Echinacea powder: Treatment for canine chronic and seasonal upper respiratory tract infections

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Summary

An open multi-centered veterinary clinical trial, comparing conditions before and after treatment with a herbal preparation, containing the powdered root of *Echinacea purpurea*, was conducted by 6 practicing veterinarians in Switzerland. The plant-based immune stimulant was administered to 41 dogs with manifestations of chronic and seasonal upper respiratory tract infections, including pharyngitis/tonsillitis, bronchitis and kennel cough. Each animal was at an individual stage of the disease, with various symptoms and different severity scores, at start of treatment. There was no control group. Echinacea powder (1:3) was administered with the food at a dose of 1.0 g/10 kg body weight once daily for 8 weeks. Overall efficacy showed significant improvement for 92% of 39 dogs after 4 weeks of treatment and this was confirmed after 8 weeks. Significant reductions of severity and resolution of typical clinical symptoms, of clear nasal secretions, enlargement of lymph nodes, dry cough, dyspnea and dry lung sounds, were evident after 4 weeks. Only two adverse effects, not suspected to be attributable to the study drug, were recorded. Because quality and stability of the Echinacea powder were defined, using an analytical standard and purity tests, these data suggest, that the Echinacea preparation can be recommended as a well tolerated alternative treatment of canine upper respiratory tract infections.

Key words: dog – respiratory tract infection – immune stimulation – *Echinacea purpurea* – herbal medicinal product.

Echinacea Pulver: Behandlung bei Hunden mit chronischen und saisonal bedingten Infektionen der oberen Atemwege


Introduction

Pharyngitis, tonsillitis, bronchitis, kennel cough and seasonal upper respiratory tract infections constitute clinical conditions that require attention and treatment by a veterinarian (Suter, 2001). These manifestations of chronic upper respiratory tract infection are often associated with viral infections that can have a negative impact on the immune system. Viral infections impair the local defenses of the upper airways and enable secondary infections by various microorganisms. The healing properties of whole plants, parts of plants or their multi-component extracts (herbal preparations) administered at high pharmacologically active doses (phytotherapy) have been confirmed in modern scientific research. However, their medicinal use in dogs and other animals has hardly been investigated. A survey of clinical and pharmacology studies in man reveal that Echinacea purpurea, both modulates and non-specifically stimulates the immune system by activating the phagocytic capacity of granulocytes and macrophages and their secretion of cytokines (Liersch and Bauer, 1993; Melchert et al., 1995; Newall et al., 1996; Schulz et al., 1998). A monograph has been published describing the medicinal properties of Echinacea purpurea (ESCRP; European Scientific Cooperative on Phytotherapy, 1999). In the present study it was decided to assess clinical efficacy and safety and at the same time confirm the effective dosage in dogs, of a herbal preparation with immune stimulating properties, consisting of the powdered root of Echinacea purpurea (a standardized 1:3 powder formulation). The study was designed as an open multi-centre clinical trial with the goal of assessing the effects of the Echinacea powder in chronic and seasonal upper respiratory tract infections of dogs, recruited in veterinary practice.

Animals, Materials and Methods

Selection of animals: Since the treatment under investigation is targeted towards symptomatic relief, it was considered important to investigate animals showing a broad band of different indications and different stages of chronic or seasonal upper respiratory tract infections. Selection by 6 investigators who were practising veterinarians in Switzerland, was performed, based on compatibility with inclusion/exclusion criteria derived from the medical history and from the clinical examination and the pet owners signed informed consent. A total of 41 dogs (23 males and 18 females), aged between 0.3 and 13 years, weighing between 3.5 kg and 70 kg, and suffering from at least one of the following manifestations of chronic or seasonal upper respiratory tract disease were enrolled in the study: kennel cough, bronchitis, pharyngitis/tonsillitis and non-thriving young animals. The chronic condition was expected (in the opinion of the investigator) to continue for more than 8 weeks if left untreated. One investigator at one site enrolled thirty-four dogs, causing a final imbalance between sites. The different breeds of the 41 dogs in the study were (1 of each breed if not otherwise indicated in brackets): Airedale Terrier, American Staffordshire (3), Appenzeller Mountain Dog (2), Beagle, Berger Piccard, Berger Piccard Crossbreed, Border Collie, Cairn Terrier, Dachshund, Doberman, Dökji, English Bulldog, German Shepherd, German Shepherd Crossbreed, Giant Schnauzer, Great Swiss Mountain Dog, Hovawart Crossbreed, Labrador (2), Lapinokaira, Malinoi (3), Miniature Poodle, Newfoundland, Old English Mastiff, Papillon, Pomeranian Dog, Poodle, Sheep Dog, Spaniel (2), Standard Schnauzer, Swiss Mountain Dog, Terrier, Tervuren (2), Tib. Temple Dog.

