Dietary support with Boswellia resin in canine inflammatory joint and spinal disease

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Summary

An open multi-centre veterinary clinical trial, comparing conditions before and after treatment with a herbal dietary supplement consisting of a natural resin extract of Boswellia serrata, was conducted by 10 practicing veterinarians in Switzerland. This traditional plant-based supplement is known for its anti-rheumatic and anti-inflammatory properties. 29 dogs with manifestations of chronic joint and spinal disease were enrolled. Osteoarthritis and degenerative conditions were confirmed radiologically in 25 of 29 cases. The resin extract (BSB108, product of Bogar AG) was administered with the regular food at a dose of 400mg/10 kg body weight once daily for 6 weeks. Already after two weeks of treatment, an overall efficacy of the dietary supplement was evident in 71% of 24 eligible dogs. A statistically significant reduction of severity and resolution of typical clinical signs in individual animals, such as intermittent lameness, local pain and stiff gait, were reported after 6 weeks. Effects of external factors that aggravate lameness, such as “lameness when moving” and “lameness after a long rest” diminished gradually. In 5 dogs, reversible brief episodes of diarrhea and flatulence occurred, but only once was a relationship to the study preparation suspected. Because quality and stability of the resin extract were ensured, these data suggest that a standardized preparation can be recommended as a herbal dietary supplement providing symptomatic support in canine osteoarthritic disease.

Key words: dog – osteoarthritis – inflammatory joint disease – herbal dietary supplement – Boswellia serrata

Boswellia Harz, Ergänzungsfuttermittel bei entzündlichen Gelenks- und Wirbelsäulenerkrankungen des Hundes.


Introduction

Chronic degenerative joint and spinal disease, presented as osteoarthritis with its debilitating consequences for everyday’s life, is commonly encountered in the veterinary practice and is a major cause of lameness in dogs. This condition is found among dogs of all ages, but is prominent in older as well as certain breeds of larger dogs. Canine osteoarthritis can develop secondary to, for example, hip or elbow dysplasia, osteochondrosis and trauma. Genetic factors have been associated with the risk of developing hip osteoarthritis in predisposed dogs (Smith et al., 1995). Osteoarthritis is characterized by deterioration of articular cartilage, bone remodeling, osteophyte formation, inflammation and pain. Once clinically evident, osteoarthritis cannot be cured, therefore any treatment has to be directed towards correction of biomechanical causes and slowing progression of disease, by improving mobility, exercise tolerance and quality of life of the dog. Possible treatments include synthetic drugs (steroidal or non-steroidal anti-inflammatory drugs NSAIDs) or surgical treatment. Expense as well as limitations to surgical intervention and known side effects of anti-inflammatory drugs in dogs are reasons to look for alternative and supportive products available on the market. The nutritional or medicinal use of herbal dietary supplements and traditional herbal medicinal products in dogs and other companion animals are only recently becoming a topic of interest in the scientific veterinary community (Dicarlo et al., 2003; Reichling et al., 2003; Fitzi et al., 2002; Reichling and Saller, 2001). The resin of *Boswellia serrata* has been used traditionally for centuries supplementary to the diet of man, under the designation «salai guggal» in Ayurvedic medicine (Kreck and Saller, 1998). Pharmacological and clinical studies in both humans and animals have confirmed that Boswellia resin can inhibit a branch of the arachidonic acid cascade related to leukotriene synthesis, apparently without affecting prostaglandin synthesis. A possible selective anti-inflammatory effect relating to competitive and reversible inhibition of the leukotriene synthesizing 5-lipoxygenase is at least partially due to characteristic constituents of the resin, triterpenic acids, among them the boswellic acids. These acids could therefore prevent excessive formation of leukotrienes. Moreover, it is assumed that excessive formation of leukotrienes is responsible for maintenance of a chronic inflammation process and that inhibition may down regulate the progress of disease (Kreck and Saller, 1998; Ammon, 1996).

