Academy of PHYSICAL MEDICINE

Research Paper Review

This review is published with the permission of Research Review Service (www.researchreviewservice.com)

Development of a clinical prediction rule to identify patients with neck pain likely to benefit from thrust joint manipulation to the cervical spine

Journal of Orthopaedic & Sports Physical Therapy 2012; 42(7): 577-592

Puentedura EJ, Cleland JA, Landers MR et al.

ABSTRACT

STUDY DESIGN: *Prospective cohort/predictive validity study.*

OBJECTIVE: *To determine the predictive validity of selected clinical examination items and to develop a clinical prediction rule to determine which patients with neck pain may benefit from cervical thrust joint manipulation (TJM) and exercise.*

BACKGROUND: *TJM to the cervical spine has been shown to be effective in patients presenting with a primary report of neck pain. It would be useful for clinicians to have a decision-making tool, such as a clinical prediction rule, that could accurately identify which subgroup of patients would respond positively to cervical TJM.*

METHODS: *Consecutive patients who presented to physical therapy with a primary complaint of neck pain completed a series of self-report measures, then received a detailed standardized history and physical examination. After the clinical examination, all patients received a standardized treatment regimen consisting of cervical TJM and range-of-motion exercise. Depending on response to treatment, patients were treated for 1 or 2 sessions over approximately 1 week. At the end of their participation in the study, patients were classified as having experienced a successful outcome based on a score of +5 ("quite a bit better") or higher on the global rating of change scale. Sensitivity, specificity, and positive and negative likelihood ratios were calculated for all potential predictor variables. Univariate techniques and stepwise logistic regression were used to determine the most parsimonious set of variables for prediction of treatment success. Variables retained in the regression model were used to develop a multivariate clinical prediction rule.*

RESULTS: *Eighty-two patients were included in data analysis, of whom 32 (39%) achieved a successful outcome. A clinical prediction rule with 4 attributes (symptom duration less than 38 days, positive expectation that manipulation will help, side-to-side difference in cervical rotation range of motion of 10° or greater, and pain with posteroanterior spring testing of the middle cervical spine) was identified. If 3 or more of the 4 attributes (positive likelihood ratio of 13.5) were present, the probability of experiencing a successful outcome improved from 39% to 90%.*

CONCLUSION: *The clinical prediction rule may improve decision making by providing the ability to a priori identify patients with neck pain who are likely to benefit from cervical TJM and range-of-motion exercise. However, this is only the first step in the process of developing and testing a clinical prediction rule, as future studies are necessary to validate the results and should include long-term follow-up and a comparison group.*

LEVEL OF EVIDENCE: *Prognosis, level 2b.*

ANALYSIS

Reviewed by Dr. Jeff Muir DC (Research Review Service)

Author's Affiliations
Department of Physical Therapy, School of Allied Health Sciences, University of Nevada, Las Vegas; Department of Physical Therapy, Franklin Pierce University, Concord, NH; School of Medicine, University of Colorado; Department of Physical Therapy, Occupational Therapy, Rehabilitation and Physical Medicine, Universidad Rey Juan Carlos, Alcorcón, Madrid, Spain.

Background Information
Neck pain is a common complaint in adults, with typical 1-year prevalence estimates of between 30% and 50%. Though chronic neck pain is less common, with 1-year prevalence estimates ranging from 2% to 11%, it often results in prolonged disability and substantial negative economic impact. Studies evaluating the cost-of-illness and cost-effectiveness of therapeutic interventions for neck pain have concluded that clinical research should focus on developing and investigating the most effective treatments for acute neck pain, with the goal of preventing patients from developing chronic pain and disability. To this end, clinical practice guidelines have recommended the use of spinal manipulative therapy (SMT) and mobilization in this patient population.

The potential risks associated with cervical spine SMT are well-known. Although mild, transient side-effects of this treatment are most common, the discussion on this issue had traditionally focused on cervical artery dissection. Pre-manipulative screening tools have primarily focused on identifying patients who may experience vertebrobasilar insufficiency or may have cervical arterial dysfunction. The use of these screening tools to rule out risk of arterial dissection associated with SMT is, however, very controversial. There is a distinct lack of evidence for the utility of pre-manipulative screening procedures, which has prompted some to suggest that identifying patients for whom there may be risks associated with cervical SMT is virtually impossible, and that perhaps the potential benefits may not outweigh the inherent risks.

