# Heart TALK

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

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*Thoughts from Dr. Amy*

## 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 new 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. If it goes undetected and untreated, this disease often causes no symptoms until it becomes severe enough to trigger a heart attack, stroke or other catastrophic events. 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.

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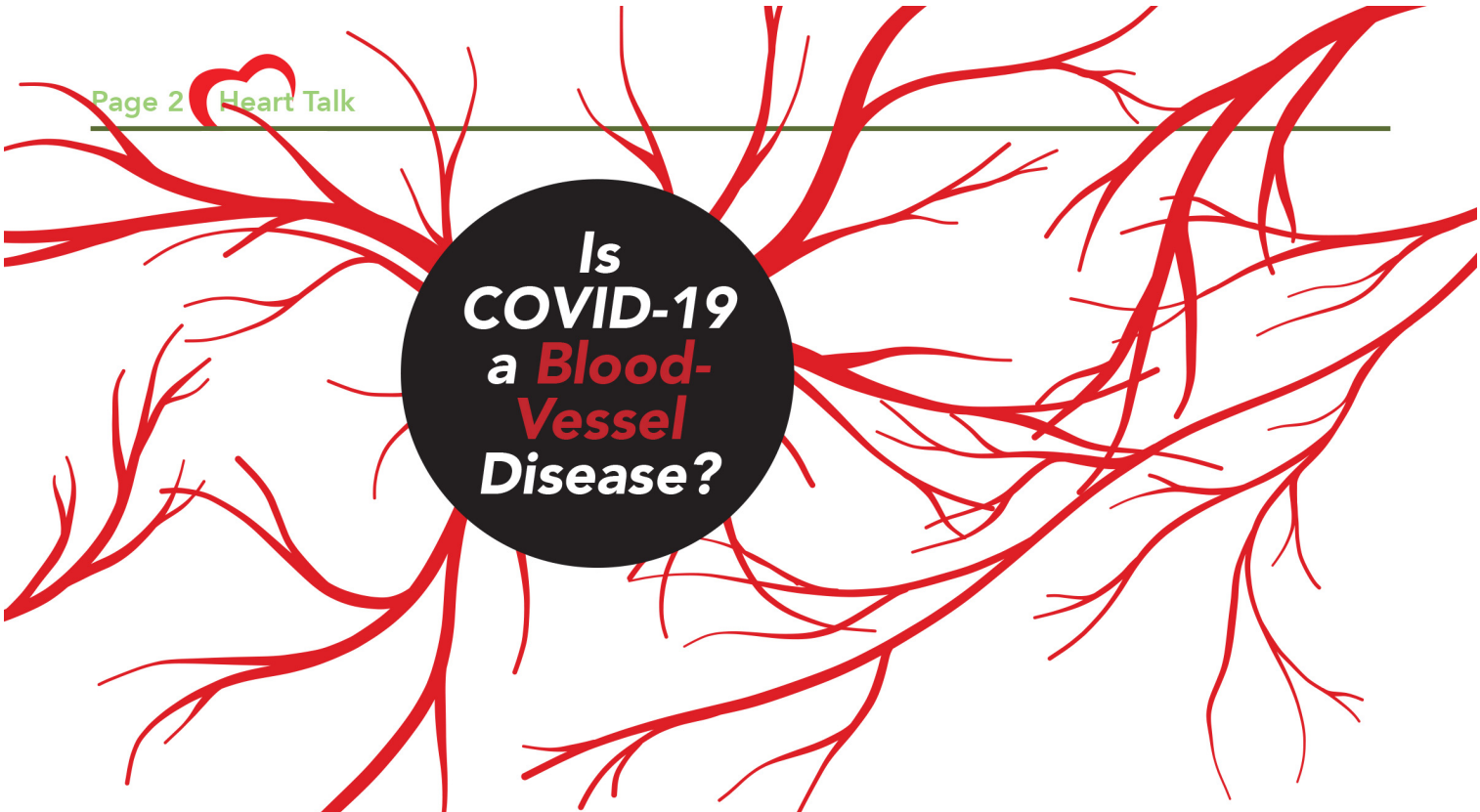

# Is COVID-19 a Blood-Vessel Disease?

Originally thought to be a respiratory disease, COVID-19 is now known to attack the body from head to foot, causing everything from strokes and heart attacks to deep vein thrombosis, pulmonary embolism and even painfully red or purple "Covid toes." All of these potential complications of the new coronavirus have something in common: They stem from vascular disorders, such as blood clots, blood-vessel inflammation and/or impaired blood circulation. What's more, about 40 percent of COVID-19 fatalities are linked to cardiovascular complications.

