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SCOT Study Quells Concerns About NSAID Safety

In older patients with arthritis and no history of cardiovascular disease, chronic use of any non-steroidal anti-inflammatory drug appears safe from a cardiovascular and gastrointestinal stand-point, and regular, non-selective NSAIDs such as ibuprofen and diclofenac appear just as safe as the selective cyclooxygenase-2 (COX-2) inhibitor celecoxib according to results the SCOT trial.

The Standard care versus Celecoxib Outcome Trial (SCOT) was presented in a Hot Line session at ESC Congress 2015.

The large trial, which included more than 7-thousand subjects taking chronic, prescribed NSAIDs in a primary care setting, is strong evidence for the safety of these medications overall, in light of recent debate about whether COX-2 inhibitors might carry less gastrointestinal risk but more cardiovascular risk compared to non-selective NSAIDs (nsNSAIDs), said Professor Thomas M MacDonald, MD, principal investigator of the study, from the University of Dundee in Scotland.

“We found no difference between nsNSAIDs and celecoxib, with low cardiovascular and upper gastrointestinal adverse event rates overall,” he commented. “In our view, it seems unlikely that another trial of nsNSAIDs versus COX2 inhibitors in subjects free from cardiovascular disease will ever be done due to the low event rates in this population.”

The trial included primary care patients aged 60 years and more who were free from known cardiovascular disease and taking chronic nsNSAIDs for their osteoarthritis or rheumatoid arthritis.

Subjects were randomly assigned to continue their nsNSAID or switch to celecoxib and then followed for a median of three years. The primary endpoint was a cardiovascular composite of hospitalisation for non-fatal myocardial infarction, hospitalisation for other biomarker positive acute coronary syndrome, non-fatal stroke or cardiovascular death.

The main secondary outcome was hospitalisation or death for upper gastrointestinal ulcer complications such as bleeding, perforation or obstruction.

The study found no significant differences between groups for any of the outcomes, with the cardiovascular outcome occurring in 1.8 % of the celecoxib group and 2.2% of the nsNSAID group (hazard ratio1.12; P=0.50).

Ulcer-related upper gastrointestinal complications were also uncommon in both groups.

Serious adverse reactions occurred at a similar rate (5.2% in the celecoxib group versus 5.8% in the nsNSAID group), but there were significantly more non-serious adverse reactions in the celecoxib group than the nsNSAID group (22% versus 16.1%, P<0.001) and significantly more patients withdrew from celecoxib compared to nsNSAID treatment (50.9% versus 30.2%, P< 0.0001).

“The main reasons given for withdrawal from celecoxib were lack of efficacy, poor tolerability and adverse effects suggesting that celecoxib was not as potent or as well tolerated as nsNSAIDs,” commented Professor MacDonald.

“However, it is fair to say that there was a lot of adverse publicity about selective COX-2 inhibitors and also subjects who have been taking long term nsNSAIDs might less likely to stay on celecoxib,” he added.

“Overall, in subjects who do not have significant cardiovascular disease, taking nsNSAIDS or celecoxib does not appear to confer major risk of subsequent cardiovascular disease,” he concluded.

Source: ESC

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