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ORIGINAL ARTICLES

Combined Ischemic Compression and Spinal Manipulation in the Treatment of Fibromyalgia: A Preliminary Estimate of Dose and Efficacy

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ABSTRACT

Objectives: To provide preliminary information on whether a regimen of 30 chiropractic treatments that combines ischemic compression and spinal manipulation effectively reduces the intensity of pain, sleep disturbance, and fatigue associated with fibromyalgia. In addition, to study the dose-response relation and identify the baseline characteristics that may serve as predictors of outcome.

Design: Subjects were assessed with self-administered questionnaires taken at baseline, after 15 and 30 treatments, and 1 month after the end of the treatment trial.

Setting: Private practice.

Methods: Participating subjects were adult members of a regional Fibromyalgia Association. Participating subjects had fibromyalgia for more than 3 months. They received 30 treatments including ischemic compression and spinal manipulation. The 3 outcomes being evaluated were pain intensity, fatigue level, and sleep quality. A minimum 50% improvement in pain intensity from baseline to the end of the treatment trial was needed to include the patient in the respondent category.

Results: Fifteen women (mean age 51.1 years) completed the trial. A total of 9 (60%) patients were classified as respondents. A statistically significant lessening of pain intensity and corresponding improvement in quality of sleep and fatigue level were observed after 15 and 30 treatments. After 30 treatments, the respondents showed an average lessening of 77.2% (standard deviation = 12.3%) in pain intensity and an improvement of 63.5% (standard deviation = 31.6%) in sleep quality and 74.8% (standard deviation = 23.1%) in fatigue level. The improvement in the 3 outcome measures was maintained after 1 month without treatment. Subjects with less than 35% improvement after 15 treatments did not show a satisfactory response after 30 treatments. A trend, determined as not statistically significant, suggests that older subjects with severe and more chronic pain and a greater number of tender points respond more poorly to treatment.

Conclusion: This study suggests a potential role for chiropractic care in the management of fibromyalgia. A randomized clinical trial should be conducted to test this hypothesis. (J Manipulative Physiol Ther 2000;23:225-30)

Key Indexing Terms: Clinical Trial; Fibromyalgia; Chiropractic; Myofascial Therapy; Ischemic Compression.

INTRODUCTION

Fibromyalgia is defined as a chronic, generalized pain condition associated with symptoms of fatigue, stiffness, and sleep disturbance and is characterized by the physical findings of local tenderness in many specific but widely dispersed sites.[1] Fibromyalgia is the most common cause of widespread pain. The prevalence of this disorder in the general population is between 3% and 5%.[2] It has been estimated that 2% to 6% of patients seen in a primary care practice have this chronic condition. However, this number may rise to 20% in a rheumatology practice.[3] Women appear to be 10 to 20 times more likely to acquire the disorder than men. The mean age at onset is estimated between 20 and 40 years of age but fibromyalgia can affect most age groups.[4]

Most patients with fibromyalgia remain symptomatic for several years, and no cure has been identified.[4,5] However, several treatments have been suggested. The aim of treatment is to minimize multifaceted symptoms, such as myofascial pain, poor quality of sleep, chronic fatigue, functional disability, poor physical fitness, psychologic distress, and poor quality of life. A multidisciplinary approach has been proposed with treatments of other musculoskeletal conditions such as low back pain.[6,7] However, little scientific evidence supports the usefulness of these modalities for the treatment of fibromyalgia.[8]

Chiropractic approaches to the treatment of musculoskeletal conditions have involved studies of the management of regional pain syndromes such as low back pain, neck pain, and headache. Scientific evidence indicates the effectiveness and safety of chiropractic care for such disorders.[9-12]

Two studies suggest a potential role for chiropractic care in the management of patients with fibromyalgia. Wolf[13] conducted a survey of 81 patients with fibromyalgia and found that 40 sought chiropractic care for their condition with 45.9% reporting moderate to great improvement. In this study, the reported benefit of antidepressant medication and exercise was limited to 36.3% and 31.8%, respectively.

