

Bulletin

Boehringer Ingelheim Vetmedica, Inc.

TECHNICAL

Ingelvac MycoFLEX® provides at least 26 weeks duration of immunity

Introduction

Mycoplasma hyopneumoniae is the primary causative agent of porcine enzootic pneumonia. Vaccination can be a highly effective tool for reducing the consequences of these infections. Ideally, vaccination should provide protection against enzootic pneumonia to market weight. Ingelvac MycoFLEX is a new, non-viscous, single-dose *M. hyopneumoniae* vaccine from Boehringer Ingelheim Vetmedica, Inc. The purpose of this study was to assess 26-week duration of immunity provided by Ingelvac MycoFLEX vaccination against a virulent *M. hyopneumoniae* challenge.

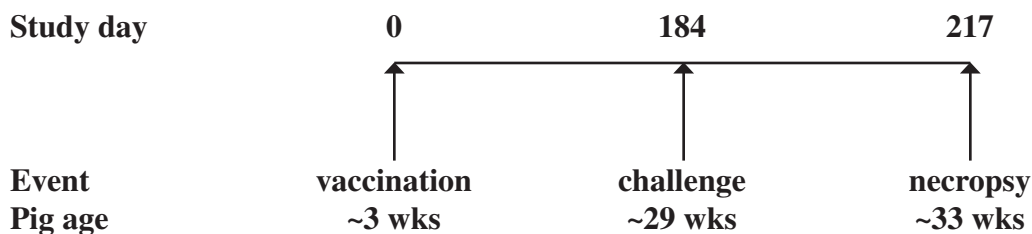
Study Design

M. hyopneumoniae and PRRS virus antibody-negative pigs were randomly assigned to 4 treatment groups in this blinded clinical trial. Treatment regimens included:

- Group 1: Received a 1 ml dose/I.M. Ingelvac MycoFLEX (n=20)
- Group 2: Received a 2 ml dose/I.M. Ingelvac® M. hyo (n=20)
- Group 3: Challenge controls, received a 1 ml dose/I.M. saline placebo (n=20)
- Group 4: Strict controls, non-vaccinated and non-challenged (n=10)

Pigs had been weaned and were approximately 3 weeks of age at the time of vaccination. Groups 1, 2, and 3 were challenged intratracheally with a virulent strain of *M. hyopneumoniae* approximately 26 weeks post-vaccination. Daily observations for adverse events occurred for the first week post-vaccination. Pigs were necropsied 33 days post-challenge, and lungs were removed and scored for lesions using the PigMon lung scoring system. The criterion for establishing duration of immunity was a significant reduction in *M. hyopneumoniae* lung lesion scores in vaccinates compared to the challenge controls.

Figure 1. Study timeline



Results

Significantly lower lung lesion scores were observed in both vaccinated groups compared to the challenge control group (Table 1). No local injection site or systemic adverse reactions were observed during the 7-day post-vaccination period.

Table 1. Lung lesion scores by treatment group

Group	Treatment	Median Lung Lesion Score (%)	P Value*
1	Ingelvac MycoFLEX	5.9	0.0025
2	Ingelvac M. hyo	8.3	0.0460
3	Challenge controls	11.6	NA
4	Strict controls	0	<.0001

*Wilcoxon Rank Sum test pairwise comparisons vs Group 3

Conclusions and Implications

1. **Ingelvac MycoFLEX is highly effective**, providing at least 26-weeks duration of immunity in weaned pigs vaccinated at 3 weeks of age.
2. **Ingelvac MycoFLEX is safe.**
3. **Ingelvac MycoFLEX provides efficacy equivalent to Ingelvac M. hyo**, which has demonstrated gold-standard efficacy globally.

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