Tittle
Physiological effects of a multidirectional random vibration device on humans

Decrease of pain, arterial pressure and leg volume with a multidirectional whole body undulatory (andullation) therapy in humans

Parras-Moltó Alba, Ribas-Serna Juan

Key words: pain, systolic and diastolic arterial pressure, leg volume, random vibration therapy, whole body, resting condition

ABSTRACT

Our aim has been to test the effects of a new vibratory therapy on the pain threshold, the pain perception, the arterial pressure and the leg volume in humans. We used a multidirectional vibration (ranging frequency: 5-40 Hz, amplitude: 2-8 mm) in an undulatory way through the contact surface of the human body with a mattress. The vibes travel from the heel to the head in a random way while subjects (n=50) lying on the mattress. We measured pain threshold by means of an algometer and a visual analog scale, arterial pressure with an electronic sphygmomanometer and the leg volume using the Kuhnke's technique. Measurements were made just before and after the andullation session. Pain threshold significantly ($p<0.001$) increased 34.48% and 25.79% in the lumbar and the trapezius zone respectively after 5 sessions therapy. VAS data showed a 52.3% decrement for subjective perception of pain and an increment of 45.1% for the well-being sensation. Systolic and diastolic pressures significantly ($p<0.001$) decreased 6.44 and 4.68 mmHg in average respectively. The leg volume significantly ($p<0.01$) diminished in 64.39 mL after the 5 andullation sessions. In conclusion the andullation therapy is a useful tool to reduce pain, arterial pressure and leg volume in subjects resting on a horizontal position.

INTRODUCTION

Effects of vibration on human body have been widely studied in both directions as a source of injuries and as a way to treat different pathologies. The potential risk of using vibration has been well established in International Standards Organization (ISO, 5349-1 and in British Standard (BS 6841) [1-4]. By other side, the use of vibrations to improve the physical training effects and to ameliorate different pathologies has been extendedly reported [6-10]. However, most intervention has been made with the whole-body vibration (WBV) technique combined with exertion[11-15]. The WBV is normally applied through a platform that vibrates at a fixed frequency and amplitude previously selected by the user. Users stand up, lean, or sit on the vibrating platform meanwhile realize exercise during short time periods (less than 5 minutes). The WBV has been postulated to improve quality of life of patients with metabolic syndrome, patients with severe chronic obstructive pulmonary disease, or to improve blood flow in type 2 diabetic patients, or muscle flexibility and pain in neurological patients [16-19]. However, most of the time whole-body vibration technique has been associated to exercise or to any related therapy which makes difficult to disjoin the effects due to exercise or adjuvant

therapy and those due to WBV technique. The use of vibrations for diagnosis purposes are not considered here**.**

Here we presented for the first time data obtained before and after applying a multidirectional random vibration device ("andullation") on the whole-body of horizontal lying subjects. This device uses frequencies below 40 Hz and peak to peak amplitudes between 2 to 8 mm. Vibrations are applied in distinct body areas and in different directions along the body of the individual. These values are far from those referred as risky by ISO 5349 and BS 6841. The aim of our work has been to ascertain the effects on objective and subjective pain indicators, on the arterial pressure and on the leg volume induced by andullation.. We have obtained significant changes in pain, arterial pressure and leg volume after applying andullation for a 30 min period during 5 days.

METHODS

Subjects

Seventy human subjects were recruited to participate in this study. Finally fifty subjects were selected for andullation experiments. Subjects aged between 18 to 68 years old. Biometrics characteristics are shown in Table 1. The following inclusion and exclusion criteria to participate in this study were established:

Inclusion criteria:

- Healthy subjects
- Subjects with mild pathologies (fibromyalgia, arthropathies, etc.)

Exclusion criteria:

- Subjects with severe cardiac disease
- Subjects with prosthesis with less of 6 months from implantation
- Subjects with severe retinopathies
- Subjects with circulatory vertebra-basilar insufficiency

All subjects were fully informed about the characteristics of the andullation device and about the whole procedure to be carried out. Finally all of them voluntarily signed a written consent. Subjects were also informed about their possibility to abandon the study at any time. Subjects agreed to participate for five days during one hour per day. The experiments were carried out at the same place and at the same environment.. The experimental condition and the protocol used in this study were approved by the local ethic committee (Comité Ético de los Hospitales Universitarios Virgen del Rocío y Virgen Macarena de la Junta de Andalucía, Spain), following the Helsinki's declaration of 2003.

Procedure

A medical anamnesis was completed for every subject and their anthropometric characteristics measured and stored in a bioimpedancemeter (In Body, USA). We used a modified Borg scored scale (VAS) (Figure 1) for pain and wellness perception which was presented before and after the andullation therapy. The VAS showed ten steps to assign a numerical negative value from 0 (no pain at all) up to minus 10 (maximal pain)

scores and ten steps of positive numbers from 0 (no well-being feeling) up to 10 (highest feeling of well-being).
We also used an algometer (Dolorimeter, Rhabmedic, Spain) to obtain an objective measurement of the pressure-induced pain on the skin surface over the trapezius muscle and over the lumbar muscle. Pressure pain threshold was defined as the minimal pressure that produces pain[20-24].

