



The efficacy of cyclosporine A in cats with presumed atopic dermatitis: A double blind, randomised prednisolone-controlled study

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Abstract

The objective of this study was to compare the efficacy of cyclosporine A (CsA) and prednisolone in feline atopic dermatitis (AD) in a randomised, controlled double blind study. Twenty-nine cats with feline AD were randomly allocated to two groups. Eleven cats were treated orally with prednisolone (1 mg/kg SID) and 18 were treated with CsA (5 mg/kg/day) for 4 weeks. At day 0 (D0) and D28, skin lesions were graded by means of the canine atopic dermatitis extent and severity index (CADESI). Skin biopsies and intradermal allergy tests were performed at D0 and blood samples for haematology and serum biochemistry were collected at D0 and D28. During the trial the cat owners were asked to evaluate the intensity of the pruritus once weekly on a linear analog scale and to record side effects.

Based on the CADESI there was no significant difference between the two groups in the amount of remission ($P = 0.0562$) or in the number of cats that improved by $>25\%$ ($P = 0.0571$). The effect of CsA and prednisolone on pruritus as evaluated by the owners was not significantly different ($P = 0.41$) between the two groups. No serious side effects were observed. The conclusion was that CsA is an effective alternative to prednisolone therapy in cats with presumed atopic dermatitis.

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Introduction

In 1982, Reedy introduced the term ‘atopic dermatitis’ for a group of cats that had pruritic recurrent dermatitis and immediate skin test reactivity to common aeroallergens, and in which other causes of pruritus were excluded (Reedy, 1982). Since then, breed or sex predilections have not been demonstrated and young cats especially seem to be predisposed to the condition. The most consistent feature is a chronic recurrent pruritus.

A distinct clinical phenotype has never been described, but the most common clinical presentations of atopic dermatitis (AD) in cats include miliary dermatitis, pruritus of

the face, neck or pinnae, eosinophilic granuloma complex lesions (lip ulcers, cutaneous and oral plaques or nodules) and self-induced alopecia. Skin lesions include erythematous macules, papules, excoriations or ulcerative lesions (Reedy, 1982; Scott et al., 2001). Histological features involve a superficial to mild dermal perivascular to diffuse cellular infiltrate with eosinophils, lymphocytes, mast cells and macrophages (Scott et al., 2001; Gross et al., 2005). Although not decisive for AD, this pattern is compatible with an allergic dermatitis and, as such, contributes to the presumed diagnosis (Scott et al., 2001; Gross et al., 2005). Support for an allergic pathogenesis has also come from the studies of Roosje et al. (1998) who identified high concentrations of CD4⁺ T cells in affected skin. The same group also identified Langerhans cells as antigen-presenting cells (Roosje et al., 1997), and evidence was presented

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for the enhanced proliferation of Th2-like subsets (Roosje et al., 2002a).

The diagnosis of feline AD is based on the clinical signs, exclusion of other cutaneous diseases such as flea bite allergy, food hypersensitivity, parasitic diseases, dermatophytosis, the histological features of affected skin, skin test results (although somewhat controversial), and the response to glucocorticoids (Scott et al., 2001; Medleau and Hnilica, 2001; Schleifer and Willemse, 2003).

So far, most cats diagnosed with AD are treated in a variety of ways depending upon the severity of clinical signs, duration or owner preference. This treatment may include immunotherapy or antipruritic drugs, particularly prednisone, or a combination of both (Scott et al., 2001). However, the long term side effects of prednisolone may be a reason for seeking alternative medication. Cyclosporine A (CsA) has been described as a cost effective alternative to immunotherapy in dogs with AD and without serious side effects (Olivry et al., 2002; Steffan et al., 2003). It selectively depresses the proliferation of cytotoxic T cells, antibody production by helper T cell-dependent B cells, cytokine secretion by keratinocytes, the number and activities of Langerhans cells in the epidermis, and the functions of mast cells and eosinophils (Marsella and Olivry, 2001).

