

New analysis of the cardiovascular risks of common non-steroidal anti-inflammatory drugs

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An updated study published in this week's *PLoS Medicine* gives some new information on the cardiovascular risks of non-steroidal anti-inflammatory drugs (NSAIDs) and suggests that among these commonly used drugs, naproxen and low dose ibuprofen are least likely to increase cardiovascular risk whereas diclofenac, even in doses available without prescription, elevates risk.

Using only <u>observational studies</u> (30 case-control studies and 21 cohort studies) because <u>randomised controlled trials</u> have only reported small numbers of <u>cardiovascular events</u>, the authors, Patricia McGettigan (Hull York Medical School, Hull, UK), and David Henry (Institute for Clinical Evaluative Sciences, Toronto, Canada) also found that the new NSAID, <u>etoricoxib</u>, has a high risk of cardiovascular events similar to that of drugs that have been withdrawn because of safety concerns and that new evidence on <u>cardiovascular risk</u> of indomethacin, an older drug, casts doubt on its continued clinical use.

The authors say: "the large sizes of the studies reviewed here, the presence of consistent dose-response relationships, and general agreement with the results of randomised trials give us confidence in the results." They add: "In our view, the results are sufficiently robust to inform clinical and regulatory decisions."

This study highlights the importance of adequately assessing drug safety



in clinical trials and in an editorial the <u>PLoS Medicine</u> editors write: "debates continue about the best ways to meaningfully synthesize and interpret data on the possible harmful effects of drugs – for example, how passive surveillance systems (spontaneous reports of suspected adverse reactions) should be improved, whether new drugs should go through a phased launch process with enhanced safety evaluation, and the appropriateness of risk mitigation strategies for drugs with safety concerns."

The editors conclude: "However, these challenges should not detract investigators, regulators, and patients from demanding a higher safety standard for approved drugs. Higher standards will require both greater transparency – in revealing what studies are being conducted and what data have been generated – and greater willingness of funders to support new studies specifically addressing drug safety."

More information: McGettigan P, Henry D (2011) Cardiovascular Risk with Non-Steroidal Anti-Inflammatory Drugs: Systematic Review of Population-Based Controlled Observational Studies. *PLoS Med* 8(9): e1001098. doi:10.1371/journal.pmed.1001098

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