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Clinical Study

The prognostic value of catastrophizing for predicting the clinical evolution of low back pain patients: a study in routine clinical practice within the Spanish National Health Service

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Abstract

BACKGROUND CONTEXT: Experimental studies suggest that catastrophizing may worsen the prognosis of low back pain (LBP) and LBP-related disability and increase the risk of chronicity.
PURPOSE: To assess the prognostic value of baseline catastrophizing for predicting the clinical evolution of LBP patients in routine clinical practice and the association between the evolution of pain and catastrophizing.
STUDY DESIGN/SETTING: Prospective study in routine clinical practice of the Spanish National Health Service.

FDA device/drug status: Not applicable.

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PATIENT SAMPLE: One thousand four hundred twenty-two acute and chronic adult LBP patients treated in primary and hospital care.
OUTCOME MEASURES: Pain, disability, and catastrophizing measured through validated instruments.
METHODS: Patients were managed according to routine clinical practice. Outcome measures were assessed at baseline and 3 months later. Logistic regression models were developed to estimate the association between baseline catastrophizing score and the improvement of LBP and disability, adjusting for baseline LBP and leg pain (LP) severity, disability, duration of the pain episode, workers' compensation coverage, radiological findings, failed back surgery, and diagnostic procedures and treatments undertaken throughout the study. Another model was developed to estimate the association between the evolution of LBP and the change in catastrophizing, adjusting for the same possible confounders plus the evolution of LP and disability. Models were repeated excluding the treatments undergone after the baseline assessment.
RESULTS: Regression models showed that the degree of baseline catastrophizing does not predict the evolution of LBP and disability. Conversely, as the degree of pain improvement increases, so does the odds ratio for improvement in catastrophizing, ranging from three (95% confidence interval [95% CI], 2.00–4.50; $p<.001$) for improvements in pain between 1.1 and 4 visual analog scale (VAS) points, to 7.3 (95% CI, 3.49–15.36; $p<.001$) for improvements in pain more than 6.1 VAS points. Similar results were obtained when treatments were excluded from the models.
CONCLUSIONS: In routine practice, assessing the baseline score for catastrophizing does not help clinicians to predict the evolution of LBP and disability at 3 months.

Keywords: Low back pain; Disability; Prediction; Catastrophizing; Routine clinical practice

Introduction

Nonspecific or common low back pain (LBP) is defined as the pain between the costal margins and the inferior gluteal folds, which may be associated with the pain referred down to the leg (''leg pain [LP]'') and is usually accompanied by painful limitation of movement. Diagnosing common LBP implies that the pain is not related to conditions such as fractures, spondylitis, direct trauma, or neoplastic, infectious, vascular, metabolic, or endocrine-related processes [1].

Two of the main psychological factors that have been considered to negatively influence the prognosis of pain and disability in LBP patients are fear-avoidance beliefs (FABs) and catastrophizing [1–9]. Fear-avoidance beliefs refer to the fear-induced avoidance of movements or activities that are expected to be painful, whereas catastrophizing is defined as an exaggerated negative mental state related to an actual or anticipated painful experience [1–9]. In the Spanish cultural environment, FABs have shown to have an either negligible or nonexistent influence on LBP among elderly populations as well as acute, subacute, and chronic LBP patients treated in routine practice [10–13], whereas catastrophizing correlates with disability and explains approximately one-fourth of its variance [13,14], suggesting that it may have an influence on the prognosis of LBP patients.

From a theoretical point of view, pre-existing catastrophizing thoughts may hamper patients' clinical evolution. Conversely, it could also be hypothesized that catastrophizing would appear or be reinforced in patients who experience a disappointing clinical evolution, successive failed treatments, and continued pain and disability. This poses a ''chicken and egg'' dilemma on the potential reciprocal influence between catastrophizing and lack of clinical improvement [3,7–9].

In fact, previous cross-sectional studies have shown that catastrophizing, pain, and disability correlate with each other [13–18], but results from prospective studies are inconsistent. Some randomized controlled trials and small studies in routine practice suggest that baseline catastrophizing is associated with the evolution of pain and disability, some suggest the contrary, and others conclude that catastrophizing predicts the outcome of acute LBP but not before 6 weeks after the onset of pain [2,4,7,19–31]. Results from the only large prospective study conducted in routine practice suggest that baseline catastrophizing does not predict the evolution of LBP-related disability [32].

If catastrophizing were to actually have a negative influence on prognosis, it would follow that, in routine practice, clinicians should identify patients in whom psychological treatment to address catastrophizing should be considered. To this end, a cutoff value for baseline catastrophizing, above which reducing it would be required to treat LBP successfully, should be identified.

Therefore, the objectives of this study were to determine whether assessing baseline catastrophizing would help clinicians predict the clinical evolution of LBP patients in routine clinical practice, while establishing the cutoff point to identify subjects in whom catastrophizing may hinder recovery and should therefore be treated and to assess the association between improvement in pain and the evolution of catastrophizing.

Methods

Setting

This study was performed in 14 health-care centers from seven different regions in Spain. Twelve centers belonged to the Spanish National Health Service (SNHS) and two to the not-for-profit foundations working for the SNHS.

Participating centers included six primary care centers and eight specialty centers in rehabilitation, neuroreflexotherapy (NRT), orthopedic surgery, and rheumatology.

Subjects

Inclusion criteria were as follows: seeking care in a participating center for LBP with or without LP, not caused by direct trauma or systemic diseases, not complying with criteria for referral to surgery, and being able to read in Spanish.

