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The social tariff of EQ-5D is not adequate to assess quality of life in patients with low back pain

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Abstract

Background: We compared the quality of life perceived by patients with non-specific low back pain with that predicted by the social tariff of the Spanish version of EQ-5D questionnaire. *Methods*: For each health state of the EQ-5D, an adjusted tariff for patients with back pain was obtained using a linear regression

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model in which the linear effect of the three levels of response for each of the five domains of the EQ-5D was assumed. These coefficients were compared with those obtained for the general Spanish population. In another model, equal in structure to the standard ''Dolan N3'' model, the linear effect of the five domains was not assumed. *Results*: In 633 patients, 93 health states were recorded. Significant differences in the coefficients of self-care ($p = 0.003$) and the maximum level of severity in any dimension ($p < 0.0001$) were observed. The social tariff of the healthy population is different from the tariff of low back pain patients, with general population values being lower than those of patients, particularly in the 211 health states in which any dimension is at level 3. Weights of the different EQ-5D dimensions showed a non-linear effect on the patients' quality of life. *Conclusion*: Methods used to develop the social tariff for the Spanish version of EQ-5D were inadequate. In addition, this study shows that values given by the general population are different from those of low back pain patients, further confirming that the social tariff of EQ-5D should not be used with actual patients.

Key words: EQ-5D, Health-related quality of life, Low back pain, Preference assessment

Abbreviations: SE – Standard error; VAS – Visual analogue scale

Introduction

The EQ-5D instrument is a standardized general system for describing and valuing health-related quality of life [1]. The instrument consists of two components. The first component describes the respondent's current health within five domains, mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels of severity, corresponding to 'no problems' (level 1), 'some problems' (level 2), and 'extreme problems' (level 3), thus generating 243 theoretically possible health states (i.e., 11111 full health, 33333 the most extreme state). The second component is a visual analogue scale (VAS) ranging from 0 to 100 (0 represents the worst imaginable health and 100 represents the best imaginable health), with which respondents rate their current health. In a second phase, a scoring rule that can be used to value all 243 possible health states is obtained using linear regression models based on information generated by the five-dimensional descriptive system and the VAS. A single index value for each of these health states is referred to as the 'tariff'. General population preference values ('social tariffs') for EQ-5D health states have been obtained using the VAS and ergonometric techniques, such as the time trade-off, according to self-rated health and the rating of hypothetical health states (health states not experienced by the rater).

These population reference data, derived from representative samples of the population of different countries, are increasingly being used to compare profiles for patients with specific conditions and to assess the burden of disease. Most importantly, preference-based scores can serve as quality adjustment factors for calculating quality adjusted survival, measured in quality adjusted life years. The Spanish version of the EQ-5D is a simple, valid and practical measure for use as an outcome variable both in clinical research and in the allocation of health care resources. It has been shown that within the Spanish population, the VAS tariff of the EQ-5D questionnaire ranges from −0.1304 (worst possible quality of life) to 1 (best possible quality of life), with 0 corresponding to death (and the range between −0.1304 and 0 to those situations that, according to the standards of the Spanish population, are thought to be worse than death). However, the methodology adopted to build up a 'social tariff' of EQ-5D values for the general Spanish population is different than that used in other settings [2].

The social tariff of EQ-5D is commonly used with low back pain patients in clinical trials aiming at comparing different management strategies [3–10], and clinicians have been encouraged to base their clinical decisions on data deriving from those studies [11]. However, it has been suggested that the social tariff of EQ-5D should not be used with actual patients, since values given by the general population and actual patients are different [12–14]. This has been demonstrated for patients with stroke and menopause [12, 13], and

some data suggest that the same could be true for low back pain patients. In a clinical trial with low back pain patients in which two treatment strategies were compared and in which pain and disability were measured through validated instruments [15, 16], the social tariff of the EQ-5D detected no differences between groups [17], in spite of pain and disability improving between 250% and 600% more in one group and the fact that those variables are the main determinants of quality of life in those patients [18–20].

