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An open, self-controlled study on the efficacy of topical indoxacarb for eliminating fleas and clinical signs of flea-allergy dermatitis in client-owned dogs in Queensland, Australia

Petr Fisara*, Roger M. Sargent*[1], Michael Shipstone†, Andrew von Berky‡ and Janet von Berky‡

*MSD Animal Health, 26 Artisan Road, Seven Hills, NSW 2147, Australia
†Dermatology for Animals, 263 Appleby Road, Stafford Heights, Qld 4053, Australia
‡von Berky Veterinary Services, 3 Hawthorne Street, Woody Point, Qld 4019, Australia
Correspondence: Petr Fisara, MSD Animal Health, 26 Artisan Road, Seven Hills, NSW 2147, Australia. E-mail: petr.fisara@merck.com

Background – Canine flea-allergy dermatitis (FAD), a hypersensitivity response to antigenic material in the saliva of feeding fleas, occurs worldwide and remains a common presentation in companion animal veterinary practice despite widespread availability of effective systemic and topical flea-control products.

Hypothesis/Objectives – To evaluate the clinical response in dogs with FAD treated topically with indoxacarb, a novel oxadiazine insecticide.

Animals – Twenty-five client-owned dogs in Queensland, Australia diagnosed with pre-existing FAD on the basis of clinical signs, flea-antigen intradermal and serological tests.

Methods – An open-label, noncontrolled study, in which all dogs were treated with topical indoxacarb at 4 week intervals, three times over 12 weeks.

Results – Twenty-four dogs completed the study. Complete resolution of clinical signs of FAD was observed in 21 cases (87.5%), with nearly complete resolution or marked improvement in the remaining three cases. Mean clinical scores (Canine Atopic Dermatitis Extent and Severity Index-03) were reduced by 93.3% at week 12. Mean owner-assessed pruritus scores were reduced by 88% by week 12. Mean flea counts reduced by 98.7 and 100% in weeks 8 and 12, respectively.

Conclusions and clinical importance – Topical indoxacarb treatment applied every 4 weeks for 12 weeks, without concomitant antipruritic or ectoparasiticide therapy, completely alleviated flea infestations in all dogs and associated clinical signs of FAD in a high proportion of this population of dogs in a challenging flea-infestation environment.

Introduction

Flea-allergy dermatitis (FAD) is a highly prevalent skin disease of dogs,[1–3] in which affected individuals experience a hypersensitivity response induced by antigens injected intradermally with the saliva of feeding fleas. Indoxacarb is an oxadiazine insecticide that has been shown to have significant insecticidal activity against the adult cat flea (*Ctenocephalides felis*),[4] recognized as the most common flea infesting dogs in the USA, Europe and Australia.[5–7] The insecticidal mechanism of action of indoxacarb is via blockade of neuronal voltage-dependent sodium channels.[8] Following ingestion or contact by fleas, indoxacarb is metabolized by insect esterase enzymes to a highly insecticidal form, a process called bioactivation.[9] In addition to flea adulticide activity, indoxacarb has been shown to have ovicidal activity[4] and to eliminate flea larval stages effectively in the host environment.[10]

The aim of this study was to quantify the reduction in flea infestation and associated clinical signs in client-owned dogs with FAD, treated topically with indoxacarb every 4 weeks for 12 weeks as the sole therapy.

Materials and methods

This was an open-label, noncontrolled study conducted according to Good Clinical Practice standards and compared mean quantified pretreatment clinical indices with values on three subsequent re-examinations at 4 week intervals.[11] Twenty-five client-owned dogs suspected to have FAD were enrolled in the study with written informed consent of their owners. A relocating owner withdrew one dog after week 4, leaving 24 dogs that completed the study. Results for this dog are included in the week 4 but not the week 8 and 12 calculations. Enrolled dogs were mixed and pure breeds, ranging from 10 months to 12 years old and weighing between 3.2 and 41.6 kg. The initial gender breakdown was as follows: five intact males, 11 neutered males, four intact females and five neutered females (the dog withdrawn from the study was an intact female). The study was conducted during the summer months in Queensland,

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Australia (between January and April), when the risk of flea exposure was high. Dogs were kept at home by their owners and fed and exercised according to their usual routine.

