Heart TALK

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

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Thoughts from Dr. Amy

LOW-DOSE ASPIRIN FOR HEART ATTACK AND STROKE PREVENTION:

HELPFUL OR HARMFUL?

Aspirin is the world's most widely used drug — and one of the most controversial. Its medicinal use dates back to circa 1542 B.C., when extracts of willow bark (which contain salicylate, the active ingredient in aspirin) were described in an ancient Egyptian papyrus as a remedy for pain and fever. Also known as acetylsalicylic acid (ASA), aspirin has proven anti-clotting effects, thus helping to prevent heart attacks and 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.

Three new studies have highlighted the challenge of deciding if the benefits of low-dose ASA outweigh the potential harms. You may have seen headlines like these: "Daily Aspirin Could Be Harmful for Older Adults," "Daily Aspirin: Risks Outweigh Benefits, According to New Research" and "Does Daily Aspirin Therapy Work?" Here's a look at the latest research and key takeaways from the BaleDoneen Method of heart attack, stroke and diabetes prevention about how to decide if daily low-dose aspirin is right for you.

Are Current Guidelines on Low-dose Aspirin Use Trustworthy?

The effectiveness of low-dose ASA for people who have already suffered one or more heart attacks or strokes remains undisputed. The standard of care calls this use of daily aspirin "secondary prevention," while "primary prevention" is defined as aspirin therapy to prevent cardiovascular disease (CVD) in people who have not yet had a heart attack or stroke. For secondary prevention, more than 200 studies have shown that ASA significantly reduces rates of repeat heart attacks and strokes, with this potentially lifesaving benefit clearly outweighing the low, but serious risk for bleeding associated with this drug.

Current guidelines from the U.S. Preventive Services Task Force (USPSTF) base the decision on use of low-dose ASA for primary prevention of CVD and colon cancer on the patient's risk for developing CVD, using the Framingham Risk Score (FRS). The USPSTF only recommends the drug for people who are ages 50-69, have a 10% or higher ten-year risk for CVD and are at no increased risk for bleeding. The USPSTF considers the evidence insufficient to recommend low-dose ASA for people under age 50 or over age 69, regardless of the magnitude of their risk.

This is where the standard of care and the BaleDoneen Method (BDM) differ. "Risk-factor profiling" has been shown to be a highly inaccurate predictor of heart attack and stroke danger. Indeed, a 2017 systematic review of randomized clinical trials of widely used risk scoring systems, including FRS, found "no evidence" that these tools save lives or reduce rates of cardiovascular events.

Patients in Peril

Because FRS and other scoring systems are often unreliable, patients in peril may be missed because they don't have the specific risk factors that these tools analyze. For example, a national study of 136,905 people hospitalized for a heart attack found that nearly 75% had "normal" cholesterol, while about half had "optimal" levels of LD (bad) cholesterol. CVD in women is particularly likely to go undiagnosed and untreated, potentially leading to tragic consequences. Nearly two-thirds of women who die suddenly from a heart attack were previously unaware that they had CVD, a disease that frequently causes no symptoms until it becomes severe enough to cause a heart attack or stroke.

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Breaking ground with the Bale/Doneen Method

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Bale Doneen METHOD™

The 15-minute Scan
That Could Save Your Life

As a journalist covering the medical field, Thomas M. Burton has written many articles about strokes, but he never considered himself to be at risk for one. After all, he didn't smoke, worked out almost every day and ate a healthy diet. "Most doctors would have put me in the asymptomatic, or less-risky, category," he reported in *The Wall Street Journal*. Actually, Burton, 68, did have an odd symptom. Five years ago, he noticed that after a long run, his right leg sometimes shook. A few months ago, this started happening frequently and his right arm also shook after exercise.

Suspecting that the culprit might be a pinched nerve, he underwent a battery of tests. An ultrasound scan of his neck revealed that one of his carotid arteries was 99% blocked. He was told without immediate surgery to unclog the artery, he'd be at extreme risk for a major stroke. "I feel lucky to have gotten a test that may have saved my life," he wrote in an article that has sparked confusion and controversy about the best way to screen people for hidden heart attack and stroke risk. Here are the key facts you need to know to protect your arterial wellness.

