Clinical rule predicts patients likely to benefit from spinal manipulation

Synopsis


Question Is it possible to identify the low back pain patients who will respond to spinal manipulation? Design Randomised controlled trial with pre-planned subgroup analysis. Setting Eight physical therapy clinics in USA. Patients Patients aged 18–60, with a primary complaint of low back pain and an Oswestry Disability score of at least 30%. Exclusions were serious spinal pathology, nerve root compromise, pregnancy, and previous surgery. 543 patients were screened; 131 were eligible and were randomised using sealed envelopes to a manipulation group (70 patients) or an exercise group (61 patients). Interventions Patients in both groups attended physiotherapy for 5 sessions over 3 weeks. The manipulation group received a high velocity thrust spinal manipulation during the first two sessions and then low stress aerobic and lumbar strengthening exercises. The exercise group received exercise alone. Two participants in the manipulation group and 9 in the exercise group discontinued treatment. An independent examiner assessed the patients and classified them as positive on the clinical prediction rule if they met 4 of the 5 following criteria: symptom duration < 16 days, no symptoms distal to knee, <19 on Fear Avoidance Beliefs Questionnaire, at least one hypomobile segment and at least one hip with > 35 degrees of internal rotation. Outcomes The primary outcome was disability measured using the 0–100% Oswestry disability index, measured at baseline, 1 week, 4 weeks, and 6 months. Treatment success was defined as 50% reduction in disability. All participants completed the baseline assessment and 1 week follow-up, 130/131 the 4 week follow-up, and 92/131 the 6 month follow-up. Analysis was by intention to treat with pre-planned subgroup analysis. Results 47/131 participants were positive to the rule. ANOVA revealed that the outcome depended upon the both the participant’s treatment group and status on the rule. Pairwise disability mean (95%CI) differences at one week were: manipulation vs exercise 9.2 (4.4 to 14.1), manipulation (+ve on rule) vs manipulation (-ve on rule) 15.0 (8.5 to 21.5), manipulation (+ve on rule) vs exercise (+ve on rule) 20.4 (13.0 to 28.8) and exercise (+ve on rule) vs exercise (-ve on rule) -1.9 (-8.6 to 4.9). (+ve values signify greater improvement with the first named group in a pair). At 1 week 44% of the manipulation group had a successful outcome, however the success rate was 92% in the manipulation subgroup positive to the rule and only 7% in the subgroup who met less than 3 of the criteria. Conclusion Patients were more likely to benefit from spinal manipulation if they met the clinical prediction rule.

Commentary 1

The evidence supporting the validity of schemes that guide treatment in non-specific low back pain is sparse and contradictory. Such schemes are useful only if they improve prognostic accuracy, or result in more effective treatment decisions.

The approach that Childs and co-workers (2004) have taken is novel to non-specific low back pain research. The clinical prediction rule is derived empirically, and pragmatically sidesteps the minefield of pathoanatomical labelling. The prediction rule was derived in a clinical population (patients within the armed services presenting with short-term non-specific low back pain and at least moderate activity limitation) to identify responders to a particular manipulation and range-of-motion exercise regimen. Importantly, it has been validated in this multi-centre study. Without the prediction rule clinicians could expect that about one in two patients will respond to this treatment regimen (pre-test probability 44%); by using the prediction rule clinicians can expect greater confidence in knowing which patients will and will not respond to this regimen. A patient who is positive on the prediction rule has a 91% probability (95%CI 73% to 98%) of a favourable response, while a patient who is negative on the prediction rule has only a 7% probability (95%CI 2% to 25%) of responding to this treatment regime. Approximately one in three patients were positive on the prediction rule. This is very useful information for referrers, treaters, and researchers.

However, there are reasons for caution and these may impact the capacity of this prediction rule to influence clinician behaviour. The prediction rule was derived and validated using a particular patient population, and requires replication in more diverse patient populations (non-military, low activity limitation, and other cultures) for it to have unreserved generalisability. It was also derived for a treatment regime consisting of a specific manipulative technique and range-of-motion exercise. Its generalisability to other manipulative techniques is unknown, although there is some evidence that technique choice may not make much difference (Chiradejnant et al 2003).

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Reference
Commentary 2

This high quality study provides information about three important issues.

First it tells us about prognosis for people aged 18–60 presenting to physiotherapy clinics with moderate or severe low back pain (Oswestry scores ≥ 30%). The data are reliable because they were obtained from a near-consecutive sample with a high rate of follow-up, and they are relevant because the patients were those presenting to physiotherapy clinics. In this heterogeneous group, including patients with acute and chronic pain, there were moderate to large reductions in disability over time. In subjects who received exercise and subjects with negative prediction rules who received manipulation the average reduction in disability was of the order of 20% at 1 week, and 40%–50% at 4 weeks and 6 months. Subjects with positive prediction rules who received manipulation experienced greater average reductions in disability: about a 70% reduction at 1 week and 80% at 4 weeks and 6 months. These reductions in disability are due to a range of factors, including the natural course of back pain and the effects of intervention.

This study also tells us about effects of manipulation compared to exercise. Again, the findings are credible because the trial used rigorous methods, including concealed random allocation, analysis by intention to treat, and excellent follow-up. When manipulation is applied to this heterogeneous group it produces, on average, a reduction of just less than 10 percentage points on the Oswestry disability scale.

Last, and most important, this study has shown that a simple decision rule can be used to identify subgroups of patients in whom manipulation is and is not effective. This study is one of very few to examine treatment effect modifiers nominated a priori in the context of a randomised trial, so it provides rare evidence of a treatment effect modifier. The study shows that the average effect of manipulation (compared to exercise) is about 20 points in patients who are positive to the prediction rule, but only about 4 points in patients who are negative to the prediction rule (calculated from data). (It would be interesting to know how much more likely a positive outcome is in people who test positive and are manipulated compared to people who test positive and receive exercise, but these data were not provided.) Until more refined prediction rules become available, physiotherapists should consider manipulation for patients with low back pain who are positive to the prediction rule, and they should consider not manipulating people who are negative to the prediction rule.

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