The dogs were diagnosed with FAD on the basis of clinical signs consistent with published descriptions of FAD.[12] All dogs were tested for immediate- and delayed-type hypersensitivity reactions to intradermally injected flea antigen (Greer Laboratories, Greer Veterinary, Lenoir, NC, USA). Wheal formation at the flea-antigen injection site at 5–10 min (immediate reaction) or 24 h (delayed reaction) postinjection was compared with reactions to the negative (saline) control, maize as a positive irritant control (grade 2+ wheal) and histamine (grade 4+ wheal). A flea-antigen site wheal between grades 2+ and 4+ was classified as consistent with flea-saliva hypersensitivity. If there were no skin reactions then a serum sample was submitted to a commercial laboratory for flea-antibody (IgE) serology testing (Allercept assay; Heska, Gribbles Veterinary Pathology Laboratory, Clayton, Victoria, Australia). There was a positive immediate- or delayed-type wheal response in 22 of the 25 dogs tested; blood samples from the three negative dogs tested positive for flea antibodies. Additional diagnostic tests for all dogs included skin scrapings, skin cytology and fungal culture; in all cases, these did not reveal any findings that provided an alternative explanation for the observed clinical signs.

Following completion of diagnostic testing, each dog was assessed during weeks 0, 4, 8 and 12 using three parameters as follows.

1. Lesions were measured by a veterinary dermatologist using the Canine Atopic Dermatitis Extent and Severity Index (CADESI-03).[13] For the purposes of analysis, the CADESI-03 results were arbitrarily and empirically converted into the following four nonvalidated categories of increasing severity, i.e. 'in remission' or 'insignificant', 'mild', 'moderate' and 'severe', based on score intervals of 0–15, 16–59, 60–119 and 120+, respectively. The CADESI scoring system is validated only for assessing clinical signs in dogs with atopic dermatitis.
2. Owners assessed pruritus severity using a score between 0 and 100 obtained from a cross (X) marked on a Pruritus Visual Analog Scale (PVAS).[14]
3. Flea counts were carried out at home using a modified method, where six representative skin areas were searched for fleas for 1 min. If no fleas were found then the entire body was searched for an additional 2 min and if no fleas were seen then the dog was classified as flea free.[15]

Treatment

Following diagnostic testing and baseline disease assessment, the attending veterinarian treated the dog topically with indoxacarb (Activyl®; Merck/MSD Animal Health, Summit, NJ, USA) at weeks 0, 4 and 8. The dose was applied to achieve a target dose of at least 15 mg/kg indoxacarb. Treatment was applied at one or more evenly distributed spots along the dorsal midline between the shoulder blades and base of the tail, with larger and heavier dogs receiving more treatment locations.

Owners were advised not apply any insecticidal treatment to their households or premises during the study period. The dogs received no concomitant treatment with any other flea-control products or with any drug having antipruritic or anti-inflammatory activity, including glucocorticoids, antihistamines and nonsteroidal anti-inflammatory agents, throughout the 12 week study; bathing was permitted. One dog developed bilateral otitis externa and a secondary aural haematoma during the study and received oral cefalexin (14 days), topical otic enrofloxacin and carprofen (3 days); the dog recovered fully. Another dog was diagnosed with a skin and ear infection on the initial study visit and was treated with cefalexin for 21 days and recovered fully.

Each owner gave informed signed consent, and the study was conducted according to Australian Animal Welfare guidelines, with pre-approval from the Queensland Department of Primary Industries and Fisheries: Community Access Animal Ethics Committee prior to commencement.[16]

Statistical analysis

All reported means are arithmetic, and data were transformed as described below to apply appropriate statistical techniques. Significance on statistical tests was declared for P-values <0.05.

