



Update week 39 & 40 - 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. **Statins work; as long as you use them....**
2. **Are statins protective in dialysis patients? An update from the 4D study**
3. **Statin treatment strategies tested in LODESTAR study**
4. **Rosuvastatin and renal safety; AKI in post cardiac surgery patients**
5. **Case series of HK patients that developed rhabdomyolysis on rosuvastatin 40 mg**

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## Key publications

### **Statin non-adherence a challenge with dire consequences**

The authors examined the crucial issue of statin adherence and its impact on patients with coronary artery disease (CAD) in real-world practice. The research, based on data from the CREDO-Kyoto Registry Cohort-3, offers several notable findings.

Firstly, the study reveals that approximately one in five patients discontinue statin therapy within a median follow-up period of six years after undergoing coronary revascularization. This rate is significantly higher than what was observed in clinical trials like ISCHEMIA and REVIVED, highlighting the importance of examining real-world adherence.

Secondly, the reasons for statin discontinuation were varied, with nonadherence, side effects, and worsening co-morbidities being the most common causes. Notably, patients who discontinued due to nonadherence were often younger, male, had acute coronary syndrome, and were current smokers, underscoring the need for targeted interventions in this group.

The study also found a strong association between statin discontinuation and subsequent mortality. This association held true for various reasons, except for a small group with prescription errors.

The findings emphasize the importance of addressing statin adherence issues in CAD patients, especially in the context of shared decision-making around coronary revascularization. It also highlights the need for multidisciplinary approaches to improve adherence, manage statin intolerance, and educate patients about potential side effects. However, some limitations in the study, such as the high prevalence of patients with statin discontinuation for unknown reasons and the lack of central adjudication for side effects, should be considered when interpreting the results.

This study underscores the critical role of statins in CAD management and the challenges posed by nonadherence and side effects. It calls for a comprehensive approach to ensure that patients receive the full benefits of statin therapy after coronary revascularization in real-world clinical practice.

**Statin Discontinuation After Coronary Revascularization.** *Am J Cardiol* 2023; Yamamoto K, Morimoto T, Natsuaki M *et al.* <http://www.ncbi.nlm.nih.gov/pubmed/?term=37798170>

### **Statins in dialysis patients remains enigmatic – update from the 4D study**

In this critical analysis the authors examine the complexities of cardiovascular risk management in a high-risk population. The 4D Study, a placebo-controlled trial, aimed to evaluate the impact of atorvastatin on major adverse cardiovascular events (MACEs) in patients with type 2 diabetes undergoing haemodialysis. The primary endpoint, which included death from cardiac causes, fatal stroke, non-fatal myocardial infarction (MI), and non-fatal stroke, did not show a significant benefit from atorvastatin.

This analysis delves deeper to examine recurrent events and the effects of previous clinical events on future outcomes. Notably, sudden cardiac death and death due to infection/sepsis were frequent in this high-risk population. The study suggests that atorvastatin may only stabilize cardiovascular risk after 1-2 years, with a possible positive effect on MI.

The findings underscore the unique risk profile of patients with type 2 diabetes on haemodialysis, with sudden cardiac death being a major concern. Previous hospitalizations were identified as a significant predictor of future events, emphasizing the need for comprehensive management beyond cardiovascular complications.

The use of statins in dialysis patients with chronic kidney disease (CKD) is a topic of ongoing debate and research. Dyslipidemia is common in CKD patients and can contribute to cardiovascular complications. However, the role of lifelong statin therapy in improving the long-term outcomes of dialysis patients is still not well-established.

In CKD patients who are not on dialysis, cholesterol-lowering treatment with statins is recommended based on studies like the Study of Heart and Renal Protection (SHARP) study and post hoc subgroup analyses of large, randomized trials. However, in dialysis patients,

the evidence is less clear. One recent post hoc analysis of the 4D study indicated that while there was no significant difference in major adverse cardiovascular events (MACE) and mortality between the statin-treated groups and the placebo group, there was a suggestion that the risk of MACE increased in the placebo group over time, while it remained stable in the atorvastatin group after about 1.5 years. However, this finding should be interpreted cautiously due to study limitations. It's important to note that the therapeutic potential of statins in CKD patients may be more related to reducing atherosclerotic cardiovascular diseases rather than non-atherosclerotic events like arrhythmias. As renal function declines, non-atherosclerotic cardiovascular events become more common. There are still many questions and uncertainties regarding statin therapy in dialysis patients, Observational data from certain regions suggest potential benefits of statins in this setting. Ultimately, while the paper by Marx et al. provides some interesting insights, guidelines for statin treatment in dialysis patients have not changed, and further research is needed to clarify the role and optimal use of statins in this patient population.

**Recurrent cardiovascular events in patients with type 2 diabetes and haemodialysis: analysis from the 4D Study.** Clinical kidney journal 2023; 16:1612-1621Marx N, Wanner C, Jankowski J *et al.* <http://www.ncbi.nlm.nih.gov/pubmed/?term=37779851>  
**Lifelong statins for long life in dialysis patients?** Clinical kidney journal 2023; 16:1541-1542Ebert T, Bárány P. <http://www.ncbi.nlm.nih.gov/pubmed/?term=37779843>

## **The LODESTAR Study – Treat to targets vs high intensity statins**

The LODESTAR trial aimed to ascertain the comparative benefits of two lipid-lowering regimens in coronary artery disease (CAD) patients, primarily focusing on those with and without diabetes mellitus (DM). Participants were assigned to either a "treat-to-target" approach where the target LDL-C level was set between 50-70 mg/dL or a fixed high-intensity statin regimen. Over three years, the primary outcomes, including all-cause death, myocardial infarction, stroke, or coronary revascularization, were assessed. The study enrolled 4,400 CAD patients, with a third having DM. Results revealed no significant difference in primary outcomes between the two treatment groups for both DM and non-DM patients.

