Impact of a terbinafine–florfenicol–betamethasone acetate otic gel on the quality of life of dogs with acute otitis externa and their owners

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Background – Treatment of canine otitis externa with owner-administered products can be difficult.

Objectives – To evaluate otic treatment administered by a veterinarian on quality of life (QoL) of dogs with otitis externa and their owners, and on clinical and cytology parameters of otitis; compared to an owner-administered treatment.

Animals – Fifty client-owned dogs randomly randomized into two groups and treated for 2 weeks.

Methods – Veterinarians treated Group A dogs with a veterinary licensed otic gel on two occasions at a 1 week interval; owners treated Group B dogs once daily with a veterinary licensed otic drop based product along with twice weekly cleaning. Veterinarians evaluated otitis with the OTI-3 scale and semi-quantitative cytological examination on days 0, 7, 14 and 28. At each visit, owners assessed QoL with a validated questionnaire and pruritus with a Visual Analog Scale. Scores before and after treatment of each group, and differences between groups were analysed statistically.

Results – In both groups, all parameters improved significantly. There was a significantly higher improvement of QoL scores, for dogs and owners, in Group A, compared to Group B at all time points (P < 0.05), except for owner QoL on Day 28. There was no difference in improvement of OTI-3 between groups at any time point, whereas Group A cytology scores and pruritus improved significantly more by Day 7 (P = 0.0026 and P = 0.0294, respectively).

Conclusion – A veterinarian-administered otic gel provided equivalent efficacy and higher QoL to dogs with otitis externa and their owners, compared to an owner-administered topical otic therapy.

Introduction

Otitis externa is a common skin disease in dogs, accounting for 22% of dermatology patients and 13–16% of the general hospital population. Ottis externa is often complicated by bacterial and/or yeast (Malassezia) infection that requires specific otic topical therapy. Treatment protocols for this purpose are usually based on ear cleaning, aimed at eliminating excessive debris and exudates, followed by once or twice daily administration of antibacterial/antifungal/corticosteroid-containing otic solutions. Therapeutic courses typically last 1–3 weeks and are usually performed at home by the owners. Treatment compliance is very important for successful therapy; however, the administration of ear cleaners and medication is not always easy to perform in refractory patients. This may lead to stress for the owner and dog, with subsequent degradation of their relationship, and ultimately to treatment failure.

Quality of life (QoL) has been defined as “the degree to which an individual enjoys his or her life”. Tools have been developed to assess the QoL in dogs with skin disease, including the positive impact of treatment on QoL. One study confirmed that otitis externa is able to negatively influence the QoL in dogs and in their owners, due to nuisance and stress related to the disease. Expensive, time consuming, tiresome or difficult treatments can also negatively affect the QoL of owners and their pets. Therefore, an improvement of the clinical parameters induced by the therapy does not necessarily result in a similar improvement of QoL of patients and owners, as previously observed in skin diseases in dogs and cats. For this reason, the evaluation of QoL should always be performed in parallel with the assessment of clinical parameters in studies investigating therapeutic efficacy.

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Osurnia® (Elanco; Sesto Fiorentino, Italy) is an otic gel for dogs which contains 1% florfenicol, 1% terbinafine and 0.1% betamethasone in a gel vehicle. It is indicated for the treatment of acute otitis, or recrudescence of chronic cases caused by bacteria and/or yeast in dogs with intact tympanic membrane. The manufacturer recommends that the product be administered twice, at a one week interval, after a thorough cleaning of the ear canal before the first application, and without cleaning for three weeks after the second dose. Once applied, the liquid product forms a gel which provides antibacterial and antifungal properties. The concentration of the drug in the ear canal is stable for over five weeks. Treatment is recommended to be administered by a veterinarian. If an otic gel is as effective as standard otitis treatment protocols that are based on frequent ear cleanings and daily administration of topical products at home, it would represent an alternative option for cases in which treatment by the owner is difficult or impossible.

The present study had two aims. (i) To evaluate improvement of QoL of dogs with otitis externa and their owners, after treatment with otic gel compared to a reference protocol which requires owner directed therapy. (ii) To evaluate and compare the improvement of clinical and cytological parameters of otitis externa in these two groups. It was hypothesized that the otic gel would provide equivalent efficacy and a higher QoL to dogs and their owners as compared to the reference protocol.

Materials and methods

Experimental design
This was an open, multi-centre, controlled and randomized study. The study was not blinded because the primary outcome (improvement in QoL) was evaluated by the owners and the two treatment protocols were too different from each other for adequate masking. Dogs with acute otitis externa or recrudescence of recurrent otitis externa complicated by Malassezia spp. and/or bacterial overgrowth, with or without the presence of neutrophils, were included by twelve investigators.