Exclusion criteria and concurrent treatment: Antibiotics, sulphonamides, corticosteroids, non-steroidal anti-inflammatory drugs, anabolic steroids and other herbal preparations were not to be administered during the study or within 2 weeks prior to study commencement. Other types of medicine not targeted at upper respiratory tract infections could be used during the study and had to be documented in the CRF (case record form).

Study protocol

The study was designed as an open multi-centre clinical field trial in dogs. The chronic or seasonal nature of the clinical condition was to be documented in the medical history before the start of the study. Entry diagnosis was supported by the clinical examination. Each case was unique with respect to the individual stage of chronic disease and exhibited its own individual spectrum of symptoms at different degrees of severity out of 12 specific symptoms, that are known to be associated with different manifestations of canine upper respiratory tract infections.

Primary efficacy parameter: The investigator performed a clinical examination at each visit (at the beginning of the study and after 4 and 8 weeks of treatment). He assessed the overall efficacy (primary study endpoint) by comparing the severity and resolution of the different clinical symptoms, that existed before, during and after treatment for each individual animal. The 4 possible scores for efficacy were: very good, good, moderate or insufficient.

Secondary efficacy parameters: All symptoms were scored according to actual severities of symptoms observed by the investigator. Details of coat condition, appetite and lethargy (apathy) together with the following 12 clinical signs or symptoms: ocular secretions (clear,
Tolerability and safety of the study was cultivated Echinacea purpurea, (1:3) and a natural mineral base (formula EPB102, a product of Bogar AG, Zurich, Switzerland). The study drug, a herbal preparation, is a powder preparation containing the root of Echinacea purpurea (1:3) and a natural mineral base (formula EPB102, a product of Bogar AG, Zurich, Switzerland). The plant, Echinacea purpurea, was cultivated according to Good Agricultural Practice (GAP) and certification included region of growing, harvesting date, washing and drying conditions. Quality was controlled for total ash, heavy metals, pesticides and microbiology. Chicoric acid was the marker constituent for standardization of the Echinacea powder. The raw plant material has to contain between 0.6% and 2.1% chicoric acid (ESCORP, 1999; Liersch and Bauer, 1993). Synthetic chicoric acid was used as an analytical reference. The final product was standardized accordingly (Hänsel and Spiess, 1999). Stability is proven by storing Echinacea powder at 25°C/60% relative humidity for 3 years. Periodically the amount of chicoric acid, loss on drying and microbiology is controlled. During a storage time of up to 3 years no significant degradation of the marker substance chicoric acid was recorded.

Safety evaluation: Tolerability and safety of the study medication were addressed by recording all adverse events. The investigator gave an overall assessment of tolerability of the Echinacea preparation at both visits. Four possible scores were: very good, good, moderate and severe. Body weight and rectal temperature were also recorded.

Ethical considerations

The study was conducted according to the VICH-GL9 guidelines of Good Clinical Practice for Veterinary Medicinal Products (GCPV). The study was conducted in agreement with valid national regulations for testing veterinary medicines in Switzerland.

