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Journal
Spine Journal, 15(7)

ISSN
1529-9430

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Publication Date
2015-07-01

DOI
10.1016/j.spinee.2015.03.003

Peer reviewed

The Spine Journal 15 (2015) 1577–1586

Clinical Study

Clinical decision rule for primary care patient with acute low back pain at risk of developing chronic pain

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Received 17 October 2014; revised 20 February 2015; accepted 7 March 2015

Abstract

BACKGROUND CONTEXT: Primary care clinicians need to identify candidates for early interventions to prevent patients with acute pain from developing chronic pain.

PURPOSE: We conducted a 2-year prospective cohort study of risk factors for the progression to chronic pain and developed and internally validated a clinical decision rule (CDR) that stratifies patients into low-, medium-, and high-risk groups for chronic pain.

STUDY DESIGN/SETTING: This is a prospective cohort study in primary care.

PATIENT SAMPLE: Patients with acute low back pain (LBP, ≤30 days duration) were included.

OUTCOME MEASURES: Outcome measures were self-reported perceived nonrecovery and chronic pain.

METHODS: Patients were surveyed at baseline, 6 months, and 2 years. We conducted bivariate and multivariate regression analyses of demographic, clinical, and psychosocial variables for chronic pain outcomes, developed a CDR, and assessed its performance by calculating the bootstrapped areas under the receiver-operating characteristic curve (AUC) and likelihood ratios.

RESULTS: Six hundred five patients enrolled: 13% had chronic pain at 6 months and 19% at 2 years. An eight-item CDR was most parsimonious for classifying patients into three risk levels. Bootstrapped AUC was 0.76 (0.70–0.82) for the 6-month CDR. Each 10-point score increase (60-point range) was associated with an odds ratio of 11.1 (10.8–11.4) for developing chronic pain. Using a less than 5% probability of chronic pain as the cutoff for low risk and a greater than 40% probability for high risk, likelihood ratios were 0.26 (0.14–0.48) and 4.4 (3.0–6.3) for these groups, respectively.

CONCLUSIONS: A CDR was developed that may help primary care clinicians classify patients with strictly defined acute LBP into low-, moderate-, and high-risk groups for developing chronic pain and performed acceptably in 1,000 bootstrapped replications. Validation in a separate sample is needed.

Keywords: Low back pain; Chronic pain; Acute pain; Clinical decision rule; Prediction; Primary care

FDA device/drug status: Not applicable.

Author disclosures: ***WEM:*** Grant: NIH/NCCAM (Nos. K23 AT002298 and R21 AT004467, G, Paid directly to institution), REAC/UCSF (C, Paid directly to institution), Mount Zion Health Fund (E, Paid directly to institution); Research Support (Investigator Salary, Staff/Materials): UCSF Osher Center Grants (A, Paid directly to institution); Grants: NIH/NCCAM (F, Paid directly to institution), Mount Zion Health Fund (E, Paid directly to institution). ***MHE:*** Nothing to disclose. ***ALA:*** Nothing to disclose. ***FMH:*** Grants: NIH K24 (No. AT007827 , D per year, Paid directly to institution), NIH P01 (I, Paid directly to institution).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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http://dx.doi.org/10.1016/j.spinee.2015.03.003
1529-9430/

EVIDENCE & METHODS

Context

The authors maintain that a clinical decision rule (CDR) is necessary to help primary care clinicians identify patients who may be at risk of developing chronic back pain at the time of presentation. This CDR was developed by the authors using a prospective cohort design that included 605 patients.

Contribution

An 8-item CDR was ultimately developed by the authors, classifying patients into three risk levels for chronic back pain. The discriminative capacity of this rule was found to be moderate using bootstrap techniques. Each 10-point increase in CDR score increased the odds of chronic back pain by a factor of 11.

Implications

The efficacy of this CDR is predicated on the generalizability of the population used to develop the rule to other patients who may be at risk of chronic low back pain. The clinical utility of the tool also rests on the notion that early intervention will alter the clinical course for those identified as being at high risk. This particular investigation is unable to address that pivotal issue. As the authors appropriately recognize, further validation of the CDR itself as well as its capacity to inform clinically relevant care is required.

