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Racial Differences in Antilipemic Use and Lipid Control in High Risk Older Adults Post Medicare Part D

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Abstract

Background—Older blacks are less likely to receive guideline-recommended antilipemic therapy and achieve lipid control than older whites due in part to out-of-pocket costs. We sought to determine whether racial differences in antilipemic use and lipid control narrowed after Medicare Part D's implementation.

Methods—This before-after study included 1091 black and white adults age >70 with coronary heart disease and/or diabetes mellitus from the Health Aging and Body Composition Study. Primary outcomes were antilipemic use and LDL-C control. Key independent variables were race, time (pre- vs. post-Part D), and their interaction.

Results—Before Part D, fewer blacks than whites reported taking an antilipemic (32.70% vs 49.35%) and this difference was sustained after Part D (blacks 48.30% vs whites 64.57%). Multivariable generalized estimating equations confirmed no post Part D change in racial differences in antilipemic use (adjusted ratio of the odds ratios [AROR] 1.07, 95% CI 0.79–1.45). Compared to whites, more blacks had poor lipid control both before Part D (24.30% vs 12.36% respectively) and after Part D (24.46% vs 13.72% respectively), with no post Part D change in racial differences in lipid control (AROR 0.82, 95% CI 0.51–1.33).

Conclusion—While antilipemic use increased after Medicare Part D for both races, this policy change was associated neither with a change in lipid control for either racial group nor in the racial differences in antilipemic use or lipid control.

Coronary heart disease (CHD) and its risk equivalent, diabetes mellitus (DM), commonly occur in older adults and are leading causes of morbidity and death, particularly among older

blacks.¹ One potentially modifiable risk factor for this morbidity and mortality in elders with CHD and DM is dyslipidemia for which national guidelines recommend treatment with statins and other antilipemics.^{2–7} Unfortunately, several studies have shown that older blacks are less likely to be prescribed antilipemics, compared to older whites with CHD and/ or DM.^{8–11} Moreover, a study of older adults enrolled in Medicare managed care plans that provided a prescription drug benefit showed that older blacks with CHD were less likely than older whites to have adequate lipid control.¹²

One barrier to initiation and adherence to antilipemic therapy, which may account for some of the racial disparity in lipid control, is out-of-pocket medication costs. ^{11,12} Until recently, most statins were available only as brand-name drugs and were thus costly to those without a prescription drug benefit. Prior to 2006 when the Medicare prescription drug benefit (Part D) was implemented, older blacks were less likely than whites to have any insurance coverage for prescription drugs, and thus experienced greater out-of-pocket costs. ^{11,12} Blacks compared to whites had higher rates of cost-related medication non-adherence (i.e., failing to fill prescriptions or skipping doses of prescribed medicines). ^{11,12} Medicare Part D has the potential to expand the number of older black adults with drug coverage. Moreover, a substantial share of blacks who were not previously dually eligible for Medicaid drug coverage may be eligible for generous low-income subsidies which provide Part D benefits at no monthly premium, and very low copayments, substantially reducing the financial burden for medications. ¹³

To the best of our knowledge, no studies to date have examined the impact of this policy change on racial differences in medication use and associated laboratory measures of lipid control. Therefore, the study objective was to determine whether racial differences in antilipemic use and lipid control among those with any CHD and its risk equivalent DM narrowed in the time period after the implementation of Part D.

METHODS

Study Design, Source of Data and Sample

This before-after study used data from the Health Aging and Body Composition (Health ABC) Study supported by National Institute on Aging Intramural Research program. ¹⁴ At baseline (1997–1998), 3,075 black and white men and women, aged 70–79, were recruited from a random sample of Medicare beneficiaries residing in Pittsburgh, PA and Memphis, TN and longitudinally followed every 6 months for purposes of the current project 10 years. To be included, participants had to report no difficulty walking for ½ mile, climbing 10 steps, or performing basic activities of daily living. For the current analyses, the cross-sectional pre-Medicare Part D sample was restricted to those who had CHD and/or DM between 2002–2005. The cross-sectional post-Part D sample included those with CHD and/or DM in 2006–2008. The latter study years correspond to the period 6–30 months after the implementation of Medicare Part D on January 1, 2006. This six month lag period from the start of Part D is important as beneficiaries could enroll in Part D until May 15, 2006.

