Abstract ID 7

Evolocumab is initiated in Central and Eastern Europe at much higher LDL-C levels than recommended in guidelines: Results from the observational HEYMANS study

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KEY RESULTS

- In the CEE cohort, patients initiated on evolocumab had baseline LDL-C levels >3x higher than guideline-recommended thresholds for PCSK9 inhibitor initiation. Only half of patients achieved the LDL-C goal of <1.4 mmol/L.
- However, evolocumab use was associated with an LDL-C reduction of >50% within the first 3 months, which was sustained over time.
- Lowering the LDL-C reimbursement threshold for PCSK9 inhibitor initiation would allow more patients to receive combination therapy, thus improving LDL-C goal attainment.

INTRODUCTION

- Elevated low-density-lipoprotein cholesterol (LDL-C) is a major risk factor for cardiovascular disease (CVD)[1,2]
- PCSK9 inhibitors are recommended if LDL-C goals are not attained despite maximum tolerated statin dose ± ezetimibe[2]
- LDL-C control as per 2019 ESC/EAS dyslipidemia guidelines is a challenge in clinical practice[2,3,4]

AIM

- HEYMANS (CHaractEristics of HYperlipidaeMic PAtieNts at Initiation of Evolocumab and Treatment PatternS) describes clinical characteristics and LDL-C control among patients initiating the PCSK9 inhibitor evolocumab, across 12 EU countries[3]; study period: 05/2016 to 06/2021
- Data from Central Eastern Europe (CEE), i.e. Bulgaria (BG), Czechia (CZ), and Slovakia (SK) are reported here

METHODS

- Observational study (NCT02770131) collecting data for ≤6 months before and for ≤12 months (core period) and 13 to ≤30 months (extension phase) after evolocumab initiation
- Patients ≥18 years newly initiating evolocumab were included; patient informed consent was obtained
- Primary outcomes: clinical characteristics of patients receiving evolocumab in routine clinical practice
- Additional outcomes: lipid-lowering therapy (LLT) and lipid profile over time

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RESULTS

Tab. 1. Patient characteristics

	Bulgaria (N=88)	Czechia (N=120)	Slovakia (N=125)
Mean (SD) duration of FU, mo	23.2 (9.0)	26.1 (5.6)	25.7 (7.7)
Male sex, n (%)	46 (52.3)	64 (53.3)	68 (54.4)
Median (Q1, Q3) age, yrs	57 (50, 63)	60 (51, 67)	62 (54, 67)
Statin intolerance, n (%)	50 (56.8)	77 (64.2)	74 (59.2)
Primary prevention, n (%)	21 (23.9)	31 (25.8)	16 (12.8)
Secondary prevention, n (%)	67 (76.1)	89 (74.2)	109 (87.2)
FH, n (%)	76 (86.4)	65 (54.2)	32 (25.6)
Diabetes mellitus type 2, n (%)	15 (17.0)	16 (13.3)	30 (24.0)
Hypertension, n (%)	70 (79.5)	69 (57.5)	101 (80.8)
Baseline LLT, n (%)			
No statin or ezetimibe	27 (30.7)	68 (56.7)	64 (51.2)
Statin with ezetimibe	22 (25.0)	28 (23.3)	32 (25.6)
Statin without ezetimibe	38 (43.2)	9 (7.5)	11 (8.8)
Ezetimibe without statin	1 (1.1)	15 (12.5)	18 (14.4)

FH, familial hypercholesterolemia; LLT, lipid-lowering therapy; Q, quartile; SD, standard deviation

