

Higher Cardiovascular Event Rates for Americans Who Do Not Meet 2018 Multidisciplinary Guideline on the Management Of Blood Cholesterol Thresholds

Kelly D. Myers^{1,2}, Katherine A. Wilemon¹, Catherine D. Ahmed¹, Hilliard Paige Jr¹, William Howard², Diane E. MacDougall¹, Mary P. McGowan¹ Family Heart Foundation, Pasadena CA; ²Atomo Inc., Austin TX

SYNOPSIS

The 2018 Multidisciplinary Guideline on the Management of Blood Cholesterol calls for the initiation and intensification of lipid-lowering therapy (LLT) if low-density lipoprotein cholesterol (LDL-C) exceeds thresholds in patients at elevated risk. Despite LDL-C being a major modifiable cardiovascular risk factor, most patients fail to meet guideline thresholds.

PURPOSE

To assess the consequences of failure to achieve LDL-C guideline threshold in patients at elevated risk using the Family Heart Database™.

METHODS

The Family Heart Database™ is comprised of diagnostic, procedure and prescription data from medical claims as well as lab result data for >324 million individuals in the US from 2012 to 2021.

The dataset used in this retrospective analysis assessed annual cardiovascular event (CE) rates in 56,349 patients with severe primary hypercholesterolemia (LDL-C ≥190 mg/dL), other risk factors, or ASCVD who met the following criteria:

- ≥ 48 months of sufficient diagnosis, procedure, prescription, and lab data
- ≥ 3 cholesterol results
- Above Threshold or Below Threshold for at least 70% of the study period (including baseline).

LDL-C guideline thresholds are defined as:

- ≥100 mg/dL for patients with severe primary hypercholesterolemia (LDL-C ≥190 mg/dL) and/or other risk factors
- ≥70 mg/dL for individuals with clinical ASCVD

RESULTS

- 39,117 and 17,232 individuals met the criteria for Above Threshold and Below Threshold cohorts, respectively.
- A 1:1 PSM resulted in 14,755 individuals in each group.
- The assessment period (mean ± standard error) was 2,091.58 ± 3.46 days/PSM patient.

Real-world data from the Family Heart Database[™] showed that Americans in the Above Threshold group had an AIR of first CE 44.2% (p<0.0002) higher than those in the Below Threshold group (2.2% or 1,879 vs. 1.5% or 1,226).

Total CEs (first and subsequent) in the Above Threshold group were also 49% higher (p< 0.0002) than those in the Below Threshold group (3,510 vs. 2,356).

Unfortunately, few Americans ever reached recommended LDL-C levels, despite the availability of many effective and safe LLTs.

CONCLUSIONS

In this real-world evaluation of patients at elevated risk, achieving LDL-C guideline thresholds substantially reduces cardiovascular events.

Greater emphasis on achieving LDL-C control would improve cardiovascular health at a population level.

The Family Heart Foundation is a 501c3 public charity research and advocacy organization that receives contributions and sponsorships from individuals, foundations, and pharmaceutical companies. This research was partially funded by Amgen, although it played no role in study design, conduct, interpretation, or plans for publication.

FamilyHeart.org



METHODS (cont.)

Patient histories were divided into **contiguous episodes** characterized by LLT use (mono/combination/no therapy), prescriptions filled, and LDL-C levels (see Figure 1).

An 18-month baseline period was used to determine the covariates for propensity score matching (PSM). Individuals with a CE during the baseline were excluded.

Following the baseline period, individuals were observed for **>30 months** to determine the date of the **first CE and annual incidence rates (AIR)** were calculated.

Figure 1: AIR of first CE in patients Above and Below Threshold

Representative patients are shown with complex and variable lipid profiles over time, including episodes (represented by colored blocks) that are characterized by LDL-C level and medication use. Periods of time with missing or insufficient data appear as white gaps and are not episodes.

