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Randomized clinical trial evaluating the effect of bandaging on the healing of sole ulcers in dairy cattle

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ABSTRACT

This randomized clinical trial investigated the effect of bandaging on 56 uncomplicated sole ulcers (SU) among a sample of 52 dairy cows. Following therapeutic hoof trimming and povidone-iodine treatment, all cows received a wooden block on the unaffected claw and were randomly assigned into either a bandaged or non-bandaged group. The bandaging process was standardized and applied by the same veterinarian. Wound size and locomotion were measured weekly. Overall, 19 of 32 SU (59.4%) in the non-bandaged group were healed at week 4 compared to 7 of 24 ulcers (29.2%) in the bandaged group. Healing was significantly higher for non-bandaged than bandaged SU ($P = 0.024$). Bandaging had no effect on locomotion ($P = 0.9$). Cows with a lower locomotion (Sprecher 1 + 2) had significantly smaller lesion sizes (median lesion size, 0.5 cm^2, IQR = 0.21 to 0.92 cm^2) than animals with locomotion score 3–5 (median lesion size, 0.9 cm^2, IQR = 0.42 to 1.81 cm^2; $P < 0.001$). A multivariate cox proportional hazard regression indicated that bandaging and parity had a significant effect on healing. Specifically, bandaged SU had a significantly lower hazard ratio (HR) to cure compared to non-bandaged SU (HR = 0.32; $P = 0.01$; 95% CI = 0.13 to 0.78). Furthermore, cows with parity ≥3 had a significantly higher HR to cure compared to cows in their first lactation (HR = 2.73; $P = 0.025$; 95% CI = 1.14 to 6.56).

1. Introduction

Lameness in dairy cattle is a global issue that causes impaired animal wellbeing (Whay, Waterman & Webster, 1997), milk production loss (Amory et al., 2008), decreased fertility (Hernandez, Garbarino, Shearer, Risco & Thatcher, 2005) and a higher culling risk (Cramer, Lissemore, Guard, Leslie & Kelton, 2009) leading to substantial economic losses in the dairy industry. Sole Ulcer (SU) is considered the most expensive claw horn disorder with a loss of $178 USD to $216 USD per case (Cha, Hertl, Bar & Gröhn, 2010; Dolecheck, Overton, Mark & Bewley, 2019).

With a prevalence of 5.6 to 9.2%, SU is one of the most common non-infectious cause of lameness in cattle (Cramer, Lissemore, Guard, Leslie & Kelton, 2008; Holzhauer, Hardenberg & Bartels, 2008; Manske, Hultgren & Bergsten, 2002). Sole ulcer is defined as a penetration through the sole horn, whereby fresh or necrotic corium is exposed (Egger-Danner et al., 2014). The depth of the affected tissue determines the severity of the SU. In uncomplicated lesions, the corium is exposed during this initial stage of the condition. Complicated SU, however, can develop once deeper structures of the claw become infected (Smedegaard, 1985). Often seen in cows restricted to concrete surfaces, sole ulcers mostly manifest on the lateral claw of the rear foot and can also occur bilaterally (Greenough & Weaver, 1997). Sole ulcer can cause chronic pain. For more than 28 days after treatment, a lowered nociceptive threshold was found in cows with SU (Whay, Waterman, Webster & O'brien, 1998).

Accordingly, standard treatment for uncomplicated sole ulcers includes therapeutic trimming and supporting the unaffected claw with a wooden block to relieve weight bearing pressure from the affected claw. This promotes both pain relief and healing (Greenough, 1987). Though researchers contraindicate the use of bandaging claw horn lesions alone (Pyman, 1997; White, Glickman, Embree, Powers & Pearson, 1981), no study has investigated the benefit of applying a block to the unaffected claw and bandaging the affected claw. Protecting the exposed corium from mechanical irritation and slurry may prove beneficial for healing of SU (J. K. Shearer, Plummer & Schleining, 2015). Bandaging has been shown to be effective in healing other claw diseases by prolonging the exposure of treatment to the lesion (Klawitter, Döpfer, Braden, Amene & Mueller, 2019). A review, however, by Potterton et al. (2012) highlights a need for more evidence-based treatment options for claw lesions.

