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## Socioeconomic Disparities in Use of Cardioprotective Medications Among Patients with Peripheral Artery Disease—An Analysis of the American College of Cardiology’s NCDR PINNACLE Registry®

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### Abstract

**Objective**—Examine disparities in use of cardioprotective medications in treatment of peripheral artery disease (PAD) by socioeconomic status (SES).

**Background**—PAD is associated with increased cardiovascular risk and is more prevalent among those of lower SES. However, the use of guideline-recommended secondary preventive measures for the treatment of PAD across diverse income subgroups and the influence of practice site on potential treatment disparities by SES are unknown.

**Methods**—Within the National Cardiovascular Disease Registry (NCDR®) PINNACLE Registry®, 62,690 patients with PAD were categorized into quintiles of SES, as defined by the median income of each patient’s zip code. The association between SES and secondary prevention treatment with antiplatelet and statin medications was evaluated using sequential hierarchical modified Poisson models, adjusting first for practice site and then for clinical variables.

**Results**—Compared with the highest SES quintile (median income >\$60,868), PAD patients in the lowest SES quintile (median income <\$34,486) were treated less often with statins (72.5 % vs. 85.8%; RR 0.84 [0.83–0.86]; P<0.001) and antiplatelet therapy (79.0% vs. 84.6 %; RR 0.93 [95% CI: 0.91–0.94]; P<0.001). These differences were markedly attenuated after controlling for

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practice site variation: statins (adjusted RR: 0.97 [0.95–0.99]; P=0.003) and antiplatelet therapy (adjusted RR 0.98 [0.97–1.00]; P=0.012). Additional adjustment for patients' clinical characteristics had minimal impact with slight further attenuation: statins (adjusted RR: 1.00 [0.99–1.01]; p=0.772) and antiplatelet therapy (adjusted RR: 1.00 [0.99–1.01]; p=0.878).

**Conclusion**—Among PAD patients, the practice site at which patients received care largely explained the observed SES differences in treatment with guidelines-recommended secondary prevention medications. Future efforts to reduce treatment disparities in these vulnerable populations should target systems improvement at practices serving high proportions of patients with low SES.

## Background

The Institute of Medicine has challenged the US health care system to minimize disparities in treatment and provide equitable access to evidence-based therapies to all patients<sup>1</sup>. While there have been numerous studies investigating disparities in the care of cardiac patients,<sup>2–4</sup> disparities research in peripheral arterial disease (PAD) has been limited,<sup>5–9</sup> even though PAD affects over 7 million Americans<sup>10</sup> and disproportionately affects those of lower socioeconomic status (SES).<sup>11,12</sup> Equitable access to inexpensive guideline-recommended secondary preventive therapies has the potential to improve cardiovascular outcomes in this vulnerable population, but whether treatment rates differ across income groups remains unknown. Given that PAD is associated with increased cardiovascular risk and mortality<sup>18–22</sup>, illuminating current practice patterns by SES for evidence-based secondary preventive strategies is particularly important in defining opportunities to better improve care.

Accordingly, we examined PAD treatment rates by SES within the American College of Cardiology's National Cardiovascular Disease Registry (NCDR<sup>®</sup>) PINNACLE Registry<sup>®</sup>, which prospectively captures information on the clinical care of outpatients, including the use of guideline-recommended secondary preventive therapies. Given the potential variability in care across clinics, we explicitly sought to examine both variations in secondary prevention treatment of PAD by SES and whether treatment differences by SES were explained at the site level, with the hope that our findings could not only identify potential disparities by income, but also define targets for future interventions to reduce disparities in PAD care.

## Methods

### Study Population

The PINNACLE Registry was launched in 2008 and represents the first national, prospective, office-based, quality improvement registry of cardiovascular patients in the United States.<sup>23,24</sup> Among participating practices, patient data were collected at the point of care for a variety of cardiovascular conditions, including coronary artery disease, heart failure, atrial fibrillation and PAD. Participation in this quality improvement initiative is voluntary.

For the purposes of this study, we identified 66,282 patients with a diagnosis of PAD enrolled from 61 practices between July 1, 2010, and June 30, 2011. Within the PINNACLE Registry, PAD was defined by one of the following self-identified criteria by the patients: 1) claudication, either with exertion or at rest; 2) amputation for arterial vascular insufficiency; 3) vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities (excluding dialysis fistulas and vein stripping); 4) documented aortic aneurysm with or without repair; or 5) positive non-invasive test (e.g., ankle brachial index  $\leq 0.9$ , ultrasound, magnetic resonance, computed tomography) or diagnostic angiographic stenosis of  $> 50\%$  in

any major peripheral artery (e.g., renal, subclavian, femoral, iliac). We excluded 2,945 patients for whom information on SES was missing (zip code data was not available). Our final study cohort was comprised of 62,690 PAD patients from 61 sites. For the analyses in this study, as patients may have had multiple visits in the PINNACLE Registry, we used information from the first visit to represent each patient only once.

