Heart TALK

Heart-healthy and Stroke-free Living with Dr. Amy L. Doneen, DNP, ARNP

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Thoughts from Dr. Amy

New Guidelines on Aspirin for Heart Attack and Stroke Prevention: What Should You Do?

For decades, aspirin has been hailed as a panacea to prevent heart attacks and strokes, as well as some forms of cancer. Until recently, guidelines from leading medical groups, including the U.S. Preventive Services Task Force (USPSTF), advised certain patients to take daily low-dose aspirin to avoid cardiovascular (CV) events — and about 40% of Americans over age 50 followed that advice.

On April 26, however, the task force dramatically reversed its position on who should use the popular preventative therapy. Millions of older adults who take a baby aspirin a day to keep heart attacks and strokes away were alarmed by a flurry of headlines like these: "Daily aspirin to prevent heart attacks and strokes could do more harm than good," "Task force issues new warning about daily aspirin" and "Doctors no longer recommend daily baby aspirin." Here is a closer look at the USPSTF's new guidelines, plus key takeaways from the BaleDoneen Method for the prevention of heart attack, stroke, dementia and chronic disease:

What are the cardiovascular risks and benefits of aspirin?

Also known as acetylsalicylic acid (ASA), aspirin has proven anti-clotting effects, thus helping to prevent heart attacks and ischemic strokes, which occur when a clot blocks flow of blood to the heart or brain. However, ASA can also be dangerous due to a significant risk for internal bleeding.

More than 200 studies have shown that low-dose aspirin (75 to 100 mg daily) significantly reduces risk for repeat heart attacks and strokes in patients who have already suffered one or more of these events, with this potentially lifesaving benefit clearly outweighing the low, but serious, risk for bleeding linked to this drug. The efficacy of ASA for these patients remains undisputed and guidelines recommending it for "secondary prevention" have ***not*** changed.

Aspirin use by patients who have not yet had a heart attack or stroke (defined as "primary prevention" by the standard of care) has long been controversial. As we recently reported, more than 30 years of randomized controlled trials (RCTs) — the gold standard of scientific

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research — have yielded conflicting findings about the risks, benefits and effectiveness of aspirin for these patients. This has led to inconsistent guidelines from medical societies and government agencies in the U.S. and Europe, recommending both for and against aspirin for "primary prevention."

What's different about the task force's new guidelines for aspirin use?

The USPSTF's guidelines contain several new recommendations for "primary prevention" of cardiovascular disease (CVD), the leading killer of American men and women. Key changes in the group's guidelines for healthcare providers include the following:

- Providers should consider starting low-dose aspirin therapy in people with a 10 percent or greater 10-year risk for CVD at a younger age: 40 instead of 50.
- In patients ages 40 to 59 who fit this profile, and who are not at increased risk for bleeding, aspirin therapy should be initiated based on individual decision-making, rather than being routinely prescribed to everyone in this age and CVD risk group.
- The task force now recommends against the use of aspirin for primary prevention in people ages 60 and older, stating that this practice has "no net benefit" for this group.

What do other medical groups recommend?

Current guidelines from the American Heart Association and American College of Cardiology, which were jointly issued in 2019, advise the following:

- Low-dose aspirin (75-100 mg daily) might be considered for select adults ages 40 to 70 who are at increased risk for CVD, but not at increased risk for bleeding.
- Low-dose ASA should not be prescribed routinely for adults under age 70.
- Low-dose ASA should not be prescribed for patients of any age who are at increased risk for bleeding.

How trustworthy are these conflicting guidelines?

To decide which treatment would be most beneficial for people who are being evaluated for CVD prevention, both the USPSTF and the AHA/ACC guidelines recommend that clinicians to use a 10-year risk assessment estimation (such as the well-known Framingham Risk Score, or FRS) before prescribing medications, such as aspirin, cholesterol-lowering statins, or drugs for high blood pressure.

