

# Million Hearts®: Common Patient Questions About Statins

## **Q** How do doctors decide who is prescribed a statin?

**A** Physicians determine which patients have the greatest need and who would benefit most from taking statins by considering patients on an individual basis. Generally speaking, as a person's ASCVD risk increases, the potential net benefit from a statin also increases.

Like all medications with risks and benefits, there are specific guidelines doctors follow to ensure that we prescribe statins only to people who really need them. The American College of Cardiology and American Heart Association updated their [cholesterol management guidelines](#) in 2018 after carefully reviewing the decades of published studies about statins.<sup>1</sup>

- First, physician determines whether a patient falls into one of four possible statin treatment groups.
- These groups are determined by the patient's overall risk of cardiovascular disease, taking into account their cholesterol levels as well as other risk factors such as blood pressure, smoking history, diabetes, age, and sex.
- Some patients who do not fall into these four statin treatment groups may also benefit from statin treatment if they have additional risk enhancing factors. Sometimes a coronary artery calcium score is used to clarify a patient's risk for cardiovascular disease when their risk is uncertain.

- After discussing potential benefits and risks with the patient, the physician will typically recommend statin treatment for people that fall into one of the statin treatment groups.

## **Q** How are doctors sure that statins really are safe and beneficial?

**A** Statins have been studied more than just about any class of medication on the market. The Cholesterol Treatment Trialists Collaboration conducts periodic meta-analyses on statin effectiveness and adverse events. They cite evidence from about **30 major statin trials encompassing approximately 175,000 participants spanning over 20 years.**<sup>2</sup>

For high risk patients (e.g., those with clinical ASCVD, type 2 diabetes, and LDL-C  $\geq 190$  mg/dL), the potential benefits of statins far outweigh the risk of side effects. The risk of serious statin-associated side effects is extremely low. For example, the risk of statin-induced serious muscle injury (including rhabdomyolysis) is  $<0.1\%$ , and the risk of serious hepatotoxicity is approximately  $0.001\%$ .<sup>3</sup>

Meanwhile, the potential benefits are clear. A meta-analysis of 27 randomized trials demonstrated that for every  $\sim 40$  mg/dL LDL-C reduction with statin therapy, the relative risk of major adverse cardiovascular events is reduced by 20-25%, and all-cause mortality is reduced by 10%.<sup>4</sup>

For patients who want to learn more, this article entitled [10 Truths About Statins and High Cholesterol](#) by physicians at UT Southwestern Medical Center is a straightforward resource.

**ACKNOWLEDGEMENT:** With thanks to the American Medical Association for their clinical expertise in developing the content for this educational resource.

<sup>1</sup> Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2019;139:e1082-e1143. 1

<sup>2</sup> Cholesterol Treatment Trialists Collaboration. <https://www.cttcollaboration.org/> Accessed December 8, 2019.

<sup>3</sup> Newman CB, Preiss D, Tobert JA. Statin Safety and Associated Adverse Events: A Scientific Statement from the American Heart Association. *Arterioscl Thromb Vas*. 2019;39:e38-e81.

<sup>4</sup> Aronis KN, Blumenthal RS, Shay Martin S. Summarizing the Current State and Evidence on Efficacy and Safety of Statin Therapy. Expert Analysis: Summarizing the Current State and Evidence on Efficacy and Safety of Statin Therapy. *American College of Cardiology*. November 17, 2016. <https://www.acc.org/latest-in-cardiology/articles/2016/11/17/09/03/summarizing-the-current-state-and-evidence-on-efficacy-and-safety-of-statin-therapy>. Accessed December 8, 2019.

## Q Aren't I too young to take a statin?

**A** For individuals in their 20's and 30's at elevated lifetime risk, recommendations focus on achieving and maintaining healthy lifestyle behaviors with statin use largely limited to those with very elevated LDL-C  $\geq 190$  mg/dL or a longstanding history of diabetes.

