SHORT COMMUNICATIONS

Randomized, non-inferiority trial evaluating the efficacy of a novel teat sealant in pasture grazed dairy cows

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INTRODUCTION

- Failure to form a teat-plug has been shown to be a risk factor for acquiring a new intramammary infection (IMI) and clinical mastitis in dairy cows in the dry period[1]. Intramammary infusion of a bismuth subnitrate internal teat sealant (ITS) at the end of lactation in cows, with the aim of providing a physical barrier, has been shown to significantly reduce new IMI over the non-lactating period.[1,2]
- This non-inferiority field study was designed to compare the efficacy of a new internal teat sealant in the New Zealand market, IVP (MSD Animal Health), with the NZ market-leading internal teat sealant, CP (Zoetis).[3]

OBJECTIVE

The overall objective of the study was to demonstrate non-inferiority of IVP to CP in an NZ commercial dairy setting. This was achieved by investigation of the following:

- Comparison of cow-level clinical mastitis case risk from dry-off to the first 30 days post-calving between IVP and CP treated cows. Non-inferiority margin = 2%
- Comparison of the presence or absence of internal teat sealant in quarters at calving between IVP and CP treated cows, as reported by farmers. Non-inferiority margin = 5%
- Comparison of cow-level somatic cell counts (SCC) at the first herd-test post-calving between IVP and CP treated cows. Non-inferiority margin = 10,000 cells/mL

MATERIALS AND METHODS

The study was a randomised clinical interventional study. Cows from two commercial dairy farms were eligible for the study once they met the following selection criteria:

- A planned dry period of between 60 and 120 days
- At least three functional quarters
- A body condition score > 3.0 (Dairy NZ BCS)
- A lameness score of 0 to 1 (Dairy NZ lameness scoring system)
- Individual cow SCC < 150,000 for mixed-age cows, or SCC<120,000 if a first lactation heifer, at the most recent herd test (<80 days prior to dry off[4])
- No clinical mastitis in the current lactation (including on the day of dry-off), and acceptable teat end damage (Teat end score of N or S)[5]
- Positive pregnancy scan within 30 days of dry-off

Eligible cows were randomly enrolled into treatment (IVP) or positive control (CP) groups. Treatments were administered at the cow level at dry-off, with retention analysed at the quarter-level, and the other two outcomes analysed at the cow level. The veterinarians and the technicians administering the product were not blinded when administering treatment products, however all farm staff were blinded as to which cows received which treatment as they did not administer the products. This allowed non-biased assessment by the farm staff of the cows over the dry period and at calving. The biometrician was also blinded as to which group received IVP or CP when analysing the data.

In NZ field conditions, the Investigational Product was non-inferior to the Control Product for the prevention of clinical and sub-clinical mastitis over early lactation. Furthermore, the Control Product performed better than the Investigational Product in terms of retention of product in the teat canal.

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RESULTS

A total of 1105 cows were randomly enrolled across the two farms, 555 in the IVP group and 550 in the CP group. Clinical mastitis data were available for 1081 of these cows.

1. Clinical Mastitis

IVP was **NON-INFERIOR** to CP for clinical mastitis. In total, 4.1% (44/1081) of cows had a case of mastitis between dry-off and 30 days post-calving. There were 3.7% (20/540) of cows in the IVP group with clinical mastitis compared to 4.4% (24/541) of cows in the CP group with clinical mastitis. The risk of mastitis was 0.7% lower (95% confidence interval = 3.1% lower to 1.6% greater) in cows in the IVP group compared to CP (data not shown).

2. Retention

From the 470 animals in the IVP group, 449 (95.3%) animals had ITS retention in at least one quarter. For the 401 animals in the CPT group, 363 (90.5%) had detection of ITS sealant in at least one quarter **(Table 1)** . IVP was not only **NON-INFERIOR** to CP for retention, IVP was also **SUPERIOR** to CP for retention, with quarters treated with IVP associated with a 26% increased odds of retention (95% CI = 2% to 44%; p=0.036).

3. Somatic Cell Count

Descriptive results show the median SCC for all animals was 23,000 cells/mL, with a mean of 92,000 cells/mL **(Table 2).**

IVP was **NON-INFERIOR** to CP for SCC. The predicted mean SCC was 84,000 cells/ml for cows in the IVP group and 99,000 cells/ml for cows in the CP group. The incidence risk of SCC was 14% lower in cows in the IVP group compared to animals in the CP group (95% CI = 28% lower to 2% greater).

TABLE 1. Descriptive statistics for the animals (n = 871) that had data on ITS retention from the following calving in winter/spring in a study comparing two internal teat sealants (IVP[1] and CP[1]) administered at drying off in the autumn in dairy cattle in New Zealand.

Variable	IVP[1]	CP[1]	Overall
Number of animals	470	401	871
Number of quarters	1880	1604	3484
Cow level retention (%)	449 (95.3%)	363 (90.5%)	812 (92.2%)
Quarter level retention (%)	1344 (71.5%)	1076 (67.1%)	2420 (69.5%)

[1] **IVP =** Investigational Product (Shutout, MSD Animal Health) and **CP =** control product, Teatseal (Zoetis).

TABLE 2. Descriptive statistics for the animals (n = 1,057) that had data on SCC from the first herd test following calving in winter/spring in a study comparing 2 internal teat sealants[1] administered at drying off in the autumn in dairy cattle in New Zealand.

Variable	IVP[1]	CP[1]	Overall
Number of animals	527	530	1057
Median SCC (,000 cells/mL; IQR range)	22 (11-50)	24 (13-43)	23 (12-48)
Number >150,000 SCC (%)	49 (9.3%)	43 (8.1 %)	92 (8.7%)
Days-in-milk (range)	33 (20-61)	30 (20-60)	32 (20-60)

[1] **IVP =** investigational product, ShutOut (MSD Animal Health); **CP =** control product, Teatseal (Zoetis).

CONCLUSIONS

This study compared the performance of 2 internal teat sealants from 1105 dairy cattle in New Zealand and showed that the IVP was non-inferior to the CP to which it was compared with in NZ field conditions for the prevention of clinical and sub-clinical mastitis over early lactation. Furthermore, in this study, the IVP was superior to that of the CP in terms of detection (retention) of the product in the teat canal.

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REFERENCES

1. M.W. Woolford, J.H. Williamson, A.M. Day & P.J.A. Copeman. The prophylactic effect of a teat sealer on bovine mastitis during the dry period and the following lactation.New Zealand Veterinary Journal, 46:1, 12-19, 1998
2. Rabiee A.R., Lean I.J. The effect of internal teal seal products (Teatseal and Orbeseal) on intramammary infection, clinical mastitis, and somatic cell counts in lactating dairy cows: A meta-analysis. Journal of Dairy Science 96:6915-6931, 2013
3. Baron Data Qtr 4 2021
4. Smart SAMM Technote 14, DairyNZ, Hamilton, New Zealand)
5. Mein et al., AABP-NMC International Symposium on Mastitis and Milk Quality in Vancouver, BC, Canada. September 13-15, 2001)

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