This is where the BaleDoneen Method differs from the standard of care. Because FRS and other risk estimation tools have been shown in many studies to be unreliable, patients at high risk for heart attacks and strokes can be missed because they don't have the specific risk factors that these tools analyze. For example, a national study of more than 136,000 people hospitalized for heart attacks found that 75% had "normal" cholesterol levels and about half had "optimal" levels of LDL (bad) cholesterol.

As we recently reported, CVD in women is particularly likely to go undiagnosed and untreated. Sixty-four percent of women who die suddenly from a heart attack were previously unaware that they had CVD, which kills 10 times more women each year than all forms of cancer combined. Recent studies also show that rates of heart attacks and strokes are on the rise in young adults (those under age 55) — and in a study of heart attack survivors ages 18 to 55, only about half knew they were at risk before the event.

What are the BaleDoneen takeaways on aspirin use?

Unlike the standard of care, the BaleDoneen Method does not rely on risk-factor analysis alone. Our approach to prevention is based on a disease/inflammation paradigm in which all patients are considered "guilty" of harboring silent, deadly plaque in their arteries unless proven "innocent" through comprehensive laboratory and imaging testing, including carotid intima-media thickness (cIMT), an FDA-approved minute ultrasound scan of the neck's largest arteries.

The AHA/ACC guidelines advise that in making treatment decisions, including whether or not to prescribe ASA for "select patients," providers consider using a different imaging test called coronary artery calcium score (CACS) to evaluate the person's arterial health. While CACS is an excellent test, it can only detect calcified (stable) plaque, while cIMT can detect soft, vulnerable plaque (the most dangerous kind).

While we consider the inclusion of imaging in the guidelines an important step forward for the standard of care, we believe that the advice to limit it to select patients and base most decisions solely on risk factor estimates continues to leave behind millions of patients who have non-traditional risk factors — and silent, deadly plaque in their arteries in potential peril.

Instead, in a landmark peer-reviewed paper published in *Frontiers in Cardiovascular Medicine*, we have proposed a precision-medicine, three-tiered approach that starts with a comprehensive evaluation that includes lab and vascular imaging tests. Patients would then be divided into three groups, based on the presence or absence of disease (plaque) as follows:

1. Primary prevention

In the absence of arterial disease (plaque), the risk for a heart attack or stroke is so low that the benefits of ASA would be overshadowed by its potential harms. Instead, these patients should receive personalized therapies to reduce any risks they may have for future development of CVD, including genetic risks.

2. Secondary prevention

We propose use of this term for patients who have arterial plaque but have not yet experienced a CV event. Given the presence of plaque, especially in patients who also have chronic inflammation, the risk for a heart attack or stroke outweighs the potential harms of low-dose ASA.

3. Tertiary prevention.

We propose this term to describe what the standard of care currently calls "secondary prevention," i.e. patients who have already experienced one or more CV events. The benefits of aspirin for this group are undisputed.

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May Recipe • Grilled Cilantro Lime Chicken with Avocado Salsa

INGREDIENTS

Avocados abound with such a rich array of healthy nutrients that they've been called "nature's most perfect food." In this easy, low-calorie recipe, an avocado-tomato salsa is paired with tender, perfectly grilled chicken. The result is a delightful blend of classic Southwestern flavors your family and friends are sure to love. You can also vary the recipe by replacing the cilantro with parsley or other fresh herbs of your choice. For a vegetarian version, replace chicken with grilled tofu or meatless chicken tenders.

FOR THE CHICKEN

¼ cup fresh chopped cilantro
4 cloves garlic, finely minced
½ teaspoon cumin
1 tablespoon lime zest
2 tablespoon fresh lime juice
½ teaspoon black pepper
2 tablespoons extra-virgin olive oil
2 pounds raw skinless chicken (once cooked = four 6 oz. servings)

FOR THE SALSA

3 medium avocados, cubed
½ cup fresh cilantro or parsley, minced
1 cup tomatoes, chopped
2 tablespoons chopped red onion
2 tablespoon lime juice
½ teaspoon red pepper flakes

PREPARATION

In a medium bowl, whisk together the cilantro, garlic, lime zest and juice, cumin and olive oil. Season with black pepper, to taste. Add chicken to the marinade in a large ziplock bag and marinate at room temperature for 15 minutes. Preheat the grill to medium-high heat (about 400°F). Grill chicken for 5-6 minutes per side, until no longer pink. Use a meat thermometer to make sure the internal temperature reaches 165°F. Remove chicken from grill and transfer to a serving platter. Combine all salsa ingredients in a medium bowl and toss gently to mix. Top chicken with salsa and enjoy!

