1	Psychometric Properties of the Spanish Version of the Functional Evaluation of				
2	Cardiac Health Questionnaire "FETCH-Q™" for Assessing Health-related				
3	Quality of Life in Dogs with Cardiac Disease				
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5	Spanish version of the FETCH-Q™ for assessing health-related quality of life in				
6	Dogs with cardiac disease				
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29

22

#### 30 Abstract

31 Objective

To evaluate the psychometric properties of the Spanish version of the "FETCH-Q™"
 Animals

34 Two hundred forty dogs with cardiovascular diseases and no comorbidities

35 Methods

After forward and back translation, the content validity was evaluated through 36 feedback from veterinary colleagues. For convergent validity, the total score was 37 correlated with the heart disease/failure (ISACHC) class. For construct validity, the 38 overall quality of life of the dog and the results obtained in each item was correlated. 39 The reliability of the questionnaire was assessed using the Cronbach's alpha test. To 40 evaluate the test-retest validity the intra-class correlation coefficient and Wilcoxon-41 42 rank test were used to analyze the changes in total score of dogs that were reexamined. 43

44 Results

A good agreement with the original questionnaire was evident. The face and content 45 validity was appropriate. For construct validity, the questionnaire obtained r > 0.096 46 to < 0.82; (p<0.05). The convergent validity was appropriate and the correlation was r 47 = 0.819 (p<0.001). Cronbach's alpha test was ( $\alpha$  = 0.887) showing an appropriate 48 internal consistency. The test-retest evaluation revealed adequate repeatability (ICC 49 = 0.87; p <0.001). There was no difference in the owner responses to the 50 questionnaire at baseline and two weeks later (p>0.05) in dogs that had stable 51 cardiac disease. The mean and standard deviation (SD) of patients with the 52 maximum score obtained was 3.5 ± 1.5. The mean and SD of patients with the 53 minimum score obtained was 7 ± 2.4. 54

55 Conclusion

This study supports the conclusion that this Spanish version of the functional evaluation of cardiac health questionnaire "FETCHSV2-Q" to assess HRQoL in dogs with cardiovascular disease is valid.

59

Key Words: Qualities of life, health-related, fetch questionnaire, psychometric
 evaluation, dog, congestive heart failure

62

#### 63 Introduction

Traditionally, physicians and veterinarians have acquired key information from patients and pet owners that focuses on history, including the frequency and severity of clinical signs at presentation, and on recurrence of events, such as hospitalization [1-3]. In recent decades, especially in human medicine, additional information has been sought out and collected regarding variables that are indicative of the day-to-

day changes in variables that relate to quality of life that are important to patients and 69 owners [1, 4, 5]. This concept is known as patient-reported outcome measures 70 (PROMs), with the health-related quality of life (HRQoL) measures being the most 71 important [6-9]. PROM is a broad term that refers to the standardized collection of 72 information that is focused on the perspective that the patient or owner has on the 73 74 quality of life at a point in time. This information is commonly obtained through a validated questionnaire [1, 2, 10]. The primary focus is often to monitor the 75 76 progression of the diseases and the impact of therapeutic intervention [4, 11]. PROM can also be useful in predicting outcome and survival [5, 12, 13]. 77

78

Measures of quality of life are used to complement traditional measures of success 79 such as to survival time [1, 14]. They have been used in areas as diverse as drug 80 discovery [15] and clinical practice [4]. Their significance in documenting therapeutic 81 success has been reported [16, 17]. Agencies such as the European Medicines 82 83 Agency [18] and the US Food and Drug Administration [19] recommend the use of HRQoL measures to document the effects of drugs in public health [20], clinical 84 medicine and preventive care settings [3]. The American Heart Association (AHA) 85 [21] and Colombian Society of Cardiology (SCC) [22] also support this approach in a 86 87 wide spectrum of approaches to heart disease and during cardiovascular rehabilitation [23]. 88

