

Original Article

Adequacy of elective coronary angiography indication for the diagnosis of coronary artery disease in the Brazilian public health system

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ABSTRACT

Background: The diagnosis of coronary artery disease is challenging because of the considerable variability in its clinical presentation. It also requires a cautious decision between invasive or conservative stratification. We aimed to evaluate the adequacy of coronary angiography indication in patients from the Unified Health System (SUS, in the Portuguese acronym) based on the guidelines for stable coronary disease.

Methods: Consecutive patients who underwent coronary angiography between March 2014 and November 2015 were evaluated. Clinical presentation and functional tests were evaluated to define the class of recommendation. In quantitative coronary angiography, significant luminal obstruction was considered $\geq 50\%$ and $< 70\%$, while severe luminal obstruction was considered $\geq 70\%$.

Results: A total of 250 patients were included (52% male), with a mean age of 61.2 years. Of these, 35.2% had class II-IV angina. Exercise tests or myocardial scintigraphy with high-risk criteria were present in 22% and 10.8% of the sample, respectively. Among the patients, 61.2% did not present significant coronary artery disease. In addition, 60.8% had class I or IIa indication for coronary angiography, and 19.2% had a class III indication. Among the former, 44.7% had significant or severe coronary artery disease vs. 29.6% of those with recommendations IIb or III ($p = 0.01$). Class I or IIa indications were independently associated with the presence of coronary artery disease (OR = 1.91, 95% CI 1.02-3.56, $p = 0.04$).

Conclusions: The adequacy of the indications for coronary angiography was only moderate, and the prevalence of coronary disease in the groups with class I or IIa recommendation was low. Difficulties regarding clinical evaluation and the adequate interpretation of functional tests may be one explanation for these findings.

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Adequação das indicações de coronariografia eletiva para o diagnóstico de doença arterial coronária no sistema público de saúde brasileiro

RESUMO

Introdução: O diagnóstico da doença aterosclerótica coronária é desafiador pela grande variabilidade de apresentações clínicas e requer cautelosa decisão entre estratificação invasiva ou conservadora. Objetivamos avaliar a adequação das indicações de coronariografia em pacientes do Sistema Único de Saúde (SUS) com base nas diretrizes de doença coronária estável.

Métodos: Foram avaliados pacientes consecutivos submetidos à coronariografia entre março de 2014 e novembro de 2015. Por meio da apresentação clínica e de testes funcionais realizados, definiu-se a classe de indicação. Em avaliação quantitativa, consideraram-se significativas obstrução luminal $\geq 50\%$ e $< 70\%$, e graves aquelas $\geq 70\%$.

Resultados: Foram incluídos 250 pacientes, com média de idade de 61,2 anos e 52% do sexo masculino. Destes, 35,2% tinham angina classe II-IV. Teste ergométrico ou cintilografia miocárdica com critérios de alto risco estavam presentes em 22% e 10,8% da amostra, respectivamente. Dentre os pacientes, 61,2% não apresentavam coronariopatia significativa. Ainda, 60,8% tinham indicação classe I ou IIa para coronariografia e 19,2%, indicação classe III. Entre os primeiros, 44,7% eram portadores de coronariopatia significativa ou grave vs. 29,6% daqueles com indicação IIb ou III ($p = 0,01$). Indicação classe I ou IIa associou-se de forma independente com a presença de doença aterosclerótica coronária (OR = 1,91; IC 95% 1,02-3,56; $p = 0,04$).

Palavras-chave:

Doença das coronárias

Angiografia coronária

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Conclusões: A adequação das indicações de coronariografia eletiva foi apenas moderada, e a prevalência de coronariopatia nos grupos com indicação classe I ou IIa foi baixa. As dificuldades em relação à avaliação clínica e à interpretação adequada dos testes funcionais podem figurar entre as causas destes achados.

