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ORIGINAL RESEARCH

Additional Effects of a Physical Therapy Protocol on Headache Frequency, Pressure Pain Threshold, and Improvement Perception in Patients With Migraine and Associated Neck Pain: A Randomized Controlled Trial

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Abstract

Objective: To evaluate the additional effect provided by physical therapy in migraine treatment.

Design: Randomized controlled trial.

Setting: Tertiary university-based hospital.

Participants: Among the 300 patients approached, 50 women (age range, 18−55y) diagnosed with migraine were randomized into 2 groups: a control group (n=25) and a physiotherapy plus medication group (n=25) (N=50).

Interventions: Both groups received medication for migraine treatment. Additionally, physiotherapy plus medication patients received 8 sessions of physical therapy over 4 weeks, comprised mainly of manual therapy and stretching maneuvers lasting 50 minutes.

Main Outcome Measures: A blinded examiner assessed the clinical outcomes of headache frequency, intensity, and self-perception of global change and physical outcomes of pressure pain threshold and cervical range of motion. Data were recorded at baseline, posttreatment, and 1-month follow-up.

Results: Twenty-three patients experienced side effects from the medication. Both groups reported a significantly reduced frequency of headaches; however, no differences were observed between groups (physiotherapy plus medication patients showed an additional 18% improvement at posttreatment and 12% improvement at follow-up compared with control patients, $P>.05$). The reduction observed in the physiotherapy plus medication patients was clinically relevant at posttreatment, whereas clinical relevance for control patients was demonstrated only at follow-up. For pain intensity, physiotherapy plus medication patients showed statistical evidence and clinical relevance with reduction posttreatment ($P<.05$). In addition, they showed better self-perception of global change than control patients ($P<.05$). The cervical muscle pressure pain threshold increased significantly in the physiotherapy plus medication patients and decreased in the control patients, but statistical differences between groups were observed only in the temporal area ($P<.05$). No differences were observed between groups regarding cervical range of motion.

Conclusions: We cannot assume that physical therapy promotes additional improvement in migraine treatment; however, it can increase the cervical pressure pain threshold, anticipate clinically relevant changes, and enhance patient satisfaction.

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Migraine is a prevalent disease affecting approximately 12% of the world's adult population.[1] It is a burdensome disease that affects individuals, their families, and society.[2,3] As part of migraine pathophysiology, sensitization of certain neuronal groups in the

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brainstem leads to allodynia and muscle sensitivity.[4] Furthermore, muscle dysfunctions, especially in the craniocervical area, may trigger migraine attacks and also increase their frequency.[5,6]

Compared with individuals without migraine, individuals with migraine are more likely to report cervical pain,[7,8] altered postural alignment,[9] reduced cervical mobility,[10] myofascial trigger points,[5,6,11] and increased muscle sensitivity.[12,13] Cervical pain contributes to disability in individuals with migraine[14] and may be a risk factor for migraine chronification.[15]

Accordingly, physical therapy addressing the craniocervical region may be beneficial for patients with migraine. Most recent reviews of manual therapy for migraine report that massage and combined modalities of physical therapy are as effective as pharmacologic treatment; however, recommendations for spinal manipulation remain controversial.[16-18] A common feature of these reviews is the lack of more robust evidence for recommending, or not recommending, some manual therapy modalities to treat migraine because of the poor methodologic quality of the available clinical trials. Most of these studies were not randomized or controlled, as recommended by the Consolidated Standards of Reporting Trials (CONSORT) statement,[19] and they did not follow the criteria of the International Headache Society.[20] The physiotherapy treatment chosen in this study was based on current literature[16-18] and on our clinical routine at the Temporomandibular Disorders and Headache Dysfunction Physiotherapy Clinic.

Pharmacologic treatment has been established as the criterion standard approach for patients with migraine. However, because a multidisciplinary approach is also recommended,[21] it is important to verify to what extent physiotherapy, as an additional protocol, can influence or enhance the effectiveness of prescribed medications to justify its inclusion in the management of migraine and optimize prognosis.

