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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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| Abstract:                           | <p>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.</p> <p>Design: Randomized controlled blinded clinical study.</p> <p>Settings/location: The Nephrology Departments of 2 hospitals and one private consultancy of physiotherapy in Valencia (Spain).</p> <p>Subjects: Forty-six patients suffering from renal lithiasis.</p> <p>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.</p> <p>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.</p> <p>Results: Intragroup comparison showed a significant improvement for the EG in the lumbar flexion range of motion (<math>P &lt; 0.001</math>) and in all the PPT (<math>P &lt; 0.001</math> in all cases). Between groups comparison showed significant</p> |

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|  | <p>changes in PPT in both quadratus lumborum (<math>P &lt; 0.001</math>) as well as in the spinous processes of all of the evaluated levels (<math>P &lt; 0.05</math>). No changes in urinary pH were observed (<math>P = 0.419</math>).</p> <p>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.</p> |
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**Title of the manuscript**

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

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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~~ Lithiasislithiasis

SMT: ~~Spinal-spinal~~ 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

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7 mm/sec: milimetres/second

8 CI: confidence level

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10 i.e.: id est (that is)

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13 **Conflicts of interest:** The authors declare no conflicts of interest.

14  
15  
16 **Financial support:** This study has not received any financial support.

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18  
19 **Authors' contributions:** AOPV and CRB designed the study. AOPV and RPR  
20 and FR and MAFS conducted the literature research. RPR and PEA were  
21 responsible for data acquisition. AOPV and JCFD and CRB were involved in  
22 data analysis. AOPV and JCFD and MAFS were involved in writing the  
23 manuscript. All authors were responsible for drafting the manuscript and have  
24 read and approved the final version.  
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30 13/05/2014: ACTRN12614000506695  
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**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:** Forty-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 ( $P < 0.001$ ) 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, ~~worldwide~~.<sup>1</sup>

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.<sup>2</sup>

The etiological factors of kidney stone formation are complex and diverse and involve genetic, metabolic and environmental risk factors,<sup>3</sup> some of which may be adjustable;<sup>4,5</sup> so that the stone formation usually results from an imbalance between factors that promote urinary crystallization, and those that inhibit crystal formation and growth.<sup>6</sup> 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.<sup>6</sup> Therefore, urinary pH is a decisive element to be considered in supersaturation of many stones;<sup>6,7</sup> 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.<sup>8</sup> 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,<sup>7</sup> 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);<sup>9,10</sup> and even less on the use of manual therapy or spinal manipulative therapy (SMT).<sup>11,12</sup> 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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7 The purpose of this study was to evaluate the immediate effect of  
8 thoracolumbar spinal manipulation in **pressure pain threshold (PPT)** in the  
9 thoracolumbar region, in the back range of motion, in postural control **and**  
10 **balance** and in urinary pH-metry in subjects suffering from RL.  
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## 14 **MATERIALS AND METHODS**

### 15 **Study design**

16 The study **consisted** in a controlled **randomized** double-blind clinical trial  
17 (Registration Number ACTRN 12614000506695).  
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### 22 **Randomization and blinding procedures**

23 To **randomize** patients into their respective groups, a **randomized** number table  
24 designed by an Internet website (randomized.com) was used. The computer-  
25 based **randomization** also **helped** establish allocation concealment. An external  
26 consultant prevented access to the sequence for those participating in the  
27 study.  
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### 32 **Blinding**

33 **Subjects remained unaware of the number of study groups and the treatment**  
34 **allocation group, whereas evaluators who collected or analysed data remained**  
35 **unaware of critical study factors and also the treatment allocation group in order**  
36 **to ensure participant blinding and outcome assessor blinding respectively.**<sup>13</sup> The  
37 clinician in charge of the intervention did not participate in the assessment  
38 protocol and was not aware of the purposes of the study.  
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### 44 **Study and sampling population**

