



IAVH
International Association for
Veterinary Homeopathy

Letter to the Editor of Veterinary Record concerning the article “Comparative effectiveness of individualised homeopathy and antibiotics in the treatment of bovine clinical mastitis: randomised controlled trial” KELLER, D., SUNDRUM, A. 2018

General points

We commend the attempt to design an experiment to compare homeopathic and antibiotic treatment of mastitis in dairy cows. This type of research is vital in order to make the best choice of available treatment, particularly in light of, but not limited to, antimicrobial resistance (AMR) issues. However, there are several shortcomings in the experiment itself, and in the article relating the results.

Language

The article lacks clarity about terminology: the authors speak about ‘homeopathic remedies’, then ‘remedies’ (which seems to include conventional medicine), and then use the term ‘homeopathic products’ when discussing the need for effective treatments. In addition, homeopathy is defined as a technique. This does not cause a major issue of understanding but sets the scene for what follows. The language is also misleading about some of the principles of homeopathy, and about achievable goals. Individuality and repertorisation are not the basic principles of homeopathy; they are the Law of Similars, individualisation and potentiation. By the way, homeopathy has never claimed to be a universal treatment alternative for mastitis or any other ailment.

Premises

The authors state that RCTs are the gold standard to determine the effectiveness of medicinal procedures. Even though sound, randomised, controlled, pragmatic trials have been performed demonstrating the effectiveness of homeopathy, currently the validity of RCTs to determine the effectiveness of homeopathy is under discussion (1).

Study background

The article does not mention any background information about incidence of mastitis in the population studied, incidence variability between organic and conventional herds, prevalence of microbial population, resistance of microbial populations. Other environmental factors, such as feed and housing, should have been reported and accounted for in the evaluation of disease incidence and response to treatment. In particular, it would have been of interest to know how the somatic cell counts (SCCs) varied over time in each farm population before this RCT. There were several excellent exclusion criteria applied, but without a general understanding of the course of mastitis in the population, results are difficult to interpret meaningfully.

‘Remedies’

1) There is no such thing as homeopathic “remedies dedicated for the treatment of animals with mastitis”. There are only homeopathic medicines. Some homeopathic medicines are more often employed in the treatment of mastitis than others, based on the clinical picture of the cases matching that of these homeopathic medicines. Although the study allowed for homeopathic medicines other than the chosen ones to be used, it appears that in the trial efforts were made to reduce the number of homeopathic medicines used. This is in contrast to individualized homeopathic practice. It is also unclear what role the ‘specially developed software tool {...} for standardised repertorisation’ played in the reduction of homeopathic medicines.

2) We are cautious about the use of Radar Opus software to select homeopathic medicines for mastitis in cattle, because this software requires specific expertise to be used properly as it is primarily



IAVH
International Association for
Veterinary Homeopathy

used for treatment in humans. For homeopathic treatment of animals, other softwares exist. Nevertheless, a software program is not a replacement for homeopathic training and knowledge.

3) We would like to find out more about the 'specially developed software tool for standardised repertorisation'. This tool is unknown in the wider veterinary homeopathic large animal community and remains undescribed in the article. How was it created? Which algorithm was used? How was it used? In addition, it is unclear what is meant by standardised repertorisation. Standardising does not agree with individualisation. As acknowledged by the authors, it is unclear whether adequate and appropriate homeopathic individualisation took place. It is also unclear if after consulting the repertorisation tool, homeopathic medicines were studied in the *Materia Medica*, and a simile was chosen. A repertory should never be used to select a homeopathic medicine in a standard way. Choice of the simile is essential for the effectiveness of homeopathy. The study set up did not comply with classical homeopathic technique, creating a strong bias against homeopathy. Another apparent pitfall of standardisation is the lack of differentiation between acute and chronic cases in the homeopathic sense. According to good homeopathic practice, treatment approaches for acute and chronic cases should differ in relation to the remedy chosen, the dilution and the frequency of administration.

'Treatment procedure'

4) It is not clear what is meant by "clinical and homeopathic symptoms" under the Treatment procedure heading. It is important to distinguish between these two types of symptoms: clinical symptoms lead to a medical diagnosis, while homeopathic symptoms are used for repertorisation. These symptoms can overlap but are used differently.

5) Choice of homeopathic medicine and administration have to be done at the time of anamnesis and clinical examination. In an acute case, choice of the simile and its administration several days later means that it might no longer be the simile and will no longer be effective. It is essential to clarify if anamnesis, clinical examination and choice of the simile were done at time of administration of the homeopathic medicine, or at another time, and if so, how this affected the case.

