“Potential Pitfalls of Clinical Prediction Rules”

We appreciate the Editorial of Chad Cook, PT, PhD “Potential Pitfalls of Clinical Prediction Rules” published in the last issue of JMMT describing Clinical Prediction Rules (CPRs) and emphasizing the need for standardization of reporting in the methodology and results. As indicated in the editorial, CPRs have a valuable role in the realm of clinical research and can provide useful and directly applicable clinical information. Once found, there must be some assurance that the studies were carried out satisfactorily and the execution of the methodology was sound. Reporting of randomized controlled trials (RCTs) has been a subject of concern that has led to international standards on how trials should ideally be reported in medical journals, resulting in the CONSORT statement. This includes a checklist of 21 items related to different aspects of a trial report that are considered important in the publication of an RCT. Similarly, the development of quality assessment of studies of diagnostic accuracy (QUADAS) has standardized quality assessment and improved the validity of the reported results. To ensure the quality of CPRs and standardization of reporting, similar guidelines should be developed that require (a) a representative random sampling of the population that would normally receive this treatment; (b) an outcome measure that is reliable, valid and sensitive to change; (c) a justification for the use of predictor tests; and (d) appropriate power and report of the model.

It is our impression that the timing for guidelines for CPRs is not only optimal, but critical.

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Misguided Guidelines for Low Back Pain Interventions

We applaud the American College of Physicians (ACP) and the American Pain Society (APS) for attempting to establish guidelines for the management of low back pain, and we concur with the recommendations regarding diagnostic testing, patient education and pharmacological interventions. However, the recommendations for non-pharmacologic treatment for acute low back pain are a cause for concern. Recommending heat as the only therapy which demonstrated effectiveness is misguided. A thorough review of the literature, especially with regard to physical therapy intervention, supports an active, classification-based approach to acute low back pain. In fact, an argument can be made that reliance upon heat alone, as an initial care strategy for low back pain without other early physical therapy intervention, can actually promote unfavorable outcomes and an increased inci-
idence of chronic low back pain. Following the ACP/APS recommendations as currently published will probably do more harm than good.

We agree that it is very important to educate patients about the expected course of low back pain and to encourage physical activity, but that is not enough to reduce the likelihood of chronicity. Studies have clearly demonstrated that for acute low back pain, as for all acute musculoskeletal injuries, early physical therapy intervention, to modulate pain, restore normal mobility with manipulation/mobilization and improve biomechanical function with specific exercise routines, reduces the chance of developing chronic pain from 15% to 2%\textsuperscript{7,8}. Additionally, comparisons of having low back patients treated with classification based physical therapy, as compared to a practice guideline approach similar to that being recommended\textsuperscript{9} show superior outcomes for the classification based therapy group\textsuperscript{5}.

A study by Linton et al\textsuperscript{10} of the Department of Occupational Medicine at the Orebro Medical Center in Sweden has demonstrated that early active physical therapy intervention for patients suffering their first episode of acute musculoskeletal pain significantly decreased the incidence of chronic pain. In this study, injured workers complaining of acute musculoskeletal pain were either seen by a physical therapist within the first few days after injury or had to wait a week or more to be seen. Both groups were seen by a general practitioner to rule out aggressive disease or problems that might require medical treatment. Patients in the early intervention group saw a physical therapist within the first three days following their injury. The control group might be sent for physical therapy, but would often have to wait between three weeks to three months for their appointment. The physical therapists performed a functional examination followed by education and treatment if needed. The physical therapists reinforced healthy behaviors, specifically the maintenance of daily activities and the practice of specified \textit{training} activities. Specific advice was provided as to how the patient might help him or herself to improve and which activities should be maintained during the recovery. If the therapist deemed it necessary, individual treatments were administered for up to 12 weeks.

