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ORIGINAL ARTICLE

Efficacy and safety of a hydrocortisone aceponate-containing ear spray solution in dogs with erythemato-ceruminous otitis externa: A randomised, multicentric, single-blinded, controlled trial

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Abstract

Background: Erythemato-ceruminous otitis externa (ECOE) is frequently seen in dogs affected with an allergic skin disease, with recurrent secondary bacteria and yeast overgrowths (detected on cytological examination).

Objectives: The objective of the study was to compare the efficacy and safety of an ear spray containing only hydrocortisone aceponate glucocorticoid diester (HCA) to a control product (CTRL), an approved otic formulation containing prednisolone-miconazole-polymyxin combination, in dogs with ECOE.

Animals: In total, 97 and 104 dogs with ECOE were respectively randomly assigned to the tested ear treatment product group (HCA) or the commercially available ear treatment control product group (CTRL).

Materials and Methods: Dogs were treated for 7–14 days, as needed. At Day (D)0, D7, D14, D28 and D42, Otitis Index Score-3, hearing test, pruritus and pain visual analogue scales, and cytological scores were graded. The overall response to treatment also was assessed.

Results: All clinical parameters decreased rapidly and in a similar way without any significant difference at any time between treatment groups. A good-to-excellent response to treatment was seen in >90% of dogs of both groups as early as D14. The treatment was considered safe in all dogs.

Conclusions and Clinical Relevance: A 7- to 14-day ear topical application of HCA alone to dogs with ECOE accompanied with bacterial and/or fungal (yeast) overgrowth was safe and led to no statistical difference in improvement of clinical scores relative to the CTRL combination. Based on these results, it may be necessary to reconsider the routine use of antimicrobial drugs such as antibiotics and antifungals as a first-line treatment for ECOE that is likely to have been caused by an allergic reaction.

KEYWORDS
atopic dermatitis, atopy, dog, glucocorticoid, hydrocortisone aceponate, otitis

INTRODUCTION

Otitis externa (OE) is a common problem that affects dogs, with various clinical presentation.[1–7] Three studies, two prospective and one retrospective, have reported that erythemato-ceruminous OE (ECOE) was by far the most common phenotype of canine OE, as it was diagnosed in 75%,[1] 79%[2] and 85%[3] of 752, 844 and 82 dogs with OE, respectively.

In the retrospective case series where this information was clearly specified, it was found in 75% of dogs with ECOE not related to ear parasites, that an allergic dermatitis [including atopic dermatitis (AD), flea bite allergy and food allergy] was the most commonly

identified underlying disease.[1] The other two prospective studies reported that AD was the most common pre-existing disease diagnosed in dogs with OE.[2,3]

The studies above allowed the comparison of ear cytological results with the phenotype of canine OE. In dogs with ECOE not related to parasites of the ears, the cytological examination of otic cerumen revealed *Malassezia* yeast in 79%–82% of cases and *Staphylococcus* bacteria in 50%–57% of cases. The microscopic detection of *Malassezia* alone (40% in two studies[1,2]) was common. A different study showed that an increasing excess of cerumen was associated with a higher probability of culture of *Malassezia* spp.[8]

One abstract supported the benefit of a commercial hydrocortisone aceptonate (HCA) solution in dogs with allergic OE.[9] The HCA was applied in the ear canals of dogs with OE of allergic origin, once daily for 7–14 days: both erythema and cytological scores were reduced significantly. A study on the treatment of AD skin lesions in humans showed that topical glucocorticoids alone improved the bacterial microbiota in lesional skin (mainly *Staphylococcus aureus*) to a level similar to that found in atopic yet nonlesional skin.[10] However, that study did not examine the impact on fungal flora, and microbial overgrowth in dogs, especially in the ear canal, that may be of more pathophysiological significance and difficult to reduce with topical glucocorticoids alone.

This study aimed to assess the effectiveness and safety of a corticosteroid ear spray solution for treating canine ECOE. The tested spray contained only one active ingredient, hydrocortisone aceponate (HCA at 0.584 mg/mL) and did not include any specific antibiotic or antifungal components. The diester chemical form of HCA has particular pharmacodynamic properties that increase the efficacy/safety ratio.[11]

The objective was to demonstrate that the tested product was not inferior to a commercial ear drop suspension used as a control product which contained a combination of corticosteroid (prednisolone acetate at 5 mg/mL), antibiotic and antifungal active ingredients.

MATERIALS AND METHODS

Ethics

In this multicentre study, which had been approved by an ethics committee (EU-ERC I 201906–09), all animals were recruited within the clientele of investigators' clinics in France, Spain and Ireland. Owners were required to sign an informed consent before enrolment of their dog.

