Lipid-Lowering Therapy Use in High-Risk ASCVD Patients Without Prior MI or Stroke – Preliminary Data From VESALIUS-REAL, US

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BACKGROUND

- Early reduction of low-density lipoprotein cholesterol (LDL-C) in patients with atherosclerotic cardiovascular disease (ASCVD) reduces the risk of recurrent cardiovascular (CV) events.
- Intervening prior to an ischemic event may result in a larger clinical benefit. An ongoing phase 3 study is investigating the "Effect of E**V**olocumab in Pati**E**nt**S** at High C**A**rdiovascu**L**ar R**I**sk Witho**U**t Prior Myocardial Infarction or **S**troke (VESALIUS-CV)."
- Our observational study examines the lipid management patterns in a VESALIUS-CV–like population in the real world (VESALIUS-REAL) across 11 regions/countries. Here, we present data from the US.

OBJECTIVE

- To describe lipid management patterns in patients in the US at high CV risk without prior myocardial infarction (MI) or stroke.

METHODS

- Data source: HealthVerity medical and pharmacy claims, linked to laboratory data (2016–2022).
- Eligibility criteria were aligned with the clinical trial (see QR code).
  - Index was defined as the earliest date when patients met all eligibility criteria.
- The first possible cohort entry date was January 1, 2018.
- Treatment intensification was defined as the first dose increase (for statins), a switch to a more intensive lipid-lowering therapy (LLT), or an increase in the number of drug classes.

PATIENT CHARACTERISTICS

- Of 278,489 US patients (median age: 67.6 years)
  - 55.8% were female, 24.9% had a history of smoking
- **Medical history**
  - 39.1% had coronary artery disease
  - 11.6% had peripheral artery disease
  - 15.9% had cerebrovascular disease
  - 37.3% had high-risk diabetes
- **LLT and LDL-C**
  - Median baseline LDL-C: 119 mg/dL
  - 60% were receiving no LLT at index

DISCLOSURES: **QC**, **SS**, **AO**, **ND**, **ES**, **CB**, **GPDSL**, and **SA**: employees and shareholders of Amgen Inc. **MJB**: grants from Amgen Inc., AstraZeneca, Boehringer Ingelheim, GE Healthcare, Heartflow, National Institutes of Health, Novartis, Novo Nordisk, and U.S. Department of Defense; personal fees from AstraZeneca, Eli Lilly, Esperion, Janssen, Merck, and Novo Nordisk. **ICKW**: research grants from Amgen Inc., Bayer, Bristol Myers Squibb, European Commission, European Union's Seventh Framework Programme for Research and Technological Development, GSK, Health and Medical Research Fund Hong Kong, Institute for Health Research in England, Janssen, National Health and Medical Research Council in Australia, Novartis, Pfizer, Research Grants Council Hong Kong, and Takeda; consulting fees from IQVIA and WHO; payment for expert testimony for Appeal Court in Hong Kong; advisory committees for Member of Pharmacy and Poisons Board, the Expert Committee on Clinical Events Assessment Following COVID-19 Immunization, and the Advisory Panel on COVID-19 Vaccines of the Hong Kong Government; non-executive director of Jacobson Medical in Hong Kong; founder and director of Advance Data Analytics for Medical Science (ADAMS) Limited (HK), Asia Medicine Regulatory Affairs (AMERA) Services Limited, and OCUS Innovation Limited (HK, Ireland and UK). Medical writing and editorial support provided by Lisa Carson, PhD, of Red Nucleus, and funded by Amgen Inc. Editorial support provided by Ellen Stoltzfus, PhD, of Amgen Inc.

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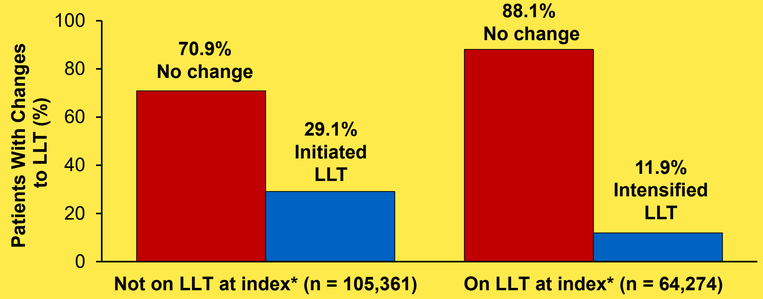
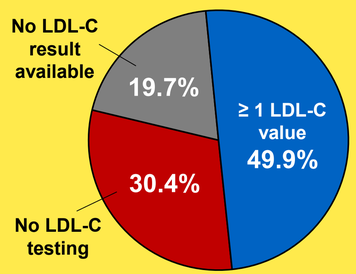
Among patients with high CV risk and no prior MI or stroke, 70.9% of patients did not initiate and 88.1% did not intensify LLT within 1 year of follow-up



