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Reliability and discriminatory testing of a client-based metrology instrument, feline musculoskeletal pain index (FMPI) for the evaluation of degenerative joint disease-associated pain in cats

J. Benito [a], V. DePuy [b], E. Hardie [a], H. Zamprogno [a], A. Thomson [a], W. Simpson [c], S. Roe [a], B. Hansen [a], B.D.X. Lascelles [a,d,*]

[a] Comparative Pain Research Laboratory, Department of Clinical Sciences, College of Veterinary Medicine, North Carolina State University, Raleigh, NC, USA
[b] Bowden Statistical Consulting, Oxford, NC, USA
[c] Morrisville Cat Hospital, Morrisville, NC, USA
[d] Center for Comparative Medicine and Translational Research, College of Veterinary Medicine, North Carolina State University, Raleigh, NC, USA

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ABSTRACT

The objective of this study was to test the readability, reliability, repeatability and discriminatory ability of an owner-completed instrument to assess feline degenerative joint disease (DJD)-associated pain (feline musculoskeletal pain index, FMPI). Readability was explored using four different formulas (Flesch, Fry, SMOG and FOG) and the final FMPI instrument was produced. To assess the instrument, client-owned cats that were defined as normal (normal group) or as having DJD-associated pain and mobility impairment (pain-DJD group) were recruited. A total of 32 client-owned cats were enrolled in the study (normal, $n = 13$; pain-DJD, $n = 19$). Owners completed the FMPI on two occasions, 14 days apart. Internal consistency (reliability) and repeatability (test–retest) were explored using Cronbach's α and weighted κ statistic, respectively. Data from the two groups were compared using analysis of covariance (controlling for age) to evaluate discriminatory ability.

The FMPI was constructed with 21 questions covering activity, pain intensity and overall quality of life. It had a 6th grade readability score. Reliability of the FMPI was excellent (Cronbach's $\alpha > 0.8$ for all groupings of questions in normal and pain-DJD cats) and repeatability was good (weighted κ statistic >0.74) for normal and pain-DJD cats. All components of the FMPI were able to distinguish between normal cats and cats with DJD ($P < 0.001$ for all components). This initial evaluation of the FMPI suggests that this instrument is worthy of continued investigation.

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Introduction

Published information indicates that degenerative joint disease (DJD) is common in domesticated cats (Beadman et al., 1964; Clarke and Bennett, 2006; Clarke et al., 2005; Godfrey, 2005; Hardie et al., 2002; Koeppel and Ebner, 1990; Langenbach et al., 1998; Lascelles et al., 2010b; Slingerland et al., 2011). Several studies have identified cats with radiographic DJD and mobility impairment (Bennett and Morton, 2009; Clarke and Bennett, 2006; Lascelles et al., 2001, 2007, 2010a) and these studies have found that non-steroidal anti-inflammatory drug (NSAID) administration significantly improved mobility (Clarke and Bennett, 2006; Lascelles et al., 2001, 2007).

In the USA there are no approved drug therapies for the treatment of feline chronic musculoskeletal pain. This is partly due to the fact that there is no validated assessment tool for use in clinical trials, such as an owner-completed questionnaire. Previous work in our laboratory has identified items that might be valid for inclusion in such a questionnaire and we have also identified the preferred structure of such a questionnaire (Zamprogno et al., 2010). The aim of the study described here was to build on previous work and further develop and evaluate a questionnaire for the assessment of feline musculoskeletal pain.

We hypothesized that an appropriately developed subjective owner-completed instrument to assess chronic feline DJD-associated pain (feline musculoskeletal pain index, FMPI) would prove reliable and have discriminatory validity. The objectives of this study were (1) to use information generated in previous work (Zamprogno et al., 2010) to construct a candidate instrument; (2) to perform readability testing of the candidate instrument and generate the test instrument (FMPI); (3) to perform reliability test-

* Corresponding author at: Comparative Pain Research Laboratory, Department of Clinical Sciences, College of Veterinary Medicine, North Carolina State University, Raleigh, NC, USA. Tel.: +1 919 513 6762.
E-mail address: duncan_lascelles@ncsu.edu (B.D.X. Lascelles).