In cats, the use of CsA has been described in non-controlled studies where it was effective in the treatment of the eosinophilic granuloma complex (Guaguère and Prélard, 2000; Vercelli et al., 2006), feline AD (Noli and Scarpella, 2006), 'dirty face syndrome' in Persian cats (Fontaine and Heimann, 2004), feline acquired alopecia (Olivry et al., 2000), pemphigus erythematosus and pemphigus foliaceus (Rosenkrantz et al., 1989), idiopathic pruritus and stomatitis (Vercelli et al., 2006), granulomatous folliculitis and furunculosis (Noli and Toma, 2006), and sebaceous adenitis (Noli and Toma, 2006).

The objective of the present study was to investigate the efficacy of CsA in feline AD in a prednisolone-controlled double blind trial. In this way we tested the hypothesis that in cats with feline AD, CsA has equal or better effects on pruritus and cutaneous inflammation than prednisolone.

Materials and methods

Animals

Twenty-nine household cats were referred to the Utrecht University Veterinary Medical Teaching Hospital because of chronic, non-seasonal pruritus. There were 13 European short-haired cats, nine domestic cats, one Abyssinian cat, one Siamese, three Persians, one Norwegian and one British short-hair cat. There were 16 female and 13 male cats and their ages ranged between 1 and 10 years (median 3 years.).

The inclusion criteria were pruritus with resulting skin lesions and cutaneous histopathology compatible with feline AD. Otherwise the cats had to be healthy at routine physical examination. Parasitic disorders, dermatophytosis, flea bite hypersensitivity, and food hypersensitivity were excluded by standard procedures that included microscopy of skin scrapings and hairs, flea control measures and dietary trials (Scott et al.,

2001). Food hypersensitivity was excluded with a strict home-cooked elimination diet with ostrich, goat or horse meat and rice for 6–12 weeks. Corticosteroids or antihistamines were withdrawn for at least 4 weeks before the start of the trial. Prior to referral, most cats had been treated with antibiotics without effect, and all cats had responded partially and temporarily to prednisolone. Before and during the study flea control was performed with adulticides and insect growth inhibitors.

Study design

Two groups of cats with feline AD were included (Table 1). Animals were randomly assigned by the Department of Pharmacy to receive an oral therapy for 4 weeks with either one capsule of CsA 5 mg/kg SID ($n = 18$) or one capsule of prednisolone 1 mg/kg SID ($n = 11$). The capsules were identical and given 2 h before meals. Both the investigator and the cat owner were blinded to the therapy.

At day 0 (D0) an intradermal allergy test was performed with 15 allergens commonly used in dogs (Artu Biologicals Europe) following a previously described protocol (Schleifer and Willemse, 2003). In short, each cat was sedated with medetomidine (100 µg/kg, IM), and the hair was gently clipped. An intradermal injection of 0.05 mL of each allergen and control solutions (saline and 0.01% histamine) was administered. Immediately after injection, a 10% fluorescein sodium solution (4.4 mg/kg) was injected IV to facilitate assessment of the skin test response. Reactions were considered positive when the long axis of the wheal was equal to or larger than half of the sum of the response to the control solutions. Scoring was performed under ultraviolet light in a darkened room at 15 min after injection of the allergens.

At D0 and D28, multiple skin biopsies were taken for histopathological examination and blood samples were collected for haematology and serum biochemistry. At the same time points, the same investigator graded the type of skin lesions, the localisation and the extensity of skin lesions based on the canine atopic dermatitis extent and severity index (CADESI 02) symptom score. Four different skin lesions (erythema, lichenification, excoriations and self-induced alopecia) were scored at 40 body sites with a severity scale varying from absent (0), mild (1), moderate (3) to severe (6). This scale was recommended as a validated tool for assessment of disease severity in clinical trials testing the efficacy of interventions in dogs with atopic dermatitis (Olivry et al., 2002). The total score at D0 and D28 was compared to calculate the percentage of clinical improvement or deterioration. Improvement was defined as a score of >25%.

