Osteopathic Manipulative Therapy and Multiple Sclerosis: A Proof-of-Concept Study

Christian Cordano, MD, PhD; Annalisa Armezzani, DO (Italy); Jacopo Veroni, DO (Italy); Matteo Pardini, MD, PhD; Davide Sassos, MD; Maria Teresa Infante, MD; Andrea Tacchino, PhD; Caterina Lapucci, MD; Maria Cellerino, MD; Valentina Calabrò, MD; Luigi Ciullo, DO (Italy); Bardia Nourbakhsh, MD, MAS

From the Departments of Neurosciences, Rehabilitation, Ophthalmology, Genetics, and Maternal and Child Health at the University of Genoa in Italy (Drs Cordano, Pardini, Sassos, Infante, Lapucci, Cellerino, and Calabro); the Department of Neurology at the University of California, San Francisco (Dr Cordano); the Italian Multiple Sclerosis Foundation in Genoa, Italy (Dr Tacchino); the European Institute of Osteopathic Medicine in Genoa, Italy (Ms Armezzani, Mr Veroni, and Mr Ciullo); and the Department of Neurology at Johns Hopkins University School of Medicine in Baltimore, Maryland (Dr Nourbakhsh).

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Address correspondence to Christian Cordano, MD, PhD, University of California, San Francisco Department of Neurology, 675 Nelson Rising Ln, San Francisco, CA 94143-0003.

Email: cordanochristian@gmail.com

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Context: Research on the effect of osteopathic manipulative therapy (OMTh; manipulative care provided by foreign-trained osteopaths) on chronic symptoms of multiple sclerosis (MS) is lacking.

Objective: To evaluate the effect of OMTh on chronic symptoms of MS.

Methods: Patients with MS who were evaluated at the neurology clinic at Genoa University in Italy were recruited for this study. Participants received 5 forty-minute MS health education sessions (control group) or 5 OMTh sessions (OMTh group). All participants completed a questionnaire that assessed their level of clinical disability, fatigue, depression, anxiety, and quality of life before the first session, 1 week after the final session, and 6 months after the final session. The Extended Disability Status Scale, a modified Fatigue Impact Scale, the Beck Depression Inventory-II, the Beck Anxiety Inventory, and the 12-item Short Form Health Survey were used to assess clinical disability, fatigue, depression, anxiety, and quality of life, respectively.

Results: Twenty-two participants were included in the study (10 in the control group and 12 in the OMTh group). In the OMTh group, statistically significant improvements in fatigue and depression were found 1 week after the final session (P=.002 and P<.001, respectively). An increase in quality of life was also found in the OMTh group 1 week after the final session (P=.36).

Conclusion: Results demonstrate that OMTh should be considered in the treatment of patients with chronic symptoms of MS.

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Multiple sclerosis (MS) is an inflammatory and neurodegenerative disease of the central nervous system that often leads to inexorable neurologic disability. Current treatment options for patients with MS address the inflammatory component of the disease and fail to prevent the underlying neurodegeneration, which is the cause of gradual worsening of symptoms.[1] Thus, symptomatic treatment plays an important role in relieving chronic symptoms in patients with MS, such as weakness, ataxia, cognitive deficits, depression, fatigue, and pain, but current methods are often ineffective.[2] Approaches to MS management that can reduce the effect of these symptoms on patients' quality of life are needed.

Osteopathic manipulative therapy (OMTh; manipulative care provided by foreign-trained osteopaths) is a drug-free, safe, and noninvasive method that uses a manual approach to diagnose and manage somatic dysfunctions, with a demonstrated potential immunomodulatory effect.[3] In this proof-of-concept study, we evaluated the effect of OMTh on fatigue, depression, anxiety, and quality of life in patients with MS.

Methods

This retrospective analysis included patients who were evaluated at the neurology clinic at Genoa University in Italy from August 2013 to the time of this study. The study was conducted in accordance with the Declaration of Helsinki, and all participants provided written informed consent. Patients eligible for inclusion in the study were aged between 20 and 55 years, met the modified McDonald diagnostic criteria for MS,[4] had an Extended Disability Status Score (EDSS)[5] between 0 and 6, were relapse-free for the past 4 weeks, and provided informed consent. The patients also had to have a Symbol Digit Modalities Test (SDMT)[6] score higher than the fifth percentile of the Italian normative data SDMT score (ie, >37.9). The exclusion criteria for participation were as follows: previously reported or recorded diagnoses of life-threatening or severely disabling physical disorders other than MS, use of psychotropic medications to manage psychiatric disorders, change in MS medication in the past 3 months, other disorders of the central nervous system, and pregnancy.

Participants self-selected into a control group or an OMTh group. Each participant, in addition to receiving conventional care, underwent 5 forty-minute sessions once per week during the 1-month study period. Participants in the control group received MS health education during each session. These sessions, conducted by neurology residents, comprised Microsoft PowerPoint presentations on MS epidemiology, symptoms, diagnosis, treatment, and rehabilitation. Participants in the OMTh group underwent an osteopathic structural examination (OSE) at each session to locate and diagnose the presence of somatic dysfunction, and they received OMTh based on the OSE findings in each session. The operator (A.A. or J.V.) started the OSE at the participant's skull, continuing with the spine and the pelvis, passing through the upper and lower limbs, and ending with the rib cage and viscera. During the OSE, the operator applied only passive techniques, as they do not require the active collaboration of the subject. Osteopathic manipulative therapy techniques performed during the sessions included myofascial release, balanced ligamentous tension, balanced membranous tension, and craniosacral.

