Impact of Statin Guidelines on Statin Utilization and Costs in an Employer-Based Primary Care Clinic

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ABSTRACT

OBJECTIVES: The purpose of this study was to describe statin utilization and costs in an employer-based patient cohort by comparing actual practice and assumed adoption of the 2013 American College of Cardiology/American Heart Association (ACC/AHA) or 2016 US Preventive Services Task Force (USPSTF) statin recommendations versus the guidelines described in 2001 (and supplemented in 2004) in the Third Report of the National Cholesterol Education Program's Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (ATPIII).

STUDY DESIGN: Descriptive cohort analysis included patients treated in an employer-based primary care clinic between January 2012 and April 2014.

METHODS: ATPIII, ACC/AHA, and USPSTF recommendations were retrospectively applied at the patient level based on lipid levels and statin prescribing data collected from a health risk assessment and electronic health record. Actual statin prescribing was compared with prescribing predicted by guideline recommendations. Costs for each strategy were estimated using employer pharmacy claims data.

RESULTS: The study included 555 patients, of whom 112 (20.2%) were treated with a statin at baseline. ATPIII and ACC/AHA recommended statin use in 284 (51.2%) and 279 (50.3%) patients, respectively. Within the subgroup of 479 primary prevention patients, ACC/AHA recommended statin use in 203 (42.4%) versus USPSTF, which recommended statin use in 91 (19.0%). The 90-day cost per patient was similar to baseline with implementation of ATPIII or ACC/AHA recommendations, excluding use of brand name–only high-intensity statins, and costs could be reduced slightly with implementation of USPSTF guidelines.

CONCLUSIONS: Despite differences in ATPIII, ACC/AHA, and USPSTF guidelines, application of any of these statin recommendations would result in optimized statin utilization and fairly neutral effects on cost in this real-world employer-based population.

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The use of statins for primary prevention and evidence-based management of atherosclerotic cardiovascular disease (ASCVD) is of interest to employers and other payers eager to improve health outcomes and reduce costs.[1-4] The Third Report of the National Cholesterol Education Program's Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (ATPIII) was published in 2001, followed by a supplemental publication in 2004 that incorporated additional risk assessment strategies.[2,3] ATPIII focuses on assessing patient risk for coronary heart disease (CHD), establishing low-density lipoprotein cholesterol (LDL-C) goals, and identifying when to initiate statin therapy or lifestyle modifications.[2,3] Patient risk is assessed using the Framingham Risk Score (FRS) and risk factors such as age, comorbid conditions, and family history.[2,3]

In 2013, the American College of Cardiology (ACC) and American Heart Association (AHA) released the ACC/AHA guideline for the treatment of cholesterol.[4] The emphasis of ACC/AHA shifted toward identifying patients in whom the strongest evidence existed to support the benefit of statin therapy to reduce ASCVD.[4] In contrast to ATPIII, ACC/AHA determined there was insufficient evidence from randomized controlled trials to support the use of specific LDL-C goals to guide therapy. Instead, ACC/AHA recommended moderate- or high-intensity statin therapy for individuals in 4 statin benefit groups. ACC/AHA also utilized a new risk assessment, the pooled cohort equation, which incorporated risk factors such as diabetes and race. In contrast with FRS, which calculates 10-year risk of CHD, the pooled cohort equation estimates 10-year risk of ASCVD, including stroke.[4]

In 2016, the US Preventive Services Task Force (USPSTF) released recommendations for statin use for primary prevention of ASCVD.[5] USPSTF cited several studies' results which found that the pooled cohort equation overestimates actual ASCVD risk in certain cohorts.[6-8] USPSTF also noted that randomized clinical trials evaluating statin use for primary prevention typically utilized low- to moderate-intensity statins, in comparison with ACC/AHA, which emphasized moderate- to high-intensity statins. Given these

TAKEAWAY POINTS

- The 2013 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for treatment of cholesterol defined new criteria for therapy with statins to reduce atherosclerotic cardiovascular disease risk.
- The US Preventive Services Task Force released statin guidelines in 2016, which suggested statin treatment for fewer primary prevention patients compared with ACC/AHA guidelines.
- Full adoption of any of the major statin guidelines would improve statin utilization with neutral cost effects when generic statins are emphasized.
- Substantial opportunity exists within real-world patient cohorts to improve statin utilization. A greater understanding of barriers to guideline implementation is needed.

