EFFICACY EVALUATION OF A NEW VACCINE AGAINST BOVINE MASTITIS: FIELD TRIALS RESULTS

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Introduction
Bovine mastitis is the most important infectious disease of dairy cows that affects both quality and quantity of milk. There are different control strategies and vaccination can be used as a component of a control program intended to increase the cows’ natural resistance to disease. The objective of the present study was to analyze the efficacy of a new vaccine against bovine mastitis in a field trial.

Material and Methods
Vaccine: The vaccine used was STARTVAC (HIPRA), containing inactivated Escherichia coli J5 and inactivated Staphylococcus aureus SP140 strain. The S. aureus inactivated cells contain an extracellular component that we refer to as Slime Associated Antigenic Complex (SAAC), related to the slime producing phenotype and the biofilm formation ability. Herds: The trial was carried out in six dairy farms with a known history of staphylococcal, and/or coliforms mastitis within the last year. The farms included in the study had different type of milking, working procedures, park design, nutrition, etc. The type of management employed in these farms (housing conditions, feeding, type of milking, parameterization,...) as well as the genetics of the animals used and the habitual mastitis problems found are common in the dairy farms around Europe. None of the management conditions that were applied in the dairy before the trial were modified during the trial. Experimental design: The field trial was conducted following Good Clinical Practices (GCP) (VICH) and was multicentric, randomized, double blind, controlled (with a parallel negative control group) and stratified (primiparous and multiparous). A total of 386 gestating cows (198 vaccinated and 188 inoculated with a Placebo) were included. Cows and heifers at an age of 22 months onwards were immunized in accordance with the proposed immunization schedule by intramuscular route either with the vaccine or with a placebo: 1st injection 45 days before the expected parturition date, 2nd injection 35 days thereafter (corresponding to 10 days before the expected parturition date) and 3rd injection 62 days after the 2nd injection (corresponding to 52 days after the expected parturition date). The following variables were examined and evaluated: - Incidence of intramammary infections (IMI), clinical mastitis (CM) and subclinical mastitis (SCM) by means of the aseptic taking of milk per cow (weekly sampling from the 4 quarters) for microbiological analysis and somatic cell count. - Severity of the symptoms, analyzing the Somatic Cell Counts (SCC), general clinical signs, local clinical signs (milk and quarter appearance) and dead cows due to mastitis or severe mastitis. - Spontaneous cure rate. That means the cured cases of mastitis per number of infected animals. Cured cases of mastitis were considered all those animals that recovered from mastitis spontaneously, without the administration of any pharmacological mastitis treatment. All the variables were recorded weekly in all of the animals included in the study and throughout the entire observation period (130 days post-partum), but they were statistically analyzed to assess the reduction of the severity of the symptoms only in those animals in which clinical or subclinical mastitis were diagnosed according to the study plan criteria.

Results
Figure 1 shows the total number of cases of IMI (clinical or subclinical). Two cows of the vaccinated group (1.2%) and 18 of the placebo group (10.3%) showed an IMI caused by Staphylococcus aureus. Seven cows from vaccinated group (4.1%) and 31 of the Placebo group (17.8%) showed an IMI caused by coliforms, and twenty-eight cases of vaccinated group (16.6%) and 56 of the Placebo group (32.2%) showed an IMI caused by CNS. The number of clinical mastitis are showed also in Figure 1, and none of the vaccinated group (0%) compared to five cows of the placebo group (2.8%) showed clinical mastitis due to Staphylococcus aureus. Three cows of the vaccinated group (1.8%) and twelve cows of the placebo group (6.9%) showed clinical mastitis due to coliforms, and 4 cows of the vaccinated group (2.37%) compared to twelve of the placebo group (6.9%) showed clinical mastitis caused by CNS. If we look at the subclinical mastitis (SCM) in figure 1, the results showed that two cows of the vaccinated group (1.18%) and seventeen of the placebo group (9.77%) showed subclinical mastitis caused by Staphylococcus aureus, four cows of the vaccinated group (2.37%) and twenty-three of the placebo group (13.22%) caused by coliforms, twenty-seven of the vaccinated group (15.98%) and fifty-two of the placebo group (29.89%) showed subclinical mastitis caused by CNS.
If we analyze the SCC from cows with clinical or subclinical mastitis, the results were significantly lower in the vaccinated group compared to the placebo group (figure 2). In relation with clinical signs of mastitis (milk and quarter appearance), there was a 14.44% of cows with abnormal quarter appearance in the vaccinated group, whereas in the placebo group the percentage of cows with abnormal quarter appearance was 24.03%. In the vaccinated group there was 11.42% of cows with abnormal milk appearance, whereas in the placebo group the percentage with abnormal milk appearance was 19.79% (see figure 2). Both, milk and quarter appearance, were significant different between both groups. There were no dead cows in the vaccinated group but in the placebo there were three cows dead due to severe mastitis. The differences were not significant due to the low number of dead cows.
Another variable assessed was the spontaneous cure rate, which means the cases cured of mastitis per number of infected animals during the observation period. It has to be clarified that cured cases of mastitis were considered all those animals that recovered from mastitis spontaneously, without the administration of any pharmacological mastitis treatment. Taking into account the total number of cows (multiparous + primiparous) and all the pathogens together, vaccinated cows showed a cure rate of 51.43 % whereas the placebo cows showed a cure rate of 32.18 %, so there were 19.25 % more cows cured in the vaccinated group than in the placebo group.

**Conclusions**

All these results indicate that the immunization program, as well as the dosage of 2 ml/animal and the administration route of the vaccine, is efficacious in the reduction of the incidence of intramammary infection due to S. aureus, coliforms or coagulase-negative staphylococci, with clinical or subclinical manifestations in cows (multiparous) and heifers (primiparous) in the period of maximum incidence, i.e. post parturition. Immunization also significantly reduces the severity of the symptoms and causes a significant increase in the spontaneous cure rate of the infected cows.

**Key words**: field trials, mastitis, vaccine, *Staphylococcus aureus*, *Escherichia coli*.
References:
