

**Celecoxib inhibitor no safer than naproxen plus proton pump inhibitor**

**Clinical question** In patients with previous peptic ulcer, is celecoxib safer than naproxen taken with a proton pump inhibitor?

**Bottom line** For patients at high risk of recurrent peptic ulcer with non-steroidal anti-inflammatory drug (NSAID) therapy, celecoxib was no more effective than the combination of naproxen and lansoprazole in preventing serious adverse effects and was more likely to cause dyspepsia symptoms. The benefit of cyclo-oxygenase-2 inhibitors in preventing serious gastrointestinal adverse events is likely to be overstated.

**Synopsis** The researchers, conducting this study in Hong Kong, identified adults who developed upper gastrointestinal bleeding while receiving NSAIDs. Approximately half (56 per cent) of the patients were positive for *Helicobacter pylori*. Following treatment of the ulcer for six weeks, the 242 patients were randomly assigned (allocation concealment uncertain) to receive six months of treatment with either celecoxib 200mg daily or naproxen 250mg three times daily with lansoprazole 30mg daily. The investigators and the patients were aware of treatment assignment, although a team of gastroenterologists, who were unaware of treatment assignment, adjudicated all end points. Analysis was by intention to treat. The study had the power to demonstrate a 7-percentage point difference in ulcer relapse, assuming a 4.5 per cent incidence of ulcer relapse. The major outcome was complicated ulcer complications: bleeding with

melaena or haematemesis or a drop in haemoglobin of at least 2g/dL, perforation or obstruction. This outcome occurred in 11 patients (4.5 per cent) and, although more occurred in the naproxen/lansoprazole group (n=7), the rates were not statistically different. Patients receiving celecoxib were more likely to report dyspepsia symptoms during treatment, although other adverse events were similar between the two groups. A similar study found no difference in adverse events comparing celecoxib with diclofenac plus omeprazole (*Gastroenterology* 2004;127:1038–43). The proton pump inhibitor therapy may not be necessary; one other study has shown that celecoxib is not better than either ibuprofen or diclofenac without acid suppression in preventing serious gastrointestinal side effects in patients (*JAMA* 2000;285:1247–55).

**Level of evidence** 1b– (individual randomised controlled trial with a wide confidence interval)

**Reference** Lai KC, Chu KM, Hui WM, et al. Celecoxib compared with lansoprazole and naproxen to prevent gastrointestinal ulcer complications. *American Journal of Medicine* 2005;118:1271–78.

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