Real-World Use of PCSK9 Inhibitors and Adherence to Guideline-Directed Therapy in an Integrated Specialty Pharmacy

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BACKGROUND

- Proprotein Convertase Subtilisin/Kexin Type 9 inhibitors (PCSK9i), evolocumab and alirocumab, decrease low-density lipoprotein (LDL) levels and risk of coronary events. 1,2
- Clinical guidelines recommend PCSK9i therapy for the following: 3
  - Familial hypercholesterolemia with LDL ≥100mg/dL
  - Atherosclerotic cardiovascular disease (ASCVD) LDL ≥70mg/dL for ASCVD type HeFH
  - Diabetes or other metabolic syndrome
- Research evaluating adherence to these guidelines in real-world clinical practice has been scarce.

OBJECTIVES

- To assess adherence to guideline-directed lipid management and PCSK9i use in a real-world setting
- To identify clinical outcomes after 24 months of PCSK9i therapy

METHODS

Design
- Single-center retrospective review conducted at Vanderbilt University Medical Center (VUMC)

Inclusion
- Patients prescribed a PCSK9i by a VUMC provider from September 2015 to August 2018

Exclusion
- Never started therapy
- Received a PCSK9i through a manufacturer patient assistance program (PAP)
- Never received insurance approval

Outcomes
- Adherence to guideline-directed lip-lowering therapy
- Attainment of LDL goal based on indication (≤70mg/dL for ASCVD or ≤100mg/dL for heterozygous familial hypercholesterolemia (HeFH))
- Change in LDL from baseline to 24 months
- Incidence of adverse cardiovascular events or new onset diagnosis after PCSK9i initiation

RESULTS

- 67 patients incurred a total of 96 new onset cardiovascular events or diagnoses post-PCSK9i initiation.

CONCLUSIONS

- Less than half of patients were utilizing statin or ezetimibe therapy at the time of PCSK9i initiation as recommended by guidelines.
- Consistent with other clinical trials, our real-world study showed that most patients who were persistent to therapy at 24 months achieved their target LDL goal.
- Additional research is needed to evaluate PCSK9i use outside of guideline-directed recommendations to fully evaluate the effects on future cardiovascular events.

REFERENCES