Inclusion criteria
Otitis externa was diagnosed by observation of clinico-pathological alterations (erythema, oedema, erosions/ulcerations, offending odour and excessive exudate) and by means of cytological examination of the otic exudate collected with a cotton swab and rolled onto a glass slide. Cytological samples were stained with a rapid Romanowsky stain (Diff-Quick®, Dade Behring Inc.; Deerfield, IL, USA) and observed at 1,000× magnification (under oil immersion) to confirm the presence of micro-organisms. In cases of otitis externa due to foreign bodies, the animal was included in the study only upon removal of the foreign body. Concomitant therapies which were allowed included heartworm prophylaxis, endo- or ectoparasiticides, allergen-specific immunotherapy (which had been initiated at least 1 year prior to enrolment) and any other product necessary for health maintenance (e.g. insulin, thyroxine or cardiology drugs).

Exclusion criteria
The following categories of dogs were excluded: dogs without cytological findings of abnormal numbers of bacteria and/or Malassezia yeast bodies; dogs suspected to have Pseudomonas otitis externa (observation of rods on cytology together with foul odour, purulent exudate with blood, ulceration of the ear canal and pain on palpation); dogs with parasitic otitis, tympanic membrane perforation, neoplasia in the ear canal, chronic otitis externa (longer than 2 weeks), hyperplastic alteration of the external ear canal, or generalized demodicosis; dogs treated with otological products within the prior 14 days or which needed systemic antimicrobial or steroidal treatment during the study, and those which showed adverse reactions to the otic treatments; and pregnant, lactating or breeding animals.

Treatment
A graphic representation of the interventions and evaluations of included animals is given in Figure 1. After inclusion in the study, the affected ears were thoroughly cleaned by a veterinarian with a ceruminolytic solution (Suerosolv®, Elanco Animal Health; Sesto Fiorentino, Italy, or Otoact®, CFFPet; Cremona, Italy). Animals then were randomly assigned to one of two groups by means of a predetermined block randomization sequence (four dogs for each block). Group A was treated with a single application of 1 mL of Osurnia® in each affected ear on Day 0 and Day 7, following the manufacturer’s recommendations. The ears were not cleaned again until the end of the study. No treatment was applied at home by the owner.

Group B was treated by the owner with a reference therapy protocol consisting of once daily application of a 0.09% posaconazole–0.85% orbifloxacin–0.09% mometasone furoate otic suspension (PosaAct®, Intervet Srl; Segrate, Italy), following the manufacturer’s recommendations, for one week, along with twice weekly cleaning with Surosolv® or Otoact®. If at the end of the first treatment week there was residual presence of bacteria and/or yeasts assessed with cytology, the treatment regimen was continued for an additional week. If excessive cerumen was present at the end of treatment for Group B dogs (at either Day 7 or Day 14 and until Day 28), these dogs were treated with twice weekly ear cleaning at home using the permitted ceruminolytic agents. Ear cleaning was stopped 24 h before each follow-up visit.

Assessment
Each dog was examined on days 0, 7, 14 and 28; data were recorded on a case report form. At each visit the dog received a general and an otological examination, and otic exudate was collected by means of a cotton swab for cytological evaluation. Clinical signs of otitis were scored by means of the validated OTI-3 scale, assessing four clinical manifestations (erythema, oedema, erosions/ulcerations and quantity of exudate) with a four point (0–3) scale (0 = none, 1 = mild, 2 = average, 3 = severe; range 0–12).13 Cytological preparations of otic exudate were stained with Diff-Quick® and scored following a validated semi-quantitative method (range 0–4).14 Each ear was evaluated and scored separately. At each visit the owners assessed pruritus by means of a 10 cm long Visual Analog Scale (VAS) with descriptors, and QoL for themselves and their dogs by means of a validated questionnaire with 15 questions.7,8,15 The first question evaluates the general severity of the disease, questions 2–8 deal with the dog’s quality of life (QoL1) and questions 9–15 with the owner’s quality of life (QoL2). Questions could be answered following a three point (0–3) scale (0 = none, 1 = mild, 2 = average, 3 = severe), with a range of 0–21 for each QoL measure. At the end of the study (Day 28), veterinarians and owners evaluated the global efficacy by means of an unvalidated five point (0–4) scale (0 = none; 1 = mild; 2 = fair/average; 3 = good; 4 = excellent). The primary outcome measure was improvement in QoL1 and QoL2 on days 7, 14 and 28, as evaluated by the owner. Secondary outcomes were the improvement of OTI-3 scores, cytology scores and pruritus, on days 7, 14 and 28, as well as the global efficacy scores assessed by veterinarians and owners on Day 28. Adverse reactions were documented on the Case Report Form, and any dog was withdrawn from the study if a severe reaction, defined as requiring disruption of drug administration, occurred.

