

Effect of Hydrocortisone Aceponate - Gentamicin - Miconazole Topical Otic Combination for Treating Canine Otitis Externa

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Abstract : Fifty-four dogs with otitis externa were enrolled in the study for the Evaluation of efficacy of a Hydrocortisone aceponate - Gentamicin - Miconazole otic combination (Easotic[®], Virbac, Carros, France). Otitis externa patients were treated by Easotic[®] once daily for 5 days and 2 days off treatment and evaluated on 7th day. If otitis externa persisted, additional Easotic[®] treatment was administered once daily for 5 days and rested 2 days and re-evaluated on 14th day. For the evaluation of efficacy of Easotic[®], eight clinical signs were scored on a severity scale and infectious agents from ear sample were also graded using semi-quantitative scale at each visit. Sum of clinical scores and cytological scores was defined as Global Clinical Score. When Easotic[®] was applied once daily for 5 days, global clinical score was reduced 76.0%. When Easotic[®] was administered for 10 days, during first 5 days administration, 46.6% reduction of global clinical score was detected. During additional 5 days administration, 82.2% reduction of global clinical score was observed compared with Day 0. Any relevant adverse effect was not reported during the study in all cases. Thus, Easotic[®] treatment once daily for 5 days and 10 days appears to be effective and safe treatment for canine otitis externa.

Key words : Otitis externa, dog, Easotic[®].

Introduction

Otitis externa is defined as inflammation of the external ear canal which consists of vertical and horizontal ear canal (20). The incidence of otitis externa is common in dogs which ranges from 4% ~ 20% in veterinary clinics (10,20).

Otitis externa has many causes and they are divided 3 factors, predisposing factors, primary factors and perpetuating factors (20,25). Predisposing factors alter environment of the ear canal, likely to be sensitive to the otitis externa. They include anatomic problem, such as stenotic canals and pendulous ears, and temperature and humidity of the ear canal (24,25). Primary factors are main causes of the otitis externa, including hypersensitivities, ectoparasites, foreign bodies, etc (24,25). Perpetuating factors exacerbate the inflammatory status and they continue the disease until the primary factors are removed. Secondary bacterial and yeast infections are the common perpetuating factors in dogs which have severe otitis externa (17,19,24,25).

Ear cleaning, topical therapy and systemic therapy are required for the management and the treatment of otitis externa. Ear cleaning serves as the management of ear canal, removing cerumen, exudates, debris and perpetuating mate-

rial (20). Systemic therapy is effective in some cases with severe inflammation, chronic proliferative changes of ear canal and allergic otitis. Topical therapy is beneficial because it has small side effects compared with systemic therapy and is only limited to local ears. Many topical treatment agents consist of glucocorticoid, which reduces inflammation of ear, antimicrobial and antifungal agent for controlling secondary bacterial or yeast overgrowth or infection. For this reason, topical product containing glucocorticoid, antimicrobial and antifungal combination is frequently used for severe otitis externa with mixed bacterial and yeast infection (1,21,22).

Administration of the ear medication usually carried out daily by owner. However, correct administration of the topical treatment is practically difficult in otitis externa patients, because the patients could not endure the treatment, especially when the ear condition is painful and uncomfortable. For this reason, treatment failure may thus happen before the end of period (21).

The new topical combination otic suspension, which contains hydrocortisone aceponate - gentamicin - miconazole, was recently developed (Easotic[®], Virbac). Easotic[®] had some advantages compared with other topical ear treatment. Easotic[®] reduced number of administrations (once daily dosing) and shortened duration of treatment application (5 days). This reduced dog-handling and improved convenience of administration (21).

As a component of Easotic[®], Hydrocortisone aceponate is

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the non-halogenated, di-ester topical glucocorticoid as a moderate potent. Hydrocortisone aceponate greatly enhances penetration of the stratum corneum and is inactivated by specific metabolism in the deeper dermis, decreasing the likelihood of local cutaneous and systemic adverse effect (2,3,18,23).