Who should get cIMT testing?

BaleDoneen Method cofounder Dr. Amy Doneen recently served on a Society of Atherosclerosis Imaging (SAIP) expert committee that developed guidelines for appropriate use of cIMT, including these:

- Screening people whose ten-year risk for coronary heart disease (CHD) is moderate (6% to 20%).
- Screening people age 30 or older who have metabolic syndrome, a cluster of risk factors that triple risk for heart attack and stroke, and quintuples it for type 2 diabetes.
- Screening people with diabetes or a family history of early CHD.
- Screening people with two or more of the following risk factors: low HDL (good) cholesterol, high LDL (bad) cholesterol, diabetes, age (being over 45 for a man or over 55 for a woman), and a family history of early CHD.

Should healthy people be screened for plaque in their neck arteries?

Eighty percent of strokes — and 70% of fatal heart attacks — occur in people who had no previous symptoms. Yet these catastrophes are potentially preventable with early detection and treatment, highlighting the potentially lifesaving value of the comprehensive, personalized evaluation the BaleDoneen Method offers. To directly check each patient for hidden signs of arterial disease, we use leading-edge lab and vascular imaging tests, include a painless, FDA-approved ultrasound exam of the neck called carotid intima-media thickness or cIMT.

The cIMT test measures the thickness of the two inner layers — called the intima and the media — of the carotid arteries, the major arteries of the neck, which carry oxygenated blood from the heart to the brain. Most importantly, cIMT can detect cholesterol plaque growing in the wall of the artery, which is also known as atherosclerosis. If plaque deposits become inflamed, they can rupture explosively, like a volcano, leading to the formation of a blood clot that causes a heart attack or a stroke. As Burton's story highlights, even seemingly healthy people may be harboring silent, deadly plaque in their arteries.

While checking the neck may seem like a surprising way to tell if you might be headed for a stroke or heart attack, the carotid arteries, which lie near the surface of the skin on both sides of your neck, offer an easily accessible "window" into your arterial health — without any exposure to X-rays. CIMT is safe, painless, widely available and takes only 15 minutes to perform. Many studies have shown that cIMT can dramatically improve ten-year predictions of risk for heart attack and stroke, as compared with only looking at the patient's risk factors.

Should I get the carotid duplex ultrasound scan recommended in The Wall Street Journal?

The U.S. Preventive Services Task Force — a group of public health doctors who issue evidence-based guidelines for medical providers — recommends against use of this scan, carotid duplex ultrasound, as a screening test for people with no symptoms of carotid artery disease, as does the BaleDoneen Method. Yet most people over age 50 have gotten unsolicited letters in the mail touting this test as "a simple, potentially lifesaving screening to access your risk for stroke." Typically these ads are sent by direct-to-the-consumer marketers, such as Life Line Screening, and urge older adults to buy a package of ultrasound tests to check for several vascular diseases.

For people with symptoms of reduced blood flow through the carotid arteries, carotid duplex ultrasound is a safe, painless and potentially lifesaving diagnostic test to indirectly check for signs of arterial blockage. Medical providers typically use this test to evaluate blood flow in people who have had mini-strokes (transient ischemic attacks), which typically cause brief periods in which the person loses vision in one eye, experiences weakness or numbness in one leg or arm, or has difficulty speaking.

The test appears to have been appropriately ordered in Burton's case, given his symptoms and findings from a MRI suggesting that he may have suffered brain injuries from multiple "silent strokes." However, his article goes on to argue that the diagnostic test that detected his severely blocked artery should also be used as a screening tool, despite the USTSPF guidelines to the contrary. A recent study found no evidence that this type of screening is

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October Recipe

Hearty Pumpkin Spice Chicken Curry

Ready in less than 30 minutes, this easy recipe is rich in flavor and heart-healthy nutrients, including disease-fighting antioxidants. Studies suggest that pumpkins and their seeds help support the heart and cardiovascular system, reduce risk for type 2 diabetes, decrease inflammation throughout the body and improve blood pressure. The beta carotene compounds that give pumpkins their vivid orange color may also reduce risk for some forms of cancer. If you use canned pumpkin puree for this recipe, be sure to buy the unsweetened variety, not pumpkin pie filling.

