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PRESS RELEASE

Weill Cornell research highlights pros and cons of non-prescription painkillers

Reaffirming Weill Cornell's role as a leader in the field of medical research, a recent collaborative study published online in the medical journal, *The Lancet*, on October 7th 2005, finds that the use of pain relievers such as ibuprofen and naproxen for six months or more, whilst reducing the risk of oral cancer, increases the users' risk for cardiovascular death. Cardiovascular-dose aspirin was the exception to the rule, in that it did not increase users' risk for cardiovascular death.

The study was conducted by researchers at the Norwegian Radium Hospital and The National Hospital in Oslo; University of Science and Technology, Trondheim, Norway; New York-Presbyterian Hospital / Weill Cornell Medical Center in New York City; The University of Texas M. D. Anderson Cancer Center in Houston; and the University of Helsinki.

An analysis of 20 years of data on the health of over 900 adults found that while long-term use of traditional non-steroidal anti-inflammatory drugs (NSAIDs) cuts the risk for oral cancer in smokers by half, it also doubles users' risks for cardiovascular death.

"Our findings highlight how a commonly used drug can have a benefit from the standpoint of cancer prevention but can also have side effects -- in this case, an increased risk for cardiovascular death," said co-researcher Dr. Andrew Dannenberg, the Henry R. Erle, M.D., Professor of Medicine at Weill Medical College of Cornell University and Director of Cancer Prevention at NewYork-Presbyterian / Weill Cornell.

The Weill Cornell team in collaboration with its co-researchers took a retrospective look at the data collected prospectively from 1975 to 1995 on more than 123,000 adults participating in

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the Norwegian Health Survey. The survey tracks participant lifestyles, habits and long-term health outcomes, and is one of the richest such databases in the world.

The team narrowed their focus to 454 people with oral cancer and 454 others without such malignancies matched for age and sex. All of the individuals had a history of heavy smoking.

Specifically looking for associations between the long-term use of traditional, non-COX-2-specific NSAIDs and the risk of oral cancer, the researchers did find a correlation: adults who were prescribed NSAIDs such as aspirin, ibuprofen, naproxen, indomethacin, piroxicam and ketoprofen for six months or more (most of them for much longer periods, with 88 per cent taking NSAIDs for five years or more) were at a 53 per cent lowered risk for oral malignancies compared with those who did not take the drugs over the long-term.

But even though the drugs appeared to protect users from oral cancer there was no added benefit overall in terms of prolongation of life or reduced mortality. Digging deeper, they identified that the long-term use of traditional NSAIDs, except for cardiovascular-dose aspirin, doubled users' risk for cardiovascular death.

This type of elevated heart risk had already been noted with a subclass of NSAIDs called COX-2 inhibitors, drugs like the now-recalled Vioxx and Bextra and a third (still available) painkiller, Celebrex, which target a specific enzyme linked to inflammation, but this is the first time such findings have been associated with main stream NSAIDs.

The investigators stressed that the study does have its limitations. Although the data itself was collected prospectively, the study remains a relatively small, retrospective effort, and the results have to be confirmed by much larger, prospective trials.

So, might long-term use of traditional NSAIDs still be right for some people? According to the study, investigators recommend a careful risk-benefit assessment, taking into consideration the specifics of each individual case. This should be undertaken by a doctor in consultation with his patient.