The objective of this study is to evaluate the *in vivo* efficacy of a topical ear suspension (Easotic[®], Virbac) containing hydrocortisone aceponate - gentamicin - miconazole for the treatment of otitis externa in dogs by using clinical and cytological score.

Materials and Methods

Test population

Dogs with otitis externa were recruited at Seoul National University Hospital for Animal. They are diagnosed through the physical examination and clinical examination. Before treatment, the owner's consent was obtained to the assessment of efficacy of the new ear medication. Dogs over 6 months were selected and there was no breed selection. The otitis externa was classified either as the first occurrence reported by the owner or as recurrent case if the dog had disease two or more case before treatment. The dogs which had bilateral otitis externa and unilateral otitis externa were also recorded and divided. Patients were excluded in some cases, which had delayed reservation and couldn't evaluate correctly, and which received any systemic antifungal, antibiotic and corticosteroid or other immunosuppressive treatment during the assessment. Dogs with damaged tympanic membrane and any signs of otitis media were also excluded.

Treatment

After the otitis externa was diagnosed, Easotic[®] was administered once daily in each ear for 5 days by owners. The daily dose of 1 mL was delivered by one single depression of the pump on the head of dispenser. Owners used ear suspension for 5 days and rested for 2 days. If otitis externa persisted, additional Easotic[®] treatment was administered once daily for 5 days and 2 days off treatment. With Easotic[®] treatment, the owners were trained to perform daily ear flushing to the patients. Any other otitis externa treatment was prohibited during the study.

Clinical and cytological evaluation

Ears were examined at each visit by the veterinarian using the clinical and cytological examination. For evaluation of the clinical sign of the otitis externa, the degree of erythema, ear canal stenosis, excoriation-crusts, quantity of exudates and suppuration were scored for 0 to 3 (0 = none, 1 = mild, 2 = moderate, 3 = severe). The owner's perception of the clinical signs of otitis externa, including head-shaking, otic pruritis and pain with a grade of 0 to 3 (0 = none, 1 = mild, 2 = moderate, 3 = severe) except head shaking scored from 0 (none) to 1 (presence).

For cytological examination ear swab sampling of the

external ear canal was performed at each visit. The clinicians swabbed the ear sample by cotton-tipped swab with isotonic saline wetting and smeared onto a clean microscope slide. After drying, the slide was stained with a quick staining kit (Diff-Quik, Baxter Healthcare, Dade Division, Miami, FL). The slide was scanned at low power (100×) to find the place where infectious organisms expected to be located. Organisms were estimated from 10 consecutive microscope fields at higher magnification field (1000×) by same veterinarian to reduce the individual differences. Cytological score was calculated by using a semi-quantitative scale for bacterial and fungal count (Table 1). Sum of the clinical and cytological score gives global clinical score from 0 to 31.

If the clinical signs of otitis externa persisted on second visit (Day 7), additional treatment with 5 days administration and 2 days off was performed and re-evaluated every 7th day (Day 14, Day 21) until the improvement of clinical sign was enough to stop the treatment.

Statistical Analysis

All analysis was performed using commercial statistical software (PASW Statistical 18, SPSS Inc. Chicago, IL). The significance threshold was set to $P < 0.05$. Each clinical and cytological score was calculated the average and compared the changes between before treatment (day 0) and after treatment (Day 7, Day 14). Score reducing was expressed by percentage reduction method.

T-test was used to identify significant relationships of clinical and cytological score changes. In Standard Treatment Group, scores of first visit (Day 0) and second visit (Day 7) were compared. In Additional Treatment Group, scores of second visit (Day 7) and third visit (Day 14) were compared to score of first visit (Day 0).

