ORIGINAL RESEARCH

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Osteopathic Manipulative Treatment in Patients with Anxiety and Depression: A Pilot Study, Part 2

Abstract

Background & Aims: This is part 2 of an original study with a focus on pain. The role of touch in psychiatry is debatable; the purpose of this pilot study was to determine the effectiveness of osteopathic manipulative treatment (OMT) in treating pain in patients with comorbid anxiety and/or depression.

Methods: The study was an 8-week prospective, experimental, randomized, controlled pilot study to examine the effects of OMT as an adjunctive treatment of chronic anxiety and depression and pain. The study compared a treatment group to a control group, each consisting of 10 randomly-assigned adult participants with anxiety and/or depression on psychotropics, with a focus on pain. All patients were assessed and evaluated weekly using a musculoskeletal screening assessment which included the Numeric Rating Scale (NRS-11) to grade the level of pain or discomfort. From the initial cohort (n=20), a complete database was achieved for 16 of the patients. Statistical analysis was performed using RStudio.

Results: Of the 16 patients who successfully participated in the study, 6 received OMT, and 10 were part of the control group. Statistical analysis of pain treatment group data revealed a week one mean of 7.0 ± 2.4 (n=6) with a paired t-test showing significance as early as week three 5.7 ± 2.1 (n=6), P = 0.025* and thereafter. Analysis of pain control group data revealed a week 1 mean of 6.4 ± 1.8 (n=10) with paired t-test significant at weeks 6 through 8. All patients in the treatment group showed significant improvements in their pain levels in half the time compared to those in the control group.

Conclusions: Findings in this study indicate that OMT may be an effective adjunctive treatment modality for alleviating pain in patients with comorbid depression and anxiety.

Background

Pain is a costly health concern that can impact people of all ages worldwide. In the US alone, its estimated annual economic cost is greater than the nation's other top health concerns, ranging from $560 to $635 billion annually.[1] Pain is not only a societal economic toll, but a physical and emotional detriment as well. It can limit one's ability to function and hinder quality of life.

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Disclosures

There was no financial support provided for the work in which this manuscript is based. Additionally, the authors do not have any financial disclosures or potential conflicts to disclose.

Keywords

pain, depression, anxiety, OMT, psychiatry, alternative treatment modality

From a biopsychosocial perspective, it is evident that there is a synergistic relationship between pain and psychiatric disorders, more specifically, mood disorders such as anxiety and depression. Studies have shown that individuals with chronic pain conditions are more likely to experience clinically significant mood symptoms and, conversely, mood symptoms are strong predictors of pain response and guide the shift from acute to chronic pain.[2] This brings up the question of whether mood disorders such as anxiety and depression precede or follow pain. However, a clear cause and effect relationship does not exist and no hypotheses serve as the best fit, making it difficult to decipher which occurred first or if they occurred simultaneously. While many studies have established an association between pain and mood, with serotonin and norepinephrine playing a major role, the exact mechanism of this association remains unclear.[3] Although it is evident that pain and mood disorders can occur independently, secondary to each other, or concurrently, there appears to be a cyclical pattern to the nature of these conditions. Untreated, both pain and mood disorders can exacerbate one another, leading to a cycle of worsening symptomology, and when the 2 conditions occur concomitantly, outcomes are unfavorable. Perhaps one cost-effective way to address these problems and decrease morbidity is through the use of osteopathic manipulative treatment (OMT). Using OMT and focusing on a holistic approach, the biopsychosocial model helps illuminate individual differences in pain and psychiatric disorders and develop effective treatment modalities to address these problems. Many studies have demonstrated that OMT is effective in reducing acute and chronic pain syndromes.[4] Given that comorbid mental health conditions such as depression and anxiety are often associated with chronic pain, it may be more cost-effective to utilize OMT to address this triad. In the original study conducted by Miranda et al. to ascertain the effectiveness of OMT in psychiatric patients with anxiety and depression, it was found that OMT helped reduce the symptom burden of anxiety and depression.[5] Further analysis of the data revealed a significant reduction in pain, correlating with other studies that have shown OMT to be effective in treating pain.[6-8]

Methods

The authors would like to point out that the study methods remained the same for both part one and two of the study. While part 1 focuses on the data obtained to study the efficacy of OMT as a treatment modality for anxiety and depression, part 2 focuses on its efficacy as a treatment for pain within the same patient population. Further details regarding the methods utilized for the study are available in part 1 of this article.[5]

The study was an 8-week prospective, experimental, randomized, controlled study to examine the effects of OMT as an adjunctive treatment of chronic anxiety and depression. Patients 21 years and above with a history of chronic depression and or anxiety, under the care of a healthcare provider (psychiatrist or PCP), and on psychotropics were selected for participation in the study. Twenty patients were randomized to "touch" or "no-touch" groups. From the initial cohort (n= 20), a complete database was achieved for 16 of the patients. Secession from the study was due to failure to keep appointments for OMT and psychiatric follow-up; more frequent follow-up reminders might help with the significant drop out rate in future studies.