The andullation device consists on a mattress including 70 motors producing vibrations of different amplitude (ranging from 2 to 8 mm) and frequency (ranging from 5 to 70 Hz) extended over the entire body surface in contact with the mattress. The activation and amplitude of vibes was computer controlled and sequentially activated to produce a vibratory wave through the whole body meanwhile stayed in a decubitus supine position on the mattress. The wave travels from the heel to the head or vice versa (HHP-Home Health Product; Medical device (andumedic) certificated as Class IIa by Health Spanish Authorities).
We also measured the volume of the thigh and leg using the Kuhnke's technique[25]. In short, we measured 5 circumferences separated 4 cm along the thigh and the leg and the volume of every 4 cm long cylinder was calculated and added following the Kuhnke's corrections.

The time course of the procedure (figure 2) was the following: a) after medical anamnesis a bio impedance was performed, b) both subjective and objective evaluation of pain threshold was performed using the algometer and the VAS scale described above, c) subjects were placed in decubitus supine position upon the andullation device and stay so during 15 min, at the end of this period arterial pressure (Omron sphygmomanometer device with arm cuff, Oregon Inc. USA) and thigh and leg volumes were measured, every measurement was repeated twice for the same researcher and the average value incorporated to the data base, e) later a sequence of undulatory vibration generated by the andullation device was applied for 30 min. Thereafter subjects stayed in the same position during 15 min more. In the last 5 min of this period arterial pressure and thigh and leg volume were measured again. These measurements were performed the day 1st and 5th of the therapy period.

Statistic
We used the standardized differences of the mean to pre-determine an acceptable size of the sample. For an expectable mean difference equal or higher than 25% (2 units variability) and 0,05 of significance level, the sample size for a 90% of statistical power was 49. A normality test was passed to the differences in mean values of selected variables before and after the andullation therapy. When data proceeded from a normally distributed population, a t-Student test for paired samples was used and the signification established for α<0.05. Those variables coming from not normal distributed population were analyzed with the Wilcoxon-Shaphiro test. In every case, a confidence interval at 95% was calculated. Eventually, we also calculated the size of the effect produced by the andullation intervention. We estimated the size of the effect considering <0.2 as low, 0.5 as medium and 0.8 as large. All the statistical calculation were carried out by means of a professional spreadsheet (OriginPro (2015), OriginLab corp. Northamton, MA 0106, USA) and SPSS (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.)

RESULTS

We made a non-invasive intervention on a sample of healthy subjects and subjects with non-severe pathologies using a waving vibes device (andullation). The device applied vibrations as a wave running by the whole body back surface over the mattress from the heel to the head or vice versa. The subjects stayed in horizontal position during all the andullation session. We measured several physiological variables of each subject before and after the intervention so a pairwise analysis was possible. We obtain remarkable changes after the andullation sessions on pain threshold, well-being and leg volume.

Pain

To assess the pain perception of subjects before and after the andullation intervention we used an algometer and a visual analog scale (VAS). The algometer provided an objective measure (expressed as kg/cm^2) of the pain threshold. The pain threshold for trapezius zone increased 25.79% after the andullation intervention. The mean value of pain threshold (n=50) over the skin on trapezius muscle before the first andullation session was 3.76 (1,79)Kg/cm^2 (mean (SD)) and 4.73 (2,14) Kg/cm^2 (<0.01) after the andullation in the 5th day, the confidence interval (CI) (95%) was 0.51665 to 1.38735 . Nevertheless, after the first 30 min session the pain threshold rise from 3.76 (1.79) to 4.48 (1.78)kg/cm^2 with a lower limit of 0.4316 and upper limit of 0.9783 for the CI(95%). The pain threshold in the lumbar zone augmented 34.48 % after the andullation intervention. The mean value of the pain threshold in the lumbar zone immediately before the first intervention with andullation was 4,152 (1,77) Kg/cm^2 increasing up to 5,584 (2,19) Kg/cm^2 after the last andullation session at day 5th (Figure 3) with a CI (95%) from 0,99888 to 1,86512. Already after the first andullation session (day 1) the pain threshold increased in both the trapezius area as well as in the lumbar area. In the trapezius area the mean value of the pain threshold rise significantly up from 3.76 (1.79) to 4.485 (1.78) kg/cm^2 with a lower limit of 0.4316 and upper limit of 0.9783 for the CI(95%). By other side, the pain threshold in the lumbar zone augmented significantly from 4.152 up to 5.01 kg/cm^2. The largest pain threshold increment (1,432 kg/cm^2) was measured between the pre-andullation session in the first day and the post-andullation session in the fifth day. The first day the effect size was 0.48 and 0.39 for lumbar and trapezius zones increasing up to 0.807 and 0.528 at the day 5th respectively Full data are presented in table 2.

The subjective perception of pain was pointed out by the experimental subjects over the modified Borg scale (VAS, Figure 1). So it was done for well-being status (mental tension, moodness, relaxing condition). Data from the first day, before the intervention with andullation and from the fifth day after the intervention were compared and the results showed in figure 4. The subjective perception of pain significantly ($p<0.001$) decreased a 52.3% in average from 2.92 (2.66) to 1.09 (1.85).
Using the same modified VAS as described in Methods, the well-being of the subjects improved after intervention with the andullation device. The well-being score change significantly ($p<0.001$) from 5.88 (2.24) to 8,46 (1.88), that is a 45.1 % as showed in figure 5.

