Boehringer Ingelheim

TECHNICAL BULLETIN

REPROCYC PARVOFLEX® VACCINE DEMONSTRATES SAFETY IN AN OBSERVATIONAL FIELD STUDY OF GESTATING SOWS AND GILTS

Porcine parvovirus (PPV) is a significant swine pathogen that can cause reproductive failure in dams. Infection can cause fetal death and resorption, presentation of mummified fetuses at farrowing, and an irregular return to estrus. REPROCYC PARVOFLEX aids in the prevention of reproductive disease, and significantly reduces reproductive failure caused by PPV when administered to healthy sows and gilts 6 months of age or older prior to breeding.[1] The vaccine is safe to administer at any stage of gestation, protecting dams against reproductive failure caused by PPV.[2]

An observational field study was conducted to determine the safety of REPROCYC PARVOFLEX, a new, innovative vaccine that uses an adjuvanted baculovirus vector platform to produce a safe, highly immunogenic and non-virucidal vaccine. Conventional killed vaccines for PPV have been available for decades,[3] but until REPROCYC PARVOFLEX, new technologies have not been applied to vaccines for this important swine disease. REPROCYC PARVOFLEX utilizes the recent PPV strain 27a, which research has shown to be effective in establishing a broad spectrum of protection when incorporated into vaccines.[4] It also utilizes the latest technology for production, in which the key immunogenic PPV protein (VP2) is produced in a non-pathogenic baculovirus expression system and forms antigenic, virus-like particles (VLPs). Finally, REPROCYC PARVOFLEX includes the proprietary ImpranFLEX® adjuvant, an aqueous-based (non-oil) polymer adjuvant that improves the immune response of the vaccine within gilts and sows, resulting in faster, long-lasting disease protection.

STUDY KEY FINDINGS

- In an observational field safety study, of the 771 sows and gilts vaccinated with REPROCYC PARVOFLEX, 676 (87.7%) were observed as healthy and experienced no adverse reactions throughout the course of the study.[2]
- Few adverse events (AEs) were recorded overall in the study, and none of the AEs was determined to be vaccine related. The most-observed AE was lameness in 32 dams (4.2%), and only 23 dams (3%) had injection-site lesions.[2]
- REPROCYC PARVOFLEX supports mass-vaccination protocols in breeding herds. It is safe to administer to healthy sows at any stage of gestation and gilts 6 months of age or older.[2]

REFERENCES

[1] Data on file. Boehringer Ingelheim Animal Health USA Inc. Study #2013057.

[2] Data on file. Boehringer Ingelheim Animal Health USA Inc. Study #2016270.

[3] Mengeling WL, Brown TT, Paul PS, Gutekunst DE. Efficacy of an inactivated virus vaccine for prevention of porcine parvovirus-induced reproductive failure. *Am J Vet Res* 1979;40(2):204–207.

[4] Zeeuw E, Leinecker N, Herwig V, et al. Study of the virulence and cross-neutralization capability of recent porcine parvovirus field isolates and vaccine viruses in experimentally infected pregnant gilts. *J Gen Virol* 2007;88:420–427.

[5] USDA APHIS, Veterinary Services, NAHMS. Swine 2012: Baseline reference of swine health and management in the United States.

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STUDY DESIGN

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The non-blinded safety study was conducted at three farm sites in different regions. A total of 771 sows and gilts in pre-breeding, early-gestation and mid- to late-gestation stages of production were vaccinated with REPROCYC PARVOFLEX (2 mL) on Day 0 of the study. On Day 21, all dams received a booster dose of the vaccine (2 mL) (Table 1). Health observations were recorded daily for all enrolled dams. The pregnant vaccinated dams were observed until farrowing, loss of pregnancy, removal for humane reasons, or mortality occurred. At farrowing, the number of healthy, weak, stillborn and mummified piglets per litter was documented.[2]

TABLE 1 – GESTATION PHASES OF ANIMALS IN THE FIELD STUDY[2]

	PRE-BREEDING 7W and 4W (prior to breeding) (D0 & D21)		EARLY GESTATION† 35dG & 56dG (D0 & D21)		MID-LATE GESTATION† 70dG & 91dG (D0 & D21)		
SITE	N	%	N	%	N	%	TOTAL
TOTAL	319	41.4%	227	29.4%	225	29.2%	771

N = number, dG = days of gestation.
† Percentage calculated based on the total number of confirmed pregnant animals.

STUDY RESULTS

RESULTS SUMMARY

Table 2 summarizes animals with adverse events (AEs) of primary concern across all sites for all days enrolled in the study. Overall, few AEs were observed in this study, and none of the recorded AEs was determined to be vaccine related. Of the enrolled animals, 87.7% (676/771) were observed as "normal" (healthy, no signs of AEs) for the entire study. The most observed AE was lameness in 32 dams (4.2%), followed by abortion or premature farrowing in 27 dams (3.9%). When available, the aborted fetuses were tested for PPV, and all tests were negative. Injection-site lesions were observed in 23 dams (3.0%).[2]

TABLE 2 – SUMMARY OF ANIMALS WITH ADVERSE EVENT[2]

Daily Observations	Total Animals	Percent Animals
Healthy (no signs)*	676	87.7%
Lameness	32	4.2%
Abortion/Premature farrowing	27	3.9%
Injection-site lesion	23	3.0%
Mortality (Death)	11	1.4%
Vaginal prolapse	4	0.6%
Anorexia	4	0.6%
Recumbency	2	0.3%
Fracture	1	0.1%
Injection-site erythema	1	0.1%

Individual sows/gilts may be represented in >1 observation category.
*From all enrolled sows/gilts.

Table 3 summarizes the litter characteristics of dams that farrowed. The combined mean percentage of stillborn and mummies was 7.98%,[2] which is in line (not significantly different) with the national averages for stillborn and mummified piglets.[5]

TABLE 3 – REPRODUCTIVE PERFORMANCE: SUMMARY OF NUMBER AND PERCENTAGE OF PIGLETS IN LITTERS ACROSS SITES[2]

Number of Litters	Category	Average and Percentage of Piglets per Litter
648	Healthy	12.71 (90.66%)
	Mummies	0.28 (1.89%)
	Stillborn	0.92 (6.09%)
	Weak born	0.21 (1.36%)

CONCLUSION

Overall, 87.7% of sows and gilts were observed as healthy for all days enrolled in the study. None of the adverse events that were recorded were considered to be vaccine related. This field-based safety study demonstrates that REPROCYC PARVOFLEX is safe for use in healthy sows and gilts prior to breeding and during all phases of gestation.[2]

FLEX REPRODUCTIVE

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