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A randomized clinical trial of topical treatments for mild and severe udder cleft dermatitis in Dutch dairy cows

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ABSTRACT

Udder cleft dermatitis (UCD) is a skin lesion in dairy cows affecting the anterior parts of the udder, with the lesions often needing a long time to heal. The lesions can be characterized as mild or severe. The etiology of UCD is not fully understood and studies on the effectiveness of topical treatments have not been published. The objective of this study, therefore, was to conduct a randomized clinical trial to investigate the effectiveness of 2 different topical treatments, one for mild and one for severe UCD lesions, compared with untreated control groups. The treatment and control groups were randomized within herd for mild and severe UCD. The treatments were applied for a maximum period of 12 wk on 8 Dutch dairy farms. Mild UCD lesions were treated once a d 3 times a week on fixed days with a non-sting barrier film. Severe UCD lesions were first stratified into class A (lesion length <5 cm) or class B (lesion length ≥5 cm) and then randomly allocated to treatment or control groups within herd. Both severe lesion classes were treated once per day every day with an enzyme alginogel. Every week, the lesions of affected animals were inspected and photographed by the investigator. These photographs were reviewed weekly by an external wound expert who classified the lesions as mild, severe class A, severe class B, or healed. Based on this classification, the investigator judged weekly whether the lesions had improved compared with their classification of the previous week. For mild UCD lesions, improvement was defined as occurring when lesions were healed. For severe UCD lesions, improvement was defined as a transition from class B to class A, transition from any severe UCD lesion (class A or B) to a mild UCD lesion, or when the lesion was defined as healed. Data were analyzed using a discrete time survival analysis with time to first improvement as dependent variable. In total, data from 214 animals were analyzed to estimate the effectiveness of treatment. Results showed that treatment of mild UCD lesions had no influence on improvement compared with untreated lesions. Treated severe lesions, however, showed 3.4 times more improvement compared with the untreated controls. Improvement varied between herds, and cows with a parity of 5 or higher showed significantly less improvement than first parity animals. Early identification of severe UCD lesions followed by prompt treatment with an enzyme alginogel supports the healing process.

Key words: udder cleft dermatitis, dairy cow, topical treatment, randomized clinical trial

INTRODUCTION

Skin lesions in dairy cows located between the front quarters of the udder or at the anterior junction between the udder and abdomen are known as udder cleft dermatitis (**UCD**). Udder cleft dermatitis lesions have been reported in the United Kingdom (Beattie and Taylor, 2000), United States (Warnick et al., 2002), Sweden (Persson Waller et al., 2014; Ekman et al., 2018), and the Netherlands (Bouma et al., 2016). The herd prevalence ranges between 0 and 43% and the severity of UCD lesions varies between herds. Udder cleft dermatitis lesions heal poorly (Bouma et al., 2016) and have been shown to increase the risk of embolic pneumonia (Millar et al., 2017), affecting both animal health and animal welfare.

The etiology of UCD is not fully understood. Some studies suggest the involvement of infectious agents, such as sarcoptic mange (Warnick et al., 2002) or *Treponema* (Stamm et al., 2009; Evans et al., 2010). However, a Dutch study could not identify any involvement of *Treponema*, *Escherichia coli*, *Staphylococcus aureus*, yeast, or fungi (van Engelen et al., 2014). The Dutch study did detect *Bacteroides pyogenes* and *Trueperella pyogenes* significantly more often in severe UCD lesions compared with mild UCD lesions. The presence of these opportunistic anaerobic bacteria seems more indicative of secondary bacterial involvement than of

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a primary bacterial infection. Mechanical factors that could irritate the skin such as certain udder conformation traits (Olde Riekerink et al., 2014; Ekman et al., 2018), or housing- related factors such as shorter cubicles or matrasses as cubicle base (Ekman et al., 2018) have been identified as risk factors. Other risk factors that have been identified are more DIM (Bouma et al., 2016; Ekman et al., 2018) and breed and parity (Persson Waller et al., 2014; Bouma et al., 2016; Ekman et al., 2018). As yet a causal mechanism has not been identified, but a multi-factorial etiology is most likely.