45 Those subjects meeting the study criteria were selected according to non-  
46 probabilistic consecutive sampling techniques and were recruited for the study  
47 from the Nephrology Departments of 2 hospitals and one private consultancy of  
48 physiotherapy in Valencia (Spain).  
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7 Considering a bilateral contrast with an alpha risk of 0.05 and a beta risk of 0.20  
8 and assuming a common standard deviation of 0.6, as well as the lack of losses  
9 during the monitoring, a sample size of 23 subjects per group was estimated  
10 through the Granmo online v7.12 software  
11 [<http://www.imim.es/ofertadeserveis/software-public/granmo/>], in order to detect  
12 a 0.5 pH units difference between the groups.  
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### 17 **Inclusion and exclusion criteria**

18 The inclusion criteria for participants were: (a) sub-clinical Renal Lithiasis (RL)  
19 diagnosed by a Nephrology specialist (following the *European Association of*  
20 *Urology* criteria);<sup>14</sup> (b) ages between 25 and 55 years; and (c) signing the  
21 informed consent.  
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24 Patients with any of the following characteristics were excluded: (a) having  
25 suffered from nervous tissues or bone tumours; inflammatory rheumatism,  
26 infectious diseases or other non-lithiasic nephropathies; (b) pregnancy; (c)  
27 central or peripheral neurological pathology or suffering or having suffered  
28 pathologies showing impaired balance; (d) breathing disorders capable of  
29 changing the urinary pH; (e) contraindications for the intervention technique;  
30 and (f) having taken some kind of medication within the last 72 hours.  
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### 36 **Participants**

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

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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.<sup>16</sup> 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.<sup>17,18</sup> 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 position<sup>19</sup>, and in the trigger point of the quadratus lumborum just below the 12<sup>nd</sup> rib with the subject placed in lateral decubitus and the homolateral upper limb placed above the head.<sup>20</sup> The algometer pointer was placed perpendicular to the point of evaluation, increasing the pressure force with a constant rate of 1 kg/cm<sup>2</sup> /s evenly and continuously until the perception of a tender point.<sup>21</sup> 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.<sup>22</sup> 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 were waited between each one of the 3 measurements and 20 seconds when changing the point.<sup>23</sup>

#### **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).<sup>24</sup> 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.<sup>25</sup> 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 each<sup>26</sup> and taking the mean as the reference value.<sup>27</sup> ~~The same measurement was repeated three times leaving 30 seconds between each.~~<sup>26</sup>

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### 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.<sup>28</sup> 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 involved<sup>29</sup> and the correct way to stand on the platform.<sup>30</sup> Three measures of 30 seconds each were performed, taking the third measure.<sup>31</sup> After each reading, patients were asked to take a step back and leave the platform ~~indicated~~, after which the measurement process started again until all three measurements were completed.<sup>32</sup>

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

Based on the sympathetic innervation of the kidneys<sup>33</sup> and the fact that spinal manipulations modulates some organ functions in some cohorts,<sup>34</sup> the therapist applied a thrust manipulation of the thoracolumbar junction that can be described as:<sup>35</sup>

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,<sup>36,37</sup> 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 ~~non-active~~ placebo manoeuvre.<sup>38</sup> 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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7 Data were analyzed and processed using the statistical package R, version  
8 3.0.1 (<http://cran.r-project.org>).

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10 At baseline, the mean and standard deviation were described (for quantitative  
11 variables with normal distribution), or medians and percentiles [P25-P75] (for  
12 those without a normal distribution). To assess the normality of distributions, the  
13 Shapiro-Wilk test was performed for each of the variables analyzed.