### SES and Processes of Care

The key independent variable was patients' SES, which was defined by the median income of the patient's zip code of residence. This approach to categorize levels of socioeconomic status has been used in previous reports of various disease conditions.<sup>25–27</sup> The primary study outcome was treatment with 2 secondary prevention medication therapies: antiplatelet therapy (aspirin or clopidogrel) and statins, which are both Class I indications for PAD by the ACC/AHA PAD guidelines and PAD performance measures.<sup>28,29</sup> Patients with documented contraindications to antiplatelet therapy (e.g., history of gastrointestinal bleeding) or statins were excluded within the analysis for each treatment. Moreover, for the analyses with antiplatelet therapy, we further excluded 9,295 patients already on warfarin therapy given that warfarin may influence use of antiplatelet therapy.

### Statistical Analysis

Patients were categorized into quintiles of SES, with Quintile 1 representing the lowest SES and Quintile 5 the highest. Baseline differences across quintiles of SES were then compared using Mantel-Haenszel trend test for categorical variables and linear trend test for continuous variables.

Separate multivariable hierarchical modified Poisson models were used to assess the relationship between SES and treatment with antiplatelet therapy and statins. We employed 2-level hierarchical models to adjust for clustering of patients within practices, with individual practices modeled as random effects and other patient characteristics modeled as fixed effects within each practice<sup>30</sup>. This approach allowed us to control for measured and unmeasured *between-practice* confounding, as the use of hierarchical models ensured that patients with similar SES were compared with each other from the same practice.

To better understand the extent of the practice site variation in accounting for treatment differences by SES, we performed a 2-step sequential adjustment. First, we adjusted for practice site only to assess the extent to which differences by SES were attenuated. This step allows us to understand whether treatment differences by SES persist when comparing patients of different SES within the same site. Next, we additionally controlled for clinical characteristics, including age, gender, insurance status, diabetes, dyslipidemia, history of MI, history of revascularization in the past 12 months, history of congestive heart failure, and history of stroke.

For each analysis, the null hypothesis was evaluated at a two-sided significance level of 0.05, with 95% confidence intervals (CIs) calculated using robust standard errors. All analyses were performed with SAS 9.3 (SAS Institute, Cary, NC) and R version 2.10.0.

### Results

Baseline characteristics of the 62,690 PAD patients by SES quintiles are summarized in Table 1. Patients in the lowest SES quintile were from zip codes with median household incomes of less than \$34,486 annually, while those in the highest quintiles were from zip codes with annual median household incomes of greater than \$60,868.

The median age of the overall cohort was 70.0 (IQR 62.0, 78.0) years and 62.4% were men. Nearly 60% of patients had private insurance, and only 4.2% were uninsured. There was a high prevalence of coronary artery disease (85.4%), dyslipidemia (81.5%), and hypertension (83.3%) in the cohort. Nearly one-third of patients were diabetic and one-quarter were active smokers. Finally, 30.3% of patients had undergone coronary artery bypass surgery whereas 41.4% had undergone percutaneous coronary intervention within the past year.

Compared with patients in the highest SES quintiles, patients in the lower SES quintiles were slightly younger, more frequently female, and less likely to have private health insurance. Patients in lower SES quintiles were also more likely to have undergone percutaneous coronary intervention in the past year and be active smokers, and were less likely to have undergone coronary artery bypass surgery in the past year or have had a prior stroke. Lastly, rates of dyslipidemia, diabetes, hypertension, congestive heart failure, and prior myocardial infarction were clinically similar across quintiles.

### Use of Cardioprotective Therapy

Treatment rates with statins decreased in a graded fashion going from higher to lower SES: 85.8% among quintile 5 to 72.5% for quintile 1 (Table 2). Compared with patients in the highest SES quintile, PAD patients in the lowest SES quintile were 16% less likely to be treated with statins (unadjusted rate ratio [RR], 0.84; 95% confidence interval [CI], 0.83–0.86,  $p < 0.0001$ ). Notably, sites with higher mean income among its patients had greater percentage of patients prescribed a statin medication (weighted correlation coefficient = 0.48) (Figure 1). After adjustment for the practice at which a patient received care, treatment differences by SES were markedly attenuated (adjusted RR for quintile 1 vs. 5, 0.97; 95% CI, 0.97–0.99,  $p = 0.003$ ). Further adjustment for clinical variables was associated with only a small attenuation of differences by SES (fully adjusted RR, 1.00; 95% CI, 0.99–1.01,  $p = 0.772$ ). A similar pattern was observed for quintiles 2, 3, and 4 (Table 3).

