

Study Protocol

Prediction of the Axial Rotation of the Atlanto-Occipital Joint by Means of the Modified Manual Ankle Rigidity Test and Radiography: Study Protocol for a Randomized Double-Blind, Controlled Trial

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Abstract

Background: Chiropractors use a wide variety of diagnostic tests to detect and adjust vertebral subluxations. Measures of leg length inequality have evidenced some validity and one of its types, the supine leg check, is used by some chiropractic upper cervical procedures to measure in millimeters functional leg discrepancy that is supposed to occur due to an atlas misalignment lesion. Yet, this measurement is not supported by face validity. The modified ankle rigidity test may be more valid in measuring the muscular dysfunction related to the atlas subluxation, if any. The objective of this study is to evaluate the accurateness of the predicted rotational degree of the first vertebra as measured by X-ray through the response elicited by a chiropractic device at a particular rotational setting detected by the modified ankle rigidity test. Another secondary outcome will be measured to observe possible changes in functional leg discrepancy with the leg length inequality test. A mechanical chiropractic device will be used as the adjustment method.

Methods/Design: A double-blind, randomized controlled trial consisting of 50 patients with chronic back pain will be conducted. Patients with no contraindications for spinal adjustment will be recruited. During the course of the session, different adjustments will be delivered with a mechanical chiropractic device until a change is observed as measured by the primary outcome test. Also, two secondary outcome measures will be taken. Patients will be randomized into two groups to receive the intervention at two different cervical spinal levels.

Discussion: We expect the primary outcome test to measure a neurophysiological response elicited after the application of the mechanical chiropractic device at a certain rotational degree. This degree should match by at least one degree of rotation the rotational radiographic measurement of the first vertebra. The leg length inequality test may or may not show changes before and after the procedure. If the clinician is able to predict the matching by means of the primary outcome test, this would indicate a predictable and more valid diagnostic test for the spinal condition treated.

Trial registration: ISRCTN20667529. Registered 25 May 2017.

Keywords: *Chiropractic, manual therapy; diagnostic test; leg length inequality; functional leg length; ankle rigidity; atlantooccipital joint; chiropractic intervention; adjustment, vertebral subluxation, spinal manipulation; radiography*

Introduction

Diagnostic tests have been studied to measure the effectiveness of chiropractic.¹⁻⁵ A review of the literature by Triano et al. (2013) indicated "high quality evidence supporting the use, with limitations, of static and

motion palpation, and measures of leg length inequality"¹ (LLI). The ten most commonly practiced chiropractic techniques use traditional leg checking procedures⁶ for diagnostic and intervention purposes.

Chiropractic upper cervical techniques use the "supine leg check" test to measure functional leg discrepancy (FLD) changes before and after an intervention,⁷ a procedure criticized for not showing face validity since millimeters measure length not spinal subluxation.⁸ A theoretical physiologic mechanism for that phenomenon is that "the atlas misalignment affects the nervous system through altered weight bearing on the occipital-atlanto-axial joints, thereby stimulating joint mechanoreceptors. Resultant reflexes may create a functional leg length inequality and observable postural asymmetry."⁷ Woodfield et al. (2011) concluded "moderate reliability in assessing leg-length inequality at 1/8-in increments and good reliability in determining the presence of a leg-length inequality".⁹

To overcome the clinician variability in measuring millimeter leg length distances, DeWitt et al. (1994), used an optoelectric device for obtaining leg length inequality measurements in sub-millimeters.¹⁰ Biomechanical assessment of human posture using automated devices for clinical applications have been reviewed.^{11,12} This study will use the leg length inequality test (LLIt) to measure LLI with a motion capture device (MoCap) model Optitrak Motion system, which has been shown "comparably accurate to their high-end competitors."¹³⁻¹⁴

The manual ankle rigidity diagnostic test is used by clinicians¹⁵ to assess levels of muscle rigidity in upper motor neuron conditions such as spasticity. Although the most used and cited definition of spasticity makes reference to Lance's work more than 30 years ago in which "spasticity is a motor disorder characterized by a velocity-dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex,"¹⁶ other authors have considered the alternative terminology "reversible muscle hypertonia" to define "a focal, regional or generalized constant or posture- and/or activity-related state of skeletal muscle tension due to an upper motor neuron lesion that clinically manifests as resistance to passive muscle stretch, which may interfere with body functions, tasks and actions potentially treatable with conservative methods."¹⁷ This terminology allows the clinician to distinguish on the components of spasticity (clonus, spasms, hypertonia) that may be due to poor motor control rather than on spasticity itself.¹⁸ This study will use a modified version of the manual ankle rigidity test (MART) to measure the outcomes of the treatment.

