The purpose of this study was to investigate the comparative effectiveness of early use of thrust (TM) and non-thrust manipulation (NTM) in a sample of patients with mechanical low back pain (LBP). The randomized controlled trial included patients with mechanically reproducible LBP, age 18-years who were randomized into two treatment groups. The main outcome measures were the Oswestry Disability Index (ODI) and a Numeric Pain Rating Scale (NPRS), with secondary measures of Rate of Recovery, total visits and days in care, and the work subscale of the Fears Avoidance Beliefs Questionnaire work subscale (FABQ-w). A two-way mixed model MANCOVA was used to compare ODI and pain, at baseline, after visit 2, and at discharge and total visits, days in care, and rate of recovery (while controlling for patient expectations and clinical equipoise). A total of 149 subjects completed the trial and received care over an average of 35 days. There were no significant differences between TM and NTM at the second visit follow-up or at discharge with any of the outcomes categories. Personal equipoise was significantly associated with ODI and pain. The findings suggest that there is no difference between early use of TM or NTM, and secondarily, that personal equipoise affects study outcome. Within-groups changes were significant for both groups.
position, grasping the knees of the patient with one hand, and pressing downward on the spine with the other. The authors indicated that this method functioned as a NTM technique “without the rotational forces and leverage required to move facet joints”. The NTM used by Cleland et al. (2009) included 2 sets of 60-s oscillatory NTMs performed with contact to the L4 and L5 spinous processes. The technique did not involve patient feedback, modification of position, angle, force, or rate based on patient response, nor did the procedure target the comparable level of the spine.

Notable restrictions in study inclusion/exclusion were present in both studies as well. Cleland et al. (2009) limited enrollment to those who met a clinical prediction rule (CPR) of spinal manipulation (Flynn et al., 2002; Childs et al., 2004) and who were between 18 and 60 years of age. Hadler et al. (1987) restricted inclusion to <40 years, symptoms of less than 1-month, and excluded individuals who had ever received TM at any point prior to the study experience. What remains unknown is whether early application of a specific TM is truly more effective than early application of a NTM when these procedures retain the constructs and treatment modifications that are unique to clinically applicable methods and concurrent with technique methods historically advocated within a wider age-range of patients with LBP. Consequently, the objective of this study was to investigate the comparison of TM and NTM, when performed early in the treatment care process, in a sample of patients with mechanical LBP.

2. Methods

2.1. Trial design

The study was a randomized controlled trial (RCT) registered within clinicaltrials.gov#NCT01438203. The study used the Consolidated Standards of Reporting Trials guidelines to improve reporting standards (Moher et al., 2001), and was approved by the Walsh University Human Ethics Board.

2.2. Participants

All patients who participated in this study were from 16 distinct outpatient physiotherapy practices within the United States (USA). For inclusion into the RCT patients needed to be >18 years of age with mechanically producible LBP, and required a within-session change (improvement in pain and/or range of motion) during the assessment phase of the clinical examination; specifically during passive accessory examination. This finding has been advocated as an effective mechanism to determine if a patient is a candidate for manual therapy (Maitland, 1997).

Exclusion criteria included the presence of red flags (i.e., tumor, metabolic diseases, RA, osteoporosis, prolonged history of steroid use, etc.), or signs consistent with nerve root compression (reproduction of LBP or leg pain with straight leg raise <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 lumbar spine surgery or current pregnancy. Lastly, if patients were enrolled in the study but did not receive a second outcome measure (follow up visit) they were excluded from the final analyses.

Fig. 1 outlines the enrollment characteristics of the study. Final analyses involved 149 participants whose characteristics are presented in Table 1, split by treatment group. There were no significant differences in any of the baseline characteristics between the two groups.

2.3. Clinicians

Seventeen different physiotherapists participated in enrollment/treatment and practiced in the USA. The outpatient clinics were privately owned, hospital-based, or academically-affiliated. All clinicians had undergone extensive manual therapy training, certification, or were fellows within the American Academy of Orthopaedic Manual Physical Therapists. Table 2 outlines the characteristics of the clinicians who participated in the study.

