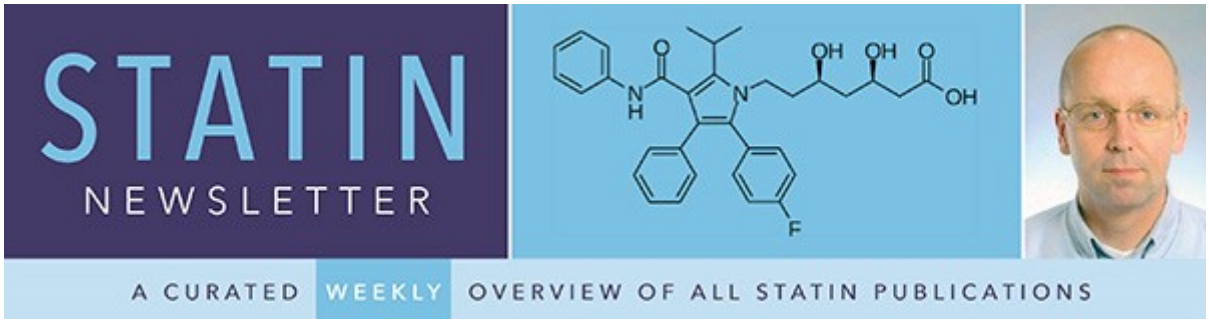

Update week 29 & 30 - 2022

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. **Non-LDL-c lowering properties of statins; more than meets the eye**
2. **Real World data on adherence and statin intensity in secondary prevention**
3. **Statins add-on therapy in Kawasaki disease**
4. **Renal safety of rosuvastatin compared to atorvastatin - Real World evidence**
5. **Single dose Simvastatin in liver donor improves (transplant) survival**

The surprising non-LDL-c lowering effects of statins

For preventing ASCVD complications, statins have an impressive burden of evidence. Pivotal is their remarkable plasma LDL-c reducing potential, related to the type of statin and the dosage used. A continuing controversial topic is the non-LDL-c related effects known as pleiotropic effects. In this current review, the authors explore the rich literature sources that focus on the angiogenic effects of statins. One prominent process, the NO synthesized by endothelial cells, is highlighted, and the pro- and anti-angiogenic effects are discussed. Statin dosage is shown to be crucial for these angiogenic effects; low dose is shown to be pro-angiogenic while high dose shows more anti-angiogenic changes. Local vascular conditions were shown to be responsible for stimulating pro- or anti-angiogenic changes; inflammation was associated with anti-angiogenic effects, while hypoxia stimulated pro-angiogenic effects when using the same simvastatin dosage. Most studies used in-vitro models and animal in-vivo used. Intriguing findings that warrant clinical trials to evaluate the impact on complications and ASCVD events as well as exploring these pathways for innovative novel therapeutic strategies

Zahedipour F, Butler AE, Eid AH, Sahebkar A. Pleiotropic properties of statins via angiogenesis modulation in cardiovascular disease. Drug discovery today 2022; 27:103325. http://www.ncbi.nlm.nih.gov/pubmed/?term=35872297

Is statin adherence superior to statin intensity in secondary Prevention?

Two major determinants of preventing ASCVD events, When using statins are plasma LDL-c targets reached (“the lower, the better”) and adherence (“the longer, the better”). To evaluate the effect of both outcomes and the combined benefits, statin intensity and adherence to statins in 20 490 patients that had an AMI or coronary revascularization and initiated statins during 2012-2018. The primary outcomes were MACE (nonfatal myocardial infarction or stroke and death); secondary outcomes were LDL-cl goal attainment and individual components of MACE. The data source of this study was the Stockholm Creatinine Measurement database. The mean follow-up was 2.6 (±1.1) years (72 839 patient-years). Adherence to lipid-lowering therapy was associated with the most significant benefit, regardless of treatment intensity. However, LDL-c goal accomplishment was improved by high-intensity statin treatment. The last two conclusions seem contradictory, based on the firmly established paradigm of “lower is better.” A possible explanation for this unexpected finding is confounding factors; better adherence could be associated with adherence to other CV medications plus a better lifestyle, and although the majority of patients were prescribed high-intensity statins, post-AMI (62,2%), statin intensity steadily declined to reach 47.9% after 7-years follow-up. In comparison, low-moderate intensity statin use increased from 37.8% to 51.3%. Statin adherence is shown to be one of the best predictors of reduced event rates but is also one of the most challenging ones. The authors suggest a multifaceted and person-centered approach for secondary prevention strategies to promote adherence and optimal treatment.

