



## Original Article

## Development of a clinical prediction rule to identify initial responders to mobilisation with movement and exercise for lateral epicondylalgia

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## ABSTRACT

The aim of this post hoc analysis was to develop a preliminary clinical prediction rule (CPR) for identifying patients with lateral epicondylalgia (LE) likely to respond to mobilisation with movement and exercise (PT). Currently practitioners do not have an evidence-based means to identify such patients a priori. Potential predictive factors were recorded at baseline and reference measures at 3 weeks after treatment was initiated. Participants ( $n = 64$ ) received standardised PT. After 3 weeks, participants were categorised as having experienced 'improvement' or 'no improvement' with treatment. Factors with univariate relationship ( $p < 0.15$ ) to 'improvement' were entered into a step-wise logistic regression model. Receiver operator characteristic curves were used to calculate cut-off points for continuous variables. Analyses resulted in a CPR that included: age ( $< 49$  years,  $+LR = 2.6$ ) as well as pain free grip strength on the affected ( $> 112$  N,  $+LR = 2.3$ ) and unaffected side ( $< 336$  N,  $+LR = 2.1$ ). Probability of improvement rose from 79 to 100% if all three were positive. The CPR did not predict outcome for wait and see ( $n = 57$ ), indicating it was more accurate for PT. This post hoc analysis has created a Level IV CPR that with further validation will help practitioners identify responders. Future studies are required to validate the rule.

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## 1. Introduction

Lateral epicondylalgia (LE), commonly known as 'tennis elbow', is clinically defined as pain over the lateral epicondyle of the humerus that is aggravated by gripping activities and wrist extension (Stratford et al., 1987; Haker, 1993; Pienimaki et al., 2002). Prevalence ranges from 1.3% among the general population to 15% among individuals in employment requiring repetitive gripping (Chiang et al., 1993; Ranney et al., 1995; Shiri et al., 2006). Many conservative treatments are used to manage LE (Smidt et al., 2003; Bisset et al., 2005), but there is limited evidence supporting their efficacy. A recent randomised clinical trial (RCT) highlighted the benefits of a physiotherapy program including joint mobilisation and exercise compared to either corticosteroid injection or wait and see approach (Bisset et al., 2006a; Vicenzino, 2003; Vicenzino and Bisset, 2007). The mobilisation technique used was the mobilisation with movement (MWM) of the elbow as described previously

(Mulligan, 1999). Despite the fact that physiotherapy exhibited positive outcomes, not all patients with LE responded to this intervention. At present, practitioners do not have the means to differentiate between patients who will respond to this intervention from those who will not.

Clinical prediction rules (CPR) are tools that can be used to assist health care practitioners in overcoming the dilemma of identifying responders to a treatment prior to initiation (Laupacis et al., 1997; McGinn et al., 2000). The purpose of a CPR is to improve the practitioner's ability to accurately predict an outcome to intervention. Clinical prediction rules have been successfully created to identify patients with back pain who are likely to benefit from spinal manipulation (Childs et al., 2004) and lumbar stabilisation programs (Hicks et al., 2005). A CPR with the ability to identify patients with LE likely to respond favourably to physiotherapy would aid clinical decision-making. The first step in creating a CPR is to develop the rule through the identification of possible predictor factors (Childs and Cleland, 2006). The purpose of this post hoc analysis of the data from Bisset et al. (2006a) was to develop a preliminary CPR for identifying patients with LE likely to respond to physiotherapy MWM and exercise intervention early in the rehabilitation program.

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## 2. Methods

Data for this analysis was collected as part of a previous RCT that investigated the effectiveness of physiotherapy, wait and see and corticosteroid approaches to treating LE of greater than 6 weeks duration (Bisset et al., 2006a). The group receiving physiotherapy was used to develop the CPR and the group who followed a wait and see policy were used in a preliminary validation analysis. The groups were similar at baseline (Bisset et al., 2006a)

### 2.1. Participants

Volunteers from the greater Brisbane region of Australia were recruited through advertisements and media releases between March 2002 and April 2004. Volunteers were eligible for inclusion if they were aged between 18 and 65 years, had pain over the lateral elbow of at least 6 weeks duration that was provoked by palpation of the lateral epicondyle, gripping and resisted extension of the wrist, second or third finger (Haker, 1993). Volunteers were excluded from participation if they had been treated by a health care practitioner for their lateral elbow pain in the preceding 6 months; they had bilateral elbow symptoms, cervical radiculopathy, concomitant shoulder, elbow or hand pathology, peripheral nerve involvement, previous surgery of the elbow, a history of elbow dislocation, fracture or tendon rupture, systemic neurological disorders or contraindications to steroids. Self-prescribed analgesia, braces and stretches were not excluding factors. The study received approval from the institutional ethics committee and all 64 participants provided informed consent.

