

Studies: Drug, device help treat heart failure

November 14 2010, By MARILYNN MARCHIONE , AP Medical Writer

(AP) -- Millions of people with mild or moderate heart failure got good news Sunday, with studies showing a Pfizer drug and a device from Medtronic can boost survival and cut trips to the hospital by patients having trouble breathing.

But another drug that's been used for nearly a decade - Johnson & Johnson's Natrecor - did little to help those with severe heart failure in a big study aimed at settling whether the drug raised the risk of death or kidney problems.

"They resolved the safety issue but in the meantime showed it was not very effective," and it's hard to tell now which patients should get the pricey medicine, said Dr. Alfred Bove, a Temple University heart specialist and past president of the American College of Cardiology.

All three studies were presented Sunday at an American Heart Association conference in Chicago and are expected to have an immediate effect on care.

More than 5 million Americans and 22 million people worldwide have heart failure. It develops when the heart muscle weakens over time and can no longer pump effectively, often because of damage from a heart attack. Fluid can back up into the lungs and leave people gasping for breath.

Inspra, made by New York-based Pfizer Inc., helps block water retention

and is already used for advanced heart failure. In a study of more than 2,700 people with milder symptoms, it cut the risk of death or hospitalization by 37 percent. After nearly two years, less than 13 percent of those on Inspra had died of heart problems versus less than 16 percent of those given dummy pills.

Only 19 people would need to be treated for a year to prevent one heart failure hospitalization, and 51 to prevent one death, said the study's leader, Dr. Faiez Zannad of Nancy University in Nancy, France.

"This has the potential of changing the guidelines," said Dr. Mariell Jessup, who heads the conference and the heart failure program at the University of Pennsylvania.

Many doctors saw an alternative: wider use of an older relative of Inspra, spironolactone, a generic medicine that costs less than 20 cents a day, versus about \$133 a month for Inspra.

Trying the older drug first and reserving Inspra for the few who suffer bad side effects is "a reasonable tactic," Dr. Paul Armstrong of the University of Alberta in Edmonton, Canada, wrote in an editorial published online with the study by the New England Journal of Medicine.

The other good news came from a test of an implanted heart device made by Minneapolis-based Medtronic Inc. Many people with severe heart failure already have defibrillators to zap their hearts if they suffer a rhythm problem. Newer combination devices also control how blood moves through the heart, improving pumping capacity.

"It's all electronics. You can almost build in an alarm clock and a Bluetooth device. You can put anything in those little boxes," but the issue is whether that is worth the extra cost, Bove said. Defibrillators

cost \$20,000 to \$25,000; the combos are \$5,000 to \$7,000 more.

The study tested them in 1,800 Canadian patients with mild to moderate heart failure. More than three years later, 40 percent of those with simple defibrillators had died or been hospitalized for heart failure versus 33 percent of those with combo devices, said Dr. Anthony Tang of the University of Ottawa in Ontario, Canada.

Medtronic and the Canadian Institutes of Health Research paid for the study, and results were published online by the New England Journal of Medicine.

The bad news came from a test of Natrecor, a drug that had meteoric sales after its approval in 2001 because it was the only medicine that seemed to help shortness of breath. One out of every six people hospitalized with heart failure were given Natrecor until it came under a cloud in 2005 when studies suggested it raised the risk of death and kidney problems.

An independent panel recommended that its maker - Scios Inc., a division of New Brunswick, N.J.-based Johnson & Johnson - do a large study to resolve the issue.

In tests involving more than 7,000 patients in 30 countries, Natrecor made no difference in rates of hospitalization or death in the following month and only modestly relieved shortness of breath within 6 hours of its infusion, said Drs. Robert Califf and Adrian Hernandez, Duke University cardiologists who led the study.

Natrecor costs \$500 to \$700 plus infusion costs, Jessup said. If the drug "makes people feel better faster but doesn't impact outcomes, I'm not sure what the role is," she said.

Natrecor still had \$66 million in annual sales in the United States last year, according to IMS Health, a healthcare information company.

More information:

Heart failure information: <http://www.americanheart.org>

and <http://www.nhlbi.nih.gov/health/dci/Diseases/Hf/HF-WhatIs.html>

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