Immediate effects of joint mobilization compared to sham and control intervention for pain intensity and disability in chronic low back pain patients: randomized controlled clinical trial

Efeitos imediatos da mobilização articular em relação à intervenção sham e controle na intensidade de dor e incapacidade em pacientes com dor lombar crônica: ensaio clínico aleatorizado controlado

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ABSTRACT

BACKGROUND AND OBJECTIVES: A possibility to treat chronic low back pain is joint mobilization. There is moderate literature evidence of the effects of mobilization on chronic low back pain; however, few studies have used sham mobilization as comparison group. This study aimed at evaluating the effects of back joint mobilization on the following outcomes: pain intensity and incapacity in chronic low back pain patients.

METHODS: Participated in the study 60 individuals of both genders with the following eligibility criteria: aged between 18 and 55 years with chronic nonspecific low back pain for at least three months. Selected volunteers were randomly distributed in three groups of 20 individuals: joint mobilization group MG: 39.15±11.45 years, sham mobilization group SG: 37.10±12.57 years, and control group CG: 30.60±8.97. All groups were evaluated by the same blind investigator and have answered to the following tools pre-and immediately after the ten intervention sessions: pain numeric scale to evaluate pain intensity, Oswestry Disability Index to evaluate low back pain-related incapacity and Catastrophic Thoughts Scale to evaluate pain-related catastrophizing.

RESULTS: There were significant pre-and post-treatment differences in pain intensity for MG ($p<0.001$) and SG ($p<0.001$). There has been significant difference in mean pain intensity value in MG as compared to CG (-2.55).

CONCLUSION: Our results suggest sham effect related to the application of mobilization in chronic low back pain patients.

Keywords: Clinical trial, Joint mobilization, Low back pain, Manual therapy, Pain catastrophizing.

RESUMO

JUSTIFICATIVA E OBJETIVOS: Uma das possibilidades de tratamento da dor lombar crônica são as mobilizações articulares. Há evidência moderada na literatura sobre os efeitos de mobilizações para dor lombar crônica, entretanto, poucos estudos têm utilizado mobilizações-sham como grupo de comparação. O objetivo deste estudo foi avaliar os efeitos da mobilização articular lombar sobre os seguintes desfechos: intensidade da dor e incapacidade em pacientes com dor lombar crônica.

MÉTODOS: Foram selecionados 60 indivíduos de ambos os sexos com os seguintes critérios de elegibilidade: idade entre 18 e 55 anos, que apresentassem dor lombar crônica não específica há pelo menos três meses. Os voluntários selecionados foram distribuídos aleatoriamente em três grupos de 20 indivíduos: grupo mobilização articular GM: 39,15±11,45 anos, grupo mobilização sham GS: 37,10±12,57 anos e grupo controle GC: 30,60±8,97 anos. Todos os grupos foram avaliados por um mesmo pesquisador encoberto e responderam os seguintes instrumentos pré e imediatamente após as 10 sessões de intervenção: escala numérica de dor para avaliação da intensidade da dor, *Oswestry Disability Index* para avaliação da incapacidade relacionada à dor lombar e Escala de Pensamentos Catastróficos para avaliação da catastrofização relacionada à dor.

RESULTADOS: Foram observadas diferenças significativas pré e pós-tratamento para a variável de intensidade de dor nos GM ($p<0,001$) e GS ($p<0,001$). Na comparação entre os grupos de intervenção, foi verificada diferença significativa no valor médio de intensidade de dor entre GM *versus* GC (-2,55).

CONCLUSÃO: Os presentes resultados sugerem efeito sham relacionado à aplicação de mobilizações em pacientes com dor lombar crônica.

Descritores: Catastrofização da dor, Dor lombar, Ensaio clínico, Mobilização articular, Terapia manual.

INTRODUCTION

Low back pain (LBP) is a multifactorial disease which may affect functional activities. It may be considered a major cause of musculoskeletal incapacity with impairment of adjacent

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structures and secondary joints, leading to biomechanical compensations and overload[1].

Approximately 10 to 40% of individuals with LBP develop chronic pain where pain episode duration is maintained for more than three months[2]. LBP duration may be an important factor for its chronicity and consequent incapacity. Approximately 90% of cases are classified as nonspecific LBP where no evidence of pathologic abnormality can be observed by means of available imaging techniques[3].