Acute, sub-acute and chronic toxicity and safety studies were carried out in mice, rats and monkeys and have shown that the resin is safe for use in different animals (Singh et al., 1996; Atal et al., 1983). It is the aim of the prospective open multi-centre clinical field trial presented here, to investigate effects of this natural plant-based dietary supplement in dogs with osteoarthritis, in the veterinary practice.

Animals, Materials and Methods

Selection of animals and recruitment

Since the treatment under investigation is targeted towards symptomatic relief, it was considered important to investigate animals showing a broad band of related inflammatory joint diseases and disease stages presented in the veterinary practice. Selection by 10 investigators who were practicing veterinarians in Switzerland was performed based on compatibility with inclusion and exclusion criteria derived from the medical history and from the clinical examination.

Inclusion criteria

The inclusion criteria included male and female dogs treated on an outpatient basis, in a good overall condition with a body temperature not in excess of 39°C, suffering from chronic inflammatory joint disease and/or disease of the spinal column with clinical signs associated with this disease. The chronic condition (disease state) was expected (in the investigator’s opinion) to remain approximately unchanged for more than 6 weeks unless effectively treated. The animal owner gave signed informed consent for the animal to participate in the study.

Exclusion criteria and concurrent treatment

Following patients were excluded from the study: dogs with neurologic deficits (paresis, paralysis); dogs given injections with cortisone, other steroids, NSAIDs or intraarticular injections (e.g. hyaluronic acid) during 6 weeks before the start of treatment; dogs treated with physical therapy in the form of ultrasonic, electrical stimulation, cryotherapy or heat therapy during 2 weeks before the start of treatment; dogs whose diet was changed within the past two weeks; dogs given herbal dietary supplements or other supplements, such as mussel extracts, glycosamine-chondroitin sulphate, etc., during 3 weeks before the start of treatment; dogs pregnant or in the lactation period intended for breeding; dogs with suspected gastric ulcer; dogs with joint or spinal disease due to tumors or septic infections; dogs suffering from arthropathies requiring surgical intervention (i.e. patella luxation, rupture of a crucial ligament, OCD). During the study, medications or supplements, including herbal dietary supplements, that might affect the condition of chronic inflammatory joint and spinal disease were not allowed.
Design of the study

The study was designed as a prospective open multi-centre clinical field trial in dogs and was conducted in the veterinary practice. The chronic 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 and independently (with an external expert) confirmed by X-ray. Each case was unique with respect to the individual stage of chronic disease with its own manifestation of joint disease and exhibited its own individual spectrum of clinical signs at different degrees of severity out of 9 specific signs that are known to be associated with manifestations of canine osteoarthritis. The statistical evaluation was therefore targeted to assess individual progress of disease. The daily meal of all animals was supplemented with a standardized resin extract for 6 weeks. The investigator determined the disease state at visits before and at 2, 4 and 6 weeks of treatment.

Ethical Considerations

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

Study preparation, dosage and administration

The dietary supplement was supplied in blister packs containing units of 400 mg of standardized extract from Boswellia resin (extract BSB108, product of Bogar AG, Zürich) in combination with natural carrier substances. Marker substances in the resin extract are boswellic acids that constitute part of the triterpenic acid group. The extract contains ≥50% triterpenic acids. These markers were quantified with HPLC, using reference standards, that were isolated from the crude resin. The daily dose was equivalent to 400 mg resin extract per 10 kg of body weight. The rationale for the daily dose used in the diet of animals in this study is largely based on Boswellia resin used in man at a dose range of 2400–3600 mg of resin extract per day (Kreck and Saller, 1998; Lokohare, 1995). The supplement was given once per day, during the regular meal by the pet owner, following instruction by the investigator. The pet owner recorded the product administered, in his diary during 42 consecutive days and signed his entries daily.