### 2.2. Treatment protocol

Participants in the physiotherapy group received five 30-min treatments over 3 weeks by one of six physiotherapists with postgraduate qualifications in musculoskeletal physiotherapy. All participating therapists received specific training to assure standardisation of treatments. Treatment consisted of MWM, specifically either lateral glide of the elbow or posteroanterior glide of the radiohumeral joint (Mulligan, 1999), and prescription of an exercise program. Participants were taught home exercises and self-MWM, as previously described (Vicenzino, 2003; Vicenzino and Bisset, 2007), and given exercise equipment and an instruction booklet on how to correctly perform exercises at home. The participants following the wait and see policy were given no treatment and as for all participants in the RCT they were discouraged from seeking further treatment and were given information about the disease process, self-management and ergonomic advice.

### 2.3. Outcome measures

An assessor blinded to treatment assignment, recorded outcome measures at baseline and 3 weeks after treatment. Global perceived effect (GPE) was measured on a six-point scale from 0 ('completely recovered') to 5 ('much worse') (Smidt et al., 2002). Pain was measured via continuous visual analogue scale (VAS) from 0 mm ('no pain') to 100 mm ('worst pain imaginable') (Carlsson, 1983).

### 2.4. Potential predictor variables

A search of the literature revealed factors that should be considered in this study as potential predictor variables. Severity of pain, duration of symptoms and manual employment have been identified as prognostic of poor outcome in LE (Haahr and Andersen, 2003b; Smidt et al., 2006) and were included a priori in this analysis. Gender and involvement of the dominant arm were also included a priori because some studies show a bias of these factors

among people with LE (Pienimaki et al., 2002; Haahr and Andersen, 2003a; Shiri et al., 2007).

The assessor who was blinded to treatment assignment performed a clinical examination of each participant at baseline. Duration was recorded in weeks, with those of duration greater than 3 years truncated to 156 weeks. Employment was categorised into three sub-groupings: 'manual work,' 'non-manual work', and 'unemployed'. Pain was measured with a VAS and pain free grip strength (PFGS), the latter being a key defining feature of LE and its response to treatment (Thurtle et al., 1984; Stratford et al., 1987; Haker, 1993; Pienimaki et al., 1997; Pienimaki et al., 2002; Bisset et al., 2006b). PFGS was measured using a digital grip dynamometer (MIE, Medical Research Limited, UK; Newtons).

The initial effect of MWM on PFGS was also included as a potential predictor variable. Although it has not been previously examined as a possible predictor of treatment outcome, the initial effect of MWM on PFGS is used as a guide clinically (Mulligan, 1999; Vicenzino, 2003). Percentage change in PFGS on the initial application of MWM was calculated from the treating physiotherapist's records. PFGS was measured before and during the MWM application as described in the literature (Vicenzino, 2003). These records were then used to calculate the percentage change in PFGS during MWM expressed as a percent of pre-treatment PFGS.

