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.

1. Introduction

Physiotherapists often use manual therapy treatment techniques for patients with low back pain whom are hypothesized to have altered intervertebral mobility (Banks, 1998). When determining who is a plausible candidate for manual therapy, clinicians may rely on the patient’s response to passive movements applied during the initial examination and subsequent sessions, resulting in a reduction in pain or an improvement in movement after application of passive forces (Haas et al., 2003; Tuttle et al., 2006). A primary and simplistic principle of manual therapy decision making suggests that if a patient improves after application of a passive technique then that patient is a candidate for a manual therapy treatment regimen, whereas if the patient worsens, then the technique should be altered or abandoned (Maitland, 1986, 1991; Hahne et al., 2004).

Terminology currently exists to describe the responses to manual therapy approaches during a visit and also at subsequent visits. A within-session change is an improvement (of either reported pain or observed range of motion) that occurs during the single visit (Maitland et al., 2001). A between-session change (also known as a carry-over effect) describes improvement in either pain or range of motion that is carried over to a subsequent visit or “visits” (Maitland et al., 2001). Both within- and between-session changes have been investigated for their capacity to determine short- or long-term improvements in pain, impairment, or function, in patients who receive a manual therapy treatment approach (Hahne et al., 2004; Tuttle, 2005; Tuttle et al., 2006; Wright et al., 2010; Garrison et al., 2011).
Within-session changes do appear to predict between-session changes after application of manual therapy in patients with low back or cervical pain (Hahne et al., 2004; Tuttle, 2005). However, within-session changes of pain and/or a dedicated impairment may not be associated with long-term functional reports from patients who have cervical (Tuttle, 2005) or hip pain (Wright et al., 2010). To date, between-session changes have been explored by two studies, one study which involved patients with sub-acute neck pain (Tuttle et al., 2006), and another which involved patients with shoulder impingement syndrome (Garrison et al., 2011). The studies suggest that between-sessions changes are related to improvements in impairments (Tuttle et al., 2006), pain (Tuttle et al., 2006; Garrison et al., 2011), or global report of change (Garrison et al., 2011), but have a poor relationship to long-term improvements in function/activities of daily living.

There are two potential reasons for the poor relationships among function and within- and between-session findings. First, none of the prior studies combined a within- and between-session change (meaning both occur in sequence). Most clinicians' reasoning methods mandate that both are present before one can assume the response seen is specific to the manual therapy applied. Second, none of the prior studies have investigated the extent of the change that is needed for significant functional improvement. Manual therapy treatment techniques result in short-term improvements in self-report of pain in almost all recipients, a finding that also occurs in a number of non-manual therapy interventions, including those that are considered to have no true clinical effectiveness (Cook, 2011). All individuals demonstrated an improvement in between-session impairment and report of pain in Tuttle et al.'s (2006) paper, which investigated between-session changes over several visits. In Wright et al. (2010) paper, any report of increased pain after a single bout of traction was considered a within-session finding, even a reduction of pain as minor as 0.5 points. The within- and between-session changes are often focused on pain or impairments and whether pain or impairments are related to long-term change in function is still unknown. Further, the extent of change that is necessary for clinical relevance, specifically with association to long-term improvement in report of function in patients who demonstrate a concurrent within/between-session change has yet to be investigated. Subsequently the objectives of this study were two-fold; with the second objective dependent on a significant finding of the first. The first objective was 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 for low back pain. The secondary objective (if the primary objective was statistically significant) was to determine the extent of change needed for the within/between-session change with association to function.

2. Methods

2.1. Study design

This study was a secondary database analysis that involved the first 100 enrolled participants from both arms of a randomized clinical trial (RCT) registered within clinicaltrials.gov #NCT01438203. Because both arms were combined for the analyses in this study, the STROBE guidelines were used to improve reporting standards. The STROBE guidelines are a user-friendly checklist for cohort, case-control, cross-sectional studies (Gallagher et al., 2011). The purpose of the randomized clinical trial was to investigate the comparative benefit of thrust and non-thrust manipulation on a population of patients with low back pain. In the trial, both groups received a standardized evaluation and one of two different forms of manual therapy. The interventions within the trial included manual therapy techniques that were designed to reflect a “real-world” treatment environment, to enhance external validity. Study participants were enrolled only if they were deemed “manual therapy candidates” during the initial visit. Germane to this intention was the use of within/between-session changes, which were used to guide the physical therapists through the treatment decision making process.

2.2. Participants

All patients who participated in this study were from 14 distinct outpatient physical therapy practices within the United States. For inclusion into the RCT, patients needed to be 18 years of age or older with mechanically producible low back pain (LBP). For patients to meet inclusion criteria, they required a within-session change in pain and/or range of motion during the assessment phase of the clinical examination (a positive response to a manual therapy oriented treatment); specifically during passive accessory examination. This finding was primarily used to determine if the patient was a candidate for manual therapy. Patients did not need to exhibit a between-session change at subsequent visits for continued enrollment in the trial.