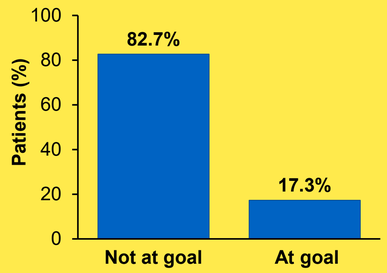
*Defined as LLT prescription fill on or up to 90 days prior to the index date. Includes patients with 1 year of follow-up (n = 169,635). Excludes patients on other LLT at index (ie, bempedoic acid, fibrates, bile acid sequestrants, niacin, mipomersen, and lomitapide). LLT, lipid-lowering therapy.

Within 1 year of follow-up, 50.1% of patients did not have an LDL-C test result. Of those with an LDL-C result, 82.7% did not achieve the guideline-recommended LDL-C goal

LDL-C Testing Within 1 Year of Follow-up (n = 178,361)*



Achievement of LDL-C < 70 mg/dL Goal Within 1 Year of Follow-up (n = 89,002)

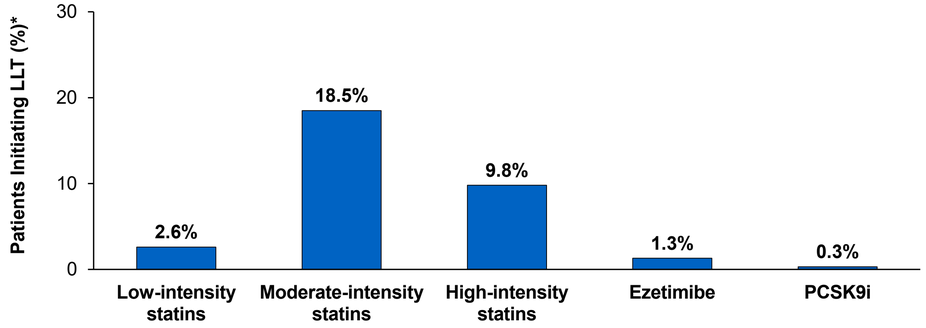


*Includes patients with at least 1 year of follow-up. Goal achievement evaluated using the last LDL-C value during the follow-up year. LDL-C, low-density lipoprotein cholesterol.

For more information, scan the QR code

RESULTS

Figure 1. LLT initiation patterns within 1 year of follow-up among those with no LLT at index (n = 105,361)



*Patients could initiate multiple LLTs. PCSK9i includes evolocumab, alirocumab, or inclisiran. Data are not shown for bempedoic acid due to the low rate of initiation (n = 64 [0%]). LLT, lipid-lowering therapy; PCSK9i, proprotein convertase subtilisin/kexin type 9 inhibitor.

- The most frequently initiated LLT was moderate-intensity statins (18.5%).
- Less than 2% of patients initiated a nonstatin LLT.

Table 1. LLT intensification patterns within 1 year of follow-up for patients already on LLT at index (n = 64,274)

		Intensification of LLT within 1 year of follow-up					
		Any intensification	Low-intensity statin	Moderate-intensity statin	High-intensity statin	Add ezetimibe	Add PCSK9i
LLT at index	Low-intensity statin (n = 6,420)	1,563 (24.3%)		1,226 (19.1%)	408 (6.4%)	54 (0.8%)	**
	Moderate-intensity statin (n = 37,999)	4,876 (12.8%)			4,574 (12.0%)	378 (1.0%)	81 (0.2%)
	High-intensity statin (n = 17,110)	649 (3.8%)				561 (3.3%)	93 (0.5%)
	Ezetimibe (n = 1,045)	383 (36.7%)	35 (3.3%)	211 (20.2%)	124 (11.9%)		49 (4.7%)
	LLT combination (n = 1,700)	144 (8.5%)	**	19 (1.1%)	77 (4.5%)	12 (0.7%)	34 (2.0%)

Blue shading represents the most frequent intensification for a given baseline LLT. **Data are not shown due to the low sample size. LLT, lipid-lowering therapy; PCSK9i, proprotein convertase subtilisin/kexin type 9 inhibitor.