All patients were assessed and evaluated on a weekly basis using standard screening tools containing a musculoskeletal screening assessment which included the Numeric Rating Scale (NRS-11), a modified Harvard National Depression Day Screen (HANDS), and a Generalized Anxiety Disorder 7 item (GAD-7) questionnaire as shown in Figure 1. Screening assessments were provided at the beginning of each session for both the treatment and control groups. It should be noted that the osteopathic structural examination was not used as a placebo control in this study, as the purpose of this study was to determine the effectiveness of OMT as an adjunctive treatment modality for patients with pain and comorbid anxiety and depression. Due to the size limit, it was decided to compare only "touch" and "no-touch" groups as opposed to the ideal three group (touch, no touch, sham) comparison. The setting, timing of assessment, and treatment were identical between the two groups. Psychiatric resident physicians administered the structural exams and OMT under the supervision of an osteopathic physician instructor. The structural examination focused on assessing dysfunction from the head to the lumbosacral joint, and findings were recorded as either positive or negative. Segmental dysfunction, tissue texture abnormality, altered range of motion, asymmetry, and tenderness indicated positive findings.

Treatment techniques included a combination of soft tissue release, muscle energy, counterstrain, suboccipital

release, and venous sinus release. Although special attention was given to certain areas of dysfunction as described in the musculoskeletal screening assessment, the specific techniques applied were a clinical decision made by the resident physicians in consultation with the supervising attending. Statistical significance between treatment and control groups was analyzed using RStudio.[11] Part 1 of the study has an in-depth description of the specific regions assessed and OMT protocol utilized to ensure treatment continuity.[5]

Results

Of the 16 patients who successfully participated in the study, 6 received OMT, and 10 were part of the control group. One patient was diagnosed with anxiety only and one with depression only in both groups. The data gathered from each screening tool varied for all patients at the start of the study. Data were analyzed in two subgroups, comparing the changes in pain scores of the treatment group to the control group, respectively. An independent t-test analyzed data between treatment groups and control

Figure 1. *Screening Assessment Tools* [9-10]

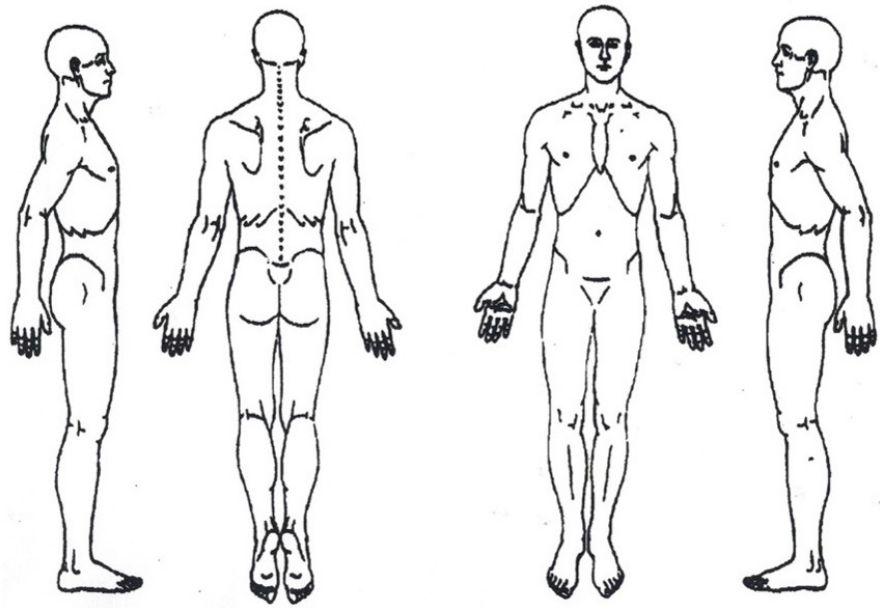
Generalized Anxiety	Not at all (0)	Several Days (1)	More than half the days (2)	Nearly Every Day (3)
In the past 6 months how often have you:				
Felt very Nervous				
Worried about lots of things				
Felt like you could not stop worrying				
Felt worry is hard to control				
Felt restless, keyed up or on edge				
Tired easily				
Had trouble concentrating				
Easily annoyed or irritated				
Felt muscle tension and tightness				
Had trouble sleeping				
Did the things you noted affect your daily life or cause you a lot of distress				

