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Influence of the cervical spine manipulation in the neck disability index in patients with chronic neck pain: A preliminary study

Influência da manipulação articular cervical no índice de incapacidade do pescoço em pacientes com dor cervical crônica: Um estudo preliminar.

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ABSTRACT

Introduction: Neck pain is one of the major problems managed by chiropractors, therefore its common the use of spinal manipulation to manage this problem. **Objective:** To evaluate the influence of Cervical Spine Manipulation (CSM) in the Neck Disability Index (NDI) of patients with chronic neck pain compared to a manipulative sham group. **Method:** 15 patients with chronic neck pain, were randomly assigned into one of two groups. Experimental Group (EG), with 8 patients, mean age of 30.6(13.7) years and Sham Group (SG), with 7 patients, mean age of 38.9(17.0) years. All the patients signed a Voluntary Informed Consent Document, approved by the university's research ethics committee (n°555.015). The NDI was used to evaluate the outcome. The EG intervention was the CSM, performed 4 times, along a mean of 39.2 days. The SG was subjected to a similar cervical manipulative sensory experience, also performed 4 times, along a mean of 30.6 days. Paired and unpaired Student's t-test was used to assess intra and inter group differences, respectively. **Results:** Statistically significant differences ($p=0.000$) were found for NDI between the pre and post-treatment evaluations of both the EG (26.3(5.0) % pre; 10.9(7.1) % post) and the SG (30.1(3.7) % pre; 18.4(5.3) % post). There were no significant differences for NDI in the pre-treatment between groups ($p=0.122$), however statistically significant differences were found in the post-treatment between the EG and the SG ($p=0.039$). **Conclusion:** The result shows that after the treatment period both groups showed improvement for NDI, however the CSM in the EG resulted in an improved outcome in the treatment of patients with chronic neck pain.

Keywords: Chiropractic manipulation; Neck pain; Chronic pain.

RESUMO

Introdução: A dor de garganta é um dos principais problemas tratados por quiropráticos, portanto, é comum o uso da manipulação vertebral pra solucionar este problema. **Objetivo:** Avaliar a influência da manipulação da coluna cervical (MCC) no Índice de Incapacidade do Pescoço (IIP) em pacientes com dor de garganta crônica em comparação com um grupo de manipulação sham. **Método:** 15 pacientes com dor de garganta crônica, foram distribuídos aleatoriamente em um dos dois grupos. Grupo Experimental (GE), com 8 pacientes, com media de idade de 30,6 (13,7) anos, e Grupo Sham (GS), com 7 pacientes, com media de idade de 38,9 (17,0) anos, Todos os pacientes assinaram um termo de consentimento livre e esclarecido voluntário, aprovado pelo comitê de ética em pesquisa da universidade (n° 555,015). O IIP foi utilizado para avaliar o resultado. A intervenção EG era o CSM, realizada 4 vezes, ao longo de uma média de 39,2 dias. O SG foi submetido a uma experiência sensorial manipuladora cervical semelhante, também realizado 4 vezes, ao longo de uma média de 30,6 dias. Emparelhado e foi utilizado o teste t de Student não pareado para avaliar as diferenças intra e inter grupos, respectivamente. **Resultados:** Diferenças estatisticamente significantes ($p = 0,000$) foi encontrado com NDI entre o pré e pós-tratamento avaliações tanto do EG (26,3 (5,0)% pre; 10,9 (7,1)% post) eo SG (30,1 (3,7)% pre; 18,4 (5,3)% post). Não houve diferenças significativas para NDI no pré-tratamento entre os grupos ($p = 0,122$), no entanto, diferenças estatisticamente significativas foram encontradas no pós-tratamento entre o EG eo SG ($p = 0,039$). **Conclusão:** Os resultados mostram que após o período de tratamento de ambos os grupos mostraram uma melhoria para o NDI, no entanto, o MCS no EG resultou em um melhor resultado no tratamento de pacientes com dor crônica pescoço.

Palavras-chave: Manipulação quiroprática; Dor de garganta; Dor crônica.