Pain not caused by systemic diseases was defined as pain in patients who had not been diagnosed with cancer, fibromyalgia, or inflammatory diseases, such as rheumatoid arthritis or Bechterew disease (ankylosing spondylitis), and who did not show signs suggesting fibromyalgia or ''red flags'' for potential underlying systemic diseases.

''Signs suggesting fibromyalgia'' were defined as diffuse pain with unexplained fatigue or sleep disturbances, and ''red flags'' for potential underlying systemic diseases were defined as oncologic disease during the previous 5 years, constitutional symptoms (unexplained weight loss, fever, and chills), history of intravenous drug use, or immunocompromised host [1,33–35].

Criteria for referral to surgery were defined as signs suggesting cauda equina syndrome or nerve root compression resulting from disc herniation or spinal stenosis potentially qualifying for surgery. Relevant or progressive paresia, loss of sphincter control, or saddle anesthesia were considered as signs suggesting cauda equina syndrome. Potential surgical criteria for disc herniation were defined as disabling sciatic pain lasting 6 weeks or more, caused by a compromised nerve root demonstrated by magnetic resonance imaging (MRI). Potential surgical criteria for symptomatic lumbar spinal stenosis were defined as radicular pain lasting 3 or more months or claudication unrelated to peripheral vascular disease, with an evidence of stenosis on MRI or computed tomography scans [1].

Patients who had undergone unsuccessful spine surgery (''failed back surgery'') and those with ''red flags'' in which appropriate test procedures had ruled out systemic diseases were invited to participate in the study.

Exclusion criteria were as follows: treated or untreated central nervous system impairment, refusal to sign the informed consent, and leaving a questionnaire assessing any of the variables unanswered.

The design of this study did not imply any variation in the patients' clinical management. Therefore, as opposed to randomized clinical trials, there were no ethical reasons for keeping the sample size as small as possible. As a result, sample size for this study was established at 1,500 to ensure enough statistical power, given that previous studies had suggested that the potential effect of catastrophizing in Spanish subjects could be small [10,11,16], approximately 80% of LBP patients treated in routine practice within the SNHS report a clinically relevant improvement at 3 months [36,37], and previous studies have shown that improvements are not normally distributed [36,38], which excludes linear regression analysis and implies the need to dichotomize continuous variables for logistic regression analyses, which in turn may reduce statistical power, and this sample size would allow the introduction of up to 30 variables in the regression models as potential confounders [39].

EVIDENCE & METHODS

Context
Fear-avoidance behavior and catastrophizing have been associated with poorer outcomes in some low back pain patients. In this study, the authors aimed to assess the impact of catastrophizing in a Spanish population.

Contribution
The authors found that baseline scores measuring catastrophizing did not predict the course of low back pain or disability at 3 months.

Implication
Psychosocial factors that might impact low back pain are, by definition, contextual. That is, the effect they might have in one cultural setting may not be present in another. Accordingly, it is important that the results of psychosocial studies are not peeled off and blindly applied to populations not studied, especially if such results will be used to alter care given to patients.

—*The Editors*

Procedure

The study protocol was approved by the ethical committees of the participating hospitals and institutions. All patients seeking care for LBP who were treated by physicians participating in this study were screened for inclusion and exclusion criteria. The physicians explained the study's characteristics to eligible patients as well as how important it was for them to fully and accurately answer the questionnaires. They finally invited patients to sign the corresponding informed consent. The patients who signed it were included in the study. Neither patients nor recruiting physicians received any compensation for their participation in this study.

Patients were assessed on recruitment and 3 months later. At both assessments, patients completed all the self-administered questionnaires by themselves, in private. The

only instructions they received were those included in the standard validated versions of the self-administered questionnaires. They received no help or further directions from health-care personnel, research staff, or other third parties. Once completed, the questionnaires were collected by auxiliary personnel not related to the study. Data were introduced into a database at a central coordination office by two administrative assistants, who double checked that the data introduced coincided with ratings on the questionnaires.

Following routine practice conditions, all decisions on clinical management, including the prescription of any kind of diagnostic tests or treatments, were left up to the treating clinicians, and no measures were taken to homogenize their criteria. Clinicians had access to the scores for pain and disability because these data can influence their clinical recommendations but not to the score for catastrophizing.

Variables

At the first assessment, patients were asked to complete questionnaires gathering data on gender, age (date of birth), duration of current pain episode (days), and working status (classified as ''not eligible,'' ie, students, housewives, unemployed, retired, or ''eligible for worker's compensation benefits,'' which in Spain can represent up to 100% of the salary irrespective of whether the worker is working or not, ie, working, on sick leave, or disabled).

In this study, LBP and LP severity as well as LBP-related disability were considered the main indicators of patients' clinical evolution [40]. At both assessments, patients were asked to rate the intensity of LBP, LP, LBP-related disability, and catastrophizing. Pain intensity was measured with a 10-cm visual analog scale (VAS, for which 0=no pain and 10=worst possible pain) [41]. Low back pain-related functional disability was measured using the validated Spanish version of the Roland-Morris questionnaire (RMQ) [42], in which disability is scored from 0 to 24 points (better to worse). Catastrophizing was measured using the catastrophizing subscale of the validated Spanish version of the Coping Strategies Questionnaire (CSQ), in which patients' use of catastrophizing strategies to cope with pain is scored from 0 (no use) to 36 (maximum possible use of those strategies) [43].