No study has so far determined the consistency of the social tariff of EQ-5D and the experience based values given by actual low back pain patients. Therefore, this study was designed to measure the difference between EQ-5D tariffs from the general population and from actual patients with low back pain, as well as to determine whether the weight of the different domains of the questionnaire on the social tariff is similar to that estimated using patient values.

Materials and methods

A total of 361 physicians from 40 primary care centers (reference population 693,206 people) of the Spanish National Health Service involved in the Spanish Back Pain Research Network were invited to participate in a prospective study. The objective of the study was to assess the health-related quality of life of patients consulting their primary care physician for a current episode of low back pain. Ninety-five physicians (26.3%) agreed. The study protocol was approved by the institutional review boards of the participating centers and all patients gave written informed consent for the use of his/her data regarding presenting complaints and results of outcome assessments.

Primary care physicians were asked to recruit all consecutive patients aged 18 years or older with low back pain, with or without referred pain that lasted for less than 90 days. Exclusion criteria were functional illiteracy (mental status insufficient to complete pain, disability, and quality of life questionnaires); suspicion of cauda equina syndrome or neurological disorder (saddle anesthesia, recent onset of bladder dysfunction or anal sphincter impairment, major or progressive motor weakness, sensory level, or widespread neurological signs); and 'red flags' (oncologic disease during the previous 5 years, constitutional symptoms (unexplained weight loss, fever, chills), recent urinary tract infection, history of intravenous drug use, or immunocompromised host) [21].

Each patient's condition was assessed on his/her first visit to the primary care center (day 1 assessment) and 15 and 60 days later (second and third assessments). The following variables were recorded: age (date of birth); sex; educational level (divided into four categories: less than elementary school, elementary school, high school, university); duration of pain (days); other chronic diseases (yes/no); current use of drug treatment (yes/no); usual job; job situation (classified as follows: potentially active, housewife, disabled/retired, other (students, unemployed)); sick leave (no/yes or not applicable); severity of low back and referred pain (independent VAS scores) [15]; degree of disability (Spanish version of the Roland–Morris questionnaire) [16]; and health-related quality of life (Spanish version of the EQ-5D questionnaire) [1].

At each visit, questionnaires on pain, disability, and quality of life were self-administered and completed by the patient on his/her own in the absence of the treating physician, other health care staff, family members, or accompanying persons. Completed self-report instruments were then given to the auxiliary staff of the primary care center who stapled scales and questionnaires to the patient's data collection form. At the end of the working day, final ratings of the scales were transcribed to the data collection form by the treating physician, and afterward concordance of scores in the data collection form and ratings of self-administered instruments were independently verified by the study coordinator in each primary care center.

Data were entered in a database at a central office by two administrative assistants who double-checked that data entered coincided with ratings of the VAS and Roland–Morris and EQ-5D questionnaires.

Statistical analysis

One EQ-5D questionnaire per patient was analyzed. The questionnaire which was analyzed was the one corresponding to the baseline visit, except

in those patients who showed, at the visits on day 14 or 60, a health state which had not been observed at baseline in any subject. Two multiple linear regression models were developed with EQ-5D VAS scores as the dependent variable, and the three levels of severity for each dimension of the EQ-5D questionnaire as the independent variables. One of the models tested (henceforth called 'original model'), followed the same approach as that of the model adopted to build up the social tariff of EQ-5D values for the Spanish general population. The Spanish social tariff for the general population was estimated by Badia et al. [1]. Members of the general population were asked to value a selected subset of hypothetical health states using the VAS accompanying the questionnaire. The final model adjusted by the authors included six independent variables, one for each of the five dimensions of the questionnaire (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) broken into three categories (0 = "level 1", 1 = "level 2", 2 = "level 3") and a sixth dummy variable (N_3) broken into two categories (1 = when level 3 or "extreme problems" occur within at least one dimension, 0 = all the remaining cases). It should be noted that this model requires the assumption of a linear effect of the level of severity associated with each dimension, the coefficient of the dummy variable N_3 being responsible for eventual non-linear relationships. The equation was as follows:

