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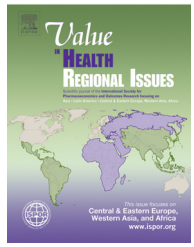

The Potential Effects of Implementing the 2013 ACC/AHA Cholesterol Guidelines on the Use of Statins in a Large Health Maintenance Organization in Israel

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ABSTRACT

Background: The 2013 American College of Cardiology and American Heart Association (ACC/AHA) guidelines for the management of blood cholesterol identify candidates for statin therapy to prevent atherosclerotic cardiovascular disease (ASCVD). **Objective:** The objective was to estimate the effect of adopting the ACC/AHA guidelines in Maccabi Healthcare Services (MHS), a large health maintenance organization in Israel. **Methods:** This population-based study, conducted in June 2014, included all MHS members 40 years or older. We searched the computerized database of MHS to determine the number of members currently on statins, calculated the number of additional members newly eligible for statin treatment according to the new guidelines, and estimated the cost of implementing the guidelines in MHS. **Results:** In June 2014, there were 798,076 MHS members 40 years or older. Of the 725,784 members included, 30% were receiving statin treatment at baseline. Adopting the new guidelines would increase the proportion of statin-treated members to 48% (58% and 39% among men and women, respectively). Newly eligible members were more likely to be 55 to 69 years old, men, and have a predicted 10-year ASCVD risk of 7.5% or more. The calculated incremental annual cost for medications is 54 million new Israeli shekels (US $13.5 million). The cost per cardiovascular event prevented is estimated at 82,000 new Israeli shekels (US $20,500). **Conclusions:** Adopting the ACC/AHA 2013 cholesterol guidelines would increase the number of MHS members 40 years or older eligible for statin therapy by 60%, with the increase mainly in primary prevention due to the predicted 10-year ASCVD risk.

Keywords: cholesterol guidelines, application, cost, eligibility, statin therapy, population-based.

Introduction

Cardiovascular disease is the second leading cause of death in Israel [1]. Lifestyle and risk factor modification and pharmacological interventions are essential in reducing cardiovascular events. Statins play a key role in both primary and secondary prevention [2,3]. The American College of Cardiology and the American Heart Association (ACC/AHA) published new guidelines for the management of blood cholesterol in November 2013 [4] replacing the National Cholesterol Education Program Adult Treatment Panel III (ATP III) guidelines published over a decade ago [5].

The ACC/AHA 2013 guidelines abandon the previous paradigm of treating according to specific low-density lipoprotein cholesterol (LDL-C) targets. Instead, the new guidelines recommend statin therapy for patient groups for whom statins reduced the risk of atherosclerotic cardiovascular disease (ASCVD), including coronary heart disease and stroke, in randomized controlled trials. The ACC/AHA 2013 guidelines identify four patient groups who are candidates for statin therapy: 1) patients with clinical ASCVD (acute coronary syndrome, myocardial infarction, stable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, and peripheral arterial disease of atherosclerotic origin); 2) patients with LDL-C levels of 190 mg/dl or more; 3) 40- to 75-year-old patients with diabetes and LDL-C levels of 70 to 189 mg/dl; and 4) 40- to 75-year-old patients without diabetes, with LDL-C levels of 70 to 189 mg/dl and a predicted 10-year ASCVD risk of 7.5% or more, as calculated by the new pooled cohort equations published along with the guidelines [6].

Following the publication of the new guidelines, concern arose that they would substantially expand the population eligible for statin treatment [7–10]. Pencina et al. [11] estimated that the number of US adults receiving or eligible for statin therapy would increase from 43 million (37.5% of US adults) to 56 million (48.6%). Among 60- to 75- year-old adults not receiving statin therapy, 87.4% of men and 53.6% of women would be eligible for treatment [11].

Conflict of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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The present study was conducted in Maccabi Healthcare Services (MHS), the second largest national health maintenance organization in Israel, in the context of updating statin treatment policy; MHS is considering adopting the ACC/AHA 2013 guidelines. Our aims were to determine the number of members 40 years or older currently on statins, to estimate the number who would be eligible for statins under the new guidelines, and to estimate the cost of treating these additional patients.

Methods

Study Population

The study population included all MHS members 40 years and older on June 2014. Members were stratified into the primary prevention group (i.e., no history of ASCVD events) or the secondary prevention group (i.e., history of ASCVD events). Members whose blood cholesterol levels were never tested were excluded from the study. In the primary prevention group, members with LDL-C levels of less than 190 mg/dl, with no indication of diabetes, who never purchased statins were excluded if data were not available on blood pressure measurement and smoking history because these variables are required for ASCVD risk calculation.

