Field Trials Prove Efficacy and Safety of Porcilis® PCV M Hyo Combination Vaccine

Summary

The efficacy and safety of Porcilis® PCV M Hyo, a new ready-to-use one-dose combination vaccine, was studied under a range of field conditions. Separate trials were conducted in France and two in Greece in commercial swine herds.

In the end, the efficacy and safety data from these field trials show that Porcilis PCV M Hyo:

- Reduced the severity of M. hyo lung lesions.
- Significantly improved average daily weight gain (ADWG) through the finishing phase in pigs infected with M. hyo and/or PCV2.
- Significantly reduced PCV2 viral load, shedding and viremia.
- Produced minimal local or systemic reactions (in < 1% of pigs, transient local injection site reactions were restricted to minor swellings [< 2 cm in diameter] that disappear within one day). In other words, those that did occur were small and transient, and pigs recovered quickly.
- Had no negative effect on growth during the nursery phase.

Introduction

PCV2 and M. hyo are the two most prevalent pathogens within swine production systems worldwide. These agents can have a significant negative impact on pig performance during the vital grow/finish phase, particularly on weight gain and feed conversion. This in turn results in economic losses and increased animal treatment costs.

PCV2 is such a ubiquitous virus in swine production systems that up to 100% of pigs are seropositive for PCV2 at slaughter. During the growing phase, subclinical PCV2 infections are characterized by poor growth performance in apparently healthy pigs. Although PCV2 is the causative agent of post-weaning multi-systemic wasting syndrome and other circovirus-related diseases, it also is a significant contributor to the porcine respiratory disease complex (PRDC). Subclinical PCV2 infections are considered to be a major form of PCV2 expression in PRDC.

M. hyo is a respiratory pathogen in pigs and is the primary agent of enzootic pneumonia – a common and chronic disease in swine herds. Combined with other viral and bacterial pathogens, M. hyo is among the agents implicated in the development of PRDC.

Field trials study design

In each of the three field trials conducted in France and Greece, piglets were randomly sorted into equal-sized groups, including a placebo-vaccinated control group and a Porcilis PCV M Hyo-vaccinated group. The vaccine was given as a single 2-mL dose to 3-week-old piglets according to the product label.

In each trial, serum samples were taken at regular intervals from 25 to 35 pigs per treatment group. In the French trial, rectal and nasal swabs were taken every 4 weeks from 25 pigs per treatment group. Samples and swabs were tested by quantitative polymerase chain reaction (qPCR) for PCV2 viral DNA. Although vaccine safety was not the primary objective of these trials, pigs were monitored individually at vaccination, and then by group at 4 hours and on days 1, 4, 7 and 14 post-vaccination. Abnormalities were recorded.

Pigs were weighed individually at vaccination, at transfer to the finishing unit and before slaughter. Medication was recorded and post-mortem exams were conducted on any pig that died during the study to establish the cause of death. At slaughter, the severity of M. hyo lesions was scored using the Goodwin method (maximum 55).

Figure 1: Timeline of events

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*Record immediate and injection site reactions; recheck at 4 hours, days 1 and 4 post-vaccination.
*25 to 35 pigs per treatment group were sampled each time.

Sltr = Slaughter
French Trial Results

Minimal reaction; safe vaccination

**Figure 2:** In general, vaccination resulted in a modest temperature increase on the day of vaccination. Systemic and local reactions were found in only a low percentage of vaccinated pigs and the local reactions were small and transient. No significant difference in weight gain was observed between vaccinated and control animals during the nursery period.

Higher daily gain throughout finishing period

**Figure 3:** Vaccination with Porcilis PCV M Hyo resulted in a 34 grams higher ADWG during the finishing period compared with the controls. Over the course of the entire trial period, vaccinates gained an average of 19 more grams per day than pigs in the control group.

Reduced PCV2 viral load, shedding and viremia

**Figure 4:** PCV2 presence was first detected at low amounts in control animals at 8 weeks post-vaccination, with nasal and fecal shedding peaking at 12 weeks and viremia peaking at 16 weeks, indicating an onset of PCV2 infection between 8 and 12 weeks post-vaccination. In comparison, PCV2 viremia and nasal and fecal shedding in vaccinated animals was reduced by 79%, 70% and 55%, respectively.

Reduced M. hyo lung lesions

**Figure 5:** At slaughter, lung lesion scores in the vaccinated group were 46% lower than in the control group; the percentage of pigs with severe lung lesions (score >10) dropped by 56%.

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Greek Trial I – Results

Higher weight gain per day

Figure 6: Porcilis PCV M Hyo significantly improved ADWG during the finishing period, with vaccinated pigs gaining 25 grams more per day than the control group. For the full trial period, the vaccinated pigs’ ADWG was 18 grams per day higher than for the controls.

During the finishing period, the vaccinated pigs’ ADWG was 18 grams per day higher than for the controls. Figure 6: Porcilis PCV M Hyo significantly improved ADWG higher weight gain per day.