Statistical analysis
The single statistical unit was one dog for pruritus, QoL1 and QoL2, and one ear for OTI-3 and cytology scores. Normality of data was tested using the Shapiro–Wilk test. Differences in weight, age, pruritus, QoL1 and QoL2 scores between groups at Day 0 were calculated by means of Student’s unpaired t-test, because these variables were not normally distributed.
were normally distributed. Differences between groups of OTI-3 and cytology scores at Day 0 were calculated by means of the Wilcoxon-Mann-Whitney two-sample test with two-sided \( P \)-value, because these data were not normally distributed. The difference of male/fe- male, monolateral/bilateral, first occurrence/recrudescence and type of otitis distribution between groups on Day 0 was calculated by means of the chi-square test. Comparisons of least-squares means between time points within each treatment group were performed using appropriate contrasts within the mixed-effect models for repeated measures, followed by Bonferroni correction. Fixed effects for treatment (Group A or B), time (day 0, 7, 14 and 28) and time-by- treatment interaction were calculated by means of the PROC MIXED procedure. The difference in percentage improvement between groups for all parameters was calculated by means of the Wilcoxon two-sample test with a two-sided \( P \)-value. In case of premature with- drawal, for all dogs and ears for which there were data of at least one treatment day, these data were carried forward to the other visit points (last observation carried forward). Analyses were performed using sas software, v9.2 (SAS Institute Inc.; Cary, NC, USA). Statisti- cal significance was set as a two-sided \( P \)-value < 0.05.

Results

Animals

Fifty dogs were enrolled between January and May 2016 comprising 25 males (three castrated) and 25 females (18 spayed). The mean age was 5 years and 4 months (range 0.67–14 years) and mean body weight was 20.8 kg (range 3.8–43 kg). Mixed breed dogs, Labrador and golden retrievers (seven of 50 each, 14%), West Highland white terriers (six of 50, 12%), German shepherd dogs, cocker spaniels and English bulldogs (three of 50 each, 6%) were the most commonly represented breeds. There were no differences in age, sex, body weight and breed distribution between Group A and Group B (Table 1). Fifteen dogs had unilateral and 35 had bilateral otitis externa on presentation, giving a total of 85 affected ears. Twenty three dogs presented as new cases of otitis, whereas the remaining 27 were undergoing recrudescence of a prior episode.

Quality of Life

Mean (SD) QoL1 and QoL2 scores on Day 0 were 8.92 (4.38) and 9.36 (4.20), respectively. First occurrence dogs had lower QoL1 [7.39 (4.37)] and QoL2 scores [7.04 (3.78)] than relapsing cases [10.22 (4.03) and 11.33 (3.53), respectively]. There was no difference in QoL scores between groups on Day 0 (Table 1).

In Group A there was a significant improvement of QoL1 and QoL2 scores at all time points compared to Day 0 (\( P < 0.0001 \) for both parameters). For Group B, improvement of QoL1 over Day 0 was significant on days 14 (\( P = 0.0002 \)) and 28 (\( P < 0.001 \)), but not on Day 7 (\( P = 0.38 \)). Improvement of QoL2 compared to Day 0 was significant only on Day 28 (\( P = 0.039 \); Figure S1a and S1b). The improvement of therapy-related questions 8 (“How much was the dog disturbed by the administration of therapies?”), 9 (“How much time did you lose for your dog’s disease, e.g., for administration of therapies, sham- pooning, home cleaning, cooking, veterinary consulta- tions?”) and 10 (“How much effect had your dog’s disease on your tiredness e.g., for extra cleaning, cooking, shampooing?”) of groups A and B are presented in Figure S1c and S1d. The improvement of therapy-related questions 8 (“How much was the dog disturbed by the administration of therapies?”), 9 (“How much time did you lose for your dog’s disease, e.g., for administration of therapies, sham- pooning, home cleaning, cooking, veterinary consulta- tions?”) and 10 (“How much effect had your dog’s disease on your tiredness e.g., for extra cleaning, cooking, shampooing?”) of groups A and B are presented in Figure S1c and S1d.

For QoL1 and QoL2 scores at all time points compared to Group A, improvement of QoL1 over Day 0 was significant on days 14 (\( P = 0.0002 \)) and 28 (\( P < 0.001 \)), but not on Day 7 (\( P = 0.38 \)). Improvement of QoL2 compared to Day 0 was significant only on Day 28 (\( P = 0.039 \); Figure S1a and S1b). The improvement of therapy-related questions 8 (“How much was the dog disturbed by the administration of therapies?”), 9 (“How much time did you lose for your dog’s disease, e.g., for administration of therapies, sham- pooning, home cleaning, cooking, veterinary consulta- tions?”) and 10 (“How much effect had your dog’s disease on your tiredness e.g., for extra cleaning, cooking, shampooing?”) of groups A and B are presented in Figure S1c and S1d.

