



Update week 43 & 44 - 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

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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. Continued Use of Cholesterol Medications in a Broad Japanese Population Study
2. Assessing the Safety of Statins and PCSK9 Inhibitors in Chinese Teenagers Through MR
3. "Analyzing the Effect of Cholesterol Levels on MACE in Korean Patients with T2DM
4. Comprehensive Review Reveals Nocebo Effect Among Placebo Recipients in Studies of Statin Intolerance
5. Assessing Blood Clot Risk Following Ankle Fractures with Statins Using Machine Learning Analysis"

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## Key publications

### Adherence and persistence of lipid lowering drugs in a large Japanese cohort

The authors of this study assessed the use of lipid-modifying agents (LMAs) in Japan for patients aged 55 years and older. Their findings provide valuable insights into the real-world application of these treatments. The study's key objective was to compare the initiation and subsequent use of statins, ezetimibe, and fibrates for both primary and secondary prevention of cardiovascular diseases (CVDs). Utilizing a retrospective cohort design and the National Database of Health Insurance Claims and Specific Health Checkups of Japan, it examines the persistence and adherence to these LMAs among a large cohort. The study highlights a rapid decline in persistence rates post-initiation across all LMA classes, with about 50% of patients discontinuing within the first year for primary prevention without risk. This trend raises concerns about the effectiveness of these treatments in a real-world setting, emphasizing the need for enhanced patient education and follow-up. Secondly, the study reports notable sex differences in persistence rates, particularly for statins in secondary prevention, suggesting that female patients might have different experiences or outcomes with statin therapy. This finding warrants further investigation into the underlying causes, such as differences in side effects or disease progression between sexes. Thirdly, while statins remain the predominant LMA used, the low switching rate to ezetimibe within a year of initiation suggests a potential underutilization of this treatment option. This gap highlights the need for continuous evaluation of treatment strategies to ensure optimal patient outcomes. Lastly, the study uncovers that a significant proportion of patients who discontinued treatment restarted within a year. This pattern indicates a complex dynamic in patient adherence and suggests that temporary discontinuation doesn't always mean permanent cessation. Healthcare providers should consider this when planning follow-up and patient engagement strategies. This study offers crucial insights into the use of LMAs in older Japanese patients, revealing patterns in medication persistence and adherence that could inform future clinical practice and policy-making. However, its reliance on claims data and the lack of clarity on reasons for discontinuation are notable limitations that should be addressed in future research.

**Statin, Ezetimibe, or Fibrate Initiation and Subsequent Use for the Primary and Secondary Prevention of Cardiovascular Diseases among Japanese Patients Aged  $\geq 55$  Years: A Nationwide Cohort Study.** *Biological & pharmaceutical bulletin* 2023; 46:1548-1557 Tomida J, Sato T, Yoshida T *et al.* <http://www.ncbi.nlm.nih.gov/pubmed/?term=37914357>

### Using MR to predict safety of statins and PCSK9 inhibitors in Chinese adolescents

This article presents a pioneering study assessing the safety of HMGCR inhibitors (statins) and PCSK9 inhibitors in East Asian adolescents, particularly those from China. The study's novelty lies in its application of drug-target Mendelian randomization, leveraging genetic data to mimic the effects of these drugs, thereby overcoming the limitations of observational studies prone to biases like confounding by indication. Methodologically, the study is robust, utilizing data from the Global Lipid Genetics Consortium and the Hong Kong "Children of 1997" birth cohort. This large-scale genetic approach, covering over 146,000 East Asian individuals and 3,443 Chinese adolescents, ensures a comprehensive analysis. The study investigates a wide range of safety outcomes, including anthropometric, hematological, renal, and liver functions, and utilizes both genetic and nuclear magnetic resonance metabolomics data. The results indicate that genetic inhibition of HMGCR and PCSK9 effectively reduces cholesterol-related metabolites, aligning with existing randomized controlled trials (RCTs) and Mendelian randomization studies in adults. Crucially, the study did not find significant adverse effects related to these genetic inhibitions, suggesting the safety of statins and PCSK9 inhibitors in the adolescent population. However, it's important to note that these findings are based on genetic proxies and may not fully represent the effects of actual pharmacological interventions. The study's limitation is acknowledged in its inability to precisely replicate the pharmacological effects

