

CLINICAL SYMPTOMS AND ANGIOGRAPHIC FINDINGS OF PATIENTS
UNDERGOING ELECTIVE CORONARY ANGIOGRAPHY WITHOUT PRIOR STRESS
TESTING

BY

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Abstract

Background: Many patients undergo elective coronary angiography without prior stress testing, precluding an assessment of their appropriateness for percutaneous coronary intervention (PCI). If, however, these patients have more severe angina or obstructive coronary artery disease (CAD), proceeding directly to angiography would represent efficient resource utilization.

Methods: We identified patients without a prior history of obstructive CAD undergoing elective coronary angiography performed between July 2009 and March 2012 in the NCDR CathPCI Registry[®] and assessed for differences in angina (Canadian Cardiovascular Society [CCS] class) and severity of obstructive CAD ($\geq 70\%$ stenosis in an epicardial or $\geq 50\%$ in a left main coronary artery) in those with and without pre-procedural stress testing. Given the large sample size, differences were considered clinically meaningful if the standardized difference was $>10\%$. To further understand whether proceeding to coronary angiography without prior stress testing was justified because of a high clinical pre-test probability for CAD, we also compared the frequency of obstructive CAD.

Results: Of 403,182 patients undergoing elective coronary angiography, nearly half (49.7%) were performed without prior stress testing. Patients without prior stress testing were more frequently asymptomatic (CCS class 0), as compared with those who had prior stress testing (40.5% vs. 28.7%; standardized difference 19.1%). There were no meaningful differences in the frequency of proximal LAD (5.1% in no stress test group vs. 6.4% in stress test group; standardized difference 5.7%), left main (2.9% vs. 3.5%; standardized difference 3.5%) or 3-vessel CAD (4.4% vs. 6.1%; standardized difference 6.0%) between the 2 groups. Moreover, the likelihood of obstructive CAD in patients

undergoing coronary angiography without prior stress testing was 18.0%, as compared with 43.0%, 22.9%, and 12.6% for those with stress testing showing severe, moderate, and mild ischemia.

Conclusion: In elective angiography, proceeding to coronary angiography without prior stress testing was not associated with greater symptoms, higher-risk coronary anatomy, nor a greater presence of obstructive CAD. Many angiographic procedures might be avoided with pre-procedural stress testing.

Keywords: Coronary angiography, appropriateness of care, stress test, stable angina

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Introduction:

While the American College of Cardiology (ACC) and the American Heart Association (AHA) recommend pre-procedural risk stratification in patients with stable angina prior to invasive coronary angiography,¹ it is commonly performed² without non-invasive stress testing.³⁻⁶ Clinically, the decision to proceed directly to coronary angiography without prior stress testing may be justified if patients have significant symptoms or a more severe obstructive coronary artery disease (CAD), in whom percutaneous coronary intervention (PCI) could impact symptoms or prognosis. In such circumstances, stress test results might not alter the decision to pursue revascularization and would increase the costs of care.

The importance of understanding current practice patterns of proceeding directly to coronary angiography without prior stress testing was underscored by a recent report from the National Cardiovascular Data Registry (NCDR) CathPCI Registry[®], in which 11.6% of non-acute PCIs were deemed inappropriate and unlikely to be of clinical benefit to patients.³ In that study, more than 1 in 5 non-acute procedures were excluded from the analysis due to absence of pre-procedural non-invasive stress testing, which prevented the authors from assigning an appropriateness rating. Whether patients who do not undergo stress testing prior to coronary angiography have more severe symptoms, or a greater burden of obstructive CAD, is unknown.⁷

To address this current gap in knowledge and better understand the characteristics of patients who undergo coronary angiography without prior stress testing, we compared clinical characteristics, symptom severity, and the extent of obstructive CAD among patients undergoing elective coronary angiography with and without pre-procedural stress testing. Furthermore, we

examined the likelihood of any obstructive CAD in patients who underwent coronary angiography without pre-procedural stress testing, as compared with patients having a high-, intermediate-, and low-risk stress test result.