Drug, dosage and administration

The study medication, Echinacea powder, was administered to the dogs for 8 weeks, mixed in moist food, at a daily dose of 1g (corresponding to 0.3g Echinacea) per 10 kg body weight, by the pet owner and recorded in the pet owner’s diary. The administration of the study medication was supervised by the investigating veterinarian. The study drug, a herbal preparation, is a powder preparation containing the root of Echinacea purpurea (1:3) and a natural mineral base (formula EPB102, a product of Bogar AG, Zurich, Switzerland). The plant, Echinacea purpurea, was cultivated according to Good Agricultural Practice (GAP) and certification included region of growing, harvesting date, washing and drying conditions. Quality was controlled for total ash, heavy metals, pesticides and microbiology. Chicoric acid was the marker constituent for standardization of the Echinacea powder. The raw plant material has to contain between 0.6% and 2.1% chicoric acid (ESCORP, 1999; Liersch and Bauer, 1993). Synthetic chicoric acid was used as an analytical reference. The final product was standardized accordingly (Hänsel and Spiess, 1999). Stability is proven by storing Echinacea powder at 25°C/60% relative humidity for 3 years. Periodically the amount of chicoric acid, loss on drying and microbiology is controlled. During a storage time of up to 3 years no significant degradation of the marker substance chicoric acid was recorded.

Statistical analysis

The primary study end point (overall efficacy) was listed in a descriptive table with percentages of animals in each of the four categories. Differences between begin and end point of treatment phase were calculated. The unique clinical situation of each case was considered in analysis of the study. The secondary study endpoints (severity of clinical symptoms) were analyzed using Bowker's test (Bowker, 1948; Zar, 1999; SAS PROC FREQ). This statistical test constitutes an extension to the well-known McNemar test and is used when more than two data categories are present. It is especially well suited for the kind of data analysis encountered in this study because it takes into account the course of the disease for every individual animal by comparing the changes in category (severity) of the symptom. A 5% 2-sided level of significance was used unless mentioned otherwise. Statistical analyses were performed using version 6.12 of the SAS statistical package by BIOP (Basel).

Results

Pre-treatment data, entry diagnosis, mean duration of condition and mean duration of treatments as well as mean daily dose and compliance with study medication are summarized in Table 1. The duration of the condition, before onset of treatment, was greater than

**Table 1: Animals and documentation of the study population (n=41).**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (number of dogs)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>18 (44%)</td>
</tr>
<tr>
<td>Male</td>
<td>23 (56%)</td>
</tr>
<tr>
<td>Mean (± SD) age (years)</td>
<td>3.5±3.2</td>
</tr>
<tr>
<td>Mean (± SD) body weight (kg)</td>
<td></td>
</tr>
<tr>
<td>Pre-treatment (n=39)</td>
<td>21.6±13.2</td>
</tr>
<tr>
<td>After 4 weeks (n=39)</td>
<td>22.1±13.5</td>
</tr>
<tr>
<td>After 8 weeks (n=38)</td>
<td>22.0±13.7</td>
</tr>
<tr>
<td>Clinical entry diagnosis (number of dogs):</td>
<td></td>
</tr>
<tr>
<td>Pharyngitis/tonsillitis</td>
<td>40 (98%)</td>
</tr>
<tr>
<td>Kennel cough</td>
<td>16 (39%)</td>
</tr>
<tr>
<td>Bronchitis, mild forms</td>
<td>6 (15%)</td>
</tr>
<tr>
<td>Non-thriving young animals</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Condition seasonal</td>
<td>7 (17%)</td>
</tr>
<tr>
<td>Mean duration of condition prior to study begin (number of dogs):</td>
<td></td>
</tr>
<tr>
<td>&gt;3 months</td>
<td>21 (51%)</td>
</tr>
<tr>
<td>&gt;2 months</td>
<td>26 (63%)</td>
</tr>
<tr>
<td>≥1 month</td>
<td>36 (88%)</td>
</tr>
<tr>
<td>&lt;1 month</td>
<td>5 (12%)</td>
</tr>
<tr>
<td>Mean (± SD) duration of treatment (days)</td>
<td>54.6±2.8</td>
</tr>
<tr>
<td>Compliance with study medication (number of dogs):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>40 (98%)</td>
</tr>
</tbody>
</table>
one month in 88% (36/41) of dogs. The mean duration of treatment was 54.6 days, thus approximately 98% of the intended treatment days were fulfilled. Compliance was calculated as the number of days the drug was taken divided by the number of days in the study, taken as a percentage, and was 97.7% with a standard deviation of 4.8%. There were no significant changes in bodyweight after 4 and 8 weeks of treatment compared to pre-treatment (Tab. 1). Study populations evaluated for efficacy and safety after 4 and 8 weeks of treatment are shown in Table 2. There was no prior medication given to any dog enrolled in the study that would have had continued therapeutic effects into the study period and affected the quality and integrity of the data generated. During the study 2 deviations occurred: 2 dogs (nos. 8 and 39) received concurrent antibiotic medication (not allowed) concurrently with Echinacea powder, but continued taking the study medication. Data from these two animals were therefore excluded from efficacy analysis (Tab. 2).