14  
15 The existence of baseline differences was analysed between both groups using  
16 both parametric tests (Student t test for independent samples), or using non-  
17 parametric tests (Wilcoxon-Mann-Whitney) based on the results of the normality  
18 test. ~~(Table 1).~~

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

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

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#### 35 36 37 38 39 40 41 42 43 44 **Ethical considerations and data protection**

45 The study was conducted according to the Code of Ethics of the World Medical  
46 Association (Declaration of Helsinki)<sup>39</sup> and the data privacy was respected.<sup>40</sup>

47 Before randomization, all participants were informed of the general aspects of  
48 the trial, including, among others, the aims, methods, institutional affiliations of  
49 the researchers, possible benefits, risks, side effects of assessments and  
50 interventions, and the right to withdraw consent to participate at any time  
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7 without reprisal. The subject filled in and signed an informed consent form, as  
8 established by the Declaration of Helsinki. The study received approval of the  
9 Institutional Ethical Committee of the Scientific European Federation of  
10 Osteopaths.  
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## 13 14 15 RESULTS

16 ~~Data were analyzed and processed using the statistical package R, version~~  
17 ~~3.0.1 (<http://cran.r-project.org>).~~

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18 ~~At baseline, the mean and standard deviation were described (for quantitative~~  
19 ~~variables with normal distribution), or medians and percentiles [P25-P75] (for~~  
20 ~~those without a normal distribution). To assess the normality of distributions, the~~  
21 ~~Shapiro-Wilk test was performed for each of the variables analyzed.~~

22 ~~The existence of baseline differences was analysed between both groups using~~  
23 ~~both parametric tests (Student t test for independent samples), or using non-~~  
24 ~~parametric tests (Wilcoxon-Mann-Whitney) based on the results of the normality~~  
25 ~~test (Table 1).~~

26 ~~For comparison between the pre and post intervention phase (intrasubject~~  
27 ~~differences), the differences between variables were calculated, and the~~  
28 ~~Shapiro-Wilk normality tests was applied to the changes to determine the~~  
29 ~~adequacy of parametric tests (Student's t test for intrasubject measurements)~~  
30 ~~and nonparametric tests (Wilcoxon test). Due to the small sample size, also in~~  
31 ~~the variables where no significant deviation from normality were appreciated, all~~  
32 ~~contrasts were repeated in the nonparametric version (Table 2).~~

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

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7 The CG was composed of 23 subjects, 57% are men, with a mean age of 38.65  
8 years  $\pm$  6.20 years and a mean BMI of  $25.12 \pm 2.87$  kg/m<sup>2</sup>. The EG was  
9 composed of 23 subjects, 61% are men, with a mean age of 38.34 years  $\pm$  7.48  
10 years and a mean BMI of  $25.03 \pm 3.41$  kg/m<sup>2</sup>. No differences between groups  
11 were found at baseline in any of the control variables collected.  
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13  
14 **Table 1** shows the baseline physical and clinical characteristics of the study  
15 sample and compares the existence of differences between-groups. Despite  
16 randomization, significant baseline differences were found between groups in  
17 almost all algometry values and those of the inclinometry, and in values of  
18 average lateral variation in the stabilometry. Moreover, it is appreciated that the  
19 values of PPT in the QL muscle, and all variables related with stabilometry  
20 (except for the mean X and mean Y) did not follow a normal distribution.  
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22  
23 In regard to the score differences after intervention, **Table 2** indicates the  
24 intragroup comparison results. There was a very significant increase in the  
25 range of trunk flexion in the EG ( $P < 0.001$ ). The EG also observed a very  
26 significant increase in the PPT in both muscles (right and left QL;  $P < 0.001$  in  
27 both cases) and at the level of the thoracic and lumbar spinous process ( $P$   
28  $< 0.001$  in all cases). There were no differences between treatments in the other  
29 variables analysed. In the CG there was also a significant ~~increase decrease~~ in  
30 the PPT of the spinous process of T12 and L1.  
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32  
33 **Table 3** lists the intergroup comparison of differences from post-intervention to  
34 pre-intervention values. There were significant differences, with better values for  
35 the experimental group, for PPT in the right QL [ $P < 0.001$ ;  $F(1,39) = 49.623$ ;  
36  $R^2 = 0.636$ ] and in the left one [ $P < 0.001$ ;  $F(1,39) = 35.586$ ;  $R^2 = 0.527$ ]; and  
37 also in the spinous process of all levels valued: T10 [ $P < 0.001$ ;  $F(1,39) =$   
38  $26.507$ ;  $R^2 = 0.461$ ]; T11 [ $P < 0.001$ ;  $F(1,39) = 80.481$ ;  $R^2 = 0.716$ ]; T12 [ $P <$   
39  $0.001$ ;  $F(1,39) = 103.173$ ;  $R^2 = 0.763$ ]; L1 [ $P < 0.001$ ;  $F(1,39) = 40.820$ ;  $R^2 =$   
40  $0.731$ ]; and in the range of motion in the level T12-L1 [ $P < 0.001$ ;  $F(1,39) =$   
41  $48.686$ ;  $R^2 = 0.603$ ].  
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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.<sup>41</sup> Not surprisingly, the mean scores of BMI were above 25 and therefore can be classified as overweight or obese grade I.<sup>4,42</sup>