Animals

We enrolled dogs of any breed or sex, older than seven months, exhibiting clinical signs of ECOE with a minimum Otitis Index Score (OTIS)-3 score of 5 (of a maximum score of 12).[12] Bacteria and/or yeast had to be easily visible on the cytological examination of a smear of the otic exudate on Day (D)0. Dogs had to be in good general health or with stable chronic conditions. When two ears were affected, both were treated, yet only the most severely affected (based on OTIS-3 score) was followed during this trial. Allergen-specific immunotherapy was permitted if used for more than a year; nonsteroidal anti-allergic drugs were allowed if used for longer than two months, provided that the treatment would remain unchanged and the clinical signs had been stable with these interventions.

Pregnant or lactating bitches, dogs with suppurative OE (SOE), or with parasites in the ears or with OE caused by a foreign body, were excluded from enrolment. We likewise did not enrol dogs with a clinical suspicion, or evidence, of a ruptured tympanic membrane on careful otoscopic examination. Also eliminated from consideration were dogs with other diseases not controlled at enrolment, or those with a known allergy to any of the ingredients contained in the administered products. Finally, dogs that had been treated with topical or systemic antifungals, antibiotics, glucocorticoids or nonsteroidal anti-inflammatory drugs in the two weeks preceding potential enrolment and dogs treated previously with long-acting glucocorticoids (as defined by >1 week of activity) within two months of potential enrolment also were excluded.

Interventions

After clinical and otoscopic examinations, selected dogs were randomly allocated 1:1 to be treated with an HCA ear spray solution (Cortotic; Virbac) or with a prednisolone acetate-polymyxin B-miconazole ear drop suspension combination (CTRL; Surolan, Elanco Animal Health).

For the first seven days, the HCA was applied in the external ear canal at 0.44 mL (two pump sprays) once daily, while the CTRL was given as per the registered instructions for use, five drops twice daily in the external ear canal. On D7, if the OTIS-3 score was ≥4, the treatment was continued for another week until D14. Ear cleaning was performed in all dogs of both groups only once on D0 using Epiotic S.I.S (Virbac), just before the first treatment. Throughout the entire trial, to keep the primary investigator blinded to the nature of treatment, a different investigator was responsible for group allocation, first ear cleaning, drug dispensing to the owner and contact with clients regarding any drug-related concern.

Efficacy outcomes

On D0, D7, D14±1, D28±2 and D42±2, the investigator performed a general physical evaluation and assigned an OTIS-3 score and a pain grade using a four-point Visual Analog Scale (0='no pain' to 3='painful when the pinna is raised'). The owner also was asked to rate the pain and the pruritus using a VAS ranging from 0 to 10,[13] once daily from D0 to D6, and then at each re-evaluation visit. Finally, both investigators and owners

provided a subjective overall assessment of the response to treatment (poor, moderate, good, excellent) at each visit from D7 to the end of the trial.

On D28, we defined *treatment success* as an OTIS-3 score of ≤3. However, *treatment failure* was considered to be an OTIS-3 score of ≥4; this included cases of withdrawal of the dog before D28. Between D28 and D42, an *otitis relapse* was defined if the OTIS-3 score was >3 in any dog that had been a treatment success on D28.

At each evaluation visit, and before ear cleaning at D0, an ear swab was taken and sent to a central laboratory for semiquantitative cytological evaluation. For each smear, five single fields of vision at ×400 magnification were examined. Each field of vision received a single scoring for bacteria and yeast based on the Budach and Mueller scoring (0–4+ scale).[14] Then, the mean of the five single scorings was calculated and rounded to the nearest value on the 0–4+ scale. In addition, micro-organisms were cultured and identified: The identification of bacteria was carried out using a combination of matrix-assisted laser desorption ionisation–time-of-flight–mass spectrometry (MALDI-TOF-MS), biochemical testing (VITEK), rapid detection of cytochrome oxidase or catalase, or serological testing (e.g. Wellcolex). This procedure was repeated in case of treatment failure or OE relapse.

The primary efficacy end-point was the change in OTIS-3 score from baseline to D28. Secondary efficacy outcome measures were changes from baseline of the following: OTIS-3 score on D7 and D14, each of the clinical signs of the OTIS-3 score at each visit, the semiquantitative cytological score, ear pain assessments by the investigator and ear pain and pruritus VAS assessments by the owner. The overall assessment of response to treatment, the percentage of recovery (OTIS-3 score ≤ 3) at each visit and the relapse rate also were considered.

Safety evaluation

A clap test, a subjective evaluation of the dog's hearing ability, was performed at each visit. The investigators clapped their hands in a location outside the dog's field of vision and the ability of the dog to turn its head towards the noise was observed. The results of this test were recorded either as positive or negative response.

Haematological, serum biochemical and urine analyses were performed before treatment administration on D0, and at the end of the study. At each visit, investigators assessed the dogs for any abnormal systemic and local (i.e. ears) signs, and the owners were instructed to report any perceived adverse events.