Rates of any antiplatelet were lowest among those in quintile 1 (79.0% among quintile 1 vs 84.6% among quintile 5) (see Table 2). Compared with patients in the highest SES quintile, patients in the lowest SES quintile were 7% less likely to be treated with any antiplatelet medication (unadjusted RR, 0.93; 95% CI, 0.91–0.94,  $p < 0.0001$ ). As with statin treatment, sites with higher median income among its patients had greater percentage of patients prescribed an antiplatelet agent (weighted correlation coefficient = 0.30) (Figure 2). After adjustment for the practice at which a patient received care, treatment differences by SES were nearly eliminated (adjusted RR, 0.98; 95% CI, 0.97–1.00,  $p = 0.012$ ). Further adjustment for the clinical characteristics of patients had minimal effect on attenuation of effect between the quintiles of SES (fully adjusted OR, 1.00; 95% CI, 0.99–1.01,  $p = 0.878$ ) (see Table 3).

### Discussion

Among outpatients with PAD, we found that treatment with antiplatelet and statin therapies differed by SES. These differences, however, were largely explained by the clinical practice at which patients received care. Our findings suggest that initiatives to reduce disparities in medication treatment for PAD should target practices with high proportions of low SES patients.

Studies from different populations have demonstrated that cardiovascular risk factors and disease disproportionately affects those of lower SES,<sup>31–36</sup> and among patients with cardiac disease, those with lower SES experience higher morbidity and mortality.<sup>4,37–40</sup> Patient level risk factors, such as increased health risk behaviors, may account for some of the increased morbidity and mortality seen in patients with low SES.<sup>4,41</sup> However, identifying

factors beyond patient risk factors and behaviors,<sup>36</sup> which are not easily modifiable, are critical to quality initiatives that address the Institute of Medicine mandates to improve outcomes and reduce disparities. For instance, several studies have reported variation in adherence to evidence-based therapies for other cardiac conditions by SES, and may partly explain the association between lower SES and worse outcomes.<sup>37,42,43</sup> However, these prior studies have not examined treatment differences by SES for PAD. Moreover, they have not examined the extent to which the site at which a patient receives his or her care influences treatment rates.

The present study expands on findings of other disparities research, and focuses on PAD, where outcomes research has been limited. Prior studies of disparities in PAD have focused on utilization rates of lower extremity revascularization by SES or reported rates of optimal medical therapy by insurance status<sup>5-9</sup> This present study confirms findings similar to other cardiac disease states in that the use of secondary prevention treatments for PAD was lower among those of low SES. This finding highlights an important gap in the quality of care for patients with PAD, especially since the cost of aspirin and generic statins is low and should not pose significant barriers to patient access to these evidence-based therapies.

The present analysis further contributes to disparities research by highlighting the central role of the practice at which patients receive their care in explaining treatment differences by SES. We found that disparities in medication use between the highest and lowest SES were markedly attenuated after adjusting for site level variation; this suggests that differences in medication use were predominately explained by differences in sites that largely treat low SES compared with sites caring for largely higher SES patients. We believe these findings serve as an important paradigm for future efforts to reduce disparities in care, which will need to target clinical practices as intervention units and go beyond patient-level interventions. For PAD, future studies are needed to determine whether system-wide improvements at the practice level (e.g., identification of patients with PAD, initiation of secondary prevention medications, and physician education) or resource interventions at practices with high proportions of low SES patients (e.g., electronic medical systems, decision aids) will reduce disparities in treatment by SES. Quality improvement initiatives that provide feedback to sites by providing reports benchmarking performance of the site in relation to prespecified goals or national average for select performance metrics may help change behavior at a site.