Statistical analysis

The primary study end points (changes in the disease state, progression of disease and resulting overall efficacy of the study preparation) were listed in descriptive tables with percentages of animals in each of the four categories. A key for the investigator was used in order to assess and compare “severity of the inflammatory condition” (disease state) on day 1 with “severity” on subsequent visits, in order to allow judgement of overall efficacy of the investigated product consistently between investigators (Tab. 1). Differences between begin and end points of the treatment phases were calculated. The unique clinical situation and progress of disease of each animal was analysed in the study. Study endpoints (severity of disease; severity of clinical signs) were analysed using Bowker’s test, an extension of the McNemar test (Bowker, 1948; Zar, 1999; SAS PROC FREQ). The p-value associated with the test is the probability for getting a result that is at least as asymmetric with respect to improvements vs. deteriorations as is the case in the actual outcome if the null hypothesis is true, i.e., if the changes in severity between “before” and “after” are purely coincidental (alternative hypothesis: they are not coincidental). 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

Baseline characteristics of the dogs in study

Ten practicing veterinarians in Switzerland enrolled 29 dogs in the study (16 males and 13 females), aged between 2.0 and 16 years, weighing between 10.2 kg and 49 kg, and suffering from inflammatory joint and spinal disease. Details regarding the pretreatment study
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population are summarized in Tables 2 and 3. The duration of the condition, before onset of treatment with the study preparation, was between 0.5 and 96 months with a median of 10 months. The mean duration of treatment was 39.5 days, thus approximately 94% of the intended treatment days were fulfilled.

Breeds of dogs in the study were (number of dogs enrolled per breed): American/Canadian White Shepherd (1), Bearded Collie (1), Bergamasco Shepherd Dog (1), Berger Picard (1), Bernese Mountain Dog (1), Bernese Mountain Dog Crossbreed (1), Boxer (2), Chow Chow (1), Collie (1), Engl. Cocker Spaniel (1), Flat Coated Retriever (2), German Shepherd (4), Golden Retriever (4), Huskybast/Rottweiler Crossbreed (1), Labrador (3), Labrador Crossbreed (1), Malinois (1), Shepherd Crossbreed (1), West Highland White Terrier (1). There was no prior medication given to any dog enrolled in the study that would have had continuing therapeutic effects into the study period and affected the quality and integrity of the data generated. The entry diagnoses for all animals (N = 29) covered the following indications: osteoarthritis (N = 22), degenerative osteoarthritis of the spine (N = 9), dysplastic conditions (N = 8) and osteoarthritis due to acquired joint deformation (N = 5). Osteoarthritis was considered to be due to direct excess stress for 4 animals and to indirect excess stress for 13 animals. In 25 of 29 cases (86%) the diagnosis could be confirmed by X-ray and was accordingly verified by the independent expert. Joint complaints were localized in the following regions (N is the number of animals with a specific location): lumbar (N = 7), sacral (N = 1), shoulder (N = 2), elbow (N = 7), carpal (N = 1), hip (N = 11), stifle (N = 2) and digital joints (N = 1).

Efficacy

Of the 29 dogs enrolled, efficacy data from 24 dogs were analysed after two and four weeks of treatment, and 21 dogs were analysed after six weeks of treatment. Details of study populations presented in Table 3 show, that five animals were excluded from efficacy analysis.

Assessment of the inflammatory joint and spinal disease state and overall efficacy

The investigator performed a clinical examination at each visit (at the beginning of the study and after 2, 4, and 6 weeks of treatment). He assessed the disease state at each visit by evaluating and summarizing severity of clinical signs (scores) per animal. Overall efficacy of treatment was then estimated by comparing the severity of the different disease states that existed before, during and after treatment (after 2, 4 and 6 weeks) for each individual animal. The investigator used a key to determine the degree of success of efficacy of treatment, by comparing the disease states at the various visits (Tab. 1). The 4 possible scores for overall efficacy were: very good, good, moderate or insufficient.

Changes of the inflammatory joint and spinal disease state and overall efficacy of resin supplementation

Results of clinical assessments of severity of the osteoarthritic disease state for the efficacy population at each visit are presented in Figure 1. There is a significant improvement, expressed as “reduction of severity of the disease state”, between visits 1 and 2.

Table 2: Base-line characteristics of the study population (n = 29).