Table 1. Semi-quantitative scale for bacterial and fungal counts recorded at cytology from ear swabs

Organism	Count per oil immersion field (× 1,000)	Score
	0	0
Malassezia yeasts	1-2	1
	3-8	2
	> 8	3
Rods	0-2	0
	3-8	1
	9-40	2
	> 40	3
Cocci	0-2	0
	3-8	1
	9-40	2
	> 40	3

Results

Forty nine dogs (54 cases) were recruited for the study from April 2010 to August 2011. Breeds represented in the study included Cocker spaniel (15 cases, 27.7%), Shih-Tzu (15 cases, 27.7%), Maltese (6 cases, 11.1%), Yorkshire terrier, Miniature Schnauzer (3 cases, 5.5%), Miniature Poodle, Afghan hound, Mixed breed (2 cases, 3.7%), and other 6 breeds had only one case (Pekinese, French Bulldog, Golden Retriever, German shepherd, Japanese Spitz, Bichon Frise). The dogs ranged in size from 1.8 to 29 kg (median = 8.9 kg) and ranged in ages from 2 years to 19 years (median = 8.2 years). Otitis externa cases with pendulous ears were more common (31 cases, 63.2%) compared with otitis externa with erect ears (23 cases, 36.8%). Most cases were bilateral otitis externa (46 cases, 85.2%) and all cases were mixed type (erythematous-ceruminous and purulent). Dominant cases were chronic and recurrent otitis externa which relapsed two or more times within a year (44 cases, 81.5%). Only 5 cases (9.2%) were primary and acute otitis externa which are defined as the first outbreak of the disease. Otitis externa was recurred in 4 dogs during the assessment (three dogs relapsed twice and one dog relapsed three times).

Thirty eight Cases, 70.4%, were finished the Easotic® treatment on second visit (Day 7). These cases were defined as Standard Treatment Group. In this group, significant reduction of the clinical score and cytological score were detected. Mean global clinical scores was reduced 76.7% between first visit (Day 0) and second visit (Day 7) (Fig 1). As a each score

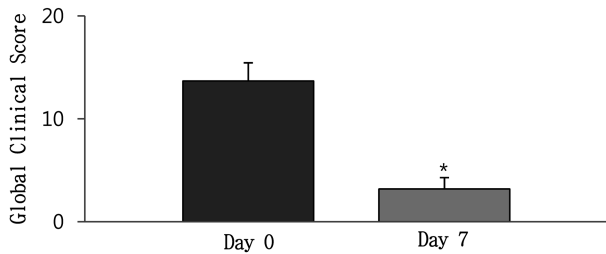


Fig 1. Global clinical score change in Standard Easotic® Treatment Group. Mean global clinical score was reduced 76.7% between Day 0 (13.68 point) and Day 7 (3.18 point) (**P* < 0.05).

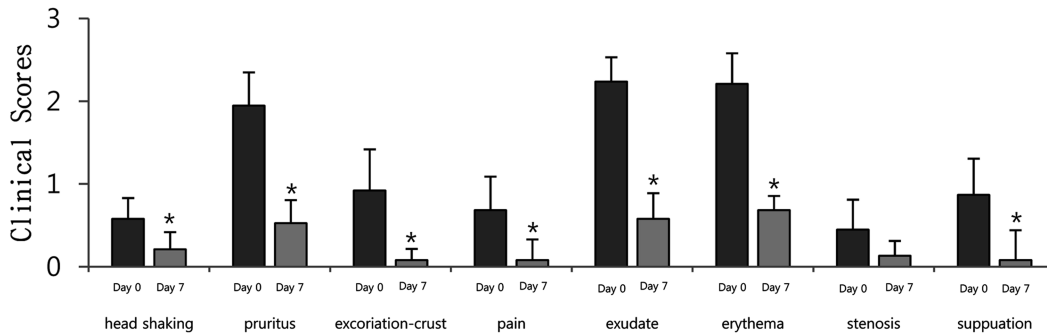


Fig 2. Clinical score change in Standard Easotic® Treatment Group. All scores were significantly reduced except stenosis, including excoriation-crust (91.4%), suppuration (90.9%), pain (88.4%), pruritus (72.9%), exudates (74.1%) (**P* < 0.05).

