

were selected for inclisiran therapy by the cardiologist. All participating patients provided informed consent for the anonymous use of their clinical data for statistical analysis.

The data analyzed in this study were processed and evaluated using SPSS version 20.0 for Windows (IBM Corp, 2011. IBM SPSS, 20.0, Armonk, NY: IBM Corp.). Continuous data are presented as median [25th percentile; 75th percentile] and categorical data as counts (%). Lipid levels are reported in mmol/L, while Lp(a) values are given in mg/dL. The primary outcomes were efficacy, defined as the relative reduction in LDL-C, and safety, defined as any adverse effects identified during regular check-ups. Secondary outcomes included absolute reduction in LDL-C, achievement of target LDL-C levels according to ESC/EAS guidelines, specific side effects, and discontinuation of PCSK9 siRNA (inclisiran) therapy.

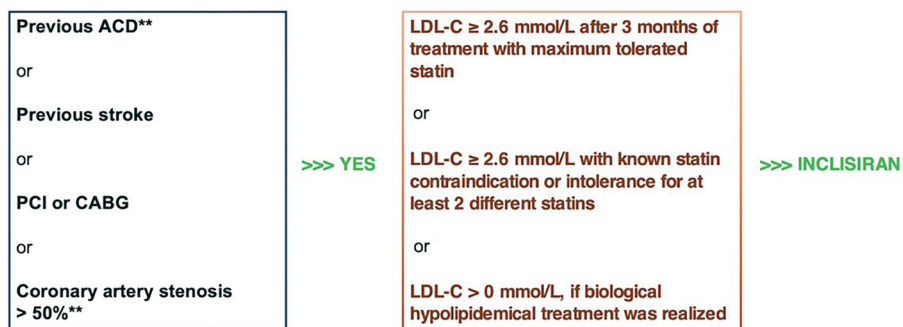
Results

Clinical characteristics of patients

During the observation period, a total of 36 patients in our clinic were approved for inclisiran therapy covered by health insurance. Of the 36 patients, 27 were diagnosed with ASCAD (75%), including 15 patients with acute coronary syndrome (ACS) (41.67%), 10 patients who underwent percutaneous coronary intervention (PCI) (27.77%), and 2 patients who had coronary artery bypass graft surgery (CABG) (5.55%) due to significant stenosis. Additionally, 9 patients had ischemic stroke (25%). In terms of risk factors, 29 patients had arterial hypertension (80.6%), 9 were obese (25%), 4 had type 2 diabetes mellitus (11.1%), and 16 patients were smokers (44.4%), as shown in Table 1.

Regarding lipid-lowering therapy, 1 patient was included due to statin intolerance (2.8%), 28 patients were on the maximum statin dose (77.8%, atorvastatin 80 mg), and 7 patients were on a reduced dose (19.4%): 3 patients on atorvastatin 40 mg (8.3%), 2 patients on atorvastatin 20 mg (5.6%), and 1 patient on lovastatin 20 mg (2.8%). Six patients were also taking ezetimibe as a co-medication (16.7%). The low percentage is due to the fact that ezetimibe use is not a criterion for inclisiran approval in Slovakia, and for most patients,

Fig. 1. Indication criteria of inclisiran in Slovakia



ACD – acute coronary disease, CABG – coronary artery bypass graft surgery, LDL-C – low density lipoprotein, PCI – percutaneous coronary intervention

LDL-C reduction with ezetimibe alone would not be sufficient to reach target LDL-C levels, but its use could disqualify patients from inclisiran therapy for failing to reach LDL-C levels > 2.6 mmol/L. There was no significant variation in the sample characteristics between genders.

The baseline characteristics of the patients and their initial lipid profile levels, along with hsCRP values, are shown in Table 1.

Therapy effectiveness

During inclisiran administration, we observed a variable response in terms of changes

in selected lipid parameters and hsCRP, as shown in Table 2. The reduction in LDL-C levels ranged from 41.88% to 86.25%, with a median of 57.5 ± 7.5 (Figure 2). Patients who were on the maximum dose of high-intensity statins as concurrent therapy and had undergone a third blood draw ($n = 28$) experienced a greater median reduction in LDL-C compared to those on a reduced statin dose ($n = 7$): 61.5 ± 12.3 vs. 53.2 ± 5.9 %. The absolute reduction in LDL-C levels was 2.1 ± 0.5 mmol/L. The reduction in Lp(a) levels was highly individual, ranging from 0% to 58.33%, with

Tab. 1. Summarized characteristics of participants

Determinant	
Patients (n)	36
Age (years)	60.2 ± 7.1
Male (n)	25 (69.4%)
Female (n)	11 (30.6%)
BMI (kg/m ²)	27.3 ± 3.6
ASCAD (n)	27 (75%)
ACS (n)	15 (41.7%)
PCI (n)	10 (27.8%)
CABG (n)	2 (5.5%)
Stroke (n)	9 (25%)
Arterial hypertension (n)	29 (80.6%)
Type 2 diabetes (n)	4 (11.1%)
Obesity (n)	9 (25%)
Smoking (n)	16 (44.4%)
Statin – the highest tolerated dose (n)	28 (77.8%)
Statin – reduced dose (n)	7 (19.4%)
Statin intolerance (n)	1 (2.8%)
Ezetimibe (n)	6 (16.7%)
LDL cholesterol (mmol/L)	3.56 ± 0.53
HDL cholesterol (mmol/L)	1.32 ± 0.39
Total cholesterol (mmol/L)	5.36 ± 0.58
Triacylglycerols (mmol/L)	1.6 ± 0.32
Lp(a) (mg/dL)	142.8 ± 45.62
hsCRP (mg/L)	0.35 ± 0.09

ACS – acute coronary syndrome, ASCAD – atherosclerotic coronary artery disease, BMI – body mass index, CABG – coronary artery bypass graft, HDL – high density lipoprotein, hsCRP – high sensitive C-reactive protein, LDL – low density lipoprotein, Lp(a) – lipoprotein a, PCI – percutaneous coronary intervention