Field Trial Models For the Evaluation of Hairy Wart Treatment Products

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Abstract

Hairy heel warts remain a major concern for dairy producers because of the effect on milk yield. Field test procedures have been developed for the evaluation of hairy wart treatment products. Potential treatment products are applied daily using a garden sprayer after pre-washing the affected area with water. Product application is done once a day for 10 days. The hairy heel wart is visually evaluated on a five part scale that includes: lesion size, description, pain, color, and swelling. Evaluation of the lesion is conducted daily to follow change in appearance of the lesion. Subjective scores are converted to a numerical index in order to develop a "total lesion score." These field trial methods are being used to develop non-antibiotic treatment products for hairy heel warts. Initial results indicate efficacy for an iodine formulation with high free iodine levels.

Background

Hairy heel warts (digital dermatitis, papillomatous digital dermatitis, strawberry heel) have become, since their characterization in the mid 1970's, a major health problem for dairy producers. A variety of treatment products have been tested, but efforts have not been focused on establishing a standard protocol for studying various treatment products or procedures. Britt[1], *et. al.*, topically applied four treatment products and used lameness to assess the rate of healing. In a later study by Britt[2], the efficacy of topically applied products were evaluated using lameness, clinical observation for change in healing and evaluation of the lesion using a scoring system. In this trial, the lameness score did not show good agreement with the clinical observation of the scoring system rating. Shearer[3] has also used lameness in combination with evaluation of lesion size and pain associated with the lesion to evaluate hairy wart treatment products. Berry[4], evaluated topically treated products using a scoring system that assessed pain and lesion size. The protocol used in the test reported here was developed as a result of discussions with Britt, Shearer and Stevens as well as our own testing.

Procedure

Evaluate proposed topical treatments in cows from commercial dairies affected with naturally occurring cases of digital dermatitis. Proposed treatments will be tested against a negative control (water) applied in the same manner and duration as the test treatments.

The trial will require 4 groups of at least 15 animals per group at the start of the trial with lesions scored as 1 or 2 based on a 3 point size scale ranging from 0 (no visible lesion) to 2 (lesion size > 2.5 cm). Three groups of 15 animals each will be assigned at random to experimental product treatment groups, with 1 group of 15 being assigned to the negative control group. Cows will be identified by means of leg bands to indicate the specific treatment group.

Each treatment will be applied once a day. Daily treatments will be performed for a period of 10 consecutive days.

Lesions will be evaluated at the time of assignment to respective treatment groups and every day throughout the duration of the trial. Noticeable changes in sensitivity and other lesion characteristics will be monitored and recorded throughout the trial period. Lesions will be described according to the scoring system in the attached form.

Therapeutic success will be determined by comparison of experimental treatments to the negative control group. Evaluation will be determined by visual appraisal of lesions. Evaluation of lesion size, color, swelling, and relief, or lack thereof, of pain elicited when lesions are sprayed with water. Photographs of representative lesions will be obtained for documentation of lesions and treatment success.

Application

Test product application will be preceded by an initial rinse of the entire hoof. The desired product will then be applied to the hoof via a commercial garden sprayer.

Analysis

Lesion Score

A lesion score will be determined for each lesion evaluation. The Total Lesion Score (TLS) will consist of the sum of scores determined for each of four categories. Only cows remaining throughout the test period will be included in the data analysis.

1. Lesion Size: 0 - No Lesion
   1 - < 2.5 cm
   2 - > 2.5 cm
2. Pain: 0 - No demonstrable pain
   1 - Sensitive
   2 - Severe Pain
3. Color: 0 - Flesh, indicating a healed lesion
   1 - Black, indicating lesion regression
   2 - Red, indicating erythema
4. Swelling: 0 - No Swelling
   1 - Swelling

Dermatitis

Each lesion will be observed to determine whether the dermatitis is of the localized or generalized form. Lesions which are in remission would be indicated by a change of dermatitis from generalized to localized.

Lesion Description

Each lesion will be placed into one of the following three classes.

Ulcerative

Flat, red, and raw lesion often times involving bleeding, pain, and extreme erythema. Usually associated with a lesion in the early stages of infection.

Granulomatous

Lesion containing a terry cloth like texture, associated with the intermediate stages of infection.

Proliferative

Raised lesion with many hair like skin growths protruding from lesion surface. Hyperkeratinization of the skin and swelling are associated with mature lesions.

