Predicting outcome in acute low back pain using different models of patient profiling.

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Abstract

Study Design

Prospective observational study of prognostic indicators, utilising data from a randomised, controlled trial of physiotherapy care of acute low back pain (ALBP) with follow up at 6 weeks, 3 months and 6 months.

Objective

To evaluate which patient profile offers the most useful guide to long-term outcome in ALBP.

Summary of Background Data

The evidence used to inform prognostic decision-making is derived largely from studies where baseline data is used to predict future status. Clinicians often see patients on multiple occasions so may profile patients in a variety of ways. It is worth considering if better prognostic decisions can be made from alternative profiles.

Methods

Clinical, psychological and demographic data were collected from a sample of 54 ALBP patients. Three clinical profiles were developed from information collected at baseline, information collected at 6 weeks, and the change in status between these two time points. A series of regression models were used to determine the independent and relative contributions of these profiles to the prediction of chronic pain and disability.

Results

The baseline profile predicted long-term pain only. The 6-week profile predicted both long-term pain and disability. The change profile only predicted long-term disability ($p < 0.01$). When predicting long-term pain, after the baseline profile had been added to the model, the 6-week profile did not add significantly when forced in at the second step ($p>0.05$). A similar result was obtained when the order of entry was reversed. When predicting long-term disability, after the 6-week profile was entered at the first step, the change profile was not significant when forced in at the second step. However, when the change profile was entered at the first step and the 6-week clinical profile was forced in at the second step, a significant contribution of the 6-week profile was found.

Conclusions

The profile derived from information collected at 6 weeks provided the best guide to long-term pain and disability. The baseline profile and change in status offered less predictive value.

Key words: acute low back pain; clinical guidelines; prognosis; physiotherapy.

Key points

- International guidelines for ALBP use information about prognosis to shape care pathways for ALBP patients.

- This information is derived largely from studies that have assessed patients at a single (early) time point.
- The clinical situation provides a much richer source of information and potential for varying models of patient profiling.
- The 6-week profile provides the most useful information for predicting long-term outcome.
- On reassessment, the overall status of the patient is a better predictor of outcome than the rate of improvement.

Mini abstract

Guidelines recommend multiple assessments of ALBP patients. We were interested in what information provides the best indicator of chronic status. The 6-week profile was the most useful predictor of long-term status. The baseline profile and change in status offered less predictive value.

Introduction

Low back pain (LBP) is a problem of vast dimensions, it affects up to 80% of the adult population[1] and accounts for considerable healthcare and socioeconomic costs[2]. The scale of the problem has prompted a number of authorities to develop evidence-based guidelines for the management of acute LBP (ALBP)[3]. These documents provide primary care clinicians with guidance on diagnosis, prognosis and management of the problem based on high quality, clinical research from these three areas.

The information used to provide guidance on prognostic issues has largely been derived from prospective, longitudinal studies where a baseline assessment is made and future clinical status predicted from this single time point[for e.g.4,5]. The typical clinical experience of managing ALBP provides clinicians with much richer sources of information as patients are generally seen on more than one occasion. Indeed, the algorithms of care that accompany many guidelines promote the idea of serially evaluating the clinical status of patients to determine progression through the algorithm[for e.g.6].

Successive patient assessment enables clinicians to formulate impressions of the patient's status based on their initial presentation, subsequent presentations and change status between presentations. It is unclear from the literature which of these three patient profiles is the most useful prognostic model. In order to determine this we decided to conduct a secondary analysis of a randomised, controlled trial of physiotherapy care for ALBP[7].

Specifically, we were interested in determining if information gathered at baseline or information gathered at an interim follow-up appointment provided the most useful information for predicting long-term pain and disability. We were also interested in determining what information clinicians should attend to at interim appointments. Particularly, whether change in status from baseline or actual status at follow-up was the most useful indicator of long-term clinical outcome. It is hoped that this information will enable primary care clinicians to provide more accurate prognostic information to patients and better inform the decision making process as patients progress through the care pathway.

Materials and Methods

Study participants

This is a secondary analysis of a data set from a randomised, controlled trial of physiotherapy care for acute non-specific low back pain (ANSLBP)[7]. Subjects were 94 ANSLBP patients referred to the Physiotherapy Department of a suburban district hospital by either their General Practitioner or the Hospital Accident and Emergency Department. To be eligible for inclusion patients had to report non-specific low back pain for less than six-weeks, be aged between 20 and 55 years of age and provide written, informed consent. Those with recurrent pain needed to have been pain free for at least three months prior to the onset of the current episode.

Potential subjects were screened by a physiotherapist for evidence of specific low back pathology (malignancy, fracture, infection, inflammatory disease, etc) or the presence of nerve root pain. Additional exclusion criteria were pregnancy or less than three months post-partum, involvement in litigation related to their back problem, coexisting major medical disease, current involvement in active physical therapy for their problem, or having undergone previous spinal surgery. The study was approved by the Health Authority's Research Ethics Committee.

