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The impact of lipid-lowering treatment patterns on LDL-C reduction and goal attainment in secondary prevention in Germany

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Summary
Background: Information on lipid-lowering treatment (LLT) patterns (statin titration, statin switching, combination therapy and no change) in clinical practice is limited. The objectives of this study were to (i) characterize LLT patterns, (ii) explore variables that influence choice of aggressive initial and subsequent statin regimens and (iii) evaluate the impact of LLT patterns on LDL-C reduction and goal attainment.
Design: Randomly drawn patients who were newly initiated on statin ($n = 603$) from 62 randomly selected practices were retrospectively evaluated for a median of 3.9 years between 1998 and 2002.
Methods: Logistic regression, Cox model, *t*-test and GLM were used in the analyses. All tests of statistical significance were two-sided with $\alpha = 0.05$.
Results: Both patient- and physician-related variables were important in the choice of initial and subsequent statin regimens. Patients initiated on LLT after revascularization were more likely to receive a high potency statin both initially and during subsequent changes. LDL-C levels influenced the choice of aggressive regimen. Switches to an aggressive regimen (68%) occurred in the first two years of therapy. Patients with more cardiac-related prescriptions at baseline had greater prescription persistence. Despite aggressive regimen changes, relatively few patients attained

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the target LDL-C of 100 mg/dL; nor was the reduction significantly different from that of the non-switched group.
Conclusion: Current statinmonotherapy-dominated LLT in Germany failed to get the majority of patients to recommended LDL-C goal of <100 mg/dL. Improved lipid management strategies are required so that patients on LLT get the necessary reductions in LDL-C and the benefits of projected reductions in CVD morbidity and mortality.

Introduction

Recent clinical trials and observational studies [1—6] have shown that aggressive management of elevated low-density lipoprotein cholesterol (LDL-C) with lifestyle modification and pharmacologic therapy can limit cardiovascular morbidity and mortality. In fact, patients with a recently diagnosed acute coronary syndrome (ACS) may benefit from early and continued lowering of LDL-C to levels substantially below the target of 100 mg/dL levels recommended by NCEP guidelines [7,8]. Despite this evidence, numerous studies have demonstrated inadequate treatment of patients having elevated LDL-C levels [9—16], and some researchers have reported a higher level of discontinuation of lipid-lowering therapy (LLT) in actual practice than in clinical trials [17]. Consistent with the above research, others have found underutilization of lipid-lowering medication and poor goal attainment in coronary heart disease (CHD) populations [18,19]. The above results could be indicative of a complex interplay among the prescribing patterns of LLT by physicians, patient behavior and characteristics of the drugs used [20]. For example, the initial choice of a particular lipid-lowering drug or a change in the lipid-lowering drug regimen will likely affect LDL-C reduction and goal attainment. Similarly, patient adherence to the prescribed therapy could influence changes in LDL-C.

Evaluation of the prescribing patterns of LLT in patients treated for cholesterol reduction should provide a better understanding of the current under-treatment associated with LLT. However, studies on the prescribing patterns of LLT in CHD patients have been sparse. Important issues in such an analysis of long-term LLT include choice of potency, regimen changes and prescribing persistence. This retrospective cohort study assessed prescribing patterns of LLT in the management of hypercholesterolemia in actual clinical practice, both in general practices and cardiology outpatient settings in Germany. In addition, the study also evaluated the effectiveness of current statin treatment in terms of LDL-C reduction and goal attainment. The specific objectives were to:

(1) Characterize prescribing patterns of LLT in terms of the following:
   - Choice of initial statin regimen in terms of potency;
   - Changes from initial regimen and
   - Prescription persistency.
(2) Factors that influence choice of initial LLT, regimen changes, time to first switch and prescription persistence.
(3) Effectiveness of LLT in clinical practice in terms of reduction in LDL-C and achievement of LDL-C treatment goal as specified by the NCEP guidelines, which are currently used in German clinical practice.

Methods

Study design

In this multicenter, retrospective, observational study, 6000 primary-care practices (GPs/internists) and 1200 cardiology practices were randomly chosen from the universe of all practices in Germany and contacted. Of the 237 practices that consented to participate, 53 primary-care and nine cardiology practices were again randomly selected and enrolled. The objective was to obtain information on 500 CHD patients in primary care and 100 CHD patients in cardiology care, a ratio that represents CHD aftercare in Germany. Data were originally collected for a study on the effect of pre-treatment LDL-C level and pretreatment risk factors on the effectiveness of LLT in males and females [21]. The current study used the same data to conduct additional analyses to address the above mentioned goals. No additional data were collected for this study.

Data were collected by trained research personnel (Kendle Int. Inc., Munich) who interviewed the physicians with the help of standardized data