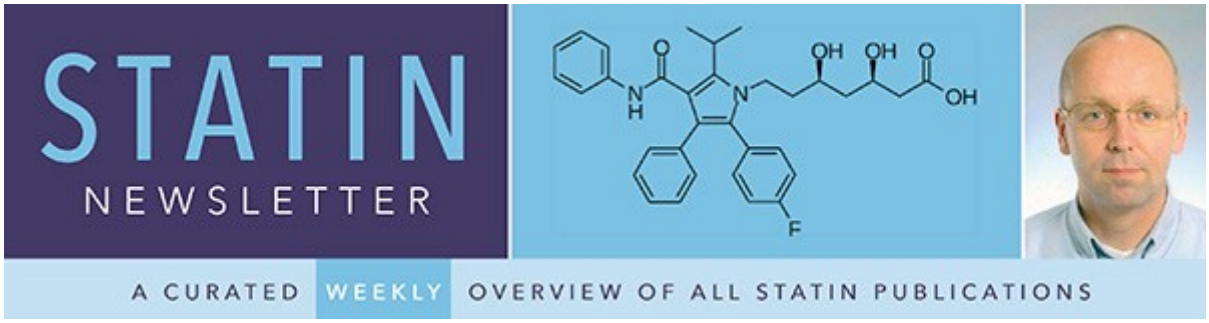

Update week 25 & 26 - 2022

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. **Statins can prevent NODM?**
2. **How to explain the nocebo effect to patients**
3. **EPA + DHA fail again in high risk patients using statins**
4. **CAVD - the next step**
5. **No increased risk of hemorrhagic stroke in IS patients treated with statins**

Statin use and risk of NODM post acute pancreatitis

Statin use can result in new-onset diabetes mellitus (NODM) in pre-diabetic or metabolic syndrome patients. Acute pancreatitis is associated with a doubling of NODM risk. Data collected in a large US insurance claims database showed that the impact of statins was evaluated in patients with no DM and who were admitted for acute pancreatitis (N=118 479). Only patients that used statins and filled their prescriptions for >80%in the year prior to the hospitalization were analyzed. After a median follow-up period was 3.5 years, the cumulative incidence of post pancreatitis diabetes mellitus (PPDM) in statin users was 7.5% (6.9-8.0%) vs. 12.7% (12.4%-12.9%) among non-users; a relative risk reduction of 42%; HR 0.58 (0.52-0.65; P<0.001) Patients that used statins infrequently had a risk reduction of 15% and no differences were noted between patients that used high, moderate, or low dosages of statins. These promising observational findings need to be confirmed with prospective long-term follow-up studies.

Thiruvengadam NR, Schaubel DE, Forde K *et al.* **Association of Statin Usage and the Development of Diabetes Mellitus after Acute Pancreatitis**. Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35750248

Review of the trials that support the nocebo effect pus practical tips

to increase adherence

Perceived statin muscle side effects are frequently reported in clinical practice. The purpose of this review is to share the current understanding of not only the nocebo effect of statins but also to provide a concise overview of the clinical trials that showed the evidence of the nocebo effect. The authors give pointers on how to help patients become aware of their misinterpretations of these muscle complaints, including setting appropriate patient expectations. Strategies to increase confidence as well as increase tolerance by lowering dosages, frequency of doses, and the use of non-statin lipid-lowering drugs, added to low dose statins or used independently from statins. Krishnamurthy A, Bradley C, Ascunce R, Kim SM. SAMSON and the Nocebo Effect: Management of Statin Intolerance. Current cardiology reports 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35759168

