



therapy of bovine mastitis? A placebo controlled randomized double-blind trial

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Introduction

Homeopathic Treatment of animal diseases is required in organic farming at least since EU Regulation 1804/99 according organic animal husbandry is valid for all organic producers. While practitioners report good results of homeopathic treatment in clinical bovine mastitis there are few studies showing satisfying effects of these remedies. In most of the studies the effects of homeopathics were controlled not at all by a reference group (OTTO, 1984) or by antibiotic treatment (MERCK et al., 1989; GARBE, 2003). RCT trials with placebo control in prevention and subclinical mastitis provided no benefits (MEANEY, 1994; EGAN, 1994; GARBE, 2003).

Thus, to evaluate net effects of homeopathics in mastitis treatment it was essential to conduct a placebo controlled RCT. In an organic herd of about 300 dairy cows the following questions should answered:

1. Are homeopathic effects stronger than placebo in clinical dairy cow mastitis?
2. Is a homeopathy supported udder health programme able reduce antibiotics in mastitis control?
3. Is such a programme able to maintain or increase udder health?

Furthermore, the results should lead to a catalogue of recommendations for conversion from a conventional to a homeopathy supported udder health control programme.

Material and Methods

The investigation was conducted in a Brandenburg bio-dyn herd of about 300 cows in two phases. After the first part in July 2002 the results preliminarily were evaluated and then the whole concept due to unsatisfying results was adapted (s. Tab. 1/2). In Phase 1 a number of 121 clinical mastitis cases with 137 affected quarters matched the including criteria, in Phase 2 the number was 126 cows with 148 quarters. These animals were allocated to a code number which classified the case to Verum (n=65 and n=60) or placebo group (n=56 and n=66).

Tab.1/2: Features of the investigations in the two phases

Characteristics Phase 1 (Aug 2001 - Jul 2002)

- No antibiotic treatment allowed
- No antibiotic dry off therapy allowed
- decreased environmental herd situation

Therapy Protocol

- **acute Mastitis:** Phytolacca D6, Echinacea D6 + selective remedies: Bryonia D6 or Aconitum D6 or Belladonna D6 depending on clinical findings as oral mixture preparation
- **chronical Mastitis:** Echinacea D6, Phytolacca D6 and Hepar Sulfuris D8 as oral mixture preparation

Characteristics Phase 2 (Jan 2003 - Dec 2003)

- Antibiotic treatment allowed in case of therapy failure
- Antibiotic dry off therapy in specific infections
- a lot of herd enhancement measures

Therapy Protocol

- **acute Mastitis:** Phytolacca D6, Echinacea D6, Bryonia D6 and Belladonna D6 as oral mixture preparation (+Aconitum D6 with fever >40°C)
- **chronical Mastitis:** Echinacea D6, Phytolacca D6 and Hepar Sulfuris D8 as oral mixture preparation

In case of clinical mastitis cows were isolated, clinically investigated and afterwards treated by the oral dilution containing the required homeopathics. Every case had its own coded package of possible remedies. Animals were treated twice a day for 5 to 14 days (Phase 2: 1 to 7 days) depending on development of disease. In case of therapy failure in Phase 1 all animals were treated by an not coded homeopathic preparation and in Phase 2 by antibiotics according to bacteriological findings.

Milk samples (double samples) for bacteriological and cell count investigation were taken before treatment (M1), 4 to 5 weeks after treatment termination (M2) and 7 to 8 weeks after treatment termination (M3). To evaluate the herd situation additional samples were taken after calving and before dry off.

Healing criteria on the cow level was the clinical cure without secondary therapy and release to production. On quarter level the cure was determined by bacterial findings (BCR) and additional by cytological findings. A quarter was determined as „completely cured“, if no bacteria were found AND the cell count was below 100.000/ml.

To assess the reduction of antibiotics within the concept we assumed that the mastitis cows yielded 20,5 kg milk per day, was treated under conventional conditions by antibiotics over 3 days with a mean withdrawal time of 5 days (doubled in organic herds) and compared these theoretical values with the extrapolated antibiotics input within our concept.

Results

In Figure 1 and 2 the cure rates in both phases on cow level and quarter level compared to placebo are shown. While there is no difference between the cows in phase 1, on quarter level the verum group showed a significant higher complete cure rate than placebo group.

