



Can rate of recovery be predicted in patients with acute low back pain? Development of a clinical prediction rule

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ARTICLE INFO

Article history:

Received 18 November 2007

Received in revised form 30 January 2008

Accepted 11 March 2008

Available online 29 April 2008

Keywords:

Low back pain

Prognosis

Predictive factors

Primary care

ABSTRACT

Some patients with low back pain recover quickly while others continue to experience pain beyond 3 months. The primary aim of this study was to develop a simple prediction rule to help clinicians identify patients with acute low back pain likely to recover at different rates. The secondary aim was to compare a clinician's prognosis judgement to the prediction rule. The study sample included 239 patients with acute low back pain who participated in a randomised controlled trial. The primary outcome was days to recovery from pain. Potential prognostic factors were initially tested for univariate association with recovery using Cox regression ($p < 0.1$). Continuous prognostic factors with a significant association were dichotomised using a median split. Significantly associated prognostic factors were then included in a multivariate forward stepwise Cox regression. We then separated participants into strata according to the number of predictors in the final model for which they were positive. Our results suggest that a clinical prediction rule using three simple prognostic factors was able to differentiate between patients who recover quickly and those who recover slowly. Patients with lower than average initial pain intensity, shorter duration of symptoms and fewer previous episodes recovered more quickly (HR = 3.5, 95% CI, 1.8–7.0) than patients without these characteristics. Therapists were able to predict patients likely to recover at different rates, (HR = 1.6, 95% CI, 1.2–2.1), however, they did not perform as well as the clinical prediction rule. The rule requires validation in a different sample of patients.

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1. Introduction

Acute low back pain is widely considered to have a good prognosis. A recent systematic review concluded that on average pain reduces by between 12% and 84% within the first 4 weeks, but many patients do not recover either quickly or completely (Pengel et al., 2003). While the proportion of patients who have recovered by different time points varies between studies, a consistent finding is that there is considerable variability in outcomes: some patients with acute low back pain recover quickly while other patients continue to experience pain beyond 3 months. The ability to identify patients with acute low back pain likely to recover at different rates has important implications for clinical practice.

Previous studies of prognostic factors for patients with acute low back pain mostly use arbitrary time points such as 6 weeks or 3 months to assess outcome. The majority of studies have concentrated on identifying those patients likely to develop chronic pain, (Bekkering et al., 2005; Grotle et al., 2005; Enthoven et al., 2006; Pransky et al., 2006; Grotle et al., 2007) as this group is

responsible for most of the costs attributable to back pain (Australian Institute of Health and Welfare, 2000). Identifying patients who recover at different rates during the first 3 months is also important but little research has focussed on this. We are unaware of any previous studies that investigated prognostic factors for the outcome of time (days) to recovery of pain during the first 3 months. We believe that time to recovery of pain is possibly the most important or understandable outcome to many patients with low back pain. A predictor of high rates of recovery by 3 months tells a patient very little about how quickly their pain is likely to recover during the first 3 months. Predictors of very rapid recovery of pain may clearly be different to predictors of recovery by 3 months. Three months is a long time to experience low back pain and providing patients with a more accurate prognosis in terms of days to recovery would be beneficial and help with decisions regarding the need for interventions.

Some authors have attempted to develop prediction rules to assist clinicians in identifying patients with low back pain with different prognoses (Bekkering et al., 2005; Pransky et al., 2006; Jellema et al., 2007). There has been little investigation into the relative performance of these prediction rules compared with a clinician's overall assessment of prognosis. One study found general

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practitioner (GP) assessment was a better predictor of outcome than individual baseline factors (Schlottz-Christensen et al., 1999) while another study found the GP assessment was less prognostic than a prediction rule developed for this purpose (Jellema et al., 2007). If estimates of prognosis based on clinicians' judgements are superior to estimates based on prediction rules then the rules have no real use and further examination of the reasoning process used by clinicians is required.

Therefore the primary aim of this study was to develop a simple prognostic rule to help clinicians identify patients with acute low back pain, presenting to primary care, likely to recover from pain at different rates. The secondary aim of the study was to determine how the clinician's judgement of prognosis compares to that of the developed prediction rule.

