The Efficacy of Osteopathic Manipulative Treatment on Decreasing the Severity of Migraine Headaches.

Abby Rhoads DO, Martha Metzgar DO, Patricia Donovan DO
St. Luke's University Health Network, Bethlehem, PA

Introduction | Methods | TAP TO GO BACK TO KIOSK MENU | Results | Discussion

Introduction

- A single institution pilot study, to evaluate the efficacy of OMT on migraine headache.
- This is an interim analysis of the first 10 patients with a plan to enroll a total n=70.
- OMT could provide a cost effective treatment option for migraine sufferers.

Hypothesis

- This pilot study evaluates the utilization of Osteopathic Manipulative Therapy (OMT) to decrease migraine disability and severity scores.
- We hypothesize that OMT will decrease migraine disability and severity scores when compared to standard of care including prophylactic pharmacological agents.
- This would ultimately decrease the utilization of office or emergency department visits, decrease the large economic burden the United States faces for migraine patients as well as improve quality of life for the 3 million chronic migraine patients.

Background

- Migraine headaches affect one billion people worldwide[1].
- In the United States, one in five women and one in sixteen men suffer from migraine headaches[1].
- Migraine headache is the sixth most disabling illness in the world[1].
- More than four million people have chronic daily migraines with at least 15 migraines per month.
- More than 90% of sufferers are unable to work or function normally during their migraine attacks.
- The economic burden of migraine reaches $78 billion dollars per year[1].
- Headache accounts for the fourth or fifth most common reason for emergency department visits[1].

The effects of OMT are two- fold[4]:

Increasing parasympathetic tone

Inhibiting pro-inflammatory substances.

OMT may balance both the release of pro-inflammatory markers as well as the autonomic nervous system[4] leading to improved clinical outcomes:

Decreasing the severity and frequency of migraine headaches

Decreasing the economic burden

Improving subjects' productivity to society

The Efficacy of Osteopathic Manipulative Treatment on Decreasing the Severity of Migraine Headaches.

Abby Rhoads DO, Martha Metzgar DO, Patricia Donovan DO

St. Luke's University Health Network, Bethlehem, PA

Introduction

Methods

Results

Discussion

Recruitment

- Subjects that are OMT candidates will be recruited at St. Luke's Family Medicine and Internal Medicine departments for the interventional group.
- A total of 70 subjects diagnosed with migraine and that meet the inclusion criteria will participate.

Participation and Data Collection

- Participants complete the MIDAS and HIT-6 questionnaires:
  - ❑ prior to first treatment
  - ❑ end of 12 weeks
- Participants receive the treatment sequence four times at weeks: 0,2,6,10
- **Primary Endpoint**: change in MIDAS score in OMT intervention group demonstrated by a decrease in level of disability.
- **Secondary Endpoints**: decrease in HIT-6 Scores, headache severity by pain scale and headache frequency over the three month timeframe.

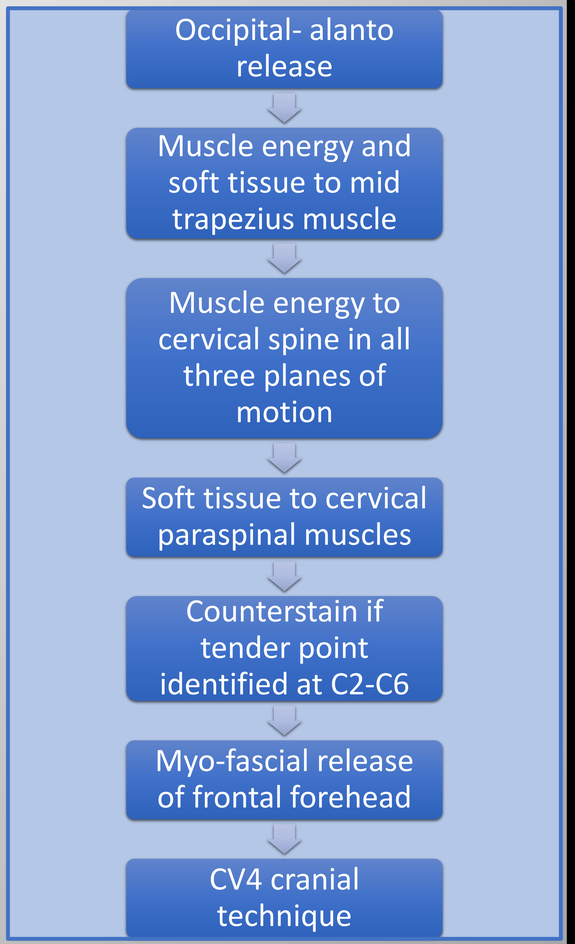
Inclusion criteria:	Exclusion Criteria:
Age: 18-50 years old	No active cancer
Gender: Male and Female	No more than two prophylactic agents
ICD 10 code of migraine with or without aura	Previous surgery to neck or cranium or history of stroke
No change in prophylactic medication during the study period	Contraindication to OMT: clinical signs of fracture in c-spine & ligament instability.
No physical therapy during 12 weeks	Poor candidate for OMT, unable to follow commands
	Seizure Disorder
	Recent head trauma
	Receiving BOTOX within last 4 months

Table 1. Inclusion and exclusion criteria for study participants (above).