**Efficacy**

Of the 41 dogs enrolled, data from 39 dogs were analyzed after four weeks of treatment. As two dogs required concurrent antibiotic medication during the trial, they were excluded from the analysis. After eight weeks of treatment, data from 38 dogs were analyzed, and one dog was withdrawn before the end of the study due to the development of an unrelated clinical condition requiring steroid therapy. Statistically significant efficacy results were shown after both four and eight weeks of treatment. The primary efficacy parameter was overall efficacy judged by the investigator after 4 weeks and 8 weeks of treatment. A statistically significant improvement of overall efficacy was recorded after 4 weeks of treatment with Echinacea powder, results were assessed as either “good” or “very good” in 92% (36/39) of dogs (with a 95% confidence interval of 88%, 102%), these results were confirmed after 8 weeks in 95% (36/38) of dogs (Fig. 1). Rectal body temperature at pre-treatment was 38.9±0.5°C, after 4 weeks of treatment, 38.7°C, and after 8 weeks, 38.6°C. In both cases, a relatively small, but significant change in mean body temperature was recorded in comparison to the pretreatment value (p=0.001) (Tab. 3). The secondary efficacy parameters were obtained by comparing the occurrence and the severity score of clinical symptoms at the beginning of the study, during and at the end of treatment. The reduction in severity or complete disappearance of all of the following major symptoms was demonstrated to be statistically significant (p<0.001) with Bowker’s test after both 4 and 8 weeks: nasal secretions (clear), enlargement of lymph nodes, cough (dry), dyspnea, and lung sounds (dry). Clear and purulent eye secretions had also improved significantly at 4 (p<0.01) and 8 weeks (Fig. 2, 3 and Tab. 4). Investigators were also
asked to record other "not listed" relevant symptoms (if any occurred) at each visit. Fifteen dogs out of 39 (38%) were recorded as presenting with "retching/choke or vomiting" pre-treatment at visit 1. This symptom group was not foreseen in the study, but it turned out to be an important marker of the respiratory disease. In the following visit at 4 weeks, only 4 of those 16 dogs (10%) still recorded retching/choke. This meant a definite improvement for 11 out of the 15 dogs (success rate of 73%) with this symptom after 4 weeks of treatment. After 8 weeks of treatment only 1 dog out of 15 still presented with vomiting, meaning a final success rate for 14/15 dogs (93%). All these dogs had a diagnosis of kennel cough and/or pharyngitis/tonsillitis. The number of dogs with a healthy/shining coat (Fig. 4) and those assessed by their owners as having a voracious appetite (Fig. 5) and being lively (Fig. 6), clearly increased after 4 weeks of treatment compared to pre-treatment. There was a particularly marked increase in the number of dogs described as being "lively" after both 4 and 8 weeks. The condition of lethargy accordingly improved by a significant degree (p<0.05). Poor coat condition and lack of appetite also improved significantly at 4 weeks (p<0.01 with Bowker's test). Overall incidence and resolution of major clinical symptoms, comparing results before, during and after treatment with Echinacea powder are summarized (Fig. 7). It can be seen that symptoms of the acuter phase of upper respiratory tract infection, such as cough, eye secretions and nasal secretions largely resolve inside of 4 weeks, whereas lung sounds and enlarged lymph nodes, reflecting more chronic phases of the infection, need longer periods of up to 8 weeks to disappear.

**Safety and tolerability**

**Overall tolerability**

At week 4, the overall evaluation of Echinacea powder tolerability was considered as being “good” or “very good” in 95% (39/41) of dogs. At week 8, the overall evaluation of drug tolerability was considered as being “good” or “very good” in 93% (38/41) of dogs.

