Development and Validation of a New Instrument to Measure Health-related Quality of Life in Patients with Psoriatic Arthritis: The VITACORA-19

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ABSTRACT. ***Objective.*** To develop/validate an instrument to measure health-related quality of life (HRQoL) in patients with psoriatic arthritis (PsA), for use in clinical studies.

Methods. An item pool of 35 items was generated following standardized procedures. Item reduction was performed using clinimetric and psychometric approaches after administration to 66 patients with PsA. The resulting instrument, the VITACORA-19, consists of 19 items. Its validity content, internal consistency, test-retest reliability, known groups/convergent validity, and sensitivity to change were tested in a longitudinal and multicenter study conducted in 10 hospitals in Spain, with 323 patients who also completed the EuroQol 5-dimensional questionnaire (EQ-5D) and a health status transition item. There were 3 study groups: group A (n = 209, patients with PsA), group B (n = 71, patients with arthritis without psoriatic aspect, patients with arthrosis, and patients with dermatitis), and group C (n = 43, healthy controls).

Results. The questionnaire was considered easy/very easy to answer by 94.7% of the patients with PsA. The factorial analysis clearly identified only 1 factor. Cronbach's alpha coefficient and inter-class correlation coefficients exceeded 0.90. Statistically significant differences ($p < 0.001$) were observed between groups: subjects from group C had better HRQoL, followed by group B, and finally group A had the worst HRQoL. The VITACORA-19 scores showed significant correlations ($p < 0.001$) to PsA disease activity, EQ-5D, and perceived health state, scoring the patients with better health state higher. The minimum important difference was established as an 8-point change in the global score.

Conclusion. The Spanish-developed VITACORA-19, designed to measure HRQoL in patients with PsA, has good validity, reliability, and sensitivity to change. (First Release Sept 1 2014; J Rheumatol 2014;41:2008–17; doi:10.3899/jrheum.131021)

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Psoriatic arthritis (PsA) has been defined as a unique type of inflammatory peripheral and/or axial arthritis that is associated with skin psoriasis[1,2]. Its exact prevalence is unknown, but studies suggest that PsA occurs in 30% of patients with psoriasis[3,4,5]. PsA imposes a considerable economic and human burden, and has a substantial effect on patients' health-related quality of life (HRQoL) and functioning[6,7,8,9,10].

HRQoL is an important indicator of the burden of musculoskeletal disease and is usually defined as a multidimensional concept encompassing the physical, mental, and social components associated with an illness or its treatment[11]. That is, HRQoL is the subjective perspective of functioning, as is defined by the World Health Organization[12,13]. Generic instruments have traditionally been used to measure HRQoL, but studies have shown that correlation between clinical assessments and subjective generic measurement like HRQoL is poor[14].

An attempt to overcome this gap was the development of specific HRQoL instruments. Only 1 disease-specific instrument has been developed to evaluate HRQoL in patients with PsA to date[15] — the PsAQoL. That questionnaire is not validated in the Spanish population nor is there any other specific questionnaire for arthritis validated in this population.

Because the PsAQoL presents some limitations, instead of adapting it into Spanish, the aim of our present study was to develop a new instrument. It would be suitable for use in clinical studies.

MATERIALS AND METHODS

The new questionnaire was developed and validated following a standardized procedure. The process consisted of 2 main phases: (1) item generation, item reduction, and questionnaire development (pilot study); and (2) validation of the final version of the questionnaire (validation study).

Item generation, item reduction, and questionnaire development. Questionnaire content was developed from a literature review, consultations with clinical experts and experts in the development and use of patient-reported outcomes measures, and focus groups of patients with PsA. A comprehensive review of the scientific literature was conducted to identify instruments already developed to measure the PsA HRQoL and to identify issues of relevance in the construction of the new instrument. There were 7 focus groups of patients with PsA, and a semistructured script was used to guide discussions. Focus groups included 5 to 7 patients, and the most relevant statements obtained from those interviews were used to prepare the questionnaire.

To identify items for inclusion in the final version of the questionnaire, the items in the item pool were administered to a sample of patients with PsA in an observational, cross-sectional, multicenter study (pilot study). Analysis of missing responses and response distribution were included to reduce the number of items. In addition, using the responses collected, an item analysis was performed following a strategy based on Classic Test Theory (CTT)[16] and the Rasch analysis[17,18] to reduce the size of the instrument. The CTT presupposes, then one can directly infer, e.g., the quality of life of a patient with PsA by summing up the responses and calculating a total score, assuming that each item contributes equally to this total score. In contrast, the Rasch model provides an alternative scaling methodology that enables the examination of the hierarchical structure and the unidimensionality and additivity of HRQoL measures. The Rasch analysis constructs a line of measurement, with the items placed hierarchically, and provides a statistical adjustment indicating to what degree an item describes the group of subjects responding to the questionnaire.

The chi-squares in common use are known as OUTFIT and INFIT. These are reported as mean-squares (chi-square statistics divided by their degree of freedom), so that they have a ratio-scale form with expectation 1 and range 0 to +infinity. INFIT and OUTFIT MNSQ indices > 1.3 or < 0.7, respectively, were eliminated. Successive Rasch analyses were performed until a final set of items satisfied the model fit requirement. Additionally, those items with a separation below 1 were eliminated. Internal consistency coefficients (Cronbach's alpha) were obtained for the overall scale as an expression of reliability.

Each item allows for 5 Likert-like response choices from "always" to "never", and the referred time period is the previous week. Score for the overall questionnaire is obtained by adding the responses to the corresponding items, with subsequent standardization to a scale ranging from 0 (worst HRQoL) to 100 (best HRQoL). Standardization is obtained as follows:

$$(\text{actual score} - \text{minimum score}) \div (\text{maximum score} - \text{minimum score}) \times 100$$

The final Spanish version of the questionnaire is called VITACORA-19 (Appendix 1).