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Figure 1. Timeline of study interventions and assessments for the two groups. QoL1 dog’s quality of life, QoL2 owner’s quality of life, OTI-3 otitis externa clinical evaluation scale, VAS Pruritus Visual Analog Scale.
Table 1. Comparison of demographic and clinical data on Day 0 for dogs receiving otic therapy from a veterinarian (Group A) or owner (Group B)

|                      | A n = 25 (SD) | B n = 25 (SD) | Difference A versus B, P |
|----------------------|---------------|---------------|--------------------------|
| Weight (kg)          | 20.38 (11.71) | 21.37 (12.51) | 0.78                     |
| Age (years)          | 5.72 (3.79)   | 5.00 (2.45)   | 0.43                     |
| Sex (M/F)            | 12/13         | 13/12         | 0.78                     |
| Otitis mono/bilateral| 6/19          | 9/16          | 0.35                     |
| First occurrence/ recurrence | |               |                          |
| QoL1 (dog)           | 9.40 (4.48)   | 8.44 (4.34)   | 0.45                     |
| QoL2 (owner)         | 9.52 (4.30)   | 9.20 (4.19)   | 0.79                     |
| VAS pruritus         | 4.82 (1.88)   | 4.35 (2.3)    | 0.46                     |

SD Standard deviation, VAS Visual Analog Score, QoL quality of life.

There was no difference in VAS pruritus scores between groups on Day 0 (Table 1). In both groups there was a significantly higher percentage improvement of all QoL parameters for dogs in Group A compared to those in Group B at all time points, with the exception of QoL2 on Day 28. It should be noted that veterinarians elected to treat all dogs in Group B for 2 weeks based on the results of the examination of cytology samples.

Proportional improvement of QoL1 and QoL2 scores at days 7, 14 or 28 from Day 0 were calculated and compared between groups. Results are presented in Table 2. There was a significantly higher percentage improvement of all QoL parameters at days 7, 14 or 28, from Day 0 were calculated and compared between groups. Results are presented in Table 3. There was a significantly higher proportional improvement of VAS pruritus on Day 7 in Group A, but not on days 14 and 28, indicating that both treatments were effective in decreasing pruritus, with the otic gel showing a more rapid onset of action.

Clinical (OTI-3) and cytology scores

The 85 affected ears evaluated comprised 44 in Group A and 41 in Group B. On Day 0, cytological samples of the otic exudate revealed cocci in 10 of 85 ears (11.8%), Malassezia in 48 of 85 (56.5%), cocci and nuclear streaming (neutrophils) in four of 85 (4.7%), and cocci and yeast in 23 of 85 ears (27.1%). Rods were not observed. For all ears, the mean (SD) OTI-3 score was 5.94 (2.41) and the mean (SD) cytology score was 3.17 (0.77). Mean (SD) OTI-3 scores, cytology scores and type of otitis for each group are reported in Table 4, with no difference between groups on Day 0.

There was a significant improvement of OTI-3 and of cytology scores when compared to Day 0, at all time points both in Group A and in Group B (P < 0.0001 for both groups and for all comparisons; Figures S3 and S4). For OTI-3 there was a significant effect of time, but not of treatment or time-by-treatment on the results. For cytology scores, there was no significant effect of treatment, whereas there was an effect of time (P < 0.0001) and time-by-treatment (P < 0.0172) on the results. At the end of the study (Day 28) both ears of one Group B dog had an OTI-3 score of 4 (3 being considered the cut-off for normal ears), whereas three ears (one in Group A and two in Group B) had a cytology score of 2 or above.

Proportional improvement of OTI-3 scores and of cytology scores on days 7, 14 or 28 from Day 0 was calculated and compared between groups. Results are presented in Table 5. There was no difference in OTI-3 percentage improvement between groups at any time point, whereas the improvement of cytology scores was significantly greater for Group A on days 7 and 14 but not on Day 28.

Overall clinician and owner satisfaction

All “study end forms” for each enrolled dog were completed by veterinarians and owners. Clinicians rated treatment efficacy in both groups as excellent or good in 23 of 25 cases (92%) and as fair/average in the remaining two cases (8%). Owners rated efficacy as excellent or good in all Group A cases (n = 25), versus 21 of 25 cases (84%) in Group B. The four remaining Group B cases (16%) were rated as fair/average.

Safety

No adverse events were observed with either treatment protocol.

Discussion

This study confirmed the hypothesis that veterinarian-directed treatment with an otic product (such as a gel) can improve the QoL of dogs and owners more than a standard owner-directed ear treatment protocol (based on healthy dogs). Seventeen dogs (five in Group A and 12 in Group B) had QoL2 values above 5 (threshold for healthy dogs). Five dogs had an abnormal QoL1 with a normal QoL2 and three had a normal QoL1 with an abnormal QoL2. The remaining dogs (n = 14) had both QoL1 and QoL2 elevated.

Proportional improvement of QoL1 and QoL2 scores at days 7, 14 or 28 from Day 0 were calculated and compared between groups. Results are presented in Table 2. There was a significantly higher percentage improvement of all QoL parameters for dogs in Group A compared to those in Group B at all time points, with the exception of QoL2 on Day 28. It should be noted that veterinarians elected to treat all dogs in Group B for 2 weeks based on the results of the examination of cytology samples.

