Prognostic implications of percutaneous coronary interventions performed according to the appropriate use criteria for coronary revascularization

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ABSTRACT

Objectives: To assess the prognostic implication of the ACCF/AHA/SCAI appropriate use criteria (AUC) for coronary revascularization in a cohort of non-acute coronary syndrome patients.
Background: The AUC for coronary revascularization were developed in order to deliver high-quality care; however, the prognostic impact of these criteria remains undefined.
Methods: Consecutive patients (n = 3817) undergoing elective percutaneous coronary intervention (PCI) at MedStar Washington Hospital Center since the 2009 AUC publication were retrospectively grouped according to AUC as an "Appropriate," "Inappropriate," or "Undetermined" indication for PCI. Outcomes to 1 year were compared.
Results: PCI was categorized as "Appropriate" in 47%, "Inappropriate" in 1.8% and as "Uncertain" in 51% of patients. "Appropriate" PCI patients had a higher prevalence of hypertension and diabetes but a lower prevalence of smoking. "Inappropriate" PCI involved the treatment of more complicated lesions, with lower rates of drug-eluting stent utilization. While there were no differences in procedural complications among the 3 groups, in-hospital major complications and outcomes were worse for "Inappropriate" PCI patients. The 30-day (3.2% vs. 7% vs. 4.1%, p = 0.32) and 1-year (13.1% vs. 11.8% vs. 15.3%, p = 0.43) major adverse cardiac event rates of the "Appropriate," "Inappropriate," and "Uncertain" PCI patients, respectively, were comparable. In multivariable analysis, the procedural appropriateness was not associated with either in-hospital or 1-year outcome.
Conclusions: At large, physicians practicing in tertiary centers adhere to the AUC when subjecting patients with non-acute coronary syndrome to revascularization. The present analysis did not demonstrate association between long-term outcome and procedure appropriateness according to the AUC.

1. Introduction

Cardiac revascularization procedures, including coronary artery bypass grafting and percutaneous coronary intervention (PCI), have become a target for overuse reduction. In an attempt to promote the appropriate use of coronary therapeutics, the American Heart Association, American College of Cardiology Foundation, and the Society for Cardiovascular Angiography and Interventions developed methodology and executed the publishing of PCI appropriate use criteria (AUC). However, substantial variability in the application of these AUC has been observed [1]. The clinical relevance and the validity of the 2009 AUC for coronary revascularization in day-to-day practice are still under debate [2–4]. Whereas practice guidelines published by professional societies are directly based on evidence, and the strength of those recommendations is based upon available scientific data to show meaningful effect on outcome, the AUC for coronary revascularization were determined by polling of a 17-member technical panel [5]. Votes on specific clinical scenarios are not necessarily based on scientific evidence, and as a result, it is unclear whether the publication of AUC for coronary revascularization and the implantation of such criteria contribute to improvement in patient care in terms of quality of clinical care. Thus, the present study was aimed at assessing the relative prognostic contribution of the different levels of appropriateness criteria for PCI in a large sample of patients in a real-world setting.

2. Methods

Data were obtained from a patient registry that included all patients undergoing PCI at MedStar Washington Hospital Center. Consecutive patients who underwent PCI after publication of the AUC for coronary revascularization, from July 2009 to July 2011, were included. All patients provided written informed consent. The study complied with the Declaration of Helsinki for investigation in humans and was approved by the institutional ethics committee.

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To identify and categorize PCI procedures as "Appropriate," "Inappropriate," or "Uncertain," a computerized algorithm was constructed based on the 2009 AUC for coronary revascularization [5] and the 2012 focused update [6]. All PCI procedures performed from July 2009 to July 2011 were assessed using this algorithm and were classified as "Appropriate," "Inappropriate," or "Uncertain." For the purpose of this analysis, we used the same classifications. In order to assess a more homogenous population, patients with acute coronary syndromes were excluded from the present analysis (Indications 1–11 [5]). Patients with missing information (i.e., results of non invasive testing) were excluded from the present analysis.

Coronary angioplasty was performed by standard percutaneous techniques and standard techniques for stent implantation. Patients received either a bare metal- or drug-eluting stent at the discretion of the practicing physician. The use of adjunctive devices and the pharmacotherapy were at the discretion of the operating interventional cardiologist. All patients received aspirin 325 mg before the procedure and were recommended to continue this regimen indefinitely. In addition, clopidogrel 75 mg/day after a 300- or 600-mg loading dose was started before the procedure and subsequently continued for 12 months.

Cardiac history and baseline demographics were collected along with angiographic data; however, data analysis was performed retrospectively. Patients were followed via telephone or survey for all major adverse cardiovascular events (MACE) during index hospitalization and at 30 days, and 1 year after PCI.

The primary end point was MACE at 1 year defined as the composite of death, myocardial infarction (MI), and target lesion revascularization (TLR). Q-wave MI was defined as evidence of new Q waves on the electrocardiogram. MI was defined as a total creatinine kinase increase $\geq 2\times$ the upper limit of normal and/or creatinine kinase (MB fraction) ≥ 20 ng/ml, together with symptoms and/or ischemic electrocardiographic changes. Major in-hospital complication was defined as either in-hospital mortality, Q-wave MI, or the need for emergency coronary artery bypass grafting. Hypercholesterolemia was defined as fasting cholesterol >250 mg/dl or the use of lipid-lowering therapy. Systemic hypertension was defined as blood pressure >140/90 mmHg or the use of antihypertensive therapy. Renal impairment was defined as serum creatinine >1.2 mg/dl. Congestive heart failure was defined as evidence of fluid retention from cardiac causes before admission. Angiographic success was defined as post-procedural stenosis of <30% and Thrombolysis In Myocardial Infarction flow grade 3. TLR was defined as ischemia-driven percutaneous or surgical repeat intervention in the stent or within 5 mm proximal or distal to the stent. Stent thrombosis was defined in accordance with the Academic Research Consortium definitions as definite or probable stent thrombosis.

