PEER REVIEWED

Comparison of 3-, 5-, and 7-Day Post-treatment Evaluation Periods for Measuring Therapeutic Response to Tilmicosin Treatment of Bovine Respiratory Disease

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Abstract

Three-hundred steer calves with clinical signs of bovine respiratory disease (BRD) and a rectal temperature of 104°F (40°C) or greater were enrolled in a 56-day study to evaluate the effect of a 3-, 5- or 7-day post-treatment evaluation (PTE) period on therapeutic response to tilmicosin. Trial calves (average weight 557 lb; 253 kg) were purchased from livestock auction markets in Colorado, Kansas, Oklahoma and Wyoming, and delivered to the trial site in Wellington, Colorado. Upon randomization to a treatment group, tilmicosin was administered at 4.55 mg/lb (10 mg/kg) of body weight. Three treatment groups were defined by the number of days (3, 5 and 7) post-treatment during which they were not eligible for retreatment for BRD.

The 7-day PTE group had a significantly higher treatment success rate compared to the 3-day PTE group ($P = 0.05$). The 3-day PTE group had a higher ($P < 0.05$) first relapse rate than the 7-day PTE group, and a higher ($P < 0.01$) second relapse rate than either the 5- or 7-day PTE groups. There were a total of five BRD-associated mortalities in the study; all occurred within the first eight days of the study.

Results from this trial suggest that a 3-day PTE period following tilmicosin administration could result in an overestimation of treatment failure rates compared to a 7-PTE period.

Résumé

Un total de 300 veaux mâles, montrant des signes cliniques reliés au complexe respiratoire bovin et une température rectale excédant 104°F (40°C), ont été inclus dans une étude de 56 jours visant à déterminer l'effet de la durée de l'évaluation post-traitement (3, 5 ou 7 jours) sur la réponse thérapeutique au tilmicosin. Les veaux de l'essai (poids moyen de 557 lb; 253 kg) ont été achetés dans des encans de bovins au Colorado, au Kansas, en Oklahoma et au Wyoming et transportés au site de l'essai à Wellington au Colorado. Après la répartition au hasard des individus dans un groupe, le tilmicosin a été administré à la dose de 4.55 mg/lb (10 mg/kg) de poids vif. Les trois groupes de traitement différaient selon la durée de l'évaluation post-traitement (3, 5, ou 7 jours) durant laquelle les animaux ne pouvaient être traités de nouveau pour des problèmes respiratoires. Le taux de succès du traitement était significativement plus élevé dans le groupe avec évaluation post-traitement de 7 jours que dans le groupe avec évaluation de 3 jours ($P = 0.05$). Le taux de première rechute était significativement plus élevé dans le groupe avec évaluation post-traitement de 3 jours que dans le groupe avec évaluation de 7 jours ($P < 0.05$). Le taux de seconde rechute était significativement plus élevé dans le groupe avec évaluation post-traitement de 3 jours que dans les deux autres groupes ($P < 0.01$). Il y a eu un total de cinq mortalités associées au complexe respiratoire bovin dans cette étude et toutes ont eu lieu dans les huit premiers jours. Les résultats de cette étude suggèrent qu'une évaluation post-traitement de 3 jours suite à l'administration de tilmicosin pourrait entraîner une surévaluation du taux d'échec du traitement par rapport à une évaluation post-traitement de 7 jours.

Introduction

Tilmicosin[a], a macrolide antibiotic, has been approved in the US for treatment of bovine respiratory disease (BRD) caused by *Mannheimia haemolytica* since 1992. Pharmacokinetic research has demonstrated that bovine alveolar macrophages and neutrophil concentrations of tilmicosin are maintained above therapeutic levels for the majority of *M. haemolytica* isolates for up to seven to 10 days.[1,2] Intracellular accumulation of macrolide antibiotics within alveolar macrophages and neutrophils of cattle enhances the bactericidal capabilities of these inflammatory cells.[3] Additionally, increased concentrations of tilmicosin at sites of localized infection, such as diseased or even consolidated lung tissue,

are associated with the ability of phagocytic cells to accumulate tilmicosin, and then serve to transport the molecule to the infection site.[4,5] The presence of tilmicosin greater than minimum inhibitory concentration (MIC) for *M. haemolytica* within these phagocytic cells may account for a prolonged duration of efficacy.[6,7]

Numerous US studies[8-11] have been conducted to evaluate the therapeutic response of calves treated with tilmicosin for BRD. However, no studies have been published that evaluate the effect of various BRD post-treatment evaluation (PTE) periods for tilmicosin-treated calves. The objective of this trial was to compare the effect of 3-, 5- and 7-day PTE periods on therapeutic outcomes in calves treated for BRD with tilmicosin.