$$\begin{aligned}\text{Tariff}_{\text{VAS}} =& \alpha_0 + \alpha_1 \times \text{mob} + \alpha_2 \times \text{sc} + \alpha_3 \times \text{ua} \\ &+ \alpha_4 \times \text{pain} + \alpha_5 \times \text{ad} + \alpha_6 \times N_3\end{aligned}$$

Once the first regression model had been fitted with data from patients with low back pain, the coefficients α_i (i.e., scoring weights) were compared with those obtained for the general population [1] by means of a z-statistic

$$z = \frac{\alpha_i - \alpha_i^*}{\sqrt{\text{SE}(\alpha_i)^2 + \text{SE}(\alpha_i^*)^2}}$$

where α_i and α_i^* are the estimated regression coefficients for patients with low back pain and the Spanish general population, respectively, and SE the corresponding estimated standard error.

In the second model (henceforth called 'Dolan-N3 model') and in order to test the assumption of the linear effect of the three levels of response for each of the five domains of the EQ-5D, two dummy variables for each dimension were used: the first representing a change from level 1 to level 2, and the second, a change from level 1 to level 3. This model was also fitted using the same set of data derived from Spanish low back pain patients. The mathematical form of the Dolan-N3 model is shown in the following equation:

$$\begin{aligned}\text{Tariff}_{\text{VAS}} = \alpha_0 + &\alpha_1 \times \text{mob}_2 + \alpha_2 \times \text{mob}_3 + \\ &\alpha_3 \times \text{sc}_2 + \alpha_4 \times \text{sc}_3 + \\ &\alpha_5 \times \text{ua}_2 + \alpha_6 \times \text{ua}_3 + \\ &\alpha_7 \times \text{pain}_2 + \alpha_8 \times \text{pain}_3 + \\ &\alpha_9 \times \text{ad}_2 + \alpha_{10} \times \text{ad}_3 + \\ &\alpha_{11} \times N_3\end{aligned}$$

VAS values and responses to EQ-5D provided by the low back pain patients who participated in this study were compared to those from the subjects in the general population which were used to calculate the social tariff of the Spanish population [1].

To calculate the tariff for patients with low back pain based on the EQ-5D data of our sample, the original model was applied to all 243 possible health states. The significance level was set at 0.05 for all tests.

The agreement between the adjusted tariff estimated by the Dolan-N3 model and the social tariff described for the general population was explored depicting both tariffs graphically by means of a scatter plot.

Results

A total of 633 patients with low back pain were recruited. The median number of patients recruited by each physician was 5 (interquartile range 3–10). The mean (standard deviation, SD) age of the study population was 46.9 (15.5) years and 48% of patients were male. The characteristics of the study sample are shown in Table 1.

Data were recorded at the first visit of 617 patients, at the second visit in 11, and at the third visit in 5, with a total of 93 health states of all possible 243. The number of patients presenting one of these 93 possible health state ranged between 1 and 63 (median 2, interquartile range 1–6). State 22221 was the most frequently observed. Six states (22221, 22222, 21221, 11221, 22232, and 11121) were estimated by more than 30 patients.

As shown in Table 2, the frequency of responses to the EQ-5D instrument made by the study sample was different when compared with the general population [1]. Moreover, the EQ-5D VAS scores of patients with low back pain were significantly lower than self-reported assessments of the general population (49.2 vs.75.8, $p < 0.05$). Table 3 lists the regression coefficients of the original model used to calculate the social tariff of the general Spanish population [1] and those of the model fitted with data from low back pain respondents. The coefficient of the variable representing the eventual non-linearity was not significantly different from zero ($p = 0.492$). When the coefficients of the models fitted for both populations were compared, it was observed that there were significant differences between patients with low back pain and the general population in the coefficients of self-care ($p = 0.003$) and in N3 level 3 (or "extreme problems") occurs within at least one dimension) ($p < 0.0001$).

