Clinical Prediction Rules: Time to Sacrifice the Holy Cow of Specificity?

For those of us practicing orthopaedic manual physical therapy (OMPT)—and, in fact, for all evidence-based manual medicine practitioners—it truly is an exciting time. Only a few years ago, systematic reviews and meta-analyses were indicating a lack of evidence to support the use of manipulation for patients with acute and chronic low back pain¹; similarly they noted no or, at best, inconclusive evidence for manipulative interventions if not combined with active exercise in patients with mechanical neck pain^{2–4}. Now in short succession research has provided us with a number of clinical prediction rules to guide our OMPT diagnosis and manipulative intervention in patients with mechanical back and neck pain^{5–9}.

Why are these clinical prediction rules so different from the earlier negative or inconclusive meta-analyses and systematic reviews? Clinical prediction rules are decision-making tools that contain predictor variables obtained from patient history, examination, and simple diagnostic tests; they can assist in making a diagnosis, establishing prognosis, or determining appropriate management¹⁰. As Childs and Flynn¹¹ pointed out, if studies included in a systematic review or meta-analysis use no patient classification other than the broad category of non-specific low back (or neck) pain, the resultant heterogenous study samples pretty much preclude finding real effects of any specific intervention. In contrast, the recent clinical prediction rules all aim to identify a more homogenous diagnostic subgroup of patients that is expected to respond to manipulative intervention. As such, these prediction rules are part of what seems to be a paradigm shift currently occurring within OMPT. The once predominant mechanism-based classification system that is based on the premise that impairments identified during examination are the cause of musculoskeletal pain and dysfunction¹² is increasingly being replaced by treatment-based classification systems^{13–15}. In the treatment-based system, a cluster of signs and symptoms from the patient history and physical examination is used to classify patients into subgroups with specific implications for management¹³.

What do these recent clinical prediction rules tell us? Flynn et al⁵ developed a clinical prediction rule consisting of five predictor criteria to identify a subgroup of patients with non-specific low back pain who were likely to benefit from thrust manipulation. This rule was subsequently validated by Childs et al⁶, who calculated an adjusted odds ratio of 114.7 at the 1-week follow-up and one of 60.8 for a positive functional outcome at the 4-week follow-up for patients who were positive on the rule (≥ 4 predictor criteria present) and received manipulation versus those patients who were negative on the rule and received exercise. Fritz et al⁷ derived a subsequent two-factor rule from this prediction rule and reported a positive likelihood ratio of 7.2 for a positive outcome in patients with low back pain positive on both predictor variables and treated with manipulation.

Tseng et al⁸ identified six predictor variables for an immediate positive response to cervical manipulation in patients with neck pain including patients diagnosed with cervical spondylosis with or without radiculopathy, cervical herniated disk, myofascial pain syndrome, and cervicogenic headache. An increasing number of predictor variables present led to progressively higher positive likelihood ratios of an immediate positive response to manipulation: 4 predictor variables present yielded a likelihood ratio of 5.33 and an 89% probability of a successful manipulation⁸. Cleland et al⁹ derived six predictor variables in patients with mechanical neck pain without neurological involvement, indicating a likely positive response to a combination of three different thoracic thrust manipulations, one simple cervical range of motion exercise, and patient education. They suggested using a criterion of 3/6 variables present as a sufficient research-based indication for the use of thoracic manipulation in patients with mechanical neck pain: 3 of 6 variables present yielded a positive likelihood ratio of 5.5 and an 86% probability of a successful outcome. Table 1 provides the predictor variables in the various clinical prediction rules.