Mazhar F, Hjemdahl P, Clase CM *et al.* Intensity of and Adherence to Lipid-Lowering Therapy as Predictors of Major Adverse Cardiovascular Outcomes in Patients With Coronary Heart Disease. J Am Heart Assoc 2022; 11:e025813. http://www.ncbi.nlm.nih.gov/pubmed/?term=35861825

Atorvastatin could be of added value in the treatment of Kawasaki disease

The cascading effects of cholesterol synthesis inhibition results in the down-regulation of critical signaling molecules that can negatively and positively impact vascular and non-vascular disorders. The authors of this study used an innovative RNA-based approach to determine potential therapeutic interventions. Human umbilical vein endothelial cells were incubated with pooled sera from acute Kawasaki disease patients before or after treatment with infliximab. Increased expression of several genes was observed`; interleukin-1, tumor necrosis factor-α, and inflammatory cell recruitment pathways. Pooled sera of patients with sub-acute manifestations, treated with infliximab and atorvastatin, showed a unique expression pattern of NOS3, Kruppel-like factor (KLF2, and KLF4 (promotes EC homeostasis and angiogenesis) and ZFP36 ring finger protein (ZFP36) and suppressor of cytokine signaling 3 (SOCS3) suppress inflammation), and suppressed expression of TGFB2 and DKK1 (induces endothelial-mesenchymal transition) and sphingosine kinase 1 (SPHK1) and C-X-C motif chemokine ligand 8 (CXCL8) (induces inflammation). Based on their findings, the authors concluded that in patients with acute Kawasaki disease, atorvastatin was shown to improve endothelial cell health, mitigate inflammation and block Kawasaki disease-induced myofibroblast proliferation. These changes could potentially block or inhibit aneurysm progression in patients suffering from Kawasaki diseas

Shimizu C, Kim J, He M *et al.* RNA Sequencing Reveals Beneficial Effects of Atorvastatin on Endothelial Cells in Acute Kawasaki Disease. J Am Heart Assoc 2022; 11:e025408. http://www.ncbi.nlm.nih.gov/pubmed/?term=35861833

Rosuvastatin 20-40 mg can harm renal function

Statins are generally grouped as high-intensity and moderate/low-intensity statins. Most guidelines advocate using high-dose, high-intensity statins; atorvastatin 40-80 mg and rosuvastatin 20-40 mg. The efficacy of these two potent statins are comparable, but are safety characteristics also comparable? In this retrospective analysis of EHR data from 40 health care organizations (“cohorts”) participating in Optum Labs Data Warehouse,

atorvastatin and rosuvastatin were compared for renal-related adverse effects. The analysis included 152 101 rosuvastatin- and 795 799 atorvastatin users (2011 – 2019). The endpoints included in this evaluation were hematuria, proteinuria, and kidney failure with replacement therapy (KFRT). The hazard ratio's (HR) for hematuria, HR: 1.08; 95% (1.04 - 1.11); proteinuria, HR: 1.17 (1.10 - 1.25), and KFRT, HR: 1.15 (102 - 1.30) were increased in patients using rosuvastatin. Despite the FDA recommendation to limit rosuvastatin dosage to 10 mg/day in patients with an EGFR<30ml/min per 1.73 m2, a substantial share (44%) of patients with impaired renal function used high-dose rosuvastatin (20 or 40 mg daily). These findings confirm earlier reports indicating the negative impact of high-dose rosuvastatin on relevant renal biomarkers. The authors suggest the need for greater care in prescribing and monitoring rosuvastatin, particularly in patients who receive high doses or have severe CKD.

Shin JI, Fine DM, Sang Y *et al.* **Association of Rosuvastatin Use with Risk of Hematuria and Proteinuria.** Journal of the American Society of Nephrology : JASN 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35853713

A single dose of simvastatin administered to brain death liver donors improves graft survival

The SIMVAstatin donor treatment before Liver Transplants (SIMVALT) study aimed to establish the benefits of a single dose of 80 mg simvastatin to donors after brain death by nasogastric tube, 2 hr. before donor cross-clamping for liver graft procurement. Ischemia/reperfusion injury in recipients of a donor's liver is an important cause of liver transplant failures. The reasoning for this trial was earlier preclinical studies showing that statins can modify nuclear transcription factors (NTF) that regulate eNOS expression in liver endothelial cells. KLF2 is an NTF that increases eNOS expression and several vasoprotective genes, including thrombomodulin and angiopoietin, resulting in a healthy endothelial phenotype, which is antiproliferative, pro-vasodilatory, anti-inflammatory, and anti-thrombotic. KLF2 is rapidly downregulated in liver grafts hence the rationale for using simvastatin in brain death liver donors. The primary endpoints were 90- and 180-day graft survival. A total of 58 patients (18-65 years old) were randomized in the study. There was 100% graft survival in the patients that received organs from simvastatin-treated donors at 90 and 1180 days (n=28). In the control arm (N=29) patient/graft survival was 93.1% and 89.66% at 90 days and 86.2% and 86.2% at 180 days. Severe complications were observed in 55.2% of the control patients vs. 25.0% in patients that received the simvastatin-treated graft. These findings are provocative, and if reconfirmed in additional (larger) studies, this simple, inexpensive, and easy-to-perform intervention could be an attractive alternative to sophisticated and expensive perfusion device-based techniques. Secondly, the observed benefits are unrelated to the LDL-c lowering effects of statins but re-affirm the clinical relevance of non-LDL-c or pleiotropic effects of statins.Pagano D, Bosch J, Tuzzolino F *et al.* **Donor Simvastatin Treatment Is Safe and Might Improve Outcomes After Liver Transplantation: A Randomized Clinical Trial**. Transplantation 2022. http://www.ncbi.nlm.nih.gov/pubmed/?term=35862782

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Basic Science

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