INGREDIENTS

4 skinless, boneless chicken breasts
Salt (optional)
Pepper
1 tablespoon olive oil
½ red onion, diced
1 jalapeno pepper, diced
2 cloves of garlic, peeled and minced
1 tablespoon fresh ginger, grated
½ teaspoon turmeric
1 tablespoon curry powder
1½ teaspoons pumpkin spice blend
1 can light coconut milk
2 cups pureed pumpkin
Roasted pumpkin seeds or chopped parsley, for garnish.

PREPARATION

Slice chicken breasts into 1-inch cubes. Season with salt (if using) and pepper. Heat olive oil over medium heat in a large, heavy-bottomed pot. Add chicken cubes and sauté, stirring every two to three minutes, until browned on all sides. Transfer to a bowl. In the same pot, cook onion, jalapeno, garlic and ginger over medium-low heat for three to four minutes, until fragrant. Add turmeric, curry powder and pumpkin spice and cook for an additional two minutes. Add coconut milk, pumpkin and chicken to the pot and stir. Simmer over medium low-heat for ten to 15 minutes, until chicken is cooked through. Transfer to serving dish and top with roasted pumpkin seeds or chopped parsley. Serve with rice, naan, pita bread, or cauliflower rice and enjoy!
Serves six.

Adapted from Adocksoven.com

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beneficial to symptom-free patients — and could even harm them, since an abnormal result could lead to invasive tests, such as an angiogram, that may not be necessary.

What do the results of this test mean?

Along with checking for plaque, this test also calculates how "old" your arteries are. Having arteries that are more than eight years "older" than your chronological age is a sign of trouble, since it's evidence that you are headed for atherosclerosis in the future, while the presence of plaque means you already have it. If cIMT testing reveals that you have plaque in your neck arteries, you are not only at risk for a stroke, but also a heart attack.

Should you breathe a sigh of relief if no plaque is found? Unfortunately, as is true of all medical tests, a normal finding isn't conclusive proof that you don't have cardiovascular disease, since this test, while highly accurate, only checks one of many arterial beds. Therefore the BaleDoneen Method recommends that people with normal cIMT results also be checked with coronary artery calcium score, which uses a different imaging method to check directly for plaque. Discuss your cardiovascular risks and the best ways to reduce them with your healthcare provider. Also check out our top ten prevention tips for women, most of which are also helpful for men.

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Unlike the standard of care, the BDM 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), a painless ultrasound scan of the neck's largest arteries to check for plaque and other signs of arterial disease.

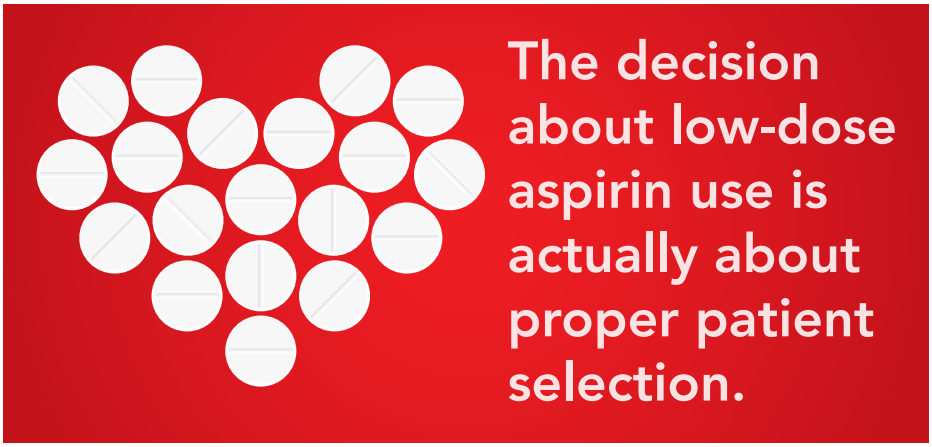
The Latest Studies on Low-dose Aspirin for CVD Prevention