Chiropractic interventions are typically applied manually. Although the mechanization of a manual chiropractic intervention with the use of a device (mechanical-assisted adjustment) may reduce the variability and increase the consistency of the applied force between examiners,^{19,20} there is no evidence indicating superior outcomes comparing manual vs instrumented chiropractic interventions.²¹⁻²³

This study will use a mechanical chiropractic device (MCD) used in upper cervical procedures.²⁴ No published study has shown the neurophysiological effects elicited by this MCD.

We believe that if the MART is able to detect an outcome, this should occur at a certain rotational setup of the MCD which should match the degrees of rotation of the atlantooccipital

joint (AOJ) in X-ray (the correct vector or CV) thus the MART should reflect the radiographic results.

Radiographic procedures for measuring spinal displacement on plain radiographs, including X-ray line drawing and patients positioning, have been documented as highly reproducible.^{25,26} Reliability studies exist showing that inter- and intra-examiner reliability are sufficient to measure rotational displacements of the AOJ to within +/- 1 degree.²⁷

Study aim

The purpose of this study is to evaluate the accurateness of the predicted rotational degree set on a mechanical chiropractic device (this is, the CV) by the main assessor in 50 subjects through the elicited immediate neurophysiological response as measured by one diagnostic test (MART) as compared to the radiographic measurement of the AOJ. Another diagnostic test (LLIt) will be used to assess possible changes in FLD.

METHODS

Methods/Design

This study is a prospective double-blind trial of one diagnostic test as primary outcome (MART) compared to radiographic measurement of the AOJ (as a gold standard) and another test (LLIt) as a secondary outcomes.

Enrollment and eligibility criteria

50 consecutive patients attending a chiropractic clinic in Girona (Spain) will be recruited by a doctor of chiropractic based on the following inclusion criteria: 1) present or past history of back pain; 2) any gender aged from 18 to 70 years old; 3) consent to participate in the study. Participants will be excluded from the study if they are presently suffering from: 1) tumour; 2) spinal fracture; 3) back pain associated with externalized cervical disc herniation; 4) previous back surgery; 4) dizziness and vertigo; 5) spasmodic torticollis. Patients will corroborate these conditions according to their knowledge of their past clinical history. Patients will also be excluded if: 1) they can't sit for more than 30 minutes; 2) they have received other manual therapies in the previous ten days of the study; or 3) they have been under similar care than the one used in this study in the past. Pregnant women will be also excluded. If and when the participant qualifies based on the above criteria and has signed the informed consent form, the recruiting chiropractor will proceed with the physical examination (PE).

Clinical history and physical examination

A short clinical history and PE will be used to assess the patients' eligibility and need for treatment. Clinical history taking includes questions referring to the onset, episode, nature and location of past and present back pain, as well as factors such as medication and use of past physical treatments. The PE will include one test, the MART.

The MART (as used to evaluate the primary outcome in this study) is a modified version of the ankle rigidity test used in spasticity evaluation, devised by the main assessor,²⁸ to measure muscle dysfunction due to an atlas rotational

misalignment lesion. It involves the assessor compressing the heels with the thumbs in a Y direction with a force of about 5lbs.²⁹ and the use of the rest of the hand to measure resistance to passive motion of dorsi-plantar flexion (at the sagittal plane) and eversion-inversion (at the frontal plane) of the patients' ankles as indicated by the shoe-sole reference of the special shoes (figure 1). Results will be recorded using a scale similar to the Ashworth scale, as used for spasticity measurement¹⁵ with 3 different levels of recorded change. If the MART does not indicate positive for ankle rigidity, the patient will be excluded from the study at this point.

Design

The study begins after the subject has agreed to participate in the study and the history and PE have confirmed the eligibility of the subject.