**Adverse effects**

One adverse effect was recorded as a new infection of "kennel cough," i.e. coughing worsened, but rapid
improvement was recorded after a course of antibiotics. Although inclusion criteria (antibiotics were not allowed during the study) were violated in this case, the dog continued treatment with Echinacea powder and completed eight weeks of treatment without further incident. The dog was therefore excluded from efficacy analysis. A second adverse event was recorded as severe coughing, which did not improve during the study. This event appeared to be related to concomitant cardiac insufficiency. The cardiac insufficiency was most likely the primary cause of the symptoms recorded in this animal with a secondary cause of respiratory tract infection. The cardiac condition appeared to be poorly controlled. This dog was on treatment with an angiotensin converting enzyme (ACE) inhibitor (Fortekor), this being an allowed co-medication in the study. Data from this dog were included in the efficacy analysis. Neither event was suspected to be attributable to the study drug. There were no mortalities in this study.

**Premature discontinuation of study**

Only one dog (no. 29) did not complete the study, and this was due to the development of an unrelated musculoskeletal condition that required steroid therapy (Tab. 2).

**Hematology and clinical chemistry results**

Two blood samples per dog were taken at the beginning and at the end of the treatment period (week 8) and analysed. Following is a summary of changes between before and after treatment values, as recorded in the study:

- Pre-treatment, one dog had leucocytosis, neutropenia and lymphopenia related to the pre-existing condition. After 8 weeks of treatment, these parameters had returned to normal.
- Another dog had an elevated hematocrit and low MCHC pre-treatment, recorded as being related to the pre-existing condition. Both these parameters had returned to within normal ranges after eight weeks of treatment.
- Seven dogs presented with pre-treatment eosinophilia. The eosinophilia was only considered as being significant and related to a pre-existing condition in 5 dogs and non-significant in two. Five dogs that had no pre-treatment eosinophilia at study begin did show this condition after 8 weeks. The eosinophilia was recorded as being due to concurrent parasitic infections in four dogs.
- One dog had a lymphopenia after eight weeks that was not present pre-treatment. This dog was diagnosed with concomitant cardiac insufficiency and a respiratory infection caused by the bacteriae Klebsiella pneumonia, Pasteurella multocida, Staphylococcus spp. and Streptococcus spp., organisms that were isolated from samples in the 3 months preceding the start of the study. This dog did not respond to treatment with Echinacea powder and the overall efficacy in this case was assessed as being “unsatisfactory.” These changes seen in lymphocyte levels, were not suspected to be related to the study drug.
- Three dogs showed an elevated GPT (ALAT) after eight weeks compared to normal values pre-treatment. These changes were not considered of clinical importance nor recorded as adverse events by the investigators, but no explanation was given for these changes. One dog showed vomiting and diarrhea at week eight. It is not unusual to see a 5-fold increase in ALT in dogs having primary gastrointestinal disease (Hall, 1998).

There were no unusual or disturbing clinically relevant changes in hematology or clinical chemistry parameters, according to the investigators, thus confirming that Echinacea powder given orally at the recommended dose was well tolerated.

**Discussion**

Chronic disease of the upper respiratory tract can occur in the absence of any specific or recognized cause. In rare cases it may represent a known allergy to something in the local environment, or an inherited defect of one or more components of the normal defense mechanisms of the upper airway. The clinical signs can include nasal discharge and occasional sneezing. Because the cause is unknown, treatment can only be directed towards the clinical signs. Laryngitis may occur in dogs with a viral infection of the upper respiratory tract. Kennel cough, as another manifestation of upper respiratory tract infections, is a disease of multifactorial origin, meaning that a virtually identical clinical syndrome can be produced by several different infectious disease agents, either alone or in combination. Individual dogs may respond positively to many different kinds of drugs. No one treatment has been proven to be more effective than another. Conventional treatment is both specific and supportive and may include one or more of the following: antibiotics (including aerosol therapy), antihistamines, cough suppressants (antitussives), bronchodilators, glucocorticoid hormones, expectorants by aerosol therapy (nebulization) to help break up mucus secretions or fluid therapy to maintain normal hydration (Suter, 2001). Echinacea preparations are considered to be an effective treatment for human patients suffering from conditions where an immune stimulant is indicated.
(Bauer et al., 1988). Controlled clinical studies in humans have demonstrated the efficacy of Echinacea extracts, e.g. administered at a dose of 0.9g drug equivalent/day per patient in “flu-like” infections (Bräunig et al., 1992; Hoheisel et al., 1997; Melchart et al., 1995). Toxicity data derived from Echinacea extracts showed that this herbal preparations is virtually non-toxic to rats and mice at oral doses amounting to many times the human therapeutic dose (Lenk, 1989). In conclusion, this study demonstrates, that a clinical trial conducted in the veterinary practice with a standardized powdered root preparation of Echinacea purpurea is an acceptable alternative treatment of chronic and seasonal respiratory tract infections in dogs. At study begin of this practice-relevant investigation, each animal had a unique clinical condition related to the chronicity of its disease, to the combination of symptoms present and to the degrees of symptom severity. The statistical analysis in this study was therefore designed to assess individual progress of disease.

