J. Dairy Sci. 99:1–6
http://dx.doi.org/10.3168/jds.2015-10666

Short communication: Efficacy of glycolic acid-based and iodine-based postmilking barrier teat disinfectants for prevention of new intramammary infections in dairy cattle

A. Lago,*[1] D. R. Bruno,† M. Lopez-Benavides,† and S. Leibowitz†
*DairyExperts Inc., Tulare, CA 93274
†DeLaval Manufacturing, Kansas City, MO 64153

ABSTRACT

A positive-control, natural exposure noninferiority field study was conducted to test the efficacy of a novel glycolic acid-based postmilking barrier teat disinfectant compared with a commercial iodine-based postmilking barrier teat disinfectant (positive control). Cows from 2 pens from a California Central Valley dairy farm were dipped after milking either with the positive-control product (PC) or the experimental product (EX) over 12 wk. New intramammary infections (NIMI) were determined by biweekly sampling of all quarters of study cows and classified as a NIMI based on somatic cell count and milk bacteriological culture results. The mean quarter-level incidence risks during a 2 wk study period were 3.50% (EX) and 4.28% (PC). The majority of NIMI were caused by coagulase-negative staphylococci, followed by non-agalactiae streptococci. The study results indicated that EX was noninferior to PC, with a 17% relative efficacy (improvement) in reducing NIMI compared with the PC group. Also, quarter somatic cell count was not affected by the postmilking teat disinfectant used. Finally, the EX product was safe in terms of teat conditioning: teat condition scores were not different between study groups. The study concluded that the glycolic acid-based experimental post-dip barrier was noninferior to the control, and could be considered a safe and effective postmilking teat disinfectant.
Key words: mastitis, postmilking teat disinfectant, bacteria, barrier

Short Communication

Bovine mastitis continues to have significant effects in the dairy industry. In spite of major advances in the prevention and treatment of mastitis in dairy cows over the past several decades, it remains the leading cause of decreased milk production, lower milk quality, animal loss, and ultimately reduced profit for the dairy producer (Hogan et al., 1984; Ruegg, 2012). Topical disinfection of teats before and after milking, with products proven effective at reducing new IMI (**NIMI**), has been used with benefit for decades. Disinfection of the teat skin after milking helps reduce the spread of mastitis pathogens by preventing them from entering and colonizing the mammary gland (Neave et al., 1969; Vijaya Kumar et al., 2012). Various products exist for pre- and postmilking teat disinfection, and several publications have documented the effectiveness of these products in preventing IMI in dairy cows (Oliver et al., 2001; Hillerton et al., 2007; Ceballos-Marquez et al., 2013). The National Mastitis Council (www.nmconline.org) has also published a bibliography of peer-reviewed research on the efficacy of commercially available teat disinfectants (National Mastitis Council, 2014). Postmilking teat disinfectants must have a persistent and effective killing action, and they must leave teats in good condition. Preservation of healthy teat skin is essential for maintaining its natural defense against infection (Hogan et al., 1990; Mein et al., 2001), because sore, dry, cracked teats may harbor mastitis-causing pathogens (Blowey and Edmondson, 2010). Barrier-type teat disinfectants have been developed to extend the germicidal properties of the disinfectant after the cow leaves the milking parlor. These products contain components that can provide a protective film and seal the teat from mastitis-causing bacteria (Nickerson and Boddie, 1995).

Split-herd study designs have some advantages over split-udder designs. Split-herd designs are more practical when enrolling large number of animals and are less likely to underestimate the effect size of prevention or treatment strategies implemented at the cow level due to interdependence between quarters (Berry et al., 2003). Recently, Ceballos-Marquez et al. (2013) was able to demonstrate the noninferiority of an experimental product relative to a positive control using a split herd with pen-level treatment allocation. The National Mastitis Council has protocols available for testing teat

Received November 19, 2015.
Accepted May 9, 2016.
[1]Corresponding author: alfonso.lago@dairyexperts.com

disinfectants under natural conditions (Nickerson et al. 2004). Adjustments to existing protocols have been proposed to test the noninferiority of an experimental product compared with a control product, based on adequate statistical approaches and reasonable logistical modifications (Ceballos-Marquez et al., 2013).

