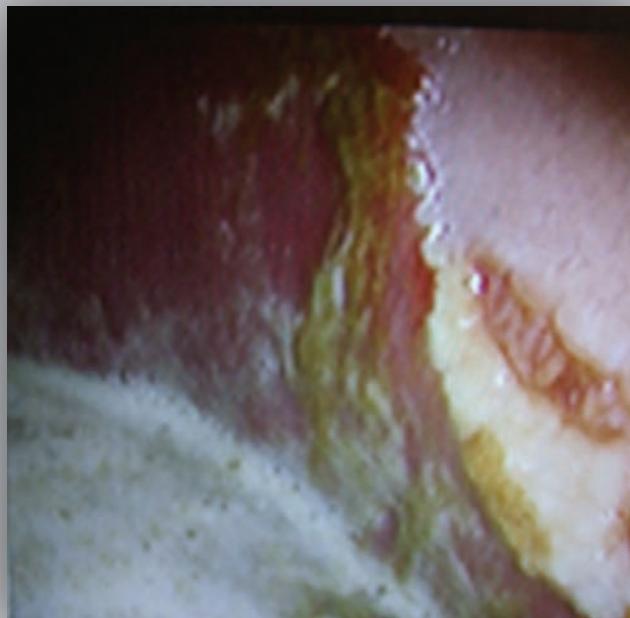


Prevention of Gastric Ulcer Formation with administration of a commercial supplement.

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- **“Ulcer scores in the placebo group increased significantly. Ulcer scores in the treatment group did not increase significantly between day 0 and 21.”**
- **“The treated horses did not get worse. The control group did get significantly worse.”**
- **“For prevention, in this model, the product was effective.”**

The objective of the study was to determine the value of U-7™ Gastric Aid for the prevention of formation of gastric ulcers in Thoroughbred horses in moderate exercise over a 21 day period.

Materials and Methods

Twenty Thoroughbred horses at a private training facility in Iowa that were to be subjected to breaking and routine training activities were enrolled. Horses were housed in the same individual stalls or paddocks throughout the study period. Rations were typical for horses on the farm, each horse received approximately 9 pounds of a 12% protein sweet feed and 20 pounds of a grass/alfalfa hay a day. Water was provided in buckets ad libitum. Horses treated with an anti-ulcer product within 2 weeks of the start of the trial or with any disease or injury or that were fractious or otherwise unsuitable were excluded.

Gastroscopy was performed on each horse on Day 0 in order to select horses without ulcers (i.e. score 0) and conducted again on all horses on Day 21 at the conclusion of the trial. Horses were sedated with 7 mg of detomidine and 5 mg butorphanol and lightly restrained in stocks with a twitch for the endoscopic examinations. Horses were fasted for a minimum of 8 hours and water was removed at least 2 hours prior to endoscopy. The entire squamous mucosa and the majority of the glandular portions of the stomach were visualized in all horses. Gastric lesion severity was scored as follows: 0 = intact mucosal epithelium (can have reddening and/or hyperkeratosis), 1 = small single lesion or small multifocal lesions, 2 = large single lesion or large multifocal lesions, 3 = extensive (often coalescing) lesions with areas of apparent deep ulceration. Reddening and hyperkeratosis were recorded as present or absent. The endoscopist was blinded as to group assignment.

Twenty horses found to be ulcer free were enrolled. All horses that met criteria were weighed, a fecal sample obtained for elisa test for hemoglobin and albumin within the feces (SUCCEED), and blood obtained for a complete blood count (WBC, RBC, Hemoglobin, Hematocrit, MCV, MCH, MCHC, Platelets, Neutrophils, Band Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, RDW, Nucleated RBC, Fibrinogen,) and serum chemistry analysis (Sodium, Potassium, Chloride, Bicarbonate, Calcium, Phosphorus, Magnesium, BUN, Creatinine, Glucose, Total Protein, Albumin, AST, Creatine Kinase, Alkaline Phosphatase, GGT, Total Bilirubin and Anion Gap). The same data was obtained from each horse again on day 21.

These horses were allocated into treatment and placebo groups based on stall/paddock location within the facility, age, weight and sex, respectively by a person that was not responsible for any observations or treatment administration. The treatment was given (2 oz orally) twice a day to ten horses and a placebo solution consisting of 99% water with FD&C green food coloring, xanthan gum, potassium sorbate, citric acid and a food grade artificial apple flavoring was administered in an equal volume at the same time. The treatment and placebo were in plain white 1 gallon containers marked only by a letter. The code identifying which were treatment and were placebo remained with personnel not performing observations until the completion of the study.

Treatments were administered prior to the morning and evening feeding. Treatment lost during administration and palatability was noted by the person who administered the treatment, who remained blinded. Palatability was subjectively evaluated. Horses were observed twice daily and any clinical signs of illness recorded. No additional medications were administered.

For days 1-3 the horses were individually housed and fed. On day 4 they began an exercise program that included initial saddling and breaking for the yearlings and exercise in a mechanical exerciser and under tack for all the horses 6 days a week through the study period. Horses were rotated through work under tack and in an exercise wheel. The exercise consisted of placing them in a 72 foot exercise wheel which turns forcing them to trot and jog until it is apparent the horse was beginning to fatigue. On alternate days horses were placed under tack and ridden until showing initial fatigue. Riding was either inside or outside based on the demeanor of the horse and the weather. All horses were individually assessed and worked by the exercise riders or trainer to maintain a continuous stress on the horse.

An informed consent agreement was obtained for each horse and the study was approved by the Industrial Animal Care and Use Committee. Blinding was released November 12, 2012 after the statistical analysis was complete.

Incidences of gastric lesion score observations, whether within or between groups, were analyzed using Fisher's Exact Test. A Fisher's exact test was used to compare the binomial data for treatment and control groups between day 0 and 21. A 2-way factorial analysis of variance model with treatment (treatment or placebo) and day (day 0 or day 21) as fixed effects was used to determine the effects of treatment and day on the continuous variables within the complete blood count and serum chemistry data.

Results

Both groups consisted of 7 yearlings, 2 two year olds and 1 three year old. The mean weight of the placebo treated group on day 0 was 979.7 (824-1075 range) and 987.4 (888-1180 range) for the treated group. The control group had 7 females and 3 castrated males and the treated group included 3 females, 6 castrated males and 1 intact male. All horses completed the 21 day study period.

Oral treatments were completed without notable loss of product being administered. The horses in both groups did not become refractory to the oral administration of the products and the treatment product appeared to be palatable to them.

Three treatment group horses and 7 horses in the placebo administered group had gastric ulcers on day 21. The ulcer scores of the horses administered placebo increased significantly ($P= 0.021$) and the ulcer scores in treated horses did not increase significantly ($P= 0.2$) between Day 0 and 21. There were no significant differences in the frequencies of hyperkeratosis or reddening of the gastric mucosa. The clinicopathological data yielded no significant findings from day 0 to day 21 related to the treatment group.