critiques, USPSTF recommends low- to moderate-intensity statins for primary prevention in adults aged 40 to 75 years with 1 or more cardiovascular disease (CVD) risk factors and a calculated 10-year ASCVD risk of at least 10%. Clinicians are encouraged to selectively offer statins to adults within the same population with a risk score of 7.5% to less than 10%, weighing potential risks versus benefits. Finally, USPSTF concludes that current evidence is insufficient to recommend statins for primary prevention to patients older than 75 years. Investigators have described the impact of ACC/AHA guideline adoption as resulting in as many as 12.8 million additional statin candidates in the United States.[9] Adoption of USPSTF recommendations instead would be expected to reduce the number of adults newly treated with statins, assuming patients with 10-year ASCVD risk scores between 7.5% and 10% or those without 1 or more risk factors for CVD were not routinely started on statins.

The impact of statin guideline implementation on an employer or similar payer is not fully understood. The purpose of our research was to evaluate the impact of full adoption of ACC/AHA or USPSTF guidelines on statin utilization and cost to a self-funded employer. The projected utilization and costs were compared with actual statin use and with estimated utilization and costs associated with full adoption of APTIII guidelines to help isolate the impact of guideline changes versus greater adherence to alternative guidelines.

METHODS

This descriptive retrospective cohort study used patient-level clinical and cost data from patients treated at an on-site primary care clinic operated by a self-insured employer between January 2012 and April 2014.

Study Population

The self-insured employer in this study operates an on-site primary care clinic for employees and their dependents. Clinic patients who completed an employer-sponsored health risk assessment (HRA) between January and October 2013 were identified. Those with 1 or more of the following characteristics associated with potential benefit from statin therapy were included: treatment with a cholesterol medication in year prior to HRA, LDL-C above ATPIII goal, self-reported ASCVD or ATPIII CHD risk equivalent, 65 years or older, ASCVD risk at least 7.5%, or FRS risk at least 20%. The date the HRA was conducted was defined as the patient's baseline.

Data Collection

The electronic health record (EHR) provided demographic and clinical information, including biometrics (body mass index, blood pressure [BP]), medication history, and laboratory results (lipid panel, glycated hemoglobin [A1C]). The HRA provided patient-reported medical history. In addition, population-level statin utilization and reimbursement information were obtained from the employer's pharmacy claims data to calculate the average cost of statins to the employer.

Guideline Recommendation Determination

EHR and HRA data were used to calculate 10-year risk of ASCVD and FRS for each patient and to identify ATPIII risk level. Hypertension was defined as BP at least 140/90 mm Hg at time of the HRA or self-reported hypertension. Hypertension and treatment for hypertension, smoking status, and clinical ASCVD were self-reported through the HRA. Patients were categorized as having diabetes if they self-reported diabetes or had an A1C of at least 6.5% at time of HRA. Those with unknown race were assumed to be white or "other" for the purposes of calculating an ASCVD risk score, as less than 2% of the patient cohort was black.

Baseline statin use was identified through review of medication orders in the EHR. Those with a statin order any time in the year prior to HRA were assumed to be using a statin at baseline. Incorporating baseline statin use and risk assessment, ATPIII, ACC/AHA, and USPSTF statin recommendations (summarized in **Table 1**) were applied to each patient.

The recommendation to start statins in ATPIII guidelines was determined using an LDL-C goal and thresholds for starting medication determined by patient risk factors and FRS. For patients taking no statin at the time of their HRA, ATPIII recommended either starting a statin or continuing with no statin. For patients taking a statin at the time of their HRA, recommendations could include intensifying therapy or no change. Through evaluation of HRA data, it was not possible to determine if any patients were currently using a statin but were not indicated according to ATPIII. ATPIII does not recommend a specific intensity of statin therapy.[4] Thus, a statin intensity was assigned to each patient based on the percent LDL-C reduction needed to reach ATPIII LDL-C goal (<30%, low-intensity; 30% to <50%, moderate-intensity; ≥50%, high-intensity statin).[4] Statin use adherence with ATPIII guidelines after the HRA was determined at the patient level by comparing