Serves four.

Adapted from joyfulhealthyeats.com and gimmedelicous.com.
And we offer a special thank you to Jennifer Kingdon Weaver for alerting us to this delicious recipe!

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Landmark BaleDoneen Paper Challenges the Status Quo in Cardiovascular Risk Assessment

Nearly half of U.S. adults — 121.5 million Americans — have some form of cardiovascular disease (CVD), a disorder that includes coronary heart disease, heart failure, stroke and high blood pressure. By 2035, it is estimated that 130 million people in the U.S. will have CVD, with the annual cost of their care projected to rise to $1.1 trillion from the current level of $351 billion. And tragically, CVD currently kills about 2,200 American men and women every day — one every 40 seconds.

What will it take to reduce these staggering statistics? "True healthcare reform will be realized only when we focus attention on disease prevention and not disease management," former American Heart Association president Dr. Gordon Tomaselli has stated. A landmark BaleDoneen paper proposes the first step toward that goal: reclassification of CVD risk assessment to identify the patients most likely to benefit from optimal preventive care to avoid heart attacks, strokes and other devastating complications of CVD. Here's a closer look at the paper and key takeaways to help you protect and enhance your arterial health:

CURRENT SCREENING TOOLS CAN MISS MILLIONS AT RISK FOR HEART ATTACKS AND STROKES

Up to 60 percent of people who die suddenly from cardiovascular (CV) causes were previously unaware that they had CVD. This disease often causes no symptoms until it becomes severe enough to trigger a heart attack, stroke or other catastrophic event. Published in the peer-reviewed journal *Frontiers in Cardiovascular Medicine*, the paper by Drs. Amy Doneen, Bradley Bale, David Vigerust and Pierre Leimgruber draws on the latest scientific evidence to argue that a new, more accurate approach to identifying at-risk patients before these events occur could help save lives.

Currently, the standard of care is to divide patients into two categories. People who have "proven" that they have CVD by having heart attacks or strokes are classified as "secondary prevention," with the goal of treatment being to help these high-risk patients avoid repeat events. Everybody else is classified as "primary prevention." Current guidelines recommend that medical providers check these patients for heart attack and stroke risk the same way they did when Bill Clinton was president — even though many studies have shown that the tool they use is dangerously unreliable.

This tool, called Framingham Risk Score (FRS), was introduced in the late 1990s. It estimates patients' 10-year risk for having a heart attack or stroke based on such factors as their age, gender, cholesterol levels, blood pressure and smoking status. Many studies, however, show that most initial CV events do not occur in people deemed at high risk by this scoring system. For example, a study of 150,000 people hospitalized for heart attacks found that 50 percent of them had "normal" cholesterol and many had "optimal" levels. Yet, a version of this faulty scoring system is still recommended in 2019 guidelines issued by the AHA and American Academy of Cardiology (ACC).

A THREE-TIERED APPROACH FOR ACCURATE CARDIOVASCULAR RISK DETECTION

Instead of a binary CV risk classification system of "have's" and "have-not's," the paper argues for a comprehensive, individualized three-tiered approach in which patients who have not yet suffered a CV event would be evaluated for the presence of arterial plaque (disease),

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using lab and imaging tests, such as a 15-minute ultrasound scan of the neck's carotid arteries. The BaleDoneen Method also uses blood and urine tests to check for inflammation, the fire that can ignite heart attacks and strokes in people with arterial plaque. Finding out if patients harbor silent, potentially deadly plaque in their arteries is fundamental for accurate assessment of their true risk for CV events. The paper proposes using these three risk categories to guide treatment decisions:

Primary prevention.
In the absence of atherosclerotic plaque, the likelihood of a plaque rupture and subsequent MI or stroke is so low that the vast majority of these patients don't need prescription medications. They could also be harmed by such commonly prescribed preventive therapies as low-dose daily aspirin, which can cause bleeding complications. Instead, the goal of treatment, such as personalized lifestyle modification to address potential risk factors, is to help the patient avoid forming plaque.