reduction between Day 0 and Day 7, over the 80% reduction was considered excoriation-crust (91.4%), suppuration (90.9%), pain (88.4%) and rod (84.6%) were included. 70~80% reduction included scores of pruritus (72.9%), exudates (74.1%), stenosis (70.5%), malassezia (77.3%) and cocci (76.7%). *P* value of all scores was under 0.05, except one clinical score (stenosis, *p* = 0.18) (Figs 2, 3). There was no relevant adverse effect recorded.

16 cases were treated by Easotic® more than twice, which defined as Additional Treatment Group. They included 2 cases which were treated by Easotic® three times. Global clinical scores were significantly reduced between first visit (Day 0) and second visit (Day 7), but not all clinical and cytological scores were statistically significant. Decrease of global clinical score was recorded 46.8% compared with scores of Day 0 and Day 7 (Fig 4). Pain (66.6%), malassezia (60.8%) and pruritus

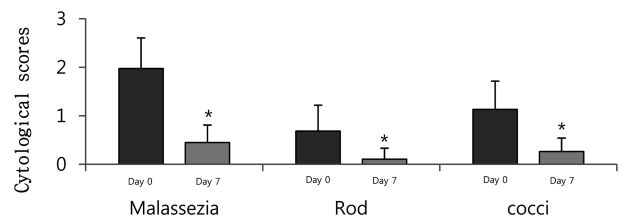


Fig 3. Cytological score change in Standard Easotic® Treatment Group. All scores were reduced, including rod (84.6%), malassezia (77.3%) and cocci (76.7%) (**P* < 0.05).

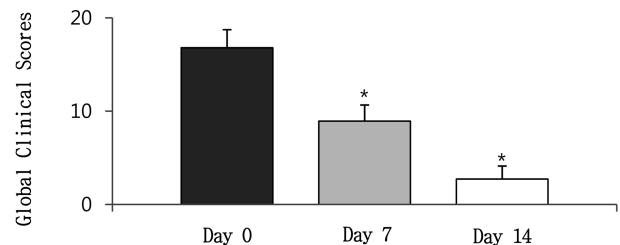


Fig 4. Global clinical score changes in Additional Easotic® Treatment Group. Decrease of global clinical score was recorded 46.8% compared with scores of Day 0 (16.78 point) and Day 7 (8.92 point). Compared with Day 0, mean global clinical score was decreased 83.8% on Day 14 (2.71 point) (**P* < 0.05).