Figure 1a. *Modified Harvard National Depression Screening (HANDS) Scale*

Depression	Not at all (0)	Several Days (1)	More than half the days (2)	Nearly Every Day (3)
In the past 2 weeks how often have you:				
Been feeling low in energy, slowed down				
Been blaming yourself for things				
Had poor appetite				
Had difficulty falling asleep or staying asleep				
Been feeling hopeless about the future				
Been feeling blue				
Been feeling no interest in things				
Had feelings of worthlessness				
Thought about or wanted to commit suicide				
Had difficulty concentrating or making decisions				
Did the things you noted affect your daily life or cause you a lot of distress				

Figure 1ab. *Modified Generalized Anxiety Disorder 7- Item (GAD 7) Scale*

Musculoskeletal Screening Assessment
Please shade in areas where you are experiencing pain/tension/discomfort.



Grade your pain/tension/discomfort currently from a scale of 0-10 (0= no pain/no discomfort, 10= the worse pain/discomfort you can imagine):
Describe your pain/tension/discomfort:
Does it radiate?
What makes it better?
What makes it worse?

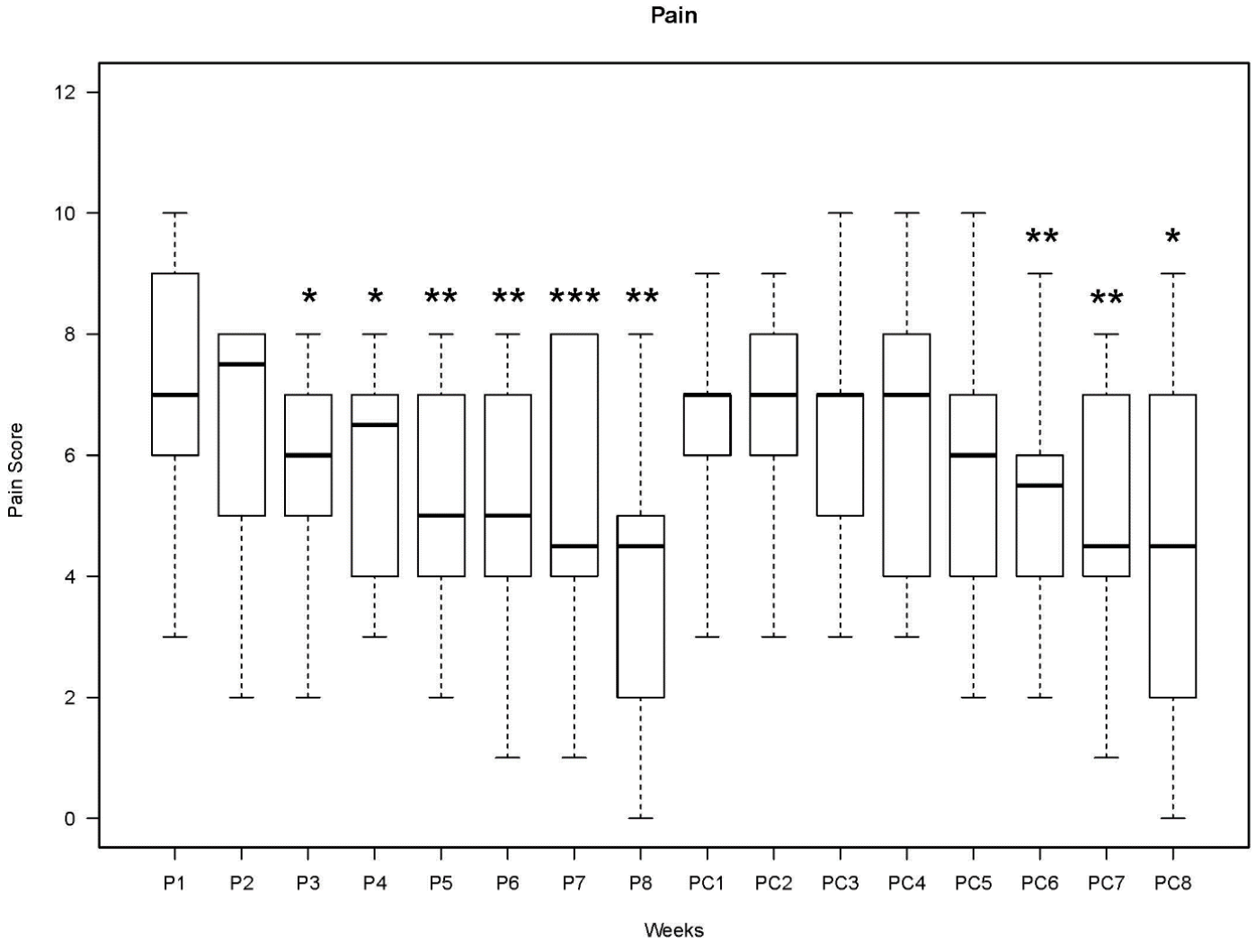
Figure 1c. *Musculoskeletal Screening Assessment*

