

Study: New drug cuts deaths after heart attack

13 November 2011, By MARILYNN MARCHIONE , AP Chief Medical Writer

People recovering from a heart attack or severe chest pain are much less likely to suffer another heart-related problem or to die from one if they take a new blood-thinning drug along with standard anti-clotting medicines, a large study finds.

But this benefit had a cost: a greater risk of serious bleeding, usually in the [digestive tract](#).

Still, some [doctors](#) said the [drug](#), Xarelto, could become a new standard of care for up to a million Americans hospitalized each year for these conditions. A low dose of the drug substantially cut the risk of dying of any cause during the study.

"[Mortality](#) trumps everything," so a drug that improves survival is a win, said Dr. Paul Armstrong of the University of Alberta in Edmonton, Alberta, Canada.

He had no role in the study, discussed Sunday at an [American Heart Association](#) conference in Florida and published online by the [New England Journal of Medicine](#). The study was sponsored by the drug's makers - Johnson & Johnson and Bayer Healthcare - and some researchers work or consult for the companies.

Xarelto is approved now at higher doses for preventing strokes in people with a common heart rhythm problem and for preventing blood clots after joint surgeries. It works in a different way than aspirin and older blood thinners do.

Dr. C. Michael Gibson of Harvard Medical School led a study testing it in 15,500 patients around the world who were leaving the hospital after a heart attack or severe [chest pain](#) from clogged arteries.

All were prescribed aspirin and an older blood thinner. One-third also received a low dose of Xarelto, and one-third got a higher dose. After about a year on average, nearly 11 percent of those on just the usual medicines had suffered a

heart attack, heart-related death or a stroke versus less than 9 percent of those on either dose of Xarelto.

The lower dose proved better and safer. Fewer than 3 percent of those getting Xarelto died of any cause during the study, compared with 4.5 percent of those getting just the usual medicines. That translates to a 32 percent lower risk with Xarelto.

"Our study group has been going for 27 years and we've not seen that" magnitude of benefit from a drug like this, said Dr. Eugene Braunwald of Harvard-affiliated Brigham and Women's Hospital, the study's chairman.

To prevent a single heart-related death, heart attack or stroke, only 56 people would need to be treated for two years with a low dose of the drug, Gibson said.

However, serious bleeding was nearly four times more common with Xarelto, including bleeding in the head, a potentially disabling side effect. Fatal bleeding was no greater with Xarelto, though.

"There's a trade-off" between thinning the blood to prevent clots and raising the risk of bleeding, said Dr. Roger Blumenthal, preventive cardiology chief at Johns Hopkins Medical Center.

Cost is another issue. Usual care for these patients is changing with newer drugs that have come on the market since this study started. One - ticagrelor, sold as Brilinta in the U.S. and other brands elsewhere - also proved beneficial for similar patients taking just aspirin instead of pricier additional medicines used in the Xarelto study.

Xarelto's makers will seek approval to sell it for people like those in this study by the end of the year, a Johnson & Johnson spokesman said. A price has not been set, but the higher doses sold now for other purposes run more than \$7 a day.

The good results with Xarelto contrast with the disappointing ones from an experimental blood thinner by Merck & Co., vorapaxar.

The drug flopped in a key late-stage study aimed at preventing heart attacks, strokes and other problems in people similar to those in the study of Xarelto - hospitalized for a [heart attack](#) or severe chest pain from clogged arteries.

Vorapaxar gave no significant benefit when added to standard medicines in a study of 13,000 patients around the world. It also raised the risk of serious bleeding.

Merck's senior vice president of cardiovascular research, Dr. Michael Mendelsohn, said results due out early next year from another large study testing vorapaxar in different types of patients will tell more about the drug's potential.

More information:

Heart Association: <http://www.americanheart.org>

New England Journal: <http://www.nejm.org>

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