Acta vet. scand. 2003, *44,* 97-101.

No Effect of a Homeopathic Preparation on Neonatal Calf Diarrhoea in a Randomised Double-Blind, Placebo-Controlled Clinical Trial

By *K. de Verdier*[1], *P. Öhagen*[2], and *S. Alenius*[2]

[1]Department of Ruminant and Porcine Diseases, National Veterinary Institute, Uppsala, and [2]Department of Ruminant Medicine and Veterinary Epidemiology, Faculty of Veterinary Medicine, Swedish University of Agricultural Sciences, Uppsala, Sweden.

Verdier de K, Öhagen P, Alenius S: No effect of a homeopathic preparation on neonatal calf diarrhoea in a randomised double-blind placebo-controlled clinical trial. Acta vet. scand. 2003, 44, 97-101. – A double-blind, placebo-controlled clinical trial of a homeopathic treatment of neonatal calf diarrhoea was performed using 44 calves in 12 dairy herds. Calves with spontaneously derived diarrhoea were treated with either the homeopathic remedy Podophyllum (D30) (n=24) or a placebo (n=20). No clinically or statistically significant difference between the 2 groups was demonstrated. Calves treated with Podophyllum had an average of 3.1 days of diarrhoea compared with 2.9 days for the placebo group. Depression, inappetence and fever were presented equally in the 2 groups. These results support the widely held opinion that scientific proof for the efficacy of veterinary homeopathy is lacking. In the European Union this implies a considerable risk for animal welfare, since in some countries priority is given to homeopathic treatments in organic farming.

Antibiotics; bovine; coronavirus; Cryptosporidium; enteritis; homeopathy; medicine; organic farming; Podophyllum; rotavirus; scour; veterinary.

Introduction

Acute undifferentiated diarrhoea in young calves (neonatal calf diarrhoea) is a daily occurrence all over the world, and rotavirus, *Cryptosporidium parvum* and coronavirus are major aetiological agents.

In the European Union, veterinary homeopathy is in common use in field practice, including for calf diarrhoea, and in some countries is increasing in popularity. Homeopathy may be defined as the treatment of animals that have signs of disease with a diluted and specially prepared substance that, in sufficient quantity in a healthy animal, would cause the same clinical signs. The existing literature on the subject comprises studies on various diseases and, although it is claimed that experimental and clinical evidence supports the use of homeopathy in some situations (see, for example *Wynn* 1998), more than 200 years in practice have not rendered convincing proof of its efficacy.

In cattle, there is limited literature on the use of homeopathy. The study design in the trials is a matter of debate, e.g. in the reviews of clinical trials on homeopathic treatment of mastitis by *Hamann* (1992) and *Vaarst* (1996). Clinical trials on calves have been reported, e.g. by *Taylor et. al.* (1989), who found no discernible differences between the treated and control groups in their manifestation of resistance to bovine lungworm or their clinical responses to the disease produced, by *Vohla* (1991), who found no effect on calf health after homeopathic treatment of

their dams with periparturient diseases, and by *Kayne & Rafferty* (1994), who claimed effect on calf diarrhoea by Arsenicum album C30, although the results were not statistically valid. To make interpretation of results possible, trials need to be double-blind and placebo-controlled, and the use of relevant statistical analyses should be made. Currently it is difficult to assess the efficacy of homeopathy from the present literature (*Persson Waller et al.* 1998), and therefore scientific evaluation of the effect of homeopathic treatment is required as a matter of urgency.

The aim of the present study was to evaluate the effect of the homeopathic remedy Podophyllum on the duration and clinical course of neonatal calf diarrhoea.

Materials and methods

The trial was performed during 1999 and 2000 in 12 dairy herds using a randomised double-blind, placebo-controlled study design. All of the herds were tested free from bovine viral diarrhoea virus (BVDV) in accordance with the Swedish voluntary control programme (*Lindberg & Alenius* 1999), and no *Salmonella spp.* had been detected. In total, 48 calves that contracted neonatal diarrhoea spontaneously were included in the trial; however, 4 calves were excluded from the analyses (missing data n=1, concurrent therapy n=3). All calves were housed in single pens. The calves were given a homeopathic preparation or placebo. Antibiotic treatment was considered not relevant to include (*Björkman et al.* 2003).

The homeopathically prepared remedy Podophyllum (D30) and the placebo were obtained from DCG Farmaceutiska AB, Göteborg, Sweden. Each of the farms received packages with randomised dosages of Podophyllum and the placebo in coded bottles. Diarrhoeic calves were treated by the farmers, to whom the contents of the bottles were unknown.

Treatment was initiated at the onset of diarrhoea and given orally for 3 consecutive days. During the course of the illness, calf health (i.e. general condition, body temperature, feed intake and faecal consistency) was monitored, rated on a 0-3 scale and recorded daily by the farmers. Score 0 referred to a clinically healthy calf, whereas score 3 signified severe depression, anorexia, a body temperature >40.5 °C and/or watery faeces. For practical reasons, farmers were not able to monitor dehydration, acidosis and electrolyte imbalance in calves.

