

Celebrex may not pose bigger heart risk than similar drugs: study

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(HealthDay)—Some people taking the pain reliever Celebrex may not have a greater risk for heart problems than those taking other nonsteroidal anti-inflammatory drugs (NSAIDs), a new study says.

Celebrex (celecoxib) is a COX-2 inhibitor. That's the same class of drugs as Vioxx and Bextra, which were pulled from the market in 2004 and 2005, respectively, because they were linked to [heart problems](#). Celebrex didn't seem to share the same issues, so has remained available.

And the new trial's "primary message is that celecoxib is not riskier for the heart than other NSAIDs," said study director Dr. Steven Nissen in a Cleveland Clinic news release. Nissen is chair of the Department of Cardiovascular Medicine.

Nissen's prior research was instrumental in uncovering the cardiovascular risks associated with COX-2 inhibitors.

The new study seems to reaffirm Celebrex's safety

profile. However, several [heart disease](#) specialists aren't convinced that this study's findings are sufficient to say that Celebrex is safe for people with a high risk of heart problems.

This study included more than 24,000 osteoarthritis or rheumatoid arthritis patients worldwide. Their average age was 64. They took one of three drugs daily for pain relief: Celebrex, Naprosyn (naproxen) or Motrin (ibuprofen). The patients all had pre-existing heart disease or an increased risk for developing heart disease.

Through 10 years of follow-up, heart attack, stroke or death occurred in 2.3 percent of patients taking Celebrex, 2.5 percent of patients taking Naprosyn, and 2.7 percent of patients taking Motrin, the study showed.

The research found that ulcers or gastrointestinal bleeding was 54 percent higher in the Motrin group and 41 percent higher in the Naprosyn group than in the Celebrex group.

Patients taking Motrin had a 64 percent higher risk of worsening kidney function than those taking Celebrex. Death from any cause was about 25 percent higher in the Naprosyn group than in the Celebrex group, but this difference was very slight, according to the researchers.

The study was funded by Celebrex maker Pfizer Inc. Four of the study co-authors work at the drug company. Pfizer took part in the study design, development of protocol and assisted with data collection and maintained the trial database.

The study was scheduled to be presented Sunday at the annual meeting of the American Heart Association, and simultaneously published Nov. 13 *New England Journal of Medicine*.

Nissen cautioned against over-interpreting the study's findings.

The study examined "full prescription doses of these drugs, not the lower doses available in over-the-counter preparations. The safety findings may or may not apply to the typical intermittent use of lower doses of these drugs by many patients," Nissen explained.

Other physicians also expressed concern.

Dr. Elliott Antman, a past president of the American Heart Association, questioned whether the clinical trial actually proved that Celebrex is safe in people with heart disease.

Antman noted that the participants in the study were being treated for arthritis, and weren't at high risk for heart disease.

"These were patients at low or maybe slightly moderate risk," Antman said. "Originally, this was a trial that was supposed to compare the outcomes in high-cardiovascular-risk patients. But I still have that question, because we don't have those high-cardiovascular-risk patients represented here."

The American Heart Association also published an editorial in its journal *Circulation* that questioned whether the new clinical trial actually proved the safety of Celebrex for heart patients.

The clinical trial is "not a study of arthritis patients at high cardiovascular risk," wrote the editorial's author, Dr. Garrett FitzGerald, a professor at the University of Pennsylvania's Perelman School of Medicine.

"It mostly included osteoarthritis patients at low cardiovascular risk—cardiac event rates were roughly 1 percent per year," he wrote.

The trial "fails to inform clinical practice," FitzGerald concluded.

"Despite the enrollment of more than 24,000 patients and more than a decade of study, we are no closer to being able to advise the millions of patients with chronic arthritic pain regarding relative efficacy and safety of the treatments available to them," he said.

Doctors should continue to avoid use of any NSAIDs in heart patients, Antman cautioned.

"If one must treat a patient with an NSAID, attempt to identify the lowest-risk patient, use the lowest-risk drug in the lowest dose needed for the shortest period of time," Antman said.

NSAIDs were first introduced in the 1960s and are now among the world's most widely prescribed drugs, with 100 million prescriptions written in the United States in 2013, the study authors said.

Osteoarthritis is the most common form of arthritis and affects more than 16 million Americans. Rheumatoid arthritis is an autoimmune disease of joints, and affects more than 1.3 million Americans. Patients with rheumatoid arthritis have an increased risk for heart disease, the researchers said.

In the study, 90 percent of [patients](#) had osteoarthritis and 10 percent had [rheumatoid arthritis](#).

More information: The U.S. Food and Drug Administration has more on [NSAIDs](#).

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