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Short term changes in algometry, inclinometry, stabilometry and urinary pH analysis after a thoracolumbar junction manipulation in patients with kidney stones

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Complete List of Authors:	Oliva-Pascual-Vaca, Ángel; University of Seville, Department of Physiotherapy Punzano-Rodríguez, Ramón; Madrid School of Osteopathy Escribá-Astaburuaga, Pablo; Madrid School of Osteopathy Fernández-Domínguez, Juan Carlos; University of Balearic Islands, Nursing and Physiotherapy Department, Ctra Valldemossa km 7.5 Ricard, Francois; Madrid School of Osteopathy School Franco-Sierra, Maria ; University of Zaragoza, Physiotherapy Department Rodriguez Blanco, Cleofas; University of Seville, Department of Physiotherapy, c/Avicena s/n	
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Mary Ann Lieł	pert Inc., 140 Huguenot Street, New Rochelle, NY 10801	

urinary pH were observed (P=0.419).

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lumbar spine flexion.

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Conclusion: Spinal manipulation of the thoracolumbar junction seems to be effective in short-term to improve pain sensitivity as well as to increase the

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Short term changes in algometry, inclinometry, stabilometry and urinary pH analysis after a thoracolumbar junction manipulation in patients with kidney stones

Running head: T-L manipulation and kidney stones

# Authors

Ángel Oliva Pascual-Vaca¹, Ramón Punzano-Rodriguez², Pablo Escribá-Astaburuaga², Juan Carlos Fernández-Domínguez^{3*}, François Ricard², <mark>Maria</mark> Angeles Franco-Sierra⁴, Cleofás Rodríguez-Blanco¹

# Affiliations:

- 1. Professor, Department of Physiotherapy, University of Seville, Spain.
- 2. Madrid School of Osteopathy, Valencia, Spain
- Professor, Department of Nursing and Physiotherapy, University of the Balearic Islands, Spain
- 4. Professor, Department of Physiotherapy, University of Zaragoza, Spain

*Address Correspondence to: Prof^o. Dr. Juan Carlos Fernández-Domínguez. Department of Nursing and Physiotherapy, University of the Balearic Islands, Spain. Ctra. Valldemossa km 7.5, Palma de Mallorca - 07122, Spain. Email: jcarlos.fernandez@uib.es. TLF: +34971259513, FAX+34971172309

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# Authors

- 1. Ángel Oliva Pascual-Vaca. PT, DO, PhD. angeloliva@us.es
- 2. Ramón
   Punzano-Rodriguez.
   PT,
   DO.

   r.punzano@escuelaosteopatiamadrid.com

   3. Pablo
   Escribá-Astaburuaga.
   PT,
   DO.
  - p.escriba@escuelaosteopatiamadrid.com
- 4. Juan Carlos Fernández-Domínguez. PT, PhD. jcarlos.fernandez@uib.es
- 5. François Ricard. DO, PhD. f.ricard@escuelaosteopatiamadrid.com
- 6. Maria Angeles Franco-Sierra PT, PhD. mafranco@unizar.es
- 7. Cleofás Rodríguez-Blanco. PT, DO, PhD. <u>cleofas@us.es</u>

This study was approved by the Ethical Committee of the Scientific European Federation of Osteopaths.

Keywords: nephrolithiasis, spinal manipulation, spine, calculi

#### List of abbreviations by order of appearance:

- EG: Experimental experimental Group group
- CG: Control control Group group
- PPT: Pressure pressure pain thresholds
- RL: Renal renal Lithiasis lithiasis
- SMT: <u>Spinal spinal</u> manipulative therapy
- SD: Standard standard Deviationdeviation
- BMI: Body body Mass mass Indexindex
- QL: quadratus lumborum muscle
- Kg: Kilogramkilogram
- cm: centimeters
- AMA: American Medical Association
- L/S: Lengthlength/Surfacesurface
- P25: percentile 25
- P75: percentile 75
- mm: milimetres

mm/sec: milimetres/second Cl: confidence level i.e.: id est (that is)

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**Authors' contributions:** AOPV and CRB designed the study. AOPV and RPR and FR and MAFS conducted the literature research. RPR and PEA were responsible for data acquisition. AOPV and JCFD and CRB were involved in data analysis. AOPV and JCFD and MAFS were involved in writing the manuscript. All authors were responsible for drafting the manuscript and have read and approved the final version.

**Registration of clinical trials:** Australian New Zealand Clinical Trials Registry 13/05/2014: ACTRN12614000506695

#### ABSTRACT

**Objectives:** To determine the efficacy of a high-velocity low-amplitude manipulation of the thoracolumbar junction in different urologic and musculoskeletal parameters in subjects suffering from renal lithiasis. Design: Randomized controlled blinded clinical study. Settings/location: The Nephrology Departments of 2 hospitals and one private consultancy of physiotherapy in Valencia (Spain). Subjects: Fourty-six patients suffering from renal lithiasis. **Interventions** The experimental group (EG, n=23) received a spinal manipulation of the thoracolumbar junction, and the control group (CG, n=23) received a sham procedure. Outcome measures: Pressure pain thresholds (PPT) of both quadratus lumborum and spinous processes from T10 to L1, lumbar flexion range of motion, stabilometry and urinary pH were measured before and immediately after the intervention. A comparison between pre and post intervention phases was performed and an analysis of variance for repeated measures using time (pre- and post-intervention) as intrasubject variable and group (CG or EG) as intersubject variable.

**Results:** Intragroup comparison showed a significative improvement for the EG in the lumbar flexion range of motion ( $\mathbf{P}$  <0.001) and in all the PPT (P<0.001 in all cases). Between groups comparison showed significant changes in PPT in both quadratus lumborum (P<0.001) as well as in the spinous processes of all of the evaluated levels (P<0.05). No changes in urinary pH were observed (P=0.419).

**Conclusion:** Spinal manipulation of the thoracolumbar junction seems to be effective in short-term to improve pain sensitivity as well as to increase the lumbar spine flexion.

#### INTRODUCTION

The prevalence of nephrolithiasis affects between 5-15% of worldwide population, resulting in a global major economic and health burden<u>worldwide.</u>¹ The recurrence rates of symptomatic stones are high, greater than 50% within 5 years of a first episode. Recurrence rates of 50% after 10 years and 75% after 20 years have been reported.²

The etiological factors of kidney stone formation are complex and diverse and involve genetic, metabolic and environmental risk factors,³ some of which may be adjustable;^{4,5} so that the stone formation usually results from an imbalance between factors that promote urinary crystallization, and those that inhibit crystal formation and growth.⁶ The most important data appear to be related to the links between genetic variability and urine calcium excretion and pH, so these risk factors seem to be at the very center of the problem of kidney stone disease.⁶ Therefore, urinary pH is a decisive element to be considered in supersaturation of many stones;^{6,7} thus, it should be taken into account that both highly acidic urine (pH < or equal to 5.5) and highly alkaline urine (pH > or equal to 6.7) predispose patients to calcium kidney stone formation.