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Paper submitted January 12, 1999; in revised form February 2, 1999.
doi:10.1067/mmt.2000.106102

Blunt et al[14] completed a pilot study with a crossover design combined with an assessment taken before and after treatment of the effectiveness of chiropractic management of 21 patients with fibromyalgia. The chiropractic intervention was a 4-week course of approximately 10 to 15 treatments that included spinal manipulation, soft-tissue therapy, and passive stretching. Patients in the control group were placed on a 4-week waiting list before receiving the actual chiropractic treatments. No statistically significant improvement was noted; however, the authors determined that the changes were clinically important and suggested repeating the trial with a larger sample size. This study does not provide the necessary information about dosage. Before conducting a randomized clinical trial, it is necessary to estimate the number of treatments that should be given. Furthermore, the effects of chiropractic care on the quality of sleep and fatigue have not yet been investigated.

The first objective of this study was to provide preliminary information on whether a regimen of 30 chiropractic treatments combining ischemic compression and spinal manipulation effectively reduces the intensity of pain, sleep disturbance, and fatigue associated with fibromyalgia. The second objective was to study the dose-response relation and identify the baseline characteristics that may serve as predictors of outcome.

METHODS

Sample Selection

Members of the regional Fibromyalgia Association were invited to participate in this study. To be eligible, the subjects were required to be aged >18 years, to have widespread pain for >3 months, and to have previously been diagnosed with fibromyalgia by their family physician or rheumatologist. Widespread pain was defined according to the American College of Rheumatology fibromyalgia criteria as pain in the axial skeleton and in the upper and lower extremities.[1] Finally, subjects were required to complete a consent form to participate in the study and to be available for the duration of the trial.

A total of 16 subjects volunteered to participate in this study; one subject was excluded because she did not meet the entry criterion of widespread pain. The study population consisted of 15 women with a mean age of 51.1 years (standard deviation [SD] = 10.4 years). The duration of widespread pain ranged from 3 to 20 years (mean = 10.1 years; SD = 5.9 years) although they had been diagnosed with fibromyalgia more recently (mean = 2.2 years, SD = 1.1 years). Visual analog scales were used to calculate the scores for the 3 outcomes evaluated. Mean scores were 75.2 of 120 (SD = 15.9) on the pain intensity scale; 8.1 of 10 (SD = 2.5) on the sleep quality scale; and 8.5 of 10 on the fatigue scale (SD = 1.5). The mean number of clinically identified tender points was 30.3 (SD = 10.6).

Baseline and Outcome Assessment

The baseline chiropractic evaluation consisted of identifying tender-point sites. To be defined as a tender point, a site had to be reported as painful when a thumb pressure of approximately 4 kg was applied.[15] The examiner used a weight scale to identify the amount of applied thumb pressure corresponding to 4 kg. The assessment included the tender-point sites used to define the presence of fibromyalgia[1] and the trigger-point sites, which were apt to reproduce pain as reported on the pain intensity questionnaire.[16]

The 3 evaluated outcomes were measured with patient self-administered questionnaires at baseline, after 15 and 30 treatments, and 1 month after the end of the treatment trial. The primary outcome measure was pain intensity. A set of 12 visual analog scales (0 to 10) assessing the level of pain in different body parts, including the head, neck, shoulder, arm, upper back, shoulder blade, lower back, hip, thigh, calf, chest, and abdomen, were developed for the purpose of this study. The quality of sleep and level of fatigue were secondary measures also evaluated with visual analog scales.

Treatment Specification

Patients underwent a course of 30 treatments 2 to 3 times weekly. The first phase of each treatment consisted of applying ischemic compression to a number of tender points previously identified by palpation; the technique was developed by Travell and Simons[16] and used by chiropractors.[17-19] A progressively stronger pressure sufficient to reach the patient pain-tolerance threshold, the limit at which the patient tries to move away or contract the affected muscle as a means of self-protection, was applied with 2 thumbs on each tender point. The digital pressure was sustained for 10 seconds; this technique was repeated during the following visits until the site was no longer painful on application of 4 kg of digital pressure or until the end of the trial.