TABLE 1. Comparison of Guideline Recommendations for Statin Eligibility

	ATPIII Guidelines[2,3]	ACC/AHA Guidelines[4]	USPSTF Guidelines[5]
Risk assessment strategy	10-year FRS CHD risk factors	10-year ASCVD pooled cohort equation	10-year ASCVD pooled cohort equation
Eligibility for statin therapy	Patients above LDL-C goal	Patients in 4 statin benefit groups	Primary prevention patients with 1 or more cardiovascular risk factors
Statin intensity utilized	Statins titrated to achieve LDL-C goal	Moderate- to high-intensity statins	Low- to moderate-intensity statins
Key guideline recommendations	• High risk (LDL-C goal <100 mg/dL, <70 mg/dL optional) if CHD, risk equivalent, or FRS ≥20% • Moderately high risk (LDL-C goal <130 mg/dL, <100 mg/dL optional) if ≥2 risk factors or FRS 10% to <20% • Moderate risk (LDL-C goal <130 mg/dL, therapy started if LDL-C >160 mg/dL) if ≥2 risk factors or FRS <10% • Lower risk (LDL-C goal <160 mg/dL, therapy started if LDL-C >190 mg/dL) if 0 or 1 risk factor	• If >21 years and have clinical ASCVD, high-intensity statin; moderate-intensity if >75 years • If >21 years and LDL-C ≥190 mg/dL, high-intensity statin • Aged 40-75 years with diabetes and LDL-C 70-189 mg/dL, moderate-intensity statin (or high-intensity if ASCVD risk ≥7.5%) • Aged 40-75 years with LDL-C 70-189 mg/dL, moderate- to high-intensity statin if ASCVD risk ≥7.5%	• Statins recommended if 10-year risk ≥10% and aged 40 to <75 years • Patient-specific approach if 10-year risk 7.5% to <10% and with 1 or more cardiovascular risk factors • Statins not recommended if ≥75 years

ACC/AHA indicates American College of Cardiology/American Heart Association; ASCVD, atherosclerotic cardiovascular disease; ATPIII, Adult Treatment Panel III; CHD, coronary heart disease; FRS, Framingham Risk Score; LDL-C, low-density lipoprotein cholesterol; USPSTF, US Preventive Services Task Force.

statin prescription orders in the EHR for 6 months post HRA against ATPIII recommendations.

Determination of ACC/AHA recommendation at the time of the HRA required that patients be categorized into statin benefit groups that dictated recommended statin intensity. Patients who did not fall into 1 of 4 statin benefit groups were classified as having no recommendation. Statin use adherence with ACC/AHA guidelines after the HRA was determined at the patient level by comparing statin prescription orders in the EHR for 6 months post HRA against ACC/AHA recommendations.

USPSTF recommendations were applied to patients aged 40 to 75 years without clinical ASCVD and with LDL-C lower than 190 mg/dL and 1 or more cardiovascular (CV) risk factors (LDL-C 130-189 mg/dL, high-density lipoprotein cholesterol <40 mg/dL, hypertension, or smoking). USPSTF recommends low- or moderate-intensity statins for primary prevention of ASCVD if patients meet these criteria and have a 10-year risk of ASCVD of 10% or higher. According to USPSTF, a patient-specific approach should be utilized in primary prevention patients with 10-year risk of ASCVD between 7.5% and 10% and with 1 or more CV risk factors. Clinicians may weigh potential risk versus benefits of statin therapy with these patients. No recommendation for statin therapy is made for patients without CV risk factors or with a 10-year ASCVD risk lower than 7.5%.

Statin Cost Determination

Although patient-level prescribing data were available for this study, patient-level drug costs were not. However, statin utilization aggregated at the product/strength level was known, as were network reimbursement rates. These data were used to calculate the 90-day average cost (US dollars) to the employer per statin at the product and strength levels (contracted amount minus a standard patient co-payment). An average 90-day statin cost was estimated for each intensity, weighted by the amount each product/strength contributed to the utilization within the intensity group. The recent availability of generic rosuvastatin has driven down the cost substantially. Given that this change occurred after collection of cost data for this study, rosuvastatin was excluded from our model. Using this method, the weighted average cost to the employer for a 90-day supply of statin was calculated to be $7.79 for low-, $4.79 for moderate-, and $20.53 for high-intensity statins.

Based on baseline use and projected utilization and intensity according to guideline recommendations, 90-day statin costs per patient were calculated from the perspective of the employer. For ATPIII recommendations, those with no recommended change in therapy were assigned the cost to the employer of the statin used at the time of the HRA. For those recommended to intensify statin therapy, the intensity of the statin used at the time of the HRA was increased by 1 intensity level. If the patient was on a high-intensity statin at the time of the HRA and the recommendation was to intensify the statin, then no change in cost was assumed. For patients for whom there was no specific recommendation (ACC/AHA or USPSTF) or no statin was recommended (ATPIII), it was assumed the patient would have no cost.

