

Suboptimal Adherence and LDL-C Goal Attainment With High-Intensity versus Moderate-to-Low Intensity Statins in Real-World Practice

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Background

- Statins are standard-of-care in hypercholesterolemia and guideline-recommended for patients that require lipid-lowering therapy (LLT)¹
- Statin monotherapy is often inadequate to achieve guideline-directed low-density lipoprotein cholesterol (LDL-C) goals, leaving residual cardiovascular (CV) risk and the need for additional nonstatin treatment options, which are guideline-recommended for certain patients not at goal with statins^{1,2,3}
- Low real-world adherence confounds statin effectiveness⁴

Objective

- To characterize real-world high-intensity statin (HIS) vs moderate-/low-intensity statin (MLIS) use patterns, LDL-C goal attainment, and adherence in patients with and without established atherosclerotic cardiovascular disease (ASCVD) or diabetes mellitus

Methods

- Komodo Claims and Research Dataset, a data schema designed for real-world evidence (RWE) and health economics and outcomes research (HEOR) studies enriched with Komodo-populated imputed allowed amounts and derived from Komodo's HealthcareMap®, were used to identify patient sets (matched on age, gender, and payer type) newly started on HIS or MLIS in 2022 (index event) with at least 60 days of statin persistence (N=1,555,978 each)
 - Pre- and post-index assessment windows were 2 years each
 - Goal attainment (**Table 1**) required ≥1 pre- and ≥1 post-index LDL-C result (achieving LDL-C <70 mg/dL or <55 mg/dL individualized to ASCVD history)
 - Other key goals were portion of patients with ≥50% LDL-C reduction or <25% LDL-C
 - Goal maintenance was defined as either 2 of 2 post-statin results at goal, or 66% of post-statin results at goal in patients who had ≥3 post-statin results
 - Adherence to statin medication was measured at 2, 6, and 12 months. Adherence calculation followed the Healthcare Effectiveness Data and Information Set (HEDIS) claims-based measurement for the proportion of days covered (PDC) for the percentage of patients with statin claims of sufficient quantity and frequency to cover at least 80% of days

Conclusions

- Baseline characteristics in both groups show substantial guideline-discordant statin prescribing in patients diagnosed with ASCVD, demonstrating a large unmet need for well-tolerated, effective therapies that address residual risk, including nonstatins
- While HIS patients were nearer to goal at baseline and significantly more achieved LDL-C goals compared with MLIS patients, both groups had suboptimal goal attainment and showed rapidly declining adherence
- Combination therapy with nonstatin LLT remains underutilized and may further lower LDL-C or be an alternative for patients with low statin adherence

Results

Table 1. Definition of LDL-C Goal

Prevention Category	Definition	Risk Categorization	Goal Definition
Primary Prevention	No ASCVD	N/A	At Goal: LDL-C <100 mg/dL
	ICDx plus statin Rx		Above Goal: LDL-C ≥100 mg/dL
Secondary prevention	ASCVD	High Risk	At Goal: LDL-C <70 mg/dL
			Above Goal: LDL-C ≥70 mg/dL
	ICDx plus statin Rx		At Goal: LDL-C <55 mg/dL
		Very High Risk	Above Goal: LDL-C ≥55 mg/dL

