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



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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.



<u>Safety</u>: animals of the 2 vaccinated groups did not display local or systemic reactions, nor abnormal rectal temperatures after the 1st and the 2nd dose administrations during the 4 days post vaccination observation periods.

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 cattle to confirm its efficacy against a virulent challenge with the currently circulating BTV3 strain.

<u>Material & Methods</u>

<u>Animals</u> :

18 calves of 21 to 33 days randomly allocated to 3 groups of 6 animals

Group	Number of animals	DO	D21	D42	D63
Vaccinated T01	6		ntent vaccine atch #1	Challenge	Euthanasia
Vaccinated T02	6		ntent vaccine atch #2	Challenge	Euthanasia
Control C	6	_	-	Challenge	Euthanasia

BTV3 antibody titers were determined by seroneutralization test after vaccination. Seroconversion was observed after the 1st dose in all vaccinated animals with a clear booster effect following the 2nd dose.

Group	Animal	D0	D21	D42
	1	< 2	2	8
	2	< 2	4	8
Vaccinated	3	< 2	4	4
T01	4	< 2	4	8
	5	< 2	2	8
	6	< 2	2	16
	1	< 2	4	8
Vaccinated T02	2	< 2	8	16
	3	< 2	4	8
	4	< 2	2	8
	5	< 2	4	16
	6	< 2	4	8

Group	Animal	D0	D21	D42
	1	< 2	< 2	< 2
	2	< 2	< 2	< 2
Control	3	< 2	< 2	< 2
Control C	4	< 2	< 2	< 2
	5	< 2	< 2	< 2
	6	< 2	< 2	< 2

* < 2: below the limit of detection

<u>Hyperthermia</u> after challenge was observed in animals from the control group (from 6 to 12 days post challenge), not in vaccinated animals.

Mean rectal temperatures

39.8

<u>Vaccination</u> :

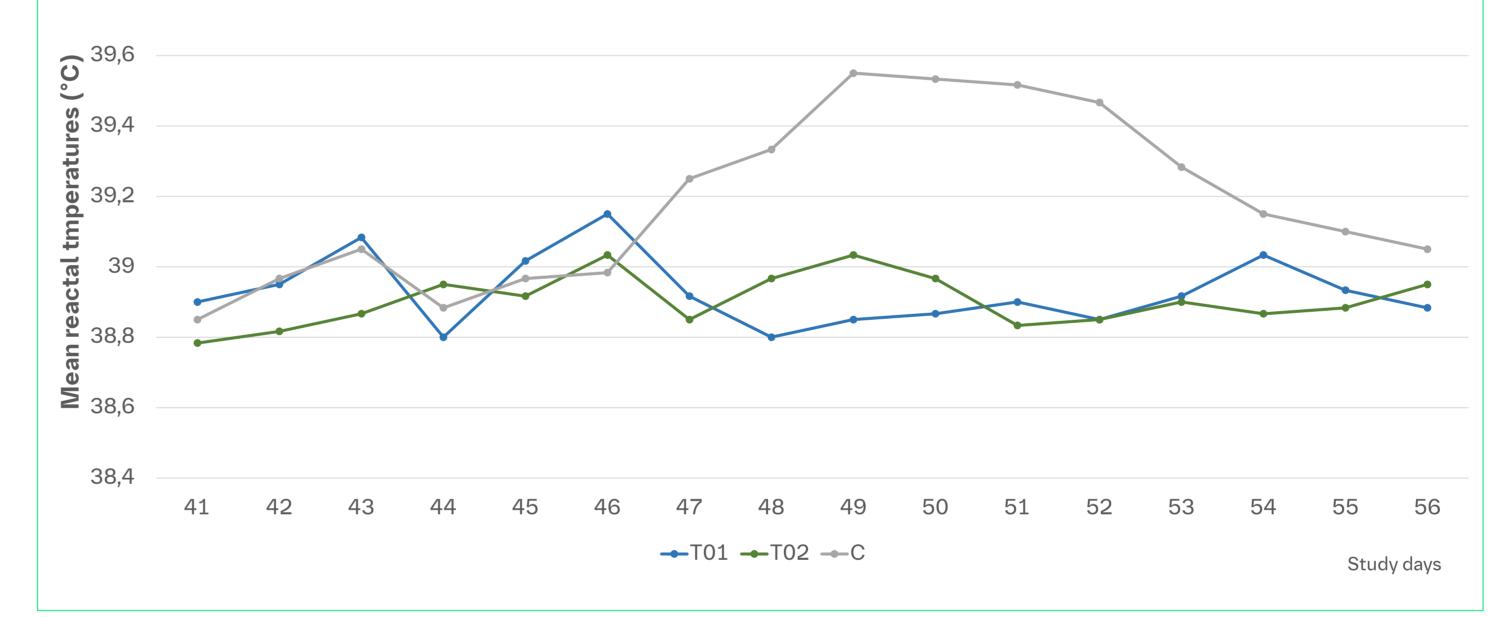
Intramuscular injections on D0 and D21 of 1mL BTV-3 inactivated AlSap vaccine at low antigen payloads, from 2 different Ag batches

<u>Challenge</u>:

Subcutaneous injection, 3 weeks after completion of the vaccination program, 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 calves.



<u>**Clinical scores</u>** after challenge showed a consistent full clinical protection in all vaccinated animals when control animals displayed conjunctivitis and nasal discharge, specific signs of BTV infection in cattle. Global Clinical Score (GCS) was calculated by summing all different signs : hyperthermia, nasal discharge, conjunctivitis over the monitoring period (21 days).</u>

Group	T01				T02						С							
Animal	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	3	4	8	5	4	1

<u>Viraemia</u> after challenge was monitored by detection of BTV3 RNA in blood analyzed by qRT-PCR. Total absence of viraemia was observed in the 2 groups of vaccinated animals

Bultavo 3TM, with a 2-shots vaccination regimen, is suitable for active immunization of cattle from 21 days of age and resulted in a complete protection against clinical signs and viraemia.

Vaccination with Bultavo 3TM is intended to fully prevent the risk of disease transmission through midge bites. With this new vaccine, farmers can not only protect their herds but also prevent the BTV3 outbreak to further progress. Indeed, the prevention of viraemia in cattle is the cornerstone to block the transmission cycle of the virus.

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.

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