



# Clinical characteristics and in hospital outcomes of heart transplant recipients with allograft vasculopathy undergoing percutaneous coronary intervention: Insights from the National Cardiovascular Data Registry

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**Background** Cardiac allograft vasculopathy is a major cause of morbidity and mortality following heart transplantation. Large multicenter studies evaluating the clinical characteristics and in-hospital outcomes of heart transplant recipients undergoing percutaneous coronary intervention (PCI) are lacking.

**Objective** To evaluate the clinical characteristics, treatment patterns and in-hospital outcomes of heart transplant recipients undergoing PCI compared to general population.

**Methods** We analyzed 1,897,328 patients from the National Cardiovascular Data Registry CathPCI registry who underwent PCI of at least 1 native vessel between July 2009 and December 2013 from 1,477 centers, of which 542 patients (0.03%) were heart transplant recipients. Clinical characteristics were evaluated and, after 1:4 propensity matching, in-hospital outcomes were compared between 538 heart transplant patients and 2,128 non-transplant patients.

**Results** Transplant recipients undergoing PCI had a higher prevalence of diabetes, dyslipidemia and peripheral vascular disease; lower prevalence of angina, acute coronary syndrome, abnormal noninvasive functional study, and type C coronary lesions compared to the non-transplant PCI population. After propensity matching, all-cause in-hospital mortality was similar between transplant and non-transplant groups (1.3% vs 1.0%; OR, 1.21; 95% CI, 0.54-2.67).

**Conclusion** This is the largest series to date outlining the characteristics of heart transplant recipients undergoing PCI. Similar in-hospital outcomes were noted in heart transplant recipients compared to the general population. Further studies evaluating long-term outcomes are warranted. (Am Heart J 2015;170:1086-91.)

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Cardiac allograft vasculopathy (CAV) is a major cause of morbidity and mortality after heart transplantation.<sup>1,2</sup> It is characterized by progressive, concentric intimal hyperplasia and has a prevalence approaching 50% within the first 10 years of transplantation.<sup>2-4</sup> It accounts for one third of all deaths beyond the first year of transplantation.<sup>5,6</sup> The only definitive treatment for CAV is repeat transplantation; however, percutaneous coronary intervention (PCI) has been used as a temporizing strategy for focal lesions associated with CAV.<sup>1</sup> Several single-center retrospective studies have demonstrated that PCI in heart transplant recipients with CAV is associated with high procedural success rates and low in-hospital adverse outcomes.<sup>3,7-11</sup> More recently, drug-eluting stents have emerged as a preferred alternative to

bare metal stents in reducing in-stent restenosis in heart transplant recipient's population.<sup>11</sup>

While reports exist in the literature describing the characteristics of transplant recipients undergoing PCI, they have been limited by small sample size and more importantly, no direct comparison to non-heart transplant patients. Moreover a contemporary analysis of transplant recipients is lacking. We therefore intend to characterize this unique group of patients and simultaneously compare to unselected non-transplant patients undergoing PCI. We utilized the National Cardiovascular Data Registry (NCDR) CathPCI Registry to examine the clinical characteristics, treatment strategies and in-hospital outcomes in heart transplant recipients undergoing PCI and compare these to matched patients without prior heart transplant.

## Methods

### Study population and data definitions

The study aimed at providing a descriptive analysis of the clinical, angiographic and procedural characteristics and in-hospital outcomes of heart transplant recipients undergoing PCI from the NCDR CathPCI Registry. The CathPCI registry is a national reporting system designed for quality improvement of diagnostic cardiac catheterization and PCI procedures, sponsored jointly by the American College of Cardiology (ACC) and the Society for Cardiovascular Angiography and Interventions.<sup>12</sup> In this registry, clinical data are abstracted in a retrospective fashion and documented using standardized data definitions to ensure validity.

Between July 2009 and December 2013, there were 2,841,075 PCI patients at 1,488 sites participating in the CathPCI registry. After excluding patients with concomitant non-coronary procedures ( $n = 466,237$ ), patients who underwent coronary intervention to a bypass graft vessel ( $n = 184,015$ ), or patients with missing information or incomplete data on whether the procedure was being performed as part of a heart transplant evaluation ( $n = 293,495$ ), a total of 1,897,328 patients from 1,477 institutions comprised the final study population (Figure). Patients were then stratified into 2 groups: patients with prior heart transplantation ( $n = 542$ ) and those without transplantation ( $n = 1,896,786$ ).

The primary clinical outcome of interest was death from any cause. Secondary endpoints were a composite of death, myocardial infarction (MI), stroke and bleeding within 72 hours.

### Statistical analysis

Baseline characteristics, clinical presentation, angiographic and PCI characteristics, and in-hospital outcomes were compared between patients with and without prior heart transplant for the 2 groups. Categorical variables were compared between using the Pearson  $\chi^2$  test. Continuous variables were presented as medians (25th,

75th percentiles) and were compared using Wilcoxon rank-sum tests.

The associations between heart transplant status and each outcome of interest were assessed in propensity-matched cohorts. Propensity score models were developed using logistic regression of whether the PCI patient had received heart transplant or not. Covariates inputted to the model were selected based on clinical judgment as well as significant differences in univariable comparisons between groups, and included age, sex, race, hypertension, diabetes, smoker, peripheral vascular disease, dialysis, baseline clopidogrel use, Canadian Classification System symptom class, heart failure within 2 weeks prior to presentation, prior myocardial infarction, PCI, coronary bypass surgery, positive non invasive study, angiographic: number of stents, lesion location, drug eluting stents (DES), previously treated lesion, type C/non-C, lesion length, enoxaparin use, DES in stent restenosis (prior to PCI), DES length and diameter. Using a Greedy-matching algorithm, we matched each heart transplant patient to 4 non-transplant patients with similar propensity scores using a caliper of 0.05. After matching, good balance was observed for most observed covariates (Table II). The association between prior heart transplant status and each outcome was analyzed using logistic regression with generalized estimating equations to account for with in-hospital clustering of outcomes. For the purposes of outcome analysis ST-segment elevation MI (STEMI) patients were excluded (due to very small numbers in the transplant group, 0.9%). ORs (95% CIs) for in-hospital mortality are presented, where the reference is transplant. All analyses were performed using SAS software (version 9.2; SAS Institute, Cary, NC). All statistical analyses were conducted independently by the Duke Clinical Research Institute (Durham, NC).

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## Results

PCI in heart transplant recipients is rare with only 542 patients undergoing PCI during the study period. Transplant recipients undergoing PCI were more likely to be younger, male, and have higher prevalence of dyslipidemia (84% vs 77%,  $P < .001$ ), diabetes (43% vs 35%,  $P < .001$ ), peripheral vascular disease (15 vs 10%,  $P < .001$ ), and dialysis (7 vs 2%,  $P < .001$ ) when compared with non-transplant patients (Table I). After propensity matching, many of the differences in key clinical characteristics between treatment

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