Utilization Data Analysis

Descriptive statistics summarized cohort characteristics overall and by baseline statin group. To report concordance between guidelines within the study cohort, as a measure of the impact of

TABLE 2. Characteristics of Cohort Patients by Baseline Statin Use Prior to HRA

Patient Characteristics	Total Cohort (N = 555)	No Statin at Baseline (n = 443)	Statin at Baseline (n = 112)
Age, years, mean (SD)	48.5 (12.8)	46.5 (12.7)	56.2 (10.3)
≥65 years, n (%)	74 (13.3%)	46 (10.4%)	28 (25.0%)
Male (%)	314 (56.6%)	248 (55.9%)	66 (58.9%)
White (%)	426 (76.8%)	334 (75.4%)	92 (82.1%)
Black (%)	6 (1.1%)	5 (1.1%)	1 (0.9%)
Other race (%)	51 (9.2%)	35 (7.9%)	16 (14.3%)
Unknown race (%)	72 (13.0%)	69 (15.6%)	3 (2.7%)
LDL-C, mg/dL, mean (SD)	131 (44.8)	139.6 (42.1)	99.3 (41.0)
Hypertension, n (%)	283 (51.0%)	209 (47.2%)	74 (66.1%)
Smoker, n (%)	52 (9.4%)	46 (10.4%)	6 (5.4%)
10-year ASCVD risk, mean (SD)	8.7 (7.7)	7.9 (7.0)	11.0 (9.0)
10-year FRS, mean (SD)	5.3 (5.9)	4.9 (5.3)	6.9 (7.5)
ATPIII Risk Category, n (%)			
High, LDL-C goal <100 mg/dL	253 (45.6%)	163 (36.8%)	90 (80.4%)
Moderately high, LDL-C goal <130 mg/dL	46 (8.3%)	42 (9.5%)	4 (3.6%)
Moderate, LDL-C goal <130 mg/dL	97 (17.5%)	90 (20.3%)	7 (6.3%)
Lower, LDL-C goal <160 mg/dL	159 (28.7%)	148 (33.4%)	11 (9.8%)
ACC/AHA Statin Benefit Group, n (%)			
Clinical ASCVD; ≥21 years	41 (7.4%)	23 (5.2%)	18 (16.1%)
LDL-C ≥190 mg/dL; ≥21 years	35 (6.3%)	32 (7.2%)	3 (2.7%)
Diabetes; aged 40-75 years	127 (22.9%)	82 (18.5%)	45 (40.1%)
ASCVD risk ≥7.5%; LDL-C 70-189 mg/dL; aged 40-75 years	76 (13.7%)	65 (14.7%)	11 (9.8%)
No statin benefit group	276 (49.7%)	241 (54.4%)	35 (31.3%)
USPSTF Primary Prevention Group (n = 479), n (%)			
ASCVD risk ≥10%; aged 40-75 years; ≥1 CV risk factor	91 (16.4%)	68 (15.4%)	23 (20.4%)
ASCVD risk 7.5%-10%; aged 40-75 years; ≥1 CV risk factor	30 (5.4%)	19 (4.3%)	11 (9.7%)
No statin recommendation	358 (64.5%)	300 (67.9%)	58 (51.3%)

ACC/AHA indicates American College of Cardiology/American Heart Association; ASCVD, atherosclerotic cardiovascular disease; ATPIII, Adult Treatment Panel III; CV, cardiovascular; FRS, Framingham Risk Score; HRA, health risk assessment; LDL-C, low-density lipoprotein cholesterol; USPSTF, US Preventive Services Task Force.

guideline changes, the number and percentage of patients were identified by statin recommendation and intensity. Baseline (actual) statin use was also compared with guideline recommendations.

Cost Data Analysis

Baseline costs were calculated based on actual statin use and weighted average cost per product and dose. The 90-day statin cost to the employer with full adoption of each guideline was estimated by statin intensity. Subgroup analysis of cost estimates were completed to determine whether cost with ACC/AHA guideline implementation differed among those patients with diabetes, with ASCVD risk scores 7.5% or higher, or those 65 years and older.