In chronic low back pain (CLBP) there might be decreased joint mobility between spinal vertebrae, worsened by movement and consequent functional loss, paravertebral muscles hypoactivity and adjacent lumbar structures inflammatory processes[4].

Among noninvasive pain control methods, Maitland Concept is characterized by specific evaluation and intervention techniques for spinal dysfunctions by means of joint mobilization and is based on the application of smooth passive movements to structures with decreased movement amplitude[5]. There are reports in the literature on the association between increased water diffusion in the intervertebral disc (L5/S1) and immediate pain intensity decrease in patients with nonspecific CLBP submitted to mobilization or manipulation[6,7].

A systematic review[8] has shown no evidence for treatments based on mobilization and exercises or mobilization and medical follow-up with orientations for pain intensity and function improvement in the short and long term in patients with nonspecific CLBP. However, most included studies have not used mobilizations alone.

There are few studies observing the isolated effects of joint mobilizations[9-11]. Immediate pain intensity decrease effects were reported as compared to an untreated control group[9] as well as decrease in pain intensity and stiffness measured by means of increasing supported load in the lumbar region of LBP individuals as compared to healthy controls[10]. One of the few studies including patients with nonspecific CLBP was by Shah & Kage[11]. Authors have observed similar results between groups submitted to mobilization versus stretching exercises in pain intensity decrease, lumbar stretching movement amplitude increase and LBP-related incapacity.

However, authors have not included a sham group. Licciardone et al.[12] have not observed differences in comparison between mobilization + manipulation versus sham manipulation in pain, incapacity and satisfaction with treatment for CLBP patients. However, there are no studies in the literature comparing the effects of mobilization intervention versus sham mobilization.

Considering above-mentioned aspects, this study aimed at primarily evaluating the effects of a 10-session program of posterior-to-anterior joint mobilization on pain intensity and LBP-related incapacity primary outcomes, as compared to a group submitted to the sham technique (inert treatment), as well as controlling possible effects of catastrophizing on pain intensity and incapacity measurements.

METHODS

This is a randomized and controlled clinical trial carried out in the Clinica Escola de Fisioterapia da União das Faculdades dos Grandes Lagos, São José do Rio Preto. The study complied with recommendations of the Consolidated Standards of Reporting Trials – CONSORT[13].

Participated in the study individuals of both genders with the following eligibility criteria: 1) age between 18 and 55 years; and 2) with nonspecific, continuous and recurrent CLBP with minimum duration of three months[14]. Sixty participants were selected. Post hoc sample calculation was performed considering the difference between groups in mean post-treatment pain intensity (Control Group - CG: 4±1.53; Mobilization Group – MG: 0.25±0.79 and Sham Group – SG: 1.65±1.76) (Power 95%, α=0.05). It was observed a power of 97% with effect size of 1.13 and the need for 18 participants per group.

Exclusion criteria were pregnancy and red flag signs (neoplasia, spinal fracture, spinal osteomyelitis, infection or cauda equina syndrome, rheumatic diseases, diseases impairing cognition). Females in luteal phase were rescheduled[15.]

Interventions

Primary outcomes considered in this study were pain intensity and incapacity. Catastrophic thoughts were considered co-variable.

Selected individuals were randomly distributed, by means of randomized sequence generation software (randomizer) and the use of brown sealed envelopes, in three groups of 20 individuals: MG patients were submitted to joint mobilization, SG to sham technique and control group (CG) has received no intervention. All groups were evaluated by the same blind investigator and have answered to the Brazilian Portuguese version of tools: Oswestry Disability Index – ODI, pain numerical scale (PNS) and Pain Catastrophizing Scale (PCS) before session 1 and after session 10.

All MG patients were blind for the therapy and a single investigator has applied the evaluation protocol for administered interventions. Treatment was always applied by the same investigator for mobilization and sham maneuvers. Treatment lasted 5 weeks, twice a week in a total of 10 sessions. MG received central posterior-to-anterior pressure technique for 30 seconds with mean of 30 repetitions in each lumbar vertebra, from L5 to L1, using level II joint mobilization.