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Introduction

Cardiovascular diseases are among the leading causes of morbidity and mortality in both developed and developing countries, accounting for approximately 10% of global mortality. It is estimated that by 2020, they will cause approximately 25 million deaths worldwide.¹ Coronary artery disease (CAD) has great variability in its clinical presentation and severity. Proper stratification requires detailed evaluations, ranging from non-invasive stress tests to more invasive stratifications.

Coronary angiography is the gold standard for coronary anatomic diagnosis, guiding the conduct and prognosis of patients with CAD. Despite its increasing availability, it should be requested judiciously since the exam is not free of complications.² The current guidelines recommend clinical follow-up for patients with a low probability of CAD; for those with a high probability, the indication of invasive stratification is more liberal.^{3,4} In cases of intermediate probability, it is necessary to employ screening tests and careful clinical judgment. Based on the pre-test probability for CAD, the guideline recommendations limit the number of patients referred to coronary angiography without adequate reasoning.

In a recent study in Brazil, only 23.8% of the patients who were invasively stratified had obstructive CAD, suggesting low efficiency in patient selection.⁵ Similarly, in a North American registry of outpatients with no known history of CAD who were subjected to coronary angiography, less than 40% of the patients had significant lesions.⁶ These data suggest possible imprecision in the propaedeutic routine for CAD.

The objective of the present study was to evaluate the adequacy of elective coronary angiography indications for CAD investigation in patients from the Unified Health System (SUS, acronym from Portuguese *Sistema Único de Saúde*).

Methods

This is a prospective, observational, unicentric epidemiological study with consecutive inclusion of individuals, approved by the Research Ethics Committee of the Faculdade de Ciências Médicas de Minas Gerais.

Inclusion criteria were patients between 18 and 85 years of age; patient sent electively to perform coronary angiography for investigation of CAD to a large-volume university hospital in the State of Minas Gerais; from the public health system, with funding from the SUS or by payment of extra expenses, performed by prefectures or health secretariats. Exclusion criteria were patients referred for cardiac catheterization by different indications (heart valve diseases, structural heart diseases, congenital heart diseases, and peripheral arterial disease); patients with acute coronary syndrome or other urgent situations; and patients who could not report clinical symptoms clearly and who did not have the test results that would support the request for the procedure.

The adequacy of coronary angiography indications was evaluated according to the class of recommendation by the Brazilian Guidelines on Stable Coronary Disease, in accordance with the American

College of Cardiology/American Heart Association (ACC/AHA) guidelines.^{3,4} The presence of CAD was defined by means of quantitative coronary analysis (XImage® software, XPro, Belo Horizonte, Brazil), performed by two interventional cardiologists, with the additional evaluation of a senior interventional cardiologist if there was disagreement in measurements, according to the following definition: normal or discrete, absence of angiographically identifiable CAD, or lesions with diameter stenosis < 50% in epicardial coronary arteries or their branches; significant CAD if diameter stenosis were between 50% and 69%; and severe CAD if diameter stenosis were ≥ 70% of the luminal diameter.

Regarding the stress tests, the following factors were considered: criteria of severe ischemia by myocardial scintigraphy (presence of reversible ischemia affecting ≥ 10% of the left ventricular mass); electrocardiography stress test (low workload ischemia, defined by typical electrocardiographic changes induced by exercise < 4 MET, or heart rate < 100 bpm, or less than 70% of the predicted maximum heart rate); and stress echocardiography (significant hypokinesia in large area of the left ventricle, defined by the echocardiographer). Detailed clinical evaluations were performed by a team of three independent researchers.

