Original Article Percutaneous coronary intervention procedures performed at a hospital in Southern Brazil

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Abstract: Background: Despite the advantages of percutaneous coronary intervention (PCI) compared to fibrinolytic therapy, it holds some potential risks such as contrast related reactions and technical problems. In addition, recent studies have shown disparities in which access is more exposed to radiation. Objectives: To analyze the clinical profile, differences between radial and femoral approach and complications presented in patients who underwent PCI performed in a hospital in the south of Brazil. Methods: A total of 733 patients who underwent PCI in 2016 were included and retrospectively analyzed through their clinical records. The primary outcomes analyzed were procedure approach and the presence of complications. Results: The median age was 62.5 years; 54.8% were male; 50.8% had hypertension and 18.6% were diabetic; and mortality was seen in 2.3% of the population. Femoral approach was the most exposed to radiation, as well as the most used in ST-elevation myocardial infarction (STEMI). Complications were seen in 16.1% of the population and cardiovascular complication was the most frequent. Different accesses or degree of urgency showed no association with complication development. On the other hand, STEMI was related to a bigger complication burden. Conclusion: The femoral approach demonstrated more expressive radiation exposure, which can be explained by anatomic reasons. Femoral access represented a safe approach for interventionists in more urgent cases, such as STEMI. Different accesses or degree of urgency did not show an association with complications, as opposed to STEMI, revealing that this condition deserves more attention regarding its procedures and post-PCI care.

Keywords: Percutaneous coronary intervention, radial artery, femoral artery, myocardial infarction

introduction

Heart disease has high levels of global morbidity and mortality. Coronary artery disease (CAD) was specifically responsible for 1 in 3 deaths in the United States in 2008, and mortality from the same disease accounted for more than 400 thousand deaths in the same year in the country [1]. In addition, CAD represents more than half of cardiovascular events in men and women up to 75 years of age [1]. The prognosis and perspective of these patients are directly affected by the fact that about one third of people who experience an acute myocardial infarction (AMI) die from the same cause within a year [1]. Cardiovascular diseases (CVD) in Brazil have also had a great influence on public health, being the main cause of death for more than 50 years [2].

Percutaneous coronary intervention (PCI) is a surgical technique used in treating CAD, being

the preferred approach for restoring myocardial perfusion in cases of acute ST-elevation myocardial infarction (STEMI) [3]. In this context, PCIs are of paramount importance. In the United Kingdom alone, the number of PCIs performed in 2012 was more than double those performed a decade earlier [4]. It is not yet well defined which is the best reperfusion modality that performs best in patients with STEMI who attend the hospital early after the onset of symptoms (<3 h). However, fibrinolysis within the first hours in patients with STEMI showed good results and a low incidence of morbidity and mortality. This benefit decreases as the onset of symptoms at the beginning of fibrinolysis increases [5].

PCIs are accompanied by risks despite the advantages in relation to fibrinolytic treatment such as lower rates of recurrent ischemia, reinfarction, intracranial hemorrhage and death. Potential complications include problems with

the arterial access site, adverse reactions to the contrast medium and volume infusion and technical problems [3]. Myocardial revascularization (MR) surgery, as well as PCI, is also an option for revascularization in patients with CAD. MR surgery is generally used as a strategy for reperfusion when it is impossible to perform PCI within the maximum time, or in its failure, if the patient has mechanical complications or CAD affecting the left coronary trunk or three arteries [6].

PCIs can be performed via the radial or femoral artery, depending on the professional's experience. The use of radial and femoral access routes for performing PCI procedures is safe in relation to the risks of cardiovascular events [7]. However, radial access has lower rates of adverse clinical events of bleeding and mortality in patients with acute coronary syndrome undergoing invasive management compared to the femoral access [8]. In contrast, recent studies have shown divergences between which pathway is most exposed to radiation [9, 10].

A large number of patients with AMI undergoing PCI are potentially exposed to high doses of radiation. Certain characteristics are related to a higher radiation dose in PCI in patients with STEMI such as being male, having a previous myocardial revascularization procedure, diabetes mellitus, major coronary disease or a greater number of treated vessels [11].

PCIs are an important part of the daily conduct of cardiac emergencies [4]. Given this, the present study aims to investigate PCI procedures by delimiting risk factors for complications in performing these procedures. Characterizing these factors can assist in the clinical management for future patients and foster greater scientific interest in the topic and thus ensure more safety and a reduction in the rates of adverse clinical events resulting from these procedures.

