

Update week 49 & 50 - 2023

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

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

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Key Publications

- 1. Stopping statins in elderly; not so fast!
- 2. Reducing VTE's in women on HRT, and using statin
- 3. Comprehensive review on statins effects on coagulation
- 4. Statins and Cognitive, more benefits than harms?
- 5. Inadequate lipid targets in patients having a first ASCVD event.



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Key publications

Observational study on the effects of Statins in elderly veterans with CKD

The study, focusing on U.S. veterans older than 65 years with chronic kidney disease (CKD), stages 3 to 4, aimed to determine the association of statin initiation with all-cause mortality and major adverse cardiovascular events (MACE). It employed a target trial emulation design using a vast dataset from the Veterans Affairs Healthcare System, Medicare, and Medicaid. The study included 14,828 veterans, primarily male and white, with a mean age at CKD diagnosis of 76.9 years. Through propensity score adjustment and nonparametric bootstrapping, the analysis showed a statistically significant 9% lower risk of all-cause mortality for statin initiators compared to non-initiators, although it did not show a statistically significant reduction in MACE.

The findings challenge the growing inclination towards deprescribing statins in older adults with CKD for primary prevention. The study's strength lies in its large sample size, long follow-up, and robust methodological approach to minimize confounding. However, the predominantly male and white cohort limits the generalizability of the findings. Also, the observational design, although well-executed, inherently carries the risk of residual confounding. The study didn't evaluate the per-protocol effect size for statin use after the initial prescription or the dose or duration of statin therapy, which could further inform the clinical application of its findings.

In conclusion, the study provides compelling evidence supporting the use of statins for primary prevention of all-cause mortality in older adults with moderate CKD but raises questions about their impact on MACE. The call for a randomized clinical trial is well-founded and necessary to confirm these results and guide clinical practice. Until then, the evidence suggests a cautious approach towards deprescribing statins in this population, considering the individual patient's context and risk profile.

Statins, Mortality, and Major Adverse Cardiovascular Events Among US Veterans With Chronic Kidney Disease. <u>JAMA network open</u> 2023; 6:e2346373 Barayev O, Hawley CE, Wellman H *et al.* http://www.ncbi.nlm.nih.gov/pubmed/?term=38055276

VTE risk in post-menopausal women on HRT and statins

The complex interplay between statin use, hormone therapy (HT), and the risk of venous thromboembolism (VTE) in perimenopausal women is reviewed in this retrospective observational study. The authors used nested case-control design based on data collected in a large US claims database, it involved women aged 50 to 64 years taking HT, with or without concurrent statin therapy. The robust sample size of 223,949 participants allowed for a detailed exploration of these associations. The findings indicate that HT alone is associated with a 53% increased risk of VTE. However, when combined with statin therapy, the risk is reduced, though not entirely mitigated. Statins alone were associated with a 12% decrease in VTE risk. Importantly, the study demonstrates a dose-response effect; higher intensity statin therapy correlates with a more significant reduction in VTE risk. The study stands out for its large, diverse cohort and detailed analysis of drug exposures. It controls for a wide range of potential confounders, including comorbidities and various lifestyle factors. Moreover, the study's design, which pairs a stringent case definition with confirmatory events, strengthens the validity of its findings. However, as a nested casecontrol study, it cannot establish causality. It's also limited by the typical constraints of claims data, such as lack of detailed patient characteristics and potential misclassification of exposures. The findings are compelling but underscore the need for randomized controlled trials to confirm the potential protective role of statins in women taking HT. This study provides valuable insights into how statin therapy might modulate the risk of VTE in women undergoing hormone therapy. The findings suggest a nuanced approach to prescribing HT in perimenopausal women, especially those at higher cardiovascular risk, and highlight the potential of statins to improve the risk-benefit profile of hormone therapy. Statin Use and the Risk of Venous Thromboembolism in Women Taking Hormone Therapy. JAMA network open 2023; 6:e2348213Davis JW, Weller SC, Porterfield L et al.

Review: statins effect on coagulation

The authors present comprehensive review on the multifaceted role of statins in blood coagulation and thromboembolic disease management. Statins have shown to exert significant anticoagulant and antiplatelet effects. These effects are attributed to the downregulation of tissue factor (TF) expression, reduced thrombin generation, impaired fibrinogen cleavage, modulation of various coagulation factors, and enhanced endothelial thrombomodulin expression. The review highlights the pleiotropic effects of statins that extend beyond cholesterol reduction, contributing to their efficacy in cardiovascular disease management. In vitro and in vivo studies demonstrate statins' influence on platelet aggregation, TF gene expression, von Willebrand factor, D-dimer levels, and several coagulation factors. Statins also impact the protein C pathway, a critical regulator of thrombin formation, and the tissue factor pathway inhibitor (TFPI), affecting the TF-FVIIa complex activity. The review underscores the variability in statins' effects on different coagulation factors and acknowledges the need for further research to clarify these mechanisms. Clinically, statins have been associated with primary and secondary prevention of venous thromboembolism (VTE), with studies indicating a potential reduction in VTE recurrences and mortality. However, the evidence is mixed, and the review calls for more targeted intervention studies to conclusively determine statins role in VTE management. The potential risks, such as increased bleeding in certain contexts and other documented side effects like myopathy and diabetes, are also discussed. While statins antithrombotic properties are promising, their impact on VTE's require further clarification through dedicated research. This review provides a critical understanding of statins complex role in coagulation and their potential therapeutic implications in thromboembolic disease management.