There are several limitations to this study. First, we relied on patient diagnoses for PAD, which were self-reported by practices. It is possible that some patients were not classified as having PAD; however, we believe any misclassification would have been non-differential and are unlikely to have influenced our findings. Moreover, we were unable to examine severity of PAD, as we did not have physiologic (e.g., ankle-brachial index) or angiographic data on all patients. Similarly, we were unable to analyze the variability in use of medication by the specific PAD diagnosis (i.e. surgery vs non-invasive test, etc.) Second, we defined SES by median residential zip code income, which is a common strategy in previous studies,<sup>25-27</sup> and did not examine other socioeconomic variables, such as educational level, which were not available in the PINNACLE registry. Third, our study was conducted among cardiology practices participating in PINNACLE, a quality improvement registry; therefore, treatment rates by SES may differ in non-participating practices including primary care centers. Given voluntary enrollment in this quality improvement initiative, it is possible that the rates of medication use are higher than expected in non-participating sites. We did not adjust for race in the clinical model given that it was frequently missing (nearly 50% of patients had missing data on this variable); however, most of the variation in treatment between the SES groups could be accounted for by practice-level variation. Furthermore, while it is possible that the differences in therapies by SES could be mediated by some, but

not all, physicians within a practice, the current PINNACLE registry does not provide sufficient information on provider characteristics to allow us to currently examine this possibility. Regardless, further education and resources geared at practices with high proportions of low SES patients have the potential to improve adherence to therapies indicated for PAD. Finally, we were unable to examine longitudinal outcomes in this study.

## Conclusion

Among patients with PAD, treatment with evidence-based antiplatelet and statin therapies differed by patients' SES. These differences, however, were largely explained by the clinical practice at which patients received care, suggesting variation in treatment patterns across centers. Future efforts to reduce treatment disparities by SES in PAD and improve outcomes in these vulnerable populations should target practices serving high proportions of patients with low SES.