Therefore, the objective of this study was to evaluate the effect of

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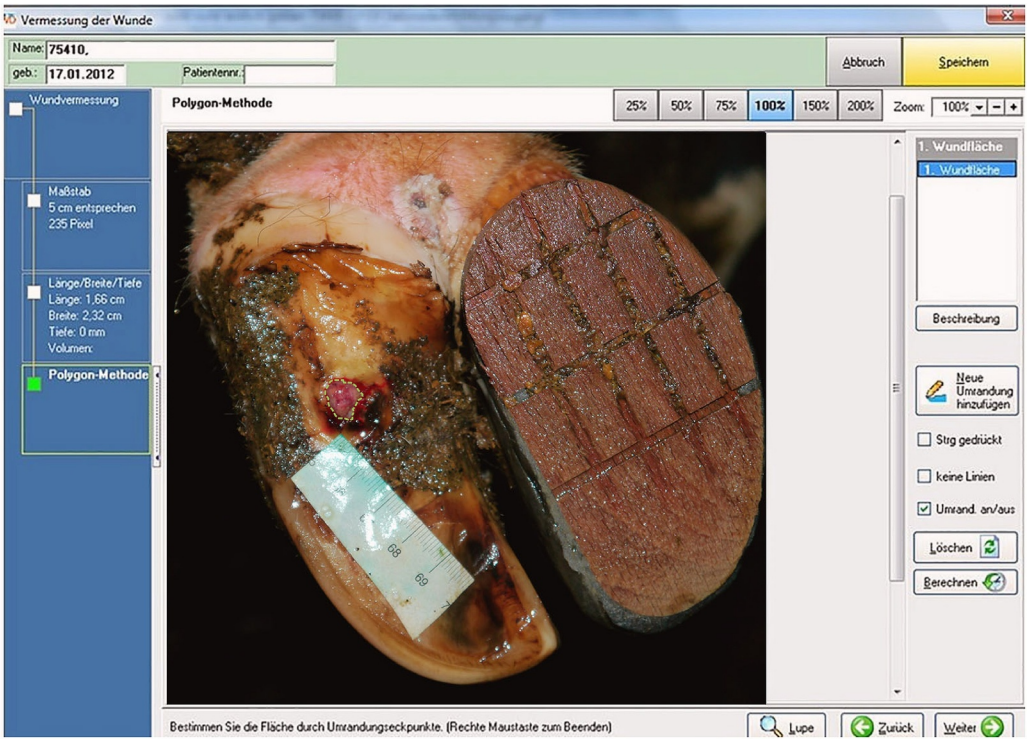

Fig. 1. The computer software "Jalomed WD" was used to measure the length, width and the lesion wound size of SU's (digital planimetry). The software calculated the lesion size using the polygon-method.

bandaging on the healing process in cows affected by SU in addition to applying a wooden block to the unaffected claw.

2. Material and methods

2.1. Study design and reporting

The present study was a positively controlled, randomized clinical trial (RCT) to test the effect of bandaging on the healing process of SU in dairy cows. The study manuscript followed the reporting guidelines of the REFLECT statement for randomized controlled trials in livestock (O'Connor et al., 2010). A positive control was chosen, whereby all animals received treatment. This prevented unnecessary animal suffering caused by untreated SUs. The Regional Veterinary Department Berlin (Landesamt für Gesundheit und Soziales) approved this study for ethical and medical issues (Number StN 0014-18).

2.2. Farm design and inclusion criteria

This study was conducted on a commercial dairy farm between August 2013 and January 2015 in Northeastern Germany. The farm comprises 800 dairy cows, excluding offspring.

Over the study period of 18 months, animals were enrolled only once. Animals included into the study ranged from being in their first to seventh lactation, belonged to German-Holstein breed and were kept in a free-stall housing system with concrete flooring and cubicles fitted with mattresses. All cows received professional routine claw trimming 2–3 times a year. Enrolled cows were diagnosed with uncomplicated SU at the typical place (Zone 4, according to Greenough & Vermunt, 1991) and had a sound partner claw for blocking. Cows that needed non-steroidal anti-inflammatory drug (NSAID) or antibiotic treatment during the period of the study were excluded. To prevent confounding the effects of treatment, footbaths were not performed during the duration of the trial.

2.3. Clinical examination and documentation recording

Locomotion was scored by the same person according to a 5-point locomotion scoring system (Sprecher, Hostetler & Kaneene, 1997), which assessed the presence or absence of an arched back and the animal's gait when standing or walking on a 12 m alley with concrete flooring. The locomotion scorer was not blinded to treatment assignment. Locomotion scores for normal to mildly lame cows ranged from 1 to 2; scores for moderately lame to severely lame cows ranged from 3 to 5. Afterwards in the trimming chute, all hooves were brushed, cleaned with soap and water, dried with a towel and trimmed by a professional hoof trimmer following the Dutch method (Toussaint Raven, 1985). Lesions were digitally photographed and measured using the software Jalomed WD (Jalomed GmbH, Lübeck, Germany; Fig. 1), which records and measures changes in lesion size and diameter (Öien, Håkansson, Hansen & Bjellerup, 2002; Richard, Daures, Parer-Richard, Vannereau & Boulot, 2000). Therefore, a digital picture of the wound including a sheet of paper with the size of 5 cm was used to calibrate measurement. Afterwards the length and the width of the lesion were measured. By manually surrounding the outer part of the lesion, the lesion size was calculated using the polygon-method. The lesions, thereafter, were classified and recorded according to a modified standardized scoring system comprising three stages (Fiedler, 2004). Sole ulcer in Stage 1 have a diameter of 1 cm or less. The diameters of SU in Stage 2 ranged from 1 to 2.5 cm. The diameters of SU lesion in Stage 3 had a diameter of 2.5 or greater. Lesion size and locomotion were evaluated, measured and photographed at week 0 and every 7 d (± 1 d) for four consecutive weeks, resulting in a total of up to five observations.

