Lipid Management in High Cardiovascular Risk Patients Without Prior Myocardial Infarction or Stroke: Preliminary Data From the VESALIUS-REAL Global Burden Study

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Background

Cardiovascular disease is the leading cause of morbidity and mortality globally.[1]

- **Low-density lipoprotein cholesterol (LDL-C)** is an important modifiable risk factor for major adverse cardiovascular events.[2]

Early initiation of lipid-lowering therapy (LLT) in high-risk patients before occurrence of a myocardial infarction (MI) or stroke may have **substantial public health benefits**; however, the size and potential healthcare burden of this population globally are not known.[1]

We conducted an observational study (**VESALIUS-REAL**) to examine **a real-world population** of **patients at high risk for a first MI or stroke** across different healthcare settings from different countries and regions.

LDL-C, low-density lipoprotein cholesterol; LLT, lipid-lowering therapy; MI, myocardial infarction.

1. McClellan M, et al. *Circulation*. 2019;139:e44-e54. 2. Martin SS, et al. *Circulation*. 2024;149:e347-e913.

Study Objectives

To describe LLT and LDL-C testing patterns in patients at high risk for a first MI or stroke.

Study Design

- Retrospective cohort study
- Analytical common data model approach
- Global statistical analysis plan: database-specific plans for 11 databases from Asia/Pacific, Europe, and North America
- Study period from 2010 to 2024, subject to data availability in study sites

Here, we report results from five countries with index dates of 2017 or later: Japan, South Korea, Germany, UK, and US.

LDL-C, low-density lipoprotein cholesterol; LLT, lipid-lowering therapy; MI, myocardial infarction.
Ochs A, et al. *BMJ Open*. 2025;15:e092702.

VESALIUS-REAL Patient Eligibility Criteria

ELEVATED LIPIDS

LDL-C
≥ 90 mg/dL
(≥ 2.3 mmol/L)

OR

Non–HDL-C
≥ 120 mg/dL
(≥ 3.1 mmol/L)

OR

ApoB
≥ 80 mg/dL
(≥ 1.56 µmol/L)

\+

PRE-EVENT DISEASE

CAD

OR

CeVD

OR

PAD

OR

HRDM*

\+

RISK FACTOR

Second disease:
CAD *OR* CeVD *OR* PAD *OR* HRDM

OR

Further elevated lipids:
LDL-C ≥ 130 mg/dL (≥ 3.4 mmol/L)
OR
Non–HDL-C ≥ 160 mg/dL
(≥ 4.1 mmol/L) *OR*
ApoB ≥ 120 mg/dL (≥ 2.3 µmol/L)

OR

CKD stage 3/4 *OR* **known FH** *OR*
history of tobacco use *OR*
≥ 65 years of age *OR*
menopause before 40 years of age

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CANNOT HAVE HAD

MI, stroke, or ESRD prior to, and including, index date

OR

< 2 years of observation period prior to index date

OR

Patients < 50 years of age at index date

***Index date** is the earliest date at which a patient meets all eligibility criteria.*

*Defined as DM with microvascular complications or chronic insulin use (≥ 2 prescriptions for insulin).

apoB, apolipoprotein B; CAD, coronary artery disease; CeVD, cerebrovascular disease; CKD, chronic kidney disease; DM, diabetes mellitus; ESRD, end-stage renal disease; FH, familial hypercholesterolemia; HDL-C, high-density lipoprotein cholesterol; HRDM, high-risk diabetes mellitus; LDL-C, low-density lipoprotein cholesterol; MI, myocardial infarction; PAD, peripheral artery disease.

Ochs A, et al. *BMJ Open*. 2025;15:e092702.

