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Common painkiller linked to increased risk of major heart problems

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The commonly used painkiller diclofenac is associated with an increased risk of major cardiovascular events, such as heart attack and stroke, compared with no use, paracetamol use, and use of other traditional painkillers, finds a study published by *The BMJ* this week.

The findings prompt the researchers to say that diclofenac should not be available over the counter, and when prescribed, should be accompanied by an appropriate front package warning about its potential risks.

Diclofenac is a traditional non-steroidal anti-inflammatory drug (NSAID) for treating pain and inflammation and is widely used across the world.

But its cardiovascular risks compared with those of other traditional NSAIDs have never been examined in large randomised controlled trials, and current concerns about these risks make such trials unethical to conduct.

So a research team, led by Morten Schmidt at Aarhus University Hospital in Denmark, examined the cardiovascular risks of starting diclofenac compared with no NSAIDS, starting other traditional NSAIDs, and starting paracetamol.

The results are based on national registry data for more than 6.3 million adults in Denmark with at least one year of continuous prescription records before study entry in January 1996.

Participants were split into low, moderate, and high baseline cardiovascular risk. Average age was 46-49 years among participants starting NSAIDs and 56 years among those starting paracetamol.

After taking account of potentially influential factors, starting diclofenac during the study period (1996-2016) was associated with an increased rate of major adverse cardiovascular events within 30 days compared with starting other traditional NSAIDs (ibuprofen or naproxen) or starting paracetamol.

Events included irregular heart beat or flutter, ischaemic stroke, heart

failure, and heart attack. The increased risks applied to men and women of all ages and also at low doses of diclofenac.

Starting diclofenac was also associated with an increased rate of cardiac death compared with no NSAIDs, and an increased risk of upper gastrointestinal bleeding compared with no NSAIDs, starting ibuprofen or paracetamol, but not with naproxen.

The authors point out that, although the relative risk was increased, the absolute risk remained low for the individual patient.

When results were analysed by baseline cardiovascular risk, the absolute number of events per 1000 diclofenac starters per year also increased. For example, among patients at low baseline risk, diclofenac starters had one additional event versus ibuprofen starters, one additional event versus naproxen starters, three additional events versus paracetamol starters, and four additional events versus no NSAIDs. Among patients at moderate baseline risk, corresponding figures were seven, seven, eight, and 14 additional events, respectively, and for those at high baseline risk, corresponding numbers were 16, 10, one, and 39 additional events, respectively.

This is an observational study, so no firm conclusions can be drawn about cause and effect. However, the study's sample size is larger than most previous analyses of observational and randomised studies taken together and provides strong evidence to guide clinical decision making.

"Treatment of pain and inflammation with NSAIDs may be worthwhile for some patients to improve quality of life despite potential side effects," they write. "Considering its cardiovascular and gastrointestinal risks, however, there is little justification to initiate diclofenac treatment before other traditional NSAIDs," they conclude.

More information: Association between diclofenac use and cardiovascular risks in Denmark: series of nationwide cohort studies, *BMJ* (2018). www.bmj.com/content/362/bmj.k3426