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RISK OF UPPER GASTROINTESTINAL BLEEDING AMONG USERS OF CLOPIDOGREL AND LOW-DOSE ACETYLSALICYLIC ACID

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Background: Case series and clinical trials suggest that combination antiplatelet therapy with low-dose acetylsalicylic acid (ASA) and clopidogrel is associated with an increased risk of upper gastrointestinal bleeding (UGIB). The aims of this study were to estimate the risk of UGIB among users of these drugs (either alone or in combination) in the general population, and to assess whether use of proton pump inhibitors (PPIs) reduces the risk of UGIB in these individuals.

Methods: The Health Improvement Network UK primary care database was used to identify all individuals aged 40-84 years with a confirmed diagnosis of UGIB in 1997-2007 (n = 2049). An age-, sex- and calendar year-matched control group was also identified from the same source population (n = 20 000). The relative risk (RR) of UGIB associated with current use of clopidogrel and low-dose ASA (75-300 mg/day) was estimated and stratified by PPI use (≥ 180 days).

Results: Current use of low-dose ASA was associated with a significant increase in the risk of UGIB compared with non-use (RR: 1.83; 95% confidence interval [CI]: 1.63-2.05). This increase in risk was slightly higher in patients who had been taking low-dose ASA for 91-365 days than in those who had been taking it for ≤ 90 days. The increase in risk remained significant in those who had been taking low-dose ASA for > 1 year. Current use of clopidogrel was also associated with a similar increase in the risk of UGIB (RR: 1.81; 95% CI: 1.37-2.39). The risk of UGIB in patients who were taking both low-dose ASA and clopidogrel (RR: 3.67; 95% CI: 2.46-5.48) was statistically higher than that in those who were taking just one of these drugs. Compared with no PPI use, concomitant PPI use was associated with a reduction in the risk of UGIB in patients who were using low-dose ASA alone (RR: 0.75; 95% CI: 0.55-1.02), in those who were using clopidogrel alone (RR: 0.56; 95% CI: 0.27-1.16) and in those who were taking low-dose ASA and clopidogrel (RR: 0.43; 95% CI: 0.15-1.25).

Conclusions: Use of low-dose ASA or clopidogrel is associated with an almost twofold increase in the risk of UGIB. Concomitant use of both drugs is associated with an additive increase in risk. PPI use can reduce the risk of UGIB associated with these drugs.