Literature
Medical MS Summary
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This is a Fresenius Medical Care summary of:

Real-world study: Escalating targeted lipid-lowering treatment with PCSK9-inhibitors and lipoprotein apheresis

Spitthöver R et al. Germany, J Clin Apher. 2019 Aug;34(4):423-433

Introduction

LDL-C reduction in high-risk patients is expected to have a constant effect on ASCVD risk, per unit absolute LDL-C reduction. For very high ASCVD-related risk patients, the LDL-C target is <1.8 mmol/L (<70 mg/dL), according to ESC/EAS guidelines. The desirable range for Lp(a) is <50 mg/dL, according to the European Atherosclerosis Consensus Panel. Complementing the escalating LLT, PCSK9 inhibition has become a treatment step before LA in very-high-risk patients. There is a paucity of data characterising patients who, after LLT escalation with PCSK9 antibody, start LA or start PCSK9 antibody treatment while already on long-term LA to reach the LDL-C target. Real-world evidence is increasingly used to confirm a treatment's clinical benefit and value.

Objective

This cross-sectional real-world study was initiated to provide insight into the impact of PCSK9 antibody on LA use in patients with established ASCVD, with achieving target LDL-C concentrations as a major goal.

Design

This was a German, multicenter (10 tertiary care centers), open, cross-sectional study, consecutively enrolling 110 very-high-risk patients with established ASCVD due to hypercholesterolemia and in part concomitant elevated Lp(a). Patients received PCSK9 antibody for the first time during routine care to reach the targeted LDL-C.

Results

PCSK9 antibody treatment increased the proportion of very-high-risk patients reaching the target LDL-C (<70 mg/dL) by 41.8%; 58.2% of patients still had LDL-C concentrations above the LDL-C target. PCSK9 antibody associated TEAE occurred in 31.8% of patients, with 22.7% of patients discontinuing PCSK9 antibody due to TEAEs.

Discussion

"Combined treatment regimens with decreasing treatment frequency appear as the preferred choice."

Conclusion

Overall, 55.5% of patients received a combination of PCSK9 antibody and LA, resulting in 54.1% reaching the LDL-C target. LA was terminated by 18.1% of long-term LA patients, and 37.3% reduced the frequency of LA. "The termination of long-term LA therapy, which has hitherto prevented the progression of ASCVD, requires careful individual risk assessment and cannot be recommended by general criteria of fixed LDL-C reduction."

1. LA indicated in spite of previous escalation with PCSK9 antibody therapy		
LA with discontinuation of PCSK9 antibody therapy	PCSK9 antibody non-responder	2.7%
	PCSK9 antibody discontinued due to TEAE	6.4%
LA and PCSK9 antibody therapy combined		**5.5%**
2. PCSK9 antibody therapy initiated in patients with established LA therapy		
Termination of LA and sole continuation of PCSK9 antibody therapy		15.5%
LA and PCSK9 antibody therapy combined		**50.0%**
LA with discontinuation of PCSK9 antibody therapy	PCSK9 antibody non-responder	3.6%
	PCSK9 antibody discontinued due to TEAE	16.4%

Table modified from: Spitthöver R et al. Germany, J Clin Apher. 2019 Aug; 34(4):423-433

Abbreviations

ASCVD: Atherosclerotic cardiovascular disease
EAS: European Atherosclerosis Society
ESC: European Society of Cardiology
LA: Lipoprotein apheresis
LDL-C: Low-density lipoprotein-cholesterol
LLT: Lipid-lowering treatment
LP(a): Lipoprotein(a)
PCSK9: proprotein convertase subtilisin/kexin type 9
TEAE: Treatment-emergent adverse events

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