Recruiting physicians provided data on patients' radiological findings (no findings, disc degeneration, scoliosis, spondylolisthesis, spondylolysis, annular tear, disc protrusion, disc herniation, >1 cm difference in leg length, lumbarization of S1, sacralization of L5, and other radiological findings) and history of failed back surgery related to current episode (yes/no), as well as diagnostic procedures (X-rays, scanner, MRI, electromyography, blood analyses, scintigraphy, and others) and treatments that the patient had undergone throughout the study (drugs [nonsteroidal anti-inflammatory drugs, muscle relaxants, and other drugs], physiotherapy or rehabilitation, NRT intervention, surgery, and other treatments).

Analysis

Absolute and relative frequencies were calculated for categorical variables, and mean and standard deviation were calculated for continuous ones. The characteristics of the patients who improved and did not improve were compared using the Mann-Whitney test for continuous variables. Categorical variables were compared through the chi-squared test or the Fisher exact probability test when chi-squared test was not applicable.

Improvements in pain and disability were defined as any reduction in the score of VAS or RMQ being higher than the minimal clinically important change (MCIC). Previous studies have established MCIC for pain and disability at 30% of their baseline score, with a minimum value of 1.5 for VAS and 2.5 for RMQ [37]. Roland-Morris questionnaire cannot be scored with decimals so, in this study, improvement was defined as ''clinically relevant'' when 1.5 or more VAS points or 3 or more RMQ points. Similarly, a ''relevant reduction'' in the CSQ score was defined as any reduction 30% or more of its baseline value [37,44]. Because no data on MCIC for CSQ are available, a sensitivity analysis was conducted in which ''change in the CSQ score'' was defined as any positive difference between assessments at baseline and 3 months. According to these definitions, improvement was impossible when baseline scores were 1.5 or less VAS points for pain, 3 or less RMQ points for disability, or 1 or less CSQ point for catastrophizing. Therefore, patients with such a baseline score for a given variable were excluded from the analysis, which focused on the improvement of that variable.

Two logistic regression models were developed to estimate the association between baseline CSQ score and the improvement of LBP and LBP-related disability during the study period, adjusting for other possible confounders. To relax the assumption of linearity among dependent variables and baseline CSQ, baseline CSQ score was categorized in quartiles and introduced into the models as dummy variables, using the first quartile as the reference one.

At the design phase of this study, it was decided that all recorded variables that might exert an influence on the evolution of pain and disability would be included as potential confounders in the models. These included gender, age (in years), baseline values for LBP (VAS points), LP (VAS points) and LBP-related disability (RMQ points), duration of the current episode (collected in days and classified as acute [less than 14 days], subacute [14–90 days], chronic [−91 to 365 days], and extremely chronic [more than 365 days]) [38,45], workers' compensation coverage, diagnosis of ''failed back surgery,'' radiological findings (disc degeneration, spondylolisthesis/spondylolysis, spinal stenosis, disc protrusion/hernia, and no findings), diagnostic procedures performed throughout the study (X-rays, MRI, computed tomography scan, scintigraphy, electromyography, blood analysis), and treatments received before and during the study (nonsteroidal anti-inflammatory drugs, steroids,

muscle relaxants, other drugs, physiotherapy, rehabilitation, NRT intervention, or surgery). To assess whether chronicity modified the association between baseline CSQ score and the evolution of pain and disability, the interaction between baseline CSQ score and chronicity was also included in the maximal model. Coping Strategies Questionnaire was forced into a nonautomatic backward elimination strategy oriented at providing a valid estimate so that the variable with the highest p value that was not a confounder was excluded at every step [46,47]. Variables were considered to be confounders if the estimate of the coefficient of CSQ changed by more than 10% when that variable was removed from the maximal model. To avoid the loss of statistical power, independent continuous variables were not categorized [48].

It was hypothesized that, although clinicians did not have access to patients' baseline CSQ scores, the degree of baseline catastrophizing might have been linked to some patients' characteristics, which, in turn, could have influenced clinicians' decisions with regard to treatment. Therefore, analyses were repeated excluding treatments received during the follow-up period.

Another logistic regression model was developed to estimate the association between the evolution of LBP (categorized in quartiles and introduced in the model as dummy variables) and the change in CSQ (defined as any change in the score being 30% or more of baseline value), adjusting for other possible confounders. In addition to all the potential confounders listed in the aforementioned models, the maximal model also included the evolution of LP and disability. Evolution of LBP, LP, and disability was defined as the baseline score minus the final one so that positive values reflect improvement. Criteria used to consider a variable as a confounder were the same as aforementioned.

To validate these three models, the sample was randomly split into two subsamples for each model. The first one (training sample) included 80% of patients. The second one (validation sample) included the remaining patients (ie, 20%) [47]. Collinearity of the maximal model in training samples was evaluated using the criteria proposed by Belsley [49]. SPSS v17 (SPSS, Inc., Chicago, IL, USA) was used for statistical analysis.

Results

Thirty-three clinicians screened 1,565 patients. Sixty-five patients declined to commit to the follow-up visit and did not sign the informed consent. The remaining 1,500 (95.67%) patients were included. There were no losses to follow-up, but 78 subjects (5.2%) were excluded at the analysis phase for having left questionnaires on LBP (32 patients), LP (47), disability (39), catastrophizing (34), or workers' compensation coverage (4), unanswered. Of 78 patients, 62 left two or more questionnaires unanswered. Therefore, 1,422 patients were included in the analysis. Their mean age was 52.6 years, and most were women (62.6%) with chronic LBP (58.4%). At baseline, their mean CSQ score was 15 points, although 143 patients (10.1%) had a CSQ score more than 75% of the maximum possible. Patients' baseline characteristics are shown in Table 1.