Questionnaire validation. To validate the VITACORA-19 questionnaire, a multicenter, observational, prospective study was conducted from January 2010 to September 2010 at the rheumatologic departments of 10 Spanish hospitals.

There were 3 study groups defined based on health condition. Group A included patients who were diagnosed with PsA according to the Moll and Wright criteria[19]. Two clinical subsets were used: peripheral PsA and axial PsA[20]. The distinction was made by each treating rheumatologist according to their clinical judgment. Group B included patients with arthritis, but not the psoriatic type (rheumatoid arthritis, ankylosing spondylitis, and undifferentiated arthritis), patients with arthrosis (any type), and patients with dermatitis (any type). Finally, Group C comprised healthy controls.

Our study aimed to include a total of 389 subjects. Each center participating consecutively included ambulatory patients aged more than 18 years, and all subjects provided informed consent to participate. The project was approved by the Ethics Committee at La Princesa Hospital in Madrid, Spain.

Sample size. The sample size was calculated for each study group. On the one hand, patients in group A (patients with PsA) were included to allow both assessment of the sensitivity to change and test-retest reliability of the questionnaire. The sample size required to assess the sensitivity to change was selected to guarantee an 80% statistical power to detect an effect size change (i.e., difference/SD) of 0.2, considered of small magnitude[21], with significance level. Assuming 10% of patients would be lost to followup or not evaluable, the sample size calculated for this group was 198 patients. The sample size required to assess the test-retest reliability was observed to obtain an interclass correlation coefficient (ICC) of 0.7 or higher, assuming a minimum ratio of 0.5. With identical statistical criteria, 1 additional sample size of 63 patients with PsA was required.

For group B, a ratio of 1 control for every 5 patients with PsA was estimated. A sample size of 78 patients was required to detect an effect size of 0.4 or higher with a 5% 2-sided significance level of 0.05 and a statistical power of 0.80.

Group C, a sample of healthy controls, comprised 50 healthy subjects.

Figure 1 shows the study design and the size of the groups.

Study measurements. All patients with PsA recruited into the study (group A) attended 3 visits: a baseline visit, a second visit at 10 days, and a final visit at 6 months. The patients in groups B and C attended only the baseline visit.

At the baseline visit, the following were recorded: sociodemographic data, clinical subsets of PsA, time since diagnosis, and PsA activity assessments [C-reactive protein, erythrocyte sedimentation rate (ESR), body surface area (BSA), Bath Ankylosing Spondylitis Function Index (BASFI), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), and the 28-joint Disease Activity Score (DAS28)]. At the final visit, the same variables were recorded, except for sociodemographic characteristics. At each visit, study participants completed the specific VITACORA-19 questionnaire, the Spanish EuroQol 5-dimensional (EQ-5D) questionnaire[22], and the visual analog scale (VAS) of the EQ-5D, and they were asked about their perceived general health using a Likert scale with 7 response options (from "very good" to "very poor"). Patients and clinicians were also asked to estimate the PsA global activity, and 1 additional item pertains to health state transition.

Statistical method. A descriptive, comparative analysis of the sociodemographic and clinical characteristics of groups A, B, and C study participants was performed. For group comparison, ANOVA test with the Bonferroni correction was used for multiple comparisons of continuous variables, and a chi-square test was used for categorical variables. Changes in PsA activity variables and overall scores from baseline to the final visit were also compared in the different study groups using the same statistical tests. The questionnaire's feasibility was assessed through the ease-of-use question. The distribution of the overall scores was analyzed by calculating mean scores, SD, observed score ranges, and floor and ceiling effects.