On average calves in the Podophyllum group were 29.0 days old and in the placebo group, 26.3 days. Altogether 46% of the calves in the Podophyllum group and 45% in the placebo group were heifer calves, and the mean age of the dams was 2.5 and 2.4 lactations, respectively. The clinical signs on the first day of treatment were equivalent in the 2 groups (mean scores 2.8 and 3.2, respectively).

Faecal samples from each calf were collected daily by the farmers, placed in plastic tubes and transported by mail to the National Veterinary Institute (NVI), Uppsala, Sweden. The samples were searched by ELISA for rotavirus (*Svensson et al.* 1983, *Svensson et al.* 1986), *Cryptosporidium parvum* (Prospect Cryptosporidium microplate assay, Alexon-Trend, Ramsey, MN, USA) and coronavirus (in-house ELISA, NVI). Analyses were performed blind.

Duration of diarrhoea was chosen as the primary variable in the analyses. The groups were compared using Poisson regression.

The study design was approved by the Ethics Committee for Animal Experiments, Uppsala, Sweden (C133/98), and the Swedish Board of Agriculture, Jönköping, Sweden (35-4272/98).

Results

No statistically significant difference between the calves treated with Podophyllum and calves treated with the placebo was demonstrated.

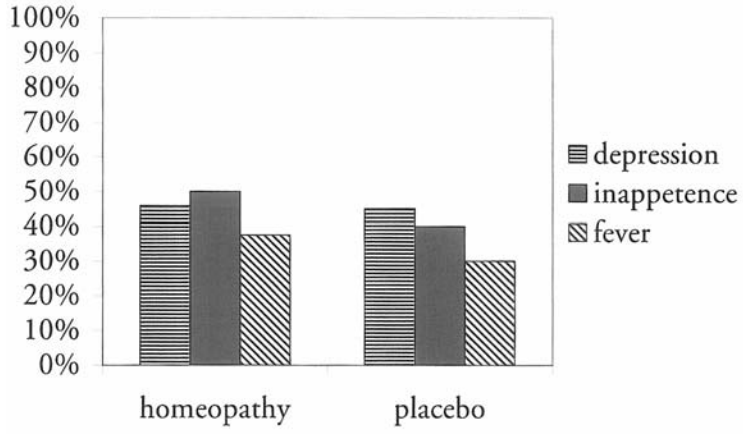

Figure 1. Clinical signs in calves with neonatal diarrhoea treated with the homeopathic preparation Podophyllum (n=24) or a placebo (n=20).

Calves treated with Podophyllum (n=24) had an average of 3.1 days' duration of diarrhoea (range 1-8 days), while calves treated with a placebo (n=20) had an average of 2.9 days' duration of diarrhoea (range 1-7 days). The confidence interval for the difference between the groups with regard to mean duration was [-0.6; 1.5]. The percentage of clinical signs in the calves in each group is shown in Fig. 1. No deaths of calves occurred during the study period.

During the diarrhoeic period, 9/24 calves treated with Podophyllum and 3/20 treated with a placebo excreted rotavirus in the faeces. On average, rotavirus-excreting calves were 19.5 days old at the onset of diarrhoea. Adjusting for rotavirus in the statistical analysis did not alter the results. In samples from 2 calves in total, *Cryptosporidium parvum* and coronavirus were detected.

Discussion

A 50% reduction in the duration of diarrhoea was considered a clinically significant effect but there was no clinically or statistically significant effect of treatment with Podophyllum, as compared with the placebo. The general condition, feed intake and body temperature of the calves were not affected by the treatment.

In the light of these results, we do not consider Podophyllum relevant for treatment of neonatal calf diarrhoea. Any medical treatment should have an effect that is visible in practice. Neonatal calf diarrhoea therapy should consist of oral rehydration and milk feeding, but preventive measures and good management practices are still fundamental in calf diarrhoea control. Antibiotics are not an appropriate treatment of choice and should be reserved for treating conditions such as pneumonia. In countries where *Salmonella* and BVDV are prevalent in cattle herds, special attention must be paid to controlling these infections.

Neonatal calf diarrhoea may be considered relatively harmless to some farmers, but it is noteworthy that 70.5% of the calves in this study showed additional signs of illness, such as fever, depression and/or inappetence. In 13.6% of the calves, all 3 additional signs were recorded concurrently. Younger calves were more frequently ill than were older calves. A comparison between calves up to 2 weeks of

age and calves older than 6 weeks showed that depression, inappetence and fever were present more frequently in the youngest animals. Rotavirus infection, which is likely to affect clinical signs, was more commonly diagnosed in younger calves than in the older animals. The more severe clinical picture seen in young calves seems only to emphazise the importance of careful handling of neonatal calves.

To our knowledge, this is the only report of a double-blind, placebo-controlled clinical trial evaluating the effect of homeopathy in neonatal calf diarrhoea. In our opinion, studies such as this are invaluable in the evaluation of the clinical effect of homeopathic or any other drugs. The homeopathic view was considered, as homeopathy experts were involved in the planning of the study and a majority of the farmers had experience in homeopathic treatment of calves.

