

Oral Presentation

TITLE	Misoprostol for the healing of small bowel ulcers in obscure bleeding related to aspirin and non-steroidal anti-inflammatory drugs (MASTERS): a randomised, double-blind, placebo-controlled, phase 3 trial.
AUTHOR(S)	Ali S Taha, Caroline McCloskey, Paula McSkimming, Theresa Craigen, Debbie Callaghan, and Alex McConnachie.
ADDRESS	University Hospital Crosshouse, Kilmarnock, University of Glasgow School of Medicine, and Robertson Centre for Biostatistics, Institute of Health and Wellbeing, University of Glasgow, Glasgow, Scotland.
ABSTRACT DETAILS:	
Background:	The incidence of obscure gastrointestinal bleeding is rising. This is now accepted to originate from the small bowel and to be mainly related to aspirin and non-steroidal anti-inflammatory drugs (NSAIDs).
Method:	This was a prospective, randomised, placebo-controlled trial, comparing the efficacy of misoprostol 200 µg with placebo, taken 4 times daily for 8 weeks, for the healing of small bowel ulcers or erosions. These lesions were detected by video capsule endoscopy in patients using low-dose aspirin or NSAIDs who had normal upper endoscopy and colonoscopy; they presented with iron deficiency anaemia, a drop in haemoglobin level of $\geq 20 \times 10^3$ mg/ L, or positive faecal occult blood test. The trial was registered at ClinicalTrials.gov (NCT02202967).
Results:	Of 232 patients screened, 102 eligible patients were randomised: 50 (49%) took misoprostol and 52 (51%) took placebo. Complete healing of ulcers and erosions was observed in 27/50 (54%) misoprostol patients vs. 9/52 (17%) in the placebo group, $p=0.0002$. Viewed separately, similar results were seen for healing of ulcers (34/50, 68% vs. 17%, $p<0.0001$) and erosions (28/50, 56% vs. 11/52, 21%, $p=0.0005$). There were no significant changes in haemoglobin levels. Mild, moderate, or severe adverse events (abdominal pain, nausea/vomiting, diarrhoea, or other events) were observed in 46% of misoprostol patients (23/50) vs. 42% placebo (22/52; $p=0.84$), but were more severe in the misoprostol group ($p=0.017$). There were 4 out of 50 (8%) patients in the misoprostol group vs. zero in the placebo group with severe adverse events (6 events in total) and no patients with any serious adverse events.
Conclusions:	Misoprostol is effective in the healing of small bowel ulcers and erosions in patients using low-dose aspirin and NSAIDs. Currently, this might be the only option for the pharmacological treatment of lesions causing obscure gastrointestinal bleeding related to these agents, and its use has to be balanced against the risk of misoprostol side effects.
References:	