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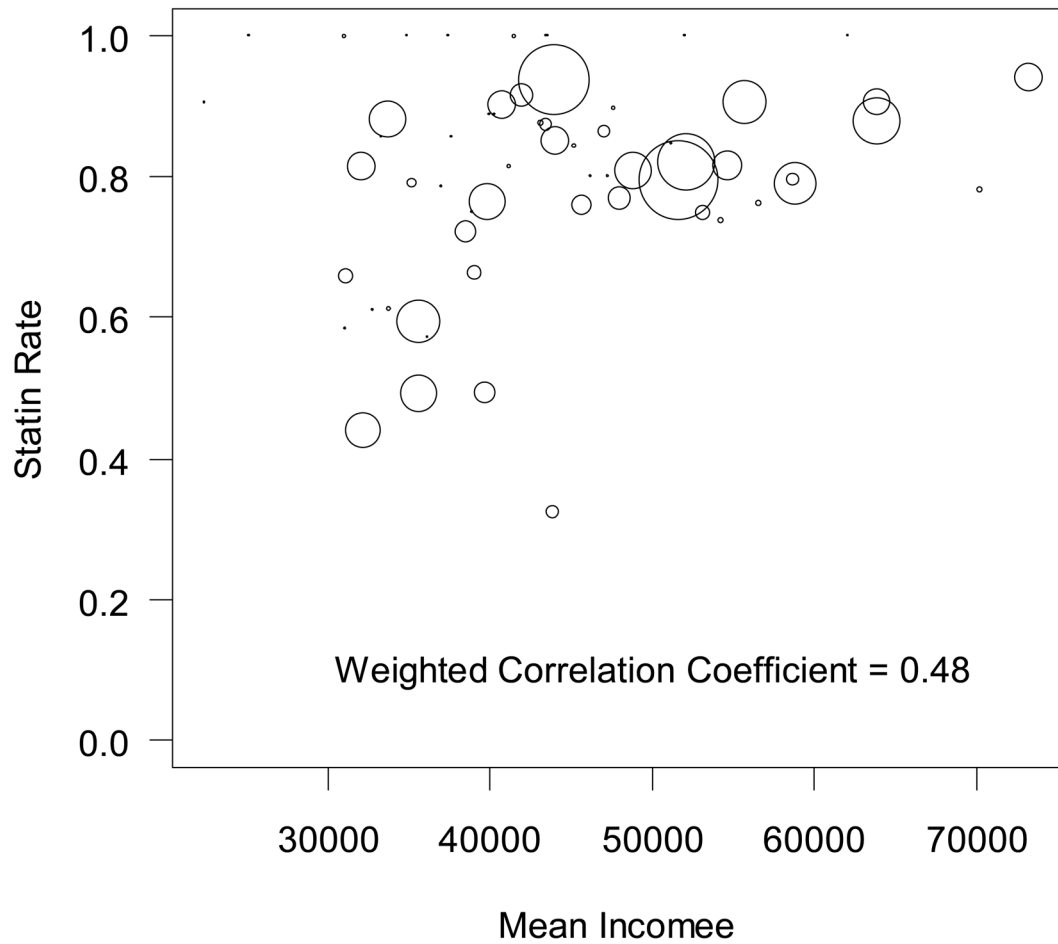
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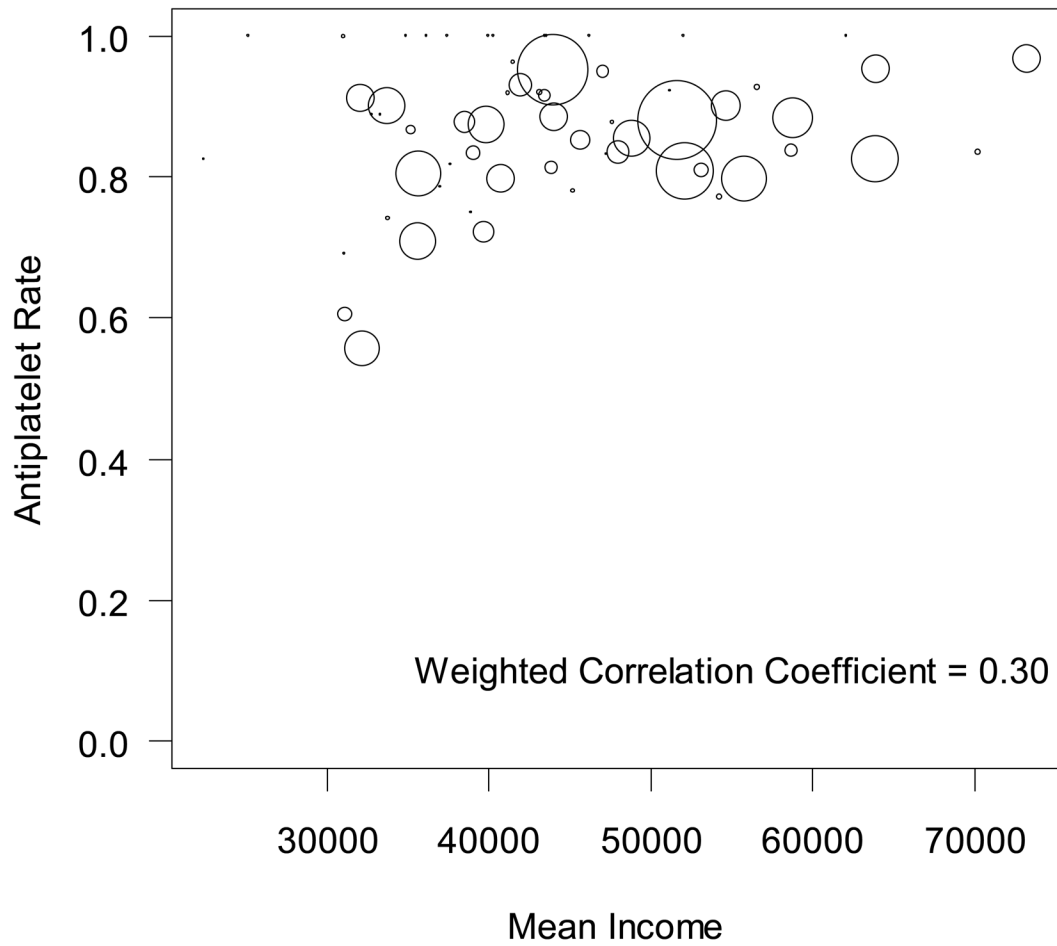
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**Figure 1. Correlation between a site's mean patient income and rate of statin treatment**  
The size of circles is a weighted representation of the number of patients with PAD at a practice.



**Figure 2. Correlation between a site's mean patient income and rate of antiplatelet treatment**  
The size of circles is a weighted representation of the number of PAD patients at a practice.

