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Evaluation of consistent efficacy of three consecutive batches of Ingelvac CircoFLEX® in clinical lab challenge trials

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Introduction and Objectives

Vaccinating piglets with PCV2 vaccines has become routine use around the world. In most countries various commercial vaccines are registered. However, in China, the biggest pork market in the world, no commercial PCV2 vaccine was available in 2009. In 2009, in collaboration with the Chinese Regulatory Authorities, an independent clinical lab trial was conducted evaluating the efficacy of 3 consecutive commercial serials.

The objective was to confirm the consistency in production processes as well as the quality of the PCV2 antigen used in Ingelvac CircoFLEX® as a prerequisite for registration in China.

Materials and Methods

In total 104 caesarian-derived, colostrum-deprived (CD/CD) pigs were included in this clinical challenge trial and were randomly allocated to 5 groups. Three serials of Ingelvac CircoFLEX® were tested. Each serial was used to vaccinate 25 pigs (groups 1-3) with 1.0 ml i.m. at approximately 3 weeks of age (study day 0). Group 4 (n=24) served as challenge control and pigs were injected with 1.0 ml of sterile diluent the same day as groups 1 to 3. Group 5 (n=5) did not receive any product and served as strict control.

On study day 28 all animals of group 1 to 4 were challenged with 1.0 ml i.m. and 1.0 ml i.n. of virulent PCV2 material (5.1 $\log_{10}$ $TCID_{50}$/ml of live virus). Strict controls were necropsied on day 28. All other animals were necropsied on study day 56. Selected tissue samples were taken and tested by histology for microscopic lesions and by immunohistochemistry (IHC) for presence of PCV2. Lymphoid depletion data, lymphoid inflammation data and IHC data were evaluated with Fisher's Exact Test for differences between groups 1 through 3 and group 4.

Results

Results for the different serials of Ingelvac CircoFLEX® and the challenge control pigs are summarized in table 1. All three vaccine serials provided excellent protection as demonstrated by the clear and significant reduction in the number of pigs with lymphoid depletion, lymphoid inflammation and the number of pigs tested positive by IHC. Strict controls, as expected, did not exhibit lymphoid depletion nor lymphoid inflammation and tested negative by IHC (data not shown).

Table 1. PCV2 challenge results (Number of pigs tested positive for each parameter/total number of pigs in the group).

Group	1	2	3	4
Treatment	Serial 1	Serial 2	Serial 3	Chall. Ctrl.
Lymphoid Depletion	1/25*	1/25*	0/25*	24/24
Lymphoid Inflam-mation	1/25*	2/25*	2/25*	24/24
IHC PCV2	1/25*	1/25*	0/25*	24/24

*Indicates significant ($P<0.0001$) difference between vaccinated group and challenge controls.

Discussion and Conclusions

The results of the present study confirm the reliability of the production process as well as the excellent and consistent efficacy of Ingelvac CircoFLEX® in a laboratory challenge trial. This is in line with the very positive experiences gained in more than 350 million pigs vaccinated in the field to date. Finally, Ingelvac CircoFLEX® was registered in China late 2009 and so far is the only commercial PCV2 vaccine available in China.