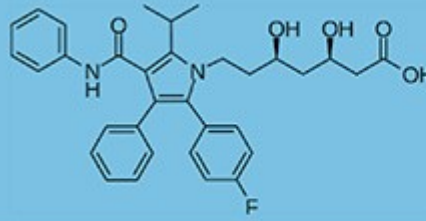


STATIN

NEWSLETTER



A CURATED WEEKLY OVERVIEW OF ALL STATIN PUBLICATIONS

Update week 03 & 04 - 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 all recent statin publications. Based on a curated approach to select relevant articles.

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Key Publications

1. **Statin use; comparing high vs middle/low income countries**
2. **Potential to prevent statin triggered NODM?**
3. **Pediatric statin use - an update**
4. **Japanese guidelines on pediatric FH**
5. **Statin intolerance in Germany.**

Disparities in statin use between high and middle/low income countries

Statin utilization has increased globally over the last five years, but there are persistent and substantial disparities in utilization between high-income and low/middle-income countries, according to a recent study published in Heart. The study examined pharmaceutical sales data to analyze statin utilization in 41 high-income countries and 50 low/middle-income countries between 2015 and 2020. It found that globally, statin utilization increased by 24.7% during this period, but significant disparities remained, with utilization in high-income countries over six times higher than in low/middle-income countries. The study also found that every \$100 increase in per capita health spending in low/middle-income countries was associated with a 17% increase in statin utilization, while every 10% increase in out-of-pocket health spending was associated with an 11% decline.

The World Health Organization's Global Non-Communicable Disease Action Plan 2013-2020 aimed to reduce premature deaths from non-communicable diseases, especially cardiovascular disease, by 25% from 2010 to 2025. The study's authors suggest that policymakers should promote increased and equitable access to statins in low/middle-income countries to achieve this goal. The study found that public investment in health has declined in low/middle-income countries during the last two decades, and out-of-pocket

spending as a share of total health spending has remained high in these countries, with only high-income and upper middle-income countries seeing moderate increases in government health spending. The authors conclude that policymakers need to address the disparities in statin utilization to reduce the global burden of cardiovascular disease. Guadamuz JS, Shoostari A, Qato DM. Global, regional and national trends in statin utilisation in high-income and low/middle-income countries, 2015-2020. *BMJ Open* 2022; 12:e061350. <http://www.ncbi.nlm.nih.gov/pubmed/?term=36691204>

Can GLP1 RA prevent NODM in statin users?

Statins are a class of drugs that are commonly used in the treatment of hyperlipidemia, or high cholesterol. They are known to have beneficial effects, such as reducing inflammation, but a growing body of evidence suggests they may also have diabetogenic properties, damaging pancreatic beta cells. A new in vitro study explored the impact of atorvastatin, a type of statin, on pancreatic islet beta cells, evaluating its influence on cell viability, insulin expression, low-density lipoprotein (LDL) receptor, and proprotein convertase subtilisin/kexin type 9 (PCSK9) expression. The experiments showed that atorvastatin significantly reduced mRNA for proinsulin and insulin expression but caused a rise in LDL receptor protein in cells exposed to the drug. Exenatide, a glucagon-like peptide 1 (GLP-1) analog used in the treatment of diabetes and known for its weight-reducing properties, was shown to alleviate the observed alterations. The study also explored the effects of atorvastatin on LDL receptor and PCSK9 expression, both of which are associated with lipid metabolism, and showed that atorvastatin increased the expression of LDL receptors in pancreatic beta cells, which might lead to increased cholesterol uptake and potential lipotoxicity. The study also demonstrated that exenatide could prevent the rise in LDL receptor in culture conditions. The authors concluded that statins may have diabetogenic properties, with reductions in insulin expression being one possible mechanism, and that the concomitant use of GLP-1 receptor agonists seems to successfully revert insulin expression.

Buldak L, Machnik G, Skudrzyk E *et al.* Exenatide prevents statin-related LDL receptor increase and improves insulin secretion in pancreatic beta cells (1.1E7) in a protein kinase A-dependent manner. *J Appl Biomed* 2022; 20:130-140. <http://www.ncbi.nlm.nih.gov/pubmed/?term=36708718>

Update on pediatric use of statins

The article provides an overview of the use of statins in children and adolescents with dyslipidemia to reduce their cardiovascular risk, delay the development of fatty streaks, slow the progression of atherosclerosis and reverse atherosclerotic plaques. Statins are the most common lipid-lowering drugs and inhibit the endogenous cholesterol synthesis in the liver. They increase the catabolism of LDL-C, reduce VLDL-C, IDL-C, and TG, and modestly increase HDL-C. Additionally, statins have pleiotropic effects, and they are generally well-tolerated in both adults and children with uncommon adverse events. However, before initiating statin treatment, several factors should be considered, such as secondary causes, familial history, and additional risk factors. It is also imperative to consult patients and families and monitor patients taking statins.