—*The Editors*

Introduction

Although most patients presenting with an episode of acute low back pain (LBP) in primary care will recover in 6 to 8 weeks with or without medical intervention [1,2], those who subsequently develop chronic pain suffer considerably [3], often are difficult to treat, and account for most LBP-related health expenses [4]. Primary care clinicians need decision support to identify candidates for early interventions for secondary prevention of chronic pain. Previous studies have identified risk factors for chronic pain and have attempted to develop clinical decision rules (CDRs) for the primary care setting [5,6]. The most important are the STarT-Back developed in the United Kingdom [7,8] and the Chronic Pain Risk Screener developed in the United States [9]. The STarT-BACK and several instruments developed in Europe (Örebro Musculoskeletal Pain Screening Questionnaire [ÖMPSQ] [10,11], Kiel Pain Inventory and Avoidance-Endurance Questionnaire [12,13], and Heidelberger Kurz-Fragebogen (HKF) [14]) have not been evaluated in the United States. Other limitations of the latter instruments are that they were not developed or validated in primary care patients and used delayed return to work as chronic pain outcomes, which only captures a subset of patients taking sick leave.

Both the STarT-BACK and Chronic Pain Risk Screener have been well validated in patients shortly after an index visit at a primary care office [15]. However, these index visit patients included patients with a wide range of LBP duration; less than half suffered from acute LBP. Because patients who suffer LBP for more than 3 months already have a much worse prognosis, instruments that work for this population may not perform as well in patients with acute LBP. Hence, clinicians need a tool that only addresses the prognosis of patients with truly acute LBP [1].

We, therefore, conducted a prospective cohort study to investigate the prognosis of patients with strictly defined acute LBP [16], and whether we can identify early risk factors that can help primary care clinicians determine a more accurate prognosis. If available, such risk stratification would be feasible for primary care clinics and could potentially support physicians in treatment allocation decisions. We included questionnaire items representative of all risk factors known at the time of the cohort's inception and set out to develop a novel CDR.

Methods

Patient selection

The prognosis of pain study was a 2-year longitudinal telephone survey of 18- to 70-year-old members of Kaiser Permanente, Northern California (KPNC), the largest integrated health plan in its region with 2.4 million adult members at the time. Acute LBP was defined as back pain between the rib cage and buttocks of less than 1 month that was severe enough to seek medical care and was not preceded by any other episodes of LBP in the past year. The 1-month criterion for acuteness of pain was chosen in part for pragmatic reasons, as we found that the time from scheduling a doctor's visit to being seen might be more than 2 weeks from the date of first pain onset. Patients were included if they spoke English and had no fever, history of cancer, chronic inflammatory disease, previous spine surgery, fibromyalgia, chronic pain conditions, disabling psychiatric diseases, or ongoing prescriptions for narcotics before the LBP episode. Patients with sciatica (ie, LBP radiating below the knee) were not excluded.

A computer program screened electronic medical records to identify patients seen the day before for LBP, and a written invitation was sent by mail to join the study. This invitation offered a $20 gift certificate and did not reveal the inclusion criterion of pain duration; it, therefore, prioritized minimization of false reporting over larger numbers of ineligible respondents. Respondents were interviewed over the phone at baseline and 6 months. For the 2-year follow-up, participants, when reached (maximum of three attempts), were given a choice between a phone interview and an Internet-based survey using

