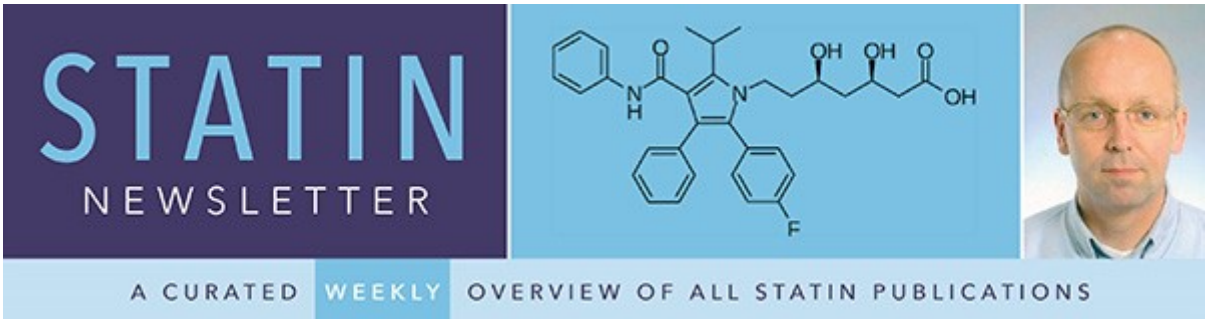

Update week 17 & 18 - 2022

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. **incremental CVD benefit of adding ezetimibe and PCSK9i to statins**
2. **VTE recurrence can statins help?**
3. **At what time should I take my statin?**
4. **Failing lipid management in secondary prevention patients**
5. **Statins post VTE, Real world data**

Impact of non-statin lipid lowering drugs to statins – network meta-analysis

The addition of add-on therapy to statins is gaining traction. The priority remains to use high-intensity statins at the highest tolerated dosage. However, the addition of non-statin agents such as ezetimibe and PCSK9i are needed to achieve more stringent guideline dictated targets in very high-risk patients. The CVD and survival benefits of PCSK9i or ezetimibe were analyzed in this network meta-analysis based on 14 randomized trials that included >500 patients and lasted longer than 6 months. In patients at very high CVD risk, adding ezetimibe reduced AMI risk by 13% (0.71-0.96) and stroke by 18% (0.80-0.94). All-cause mortality and CV mortality were not improved, RR:0.99 (0.92-1.16) and RR: 0.97 (0.78-1.09) respectively. Similar results were observed for PCSK9i, despite a much more impressive LDL-c reduction. AMI risk 0.81 (0.76-0.87) and risk for stroke, RR: 0.74 (0.64-0.85). No benefits for all-cause and CV mortality were noted in patients treated with PCSK9i, RR 0.95 (0.87-1.03) and RR: 0.95 (0.87-1.03), respectively. For patients determined to have a high CV risk, the addition of PCSK9i reduced AMI risk by 12/1000 patient-years and stroke risk by 16/1000 patient years. Adding ezetimibe reduced AMI in 8/1000 patient years (not significant) and stroke 11/1000 patient-years. Adding ezetimibe to statins + PCSK9i did not result in significant outcome improvements both for AMI and stroke. Adding PCSK9i to

statins + ezetimibe resulted in a significant stroke reduction of only 13/1000 patient years. Adding ezetimibe or PCSK9i to moderate or low CVD risk patients did not show any AMI or stroke benefits. The authors concluded that adding PCSK9i or ezetimibe to statins in (very) high CVD risk individuals may reduce non-fatal MI and stroke risk. The benefits of adding PCSK9i or ezetimibe to statins in patients with low-moderate CVD risk were absent.
Khan SU, Yedlapati SH, Lone AN *et al.* **PCSK9 inhibitors and ezetimibe with or without statin therapy for cardiovascular risk reduction: a systematic review and network meta-analysis.** Bmj 2022; 377:e069116. http://www.ncbi.nlm.nih.gov/pubmed/?term=35508321

Are statins an option to prevent VTE recurrence?

Preventing VTE recurrences remains a challenge of balancing thrombotic risk with bleeding risk when oral anticoagulants are prescribed. Could statins perhaps fill this niche based on their anti-inflammatory and anti-thrombotic properties? In this prospective randomized study, 228 VTE patients were prescribed rosuvastatin 10 mg + warfarin or rivaroxaban vs. the control group who used warfarin or rivaroxaban only. The study aimed to evaluate statins' potential anti-inflammatory and immune-modulating effects and changes in plasma D-dimer levels. After 3 months, patients had significantly reduced plasma concentrations of D-dimer and mean platelet volume, associated with inflammation and hypercoagulable state. Based on these preliminary findings adding statins to standard oral anticoagulation seems attractive. However, additional studies with larger numbers of participants are warranted to validate these findings and explore the underlying mechanisms of these biomarker changes.
Alirezaei T, Sattari H, Irilouzadian R. **Significant decrease in plasmad-dimer levels and mean platelet volume after a 3-month treatment with rosuvastatin in patients with venous thromboembolism.** Clin Cardiol 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35481712

What is the best time to take your statin?

