Evaluation of a clinical scoring system for canine demodicosis

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Background – Canine demodicosis is a common disease in small animal practice. Although a number of studies evaluating treatment efficacy for canine demodicosis have used clinical scoring systems, none have been validated.

Objectives – This study evaluated the validity, reliability, reproducibility and sensitivity to change of a clinical scoring system for canine demodicosis.

Methods and materials – Fifty-eight dogs with generalised demodicosis were evaluated using a clinical scoring system that assessed erythema, comedones/papules/pustules, follicular casts/scales/crusts and alopecia, rated from none to mild, moderate and severe in 36 body locations. Two evaluators scored lesions at monthly consecutive visits during treatment. Mites were counted to a maximum of 50 in four deep skin scrapings. With >50 mites, the approximate mite number was calculated with the help of a grid drawn onto the slide before placing the scraped material onto it.

Results – A Pearson correlation coefficient showed a high interobserver reliability (r = 0.97) between two different clinicians evaluating the same dog. The Wilcoxon signed rank test showed good sensitivity to change with a reduction of clinical scores with each of the first six evaluations (P < 0.0001). A linear mixed model also showed a clear reduction in mite counts (P < 0.001) and clinical scores (P < 0.0001) from the first evaluation with time.

Conclusion and clinical relevance – The clinical scoring system for canine demodicosis evaluated in this study showed a good sensitivity to change and interobserver reliability, and can be used in studies evaluating canine demodicosis.

Introduction

Demodicosis is a common skin disease in small animal practice resulting from excessive proliferation of Demodex mites in hair follicles. Initial clinical signs include mild hypotrichosis or multifocal alopecia, with or without erythema and scales. More severe signs such as papules, crusts and ulceration occur as the disease progresses, and these become exacerbated by bacterial folliculitis. Severe affected dogs may show systemic signs such as fever, anorexia and septicaemia caused by secondary bacterial infection.1,2

The many studies evaluating the treatment of canine demodicosis have been the topic of both systematic reviews3,4 and international guidelines.5-8 However, a reliable clinical scoring system to evaluate treatment success or failure, as reported for canine atopic dermatitis6,8 has not been reported. To validate a clinical scoring system, a number of aspects should be evaluated. Validity is evaluated by content, construct and criterion elements. To achieve content validity, a score should include all relevant clinical aspects of a disease.3 Construct validity means that related variables are in agreement with the scoring system, while assessment of criterion validity requires that the new scoring system be compared to a gold standard.9

Other scoring systems have been used to evaluate treatment success in dogs with demodicosis.10-15 Most of these evaluate the presence of lesions and extent of body surface involved, yet to the best of the authors’...
knowledge, none of them have been validated. The clinical scoring system evaluated by the present study has been used previously, yet has not yet been evaluated for reliability and validity. Therefore, the aim of this study was to evaluate the reliability and validity of a clinical scoring system for canine demodicosis. A validated scoring system should be used in future studies of canine demodicosis to strengthen the evidence base for therapeutic outcomes, where it will allow direct comparison of studies and evaluation of metadata.

Methods and materials

Study animals, diagnosis and treatment monitoring

Dogs of various breeds with generalised demodicosis were included in the study. Before inclusion, owners were asked to sign an informed consent form. A complete history was recorded at the first evaluation. When demodicosis was suspected, the diagnosis was confirmed with positive deep skin scrapings. Four deep skin scrapings were obtained from 1 cm² areas of affected skin with a #10 scalpel blade until capillary bleeding was achieved. The scraped skin was squeezed before and during the scraping to maximize yield. At each monthly evaluation, the same four lesion sites were sampled. Adult Demodex mites (short-bodied, normal and long-bodied), larvae, nymphs and eggs were counted at ×100 magnification. The slide was divided into eight parts with a permanent marker before placing the scraped material onto it to facilitate mite counts. Mites on each slide were counted to the nearest 50. In those dogs with a maximum of 50. In those dogs with a maximum of 50, the approximate mite number was determined by adding all individual scores. Figure 1a,b depicts varying degrees of severity of lesions assessed in this clinical scoring system for canine demodicosis.

