



TITLE: EFFICACY OF AN EXTENSIVELY HYDROLYZED PROTEIN-BASED DIET DESIGNED FOR FOOD ALLERGIC SMALL DOGS: A PILOT STUDY

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Abstract summary

Cutaneous adverse food reaction (cAFR) is a non seasonal dermatitis induced by ingestion of allergens and accounts for nearly one in five pruritic dogs. Currently, diagnosis relies on performing an elimination diet trial followed by a re-challenge. A diet formulated with extensively hydrolyzed protein (consisting of free amino-acids and oligopeptides) and produced with stringent quality control measures has been proven efficacious in the diagnosis and management of cAFR. This pilot study aimed at evaluating a dietary solution formulated with the same extensively hydrolyzed protein and designed specifically to meet small dogs' needs. Ten adult dogs <10 kg diagnosed or suspected to have cAFR and previously stabilized on the commercialized extensively hydrolyzed protein diet described above, were included. Over a 4-week period the response of the dogs to the test diet compared to their current diet was compared using CADESI-4 assessed by a veterinarian and the owner assessed pruritus visual analogue score. There was no significant difference between treatments and a significant equivalence. Owner-assessed food acceptance and digestive tolerance were good and kibble features deemed relevant for small dogs. This study confirms that diets based on an extensively hydrolyzed feather protein can effectively manage small breed dogs known to have or highly suspected of cAFR. More studies are warranted to confirm the digestive tolerance and acceptance in a larger group of food allergic patients of small size.

Main summary

Objectives

Dermatological ailments remain a major issue in small animal practice with an estimated 15-30% of the world's dog population affected¹. Amongst the pruritic cases, nearly 20% of the dogs² have true immune-mediated reactions to antigens present in food and express cutaneous and/or gastrointestinal signs^{3,4}. The recommended diagnostic approach involves an elimination diet trial followed by a challenge with the previous diet⁶. However, it is essential to rule out secondary infections and ectoparasites as well endocrine disorders before pursuing a dietary trial⁵. It was shown that a diet formulated with an extensively hydrolyzed protein source along with pure maize starch and produced under rigorous quality control measures is a valuable solution for the diagnosis and management of food allergies in dogs^{7,8,9}. This pilot study aimed at confirming equivalent clinical efficacy and tolerance of a new diet tailored for small breed dogs and based on the same extensively hydrolyzed protein compared to its commercially available counterpart.

Materials and methods

This was an uncontrolled, multi-centre, field trial which included four French veterinary practices. Client-owned adult dogs meeting the inclusion criteria were recruited: small dogs (body weight (BW) ≤ 10 kg), diagnosed with cutaneous adverse food reaction (cAFR) or strongly suspected. All dogs had been stabilized with an extensively hydrolyzed feather protein-diet* for at least 2 months prior to enrolment. Dogs were considered stabilized if CADESI-04 was ≤ 10 (Canine Atopic Dermatitis Extent and Severity Index-4)¹⁰ and pruritus score was ≤ 1 (PVAS; 5-point scale: 0: absence of pruritus to 5: severe and frequent pruritus). Dogs had to be assessed as healthy based on physical examination, aside from dermatological disorders, and results of CBC, serum chemistry and urinalysis to be within normal ranges. They should not receive long-acting anti-pruritic medication. Pregnant or lactating females were not included. Dogs with dental disease affecting kibble prehension were not included and changes or interruption in usual treatments (before or during the study) triggered non-inclusion or removal.

The test food was a complete and balanced extruded dry diet, formulated with extensively hydrolyzed feather protein in the form of amino acids and oligopeptides. The carbohydrate source was purified maize starch. The diet was enriched in omega-3 (docosahexaenoic acid-DHA and eicosapentaenoic acid-EPA) and omega-6 (γ -linolenic acid-GLA) polyunsaturated fatty acids (PUFAs), as well as linoleic acid (LA), zinc, and B vitamins. Following a recommended four day- transition period (longer duration if gastrointestinal sensitivity), all dogs were fed the test diet exclusively for four weeks, as per manufacturer's feeding guide. Only treats known to be tolerated by the dogs were allowed during the study. Access to other food sources including human food and other pet food was not allowed. Owners were instructed on food storage to minimize cross-contamination risks.