The aim of this study was to evaluate the effect of medication combined with a physical therapy protocol for migraine treatment using the International Headache Society recommendations[22] and the CONSORT recommendations.[19]

Methods

Design

The design was a randomized controlled trial.

Participants

This study was performed from January 2011 to March 2013 at a tertiary, university-based hospital in Ribeirão Preto City, Brazil. Volunteers were recruited by radio and television advertisements.

After agreeing to participate, volunteers came in for a prescreening visit. The study procedure and consent forms were approved by the Ethics Committee of the University of Sao Paulo (process no. 14027/2010). Migraine diagnosis, according to the International Headache Society classification criteria,[20] was assigned by a neurologist with 10 years of experience in headache diagnosis. Inclusion criteria were women between 18 and 55 years old who fulfilled the criteria for migraine with a headache frequency of at least 5 days per month and self-reported cervical pain for at least 3 months.

Exclusion criteria were concomitant headaches, including tension-type and cervicogenic headaches, previous facial and neck trauma, noncontrolled systemic diseases associated with the musculoskeletal system, physiotherapy treatment for craniocervical dysfunction in the previous year, and unwillingness to complete all of the stages of the study or to follow study procedures.

An examiner who was blinded to the nature of the study performed the sample characterization at baseline by administering the following questionnaires to evaluate comorbidities and related disabilities.

The first questionnaire was the Migraine Disability Assessment,[23] which is used to verify the severity of migraine-related disability. Classifications include no disability (0−5 points), mild (6−10 points), moderate (11−20 points), or overall illness severity (≥21 points). It is a reliable measurement with a Cronbach α of .83 and a Spearman correlation coefficient of .84.[24]

The second questionnaire was the Neck Disability Index,[25] which is used to verify disability caused by neck pain and classify it as mild (5−14 points), moderate (15−24 points), severe (25−34 points), or complete disability (≥35 points). This is the most recommended questionnaire to assess neck-related disability with a Cronbach α of .74 and moderate reliability (intraclass correlation coefficient = .50 or Spearman correlation = .92).[26,27]

The third questionnaire was the Allodynia Symptom Checklist/Brazil,[28] which is used to identify the presence and severity of cutaneous allodynia as a symptom associated with central sensitization. Presence of cutaneous allodynia during a migraine attack could be considered as mild (3−6 points), moderate (7−8 points), or severe (≥9 points). It is a reliable tool, with a Cronbach α of .76 and moderate reliability (weighted κ = .58).[28]

The fourth questionnaire was the 8-item Patient Health Questionnaire depression scale (PHQ-8)[29] to identify depressive symptoms. Classification of severity of depressive symptoms includes no significant depressive symptoms (0−4 points), mild (5−9 points), moderate (10−14 points), moderately severe (15−19 points), or severe (20−24 points). The reliability of the PHQ-8 can only be assumed to be satisfactory with regard to its internal consistency (Cronbach α = .82)[30] because test-retest reliability has not been published.

After the baseline assessment, volunteers were allocated to the control group (n = 25) or physiotherapy plus medication group (n = 25), according to the results of a simple 1:1 randomization sequence provided in sealed opaque envelopes. A researcher, who was not involved in the actual study assessment and intervention, was responsible for preparing the envelope, opening it in front of the patient, and scheduling the sessions.

This randomized controlled trial followed the checklist of the CONSORT statement.[19]

Outcome measures

Frequency of headaches was considered the primary outcome. Secondary outcomes were headache intensity, global change perception, pressure pain threshold, and cervical range of motion. Data were classified into clinical and physical outcomes; both were assessed by a blinded examiner at baseline and posttreatment, which was performed between 2 and 7 days after the last physiotherapy

List of abbreviations:

CI	**confidence interval**
CONSORT	**Consolidated Standards of Reporting Trials**
PHQ-8	**8-item Patient Health Questionnaire depression scale**