Study Variables and Definitions

Data for this study were obtained from MHS's computerized databases. For each member, data collected included age; sex; smoking status; last systolic blood pressure measurement; history of clinical ASCVD (i.e., ischemic heart disease, stroke, transient ischemic attack, or peripheral artery disease) as documented in the MHS cardiovascular registry [12]; history of diabetes as documented in the MHS diabetes registry [13]; history of hypertension as documented in the MHS hypertension registry [14]; and results of the most recent blood tests for total cholesterol, LDL-C, and high-density lipoprotein cholesterol, HDL-C. We also collected data from the pharmacy database on antihypertensive medications and statin medications that had been dispensed during the previous 6 months. The most recently dispensed statin was characterized by drug (simvastatin, atorvastatin, rosuvastatin, pravastatin, or fluvastatin) and dose. Intensity of statin therapy was graded according to the ACC/AHA 2013 guidelines [4]. Members for whom no statins had been dispensed during the previous 6 months were defined as not receiving statin treatment.

Members receiving statins were categorized as being treated for primary or secondary prevention. Among members not currently receiving statins, those who would become eligible for statins under the new guidelines were identified according to the ACC/AHA 2013 criteria: 1) clinical ASCVD; 2) LDL-C levels of 190 mg/dl or more; 3) LDL-C levels of 70 to 189 mg/dl in persons aged 40 to 75 years with diabetes; and 4) LDL-C levels of 70 to 189 mg/dl and a 10-year ASCVD risk of 7.5% or more, as calculated by the pooled cohort equations [6], in persons aged 40 to 75 years without diabetes. The variables used to calculate the 10-year ASCVD risk were age, sex, race, systolic blood pressure, total cholesterol, HDL-C, smoking status, use of antihypertensive medications, and history of diabetes [6].

To assess the cost of statin therapy for members eligible for treatment under the new guidelines, we consulted the Israeli Ministry of Health's price list for prescription medications [15]. For moderate-intensity treatment, we used the retail price of generic simvastatin 20 mg, 20.4 new Israeli shekels (NIS) per month per patient (US $5.1); for high-intensity treatment, we used the retail price of generic atorvastatin 40 mg, 62.1 NIS per month per patient (US $15.5).

Statistical Analysis

Data were summarized descriptively. Continuous variables were reported as mean ± SD, or as median with interquartile range if not normally distributed, and discrete values were reported as proportions. Demographic and medical characteristics were compared between members currently on statins and those newly eligible for statins. Statistical analysis was performed using IBM SPSS Statistics, version 21 (IBM Corporation, Armonk, NY).

The study was approved by the institutional review board of Assuta Medical Center, Tel Aviv, which oversees research conducted at MHS.

Results

In June 2014, there were 798,076 registered MHS members 40 years or older. The data required for inclusion in our analysis were available for 725,784 members (91%). Of these, 72,266 members had a history of ASCVD events (mean age 69 ± 12 years, 70% men) and 653,518 members had no previous ASCVD events (mean age 56 ± 12 years, 44% men). Seventy-nine percent of the members with a history of ASCVD events and 25% of the members with no previous ASCVD events were currently on statins (Table 1). The most frequently dispensed regimen (for either primary or secondary prevention) was simvastatin 10 mg for low-intensity treatment, simvastatin 20 mg for moderate-intensity treatment, and atorvastatin 40 mg for high-intensity treatment.

If the ACC/AHA 2013 guidelines were fully implemented in MHS members 40 years or older included in our study, 127,010 additional members (17.5%) would be eligible for statin treatment (Table 2). Of these, 15,344 would be eligible for statins for secondary prevention and 111,666 for primary prevention. Comparison of the characteristics of members currently on statins and newly eligible members for secondary prevention is summarized in Table 3, and for primary prevention is summarized in Table 4. Fig. 1 illustrates the distribution of indications for statin treatment eligibility for primary prevention, by sex and age, under the new guidelines. Most of the newly eligible persons

Table 1 – Demographic and medical characteristics of study sample.

Characteristic	History of ASCVD* (eligible for statins for secondary prevention) (N = 72,266)	No history of ASCVD (possibly eligible for statins for primary prevention) (N = 653,518)
Age (y), mean ± SD	69 ± 11.8	55.8 ± 11.7
Sex: male, n (%)	50,816 (70.3)	289,832 (44.3)
Diabetes mellitus, n (%)	27,195 (37.6)	79,234 (12.1)
Hypertension, n (%)	49,749 (68.8)	196,589 (30.1)
Smoking current, n/total N (%)	11,888/70,593 (16.8)	103,377/646,359 (16.0)
Currently on statins, n (%)	56,922 (78.8)	163,838 (25.1)

* Atherosclerotic cardiovascular disease (ASCVD) includes ischemic heart disease, stroke, transient ischemic attack, and peripheral artery disease.