Omission of Heart Transplant Recipients From the Appropriate Use Criteria for Revascularization and the Ramifications on Heart Transplant Centers

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IMPORTANCE Guidelines endorse routine coronary angiography and percutaneous coronary intervention (PCI) to screen for and treat cardiac allograft vasculopathy in heart transplant recipients. However, the current Appropriate Use Criteria for Revascularization (AUC-R) do not recognize prior heart transplant as a unique PCI indication. Whether this affects rates of rarely appropriate (RA) PCIs is unknown.

OBJECTIVE To assess the rate of RA PCI procedures in heart transplant recipients and how it pertains to hospital PCI appropriateness metrics and pay-for-performance scorecards.

DESIGN, SETTING, AND PARTICIPANTS This observational study used National Cardiovascular Data Registry CathPCI Registry data on all patients undergoing elective PCIs from 96 Medicare-approved heart transplant centers from quarter 3 of 2009 to quarter 2 of 2017. The data were analyzed in July 2018.

EXPOSURES Prior heart transplant.

MAIN OUTCOMES AND MEASURES Rates of RA elective PCIs in heart transplant recipients compared with nonrecipients and hospital rates of RA PCI before vs after exclusion of heart transplant recipients using paired t tests. In a subset of heart transplant centers participating in the Anthem Blue Cross and Blue Shield’s Quality-In-Sights Hospital Incentive Program (Q-HIP), we compared the change in Q-HIP scorecards before vs after excluding heart transplant recipients.

RESULTS Of 168,802 participants, 123,124 (72.9%) were men, 137,457 were white, and the mean (SD) age was 66.3 (11.4) years. Of 168,802 elective PCIs performed in heart transplant centers, 1854 (1.1%) were for heart transplant recipients. Heart transplant recipients were less likely to have ischemic symptoms (14.6% vs 61.4%, \( P < .001 \)), had lower rates of antecedent stress testing (15.0% vs 58.4%, \( P < .001 \)), and had higher RA PCI rates (66.0% vs 16.9%, \( P < .001 \)) compared with nonrecipients. In heart transplant centers, the absolute difference in RA rates (before vs after excluding transplant recipients) was directly associated with the proportion of PCIs performed in heart transplant recipients (\( r = 0.91; P < .001 \)). In the subset of heart transplant centers participating in Q-HIP during the 2016 and 2017 calendar years, 8 of 20 (40%) and 8 of 16 centers (50%), respectively, could have benefited from a change in their Q-HIP scorecards if their RA PCI rates excluded transplant recipients.

CONCLUSIONS AND RELEVANCE Two-thirds of PCIs in heart transplant recipients were deemed RA by the AUC-R. The failure of the AUC-R to consider prior heart transplant as a unique PCI indication may lead to inflated RA PCI rates with the potential for affecting quality reporting and pay-for-performance metrics in heart transplant centers.
he International Society of Heart and Lung Transplantation (ISHLT) clinical practice guidelines confer a class I recommendation for surveillance coronary angiography every 1 to 2 years in heart transplant recipients. Nevertheless, there is a class IIa recommendation for percutaneous coronary intervention (PCI) for discrete lesions in patients with cardiac allograft vasculopathy (CAV) regardless of symptoms or stress test results, as symptoms are often absent and stress testing has poor predictive value for patients with denervated, transplanted hearts. Accordingly, heart transplant programs perform many elective diagnostic and PCI procedures in heart transplant recipients.

In 2009, the American College of Cardiology (ACC), American Heart Association (AHA), and the Society for Cardiovascular Angiography and Interventions (SCAI) developed the Appropriateness Use Criteria for Revascularization (AUC-R) to provide evidence-based recommendations for PCI based on the potential benefit of PCI in various clinical scenarios. Importantly, the AUC-R were created to facilitate appropriate PCI use and support clinicians and patients in decision-making. Payers have also adopted the AUC-R to gauge the quality of health services provided and, in some instances, to link standardized quality metrics with financial incentives (eg, pay-for-performance programs). More recently, the AUC-R have expanded its clinical indications to include separate appropriateness ratings or guidance for PCI before percutaneous valve procedures (eg, transcatheter aortic valve replacement), patients before undergoing kidney transplant, and staged PCI procedures. However, the AUC-R do not yet acknowledge heart transplant recipients with CAV as a unique PCI indication. Consequently, PCI in prior transplant patients are often rated as rarely appropriate (RA) by the AUC-R despite being supported by guidelines. Given that heart transplants are concentrated in select centers, it is possible that these centers are disproportionately disadvantaged in external assessments of the appropriateness of PCI. Accordingly, we compared the rate of RA PCI procedures in heart transplant recipients compared with nonrecipients and the potential ramifications of excluding heart transplant recipients from the RA metric with pay-for-performance scorecards in heart transplant centers.