For statistical analysis, the software Statistical Package for Social Sciences (SPSS) version 22.0 for Mac OSX (SPSS Inc., IMB, Chicago, USA) was used. A descriptive analysis of the demographic and clinical variables was performed, in addition to the coronary angiography indication criteria, according to the recommendation classes (I, IIa, IIb, and III). The distribution pattern of the variables was evaluated using the Shapiro-Wilk test. Continuous variables were expressed as the means ± standard deviations (SD) or as medians and quartiles of 25% and 75% (Q1-Q3) when appropriate. Categorical variables were expressed as absolute and percentage values. The comparison of means was performed by Student's *t* test for continuous variables with normal distribution, while the Mann-Whitney U test was used for those with non-normal distribution. The comparison of discrete variables between groups was performed using Pearson's Chi-squared test. The main outcome analyzed was the adequacy of the indication for coronary angiography. A multivariate logistic regression model was used, considering the coronary angiography recommendation class (I/IIa and IIb/III), the symptomatology, and the clinical variables, to evaluate factors independently associated with the presence of CAD (obstruction ≥ 50%). The sample calculation was performed using the STATA 7.0 program (StataCorp® LLC, College Station, USA) using the Sample Size routine for the kappa statistic interrater agreement, with the sample size established according to a confidence interval (CI) of 95% and a margin of error of 3% of the population proportion. When necessary, transformations were made for analysis of variance. A two-tailed significance level of 0.05 was considered statistically significant.

Results

Between March 2014 and November 2015, 250 consecutive patients were included, of which 63.2% were publicly funded (SUS),

and the remainder were funded with payment of extra expenses. The mean age was 61.2 ± 10.5 years, and the population was 52% male. Clinical characteristics are shown in Table 1. Regarding symptomatology, 35.2% of patients had angina II to IV according to the Canadian Cardiovascular Society Classification, and 23.6% were asymptomatic, with positive stress tests. Electrocardiography stress test or myocardial scintigraphy with high-risk criteria were present in 22% and 10.8% of the sample, respectively. The average time between the request and the coronary angiography was higher among SUS patients than among those with payment of extra expenses (29 vs. 23 days; $p = 0.042$).

A total of 152 (60.8%) patients had a class I or IIa indication for coronary angiography; 48 (19.2%) had a class III recommendation. At coronary angiography, 61.2% of the patients had no significant CAD, 10% had significant CAD, and 28.8% had severe CAD (Table 2). Among the patients with class I or IIa indications, 68 (44.7%) had significant or severe CAD vs. 29 (29.6%) of patients with a IIb or III recommendation ($p = 0.01$). Among patients with severe CAD, 77.8% had a class I or IIa indication for coronary angiography (Figure 1).

In the multivariate model, a class I or IIa indication for coronary angiography was independently associated with the presence of significant or severe CAD (odds ratio - OR: 1.91; 95% confidence interval - 95% CI 1.02-3.56, $p = 0.04$) (Table 3).

Discussion

In this sample of stable patients referred for invasive stratification of CAD in a large tertiary center in Brazil, we observed a considerable index of inadequacy of coronary angiography indications, with 39.2% of patients with class IIb or III recommendations. In addition, the rates of significant or severe coronary artery disease were low—lower than those mentioned in the guidelines — and similar to that observed in other studies and national registries.^{7,8}

Real-world practice data, which are of great importance for the evaluation of health systems, are scarce in Brazil, especially in elective patients and that contemplate the indications and original observations of the professionals by which the population is cared. Differently from other studies, in our interpretation of coronary angiography adequacy, we considered the conclusion of the physician responsible for the stress tests results. This strategy more accurately reflects the current reality, since in a system of high demand and with high turnover of professionals, a detailed reassessment of the results by the requesting physician is often not performed, and the diagnostic conclusion often guides the additional propaedeutics.

An adequate clinical evaluation, especially regarding the classification of chest pain, is a fundamental step in presuming the pre-test probability of CAD in an individual. Regarding this criterion, it was

