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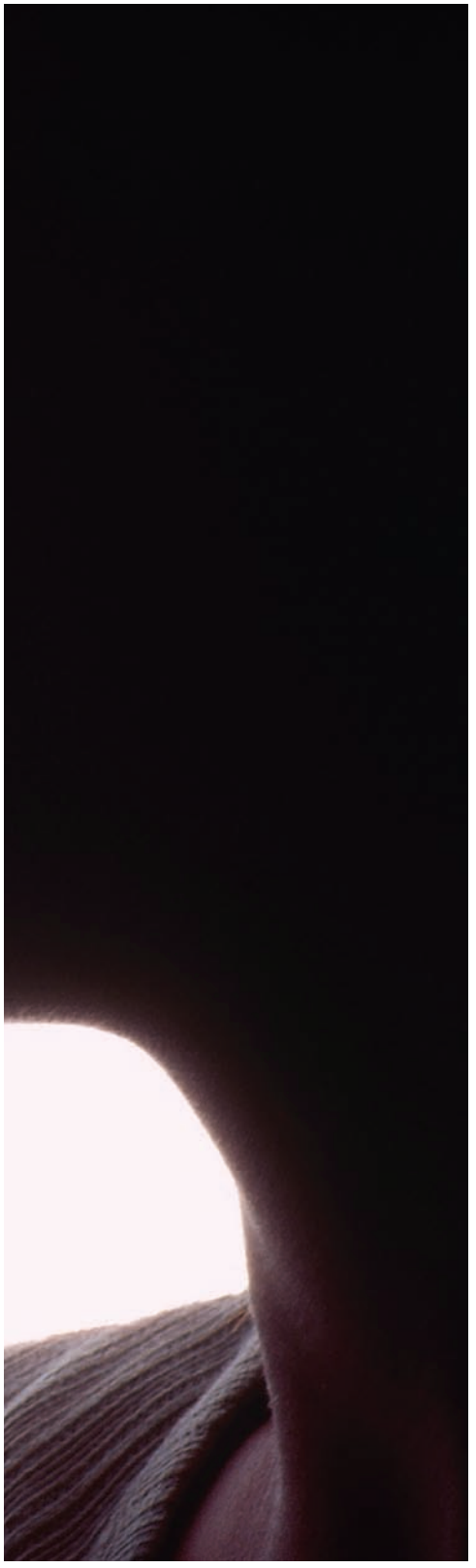

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Follow the guideline for reducing cardiovascular risk with statins

By Melissa M. Sherrod, PhD, RN, NE-BC, Nicholas McIntire Sherrod, MSN, RN, and Dennis J. Cheek, PhD, RN, FAHA

IN LATE 2013, The American College of Cardiology and The American Heart Association released new guidelines to reduce the risk of atherosclerotic cardiovascular disease (ASCVD). A significant change in scope from the previous version produced in 2004, this new initiative focuses on developing more trustworthy clinical guidelines through collaborative relationships with the National Heart, Lung and Blood Institute as well as stakeholder and professional organizations. The results of this collaborative effort were released to practitioners in the form of four clinical practice guidelines. This article describes one of these guidelines, the *2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults,* with a focus on aspects of the new guideline that cover diagnosis and management of hyperlipidemia, including going beyond a fasting lipid profile to determine estimated calculated ASCVD risk.

Focus on cholesterol management

The first of the four new clinical practice guidelines focuses on clinical assessment of cardiovascular risk, the second focuses on the management of overweight and obesity in adults, and the third relates to lifestyle management to reduce cardiovascular risk. The fourth and most controversial guideline focuses on blood cholesterol management to reduce ASCVD risk in adults.[1] ASCVD is defined in this guideline as coronary heart disease

(CHD), stroke, and peripheral arterial disease presumed to be of atherosclerotic origin. Unlike previous ACC/AHA guidelines, the 2013 guidelines aren't based on an exhaustive compilation of clinical information, but rather are limited in scope and focus on selected critical questions (CQs) on each topic.