Methods:

Data Source

The NCDR CathPCI Registry[®] is a national registry sponsored by the ACC and the Society for Cardiovascular Angiography and Interventions (SCAI).^{8,9} Briefly, it is a registry of consecutive diagnostic coronary angiography and PCI procedures from more than 1000 hospitals in the U.S. Detailed information about patient demographics, clinical features, hospital information, pre-procedural stress testing results and ischemia severity, angiography findings and in-hospital complications are abstracted by trained staff at each hospital using standardized data elements (available from the CathPCI registry website [<http://www.ncdr.com/WebNCDR/elements.aspx>]).

Study Population

Within the NCDR CathPCI Registry[®], we identified 2,071,245 coronary angiograms performed between July 2009 and March 2012 from hospitals that reported coronary angiography data. We chose this time period for analysis, as Version 4 of the data collection form contains information noninvasive stress test results and was first introduced in July 2009. As we were interested in examining the use of stress testing in non-acute presentations, we excluded 879,117 procedures performed in the setting of acute coronary syndromes (acute myocardial infarction and unstable angina), settings in which pre-procedural stress testing would be inappropriate. We further excluded procedures performed in the setting of pre-operative evaluation before non cardiac surgery (83,370 procedures), cardiomyopathy (84,389 procedures), recent heart failure exacerbation (153,712 procedures) and procedures performed in patients with prior history of myocardial infarction, PCI or coronary artery bypass graft (188,516 procedures). Moreover, we

excluded 111,869 procedures from hospitals that do not report angiography results in patients not undergoing PCI, as well as 166,885 procedures in which a stress test was performed but the result was unavailable. Our final study cohort was comprised of 403,182 elective coronary angiograms from 821 hospitals (Figure 1).

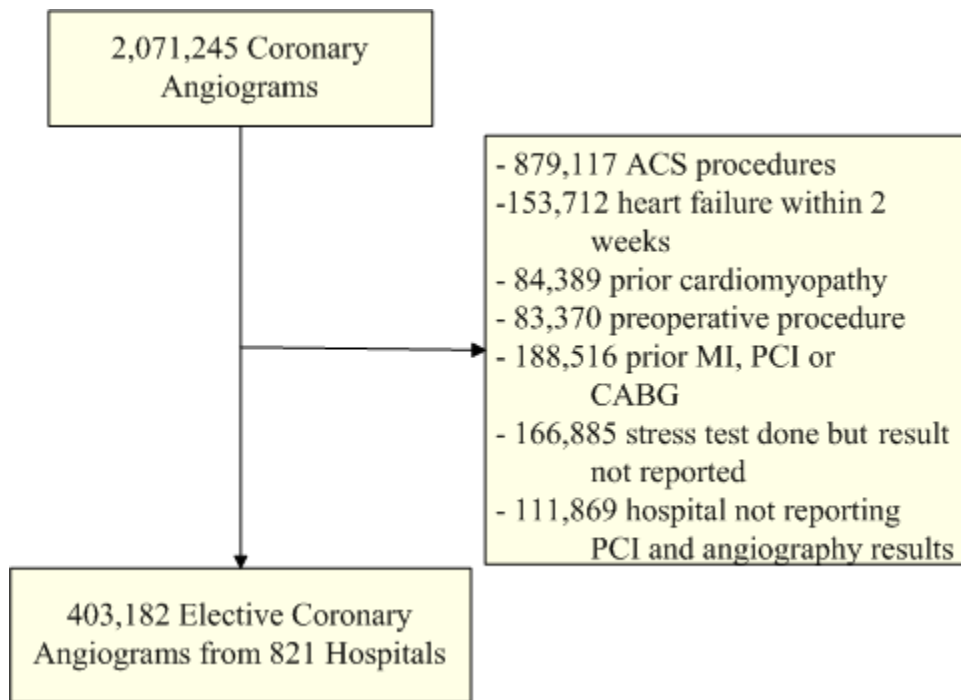


Figure 1. Study Cohort

Study Outcomes

Our primary objectives were to determine whether the symptom burden, severity of obstructive CAD, and the presence of any obstructive CAD differed between patients who underwent elective coronary angiography without prior stress testing and those with a pre-procedural stress test. Symptom burden was assessed using Canadian Cardiovascular Society (CCS) functional class for angina.¹⁰ To examine differences in the extent and severity of obstructive CAD

