Original Article

Predictors of first-year statin medication discontinuation: A cohort study

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KEYWORDS:

Discontinuation; Statins; Adherence **BACKGROUND:** The discontinuation of statin medication is associated with an increased risk of cardiovascular and cerebrovascular events and, among high-risk patients, all-cause mortality, but the reasons for discontinuation among statin initiators in clinical practice are poorly understood.

OBJECTIVE: To examine factors predicting the early discontinuation of statin therapy.

METHODS: In this prospective cohort study, participants with baseline measurements before the initiation of statin treatment were linked to national registers and followed for the discontinuation of statins during the first year of treatment (no filled prescriptions after statin initiation within the subsequent 12 months).

RESULTS: Of all the 9285 statin initiators, 12% (n = 1142) were discontinuers. Obesity, overweight, vascular comorbidities, and older age were independently associated with a reduced risk of discontinuation [odds ratios (OR) = 0.82 (95% confidence interval [CI], 0.69–0.99), 0.85 (95% CI, 0.73–0.98), 0.80 (95% CI, 0.68–0.93), and 0.82 (95% CI, 0.68–0.99), respectively]. In contrast, high-patient cost-sharing was associated with an increased odds (OR = 1.29; 95% CI, 1.03–1.62) for discontinuation. The only significant difference between the sexes (P = .002) was observed among the participants with risky alcohol use, which was associated with a decreased odds for discontinuation among the men (OR = 0.69; 95% CI, 0.49–0.98) and an increased odds among the women (OR = 1.28; 95% CI, 1.02–1.62).

CONCLUSIONS: The discontinuation of statin therapy during the first year after initiation is common. Lowering out-of-pocket expenditures and focusing on low-risk patient groups and women with risky alcohol use could help maintain the continuation of medication.

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What is already known about this subject?

Despite well-documented benefits of statins, discontinuation of statin medication is common among primary and secondary prevention patients.

What does this study add?

Several predictors of discontinuation are readily assessable and can provide information with which to identify those with an increased risk of nonadherence.

How might this impact on clinical practice?

In clinical practice, many patients for whom statins are prescribed discontinue the use of the drug within a year, which is likely to reduce any benefit of medication and increase the risk of cardiovascular events. Increased efforts to motivate treatment adherence in risk groups could reduce discontinuation and cardiovascular events.

Introduction

Statins are one of the most widely studied and evidencebased medications¹ and are an essential component of cardiovascular disease prevention. Statins are well tolerated, safe, and inexpensive (when following the generic substitution). Despite these well-documented benefits, poor adherence to statins and an extreme form of it, discontinuation—that is, quitting statin medication use²—is common among primary and secondary prevention patients.³⁻⁶ In clinical trials, the discontinuation rates range from 4% to 11%,^{7–9} but in routine care, the rates are much higher; between 11% and 53%. ^{2,3,10,11} According to studies using electronic medical records, approximately 25% to 50% of patients discontinue statin use within six months to one year after initiating their use.^{4,5,12} The number of patients continuing therapy falls sharply in the first few months of treatment, followed by a more gradual decline.^{4,13}

Discontinuation is commonly attributed to statin-related adverse events, but, because most patients who reinitiate statin use can tolerate this medication long-term, 2 many of these events may have had other etiologies. Previous studies on the determinants of discontinuation have reported mixed results. Some found a greater tendency to discontinue statin treatment among the young (<50 years) or old (>70 years), $^{11,14-16}$ with high co-payment, 2,3,17,18 for primary prevention patients, 3,5,15,19-21 and intensive dose therapy.²² An increased risk of statin discontinuation has also been found for smokers,20 and patients with diabetes^{20,23} despite the current guidelines recommending statin medication for nearly all patients with type 2 diabetes.²⁴ On the contrary, one study found diabetes to be associated with the continuation of lipid-lowering drugs (of which statins accounted for 69%).²⁵ However, other studies have shown no association between discontinuation and age, ^{19,20,26–29} diabetes, ^{6,16,27,29} or smoking. ²⁷

This study was aimed at identifying patient groups with an increased likelihood to discontinue statins in a large prospective cohort linked to prescription registers. A better understanding of the determinants of adherence to statin treatment is important because discontinuation is common, and it significantly increases both the incidence of cardio-vascular and cerebrovascular events³⁰ and, among high-risk patients, also all-cause mortality. Because the decision concerning the continuation of statin-use is commonly made during the first year of treatment, we restricted our analysis to predictors of discontinuation during the first year of medication.

Methods

Study population and design

The data used in this study came from the Finnish Public Sector Study,³⁴ a prospective study of all local government employees of 10 towns and all employees in 21 public hospitals with a \geq 6-month job contract in 1991–2005.

We initially included the 80,459 identifiable participants who responded to a survey in 1997–1998, 2000–2002, 2004, or 2008. The questionnaires involved demographic characteristics, lifestyle factors, and health status, and the average response rate was 70%. We linked the survey data to data from national health registers using unique personal identification numbers as in our earlier studies.^{34,35} Among the respondents, there were 11,949 participants who had initiated statin medication between 1 January, 1998 and 31 December, 2010. Of them, we included all the 9285 participants who had completed a survey before the statin therapy began and had not been dispensed statins in the previous two years. From the initiators, we identified the 1142 discontinuers (initiators who filled only one prescription during the first year of statin treatment; Figure 1). Follow-up data were available until 31 December 2011. In cases of repeated surveys before initiation, we selected the most recent response. The mean lag between the response and statin initiation was 3.4 years (standard deviation, SD \pm 2.4).

Discontinuation of statin treatment

In Finland, statins are available by prescription only. The National Health Insurance Scheme provides prescription drug coverage for all (~5.4 million) community-dwelling residents. All reimbursed prescriptions are registered in the Finnish Prescription Register managed by The Social Insurance Institution of Finland.³⁶ Reimbursed medicines can be supplied to a patient for three months per purchase. For each drug, reimbursement-related factors including the dispensing date, the World Health Organization Anatomical Therapeutic Chemical (ATC) code,³⁷ the quantity dispensed, and co-payment are recorded.

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