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WELLNESS REPORT

## Combo 'Polypill' May Cut Heart Attack, Stroke Risk Up to 40%

A single pill loaded with cholesterol and blood pressure medications can reduce your risk of heart attack and stroke by as much as 40%, a new international study reports.

The "polypill" containing three generic blood pressure medications and a statin dramatically reduced the risk of heart-related illness in people with no prior history of heart problems, according to clinical trial results.

When taken on its own, the polypill reduced by about 20% the risk of heart attack, stroke, procedures to reopen clogged arteries and other heart disease, the researchers reported.

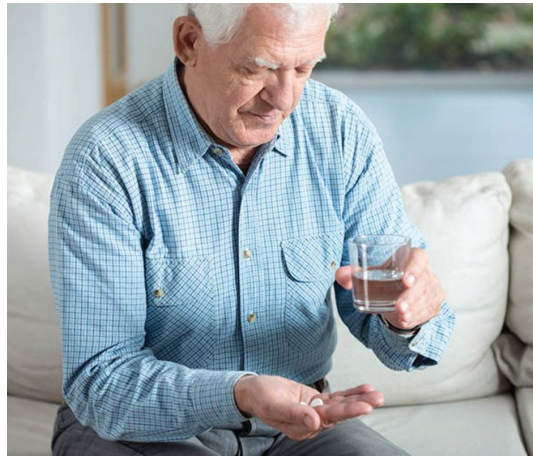
The polypill combined with daily low-dose aspirin was even more effective, reducing heart health problems by up to 40%, the findings showed.

"We've estimated that if even just one-half of people with high blood pressure or diabetes were treated with such a polypill, at least somewhere between 2 and 4 million premature deaths, heart attacks and strokes would be avoided every year," said lead researcher Dr. Salim Yusuf, a professor of medicine at McMaster University in Canada.

Such a polypill would have other benefits as well, Yusuf said. It would be easier for patients, who wouldn't have to juggle fistfuls of daily medications, and for doctors who'd only have to write one prescription. A single pill also is cheaper to market and distribute.

"I personally would just like to get people to use the components either separately or together. If it's more convenient together, why not?" Yusuf said.

The study results were published online Nov. 13 in the New England Journal of Medicine.



For the trial, more than 5,700 people from nine countries were randomly assigned to one of four groups. They were asked to take one of the following daily: both the polypill and aspirin, the polypill alone, aspirin alone, or only a placebo.

The polypill used in this study included cholesterol-lowering simvastatin and three blood pressure meds (a beta blocker called atenolol, a diuretic called hydrochlorothiazide and an ACE inhibitor called ramipril).

Compared with placebo, the polypill successfully lowered blood pressure and cholesterol, the investigators found.

Only 4.4% of those who took the polypill alone had a heart attack, stroke, artery-reopening procedure or died of heart disease, compared to 5.5% who took the placebo. About 4.1% of those who took aspirin alone developed heart-related illness, compared to 4.7% of those with the placebo.

Combining a polypill with aspirin provided the best benefits, the study authors said.

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**MEDICAL MILESTONES  
IN HISTORY**



## MEDICAL MILESTONES IN HISTORY



**1816**

Stethoscope invented by French physician, Rene Theophile Hyacinth Laennec



**1960**

First oral contraceptive approved by FDA



**1962**

First arthroscopic meniscectomy performed on a 17-year-old boy who twisted his knee by Dr. Masaki Watanabe

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The polypill/aspirin combination reduced heart problems and deaths by 31%, the researchers discovered. People who continued to take the pill without interruption for about four years saw a 40% reduced risk of heart problems.

"When you look at the combination of aspirin and the polypill, you definitely see a meaningful reduction in cardiovascular events," said Dr. Eugene Yang, chair-elect of the American College of Cardiology's Prevention of Cardiovascular Disease Council.

In the United States, such a polypill could be a valuable tool in protecting the heart health of people who have less access to health care, Yang said.

"With the health care disparities that exist in this country, there could be opportunities where a polypill in the United States would be beneficial," Yang said.

Currently, no such cholesterol/blood pressure polypill exists in the United States, Yusuf said.

Yang pointed out that "the fact that it's generic is a double-edged sword, because no

big pharma company is willing to invest a lot of money in developing and marketing a polypill. It may require either health insurance companies or governments or charitable organizations to develop polypills."

There also might be some reluctance among doctors to prescribe a pill loaded with a number of different medications, Yang added.