Design of the clinical scoring system for canine demodicosis

The scoring system included 36 body areas (Supporting information, Table S1). At each site, scores were assigned to quantify erythema, comedones/ papules/ pustules, follicular casts/scales/crusts, and alopecia, respectively. Lesions were rated from none (0), to mild (1–2), moderate (3–4) and severe (5–6), and the overall score was determined by adding all individual scores. Figure 1a,b depicts varying degrees of severity of lesions assessed in this clinical scoring system for canine demodicosis.

Evaluation of validity

The purpose of validity is to verify that a scale measures what it is intended to measure. The “content” property of validity is based on the statement of one or more experts that the scale exhibits all relevant domains. A panel of international veterinary dermatologists consisting of the authors of the Clinical Consensus Guidelines for Demodicosis initiated by the World Association for Veterinary Dermatology was asked to assess this proposed scoring system. The “construct” property of a disease scale or grading system is assessed by answering the following question: Does this scale agree with other related variables and measures of the same construct with which, in theory, it ought to agree? In order to address this, the lesion score was compared with the number of Demodex mites on skin scrapings. The “criterion” property is determined by the answer to the question: Does the scale correlate with some other measures of the disease, ideally a “gold standard” that has been used and accepted in the field? The criterion property of the proposed lesion score was evaluated by treating affected dogs with a course of oral ivermectin and determining the post-treatment change from baseline in the number of mites. Skin scrapings have been considered an objective and relevant “gold standard” measure of treatment success for canine demodicosis for decades.

Evaluation of reliability

A disease scale can be considered to be reliable if it measures what it is intended to measure in reproducible way. In this study, two veterinarians investigated the same dog within 1 h in a blinded fashion (i.e. without being aware of the other’s scoring) and their scores were compared.

Evaluation of sensitivity to change

The sensitivity to change in this study was evaluated by comparing the monthly re-evaluations of the same patient over the treatment period. All dogs were treated with oral ivermectin at a dose of 600 µg/kg/day, a treatment shown to be effective in many studies and recommended in international guidelines. It was assumed that an improvement in clinical scores should occur every month with this treatment in the majority of dogs.

Statistical evaluation

The correlation between the scores of the two veterinarians was evaluated with a graphical design, a Bland-Altman plot and a linear mixed model. The linear mixed model and a box plot were used additionally to describe the correlation between the two veterinarians’ scores, and between the mean of the two scores and the number of Demodex mites at that particular evaluation. To verify the reproducibility of the clinical scoring system for canine demodicosis, a Pearson correlation coefficient of the scores obtained by the two clinicians was calculated. For the evaluation of sensitivity to change, a Wilcoxon signed rank test and a linear mixed model were used, and the first six evaluations were evaluated statistically. In addition, a correlation analysis between mite numbers and clinical scores was conducted using a Spearman test. A P-value <0.05 was considered to be statistically significant.

Results

Study subjects

Fifty-eight dogs were included in this study. The mean age of disease onset was 5.6 months for juvenile generalised demodicosis (range 2–24 months) and 4.0 years for adult-onset demodicosis (range 2.5–5 years). Twelve dogs were mixed breed and there were nine pugs, seven English bulldogs, three Doberman pinschers and three French bulldogs. Russian toy terriers, Scottish terriers, West Highland white terriers, and Yorkshire terriers were each represented twice, and there was one each of American bulldog, American Staffordshire terrier, bull terrier, Ca de Bou, Central Asian shepherd, Chihuahua, Dachshund, dogues de Bordeaux, German shepherd dog, Jack Russell terrier, Mastino Napoletano, Russian borzoi, shar-pei, shih tzu, Mittelspitz and toy terrier. Dogs were re-evaluated every month, and the number of evaluations ranged from one to 11 (most were evaluated four times). A total of 252 visits were evaluated (Table S2). The mean clinical score on the first visit was 159 (range 20–580), the mean mite count on that visit was 237 (range 7–1,150).

