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The Spanish Journal of Gastroenterology

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DOI: 10.17235/reed.2020.7449/2020
Link: PubMed (Epub ahead of print)

Please cite this article as:
Mearin Fermín, Pajuelo Lorenzo Francesca, Ríos José. Effectiveness of Almagate in gastroesophageal reflux disease: a post-hoc analysis of a randomized cross-over double-blind study. Rev Esp Enferm Dig 2020. doi: 10.17235/reed.2020.7449/2020.

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CC 7449

Effectiveness of almagate in gastroesophageal reflux disease: a post-hoc analysis of a randomized crossover double-blind study

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Conflict of interest: the authors declare no conflict of interest.

Keywords: Almagate. Gastroesophageal reflux disease. Antacids. Esophageal pH-metry. Gastric pH-metry. Cross-over randomized trial.

Dear Editor,

Almagate (aluminium-magnesium hydroxycarbonate hydrate) is a widely used antacid in Spain as an over-the-counter formulation (1,2). However, data on the control of acidity in patients with gastroesophageal reflux disease (GERD) are scarce. Herein we report a post-hoc analysis of a randomized crossover double-blind trial (ALR-006; data on file), in which equivalent single oral doses (1.5 g) of two formulations of almagate (AlmaxRetard® and Almax®, Laboratorios Almirall, Barcelona, Spain) were both effective for reflux esophagitis.

Twenty patients (13 males, mean age 52 years) with symptomatic and endoscopy-confirmed erosive esophagitis underwent continuous gastric and esophageal pH-metry during 32 hours. Acidity-related variables were recorded during three hours following

three standardized meals, including dinner as "no-treatment condition" and two lunches (before or after the dinner), in which Almax® 1.5 g was administered in one of them according to a randomized sequence. A generalized linear model with the patient identifier, the treatment, the administration sequence and the patient's term embedded in the sequence as independent variables was used.

The mean adjusted reduction of total reflux episodes was 5.70 (95 % confidence interval [CI] 3.12-8.28), decreasing from a mean of 13.15 without treatment to 7.45 with active treatment ($p < 0.001$). Total reflux episodes lasting > 5 min decreased from 0.90 to 0.50 (mean adjusted difference 0.40, 95 % CI 0.07-0.73; $p = 0.028$) and total reflux time also decreased (mean adjusted difference 12.15 min, 95 % CI 5.51-18.79; $p < 0.001$) in favor of the treated group. The percentages of time with esophageal pH < 4.0 and intragastric pH > 4.0 were also significantly shorter and longer, respectively, with active treatment ($p < 0.001$). The reflux/time ratio showed a mean reduction of 3.28 refluxes/min (95 % CI 1.47-5.09) for the almagate-treated period.

Almagate (1.5 g) in GERD patients improved all gastric and esophageal pH-metry related variables as compared with no treatment.

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