The second phase of each treatment consisted of providing spinal manipulative therapy. Spinal manipulation was defined as a short-lever, low-amplitude, high-velocity thrust, usually accompanied by an audible cracking sound. Palpation was used to identify the spinal motion segments to be manipulated. The 2 main criteria used as indication for manipulation were a decrease in the quality of segmental motion and increased tenderness. The manipulations were conducted in the area of the cervical and thoracic spine with 2 diversified techniques. The cervical spine manipulative procedure consisted of a bilateral rotary cervical manipulation with specific contact over the zygapophyseal joints.[20] The thoracic spine manipulation consisted of a posteroanterior thrust with bilateral thenar contact on adjacent transverse processes.[21] Lumbar or sacroiliac manipulation was not applied.

Method for Controlling Bias

Noncompliance was minimized by the wide range of available treatment times and regular follow-up telephone calls to reschedule missed appointments. In addition, patient assessments were conducted with self-administered questionnaires without the chiropractor present to minimize the influence of the subject-clinician relationship.

Statistical Analysis

In the absence of a control group, what was considered a clinically significant improvement was defined *a priori*.

Table 1. *Baseline demographic and clinical characteristics of the patients with fibromyalgia by response status*

	Respondents (n = 9)	Nonrespondents (n = 6)	*P* value
Age (y)	47.0 ± 9.8	57.3 ± 8.7	.057
Number of tender points	26.2 ± 9.3	36.5 ± 9.8	.061
Duration of illness (y)	8.2 ± 5.4	12.8 ± 6.0	.144
Duration of diagnosis (y)	1.9 ± 1.0	2.7 ± 1.0	.190
Pain intensity (0 - 120)*	70.2 ± 8.7	82.7 ± 21.9	.146
Quality of sleep (0 - 10)*	7.6 ± 3.0	8.8 ± 1.3	.349
Fatigue level (0 -10)*	8.4 ± 1.8	8.7 ± 0.96	.705

Values provided are mean ± standard deviation.
*Visual analog scale scores.

Patients were classified as respondents and nonrespondents on the basis of their percent improvement in the primary outcome measure. To be classified as respondents, a minimum 50% improvement in total pain score from baseline to the end of the 30th treatment was required. This 50% improvement in pain intensity was used in an earlier study as one of the prerequisites for defining a clinically relevant improvement.[15]

Independent sample Student *t* tests were conducted to compare respondents and nonrespondents for age, duration of illness, duration of diagnosis, baseline total pain score, baseline sleep score, and baseline fatigue score.

Six multivariate 1-factor repeated-measures analyses were conducted to compare the population mean baseline scores, the 15 treatment scores, the 30 treatment scores, and the 1-month follow-up scores. These analyses were conducted separately with the respondents and nonrespondents and separately with the 3 outcome measures. Paired sample Student *t* tests assessed the changes in the outcome measures over the course of the trial within each of the 6 subgroups.

Independent sample Student *t* tests were conducted to assess whether the mean score of the 3 outcome measures between the 2 groups was different after 15 and 30 treatments and after the 1-month follow-up. A Bonferroni adjustment was conducted to take into account the multiple comparisons that were made. Missing data for any given assessment were replaced by the corresponding baseline value. For each analysis, $P = .05$ was considered statistically significant. These analyses were carried out with SPSS, release 7.5, and SYSTAT, release 8.0 (SPSS, Chicago, Ill).

RESULTS

Sample Characteristics

All 15 subjects completed the 30-treatment trial. A total of 9 (60%) subjects were classified as respondents and 6 (40%) as nonrespondents based on their percent improvement rating in pain intensity after the 30th treatment. There was no statistically significant difference between the baseline characteristics of the 2 groups. However, some clinically significant trends were noted (Table 1). Nonrespondents were apparently older with more severe and chronic pain and a higher number of tender points. The mean number of days necessary to complete the treatment trial was 92.1 days (SD = 37.3 days), without statistical significance between the respondents and the nonrespondents ($P > .05$).