Therapy was performed with therapist's caudal hand keeping 2nd and 3rd fingers abducted, being the 3rd finger with flexion of interphalangeals to standardize the length of all fingers. By means of a lumbrical clamp of the 1st and 2nd fingers of the cephalad hand. First and second fingers of the other hand were adducted to perform smooth pressure. So, caudal hand was placed in relaxed position to help palpation, with spinous processes between its fingers, and cephalad hand directed to perform palpation. The same technique was performed for remaining vertebral levels from L5 to L1[16]. During application

of the techniques, patient would remain in prone position and procedure was repeated once for each segment.
SG received the sham mobilization technique, reproducing the same positioning of hands used for the MG group, however without rhythmic oscillations, just with the hands at rest. Similarly, positioning was maintained for 30 seconds for each lumbar vertebra. CG received no intervention.

Evaluation tools

PNS was used for pain intensity evaluation. This is a simple and easy to measure scale consisting of a sequence of numbers from zero to 10, where zero represents "no pain" and 10 represents "worst possible pain". Used PNS had its measurement properties tested in CLPB patients[17].
To evaluate incapacity related to pain and pain intensity, ODI[18] version translated and adapted to Brazilian Portuguese was used. Adapted index has shown adequate measurement properties and is used to evaluate LBP-related functional incapacity[18]. It is made up of 10 items each with six alternatives. Total score is calculated by the sum of points and cannot exceed 50. Higher scores represent higher LBP-related incapacity.
PCS scale was translated and validated for Brazilian Portuguese by Sehn et al.[19]. Scale is made up of 13 staggered items in a Likert scale varying from zero to 5 and associated to the words "almost never" and "almost always" in both edges. Total score is the sum of items divided by the number of answered items, being that minimum score may be zero and maximum score 5 for each item. Higher scores indicate stronger presence of catastrophizing thoughts. Scores of the three domains of the scale are obtained by the sum of respective questions. Total scale score may vary between zero and 52 points.
This study was approved by the Ethics Committee, Faculdade dos Grandes Lagos, under number 150/15 from September 09, 2015. All participants have signed the Free and Informed Consent Term.

Statistical analysis

A model of mixed effects was used for statistical analysis to observe the effects of interventions among different groups and the interaction among treatment subgroups versus time. Terms were created for intervention and the factor time. In addition, moderator effect of catastrophizing on studies outcomes (difference before and after treatment) was observed. It was also observed the effect of interactions between terms and the co-variable catastrophizing on dependent variables pain intensity and incapacity. Bonferroni post hoc test was used to minimize the effect of multiple comparisons. Patients not completing 10 treatment sessions were included in the study as treatment intention analysis as recommended by CONSORT[13].
Variance analyses (ANOVA-one way) were used to verify differences between groups in gender and body mass index ($p<0.05$).
Linear regression analyses were carried out to verify the association between catastrophizing, weight, height and pain intensity. In the presence of significant interaction effects, Bonferroni post hoc test was used for multiple comparison analysis, while primary effects were investigated in the lack of interaction effects.
Individual Minimum Clinical Difference (MCD) values were also analyzed according to recommendations of Ostelo et al.[20] (30% for PNS and ODI before and after treatment).
Variables were described considering mean values and confidence interval of 95% (CI95%). Software used for analysis was IBM SPSS software package, version 22 (IBM Corp, Armonk, New York) and significance level for all analyses was $p<0.05$.

RESULTS

From 150 recruited patients, 90 did not fit inclusion criteria. Sixty were randomly allocated to the three study groups. However, 12 MG patients and 10 SG patients were included by treatment intention analysis. In average, patients included by treatment intention have attended to seven intervention sessions (Figure 1).
There has been significant difference in age for all groups. CG had mean age significantly lower that other intervention groups (Table 1). However, there has been no influence of age, catastrophizing and incapacity on pain intensity ($R^2=0.01$, $p=0.91$).
There have been significant differences before and after treatment for pain intensity variable in MG ($p<0.001$) and SG ($p<0.001$). For LBP-related incapacity, all groups had significant decrease in ODI scores. For catastrophizing, only CG and MG groups had significant decrease before and after treatment (Table 2).