The neurologists (C.C. and M.P.) performed neurologic evaluation and EDSS assessment before the first session, 1 week after the final session, and 6 months after the final session. The EDSS scale ranges from 0 to 10 in 0.5-unit increments that represent higher levels of disability. At these times, participants also completed a questionnaire that assessed fatigue, depression, anxiety, and quality of life. Fatigue was measured with a modified form of the Modified Fatigue Impact Scale (MFIS),[9] which has a score range of 0 to 84. Higher scores indicate more severe fatigue.[12] Depression was measured using the Beck Depression Inventory-II (BDI-II),[8] with a score range of 0 to 54. Scores from 0 to 6 indicate no depression; 7 to 17, mild depression; 18 to 24, moderate depression; and over 24, severe depression.[11] Anxiety was measured using the Beck Anxiety Inventory (BAI).[10] The BAI has a score range of 0 to 63, in which scores from 0 to 9 indicate no anxiety; 10 to 18, mild to moderate anxiety; 19 to 29, moderate to severe anxiety; and 30 to 63, severe anxiety.[13] Quality of life was measured with the 12-item Short Form Health Survey (SF-12), a shorter alternative to the SF-36 (1 of the 10 individual scales in the Multiple Sclerosis Quality of Life Survey).[7] The SF-12 allows the calculation of physical and mental index scores. Higher scores indicate better quality of life. Investigators who administered the questionnaires (M.P., D.S., M.T.I., A.T., C.L., M.C., V.C.) were blinded to the participants' group assignments.

Descriptive statistics for participant characteristics were presented either as percentages or mean (SD). Linear regression models were used to compare the change from the baseline value of each variable being measured between the control group and the OMTh group at different time points. $P \leq .05$ was considered statistically significant.

Results

Of 55 potential participants, 22 were included in the study. Ten participants were in the control group (including 2 with relapsing-remitting MS, 1 with clinically isolated syndrome, and 1 with secondary progressive MS), and 12 were in the OMTh group (including 9 participants with relapsing-remitting MS, 1 with secondary progressive MS, and 1 with primary progressive MS) (Table 1).

Raw scores for each participant revealed a wide range of baseline scores on the MFIS, BDI-II, and BAI in both groups (Table 2). One week after the final session, the OMTh group had a statistically significant improvement in MFIS and BDI-II scores (P=.002 and P<.001, respectively). Additionally, an improvement in SF-12 scores in the OMTh group was noted 1 week after the final session, but the difference was not statistically significant (P=.36) (Table 3). Six months after the final session, no statistically significant difference between the OMTh and control groups was observed (data not shown).

Table 1.
Effects of OMTh on Chronic Symptoms of Multiple Sclerosis: Characteristics of Participants

Characteristic	OMTh Group (N=12)	Control Group (N=10)	*P* Value
Female, No. (%)	5 (41.7)	5 (50.0)	.70
Age, y, mean (SD)	42.3 (8.2)	39.4 (7.3)	.39
Disease Duration, y, mean (SD)	10.3 (10.4)	11.5 (6.9)	.75
Baseline Score			
EDSS,[a] median (range)	2.25 (1.0-5.5)	2.75 (1.0-5.5)	.24
MFIS,[b] mean (SD)	24.6 (22.5)	19.3 (15.6)	.54
BDI,[c] mean (SD)	9.0 (6.7)	7.2 (5.9)	.52
BAI,[d] mean (SD)	10.2 (6.7)	11.0 (10.9)	.83

[a] The Extended Disability Status Scale (EDSS) ranges from 0 to 10 in 0.5-unit increments that represent higher levels of disability.
[b] The modified Fatigue Impact Scale (MFIS) measures fatigue, with a score range of 0-84; higher scores indicate more severe fatigue.
[c] The Beck Depression Inventory-II (BDI-II) measures depression, with a score range of 0 to 54: 0-6 indicate no depression; 7-17, mild depression; 18-24, moderate depression; and >24, severe depression.
[d] The Beck Anxiety Inventory (BAI) measures anxiety, with a score range of 0-63: 0-9 indicate no anxiety; 10-18, mild to moderate anxiety; 19-29, moderate to severe anxiety; and 30-63, severe anxiety.

