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ORIGINAL RESEARCH

Recurrent Atherosclerotic Cardiovascular Event Rates Differ Among Patients Meeting the Very High Risk Definition According to Age, Sex, Race/Ethnicity, and Socioeconomic Status

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BACKGROUND: The risk for atherosclerotic cardiovascular disease (ASCVD) events may differ by sociodemographic factors among patients meeting the definition of very high risk according to the 2018 American Heart Association/American College of Cardiology cholesterol guideline, leading to treatment disparities. We estimated the risk for recurrent ASCVD events among adults meeting the definition of very high risk by age, sex, race/ethnicity, and socioeconomic status in a US integrated health-care system.

METHODS AND RESULTS: The study cohort included Kaiser Permanente Southern California members aged ≥21 years with a history of clinical ASCVD on September 30, 2009. Very high risk for recurrent ASCVD was defined by a history of ≥2 major ASCVD events or a history of 1 major event along with ≥2 high-risk conditions. Patients were followed through 2015 for a first recurrent ASCVD event. Of 77 101 patients with ASCVD, 50.8% met the definition for very high risk. Among patients meeting the definition of very high risk, recurrent ASCVD rates were higher in older (>75 years) versus younger patients (21–40 years) (sex-adjusted hazard ratio [HR] [95% CI] 1.85; 1.23–2.79), non-Hispanic Black patients versus non-Hispanic White patients (age-, sex-adjusted HR, 1.32; 1.23–1.41), those who lived in neighborhoods with lower (<$35k) versus higher annual household income (≥$80k) (HR, 1.20; 1.11–1.30), or with lower (≥31.2%) versus higher education levels (<8.8% high school or lower) (HR, 1.26; 1.19–1.34).

CONCLUSIONS: Disparities in the risk for recurrent ASCVD events were present across sociodemographic factors among very high risk patients. The addition of sociodemographic factors to current definitions of very high risk could reduce health disparities.

Key Words: cholesterol ■ disparities ■ race and ethnicity ■ secondary prevention ■ sex ■ socioeconomic position

The 2018 American Heart Association (AHA)/American College of Cardiology (ACC) cholesterol guideline categorizes a subgroup of individuals with a history of clinical atherosclerotic cardiovascular disease (ASCVD) as having a very high risk for recurrent ASCVD events.[1] In this guideline, very high risk is defined as having multiple prior major ASCVD events or 1 prior major ASCVD event with multiple high risk conditions. High risk conditions include age ≥65 years, familial hypercholesterolemia, prior coronary procedures, diabetes mellitus, hypertension, chronic kidney disease, current smoking, persistently elevated

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CLINICAL PERSPECTIVE

What Is New?

- The proportion of patients meeting the definition for very high risk according to 2018 American Heart Association/American College of Cardiology cholesterol guideline was higher among older adults, non-Hispanic Black adults, and individuals living in neighborhoods with lower income or education.
- Among patients meeting the definition of very high risk atherosclerotic cardiovascular disease (ASCVD), those who were older, non-Hispanic Black, and those with lower socioeconomic status had a higher risk of recurrent ASCVD.

What Are the Clinical Implications?

- Discrimination of ASCVD risk among patients with very high predicted ASCVD risk and directing secondary prevention interventions could reduce disparities in recurrent ASCVD risk among racial, ethnic, and socioeconomic groups.

Nonstandard Abbreviations and Acronyms

AHA/ACC	American Heart Association/American College of Cardiology
PCSK9	proprotein convertase subtilisin/kexin type 9

low-density lipoprotein cholesterol, or congestive heart failure. The guideline states that it is reasonable to add ezetimibe and/or a PCSK9 (proprotein convertase subtilisin/kexin type 9) inhibitor for individuals who are categorized as having a very high risk and are taking maximally tolerated statin therapy.[1] A recent analysis of US adults with commercial health insurance found that 55% of those with clinical ASCVD met the definition for very high risk.[2]

Studies have shown that recurrent ASCVD events and mortality are disproportionally higher in racial/ethnic minorities,[3] women,[3] and socially disadvantaged individuals including those with lower education or income level,[4,5] and living in more disadvantaged neighborhoods.[6] However, it is unknown whether recurrent ASCVD risk varies according to age, sex, race/ethnicity, and socioeconomic status among patients meeting the 2018 AHA/ACC cholesterol guideline definition of very high risk. If risk varies among those meeting the definition of very high ASCVD risk according to these socio-demographic factors, intensive lipid-lowering therapy could be more efficiently directed to certain groups of high risk to eliminate disparities in the delivery of secondary prevention treatment, and narrow racial, ethnic, and socioeconomic disparities in recurrent ASCVD events.

The primary objective of the current study was to determine if the rates of recurrent ASCVD differ across subgroups defined by age, sex, race/ethnicity, and socioeconomic status among patients meeting the definition for very high ASCVD risk according to the 2018 AHA/ACC cholesterol guideline. The secondary objectives were to assess differences in the proportion of patients meeting the definition of very high ASCVD risk by age, sex, race/ethnicity, and socioeconomic status; and to compare the proportion of patients meeting the definition for very high risk who are taking a high intensity statin across subgroups according to age, sex, race/ethnicity, and socioeconomic status.

METHODS

Anonymized data that support the findings of this study are made available from the corresponding author on reasonable request from qualified researchers with documented evidence of training for human subjects protections.

Study Design

We identified members aged ≥21 years enrolled in Kaiser Permanente Southern California, a large US integrated healthcare system, on September 30, 2009, a date that we refer to as the index date. We required members to be continuously enrolled in the health plan with pharmacy benefits during a 12-month baseline period from October 1, 2008 to September 30, 2009. We considered patients with a gap of insurance and/or pharmacy benefit coverage ≤45 days as being continuously eligible throughout the baseline period. The baseline period was used to identify healthcare utilization, comorbidities, laboratory testing, and medication dispenses. We included patients with a history of clinical ASCVD defined as acute coronary syndrome, myocardial infarction (MI), stable or unstable angina, coronary or other revascularization procedures, ischemic stroke, or peripheral arterial disease of atherosclerotic origin based on *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*) diagnosis, and procedure codes (Table S1). For a history of clinical ASCVD, we assessed all available electronic health records before the index date, even before the baseline period. We followed patients until disenrollment from the health plan, death, the study end date (September 30, 2015), or the outcomes of interest as described next, whichever occurred first. The study was approved by the Kaiser Permanente

Southern California institutional review committee and informed consent was waived.

Definition of Very High-Risk ASCVD

The 2018 AHA/ACC cholesterol guideline defined very high risk as having (1) a history of multiple major ASCVD events, or (2) 1 major ASCVD event along with multiple high-risk conditions.[1] Major ASCVD events included recent acute coronary syndrome within the past 12 months, history of MI other than a recent acute coronary syndrome, history of ischemic stroke, or symptomatic peripheral arterial disease. High-risk conditions included age ≥65 years, familial hypercholesterolemia, prior coronary artery bypass grafting or percutaneous coronary intervention, diabetes mellitus, hypertension, chronic kidney disease, current smoking, persistently elevated low-density lipoprotein cholesterol (≥100 mg/dL) despite statin therapy, or history of congestive heart failure. Diagnoses, procedures, laboratory results used to define major ASCVD events, and high-risk conditions are included in Table S2.

Age, Sex, Race/Ethnicity, and Socioeconomic Status

Information on age, sex and race/ethnicity was extracted from both administrative records and patient self-reported data. We categorized race/ethnicity as non-Hispanic White, non-Hispanic Black, non-Hispanic Asian/Pacific Islander, Hispanic, or other (multiple races or unknown). We used neighborhood income and neighborhood education levels as surrogate indicators of socioeconomic status.[7,8] Neighborhood income and neighborhood education levels were estimated by linking Kaiser Permanente Southern California members' home addresses via geocoding and 2000 US Census block data.[9] For neighborhood income, we assigned each member the median household income of his/her block: $0 to $34k, $35k to $49k, $50k to $64k, $65k to $79k, or ≥$80k. For neighborhood education levels, we grouped each member according to the percentage of people with a high school or less education in his/her block, stratified into quartiles: ≥31.2% (Quartile 1, lowest education level), 17.1% to 31.1% (Q2), 8.8% to 17.0% (Q3), or <8.8% (Quartile 4, highest education level).

Outcomes

The clinical outcome of interest was the time to first recurrent ASCVD event during study follow-up, defined as nonfatal MI, death from coronary heart disease, or fatal or nonfatal ischemic stroke. Principal hospital discharge diagnoses were used to identify MI (*ICD-9* codes 410.x0, 410.x1)[10] and ischemic stroke (*ICD-9* codes 433.x1, 434.x1, 436.xx).[11,12] Death from coronary heart disease and stroke was identified using *ICD-10* codes (I20-I25) from hospital records, and California State death files.[13]

High intensity statin use was defined by a prescription fill during the baseline period and defined based on the 2018 AHA/ACC cholesterol treatment guidelines as any fills of atorvastatin daily dose of 40 to 80 mg, simvastatin daily dose of 80 mg, simvastatin daily dose of 40 mg when using ezetimibe-simvastatin combination, or rosuvastatin daily dose of 20 to 40 mg.[1] Other statin therapy such as fluvastatin, lovastatin, and pravastatin was not included as they are not classified as high intensity statins in the 2018 AHA/ACC cholesterol treatment guideline.[1]

Statistical Analysis

We calculated the proportion and characteristics of patients who met and did not meet the definition of very high risk based on a history of major ASCVD events and high-risk conditions. Among patients who met and did not meet the definition of very high risk separately, the cumulative incidence of recurrent ASCVD events was calculated stratified by age, sex, race/ethnicity, and socioeconomic status from Kaplan-Meier estimates. Log-rank tests were used to detect statistically significant differences of cumulative incidence across the subgroups. The recurrent ASCVD event rate was calculated as the number of recurrent events per 1000 person-years during follow-up. We used an age-adjusted cause-specific hazards regression model to determine whether risk of recurrent ASCVD differed by sex considering death other than coronary heart disease or stroke as a competing risk. Sex-adjusted models were used to estimate the hazard ratios for a first recurrent ASCVD event across age subgroups and age- and sex-adjusted regression analyses were used to estimate HRs across race/ethnicity, and socioeconomic status subgroups. The proportion of patients on high intensity statin among those meeting and not meeting the very high risk definition was calculated within subgroups defined by age, sex, race/ethnicity, and socioeconomic status. Patients aged >75 years old were excluded from the subgroup of patients not meeting the very high risk definition when calculating the proportion of patients of high intensity statin use since these patients are recommended for moderate intensity statin but not high intensity statin when low-density lipoprotein cholesterol levels are 70 to 189 mg/dL according to the 2018 AHA/ACC cholesterol guideline.[1] $P<0.05$ considered statistical significance with no adjustment for multiplicity. All analyses were conducted using SAS 9.4 (SAS Institute Inc., Cary, NC).

