# [ RANDOMISED CLINICAL TRIAL ]

# THE MUSCLE ENERGY TECHNIQUE, APPLIED TO THE C7-T1 SEGMEMT HAS NO EFFECT ON BLOOD PRESSURE IN PATIENTS WITH HYPERTENSION CLINICAL SAFETY ANALYSIS

Antonio Moro Pantoja<sup>1</sup> (PT, DO, PhD), Miguel Ángel Lérida Ortega<sup>2,3</sup> (PT, DO, PhD), Manuel Saavedra Hernández<sup>2,4</sup> (PT, DO, PhD), Cleofás Rodríguez Blanco<sup>2,5</sup> (PT, DO,PhD)

Received 4th July 2016'; accepted 26th July 2016

Introduction: AHT (arterial hypertension) is a chronic disease, characterised by a continual rise in blood pressure. In recent years, in osteopathy, attempts have been made to analyse the causes of AHT, to find safe techniques for treating patients with AHT and to obtain positive results in changes to blood pressure after applying the different techniques.

Objectives: to analyse the effectiveness of the muscle energy technique (MET), applied to the C7 segment in patients with hypertension in terms of changes in blood pressure. To analyse whether the muscle energy technique applied to the C7 segment in patients with arterial hypertension is safe.

Materials and Methods: Randomized clinical trial (RCT), experimental, blinded and controlled. Sixty one (n=61) patients with hypertension were randomly distributed into two groups: an experimental group (n=31) and a control group (n=30). An initial assessment (pre-inter-

vention) and a final assessment (post-intervention) were carried out, analysing changes in systolic blood pressure (SBP) and diastolic blood pressure (DBP) in patients with hypertension. The tests previously used were the Mitchell, Jackson and Klein tests. The intervention technique used for the study was the muscle energy technique, applied to the spinal segment C7-T1 for spinal somatic dysfunctions.

Results: No significant differences in variations in SBP or DBP were found between the subjects in the control group and the experimental group for any of the four variables, measuring improvements in blood pressure.

**Conclusions:** The muscle energy technique is a safe technique to apply to the C7-T1 vertebral segment in patients with hypertension.

#### PALABRAS CLAVE

- > Hypertension.
- > Heart rate.
- Osteopathic medicine.

Corresponding author: cleofas@us.es (Cleofás Rodríguez Blanco) ISSN on line: 2173-9242 © 2016 – Eur J Ost Rel Clin Res - All rights reserved www.europeanjournalosteopathy.com info@europeanjournalosteopathy.com

Salux Clinic. Badajoz. Spain.
Professor, Escuela de Osteopatía de Madrid (Madrid School of Osteopathy). Madrid. Spain. <sup>3</sup> Professor, Departamento de Ciencias de la Salud (Health Sciences Department).

 <sup>&</sup>lt;sup>4</sup> Professor, Departamento de Enfermería, Fisioterapia y Medicina (Department of Nursing, Physiotherapy and Medicine). Universidad de Almería. Almería. Spain.

<sup>&</sup>lt;sup>5</sup> Professor, Departamento de Fisioterapia (Department of Physiotherapy). Universidad de Sevilla. Seville Spain.

#### INTRODUCTION

Different authors have studied the benefits or the lack of contraindications of osteopathic techniques applied to different areas of the body and different pathologies and obtained positive results.

Boscá<sup>1</sup> studied the absence of contraindications for a cervical manipulation with a thrust, applied to C7-T1 in patients with heart disease. He also found no contraindication for a global hemodynamic manoeuvre, applied to patients with essential arterial hypertension (AHT). In fact, heart rate (HR) dropped, which is a significant result for patients with hypertension who tend to have a high HR.

Having established the lack of contraindications, it would be interesting to read studies with positive results, where blood pressure (BP) and/ or HR decreased after applying osteopathic techniques to different areas of the body, such as the cervical spine. Irvin Korr<sup>6</sup>, has explained the benefits of manipulating cervical vertebrae, given that somatic dysfunctions in the vertebrae can cause central sensitization. According to this model, somatic dysfunctions are mainly caused by proprioceptors, primarily neuromuscular spindles (NMS). This is because they are sensitive to muscle stress and they are receptors, which do not adapt when being stimulated mechanically and which act specifically on the joints around the dysfunctioning spinal segment<sup>7</sup>, which can irritate the organ innervated remotely<sup>6</sup>.

This concept is supported by Mcknight and Boer<sup>8</sup>, who showed that manipulating the spine reduces blood pressure.

In 2010, Santiago Gómez Castro carried out a literature review and found that a common symptom among patients with primary AHT was increased sympathetic activity and a partial loss of joint stability, which can affect blood pressure and AHT. He observed the evident effectiveness of upper cervical spine manipulations in correcting this joint instability and restoring the balance of the autonomic nervous system and therefore its effectiveness in treating certain types of AHT<sup>3</sup>.