There is a rapidly growing body of evidence that SARS-CoV-2, the virus that causes COVID-19, may infect the blood vessels and circulate throughout the body, perhaps explaining why the disease can affect a wide range of organs, including the brain, heart, lungs, kidneys, liver and GI tract. In addition, as reported in the May 2020 Bale-Doneen Method Scientific Update for healthcare providers, certain medications used to treat arterial disease may also reduce risk for COVID-19 complications or may be potential therapies. Here are some of the latest discoveries and what they mean for patients with cardiovascular disease (CVD).

## THE FIRST PROOF THAT SARS-COV-2 ATTACKS BLOOD VESSELS

A new report in *Lancet* demonstrates that cells in the blood vessel lining (endothelium) play a direct role in severe complications of the new coronavirus. Sometimes called the "brains" of the blood vessels, the endothelium acts as a smart barrier between your blood and your blood vessels, controlling the transmission of fluids and other substances between the two. Dysfunction of the endothelium is what leads to coronary heart disease (plaque deposits in artery walls). The endothelium, which is only one cell thick but ranks as the largest organ in the body, also helps regulate blood pressure, as well as the release of enzymes involved in blood clotting, immune function and platelet adhesion (stickiness).

The report's authors describe "endothelial cell involvement across vascular beds of different organs" in three patients with COVID-19, including two who died from multisystem failure. Post-mortem tests revealed "viral inclusion structures" in the endothelial cells of one patient's kidney, and "inflammatory cells associated with [the] endothelium" in his heart, small bowel and lungs. In the other patient, a 58-year-old woman, endothelial involvement was detected in the lung, heart, kidney, liver and small intestine. She also suffered a heart attack. A third patient who survived, after suffering respiratory collapse and GI complications requiring surgery, was found to have endothelial involvement of the gut.

Summing up their findings, the researchers state that in each case, "We found evidence of direct viral infection of the endothelial cell and diffuse endothelial inflammation." They also add that "the development of this disease seems to be that it utilizes the ACE2 receptors as an entry way to a range of cells causing destruction. ... This explains why the disease has such a variety of presentations and makes it potentially more dangerous." Angiotensin-converting enzyme 2 (ACE2) is a protein found on the surface of many types of cells and tissues, including the heart, lungs, kidneys, liver, GI tract and the endothelium.

"The concept that's emerging is that this is not a respiratory illness alone, this is a respiratory illness to start with, but it is actually a vascular illness that kills people through its involvement of the vasculature," study coauthor Mandeep Mehra, MD, medical director of the Brigham and Women's Hospital Heart and Vascular Center, told *Medium*.

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## June Recipe • Curried Eggs

Ready in just 35 minutes, this easy recipe is rich in flavor and heart-healthy nutrients, including vitamins C, D, B6 and B12, iron and calcium. A recent study of nearly 500,000 people ages 30 to 79 found that those who consumed up to one egg daily had an 11 percent lower risk for heart disease and a 26 percent drop in stroke risk, compared to people who rarely or never ate eggs. Other research shows that turmeric (the spice that gives curry powder its yellow color) has powerful anti-inflammatory properties, supports the immune system, reduces blood pressure and may help lower risk for Alzheimer's disease. For a milder version of this recipe, omit the chiles. For a flavor variation, substitute zest of one lemon for the chiles. Perfect for a festive family brunch or dinner, the recipe serves six.