Exclusion criteria included the presence of any red flags (i.e., tumor, metabolic diseases, rheumatoid arthritis (RA), osteoporosis, prolonged history of steroid use, etc.), or signs consistent with nerve root compression (reproduction of low back or leg pain with straight leg raise at less than 45°, muscle weakness involving a major muscle group of the lower extremity, diminished lower extremity muscle stretch reflex, or diminished or absent sensation to pinprick in any lower extremity dermatome). Other exclusion criteria included prior surgery to the lumbar spine and current pregnancy. Lastly, if patients were initially enrolled in the randomized controlled trial but did not receive a follow up (2nd visit) or final outcome assessment, after the initial (baseline) visit, they were not included in the study.

2.3. Procedures

All patients were treated by 14 experienced physiotherapists that had undergone standardized training to participate in the RCT and had a history of extensive manual therapy training and certification(s). All physiotherapists had undergone detailed certificate-based training on the patient response concept and were instructed to use this assessment method during the initial evaluation. In short, the evaluation required a comparable response (reproduction of the chief complaint of the symptoms identified by the patient) during a passive accessory movement applied as a unilateral posterior–anterior or a central posterior–anterior to a given level at the lumbar spine. This patient response concept also required the clinician to localize the response to a given spinal level that is the most concordant/comparable. Only when a patient's concordant level and when a within-session change was identified did the patient qualify for the treatment phase of the intervention. Thus, all patients enrolled in the study exhibited within-session changes during the posterior–anterior assessment.

The treatment was designed to reflect actual clinical practice and involved an experimental component only within the first two visits. In the RCT, patients were randomized to either thrust or non-thrust groups and treatment for the first two visits involved only either thrust or non-thrust manipulation (depending on allocation), and a standardized home exercise program. In all cases, the clinician was allowed to select which particular thrust or non-thrust manipulation that they felt would be most beneficial for their patient (again, replicating actual clinical practice) and were able to target the comparable site that reproduced the patient’s chief complaint. In
other words, the thrust and non-thrust technique was not applied to a pre-selected level, but was applied to the spinal level identified by the therapists as the concordant pain generator.

After completion of the first two visits, clinicians were allowed to perform any treatment procedure they felt would be beneficial for the patient population, in addition to manual therapy. The design of the RCT was such to mimic actual clinical practice related decision making. Procedures included any physiotherapy related technique, whether it involved strengthening, movement-based methods, or other, as long as the clinician felt it fit within the treatment plan of the patient. Patients were discharged once the clinician felt the patient had met their maximal improvement within the current treatment program. There were no restrictions on total visits for each patient enrolled in the trial.

2.4. Measures

All patients provided demographic information and completed a number of self-report questionnaires, followed by a standardized history and physical examination at baseline. Height, weight, age, gender, race, and duration of symptoms in weeks were captured in the baseline report of pain by the report of pain after the second visit. This allowed a capture of pain over a period of two full visits, in all cases, within a span of 1 week of care. Within/between-session scores could range from –10 to 10, depending on the baseline score and the subsequent follow up score. For this variable, there were two possible patient presentations: 1) Yes Within-Session Change—Yes Between-Session Change (coded as a within/between-session response) and 2) Yes Within-Session Change—No Between-Session Change (codes as a non-within/between-session response).

2.9. Data analysis

Data analysis included descriptive statistics and summated measures of total visits and total days in care. To determine the association between within/between-session changes and rate of recovery and within/between-session changes and the change score for pain, a two-tailed Pearson Product correlation was used. At present, there are no categorical values that reflect acceptable correlations for continuous data, however, values closer to 1 represent stronger relationships.

A receiver operating characteristic (ROC) was used to determine whether between-session pain scores were significant toward identifying an improvement of 50% or greater in Oswestry score. A ROC represents a graphical plot of the true positive rate of a finding versus a false positive rate of a finding, when the outcome variable is dichotomous and the predictor variable is continuous. The area under the curve (AUC) was used to define the extent of the relationship, with values closer to 1 suggesting near perfect findings and values closer to 0.5 suggesting no relationship or value in the independent variable. Sensitivity, specificity, and positive and negative likelihood ratios (LR+ and LR–) were calculated based on the methods described by Sackett et al. (1991). A binomial logistic regression analysis was used to determine the benefit of a positive within/between-session finding and 50% reduction in ODI. Accuracy was calculated by adding the true positives and true negatives and dividing by the total in the sample. This value was multiplied by 100. For all analyses, a p value ≤ 0.05 was considered significant.