All stones share similar presenting symptoms.⁸ Most patients present with moderate to severe colic where the painful area is determined by the location of stone in the urinary system. It may also be accompanied by other possible symptoms, such as dysuria, urination urgency and frequency,⁷ and autonomic manifestations. Less often, patients present with silent ureteral obstruction, unexplained persistent urinary infection, or painless hematuria.

There are scarce studies on the use of physical therapies as a hypoalgesic measure against Renal Lithiasis (RL),^{9,10} and even less on the use of manual therapy or spinal manipulative therapy (SMT).^{11,12} As far as we are concerned, there are no **randomized** clinical trials on the application of spinal manipulative therapy on patients suffering from RL.

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The purpose of this study was to evaluate the immediate effect of thoracolumbar spinal manipulation in pressure pain threshold (PPT) in the thoracolumbar region, in the back range of motion, in postural control and balance and in urinary pH-metry in subjects suffering from RL.

#### MATERIALS AND METHODS

#### Study design

The study consisted in a controlled randomized double-blind clinical trial (Registration Number ACTRN 12614000506695).

#### Randomization and blinding procedures

To randomize patients into their respective groups, a randomized number table designed by an Internet website (randomized.com) was used. The computerbased randomization also helped establish allocation concealment. An external consultant prevented access to the sequence for those participating in the study.

#### Blinding

Subjects remained unaware of the number of study groups and the treatment allocation group, whereas evaluators who collected or analysed data remained unaware of critical study factors and also the treatment allocation group in order to ensure participant blinding and outcome assessor blinding respectively.¹³ The clinician in charge of the intervention did not participate in the assessment protocol and was not aware of the purposes of the study.

#### Study and sampling population

Those subjects meeting the study criteria were selected according to nonprobabilistic consecutive sampling techniques and were recruited for the study from the Nephrology Departments of 2 hospitals and one private consultancy of physiotherapy in Valencia (Spain). Considering a bilateral contrast with an alpha risk of 0.05 and a beta risk of 0.20 and assuming a common standard deviation of 0.6, as well as the lack of losses during the monitoring, a sample size of 23 subjects per group was estimated through the Granmo online v7.12 software

[http://www.imim.es/ofertadeserveis/software-public/granmo/], in order to detect a 0.5 pH units difference between the groups.

#### Inclusion and exclusion criteria

The inclusion criteria for participants were: (a) sub-clinical Renal Lithiasis (RL) diagnosed by a Nephrology specialist (following the *European Association of Urology* criteria);¹⁴ (b) ages between 25 and 55 years; and (c) signing the informed consent.

Patients with any of the following characteristics were excluded: (a) having suffered from nervous tissues or bone tumours, inflammatory rheumatism, infectious diseases or other non-lithiasic nephropathies; (b) pregnancy; (c) central or peripheral neurological pathology or suffering or having suffered pathologies showing impaired balance; (d) breathing disorders capable of changing the urinary pH; (e) contraindications for the intervention technique; and (f) having taken some kind of medication within the last 72 hours.

#### **Participants**

Fifty-one subjects suffering from sub-clinical RL were evaluated for their participation in the study; however, only forty-six (n=46) subjects met the selection criteria. Participants were randomized in two groups: the control group (CG) and the experimental group (EG). The final sample included 27 men (59%) and 19 women (41%) with an average age of 38.5 (SD=6.80) and a Body Mass Index (BMI) of 25.07 (SD=3.12). No loss to follow-up was recorded during the data collection or analysis phases. The study protocol followed the CONSORT guidelines.¹⁵ (Figure 1).

#### Study protocol

Participants received the evaluation and intervention protocol together in one session. The therapist and the evaluator were both experienced senior physical therapists and osteopaths.

The assessor carried out the pre-intervention measurements, subsequently the therapist performed the assigned intervention and 10 minutes later, the evaluator repeated the said post-intervention measurements. All measurements were performed in the morning.¹⁶ The patients were asked to attend the consultancy about two hours after having had breakfast, and not having practiced any exercise throughout the morning in which the study was conducted.^{17,18} The sequence of all measurements was performed in the same way for both the EG and for the CG.

# Pressure pain thresholds on the spinous processes and the quadratus lumborum (QL) muscle

The digital compression dynamometer PCE FM-200 (Meschede, Germany) was used. The PPT were measured on T10 to L1 spinous processes with the subject placed in prone position¹⁹, and in the trigger point of the quadratus lumborum just below the 12nd rib with the subject placed in lateral decubitus and the homolateral upper limb placed above the head.²⁰ The algometer pointer was placed perpendicular to the point of evaluation, increasing the pressure force with a constant rate of 1 kg/cm² /s evenly and continuously until the perception of a tender point.²¹ Patients were asked to inform when they felt a change in the feeling of pressure pain and then the evaluator stopped applying pressure, taking the appropriate register.²² The algometer remained with the display in a position where the evaluator could not see it until the signal of the patient. Three measurements were made, taking the mean as the reference value. Ten seconds when changing the point.²³

#### Evaluation of back range of motion

Trunk flexion was measured using a digital inclinometer, BASELINE model (New York, USA), recommended by the AMA Guide (American Medical

Association).²⁴ Patients were in their underwear, standing barefoot, arms hanging, knees extended, separated feet to the width of their hips and without hip rotation. without feet, They were asked a maximum trunk flexion with knees extended and arms hanging down.²⁵ The inclinometer was placed on the spinous process of T12, and trunk flexion was requested following the above instructions. Three proper measurements were made, leaving 30 seconds between each²⁶ and taking the mean as the reference value.²⁷ The same measurement was repeated three times leaving 30 seconds between each.²⁶

#### Urinary pH analysis

The measurement was performed with the pH-meter Oakton Waterproof pHTester 30 Pocket pH Tester (Barcelona, Spain). The pH study was performed within the first two hours after the sample was taken. Following the European guidelines the mean portion of urine was collected, after washing the external genitalia. The tip of the pH-meter was immersed about 2 cm in the container with urine, it was stirred and we waited for the reading to stabilize.²⁸ A urinary pH measurement was performed before the intervention and this measurement was repeated for the first urine after the intervention.