### INGREDIENTS

6 eggs
2 tablespoons olive oil
1 medium onion, peeled and diced
1 garlic clove, minced
2 small green chiles, such as jalapeño or serrano, finely chopped (optional), divided
2 tablespoons curry powder
1 can (14 ounces) chopped tomatoes with juice
1 tablespoon lemon juice
Freshly ground black pepper, to taste
2 tablespoons fresh flat leaf parsley or cilantro, chopped

### PREPARATION

Hard boil the eggs, using your preferred method. Put eggs in ice water. When cool enough to handle, peel, pierce sides of eggs several times with a fork (to let flavors in) and slice in half lengthwise. Heat oil in a skillet over medium heat. Add onion, garlic and half of the chopped chile (if using), then sauté until fragrant and softened, without browning. Add curry powder, tomatoes, lemon juice and pepper. Stir and simmer over low-medium heat, uncovered, until bubbling. Add egg halves and stir gently, spooning sauce over egg halves to cover. Cook until eggs are hot throughout, adding more water if the sauce gets too thick. Remove from heat and transfer to a serving dish. Garnish with parsley or cilantro and the remaining chile (if using) — and enjoy! Serves six.

*Adapted from marthastewart.com and thespruceeats.com.*

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### COULD ACE INHIBITORS BE A POTENTIAL TREATMENT FOR COVID-19?

Millions of Americans take medications called ACE inhibitors (ACE-I) or angiotensin receptor blockers (ARBs) to treat high blood pressure, diabetes or heart disease. As we reported in a BaleDoneen Method white paper released in March, there is some evidence that these medications, which the BaleDoneen Method has long used to treat patients with CVD, may also help protect against serious complications in people with COVID-19.

Examples of ACE-I include Accupril (quinapril), Aceon (perindopril), Altace (ramipril), Capoten (captopril), Mavik (fosinopril) and Vasotec (enalapril). ARB medications include Benecar (Olmesartan) or Diovan (valsartan). ACE-I and ARBs fall into a class of medications called renin-angiotensin-aldosterone system (RAAS) inhibitors.

Since then, a rapidly growing body of evidence, as well as position papers from cardiology groups, have revealed that these medications may have a protective — or even lifesaving — effect. For example, a multi-center study of 1,128 patients with high blood pressure who were diagnosed with COVID-19 found that those who were taking ACE-I or ARBs had a 70 percent lower risk of death than those who were taking other types of blood pressure medication. The findings were published in the American Heart Association's journal *Circulation Research* in April.

An even newer study, published in May in *New England Journal of Medicine*, examined the relationship of CVD, medication use, and rates of in-hospital death among 8,810 patients with COVID-19. Similar to earlier studies, the researchers found the highest mortality risk was for people who were over 65 or had such comorbidities as coronary artery disease, congestive heart failure, heart arrhythmia or COPD (chronic obstructive pulmonary disease). Factors

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This tool, called Framingham Risk Score (FRS), was introduced in the late 1990s. It estimates patients' ten-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), 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:

1. ***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.

2. ***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.

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.

## 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 lifesaving 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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linked to higher rates of survival included:

- Female sex
- Use of ACE-I
- Use of statins

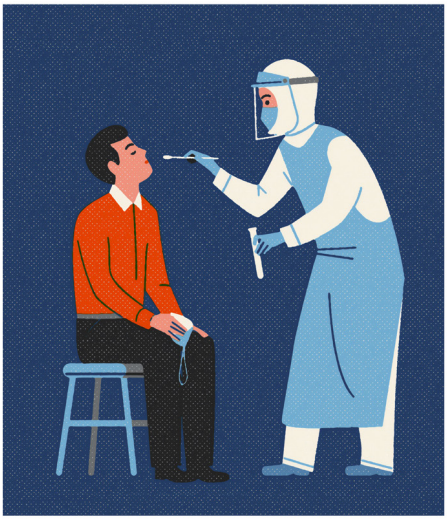
Because this was an observational study — not a randomized, placebo-controlled clinical trial — the study cannot prove a cause-and-effect relationship between taking these medications and lower risk for dying from COVID-19. Nor should patients take these, or any other medications, unless prescribed by their healthcare provider.