The cholesterol guideline resulted from an emerging realization among researchers and clinicians that in order to further reduce ASCVD risk, changes in practice must be made with respect to cholesterol management. These recommendations are intended to provide a strong evidence-based foundation for the treatment of blood cholesterol for the primary and secondary prevention of ASCVD in women and men.[1]

Like previous guidelines, the revised cholesterol guideline identifies lifestyle modification as the foundation for reducing ASCVD risk. This includes eating a heart-healthy diet, avoiding tobacco products, exercising regularly, and maintaining a healthy weight. Lifestyle modification is critical to health promotion and optimum patient outcomes, both before and in concert with cholesterol-lowering drug therapy. (See *Lifestyle modification recommendations*.)

What's new?

The panel of experts responsible for the new cholesterol guideline based their recommendations on three CQs considered to be the most important for identifying which patients to treat, what treatments to offer them, and how intensively to treat them. The first and second questions evaluated the evidence for low-density lipoprotein cholesterol (LDL-C) and non-LDL-C goals for primary and secondary prevention of ASCVD with cholesterol-lowering drug therapy. A comprehensive systematic review of the evidence supports this concept.

The third question had several objectives:

- to identify groups of patients who would benefit from the addition of medication
- to define the drug treatment with the best evidence of net benefit
- to provide guidance on the intensity of pharmacologic treatment to lower LDL-C.[1]

The recommendations synthesize the evidence from the clinical trials for answering CQs 1 and 2, along with the evidence retrieved for answering CQ 3, to guide the use of cholesterol-lowering drugs for secondary or primary prevention of ASCVD.[1]

The new guideline was written to be easily used in the clinical setting in order to help clinicians implement a risk assessment strategy and treatment plan focused on specific outcomes for preventing ASCVD. It addresses goals of treatment, "target" risk factors, ASCVD risk reduction, ASCVD risk calculation, global risk assessment for primary prevention, and safety recommendations.[1]

New thinking about cholesterol control

A review of current thought regarding cholesterol management provides insights into how the new guideline changes clinical practice. Americans have long been urged to focus on their cholesterol lab results. Many people obsess about checking their cholesterol levels and challenge themselves to achieve even better numbers. In the past, healthcare providers have been told to focus on these numbers. In some cases, health insurance companies evaluate the quality of their care based on the percentage of their patients who achieve low cholesterol scores. In addition, researchers have focused attention on foods with cholesterol-lowering

Lifestyle modification recommendations[9]

LDL–C reduction

Advise adults who'd benefit from lower LDL–C levels to:

- eat a diet that emphasizes vegetables, fruits, and whole grains. Include low-fat dairy products, poultry, fish, legumes, nontropical vegetable oils and nuts and limit intake of sweets, sugar-sweetened beverages, and red meats.
- aim for a dietary pattern that achieves 5% to 6% of calories from saturated fat.
- reduce the percentage of calories from saturated and trans fats.

BP reduction

Advise adults who'd benefit from reduced BP to:

- eat a diet as described above.
- lower sodium intake; consume no more than 2,400 mg of sodium daily. A further reduction to 1,500 mg daily is associated with even greater reduction in BP. Tell patients that reducing sodium intake by at least 1,000 mg/day will lower BP, even if they haven't achieved their desired sodium intake goal.
- combine the DASH (dietary approaches to stop hypertension) diet with lower sodium intake. For details about the DASH diet, visit http://www.nhlbi.nih.gov/files/docs/public/heart/dash_brief.pdf.

Physical activity

Advise adults who'd benefit from reduced LDL–C and reduced BP to:

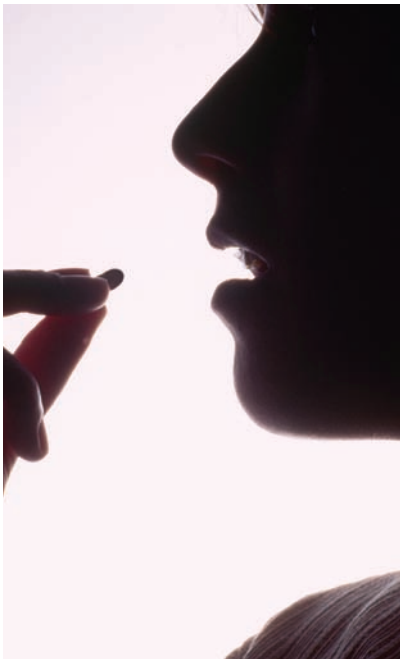
- engage in moderate-to-vigorous aerobic physical activity (unless contraindicated) three to four sessions a week, lasting on average 40 minutes per session.