between the 2 groups, we compared the distribution of 1-, 2-, and 3-vessel obstructive CAD, as well as the frequency of obstructive CAD present in the proximal left anterior descending (LAD) and left main coronary arteries. Consistent with prior studies,^{3,5} obstructive CAD was defined as a $\geq 50\%$ stenosis of the left main coronary artery or a $\geq 70\%$ stenosis of a major epicardial or branch vessel ≥ 2.0 mm in diameter.⁷ Finally, the likelihood of obstructive CAD was defined as the proportion of patients undergoing coronary angiography with evidence of obstructive CAD.

Statistical Analysis

Baseline demographics and clinical characteristics were compared between patients undergoing coronary angiography with and without prior stress testing. Because of the large sample size, which could result in statistically significant p-values without clinically relevant differences in proportions, differences between groups were evaluated by computing standardized differences (differences in group means divided by the common standard deviation) for each covariate.

Based on prior work, a standardized difference of $>10\%$ was used to define a clinically meaningful difference between groups.¹¹ We first examined whether there were clinically important differences in the severity of angina and the severity of obstructive CAD between patients undergoing coronary angiography with and without pre-procedural stress testing. We then compared the likelihood of any obstructive CAD between patients without pre-procedural stress testing and those with a high-risk, intermediate-risk, and low-risk stress test.

Finally, we examined hospital variation in the proportion of patients proceeding directly to coronary angiography without prior risk stratification with stress testing. After creating quartiles of the hospitals, based upon the proportion of coronary angiography procedures without prior stress testing, we repeated the above analyses and examined whether there were differences

in symptom burden, severity of CAD, and the presence of obstructive CAD between those with and without stress testing.

All statistical analyses were performed with SAS 9.2 (SAS Institute, Inc, Cary, NC) or R version 2.10.0 (R Foundation for Statistical Computing, Vienna, Austria). The authors had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Results:

Of 403,182 elective coronary angiograms, 202,750 (50.3%) were performed with prior stress testing and 200,432 (49.7%) without. The mean age of the study cohort was 61.2 ± 12.8 years, 48.9% of patients were men, 85.3% were white, and 70.7% had private health insurance. Table 1 compares baseline characteristics between the two groups. There were no differences between the two groups with regards to age, sex, race, insurance status or history of DM.

Table 1: Baseline Characteristics, Stratified by Pre-Procedural Stress Testing

<i>Characteristic</i>	Total (N= 403,182)	Stress Test Prior to Coronary Angiogram (N=202,750)	No Stress Test Prior to Coronary Angiogram (N=200,432)	Standardized Difference (%)*
Demographics				
Age	61.2 ± 12.8	60.6 ± 12.1	61.8 ± 13.5	8.7
Male Sex	197,255 (48.9%)	99,421 (49.0%)	97,834 (48.8%)	0.45
White Race	343,940 (85.3%)	172,026 (84.8%)	171,914 (85.8%)	2.6
Insurance				
Private Health Insurance	272,361 (70.7%)	141,940 (72.6%)	130,421 (68.8%)	8.4
None	18,145 (4.5%)	7,298 (3.6%)	10,847 (5.4%)	8.7
Clinical History				
Diabetes Mellitus	106,832 (26.5%)	55,673 (27.5%)	51,159 (25.5%)	4.4
Currently on Dialysis	5,472 (1.4%)	1,985 (1.0%)	3,487 (1.7%)	6.6
Family History of Premature CAD	104,177 (25.8%)	56,631 (27.9%)	47,546 (23.7%)	9.6
Anti-Anginal Medication within 2 Weeks	182,259 (45.3%)	95,363 (47.1%)	86,896 (43.4%)	7.3

Abbreviations: CAD, coronary artery disease.

* Standardized difference >10% denotes clinically meaningful difference

Severity of Angina Symptoms

Within the cohort, approximately 35% of patients undergoing coronary angiography reported no angina (CCS class 0) and only 11.4% reported severe angina (CCS class III or IV). Compared with patients having pre-procedural stress testing, those without stress testing were more frequently asymptomatic (CCS class 0: 40.5% vs. 28.7%; standardized difference 19.1% across the CCS classes) (Table 2).