6) Herdsmen were responsible for randomisation and the administration of treatments. No further documentation is given on this. It is imperative that there is cooperation, communication and feedback between the herdsman and the clinician to collect as many good quality homeopathic symptoms as possible, before giving a homeopathic medicine, and after, to monitor response. There is no indication in this paper that this was made possible or happened.

7) In the Consolidated Standards of Reporting Trials flow diagram (Fig.1) in the antibiotic arm 60 cows received allocated intervention, but 60 cows did not receive allocated intervention. This is difficult to interpret, if it is not a typographical error.

'Results'

8) Primary endpoint of total cure is not clearly defined in sense of time. Was it total cure at day 7, day 14, day 28 or over the whole observation period?

9) The distribution of the different bacteria identified between the three groups is not included in the article. Different pathogens have different cure rates, different response to antibiotics, and different severity of symptoms. As placebo seemed to be "more effective" than homeopathic treatment it is important to know whether the pathogens were evenly distributed between the three groups, with more severe pathogens in a greater number in the homeopathy group. For example; if *Streptococcus uberis* and *Streptococcus dysgalactiae*, best responders to antibiotic treatment, were more frequent in the antibiotic group, this would be a bias. It would also be interesting to know how the population in this study compares with the general dairy herd population from a bacteriological point of view.



IAVH
International Association for
Veterinary Homeopathy

10) P-value for the primary endpoint total cure [bacteriological, clinical and cytological (SCC < 100000 cells/ml) cure according to DVG criteria present at the same time] did not differ between the three groups at day 7 and day 14. At day 28, p-values significantly differed between homeopathy and antibiotic, but not between placebo and antibiotic. This may suggest that the pathogens present in the homeopathy group were more difficult to treat.

11) With regard to total cure over the whole observation period, it is significant that only seven cows were totally cured, with five cows belonging to the placebo group, one to the homeopathy and one to the antibiotic group. Again, this may suggest that the cases in the homeopathy group were more severely ill than in the other groups. Further, from an animal welfare point of view the level of overall total cure is poor, again casting a cloud over the design of this study. What is the real benefit of antibiotic treatment leading to bacteriological cure without clinical cure? Does it represent development of infection with new pathogens? It is not a positive result for animal welfare. Clinical cure carries the highest value in relation to animal welfare.

12) When no mastitis pathogen was found at day 0, there was no difference observed in the bacteriological as well as in the cytological cure rates between the three treatment groups at day 7, day 14 and day 28.

13) Clinical signs and p-values of results of clinical cure were not given at all. Clinical signs are the best way to assess the level of illness of patients, especially when it comes to a homeopathic assessment, and these were not mentioned in the article.

14) "Cows categorised as non-responsive at the time of final check-up in day 28 were mostly those treated with antimicrobial remedies (five out of nine animals)." How does this non-responder rate (cows with no clinical cure) fit into Table 2 and how does this agree with the high bacteriological cure rates of antimicrobial treatment?

'Discussion'

15) With regard to blinding, it has to be considered that herdsmen knew whether the cow received antimicrobial treatment, or placebo / homeopathic medicines. Observation of symptoms might have been influenced by knowledge of the treatment, and herdsmen might have stopped homeopathic or placebo treatment at an earlier stage, as acknowledged by the authors.

16) As acknowledged by the authors, the choice of the dilution and the frequency of administration of homeopathic medicines is indeed an important and frequently discussed issue. By standardizing to 10 globules daily for 5 days of a 30C potency, not only the individualization of homeopathy was lost, but equally importantly, the results cannot be interpreted meaningfully.

17) There appear to be some confusion between initial temporary aggravation of symptoms, recognition of how clinical signs change over time in response to a treatment, and progression of disease. This type of confusion (and various other points of contention) would have been avoided if the study had been planned and conducted with the help of specialists experienced and knowledgeable on the matter of homeopathy and research.

18) As the authors state, the mechanism of action of homeopathy is not completely unknown. They fail to mention the many studies conducted on this topic. Please see this recent overview (2).