Manipulating a segment of the spine has also been shown to reduce both HR and systolic blood pressure in individuals presenting with stage 1 or 2 AHT, according to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). Therefore, Chiropraxis (spinal manipulation) seems to play a significant role, at least in the short term, in managing essential AHT in patients presenting with stage 1 or 2 hypertension, given that there is no contraindication for patients with hypertension.

Rychlicilvá<sup>10</sup> described the relationship between Coronary Heart Disease and musculoskeletal dysfunctions in T3-T4. Other authors have carried out studies, measuring changes in BP and HR after performing reflexotherapy on the feet. The patients' HR decreased, which could be attributed to increased relaxation, experienced as a result of applying the technique, but there were no changes in systemic blood pressure<sup>11</sup>. Benito M.<sup>12</sup> observed a decrease in SBP in patients with hypertension after applying pressure (6mm) onto the projection of the aortic valve for 90 seconds. There have also been studies showing that manipulation of the craniocervical junction is associated with an improvement in peripheral pathologies such as a temporomandibular dysfunction, due to the anatomic-nervous relationship. This study supports the use of craniocervical junction manipulation to improve mouth opening for patients with temporomandibular joint dysfunctions<sup>13</sup>. Caparosi<sup>4</sup> demonstrated that homeostasis can be regulated by manipulating the craniocervical junction.

Having reviewed these scientific studies, it would be interesting to apply the muscle energy technique (MET) to the C7-T1 segment in patients with hypertension to try to have a positive effect on AHT. This would be especially interesting as AHT is one of the most prevalent risk factors for cardiovascular disease in the world<sup>14-16</sup> and is a serious public health issue<sup>17-19</sup>. Furthermore, it has a high cerebrovascular, cardiovascular and renal morbidity and mortality<sup>17</sup>. It is also closely related to diabetes mellitus (DM) with 80% of patients also presenting with AHT<sup>14,20</sup>.

#### **OBJECTIVES**

To determine whether it is safe to applying the MET to the C7-T1 segment in patients with AHT. To analyse whether the MET applied to the C7-T1 segment affects SBP and DBP the patients' left and right arms

# MATERIAL AND METHODS

## Study Design

A longitudinal, randomised, experimental, controlled triple-blinded clinical trial with an intervention.

Three examiners participated in the study, allowing us to blind the assessor so that they would not know which group the patient they were testing belonged to. We carried out the Mitchell Test, the Klein Test and the Jackson Test on all of the patients and measured their SBP and DBP in the right and left arm pre and post-intervention.

The patients did not know whether they belonged to the experimental group or the control group. They were told that they were participating in a study, applying a technique to either the shoulders or the cervical spine to see how it affected the cardiovascular parameters being measured. But they were not told which technique was being applied to the experimental group and which technique was being applied to the control group.

The statistical data analyst was not told the objectives of the study.

#### **Measuring Devices**

Measuring blood pressure. Blood pressure is taken before and after the intervention using the OMRON ELITE PLUS Blood Pressure Monitor (Elite Plus, OMRON, Kyoto, Japan)<sup>10</sup>.

#### Sampling and Sample Size

We used non-probability sampling for the study, selecting a sample from patients who had been assessed for eligibility: who met the selection criteria and who consented to participating in the study.

We calculated the required sample size, using the Granmo software programme, version 7.12 (Granmo, IMIM Hospital del Mar, Barcelona, Spain) to compare two independent means from a previous pilot study, accepting an alpha risk of 5% ( $\alpha$ =0.05) and a beta risk of 20% ( $\beta$ =0.2) in a bilateral contrast. We concluded that we needed 27 subjects in the first group and 27 subjects in the second group in order to be able to detect a difference in heart rate between the groups equal to or higher than 9.5% (0.095). The common standard deviation was 12% (0.12). Loss to follow-up was estimated to be 5% (0.05) and the statistical power (1- $\beta$ ) was estimated to be 80% (0.8). For that reason, we selected 61 patients in total, distributed into two groups of 30 and 31 patients respectively. There was no loss to follow-up.

# Subjects

The study population was 61 patients (n=61). They were divided into two groups: An experimental group (n=31), who received the MET on C7, depending on the dysfunction each patient presented with. And a control group (n=30), who received a placebo technique.

# Randomisation

The distribution of the patients into the two groups was randomised, using the software provided on the independent website randomized.com<sup>24</sup>. To recruit patients, we selected two Physiotherapy Centres located in Badajoz and Albuquerque. All participating patients were required to meet the following selection criteria:

#### Inclusion Criteria

Patients over the age of 18 with hypertension and with a positive Mitchell's Test<sup>25,26</sup>, who have been diagnosed with AHT, in line with the criteria outlined in the Spanish Guideline for Hypertension (SGH)<sup>27</sup> were included in the study. The SGH criteria states that the patient should have been diagnosed with AHT at least 6 months before inclusion in the study<sup>28,29</sup> and should have been taking stable antihypertensive medication for at least the last three months. Finally, to be included in the study, subjects were required to sign an informed consent form.