At baseline, 24 patients had a pain score of 1.5 or less VAS points, 77 had a disability score of 3 or less RMQ points, and 6 had a score on the CSQ of 1 or less. Therefore, they were excluded from the analysis focusing on the

Table 1
Baseline characteristics of patients included in the study

Variables	All patients (N=1,422)
Gender (males)*	532 (37.4)
Age (y)	52.6 (15.0)
Eligible for workers' compensation	824 (58.0)
Duration of pain (d)*	
Acute (<14)	113 (7.9)
Subacute (14–90)	479 (33.7)
Chronic	
91–365	553 (38.9)
>365	277 (19.5)
Failed back syndrome*	21 (1.5)
Findings on imaging tests*	
No findings	255 (17.9)
Disc degeneration	890 (62.6)
Spondylolisthesis/spondylolysis	91 (6.4)
Spinal stenosis	118 (8.3)
Disc protrusion/herniation	485 (34.1)
Annular tear	3 (0.2)
>1 cm difference in leg length	12 (0.8)
Lumbarization of S1	14 (1.0)
Sacralization of L5	9 (0.6)
Other radiological findings	15 (1.1)
Diagnostic procedures*	
X-rays	359 (25.2)
MRI	355 (25.0)
Computed tomography scan	50 (3.5)
Electromyography	58 (4.1)
Blood analysis	53 (3.7)
Scintigraphy	3 (0.2)
Drug treatment*	
NSAIDs	806 (56.7)
Corticoids	96 (6.8)
Muscle relaxants	274 (19.3)
Other	139 (9.8)
Physiotherapy or rehabilitation*	176 (12.4)
NRT*	1,242 (87.3)
Surgery*	8 (0.6)
Other treatments*	15 (1.1)
LBP (VAS)	6.7 (2.1)
LP (VAS) (n=1,098)	6.2 (2.4)
Disability (RMQ)	12.8 (5.6)
Catastrophizing (CSQ)	15.0 (8.5)

MRI, magnetic resonance imaging; NSAIDs, nonsteroidal anti-inflammatory drugs; NRT, neuroreflexotherapy; LBP, severity of low back pain; VAS, visual analog scale; LP, severity of referred pain down into the leg (leg pain, in the 1,098 patients who had it); RMQ, score in the Roland-Morris Questionnaire; CSQ, score in the Coping Strategies Questionnaire.

* Categorical variables are described with a frequency (%), and continuous variables are described with a mean (standard deviation).

Table 2
Baseline characteristics of patients in whom LBP, disability, and catastrophizing improved and did not improve throughout the study