#### Postural control and balance

The stabilometry and baropodometry platform PODOPRINT of Namrol (Barcelona, Spain) was used. This instrument allows to collect the following variables related to postural control and balance: X and Y mean oscillation, average speed and stroke length, anterior and lateral mean variation and L/S parameter (the ratio of stroke length and the surface of the ellipse). Prior to the measurement, the patient was explained what the whole process involved²⁹ and the correct way to stand on the platform.³⁰ Three measures of 30 seconds each were performed, taking the third measure.³¹ After each reading, patients were asked to take a step back and leave the platform <u>indicated</u>, after which the measurement process started again until all three measurements were completed.³²

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#### Intervention in the experimental group (Figure 2)

Based on the sympathetic innervation of the kidneys³³ and the fact that spinal manipulations modulates some organ functions in some cohorts,³⁴ the therapist applied **a** thrust manipulation of the thoracolumbar junction that can be described as:³⁵

The patient was placed first on her/his side, with the contralateral lower limb flexed and his/her foot resting on the popliteal fossa of the other lower limb, which remained in extension. Thus a flexion parameter is also placed on the upper lever with a rotation in the region of 5-10° up to T12-L1 and then in the lower lever, for which the upper lower limb is flexed and where the rotation will be about 20° until reaching the level to manipulate (T12-L1). The therapist, who is in front of the patient, has his rear leg flexed and resting on the lower limb of the patient. The caudal hand presses on the inferior articular apophyses of T12, contralateral to the side that the patient is lying on, while the cranial hand rests on the chest of the patient. From that pre-manipulative position, the therapist performs a force of high speed at the end of the available range of motion, rotating the patient towards the side he is lying on. This rotational movement of low amplitude is executed through a traction of the pelvis forward while the therapist's leg resting on the lower limb of the patient makes a sharp knee extension to further rotate the pelvis forward. Since autonomic effects can be unilateral,^{36,37} this technique was made bilaterally at the level T12-L1 only once. After the intervention, the patient was at rest for 10 minutes.

#### Intervention in the control group

The CG received a <u>non-active</u> placebo manoeuver,³⁸ The subject was lying in supine position. The therapist placed one hand on the sacrum and the other hand on the middle thoracic region, without performing any action for 90 seconds. A rest time of 10 minutes was also taken before taking the post-intervention measurements.

#### Data analysis

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Data were analyzed and processed using the statistical package R, version 3.0.1 (http://cran.r-project.org).

At baseline, the mean and standard deviation were described (for quantitative variables with normal distribution), or medians and percentiles [P25-P75] (for those without a normal distribution). To assess the normality of distributions, the Shapiro-Wilk test was performed for each of the variables analyzed. The existence of baseline differences was analysed between both groups using both parametric tests (Student t test for independent samples), or using non-parametric tests (Wilcoxon-Mann-Whitney) based on the results of the normality test. (Table 1).

For comparison between the pre and post intervention phase (intrasubject differences), the differences between variables were calculated, and the Shapiro-Wilk normality tests was applied to the changes to determine the adequacy of parametric tests (Student's t test for intrasubject measurements) and nonparametric tests (Wilcoxon test). Due to the small sample size, all contrasts were repeated in the nonparametric version in the variables with a normal distribution. (Table 2).

An analysis of variance for repeated measures was performed using time (preand post-intervention) as intrasubject variable and group (CG or EG) as intersubject variable. In those variables in which statistically significant between groups differences were found at baseline measurements, the pre-intervention value was included as a potential covariable (analysis of covariance) to adjust the effect. The statistical analysis was conducted considering statistically significant P value <0.05. (Table 3).

#### Ethical considerations and data protection

The study was conducted according to the Code of Ethics of the World Medical Association (Declaration of Helsinki)³⁹ and the data privacy was respected.⁴⁰ Before randomization, all participants were informed of the general aspects of the trial, including, among others, the aims, methods, institutional affiliations of the researchers, possible benefits, risks, side effects of assessments and interventions, and the right to withdraw consent to participate at any time

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without reprisal. The subject filled in and signed an informed consent form, as established by the Declaration of Helsinki. The study received approval of the Institutional Ethical Committee of the Scientific European Federation of Osteopaths.

## RESULTS

Data were analyzed and processed using the statistical package R, version 3.0.1 (http://cran.r-project.org).

At baseline, the mean and standard deviation were described (for quantitative variables with normal distribution), or medians and percentiles [P25-P75] (for those without a normal distribution). To assess the normality of distributions, the Shapiro-Wilk test was performed for each of the variables analyzed. The existence of baseline differences was analysed between both groups using both parametric tests (Student t test for independent samples), or using non-parametric tests (Wilcoxon-Mann-Whitney) based on the results of the normality test (Table 1).

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The CG was composed of 23 subjects, 57% are men, with a mean age of 38.65 years  $\pm$  6.20 years and a mean BMI of 25.12  $\pm$  2.87 kg/m². The EG was composed of 23 subjects, 61% are men, with a mean age of 38.34 years  $\pm$  7.48 years and a mean BMI of 25.03  $\pm$  3.41 kg/m². No differences between groups were found at baseline in any of the control variables collected.

**Table 1** shows the baseline physical and clinical characteristics of the study sample and compares the existence of differences between-groups. Despite randomization, significant baseline differences were found between groups in almost all algometry values and those of the inclinometry, and in values of average lateral variation in the stabilometry. Moreover, it is appreciated that the values of PPT in the QL muscle, and all variables related with stabilometry (except for the mean X and mean Y) did not follow a normal distribution.

In regard to the score differences after intervention, **Table 2** indicates the intragroup comparison results. There was a very significant increase in the range of trunk flexion in the EG (P <0.001). The EG also observed a very significant increase in the PPT in both muscles (right and left QL; P <0.001 in both cases) and at the level of the thoracic and lumbar spinous process (P <0.001 in all cases). There were no differences between treatments in the other variables analysed. In the CG there was also a significant <u>increase decrease</u> in the PPT of the spinous process of T12 and L1.

**Table 3** lists the intergroup comparison of differences from post-intervention to pre-intervention values. There were significant differences, with better values for the experimental group, for PPT in the right QL [P< 0.001; F (1.39) = 49.623; R2= 0.636] and in the left one [P< 0.001; F (1.39) = 35.586; R2= 0.527]; and also in the spinous process of all levels valued: T10 [P< 0.001; F (1.39) = 26.507; R²= 0.461]; T11 [P< 0.001; F (1.39) = 80.481; R2= 0.716]; T12 [P< 0.001; F (1.39) = 103.173; R2= 0.763]; L1 [P< 0.001; F (1.39) = 40.820; R2= 0.731]; and in the range of motion in the level T12-L1 [P< 0.001; F (1.39) = 48.686; R2= 0.603].