Table 1
Clinical characteristics of patients

Characteristics	Total n = 250	No significant CAD n = 153	Significant/severe CAD n = 97	p-value
Mean age, years	61.2 ± 10.4	60.0 ± 10.4	63.3 ± 10.2	0.01
Male sex, n (%)	130 (52)	67 (43.8)	63 (64.9)	0.001
High blood pressure, n (%)	216 (86.4)	130 (85.0)	86 (88.7)	0.26
Dyslipidemia, n (%)	159 (63.6)	85 (55.6)	74 (76.3)	0.001
Smoking, n (%)	33 (13.2)	16 (10.5)	17 (17.5)	0.13
Diabetes mellitus, n (%)	78 (31.2)	48 (31.4)	30 (30.9)	> 0.99
Family history of CAD, n (%)	109 (43.8)	65 (42.8)	44 (45.4)	0.70
Symptomatology				0.38
Angina CCS I, n (%)	51 (20.4)	30 (19.6)	21 (21.2)	
Angina CCS II to IV, n (%)	88 (35.2)	49 (32.0)	39 (40.6)	
Atypical chest pain, n (%)	52 (20.8)	33 (21.6)	19 (19.6)	
Asymptomatic, n (%)	59 (23.6)	41 (26.8)	18 (18.6)	
Previous PCI, n (%)	24 (9.6)	7 (4.6)	17 (17.5)	0.001
Previous CABG, n (%)	11 (4.4)	1 (0.7)	10 (10.3)	< 0.001
Associated pharmacotherapy				
Beta blocker, n (%)	137 (54.8)	78 (51)	59 (60.8)	0.15
Nitrate, n (%)	59 (23.6)	30 (19.6)	29 (29.9)	0.07
ACEI/ARB, n (%)	172 (68.8)	99 (64.7)	73 (75.3)	0.09
ECG stress test, n (%)	58 (23.3)	35 (22.9)	23 (23.7)	0.14
Myocardial scintigraphy, n (%)	41 (16.4)	27 (17.6)	14 (14.4)	0.04

CAD: coronary atherosclerotic disease; CCS: Canadian Cardiovascular Society; PCI: percutaneous coronary intervention; CABG: coronary artery bypass surgery; ACEI: angiotensin-converting enzyme inhibitor; ARB: angiotensin receptor blocker.

Table 2
Degree of coronary obstruction by recommendation class for coronary angiography

Indication level	Classes I/IIa (n = 152) n (%)	Classes IIb/III (n = 98) n (%)	p-value
No significant coronary artery disease	84 (55.3)	69 (70.4)	0.02
Significant coronary artery disease (≥ 50% and < 70%)	12 (7.9)	13 (13.3)	0.20
Severe coronary artery disease (≥ 70%)	56 (36.8)	16 (16.3)	0.0005

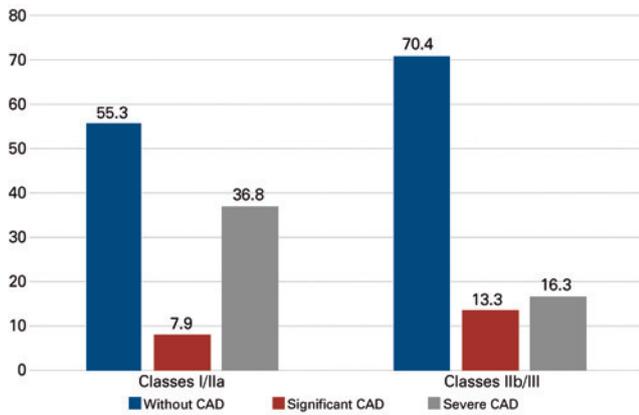


Figure 1. Results of coronary angiography by recommendation class. CAD: coronary artery disease.

Table 3

Multivariate model evaluating the independent variables associated with the presence of significant or severe coronary artery disease (CAD) at coronary angiography

Variable	OR	CI 95%	p-value
Class I/IIa indication	1.91	1.02-3.56	0.04
Angina CCS III and IV	0.77	0.35-1.70	0.53
Age ≥ 65 years old	2.48	1.36-4.51	0.003
Male sex	2.64	1.48-4.72	0.001
Hypertension	0.95	0.40-2.24	0.91
Dyslipidemia	2.70	1.42-5.12	0.002
Smoking	2.44	1.06-5.60	0.04
Diabetes mellitus	0.90	0.49-1.67	0.73
Family history of CAD	0.98	0.55-1.73	0.94

