THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE
Volume 17, Number 3, 2011, pp. 225–230

DOI: 10.1089/acm.2009.0673

Efficacy of Osteopathic Manipulative Treatment of Female Patients with Migraine: Results of a Randomized Controlled Trial

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Abstract

Objectives: Migraine is one of the most prevalent neurological disorders in Europe, severely affecting ability to work and quality of life. Medical therapies are considered to be the "gold standard" of treatment. This study addresses osteopathic treatment for acute therapy or prophylactic therapy as an alternative to traditional therapies.
Design: Forty-two (42) female patients with migraine were randomized into an intervention group ($n = 21$) and a control group ($n = 21$). Outcomes were evaluated with three questionnaires before the treatment (t1) and 6 months later (t2).
Interventions: The intervention group received five 50-minute osteopathic manipulative treatments (OMT) over a 10-week period. The control group did not receive OMT, sham treatment, or physical therapy. Patients of this group only filled the questionnaires. Both groups continued with previously prescribed medication.
Methods: The Migraine Disability Assessment (MIDAS) and Short Form–36 (SF-36) questionnaires as well as a German "pain questionnaire" were used to assess pain intensity, the impact of migraine on daily life and health-related quality of life (HRQoL), and the number of days subjects suffered from migraine.
Results: Three (3) of the eight HRQoL domains of the SF-36 form in the intervention group showed significant improvement (from t1 to t2), with a general betterment exhibited in the other domains. The total MIDAS score, pain intensity, and disturbance in occupation due to migraine as well as number of days of disablements were also significantly reduced. The control group showed insignificant differences in these areas.
Conclusions: This study affirms the effects of OMT on migraine headache in regard to decreased pain intensity and the reduction of number of days with migraine as well as working disability, and partly on improvement of HRQoL. Future studies with a larger sample size should reproduce the results with a control group receiving placebo treatment in a long-term follow-up.

Introduction

Migraine is one of the most prevalent neurological disorders in Europe, experienced by 15% of the population (7% men, 18% women) and severely affecting the ability to work.[1] The economic burden of migraine in Europe totals €27 billion for the 41 million patients aged 18–65; almost 90% of these are indirect costs (i.e., reduced efficiency when working, etc.).[2] Furthermore, the influence of migraine on the Health Related Quality of Life (HRQoL) must also be considered. Lipton et al. in England found a significantly lower score in seven of nine domains of the Short Form–36 (SF-36) questionnaire for individuals with migraine headache compared to controls without migraine.[3]

Severe migraine attacks are triggered by factors such as stress, emotions, illness, or the menstrual cycle. Typically the attacks are strong, one-sided, pulsating headaches often accompanied by anorexia, nausea (80%), vomitus (40%–50%) and phono- and photophobia (50%; 60%) and can last from 4 to 72 hours.[4,5] In 15%–20% of patients, aura symptoms such as visual interference precede the migraine.

Treatment recommendations for migraine headache according to "Guideline of the German Migraine and Headache Society and of the German Neurological Society" and the European Federation of Neurological Societies (EFNS) guideline involve nonsteroidal anti-inflammatory drugs or paracetamol. For stronger migraine headaches, the first choice is triptan. For prophylaxis, β-blockers (such as propranolol,

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metoprolol, and atenolol), calcium channel blockers (such as flunarizine) and anti-epileptic drugs (such as valproic acid and topiramate) are often sufficient, although they sometimes cause adverse effects and are usually contraindicated in women who want to become pregnant, the very group most likely to suffer migraine.[4,6] Nondrug therapies include behavioral therapy, biofeedback, and relaxation therapy, which seem highly effective particularly in combination (60% improvement rate) or when combined with medical prophylaxis (4% improvement rate).[4,7,8]

Alternative medicine therapies concerning migraine prophylaxis are controversial and based on little evidence. Ernst showed in his review that studies employing existing methods of homeopathic treatment of headaches and migraine did not support an improvement of symptoms beyond the placebo effect.[9] The comparability of randomized controlled trials (RCT) examining the effects of homeopathic treatment on patients with migraine or headaches is being criticized by Whitmarsh (2002) on the basis of different study designs and outcomes.[10] Whitmarsh et al. (1997) discussed the difficulties and limitations of clinical trials of homeopathy. They could not affirm positive effects of homeopathic treatment of migraine in clinical parameters (symptoms) in a double-blind RCT.[11] Reviews and meta-analysis should consider nonclinical outcomes, such as well-being as an indicator for HRQoL, as important outcomes as well.