# **Exclusion** Criteria

Patients with severe hypertension (BP > 180/100mm hg) at the time of the examination<sup>30</sup>, patients who have suffered any pathology with contraindications for the muscle energy technique applied to the cervical or thoracic spine<sup>31</sup>, patients diagnosed with hypertension less than 6 months before the study<sup>27</sup>, patients with secondary AHT, a terminal illness<sup>30</sup> and patients who have been taking hypertensive medication for less than three months<sup>30</sup> were all excluded from the study.

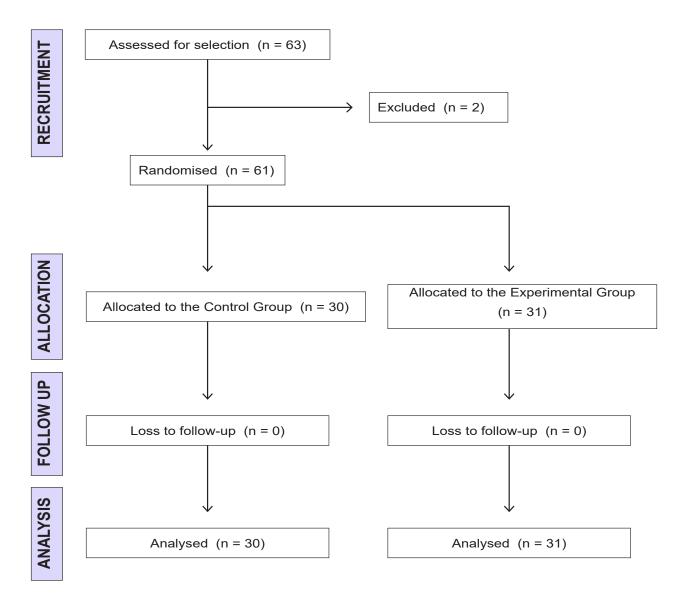


Figura 1. CONSORT Flow Diagram<sup>22,23</sup> for reporting randomised studies.

# Evaluation

Prior to the assessment and the intervention, another assessor collects the data in a file designed for the study and the patient signs an informed consent form, giving permission for their data to be used confidentially, in accordance with the Data Protection Law<sup>32.</sup>The assessor explains to the patient what the study will involve. Finally, the assessor measures and weighs the patients, who is wearing no shoes and light clothing.

In order to minimise bias, the assessors undergo a reliability assessment before the study, which involves taking a sample population of 15-20 people. Three assessors then carried out the proposed tests (blood pressure, Mitchell's test) three times on each patient at different times<sup>33</sup>. From Mitchell's test, we found moderate (0.4 > k < 0.6)and good (0.6 > k < 0.8) agreement between the assessors (inter-rater kappa coefficient;  $\ddagger$  table 1), which supports the reliability of the diagnostic test, which corresponds with other studies that validate the test<sup>34</sup>. We also found good (0.6 > k < 0.8) and very good (k > 0.8) agreement between the results obtained from the repeated tests carried out by each assessor (inter-rater kappa coefficient; § table 1), which supports the reliability of the assessors, as confirmed by the Mitchell's mobility tests. Based on this, we selected the most reliable assessor for our study.

ASSESSOR	ASSESSOR							
	А		В		С			
	K	P-VALUE	К	P-VALUE	K	P-VALUE		
А	0,793§	P<0,001*	0,612‡	0,010*	0,579‡	0,027*		
В	0,612‡	0,010*	0,802§	P<0,001*	0,586‡	0,002*		
С	0,579‡	0,027*	0,586‡	0,002*	0,837§	P<0,001*		

Table 1. Reliability Analysis for Assessors A, B and C

A: Assessor 1; B: Assessor 2; C: Assessor 3; k: kappa index; P-value: statistical significance; § inter-rater kappa;

‡ inter-rater kappa.

#### Tests carried out on both groups

#### RESULTS

Prior to the intervention, we carried the Mitchell Test<sup>35,36</sup>, followed by the Jackson Test<sup>37,38</sup>, the Klein Test<sup>31,37</sup> and a blood pressure test. Blood pressure was taken before and after the intervention using the OMRON ELITE PLUS Blood Pressure Monitor (Elite Plus, OMRON, Kyoto, Japan)<sup>21</sup>.

#### Intervention

The intervention received by the experimental group was the muscle energy technique, applied to C7-T1<sup>25,31</sup>. The control group received a placebo technique. The examiner placed the patient in the supine position and sat at the patient's head. The examiner placed their hands lightly on the patient's shoulders for 30 seconds, producing no clinical effect.

#### **Statistical Analysis**

We carried out a descriptive analysis of the quantitative variables, calculating the mean, median, standard deviation and the 25th and 75th percentiles. We used the Kolmogorov-Smirnov test to analyse whether or not the distribution of the variables was normal. We used the chi-squared and the student's T-test to check the homogeneity of variance in the groups and to establish whether there were any significant differences between the variables. We then carried out intra-group inter-group comparisons, measuring systolic and diastolic blood pressure (pre and post-intervention) and finally a multivariate analysis to assess whether any changes in blood pressure were related to extrinsic or intrinsic factors. All tests were carried out using the statistics programme PASW Statistics 18 for Windows. We used the normality test to check that all of the variables used in the study followed a normal distribution (table 2).