In this perspective, the objective of this study was to analyze the clinical profile, differences between the radial and femoral approaches and the complications presented by patients undergoing percutaneous coronary intervention procedures performed at the Nossa Senhora da Conceição Hospital, located in Tubarão-SC, Brazil.

Methods

This is a retrospective cohort study. We assessed a population of patients undergoing interventionist angiographic procedures.

Inclusion criteria

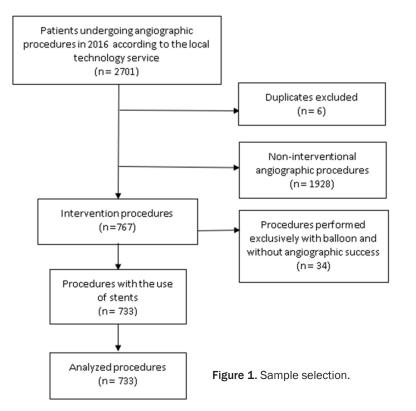
A spreadsheet with the list obtained from the Tasy Philips[™] electronic medical record of patients who underwent angiographic procedures in the period from 01/01/2016 to 12/31/2016 was requested from the site service for data collection, containing a total of 2701 procedures at the Nossa Senhora da Conceição Hospital, in Tubarão, Santa Catarina, Brazil.

Exclusion criteria

Patients who underwent non-interventionist angiographic procedures and those performed exclusively with a balloon or without angiographic success were excluded from the study. Patients who had duplicate medical records were also excluded. Also, when comparing the pathways as the primary outcome, patients who had the ulnar, left radial or left femoral approach were excluded from the sample. More than one access route addressed at the same time was also an exclusion criterion. However, all access for the description of the sample were considered. Those patients who did not contain information about the approached artery or the type and number of stents were also excluded.

Variables

In this work, patients who underwent PCI were evaluated and analyzed for gender, age (years), comorbidities, the route used to perform the procedures, radiation dose (mGy) and radiation dose x area (MGy \times cm²), time length of stay (days), artery targeted for intervention (more than one artery can be used at the same time), stents (quantity and type of stent used - pharmacological or conventional), clinical complications (classified by spectrum) and/or death during hospitalization, need for hospitalization in an Intensive Care Unit, and character of the procedure (emergency or elective). Subjects in STEMI and unstable angina were classified as urgent. In addition, the subjects were analyzed as to the need for a procedure due to STEMI.



Ethics statement

This study is in accordance with the ethical aspects proposed by the Research Ethics Committee (RECE) of University of Southern Santa Catarina - Brazil, with a favorable opinion posted on 07/10/2017 under number 2,164,931.

Data analysis

The data were stored in an Excel spreadsheet and later transferred to the Statistical Package for the Social Sciences (SPSS) 20.0 program for analysis. The numerical data were presented as central tendency and dispersion measures, and categorical data in absolute and partial frequencies.

The analysis of the numerical data was primarily performed by the Kolmogorov-Smirnov normality test. The One-way ANOVA test was used for numerical data to compare the difference between the radial and femoral pathways, while the chi-squared test was used for categorical data. Bivariate and multivariate logistic regression were used to obtain the gross and adjusted odds ratio to analyze the outcome of complication. The confidence interval was 95%, with a statistical significance level of 5%.

Results

A total of 2701 medical records of patients undergoing angiographic procedures were initially made available in 2016 according to the information technology service. However, a total of 767 cases resulted according to the exclusion criteria and considering only interventionist procedures. Of these, the following were excluded for sample standardization: 11 procedures which used a balloon alone, 8 which used a balloon associated with the stent, 9 procedures which did not obtain angiographic success, and 6 which were repeated due to technical issues in the

program used. Thus, a final total of 733 procedures were analyzed (**Figure 1**).

One of the 733 subjects evaluated did not have a description of age in their medical record. The median age (P25-P75) of the participants was 62.5 (56.0-70.0) years, with 54.8% being male. The length of stay had a median of 6.0 (1.0-11.0) days.