The intervention session starts with assessment of muscle dysfunction with the MART, followed by the LLIt with the MoCap (figure 2). Next, the adjustment is applied with the MCD according to the criteria of the main assessor.³⁰ After each application or attempt, the assessor uses the MART to evaluate changes. If no changes are observed, a second attempt is carried out and so on. If changes are observed, the assessor stops treatment and performs the LLIt. After data is recorded, the assessor and the subject go to the X-ray clinic (Gabinet Mèdic de Diagnosi i Tractament, Plaça Josep Pla 11 17001 Girona) to take the radiographic view. The assessor is blinded to the results by not seeing the X-ray at any time; he only positions the patient, following similar instructions as described for this purpose³¹ and the clinic X-ray technician takes the radiograph. The radiographic equipment is regularly aligned by the clinic owners. The results will be kept in the X-ray clinic and at the end of the study they will be sent to an independent assessor for evaluation. Then, all the results will be sent to the statistician for compilation.

Randomization

Subject randomization is designed to observe any significant change in outcomes for the placement of the instrument stylus at the time of the force delivery; that is the observed variable. Block randomization will be used, splitting the 50 subjects of the study equally in two groups: 1) The high contact group (HC group), in which the stylus of the MCD will be placed on the level of the atlas transverse process as palpated by the clinician in the first 25 subjects, an anatomical reference than has been validated³² (figure 3). 2) The low contact group (LC group), in which the stylus of the device will be placed seven centimeters below the level of the transverse process of the atlas (figure 4).

Blinding

To minimize performance bias, the assessor who is conducting the adjustment will be blinded to the radiographic information analyzed by the independent assessor that informs of the axial rotation of the AOJ which is the expected degree that needs to be set at the MCD which will deliver a neurophysiological response. The X-ray is taken after the adjustment and the results are hidden from the assessor until the conclusion of the study by the statistician.

Additionally, the subject will not be aware of the outcome since the adjustment is painless and nothing is felt at the time of the force delivery through the stylus of the MCD except a clicking sound at every attempt.

Intervention

After the agreement consent is signed by the subjects, the clinical history is taken and the PE is performed, the adjustment will be delivered using the MCD (figure 5) mounted on the Joaquin Valdivia (JV) table (figure 6).

The patient lies reclined on the JV table, with arms next to the body, in a relaxed position. The JV table and the accessories used (e.g.: the sandals) have been built to reduce the patient, procedure and clinician variability. Before the adjustment begins, patients will be instructed that they will hear a series of clicking sounds at their neck level, indicating the type of percussive force delivered at every attempt realized by the clinician. This force is undetectable by the subject. The mechanism of force has been described as "A mechanical impulse is imparted to a metal stylus by means of a spring loaded plunger. The strength of this impulse is determined by the initial degree of compression given to the plunger spring. The impulse imparted to the stylus by the plunger excites a compression wave in the stylus. The Percussion Force velocity of this wave in the stylus material is determined by the square root of the ratio of the Young's modulus to the density of the stylus material at the patient-stylus interface, dependent on the impedance match, a portion of the wave energy is transmitted into the patient and a portion is reflected back to the plunger."²⁴

The stylus of the device will be placed on the level of the atlas transverse process as palpated by the clinician in the first 25 subjects (high contact group -HC) and 7 centimeters below the level of the transverse process of the atlas in the other 25 subjects (low contact group -LC) as a way to assess possible changes in outcomes considering the positioning of device variable.

Outcomes

Primary outcomes:

Primary outcome measurement will be assessed before and after every adjustment attempt with the MART.

Secondary outcomes:

Secondary outcome measurements will be assessed with two tests:

- 1) The LLIt will measure in sub-millimeters any possible change in subjects' leg length discrepancy detected by the MoCap at the beginning of the study and after the last adjustment. One marker is placed at each of the patients' heels before any treatment. The motion capture device measures the leg discrepancy. After the last adjustment attempt the measurement is taken again. Data is stored in the computer software.
- 2) Radiography: after the last adjustment attempt and after

the second LLIt measurement, the assessor and the subject will walk to the local clinic (five minutes walking distance) to take one radiographic view. The view is similar to the medical view named Hirtz (aka “vertex” or “horizontal film”) and is used to measure the degrees of rotation of the AOJ. The X-ray will be examined following a protocol similar done in other studies³³ by an independent examiner and the results sent directly to the statistician (figure 7).

