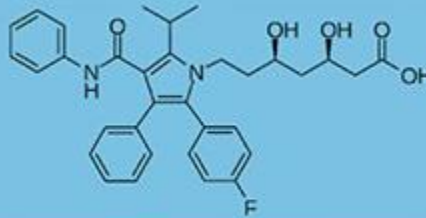


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**IAS STATIN**  
NEWSLETTER



A CURATED WEEKLY UPDATE OF ALL STATIN PUBLICATIONS

Update - Week 39 & 40, 2021



Curated by Peter Lansberg,  
a Dutch lipidologist and educator, and  
reviewed by prof. Philip Barter, Past President of the  
International Atherosclerosis Society.

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The IAS statin literature update will keep you up-to-date with all recent statin publications, using a curated approach to select relevant articles.

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## Key publications

### Statin use during pregnancy; is it safe?

The use of statins during pregnancy is contraindicated; however, women taking statins can be unaware that they have become pregnant. This meta-analysis explored pregnancy outcomes in women that used statins during their pregnancy. Data collected in 7 cohort studies, 2 clinical trials, 6 case series, and 3 case reports were used for this meta-analysis. The outcomes included stillbirth, fetal abortion, and preterm delivery. For stillbirth no associations could be determined, OR=1.30 (0.56-3.02; p=0.54; I2 = 0%). There was however a significant association with increased abortions OR=1.36 (1.10–1.68; p=0.004, I2 = 0%). Statistically non-significant associations were noted for induced abortions, OR=2.08 (0.81-5.36, p=0.129, I2 = 17.33%) and elective abortions, (OR (95% CI) = 1.37 (0.68, 2.76), p=0.378, I2 = 62.46%). Statin use did result in a non-significant reduction of preterm deliveries, OR=0.47 (0.06-3.70; p=0.47, I2 = 76.35%). This could potentially reflect protective effects of statins against preterm. The authors concluded that no serious pregnancy-related outcomes were observed in women that used statins, except for a small increase in spontaneous

abortions. The causality of this observation can only be determined in a properly designed prospective follow-up study.

Vahedian-Azimi A, Bianconi V, Makvandi S *et al.* A systematic review and meta-analysis on the effects of statins on pregnancy outcomes. *Atherosclerosis* 2021; 336:1-11.

<http://www.ncbi.nlm.nih.gov/pubmed/?term=34601188>

## High rate of recurrences in Korean secondary prevention patients

The risk of recurrences in very high-risk secondary prevention patients is evaluated in this single-center Korean study. Between 2000 and 2016, EHR data was collected of patients with established ASCVD at the Asan Medical Center Heart Registry. A total of 15 820 patients were followed for up to 3-years. The primary endpoint was a composite of MI, stroke, hospitalization for unstable angina, coronary revascularization, and all-cause mortality. The 3-year cumulative incidence of the composite endpoints was 15.3%, an incidence of 5.7% (95.5-5.9)/100 person-years. The individual endpoints were the rates of deaths 0.4 (0.3–0.4), MI 0.9 (0.8–0.9), and IS 0.8 (0.7–0.9). No association between the endpoints and different statin intensities was observed. However, only 24.4% of the participants achieved guideline-recommended LDL-c targets during the first year of follow-up. This real-world study of routine practice in Korea showed that very high-risk secondary prevention patients are prone to develop subsequent events within 3 years after their 1st ASCVD event. Sub-optimal LDL-c control could be an essential contributor to this observed high rate of recurrences. Stringent LDL-c control with high-dose high-intensity statins combined with additional non-statin LDL-c lowering therapies could reduce the risk for recurrences in Korean secondary prevention patients.

Kwon O, Na W, Hur J *et al.* Cardiovascular Event Rates in Statin-Treated Korean Patients with Cardiovascular Disease: Estimates from a Real-World Population Using Electronic Medical Record Data. *Cardiovasc Drugs Ther* 2021.

<http://www.ncbi.nlm.nih.gov/pubmed/?term=34622354>

## Measuring adherence, using plasma or questionnaires?

Adherence to statin medication remains a critical hurdle to protect patients from ASCVD complications. This study directly measured atorvastatin in spot blood plasma was compared to reported adherence, the 8-item Morisky medication adherence scale (MMAS-8), and the Gehi *et al.* adherence questions. Of the 363 Norwegian participants, 8% were non-adherent ( $\geq 2$  doses omitted) based on the blood sample measurements. In patients recognized as non-adherent, 40% reported reduced statin adherence, 32% reported reduced adherence with the MMAS-8, and 22% with the Gehi questions. In those reported adherent based on the direct measurement, 96% reported high statin adherence, 95% reported high adherence to the MMAS-8, whereas 94% reported high adherence to the Gehi questions.

