Can we predict response to the McKenzie method in patients with acute low back pain? A secondary analysis of a randomized controlled trial

Charles Sheets · Luciana A. C. Machado ·
Mark Hancock · Chris Maher

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Abstract

Purpose To evaluate whether patients' treatment preferences, characteristics, or symptomatic response to assessment moderated the effect of the McKenzie method for acute low back pain (LBP).

Methods This study involved a secondary analysis of a previous RCT on the effect of adding the McKenzie method to the recommended first-line care for patients with acute non-specific LBP. 148 patients were randomized to the First-line Care Group (recommended first-line care alone) or the McKenzie Group (McKenzie method in addition to the first-line care) for a 3-week course of treatment. The primary outcome was pain intensity at 3 weeks. The ability of six patient characteristics to identify those who respond best to McKenzie method was assessed using interaction terms in linear regression models.

Results The six investigated potential effect modifiers for response to the McKenzie method did not predict a more favorable response to this treatment. None of the point

estimates for effect modification met our pre-specified criterion of clinical importance of a 1 point greater improvement in pain. For five of the six predictors, the 95% CI did not include our criterion for meaningful clinical improvement.

Conclusion We were unable to find any clinically useful effect modifiers for patients with acute LBP receiving the McKenzie method.

Keywords McKenzie · Classification · Low back pain · Treatment effect · Physiotherapy

Introduction

Mechanical diagnosis and therapy (MDT), commonly known as the McKenzie method, is a widely used approach for the assessment and management of low back pain (LBP) [1–3]. The method uses the patient's response to repeated movements to direct evaluation and treatment [4].

Previous systematic reviews investigating the McKenzie method have found small treatment effects of questionable clinical importance [5, 6]. Two RCTs have investigated the effects of the McKenzie method in patients with acute non-specific LBP who were seeking care from a primary care physician [7, 8]. Cherkin et al. [7] found that patients randomized to treatment with the McKenzie method had only minimally improved outcomes when compared to those receiving an educational booklet. Machado et al. [8] found small reductions in pain in patients randomized to receive the McKenzie method in addition to recommended first-line care compared to those receiving first-line care only.

It is widely believed that non-specific LBP is a heterogeneous condition and patients may respond differently to

C. Sheets (✉)
Duke University Health System, 3116 N. Duke St,
Durham, NC, USA
e-mail: charles.sheets@duke.edu

L. A. C. Machado
Departamento de Medicina Preventiva Social, Universidade
Federal de Minas Gerais, Av Alfredo Balena 190,
Belo Horizonte, MG 30.190-100, Brazil

M. Hancock
Faculty of Health Sciences, University of Sydney, PO Box 170,
Lidcombe, NSW 1825, Australia

C. Maher
The George Institute, University of Sydney, PO Box M201,
Missenden Rd, Sydney, NSW 2050, Australia

individual treatments [9]. When small main effects for interventions such as the McKenzie method are found, it is possible that a larger effect of treatment occurs in a specific subgroup of patients. Establishment of relevant subgroups of non-specific LBP may allow therapists to determine which treatments will likely provide the most benefit, or determine which patients will not benefit from care and may gain further benefit by changing treatment or referring to another practitioner [10].

RCTs are the only study design in which subgroups of responders to interventions can be effectively investigated [11]. Secondary analysis of RCTs can help identify potentially important subgroups that can then be tested in future prospective investigations. The Machado et al. [8] RCT provides an opportunity to investigate if it is possible to identify a subgroup of patients where the effect of the McKenzie method is larger. The aim of the present study is to evaluate whether the patients' treatment preferences, characteristics, or symptomatic response to assessment moderated the effect of the McKenzie method.

Methods

Design overview

This study is a secondary analysis of a previous RCT on the effect of adding the McKenzie method to the recommended first-line care for patients with acute nonspecific LBP [8, 12].

Setting and participants

Primary care physicians from medical practices in Sydney, Australia, screened for eligibility consecutive patients seeking care for LBP from September 2005 to December 2007. Patients eligible for inclusion were 18–80 years old, presenting with a new episode of acute non-specific LBP and willing to visit a physical therapist within 48 h of presentation to the physician. Acute low back pain was defined as a “current episode preceded by a period of at least 1 month without low back pain where the patient was not consulting a health care practitioner” as described by de Vet et al. [13]. Subjects were screened by their general practitioner for common “red flag” conditions (infection, inflammatory condition, fracture, tumor, cauda equina syndrome, or nerve root compromise) using a standardized checklist.

Randomization and interventions

A randomization sequence was created by computer and placed in sequentially numbered, sealed opaque envelopes to ensure concealment. Patients were randomized to the

First-line Care Group (recommended first-line care alone) or the McKenzie Group (McKenzie method in addition to the first-line care) for a 3-week course of treatment.