Flea count analysis

Flea control efficacy was calculated as the percentage change between each post-treatment and pretreatment flea count using the formula: % Reduction = [1 − (PostTx value ÷ PreTx value)] × 100. Mean live flea counts on day 0 were compared with mean live flea counts at weeks 4, 8 and 12 using generalized linear models (log–linear modelling or regression, also called Poisson regression) for overdispersed Poisson data using the logarithmic link function.[17] This method produces an 'analysis of deviance', analogous to the 'analysis of variance' for normally distributed data. Observed flea counts were used for the analysis, and the mean–variance relationship was used to link mean counts to the linear model on a logarithmic scale. This analysis was calculated with the GenStat program (GenStat Release 7.2; VSN International Co., Oxford, UK).

Pruritus Visual Analog Scale analysis

Pruritus Visual Analog Scale (PVAS) results are not normally distributed because a disproportionate number of responses can be close to 0, particularly as treated dogs reach their final clinical assessment. Therefore, the nonparametric Wilcoxon signed-rank test for paired samples was used to compare differences in PVAS scores between the following three time points: day 0 and week 4; day 0 and week 8; and day 0 and week 12.

CADESI-03 scores

There were 25 pairs of categorized CADESI-03 scores for the pretreatment and week 4 time points. These were cross-classified to produce a 4 × 4 frequency table. Similar 4 × 4 tables were prepared for the 24 available pairs of scores for the pretreatment and week 8 time points and for the pretreatment and week 12 time points. Bhapkar's chi-square test for ordered categories, with three degrees of freedom, was used to test overall marginal homogeneity for the two 4 × 4 tables for each pair of time points. A significant result was declared when the sequence of marginal frequencies for the post-treatment categories differed from the sequence for the pretreatment categories to a greater extent than would be expected by chance. Each Bhapkar's chi-square test was followed by McNemar's chi-square test of the overall direction of change among the categories. The MH program [User Guide for the MH Program (version 1.2) 2006] was used for these analyses.

Results

All enrolled dogs showed significant improvement in observed clinical signs over the study period. Of the 24 dogs that completed the study successfully, 21 (87.5%) showed complete resolution of their clinical signs based on a CADESI-03 score category of 'insignificant' on the final visit. The other three dogs had almost complete resolution or very marked improvement. Some dogs recovered rapidly from clinical signs; 11 dogs (45.8%) had CADESI-03 scores categories of 'insignificant' by week 4, and seven additional dogs (29.2%) by week 8. Mean post-treatment CADESI-03 scores at week 4, 8 and 12 revisits were statistically significantly lower than the pretreatment scores (Table 1). No indoxacarb treatment-associated adverse clinical events were observed by owners or veterinarians.

Table 1. Mean pre- and post-treatment CADESI-03 scores of client-owned dogs affected with flea-allergy dermatitis treated topically with indoxacarb three times at 4 week intervals

Parameter	Pretreatment	4 weeks	8 weeks	12 weeks
Number of dogs	25	25	24	24
Mean CADESI-03 score	90.1	36.9	13.5	6.0
Percentage reduction from pretreatment	–	59.0	85.0	93.3
P value compared with pretreatment	–	<0.0001	<0.0001	<0.0001

Owner assessment of pruritus decreased significantly ($P < 0.001$) in all dogs over the study period. The mean pretreatment PVAS was 74.5, and this declined to 38.8, 18.7 and 8.9 in weeks 4, 8 and 12, representing reductions of 47.9, 74.8 and 88%, respectively. The lowest PVAS reported at the pretreatment examination was 50.5, while eight owners reported a PVAS of 0.0 at the end of the study period.

The mean pretreatment flea count was 18 per dog; all dogs were classified as flea free at the completion of the 12 week study (Table 2).