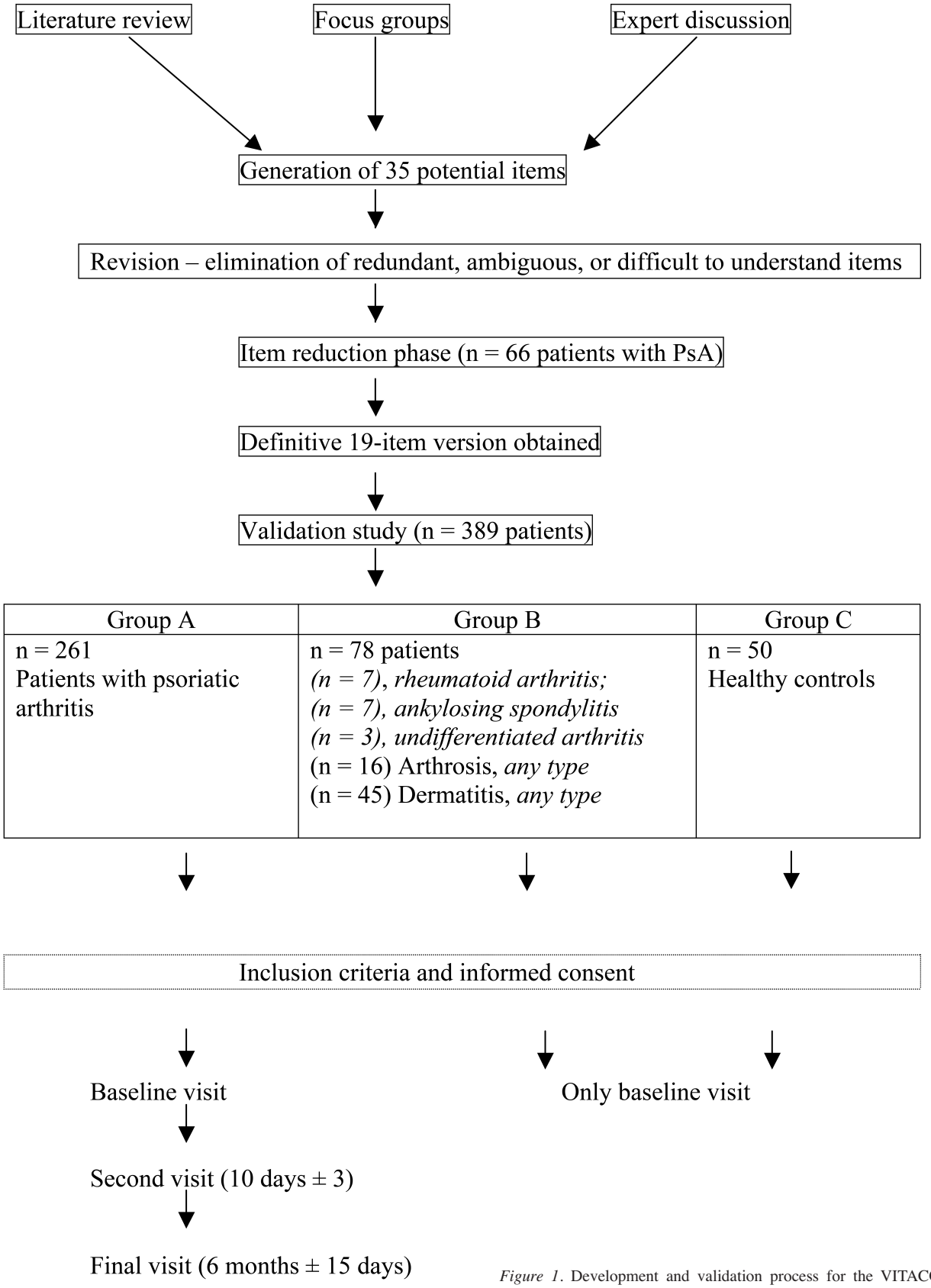

Figure 1. Development and validation process for the VITACORA-19 questionnaire. PsA: psoriatic arthritis.

The unidimensionality of the VITACORA-19 questionnaire was explored through examination of the residual correlation of a one-factor exploratory factor analysis of the items to determine whether the new instrument could be reduced to a unique summary score. A unidimensional questionnaire is one that measures only 1 concept (dimension, construct), e.g., disability (or its inverse, function).

The instrument's internal consistency was assessed by estimating Cronbach's alpha coefficient for the overall score at baseline. An alpha value of 0.70 or above is necessary to call a scale internally consistent[16]. The 10-day test-retest reliability was assessed by calculating the ICC between visits in patients who did not report any significant change on the health status transition item[23].

Known-groups validity was tested by comparing the questionnaire scores of the different study groups, using an ANOVA test. Because they could have both skin lesions and joint disease, the patients with PsA were expected to report HRQoL worse than that of patients with psoriasis, or patients with arthritis without psoriasis, or those with arthrosis or dermatitis, or healthy controls. The statistically significant differences between study groups were confirmed using a regression model that adjusted by sociodemographic characteristic differences.

To assess convergent validity, the relationship between the scores in the VITACORA-19 and scores obtained in the descriptive system of the EQ-5D was analyzed at baseline using an ANOVA test or no parametric test of Kruskal-Wallis, and the correlation between the scores in the VITACORA-19 and the scores obtained in the VAS of the EQ-5D was analyzed using Pearson's correlation coefficient. Patients with PsA were included in this analysis. Scores obtained in the questionnaire were analyzed based on the presence of problems in the items of the descriptive system of the EQ-5D questionnaire using a Student's t test.

To assess longitudinal validity, changes seen in scores in the VITACORA-19 questionnaire from the baseline to the final visit were compared to the changes seen in PsA activity assessments during the same time period. For this, a Student's t test, an ANOVA test, and the Pearson's correlation coefficient were used depending on the type of variable analyzed.

Finally, to assess sensitivity to change, the effect size obtained in VITACORA-19 was calculated. The minimal clinically important difference (MCID) of the questionnaire was estimated as the difference seen by patients who stated that their health status had a "small improvement" at 6 months after study start. Effect size values of about 0.2 were considered to represent a small change, values of about 0.5 a moderate change, and values of about 0.8 or higher a large change[21].

A significance level of 0.05 was considered for all group comparisons.

RESULTS

Item generation, item reduction, and questionnaire formatting. The literature review identified only 1 instrument to measure HRQoL in patients with PsA; it was not validated in the Spanish language. Recommendations from the expert consensus meeting concerning the characteristics of the new questionnaire included that it should contain basic symptoms and be self-administered and easy to score. The focus group sessions included 66 patients with PsA and generated an initial item pool of 35 items. The pilot test reduced the number of items to 19 and gave a preliminary indication of the good measurement properties of the questionnaire.

Validation of the VITACORA-19 questionnaire. The new questionnaire was considered easy or very easy to answer by 94.7% of 323 patients with PsA. Using the whole Rasch reduced version, the unidimensionality of the questionnaire was explored and only 1 principal component was identified that accounted for most of the observed variance (55.8%). Evaluable responses were available for a total of 323 patients at the first visit.

Table 1 provides the baseline characteristics and health of study participants. Patients in group A had a slightly higher mean age (48.7 yrs) than subjects in the 2 other groups (46.5 yrs in group B and 42 yrs in group C, $p < 0.001$). The table also includes patient-reported information about health status at the baseline in the groups under study. Worsening functional status, perceived health state, and HRQoL were reported by the group of patients with PsA compared with the other groups. Clinical features comparison between group A and group B shows the same time from diagnosis (8 yrs), and a similar percentage of comorbidities. BSA and scores for BASDAI and DAS28 were measured only in group A.

Table 2 shows the score distributions, floor and ceiling effects, internal consistency, and test-retest reliability coefficient for the questionnaire. Floor and ceiling effects were less than 2% for the overall score. Cronbach's alpha value and the ICC value for the overall score exceeded 0.90. The 10-day test-retest reliability was assessed in a subgroup of patients who did not report any significant change on the health status transition item ($n = 97$).

