Journal of Equine Veterinary Science 34 (2014) 1274–1278

Contents lists available at ScienceDirect

Journal of Equine Veterinary Science

journal homepage: www.j-evs.com

Original Research

# Efficacy of a Combination of Apolectol, Live Yeast (*Saccharomyces cerevisiae* [CNCM I-1077]), and Magnesium Hydroxide in the Management of Equine Gastric Ulcer Syndrome in Thoroughbred Racehorses: A Blinded, Randomized, Placebo-Controlled Clinical Trial

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ARTICLE INFO

*Article history:*
Received 21 May 2014
Received in revised form 20 August 2014
Accepted 7 September 2014
Available online 16 September 2014

*Keywords:*
Squamous
Glandular
Gastric
Ulcer
Pectin-lecithin

ABSTRACT

To date, prevention of equine gastric ulcer syndrome (EGUS) has relied on management changes or pharmaceutical agents. The identification of an alternative means of prevention would be useful. Therefore, the objective of this study was to evaluate the combination of Apolectol, a live yeast (*Saccharomyces cerevisiae* [CNCM I-1077]), and magnesium hydroxide for the prevention of development of, or exacerbation of existing, EGUS in Thoroughbred racehorses. Twenty-four Thoroughbred racehorses without significant gastric ulceration (grade, ≤2 of 4) were identified on gastroscopy. Treated horses received 95 g Apolectol, 2 g *S. cerevisiae*, and 20 g magnesium hydroxide 1–4 hours before exercise. Control horses received 95 g of a feed pellet as a placebo. Gastroscopy was repeated at 24–27 days. There was no change in squamous ($P = .45$) or glandular ($P = 1.0$) ulcer grade over time in horses in the treatment group. In the placebo group, ulcer grade increased in both the squamous ($P = .04$) and glandular ($P = .19$) mucosa but only reached significance in the squamous mucosa group. Worsening of the ulcer grade was more likely in the placebo group in the glandular ($P = .04$) but not in squamous ($P = .10$) mucosa. The combination studied may be an effective prophylactic against EGUS development or exacerbation.


## 1. Introduction

Equine gastric ulcer syndrome (EGUS) is a well-recognized condition of the horse that can be further divided into squamous and glandular disease. Omeprazole is generally considered to be the drug of choice for the prevention of squamous ulceration, and its efficacy for this purpose is well documented [1–5]. However, recent studies [6,7] have demonstrated that worsening of glandular ulceration is common even during treatment with therapeutic doses of omeprazole, with worsening observed in 36% of horses over a 28-day period in one study [7]. These findings suggest that the efficacy of omeprazole for the prevention of glandular ulceration is questionable and that investigation of other means of prevention is warranted.

Management changes are commonly recommended alongside pharmacologic agents to prevent the development of squamous ulceration [8,9]. Anecdotally, they are

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http://dx.doi.org/10.1016/j.jevs.2014.09.006

generally thought to be useful, although specific evidence-based data demonstrating their efficacy is lacking. Furthermore, although a lower rate of squamous ulceration was present in a population of endurance horses during the interseason period (48% vs. 93% during the competition season) [10], the high prevalence during out-of-competition periods suggests that squamous ulceration can persist despite a reduction in risk factors, albeit at a lower prevalence. Specific dietary and training practices have also been identified as risk factors for glandular ulceration [11], but similarly, the effectiveness of management changes in the prevention of glandular ulceration is unknown. Furthermore, management changes, such as a reduction in exercise or decreasing the grain content in the diet, are often difficult to achieve in the clinical setting, and the identification of an alternative means of prevention would be useful.

