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Original Article

Provider recommendations for patient-reported muscle symptoms on statin therapy: Insights from the Understanding Statin Use in America and Gaps in Education survey

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BACKGROUND: Statin-associated muscle symptoms are reported by 10% to 29% of patients in clinical practice and are a major determinant of statin nonadherence, discontinuation, and switching. Little is known about what advice patients receive from their providers when dealing with these symptoms.

OBJECTIVE: The objective of the study was to assess patient's reports of provider advice when experiencing new or worsened muscle symptoms while taking a statin.

METHODS: Data were analyzed from the Understanding Statin Use in America and Gaps in Education survey, a self-administered internet-based survey of 10,138 adults with a reported history of high cholesterol and statin use.

RESULTS: Of the respondents, 60% of former statin users (n = 1220) reported ever experiencing new or worsened muscle pain on a statin, in contrast to 25% of current users (n = 8918; $P < .001$). Former statin users reported stopping more statins because of muscle symptoms (mean ± standard deviation, 2.2 ± 1.7) compared with current users (mean 1.6 ± 1.5, $P < .0001$). For those with muscle-related symptoms while on a statin, participants reported that providers most often suggested switching to another statin (33.8%), stopping the statin (15.9%), continuing the statin with further monitoring of muscle symptoms (12.2%), reducing the statin dose (9.8%), or getting a blood test for signs of muscle damage (9.2%). A lower percentage were advised to add either vitamin D (7.0%) or coenzyme Q10 (5.8%), or to switch to nonstatin therapy (6.1%) or red yeast rice (2.6%).

CONCLUSIONS: This study highlights patient experience with statin-associated muscle symptoms and the strategies recommended by providers in managing these symptoms. More research is needed to develop patient-centric and evidence-based approaches to managing statin-associated muscle symptoms, which is especially important in light of recent data showing increased cardiovascular risk among those who discontinue statin therapy.
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Introduction

Cardiovascular disease is the leading cause of mortality in the United States.[1] Statin (3-hydroxy-3-methylglutary coenzyme A reductase inhibitor) therapy has been consistently shown to reduce cardiovascular events and mortality, and sometimes total mortality, in randomized controlled trials (RCTs).[2]

All current guidelines recommend statins as the primary treatment for decreasing atherosclerotic cardiovascular (ASCVD) risk in adults. The 2013 American College of Cardiology (ACC)/American Heart Association (AHA) guidelines[3] substantially increased the number of US adults for whom statin therapy is recommended from 43.2 million (37.5%) to 56.0 million (48.6%) and also recommended moderate to high-intensity statin doses in most patients.[3,4]

Statin therapy is well documented to be associated with an increased risk of muscle-related symptoms, myopathy, and rhabdomyolysis.[5,6] The Prédiction du Risque Musculaire en Observationnel study was 1 of many observational studies to show increased muscle symptoms associated with use of higher statin doses and higher efficacy statins.[7] Given the recommendations for greater use of statins of higher efficacy and at higher doses, incidence of statin-associated muscle symptoms is likely to increase.

Long-term adherence to statins tends to be low, even in randomized clinical trials, with 5-year discontinuation rates of 33% and 18% reported in primary and secondary prevention trials, respectively.[8,9] Nonadherence rates in clinical practice are reported to be significantly higher.[10–12] Lack of persistence and poor adherence to statin therapy has been associated with increased risk for adverse cardiovascular outcomes.[11,12] Importantly, muscle-related side effects are the primary reason for statin discontinuation.[13,14]

To help improve adherence and persistence with statin therapy, and eventually achieve greater reductions in cardiovascular morbidity and mortality, it is essential to understand patients' attitudes and behavior related to muscle-related side effects of statins. As part of the Understanding Statin Use in America and Gaps in Patient Education (USAGE) Survey, an Internet survey of 10,138 current and former statin users, we have previously described the prevalence and characteristics of patients who experienced new or worsened muscle symptoms on a statin, as well as of those who stopped taking a statin for these side effects.[13–17] In this additional analysis, we further describe patient reports of healthcare provider advice for managing new or worsened muscle symptoms on a statin.

Methods

Study design

The evaluable sample was derived from participants in the USAGE survey that was conducted from September 21, 2011, through October 17, 2011, as an Internet-based, self-administered questionnaire developed by Kantar Health (New York, NY), with input from the study investigators representing the National Lipid Association (NLA), as well as individuals from Kowa Pharmaceuticals America, Inc (Montgomery, AL), and Eli Lilly and Company (Indianapolis, IN). The survey was administered by Lightspeed Online Research, Inc (New York, NY), a subsidiary of Kantar Health. The study protocol and questionnaire were Health Insurance Portability and Accountability Act compliant and were reviewed and approved by the Essex Institutional Review Board (Lebanon, NJ).

Participants and survey

As previously reported,[13] 27,946 individuals with high cholesterol were identified from the Ailment Panel of Lightspeed Online Research (Lightspeed Consumer Panel 2009) (13) by the use of multisource recruiting methodology. After field testing the survey to approximately 10% of prequalified individuals, all potential respondents were then invited via e-mail to participate. The survey content was not described in the invitation. Approximately 2 to 4 days after the initial e-mail invitation, an additional e-mail reminder was sent to those who had not previously responded. Of 15,346 individuals (54.9%) who expressed a desire to participate in the survey, a link was then sent out with a preliminary screening questionnaire to assess whether they met the following inclusion criteria: aged ≥18 years, self-reported diagnosis of a high cholesterol level made by a health care provider, self-reported current or former use of a statin (as monotherapy or in combination with another cholesterol-lowering medication), ability to read and write English, and residence in the United States at the time of the survey. Respondents who did not meet these inclusion criteria were excluded from the survey sample.

Individuals (n = 10,138) who met survey eligibility criteria were then asked to provide informed consent, at which time the topic of the survey was explained and resources to address any questions or concerns were provided. Survey participants then completed the online survey of 89 questions related to demographics, employment, disease severity and history, treatment history and satisfaction, adherence, attitudes toward statin treatment, sources of information, and health resource costs. The respondents received a small incentive for their participation in the form of points that could be redeemed for gift certificates.

Primary data analyzed in this report

The major questions asked of participants were as follows:

(1) "Have you ever experienced new or worsening muscle symptoms while taking a statin?" Muscle symptoms were defined as pain, weakness, cramps, or aching.

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