Arterial pressure

Both systolic and diastolic pressure changed after the andullation sessions. The systolic pressure significantly ($p<0.001$) varied from 123.6 (16.9) mmHg at condition previous to the first andullation session to 117.16 (15.1) mmHg after the fifth session of andullation with a lower and upper confidence intervals (95%) of 4.005 and 8.234 and 3.709 and 9.170 for data pre-andullation and for data at fifth day after andullation respectively (Figure 6).
Diastolic pressure also significantly ($p<0.001$) decreased after the five andullation sessions. Diastolic pressure mean values before the andullation session was 77.34 (9.5) mmHg and 72.66 (8.4) mmHg after the fifth andullation session. The lower and upper limits of the confidence intervals at 95% were 1.707 and 4.492 for values of day 1st before of andullation intervention and 3.042 and 6.31 to values after the andullation session at day 5th (Figure 6).

Thigh and leg volumes

Leg volume significantly ($p<0.01$) decreased in average 64.39 (20.98) mL after the five sessions of andullation (Figure 7). The confidence intervals at 95% were 11.35 (lower limits) and 74.37 (upper limits). However thigh mean volume was not significantly ($p<0.16$) reduced in 134.65 mL after five andullation. Thigh mean (SD) volume before andullation was 4191.85 (1376.36) lowering to 4057.2 (1290.92) after the fifth day of andullation therapy (Figure 7).

DISCUSSION

Pain threshold

We chose two different body areas, the areas covering the trapezius and the lumbar muscles, to test the pain threshold of the subjects. We chose the area over the trapezius muscle because it is one of the most sensitive to psychological and physiological stress [26-28]. By other side, lumbar zone is probably the most common area in painful pathologies of the lower back[29, 30]. We measured pain threshold with an algometer device because is most frequently used by clinical therapists than controlled heating source devices. Each subject was his own control what allowed a pairwise analysis.

The increase in the pain threshold was linked to the vibration treatment provided by the andullation device. It has been largely known that vibrations are related to a decrease in pain sensitiveness[31]. The mechanical characteristics of the device allowed the stimulation of the skin as well as the muscular and subcutaneous tissues. Further, the sequential stimulation of different regions of the body as a passing wave reduced the possible adaptation of mechanical and nociceptive receptors. Attending to the gate control model of the pain, the higher the activation of mechanical peripheral receptors the weaker the nociceptive signal entering the brain[32]. Such effect might account for by decreasing the magnitude of the nociceptive input to the projection neurons in the dorsal root and underlying the increase in the pain threshold observed in our study. Whether the vibratory stimulation enables the facilitation of the synapses of the peripheral receptor fibre with the inhibitory interneurons in the dorsal root of the spinal cord

remains to be clarified. By other side, the increase of a 25 to 34 % in the pain threshold draw away the possibility of a placebo effect. This increase in pain threshold seems reasonable large since the andullation intervention was only applied during 30 min at day for five days. The possible effects of longer sessions of andullation on pain threshold are out of the scope of this study. We also measured an increase in the pain threshold of subjects undergoing one 30 min "andullation session. Surprisingly after the first session with andullation the pain threshold increased significantly. Further, after 5 daily 30 min sessions the pain threshold continued increasing, although at lower magnitude. Naturely, the effects of the applied vibrations ought to trend to a steady state along the days of treatment with the same parameters. The possibility exist that andullation may reduce the muscular tone and it account for part of the increase in pain threshold. However we have measured basic features of the electromyogram (not shown) and it did not evidence any relevant change in the muscular tone.

Our study with undulatory whole body vibration therapy (andullation) shows results where the pain VAS decreases significantly after treatment. Similarly Alev et al.[33] in his article with vertical vibrational platform (WBV) reported a reduction in VAS for pain although there is no clear consensus on the mechanism by which the vibration can reduce pain or improve the tonic reflexes by increasing the neuronal input; there is some indirect evidence of its form of action. The amplitude of the vibration and the frequency are the key points in this procedure because they determine the load imposed by the vibration in the neuromuscular system during training[33]. However, WBV differ remarkably from andullation device. WBV used the same vibratory characteristic to the part of the body uphold on the platform whereas andullation used a wave of multidirectional vibration over the whole surface of the subject reposed on the mattress.

It is known to use vertical whole-body vibratory platforms (WBV) in conjunction with exercise for the treatment of sports injuries as cited by Bokaeian et al.[34] as well as Wang et al. [35] giving positive results on the pain VAS after treatment in osteoarthritic injury [34-36]. The evidence for WBV is not clear to reduce pain in patients with diseases such as fibromyalgia[11]. Moretti et al., [37] concluded that it was not possible to evaluate the magnitude of the effect of the treatment. He concluded that the results are based on evidence of very low quality and was inconclusive with respect to pain. Nevertheless, we have obtained an effect size of 0.8 (considered as large) for the changes produced by andullation therapy on the pain threshold in the lumbar zone. There is no evidence to demonstrate the use of WBV therapy throughout the body for the treatment of women with fibromyalgia since there are no clinically important effects in reducing pain, controlling fatigue and improving quality of life[37]. Collado-Mateo et al.[38] in its review compiled 8 articles out of 68 initials, of which only in one of them was pain specifically assessed showing an improvement compared to the control group. In these studies no objective measurement of pain level was used whereas in our study the pressure applied over two body areas were quantified by an algometer.