The source of funding for this study was an R01 grant from the National Institute on Aging (R01- AG034056- Hanlon PI). The authors were solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper and its final contents.

Incident or recurrent CHD was adjudicated by a site research clinician after review of hospital medical records or death certificate for myocardial infarctions (i.e., from cardiac pain, electrocardiography and/or abnormal cardiac enzymes) or angina pectoris (i.e., chest pain, chest tightness, or shortness of breath) and associated procedures (i.e., coronary artery

bypass grafting, percutaneous transluminal coronary angioplasty). ¹⁵ Participants were identified as having DM by using an American Diabetes Association validated approach in which they self-reported that a physician told them they had diabetes or sugar diabetes, had current use of one or more antidiabetic medications (i.e., insulin, sulfonylureas, alpha glucosidase inhibitors, biguanides, thiazolidinediones, meglitinides, dipeptidyl peptidase IV inhibitors, glucagon-like peptide 1 agonists), or had a fasting glucose 126 mg/dl. ^{16,17} This study was approved by the University of Pittsburgh and University of Tennessee Memphis Institutional Review Boards and informed consent was obtained from each participant prior to data collection.

Data Collection and Management

Research assistants were trained to collect information including fasting blood samples and detailed physiologic measurements for those with in-home or clinic visits, as well as for all visit types (including telephone visits for those that were too sick or temporarily away and unable to have a home or in-clinic visit) a battery of questionnaire material regarding sociodemographic characteristics, multiple aspects of health status, and medication use.¹⁴ Blood samples were frozen and sent for storage in a central laboratory repository. For medications, a brown bag inventory was taken at baseline (1997–1998), and annually for 10 years (except 2000-2001, 2003-2004, and 2005-2006). 18 Specifically, all participants were asked to bring all their prescription medications used in the previous two weeks to clinic where a well-trained research assistant examined the vials/bottles that the prescription medications were dispensed in and transcribed from these medication containers information about the medication name, strength, dosage form. Participants were asked to report how many dosage units were taken daily or in the previous week or if the medication was taken as needed. For completeness, research assistants also asked the participant about prescription medications reported during a previous study visit. For participants with evidence of memory difficulties or were too ill to respond, a proxy survey was conducted with the person who knew the participant best. A similar approach was taken for those with telephone surveys where participants were ask to read this information to the trained research assistant from their medication containers. The medication data was coded using the Iowa Drug Information System (IDIS). 18 These methods of medication data collection are considered highly accurate and compared to information contained in pharmacy claims data provides actual use data as opposed to prescription medication dispensed that may or may not be used. 18

Antilipemic Medication Use Outcome Measure

A dichotomous primary dependent variable of any antilipemic use, defined as self-reported daily use of one or more agents from five discrete classes: 1) statins, 2) bile acid binding resin agents, 3) fibrates, 4) niacin, and 5) cholesterol absorption inhibitors, which corresponds to IDIS codes from 24060000 to 24060409, was created.^{4,18}

Lipid Control Outcome Measure

We defined poor lipid control as a dichotomous variable in which low density lipoprotein cholesterol (LDL-C) was greater than 130 mg/dl following the National Committee for Quality Assurance (NCQA) quality of care performance measure in the Health Plan Employer and Data Information Set (HEDIS) in place in 2002, our first study year. ¹² Frozen blood samples for participants included in these analyses were sent from storage to a research laboratory for lipid panel testing. ²⁰ LDL-C testing was conducted for the entire Health ABC study cohort at years 1, 6, 8,10, and 11. The research laboratory used colorimetric reaction testing procedures and LDL-C was calculated using the Friedewald equation. ²¹ For the few participants in whom triglycerides were > 300 mg/dl, a direct LDL-C test was conducted. ²² A random blind 5% sample was retested for quality assurance

purposes and the coefficient of variation of these assays during the time of the study ranged between 2–7%.

Primary Independent Variables

The primary independent variables were race, time (pre- vs post- Part D) and their interaction. Race was assessed by self-report and confirmed by asking for race identification of parents. An indicator for pre- (2002–2005) vs. post- (2006–2008) Part D was included, as was an interaction term to determine the effect of Part D on racial differences in the outcomes.