Pruritus

Mean (SD) VAS pruritus scores of dogs on Day 0 was 4.59 (2.14), corresponding to a mild to moderate pruritus. There was no difference in VAS pruritus scores between groups on Day 0 (Table 1). In both groups there was a significant improvement of pruritus scores as compared to Day 0 at all time points (P < 0.0001 for all comparisons; Figure S2). There was a significant effect of time (P < 0.0001) but not of treatment or time-by-treatment on the results. At the end of the study (Day 28), only two dogs in Group B and four dogs in Group A failed to reach a pruritus score equal to or below 2 (threshold for normal) and only two dogs (both in Group A) had a pruritus score above 4 (mild pruritus).

Table 2. Percentage improvement of quality of life (QoL1 and QoL2) compared to Day 0 (SD) for dogs receiving otic therapy from a veterinarian (Group A) or owner (Group B)

| % improvement | A n = 25 (SD) | B n = 25 (SD) | Difference A versus B, P |
|---------------|---------------|---------------|--------------------------|
| QoL1          |               |               |                          |
| Day 7         | 57.00 (32.04) | 9.80 (31.03)  | <0.0001*                 |
| Day 14        | 67.30 (38.20) | 37.52 (40.93) | 0.0026*                  |
| Day 28        | 77.47 (30.19) | 63.45 (28.12) | 0.0449*                  |
| QoL2          |               |               |                          |
| Day 7         | 33.86 (38.98) | 4.04 (33.13)  | 0.0013*                  |
| Day 14        | 46.39 (36.12) | 12.41 (35.78) | 0.0020*                  |
| Day 28        | 55.90 (36.72) | 33.10 (43.27) | 0.0723                   |

*P calculated for the difference between groups; *statistically significant difference between groups. QoL1 dog’s quality of life, QoL2 owner’s quality of life.

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Otis has been reported to greatly decrease the QoL of dogs and owners.\(^8\) Pre-treatment mean total QoL scores (QoL1 + QoL2 = 18.3) observed in this study were comparable or even higher (i.e. worse QoL) than those reported previously (mean score 15.7).\(^8\) Otis is reported to have an impact on dogs’ sleep and playing behaviours, and causes their owners physical or emotional disturbances.\(^5\) Manipulation of the ears can cause aggressive behaviour and stress in dogs, particularly if the procedure is painful. Owners complain in particular that their dog’s ear disease is time consuming, most probably due to frequent administration of otic cleaners and medication.\(^9\) Furthermore, owners may also experience stress due to physical difficulties in treating large, strong or refractory dogs, and may be disturbed by the odour or by cleansing products that are dispersed in the environment when the dog shakes its head. The net result is a deterioration of the dog–owner relationship and low treatment compliance, ultimately leading to possible treatment failure.\(^5\) In the present study, we found higher baseline QoL scores, particularly QoL2, in cases of recurrent otitis externa, compared to first occurrence disease. This may reflect the burden of repeated therapy courses on the owners.

In a separate study, a 1 week long conventional treatment based on frequent ear cleaning and daily application of otic drops did not seem to improve QoL in a significant way, with the exception of a decrease of the owner’s physical disturbance, probably due to the decrease in ear odour.\(^9\) The present study confirmed this observation, because dogs in group B (treated with the conventional protocol administered by the owner) did not demonstrate a significant improvement in QoL1, or QoL2, by Day 7. Interestingly, whereas the QoL1 seemed to improve with time (after Day 7) in this group, QoL2 did not until Day 28, possibly reflecting the burden on owners of therapy administration at home in the first weeks.

A similar discrepancy between improvements in values for QoL1 and QoL2, after clinically successful therapy courses, has been described in dogs and cats treated for allergic dermatitis.\(^8,10,11\) A further confirmation of this hypothesis could come from the analysis of the answers to the single questions of the QoL questionnaire: the conventional treatment protocol did not lead to any score improvement related to therapy administration (questions 8, 9 and 10). Similar results were observed when evaluating single QoL item changes with therapy in atopic dogs.\(^8\) In the present study, there was no difference between QoL scores at Day 28. As mentioned above, we speculate that the difference was not significant on the final visit because treatment administration in group B had been stopped 2 weeks before the study end. In Group A, contrary to Group B, scores related to therapy administration (questions 8, 9 and 10) showed great improvement as early as 7 days after treatment initiation, reflecting the lack of therapy burden on owners and dogs. Providing a quick relief of clinical signs of otitis with no need for therapeutic interventions at home was received with satisfaction and gratitude by the owners, particularly those who had been faced with otitis episodes in the past and had already gone through ear medication administration.