"We've all been taught in medical school you need to give one drug at a time and see what it does before you add a second one," Yang said.

The study was 95% funded by charitable organizations like the Wellcome Trust UK and government agencies, Yang said. The Indian company Cadila Pharmaceuticals provided 5% of the funding, which included production and distribution of the polypills.

The researchers presented their findings over the weekend at this year's virtual meeting of the American Heart Association.

## High-Dose Vitamin D Won't Prevent Seniors' Falls: Study

High doses of vitamin D may increase seniors' risk of falls, rather than reduce it, according to a new study.

Preliminary studies suggested vitamin D may increase muscle strength and improve balance, so Johns Hopkins researchers investigated whether high doses of vitamin D might reduce the risk of falls in people aged 70 and older.

But the investigators found that large doses of vitamin D supplements were no better at preventing falls in this age group than a low dose.

"There's no benefit of higher doses but several signals of potential harm," study author Dr. Lawrence Appel said in a Hopkins news release.

"A lot of people think if a little bit is helpful, a lot will be better. But for some vitamins, high-dose supplements pose more risks than benefits. There's a real possibility that higher doses of vitamin D increase the risk and severity of falls," said Appel, a professor of medicine with joint appointments in epidemiology, international health and nursing.

Taking 1,000 or more international units per day (IU/day), equivalent to 25 micrograms/day of vitamin D, was no better than 200 IU/day at preventing falls, according to the study, which was funded by the U.S. National Institute on Aging.

The results were published Dec. 8 in the journal *Annals of Internal Medicine*.

The researchers also found that vitamin D supplement doses of 2,000 and 4,000 IU/day seemed to increase the risk and severity of falls compared with 1,000 IU/day, a relatively common dose for a pure vitamin D supplement.

Another finding was that serious falls and falls that required hospitalization occurred more often in older people who took 1,000 or more IU/day than in those who took 200 IU/day (about half the typical dose found in multivitamins).

Older folks should talk with their doctors about their fall risk and vitamin D levels in order to determine whether or not to continue taking vitamin D supplements, Appel recommended.



# A 'Stunning' Alternative Rx for Arthritic Joints?

A procedure that "stuns" pain-sensing nerves might offer relief to people with severe arthritis of the hip or shoulder, a small, preliminary study suggests.

The procedure is a form of radiofrequency ablation, where doctors use needles to send a low-grade electrical current to nerves that are transmitting pain signals from the arthritic joint to the brain. The current heats and damages the nerve fibers, rendering them unable to deliver those pain messages.

In the United States, a number of ablation devices are cleared for treating low back pain and knee osteoarthritis.

At this point, the procedure is slowly becoming a more established treatment, said Dr. Felix Gonzalez, a radiologist at Emory University School of Medicine in Atlanta.

But whether ablation can help patients with severe hip or shoulder arthritis is unclear.

To find out, Gonzalez and his colleagues treated 23 patients whose hip or shoulder pain had become so bad that anti-inflammatory painkillers and cortisone injections -- two standard treatments -- were no longer helping.

Before undergoing ablation, and again three months later, patients answered standard questionnaires gauging their pain and daily function.

In the end, the study found, patients with shoulder arthritis reported an 85% drop in their pain ratings, on average. Among hip arthritis patients, pain declined by an average of 70%.

Gonzalez called the results "promising" and said, in his experience, there have been no major complications from the procedure, such as bleeding or infections -- though those are potential risks.

And before the ablation is done, Gonzalez explained, patients go through what is basically a trial run. They are given an injection of numbing medication near the nerves believed to be generating the pain signals. If the pain abates, that means targeting the same nerves with ablation will likely work, too -- longer term.

It's too soon, however, to judge the effectiveness of the approach for shoulder and hip pain, according to Dr. Rajat Bhatt, a rheumatologist who was not involved in the study.

None of the study patients received a placebo (inactive treatment) to serve as a comparison, said Bhatt, of Prime Rheumatology in Katy, Texas. So it's possible at least some of the pain relief came from the fact that patients received a novel therapy.

"With pain, there's generally a large placebo effect," Bhatt pointed out.

Larger studies, with a comparison group, are still needed, he said. Gonzalez is scheduled to present the findings at the annual meeting of the Radiological Society of North America, being held online Nov. 29 to Dec. 5. Studies reported at meetings are generally considered



preliminary until they are published in a peer-reviewed journal. Osteoarthritis is exceedingly common, affecting more than 32.5 million Americans, according to the U.S. Centers for Disease Control and Prevention.