89

Quality of life is a broad multidimensional concept that usually includes subjective
evaluation of variables that have both positive and negative effects on life [24, 25].
HRQoL refers specifically to the impact of a disease and its clinical consequences on

individual quality of life [26-28]. HRQoL functions as a common reference point that 93 can then be used to measure the impact of different interventions and treatments for 94 the same health conditions [29]. The instruments that assess HRQoL have evolved 95 to measure the impact of the disease, the effect of specific treatment and a range of 96 other health-related variables on the lives of patients [26, 30]. It is essential to subject 97 98 any instrument that is designed to assess HRQoL to rigorous testing to determine if these instruments are reliable and valid forms of measurement within the target 99 100 population (e.g., dogs with cardiac disease). That is, the instrument must be psychometrically analyzed. In addition to the test (usually a questionnaire) being valid 101 and reliable, it should also be easy to interpret and evaluate before being used in a 102 clinical setting [31-33]. 103

104

The application of a questionnaire in a specific setting does not mean it will work in another setting [34-36]. Some of the most important limitations of using a questionnaire in a different setting are language and culture [3]. Oftentimes a questionnaire needs to be adapted to the context of a new population that has different sociocultural characteristics [37, 38]. Often, the grammar, the syntax and the semantic differences upset the reliability and repeatability of the questionnaire [35, 38].

112

The Functional Evaluation of Cardiac Health Questionnaire "FETCH-Q<sup>™</sup>" created in 2005 by Freeman and colleagues [39] was originally developed and validated with 360 dogs belonging to English-speaking owners. The questionnaire was designed to be used as a disease-specific instrument for assessment of health-related quality of life in dogs with congenital and acquired heart disease. To use this questionnaire within the Spanish-speaking community, it is necessary to investigate the psychometric properties (the reliability and validity of these forms of measurement) of the questionnaire in this population of owners of dogs with cardiac disease. Therefore, the aim of this cross-sectional multicentre study was to evaluate the psychometric properties of a Spanish version of the "FETCH-Q<sup>™</sup>" and validate its use with Spanish-speaking owners of dogs with cardiac disease.

124

## 125 Materials and method

Two professional translators translated the FETCH-Q<sup>™</sup> from English into Spanish 126 independently. After forward and back translation, the face and content validity of the 127 FETCHSV2-Q were evaluated by non-experts (lay persons), ethologists and 128 129 veterinary colleague's feedback. The structure of the questionnaire consists of eighteen items that ask about how a cardiac disease negatively affects the quality of 130 life (see appendix). These questionnaires only ask to the owner about the last two 131 132 weeks of life of their pets. The possible score in the FETCHSV2-Q<sup>™</sup> ranked between 133 (0 - 85 points) was transformed to a percentage by dividing the score obtained for each patient by the maximum possible score and multiplied by 100. In the initial study 134 (n = 360) the FETCH-Q <sup>™</sup> showed good internal consistency [39]. High scores on 135 the FETCH-Q<sup>™</sup> indicate a negative impact of heart disease on quality of life. The 136 validation procedure of the Spanish version of the FETCHSV2-Q was performed 137 according to the instructions of the Mapi Research Institute [40] and the Scientific 138 Advisory Committee of the Medical Outcomes Trust [41]. Finally, the Functional 139

Evaluation of Cardiac Health - Spanish Version Questionnaire (FETCHSV2-Q) wascreated.

142

## 143 Study population

Any dog diagnosed with congenital or acquired heart disease with or without 144 documented congestive heart failure (CHF) that was examined between January 145 2015 and December 2016 was eligible to be included in this study. Dogs could be of 146 any age, weight, breed or sex. The dogs were examined at seven private veterinary 147 clinics and one veterinary teaching hospital located in four Spanish-speaking 148 countries (Manizales-Colombia, Medellin-Colombia, San Martin de los Andes-149 Argentina, Buenos Aires-Argentina, Caracas-Venezuela, Malaga-España, Vigo-150 España). After obtaining institutional review board approval from the ethics 151 committee of the University of Caldas, the respective review committees at each 152 clinic approved the project and informed consent was obtaining from each owner. 153

154

### 155 Data Collection

The referring clinician and cardiologist provided routine clinical and diagnostic data for each dog that included an echocardiogram, thoracic radiographs, an electrocardiogram, cardiac biomarkers (NT-proBNP or cardiac troponin I), an assessment of the functional class of heart failure (ISACHC class) and the results of the FETCHSV2-Q<sup>™</sup>. The questionnaire was completed by each owner using a website designed to collect these data (www.scorefetchsv2.wixsite.com/inicio). All owners had to be willing to participate in the study, had to have Spanish as their native language, had to have an acceptable level of education, had to have no
history of cognitive impairment and had to have lived with the dog for at least six
consecutive months prior to entry.

