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Treatment of hypercholesterolaemia with PCSK-9 Inhibitors in Denmark. Assessment of real-life data; safety an extent of adverse effects after the first years of clinical use

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Topic(s): Lipid-Lowering Agents

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Introduction: PCSK9 Inhibitors (PCSK9 I) are a new group of drugs for treatment of hyperlipidaemia. These drugs have been available in Denmark since October 2015. From the two existing major outcome studies (FOURIER and ODYSSEY OUTCOMES) it has been shown that there was no significant difference in the risk of serious adverse events, discontinuation due to adverse events, neurocognitive events, diabetes-related events, muscle-related events, or myalgia in the treatment group, compared with the control group. In FOURIER 12.5% came of treatment; In ODYSSEY the rate was 10.2–14.8%. Although this highlights the efficacy and safety in patients with cardiovascular disease, we have little knowledge of the use, efficacy and safety with these drugs in real-life populations

Purpose: We aim to describe the demography, the treatment efficacy and the extent of adverse effects among patients treated in Danish lipid clinics.

Methods: Data on all patients treated with PCSK9 I between October 1st, 2015 and May 1st, 2018 were obtained from lipid clinics in Denmark. A database containing information on medications before treatment, adverse effects, plasma lipids (LDL-C, Triglyceride, High density lipoprotein cholesterol (HDL-C)) and supplementary blood tests was created. Levels of plasma lipids and organ markers (Creatinine, HbA1c or Alanine aminotransferase (ALAT)) at baseline and at follow up visits were analysed.

Results: Nationwide, 383 patients were included, an estimated 90% of all patients undergoing treatment with PCSK9 I in Denmark. A large proportion (n=243 - 63.4%) were described as statin intolerant and only 94 patients were receiving statins at baseline. Adverse effects (AE) were reported by 71 patients (18.5%) on PCSK9 I therapy and 50 patients (13.1%) stopped treatment. Most common AE were flu-like symptoms and musculoskeletal aches. In two cases an increase in serum creatinine kinase was detected. One case of angioedema and three cases of local reactions to injections had been documented. No case of anaphylaxis was reported. Of the 71 patients with AEs 55 (77.5%) were statin intolerant. Of the 50, who came off treatment, 43 (86.0%) were statin intolerant. When treatment was stopped 15 patients (30.0%) tried the alternative PCSK9 Inhibitor (cross over). Of those, nine patients were able to tolerate the alternative PCSK9 I treatment.

Conclusion: Many patients (18.3%) reported AEs on a wide range of symptoms, but the rate of patients terminating PCSK9 I treatment was the same as found in the outcome studies (13.1% vs. 12.2 and 10.2–14.8%). Most of the patients who stopped treatment were statin intolerant and produced the same symptoms, as they had experienced with statins. Interestingly, nine of the 15 patients that were switched to the alternate PCSK9 I seems to tolerate this treatment.
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