Covariates

Several characteristics that could potentially confound or modify any association between race and antilipemic treatment and lipid control were adjusted for in the analyses ^{1, 10, 15, 23–25} and were grouped into three domains based on Andersen's modified health care service use model: 1) predisposing or demographic, 2) need or health status/behaviors, and 3) enabling or access to health care factors. ²⁶ Inclusion of these covariates is consistent with the Center for Disease Control's methodology recommendations for studying health disparities. ²⁷

The demographic factors collected at baseline (1997–1998) included a continuous measure for age, and dichotomous variables for sex, study site and marital status. We also controlled for a dichotomous variable for literacy level (Rapid Estimate of Adult Literacy in Medicine score equal to or higher than a ninth-grade and higher reading level versus not). ²⁸

Need or health status/behavioral factors were based on data collected in 2002–2003. and were represented by dichotomous variables for specific self-reported conditions (i.e., peripheral arterial disease, osteoporosis). ¹⁴ Cognitive impairment was defined as participants with a Modified Mini-Mental State (3MS) examination score less than 80. ²⁹ We also examined dichotomous measures of sensory impairment (i.e., vision and hearing). ¹⁴ We also created time-varying (2002–2003 and 2006–2007) dichotomous variables for self-rated health and moderate/high intensity exercise in the previous week (e.g., walking for exercise, aerobic dance, weight lifting, golfing, dancing, jogging and swimming). ³⁰ Finally, we created three time-varying (2002–2003 and 2006–2007) dichotomous health behaviors variables: obesity (i.e., body mass index >30), smoking and receipt of influenza vaccine. ¹⁴

Characteristics that may facilitate or hinder access to health care were represented by dichotomous baseline measures for family income, and other assets (e.g., pensions, stocks/mutual funds, other real estate).²⁵ We also examined whether they were hospitalized in the previous year.^{14,25} Finally, prior to and after Part D, dichotomous variables for prescription drug benefit were created for those reporting yes that they have any health insurance plan that pays for prescription medicines or receiving Medicaid. Those receiving Medicaid after Part D were auto enrolled in a stand-alone Medicare Part D plan). ³¹

Statistical Analyses

Descriptive statistics (e.g., mean, standard deviation, percentages) were computed for all dependent, independent and control variables. Most demographic and health status/behavior covariates had complete information, and none had more than 9% with missing information. Most access to care covariates had less than 10% missing information except for family income (11.5%) and home ownership (16.6%). We replaced missing covariate values with those generated using the multiple imputation (MI) procedure available in SAS® version 9.2 software (Cary, NC). The final multivariable models included adjustment for key demographic, health status/behavior factors and access to health care factors deemed

important and supported in the literature. For these final analyses, we first calculated adjusted black vs white odd ratios (ORs) and ninety five percent confidence intervals (95% CIs) for the pre-Part D and post-Part D time periods separately using generalized estimating equations (GEE) using the logit link function with an independent correlation structure using the SAS® GENMOD procedure. 32,3 We then, using GEE, calculated the ratio of ORs (RORs) to determine if there was a reduction in racial disparities (i.e., a difference in the differences between racial groups) from pre- to post- Part D. For determining the statistical significance of RORs and widths of CIs, we applied the sandwich estimator which adjusts standard errors for correlations between timepoints. This approach has been previously used in similar analyses. 34–36 All statistical analyses were performed using SAS® version 9.2 (SAS Institute, Inc., Cary, North Carolina).

RESULTS

The attrition rate between year 1 (1997–98) and year 6 (2002–2003) was low (12.7%) with only 378 deaths and 14 withdrawals. At the 2002-2003 visit, 1,091 of 2,683 participants interviewed had CHD with or without DM (n=698), or only DM (n=393). Blacks accounted for 43.17% of the sample. By 2006-2007, 771 participants had these conditions of which 38.13% were black. A total of 673 participants (whites=420, blacks=253) were longitudinally in each group pre and Post Part D. Table 1 compares black and white study participants by demographic, health status/behavior, and access to health care factors in both time periods. Blacks were more likely than whites to report fair-poor health and to be in the low income category at both time periods. Before Part D, blacks were less likely than whites to report having a drug benefit (54.99% vs 62.26%, respectively). However, more blacks than whites reported Medicaid was the reason for having a drug benefit (15.44% vs 3.63%, respectively). In both races, the percent with a prescription drug benefit increased in the Post Part D period. However blacks compared to whites continued to be less likely to have a drug benefit (74.49% vs 81.86%, respectively). As seen at baseline, more Blacks than whites had Part D due to Medicaid (8.16% vs 1.47%, respectively). The average LDL-C levels were higher in blacks than whites in both time periods.