properties.[2] Food and drug companies continue to advertise medications to the public that promote how well they help lower cholesterol levels, further driving home the point that we should focus on numbers to determine cardiovascular risk. But this is problematic because recent studies have demonstrated that improving lab scores and bringing them to target isn't equivalent to lowering the risk of heart disease and stroke.[1]

In order to improve patient outcomes, the 2013 guideline shifts attention from lab data on cholesterol levels to reducing risk. It's important to note, however, that monitoring cholesterol levels remains important. Some people with very high levels of LDL-C still need to worry about targets. But the new guideline's message related to target levels is that we shouldn't focus on cholesterol levels alone.

The media campaign urging the public to know their cholesterol levels or targets isn't sufficient to reduce risk, and the push for healthcare providers to add medications to reduce cholesterol levels isn't consistent with current evidence. Patients who've been engaged in health-promoting activities or made lifestyle changes and are considering adding drug therapy shouldn't ask whether adding a drug will lower cholesterol levels. Rather, they should ask whether it will lower their risk of cardiovascular disease or stroke.[1]

Importantly, the guideline isn't intended to replace clinical judgment. The expert panel emphasizes that the guideline is meant to be "patient centered," not a "one treatment fits all" approach. Final decisions regarding the treatment plan rest with the healthcare provider and the patient, taking into account the patient's lifestyle and the patient's ability to participate in lifestyle



Each 39 mg/dL reduction in LDL–C by statin therapy reduces ASCVD risk by about 20%.

modification and follow the medication regimen. Individual considerations notwithstanding, however, clinicians can apply the recommendations to most patients with confidence when the goal is to decrease risk of ASCVD.[1]

Assessing ASCVD risk

If improvement in patient outcomes is the goal and reducing cholesterol levels isn't always clinically relevant, determining an individual's risk of developing ASCVD is imperative. To address this need, the authors of the new guideline provide an online cardiovascular risk calculator that lets patients and healthcare providers estimate 10-year and lifetime risks for ASCVD.[3] The calculator defines ASCVD as nonfatal myocardial infarction, fatal or nonfatal stroke, and coronary death. The data used in the generation of estimated ASCVD risk include gender, race, age, systolic BP, total cholesterol, high-density lipoprotein cholesterol, use of antihypertension medications, smoking status, and diabetes status.

The introduction to the calculator points out that the 10-year estimates for ASCVD are applicable for Black and non-Hispanic White men and women ages 40 through 79. It also notes that while other racial/ethnic communities should use the non-Hispanic White equations, the risk could be either underestimated (in American Indians or Asian Americans with south Asian ancestry, for example), or overestimated (in Asian Americans of east Asian ancestry and some Hispanics such as Mexican Americans, for example).[3]

Using the online calculator to estimate stroke risk is especially important for women, who are generally at higher risk for stroke than men.[4]

Primary prevention

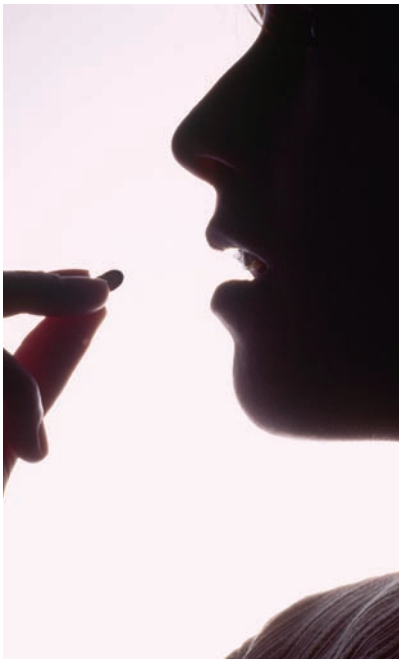
The guideline recognizes that adults age 21 or older with primary, severe elevations of LDL–C (greater than or equal to 190 mg/dL) have a high lifetime risk for ASCVD events. This is due to their lifetime exposure to markedly elevated LDL–C levels arising from genetic causes. At age 21, these patients should receive statin therapy if they haven't been diagnosed and treated before this age. Although individuals with LDL–C greater than or equal to 190 mg/dL weren't included in most clinical trials due to their need for treatment, extensive evidence shows that each 39 mg/dL reduction in LDL–C by statin therapy reduces ASCVD risk by about 20%. Patients with primary elevations of LDL–C greater than or equal to 190 mg/dL require even more substantial reductions in their LDL–C levels and intensive management of other risk

factors to reduce their ASCVD risk. Therefore, using high-intensity statin therapy to achieve at least a 50% reduction is reasonable. (See *Statin therapies: How intense?*)