<table>
<thead>
<tr>
<th>Characteristics of dogs on day 1, pretreatment</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender: female/male</td>
<td>13/16</td>
</tr>
<tr>
<td>X-ray confirmation of osteoarthritic disease (% of dogs)</td>
<td>26 (86%)</td>
</tr>
<tr>
<td>Mean ± SD age (years)</td>
<td>8.0 ± 3.5</td>
</tr>
<tr>
<td>Mean ± SD body weight (kg)</td>
<td>30.0 ± 8.9</td>
</tr>
<tr>
<td>Mean ± SD rectal body temperature (°C)</td>
<td>38.4 ± 0.3</td>
</tr>
<tr>
<td>Mean ± SD duration of treatment (days)</td>
<td>39.5 ± 5.0</td>
</tr>
<tr>
<td>Mean ± SD compliance with study preparation (% of dogs)</td>
<td>92.4 ± 6.7</td>
</tr>
</tbody>
</table>

Table 3: Definition of study populations for the six-week treatment period.

| Start Visit 2 Visit 3 Visit 4 |
| All patients population and safety population | 29 | 281 | 281 |
| Efficacy population | n/a6 | 241,2,3 | 241,2,3 | 211,2,3,4 |

1 one animal: did not attend visits
2 three animals: administration of study preparation was incompletely recorded
3 one animal: unrelated adverse event and premature study termination
4 three animals: terminated study after 28 days
5 n/a, not applicable

Figure 1: Changing degrees of the clinical disease state of osteoarthriti
tis in the efficacy population before, during and after treatment with Boswellia resin, observed between visit 1 and visits 2, 3 and 4 (days 1, 14, 28 and 42 respectively); p = 0.02 at visit 2; p = 0.01 at visits 3 and 4 (Bowker’s test).
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(p = 0.02), which is still evident at Visit 3 (p = 0.01), similarly at visit 4 (p = 0.01). Statistically significant overall efficacy was recorded after 2 weeks of treatment, results were assessed as either “good” or “very good” in 71% (17/24) of dogs with a 95% confidence interval of (51%, 90%). These results were confirmed after 4 weeks in 67% (16/24) and after 6 weeks in 71% (15/21) of animals. Thus significant positive efficacy of treatment was demonstrated after 2, 4, as well as after 6 weeks of supplementation with the resin extract (Fig. 2).

Assessment of clinical signs

The following 9 clinical signs and associated symptoms were categorized as study end point parameters: permanent and intermittent lameness, local pain, stiff gait, reduced range of motion, crepitation, increased filling of the joint, thickening of the capsule, myoatrophy, excess weight and effects of external factors, that aggravate lameness. The 4 possible severity scores were: none (meaning “sign not present”), slight, moderate, and severe. Angle of motion, body weight and rectal temperature were also recorded.

Changes of the common and major clinical signs

Severity scores of 4 major clinical signs: “Permanent lameness, intermittent lameness, local pain and stiff gait” are presented for all visits, before and after treatment with the resin extract (Fig. 3). Reduction of severity and resolution of these clinical signs in the efficacy population, shown in the graphic presentation, appear to be related to the length of herbal dietary supplementation. After 6 weeks a large proportion of dogs (ranging for the various symptoms from 40% to 70%) were symptom free. Severity scores of the 5 most common clinical signs (including 3 signs presented in Figure 3), each sign being reported in at least 50% of the efficacy population, could be statistically evaluated in the course of the disease: “Intermittent lameness, local pain, stiff gait, reduced range of motion and myoatrophy”. P-values of statistical comparisions for 4 of these 5 clinical signs, comparing pretreatment and subsequent visits in individual animals, are summarized in Table 4. One of the 5 common clini-