Descriptive statistics and normality tests

#### Intra-group analysis

We analysed four variables to assess whether or not the muscle energy technique applied to C7 would produce any changes in blood pressure. There were no differences in any of the four variables measured in the control group patients before and after the experimental manipulation (table 3).

When we analysed changes in blood pressure caused by applying the muscle energy technique to C7 in the patients in the experimental group, we observed a significant reduction in systolic blood pressure in the right arm after the experimental manipulation. We also observed a reduction in systolic blood pressure in the left arm, diastolic blood pressure in the left arm and diastolic blood pressure in the right arm but these variations were not statistically significant (table 4).

#### Inter-group analysis

No significant differences in variations in SBP or DBP were found between the subjects in the control group and the experimental group for any of the four variables (table 5).

#### Multivariate analysis

We used the SBP results obtained from the field study carried out on the 31 patients who received the MET on C7 (experimental group) and completed a secondary analysis, using IMPROVEMENTS IN SBP IN THE RI-GHT ARM as the dependent variable, analysing whether changes in SBP in patients with arterial hypertension after receiving the muscle energy technique on C7 were linked to intrinsic factors (gender, age) and/ or extrinsic factors (BMI). We used the General Linear Model (GLM) to analyse whether any of the independent variables studied (gender, age, BMI) significantly influenced the reduction in SBP observed in the right arm. For this multivariate model, we used variation in systolic blood pressure in the right arm (IMPROVEMENTS IN SBP IN THE RIGHT ARM) as the dependent variable and we used gender, age and BMI as the independent variables (explanatory variables) (table 6).

	DESCRIPTIVE STATISTICS						NORMALITY TEST	
VARIABLES	MEAN	MEDIAN	STANDARD DEVIATION	PERCENTILE 25	PERCENTILE 75	Z	P-VALUE	
AGE	64,61	64,00	10,30	56,50	71,00	0,532	0,940	
WEIGHT	78,99	77,50	16,84	68,60	89,25	0,645	0,800	
HEIGHT	159,79	159,00	9,30	152,50	167,00	0,722	0,675	
PRE_SBP_L_ARM	140,89	143,00	19,11	127,50	152,00	0,630	0,823	
POST_SBP_L_ARM	141,15	141,00	19,85	126,00	155,00	0,311	1,000	
PRE_DBP_L_ARM	80,79	80,00	11,30	74,00	88,00	0,604	0,858	
POST_DBP_L_ARM	81,13	81,00	12,68	72,00	89,50	0,488	0,971	
PRE_SBP_R_ARM	143,15	143,00	19,07	129,00	157,00	0,495	0,967	
POST_SBP_R_ARM	141,67	140,00	22,11	125,50	154,00	0,498	0,965	
PRE_DBP_R_ARM	81,48	82,00	11,22	74,00	88,50	0,506	0,960	
POST_DBP_R_ARM	80,41	79,00	11,73	71,50	88,00	0,591	0,876	

Table 2. Descriptive statistics and Kolmogorov-Smirnov normality test used for the quantitative variables of this study: Age (years),

Weight (kg), Height (cm), PRE\_SBP\_L\_ARM (pre-intervention systolic blood pressure in the left arm; mmHg), POST\_SB-P\_L\_ARM (post-intervention systolic blood pressure in the left arm; mmHg), PRE\_DBP\_L\_ARM (pre-intervention diastolic blood pressure in the left arm; mmHg), POST\_DBP\_L\_ARM (post-intervention diastolic blood pressure in the left arm; mmHg), PRE\_SB-P\_R\_ARM (pre-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), PRE\_DBP\_R\_ARM (pre-intervention diastolic blood pressure in the right arm; mmHg), POST\_ DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg). The sample size was 61 patients for all variables.

VARIABLES		DESC	RIPTIVE STATI	PAIRED T-TEST RESULTS		
		MEAN	N	STANDARD DEVIATION	Т	P-VALUE
	PRE_SBP_L_ARM	145,20	30	19,72	1 174	0,250
1	POST_SBP_L_ARM	146,87	30	21,35	-1,174	
	PRE_DBP_L_ARM	83,23	30	12,42	0.049	0,351
2	POST_DBP_L_ARM	84,30	30	12,39	-0,948	
3	PRE_SBP_R_ARM	144,80	30	21,69	0.210	0,829
	POST_SBP_R_ARM	145,60	30	26,01	-0,218	
	PRE_DBP_R_ARM	83,07	30	12,01	0.2(2	0 705
4	POST_DBP_R_ARM	82,57	30	13,58	0,263	0,795

Table 3. Descriptive statistics and student's T-test for paired data, analysing variation in the four variables studied in the patients in the control group. PRE\_SBP\_L\_ARM (pre-intervention systolic blood pressure in the left arm; mmHg), POST\_SBP\_L\_ARM (post-intervention systolic blood pressure in the left arm; mmHg), PRE\_DBP\_L\_ARM (pre-intervention diastolic blood pressure in the left arm; mmHg), POST\_DBP\_L\_ARM (post-intervention diastolic blood pressure in the left arm; mmHg), PRE\_SBP\_R\_ARM (pre-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (pre-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (pre-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg).