Evaluation of validity

An expert panel determined that lesions of demodicosis were adequately represented by the scoring rubric, yet did comment that clinical signs of deep pyoderma (not infrequently associated with severe demodicosis) such as dermal inflammation, haemorrhagic bullae, cellulitis or fistulae were not included. The construct and criterion

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Figure 1. Examples of erythema, papules and crusts (a) and alopecia (b) in dogs with generalised demodicosis judged as mild, moderate or severe.
The clinical scoring system’s response to change can be demonstrated in two different ways. The Wilcoxon signed rank test showed a statistically significant reduction of clinical scores with each of the first six evaluations ($P < 0.0001$). The linear mixed model also showed a clear reduction from the first evaluation with time (Figure 2). The Spearman correlation between mite numbers and clinical scores was strong ($r = 0.7$, $P < 0.0001$).

**Discussion**

The goal of this study was to evaluate a clinical scoring system for canine demodicosis. Its high reproducibility and sensitivity to change, and its documented validity make this a useful tool to evaluate clinical signs of canine demodicosis in therapeutic trials.

It is important in any healthcare environment to have access to validated clinical scoring systems. This allows comparison and possibly meta-analysis of studies evaluating specific diseases. It also permits clinicians to meaningfully exchange opinion about specific cases and judgement about improvement or deterioration of a specific patient over time, even when seen by different clinicians. This is particularly important in dermatological practice, where objective laboratory parameters are not always available for comparison.9

The first validated scoring system in veterinary dermatology was the Canine Atopic Dermatitis Extent and Severity Index (CADESI),6,7 which is useful for comparing patients in the clinical and research setting. The CADESI comprises four parts: two subscores to evaluate acute (erythema and excoriation) and two subscores for chronic lesions of atopic dermatitis (alopecia and lichenification). Likewise, our scoring system used lesions observed with canine demodicosis (erythema, alopecia, comedones, papules, pustules, follicular casts, scales and crusts) at 36 body sites. All of them were rated on a scale from 0 (none) to 6 (severe) for each lesion. Although this scoring system was previously used successfully in a number of published studies,16–18 to date this had not been validated.

Other studies have used different clinical scoring systems to evaluate lesions in dogs with demodicosis.10–15 In one study, a very simple combination of lesion severity and affected area was used.10 A number of studies evaluated the percentage of dogs still displaying relevant clinical signs such as erythema, crusts and alopecia after treatment.11,12,15 The affected body surface also was considered in some studies.13–15 One study evaluated alopecia, erythema, pustules, papules and scales/crusts as mild, moderate and severe, and also considered the extent of those lesions.13 This study was most similar to the clinical scoring system validated in the present study. However, none of these other scoring systems have been validated.

The expert panel which was consulted on the content validity of the scoring system commented that it failed to include signs of deep pyoderma. However, the authors chose not to add these parameters of lesion assessment as this scoring system is intended to evaluate lesions.
caused by demodicosis and not bacterial infection (although the latter may be associated with severe canine demodicosis). Thus, the score as reported here was considered to include all relevant aspects of clinical demodicosis itself. To evaluate criterion validity, the number of mites counted on skin scrapings at each visit were chosen as a surrogate variable, because a decrease in mite numbers is an accepted way to monitor treatment success\textsuperscript{2,3} and there is no other known gold standard for clinical evaluation of dogs with demodicosis. This number indeed correlated well with clinical scoring.

The interobserver reliability testing had an almost perfect outcome with a correlation coefficient close to 1. The intraobserver reliability was not determined, as this would have required that the same clinician evaluate each dog twice during a period of time long enough to decrease the chance of bias, and not sufficiently long to lead to a change in clinical status of the patient. As this study was conducted on client-owned outpatients, the alternative of asking owners to leave the dog in the hospital for several hours, or to return the next day after each appointment, was deemed to be unrealistic.

Another limitation of the study is that the two clinicians evaluating each dog were coworkers, one of whom mentored the other in a dermatology training programme. Thus, both may have had a similar way of evaluating lesion severity. It would be interesting to repeat the study using two clinicians with greater clinical independence.

In conclusion, this study evaluated a clinical scoring system for canine demodicosis, and showed good validity and reliability for the proposed score. It is hoped that future studies which evaluate therapies for canine demodicosis will use this clinical scoring system. Consistency of methodology across studies should permit comparison of results and meta-analyses of data from larger numbers of subjects.