Materials and Methods

Experimental design

During November 2004, 628 English and Continental crossbred steer calves, with a body weight range of 402 to 706 lb (183 to 321 kg), were purchased from livestock auction markets in Colorado, Kansas, Oklahoma and Wyoming, and delivered to the trial site in Wellington, Colorado. Mean pre-shipment and post-shipment weights were 572 and 557 lb (260 and 253 kg)/hd, respectively. Within 24 hours after arrival, all calves were processed and administered a modified live virus IBR, BVD, PI3 and BRSV[b] vaccine, treated for internal and external parasites[c], administered a growth promoting implant[d] and individually identified with uniquely numbered ear tags. Following processing the calves were placed in dirt-floored pens for observation in groups of approximately 25 head.

Calves were observed daily for clinical signs of BRD by personnel that were blinded to treatment group. Calves observed with a Clinical Illness Score (CIS) of 2 or more (Table 1) were removed from their initial observation pens and taken to the on-site treatment area for rectal temperature evaluation. Calves with a rectal temperature <104.0°F (40°C) were returned to their observation pens, while those with a rectal temperature of ≥104.0°F were weighed and randomly assigned to one of three treatment groups. Treatment assignment was completed within five days. Upon randomization to one of three treatment groups, tilmicosin was administered (Day 0) to all calves by subcutaneous injection in the left neck at 4.55 mg/lb (10 mg/kg) of body weight (1.5 mL/cwt). Treatment response was evaluated based on guidelines described in Table 2. Ear-notch samples from all trial calves were collected and submitted to the University of Nebraska Diagnostic Laboratory for determination of persistent infection with bovine viral diarrhea virus (BVDV) via immunohistochemistry staining. The three treatment groups were defined by the number of days (3, 5 and 7) post-treatment during which they were ineligible for retreatment for BRD. Treated calves were placed into 10-head pens by assigned treatment group. The average initial body weight and rectal temperature of the study animals were 549 lb (249.5 kg) and 105.0°F (40.5°C), respectively.

Table 1. Clinical Illness Score (CIS).

Clinical Score	Description	Clinical Appearance
1	Normal	No abnormal clinical signs.
2	Slightly Ill	Mildly abnormal character of respiration. Dyspnea may be combined with some depression, gauntness, nasal and/or ocular discharges. Hair coat may be rough.
3	Moderately Ill	Moderately abnormal character or respiration. Noticeable dyspnea, gauntness, depression, and nasal and/or ocular discharges. Hair coat may be rough.
4	Severely Ill	Severely abnormal character of respiration. Pronounced dyspnea, depression and gauntness. Nasal and/or ocular discharges. Hair coat may be rough.
5	Moribund	Down and at the point of death. Mouth breathing.

Following their respective PTE periods of 3, 5 or 7 days, calves showing clinical signs of BRD (CIS≥2), and with rectal temperatures ≥104.0°F, were considered a treatment failure and treated with enrofloxacin[e] at 5.0 mg/lb (11 mg/kg) body weight (5.0 mL/cwt). Calves with a CIS ≥2 and a rectal temperature <104.0°F were not considered a treatment failure, and were returned to their trial pen with no additional therapy. Calves were fed a flaked-corn-based diet typical for finishing cattle. The ration was formulated to meet or exceed National Research Council requirements, and was fed *ad libitum*. The diet contained monensin[f] and tylosin[g] at approved levels throughout the study. Dry matter consumption on a pen basis was calculated from recorded daily feed offerings.

Necropsy examinations were performed on all mortalities, and classified as either BRD or non-BRD mortalities.

