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A Uniform Protocol for Evaluating Response to Treatment of Papillomatous Digital Dermatitis Lesions

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Introduction

Digital dermatitis or papillomatous digital dermatitis (PDD),[17,24] commonly known as footwarts or hairy heel warts, was first reported in Italy in 1974 and in New York in the late 1970's.[15] Similar lesions have occurred in 40 or more states in the United States[8,16,19] and many other countries.[1,11] The etiology of this disease is unknown, however, two to five phylotypes of spirochetes (Treponema sp.) have been associated with active lesions and identified by using Polymerase Chain Reaction (PCR), histologic, or microbiological methods.[5,10,18,23] California workers have developed an Enzyme-Linked Immunosorbent Assay (ELISA) test to detect humoral response which is specific for 2 strains of spirochetes isolated from PDD lesions. Animals without PDD lesions show little or no response to the ELISA test while animals with PDD lesions show elevated titers.[23] One paper suggested that a *Borrelia burgdorferi* spirochete might be involved in the disease.[2] Slender, spiral organisms can be seen on sectioned lesion specimens stained with silver stain.[9] Lesions appear to begin as eroded areas, most commonly between the bulbs of the heel. As the lesion progresses, tissue proliferation occurs with growths of epidermal tissue which grossly resembles hair, thus the common name "hairy heel wart". Although the lesion is commonly referred to as a "wart", there is no evidence to support viral involvement.[13] The lesions are painful, animals tend to move reluctantly and shift weight toward the toe and off the heel.[3,14] Pain, however, is not always proportional to lesion size. Due to pain, feed intake may be reduced and milk production losses up to 50% daily may occur.[17] Signs of estrus are reduced, days open increase[17] and there are costs associated with treatment and milk discard if parenteral antibiotics are used.

The disease appears to be more common in freestall confined herds where feet are constantly exposed to moisture and manure conditions. The feet often become coated with a layer of dry manure which may produce the anaerobic conditions necessary for bacterial growth. Only anaerobes have been identified as possible agents and they require constant moisture and low oxygen to survive.

Individual surgical and medical treatment in a hospital area is expensive, labor intensive, and may not be feasible in large outbreaks. Parenteral antimicrobials have been effective in California[16] but not in other locations.[7] Application of oxytetracycline under a bandage has been reported as a highly effective treatment.[4] Bandaging is labor intensive and may not be practical in herds where the incidence of digital dermatitis is 5% or more. Rapid, efficacious treatment of large numbers of lesions is desired.

Although specific data is lacking, experience of some clinicians suggests that foot baths may be an effective method for herd control of PDD. Foot baths containing dilute solutions of formaldehyde or copper sulfate are common treatments. Some trials show that acidified copper sulfate is more effective than regular copper sulfate. Formaldehyde foot baths pose human health hazards and are only marginally effective.[19] Di-

lute oxytetracycline or lincomycin-spectinomycin foot baths control the condition.[20] Foot baths are difficult to manage on larger dairies due to the need to change the solutions every 150-300 cow passages.[7]

Direct spraying of effective medications on lesions is practical. Shearer, using a pump sprayer for three weeks, treated and controlled PDD in a 300 cow herd.[21] With topical application, all cows or individual cows with lesions can be treated.[6,12,14,21]

Purpose

The purpose of this paper is to develop a uniform protocol which can be used to evaluate results of treatment to control PDD lesions. The remainder of this paper lists our suggestions for information which should be included in each trial protocol.

Herd Information

Facilities

A herd information sheet should include the type of facility, such as freestall, stanchion, pasture, loose housing, or dry corral, as well as bedding type and animal density (sq ft/animal). It should also include a description of the manure and waste water management system such as flush, scrape, barn cleaner or other manure removal system. The data should include the frequency of manure removal and the age and number of animals exposed to the facility where most of the infected animals are housed. If foot baths are present, they should be measured for volume, and their location and number identified.

History

The duration of the problem, which groups of animals are affected, prior treatments and treatment success are useful historical information. Use of any PDD vaccine should be noted, including the brand, dosage, and dates of vaccination.

Animal Information

Each animal should have a unique ID. Lactation number, age, days in milk, daily milk production, limb(s) affected, and lesion location on the limb (see "Drawing") should be recorded. New lesions which occur after trial onset should not be considered as part of the trial.

Trial Design

Duration of trial and post trial evaluation

The duration of treatment is dependent on the product used. The animals should be monitored for 100 days to evaluate cure, remission, or recurrence. Lesion location, size, color, and pain response should be documented just prior to first treatment, at day 14 or at the end of treatments, and at 30 and 60 days post treatment. Trials which last 100 days or more may be the best way to evaluate the long term effectiveness of the treatment, including recurrence or recrudescence.

