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Psychometric properties of the Brazilian version of the Canine Brief Pain Inventory (CBPI) for dogs with clinical signs of osteoarthritis and preliminary evidence of its clinical utility

[*Propriedades psicométricas da versão brasileira do Breve Inventário de Dor Canina (BIDC) em cães com sinais clínicos de osteoartrite e evidências preliminares da sua utilização clínica*]

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ABSTRACT

This study aimed to determine the psychometric properties and clinical use of the Brazilian version of the Canine Brief Pain Inventory (CBPI) in dogs with hip dysplasia (HD). Forty-three dogs with HD and 16 clinically normal dogs were enrolled. The HD dogs were treated daily with 4.4mg/kg carprofen (GT = 21) or placebo (GP = 19), for four weeks. Owners completed the CBPI at two weeks (W-2) and immediately before the start of the treatment (W0), two (W2) and four (W4) weeks during treatment, and two weeks (W6) after the end of treatment. The internal structure was accessed, and the Cronbach's alpha coefficient was 0.97, indicating the high internal consistency of the instrument. Principal Component Analysis (PCA) suggested the retention of one component, which accounted for 78% of the variability. The ROC curve analysis concluded that the score 3 has an excellent performance to discriminate between normal and possible HD dogs (AUC of 0.973). There was no difference between dogs treated with carprofen *versus* placebo. The instrument in Portuguese showed construct and criterion validity and reliability to be used in dogs with HD.

Keywords: dogs, chronic pain, osteoarthritis, validation studies

RESUMO

Objetivou-se determinar as propriedades psicométricas e a utilidade clínica do Breve Inventário de Dor Canina na língua portuguesa, em cães com displasia coxofemoral (DCF). O inventário foi preenchido por tutores de 43 animais com DCF e por 16 tutores de cães saudáveis. Os animais com DCF foram tratados com carprofeno 4,4mg/kg (GT = 21) ou placebo (GP =19), administrados uma vez ao dia durante quatro semanas. As avaliações foram realizadas duas semanas e imediatamente antes do tratamento, duas e quatro semanas durante o tratamento e após duas semanas do término do tratamento. A estrutura interna calculada pelo alfa de Cronbach = 0,97 indicou alta consistência dos dados. A análise dos componentes principais identificou a retenção de apenas um componente responsável por 78% da variabilidade dos dados. A análise da curva ROC indicou que o escore 3 discrimina cães saudáveis de cães com possível DCF (ASC de 0,973). Não houve diferença entre os cães tratados com carprofeno daqueles que receberam placebo. O questionário apresentou validade de constructo e critério e confiabilidade e pode-se empregá-lo para avaliar a dor crônica em cães com osteoartrite em países de língua portuguesa.

Palavras-chave: cães, dor crônica, osteoartrite, estudos de validação

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INTRODUCTION

Canine hip dysplasia (HD), the most common orthopedic condition diagnosed in dogs, shows a prevalence of up to 71% in affected breeds, ranging from 1% for some sighthounds to 71% for bulldogs (King, 2017). This condition consists of varying degrees of hip laxity, progressive remodeling of the structures of the hip, and subsequent osteoarthritis (Syrcle, 2017). The diagnosis of HD is based on radiographic exams, however as there is no correlation between pain intensity and severity of radiographic signs, joint lesions, and clinical function (Brass, 1989), therapeutic decision making is based on history and clinical signs on presentation (Harper, 2017).

Generally, evaluation of chronic pain has been focused on owner assessed behavioral changes (Millis and Ciuperca, 2015), since they integrate observations over an extended period of time when dogs carry out their regular activities in the home setting (Brown *et al.*, 2013). To date, few instruments are available to assess canine chronic pain based on behavioral changes (Wiseman-Orr *et al*., 2006; Hielm-Björkman *et al.*, 2009; Walton *et al*., 2013; Cachon *et al.*, 2018). Instruments can include vitality, mobility, interaction with the owner, sociability, vocalization, and the degree of lameness, among others (Mathews *et al.*, 2014).