3. Results

One hundred (100) of the original 102 subjects enrolled in the RCT who received a reassessment after the 2nd visit and a final outcome assessment (after the initial and follow up visit) were included in the study findings (Fig. 1). The patient characteristics of the individuals are included in Table 1. The mean duration of symptoms was 23.9 (47.7) weeks and 74 subjects (of the 100) reported a 50% or greater reduction of the ODI from the first to the final visit.

The correlation investigation that analyzed association of within/between-session findings was significant for pain change scores (r = 0.51; p < 0.01) but not for rate of perceived recovery (r = –0.01; p = 0.96). The ROC curve that analyzed the relationship of within/between-session changes and ODI was significant (p = 0.03) and identified a within/between-session NPRS change score from baseline to the completion of the 2nd visit of 2.0 points or higher on an 11-point scale as a useful cut-off. The area under the curve was 0.695.

Table 2 reflects the 2 × 2 contingency table for the sample. A 2-point or greater change had a sensitivity of 87.3 (95% CI: 78.6–93.8) and a specificity of 42.2 (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 at discharge. This equates to an accuracy of 67% for the subjects in the study.

4. Discussion

The objectives of the study were to determine whether a within/between-session change of pain during application of a manual
therapy technique was associated with changes in pain, rate of recovery, and functional changes at discharge from physiotherapy. If this was the case it was then incumbent upon the investigators to ascertain what level of change in patient during a within/between-sessions finding was most compellingly associated with functional improvement. Within/between-session findings were significantly associated with a pain change score but not rate of recovery. In addition, a within/between-session report of pain reduction of 2 points or greater was associated with a 50% reduction or greater in the ODI. These findings are promising for two primary reasons. Firstly, these results lend validity to a traditional manual therapy convention that patient response is useful during application of manual therapy. Secondly, these findings provide preliminary results that suggest a 2-point change or greater in pain is useful in determining who will also benefit functionally; a finding to this point that has not been substantiated.

As stated, these results lend validity to the manual therapy convention that the positive patient responses after the application of a treatment occurred because the treatment provided was useful and warranted for that specific patient. There were 48 instances in which the 2-point change out of 11 identified improvement in ODI and 15 instances where failure of a 2-point change out of 11 predicted no improvement in the ODI. Worth noting were the poorly matched findings where a 2-point change out of 11 did not lead to overall improvement in ODI (7 instances) or the 26 cases where a 50% improvement or greater on the ODI was reached in those who did not demonstrate an early within/between-sessions difference. This may suggest that greater than two visits are needed to fully determine who will improve with a manual therapy-directed approach. It also may outline the imperfections in this assessment—reassessment model in traditional patient care. The within/between-sessions finding of a 2-point or greater reduction of pain, although statistically significantly associated with an improvement in the ODI, was only accurate in 67% of the individuals within the trial.

Tuttle (2009) recommends that care is required in the selection of reassessments used to guide ongoing management since the usefulness of any reassessment depends on how well a change in the selected impairment predicts that individual patient’s ability to achieve their goals. Others (Maitland et al., 2001) have suggested the reassessing of one or more of the most comparable subjective and objective signs during and following evaluation and treatment to help guide the clinical decision reasoning process. The clinical decision reasoning process described by Jones and Rivett (2004) utilizes a minimum of eight hypothesis categories that the therapist uses to develop hypotheses about the patient and support or negate them throughout the evaluation and treatment process. Moreover, if one examines the context of our findings, it lends support to the fact that clinical reasoning and treatment decision making methods used by clinicians are highly complex and decisions are rarely based on a single parameter (Kassirer, 2010; Boyd, 2011), such as within/between-sessions changes. Thus, any concept, including one such as within/between-sessions changes must be reasoned in conjunction with other competing or complimentary processes during clinical decision making.

### Table 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD) min/max</th>
</tr>
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<tbody>
<tr>
<td>Age (years)</td>
<td>48.0 (15.0); 20–88</td>
</tr>
<tr>
<td>Gender</td>
<td>45 – Male; 55 – Female</td>
</tr>
<tr>
<td>Race</td>
<td>90 – White; 2 – Black; 2 – Hispanic; 3 – Asian; 1 – Other; 2 – Missing</td>
</tr>
<tr>
<td>Height (inches)</td>
<td>67.2 (4.1); 55–77</td>
</tr>
<tr>
<td>Weight (pounds)</td>
<td>263.4 (5.4); 187.7–43.9</td>
</tr>
<tr>
<td>Body mass index (weight [pounds] x 703/height [inches]²)</td>
<td>170.2 (3.4); 107–285</td>
</tr>
<tr>
<td>Total visits</td>
<td>7.2 (4.5); 3–28</td>
</tr>
<tr>
<td>Total days (days from evaluation to discharge)</td>
<td>36.2 (3.1); 3–160</td>
</tr>
<tr>
<td>Duration of symptoms (weeks)</td>
<td>23.9 (47.7)</td>
</tr>
<tr>
<td>Oswestry disability index (baseline)</td>
<td>27.0 (14.2); 2–78</td>
</tr>
<tr>
<td>Oswestry disability index (discharge)</td>
<td>9.7 (11.2); 0–54</td>
</tr>
<tr>
<td>Fear avoidance beliefs-work</td>
<td>10.8 (10.4); 0–43</td>
</tr>
<tr>
<td>Visual analog scale pain (0–10) (baseline)</td>
<td>5.3 (2.1); 1–10</td>
</tr>
<tr>
<td>Visual analog scale pain (0–10) (discharge)</td>
<td>1.5 (1.5); 0–7</td>
</tr>
<tr>
<td>Rate of perceived recovery (0–100%)</td>
<td>79.5% (23.5)</td>
</tr>
</tbody>
</table>