Positive - negative controls

All trials should have a control or placebo treatment to compare with the experimental treatment. If a negative control is unacceptable on a commercial dairy, a positive control (oxytetracycline or lincomycin as a topical spray or bandage) should be used. Oxytetracycline tends to be the antibiotic to which all other treatments are currently compared. A non-affected group should be evaluated, if possible, to assess the incidence of new lesions (infections) during the course of the trial.

Drawing

A sketch drawing of the lesion should be made on the standard form. The sketch should show the location of the lesion on the limb, and include front and rear views. It should indicate whether the lesion is localized or diffuse. Florida and California workers describe the lesion using the following descriptions:

- flat or concave (red and raw)
- granular (terrycloth towel-like surface)
- proliferative (papillae on the surface).

Color - tissue proliferation

A red moist color indicates an active lesion that is continuing to grow or progress. Dark color and a dry keratinized appearance indicates likely regression or healing. Lesion color should be classified prior to the beginning of the treatment, at the end of treatment, and at some time period following the conclusion of treatment. These evaluations could be made in numerical form to enable herd scoring:

4 - red or gray, moist
2 - less moist, beginning to darken
1 - dark, keratinized
0 - no lesion

Color can be documented by using photographs or slides. People with color vision problems may have difficulty evaluating color as a usable tool for therapy evaluation.

Pain

Pain can be evaluated by spraying the lesion with a pressure sprayer (50-60 PSI) at a distance of 24", using standard household water pressure at a distance of 24", or digital pressure on the affected area. Spraying of the lesion should be preceeded by manually touching the rear leg or below the hock to test the "flinch" response. Spray-

ing both rear feet and legs with water prior to the actual testing spray helps minimize any reaction or "flinching" due to surprise alone. Pain response to water spray is evaluated as:

0 = no movement
2 = pick up foot and return to floor within 2 seconds
4 = hold foot up more than 2 seconds

Scoring results

Scoring systems previously used by the authors of this paper are shown in Table 1. A scoring system utilizing the recommendations suggested in this paper is shown in Table 2.

Size of lesion

Size of the lesion may not be related to the severity of the disease; for instance, early lesions less than 1 inch in size may be quite painful while animals with mature lesions of 2 or more inches may not exhibit pain. Size should be recorded for academic purposes, and may be useful at a later date as more is learned about the significance of lesion size. Size can be measured top to bottom and side to side on the lesion itself. It can also be determined by using identified photos or slides made of lesions both pre-treatment and post-treatment, using a standard focal length or fixed magnification. Photos should include a measurement scale or a marker device, and be held as close as practical to the lesion at the time of photography. A caliper can be used to make quick measurements on cows evaluated in a milking parlors. If time does not allow accurate measurements of lesions, a close estimate of size should be made using a standard size object, such as a coin. It may take 30 days or more to see a major change in size.

Due to differences in measuring technique, change in size may be evaluated as: equal to 80-120% of the original lesion, no change; 80% or less of the original size, decreasing; and 120% or more of original size, increasing.

Lameness score

Although lameness score has been used to evaluate treatment response, its use poses problems as there may be other causes of lameness besides PDD. Ideally, cows included in trials using lameness scoring as a measure of response would have their feet trimmed and have pain response tested with a hoof tester. Cows with non-PDD foot lesions, such as sole hemorrhage, abscesses, white line disease, chronic laminitis, heel cracks, heel erosions, sole overgrowth, trimming damage, hoof tester response, or upper limb lameness should be excluded from the trial.

Hoof trimming and checking pain response with a hoof tester, however, is not always possible or practical, especially when large numbers of cows are utilized. On occasion, trimming may cause temporary lameness, confounding clinical observations and lameness scoring.

Proper randomization of cows to treatment groups should randomly distribute other foot conditions to each group. If lameness score is included in the evaluation, the system in Table 3 is recommended.

Statistical Analysis

Single animals are the experimental unit only when individual cow treatments are used, such as spraying or wrapping affected feet. When group treatments are used, such as foot baths, group results should be reported.

Group sizes should be based on the minimum number of cows necessary to provide sufficient statistical power to show differences, including treatment groups and controls. Most reports compare mean scores of pre-treatment and post-treatment groups to determine the effectiveness of the product being tested. ANOVA and log transformation have both been used for statistical analysis of trial results, however ANOVA seems to be most common. A statistician should evaluate the trial protocol and recommend which method of data analysis is best. A form to report results is shown in Table 4.

Discussion

Evaluating response to therapy is difficult when the etiology of the disease is unknown. When PDD lesions appear to respond to therapy, it is unknown whether they are truly healed or simply in some form of remission, from which they may reoccur. Pain response causes cow discomfort and is likely the reason milk production and reproduction performance may be reduced. Color can be affected by the environment of the animal and also the color and nature of the treatment product. Red color with proliferative tissue usually indicates that a lesion is active. Some of these animals, however, show limited or no pain and lameness.