groups, while a dependent t-test evaluated change within groups over time as the effects of OMT may take time to emerge. In light of the very small and unrepresentative population, the Wilcoxon and Mann-Whitely tests were performed. However, neither test yielded significant results, therefore these results were excluded.

Statistical analysis of pain treatment group data revealed a week 1 (P1) mean of 7.0 ± 2.4 (n=6) vs week 3 (P3) 5.7 ± 2.1 (n=6), P = 0.025* vs week 4 (P4) 5.8 ± 1.9 (n=6), P = 0.034* vs week 5 (P5) 5.2 ± 2.2 (n=6), P = 0.00189** vs week 6 (P6) 5.0 ± 2.5 (n=6), P = 0.00277** vs week 7 (P7) 5.0 ± 2.7 (n=6), P = 0.000573*** vs week 8 (P8) 4.2 ± 3.1 (n=6), P = 0.016*. Analysis of pain control group data revealed a week 1 (PC1) mean of 6.4 ± 1.8 (n=10) vs week 6 (PC6) 5.1 ± 2.2 (n=10), P = 0.00373** vs week 7 (PC7) 4.9 ± 2.4 (n=10), P = 0.00174** vs week 8 (PC8) 4.7 ± 2.9 (n=10), P = 0.012*.

An average reduction in reported pain was noted from P1 of 1.3, 1.2, 1.8, 2.0, 2.0, and 2.8 in P3, P4, P5, P6, P7, and P8, respectively. The significant p-values found in weeks 3 through 8 coupled with the reduction in mean pain scores from week 1 suggest a noteworthy improvement in the overall pain score for the treatment group. A reduction in reported pain from PC1 was also seen in pain controls for PC6, PC7, and PC8 as 1.3, 1.5, and 1.7, respectively. Although significant, the reduction in pain in the control group is not as substantial as that of the treatment group. All other intragroup comparisons for pain treatment and control groups were not significant (Tables 3a-c). Intergroup comparisons via independent t-test between treatment and control group did not yield significant results (Table 3d). However, the intragroup comparison shows improved pain scores throughout the study for the treatment group, indicating the need for larger studies with a lengthier duration of treatment to

Figure 2. *Average reported pain per pain scale and standard deviation of pain treatment group (P1-P8) vs pain control group (PC1-PC8) throughout the study. * represents statistical significance found via paired t-test for that week. Please refer to Tables 3a-c for figure values.*



examine the long-term effects of OMT on this patient population. The average weekly group response for pain throughout the study for both treatment and control groups are displayed in Figure 2.

At the end of the study, the treatment group showed improvement in the pain scores when compared to the initial scores. All patients in the treatment group showed significant improvements in their pain levels as early as week 3, with further improvement in the following weeks (see Figure 2). As compared with the no-touch control group, the patients in the treatment group reported greater improvement in pain and discomfort and better mental health at week 8.