Table 2: Angina and CAD Severity, Stratified By Pre-Procedural Stress Testing

<i>Characteristic</i>	Total (N=403,182)	Stress Test Prior to Coronary Angiogram (N=202,750)	No Stress Test Prior to Coronary Angiogram (N=200,432)	Standardized Difference (%)*
<i>Anginal Classification within 2 Weeks</i>				
No symptoms	138,891 (34.6%)	57,971 (28.7%)	80,920 (40.5%)	
CCS I	85,427 (21.3%)	45,242 (22.4%)	40,185 (20.1%)	
CCS II	131,562 (32.7%)	75,889 (37.5%)	55,673 (27.9%)	19
CCS III	33,462 (8.3%)	17,290 (8.5%)	16,172 (8.1%)	
CCS IV	12,583 (3.1%)	5,888 (2.9%)	6,695 (3.4%)	
<i>Angiography</i>				
<i>Diseased Vessels, No.</i>				
0	328,138 (81.4%)	163,850 (80.8%)	164,288 (82.0%)	
1	32,006 (7.9%)	15,190 (7.5%)	16,816 (8.4%)	
2	21,750 (5.4%)	11,316 (5.6%)	10,434 (5.2%)	6
3	21,288 (5.3%)	12,394 (6.1)	8,894 (4.4%)	
Proximal LAD Disease	23,114 (5.7%)	12,966 (6.4%)	10,148 (5.1%)	5.7
Left Main Disease	12,925 (3.2%)	7,118 (3.5%)	5,807 (2.9%)	3.5

Abbreviations: CAD, coronary artery disease; CCS, Canadian Cardiovascular Society; LAD, left anterior descending

* Standardized difference >10% denotes clinically meaningful difference

Severity of Obstructive CAD

There were no differences in the extent of obstructive CAD among patients with and without pre-procedural stress tests. Rates of 3-vessel obstructive CAD were 4.4% for those without, as compared with 6.1% (standardized difference 6.1%) for those with prior stress testing (Table 2). Rates of proximal LAD (5.1% for no stress test group vs. 6.4% for stress test group; standardized difference 5.7%) and left main CAD (2.9% for no stress test group vs. 3.5% for stress test group; standardized difference 3.5%) were also similar between the 2 groups.

Likelihood of Finding Obstructive CAD on Coronary Angiography

The likelihood of obstructive CAD on coronary angiography between patients without and with a pre-procedural stress test, stratified by severity of ischemia suggested that those without testing were not more likely to have a significant lesion. Among the 200,432 patients that did not have pre-procedural stress test, 18% (36,146) had evidence of obstructive CAD. In contrast, the

prevalence of significant CAD was 43.0% (8,670/20,183) for patients with a high-risk stress test, 22.9% (16,068/70,197) for those with an intermediate-risk stress test, and 12.6% (14,162/112,370) for those with a low-risk stress test (Figure 2).

