Analytical Review of New Teat Dip Efficacy Claims

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Abstract

The success of post milking teat disinfection and more recently with premilking teat disinfection has resulted in numerous products marketed as teat dips for the control of mastisis in dairy cows. Some teat dips have been evaluated for safety and their ability to reduce the incidence of new intramammary infections, while others have not been tested at all. Currently, no U.S. governmental agency requires efficacy, safety or residue data on teat disinfectants prior to marketing. However, protocols were developed by the National Mastitis Council for efficacy evaluation of postmilking teat disinfectants and were revised in 1989 to update technology and enhance scientific merit and standardization of evaluation procedures. In addition, protocols were developed by the National Mastitis Council for evaluating efficacy of teat dips as premilking teat disinfectants. Objectives of this paper are to review how teat dips are evaluated for efficacy and safety and to present data on teat dips from recently published peer-reviewed scientific journals.

Introduction

Postmilking teat disinfection with an effective germicide is recommended widely by dairy advisors and has been adopted by dairy producers in increasing numbers. Premilking teat disinfection or predipping is a relatively new procedure that is used by some dairy producers to further reduce the rate of new intramammary infections (IMI), particularly infections caused by environmental mastitis pathogens. According to the 1992 Hoard's Dairyman Continuing Market Study, 96.6% of 415 respondents dipped or sprayed teats of cows after milking and 47.0% of respondents used a teat dip or spray before milking.[1]

The success of postmilking teat disinfection and more recently with premilking teat disinfection has resulted in numerous products marketed as teat dips for the control of mastitis in dairy cows. Some teat dips have been evaluated for safety and their ability to reduce the incidence of new IMI, while others have not been tested at all. Currently, no U.S. governmental agency requires efficacy, safety or residue data on teat disinfectants prior to marketing. However, protocols were developed by the National Mastitis Council for efficacy evaluation of postmilking teat disinfectants in an attempt to standardize procedures for evaluating teat dips. The history, development and usage of postmilking teat disinfectant protocols were reviewed by Pankey *et al.*[2]

Postmilking teat disinfectant protocols were revised in 1989 by the National Mastitis Council to update technology and enhance scientific merit and standardization of evaluation procedures, and were published recently.[3] In addition, protocols were developed by the National Mastitis Council for evaluating efficacy of teat dips as premilking teat disinfectants.[4] Objectives of this paper are to briefly review how teat dips are evaluated for efficacy and safety and to present data on teat dips from recently published peer-reviewed scientific journals.

Protocols for Evaluating Efficacy of Postmilking Teat Dips

Major revisions to previously published protocols include: 1) removal of alphabetical designation of protocols formerly referred to as Protocol A for screening germicidal activity of teat dips on excised cows' teats, Protocol B for determining efficacy of a teat dip based on prevention of intramammary infection following experimental exposure of teats to mastitis pathogens and Protocol C for determining efficacy of a teat dip based on reduction of naturally occurring new infection; 2) omission of the excised teat model for determining bactericidal activity of teat dips; 3) addition of a protocol using an experimental design with a positive control (teat dip of known efficacy) in natural exposure field trials; and 4) suggesting that efficacy of a teat dip under natural exposure conditions should be evaluated in at least two herds for at least 12 months. The above modifications were made to enhance scientific merit of protocols and to further standardize testing procedures. For a more in-depth description of the revised postmilking teat dip protocols refer to.[3]

Determining Efficacy of a Postmilking Teat Dip After Experimental Exposure of Teats to Mastitis Pathogens

This protocol is also referred to as Experimental Challenge and was previously designated Protocol B. These studies are conducted in research herds so that experimental conditions and experimental cows can be monitored closely. All teats of experimental cows are dipped immediately after milking machine removal in a

bacterial suspension generally containing *Staphylococcus aureus* and/or *Streptococcus agalactiae* at least once daily for a minimum of 5 days each week for the duration of the study. The experimental teat dip is applied to two teats of each udder immediately after exposure to the bacterial challenge suspension; the remaining teats are not dipped. Milk samples for microbiological evaluation are collected at least weekly and examined according to standard procedures described by the National Mastitis Council.[5] Efficacy of the experimental teat dip is based on mean percentage reduction in rate of new IMI in dipped quarters as compared to rate among control quarters and the statistical reliability of the mean percentage reduction. The length of an Experimental Challenge study depends on number of quarters tested, rate of new IMI in dipped and control quarters and percentage reduction of IMI in dipped quarters.

Data are presented to inform the reader about the duration of the trial, number of quarters initially eligible for infection, number of new IMI by each test organism in control and treated quarters, percentage reduction in new IMI by test organism(s), and colony-forming units of bacteria per milliliter in each challenge suspension. Some advantages of the Experimental Challenge protocol for evaluating efficacy of postmilking teat dips are that: 1) efficacy can be determined in a much shorter time, generally a few months, compared to natural exposure studies that require 12 months or more, 2) experimental conditions and experimental cows can be controlled and monitored more closely, and 3) effectiveness against a particular mastitis pathogen can be ascertained. Some disadvantages of the Experimental Challenge protocol for evaluating efficacy of postmilking teat dips are that: 1) studies need to be conducted in research herds, 2) efficacy is only determined against one or two mastitis pathogens, and 3) it does not take into account herd management factors and seasonal variation in incidence of IMI.

