

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

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The objective of the present study was to evaluate the efficacy of a new vaccine against bovine mastitis in a field trial.

## Materials and Methods

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). The vaccine used was STARTVAC<sup>®</sup> (HIPRA), containing inactivated *Escherichia coli* J5 and inactivated *Staphylococcus aureus* SP140 strain expressing Slime Associated Antigenic Complex (SAAC). A total of 386 gestating cows (198 vaccinated and 188 inoculated with a placebo) were used in accordance with the proposed vaccine schedule: the 1st injection was applied 45 days before the expected calving date, the 2nd injection 35 days thereafter and the 3rd injection 62 days after the 2nd injection by intramuscular route. Incidence of clinical mastitis (evaluating general and local symptoms), subclinical mastitis, weekly sampling of milk by quarters with microbiological analysis and SCC, daily milk production and mastitis treatments with pharmacological products were recorded throughout the entire observation period (130 days post-partum). Logistic regression analysis and the Chi-square test were used for statistical evaluation.

## Results and Discussion

When we analyze all the data of intramammary infections (IMI) caused by *S. aureus*, coliforms and coagulase-negative staphylococci (CNS), 27 cows of the placebo group and 7 of the vaccinated group showed clinical mastitis. On the other hand, 79 cows of the placebo group and 32 of the vaccinated group showed subclinical mastitis (see table 1).

Table 1. Percentage of new cases [number of cases] of intramammary infection (IMI) (clinical and subclinical) at day 130:

	Treatment		Significance ( <i>P</i> -value)
	Placebo group	Vaccinated group	
Clinical mastitis			
Total cows	15.52 [27]	4.14 [7]	0.001
Subclinical mastitis			
Total cows	45.40 [79]	18.93 [32]	0.001

In relation with severity, looking at the results observed in animals with clinical mastitis, there were significant differences between vaccinated and placebo cows in milk appearance, mammary gland appearance, SCC, number of treatments and number of treated cows (see table 2).

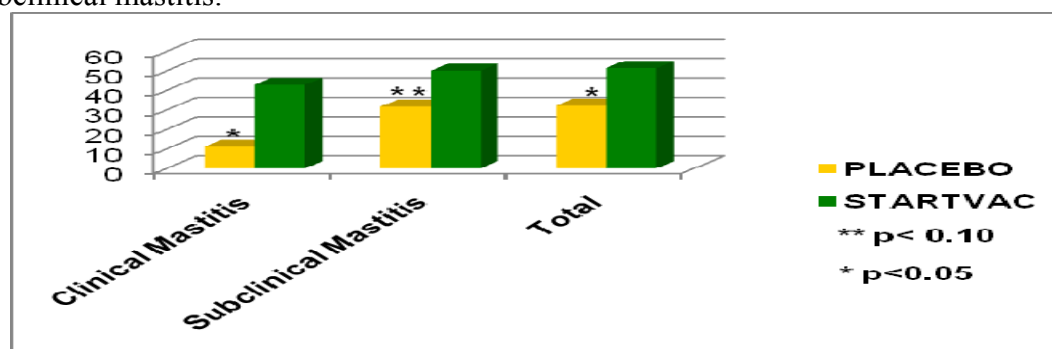
Table 2. Reduction of the severity of the symptoms.

Variable	Vaccinated group	Placebo group	Statistically significant differences between vaccinated and placebo groups ( $\alpha = 0.05$ )
Mean SCC x $10^3$ cells/ml (Least square mean* $\pm$ standard error)	328.2 $\pm$ 21.7	548.6 $\pm$ 40.3	Yes ( $P < 0.05$ )
Milk appearance (score $\geq 1$ )	11.42 %	19.79 %	Yes ( $P < 0.05$ )
Mammary gland appearance (score $\geq 1$ )	14.44 %	24.03%	Yes ( $P < 0.05$ )
Mastitis treatments	34 treatments	93 treatments	Yes ( $P < 0.05$ )
	22 cows	40 cows	
Death of cows due to mastitis	0	3	No ( $P > 0.05$ )

\* SCC corrected by the effect of treatment, category, farm and days post-parturition

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% (see figure 1).

**Figure 1.** Percentage of spontaneously cured cows over the total of mastitis cases after clinical and subclinical mastitis.



## Conclusion

The results indicate that the vaccine is efficacious in reducing 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.



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## OBJECTIVE

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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). The vaccine used was STARTVAC<sup>®</sup> (Hipra), containing inactivated *Escherichia coli* J5 and inactivated *Staphylococcus aureus* SP140 strain expressing Slime Associated Antigenic Complex (SAAC). A total of 386 gestating cows (198 vaccinated and 188 inoculated with a placebo) were used in accordance with the proposed vaccine schedule: the 1<sup>st</sup> injection was applied 45 days before the expected calving date, 2<sup>nd</sup> injection 35 days thereafter and 3<sup>rd</sup> injection 62 days after the 2<sup>nd</sup> injection by intramuscular route. Incidence of clinical mastitis (evaluating general and local symptoms), subclinical mastitis, weekly sampling of milk by quarters with microbiological analysis and SCC, daily milk production and mastitis treatments with pharmacological products were recorded throughout the entire observation period (130 days post-partum). Logistic regression analysis and Chi-square test were used for statistical evaluation.

## RESULTS

When we analyze all the data of intramammary infections (IMI) caused by *S. aureus*, coliforms and coagulase-negative staphylococci (CNS), 27 cows of the placebo group and 7 of the vaccinated group showed clinical mastitis. On the other hand, 79 cows of the placebo group and 32 of the vaccinated group showed subclinical mastitis (see table 1).