Table 2 shows that whites were more likely to receive any antilipemic before the implementation of Part D. The most common antilipemic class used at both time periods was statins accounting for at least 96% of agents used. While antilipemic use increased in both blacks and whites post-Part D, they increased by similar amounts (absolute difference of 15.60% for blacks and 15.22% for whites). After controlling for demographic, health status/behavior, and access to health care factors, as indicated by the ratio of the odds ratios (Table 2), no reduction in racial differences was seen.

Table 3 shows that more blacks than whites had poor lipid control (LDL-C>130 mg/dl) pre-Part D. Similarly, after Part D again blacks continued to be more likely to have inadequate lipid control. After controlling for demographics, health status behaviors, and access to health care factors, as indicated by the ratio of the odds ratios (ROR 0.82, 95% confidence interval 0.51–1.33) (Table 3), no reduction in racial differences was seen.

DISCUSSION

This study found that the rate of antilipemic use overall increased in the post- Part D time period for older adults. This increase in antilipemic medication use is consistent with the increases in rates of treatment for chronic conditions reported by other studies during this time period.^{37,38} One possible explanation is that percent without a drug benefit before Part D in our study group declined from nearly 40% to 20% after Medicare Part D was implemented. These changes in drug benefit rates are consistent with national data.^{38,39}

Despite this rise in antilipemic use, 1/3 to 1/2 of older adults with CHD or its risk equivalent were not treated after Part D was implemented.

This study also found no improvement overall in lipid control after Part D was implemented. Despite this, the overwhelming majority (82%) of participants overall in both time periods achieved HEDIS LDL-C goal. Moreover, this rate of goal achievement is greater than that reported by Trivedi et al. for VA and Medicare managed care patients older than 65 years of age. ^{12,40}

When examining racial differences, we found that after Part D there was no narrowing in antilipemic use differences. This finding is consistent with a recent study using Medical Expenditure Panel Survey data from 2004–2008 that found no reduction in racial differences in statins use in older adults with DM.³⁷

Our study is the first to our knowledge to examine the association between Part D's implementation and lipid control. We saw no change in the difference between blacks and whites in lipid control after Part D. One possible explanation is that older blacks compared to whites have worse medication adherence. ^{11,42} Further support for this explanation is our recent study results using Health ABC study data in the Post Part D period that found among those with CHD and/or DM that blacks compared whites were more likely to report medication non-adherence. ⁴³ Our findings suggest that expansions in drug coverage need to be accompanied by other interventions to improve rates of treatment and adherence among at-risk older adults.

The clinical interpretation of our study findings depends in part on one's view of whether the racial difference in antilipemic use and lipid control between blacks and whites should be considered a disparity.²⁷ A majority of the Health ABC sample in the post-Part D time period were greater than 80 years of age. A meta-analysis using clinical trial data from older adults aged 65 to 82 years of age showed that treatment with statins in those with CHD reduced LDL-C as well as risk of myocardial infarction, stroke and death.³ However, for those above the age of 82 years, the lack of evidence for benefit has to be tempered by the potential risks of antilipemic therapy (e.g., myalgia/myopathy, and perhaps increased glucose, cognitive impairment and mortality) in this age group.^{3,44} Indeed a recent review concluded that there was insufficient data to recommend initiation or continuation of antilipemics in those with established CHD and/or risk equivalent (e.g., DM) over the age of 80 years.⁴⁴ Thus one interpretation is that our findings represent a racial difference but not a disparity.

This study has important potential limitations that require discussion. Since our DM sample was derived, in part, from annual self-reports, the true rate may be underestimated. Moreover, any use of anti-lipemics may have been underestimated as medication use was measured at multiple fixed annual time points. Our measure of poor lipid control was conservative as many guidelines now suggest an LDL-C goal <100mg/dl in those with CHD and/or DM. ^{4–7} It is also possible that there was unmeasured potential confounding that could have influenced our findings. One factor we were not able to control for was medication adherence since it was not measured in the Pre Part D. Finally, our study sample was drawn from two major US cities and may not be generalizable to all other populations.

