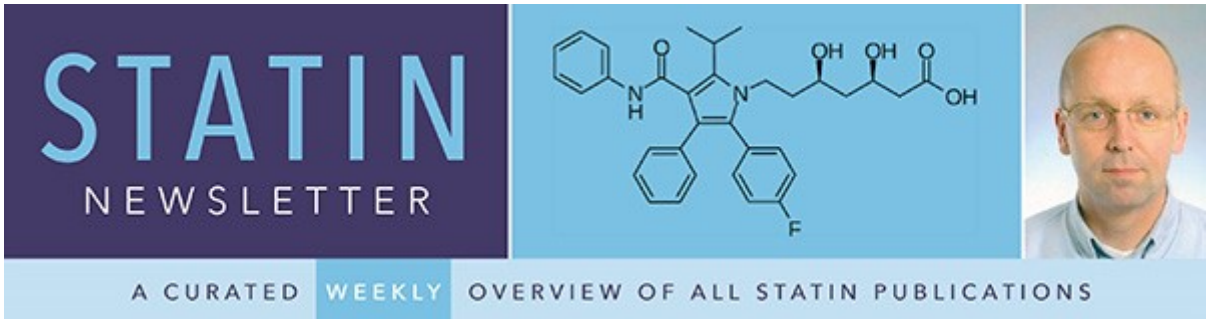

Update week 37 & 38 - 2022

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. **How frequent is NODM in statin users**
2. **Atorvastatin use associated with lower BP**
3. **Real muscle symptoms rare in statin users**
4. **High apo B + TG indicate elevate risk for NODM**
5. **Statins and PCSK9ab differ in hs CRP lowering propterties**

Is the risk of NODM in observational studies confounded?

The pro-diabetogenic effects of statins are an important reason why patients are reluctant to use statins. In this US Market Scan registry analysis, the impact of new-onset diabetes mellitus (NODM) was evaluated. Patients not using statins (215 263) were compared to those that did (N=221 263). An additional analysis was performed to compare statin continuers (N= 194 357) to patients that stopped their lipid-lowering medication <6 months (N= 26 906). NODM was increased when statin users were compared to those not taking statins; 9.9% vs. 4.4%, HR 2.2 (p < 0.001). When patients that continued taking their statins > 60 were compared to those not taking statins, the incidence of NODM was not significantly different, 10.0% vs. 9.3%,
HR 1.03, (p = 0.22). The authors suggested that selection bias could have confounded the association between statin use and NODM in observational studies. The small absolute increase observed in RCTs is likely an accurate representation of the causal effect of statin therapy NODM.
Ruzieh M, Ahmad TA, Liu G, Foy AJ. Association between statin exposure and diabetes incidence among privately-insured patients before and after applying a novel technique to control for selection bias. Am J Med Sci 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=36096188

Can Atorvastatin lower blood pressure?

Can statins improve blood pressure based on their pleiotropic effects, which include reducing oxidative stress, inflammation, and endothelial function improvement? This meta-analysis evaluated the effects of atorvastatin in human randomized controlled clinical trials (N=33) and preclinical studies (N=44). The effects included were systolic (SBP), diastolic, and mean BP; heart rate (HR) and HR variability. Atorvastatin use was associated with reduced systolic blood pressure (P = 0.05 vs. placebo; P = 0.03 vs. baseline) in normotensive and hyperlipidaemic (P = 0.04 vs. placebo; P = 0.0001 vs. baseline) and in hypertensive and hyperlipidaemic (P = 0.02 vs. placebo; P = 0.008 vs. baseline) individuals in parallel RCT, but it did not affect SBP in normotensive and normolipidemic individuals (P = 0.51 vs. placebo. P = 0.4 vs. baseline). The effects of blood pressure were not related to LDL-c changes in LDL-c. The preclinical animal data showed comparable effects; SBP was reduced in atorvastatin-treated hypertensive and normolipidemic rats (spontaneously hypertensive rats: P < 0.00001) but not in normotensive and normolipidemic rats (control rats: P = 0.97). Atorvastatin also reduced the HR in the spontaneously hypertensive rat. The findings of the meta-analysis confirm that atorvastatin can reduce blood pressure by vascular mechanisms, independent of their LDL-c lowering potential. Additional studies are warranted to understand better the underlying mechanisms of these observed blood pressure benefits.

Costa GS, Julião-Silva LS, Belo VS *et al.* A systematic review and meta-analyses on the effects of atorvastatin on blood pressure and heart rate. European heart journal. Cardiovascular pharmacotherapy 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=36138492

