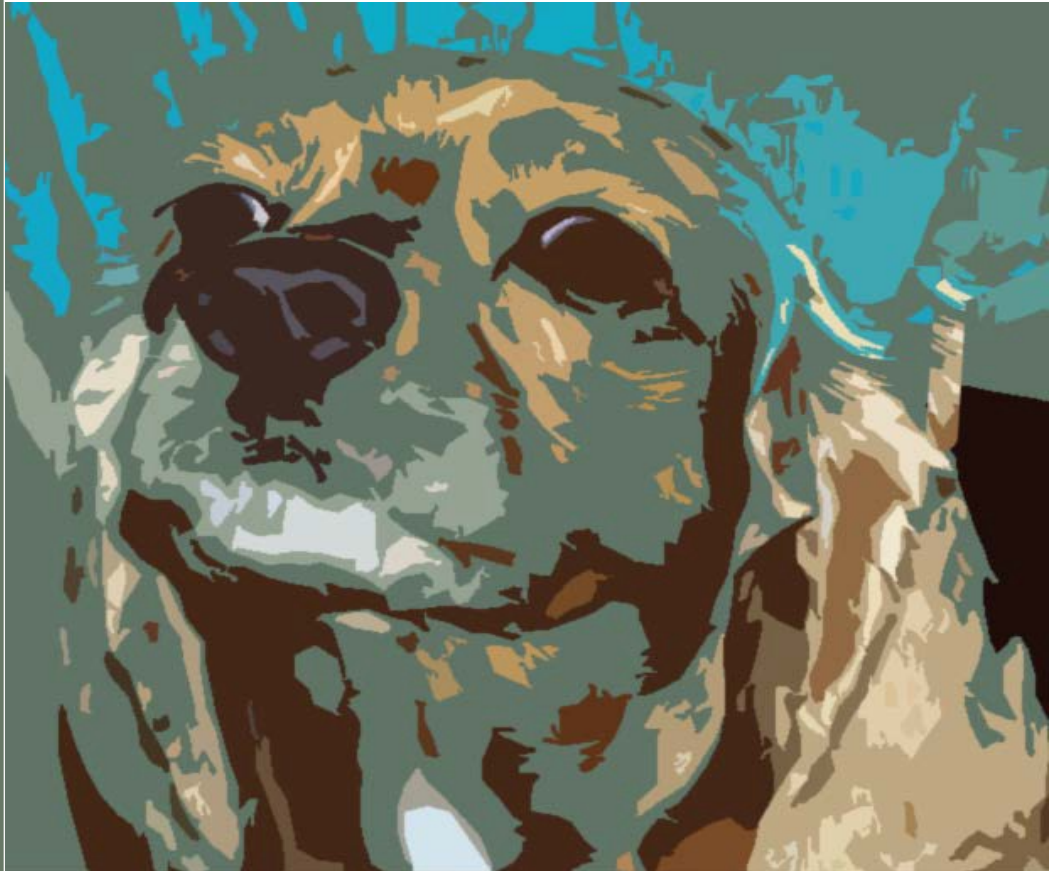


The Canine Brief Pain Inventory

www.CanineBPI.com

User Guide



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Development of the Canine Brief Pain Inventory

The **Canine Brief Pain Inventory (Canine BPI)** allows owners to rate the severity of their dog's pain and the degree to which that pain interferes with function. Initially developed to assess pain related to osteoarthritis, the Canine BPI has been shown to be an appropriate measure for pain caused by bone cancer as well.

Background

The availability of quantitative measures of chronic pain that are valid and reliable in clinical patients is crucial for the development and testing of interventions (e.g., drugs or surgical procedures) designed to reduce such pain. Studies designed to test the efficacy of interventions intended to decrease chronic pain in companion dogs with osteoarthritis have relied heavily on a veterinarian's assessment of lameness supported by values generated through the use of force plate gait analysis. When properly collected, gait analysis data offer an objective measure that can be reliably monitored over time; however, these measures of lameness only evaluate the animal at one specific point in time and outside of its typical environment. In addition, weight bearing on an affected limb is only one part of the much larger picture of chronic pain in companion dogs. A detailed behavior-based assessment of chronic pain, as described by the owner, is routinely relied upon when making clinical decisions and offers the advantages of an extended assessment of a dog in its typical environment by someone who is most knowledgeable about its behavior. In the mid-2000s, a program to develop a valid and reliable, owner-completed questionnaire for use as a chronic pain outcome assessment tool in clinical studies was initiated.