Statistical analysis was performed using SAS version 8.2 (SAS Institute, Cary, NC). Continuous variables and categorical variables are expressed as mean $\pm$ standard deviation and percentages, respectively. Analyses of differences between patients who had "Appropriate," "Inappropriate" and "Uncertain" PCI were performed using analysis of variance for continuous variables and the chi-square test or Fisher's exact test for categorical variables. After univariable analysis for baseline clinical and procedural characteristics, the following characteristics with $p < 0.1$ were incorporated into the multivariable analysis to assess independent association with all-cause mortality using the Cox proportional hazard regression model. Variables included "Appropriate" or "Uncertain" PCI versus "Inappropriate" PCI, prior coronary artery bypass surgery, systemic hypertension, diabetes mellitus, family history of coronary artery disease, peripheral vascular disease, hypercholesterolemia, history of coronary artery disease, current smoker, left anterior descending artery lesion, American College of Cardiology/American Heart Association type C lesions and the use of drug-eluting stents. The results are presented as adjusted hazard ratios (HR) with 95% confidence intervals (CI). Survival and MACE rates up to 1 year were computed using the Kaplan–Meier method, and differences in parameters were assessed using the log-rank test. P values <0.05 were considered statistically significant.

3. Results

A total of 3817 patients underwent PCI from July 2009 to July 2011. Among the total cohort, 2476 were men (65%) and the average age was 65 ± 12 years. Overall, 665 patients were excluded from the present analysis due to missing data for classification of appropriateness. PCI was categorized as "Appropriate" in 1494 patients (47%), "Inappropriate" in 54 (1.8%), and "Uncertain" in 1604 (51%).

As detailed in Table 1, there was no clinically significant difference in patient age. "Appropriate" patients were less frequently males (64%) as compared to "Inappropriate" patients (74%). Patients who had "Appropriate" PCI had a higher prevalence of systemic hypertension (92% vs. 82% vs. 87%, $p < 0.001$) and diabetes mellitus (42% vs. 20% vs. 41%, $p = 0.007$), as compared to "Inappropriate" and "Uncertain" PCI, respectively. Patients who had "Inappropriate" PCI were more frequently smokers (Appropriate 23% vs. Inappropriate 39% vs. Uncertain 20%; $p = 0.002$). "Uncertain" PCI patients had a higher prevalence of history of coronary bypass graft (Appropriate 10% vs. Inappropriate 0% vs. Uncertain 39%, respectively; $p < 0.001$); however, there was no significant difference in the rates of prior MI, PCI, baseline renal insufficiency or peripheral vascular disease. In terms of admission medications, the rates were generally comparable; however, the use of aspirin on admission was significantly lower among the "Inappropriate" PCI patients, while the use of beta blockers and calcium channel blockers on admission was most frequent among "Appropriate" PCI patients (Table 1).

Table 1
Baseline characteristics of PCI patients according to procedural appropriateness.

Variable	Appropriate (n = 1494)	Inappropriate (n = 54)	Uncertain (n = 1604)	p Value
Age (years $\pm$ SD)	66 $\pm$ 12	66 $\pm$ 13	67 $\pm$ 12	0.003
Men	960 (64%)	40 (74%)	1088 (68%)	0.05
Body mass index (kg/m^2 $\pm$ SD)	30 $\pm$ 6	29 $\pm$ 5	30 $\pm$ 7	0.26
African American	552 (37%)	22 (41%)	496 (31%)	0.001
Systemic hypertension[a]	1372 (92%)	44 (82%)	1394 (87%)	<0.001
Diabetes mellitus	624 (42%)	11 (20%)	651 (41%)	0.007
Hypercholesterolemia[b]	1286 (86%)	44 (82%)	1378 (86%)	0.63
Current smoker	343 (23%)	21 (39%)	326 (20%)	0.002
Family history of coronary artery disease	640 (43%)	18 (33%)	682 (43%)	0.38
Previous myocardial infarction	308 (21%)	13 (24%)	377 (24%)	0.12
Previous percutaneous coronary intervention	397 (27%)	11 (20%)	430 (27%)	0.54
Previous coronary bypass surgery	146 (10%)	0 (0%)	628 (39%)	<0.001
Congestive heart failure	216 (15%)	8 (15%)	252 (16%)	0.61
Chronic renal insufficiency	318 (21%)	9 (17%)	341 (21%)	0.75
Peripheral vascular disease	231 (16%)	7 (13%)	293 (18%)	0.08
Admission medication				
Aspirin	1424 (96%)	48 (89%)	1530 (97%)	0.008
Angiotensin converting enzyme inhibitors	693 (47%)	33 (61%)	733 (46%)	0.10
Angiotensin receptor blockers	279 (19%)	6 (11%)	255 (16%)	0.07
Beta blockers	1271 (86%)	41 (76%)	1167 (74%)	<0.001
Calcium channel blocker	395 (27%)	6 (11%)	261 (16%)	<0.001
Statins	1221 (82%)	47 (87%)	1301 (82%)	0.64

SD, standard deviation.
[a] History of hypertension diagnosed and/or treated with medication or currently being treated with diet and/or medication by a physician.
[b] Includes patients with a previously documented diagnosis of hypercholesterolemia. The patient may be treated with diet or medication. A new diagnosis can be made during this hospitalization with an elevated total cholesterol >160 mg/dl. Does not include elevated triglycerides.