Fig. 1: Clinical Cure Rates (CCR) of **COWS** 5 and 8 weeks after therapy termination comparing Verum (n=65 and 60 in Phase 1 and 2) and placebo group (n= 56 and 66 in Phase 1 and 2)

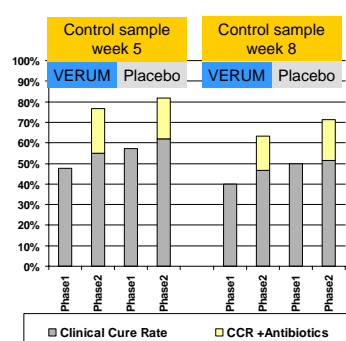
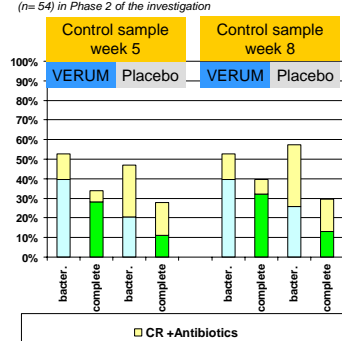


Fig. 2: Bacteriological and Complete Cure Rates (CCR) of **QUARTERS** affected by pathogenic bacteria 5 and 8 weeks after therapy termination comparing Verum (n=53) and placebo group (n= 54) in Phase 2 of the investigation



These results are balanced by additional antibiotics treatment in case of therapy failure in the placebo group. The complete cure rate in the verum group after 8 weeks is 32% compared to 13% in placebo group (p<0.05).

The limited cure results in single cows did not lead to an udder health depression of the herd (Fig. 3). During the study the mean of somatic cell count could decreased by 100.000 cells/ml while the milk yield increased slightly by 250 kg/cow to 6.500 kg/cow/year.

Fig. 3: Essential herd milk parameters „MILK YIELD“ and „SOMATIC CELL COUNT“ during the time of investigation

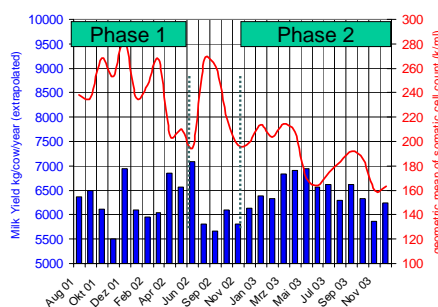
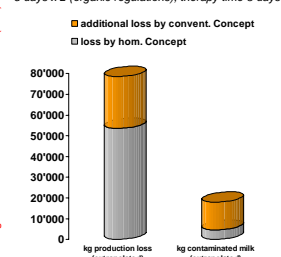


Fig. 4: Projection of Milk loss by Therapy Concept; hypothetical values considering mean Daily milk yield 20,5 kg/cow/day; withdrawal time 5 days x 2 (organic regulations); therapy time 3 days



One of the main objectives of the study was to reduce antibiotics in mastitis control of organic herds. The number of actual antibiotic treatments during observation time compared to the number of mastitis cases showed a reduction by **75%**. Figure 4 shows the extrapolated reduction of milk loss with withdrawal (-25.000kg) and the reduction of contaminated milk during treatment time (-13.100 kg).

Discussion and Conclusion

The cure rates during the investigation were not satisfying independent of the therapy protocol. But the increasing cure rates in the second part of the study are influenced by the enhancement of environmental preconditions in combination with the simplified therapy scheme. The therapists seemed to be more familiar with the fixed combinations of homeopathics so that positive effects of the homeopathics in case of bacterial caused mastitis compared to placebo can be seen in this phase.

After additional antibiotic treatments in case of therapy failure in specific infections (i.e. streptococci and staph. aureus) the cure rates could be elevated to a satisfying level. This fact shows that the limited and controlled use of antibiotics in organic herds can be helpful in the mastitis control. Similar experiences are made in the investigation of GARBE (2003).

Regardless the conceptual modification to an antibiotic emergency concept, the massive reduction of antibiotics in combination with an increase of herd udder health justifies the therapy protocol in the second phase of the study.

The answer of the amount of net effects of the homeopathic remedies could not given. Hypothetically, the self cure of the animals is higher than known. On the other hand it seems to be discussable if a not treated or attended mastitis cow is able to develop self cure. The care of the animal by the farmer and the therapist and the interaction between them and the cow could be a crucial criterion for the positive development of disease. Regardless of this point, animal welfare aspects forbid the omission of treatment.

As a conclusion, the integrated system consisting of preventive herd measures and complementary therapy added by limited antibiotic therapy can be recommended for other herds which are willing to modify conventional udder health concepts to a complementary programme. The precondition for the success is the attendance to optimize environmental conditions regardless economic aspects. The therapy system should be transparent, simple and easy to use. The farmer and involved veterinarian should not engaged to invest a lot of additional work. However, it is necessary to reflect every single mastitis case as a special one. So a limited but certain investment of work is required.

Regarding these preconditions a massive antibiotics reduction in combination with a stable udder health is possible.

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Literature available from author peter.klocke@fibl.ch.