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# DISCUSSION

The average age of people in the study coincided with most of the studies reviewed, where the highest incidence of RL occurs around age 40.⁴¹ Not surprisingly, the mean scores of BMI were above 25 and therefore can be classified as overweight or obese grade I.^{4,42}

Spinal manipulation increased trunk flexion at T12-L1 levels in the EG. The mechanical force introduced into the spine during SMT may alter the segmental biomechanics through the release of adhesions, the trapped meniscus or reducing the distortion of the annulus fibrosus.⁴³ This might explain the increase in the articular mobility. We believe that the increased mobility reflected in the study patients must be motivated by the presence of a restriction affecting the thoracolumbar region.44,45 It should be considered that it is known that the effects of a spinal manipulation on stiffness are restricted to the manipulated level. Therefore this result can be due to the detailed and specific manoeuver which was applied.⁴⁶ One of the clinical manifestations of visceral dysfunction in the large intestine is the presence of taut bands in the paravertebral lumbar muscles.⁴⁷ Thus, the significant increase recorded in inclinometry as a result of the applied treatment may also be explained by a decrease in the paravertebral lumbar and quadratus lumborum muscles tone. It could be a consequence of a sensitization process due to the presence of the kidney suffering, which might produce a spasm of the neuromeric musculature, i.e. which are included in the same metamere than the kidney, as it has been shown in previous studies.^{44,48}. It also produced a significant improvement in the average lateral variation in the EG post-intervention, which we think may be due to an improvement in the patient's proprioceptive system as a result of the manipulation.⁴⁰ Spinal manipulation (SMT) can improve postural control, forcing the nervous system to a greater proprioceptive response, so that it detects and reacts more quickly to changes in its center of gravity. Perhaps, if the sample had been larger, other stabilometric parameters could also have changed significantly.

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Similarly, the manipulation increased PPT at the level of the spinous processes of the vertebrae related to the <u>neurovegetative</u> autonomic innervation of the kidney.⁴⁹ QL muscles, which are related anatomically and through neurological innervation,^{50,51} also showed increased PPT.

This improvement was obtained despite the fact that the experimental PPT pain thresholds under pressure were significantly lower in baseline measures, which probably puts more emphasis on the importance of the result. Several studies have shown the existence of referred visceral hyperalgesia to somatic tissues based on different mechanisms in the case of recurrent and/or prolonged visceral stimuli.52 These referred visceral hyperalgesia findings have been reproduced in animal models such as those generated by the formation of artificial stone in one ureter in rats.^{53,54} This has also been studied in patients with kidney stones. It has been proved that lumbar muscle hiperalgesia, in addition to the rest of parietal tissues valued corresponding to the somatic areas of the body wall located in the same neuromeric field as the organ in question, appears soon after the first or second colic. This lumbar muscle hiperalgesia increases with the repetition of the colic, is detectable between the painful episodes (pain-free interval), and even in 90 percent of the cases persists in some degree, mostly at muscular level, after elimination of the urinary stone for months-years (even up to 10 years). It happens even without current instrumental evidence of a new calculosis or other pathology of the urinary tract.⁵⁵ That is to say, this phenomenon often outlasts not only spontaneous pain but also the presence of the primary pain trigger in the internal organ, to the extent that the somatic manifestation could be the only manifest symptom in subjects with visceral suffering.56

As for the approach of RL using SMT, case reports of unusual presentation have been described where mild reduction in pain and transient remission of symptoms were obtained respectively.^{11,12} However, the neurophysiological mechanisms underlying the effectiveness of spinal manipulation to reduce pain are not fully known. Various pathways and activation of the endogenous opioid system have been proposed, such as the activation of the endogenous opioid

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system and/or presynaptic inhibition of nociceptive pathways,⁴³ as well as the inhibition of the production of pro-inflammatory cytokines,^{43,57} or the stimulation of mechanoreceptors that would participate in the pain gating, resulting in somatosomatic and somatovisceral reflexes.⁵⁸

The literature confirms that mechanical stimulation of the spine modulates some organ functions in some cohorts.³⁴ However, no significant differences were seen in urinary pH in our study, so in the short-term, the spinal manipulation did not change the visceral status. Maybe in studies with a longer follow-up period and subsequent interventions, a change in the renal function and consequently the urinary pH could be achieved.

#### Limitations of the study

It should be taken into account that a non-randomized sampling was performed, and the potential self-selection bias, due to the voluntary nature of the participation of the subjects. It should also be considered the baseline betweengroups differences in some of the studied variables. The effects of these differences have been minimized by using the pre-intervention values as covariables. Furthermore, it was the experimental group the one that showed worse pre-intervention values.

The study has a very significant effect in the short term, but it would be interesting to assess how long the changes are maintained in the medium/long-term. It would also be noticeable to evaluate possible changes in the medium/long-term in those variables which in the short term have not showed to be significant, such as the urinary pH. It would have been interesting to include the assessment of catecholamines levels to help explain the increase in PPT, such as studies with similar rationale have done.⁵⁹ There is an absence of guidelines to design the most reliable placebo for manual randomized controlled trials.⁶⁰ We have used a sham manoeuver based on light touch, such as other recent studies have done.⁶¹ However, there are no

studies confirming that this is an adequate control. Future studies should

consider assessing the success of subject blinding and ensuring inertness of their place a priori as a minimum standard for quality.⁶² To finish with, we consider suitable to perform further studies where several techniques are combined⁶³ in order to evaluate whether the effect of the interaction is greater than the effect of an isolated technique.

#### CONCLUSIONS:

The bilateral vertebral manipulation of the thoracolumbar junction seems effective in patients with RL to improve algesic sensitivity in the thoracolumbar region at the level of the quadratus lumborum muscle, to increase spinal range of motion in flexion, and also to improve the average lateral variation as a stabilometric manifestation of the proprioceptive system. Regarding the urinary pH and other stabilometric parameters, not significant differences have been found.

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#### AUTHOR DISCLOSURE STATEMENT

No competing financial interests exist.

#### REFERENCES

- Saigal CS, Joyce G, Timilsina AR. Direct and indirect costs of nephrolithiasis in an employed population: opportunity for disease management? Kidney Int 2005;68:1808-14
- Trinchieri A, Ostini F, Nespoli R, et al. A prospective study of recurrence rate and risk factors for recurrence after a first renal stone. J Urol 1999;162(1):27-30.