To date, no proven effective treatment studies on UCD have been reported. The lack of an effective treatment often results in the field in ineffective treatments or untreated UCD lesions. When UCD lesions are not treated, the exudate desiccates and turns into crusts, which is known to be disadvantageous because wounds need moisture to heal (Winter, 1962). Udder cleft dermatitis lesions or intertrigo show many similarities in morphology and healing to human pressure ulcers. Mild UCD lesions look similar to stage 1 pressure ulcers, whereas severe UCD lesions are comparable to stage 2, 3, and 4 lesions (Black et al., 2007). Both pressure ulcers and UCD lesions show delayed healing, which is often caused by cellular and molecular imbalances in the wound bed (Eming et al., 2007). Particularly for hard-to-heal wounds it is important to adapt the treatment to the requirements of the wound and the phase of healing (Wilmink, 2017). In human medicine, some topical treatments have given good results for the different types of pressure ulcers, but these treatments have not been tested for UCD lesions in dairy cows.

Therefore, the aim of our study was to perform a randomized clinical trial to assess the clinical effectiveness of 2 different topical treatments, one for mild and one for severe UCD lesions, compared with untreated control groups. None of treatments contained antibiotics and the choice of treatments was based on evidence-based research in human medicine (Cameron et al., 2005; Beele et al., 2012; Chan and Siu, 2016). The topical treatment for mild UCD lesions consisted of a nonalcoholic film layer and focused on the protection of the lesion from moisture and dirt. Topical treatment of the severe lesions consisted of an enzyme alginogel and was directed toward stimulation of the inflammatory response and wound healing, and toward restoration of the bacterial balance.

MATERIALS AND METHODS

A randomized clinical trial was carried out on 8 Dutch dairy herds and for logistical reasons conducted in 2 rounds, each consisting of 4 participating dairy herds. A treatment period of maximum 12 wk per round was carried out based on the results of a longitudinal study (Bouma et al., 2016) that showed a median observed duration of 8.8 wk for mild UCD lesions and 16.2 wk for severe UCD lesions. Round one took place from May 12, 2014, until August 22, 2014, and round 2 from September 30, 2014, until January 9, 2015.

Herd Selection

Eight commercial dairy herds, 7 within one practice centrally located in the Netherlands (University Large Animal Practice, Harmelen, the Netherlands), and one herd in the neighboring practice (Amstel, Vecht en Venen, Vinkeveen, the Netherlands), were selected based on a total UCD prevalence of at least 6%, the likelihood of compliance with the study protocol, and enrolled in a DHI program every 4 or 6 wk. Herds with automatic milking systems were excluded because daily treatment of the affected animals by the farmer was considered to be too labor intensive in those herds.

This intervention study was approved by the Ethical Committee of Utrecht University, the Netherlands, and was not deemed to be an animal experiment under Dutch Law (email March 3, 2014).

Cow Selection

All dairy cows (dry and lactating) in the herd were eligible for enrollment in the trial. Cows were selected during the recruitment visit (**T0**), when all animals were inspected for signs indicative of UCD. Farms were visited just after morning milking, and all dry and lactating cows were fixed into headlocks and visually inspected one by one. The investigator used a lamp and hand mirror in one hand and spread the front quarters of the udder with the other hand for proper inspection of the skin between the 2 front quarters and the skin of the anterior junction between the udder and the abdominal wall. If signs indicative of UCD were present, a ventral photograph was taken via a mirror as described elsewhere (Bouma et al., 2016). If no signs indicative of UCD were observed, the udder was not photographed and the cow was not eligible to participate in the study.

UCD Classification

Skin integrity distinguished mild UCD lesions from severe UCD lesions, as this appeared to be the most distinctive characteristic for categorizing UCD (Persson Waller et al., 2014; Bouma et al., 2016). A UCD lesion was defined as mild when symptoms such as erythema, transudate, sebum, crusts, or scar tissue were present