2. Methods

2.1. Design overview

The data for this study come from a factorial trial evaluating the effectiveness of spinal manipulative therapy and/or diclofenac for patients with acute low back pain. The full details of the trial have been published previously (Hancock et al., 2005, 2007).

2.2. Setting and participants

Consecutive patients presenting with low back pain (with or without leg pain) of less than 6 weeks duration to 1 of 40 general practitioners working in primary care across Sydney (Australia) were invited to participate in the study. The inclusion criteria were a primary complaint of pain in the area between the 12th rib and buttock crease causing moderate pain and moderate disability (measured by adaptations of items 7 and 8 of the SF-36). Exclusion criteria were: current episode not preceded by a pain-free period of at least 1 month in which no care was provided; known or suspected serious spinal pathology; nerve root compromise (evidenced by at least 2 of the following: (i) myotomal weakness, (ii) dermatomal sensory loss, and (iii) hyporeflexia of the lower limb reflexes); currently receiving non-steroidal anti-inflammatory drugs (NSAIDs) or spinal manipulative therapy; surgery within the preceding 6 months; contraindication to paracetamol, diclofenac or spinal manipulative therapy. Each patient gave written informed consent. The study was approved by the Human Research Ethics Committee of the University of Sydney.

2.3. Recruitment and baseline care

All patients received general practitioner advice (to remain active and avoid bed rest, and reassurance of a favourable prognosis) and were supplied with paracetamol to be taken 1 g 4 times daily. Patients were asked to continue taking paracetamol until recovery up to a maximum of 4 weeks. A researcher then met with the patient within 2 days (excluding Sundays) to collect baseline data (including prognostic factors) and to randomize the patient to a treatment arm. All participants were allocated to 1 of 4 groups as follows:

- Placebo spinal manipulative therapy and placebo diclofenac group.
- Placebo spinal manipulative therapy and active diclofenac group.
- Active spinal manipulative therapy and placebo diclofenac group.
- Active spinal manipulative therapy and active diclofenac group.

The placebo spinal manipulative therapy was detuned pulsed ultrasound, which was matched with active spinal manipulative

therapy for the treatment duration and patient's contact with the therapist.

2.4. Outcome

The primary outcome was the number of days from the baseline assessment until recovery from pain. Recovery was defined as a pain score of 0 or 1 on a 0–10 pain scale that was maintained for 7 consecutive days (recovery was deemed to have occurred on the first of the 7 days). To ensure a precise estimate of the time to recovery, subjects completed a daily pain diary. To minimise potential for lost data, pain scores from the diaries were transcribed by the researcher during phone follow-ups by an assessor blinded to group allocation at 1, 2, 4 and 12 weeks. If patients had not recovered by 4 weeks then additional phone follow-ups were performed every 2 weeks until recovery or 12 weeks.

2.5. Prognostic factors

The following baseline prognostic factors were evaluated: average pain over last 24 h (numerical pain rating: 0 = no pain, 10 = worst pain possible) (Farrar et al., 2000), disability (Roland Morris disability questionnaire: 0 = no disability, 24 = high disability) (Roland and Morris, 1983), function (patient specific functional scale: 0 = unable to perform activity, 10 = able to perform activity at pre-injury level) (Stratford et al., 1995), gender, age, duration of current episode (days from onset to baseline assessment), number of previous episodes, area of symptoms (above or below the knee), segmental mobility (0 hypomobile joints in lumbar spine/ 1 or more hypomobile joints), hip internal rotation range (≥ 1 hip with >35 degrees of internal rotation range of motion/ no hip with >35 degrees of internal rotation range of motion), fear of pain (fear avoidance beliefs questionnaire – work subscale: 0 = no fear avoidance beliefs, 42 = high fear avoidance beliefs and activity subscale: 0 = no fear avoidance beliefs, 24 = high fear avoidance beliefs) (Waddell et al., 1993), catastrophising (patient related self statement: 0 = low catastrophising, 5 = high catastrophising), coping (patient related self statement: 0 = poor coping strategies, 5 = strong coping strategies) and the physiotherapist's prediction score (0 = very slow resolution of pain, 10 = very fast resolution of pain). Physiotherapists rated all patients after completing the examination and before providing active or placebo spinal manipulative therapy.