The Brief Pain Inventory is routinely used to provide a broad picture of the effect of chronic pain on human patients (Cleeland and Ryan, 1994). The Canine Brief Pain Inventory (CBPI) is an adapted version validated in dogs with OA (Brown *et al.*, 2007) and bone cancer (Brown *et al.*, 2009). The CBPI contains four questions pertaining to the severity of pain, to calculate the pain intensity, and six questions assessing how pain interferes in the dog's activities, providing a pain interference score. These two factors were able to identify an improvement in the pain score in dogs treated with AINE in comparison to placebo (Brown *et al.*, 2008, 2013).

The current study aimed to explore the internal structure of the CBPI and the psychometric properties of the Brazilian version of the Canine Brief Pain Inventory (CBPI) using data gathered from Brazilian dog owners within the multivariate statistics framework and to define the intervention analgesia score.

MATERIAL AND METHODS

This was a parallel study for which part of the data were reported in two previous studies (Teixeira *et al.*, 2016; Matsubara *et al.*, 2019). The current study was approved by the Ethics Committee for the Use of Animals of the institution, under protocol number (087/2013). Before data collections, all owners agreed to take part in the study and signed a consent form.

The questionnaire was contextually and semantically translated from English to Portuguese by two translators fluent in both languages. The two versions were thoroughly revised, compared, and transformed into a single version. This new version was then translated back to English by two other fluent translators (Sousa & Rojjanasrirat, 2011) (Table 1).

Forty-three dogs with HD and 16 healthy dogs were clinically and radiographically evaluated. The sample size for HD dogs was based on the study of Brown *et al.* (2008), where a sample size of 29 dogs per group would provide an 80% power to detect a 30% difference between groups (SD, 40%, 2-sided P=0.05) for changes in CBPI scores.

For inclusion in the study, HD dogs were required to have radiographic evidence of moderate to severe unilateral or bilateral HD according to the Orthopedic Foundation for Animals (Flückiger, 2007) and have been experiencing pain for longer than three months, confirmed by at least two of the following clinical signs: difficulty in (1) lying down or standing up, (2) jumping or refusing to jump, (3) climbing or descending stairs, and (4) lameness. Only dogs with normal blood count, urea, creatinine, alanine aminotransferase, alkaline phosphatase, total protein, and albumin two weeks before the start of treatment (W-2) were included. Dogs under treatment with analgesics and chondroprotectors for at least four weeks before the beginning of the study were excluded.

For the radiographic examination, the dogs were deprived of food and water for 12- and two-hour, respectively. Morphine sulfate IM (0.5mg/kg; Dimorf 10mg/mL, Cristália, SP, Brazil) was

administered to all dogs, followed, 30 minutes later, by IV propofol (approximately 5mg/kg; Propovan 10mg/mL, Cristália, SP, Brazil) to allow positioning for radiographic evaluations. In dogs from all groups, ventrodorsal and laterolateral radiographic projections were used for the hip and cervical, thoracic, lumbar, and sacral spine and mediolateral and craniocaudal radiographic projections were used for the knee and elbow to rule out other than HD radiographical changes.
Dogs with HD were randomly distributed using computer software (www.random.org) into two groups treated for four weeks: GT - 24 dogs with HD treated with carprofen (4.4 mg/kg Carproflan 100mg; Agener, SP, Brazil), orally once a day or GP - 19 dogs with HD treated with 1 mg/kg lactose (placebo), orally once a day, in capsules identical to those for carprofen along with the description of GT and GP. The owners and researchers were blinded to the treatment (double-blind design). Owners were instructed to administer tramadol (4mg/kg; Cronidor 100mg, Agener, SP, Brazil) if the same clinical signs used for inclusion criteria were worse or there were episodes of pain according to their judgment.

The owners answered the questionnaire two weeks (W-2) and immediately before (W0) the beginning of the treatment, two (W2) and four (W4) weeks after the start of the treatment, and two weeks after the end of the treatment (W6). No previous training was provided.