Trial observations included collection and recording of CIS and rectal body temperature at initial treatment, and at conclusion of the PTE period for each treatment group. Individual body weights were obtained

Table 2. Treatment-outcome categories.

Treatment response description	Definition
Treatment success	An animal with improved CIS and body temperature (<104.0°F) at completion of the PTE period, and not meeting the case definition for BRD within 21 days of receiving initial antibiotic therapy.
Treatment failure	An animal at completion of the PTE with a greater CIS than at day 0; has a CIS ≥2 and a rectal temperature ≥104.0°F (40°C); OR An animal observed with severe signs of BRD (CIS≥4) or dies, and the illness was determined to be due to BRD prior to the end of the PTE.
Relapse	An animal considered recovered (improved CIS and body temperature) at completion of the PTE, but is observed with signs of BRD (CIS≥2), has a rectal temperature ≥104.0°F (40°C) between the end of the PTE but ≤21 days from the initial antibiotic therapy.
Second relapse	An animal meeting the case definition for BRD between days 3 and 21 following second antibiotic therapy.
New episode	An animal observed with signs of BRD (CIS ≥2) and has a rectal temperature ≥104.0°F (40°C) >21 days following the previous therapy.

for each calf at the start of the trial, at Day 28 and at completion of the study (Day 56).

Statistical analysis

Changes in initial to post-treatment CIS, body temperature and performance data were analyzed using analysis of variance (ANOVA) techniques with Proc GLM in SAS (Statistical Analysis System, SAS Institute, Inc.) in a model that included treatment, replication and experimental error as sources of variation. Mean separations were compared using the PDIFF option in the least-squares-means statement in Proc GLM. Pen was the experimental unit for all analyses.

Results and Discussion

Health effects of 3-, 5-, and 7-day PTE periods following treatment of BRD with tilmicosin are reported in Table 3. Calves in the 7-day PTE group had a significantly higher treatment success rate than calves in the 3-day PTE group (P=0.05). There were no statistical differences between the three groups for treatment failures. Calves in the 3-day PTE group had a higher (P<0.05) first relapse rate than calves in the 7-day PTE group. However, the overall treatment effect across all treatments was not statistically different (P=0.12). Further, calves in the 3-day PTE group had a higher (P<0.05) second relapse rate than calves in the 5- or 7-day PTE groups, and the overall treatment effect across treatments was different (P=0.01). There were no differences in the number of new episodes among treatments. All animals removed prior to the end of their 21-day evaluation period were non-BRD removals, and were excluded from the study.

Mean temperature of calves in the 7-day PTE group tended to be lower than that of the 5-day PTE group at the end of their respective evaluation periods (P=0.07), but was similar to the mean temperature of calves in the 3-day PTE group. There were no significant differences in the CIS values of any of the groups taken on their respective post-treatment evaluation days (Table 3).

Laboratory analysis of ear notches determined that no calves were persistently infected with BVDV.

Although there was no difference among treatments in the treatment failure rate or the first relapse rate, the improved treatment success in the 7-day PTE group compared to the 3-day PTE group suggests a difference in cumulative failure and relapse rates between these two groups is likely. Results from this study indicate premature evaluation of tilmicosin-treated animals may result in an overestimation of the treatment failure and relapse rates in cattle treated with tilmicosin and evaluated for BRD therapy outcome at three days post-treatment.

There were no differences (P=0.63) among treatments for total body weight gain, average daily gain (ADG), dry matter (DM) intake or feed efficiency for the 0 to 28 day and 0 to 56 day trial periods (Table 4).

Conclusions

This study compared the relative aggressiveness of BRD therapy evaluation based on a 3-, 5-, or 7-day PTE period following treatment with tilmicosin. Periodic clinical illness scores (data not shown) and rectal temperatures suggest that tilmicosin-treated cattle appear similar between three and seven days post-treatment, thus complicating the differentiation of cattle that are adequately recovering from those that are not. A 7-day post-treatment evaluation period following treatment with tilmicosin resulted in a higher treatment success rate when compared to a 3-day PTE period, while BRD death loss was not affected. While no conclusion can be made on the mortality outcome by increasing post-treatment evaluation period, early (Day 3) evaluation of tilmicosin-treated cattle could result in a per-

Table 3. Effect of post-treatment evaluation period (PTE) on health response of calves treated for BRD with tilmicosin.