- Sakhaee K, Maalouf NM, Sinnott B. Clinical review. Kidney stones 2012: pathogenesis, diagnosis and management. J Clin Endocrinol Metab 2012;97(6):1847-60
- 4. Del Valle EE, Negri AL, Spivacow FR, et al. Metabolic diagnosis in stone formers in relation to body mass index. Urol Res 2012;40:47–52.
- Maalouf NM, Moe OW, Adams-Huet B, Sakhaee K. Hypercalciuria associated with high dietary protein intake is not due to acid load. J Clin Endocrinol Metab 2011;96:3733–40
- Coe FL, Evan AP, Worcester E. Kidney stone disease. J Clin Invest 2005;115:2598–608
- Heilberg IP, Schor N. Renal stone disease: Causes, evaluation and medical treatment. Arq Bras Endrocrinol Metabol 2006;50(4):823-31.
- 8. Bagga HS, Chi T, Miller J, Stoller ML. New insights into the pathogenesis of renal calculi. Urol Clin North Am 2013;40(1):1-12.
- Kober A, Dobrovits M, Djavan B, et al. Local active warming: an effective treatment for pain, anxiety and nausea caused by renal colic. J Urol 2003;170(3):741-4.
- 10. Mora B, Giorni E, Dobrovits M, et al. Transcutaneous electrical nerve stimulation: an effective treatment for pain caused by renal colic in emergency care. J Urol 2006;175(5):1737-41.
- 11. Wells KA. Nephrolithiasis with unusual initial symptoms. J Manipulative Physiol Ther 2000;23(3):196-201.
- 12. Wolcott CC. An atypical case of nephrolithiasis with transient remission of symptoms following spinal manipulation. J Chiropr Med 2010;9(2):69-72
- 13. Chess LE, Gagnier J. Risk of bias of randomized controlled trials published in orthopaedic journals. BMC Med Res Methodol. 2013;13:76.
- 14. Türk C, Knoll T, Petrick A, et al. Guidelines on Urolithiasis. European Association of Urology, 2013
- Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT
   2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010;8:18.

 Ensink FB, Saur PM, Frese K, et al. Lumbar range of motion: influence of time of day and individual factors on measurements. Spine 1996;21(11):1339-43.

- Longkumer T, Parthasarathy G, Kate V, et al. Assessment of vagotomy status with postprandial urinary alkaline tide. Trop Gastroenterol 2009;30(2):91-4
- 18. Moriguchi T, Tomoda A, Ichimura S, et al. Significance of postexercise increment of urinary bicarbonate and pH in subjects loaded with submaximal cycling exercise. Tohoku J Exp Med 2004;202(3):203-11.
- Keating L, Lubke C, Powerll V, et al. Mid-thoracic tenderness: a comparison of pressure pain threshold between spinal regions, in asymptomatic subjects. Man Ther 2001;6(1),34-39.
- 20. Travell JG, Simons DG. Myofascial pain & dysfunction: the trigger point manual. Vol. 2. Philadelphia: Lippincott Williams & Wilkins; 1999.
- 21. Fernández-de-las-Peñas C, Alonso-Blanco CA, Fernández-Carnero JF, Miangolarra-Page JCM. The immediate effect of ischemic compression technique and transverse friction massage on tenderness of active and latent myofascial trigger points: a pilot study. J Bodyw Mov Ther 2006;10(1):3-9.
- 22. Goulet JP, Clark GT, Flack VF, Liu C. The reproducibility of muscle and joint tenderness detection methods and maximum mandibular movement measurement for the temporomandibular system. J Orofac Pain 1998;12(1):17-26
- 23. Frank L, McLaughlin P, Vaughan B. The repeatability of pressure algometry in asymptomatic individuals over consecutive days. Int J Osteopath Med 2012;16(3):143-52.
- 24. Kachingwe AF, Phillips BJ. Inter- and Intrarater Reliability of a Back Range of Motion Instrument. Arch Phys Med Rehabil 2005;86(12):2347-53.
- 25. Prushansky T, Ezra N, Kurse N, et al. Reproducibility of sagittal pelvic tilt measurements in normal subjects using digital inclinometry. Gait Posture 2008,28(3):513-6.

- 26. Macintyre NJ, Bennett L, Bonnyman AM, Stratford PW. Optimizing Reliability of Digital Inclinometer and Flexicurve Ruler Measures of Spine Curvatures in Postmenopausal Women with Osteoporosis of the Spine: An Illustration of the Use of Generalizability Theory. ISRN Reumathology 2011; 2011:571698.
- 27. Mayer TG, Kondraske G, Beals SB, Gatchel RJ. Spinal range of motion. Accuracy and sources of error with inclinometric measurement. Spine. 1997;22(17):1976-84
- 28. Kouri TT, Gant VA, Fogazzi GB, et al. Towards European urinalysis guidelines. Introduction of a project under European confederation of Laboratory Medicine. Clin Chim Acta 2000;297(1-2):305-11.
- 29. Yoon JJ, Yoon TS, Shin BM, Na EH. Factors affecting test results and standardized method in quiet standing balance evaluation. Ann Rehabil Med 2012;36(1)112-8.
- 30. Alburquerque-Sendín F, Fernández-de- las-Peñas C, Santos-del-Rey M, Martín-Vallejo FJ. Immediate effects of bilateral manipulation of talocrural joints on standing stability in healthy subjects. Man Ther 2009;14(1):75-80
- 31. Ruhe A, Fejer R, Walker B. The test-retest reliability of centre of pressure measures in bipedal static task condicions-a systematic review of the literature. Gait Posture 2010;32(4):436-45.
- 32. Grassi D de O, de Souza MZ, Ferrareto SB, et al. Immediate and lasting improvements in weight distribution seen in baropodometry following a high-velocity, low-amplitude thrust manipulation of the sacroiliac joint. Man Ther 2011;16(5):495-500.
- 33. Snell RS. Clinical neuroanatomy. 6th edition. Philadelphia: Lippincott William & Wilkins; 2006.
- 34. Bolton PS, Budgell B. Visceral responses to spinal manipulation. J Electromyogr Kinesiol 2012;22(5):777-84.
- 35. Mintken PE, DeRosa C, Little T, Smith B; American Academy of Orthopaedic Manual Physical Therapists. AAOMPT clinical guidelines: A model for standardizing manipulation terminology in physical therapy practice. J Orthop Sports Phys Ther 2008;38(3):A1-6.

