Naproxen sodium did not lead to substantially more upper gastrointestinal tract bleeding than ibuprofen during short term use as an analgesic


Question
Do patients who use naproxen sodium as an over the counter analgesic have an increased risk of upper gastrointestinal tract bleeding compared with those who use ibuprofen?

Design
A case cohort study in which exposure to naproxen sodium and ibuprofen was compared in patients from a claims database who had upper gastrointestinal tract bleeding and in a subcohort of patients from the database.

Setting
Michigan and Ohio, USA.

Participants
Patients were eligible if they had received benefits from Ohio Medicaid or Michigan Medicaid and had received naproxen sodium or ibuprofen, but not both drugs. From a cohort of 378 919 patients in the Computerized On-Line Medical Pharmaceutical Analysis and Surveillance System (COMPASS), 59 patients (54% men) who were admitted to hospital for upper gastrointestinal tract bleeding within 14 days of their first prescription for naproxen sodium (n=26) or ibuprofen (n=33) were selected as case patients; a random sample of 37 891 patients (71% women) was selected as a subcohort to determine relative prescription rates (n=10 024 for naproxen sodium; n=27 867 for ibuprofen).

Assessment of risk factors
Age, sex, race, US state, inpatient and outpatient diagnoses, drugs dispensed for outpatients, and any over the counter drugs that were paid for by Medicaid were extracted from COMPASS.

Main outcome measures
Inpatient diagnoses recorded in COMPASS were used to identify patients who had upper gastrointestinal tract bleeding within 14 days of their first prescription of naproxen or ibuprofen.

Commentary
Epidemiological studies of patients taking prescribed non-steroidal anti-inflammatory agents (NSAIDs), or concomitant use of other NSAIDs were excluded from the analysis (n=10 for the case patients; n=7989 for the subcohort) and the results were adjusted for the state of residence, age group, sex, and presence of pre-existing gastrointestinal tract bleeding. Compared with patients who received ibuprofen, those who received naproxen sodium had an increase in the adjusted relative risk of upper gastrointestinal tract bleeding that required hospital admission (adjusted relative risk 2.0, 95% CI 1.1 to 3.8), but no increase in the absolute risk occurred (adjusted absolute risk difference 0.0011%, CI −0.0001% to 0.0023%).

Conclusions
The incidence of upper gastrointestinal tract bleeding was low for naproxen sodium and ibuprofen. Although patients who used naproxen sodium as an analgesic had an increase in the relative risk of upper gastrointestinal tract bleeding that required hospital admission, no increase occurred in the absolute risk.

Gut: first published as 10.1136/gut.43.3.315 on 1 September 1998. Downloaded from http://gut.bmj.com/ on September 24, 2023 by guest. Protected by copyright.