Developing a Measurement Model and Items

The aim of the program was to develop a scale that: (a) was owner completed; (b) would take only a short time to complete; (c) would be easy for owners to understand; (d) would capture not only pain severity, but also the perception of how pain interfered with daily life; (e) would be valid and reliable in a variety of chronic pain conditions; (f) was analogous to a scale used in human chronic pain studies,

which would facilitate capturing the cross species translational potential of canine chronic pain studies.

As a guide to scale construction, we used the psychometric standards found in *Health Measurement Scales: A practical guide to their development and use (3rd edition)* by David Streiner and Geoffrey Norman. (2003). These standards included common elements of test validity (content, criterion, and construct) and reliability (internal consistency and test-retest). These standards had not been systematically applied to the development of scales for use in veterinary medicine. To take advantage of the extensive experience of pain measurement in humans and capitalize on the translational potential of canine studies, a widely accepted reliable and valid assessment of pain severity and interference with function, the Brief Pain Inventory (BPI; Charles S. Cleeland PhD), was used as the basis for the Canine BPI. Much of the dimensional format, item structure, and response scaling of the BPI, were preserved in development of the Canine BPI.

The BPI has two dimensions (1) pain severity, which contains four items; and (2) interference with daily functions, which contains six items:

| Brief Pain Inventory | |
|-----------------------------|----------------------------|
| Severity Domain | Interference Domain |
| Worst Pain | Relations with Others |
| Least Pain | Enjoyment of Life |
| Average Pain | Mood |
| Pain Now | Sleep |
| | Walking |
| | General Activity |
| | Working |

Given that the severity items are general in nature, widely used in both self- and observer-report paradigms, and accepted as a primary outcome for human clinical

trials, they were maintained unchanged in even the earliest versions of the Canine BPI. In addition, ‘general activity’, ‘enjoyment of life’, and ‘walking’ were retained unchanged in the interference domain. Earliest versions of the Canine BPI attempted to retain the ‘mood’ and ‘sleep’ items as well; however psychometric testing proved them to be unreliable. Multiple attempts were made to retain the concept of ‘mood’ by using words such as ‘temperament’, ‘disposition’, and ‘personality, but none proved reliable and the item was dropped. It also became clear that the sleep item would not be reliable, because not all owners sleep in the same room with their dogs, so this item was dropped as well. Focus group methodology and key informant interviews were used to develop the additional items for the interference domain.

The final version of the Canine BPI contains four items pertaining to the severity of the dog’s pain and six items describing how that pain interferes with the dog’s daily activities:

| Canine Brief Pain Inventory | |
|------------------------------------|----------------------------|
| Severity Domain | Interference Domain |
| Worst Pain | General Activity |
| Least Pain | Enjoyment of Life |
| Average Pain | Rising to Standing |
| Pain Now | Walking |
| | Running |
| | Climbing |

Like the BPI, the Canine BPI items are presented with 0-10 numerical rating scales. For the severity items 0=no pain and 10=extreme pain. For the interference items 0=no interference and 10=completely interferes.

In addition, a single global quality of life question is included at the end of the questionnaire to obtain the owner’s overall assessment of the dog’s status. This item is presented with a 5-point categorical rating scale ranging from “Poor”, through “Fair”, “Good”, “Very Good”, to “Excellent”.

Scoring the Canine Brief Pain Inventory

How to Score the Canine BPI: Pain Severity

The Canine BPI assesses pain at its “worst,” “least,” “average,” and “now” (current pain). In clinical trials, these items have each been used singly to represent pain severity; however model validation for the Canine BPI included all four items. The responses to these items are averaged to deliver a pain severity score.

How to Score the Canine BPI: Pain Interference

The Canine BPI measures how much pain interferes with six daily activities, including general activity, enjoyment of life, rising to standing, walking, running, and climbing. The Canine BPI pain interference score is the mean of the six interference items. This mean can be used if more than two-thirds, or four of six, of the total items have been completed on a given administration.

Quality of Life Item

The quality of life item (“poor”, “fair”, “good”, “very good”, excellent”) is not used in any of the pain scoring for the Canine BPI. This stand-alone item was used initially as a criterion validity assessment in the validation of the severity and interference scores. It takes very large changes in pain scores to elicit a change in quality of life category. In our experience, measurement of quality of life, as an outcome measure in clinical trials, is better approached with a global assessment of change over time (i.e. ‘much worse’, “worse”, “same”, “better”, “much better”).