	Journal of Alternative and Complementary Medicine
2	36. Cagnie B, Jacobs F, Barbaix E, et al. Changes in cerebellar blood flow after
	manipulation of the cervical spine using technetium 99M-ethyl cysteinate
	dimer. J Manipulative Physiol Ther 2005;28:103-7.
3	7. Jowsey P, Perry J. Sympathetic nervous system effects in the hands
	following a grade III postero-anterior rotatory mobilisation technique applied
	to T4: a randomised, placebo, controlled trial. Man Ther 2010;15(3):248-53.
3	38. Hancock MJ, Maher CG, Latimer J, McAuley JH. Selecting an appropriate
	placebo for a trial of spinal manipulative therapy. Aust J Physiother
	2006;52(2):135-8.
3	39. Krleza-Jeric K, Lemmens T. 7th revision of the Declaration of Helsinki: good
	news for the transparency of clinical trials. Croat Med J 2009;50(2):105-10.
4	0. Ley Orgánica 15,1999, de 13 de diciembre, de Protección de Datos de
	Carácter personal: B.O.E. num 298;1999.
4	41. Parmar MS. Kidney stones. BMJ. 2004;328(7453):1420-4.
4	42. Nowfar S, Palazzi-Churras K, Chang DC, Sur RL. The relationship of obesity
	and gener prevalence changes in United States in patient nephrolithiasis.
	Urology 2011;78(5):1029-33.
43	3. Maigne, JY, Vautravers P. Mechanism of action of spinal manipulative
	therapy [Mecanismo de acción del tratamiento manipulativo vertebral].
	Osteopatía Científica 2011;6(2):61-6.
2	4. Bicalho E, Setti JA, Macagnan J, et al. Immediate effects of a high-velocity
	spine manipulation in paraspinal muscles activity of nonspecific chronic low-
	back pain subjects. Man Ther 2010;15(5):469-75.
4	5. Arguisuelas MD, Sánchez D, Lozano V, et al. Effects of lumbar spine
	manipulation and thoracolumbar myofascial induction technique on the
	spinae erector activation pattern [Efectos de la manipulación lumbar y
	técnica de inducción miofascial toracolumbar sobre el patrón de activación
	del erector espinal]. Fisioterapia 2010; 32(6):250-5.
	46. Campbell BD, Snodgrass SJ. The effects of thoracic manipulation on
	posteroanterior spinal stiffness. J Orthop Sports Phys Ther 2010;
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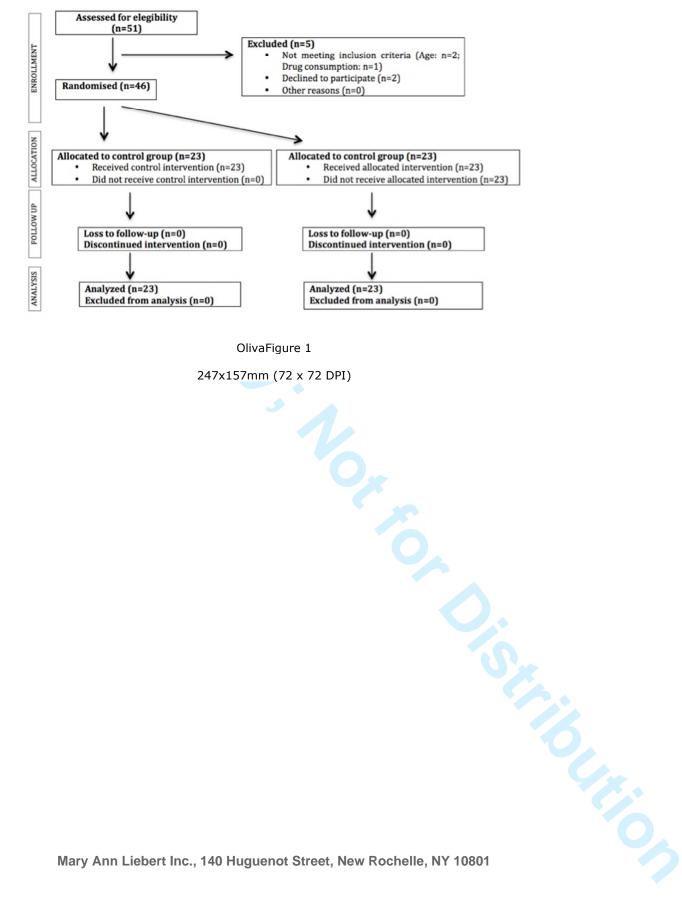
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	representations. J Musculoskelet Pain 2002; 10(1-2),165-75. Giamberardino MA, Affaitati G, Lerza R, et al. Evaluation of indices of
	skeletal muscle contraction in areas of referred hyperalgesia from an
	artificial ureteric stone in rats. Neurosci Letters. 2003;338:213-6.
<b>1</b> 9.	Ruiz-Sáez M, Fernández-de-las-Peñas C, Rodríguez-Blanco CR, et al. Changes in pressure pain sensitivity in latent myofascial trigger points in the
	upper trapezius muscle after a cervical spine manipulation in pain-free subjects. J Manipulative Physiol Ther 2007;30(8):578-83
	Lee SL, Ku YM, Rha SE. Comprehensive reviews of the interfascial plane of the retroperitoneum: normal anatomy and pathologic entities. Emerg Radiol 2010;17(1):3-11.
	Lim JH, Ryu KN, Yoon Y, et al. Medial extent of the posterior renal fascia. An anatomic and computed tomography study. Clin Imaging 1990;14(1):17- 22; discussion 73-5.
	Giamberardino MA, Affaitati G, Costantini R. Visceral referred pain. J Musculoskelet Pain. 2010;18(4):403-10.
	Cervero F, Laird JMA. Understanding the signaling and transmission of visceral nociceptive events. J Neurobiol 2004;61(1):45–54.
	Giamberardino MA, Valente R, de Bigontina P, Vecchiet L. Artificial ureteral calculosis in rats: Behavioural characterization of visceral pain episodes and their relationship with referred lumbar muscle hyperalgesia. Pain 1995; 61(3):459–69. Vecchiet L, Giamberardino MA, de Bigontina P. Referred pain from viscera:
	When the symptom persists despite the extinction of the visceral focus. Adv Pain Res Ther 1992;20:101–10.
	Jalali N, Vilke GM, Korenevsky M, et al. The tooth, the whole tooth, and nothing but the tooth: can dental pain ever be the sole presenting symptom of <mark>a myocardial</mark> infarction? A systematic review. J Emerg Med 2014;46(6):865-72.