Table 1
Prediction items

Clinical questions related to LBP	
When did your pain start? (L7)	Days
Did it ever go below the knee?	Y/N
Does it today go below the knee most of the time?	Y/N
How would you rate the *average* (H5) pain you have had during the past week? (L8)	0–10
How would you rate the pain you have had during the past week when it was most tolerable? (H6) ("… the pain you had since it began?" if answer to L7 is <1 week)	0–10
How much pain would you be willing to tolerate and still consider the therapy successful? (H7)	0–10
Are you on sick leave because of pain?	Y/N
If yes: How many days? (L5)	Days
Have you been on sick leave before for back pain?	Y/N
On how many days during the past week did back or leg pain (sciatica) cause you to cut down for more than half of the day on things you usually do?	Days
On how many days during the past week did back or leg pain (sciatica) cause you to stay in bed for more than half the day?	Days
On how many days during the past week did back or leg pain (sciatica) cause you to loose days from work or school for more than half the day?	Days
Do you have pain in other parts of your body in addition to your back pain? (H4)	Y/N
Do you have pain in the ☐ neck ☐ shoulders ☐ upper back	
McGill pain questionnaire [18]	
Roland-Morris Disability Questionnaire (RMDQ) [19] for function or disability	0–24
Do you smoke?	Y/N
If yes: more than 10 cigarettes per day?	Y/N
ÖMPSQ and HKF-R10 items [11,14,21]	
Is your work heavy or monotonous? (L4)	0–10
Based on all the things you do to cope or deal with your pain, on an average day, how much are you able to decrease it? (L11)	0–10
I can do light work for an hour. (L12)	0–10
I can walk for an hour (L13)	0–10
I can do ordinary household chores (L14)	0–10
I can do the weekly shopping (L15)	0–10
I can sleep at night (L16)	0–10
How tense or anxious have you felt in the past week? (L17)	0–10
How much have you been bothered by feeling down or depressed in the past week? (L18/H10a)	0–10
Did you cry a lot or feel like crying in the past week? (H10b)	0–10
I still enjoy doing things I liked before (H10e)	0–10
In your view, how large is the risk that your current pain may become persistent (may not go away)? (L19)	0–10
In your estimation, what are the chances that you will be working in 6 months? (L20)	0–10
If you take into consideration your work routines, management, salary, promotion possibilities, and work mates, how satisfied are you with your job? (L21)	0–10
Physical activities make my pain worse (L22)	0–10
In your view from past experience, does massage bring pain relief? (H8)	Y/N/DK
An increase in pain is an indication that I should stop what I am doing until the pain is decreasing (L23)	0–10
I should not do my normal work with my present pain (L24)	0–10
If you were aware of pain during the last week, how often did you have the following thoughts and feelings? (H9)	
g I cannot stand it any longer!	0–10
h I wonder whether I have the same bad disease as …	0–10
m How much longer do I have to endure this pain?	0–10
n I wonder whether there is a bad disease behind all of this pain?	0–10
2-Item Version of Coping Strategies Questionnaire (CSQ-2i) [22]	
Parameters: diverting attention (1 mental positive thinking); reinterpreting pain sensations + detachment (2, 9); catastrophizing (3 magnification); ignoring sensations (4, 11); praying (5); coping self-statements (6, 13 challenge appraisal, endurance); increased behavioral activity (7, 14 active/passive distraction).	
People who experience pain have developed a number of ways to deal with their pain. When you feel pain, how much do you do the following:	
1. I think of things I enjoy doing	0–10
2. I just think of it as some other sensation, such as numbness	0–10
3. It is terrible and I feel it is never going to get any better	0–10
4. I don't pay any attention to it	0–10
5. I pray for the pain to stop	0–10
6. I tell myself I can't let the pain stand in the way of what I have to do	0–10
7. I do something active, like household chores or projects	0–10
9. I pretend it is not a part of me	0–10
11. I ignore it	0–10
13. I see it as a challenge and don't let it bother me	0–10
14. I do something I enjoy, such as watching TV or listening to music	0–10

(*Continued*)

Table 1
(*Continued*)

More coping items from CPCI [23] on "asking for assistance" (42); "seeking social support" (6); CRSS/KPI [24], [30] (68)	
(introduction as in CSQ)	
CPCI 42. I ask for help in carrying, lifting or pushing something	0–10
CPCI 6. I make arrangements to see a friend or family member	0–10
KPI 68. I have somebody console me	0–10
KPI 26+66. I talk with my partner or family	0–10
Selected PCS items [25] for catastrophizing: magnification (13), rumination (9), and helplessness (2)	
"If you were aware of pain during the last week, how often did you have the following thoughts and feelings?"	
13) I wonder whether something serious may happen	0–10
9) I can't seem to keep the pain out of my mind	0–10
2) I feel I can't go on	0–10
Two work-related fear-avoidance items from FABQ [26]:	0–10
3) Physical activity such as bending, lifting, walking or driving might harm my back	0–10
11) My normal work might harm my back	0–10
2-Item version of *self-efficacy for pain* subscale [51] from Arthritis Self-Efficacy Scale (ASES)	0–10
As of now, how certain are you that you can decrease your pain quite a bit?	0–10
As of now, how certain are you that you can continue most of your daily activities?	0–10
Perceived Stress Scale (4-item version PSS-4) [20]	

DK, don't know; FABQ, Fear-Avoidance Beliefs Questionnaire; H, Heidelberger Kurz-Fragebogen [14,21]; HKF, Heidelberger Kurz-Fragebogen; L, Linton's ÖMPSQ [11]; LBP, low back pain; N, no; ÖMPSQ, Örebro Musculoskeletal Pain Screening Questionnaire; PCS, Pain Catastrophizing Scale; Y, yes.
Note: Numbers in parenthesis refer to item numbers in instruments.

SurveyGizmo (http://www.surveygizmo.com) [17]. The study was approved by the Institutional Review Boards of the University of California—San Francisco and KPNC. Two follow-up survey time points at 6 months and 2 years allowed us to determine consistency of predictors over time. The surveys were conducted between February 2008 and November 2010.

Baseline measures

In addition to the typical demographic items (age, sex, ethnicity, foreign born, education, and income), we asked about marital status, employment status, heavy or monotonous work, job satisfaction, and smoking. The following clinical parameters were assessed at baseline: duration of current episode; history of episodes; pain-free interval before current episode; pain location(s); sciatica; pain intensity by 11-point Numeric Rating Scale (NRS) as average, worst, and most tolerable pain or average bothersomeness; McGill Pain Questionnaire [18]; Roland-Morris Disability Questionnaire (RMDQ) [19]; and days on sick leave and of reduced daily activities. The complete 24-item ÖMPSQ [11], 10-item HKF [14], and the 4-item Perceived Stress Scale [20] were included. Additional psychological predictor variables were selected from the validated instruments according to strong factor loadings and face validity (Table 1).