The condition arises when the cartilage cushioning the joint breaks down over time, leading to pain, stiffness and decreased range of motion.

People with osteoarthritis often take over-the-counter painkillers, such as ibuprofen (Advil, Motrin) and naproxen (Aleve). But besides being only moderately effective, the drugs are not without risks: Prolonged use is linked to increased risks of heart disease and kidney damage. Corticosteroid injections, which reduce inflammation, are the next option. But their effectiveness wanes over time, Bhatt said, and there are long-term safety issues, including a risk of cartilage damage.

Beyond that, Gonzalez said, there are essentially two options for more severe pain: joint replacement surgery or opioid painkillers.

"But not everyone is a candidate for surgery, because of health reasons," Gonzalez said. "And some patients don't want it."

Opioids, meanwhile, carry their own well-documented problems, including the potential for addiction.

"So we need something to fill the gap," Gonzalez said.

Ablation stands as an additional therapy, he said, but it's not a "cure." For one, it addresses pain -- not the underlying joint damage of arthritis. And the pain is not banished forever: The nerve fibers eventually grow back.

When ablation is used for knee osteoarthritis, Gonzalez said, the pain relief typically lasts 6 months or more -- and up to two years in some patients. The procedure can be repeated.

In this early study, patients were only followed for three months. So it's not clear how long the pain relief will last, Gonzalez said.

And while ablation is coming into wider use for certain pain conditions, people may not be able to find it locally. Gonzalez said some of his patients come from hours away to get the treatment.

# Can You Stop COVID Precautions Once You Get Vaccinated?

It will be tempting for folks to think they can resume a "normal" life after they've received the two-dose course of the COVID-19 vaccine.

But infectious disease experts warn that you'll still need to wear a mask and practice social distancing even after getting either the Pfizer or Moderna vaccines, or perhaps one of the other vaccines still in the testing pipeline.

That's because the clinical trials that tested these vaccines for safety and effectiveness focused on whether they could prevent you from getting seriously ill or dying from COVID-19, experts say.

What isn't known is whether vaccinated folks could become unknowing "Typhoid Mary" candidates -- capable of becoming infected and spreading the coronavirus to others, even though they themselves are safe from serious illness.

"You could be infected and you could be contagious even though you had the vaccine," said Dr. William Schaffner, a professor of infectious disease with the Vanderbilt Medical Center in Nashville. "We don't know that, but we don't know it's not true."

Another expert agreed.

"We can't guarantee you that with two doses of the vaccine you're not harboring the virus in an asymptomatic manner and could spread it to other people. It's going to be important to be cautious..." added Dr. Amesh Adalja, a senior scholar with the Johns Hopkins Center for Health Security.

Vaccinated folks who wear a mask and practice social distancing will protect themselves from becoming asymptomatic carriers of the disease. Infection prevention also will keep others from becoming sick if the vaccinated have inadvertently become infected with coronavirus.

"If you're hugging somebody and they're not vaccinated and they're in a vulnerable



population, maybe they have diabetes or maybe they're over 60, you could infect them with the virus and they could become sick," Adalja said.

The vaccinated also will protect themselves from the small but real risk that they could develop a serious case of COVID-19 despite their inoculation, said Dr. Waleed Javaid, an associate professor of medicine and infectious diseases with the Icahn School of Medicine at Mount Sinai in New York City.

"The vaccine's effectiveness is at 95%. There's still that 5%," Javaid said.

States might start relaxing social distancing guidelines as vaccination spreads through vulnerable groups like seniors and people with medical problems, Adalja said.

"Once the vulnerable populations are vaccinated, people are going to be breathing a sigh of relief because that's what is driving hospitalizations and deaths," Adalja said. "You may see some of the guidance in states loosening up once that group of the population has been protected."

However, it will likely take until late summer or fall 2021 to produce the estimated 300 million doses needed to protect all of the vulnerable groups in the United States, said Dr. Paul Offit, director of the Vaccine

Education Center at the Children's Hospital of Philadelphia.

Patience will be paramount, Javaid said. "The most important thing right now is this is a historic time, in terms of having a vaccine so quickly available that has great efficacy. We are at the cusp of halting this pandemic, if all of us get the vaccine," Javaid said.

Offit has his own personal goal for the end of the pandemic.

"How will I know personally that I now feel we have stopped the spread of this virus and I feel comfortable? It's when I can go to Eagles games, because I'm an Eagles season ticket holder, knowing I don't have to wear a mask because it's hard to boo through a mask," Offit said.

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