Table 3 shows the results of testing the known groups' validity of the VITACORA-19 questionnaire. Statistically very significant differences ($p < 0.001$) were observed among the groups: subjects from group C (healthy controls; mean overall score 93.7, SD 9.1) had a better HRQoL, followed by group B (patients with arthritis but not PsA, and those with arthrosis or dermatitis; mean overall score 69.2, SD 24.8), and finally group A (PsA; mean overall score 56.2, SD 24.8), which had the worst HRQoL. No significant differences were found between PsA clinical subsets (axial vs peripheral) or oligoarthritis versus polyarthritis. On the contrary, statistically significant differences were found between patients with PsA and patients with psoriasis (group B control, $p < 0.05$). Patients with psoriasis had higher HRQoL scores than did patients with PsA. In patients with PsA with different disease activity, as measured by DAS28, significant differences were found ($p < 0.001$) among groups using the accepted cutoff value of remission (better HRQoL), moderate activity, and high activity (worse HRQoL). When VITACORA-19 global score was analyzed according to the level of problems in each of the EQ-5D dimensions and to patient/clinician perceived health state, significant differences were found ($p < 0.001$).

Table 4 shows the results of testing convergent validity of the VITACORA-19. The highest correlation coefficients were the relationships for ESR, DAS28, EQ-5D VAS, and for the estimation of PsA global activity according to patients and physicians.

Finally, Table 5 shows the results of testing the sensitivity

Table 1. Baseline characteristics and health of the study participants (n = 323). Group A: patients with PsA. Group B: patients with arthritis and no psoriatic—any type of arthrosis—any type of dermatitis. Group C: healthy controls.

Characteristics	Group A, n = 209	Group B, n = 71	Group C, n = 43
Sociodemographic features			
Age, yrs*, mean (SD)	48.7 (11.8)	46.5 (15.2)	42 (8.2)
Female*, n (%)	89 (42.6)	43 (75.7)	32 (74.4)
Educational level*, n (%)			
No education	6 (2.9)	3 (4.3)	0
Primary education	94 (45)	34 (48.6)	7 (16.4)
Secondary education	72 (34.3)	13 (18.6)	12 (27.9)
University studies	37 (17.7)	20 (28.6)	24 (55.8)
Total	209 (100)	70 (100)	43 (100)
Employment status*, n (%)			
Working	105 (50.5)	31 (44.9)	40 (93)
Unemployed	16 (7.6)	5 (7.3)	0
Student	3 (1.4)	3 (4.3)	0
Retired	46 (22.1)	11 (15.9)	0
Housekeeper	26 (12.5)	16 (23.2)	3 (7)
Other	12 (5.8)	3 (4.3)	0
Total	208 (100)	69 (100)	43 (100)
Health assessments			
EQ-5D VAS*, mean (SD)			
VAS (0–100)†	65.4 (22.1)	65.1 (26.4)	91.4 (14.1)
EQ-5D descriptive system*, %			
Mobility problems	44.3	26.9	2.5
Self-care problems	28.6	27	0
Daily activities problems	47.8	19.1	0
Pain/discomfort	68.6	56.5	4.9
Anxiety/depression	50	39.1	0
Perceived health state*, %			
Good/very good	39.1	45.5	97.1
VITACORA-19*, mean (SD)			
Global score‡	56.24 (24.8)	69.23 (24.8)	93.7 (9.1)
Clinical features			
Time from diagnosis, yrs, mean (SD)	8 (7.5)	8 (7.7)	—
Psoriasis/other dermatitis diagnosis, n (%)	203 (98.5)	40 (56.3)	—
Comorbidities, n (%)	96 (45.9)	30 (43.2)	—
BSA, % (SD)	22.4 (28.1)	—	—
BASDAI, 0–10, mean (SD)	2.2 (6.3)	—	—
DAS28, 2–10, mean (SD)	2.7 (1.5)	—	—

*$p < 0.001$. †Range from 0 (worst health status) to 100 (best health status). ‡Global score range from 0 (worst health-related quality of life) to 100 (best health-related quality of life). Statistical significant differences between study groups after adjusting by sociodemographic differences. PsA: psoriatic arthritis; EQ-5D: EuroQol questionnaire 5-Dimensional; VAS: visual analog scale; VITACORA-19: PsA quality of life questionnaire; BSA: body surface area; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; DAS28: 28-joint Disease Activity Score.

to change of the VITACORA-19 questionnaire among patients reporting at least a small improvement in health state (n = 73). Effect sizes for the global score changes between 2 study visits among patients with PsA ranged from 0.20 to 0.80. The MCID was established as an 8-point change in the global VITACORA-19 score.

DISCUSSION

Our present study has described the development of a new specific questionnaire designed to assess HRQoL in patients with PsA. This kind of patient-reported outcome is an attractive option in a busy medical practice[24]. The idea of developing a specific questionnaire based on systematic methodology arose from the scarce number in the literature of PsA HRQoL instruments and their limitations.

Only 1 disease-specific instrument (PsAQoL) has been developed to date to evaluate HRQoL in patients with PsA, using the needs-based model[15]. We decided not to adapt this questionnaire into Spanish because it does not take into account basic symptoms in these patients nor repercussions of the dermatological process on the HRQoL. Thus, we felt the need to develop a new instrument, considering the

Table 2. Score distributions, floor and ceiling effects, internal consistency, and test-retest reliability of the VITACORA-19 questionnaire.