Determining Efficacy of a Postmilking Teat Dip Based on Reduction of Naturally Occurring New Intramammary Infections

This protocol is also referred to as Natural Exposure and was previously designated Protocol C. These studies can be conducted in commercial or research herds and a minimum of two herds should be used where cooperation of herd managers to comply with experimental procedures can be assured. Duration of the trial should be at least 12 months to include each season of the year. Experimental design can be either split-herd or split-udder. In the split-herd design, teats of half the cows are dipped immediately after milking machine removal in the experimental product while teats of remaining cows serve as undipped negative controls. Cows in each treatment group are balanced by parity, stage of lactation and bacteriological status of quarters. In a spilt-udder design, either two diagonal teats or teats on either the right or left side of each udder are dipped in the experimental product immediately after milking machine removal; remaining teats are not dipped and serve as negative controls. Milk samples for microbiological evaluation are collected to determine existing infections in the herd at the beginning of the study and then either monthly or bimonthly thereafter. Samples are also collected when cows calve, when cows enter or leave the herd, and when clinical mastitis is detected. An infection is diagnosed when the same bacterial species is isolated from both of the duplicate samples taken bimonthly or from clinical quarters, or from two consecutive monthly samples taken during the trial.

Efficacy of the experimental teat dip under natural exposure conditions is based on mean percentage reduction in rate of new IMI in dipped quarters as compared to rate among undipped control quarters. Data are presented to inform the reader about the duration of the trial, number of quarters in the trial at the onset and throughout the study, number of total new IMI categorized by bacterial species or type that occurred in control and dipped quarters, the percentage difference in total new IMI between dipped and control quarters and for each bacterial species and the statistical reliability of the mean percentage reduction, the number of new clinical cases categorized by bacteriological status that occurred in control and dipped quarters, and the percentage difference in new clinical cases between treated and control quarters.

Advantages of the Natural Exposure protocol for evaluating efficacy of postmilking teat dips are: 1) it does not require a research herd to conduct the study, 2) can evaluate the experimental teat dip under more realistic conditions, 3) it takes into account stage of lactation and seasonal influences,and 4) can obtain data on a wider array of mastitis pathogens. Disadvantages of the Natural Exposure protocol for evaluating efficacy of postmilking teat dips are: 1) that it requires at least 12 months to obtain efficacy data, and 2) if commercial herds are used it may be difficult to monitor and control experimental procedures.

Comparing an Experimental Postmilking Teat Dip with a Product of Known Efficacy Based on Incidence of Naturally Occurring New Intramammary Infections

This protocol is essentially the same as the Natural Exposure protocol just described except that a positive control or a teat dip with known efficacy is used instead of a negative control or no dip. For example, if a split-herd design is used, all teats of half the cows are dipped in the experimental product and teats of cows in the remaining half of the herd are dipped in a product of known efficacy and serve as positive controls. The use of

this type of study is advantageous when it is impractical to not dip teats of cows such as in commercial dairy herds; or if the purpose of the trial is to determine if the experimental product is more efficacious than the positive control or if the efficacy of the product does not vary from that of the positive control by greater than a predetermined amount.

Protocol for Determining Efficacy of Premilking Teat Dips

Premilking teat disinfection or predipping is a relatively new procedure practiced by some dairy producers. In 1991, a protocol for determining efficacy of premilking teat dips was published in an attempt to provide some guidance and standardization in the conduct of these studies.[4]

Determining Efficacy of a Premilking Teat Dip Based on Reductionof Naturally Occurring New Intramammary Infections

Experimental design can be either split-herd or split-udder as described for postdipping Natural Exposure trials. Milking routine for cows or quarters in predip and control groups should be identical with the exception of predipping teats in the treatment group. Teats of cows in the control group should be forestripped, washed and dried with single service paper towels in preparation for milking. Teats of cows in the treatment group should be forestripped, washed, experimental predip applied with a minimum contact time of 15-30 seconds or as recommended by the manufacturer, and teats should be dried thoroughly with a single service paper towel in preparation for milking. A detailed description of teat preparation procedures including how teats are washed and type and concentration of sanitizer in wash solution should be provided. A postmilking teat dip of known efficacy based on NMC recommended protocols for evaluating efficacy of postmilking teat dips should be applied to all teats after milking machine removal. Sampling schedule and procedures, and criteria for diagnosing infections are essentially as described for postmilking teat dips. Trials should be conducted in at least two herds for a minimum of 12 months.

Data are presented to inform the reader about the duration of the trial, number of quarters available for infection, number of new IMI categorized by bacterial species in control and predipped quarters, percentage difference in new IMI between predipped and control quarters for each bacterial species and the statistical reliability of the mean percentage reduction, number of new clinical cases categorized by bacterial species in control and predipped quarters, and percentage difference in new clinical cases between predipped and control quarters.