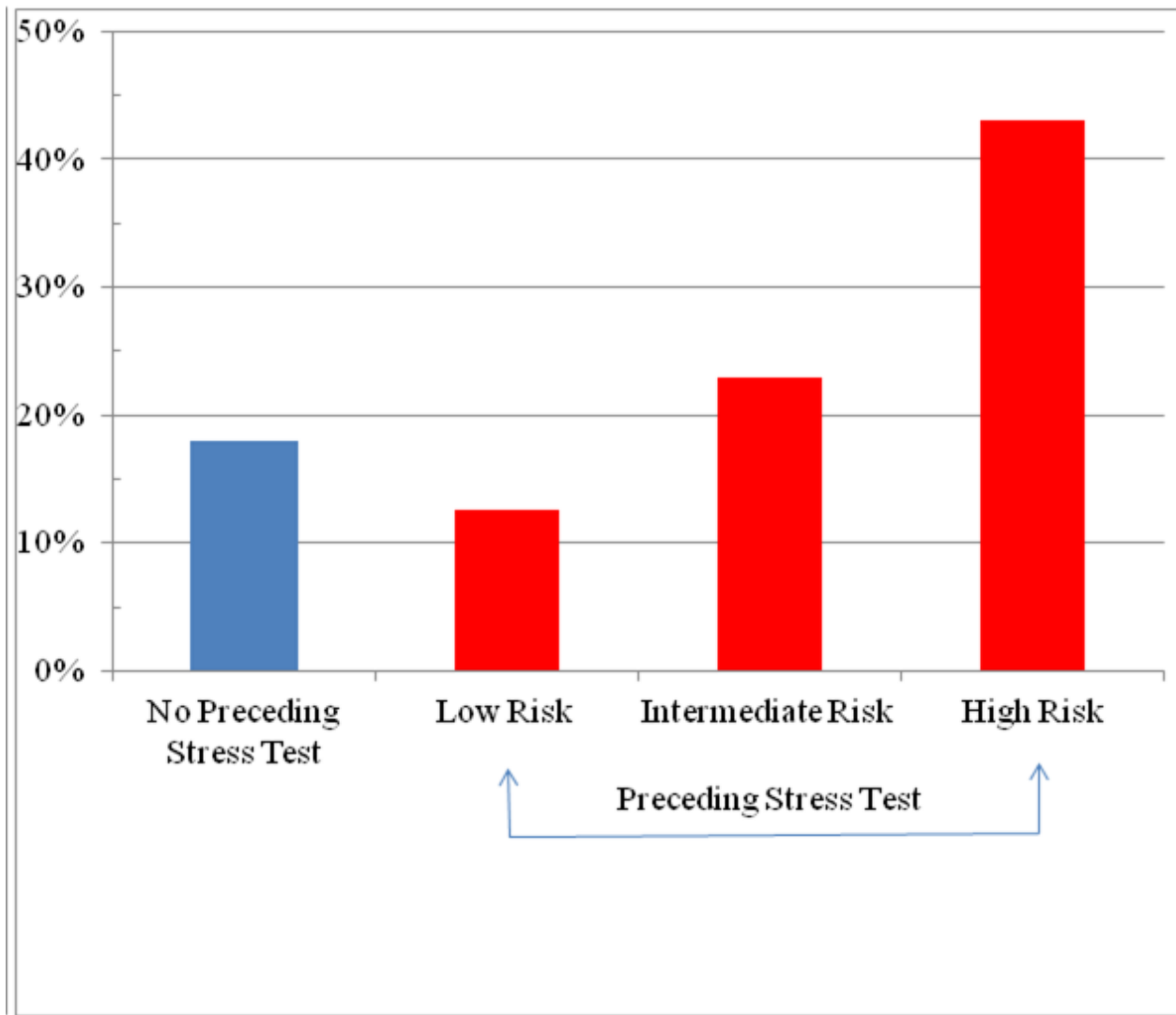


Figure 2: Diagnostic Yield of Coronary Angiography Stratified by Severity of Ischemia on Stress testing

Hospital Variation

There was significant hospital variation in the proportion of elective coronary angiograms without a pre-procedural stress test (median hospital rate, 51.2%; inter-quartile range, 40.2% to 64.2%; range 0% to 95.2%) (Figure 3).