Healthy dogs (GC) (n=16) were evaluated by the owners at a single moment to rule out chronic pain, and radiography was performed to rule out radiographic signs of HD according to the standards of the Orthopedic Foundation for Animals and to provide evidence for the criterion validity of the questionnaire.

For the statistical analyses, only the first 10 questions were used because the 11th question refers to the dog´s quality of life (poor, fair, good, very good, and excellent) and is not quantified with a score from zero to 10 like the other questions. The data set was visually investigated for outliers and missing cases. No outliers were found. The full information maximum likelihood estimation was used for missing cases. All steps currently recommended to deal with pre-existing tools were followed for the psychometric analysis. Thus, running a confirmatory analysis before exploratory analyses is suggested when an instrument has been previously published and presents evidence of dimensionality (Reuterberg and Gustafsson, 1992; Gagnon, 2019), which is the case of the CBPI (Brown *et al.*, 2007). Fit indices such as the Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), and root mean square error of approximation (RMSEA) were used to check if the model fit the data. The minimum CFI and TLI were set at 0.9 and the maximum RMSEA result was set at 0.8.

As these indices were not achieved, the exploration procedures were carried out in a multistage framework. Parallel analysis was used to determine the number of dimensions to retain, then the same dimensional analyses were performed as reported in the original article (Brown *et al.*, 2007). Reliability and item-total correlation analyses were performed using Cronbach's alpha and the Spearman test between all items at the two baseline moments (W-2 and W0). The spearman correlation at the first baseline and the second one was carried out due to its monotonicity properties.

To enhance the clinical utility of this tool, we defined the optimal cut-off using the Youden index to balance the sensitivity (true positive) and specificity (true negative), as recommended by the best practices (Perkins and Schisterman, 2005).

To check the group and time effect of the CBPI results, a multilevel modeling was carried out. Therefore, as the individual difference at the baselines increases the within-subject error variance, all longitudinal data were modeled including random intercepts for each subject.

All analyses were performed in R (R Core Team 3.6 Statistical software Inc, Vienna, Austria) Statistical software. The alpha level was set at 5%.

Table 1. Portuguese version of the Canine Brief Pain Inventory (CBPI)

Descrição da dor:	Sem dor										Dor extrema
Classifique a dor do seu cão:											
1.Preencha o número que melhor descreve a pior dor nos últimos sete dias	0	1	2	3	4	5	6	7	8	9	10
2. Preencha o número que melhor descreve a menor dor nos últimos sete dias	0	1	2	3	4	5	6	7	8	9	10
3. Preencha o número que melhor descreve a média de dor nos últimos sete dias	0	1	2	3	4	5	6	7	8	9	10
4. Preencha o número que melhor descreve como está agora	0	1	2	3	4	5	6	7	8	9	10
Descrição da função:	Não interfere										Interfere completamente
Preencha o número que melhor descreve como, durante os últimos sete dias, a dor interferiu no seu cão com relação a:	0	1	2	3	4	5	6	7	8	9	10
5. Atividades em geral	0	1	2	3	4	5	6	7	8	9	10
6. Prazer da vida	0	1	2	3	4	5	6	7	8	9	10
7. Capacidade de se levantar de quando estava deitado	0	1	2	3	4	5	6	7	8	9	10
8. Capacidade de andar	0	1	2	3	4	5	6	7	8	9	10
9. Capacidade de correr	0	1	2	3	4	5	6	7	8	9	10
10. Capacidade de subir (por exemplo, escada e calçada)	0	1	2	3	4	5	6	7	8	9	10
Impressão geral											
11. Preencha a resposta que melhor descreve a qualidade de vida em geral do seu cão nos últimos sete dias	Ruim			Razoável		Boa		Muito boa			Excelente

RESULTS

There were no differences in body weight of the dogs of GT (34.3kg±8.4) and GP (32.2kg±8.9) and GC (29.2kg±8.6), however dogs from GC (2.9±1.9 years old) were younger than those from GT (6.3±4,2 years old) and GP (6.1±4.4 years old).