VARIABLES		DESC	RIPTIVE STATI	PAIRED T-TEST RESULTS		
		MEAN	N	STANDARD DEVIATION	Т	P-VALUE
	PRE_SBP_L_ARM	136,71	31	17,84	0 ( 25	0,537
1	POST_SBP_L_ARM	135,61	31	16,83	0,625	
2	PRE_DBP_L_ARM	78,42	31	9,73	0.209	0,837
	POST_DBP_L_ARM	78,06	31	12,39	0,208	
2	PRE_SBP_R_ARM	141,55	31	16,34	2 2 2 0	0,026 *
3	POST_SBP_R_ARM	137,87	31	17,14	2,339	
	PRE_DBP_R_ARM	79,94	31	10,36	1.01/	0.222
4	POST_DBP_R_ARM	78,32	31	9,37	1,216	0,233

Table 4. Descriptive statistics and student's T-test for paired data, analysing variation in the four variables studied in the patients in the experimental group. PRE\_SBP\_L\_ARM (pre-intervention systolic blood pressure in the left arm; mmHg), POST\_SBP\_L\_ARM (post-intervention systolic blood pressure in the left arm; mmHg), PRE\_DBP\_L\_ARM (pre-intervention diastolic blood pressure in the left arm; mmHg), POST\_DBP\_L\_ARM (post-intervention diastolic blood pressure in the left arm; mmHg), PRE\_SBP\_R\_ARM (pre-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the right arm; mmHg), POST\_SBP\_R\_ARM (post-intervention systolic blood pressure in the

		DE	SCRIPTIVE STA	STUDENT'S T-TEST		
VARIABLE	GROUP	N	MEAN	STANDARD DEVIATION	Т	P-VALUE
IMPROVEMENT_SBP_	Control	30	1,667	7,778	1 210	0,228
LEFT	Experimental	31	-1,097	9,772	1,219	
IMPROVEMENT SBP	Control	30	1,067	6,164	0,690	0,493
RIGHT	Experimental	31	-0,355	9,510	0,690	
IMPROVEMENT_DBP_ LEFT	Control	30	0,800	20,106	1 1 2 4	0,261
	Experimental	31	-3,677	8,754	1,134	
IMPROVEMENT_DBP_ RIGHT	Control	30	-0,500	10,418	0.492	0 (21
	Experimental	31	-1,613	7,383	0,483	0,631

the right arm; mmHg), PRE\_DBP\_R\_ARM (pre-intervention diastolic blood pressure in the right arm; mmHg), POST\_DBP\_R\_ARM (post-intervention diastolic blood pressure in the right arm; mmHg). \* Significance level < 0.05

Table 5. Descriptive statistics and student's T-test for independent data in the four variables used to analyse improvements in blood pressure. IMPROVEMENT\_SBP\_LEFT (Improvement in systolic blood pressure in the left arm; mmHg), IMPROVEMENT\_DBP\_LEFT (Improvement in diastolic blood pressure in the left arm; mmHg), IMPROVEMENT\_SBP\_RIGHT (Improvement in systolic blood pressure in the right arm; mmHg), IMPROVEMENT\_DBP\_RIGHT (Improvement in diastolic blood pressure in the right arm; mmHg).

In the multivariate analysis carried out, the values obtained for the variables age and BMI were close to the significance level (p = 0.092 and p = 0.068, respectively) (table 6). In a graph showing the relationship between IMPROVEMENT SBP RIGHT and age, we observed a positive relationship between the variables, indicating that the greatest reduction in systolic blood pressure occurred in younger patients (figure 1). Similarly, we also observed a positive relationship between IMPROVEMENT SBP RIGHT and BMI in a scatter plot, showing a greater reduction in blood pressure, after applying the muscle energy technique to C7, in patients with a lower BMI (figure 2). However, there was no relationship between SBP measured in the right arm and the patient's gender (table 6).

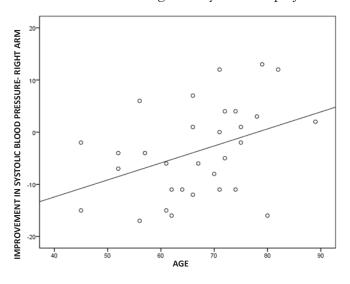
## DISCUSSION

The results obtained reveal that the MET is safe and non-aggressive and has few contraindications.

INDEPENDENT VARIABLE	TYPE III SUM OF SQUARES	F	P-VALUE	
GENDER	162,646	2,766	0,108	
AGE	179,407	3,051	0,092	
BMI	212,961	3,621	0,068	

**Table 6.** Factors explaining variation in the reduction of SBP in the right arm (IMPROVEMENT SBP RIGHT) (mm Hg) in patients in the experimental group (n = 31). Gender (male or female), age (years) and BMI were included in the multivariate model (GLM) as predictor variables.