Procedure

At baseline, subjects completed a set of questions related to their demographic and clinical status. The demographic information collected included, age, gender and work status. The clinical characteristics recorded were duration of the problem and symptom distribution[8]. A screening instrument for psychosocial risk factors, the acute low back pain screening questionnaire (ALBPSQ)[9], was also administered at baseline.

In addition, patients completed a set of standardised questionnaires that assessed pain, disability, quality of life and psychological functioning. LBP related disability was measured using the Roland and Morris Disability Questionnaire (RMDQ)[10]. Pain intensity was calculated by asking subjects to rate their usual pain intensity during the last week on a 0-10 numerical rating scale[11]. State anxiety was estimated using six items from the Spielberger State-trait Anxiety Inventory (STAIS)[12]. The presence of depressive symptoms was

determined using the Modified Zung Self Rated Depression Score (Zung)[13], and distress was estimated using the Modified Somatic Perception Questionnaire (MSPQ)[14]. Quality of life was measured using the EuroQol health transition score (EQ5D)[15], Physical well-being was calculated from the Short Form-36 physical component score (PCS)[16] and mental well-being from the Short Form-36 mental component score (MCS)[16]. All patients completed these questionnaires at baseline and were resent the assessments at six-weeks, three-months and six-months.

Predictor variables

All variables measured at baseline (shown in table 1.) were used as predictor variables. The six-week scores for Pain, RMDQ, STAIS, Zung, MSPQ, EQ5D, PCS and MCS were also used as predictor variables. Change scores were calculated by subtracting the six-week scores from the baseline scores for those variables that were measured at these two time points, giving each patient a value that represented the relative amount of change, these change scores were also included as predictor variables. Predictor variables measured at baseline formed the *acute clinical profile*, those measured at six-weeks formed the *sub-acute clinical profile* and the change scores were used to determine the *change clinical profile*.

Outcome

The outcomes of interest were long-term back pain related disability and long-term pain intensity. These were derived from the mean scores of the three and

six month assessments of the RMDQ and the usual pain intensity numerical rating scale respectively.

Data analysis

Predictor variables that demonstrated significant bivariate correlations (Pearson's r) with long-term disability and long-term pain were identified and classified into their respective acute, sub-acute and change clinical profiles. The significance level was set at $p < 0.01$ to account for multiple comparisons.

A series of multiple regression models were fit to determine the independent contribution of the acute, sub-acute and change profiles to the prediction of long-term disability and long-term pain. The relative contribution of the clinical profiles to the two outcomes was determined by a series of hierarchical regressions models were the order of entry of the profiles was rotated. All analyses were undertaken using SPSS for windows version 15.

Results

Full data was available for 54 patients. The baseline demographic and clinical characteristics of responders and non-responders are presented in table 1. There were no significant differences in baseline values between those patients who provided complete data at all time points and those who did not ($p>0.05$).

Correlation summary

The variables that had significant Pearson's correlations (p<0.01) with either long-term pain or long-term disability are presented in table 2, classified into their respective clinical profiles.

Regression models

The regression models showing the relationships between the clinical profiles and long-term pain and disability are shown in table 3. This demonstrates that the sub acute (R^2 = 0.607) and change (R^2 = 0.131) profiles were associated with long-term disability and the acute (R^2 = 0.159) and sub-acute profiles (R^2 = 0.257) were associated with long-term pain.

The results of the hierarchical regression model with long-term pain as the dependent variable showed that when the acute clinical profile was entered at the first step, the sub-acute profile was not significant when forced into the model at the second step (p>0.05). A similar result was obtained when the order was reversed.

The result of the hierarchical regression model with long-term disability as the dependent variable showed that when the sub-acute profile was entered at the first step, the change profile was not significant when forced into the model at the second step. However, when the change profile was entered at the first step and the sub-acute profile was forced in at the second step, a significant contribution of the sub-acute profile was demonstrated (R^2 change = 0.486; F change = 15.203; df = 4, 48; p<0.001).

These results indicate that the sub-acute profile provides the most valuable information for predicting long-term disability. Some useful information on long-term pain may be obtained from the acute and sub-acute profiles, however it appears the sub acute profile has stronger predictive value

Discussion

Summary of main findings

Clinicians have been encouraged to consider the acute patient profile in treatment planning and prognostic decision-making. Despite a comprehensive baseline profile of patients with ALBP, we found very little of interest in predicted chronic status. No baseline variable was predictive of long-term disability and only the ALBPSQ score was predictive of long-term pain. Notably, no uni-dimensional estimate of patients' acute psychological function appeared to impact on long-term outcome.