### 2.5. Data analysis

Data analysis was performed using the SPSS Version 14.0 statistical software package (SPSS Inc, Chicago, IL, USA). Patients with GPE less than 3 ('improved', 'much improved' or 'completely recovered') were labelled as 'improved' and the remainder as 'no improvement'; ensuring an adequate number of improved cases. Treatment induced changes in pain VAS were calculated for the 'improved' and 'no improvement' groups and differences between groups were analysed using an independent *t*-test. Percentage change in PFGS during application of the initial MWM was expressed by a series of dichotomous variables that grouped results at cut-offs of greater than 25, 50, 75 or 100%, respectively (i.e., we tested four possible cut-offs). Potential predictor variables were tested for univariate relationship to 'improvement' using independent samples *t*-tests for continuous variables and  $\chi^2$  tests for categorical variables. Variables with a significance level of  $p < 0.15$  were retained as potential prediction variables (Freedman, 1983). Often studies that set out to develop a CPR set a liberal significance level at this stage to avoid excluding any potential predictor variables (Flynn et al., 2002). For continuous variables with a significant univariate relationship, sensitivity and specificity values were calculated for all possible cut-off points, and then plotted as a receiver operator characteristic (ROC) curve (Deyo and Centor, 1986). The point on the curve nearest the upper left-hand corner represented the value with the best diagnostic accuracy, and this point was selected as the cut-off defining a positive test (Deyo and Centor, 1986). Sensitivity, specificity and positive and negative likelihood ratios (+LR, -LR) were calculated for potential predictor variables. Retained potential predictor variables were entered into a step-wise logistic regression model to determine the most accurate set of variables for prediction of treatment improvement. A significance level of 0.05 was necessary to enter the variable into the model and 0.10 was required for removal from the equation to minimise the likelihood of excluding potentially helpful variables (Freedman, 1983). Variables retained in the regression model were included in the CPR for classifying patients with LE likely to benefit from 3 weeks of MWM and exercise.

To further ascertain the validity of the developed CPR, and investigate if indeed it predicted response to MWM and exercise rather than the natural history of the disorder, we also calculated diagnostic accuracy statistics and post-test probability of the

**Table 1**  
Potential predictor variables and their univariate relationship to 'improvement'.

Variable	All participants	Improved	Not improved	<i>p</i> value
Number <sup>a</sup>	62 (100)	49 (79)	13 (21)	–
Sex: women <sup>a</sup>	21 (33.9)	18 (36.7)	3 (23)	0.52 <sup>d</sup>
Dominant side affected <sup>a</sup>	38 (61)	30 (61)	8 (62)	0.62 <sup>d</sup>
Manual labour <sup>a</sup>	20 (43)	17 (34.6)	3 (23)	0.51 <sup>d</sup>
Age (years) <sup>b</sup>	48.2 (7.4)	47.2 (7.6)	50.8 (5.8)	<b>0.11</b> <sup>c</sup>
Duration of symptoms (weeks) <sup>b</sup>	26.3 (28.0)	24.8 (24.6)	29.4 (40.1)	0.61 <sup>c</sup>
Baseline pain on 100-mm VAS <sup>b</sup>	58.3 (24.8)	56.4 (25.1)	65.2 (25.1)	0.27 <sup>c</sup>
Affected pain free grip at baseline (N) <sup>b</sup>	127 (67.1)	133.8 (72.2)	98.8 (39.0)	<b>0.10</b> <sup>c</sup>
Unaffected pain free grip at baseline (N) <sup>b</sup>	320.3 (107.6)	308.7 (106.3)	358 (106)	<b>0.14</b> <sup>c</sup>
<i>First treatment session: changes with MWM</i>				
MWMPFG > 25% <sup>a,e</sup>	32 (52)	27 (55)	5 (38)	<b>0.13</b> <sup>d</sup>
MWMPFG > 50% <sup>a,e</sup>	24 (39)	19 (39)	5 (38)	0.58 <sup>d</sup>
MWMPFG > 75% <sup>a,e</sup>	17 (27)	14 (29)	3 (23)	0.45 <sup>d</sup>
MWMPFG > 100% <sup>a,e</sup>	7 (11)	4 (9)	3 (23)	0.16 <sup>d</sup>

*p* values <0.15 are shown in bold type.

<sup>a</sup> Categorical data expressed as number count (% of respective group).

<sup>b</sup> Continuous data expressed as mean (SD).

<sup>c</sup> Independent samples *t*-tests.

<sup>d</sup> Chi-square tests.

<sup>e</sup> Cells in these rows refer to counts (% of group) of participants who demonstrated >25, 50, 75 or 100% change from baseline in pain free grip during the Mulligan mobilisation with movement (e.g., in the first cell, 32 participants exhibited a >25% change in pain free grip strength from baseline during the application of the MWM at the first treatment session).

developed CPR in the group of patients who followed a wait and see approach ( $n = 57$ ) in the primary clinical trial (Bisset et al., 2006a).