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ing of the FMPI (test–retest and internal consistency) in normal cats and cats with DJD-associated pain, and (4) to test the instrument for its ability to discriminate between normal cats and cats with DJD-associated pain.

Materials and methods

Animals

This study was approved by the Animal Care and Use Committee at North Carolina State University College of Veterinary Medicine (NCSU-CVM; IACUC 08-124-O), and informed owner consent was granted in each case. The instrument was constructed, tested for readability and adjusted accordingly. Then, using normal cats and cats with DJD-associated pain and mobility impairment, the instrument was evaluated for reliability and repeatability and its ability to discriminate between normal and DJD-affected animals.

The aim was to recruit a total of 40 cats to the study, namely, 20 normal client-owned cats without reported mobility impairment, and radiographic DJD and pain scores that were considered clinically insignificant (normal group), and 20 cats with mobility impairment, significant radiographic DJD and at least one joint with both radiographic DJD and pain on manipulation (DJD group). Potential owner participants were required to be 18 years or older, to appear to understand the study and the study demands, and to be able to keep their household routine as constant as possible for the duration of the study.

Evaluation of potential study candidates (screening)

Prior to the screening visit, owners of cats that could potentially be enrolled in the study were contacted and sent a consent form to review and a detailed questionnaire to complete. The questionnaire contained approximately 70 questions pertaining to the cat's lifestyle and mobility, and was reviewed to determine if there were indicators of mobility impairment. Potential candidates were then screened at the Veterinary Health Complex. Owners who reported any mobility impairment completed a Client Specific Outcome Measures evaluation as previously described (Lascelles et al., 2007) to determine whether any specific activities were impaired. Cats were screened with a physical examination, orthopedic and neurological examinations, CBC, blood chemistry, urine analysis and orthogonal radiographs of all appendicular joints and all parts of the axial skeleton. Each cat was weighed, and body condition score (BCS) and temperament (Lascelles et al., 2012) recorded.

Inclusion criteria

To be included in the normal group, cats were required to have a total pain score (see below) of $\leqslant$5 with no one joint pain score being >2, and a total DJD score (see below) of $\leqslant$10, with no one joint score >4 and no evidence of owner-reported mobility impairment. To be included in the pain-DJD group, cats were required to have a total pain score >5 and a total DJD score >10, and have overlap of positive pain and DJD scores in at least one joint. Additionally, cats in the pain-DJD group were required to have a CSOM score of at least 7 (with at least two of the five activities with a score of at least 2, the other three having a score of at least 1).

Orthopedic evaluation

Every joint (the manus and pes were considered single joints) and each part of the axial skeleton (cervical, thoracic, lumbar, and lumbo-sacral) was palpated and manipulated. A pain response score resulting from the manipulation was assigned to each joint or axial skeleton segment on a 0–4/4 scale, as described previously (Lascelles et al., 2010a, 2012; Zamprogno et al., 2010). The total pain score was the addition of all the individual appendicular joint and axial skeleton segment scores.

Under sedation, orthogonal radiographs of all the appendicular joints and axial skeleton segments were made. The orthopedic evaluation was repeated under sedation to rule out concomitant orthopedic diseases. Radiographs were reviewed and scored by two investigators (BDXL and JB) as previously reported (Freire et al., 2011; Lascelles et al., 2010b) resulting in a DJD score (out of 10) for each joint and part of the axial skeleton. The addition of these resulted in a total DJD score (maximum 200).

Exclusion criteria

Exclusion criteria for all cats included the presence of suspected or diagnosed infectious diseases, symptomatic cardiac disease, immune-mediated disease, neoplasia, moderate or severe renal disease (see later), inflammatory bowel disease, urinary tract infection, hyperthyroidism, and diabetes mellitus. These diagnoses were ruled out by careful review of medical records, owner history, physical examination, blood work, and urine analysis. For the normal group, cats were excluded if any orthopedic disease (e.g. cruciate ligament rupture, joint luxation) or neurological disease (e.g. lumbo-sacral nerve impingement) that might impair mobility was detected.