RESULTS

Of 3938 patients completing an HRA, 555 (14.1%) patients had 1 or more characteristics associated with potential benefit from statin therapy and are described in **Table 2**. The mean (SD) age of the cohort was 48.5 (12.8) years, and 314 (56.6%) were male. The majority of patients were white, with a small proportion of black patients. Those in the "other" race category were predominately Asian, Latino, or Native American.

Table 3 compares recommendations for each guideline. Statin use was recommended in 284 (51.2%) and 279 (50.3%) patients per ATPIII and ACC/AHA, respectively. Adherence to ATPIII guidelines would have resulted in 31% of patients starting a statin, 5.2% intensifying their current statin therapy, 15% continuing their current statin, and 48.8% remaining on no therapy. Even among the 253 patients in the highest-risk group (LDL-C goal <100 mg/dL) according to ATPIII, 74 (29.2%) were meeting their LDL-C goal at baseline and had no recommendation to start a statin. Adherence to ACC/AHA guidelines would result in treatment with a high-intensity statin in 24.1%, a moderate- to high-intensity statin in 13.7%, and a moderate-intensity statin in 12.1% of statin-eligible patients within the cohort. Adherence to USPSTF guidelines within the primary prevention cohort resulted in 82 fewer patients treated with a statin compared with ACC/AHA. These 82 individuals were aged 40 to 75 years and recommended by ACC/AHA to receive a statin, but were not recommended to receive a statin according to USPSTF because their 10-year ASCVD risk score was lower than 7.5%. The 30 patients in the "selectively offer" statin group had a 10-year ASCVD risk score between 7.5% and <10%. No statin was specifically recommended for 69.9% versus 49.7% of primary prevention patients applying USPSTF and ACC/AHA guidelines, respectively.

Overall rates of adherence to ATPIII guidelines were 67.6% after HRA, with the highest adherence to the recommendation for "no statin" (**Table 4**). Of the 172 patients with ATPIII recommendations

TABLE 3. Correlations Among Guideline Recommendations for Statin Therapy, n (%)

Total Cohort (N = 555)				
	ACC/AHA Statin Recommendations			
ATPIII Statin Recommendations	High-Intensity (n = 137)	Moderate- to High-Intensity (n = 76)	Moderate-Intensity (n = 66)	No Statin Recommendation (n = 276)
Start Statin (n = 172)	71 (12.8%)	34 (6.1%)	20 (3.6%)	47 (8.5%)
Intensify Statin (n = 29)	15 (2.7%)	2 (0.4%)	8 (1.4%)	4 (0.7%)
Continue Current Statin (n = 83)	29 (5.2%)	9 (1.6%)	14 (2.5%)	31 (5.6%)
Statin Not Recommended (n = 271)	22 (4.0%)	31 (5.6%)	24 (4.3%)	194 (35.0%)
Primary Prevention Cohort (n = 479)				
	ACC/AHA Statin Recommendations			
USPSTF Statin Recommendations	High- Intensity (n = 61)	Moderate- to High-Intensity (n = 76)	Moderate-Intensity (n = 66)	No Statin Recommendation (n = 276)
Low- to Moderate-Intensity (n = 91)	44 (9.2%)	47 (9.8%)	–	–
Selectively Offer Statin (n = 30)	17 (3.6%)	13 (2.7%)	–	–
No Statin Recommended (n = 358)	–	16 (3.3%)	66 (13.8%)	276 (57.6%)

ACC/AHA indicates American College of Cardiology/American Heart Association; ATPIII, Adult Treatment Panel III; USPSTF, US Preventive Services Task Force.

TABLE 4. Baseline Adherence to Guideline by Recommendation, n (%)

