

## Optimal Medical Care as Effective as Stents and Bypasses for Preventing Heart Attacks



Common invasive heart procedures, such as stents and bypass surgery, are no better for preventing heart attacks and death in people with stable coronary artery disease (CAD) than medications and lifestyle improvements, according to a large, federally funded clinical trial that has been hailed as one of the most important studies in cardiology. The findings could transform medical practice, spare many heart patients the hazards of unnecessary surgery and reduce healthcare spending by \$570 million — or more — each year.

While stents and bypasses can be lifesaving for people who are in the throes of a heart attack, these procedures only treat a few inches of the more than 60,000 miles of blood vessels in our bodies. For people without emergency symptoms, excellent medical care and healthier habits offer the benefit of treating the entire arterial system at a fraction of the average \$25,000 cost for stent implantation or \$45,000 for a bypass. Here's a look at some key takeaways from the study — and what they mean for the millions of Americans with CAD.

### **What was the purpose of the study?**

The \$100 million ISCHEMIA clinical trial was designed to compare two approaches to treating ischemia (reduced blood flow to the heart due to plaque

buildup inside the walls of the arteries that supply it with blood). This disorder is called CAD, ischemic heart disease or coronary heart disease and ranks as the most common form of cardiovascular disease, the leading killer of American men and women.

In some cases, CAD can cause stable angina, chest pain or discomfort that typically occurs with exercise or emotional stress. (Unstable angina is a medical emergency that usually causes unexpected chest pain when the person is at rest. A common cause is blood clots resulting from the rupture of a plaque deposit, putting the person at high risk for a heart attack if untreated.)

### **How was the study conducted?**

Funded by the National Heart, Blood

and Lung Institute, the trial included 5,179 men and women from 37 countries who had moderate to severe ischemia, making the study more than twice as large as any previous study of its kind. About two-thirds of the participants had frequent or daily angina at the start of the study, while the rest had no chest pain. About 40% of the patients had diabetes. The median age of the patients was 64.

All of the participants received optimal medical therapy (OMT) consisting of cholesterol-lowering statins, low-dose aspirin, blood pressure drugs and other medications, along with lifestyle advice to help them adopt healthier habits. Half of the patients were randomly

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# THE TEN BEST AND WORST FOODS

## FOR YOUR HEART AND BRAIN HEALTH



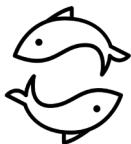
“Let food be thy medicine,” wrote Hippocrates centuries ago. But which foods should you choose to protect the health of your heart, brain and arteries — and which ones should you avoid? In 2017, an analysis of American dietary patterns linked eating suboptimal amounts of ten foods and nutrients — too much of some and not enough of others — to nearly half of deaths from a cardiometabolic disease (CMD), such as heart disease, stroke or type 2 diabetes.

Conversely, people who ate the recommended amounts of the ten foods had the lowest risk for CMD, according to the study, which was published in *Journal of the American Medical Association (JAMA)*. Since then, however, new studies have yielded sometimes contradictory findings about these foods, leaving Americans confused about the best and worst dietary choices. Here’s a look at the latest nutritional wisdom about these foods and how to optimize your diet for cardiometabolic wellness.

## EAT MORE OF THESE FIVE FOODS



**NUTS.** People who eat nuts regularly have a lower risk for developing heart disease or experiencing cardiovascular (CV) events, such as heart attacks and strokes, compared to those who rarely or never eat nuts, according to [a study of more than 210,000 men and women](#). Although the tasty treats are high in calories, they can also help people avoid long-term weight gain or obesity, [other research shows](#). Moreover, eating almonds or hazelnuts may raise HDL “good” cholesterol, while pistachios help lower triglycerides. The BaleDoneen Method recommends eating a palmful of nuts daily, preferably tree nuts with skins, such as almonds, walnuts, hazelnuts and pistachios.



**FISH.** The omega-3 fatty acids in seafood have a wide range of cardiovascular benefits, including helping prevent heart disease, stroke, heart failure and sudden cardiac death; reducing triglycerides, blood pressure and chronic inflammation; and improving insulin sensitivity. The best sources of omega-3s are oily fish, such as salmon, herring, sardines, tuna and lake trout. The [American Heart Association \(AHA\)](#) recommends eating at least two 3½-ounce servings of non-fried fish per week.