No benefits of EPA+DHA in statin treated high risk patients – OCEAN3 survey

The OCEAN3 survey is a post-marketing surveillance study to evaluate the effect of 2 grams per day of Omega-3 fatty acids (EPA + DHA) added to statins in high-risk hyper triglyceridemic Japanese patients. The follow-up period was three years. During this period, 2.5% of the participants experienced a CV complication (cardiovascular death, myocardial infarction, stroke, angina requiring coronary revascularization, or peripheral arterial disease requiring surgery or peripheral arterial intervention). In the treated patients (N=7784) the cumulative incidence of CV events was 2.5% (2.1-2.9%) vs 2.7% (2.4-3.1%) in the patients that did not receive Omega-3 fatty acids (N=6580); HR:0.99 (0.79-1.13). heart failure requiring hospitalization showed borderline significantly better outcomes in patients treated, HR:0.47 ().28-0.78; P<0.05). No differences in CV outcomes were observed in high-risk Japanese patients treated with Omega-3 fatty acids + statins. Although this was not a randomized trial, the results are in line with the findings of the recently published STRENGHT study. Teramoto T, Ogawa H, Ueshima H *et al.* Effect of omega-3 fatty acids on cardiovascular events in high-risk patients with hypertriglyceridemia in Japan: a 3-year post-marketing surveillance study (OCEAN3 survey). Expert opinion on drug safety 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35772177

CAVD – a review on pathophysiology and treatment

Calcific Aortic Valve Disease (CAVD) is a severe chronic and progressive cardiac condition. Lipids play an essential role in the pathological changes observed, but statins could not prevent or reduce the progression of CAVD. Current understanding points toward oxidized phospholipids and Lp(a), an important carrier of phospholipids, as primary factors in initiating aortic valve pathological changes starting with endothelial dysfunction, followed by inflammation secretion of growth factors and the synthesis of extracellular matrix to ultimately trigger osteogenic changes. New treatments that lower Lp(a) could be an effective alternative for patients with CAVD. Clinical trials with PCSK9ab have shown promising results in reducing the severity of this complication, and the novel siRNA therapies targeting Lp(a) are positioned to be of even greater impact. This review highlights our current understanding of the pathophysiology of CAVD as well as the potential benefits of lipid modulation therapies.
Nsaibia MJ, Devendran A, Goubaa E *et al.* Implication of Lipids in Calcified Aortic Valve Pathogenesis: Why Did Statins Fail? Journal of clinical medicine 2022; 11. http://www.ncbi.nlm.nih.gov/pubmed/?term=35743402

Meta-analysis on statin benefits on recurrences in patients with a first stroke.

The benefits of statins in patients with ischemic stroke or TIA are underlined in this systematic review and meta-analysis. Of the initially found 559 papers, 11 RCTs and 12 observational studies were included in this evaluation. Both RCT's, OR: 0.87 (0.77-0.97, P=0.02), and observational studies; OR: 080 (0.66-0.96, P=0.02) showed a significant reduction of recurrent strokes (of any type). A highly significant benefit of statins was observed for Ischemic strokes specifically; OR: 0.67 (0.61-0.75, P<0.00001). Hemorrhagic stroke risk was not significantly increased or decreased in statin users, based on 7 RCTs,

OR: 1.15 (0.62-2.13; P=0.66), and 8 cohort studies, OR:0.93 (0.71-1.71, P=0.59), but substantial increases or decreases could not be ruled out. Overall the authors presented clear evidence of the impact of statin users in stroke patients to prevent a recurrent ischemic stroke and no clear indications of an increased hemorrhagic stroke risk.
Yin Y, Zhang L, Marshall I *et al.* **Statin Therapy for Preventing Recurrent Stroke in Patients with Ischemic Stroke: A Systematic Review and Meta-analysis of Randomised Controlled Trials and Observational Cohort Studies.** Neuroepidemiology 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35753307

Relevant Publications

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with Glucolipid Metabolism and Adverse Cardiovascular Prognosis. Disease markers 2022; 2022:8714392. http://www.ncbi.nlm.nih.gov/pubmed/?term=35756493
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Basic Science

1. **Prieto Garcia L, Lundahl A, Ahlström C *et al.* Does the choice of applied physiologically-based pharmacokinetics platform matter? A case study on simvastatin disposition and drug-drug interaction. CPT Pharmacometrics Syst Pharmacol 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35722750**
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mailing address:
lansberg@gmail.com