RESULTS

Patient Characteristics

There were 77 101 patients with a history of clinical ASCVD who met the inclusion criteria for the current

analysis. The mean (SD) age of participants was 70.4 (11.7) years, 35.3% were women and 61.1% of patients were non-Hispanic White, 10.2% non-Hispanic Black, 19.3% Hispanic, and 7.6% non-Hispanic Asian (Table 1). Overall, 26.3% of patients had a recent acute coronary syndrome, 30.8% had a history of MI other than a recent acute coronary syndrome, 3.4% had a history of stroke, and 1.9% had a symptomatic peripheral artery disease. The most common high-risk conditions were age ≥65 years (69.2%), hypertension (64.2%), and prior revascularization procedure (53.5%). A majority of patients (98.9%) had 1 or more low-density lipoprotein cholesterol measurements during the baseline period and 72.2% had low-density lipoprotein cholesterol levels ≥70 mg/dL.

Proportion of Patients Meeting the Very High Risk Definition

A total of 39 174 (50.8%) patients met the 2018 ACC/AHA cholesterol guideline definition for having very high risk. Among this group, 10 524 patients (26.9%) had experienced multiple ASCVD events and 28 650 patients (73.1%) had experienced 1 ASCVD event and had 2 or more high-risk conditions. The proportion of patients meeting the definition of very high risk was higher in older age groups (55% versus 30% comparing age >75 years to 21–40 years) and among non-Hispanic Black patients (55% versus 50% in non-Hispanic White patients, 52% in Hispanic patients and 47% in non-Hispanic Asian patients), those who lived in lower income neighborhoods (54% versus 48% comparing median household income of $0–$34k to ≥$80k), or lower education levels (53% versus 49% comparing neighborhood with a percentage of high school or lower education of ≥31.2% to <8.8%) (Figure 1).

Risk of Recurrent ASCVD by Age, Sex, Race/Ethnicity, and Socioeconomic Subgroups

A total of 13 281 patients had a recurrent ASCVD event during a median follow-up of 6 years. Among patients with very high risk, the cumulative incidence of recurrent ASCVD was higher in older versus younger patients, women versus men, non-Hispanic Black patients versus those of other race/ethnic groups, those who lived in neighborhoods with lower versus higher income or lower versus higher education (Figure 2). Among those not meeting the definition of very high risk, the cumulative incidence of recurrent ASCVD was higher in men versus women.

The rate of having a first recurrent ASCVD event during follow-up was 39.7 per 1000 person-years. The recurrent ASCVD event rate was higher among patients meeting versus not meeting the definition of very high ASCVD risk (51.8 versus 28.6 events per 1000 person-years) (Table 2). The cumulative incidence of recurrent ASCVD was higher among patients meeting versus not meeting the definition of very high ASCVD risk among all subgroups of age, sex, race/ethnicity, and socioeconomic status (Figure S1). Among patients meeting the definition of very high ASCVD risk, recurrent ASCVD rates were higher in older (>75 years) versus younger patients (21–40 years) (sex-adjusted HR, 1.85 [95% CI, 1.23–2.79]). Among patients meeting the definition of very high risk, there were no evidence of a difference in recurrent ASCVD risks between men and women after adjustment for age (age-adjusted HR, 0.96 [95% CI, 0.92–1.01]). After adjustment for age and sex, among patients meeting the definition of very high risk, adjusted HRs were 1.32 (95% CI, 1.23–1.41) comparing non-Hispanic Black patients versus non-Hispanic White patients, 1.20 (95% CI, 1.11–1.30) comparing those living in neighborhoods with median household income <$35k to ≥$80k, and 1.26 (95% CI, 1.19–1.34) comparing those living in neighborhoods with a percentage of high school or lower education of ≥31.2% to <8.8%.

High Intensity Statin Use by Age, Sex, Race/Ethnicity, and Socioeconomic Subgroups

Over 70% of patients within every subgroup investigated except those aged 21 to 40 years old was taking a statin. The proportion of patients taking a high intensity statin ranged across subgroups from 21% to 34% for those meeting the very high risk definition, and from 14% to 32% for those not meeting the very high risk definition (Figure 3). Among patients meeting the definition of very high risk, the proportion of patients taking a high intensity statin was lower in older age groups (>75 years) versus younger age groups (41–65 years), women versus men, non-Hispanic White patients or Hispanic patients versus non-Hispanic Black patients or non-Hispanic Asian patients.

DISCUSSION

In the current study, the proportion of patients meeting the definition of very high ASCVD risk according to the 2018 AHA/ACC cholesterol treatment guideline was higher among older patients, non-Hispanic Black patients, and those who lived in neighborhoods with lower income or education. Among patients meeting the definition of very high risk, those who were older, non-Hispanic Black, and living in neighborhoods with lower income or education had a higher age- and/or sex-adjusted risk for recurrent ASCVD events. These findings suggest that age, race/ethnicity and

Table 1. Characteristics of Patients Meeting the Very High ASCVD Risk Definition Versus Not Meeting the Definition

	Total	Very High Risk			
		No	Yes		
			Total	One ASCVD Event Plus Multiple (≥2) High-Risk Conditions	Multiple (≥2) ASCVD Events
Patient, N (row percent)	77 101 (100%)	37 927 (49.2%)	39 174 (50.8%)	28 650 (37.2%)	10 524 (13.6%)
Age in y, mean (SD)	70.4 (11.7)	69.3 (11.9)	71.5 (11.3)	71.8 (11.0)	70.8 (12.0)
21–40 y	629 (0.8%)	440 (1.2%)	189 (0.5%)	108 (0.4%)	81 (0.8%)
41–65 y	25 046 (32.5%)	13 920 (36.7%)	11 126 (28.4%)	7717 (26.9%)	3409 (32.4%)
66–75 y	23 645 (30.7%)	11 010 (29.0%)	12 635 (32.3%)	9623 (33.6%)	3012 (28.6%)
>75 y	27 781 (36.0%)	12 557 (33.1%)	15 224 (38.9%)	11 202 (39.1%)	4022 (38.2%)
Women	27 236 (35.3%)	13 594 (35.8%)	13 642 (34.8%)	10 053 (35.1%)	3589 (34.1%)
Race/Ethnicity					
Non-Hispanic White	47 075 (61.1%)	23 404 (61.7%)	23 671 (60.4%)	17 451 (60.9%)	6220 (59.1%)
Non-Hispanic Black	7853 (10.2%)	3507 (9.2%)	4346 (11.1%)	3112 (10.9%)	1234 (11.7%)
Hispanic	14 887 (19.3%)	7131 (18.8%)	7756 (19.8%)	5616 (19.6%)	2140 (20.3%)
Non-Hispanic Asian	5877 (7.6%)	3129 (8.3%)	2748 (7.0%)	2025 (7.1%)	723 (6.9%)
Others*	1409 (1.8%)	756 (2.0%)	653 (1.7%)	446 (1.6%)	207 (2.0%)
Major ASCVD events					
≥1 recent acute coronary syndrome	20 280 (26.3%)	1706 (4.5%)	18 574 (47.4%)	11 258 (39.3%)	7316 (69.5%)
≥1 acute myocardial infarction	23 741 (30.8%)	4651 (12.3%)	19 090 (48.7%)	16 011 (55.9%)	3079 (29.3%)
≥1 ischemic stroke	2599 (3.4%)	269 (0.7%)	2330 (5.9%)	753 (2.6%)	1577 (15%)
Symptomatic peripheral artery disease	1472 (1.9%)	158 (0.4%)	1314 (3.4%)	628 (2.2%)	686 (6.5%)
High-risk conditions					
Age ≥65 y	53 389 (69.2%)	24 449 (64.5%)	28 940 (73.9%)	21 655 (75.6%)	7285 (69.2%)
Familial hypercholesterolemia	2167 (2.8%)	850 (2.2%)	1317 (3.4%)	990 (3.5%)	327 (3.1%)
Prior revascularization procedure (coronary artery bypass grafting or percutaneous coronary intervention)	41 270 (53.5%)	17 123 (45.1%)	24 147 (61.6%)	17 259 (60.2%)	6888 (65.5%)
Diabetes mellitus	26 281 (34.1%)	10 525 (27.8%)	15 756 (40.2%)	11 349 (39.6%)	4407 (41.9%)
Hypertension	49 530 (64.2%)	20 907 (55.1%)	28 623 (73.1%)	21 111 (73.7%)	7512 (71.4%)
Chronic kidney disease	18 913 (24.5%)	6813 (18%)	12 100 (30.9%)	8243 (28.8%)	3857 (36.6%)
Current smoking	4826 (6.3%)	1945 (5.1%)	2881 (7.4%)	2175 (7.6%)	706 (6.7%)
Persistently elevated LDL-C	8976 (11.6%)	3870 (10.2%)	5106 (13.0%)	3928 (13.7%)	1178 (11.2%)
Heart failure	15 109 (19.6%)	3730 (9.8%)	11 379 (29.0%)	7026 (24.5%)	4353 (41.4%)
LDL-C (mg/dL), mean (SD)†	87.5 (31.2)	89.1 (30.8)	86.0 (31.4)	86.7 (31.3)	84.0 (31.7)