During the trial the cat owner was asked to evaluate the intensity of the pruritus once weekly on a linear analog scale (LAS) from 1 (no pruritus) to 5 (severe pruritus), and to record side effects.

Statistical analysis

To compare the effect of CsA and prednisolone on the number of cats that improved and to compare the effect on pruritus (LAS) the χ -square test was used. To compare the effect on the skin lesions (CADESI) between the groups the two sample t test was used. The difference was considered significant when the P -value was <0.05.

Results

Skin lesions and pruritus

In 14 cats pruritus was only located at the head, pinna or neck. In 14 other cats the axillae, inguinal region, abdomen, front and hind legs were also involved. In one cat pruritus was only observed at the flanks, the front and hind legs. Depending on the chronicity and intensity of the pruritus, skin lesions varied between erythema, self-induced alopecia lichenification and excoriations.

Table 1
Demographic and clinical data of 29 cats with presumed atopic dermatitis

Cat	Age (years)	Signalment	Duration (years)	Location	STR	Treatment group
1	1.5	European short-hair, m	1	Neck, head, hind legs	Neg	Pr
2	2	Domestic cat, m	1	Head, neck, front- hind legs, groin	Neg	CsA
3	5.5	Abyssinian cat, f	4	Head, neck, axillae, hind legs, groin	np	Pr
4	4	European short-hair, m	3.5	Head, neck, front legs	Neg	Pr
5	8	European short-hair, m	1	Head, neck, pinna	Tpm,Dp	CsA
6	2	Domestic cat, m	1	Head and neck	Tp	CsA
7	2	Domestic cat, f	1.5	Head, pinna	np	CsA
8	3	European short-hair, m	1	Head	Tpm,Wpm,As Df,Dp	Pr
9	2.5	Norwegian cat, f	2	Head, neck, groin, pinna	Neg	CsA
10	8	Domestic cat, m	1	Head and neck	np	CsA
11	2	Persian cat, f	1.5	Neck, groin, pinna hind legs	np	CsA
12	1	Domestic cat, f	0.5	Head and neck	np	Pr
13	5	Domestic cat, f	0.8	Head, axilla, abdomen	np	CsA
14	1	European short-hair, f	0.5	Head, pinna, neck, front legs, abdomen	Wpm,As,Dp	CsA
15	9	European short-hair, f	7	Head and neck	Neg	CsA
16	4	Persian cat, f	3.5	Head and pinna	Neg	Pr
17	2	European short-hair, m	1.5	Head	Tpm,cat,Dp	Pr
18	3.5	Domestic cat, f	2.5	head, axilla, groin	Neg	Pr
19	3	Persian cat, f	2	Head, pinna	Neg	Pr
20	4	European short-hair, f	2	Head, groin	Neg	CsA
21	2.5	Siamese cat, f	1.5	Front legs, hind legs, flanks	Neg	CsA
22	7.5	European short-hair, f	5	Head, pinna, hind legs	Dp	Pr
23	10	European short-hair, m	4	Head, neck, axilla, groin	Wpm,Tp	CsA
24	2	Domestic cat, m	1.5	Head, pinna, neck	Neg	Pr
25	2	British short-hair, m	1.5	Head	Neg	CsA
26	9	European short-hair, m	5	Head, neck, pinna, thorax, groin	Wpm	CsA
27	7	Domestic cat, f	2	Head, abdomen, front legs	Neg	CsA
28	6	European short-hair, m	1	Head, pinna	Neg	CsA
29	1	European short-hair, f	0.5	Head, pinna	Neg	CsA

m: male, f: female.

STR: skin test reactivity, Dp: *Dermatophagoides pteronyssinus*, Df: *D. farinae*, Tp: *Tyrophagus putrescentiae*, As: *Acarus siro*, Wpm: weed pollen mixture, Tpm: tree pollen mixture, np = not performed, neg = negative.

Pr: prednisolone, CsA: cyclosporine A.