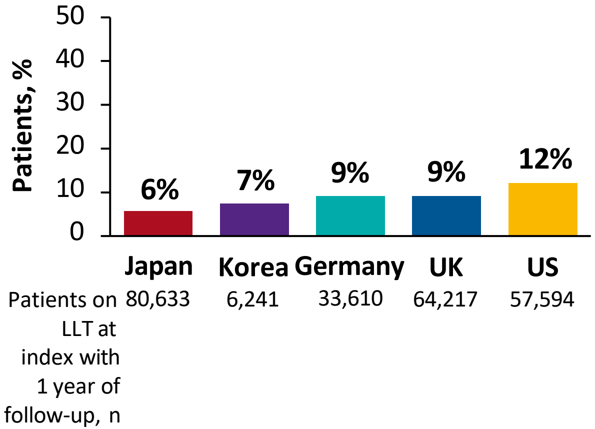
Patient Characteristics

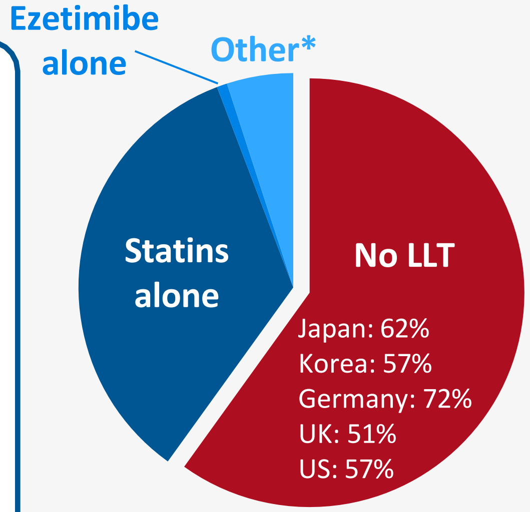
	Japan 2017–2022	South Korea 2017–2019	Germany 2017–2022	UK 2017–2020	US 2018–2022
Database	DeSC claims database	National Health Insurance Service-National Health Screening	German Disease Analyzer	Clinical Practice Research Datalink Aurum	HealthVerity claims database
N	330,855	24,920	141,380	167,420	234,785
Female	53%	47%	49%	49%	56%
Age, (years)*	79 (67, 84)	65 (59, 70)	70 (62, 79)	71 (62, 79)	64 (58, 71)
CAD	41%	38%	50%	38%	38%
CeVD	35%	23%	15%	24%	16%
PAD	9%	15%	16%	14%	12%
High-risk DM	25%	30%	32%	28%	39%

*Age: median (Q1, Q3).
CAD, coronary artery disease; CeVD, cerebrovascular disease; DM, diabetes mellitus; N, number of patients; PAD, peripheral artery disease; Q1, first quartile; Q3, third quartile.

LLT at Index and Within 1 Year of Follow-up

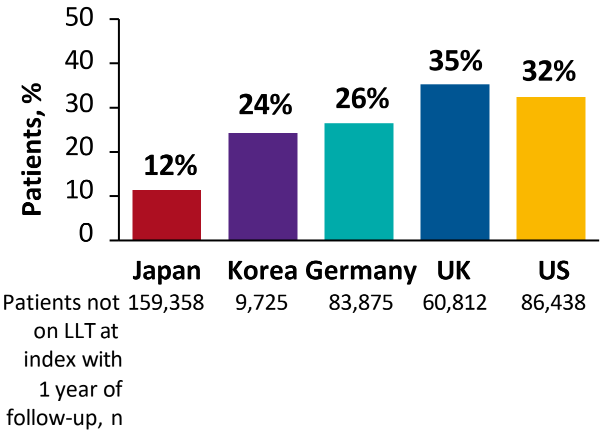
Patients With LLT Intensification Within 1 Year