There was no difference for HD degree between the GT and GP dogs. Forty-three dogs with HD were evaluated. Three male dogs from GT were excluded based on the inclusion criteria. In one dog another analgesic rather than tramadol was administered and in two dogs there was a posology mistake.

Three of 21 dogs from GT received tramadol (14.3%). Two dogs were treated between W2 and W4 and another between W0 and W2.

The original article (Brown *et al.*, 2007) reported that CBPI had a two-dimensional orthogonal structure based on a Principal Component Analysis (PCA) using a Varimax rotation modeling. In that study the first domain accessed the severity of pain and the second the interference in function. Based on their proposed model, we ran a CFA including the same original model features, considering a two-dimensional solution with orthogonal components and used the Maximum Likelihood approach as the estimation method. The results revealed a lack of fit: $X^2(35) = 169.43$, $p<0.001$, CFI = 0.83, TLI = 0.78, RMSEA = 0.26, so exploratory multivariate procedures were performed. According to Brown *et al.* (2007), data from all dogs from both groups were used to compute a scree plot via parallel analysis to decide how many components to retain. Fig. 1 displays the results:

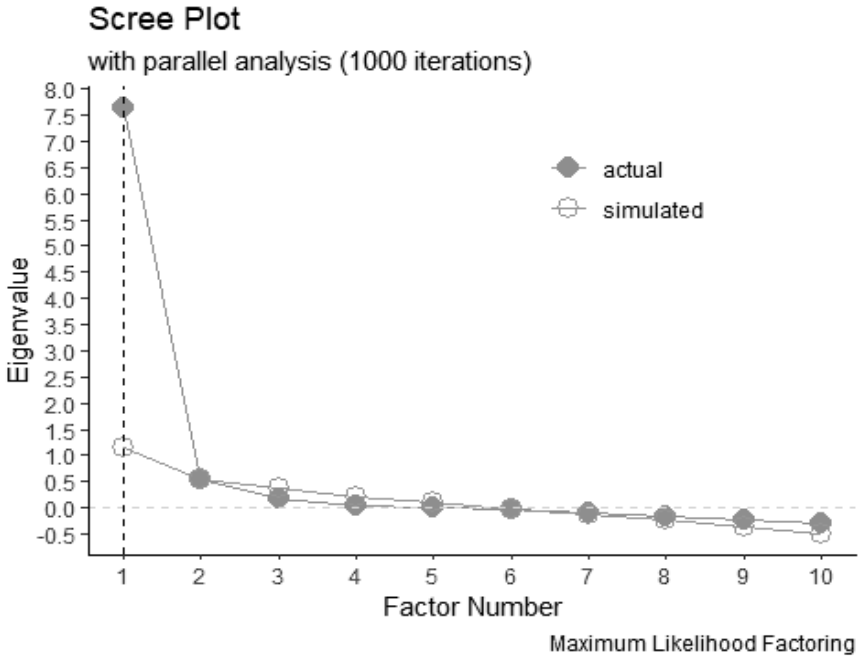

Figure 1. Scree plot of the eigenvalues resulting from factor analysis of the CBPI at W0.

The unidimensional solution was then computed. Principal component analysis is useful for reducing many variables into a smaller set. The component computed is a linear combination of the original variables that maximizes the total of the explained variance (R^2) statistics when predicting the original variables as a regression function of the linear combination. The first component accounted for 78% of the variance, and all loadings were positive.

Regarding reliability, the Cronbach's alpha coefficient was ≥ 0.96, indicating excellent internal consistency of the data.

Item-total correlation represents correlations of each individual item with the total scale (with that item omitted). Items should have a correlation > 0.30 for the total score to be retained (Streiner *et al.*, 2015). The test-retest reliability was calculated via Spearman correlation and intraclass correlation coefficient (ICC), with 95% confidence interval. This measure accounts for random and systematic errors in scores and it`s currently recommended for checking the stability of the results (Koo and Li, 2016). The results were above 0.3, suggesting the stability of the data (Table 2).