Figure 1. Study Flowchart of the Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>629378</th>
<th>Total PCI procedures performed in 96 Medicare-approved heart transplant centers in NCDR CathPCI Registry (quarter 3 of 2009 to quarter 2 of 2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>460570</td>
<td>Excluded</td>
</tr>
<tr>
<td>460442</td>
<td>ACS (UA, NSTEMI, STEMI)</td>
</tr>
<tr>
<td>128</td>
<td>Evaluation = donor/recipient</td>
</tr>
<tr>
<td>168802</td>
<td>Analytic cohort of elective PCI procedures performed in all patients of heart transplant centers</td>
</tr>
</tbody>
</table>

ACS indicates acute coronary syndrome; NCDR, National Cardiovascular Data Registry; NSTEMI: non–ST-elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; UA: unstable angina.

### Key Points

**Question** What proportion of guideline-indicated percutaneous coronary intervention (PCI) procedures in heart transplant recipients are deemed rarely appropriate (RA) per the Appropriate Use Criteria for Revascularization?

**Findings** In this study, National Cardiovascular Data Registry CathPCI Registry data from transplant centers showed heart transplant recipients had a higher RA PCI rate from quarter 3 of 2009 to quarter 2 of 2017 vs nonrecipients (66.0% vs 16.9%). Nearly half of transplant centers participating in 1 well-known pay-for-performance program could have benefited from a change in their quality scorecards if their RA PCI rates excluded transplant recipients.

**Meaning** Heart transplant centers may be penalized in pay-for-performance programs because the Appropriate Use Criteria for Revascularization omits prior heart transplant as a unique PCI indication.

### Methods

**Data Source** The National Cardiovascular Data Registry CathPCI Registry is a national quality improvement registry that captures data regarding patient demographics, comorbidities, angiographic details, and outcomes following diagnostic catheterizations and/or PCI procedures. With more than 1400 participating institutions across the United States, this registry represents the largest national database containing comprehensive clinical information on coronary angiography and PCI procedures. The design of the CathPCI Registry, data collection process, and methods for quality assurance have been previously described. The registry has been approved by the institutional review board of Emory University and a waiver of consent has been granted because only deidentified data were in the data analysis for this study.

**Study Cohort** Our analyses included all patients undergoing elective PCI from 96 Medicare-approved heart transplant centers from quarter 3 of 2009 to quarter 2 of 2017 (Figure 1). We did not analyze data from nontransplant centers because only 0.02% of all elective PCIs in nontransplant centers were for the indication of posttransplant follow-up in the CathPCI Registry. The analytic period of quarter 3 of 2009 to quarter 2 of 2017 was chosen as it represents when the AUC-R metrics were incorporated into the CathPCI Registry performance summaries distributed to participating centers on a quarterly basis. Centers approved by Medicare as adult heart transplant programs were identified from publicly available records from the US Centers for Medicare and Medicaid Services and cross-referenced to the CathPCI Registry by hospital National Provider Identifier number. Patients receiving PCI for acute coronary syndrome (unstable angina, non–ST-elevation myocardial infarction, ST-elevation myocardial infarction) were excluded from the analysis. In addition, patients undergoing PCI...
as either potential heart transplant donors or at the time of the index cardiac transplant were excluded.

**Exposure Variables**
From our cohort, PCIs were categorized as being performed in heart transplant recipients or in non–heart transplant recipients. Heart transplant recipients were identified from the CathPCI Registry using data element 6030 “Cardiac Transplant Evaluation” = “Yes” and data element 6035 “Type” = “Post cardiac transplant follow-up.” Covariates of interest included patient demographics (age, sex, and race), insurance payer mix, comorbidities (eg, tobacco use, hypertension, diabetes, dyslipidemia, kidney insufficiency, prior myocardial infarction, prior coronary revascularization, stroke, peripheral arterial disease, and/or chronic obstructive pulmonary disease), presenting symptoms, stress testing within 6 months of PCI, and findings on coronary angiography.