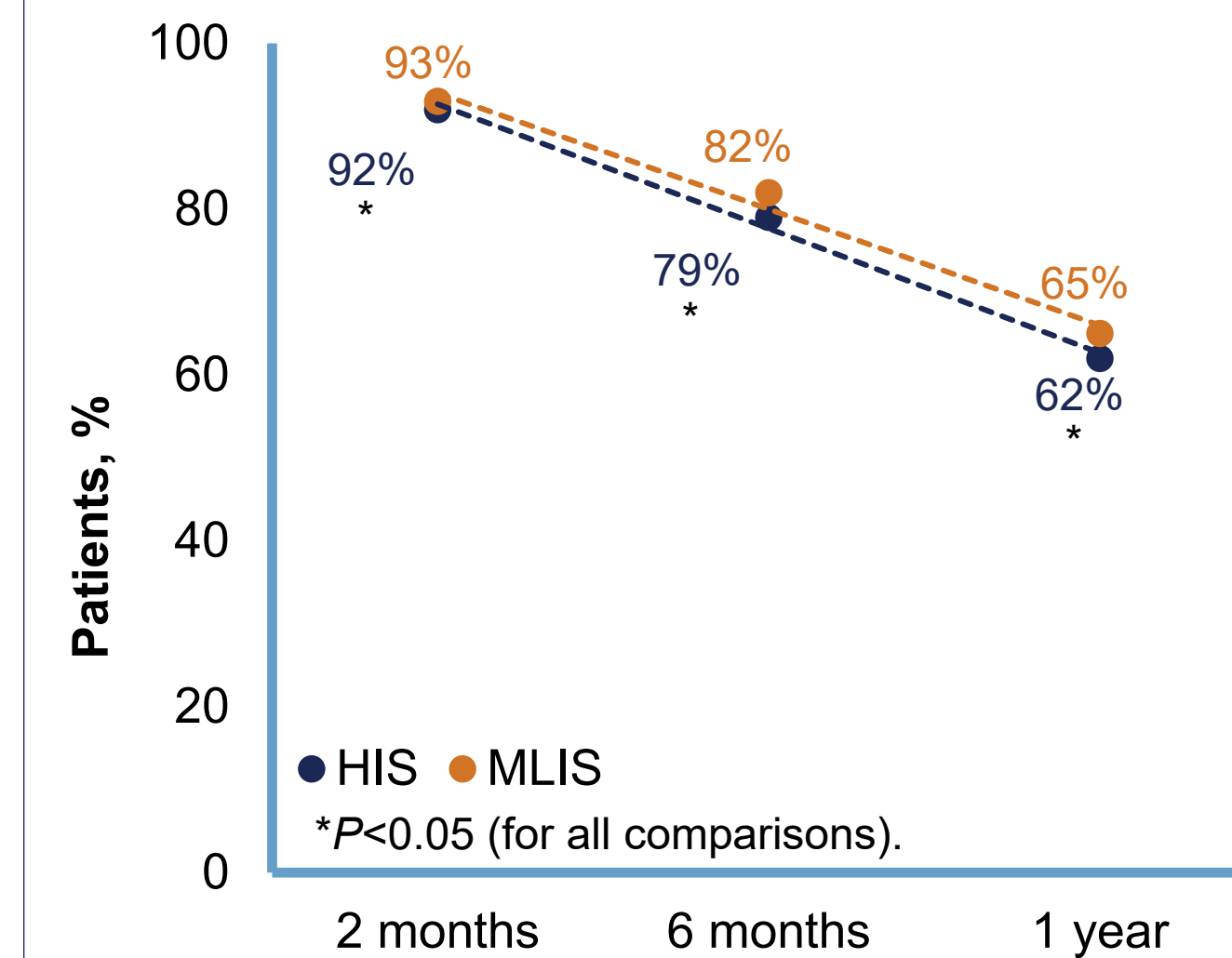
ICDx, International Classification of Diseases diagnosis; N/A, not applicable; Rx, prescription.

Table 2. CV Risk Baseline Characteristics

	HIS (N=1,555,978)	MLIS (N=1,555,978)
Mean LDL-C, mg/dL	83	90
Median LDL-C, mg/dL	59	61
Diabetes, % patients	43	35
ASCVD, % patients	33	12
Myocardial Infarction, % patients	10	2
Ischemic Stroke, % patients	12	6
Peripheral Arterial Disease, % patients	10	6
CCI	mean: 1.62±1.61 median: 1.00 (IQR: 2.00)	mean: 1.14±1.33 median: 1.00 (IQR: 2.00)