Two nonrespondents underwent an additional course of 30 treatments and therefore did not complete the 1-month follow-up period required for the last assessment. A total of 13 subjects completed the 1-month follow-up assessment.

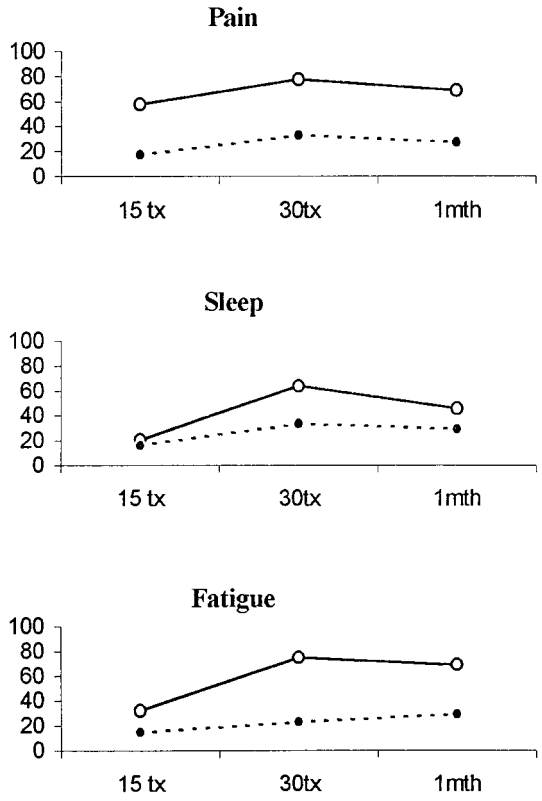

Fig 1. *Percent improvement in visual analogue scale scores for pain intensity, quality of sleep, and fatigue level from baseline to the 1-month follow-up by response status.* Solid lines, *Respondents;* dotted lines, *nonrespondents.*

Response to Treatment

After 30 treatments, the respondents showed a mean percent drop in pain intensity (77.1%, SD = 12.3%) with an enhanced quality of sleep (63.5%, SD = 31.6%) and lessened fatigue level (74.8%, SD = 23.1) (Table 2). Figure 1 is a graphic representation of the percent improvement observed in the 3 outcome measures from baseline to the 1-month follow-up assessment for the respondents and nonrespondents.

The 1-factor, repeated–measures analyses of variance conducted showed that pain intensity, quality of sleep, and fatigue level improved significantly ($P = .0001$) during the trial for both respondents and nonrespondents. Table 3 shows the mean score differences at each assessment with their statistical significance. The respondents and the nonrespondents demonstrated a significant improvement in pain intensity, quality of sleep, and fatigue level after 15 and 30 treatments. However, no significant change in the 3 outcome

Table 2. *Visual analogue scale scores for pain intensity, quality of sleep, and fatigue level from baseline to 15- and 30-treatment assessment and to the 1-month follow-up assessment for each subject*

	Baseline assessment			15-treatment assessment			30-treatment assessment			1-month follow-up assessment		
ID	Pain	Sleep	Fatigue	Pain	Sleep	Fatigue	Pain	Sleep	Fatigue	Pain	Sleep	Fatigue
1*	63	10	10	34	4	5	19	2	3	19	2	3
2	81	7	0	53	5	0	43	4	0	36	2	0
3*	59	3	8	4	1.5	5	4	1.5	1.5	29.5	1.5	1
4*	77	10	10	20	4	2	2	0	0.5	2.5	0	0
5	88	10	0	89	10	0	65	8	0	—	—	—
6*	84	2	10	46	7	10	18	2	5	18	5	7
7	104	10	9	93	8	8	62	7	7	—	—	—
8*	76	10	7	42	4	5	20	0	0	19	0	0
9*	59	8	9	26	1	7	9	3	0	6	2	0
10*	68	8	8	37	4	5	23	2	3	38	4	6
11*	75.5	9	0	24	5	0	23.5	3	0	21.5	3	0
12	65	8	8	48	6	7	41	5	5	36	4	5
13	107	10	8	82	10	6	71	8	7	57	7	4
14	51	8	10	46	6	9	45	4	8	44	6	7
15*	71	8	5	40	6	5	27	5	3	42	5	3

*Subjects classified as respondents. *ID*, Patient identification number.

measures was observed for either group between the last treatment and the 1-month follow-up assessment.