Discussion

Many patients with MS use adjunctive treatments to supplement traditional treatment.[14] Results of the current study showed that OMTh is effective in improving self-reported fatigue and depression in patients with MS and that there was a trend in improvement in quality of life. Our results confirm the findings of Yates et al,[15] who found that osteopathic manipulative treatment combined with maximal-effort exercise reduced fatigue in 7 women with multiple sclerosis. Results showed a decrease in fatigue in 5 of 7 women and a significant increase in strength and ambulatory levels.[15]

Fatigue is the most common symptom in patients with MS.[16] There is currently no satisfactory pharmacologic treatment option for patients with MS-related fatigue. Demonstration of the efficacy of an intervention in reducing fatigue can help clinicians to better manage this disabling symptom. We believe that the short-term improvement in symptoms observed in this study is a clinically important finding. The lack of statistical significance at 6 months suggests that the effect of the OMTh is temporary, and OMTh should be continued to stabilize the improvement in fatigue and depression.

Our study has several limitations. The primary limitations are the nonrandomized allocation of study

Table 2.
Effects of OMTh on Chronic Symptoms of Multiple Sclerosis: Raw Fatigue, Depression, and Anxiety Scores of Participants

	MFIS[a]			BDI-II[b]			BAI[c]		
Participants	Baseline	1 wk After Final Session	6 mo After Final Session	Baseline	1 wk After Final Session	6 mo After Final Session	Baseline	1 wk After Final Session	6 mo After Final Session
Control Group									
1	19	25	24	3	6	5	6	6	6
2	44	61	59	7	11	8	10	11	10
3	36	35	35	9	13	23	32	44	34
4	0	0	3	0	0	3	4	2	8
5	8	6	6	0	0	2	28	25	26
6	24	40	22	19	23	18	7	7	9
7	5	9	8	14	19	19	0	1	0
8	2	7	12	5	6	6	0	0	0
9	36	44	40	8	12	13	12	8	12
10	19	25	23	7	10	11	11	11	11
OMTh Group									
1	0	0	1	1	0	0	4	3	0
2	31	19	15	12	4	…	12	5	7
3	8	3	15	4	3	4	3	3	3
4	2	2	32	3	0	36	3	1	19
5	48	42	49	20	19	…	10	7	11
6	16	14	12	10	10	5	11	10	6
7	20	18	28	9	4	9	8	4	3
8	66	59	33	9	10	23	23	39	33
9	30	1	14	5	1	2	15	0	5
10	50	49	48	17	16	11	14	14	15
11	0	0	0	0	0	…	1	0	…
12	…	…	50	18	22	26	18	13	25

[a] The modified Fatigue Impact Scale (MFIS) measures fatigue, with a score range of 0 to 84; higher scores indicate more severe fatigue.
[b] The Beck Depression Inventory-II (BDI-II) measures depression, with a score range of 0 to 54: 0-6 indicate no depression; 7-17, mild depression; 18-24, moderate depression; and >24, severe depression.
[c] The Beck Anxiety Inventory (BAI) measures anxiety, with a score range of 0-63: 0-9 indicate no anxiety; 10-18, mild to moderate anxiety; 19-29, moderate to severe anxiety; and 30-63, severe anxiety.

Abbreviation: OMTh, osteopathic manipulative therapy (manipulative care provided by foreign-trained osteopaths).

Table 3.
Effects of OMTh on Chronic Symptoms of Multiple Sclerosis: Mean (SD) Change From Baseline to 1-Week Follow-up and 6-Month Follow-up Fatigue, Depression, and Anxiety Scores

	1 wk After Final Treatment		6 mo After Final Treatment
Questionnaire	Control Group	OMTh Group	OMTh Group
MFIS[a]	5.9 (6.5)	−5.8 (8.6)[b]	2.9 (15.6)
BDI[c]	2.8 (1.8)	−1.6 (3.1)[d]	0.5 (5.4)
BAI[e]	0.5 (4.4)	−1.9 (7.0)	4.0 (8.6)

[a] The modified Fatigue Impact Scale (MFIS) measures fatigue, with a score range of 0 to 84; higher scores indicate more severe fatigue.
[b] Statistically significant difference from baseline to 1 week follow-up at P=.002
[c] The Beck Depression Inventory-II (BDI-II) measures depression, with a score range of 0 to 54: 0-6 indicate no depression; 7-17, mild depression; 18-24, moderate depression; and >24, severe depression.
[d] Statistically significant difference from baseline to 1 week after the final treatment at P<.001.
[e] The Beck Anxiety Inventory (BAI) measures anxiety, with a score range of 0 to 63: 0-9 indicate no anxiety; 10-18, mild to moderate anxiety; 19-29, moderate to severe anxiety; and 30-63, severe anxiety.

Abbreviation: OMTh, osteopathic manipulative therapy (manipulative care provided by foreign-trained osteopaths).

groups, the small size of the study sample, and the use of self-reported data via questionnaires, which are less reliable than clinician-administered instruments. Future studies are needed to evaluate precisely how long improvement with OMTh lasts and how it can be optimized to maintain improvements, as well as to replicate these findings in a larger sample.

Conclusion

Adjunctive OMTh can be a useful tool for the management of chronic MS symptoms, particularly in patients with fatigue and depression. Of course, these results need to be replicated in randomized trials. If so, OMTh, as an intervention with minimal adverse effects, can be implemented as an adjunct to pharmacotherapy.

Author Contributions

All authors provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; all authors drafted the article or revised it critically for important intellectual content; all authors gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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