Treatments

1% iodine with elevated free iodine (100 ppm.)
Thickened 1% iodine with elevated free iodine
Acidified Quaternary ammonium
Negative control-colored water

Results

Table 1 shows the results from one trial conducted according to the method described above. The results for each criterion are a sum of the individual lesion scores. At day one, all treatment groups showed a similar score for each of the individual criteria scores and the Total Lesion Score indicating parity between the treatment groups. The negative control, thickened iodine and acidified quat all showed a low level of improvement over the eleven day trial. Improvements for these three treatments ranged from 13.5% to 15.2%. In contrast the 1% iodine formulation with elevated free iodine showed a higher level of improvement, 37.3%. The iodine formulation with elevated free iodine showed a greater degree of improvement for size, color and pain than any of the other three treatments. The data suggests that this composition may be suitable for use as a treatment product for hairy heel warts. The data also shows that improvement can be seen in a relatively short time. Noticeable improvement was seen within the eleven day test period.

Table 1. Total Criteria Score By Treatment Group

Treatment	Criteria	Day 1	Day 11	% Change*
1% Iodine/Elevated Free Iodine				
	Size	21	16	-24.0
	Pain	21	11	-42.0
	Color	28	17	-39.3
	Swelling	2	3	50.0
	TLS**	75	47	-37.3
Thickened Iodine				
	Size	24	23	- 4.2
	Pain	23	17	-26.1
	Color	27	22	-18.5
	Swelling	5	5	0
	TLS	79	67	-15.2
Acidified Quat				
	Size	21	20	-4.8
	Pain	22	16	-27.3
	Color	25	21	-16.0
	Swelling	6	6	16.7
	TLS	74	64	-13.5
Negative Control				
	Size	21	22	4.8
	Pain	24	18	-25.0
	Color	27	22	-18.5
	Swelling	2	1	-50.0
	TLS	74	63	-14.9

* For % Change a negative score indicates that the lesion improved.
** TLS = Total Lesion Score

Table 2 shows a summary of the individual cow scores by treatment group. The range of total lesion scores on day 1 for each treatment indicates that we had parity between treatment groups with respect to

the severity of the lesion. The 1% iodine/elevated free iodine treatment group showed the lowest lesion scores on day eleven. Also shown in the Table is a frequency distribution for the change in total lesion score. All cows in the 1% iodine/elevated free iodine treatment group demonstrated a reduction of at least 1 in the total lesion score and 62% of the cows in this group showed a reduction in the score of 2 or more.

Table 2. Total Lesion Score Improvement By Cow

	1% Iodine	Thickened Iodine	Acidified Quat	Negative Control
Total Lesion Score Range Day 1	5-8	5-8	5-8	5-8
Total Lesion Score Range Day 11	1-5	4-7	2-8	4-6
Number of Lesions	13	12	13	12
Frequency TLS Change Day 1 - 11				
+2			1	
+1		1		
0		3	4	5
-1	5	3	5	3
-2	3	5	1	4
-3	3		2	
-4	1			
-5	1			
% Changed >/= -1	100%	67%	62%	58%
% Changed >/= -2	62%	41%	23%	33%

A review of the criteria used to evaluate the status of the hairy heel wart indicates that swelling should probably not be included. (Table 3) The level of swelling was low in each of the four treatment groups and is most likely not directly related to the presence of the heel wart. Of the other criteria, color and pain showed a high degree of correlation for the four treatments. Lesion size showed an appreciable change only for the 1% Iodine treatment.

Table 3. Percent Total Lesion Score Change By Criteria

	% Change			
	Iodine	**Thickened Iodine**	**Acid Quat**	**Negative Control**
Criteria				
Size	-24.0	- 4.2	- 4.8	4.8
Color	-42.0	-26.1	-27.3	-25.0
Pain	-39.3	-18.5	-16.7	-18.5
Swelling	50.0	0	16.7	-50.0

Conclusions

Development of treatment and prevention products for the hairy wart disease will require the continued improvement and modification of test methodologies used. This, as well as earlier trials suggest that color, pain and size are important criteria for evaluating the status and change of hairy wart lesions. In this trial, a 1% iodine formulation with elevated free iodine showed better efficacy than the other treatments tested and may be suitable for use as a treatment product for hairy heel warts. The data also show that improvement can be seen in a relatively short time. Noticeable improvement was seen within the 11 day test period. Additional trials will be conducted to determine efficacy compared to antibiotic products that have shown efficacy in earlier trials.