Table 1. Data of patients included in the study

Characteristic	Value
Age, years, mean (SD) [range]	46.9 (15.5) [18–87]
Sex, no. (%)	
Male	306 (48)
Female	327 (52)
Job situation, no. (%)	
Potentially active	362 (57)
Housewife	129 (20)
Disabled/retired	92 (15)
Other (students, unemployed)	50 (8)
Sick leave, no. (%)*	161 (44)
Education	
Less than elementary school	203 (55)
Elementary school	81 (22)
High school	56 (15)
University	26 (8)
Missing	17 (3)
Pain, visual analogue scale (VAS), mean (SD) [range]	5.9 (2.2) [0–10]
Referred pain, VAS, mean (SD) [range]	2.7 (3.0) [0–10]
Disability, Roland–Morris questionnaire, mean (SD) [range]	11.2 (5.5) [0–24]
Quality of life, VAS, mean (SD) [range]	49.2 (21.2) [2–100]
Duration of pain, days, median (interquartile range)	4 (2–10)

* In 362 potentially active workers.

Table 2. Comparison of responses to the EQ-5D instrument between patients with low back pain and healthy subjects used to obtain the social tariff

Domains	Patients with low back pain		Spanish general population	
	No.	%	No.	%
Mobility				
Level 1	183	28.9	249	84.7
Level 2	387	61.1	45	15.3
Level 3	63	10.0	0	0
Self-care				
Level 1	285	45.0	285	98.3
Level 2	304	48.0	9	1.7
Level 3	44	7.0	0	0
Usual activities				
Level 1	101	16.0	252	85.7
Level 2	427	67.5	41	13.9
Level 3	105	16.6	1	0.3
Pain/discomfort				
Level 1	13	2.1	163	55.4
Level 2	409	64.6	124	42.2
Level 3	211	33.3	7	2.4
Anxiety/depression				
Level 1	338	53.4	221	75.2
Level 2	255	40.3	68	23.1
Level 3	40	6.3	5	1.7
Visual analogue scale (VAS) score, mean (95% CI)	49.2 (47.5–59.8)		75.8 (73.9–77.7)	

Table 4 shows the results of the second model tested ('Dolan-N3 model'), in which the regression coefficients noticeably indicated the presence of non-linear effects in the different dimensions of the EQ-5D instrument. The R^2 between state valuations derived from the model and valuations for the 93 health states present in the study sample was 0.36.

Figure 1 represents in the horizontal axis for each possible health state, the tariffs obtained from the coefficients of the 'Dolan-N3 model' for patient data and in the vertical axis the social tariff of the Spanish general population. As shown in Figure 1, points below the 45° line in the plot are those health states in which the social tariff of healthy subjects underestimated quality of life in the 211 health states in which at least one dimension showed level 3 (median 0.17) and overestimated that of the remaining 32 (median 0.07). Overall, differences between the social tariff calculated in

Table 3. Regression coefficients of the original model used to calculate the social tariff of the general Spanish population [1] and those of the model fitted with data from patients with low back pain

	Low back pain data $N = 633$; $R^2 = 0.35$			General population			z-Test comparison	
	Coefficient	SE	P value	Coefficient	SE	P value	z	P value[a]
(Constant)	0.7531	0.0262	0.000	0.8498	0.016	0.000	−3.15	0.002
Mobility	−0.0719	0.0147	0.000	−0.0897	0.0121	0.000	0.94	0.349
Self-care	−0.0441	0.0143	0.002	−0.1012	0.0124	0.000	3.02	0.003
Usual activities	−0.0445	0.0153	0.004	−0.0551	0.0139	0.000	0.51	0.607
Pain/discomfort	−0.0695	0.0230	0.003	−0.0596	0.0108	0.000	−0.39	0.697
Anxiety/depression	−0.0645	0.0122	0.000	−0.0512	0.0112	0.000	−0.80	0.422
At least one domain with extreme problems (N3)	−0.0180	0.0262	0.492	−0.2119	0.0246	0.000	5.40	0.000