VITACORA–19	Global Score
Items, n	19
Mean	55.7
SD	24.6
Theoretical range	0–100
Observed range	10.5–100
Floor*, %	0
Ceiling†, %	1
Cronbach's alpha	0.95
ICC‡	0.94

*Percentage of patients with the worst possible score. †Percentage of patients with the best possible score. ‡Stability assessed by patient; subgroup of stable patients, n = 97. VITACORA-19: PsA quality of life questionnaire; ICC: interclass correlation coefficient.

HRQoL as a multidimensional construct and keeping in mind the Wilson and Cleary-integrated HRQoL model for health outcomes[14,25,26]. In the VITACORA-19 validation process, we have seen that basic symptoms in patients with PsA (swelling or pain) and psychosocial aspects of the dermatological disease (sense of shame or social rejection) affect HRQoL. Therefore, several items of the questionnaire are related to these PsA-specific problems.

The VITACORA consists of only 19 items and has proven quick and easy to complete. It is thus considered suitable for use in standard clinical practice.

The development of the VITACORA-19 followed recommended guidelines[27,28], and a considerable effort was made to include the point of view of the clinicians/patients from different parts of Spain, and to ensure that the sample was reasonably geographically representative. Although content validity evaluations tend to be fairly subjective, the rational basis, the comparison with existing standards, expert opinions, and the inclusion of focus groups of patients with PsA in the development process of the questionnaire ensured the new instrument's content validity. The fact that only 1 component/dimension was obtained in the inspection of the residual correlation of 1-factor exploratory factor analysis suggests the instrument's uni-dimensionality and supports the use of the summary scores.

The VITACORA-19 shows good psychometric characteristics, and meets accepted criteria for use in clinical studies[27,28,29]. Floor and ceiling effects were within acceptable limit[30]. The instrument also shows good internal consistency for the overall score and meets the recommended level of 0.7 for use at group level[27,28,29]. The Cronbach's alpha value (0.95) is sufficient to permit its use at individual level[16]. Test-retest reliability results were positive; they are higher than the recommended threshold of 0.70.

The analysis of known groups' validity showed that the VITACORA-19 questionnaire discriminated well between groups under study. Likewise, it has discriminated well between PsA clinical subsets, between patients with PsA and patients with psoriasis, and according to different disease activity levels. These findings are coherent with our previous hypothesis and coincide with reports by other authors[6]. Significant differences between patients with PsA and the general population have been shown[9,31,32,33]; it causes as much disability as do other major diseases[34].

As expected, a higher level of problems in each of the EQ-5D variables corresponds to a lower HRQoL global score in the VITACORA-19 questionnaire. The high percentage of patients with PsA with anxiety/depression and pain/discomfort can explain the high PsA HRQoL deterioration because these symptoms are important correlates of HRQoL. Kotsis, *et al* have described a correlation in this sense[35], and a consequential and bidirectional relationship has been seen between depressive symptoms and pain[36]. Reinforcing this hypothesis, patients with PsA reported greater role limitations attributable to emotional problems and more bodily pain than did patients with other inflammatory arthritis, such as rheumatoid arthritis[37]. Although this last fact can be supposed from our findings, attributable to a low number of patients with arthritis within group B, further investigation is needed to establish that HRQoL in patients with PsA is worse than in other types of arthritis as measured by the VITACORA-19 questionnaire.

The psychological and social effects of skin involvement have been well documented in patients with psoriasis[38,39], and dimensions typically affected by PsA were mental health and social functioning[33]. Khraishi, *et al* reported that patients who had PsA for longer than 2 years had rates of depression 2 to 5 times higher than those of age-matched controls who had no history of PsA or psoriasis[40]. The extent of disability and the effect on physical and mental HRQoL is possibly related to the psoriatic skin lesions and peripheral and/or axial joint disease[33,41] that these patients have. These statements correspond to our findings.

The correlations revealed a moderate relationship between VITACORA-19 global score with EQ-5D VAS, BASFI, and DAS28, and a weak relationship with the BSA, in line with similar results shown by the other PsA-specific HRQoL instrument[42]. Significant correlations between VITACORA-19 overall score and perceived health state by patient/clinician indicated that patients with better health state reported higher HRQoL.

At followup, no significant correlations were found between VITACORA-19 overall score changes and PsA clinical assessment changes. Usually, no correlations values higher than 0.7 were reported[43]. This indicates that the clinical HRQoL-specific assessments should be considered not as overlapping but as complementary.

Finally, the instrument appears to be sensitive to changes in patients' health status. Effect sizes for the global score

Table 3. Known-groups validity of VITACORA-19 questionnaire according to groups under study, to subset/clinical/activity features, and to EQ-5D and health state perception scores of patients with PsA at baseline (n = 209). Values given are means ± SD. Higher scores signify better HRQoL. Range from 0 to 100.