Interestingly, there was no significant difference in the risk of new-onset DM in the treat-to-target group compared to those using high-intensity statins for non-DM patients. Statin therapy is critical to managing patients with CAD and DM due to their increased risk. While high-intensity statin therapy is recommended for most patients, concerns about side effects, including potential exacerbation or onset of DM, persist. This study suggested that the treat-to-target approach, which focused on achieving an LDL-C range, performed comparably to the high-intensity statin therapy in terms of efficacy and safety over the three years. What makes this study hard to interpret is the absence of which statins and dosages were used in both treatment arms. Noteworthy are the observations that in the patients using high-intensity statins, CK elevations (supplemental table) were observed in only one nondiabetic patient (0 in the treat-to-target group) and five diabetic patients (4 in the treat-to-target group). Reports on muscle complaints were absent. The study limitations include being open-label and potential biases therein.

Additionally, while guidelines have recently shifted to recommend even lower LDL-C targets, the study's treat-to-target range was set at 50-70 mg/dL. The conclusions drawn might also suffer from insufficient power, given that it is based on a subgroup analysis. These findings necessitate further validation in larger, perhaps blinded, studies.

**Treat-to-target versus high-intensity statin treatment in patients with or without diabetes mellitus: a pre-specified analysis from the LODESTAR trial.** EClinicalMedicine 2023; 64:102227Lee SJ, Kang WC, Lee JY *et al.* <http://www.ncbi.nlm.nih.gov/pubmed/?term=37767195>

## **Rosuvastatin associated AKI post cardiac surgery**

The The Statin Therapy In Cardiac Surgery (STICS) trial, was a randomized, double-blind, placebo-controlled study to investigate the impact of perioperative rosuvastatin on patients undergoing cardiac surgery. The primary focus was on assessing postoperative atrial

fibrillation and cardiac injury. Surprisingly, the study found that while rosuvastatin didn't significantly affect these primary outcomes, it was associated with a significantly higher incidence of acute kidney injury (AKI) compared to the placebo group. The study involved analyzing various biomarkers, including creatinine, cystatin C, and other inflammation-related markers. The results revealed that both creatinine and cystatin C-defined AKI were more common in the rosuvastatin group. Additionally, postoperative levels of kidney injury molecule-1 (KIM-1) were higher in the rosuvastatin group, suggesting potential renal proximal tubular injury. The findings from the STICS trial are crucial for clinical practice, as they indicate that perioperative rosuvastatin may increase the risk of AKI in cardiac surgery patients. This risk could have implications for the development of chronic kidney disease and future cardiovascular events. While further research is needed, it may be reasonable to consider temporarily discontinuing perioperative statin therapy in cardiac surgery patients on a case-by-case basis to mitigate this risk.

The authors concluded that the STICS trial highlights the unexpected association between rosuvastatin and increased AKI risk in cardiac surgery patients, emphasizing the importance of careful consideration when prescribing statins in this context.

**Mechanisms of rosuvastatin-related acute kidney injury following cardiac surgery: the STICS trial.** *Eur Heart J* 2023; Wijesurendra RS, Sardell R, Jayaram R *et al.* <http://www.ncbi.nlm.nih.gov/pubmed/?term=37793132>

## Rhabdomyolysis after use Rosuvastatin 40 mg in HK patients

In this short article, based on data from the Hong Kong Poison Information Centre, the authors aim to warn healthcare providers on the use of rosuvastatin 40 mg in Asian patients. Between July 2022 and April 2023, 6 cases of severe rhabdomyolysis were reported. Pharmacogenetic factors predispose Asian patients to increased plasma levels of rosuvastatin. Pharmacokinetic and pharmacogenetics studies have observed a more than doubling of rosuvastatin plasma levels in Asians compared to Caucasians. The authors reflect on recommendations from China, the UK, Australia, and Canada, restricting the use of rosuvastatin to a maximum dosage of 20 mg in Chinese/Asian patients.

**Cluster of cases of high-dose rosuvastatin-associated rhabdomyolysis and recent reduction of rosuvastatin dose for Asians in other countries.** *Hong Kong medical journal = Xianggang yi xue za zhi* 2023; Tse ML. <http://www.ncbi.nlm.nih.gov/pubmed/?term=37766464>

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3. Efficacy and Safety of Single-Pill Combination of Rosuvastatin and Ezetimibe in Chinese Patients with Primary Hypercholesterolemia Inadequately Controlled by Statin Treatment (ROZEL): A Randomized, Double-Blind, Double Dummy, Active-Controlled Phase 3 Clinical Trial. *Adv Ther* 2023; Su Q, Liu Y, Zhang G *et al.* <http://www.ncbi.nlm.nih.gov/pubmed/?term=37770770>
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