CONCLUSIONS

These findings suggest an opportunity to improve lipid management and attain guideline-recommended LDL-C goals among patients with high CV risk and no prior history of MI or stroke

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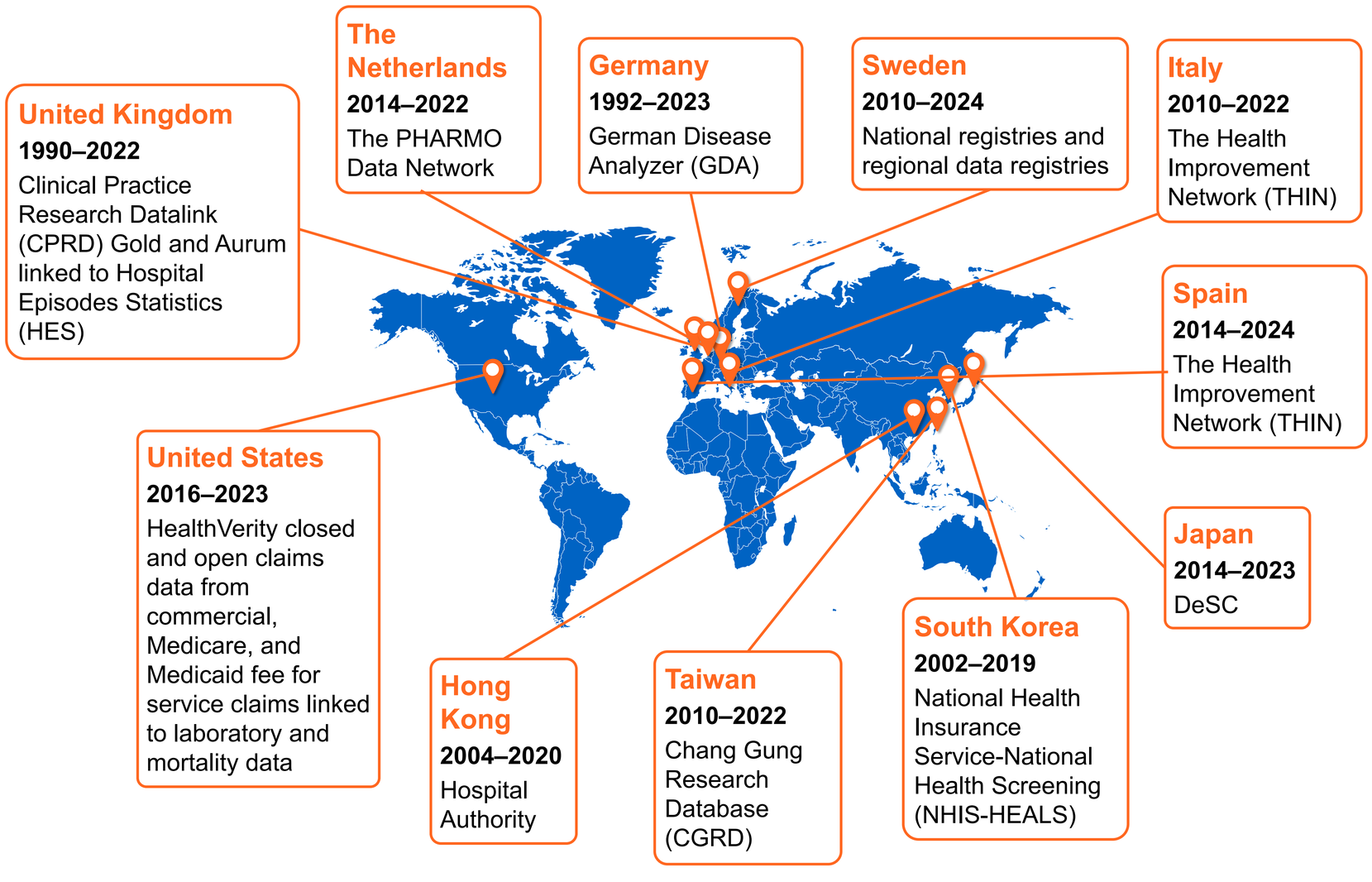
Setting: Countries and sites



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)

+

DISEASE

Coronary artery disease (CAD) **OR** **Cerebrovascular disease** (CeVD) **OR** **Peripheral arterial disease** (PAD) **OR** **High-risk diabetes mellitus** (DM)*

+

RISK FACTOR

Second disease: CAD or CeVD or PAD or High-risk DM

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

Chronic kidney disease stage 3/stage 4 OR
Known familial hypercholesterolemia OR
Ever tobacco use OR
≥ 65 years of age OR
Menopause < 40 years of age

×

CANNOT HAVE HAD

Myocardial infarction, stroke, or end-stage renal disease 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: earliest date at which patient met all eligibility criteria.

*High-risk DM defined as DM with microvascular complications or chronic insulin use (≥ 2 prescriptions for insulin). ApoB, apolipoprotein B; CAD, coronary artery disease; CeVD, cerebrovascular disease; DM, diabetes mellitus; LDL-C, low-density lipoprotein cholesterol; HDL-C, high-density lipoprotein cholesterol; PAD, peripheral artery disease.