<table>
<thead>
<tr>
<th>Reduction and resolution of clinical signs compared to pretreatment values</th>
<th>Week 2</th>
<th>Week 4</th>
<th>Week 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermittent lameness</td>
<td>P = 0.05*</td>
<td>P = 0.07</td>
<td>P = 0.02*</td>
</tr>
<tr>
<td>Local pain</td>
<td>P = 0.05*</td>
<td>P = 0.01*</td>
<td>P = 0.02*</td>
</tr>
<tr>
<td>Stiff gait</td>
<td>P = 0.06</td>
<td>P = 0.07</td>
<td>P = 0.05*</td>
</tr>
<tr>
<td>Reduced range of motion</td>
<td>P = 0.13</td>
<td>P = 0.13</td>
<td>P = 0.06</td>
</tr>
</tbody>
</table>

* p ≤ 0.05 means that a change/reduction in symptom severity observed, is unlikely to be coincidental (Bowker’s test).
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Clinical signs, myoatrophy, did not change significantly in the observation period and is not listed here.

Lameness “when moving”, “after a long rest” and “during cold weather”

The frequencies of 3 external factors that can influence lameness (lameness “when moving”, “after a long rest” and “during cold weather”) were also investigated (Fig. 4). As can be seen in the graphical presentation, the importance of these external factors influencing lameness, decreased impressively from one visit to the next. Statistically significant clinical improvements were found for “lameness when moving, (p = 0.001)” and “lameness after a long rest, (p = 0.004)” by applying Fisher’s Exact Test.

Joint angle measurements

Joint angle measurements were available for a limited number of 9 dogs at visits 2 and 3, and for 7 dogs at visit 4 (6 weeks). The mean change of the maximal angles for the right and the left joints was slightly but not significantly higher throughout the duration of the treatment period, when compared with the pretreatment visit (paired t-test). The mean angle difference between pretreatment values and the last visit was $+5.71 \, (\degree)$ for the left joints and $+2.80 \, (\degree)$ for the right joints.

Safety and tolerability

Safety evaluation and overall tolerability

Tolerability and safety of the study preparation were judged by the investigator by evaluating all adverse events, as well as hematology and clinical chemistry results. At visits 2 and 3, 96% of dogs were judged as “good” or “very good” (95% confidence interval is 98%, 104%); all dogs at visit 4, 100% were judged to have overall tolerability of either “good” or “very good” (Fig. 5).

Adverse events and discontinuations

Adverse events were reported for a total of 11 out of 29 animals. In 5 dogs reversible episodes of diarrhea occurred, but only once did the study have to be discontinued for this reason. In one animal with brief episodes of flatulence and diarrhea a relationship to the study preparation was suspected. Two dogs discontinued the study due to severe adverse events unrelated to the study medication: one due to a car accident and another dog due to poisoning suspected to be related to moxidectin administration.

Hematology and clinical chemistry results, temperature and body weight

No significant trends were found. Nine animals had a total of 14 abnormal pretreatment values of some clinical relevance, but these values either stayed abnormal (10 values) or they returned to normal by day 28 (visit 3). Only one normal value (alpha-amylase) became abnormal during the treatment phase. This value was suspected to be related to a pre-existing gastroenteritis. The rectal body temperature at pre-treatment

![Figure 4: External factors influencing lameness, before, during and after treatment with the resin extract, comparing results of visits 1, 2, 3 and 4, at days 1, 14, 28 and 42, respectively (% of dogs with lameness at visit 1 in the efficacy population: n = 21 on visits 1, 2, and 3 and n = 18 on visit 4). The decrease between visits 1 and 4 is significant for “lameness when moving” (p = 0.001) and “lameness after a long rest” (p = 0.004) but not for “lameness during cold weather” (p = 0.247).]

![Figure 5: Assessment of overall tolerability in the all patients population at visits 2, 3 (n = 28) and 4 (n = 24), by the investigators.]

was 38.4 ± 0.3 °C (mean ± SD) this did not change significantly during the treatment period (paired t-test). Similarly body weight was constant over the study period.

**Acceptance of study medication**

The acceptance of the study medication (“taste”) was assessed at all visits following the entry visit and categorized as good for 82% of the animals. For the remainder the acceptance was recorded as moderate or poor.

