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Study shows celecoxib as safe as other prescribed NSAIDs

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A large-scale international study of thousands of arthritis patents has found the risks arising from prescribed use of some of the most common pain killers are relatively low, offering reassurance to doctors and patients.

The SCOT study (Standard care versus Celecoxib Outcome Trial), which is published today in the *European Heart Journal*, set out to examine the comparative safety of treating arthritis either with commonly used non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, diclofenac and naproxen, or a newer class of more targeted drugs called COX2 inhibitors, which include celecoxib.

The trial, involving more than 7000 patients, found the use of either NSAIDS or celecoxib was associated with only a low rate of the cardiovascular problems studied. In addition, gastrointestinal adverse effects studied were very rare indeed.

"If you need to take these medicines for arthritis pains and you have no history of heart attack or stroke, then either type of medicine seems acceptably safe," said Professor Tom MacDonald, of the University of Dundee School of Medicine and Chief Investigator on the study.

"These results offer significant reassurance to the many patients taking these medicines and can give increased confidence to the doctors prescribing these drugs."

The SCOT trial was led by the University of Dundee, working in collaboration with a wide range of universities in Scotland (Aberdeen, Glasgow and Edinburgh), England (Nottingham, Oxford, Birmingham, University College London), Denmark (University of Southern Denmark) and the Netherlands (Julius Centre, University of Utrecht). The study data centre was the Robertson Centre for Biostatistics at the University of Glasgow.

The study was sponsored by the University of Dundee, with an unrestricted Investigator Initiated Research Grant from Pfizer USA.

The potential gastrointestinal adverse effects, such as stomach ulcers and gut bleeding, arising from the use of NSAIDs have led to concerns from both doctors and patients about using these treatments for the long term relief of arthritis symptoms.

It was hoped that the new group of more targeted COX2 drugs would reduce some of these possible problems, but prescribing of these reduced when concerns arose that they may be associated with increased cardiovascular (CV) diseases.

Despite ongoing scientific debate, a reliable comparison of celecoxib and older non-selective NSAIDs which specifically examined cardiovascular consequences was lacking. The SCOT Trial was carried out to help answer the question, is it similarly safe to treat arthritis with the selective COX2 NSAID celecoxib or other older non-selective NSAIDs?

About 7,300 patients, average age 68, with arthritis managed in family doctor practices in the UK, Denmark and the Netherlands took part in the study. Patients taking chronic non-selective NSAID treatments for arthritis and who had no history of established CV disease were written to by their family doctor asking if they would like to participate.

Subjects who agreed were screened for suitability then were randomly allocated to continue their usual NSAID painkiller or switch to celecoxib. Patients were then tracked looking for hospitalisations for heart attacks, strokes or CV deaths.

Whilst no subject in SCOT had established CV disease at entry to the study, this population of people had the usual risk factors for CV disease such as high blood pressure (44%), high cholesterol (34%), smoking (15%) and diabetes (8%). Despite these risk factors the rate of CV events that occurred during the study was low, at less than half of that expected at about 9 events per 100 patients over a ten-year period.

"This risk is close to what one might expect to find in a healthy population without risk factors or arthritis," said Professor MacDonald.

"With such a low rate of CV or gastrointestinal problems occurring, it is difficult to say that celecoxib or other NSAIDs can be causing much disease. However, the very low rate of gastrointestinal problems may be due to the concomitant use of proton pump inhibitor drugs such as omeprazole which are now very widely prescribed alongside NSAIDs.

"Whilst celecoxib and NSAIDs had similar safety, there was no overall benefit of a strategy of switching arthritis patients from their usual NSAID to celecoxib. However SCOT provides reassuring data that the risks of taking prescription celecoxib or other NSAIDs are low."

An additional finding from the study was that when the prescribing of the NSAID that the patient had been taking for a long time was switched to celecoxib, then quite a high proportion of people switched back to their previous NSAID.

"There are 23 different NSAIDs available for prescription and we know that some patients try a few before finding one that suits them best,"

added Professor MacDonald. "Switching back was more common in subjects taking diclofenac at entry and this might be because diclofenac is one of the most effective NSAIDs for arthritis."

More information: Thomas M. MacDonald et al. Randomized trial of switching from prescribed non-selective non-steroidal anti-inflammatory drugs to prescribed celecoxib: the Standard care vs. Celecoxib Outcome Trial (SCOT), *European Heart Journal* (2016). DOI: 10.1093/eurheartj/ehw387

Provided by University of Dundee