So, how do we get from these prediction rules to questioning the validity of what is undoubtedly the most firmly held belief or—to return to the premise of this editorial—the sacred cow of the mechanism-based classification systems at the basis of not just the various approaches to OMPT but seemingly prominent throughout the whole manual

medicine community, that is, the concept of specificity? As was likely the case for many of you, I was taught in the case of a hypomobility that was possibly amenable to manipulation to identify not only the segmental level of dysfunction but also the direction of restriction and even the endfeel indicating the tissue responsible for said restriction. This then in theory also indicated the most appropriate manual technique to use for addressing the identified hypomobile spinal segment or sacroiliac joint. Within the mechanism-based classification systems still very prevalent in OMPT education, a technique is required to be specific as to segment, direction, and tissue responsible for the lack of mobility. Now, in the lumbar manipulation prediction rule, there is, in fact, mention of segmental mobility findings. However, we can hardly label these as specific, especially because the intervention used is, in fact, a manipulative technique purported to affect the sacroiliac joint. Both Tseng et al⁸ and Cleland et al⁹ did include segmental mobility tests in their standardized examination but none of these tests had sufficient predictive validity to be included in the eventual prediction rules.

Is any other evidence putting our perhaps now somewhat shaken belief in the need for specificity to the test? Research has shown that segmental specificity is a biomechanical impossibility when applying central postero-anterior pressures. In the lumbar spine, for example, postero-anterior pressures resulted in motion of the entire lumbar region^{16,17} whereas in the cervical spine, the same technique produced minimal if any intervertebral motion when applied at C2 or C6¹⁸. So what about the need for directional specificity? Chiradejnant et al¹⁹ noted no between-group differences on any of the outcome measures used in a group of patients with low back pain who were treated with either unilateral or central postero-anterior or transverse pressures that had been selected by the therapist based on examination findings or randomly generated.

Does the technique we use matter or will any manipulation do? In a case series, Cleland et al²⁰ noted favorable outcomes in patients who fit the prediction rule for manipulation in low back pain but who were treated with a rotational technique aimed at the lumbar spine and not the technique purported to affect the sacroiliac joints used in the original studies^{5,6}. Similarly, Van Schalkwyk and Parkin-Smith²¹ found no between-group post-intervention differences in patients with mechanical neck pain and segmental restriction when using either a rotational or lateral break manipulation technique. In their systematic review of randomized controlled trials investigating manual therapy for patients with non-specific low back pain, Kent et al²² noted that studies where the clinician was not given the choice of treatment technique actually had better short-term outcomes with regard to pain and activity limitation than those studies where the clinicians were given a treatment choice; long-term outcomes were equal in both types of studies. Haas et al²³ showed that there were no short-term between-group differences in pain and stiffness ratings when patients with neck pain were manipulated at a segment with decreased segmental mobility or at a randomly generated segment.

The fact that the assumption that clinicians can actually produce cavitation in a targeted joint has also been questioned further complicates matters. Beffa and Mathews²⁴ noted an equal distribution of cavitation induced from the sacroiliac to the L3-L4 joints with thrust techniques aimed at either the sacroiliac or the L5-S1 joints. Ross et al²⁵ noted that manipulation to the lumbar and thoracic spine cavitated the targeted joint only about half the time: however, most procedures resulted in multiple cavitations thereby including the target segment.

Finally, we have to wonder about the very existence of a joint-specific, mono-segmental lesion appropriate for specific thrust intervention if we are still unable to determine its presence and characteristics used to guide manipulative interventions with any degree of clinically acceptable interrater agreement^{26,27}.

So what do we do with all this evidence that brings into question one of the fundamental tenets of many schools of thought within OMPT and manual medicine in general? Do we now sacrifice our holy cow of specificity? Should we be guided solely by clinical prediction rules with regard to diagnosis and management of patients with back and neck pain? Many clinicians and researchers more experienced and learned than I am have weighed in on this issue. Some have rightfully questioned the value we have traditionally placed on biomechanical constructs and suggested a greater emphasis on evidence-based diagnosis and management and continued research^{28,29}, whereas others have justifiably noted that we should apply the same standards of scientific rigor we would apply to any study relevant to diagnosis and management of neuromusculoskeletal dysfunction to these studies seemingly not supporting the concept of specificity³⁰.

