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Short Communication

pHyloGASTRO in the Treatment of Equine Gastric Ulcer Lesions

Francesca Bonelli [a], Sara Busechian [b], Valentina Meucci [a], Giusy Caporrino [c], Angela Briganti [b], Fabrizio Rueca [b], Francesco Zappulla [b], Ersilia Ferini [d], Luana Ghiandai [d], Micaela Sgorbini [a,*]

[a] Department of Veterinary Sciences, University of Pisa, Pisa, Italy
[b] Department of Clinical Sciences, University of Perugia, Perugia, Italy
[c] Equine Practitioner, Pisa, Italy
[d] Union B.I.O. srl, Arezzo, Italy

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ABSTRACT

Equine gastric ulcer syndrome (EGUS) is the most common disease of the equine stomach with high prevalence of both squamous and glandular disease reported in various populations. The aim of this study was to evaluate the effectiveness of a phytotherapic compound (pHhyloGASTRO) in the therapy of EGUS. The study was performed as a randomized double-blinded single-center study. The study population was composed of 19 equids which were submitted to gastroscopy before and after a 6-week treatment with feed additive (10/19) (pHyloGASTRO, [4]Union B.I.O. srl, Italy) or a placebo (9/19). Severity grade was evaluated on a scale from 0 to 4. The variables of interest were gastric lesion score and improvement grade. Changes and comparisons of variables were performed by contingency table analyses. P level of significance was set at .05 in all analyses. In terms of gastric lesion scores, the treated group improved significantly compared to the placebo group. pHyloGASTRO seems to be effective in the treatment of EGUS. Further studies are needed to verify whether prolonged administration of pHyloGASTRO could be more effective in completely healing gastric lesions.

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1. Introduction

Gastric ulceration is the most common disease of the equine stomach with a high prevalence of both squamous and glandular disease reported in various populations [1–3]. The term equine gastric ulcer syndrome (EGUS) was first adopted by the EGUS Council in 1999 and includes a complex of pathological conditions characterized by the presence of ulcers in the terminal portion of the esophagus, in the proximal (squamous) and distal (glandular) parts of the stomach, and in the proximal part of the duodenum of equids [4]. Recently, various authors [5–7] and the European College of Equine Internal Medicine (ECEIM) Consensus Statement [8] have provided a new nomenclature of EGUS and proposed updated guidelines regarding pathophysiology, diagnosis, and treatment [5,8].

Many drugs have been investigated and are available for the treatment and management of EGUS [8–11]. The proton pump inhibitor omeprazole has been found to be very efficient in both treating and preventing gastric ulcers in horses [8]. Other drugs such as histamine$_2$ antagonists, or gastric mucosal protectors have shown less efficacy than omeprazole in the treatment of EGUS [8,11,12].

Along with pharmacologic therapies, nutraceutical compounds appear to have a positive effect on preventing or healing naturally occurring gastric ulcers [13–20]. Thus, interest in more natural products has been growing. The purpose of this study was to evaluate the effect of the feed additive pHyloGASTRO (Union B.I.O. srl, Italy) on the

* Corresponding author at: Micaela Sgorbini, Department of Veterinary Sciences, Via Livornese snc, 56122, San Piero a Grado, Pisa, Italy.
E-mail address: micaela.sgorbini@unipi.it (M. Sgorbini).

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treatment of spontaneously occurring gastric ulcers of the squamous mucosa in a population of equids.

2. Methods

2.1. Materials

The study population was composed of 19 equids (10 Standardbred trotting horses and 9 Amiata donkeys). The equids were equal regarding distribution of gender and breed. None of the animals showed clinical signs of EGUS, were athletes, and were used for reproduction. Inclusion criteria: (1) all the equids were affected by gastric ulcers at gastroscopy; no changes in the feeding and environment during the study period were made.

2.2. Study Design

The study was performed as a randomized double-blinded single-center study, and the protocol was approved by the Ethical Committee of the University of Pisa (no. 9069/2014). Group allocation and blinding: once enrolled into the study, horses were randomly allocated to a dose group by pulling their names out of a hat. One investigator (F.B.) was responsible for randomization, whereas another investigator (S.B.) remained blinded to the group allocation until scoring was completed and recorded.