An intra-group analysis of the results from the experimental group revealed that SBP in the right arm decreased significantly after applying the MET. SBP also decreased in the left arm and DBP decreased in both arms in the experimental group, but not significantly. Time was taken into account as a factor when obtaining the results- they were obtained after the intra-group data had been analysed. With a larger sample population, we could probably have achieved significant results from the inter-group analysis, which would be interesting to study in future projects.



**Figure 1.** Scatter plot showing the relationship between the variation in systolic blood pressure (BP) measured in the right arm (IMPROVEMENT SBP RIGHT) (mm Hg) and age (years) in patients in the experimental group (n = 31). The results are plotted as a regression line.

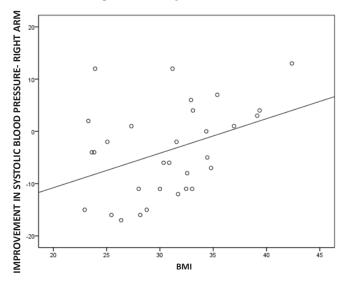


Figure 2. Scatter plot showing the relationship between the variation in systolic blood pressure (BP) measured in the right arm (IMPROVEMENT SBP RIGHT) (mm Hg) and body mass index (BMI) in patients in the experimental group (n = 31). The results are plotted as a regression line.

There were no differences in any of the 4 SBP and DBP measurements taken before the manipulation between the patients in the control group and experimental group.

We have analysed the only variable that showed significant variation, using the GLM (IMPROVEMENT\_SBP\_R: SPB\_R after the manipulation minus SBP\_R before the manipulation). P is never lower than 0.05 (table 5). We concluded that applying the MET to C7 produced a variation, reducing SBP in all of the patients, regardless of their age, gender or BMI. The significance level (p) for BMI and age obtained using the GLM for IMPROVE-MENT\_SBP\_R was close to significance (p = 0.068 and p = 0.092, respectively). When we plotted these results in a graph, we observed that although variation (reduction) in SBP was seen in all of the patients, this reduction is more pronounced in younger patients and patients with a lower BMI. These results support other studies in which obesity is observed as being a negative factor in patients with AHT<sup>0</sup>.

However, in the inter-group analysis, the difference in POST\_SBP\_L\_ARM was significant (p = 0.026), the difference in POST\_DBP\_L\_ARM was almost significant (p = 0.054) and there was a tendency towards significance in the differences in POST\_SBP\_R\_ARM (p = 0.174) and POST\_DBP\_R\_ARM (p = 0.160). In all of these, AHT was lower in the EG than in the CG.

This supports Luke Hamilton<sup>40</sup> who has pointed out that there has been very little research done on the MET and he found no research relating the MET to AHT or HR studies. There are authors who have obtained significant results, testing other osteopathic techniques, such as "Alternative Rocking of Temporal Bones" attempting to establish and validate the most efficient protocol for this treatment in decreasing blood pressure (BP) and HR, studying its effect immediately and after one month. It was observed that the examiner's subjective assessment correlated with the objectively quantifiable data of time, obtained by employing this method. The most effective treatment protocol is to apply the technique once a week, with support on the occipitalis and mastoid process. It made no difference who administered the technique, nor how much force was used. The use of this technique reduced BP and HR immediately and over 4 weeks. This technique has been shown to be useful when used alongside pharmacological treatment for arterial hypertension<sup>41</sup>.

In this study, we are continuing the line of investigation begun by previous authors regarding arterial hypertension, such as the study done by Benito and Calvente in 200812. They applied the pressure technique onto a projection of the aortic valve on the sternum in patients with hypertension, measuring their heart rate, finding significant changes in heart rate and SBP. On the other hand, Boscá<sup>1</sup> studied the danger of manipulating C7 in heart disease patients, measuring BP, HR and electrocardiographic mapping as indicators to assess the safety of the manoeuvre.

These parameters were measured in both study groups. He concluded that the technique did not produce any significant changes in HR or BP. He completed a follow-up assessment on the patients and confirmed the safety of using the technique on heart disease patients, as it produced no abnormal effects in the parameters studied.

# Limitations of the study

The main limitation of this study was not applying the technique to additional cervical vertebrae, to obtain positive results, reducing blood pressure, as well as not controlling the effects of the technique in the patients over time. Another limitation that arose was the difficulty of recruiting patients for the study to allow us to work with a larger sample size, which would have produced more statistically significant results. The reductions we observed in some of the variables would probably have been significant if the sample size used had been bigger. We also cannot know how long-lasting the effects would be from extended treatment over time, as the patients were not re-assessed after different lengths of time, which could be interesting for future studies.

## CONCLUSIONS

We have been able to conclude that the MET can be applied safely to the C7-T1 vertebrae in patients with hypertension, as it does not have an adverse effect on their blood pressure. After applying the MET to the C7-T1 vertebrae, we observed no significant changes in SBP or DBP in the right or left arm.

