Are stents really useless after chest pain? Cardiologists not sure

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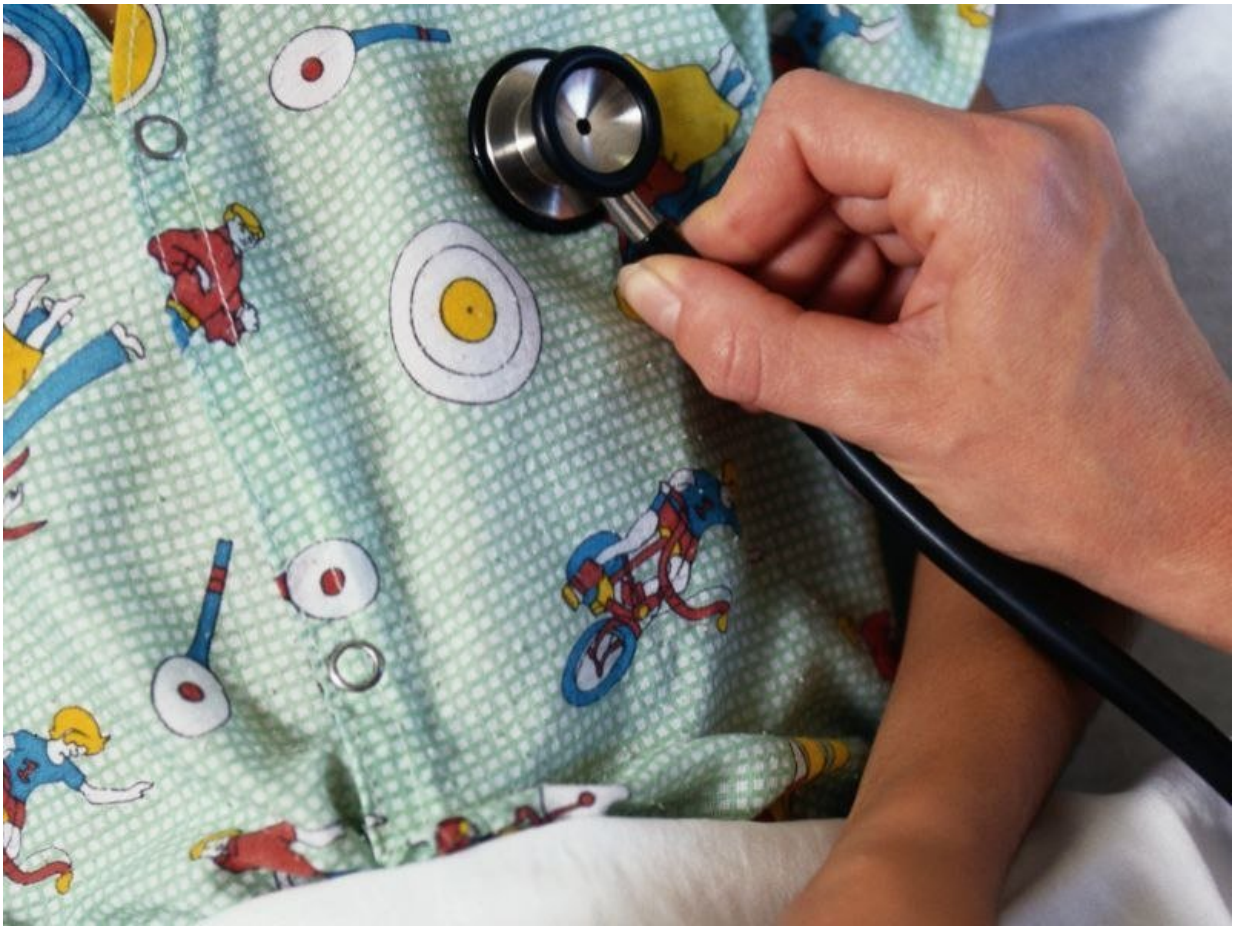

(HealthDay)—Heart experts are cautiously embracing the results of a

new, landmark clinical trial that questions the value of opening blocked arteries to relieve chest pain.

Chest pain sufferers who received a stent—a tiny wire mesh tube—to reopen an obstructed artery did not show any more improvement than people who only took medicine to improve their condition, the British researchers reported.

"This definitely has made big waves," said Dr. Samin Sharma, director of interventional cardiology at Mount Sinai Health System in New York City.

But cardiologists can't say whether the trial, published Nov. 2 in *The Lancet* journal, will have much immediate impact on clinical decision-making.