2.6. Statistical analysis

Survival analysis showed the two interventions (spinal manipulative therapy and diclofenac) in the trial did not influence rate of recovery (HR for diclofenac = 1.09 (95% CI, 0.84–1.42), HR for spinal manipulative therapy = 1.01 (95% CI, 0.77–1.31)). Therefore data from the four groups were pooled for this study.

Univariate Cox regression was performed on all of the pre-specified predictor variables to evaluate their prognostic value. Variables with significant associations ($p < 0.1$) were selected for possible inclusion in the multivariate analysis. We then inspected the correlations between the significant variables and where any correlation was greater than 0.4 we selected 1 of the variables based on ease of assessment and psychometric properties.

The remaining continuous variables were converted into dichotomous variables by using a median split to limit bias (Keegan et al., 2000). Coding of dichotomous variables was performed so that features associated with rapid recovery were scored as 1. Therefore in the final model predictors with hazard ratios (HR) > 1 are those associated with a greater rate of recovery. Significantly associated variables were then included in a multivariate stepwise Cox regression ($p < 0.05$ to enter, $p > 0.1$ to remove) to

identify variables with independent prognostic value. We then separated participants into strata according to the number of independent predictors for which they were positive. We present separate survival curves, HR and median days to recovery for each stratum. The discriminative ability of the final model was determined by assessing the area under the receiver operating characteristic curve (ROC) for recovery status dichotomised at 11 weeks. Bootstrapped estimates were obtained of the area under the curve (1000 replications).

The primary analysis did not include the physiotherapist prediction score, but we performed a secondary analysis evaluating the ability of the physiotherapist prediction score to predict outcome. The predictive value of the physiotherapist prediction score was evaluated in two ways. Firstly the scores were dichotomised about the median. Secondly scores were separated into four strata about the quartiles.

3. Results

3.1. Baseline data and follow-ups

Between June 2005 and October 2006 19 general practitioners from 14 practices screened 320 consecutive patients with acute low back pain. The practices were located across a full range of socioeconomic areas, reflecting an urban population. Five patients did not meet the inclusion criteria, while 33 met the exclusion criteria leaving 282 patients who were invited to participate. Forty-two eligible patients declined to participate, leaving 240 who were randomised into the trial. One patient was excluded on the day of enrollment when the physiotherapist and referring general practitioner both became concerned that the patient may have a serious pathology as the source of his low back pain. Therefore 239 patients were included in the study. There were no missing data on any of the baseline predictors for all patients. Two hundred and thirty-seven (99%) patients were successfully followed up until they either recovered or were censored 12 weeks after enrolling in the trial. This equates to a completeness of follow-up measure as developed for survival data of 98% (Clark et al., 2002).

Table 1 presents the baseline demographic and predictive variables for patients enrolled in the trial and the univariate associations (*p* values) with the primary outcome of days to recovery. Predictors with significant univariate associations with recovery

time were baseline pain, duration of current episode, number of previous episodes, FABQ work subscale and catastrophising (PRSS). The correlations between these variables were weak ($r < 0.313$). Therefore all five variables were dichotomised using a median split before being entered into the multivariate model. Dichotomised features associated with a more rapid recovery were lower baseline pain (≤ 7), shorter duration of current episode (≤ 5 days), fewer previous episodes (≤ 1), lower score on FABQ work subscale (≤ 14), and lower levels of catastrophising (≤ 1.78) (PRSS).

After the stepwise selection procedure three variables remained in the final multivariate model (baseline pain (HR = 1.5, 95% CI, 1.1–1.9), duration of current episode (HR = 2.0, 1.5–2.7), number of previous episodes (HR = 1.3, 95% CI, 1.0–1.8)). Fig. 1 presents the survival curves for patients who were positive on 0, 1, 2 or 3 of the predictors. Table 2 presents the HR, median days to recovery and proportion recovered at 1 and 12 weeks for each stratum. The discriminative ability of the final model was satisfactory with area under the curve of 0.68 (95% CI, 0.57–0.79).

