

# The Effect of OMM on Opioid Users with Chronic Low Back Pain

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## Background and Significance

In the United States, approximately 100 million adults are affected by chronic pain, which reduces their quality of life and productivity, while accounting for billions in health care costs and lost revenue.<sup>1</sup> Opioids are considered the gold standard in the pharmacological treatment for chronic pain conditions, and prescriptions for opiates/opioids increased by 400% from 1999 to 2010.<sup>1,2</sup> Although opioid treatment is warranted during postsurgical and active cancer pain, physicians still commonly overprescribe opioids, which has led to addiction, high deaths rates by overdose, and the spread of communicable diseases.<sup>1</sup>

Since chronic pain is sustained by noxious sensory input originating in the musculoskeletal system, it becomes a major target for osteopathic practices.<sup>1</sup> Osteopathic manipulative medicine (OMM) may provide the balance that patients with chronic pain seek between state-of-the-art interventions and individualized patient-centered care.<sup>3</sup> Studies have shown the role of OMM in altering circulatory pain biomarkers, including the endogenous opioid system by  $\beta$ -endorphin ( $\beta$ E).<sup>4</sup> Yet, any direct significant association of these changes to a therapeutic effect from OMM remains speculative. These studies acknowledge the further need for a larger sample size and a controlled prospective design to help physicians and patients make safer opioid therapy decisions.

## Study Aims and Hypothesis

- Study aims: a) Does active OMM treatment result in decreased opioid medications?; b) Will OMM treatment serve as an effective adjunct for patients currently using opioids?
- Our hypothesis is that this OMM treatment protocol will help patients reduce their current opioid therapy usage over time. We predict that the treatment and control group will display statistically significant changes over time with respect to the following health scales: physical functioning, pain, and psychosocial health.

## Material and Methods

- We approached 273 NMI patients on opioid therapy with chronic low back pain to participate in the study; overall, 95 patients enrolled in the study.
- We randomized the subjects into two groups: the treatment group (OMM treatment + opioid therapy) and control group (opioid therapy). The OMM treatment modalities consisted of the following: soft tissue, muscle energy (ME), myofascial release (MFR), balanced ligamentous tension (BLT), and counterstrain (CS)
- After subject attrition, there were a total of 55 subjects who completed the study: treatment group = 24, control group = 31.
- To assess the effectiveness of treatment, patients filled out two forms after each visit, approximately every 4-6 weeks for 3-6 months.
- The Wong-Baker FACES Pain Rating Scale (Figure 1) evaluated the intensity of pain, with scores from 0 to 10. The Pain and Disability Questionnaire (PDQ) measured the disability caused by pain with two components: the functional (Func: 90) and the psychosocial component (PS: 60), for a maximum score of 150.<sup>5</sup>
- The EMR records and NJRx documents helped identify and track opioid usage in milligram morphine equivalents (MME) throughout the protocol.



Figure 1: Wong-Baker FACES Pain Rating; patients mark current level of pain they are experiencing

## Results: Frequencies

Group	Frequency	Percent	Total
Treatment	24	43.6	55
Control	31	56.4	
<b>Gender</b>			
Male	11	20	55
Female	44	80	

Table 1: Summarizing frequencies of patients who enrolled and completed the study

### Paired t tests : Treatment Group

Variable	Pre-study		Post-study		Correlation	t(23)	P-value
	Mean	SD	Mean	SD			
PDQ (Func)	66.56	14.91	63.10	17.46	0.70	1.32	0.20
PDQ (PS)	44.96	13.23	40.73	14.69	0.74	2.05	0.05*
FACES	7.00	1.69	5.75	2.33	0.09	2.22	0.04*
MME	115.33	83.10	115.67	76.27	0.98	0.10	0.92

Table 2: Pre and Post-study results of PDQ scores, FACES scale, and MME dosage for the treatment group. N = 24

### Paired t tests : Control Group

Variable	Pre-study		Post-study		Correlation	t(30)	P-value
	Mean	SD	Mean	SD			
PDQ (Func)	62.47	17.50	59.45	18.00	0.92	2.30	0.03*
PDQ (PS)	40.95	14.10	39.81	14.53	0.78	0.67	0.51
FACES	6.00	2.11	5.94	1.77	0.73	0.25	0.81
MME	128.49	76.24	127.15	80.69	0.98	0.45	0.66

Table 3: Pre and Post-study results of PDQ scores, FACES scale, and MME dosage for the control group. N = 31

## Pre and Post-study Averages for Measured Variables



Figure 2: Before and after averages for the treatment (dashed) vs. control (solid) groups.

## Conclusions and Future Work

- The results indicate that there was a trend for decreases in both the PDQ (PS) and FACES scores in the treatment group; there was also a decreasing trend in the PDQ (Func) scores for the control group
- Possible age and gender effects were tested for and did not contribute any significant variance in either group
- There was no significant change in the MME dosages; there needs to be a more effective way to measure the patients' medication intake in a controlled manner
- Suggestions for future research include using the OMM intervention every two weeks over a longer period of time (~ 6 months) , substituting the PDQ with the Roland-Morris LBP questionnaire, and adding a post-study survey for patient feedback

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