To avoid overextensive participant burden from lengthy questionnaires, we limited the survey to selected items expected to perform reasonably well when a reduced item set was needed [22]. In addition to the psychological items in ÖMPSQ and HKF, we included another fear-avoidance belief item from the Fear-Avoidance Beliefs Questionnaire [26], another catastrophizing item from the Coping Strategies Questionnaire [22] and two from the Pain Catastrophizing Scale [25]. As additional coping style items, we included ignoring and positive distracting using single items from the Coping Strategies Questionnaire, seeking instrumental and emotional support using four items from Chronic Pain Coping Inventory [23,27,28] and Kiel Pain Inventory [24,29,30] and denial of stress using two items from Brief-COPE [31]. The two-item version of the self-efficacy for pain subscale [22] from Arthritis Self-Efficacy Scale was also included. Anxiety and depression were assessed by multiple ÖMPSQ and HKF items and positive effect by one item from the CES-D [32] (Table 1).

Follow-up outcome measures

No gold standard or international consensus exists regarding the outcome definition for chronic LBP in cohort studies. Following the recommendations from expert LBP epidemiologists in The Netherlands [33], we applied a previously published primary outcome measure that combines a lack of perceived recovery (less than "much improved" on a six-point Likert Perceived Recovery Scale) [34] with current pain intensity of three or more on 0 to 10 NRS [33,35]. Its accuracy was assessed for this population sample in a previous study [35]. In an exploratory fashion, we also used a Grade 2 or higher chronic pain level according to the validated Graded Chronic Pain Scale (GCPS) by von Korff (this instrument yields a four-grade–level chronic pain score as a function of pain intensity and pain-related disability for the past 6 months), but only for 2-year follow-up analyses, as it includes recall of the acute phase LBP at onset [9].

Statistical analyses

All analyses were conducted using Stata12 (Stata Corp, College Station, TX, USA). We proceeded in a series of analytic steps from bivariate to multivariate analysis of

predictor variables, data, and consensus-driven decisions for scoring and cutoff and the calculation of areas under the receiver-operating characteristic curve (AUC) and likelihood ratios for the resulting CDR.

Step 1 was raw bivariate logistic regression analysis of predictor variables for our primary outcome at 6 months and 2 years. We used individual items assessed at baseline as predictor variables. In addition, we compared the odds ratios for predictors of the primary 2-year outcome with those of the 2-year GCPS. We selected variables that were associated with our outcome at $p<.1$ consistently at both time points for inclusion in Step 2.

Step 2 used the variables selected in Step 1 in multivariate logistic regression models and proceeded to stepwise backward elimination of the least supported variables. In addition, we analyzed the correlations between predictor variables and eliminated collinear redundant variables ($r>.35$) to arrive at the most parsimonious sets, separately for the 6-month and the 2-year predictions.

Step 3 used the beta coefficients of each of the final multivariable regression models (one predicting 6-month outcomes and one predicting 2-year outcomes), multiplied by 10 and rounded to the closest half integer, to create two scoring rules. The performance of each scoring rule was assessed by bootstrapped analysis with 1,000 replications and calculation of the area under the receiver operating characteristics curve and associated 95% confidence intervals (CIs).

Step 4 determined the number of patients who were positive or negative on our outcome measures for each point score. We then empirically identified reasonable cutoffs for low-, moderate- and high-risk groups based on the discussion with content experts. A minimal risk group was defined as patients who have a less than 5% chance of developing chronic pain at 6 months and less than 10% at 2 years. Conversely, if a patient has a risk of 40% or more of developing chronic pain at either 6 months or 2 years, a clinician likely would consider closer follow-up office appointments and potentially more intensive early interventions to prevent chronic pain, and these were defined as a high-risk group. In the middle range, less intensive interventions may suffice until further follow-up assessments. By simple inspection of the table (table of all individual score points and associated percentage of chronic pain cases; table not shown) with the two patient groups being either positive or negative on the outcome for each score point, we determined the cutoff for the summary score and assessed the proportion of patients in each risk group.

In Step 5, we calculated likelihood ratios with 95% CIs for the classification into these three risk groups by our CDR, according to the formula by Simel et al. [36].

Results

The prognosis of pain study enrolled 605 eligible members of KPNC, from February 2008 to March 2009 (Figure).