	ATPIII Recommendation				
Baseline Adherence	No Statin (n = 271)	Start Statin (n = 172)	Intensify Statin (n = 29)	No Statin Change (n = 83)	Total (N = 555)
Yes (n = 375)	263 (97.0%)	35 (20.3%)	7 (24.1%)	70 (84.3%)	375 (67.6%)
No (n = 180)	8 (3.0%)	137 (79.7%)	22 (75.9%)	13 (15.7%)	180 (32.4%)
	ACC/AHA Recommendation				
Baseline Adherence	High-Intensity Statin (n = 137)	Moderate- to High-Intensity Statin (n = 76)	Moderate-Intensity Statin (n = 66)	None[a] (n = 276)	Total (N = 555)
Yes (n = 42)	12 (8.8%)	15 (19.7%)	15 (22.7%)	0 (0%)	42 (7.6%)
No (n = 237)	125 (91.2%)	61 (80.3%)	51 (77.3%)	0 (0%)	237 (42.7%)
None[a] (n = 276)	0 (0%)	0 (0%)	0 (0%)	276 (100%)	276 (49.7%)
	USPSTF Recommendation				
Baseline Adherence	Low- to Moderate-Intensity Statin (n = 91)	Selectively Offer Statin (n = 30)		None[a] (n = 358)	Total (N = 479)
Yes (n = 23)	23 (25.3%)	0 (0%)		0 (0%)	23 (4.8%)
No (n = 68)	68 (74.7%)	0 (0%)		0 (0%)	68 (14.2%)
None[a] (n = 388)	0 (0%)	30 (100%)		358 (100%)	388 (81.0%)

ACC/AHA indicates American College of Cardiology/American Heart Association; ATPIII, Adult Treatment Panel III; USPSTF, US Preventive Services Task Force.
[a]None indicates no recommendation per guideline.

to start a new statin, only 35 (20.3%) actually received a new statin prescription within 6 months of completing the HRA (Table 4). Although ACC/AHA recommendations had not yet been released, only 42 (7.6%) patients would have been treated according to ACC/AHA guidelines and 276 (49.7%) had fallen into ACC/AHA's "no recommendation" category (Table 4). Of the 112 patients taking a statin prior to the HRA, 35 (31.3%) were not included in any of the 4 ACC/AHA statin benefit groups (Table 2), meaning that clinicians would need to reassess if ongoing statin therapy was warranted, as there was no clear recommendation for statin use. Although USPSTF recommendations had not yet been released, only 25.3% of the primary prevention cohort who was statin-eligible, according to USPSTF, were receiving statin treatment at baseline.

Cost Analysis

The 90-day statin cost to the employer per patient in the overall cohort at baseline ($9) was less than the cost within several subgroups: diabetes ($11), ASCVD 7.5% or greater ($10), or 65 years or older ($15). Overall, 90-day costs were slightly higher with full adherence to ACC/AHA ($8) versus ATPIII ($4) guidelines in the overall cohort. Ninety-day costs per patient were similar between baseline and full adherence to ACC/AHA recommendations, even among subgroups in which high-intensity treatment is emphasized: patients with 10-year ASCVD score 7.5% or higher ($10 vs $19), patients 65 years or older ($15 vs $17), and patients with diabetes ($11 vs $9). Within the primary prevention cohort, 90-day costs per patient were lowest with USPSTF guidelines ($1) compared with baseline ($5), ATPIII ($4), or ACC/AHA ($4) statin utilization.

DISCUSSION

The ACC/AHA guidelines in 2013 represented a significant shift in the approach to preventing ASCVD. Retrospective cohort evaluations have predicted that implementation of ACC/AHA would result in an overall 15% to 30% increase in the number of patients eligible for treatment with statins, primarily driven by adults classified on the basis of their 10-year risk.[9-12] Similar to our results, Pencina et al noted fairly stable rates of statin eligibility with ATPIII versus ACC/AHA among adults aged 40 to 59 years. In contrast, the percentage of men aged 60 to 75 years eligible for a statin for primary prevention increased from 30.4% to 87.4% with ACC/AHA guideline implementation.[9] These findings suggest that the predicted increase in statin eligibility among primary prevention patients is most apparent in older adults, which may explain why overall statin eligibility remained stable in our younger employer-based cohort with implementation of ACC/AHA versus ATPIII guidelines.

Controversy surrounds the clinical utility of treating more patients, particularly those at lower risk, with statins for primary prevention. Recent investigations suggest that ACC/AHA may better predict patients at risk than ATPIII, perhaps enabling clinicians to better prevent ASCVD through the use of statins.[12] On the other hand, concerns exist that the pooled cohort equation may overestimate actual ASCVD risk in certain cohorts.[5-8] The optimal intensity of statins for primary prevention also remains controversial, with USPSTF recommending low- to moderate-intensity statins, compared with ACC/AHA's suggestion of moderate- to high-intensity statins.[4,5] Comparisons of the real-life clinical and economic impact of implementing the ATPIII versus ACC/AHA or USPSTF guidelines are limited.