[a] Statistical significance for the comparison between coefficients of low back pain and general population models.
For example, the EQ-5D tariff estimated by the model fitted for low back pain population for health state '12232' would be (0.7531-0-0.0441-0.0445-2 × 0.0695-0.0645-0.018) = 0.425. Using the model fitted for the general population to compute the tariff for the same health state would be 0.3112.

Table 4. Regression coefficients of the Dolan-N3 model

Data	Dolan-N3 model low back pain data $n = 633$; $R^2 = 0.36$		
	Coefficient	SE	P value
(Constant)	0.7130	0.0417	0.000
Mobility			
Mobility 2	−0.0638	0.0174	0.000
Mobility 3	−0.1608	0.0334	0.000
Self-care			
Self-care 2	−0.0438	0.0162	0.007
Self-care 3	−0.0801	0.0376	0.034
Usual activities			
Usual activities 2	−0.0587	0.0203	0.004
Usual activities 3	−0.0860	0.0304	0.005
Pain/discomfort			
Pain/discomfort 2	−0.0246	0.0421	0.559
Pain/discomfort 3	−0.1193	0.0446	0.008
Anxiety/depression			
Anxiety/depression 2	−0.0528	0.0148	0.000
Anxiety/depression 3	−0.1583	0.0292	0.000

For example, the EQ-5D tariff estimated by the Dolan-N3 model for health state '12232' would be (0.7130-0-0.0438-0.0587-0.1193-0.0528) = 0.4385.

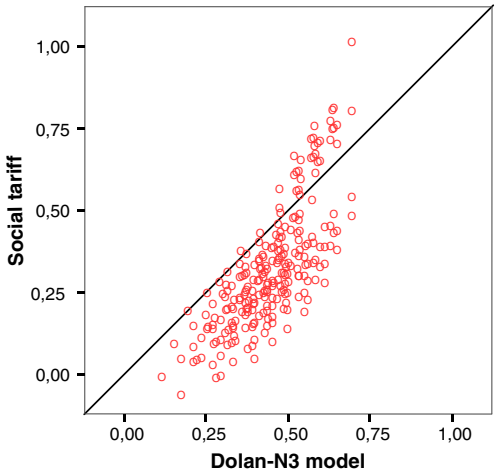

Figure 1. Agreement between quality of life estimated for the 243 health states from the weighted coefficients in the model of the general population and the Dolan-N3 model for the population of patients with low back pain. Health states in which some dimension showed level 3 are represented by circles.

the general population and the tariff for patients with low back pain ranged between −0.27 and 0.25, with a mean (SD) of −0.13 (0.09).

Discussion

Patients included in this study can be considered representative of individuals with non-specific low back pain attended in the Spanish National Health Service. The 633 study participants were recruited in eight of the seventeen Spanish administrative regions, representing the economic and cultural geography of the country. The study sample included subjects with different socio-educational and economic profiles, and patients were treated according to standard clinical practice of the National Health Service [22]. Furthermore, the patients' complaints covered the entire spectrum of intensity of pain and functional disability

associated with an episode of low back pain, and 93 of all possible 243 health states were represented.

As expected, patients included in the study showed a higher frequency of limitations in all dimensions of the EQ-5D instrument than the general population included in the original study [1]. In fact, the mean VAS score of the general population was 75.8 compared with 49.2 of the study sample, which is similar to that obtained in critically ill patients on admission to the intensive care unit [23]. It is impossible to determine whether this observation actually reflects a similarity between the quality of life perceived by patients with low back pain and patients requiring critical care, or whether it reflects an insufficient sensitivity of EQ-5D to quantify quality of life in back pain patients. It should be noted that the study sample based on patients consulting the physician for a current episode of low back pain was not balanced for the different health states as defined in the EQ-5D instrument, and 51 of the 93 health states were represented by more than one patient, a slightly greater number than the health states represented in the original study.