Discussion

This study demonstrated that, in this population, topical treatment of FAD-affected dogs every 4 weeks for 12 weeks with indoxacarb, with no concomitant ectoparasiticidal or antipruritic therapy, provided excellent control of clinical signs. All measures, including CADESI-03 scores; owner-assessed pruritus and flea counts, decreased significantly over the study period. The CADESI-03 scoring system is validated only for canine atopic dermatitis and not for FAD; furthermore, the CADESI system cannot be used to classify clinical signs as being definitively caused by FAD; therefore, the classification of the scores into four severity categories was empirical and not based on any formal assessment of the validity of this scoring system for dogs with signs of FAD. For the purposes of this study, it was considered that CADESI-03 provided a useful measurement of the severity of clinical signs. Clinical signs were reduced to 'insignificant' in 21 of the 24 enrolled dogs that completed the study. The one dog that did not complete the study had exhibited marked clinical improvement with an 'insignificant' CADESI-03 score at the time of withdrawal.

Table 2. Flea-control efficacy on dogs affected with flea-allergy dermatitis treated topically with indoxacarb three times at 4 week intervals

Paramter	Pretreatment	Week 4	Week 8	Week 12
No. of dogs	25	25	24	24
Mean flea count	18.0	1.1	0.3	0.0
Range	0–124	0–6	0–3	0
Efficacy (% reduction)	–	93.8	98.7	100.0
P value versus pretreatment	–	<0.001	<0.001	<0.001

Flea counts in all treated dogs decreased to zero by the end of the 12 week post-treatment period. Flea lifestage populations at the owners' homes were not assessed in this study; however, it has been shown previously in cats that indoxacarb treatment can eliminate flea lifestages in the environment and that indoxacarb treatment eliminated or markedly reduced flea egg production over a 45 day evaluation period.[4,9]

This study provided additional supporting evidence that clinical signs may still represent the optimal method for diagnosing FAD in dogs. All dogs enrolled in the study were considered to have clinical signs consistent with FAD; however, three of these 25 dogs were negative on skin testing with flea allergen and six of the dogs were flea free on pretreatment flea counts. Clinicians suspecting FAD based on clinical signs will probably continue to recommend effective flea treatment as a reliable method for subsequent evaluation of the aetiology of these signs.

The results of this study show that topical indoxacarb treatment controlled flea infestations, and it can be recommended for the management of flea-allergy dermatitis in dogs. Given the likelihood of reinfestation of dogs, veterinarians should recommend that owners maintain an ongoing programme of effective flea control to prevent re-emerging flea infestations triggering a recurrence of clinical signs in flea-allergic dogs.

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Résumé

Contexte – La dermatite par allergie aux piqures de puces (FAD), une hypersensibilité aux antigènes salivaires des puces, est décrite dans le monde entier et reste une présentation fréquente en médicine vétérinaire des animaux de compagnie malgré une large gamme d'antiparasitaires topiques et systémiques efficaces disponibles.

Hypothèses/Objectifs – Estimer la réponse clinique des chiens atteints de FAD recevant de l'indoxacarb topique, un nouvel insecticide de la classe des oxadiazines.

Sujets – Vingt cinq chiens de propriétaires du Queensland, Australie, précédemment diagnostiqués allergiques aux puces à partir des signes cliniques, des tests intradermiques et des tests sérologiques.

Méthodes – Une étude ouverte, non contrôlée, dans laquelle tous les chiens ont été traités avec de l'indoxacarb topique à 4 semaines d'intervalles, trois fois sur 12 semaines.

Résultats – Vingt quatre chiens ont été inclus dans l'étude. Une résolution complète des signes cliniques de FAD a été observée pour 21 cas (87.5%), ave une résolution presque complète ou une amélioration marquée pour les trois autres cas. Les scores cliniques moyens (Canine Atopic Dermatitis Extent and Severity Index-03) ont été réduits de 93.3% à la semaine 12. Les scores de prurit moyens ont été réduits de 88% à la semaine 12. Les comptages moyens de puce ont été réduits de 98.7% et 100% respectivement aux semaines 8 et 12.