OR: odds ratio; 95% CI: 95% confidence interval; CCS: Canadian Cardiovascular Society.

observed that more than 40% of the patients referred were asymptomatic or had atypical symptomatology. Our data resemble those of other observational studies, in which approximately one-fifth of the individuals examined did not present with angina symptoms.^{9,10} In view of these findings, high proportions of patients with ischemic stress tests would be expected, justifying invasive stratification, which was not observed, thus anticipating the rates of normal tests above the recommended level.¹¹ This finding may represent limited access to methods, which is a frequent situation in the reality of the SUS, or even the lack of knowledge of the correct indications by the attending physicians. Such information is relevant since the invasive procedure is not free from complications and may even lead to unnecessary therapeutic indications.

Similar to clinicians, physicians who perform functional tests work under high demand. It is fundamental to observe work routines in these environments so that the ideal time to execute the protocols and interpretation of the results can be made available, minimizing the risk of imprecise interpretations. These propaedeutic support services are fundamental for the maintenance of the adequacy indexes of invasive exams. In addition, it is often noted that the requesting physician does not differentiate between a positive stress test and that of a high-risk of having multi-vessel CAD – a criterion that is recommended for the stratification of the groups in which revascularization may reduce clinical events.^{12,13}

The average length of time between the request and the execution of the procedure were approximately 29 days (14 to 71) for SUS patients and 23 days (8 to 47) for patients who provided private pay-

ment for extra expenses. In the State of Minas Gerais, 9 years ago, the average length of time for coronary angiography was 78 days for SUS patients, with no suppressed demand in supplementary health.^{5,14} Possible causes for the reduction of this gap include the increase in the number of institutions accredited by the public system, mainly in the interior, and the implementation of a computerized system for managing and directing high-cost examinations by geographic area.¹⁵

In our sample, 60.8% of the patients had class I or IIa indications for coronary angiography, contrasting with what was previously observed in a publication on a similar population in Belo Horizonte, where 32.1% of SUS patients and 35.9% of medical cooperatives had class I or IIa recommendation class for coronary angiography.⁵ Methodologically, the studies differ in relation to the verification of the indication of the procedure; in the latter, the indications were fully revalidated by the researchers, including the interpretation of the functional tests. Our research site was a tertiary hospital linked to a medical school, which may have had a positive effect on this outcome since the sample consisted of outpatients referred by the institution. However, with the greater dissemination of guidelines and educational projects directed at SUS professionals, more adequate indications may be occurring.¹⁵

Despite the difficulties highlighted the correct indication of coronary angiography was independently associated with the presence of obstructive CAD, which reinforces the need to comply with the guidelines. In addition to the class of recommendation, traditional risk factors, such as smoking, dyslipidemia, male sex, and age, were part of the final model, corroborating previous findings.¹⁶ Our data may be useful to managers in establishing flowcharts for authorization of coronary angiography and in the overall evaluation of the costs involved in procedures of high complexity, aiming at a better allocation of resources.

This study has limitations. The unicentric collection of data does not allow the generalization of the results to the national territory or to other realities. The study was conducted in a university hospital, in a capital city with outstanding socioeconomic indexes, which may represent a selection bias, both in relation to the quality of medical care and the availability of health resources. Moreover, the design of the study does not allow an evaluation of the accuracy of the functional tests in practice, and it is not feasible to collect more detailed data, which would make it possible to identify sources of diagnostic imprecision.

Conclusions

The adequacy of the indications for coronary angiography was only moderate, with a low final prevalence of coronary disease, lower than that recommended by the guidelines. In addition to traditional risk factors, the indications of class I or IIa were independently associated with the presence of significant or severe coronary atherosclerotic disease, reinforcing the importance of adequate clinical evaluation and the correct interpretation of functional tests to support invasive stratification.

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Conflicts of interest

The authors declare no conflicts of interest.

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