There is evidence that acupuncture does not have a better effect on migraine than sham acupuncture.[9,12,13] A recent Cochrane review concluded that patients with migraine benefit from acupuncture, but the correct placement of needles appears to be nonrelevant.[13] Moreover, Vickers et al. observed in a RCT on 401 patients that acupuncture leads to significant improvement in some aspects of HRQoL.[14]

Biofeedback therapies show some improvement compared to untreated control but negligible improvements in subjects receiving placebo.[15] However, Marcus et al. saw physical treatment as a reasonable adjunct for relaxation/thermal biofeedback in cases for which the latter alone was ineffective.[16] In general, however, research concerning the effects of physical treatment, chiropractic treatment, or osteopathic manipulative treatment (OMT) on migraine headache is limited.

Because of the paucity of evidence-based studies of the effectiveness of OMT on migraine headache, the present trial sought to investigate HRQoL, pain intensity, and the number of days with migraine as well as working disability as gauges.

Methods

The randomized controlled trial with follow-up was approved by the ethics commission of the Faculty of Medicine Carl Gustav Carus of the Dresden University of Technology (EK 111052007 from August 28, 2007).

Participants

Patients were recruited through an advertisement in a local newspaper and flyers placed in doctors' offices in Dresden, Germany and surrounding areas in 2007/2008. Candidates were interviewed by telephone with respect to the inclusion criteria. Of 65 interested subjects, 42 female patients were accepted as subjects and randomized without blinding into an intervention group ($n = 21$) and a control group ($n = 21$).

Inclusion and exclusion criteria

The study group included female patients between 18 and 65 with a minimum of three migraine attacks per month. Migraine was defined according to the International Classification of Disease (ICD-10, G43; migraine with or without aura), and the diagnosis was confirmed by a physician. Exclusion criteria were as follows: nonmedical therapies (such as acupuncture, homeopathy) within 8 weeks before the beginning of the study, pregnancy, lactation, and neurological underlying diseases (such as brain tumors, multiple sclerosis).

Intervention

Patients in the intervention group were treated by an osteopath: a physiotherapist with licensure to practice osteopathic treatment (completed osteopathic education of 5 years and approximately 1.500 hours at the AVT-College for Osteopathic Medicine). OMT was given 5 times for 50 minutes over a 10-week period in 2008. The type of applied OMT (manual, visceral, and/or cranial) was dependent on the particular osteopathic (diagnostic) findings in each patient. The control group did not receive OMT, sham treatment, or physical therapy. Patients of this group only filled out the questionnaires. All subjects continued with their previously prescribed medication.

Instruments

The outcome measures—HRQoL, pain intensity, number of days with migraine headache and working disability—were surveyed in three standardized questionnaires. The German "Pain Questionnaire" (Schmerzfragebogen des Schmerztherapeutischen Kolloquium e.V. Dr. Löwendorf)[17] was employed to measure pain intensity and disturbance in occupation due to migraine. The MIDAS Questionnaire [Migraine Disability Assessment] was used to assess the impact migraine has on a person's life:[18] *inter alia* the number of days with migraine headache (MIDAS A) as well as the number of days of disablement (MIDAS 1). The final score combines the latter variable plus other aspects of daily duties and activities (MIDAS 1–MIDAS 5) and assesses pain intensity (MIDAS B). The SF-36® Health Survey is a common reliable generic outcome measure designed to examine a person's perceived health status and the HRQoL.[19]

The outcome measures were determined twice for both groups: initially before the intervention (t1) and again after 6 months (t2).

Statistics

Statistical analysis was done with SPSS 15.0 software with an intention-to-treat design. First, normal distribution for metric parameters was assured by the Kolmogorov-Smirnov test as premises for selection of statistical tests (parametric versus nonparametric). *T* tests for independent samples were used when comparing statistical differences between both groups. χ^2 tests were used comparing categorical data. When analyzing statistical deviation from t1 to t2 within each group, paired-samples *t* tests were employed. In case normal distribution was not given, the nonparametric Wilcoxon tests were used. When comparing the data of the SF-36 to a representative sample for normative comparison, the one-sample *t* test was used. The level of significance was defined at $p \leq 0.05$.