Conclusion

In the discussion, the authors acknowledge many of the shortcomings of this trial regarding the application of good homeopathic principles and practices. This then begs the question of how they can support their results, and reach the conclusion they do, which simply stated says that homeopathy is not a valid substitute for antibiotic treatment in mastitis cases. This trial actually examined whether a restricted application of homeopathy in the type of farms chosen could be effective respectively it failed to provide 'proof' that the homeopathic medicines, in the way they were utilized in this study,



IAVH
International Association for
Veterinary Homeopathy

are efficacious in mastitis. While the “absence of proof” does not mean “proof of absence”, the outcome of this trial does not say anything about homeopathy itself but is interesting from a homeopathic point of view: it shows that any deviation from good homeopathic knowledge and technique, hence lack of good homeopathic practice, reduces its effectiveness. As in conventional medicine, if you do not apply a technique correctly, it is bad practice: we did not need this trial to find this out. Incidentally, this trial proved quite well how antibiotic treatment is redundant in many cases of mastitis, and equivalent to poorly applied homeopathy in reaching total cure. Given the negative side effects of antibiotics, it could be easily argued that homeopathy is as effective and more benign, if the results were framed that way.

Ethics and funding

From an ethical point of view, this trial should not have taken place because the study groups allocated to homeopathy were given little chance to benefit from effective treatment.

From a financial point of view, the funding by the European Union’s Seventh Framework Program for research, technological development and demonstration under grant agreement no. 311824 (IMPRO) should go into research in veterinary homeopathy vetted by the scientific committee of the Homeopathy Research Institute (HRI), which consists of experts from around the world who understand and participate in research in homeopathic medicine. Well-known experts were proposed to Professor Sundrum by IAVH on several occasions. We offered help and advice on how to best organise such a trial. Our offers were dismissed with no explanation. If proper advice had been sought, it would have resulted in a better trial, with results that would be validated in an unbiased manner, and therefore useful to the dairy industry, the veterinary community, and the regulatory community.

It is surprising that this article has passed peer review, given its shortcomings in methodology, analysis, presentation of results and unsubstantiated conclusion. We are encouraged by attempts to apply RCT standards to research on homeopathy, and therefore make it more mainstream. But this article shows clearly that it is a complex and nuanced task, due to the nature of homeopathy. There are serious concerns about the 'model validity' of this study from a homeopathic perspective. Mathie et al (3) have done extensive work about the importance of 'model validity' in trials of individualized homeopathy. Given the serious validity concerns raised, the "absence of proof" in this study was unsurprising. To set up good trials examining homeopathy it is important to consult experts in order to apply the appropriate standards. This avoids producing irrelevant research and avoids animal welfare issues.

For further information on homeopathy

Please follow this link for comprehensive explanation about individualised homeopathy:

<http://www.iavh.org/en/for-veterinarians/homeopathy/>

For a short summary on the current situation and of the scientific evidence of veterinary homeopathy especially in relation to AMR, please read further below, or visit the link to the IAVH website where you can find the references to research papers. <http://www.iavh.org/en/why-homeopathy/antimicrobial-resistance/>

References

(1) TOURNIER, A., ROBERTS, R. (2013) Homeopathy on trial – The need for targeted research into specific medical conditions. HRI Research Article Issue 21. <https://www.hri-research.org/wp->



IAVH
International Association for
Veterinary Homeopathy

[content/uploads/2014/08/HRI_ResearchArticle_21_TournierRoberts_TargetedResearch.pdf](#)

(2) KLEIN, S.D., WUERTENBERGER, S., WOLF, U., BAUMGARTNER, S., TOURNIER, A. (2018) Physicochemical investigations of homeopathic preparations: a systematic review and bibliometric analysis-part 1. J Altern Complement Med, epub ahead of print <https://www.ncbi.nlm.nih.gov/pubmed/29377709>

(3) MATHIE, R.T., RONINGER, H., WASSENHOVEN, M.V., FRYE, J., JACOBS, J., OBERBAUM, M., BORDET M.F., NAYAK, C., CHAUFFERIN, G., IVES J.A., DANTAS, F., FISHER, P. (2012) Method for appraising model validity of randomised controlled trials of homeopathic treatment: multi-rater concordance study. BMC Med Research Method 12: 49. <https://bmcmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-12-49>

Yours sincerely,

Dr. Edward De Beukelaer

President – IAVH (International Association for Veterinary Homeopathy), office@iavh.org

Dr. Hélène Renoux

President – ECH (European Committee for Homeopathy), president@homeopathyeurope.org

Dr. Ton Nicolai

EUROCAM spokesperson – EUROCAM, spokesperson@cam-europe.eu

Dr. Alexander Tournier

Executive Director – HRI (Homeopathy Research Institute), info@homeoinst.org

Univ.-Prof. Dr. Michael Frass

University for Human Medicines, Clinics for Internal Medicine I, Vienna, Austria,
Michael.frass@meduniwien.ac.at