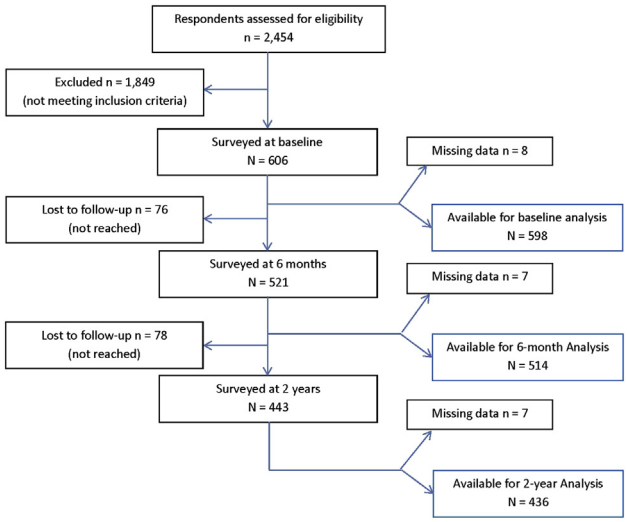

Figure. Flow diagram.

This represents 25% of the 2,454 respondents to invitations mailed to 42,650 patients who were seen for any kind of LBP in clinics of the health plan during the 12 months of recruitment. Overall, 521 participants (86%) responded at 6 months and 443 (73%) at the 2-year follow-up. The average age was 50.5 (±12.6) years, 56% were female, 65% Caucasian-American, 18% foreign born, 61% had a college degree, and 59% were employed full time (for further details, see Mehling et al. [16]) The sample represented the socioeconomic and ethnic diversity of primary care patients in the San Francisco Bay Area [37]. These patients sought medical care for pain of considerable intensity (average in past week 5.6±1.8, 2.6±1.8 when most tolerable, 8.6±1.4 when worst, on an 11-point NRS), bothersomeness (6.5±2.3), and disability (mean Roland-Morris score 15.8±4.7). The median duration of pain at baseline interview was 14 days; 8% had been on sick leave, and 27% had some sciatic pain below the knee during this episode and 10% at the time of the interview. The final sample included 510 patients with complete 6-month follow-up data and 443 patients with complete 2-year data. Using our primary combined outcome criterion [35], 13% of the patients (95% CI: 10–16) experienced persistent or recurrent pain at 6 months and 19% (95% CI: 15–22) at 2 years after pain onset [16]. Numerous patients who self-reported as much improved at 6 months felt worse at 2 years (details in Mehling et al. [16]). Participants lost to follow-up were slightly younger and included slightly more females but did not differ in those variables that were included in the CDR.

Bivariate analyses (Step 1)

All variables had less than 2% missing responses and were used without substitution. The following 12 variables had odds ratios at significance levels of $p<.1$ for our primary outcome at both time points, 5 were protective and 7 were predictive of chronic pain. Protective variables were

completed college, ability to walk for 1 hour, ability to sleep tonight, coping by TV or music, and self-efficacy in ability to decrease pain; predictive variables were additional pain in upper back, higher level of least pain since onset, smoking, catastrophizing (two items), expectancy of chronicity, and the need to holding onto something when getting off the sofa. Additional variables that satisfied at least one of our outcome criteria and the GCPS were perceived stress, coping by ignoring, coping by prayer, belief that activity worsens pain, anxiety or tension, RMDQ items 2, 5, 18, and 22, yoga at baseline, McGill overall pain intensity, worst pain since onset, sciatica since onset, African-American ethnicity, and being separated or widowed. No significant bivariate associations consistent across at least two outcome measures were found for age, sex, income level, born outside the United States, duration of pain, sciatica at time of interview, average pain intensity since onset, pain level willing to tolerate, cut-down activity days, days in bed, days lost from work, retirement, job satisfaction, other RMDQ items, positive effect, enjoyment, positive thinking, depression, ability to do light work or household chores for 1 hour, heavy or monotonous work, multiple other pain-avoidance and catastrophizing items, coping by seeking a friend or talking with family member, staying active, detachment, reinterpretation, challenge appraisal, asking for instrumental or emotional support, and other perceived stress or stress denial items.

Multivariate analyses (Step 2)

After backward elimination, eight variables remained for the 6-month prediction model and eight slightly different variables for the 2-year model. They are listed in Table 2 and discussed subsequently. When using only these eight variables for each model, the regression models explained 16% (6 months) and 10% (2 years) of the respective outcome variance. Using Grade 2 or higher of the GCPS as outcome (instead of our primary outcome combining perceived recovery with pain intensity) at 2 years provided similar results (not shown) for included parameters, AUC, and explained variance.