The pain intensity scores were significantly different between the respondents and nonrespondents after 15 and 30 treatments and remained so at the 1-month follow-up assessment (Table 4). The only significant difference in the quality-of-sleep score between the 2 groups was noted after 30 treatments. No significant difference between the 2 groups was noted in the fatigue level at any of the assessments.

DISCUSSION

The results of this study suggest that chiropractic care combining ischemic compression and spinal manipulation may help patients with fibromyalgia. A total of 60% of this sample reported a mean improvement of 77.1% in pain intensity in addition to a 63.5% improvement in the quality of sleep and a 74.8% improvement in fatigue level. The causes of poor quality of sleep and high fatigue levels reported in fibromyalgia are poorly understood. The observed improvement in this study may suggest that these symptoms were aggravated, at least in part, by the presence of pain. The reduction of pain may have led to the improvement in the quality of sleep and fatigue observed in this study. These symptoms may be part of a vicious cycle caused by pain.[6,7]

The lessening of pain was maintained throughout the follow-up period of 1 month, suggesting that chiropractic care may help patients beyond the actual provision of care. This effect was not observed in the different drug trial, which tested the efficacy of amitriptyline and cyclobenzaprine for the treatment of fibromyalgia.[15] These drugs were not shown to be effective after stopping medication intake.

Side effects were not monitored during the trial. However, compliance was excellent, and no patient dropped out of the treatment section of the study. This compliance suggests that patients were satisfied with the care received and did not have side effects or complications sufficiently intense for them to withdraw from the study. The opposite problem was encountered; two subjects in the nonrespondent group requested to continue treatment during the 1-month follow-up period because of a recurrence of the original symptoms. For ethical reasons, these patients were excluded from the follow-up section of the study and remained under active care.

Previous drug trials with fibromyalgia have reported a strong placebo response.[15,22,23] The decision to require a minimum 50% improvement after 30 treatments to classify subjects as respondents was an attempt to exclude subjects whose response to treatment was more likely to be attributed to this effect. On its own, such a placebo effect would be unlikely to produce the magnitude of improvement noted in this group of respondents and even less likely to produce a sustainable improvement 1 month after the end of the treatment trial. In addition, the more treatment patients received, the less symptoms they reported. This dose-response relation supports the hypothesis that the observed improvement may be caused by the physiologic effect of the treatment itself.[24]

Cost effectiveness is important when considering the use of a new treatment approach. This sample showed a progressive improvement in outcome during the treatment trial, suggesting that the course of 30 treatments was adequate. The sustaining of the effect at the 1-month follow-up assessment also suggests that this chiropractic approach may have a prolonged benefit.

It may also be possible to identify which patients are most likely to respond positively to chiropractic care. In our sample, some not statistically significant trends that warrant attention in a larger clinical trial were observed. For instance, older subjects with a more chronic illness and a greater intensity of symptoms who have more tender points at baseline assessment appeared to respond more poorly to treatment. In addition, the percent lessening of pain intensity after 15 treatments was significantly inferior in the nonrespondents. Subjects who showed <35% improvement after 15 treatments did not show a satisfactory response after 30 treatments. This observation suggests that a minimum 35% improvement in pain intensity must be observed after 15

Table 3. *Population mean score differences in pain intensity, quality of sleep, and fatigue level after 15 treatments, 30 treatments, and 1-month follow-up compared with the preceding assessment scores*

