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Research Paper Review

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Can a within/between-session change in pain during reassessment predict outcome using a manual therapy intervention in patients with mechanical low back pain?

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ABSTRACT

The purposes of the study were to determine whether the combined occurrence of within/between-session changes were significantly associated with functional outcomes, pain, and self-report of recovery in patients at discharge who were treated with manual therapy for low back pain. A secondary purpose was to determine the extent of change needed for the within/between-session change with association to function. The study involved 100 subjects who were part of a randomized controlled trial that examined manual therapy techniques who demonstrated a positive response to manual therapy during the initial assessment. Within- and between-session findings (within/between session) were defined as a change in pain report from baseline to after the second physiotherapy visit. Within/between-session changes were analyzed for associations between pain change scores at discharge, rate of recovery, and a 50% reduction of the Oswestry disability index (ODI) by discharge. The results suggest there is a significant association between a within/between-session change after the second physiotherapy visit and discharge outcomes for pain and ODI in this sample of patients who received a manual therapy intervention. A 2-point change or greater on an 11-point scale is associated with functional recovery at discharge and accurately described the outcome in 67% of the cases. This is the first study that has shown an association of within/between-session changes with disability scores at discharge and is the first to define the extent of change necessary for prognosis of an outcome. A within/between-session change should be considered as a complimentary artifact along with other examination findings during clinical decision making.

ANALYSIS

Reviewed by Dr. Daniel Avrahami DC (Research Review Service)

Background Information

Spinal manipulative therapy (SMT) is a common intervention used by Chiropractors, Physical Therapists and Osteopathatic Physicians, for the treatment of low back pain (LBP). In 2002, a prescriptive clinical prediction rule (CPR) was developed (1) to identify individuals who would benefit from this intervention. To review, it included: duration of symptoms < 16 days, at least one hip with internal rotation ROM > 35°, hypomobility of at least one lumbar segment with spring testing, Fear Avoidance Beliefs Questionnaire (FABQ) score of < 19, and no symptoms distal to the knee. The outcome for success was measured as a mean reduction in the Oswestry disability index and a mean reduction of 73% was seen in individuals who were manipulated and met at least four of these five predictors.

Since its inception, this clinical prediction rule has been accepted as the best predictive model for SMT. Yet, there is controversy, as some experts have raised questions in regards to its true clinical significance. For example, in the validation of the rule (2), SMT was compared against a group of individuals who received exercise. Experts have questioned whether this was the best comparative intervention, suggesting we should instead be comparing the type of manual interventions used in addition to taking into account a 'patient response' (i.e. Are the effects truly due to a high velocity, low amplitude thrust?).

The goal of this secondary database analysis was to look at the effects of 'patient response' as a potential prognostic indicator for outcomes in LBP patients. Specifically, the authors set out to determine if the combined occurrence of within- and between-session changes (positive self-reported changes following an intervention [within] and at a subsequent session [between]) were significantly associated with functional outcomes, pain and self-report of recovery in individuals with LBP. They also attempted to determine the amount of change necessary to affect function.

PERTINENT RESULTS

Primary Outcome Measures:

- 100 participants (45 males; 55 females – average age 48) enrolled in the RCT were included in the analysis. The mean duration of symptoms was 23.9 weeks and the mean number of visits was 7.2 (SD 4.5).
- By discharge, 74% of participants reported a 50% or greater reduction in the ODI from baseline to discharge.
- A correlation investigation that analyzed association of within-between-session changes was significant for pain change scores ($r = 0.51$; $p < 0.01$) but not for rate of perceived recovery ($r = -.01$; $p = .96$). A ROC (receiver characteristic operator) curve found that the relationship between within-between session changes and the ODI was significant ($p = 0.03$) and identified a within-between-session numeric pain rating score change of 2.0 points on an 11-point scale as a useful cut-off.
- A 2x2 contingency table found that a 2.0 point or greater change in pain had a sensitivity of 87.3 (95% CI: 78.6-93.8) and a specificity of 42.4 (95% CI: 31.6-50.2) and an odds ratio of 5.0 (95% CI: 1.9-13.4) in identifying a 50% reduction of pain by discharge.

CLINICAL APPLICATION & CONCLUSIONS

Based on the data presented, the authors demonstrate that 'patient response' appears to be a prognostic indicator for those who will respond to manual care. This is in line with other recent investigations (4 – also linked in Related Reviews). This is the first study that has shown an association of within- and between-session changes with disability scores at discharge, and is the first to determine the amount of change in pain necessary to prognosticate an outcome.

This study highlights the importance of an early 'patient response'. It also helps us predict who will most likely benefit from manual care (i.e. if they do not respond within the initial or subsequent session, it may be wise to consider an alternative treatment approach), and may explain why some individuals did not respond to manipulation in the early CPR studies. With the burdening costs of chronic low back pain plaguing health care systems around the globe, prognostic indicators should be in place to predict who will benefit from manual care.

STUDY METHODS

This study was a secondary database analysis, from a randomized-controlled trial that compared thrust vs. non-thrust manipulation on a patient population with low back pain (see reference 3 and Related Reviews). Participants enrolled in this study were from fourteen distinct outpatient physical therapy practices across the United States.

Initial inclusion criteria were based upon a comparable response (defined by the authors as a reproduction of the chief complaint of the symptoms identified by the patient) during a passive accessory movement to a given level of the lumbar spine. This response required the clinician to localize the response to a given spinal level that was most concordant or comparable to that chief complaint. Once identified, the examiner assessed for a within- session change which would qualify them for the treatment phase of the intervention in this study.

Exclusion criteria included the presence of any red flags or signs consistent with nerve root compression. In addition, the researchers excluded individuals with prior lumbar surgeries, current pregnancy, or loss of participation by the second session.

The enrolled participants, after experiencing a within-session change during the initial evaluation (with mobility assessment), were randomized to receive either thrust or non-thrust manipulation, to the lumbar spine. The randomized allocation determined the treatment the participants would receive for the first two visits. In addition to the randomization, both groups were given a standardized home exercise program (described in [3]) – see Related Reviews. In all cases, the clinician was allowed to select which particular thrust or non-thrust manipulation they felt would more benefit that participant (in an attempt to replicate real-life clinical practice). After completion of the first two visits, clinicians were allowed to perform any treatment procedure they felt would be beneficial, in addition to manual therapy, and could discharge the participant once they felt the participant had reached maximal improvement.

All participants completed a number of self-report questionnaires (numeric pain rating scale [NPRS], the Oswestry Disability Index [ODI], rate of recovery) as well as demographical information (height, weight, age, gender, race and duration of symptoms) after enrollment. In addition, the total number of

days and visits under physiotherapy care were collected. Self-report findings were collected at baseline, after the second visit and at discharge. Within- and between-session pain scores were calculated by subtracting the baseline report of pain from the report of pain after the second visit.

STUDY STRENGTHS / WEAKNESSES

Study Strengths

- The study maintained external validity and the results can be extrapolated to clinical practice. The researchers cleverly allowed the participating clinicians to chose the techniques which they thought would most benefit the participants.
- The study was built upon the concept of the 'patient response', and took an interactive vs. operational approach to care. With the emergence of the biopsychosocial model of care, it is important for us to pay attention to and include patient responses into our direction of care.

Study Weaknesses

- Lack of control group – the researchers would have been able to better determine whether or not the within-between session change was truly associated to the manual therapy intervention given if a control group was included.
- The study focused heavily on subjective responses of the patient and lacked objective measurements such as range of motion (keeping in mind the limitations of these measures as well).

Additional References

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