Cohen's kappa agreement score with the direct method was 0.4 for self-reported statin adherence, 0.3 for the Gehi question, and 0.2 for the MMAS-8. Measurement of statin adherence by determining atorvastatin concentration in the plasma sample was far more reliable than reported adherence, MMAS-8, and the Gehi questions. To improve lipid control by reducing non-adherence, direct measurement of atorvastatin in plasma could provide more reliable information on patient adherence.

Kristiansen O, Sverre E, Peersen K *et al.* The relationship between directly measured statin adherence, self-reported adherence measures and cholesterol levels in patients with coronary heart disease. *Atherosclerosis* 2021; 336:23-29.

<http://www.ncbi.nlm.nih.gov/pubmed/?term=34610521>

## Comparing combination therapy with ezetimibe with statin monotherapy

Data collected in the Korean National Health Insurance service's database was queried to compare high-intensity, high-dose statins to moderate intensity statins plus ezetimibe. Of the 82 941 AMI patients that had a PCI (2013 -2016), atorvastatin 40 mg was used by 9 908 patients; 233 used atorvastatin 20 mg + ezetimibe 10 mg; 5 251 used Rosuvastatin 20 mg and 383 used rosuvastatin 10 mg plus ezetimibe 10 mg. The primary outcome of this observational retrospective analysis was MACE (all-cause death, non-fatal myocardial infarction undergoing PCI, repeat revascularization, and ischemic stroke). The incidence of MACE in this cohort was 42.97 cases/1000 person-years. Overall, no statistically significant differences were observed between the four groups, except for the rosuvastatin 10 mg + ezetimibe 10 mg group. Patients allocated to this combination of lipid-lowering drugs had a higher mortality risk compared to the atorvastatin 40 mg cohort; HR:2.07 (1.08–3.94). The authors concluded that no statistically significant difference in MACE was noted when high CVD risk patients using statin monotherapy were compared to patients that used a combination of moderate-intensity statin plus ezetimibe. Patient groups were relatively small in those allocated combination therapy, and no data on achieved LDL-c levels were available.

Kim K, Bang WD, Han K *et al.* Comparison of the Effects of High-intensity Statin Therapy with Moderate-Intensity Statin and Ezetimibe Combination Therapy on Major Adverse Cardiovascular Events in Patients with Acute Myocardial Infarction: a Nationwide Cohort Study. *J Lipid Atheroscler* 2021; 10:291-302.

<http://www.ncbi.nlm.nih.gov/pubmed/?term=34621700>

## Statins for the treatment and prevention of NAFLD

Our understanding of how statin therapy can influence hepatic function has shifted 180 degrees; from harms to benefits. In patients with NAFLD , ASCVD risk prompts to use

statins, to reduce risk for major cardiovascular events, but improved hepatic function could also be an unexpected added benefit of statins. This meta-analysis combined data from 14 published studies (N=1 247 503) that explored the harms and benefits of statins in NAFLD patients. The primary outcomes of the meta-analysis were the effect of statins on liver histology (steatosis, fibrosis and necroinflammation, NAFLD activity score (NAS)) and liver enzymes (Alanine transaminase (ALT), Aspartate transaminase (AST), and Gamma-glutamyl transferase (GGT) levels). Statin use was associated with a significant reduced risk of developing NAFLD, OR:0.69 (0.57-0.84; p = 0.0002; I2 =36%). Transaminases showed a similar favourable response in NAFLD patients as well, ALT: -27.28 (-43.06 to -11.51; p = 0.0007; I2 =90%), AST: -10.99, (-18.17 to -3.81; p = 0.003; I2=79%) and GGT:-23.40 (-31.82 to -14.98); p < 0.00001; I2 = 21%). For liver histology outcomes, significant improvements were observed as well; steatosis grade: -2.59 (-4.61to -0.56); p = 0.01; I2 = 95%); NAS: -1.03 (-1.33 to -0.74; p < 0.00001; I2 = 33%); necro-inflammatory stage: -0.19 (-0.26 to -0.13; p < 0.00001; I2 = 0%) and significant fibrosis, OR:0.20 (0.04 to 0.95; p = 0.04; I2 = 97%). Only fibrosis stage outcome: 0.07 (-0.05, 0.20); p = 0.27; I2 = 0%) was non-significant. The promising results of this meta-analysis warrants large scale trials to study the effects of statins for the treatment and potentially for the prevention of NAFLD.

Fatima K, Moeed A, Waqar E *et al.* Efficacy of statins in treatment and development of non-alcoholic fatty liver disease and steatohepatitis: a systematic review and meta-analysis. Clin Res Hepatol Gastroenterol 2021:101816. <http://www.ncbi.nlm.nih.gov/pubmed/?term=34607067>

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RECOMMENDATIONS. Acta clinica Croatica 2021; 60:63-67.

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