Table 1. Demographic and Migraine Characteristics of Intervention Group and Control Group at the Beginning of the Study (t1, Before Intervention)

Characteristics	*Intervention group (OMT, n = 21)*	*Control group (no treatment, n = 21)*	*Total (n = 42)*
Age, mean (SD)	47.7 (11.3)	42.4 (11.0)	45.1 (11.3)
Aura, *n*	8	5	13
Without aura, *n*	13	16	29
Years with migraine, mean (SD)	25.5 (11.9)	19.9 (9.3)	23 (10.9)

OMT, osteopathic manipulative treatment; SD, standard deviation.

Results

Baseline characteristics across the 2 groups were similar (Table 1). There were no statistically significant ($p > 0.05$) deviations between the 2 groups concerning age, years with migraine, and aura symptoms. Ages ranged from 24 to 66 years, with a mean of 45 years. A diagnosis of migraine with aura was assigned to 13 patients, and the years with migraine ranged from 2 to 45, with a mean of 23 years. Each group had two dropouts due to unknown reasons.

Days with migraine

We found a significant reduction in the Total MIDAS outcome. This score was significant ($p < 0.05$) from 37.6 to 24.8 in the intervention group in contrast with the control group ($p > 0.05$; 33.6–28.6, Table 2). The number of days with migraine abated from 23.1 days to 19.2 days in the intervention group compared to a smaller decline in the control group (19.1–18.7 days, Table 2), although it was statistically insignificant in both groups ($p > 0.05$).

Working disability

On the one hand, a significant ($p < 0.05$) decrease in disturbance in occupation due to migraine was found in the "Pain Questionnaire" in the intervention group (66.7–50.0, on a negatively poled scale from 0 to 100). In the MIDAS questionnaire, a significant improvement ($p = 0.06$) was seen in days of disablement (2.5–0.5 days). In t1, a total of 19 subjects declared an influence of migraine on their occupation, which was reduced to a total amount of 17 in t2 (Table 2).

On the other hand, in the control group, a significant ($p = 0.06$) reduction of disturbances in occupation due to migraine in the "Pain Questionnaire" was ascertained. Likewise, there was no significant change in days of disablement (2.25–1.42). Similarly, there was no alteration in the total number of subjects declaring an influence of migraine on their occupation (t1 = 19; t2 = 19).

Pain intensity

The pain intensity in the intervention group declined significantly ($p < 0.05$) from t1 to t2 and from 66.7 to 53.8 on a scale of 0 for no pain to 100 for worst imaginable pain (MIDAS B). Also significant was the pain intensity outcome measure of the "Pain Questionnaire" from 70.8 to 51.5 on an equal scale. However, the control group did not show a significant reduction in either of the pain intensity scales (Table 2).

HRQoL, SF-36

A significant ($p \leq 0.05$) improvement in terms of vitality, mental health, bodily pain, and physical role functioning was established in the OMT group. Improvement in the SF-36 domains of social role functioning, emotional role functioning, general health perceptions, and physical functioning was observed but the effects remained statistically insignificant. The data for the control group show no significant improvement, and occasional worsening. In terms of emotional role functioning, a significant deterioration was found in the control group (Table 3).

Comparing the SF-36 outcomes in t1 to the representative sample for normative comparison of the German National Health Survey,[20] we discovered significant differences ($p \leq 0.05$) in physical role functioning, bodily pain, general

Table 2. Outcome Measures of the MIDAS Questionnaire and the Pain Questionnaire for t1 and t2

		Intervention group (OMT)			*Control group (no treatment)*		
Outcome measures	*Questionnaire*	*t1*	*t2*	p-*Value*	*t1*	*t2*	p-*Value*
Numbers of days with migraine	MIDAS A	23.1	19.21	0.31	19.1	18.7	0.89
Total MIDAS outcome[a]	MIDAS 1–MIDAS 5	37.6*	24.8*	0.04	33.7	28.6	0.76
Days of disablement	MIDAS 1	2.5	0.5	0.06[b]	2.3	1.4	0.47
Disturbance in occupation due to migraine[c]	Pain Questionnaire	66.7*	50.0*	0.04	62.9	54.7	0.06
Subjects (*n*) with pain interference with occupation	Pain Questionnaire	19	17	–	19	19	–
Pain intensity; poled negatively (0–100)							
Pain intensity 1	MIDAS B	66.7*	53.8*	0.04	65.3	62.6	0.87
Pain intensity 2	Pain Questionnaire	70.8**	51.5**	0.01	67.0	64.7	0.72

[a]Total MIDAS outcome: Concludes five questions concerning the quantity of days in which migraine had impact on different aspects in life (i.e., productivity at work, household duties, socially activities).
[b]Nonparametric statistical tests.
[c]On a scale from 0 to 100, poled negatively.
*Significant difference at $p \leq 0.05$.
**Significant difference at $p \leq 0.01$.
MIDAS, Migraine Disability Assessment; OMT, osteopathic manipulative treatment; t1, before the treatment; t2, 6 months later.