As an active OMPT clinician, I personally am very excited that recent research has provided me with evidence-based guidelines with regard to diagnosis and management of some of the patients who come to see me for back and neck pain. I believe that treatment-based classification systems hold great promise to change the way we practice OMPT. However, I cannot help but notice that I, as probably most of you, see a large number of patients who do not fit within the clinical prediction rules discussed above. In fact, the number of patients to whom these rules apply is quite limited. So with many patients I still make my mechanism-based diagnosis where I attach importance to segmental level, direction of perceived restriction, and endfeel. I guess I am not yet ready to let go of my firmly held belief, although I am less worried that manipulating the "wrong" level in the "wrong" direction may have dreadful results for my patient. It looks like my own sacred cow will survive for a bit longer although she definitely seems less sacred than she once appeared to be . . .

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TABLE 1. Clinical prediction rules predictor variables

CPR to identify patients with LBP most likely to benefit from manipulation

- Duration of current episode < 16 days
- No symptoms distal to the knee
- FABQW score < 19
- ≥ 1 hypomobile segment on lumbar segmental mobility testing
- One or both hips with > 35 degrees of internal rotation range of motion

Abbreviated CPR to identify patients with LBP most likely to benefit from manipulation

- Duration of current episode less than 16 days
- · No symptoms distal to the knee

CPR to identify patients with immediate response to cervical manipulation

- Initial NDI < 11.50
- Bilateral involvement pattern
- Not performing sedentary work > 5 hours per day
- Feeling better while moving the neck
- Not feeling worse when extending the neck
- Diagnosis of spondylosis without radiculopathy

CPR to identify patients with neck pain likely to respond to thoracic manipulation

- Symptom duration < 30 days
- No symptoms distal to the shoulder
- · Looking up does not aggravate symptoms
- FABQPA score < 12
- Diminished upper thoracic kyphosis
- Cervical extension range of motion < 30 degrees

CPR-Clinical prediction rule; LBP-low back pain; FABQW-Fear Avoidance Beliefs Questionnaire Work Subscale; NDI-Neck Disability Index; FABQPA-Fear Avoidance Beliefs Questionnaire Physical Activity Subscale

REFERENCES

- 1. Assendelft WJJ, Morton SC, Yu EI, Suttorp MJ, Shekelle PG. Spinal manipulative therapy for low back pain: A meta-analysis of effectiveness relative to other therapies. *Ann Intern Med* 2003;138:871–881.
- 2. Gross AR, Kat T, Hondras M, Goldsmith C, Haines T, Peloso P, Kennedy C, Hoving J. Manual therapy for mechanical neck disorders: A systematic review. *Man Ther* 2002;7:131–149.
- 3. Gross AR, Hoving JL, Haines TA, Goldsmith CH, Kay T, Aker P, Bronfort G, et al. A Cochrane Review for manipulation and mobilization for mechanical neck disorders. *Spine* 2004;29:1541–1548.
- 4. Sarigiovannis P, Hollins B. Effectiveness of manual therapy in the treatment of non-specific neck pain: A review. Phys Ther Rev 2005;10:35-50.
- 5. Flynn T, Fritz J, Whitman J, Wainner R, Magel J, Rendeiro D, et al. A clinical prediction rule for classifying patients with low back pain who demonstrate short-term improvement with spinal manipulation. *Spine* 2002;27:2835–2843.
- 6. Childs JD, Fritz JM, Flynn TW, Irrgang JJ, Johnson KK, Majkowski GR, Delitto A. A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: A validation study. *Ann Intern Med* 2004;141:920–928.
- 7. Fritz JM, Childs JD, Flynn TW. Pragmatic application of a clinical prediction rule in primary care to identify patients with low back pain with a good prognosis following a brief spinal manipulation intervention. *BMC Family Practice* 2005;6:29.
- 8. Tseng YL, Wang WTJ, Chen WY, Hou TJ, Chen TC, Lieu FK. Predictors for the immediate responders to cervical manipulation in patients with neck pain. *Man Ther* 2006;11:306–315.
- 9. Cleland JA, Childs JD, Fritz JM, Whitman JM, Eberhart SL. Development of a clinical prediction rule for guiding treatment of a subgroup of patients with neck pain: Use of thoracic spine manipulation, exercise, and patient education. *Phys Ther* 2007;87:9–23.
- Laupacis A, Sekar N, Stiell I. Clinical prediction rules: A review and suggested modification of methodological standards. JAMA 1997;277:488–494.
- 11. Childs JD, Flynn TW. Spinal manipulation for low back pain. Ann Intern Med 2004;140:665.

