FIP: Evaluation of the Vaccine

Feline Infectious Peritonitis

ROBERT H. WINN FOUNDATION COMPLETED STUDY REPORT

PRIMUCELL-FIP (INTRANASAL FIP VACCINE): A REPORT AND ANALYSIS OF THE EVALUATION OF A NEW FIP VACCINE

by Catherine Rokaw

Dr. Fred W. Scott, of the Cornell Feline Health Center, has conducted three experiments to evaluate the safety and efficacy of the new intranasal FIP vaccine, Primucell-FIP, currently being marketed by SmithKline Beecham Animal Health (SBAH, formerly Norden Laboratories). In a brief pilot study conducted at Cornell prior to licensure by SBAH, researchers vaccinated 8 kittens intranasally with one (1) dose of the vaccine rather than the two doses recommended by the vaccine manufacturer. No adverse effects were noted following vaccination. Twenty-eight days following vaccination the 8 vaccinated kittens and 4 unvaccinated controls were challenged via aerosol exposure to the FIP virus. 4 of the 8 vaccinates (50%) and 3 of the 4 controls (76%) developed FIP within two months of the challenge. The remaining unvaccinated control kitten exhibited a fever following exposure, followed by a long asymtomatic period. This kitten eventually developed FIP 7 months after the challenge.

Dr. Scott submitted a grant request to the Robert H. Winn Foundation in January 1991 based on this pilot study. In a second experiment (funded by the Winn Foundation), eleven 16-week old kittens were vaccinated intranasally in two doses, 28 days apart. Four kittens of the same age were kept as unvaccinated contact controls and allowed to live with the vaccinated kittens. An additional four kittens were kept as unvaccinated controls with no contact with the vaccinated kittens. Twenty-eight days after the second vaccination, all the kittens were challenged via aerosol exposure to the FIP virus. Ten of the eleven kittens developed FIP.

Dr. Scott then requested the cooperation of SmithKline Beecham Animal Health for the third experiment. Thirty 16 week old kittens were vaccinated at Cornell University with two doses of the intranasal vaccine, twenty-eight days apart. An additional 9 kittens were vaccinated at SBAH facilities with two doses of the vaccine 28 days apart. Both Cornell and SBAH used the same vaccine lot. Four additional groups of kittens were used as unvaccinated controls. Twenty-seven to twenty-eight days following the second vaccination, all kittens were challenged with the FIP virus, either via aerosol, intranasal, or oral routes. Some of the kittens were challenged at Cornell University with the 1146 Strain of the FIP virus and others were shipped to SBAH, where they were challenged with the DF2 strain of the FIP virus (this is the same viral strain from which the vaccine was developed), along with the kittens originally vaccinated at SBAH. The kittens challenged at SBAH were all challenged by the oral route. ALL 21 vaccinated kittens challenged at Cornell University developed FIP during the 35 day observation period following challenge, only 6 of 9 unvaccinated controls developed FIP during the same period. Of the kittens challenged at the SBAH facilities, 2 of 8 Cornell-vaccinated kittens (25%) and 3 of 6 unvaccinated controls (50%), developed FIP. For those kittens originally vaccinated at SBAH, 1 of 9 vaccinated kittens (11%) and 3 of 4 (75%) unvaccinated controls developed FIP following a low-dose challenge with the DF2 FIP virus strain.

Enhanced clinical disease, as evidenced by a fulminant and severe clinical disease pattern with a shorter time to euthanasia, was observed in 2 of 10 vaccinated kittens (20%) in the group challenged by aerosol exposure, and in 8 of 11 vaccinated kittens (73%) in the group challenged intranasally. None of the control (unvaccinated) kittens had enhanced disease.

The safety of Primucell-FIP has been monitored by Smith Kline Beecham through a field safety trial and by practitioner complaints. Post-vaccination complaints to SmithKline Beecham Animal Health and to the Cornell Feline Health Center have been minimal to date. Clinical signs of serious post-vaccination illness (prior to virus challenge) were not observed in the kittens comprising the Cornell study. Some practitioners have reported varying degrees of upper respiratory symptoms post-vaccination, according to other sources.

In the virus-challenge systems used in these studies (oral, intranasal, and aerosol), vaccine protection was only observed at the lower doses of the virus. With higher doses of the 1146 FIP virus strain used at Cornell University, (using either aerosol or intranasal exposure, the most likely type of exposure to occur in natural conditions), protection was not observed. Enhancement of infection occurred in several cases, especially with intranasal exposure. This is especially interesting considering that the vaccine route is also intranasal. One of the concerns in developing a vaccine for FIP has always been that infection with this disease does not follow normal patterns. It has long been accepted that the initial exposure to the virus seldom, if ever, causes clinical disease, but rather serves to "sensitize" the animal, making it more vulnerable to active disease on subsequent exposure. Usual methods of vaccination, therefore, might serve to act as the initial, "sensitizing" exposure, rendering the vaccinated animal more vulnerable rather than protecting it from the disease. At high doses with one strain of the virus, Cornell's study would seem to bear this out.

Dr. Scott states that **based on the limited efficacy and the potential to stimulate immune enhancement under certain conditions, the routine use of Primucell-FIP in low-risk populations of cats (i.e. household pets) cannot be recommended.** He indicates that in high-risk populations, such as breeding catteries and multicat facilities, the veterinarian must assess the risk of FIP without vaccination compared to the risks and benefits of vaccination. **Since we do not really know the dose-level of exposure in such an environment (we can only assume the existence of carrier cats and have no way of determining who they are), and since we do not routinely know which of the many different strains of the virus may be present in a given cat population, such an assessment of risk would appear to be a difficult, if not impossible, proposition at this time. Further, the appearance of antibody dependent enhancement cannot be ruled out in such environments.**

References

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