Point score creation (Step 3)

Table 3 shows the beta coefficients and odds ratios for each model. Multiplying the beta coefficients by 10 and rounding to the closest half integer created the 6-month and 2-year scoring rules. This method gives differential weights to individual predictors according to their beta coefficients in the multivariate model. Note that multipliers for dichotomous items are based on values of 0 or 1, whereas continuous variables are multiplied by values between 0 and 10. The 6-month scoring rule ranged from −25 to 34 points. Applied to our sample, the AUC was 0.78 (95% CI: 0.72–0.84). Applying the bootstrap procedure for 1,000 replications, a 10-point increase in the 60-point score was associated with a 11.1 odds ratio (95% CI: 10.8–11.4, $p<.001$) for having chronic pain 6 months after baseline. After bootstrapping, the AUC was slightly lower: 0.76 (95% CI: 0.70–0.82).

Using the same process for creating a scoring rule for the eight strongest predictor variables at the 2-year outcome, we obtained summary scores between −18 and 28.5. Applied to our sample at the 2-year follow-up, the AUC was 0.70 (95% CI: 0.64–0.76, bootstrapped 0.69 [0.62–0.75]). Applying the bootstrap procedure for 1,000 replications, a 10-point increase in the score was associated with a 11.1 odds ratio (95% CI: 10.7–11.5, $p <.001$) for having chronic pain 2 years after baseline.

Table 2
Items used in the 6-month and 2-year risk scores

Item	Response	6-Mo model	2-Y model
Did your pain ever go below the knee during this episode of back pain?	Y/N	X	
Do you have additional pain in the upper back?	Y/N	X	X
How would you rate the pain you have had during the past week when it was most tolerable? [14]	0–10		X
Can you sleep at night?* [11]	0–10	X	
Can you walk for an hour* [11]	0–10		X
In your view, how large is the risk that your current pain may become persistent (may not go away)? [11]	0–10	X	
You think it is terrible and you feel it is never going to get any better† [22]	0–10	X	X
When you feel pain you ignore it† [22]	0–10	X	X
You do something you enjoy, such as watching TV or listening to music† [22]	0–10	X	X
In the last month, how often have you felt confident about your ability to handle your personal problems?‡ [20]	0–10		X
Did you complete college education (BS, BA)?	Y/N	X	X

Note: Items used in the 6-month and 2-year risk scores indicated by X in the respective column. N, no; Y, yes.

* "Could you please answer with a number on a scale from 0–10? The 0 means 'I can NEVER do this because of pain' and the 10 means 'I can ALWAYS do this without pain being a problem'."

† "When you feel back pain, how much do you do the following, where a 0 indicates 'you never do that' and a 10 indicates 'you always do it when you feel back pain'."

‡ "The next question asks about your life in general, and about stress you have, not only from your back pain, but also stress from other aspects of your life including family, relationships, work, health etc. We would like for you to tell us about your feelings and thoughts during the last month. Again, use the scale from 0 to 10, where 0 is never, and 10 is always, and tell us how often you felt or thought a certain way."

Table 3
Odds ratios and β coefficients for multivariate regression model for predicting chronic pain at 6 months and 2 years and corresponding point score

	6-Mo prediction model			2-Y prediction model		
Parameter	β Coefficient	6-Mo OR (95% CI)	Point multiplier	β Coefficient	2-Y OR (95% CI)	Point multiplier
College education (Y/N)	−0.47 (−1.05 to 0.10)	0.62 (0.35 to 1.10)	−5	−0.29 (−0.83 to 0.24)	0.75 (0.44 to 1.27)	−3
Coping with TV and music (0–10)	−0.11 (−0.20 to –0.02)	0.90 (0.82 to 0.98)	−1	−0.11 (−0.20 to 0.03)	0.89 (0.82 to 0.97)	−1
Ability to sleep (0–10)	−0.09 (−0.18 to 0.01)	0.92 (0.84 to 1.01)	−1			
Ability to walk 1 h (Y/N)				−0.05 (−0.11 to 0.02)	0.95 (0.89 to 1.02)	−.5
Pain in upper back (Y/N)	1.80 (1.09 to 2.51)	6.06 (2.98 to 12.31)	18	0.65 (–0.12 to 1.42)	1.92 (0.89 to 4.13)	6.5
Pain below knee (Y/N)	0.59 (–0.01 to 1.19)	1.80 (0.99 to 3.27)	6			
Pain willing to tolerate (0–10)				0.16 (0.00 to 0.31)	1.17 (1.00 to 1.36)	1.5
Expectancy of chronic pain (0–10)	0.12 (0.01 to 0.24)	1.13 (1.01 to 1.27)	1			
Catastrophizing (0–10)	0.11 (−0.01 to 0.22)	1.12 (1.01 to 1.24)	1	0.08 (−0.01 to 0.17)	1.08 (0.99 to 1.19)	1
Coping by ignoring pain (0–10)	0.10 (0.01 to 0.19)	1.11 (1.01 to 1.21)	1	.15 (.06 to .23)	1.16 (1.06 to 1.26)	1.5
Perceived stress 4 (0–10)				0.12 (0.02 to 0.21)	1.12 (1.02 to 1.24)	1

CI, confidence interval; N, no; OR, odds ratio; Y, yes.