Ulcers were diagnosed by gastroscopy performed under sedation after 12 hours of fasting and 4 hours of water deprivation as reported in the literature [21]. Severity grade was evaluated on a scale from 0 to 4 as proposed by others [4]. Gastroscopy was always performed by the same operator (S.B.), as indicated by others [22]. For the examination, a 300-cm scope (Karl Storz, Germany) and a portable processor (Gastropack, Karl Storz, Germany) were used. The images were stored on a DVD recorder. The stomach was insufflated with air through an air-flow system attached to the biopsy channel of the scope until the internal stomach folds appeared flattened. Feed material adhering to the nonglandular mucosa was flushed away with sterile water to visualize the entire nonglandular portion of the stomach, including the greater curvature, the lesser curvature, and the dorsal fundus. The number and degree of ulcers were recorded in accordance with the Equine Gastric Ulcer Council (EGUC) recommendations [4].

Equids were divided into two groups: the “placebo group” was composed of 9/19 animals (median age 10 years) and the “treated group” was composed of 10/19 animals (median age 8 years). The two treatment groups were clinically equal regarding distribution of gender and breed. The “treated group” was treated with pHyloGASTRO (Union B.I.O. srl, Italy) at a dose of 60 mL per equid BID PO for 6 weeks, whereas the “placebo group” was treated BID with a similar-looking same-volume placebo for 6 weeks. Both pHyloGASTRO and placebo were administered using a feeding device. The administration was always performed by the same operator (C.G.). pHyloGASTRO is composed of medical herbs (*Althaea officinalis, Aloe barbadensis, Hoedeum vulgar, Malva sylvestris, Glycyrrhiza glabra, Echinacea angustifolia, calendula officinalis, Clay ventilated*) powered by *Matrix UB* (the aqueous extract of *Olea europaea*, a phyto-active enhancer). The medical herbs previously reported showed antinflammatory, cytoprotective, antioxidant, mucus healing, and acid-base balance restoring activities (Table 1) [23–38]. A clinical examination was carried out daily for each animal to monitor gastrointestinal side effect. All the equids were submitted to a gastroscopy after the 6-week treatment.

2.3. Statistical Analysis

The variables of interest were gastric lesion score and improvement grade. Changes and comparisons on variables were performed by contingency table analyses. Significance was set at 0.05 in all analyses. All the analyses were performed using a GraphPad Prism 6.0 (USA).

3. Results

All the equids in the study were affected by gastric ulcers in the nonglandular mucosa (equine squamous gastric disease [ESGD]) [5,8]. No health problems or side effects (diarrhea, stipsis, disorexia or anorexia, colic) related to treatment with pHyloGASTRO were observed during the all study period. The feed additive was readily accepted by all the pHyloGASTRO-treated horses in the same manner as the placebo.

Before treatment, the “treated group” equids showed 2/10 grade 1, 6/10 grade 2, 1/10 grade 3, while no equids showed grade 4; the “placebo group” equids showed 3/9 grade 1, 3/9 grade 2, 3/9 grade 3, while no equids showed grade 4. The pretreatment distribution of gastric lesion scores was not significantly different between the two groups.

After 6 weeks of treatment, the “treated group” showed 2/10 equids with grade 0, 7/10 with grade 1, 1/10 with grade 3, while no animals showed grades 2 and 4; the “placebo group” showed 2/9 with grade 0, 2/9 with grade 1, 3/9 with grade 2, and 2/9 with grade 3, while no animals showed grade 4. Outcomes for both “placebo” and “treated” groups are reported in Table 2.

The “treated group” improved significantly compared to the “placebo group” ($P = .04$). Concerning the improvement score of the gastric lesions, equids treated with pHyloGASTRO showed a significantly ($P = .0001$) higher improvement than equids treated with the placebo (Table 3).

No differences were found between the two groups considering complete healing of gastric lesions versus improvement.

Table 1
Mechanism of action of medical herbs that are compounds of pHyloGASTRO (Union B.I.O. srl, Italy).

Medical Herbs	Mechanism of Action	Literature
Althaea officinalis	Antinflammatory, cytoprotective	[23,24]
Aloe barbadensis	Antinflammatory, cytoprotective, mucus healing	[23]
Hordeum vulgare	Cytoprotective, mucus healing, acid-base restoring	[25]
Malva sylvestris	Antiulcerogenic activity	[26–28]
Glycyrrhiza glabra	Gastric healing	[29–31]
Echinacea angustifolia	Oxidant-antioxidant balance	[32]
Calendula officinalis	Antiulcer, antinflammatory effect	[33]
Clay ventilated	Ulcer healing	[34]
Olea europea	Gastroprotective agent, antioxidant activity	[35–38]

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