To the best of the authors’ knowledge, this is the first study to assess the efficacy of Osurnia\(^\circledast\) for otitis externa compared to a reference treatment protocol for cases of acute otitis externa associated with cocci and/or yeast. Our data suggest that the otic gel may produce a more rapid decrease in pruritus, which could be due to the presence of betamethasone acetate in contact with the ear canal. However, at the end of the study, pruritus scores of the two groups were not statistically different, indicating an equal efficacy for pruritus for both treatment protocols. It is worth mentioning here that on Day 28 some animals in Group A and in Group B (four and two, respectively) were still abnormally pruritic. This could have been due to uncontrolled underlying allergic disease; even so, for each of these dogs, the owners and veterinarians still judged the treatment outcome to be excellent or good. The VAS pruritus scale is a general measure of pruritus on all body areas and is not able to differentiate whether itch is present on the ears or elsewhere. As allergic disease is one of the main underlying causes of otitis externa, pruritus scores could have been influenced by it.
Unfortunately, the potential for primary causes of otitis were not assessed or recorded and the distribution of allergic dogs among the groups could not be assessed retrospectively.

Likewise, cytology scores improved for both groups. It is worth noting that the percentage reduction was significantly greater in Group A on days 7 and 14, but not on Day 28, suggesting a more rapid onset of action of the gel product on micro-organisms. This could be caused by the persistence in the ear canal of the gel containing terbinafine and florfenicol at concentrations above the minimum inhibitory concentration for several days after the application.12 The use of an antiseptic ear cleaning solution, usually administered in conventional treatment protocols, could have decreased micro-organism numbers in Group B; however, it was decided to use a ceruminolytic (non-disinfectant) solution in order to comply with the manufacturer’s recommendations for the ear drop product, and to better evaluate and compare the pharmacological efficacy of the comparator product. In any case, cytology scores were not statistically different between the groups at the end of the study, suggesting that the reference protocol was equally successful even without the disinfectant action of the cleaning solution.

In the veterinary literature, there are several studies investigating the clinical efficacy of antibiotic/antifungal/corticosteroid combination ear products, but none of them have used the validated otitis scoring scale OTI-3, pruritus VAS scale or the semiquantitative cytology scale described by Budach & Mueller,14 so that comparisons are not possible.5,16–20 Although some of these studies used an otic cytology scale described by Ginel et al.,21 we preferred to use the one by Budach & Mueller because it has been validated independently.14,22 A pilot study on the use of medical grade honey in 15 dogs affected by acute bacterial and/or yeast otitis reported on the use of the OTI-3 scale. It reported an initial mean score lower than that of our study (5 versus 6), but a similar improvement curve, confirming that clinical resolution of otitis may occur within 2 weeks of starting treatment.22

The weaknesses of our present study include lack of blinding, which was not possible due to the greatly different treatment regimens, and failure to determine the primary causes of otitis (particularly allergic diseases which could have influenced the pruritus assessment). It is recommended that future studies attempt to capture these data so that the distribution of primary diseases can be considered in the analysis.

In conclusion, the present study has confirmed that an otic gel provided equivalent efficacy and a higher QoL for dogs and their owners compared with a reference protocol, based on owner-administered ear cleansing and drops, for otitis externa. The improvement in owner satisfaction and compliance may be especially important for cases of recurrent otitis externa, and for dogs that are difficult to medicate.

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**Supporting Information**

Additional Supporting Information may be found in the online version of this article.

**Figure S1.** Improvement of dog’s Quality of Life scores (QoL).

**Figure S2.** Improvement of Visual Analog Scale (VAS) pruritus scores.

**Figure S3.** Improvement of OTI-3 clinical otitis scores.

**Figure S4.** Improvement of cytology scores as assessed with a semiquantitative method.

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**Résumé**

**Contexte** – Le traitement des otites externes du chien par des produits àadminister par les propriétaires peut être difficile.

**Objectifs** – Évaluer les traitements auriculaires administrés par le vétérinaire sur la qualité de vie (QoL) de chiens atteints d’otite externe et de leurs propriétaires, et que les paramètres cliniques et cytologiques de l’otite, en comparaison à des traitements administrés par les propriétaires.

**Sujets** – Cinquante chiens de propriétaires répartis au hasard en deux groupes et traités pendant 2 semaines.

**Méthodes** – Les vétérinaires traitaient les chiens du groupe A avec un gel auriculaire deux fois à une semaine d’intervalle; les propriétaires traitaient les chiens du groupe B une fois par jour avec des gouttes auriculaires associés à des nettoyages deux fois par semaine. Les vétérinaires ont évalué l’otite avec l’échelle OTI-3 et un examen cytologique semi-quantitatif à jours 0, 7, 14 et 28. A chaque visite, les propriétaires évaluaient la QoL avec un questionnaire validé et le prurit avec une échelle visuelle analogue. Les scores avant et après traitement de chaque groupe et les différences entre les groupes ont été analysés statistiquement.