The guideline recognizes that maximal statin therapy might not be adequate to lower LDL–C enough to reduce ASCVD risk in patients with primary severe elevations of LDL–C. In addition to a maximally tolerated dose of statin, these patients may need nonstatin cholesterol-lowering medications, such as fibrates, bile acid sequestrants, nicotinic acid, and Omega-3 fatty acids to lower LDL–C to acceptable levels.[1]

Secondary prevention

In the randomized controlled trials inclusion criteria, clinical ASCVD is defined as acute coronary syndromes; history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin. Men and women with clinical ASCVD are at increased risk for recurrent ASCVD and ASCVD death. An extensive body of evidence demonstrates that high-intensity statin therapy reduces ASCVD events better than moderate-intensity statin therapy in patients with clinical ASCVD. High-intensity statin therapy should be initiated for adults age 75 or younger with clinical ASCVD who aren't receiving statin therapy. The intensity should be increased for patients in this group receiving low- or moderate-intensity statin therapy unless they have a history of intolerance to high-intensity statin therapy or other characteristics that may influence safety.[1]



Statins are increasingly thought of as risk-reduction medications instead of medications that modify cholesterol levels.

Who benefits from statin therapy?

The guidelines identify specific groups of patients who, based on the evidence, will benefit from statin therapy (see *Four statin benefit groups*). No recommendations are made about treatment decisions for selected individuals who aren't included in these four benefit groups. In those whose 10-year risk is less than 7.5% or when the decision is unclear, other factors come into play, such as family history of premature ASCVD, LDL-C greater than or equal to 160 mg/dL, high-sensitivity C-reactive protein greater than or equal to 2 mg/dL, coronary artery calcium score greater than or equal to 300 Agatston units or greater than or equal to 75th percentile for age, gender, ethnicity, or ankle-brachial index less than 0.9, or elevated lifetime risk of ASCVD.[1] Research supported by the National Heart, Lung, and Blood Institute indicates that coronary artery calcium scanning enhances risk assessment and clinical decision making in certain patients considered to be at intermediate risk for cardiovascular events.[5]

These thresholds are based on a 10-year risk for an ASCVD event. If, for example, the 10-year risk of heart disease and stroke is 7.5% or higher for a patient in the fourth statin benefit group, then according to the guideline the patient should be treated with a moderate-to-high intensity statin regimen.[1]

As the guideline notes, the evidence shows that the absolute benefit of statin treatment is proportional to baseline ASCVD risk. Treatment decisions for women and racial and ethnic subgroups should be based on the estimated 10-year risk

Statin therapies: How intense?[1]

	High intensity	Moderate intensity	Low intensity
Daily dose lowers LDL-C on average by approximately	≥50%	30% to <50%	<30%
Medications	• atorvastatin • rosuvastatin	• atorvastatin • rosuvastatin • simvastatin • pravastatin • lovastatin • fluvastatin • pitavastatin	• simvastatin • pravastatin • lovastatin • fluvastatin • pitavastatin

of ASCVD. This is in part because previous approaches focused on LDL-C levels to guide treatment decisions, which led to overtreatment in lower risk groups such as younger, non-Hispanic White women and undertreatment in higher risk groups such as Black women and men.[6]

Statins reduce risk

The new guideline is very clear that lifestyle modification continues to be critical for ASCVD risk reduction, with or without statin therapy. For patients who've attempted lifestyle modifications with limited success as defined by the clinician, the guideline stresses that statins should be considered as an adjunct therapy. In such cases, the guideline offers evidence that moderate to intensive statin therapy lowers ASCVD risk.

Lipid lowering treatment with hydroxymethylglutaryl CoA reductase inhibitors or statins is beneficial in patients with dyslipidemias for both primary and secondary prevention of CHD.[7] In fact, statins seem to lower risk regardless of cholesterol levels.[1]

As a result, statins are increasingly thought of as risk-reduction medications instead of medications that modify cholesterol levels. The guideline clearly states that if drug therapy is used for patients with a higher ASCVD risk, statins should be used. If a patient can't tolerate one statin, the provider is encouraged to try another.