Those in the First-line Care Group received the provision of advice to remain active and to avoid bed rest, reassurance of the favorable prognosis of acute LBP and instructions to take paracetamol on a time-contingent basis. Those in the McKenzie Group were immediately referred to highly trained physical therapists to receive treatment based on the principles described in McKenzie's textbooks [4]. The maximum number of treatment sessions was limited to six sessions over 3 weeks. A copy of the *Treat Your Own Back* book [14] was provided to all participants and some also received a lumbar support. For more details on the treatments see the previously published trial protocol [12] and the trial report [8].

Outcomes

The original analysis of the RCT considered pain (at 1 and 3 weeks, and mean pain over the first week) and global perceived effect (at 3 weeks) as the primary outcomes. For this secondary analysis, pain at 3 weeks was chosen a priori as the primary treatment outcome. The characteristics of the participants and their outcomes were collected at baseline and at all subsequent follow-ups by a researcher who was blinded to treatment allocation (LM).

Baseline predictors

The lead author (CS), who had completed over 400 h of postgraduate training and had achieved the status of diplomate McKenzie therapist, in consultation with the co-authors and members of the McKenzie Institute International, selected six baseline variables considered to be plausible effect modifiers for the McKenzie method (Table 1). The selection was limited to six variables to reduce the possibility of a type I error. To further increase the validity of our findings a directional hypothesis was established for each variable in accordance with the recommendations of Sun et al. [15].

The first variable of baseline pain was chosen because higher pain levels are consistent with a worse prognosis in patients with acute LBP [16]; it was postulated that patients with higher pain levels would benefit more from treatment. The second and third variables, pertaining to pain that changes with posture or movement and the presence of leg pain, were chosen because clinical texts suggest that they are predictors of response to the McKenzie method [14]. Additionally, the presence of leg pain is often described as an indication for performance of direction-specific exercises associated with this treatment method [17]. The fourth variable of increased symptoms with flexion was

Table 1 Summary of pre-specified predictor variables

Predictor variables		
Baseline pain ^a	Mean (SD)	6.41 (1.87)
Pain changes with position or movement ^b	Yes	120 (81%)
	No	28 (19%)
Presence of leg pain ^c	Yes	70 (47%)
	No	78 (53%)
Constant pain ^d	Yes	89 (60%)
	No	59 (40%)
Pain is worse with flexion ^e	Yes	94 (64%)
	No	54 (36%)
Preferential expectation for the McKenzie method ^f	Mean (SD)	2.90 (2.72)

Continuous variables are presented as means and standard deviation (SD); dichotomous variables are presented as frequencies and percentages

^a Baseline pain: numerical pain rating scale: 0 (no pain) to 10 (worst pain possible), measured by general practitioner before randomization

^b Pain changes with movement or position: patient describes changes in symptoms based on movements or position

^c Presence of leg pain: symptoms extending below the buttock in one or both legs

^d Constant pain: patient reports unremitting symptoms

^e Pain is worse with flexion: positive response to both questions “Because of the pain in my back, I try not to bend or kneel down” and “I have trouble putting on my socks (or stockings) because of the pain in my back”

^f Preferential expectation for McKenzie method: 0–10 scale anchored at ‘not at all helpful’ and ‘extremely helpful’ for each treatment. Score was computed by subtracting the score of first-line care alone from the score of first-line care plus McKenzie method

created by inspecting the answers from the two questions on the Roland Morris Disability Questionnaire (RMDQ) judged most specific to aggravation with flexion: “Because of the pain in my back, I try not to bend or kneel down” (question 11) and “I have trouble putting on my socks (or stockings) because of the pain in my back” (question 16). A positive response required the patient to answer “yes” to both questions. This was included as a potential effect modifier based on clinical experience and previous findings that extension movements are most commonly found to decrease symptoms during treatment with the McKenzie method [18]; patients encountering more difficulty with flexion were expected to demonstrate increased response to treatment.

Preferential expectation for the McKenzie method was the fifth variable chosen as a baseline predictor of response to treatment. Before randomization, both treatments (first-line care alone and first-line care plus McKenzie method) were described to trial participants, and they were asked how helpful they believed each treatment would be for their current back problems. A 0–10 scale anchored at ‘not at all helpful’ and ‘extremely helpful’ was used to record patients’ ratings for each treatment. A preference score for McKenzie method was computed by subtracting the score of first-line care alone from the score of first-line care plus McKenzie method; thus, the higher the score, the greater the preference for McKenzie. A larger difference in expectation in favor of the McKenzie method was expected to predict a preferential response to treatment.