### 3. Results

Sixty-four (42 male) participants who underwent physiotherapy completed the 3-week reassessment, however two participants did not have sufficient clinician-recorded treatment data and were excluded from analysis. Participant demographics and initial baseline variables from the clinical examination for the entire sample ( $n = 62$ ), 'improvement' group ( $n = 49$ ) and 'no improvement' group ( $n = 13$ ) can be found in Table 1. Analysis of pain scores revealed the 'improved' group experienced a significantly greater reduction in pain compared to the 'no improvement' group (15.3 points, 95% CI = 0.50, 30.1).

Four potential predictor variables exhibited a significance level of less than 0.15 (seen in Table 1) and were entered into logistic regression: age < 49 years, PFGS of the affected arm > 112 N, PFGS of the unaffected arm < 336 N and change in PFGS with the first MWM in situ > 25%. The univariate accuracy statistics can be seen in Table 2. Three variables were retained in the final regression

**Table 2**  
Accuracy statistics (95% confidence intervals) for potential predictor variables for 3-week response and percentage of patients who satisfied each criterion.

Variable	Sensitivity (95% CI)	Specificity (95% CI)	Positive likelihood ratio (95% CI)	Post-test probability of improvement (%) <sup>c</sup>	Percentage of patients that met criteria (%)
Age < 49 years	0.61 (0.46, 0.74)	0.77 (0.46, 0.94)	2.6 (0.96, 7.3)	91	53
Affected pain free grip > 112 N <sup>a</sup>	0.53 (0.38, 0.67)	0.77 (0.46, 0.93)	2.3 (0.82, 6.4)	90	47
Unaffected pain free grip < 336 N <sup>a</sup>	0.49 (0.35, 0.63)	0.77 (0.46, 0.94)	2.1 (0.76, 6.0)	89	44
MWMPFG > 25% <sup>b</sup>	0.75 (0.58, 0.87)	0.5 (0.20, 0.80)	1.5 (0.78, 2.9)	85	52

<sup>a</sup> N, Newtons.

<sup>b</sup> MWMPFG = percent change in pain free grip following the Mulligan mobilisation with movement.

<sup>c</sup> The probability of improvement is calculated using the positive likelihood ratios and assumes a pre-test probability of 79%.

model and used to form the CPR. In order of predictive value, they were: age < 49 years, affected arm PFGS > 112 N and PFGS for the unaffected arm < 336 N ( $p < 0.01$ , Nagelkerke's  $R^2 = 0.45$ ). The final CPR criterion and their accuracy statistics can be found in Table 3. Of the 57 patients who were at least positive for one of the criteria, 46 were improved. Of the 34 patients that were positive for at least two of the three criteria in the CPR 31 were improved. All four of the patients that exhibited three/three criteria experienced improvements.

The diagnostic accuracy analyses of the CPR in the group of patients following a wait and see policy ( $n = 57$ ) revealed that the lower bound estimate for the 95% confidence interval for all positive LRs was below 1 (0.23, 0.42, 0.29 for one/three, two/three and three/three variables present, respectively, Table 3).

### 4. Discussion

The main aim of this post hoc analysis was to develop a preliminary CPR by determining predictors of a positive response to a treatment program consisting of MWM and exercise for patients presenting with LE. Patients who were younger than 49 years and who had a high PFGS on the affected side (>112 N) and low PFGS on the unaffected side (<336 N) were most likely to respond to this intervention. This preliminary evidence indicates it may well be possible to predict which patients will respond positively to MWM and exercise early in rehabilitation. Importantly when each CPR criterion was met, the probability of improvement increased from 79% pre-test to 100% post-test. Future studies are necessary to determine if this increase is clinically meaningful. The ability to identify patients with 100% accuracy seems unlikely to remain in future studies.

It is interesting to speculate about the plausibility of the CPR criteria. Age was the most significant CPR criterion, which may reflect an age-related decline in the response to short-term resistance training (Hameed et al., 2003, 2004). Hameed and colleagues found an age-related insensitivity of skeletal muscle to mechanical loading, implied by an attenuated mechano-growth factor response to high-load resistance training. PFGS also contributed to the CPR, which is consistent with prior studies showing PFGS to be a valid indicator of functional impairment (Pienimäki et al., 2002) and to be sensitive to patient improvement (Stratford et al., 1987). Interestingly, though severity of pain and duration of symptoms are prognostic indicators in LE (Smidt et al., 2006), they did not contribute to the CPR. Future studies may further investigate them for positive predictive power.