### Table 2

2 × 2 Contingency table (N = 100). Fifty-five of the 100 subjects had a 2-point or greater change (out of 11 points) and a 50% reduction on the Oswestry disability index whereas 26 who demonstrated a 2-point change or greater did not achieve a 50% reduction.

<table>
<thead>
<tr>
<th>2-Point change from baseline to end of 2nd session</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Met</td>
<td>Did not meet</td>
</tr>
<tr>
<td>Met</td>
<td>48</td>
</tr>
<tr>
<td>Did not meet</td>
<td>7</td>
</tr>
<tr>
<td>Totals</td>
<td>55</td>
</tr>
</tbody>
</table>
The finding that a within-/between-session change is significantly associated with improvement in function is notably different from that of prior researchers who have indicated that isolated within- and between-session changes do not predict long-term functional changes. There may be a number of plausible reasons for our unique findings. First and foremost, we combined a within-/between-session finding in our study because we felt that this phenomenon most closely represents the clinical data used by manual therapists when determining the success and applicability of a manual therapy directed approach. In our trial, patients were only enrolled if they exhibited a within-session change during initial assessment. Patients were then determined to exhibit between-session changes, or not. Other studies either used a within-session change only (Hahne et al., 2004; Tuttle, 2005; Wright et al., 2010), or measured results from a between-session change only (Tuttle et al., 2006; Garrison et al., 2011), without reporting if an initial within-session change occurred. Another reason may be the sample size of our study, which was the largest of those who have investigated this phenomenon. Our sample size was 71 patients larger than Tuttle’s (2005, 2006) and nearly 50 more than Hahne et al. (2004) and Garrison et al. (2011). Sample size is an important consideration since the likelihood of statistical significance in studies of associations improves with larger sample sizes (Gravetter and Wallnau, 1988). Lastly, we studied within-/between-session changes in patients with low back pain, whereas others have investigated patients with cervical spine, hip, and shoulder disorders. One other study (Hahne et al., 2004) did investigate the low back but looked only at whether within-session changes predicted between-session changes. Further work is needed to determine whether different body regions are more inclined to exhibit useful findings from within- and between-session findings, or combined within-/between-session findings.

Worth noting is the limitation of the treatment design in determining whether a within-/between-session change of any level is useful in identifying who will benefit from manual therapy. This study did not include a control group, thus whether or not the within-/between-session finding was associated purely with the manual therapy intervention is unknown. All subjects enrolled in the RCT from which these patients were derived received a dedicated manual therapy approach. To our knowledge, only Wright et al. (2010) have used a comparison group to determine whether a similar finding (in their case a within-session only finding) was useful in a manual therapy group compared to a control group who did not receive care. The authors suggested that the interaction between the examination findings (within-session) and the manual therapy treatment were likely the reasons for the differences when compared against a control group who received no treatment; but did not support a direct cause and effect relationship among a within-session change and a long-term improvement in function.

### 4.1. Limitations

As stated, the study lacked a comparator group that is necessary to determine whether a 2-point change in a within-/between-sessions finding is useful in determining whether one is a manual therapy candidate or not. Another limitation is the failure of this study to capture range of motion differences (impairments), which are also commonly used to determine the benefit of a manual therapy approach. As such, the within-/between-session change used in this study was limited to pain-only, and does not fully represent a within-/between-session change used in clinical practice.

### 5. Conclusion

A within-/between-session change of pain of 2 or greater that occurs after the second visit appears to be useful in determining a positive outcome associated with pain and function in patients who receive a manual therapy approach. The approach does not seem to demonstrate usefulness in identifying higher self-report rate of recovery. The commonly used philosophical construct, of evaluating the patient’s comparable sign, and applying treatment to directly affect this movement sign, when applied during manual therapy interventions, may be useful as a complimentary process during clinical decision making.

### References


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