Item	Post-treatment evaluation period 3-day	5-day	7-day	Overall PTE period *P*-value
No. pens	10	10	10	
No. head	97*	96**	98***	
Treatment success, %	67.9[a]	73.0[ab]	86.9[b]	0.05
Treatment failure, %	12.6	14.5	8.1	0.54
Relapse, %	19.6[a]	12.5[ab]	5.0[b]	0.12
Second relapse, %	9.3[a]	1.0[b]	0.0[b]	0.01
New respiratory episode, %	2.1	4.0	1.1	0.62
BRD mortality, %	2.0	3.0	0.0	0.26
Other mortality, %	1.0	0.0	0.0	0.39
No. removals <21 days	3	4	2	
No. removals >21 days	3	3	2	
Initial temperature, °F	104.9	105.0	104.9	0.21
Temperature, °F****	103.1[ab]	103.6[a]	102.4[b]	0.07

[ab]Different superscripts in the same row differ $P \leq .05$
*Three removals before 21 days: (2 infectious pododermititis, 1 coccidiosis)
**Four removals before 21 days: (4 infectious pododermititis)
***Two removals before 21 days (2 infectious pododermititis)
****Temperature at the end of evaluation period.

Table 4. Effect of post-treatment evaluation period (PTE) on performance of calves treated for BRD with tilmicosin.*

Item	Post-treatment evaluation period 3-day	5-day	7-day	Overall PTE period *P*-value
No. pens	10	10	10	
Initial weight, lb	550.8	548.6	545.0	
Day 0-28				
Average weight gain, lb	107.5	112.1	107.4	0.63
Average daily gain, lb	3.84	4.00	3.83	0.63
DM intake, lb	12.29	12.51	12.24	0.84
Feed/gain	3.24	3.14	3.23	0.77
Day 0-56				
Average weight gain, lb	228.0	230.1	224.6	0.84
Average daily gain, lb	4.07	4.11	4.01	0.84
DM intake, lb	14.47	14.67	14.21	0.70
Feed/gain	3.57	3.61	3.57	0.96

*Values expressed on a "deads out" basis.

ceived higher treatment failure rate, resulting in unnecessary retreatment of some cattle for BRD, thereby increasing overall BRD treatment costs.

Endnotes

[a] Micotil®, Elanco Animal Health, Greenfield, IN 46140.
[b] Bovishield® 4, Pfizer Animal Health, New York, NY 10017.
[c] Ivomec® Pour-On, Merial, Inc., Duluth, GA 30096.
[d] Synovex® Choice, Fort Dodge Animal Health, Fort Dodge, IA 50501.
[e] Baytril® 100, Bayer Animal Health, Shawnee Mission, KS 66216.

[f] Rumensin®, Elanco Animal Health, Greenfield, IN 46140.
[g] Tylan®, Elanco Animal Health, Greenfield, IN 46140.

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Again, thank you for your support.

David McClary, Chairman AABP Amstutz Scholarship Committee

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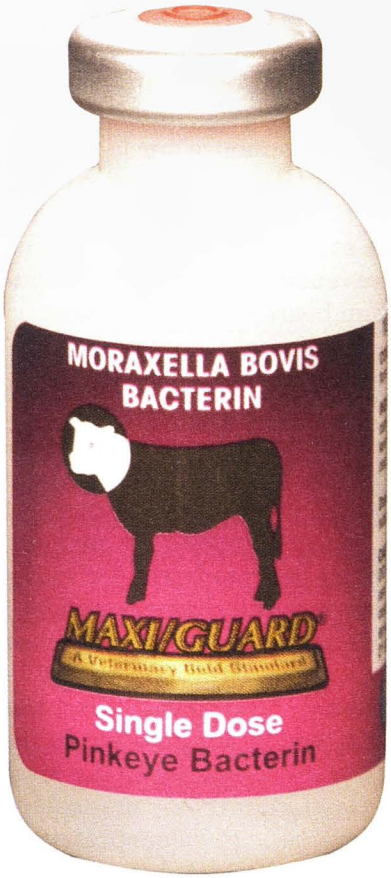

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