Statistical methods

Number of test subjects

A sample size of 50 consecutive patients attending a chiropractic clinic will be recruited after the eligibility process. Similar trials of diagnostic tests studies have utilized approximately this number of patients.^{9,34,35}

Statistical analysis

The degree of the CV at which the MCD elicited the neurophysiological response will be recorded manually by the main assessor listing the right side of the patient. An anterior rotation will show a + sign, and a posterior rotation will show a - sign (as stated by the Y axis of rotation in the horizontal plane by the Cartesian coordinate system suggested for the human body³⁶), followed by an integer from 0 to 10. Ten degrees of atlas rotation is the maximum the main assessor has seen in clinical practice. The atlas rotation to the nearest one-tenth of degree (one position decimal number) as analyzed by the independent assessor will be recorded digitally, listing the right side of the patient followed by a + or - negative sign. Both degrees will be compared as to the approximation between the blinded main assessor and the gold standard as measured in X-ray, as the first statistical calculation outcome. The amount of millimeters of LCD discrepancy before the adjustment and after the last adjustment that elicited the neurophysiological response by the MART will be recorded digitally by the motion capture device software in a laptop computer running with Windows10. A positive sign will be used to record a right short leg followed by a one position decimal number. No sign will be used to record a left short leg followed by a one position decimal number according to the degrees of freedom for non-weight bearing foot posture.³⁷ Both millimeter measurements will be compared as to assess the possible change before and after, as the second statistics calculation outcome.

A database descriptive statistics will be made. Descriptive tables will be used in case of continuous variables. Frequency tables will be used in case of qualitative variables. Depending on the data distribution (Shapiro-Wilk test), a comparative parametric test (normal distribution; ANOVA) or a median non-parametric test will be used to compare the first and second statistical calculation outcomes. Statistical decisions will be taken at 5%, this is, with a 95% confidence level.

With the use of the same statistics, the outcomes in participants sub-grouped in the HC and LC group will be assessed to analyze the variable of the study (placement of the MCD stylus). If outcomes are not similar, other variables (e.g.: age, sex) can be assessed with the help of logistic regression.

The data will be collected, stored and analyzed in the SPSS v23 statistics program.

Ethics and data security

This trial has not yet been approved by the local IRB. All patients will be asked to provide written informed consent prior to participating in this study. The collected data will be in the assessors' clinics until sent to the statistician.

Discussion

A manual diagnostic test should be able to predict an outcome²⁰ able to be represented by a gold standard.^{1,4,35} In this study we want to assess how much the rotational vector set on the MCD approximates the rotational measurement analyzed on an X-ray for the AOJ. Radiography is the gold standard but it can't be used during every patient's visit because of radiation issues, thus the need for a radiation-free test.

The purpose of this study is to assess how accurately can a clinician predict the degrees of axial rotation of the AOJ in 50 subjects relying on the immediate neurophysiological response measured by the MART after a series of attempts, set on different vectors, using a MCD. Our range of predictability is one degree or less. That's a good prediction in our opinion that can't randomly be obtained (null hypothesis). The prediction includes if the CV on the right side of the patient is anterior or posterior and the degree number. Although the normal degree of static atlas rotation has been reported to be between zero and five degrees^{33,36} it is common in clinical practice to measure larger rotations. The assessor has measured rotations up to 10 degrees. Bone anomalies may play a role on that.

We do not expect to see a post adjustment change in the AOJ axial rotation X-ray. If there was a change to neutral position of C1 after the adjustment, our post X-rays would show a zero-degree rotation in a significant number of subjects. That's not what we observe in clinical practice nor have we seen it in any study.

If the sample size is not big enough to find a statistical significance, the study will be carried out further with more subjects. We found that gathering 50 consecutive patients attending a chiropractic office matches the average number of patients used in similar studies.^{9,34,35} On the other hand, we can't control variables such as group ages, gender, physical conditions, etc.

Regarding blinding and randomization, we don't see an obstacle to blinding the assessor to the HC and LC groups since the outcome is what matters and the assessor is totally blinded to it.

The chiropractic device used in this study has not been previously validated although it's been in use since about 1980.²⁴ There has not been any study showing data if the device elicits a neurophysiological response. What type of response is. when and why the response is elicited. What test measures the response. The reproducibility and accuracy of the test. The face validity of the test. The predictability of the results compared to a gold standard. What condition is being

treated. The results of this study may provide useful information and answers for clinicians on those questions. To our knowledge, no device or manual physical treatment or test has been fully documented with that type of data. Until that type of data is obtained by clinicians or researchers we understand that no clinical trials can be carried out efficiently to assess clinical outcomes on patients.