Statins Effects on Blood Clotting: A Review. <u>Cells</u> 2023; 12Siniscalchi C, Basaglia M, Riva M et al. http://www.ncbi.nlm.nih.gov/pubmed/?term=38067146

The potential of atorvastatin to mitigate cognitive impairment

Remarkable findings in this basic science study using ApoE-/- mouse model, investigated the therapeutic potential of Atorvastatin in mitigating memory deficits and brain monocyte infiltration caused by chronic hypercholesterolemia, Mild Cognitive Impairment (MCI) is prevalent in individuals over 60 and is exacerbated by hypercholesterolemia, leading to neuron damage and cognitive impairment through neuroinflammation, BBB dysfunction, and monocyte infiltration. The study suggests that hypercholesterolemia-induced changes, including increased plasma cholesterol, reduced Recognition Index (RI) in memory tests, decreased mobility, and downregulated PSD-95 and BDNF, are significantly reversed by Atorvastatin. Moreover, Atorvastatin notably represses increased brain and blood Ly6Chi CD45+ cells, plasma IL-12/IL-23, and IL-17 levels, all indicators of inflammation and immune activation. The authors also highlight that Atorvastatin prevents the increased permeability of the blood-brain barrier (BBB) and restores the expression of tight junction proteins (ZO-1 and occludin) and KLF2, a transcriptional factor regulating these proteins. This suggests its role in protecting against BBB disruption and suppressing neuroinflammation, thereby mitigating cognitive impairment. The methodology involves using aged ApoE-/- mice to mimic chronic hypercholesterolemia and assessing the effects of Atorvastatin treatment on various physiological and molecular markers related to memory, inflammation, and BBB integrity. Atorvastatin demonstrates a promising therapeutic potential in reducing memory deficits and monocyte infiltration in the brain, possibly through mechanisms involving lipidlowering, anti-inflammatory effects, and BBB protection. This suggests its potential utility in treating hypercholesterolemia-related cognitive impairments, though further investigation is needed to understand the underlying mechanisms and its effectiveness in human subjects. Atorvastatin mitigates memory deficits and brain monocyte infiltration in chronic hypercholesterolemia. Aging 2023; 15Gong F, Shi Q, Mou X et al. http://www.ncbi.nlm.nih.gov/pubmed/?term=38048213

The HEARTBEAT study confirms inadequate lipid targets in high risk

primary prevention patients suffering a first ASCVD event

The HEARTBEAT study, a retrospective multicentre observational study conducted in Spain, evaluated the attainment of low-density lipoprotein cholesterol (LDL-C) targets in patients on lipid-lowering therapy (LLT) before experiencing a first major acute cardiovascular event (MACE). The study encompassed 334 patients, predominantly male and Caucasian, with a median age of 72 years, most of whom were at high or very high cardiovascular risk prior to MACE. Astonishingly, 87.5% and 89.7% of patients at high and very high cardiovascular risk, respectively, failed to achieve the LDL-C targets. Furthermore, only a small fraction had received high-intensity LLTs before MACE, indicating that patients were generally undertreated and far from lipid targets. The significance of managing dyslipidemia, particularly LDL-C, as a major risk factor for cardiovascular disease (CVD) is wellestablished. Lowering LDL-C has been shown to significantly reduce the incidence of major cardiovascular events, and specific LDL-C targets have been recommended for patients based on their risk levels. However, the study reveals a concerning gap between these guidelines and real-world practices, with a high incidence of failure to meet LDL-C targets among patients on LLT for primary prevention. This suboptimal performance in reaching LDL-C targets and undertreatment highlights a significant issue in the management of CVD risk, especially considering that nearly 70% of the patients were at high or very high cardiovascular risk before their first major cardiovascular event. The findings are in line with previous reports of suboptimal LDL-C target achievements in primary prevention in Europe and Spain. It points out the need for increased awareness and adherence to international guidelines among healthcare professionals to improve the use of LLTs in clinical practice and help more patients achieve their LDL-C goals. The authors call for action to optimize primary prevention strategies using more effective/intensive LLTs tailored to cardiovascular risk to avoid the first occurrence of MACE.

Patients who suffer a first atherosclerotic cardiovascular event while taking statins are often far off of lipid targets. <u>Nutrition, metabolism, and cardiovascular diseases : NMCD</u> 2023; Masana L, Díaz Moya G, Pérez de Isla L. http://www.ncbi.nlm.nih.gov/pubmed/? term=38092606

Relevant Publications

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