Table 3. Health-Related Quality of Life Outcomes (SF-36 Scores Poled Positively on a Scale from 0 to 100) for t1 and t2 Comparing to the Representative Sample of the German National Health Survey[15]

	Intervention group (OMT)			Control group (no treatment)			German representative sample				
								p-Value for intervention group (OMT)		p-Value for control group (no treatment)	
Outcome measure	t1	t2	p-Value	t1	t2	p-Value	SF-36 score	t1	t2	t1	t2
Vitality	44.8**	61.9**	<0.01	48.8	48.2	0.69	57.6	<0.01	0.30	0.01	0.03
Mental health	61.9*	70.9*	0.05	67.2	63.8	0.12	69.8	0.06	0.80	0.41	0.15
Physical functioning	81.2	87.6	0.08	87.1	82.6	0.13	82.7	0.71	0.19	0.20	0.99
Bodily pain	37.8*	47.3*	0.05	40.0	42.8	0.28	63.9	<0.01	<0.01	<0.01	<0.01
General health perceptions	53.1	61.9	0.14	49.4	52.9	0.52	66.0	0.02	0.40	<0.01	<0.01
Physical role functioning	51.2**	76.3**	<0.01[a]	48.8	51.4	0.91	79.2	<0.01	0.75	<0.01	0.02
Emotional role functioning	74.6	82.5	0.40[a]	88.9*	70.2*	0.02[a]	86.7	0.19	0.63	0.75	0.09
Social role functioning	66.7	74.3	0.32	62.5	63.2	1.00	84.2	<0.01	0.05	<0.01	<0.01

[a]Nonparametric statistical tests.
*Significant difference at $p \leq 0.05$.
**Significant difference at $p \leq 0.01$.
SF-36, Short Form–36; t1, before the treatment; t2, 6 months later; OMT, osteopathic manipulative treatment.

health perceptions, vitality, and social role functioning for each group, respectively.

The SF-36 outcomes in t2 compared to the German representative sample for the intervention group showed significant ($p \leq 0.05$) statistical deviations only in bodily pain and social role functioning. For the controls, we found significant statistical deviations in the five of eight domains of the SF-36 scores: vitality, bodily pain, general health perceptions, physical role functioning, and social role functioning.

Discussion

Within the general German population as well as physicians, there is an increasing acceptance of complementary and alternative medicine.[21–23] In addition to drug therapies, German treatment recommendations for acute therapies of migraine headache and the EFNS guideline include recommendations for complementary and alternative therapies such as biofeedback and relaxation therapy.[4,6]

Many studies and reviews have assessed the efficacy of homeopathic treatment,[9] acupuncture,[9,12,13,24,25] biofeedback,[15] and physical treatment in combination with relaxation and thermal biofeedback[16] for patients with migraine; however, there is a lack of evidence-based studies about OMT's effectiveness for migraine headache. There are a few references investigating short-term effects of manipulative therapy (as a part of OMT) on pain intensity of patients with migraine.[26] There has been a hint of evidence of OMT helping patients suffering from tension-type headache,[27] cervicogenic headache,[28] or chronic nonspecific neck pain[29] and good evidence for its alleviation of lower back pain.[30]

To our knowledge, this is the first study in Germany investigating the effects of OMT on migraine headache in regard to working disability and HRQoL in addition to common outcomes such as pain intensity and the number of days with migraine.

Pain and HRQoL

Investigating effects of OMT on patients' degrees of pain and HRQoL in a case–control design, we found significant improvements in the OMT-intervention group concerning reduction of the number of days that patients with migraine suffered with their daily duties and activities as well as HRQoL outcomes such as physical role functioning, mental health, vitality, and bodily pain.