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.<sup>43</sup> 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.<sup>44,45</sup> 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.<sup>46</sup> One of the clinical manifestations of visceral dysfunction in the large intestine is the presence of taut bands in the paravertebral lumbar muscles.<sup>47</sup> 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.<sup>44,48</sup>

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.<sup>40</sup> 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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7 Similarly, the manipulation increased PPT at the level of the spinous processes  
8 of the vertebrae related to the ~~neurovegetative~~-autonomic innervation of the  
9 kidney.<sup>49</sup> QL muscles, which are related anatomically and through neurological  
10 innervation,<sup>50,51</sup> also showed increased PPT.

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14 This improvement was obtained despite the fact that the experimental PPT  
15 ~~pain thresholds under pressure~~ were significantly lower in baseline measures,  
16 which probably puts more emphasis on the **importance** of the result.

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17 Several studies have shown the existence of referred visceral hyperalgesia to  
18 somatic tissues **based** on different mechanisms in the case of recurrent and/or  
19 prolonged visceral stimuli.<sup>52</sup> These referred visceral hyperalgesia findings have  
20 been reproduced in animal models such as those generated by the formation of  
21 artificial stone in one ureter in rats.<sup>53,54</sup> This has also been studied in patients  
22 with kidney **stones**. It has been proved that lumbar muscle hyperalgesia, in  
23 addition to the rest of parietal tissues valued corresponding to the somatic areas  
24 of the body wall located in the same neuromeric field as the organ in question,  
25 appears soon after the **first or second colic**. **This lumbar muscle hyperalgesia**  
26 increases with the repetition of the colic, is detectable between the painful  
27 episodes (pain-free interval), and even in 90 percent of the cases persists in  
28 some degree, mostly at muscular level, after elimination of the urinary stone for  
29 months–years (even up to 10 years). **It happens** even without current  
30 instrumental evidence of a new calculus or other pathology of the urinary  
31 tract.<sup>55</sup> **That is to say, this** phenomenon **often** outlasts not only spontaneous  
32 pain but also the presence of the primary pain trigger in the internal **organ, to**  
33 the extent that the somatic manifestation could be the only manifest symptom in  
34 subjects with visceral suffering.<sup>56</sup>