The physiotherapist prediction score was significantly associated with rate of recovery using both the median split method ($p = 0.002$) and the quartiles method ($p = 0.002$). Using the median split method, patients rated positive recovered more quickly than those rated negative (HR = 1.6, 95% CI, 1.2–2.1). Using the quartile method, HRs for recovery were 1.3 (95% CI, 0.8–2.1), 1.6 (95% CI, 1.0–2.4) and 2.2 (95% CI, 1.4–3.5) for patients in the second, third and fourth most positively rated quartiles respectively, compared to patients in the least positive quartile.

4. Discussion

This study prospectively monitored 239 patients with acute low back pain presenting to primary care. A very high follow-up rate (98%) was attained. The study developed a clinical prediction rule using three simple prognostic factors (baseline pain, duration of current episode and number of previous episodes) that was able to identify patients with acute low back pain likely to recover at different rates. Patients with lower than average initial pain intensity, shorter duration of symptoms and fewer previous episodes, were 3.5 times more likely to be recovered at any time point (HR = 3.5, 95% CI, 1.8–7.0) than patients without these characteristics.

Table 1
Baseline prognostic factors and univariate associations

Characteristic	All subjects	Univariate <i>p</i> values
Age (years)	40.7 (15.6)	0.321
Sex; <i>n</i> (% female)	105, 44%	0.817
Duration of current symptoms (days)	9.13 (9.31)	<0.001 ^a
Previous episodes	3.7 (6.4)	0.095 ^a
Disability ^b	13.1 (5.4)	0.373
Function ^c	3.9 (1.8)	0.327
Pain ^d	6.5 (1.7)	0.001 ^a
PRSS-coping ^e	3.56 (0.78)	0.125
PRSS-catastrophising ^f	1.85 (0.94)	0.001 ^a
FABQ-work subscale ^g	14.5 (10.4)	0.017 ^a
FABQ-activity subscale ^h	17.0 (5.4)	0.908
No pain distal to knee; <i>n</i> (%)	213, 89%	0.144
≥ 1 Hypomobile segment; <i>n</i> (%)	194, 81%	0.683
≥ 1 Hip with >35 degrees of internal rotation range of motion; <i>n</i> (%)	110, 46%	0.343

^a Variables entered into multivariate model.

^b RMDQ: Roland Morris disability questionnaire: 0 (no disability) to 24 (high disability).

^c PSFS: patient specific functional scale: 0 (unable to perform activity) to 10 (able to perform activity at pre-injury level).

^d NPRS: numerical pain rating scale: 0 (no pain) to 10 (worst pain possible).

^e PRSS-coping: pain-related self statement scale – coping: 0 (poor coping strategies) to 5 (strong coping strategies).

^f PRSS-catastrophising: pain-related self statement scale – catastrophising: 0 (low catastrophising) to 5 (high catastrophising).

^g FABQ-work: fear avoidance beliefs questionnaire – work: 0 (no fear avoidance beliefs) to 42 (high fear avoidance beliefs).

^h FABQ-physical activity: fear avoidance beliefs questionnaire – physical activity: 0 (no fear avoidance beliefs) to 24 (high fear avoidance beliefs).

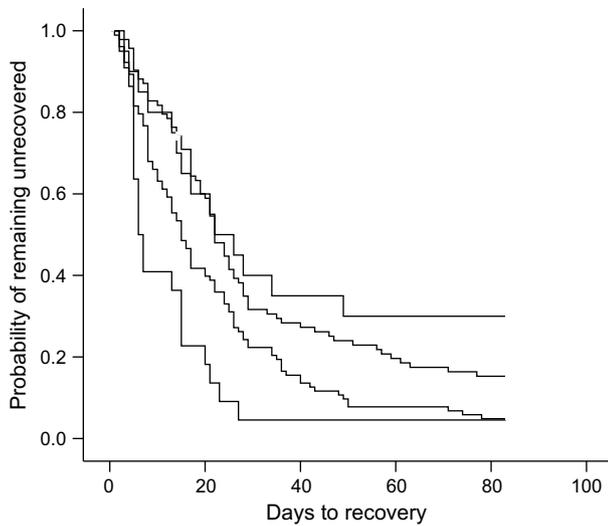


Fig. 1. Survival curves for recovery from low back pain. The four lines from top to bottom represent patients with 0, 1, 2 or 3 prognostic factors associated with faster recovery, respectively.