2.4. Randomization and treatments administered

Enrolled animals were randomly assigned to treatment group 1 or 2 by using a random number chart from a randomization generator. Cows in group 1 (G1) received a therapeutic foot trim using the Dutch five step method (Toussaint Raven, 1985). The sole horn around the ulcer

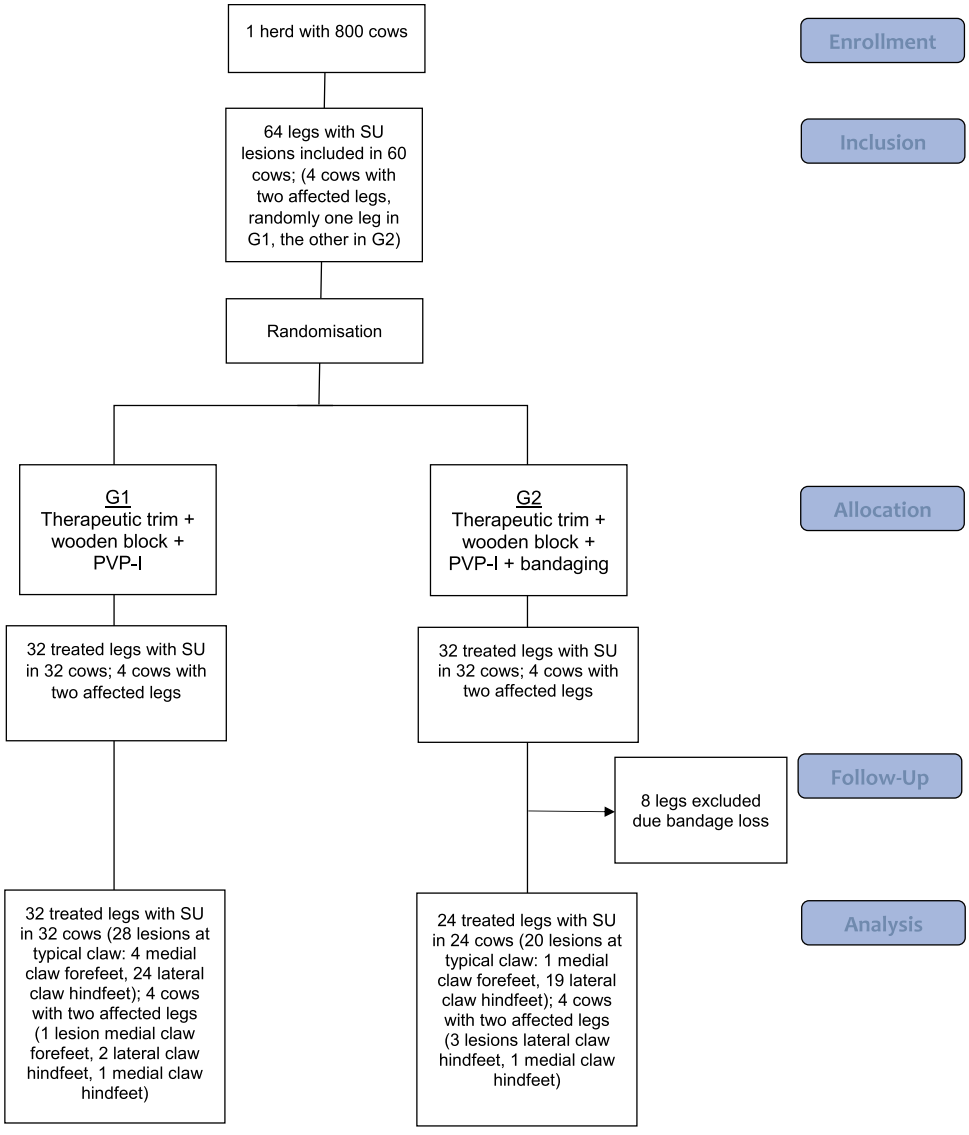

Fig. 2. Flow diagram of leg inclusion of a randomized clinical trial of two groups. SU, sole ulcer; PVP-I, Povidone-iodine.