Intradermal allergy test

Twenty-three of the 29 cat owners agreed to skin testing. The remaining owners did not permit sedation. Immediate type reactions (20 min) were observed in eight cats (Table 1). The most commonly observed positive allergens were: *Dermatophagoides pteronyssinus* (five cats), weed pollen mixture (mugwort, nettle, goldenrod, lamb's quarters, dandelion, sheep sorrel, English plantain; four cats), tree pollen mixture (birch, alder, hazel, oak, beech, elm; three cats), *Acarus siro* (two cats), and *Tyrophagus putrescentiae* (two cats). In the prednisolone-treated group (nine cats) the intradermal test was positive in three and in the CsA-treated group (14 cats) in five animals. Of the eight individuals with a positive skin test four improved on CsA, and one on prednisolone. Of the 15

cats with a negative skin test five improved on CsA and two on prednisolone.

Blood counts and serum chemistry

Blood counts and serum chemistry were performed on 14 cats treated with CsA and eight on prednisolone. In the CsA-treated group (12/14 cats) and in all cats of the prednisolone-treated group, leucocytes, lymphocytes, monocytes and eosinophils were elevated at D0 and D28. In three cats in the CsA group, bile acids (reference value: 1–13 µmol/L) were slightly increased at D0 (19, 38 and 33 µmol/L, respectively). At D28 these values were normal. In one cat of the CsA group at D0 ALAT (reference value 30–73 U/L) was elevated (210 U/L), but within the reference range at D28.

Lesional score by the investigator

In the CsA group, 13/18 CsA-treated cats (72%) improved by >25%. The percentage improvement at D28 in these 13 cats was $62.3 \pm 19.3\%$ (mean $\pm$ SD; range 30–100%). The mean percentage improvement in the entire CsA group was $38.2 \pm 44.7\%$ (mean $\pm$ SD; range: –54–100%). Complete remission was only seen in one animal.

In the prednisolone group ($n = 11$), four cats (36%) had improved >25% at D28. The percentage of improvement in these four animals was $64.5 \pm 26.5\%$ (mean $\pm$ SD), with a range from 38% to 92%, whereas the mean reduction for the entire group was $-6.9 \pm 77.8\%$ (mean $\pm$ SD), with a range from –178% to 92%.

The number of cats that had an improvement of >25% on CsA was not significantly ($P = 0.0571$) higher than those on prednisolone. Neither was there a significant difference ($P = 0.857$) between the two groups in the amount of remission. Comparison of the two entire groups, including the cats that deteriorated, revealed no significant difference ($P = 0.0562$) in the amount of remission (Table 2).

Evaluation of pruritus (LAS)

Based on the LAS analysis, 11/18 cats (61%) treated with CsA showed less pruritus at D28, whereas in the same group five cats deteriorated and in two cats no difference was observed. In contrast, in the prednisolone group ($n = 11$) five cats (45%) improved, five deteriorated, and in one animal there was no apparent difference in the amount of pruritus. The effect of CsA and prednisolone on the reduction of pruritus was not significantly different ($P = 0.41$) (Table 3).

Side effects

Within the prednisolone group, hyperactivity and diarrhoea was observed in 1/11 cats, whereas in the CsA group ($n = 18$) side effects were seen in 11 cats involving intermit-

tent vomiting (three cats), diarrhoea or loose stools (five cats), and hyperactivity, increased appetite, and polydipsia (one cat each). These signs were mild and stopped in all cases at the end of the treatment.

Discussion

Cyclosporine A has been successfully used in human and canine AD (Marsella and Olivry, 2001; Steffan et al., 2003). Although the exact pathogenesis of feline allergic dermatitis is unknown, there are enough similarities with canine AD (Roosje, 2002b) to justify the symptomatic use of CsA in feline AD. Until now only limited information has been available on the use of CsA in cats with feline AD. Successful use of CsA has been described only in open, uncontrolled trials (Noli and Scarampella, 2006; Vercelli et al., 2006). In this study we have compared the effects of prednisolone and CsA on skin lesions and pruritus in a double blind pattern.