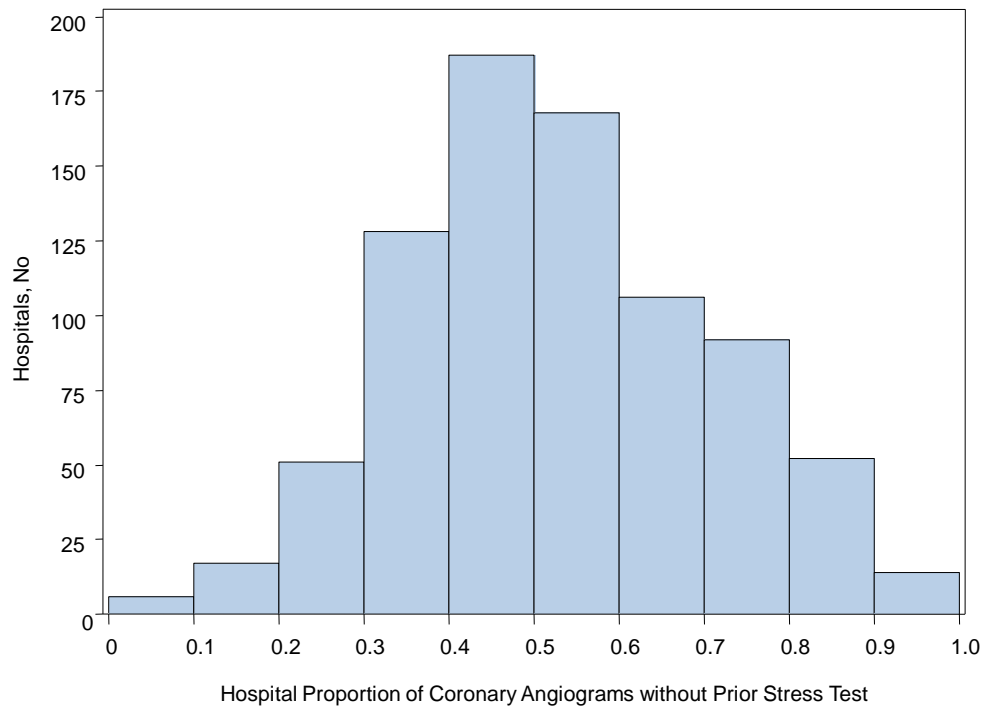


Figure 3: Variation in Hospital Rates of Performing Coronary Angiography without Prior Stress Test

However, within each quartile, there remained no clinically meaningful differences in angina severity or extent of obstructive CAD between patients with and without prior stress testing (Supplementary Appendix eTable 1).

eTable 1: Angina and CAD Severity, Stratified By Hospital Quartile of Proportion of Coronary Angiograms without Prior Stress Test

<i>Characteristic</i>	Quartile 1		Quartile 2		Quartile 3		Quartile 4	
	Stress Test Prior to Coronary Angiogram (N=74,161)	No Stress Test Prior to Coronary Angiogram (N=31,678)	Stress Test Prior to Coronary Angiogram (N=60,606)	No Stress Test Prior to Coronary Angiogram (N=45,701)	Stress Test Prior to Coronary Angiogram (N=46,151)	No Stress Test Prior to Coronary Angiogram (N=56,191)	Stress Test Prior to Coronary Angiogram (N=21,832)	No Stress Test Prior to Coronary Angiogram (N=66,862)
<i>Anginal Classification within 2 Weeks</i>								
No symptoms	20,375 (27.5%)	13,539 (42.8%)	17,097 (28.3%)	18,642 (41.0%)	14,703 (31.9%)	24,916 (44.4%)	5,796 (26.6%)	23,823 (35.8%)
CCS I	15,685 (21.2%)	5,076 (16.1%)	13,188 (21.8%)	8,219 (18.1%)	10,754 (23.3%)	10,709 (19.1%)	5,615 (25.8%)	16,181 (24.3%)
CCS II	28,983 (39.2%)	9,162 (29.0%)	23,583 (39.0%)	13,146 (28.9%)	15,458 (33.5%)	14,311 (25.5%)	7,865 (36.1%)	19,054 (28.7%)
CCS III	6,803 (9.2%)	2,683 (8.5%)	4,842 (8.0%)	3,785 (8.3%)	3,860 (8.4%)	4,425 (7.9%)	1,785 (8.2%)	5,279 (7.9%)
CCS IV	2,170 (2.9%)	1,148 (3.6%)	1,699 (2.8%)	1,680 (3.7%)	1,309 (2.8%)	1,703 (3.0%)	710 (3.3%)	2,164 (3.3%)
<i>CAD Presentation</i>								
No symptoms	14,236 (19.2%)	9,860 (31.1%)	13,099 (21.6%)	14,172 (31.0%)	9,879 (21.4%)	18,324 (32.6%)	4,237 (19.4%)	17,717 (26.5%)
Symptoms unlikely to be Ischemic Stable Angina	24,948 (33.6%)	11,834 (37.4%)	21,561 (35.6%)	17,407 (38.1%)	16,789 (36.4%)	20,452 (36.4%)	7,910 (36.3%)	24,203 (36.3%)
<i>Angiography</i>								
Diseased Vessels, No.								
0	59,897 (80.8%)	25,696 (81.1%)	48,873 (80.6%)	37,591 (82.3%)	37,068 (80.3%)	45,780 (81.5%)	18,012 (82.5%)	55,221 (82.6%)
1	5,627 (7.6%)	2,777 (8.8%)	4,428 (7.3%)	3,859 (8.4%)	3,571 (7.7%)	4,863 (8.7%)	1,564 (7.2%)	5,317 (8.0%)
2	4,061 (5.5%)	1,708 (5.4%)	3,529 (5.8%)	2,317 (5.1%)	2,657 (5.8%)	2,984 (5.3%)	1,069 (4.9%)	3,425 (5.1%)
3	4,576 (6.2%)	1,497 (4.7%)	3,776 (6.2%)	1,934 (4.2%)	2,855 (6.2%)	2,564 (4.6%)	1,187 (5.4%)	2,899 (4.3%)
Proximal LAD Disease	4,703 (6.3%)	1,588 (5.0%)	3,967 (6.5%)	2,173 (4.8%)	3,017 (6.5%)	2,890 (5.1%)	1,279 (5.9%)	3,497 (5.2%)
Left Main Disease	2,586 (3.5%)	977 (3.1%)	2,250 (3.7%)	1,304 (2.9%)	1,625 (3.5%)	1,682 (3.0%)	657 (3.0%)	1,844 (2.8%)