Table 1
Descriptive statistics of animals in two treatment groups in a randomized clinical trial conducted to test the effect of bandaging on healing of sole ulcers in dairy cows.

	Group 1 Therapeutic trim + wooden block + PVP-I (n = 32)	Group 2 Therapeutic trim + wooden block + PVP-I + bandaging (n = 24)	P value
Parity	1	2	0.2
Median (IQR)	1–2.25	1–3.25	
305-day ECM (kg)	8483	9018	0.7
Median (IQR)	7560–10,029	7478–10,146	
DIM (days)	191	177	0.9
Median (IQR)	116–231	121–271	
Initial lesion size (cm^2)	1.18	1.7	0.3
Median (IQR)	0.7–2.56	1.01–2.43	

IQR, Interquartile range; 305-d ECM, 305-day Energy corrected Milk; DIM, Days in Milk; PVP-I, Povidone-iodine.

including wall horn was carefully dished-out to remove pressure. Afterwards a wooden block was glued on the unaffected claw using Demotec 95 (Demotec®, Nidderau, Germany) to elevate the affected claw. To reduce microbial growth, 15 g of a povidone-iodine (PVP-I) ointment (Vet-Sept® Salbe, Albrecht, Aulendorf, Germany) was applied onto the ulcer. Cows in group 2 (G2) received the same treatment as G1, but also a bandage around the affected claw. The bandaging technique was standardized and always administered by the same person to ensure methodological reliability. A 10 × 20 cm gauze square (NOBATOP®8, NOBA Verbandmittel Danz GmbH u. Co KG, Wetter, Germany) was applied to the affected area to keep the PVP-I ointment in place and to cover the lesion. Subsequently, cotton wool padding (Klauen- und Polsterbinde, Albrecht GmbH, Aulendorf, Germany) was applied in thin circular layers around the foot starting at the interdigital cleft. A strong, rigid bandage (NOBASOLID®, NOBA Verbandmittel Danz GmbH u. Co KG, Wetter, Germany) covered the underlying application in circular layers, starting at the interdigital cleft. The bandage twisted at 180° to include the tip of the claw and to ensure stability. Finally, Rusterholz technique was applied whereby the bandage was knotted at the lateral side of the hoof to alleviate pressure on the tendons. Adhesive tape (08135 Gewebeklebeband, Wirtschaftsgenossenschaft deutscher Tierärzte eG, Garbsen, Germany) was applied to

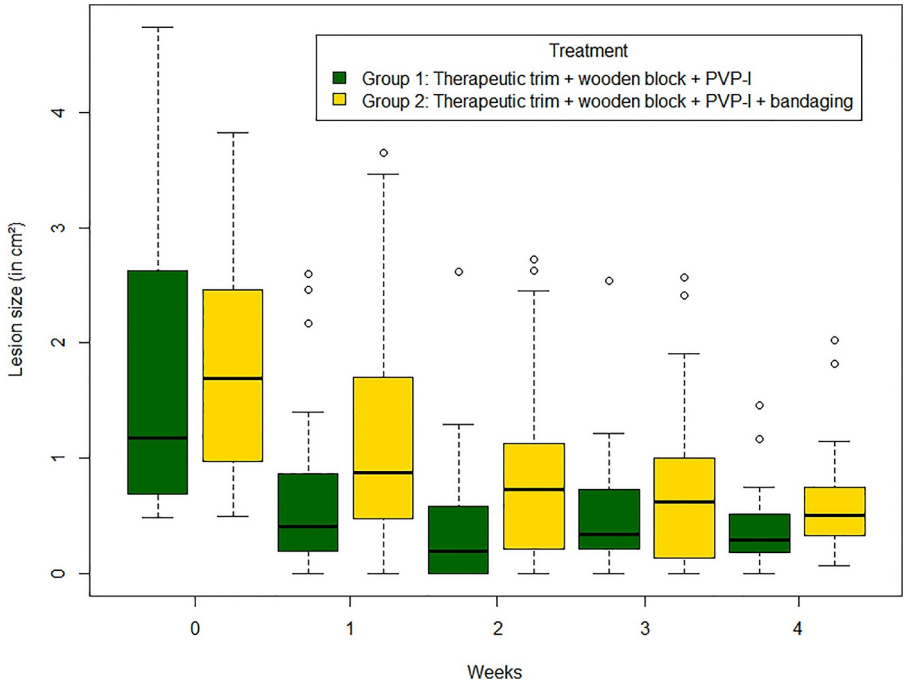

Fig. 3. Boxplot showing lesion sizes of sole ulcer in the non-bandaged Group 1 and the bandaged Group 2 at each examination in a randomized clinical trial. PVP-I, Povidone-iodine.