The morbidities were organized in a total of 94 conditions which included the main chronic diseases such as Hypertension, Diabetes Mellitus (DM), Chronic Obstructive Pulmonary Disease (COPD), thyroid diseases and dyslipidemia. Previous conditions such as surgery, history of acute myocardial infarction (AMI), smoking or previous history of smoking were also included in the morbidities (**Table 1**).

Complications

From the patients with a specific description of complications (114), the most frequent was cardiovascular being present in 81 subjects (71.1%), followed by infectious and neurological. Complications were classified by spectrum: cardiovascular (angina-type chest pain, acute

Table 1. Clinical characteristics of the population undergoing percutaneous coronary intervention at the Nossa Senhora da Conceição Hospital in 2016 and in-hospital complications reported in the study population during or after the procedure

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Morbidity	N (%)
Hypertension	373 (50.8)
Diabetes mellitus (types 1 and 2)	137 (18.6)
Active smoking	84 (11.4)
Dyslipidemia	87 (11.8)
Previous TCA	81 (11)
Previous AMI	71 (9.6)
CHF	69 (9.4)
Previous MRS	57 (7.7)
CAD	44 (6)
History of smoking	44 (6)
Chest pain, unspecified	38 (5.1)
COPD	33 (4.5)
Unstable angina	31 (4.2)
MDD	19 (3.6)
Stable angina	24 (3.2)
Previous CVA/stroke	24 (3.2)
Others*	184 (25.1)

TCA: transluminal coronary angioplasty, AMI: acute myocardial infarction, CHF: chronic heart failure, MRS: previous myocardial revascularization surgery, CAD: coronary artery disease, COPD: chronic obstructive pulmonary disease, MDD: major depressive disorder, CVA: stroke/ cerebral vascular accident. *: Immunological, rheumatological, psychiatric, behavioral, endocrine-metabolic, cardiological, oncological, hematological, gastrointestinal, infectious, vascular, neurological, ophthalmological, previous surgery, dermatological and renal.

myocardial infarction [AMI], cardiogenic shock, acute heart failure, arrhythmias, acute lung edema), pulmonary (asthma exacerbation, unspecified respiratory failure), infectious (urinary tract infection, pneumonia, sepsis), neurological (stroke), transient ischemic attack [TIA], related to the access site (local hematoma, pain), renal (acute renal failure [ARI], exacerbation of chronic renal failure [CRF]), hepatic, psychiatric, hemodynamic, immunological, contrast-related, urological or metabolic (**Figure 2**).

Out of the total amount of patients who underwent the intervention and who had sufficient information regarding complications (731), 118 (16.1%) presented some type of complication immediately after the procedure or throughout their hospitalization. Each patient may have had more than one complication, as well as more than one morbidity (**Table 2**).

All studied subjects (733) had some artery covered in the procedures and informed in medical record data. Regarding the number of stents, one subject did not have the necessary data in their medical record. A total of 494 (67.5%) of the 732 procedures used only one stent, 199 (27.2%) used two stents, while three stents were used in 28 (3.8%) procedures and four stents were used in 11 (1.5%). Regarding the stent types, one subject also did not have complete data in their medical record. Another subject in the sample did not contain information on admission to the Intensive Care Unit.

Most subjects were submitted to the procedure on an urgent basis, even if only a portion was in STEMI. Patients who died have this data regarding death during the procedure or after it during the entire hospitalization period (**Table 2**).

The access routes used varied from right radial, left radial, right femoral, left femoral, right ulnar and right radial and femoral in the same procedure.

Radial versus femoral access

When comparing the radial and femoral access routes, only the right radial and femoral routes were considered, which comprised 97.7% of the procedures. There was a predominance of using the femoral approach to access the procedure in both men and women. Regarding the character of the procedure, preference was observed for the femoral approach in both groups. The use of the radial approach became more prevalent in the group which did not have STEMI. These comparisons are shown in the **Table 3**.

Odds ratio for complication

Table 4 below shows the characteristics anddifferences between the groups regarding thepresence or absence of any complications. Agreater association with complication(s) isobserved when analyzing the femoral approach.Patients who underwent the procedure withoutSTEMI had a lower rate of complications.Moreover, patients with some type of complica-tion had a longer hospital stay. When evaluatedtogether, the route, procedure character and

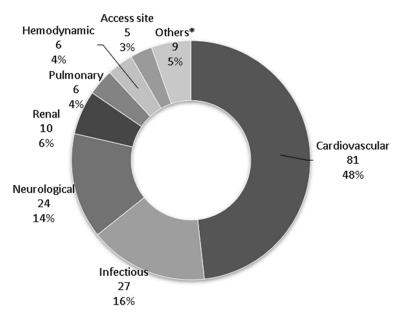


Figure 2. In-hospital complications reported in the study population during or after the procedure. *: Metabolic, hepatic, psychiatric, immunological, adverse reaction to contrast, urological, occlusion when passing through a guide catheter due to thrombus formation.