An adverse event was defined as any observation in the animals that was unfavourable, unintended and occurred after the use of the veterinary product or investigational veterinary product, whether or not the event was considered to be product-related. Therefore, any observations made by the owner or investigator were reported from D0 until the end of the follow-up of the dog. The causality assessment of all adverse events was subsequently performed by the Virbac pharmacovigilance department following the 'Guideline on procedures for competent authorities for pharmacovigilance information for veterinary medicinal products' from the European Agency for the Evaluation of Medicinal Products.

Statistics

Each individual dog was considered a separate experimental unit. Sample size calculation was based on a previous pilot study, and the noninferiority margin of 15% was selected, as used previously.[15] A mixed model with repeated measures (MMRM) was generated for OTIS-3 percentage change from baseline values, and the least squares means difference between treatments with their 95% confidence intervals (CIs) were reported. Noninferiority was claimed if the lower bound of the difference between HCA and CTRL did not exceed –15% on D28, while all of the other time points were considered secondary. Analyses were conducted on both full analysis set (FAS) population (presented here), and per protocol (PP) population (which leads to the same conclusions). Changes from baseline owner-assessed ear pain and pruritus also were examined using a MMRM method, and we determined the difference in least-squares means between treatments at each time point. All other secondary efficacy outcomes were analysed using Cochran Mantel Haenszel stratified by site with ridit transformation, general association or row mean score statistics.

All analyses were performed using SAS software v9.4 (Cary, NC, USA), and the significance was reached at the $p=0.05$ two-sided level.

RESULTS

Animals

In total, 201 dogs with ECOE were admitted to the study, 97 were assigned to the tested ear treatment product group (HCA), and 104 were assigned to the commercially available ear treatment control product group (CTRL).

At the start of the study (D0), the two treatment groups were similar in terms of age, sex, body weight, breed and OTIS-3 scores (Table 1). The majority (71%) of the enrolled dogs were purebred, with seven breeds making up 31% of the total: Yorkshire terrier (7%), Golden or Labrador retriever (5%), West Highland white terrier (4%), English cocker spaniel (4%), German shepherd dog (3%), French bulldog (3%) and Dogue de Bordeaux (3%). Over 75% of dogs in both groups had bilateral ECOE.

The majority of dogs with ECOE (88.6%) had yeast as the predominant micro-organisms identified on cytological examination at baseline (D0), while bacteria were present in 53.7% of dogs. *Malassezia pachydermatis* was the most common type of yeast isolated, representing 98.8% of yeast cultures. For

bacteria, *Staphylococcus pseudintermedius* was identified in 32.3% of dogs, *Pseudomonas* spp. in 11.9%, *Escherichia coli* in 5.0% and *Proteus mirabilis* in 5.0%. The distribution of micro-organisms between the HCA and CTRL treatment groups was similar.

In the HCA group, one dog was withdrawn from the study owing to an adverse event, one dog because of withdrawal of owner's consent, and two dogs were lost to follow-up; in the CTRL group, one dog was withdrawn from the study because of the administration of a forbidden treatment and five additional dogs were lost to follow-up. Thus, 93 dogs in the HCA group and 98 dogs in the CTRL group completed the study.

Outcome

OTIS-3 scores. After D7, 57.7% of dogs in the HCA group and 57.3% of dogs in the CTRL group required an additional week of treatment as they had not fully recovered (OTIS-3 still >3).

Mean OTIS-3 scores evolved favourably and in a similar way in both groups (Figure 1).

Percentages of reduction of mean OTIS-3 scores at each visit are detailed in Table S1. On D28, the noninferiority in the percentage reductions in OTIS-3 scores from baseline was established. The observed difference between HCA and CTRL was +2.74% and the lower bound of the 95% CI of that difference was −4.23% which was above the pre-defined noninferiority margin of −15%.

Similar favourable evolution of the proportion of *treatment success* at D28 and *recovery* at D7, D14 and D42 (i.e. dogs with an OTIS-3 score of ≤3) was recorded in both groups over time with no significant difference between groups at any visit (Figure 2).

Treatment failure was observed in six of 97 (6.2%) HCA-treated dogs and in nine of 104 (8.7%) CTRL-treated dogs. An *otitis relapse* (OTIS-3 score>3 after a *treatment success* on D28) was recorded in seven of 87 (8.0%) and four of 89 (4.5%) dogs from the HCA and CTRL groups, respectively.

TABLE 1 Study subject demographics.

