors for any post-procedural complication. Age (A), baseline creatinine (C), and troponin I (D) were directly associated with the probability of any complication, whereas baseline hemoglobin level (B) was inversely related to this outcome.



**Fig. 2.** Kaplan Meier curves for survival according to the hospital where the procedure was performed. Follow-up was censored at 30 months and there were no differences in survival between patients from the two healthcare providers. *HR* – *hazard ratio; CI* – *confidence interval.* 

patients), particularly in the private hospital. Not surprisingly, patients from that hospital had a greater prevalence of baseline risk factors for contrast-induced renal toxicity. Also, asymptomatic  $\geq$ 5 times enzyme elevation, currently classified as "myocardial

injury" according to the universal MI definition, has an adverse prognostic value on its own and it occurred at a higher rate when compared to other studies.8,9

In some measure, the survival curves may have been similar between both hospitals because the total complication rates were comparable. Most importantly, these results raise important questions as to whether guideline-based medical treatment, patient selection, and procedural protocols are actually being followed throughout both the public and private healthcare systems. The low percentage of patients under antiplatelet therapy on admission, particularly in the public hospital, raises concerns as to whether adequate optimized medical therapy is in fact being offered before invasive therapy is considered. Furthermore, the preferential use of the radial artery access site is a significant measure that has been associated with less bleeding and improved clinical outcomes, although this information was not collected in the current study.10 The assessment of these variables in future studies is a vital step toward improving patient care and clinical outcomes in this scenario, both in private and public institutions.

This study has limitations that must be acknowledged. Even though the results may not necessarily reflect what happens in other countries or even in other regions throughout Brazil, our data emphasize the need to constantly evaluate the results of high complexity interventions, regardless of the type of healthcare provider. Selection bias cannot be completely excluded since patients were included according to the presence of a postprocedural Tnl measurement. However, the similar one-year mortality rates between the groups with and without Tnl values suggest that our cohort adequately reflects the clinical profile of all procedures that were performed during the study period.

Since the data was collected from retrospective chart review, there were no predefined criteria for the complications that were reported, as the information reflected "real world" observations. Moreover, bleeding complications were diverse, since the only criterion that was applied was the necessity of a diagnostic or therapeutic intervention. Although this could have overestimated bleeding complications, the average HGB decline after each procedure suggests that these events did occur frequently. The restricted information regarding specific procedural characteristics such as arterial access site, stent type, length, and diameter is another limitation. Furthermore, it was not possible to discriminate between the various causes of death in the online system used to determine mortality. Finally, follow-up data on medication usage and other clinical variables that may have influenced survival were not recorded.

#### 5. Conclusion

In a healthcare system where both public and private providers of PCI coexist, the complication rate appears to be similar regardless of where the procedure is performed. Low baseline HGB, higher baseline creatinine and TnI, and older age were all associated with the occurrence of complications. Therefore, meticulous pre-procedural clinical assessment and patient selection as well as adherence to guideline-based practices might minimize the risk of adverse events, both in public and private hospitals. Further studies are needed to elucidate the most effective preventive measures.

### **Conflict of interest**

All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation. All authors have approved the final article.

None of the authors have any conflicts of interest to declare.

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