	VITACORA-19 Global Score	ANOVA
Groups under study		
Group A, mean (SD), n = 209	56.24 (24.8)	p < 0.001
Group B, mean (SD), n = 71	69.23 (24.8)	
Group C, mean (SD), n = 43	93.76 (9.1)	
Total, n = 323	64.1 (26.6)	
p	All comparisons (Group A–Group B, Group A–Group C, Group B–Group C) were significant at p < 0.001 after adjusting for sociodemographic differences.	
PsA clinical subsets		
Axial, mean (SD), n = 37	53.6 (24.1)	p = 0.48
Peripheral, mean (SD), n = 161	56.8 (25.1)	
Oligoarthritis, mean (SD), n = 90	59.6 (25.1)	p = 0.11
Polyarthritis, mean (SD), n = 71	53.3 (24.8)	
Total, n = 198	56.23 (24.8)	
PsA vs psoriasis		
Psoriatic arthritis, mean (SD), n = 198	56.24 (24.8)	p < 0.05
Psoriasis (Group B), mean (SD), n = 11	79.96 (30.1)	
PsA disease activity, DAS28 (range 2–10)		
Remission (< 2.6), n = 62	71.60 (19.8)	p < 0.001
Moderate disease activity (2.6–5.1), n = 46	48.36 (20.6)	
High disease activity (≥ 5.1), n = 10	43.41 (19.5)	
EQ-5D descriptive system, mean (SD)		
Mobility problems		
No, n = 110	68.2 (20.8)	
Yes, n = 86	40.7 (21.1)	p < 0.001
Total, n = 196	56.1 (24.9)	
Self-care problems		
No, n = 143	64.7 (21.8)	
Yes, n = 53	35.7 (14.6)	p < 0.001
Total, n = 196	56.4 (24.7)	
Daily activities problems		
No, n = 105	71.8 (19.1)	
Yes, n = 91	31.8 (13.1)	p < 0.001
Total, n = 196	56.2 (24.9)	
Pain/discomfort		
No, n = 63	78.9 (17.5)	
Yes, n = 134	39.8 (17.6)	p < 0.001
Total, n = 197	56.2 (24.9)	
Anxiety/depression		
No, n = 99	70.3 (19.4)	
Yes, n = 98	38.9 (20.6)	p < 0.001
Total, n = 197	56.2 (24.9)	
Perceived health state, mean (SD)		
According to patient		
Good/very good, n = 132	65.0 (19)	
Neither good nor bad, n = 17	45.9 (23.2)	p < 0.001
Poor/very poor, n = 49	30.7 (15.25)	
Total, n = 198	56.2 (24.8)	
According to clinician		
Good/very good, n = 111	71.6 (14.6)	
Neither good nor bad, n = 37	47.2 (19.9)	p < 0.001
Poor/very poor, n = 47	30.3 (14.7)	
Total, n = 195	56.4 (24.6)	

VITACORA-19: PsA quality of life questionnaire; EQ-5D: EuroQol questionnaire 5-Dimensional; PsA: psoriatic arthritis; DAS28: 28-joint Disease Activity Score; HRQoL: health-related quality of life.

Table 4. Convergent validity of VITACORA-19 overall score with EQ-5D VAS, PsA activity assessments, axial night pain intensity, and PsA global activity estimation by clinician and patients.

Clinical Assessments	Pearson's r	VITACORA–19 Global Score
EQ-5D (VAS)		
VAS	r	–0.493**
	n	197
PsA activity assessments		
ESR	r	–0.287**
	n	180
CRP	r	–0.042
	n	183
BSA	r	–0.664
	n	180
BASFI	r	–0.197
	n	191
BASDAI	r	–0.055
	n	39
DAS-28	r	–0.423**
	n	118
Axial night pain intensity	r	0.029
	n	195
PsA global activity		
According to clinician	r	0.566**
	n	197
According to patients	r	0.234*
	n	197

*The correlations were statistically significant at $p < 0.01$. **The correlations were statistically significant at $p < 0.001$. VITACORA-19: PsA quality of life questionnaire; EQ-5D: EuroQol questionnaire; PsA: psoriatic arthritis; VAS: visual analog scale; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; BSA: body surface area; BASFI: Bath Ankylosing Spondylitis Function Index; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; DAS28: 28-joint Disease Activity Score.

changes showed an improvement in health status. This helps determine the longitudinal validity of the instrument. The MCID was established as an 8-point change in the global VITACORA-19 score, useful in the interpretation of scores in the clinical practice.

A criticism of disease-specific measures is that they do not allow comparisons to be made across diseases and cultures. Taking this into account[44,45], an English version of VITACORA-19 is being developed following the recommended guidelines[46]. Further studies should concentrate on both testing the VITACORA-19 with current measures of PsA comorbidity and linking its content to The International Classification of Functioning, Disability and Health[47,48] as an authorized external reference of what to measure[49].

Our study permitted the evaluation of the measurement properties of this new instrument, which has been designed to measure the PsA HRQoL and has shown good reliability, validity, and responsiveness.

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REFERENCES

1. Wright V, Moll JMH. Psoriatic arthritis. In: Wright V, Moll JMH, eds. Seronegative polyarthritis. Amsterdam: North Holland Publishing Co.; 1976:169–223.
2. Torre Alonso JC, Rodriguez Perez A, Arribas Castrillo JM, Ballina Garcia J, Riestra Noriega JL, Lopez Larrea C. Psoriatic arthritis: A clinical, immunological and radiological study of 180 patients. Br J Rheumatol 1991;30:245-50.
3. Zachariae H. Prevalence of joint disease in patients with psoriasis: implications for therapy. Am J Clin Dermatol 2003;4:441–7.
4. Gladman DD, Antoni C, Mease P, Clegg DO, Nash P. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann

Table 5. Sensitivity to change over time of the VITACORA-19 questionnaire among patients with PsA according to perceived health state changes.

Patient's Perceived Health State Changes	Baseline Changes mean	SD	n	Changes at 6 Mos mean	SD	n	Changes mean	SD	n	ES
High improvement	54.85	27.68	10	77.06	16.59	10	22.21	20.39	10	0.80
Quite improvement	52.15	23.79	35	64.74	21.45	35	12.59	18.94	35	0.53
Small improvement	57.05	22.81	28	64.99	21.29	28	7.94	16.49	28	0.35
The same	61.70	24.88	62	66.66	22.61	62	4.96	15.67	62	0.20
Small worsening	60.25	26.27	11	51.61	18.80	11	–8.64	17.96	11	–0.33
Quite worsening	37.06	21.09	6	28.02	15.83	6	–9.04	12.57	6	–0.43
Global	57.12	24.66	152	63.98	22.73	152	6.86	18.23	152	0.28

VITACORA-19: PsA quality of life questionnaire; ES: effect size; PsA: psoriatic arthritis.