Overall, the treatment group reduced the number of days per month with migraine headache by 4. The control group did not show these positive changes. These results are similar to those reported by Jull et al. (2002), showing a significantly reduced headache frequency (defined as number of headache days in the past week) found in patients with cervicogenic headache during and after 12 months of manipulative therapy-intervention.[28] Anderson et al. (2006) found similar results for patients with tension-type headaches, comparing the effects of osteopathic treatment and progressive muscular relaxation exercises. Patients treated once a week by osteopathic therapy showed a significant improvement in the number of headache-free days per week compared to the control group.[27]

Furthermore, there was a significant reduction of pain intensity (from t1 to t2) in the intervention group. These

findings are approximately comparable to those of Schwerla et al. (2008), who found positive effects on pain intensity after OMT intervention on patients with chronic nonspecific neck pain.[29] Jull et al. (2002) also showed significant improvements of pain intensity after a manipulative therapy-intervention as short-term (changes to week 7) and long-term (after 12 months) effect on patients with cervicogenic headache.[28]

Regarding the HRQoL outcomes, we found improvements for all SF-36 subscales, but it is evident that only vitality, physical role functioning, mental health, and bodily pain improved significantly ($p \leq 0.05$) in the OMT group (from t1 to t2). Schwerla et al. also described improvements for all other SF-36 subscales in the OMT-intervention group of patients with chronic nonspecific neck pain compared to a control group receiving sham treatment. They reported a significant improvement for the SF-36 subscale bodily pain from 43.4 to 61.1 in the OMT-intervention group.[29] We also found a significant, but weaker improvement from 37.8 to 47.3 in this scale ($p = 0.05$).

Comparing our SF-36 data at t1 with the representative sample from the German National Health Survey,[20] significantly lower values of HRQoL were found in five of eight domains for all patients with migraine (in both groups). These findings show that patients with migraine are more affected in their HRQoL than the "normal" population of the German representative sample. A possible explanation for not finding significant differences in all domains lies as well in the structure of the sample from the German National Health Survey.[20] This sample ($n = 6964$) had a similar mean for age compared to the present one, but a different age range (18–80 years).

Lipton et al.[3] also found a reduced HRQoL for patients with migraine in relation to healthy controls in a British population-based study; seven of nine subscales showed significantly lower scores.

Comparing our participants with the German representative sample in t2, all of the aforementioned five significant differences except for bodily pain were invalid only in the intervention group, while in t1 there were significant differences of HRQoL in five of eight domains. Therefore, one can speak of a general improvement from t1 to t2 concerning the HRQoL domains. This was not true for the control group.

Working disability

Significant improvements were ascertained in parameters of indirect costs, which play an important role in the discussion of health-related outcomes of migraine.[2] In the OMT group, there was a significant reduction from t1 to t2 of the number of days of disablement, but there was no significant change observed in the control group.

Furthermore, significant decline in disturbance in occupation due to pain in the intervention group was found. The control group, however, showed a significant improvement concerning this matter as well. This might be explained by the Hawthorne effect, which describes an improvement of outcomes solely attributable to the participation in a study, regardless of methods of treatment or nontreatment. These findings allow no conclusion regarding the effects of OMT on disturbance in occupation due to migraine pain.

Limitations of the study

It should be noted that the participants were self-selected, and this may have effects on the outcomes of the treatment. Comparability was assured through randomization into the intervention group and the control group.

In interpreting our data, one should consider that OMT is a method that should be tailored to each individual. Although all participants in the intervention group received five treatments, in some cases more frequent or fewer OMT sessions would have been necessary for achieving the desired tissue change. Because of the case–control design, it could be shown that the intervention group exhibited more significant and generally greater improvements than the control group; however, a sham-treatment for the control group was not performed. For this reason, the improvements could not be directly ascribed to the osteopathic intervention because the placebo effect could also have been a factor.

Because of the relatively small sample size, weak associations could not be affirmed by statistical tests. Furthermore, there was no long-term follow-up; effects of treatment were only evaluated for 6 months.

Conclusions

Significant improvements were ascertained in parameters of pain, HRQoL, and working disability in female migraine-patients receiving OMT. Because of the case–control design, we could control the impact of the Hawthorne effect. Future studies incorporating a control group receiving placebo treatment and long-term follow-up are absolutely essential for demonstrating whether these results can be reproduced.

Acknowledgments

We are grateful for the cooperation and the time invested by the patients who participated in this study.

Disclosure Statement

No competing financial interests exist.

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