2.4. Randomization sequence

Once consented, the treating physiotherapist randomly allocated the patient to a TM or NTM treatment group with the roll of a die (1,3,5 – thrust, 2,4,6 – non-thrust). No blocking procedures were used. Neither physiotherapist nor patients were blinded to group allocation.

2.5. Interventions

All treating physiotherapists participated in a 30-min standardized educational video/webinar that discussed the study purposes, techniques, and outcomes. In addition, all physiotherapists had undergone detailed clinical training on the patient-response concept espoused by Maitland (1997) and were instructed to use this assessment method during the initial evaluation. In short, the evaluation required the therapist to localize the most 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 (UPA) or a central posterior–anterior (CPA) to a specific level at the lumbar spine. Only when a patient’s comparable level and a within-session change was identified did the patient qualify for the treatment phase of the intervention.

The pragmatic treatments were designed to reflect actual clinical decision making in conventional clinical practice. Patients were randomized to TM or NTM groups and treatment consisted of the clinically appropriate technique for group allocation and a standardized exercise program for the first two visits only. In all cases, the physiotherapist was allowed to select the TM/NTM procedure 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 patients’ chief complaint. Patient feedback was used in all techniques which allowed modification of position, angle, force, or rate based on patient response. In other words, the treatment technique was not applied to a pre-selected or randomized level, but was applied to the spinal level identified by the physiotherapists as the concordant pain generator.

After completion of the first two visits, physiotherapists were allowed to perform any treatment procedure, in addition to manual therapy, that they felt would be beneficial for the patient. The physiotherapist discharged the patient when they attained their maximal improvement or if the patient self-discharged. There were no restrictions on visits for each patient enrolled in the trial.

2.6. Manipulation techniques

Thrust manipulation consisted of a high-velocity, low amplitude end range procedure, involving a short- or long-lever that was targeted to the comparable segment. The TM techniques were adjusted according to physiotherapist assessment and patient feedback. Techniques used in the study included the sidelying rotational manipulation (Maitland, 1997; Cleland et al., 2009) and the supine anterior superior iliac spine thrust manipulation,
commonly used in previous studies (Flynn et al., 2002; Childs et al., 2004; Cleland et al., 2009).

Non-thrust manipulation techniques were based on the original concepts outlined by Maitland (1997) and consisted of passive, low-velocity, oscillatory movements within the physiological range of the joint, applied to the patient’s comparable spinal level. The techniques were modified based on clinician assessment and patient feedback and consisted of Grade I through Grade IV movements. Common technique descriptions used in the study included UPAs, CPAs, and sidelying rotations (Maitland, 1997).

2.7. Standardized home exercise program

Patients in both treatment groups received a standardized home exercise program of hamstring/piriformis stretches, quadruped cat/camel, and prone press-ups for lumbar extension. These exercises were to be performed 3 times each day for 10 repetitions each through the first 2 sessions of care and then could be modified or eliminated at the therapist’s discretion beyond the second visit.

2.8. Outcomes 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 and total days under physical therapy care and total number of visits were collected.

Self-report findings were collected at three timeframes: 1) at baseline, 2) after two visits, and 3) at discharge, with the exception of the Fear Avoidance Beliefs Questionnaire work subscale (FABQ-w) which was captured at baseline and after two visits only. All outcomes measures were collected and were mailed to a third party database steward, who created and managed the dataset, but was not involved in the patient care process.