- 12. Van Dillen LR, Sahrmann SA, Norton BJ, et al. Reliability of physical examination items used for classification of patients with low back pain. *Phys Ther* 1998;78:979–988.
- 13. Delitto A, Erhard RE, Bowling RW. A treatment-based classification approach to low back syndrome: Identifying and staging patients for conservative treatment. *Phys Ther* 1995;75:470–485.
- 14. Fritz JM, Brennan GP, Clifford SN, Hunter SJ, Thackeray A. An examination of the reliability of a classification algorithm for subgrouping patients with low back pain. *Spine* 2006;31:77–82.
- 15. Childs JD, Fritz JM, Piva SR, Whitman JM. Proposal of a classification system for patients with neck pain. *J Orthop Sports Phys Ther* 2004;34:686–696.
- 16. Kulig K, Landel RF, Powers CM. Assessment of lumbar spine kinematics using dynamic MRI: A proposed mechanism of sagittal plane motion induced by manual posterior-to-anterior mobilization. *J Orthop Sports Phys Ther* 2004;34:57–64.
- 17. Powers CM, Kulig K, Harrison J, Bergman G. Segmental mobility of the lumbar spine during a posterior to anterior mobilization: Assessment using dynamic MRI. *Clin Biomech* 2003;18:80–83.
- 18. McGregor AH, Wragg P, Gedroyc WMW. Can interventional MRI provide an insight into the mechanics of a posterior-anterior mobilisation? *Clin Biomech* 2001;16:926–929.
- 19. Chiradejnant A, Maher CG, Latimer J, Stepkovitch N. Efficacy of "therapist-selected" versus "randomly selected" mobilization techniques for the treatment of low back pain: A randomized controlled trial. *Aust J Physiother* 2003;49:233–241.
- 20. Cleland JA, Fritz JM, Whitman JM, Childs JD, Palmer JA. The use of a lumbar spine manipulation technique by physical therapists in patients who satisfy a clinical prediction rule: A case series. *J Orthop Sports Phys Ther* 2006;36:209–214.
- 21. Van Schalkwyk R, Parkin-Smith GF. A clinical trial investigating the possible effect of the supine cervical rotatory manipulation and the supine lateral break manipulation in the treatment of mechanical neck pain: A pilot study. *J Manipulative Physiol Ther* 2000;23:324–331.
- 22. Kent P, Marks D, Pearson W, Keating J. Does clinician treatment choice improve the outcomes of manual therapy for non-specific low back pain: A meta-analysis. *J Manipulative Physiol Ther* 2005;28:312–322.
- 23. Haas M, Groupp E, Panzer D, Partna L, Lumsden S, Aickin M. Efficacy of cervical endplay assessment as an indicator for spinal manipulation. *Spine* 2003;28:1091–1096.
- 24. Beffa R, Mathews R. Does the adjustment cavitate the targeted joint? An investigation into the location of cavitation sounds. *J Manipulative Physiol Ther* 2004;27:e2.
- Ross JK, Bereznick DE, McGill SM. Determining cavitation location during lumbar and thoracic spinal manipulation: Is spinal manipulation accurate and specific? Spine 2004;29:1452–1457.
- 26. Huijbregts PA. Spinal motion palpation: A review of reliability studies. J Manual Manipulative Ther 2002;10:24–39.
- 27. Huijbregts PA. Sacroiliac joint dysfunction: Evidence-based diagnosis. Orthop Division Rev 2004 May/June:18–32,41–44.
- 28. Flynn TW. There's more than one way to manipulate the spine. J Orthop Sports Phys Ther 2006;36:198–199.
- 29. Cleland JA, Childs JD. Does manual therapy technique matter? Orthop Division Rev 2005 Sept/Oct:27–28.
- 30. Grimsby O, Miller E. A critical review of Dr. Timothy Flynn's guest editorial in the April 2006 issue of JOSPT. Scientific Physical Therapy 2006;15(4):6–8.