For one, the trial focused on a set of patients with relatively mild symptoms, and it did not include a long enough follow-up to see whether those who didn't receive stents wound up with ever-worsening heart problems.

"As a physician who has cared for many patients with coronary artery disease, I have grave concerns about overgeneralizing the results of the trial to patients with more severe symptoms and limitations from their coronary artery disease," said Dr. Ajay Kirtane, director of the Cardiac Catheterization Laboratories at New York-Presbyterian/Columbia University Irving Medical Center in New York City.

Stents are proven lifesavers for people suffering from a heart attack due to a blocked artery, and also undeniably improve the health of people with unpredictable bouts of chest pain, said Sharma and Dr. Sidney Smith, an American Heart Association spokesman and professor with the University of North Carolina School of Medicine.

But there's been some serious debate over the benefits of stenting in people with stable angina—predictable, short-lived chest pain that occurs when stress is placed on the heart. Angina is typically caused by the buildup of fatty plaques in the arteries.

The latest trial addressed this question using methods relatively unique in modern medicine, cardiologists said.

The researchers randomly performed a "sham" stenting procedure on half of 200 patients with stable angina, to see if they experienced the same improvement as those who did get a partially blocked artery reopened with a stent. All of the patients received aggressive drug treatment for their chest pain.

The findings have rocked the heart health world. Patients who underwent the fake procedure improved just as much as those who received stents. They reported less chest pain and improved their performance on treadmill tests.

However, questions already are being raised about how applicable the results will be for the world at large.

The British trial involved a very select group of chest pain patients, heart experts noted.

"The fact that it took 3 1/2 years and five large hospitals to enroll only 200 patients suggests that this strategy was applied to a small fraction of patients who were seen at those hospitals," said Dr. Cindy Grines, an interventional cardiologist with Northwell Health's Sandra Atlas Bass Heart Hospital in Manhasset, N.Y.

For example, the patients' chest pain had to come from only one blocked artery, said Dr. Mary Norine Walsh, president of the American College

of Cardiology.

"They didn't include anybody who had more than one vessel seriously narrowed," Walsh said. "We can't extrapolate this study to other patients with more than one vessel involved."

The patients also appeared to be in relatively good health, and initially were able to spend more than eight minutes on a treadmill. That "suggests this is a very low-risk group in whom one could have predicted patients may not benefit from" receiving a stent, Grines said.

But the greatest concern over the trial involves the six-week follow-up period, which many considered too short.

"The true impact clinically of this trial requires more than a six-week follow-up," Smith said. "We need to know what happens to the unstented lesion over a longer period of time."

Previous trials of stenting and other heart procedures typically have followed patients out for six to nine months or even longer, Sharma said.

For example, another clinical trial found that it took at least six months for patients who didn't receive a stent to run into trouble, either suffering a heart attack or requiring an emergency angioplasty, Sharma said.

"The benefit of the stent procedure may not be known at six weeks," Sharma said. "It may take a little longer. If I had designed the study, I would have kept it at six months."

Walsh agreed. "Whether or not long-term people do as well on medical therapy is really not known. This study doesn't answer that question," she said.

Longer follow-up trials will be needed to see whether a purely drug-based approach is better in the long run for patients with stable angina, experts said.

In the meantime, the latest study could promote better conversations between cardiologists and their patients, Walsh said.

"For the patient who is similar to the patients in this trial, that type of patient with one-vessel disease should certainly be in conversation with his or her cardiologist about whether maximizing medical therapy would be as beneficial," Walsh said.

"There are many patients who may prefer stenting, who don't wish to be on as many medications, for example," Walsh continued. "A lot of this really will come down to doctors and patients talking to each other, reviewing this important new piece of data, and making a decision together."

The trial is also a reminder that cardiologists "have to be more careful and analytical of which patients receive a stent," Sharma said.

One relatively recent innovation involves a test of fractional flow reserve (FFR), which measures blood pressure and blood flow through partial blockages of an artery, Sharma said.

Nearly every catheterization lab in the country has one of these devices, which have been shown to accurately predict who needs a stent, regardless of how blocked their artery has become, Sharma said.

In fact, all of the patients in this latest trial underwent an FFR test, and the results showed that about 30 percent had an FFR that would have led them to be placed on medication rather than receive a stent, Sharma noted.

"At present in stable angina, we do additional testing to see whether that blockage is going to give the patient trouble in the future," Sharma said, estimating that about 4 out of 6 patients are placed on drug therapy following their FFR test.

More information: Visit the American Heart Association for more on angina.