The self-report questionnaires included the Numerical Pain Rating Scale (NPRS) (Kamper et al., 2009), which was used to capture the patient’s level of pain using an 11-point ordinal scale ranging from 0 “no pain” to 10 “worst pain imaginable.” A two point change score represents a meaningful change (Childs et al., 2005). The FABQ-w (Waddell et al., 1993) was used to quantify the patient’s fear of pain and beliefs about avoiding activity. FABQ-w change scores were calculated by subtracting the data collected after the second visit from the baseline scores. The Oswestry Disability Index (ODI) (Fairbank et al., 1980) was used to measure disability. A 50% reduction in the ODI or greater from baseline has been considered a clinically important outcome (Fritz et al., 2009). Self-report of recovery (0–100%) was captured at discharge. Scoring ranged from 0 percent (meaning not at all) to 100 percent (meaning totally recovered) and was a variant of the single alphanumeric

Fig. 1. CONSORT Flow diagram for study enrollment.
evaluated, which has been used with patients with shoulder pain (Williams et al., 1999) and LBP (Van Kleef et al., 1999).

Total visits and days of care were calculated for each patient. Total visits included the summation of the initial and subsequent visits. Days of care were calculated by taking the last recorded visit or discharge date and subtracting the days since the initial session. Physiotherapists were also queried upon study completion what procedures of the study were explained to the patient and after the patients were told that they would receive either a TM or NTM they were asked which of the two procedures they felt would benefit their case the most. Patients were instructed to choose one or the other but were allowed to indicate “no preference”.

2.10. Sample size determination

We estimated a medium effect (0.30) of TM greater than NTM at discharge. Using a two-way mixed model, multivariate analysis of covariance (MANCOVA), with a 2 group design and 3 time points, while controlling for 2 covariates, and targeting a power of 80% and an alpha level of 0.05, we estimated the need for 126 total subjects in this trial. To allow for a drop out percentage of 20%, we targeted 148 subjects for enrollment.

2.11. Data analysis

All analyses were performed using SPSS version 18.0. Baseline characteristics between groups were reported and compared using a t-test/chi-square as appropriate. A two-way mixed model MANCOVA was used to compare outcomes of ODI and NPRS, at baseline, after visit 2, and at discharge, while controlling for two variables (patient expectations and personal equipoise). A MANCOVA was also calculated for rate of recovery, total visits, FABQ-w change and number of days in treatment. Both two-way mixed-model MANCOVA and MANOVA are general linear models, which are appropriate for use when there are two or more predictors. When only one follow up measure was captured, intention to treat analysis was used. For all calculations, a P value of <0.05 was considered significant. Although MANCOVA and MANOVA are robust to moderate deviations from normality (Tabachnick and Fidell, 2007), normality of the distributions of each of the dependent variable cells within the analysis was plotted with histograms and normal distribution curves and Q–Q plots to assure a visual fit. Furthermore, skewness and kurtosis for each of the cells was analyzed for significance using Kolmogorov–Smirnov analysis. In addition, Linearity was examined using bivariate scatter plots of observed residual values against the expected values.

3. Results

Mild to moderate deviations from normality were noted for NPRS and FABQ-w variables (P < 0.05); however, Q–Q Plots visually represented data that were normally distributed. Non-normality was due to skewness (some of the final NPRS and FABQ-w variables were scored as 0) and not observable outliers and the fact that sample size was fairly large. Linearity of each variable pair demonstrated predominantly elliptical to oval formation with mild deviations likely from mild to moderate non-normality previously mentioned. The scatter plot shapes would suggest that the relationships do not demonstrate high linearity but they do not demonstrate consistent variation requiring variable transformation.

The results of the two-way mixed model MANCOVA were as follows: The between-subjects results revealed there were no significant between group differences noted for pain or disability.
The covariate, personal equipoise, significantly influenced the combined dependent variable, Wilks’ \( \Lambda = 0.916, F(2,139) = 6.37, P < 0.01 \), multivariate \( \eta^2 = 0.084 \). The univariate analysis revealed that the covariate, personal equipoise significantly influenced both pain \( (F(1,140) = 8.43, P < 0.01, \eta^2 = 0.06) \) and disability \( (F(1,140) = 10.02, P < 0.01, \eta^2 = 0.067) \).

