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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.

1. Introduction

Lateral epicondylalgia (LE), commonly know 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 χ^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