Title

“Immediate effects on cervical mobility and spiratory flow, after bilateral manipulation of first rib, in non-specific chronic neck pain: study protocol for a randomized controlled trial”

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Abstract

- **Background:** Numerous publications have showed the biomechanical influence of thoracic spine on cervical spine. Recently, some authors have pointed out the role of other physiological systems in this relationship, what have been called interdependence regional model. It has been studies that interventions applied over thoracic spine have a neurophysiological influence on cervical spine and respiratory system. Our study evaluates the influence of bilateral manipulative technique of first rib on pain and pulmonary function in subjects with chronic non-specific neck pain.
- **Methods:** The immediate changes produced by bilateral direct manipulation (HVLA) of first rib in subjects with non-specific chronic neck pain will be studied. The sample will be randomly divided into two groups, experimental and placebo. As dependent variables of the study, we will measure the peak expiratory flow and cervical rom. Findings will be analyzed statistically considering a 5% significance level ($p \leq 0.05$)
- **Discussion:** Our study aims to provide knowledge about the influence of bilateral manipulative technique of first rib in pain and pulmonary capacity in subjects with non-specific chronic neck pain. The efficacy of this technique may entail an easy access and low cost strategy in patients with pain and a reduction in pulmonary function.

Trial registration

Brazilian Clinical Trial Registry, **RBR-4dsvfy**.

Registered on 17 March 2020. Retrospectively registered

Keywords

Neck Pain – Chronic Pain – Musculoskeletal Manipulations – Ribs – Physical Therapy
Specialty – Range of Motion, Articular – Pulmonary Ventilation – Maximal Voluntary
Ventilation

Background

Nonspecific neck pain is pain that does not show pathognomonic signs and symptoms, [1] when the duration of symptoms is greater than 12 weeks of evolution, it acquires the value of chronicity, being denominated non-specific chronic neck pain. [2] It is a common disorder, which generates a great impact and socio-economic cost. [3] This impact in personal life, social environment, community, health system and enterprises is high. Although some studies show that among 33% and 65% of subjects recover from an episode of neck pain after a year, most of cases refer that symptomatology remains during life and, thus, recurrence is common [4]. Moreover, psychosocial factors in neck pain are determinants for understanding and management of this condition, not just paying attention to musculoskeletal factors and approaching this condition from a biopsychosocial perspective. [5,6]

In last years, epidemiologic research in relation to neck and shoulder pain has shown the relationship between these anatomic regions. In that sense, a recent study performed in 18 different countries which included 12195 workers shows that it is important to assess the different forms of presentation in relation to neck/shoulder pain and other associated signs and symptoms. [7] In addition, some authors have developed the regional interdependence model, [8-10] defined by Wainner RS as "the concept that seemingly unrelated impairments in a remote anatomical region may contribute to, or be associated

with, the patient's primary complaint." [11] Meanwhile, Bialosky et al argued that although the regional interdependence model has been focused on musculoskeletal system, underlying mechanisms to patient's complaints and main signs and symptoms could be more complex, involving other physiological systems including those related to peripheral, spinal cord or supraspinal mechanisms. Any condition or pathology trigger a cascade of reactions that affects not just musculoskeletal system, but also biopsychosocial, somatovisceral and neurophysiological systems. [8]

Clinical interest in thoracic spine has grown despite the lack of evidence that supports the implication of this region as main source of pain symptomatology [12], what can be observed in the number of studies investigating and supporting the application of manipulative therapy in thoracic spine for treating cervical signs and symptoms, as disability, pain and range of motion. [13-16] In that sense, Heneghan N. and Rushton A. theorized about how thoracic dysfunction could be involved in triggering and maintenance of pain in other region [17]. In the same way, McDevitt A. et al supported the interventions applied over thoracic spine for the treatment of upper quarter conditions, in line with the interdependence regional model and the neurophysiological effects of spine manipulation. [10] From the point of view of thoracic mobility, Tanaka R. et al studied the quantitative analysis of rib kinematics through dynamic chest bone images, and they found that bone fractures and vertebral deformities limit respiratory function because of reduction of ribs mobility, what leads to a decrease in vital capacity. Thus, this fact explain the influence of thoracic mobility in pulmonary function and vital capacity [18]. Abnormal movement of rib and chest wall is very common among patients with chronic obstructive pulmonary disease. [23,24] Different studies have tried to prove the influence of manual therapy in respiratory function, although results are highly variable, so no determining conclusions have been found between different authors [25-31].

