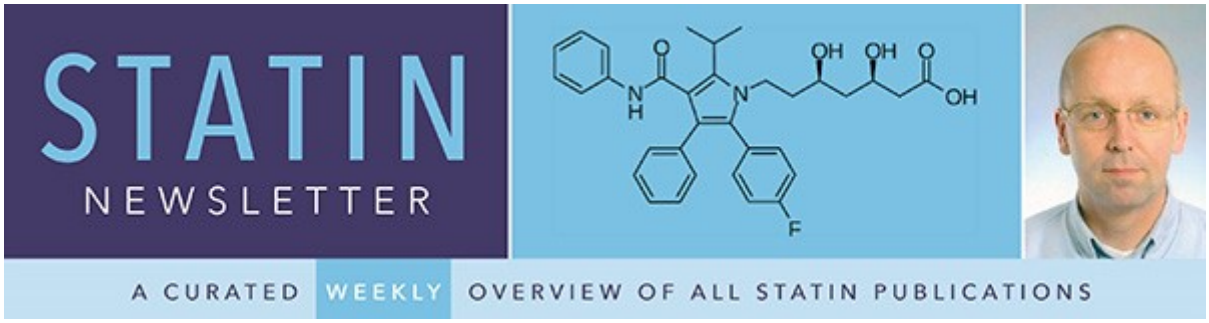

Update week 39 & 40 - 2022

Dr. Peter Lansberg is a Dutch lipidologist, educator and innovator. He has been instrumental in setting up The Dutch National Lipid Clinic Network, the Dutch Lipid Clinic Criteria for Familial Hypercholesterolemia (FH), and the Dutch National FH screening program

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The Statin Newsletter will keep you up-to-date with all recent statin publications. Based on a curated approach to select relevant articles.

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Key Publications

1. **Calcium score and glycemic control in statin users**
2. **Reduced incidence of NAFLD in adherent statin users**
3. **Improved outcomes in CKD patients when LDL-c <100 mg/dL with statins**
4. **Adding fenofibrate to statin in HTG patients reduced CVD risk**
5. **Is magnitude of LDL-c lowering relevant ?**

Statins and NODM – more than meets the eye

Statin use has been associated with an increased risk of new-onset diabetes mellites (NODM). For this analysis data from the Multi-Ethnic Study of Atherosclerosis (MESA) was used; a more racially diverse cohort. Those with pre-diabetes or metabolic syndrome are exposed to an increased ASCVD risk and are more likely to develop diabetes. For this, the coronary calcium score (CAC) was used as a surrogate marker for increased ASCVD risk. The authors sought to determine if a relationship exists between CAC score and NODM. Performing a multivariable Cox proportional hazard analysis with adjustments for sociodemographic and cardiovascular risk factors, including time-varying statin use and stratifying by baseline CAC (0, 1 to 100, ≥100), a strong association of NODM and statin use was noted in the unadjusted model only, HR:1.63 (1.27-2.06). After adjustments, the risk was no longer statistically significant, HR:1.13 (0.83-1.54). When comparing the different CAC score groups, the risk for NODM was lower in patients with a CAC score of 0; HR 0.80 (0.45 to 1.40) compared to a higher CAC burden. HR 1.30 (0.71 to 2.39) and for CAC 1 to 100 and an HR: 1.39 (0.85 to 2.28) for CAC ≥100. However, the differences were not statistically significant. Based on these observations, the authors concluded that statin therapy was not significantly associated with incident diabetes mellitus in this observational study cohort.
Al Rifai M, Szklo M, Patel J *et al.* Statin Use and Risk of Diabetes by Subclinical

Atherosclerosis Burden (from a Multi-Ethnic Study of Atherosclerosis Report). Am J Cardiol 2022; 184:7-13. http://www.ncbi.nlm.nih.gov/pubmed/?term=36192199

Do statins provide protections against NAFLD?

The increases in transaminases observed in patients that participated in the early statin studies prompted warnings and the advice to stop the medication. More recent data showed that statins could promote hepatic benefits instead of damaging liver cell function. In this study, patient data collected in the Japanese Claims Database (2005-2020) was used to evaluate the effect of statin on NAFLD. Each patient that developed NAFLD was matched with 10 controls. Statin adherence was defined as the proportion of days covered (PDC) >80%. First statin prescriptions were noted in 253 383 participants; 7080 developed NAFLD, and they were matched with 70734 controls. Median PDC was 0.86 (IQR: 0.61-0.96) when NAFLD patients were compared to controls. The OR for developing NAFLD in patients with good PDC was 0.82 (0.78-0.86). No differences were observed when comparing patients that used higher-intensity statins or lower-intensity statins. In Japan, atorvastatin and rosuvastatin are used in a much lower dosage range of 5-10 mg and 2.5-5 mg, respectively.
Nakagawa C, Yokoyama S, Hosomi K. **Association of Statin Adherence With the Development of Nonalcoholic Fatty Liver Disease: A Nested Case-Control Study Using a Japanese Claims Database.** The Annals of pharmacotherapy 2022:10600280221126971. http://www.ncbi.nlm.nih.gov/pubmed/?term=36168669

