

Once-a-day heart combo pill shows promise in study

March 30 2009, By MARILYNN MARCHIONE , AP Medical Writer

(AP) -- A single daily pill that combines aspirin and four blood pressure and cholesterol medicines has passed its first big test, potentially offering a cheap, simple way to prevent both heart disease and stroke.

The experimental "polypill" proved as effective as nearly all of its components taken alone, with no greater side effects, a major study found. Taking it could cut a person's risk of [heart disease](#) and stroke roughly in half, the study concludes.

This "one-size-fits-most" approach could make heart disease prevention much more common and effective, doctors say.

"Widely applied, this could have profound implications," said Dr. Robert Harrington, an American College of Cardiology spokesman and chief of Duke University's heart research institute. "President Obama is trying to offer the greatest care to the greatest number. This very much fits in with that."

The polypill also has big psychological advantages, said Dr. James Stein of the University of Wisconsin-Madison.

"If you take any medicines, you know that every pill you see in your hand makes you feel five years older. Patients really object to pill burden," and respond by skipping doses, he said.

The study was led by Dr. Salim Yusuf of McMaster University in

Hamilton, Ontario, and Dr. Prem Pais of St. John's Medical College, Bangalore, India. Results were presented Monday at the cardiology college's conference in Florida and published online by the British medical journal [Lancet](#).

The study tested the Polycap, an experimental combo formulated by Cadila Pharmaceuticals of Ahmedabad, India. It contains low doses of three [blood pressure](#) medicines (atenolol, ramipril and the "water pill" thiazide), plus the generic version of the cholesterol-lowering statin drug Zocor, and a baby aspirin (100 milligrams).

Participants were about 2,000 people at 50 centers across India, average age 54, with at least one risk factor for heart disease - high blood pressure, [high cholesterol](#), obesity, diabetes or smoking.

Four hundred were given the polypill. The rest were placed in eight groups of 200 and given individual components of the pill or various combinations. Treatment lasted 12 weeks.

Compared to groups given no blood pressure medicines, the polypill lowered systolic blood pressure (the top number) by more than 7 units and diastolic (bottom number) by about 6 - comparable to levels for people given the three drugs without aspirin and the cholesterol drug.

LDL, or bad cholesterol, dropped 23 percent on the polypill versus 28 percent in those taking the statin drug separately. Triglycerides dropped 10 percent on the combo pill versus 20 percent with individual statin use. Neither pill affected levels of HDL, or good cholesterol.

Anti-clotting effects seemed the same with the polypill as with aspirin alone.

Side effect rates also were the same for the polypill as for the five

separate medicines.

"That was a big surprise. I would have expected five times the number of people to have side effects," said Dr. Christopher Cannon, a cardiologist at Harvard-affiliated Brigham and Women's Hospital in Boston who had no role in the study.

Collectively, the results show the polypill could cut the risk of heart disease by 62 percent and the risk of stroke by 48 percent, based on what previous studies show from lowering risk factors by these amounts, the study concludes.

Polycap's maker sponsored the study, and Yusuf has been a paid speaker for several makers of heart drugs. No price for the polypill is available, but its generic components cost only \$17 a month, Cannon said.

A bigger study is now needed to see whether the polypill actually does cut heart attacks and strokes, he wrote in a commentary in the medical journal.

"It won't be for everybody," he said. Some people would be overtreated by getting medicines for conditions they don't yet have, such as high cholesterol. Others may be undertreated by too-low doses in the combo pill. Several polypills of different strengths may be needed, Cannon said.

"We have to be cautious about assuming that one size fits all," Stein said. "Treating risk factors is a lot like cooking - the ingredients count."

A polypill also would need federal Food and Drug Administration approval, even though all of its components have long been sold separately. The dosing issue could become a regulatory nightmare, Cannon warned.

"A final challenge: would the availability of a single magic bullet for the prevention of heart disease lead people to abandon exercise and appropriate diet?" he wrote in the medical journal.

That could make the risk of heart disease worse, and undo the good of the drug, Cannon said.

On the Net:

Cardiology meeting: <http://www.acc.org>

Medical journal: <http://www.lancet.com>

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