Greek Trial II – Results

PCV2 protection provided

Figure 8: The mean antibody titers against PCV2 in the vaccination group increased between weeks 12 and 20 of the trial, indicating that a field infection occurred during finishing. Vaccinated pigs had a higher PCV2 titer than control pigs from 4 weeks post-vaccination on.

PCV2 protection provided

Greek Trial II – Results

PCV2 protection provided

Greek Trial II – Results

Improved lung lesion scores

Figure 11: Vaccination with Porcilis PCV M Hyo significantly reduced the mean M. hyo-induced lung lesion score from 17.1 in the control group to 10.6 in the vaccinated group.

Improved lung lesion scores

Provided M. hyo protection

Figure 7: Porcilis PCV M Hyo reduced the overall mean lung lesion score from 12.2 in the control group to 9.6 in the vaccinated pigs. Statistical analysis showed a significant interaction between vaccination group and production batch. The reduction of M. hyo lung lesion score was statistically significant in the first two production batches, but was not achieved in the third.

Provided M. hyo protection

Reduced PCV2 viremia

Figure 9: At the pre-trial screening, a PCV2 infection was observed in the finishing phase and was confirmed by qPCR results. Figure 9: Even though pigs were vaccinated in the presence of high maternal antibodies (See Figure 8; >10 log2), viremia was significantly reduced compared to controls. Serum samples were taken at 12, 16 and 19 weeks. PCV2 mean viral load and positive samples were lower at each time-point in the vaccinated pigs than in the controls.

Reduced PCV2 viremia

Improved lung lesion scores

Figure 11: M. hyo lung lesion results at slaughter

Figure 7: M. hyo lung lesion results at slaughter

Figure 11: M. hyo lung lesion results at slaughter

Figure 10: Weight gain results (g/day)

Figure 8: PCV2 serology ELISA results

Figure 9: PCV2 viremia results

Figure 10: Weight gain results (g/day)
Conclusions

In all three trials, no or very few local or systemic reactions (in < 1% of pigs, transient local injection site reactions were restricted to minor swellings [< 2 cm in diameter] that disappear within one day) were observed following Porcilis PCV M Hyo vaccination. In other words, the local reactions that did occur were small and transient, and pigs recovered quickly. Plus, vaccination with Porcilis PCV M Hyo had no negative effect on growth during the nursery phase.

In terms of performance, the trials support that Porcilis PCV M Hyo:

• Reduced the severity of M. hyo lung lesions.
• Significantly improved ADWG through the finishing period in pigs infected with M. hyo and/or PCV2.
• Significantly reduced PCV2 viral load, shedding and viremia.

Therefore, it can be concluded that Porcilis PCV M Hyo is effective and safe as a ready-to-use, single-dose vaccine in herds with M. hyo and/or PCV2 infection.

Discussion

M. hyo and PCV2 are wide-spread and commonly affect swine herds worldwide. Alone they are costly, robbing performance and increasing production costs, but M. hyo and PCV2 also are significant contributors to the development of PRDC within pig groups.

To minimize the economic impact and effectively manage the health and well-being of growing pigs, swine veterinarians and pork producers routinely administer PCV2 and M. hyo vaccines. But in the case of dual infection, it has been demonstrated that vaccination against either PCV2 or M. hyo alone does not reduce the severity of the other pathogen nor does it protect against the other pathogen.

Therefore, a safe, effective combination vaccine that protects pigs from both PCV2 and M. hyo during the vital growing period, when most infections occur, would be beneficial. A ready-to-use, single-dose combination vaccine is not only convenient and saves labor for the user, but it also minimizes pig handling and stress.

To meet this need, MSD Animal Health developed Porcilis PCV M Hyo. This new, ready-to-use vaccine contains inactivated M. hyo cells and baculovirus-expressed ORF2 antigen of PCV2 and the proprietary Emunade® adjuvant. Emunade is a combination of an oil-in-water emulsion with aluminum hydroxide that is smooth and gentle on the animal, offering a dependable safety profile without adverse injection site reactions. This effective formula elicits a prolonged and enhanced immune response to both PCV2 and M. hyo.

Porcilis PCV M Hyo immunity profile:

• PCV2 onset of immunity begins 2 weeks after vaccination.
• PCV2 duration of immunity (DOI) is 22 weeks after vaccination.
• M. hyo onset of immunity begins 4 weeks after vaccination.
• M. hyo DOI is 21 weeks after vaccination.

Porcilis PCV M Hyo combination vaccine:

• Comes in a convenient ready-to-use formulation.
• Is administered as a single 2-mL dose.
• Is approved for use in healthy pigs starting at 3 weeks of age.
• Pigs are injected intramuscularly in the neck.

Through research and development, MSD Animal Health is committed to providing the most effective, beneficial and convenient products to add value and better meet the customers’ evolving needs.

References:

2. Publication TBD
3. Publication TBD