The within-subject comparison was significant for time with Wilks’ \( \Lambda = 0.691, F(4,137) = 15.29, P < 0.01 \), multivariate \( \eta^2 = 0.31 \) without interaction with the covariates. Continued analysis suggested a violation of sphericity with Mauchly’s \( W = 0.882 \) \( \chi^2(2) = 17.50, P < 0.01 \) for NPRS and Mauchly’s \( W = 0.846 \) \( \chi^2(2) = 23.19, P < 0.01 \) for ODI. Employing the Greenhouse–Geisser correction for univariate analysis revealed a significant effect for time on the NPRS \( (F(1.79,250.38) = 28.69, P < 0.01, \eta^2 = 0.17) \) and ODI \( (F(1.74,250.38) = 32.24, P < 0.001, \eta^2 = 0.19) \). Pairwise comparisons indicate significant differences at each time point for both NPRS and ODI (see Figs. 2 and 3).

The MANCOVA demonstrated no significant differences between the two groups (FABQ-w: \( P = 0.83 \), Rate of recovery: \( P = 0.40 \), total visits: \( P = 0.48 \), and days of care: \( P = 0.34 \)). The analysis also revealed that neither covariate significantly influenced the dependent variables (patient expectation: \( P = 0.20 \), and equipoise: \( P = 0.06 \)). Table 3 provides the comparative findings of the outcomes measures.

Table 2
Therapists’ background (\( N = 17 \)).

<table>
<thead>
<tr>
<th>Clinician</th>
<th>Age</th>
<th>Gender</th>
<th>Years of experience</th>
<th>Highest academic degree</th>
<th>Certification or fellowship</th>
<th>Personal equipoise</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>44</td>
<td>M</td>
<td>23</td>
<td>DPT</td>
<td>Manual Therapy Certification, OCS, SCS, +1 Thrust</td>
<td></td>
</tr>
<tr>
<td>Two</td>
<td>42</td>
<td>M</td>
<td>19</td>
<td>BS</td>
<td>Manual Therapy Certification, OCS +1 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Three</td>
<td>46</td>
<td>M</td>
<td>23</td>
<td>PhD</td>
<td>Fellow/OCS 0 Equipoise +4 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Four</td>
<td>53</td>
<td>M</td>
<td>29</td>
<td>BS</td>
<td>Fellow/OCS 0 Equipoise +4 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Five</td>
<td>31</td>
<td>M</td>
<td>6</td>
<td>DPT</td>
<td>Manual Therapy Certification +2 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Six</td>
<td>38</td>
<td>M</td>
<td>15</td>
<td>DPT</td>
<td>Manual Therapy Certification +2 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Seven</td>
<td>44</td>
<td>M</td>
<td>19</td>
<td>MS</td>
<td>Manual Therapy Certification +1 Thrust</td>
<td></td>
</tr>
<tr>
<td>Eight</td>
<td>39</td>
<td>M</td>
<td>11</td>
<td>MS</td>
<td>Manual Therapy Certification, OCS +1 Thrust</td>
<td></td>
</tr>
<tr>
<td>Nine</td>
<td>42</td>
<td>M</td>
<td>18</td>
<td>MS</td>
<td>Manual Therapy Certification, Fellow 0 Equipoise</td>
<td></td>
</tr>
<tr>
<td>Ten</td>
<td>38</td>
<td>F</td>
<td>13</td>
<td>MS</td>
<td>Fellow 0 Equipoise +3 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Eleven</td>
<td>40</td>
<td>F</td>
<td>18</td>
<td>BSc</td>
<td>Manual Therapy Certification +3 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Twelve</td>
<td>28</td>
<td>M</td>
<td>3</td>
<td>DPT</td>
<td>None 0 Equipoise +1 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Thirteen</td>
<td>45</td>
<td>M</td>
<td>25</td>
<td>DPT</td>
<td>Manual Therapy Certification, Fellow, OCS +1 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Fourteen</td>
<td>46</td>
<td>F</td>
<td>21</td>
<td>DPT</td>
<td>Fellow +1 Non-thrust</td>
<td></td>
</tr>
<tr>
<td>Fifteen</td>
<td>49</td>
<td>M</td>
<td>24</td>
<td>BS</td>
<td>Manual Therapy Certification, Fellow 0 Equipoise</td>
<td></td>
</tr>
<tr>
<td>Sixteen</td>
<td>51</td>
<td>M</td>
<td>28</td>
<td>MHS</td>
<td>Manual Therapy Certification, Fellow, OCS +1 Thrust</td>
<td></td>
</tr>
<tr>
<td>Seventeen</td>
<td>36</td>
<td>F</td>
<td>10</td>
<td>BS</td>
<td>Manual Therapy Certification, OCS +2 Non-thrust</td>
<td></td>
</tr>
</tbody>
</table>