Rheum Dis 2005;64 Suppl II:ii14–17.
5. Eder L, Chandran V, Shen H, Cook RJ, Shanmugarajah S, Rosen CF, et al. Incidence of arthritis in a prospective cohort of psoriasis patients. Arthritis Care Res 2011;63:619–22.
6. Lee S, Mendelsohn A, Sarnes E. The burden of psoriatic arthritis: a literature review from a global health systems perspective. P T 2010;35:680-9.
7. Krueger G, Koo J, Lebwohl M, Menter A, Stern RS, Rolstad T. The impact of psoriasis on quality of life: results of a 1998 National Psoriasis Foundation patient-membership survey. Arch Dermatol 2001;137:280-4.
8. Gladman DD. Disability and quality of life considerations. Psoriatic arthritis. In: Gordon GB, Ruderman E, eds. Psoriatic and psoriatic arthritis: an integrated approach. Heidelberg: Springer-Verlag; 2005:118-23.
9. Husted JA, Gladman DD, Farewell VT, Long JA, Cook RJ. Validating the SF-36 health survey questionnaire in patients with psoriatic arthritis. J Rheumatol 1997;24:511–7.
10. Zachariae H, Zachariae R, Blomqvist K, Davidsson S, Molin L, Mork C, et al. Quality of life and prevalence of arthritis reported by 5795 members of the Nordic Psoriatic Associations. Data from the Nordic Quality of Life Study. Acta Derm Venereol 2002;82:108–13.
11. Revicki DA. Health-related quality of life in the evaluation of medical therapy for chronic illness. J Fam Pract 1989;29:377–80.
12. Stucki G, Boonen A, Tugwell P, Cieza A, Boers M. The World Health Organisation International Classification of Functioning, Disability and Health: a conceptual model and interface for the OMERACT process. J Rheumatol 2007;34:600–6.
13. Cieza A, Bickenbach J, Chatterji S. The ICF as a conceptual platform to specify and discuss health-related concepts. Gesundheitswesen 2008;70:47-56.
14. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. JAMA 1995;273:59-65.
15. McKenna SP, Doward LC, Whalley D, Tennant A, Emery P, Veale DJ. Development of the PsAQoL: a quality of life instrument specific to psoriatic arthritis. Ann Rheum Dis 2004;63:162–9.
16. Nunnally JC, Bernstein IH. Psychometric theory, 3rd ed. New York: McGraw-Hill; 1994.
17. Cella D, Chang CH. A discussion of item response theory and its applications in health status assessment. Med Care 2000;38 Suppl 9:SII66–72.
18. Young TA, Yang Y, Brazier JE, Tsuchiya A. The use of Rasch analysis in reducing a large condition-specific instrument for preference valuation: the case of moving from AQLQ to AQL-5D. Med Decis Making 2011;31:195–210.
19. Moll J, Wright V. Psoriatic arthritis. Semin Arthritis Rheum 1973;3:55-78.
20. Zink A, Thiele K, Huscher D, Listing J, Sieper J, Krause A, et al. German Collaborative Arthritis Centres: Healthcare and burden of disease in psoriatic arthritis. A comparison with rheumatoid arthritis and ankylosing spondylitis. J Rheumatol 2006;33:86-90.
21. Cohen J. Statistical power analysis for behavioral sciences, 2nd ed. Hillsdale: Routledge; 1988.
22. Badia X, Roset M, Montserrat S, Herdman M, Segura A. [The Spanish version of EuroQol: a description and its applications. European Quality of Life scale]. [Review in Spanish] Med Clin 1999;112 Suppl 1:79–85.
23. Aaronson N, Alonso J, Burnam A, Lohr KN, Patrick DL, Perrin E, et al. Assessing health status and quality-of-life instruments: attributes and review criteria. Qual Life Res 2002;11:193–205.
24. Greenhalgh J, Long AF, Flynn R. The use of patient reported outcome measures in routine clinical practice: lack of impact or lack of theory? Soc Sci Med 2005;60:833-43.
25. Ferrans CE, Zerwic JJ, Wilbur JE, Larson JL. Conceptual model of health-related quality of life. J Nurs Scholarsh 2005;37:336-42.
26. Valderas JM, Alonso J. Patient reported outcome measures: a model base classification system for research and clinical practice. Qual Life Res 2008;17:1125-35.
27. Streiner DL, Norman GR. Health measurement scales: a practical guide to their development and use, 2nd ed. Oxford: Oxford University Press; 1995.
28. Lohr KN, Aaronson NK, Alonso J, Burnam MA, Patrick DL, Perrin EB, et al. Evaluating quality-of-life and health status instruments: development of scientific review criteria. Clin Ther 1996;18:979–92.
29. Deyo RA, Diehr P, Patrick DL. Reproducibility and responsiveness of health status measures. Statistics and strategies for evaluation. Control Clin Trials 1991;12 Suppl 4:S142–58.
30. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? Qual Life Res 1995;4:293–307.
31. Borman P, Toy GG, Babaoğlu S, Bodur H, Ciliz D, Alli N. A comparative evaluation of quality of life and life satisfaction in patients with psoriatic and rheumatoid arthritis. Clin Rheumatol 2007;26:330–4.
32. Nichol MB, Margolis JE, Lippa E, Rowe M, Quell J. The application of multiple quality of life instruments in individuals with mild-to-moderate psoriasis. Pharmacoeconomics 1996;10:644–53.
33. Salaffi F, Carotti M, Gasparini S, Intorcia M, Grassi W. The health-related quality of life in rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis: a comparison with a selected sample of healthy people. Health Qual Life Outcomes 2009;7:25.
34. Rapp SR, Feldman SR, Exum ML, Fleischer AB Jr, Reboussin DM. Psoriasis causes as much disability as other major medical diseases. J Am Acad Dermatol 1999;41:401–7.
35. Kotsis K, Voulgari PV, Tsifetaki N, Machado MO, Carvalho AF, Creed F, et al. Anxiety and depressive symptoms and illness perceptions in psoriatic arthritis and associations with physical health-related quality of life. Arthritis Care Res 2012;64:1593-601.
36. Husted JA, Tom BD, Farewell VT, Gladman DD. Longitudinal study of the bidirectional association between pain and depressive symptoms in patients with psoriatic arthritis. Arthritis Care Res 2012;64:758-65.
37. Husted JA, Gladman DD, Farewell VT, Cook RJ. Health-related quality of life of patients with psoriatic arthritis: a comparison with patients with rheumatoid arthritis. Arthritis Rheum 2001;45:151-8.
38. Chorus AM, Miedema HS, Boonen A, Van Der Linden S. Quality of life and work in patients with rheumatoid arthritis and ankylosing spondylitis of working age. Ann Rheum Dis 2003;62:1178-84.
39. Lundberg L, Johannesson M, Silverdahl M, Hermansson C, Lindberg M. Health-related quality of life in patients with psoriasis and atopic dermatitis measured with SF-36, DLQI and a subjective measure of disease activity. Acta Derm Venereol 2000;80:430-4.
40. Khraishi MM, Longo N, Pellegrino A, Sampalis JS. The prevalence of co-morbidities in a psoriatic arthritis cohort [abstract]. Arthritis Rheum 2009;60 Suppl 10:514. [Internet. Accessed July 18, 2014.] Available from: www.blackwellpublishing.com/acrmeeting/abstract.asp?MeetingID=761&id=80146
41. Sokoll KB, Helliwell PS. Comparison of disability and quality of life in rheumatoid and psoriatic arthritis. J Rheumatol 2001;28:1842–6.
42. Brodszky V, Péntek M, Bálint PV, Géher P, Hajdu O, Hodinka L, et al. Comparison of the Psoriatic Arthritis Quality of Life (PsAQoL) questionnaire, the functional status (HAQ) and utility (EQ-5D) measures in psoriatic arthritis: results from a cross-sectional survey. Scand J Rheumatol 2010;39:303-9.
43. Alonso J, Ferrer M. Chronic obstructive airways disease and