Most people with LDL-C  $\geq 190$  mg/dL have Familial Hypercholesterolemia (also called Pure Hypercholesterolemia).<sup>5</sup> People with this condition have an accelerated risk of developing coronary heart disease: about 10-20 years for men and 20-30 years for women.<sup>6</sup>

Additionally, the studies of statin treatment for people with LDL-C  $\geq 190$  mg/dL include young adults.<sup>7</sup> So, there is clear evidence about the risk of ASCVD in young adults with this condition, as well as the benefits of statin treatment.

## Q Do I have to take statins forever?

**A** Statins are generally prescribed for life— For most people, a “silver bullet” to decrease their cholesterol levels and ASCVD risk isn't available. For some people, it may be appropriate to discontinue statins very late in life or if they have other conditions that limit the benefit of using a statin.<sup>4</sup>

A person's cholesterol profile is significantly influenced by their genes. A simple way to discuss this is the idea that we can't pick who our parents are, so we can't really influence our genetic risk. Patients also frequently ask if they can focus on improving their lifestyle as a means to eventually stop their statin. While lifestyle therapy is always an important

component of ASCVD risk reduction, lifestyle therapy alone will not reduce risk adequately in patients who fall into one of the high-risk treatment groups.<sup>4</sup> More information about lifestyle therapy is included in a subsequent question below.

## Q Do statins cause muscle pain and weakness?

**A** Muscle aches, or statin-associated muscle symptoms (SAMS), occur in about 10% of patients. This means nine out of 10 patients don't experience SAMS at all.<sup>4</sup>

### When patients do have muscle pain:

- The symptom is often resolved by adjusting the medication dosage or switching to a different statin;
- Only rarely do statins have to be stopped altogether; and
- When the medication is switched or stopped, the symptoms frequently go away and there is no damage to the muscle.

Actual muscle damage occurs in only one in 10,000 patients. In the rare event that muscle damage occurs, it is almost always reversible.<sup>2</sup>

It's important to let patients know that if they do experience muscle pain that they believe is due to their statin, don't stop taking it without first talking with their doctor. For almost all patients, we're able to find an effective medication that they can tolerate well. In the unusual event that a person simply can't tolerate statins, there are other cholesterol medications we can prescribe.<sup>9</sup>

<sup>2</sup> Cholesterol Treatment Trialists Collaboration. <https://www.cttcollaboration.org/> Accessed December 8, 2019.

<sup>4</sup> Aronis KN, Blumenthal RS, Shay Martin S. Summarizing the Current State and Evidence on Efficacy and Safety of Statin Therapy. Expert Analysis: Summarizing the Current State and Evidence on Efficacy and Safety of Statin Therapy. *American College of Cardiology*. November 17, 2016. <https://www.acc.org/latest-in-cardiology/articles/2016/11/17/09/03/summarizing-the-current-state-and-evidence-on-efficacy-and-safety-of-statin-therapy>. Accessed December 8, 2019.

<sup>5</sup> Bouhairie VE, Goldberg AC. Familial hypercholesterolemia. *Cardiol Clin*. 2015;33(2):169–179.

<sup>6</sup> Perak AM, Ning H, de Ferranti SD, Gooding HC, Wilkins JT, Lloyd-Jones DM. Long-Term Risk of Atherosclerotic Cardiovascular Disease in US Adults With the Familial Hypercholesterolemia Phenotype. *Circulation*. 2016;134(1):9-19.

<sup>7</sup> Besseling J, Hovingh GK, Huijgen R, et al. Statins in Familial Hypercholesterolemia: Consequences for Coronary Artery Disease and All-Cause Mortality. *J Am Coll Cardiol*. 2016;68:252-60.

<sup>9</sup> Reimold S, Khera A, Hill JA. 10 Truths About Statins and High Cholesterol. UT Southwestern Medical Center. Published February 2, 2016. <https://utswmed.org/medblog/statins-answers/>. Accessed December 8, 2019.