M = Male; F = Female; BS = Bachelor’s Degree; MS or MHS = Master’s Degree; DPT = Doctorate in Physical Therapy; PhD = Doctorate of Philosophy; Fellow = Fellow of the American Academy of Orthopaedic Manual Physical Therapists.

Fig. 2. Comparison of adjusted mean scores for the numeric pain rating score over time for the thrust and non-thrust manipulation groups. Error bars represent 95% confidence intervals for the values. All time points were statistically significant within groups; however, no between group time points were significant.
4. Discussion

This study endeavored to determine the comparative effectiveness of early TM or NTM in a population of patients who received care for mechanical LBP from highly skilled physiotherapists with formal manual therapy training. The physiotherapists were also evaluated for their personal equipoise regarding which technique they felt would benefit patients. This potential bias was controlled within the study along with the possible bias associated with patient expectation and both TM and NTM were performed in ways that were specific for each given patient, with flexibility provided to each physiotherapist to modify the treatment accordingly based on responses of each patient. Our findings suggest there are no between groups difference in the outcomes between early use of TM and NTM. Both groups demonstrated significant within-session improvements from baseline to the end of the second visit and both groups also demonstrated within-session improvements from the end of the second visit to discharge.

There were no reported adverse events. The non-thrust procedures consisted of a variety of manual therapy techniques including mobilization with movements, UPAs and CPAs, all performed in pre-positions or neutral spinal positions to maximize effectiveness for each given patient. A majority of thrust manipulations included a rotational manipulation in sidelying (Maitland, 1997; Cleland et al., 2009), which was designed to "gap" the painful region, whereas fewer reported situations involved a supine anterior superior iliac spine thrust manipulation. Adjunctive treatment after the initial 2 visits generally included core stabilization and general strengthening exercises, but also included neurodynamic glides, patient education, and modalities.

Our study evaluated and controlled manipulative technique during the first two visits of the patient care process only because others (Flynn et al., 2002; Childs et al., 2004; Airaksinen et al., 2006; Laerum et al., 2007) have claimed that early TM is necessary for long-term changes and this time-oriented design is similar to past studies (Flynn et al., 2002; Childs et al., 2004; Cleland et al., 2009) that have demonstrated improvements in outcomes with 2 visits of TM only. Further, we wanted to reflect actual clinical practice in which physiotherapists were allowed to alter their treatment decision making based on patient presentation. This meant that clinicians were able to adjust treatments after the first 2 visits using any treatment mechanism they felt useful. The clinicians most

<table>
<thead>
<tr>
<th>Variable</th>
<th>Non-thrust manipulation</th>
<th>Thrust manipulation</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)/frequency</td>
<td>Mean (SD)/frequency</td>
<td></td>
</tr>
<tr>
<td>Pain Rating Score for Pain (0–10 scale)</td>
<td>1.9 (1.5)</td>
<td>1.8 (1.8)</td>
<td>0.66</td>
</tr>
<tr>
<td>Discharge Oswestry Disability Index (ODI)</td>
<td>17.2 (13.1)</td>
<td>14.9 (13.9)</td>
<td>0.31</td>
</tr>
<tr>
<td>Discharge Fear Avoidance Beliefs Questionnaire work subscale (FABQ-w)*</td>
<td>10.7 (11.0)</td>
<td>10.9 (9.9)</td>
<td>0.93</td>
</tr>
<tr>
<td>Report of Rate of Recovery at Discharge (0–100%)</td>
<td>80.1 (20.2)</td>
<td>78.3 (24.2)</td>
<td>0.62</td>
</tr>
<tr>
<td>Total visits (at discharge)</td>
<td>7.2 (5.0)</td>
<td>6.6 (4.1)</td>
<td>0.42</td>
</tr>
<tr>
<td>Total days in care (at discharge)</td>
<td>37.6 (33.4)</td>
<td>33.8 (26.2)</td>
<td>0.46</td>
</tr>
</tbody>
</table>