The procedure used to compute treatment preference scores was similar to that used in the study of Kalauokalani et al. [19].

The final variable of constant pain was taken from patients’ responses to question 13 of the RMDQ (“My back is painful almost all the time”); pain that is not constant, even for short periods during the day, has been described as being more likely to respond to the McKenzie method [4].

Analysis

Linear regression was carried out separately for each of the six predictor variables. The dependent variable was pain (0–10 pain scale) measured at 3 weeks. Each regression model included the predictor, the group allocation, and the interaction term predictor $\times$ allocation. This interaction term was the focus of the analyses, as it isolates the impact of the predictor on the effect of the experimental treatment versus the control. We considered interactions producing greater than 1 point difference in pain scores to be clinically important for categorical variables. For continuous variables we considered a 1 point difference for a 1 standard deviation (SD) change in the predictor variable to be clinically important. Confidence intervals were also inspected for potential clinically important effects. All analyses followed the intention to treat principle and were performed using SPSS for Windows version 17.0 (SPSS Inc., Chicago, IL, USA).

Results

From 260 patients screened by primary care physicians, 148 participants were randomized (74 to each treatment group). One patient randomized to each group was ruled ineligible to participate in the trial and both were excluded; i.e., one had pain from kidney stones and the other had pain in the thoracic spine only. A total of 69 and 70 participants completed the assessment at 3 weeks in the First-line Care Group and in the McKenzie Group, respectively (Fig. 1).

Participants in both groups were similar with regards to socio-demographic and clinical characteristics at baseline, including age, gender, physical activity level, days off work or school, general health status, and also those characteristics chosen as predictors for this secondary analysis [8]. Table 1 presents patients' status on the six pre-selected predictor variables. Participants had on average moderate levels of pain at baseline and the majority reported constant pain that changed in intensity with movement and was worse with spine flexion. Leg pain was present in approximately half of the sample. Participants showed, on average, greater expectations towards the McKenzie method when compared to first-line care (Table 1).

The results of the regression analyses are shown in Table 2. To aid interpretation the continuous predictors are expressed as the change in effect of intervention associated with a 1 SD increase of the baseline score of each putative effect modifier. The point estimate for interaction terms demonstrate no clinically meaningful treatment moderating

effects for the variables baseline pain (-0.11 ; 95% CI, -0.84 – 0.62), constant pain (0.04 ; 95% CI, -1.40 – 1.48), or preferential expectation for the McKenzie method (-0.003 ; 95% CI, -0.73 – 0.71). There were larger point estimates for the variables presence of leg pain (0.73 ; 95% CI, -0.70 – 2.16), pain that was worse with flexion (0.86 ; 95% CI, -0.62 – 2.34), pain changed with position or movement (1.30 ; 95% CI -0.51 – 3.11). But only pain changed with position met our criteria of 1 point for clinical importance and all these estimates are in the opposite direction to our hypotheses.

Inspection of the confidence intervals indicated that potentially meaningful effects cannot be ruled out for the variables constant pain, presence of leg pain, pain that was worse with flexion and pain changed with position or movement.

Discussion

Our study showed that six potential effect modifiers for response to the McKenzie method do not predict a more favorable response to this treatment. None of the point estimates for effect modification met our pre-specified criterion of clinical importance of a 1 point greater improvement in pain. For five of the six predictors, the 95% CI did not include our criterion for meaningful clinical improvement so we are confident that the study has not missed a true effect of these predictors. We did not obtain a precise estimate of the effect of constant pain so we cannot

Fig. 1 Flow of participants through the trial. Asterisk indicates that some patients presented more than one exclusion criteria [8]

Table 2 Results of linear regression models for pain at 3 weeks

	Beta coefficient	95% CI
Baseline pain		
Constant	0.55	−1.22–2.32
Allocation	−0.03	−2.62–2.57
Predictor	0.28	0.01–0.55
Predictor × allocation	−0.06	−0.45–0.33
1 SD difference in predictor × allocation	−0.11	−0.84–0.62
Pain changes with position or movement		
Constant	2.29	1.18–3.40
Allocation	−1.37	−3.00–0.26
Predictor	−0.01	−1.25–1.24
Predictor × allocation	1.30	−0.51–3.11
Presence of leg pain		
Constant	2.58	1.89–3.28
Allocation	−0.64	−1.61–0.34
Predictor	−0.65	−1.66–0.37
Predictor × allocation	0.73	−0.70–2.16
Constant pain		
Constant	1.68	0.86–2.50
Allocation	−0.29	−1.42–0.84
Predictor	0.95	−0.08–1.98
Predictor × allocation	0.04	−1.40–1.48
Pain is worse with flexion		
Constant	2.76	1.93–3.60
Allocation	−0.84	−2.02–0.34
Predictor	−0.76	−1.81–0.29
Predictor × allocation	0.86	−0.62–2.34
Preferential expectation for the McKenzie method		
Constant	2.11	1.34–2.88
Allocation	−0.27	−1.30–0.76
Predictor	0.06	−0.14–0.25
Predictor × allocation	−0.001	−0.27–0.26
1 SD difference in predictor × allocation	0.003	−0.73–0.71