**Outcomes**
The primary outcome of interest was the quarterly rate of PCIs deemed RA using the nomenclature adopted with the 2012 focused AUC-R update. The methods in developing the AUC-R have also been previously reported. Briefly, based on available literature, current practice guidelines, and clinical expertise, a set of patient scenarios were created and assigned an appropriateness rating by an expert panel of subspecialists. Each clinical situation was scored on a scale of 1 to 9 and the median rating among the experts was used. Low scores (1-3) represent RA indications for revascularization, as the intervention was deemed unlikely to improve patient health or survival, midrange scores (4-6) reflected indications that were considered “may be appropriate” for revascularization given limited existing research data or patient information, and high scores (7-9) implied revascularization was appropriate and likely to improve patient outcomes.

The association of RA PCI rates with AUC metrics was estimated using the AUC-R performance thresholds published by Anthem Blue Cross and Blue Shield’s Quality-In-Sights Hospital Incentive Program (Q-HIP). Q-HIP is an incentive-based pay-for-performance program that rewards hospitals annually for meeting or exceeding clinical benchmarks on various health outcomes, safety measures, and AUC-R performance. Participating hospitals may earn a maximum of 100 Q-HIP points based on performance levels in several patient safety, quality, outcomes, and patient satisfaction metrics that span multiple registries and medical conditions, and a hospital’s Q-HIP score in any given participation year determines the dollar incentive that Anthem Blue Cross Blue Shield pays that hospital in that year. The 35 to 45 metrics that comprise the 100 Q-HIP points are updated annually; historically, anywhere from 3 to 6 metrics (comprising 9-14 Q-HIP points) directly pertain to PCI procedures and are reported by the CathPCI Registry. One of the PCI metrics in Q-HIP reported by the CathPCI Registry is the proportion of RA PCIs performed in patients without acute coronary syndromes. Specifically, Q-HIP confers 2 scorecard points to hospitals that achieve an RA elective PCI rate of less than or equal to 12%. Hospitals with a rate of greater than 12% RA PCI procedures would receive no Q-HIP points for that metric. Although this single RA PCI metric confers only 2 points (of 100 total Q-HIP points), these 2 points can be enough to tip hospitals above or below an incentive payment tier threshold; therefore, performance in even a single Q-HIP metric is vitally important to participating hospitals.

**Statistical Analysis**
Baseline characteristics were compared between heart transplant recipients and nonrecipients undergoing PCI using Pearson χ² tests for categorical variables and t tests for continuous variables. Hospitals’ rates of RA PCIs were evaluated before and after excluding heart transplant patients at each quarter from July 1, 2009, to June 30, 2017. The absolute difference in RA PCI rates after excluding heart transplant recipients was also assessed as a function of the center’s PCI volume in heart transplant recipients. We also repeated the calculation of the absolute difference in RA PCI rates as a function of centers’ PCI volumes in heart transplant recipients after reclassifying all PCIs in heart transplant recipients as appropriate (instead of excluding posttransplant patients). Finally, in an exploratory analysis, Anthem simulated revising the Q-HIP pay-for-performance scorecards for the 2016 and 2017 measurement periods for participating transplant hospitals to estimate the potential financial ramifications of excluding heart transplant patients from the AUC-R metrics.

A 2-tailed P value of < .05 was considered statistically significant for each analysis. All statistical analyses were performed using SAS, version 9.4 (SAS Institute).

**Results**

**Baseline Characteristics**
A total of 168,802 elective PCIs were performed in 96 heart transplant centers from July 1, 2009, to June 30, 2017 (Table 1). Of these, 1854 (1.1%) were performed in heart transplant recipients. Heart transplant recipients, compared with patients who did not undergo transplant, were younger (mean [SD] age 56.4 [15.4] years vs 66.4 [11.3] years; P < .001) and more often men (76.3% vs 72.9%; P < .001). Heart transplant patients also had a higher proportion of diabetes (44.6% vs 42.2%; P = .04) but lower rates of hypertension (84% vs 87.6%; P < .001), dyslipidemia (83.3% vs 86.7%; P < .001), and tobacco use (3.7% vs 16%; P < .001). More than half of transplant recipients (54.8%) had prior coronary revascularization during their lifetime. Furthermore, 85.4% of heart transplant recipients were either asymptomatic or did not have symptoms consistent with ischemia at the time of PCI compared with only 38.6% of patients who were not heart transplant recipients (P < .001). Rates of stress testing were also lower in transplant recipients compared with patients who were not heart transplant recipients (15% vs 58.4%; P < .001).