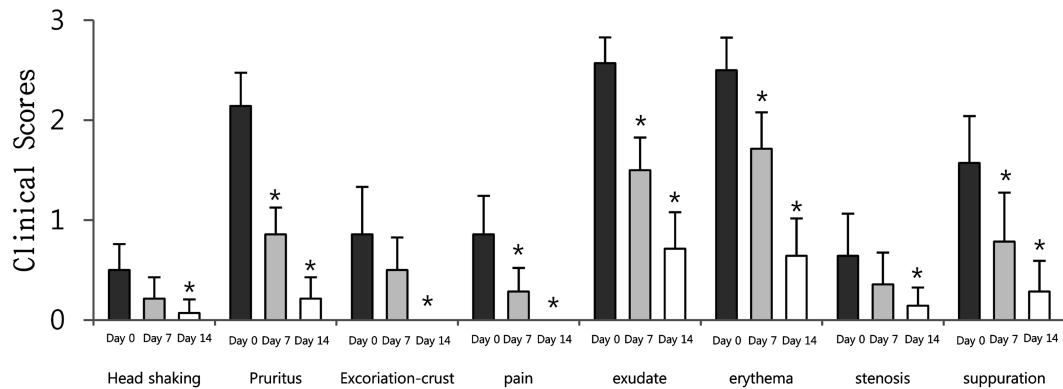


Fig 5. Clinical score changes in Additional Easotic® Treatment Group. Between Day 0 and Day 7, pain (66.6%) and pruritus (60.0%) were decreased over 60%, followed by suppuration (50.0%), exudates and erythema (31.4%). Between Day 0 and Day 14, excoriation-crust and pain were completely improved (100%), followed by pruritus (90%), head shaking (85.7%), suppuration (81.8%), stenosis (77.7%), erythema (74.2%) and exudates (72.2%). P value between Day 0 and Day 14 was under 0.05 in all scores (* $P < 0.05$).

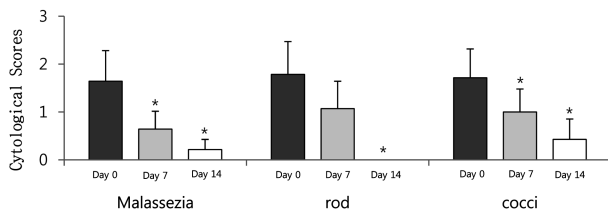


Fig 6. Cytological score change in Additional Easotic® Treatment Group. Between Day 0 and Day 7, malassezia (60.8%) and cocci (41.6%) were significantly reduced. Between Day 0 and Day 14, rod was reduced completely (100%) and malassezia (86.9%) and cocci (75.0%) infection were also improved (* $P < 0.05$).

(60.0%) scores decreased about 60% followed by suppuration (50.0%), exudates and cocci (41.6%) scores. Erythema (31.4%) scores reduction was under the 40% (Figs 5,6). On third visit (Day 14), mean global clinical score was decreased 83.8% compared with Day 0 (Fig 4). Excoriation-crust, pain and rod infection were completely improved (100%) in all cases. Improvement of pruritus (90%), malassezia (86.9%), head shaking (85.7%), suppuration (81.8%), stenosis (77.7%), cocci (75.0%), erythema (74.2%) and exudates (72.2%) scores were followed. P value between Day 0 and Day 14 was under 0.05 in all scores (Figs 5, 6). During the treatment there was no relevant adverse effect.

Discussion

In this study, Easotic® administration to the otitis externa patients showed great improvement of clinical sign and the number of infectious agents were reduced significantly with one or more treatments.

Ear type is classified by two groups, pendulous ear and erect ear. Cocker spaniel, Afghan hound, Maltese and Shih-Tzu represent the pendulous ear breed. Compared with erect ear, pendulous ear aggravates the ear condition. It makes ear

canal get more moisture and infectious agents are easily proliferated (20,24). Patients with pendulous ear were predominantly presented in this study. This result reflects previous theory. In this study, most cases were mixed type and chronic otitis externa. Because chronic, severe and mixed type otitis externa is intractable disease and easily relapses, local animal clinics tends to refer this type to secondary medical hospital, Seoul National University Hospital for Animal. For this reason, only a few cases of primary and acute otitis externa were included this study.

For objectivity and accuracy of clinical sign scores, this study was conducted by veterinary dermatologist. Within the clinical signs, erythema, pruritus and exudates were common signs of otitis externa, frequently reported on the other studies of otitis externa (20,24,25). In this study, these three clinical signs were prevalent signs and scored high, compared with other signs. Erythema, pruritus and exudates, got the score about 2.0 points on Day 0 in the Standard Treatment Group and about 2.5 points on Day 0 in the Additional Treatment Group. It can be speculated that patient with severe these 3 clinical signs might need more treatment than recommended period. Reduction of stenosis score was not statistically significant ($p = 0.18$). In the chronic otitis externa, stenosis of the ear canal is a common anatomical change and it is associated with soft tissue edema following hardening the tissue because of chronic inflammation (20,25). Steroid can reduce the edema but cannot cure the stenosis because stenosis is irreversible anatomic change.