After these results, we explored the clinical utility of the CBPI via known-group (contrasting-groups method) analysis. This procedure is encompassed by the evidence based on the relation to other variables (Shewhart and Wilks, 2012) and involves the comparison between groups supposed to differ.

The hypothesis was that the results could correctly discriminate disease-free dogs from HD dogs, which would provide a useful resource for clinicians when assessing the pain level of a dog. An independent t test revealed a significant difference between the GC vs GT and GP dogs grouped ($p<0.01$) (Fig. 2), also validating the selection procedures of the participants.

The investigation of the optimal cutoff value was carried out via the Youden Index, which shows the product of sensitivity and specificity, and discriminates the disease-free and clinical group. The mean score of 3 demonstrated excellent performance, with an area under the receiver operating characteristic (ROC) curve (AUC) of 0.973 (Fig. 3), therefore analgesic treatment should be considered in dogs showing scores ≥3.

Table 2. Mean±standard deviation (SD) of CBPI scores for items with the corresponding PCA loading, item-total correlation and Cronbach α values (n= 40)

	Descriptive stats		Internal consistency	Item- total	Test-retest stability		PCA	
CBPI items	Mean	SD	(α)	Spearman	Corr. (W-2, W0)	ICC	Load (λ)	Communality (U^2)
1	3.1	2.8	0.96	0.87	0.62	0.72	0.90	0.80
2	2	2.3	0.97	0.78	0.71	0.68	0.83	0.69
3	2.4	2.5	0.97	0.84	0.68	0.72	0.88	0.77
4	2.5	2.6	0.96	0.86	0.61	0.66	0.89	0.79
5	3	2.9	0.96	0.89	0.64	0.69	0.91	0.82
6	2.7	2.8	0.97	0.79	0.77	0.78	0.82	0.67
7	3.7	3.4	0.96	0.90	0.57	0.70	0.92	0.84
8	2.6	2.7	0.96	0.88	0.58	0.54	0.90	0.81
9	3.4	3.3	0.96	0.90	0.71	0.80	0.92	0.84
10	3.7	3.5	0.96	0.88	0.76	0.83	0.90	0.81

Sum of Squared Loadings = 7.85

Proportion of variance explained = 78%

Fit based upon off diagonal values = 0.99

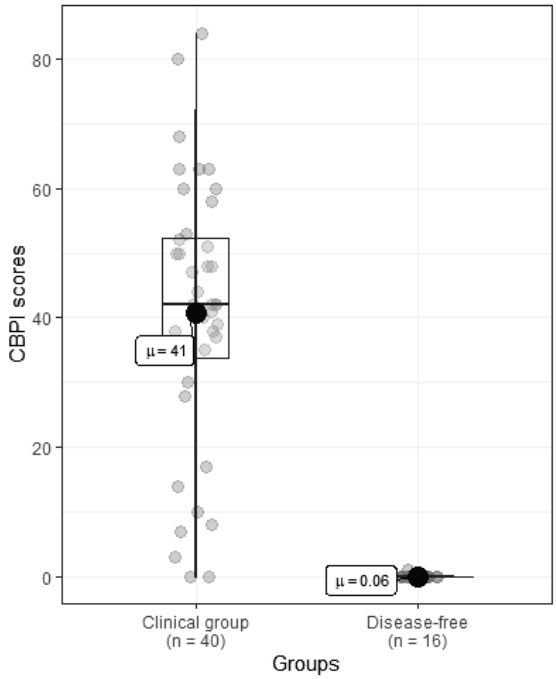

Figure 2. The CBPI mean (SD) values in dogs with osteoarthritis (n=40) and disease-free dogs (n=16) two weeks before treatment (W-2) ($p < 0.01$).