	Total	HCA group	CTRL group
Age (years)			
N	201	97	104
Mean (±SD)	5.7 (±3.8)	5.7 (±3.9)	5.8 (±3.6)
Median	5.0	5.0	5.5
Q1; Q3	2.0; 9.0	2.0; 10.0	2.7; 8.0
Min; Max	0.6; 14.0	0.6; 14.0	0.7; 14.0
Sex			
Male	54/201 (26.9%)	26/97 (26.8%)	28/104 (26.9%)
Male neutered	26/201 (12.9%)	14/97 (14.4%)	12/104 (11.5%)
Female	49/201 (24.4%)	23/97 (23.7%)	26/104 (25.0%)
Female spayed	72/201 (35.8%)	34/97 (35.1%)	38/104 (36.5%)
Breed			
Pure-bred	142/201 (70.6%)	71/97 (73.2%)	71/104 (68.3%)
Mixed	59/201 (29.4%)	26/97 (26.8%)	33/104 (31.7%)

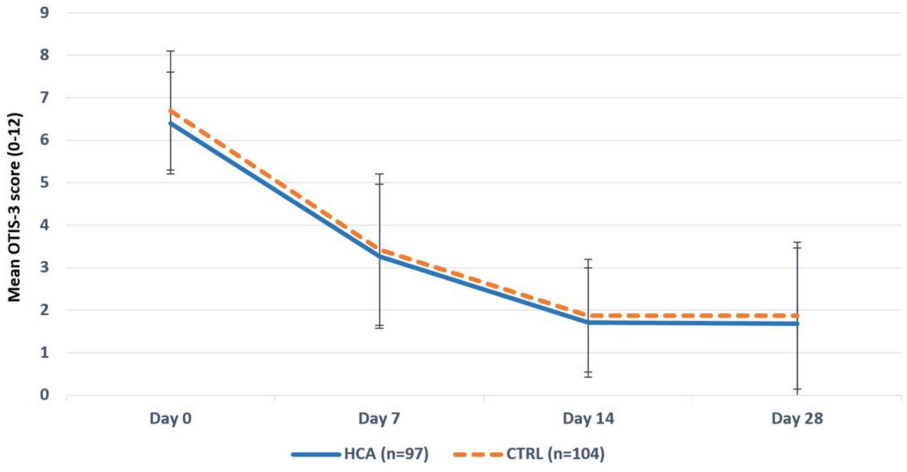

FIGURE 1 Evolution of Otitis Index Score (OTIS)-3 scores over time in both groups. Data presented are the means±SDs. Blue line, hydrocortisone aceponate (HCA) ear spray solution; orange dotted line, prednisolone acetate-polymyxin B-miconazole ear drop suspension combination (CTRL).

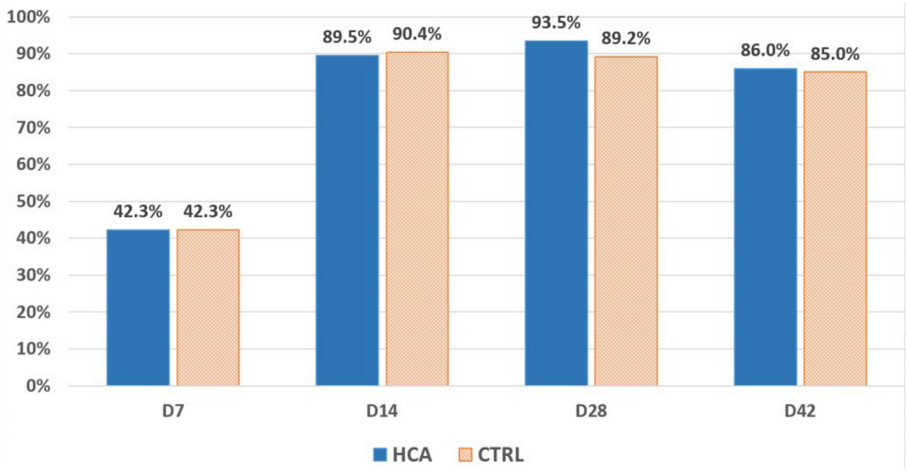

FIGURE 2 Evolution of the percentages of recovery over time (percentage of dogs with an Otitis Index Score (OTIS)-3 score ≤ 3). Blue columns, hydrocortisone aceponate (HCA) ear spray solution; orange columns, prednisolone acetate-polymyxin B-miconazole ear drop suspension combination (CTRL).

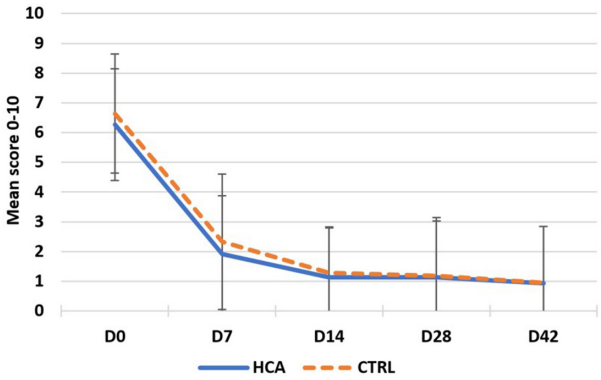

FIGURE 3 Evolution of owner-assessed pruritus scores over time (Visual Analog Scale from 0 to 10). Blue line, hydrocortisone aceponate (HCA) ear spray solution; orange dotted line, prednisolone acetate-polymyxin B-miconazole ear drop suspension combination (CTRL).