The subjective evaluation of the pain feeling on different parts of the body through the modified VAS evidenced a reduction in the painful sensation of subjects. Specularly, the well-being scores also improved after the andullation therapy. Provided the percentage of increment in the two scales after andullation it cannot be attributed to the placebo effect that rarely is more than 15%[39]. Since experimenter did not intervene in the decision of the subjects neither the subjects were informed of any expectancy of the treatment, the changes in the score values proceeded from the internal feeling of the

subjects. Interestingly, the values of pain threshold (algometered) and VAS were slightly higher and lower respectively in the measuring previous to the andullation session at day 5th (not shown) what points out an accumulative effect along the days of therapy.

Arterial pressure

The systolic and diastolic arterial pressure lowered respectively 6.44 mmHg and 4.68 mmHg in average. This change might be attributed to the change in body position from standing up to lying over the mattress. Nevertheless, to allow the cardiovascular adaptation we waited 15 min to measure pressure after the change in body position and other 15 min after the andullation session in the same position. So we ensured that changes in arterial pressure were closely related to the vibration therapy. By other side, the magnitude of the changes was small as expectable taking into account the 30 min of vibratory stimulation period even so these changes were statistically significant. Other authors have reported changes in arterial pressure with vibratory devices (WBV) but always associated to exertion which is known to affect the arterial pressure[7,40]. In our study subjects did not performed any exercise meanwhile over the mattress. Arterial pressure of the subjects was measured by a conventional electronic sphyigmomanometer. Nevertheless to reduce the variability in the final reported values of this device we did double determination and the mean of these two value used for comparison. The electronic blood pressure measurer also avoided the subjective appraisal of the Korokov sounds by the experimenter in not-electronic techniques.

The changes in lower extremity volume could be ascribed to the lying position on the mattress. Nevertheless, we wait for 15 min in the same position than during the andullation session before measuring the leg volume, so fluid drainage from leg had to be stabilized before the andullation session. The fact that the change in thigh volume after andullation sessions were no significant ($p<0.16$) may be explained for the large volume of this area requiring largest increment of volume magnitude to become significant or largest population.
Although other technique such that of disc model or water displacement volumetry for limb volume determination are available[41], the Kuhnke's technique used in our study is simply, precise and easily adaptable to different shape of legs .

CONCLUSIONS

Our results show significant augmentation of the pain threshold after 30 min of andullation session. Although the largest differences were seen between the pre-session at first day and the post-session condition at the fifth day, already after the first session it was evidenced a significant increase of the pain threshold. Also values of arterial pressure and leg volumes decreased significantly after the andullation sessions. The andullation device have shown to be a non-risky instrument to be applied as a therapy for pain relieve and a valuable help for lessen arterial pressure and leg volume.

References

1.M.J. Griffin, Handbook of Human Vibration, Academic Press Limited, London, 1990.

2.International Organization for Standardization ISO 2631-1, Mechanical vibration and shock—evaluation of human exposure to whole-body vibration, 1997.

3. Se-Jin Ahn, Michael J Griffin Effects of frequency, magnitude, damping, and direction on the discomfort of vertical whole-body mechanical shocks *Journal of Sound and Vibration* . 2008; 311: 485–497

4. Krajnak K, Riley D A, Wu J, McDowel T, Welcome D E, Xueyan S. Xu and Dong RG Frequency-dependent effects of vibration on physiologicals systems: experiments with animals and other human surrogates.. *Industrial Health* 2012; 50, 343-353

5. Rittweger J, Beller G, Felsenberg D Acute physiological effects of exhaustive whole-body vibration exercise in man. *Clin Physiol* 2000; 20(2):134-142

6. Rittweger J. Vibration as an exercise modality: how it may work and what its potential might be. *Eur J Appl Physiol*. 2000;108(5):877-904

7. Robbins D, Yoganathan P, Goss-Sampson M. The influence of whole-body vibration on the central and peripheral cardiovascular system. *Clin Physiol Funct Imaging*. 2013; 17 doi:10.1111/cpf.12103

8. Figueroa A, Gil R, Wong A, et al. Whole-body vibration training reduces arterial stiffness, blood pressure and sympathovagal balance in young overweight/obese women. *Hypertens Res*. 2012;35(6):667-672

9. Cardinale M, Bosco C. The use of vibration as an exercise intervention. *Exer Sport Sci rev*. 2003;31(1):51-57

10. Sawatzky B. Effects of vibration on Spasticity in individuals with Spinal cord injury. *Am J Phys Med Rehabil*, 2014; 93:995-1007

11. Sañudo B, Carrasco L, de Hoyo M, Oliva-Pascual-Vaca A, Rodríguez-Blanco C. Changes in body balance and functional performance following whole-body vibration training in patients with fibromialgia síndrome: a randomized controlled trial. *J Rehabil Med.* 2013;45(7):678-684

