Efficacy, safety, adherence and persistence of PCSK9 inhibitors in clinical practice: a single country, multicenter, observational study (AT-TARGET-IT)

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Background: PCSK9 inhibitors (PCSK9i) significantly decrease LDL cholesterol (LDL-C), either as monotherapy or in addition to the maximally tolerated dose of statin and/or ezetimibe. Yet, few data are available on efficacy and background lipid-lowering therapy (LLT) adjustment in patients treated with PCSK9i in real-world observations.

Purpose: AT-TARGET-IT is an Italian multicenter registry involving 9 Italian centers, designed to assess efficacy, adherence, and persistence of PCSK9i, as well as prescribing doctors’ behavior in patients with atherosclerotic cardiovascular disease (ASCVD) or familial hypercholesterolemia (FH).

Methods: From June through November 2021, we enrolled patients with PCSK9i first prescription from 6 months before inclusion through starting of PCSK9i use. Clinical and demographic characteristics, concomitant therapies, blood chemistry, were recorded at the time of first prescription and at the latest observation preceding inclusion in the study. Background therapy was assessed at baseline and during follow-up, evaluating treatment withdrawal, reduction of doses, or changes from statin-ezetimibe association to single drug therapy.

Results: 798 patients were enrolled. The median reduction in LDL-C levels was 64.9%. After stratification for CV risk, 63.8% achieved LDL-C target; of them, 83.3% took LLTs at PCSK9i initiation and 16.7% did not (Figure 1). 760 patients (95.2%) showed high adherence to therapy, 13 (1.6%) partial adherence, and 25 (3.1%) poor adherence (Figure 2). At 6 months, 99.7% of patients enrolled in the study remained on therapy; there were 519 and 423 patients in the study with a follow-up of at least 12 and 18 months, respectively. Persistence in these groups was 98.1% and 97.5%, respectively. Overall, 3.5% of patients discontinued therapy. No differences in efficacy, adherence, and persistence were found between alirocumab and evolocumab.

Conclusion: PCSK9i are safe and effective in clinical practice, leading to very high adherence and persistence to therapy, and achievement of recommended LDL-C target in most patients, especially when used as combination therapy.

Stratified LDL-C target achievement
Adherence and persistence status

**Adherence status**
- High adherence: 95.2% (760 patients)
- Partial adherence: 1.6% (13 patients)
- Poor adherence: 3.1% (25 patients)

**Persistence status**
- 6 months: 99.7% (795 patients)
- 12 months: 98.1% (569 patients)
- 18 months: 97.5% (413 patients)