Microbial infection of otitis externa was improved by Easotic® treatment. Malassezia infection was the most common than other infectious agent (19). *Malassezia pachydermatitis* is commonly isolated in normal ear, but increased number of malassezia compromises barrier function of stratum corneum and makes easy to penetrate the skin tissue (5,16). Malassezia also increases moisture and surface lipids, so it causes erythematous-ceruminous otitis externa (5,16). In this study, rapid decrease of malassezia score was observed,

77% reduction on Day 7 in Standard Treatment Group and, 86.9% reduction on Day 14 in Additional Treatment Group.

Malassezia and Cocci may be isolated from normal ears as they are commensal organism, otherwise rods are rarely found in normal ear swab (6,11,12,20,27). Therefore, rod score represents the severity of otitis externa and if rod score reduces significantly, it can be assumed that the antimicrobial activity of Easotic is enough to eliminate the infectious agent. In Standard Treatment Group, administration of Easotic[®] reduced rod infection 84% and in Additional Treatment Group, 100% reduction between Day 0 and Day 14 were recorded. From this result, Easotic[®] treatment is very effective to improve the severe otitis externa cases.

The efficacy of the Standard Treatment Group was measured by the comparison of the scores between Day 0 and Day 7. All clinical scores except stenosis reduced statistically significantly, especially pain, excoriation-crust and suppuration scored under 0.1 on day 7. It means that these clinical signs almost disappear in all cases. Pruritus, exudates and erythema score also reduced significantly, but these signs remain on Day 7, scoring up to 0.5 points. This might be because these 3 clinical signs got the high score on day 0. These results reflect that pruritus, exudates and erythema signs tend to remain after treatment compared with other clinical signs. In mean cytological score, low rod score in Standard Treatment Group (0.68) shows that the cases of this group are mild and not serious compared with the cases of the Additional Treatment Group. After the administration of standard treatment, mean cytological scores reduce under 0.5. Reduction of the malassezia, cocci and rod scores explain the excellent antibacterial and antifungal drugs effect in Easotic[®] treatment.

In Additional Treatment Group, administration of Easotic[®] was evaluated at Day 0, Day 7 and Day 14. All scores significantly decreased, especially excoriation-crust, pain and rod score diminished 100% at the end of the study. Compared with Standard Treatment Group, Suppuration and Rod scored significantly higher than other scores. When it considered Additional Treatment Group is more severe than the Standard Treatment Group, this result is assumed that rod infection plays an important role as a aggregation factor of otitis externa and severe suppuration is related with severity and intractability of otitis externa. In the Additional Treatment Group, clinical improvement between Day 0 and Day 7 was not obvious, remaining clinical sign and infectious agents. Only 46.8% reduction of global clinical score were recorded when first Easotic[®] administration was used in Additional Treatment Group. On the other hand, 69.6% reduction was detected when second administration is used in additional treatment. This result suggest that additional Easotic[®] administration should be considered in patients with severe and recurrent otitis externa when clinical improvement is not obvious in standard treatment.

Two cases still showed clinical sign of otitis externa after

additional treatment. They were administered Easotic treatment 5 days again and re-evaluated on next visit (Day 21). In one case, clinical and cytological improvement was detected and treatment finished treatment on Day 21. The other case, however, clinical sign was improved but infectious agents were still remained on Day 21. Microbial infection of these cases could be too severe to be treated by Easotic[®] and ear cleaning only. Other hypothesis could be a mistake of administration by owners. To conclude, if otitis externa persists despite additional administration of Easotic[®] treatment, Bacterial culture with antimicrobial susceptibility test should be recommended. In spite of the long-term medication (15 days), adverse effect was not reported in these cases.