166

## 167 Reliability Cohort

Randomly selected, 51 owners completed the questionnaire during the first visit and again 2 weeks later to perform the questionnaire's test-retest reliability [42]. Clients included in this group completed the questionnaire two weeks after completing the questionnaire for the first time. Because of this, the most severe affected dogs were not included in this analysis because it was essential that the patients remained stable during this observation period.

174

# 175 The FETCH-Q<sup>™</sup> and FETCHSV2-Q

The FETCH-Q <sup>™</sup> is a questionnaire devised to be easily completed by owners. It 176 only takes into account the last two weeks of the pet's life. In the initial study (n = 177 360) it showed good internal consistency [39]. High scores on the FETCH-Q™ 178 179 indicate a negative impact of heart disease on quality of life. The validation procedure of the Spanish version of the FETCHSV2-Q was performed according to the 180 instructions of the Mapi Research Institute [40] and the Scientific Advisory Committee 181 of the Medical Outcomes Trust [41]. Finally, the Functional Evaluation of Cardiac 182 Health - Spanish Version Questionnaire (FETCHSV2-Q) was created. 183

184 185

186 Validation of the FETCHSV2-Q instrument

To demonstrate convergent validity the total FETCHSV2-Q score was correlated with the ISACHC class (International Small Animal Cardiac Health Council) using Spearman rank correlation test. For construct validity, owners at the same time were asked to evaluate the overall quality of life of the dog and their answers were correlated with the results obtained in the individual items using Spearman rank correlation test. A p-value < 0.05 was considered statistically significant.

193

## 194 Statistical analysis for reliability and repeatability

All the statistical analyses were carried out using the statistical software R V.2.15.3. 195 Data normality was evaluated using the Kolmogorov-Smirnov test. The reliability of 196 197 the questionnaire was assessed with the Cronbach's alpha test ( $\alpha$ ) [43]. This test reflects the cohesion of each item or question with the same objective (e.g., assess 198 the impact of disease on quality of life). Cronbach's alpha ( $\alpha$ ) values  $\geq 0.7$  have been 199 considered acceptable, a value > 0.8 have been considered good and a value > 0.9 200 201 has been considered excellent. To evaluate the test-retest repeatability of the questionnaire, the intra-class correlation coefficient and the Wilcoxon rank test were 202 used to analyze the changes in FETCHSV2-Q score of patients that were followed-203 up two weeks later as described by Terwee [42]. The intra-class correlation 204 205 coefficient (ICC) denotes the proportion of variability in scores and an ICC > 0.4, 0.6 and 0.8 indicate moderate, substantial and excellent repeatability, respectively. The 206 ceiling and floor effect was displayed with the mean scores, standard deviation and 207 percentage of patients with the maximum possible score and minimum possible 208 score, respectively as described by Gonzalez [44]. A p-value < 0.05 was considered 209 statistically significant. 210

211

## 212 Results

#### 213

#### 214 **Population**

Records from Two hundred forty dogs (n = 240) were evaluated. Table 1 shows the 215 demographic information and Figure 1 shows the distribution of the different stages 216 of heart disease/failure. Most dogs were suffering from myxomatous atrioventricular 217 valve disease (n = 159, 66%). Dilated cardiomyopathy was present in 29 % of the 218 dogs (n = 69), most frequently affecting giant breeds and cocker spaniel. Pulmonary 219 hypertension (n = 3) and arrhythmogenic right ventricular cardiomyopathy of Boxers 220 221 (n = 4) were present in 3% of dogs. Atrial septal defect (n = 2), cor triatriatum dexter (n = 1), subaortic stenosis (n = 1) and patent ductus arteriosus (n = 1) added up to 2 222 223 % of the diseases of dogs included in this study. Twenty-seven dogs (11 %) had died by the time of data collection. 224