35 As for the approach of RL using SMT, case reports of unusual presentation  
36 have been described where mild reduction in pain and transient remission of  
37 symptoms were obtained respectively.<sup>11,12</sup> However, the neurophysiological  
38 mechanisms underlying the effectiveness of spinal manipulation to reduce pain  
39 are not fully known. **Various pathways** ~~and activation of the endogenous opioid~~  
40 ~~system~~ **have been proposed, such as the activation of the endogenous opioid**  
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7 system and/or presynaptic inhibition of nociceptive pathways,<sup>43</sup> as well as the  
8 inhibition of the production of pro-inflammatory cytokines,<sup>43,57</sup> or the stimulation  
9 of mechanoreceptors that would participate in the pain gating, resulting in  
10 somatosomatic and somatovisceral reflexes.<sup>58</sup>  
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14 The literature confirms that mechanical stimulation of the spine modulates some  
15 organ functions in some cohorts.<sup>34</sup> However, no significant differences were  
16 seen in urinary pH in our study, so in the short-term, the spinal manipulation did  
17 not change the visceral status. Maybe in studies with a longer follow-up period  
18 and subsequent interventions, a change in the renal function and consequently  
19 the urinary pH could be achieved.  
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#### 24 **Limitations of the study**

25 It should be taken into account that a non-randomized sampling was performed,  
26 and the potential self-selection bias, due to the voluntary nature of the  
27 participation of the subjects. It should also be considered the baseline between-  
28 groups differences in some of the studied variables. The effects of these  
29 differences have been minimized by using the pre-intervention values as  
30 covariables. Furthermore, it was the experimental group the one that showed  
31 worse pre-intervention values.  
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34 The study has a very significant effect in the short term, but it would be  
35 interesting to assess how long the changes are maintained in the medium/long-  
36 term. It would also be noticeable to evaluate possible changes in the  
37 medium/long-term in those variables which in the short term have not showed to  
38 be significant, such as the urinary pH. It would have been interesting to include  
39 the assessment of catecholamines levels to help explain the increase in PPT,  
40 such as studies with similar rationale have done.<sup>59</sup>  
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43 There is an absence of guidelines to design the most reliable placebo for  
44 manual randomized controlled trials.<sup>60</sup> We have used a sham manoeuvre based  
45 on light touch, such as other recent studies have done.<sup>61</sup> However, there are no  
46 studies confirming that this is an adequate control. Future studies should  
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7 consider assessing the success of subject blinding and ensuring inertness of  
8 their place a priori as a minimum standard for quality.<sup>62</sup>

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10 To finish with, we consider suitable to perform further studies where several  
11 techniques are combined<sup>63</sup> in order to evaluate whether the effect of the  
12 interaction is greater than the effect of an isolated technique.  
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#### 15 **CONCLUSIONS:**

16  
17 The bilateral vertebral manipulation of the thoracolumbar junction seems  
18 effective in patients with RL to improve algescic sensitivity in the thoracolumbar  
19 region at the level of the quadratus lumborum muscle, to increase spinal range  
20 of motion in flexion, and also to improve the average lateral variation as a  
21 stabilometric manifestation of the proprioceptive system. Regarding the urinary  
22 pH and other stabilometric parameters, not significant differences have been  
23 found.  
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30  
31 None  
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#### 35 **AUTHOR DISCLOSURE STATEMENT**

36  
37 No competing financial interests exist.  
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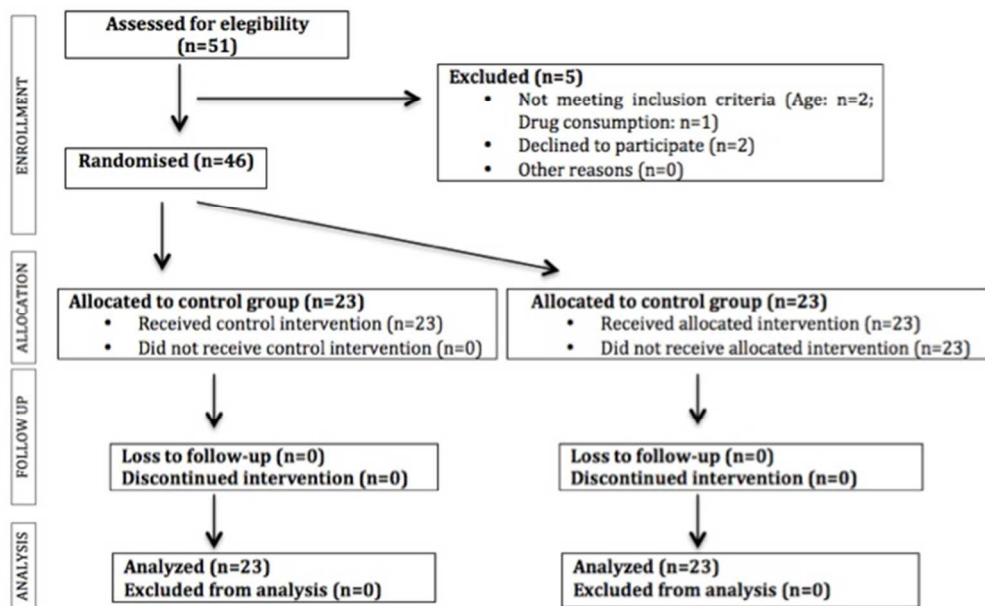
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**Figure 1.** Flow Chart according to the CONSORT Statement for Randomised Trial Reports.