## DO HEART AND BLOOD PRESSURE MEDICATIONS PROTECT AGAINST GETTING COVID-19?

Other new studies do not provide any evidence of an independent relationship between taking ACE-I and ARBs and susceptibility to COVID-19 infection. Three studies examining the effects of these medications on patients with COVID-19 were published in NEJM in May. Subsequently, NEJM published an editorial "expression of concern" about the quality and reliability of the data used for one of the studies, "Cardiovascular Disease, Drug Therapy and Mortality in Covid-19" because the study drew on medical records from a controversial international database.

The editorial urged readers to instead consult the other two studies, which used completely different, independent data from other sources. In one of these studies, researchers from New York University Grossman School of Medicine analyzed records from 12,594 patients who were tested for the virus, 17 percent of who had developed severe COVID-19. More than one-third of the patients had high blood pressure. The study found no increased risk for testing positive for the virus in people — or for developing severe illness — in people who took any of the common types of blood pressure medication. The other study reported no independent link between taking RAAS inhibitors and susceptibility to COVID-19.

Instead, the latest research suggests that RAAS inhibitors, statins and low-dose aspirin (three of the cornerstones of the BaleDoneen Method's evidence-based treatment plan to help people with CVD avoid heart attacks, strokes, dementia and other



complications of arterial disease) may change the progression of COVID-19, potentially reducing its severity. Here are some research findings demonstrating why these treatments — when combined with an optimal lifestyle — might help lower risk for severe complications of the virus:

- Along with decreasing blood pressure, RAAS medications also decrease inflammation, oxidative stress and endothelial dysfunction.
- ACE inhibitors reduce inflammation and blood clotting and improve the functioning of the endothelium, heart and kidneys.
- Low-dose aspirin helps prevent blood clots that can lead to heart attacks, strokes and damage to other organs. About 30 percent of people with COVID-19 develop blood clots.
- Aspirin can also improve the prognosis of people with sepsis, a potentially life-threatening complication of severe COVID-19. In ICU patients overall, sepsis is the primary cause of death, although this has not been confirmed in COVID-19 patients.
- Uncontrolled inflammatory reactions and dysfunctional blood clotting are among the primary pathologies underlying sepsis. Therefore antiplatelet therapies, such as low-dose aspirin, is predicted to become a line of treatment for sepsis in the future.
- SARS-CoV-2 enters the cells mainly through ACE2 receptors and can trigger an intense inflammatory reaction called cytokine storm.
- Statins have powerful anti-inflammatory effects and also influence the immune system response in several ways, including cytokine production. Statins also improve the functioning and efficacy of the endothelium.
- In people with certain inflammatory autoimmune disorders, such as rheumatoid arthritis, multiple sclerosis, and lupus, statins have been shown to be beneficial as an add-on therapy.
- Statins have also been shown to improve outcomes in people with community-acquired pneumonia/sepsis.
- During the 2009 H1N1 flu pandemic, a link between statin use and reduced disease severity in hospitalized patients was demonstrated. In 2019, researchers advocated statin use as an immunomodulatory therapy for viral infections with potential benefits during epidemics and pandemics.
- Statins are also known to influence ACE2 expression

## WHAT'S THE BOTTOM LINE ON BLOOD-VESSEL HEALTH AND COVID-19?

About 50 percent of American adults have some form of CVD, including coronary heart disease and high blood pressure. It is now well-established that these patients have worse outcomes overall if they develop COVID-19 and a higher risk of death from the virus. People with CVD are also at increased risk for heart attacks, strokes, dementia and many other complications of vascular disease.

Combined with the optimal lifestyle that forms the fourth cornerstone of the BaleDoneen Method's treatment plan for people with arterial disease, these therapies have been shown in two recent peer-reviewed studies to halt and even reverse arterial disease, helping people avoid heart attacks, strokes and other devastating complications.

As evidence grows that RAAS inhibitors, statins and low-dose aspirin may play a role in helping people who have CVD avoid the most severe complications of the virus if they become infected, it is essential for patients to find out if they have CVD — and if so, to get the best available, personalized therapies to protect and stabilize their arterial and endothelial health.