Selection of cut points (Step 4)

After inspection of the outcomes table for each rule, we identified optimal score cutoffs for creating the three clinically useful risk groups at 6 months and 2 years and assessed the proportion of patients in each risk group. The results are shown in Table 4.

After a discussion among clinical colleagues, we assumed that a score with a predictive value of or near 5% would be a good cutoff for the lowest risk group and that a 40% predictive value would be an appropriate cutoff for recommending further assessment and therapeutic measures. Applying these criteria to the 6-month prediction, score cutoffs were less than −4 for low-risk and more than +7 for high-risk groups. The low-risk group included 47% of all patients, the medium-risk group 38%, and the high-risk group 15%. The resulting proportions of chronic pain patients in the three risk groups were 3.8%, 14.1%, and 39.7%, respectively.

Applying the 2-year decision rule in the 2-year follow-up dataset, we obtained scores between −18 and 28.5 and found that relatively low scores had a higher than 5% risk of developing chronic pain. We, therefore, chose a 10% cutoff for the low-risk group, maintained the 40% cutoff for the high-risk classification, and thus classified 49% as low risk at a score of less than or equal to 1, 36% as medium risk at scores of more than 1 and less than 9, and 15% as high risk with scores of more than or equal to 9.

Likelihood ratios (Step 5)

Likelihood ratios for correctly classifying patient into low-, medium-, and high-risk categories were 0.26 (95% CI: 0.14–0.48), 1.08 (0.79–1.5), and 4.35 (3.0–6.3) at 6 months and 0.50 (0.34–0.72), 1.12 (0.82–1.52), and 3.14 (2.06–4.78), respectively, at 2 years (Table 4).

Discussion

To the best of our knowledge, this is the first attempt to develop a CDR for the prediction of chronic LBP among patients with strictly defined acute LBP of less than 4 weeks duration in the United States. A variety of methods exist for developing such rules [38,39]. This CDR was developed using multivariable logistic regression to help primary care clinicians decide whether a patient who presents with a new episode of nonspecific LBP with or without sciatica is at risk of developing chronic pain and may warrant closer follow-up and potentially a more intensive therapeutic intervention. The CDR is limited to patients who had no LBP in the previous year and never had spine

Table 4
Proportion of patients with chronic pain in each risk group and likelihood ratios for correct risk classification

	Number of patients			
Risk group (total N)	With chronic back pain	Without chronic back pain	Percentage with chronic back pain (95% CI)	Likelihood ratio (95% CI)
6-mo model (509)	67	442		
Low risk (score 4)	9	230	3.8 (1.7–7.0)	0.26 (0.14–0.48)
Moderate risk (score −4 to 7)	27	165	14.1 (9.5–19.8)	1.1 (0.79–1.5)
High risk (score ≥8)	31	47	39.7 (28.8–51.5)	4.4 (3.0–6.3)
2-y model (440)	82	358		
Low risk (score smaller than -4)	22	194	10.1% (6.49–15.0)	0.50 (0.34–0.72)
Moderate risk (score −4 to 7)	32	125	20.4% (14.4–27.5)	1.12 (0.82–1.52)
High risk (score ≥8)	28	39	41.8% (29.8–54.5)	3.14 (2.06–4.78)

CI, confidence interval.

surgery. Previous CDRs were developed and validated in patients with LBP of any duration; a majority of these had pain for more than 3 months and already had a higher pretest probability for persistent pain. When a CDR constructed of items that were identical or highly similar to the nine-item STarT-Back from the United Kingdom was applied in our sample, its performance was found unsatisfactory in patients with truly acute LBP [40].

The variables included in the new CDRs reflect risk factors that have been found in the previous studies: College education was protective and the only significant demographic predictor [41]. Pain spreading to the upper back was a consistent clinical risk factor. Sciatica [42] and difficulty sleeping [10] predicted poor outcomes at 6 months, the inability to walk for 1 hour [10], and poor outcomes at 2 years. At both follow-ups, a coping style of watching TV or listening to music [43] was protective, whereas catastrophizing [44] and coping with pain by ignoring [13] were psychological risk factors. Five of eight predictor variables were identical for outcomes at our two follow-up time points, and three were different. The expectancy of pain to persist was maladaptive at 6 months [45,46], whereas a low willingness to tolerate pain [14] and perceived stress [41,42] increased risk at 2 years. We do not have an explanation for the difference.