Variable	LBP improved (n=1,043)*	LBP did not improve (n=355)*	p	Disability improved (n=879)†	Disability did not improve (n=466)†	p	Catastrophizing improved (n=1,010)‡	Catastrophizing did not improve (n=406)‡	p
Gender (males)§	391 (37.5)	126 (37.2)	.501	333 (37.9)	167 (35.8)	.460	378 (37.4)	152 (37.4)	.996
Age (y)	52 (41, 63)	52 (41, 64)	.983	52 (41, 63)	53 (43, 65)	.071	53 (42, 64)	50 (40, 62)	.035
Eligible for workers' compensation	598 (57.3)	207 (58.6)	.668	519 (59.0)	255 (55.0)	.149	585 (57.9)	235 (58.2)	.932
Chronicity (d)§			.006			.177			.944
<14	91 (8.7)	18 (5.1)		71 (8.1)	30 (6.4)		82 (8.1)	30 (7.4)	
14–90	362 (34.7)	105 (29.6)		307 (34.9)	143 (30.7)		341 (33.8)	137 (33.7)	
91–365	403 (38.6)	146 (41.1)		341 (38.8)	193 (41.4)		394 (39.0)	157 (38.7)	
>365	187 (17.9)	86 (24.2)		160 (18.2)	100 (21.5)		193 (19.1)	82 (20.2)	
Failed back surgery§	8 (0.8)	13 (3.7)	<.001	8 (0.9)	13 (2.8)	.008	8 (0.8)	12 (3.0)	.002
Findings on imaging tests§									
Disc degeneration	662 (63.5)	221 (62.3)	.681	546 (62.1)	314 (67.4)	.056	651 (64.5)	238 (58.6)	.040
Spondylolisthesis/ spondylolysis	71 (6.8)	19 (5.4)	.335	55 (6.3)	33 (7.1)	.561	63 (6.2)	28 (6.9)	.647
Spinal stenosis	79 (7.6)	38 (10.7)	.066	74 (8.4)	41 (8.8)	.813	84 (8.3)	34 (8.4)	.972
Disc protrusion/hernia	330 (31.6)	145 (40.8)	.002	298 (33.9)	169 (36.3)	.386	333 (33.0)	151 (36.9)	.130
Annular tear	2 (0.2)	0 (0)	1.000	2 (0.2)	1 (0.2)	1.000	1 (0.1)	2 (0.5)	.199
>1 cm difference in leg length	8 (0.8)	3 (0.8)	1.000	7 (0.8)	3 (0.6)	1.000	9 (0.9)	2 (0.5)	.738
Lumbarization of S1	9 (0.9)	4 (1.1)	.749	8 (0.9)	6 (1.3)	.576	7 (0.7)	4 (1.0)	.522
Sacralization of L5	6 (0.6)	2 (0.6)	1.000	4 (0.5)	5 (1.1)	.290	6 (0.6)	2 (0.5)	.818
No findings	177 (17.0)	70 (19.7)	.241	142 (16.2)	88 (18.9)	.026	160 (15.8)	94 (23.2)	.001
Diagnostic procedures§									
X-rays	223 (21.4)	127 (35.8)	<.001	178 (20.3)	157 (33.7)	<.001	213 (21.1)	141 (34.7)	<.001
MRI	230 (22.1)	114 (32.1)	<.001	206 (23.4)	134 (28.8)	.033	226 (22.4)	126 (31.0)	<.001
Computed tomography scan	23 (2.2)	26 (7.3)	<.001	18 (2.0)	28 (6.0)	<.001	21 (2.1)	28 (6.9)	<.001
Electromyography	25 (2.4)	28 (7.9)	<.001	21 (2.4)	32 (6.9)	<.001	21 (2.1)	35 (8.6)	<.001
Blood analysis	22 (2.1)	28 (7.9)	<.001	17 (1.9)	31 (6.7)	<.001	17 (1.7)	34 (8.4)	<.001
Scintigraphy	2 (0.2)	0 (0)	1.000	2 (0.2)	1 (0.2)	1.000	1 (0.1)	2 (0.5)	.199
Drug treatment§									
NSAIDs	584 (56.0)	209 (58.9)	.344	492 (56.0)	278 (59.7)	.194	550 (54.5)	254 (62.6)	.005
Corticoids	51 (4.9)	41 (11.5)	<.001	42 (4.8)	47 (10.1)	<.001	44 (4.4)	51 (12.6)	<.001
Muscle relaxants	183 (17.5)	84 (23.7)	.011	169 (19.2)	94 (20.2)	.677	163 (16.1)	109 (26.8)	<.001
Other	100 (9.6)	39 (11.0)	.447	84 (9.6)	54 (11.6)	.243	93 (9.2)	46 (11.3)	.225
Physiotherapy or rehabilitation§	101 (9.7)	70 (19.7)	<.001	86 (9.8)	78 (16.7)	<.001	92 (9.1)	81 (20.0)	<.001
NRT§	975 (93.5)	258 (72.7)	<.001	832 (94.7)	365 (78.3)	<.001	947 (93.8)	295 (72.7)	<.001
Surgery§	3 (0.3)	5 (1.4)	.029	3 (0.3)	5 (1.1)	.134	2 (0.2)	6 (1.5)	.009
Other treatments§	7 (0.7)	6 (1.7)	.106	5 (0.6)	9 (1.9)	.025	6 (0.6)	9 (2.2)	.017
Severity of LBP (VAS)	7 (6, 8)	6 (4, 8)	<.001	7 (5, 8)	7 (5, 8)	.290	7 (5, 8)	7 (5, 8)	.009
Patients with LP§	775 (74.4)	247 (69.6)	.078	647 (73.7)	348 (74.7)	.694	754 (74.7)	277 (78.2)	.013
Severity of LP (VAS)	7 (5, 8)	1 (0, 6)	.154	6 (2, 8)	5 (2, 8)	.481	5 (1, 8)	5 (2, 7)	.911
Disability (RMQ)	14 (0, 18)	12 (8, 16)	.451	14 (10, 18)	12 (8, 16)	<.001	13 (9, 17)	13 (8, 17)	.970
Catastrophizing (CSQ)	16 (9, 22)	13 (7, 19)	.443	15 (9, 21)	14 (8, 20)	.028	15 (8, 21)	14 (8, 20)	<.001

LBP, low back pain; MRI, magnetic resonance imaging; NSAIDs, nonsteroidal anti-inflammatory drugs; NRT, neuroreflexotherapy; VAS, visual analog scale; LP, referred pain down into the leg (in the 1,098 patients who had it); RMQ, score in the Roland-Morris Questionnaire; CSQ, score in the Coping Strategies Questionnaire.

* Only includes patients whose pain severity at baseline was high enough to allow for a clinically relevant improvement (ie, baseline VAS >1.5).

† Only includes patients whose disability at baseline was high enough to allow for a clinically relevant improvement (ie, baseline RMQ >3).

‡ Only includes patients whose catastrophizing at baseline was high enough to allow for improvement (ie, baseline CSQ ≥1).

§ Categorical variables are described with a frequency (%), and continuous variables are described with a median (p25, p75).

improvement of the corresponding variable (Table 2). Pain worsened in only 36 patients (2.5% of the sample), disability in 40 (2.8%), and catastrophizing in 91 (6.4%). Therefore, no separate analyses were made for these patients, and they were included in the ''did not improve'' category for the corresponding variable.

There were some differences between patients who experienced improvements in pain, disability, and catastrophizing and those who did not (Table 2). Among patients who improved, failed back surgery was less common, diagnostic procedures were less frequently performed, and the treatments prescribed differed from those undergone by patients who did not improve. In addition, among the 1,043 patients in whom pain improved throughout the study period, baseline pain severity was higher, fewer were chronic, and fewer showed disc protrusion or hernia on MRI. Among the 879 in whom disability improved, baseline RMQ scores were higher, and fewer showed no radiological findings in imaging. Among the 1,010 in whom catastrophizing improved, baseline CSQ scores were higher, LP was more common, and fewer showed no radiological findings in imaging (Table 2).

