Evidence for Self-Medication
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Omeprazole vs. Poliprotect®

Clinical trial demonstrating non-inferiority of Poliprotect for heartburn and epigastric pain in patients without erosive esophagitis

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A randomised, controlled, multicentre, double-blind and double-masked study confirmed the efficacy of Poliprotect®, a molecular complex of natural ingredients designed for the protection of the gastroesophageal mucosa, contained in the medicinal product NeoBianacid®. Poliprotect was non-inferior to the standard dose of omeprazole (20 mg/day) in the treatment of symptoms of non-erosive gastroesophageal reflux and painful functional dyspepsia.

First comparison between proton pump inhibitors and mucosal protectants

A study published in the American Journal of Gastroenterology [1] presented data for the first time directly comparing a mucosal protective agent (MPA) with a proton pump inhibitor (PPI) in terms of reflux and epigastric symptoms. The randomised, controlled, multicentre, double-blind and double-masked study assessed the efficacy of Poliprotect® (NeoBianacid®, 1.55 g) compared to omeprazole (20 mg) in the relief of heartburn and epigastric symptoms. NeoBianacid® is a non-prescription medical product consisting of Poliprotect® (a polysaccharide fraction from Aloe vera, Malva sylvestris and Althaea officinalis and a mineral component from limestone and nahcolite) as well as a flavonoid fraction from Glycyrrhiza glabra and Matricaria recutita. Findings from preclinical studies suggest that MPA provides the mucosa with a complex, mucoid, adherent, antioxidant, pH-lowering matrix. This protects the gastroesophageal epithelium against the deleterious effects of acid, bile, and other luminal irritants.

The study included 275 outpatients with reflux and epigastric symptoms based on the Rome III criteria, without endoscopically detectable erosive lesions. Participants had an assessment of pain symptoms on the 100 mm visual analogue scale (VAS) between ≥ 30 and ≤ 70 for at least 6 of the 14 days before the commencement of the study. Study participants were randomised into two treatment arms. The study was conducted using a double-dummy design.

The Poliprotect group (n = 131) received Poliprotect in the initial phase (Day 1 to 14) at a dosage of five NeoBianacid® tablets daily. In the maintenance phase (Day 15 to 28) and after discontinuation of the PPI placebo on Day 28, the subjects were able to adjust the dosage of Poliprotect at their own discretion (Day 15 to 56). From Day 1 to Day 28, the group received a PPI placebo once daily. The study was completed by 124 participants.

The PPI group (n = 126) received the PPI at a dosage of 20 mg daily in the initial and maintenance phases (Day 1 to 28). In the initial phase, the dosage of Poliprotect placebo was set at five tablets daily. From Day 14 to Day 28, the subjects were able to determine the dosage of the Poliprotect placebo at their own discretion. From Day 29 to 56, the PPI group switched to active Poliprotect, which was used according to personal needs as in the maintenance phase. The study was completed by 116 subjects.

Results of the study and significance for treatment

Reduction in pain: Throughout the study period, mean VAS scores did not differ significantly between groups, confirming the non-inferiority of Poliprotect to the PPI omeprazole in the treatment of study participants with moderate symptoms of heartburn and/or epigastric pain/burning. In contrast to the PPI, the VAS values continued to improve to a small extent in participants receiving the on-demand dose of Poliprotect (**Fig. 1**).

On-demand dosing: Study participants were instructed to adjust the dosage of mucosal protection from Day 15 onward to achieve an effect equivalent to that observed during the study period V0–V1. Both groups reduced the dosage in a comparable manner in the period V1–V2 (Poliprotect group,

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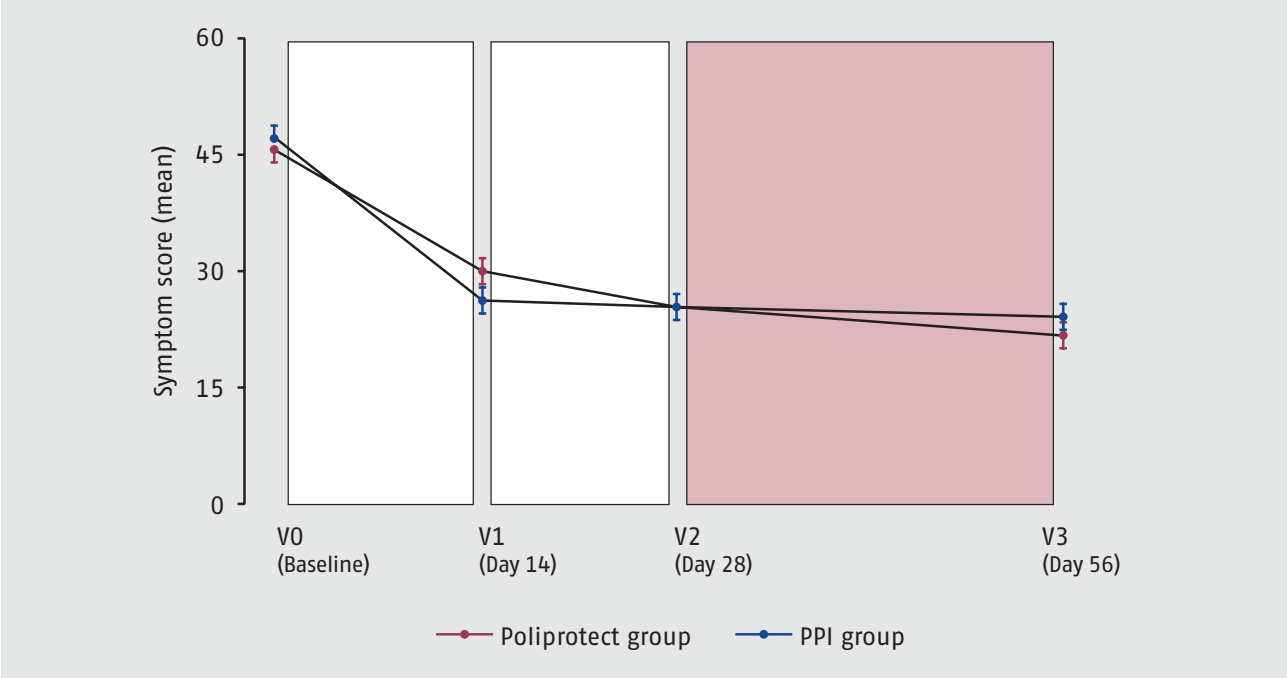