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INTRODUCTION

Chronic neck pain is one of the main problems treated by chiropractors, 27% of patients seeking chiropractic treatment report neck or cervical problems,⁽¹⁾ also, 67% of individuals will suffer from neck pain at some stage of their life.⁽²⁾ Moreover, it is considered of great economic impact to the health system, as exemplified by the case of the Netherlands, that estimated an expense of \$ 686.2 million dollars in 1996 just in the treatment of neck pain.⁽³⁾

Cervical Spine Manipulation (CSM) is one of the main treatment modalities used by chiropractors in the management of neck pain also with scientific evidence.⁽⁴⁻¹⁰⁾ However, chiropractors should not be viewed as mechanics performing spinal manipulation. Typically, chiropractic patient management also involves various soft-tissue techniques, home-care instructions, ergonomic advice, and return-to-activity management, including rehabilitative exercise.⁽¹¹⁾

The goals of CSM are to restore dysfunctional joint mechanics and to reduce mechanical stress on the adjacent tissues, thereby reducing pain. High-Velocity, Low-Amplitude (HVLA) manipulation is performed by delivering a quick, impulse-like thrust within a joint's range of motion.⁽¹²⁾ The chiropractor may choose a specific spinal manipulation technique considering such factors as the patient's age, stature, and diagnosis.⁽¹³⁾

In chiropractic, there is a huge controversial argument about the issue of the placebo effect,⁽¹⁴⁾ it can be defined as any improvement or change in subjective discomfort or illness resulting from an intervention possessing no physical effect⁽¹⁵⁾. Therefore, the placebo effect generated by the treatment with spine manipulation⁽¹⁴⁾ is important for achieving improvement of the patient as well as the actual effect of the treatment that is already studied.^(7,9,16,17)

Clinical studies, especially randomized clinical trials, of chiropractic treatment or care may be complicated by the presence of what have been described as nonspecific treatment factors such as expectation of benefit, general manual contact, and other health related beliefs.⁽¹⁴⁾

There is a small sample of sham-controlled trials for spinal manipulation therefore using a sham-controlled spinal manipulation is important and feasible to evaluate the outcomes of the treatment in experimental studies with some spine manipulation.⁽⁶⁾

It is notable that manipulation can lead to an improvement on the course of neck pain and disability with better patient satisfaction.^(7,9,10,18) Therefore, the main objective of this study was to evaluate the CSM^(19,20) in comparison with a Sham Manipulative Procedure for the Cervical Spine (SMPCS)^(14,21,22) on the course of the neck pain and disability.

METHOD

Participants

The study was carried out in the Chiropractic Clinical School of the Feevale University, at Novo Hamburgo, Brazil. In addition, this project followed the resolution of the National Health Council Nº 466, December 12, 2012, which provides guidelines and standards involving human subjects and was approved by the university's research ethics committee of the Feevale University (nº555.015). Moreover, all participants were informed about the procedures, benefits and risks before signing a written informed consent.

Additionally, 15 patients with chronic neck pain, were randomly assigned into one of two groups. Experimental Group (EG), with 8 patients (2 male and 6 female), mean age of 30.6(13.7) years and Sham Group (SG), with 7 patients (1 male and 6 female), mean age of 38.9(17.0) years.

Patients who satisfied the following inclusion criteria were recruited: both genders, between 18 and 59 years of age, NDI higher or equal to 10%, with chronic neck pain and who weren't subjected to any CSM procedure in the last 3 months of the beginning of the research and that signed the written informed consent. The exclusion criteria were: contraindications to manipulation (e.g., infection, malignancy, osteoporosis, spinal fracture, inflammatory conditions, nerve root involvement, etc.), NDI less than 10%, neck surgery, having received CSM in the past 3 months.

Outcome measures

Data collection was performed in previously scheduled appointments with patients interested in participating in the project and was divided into three steps: Step 1 consisted of the voluntary acceptance of the participant in the study, assessment to verify the inclusion and exclusion criteria of the study, interview and the questionnaire of the neck disability index (pre-treatment). Step 2 was to randomly assign the patient into one of the groups, followed by the interventions to each group, which was 4 interventions. Step 3 was on the last intervention, when the NDI was applied immediately after the last intervention (post-treatment). All the interventions were provided within a mean interval of 39.2 days for the EG and 30.6 days for the SG, however, all evaluations and interventions were conducted during a 5-month period by the same trained examiner.