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Poudre d’Echinacea: traitement de chiens atteints d’infections chroniques et stagionales des voies respiratoires supérieures

Dans une étude clinique multicentrique ouverte, l’état clinique de 41 chiens atteints d’infection chronique saisonnière des voies respiratoires supérieures a été examiné par six vétérinaires praticiens avant et après un traitement oral de huit semaines avec une préparation contenant de la poudre de racine de la plante médicinale Echinacea purpurea. L’effet de cette plante repose sur une stimulation non spécifique du système immunitaire. Les maladies traitées étaient la pharyngite/amygdalite, la bronchite et la toux du chien pour lesquelles chaque animal se trouve dans un stade défini de la maladie avec des symptômes variés et à des degrés variés. Aucun groupe témoin n’était inclus dans l’étude. L’effet général a été évalué par des vétérinaires comme significativement amélioré après quatre semaines pour 92% parmi 39 cas avec confirmation après huit semaines. Après quatre semaines, une réduction significative du degré de gravité ainsi que la disparition des symptômes cliniques suivants jetage nasal, agrandissement des nœuds lymphatiques, toux sèche, dyspnée et bruits sur le poumon ont été obtenues. Dans toute l’étude, il n’y a eu que deux événements non désirés sans relation avec le médicament examiné. Puisque la qualité et la stabilité des médicaments est définie et est contrôlée par des tests, les données de cette étude indiquent que la préparation à base d’Echinacea peut être utilisée en tant qu’alternative acceptable pour le traitement d’infections des voies respiratoires supérieures chez le chien.

Polvere di Echinacea: trattamento di cani con infezioni croniche e stagionali delle vie respiratorie superiori

In un studio clinico aperto multicentrico è stato esaminato da sei veterinari lo stato clinico di 41 cani con infezioni croniche e stagionali delle vie respiratorie superiori prima e dopo il trattamento de 8 settimane con un preparato contenente la polvere della radice della pianta medicinale Echinacea purpurea. L’azione di questa pianta si basa su una stimolazione non specifica del sistema immunitario. I quadri clinici trattati comprendevano faringite/tonsillite, bronchite e tosse canina. Ogni animale si trovava in uno studio individuale della malattia, con sintomi clinici e gravità diversi. Lo studio non comprendeva gruppi di controllo. Dopo 4 settimane lo stato del 92% di 39 animali è stato giudicato dai veterinari migliorato in maniera significativa. Dopo 8 settimane questo risultato è stato confermato. Inoltre dopo 4 settimane è stata realizzata una riduzione significativa della gravità e rispettivamente la scomparsa dei seguenti sintomi clinici tipici: secrezione nasale, ingrossamento dei linfonodi, tosse secca, dispnea e rumori polmonari. In tutto lo studio si sono verificati solo 2 eventi non graditi, che comunque non sembrano essere in relazione con il trattamento. Dato che la qualità e la stabilità del trattamento usato nello studio sono stati definiti e confermati da esami, i dati di questo studio indicano che è possibile raccomandare il preparato di Echinacea quale alternativa ben tollerabile per il trattamento di infezioni delle vie respiratorie superiori del cane.
References


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