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OC-016

REDUCING THE INCIDENCE OF PEPTIC ULCERS WITH IBUPROFEN-FAMOTIDINE COMBINED PILL, HZT-501 (REDUCE): PHASE-III, DOUBLE-BLIND MULTI-CENTRE TRIALS

doi:10.1136/gut.2011.239301.16

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Introduction The prevention of peptic ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs) is hampered by the high pill burden and suboptimal adherence to protective therapy. We therefore investigated the efficacy of HZT-501 (ibuprofen 800-mg plus famotidine-26.6 mg) in the prevention of peptic ulcers in patients requiring NSAIDs.

Methods Patients without ulcers at baseline were randomly assigned, in approximately a 2:1 ratio, to receive HZT-501 or ibuprofen 800-mg three times daily and entered into two multi-centre trials (REDUCE-1 and REDUCE-2) with identical designs. They were re-endoscoped at 8, 16 and 24 weeks. The primary endpoints were the development of new ulcers during 24 weeks. The data from the two trials were pooled and analysed using a primary population analysis.

Results At 24 weeks, comparing patients assigned to HZT-501 with patients assigned to ibuprofen, gastric ulcers had developed in 92 (9.9%) of 930 patients compared with 86 (19.0%) of 452 patients ($p < 0.0001$); duodenal ulcers in 10 (1.1%) patients compared with 23 (5.1%; $p < 0.0001$); and at least one gastric or duodenal ulcer in 102 (11.0%) patients compared with 99 (21.9%; $p < 0.0001$). The cumulative incidence of gastro-duodenal ulcers was also lower in the HZT-501 group, as shown in figure 1. Also, fewer patients developed ulcers while taking low-dose aspirin or other anti-thrombotic agents with HZT-501 than those taking such agents with ibuprofen.

Figure 1 The cumulative incidence of gastro-duodenal ulcers in patients receiving HZT-501 (ibuprofen plus famotidine) or ibuprofen alone.

Conclusion Ibuprofen combined with famotidine (HZT-501) results in fewer peptic ulcers regardless of aspirin use. This might improve adherence to mucosal protective therapy in NSAID users.

Competing interests A. Taha Consultant for: Membership of Advisory Panel for Horizon Pharma, L. Laine Consultant for: Membership of Advisory Panel for Horizon Pharma, A. Grahn Conflict with: Employee of Horizon Pharma.

Keywords aspirin, duodenal ulcer, famotidine, gastric ulcer, ibuprofen, NSAIDs.