Apolectol is a unique pectin-lecithin complex that has been suggested as an adjunctive therapy for the treatment of gastric ulceration [8]. It has been shown to increase the total mucus concentration in gastric juice for a period of 5 hours [12], whereas another study suggested that it may have a role in the treatment of EGUS in clinical patients [13]. Despite initially promising results in a single clinical trial [13], to date the efficacy of pectin-lecithin complexes as a therapeutic agent is unproven with two studies failing to demonstrate a protective effect in a fasting model of squamous ulceration [14,15]. Magnesium hydroxide is a potent buffer that has previously been studied in horses and cattle. In the horse, a dose of 15 g of magnesium hydroxide combined with 30 g of aluminum hydroxide resulted in a significant increase in gastric pH for 2 hours [16]. *Saccharomyces cerevisiae* has been well studied in the horse and has been shown to attenuate the reduction in cecal pH associated with the feeding of high-grain diets [17] and to improve feed digestibility under a variety of conditions through stabilization of large intestinal fermentation [18–21]. The authors hypothesized that the combination of Apolectol, *S. cerevisiae*, and magnesium hydroxide would prevent the development of, or exacerbation of existing, squamous and glandular gastric ulceration in a population of racing Thoroughbred horses.

## 2. Materials and Methods

### 2.1. Recruitment and Examination

Thoroughbred racehorses from four stables were examined. Before examination, all horses were fed their normal evening feed, but any remaining food was removed 6–8 hours before endoscopy as previously described [22]. Water was not withheld, and horses exercised normally on the morning of the examination at the trainers' discretion. Horses were sedated with detomidine (10–20 μg/kg IV; Dozadine; Axon Animal Health, Belrose, New South Wales, Australia) and examined using a 3-m flexible gastroscope (Portascope; Portascope.com, Bradenton, FL). The squamous and glandular mucosa were graded by a single investigator B.W.S. using a four-point scale as described by the EGUS council [23]. Based on the results of the gastroscopic examination, horses that met the inclusion criteria were enrolled into the study. Inclusion criteria for the study were horses in race training, not receiving any medical treatment for EGUS, not considered to have EGUS requiring medical therapy at the discretion of the examining veterinarian, and otherwise considered to be free of other significant disease. Clinically significant ulceration was defined as grade 3–4 of 4 ulceration of either the squamous or glandular mucosa, with or without concurrent clinical signs, or horses with grade 2 of 4 ulceration of either the squamous or glandular mucosa, with clinical signs that were potentially attributable to EGUS.

### 2.2. Group Allocation and Blinding

Once enrolled into the study, horses were randomly allocated to the treatment or placebo group. One investigator (K.M.S.) was responsible for randomization and administration of the medications, whereas the remaining investigators, including the principal investigator (B.W.S.) who undertook all of the gastroscopic examinations and scoring, remained blinded to the group allocation until scoring was completed and recorded. The study protocol allowed for randomization to be broken in the event of an adverse event.

### 2.3. Treatment and Placebo Protocols

Horses were fed and exercised at the trainers' discretion driven by their normal routine. All horses were housed on wood shavings and fed a diet typical of Australian racehorses [24]. Each morning, 1–4 hours before exercise, any remaining food was removed from the horses' stables. The treatment group was then fed 95 g of Apolectol (Pronutrin; Boehringher Ingelheim, Ingelheim, Germany), whereas the placebo group was fed 95 g of a commercially available pellet that was similar in appearance (Equine Relax Pellets; Robank Feeds, Ebenezer, New South Wales, Australia). The dose of Apolectol was standardized for ease of administration and approximated to a 450-kg horse. In addition to Apolectol, horses in the treatment group received 2 g of live *S. cerevisiae* (CNCM I-1077) (Levucell; Lallemand Animal Nutrition, Maroochydore, Queensland, Australia) and 20 g of magnesium hydroxide (Consolidated Chemical Co, Arndell Park, New South Wales, Australia) that was mixed with water to form a paste and administered orally using a dosing syringe. Treatment commenced within 3 days of the initial gastroscopic examination.

### 2.4. Follow-up Endoscopy

Gastroscopy was repeated, as described previously, between days 24 and 27. Some variation was allowed in the timing of the repeat gastroscopic examination to accommodate for the individual horses' racing schedules. The squamous and glandular mucosas were graded separately. Horses were considered to have worsened if their ulcer grade for that particular mucosal area increased by at least one grade. Horses with an ulcer grade $\geq$1 at enrollment were considered to have improved if their ulcer grade for the affected mucosa decreased by at least one grade.