(*Continued*)

Table 1. Continued

	Total	Very High Risk			
		No	Yes		
			Total	One ASCVD Event Plus Multiple (≥2) High-Risk Conditions	Multiple (≥2) ASCVD Events
LDL-C ≥70 mg/dL	55 065 (72.2%)	27 990 (75.1%)	27 075 (69.5%)	20 154 (70.7%)	6921 (66.3%)
Ambulatory visits					
0	2092 (2.7%)	1478 (3.9%)	614 (1.6%)	412 (1.4%)	202 (1.9%)
1–5	17 305 (22.4%)	10 312 (27.2%)	6993 (17.9%)	5528 (19.3%)	1465 (13.9%)
≥6	57 704 (74.8%)	26 137 (68.9%)	31 567 (80.6%)	22 710 (79.3%)	8857 (84.2%)
Charlson Comorbidity Score					
0	12 065 (15.6%)	9363 (24.7%)	2702 (6.9%)	2292 (8.0%)	410 (3.9%)
1	14 599 (18.9%)	8256 (21.8%)	6343 (16.2%)	5017 (17.5%)	1326 (12.6%)
2	12 229 (15.9%)	6120 (16.1%)	6109 (15.6%)	4749 (16.6%)	1360 (12.9%)
≥3	38 208 (49.6%)	14 188 (37.4%)	24 020 (61.3%)	16 592 (57.9%)	7428 (70.6%)
Health plan type					
Commercial	28 695 (37.2%)	15 446 (40.7%)	13 249 (33.8%)	9385 (32.8%)	3864 (36.7%)
Medicare	46 588 (60.4%)	21 413 (56.5%)	25 175 (64.3%)	18 728 (65.4%)	6447 (61.3%)
Medicaid	492 (0.6%)	243 (0.6%)	249 (0.6%)	175 (0.6%)	74 (0.7%)
Private pay	1325 (1.7%)	824 (2.2%)	501 (1.3%)	362 (1.3%)	139 (1.3%)
Neighborhood income (annual median household income)‡					
≥$80k	23 107 (30.1%)	11 943 (31.6%)	11 164 (28.6%)	8258 (28.9%)	2906 (27.7%)
$65k–$79.9k	14 069 (18.3%)	6950 (18.4%)	7119 (18.2%)	5239 (18.3%)	1880 (17.9%)
$50–$64.9k	16 687 (21.7%)	8110 (21.5%)	8577 (21.9%)	6255 (21.9%)	2322 (22.1%)
$35k–$49.9k	15 624 (20.3%)	7377 (19.5%)	8247 (21.1%)	5979 (20.9%)	2268 (21.6%)
$0–$34.9k	7379 (9.6%)	3406 (9.0%)	3973 (10.2%)	2854 (10.0%)	1119 (10.7%)
Neighborhood education (% with high school or lower, quartiles)‡					
Q4 (highest education level): <8.8%	19 497 (25.4%)	10 038 (26.6%)	9459 (24.2%)	7049 (24.7%)	2410 (23.0%)
Q3: 8.8–17.0%	19 276 (25.1%)	9614 (25.4%)	9662 (24.7%)	7131 (24.9%)	2531 (24.1%)
Q2: 17.1–31.1%	19 213 (25.0%)	9298 (24.6%)	9915 (25.4%)	7160 (25.0%)	2755 (26.3%)
Q1 (lowest education level) ≥31.2%	18 879 (24.6%)	8835 (23.4%)	10 044 (25.7%)	7245 (25.3%)	2799 (26.7%)

Data are shown as N (column percent) or mean (SD), unless otherwise noted. ASCVD indicates atherosclerotic cardiovascular disease; CABG,; and LDL-C, low-density lipoprotein cholesterol.
*Other race/ethnicity=multirace, other race/ethnicity, or unknown.
†Missing=1.1%.
‡Missing=0.3%

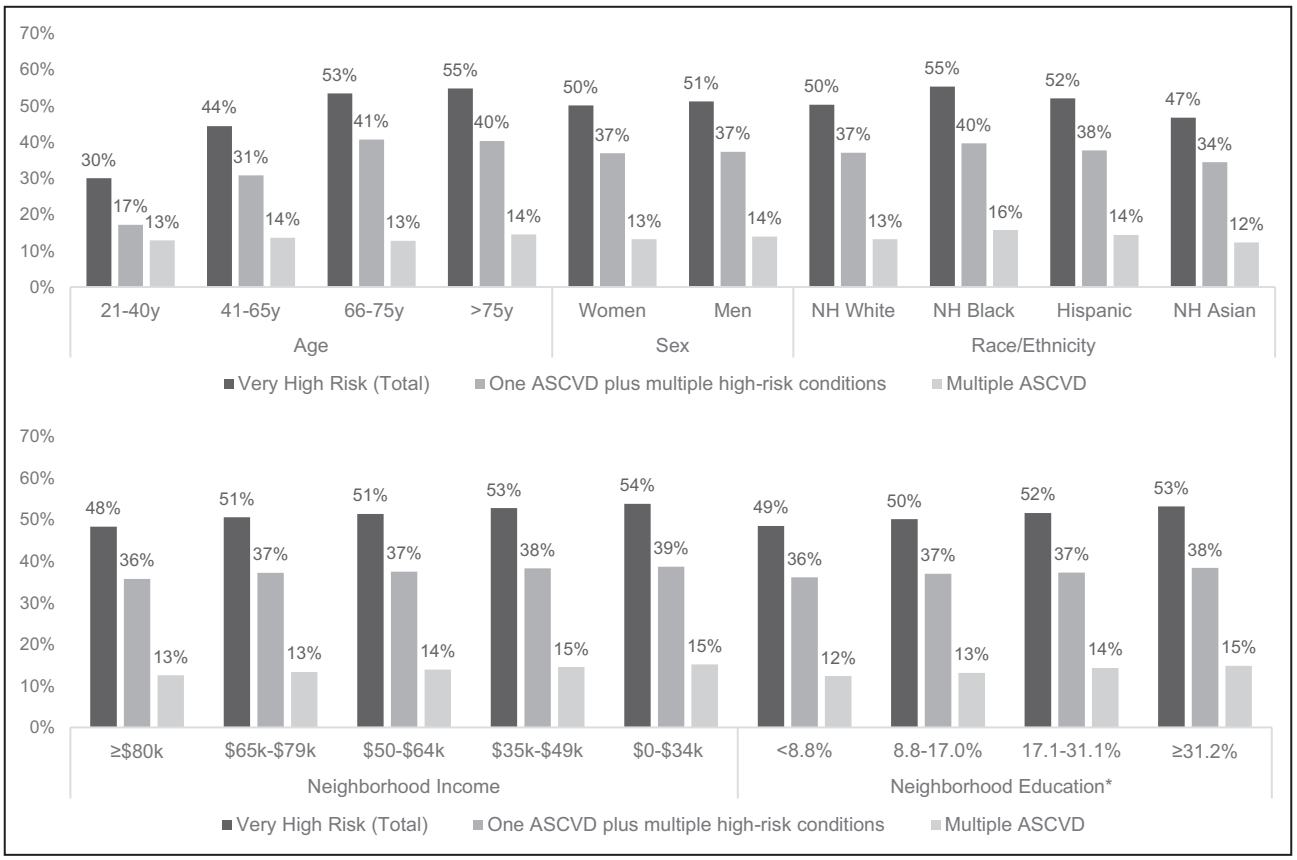

Figure 1. Proportion of patients meeting the very high ASCVD risk definition stratified by age, sex, race/ethnicity, and socioeconomic status.

Percentages of one ASCVD plus multiple (≥2) high-risk conditions and multiple (≥2) ASCVD may not sum to the total very high risk because of rounding. ASCVD indicates atherosclerotic cardiovascular disease; and NH, non-Hispanic. *Percentages of high school education or lower.

socioeconomic status are factors that can be used to refine the current algorithm for identifying patients with very high risk ASCVD.

More than half of the patients with a history of clinical ASCVD in the current analysis met the definition of very high risk according to the 2018 AHA/ACC cholesterol treatment guideline. These findings are consistent with a recent study of 27 775 US adults with commercial health insurance, which found that 55.3% of those with clinical ASCVD met the definition for very high risk.[2] The current study expands on this prior work by further assessing the differences in the proportion of patients meeting the definition of very high risk ASCVD across subgroups of age, sex, race/ethnicity, and socioeconomic status. The proportion of patients meeting the definition of very high risk was 4% to 8% higher in non-Hispanic Black adults compared with other race/ethnic groups, and in patients who lived in neighborhoods with lower versus higher income and education levels. The definition of very high risk includes previous ASCVD events and high-risk conditions such as diabetes mellitus, hypertension, chronic kidney disease, which have shown to be more prevalent among older patients, non-Hispanic Black patients, and patients with low socioeconomic status.[3]

The rate of recurrent ASCVD events was almost doubled among those categorized as very high risk versus not very high risk, confirming that the 2018 AHA/ACC cholesterol guideline appropriately discriminates patients with and without very high risk. In all socio-demographic subgroups, the rate of recurrent ASCVD was at least 60% higher among those meeting versus not meeting the definition of very high risk. Additionally, among those with meeting the very high risk definition in the current study, the risks of recurrent ASCVD events were 85% higher among older (>75 years) versus younger (21–40 years) patients, at least 20% higher among non-Hispanic Black patients versus non-Hispanic White patients and those who lived in disadvantaged versus non-disadvantaged neighborhoods, with similar patterns being present in those categorized as having very high risk and not having very high risk. These findings suggest the 2018 AHA/ACC cholesterol guideline algorithm for