*Contains data collected after the 2nd visit only.
frequently added core stabilization or general strengthening exercises as an adjunctive intervention.

Our findings are different than those of Hadler et al. (1987) and Cleland et al. (2009). There may be a number of reasons for the differences, most notably the differences in samples and techniques. Hadler et al. (1987), selected a small (N = 53), young sample who were less confounded by comorbidities and issues of disability. In contrast, >80% of the subjects in our trial were >40 years old. Our sample size was similar to Cleland et al. (2009). Another reason may be the enrollment criteria we used within our study. For inclusion into the study, patients had to demonstrate a within-session change during the initial examination because we felt this exhibited candidacy for a dedicated manual therapy approach. It was our way of classifying subjects to a manual therapy treatment group. This process may have self-selected subjects for NTM since the procedure used to define a within-session change is also similar to the NTM used during treatment. To our knowledge, neither Hadler et al. (1987) nor Cleland et al. (2009) used a similar inclusion requirement.

Another reason our findings may be different from those of Cleland et al. (2009) is because we investigated two processes; processes that involved techniques, versus two different techniques performed in a randomized controlled fashion. We elected to use a pragmatic trial design versus the prescriptive trials that have been used in the past. We designed our study to reflect actual clinical decision making processes involving manual therapy and did so at the expense of tight internal technique-oriented controls. The decision process involving which TM or NTM to use and/or continued to use during clinical practice is typically based on clinician’s clinical reasoning and the assessment results (Bromfort et al., 2008). The type of application, including the modifications in force, rate, contact points, and direction comprises a complex process that is facilitated from the feedback provided during clinician and patient interactions (Matyas and Bach, 1985).

Perhaps the most interesting and potentially impactful finding that is unique to our study is the use of personal equipoise as a control mechanism. Only 6/17 physiotherapists had true personal equipoise and did not have expectations that one technique would lead to better outcomes than another. Indeed, personal equipoise was significantly associated with outcomes associated with pain and disability in our multivariate model. Although our results were the same using adjusted or non-adjusted models, it suggests that a lack of personal equipoise can impact outcome and that past studies involving manual therapy may have also been influenced by a lack of equipoise. To our knowledge there are no other studies that have controlled for personal equipoise during comparative investigation of manual therapy procedures.

4.1. Limitations

Limitations included no long-term follow up (discharge occurred on average at approximately 35 days). Additionally, although this study was prospective, report of adverse events, and types of adjunctive techniques were captured retrospectively and clinician recall may have affected the accuracy of reporting. Third, the clinicians in this study were highly skilled at TM/NTM and were individuals who had received years of formal manual therapy training. Fourth, a therapist’s own skills and abilities for one intervention over another (TM versus NTM) may have also influenced their perception of personal equipoise. Our query only captured therapist’s beliefs and was unable to differentiate skill of intervention as a contributing confounder. Fifth, there was no true control group used in this study. Finally, the sample was overwhelmingly Caucasian and is unlikely a reflection of the sample characteristics of all clinical sites within the USA.

5. Conclusion

This study found no differences in outcomes of pain, disability, reported rate of recovery, total visits, or days in care, between early use of TM and NTM, when used early in the intervention of patients with mechanical LBP. Future studies should investigate which adjunctive processes lead to better outcomes and whether similarities in outcomes occur during long-term follow up.

Acknowledgments

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