Abbreviations: CAD, coronary artery disease; CCS, Canadian Cardiovascular Society; LAD, left anterior descending

Discussion:

In this large, contemporary, national sample of patients without a history of obstructive CAD undergoing elective coronary angiography, we found that half of patients proceeded directly to invasive management without prior stress testing. When comparing patients with pre-procedural stress testing to those without, we found less pre-procedural angina and no differences in obstructive CAD. Notably, 40% of patients without pre-procedural stress testing were asymptomatic and only 12% had severe angina (CCS class III or IV) to support the decision to proceed directly to invasive testing and revascularization based upon symptom relief. Moreover, finding that the prevalence of obstructive CAD among patients without pre-procedural stress testing was lower than that for patients with a high-risk or intermediate risk stress test result suggests that clinical judgment was not superior to pre-procedural stress testing in identifying patients in whom such testing would not have altered the diagnostic or treatment strategy. Collectively, our findings suggest that current practice patterns of proceeding directly to coronary angiography without prior stress testing may be premature in some patients.

Our study extends the observations of prior studies that described rates of pre-procedural stress testing prior to coronary angiography. For example, Lin et al. found that nearly half of all elective PCIs were performed without pre-procedural stress testing.⁴ As that study was performed in an administrative Medicare claims database, however, the authors were not able to examine whether patients who proceeded directly to invasive treatment had more severe symptoms (e.g., CCS Class III or IV angina) or more severe CAD to justify the decision to forego a stress test. In a prior study of patients within the NCDR CathPCI Registry[®], Patel et al. reported that 84% of patients had some form of noninvasive assessment prior to diagnostic

coronary angiography.⁵ However, this study included electrocardiographic abnormalities, resting echocardiograms, and any form of computed tomography imaging (e.g., coronary calcium screening) as part of their definition of noninvasive testing, even though these modalities are not typically considered capable of performing noninvasive risk stratification to define the potential benefits of revascularization. Moreover, that study was not able to assess the severity of angina or ischemia, as it used a prior version of the CathPCI data collection form that did not contain detailed information on CCS angina class and stress testing results. By leveraging the information on new variables that are now included in Version 4 of the NCDR CathPCI Registry[®], our study was able to assess both pre-procedural angina and the severity of stress testing results and found that the decision to proceed directly to coronary angiography for elective patients without prior stress testing was not associated with more severe angina symptoms or obstructive CAD as compared with patients who underwent pre-procedural stress testing.