Fig. 1 Persistence with evolocumab at month 12 and 30

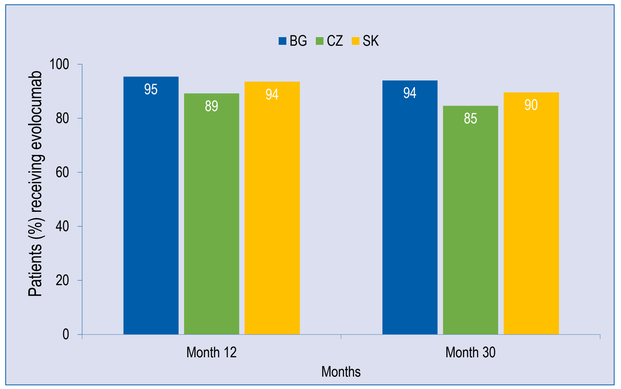
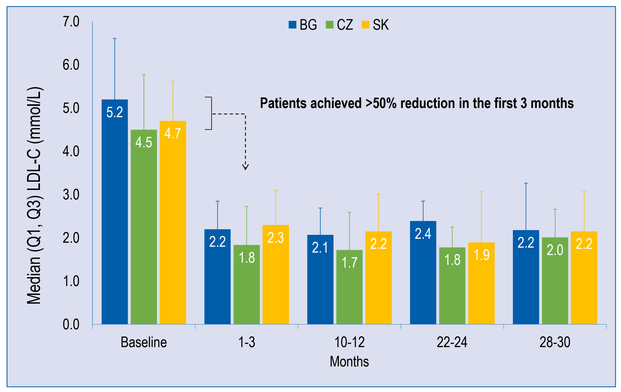


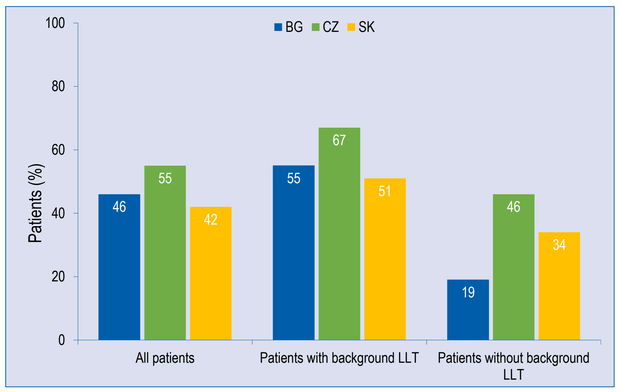
Fig. 2 LDL-C levels in patients at baseline and during evolocumab treatment



BG, Bulgaria; CZ, Czechia; LDL-C, low-density lipoprotein cholesterol; Q, quartile; SK, Slovakia

References. 1. Catapano A, et al. Eur Heart J 2016;37:2999–3058; 2. Mach F, et al. Eur Heart J 2020;41(1):111–188; 3. Ray KK, et al. EHJ - QCCO 2022;8(4):447-460; 4. Ray KK, et al. EJPC 2021;28(11):1279-1289

Fig. 3 Attainment of the LDL-C goal of <1.4 mmol/L at least once[1,2]



BG, Bulgaria; CZ, Czechia;; LLT, lipid-lowering therapy; SK, Slovakia; The 2019 ESC/EAS guidelines recommend a ≥50% LDL-C reduction and the achievement of LDL-C <1.4 mmol/L for patients with very high cardiovascular risk. The numbers of patients with high cardiovascular risk was 7, 16, and 5, respectively for BG, CZ, and SK. For these an LDL-C goal of <1.8 mmol/L applies

Patient disposition

- 333 patients from CEE were included (BG=88, CZ=120, SK=125), 325 completed the core period, 200 completed the extension
- The mean (SD) duration of follow-up was between 23.2 months (BG) and 26.1 months (CZ)

Evolocumab use

- Almost all patients received evolocumab at the standard dose of 140 mg once every two weeks
- The mean duration of exposure to evolocumab was between 22.6 months in BG and 25.1 months in CZ
- Persistence with evolocumab was between 95.4% in BG and 89.2% in CZ at month 12 and between 94.0% in BG and 84.6% in CZ at month 30 (Fig. 1)

Lipid-lowering therapy over time

- Patterns of background LLT use varied among countries with 31% not using any background LLT at baseline in BG, 57% in CZ, and 51% in SK (Tab. 1)
- While in BG and SK the number of patients not receiving background LLT increased over time, it remained stable in CZ

LDL-C over time and LDL-C goal attainment

- In all countries, LDL-C was above 4 mmol/L at baseline and was reduced by between 52.5% (SK) and 63.8% (CZ) within the first three months and remained sustainably low thereafter (Fig 2)
- Attainment of <1.4 mmol/L was between 55% (CZ) and 42.3% (SK) and goal attainment was higher in patients receiving background LLT (Fig. 3)

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