The role of statins and LDL-c in advanced CKD

The role of statins in patients with renal disease remains unclear. Both harms and benefits have been reported, and two large RCTs in patients with advanced renal disease failed to show benefits. For this analysis, data collected in Chang Gung Research Database (China) was used to evaluate the potential benefits or harm of statins in patients with advanced (stage 3) chronic kidney disease (CKD). Included were 8500 newly diagnosed CKD (stage 3) patients that used statin, who were divided into 3 groups based on baseline LDL-c; <70 mg/dL, 70 to 100 mg/dL, and >100 mg/dL. Those with an LDL-c >70 and <100 mg/dL group were less likely to develop ASCVD complications, 6.8% versus 8.8%; HR: 0.76 (0.64–0.91). For intracerebral hemorrhage, 0.23% versus 0.51%; HR: 0.44 (0.25–0.77). Dialysis 7.6% versus 9.1%; HR: 0.82 (0.73–0.91). Patients in the group with LDL-c <70 mg/dL only showed marginally improved major adverse cardiac and cerebrovascular events, 7.3% versus 8.8%; HR: 0.82 (0.65–1.02). However, a significantly lower risk of new-onset end-stage renal disease requiring chronic dialysis, 7.1% versus 9.1%; HR: 0.76 (0.67–0.85). The results of this large observational registry show that statins used by patients with CDK (III) and resulting in lower LDL-c levels of <100 mg/dl resulted in improved outcomes. Lower LDL-c (<70 mg/dL) showed similar benefits; however, in patients < 65 years a, a slightly improved risk for CV events was noted.
Yen CL, Fan PC, Lee CC *et al.* **Association of Low-Density Lipoprotein Cholesterol Levels During Statin Treatment With Cardiovascular and Renal Outcomes in Patients With Moderate Chronic Kidney Disease**. J Am Heart Assoc 2022; 11:e027516. http://www.ncbi.nlm.nih.gov/pubmed/?term=36172933

Statin + (feno)fibrate an attractive combination in elevated TG's?

The PROMINENT study, presented at the AHA conference last November, showed no CVD benefit of Pemafibrate add-on therapy in patients with elevated TG and low HDL-c that used statins. In this study, clinical data collected in the Korea National Health Information Database (2010 – 2017), the effect of fenofibrate add-on to statins in patients with elevated triglycerides on all-cause death and CV outcomes were evaluated. Patients with a TG >150 mg/dL that used statins in combination with fenofibrate (N=277 836) were compared with those that only used statins (N=277 836), using an aged and sex match design. Over a median follow-up period of 4.13 years, patients that used statin + fenofibrate showed improved mortality and CVD outcomes. Total mortality per 1000 person-years 4.812 vs. 5.354 (p < 0.0001). For CVD 6.283 vs. 6.420 (p< 0.0001). The HR for all-cause death and CVD was 0.826 (0.795–0.858) and 0.929 (0.898–0.962), respectively. Risks were even more attenuated in patients that used fenofibrate >1 year; all-cause death, HR: 0.618, and CVD, HR: 0.853. No benefits were noted in patients that used fenofibrate for a shorter duration.

Kim KS, Hong S, Han K, Park CY. **Fenofibrate add-on to statin treatment is associated with low all-cause death and cardiovascular disease in the general population with high triglyceride levels.** Metabolism 2022; 137:155327. http://www.ncbi.nlm.nih.gov/pubmed/?term=36202222

Is the magnitude of LDL-c reduction more important than LDL-c target? Sub-analysis of TST study

n the Treat Stroke to Target (TST) study, the benefits of LDL-c lowering in patients with a recent stroke or TIA were evaluated by comparing those reaching an LDL-c < 100 mg/dl vs. < 70 mg/dL. The primary outcome was the composite of ischemic stroke, myocardial infarction, new symptoms requiring urgent coronary or carotid revascularization, and vascular death. This sub-analysis evaluated the type of treatment, statin monotherapy vs. statin + ezetimibe. Patients using dual therapy in the lower LDL-c target group had a higher baseline LDL-c than those using monotherapy statins, 141±38 versus 131±36, respectively. (P<0.001). LDL-c reached by patients on dual therapy vs. monotherapy were 66.2 and 64.1 mg/dL, respectively. Patients in the low LDL-c group were better protected compared to those that reached an LDL-c < 100 mg/dL if they were treated with a combination of statin and ezetimibe, HR: 0.60 (0.39-0.91, P=0.016). Patients on statin monotherapy that reached an LDL-c <70mg/dL showed a not statistically significant trend for improved outcomes compared to patients with an LDL-c <100 mg/dL; HR: 0.92 (0.70-1.20, p=0.51). No significant increased risk for intracranial bleeds was observed. Despite the caveats of post-hoc analysis, the result of this study supports lower LDL-c targets for stroke patients, pointing towards better protections for subsequent CV events and no indication of an increased risk of hemorrhagic stroke. One interesting additional finding needs to be emphasized, the magnitude of LDL-c reduction seems equal, if not more important than the LDL-c target reached. Amarenco P, Kim JS, Labreuche J *et al.* **Yield of Dual Therapy With Statin and Ezetimibe in**
the Treat Stroke to Target Trial. Stroke 2022; 53:3260-3267. http://www.ncbi.nlm.nih.gov/pubmed/?term=36154103

Relevant Publications

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Basic Science

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