A clinical prediction rule is classification system in which a collection of clinical and/or historical patient symptoms, signs, test results, or responses to treatment are used to identify sub-groups of patients more likely to respond favourably to a particular intervention (1). Such a tool to better identify those patients that would benefit from SMT in the cervical spine would be beneficial in regards to both patient outcomes and safety. Tseng et al. developed such a tool in 2006, although their study did not address long-term outcomes and had a relatively low threshold for success (2). The purpose of this study was to develop a clinical prediction rule using a more rigorous design (i.e. higher threshold for success, longer-term outcome) to identify patients with neck pain likely to benefit from SMT to their cervical spine, based on a reference standard of patient-reported improvement.

PERTINENT RESULTS

- 82 patients were enrolled in the study – 32 (39%) were categorized as having achieved a successful outcome and 50 (61%) as a non-successful outcome.

- 20 of the 32 'successful outcome' patients (62.5%) reported success after the initial treatment, and the remaining 12 after 2 sessions.

- Analysis of the numeric pain rating scale (NPRS) and neck disability index (NDI) change scores revealed that the success group experienced significantly greater improvements ($P < 0.001$) in pain (NPRS change score, 3.5; 95% CI: 3.0-4.1) compared to the non-success group (NPRS

change score, 1.1; 95% CI: 0.7-1.5) and significantly greater improvements (P < 0.001) in disability (NDI change score, 9.6; 95% CI: 8.2-11.0) over the non-success group (NDI change score, 5.4; 95% CI: 4.2-6.7).

- The +LR (positive likelihood ratio) ranged from 1.75 to 6.77, with the strongest predictor being side-to-side difference in cervical rotation ROM of 10° or greater.

- Of the 9 predictor attributes analyzed using regression analysis, the following 4 attributes were retained in the final model:
    1. symptom duration less than 38 days;
    2. a positive expectation that manipulation will help;
    3. side-to-side difference in cervical rotation ROM of 10° or greater; and
    4. pain with postero-anterior spring testing of the middle cervical spine.

- All 27 patients in the study who exhibited only 1 of the predictor attributes and all 8 patients who had none of the attributes failed to achieve success.

CLINICAL APPLICATION & CONCLUSIONS

Four clinically important criteria were established in this study:

1. *Duration of Symptoms:* shorter duration of symptoms (< 38 days) demonstrated a high +LR (6.0);

2. *Differences in Cervical Rotation ROM:* a side-to-side difference in cervical rotation ROM of 10° or greater was the predictor that demonstrated the highest +LR (6.8). Patients who exhibited decreased ROM in rotation to one side also demonstrated decreased ROM in lateral flexion to the same side. Side-to-side difference in cervical rotation ROM was found to be highly correlated with a side-to-side difference in cervical lateral flexion ROM ($r = 0.80$, $P < 0.001$). For the purposes of a clinical predictor, cervical rotation was chosen as the more common and more easily tested ROM evaluation method;

3. *Pain with PA Spring Testing of Mid-Cervical Spine:* palpation for spinal tenderness has been shown to be highly reliable. The presence of local symptoms (pain) in the cervical spinal segments to receive a cervical SMT technique was identified as a predictor of success of SMT;

4. *Positive Expectation of SMT:* a positive expectation of manipulation is classified as a treatment moderator because it is a baseline characteristic that may influence the outcome of treatment. A positive expectation for manipulation being predictive of success is consistent with the fact that expectation of benefit (from a placebo, for example) has been shown to have a robust effect on pain in numerous studies.

A patient with neck pain who exhibited at least 3 of 4 criteria and was treated with SMT to the cervical spine showed an increase from a pretest probability of success of 39% to a posttest probability of success of 90%. This represents a significant shift in probability and a potentially powerful tool to guide clinical decision making in the use of cervical SMT for treating patients with non-radiating neck pain.

Developing a CPR takes time and there are multiple steps in the process. The next stages in this line of research are to validate these findings in a similar patient population and clinical setting (called 'narrow validation'), then in multiple clinical settings (called 'broad validation') before conducting impact analyses, where it is determined whether the rule changes clinicians' behavior, improves patient outcomes, or reduces costs/healthcare expenditures. This is a long process, but clinicians need to be aware of the early research in order to integrate this thought process into practice, observe the results and establish the 'real-world' utility of this important work.

STUDY METHODS

Consecutive patients with a primary complaint of neck pain were screened for eligibility criteria at outpatient physical therapy clinics in 4 different locations (Las Vegas, NV; Aurora, CO; Overland Park, KS; and Madrid, Spain).

