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Ingelvac MycoFLEX® provides at least 26 weeks duration of immunity against *M. hyopneumoniae*

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Introduction and Objectives

This study was conducted to assess 26 week duration of immunity for Ingelvac MycoFLEX®, a new *Mycoplasma hyopneumoniae* (M hyo) vaccine by Boehringer Ingelheim Vetmedica Inc, against heterologous challenge.

Materials and Methods

A challenge study was performed following GCP guidelines. Commercial piglets 21 +/- 5 days of age and seronegative for *M. hyo* and PRRSV antibodies were included into 5 treatment groups (Table 1). Groups 1-4 contained 20 pigs each while Group 5 had 10 pigs with individual pig designated as the experimental unit.

Table 1. Study design

Group	Treatment	Dose/Route	Challenge (intratracheal)	Necropsy
1	Ingelvac MycoFLEX®	1mL IM	26 weeks post-vaccination	33 days post-challenge
2	Ingelvac MycoFLEX® (safety serial)	1 ml IM		
3	Licensed M hyo vaccine	2 ml IM		
4	Saline placebo (challenge controls)	1 ml IM		
5	No treatment (negative controls)	----	No challenge	

Groups1-4 were challenged 26 weeks post-vaccination with a heterologous strain of virulent *M. hyo.* Pigs were necropsied 33 days post-challenge and lungs were extracted and scored for lesions[1]. The primary criterion for duration of immunity was a clinically relevant reduction of lung lesion scores by ≥40%. The underlying distributions for total percent lung lesion scores were not normal. Therefore the Kruskal-Wallis extension of the Wilcoxon Rank Sum Test was used to test for differences among all groups. Pairwise comparisons were made using the Wilcoxon Rank Sum Test.

Results

Significant reductions in lung lesion scores were found in all vaccinated groups compared to the challenge control group (Table 2). Median lung lesion percentage scores were significantly reduced in vaccinates by ≥45% (Table 3).

Table 2. Wilcoxon rank sum test pairwise group median lung lesion score comparisons to challenge controls.

	Group comparison		
	1 vs 4	2 vs 4	3 vs 4
P value	0.0023	0.0031	0.0334

Table 3. Median percent lung lesion scores by treatment group.

Group ID	Median lung lesion score (%)
1	6.0
2	4.0
3	7.0
4	13.0
5	0.0

No local injection site or systemic adverse reactions were observed for the first 7 days post-vaccination.

Conclusions

Vaccinated animals showed a clinically relevant and statistically significant reduction of lung lesion scores confirming at least 26 weeks duration of immunity.

References

1. Straw B.E., et al., 1986.