** Appropriateness of PCI**
After excluding not classifiable PCIs, the rate of RA elective PCI was 66.0% vs 16.9% (P < .001) in heart transplant recipients compared with nontransplant recipients (Table 2). The me-
The quarterly difference in the absolute rate of RA PCI procedures performed in transplant recipients vs nonrecipients was 48.9% (interquartile range [IQR], 45%-53%; \( P < .001 \); Figure 2). Only 20.6% of PCIs were defined as appropriate in the transplant population vs 52.8% in the nontransplant population (\( P < .001 \)).
The proportion of elective PCIs performed in transplant recipients varied by transplant center from 0% to 11% (median 1.0% [IQR, 0.3%-1.9%]). After excluding PCIs performed in transplant recipients, the absolute reduction in RA PCI rates ranged from 0.04% to 3.15% when stratified by transplant PCI volume, with higher-volume centers having a larger reduction (Figure 3). A similar reduction in RA PCI rates across transplant centers was observed if all transplant PCIs were considered appropriate (eFigure 1 in the Supplement). The change in RA PCI rates before and after excluding heart transplant recipients strongly correlated with the proportion of PCIs performed in transplant recipients ($r = 0.91$; $P < .001$), as shown in eFigure 2 in the Supplement. The median aggregate RA PCI rate decreased by 0.56% (IQR, 0.47%-0.67%) each quarter after excluding PCI procedures in transplant patients (eFigure 3 in the Supplement). In addition, the reduction in the RA PCI rate (after excluding PCI procedures in heart transplant recipients) became even more pronounced when analyzing only the top 10 centers in cardiac transplant PCI volumes (median absolute decrease in RA rate, 3.4%; IQR, 2.9%-4.3%) (eFigure 4 in the Supplement).

**Ramifications on Pay-for-Performance Incentives**

In an exploratory analysis, a subset of heart transplant centers participating in Q-HIP were examined during the 2016 and 2017 calendar year measurement periods. In 2016, 8 of 20 participating centers (40%) could have experienced a mean improvement in the Q-HIP score of 1.48 points (range, 1.07-1.95) if they were rescored after excluding transplant PCI procedures from the RA metric. In 2017, 8 of 16 Q-HIP participating centers (50%) could have improved their Q-HIP score by a mean of 1.44 points (range, 1.1-1.73). Of these transplant centers, 2 (10%) in 2016 and 2 (12.5%) in 2017 could have been reclassified to a higher incentive payment tier from an increase in Q-HIP scores based on the AUC metric.

**Discussion**

The AUC-R are a powerful tool for ascertaining and comparing the appropriateness of PCI across centers. However, the AUC-R have failed to include guideline-recommended PCI in non–heart transplant patients. Appropriateness ratings are as defined according to the 2012 Appropriate Use Criteria for Revascularization.

*R* values are calculated using the Pearson $\chi^2$ test and are comparing non–heart transplant patients vs transplant patients. Rates were calculated after excluding the not classifiable percutaneous coronary interventions from the population.

### Table 2. Appropriateness Ratings of Percutaneous Coronary Intervention Procedures Performed

<table>
<thead>
<tr>
<th>Classification</th>
<th>Total (N = 168,802)</th>
<th>Heart transplant recipients (n = 1854)</th>
<th>Nontransplant patients (n = 166,948)</th>
<th>$P$ value$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appropriateness rating</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rarely appropriate$^b$</td>
<td>21,013 (17.5)</td>
<td>891 (66.0)</td>
<td>20,122 (16.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>May be appropriate$^b$</td>
<td>36,138 (30.1)</td>
<td>180 (13.3)</td>
<td>35,958 (30.3)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Appropriate$^b$</td>
<td>62,968 (52.4)</td>
<td>278 (20.6)</td>
<td>62,690 (52.8)</td>
<td></td>
</tr>
<tr>
<td>Not classifiable</td>
<td>48,683 (38.8)</td>
<td>505 (37.2)</td>
<td>48,178 (29.8)</td>
<td>.13</td>
</tr>
<tr>
<td>Reason not classifiable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No stress test performed</td>
<td>31,096 (18.4)</td>
<td>463 (25.0)</td>
<td>30,633 (18.3)</td>
<td></td>
</tr>
<tr>
<td>No stress test result</td>
<td>14,731 (8.7)</td>
<td>31 (1.7)</td>
<td>14,700 (8.8)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Not classifiable for other reason</td>
<td>2856 (1.7)</td>
<td>11 (0.6)</td>
<td>2845 (1.7)</td>
<td></td>
</tr>
</tbody>
</table>

$^a$ *P* values are calculated using the Pearson $\chi^2$ test and are comparing non–heart transplant patients vs transplant patients. Appropriateness ratings are as defined according to the 2012 Appropriate Use Criteria for Revascularization. Rates were calculated after excluding the not classifiable percutaneous coronary interventions from the population.