The observed likelihood ratios for the 6-month CDR of 0.26 (95% CI: 0.14–0.48) for the low-risk classification and 4.4 (95% CI: 3.0–6.3) for the high-risk classification are moderately accurate [47]. The rule is likely to be clinically useful, as almost half of all patients fell into a low-risk group that was unlikely to develop chronic pain at 6 months. Approximately 15% of patients were classified as high risk and may warrant more intensive interventions. The remaining 38% of medium-risk patients, assessed at an average of 2 weeks (range, 2–30 days) after pain onset, had a mean risk of 14% for developing chronic pain. They may warrant closer oversight by their primary care clinician than the low-risk group, but it may be justified to suggest waiting a bit longer before prescribing more intense and costly interventions.

We previously reported for this cohort that because of the recurring course of chronic LBP, individuals with persistent pain at 6 months were not identical to those at 2 years and that the proportion of persistent pain patients had increased between the two follow-up time points [16]. Creating a 2-year decision rule with the 2-year follow-up made it impossible to use the 5% criterion as cutoff for low-risk classification. We, therefore, used a 10% criterion but maintained the 40% risk for the high-risk classification cutoff. The results show that the prediction of the long-term outcome is challenging in patients with strictly defined acute LBP. Long-term predictions over years appear to be less precise than the prediction for 6 months, which is not surprising as the outcome is much further into the future than for the 6-month CDR.

A scoring method that assigns weights to individual predictor variables may best be used by a programmed risk classification calculator rather than by hand, but it increases the precision of the prediction [38]. Whereas the 6-month CDR may be most useful for the primary care clinical practice, the 2-year CDR may be useful for long-term clinical research. Five of the predictive items for the 6-month rule are identical with those for the 2-year rule. For validation of the rules in a separate sample and in particular for clinical application, we would recommend assessing all 11 items and then applying the relevant 8 items for 6-month predictions and the slightly different set of 8 items for a 2-year prediction.

The main limitation of our study is that we have not assessed the decision rules' performance in a separate validation sample. The observed variance in these predictor item scores among study participants with acute LBP early into their episode is rather large and reduces their predictive power. Moreover, as shown for this cohort, a high recurrence rate leads to different individuals having persistent pain at different time points [16]. This variance creates a challenge for creating a rule that performs strongly with patients where it is most needed, early in the course of a new episode of LBP.

A second limitation is that we included only questionnaire items that were known to be potentially predictive at the time of the study's implementation. Somatization [48], reduced levels of body awareness [49], and potentially many others may be further parameters of predictive value and were not included in our questionnaire. However, we included a wide range of demographic, clinical, and psychological predictor variables carefully chosen according to the best knowledge of the time.

A third limitation is that we relied on diagnostic codes from electronic medical records created by primary care providers and patient self-report. It is possible that clinical findings that indicate a more severe baseline condition, such as positive signs for spinal nerve compression or spinal claudication from spinal stenosis, can be identified as important risk factors for chronic pain at the very first onset of LBP by clinical examination and imaging studies. However, current clinical guidelines do not recommend imaging in the first weeks after new-onset LBP in patients who most likely would not need an immediate referral to a spine surgeon. Future studies would benefit from clinical exams at study entrance.

A fourth potential limitation is that the study population did not include uninsured patients; only 3% reported annual household incomes less than $25,000. However, income level was not predictive of the outcome.

Conclusions

Despite these limitations, we conclude that our study provides a CDR that is urgently needed for one of the

most frequent and most costly conditions in primary care [50]. It contains eight items for the 6-month and eight items for the 2-year risk classification (five are common to both) into three levels of risk for developing chronic pain in patients presenting in primary care with a new-onset episode of strictly defined acute LBP. The next step is to prospectively validate this tool in an independent population.

Acknowledgments

This study was supported by National Institutes for Health/National Center for Complementary and Alternative Medicine (NIH/NCCAM) grants K23 AT002298 (Mehling), R21 AT004467 (Mehling), NIH/NCCAM K24 AT007827 (Hecht), the Research Evaluation and Allocation Committee of the University of California—San Francisco, and the Mount Zion Health Fund, San Francisco. The funding agencies played no role in design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript. We would like to acknowledge the cooperation of the many patients who took time to answer our surveys in spite of being in pain and thank them. The authors report no conflict of interests. We would like to thank Timothy S. Carey, MD, MPH, for his contributions to study design, item selection, and manuscript review; Alice Pressman for creating the computer program for the electronic medical records; Viranjini Gopisetty and Elizabeth Bartmess for project management; Pete Bogdanos for research assistance; and the many volunteers who helped with the interviews.

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