#### **ETHICAL PRINCIPLES**

This study complies with the ethical principles outlined in the Declaration of Helsinki and all subsequent amendments and was approved by the Research Ethics Committee of the Extremadura

Health Service (el Comité Ético de Experimentación del Servicio Extremeño de Salud), complying with all requirements for research on humans and animals as well as current legislation in Spain and the European Union.

#### **ACKNOWLEDGMENTS**

For all those who have collaborated in the development of this investigation.

#### **CONFLICT OF INTEREST**

Los autores declaran que no existen conflictos de intereses asociados a esta investigación.

## **BIBLIOGRAPHICAL REFERENCES**

- 1. Boscá-Gandía JJ. *La manipulación de la charnela cérvico-torácica ¿es peligrosa en caso de cardiopatías?* Escuela de Osteopatía de Madrid. 2003.
- Mabel-Garay O. Cambios en la presión arterial y la frecuencia cardíaca tras la aplicación de la maniobra hemodinámica global en sujetos con hipertensión arterial esencial. Osteopatía Científica. 2006; 1(3): 81-85.
- 3. Gómez-Castro SA. *Manipulación de las cervicales e hipertensión arterial*. Revista de fisioterapia. 2010;9(1): 7-19.
- 4. Caparosi R. Le sisteme neurovegetatif et ses troubles fonctionels. Paris; 1989.
- Levy RL, White PD, Stroud WD, Hilmann CC. Transient tachycardia prognostic significance alone and in association with transient hypertension. J Am Med Assoc. 1945;129(9):585-588.
- 6. Korr I. Bases psysiologiques de l'osteépathie. (S.B.O. London); 1982.

- González I. Impacto de las técnicas manuales usadas en osteopatía sobre los propioceptores musculares: revisión de la literatura científica. Osteopatía Científica. 2009; 4(2):70-75.
- 8. Mcknght ME, DeBoer kF. Preliminary study of bloor pressure changes in nomotensive subjects undergoing chiropractic care. J Manipulative Physiol Ther. 1988; 11(4):261-6.
- 9. Pistacchia R, Ruggieri J, Glavina B. Comportamiento de la Presión Arterial Sanguínea en Pacientes Hipertensos y Normotensos Tratados con Praxis Vertebral.
- 10. Rychlikivá F. Vertebrokardiálni Syndrom. Avicenum. Praga; 1975.
- La Touche Arbizu R, Escalante Reventós K. Efecto pos-tratamiento de la reflexología podal en la tensión arterial y la frecuencia cardíaca. Revista de salud, discapacidad y terapéutica física. 2006;28(3):125-131.
- 12. Benito MCM, Calvente R. Escuela Osteopatía de Madrid. Cambios en la presión arterial y frecuencia cardiaca después de una presión sobre la válvula aórtica en sujetos con hipertensión arterial esencial. 2008.
- Mansilla-Ferragud P, Boscá-Gandía JJ. Efecto de la manipulación de la charnela occipito-atlo-axoidea en la apertura de la boca. Osteopatía Científica. 2008;3(2):45-51.
- 14. Benítez-Camps M, Dalfó-Baqué A, González-Elena LJ, Almazán-Altuzarra J, Martín-Rioboo E, Pérez-Zamora S. DISEHTAE: diagnóstico, seguimiento y control de la HTA. Visiónde su abordaje global en España. Hipertensión y Riesgo Cardiovascular Elsevier Doyma. 2010;27(3):99-107.
- 15. Kaplan NM, Opie LH. Controversies in hypertension. Lancet. 2006;367:168-175.
- 16. Wolf-Maier K, Cooper RS, Banegas JR, Giampaoli S, Hense HW, Joffres M, et al. *Hypertension prevalence* and blood pressure levels in 6 European countries, Canada, and the United States. JAMA: the journal of the American Medical Association. 2003;289(18):2363-2369.
- 17. Banegas-Banegas JR, Rodríguez-Artalejo F, De La Cruz Troca, JJ, de Andrés Manzano B, del Rey Calero