Nine out of 10 reported muscle symptoms are nocebo effects

The most common reason patients stop statins is muscle-related side effects (MRS). The reported number of events in observational studies or registries is very high and contrasts with the relatively well-tolerated statin use in RCTs. The Oxford group conducted a meta-analysis of studies that registered patient-reported muscle symptoms; there were19 placebo-controlled studies (N=123 940) and four high-dose vs. low-dose statins trials(N=30 742). In the placebo-controlled trials, MRS was reported by 27.1% of the statin users and 26.9% by the controls using placebo; RR:1.03 (1.01-1.06). After 1-year, there was a 7% relative risk increase of MRS; this reflected an absolute event rate of 11 (6-16) events per 1000 patients. Only one in 15 ([1·07–1·00]/1·07) of MRS reports by participants allocated to statin therapy were due to the statin! After one year, no significant difference in MRS was observed when comparing statin users with controls; RR:0·99 (0·96–1·02). In studies that compared high-dose statins (atorvastatin 40-80 mg or rosuvastatin 20-40 mg), patients using the high dose were more likely to report MRS when compared to patients using low or intermediate dose statins; RR: 1·08 (1·04–1·13) vs. RR: 1·03 (1·00–1·05). Compared to placebo, patients with high-dose statins reported slightly more MRS, RR: 1·05 [0·99–1·12). There was no indication that different statins showed different MRS outcomes. Statin therapy was associated with a small, clinically insignificant increase in median creatine kinase, approximately 0·02 times the upper limit of normal. Based on the findings of this large and well-conducted meta-analysis, statins do not cause MRS in 9 out of 10 people that report SRM while taking the medication.Effect of statin therapy on muscle symptoms: an individual participant data meta-analysis of large-scale, randomised, double-blind trials. Lancet 2022; 400:832-845. http://www.ncbi.nlm.nih.gov/pubmed/?term=36049498

Elevated triglycerides and apo B predict Diabetes risk

Can the risk of NODM be predicted by increases in lipid markers associated with hyperinsulinemia and metabolic syndrome? Data from the Framingham offspring study (N=3446) was used to evaluate the effects of increased plasma TG and apo B concentrations, low LDL cholesterol to apo B ratio, and low HDL cholesterol. Participants included in the Framingham offspring study were aged 49-60 years and free of ASCVD and diabetes at baseline (April 1987 – November 1991). They were followed up until March 2014. Included in the analysis were 2515 individuals. The median follow-up period was 21.1 years

IQR 11.1-23.1), and during this period, 402 participants (16.0% developed diabetes. Predictors for NODM were age (p=0·032), waist circumference (p<0·0001), fasting blood glucose (p<0·0001), and natural logarithm-transformed triglycerides (p<0·0001), as were apo B (p=0·0016), LDL cholesterol to apoB ratio (p=0·0018), and HDL cholesterol (p=0·0016). In the hypertriglyceridaemic + hyperapoB group NODM was observed in 32·4% (27·8–37·7) versus 5·5% (3·5–8·6) in the optimal lipid phenotype group and 15·5% (13·5–17·7) in the mixed lipid phenotype group. This translated into a hazard ratio (HR) of 3.30 (2·06–5·30; p=0·0008). In the mixed lipid phenotype group, the HR was 2.17 (1·38–3·40; p<0·0001) compared to the optimal lipid phenotype. These findings support the role of the increased clearance of apo B-carrying particles from the plasma that could impair the insulin secretion of pancreatic islet cells. A mechanism that could also explain the observed increase in NODM of patients using statins.

Pencina KM, Pencina MJ, Dufresne L *et al.* **An adverse lipoprotein phenotype-hypertriglyceridaemic hyperapolipoprotein B-and the long-term risk of type 2 diabetes: a prospective, longitudinal, observational cohort study.** Lancet Healthy Longev 2022; 3:e339-e346. http://www.ncbi.nlm.nih.gov/pubmed/?term=36098309

Meta-analysis shows similarities and differences between statins, ezetimibe and PCSK9ab

In this meta-analysis statins, ezetimibe and PCSK9ab studies were compared for their effects on LDL-c, CRP and CVD complications. Plasma LDL-c levels were significantly reduced with statins WMD: −47.94 mg/dL (−51.21 to −44.67 mg/dL); ezetimibe, WMD: −22.84 mg/dL, (−26.76 to −18.92 mg/dL), and PCSK9ab, WMD: -54.24 mg/dL, (−59.77 to −48.70 mg/dL)

CRP levels were statins: WMD −0.67 mg/L, 95% CI −0.90 to −0.45 mg/dL; ezetimibe: −0.64 mg/L, 95% CI −1.07 to −0.21 mg/dL). CRP level improved as well with statins, WMD: −0.67 mg/L (−0.90 to −0.45 mg/d), and ezetimibe, WMD: −0.64 mg/L (−1.07 to −0.21 mg/dL).

No significant CRP lowering effects were observed after the use of PCSK9ab. Based on a Meta-regression analysis no significant association was noted between CRP reductions and change in LDL-c levels. Although PCSK9ab use was associated with a greater LDL-c reduction compared to statins and ezetimibe, the observed changes in the risks for CV death, myocardial infarction (MI), and stroke showed no significant differences. The authors concluded that all three LDL-c lowering drugs showed significant and clinically relevant improvements of plasma LDL-c, only statins and ezetimibe use was associated with a significant reduction of CRP. Clinical CV outcomes were reduced similarly by the statins, ezetimibe and PCSK9 ab

Yang W, Cai X, Lin C *et al.* **Reduction of C-reactive protein, low-density lipoprotein cholesterol, and its relationship with cardiovascular events of different lipid-lowering therapies: A systematic review and meta-analysis of randomized controlled trials.** Medicine (Baltimore) 2022; 101:e30563. http://www.ncbi.nlm.nih.gov/pubmed/?term=36123891

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