Studies have shown that statin therapy is efficient at lowering lipid levels and reducing CIMT progression and cumulative estimated atherosclerotic burden in children, similar to adults. However, many children with lipid disorders are not on statin therapy and are not receiving the full potential benefit of adequate lipid-lowering therapies. It is, therefore, important for clinicians to become familiar with statins, especially primary care providers who often diagnose childhood dyslipidemia. Statin contraindications include children with hypersensitivity to any of its components and patients with active liver disease. They should be prescribed with caution in patients with concurrent administration of interfering drugs, predisposing factors for myopathy, and chronic kidney disease. While statins are considered the first-line pharmacologic therapy and the cornerstone of FH treatment during childhood, more studies are needed to evaluate statin use in children with other risk conditions, such as obesity and diabetes, which currently comprise the most frequent phenotype of lipid abnormalities.

Fiorentino R, Chiarelli F. Statins in Children, an Update. *Int J Mol Sci* 2023; 24.

The Japanese guidelines for pediatric FH

The "Guidelines for the Diagnosis and Treatment of Pediatric Familial Hypercholesterolemia 2022" emphasizes the importance of early diagnosis and treatment of familial hypercholesterolemia (FH) in children, as atherosclerosis can begin in childhood. The diagnosis of pediatric FH is based on hyper-low-density lipoprotein (LDL) cholesterolemia and a family history of FH. However, to reduce overlooked cases, "probable FH" has been established. Once diagnosed, lifestyle guidance, including diet, should be provided, and an intrafamilial survey should be conducted to identify other family members with the same condition. If the LDL-C level remains above 180 mg/dL, drug therapy should be considered at the age of 10, with statins being the first-line drug. Non-invasive techniques, such as ultrasound, should be used for evaluating atherosclerosis, and the management target level is an LDL-C level of less than 140 mg/dL. In case of suspected homozygous FH, a specialist should be consulted, and if the response to pharmacotherapy is inadequate, lipoprotein apheresis should be initiated as soon as possible.

The guidelines were established due to the lack of consensus in Japan on the screening of FH in childhood, the type and starting age of treatment, the assessment of atherosclerosis, and the goals of treatment. The previous guidance was reviewed and revised after five years, with clinical questions and evidence evaluation used to develop the new guideline for medical practice. The aim of this update is to prevent possible future atherosclerosis by diagnosing the disease at an early stage and applying therapeutic intervention.

Harada-Shiba M, Ohtake A, Sugiyama D *et al.* **Guidelines for the Diagnosis and Treatment of Pediatric Familial Hypercholesterolemia 2022.** *J Atheroscler Thromb* 2023.

<http://www.ncbi.nlm.nih.gov/pubmed/?term=36682777>

German perspective on prevalence of statin intolerance

Statin intolerance (SI) is a common problem, with non-adherence and discontinuation of treatment posing a challenge to optimal lipid management. However, there is no widely accepted definition of SI, and patient profiles and characteristics remain poorly understood. A new study used machine learning (ML) techniques to estimate SI and understand patient characteristics in Germany using real-world data. The study included 292,603 patients with a high cardiovascular risk, atherosclerotic cardiovascular disease, or hypercholesterolemia, and those on lipid-lowering therapies between 2017 and 2020. Patients were categorized as having "absolute" or "partial" SI, and ML techniques were applied to calibrate prevalence estimates derived from different rules and levels of confidence (high and low). The results indicated that approximately 6.4% and 2.8% of patients had high-confidence absolute and partial SI, respectively. After deploying ML, SI prevalence increased approximately by 27% and 57% ($p < 0.00001$) in absolute and partial SI, respectively, eliciting a maximum estimate of 12.5% SI with high confidence. The study's results may inform the identification, optimal treatment, and pragmatic, patient-centered management of SI in Germany. The study also revealed that intolerance was observed more often among women and the elderly, and obesity, hypothyroidism, vitamin D deficiency, and chronic kidney disease were the more prevalent risk factors for the manifestation of SI. The results highlighted the need for a patient-centric approach to the optimal CV risk reduction, continued therapy or alternative drugs, and management strategies.

Parhofer KG, Anastassopoulou A, Calver H *et al.* **Estimating Prevalence and Characteristics of Statin Intolerance among High and Very High Cardiovascular Risk Patients in Germany (2017 to 2020).** *Journal of clinical medicine* 2023; 12. <http://www.ncbi.nlm.nih.gov/pubmed/?term=36675634>

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