12. Dallas G, Paradisis G, Kirialanis P, Mellos V, Argitaki P, Smirniotou. The acute effects of different training loads of whole-body vibration on flexibility and explosive strength of lower limbs in divers. *Biol sport.*2015;32(2):235-241

13. Rauch F, Sievanen H, Boonen S et al., International Society of Musculoskeletal and neuronal Interactions. Reporting whol-body vibration intervention studies: recommendations of the International Society of Musculoskeletal and Neuronal Interaction. *J Musculoskelet Neuronal Interaction*. 2010;10(3):193-198

14. Sá-Caputo Dda C, Ronikeili-Costa P, Carvalho-Lima RP et al., Whole-body vibration exercises and the improvement of the flexibility in patient with metabolic síndrome. *Rehabil Res Pract.* 2014; 2014:628518.

15. Wei N, Pang MY, Ng SS, Ng GY. Optimal frequency/time combination of whole-body vibration training for improving muscle size and strength of people with age-ralated muscle loss (sarcopenia): a randomized controlled trial. *Geriatr Gerontol Int.* 2016;doi:10.1111/ggi.12878

16. Carvalho-Lima RP, Sá-Caputo DC, Moreira-Marconi E, et al., Quality of life of patients with metabolic syndrome is improved after whole-body vibration exercises. *Afr J Tradit Complement Altern Med.* 2017;14(4 suppl):59-65

17. Braz Junior DS, Domelas de Andrade A, Teixeira AS, Cavalcanti CA, Morais Ab, Marinho PE. Whole-body vibration improves functional capacity and quality of life in patients with severe chronic obstructive pulmonary disease (COPD): a pilot study. *Int J Chron Obstruct Pulmon Dis.* 2015;10:125-132

18. Sañudo B, Alfonso-Rosa R, Del Pozo-Cruz B, Del Pozo-Cruz J, Galiano D, Figueroa A. Whole-body vibration training improves leg blood flow and adiposity in patients with type 2 diabetes mellitus. *Eur J Appl Physiol.* 2013;113(9):2245-2252

19. Di Giminiani R, Manno R, Scrimaglio R, Sementilli G, Tibany J. Effects of individualized whole-body vibration on muscle flexibility and mechanical power. *J Sports Med Phys Fitness* 2010;50(2):139-151

20. Ohrbach R, Gale E N, Pressure pain threshold in normal muscles: reliability, measurement effects and topographic differences. Pain, 1989; 37:257-263

21. Nussbaum E.L. and Downes L., Reliability of clinical pressure-pain algometric measurements obtained on consecutive days. Phys Ther 1998;78:160-169

22. Farasyn A., Meeusen R. Pressure pain thresholds in healthy subjects: Influence of physical activity, history of lower back pain factors and the use of endermology as a placebo-like treatment. *Journal of Bodywork and Movement Therapies,* 2003;7:53-61

23. Farasyn A, Meeusen R. The influence of non-specific low back pain on pressure pain thresholds and disability. *European Journal of Pain* 2005;9:375-81

24. Farasyn A., Meeusen R. Effect of Roptrotherapy on Pressure Pain Thresholds in Patients with Non-specific Low Back Pain. *Journal of Musculoskeletal Pain* 2007;15:41-53.

25. Kuhnke E. Volumbestimmung aus Umfangmessungen. Folia Angiologica 1976; 24: 228-32.

26. Hagber Mats. Occupational musculoskeletal stress and disorders of the neck and shoulder: a review of possible pathophysiology. *Int Arch Occup Environ Health* 1984; 53:269-278

27. Draspa L J. Psychological factors in muscular pain. *Psychology and psychotherapy* 1959; 32:106-116

28. Vlaeyen JW[1], Seelen HA, Peters M, de Jong P, Aretz E, Beisiegel E, Weber WE. Fear of movement/(re)injury and muscular reactivity in chronic low back patients: an experimental investigation. *Pain* 1999; 82(3):297-304

29. Kovacs F M, Fernández C, Cordero A, Muriel A, González-Luján L, Gil del Real MT. Non-specific low back pain in primary care in the Spanish National Health Service: a prospective study on clinical outcomes and determinants of management. *BMC Health Services Research* 2006; 6:57 doi:10.1186/1472-6963-6-57

30. Zamani E[1], Kordi R[1], Nourian R[2], Noorian N[1], Memari AH[1], Shariati M[3]. Low back pain functional disability in athletes; conceptualization and initial development of a questionnaire. *Asian J Sports Med.* 2014; 5(4):e24281. doi: 10.5812/asjsm.24281

31. Basbaum A I, Jessell TM, In Principles of Neural Science. ED.: E R Kandel, Schwartz J H And Jessell T M.. McGraw-Hill/ Interamericana España. Madrid. Basbaum A I, Fields H I (1984) Endogenous pain control system: brainstem spinal pathway and endorphin circuitry. *Ann. Rev. Neuroscience* 2001;7:309-338.