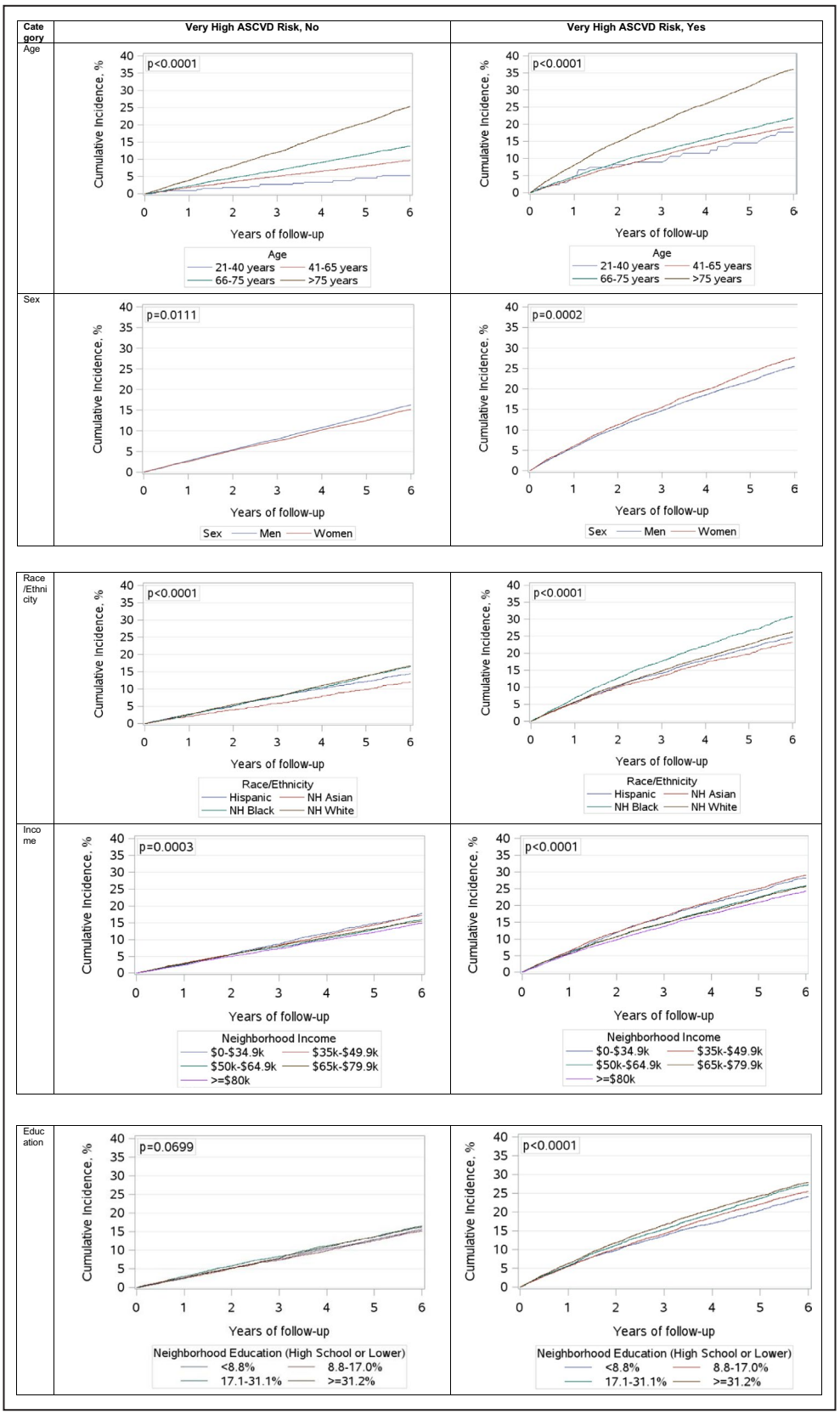

Figure 2. Cumulative incidence of recurrent ASCVD events stratified by age, sex, race/ethnicity, and socioeconomic status.
ASCVD indicates atherosclerotic cardiovascular disease; and NH, non-Hispanic.

Table 2. Rates and Hazard Ratios for Recurrent ASCVD Events Stratified by Age, Sex, Race/Ethnicity, and Socioeconomic Status

	Very High ASCVD Risk, No				Very High ASCVD Risk, Yes			
	Number of ASCVD	Person-Years	Rate Per 1000 Person-Years	Hazard Ratio*	Number of ASCVD	Person-Years	Rate Per 1000 Person-Years	Hazard Ratio*
Overall	5001	175 053	28.6	…	8280	159 841	51.8	…
Age								
21–40 y	17	1829	9.3	Ref	23	675	34.1	Ref
41–65 y	1112	65 121	17.1	1.81 (1.12, 2.92)	1747	47 886	36.5	1.08 (0.72, 1.63)
66–75y	1356	55 007	24.7	2.54 (1.58, 4.10)	2369	56 748	41.7	1.19 (0.79, 1.79)
>75y	2516	53 095	47.4	4.40 (2.73, 7.09)	4141	54 531	75.9	1.85 (1.23, 2.79)
Sex								
Men	3302	112 568	29.3	Ref	5316	105 851	50.2	Ref
Women	1699	62 485	27.2	0.82 (0.78, 0.87)	2964	53 990	54.9	0.96 (0.92, 1.01)
Race/Ethnicity								
Non-Hispanic White	3262	108 323	30.1	Ref	4991	96 761	51.6	Ref
Non-Hispanic Black	483	16 347	29.6	1.15 (1.04, 1.26)	1074	17 186	62.5	1.32 (1.23, 1.41)
Hispanic	862	32 965	26.2	1.05 (0.97, 1.13)	1570	32 317	48.6	1.07 (1.01, 1.13)
Non-Hispanic Asian	322	15 192	21.2	0.85 (0.76, 0.96)	535	11 845	45.2	1.02 (0.93, 1.12)
Neighborhood income (annual median household income)								
≥$80k	1516	56 983	26.6	Ref	2237	47 456	47.1	Ref
$65k–$79.9k	899	32 087	28.0	1.06 (0.97, 1.15)	1482	29 399	50.4	1.07 (1.00, 1.14)
$50–$64.9k	1066	37 359	28.5	1.08 (0.99, 1.16)	1790	35 034	51.1	1.10 (1.03, 1.17)
$35k–$49.9k	1027	33 173	31.0	1.16 (1.08, 1.26)	1890	32 346	58.4	1.22 (1.15, 1.30)
$0–$34.9k	482	15 042	32.0	1.21 (1.09, 1.34)	870	15 409	56.5	1.20 (1.11, 1.30)
Neighborhood education (high school or lower)								
<8.8%	1330	47 508	28.0	Ref	1880	40 020	47.0	Ref
8.8–17.0%	1218	44 703	27.3	1.01 (0.94, 1.09)	1998	39 948	50.0	1.08 (1.02, 1.15)
17.1–31.1%	1270	42 329	30.0	1.14 (1.06, 1.24)	2168	40 102	54.1	1.20 (1.13, 1.28)
≥31.2%	1172	40 099	29.2	1.16 (1.07, 1.26)	2223	39 574	56.2	1.26 (1.19, 1.34)

ASCVD indicates atherosclerotic cardiovascular disease.

*Age, sex-adjusted cause-specific hazard ratios (only sex is adjusted when stratified by age, and only age is adjusted when stratified by sex)

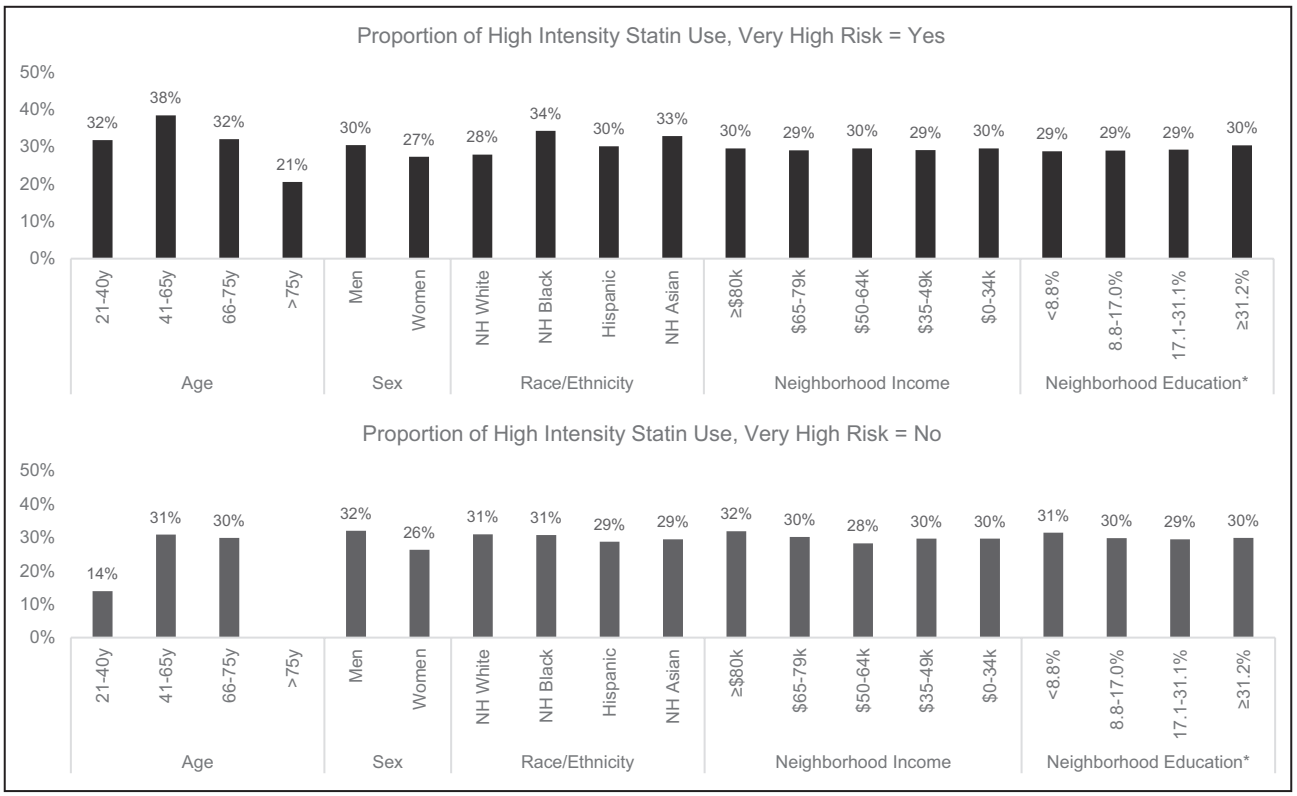

Figure 3. Proportion of patients taking a high intensity statin stratified by age, sex, race/ethnicity, and socioeconomic status.
ASCVD indicates atherosclerotic cardiovascular; and NH, non-Hispanic. *Percentages of high school education or lower.

categorizing very high risk could potentially be refined to further discriminate risk among those meeting the definition of very high risk. Further discrimination may narrow racial, ethnic, and socioeconomic disparities in recurrent ASCVD risk.