**FRESH VEGETABLES.** A diet high in these nutritional powerhouses could add years to your life. A new study presented at the Nutrition 2019, the annual meeting of the American Society for Nutrition, suggests that globally, low intake of vegetables is the culprit in more than 800,000 deaths from heart disease — and about 200,000 deaths from stroke — per year. The USDA advises eating two to three cups of veggies daily. Yet only one in ten adults consumes the recommended amount. An easy way to meet your goal is to fill half of your plate with vegetables and fruit. For optimal CV benefits, the BaleDoneen Method suggests [“eating the rainbow” of colorful produce](#).



**FRESH FRUIT.** Do people who eat a lot of veggies, such as the Chinese, get any extra cardiometabolic benefits from eating fresh fruit? [A study of more than 510,000 adults in China](#), where fresh fruit intake is very low, found that those who ate it daily had 36 percent lower risk for heart attack and stroke than those who ate no fresh fruit. Another [recent study](#) found that people who ate higher amounts of fresh fruit had a lower risk for diabetes. Among those who were already diabetic, the study also reported reduced rates of diabetes-related deaths and other complications in those who ate more fruit. [As we recently reported](#), fresh fruit also lowers blood pressure and helps prevent obesity. Fruits with proven CV benefits include blueberries, apples, tomatoes and pears.



**WHOLE GRAINS/ HIGH-FIBER FOODS.** People who eat the most fiber (found in whole grains, fruit and veggies) have a 56 to 59 percent lower risk of dying from cardiovascular disease (CVD), infectious diseases or respiratory disorders, according to a study of nearly 400,000 people ages 50 and older. An even larger study found that for each extra 10 grams of fiber people ate daily, their risk for death from any cause fell by 10 percent. The USDA recommends eating 14 grams of fiber for every 1,000 calories adults consume daily (about 25 grams a day for women and 38 grams daily for men).

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Perfect for a holiday celebration or any festive occasion, this elegant recipe offers a feast of hearty, heart-healthy flavors. Not only are mushrooms one of the few plant sources of vitamin D, but a new study reports that older adults who eat them more than twice a week have lower risk for developing mild cognitive impairment, a precursor to Alzheimer's disease. Walnuts abound in heart-protective omega-3 fatty acids and may also reduce inflammation. In a recent analysis of studies, a diet high in legumes (such as peas and beans) was linked to decreased risk for heart disease, high blood pressure and obesity, while other research has shown that for each additional serving of fruit and veggies you eat daily, your risk for stroke drops.

For a flavor variation, substitute stone-ground mustard for the vegan Worcestershire sauce or enliven the seasoning with ¼ teaspoon of pumpkin pie spice. Most store-bought puff pastry sheets are totally vegan, but check the ingredient list to make sure. For a gluten-free version, use gluten-free puff pastry or shape the mushroom-lentil-walnut mixture into a loaf and bake in a loaf pan. Serve with your favorite salad or steamed veggies.



## INGREDIENTS

- 1 medium onion, diced
- 3 cloves garlic, minced
- 2 tablespoons olive oil, divided
- ½ cup walnuts, coarsely chopped
- 8 ounces mushrooms, coarsely chopped
- ¾ cup carrots, chopped
- ¼ cup peas
- 1 teaspoon ground sage
- ¼ teaspoon cayenne
- 1 tablespoon fresh thyme, minced
- 1 tablespoon fresh oregano
- 1½ cups cooked brown lentils
- 1 teaspoon vegan Worcestershire sauce (optional)
- Nonstick cooking spray
- 1 sheet vegan puff pastry, thawed
- Flour, for rolling out puff pastry
- Vegan gravy, for serving

## PREPARATION

Preheat oven to 375°F. Heat olive oil in a medium pan over medium heat. Sauté onion and garlic until fragrant and golden (3 to 5 minutes). Add walnuts and cook an additional 2 to 3 minutes to toast. Add mushrooms and carrots and cook 5 to 7 minutes, until most of the liquid has evaporated from the mushrooms. Add peas, spices and herbs and cook for one minute. Add lentils and cook until heated through. Stir in vegan Worcestershire sauce, if using. Mash some of the lentils to thicken mixture.