Pain scores. On D14, a complete relief of pain, assessed by the investigators (Figure S1), was obtained in 83.2% and 69.6% of the dogs from the HCA and CTRL groups, respectively. No pain was detected in 84.9% and 89.8% of dogs from the HCA and CTRL groups, respectively, at the end of the trial. There were no significant differences between groups at any of the re-evaluation visits.

The VAS pain score assessed by the owners (Figure S2) evolved in a similar manner to that graded by the investigators: as soon as D5, they were reduced by half in both groups. There were no significant differences in scores between groups on any of the rated days.

Pruritus scores. Pruritus scores (Figure 3) were reduced likewise in both groups and there were no significant differences between scores of the two groups at any of the days evaluated.

Overall assessment of treatment response. A good-to-excellent treatment response was recorded by investigators and by owners (Figure 4) as soon as D7 in both groups and their percentages increased regularly up to the end of the study. There were no significant differences between groups.

Cytological scores

Cytological subgroup analyses were performed on dogs with only yeast overgrowth, or with only bacteria overgrowth, or both on D0. These analyses were descriptive only, statistical comparisons were not relevant owing to the inadequate number of dogs in each subgroup. Further studies would be required on a larger number of dogs to specifically analyse the microbial outcome.

On D0, 43 (45.3%) and 47 dogs (46.5%), respectively, in the HCA and CTRL groups, had both yeast and bacterial overgrowth and 43 (45.3%) and 45 dogs (44.6%), respectively, in the HCA and CTRL groups exhibited only yeast overgrowth. Only nine dogs from both groups (representing 9.5% and 8.9%, respectively, in the HCA and CTRL groups) had only bacterial overgrowth (Figure 5).

Yeast cytological scores (Figure S3). When both yeast and bacterial overgrowth was recorded on D0, the mean yeast cytological scores decreased from 2.3 to 1.4 and 2.4 to 1.0 on D28, respectively, in the HCA and CTRL groups.

When only yeast overgrowth was recorded on D0, the mean yeast cytological scores decreased from 2.6 to 1.2 and 2.6 to 1.7 on D28, respectively, in the HCA and CTRL groups.

When only bacterial overgrowth (nine dogs only in each group) was recorded on D0 (yeast score = 0), yeast scores increased to 0.1 and 0.2 on D28, respectively, in the HCA and CTRL groups.

Bacteria cytological scores (Figure S4). When both yeast and bacterial overgrowth was recorded on D0, the mean bacteria cytological scores decreased from 1.8 to 0.8 and 2.3 to 0.9 on D28, respectively, in the HCA and CTRL groups.

When only bacterial overgrowth (nine dogs only in each group) was recorded on D0, the mean bacteria cytological scores decreased from 2.8 to 2.1 and 3.3 to 2.4 on D28, respectively, in the HCA and CTRL groups.