As of this writing, there is no National Mastitis Council published protocol for determining efficacy a premilking teat disinfectant after experimental exposure of teats to mastitis pathogens. Some research is being conducted in this area which may result in an acceptable experimental challenge design in the not-to-distant future.

Product Types and Efficacy Data on Some Postmilking and Premilking Teat Dips

Several different germicides have been incorporated into teat dip formulations. These include iodophor, chlorhexidine, linear dodecyl benzene sulfonic acid (LDBSA), chlorous acid-chlorine dioxide and others. Various concentrations and combinations have been formulated and evaluated for safety and efficacy.

A summary of some recent studies on efficacy of various teat dipformulations as postmilking teat dips is presented (Tables 1-5). Efficacy data on recent studies evaluating various premilking teat dips is in Table 6.

Table 1. Efficacy Data for Some Iodophor Postmilking Teat Dips.

Type of study	Conc	Significant effect against	Manufacturer	Ref
Natural[1]	.5	*S aureus, Staph spp, C bovis*	Theratec Babson Bros.	6
Natural	1.0	*S aureus, S agalactiae, Strep spp*	TeatKote Babson Bros.	6
Natural	.25	*S aureus, S agalactiae, C bovis, Staph spp*	H.B. Fuller	7
Exper.[2]	.18	*S aureus S agalactiae*	Bristol-Myers	8

1 Natural exposure protocol
2 Experimental challenge protocol

Table 2. Efficacy Data From Some Studies Evaluating LDBSA[1] as a Postmilking Teat Dip.

Type of study	Significant effect against	Ref
Natural	*S aureus*	9
Natural	*S agalactiae*	10
Experimental	*S aureus*	11

1 Blu-Guard, Economics Laboratory.

Table 3. Efficacy Data From Some Studies Evaluating Chlorhexidine as a Postmilking Teat Dip.

Type of study	Conc	Significant effect against	Manufacturer	Ref
Natural	.35	*S uberis, C bovis Staph spp*	H. B. Fuller	12
Exper.	.50	*S aureus, S agalactiae*	Babson Bros.	13

Table 4. Efficacy of Chlorous Acid-Chlorine Dioxide[1] as a Postmilking Teat Dip.

Type of study	Significant effect against	Ref
Natural	*S aureus, S dysgalactiae C bovis, Staph spp*	14
Natural	Contagious, some environmental	15
Experimental	*S aureus, S agalactiae*	16

[1]UDDERgold, Alcide Corporation.

Table 5. Efficacy of Some Postmilking Teat Dips by Experimental Exposure

Germicide	Significant effect against	Manufactuer	Ref
LDBSA & iodophor	*S aureus, S agalactiae*	IBA	17
Dodecylamino-alkyl glycine	*S aureus, S agalactiae*	3M	18
Lauricidin, fatty acids, lactic acid	*S aureus, S agalactiae*	Upjohn	19

Table 6. Efficacy of Some Premilking Teat Disinfectants Under Natural Exposure Conditions.

Germicide	Conc	Significant effect against	Manufacturer	Ref
Iodophor	.25	Environmental	IBA	20
Iodophor	.10	Environmental	IBA	20
LDBSA and iodophor	1.94 .55	Environmental	IBA	20
Iodophor	.25	Gram-negatives	H. B. Fuller	21
Chlorous acid-chlorine dioxide		*S aureus, S uberis*	Alcide Corp.	22

Summary

The success of postmilking and premilking teat disinfection has resulted in numerous products marketed as teat dips for the control of mastitis in dairy cows. Some teat dips have been evaluated for safety and efficacy following established protocols. On the other hand, some teat dips that are marketed have not been tested at all. Currently, no U.S. governmental agency requires efficacy, safety or residue data on teat disinfectants prior to marketing. However, this is subject to change in the future. A draft guideline entitled " Guideline for Target Animal and Human Food Safety, Drug Efficacy, Environmental and Manufacturing Studies for Teat Antiseptic Products" was prepared recently by the Food and Drug Administration and comments concerning this document were solicited.

Protocols for evaluating the safety and efficacy of postmilking and premilking teat disinfectants have been developed by the National Mastitis Council. Postmilking teat disinfectant protocols published initially in 1977 were revised recently to update technology and enhance scientific merit and standardization of procedures. Teat dip manufacturers are encouraged to utilize National Mastitis Council protocols for determining the safety and efficacy of teat dips. However, data on the safety and efficacy of an experimental teat dip are not required to market a teat dip.

Choosing an effective teat dip for use in a mastitis control program is no easy task. A teat dip should not be chosen solely on the basis of advertisements in popular dairy magazines. Rather, a teat dip should be chosen based on research evidence demonstrating safety and efficacy. Many new products have been introduced that are safe and effective and have research data to support their claims. If manufacturer's have conducted the appropriate studies, they will be more than willing to share results of teat dip safety and efficacy studies with potential customers. Teat dips that have not been evaluated should not be assumed to be safe and effective and should not be recommended. Furthermore, an effective postmilking teat dip should not be assumed to be safe and efficacious as a premilking teat dip.

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