Conclusions et importance clinique – Le traitement topique d'indoxacarb appliqué toutes les 4 semaines pendant 12 semaines, sans antiprurigineux ou ectoparasitaire concomitant, a complètement supprimé l'infestation de puces pour tous les chiens et les signes cliniques associés à la FAD pour une large proportion de cette population de chiens dans un environnement contenant des puces.

Resumen

Introducción – la dermatitis alérgica a las pulgas en perros (FAD), es una respuesta de hipersensibilidad a material antigénico en la saliva de las pulgas que se alimentan en los perros. Ocurre a nivel mundial y aún permanece como una presentación común en los animales de compañía en las prácticas veterinarias, a pesar de la disponibilidad de efectivos tratamientos sistémicos y tópicos para el control de las pulgas.

Hipótesis/Objetivos – evaluar la respuesta clínica en perros con FAD tratados tópicamente con inoxacarb, novedoso insecticida de tipo oxadiacina.

Animales – 25 animales de propietarios particulares en Queensland, Australia, diagnosticados con FAD en base a los signos clínicos, y pruebas serológicas intradérmicas para el antígeno de las pulgas.

Métodos – se realizó un estudio abierto no controlado en el cual los perros fueron tratados con indoxacarb por vía tópica a intervalos de cuatro semanas, tres veces en el curso de 12 semanas.

Resultados – 24 perros completaron el estudio. La resolución completa de los signos clínicos de FAD fue observada en 21 casos (87,5%), con casi completa resolución o una marcada mejora en los restantes tres casos. El valor medio de evaluación clínica (índice de extensión y severidad de la dermatitis atópica canina-03) se redujo un 93,3% en la semana 12. Los valores medios de prurito evaluados por los propietarios se redujeron en un 88% en la semana 12 los recuentos medios de pulgas se redujeron un 98,7 y un 100% en las semanas 8 y 12, respectivamente.

Conclusiones e importancia clínica – el tratamiento tópico con indoxacarb aplicado cada cuatro semanas durante 12 semanas, sin tratamientos complementarios antipruriticos o terapia ectoparásiticida, alivian completamente la infestación por pulgas en todos los perros y los signos clínicos asociados con FAD en una alta proporción de esta población de perros en un ambiente con contacto con pulgas.

Zusammenfassung

Hintergrund – Die Flohspeichelallergie des Hundes (FAD), bei der es sich um eine Hypersensibilitätsreaktion auf das Antigenmaterial im Speichel von saugenden Flöhen handelt, kommt weltweit vor und stellt einen häufigen Vorstellungsgrund in der Kleintierpraxis dar, obwohl weltweit wirksame systemische und topische Flohkontrollprodukte verfügbar sind.

Hypothese/Ziele – Eine Evaluierung der klinischen Antwort von Hunden mit FAD, die topisch mit Indoxacarb, einem neuen Oxadiazin Insektizid, behandelt worden waren.

Tiere – Fünfundzwanzig private Hunde in Queensland, Australien, die mit bereits existierender FAD basierend auf klinischer Symptomatik, positiven Intradermaltests und positiver Serologie auf Flohallergen diagnostiziert worden waren.

Methoden – Eine offene, nicht kontrollierte Studie, in der alle Hunde mit topischem Indoxacarb in 4 wöchigen Intervallen, drei Mal über einen Zeitraum von 12 Wochen behandelt wurden.