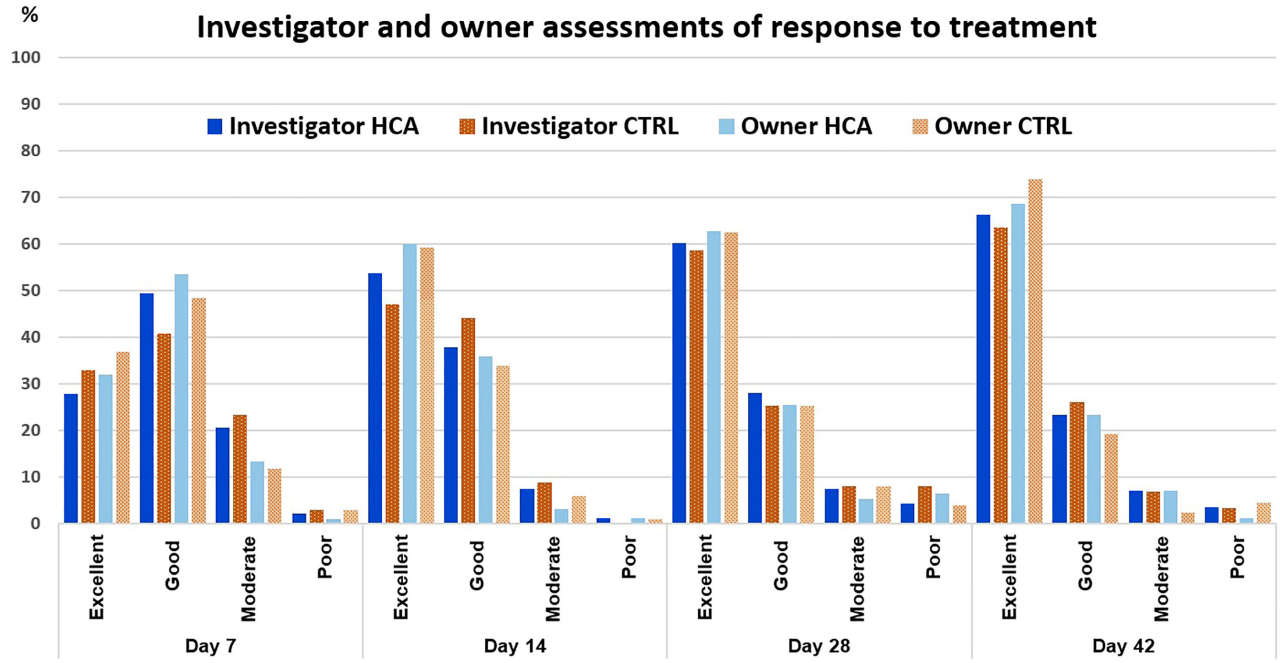

FIGURE 4 Evolution of the overall response to treatment assessed by investigators and owners. Blue columns, hydrocortisone aceponate (HCA) ear spray solution; orange columns, prednisolone acetate-polymyxin B-miconazole ear drop suspension combination (CTRL).

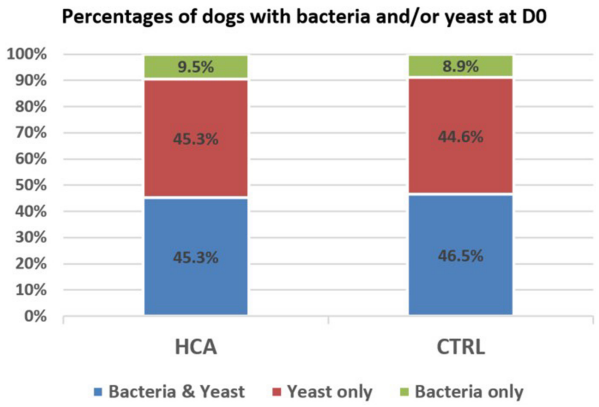

FIGURE 5 Percentages of dogs with bacteria and/or yeast in the smear of the otic exudate at Day 0.

When only yeast overgrowth was recorded on D0 (bacteria score=0), bacteria scores increased to 0.4 on D28, in both groups.

Safety

Overall, 16 dogs experienced 22 adverse events. 10 dogs (10.3%) from the HCA group experienced 14 adverse events (two digestive disorders, three anaemia, one elevated protein/creatinine ratio, two dermatitis and eczema, two otitis appearing in the nonaffected ear at D0, one conjunctivitis, one neoplasia, one trauma, one ataxia), while six (5.8%) from the CTRL group experienced eight adverse events (three digestive disorders, one dermatitis and eczema, one blepharitis, one mammary gland disorder, one lameness, one gynaecomastia). All adverse events were rated as not related to the ear treatments, except for one dog with head tilt in the HCA group, for which a relationship with the treatment could neither be confirmed nor excluded. In this case, the treatment was not stopped and the patient experienced a rapid, spontaneous and complete recovery without any additional medication.

At the end of the study, the subjective clap test did not lead to any suspicion of hearing loss.

No differences were observed between the two groups during the trial in terms of physical examination findings or blood parameters: All of which remained within the normal reference range.

DISCUSSION

In this article, we report the results of a randomised, controlled, investigator-blinded trial in which dogs with ECOE were treated either with a commercial hydrocortisone aceponate spray (HCA) or a commercially available otic product (CTRL) containing a glucocorticoid (prednisolone), an antifungal (miconazole) and an antibiotic (polymyxin B).

Even though micro-organisms (and most commonly *Malassezia* yeast) were found equally in most dogs before treatment, all clinical parameters evaluated (OTIS-3, pain and pruritus VAS) improved without statistical difference between both treatment groups. The reduction in the clinical scores over time was associated with higher overall assessments of treatment response by both investigators and owners.

Observational cytological subgroup analyses, separating dogs on D0 with only yeast overgrowth, only bacterial overgrowth or both bacterial and yeast overgrowth, highlighted some interesting trends. Although a return to normal flora in individual dogs is difficult to define and was not attempted in this study, and while

statistical significance was not attempted because of the numbers of cases, both products appeared to substantially reduce yeast overgrowth and bacterial overgrowth when associated with yeast overgrowth. There were even fewer dogs with bacterial overgrowth only (nine in each group) and the cytological reduction in bacterial overgrowth in this group was not as marked as the other groups. Evidence for microbial efficacy of treatment in those particular cases will require further study.