Short-term clinical response of PDD to topical treatment with antimicrobials is usually good, but by 90 days post-treatment, recurrence or recrudescence is common.[14] In one study, half of the lesions that appeared to be clinically healed had some histological evidence of activity.[15] Lesion character, color, and size are fairly easy to evaluate in the milking parlor before treatment. If the treatment has a good clinical effect, cows will bear more weight on the heels as the pain subsides, which makes observing the lesions more difficult. Lesions are best observed while cows are restrained in a hoof trimming chute or when the leg is lifted, but this is labor intensive and time consuming. The pain response to water spray or digital pressure is the easiest and most objective way to evaluate response to treatment when cows must be evaluated during milking.

Table 1. Evaluating systems used by authors of this paper (letters by states refer to paper authors)

Location	Wisconsin (a)	California (b)	Florida (c)	Missouri (d)
Size				
0	No lesion	No lesion	No lesion	No lesion
1		< 2.5 cm	<2.5cm	Size to nearest 0.25 cm
2	<1"	>2.5 cm	>2.5cm	
4	>1"<1.5"			
6	>1.5"<2"			
8	>2"<2.5"			
10	>2.5"			
Pain				
0		No pain	No pain	No pain
1		Moderate pain **c**	Moderate pain **a**	Sensitive **e**
2		Obvious pain **d**	Severe pain **b**	Severe **f**
Color				
0		Normal flesh	Normal flesh	Normal flesh
1		Black **g**	Black or brown **i**	Black **k**
2		Red,tan,grey **h**	Red or gray **j**	Gray **l**
3				Skin outgrowth **m**
4				Red **n**
Swelling				
0				No swelling
1				Swelling
Lesion score				
0			No lesion	
1			Flat **o**	
2			Raw and granular **p**	
3			Raised, papillae **q**	
4			Mature **r**	
Tissue proliferation				
0	None			
2	Trace **s**			
4	Moderate **t**			
6	Extensive **u**			
Papillae formation				
0	None			
1	Few <6			
2	More than 6			
Skin ulcers				
0	None			
1	Early **v**			
2	Late **w**			
Lameness				
0	None			
1	Very slight			
2	Noticeable			
3	Carries foot			
Lesion location				
		Drawing of foot		
Duration of trials				
	21 days	30-60 days	110 days	11 days

a Cow moves foot when sprayed, **b** holds foot and shakes, **c** mild to not discernable, **d** obvious, **e** sensitive, **f** severe, **g** dark scabbed over, **h** red, tan, gray, **i** black or brown healing, **j** red, grey, active, **k** black regression, **l** middle stage, **m** skin overgrowth, **n** erythema, **o** flat, **p** raw, distinct, **q** raised, early papillae, **r** mature raised, **s** flat, **t** raised proliferation, **u** raised proliferation, 1", **v** early and central, **w** ulcers surrounding lesion

Table 2. Total lesion score

Measurement	Comments	Score
Size - Either by direct measurement or 2X2 slide		
<80% of original size		0
80 to 120% of original size		2
>120% of original size		4
Pain - Using digital pressure then water spray at 50-60 PSI		
No pain	no movement	0
Moderate pain	raises foot for <2 seconds	2
Obvious pain	raises foot for >2 seconds	4
Color - As observed with a clean lesion		
No lesion		0
Dark, keratinized		1
Less moist, beginning to darken		2
Red or gray, moist		4
Lesion Disappearance Score		
No Lesion	normal skin	0
Flat	flattened surface	1
Raw and granular	granular tissue formation	2
Raised with papillae	granular with papillae	3
Mature	raised rounded or diffuse lesion	4

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Table 3. Lameness score and description[22]

Lameness score	Clinical description	Assessment criteria
1	Normal	The cow stands and walks with a level-back posture. Her gait is normal.
2	Mildly lame	The cow stands with a level-back posture but develops an arched-back posture while walking. Her gait remains normal.
3	Moderately lame	An arched-back posture is evident both while standing and walking. Her gait is affected and is best described as short-striding with one or more limbs.
4	Lame	An arched-back posture is always evident and gait is best described as one deliberate step at a time. The cow favors one or more limbs/feet.
5	Severely lame	The cow additionally demonstrates an inability or extreme reluctance to bear weight on one or more of her limbs/feet.

Table 4. Total lesion score from trials*

Category	Mean score pre-trial	Mean score post-trial	Deviation from mean pre/post	Std. dev.	P value
Size					
Pain					
Color					
Lesion disappearance					
Lameness					

* Scores are for each category and not a total for all categories

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