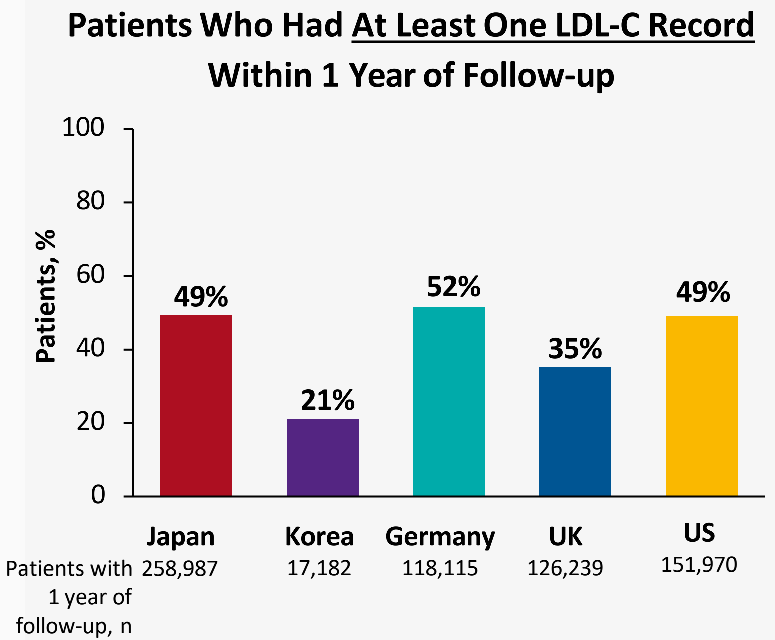
LLT for All Patients at Index

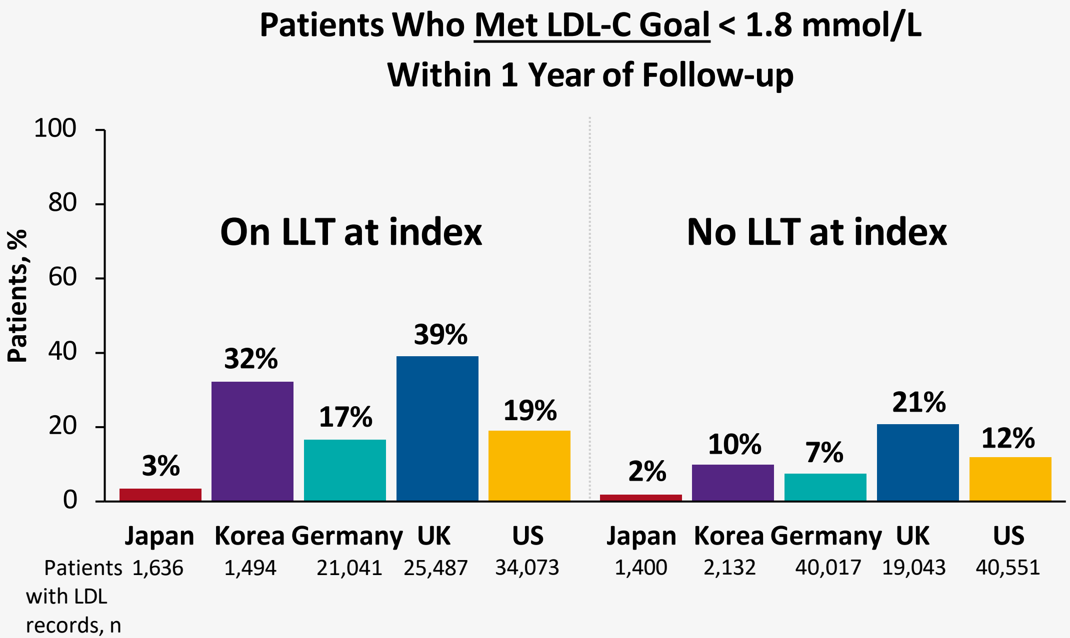
Patients Who Initiated LLT Within 1 Year



*Other LLT or combination therapy.
LLT, lipid-lowering therapy.

Achieved ESC-Recommended LDL-C Goals Within 1 Year of Follow-up





ESC, European Society of Cardiology; LDL-C, low-density lipoprotein cholesterol; LLT, lipid-lowering therapy.

Conclusions

Despite being at high CV risk, most patients (51%–72%) had no LLT at index and ≤ 35% had initiated or intensified LLT within 1 year.

Only up to approximately half of patients at high CV risk had an LDL-C test recorded within 1 year of follow-up.

At 1 year of follow-up, only 2%–39% of patients met the ESC-recommended LDL-C goal of < 1.8 mmol/L.

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CV, cardiovascular; ESC, European Society of Cardiology; LDL-C, low-density lipoprotein cholesterol; LLT, lipid-lowering therapy.