* Rates were calculated after excluding the not classifiable percutaneous coronary interventions from the population.
Cardiac allograft vasculopathy remains a major cause of graft failure and is among the top 3 causes of mortality after the first year after transplant.1 The angiographic incidence of CAV also accelerates after the first year and increases to 40% to 70% by 5 years after transplant. The angiographic incidence of CAV also accelerates after the first year and increases to 40% to 70% by 5 years after transplant. Given the poor outcomes associated with CAV, early and frequent screening for CAV by coronary angiography has been endorsed by ISHLT guidelines.1,9-12 These recommended treatments for heart transplant recipients are not reflected in current AUC-R, which favor selective revascularization only in patients with refractory angina and/or high-risk findings on noninvasive testing.3

To our knowledge, this analysis highlights for the first time that 66% of PCI procedures are deemed RA when traditional AUC-R metrics are applied to the transplant population, mainly driven by an expected lack of ischemic symptoms (85.4%) and low use of stress testing (15%). Although the total proportion of PCI procedures performed in transplant patients was approximately 1%, excluding transplant evaluations reduced the absolute rate of RA PCIs by more than 3% in the highest-volume transplant-PCI centers. Our data suggest that RA PCI rates may be inflated in heart transplant programs because of the potential mislabeling of transplant PCI procedures as RA when many interventions are standard-of-care and congruent with transplant guidelines.1 These findings carry substantial implications for hospitals, patients, and payers, all of whom rely on accurate performance data in the current era of quality reporting.

The need to improve the accuracy of AUC metrics also extends beyond public reporting and may have direct financial consequences for health care systems. With continued rises in health care costs, there has been an increased demand for hospitals to deliver cost-effective interventions while maintaining a high level of quality. To adapt to this growing emphasis for a value-based model, several federal and private quality improvement initiatives have been implemented to improve the quality of care delivered and reduce the excessive use of costly services. More recently, with the advent of the US Affordable Care Act, pay-for-performance programs have been created to link performance on standardized quality metrics with hospital/physician payments.13-15 Q-HIP is one pay-for-performance program through Anthem Blue Cross and Blue Shield that directly incorporates data reported from the CathPCI Registry to incentivize high-value cardiovascular care. Our study examined how 1 AUC metric affected the Q-HIP score (eg, RA PCI rate). In a sample of Q-HIP–participating transplant programs, we estimated that nearly half of centers in 2016 and 2017 could have improved their Q-HIP scorecards based on a reduction in the RA PCI rate if transplant evaluations were excluded.

Overall, these results underscore the importance of accurately reporting quality metrics, as high-volume heart transplant programs are disproportionately penalized by inflated RA PCI rates even though they may be delivering guideline-consistent care. Notably, the AUC-R was never originally intended to be used by insurers to determine payment for services, but rather to serve as a framework to gauge performance and recognize potential mechanisms to...
improve the delivery of high-quality, efficient care. However, increasing visibility and use of the AUC-R has tied quality metrics to direct and indirect financial incentives. The AUC-R has continued to expand the list of clinical scenarios and unique patient cohorts in which the appropriateness of revascularization is being considered. Our study helps to fill in a critical gap by providing real-world quality and pay-for-performance data in the cardiac transplant population that the AUC task force can hopefully consider when revising the AUC-R in future iterations.

Limitations
Our findings should be interpreted in the context of several possible limitations. First, we were unable to differentiate between PCI procedures performed in patients who underwent transplant for CAV vs traditional atherosclerotic plaque based on the available coding schema in the CathPCI Registry. Although there are distinct pathophysiologic differences between the 2 types of stenosis, many transplanted hearts will develop CAV over time and both lesion types may be treated by PCI. Furthermore, nearly 30% of PCI procedures performed were not classifiable by AUC-R, which may have affected the estimated rate of RA interventions performed; however, there was no statistically significant difference between the proportion of not classifiable PCIs by heart transplant status. Finally, Anthem is only an available payer in 14 states and the number of hospitals, including heart transplant centers, participating in Q-HIP varies yearly. As such, our analysis is not intended to provide the exact cost of financial incentives lost in the United States, but rather an exploratory estimate of the how the accuracy of reported quality metrics potentially affects hospital financial incentives.

Conclusions
Most PCI cases in heart transplant recipients are deemed RA by the AUC-R. The failure of the AUC-R to recognize heart transplant recipients as a unique clinical population may lead to inflated RA PCI rates with potential negative implications on quality metrics in heart transplant centers.

References
Research  Original Investigation

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