Grease an 18-by-13 baking pan with nonstick spray. On a lightly floured surface, roll out puff pastry to fit baking pan. Transfer puff pastry to baking pan. Spread vegetable mixture evenly to cover the center third of the pastry. Fold one side of the pastry over the filling, then the other side. Seal top and bottom ends over the filling and score the top of the Wellington diagonally with a sharp knife. Poke air vents in sides of pastry then brush with remaining olive oil. Bake for 35 to 40 minutes, until golden brown and puffed. Remove from oven and let rest for 10 minutes. Serve with vegan gravy and enjoy! Serves six.

Adapted from [Tasty.co](http://Tasty.co) and [veganricha.com](http://veganricha.com).

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## EAT LESS OF THESE FIVE FOODS



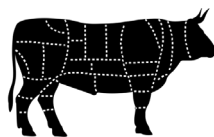
**SALT.** The AHA recommends a limit of no more than 2,300 mg. per day of sodium and ideal limit of no more than 1,500 mg. for most adults. Cut back on the [“Salty Six:”](#) bread and rolls, pizza, sandwiches, cold cuts and cured meats, soup and burritos and tacos, all of which typically contain high levels of sodium. Limiting or avoiding packaged, processed foods, which are typically high in salt, may lower your blood pressure or help you avoid hypertension in the first place, the AHA reports.



**PROCESSED MEATS.** People who eat the most processed meat — such as bacon, beef jerky, salami and other deli meats — have a higher risk for CVD. A study published in JAMA linked processed meat consumption to 57,766 deaths from CMD in 2012. What’s more, eating as little as one hot dog or a few strips of bacon daily raises colon cancer risk by 20 percent, according to a new study published in International [Journal of Epidemiology \(IJE\)](#). Processed meat has also been tied to increased risk for cancers of the breast, pancreas and prostate.



**SUGAR-SWEETENED BEVERAGES.** Consuming just one or two sugar-sweetened beverages daily – such as energy drinks, fruit drinks, soda or coffee drinks – raises risk for a heart attack or dying from CVD by 35 percent, diabetes risk by 26 percent and stroke risk by 16 percent, according to [a recent Harvard study](#). Sweet drinks have been called “liquid candy” and rank as the top source of added sugar in the U.S. diet. Quench your thirst with plain or sparkling water flavored with a spritz of lemon or lime or try our [refreshing fruit and herb infused water recipes](#).



**RED MEAT.** Recently, conflicting studies have stirred debate about the effects of red meat. In the IJE study discussed above, eating 2½ ounces or more of red meat per day raised colon cancer risk by 20 percent. However, [controversial new “guidelines” published in Annals of Internal Medicine](#) in November contend there is not enough scientific proof of harm to tell people to cut back on red meat. This paper by a panel of nutritionists contradicts the federal government’s Dietary Guidelines for Americans, recommendations from the World Health Organization and other medical groups, and numerous studies pointing to the health benefits of eating less meat and more plant foods. The BaleDoneen Method joins these authorities in continuing to advise patients to limit red meat. Healthy sources of protein include seafood, legumes (beans and peas), nuts, oats and low-fat dairy products, while leafy, green vegetables are an excellent source of iron.



**SATURATED FAT.** For 50 years, saturated fats were demonized as the No. 1 dietary culprit for arterial disease. Two major studies report that the effect of cutting down on saturated fats depends on how you replace them. Swapping them with healthy fats (such as those found in oily fish, olive oil, most nuts and avocados) or high-fiber carbs (such as whole grains) may benefit heart health, while replacing saturated fat with refined carbs (such as baked goods or sweets) is likely to do the opposite. In fact, as we recently reported, [sugar is actually worse for heart health than saturated fats](#).

## WHAT'S THE BEST DIET TO PROTECT CARDIOMETABOLIC HEALTH?

Rather than advise a one-size-fits-all diet based on the average results from large studies, the BaleDoneen Method recommends [a diet based on your DNA](#). We use genetic tests to identify the optimal eating plan for each patient. Ask your healthcare provider for more info on the two genetic tests discussed below. Using them to guide your dietary choices can help you lower your risk for heart attacks, strokes and diabetes:

**APO E GENOTYPE.** This test analyzes your Apolipoprotein E (Apo E) genotype, which influences both your lifetime risk for heart disease and the best diet to avoid it. The results can be used to determine the optimal amount of fat in your diet and whether you should limit or avoid alcohol. A diet based on your Apo E genotype fights the leading risk for heart attack and a major risk for stroke: abnormal lipid levels. Studies show that eating the right foods for your Apo E genotype raises levels of HDL (good) cholesterol and lower levels of LDL (bad) cholesterol and triglycerides.