Although the semiquantitative methodology of cytological assessment may have limited interpretation, bacteria and yeast seemed to reappear during treatment when they were not present at the start of treatment, suggesting a possible return to normal flora. To confirm these trends and findings, additional studies are needed to examine the changes in the ear canal microflora after treatment with various ear medications.

An important observation of this trial is that, even though the ECOE was treated only for 7–14 days, the improvement of clinical parameters and the overall response to treatment was maintained up to at least D28 in both groups. Although larger studies are required, these results suggest that a glucocorticoid might not worsen existing ear dysbiosis or infection, a phenomenon that has been confirmed recently using high-throughput next-generation sequencing of the ear microbiota and mycobiota.[16] Some of the recorded relapses may have been a consequence of rapid relapse of a new infection and others to an incomplete recovery. The identification of the microorganisms did not allow confirmation of the cause of these relapses.

It is noteworthy that such a positive outcome was reached with the sole use of the HCA diester glucocorticoid. It cannot be excluded that the vehicle of the HCA spray solution had some effects in this study; however, a major action is considered unlikely owing to its very high volatility. To further study this potential effect, a placebo-controlled clinical study of the tested product compared with the vehicle only in the treatment of canine OE should be performed.

Our study on canine ECOE has raised similar questions to some of those in human AD, where treatment of lesions infected with staphylococci have been proposed to be treated without the use of antibiotics,[10] although systematic reviews[17,18] on the topic have failed to establish clear recommendations.

The clinical benefit of HCA monotherapy is mirrored by its safety in dogs with intact tympanic membranes. In this trial, all adverse events seen were deemed not related to the treatment, except for a transient and self-resolving head tilt. Laboratory parameters likewise remained within the reference range.

CONCLUSIONS

The topical application of a commercial HCA diester glucocorticoid-containing ear spray solution for 7–14 days to dogs with ECOE was safe and led to a comparable improvement to a commercially available antibiotic–antifungal–glucocorticoid formulation, controlling both the primary inflammation and associated microbial (bacterial and yeast) overgrowth.

Even though further studies are required to confirm these findings, the results of this trial suggest that, in canine ECOE, even if microbial overgrowth is detected on cytological examination, the use of a commercial topical glucocorticoid spray without the addition of antimicrobials (antibiotic and antifungal) could be used as a first-line therapy. This is a positive and welcome observation in light of increasing frequencies of antimicrobial resistance in animal and human patients.

AUTHOR CONTRIBUTIONS

Pierre Jasmin: Writing – original draft; supervision. **Delphine Rigaut:** Methodology; validation; conceptualization; project administration. **Philippe Briantais:** Methodology; validation; formal analysis. **Alice Bidaud:** Conceptualization; methodology; validation.

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CONFLICT OF INTEREST STATEMENT

Delphine Rigaut, Philippe Briantais, Pierre Jasmin and Alice Bidaud are employees of Virbac SA.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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Résumé

Contexte: L'Otite externe érythémato-cérumineuse (OEEC) est fréquemment observée chez les chiens atteints d'une maladie cutanée allergique, avec des proliférations secondaires récurrentes de bactéries et de levures (détectées à l'examen cytologique).

Objectifs: L'objectif de l'étude était de comparer l'efficacité et l'innocuité d'un spray auriculaire contenant uniquement de l'aceponate d'hydrocortisone (HCA), un glucocorticoïde diester, à un produit de contrôle (CTRL), une formulation auriculaire approuvée contenant une combinaison de prednisolone-miconazole-polymyxine, chez les chiens atteints d'OEEC.

Animaux: Au total, 97 et 104 chiens atteints d'OEEC ont été assignés au hasard au groupe du produit de traitement des otites testé (HCA) ou au groupe contrôle du produit de traitement des otites disponible dans le commerce (CTRL).

Matériels et Méthodes: Les chiens ont été traités pendant 7 à 14 jours, au besoin. Au jour (J)0, J7, J14, J28 et J42, le score d'indice d'otite 3 (OTIS-3), le test auditif, les échelles analogiques visuelles du prurit et de la douleur, et les scores cytologiques ont été gradés. La réponse globale au traitement a également été évaluée.

Résultats: Tous les paramètres cliniques ont diminué rapidement et de manière similaire sans aucune différence significative entre les groupes de traitement à tout moment. Une réponse au traitement bonne à excellente a été observée chez plus de 90% des chiens des deux groupes dès J14. Le traitement a été considéré comme sûr chez tous les chiens.

Conclusion et pertinence clinique: Une application topique de 7 à 14 jours d'hydrocortisone aceponate (HCA) uniquement, sur les chiens atteints d'OEEC accompagnée d'une prolifération bactérienne et/ou fongique (levure), était sans danger et n'a conduit à aucune différence statistique dans l'amélioration des scores cliniques par rapport à la combinaison CTRL. Sur la base de ces résultats, il peut être nécessaire de reconsidérer l'utilisation systématique de médicaments antimicrobiens tels que les antibiotiques et les antifongiques comme traitement de première intention lors d'otite externe érythémato-cérumineuse susceptible d'avoir été causée par une réaction allergique.