Table 2
Treatment group assignment and effect of different therapeutic protocols for sole ulcer therapy of 56 lesions in 52 dairy cows in a randomized clinical trial.

Group	Treatment	No. of SU	No. of healed SU* (%)
1	Therapeutic trim + wooden block + PVP-I	32	19 (59.4%)
2	Therapeutic trim + wooden block + PVP-I + bandaging	24	7 (29.2%)

* All transitions from SU with exposed corium to lesions fully covered with new horn.

the knot to prevent breakage. An outer layer of beech tar (Wirtschaftsgenossenschaft deutscher Tierärzte eG, Garbsen, Germany) was brushed onto the bandage to waterproof the bandage against slurry (Lischer et al., 2000). All cows remained on a dry surface for 30 min post treatment. For cows with SU lesions on both legs at week 0, lesions were randomly assigned into either the bandaged or non-bandaged group through coin flipping. The same person inspected all animals at weekly intervals. A blinding of the person administering the intervention to group assignment was omitted because of feasibility reasons. Treatment ended for cows deemed healed, which was defined as lesions fully covered with new horn. Unhealed lesions received up to five repeated applications of treatment during weekly inspections for up to four weeks after inclusion into study.

2.5. Statistical analysis

Data analyses were performed using R (V.3.5.2, R Core Team, 2018). A Wilcoxon Rank Sum Test measured differences in bivariate populations. Results of the Wilcoxon Rank Sum Test are reported as median and interquartile range (IQR). Kaplan-Meier survival functions and Cox proportional hazard regression estimated the time until cure for sole ulcers. Specifically, the multivariate Cox proportional hazard regression was performed in a backward stepwise manner. The event of "cure" was the variable of interest, while bandaging, parity, initial lesion size, locomotion score, 305-d energy corrected milk (305-d ECM) and interaction terms for parity by locomotion score and locomotion score by initial lesion size were covariates.

The variable with the highest P-value was eliminated at each step with reanalysis between steps, until the final model was obtained. Results of the Cox proportional hazard regression are reported as hazard ratios (HR) with 95% confidence intervals (CI). It was assumed that the probability to cure was the same for SU lesions recruited early and late in the study. This assumption was tested by comparing the survival curves between cohorts recruited early in the study to those recruited late.

Furthermore, a random effect of having two SU was added to the Cox mixed-effects model to assess its' impact on healing. An ANOVA compared the model with the random effect of having two SU to a multivariate Cox proportional hazard model that omitted this effect. For all tests the level of significance was set at $P < 0.05$.

3. Results

3.1. Descriptive results

In total, 64 sole ulcers in 60 cows were included into this study at week 0. Cows that lost their bandage at the time of follow up were excluded from this study ($n = 8$ sole ulcers in 8 cows); resulting in a final sample size of 52 cows with 56 lesions. Four cows had two affected legs. 86% of SU (48/56 lesions) were located at the typical claws (43/56 hind lateral claw; 5/56 lesions front medial claw). A flow diagram of leg inclusion is shown in Fig. 2. Differences for parity, 305-d ECM production and initial lesion size between both treatment groups were calculated using the Wilcoxon Rank Sum Test and are shown in Table 1.

3.2. Bivariate analysis

Bandaging of SU had no effect on animal's locomotion ($P = 0.9$). But cows with lower locomotion scores (Sprecher 1 + 2) had significantly smaller lesion sizes (median lesion size, 0.5 cm^2, IQR = 0.21 to 0.92 cm^2) than animals with locomotion score 3–5 (median lesion size, 0.9 cm^2, IQR = 0.42–1.81 cm^2; $P < 0.001$). The distribution of lesions sizes in G1 and G2 at each examination is shown in Fig. 3.

