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

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BACKGROUND

The 2018 Multidisciplinary Guideline on the Management of Blood Cholesterol calls for initiation and intensification of cholesterol lowering therapy if low density lipoprotein cholesterol (LDL-C) exceeds specific thresholds**. Despite LDL-C being a major modifiable cardiac risk factor, most Americans fail to reach below recommended LDL-C thresholds.

This analysis aims to quantify the consequence of failure to reach below recommended LDL-C thresholds by quantifying the impact on cardiovascular events using real world data from the Family Heart Database™.

METHODS

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

This retrospective analysis assessed annual cardiovascular event rates in a subset of high-risk patients (see definition below) who met the following criteria:

- ≧ 48 month of sufficient diagnosis, procedure, prescription, and lab data
- ≧ 3 cholesterol measures
- AT GOAL** or NOT AT GOAL** for ≥70% of the study (including baseline).

Guideline Defined High-Risk Patients	LDL-C Goal**
Severe primary hypercholesterolemia (LDL-C ≥190 mg/dL)	<100 mg/dL
ASCVD	<70 mg/dL

Patient histories were divided into contiguous episodes characterized by cholesterol-lowering therapy use (including no therapy, mono and combination therapy), prescriptions filled, and LDL-C level (see Figure 1).

An 18-month baseline period was used to determined the covariates for propensity score matching (PSM). Individuals with a cardiovascular event during the baseline were excluded. Following the baseline period, an observation period of ≥30 months was used to determine the date of the 1st cardiovascular event and annual incidence rates (AIR) were calculated.

**** Note – the 2018 Cholesterol Guideline uses the term, "*LDL-C threshold*." For clarity and ease of description this term is referred to here as "*LDL-C goal*" (i.e., a guideline recommended *LDL-C threshold* of ≥100 mg/dL is referred to here as an *LDL-C GOAL* of <100 mg/dL).**

Real-world data from the Family Heart Database shows that high-risk Americans who consistently fail to reach guideline-recommended LDL-C levels have an annual rate of cardiovascular events that is 44.2% (p<0.0002) higher than those who consistently reach recommended LDL-C levels.

Unfortunately, few high-risk Americans ever reach guideline recommended LDL-C levels, despite the availability of many effective and safe lipid-lowering therapies.

The annual 1st cardiovascular event rate (AIR) in high-risk individuals was:

- **2.2% if "NOT AT GOAL" at least 70% of the time, versus**
- **1.5% if "AT GOAL" at least 70% of the time.**

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RESULTS

The Family Heart Database included 38,110,734 high-risk patients, of whom 39,117 were "NOT AT GOAL" and 17,232 were "AT GOAL" and met all other inclusion criteria. After 1:1 PSM, 14,755 individuals were included in each group. Assessment period (mean ± standard error) was 2,091.58 ± 3.46 days/PSM patient.

See middle panel. First cardiovascular events were 44.2% higher (p<0.0002) in the "NOT AT GOAL" versus "AT GOAL group (1,879 vs 1,226 first events).

Total cardiovascular events (1st and subsequent) were also 49% higher (p< 0.0002) in the "NOT AT GOAL" versus "AT GOAL" group (3,510 vs 2,356 total events).

CONCLUSION AND DISCUSSION

These real-world data demonstrate the consequence of sub-optimal LDL-C management over time. High-risk patients that may be taking cholesterol lowering medications but are consistently above guideline-recommended LDL-C levels over 4 or more years have substantially more cardiovascular events. Greater emphasis on achieving LDL-C control, using widely-available medications and applying current guidelines, would improve cardiovascular health at a population level.

FIGURE 1

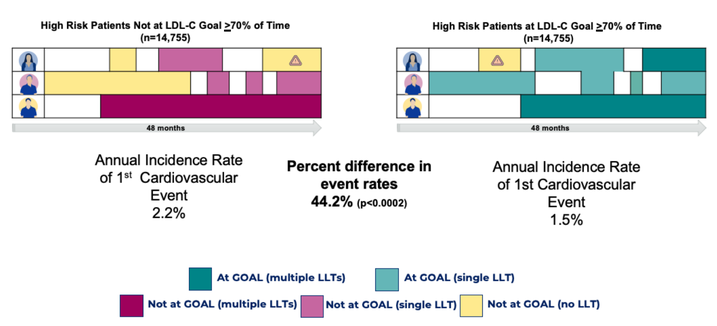

Figure 1: All patients are propensity score matched. Representative patients are shown with complex and variable lipid profiles over time, including e*pisodes* (represented by colored blocks) that are characterized by LDL-C level and medication use. Periods of time with missing or insufficient data appear as white gaps and are not episodes. LLT, lipid lowering therapy

DISCLOSURE INFORMATION

Author Disclosures: none

FAMILY HEART FOUNDATION

Lipoprotein(a) & Familial Hypercholesterolemia