This study also may provide answers to issues previously debated and researched by several authors^{5,38-49} on the topic of assessing the effects of manual therapies and patient outcomes, such as the importance 1) of whether a segmental level requires adjustment or a force application; 2) at which side of the body of the patient adjustment is required; 3) of the specific segmental contact; 4) of the vector of adjustment (commonly termed line of drive).

Finally, this study could show clinical significance: reduction of muscle dysfunction as measured by the MART.

Abbreviations: LLI: leg length inequality; FLD: functional leg discrepancy; MoCap: motion capture device; MART: modified ankle rigidity test; LLIt: leg length inequality test; MCD: mechanical chiropractic device; AOJ: atlantooccipital joint; CV: correct vector; PE: physical examination; JV: Joaquin Valdivia; ANOVA: analysis of variance.

Declarations:

Ethics approval and consent to participate: The study is awaiting ethical approval from the local IRB from Girona, Spain (Comitè d'Ètica d'investigació Clínica (CEIC) de l'Hospital Universitari Doctor Josep Trueta).

Consent for publication: Written informed consent was obtained from the patient for publication of accompanying images.

Availability of data and materials: Data sharing is not applicable to this article as no datasets were generated or analysed during the current study. The equipment used in this study is owned by the main assessor of this article.

Competing interests: The author declares no competing interest.

Funding: There is no funding.

Authors' contributions: Joaquin Valdivia Tor is the only author of this manuscript.

Acknowledgements: Not applicable.

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Figures



Figure 1. The Mart. The electric part of the JV table elevates the legs of the patient and the assessor performs the MART to assess ankle rigidity, a sign of muscle dysfunction due to AOJ misalignment lesion. Special shoes made of wood that fit almost all patients (similar to sandals).



Figure 2. The LLIt. Markers are placed on the patients' heels to measure FLD or LLI with the MoCap through the LLIt. The assessor doesn't touch the subject and the computer software (developed by STT-systems. <http://www.stt-systems.com/>) takes sub-millimeters measurements.



Figure 3. The high contact group (HC group). In the "high contact group," the stylus of the device is placed below the ear lobe at the C1 transverse process palpation landmark.



Figure 4. The low contact group (LC group). In the "low contact group," the stylus is placed seven centimeters below the transverse process of the atlas landmark reference.



Figure 5. The MCD. The chiropractic adjusting device used for the intervention in this study is a percussive mechanical instrument delivering a force through the stylus (previously manually spring-loaded) of 5.40 lbs. It is used by the Atlas Orthogonal Chiropractic Technique (FDA 510 (K) Number K951217). Three main parts can be observed: 1) the stylus (where the force is transmitted from the device to the subject; 2) the loading mechanism (which loads the spring; 3) the trigger (which delivers the force upon its pressure).



Figure 6. The JV table. The JV table (stationary and reclined) has been built (Atroy Fitness. atroy.com) for research purposes. The patient doesn't move during the whole procedure and the clinician moves and touches the patient the least possible. It also allows accommodation to patients who can't lay supine, such as the elderly or patients suffering with vertigo. Its parts consist of: 1) The reclined seat blocks the patient by the hip; 2) The head support accommodates the subjects' head; 3) The strap on the head support blocks the patient by the head; 4) The motor elevates the patient's legs as the assessor needs; 5) The feet holders block the legs by the distal part of the fibula; 6) The **moveable arm** (built by AUTTIN S.C.-17178 Les Preses, Girona, Spain) attaches the chiropractic adjusting device to the JV table by means of a cone-type support of 23 centimeters diameter. This allows placement of the stylus of the device to any cervical anatomical reference of the patient and makes it possible to change the rotational settings of the device 360° without missing contact.



Figure 7. The Hirtz radiographic view and analysis. The Hirtz radiographic view (aka “vertex” or “horizontal film”) is taken with the patient seated in a stool and the head slightly elevated with the chin leaning onto the bucky. The positioning is adapted for the X-ray machine used (GE Medical Systems MS-18S). The central ray is at 115 centimeters, passing from the top of the skull to the transverse process of the atlas bone.

The purpose of the X-ray is to analyze the AOJ rotation in degrees in relation to the center of the skull using the center of the transverse processes of the atlas and a line drawn through the nasal septum parallel to the edge of the film as references by the independent assessor.