The model analyzing the association between baseline catastrophizing and the evolution of LBP had to be adjusted by baseline severity of LBP, baseline degree of disability, and whether the patient received NRT intervention. The training sample included 1,103 patients, and the validation sample, 295 patients. There were no collinearity problems. No association was found between baseline CSQ score and the evolution of LBP (Table 3). This was the case for both the training and validation samples. When treatments were removed from the model, changes in results were minor (Table 3).

The model analyzing the association between baseline catastrophizing and the evolution of disability had to be adjusted by baseline score for disability and whether the patient received NRT intervention. The training sample included 1,088 patients, and the validation one included 257 patients. There were no collinearity problems. No association was found between baseline CSQ and the evolution of disability (Table 4). This was the case for both the training and validation samples. When treatments were removed from the model, changes in results were minor (Table 4).

The last regression model showed that the evolution of catastrophizing throughout the study period was associated with the evolution of LBP (Table 5). The training sample included 1,124 patients, and the validation one included 292 patients. As the degree of pain improvement increased, so did the odds ratio (OR) for improvement in catastrophizing, ranging from 3 (95% confidence interval [95% CI], 2.00–4.50; $p<.001$) for improvements in pain between 1.1 and 4 VAS points to 7.3 (95% CI, 3.49–15.36; $p<.001$) for improvements in pain more than 6.1 VAS points (Table 5). The ORs (95% CI) in the validation sample were similar to the ones found in the training sample (data not shown). When treatments were removed from the model, changes in results were minor (Table 5). There were no collinearity problems. In the sensitivity analysis in which ''change'' in the CSQ score was defined as ''any change,'' instead of a variation 30% or more of its baseline score, the results were virtually identical (Table 5).

Among the 34 patients who left the CSQ unanswered at the follow-up assessment, 27 had answered it at the baseline assessment, and their median (interquartile range) score was seven (2.11). The baseline CSQ score was unknown for

Table 3
Association between catastrophizing at baseline and the evolution of the severity of LBP throughout the study period (3 mo)

Catastrophizing at baseline†	Crude analysis		Adjusted analysis*	
	OR (95% CI)	p	OR (95% CI)	p
		.253		.163
Q1 (≤8)	Reference category		Reference category	
Q2 (9–15)	1.42 (0.99, 2.02)	.055	0.87 (0.58, 1.31)	.509
Q3 (16–21)	1.13 (0.79, 1.61)	.502	0.66 (0.43, 1.01)	.056
Q4 (≥22)	1.28 (0.88, 1.85)	.197	0.63 (0.39, 1.02)	.060

LBP, low back pain; OR, odds ratio; 95% CI, 95% confidence interval.

In the model in which prescribed treatments were removed from the models, only baseline severity of LBP showed a confounding effect, and changes in results were minor (adjusted global p=.080 and adjusted ORs [95% CI] for Q2; Q3; and Q4 were 1.16 [0.80, 1.69]; 0.81 [0.55, 1.18]; and 0.71 [0.47, 1.07], respectively).

* Variables included in the model were gender, age, baseline values for LBP, leg pain and LBP-related disability, duration of the current episode (acute, subacute, chronic, and extremely chronic), the interaction between baseline Coping Strategies Questionnaire and chronicity, workers' compensation coverage, diagnosis of ''failed back surgery,'' radiological findings, diagnostic procedures performed throughout the study, and treatments received. Results had to be adjusted only by baseline severity of LBP, baseline degree of disability, and having undergone neuroreflexotherapy intervention. Odds ratios for these variables are not shown because they may have been confounded by unknown variables that were not controlled for [24].

† Categorized in quartiles.

Table 4
Association between catastrophizing at baseline and the evolution of disability throughout the study period (3 mo)

Catastrophizing at baseline†	Crude analysis		Adjusted analysis*	
	OR (95% CI)	p	OR (95% CI)	p
		.003		.167
Q1 (≤8)	Reference category		Reference category	
Q2 (9–15)	1.43 (1.04, 1.97)	.028	0.87 (0.61, 1.23)	.428
Q3 (16–20)	1.71 (1.21, 2.41)	.002	0.76 (0.51, 1.12)	.167
Q4 (≥21)	1.73 (1.24, 2.40)	.001	0.64 (0.43, 0.96)	.029

OR, odds ratio; 95% CI, 95% confidence interval.

In the model in which prescribed treatments were removed from the models, only baseline severity of disability showed a confounding effect, and changes in results were minor (adjusted global p=.459 and adjusted ORs [95% CI] for Q2; Q3; and Q4 were 1.14 [0.82, 1.60]; 1.01 [0.70, 1.47]; and 0.85 [0.58, 1.25], respectively).

* Variables included in the maximal model were gender, age, baseline values for low back pain (LBP), leg pain and LBP-related disability, duration of the current episode (acute, subacute, chronic, and extremely chronic), the interaction between baseline Coping Strategies Questionnaire and chronicity, workers' compensation coverage, diagnosis of ''failed back surgery,'' radiological findings, diagnostic procedures performed throughout the study, and treatments received. Results had to be adjusted only by baseline degree of disability and having undergone neuroreflexotherapy intervention. Odds ratios for these variables are not shown because they may have been confounded by unknown variables that were not controlled for [24].

† Categorized in quartiles.