- 57. Teodorczyk-Injeyan J, Injeyan H, McGregor M, et al. Enhancement of in vitro interleukin-2 production in normal subjects following a single spinal manipulative treatment. Chiropr Osteopat 2008;16:5.
- 58. Pickar J. Neurophysiological effects of spinal manipulation. Spine J 2002;2(5):357-71.
- 59. Molins-Cubero S, Rodriguez-Blanco C, Oliva-Pascual-Vaca A, et al. Changes in pain perception after pelvis manipulation in women with primary dysmenhorrea: a randomized controlled trial. Pain Med 2014;15(9):1455-63.
- 60. Cerritelli F, Verzella M, Cichchitti L, et al. The paradox of sham therapy and placebo effect in osteopathy. Medicine 2016;95(35):e4728.
- 61. Bautista-Aguirre F, Oliva-Pascual-Vaca A, Heredia-Rizo AM, et al. Effect of cervical versus thoracic spinal manipulation on peripheral neural features and grip strength in subjects with chronic mechanical neck pain: a randomized controlled trial. Eur J Phys Rehab Med. 2017. In press.
- 62. Puhl AA, Reinhart CJ, Doan JB, et al. The quality of placebos used in randomized, controlled trials of lumbar and pelvic joint thrust manipulation a systematic review. Spine J 2017;17(3):445-56.
- 63. Rodriguez-Blanco C, Cocera-Morata FM, Heredia-Rizo AM, et al. Immediate Effects of Combining Local Techniques in the Craniomandibular Area and Hamstring Muscle Stretching in Subjects with Temporomandibular Disorders: A Randomized Controlled Study. J Altern Complement Med. 2015;21(8):451-9.
- 64. Bolton PS, Budgell B. Visceral responses to spinal manipulation. J Electromyogr Kinesiol 2012;22(5):777-84.

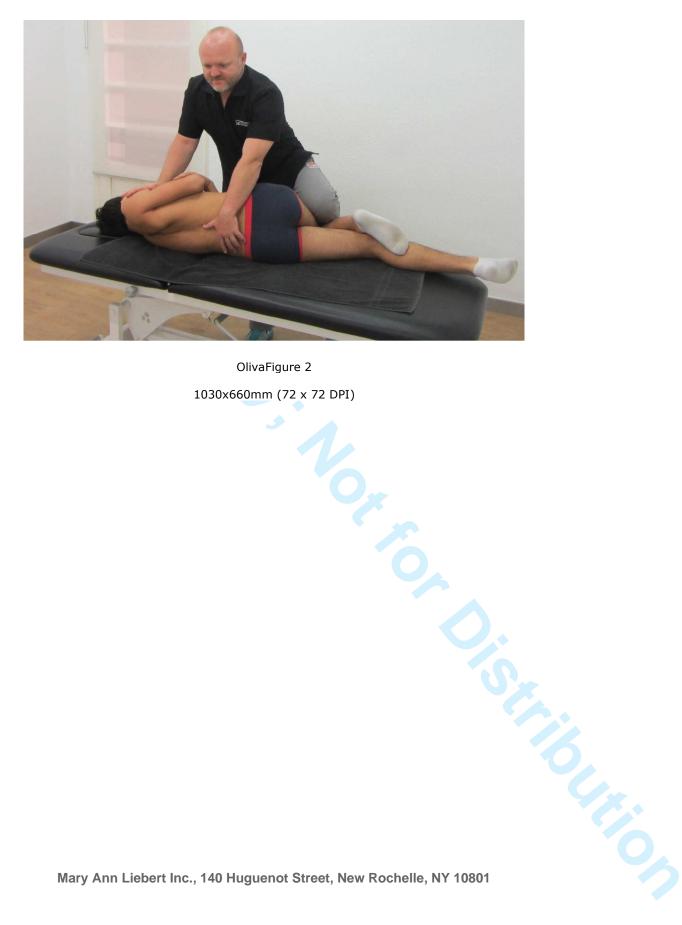
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Table 1. Baseline Characteristics of the entire sample (by group), analysis of the existence of baseline differences between both intervention groups and analysis of the normal distribution of quantitative variables using the Shapiro-Wilks test*.

	n	Experimental	Control	P-value	Shapiro-Wilk
Sex, Male %(n)		60.87(14)	56.52(13)	1.000	
Age	<mark>23/23</mark>	<mark>38.34 (7.48)</mark>	<mark>38.65 (6.20)</mark>	<mark>0.881</mark>	<mark>0.249</mark>
Body Mass Index	<mark>23/23</mark>	<mark>25.02 (3.41)</mark>	<mark>25.12 (2.87)</mark>	<mark>0.917</mark>	<mark>0.557</mark>
рН	23/23	5.86 (0.04)	5.80 (0.03)	0.784	0.332
Quadratus lumborum algometry R (kg)	23/23	1.44 [1.00-1.63]	1.88 [1.49-2.21]	0.005	0.001
Quadratus lamborum algometry L (kg)	23/23	1.50 [1.19-1.85]	1.86 [1.17-2.15]	0.063.	0.034
Thoracic spinous algometry 10 (kg)	23/23	2.63 (0.03)	3.28 (0.04)	0.007	0.334
Thoracic spinous algometry 11 (kg)	23/23	2.5 (0.03)	3.36 (0.05)	0.008	0.111
Thoracic spinous algometry 12 (kg)	23/23	<mark>2.66 [2.16-3.67]</mark>	3.17 [2.89-3.49]	0.048	<0.001
Lumbar spinous algometry 1 (kg)	23/23	3.83 [3.14-4.87]	3.12 [2.88-3.75]	0.001	<0.001
Inclinometry T12-L1 (degrees)	23/23	84.68 (0.66)	94.93 (0.47)	0.012	0.943
Mean X (mm)	23/23	-2.85 (0.28)	-5.11 (0.32)	0.278	0.171
Mean Y (mm)	23/23	-7.64 (0.46)	-13.93 (0.54)	0.070.	0.325
Average speed of the stroke (mm / sec)	23/23	1.20 [0.9-1.6]	1.30 [0.9-1.9]	0.365	<0.001
Stroke Length (mm)	23/23	38.10 [31.3-47.2]	42.5 [28.5-62.1]	0.282	<0.001
Average front variation (mm)	23/23	0.8 [0.5-1.1]	1.0 [0.6-1.4]	0.173	<0.001
Average lateral variation (mm)	23/23	0.5 [0.4-0.8]	0.8 [0.5-1.1]	0.011	<0.001
L/S (1/mm)	23/23	4.4 [3.7-7.4]	3.9 [2.5-5.1]	0.050.	<0.001

 Table 2. Pre- and post-intervention values and intragroup differences in each group (experimental and control)*

