

ORIGINAL PAPER

The suppression of gastro-oesophageal reflux by alginates

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Disclosures

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SUMMARY

Aims: The aim of this study was to compare alginate products with the same amount of active ingredients but different dosage forms, in the suppression of reflux provoked by a standard meal in healthy human volunteers, using ambulatory oesophageal pH monitoring. **Methods:** This was a single centre, randomised, open, three-period crossover, controlled study comparing Gaviscon Advance® (10 ml) with a control (10 ml water) and with a new tablet product containing the same active ingredients as Gaviscon Advance®. Volunteers who had oesophageal pH < 4 for at least 2% of the 4-h period after ingestion of a test meal followed by control at a reflux screening visit were included in the study. **Results:** The difference between Gaviscon Advance® and control in the mean angular transformed percentage of time for which oesophageal pH fell below four was statistically significant ($p < 0.0001$) demonstrating the sensitivity of the method. No significant difference between the two alginate products was found based on the least squares adjusted mean angular transformed percentage of time for which pH fell below four. There were also no significant differences between the two alginate dosage forms in the angular transformed percentage of time for which oesophageal pH fell below five and in the log-transformed number of occasions on which oesophageal pH fell below four and five. **Discussion and conclusion:** The study shows that alginate reflux suppressants containing a low amount of antacid are effective in suppressing acid reflux and that suspension and tablet forms are able to give equivalent acid suppression.

What's known

Measurement of acid in the oesophagus by oesophageal pH monitoring is the most accepted diagnostic tool for reflux measurement. Previous studies have been sufficiently sensitive to demonstrate reduced oesophageal reflux exposure using alginate-based reflux suppressants compared with water, without preselecting volunteers. They have not however been sensitive enough to provide evidence that two similar reflux suppressants are not statistically different from each other in their ability to reduce acid exposure.

What's new

Optimum sensitivity in healthy volunteers can be achieved by preselecting only those who had a pH < 4 for at least 2% of the 4-h period after ingestion of a test meal followed by a water control. This has been used to show that tablet and suspension forms of an alginate reflux suppressant containing low antacid perform equally well, producing strong raft formation and effective reflux suppression.

Introduction

Gastro-oesophageal reflux disease (GORD) is a common disorder diagnosed in up to 40% of the population of western countries on a western diet (1). The most common perception of the disease is that of a burning sensation or pain in the region of the chest close to the heart (hence the term 'heartburn') caused by reflux of acidic stomach contents into the unprotected oesophagus (2,3). Most sufferers have the mild-to-moderate form of the disease and are likely to use self-medication products such as simple antacids, H₂-receptor antagonists or alginates. All of these have been shown to give pain relief in clinical studies (4–7), but as there may be different pathological causes in different patients endoscopic or histologic diagnosis does not always correlate to the presence of GORD symptoms (8,9) and there needs to be an independent way of assessing the presence and severity of reflux in

individuals so that the appropriate treatments can be determined for each patient.

Gastric refluxate contains acid from the stomach and it is this, combined with other agents such as pepsins and bile, which has been shown to cause damage to the delicate oesophageal mucosa (10). Measurement of acid in the oesophagus by oesophageal pH monitoring has consequently become the most accepted diagnostic tool for reflux measurement (11). Acidic conditions where the oesophageal pH is below four are considered to be damaging as this is the condition where gastric proteases (pepsins) become most active, although some are said also to be active as high as pH 6 and remain stable until irreversibly denatured above pH 7(12,13). The lowest part of the oesophagus is the most likely to be affected by reflux of gastric contents so pH monitoring probes are normally positioned 5 cm above the lower oesophageal sphincter (LOS) and the amount