Chia et al conducted a retrospective cohort study in 847 Asian patients and found that although ACC/AHA would increase eligibility for statin treatment, there would also be a large cohort of patients potentially treated inappropriately with statins.[10] Similarly, we observed that 17.4% of our cohort with no statin at baseline would become eligible for statin therapy with ACC/AHA but not with ATPIII guidelines, whereas 8.5% of patients would start a statin according to ATPIII but not according to ACC/AHA. These results suggest that utilization of ACC/AHA may not result in an absolute increase in the use of statins but instead an improved ability to identify patients for treatment. Within the primary prevention cohort specifically, fewer patients were eligible for statins with USPSTF (19.0%) versus ACC/AHA (42.4%), further refining statin-eligible patients to those presumably with increased risk.

Acknowledging that real-world application of guidelines is usually imperfect, we compared actual statin use with full adherence to guidelines. Undertreatment with statins is well documented, with significant gaps between clinical guidelines and actual practice.[13] We found that nearly one-third of patients were not being treated in accordance with ATPIII at the time of ACC/AHA publication, comparable with rates of nonadherence to guidelines published by others.[13] Implementation of ACC/AHA within our cohort would require an adjustment in therapy for more than 40% of the patients, making full implementation a substantial undertaking within the primary care setting and one that is still ongoing. The USPSTF recommendations for statins for primary prevention, which were released after ACC/AHA, would require an adjustment in therapy for only 14.2% of primary prevention patients compared with baseline use, although like ACC/AHA, USPSTF relies heavily on patient–provider discussions of the risk versus benefit of statins.

With the recent availability of generic rosuvastatin, adopting ACC/AHA guidelines in an employer-based primary care setting had a neutral effect on cost of statin treatment from a payer perspective. Subgroup analysis identified slight increases in costs driven by a shift toward the use of higher-intensity statins and new statin eligibility among older patients or those identified using the ASCVD risk score. Cost per patient with diabetes was similar to the cost for the overall cohort. Implementation of USPSTF, which limits statin use to higher-risk primary prevention patients and emphasizes low- to moderate-intensity statins, resulted in a decrease in statin prescribing costs compared with baseline or with ATPIII and ACC/AHA implementation in the primary prevention cohort.

Limitations

It is important to balance the cost of statins and statin-related adverse effects with potential cost savings through reduction in ASCVD events. Maddox et al also identified a reduction in the use of nonstatin cholesterol treatments and reduced laboratory costs following implementation of ACC/AHA.[11] Our study was not able to account for total cost effectiveness, including costs of adverse effects, ASCVD events, nonstatin medications, nonadherence, or laboratory testing.

The patient cohort in our study was composed of adults treated in an employer-based clinic. Although the population was diverse in socioeconomic status and level of education, those demographics may not be applicable to other patient populations. For example, the average age in our cohort was 48.5 versus 56 years in Pencina et al,[9] which may explain why a large increase in overall statin-eligible patients was not observed, unlike other studies with older patient cohorts. The weighted cost estimates for low-, moderate-, and high-intensity statins may not be generalizable, reflecting reimbursement rates and prescribing patterns within 1 patient cohort.

Using both EHR and patient-reported data for calculation of risk scores and determination of guideline application enhanced our ability to identify several important risk factors. For example, patients with either self-reported diabetes or laboratory data demonstrating an A1C 6.5% or greater were considered to have diabetes for the purposes of calculating a 10-year ASCVD risk score. For other variables, including history of prior ASCVD, only patient-reported data were available, and incomplete self-reporting is a potential limitation. However, this is a limitation shared by similar studies.[9]

Finally, the study required the use of several assumptions, such as estimating costs based on full adherence to guidelines or assumptions when guidelines are not specific. However, reporting estimated use and costs assuming full adherence to ATPIII alongside baseline and ACC/AHA projections helps to understand the incremental impact of ACC/AHA guideline adoption relative to both real-world and fully adherent situations.

CONCLUSIONS

In this patient cohort, implementation of ACC/AHA compared with ATPIII guidelines or actual statin use increased the intensity of statin utilization, with overall neutral effects on cost when generic statins are emphasized. Implementation of USPSTF recommendations may lower costs slightly compared with ACC/AHA and may improve identification of high-risk primary prevention patients. Application of any of these statin guidelines would result in improved statin utilization and fairly neutral cost effects in this employer-based population. Further research is needed to more fully understand the clinical and economic impact of lipid guideline implementation and barriers to guideline adherence within real-world patient cohorts. ■

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