J. Mortalidad relacionada con la hipertensión y la presión arterial en España. Med Clin. 1999;112(13): 489-494.

- Angeles Martinez-Lopez M, Garcia-Puig J. Medición de la presión arterial en el domicilio. Med Clin. 2006; 126(3):105-109.
- 19. Banegas J, Rodríguez Artalejo F. *El problema de la hipertensión arterial en España*. Rev Clin Esp. 2002; 202(1):12-15.
- Tarnow L, Rossing P, Gall MA, Nielsen FS, Parving HH. Prevalence of arterial hypertension in diabetic patients before and after the JNC-V. Diabetes Care. 1994; 17(11):1247-1251.
- 21. Stergiou GS, Yiannes NG, Rarra VC. Validation of the Omron 705 IT oscillometric device for home blood pressure measurement in children and adolescents: the Arsakion School Study. Blood Press Monit. 2006;11(4):229-234.
- 22. Baker TB, Gustafson DH, Shaw B, Hawkins R, Pingree S, Roberts L, et al. *Relevance of CONSORT reporting criteria for research on eHealth interventions*. Patient Educ Couns. 2010; 81 Suppl:S77-86.
- 23. Moher D, Hopewell S, Schulz KF, Montori V, Gotzsche PC, Devereaux PJ, et al. Explicación y elaboración: directrices actualizadas para la presentación de informes de grupos paralelos ensayos aleatorios. Int J Surg. 2012; 10(1):28-55.
- 24. Plaugher G, Long CR, Alcantara J, Silveus AD, Wood H, Lotun K, et al. *Practice-based randomized* controlled-comparison clinical trial of chiropractic adjustments and brief massage treatment at sites of subluxation in subjects with essential hypertension: pilot study. J Manipulative Physiol Ther. 2002;25(4):221-239.
- 25. Gibbons PT. Muscle energy concepts and coupled motion of the spine. 1998(Osteopathic Medicine Program, Faculty of Human Development, Victoria University; Private Practice, Melbourne, Australia).
- 26. Mitchell F, Basmajian J, Nyberg R. *Rational Manual Therapies*. 1993.
- 27. Komajda M, Lapuerta P, Germans N, González-Juantey JR, Van Veldhuisen DJ, Erdmann E, et al. *Adherence to guidelines is a predictor of outcome in chro-*

nic heart failure: the Mahler survey. Eur Heart J. 2005; 26(16):1653-9.

- Martín-Baranera M, Campo C, Coca A, de la Figuera M, Marín R, Miguel Ruilope L. Estratificación y grado de control del riesgo cardiovascular en la población hipertensa española. Resultados del estudio Dicopress. Med Clin. 2007;129(7):247-251.
- 29. Martín-Rioboó E, García-Criado E, Pérula-De-Torres L A, Cea-Calvo L, Anguita-Sánchez M, López-Granados A, et al. Grupo de Hipertensión Arterial de la Sociedad Andaluza de Medicina Familiar y Comunitaria (SAMFyC) y de los investigadores del estudio Prehvia. Prevalencia de hipertrofia ventricular izquierda, fibrilación auricular y enfermedad cardiovascular en hipertensos de Andalucía. Estudio Prehvia. Med Clin (Barc). 2009:132(7):243-250.
- 30. Márquez-Contreras E, Von Wichmann MF, Aguilera-de-la-Fuente MT, Garrido-García J. Influencia de la medida correcta de la presión arterial en la toma de decisiones diagnósticas en la hipertensión arterial. Estudio Medida. Med Clin. 2008;131(9):321-325.
- 31. Ricard F. Tratamiento osteopático de las algias de origen cervical. Madrid; 2008.
- 32. Cejo P, Legal L. *Efectos de las técnicas de anclaje miofascial y energía muscular en pacientes con bruxismo*. Osteopatía Científica. 2011.
- Vanderween L, Oostendrop R, Vaes P, Duquet W. *Pressure algometry in manual therapy*. Man Ther. 1996; 1:258-265.
- 34. Landis JR, Koch GG. *The measurement of observer* agreement for categorical data. Biometrics. 1977;33(1): 159-174.

- 35. Fernández-de-las-Peñas C, Downey C, Miangolarra-Página JC. Validez de la prueba de deslizamiento lateral como herramienta para el diagnóstico de la intervertebral disfunción de la articulación de la columna cervical inferior. J Manipulative Physiol Ther. 2005; 28(8):610-616.
- 36. Rey-Eiriz G, Alburquerque-Sendin F, Barrera-Mellado I, Martin-Vallejo FJ, Fernandez-de-las-Peñas C. Validity of the posterior-anterior middle cervical spine gliding test for the examination of intervertebral joint hypomobility in mechanical neck pain. J Manipulative Physiol Ther. 2010;33(4):279-285.
- 37. Guerrero AM, Rodríguez RP. Técnica semidirecta de thrust para una disfunción somática no neutra en ERS izquierda de la tercera vértebra cervical. Osteopatía Científica. 2011;6(1):30-34.
- 38. Cortijo Sánchez CJ. En caso de neuralgia cervicobraquial, el test de Jackson es patognomónico de patología discal. ¿Corresponde a la realidad? Revista científica de terapia manual y osteopatía. 2002;(14):12-15.
- Coca A. Evolución del control de la hipertensión arterial en atención primaria en España. Resultados del estudio Controlpres 2003 Hipertensión. 2005;22:5-14.
- 40. Hamilton L, Boswell C, Fryer G. The effects of high-velocity, low-amplitude manipulation and muscle energy technique on suboccipital tenderness. Int J Osteopath Med. 2007;10(2-3):42-49.
- 41. Martínez-Mateo D. *Influencia del «rodamiento alternativo de temporales» sobre la presión arterial y la frecuencia cardíaca*. Proyecto de investigación: 2013.

ISSN on line: 2173-9242 © 2016 – Eur J Ost Rel Clin Res - All rights reserved www.europeanjournalosteopathy.com info@europeanjournalosteopathy.com