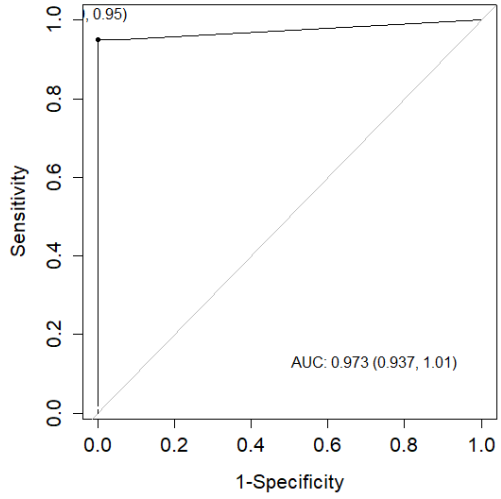

Figure 3. Area under the ROC curve.

The final analysis was to check the effects of treatment over time and between GT and GP groups. All dogs were assessed over three time-points during the treatment protocol. To check differences within subjects and between groups, the data were modeled by a linear mixed model, also known as multilevel modeling or random regression model. There was no effect for the carprofen versus placebo treatment ($F(1, 38)=0.24$, $p=0.63$), or for the interaction ($F(4, 152) = 0.90$, $p=0.47$). The main effect of time was significant ($F(4, 152)=5.88$, $p<0.01$), indicating that total scores decrease in both carprofen and placebo treatment over time (Fig. 4)

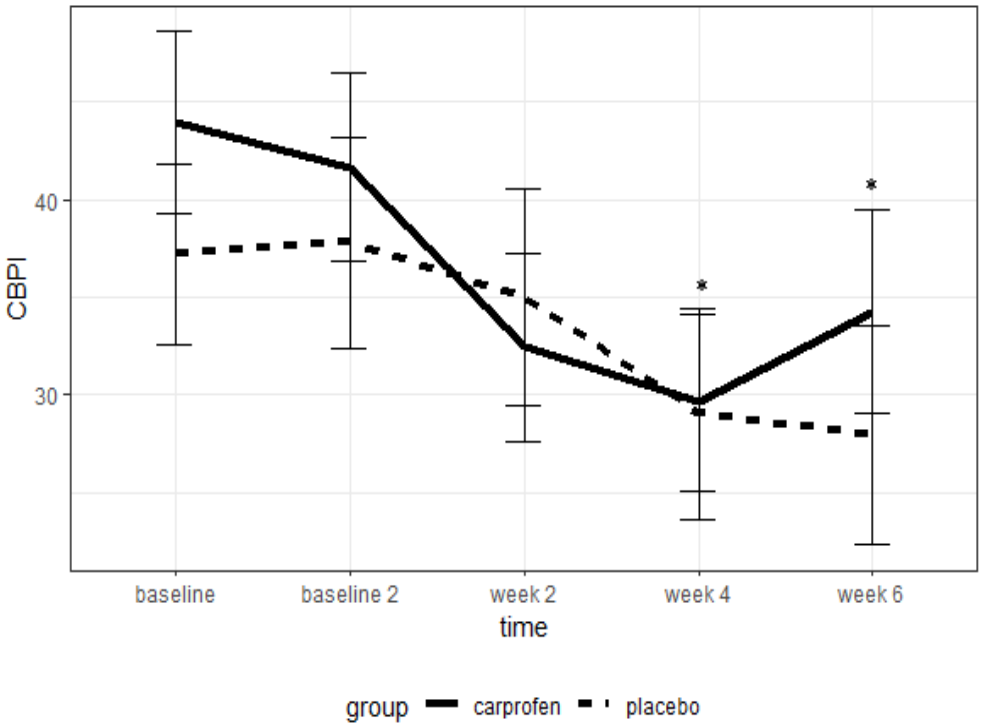

Figure 4. Mean (Standard error of mean) total scores of CBPI in dogs with hip dysplasia treated with carprofen (GT = 21) or placebo (GP = 19) for four weeks. * indicates significant difference between baselines vs W4 and W6 for both treatments.