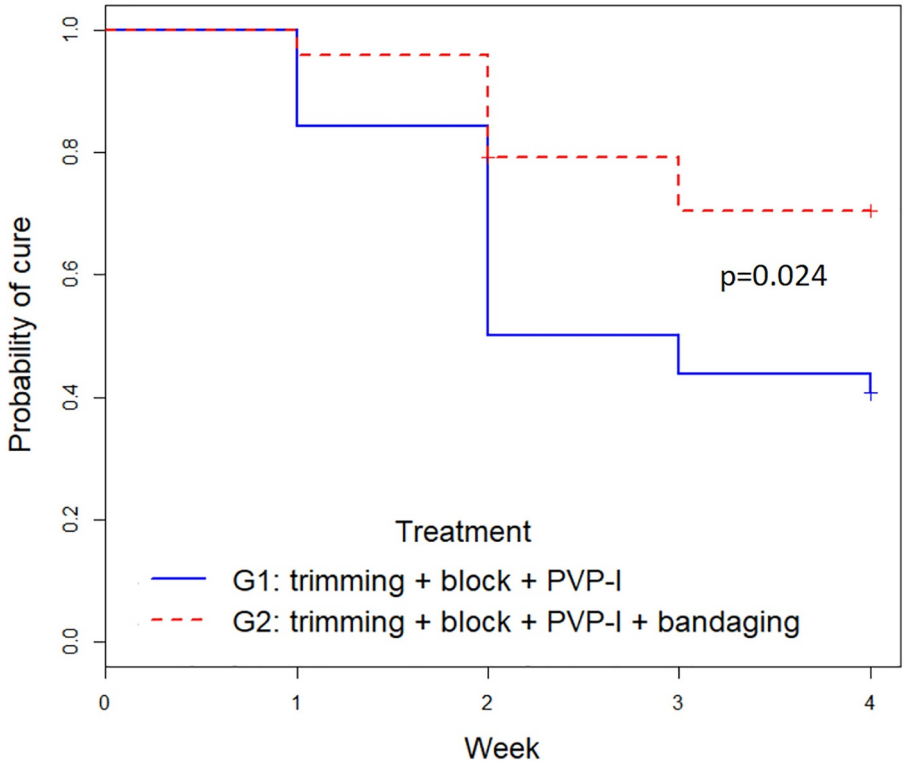

Fig. 4. Kaplan-Meier survival plots for propability of cure for sole ulcers stratified by two treatment groups enrolled in a randomized clinical trial (P = 0.024). PVP-I, Povidone-iodine.

3.3. Survival analysis–time until healing

By week four, 59.4% of non-bandaged (n = 19, G1) and 29.2% of bandaged SU (n = 7, G2) were macroscopically deemed healed (Table 2). The log-rank test identified a significantly higher healing rate for SU in the non-bandaged group compared to the bandaged group (P = 0.024). Fig. 4 displays a Kaplan–Meier Graph of the estimated probability of cure as the outcome of interest for both treatment groups. A multivariate Cox proportional hazard regression found that bandaging and parity had a significant effect on healing. Bandaged SU had a significantly lower hazard ratio (HR) to cure compared to non-bandaged SU (HR = 0.32; P = 0.01; 95% CI = 0.13 to 0.78). Furthermore, cows with a lactation number ≥3 had a significantly higher hazard ratio to cure compared to cows in their first lactation (HR = 2.73; P = 0.025; 95% CI = 1.14 to 6.56, Fig. 5).

Results of the four cows with two affected legs matched general findings. More SU healed in the non-bandaged G1 (3/4 SU) compared to the bandaged G2 (1/4 SU). The ANOVA found no significant difference in the multivariate Cox proportional hazard model with the random effect of having two SU compared to a model that omitted this effect (P = *0.6*).

4. Discussion

Lameness is one of the most significant endemic disease problems facing the dairy industry. Claw horn lesions (principally sole hemorrhage, sole ulcer, and white line disease) are some of the most prevalent conditions. Though thousands of cows are treated for these conditions every year (Thomas et al., 2015), experimental evidence is limited on the most effective treatment protocols (Potterton et al., 2012). A randomized, controlled clinical trial was conducted to investigate the effect of bandaging on healing in cows affected by SU in addition to applying a wooden block to the unaffected claw. Healing was defined as lesions fully covered with new horn.

The healing rate of non-bandaged lesions (59.4%) was twice the rate of bandaged lesions (29.2%) at the fourth week of the study. Our healing rate of 59.4% for non-bandaged lesions was slightly below the one reported by Lischer, Dietrich-Hunkeler, Geyer, Schulze and Ossent (2001), whom observed a healing rate of 68.0% for non-bandaged lesions after 30 days of treatment. This study differs from previous ones as this is the first study to examine the effect of bandaging the affected foot in addition to blocking the sound foot. Previous studies either examined the solitary effect of bandaging the whole affected foot versus leaving the lesion uncovered (White et al., 1981), or studied elevation of the affected claw versus bandaging the whole affected foot (Pyman, 1997; Sala, Igna & Schuszler, 2008). Our results supported previous findings that bandaging does not improve the healing process in SU. Pyman (1997) compared three different treatment types for sole injuries (1) a wooden block, (2) a rubberized shoe, and (3) applying a padded bandage to the whole foot. The author concluded that both wooden blocks and rubberized shoes had the strongest effect on healing. Wooden blocks and rubberized shoes promoted healing through alleviating weight bearing pressure on the injured claw (Greenough, 1987). Within the context of our study, the elevation gained by blocking might have been diminished by the bandage. Furthermore, the reepithelization process may have been interrupted by the shearing friction between the rigid texture of the cotton layer on the delicate surface of the lesion.