Inclusion criteria

Subjects had to be between 18 and 60 years of age, have a primary report of neck pain with or without unilateral upper extremity symptoms, and have a baseline Neck Disability Index (NDI) score of 10 points (out of 50) or greater.

Exclusion criteria

Subjects were excluded if they had any medical red flags suggesting that the etiology of symptoms might be non-musculoskeletal; diagnosis of cervical spinal stenosis (as identified in the patient's medical intake form); bilateral upper extremity symptoms; evidence of central nervous system involvement; history of whiplash injury within 6 weeks of the examination; pending legal action regarding the neck pain; two or more positive neurologic signs consistent with nerve root compression (changes in sensation, myotomal weakness, or decreased deep tendon reflexes); or any history of cervical spine surgery, rheumatoid arthritis, osteoporosis, osteopenia, or ankylosing spondylitis.

Therapists

Five physical therapists participated in the examination and treatment of patients in this study. All therapists participated in a standardized training program, which included studying a manual of standard procedures with operational definitions and video clips demonstrating each examination and treatment procedure. They also attended a 1-hour training session with the principal investigator, and were required to successfully demonstrate the examination and treatment techniques to ensure that all study procedures were performed in a standardized fashion. All 5 participating therapists were male, with a mean (range) of 43.6 (36-54) years of age and 17.9 (9-31) years of experience.

Treatment

SMT plus prescription of range of motion (ROM) exercise (10 repetitions performed 3-4 times daily). The patient was scheduled for a follow-up visit 2 to 4 days after the baseline exam.

Measurement of Effect

Global rate of change (GROC) – the GROC is a 15-point scale with the anchors at –7 (a very great deal worse), 0 (about the same), and +7 (a very great deal better). It was determined *a priori* that patients who rated their perceived recovery on the GROC as +7 (a very great deal better), +6 (a great deal better), or +5 or higher (quite a bit better) at the second session would be categorized as a success and their participation in the study would be complete. Subjects also completed the Neck Disability Index (NDI) and a Numeric Pain Rating Scale (NPRS).

This was a derivation study – the first step in developing clinical prediction rules (3). The goal was to determine factors predictive of successful outcome after cervical SMT. In order to accomplish this, the authors calculated sensitivity, specificity, and positive and negative likelihood ratios for all potential predictor variables. Then, univariate techniques and stepwise logistic regression were used to determine the most accurate set of variables for prediction of treatment success. The variables retained in this regression model were then used to develop a multivariate clinical prediction rule.

STUDY STRENGTHS/WEAKNESSES

CPR derivation studies are rarely perfect. In this case, the authors appropriately acknowledge several limitations with their study, including:

- Co-interventions such as medication and self-directed exercise are potentially con-founding variables. The authors sought to control for these confounding variables by directing patients in the study to continue with their present medication and activities, while not initiating the use of any new medication or activity while they were participating in the study.

- Data for this study were collected from 4 geographic locations and there was an unequal distribution of patients among the 4 sites. Data were collected from 42 patients (51%) in Madrid, Spain, 26 patients (32%) in Las Vegas, NV, 9 patients (11%) in Aurora, CO, and, finally, 5 patients (6%) in Overland Park, KS. Rates of success reported by patients at each location were as follows: Madrid, 38.1%; Las Vegas, 30.8%; Aurora, 66.7%; and Overland Park, 40.0%.

- A further limitation applicable to this study was that the cervical SMT technique used might not have been specific to the targeted vertebral segments. Current evidence suggests that both thrust and non-thrust manipulation techniques may not be joint specific; however, this was adequately addressed by not claiming that the cervical SMT technique used in this study was specific to any segment.

- Finally, as with other clinical prediction rule derivation studies, this was a single-arm design, and without a control group it is not possible to determine whether the clinical prediction rule identifies prognosis (regardless of treatment) or response to the specific treatment.

Additional References:

1. Hebert JJ & Fritz JM. Clinical decision rules, spinal pain classification and prediction of treatment outcome: A discussion of recent reports in the rehabilitation literature. BMC Chiro & Man Ther 2012; 20: 19.
2. Tseng YL, Wang WT, Chen WY et al. Predictors for the immediate responders to cervical manipulation in patients with neck pain. Man Ther 2006; 11: 306-315.
3. Stanton TR, Hancock MJ, Maher CG & Koes BW. Critical appraisal of clinical prediction rules that aim to optimize treatment selection for musculoskeletal conditions. Phys Ther 2010; 90: 843-854.