**HAPTOGLOBIN GENOTYPE.** If you have type 2 diabetes, this test can reveal if you have a genotype that quintuples risk for heart disease — and guide precision-medicine treatments to almost eliminate this risk, [a peer-reviewed recent BaleDoneen study reported](#). If you are not diabetic, you can learn if you have a genotype linked to increased risk for intestinal, autoimmune and inflammatory disorders and if you’d benefit from a gluten-free diet and probiotics.



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assigned to receive coronary angiography (an invasive x-ray test used to evaluate blood flow in coronary arteries) and if appropriate, invasive treatments, such as stents to prop open constricted areas in their coronary arteries or coronary artery bypass surgery to reroute blood around such areas.

The other group of patients received OMT alone. For example, one participant in this group [told The Washington Post](#) that he switched to a mostly vegan diet, took a regimen of pills and exercised several times a week with an elliptical machine, hiking and golfing. He also reported that he felt much better after receiving OMT alone, was able to travel and enjoy an active lifestyle and was “glad to have avoided more extreme interventions.”

The OMT group was only treated invasively if their symptoms got worse or they had heart attacks. The invasive group took powerful anti-clotting medications for six to 12 months after their surgeries. The stents used in the study also contain drugs that are slowly released to reduce risk that the blockage would recur.

**How well did these treatments work?**

During the study, participants were tracked for up to seven years and monitored for five types of events: heart attack, death from cardiovascular causes, resuscitation after cardiac arrest or hospitalization either for unstable chest pain or heart failure. Overall, there were no differences in rates of these five events between the OMT and interventional groups, the researchers reported.

However, six months into the study, the group that had invasive procedures had a slightly higher rate of heart attacks than the OMT group (5.3% vs. 3.4%). Four years into the study, the results flipped and a slightly higher rate of cardiovascular (CV) events was reported in the OMT group (13.9% vs. 11.7%). By the end of the study, there were no significant differences in the rate of CV events, heart attacks or cardiovascular-related death. About 14% of people in each group experienced cardiovascular issues at some point during the study, which began in 2012.

The study found that people with angina had greater improvement after invasive procedures, compared to those who were treated with pills and lifestyle improvements, such as quitting smoking, increasing exercise and dietary changes. Among patients who reported daily or weekly chest pain at the

start of the study, 50% of those treated invasively were angina free a year later, versus 20% of those treated with OMT. Those without angina has no changes in the quality of their lives after the procedure.

**What did the researchers conclude?**

“In line with evidence from prior studies, our results suggest that routine use of heart procedures was not superior in reducing risk for the five-part disease endpoint or death overall compared to treatment only with optimal medical therapy,” [stated ISCHEMIA trial chair Judith Hochman, MD](#), who presented the results at the AHA annual meeting.

“On the other hand, patients symptomatic to start that got heart procedures, over the years, had fewer symptoms and felt better,” added Dr. Hochman, who is a professor of medicine and senior associate dean for clinical sciences at NYU Langone Health in New York City.

“Based on our results, we recommend that all patients take medications proven to reduce the risk of a heart attack, be physically active, eat a healthy diet, and quit smoking,” stated ISCHEMIA co-chair David Maron, director of preventive cardiology and the Stanford Prevention Research Center at Stanford University.

The study adds to earlier research, including the landmark 2007 COURAGE clinical trial, that has also shown OMT to be as effective as invasive

procedures for the prevention of heart attack and death from cardiovascular causes. Several subsequent studies have had similar findings. In 2012, a [systematic review and meta-analysis](#) of eight randomized clinical trials (the gold standard of scientific research) found that coronary stents offer no benefit over medical treatment for prevention of death, nonfatal MI, unplanned revascularization or angina in people with non-acute CAD.

The ISCHEMIA study findings suggest that many of the 1 million Americans who undergo stent and bypasses procedures each year could be safely managed at far lower cost with OMT. About one-third of these procedures are performed on patients with stable CAD. Medications for CAD have improved over the past several years, increasing this group’s prospects for safe, successful treatment without the risks and high cost of heart surgery.