Ergebnisse – Vierundzwanzig Hunde beendeten die Studie. Eine gänzliche Abheilung der klinischen Anzeichen von FAD wurde in 21 Fällen beobachtet (87,5%), bei nahezu völligem Verschwinden oder einer deutlichen Verbesserung in den restlichen drei Fällen. Die durchschnittlichen klinischen Werte (Canine Atopic Dermatitis Extent and Severity Index-03) waren in der zwölften Woche um 93,3% reduziert. Die durchschnittlichen, von den BesitzerInnen beurteilten, Juckreizwerte waren in der zwölften Woche um 88% reduziert. Die durchschnittliche Anzahl an Flöhen war in den Wochen 8 und 12 um 97,7 bzw 100% reduziert.

Schlussfolgerungen und klinische Bedeutung – Indoxacarb, welches topisch alle 4 Wochen 12 Wochen lang ohne begleitende juckreizstillende Behandlung oder einer Behandlung von Ektoparasiten verabreicht wurde, milderte die Flohinfestationen bei allen Hunden und die mit FAD auftretenden klinischen Symptome in einer großen Proportion dieser Hundepopulation, die in einer schwierigen Umgebung mit hohem Flohvorkommen, lebten.

要約

背景 – イヌのノミアレルギー性皮膚炎(FAD)は寄生したノミの唾液中の抗原物質に反応する過敏症であり、効果的な全身性および外用ノミ駆虫製品が世界中で入手可能であるにも関わらず、世界中で発生し、コンパニオンアニマルの獣医診療において相変わらず一般的な来院理由となっている。

仮説/目的 – 新規のオキサジアジン系殺虫剤のインドキサカルブを外用で治療したFADのイヌにおける臨床反応を評価すること。

供与動物 – 臨床症状とノミ抗原の皮内反応、血清学的検査をもとにFADが基礎として存在すると診断されたオーストラリアのクイーンズランドの25頭の飼い犬。

方法 – 全てのイヌで外用インドキサカルブを4週間隔で12週にわたり治療した非盲検、非対照研究。

結果 – 24頭のイヌが調査を完了した。FADの臨床症状の完全な消失は21頭で認められ(87.5%)、残りの3症例ではほぼ完全な消失、あるいは著しい改善がみられた。平均臨床スコア(Canine Atopic Dermatitis Extent and Severity Index-03)は12週の時点で93.3%減少した。平均オーナー評価そう痒スコアは12週までに88%減少した。平均ノミ数は8週と12週でそれぞれ98.7%および100%減少した。

結論および臨床的な重要性 – 4週毎、12週間の外用インドキサカルブ療法は抗そう痒薬や外用寄生虫駆虫治療の併用なしで、すべてのイヌで完全にノミ感染を緩和し、ノミが蔓延した困難な環境中におけるイヌの集団でも高い割合でFADに関連する臨床症状を完全に緩和した。

摘要

背景 - 犬跳蚤过敏性皮炎(FAD)是一种对跳蚤唾液中的抗原物质有反应的过敏症。尽管广泛的使用全身或局部的驱蚤药，在世界各地的兽医临床，此病仍经常出现。

假设/目的 - 茚虫威是一种新型噁二嗪杀虫剂，评估这种外用药治疗FAD患犬的临床反应。

动物 - 25只来自澳大利亚昆士兰州的犬，曾通过临床症状、皮内抗原实验和血清学试验确诊为FAD。

方法 - 在非盲无对照性实验中，所有患犬外用茚虫威4周一次，连用12周。

结果 - 24只犬完成实验。21只犬(87.5%)临床症状完全消失，剩下3只几乎完全消失或有显著改善。12周后临床评分（犬异位性皮炎程度和严重指数-03）平均下降93.3%。12周后主人进行的瘙痒评分平均下降了88%。跳蚤数量8周和12周分别平均减少了98.7%和100%。

总结和临床意义 - 外用茚虫威治疗每四周一次，连续治疗12周，不需止痒剂及杀外寄生虫剂，可以彻底缓解所有犬的跳蚤感染，以及大多数犬相关的FAD临床症状，即使犬生活在能够受到跳蚤感染的环境中。

