A real-world assessment of treatment patterns in patients with atherosclerotic cardiovascular disease with hypercholesterolemia: a retrospective database analysis in Germany

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Background: The European Society of Cardiology (ESC) guidelines suggest that greater absolute reduction in low-density lipoprotein cholesterol (LDL-C) leads to greater cardiovascular risk reduction. Several lipid-lowering treatments (LLTs) are available in Germany; however, the research on treatment patterns and LDL-C outcomes among patients (pts) receiving LLTs in real-world setting is limited.

Purpose: To characterize the pts characteristics, treatment patterns and LDL-C outcomes of pts with atherosclerotic cardiovascular disease (ASCVD) with hypercholesterolemia (ASCVD-H) in Germany.

Methods: This is a descriptive, non-interventional, retrospective cohort study of ASCVD-H pts identified from general physician (GP) practices available in the electronic medical record (EMR) database Disease Analyzer (January 1992-June 2020) in Germany. ASCVD-H pts were included if they had a recorded diagnosis, were prescribed LLTs or had LDL-C levels of ≥55 mg/dL anytime within 6 months before and 3 months after the index date (ID), as per the data recorded by the participating physician. The first encounter of ASCVD after hypercholesterolemia during the identification period (1/07/2015–30/06/2019) was considered as the ID. Persistence was measured as the duration (in days) with allowed gap of 60 days and adherence as proportion of days covered (PDC) within 12 and 24 months after ID.

Results: We included 147,905 pts with ASCVD-H (57.2% male; mean age: 70.6 yrs; ≥75 yrs-old: 43.3%; mean BMI: 29.0 kg/m^2). Coronary artery disease was the most common index diagnosis (73.2%), followed by cerebrovascular disease (31.7%) and peripheral vascular disease (21.5%). Hypertension (83.5%) and diabetes (27.6%) were the most common comorbidities among these pts. At ID, statin monotherapy (58.6%) was the most commonly prescribed LLT, with simvastatin being the most common drug (36.4%). The use of PCSK9 inhibitors, ezetimibe and fibrates was very limited (<1%; Table 1). Of note, LDL-C measurements (6 months prior and 3 months post index) were available for 50.7% of pts. In pts with uncontrolled LDL-C (≥55 mg/dL), 47.9% were receiving statin monotherapy (28.6% were on simvastatin), whereas there was no LLT prescribed in 48.0% of pts. The mean (SD) persistence and adherence to statins monotherapy within 24 months follow-up was 522 (260) days and 0.721 (0.345), respectively, with 60% of pts being adherent (PDC ≥0.80) to statins monotherapy.

Conclusions: Pts with ASCVD-H in Germany treated by GPs are elderly pts with multiple cardiovascular comorbidities. LDL-C was measured in nearly half of the pts, and almost all had LDL-C ≥55 mg/dL at ID. Findings indicate low prescription of LLTs in GP setting, particularly non-statin LLTs. The mean adherence (PDC) to statin monotherapy was 72% within the 24-month after ID. Data suggest the need for newer therapies with potential to control LDL-C levels.

Table 1: Treatment patterns and persistence and adherence to index treatments during 24 months of follow-up in patients with ASCVD and hypercholesterolemia at general physician practices in Germany

Index treatment	Overall population (N=147,905)	Patients with LDL-C measurement (n=74,955; 50.7%)[1]					
		Controlled LDL-C (<55 mg/dL) (n=1,899; 2.5%)	Uncontrolled LDL-C (≥55 mg/dL) (n=73,056; 97.5%)	Uncontrolled LDL-C (≥55 mg/dL) at ID with 24 months follow-up			
				Observable patients (N)	Persistence[2] (days) to index treatment, mean (SD)	Adherence[3] (PDC) to index treatment, mean (SD)	Adherent (PDC ≥0.8) to index treatment, n (%)
Statin (monotherapy)	86,674 (58.6%)	1,410 (74.2%)	34,991 (47.9%)	26,658	522 (260)	0.721 (0.345)	16,003 (60.0%)
Simvastatin	53,770 (36.4%)	845 (44.5%)	20,861 (28.6%)	16,481	538 (254)	0.741 (0.338)	10,318 (62.6%)
Atorvastatin	27,509 (18.6%)	531 (28.0%)	11,826 (16.2%)	8,489	488 (268)	0.676 (0.356)	4,599 (54.2%)
PCSK9i	16 (0.01%)	0 (0.0%)	9 (0.01%)	6	118 (65)	0.150 (0.094)	0 (0.0%)
Evolocumab	9 (0.006%)	0 (0.0%)	5 (0.0%)	3	118 (86)	0.141 (0.117)	0 (0.0%)
Alirocumab	7 (0.005%)	0 (0.0%)	4 (0.0%)	3	118 (58)	0.160 (0.091)	0 (0.0%)
Ezetimibe	721 (0.5%)	7 (0.4%)	350 (0.5%)	278	435 (284)	0.616 (0.365)	130 (46.8%)
Fibrates	909 (0.6%)	13 (0.7%)	372 (0.5%)	292	550 (255)	0.763 (0.323)	195 (66.8%)
Statins + any drug	4,626 (3.1%)	199 (10.5%)	2,242 (3.1%)	1,814	512 (266)	0.643 (0.370)	936 (51.6%)
No LLT	54,865 (37.1%)	266 (14.0%)	35,052 (48.0%)	-	-	-	-

[1]LDL-C was measured within 6-month before and 3-month after index date. [2]Persistence to index treatment(s) was measured as the duration of index treatment with allowed gap of 60 days. [3]Proportion of Days Covered (PDC) was defined as the number of days with drug on-hand divided by the number of days in the specified time interval.
LDL-C: low density lipoprotein cholesterol; LLT: lipid lowering treatment; PCSK9i: proprotein convertase subtilisin/kexin type 9 inhibitor; SD: standard deviation.