of these drugs, particularly concerning dosage, duration, and specific patient populations. Moreover, while the study covers a broad range of health outcomes, it does not encompass all possible side effects, such as muscle symptoms or testosterone reduction. In conclusion, this study represents a significant step forward in understanding the safety of lipid-modifying medications in East Asian adolescents. It underscores the potential of genetic approaches in drug safety assessment, especially in populations where long-term RCTs are challenging. However, its findings need to be validated in larger, more diverse studies to fully ascertain the safety profile of these medications in the adolescent population.

**Assessing the safety of lipid-modifying medications among Chinese adolescents: a drug-target Mendelian randomization study.** *BMC Med* 2023; 21:410 Luo S, Lam HS, Chan YH et al. <http://www.ncbi.nlm.nih.gov/pubmed/?term=37904165>

## **Examining the impact of lipid markers on MACE in Korean T2DM patients**

This study, focusing on patients with Type 2 Diabetes Mellitus (T2DM) under statin therapy, aims to determine which lipid and lipoprotein levels are most predictive of major adverse cardiovascular events (MACE). The study involved a considerable cohort of 11,900 T2DM patients, aged 40 and above, from the Korean Nationwide Cohort. These patients had no history of cardiovascular disease and were receiving moderate- or high-intensity statins. The primary outcome was the first occurrence of MACE, including ischemic heart disease, ischemic stroke, and cardiovascular death. The study's strength lies in its large sample size and its focus on a specific, high-risk group – T2DM patients on statin therapy. The study found that during a median follow-up of 37.9 months, MACE occurred in 712 patients. The most critical finding was that LDL-C (low-density lipoprotein cholesterol) and non-HDL-C (non-high-density lipoprotein cholesterol) levels were better predictors of cardiovascular events than triglycerides (TG) or HDL-C (high-density lipoprotein cholesterol), especially in high-risk patients or those with LDL-C  $\geq 70$  mg/dL. This conclusion is significant, as it points to the need for a more nuanced approach to managing dyslipidemia in T2DM patients, beyond the traditional focus on LDL-C levels. The study's results reinforce the understanding of the pathogenic role of LDL-C in atherosclerosis and highlight the importance of non-HDL-C as a predictor of cardiovascular events. This is particularly relevant in the context of T2DM, where multiple lipid abnormalities are common. However, the study has limitations, including its retrospective nature, potential for unaccounted confounders, and lack of consideration for other important long-term glycemic markers. The study makes a valuable contribution to understanding the predictive power of different lipid parameters for cardiovascular events in T2DM patients on statin therapy. It underscores the importance of monitoring both LDL-C and non-HDL-C levels for better cardiovascular risk assessment in this population. However, further prospective studies and randomized controlled trials are needed to establish more definitive guidelines for lipid management in T2DM patients.

**Comparison of On-Statin Lipid and Lipoprotein Levels for the Prediction of First Cardiovascular Event in Type 2 Diabetes Mellitus.** *Diabetes Metab J* 2023; Kim JY, Choi J, Kim SG, Kim NH. <http://www.ncbi.nlm.nih.gov/pubmed/?term=37915183>

## **Meta-analysis on statin intolerance highlights nocebo effect in placebo users**

The study employs a robust systematic review methodology, searching databases like CENTRAL, MEDLINE, and EMBASE up to March 2023. The inclusion of randomized control trials focusing on patients with a history of statin intolerance who received a placebo adds credibility to the findings. The use of a random-effects meta-analysis and the presentation of results with confidence intervals are commendable, enhancing the reliability of the outcomes. The finding that >21% of patients labelled as statin-intolerant exhibited muscle symptoms when on a placebo is striking. This finding is crucial because it suggests a significant nocebo effect, where symptoms might not be directly attributed to statin use but rather to patient expectations or other non-pharmacologic factors. The study's distinction between different modes of placebo administration (subcutaneous vs. oral) and their differing incidence rates is an insightful observation, further illuminating the complexity of