In contrast to baseline PFGS, the change in PFGS affected by the initial application of MWM was not identified as a predictor in the current CPR. This study was the first, to the authors' knowledge, to have evaluated the effect of the first MWM application as a predictor of outcome following ongoing physiotherapy. Though undocumented for LE, it is a widely held clinical paradigm that a pain-relieving technique should improve pain free exercise

**Table 3**

(a) Criterion of the clinical prediction rule identified by the logistic regression analysis and their accuracy statistics for (b) the mobilisation with movement and exercise group and (c) the group who followed a wait and see policy.

<b>(a) Criterion of the clinical prediction rule identified in logistic regression analysis</b>						
Age < 49 years						
Affected pain free grip > 112 N <sup>a</sup>						
Unaffected pain free grip < 336 N <sup>a</sup>						
Positive criterion	Sensitivity <sup>b</sup>	Specificity <sup>b</sup>	Positive LR <sup>b</sup>	Probability of success (%) <sup>c</sup>	Number in improved group	Number in non-improved group
<b>(b) Mobilisation with movement and exercise</b>						
3	0.08 (0.03, 0.20)	1.0 (0.7, 1.0)	∞	100	4	0
2	0.57 (0.42, 0.71)	0.85 (0.54, 0.97)	3.7 (1.0, 13.6)	93	27	3
1	0.98 (0.88, 0.99)	0.46 (0.20, 0.74)	1.8, (1.1, 3.0)	87	15	8
<b>(c) Wait and see policy</b>						
3	0.18 (0.03, 0.52)	0.85 (0.71, 0.93)	1.2 (0.29, 5.0)	19	2	9
2	0.19 (0.09, 0.35)	0.94 (0.68, 0.99)	3.1 (0.42, 23.0)	37	6	24
1 <sup>d</sup>	0.17 (0.09, 0.30)	0.83 (0.20, 1.0)	1.0 (0.08, 13.6)	16	1	13

<sup>a</sup> N, Newtons.

<sup>b</sup> 95% CI.

<sup>c</sup> Probability of improvement is calculated using the positive likelihood ratios (LR) and assumes a pre-test probability of 79%;  $R^2 = 0.45$  for mobilisation with movement and exercise and a pre-test probability of 16% for the wait and see group.

<sup>d</sup> 0.5 was added to each cell in the table to allow for the calculation of LRs.

performance by 50% to be of therapeutic value. For example in patellofemoral syndrome where taping rather than MWM is used to alleviate pain with exercise, there is a CPR indicating that the tape must improve the condition by 50% for it to be of benefit (Leshner et al., 2006). In our study, a greater than 25% increase in PFGS on application of the MWM was significantly associated with improvement in the univariate analyses, but this association was not present in the multivariate analysis from which the preliminary CPR was developed. Thus in our preliminary study, response to initial MWM intervention appears not to predict the outcome of continued treatment.

This study has developed a Level IV CPR, which by definition should not be immediately taken as the ultimate CPR in guiding clinical practice (McGinn et al., 2000). That is, the study was not definitive, largely due to its explorative nature as a post hoc analysis of a study powered for other hypotheses. It is important to recognise that the rating of 'improvement' defined a priori to this study as per the dichotomisation of GPE, was different from the more stringent definition of 'success' adopted previously (Smidt et al., 2002; Bisset et al., 2006a). Specifically, 'completely recovered,' 'much improved' and 'improved' were classified as 'improvement' in this study, rather than only 'completely recovered' and 'much improved.' Clinicians should draw inferences from this study with this in mind.

It should also be recognised that only four patients (all of which were in the improved group) exhibited three/three criteria on the CPR. Hence, the 100% post-test probability in this study should not be expected to directly apply to other populations, as it is not likely that any variables will predict outcomes with 100% accuracy. Additionally, in such a study design it is possible that the predictors may simply predict improvement to any intervention or no intervention. However, when we investigated the diagnostic accuracy of the CPR in the group which followed a wait and see policy it appears that the predictors are specific to response to MWM and exercise. Prior to being confidently employed in clinical practice, the CPR would need to be validated by its reproduction in different groups of patients or in an alternate clinical setting and by an impact analysis utilising a prospective study design (Childs and Cleland, 2006).

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