Table 5
Association between the evolution of the severity of LBP and the improvement of catastrophizing*

Evolution of severity of LBP‡	Crude analysis		Adjusted analysis†	
	OR (95% CI)	p	OR (95% CI)	p
		<.001		<.001
Q1 (≤1.0)	Reference category		Reference category	
Q2 (1.1–4.0)	4.97 (3.54–6.97)	<.001	3.00 (2.00–4.50)	<.001
Q3 (4.1–6.0)	10.61 (6.92–16.27)	<.001	3.18 (1.91–5.29)	<.001
Q4 (≥6.1)	35.87 (18.65–68.98)	<.001	7.32 (3.49–15.36)	<.001

OR, odds ratio; 95% CI, 95% confidence interval.

In the model in which prescribed treatments were removed from the models, only baseline degree of disability and improvement in disability throughout the study period showed a confounding effect, and changes in results were minor (adjusted global p<.001 and adjusted ORs [95% CI] for Q2; Q3; and Q4 were 3.43 [2.30, 5.10]; 4.06 [2.48, 6.66]; and 9.58 [4.62, 19.84], respectively).

* Defining ''improvement'' as any reduction in the CSQ score being ≥30% of its baseline value. In the sensitivity analyses in which ''improvement'' was defined as ''any reduction in the CSQ score,'' regardless of its size, results had to be adjusted only by improvement in disability throughout the study period, and adjusted ORs (95% CI) for Q2; Q3; and Q4 were 2.87 (1.91, 4.32); 4.04 (2.28, 7.16); and 5.49 (2.46, 12.24), respectively.

† Variables included in the maximal model were gender, age, baseline values for LBP, leg pain and LBP-related disability, duration of the current episode (acute, subacute, chronic, and extremely chronic), the interaction between baseline Coping Strategies Questionnaire (CSQ) and chronicity, workers' compensation coverage, diagnosis of ''failed back surgery,'' radiological findings, diagnostic procedures performed throughout the study, treatments received, the evolution of referred pain, and the evolution of disability. Results had to be adjusted only by baseline degree of disability, improvement in disability throughout the study period, and having undergone neuroreflexotherapy intervention. Odds ratios for these variables are not shown because they may have been confounded by variables that were not controlled for [24].

‡ Categorized in quartiles. The evolution of low back pain (LBP) was defined as the baseline score minus the final one so that positive values reflect improvement.

only seven patients (0.5%). Therefore, it was decided not to perform a sensitivity analysis.

Discussion

Results from this study show that baseline catastrophizing is of no clinical value for predicting the evolution of LBP and disability. Hence, it is not appropriate to use catastrophizing for early identification of those patients with a bad clinical prognosis.

''Association'' is different from ''causality.'' Therefore, results from this study might be interpreted as suggesting that improvement in pain leads to improvement in catastrophizing or vice versa. However, from both a psychological and a biological perspective, it is more likely that catastrophizing may appear or worsen when pain does not improve despite treatments received. The fact that the baseline degree of catastrophizing does not predict the evolution of pain and disability (Tables 3 and 4) further supports this interpretation. However, it might be argued that in patients with a higher degree of catastrophizing, pain needs to improve further before they notice any improvement and that the placebo effect may be smaller or shorter. Therefore, further studies should assess the potential influence of catastrophizing on the MCIC for pain and disability as well as on the size and duration of the placebo effect.

These results suggest that the correlation previously found between catastrophizing, LBP, and LBP-related disability in cross-sectional studies [13–18] may be of little practical clinical value because it might be explained by the fact that the OR for improvement in catastrophizing increases with pain improvement (Table 5). Results from a study conducted in the same cultural setting showed that the correlation of catastrophizing and other psychological variables with disability ceases to be significant when variations of trait anxiety are taken into account, suggesting that other psychological variables may play a more relevant role than catastrophizing [50]. This is also consistent with results from a large study conducted in routine practice in the Anglo-Saxon cultural context, which showed that among 20 potential psychological obstacles to recovery, only four (including neither FAB nor catastrophizing) were predictive of the clinical evolution of disability [32]. Results from randomized controlled trials and small prospective studies are inconsistent [2,4,7,12,18–31]. Differences in sample size, recruitment context (eg, patients treated in routine practice vs. secondary analyses of data gathered in clinical trials), patients' characteristics, and statistical methods used across studies (eg, use of hierarchical vs. non-hierarchical models) can account for this inconsistency. For instance, the use of hierarchical models implies pre hoc assumptions and favors those variables that the authors choose to enter first because these have a greater chance of attaining statistical significance.

It seems theoretically plausible that catastrophizing may be influenced by the duration of pain, radiological findings (and potential explanations given to the patients with regard to it), and having undergone aggressive treatments. However, in this study, catastrophizing scores were not influenced by these variables. In fact, the association between pain improvement and catastrophizing was the same among acute and chronic patients, and the prognostic value of baseline catastrophizing for predicting the clinical evolution was null among both acute and chronic patients (Tables 3–5). Results from the logistic regression models showed that the only relevant feature with respect to the evolution of catastrophizing is whether pain severity improves (Table 5). This might be interpreted as suggesting that patients do not tend to catastrophize if pain severity is improving, independently of its duration.