#### 225

## 226 Validation

After forward and back translation, no changes were identified in the questionnaire and a good agreement with the original questionnaire was subjectively evident. The face and content validity were approved by all the pre-evaluators who considered it to be appropriate easy to understand by the owner. For construct validity, each item was correlated with the overall quality of life evaluated by the owner. Correlations (r) ranged > 0.096 to < 0.82; (p< 0.05). The convergent validity was appropriate (Figure 2) and the correlation between a set of ranges of the total score obtained in the FETCHSV2-questionnaire and the classes of heart disease/failure ISACHC was r = 0.82 (p < 0.001).

236

## 237 Reliability and repeatability

The Kolmogorov-Smirnov test showed a non-normal data distribution (p < 0.05). 238 239 Cronbach's alpha was ( $\alpha = 0.887$ ) showing an appropriate internal consistency of the questionnaire. The test-retest had an adequate repeatability on the intra-class 240 correlation coefficient test (ICC = 0.87; p < 0.001). The Wilcoxon rank test showed no 241 242 difference in responses at baseline and two weeks later (p > 0.05). The mean, standard deviation (SD) and percentage of patients with the maximum score 243 obtained (ceiling effect) was 3.5 ± 1.5 (0.77 %). The mean and SD of patients with 244 the minimum score obtained (floor effect) was 7 ± 2.4 (1.05 % of total population). 245

246

## 247 Discussion

Our research describes step-by-step the rigorous psychometric evaluation to which 248 the Spanish version of the functional evaluation of cardiac health questionnaire 249 250 (FETCHSV2-Q) was submitted in a cross-cultural validation context. It proved to be a questionnaire that was apparently clear, valid, reliable, repeatable in clinical settings 251 252 and useful as a measurable result for clinical research. The high internal consistency ( $\alpha = 0.887$ ) supports the evidence that all eighteen items are highly correlated with 253 each other and suggests that the instrument is reliable for measuring the health-254 related quality of life in this group of dogs with different naturally occurring 255 cardiovascular diseases. This value was somewhat lower than the results obtained 256 during the initial validation of the FETCH-Q instrument [39] where authors obtained a 257 > 0.90. Nevertheless, our research still confirms the FETCHSV2-Q can be used to 258

evaluate the clinical course of cardiovascular diseases in dogs since there was a 259 strong correlation with the functional class of CHF (ISACHC) [45]. However, the 260 scattered correlation of each item suggests that some questions may not be 261 important enough to remain in the questionnaire. In addition, the high correlation 262 between all items (Cronbach alpha greater than 0.90) means there may be 263 264 redundant items in the questionnaire [1] [31]. On the other hand, in this study a reliability coefficient > 0.80 is excellent as it implies that 80% of the measured 265 variances are reliable and only 20% are due to random error [46, 47]. 266

In the study design, if more than 30% of the FETCHSV2-Q questions were not properly filled in, the questionnaire was excluded from the statistical analysis. The fact that no questionnaire was excluded demonstrates the ease and simplicity of completing the questionnaire and apparently confirms to some extent the content validity [48]. The need for a questionnaire to be simple (easy to understand) has been reported in other research in order for it to be a valid instrument for clinical use. [45, 49].

274

275 The growing need to use alternative tools to demonstrate treatment outcomes for cardiovascular disease has placed focus on HRQoL questionnaires in public health 276 277 where the QoL of the patient is often considered to be the main objective [38]. Currently in human health economics, HRQoL questionnaires are adjusted to reflect 278 the quality of life over years. This has been identified as a useful tool in cost-utility 279 analyses [50]. Moreover, HRQoL questionnaires have become a widely used tools 280 for assessing the rehabilitation of several different chronic diseases [51, 52], 281 demonstrating particular advantages over traditionally measured biological variables 282 [36]. It is clear that the evaluation of biological outcomes such as the development of 283