Although the validity, reliability, and sensitivity of changes of the VAS scoring system to determine quality of life in patients with low back pain are unknown, the EQ-5D offers no other means to assess it. Therefore, in the present study those scores have been assumed to be the 'gold standard' for respondents' assessment of their current health-related quality of life.

Results of the present study show that the Dolan-N3 model is better than the one which was used to estimate the Spanish social tariff of the EQ-5D [1, 2]. In contrast with those observed in the Spanish general population [1], weights of the different dimensions of the EQ-5D instrument showed a non-linear effect on the quality of life of patients with nonspecific low back pain. It should be noted that this non-linear effect has also been observed in the model built up for the social tariff from a representative sample of the UK population [2], and in the model developed to adjust the social tariff for the EQ-5D instrument to patients with aneurysmal subarachnoid hemorrhage, a type of hemorrhagic stroke [12].

Results from this study also show that the values given by the general population are different from those of low back pain patients. Differences in valuing health states between patients and the general population are well known and have been shown in stroke patients, menopausal women, and low back pain patients [12–14, 20, 24–28]. Proposed reasons for these discrepancies include differences in the states being valued by those groups (i.e., based on experience vs. imagination), differences in measurement scales, the effect of the adaptation to the state by those actually experiencing it, the contrast effect and shifting comparisons [14]. In the case of EQ-5D, those differences could also be due to potential deficiencies in its descriptive system [14]. Those possibilities are not mutually exclusive and this study was not designed to assess them. However, subjects included in this study were acute low back pain patients (Table 1), and the lifetime prevalence of that condition is over 70% [29, 30]. This suggests that most subjects from the general population were not protected by a "veil of ignorance" when they gave their values [14]. Should that be the case, the results of this study could be interpreted as supporting the existence of potential deficiencies in the descriptive system of EQ-5D.

Using values from the general population or actual patients has major implications for funding decisions on many interventions [14]. For instance, in this study the social tariff of the healthy population underestimated the impact on the quality of life of the 211 health states in which any dimension is at level 3, whereas it overestimated the impact on the quality of life of the remaining health sates. Therefore, the use of EQ-5D tariffs in clinical trials with low back pain patients may erroneously estimate the effect on the quality of life of effective measures implemented to improve dimensions overestimated or underestimated by these particular patients, as has been shown in other settings and for other conditions [12–14, 20].

This further confirms that EQ-5D tariffs should not be used to assess the quality of life of actual patients, including those seeking care for low back pain, and that data on cost/utility based on the EQ-5D in low back pain patients should be interpreted with caution [3–10]. In fact, the social tariff of EQ-5D was not developed to be used on actual patients. Its goal is not to assess or predict the actual decrease in the patient's quality of life associated with particular disorders, but to develop a preference-weighted health state classification

that may be used for the allocation of resources and assignment of priorities from the perspective of the decision-maker.

Whether values used for efficiency analysis should derive from the general population or from patients is an ongoing debate and it ultimately is a normative question [14]. Both options have theoretical advantages and problems, and one proposed solution is to obtain better informed general population preferences by providing more information to the sample from the general population on what the health state is like for patients [14].

In conclusion this study shows that, in patients with non-specific low back pain, weights of the different dimensions of the EQ-5D instrument are different from those of healthy subjects, show a non-linear effect, and the social tariff is unreliable to accurately predict the patients' quality of life. This further confirms that EQ-5D should not be used with patients, and that results based on the evolution of EQ-5D in low back pain patients should be interpreted with caution [3–10, 17].

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