The objective of this study was to appraise the usefulness of assessing catastrophizing in the management of LBP patients in routine clinical practice. As a result, all kinds of LBP patients were included in this study: acute and chronic, with and without LP, having undergone unsuccessful spine surgery or not, and so on. However, regression models show that none of these characteristics influence the null

prognostic value of baseline catastrophizing for predicting patients' clinical evolution. At the design phase, it was also decided that this study should be conducted in conditions as close as possible to routine practice in the SNHS. As a result, patients were managed as they usually are in routine practice, and clinical decisions were left up to the treating physician. However, LBP-related clinical practice is roughly consistent within the SNHS, and it generally follows current evidence-based guidelines [36,51,52]. The seven Spanish regions in which this study was conducted represent most of the economic and cultural spectra of the country. Acute (41.9%) and chronic (58.1%) patients were recruited in routine clinical practice, in primary and specialty centers belonging to or working for the SNHS. The SNHS is a tax-funded public organization in which all health-care services are provided free to every resident in Spain (except aesthetic surgery and some dental procedures) [36]. Only a small minority of patients in the upper economic class seek health care exclusively through private health care. Low rates of included patients among those screened, losses to follow-up, and missing data may introduce a risk of bias. In this study, more than 95% of the patients screened were included, there were no losses to follow-up, and only 78 of 1,500 patients (5.2%) were excluded from the analysis because of missing data. All these features suggest that generalizability of these results to LBP patients treated within the SNHS should not be a concern.

It has been suggested that the role of psychological variables in the evolution of LBP may vary across cultural contexts. In fact, although associations between LBP and catastrophizing have been observed in some studies conducted in the Northern European and Anglo-Saxon cultural contexts [2–4,7,20–31,53–56], to date no psychological variable has shown to be relevant with regard to the treatment or clinical evolution of LBP patients in the Spanish context [11–13,18]. Therefore, further studies should identify which psychological variables influence the prognosis of LBP in the Spanish cultural context and assess the generalizability of current results to other cultural environments. Those studies should be longitudinal, include large representative samples of acute and chronic patients recruited in clinical practice and use nonhierarchical models to be comparable with the current one and to lead to results that are potentially relevant to clinical practice.

According to the results of this study, a high baseline score for catastrophizing does not predict the clinical course of pain or disability (Tables 3 and 4), whereas improvement in pain is associated with a higher OR for improvement in catastrophizing (Table 5). This might be interpreted as suggesting that it is more likely that a high score in catastrophizing follows lack of improvement in pain compared with that of a high baseline catastrophizing score that hinders improvement in pain or disability. This interpretation would contribute to the ''chicken and egg dilemma'' debate with regard to the potential reciprocal influence between catastrophizing and lack of clinical improvement [3,7–9].

The strengths of this study include its large sample, the low number of exclusions, losses to follow-up and missing data, and generalizability of its results to routine clinical practice. Weaknesses are its observational design, relatively short follow-up, that catastrophizing was the only psychological variable assessed, that continuous variables had to be dichotomized at the analysis stage, and the lack of evidence on the size of the MCIC for catastrophizing. These potential limitations are discussed in the following paragraphs.

Some patients included in this study showed high levels of catastrophizing and low levels of pain and disability at baseline, whereas others showed the opposite (Tables 1 and 2). The large sample size and the absence of losses to follow-up allowed the identification of sizable subgroups comprising those in whom each variable improved and did not improve throughout the study period. This allowed this study to assess the prognostic value of baseline catastrophizing for predicting the evolution of pain and disability, despite its observational design.

Chronic patients generate most of the social and economic burdens associated with LBP [57,58]. Therefore, in this study, follow-up was planned at 3 months to ensure that all patients who were still symptomatic at the follow-up assessment would be chronic [45] and to minimize the risk of losses associated with longer follow-up periods within the routine clinical practice of the SNHS [36]. However, because baseline catastrophizing does not predict the clinical evolution of pain or disability during the first 3 months, it is not likely for it to become relevant at a later stage. In fact, the prognosis of chronic LBP is determined by changes in pain and disability occurring in the initial period [59].

Catastrophizing might influence other psychological variables that have not been assessed in this study and which may influence patients' general health and well-being, such as fear, anxiety, or depression [20,21,52,53,60–62]. Therefore, although catastrophizing score cannot be used to identify those patients in whom LBP has a worse prognosis, it may still be useful to identify those subjects with underlying emotional or psychological comorbidities. Further studies should compare the validity, reliability, and feasibility of measuring catastrophizing or other psychological variables (eg, anxiety or depression) to identify these patients in routine practice.

On the other hand, results from this study show that the improvement of pain is associated with the improvement of catastrophizing, suggesting that successfully treating pain might be an effective way of improving catastrophizing and other potentially related psychological variables. Further studies should test this hypothesis.

Continuous variables had to be dichotomized into categories for logistic regression analyses. This might have led to a loss of statistical power. Anticipating this, a large sample was established at the design phase, and measures to reduce missing data and losses to follow-up were planned and successfully implemented. In fact, statistical power was enough to show that pain improvement is associated with the evolution of catastrophizing (Table 5).

Previous studies have shown that the cutoff point to consider a change in pain as ''clinically relevant'' corresponds to 30% of its baseline value and that the same criterion is valid for disability [37,44]. Therefore, at the design phase of this study, it was decided to establish the same cutoff point for catastrophizing. It was also decided to perform a sensitivity analysis in which ''any positive change,'' regardless of its size, would be considered as clinically relevant. Results from analyses using both cutoff points are consistent, which suggests that the lack of previous evidence on the MCIC for catastrophizing does not challenge the validity of results from this study (Table 5).

In conclusion, this study shows that, in routine clinical practice, assessing baseline catastrophizing does not help clinicians to predict the evolution of LBP and disability at 3 months.

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