Table 1

Baseline demographics of the study cohort, stratified by socioeconomic status

	Quintiles of Socioeconomic Status					Total n = 62690	P-Value
	Quintile 1 n = 12521	Quintile 2 n = 12513	Quintile 3 n = 12565	Quintile 4 n = 12511	Quintile 5 n = 12580		
Median Income (IQR)	4,583–34,486	34,486–41,117	41,118–50,371	50,372–60,868	60,869–200,001		<0.001
Age (Median (IQR))	69.0 (61.0, 78.0)	71.0 (62.0, 79.0)	70.0 (62.0, 78.0)	71.0 (63.0, 79.0)	71.0 (63.0, 79.0)	70.0 (62.0, 78.0)	<0.001
Male	60.6	62.8	62.5	61.7	64.2	62.4	<0.001
<i>Insurance Category</i>							
Private Insurance	54.5	63.3	59.7	58.7	61.0	59.4	<0.001
Public Insurance	41.1	33.0	37.2	37.9	35.2	36.9	<0.001
No Insurance	4.5	3.7	3.1	3.4	3.8	3.7	<0.001
<i>Comorbidities</i>							
Coronary artery disease	86.9	86.2	86.6	83.6	83.5	85.4	<0.001
Dyslipidemia	77.2	80.8	82.1	82.7	84.5	81.5	<0.001
Diabetes	33.4	34.0	32.2	31.5	32.2	32.7	<0.001
Hypertension	82.3	85.2	84.4	82.3	82.4	83.3	0.010
Prior stroke or TIA	11.5	24.1	25.2	16.4	18.0	19.0	<0.001
Heart failure	45.4	53.6	50.9	40.1	36.5	45.3	<0.001
Myocardial infarction history	30.9	29.9	31.8	28.7	31.5	30.6	0.982
CABG within 12 months	23.29	25.4	33.8	33.2	35.8	30.3	<0.001
Percutaneous coronary intervention within 12 months	47.0	48.8	43.0	33.7	34.7	41.4	<0.001

Continuous variables compared using linear trend test.

Categorical variables compared using Mantel-Haenszel trend test.

\* Defined by patient's zip code level annual median household income

+ Public insurance refers to Medicare, Medicaid, military, and state insurance

**Table 2**

Medications Treatment Rates by Quintiles of Socioeconomic Status,\*

	Median income by zip code					Total N=62,690	P-Value
	Quintile 1 n = 12521	Quintile 2 n = 12513	Quintile 3 n = 12565	Quintile 4 n = 12511	Quintile 5 n = 12580		
Any antiplatelet: Clopidogrel and/or Aspirin	79.0	83.0	84.8	83.1	84.6	82.9	< 0.001
Statin	72.5	77.6	83.2	81.5	85.8	80.1	< 0.001

Continuous variables compared using linear trend test.

Categorical variables compared using Mantel-Haenszel trend test.

(Except as noted: KW = Kruskal-Wallis test)

\* Medications described among those eligible (without contraindication)

Table 3

Association of Socioeconomic Status with PAD Treatment

	Unadjusted		Adjustment for practice level variation		Further adjustment for clinical characteristics*	
	RR, 95% CI	P-Value	RR, 95% CI	P-Value	RR, 95% CI	P-Value
Statin Therapy						
<b>Quintile 5</b>	[Reference]	-	[Reference]	-	[Reference]	-
<b>Quintile 4</b>	0.95(0.94, 0.96)	<0.001	0.98(0.97, 1.00)	0.0134	0.98(0.97, 1.00)	0.007
<b>Quintile 3</b>	0.97(0.96, 0.98)	<0.001	0.98(0.97, 1.00)	0.0124	0.99(0.98, 1.00)	0.172
<b>Quintile 2</b>	0.90(0.89, 0.91)	<0.001	0.98(0.95, 1.00)	0.0341	0.99(0.97, 1.01)	0.327
<b>Quintile 1</b>	0.84(0.83, 0.86)	<0.001	0.97(0.95, 0.99)	0.0029	1.00(0.99, 1.01)	0.772
Any Antiplatelet**						
<b>Quintile 5</b>	[Reference]	-	[Reference]	-	[Reference]	-
<b>Quintile 4</b>	0.99(0.98, 1.00)	0.022	1.00(0.99, 1.01)	0.556	1.01(1.00, 1.01)	0.237
<b>Quintile 3</b>	1.00(0.99, 1.01)	0.946	0.99(0.98, 1.01)	0.347	1.00(0.99, 1.01)	0.788
<b>Quintile 2</b>	0.98(0.97, 0.99)	<0.0001	1.00(0.99, 1.01)	0.794	1.01(1.00, 1.02)	0.071
<b>Quintile 1</b>	0.93(0.91, 0.94)	<0.0001	0.98(0.97, 1.00)	0.012	1.00(0.99, 1.01)	0.878

\* Clinical characteristics adjusted model: model adjusted for practice, age, gender, history of myocardial infarction, revascularization in the past 12 months, insurance, congestive heart failure, diabetes, stroke, dyslipidemia, and tobacco use

\*\* Excluding patients on warfarin