A low proportion of patients with ASCVD, including those who met the definition for very high risk were taking a high intensity statin, which is consistent with previous studies.[14,15] Although a previous study from Kaiser Permanente Southern California showed an increasing trend of high intensity statin use in recent years,[16] more efforts are needed to optimally manage patients with very high ASCVD risk. The 2018 AHA/ACC cholesterol guideline newly categorizes a subgroup with very high ASCVD risk who can potentially benefit from adding ezetimibe and/or PCSK9 inhibitors to the maximally tolerated statin therapy based on recent evidence.[1] Randomized trials demonstrated 15% to 21% relative risk reduction of recurrent ASCVD with PCSK9 inhibitors for patients receiving high or moderate intensity statin,[17–19] and 6% relative risk reduction when ezetimibe is added to statin therapy.[20] Given the high risk for recurrent ASCVD that patients meeting the very high risk definition have, there may be a large absolute risk reduction with the use of ezetimibe/PCSK9 inhibitors.[21] Future strategies to increase the use of high intensity statin, ezetimibe, and/or PCSK9 inhibitors need to be developed.

There was no evidence in the current study for high intensity statin treatment disparities across socioeconomic subgroups. Also, among those meeting the 2018 AHA/ACC cholesterol guideline definition of very high risk, the proportion of patients taking a high intensity statin was higher in non-Hispanic Black adults compared with non-Hispanic White adults. Lower statin adherence among non-Hispanic Black adults versus other race/ethnic groups may explain their higher risk of ASCVD events.[22–24] Regardless, there was limited evidence to indicate that adherence to a statin therapy would preclude those at elevated risk from benefiting from the added lipid therapy.

This study has several strengths including the inclusion of a large cohort of patients with a history of clinical ASCVD. Patients were followed for a median of 6 years. This large diverse population was able to address the differences in proportion of very high risk as well as the recurrent ASCVD event rates among subgroups of age, sex, racial/ethnicity, and socioeconomic status. This study also has several potential limitations. First, measurement error may be present. Proxy measures of several conditions

such as familial hypercholesterolemia and symptomatic peripheral artery disease were defined based on diagnosis, procedures, laboratory, and pharmacy records due to lack of genetic testing and complete clinical information. Second, the study period was from 2009 to 2015. With increased high intensity statin utilization in recent years,[16] the current rate of recurrent ASCVD events may be lower than we report. Also, the use of ezetimibe was very low in this population and the use of PCSK9 inhibitors was not evaluated since they became available towards the end of the study period. Future studies may be beneficial to further evaluate the recurrent ASCVD event rates with increased use of non-statin lowering therapy in addition to statins. Third, statin use was determined based on pharmacy refill data and it is unknown whether statin medications were taken as prescribed. Lastly, the current analysis reflects an integrated healthcare system with good access to pharmacy services for all members. In the general population, racial, ethnic, and socioeconomic treatment disparities may be greater due to differences in health care and medication access.

CONCLUSIONS

Over half of the patients with a history of clinical ASCVD in the current study met the 2018 AHA/ACC cholesterol guideline definition for very high risk. The proportion meeting the definition for very high risk was higher among older adults, non-Hispanic Black patients, and those with lower socioeconomic status. Non-Hispanic Black adults versus other race-ethnic groups and those with lower versus higher socioeconomic status had a higher risk of recurrent ASCVD events. These results suggest that ASCVD risk varies substantially, even among patients meeting the very high risk definition. Directing secondary prevention interventions to specific populations may more efficiently lower ASCVD risk and potentially close the gap in recurrent ASCVD risk among racial, ethnic, and socioeconomic groups.

ARTICLE INFORMATION

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Supplementary Material

Tables S1–S2
Figure S1

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Supplemental Material

Table S1. Definition of a History of Clinical ASCVD.

1. A history of clinical ASCVD was defined as: history of CHD (acute myocardial infarction, coronary revascularization, ischemic heart disease), ischemic stroke, or peripheral arterial disease to be of atherosclerotic origin.

2. History of CHD was defined as any of the following:
   a. Acute myocardial infarction: At least one inpatient discharge diagnosis of ICD-9 code 410.x1 (any position, does not have to be primary diagnosis).
   b. Coronary revascularization: At least one procedure ICD code, CPT code, or HCPCS code for PCI
   c. Other ischemic heart disease: Either at least one inpatient diagnosis (any position) or at least two outpatient diagnoses within a two-year window (any position) of: 411.xx, 413.xx (excluding 413.1).

3. History of Stroke was defined as any of the following:
   a. Ischemic stroke: At least one inpatient diagnosis or at least two outpatient diagnoses within a two-year window of ICD-9. 433.

4. History of Peripheral Arterial Disease was defined using criteria specified by as any of the following:
   a. Atherosclerosis of native arteries of the lower extremities: At least one primary inpatient diagnosis or two or more outpatient diagnoses within a two-year window of ICD-9 440.1, 440.2x, 440.3x, 440.4, 440.9, 445.xx.

Table S2. Definition of Major ASCVD Event and High-Risk Conditions.

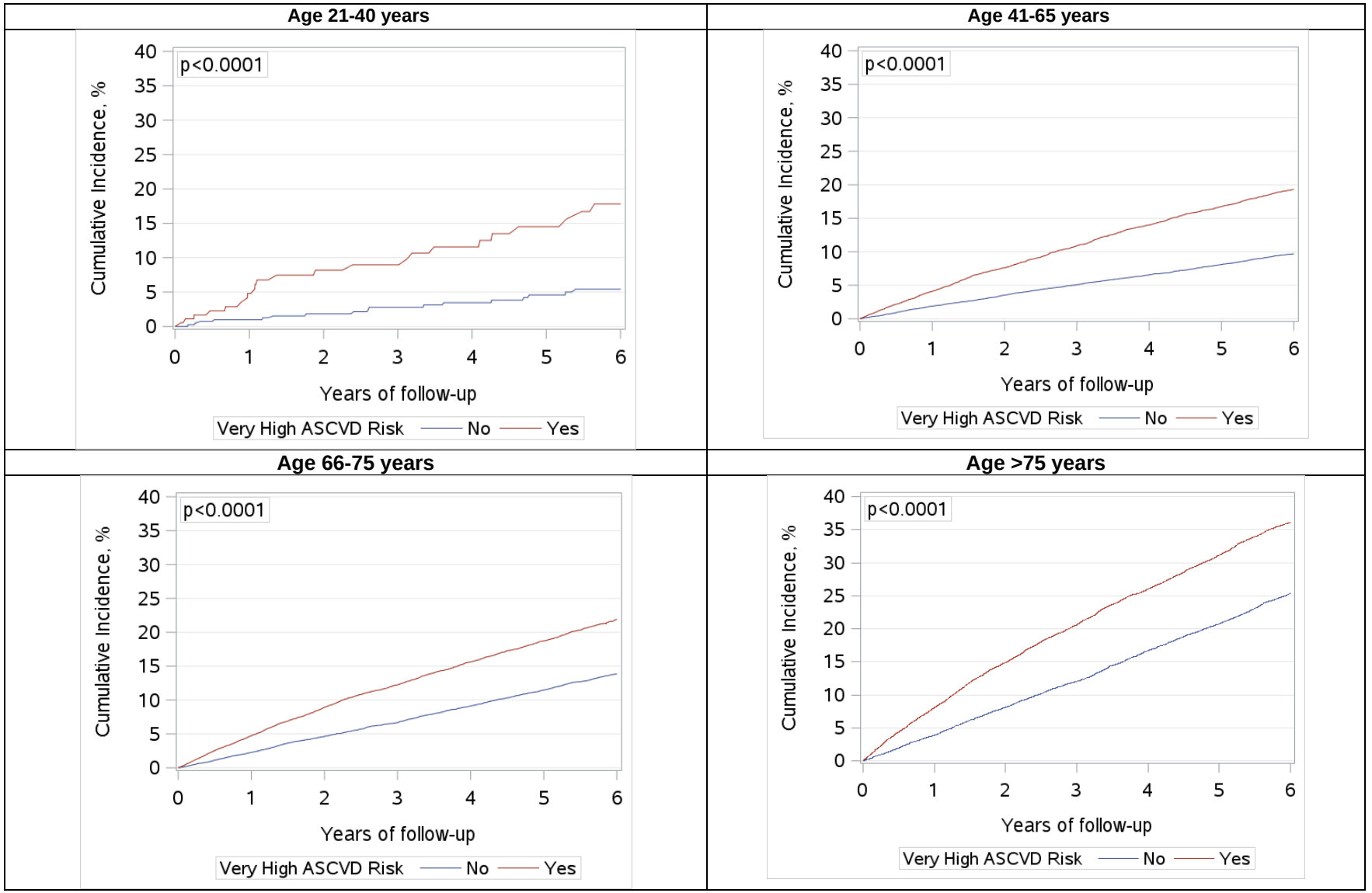
Major ASCVD event	Algorithm	List of diagnosis and procedure codes
Recent acute coronary syndrome (ACS)	An inpatient discharge diagnosis code for acute myocardial infarction or unstable angina in any discharge diagnosis position during the 12 months prior to the index date counted as one event. To avoid double counting, an inpatient discharge diagnosis code for acute myocardial infarction or unstable angina which were less than 30 days apart were considered to be part of the same event.	*Diagnosis codes for acute myocardial infarction:* ICD9: 410.x0, 410.x1. *Diagnosis codes for unstable angina:* ICD9: 411, 411.1, 411.81, 411.89, 414.x.
History of myocardial infarction (MI) other than ACS listed above	An inpatient discharge diagnosis code for acute myocardial infarction in any discharge diagnosis position prior to the index date was counted as one event. To avoid double counting, an inpatient discharge diagnosis code for acute myocardial infarction which were less than 30 days apart were considered to be part of the same event.	*Diagnosis codes for acute myocardial infarction:* ICD9 diagnosis codes for acute myocardial infarction: 410.x0, 410.x1.
History of Ischemic stroke	An inpatient discharge diagnosis code for ischemic stroke in any discharge diagnosis position during two years prior to the index date was counted as one event. To avoid double counting, an inpatient discharge diagnosis code for ischemic stroke in the primary position which were less than 30 days apart were considered to be part of the same event.	ICD9 diagnosis codes: 433.x1, 434.x1, 436
Symptomatic peripheral artery disease (PAD)	During the two years prior to the index date: • ≥1 inpatient discharge diagnosis code or ≥1 outpatient diagnosis code for peripheral artery disease AND • ≥1 lower limb amputation procedure code within 90 days prior to or after a code for peripheral artery disease	*Diagnosis codes for peripheral artery disease:* ICD9: 440.2, 440.21, 440.22, 440.23, 440.24, 440.29, 440.30, 440.31, 440.32, 440.4, 443.9. *Procedure codes for major amputation, peripheral artery revascularization:* CPT: 28800, 28805, 34151, 34201, 34203, 34900, 35081, 35082, 35091, 35102, 35103, 35131, 35132, 35141, 35142, 35151, 35152, 35331, 35341, 35351, 35355, 35361, 35363, 35371, 35372, 35381, 35450, 35452, 35454, 35456, 35459, 35470, 35471, 35472, 35473, 35474, 35481, 35482, 35483, 35485, 35490, 35491, 35492, 35493, 35495, 35521, 35531, 35533, 35541, 35546, 35548, 35549, 35551, 35556, 35558, 35563, 35565, 35566, 35571, 35583, 35585, 35587, 35621, 35623, 35646, 35647, 35651, 35654, 35656, 35661, 35663, 35665, 35666, 35671. *Procedure codes for major amputation, peripheral artery revascularization:* ICD9: 84.1, 84.10, 84.11, 84.12, 84.14, 84.15, 84.17, 84.91. ICD9: 39.25, 39.26, 39.29, 39.50, 39.90.