Statistical Analysis Using the Canine Brief Pain Inventory

As originally validated, and often the analysis of choice in the literature, the overall mean or median differences in pain scores can be compared between groups (i.e. treatment and control groups). However, in addition, the Canine BPI can be used to assess whether the treatment has a measurable effect for each dog in a study. When the criteria for successful treatment of an individual patient are predefined as a reduction ≥ 2 in pain interference score and ≥ 1 in pain severity score, the number of treatment successes and failures in each group can then be compared. While this method of analysis requires a larger sample size, it has the advantage of providing individual dog response data which is often required by regulatory agencies.

Psychometric Properties of the Canine Brief Pain Inventory

Dimensions of the Canine BPI

Several approaches have explored the underlying dimensions of the Canine BPI. As described above, the Canine BPI was designed to capture two dimensions of pain: severity and interference. This two-factor structure was confirmed in a study of dogs with osteoarthritis (n=70). Two factors (severity and interference) were identified with an eigenvalue (variance of the factor) > 1.0, which was confirmed by use of a scree plot. The severity of pain factor had an eigenvalue of 5.8, and the interference with function factor had an eigenvalue of 1.4. These 2 factors accounted for 72% of the variance. Cronbach's α was 0.92 for the total instrument and 0.93 and 0.89 for severity of pain and interference with function, respectively.

This two-factor structure was also confirmed in a study of dogs with bone cancer (n=100). Two factors (severity and interference) were identified with an eigenvalue (variance of the factor) > 1.0, which was confirmed by use of a scree plot. The severity of pain factor had an eigenvalue of 7.0, and the interference with function factor had an eigenvalue of 1.0. The 2 factors accounted for 81% of the variance. Cronbach's α was 0.95 for the total instrument and 0.95 and 0.93 for severity of pain and interference with function, respectively.

Test-Retest Reliability

Values from any measure should not differ significantly between assessments, assuming the study subject has not changed significantly. This psychometric concept is examined by test-retest reliability. The test-retest reliability of the Canine BPI has been studied in dogs with osteoarthritis examining consistency of the responses between two administrations of the instrument to the same owners one week apart. Performance of the instrument revealed κ values of 0.75 for the severity score and 0.81 for the interference score, suggesting good stability of the instrument among repeated administrations. Similar results were

found in dogs with bone cancer, where the test–retest performance of the instrument revealed κ values of 0.73 and 0.65 for the severity and interference scores, respectively. It is not surprising that the κ values were slightly lower in the dogs with bone cancer, because it is a much more dynamic disease than osteoarthritis. It is likely that some of the dogs did deteriorate in the period between the two assessments and differing scores were actually warranted by progression of disease and worsening clinical signs.

Translations of the Canine Brief Pain Inventory

French

The English version of the Canine BPI was translated into French and the psychometric properties evaluated. Native French speaking owners of dogs with osteoarthritis completed a single administration of the translated questionnaire. Factor analysis on the responses from this cohort confirmed a two-factor questionnaire: the pain severity factor and the pain interference factor. The mean inter-item correlation for the severity questions and the interference questions was 0.74 and 0.53 respectively. Community for all questions ranged from 0.61 to 0.96. These findings revealed strong internal consistency, suggesting that the questions contained within each factor measure the same concept and can be pooled to generate the pain severity score and the pain interference score. Cronbach's α was 0.91 and 0.87 for the severity and interference scores, respectively. There was strong negative correlation between the severity score and interference score with the overall quality of life score ($r = -0.62$ and $r = -0.79$, respectively with $p < 0.001$ for both), consistent with the hypothesis that increases in pain severity and interference with function are highly correlated with a corresponding decrease in overall quality of life.

Tips for Using the Canine Brief Pain Inventory

1. When, during the study visit, should the questionnaire be completed?

It is best to have the owners fill out the questionnaire at the very beginning of each study visit before the veterinarians, nurses, or study personnel begin taking a history or discussing the dog's health status. The owners may be swayed in their thinking by hearing what other people say about their dog. For example the nurse coming in and saying "Buddy looks great today" before the owner gets their thoughts on paper could bias them. We recommend that owners are handed questionnaires very first thing and then study personnel work with the dog in silence while the owner completes the instrument. Completed questionnaires are collected and then a detailed history is collected.