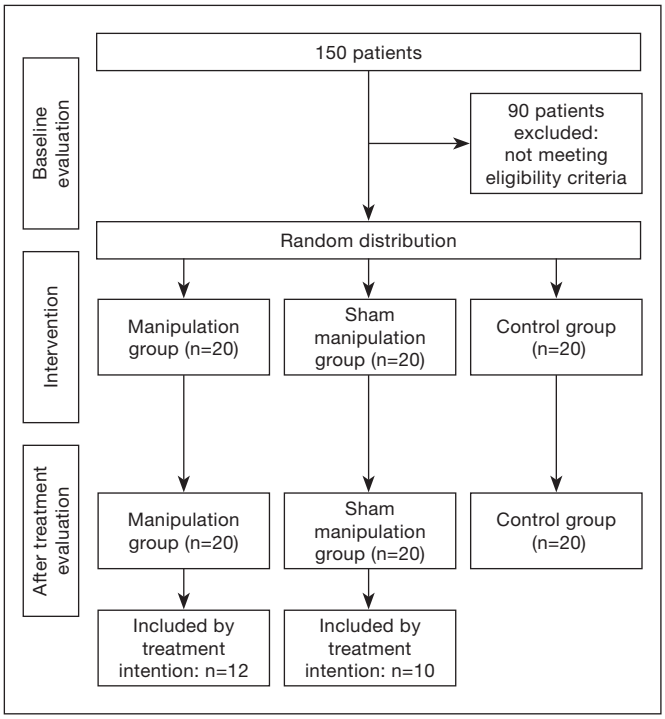

Figure 1. Flowchart describing involved participants and who attended to different study stages

Table 1. Clinical and anthropometric characteristics[1]

Treatment groups	Catastrophizing	High score PCS>23[1]	Mean age (SD)	Mean BMI (SD)	Gender
MG (n=20)	20.4 (7.92)	9	39.15 (11.45)	25.80 (4.46)	15F/5M
SG (n=20)	19.75 (13.62)	9	37.10 (12.57)	25.43 (4.19)	18F/2M
CG (n=20)	21 (10.19)	8	30.60 (8.97)*	23.66 (3.36)	18F/2M
ANOVA	$F=_{(2.57)}0.06$ p = 0.93		$F=_{(2.57)}3.23$. p = 0.05	$F_{(2.57)}=1.61$. p = 0.21	

PCS = Pain Catastrophyzing Scale; MG = mobilization group; SG = sham mobilization group; CG = control group; SD = standard deviation, F: females, M: males; BMI = body mass index; * significant difference with regard to other groups (MG and SG).

Table 2. Description of mean values, standard-deviation and mean difference (before and after intervention) of primary outcome variables (pain intensity, incapacity) and co-variable (catastrophizing) in the three groups

Outcome variables	Before	After	Adjusted mean difference Before-after (CI95%)	p level
CG (n=20)				
PNS	4.10 (3.10 – 5.03)	3.85 (3.09 – 4.61)	-0.25 (0.47 – 0.97)	0.48
ODI	7.10 (5.25 – 8.95)	4.50 (3.08 – 6.01)	-2.55* (1.58 – 3.51)	p<0.001
PCS	21.00 (16.02 – 25.98)	15.60 (10.85 – 20.34)	-5.40* (2.90 – 7.90)	p<0.001
MG (n=20)				
PNS	4.85 (3.50 – 6.15)	0.25 (-0.12 – 0.63)	-4.60* (3.33 – 5.87)	p<0.001
ODI	11.35 (8.41 – 14.28)	3.10 (1.23 – 4.96)	-8.25* (5.10 – 11.30)	p<0.001
PCS	20.40 (16.51 – 24.29)	6.60 (1.25 – 11.94)	-13.80* (8.90 – 19.50)	p<0.001
SG (n=20)				
PNS	4.75 (3.57 – 5.91)	1.65 (0.79 – 2.50)	-3.10* (2.10 – 4.11)	p<0.001
ODI	9.40 (7.53 – 11.27)	4.50 (2.75 – 6.35)	-4.85* (3.27 – 6.42)	p<0.001
PCS	19.75 (13.05 – 26.44)	13.90 (6.68 – 21.11)	-5.85 (-0.52 – 12.22)	0.07

*Mixed effects model, Bonferroni post hoc (p<0.05); PNS = pain numeric scale; ODI = Owestry Disability Index; PCS = Pain Catastrophyzing Scale.