congestive heart failure, ventricular function and survival time are not all the essential 284 evidence needed to provide proper management of dogs with cardiovascular disease 285 [21, 26, 53]. Addressing only objective variables and survival fails to address the 286 multi-dimensionality of quality of life in an animal [54]; especially the subjective 287 nature of some of its components [55, 56]. The evaluation of some results as 288 289 subjective factors [57] that can be measurable is the complement that must be necessarily included in future investigations that evaluate the success of a medical or 290 291 surgical treatment [16, 58, 59]. Some subjective non-physical aspects such as 292 emotional stress, physical discomfort, restrictions on daily life and loss of socialaffective interaction are indicators of health-related quality of life in dogs [60, 61]. 293 Thus, improvement in HRQoL is considered an important therapeutic benefit, similar 294 to mortality and morbidity [60, 62, 63]. In addition, congestive heart failure morbidity 295 not only increases the recurrence of hospitalization [21, 64] and limitations during 296 exercise (fatigue, dyspnea or syncope), but is also responsible for psychological and 297 emotional complications in people and animals affecting well-being [37, 56]. In 298 contrast, in some studies HRQoL has been shown to be a good predictor of mortality 299 300 and hospitalization in patients with CHF [65]. However, even after evidence, healthrelated quality of life is not yet a primary goal in some treatments [26]. 301

302

It has been shown that disease-specific questionnaires are superior to general questionnaires. In humans, general questionnaires cannot properly evaluate and take into account the complexity of the psychosocial and physical sequelae of a particular disease and so can create erroneous results [45, 66]. It is also possible that specificdisease questionnaires are superior to general questionnaires in dogs if they can be shows to have adequate psychometric properties for a particular sick dog population

[67, 68]. An example of a specific questionnaire in humans is the Minnesota Living 309 with Heart Failure Questionnaire, which is the most frequently used questionnaires in 310 people with CHF [37]. It is used to evaluate patients' perceptions of the effects of a 311 variety of physical and emotional variables on the lives of people with heart failure. 312 There are at least 34 different language versions of the questionnaire [34]. The 313 314 original English version was developed by Thomas Rector in 1987 [69] to assess the impact of CHF on HRQoL. Most of the linguistic adaptations of the MLHFQ have 315 316 been created following the same forward and back translation process used in the 317 current study [37].

318

There are several limitations in our study that deserve consideration. First, the 319 sample size was relatively small. However, this study was conducted at different 320 veterinary centers in four countries, providing a wide range of sociocultural, 321 economic, educational and environmental contexts that enriches the psychometric 322 properties of the questionnaire with a heterogeneous group of dogs and possibly 323 overcome the limitation of sample size. Second, it is unknown if the questionnaire is 324 325 unidimensional or multidimensional in nature. All items in the questionnaire were treated as if they were equally important. There is a possibility that some factors may 326 327 be more important than others in dogs with heart disease and future research is necessary to determine these different factors by advanced statistical methods [70], 328 such as principal component analysis [71] or by a subjective approach [72]. Third, no 329 sub-group analysis was done. This occurred because the number of dogs from each 330 clinic was too small for robust statistical analysis; the entire population was 331 considered as a total sample. The small number of critical dogs (n = 9) in the late 332 stages of heart failure was also a limitation. Unfortunately, the difficulty of follow-up 333

dogs limited the collection of data for evaluated the responsiveness of the questionnaire to changes in the clinical status of the disease or the impact of the therapy over time and further research is needed.

337

## 338 Conclusion

The results of this study support the validity of the Spanish version of the functional 339 evaluation of cardiac health questionnaire "FETCHSV2-Q" to evaluate HRQoL in 340 341 dogs with naturally occurring cardiovascular disease. These results provide new information that justifies its use in clinical settings and the authors hope it will be use 342 in future research where the quality of life is an important goal. In the other hand, the 343 satisfaction of dog health care needs can be promoting through the HRQoL 344 assessment. However, the cooperation of owners and their participation in the health 345 care of their own pet are the most important factors that facilitate education, 346 communication and improve adherence with cardiologist's recommendations, 347 especially in decision-making (e.g definitive surgical correction, rehabilitation and 348 change in therapy or euthanasia). Finally, future researches should be develop to 349 350 demonstrate responsiveness of the FETCH-Q or FETCHSV2-Q to change in the clinical status of dogs with heart disease as well as responsiveness to change when 351 352 a therapy is established.