The aim of the present study is to evaluate the influence of bilateral manipulative technique over first rib, so common in clinical practice, on cervical range of motion and peak expiratory flow in subjects with non-specific neck pain.

Primary Objective

To determine if bilateral manipulative technique (HVLA) over first rib in prone position modifies middle cervical range of motion and the spirometric value of maximum expiratory flow at short term in subjects with non-specific neck pain.

Hypothesis

Bilateral manipulative technique over first rib in prone position modifies mobility of middle cervical spine in subjects with non-specific neck pain, in flexion, extension, rotation and side bending, as well as the peak expiratory flow.

Trial Design:

Randomized, controlled, multicenter, parallel, double-blind, two-arm clinical trial of treatment.

Methods/Design

Sample Selection

Individuals with NCNP will be recruited through a text message broadcast on social networks in the city of Almeria (Spain) and will be selected based on the eligibility criteria listed below. The study will take place in the facilities Clinic Fisiosur i+D NICA: 15233 and Clinic Health XXI, NICA: 28841.

Inclusion criteria

- Age 18–55 years
- Current neck pain
- Neck pain continued for at least the last twelve weeks. [2]

Exclusion criteria

- Irradiated neck pain
- Neck pain associated with vertigo
- Osteoporosis
- Vertebral fractures
- Tumors
- Metabolic diseases
- Previous neck surgery
- Red Flags (Night pain, severe muscle spasm, loss of involuntary weight, symptom mismatch)

Interventions

The participants can only receive the assigned treatment; they can not combine the treatment with drugs or other physiotherapeutic treatment. Any interference in the treatment will be grounds for exclusion.

Group 1: Bilateral First Rib Manipulation

The subject will be in seated position while the therapist stood behind. One of the therapist's hands will contact the rib's body with the metacarpophalangeal joint of the index finger, while the thumb will lie over the supraspinatus fossa, and the rest of the fingers over the clavicle. The other therapist's hand will be holding the patient's head, exerting ipsilateral cervical side bending towards the first rib, and contralateral head

rotation. Then, an inferomedial pressure will be applied to the first rib until the end-feel, and this will be followed by the thrust manipulation. [32]

Group 2: Sham Treatment

Patients will be placed in the supine position, while the physiotherapist, sited at the head of the table, will place the palms of his hands under the subject's head, his fingers contacting the space between the occipital condyle and the spinal process of the second cervical vertebra, but with no pressure at this region, simulating the technique of suboccipital inhibition. This procedure has been used in previous studies [33,34]

Outcomes Measures

- Cervical range of motion in flexion, extension, right and left side bending and right and left rotation. It will be measured with "Clinometer version 4.3 on iOS for Smartphone (Iphone 6, Apple, USA). The subject will be seated for all measurements, and the device will be placed in subject's head through an element with adaptive support. [35-37]
- Peak Expiratory Flow (PEF). It will be measured with the device PIKO 1 (PIKO 1, FERRARIS RESPIRATORY, USA). [38,39] The subject will be seated, and we will ask him/her to inspire through the nose. After that, he/she will place the spirometer in his mouth, and we will ask the subject to expel all the air. This procedure will be repeated three times. All measurements will be registered, and the definitive value will be the mean of the three repetitions.

These variables will be measured in the pre-evaluation and post-evaluation (short-term). These evaluations will be carried out by an evaluator trained in developing them, and the data will be stored in an excel document.

Participants' timeline

A brief Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) flow diagram is provided in Fig. 1, and a populated SPIRIT checklist is provided in Additional file 1.