**Discussion**

In this clinical study, supplementation of the daily meal with a traditional medicinal herb was provided to dogs with osteoarthritic disease, who were not treated simultaneously with other anti-inflammatory agents. This practice relevant investigation in dogs expressing the typical complaints related to a chronic inflammatory joint or spinal disease at the start of the investigation, demonstrated that a Boswellia resin extract at a dose of 400 mg/10 kg body weight once daily for 42 consecutive days, was able to improve the clinical condition of those dogs significantly. Disadvantages, such as well-known side effects of the commonly used steroidal and non-steroidal anti-inflammatory synthetic drugs in this indication, are the reason that the search for better and safer treatments of osteoarthritic canine patients is still ongoing. NSAIDs, various COX inhibitors, such as aspirin, phenylbutazone, meclofenic acid or carprofen may cause vomiting, ulceration of the stomach or duodenum (Wallace et al., 1990; Forsyth et al., 1998) and even renal or liver injury or bone marrow suppression. Corticosteroids, although highly effective, might induce further deterioration of cartilage and induce iatrogenic cushing disease, thus limitations to their application in osteoarthritis are obvious (Ungemach et al., 2002). In the present study, in only one dog of 29, with recurrent brief episodes of diarrhea and flatulence, was a relationship suspected between the adverse event and the investigated product, confirming that this product appears to be well tolerated in dogs. There are other natural products in use, as supportive treatments and dietary supplements, that might benefit dogs with degenerative joint disease. Recent publications about diets supplemented with natural products, such as polyunsaturated fatty acids that can compete with arachidonic acid metabolic pathways (Miller et al., 1992) or chondroprotective supplements such as glucosamine–chondroitin sulfate and green lipped mussel preparations (Anderson et al., 1999), provide some information, but these supplements need to be better defined and need to be further investigated in animals. The clinical efficacy of Boswellia resin in the treatment of dogs with osteoarthritis compares favourably with the results of similar clinical trails performed with synthetic NSAIDs (Doig et al., 2000; Vasseur et al., 1995). In a multicenter, controlled trial with carprofen 55% of the treated dogs showed a clinical improvement of their symptoms, compared to the 71% in the study presented here by using the herbal extract (Vasseur et al., 1995). That the symptoms joint crepitus, joint thickening and muscle atrophy were not significantly reduced by the treatment is not surprising and might be expected because these are chronic tissue changes and the study had a relatively short treatment phase. The data presented here indicate that a standardized Boswellia resin extract with well documented quality and stability can be recommended as a safe herbal dietary supplement for dogs, providing symptomatic relief in osteoarthritic disease.

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L’état de chiens souffrant de pathologies arthritiques avant et après traitement avec un aliment complémentaire contenant la résine de la plante médicinale *Boswellia serrata* a été examiné dans une étude ouverte multicietrique réalisée dans 10 cabinets vétérinaires suisses. Cette plante est traditionnellement utilisés pour ses effets anti-rhumatismaux et anti-inflammatoires. Dans cette étude, 29 chiens ont été inclus et, pour 25 d’entre eux, les modifications ostéo-arthritiques et dégénératives ont été confirmées par la radiologie. L’extrait de suc a été administré une fois par jour à la dose de 400 mg/10 kg de poids corporel pendant 42 jours. Après 2 semaines de traitement déjà, une efficacité a été constatée dans 71% (17/24) des cas. A la fin du traitement (6 semaines) des améliorations statistiques significatives et la disparition des symptômes typiques telles que boiterie intermittente, douleur locale et démarche raide ont été constatées. L’influence de facteurs extérieurs sur la boiterie («boiterie en mouvement» et «boiterie après une phase de repos importante») a diminué nettement au cours du traitement. Des épisodes réversibles de diarrhées et de flatulences sont apparus chez 5 animaux mais la relation avec le produit n’a été supposée que dans un cas. Comme le qualité et la stabilité du produit examiné sont garanties, cet aliment complémentaire peut être considéré, sur la base des données enregistrées, comme bien toléré et être recommandée pour des chiens souffrant d’affections ostéo-arthritiques pour obtenir un soulagement symptomatique.

**References**


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