Secondary prevention
We propose use of this term for patients who have plaque, but have not yet experienced a CV event. Given the presence of plaque, especially in patients who also have chronic inflammation, the risk of a plaque rupture and subsequent CV events outweighs the potential harms of such medications as low-dose aspirin.

Tertiary prevention
We propose this term to describe what the standard of care currently calls "secondary prevention," i.e. patients who have already experienced one or more CV events.

HEART HEALTH VECTORS BY VECTEEZY

Benefits of a Proven, Personalized Approach to Prevention

Redefining CV risk assessment from a binary system to our proposed three-tiered approach has several important advantages for patients who currently fall into the "primary prevention" category. By directly checking patients for plaque with safe, accurate and widely available FDA-approved lab and imaging tests, healthcare providers can find out which patients actually need treatment. Under the current system, patients who lack the traditional risk factors — but have silent plaque in their arteries — may miss out on potentially life-saving treatments.

For example, as we recently reported, J.P. Moore thought he was in perfect health until he suffered a widow-maker heart attack on July 4, 2014, at age 42. He's a physically fit nonsmoker with normal blood pressure and cholesterol levels, eats a healthy diet, and exercises twice a day. And when we plugged the numbers from his annual physical, performed one month before this near-fatal event, into the latest AHA/ACC risk scoring algorithm, it predicted that his likelihood of having a heart attack in the next decade was only 1.4 percent! Based on this result, he would not have qualified for preventive treatments that could have reduced his risk, such as low-dose aspirin and statin medications.

Conversely, early detection and treatment with the BaleDoneen Method has been shown in two recent peer-reviewed studies to quickly shrink and stabilize plaque depositions in people with CVD, helping them avoid heart attacks and strokes. One of these studies, published in *Archives of Medical Science*, found that during the first year of treatment, our precision-medicine approach to medical management led to a 52.7 decrease in the size of plaque deposits in the patients' neck arteries (compared to baseline), helping them avoid heart attacks and strokes. It was also proven that our method eradicated lipid-rich arterial plaque (the most dangerous kind) in 100 percent of cases.

The study, which included 328 patients of the Heart Attack & Stroke Prevention Center in Spokane, Washington, who were tracked for five years, also demonstrated striking improvements in cholesterol levels, blood pressure and triglycerides. An earlier peer-reviewed study of 572 patients treated with the BaleDoneen Method found dramatic reductions in plaque deposits, blood sugar, cholesterol, blood pressure and inflammation over an eight-year period, further highlighting the benefits of early detection and treatment of plaque — before it becomes deadly.

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We also recommend that patients who are being considered for low-dose ASA for prevention of CVD or CV events be screened for aspirin resistance. In a meta-analysis of 1,813 patients with CVD from 12 prospective studies, the average prevalence of aspirin resistance was 27 percent. Aspirin-resistant patients were also found to have nearly quadruple the rate of CV events, compared to aspirin-responsive patients. These findings highlight the importance of determining each patient's ASA status before prescribing a therapy that may fail to protect a large proportion of patients.

Moreover, this research — and another recent study reporting that aspirin-resistant patients are 14 times more likely to suffer recurrent strokes than ASA-responders — also reveals the value of a personalized approach to prevention in which each patient is treated as a unique individual, not according to the average results of large studies. Also talk to your medical provider about getting a new test called MyPGt to personalize your care so you get the safest, most effective medications at the right dose, based on your unique genetics.