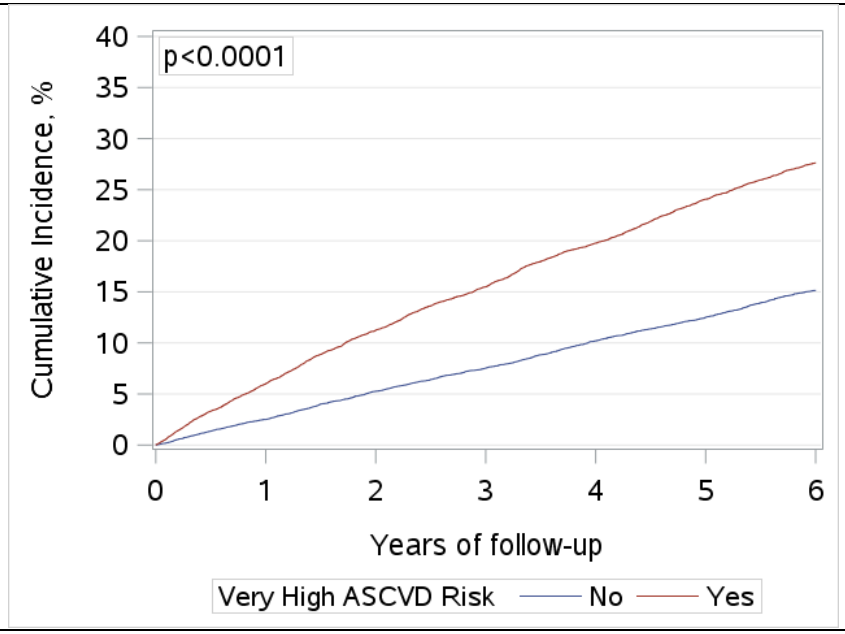
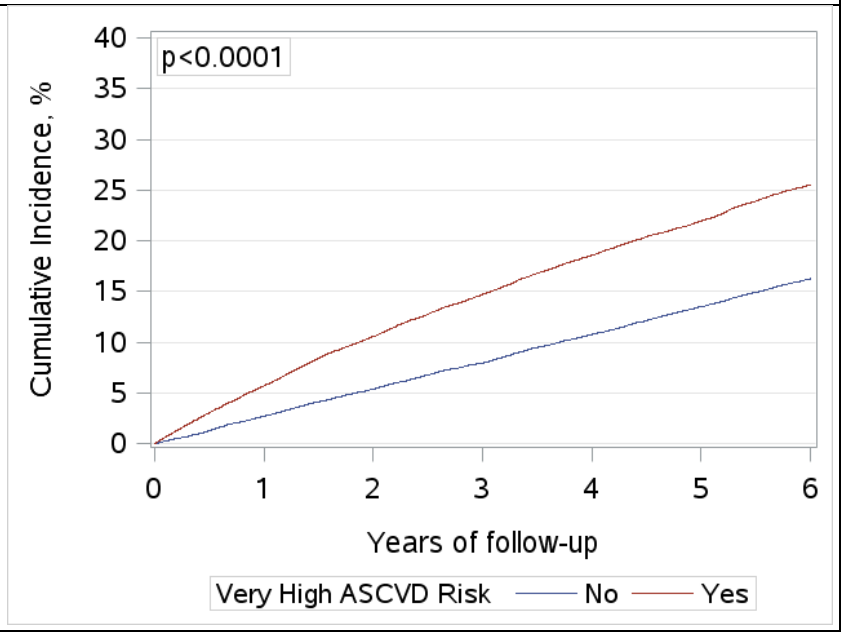
High risk conditions		
Age ≥65 years	Age at index date	None.
Familial hypercholesterolemia	Any of the following: • If no statin prescription, ≥2 LDL cholesterol values ≥190 mg/dL during the 12 months prior to the index date (if there is only one LDL cholesterol measure, then 1 LDL cholesterol values ≥190 mg/dL). • If there is a statin prescription, ≥1 LDL cholesterol values ≥190 mg/dL and ≥1 LDL cholesterol values ≥130 mg/dL during the 12 months prior to the index date (if there is only one LDL cholesterol measure, then 1 LDL cholesterol values ≥130 mg/dL).	None.
Prior coronary artery bypass grafting or percutaneous coronary intervention	Coronary revascularization: At least one procedure ICD code, CPT code, or HCPCS code for PCI prior to the index date	ICD-9 procedure codes: 00.66, 36.0x, 36.1x, 36.2 CPT codes: 92920, 92924, 92928, 92933, 92937, 92941, 92943, 92980, 92982, 92995, 33510-33519, 33521-33523, 33533-33536 HCPCS code: C9600, C9602, C9604, C9606, C9607
Diabetes mellitus	During the 12 months prior to the index date: • At least one primary inpatient discharge diagnoses • At least two or more outpatient diagnoses occurring on separate dates • At least one or more dispensed prescriptions for an oral hypoglycemic agent (excluding use of metformin or insulin exclusively without diagnosis of diabetes). • Women diagnosed with gestational diabetes (ICD-9 codes 648.0x, 648.8x, 790.22, 790.29) within 12 months of the index date were excluded from the definition of diabetes.	ICD9 diagnosis codes: 250.x
Hypertension	During the 12 months prior to the index date: • ≥2 outpatient diagnosis codes for hypertension at least 30 days apart	ICD9 diagnosis codes: 401.x-404.x
Chronic kidney disease	During the 12 months prior to the index date: • ≥2 estimated glomerular filtration rate less than 60 ml/min/1.73 m^2 at least 90 days apart	
Current smoking	Members self-report	
Persistently elevated low-density lipoprotein cholesterol despite statin therapy and ezetimibe	During the 12 months prior to the index date: • ≥1 statin prescription AND • The most proximal consecutive ≥2 LDL cholesterol values prior to the index date ≥100 mg/dL (if there is only one LDL cholesterol measure, then 1 LDL cholesterol values ≥100 mg/dL).	

History of heart failure	Any of the following during the two years prior to the index date: • ≥ inpatient discharge diagnosis code for heart failure in any discharge diagnosis position • ≥3 outpatient diagnosis codes for heart failure	ICD9 diagnosis codes: 398.91, 402.01, 402.11, 402.91, 404.01, 404.03, 404.11, 404.13, 404.91, 404.93, 428.0, 428.1, 428.2, 428.20, 428.21, 428.22, 428.23, 428.3, 428.30, 428.31, 428.32, 428.33, 428.4, 428.40, 428.41, 428.42, 428.43, 428.9.