Although our findings suggest that bandaging had no beneficial effect on healing uncomplicated sole ulcers, a bandage may be necessary for more severe cases and specific purposes like controlling hemorrhaging, preventing granulation tissue formation, or protecting large areas of exposed corium (Shearer & van Amstel, 2017) especially in unhygienic environment with slurry and faecals (Toholj, Kos, Smolec & Potkonjak, 2012). Bandaging is also indicated in non-healing SU lesions, whereby the exposed corium is infected with Treponema spp. (Evans et al., 2011). In these cases a rigorous surgical debridement in combination with an antibiotic spray (chlortetracycline), a block on the sound claw and a bandage led to 72.7% healing rate after 28 days (Kofler et al., 2015). Bandaging enhances the efficacy of treatment for

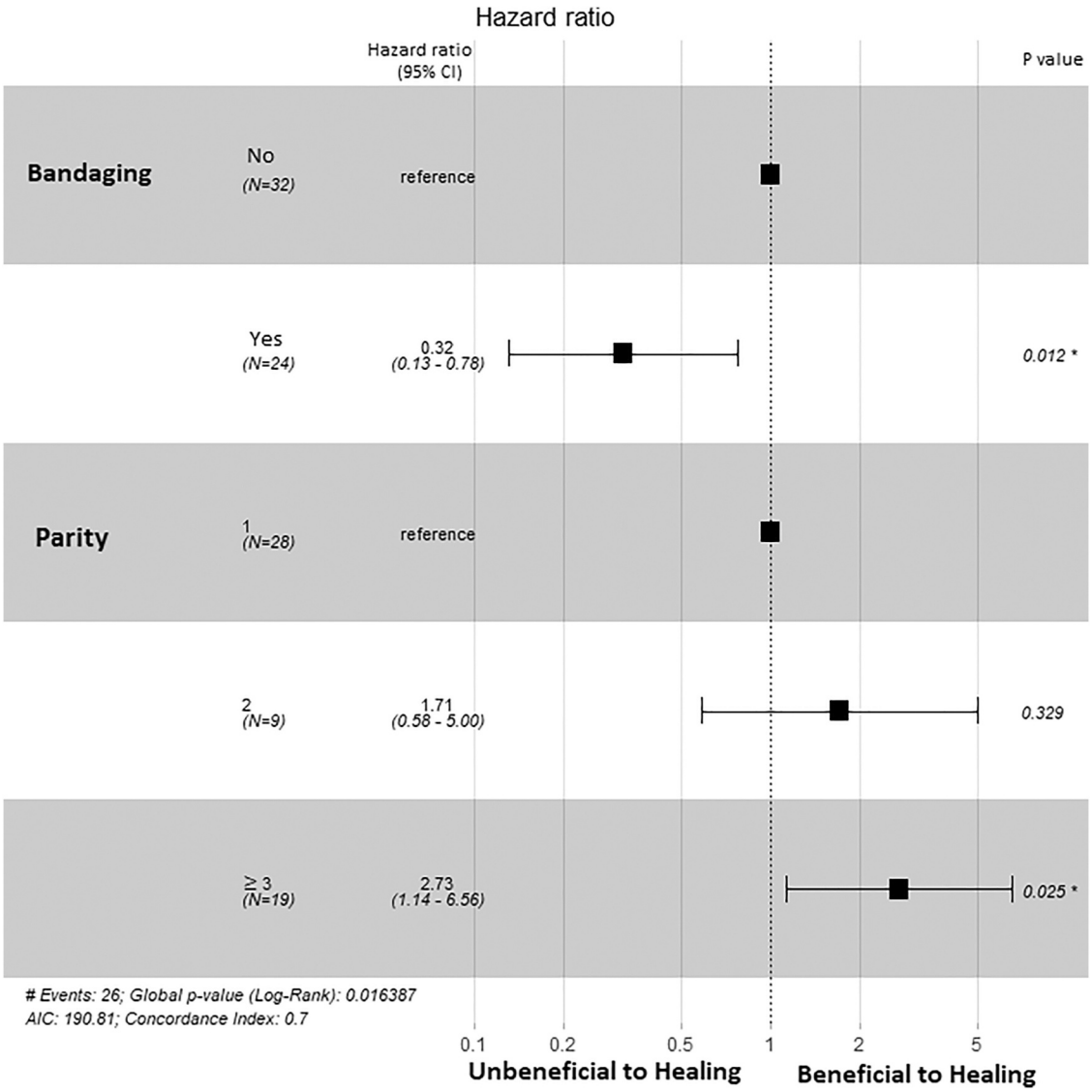

Fig. 5. Forest Plot shows the hazard ratios for cure of sole ulcers in relation to the significant covariates bandaging and parity. The hazard ratios with 95% confidence intervals (95% CI) are represented as black boxes and bars. The area to the right of the dotted vertical line represents the beneficial zone for healing.