We were interested in whether other information may be useful to clinicians and found that the sub-acute clinical profile and the short-term rate of change provided some information on who may develop chronic symptoms. The sub-acute profile appears to be more meaningful. Measures of sub-acute pain intensity, disability (RMDQ), physical well being (PCS), mood (Zung) and general health (EQ5D) were predictive of long-term disability and together explained over 60% of the variance. Only pain intensity, disability (RMDQ) physical well being (PCS), and general health (EQ5D) were useful predictors of chronic pain, and the combined explanatory power was significantly less (26%).

The change in disability (RMDQ) was significantly associated with chronic disability and explained about 13% of the variance. No change variable was significantly related to long-term pain. Change in clinical status is only marginally useful in predicting chronic disability, and of no value in predicting chronic pain. This finding was contrary to our expectations. We had anticipated that patients who demonstrated large changes in their clinical profile would have favourable outcomes. These data suggest that on reassessment the overall status of the patient is a better predictor of outcome than the rate of improvement.

We conducted a series of multivariate analyses to try to discern the *relative* importance of the different clinical profiles. These analyses demonstrated that the sub-acute profile contains the most unique information for predicting long-term disability, providing considerable information above that which is derived from change status. When predicting long-term pain, the acute and sub-acute profiles provide equally important information.

These results highlight the complex relationship between pain and disability. The clinical features that predict chronic pain and disability vary and the explanatory power is very different. When seeking information on prognosis it is important that clinicians are clear on what outcomes are of interest to them and their patients and at what stage the patient is when making this decision.

Strengths and limitations

There are several strengths to this research. We used a comprehensive set of assessments which sampled pain, disability, psychological function and health related quality of life, measured on the same cohort of patients, longitudinally. Furthermore, data were collected in the clinical environment, which reflects the reality of day-to-day clinical practice.

The main limitations include the small number of subjects and the proportion of patients who did not provide full follow-up data and were therefore excluded from the analyses. However, patients who were excluded for these reasons did not have significantly different initial presentations from those who provided complete data at all time points (table 1.). While this analysis indicates that the data may be missing at random, care must always be taken when interpreting results with this level of loss to follow up.

Additionally, this study was performed within the framework of a randomised controlled trial potentially lowering the external validity for answering prognostic questions. All outcomes used were self-reported measures and may be biased by some shared method variance[17]. Finally, as with all prognostic research, our models may be limited by not having measured adequate prognostic factors. Our findings should be interpreted with some caution and our prognostic models now require testing in large-scale prospective clinical studies.

Comparison with existing literature

Our results support earlier work that suggests the ALBPSQ has some value in predicting chronic status in ALBP patients[9,18,19,20]. It appears that information about long-term pain levels can be obtained from multidimensional evaluation of psychosocial status at baseline. Other researchers have noted that some uni-dimensional measures of psychosocial status are also predictive of outcome. job dissatisfaction[21], previous sick leave for LBP[5], somatic distress [22,23], depression [24,25,26 27,28,29], fear of movement[17] and passive coping [23,30] have all been shown to predict long-term status when measured at baseline. We assessed patient's anxiety, somatic distress, depression and mental well-being at baseline and found little of importance in determining long-term pain or disability with these measures.

Some of this discrepancy may lie in the timing of clinical evaluation. The present study only sourced patients whose current episode was less than six weeks, and the average time since onset of the baseline assessment was less than three weeks. Studies that have found depression a useful predictor have used a less strict inception cohort[24,25,26,29] or collected data sometime after the initial consultation[27]. In support of this view, we found that depression measured at six weeks was significantly correlated with chronic disability. It may be that high levels of depressive symptoms in the very acute phase are less important, maintenance of depression into the sub-acute phase or development at the sub-acute phase might be the primary problem.

A common finding in prognostic studies on ALBP is the relationship between high pain intensity at baseline and future status[31]. Our analyses found no

relationship between baseline pain and either chronic pain or chronic disability. We noted a similar trend to that seen for depressive symptoms. Pain levels measured acutely were not related to chronic outcome, though sub-acute measures of pain were correlated with long-term pain and disability. The explanation may lie in mixed populations[23,22] and different inception cohorts[24,30,32] used by other investigators. In support of this, the systematic review by Pengel et al.[33] reviewed only papers with an inception cohort of less than three weeks and did not find pain intensity a useful predictor of outcome.

Other groups have also noted improvement in prognostic accuracy with repeated assessment. Enthoven et al.[34] performed a series of physical tests on a group of patients with LBP of varying duration at initial presentation and again four weeks later. They found none of the physical measures at baseline to be associated with long-term disability, yet three of the four measures taken at week four were related to disability at 12 months. Klenerman et al.[35] assessed patients at one week and two months. The two month data explained considerably more of the variance in 12 month outcome than data collected at week one. Likewise Carey et al.[36] found week four assessment of functional status a far stronger predictor of chronic outcome than baseline assessment. Heneweer and colleagues[37] dichotomised patients into recovered and not recovered at 12 weeks. They noted no difference in pain and disability between these two groups at the two-week assessment. However, they were clearly delineable at the four and eight week assessments.