Negative values represent decreased pain scores favoring the McKenzie Group. The interaction effect of the predictor variables on pain is indicated by the line predictor × allocation

exclude the possibility that this variable may modify the effect of McKenzie treatment.

The main strength of this study is the use of an RCT to evaluate treatment effect modification, whereas other authors have erroneously used single-arm trials to identify potential predictors of response to treatment [20, 21]. A recently published systematic review [22] identified 15 clinical prediction rules developed (CPRs) to assist the selection of treatments for various musculoskeletal conditions and all of them have used single-arm study designs to derive their predictors. To minimize the chance of spurious findings, we investigated a limited number of baseline predictors, all of which were believed to have a logical rationale, and we also specified the direction of the expected effect a priori [15].

This study was a post-hoc analysis of a previously conducted RCT. The main limitation of studies such as this

is that they are powered to identify the main effect of treatment rather than the interaction effect of potential predictors [23]. However, we were able to obtain precise estimates of effects for all but one of the six potential effect modifiers. Another limitation is that because only the participants randomized to the McKenzie Group underwent a complete assessment based on McKenzie principles, information from this assessment, such as the presence of centralization or peripheralization could not be used in our analyses.

A review of the effects of patient preferences concluded that while preferences may affect perceptions of the treatment and satisfaction with treatment, they appear to exert few major effects on clinical outcomes [24]. Two previous studies in the back pain field that have evaluated the effect of treatment preference found similar results to our own [25, 26]. A potential limitation of evaluating the

effect of treatment preferences in an RCT is that volunteers to an RCT probably do not have strong treatment preferences because they have to accept the possibility of being randomized to either treatment arm. Cohort studies avoid this limitation but at the expense of confounding.

The procedure used to assess the preferential expectation for the McKenzie method in the current study was similar to that used by Kalauokalani et al. [19]. However, Bialosky et al. [27] recently recommended assessing patients' expectations as a dichotomous variable. To investigate whether this would change our findings, we performed a subsequent analysis dichotomizing the variable (with preference for the McKenzie method defined as scores greater than 1), but our findings remained the same apart from producing wider confidence intervals.

Despite the limited evidence on patients' expectations as treatment effect modifiers, there is a considerable amount of research supporting their impact on outcomes. For example, recent evidence supports the role of higher expectancy levels in predicting more favorable outcomes irrespective of the treatment received in patients with acute [28] and chronic [29] LBP, as well as in patients with a wide range of medical conditions [30].

Baseline pain was included as a variable due to its impact on the rate of recovery from acute low back pain [16]. Our findings of no treatment effect, however, are similar to another secondary analysis of a recent RCT with an equivalent design, in which baseline pain was not found to moderate the effects of non-steroidal anti-inflammatory drugs (NSAIDs) in acute LBP patients with characteristics very similar to those included our analysis [31].

This study questions the predictive value of common predictors of treatment effect for MDT in acute pain, particularly baseline pain or patient expectation. The nature of informed consent and randomization involved in RCTs may influence the effect of treatment expectation, as potential subjects with strong treatment preferences are less likely to agree to participate in a randomized trial [32]. Even with this caveat, our results showed essentially no treatment effect for expectation.

The results of our study should not be generalized beyond the population of patients with acute nonspecific LBP. By 3 weeks, the majority of patients in both study groups reported pain levels of 0 or 1 points on a 0–10 pain scale. When the natural history of the condition is so favorable, treatment effects and therefore treatment effect modifiers are more difficult to identify. It is possible that the moderating effect on treatment of the studied variables may be different in a population with subacute or chronic symptoms, who would be expected to have more stable symptoms. Additionally, the effect of changes in patient status (i.e. pain intensity, location of symptoms) could not be determined through the design of our study. Future

research addressing the treatment effect of MDT should include patients with subacute or chronic symptoms, as well as specific demographic and patient–response variables defined prior to the study.

Conclusion

We undertook a secondary analysis of an RCT to determine if six potential treatment effect modifiers for the McKenzie method could be identified. None of the six were shown to modify the effect of treatment and for five of the six variables the estimates were sufficiently precise to confidently exclude any greater improvement associated with the variable.

Conflict of interest None.

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