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation (treatment)		
TIMEPOINT	3 Month	Day 0	Day 1 Pre-Evaluation	Day 1 Intervention	Day 1 Post-Evaluation
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
<i>Clinical Evaluation and Inclusion -Exclusion Criteria</i>	X				
Allocation		X			
INTERVENTIONS:					
<i>First Rib Manipulation</i>				X	
<i>Sham Protocol</i>				X	
ASSESSMENTS:					
<i>Demographic Data</i>	X				
<i>Cervical Flexion ROM</i>			X		X
<i>Cervical Extension ROM</i>			X		X
<i>Cervical Lateral Inclination ROM</i>			X		X
<i>Cervical Rotation ROM</i>			X		X
<i>Peak Expiratory Flow</i>			X		X

Sample Size Calculation

Sample size calculation resulted in a total of 49 subjects, who were divided into two groups: a control group of 24, and an experimental group of 25. Differences between groups minimum to detect of 11.5% (0.115) for cervical flexion mobility. [40] Considering an alpha value of 5% (0.05); a beta value of 20% (0.20) in an unilateral contrast; a standard deviation of 15%; an unit ratio between subject of each group; and finally, a loss rate of 8%. Software Granmo online (version 7.12) was used for sample size calculation and a significance value of 5% (0.05).

Randomization

Subjects will be divided into two groups by means of balanced randomization, carried out with free software (<http://www.randomized.org/>). The randomization sequence will only be done by the principal investigator and auditor.

Blinding

Evaluator and participants in the study will be blinded during the entire process.

Statistical Analysis

The statistical analysis will be carried out through the IBM-SPSS Statistics 24 software. The normality test applied to all the variables will be the Kolmogorov-Smirnov test. For the contrast of intragroup hypotheses, Student's T test for paired variables will be applied in the case of parametric distributions and Kruskal-Wallis H for non-parametric distributions. For the intergroup hypothesis contrast, t-Student will be used in the case of parametric distributions and Mann-Whitney's U for nonparametric distributions. The confidence level used will be 95% (0'05) and the power of the study will be 90% (0'1).

Discussion

This article presents a detailed description of a randomized controlled trial designed to analyze the results in terms of range of motion and peak expiratory flow produced by bilateral manipulative technique of first rib through HVLA.

High variability of results can be observed in scientific literature. Thus, we try to determine the influence of this kind of manual techniques, which can be an easy access and low-cost strategy, in patients with respiratory conditions, who presents expiratory deficits and reduction in cervico-thoracic mobility, improving mainly in-hospital periods. In relation to chronic conditions, the increased work of accessory inspiratory musculature (scalenes, upper trapezius and sternocleidomastoid) in respiratory pathologies could lead to an overuse of this musculature, [41] which could, at the same time, produce repercussion in high rib biomechanics and, specially, of first rib, triggering difficulties at the inspiratory and expiratory functions, both at rest and during basic activities of daily life. In that sense, manipulative technique of first rib could generate significative changes in chronic subjects.

On the other hand, anatomobiomechanical disposition of cervicothoracic complex could also be affected in cases of chronic neck pain due to movement limitation in different joint planes from this region, [42] where first rib is a point of union and interconnection between cervical region and high thoracic wall. [42-44] That's why the input over first rib and his neurophysiological effect could improve range of movement, pain perception and respiratory function present in subjects with chronic non-specific neck pain. [45]

We have designed a randomized, controlled, double-blinded clinical trial, with the aim that our study could contribute to increase scientific knowledge about this issue, and could initiate new lines of future research.

Trial status

This is the first protocol version. Participants will be recruited between January-March 2020. Study completion is expected to be May 2020.

List of abbreviations

NCNP: Non-Specific Chronic Neck Pain

HVLA: High-Velocity Low-Amplitude

Declarations

Ethics approval and consent to participate

This study complies with the Helsinki guidelines for human research and it has been approved by the ethics committee of the University Hospital Virgen Macarena – Virgen del Rocío. The identification of each individual will remain concealed based on the ethical principles of confidentiality and privacy. All participants will receive an informed consent with information about all treatments and the randomization process that they will approve for participation in the study. Patients assigned to the control group will receive treatment 1 after completing the study.

Consent for publication

Not applicable.

Availability of data and material

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Funding

This trial was conducted with no external funding and its costs have been assumed by researchers.

Authors' contributions

CRB is the director of the project, contributed to the protocol development, provided clinical expertise and he is responsible for designing statistical procedures. CBU is the co-director of the project and contributed to the protocol development and provided clinical expertise. EAL contributed to the protocol in the methodological design and provided clinical expertise. JJGG is the principal investigator and has contributed to the concept and study design, provided clinical expertise and manuscript development. All authors read and approved the final manuscript.

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