2. Who should complete the questionnaire?

Ideally, the owner who knows the dog best – spends the most time with the dog and is most familiar with its behaviors - should complete the questionnaire. In a longitudinal study, the same owner of each dog must complete the form at each time-point. We find that sometimes, when 2 or 3 people bring the dog in for their study visit, they will try to complete the questionnaires as a group. Therefore, we recommend that study personnel remain in the room while the owner is filling out the questionnaire. Personnel can remain busy with the dog performing a physical exam, or completing other paperwork, but they can speak up and remind the owner that questionnaire completion is a one person job if a group effort starts to emerge.

3. Using a cut-off score for enrollment

If a minimum pain score is being used as a cut-off for enrollment into a study, it is important that the owner is not aware of it. They may (consciously or not) inflate the baseline responses on the questionnaire because they want the dog to qualify for the study. We recommend including the Canine BPI in the middle of other

paperwork that is filled out by the owner at every visit, such as history, medication, and other data collection forms. This ensures that owners do not see any 'extra' significance to the Canine BPI as they fill it out.

Baseline score inflation can also be an issue if study sites or study personnel are being incentivized based on enrollment numbers. It is in the site or study personnel's interest to have as many dogs as possible exceed the pain score cut-off value and it is possible (unconsciously or not) to sway an owner into higher baseline scores by saying things like "wow, he really is lame" or "he is having a tough time on these floors isn't he?" etc. before the owner fills out the questionnaires. Refer to #1 above to help control for this.

4. Timing of the baseline pain scores

In longitudinal studies, we recommend that the owner's very first completion of the Canine BPI not be used to calculate the baseline scores against which intervention efficacy will be assessed. This is primarily important for controlling for regression-to-the-mean (RTM). RTM is a ubiquitous phenomenon that can occur whenever there are repeated measurements on the same study subject. Relatively high (or low) values are likely to be followed by less extreme values nearer the subject's mean because of the natural variation in the pain and functionality of dogs with chronic pain such as osteoarthritis. They will oscillate between good days and bad days, depending on things such as weather and amount of activity. These oscillations may influence the time at which owners seek treatment for their pets. For example, they may be more likely to seek treatment when an animal is having a period of several bad days. These dogs would then score higher on the Canine BPI at the baseline assessment than they would during a period of typical days. As these dogs progress through the natural variability of the clinical signs, they will regress back to the mean value for discomfort and functionality, and their scores on the Canine BPI will improve even with no intervention initiated. Waiting at least 7-10 days after the screening appointment to begin baseline data collection will allow many dogs to be at their

'average' level of pain and disability and remove some of the placebo effects due to RTM in any longitudinal study.

In addition, there may be some advantage to the owners having some 'practice' filling out the questionnaire. They will feel more comfortable with the questions and have an awareness of which behaviors are going to be assessed throughout the study.

5. Owner questions about the questionnaire

Occasionally an owner will express some uncertainty as to how to respond to a question. We use a standard response to any owner questions about completing the questionnaire:

"There are no right or wrong answers. You know your dog better than anyone else. Just go with the response that feels best to you. Some questions may seem easier to answer than others and that's normal. There are no right or wrong answers to any of the questions, just go with what seems like the best choice."

References for Validation of the Canine Brief Pain Inventory

1. Brown DC, Boston RC, Coyne JC, Farrar JT: Development and psychometric testing of an instrument designed to measure chronic pain in dogs with osteoarthritis. *American Journal of Veterinary Research* 68:631-637; 2007
2. Brown DC, Boston RC, Coyne JC, Farrar JT: Ability of the Canine Brief Pain Inventory to detect response to treatment in dogs with osteoarthritis. *Journal of the American Veterinary Medical Association* 233: 1278-83; 2008
3. Brown D, Boston R, Coyne J, Farrar J: A novel approach to the use of animals in studies of pain: Validation of the Canine Brief Pain Inventory in canine bone cancer. *Pain Medicine* 10: 133-142; 2009
4. Brown DC, Boston R, Farrar JT: Comparison of force plate gait analysis and owner assessment of pain using the Canine Brief Pain Inventory in dogs with osteoarthritis. *Journal of Veterinary Internal Medicine* 27:22-30; 2013
5. Brown DC, Bell M, Rhodes L: Analysis of the power of treatment success definitions when the Canine Brief Pain Inventory is used to evaluate carprofen treatment for the control of pain and inflammation in dogs with osteoarthritis. *American Journal of Veterinary Research* 2013; 74: 1467-1473 with erratum *American Journal of Veterinary Research* 75: 353; 2014
6. Ragetly G, Massey L, Brown DC. Psychometric testing of the French version of the Canine Brief Pain Inventory. Submitted to *Canadian Journal of Veterinary Research* 2017