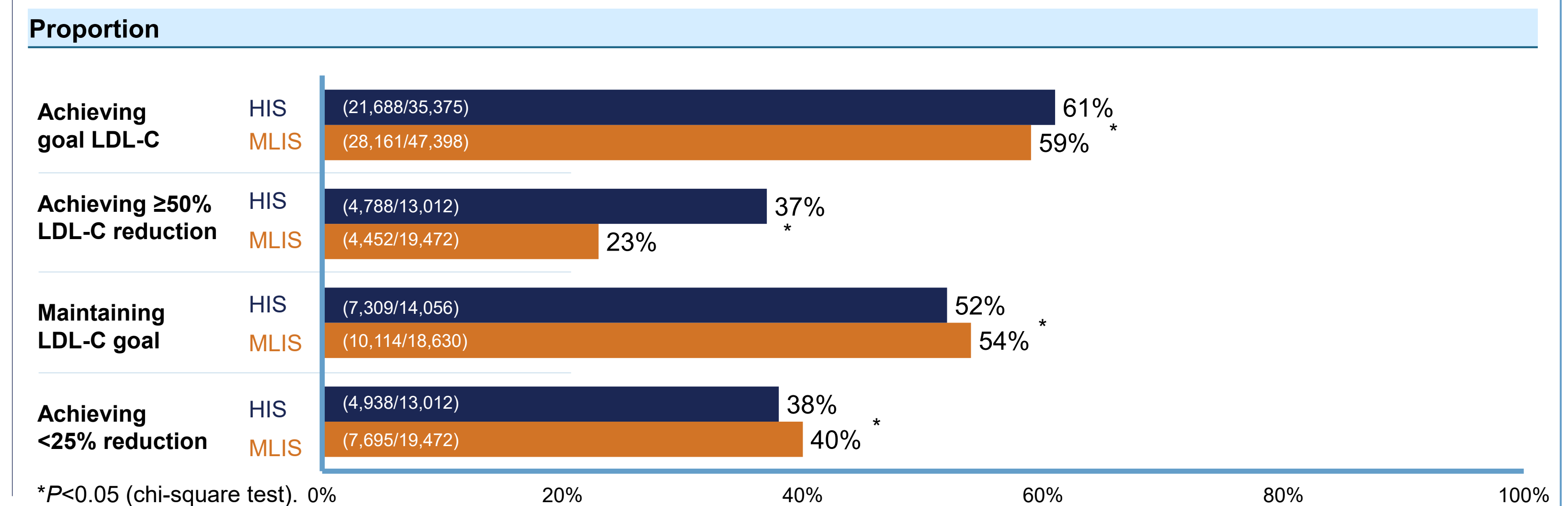
CCI, Charlson Comorbidity Index; IQR, interquartile range.

Figure 1. Adherence (Proportion of Days Covered ≥80%)



- Baseline characteristics are shown in **Table 2**
 - Matched groups were 59% male, mostly >45 years old, with commercial (49%) or Medicare (43%) insurance
 - Compared with MLIS patients, HIS patients had lower mean LDL-C and greater baseline comorbidity
- The portion of patients with threshold adherence dropped significantly at 1 year, with 62% of HIS and 65% of MLIS at a PDC ≥80% (**Figure 1**)
- Patients in both treatment groups had modest LDL-C goal attainment (**Figure 2**)
 - LDL-C goals were achieved by 61% of patients treated with HIS and by 59% of patients treated with MLIS
 - 37% of HIS patients achieved ≥50% LDL-C reduction
 - About half of HIS or MLIS patients maintained LDL-C goal reduction
 - About 4 in 10 patients experienced <25% LDL-C reduction
 - Median time to goal exceeded a year in both groups

Figure 2. Goal Attainment, All Patients



Limitations

- Limitations include focusing only on new statin users, incomplete laboratory data, and a follow-up period that may be too short to reliably observe routine monitoring or disease progression. Additionally, cohorts excluded patients with high LDL-C who did not begin statins. Results may be subject to frequency of monitoring rather than actual time to statin effect



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Affiliations and Disclosures: JK, NO: Employees and shareholders of NewAmsterdam Pharma; AA, DD, NH: Employees of Trinity Life Sciences. Trinity Life Sciences funded by NewAmsterdam Pharma for conduct and completion of analyses; ND: Nothing to disclose.