32. Melzack R, Wall PD. Pain mechanism: a new theory. *Science* 1965;150:971-979

33. Alev A, Mihriban A, Bilge E, Ayça E, Merve K, Şeyma C, Uğur E, Adnan B, Zeynel K, Mahmut GS. Effects of whole body vibration therapy in pain, function and depression of the patients with fibromyalgia. *Complement Ther Clin Pract*. 2017;28:200-203. doi: 10.1016/j.ctcp.2017.06.008

34. Bokaeian HR, Bakhtiary AH, Mirmohammadkhani M, Moghimi J. The effect of adding whole body vibration training to strengthening training in the treatment of knee osteoarthritis: A randomized clinical trial. *J Bodyw Mov Ther.* 2016;20(2):334-40. doi: 10.1016/j.jbmt.2015.08.005

35. Zafar H, Alghadir A, Anwer S, Al-Eisa E. Therapeutic effects of whole-body vibration training in knee osteoarthritis: a systematic review and meta-analysis. *Arch Phys Med Rehabil.* 2015; 96(8):1525-32. doi: 10.1016/j.apmr.2015.03.010

36. Wang P, Yang X, Yang Y, Yang L, Zhou Y, Liu C, Reinhardt JD, He C. Effects of whole body vibration on pain, stiffness and physical functions in patients with knee osteoarthritis: a systematic review and meta-analysis. *Clin Rehabil.* 2015; 29(10):939-51. doi: 10.1177/0269215514564895

37. Moretti E, Tenório A, Holanda L, Campos A, Lemos A. Efficacy of the whole-body vibration for pain, fatigue and quality of life in women with fibromyalgia: a systematic review. Disabil Rehabil. 2018; 40(9):988-996. doi: 10.1080/09638288.2017.1282989

38. Collado-Mateo D, Adsuar JC, Olivares PR, Del Pozo-Cruz B, Parraca JA, Del Pozo-Cruz J, Gusi N. Effects of Whole-Body Vibration Therapy in Patients with Fibromyalgia: A Systematic Literature Review. *Evid Based Complement Alternat Med.* 2015;2015:719082. doi: 10.1155/2015/719082

39. Reicherts P, Gerdes ABM, Pauli P, Wieser MJ. Psychological Placebo and Nocebo Effects on Pain Rely on Expectation and Previous Experience *Journal of Pain,* 2016:17(2):203-214)

40. Yarar-Fisher C, Pascoe DD, Gladden LB, Quindry JC, Hudson J, Sefton J. Acute physiological effects of whole body vibration (WBV) on central hemodynamics, muscle oxygenation and oxygen consumption in individuals with chronic spinal cord injury. *Disabil Rehabil.* 2014;36(2):136-45. doi: 10.3109/09638288.2013.782358

41. Kaulesar Sukul DMKS, den Hoed PT, Johannes EJ, van Dolder R and Benda E. Direct and indirect methods for the quantification of leg volume: comparison between water displacement volumetry, the disk model method and the frustum sign model method, using the correlation coefficient and the limits of agreement. *J. Biomed. Eng.* 1993; 15:477-480

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FIGURES

Figure 1

Figure 1*. Visual analog scale (VAS) for pain perception and well-being feeling.*

Figure 2

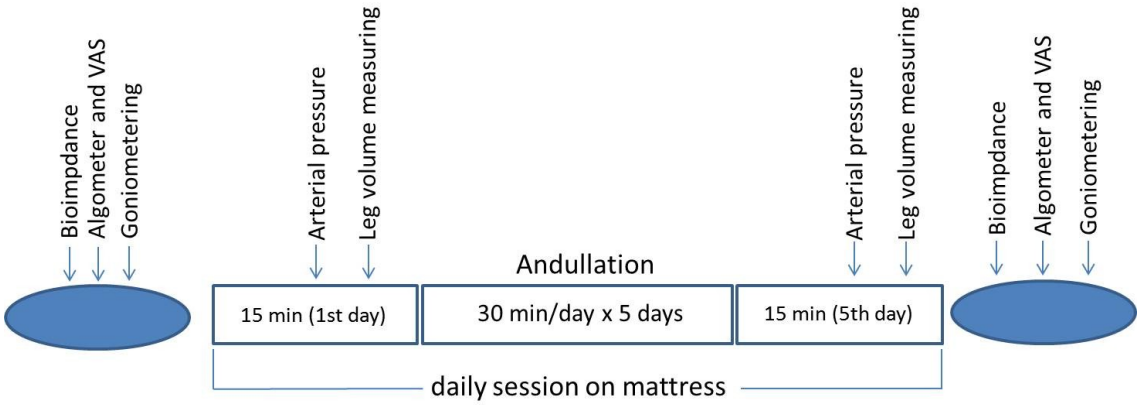

Figure 2*.Set up and timing of the selected variables and the intervention with andullation device. Variables on blue circle were recording in stand up position before and after the andullation. Although measurements were realized every day we chose those recordings before the first session at day 1 and at the end of the fifth session at day 5 for comparison. Squares: time and recordings on decubitus supine position on the andullation mattress.Blue ellipse: measurements carried out in standing up position.*