Intervention Group			Control Group		
Pre-intervention	Post-intervention	P-value	Pre-intervention	Post-intervention	P-value
5.86 (0.04)	5.87 (0.18)	0.432	5.80 (0.03)	5.86 (0.20)	0.842
1.44 [1.00-1.63]	1.99 [1.55-2.70]	<0.001	1.88 [1.49-2.21]	1.79 [1.39-2.09]	0.378
1.50 [1.19-1.85]	2.13 [1.57-2.65]	<0.001	1.86 [1.17-2.15]	1.73 [1.30-2.14]	0.733
2.63 (0.03)	3.69 (0.27)	<0.001	3.28 (0.04)	3.19 (0.34)	0.173
2.5 (0.03)	3.85 (0.24)	<0.001	3.36 (0.05)	3.06 (0.29)	0.088
2.66 [2.16-3.67]	3.89 [3.21-5.42]	<0.001	3.17 [2.89-3.49]	2.84 [2.29-3.27]	0.001
<mark>2.62 [2.06-3.00]</mark>	3.83[3.14-4.87]	<0.001	3.12 [2.88-3.75]	2.83 [2.46-3.68]	0.020
84.68 (0.66)	90.07 (3.59)	<0.001	94.93 (0.47)	92.24 (2.38)	0.570
-2.85 (0.28)	-1.51 (1.80)	0.778	-5.11 (0.32)	-3.85 (2.18)	0.426
-7.64 (0.46)	-11.49 (3.13)	0.469	-13.93 (0.54)	-17.02 (1.95)	0.294
1.20 [0.9-1.6]	1.20 [1.00-1.30]	0.655	1.30 [0.9-1.9]	1.10 [0.8-1.6]	0.116
38.10 [31.3-47.2]	37.7 [32.6-42.7]	0.687	42.5 [28.5-62.1]	36.5 [26.3-50.9]	0.173
0.8 [0.5-1.1]	0.8 [0.6-1.0]	0.896	1.0 [0.6-1.4]	0.8 [0.6-1.2]	0.106
0.5 [0.4-0.8]	0.6 [0.4-0.9]	0.614	0.8 [0.5-1.1]	0.6 [0.5-0.9]	0.204
4.4 [3.7-7.4]	5.0 [2.5-10.0]	0.760	3.9 [2.5-5.1]	5.7 [4.6-7.7]	0.025
	Pre-intervention       5.86 (0.04)       1.44 [1.00-1.63]       1.50 [1.19-1.85]       2.63 (0.03)       2.5 (0.03)       2.5 (0.03)       2.66 [2.16-3.67]       2.62 [2.06-3.00]       84.68 (0.66)       -2.85 (0.28)       -7.64 (0.46)       1.20 [0.9-1.6]       38.10 [31.3-47.2]       0.8 [0.5-1.1]       0.5 [0.4-0.8]	Pre-interventionPost-intervention5.86 (0.04)5.87 (0.18)1.44 [1.00-1.63]1.99 [1.55-2.70]1.50 [1.19-1.85]2.13 [1.57-2.65]2.63 (0.03)3.69 (0.27)2.5 (0.03)3.85 (0.24)2.66 [2.16-3.67]3.89 [3.21-5.42]2.62 [2.06-3.00]3.83[3.14-4.87]84.68 (0.66)90.07 (3.59)-2.85 (0.28)-1.51 (1.80)-7.64 (0.46)-11.49 (3.13)1.20 [0.9-1.6]1.20 [1.00-1.30]38.10 [31.3-47.2]37.7 [32.6-42.7]0.8 [0.5-1.1]0.8 [0.6-1.0]0.5 [0.4-0.8]0.6 [0.4-0.9]	Pre-interventionPost-interventionP-value5.86 (0.04)5.87 (0.18)0.4321.44 [1.00-1.63]1.99 [1.55-2.70]<0.001	Pre-interventionPost-interventionP-valuePre-intervention5.86 (0.04)5.87 (0.18)0.4325.80 (0.03)1.44 [1.00-1.63]1.99 [1.55-2.70]<0.001	Pre-interventionPost-interventionP-valuePre-interventionPost-intervention5.86 (0.04)5.87 (0.18)0.4325.80 (0.03)5.86 (0.20)1.44 [1.00-1.63]1.99 [1.55-2.70]<0.001

* Data are reported as mean (SD) or as median [P25-P75]. P value: intragroup comparison between pre- and post-intervention results.

#### Table 3. Between-group comparison of the differences from post- to pre-intervention*

	Experimental Group	Control Group	Р
рН	-0.09±0.09 (-0.29/0.11)	0.05±0.15 (-0.28/0.38)	0.419
Quadratus lumborum algometry R (kg)	0.83±0.09 (0.62/1.03)	-0.05±0.06 (-0.18/0.07)	<0.001
Quadratus lamborum algometry L (kg)	0.76±0.10 (0.54/0.98)	-0.02±0.07 (-0.16/0.12)	<0.001
Thoracic spinous algometry 10 (kg)	1.05±0.17 (0.70/1.41)	-0.07±0.19 (-0.48/0.34)	<0.001
Thoracic spinous algometry 11 (kg)	1.26±0.12 (0.99/1.52)	-0.19±0.09 (-0.39/0,001)	<0.001
Thoracic spinous algometry 12 (kg)	1.45±0.14 (-1.15/1.76)	-0.35±0.08 (-0.52/-0.18)	<0.001
Lumbar spinous algometry 1 (kg)	1.35±0.16 (1.02/1.68)	-0.40±0.18 (-0.79/-,0005)	<0.001
Inclinometry T12-L1 (degrees)	5.17±0.65 (3.81/6.53)	-0.34±0.33 (-1.05/0.38)	<0.001
Mean X (mm)	1.27±1.74 (-2.40/4.93)	1.66±1.73 (-2.04/5.36)	0.876
Mean Y (mm)	-1.36±1.87 (-5.28/2.56)	1.41±1.43 (-1.66/4.48)	0.461
Average speed of the stroke (mm / sec)	-0.03±0.08 (-0.21/0.15)	-0.21±0.12 (-0.48/0.05)	0.222
Stroke Length (mm)	-0.73±2.62 (-6.25/4.78)	-6.49±4.27 (-15.65/2.68)	0.240
Average front variation (mm)	-0.02±0.14 (-0.31/0.26)	-0.31±0.14 (-0.61/0,002)	0.161
Average lateral variation (mm)	0.08±0.08 (-0.09/0.24)	-0.40±0.27 (-0.97/0.17)	0.042
L/S (1/mm)	1.18±1.83 (-2.67/5.02)	1.31±0.68 (-0.16/2.78)	0.953

* Data are reported as mean ± SD and (95% confidence level-CI). P value: intergroup comparison between pre- and post-intervention values (ANOVA).