The CADESI has proved valuable in the evaluation of atopic dermatitis lesions in dogs (Olivry et al., 2002; Steffan et al., 2003). In addition, the system has been successfully used as a basis for grading skin lesions in the cat (Noli and Scarampella, 2006). In the CsA-treated group 5/18 cats deteriorated and in the prednisolone group 7/11 cats. A poor response to prednisolone is frequently observed by veterinary dermatologists and this may be a dose-dependant phenomenon or it appears that the cats do better on dexamethasone. Moreover, it is suggested by the results of this study, not to consider a response to prednisolone as part of the inclusion criteria for feline AD.

The effect of CsA is comparable to that found in dogs (approximately 70%). In our study, we found that there was no significant difference in remission or in the number of cats that improved between the CsA group and the prednisolone treated group. These results are in agreement with those described in dogs (Olivry et al., 2002) where the effects of CsA and prednisolone were compared in 30 dogs and it was concluded that there was a similar effect of prednisolone and CsA on the skin lesions and the pruritus. Also in our study pruritus reduction was in line with clinical remission. The study provides randomised controlled trial evidence that CsA reduces the severity of clinical signs of cats with non-seasonal AD and that the effect is comparable to that of prednisolone.

There was no difference in response to either CsA or prednisolone when comparing the subgroups of cats with or without immediate skin test reactivity to one or more allergens. This probably reflects the recognised inconsistency of skin testing in cats (Scott et al., 2001; Schleifer and Willemse, 2003). Thus, the cornerstones for the diagnosis feline AD remain clinical symptoms, the exclusion of other important differential diagnoses and the histopathology.

In cats, few adverse reactions to CsA have been reported. Gastrointestinal signs (diarrhoea, vomiting and

Table 2

The effect of CsA ($n = 18$) and prednisolone ($n = 11$) based on the canine atopic dermatitis extent and severity index (CADESI) in cats with presumed atopic dermatitis

	Deterioration	Improvement		
		0–25%	25–50%	>50%
CsA	4	1	3	10
Prednisolone	7	0	2	2

Table 3

The effect of CsA ($n = 18$) or prednisolone ($n = 11$) on pruritus linear analog scale (LAS) in cats with atopic dermatitis

	Not improved	Improved
CsA	7/18 (39%)	11 (61%)
Prednisolone	6/11 (55%)	5 (45%)

anorexia) are the most frequently reported reactions. Noli and Scarpella (2006) mentioned a mild diarrhoea in 1/10 cats, whereas Vercelli and others (2006) reported soft faeces or occasional vomiting in 4/23 cats. Also, in the dog, gastrointestinal signs are observed in 20–47% of CsA-treated animals (Olivry et al., 2002; Steffan et al., 2003). In the present study, 11/18 CsA-treated cats developed mild and transient side effects of which vomiting and mild diarrhoea were most common in agreement with previous observations. The changes from mean baseline levels of the blood cell counts and various serum concentrations were seen equally in both groups, but were not very impressive, or had returned to normal by the end of the study. It seems likely that most of these changes were unrelated to the CsA or prednisolone treatment but associated with the skin disease itself. In general, CsA was well-tolerated by the cats in this 4-week trial.

We should keep in mind, however, that CsA is not registered for use in cats. This means that, at least in the European Union, veterinarians are only allowed to use CsA in cats if the registered routinely used medicaments are not effective. Moreover, it is important to test cats for toxoplasmosis before and after treatment with CsA, as possible immune suppression may induce systemic toxoplasmosis (Last et al., 2004). Our study began before this risk was known, so cats were not tested prior to inclusion. Likewise it may be advisable to test for FIV and FeLV, even though the risk of these diseases seems to be very low (Robson and Burton, 2003; Vercelli et al., 2006).

Conclusions

CsA is a valuable alternative to prednisolone therapy in cats with presumed atopic dermatitis.

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