Figure 3

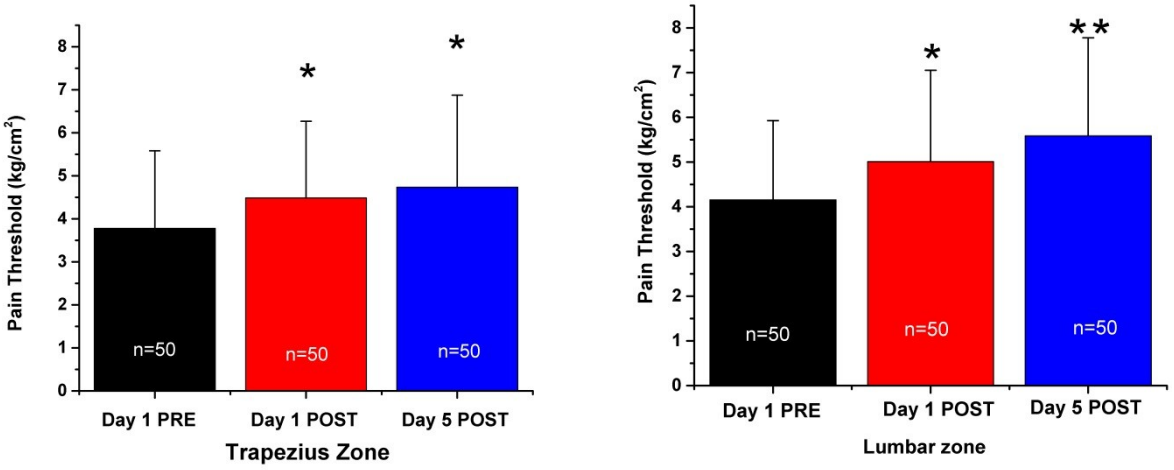

Figure 3**. Change in the pain threshold induced by andullation. Pain threshold increased from the first day to the fifth day in both lumbar and trapezius zones. Columns represent the mean and the standard deviation of the mean (SD) of the pain thresholds. Day 1 PRE are data previous to the first andullation session; DAY 1 POST are data obtained after the first andullation session; Day 5 POST are data measured after the andullation session in the 5th day of therapy. n: number of subjects **:statistical significance (p<=.05) respect to Pain threshold before the first session of andullation (Day 1 PRE). ******: statistical significance as respect Day 1 PRE and Day 1POST*

Figure 4

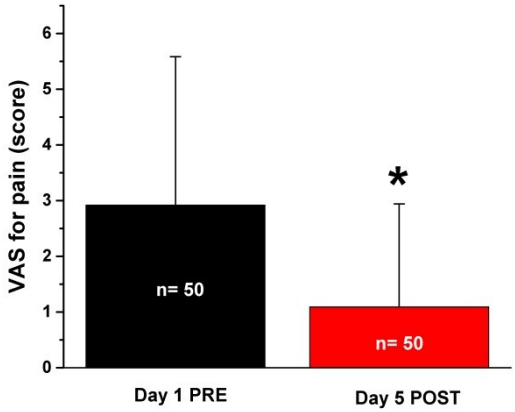

***Figure 4**. Changes in mean values of VAS score before the first intervention and after the fifth intervention with the andullation device. *: statistical significance (p<0.01)*

