High efficacy in sheep of a new vaccine against BlueTongue Virus Serotype 3 (BTV3)

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Introduction

The recent BTV serotype 3 (BTV3) outbreak, rapidly spreading through Europe, has a significant impact on animal health and is causing severe losses for farmers.

In the absence of cross-protection by existing vaccine strains, a BTV3 vaccine accelerated development was triggered to respond to this emergency.

This new vaccine has been tested in sheep to confirm its efficacy against a virulent challenge with the currently circulating BTV3 strain.

Material & Methods

Animals :

24 white face lambs of 26 to 31 days randomly allocated to 4 groups of 6 animals

Group	Number of animals	D0	D21	D37
Vaccinated T01	6	Very low Ag content vaccine	Challenge	Euthanasia
Vaccinated T02	6	Low Ag content vaccine	Challenge	Euthanasia
Vaccinated T03	6	Standard Ag content vaccine	Challenge	Euthanasia
Control C	6	-	Challenge	Euthanasia*

* One animal of the control group had to be euthanized on ethical grounds at D34

Vaccination :

Subcutaneous injection on D0 of 1mL BTV-3 inactivated AlSap vaccine at 3 different antigen payloads : very low / low / standard

Challenge :

Subcutaneous injection, 3 weeks after vaccination, of a virulent heterologous BTV-3 strain (virus isolated 2023, The Netherlands)

Conclusion

The safety and efficacy of this new vaccine (Bultavo 3™) against BTV3 was successfully demonstrated after virulent challenge in lambs.

Bultavo 3™ is suitable for active immunization of sheep from 26 days of age and is indicated for the prevention of clinical signs and mortality and for reduction of circulating virus in the blood of vaccinated animals.

Vaccination with Bultavo 3™ is intended to significantly reduce the risk of disease transmission through midge bites. With this new vaccine, BTV3 outbreaks can be prevented, and farmers can protect not only their herds, but also their livelihoods.

The study was carried out in accordance with the Act on Animal Health and Animal Welfare of The Czech Republic and European regulations. The test sites had accreditation allowing biological testing on animals. All personnel involved were fully trained and provided with necessary instructions to ensure that the care and welfare of the animals were not compromised during the study period.

Results

Safety: animals of the 3 vaccinated groups did not display local or systemic reactions, nor abnormal rectal temperatures during the 4 days post vaccination observation period.

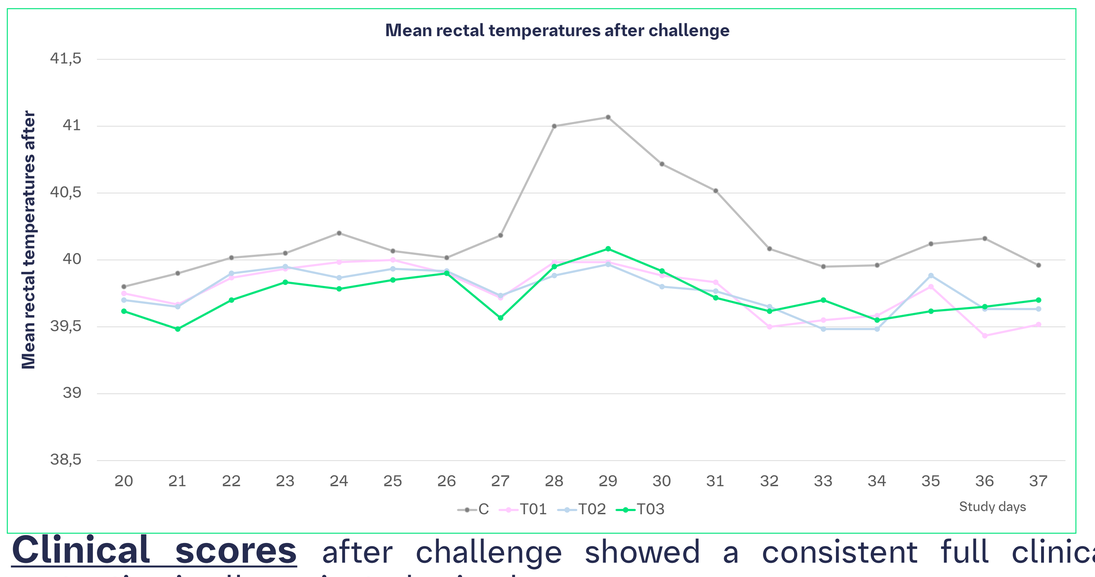
BTV3 antibody titers were determined by seroneutralization test after vaccination. A clear dose effect on seroconversion was observed in vaccinated animals from low to standard payloads.

Group	Animal	Vaccine	D0	D21
Vaccinated T01	1	Very low- Ag	< 2	< 2
	2		< 2	< 2
	3		< 2	< 2
	4		< 2	< 2
	5		< 2	< 2
	6		< 2	< 2
Vaccinated T02	1	Low- Ag	< 2	4
	2		< 2	< 2
	3		< 2	2
	4		< 2	2
	5		< 2	4
	6		< 2	2

Group	Animal	Vaccine	D0	D21
Vaccinated T03	1	Standard- Ag	< 2	8
	2		< 2	4
	3		< 2	8
	4		< 2	2
	5		< 2	4
	6		< 2	8
Control C	1	-	< 2	< 2
	2		< 2	< 2
	3		< 2	< 2
	4		< 2	< 2
	5		< 2	< 2
	6		< 2	< 2

* < 2: below the limit of detection

Hyperthermia after challenge was observed in animals from the control group (with a peak about one week after challenge), not in vaccinated animals.



Clinical scores after challenge showed a consistent full clinical protection in all vaccinated animals.

Global Clinical Score (GCS) was calculated by summing all different signs : hyperthermia, nasal discharge, conjunctivitis, locomotion troubles, diarrhoea and apathy over the monitoring period (16 days).

Group	T01						T02						T03						C					
Animal	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6	1	2	3	4	5	6
GCS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	22	19	33	34*	20	29

* Animal had to be euthanized on ethical ground at D34

Viraemia after challenge was monitored by detection of BTV3 RNA in blood analyzed by qRT-PCR. A significant reduction of viraemia was observed in 2 groups of vaccinated animals (very low and low payloads) and full protection (absence of viraemia) in the group with the standard antigen content (Mann-Whitney U test).