DISCUSSION

The Brazilian Portuguese version of the CBPI is a one factor, 11 item questionnaire designed to measure owners' assessments of the severity and impact of chronic pain on their dogs with osteoarthritis. Partially different from the original questionnaire (Brown *et al.*, 2007), for the factor analysis results, this version showed only one component (chronic pain), since owners were unable to differentiate pain and interference in limb function.

It is crucial to develop measures with adequate psychometric properties to assess chronic pain in animals. This endeavor makes it possible to test therapeutic interventions, such as pharmaceutical compounds, palliative techniques, or surgical procedures designed to reduce pain (Brown *et al.*, 2007). However, when any instrument is used in another language, it cannot simply be translated into another language but must be translated, back-translated to guarantee semantic equivalence and cultural adaptation, and then undergo a new process of validation (Sousa and Rojjanasrirat, 2011).

The first step for validation is to check the performance of the factorial model of the instrument to indices such as X^2, CFI, TLI, and RMSEA. In this study the original theoretical model (Brown *et al.*, 2007) was not confirmed by the empirical data. These situations have been commonly reported in the literature and the

current methods to deal with them are grouped into two strategies: (i) re-specify using modification indices (MI) or (ii) perform exploratory procedures to better understand the data pattern. While some argue that MI should be considered the typical procedure, since it demonstrates the amount by which the overall chi-square of the model will drop if a suggested parameter is estimated as part of the model, there is a growing consensus suggesting this procedure should be avoided, especially when the goal relies on the improvement of the model fit (Shewhart and Wilks, 2012).

The scree plot of the eigenvalues resulting from factor analysis of the CBPI concluded that only one component explained data variability because the first dimension retained 78% of the variance and the other 9 components had a linear pattern. The shape of the graph indicates that the CBPI is best explained as a single component index (chronic pain), contrasting the results of Brown *et al.* (2007), where the two factors retained 72% of the variance and were identified based on items contained in them.

Apparently, it is easier for owners to assess their dog's pain if they limp, however lameness is not always present because HD is a chronic and adaptable disease, and the owner may think that the signs are age-related rather than due to the disease. The advantage of the scree plot retaining only one component for the Portuguese version of the CBPI is that the arithmetic mean of the 10 questions can be calculated to obtain a score that indicates the patient global status. Possible differences in data from Brazil and the USA (Brown *et al.*, 2007), Italy (Rocca *et al*., 2021) and France (Ragetly *et al.,* 2019) may be due to cross-cultural differences and pain perception by the owners. The Brazilian owners apparently had difficulty understanding the questions about pain, and difficulty to differentiating pain from limb functionality, since if the patient feels pain, there will also be a decrease in limb function, but this may not be noticeable to owners. This is suggested since the CBPI in the version studied herein retained only one component, which is pain. The Swedish version of CBPI (Essner *et al*., 2017) also showed one-factor structure as in the present study.

As the instrument is unidimensional, Cronbach's Alpha was used and indicated high reliability. The item-total correlation was greater than 0.3 in all items and therefore all of them can be used, suggesting the stability of the data. When the values are greater than 0.7, the items can be redundant (Streiner *et al.*, 2015) corroborating once again the difficulty that owners had in differentiating pain and interference in limb function.

The test-retest, which is also a measure of repeatability, indicated data stability of the results over-time, i.e., a 15-day interval between baseline assessments was adequate. The intraclass correlation coefficient (ICC) ranged from moderate (0.5 - 0.75) to good (0.75 - 0.9) reliability and reflects the agreement between the two baseline moments (Koo and Li, 2016).

The total CBPI mean scores of around 4 in the clinical group dogs and close to zero in the control group dogs, indicates high responsivity of the instrument to differentiate HD dogs from healthy ones. Therefore, the instrument's reliability was confirmed by internal consistency, repeatability, and responsivity.