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Supporting Information

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

Table S1. Clinical scoring system used to assess lesions in dogs with generalised demodicosis.

Table S2. Scores of dogs and mite numbers of skin scrapings of each evaluation of all dogs included in the study evaluating a scoring system for canine demodicosis.

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**Objectifs** – Cette étude évalue la validité, la fiabilité, la reproductibilité et la sensibilité pour changer le système de scorage clinique pour la démodicécie canine.

**Matériaux et méthodes** – Cinquante huit chiens avec démodicécie généralisée ont été évalués à l’aide d’un système d’évaluation clinique qui concerne érythème, comèdons/papules/pustules, manchons pilaires/squames/croûtes et alopecie notés de aucun à faible, modéré et sévère sur 36 zones corporelles. Deux investigateurs ont noté les lésions à des visites consécutives mensuelles au cours du traitement. Les acariens ont été comptés pour un maximum de 50 dans quatre raclages cutanés profonds. Avec plus de 50 acariens, le nombre approximatif d’acariens a été calculé avec l’aide d’une grille sous la lame avant de pla- 
et le matériel raclé dessus.

**Résultats** – Un coefficient de corrélation de Pearson a montré une fiabilité inter-observateur élevé ($r = 0.97$) entre deux différents cliniciens évaluant le même chien. Le test de Wilcoxon a montré une bonne sensibilité au changement avec une réduction des scores cliniques avec chacune des six premières éva- 
uations ($P < 0.00001$). Un modèle mixte linéaire a aussi montré une réduction claire des comptages d’acariens ($P < 0.001$) et des scores cliniques ($P < 0.00001$) de la première évaluation avec le temps.

**Conclusion et importance clinique** – Le système de scoring clinique pour la démodicécie canine évalué dans cette étude a montré une bonne sensibilité au changement et à la fiabilité interobservateur et peut être utilisé dans les études évaluant la démodicécie canine.

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**Resumen**

**Introducción** – la demodicosis canina es una enfermedad común en la práctica de animales pequeños. Aunque se han publicado estudios que evalúan la eficacia del tratamiento para la demodicosis canina utilizando sistemas de puntuación clínica, ninguno ha sido validado.

**Objetivos** – en este estudio evaluó la validez, fiabilidad, reproducibilidad y sensibilidad a cambios de un sistema de valoración clínica para la demodicosis canina.

**Métodos y materiales** – se evaluaron cincuenta y ocho perros con demodicosis generalizada utilizando un sistema de valoración clínica que puntuaba eritema, comedones/papules/pustules/cílios/foliculares/es- 
camas/costras y alopecia, calificados de nada a leve, moderado y grave en 36 ubicaciones corporales. Dos evaluadores puntuaron las lesiones en visitas mensuales consecutivas durante el tratamiento. Los acaros se contaron hasta un máximo de 50 en cuatro raspados profundos de la piel. Con > 50 acaros, el número aproximado de acaros se calculó con la ayuda de una cuadrícula dibujada en el portaobjetos antes de colo- 
car el material raspado sobre él.

**Resultados** – el coeficiente de correlación de Pearson mostró una alta fiabilidad interobservador ($r = 0.97$) entre dos clínicos diferentes que evaluaban al mismo perro. La prueba de rango señalado de Wilcoxon mostró una buena sensibilidad al cambio con una reducción de las puntuaciones clínicas con cada una de las primeras seis evaluaciones ($P < 0.00001$). Un modelo lineal mixto también mostró una clara reducción en los recuentos de acaros ($P < 0.001$) y puntuaciones clínicas ($P < 0.00001$) desde la primera evaluación con el tiempo.

**Conclusión y relevancia clínica** – el sistema de puntuación clínica para la demodicosis canina evaluado en este estudio mostró una buena sensibilidad al cambio y fiabilidad entre observadores, y puede utilizarse en estudios que evalúen la demodicosis canina.