The NDI questionnaire was used to assess the neck function. It is an extremely important tool to quantify the disability caused by neck pain, being considered the "gold standard" for assessing function of the cervical spine. Furthermore, this test consists of 10 objective questions on the intensity of pain, daily activities, loading weight and quality of sleep with a total score of 0 to 100%.⁽²³⁻²⁵⁾

Interventions

All of the patients went through the same clinical evaluation, with imaging and laboratorial analysis when necessary, physical examination with specific orthopedic tests to confirm the inclusion and exclusion criteria according to each patient presentation.

To analyze the cervical spine articular dysfunction both groups underwent a clinical examination including static and dynamic palpation to identify cervical joint dysfunctions which were defined as either an abnormal palpable motion and/or a local joint pain palpable spot, as these criteria are shown to be acceptable and reliable in the literature for the analysis of the cervical spine.^(16,17)

After the evaluation of one or more joint dysfunctions, the intervention at the EG consisted in the CSM with high-velocity, low-amplitude thrust to the spine held in lateral flexion, with slight rotation and slight extension, with the patient in a seated position (see Figure 1).^(19,20) This type of CSM is a standard procedure commonly used by chiropractors, named as Gonstead Technique's Cervical Chair manipulative procedure.

For the SG, it was used a validated SMPCS simulating the sensory experience of a high-velocity, low-amplitude manipulation procedure with the 4 components of the procedure: touch the region with dysfunction, head positioning, movement and sound with the help of the headpiece table-drop (see Figure 2),^(14,21) that is a tool for improve the speed in some types of manipulations. This procedure proved to be valid immediately after and until 48 hours after the intervention to blind the SG and should be applied in experimental studies to determine whether the treatment results are attributed to the intervention or to a non-specific placebo effect.⁽²²⁾

Statistical analysis

The statistical analysis was done with the SPSS-22.0 software. Descriptive and Inferential statistics were used. Descriptive statistics consisted of mean, standard deviation, minimum and maximum. To assess data normality the Shapiro-Wilk test was employed. Inferential statistics consisted of paired and unpaired Student's t-test to assess intra and inter group differences, respectively.

RESULTS

There were no statistically significant inter group differences for age, height, weight and NDI in the pre-treatment assessment ($p < 0.05$), confirming adequate subject randomization.

Statistically significant differences ($p = 0.000$) were found for NDI between the pre and post-treatment evaluations of both the EG (26.3(5.0) % pre; 10.9(7.1) % post) and the SG (30.1(3.7) % pre; 18.4(5.3) % post). Additionally, statistically significant differences were found in the post-treatment between the EG and the SG ($p = 0.039$) (Table 1 and 2).

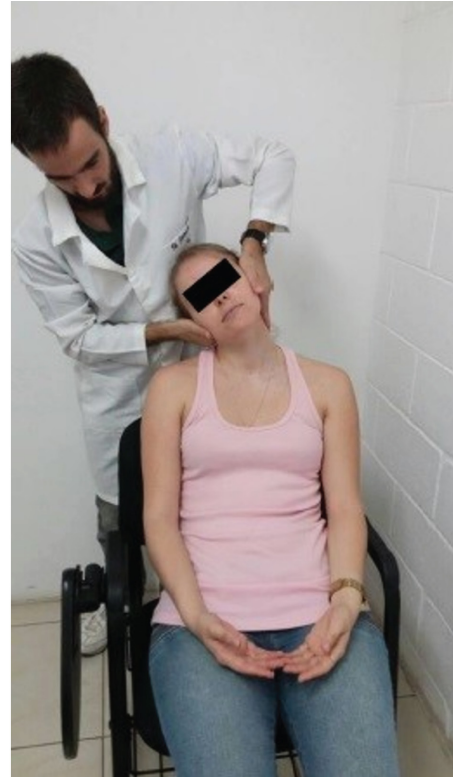


Figure 1. Cervical Spine Manipulation.



Figure 2. Sham Manipulative Procedure for the Cervical Spine. Small arrow: Chiropractor's hand on the paraspinal area in the restricted vertebra. Big arrow: Chiropractor's forearm as a support for patient head and giving a thrust against the drop headpiece.