Table 3. Description of mean difference and 95% confidence interval (CI) of the difference among mobilization (MG), mobilization-sham (SG) and control (CG) subgroups for primary outcome variables (pain intensity, incapacity)

Outcome variables	Adjusted mean difference	CI 95%	p level (post hoc)
Pain intensity		F = 39,17, p <0,001	
MG – CG	-2,55*	(0,83 - 4,26)	0,02
MG – SG	-0,84	(-2,16 - 0,45)	0,34
SG – CG	-1,70*	(0,02 – 3,36)	0,05
Lumbar incapacity		F = 2,30, p =0,10	
MG – CG	-1,18	(-2,61 – 5,00)	0,16
MG – SG	-0,52	(-3,43 – 2,38)	0,24
SG – CG	0,68	(-3,03 – 4,41)	1,00

* Mixed effects model, Bonferroni post hoc (p<0.05).

When difference in catastrophizing before and after treatment was considered in the model (catastrophizing as treatment mediator effect) there has been interaction between time versus catastrophizing ($F_{(1.54)}=12.23$, p<0.001) and interaction between treatment versus catastrophizing ($F_{(2.54)}=5.00$ p=0.01). However, there has been no interaction between time versus treatment versus catastrophizing ($F_{(2.54)}=1.65$, p=0.19). There has been significant difference in mean pain intensity value between MG versus CG (-2.55, p=0.02) and SG versus CG (1.70, p=0.05) when comparing among intervention groups. There have been no differences in incapacity levels among groups (Table 3).

MCD was calculated for each group. In CG just 15% (n=3) had PNS changes before and after treatment of at least 30%, in MG 75% and in SG 60%. For incapacity, it was observed that just 20% (n=4) of MG patients with LBP had MCD. In remaining groups, no patient had 30% of ODI improvement.

DISCUSSION

Our first hypothesis was that significant decreases in pain intensity and incapacity in the group of patients submitted to joint lumbar spine mobilization with regard to controls

and sham would be observed. Our study results partially support the initial hypothesis since there has been significant pain intensity decrease in mobilization and sham groups as compared to control group; however, this difference was not observed between mobilization and sham groups. So, results show effects of mobilization and sham intervention on pain intensity on individuals with nonspecific CLBP. And the lack of differences between mobilization and sham groups shows that it is possible that the effect of the treatment with mobilization be basically placebo/sham effect.

In our study, there has been significant pain intensity decrease in the group treated with mobilization and mobilization-sham as compared to control group. In the mobilization group, 75% of participants had 30% change (value considered clinically relevant)[20] in pain intensity versus 60% in the sham group, while in control group this was true for just 15% of participants. Comparison among groups has not shown significant difference between mobilization and mobilization-sham groups. These results emphasize possible sham effect of mobilization.

Previous studies have shown effects of joint mobilization techniques for pain intensity, incapacity and joint stiffness. Studies of Goodsell, Lee & Latimer[9], and Shum, Tsung & Lee[10] have evaluated the effect of just one intervention session. Shah & Kage[11] have observed similar effects between groups submitted to seven mobilization sessions versus prone press-up exercises in decreasing pain intensity, increasing lumbar stretching movement amplitude and improving LBP-related incapacity. There were also better effects for mobilization as compared to stretching exercises. However, authors have not included a sham group[9,10].

One of the few studies comparing mobilization interventions and an inert technique has not observed sham effect after application of just one Hidalgo et al.[8] type mobilization session. There has been significant decrease in pain intensity and pain at movement in the mobilization group as compared to control group (without treatment). Authors suggest sham effect related to intervention since there were no differences before and after intervention in objective movement amplitude measurements and joint stiffness between sham versus intervention groups.

In line with our results, Hancock et al.[21] have observed sham effect when comparing mobilization and turned-off US in patients with acute LBP for pain and functionality. One of the few studies using manual technique as sham technique was performed by Licciardone et al.[12]. Authors have also not observed differences in comparison between mobilization + manipulation versus sham manipulation in pain intensity, incapacity and satisfaction with treatment of CLBP patients, but there have been differences regarding the group with no intervention. Both results were considered as moderate evidence by a recent systematic review[8].