**Résultats** – Dans les deux groupes, tous les paramètres se sont significativement améliorés. Il y avait une amélioration significativement plus élevée des scores de QoL, pour les chiens et les propriétaires, dans le groupe A, comparé au groupe B à tous les moments (P < 0.05), à l’exception de la QoL des propriétaires à J28. Il n’y avait aucune différence d’amélioration de l’OTI-3 quel que soit l’instant tandis que les scores de cytologie et du prurit du groupe A se sont améliorés significativement à jour 7 (respectivement P = 0.0026 et, P = 0.0294).

**Conclusion** – Un gel auriculaire administré par le vétérinaire fournir une efficacité équivalente et une QoL plus élevée pour les chiens atteints d’otite externe et leurs maitres comparé à un traitement administré par les propriétaires eux-mêmes.

**Resumen**

**Introducción** – El tratamiento de la otitis externa canina con productos que puedan ser administrados por el propietario puede ser difícil.

**Objetivos** – Evaluar el impacto de tratamiento ótico en la calidad de vida (QoL) de los perros con otitis externa y sus propietarios, y sobre los parámetros clínicos y citológicos de la otitis, en comparación con un tratamiento administrado por el veterinario.

**Animales** – Cincuenta perros de propietarios privados divididos al azar en dos grupos y tratados durante 2 semanas.

**Métodos** – Los veterinarios trataron a los perros del Grupo A con un gel ótico veterinario autorizado en dos ocasiones a intervalo de una semana; los propietarios trataron a los perros del grupo B una vez al día con un producto veterinario licenciado de gotas junto con limpieza dos veces por semana. Los veterinarios evaluaron la otitis con la escala OTI-3 y realizaron examen semicuantitativo de la citología en los días 0, 7, 14 y 28. En cada visita, los propietarios evaluaron la calidad de vida con un cuestionario validado y el prurito con una escala análoga visual. Se analizaron estadísticamente las puntuaciones antes y después del tratamiento de cada grupo, y las diferencias entre los grupos.

**Resultados** – En ambos grupos todos los parámetros mejoraron significativamente. Hubo una mejora significativamente mayor en las puntuaciones de QoL para perros y dueños en el grupo A, en comparación con el grupo B en todos los días evaluados (P <0,05), con excepción de la QoL del propietario en el día 28. No hubo diferencias en la mejora de OTI-3 en ninguno de los días, mientras que en el grupo A las puntuaciones de citología y el prurito mejoraron significativamente en el día 7 (P = 0,0026 y P = 0,0294, respectivamente).

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Conclusion – Un gel ótico administrado por el veterinario proporcionó una eficacia equivalente y mejor QoL a los perros con otitis externa y sus propietarios, en comparación con una terapia tópica administrada por el propietario.

Zusammenfassung

Hintergrund – Die Behandlung einer Otitis externa des Hundes durch Produkte, die vom Besitzer appliziert werden müssen, kann schwierig sein.

Ziele – Eine Evaluierung der Ohrbehandlung durch einen Tierarzt in Bezug auf Lebensqualität (QoL) von Hunden mit einer Otitis externa und ihrer BesitzerInnen, sowie die Erfassung klinischer und zytologischer Parameter einer Otitis im Vergleich zu einer durch die Besitzer durchgeführten Behandlung.

Tiere – Fünfzig Privathunde wurden zufällig in zwei Gruppen eingeteilt und zwei Wochen lang behandelt.

Methoden – TierärztInnen behandelten die Hunde der Gruppe A zweimal im Abstand von einer Woche mit einem veterinärmedizinisch zugelassenen Ohrenöl; die BesitzerInnen behandelten die Hunde der Gruppe B einmal täglich mit veterinärmedizinisch zugelassenen Ohrentropfen zusammen mit einer zweimal wöchentlichen Reinigung. Die TierärztInnen beurteilten die Otitis mit der OTI-3 Skala und einer semi-quantitativen zytologischen Untersuchung an den Tagen 0, 7, 14 und 28. Bei jedem Besuch beurteilten die BesitzerInnen die QoL mittels validiertem Fragebogen und den Juckreiz mittels Visual Analog Scale. Die Werte vor und nach der Behandlung einer jeden Gruppe und die Unterschiede zwischen den Gruppen wurden statistisch analysiert.

Ergebnisse – In beiden Gruppen verbesserten sich alle Parameter signifikant. Es bestand zu allen Zeitpunkten eine signifikant höhere Verbesserung der QoL Werte für Hunde und BesitzerInnen in Gruppe A im Vergleich zu Gruppe B (P < 0.05), außer für die QoL der BesitzerInnen am Tag 28. Es bestand zu keinem Zeitpunkt ein Unterschied der OTI-3 Werte, während sich die Zytologie und Juckreiz Werte der Gruppe A am Tag 7 signifikant (P = 0.0026 bzw P = 0.0294) verbessert hatten.