perceived health. Med Clin 1998;111:580-2.
44. Hunt SM. Cross-cultural issues in the use of quality of life measures in randomized controlled trials. In: Staquet MJ, Hays RD, Fayers PT, ed. Quality of life assessment in clinical trials: methods and practice. New York: Oxford University Press; 1998:51-69.
45. Hunt SM, Alonso J, Bucquet D, Niero M, Wiklund I, McKenna SP. Cross cultural adaptation of health measures. Health Policy 1991;19:33-44.
46. Bullinger M, Alonso J, Apolone G, Leplège A, Sullivan M, Wood-Dauphinee S, et al. Translating health status questionnaires and evaluating their quality: The IQOLA project approach. J Clin Epidemiol 1998;51:913-23.
47. Cieza A, Stucki G. Content comparison of health related quality of life instruments based on the ICF. Qual Life Res 2005;14:1225-37.
48. Cieza A, Geyh S, Chatterji S, Kostanjsek N, Ustün BT, Stucki G. ICF linking rules: an update based on lessons learned. J Rehabil Med 2005;37:212-8.
49. Cieza A, Boldt C, Ballert CS, Eriks-Hoogland I, Bickenbach JE, Stucki G. Setting up of a cohort study on functioning: deciding what to measure. Am J Phys Med Rehabil 2011;90:S17-28.

APPENDIX 1. Validated version of the VITACORA-19 questionnaire. The following statements refer to how signs and symptoms of psoriatic arthritis could affect your daily life. Your answers will help us to determine your health status, and how your illness affected your ability to perform your daily activities during the last week. There are 5 possible answers following each statement. Please read each statement carefully, answering every question. In case you are not confident, please choose the answer that fits to your reality more accurately. Answers are neither correct nor incorrect. We are just interested in how your illness affects your daily life.

During the last week, because of your psoriatic arthritis…

	Always	Very Frequently	Occasionally/ Sometimes	Rarely	Never
1. Limited mobility conditioned my life.	1	2	3	4	5
2. Takes me a long time to recover from any physical effort.	1	2	3	4	5
3. It was difficult to change my position in bed (e.g., roll over).	1	2	3	4	5
4. My physical strength diminished.	1	2	3	4	5
5. I was unmotivated, not in the mood of doing anything.	1	2	3	4	5
6. Due to my exhaustion, I was sad and sorrowful.	1	2	3	4	5
7. My mood was affected by illness pain.	1	2	3	4	5
8. I was afraid of pain.	1	2	3	4	5
9. I was worried about being dependent on third parties because of signs and symptoms.	1	2	3	4	5
10. I felt desperate because of symptoms' pain.	1	2	3	4	5
11. I avoid meeting people. I can't keep up their pace.	1	2	3	4	5
12. My usual work/non–employment activities (including housework) performance went down.	1	2	3	4	5
13. I was afraid of lose my job after asking for a sick leave.	1	2	3	4	5
14. People shun me because of my skin appearance.	1	2	3	4	5
15. I had difficulties doing some manual activities (e.g., grab something, driving, cooking, use computer…).	1	2	3	4	5
16. My pain woke me up in the middle of the night, not allowing me to rest.	1	2	3	4	5
17. Pain affected me the most.	1	2	3	4	5
18. Inflammation and joint discomfort (e.g., ankle, knee, wrist, fingers…) affected me the most.	1	2	3	4	5
19. I was worried about the future evolution of my illness (e.g., needing a cane or crutches…).	1	2	3	4	5

This version in English of the VITACORA-19 questionnaire is provided only to give readers an idea of questionnaire content. It is not an official adapted version, and should not be used in any type of study or in clinical practice. Anyone wishing to use the VITACORA-19 questionnaire should contact the corresponding author.