Testing of the Safety and Efficacy of a Vaccine Containing a Genetically Modified Stx2e-Antigen in Laboratory and Field Studies

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Introduction

Edema disease of pigs (E.coli enterotoxemia) occurs worldwide and causes substantial economic loss. It appears mainly in piglets during the first two weeks after weaning. The Stx2e is the causal agent of edema disease. The treatment of edema disease is extremely difficult because it runs a peracute to acute systemic course. Therapeutic attempts offer a doubtful prognosis and are usually also uneconomic. The active immunization is the economic and veterinary alternative for the prevention of edema disease. A new adsorbat-vaccine containing a genetically modified Stx2e-antigen[1] was tested for safety and efficacy in laboratory and field studies on the target animals according to the EU laws and guidelines.

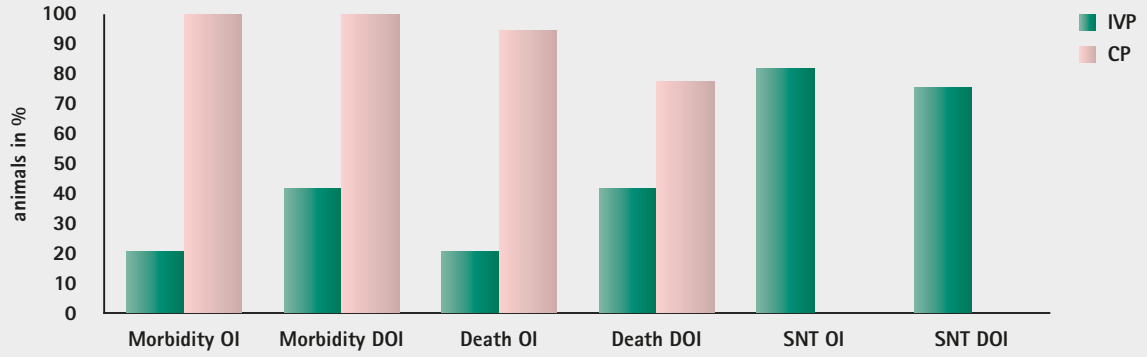
Materials and Methods

Studies conducted under controlled laboratory condi-tions: In safety studies piglets were vaccinated twice (4th and 18th day of life) with the single dose (1.0 ml) or double dose (2.0 ml) of clinical batches respectively 0.9 % NaCl-solution. The safety was determinated by a scoring system to evaluate systemic and local reactions, by histopathological examinations of the injection sites and by measurement of the weight gain. In efficacy trials the piglets were vaccinated once on the 4th day of life with a single dose (1.0 ml). The efficacy was evaluated for the onset of immunity (OI) and duration of immunity (DOI) by means of a challenge model. In field studies the piglets of different farms were vaccinated with a single dose (1.0 ml) of clinical batches (IVP) respectively 0.9 % NaCl-solution (CP) at the average age of 4 days. The safety and efficacy were evaluated by a scoring system, by the determination of neutralising antibodies against Stx2e and by measurement of weight gain. During the course of the field studies on two farms breakouts of edema disease were observed.

Results

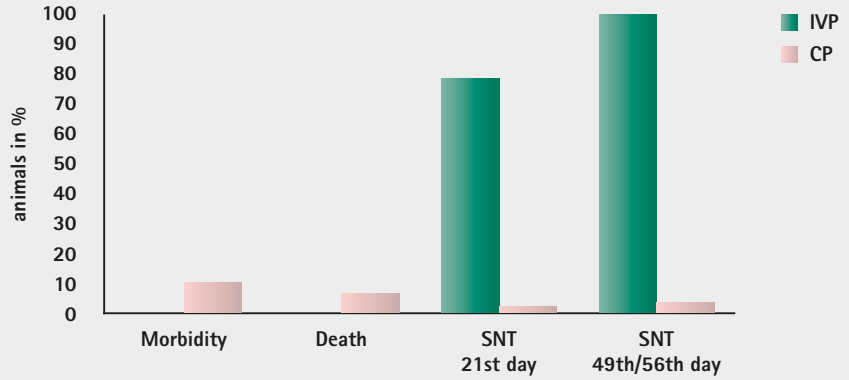
The repeated intramuscular injections of a double dose in very young suckling piglets at the age of 4 days do not result in any notable adverse effects either in terms of general clinical health, local reactions, gross findings at the injection sites, histopathological findings and rectal body temperature. Moreover, there were no notable differences when compared with the group injected with similar volumes of sodium chloride solution (0.9 %). The incidence ratios for systemic and local reactions after application of a single dose in suckling piglets at the age of 4 days calculated from the results of corresponding animal studies under laboratory and field conditions were altogether below 1 %. The OI was confirmed 21 days after a single shot vaccination of suckling piglets at the age of 4 days. The DOI was tested as successfull until the 105th day of life (Fig 1).

Figure 1 Percentage of morbidity, death and neutralising antibodies (SNT) tested under laboratory conditions in a challenge model.



In two field trials with breakouts of edema disease there was a marked induction of neutralising antibodies against Stx2e together with a clear protection against morbidity and death (Fig 2).

Figure 2 Percentage of morbidity, death and neutralising antibodies (SNT) in pig herds with an actual break-out of edema disease during the course of the field studies.



Conclusions and Discussion

The vaccine containing the genetically modified Stx2e-antigen applied i.m. once in suckling piglets at the age of 4 days is safe and effective. In challenge studies a clear correlation between the induction of neutralising anti-bo-dies against Stx2e and protection against edema disease at the times of OI as well as DOI was demonstrated. ▪

References

[1] Florian et al., 2012, IPVS