353

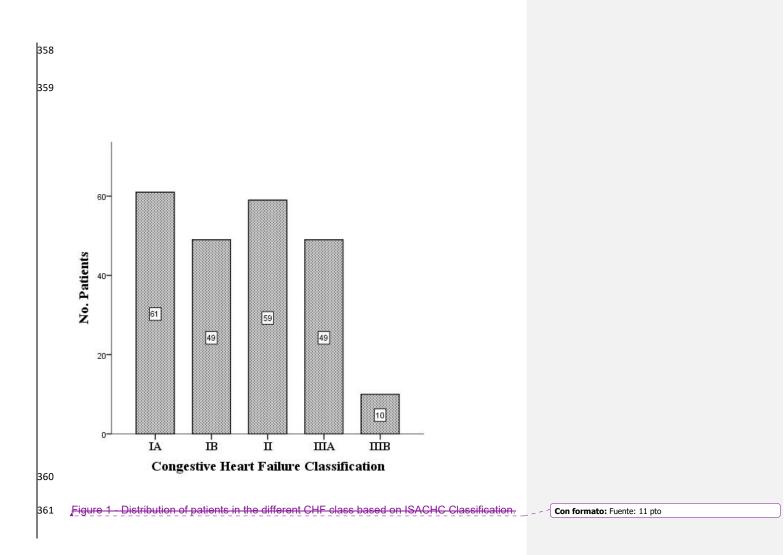
## 354 Conflict of Interest Statement

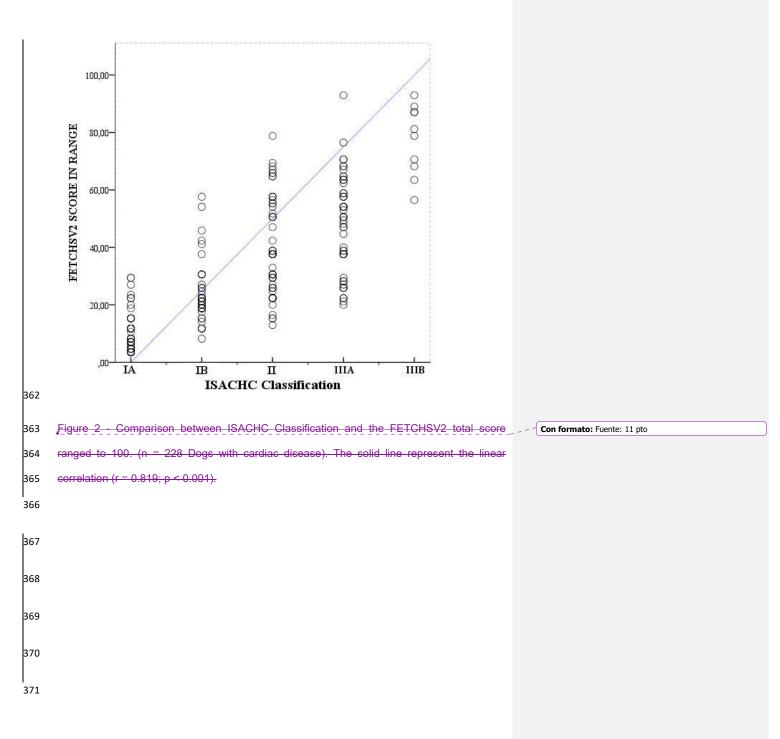
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The authors do not have any conflicts of interest to disclose

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# 589 Table 1 - Demographic characteristics of dogs without CHF and with CHF

	Non-CHF	CHF	Range/ Percentage***
Ages (years)	8.9 ± 4.2*	12.1 ± 5.4*	1.2 – 17.1**
Sex (females)	111 ± 22*	47 ± 9*	19.5 - 46.2 %
Weight (Kg)	16.72 ± 5.9*	12.28 ± 7.0*	3.9 – 59.7**
Neutered	87 %	49 %	-

591 (\*Mean ± SD) (\*\*Range)(\*\*\*total population)