Figure 5

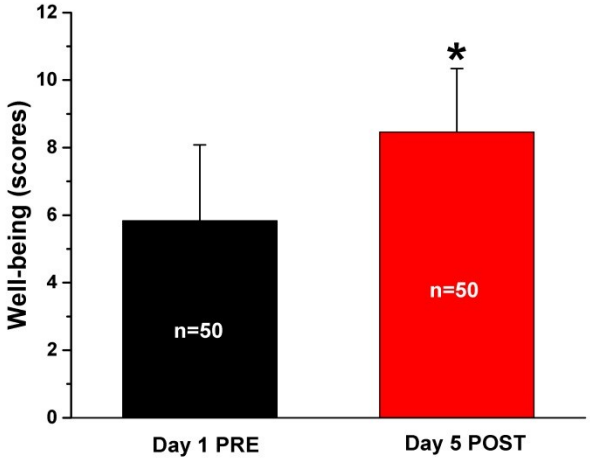

***Figure 5**. Changes in well-being of the participants (n=50) in the study. *: statistical significance (p<0.001)*

Figure 6

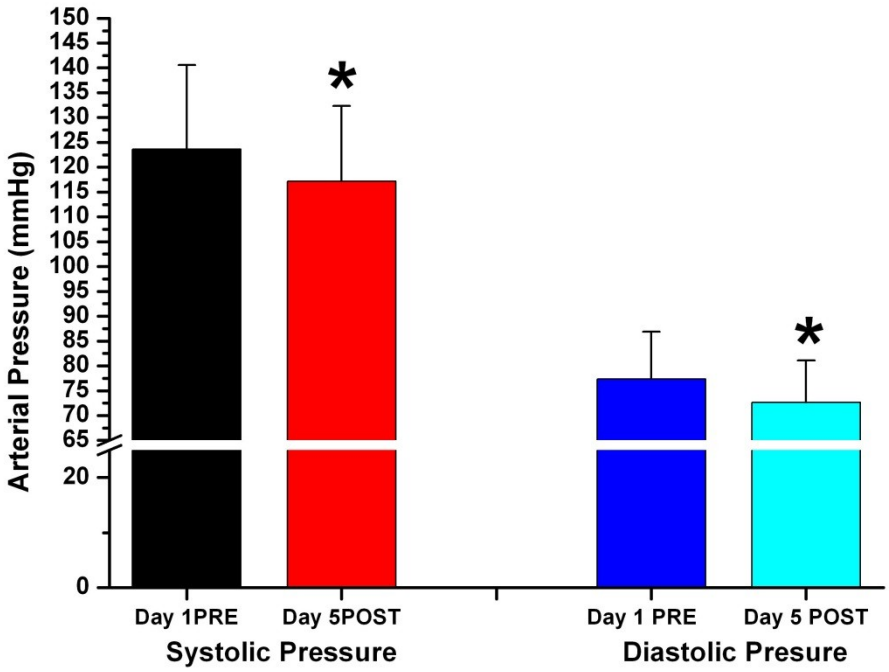

Figure 6*. Changes in systolic and diastolic pressure before the first and after the fifth andullation session. Data plot are truncated to a better visualization of the change. Day 1PRE: data obtained before the first intervention at day first. Day 5POST: data measured after the fifth andullation session. *: p<=0.001. N=50*

Figure 7

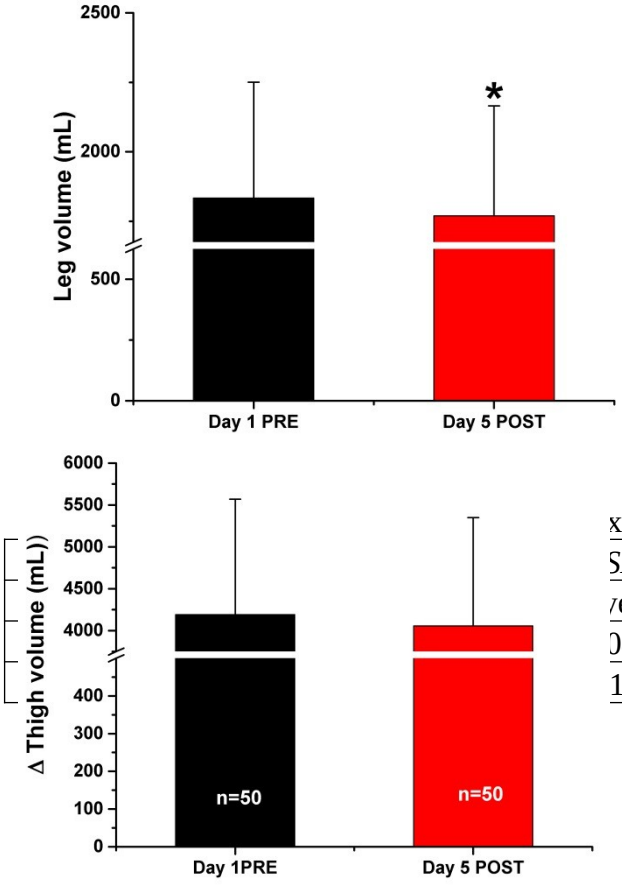

Figure 7. Changes in volume in leg and thigh of subjects (n=50). Values are expressed as mean and standard deviation. Day 1 PRE: measurements made before andullation session. Day 5 POST: measurements made after the fifth session of andullation therapy. *: statistical significance for p<0.05. (n=50 for leg and thigh volumes).

TABLES

xperimental subjects

SD)	*(range)*
ears old	(18-68) years
04) cm	(147-203) cm
16) kg	(46.5-138.1) kg

Weight (after andullation)	73.42 (16.79) kg	(47.3-135.8) kg

Table 2. Pain threshold changes before and after the intervention with andullation

Muscle zone	Mean (kg/cm^2)	SD	SEM	α =	CI 95% limits Lower	Upper	Effect size
LZ day 1 POST	5,01	2,0431	0,28894	$6.83 \cdot 10^{-8}$	0,58631	1,12969	0,4841
LZ day 1 PRE	4,152	1,77238	0,25065				
LZ day 5 POST	5,584	2,19437	0,31033	$2.3 \cdot 10^{-10}$	0,78	1,308	0,50444
LZ day 5 PRE	4,54	2,06961	0,29269				
LZ POST day 5	5,584	2,19437	0,31033	$2.36 \cdot 10^{-6}$	0,99888	1,86512	0,80795
LZ PRE day 1	4,152	1,77238	0,25065				
TRP day 1 POST	4,485	1,78349	0,25222	$4.11 \cdot 10^{-6}$	0,43168	0,97832	0,39169
TRP day 1 PRE	3,78	1,79989	0,25454				
TRP day 5 POST	4,732	2,14071	0,30274	$6.67 \cdot 10^{-8}$	0,50729	0,97671	0,40496
TRP day 5 PRE	3,99	1,83228	0,25912				
TRP POST day 5	4,732	2,14071	0,30274	$5.94 \cdot 10^{-5}$	0,51665	1,38735	0,52892
TRP PRE day 1	3,78	1,79989	0,25454				

LZ: lumbar zone; TRP: trapezius zone; SD: standard deviation; SEM: standard error of the mean; CI: confidence interval. Effect size: as described in Statistic. PRE and POST is related to before and after the andullation intervention.