Title: Neuromechanical responses to spinal manipulation and mobilization: a crossover randomized trial (NCT02660801)

Study Protocol

January 2016

Design

This crossover randomized clinical trial was part of a broader research program that aimed to investigate the effects of chronic thoracic spinal pain on spinal stiffness value and its reliability as well as to explore the association between spinal stiffness pain, and muscle activity during assessment.

Participants

Volunteers with chronic non-specific MBP were recruited within the local community. Two experienced chiropractors assessed if volunteers were eligible for the protocol according a list of specific inclusion and exclusion criteria. Inclusion criteria included chronic non-specific MBP for at least 3 months (constant or recurrent), and an age of 18-60 years. Participants were excluded if they presented at least one of the following criteria: contraindications for SMa/SMo , spinal surgery history, thoracic scoliosis, thoracic herniated disc, radiculopathy, myelopathy neurological disease, osteoporosis, uncontrolled hypertension, aortic aneurysm, inflammatory or infectious disease and pregnancy. The study protocol was registered in ClinicalTrials.gov (NCT02660801) and approved by the local university research ethics committee (CER-16-220-07.04). All participants provided their written informed consent.

Experimental Protocol

Baseline information

The protocol consisted in two experimental sessions within 72 hours. Prior to the experimentation, participants completed various questionnaires to document demographic data (afe, sex, weight, height), pain the last three months and to assess disability (Quebec Back Pain Disability questionnaire, QBPDQ), kinesiophobia (Tampa Scale for Kinesiophobia, TSK), and risk of poor prognosis (STarT Back Screening Tool, SBST).

Outcome variables

Spinal stiffness assessment and pressure provoked pain

Spinal stiffness is the relationship between spinal displacement and the resistive force to that movement. All participants received information about the basic functioning and main security features of the experimental apparatus. Once baseline information was collected, spinal stiffness was assessed at T5, T6, T7 and T8 using a custom-made apparatus. This latter uses a servo controlled linear actuator motor (Linear Motor Series P01-48x360; LinMot, Inc,

Zurich, Switzerland) and was initially developed to simulate spinal manipulation. According the used parameters, it could also be possible to use this apparatus to assess segmental spinal stiffness as well as to simulate spinal mobilization. During the spinal stiffness assessment, the apparatus, using a single-tip padded rod, vertically displaces a slider directly applied over the targeted spinous process (i.e. T5, T6, T7 or T8). During this procedure, a force is progressively applied to reach a peak force of 45N (rate of force application: 18N/s) that is held for 1 second before being released. Instructions were given to the participants to hold their breath at the end of exhalation before the apparatus contacted the spinous process for the time of the assessment. This procedure was repeated 4 times for each spinous process before and after the therapeutic modality application. The order at which the four spinal levels were assessed was randomly generated by an online scheme generator.

Pressure provoked pain intensity was assessed immediately after each spinal stiffness assessment using a 0 to 100 visual analog pain scale. Spinal stiffness assessment and clinical pain levels were assessed before and after the interventions at T5, T6, T7 and T8 levels.

Muscular responses

Muscular responses and pain intensity were recorded during the experimental protocol. Muscular activity was recorded using surface electromyography (sEMG) electrodes during the modalities (Trigno EMG systems, Delsys inc., Natick, Massachusetts, United States). This activity was recorded at 2K Hz using four Trigno Wireless EMG sensors, which were applied bilaterally, just above and below the area contacted by the apparatus (approximately 2 cm from midline), where the therapeutic modality was executed. Skin impedance was reduced by shaving body hair, abrading the skin with sandpaper and cleaning it with alcohol. To reduce EMG signals variability, a normalization trial was performed at the beginning of the protocol. Participants were asked to perform an active extension of thoracic spine from a prone position and to hold this position for 4 seconds.

Therapeutic modalities

The therapeutic modality was applied on transverse processes of the most painful vertebral level reported by the participants during the spinal stiffness assessment. SMa and SMo were applied to the spine by the apparatus through a twin-tip padded rod. The site where

SMa or SMo was applied at the first session was randomly generated by a computer. If SMa was delivered at the first session, SMo was applied at the second one and vice versa. The apparatus was programmed to execute a SMa characterized by a preload force of 70 N for 500 ms leading to a peak force of 260 N in 125 ms (rate of force application: 1520 N/s) and to execute a SMo using 3 oscillatory cycles of 85 N in 800 ms (rate of force application: 106 N/s) (figure 1).

Statistical Analysis

Descriptive statistics were used for baseline characteristics (gender, age, height, weight, pain the last three months, QBPDQ, SBST and TSK) and clinical characteristics of participants (spinal stiffness, provoked pressure pain and muscular response).

Normality and equality of variances were assessed using the Shapiro-Wilk and the Levene test, respectively. The Wilcoxon signed-rank test was used to compare muscular responses during SMa and SMo. A mixed model two-way repeated measures ANOVA was performed to assess Treatment and time main effects as well as the interaction effect (treatment x time) for spinal stiffness and pressure provoked pain. If a variable was not normally distributed, a mathematical transformation was performed to comply with ANOVA assumptions. Whenever ANOVA yielded a significant effect, a Tukey post-hoc test was computed. The level of statistical significance was set at $p<0.05$ for all analyses and the STATISTICA statistical package version 7.1 (Statsoft, USA) was used to conduct analyses