**Figure 2.** Indirect manipulation technique of the thoracolumbar **junction**



OlivaFigure 1

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OlivaFigure 2

1030x660mm (72 x 72 DPI)

**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\*.**

| Variable                               | n     | Experimental      | Control          | P-value | Shapiro-Wilk |
|--|-------|-------------------|------------------|---------|--------------|
| Sex, Male %(n)                         |       | 60.87(14)         | 56.52(13)        | 1.000   |              |
| Age                                    | 23/23 | 38.34 (7.48)      | 38.65 (6.20)     | 0.881   | 0.249        |
| Body Mass Index                        | 23/23 | 25.02 (3.41)      | 25.12 (2.87)     | 0.917   | 0.557        |
| pH                                     | 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 | 2.66 [2.16-3.67]  | 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       |

\* Data are reported as mean (SD) or as median [P25-P75]

**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 |
| pH                                     | 5.86 (0.04)        | 5.87 (0.18)       | 0.432   | 5.80 (0.03)      | 5.86 (0.20)       | 0.842   |
| Quadratus lumborum algometry R (kg)    | 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   |
| Quadratus lumborum algometry L (kg)    | 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   |
| Thoracic spinous algometry 10 (kg)     | 2.63 (0.03)        | 3.69 (0.27)       | <0.001  | 3.28 (0.04)      | 3.19 (0.34)       | 0.173   |
| Thoracic spinous algometry 11 (kg)     | 2.5 (0.03)         | 3.85 (0.24)       | <0.001  | 3.36 (0.05)      | 3.06 (0.29)       | 0.088   |
| Thoracic spinous algometry 12 (kg)     | 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   |
| Lumbar spinous algometry 1 (kg)        | 2.62 [2.06-3.00]   | 3.83[3.14-4.87]   | <0.001  | 3.12 [2.88-3.75] | 2.83 [2.46-3.68]  | 0.020   |
| Inclinometry T12-L1 (degrees)          | 84.68 (0.66)       | 90.07 (3.59)      | <0.001  | 94.93 (0.47)     | 92.24 (2.38)      | 0.570   |
| Mean X (mm)                            | -2.85 (0.28)       | -1.51 (1.80)      | 0.778   | -5.11 (0.32)     | -3.85 (2.18)      | 0.426   |
| Mean Y (mm)                            | -7.64 (0.46)       | -11.49 (3.13)     | 0.469   | -13.93 (0.54)    | -17.02 (1.95)     | 0.294   |
| Average speed of the stroke (mm / sec) | 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   |
| Stroke Length (mm)                     | 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   |
| Average front variation (mm)           | 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   |
| Average lateral variation (mm)         | 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   |
| L/S (1/mm)                             | 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   |

\* 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              | P      |
|--|-------------------------|----------------------------|--------|
| pH                                     | -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 lumborum 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/-0.0005) | <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).