

Diclofenac still frequently prescribed to high-risk patients despite warnings

Taking the painkiller diclofenac may significantly increase the risk of heart attack and stroke in heart patients. Already six years ago, an official warning was issued from the European Medical Agency. Yet, many high-risk patients continue to receive the painkiller.

Scientists from the Leibniz Institute for Prevention Research and Epidemiology – BIPS in Germany recently reached this conclusion in a study published in the Journal of Internal Medicine (JIM).

As early as 2013, a so-called "Dear Doctor Letter", used to inform experts about newly identified drug risks, was sent to doctors stating that diclofenac should no longer be prescribed to certain patient groups. These include, for example, patients with heart insufficiency, ischemic heart disease or cerebrovascular diseases. A drug called Vioxx (active ingredient: rofecoxib) with a risk profile similar to that of diclofenac was taken off the market in 2004 after leading to numerous cardiovascular deaths.

Warning to no avail

On the basis of health insurance claims data from Germany, the BIPS team examined the prescribing behavior of diclofenac before and after the 2013 "Dear Doctor Letter". It turned out that in absolute terms there were significantly less first-time diclofenac prescriptions in 2014 than in 2011. Of the more than 10 million people observed, 30 percent fewer received diclofenac for the first time in 2014 compared to 2011. However, 12 percent of the people with diclofenac prescriptions in 2014 still had cardiovascular contraindications—the same proportion as in 2011. "It appears that the decline in diclofenac prescriptions was a general trend without any special effect on the risk groups. The prescribing behavior does not really reflect the new contraindications," says Oliver Scholle, first author of the study.

"We are planning further analyses with even more recent data, but we expect that without further warnings there will be no changes in the prescribing behavior. It must be assumed that these prescriptions have led to heart attacks and strokes that could have been avoided, because there are safer alternatives to diclofenac," adds Prof. Dr. Ulrike Haug, last author of the study and head of the Department of Clinical Epidemiology at BIPS. She adds: "It is absolutely vital to raise awareness of the risks of diclofenac in medical practices—even for



short-term use and lower doses. Likewise, there is a need for studies investigating how prescription behavior in risk groups may be sustainably modified."

Original publication: Scholle O, Kollhorst B, Haug U. Are prescribers not aware of cardiovascular contraindications for diclofenac? A claims data analysis. Journal of Internal Medicine. 2019; (Epub 2019 Nov 11th). https://doi.org/10.1111/joim.12990

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