Table 2. Characteristics of percutaneous coronary interventionprocedures performed at Hospital Nossa Senhora da Conceição in2016 in the study population

	N (%)
TARGET ARTERY	
descending anterior	382 (52.1)
right coronary	202 (27.5)
circumflex	115 (15.6)
first left marginal branch	25 (3.4)
first diagonal branch	22 (3)
second left marginal branch	19 (2.5)
others*	9 (1.2)
STENTS	
Pharmacological	375 (51.2)
Conventional	351 (48)
Conventional association x pharmacological	6 (0.8)
ROUTE USED	
Radial	265 (36.2)
Femoral	451 (61.5)
ICU NECESSITY	
Yes	144 (19.7)
No	588 (80.3)
CHARACTER OF THE PROCEDURE	
Elective	208 (28.6)
Urgent/emergency	520 (71.4)
STEMI	
Yes	112 (15.3)
No	620 (84.7)
MORTALITY	17 (2.3)

*: left coronary trunk for left anterior descending artery, left internal mammary, saphenous vein bridge for left marginal branch, saphenous vein bridge for left marginal branch, left coronary trunk.

the necessity for ICU variables lose significance, suggesting the influence of the other variables on the outcome.

Discussion

This study demonstrated that the majority of patients undergoing PCI were older adults with a predominance of men, but with greater balance between the genders in the procedures when compared to other studies [12, 13], demonstrating that the male gender in the study population did not exert as much influence as in other works. One study also reports an even greater male presence when studying patients in acute coronary syndromes (ACS) (72.4 and 74.5% in the femoral and radial pathways, respectively), suggesting a gender influence in greater risk situations [8].

Among the morbidities that characterized the study population, those with high cardiovascular repercussions such as Hypertension and Diabetes Mellitus deserve attention. However, they were presented more discreetly than in other studies [8, 12, 14]. The proportion of patients with previous myocardial revascularization surgery who underwent PCI was relatively high when compared with international data, but at the same time it is within the same range in a national panorama [8, 12].

The current study found lower complication rates compared to Brazilian rates, which identified 22.3% complications. However, procedures without angiographic success were also included in the studied population herein, suggesting that it is possible for these rates to have similar levels [12].

	Via radial N (%)	Via femoral N (%)	Ρ
Age*	61.0±15.0	63.0±15.0	0.123
Gender			
Male	146 (37.2)	247 (62.8)	0.932
Female	119 (36.8)	204 (63.3)	
Radiation dose (mGy)*	1055±563	1055±171	<0.001#
Dose x radiation area $(mGy.cm^2)^*$	40689±32191	51787±18279	<0.001#
Character of the procedure			
Elective	73 (36.3)	128 (63.7)	0.778
Urgent/emergency	191 (37.5)	319 (62.5)	
STEMI			
Yes	19 (17.1)	92 (82.9)	<0.001#
No	245 (40.6)	359 (59.4)	
Previous MRS			
Yes	5 (9.1)	50 (90.9)	<0.001#
No	260 (39.3)	401 (60.7)	
ICU necessity			
Yes	33 (23.2%)	109 (76.8)	<0.001#
No	231 (40.3)	342 (59.7)	
Length of stay (days)*	5.0±5.0	6.0±6.0	0.002#

 Table 3. Profile of groups and characteristics of the procedure according to the access route

*median ± interquartile distance; #P<0.05.

Improvement in techniques and devices has reduced the incidence of serious complications resulting from PCI, such as contrast reaction, bleeding, infections, nephropathy and complications related to the access site [15]. However, focusing more on complications can detail them and contribute to the potential of this procedure. Thus, the cardiovascular complication rate was the most prevalent in the current study. When evaluating complications in PCI for chronic total coronary occlusion, one study observed a cardiovascular complication (coronary and non-coronary) rate of 17.9%. Furthermore, it demonstrated higher rates of complications related to the access site and contrast [16]. Chronic total coronary occlusion lesions are a specific and complex type of situation in terms of percutaneous treatment, which partly explains the higher observed complication rate.