		Baseline to 15-treatment assessment			15- to 30-treatment assessment			30-treatment to 1-month assessment		
		Mean	SD	*P* value*	Mean	SD	*P* value*	Mean	SD	*P* value*
Pain	R	39.9	11.3	.0001	14.2	9.1	.002	–5.6	10.2	.142
	NR	14.2	11.3	.028	14.0	11.2	.028	–6.3	21.6	.504
Sleep	R	3.5	3.7	.022	2.0	2.2	.025	–0.4	1.2	.312
	NR	1.3	1.0	.025	1.5	0.6	.001	–0.5	2.1	.580
Fatigue	R	2.9	2.6	.018	3.5	2.0	.002	–0.5	1.3	.306
	NR	1.3	0.5	.015	0.8	0.5	.058	0.5	1.7	.604

*Paired sample *t* tests were conducted to determine the statistical significance of the observed changes between each assessment. Individual *P* values in this table should be interpreted with caution because of the multiplicity of tests. *R*, Respondents; *NR*, nonrespondents.

Table 4. *Mean visual analogue scale scores for pain intensity, quality of sleep, and fatigue level at 15-treatment assessment, 30-treatment assessment, and 1-month follow-up assessment by response status*

		15-treatment assessment			30-treatment assessment			1-month follow-up assessment		
		Mean	SD	*P* value	Mean	SD	*P* value	Mean	SD	*P* value
Pain	R	30.3	13.2	.001*	16.2	9.0	.0001*	21.7	16.2	.003*
	NR	68.5	21.8		54.5	13.0		60.8	28.8	
Sleep	R	4.1	1.9	.006	2.1	1.6	.001*	2.5	1.9	.009
	NR	7.5	2.2		6.0	1.9		6.5	3.2	
Fatigue	R	5.5	2.3	.950	2.0	1.8	.074	2.5	2.8	.258
	NR	7.5	1.3		6.8	1.3		6.3	2.2	

*Bonferroni adjusted significance level required for the independent sample *t* tests is $P < .003$. *R*, Respondents; *NR*, nonrespondents.

treatments or it may no longer be appropriate to pursue this form of treatment.

A selection bias may have occurred because subjects volunteered to participate in this study and because of the small sample size. However, the baseline characteristics of our subjects were similar to those in another fibromyalgia trial.[15] The outcome was strictly measured with self-administered questionnaires to minimize the risk that the physician's expectations might influence the results. Moreover, these questionnaires were completed without the clinician present to limit possible bias related to the desire of the subjects to please the clinician and report an inaccurate improvement. Furthermore, fibromyalgia is a chronic illness that rarely remits, making it unlikely that improvement was related to the natural history of the condition. Although subjects did not report initiating new forms of treatment during the course of the trial, collecting data about the usage of medication, exercise, or other forms of therapy to minimize biases related to cointerventions would have been more appropriate. Finally, the baseline assessment should have included a more rigorous physical and mental health evaluation. For instance, one of the nonrespondents had chronic leukemia and another was psychologically distressed because her daughter had a life-threatening disease. Such conditions may have adversely influenced the effect of treatments.

The small sample size, the use of a single treating physician, and the absence of a control group with appropriate blinding procedures are some of the most significant limitations of this clinical trial. The hypotheses raised in this study need to be tested with a larger sample size, more than one treating physician, and a blinded design. Based on these results and data from drug trials,[15,22] the sample size requirement of a placebo-controlled randomized clinical trial was estimated at 50 patients per group to be adequate on the basis of an estimated improvement of 50% in the chiropractic group versus 15% in the placebo group. Future studies should be designed with 90% power and a 2-tailed test with a significance level of .05, assuming a 10% dropout rate in future studies.

CONCLUSION

This study suggests a potential role for chiropractic care in the management of fibromyalgia. Most subjects with fibromyalgia appear to have responded favorably to a course of 30 chiropractic treatments including spinal manipulation and ischemic compression therapy. Fifteen treatments seem to be an adequate cutoff point to determine if a significant improvement in pain has occurred and if further care is warranted. Chiropractic care appears to provide benefits for at least 1 month after stopping therapy. A placebo-controlled randomized clinical trial is recommended in the near future to test these hypotheses.

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