At follow-up, 12 months later, investigators looked at patient outcomes, particularly with regard to time off of work and development of chronic pain. Chronic cases were defined as those individuals sick listed for more than 200 days during the following year. The results demonstrate that early active physical therapy significantly reduces the incidence of the development of chronic pain and the amount of lost work time for patients suffering acute musculoskeletal injury. The results can be summarized as follows:

- Of those people who were suffering their first episode of musculoskeletal pain who had early physical therapy intervention only 2% went on to develop chronic pain. Of those who did not get early intervention, 15% became chronic pain patients.
- 32% of the early activation group lost no workdays as compared to only 23% of the control group.
- Only 26% of the early activation group lost 11–30 days while 33% of the control group missed that much work.
- 17% of the early activation group lost more than 30 days. Almost twice that many, 31% of the control group were off work for more than 30 days.

The physical therapy a patient needs following acute onset of low back pain varies depending on the patient's presenting signs and symptoms. A classification system on which to base treatment was proposed by DeLitto et al in 1995\textsuperscript{5}. The treatment-based classification has been expounded upon and refined since that time\textsuperscript{5,7,8}. It recognizes four classifications of patient presentation that help to guide appropriate treatment. Using this system a patient can be placed into one of four treatment approaches that they are most likely to respond well to. These four classifications are Manipulation, Stabilization, Specific Exercise or Traction. The Specific Exercise group is further subdivided by type of exercise. It was also recognized that some patients may start under one classification but then progress into another. For instance a patient who initially demonstrates immobility, and therefore requires manipulation, might later require specific exercises either to maintain that mobility in a specific direction or to stabilize the trunk and spine to prevent what caused the end range immobility in the first place.

Fritz et al demonstrated that there were better short-term outcomes for patients with acute work related low back pain when they were treated using a classification based approach to physical therapy instead of an approach based on recommendations from the AHCPR clinical practice guidelines which does not take a patient’s pathokinesiological signs and symptoms into account. Fritz et al\textsuperscript{11} have also demonstrated improved outcomes in patients in an occupational setting when the treatment of manipulation is applied in concordance with the treatment-based classification.

Brennan et al examined the patient care for low back pain in subjects that demonstrated concordance (i.e. matched or not matched) of care with the classification categories. The authors found the matched treatment groups had a clinically significant improvement in outcomes compared to the subjects not treated with appropriate classification treatments in short term and long term outcomes (Oswestry scores)\textsuperscript{12}. Spengler et al reported that just 10% of the total number of people who suffer back injuries account for 79% of the total incurred costs and that the most chronic cases, just 1.2%, account for 27%\textsuperscript{6}. Direct medical expenses are only a small part of the total cost of back pain. To an even larger extent were the costs of temporary disability payments and permanent disability awards\textsuperscript{13}.

Failure to refer first episode musculoskeletal pain patients for physical therapy in the first few days following injury results in an eight fold increase in the number of patients going on to have chronic pain, and a 50% increase in patients who lose more than 10 workdays. The cost of caring for and reimbursing
these patients is tremendous. The cost of early active physical therapy is minimal by comparison. Many acute patients will require only 1–3 visits for education and an exercise program. Some will require more visits and a few; approximately 15% will need extensive treatment.

In the industrial setting the reduction in temporary disability payments to cover the lost days and permanent disability awards for chronic pain far outweighs the cost of early intervention. Even for the non-industrial injuries though, the savings in money, pain and suffering far outweigh the cost of early physical therapy intervention.

Following clinical practice guidelines for low back pain that do not call for early classification based physical therapy intervention is a violation of the very first rule of medicine, Primum non nocere, above all do no harm. Early intervention can reduce the incidence of chronicity from 15% to 2%. Conversely, failure to institute early physical therapy results in 13 out of every 100 patients who injure their backs developing chronic pain that could have been avoided. That is a level of potential harm that is unacceptable. We therefore encourage the ACP and APS to revise their guidelines for treating low back pain and to include recommendations for early referral to a physical therapist, with expertise in orthopedic manual physical therapy, for classification based diagnosis and treatment. The best evidence available shows that to be the best and only proven way to reduce the incidence of chronicity.

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