Our study also found that the likelihood of obstructive CAD on coronary angiography in patients without prior obstructive CAD and with a high-risk stress test was only 43%. The reasons for the low likelihood rates are unknown but may be due to 1) our intentional restriction of the study population to those without known CAD (i.e., patients with prior obstructive CAD, myocardial infarction, and coronary revascularization were excluded), 2) inconsistent or lack of reporting standards for ischemia risk across sites, and 3) limitations of the prognostic value of detecting ischemia on stress testing. As assessments of ischemia risk are important components of appropriate use criteria for diagnostic coronary angiography and coronary revascularization, future studies are needed to assess the whether the low predictive value for stress testing

observed in our study is due to the lack of rigorous standards among operators and hospitals in reporting ischemia risk or other intrinsic limitations of noninvasive ischemia risk evaluation.

Our study also provides important insights into the patients who were excluded from recent evaluations of the appropriateness of PCI in the U.S. due to lack of pre-procedural stress testing.^{3, 12-13} In these prior reports, there were some concern that the exclusion of these patients may have led to an overestimation of the inappropriate PCI rate in non-acute settings, especially if patients undergoing PCI without pre-procedural stress testing had more severe angina symptoms and CAD than those with pre-procedural stress testing. Our findings do not support this concern and may suggest the contrary—that patients who proceed to invasive management without pre-procedural stress testing do not have more severe angina or higher-risk coronary anatomy and thus may have PCIs which are even less appropriate than those with stress tests who were included in the appropriateness assessments.

Finally, we found that ~90% of patients without pre-procedural stress testing did not have severe angina to justify the decision to proceed without prior stress testing. Although it remains unclear which clinical factors, in the absence of severe angina, prompted physicians to pursue invasive coronary angiography without prior non-invasive stress testing, such practice raises questions about deviations from current ACC/AHA/SCAI guidelines,¹⁴ which recommend risk stratification (non-invasive imaging or other modalities) in elective patients prior to non-acute PCIs—a strategy shown to be cost effective¹⁵⁻¹⁷ and associated with improved outcomes.¹⁸

Our study should only be interpreted in the context of the following potential limitations. First, hospital participation in the NCDR[®] CathPCI registry is voluntary, and our results may not be generalizable to non-NCDR hospitals. However, our findings were derived from data at over 1000 U.S. hospitals and provide the first large-scale, detailed study on characteristics of patients

undergoing elective coronary angiography without pre-procedural stress testing. Second, our study excluded patients with acute myocardial infarctions and unstable angina, as the decision to proceed without pre-procedural stress testing may be justified in these setting where few clinical scenarios are considered inappropriate. We also excluded patients with history of cardiomyopathy, recent heart failure exacerbation or prior history of CAD, PCI or CABG, since the clinical indications for angiography and revascularization in the former 2 scenarios may not be based upon symptoms or CAD severity. Third, our study used CCS class to assess angina severity, which is not patient-reported and may result in some mis-classification of patients' true symptom status. However, the CCS class is commonly employed in routine practice and assessments of appropriate use of PCI; moreover, any misclassification of CCS class would be expected to be non-differential. Fourth, our study did not exclude patients who underwent coronary angiography according to pre-specified protocols (e.g. patients with heart transplant) since the NCDR does not collect the data necessary to identify such patients. However, these scenarios should represent a small minority of the examined studies. Finally, the reasons for foregoing risk stratification with non-invasive stress testing were not collected by the NCDR CathPCI registry. Therefore, we were unable to provide insights as to which patient and physician factors influenced the decision to proceed directly to angiography in the absence of severe angina symptoms or stress testing.

Conclusion:

In this large national study, we found that nearly half of the patients undergoing elective coronary angiography did not have pre-procedural risk stratification with non-invasive stress testing, despite the fact that most lacked severe angina. Compared with patients undergoing elective coronary angiography with pre-procedural stress testing, those without pre-procedural stress testing did not have more severe symptoms or higher-risk CAD. We also found that the rates of any obstructive CAD were similar between those with and without pre-procedural stress testing and that the lower-than-expected value of ischemic stress testing to identify obstructive CAD may warrant additional quality improvement efforts to improve the consistency and value of these tests. Nevertheless, our findings suggest that current practice patterns of proceeding directly to invasive management without stress testing may be premature in some patients.

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