The French (Ragetly *et al.*, 2019) and Italian (Rocca *et al*., 2021) versions of the CBPI demonstrated construct and criterion validity and internal consistency like the original English version and the Brazilian Portuguese version in the present study. However, fit indices and diagnostic procedures of the model were not reported. The Swedish version (Essner *et al*., 2017) showed high internal consistency and ability to discriminate clinically sound dogs from OA. However, similarly to our results, according to confirmatory factor analysis, the hypothesis of two-factor structure defined for the English, French, and Italian versions was not confirmed.

The high AUC of the ROC curve indicated that the instrument was highly sensitive to detect true positive HD dogs and specific to detect true negative HD-free dogs. This is the first report showing the CBPI intervention point based on the Youden index, suggesting that dogs with total scores ≥ 3 are suffering from osteoarthritis. This is very useful information to support the practitioner´s decision making both for starting or not analgesic treatment and for the therapeutic choice in dogs suffering from HD.

The possible reasons why the questionnaire did not differentiate the clinical improvement effect of treatment were because i) the instrument is not sensitive to change, and/or ii) carprofen is not effective to abate pain in dogs suffering from OA, and/or iii) the number of dogs was insufficient, leading to type II error and/or iv) this is not the ideal model to be used for validation of the instrument because HD shows complex, variable, and adaptive clinical signs and may affect one or both legs.

In this study, the sample size for the HD group (before dogs were submitted to any treatments) was 40, therefore above the one calculated in the original study of Brown *et al*. (2008), which was 29. This sample size was similar to previous cross-cultural studies in French (Ragetly *et al*., 2019) and Italian (Rocca *et al*., 2021). However, the sample size of each treatment (carprofen and placebo) in our study was possibly low to detect differences between the treated and untreated groups. Although the sample size of the healthy dogs was also possibly small, the sample was very homogeneous and there was almost no variation from score 0.

Although there were no differences between dogs treated with carprofen and placebo, previous studies with a larger number of dogs showed differences over time and between carprofen and placebo treatment in dogs suffering from osteoarthritis *(*Brown *et al.*, 2008, 2013), however these studies use hind limb and forelimb joints. Indeed, OA is a lifelong disease, and HD is even more complex than other affected joints (Madore *et al.*, 2007). Clinical signs of osteoarthritis may only be alleviated (Rychel, 2010) and it is not expected that the sole use of carprofen would be sufficient to abate pain, therefore multimodal treatment should be provided, including other techniques beyond drugs (Innes *et al.*, 2010; Teixeira *et al.*, 2016).

This study had some limitations. The inclusion criteria were based on a radiographic diagnosis of HD and only two clinical signs of pain. A minimum score for including HD dogs was not considered because there is no correlation between pain intensity and severity of radiographic signs, joint lesions, and clinical function (Brass, 1989). Because there was not a minimum CBPI score defined for HD dogs, several dogs were included in the study with scores lower than the cut-off point for rescue analgesia. The small number of dogs used in each group possibly prevented detection of statistical differences between treatments, however this was not the primary aim of the study. Another limitation was that HD is a complex disease, which may be uni or bilateral, and show different levels of severity, making it difficult to standardize the degree of pain.

In summary, possibly because of the complexity of clinical signs of HD and due to the cultural differences between the USA and Brazil, owners were unable to differentiate limb function from limb pain, therefore the Brazilian Portuguese version of the instrument is unidimensional, like the Swedish version (Essner *et al*., 2017) but different from the English (Brown *et al.*, 2007), French (Ragetly *et al*., 2019), and Italian (Rocca *et al*., 2021) versions which are bidimensional. This result reinforces the need for cross-cultural adaptation and validation of translated versions of metric instruments in biology to guarantee data reproducibility (Sousa and Rojjanasrrirat, 2011).

CONCLUSIONS

The Brazilian Portuguese version of the CBPI is a unidimensional instrument that showed excellent internal consistency, moderate to very good test-retest reliability, adequate item-total correlation, and sensitivity to differentiate dogs with HD from healthy dogs and may be used to assess chronic pain in dogs with osteoarthritis in Portuguese-speaking countries. The suggestive intervention point to provide analgesia in dogs suffering from HD is ≥ 3.

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