References

1. Britt, J.S., *et al*, "Comparison of Topical Application of Three Products for Treatment of Papillomatous Digital Dermatitis in Dairy Cattle", *JAVMA,* Vol 209, No. 6, Sept. 15, 1996. 2. Britt, J.S., personal communication 3. Shearer, J.K., Elloitt, J.B., "Preliminary Results from a Spray Application of Oxytetracycine to Treat, Control, and Prevent Digital Dermatitis in Dairy Herd". International Conference on Bovine Lameness, June 26-30, 1994, p 182. 4. Berry, S.L., Maas, J., Reed, B.A., Schechter, A., "The Efficacy of 5 Topical Treatments of Papillomatous Digital Dermatitis In Dairy Herds," *Proceedings of the American Association of Bovine Practitioners Meeting,* Sept. 12-15, 1996.

Addendum

Several researchers interested in the study of heel wart treatments have discussed and agreed upon a standard protocol for the investigating the response of heelwarts to treatments. A copy of the protocol follows.

Evaluating Heelwart (PPD) Lesions During Clinical Trials

Purpose

To develop a standard protocol for evaluating response of PDD to treatments.

Methods

Each trial animal should have a data sheet or data lines on a spread sheet. Data should include a minimum number of facts but should include:

* a double I/D
* lactation # and age
* days in milk and daily production
* which limbs are affected and lesion location on the limb (see below "drawing")
* which treatment product and group
* other current on farm foot baths or treatments

Pain

Use of a pressure spray (???PSI) on the affected area. Spray should be preceded by manually touching the rear leg at the hock or below to test the "flinch" response. A test spray on both rear feet and legs should be administered to adapt the animal prior to the actual testing spray. Water sprayed under pressure is evaluated:

0 - no movement
1 - pick up foot and return to floor within 2 seconds
2 - hold foot up 3 seconds or more

Size

Size can be measured on actual lesions or on 2x2 slides which are made of lesions both pre and post treatment using a standard focal length camera. Size should be measured top to bottom and side to side and reported in mm. If 2x2 slides are made, cow I/D, date and a measurement scale should be written on a marker device (paper or etc) and be held as close as possible to the lesion for calibration. Size can be measured with a caliper then converted to mm. Change should be measured in % change in size, thus each lesion serves as its own control.

Color - Tissue Proliferation

Red moist color indicates the likelihood of continued lesion growth or progression. Dark dry keratin like color indicates likely regression or healing. Lesions should be classified prior to the beginning of the treatment, at the end of treatment, and some time period after the end of treatment. These evaluations could be made in numerical form to enable herd scoring.

Score 3: red, moist, proliferative
Score 2: less moist, beginning to darken
Score 1: dark, keratinized, dry
Score 0: no lesion

Drawing

A drawing should be made of the lesion on the standard form which should include front and rear views of all 4 feet. Indicate whether the lesion is localized or diffuse.

Positive - Negative Controls

All trials should have a negative control "placebo" treatment in the form of water and a positive control in the form of oxytetracycline at concentrations between 25-100 mg/ml. A no lesion, no treatment group should be evaluated along with the + and - controls and the treated group. Using a negative control may be difficult on commercial herds which would rather not have animals with no treatment during the trial.

Statistical Analysis

Some type of standard analysis program should be devised to verify the stated results. Group sized should be based on minimum animals necessary to provide statistical results, including treatment groups and + and - controls.

Duration of trial and post trial scoring

Trials should last a minimum of 14 days. Lesion evaluation, size and color, should be made a minimum of:

* day prior to first treatment
* day 14 or end of trial
* 30 days post trial
* 60 days post trial

Lameness Score

Although lameness score has been used before to evaluate response its use poses some problems in the form of differentiation from other causes of lameness. Any trials using lameness score for response must include a complete foot trimming and testing of pain response with an equine foot tester. Any animals showing non-PDD foot lesions (sole hemorrhage, abscesses, white line disease, separated hardship rings, painful heel cracks or erosions, sole overgrowth, trimming damage, etc), foot tester response, or upper limb lameness should be excluded from the trial. Prior lameness scoring systems have been rated as:

0 = no perceptible lameness
1 = slightly perceptible lameness
2 = noticeable lameness
3 = carrying a foot

Facilities

A herd information sheet should include the type of facility as; free stall, stanchion, pasture, loose housing, bedding type, dry corral. It should also include flush, scrape, barn cleaner or other manure removal system information.

History

The length of time the herd has had the problem as well as which groups of animals are affected should be included. Prior treatments and success is important.