the nocebo phenomenon. This study highlights a critical aspect of patient management in statin therapy. The high incidence of muscle symptoms in the placebo group underscores the need for clinicians to carefully evaluate muscle complaints in patients deemed statin-intolerant. It suggests that a portion of these patients might tolerate statins better than initially thought. This could lead to a re-evaluation of statin discontinuation in some patients, potentially improving their cardiovascular risk management. The article rightly points out the possibility of muscle symptoms arising from sources other than statins. This is a crucial reminder for clinicians to consider differential diagnoses and not hastily attribute muscle symptoms to statin intolerance. Such an approach could prevent unnecessary discontinuation of an effective therapy. The systematic review's limitations, such as the potential for selective outcome reporting bias and the variability in definitions of statin intolerance, are well-acknowledged. These limitations highlight the need for a standardized definition of statin intolerance and more nuanced clinical trials. Future studies should focus on establishing a clear, unified definition of statin intolerance and investigating the nocebo effect in more depth. The article offers valuable insights into the phenomenon of muscle symptoms in statin-intolerant patients receiving placebo. It challenges the conventional understanding of statin intolerance, emphasizing the importance of careful patient evaluation and management. The findings have significant implications for improving adherence to statin therapy, which is crucial for effective cardiovascular risk reduction.

**Incidence of muscle symptoms in placebo arm among statin-intolerant patients: a systematic review with meta-analysis.** *Expert Rev Cardiovasc Ther* 2023; Louro R, Gouveia EMR, Ruivo J *et al.* <http://www.ncbi.nlm.nih.gov/pubmed/?term=37916684>

## **Examining Statin Impact on Blood Clot Risk in Ankle Fractures via Machine Learning**

Observational study confirms statin use reduces risk of thrombosis in ankle fracture patients

The retrospective, case-controlled study explored associations of statin use and risk of thrombosis. The selection of patients based on ankle fractures provides a specific context, which is relevant yet limits the generalizability of the findings. The study's focus on statin use, body mass index (BMI), age, and biological sex as predictors is logical, but the exclusion of other potentially influential variables like comorbidities, lifestyle factors, or the duration of statin use might oversimplify the model. The reported significant association between statin use and lower VTE incidence is noteworthy and aligns with some previous studies. However, the exact mechanism of this effect is not thoroughly explored in this study. An AUROC of 78% indicates moderate predictive power, but this alone is insufficient for clinical application without further validation. The sensitivity and specificity values are promising but need to be considered in the context of the model's limitations. The relatively low importance assigned to statin use in the model compared to age and BMI raises questions about the actual clinical significance of statin use in preventing VTE in this context. While the study suggests statins could potentially lower VTE risk in ankle fracture patients, clinicians should be cautious in extrapolating these results to practice without further robust evidence. The study opens avenues for further research, especially in understanding the role of statins in VTE prophylaxis. Future studies should focus on diverse populations, include a broader range of variables, and ideally adopt a prospective design to validate these findings. The authors' recognition of the study's limitations, including data constraints and the retrospective nature, is commendable. This transparency is crucial for the scientific community to appropriately weigh the study's findings. This article presents an intriguing insight into the potential role of statins in reducing VTE risk in patients with ankle fractures. However, due to methodological limitations and the inherent constraints of a retrospective study, these findings should be interpreted with caution. The study importantly contributes to the ongoing discourse on statin use beyond lipid-lowering effects and underscores the need for further, more comprehensive research in this area.

**Incidence of muscle symptoms in placebo arm among statin-intolerant patients: a systematic review with meta-analysis.** *Expert Rev Cardiovasc Ther* 2023; Louro R, Gouveia EMR, Ruivo J *et al.* <http://www.ncbi.nlm.nih.gov/pubmed/?term=37916684>

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## Relevant Publications

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