**Table 1.** Baseline data and inter group comparison.

Sample Data	Experimental Group	Sham Group
Age (years)	30,6±13,7	38,8±17,0
Height (meters)	1,64±0,06	1,63±0,08
Weight (kilogram)	68,3±10,3	78±18,1
Gender (Female/Male)	6F/2M	6F/1M

Table 2. Data of NDI in the pre- post-intervention for either groups.

Groups	Neck Disability Index		
	Pre-Intervention	Post-Intervention	p
Experimental (n=8)	26.3 (5.0)%	10.9 (7.1)%	0,000*
Sham (n=7)	30.1(3.7)%	18.4(5.3)%	0,000*
p	0,122	0,039*	

*Statistically significant differences ($p < 0,05$); Student's t-test for independent samples

DISCUSSION

Women are more likely to experience an episode of neck pain than men, also more likely to report symptoms of persistent neck pain and less likely to have a complete resolution of the symptoms of cervical pain and disability⁽²⁶⁾. This information is confirmed by the findings of this study that evaluated 12 women and 3 men only (Table 1).

As for age, there is a greater likelihood of symptoms of neck pain in young patients, less than 46 years of age.^(2,26) The same information was found in this study, which had a mean age of 30.6 years for EG and 38.9 for SG (Table 1). Factors such as body weight and height in previous studies did not presented themselves as important cervical pain incidence predictors.⁽²⁾

At the Table 2, it was analyzed the data about the NDI at the pre-treatment and the post-treatment for both groups. As aforementioned, there was no statistically significant differences for NDI in the pre-treatment between groups showing that both groups had similar NDI before the intervention. As for the post-treatment, both interventions improved the NDI but the EG with a real CSM was better in the improvement of NDI than the SG with a SMPCS.

To our knowledge, this study was the first to compare the treatment outcomes among that type of CSM^(19,20) and a validated cervical manipulative sham procedure^(14,21) using the NDI to evaluate patients with chronic neck pain. A systematic review showed that sham-controlled trials of CSM are feasible; also, they demonstrate that CSM is associated with a sizeable placebo effect, which arguably creates the necessity to test CSM with sham-controlled clinical trials, particularly if the research question is aimed at identifying specific therapeutic effects.⁽⁶⁾

When Vernon et al.⁽²¹⁾ validated SMPCS, they analyzed that more patients reported improvement in pain following the real manipulation than the sham manipulation (38% vs 28% in the sham group) with the same sham procedure used in this study,

but with no statistically significant intergroup differences in pain, pain threshold or range of motion.

Many other trials attempted to employ other forms of placebo or sham control for spine manipulation.^(4,5,14,21,22,27) In addition, in a systematic review of Vernon et al.⁽²⁷⁾ they affirmed that in 8 of 21 trials that evaluated CSM and some type of sham-controlled manipulation the control procedure resulted in a mean change that wasn't clinically important and bellow the minimal clinically important threshold. Moreover the SMPCS used in a single treatment application suggested that it is a clinically inert treatment due to the lack of change in measures of pressure pain threshold, spontaneous pain and range of motion.⁽²¹⁾

Several limitations must be considered with these results. The sample size was small, limiting the sample to a non-probabilistic sample. It could have been used questionnaires (General Health Questionnaire, PHQ, CPSS, TAMPA Scale for Kinesiophobia or Fear Avoidance Behaviours Questionnaire, etc.) to identify biopsychosocial factors that can lead to catastrophizing and interfere with the outcome of neck disability.^(8,28-31) Thus, studies with spine manipulation involving mechanical pain could use the success predictors for spine manipulation, to verify which patients will be more benefited with spine manipulation.^(8,31) In addition, it is emphasized that in this study the interval between each treatment session and the use of only one chiropractic technique may have influenced the results.

CONCLUSION

The results of this study support that even with the placebo effect of spine manipulation, the Gonstead Technique's Cervical Chair manipulative procedure is superior to the Sham Manipulative Procedure for the Cervical Spine in improving the NDI in a sample of patients with chronic neck pain.

AUTHORS CONTRIBUTION

IFM developed the project, the methodological and experimental parts and contributed to the development of the manuscript. DF was part of the review process of the project and took part on the writing of the manuscript. EFM oriented the study as a reviewer for the methodological and experimental parts, and also contributed to the development of the manuscript.

COMPETING INTERESTS

The authors declare no conflicts of interest.

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