## **Q** Why can't I work on changing my lifestyle instead of taking a statin?

**A** **The beneficial effects of statin drugs** extend beyond the measured level of total cholesterol and other lipids such as triglycerides.<sup>4</sup> Statin drugs markedly reduce LDL and triglycerides, while increasing levels of HDL or 'good' cholesterol.<sup>8</sup>

Lifestyle therapy produces meaningful reductions in ASCVD risk and is a cornerstone of treatment for all patients with elevated risk. However, lifestyle therapy alone does not produce the desired 30-50+% reduction in LDL-C, and associated reduction in ASCVD risk. Therefore, lifestyle therapy alone is not appropriate for patients in the four statin treatment groups, particularly those in the highest risk groups. Lifestyle therapy should always be combined with statin therapy in patients with high risk for ASCVD.

## **Q** Does taking a statin cause diabetes?

**A** **There is evidence of a modest increase** in the risk of new-onset diabetes mellitus associated with statin use in individuals who have predisposing risk factors for diabetes mellitus, components of metabolic syndrome, and higher-intensity statin use. Patients should be informed of the risk before initiating statin therapy.

The benefits of statin therapy outweigh the risks for new-onset diabetes mellitus and this risk should not be considered a contraindication for initiating therapy or a reason to discontinue the statin. For those with an increased risk for both ASCVD and diabetes mellitus, education based on the American Diabetes Association's approach to prevention should be provided.<sup>4</sup>

## **Q** Is there any benefit to taking coenzyme Q10 (CoQ10) or red yeast rice to help with side effects of statins or to replace statins?

**A** **Depletion of ubiquinone or coenzyme** Q10 has been suggested to contribute to statin-associated muscle symptoms (SAMS). However, current evidence does not support the use of Coenzyme Q10 supplementation for routine use in patients treated with statins or for the treatment of SAMS.<sup>4</sup>

Red yeast rice products may contain monacolin K, which is chemically identical to the cholesterol-lowering agent lovastatin. Some red yeast rice products were found to contain little or no monacolin K and it is not known if there is any effect on blood cholesterol levels. The U.S. Food and Drug Administration (FDA) has determined that red yeast rice products that contain more than trace amounts of monacolin K are unapproved new drugs and cannot be sold legally as dietary supplements. Do not use red yeast rice to replace statin treatment.<sup>10</sup>

## **Q** What is the effect of statins on cognition/memory, especially in the elderly?

**A** **Overall, the data regarding the effect** of statins on cognitive function are favorable. Small studies have not shown an impact on short-term cognitive outcomes. A meta-analysis of longer-term outcomes showed that if statins are taken for more than one year, they appear to reduce the risk of dementia by 29%.<sup>11</sup>

This publication was supported by the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award totaling \$2,090,080 with 100 percent funded by CDC/HHS. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement, by CDC/HHS, or the U.S. Government.

<sup>4</sup> Aronis KN, Blumenthal RS, Shay Martin S. Summarizing the Current State and Evidence on Efficacy and Safety of Statin Therapy. Expert Analysis: Summarizing the Current State and Evidence on Efficacy and Safety of Statin Therapy. *American College of Cardiology*. November 17, 2016. <https://www.acc.org/latest-in-cardiology/articles/2016/11/17/09/03/summarizing-the-current-state-and-evidence-on-efficacy-and-safety-of-statin-therapy>. Accessed December 8, 2019.

<sup>8</sup> Meor Anuar Shuhaili MFR, Samsudin IN, Stanslas J, Hasan S, Thambiah SC. Effects of Different Types of Statins on Lipid Profile: A Perspective on Asians. *Int J Endocrinol Metab*. 2017;15(2):e43319.

<sup>10</sup> Red Yest Rice. NIH: National Center for Complementary and Integrative Health. Last updated July 2013. <https://nccih.nih.gov/health/redyeastrice>. Accessed December 8, 2019.

<sup>11</sup> Swiger KJ, Manalac RJ, Blumenthal RS, Blaha MJ, Martin SS. Statins and cognition: a systematic review and meta-analysis of short- and long-term cognitive effects. *Mayo Clin Proc*. 2013;88(11):1213-21.