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Original Research

Implementation of the American Diabetes Association's Standards of Medical Care post-Medicare Part D: The case of statin utilization in the elderly with diabetes

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Abstract

Background: The American Diabetes Association's (ADA's) Standards of Medical Care in Diabetes for statin use have changed to be driven by risk status rather than low-density lipoprotein cholesterol level.
Objectives: The objectives of this study were to 1) examine how statins were used by risk status in elderly diabetics for whom they are recommended by the ADA's Standards with high levels of evidence, and 2) identify potential predictors of statin non-use using data containing Medicare Part D information in understanding how to further align patient care with the ADA's Standards.
Methods: This study was a pooled cross-sectional study of the Medicare Current Beneficiaries Survey from 2006 to 2010. Sampling weights were applied to generate national estimates. Weighted logistic regression was performed to identify potential predicators of statin non-use.
Results: Between 2006 and 2010, 53.96%, 52.14%, 52.28%, 57.74%, and 59.81% of eligible diabetics used statins, respectively. About 70% of the patients with overt cardiovascular disease (CVD) took statins while only about 50% of those with CVD risk factors used statins in 2010. Compared to those with overt CVD, patients with CVD risk factors were less likely to take statins (OR: 0.56; 95% CI: 0.48–0.64). Other non-use predictors included: non-Hispanic Black, non-metropolitan areas, and comorbidities.
Conclusions: Implementation of the ADA's statin recommendations increased over the study period. Statin use differed significantly by patients' risk status. Future ADA's Standards focusing on how to improve utilization of statins for individuals with different risk status, particularly those with CVD risk factors but without overt CVD, are warranted.

Keywords: Statin; Diabetes; Elderly; American Diabetes Association; Standards of Medical Care

Introduction

Cardiovascular disease (CVD) is the leading cause of morbidity and mortality for individuals with diabetes.[1] CVD mortality rates are about 2 times higher among individuals with diabetes compared to individuals without diabetes.[2]

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Dyslipidemia is one of the common comorbidities among individuals with diabetes and is a modifiable risk factor for CVD. Some strategies in the management of dyslipidemia, including lifestyle modification and some pharmacological treatments have demonstrated efficacy in reducing major CVD events in diabetic patients.[3]

Among different pharmacotherapy options for dyslipidemia, statins have demonstrated the most significant CVD risk reduction in patients with diabetes.[4] Several analyses of diabetic subgroups in large randomized trials found that statin therapy was efficacious in reducing major CVD events and lowering low-density lipoprotein (LDL) cholesterol.[5–9] The efficacy of statins was discordant in two large randomized trials of patients with diabetes. In 2004, the Collaborative Atorvastatin Diabetes Study (CARDS) reported that statin therapy was efficacious in reducing the risk of major CVD events; while in 2006, the Atorvastatin Study for Prevention of Coronary Heart Disease Endpoints in Non-Insulin-Dependent Diabetes Mellitus (ASPEN) reported that the reduction of CVD death due to statin therapy was not significant.[10,11] The efficacy of statins was further evaluated in a meta-analysis in 2008. The meta-analysis included 14 randomized trials of statins comparing individuals with and without diabetes and concluded that statin therapy was efficacious in reducing CVD mortality.[12]

Based on the emerging evidence, the American Diabetes Association (ADA) updates the Standards of Medical Care in Diabetes every year. The basis of recommendations in the ADA's Standards is a grading system, including four levels of evidence (A, B, C, and E). A-level is the highest level and represents clear evidence from well-conducted randomized controlled trials (RCTs), compelling non-experimental evidence, or supportive evidence from well-conducted RCTs. B-level is based on supportive evidence from well-conducted cohort or case-control studies. A and B are considered to be high levels of evidence; while C and E are considered as low levels of evidence. In the past decade, the proportion of high level recommendations increased by 35% in CVD-related care.[13]

Since 2005, based on high levels of evidence (level A and B), the ADA's Standards have recommended statin therapy for diabetic patients with overt CVD or for diabetic patients without overt CVD who are over the age of 40.[14] Over the last decade, the ADA's Standards have remained fairly stable with regard to statin therapy recommendations, with a few changes being made in 2008, 2013, and most recently, in 2015. In 2008, the ADA's lipid management recommendations were reorganized to reduce the number of treatment recommendations, to emphasize the broad eligible population of statin therapy, and to start a focus on risk status rather than LDL cholesterol level.[15] Later on, the ADA's Standards in 2013 and 2015 further specified CVD risk factors as family history of CVD, hypertension, smoking, dyslipidemia, albuminuria, overweight, or obesity and defined overt CVD as previous cardiovascular events or acute coronary syndromes.[4,16] These modifications generally made the statin therapy recommendations in the ADA's Standards easier to follow and operationalize in practice.

In the United Sates, the use of statins among patients with diabetes increased consistently in the past two decades.[17] However, in different populations (adults, ambulatory patients, managed care participants, or Medicare beneficiaries) only 20% to 70% of diabetic patients received statins.[17–22] Published studies on statin use among diabetics had significant limitations in light of the ADA's recommendations. For instance, in some published studies, study populations were different from eligible populations defined in the ADA's Standards.[19–22] Study populations in other studies were based on recommendations with a mixture of both high and low levels of evidence.[17,18] In clinical practice, however, health care providers may be less likely to follow recommendations supported by low levels of evidence. No studies have examined how statins are used in eligible diabetic patients based on recommendations from high-level evidence in the ADA's Standards, although a focus on high-level evidence has increased by 30% since 2005.[13] Furthermore, no studies have explored the new trend of statin use based on risk status (overt CVD and CVD risk factors) – an emerging focus of ADA's recommendations for statin treatment and lipid management for diabetics. Last, statin utilization research in the Medicare population, especially after the implementation of Medicare Part D, has been limited. Examining how statins are used by Medicare beneficiaries with diabetes for whom they are recommended by the ADA's Standards with high levels of evidence, based on risk status, and identifying potential predictors of statin use using data containing Medicare Part D information would be essential in understanding how to further align patient care with the ADA's Standards.