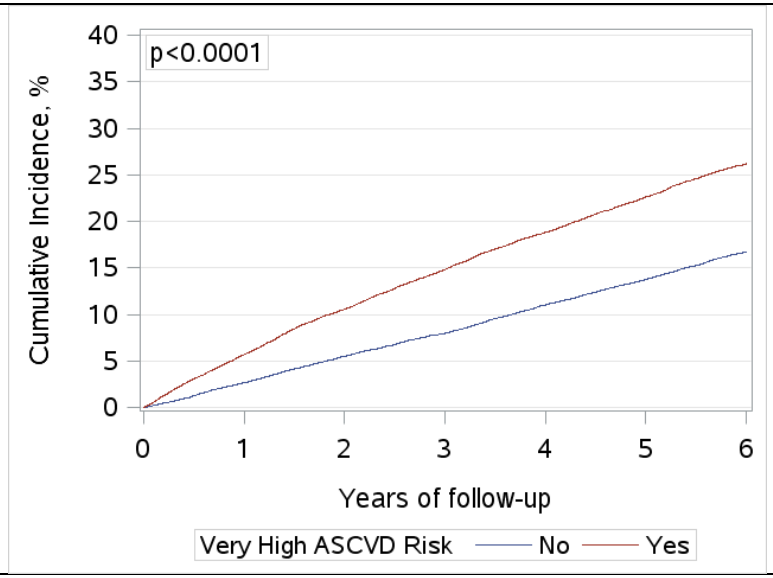
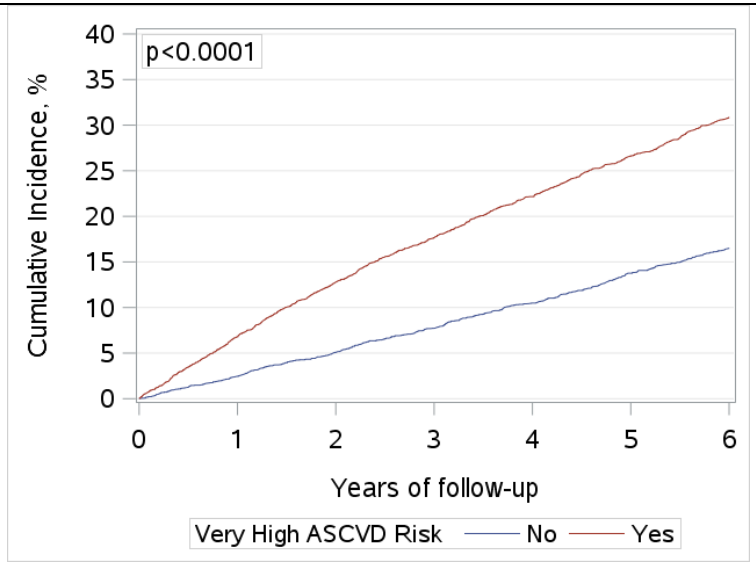
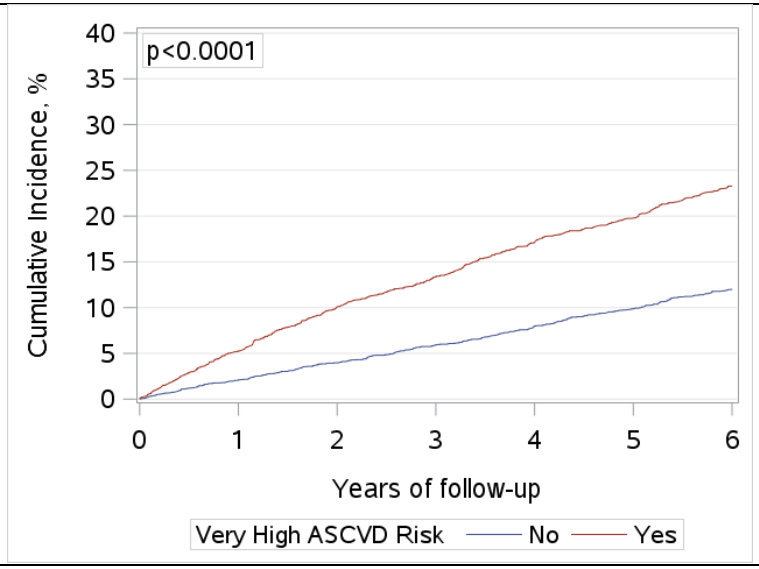
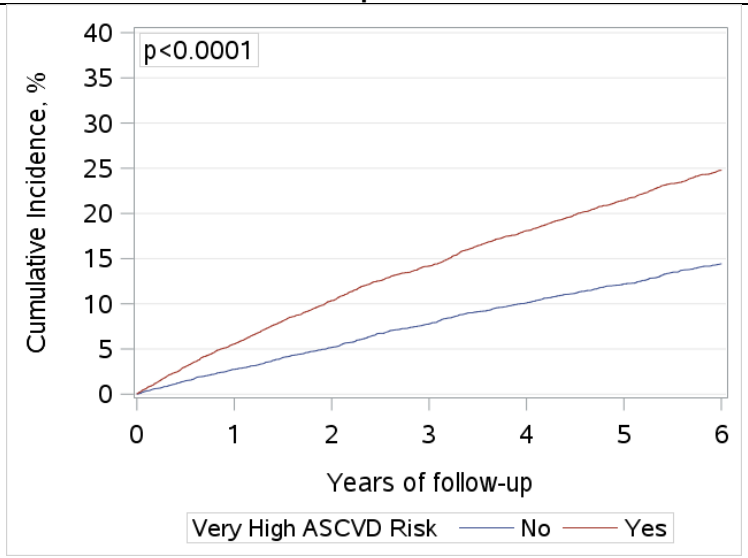
CPT: current procedural terminology; ICD9: International Classification of Diseases, ninth version

Figure S1. Cumulative Incidence of Recurrent ASCVD Events between Patients who meet the definition of Very High Risk vs Not Very High Risk Among Subgroups by Age, Sex, Race/Ethnicity, and Socioeconomic Status.

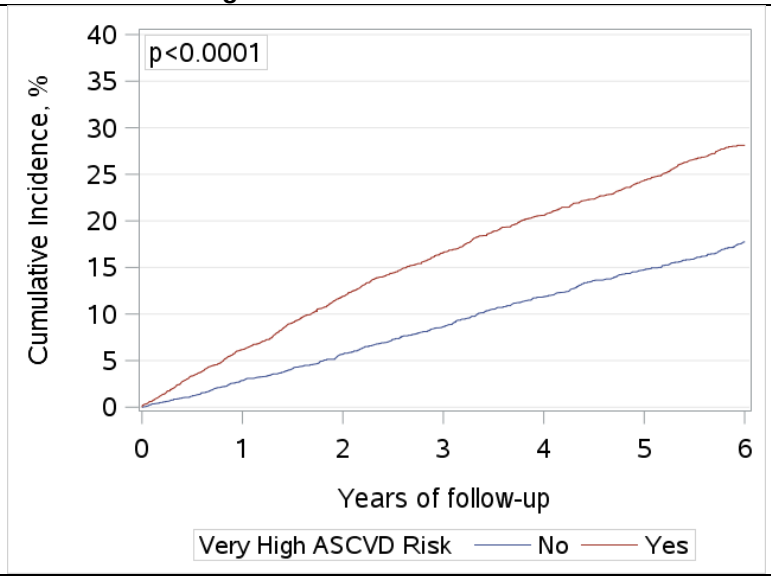


Women	Men
	

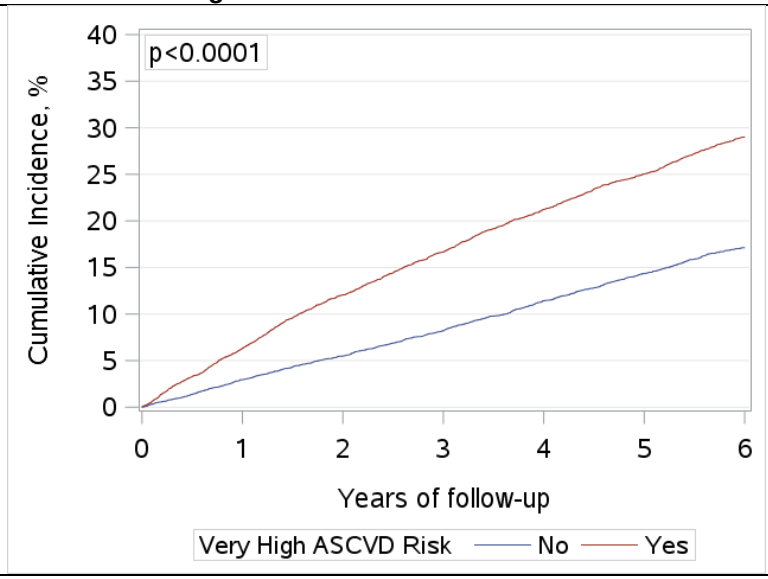
p<0.0001
Cumulative Incidence, %
40
35
30
25
20
15
10
5
0
0
1
2
3
4
5
6
Years of follow-up
Very High ASCVD Risk
No
Yes