Treponema related diseases because it promotes a prolonged exposure to treatment (Klawitter et al., 2019).

This study also found the highest occurrence of SU around 6 months in milk (G1: median 191 DIM, G2: median 177 DIM). This finding is similar to Barker et al. (2009), whom identified the highest rate of SU after 5 months in milk. Differences may stem from individual and farm differences and sample size.

Although parity of 4 or greater is a significant risk factor for developing a sole ulcer (Barker et al., 2009), our results indicated that the healing rate of SU was significantly faster among cows with a higher parity (parity ≥ 3 lactation) than those with a lower parity. Rank order within a mixed herd may explain this result. Cows with a higher lactation number tend to dominate cows with a lower lactation number (Phillips & Rind, 2002; Šárová et al., 2013). Dominant, typically multiparous cows are characterized by intense feeding behavior: spending less time at the feeding allay, consuming more food and water in shorter intervals, and ruminating longer and more quickly than primiparous cows (Dado & Allen, 1994). Furthermore, multiparous cows lie down longer than primiparous cows (Dippel, Schröder, Gutmann, Winckler & Spinka,). Accordingly, healing rates between multiparous and primiparous cows may stem from differences in behaviors that implicate weight bearing pressure on the affected foot. More research is needed to confirm this assumption.

Sole ulcer is a very painful condition (Whay et al., 1998). This study measured locomotion to approximate the degree of protection or irritation that bandaging could cause lesions. We found that the size of the SU, not bandaging, had a significant effect on locomotion whereby larger lesion sizes were associated with higher locomotion scores (Locomotion score 3–5). Theoretically, the number of damaged neurons increases with the size of the wound.

This study omitted the use of NSAIDs to detect changes in locomotion score between bandaged and non-bandaged groups. In general, the benefit of NSAIDs in the treatment of SU is mixed. Laven, Lawrence, Weston, Dowson and Stafford (2008) found no significant difference in outcomes for claw horn lesions treated with tolfenamic acid (2 mg/kg body weight) and a plastic shoe compared with a therapeutic trim alone. Thomas et al. (2015), however, demonstrated a benefit of NSAID treatment (ketoprofen; 3 mg/kg body weight) in addition to either a therapeutic trim or elevation of the diseased claw using a foot block. The authors concluded that NSAID inflammation reducing properties could promote reepithelization of the corium.

In a survey for treatment methods of claw lesions 59% of veterinarians and 53% of hoof trimmers reported the application of topical treatments (Kleinhenz et al., 2014). Following the principle of “first do

no harm" (Shearer & van Amstel, 2017), this study omitted the use of both caustic agents (e.g. copper sulfate) and oxytetracycline soluble powder as these treatments delay healing when directly applied to exposed corium (Shearer, Plummer & Schleining, 2015). Therefore, we chose PVP-I paste as an antiseptic ointment, which has a broad antimicrobial spectrum (WHO, 2016), a lack of resistance, efficacy against biofilms, and is well tolerated (Bigliardi et al., 2017). Clinical studies in human medicine showed that PVP-I does not impede wound healing (Banwell, 2006; Vermeulen, Westerbos & Ubbink, 2010).

Overall, we mention three limitations of our trial: First, the study took place on only one farm. Thomas et al. (2015) reported differences in the tendency to heal for claw horn lesions on different farms. Essentially, farmers may differ in their cow management practices (e.g. environmental cleanliness, follow up treatments, etc.), that could influence the healing process. This aspect could limit the generalizability of our findings. Second, no blood samples were taken from the animals to determine the concentration of iron, vitamin A and biotin. Lischer et al. (2001) found that healing was associated with higher concentrations of these elements. The benefit of these elements, however, depends highly on the vascularization in this area (Eggers, 2001). Third, the authors recognize the importance of blinding treatment assignment and locomotion scoring. It, however, was not feasible for this study due to limited expenses.

Our findings of an improved healing rate of non-bandaged SU treated with a wooden block and PVP-I ointment could help farmers, veterinarians and hoof trimmers to choose the best treatment modality for their cows. An enhanced healing rate of SU supports animal welfare and reduces economic losses.

5. Conclusions

In this study, the authors found that non-bandaged sole ulcers treated with a therapeutic trim, a wooden block and PVP-I ointment were significantly more likely to heal than SU lesions, where an additional bandage was applied. Wound size of SU had a significant effect on locomotion, whereas bandaging had no effect. Most healing occurred during the first three weeks of treatment.

Declaration of Competing Interest

All authors report no conflicts of interest relevant to this article.

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