The guideline recommends that the potential for an ASCVD risk reduction benefit be considered within the framework of patient preference as well as within the scope of potential adverse reactions and drug-drug interactions before statins are initiated for the primary prevention of ASCVD.

Grounds for controversy

As soon as the guidelines were released, academicians and clinicians responded with several concerns. The first and immediate criticism relates to the CV risk calculator and whether it overestimates ASCVD risk for many people. Such overestimation would mean that millions of otherwise healthy people would take a statin long term with no health benefit, and the real possibility of potentially serious adverse reactions.[8] The controversy over the calculator doesn't affect everyone. For patients in statin benefit categories 1, 2, and 3, a significant amount of research has shown the benefits of taking a statin far outweigh the risks.[1] It does affect those who haven't yet developed clinical ASCVD.[8]

The guideline's authors respond to this concern by acknowledging the imprecision in the assessment of lifetime risk. In view of this potential, the cholesterol panel did not recommend statin therapy at the threshold of 5%, at which benefit was suggested by the clinical trial data. Instead, the panel recommended a treatment threshold of 7.5%, creating a buffer against potential overestimation of risk.[8] They stress that the primary focus of using lifetime risk estimates is to facilitate an important discussion between the healthcare provider and the patient regarding risk reduction through lifestyle change and that the imprecision introduced is small enough to justify proceeding with lifestyle change counseling informed by these results.[3]

The authors encourage providers to use clinical judgment in such situations, weighing potential benefits and adverse reactions, drug-drug interactions, and patient preferences. They note that the guidelines are presented as information to guide a decision, not to mandate it. The guideline is just one part of a comprehensive approach to risk reduction that begins with the use of the ASCVD risk calculator and with the assumption that the healthcare provider is addressing each of the modifiable risk factors.

For some providers, the lack of time and difficulty of using the ASCVD risk calculator are problematic. The guideline promotes an individualized approach to risk assessment and treatment that is time intensive. The guideline authors recognize that change is difficult but believe providers will adapt when that change is consistent with the current evidence.

Nursing's role

Nurses can play an active role in alerting the public that the new AHA guidelines address risk reduction instead of focusing on reducing lipid levels alone. Nurses must become familiar with the risk factors for ASCVD, the ASCVD assessment risk tool, risk factors for different treatment groups, and the needs of high-risk populations. Nurses also play a key role in prevention efforts by educating patients and their

Four statin benefit groups[1]

The guideline identifies these four statin benefit groups:

1. Patients with clinical ASCVD without New York Heart Association class II-IV heart failure and who are not receiving dialysis. (The New York Heart Association classification of patients with cardiac disease is based on clinical severity and prognosis; it's used for all patients regardless of age.)
2. Patients with primary elevations of LDL-C ≥190 mg/dL.
3. Patients age 40 to 75 with diabetes and LDL-C 70 to 189 mg/dL without clinical ASCVD.
4. Patients without clinical ASCVD or diabetes, age 40 to 75, with LDL-C 70 to 189 mg/dL and who have an estimated 10-year ASCVD risk of 7.5% or higher.

families about lifestyle modifications that reduce the risk of ASCVD, changes from a focus on lipid levels to risk reduction, and the importance of seeing their healthcare provider if they're in any of the four major statin benefit groups identified in the guideline.

Nurses can also be part of a multidisciplinary team working to achieve desired patient outcomes. When a healthcare provider, nurse, dietitian, patient, and family come together to create a plan that works with the patient's lifestyle and goals, the patient is more likely to adhere to the treatment plan.[1]

Changing times

The new guideline represents a substantial change from previous guidelines and the burden to healthcare professionals shouldn't be underestimated. Lifestyle counseling, which should occur at the initial and follow-up visits and prior to initiating statin therapy, is time intensive. Learning to use the ASCVD risk calculator and incorporate it into practice also takes time. As the new guidelines become more widely implemented, time and the continuing accumulation of high-quality research data will tell if individualized therapy is a better approach to reducing ASCVD mortality than the previous treat-to-target strategy. ■

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