In conclusion, antilipemic use increased substantially for both races following the introduction of Medicare Part D. However, race-related differences in either antilipemic use or lipid control did not diminish following the implementation of Medicare Part D. Notwithstanding the mixed evidence of the benefits and risks of antilipemic use among the oldest old (85+ tears of age), our findings indicate that expanding prescription drug benefits

to older adults may not adequately reduce racial differences in medication treatment and control for chronic conditions.

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 $\label{eq:Table 1} \textbf{Table 1}$ Characteristics of Participants with CHD and/or DM by Race Before and After Part D*

	Refore (n=1,091)	After (n=771)
	Black	White	Black	White
Factors	n (%)	n (%)	n (%)	n (%)
<u>Demographics</u>				
Age, mean (SD)	78.23	78.75	81.79	82.46
	(2.90)	(2.86)	(2.70)	(2.81)
Female	275	204	172	159
	(58.39)	(32.90)	(58.50)	(33.33)
Pittsburgh site	240	300	148	250
	(49.04)	(48.39)	(50.34)	(52.41)
Married	167	391	101	276
	(35.46)	(63.06)	(34.35)	(57.86)
Literacy level 9th grade	243 (51.59)	539 (86.94)	161 (54.76)	425 (89.10)
<u>Health Status</u> <u>Factors</u>				
Peripheral arterial disease	39 (8.28)	45 (7.26)	29 (9.86)	43 (9.01)
Osteoporosis	39	59	18	49
	(8.28)	(9.52)	(6.12)	(10.27)
Cognitive impairment	116	34	103	41
	(24.63)	(5.48)	(35.03)	(8.60)
Vision impairment	11	8	21	11
	(2.34)	(1.29)	(7.14)	(2.31)
Hearing impairment	22	36	13	29
	(4.67)	(5.81)	(4.42)	(6.08)
Fair/poor self-	192	146	108	111
rated health	(40.76)	(23.55)	(36.73)	(23.27)
Mod/high intensity exercise	51 (10.83)	148 (23.87)	56 19.05)	132 (27.67)
BMI>=30	183	151	108	120
	(38.85)	(24.35)	(36.73)	(25.16)
Smoker	30	14	18	10
	(6.37)	(2.26)	(6.12)	(2.10)
Received influenza vaccine	307 (65.18)	509 (82.10)	211 (71.77)	431 (90.36)
Access to Health Care				
Family Income< \$25,000	322 (68.37)	225 (36.29)	188 (63.95)	143 (29.98)
Has other assets	186	531	140	471
	(39.49)	(85.65)	(47.62)	(87.42)
Recent	80	86	53	78
hospitalization	(16.99)	(13.87)	(18.03)	(16.35)
Has drug	259	386	219	390
benefit	(54.99)	(62.26)	(74.49)	(81.86)
LDL-C, mean (SD)	107.33	95.54	109.28	96. 18
	(34.86)	(29. 58)	(38.40)	(33.04)

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Table 2

Any Use of Anti-lipemics Before and After Part D by Race

	Unad Anti-lip	Unadjusted Anti-lipemic Use	Adjusted Racial Difference	. Racial ence	Comparison of Av Impact of Part D	Comparison of Adjusted* Impact of Part D
	Blacks (%)	Whites (%)	Adjusted Odds Ratio	95% CI	Ratio of Odds Ratios	95% CI
Pre-Part D	32.70	49.35	0.56	0.41 - 0.76	,	Reference
Post Part D 48.30	48.30	64.57	09.0	0.43-0.84	1.07	0.79-1.45

*
Controlling for age, sex, health literacy, site, peripheral arterial disease, self-rated health, cognitive impairment, hearing impairment, moderate/high intensity exercise, obesity, smoking, influenza vaccination, income, other assets, recent hospitalization and prescription drug benefit

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Table 3

Poor Lipid Control Before and After Part D by Race

	Unadjus Lipid (Unadjusted Poor Lipid Control	Adjusted Racial Difference	Racial ence	Comparison Impact	Comparison of Adjusted* Impact of Part D
	Blacks (%)	Whites (%)	Adjusted Odds Ratio	95% CI	Ratio of Odds Ratios	95% CI
Pre-Part D	24.30	12.36	1.74	1.15–2.64	1	Reference
Post-Part D	24.46	13.72	1.43	0.92-2.24	0.82	0.51 - 1.33

*
Controlling for age, sex, health literacy, site, osteoporosis, self-rated health, moderate/ high intensity exercise, influenza vaccination, obesity, income, and prescription drug benefit

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