There was a total of three visits, inclusion visit 1 (V1), and V2 and V3, 2 and 4 weeks after inclusion respectively. A phone call on day 10 was made by the recruitment agency to evaluate food tolerance and acceptance. Dogs were clinically assessed by a veterinarian skilled in dermatology at the 3 visits. Assessments comprised full clinical examination, scoring of skin lesions (CADESI-04) and pruritus along with recording of body weight (BW) and body condition score. Owners made daily assessments of their dog's feeding behaviour and their dog's digestive tolerance was determined using a fecal score chart. The CADESI-4 and PVAS scores at V3 were compared to V1 through a difference test (linear mixed model with time as fixed effect and animal as random effect), then an equivalence test (paired Two-One-Sided-t-test). The palatability and prehension of the test kibbles were also evaluated, constituting secondary criteria.

**Anallergenic canine dry diet, Royal Canin, France*

Results

Ten dogs were included and all dogs completed the study (8 females including 6 neutered, and 2 intact males, from 5 different breeds and 2 cross-breed dogs, aged $5.3 \text{ yrs} \pm 2.6$, mean BW at inclusion $7.2 \text{ kg} \pm 2.4$). The mean CADESI-04 scores showed no significant difference over the test phase (V1 to V3; see figure 1); and the equivalence test was significant ($p < 0.001$). The pruritus score analyses showed no significant differences over the test phase and a significant equivalence ($p < 0.001$).

Faecal scores remained good over the study; one dog with historical constipation improved by V3. All meals were consistently ingested and 90% of owners deemed the kibble texture and

chewiness as 'just about right'. No adverse events were reported, and no animals were withdrawn.

Discussion and conclusions

Adapted nutrition can provide support as part of the multimodal management of various skin issues and plays a crucial role in diagnosis and management of food allergies¹¹. Poultry feather hydrolysate is the protein source utilized in this diet, it is not reported to have antigenic properties in dogs and is dissimilar to feather and chicken meals found in pet food^{7,12,13}. Poultry feather is hydrolyzed extensively so that it consists mainly in free amino-acids, thus minimizing the risk of an adverse immune response and improving digestive tolerance^{7,9,13}. The benefits of omega-3 PUFAs on improving skin condition and modulating inflammation have been reported^{14,15}. Dietary LA has been shown to act on stratum corneum lipids, increased LA and zinc intake improved skin barrier properties and GLA has positive effects on coat quality^{16,17}.

Prior to enrollment, dogs of this study were previously fed a commercialized diet* indicated for cAFR and were considered stabilized according to their veterinarian and owner. These dogs were successfully switched over to the test food with no significant changes in skin lesions or pruritus scores. The results presented confirm that the test diet designed for small dogs had a similar efficacy on skin condition as the previous diet* and was widely accepted by owners of small breed dogs.

Limitations of the study include the absence of a control group and the small number of dogs. More studies are warranted to confirm good tolerance and acceptance in a larger population of small breed dogs diagnosed with cAFR.

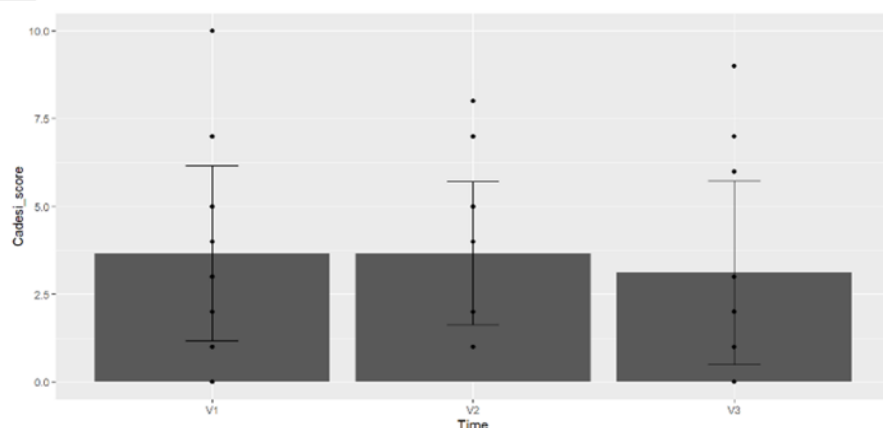
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Attached file

Figure 1



Evolution of the scores for skin lesions (barplots with 95% confidence interval) assessed in the ten included dogs, through the CADESI-04 scale, at veterinary visits V1-V3, where V1 represents inclusion visit and V2 -V3 the visits after 2 weeks and 4 weeks on the test diet. **No statistically significant difference was obtained over the test phase V1-V3**