Fig. 1. The mean absolute values of symptom severity, measured using a visual analogue scale (VAS) ranging from no symptoms (0 mm) to overwhelming symptoms (100 mm), showed no significant difference between the two study groups. From V2 to V3 (coloured background), both the comparator treatment (PPI) and blinding were removed. All patients received active Poliprotect as needed. The error bars represent the standard error. V: visit

active substance, 2.11 tablets/day; PPI group, placebo 2.23 tablets/day) and in the period V2-V3 (Poliprotect group, active substance, 2.11 tablets/day; PPI group, active substance, 2.36 tablets/day). At this dosage, participants maintained the clinical benefits achieved and counteracted the anticipated worsening of symptoms after PPI discontinuation in the PPI group.

Need for emergency medication: Magaldrat gel (Riopan gel, 80 mg/ml) was allowed as rescue medication throughout the study period. The number of rescue medication gel sachets used was significantly lower in the Poliprotect group in the on-demand period than in the PPI group (see **Fig. 2**).

Changes in the microbiome: After 4 weeks (V2), the intestinal microbiome in the Poliprotect group remained unchanged, whereas an increased frequency of oral bacterial strains was detectable in the intestinal microbiome after the intake of 20 mg omeprazole.

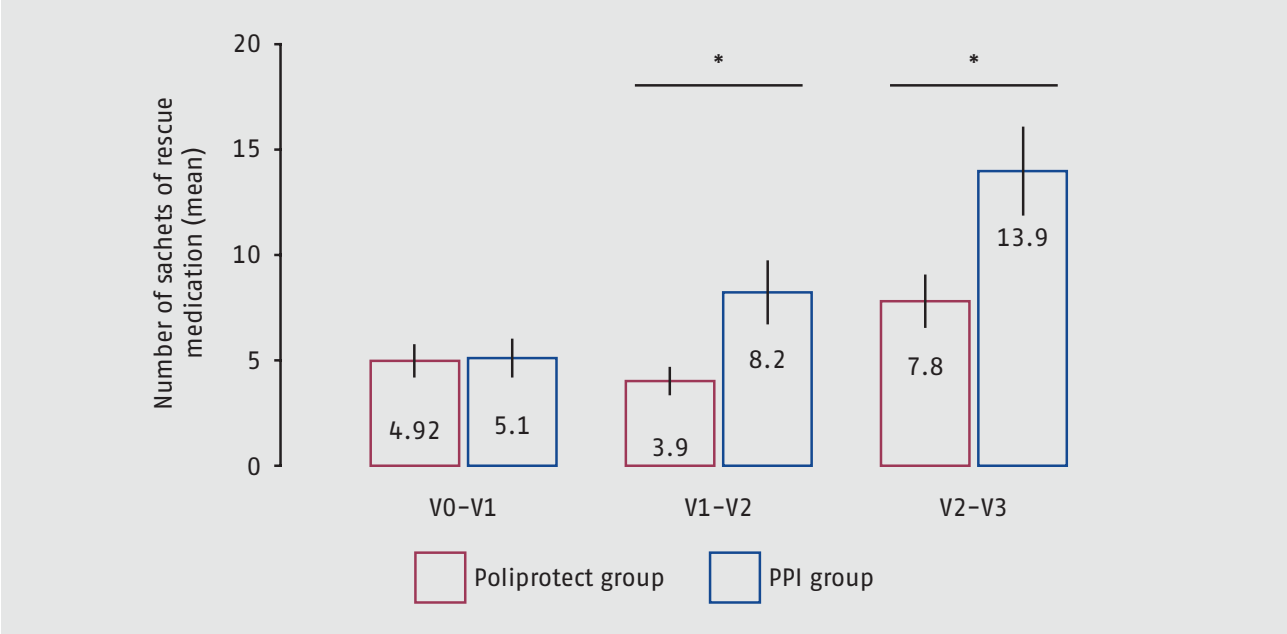

Fig. 2. Number of sachets of magaldrate gel used during the indicated study periods. The PPI group required more rescue medication, showing a statistically significant difference (*p < 0.05) compared to the Poliprotect group.

Literature

1. Corazziari ES, Gasbarrini A et al. Poliprotect vs Omeprazole in the relief of heartburn, epigastric pain and burning in patients without erosive esophagitis and gastro-duodenal lesions: A Randomized, Controlled Trial. Am J Gastroenterol. 2023 Sep 11. doi: 10.14309/ajg.0000000000002360. Epub ahead of print. PMID: 37307528.

Conflict of interest: Frederick Herbst is employed at Aboca S.p.A, Germany branch.

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