Discussion

Regardless of the underlying mechanisms that provide its benefits, these results show that OMT can play a role in the alleviation of pain, whether physical or psychological. Multiple studies have demonstrated the effectiveness of OMT in relieving pain through the analgesic effects of touching. Touch has been shown to inhibit concurrent nociceptive input at the subcortical and supraspinal levels indicating that many mechanisms mediate touch-induced analgesia.[12] Touching has been linked to emotional support, lessened preoccupation, and providing a sense of normalcy and belonging, contributing to a holistic approach to patient care.[13-17] Touch, when used

Table 3a. *Pain treatment group (P) size, average pain scoring, and standard deviation for each week of the study.*

Week	n	Mean	Standard deviation
P1	6	7	2.4
P2	6	6.3	2.4
P3	6	5.7	2.1
P4	6	5.8	1.9
P5	6	5.2	2.2
P6	6	5	2.5
P7	6	5	2.7
P8	6	4	2.8

Table 3b. *Pain treatment group (P) dependent t-test results. Intragroup comparison to week one (P1).*

	t	p-value	95% Confidence Interval	mean of differences
P1XP2	1.581	0.18	(-0.417, 1.751)	0.7
P1XP3	3.162	0.025*	(0.249, 2.417)	1.3
P1XP4	2.907	0.034*	(0.135, 2.198)	1.2
P1XP5	5.966	0.00189**	(1.043, 2.623)	1.8
P1XP6	5.477	0.00277**	(1.061, 2.938)	2
P1XP7	7.746	0.000573***	(1.336, 2.664)	2
P1XP8	4.392	0.007078**	(1.244, 4.756)	3
P8	6	4		2.8

Table 3c. *Data for pain control group showing the population size, average pain scoring, and standard deviation for the population in weeks 1 (PC1) – 8 (PC8).*

Week	n	Mean	Standard deviation
PC1	10	6.4	1.8
PC2	10	6.5	1.8
PC3	10	6.3	2.2
PC4	10	6.2	2.5
PC5	10	5.6	2.5
PC6	10	5.1	2.2
PC7	10	4.9	2.4
PC8	10	4.7	2.9

Table 3d. *P-value results for reported pain from independent t-test of experimental group and control group. Intergroup week by week comparison.*

	PC1	PC2	PC3	PC4	PC5	PC6	PC7	PC8
P1	0.6147							
P2		0.8879						
P3			0.5714					
P4				0.7499				
P5					0.7258			
P6						0.9375		
P7							0.9415	
P8								0.7369

therapeutically, has proven to be a useful tool for patient care that is frequently ignored, especially in psychiatry.

About 40-60% of patients with chronic pain have comorbid mental health disorders such as depression or anxiety, leading to the varying prevalence of these conditions.[3] This dilemma becomes more concerning in psychiatry where some treatment modalities may be restricted. Research has shown that there is almost a 10-time fold increase for patients who endorse pain to screen positive for mood disorders such as generalized anxiety and major depressive disorder. Similarly, patients with an anxiety or depressive disorder were found to have significantly higher pain symptoms, with an odds ratio between 3 to 9.[18] These results demonstrate that a critical correlation between pain and anxiety and depression exists. As such, these relationships also raise questions about the treatment modalities available to treat these conditions. With limited resources and access to care, it would be ideal to provide patients with nonpharmacological treatment modalities such as OMT, which is not only efficacious but cost effective. One novel study conducted by Edward and Toutt found that in as little as 2 weeks of receiving OMT, patients with comorbid mental health conditions such as anxiety and depression and chronic pain experienced a significant reduction in symptoms and improvements in selfcare.[4] Many other studies have shown OMT to be effective in alleviating pain; given the correlation and cyclical relationship between pain, anxiety, and depression, OMT may be a promising treating modality regardless of which symptoms manifest first.

This study aimed to explore the impact of osteopathic treatment on several psychological outcome measures relating to pain, anxiety, and depression. The findings of this study indicate that OMT may serve as an adjunct to standard treatments of pain and comorbid anxiety and depression as measured by NRS-11 and GAD-7 and HANDS, respectively. Patients in the treatment group showed a significant reduction in reported pain, anxiety, and depression levels. Although there were limitations to this study, specifically the small sample size which challenges the strength of the study and restricts any accurate predictions as it relates to the general larger population, the results are promising and suggest a full-scale randomized controlled trial should be conducted in psychiatric patients. It should be noted that the authors did not check for normality or remove any outliers to avoid further decreasing the already small sample size of the study. If the results can be duplicated, OMT could be utilized to improve patient health and provide cost-effective care for pain and two of the most common chronic psychiatric illnesses. The authors are hoping once COVID-19 restrictions are lifted the sample size can be increased and correlations between groups can be better analyzed and quantified.

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