The three predictors in our final model are similar to those previously recorded in the literature (Bekkering et al., 2005; Croft et al., 2006; Enthoven et al., 2006). Previous researchers have found psychological factors to predict prognosis of acute low back pain (Pincus et al., 2002; Grotle et al., 2005; Grotle et al., 2007). We did find significant univariate associations with recovery rate for both catastrophising and fear avoidance (FABQ-work subscale) but neither of these items remained in the final multivariate model. The three predictors identified are not amenable to change but appear to be the most important prognostic factors for patients with acute low back pain when the outcome of interest is time to recovery from pain.

As a secondary aim of the study we were interested to see whether treating physiotherapists were able to predict recovery following their initial examination and how the accuracy of their predictions would compare to the prediction rule. Our results suggest that physiotherapists are able to identify those patients who recover at different rates during the first 3 months, but they do not perform as well as the prediction rule. Our results are consistent with those recently reported by Jellema et al. investigating estimates of prognosis made by a GP compared to a clinical prediction rule (Jellema et al., 2007). When the physiotherapist prediction in our trial was dichotomised using a median split the HR for recovery in those rated positive by the physiotherapists was 1.6 (95% CI, 1.2–2.1). When we divided the physiotherapist prediction score into quartiles, to enable a more similar comparison to the four strata of the prediction rule, we found patients receiving the most positive prognosis from the physiotherapists had HR for recovery of 2.2 (95% CI, 1.4–3.5) compared to patients with the lowest scores. Interestingly the physiotherapist prediction rating remained informative (HR = 1.4, 95% CI, 1.1–1.9) when added to

the final model. This suggests that the physiotherapists based their prediction of recovery on factors other than those included in the prediction rule. Further investigation of what information clinicians use to estimate prognosis may help identify other useful prognostic factors.

In our study the physiotherapists rated speed of recovery on a scale from 0 to 10, where 0 represented very slow recovery of pain and 10 represented very fast resolution of pain. A limitation of this scale is that it does not assess how accurately therapists can predict the actual number of days to recovery but rather how well they can discriminate between those who recover quickly or slowly. It is possible that physiotherapists may systematically over or under estimate the actual time to recovery. Previous work in the field of terminal cancer has shown clinicians can discriminate between patients who survive for shorter or longer periods, however, they typically over estimate survival time (Chow et al., 2001; Glare et al., 2003).

We set out to develop a prediction rule which would be simple to use in a clinical setting and were willing to compromise some accuracy to achieve this. We determined a priori that we would simplify the model so each factor had an equivalent weighting unless the coefficients were markedly different. While the coefficients for the three variables in the final model were somewhat different ranging from 1.3 to 2.0, we felt these were not sufficiently different to require weighting them and making the final rule more difficult to use. The discrimination of the rule measured using the area under the curve did not reduce much when equivalent weighting was used (0.68, 95% CI, 0.57–0.79) rather than weighting based on coefficients from the multivariate model (0.71 (95% CI, 0.62–0.81)). We believe the simplicity of our rule makes it a good candidate for future external validation as simple clinical prediction rules are more likely to be used in clinical practice than more complicated rules (Laupacis et al., 1997).

The discrimination of the rule measured using area under the curve (0.68, 95% CI, 0.57–0.79) represents moderate discriminative ability. The implication of this is that while the rule improves the ability of clinicians to predict time to recovery a considerable number of patients will not recover as predicted by the model. Data presented in Table 2 also demonstrate quite wide confidence intervals. The rule is best at discriminating between patients with 0 or 3 predictors but a relatively small proportion (42/239) of patients belong to these groups.