Resumen

Antecedentes: Otitis externa eritemato-ceruminosa (OEEC) se observa con frecuencia en perros afectados con una enfermedad alérgica de la piel, con bacterias secundarias recurrentes y levaduras en exceso (detectado en el examen citológico).

Objetivos: El objetivo del estudio fue comparar la eficacia y la seguridad de un aerosol para los oídos que solo contiene hidrocortisona aceponato diéster glucocorticoide (HCA) con un producto de control (CTRL), una formulación ótica aprobada que contiene una combinación de prednisolona-miconazol-polimixina, en perros con ECOE.

Animales: En total, 97 y 104 perros con ECOE fueron asignados al azar, respectivamente, al grupo de productos de tratamiento de oídos (HCA) o al grupo de productos de control de tratamiento de oídos (CTRL) comercializados.

Materiales y Métodos: Los perros fueron tratados durante 7-14 días, según lo necesario. En el Día (D)0, D7, D14, D28 y D42, Otitis Index Score 3 (OTIS-3), prueba de audición, prurito y dolor, se calificaron escalas visuales analógicas y puntuaciones citológicas. También se evaluó la respuesta general al tratamiento.

Resultados: Todos los parámetros clínicos disminuyeron rápidamente y de manera similar sin ninguna diferencia significativa en ningún momento entre los grupos de tratamiento. Una respuesta al tratamiento de buena a excelente se observó en ⟩90% de los perros de ambos grupos ya D14. El tratamiento fue considerado de buena seguridad en todos los perros.
Conclusiones y Relevancia Clínica: Una aplicación tópica del oído de 7 a 14 días de HCA solo a perros con ECOE acompañados de crecimiento excesivo bacteriano y/o fúngico (levadura) tuvo seguridad y no condujo a ninguna diferencia estadística en la mejora de las puntuaciones clínicas en relación con la combinación de CTRL. En base a estos resultados, puede ser necesario reconsiderar el uso rutinario de medicamentos antimicrobianos como antibióticos y antifúngicos como un tratamiento de primera línea para otitis externa eritemato-ceruminosa probablemente causada (que probablemente haya sido causado) por una reacción alérgica.

Zusammenfassung

Hintergrund: Erythemato ceruminous otitis externa (ECOE) tritt häufig bei Hunden auf, die an einer allergischen Hauterkrankung leiden, mit wiederkehrenden sekundären Bakterien und Hefeüberwucherungen (zytologisch nachgewiesen).
Ziele: Ziel der Studie war es, die Wirksamkeit und Sicherheit eines Ohrsprays, das nur Hydrocortisonaceponat-Glucocorticoid-Diester (HCA) enthält, mit einem Kontrollprodukt (CTRL) zu vergleichen, einer zugelassenen Formulierung, die Prednisolon-Miconazol-Polymyxin-Kombination enthält, bei Hunden mit ECOE.
Tiere: Insgesamt wurden 97 bzw. 104 Hunde mit ECOE zufällig der getesteten Ohrbehandlungs-Produktgruppe (HCA) bzw. der kommerziell erhältlichen Ohrbehandlungs-Kontroll-Produktgruppe (CTRL) zugeordnet.
Materialien und Methoden: Hunde wurden nach Bedarf 7-14 Tage lang behandelt. Am Tag (D)0, D7, D14, D28 und D42 wurden Otitis Index Score 3, Hörtest, Pruritus und Schmerz visuelle Analogskalen und zytologische Scores benotet. Das Gesamtansprechen auf die Behandlung wurde ebenfalls bewertet.
Ergebnisse: Alle klinischen Parameter nahmen schnell und in ähnlicher Weise ab, ohne dass es zu einem signifikanten Unterschied zwischen den Behandlungsgruppen kam. Ein gutes bis exzellentes Ansprechen auf die Behandlung wurde bei ⟩90% der Hunde beider Gruppen bereits bei D14 beobachtet. Die Behandlung wurde bei allen Hunden als sicher angesehen.
Schlussfolgerungen und klinische Relevanz: Eine 7- bis 14-tägige topische Anwendung von HCA allein auf Hunde mit ECOE, begleitet von bakteriellem und/oder pilzlichem (Hefe-) Überwachsen, war sicher und führte zu keinem statistischen Unterschied in der Verbesserung der klinischen Ergebnisse im Vergleich zur CTRL-Kombination. Basierend auf diesen Ergebnissen kann es notwendig sein, die routinemäßige Verwendung von antimikrobiellen Medikamenten wie Antibiotika und Antimykotika als Erstlinienbehandlung für ECOE zu überdenken, die wahrscheinlich durch eine allergische Reaktion verursacht wurde.