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**Zusammenfassung**

**Hintergrund** – Die canine Demodikose ist eine häufige Erkrankung in der Kleintierpraxis. Obwohl eine Anzahl an Studien die Wirksamkeit der Behandlung mit Hilfe eines klinischen Bewertungssystems evaluiert hat, ist noch keines davon validiert worden.

**Ziele** – Diese Studie evaluierte die Validität, Reliabilität, Reproduzierbarkeit und Sensibilität auf Verände- 
ung eines klinischen Bewertungssystems für die canine Demodikose.

**Methoden und Materialien** – Achtundfünfzig Hunde mit einer generalisierten Demodikose wurden mit- 
tels klinischem Bewertungssystem welches an 36 Körperstellen Erythem, Komedonen/Papeln/Pusteln, Follikuläre Manschetten/Schuppen/Krusten und Alopecie, von nicht vorhanden bis mild, moderat und schwerwiegend bewertete. Zwei BeurteilerInnen bewerteten die Veränderungen an monatlich aufeinan- 
derfolgenden Besuchen während der Behandlung. Die Milben wurden bis zu einem Maximum von 50 in vier tiefen Hautgeschabsels gezählt. Bei > 50 Milben wurden die annähernde Milbenzahl mit Hilfe eines Ras- 
ters, welcher auf den Objektträger aufgezeichnet wurde, bevor das Material des Hautgeschabsels darauf aufgebracht wurde, kalkuliert.

**Ergebnisse** – Ein Pearson Korrelationskoeffizient zeigte eine hohe Interbeobachter Reliabilität ($r = 0.97$) zwischen zwei unterschiedlichen KlinikerInnen, die denselben Hund untersuchten. Der Wilcoxon- 
Vorzeichen-Rang-Test zeigte eine gute Sensibilität auf Veränderung durch eine Verringerung der klinischen 
Werte bei einer jeden der ersten sechs Evaluierungen ($P < 0.0001$). Ein lineares gemischtes Modell zeigte 
auch eine klare Reduzierung der Milbenzahl ($P < 0.001$) und der klinischen Werte ($P < 0.00001$) mit der 
Zeit nach der ersten Evaluierung.
要約
背景 - 犬ニキビダニ症の皮膚病学的特徴を理解するため、犬ニキビダニ症に対する治療効果を評価する研究では、臨床的なスコアリングシステムの有用性が示唆されているが、その検証の必要性がある。

目的 - 本研究の目的は、犬ニキビダニ症の臨床スコアリングシステムの妥当性、信頼性、再現性、変化に対する感度を評価することであった。

材料と方法 - 減発性ニキビダニ症の58頭の犬、及び、その36箇所で、軽度、中等度、重度のニキビダニ症を含む50匹のダニの個体を対象とした。ダニの数は4頭の深部皮膚探取で最大50匹まで数えられた。50匹以上の場合は、検体をスライドに載せる前に、スライドに描かれたグリッドを用いて対応するダニの数を算出した。

結果 - ビアソン相関係数により、同じ犬を評価する2人の異なる綱維の間で高い観察者間信頼性 (r = 0.97) が示された。Wilcoxon signed rank testでは、最初の6回の評価ごとに臨床スコアが低下し、変化に対する感度が高いことが示された (P < 0.0001)。また、線形混合モデルでは、最初の評価から時間の経過とともにダニの数 (P < 0.0001) と臨床スコア (P < 0.0001) が明らかに減少した。

結論 - 本研究で評価された犬ニキビダニ症の臨床スコアリングシステムは、変化に対する良好な感度と観察者間の信頼性を示し、犬ニキビダニ症を評価する研究に使用することが可能である。

Findings
Background - The clinical features of canine demodicosis were evaluated in a study of 58 dogs with lesions of various severities (light, moderate, severe). The number of Demodex mites was measured using a grid on slides.

Results - The inter-observer reliability (r = 0.97) was high. Wilcoxon signed rank test showed a decrease in clinical score over the first 6 visits. Linear mixed models showed a decrease in mite numbers (P < 0.0001) and clinical score (P < 0.0001) over time.

Conclusion - The clinical scoring system for canine demodicosis was shown to be reliable and valid for use in research.

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