The study was performed on Swedish dairy farms and thus based on local conditions, e.g. are veterinarians not allowed to use homeopatic preparations in practice. Homeopathic treatment of the calves in the study were done by the farmers. Swedish farms traditionally rear calves in single pens which likely has impact on the age when calves encounter infectious agents, compared with other countries. Salmonella spp and BVDV are rare in cattle herds in Sweden.

Any medical treatment without a clinical effect poses a risk, as it may delay recovery or deprive the animal of adequate therapy. This is especially crucial in the case of serious infectious diseases or any other illness which may prove fatal. Possible neglect of animal welfare must always be a concern.

During the past decade, there has been a considerable development of organic farming in the European Union, and in adopting EC Regulation No. 1804/1999 rules for organic livestock production are being set up. Priority is often given to homeopathic treatment rather than allopathic veterinary medicine on organic farms, and in our view this involves a considerable risk for animal welfare as scientific proof of the efficacy of homeopathy is lacking.

Acknowledgements

The authors would like to thank Helena B. Reineck and Bodil Christensson, NVI, for technical assistance, the farmers for participating in the study, the veterinary practitioners Helen Loor, Cecilia Hamilton and Sven Viring for practical support, Lisbeth Larsson and Chris Jörgenfeldt for expert knowledge in homeopath, and DCG Farmaceutiska AB for providing Podophyllum and the placebo. The study was made possible by a grant from the Swedish Farmers' Foundation for Agricultural Research (grant No. 063/98).

References

Björkman C, Svensson C, Christensson B, de Verdier K: Cryptosporidium parvum, Giardia intestinalis and other enteric pathogens in Swedish dairy calves. 2003 (submitted).

de Verdier Klingenberg K & Svensson L: Group A rotavirus as a cause of neonatal calf enteritis in Sweden. Acta vet scand 1998, *39,* 195-199.

Hamann J: Homeopathic treatment of bovine mastitis. Short report to IDF-Group A2 (Mastitis). 1992. Institute for Hygiene, Federal Dairy Research Centre, Kiel, Germany.

Kayne S & Rafferty A: The use of Arsenicum album 30C to complement conventional treatment of neonatal diarrhoea ("scors) in calves. Br Homeopath J 1994, *83,* 202-204.

Lindberg AL & Alenius S: Principles for eradication of bovine viral diarrhoea virus (BVDV) infections in cattle populations. Vet Microbiol 1999, *64* (2-3), 197-222.

Persson Waller K, Beyer W & Ekman T: Veterinär homeopati till lantbrukets djur - en sammanställning av vetenskapliga försök (Veterinary homeopathy to farm animals - a review of clinical trials (article in Swedish)). 1998. Report, Swedish University of Agricultural Studies.

Svensson L, Uhnoo I, Grandien M & Wadell G: Molecular epidemiology of rotavirus infections in Uppsala, Sweden, 1981. J Clin Microbiol 1986, *18,* 101-111.

Taylor SM, Mallon TR & Green WP: Efficacy of a

homeopathic prophylaxis against experimental infection of calves by the bovine lungworm Dictyocaulus viviparus. Vet Rec 1989, *124,* 15-17.

Vaarst M: Veterinær homøopati: Baggrund, principper og anvendelse med speciel fokus på økologiske malkekvægbesætninger – et litteraturreview. (Veterinary homeopathy: Background, principles and use with special focus on dairy herds in organic farming - a review (article in Danish)). 1986. Report no 731, Landbrugs- och Fiskeriministeriet, Statens Husdyrbrugforsøg, Denmark.

Vohla A: Zur vorbeugenden Anwendung von Sabina in unterschiedlichen Potenzen beim hochtragenden Rind. (On the prophylactic use of homeopathic preparations of Sabina in pregnant cattle (article in German)). 1991. Inaug. Diss., Hannover, Germany.

Wynn SG: Studies on use of homeopathy in animals. JAVMA 1998, *212,* 719-724.

Summary

Ingen effekt av homeopatisk behandling av kalvdiarré i en klinisk studie.

En dubbel-blind och placebokontrollerad klinisk studie av homeopatisk behandling av spädkalvsdiarré beskrivs. Fyrtiofyra kalvar från 12 mjölkkobesättningar ingick i studien. Kalvarna behandlades med antingen det homeopatiska preparatet Podophyllum D30 (n=24) eller placebo (n=20). Varken kliniskt eller statistiskt signifikanta skillnader mellan de båda grupperna kunde påvisas. Kalvar som behandlats med Podophyllum hade diarré i medeltal 3,1 dagar jämfört med placebogruppens 2,9 dagar. Nedsatt foderlust, påverkat allmäntillstånd och feber registrerades i samma utsträckning i båda grupperna. Resultaten styrker åsikten att vetenskapliga bevis för homeopatisk effekt saknas. Att, som i länder inom EU, förorda homeopatisk behandling i ekologiskt jordbruk innebär därmed en risk för djurens hälsa och välbefinnande.

(Received January 31, 2003; accepted April 23, 2003).

Reprints may be obtained from: K. de Verdier, Department of Ruminant and Porcine Diseases, National Veterinary Institute, SE-751 89 Uppsala, Sweden. E-mail: kerstin.de-verdier@sva.se