NH White	NH Black
	
NH Asian	**Hispanic**
	

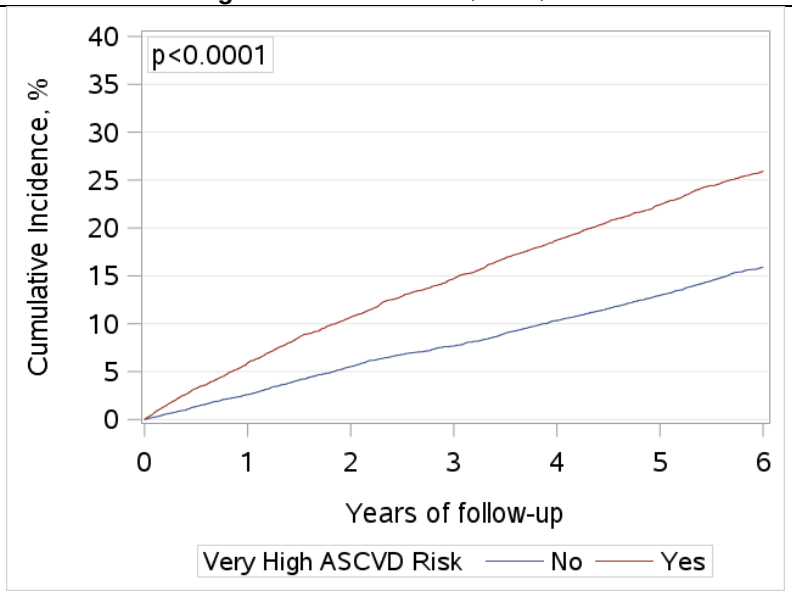
Neighborhood Income $0-$34.9k



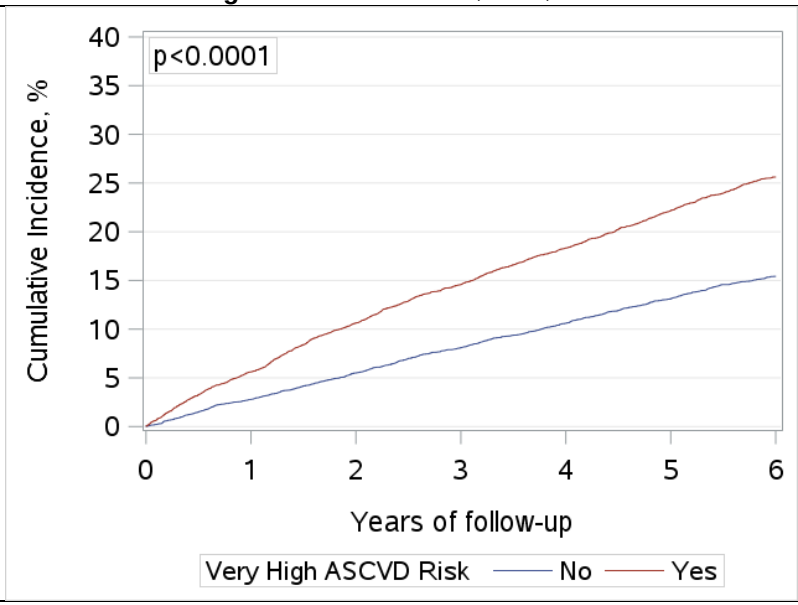
Neighborhood Income $35k-$49.9k

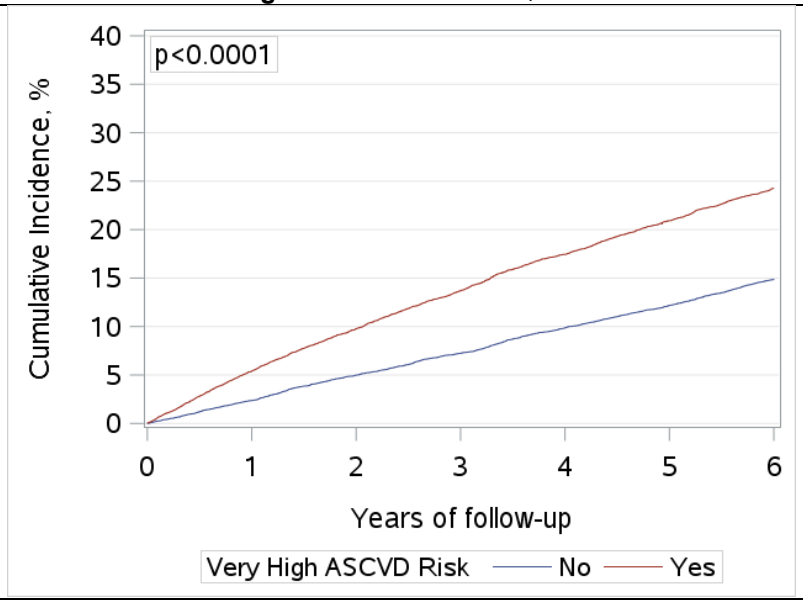


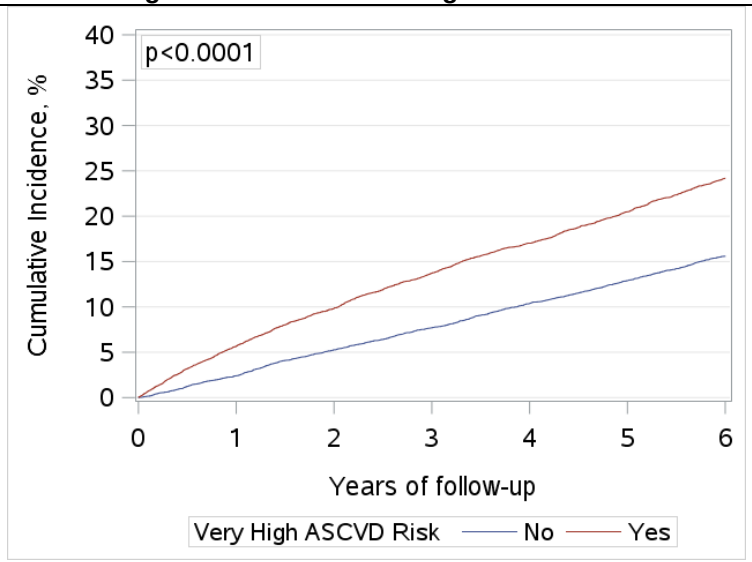
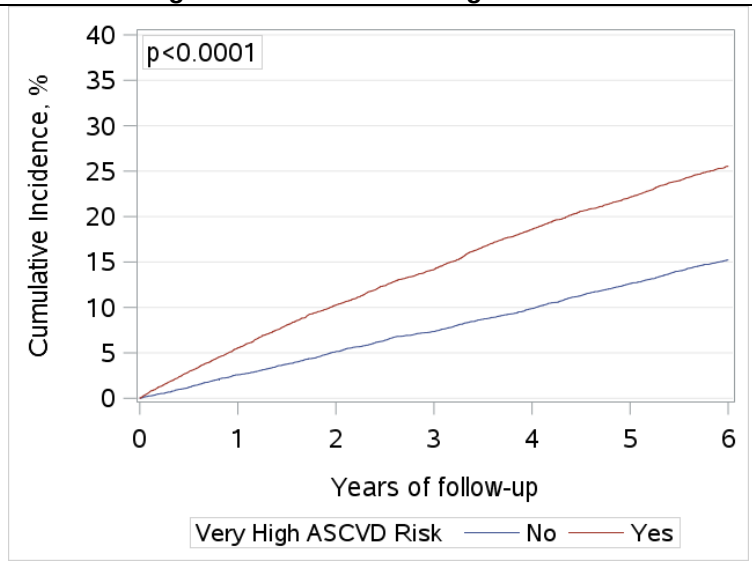
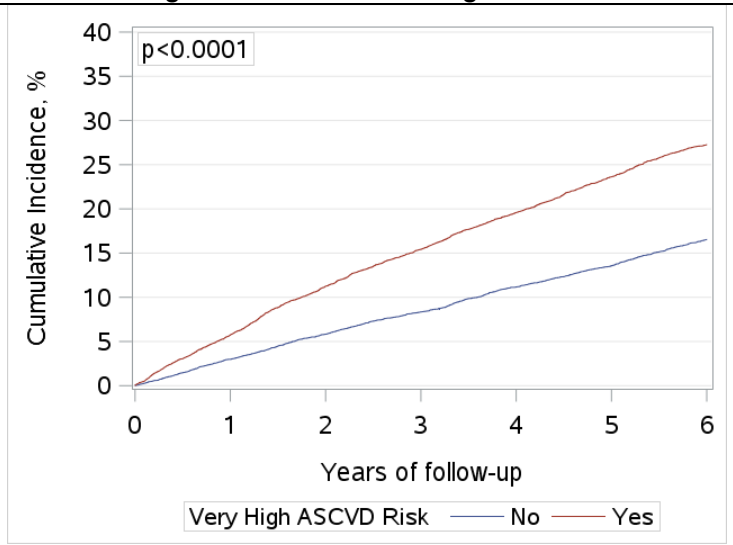
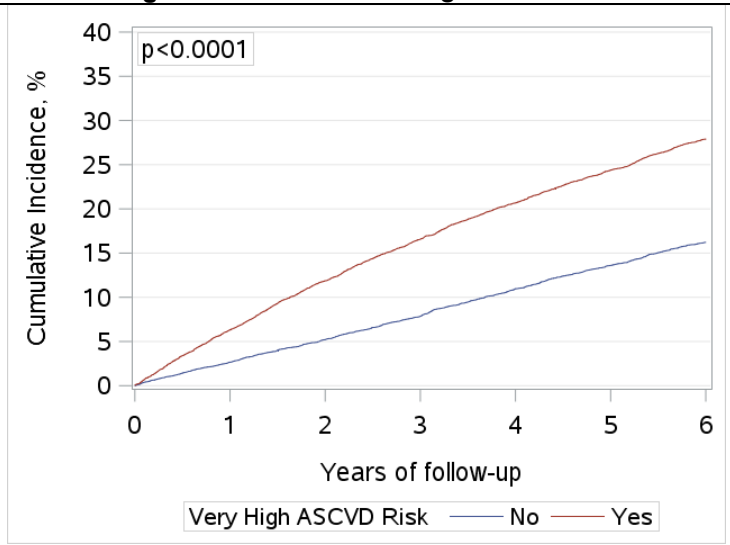
Neighborhood Income $50k-$64.9k



Neighborhood Income $65k-$79.9k



Neighborhood Income ≥$80k	
	

<8.8% High School or Lower Neighborhood Education	8.8-17.0% High School or Lower Neighborhood Education
	
17.1-31.1% High School or Lower Neighborhood Education	**≥31.2% High School or Lower Neighborhood Education**
	

ASCVD = atherosclerotic cardiovascular disease, NH = Non-Hispanic