The most prevalent target artery in the procedures was the anterior descending artery, followed by the right and circumflex coronary artery. Another study [8] describes a greater presence of the circumflex artery in interventions when evaluating patients experiencing ACS, suggesting greater involvement of this artery and greater clinical repercussion in urgent or emergency cases. In addition, when studying the involvement of circumflex and right coronary arteries in patients with lower wall STEMI, it was observed in the literature that the group affected by the circumflex artery had a higher rate of unfavorable outcomes [8, 17].

A balanced distribution of the stent types used was observed, with a small predominance of the pharmacological type. Patients who are experiencing STEMI may have a greater predominance of non-pharmacological stents [7]. On the other hand, a certain study found a greater preva-

lence of the use of drug-eluting stents, being present in more than 66% of procedures [18]. The recent introduction of the use of drug-eluting stents for patients in clinical subgroups in the Unified Health System (*SUS*) in 2014 may partly explain a lesser use of this device compared to the literature in developed countries [18, 19]. In addition, the current study did not discriminate between procedures performed in the public and private spheres, constituting a factor which may have directly influenced this variable.

The route used was mostly femoral, and this finding is in accordance with other studies. Regarding this, the importance of the learning curve for introducing the radial access in the centers is highlighted, with a tendency for a lower success rate of the procedures for the radial route [7, 20].

ICU admission after PCI was considerably high. An ICU admission rate of 3.5% is found in the literature when only evaluating patients with STEMI undergoing primary PCI. This difference in the proportion of ICU admissions may suggest that a certain internal protocol of the ser-

	No Complication N (%)	Complication N (%)	Crude OR (95% CI)	Р	Adjusted OR (95% CI)	Р
Age (years)*	62.0±14.0	63.0±16.0	1.004 (0.984-1.023)	0.712	0.994 (0.971-1.018)	0.640
Gender						
Male	334 (83.1)	68 (16.9)	1.000		1.000	
Female	279 (84.8)	50 (15.2)	0.880 (0.591-1.311)	0.530	1.185 (0.729-1.924)	0.494
Route						
radial	236 (89.4)	28 (10.6)	1.000		1.000	
femoral	364 (80.9)	86 (19.1)	1.991 (1.261-3.144)	0.003#	1.221 (0.724-2.130)	0.432
Character of the procedure						
elective	196 (94.2)	12 (5.8)	1.000		1.000	
urgent/emergency	413 (79.7)	105 (20.3)	4.153 (2.232-7.727)	<0.001#	1.500 (0.725-3.103)	0.274
STEMI						
No	541 (87.5)	77 (12.5)	1.000		1.000	
Yes	71 (63.4)	41 (36.6)	4.057 (2.580-6.379)	<0.001#	4.170 (2.362-7.362)	<0.001#
Number of stents						
1	417 (84.6)	76 (15.4)	1.000		1.000	
2	28 (14.1)	171 (85.9)	0.898 (0.562-1.435)	0.654	0.870 (0.506-1.493)	0.612
3	9 (32.1)	19 (67.9)	2.599 (1.133-5.960)	0.024#	1.329 (0.424-4.163)	0.625
4	4 (40.0)	6 (60.0)	3.658 (1.008-13.269)	0.049#	0.706 (0.090-5.528)	0.741
ICU Necessity						
No	514 (87.7)	72 (12.3)	1.000		1.000	
Yes	98 (68.1)	46 (31.9)	3.351 (2.183-5.143)	<0.001#	1.432 (0.812-2.524)	0.214
Length of stay (days * (days))	5.0±5.0	10.0±13.0	1.168 (1.127-1.211)	<0.001#	1.158 (1.111-1.208)	<0.001#

*: median ± interquartile distance, #P<0.05.

vice is in force, with specific criteria for admitting high-risk patients to the intensive care unit [21].

Most patients performed the procedure on an urgent/emergency basis, and this finding is in line with other studies [8, 18]. Elective cases were slightly below those compared to other authors (34.6%). The latter observed that the proportions of elective procedures decrease as the intervention center increases its volume of operations, and this factor may be associated with the presence of a surgical team at all times, although their availability does not show any difference between mortality in elective PCI [22]. In addition, characteristics and difficulties of the public health system (*SUS*) can define situations in which elective procedures encounter resistance to be performed.

