Abstract: P654

Effectiveness of evolocumab for patients with familial hypercholesterolemia (FH) in European clinical practice

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Background FH is a genetic disorder which causes lifelong elevations in LDL-C from birth, resulting in a significantly increased risk of premature atherosclerotic cardiovascular disease (ASCVD). In clinical trials among patients with heterozygous FH (HeFH) and homozygous FH (HoFH), evolocumab significantly reduced LDL-C by approximately 40-60% from baseline. Few data are available on evolocumab use among FH patients treated in a real-world setting.

Purpose Describe the characteristics of FH patients receiving evolocumab in routine clinical practice and their response to therapy.

Methods This observational study across 10 European countries follows subjects from the date of evolocumab initiation (baseline) for up to 2.5 years, with relevant clinical data abstracted from medical charts (for subjects on apheresis, LDL-C measures included those obtained directly following apheresis). We analysed a cohort of FH subjects from an interim analysis which included subjects initiating evolocumab from Aug 2015 through Jun 2018. FH was diagnosed by the treating physician using standard criteria.

Results A total of 502 FH subjects were included, 477 had HeFH (95%) and 25 HoFH (5%). The main diagnostic methods used included: the Dutch Lipid Clinic Network criteria (39% of HeFH, 28% of HoFH), genetic testing (27% of HeFH, 36% of HoFH), LDL-C values alone (23% HeFH, 16% HoFH). Mean (95% Confidence Interval [CI]) age was 58 (57-59) years for HeFH and 56 (50-61) for HoFH; 71% and 84% <65 years, respectively. 60% of HeFH subjects were male (HoFH: 40% male). In the overall FH cohort, additional CV risk factors were common (59% hypertension, 15% diabetes, 6% chronic kidney disease = stage 2, 17% current smoker, 22% BMI=30), with the majority having experienced a prior CV event (77% of HeFH, 80% of HoFH). Among HeFH subjects, 40% were receiving a high intensity statin at baseline, 11% medium intensity, 2% low intensity and 47% no statins. For HoFH, the corresponding values were 36%, 16%, 0 and 40%, respectively. Baseline ezetimibe use was 53% in HeFH and 48% in HoFH. Among HeFH patients, median (IQR) baseline LDL-C was 4.30 (3.41, 5.50) mmol/L; this dropped to 1.73 (1.03, 2.97) mmol/L within 3 months of evolocumab initiation, median LDL-C reduction 56% (Figure 1). Only 20 HoFH patients had a baseline LDL-C value; median (IQR), 4.07 (2.68, 6.17) mmol/L which dropped to 2.59 (1.63, 3.40) by month 3 [n=16]. No serious and no fatal adverse reactions were observed. Conclusions In this real-world study of evolocumab use in clinical practice, a large proportion of FH patients were not on statins and had LDL-C levels...
> 4 mmol/L. After initiation of evolocumab median LDL-C fell by about one half in HeFH and by about one third in HoFH. Evolocumab was well-tolerated.