Additionally, eligible cats were required to not have received any anti-inflammatory medications for at least 4 weeks prior to the study, to have been on the same diet with or without nutritional supplements for at least 4 weeks prior to the study, to be free from clinically abnormal hematological or blood chemistry values (creatinine increases up to 2.8 mg/dL were acceptable if they had been stable for at least 4 weeks before the study and this was documented with plasma biochemistry results), and be housed indoor-only. Owners were required to have a stable routine of daily living that was unlikely to change over the duration of the study.

Instrument design and readability testing

Using the question topics and the preferred instrument design previously reported (Zamprogno et al., 2010) an owner-directed questionnaire (the FMPI) was constructed. The questionnaire followed a descriptive rating scale design with descriptors from left to right (normal to abnormal). The instrument was created and adapted following input from all investigators, then tested for readability (Clear Language Group, CLG; Mettger Communications and Plain Language Works, LLC) based on four readability formulas, namely, Flesch, Fry, SMOG and FOG (Fry, 1968; Kincaid et al., 1975; McLaughlin, 1969). Following changes to optimize readability, the final 21-question FMPI instrument was produced.

Reliability testing (internal consistency and test–retest)

Questionnaires from owners of normal and pain-DJD cats were used for reliability testing. At the screening visit, and prior to any evaluation of the cat, owners completed the FMPI (D1), and they returned to the clinic 14 days later (D14) to complete the FMPI a second time. Completion of the instrument was done in the same environment on each occasion, and administered by the same person each time. A standard paragraph of instructions was read to the owner prior to completion of the instrument. Data from D1 and D14 were used to calculate reliability and internal consistency (see below).

Discriminatory ability testing

FMPI data in normal and pain-DJD cats were collected as described above. FMPI instrument scores at D1 and D14 were compared between groups. In an attempt to see if the instrument could discriminate between degrees of impairment, the pain-DJD cats were divided into low DJD (L-DJD) and high DJD (H-DJD) by adding the total radiographic DJD and total pain scores for each cat, and dividing the pain-DJD cats into two groups based on the median value of the combined score. D1 and D14 data were compared between groups.

Statistical analysis

Power analysis calculations for this study were based on preliminary data suggesting a standard deviation of 10 in a group of cats with DJD, and a decision that we wanted to discriminate between normal cats (mean score 0/83) and cats with some mobility impairment (a positive score on half of the activity questions and two out of three of the pain and quality of life questions – score of 11/83). These parameters suggested that in the discrimination portion of the study, a total of 38 cats were required to achieve statistical power of 90%.

Data were compared between groups using Fisher's Exact and Mann–Whitney tests as appropriate. If owners selected 'I don't know', or 'Does not apply', these were considered missing data points. An estimate of internal consistency reliability of the FMPI questions for both normal and pain-DJD cats was assessed using Cronbach's α. Repeatability was assessed by calculation of the weighted κ statistic for FMPI scores from D1 and D14 visits in the normal and pain-DJD cats. The FMPI scores evaluated were the FMPI activity score (sum of questions 1–18), the FMPI pain score (sum of questions 19–20), FMPI quality of life (QoL) score (question 21) and the FMPI total score (sum of questions 1–21).

In addition to calculation of the weighted κ statistic, repeatability was evaluated by comparing D1 and D14 data within each group using a Wilcoxon signed rank test. To test discriminatory ability, FMPI scores were grouped together within day of assessment, and ranked from smallest to largest, average values were assigned to ties and ages of cats were similarly grouped together and ranked. An analysis of covariance was performed on the ranked FMPI scores, using ranked age and normal/pain-DJD group as covariates. The P value for the effect of group, after controlling for ranked age, was then reported. As a sensitivity analysis, the same regression was performed using age instead of ranked age. Data from D1 and D14 were compared between both DJD subgroups (L-DJD and H-DJD) using a Mann Whitney test. In all analyses, FMPI activity, FMPI pain, FMPI QoL and FMPI total scores were compared.