Furthermore, the STEMI was as much present as in other centers in relation to its PCI volume. A similar proportion of procedures due to STEMI were found in another study (17.9%) [18]. The mortality rate observed in the current study was at similar levels to those found in other studies [8, 13].

In analyzing the outcome of the routes used for the procedure, it is possible to denote a higher dose of radiation through the femoral approach. However, it is suggested that radiation exposure is comparable to that of accesses depending on the interventionist's experience with both routes and the proportion of routes used by the centers, although the transradial route generally presents a higher rate of radiation exposure [20]. On the other hand, another study analyzing patients with PCI and angiography demonstrated greater exposure to radiation (area-product dose) via the transfemoral route, thus corroborating the current study [9]. The discrepancy in the data raises the hypothesis of operational differences during procedures in different centers. In addition, the femoral approach may require greater radiation compared to the radial approach when it is at the origin of the lower limb. Even so, the radial artery suggests that the interventionists have greater difficulty in its access due to anatomical reasons of its caliber, increasing the fluoroscopy time. This duality may explain the different findings in the studies.

The femoral approach proved to be highly prevalent during STEMI, while patients who were not experiencing STEMI had both routes more equally explored. Literature data indicate that the radial approach requires greater experience for its success in the interventionist's routine [23]. This means that the best option in facing urgent clinical situations is one in which angiographic success is guaranteed, which may explain this predilection. In addition, this finding is in accordance with what was found when evaluating patients in primary angioplasty [7]. The proportion of patients with previous MRS who underwent the femoral procedure was high compared to international data, also according to what was previously placed [24].

A greater presence of femoral access was observed in those who had clinical complications when assessing the complication outcome, constituting a factor which (in isolation) is corroborated by the literature [7, 20]; however, this variable loses significance in multivariate logistic regression analysis, suggesting that the route had no influence among other variables, and that the choice of access may be related to the operational safety of the interventionist (confirming what was previously mentioned).

In the same way, the procedure character component showed a loss of significance in the same analysis, which raises the hypothesis that patients in urgent conditions have a higher complication rate due to previous conditions which placed them in an emergency situation, such as a certain morbidity or affected artery, and not due to the urgency episode itself [8, 17]. This assumption can be similarly applied to the loss of significance of the ICU necessity variable.

The STEMI variable was associated with the complication when it was evaluated together with the other variables. STEMI represents a situation which requires different conduct within the ACS, with reperfusion being the main objective [25]. There is generally total occlusion of the coronary artery in this type of infarction, which can cause more serious injuries and present greater clinical repercussion. Also, the length of hospital stay showed an association for complications. However, it is a retrospective characterization variable, meaning that patients who experienced complications had a longer hospital stay and not the other way around.

It is worth mentioning that one of the limitations of the present study was the relationship of dependence with the exclusive information from medical records, with comorbidities not always being ideally described, nor other information either qualitatively and quantitatively. This fact may have directly influenced the current results. Important data which was not analyzed because it was not described in the medical records was the fluoroscopy time. In addition, exclusive data collection from a single center submits the results of the work to the internal routine and the reality of the service, as well as to the social, economic and geographical characteristics of the studied population.

Conclusions

PCIs were presented as safe procedures, with few complications and a low mortality rate. The most common complications were cardiovascular. In addition, overall mortality between interventions was low. The lower use of drugeluting stents may represent a difficulty in the service routine. In addition, admission to the ICU after the procedure was high, which questions the severity and clinical condition of the patients, although the STEMI procedure rate was similar to the literature.

Regarding the outcome of the routes, the femoral access showed greater radiation, defending the hypothesis that this route requires a higher dose of radiation for its performance due to anatomical reasons. The predilection for the femoral approach during STEMI demonstrates that the femoral approach also represents an operational safety factor for interventionists.

The present study also showed that the routes did not show differences in relation to clinical complications, unlike the STEMI condition. This corroborates the "time-muscle" relationship established for patients with this condition. However, this finding revealed that patients experiencing STEMI or their possibility deserve even more attention in terms of procedures, as well as after them, reducing the impact of their complications.

Disclosure of conflict of interest

None.

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