**Table 1.** Percentage (%) of new cases [number of cases] of intramammary infection (IMI) (clinical and subclinical) at day 130:

	Treatment		Significance ( <i>P</i> -value)
	STARTVAC® group	Placebo group	
Clinical mastitis			
Total cows	4.14 [7]	15.52 [27]	Yes ( <i>P</i> <0.001)
Subclinical mastitis			
Total cows	18.93 [32]	45.40 [79]	Yes ( <i>P</i> <0.001)

In relation with severity, looking to the results observed in the animals with clinical mastitis, there were significative differences between vaccinated and placebo cows in milk aspect, mammary gland aspect, SCC, number of treatments and number of treated cows (see table 2).

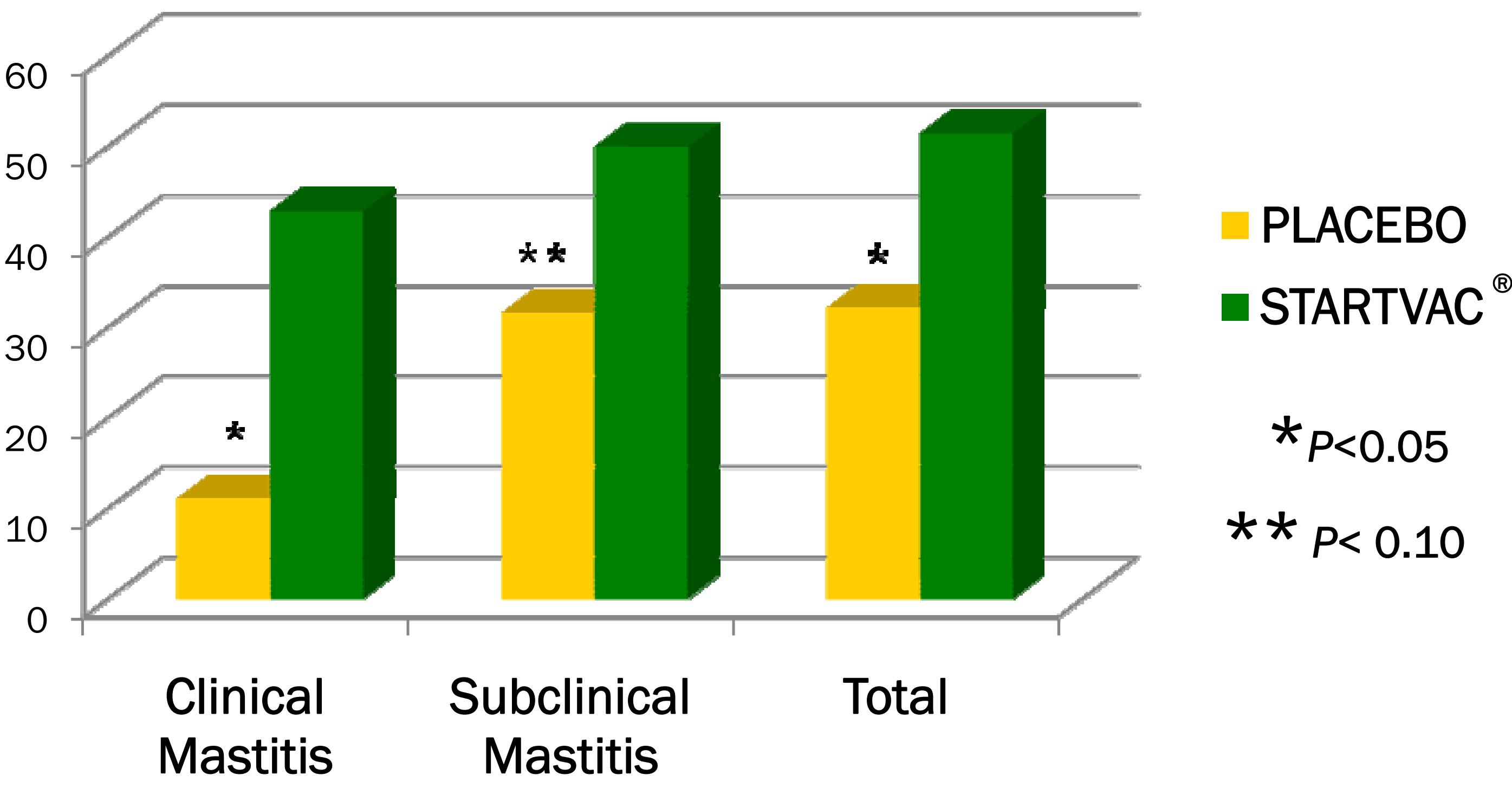
**Table 2.** Reduction of the severity of the symptoms:

Variable	STARTVAC <sup>®</sup> group	Placebo group	Significance (P-value)
Mean SCC x 10 <sup>3</sup> cells/ml (Least square mean* ± standard error)	328.2 ± 21.7	548.6± 40.3	Yes (P<0.05)
Milk aspect (score ≥ 1)	11.42 %	19.79 %	Yes (P<0.05)
Mammary gland aspect (score ≥ 1)	14.44 %	24.03%	Yes (P<0.05)
Mastitis treatments	34 treatments	93 treatments	Yes (P<0.05)
	22 cows	40 cows	
Death of cows due to mastitis	0	3	No (P>0.05)

\* SCC corrected by the effect of treatment, category, farm and days post-parturition

Taking into account the total number of cows (multiparous + primiparous) and all the pathogens together, STARTVAC<sup>®</sup> vaccinated cows showed a cure rate of 51.43% whereas the placebo cows showed a cure rate of 32.18% (see figure 1).

**Figure 1.** Percentage of spontaneously cured cows over the total mastitis cases after clinical and subclinical mastitis:



## CONCLUSIONS

The results indicate that 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. Immunisation also significantly reduces the severity of the symptoms and causes a significant increase in the spontaneous cure rate of the infected cows.



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