Background

Hypercholesterolemia leads to higher risk of atherosclerosis and cardiovascular events. **Familial hypercholesterolemia is more resistant** to usual treatments. In 2015 **PCSK9 inhibitors (PCSK9I)** alirocumab and evolocumab were approved for the treatment of primary hypercholesterolemia (heterozygous family [HFHe] and non-familial [HNF]) and mixed dyslipidemia (DM). Due to their recent approval and high cost, it is crucial to evaluate their results in the real-world setting.

Material and methods

**OBSERVATIONAL, RETROSPECTIVE STUDY** [Jan 2016-Mar 2019]

- All PCSK9I were evaluated by the PS according to Regional Pharmacotherapeutic Commission criteria.
- Patients approved who initiated the treatment were included.
- Biodemographic, clinical and pharmacotherapy data were collected from medical records.
- Parameters were evaluated at treatment initiation and after 6 months.
- Clinical response, defined as low density lipoprotein (LDL) reduction greater than 30%, was analyzed by indications.

Results

- **Cardiovascular risk factors:** hypertension (47.2%), family history of ischemic heart disease (40.3%), smoking (38.3%), obesity (15.3%), diabetes (12.5%) and ischemic heart disease (58.3%).
- **Initial LDL value (mg/dl):** [100-129]: 23.6% [130-159]: 34.8% [160-190]: 20.8% >190: 20.8%
- **Frequency of additional hypolipemiant treatments:** atorvastatin (40.3%), rosuvastatin (27.8%), fluvastatin (2.8%), pitavastatin (2.8%), statin-free (26.4%), and ezetimibe (72.2%)
  - *During the study 41.7% patients showed statin intolerance and 88.9% reached their maximum tolerated dose.*
- **After initiating PCSK9I:**
  - a) **Statin dose:** 83.3% maintained, 8.3% reduced, 6.9% stopped, 4.3% switched and 1.4% increased.
  - b) **LDL plasma concentration decreased > 50%** in 52.1% of the patients, 30-50% in 31.2%, < 30% in 16.7%.

<table>
<thead>
<tr>
<th>Patients(%) who reached Clinical response with :</th>
<th>Alirocumab</th>
<th>Evolocumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>primary HFHe prevention</td>
<td>16.7</td>
<td>50</td>
</tr>
<tr>
<td>secondary HFHe prevention</td>
<td>68.8</td>
<td>83.3</td>
</tr>
<tr>
<td>primary HNF prevention</td>
<td>60</td>
<td>(no evolocumab patient)</td>
</tr>
<tr>
<td>HNF/DM secondary prevention</td>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

Conclusions

- The 16.7% of our population did not reach clinical response.
- Pharmacy Service may play a relevant role suggesting treatment cessation in these patients.
- Evolocumab could be specially effective in HFHe; more studies are needed to confirm this finding.