In the 1 ml of Easotic[®], it contains 1.11 mg of hydrocortisone aceponate, 15.1 mg of miconazole nitrate and 1505IU of gentamicin sulphate (21). Hydrocortisone aceponate, as the increased stability and permeability of stratum corneum by double esterification at C17 and C21, diminishes inflammation sign, pruritus, erythema and edema, which are primary and predisposing factors of otitis externa (2,3). Despite short 5-day administration of medication, a high dose of Hydrocortisone aceponate, which has a good penetration activity and possible accumulation at the site of inflammation, may play an important role in the clinical result (18,23). Gentamicin is the aminoglycoside antibiotics which has the sensitivity in 83 to 95% of Pseudomonas and staphylococci isolated from dogs with otitis externa in earlier reports (7,9,13,15,26). In this study, after administration of Easotic[®] treatment, cytological score reduced significantly. This result demonstrates sensitivity of gentamicin in otitis externa. Miconazole is a good activity of imidazole compounds reported elsewhere, affecting on Malassezia overgrowth (8,14,28)

Increased erythema in some dogs and temporary reduced hearing with Easotic[®] administration were reported in other assessment (21). However, in this study, adverse effect of Easotic[®] treatment was not reported both Standard and Additional Treatment Group.

There are some shortcomings in this study. In fact, microbial infection of otitis externa was represented only the scores in this study and there could be somewhat difference between clinical severity and scores. Because there is a debate about - the number of organism can be considered as the indication of infection. Moreover, bacterial and fungal isolation and antibiotic sensitivity test were not investigated in this study. As a result, Cocci, Rod and Malassezia count in the otitis externa patients cannot be co-related with the infectious organism. However, there was a tendency that with the reduction of microbial scores clinical signs of otitis externa were improved. For the efficacy of the medication, clinical and cytological improvement is more important than the type of infectious agent. However in some cases with sever chronic and recurrent otitis externa, bacterial isolation and sensitivity test should be conducted because infectious agents may be resistant to antimicrobial drugs.

Conclusion

In cases of Easotic[®] administration once daily for 5 days and 10 days, Clinical and cytological scores in cases of canine otitis externa reduced statistically significantly. During Easotic[®] treatment, no adverse effect was reported. Therefore, Easotic[®] administration for otitis externa patient could be a useful and safe selection for reducing bacterial and yeast infections and providing clinical improvement of otitis externa in dogs.

Acknowledgements

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개 외이염 치료에서 하이드로코티손 아세포네이트-겐타마이신-미코나졸 국소 혼합제제의 효과

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요 약 : 54 마리의 외이염에 이환된 개에서 하이드로코티손 아세포네이트-겐타마이신-미코나졸 국소 혼합제제인 이소틱(Easotic[®], Virbac, Carros, France)의 효과를 평가하였다. 외이염 환자들은 이소틱을 하루 1번 적용하여 5일 동안 치료 받았고 2일 동안 휴약 하였으며 처음 적용일로부터 7일 후 평가되었다. 적용 후에 외이염이 지속되는 경우 추가적으로 이소틱을 하루 1번 5일 동안 사용하고 2일 휴약 후에 처음 적용일로부터 14일 후 평가되었다. 이소틱의 효과를 평가하기 위해 8항목의 임상증상을 증상의 심한 정도로 등급을 매겨 점수화하였고 귀의 도말 표본에서 감염인자들을 준정량적으로 등급을 매겨 점수화하였다. 임상증상점수와 감염인자점수의 합을 전체임상점수로 정의하였다. 이소틱을 5일 동안 적용하였을 때 전체임상점수는 76% 감소하였다. 이소틱을 10일 동안 적용하였을 때 처음 5일 동안 전체임상점수는 46.6% 감소하였다. 추가적인 5일간 적용 후 처음 적용할 때와 비교하여 전체임상점수는 82.2% 감소하였다. 모든 케이스에서 실험 기간 동안 치료제와 관련된 부작용은 나타나지 않았다. 따라서 5일 간 이소틱 치료 및 10일 간 이소틱 치료는 개의 외이염을 치료하는데 있어서 효과적이고 안전한 방법으로 생각된다.

주요어 : 외이염, 개, 이소틱