Schlussfolgerung – Ein durch TierärztInnen appliziertes Ohrenöl war im Vergleich zu einer durch die BesitzerInnen applizierten topischen Ohrtherapie von gleicher Wirksamkeit und erbrachte eine höhere QoL für Hunde mit einer Otitis externa und für ihre BesitzerInnen.

要約

背景 – 像主が投薬する製品による犬の外耳炎の治療は困難な場合がある。

目的 – 兽医師による外耳炎治療薬投与による、犬およびその飼い主の生活の質(QoL)と外耳炎の臨床的細胞学的パラメーターについて、飼い主が外耳炎を投与する場合と比較する。

供与動物 – 50頭の飼い主を無作為に2つのグループに振り分け、2週間治療した。

方法 – 兽医師はグループAの犬を1週間間隔で2回、動物用の耳ゲルで治療した。飼い主はグループBの犬を動物用の耳ゲルで毎日治療し、週2回の耳洗浄を実施した。獣医師は、0日、7日、14日および28日目に、OTI-3スケールおよび半定量的細胞診検査で外耳炎を評価した。各来院時に、オーナーは妥当性を検証されたアンケートでQoLを、Visual Analog Scaleで評価し、QoLの変動を測定した。

結果 – 両群において、全てのパラメータが有意に改善した。グループAでは、28日目の飼い主QoLを除いて、すべての時点においてグループBと比較して、犬および飼い主のQoLとスコアに有意に高い改善を認めた（P < 0.05）。いずれの時点においても、OTI-3の改善率は約25%であり、A群の細胞学的スコアが改善した。

結論 – 獣医師が投薬した耳用ゲルは、飼い主が投薬する局所用耳療法と比較して、外耳炎を患っている犬およびその飼い主に同等の効能およびより高いQoLをもたらした。

摘要

背景 – 对于犬的外耳炎,由主人上药治疗比较困难。

目的 – 评价外耳炎患犬及其主人的生活质量(QoL), 以及临床和细胞学参数,比较兽医和主人上药治疗的不同。

动物 – 50只家养犬随机分为两组,并治疗2周。

方法 – 兽医治疗A组,使用有兽药文号的耳道凝胶,给犬使用两次,间隔一周;主人治疗B组,每天给犬使用有兽药文号的耳道凝胶,并每周两次清洁耳道。兽医评估耳炎,依据OTI-3量表,并在第7、14、28天进行半定量细胞学检查。在每次就诊时,通过问卷形式调查主人生活质量,并且通过视觉模拟量表给出瘙痒评分。治疗前和治疗后给每组评分，并统计分析两组之间的差异。

结果 – 两组的所有参数均显著改善。与B组的所有时间点 (P < 0.05)相比,A组的犬和主人生活质量评分明显增高。第28天的主人生活质量除外。在所有时间点,OTI-3的改善没有差异,但A组的细胞学评分和瘙痒在第7天均有显著改善 (分别为P = 0.0026和P = 0.0294)。

结论 – 兽医给予耳道凝胶与主人耳薬上药相比有同等疗效,但前者可带来外耳炎患犬和主人更高的生活质量。
Resumo
Contexto – O tratamento da otite externa canina com produtos aplicados pelos proprietários pode ser difícil.
Objetivos – Avaliar o impacto do tratamento otológico na qualidade de vida (QoL) dos cães com otite externa e de seus proprietários, e nos parâmetros clínicos e citológicos, comparando um tratamento aplicado pelos veterinários e um aplicado pelos proprietários.
Animais – Cinquenta cães domiciliados, randomizados aleatoriamente em dois grupos, tratados por duas semanas.
Métodos – Os veterinários trataram os cães do Grupo A com um gel otológico veterinário em duas ocasiões intervaladas de uma semana; os proprietários trataram os cães do Grupo B uma vez por dia, com uma solução otológica veterinária associada à limpeza dos condutos duas vezes por semana. Os veterinários avaliaram a otite com a escala OTI-3 e por citologia semi-quantitativa nos dias 0, 7, 14 e 28. Em cada visita, os proprietários avaliaram a QoL com um questionário validado e o prurido a partir de escala analógica visual. Os escores antes e depois de cada tratamento para cada grupo, e as diferenças entre os grupos foram analisados estatisticamente.
Resultados – Nos dois grupos, houve melhora significativa em todos os parâmetros. Observou-se uma melhora no escore de QoL, para cães e proprietários, significativamente maior no Grupo A, quando comparado ao Grupo B em todos os tempos do tratamento (P< 0.05), exceto no escore de QoL de proprietários no dia 28. Não houve diferença na melhora de OTI-3 em nenhum tempo, enquanto no Grupo A, os escores de citologia e prurido melhoraram significativamente por volta do dia 7 (P = 0.0026 e P = 0.0294, respectivamente).
Conclusão – Um gel otológico administrado por veterinários forneceu eficácia equivalente e maior QoL para cães com otite externa e seus proprietários, comparado a uma terapia otológica tópica aplicada pelos proprietários.