The timing of statin medication, what would be the best time to take a statin, is often asked question by patients; the answer can be found in this systematic review and meta-analysis of statin trials that recorded the time statins were taken. Of the initial 671 reports, 13 RCTs were included in this meta-analysis. In total 1, 129 patients were included; 621 used statins in the evening, and 631 patients took their statins in the morning. Included as well were four cross-over trials using the same statin dose in the morning or the evening. In this meta-analysis, a significant reduction of LDL-c and total C were observed in patients taking statins in the evening. An evening dosing of a statin led to a greater reduction in LDL-C [MD=−6.27 mg/dl (−9.92 to −2.63), I2=37%; 12 trials], and total-C [MD=−6.09 mg/dl (−10.80 to −1.38), I2=54%; 11 trials] compared with morning dosing. Patients taking short half-life statins showed an even greater effect of −11.6 mg/dl vs. −4.3 mg/dl. Adverse events were similar between evening and morning dosing in main; OR=1.22 (0.79–1.88), I2=0%; 7 trials. The explanation for this observed difference is that due to the circadian rhythm of the liver, HMG-CoA reductase, the rate-limiting enzyme in cholesterol biosynthesis, has higher expression and hence biosynthesis at night. Haisum Maqsood M, Messerli FH, Waters D *et al.* **Timing of Statin Dose: A Systematic Review and Meta-analysis of Randomized Clinical Trials.** Eur J Prev Cardiol 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35512427

Are we failing to adequately manage very high ASCVD risk patient with statins?

The overwhelming scientific evidence and universal guideline recommendations underline the importance of LDL-c control in patients with established ASCVD. Statins remain the drug of first choice, preferably the high-intensity variety, and used with the high(est) dose. Real-World evidence reveals that patients remain under-treated and subsequently at high risk for a (recurrent) event. In this retrospective cohort study, pharmacy and medical claims data from a commercial health plan were used to evaluate the type and dosage of statin used by 601 934 patients with established ASCVD. (41.7% female; mean age 67.5 ±13.3 years). High-intensity statins were used by 22.5; 27.6% were on a low- or moderate-intensity statin, and 49.9% were not on any statin. Female patients and those with higher Charlson comorbidity score were less likely to be prescribed any statin. Female patients, older patients, and those with peripheral artery disease were less likely to be on a high-intensity

formulation among statin users. In contrast, a cardiology encounter in the prior year increased the odds. The majority of high-intensity stain users achieved high levels of adherence. The observed lack of guideline adoption is of great concern and warrants improved strategies to address this gap in managing very high ASCVD.
Nelson AJ, Haynes K, Shambhu S *et al.* **High-Intensity Statin Use Among Patients With Atherosclerosis in the U.S.** J Am Coll Cardiol 2022; 79:1802-1813. http://www.ncbi.nlm.nih.gov/pubmed/?term=35512860
Virani SS, Ballantyne CM, Petersen LA. **Guideline-Concordant Statin Therapy Use in Secondary Prevention: Should the Medical Community Wait for Divine Intervention?** J Am Coll Cardiol 2022; 79:1814-1817. http://www.ncbi.nlm.nih.gov/pubmed/?term=35512861

Benefits of statins in post VTE patients

In this retrospective analysis of the Spanish Registro Informatizado de Pacientes con Enfermedad TromboEmbólica, the 30-day all-cause mortality in acute pulmonary embolism (PE) patients using statins were compared to patients, not on statins. Over the period between January 2009 and April 2021, 31 169 PE patients were entered into the registry. Statins were used by 5 520 (18%) patients at baseline. Low-intensity statins in 829 patients, moderate-intensity statins in 363 patients, and 1055 used high-intensity statins. Statin users were older and had a higher frequency of diabetes, hypertension, or atherosclerotic disease than non-users (P <0.000). Over the 30-day study period, 1475 patients died (fatal PE, 255). Based on multivariate analysis, both al cause death and fatal PE were significantly reduced in statin users; OR: 0.65 (0.56–0.76) and OR: 0.42 (0.28–0.62), respectively. Comparing low-moderate- or high-intensity statins showed similar benefits; OR: 0.51(0.34–0.77), OR: 0.68 (0.57–0.81), and OR: 0.68 (0.51–0.92), respectively. Statin use was not associated with increased cancer mortality risk (falsification endpoint). Patients that suffered a PE and used statins at baseline had a significantly lower risk of dying within the first 30 days than non-users. Properly designed randomized trials are warranted to confirm these findings.
Siniscalchi C, Muriel A, Suriñach Caralt JM *et al.* **Statin use and 30-day mortality in patients with acute symptomatic pulmonary embolism.** Journal of thrombosis and haemostasis : JTH 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35510755

Relevant Publications

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Basic Science

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