Dunn and Croft[38] undertook a detailed analysis of this phenomenon on a group of predominantly chronic LBP (CLBP) patients. Their results clearly demonstrate that repeat assessment of patients enables a more accurate prediction of prognosis. The analyses used included classifying patients based on the stability of clinical characteristics between the two time points. They showed that people who have persistence of prognostic indicators had the greatest risk of poor outcome. Finally, Sieben et al.[39] saw a slightly different pattern in a group of ALBP patients who were monitored daily for two weeks. This study found rising levels of pain-related fear, rather than stable levels, were a stronger predictor of outcome. We found the change in status to be less informative than actual sub-acute status and the hierarchical regression analysis demonstrated that the change profile did not significantly improve the explanatory power of the sub-acute profile. Further work is needed to ascertain the most meaningful information that can be extracted from serial evaluation and whether this differs between acute and chronic patients.

Conclusion

The usefulness of clinical information in making decisions about prognosis in ALBP patients is influenced by the time at which it is collected and the outcome of interest. A number of features of the sub-acute clinical profile are significantly associated with chronic disability and together explain a large amount of the variance in chronic status. We found no feature of the acute profile predictive of long-term disability and only one feature of the change profile. It seems that chronic pain status is more difficult to predict. We found slightly fewer useful predictors of pain and were only able to explain a small

amount of the variance. A number of features of the sub-acute profile and one feature of the acute profile were related to long-term pain, whereas no change variables were predictive. When serially assessing ALBP patients, clinicians will obtain more accurate information about long-term outcome from follow-up assessments. Furthermore, the actual status at follow-up appears to be a much more useful guide to long-term outcome than the amount of change in status from baseline.

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Table 1: Comparison of baseline status between those included and excluded from analysis

Variables	*Included (n=54)*		*Excluded (n=40)*		**p-value**
	N or mean	% or (SD)	N or mean	% or (SD)	
Age	35	(9)	34	(8)	0.616
Male	26	48	21	53	0.677
BMI	25	(4)	26	(4)	0.565
Symptom distribution					
No symptoms	0	0	1	3	0.724
LBP without radiation	30	56	22	55	
Proximal radiation	12	22	7	18	
Distal radiation	12	22	10	25	
Uses analgesics	31	57	21	53	0.636
Duration (weeks)	2.9	(1.4)	3.0	(1.5)	0.766
Work status					
Off work	22	41	16	40	0.480
Employed	28	52	18	45	
N/A	4	7	6	15	
ALBPSQ	89	(27)	95	31	0.307
PCS	36	(7)	38	(7)	0.305
MCS	48	(8)	46	(9)	0.213
EQ5D	0.60	(0.25)	0.57	(0.28)	0.590
Pain	5.2	(2.3)	5.8	(2.2)	0.195
RMDQ	11	(6)	12	(6)	0.565
Zung	21	(10)	23	(12)	0.286
MSPQ	7.3	(5.3)	7.5	(5.0)	0.843
STAIS	13	(4)	13	(4)	0.973

BMI indicates body mass index; ALBPSQ, acute low back pain screening questionnaire; PCS, SF36 physical component score; MCS, SF36 metal component score; EQ5D, EuroQol health transition score; Pain, numerical rating scale for usual pain intensity; RMDQ, Roland and Morris disability questionnaire; Zung, Modified Zung self reported depression scale; MSPQ, Modified somatic perceptions questionnaire; STAIS, Spielberger state-trait anxiety inventory score

Table 2. Correlation coefficients for significant (p <0.01) predictor variables classified into their respective clinical profiles.

	r long-term disability	*r long term pain*
acute profile		
ALBPSQ	N/A	0.40
subacute profile		
Pain	0.50	0.40
RMDQ	0.73	0.48
PCS	-0.46	-0.36
EQ5D	-0.70	-0.42
Zung	0.45	
change profile		
RMDQ	0.36	N/A

Table 3: Results of the multiple regression models of the three clinical profiles on the dependent variables of long-term pain and disability

clinical profiles	*dependent variable*	*R*	R^2	*Ad* R^2	*F*	*df*	*Sig F change*
acute	*Long-term RMDQ*	N/A					
	Long-term Pain	0.398	0.159	0.143	9.809	1, 52	0.003
subacute	*Long-term RMDQ*	0.779	0.607	0.566	14.809	5, 48	<0.001
	Long-term Pain	0.507	0.257	0.196	4.237	4, 49	0.005
change	*Long-term RMDQ*	0.362	0.131	0.114	7.843	1, 52	0.007
	Long-term Pain	N/A					