The goal of the present study was to evaluate the effectiveness and safety of a newly developed glycolic acid-based postmilking barrier teat disinfectant OceanBlu Barrier (**EX**; GlyTec and 10% emollients; DeLaval Manufacturing, Kansas City, MO). Glycolic acid is naturally present in milk (NICNAS, 2000) and has limited germicidal activity, but GlyTec (DeLaval Manufacturing) is a proprietary blend of glycolic acid (3%) and other ingredients that overcomes glycolic acid's limitations related to germicidal efficacy. The primary objective of this study was to demonstrate the noninferiority of EX compared with an existing iodine-based positive-control postmilking barrier teat disinfectant, Blockade (**PC**; 1% iodine and 10% emollients; WestAgro Chemical Inc., Des Plaines, IL) in preventing NIMI that occur under natural circumstances on a commercial dairy farm. The secondary objective of this study was to assess the teat skin safety of the 2 products by monitoring teat condition.

Sample size calculation ($\alpha = 0.05$ and 80% power) estimated that 125 to 150 animals (500–600 quarters) per group would be necessary to adequately power the study. The required sample size was calculated using a confidence interval approach, considering where the confidence intervals for the test product effects lay with respect to the margin of noninferiority ($\boldsymbol{\Delta}$) and a null effect (all products are equal). A prestated Δ of 30% was specified as a difference in proportion of NIMI. In general, a product is considered efficacious if its efficacy is at least 40% for negative-control trials and 70% for positive-control trials (Schukken et al., 2013). Therefore, the efficacy of a test product cannot be less than 30% compared with a positive control. The estimate for test product efficacy relative to a positive control was defined as Efficacy (test product$_1$ vs. positive control) $= 1 - \exp(\beta 1)$, where $\beta 1$ is the log of the incidence risk of NIMI between the test product and the positive control. To obtain the actual ratio, the value of $\beta 1$ is exponentiated.

This 12-wk, split-herd, positive-control noninferiority field trial was conducted in a commercial dairy farm in the Central Valley of California in the United States. Cows were housed in open-lot pens bedded with manure dried out by stirring and sun exposure, and milked twice a day in a double-21 herringbone parlor. At the dairy, cows in all lactations were moved to high-yield milking pens without following any cow-dependent criteria at about 1 mo after calving; cows left their pens when they were moved to a dry-off pen or were culled. In the current study, cows from 2 high-yield milking pens were used: cows from one pen were assigned to EX and cows from the other were assigned to PC. Feeding and management practices were the same in both pens. The same premilking teat disinfectant, Opti Blue (1.6% linear dodecyl benzene sulfonic acid and 2% glycerin; DeLaval) was used in both pens. We used stratified randomization between first-lactation and mature cows at the pen level to ensure that the same number of cows were enrolled in both study groups. Late-lactation cows were not enrolled in the study, so that all cows in both groups were less than 260 DIM. Finally, cows in both groups were balanced by status of infection before the beginning of the study period.

Once the trial started, pre- and postmilking products were applied using a color-coded nonreturn dip cup that matched the numbered, colored leg bands on the cows, identifying the cow and the study group assigned. Two milk samples, one for SCC determination and another for aerobic culture, were collected every 2 wk from each quarter of all cows from wk −2 to 12. Each teat was prepared using a fastidious sampling technique that included the following steps: premilking disinfection, forestripping, wiping dry after 30 to 45 s of contact time, scrubbing the teat end with an alcohol scrub, discarding 3 or 4 squirts of foremilk, and finally collecting 2 milk samples. Milk samples for SCC analysis were collected into 60 mL vials containing bronopol and analyzed the next day at the DHIA (Tulare, CA). Milk samples for aerobic culture were collected into sterile 13 mL flip-top milk sampling vials and placed in a cooler with ice to be transported on the same day to DairyExperts Laboratory (Tulare, CA) and stored in a freezer (−20°C). For the first sampling (wk −2) samples from all quarters of all cows underwent SCC determination and culture for bacteriology. In subsequent samplings (wk 0 to 12) SCC was determined on all samples and thresholds were used to determine which samples were eligible for culture (Schepers et al., 1997; Lopez-Benavides et al., 2012). Only milk samples from first-lactation heifers with SCC ≥100,000 cells/mL and from cows in second or greater lactation with SCC ≥200,000 cells/mL were submitted for culture. Although the application of products on-farm could not be blinded, all laboratory outcome assessments for SCC and milk bacteriology were done blindly without knowledge of treatment assignment.

We determined SCC using a Somatocount 500 (Bentley Instruments Inc., Chaska, MN), according to the document on enumeration of SCC in milk FIL.IDF 148 A:95 norm (IDF, 1995). When SCC results were available, qualifying milk samples were cultured using aerobic microbiological techniques. Briefly, individual