REAL-WORLD USE OF PCSK9 INHIBITORS AND ADHERENCE TO GUIDELINE-DIRECTED THERAPY IN AN INTEGRATED SPECIALTY PHARMACY

Fatima Rizvi, PharmD Candidate 1 | Nicole Hall, PharmD Candidate 1 | Josh DeClercq, MS 1 | Leena Choi, PhD 1 | Dustin R. Donald, PharmD, CSP 1 | Victoria W. Reynolds, PharmD, BCACP 1
1University of Tennessee College of Pharmacy, 2Belmont University College of Pharmacy, 3Department of Biostatistics, Vanderbilt University Medical Center, 4Specialty Pharmacy, Vanderbilt University Medical Center

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

- 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

<table>
<thead>
<tr>
<th>Design</th>
<th>Single-center retrospective review conducted at Vanderbilt University Medical Center (VUMC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion</td>
<td>Patients prescribed a PCSK9i by a VUMC provider from September 2015 to August 2018</td>
</tr>
<tr>
<td>Exclusion</td>
<td>Received a PCSK9i through a manufacturer patient assistance program (PAP)</td>
</tr>
<tr>
<td>Never received insurance approval</td>
<td></td>
</tr>
<tr>
<td>Never started therapy</td>
<td></td>
</tr>
</tbody>
</table>

Outcomes

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

RESULTS

- Of the 228 patients with both baseline and 24-month LDL data, median LDL decreased from 156 mg/dL to 64 mg/dL (i.e. reduced by 59%)

- Wilcoxon signed rank test p-value: <0.001

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