A key-issue of the Manual Therapy research is related to the development of a feasible placebo/sham. Sham manipulation/mobilization may be considered a more adequate placebo procedure since it mimics the interaction among patient, therapist and the clinical context. However, it is necessary to consider that it is not possible to exclude all effects of a technique applied with the aim of not inducing therapeutic effects. So, it is possible that sham technique applied in this study has not worked exactly as a placebo/sham technique.

This way, some factors could be related to real effects in the application of simulation techniques, such as the sham technique applied in this study: 1) effect of laying on of hands, 2) effect of the interaction between therapist and patient, and 3) effect of expectation with regard to applied therapy. Licciardone et al.[12] and Bialosky et al.[22] discuss in a review article the importance of redefining sham/placebo. Conventionally accepted definition of placebo is that it is an inert or "with no effect" treatment. However, it is suggested that placebo is an active psychological and physiologic process associated to robust hypoalgesic response[23]. So, placebo/sham should be considered not only an inert treatment method, but rather as simulations of active treatment, dependent on the psychosocial context where they occur.

Our study has used Maitland posterior-to-anterior mobilizations level II because one primary outcome of the study was pain intensity[17] as well as the fact that many CLBP patients are susceptible to local painful sensitization processes[24]. Major neurophysiologic effects of mobilization are related to passive stretching of contracted tissues. Rhythmic and repetitive mobilization movements increase synovial fluid distribution on joint cartilage and disc, resulting in lower resistance to joint movement[25]. There are some studies emphasizing possible hypoalgesic effects of mobilization at spinal and supraspinal levels. Studies have shown a bombardment of proprioceptive stimuli in spinal cord after manipulations[26] which in turn may lead to hypoalgesia through the pain gateway mechanism. Decreased pain intensity and increased parasympathetic activity seem to be associated to action mechanisms mediated by periaqueductal gray matter (descending pain inhibitory mechanisms) after the application of manual therapy techniques[22], as well as local release of endogenous opioids[26].

However, such neurophysiologic mechanisms explain effects observed in the group treated with mobilizations, but not in the sham group. So, some authors suggest a psychological effect associated to the application of mobilization/manipulation techniques. Considering that psychosocial context might influence results of simulated interventions (sham) it is possible that differences in catastrophizing levels may explain differences in our findings. However, there were no differences in total baseline PCS score among the three studied groups, as well as there were no differences in percentage of individuals classified with high catastrophizing levels (PCS score above 23)[27-29].

On the other hand, all groups had significant decrease in catastrophizing levels before and after intervention, except for the group treated with sham, and all analyses were conducted considering the difference before and after catastrophizing as the co-variable. This result suggests some possible mechanisms: 1) mobilization has major neurophysiologic effects which influence catastrophizing levels and pain intensity reports, or 2) the group receiving the sham technique was not "convinced" of the treatment received. Anyway, our results

suggest that a mediator effect of catastrophizing is possible on pain intensity of CLBP patients[30].

In addition, almost half the sample of this study (43%) had higher catastrophizing levels, suggesting a sample susceptible to sham/placebo effect regardless of administered interventions. So, future studies could verify possible differences in the effect of intervention with mobilization versus sham between subgroups with and without predominance of high psychosocial aspects (catastrophizing, depression, anxiety and fear-avoidance).

Our study had several limitations: 1) Sample size may be considered small and future studies should consider larger samples, notwithstanding post hoc sample calculation showing a Power of 97%; 2) Future studies should verify effects of mobilizations with higher levels as compared to the simulated technique (sham) used in this study; 3) It is also recommended the inclusion of an inert comparator treatment to rule out possible therapeutic effects of the sham technique; and 4) This study was not registered as clinical trials, which could contribute to minimize possible report biases.

CONCLUSION

Our results have shown that joint mobilization was effective to improve incapacity, pain intensity and catastrophizing before and after intervention. However, when comparing the effects among intervention groups, there has been significant pain intensity decrease just in mobilization and sham groups as compared to control group. So, we suggest a sham/placebo effect associated to the application of 10 level II mobilization sessions.

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