The use of data from randomised controlled trials to investigate prognosis can limit the generalisability of the findings. This is particularly the case if patients in the study are highly selected and not typical of patients with the condition. In our study the inclusion criteria were deliberately broad and aimed at including all patients with non-specific acute low back pain. The exclusion criteria were only those required to ensure safety and blinding of patients. Of 320 consecutive patients presenting to their GP with acute low back pain 240 entered the trial. Only 33 patients met the exclusion criteria and 42 patients who were eligible for the trial declined to participate. We believe that as two thirds of consecutive patients with acute low back pain who presented to their GPs entered the

Table 2
Recovery for different strata based on number of predictors

Number of predictors present	Hazard ratio (95%, CI) (n = 239)	Median days to recovery (95%, CI) (n = 239)	Proportion recovered at 1 week (n) (n = 238)	Proportion recovered by 12 weeks (n = 237)
0	1	22 (11–33)	15% (3/20)	70% (14/20)
1	1.3 (0.7–2.3)	22 (19–24)	13% (12/93)	85% (78/92)
2	2.0 (1.2–3.6)	15 (12–18)	23% (24/103)	95% (987/103)
3	3.5 (1.8–7.0)	6 (4–8)	60% (13/22)	95% (21/22)

Predictors: baseline pain $\leq 7/10$, duration of current episode ≤ 5 days, and ≤ 1 previous episodes.

trial the results of this trial are likely to have acceptable external validity.

Patients involved in this study all received guideline recommended care of advice and paracetamol with 50% also receiving diclofenac and 50% receiving spinal manipulative therapy. As neither diclofenac nor spinal manipulative therapy produced significant effects we believe the results may generalise to patients receiving different treatments, however, this requires further validation. Due to the nature of our trial very few patients with workers compensation claims entered the trial and the validity of the prediction rule in those patients is not clear. We excluded patients with nerve root compromise (evidenced by at least two of the following: (i) myotomal weakness, (ii) dermatomal sensory loss, (iii) hyporeflexia of the lower limb reflexes) and the prognosis for patients with nerve root compromise has previously been shown to be worse than for patients without (Grotle et al., 2005). The physiotherapists involved in the trial all had postgraduate qualifications in spinal manipulative therapy. How the predictive ability of these physiotherapists would compare to other clinicians who manage patients with low back pain is not known.

Previous articles have suggested methodological standards for the development of clinical prediction rules (Wasson et al., 1985; Laupacis et al., 1997). Our study met most of the criteria for a derivation study suggested by Laupacis et al. (1997), demonstrating its methodological quality. In our study the assessment of outcome was not blinded to the predictor variables as this was not the primary focus of the randomised controlled trial. It is unlikely that this led to any bias in the study as patients self rated days to recovery in a daily pain diary. We did not test the reproducibility of the predictive variables, however, the majority of predictors were either widely used and tested measures with demonstrated reliability, such as the numerical pain rating score, or patient ratings such as the duration of the current episode of pain. These variables would be expected to have reasonable reliability.

As the current study is a derivation study, it is not appropriate to recommend use of the developed rule in clinical practice until further validation is performed (McGinn et al., 2000; Reilly and Evans, 2006). As several prediction rules have now been developed for the prognosis of acute low back pain we believe it is important for future research to focus on high quality, prospective, head to head comparison of these rules to determine which rules stand up best to external validation. As part of this process it would also be important to consider the practicality of the rules before making recommendations regarding which rules to use in clinical practice (Laupacis et al., 1997).

In conclusion we have developed a simple clinical prediction rule to help clinicians identify the prognosis, in terms of days to recovery, for patients with acute low back pain presenting to primary care. The rule performs better than clinician's judgement but needs external validation before being recommended for clinical use.

Acknowledgements

The authors acknowledge the assistance of the general medical practitioners and physiotherapists who participated in the trial. Chris Maher and Rob Herbert's research fellowships and Mark Hancock's Ph.D. scholarship are funded by Australia's National Health and Medical Research Council (NHMRC). An NHMRC project grant

funded the trial. We also acknowledge the assistance of Megan Spindler in helping collect much of the data for this trial.

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