Despite 30 years of randomized controlled trials (RCTs) — the gold standard of scientific research — the role of ASA in primary prevention has remained controversial. Five RCTs conducted between 1988 and 2003 linked aspirin use to a 32% reduction in first-time heart attacks. Since then additional RCTs have been published with inconsistent findings, leading to inconsistent guidelines, with medical societies and government agencies in the U.S. and Europe recommending both for and against low-dose aspirin for primary prevention. Here are key findings from the three latest RCTs:

ASPREE (Studied aspirin and the elderly). Nearly 20,000 men and women ages 70 or older, or age 65 and older among African-Americans and Hispanic people in the U.S., were randomly assigned to either take 100 mg of aspirin daily or a placebo. During nearly five years of follow-up, rates of CV events were lower in the ASA group, but the researchers didn't consider the difference to be statistically significant. The authors concluded that "The use of low-dose aspirin as a primary prevention strategy in older adults resulted in a significantly higher risk of major hemorrhage and did not result in a significantly lower risk of CVD than placebo."

ASCENT (Studied aspirin in people with diabetes). More than 15,000 adults with type 2 diabetes, but no evident CVD, were randomly assigned to take ASA at a dose of 100 mg or a placebo, then were tracked for a mean of 7.4 years. The authors concluded that "Aspirin use prevented serious vascular events in persons who had diabetes and no evident cardiovascular disease at trial entry, but it also caused major bleeding events. The absolute benefits were largely counterbalanced by the bleeding hazard."

ARRIVE (Studied aspirin for people at moderate risk for CVD). In this multi-center trial conducted in seven countries, 12,546 patients were randomly assigned to either receive 100 mg aspirin tablets daily or a placebo, then were tracked for a median of five years. Eligible patients were age 55 or older for men and 65 or older for women, deemed to have a 20% to 30% ten-year risk for CVD, based on various U.S. and European risk calculators. The authors concluded that "The event rate was much lower than expected, which is probably reflective of contemporary risk management strategies, making the study more representative of a low-risk population. The role of aspirin in primary prevention among patients at moderate risk could therefore not be addressed."



Key Takeaways on Aspirin for Primary Prevention

Given the conflicting findings of 30 years of research on the role of low-dose ASA in primary prevention, and recent RCTs raising questions as to whether the benefits outweigh the harms, what should patients and medical providers conclude?

The BDM takeaway is that the decision about low-dose aspirin use is actually about proper patient selection. While the standard of care divides patients into two groups based on whether or not they have experienced a CV event, we recommend a precision-medicine, three-tiered approach that starts with a comprehensive evaluation that includes laboratory testing and vascular imaging. Patients should then be divided in the following three groups, based on the presence or absence of disease (plaque):

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 potential risks they may have for future development of CVD, including genetic risks.

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.

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.

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 twelve prospective studies, the average prevalence of aspirin resistance was 27%. Aspirin-resistant patients were also found to have nearly quadruple the rate of CV events, compared to aspirin-responsive patients. Another recent study revealed that the odds ratio for recurrent stroke is 14 times higher in non-responders to ASA. These findings highlight the paramount importance value of determining the patient's ASA status before initiating a therapy that may fail to protect a large proportion of patients.

In conclusion, we consider the current controversy about low-dose ASA for "primary prevention" a valuable opportunity for patients and providers to shift away from using traditional "risk-factor profiling" to guide treatment decisions to being guided by the disease/inflammation approach employed by the BaleDoneen Method. Two recent peer-reviewed studies have demonstrated our precision-medicine approach to prevention and treatment can effectively detect, stabilize and reverse CVD, helping patients avoid heart attacks and strokes even if they have previously suffered one or more of these events.

It is our belief that to provide truly optimal care and protection against the world's most deadly disease — CVD — clinicians must treat each patient as a unique individual. Only with this very personalized approach, guided by the best available evidence, can medical providers confidently answer the increasingly common question we are hearing from our patients, "Doctor, is aspirin right for me?"