Table 2. Demographic data of participants, n=10 (below).

Demographics	n(%)
Gender	
Male	1 (10%)
Female	9 (90%)
Age; Years	36 ± 7 (Mean + SD)
18-30	4 (40%)
31-50	6 (60%)
Baseline MIDAS Score	n(%)
0-5	1 (10%)
6-10	1 (10%)
11-20	0 (0%)
21 +	8 (80%)

Treatment Algorithm



The Efficacy of Osteopathic Manipulative Treatment on Decreasing the Severity of Migraine Headaches.

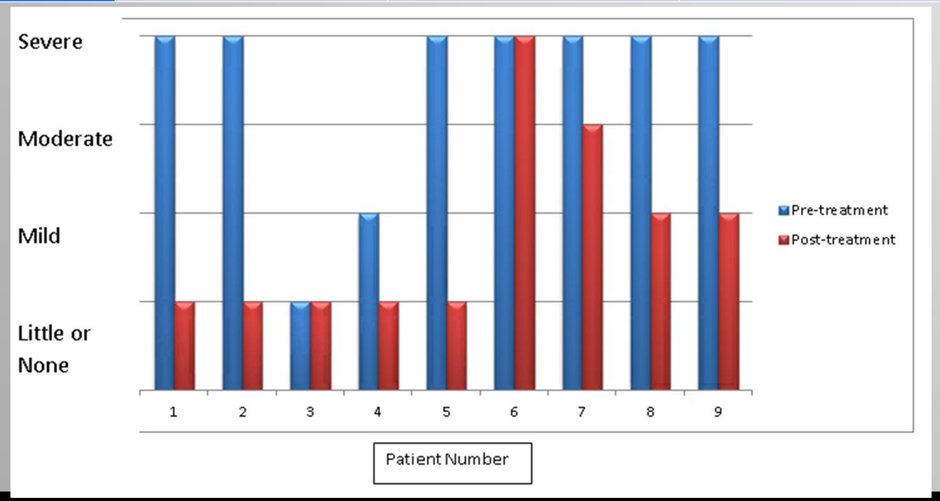
Abby Rhoads DO, Martha Metzgar DO, Patricia Donovan DO
St. Luke's University Health Network, Bethlehem PA

Introduction | Methods | Results | Discussion

All statistical analyses were conducted in IBM SPSS for Windows Version 18. Wilcoxon signed rank test was used for the comparisons. P values <0.05 are considered statistically significant.

Table 3 and Figure 1. Comparing MIDAS level of disability from pre- to post-treatment.

Patient ID	Pre-Treatment MIDAS	Level of Disability**	Post-Treatment MIDAS	Level of Disability
1	32	Severe	2	Little or none
2	95	Severe	5	Little or none
3	0	Little or none	0	Little or none
4	9	Mild	1	Little or none
5	38	Severe	2	Little or none
6	27	Severe	40	Severe
7	26	Severe	15	Moderate
8	23	Severe	6	Mild
9	110	Severe	8	Mild



**** MIDAS level of disability:**
0 to 5: Grade I
little or no disability
6-10: Grade II
mild disability
11 to 20: Grade III
moderate disability
21+: Grade IV
severe disability

Table 4. Comparing P values for all endpoints after OMT intervention.

Endpoint	Median (Minimum/Maximum)	P value
HIT-6 Score:	Pre-Treatment 67.0 (65/72) Post-Treatment 58.00 (45/66)	<0.01
MIDAS Score:	Pre-Treatment 27.0 (0/110) Post-Treatment 5.0 (0/40)	0.03
Headache Days:	Pre-Treatment 20.00 (9/60) Post-Treatment 4.0 (1/15)	<0.01
Headache Intensity:	Pre-Treatment 8 (4/10) Post-Treatment 6.0 (5/9)	0.04

The Efficacy of Osteopathic Manipulative Treatment on Decreasing the Severity of Migraine Headaches.

Abby Rhoads DO, Martha Metzgar DO, Patricia Donovan DO
St. Luke's University Health Network, Bethlehem, PA

Introduction | Methods | Results | Discussion

Discussion

- Results of nine subjects were included for the interim analysis of this pilot study after one participant was withdrawn due to loss of follow up.
- Seven out of nine participants had improvement in the primary endpoint of MIDAS disability grade level.
- In conclusion, we have seen statistically significant improvement in both primary and secondary endpoints for the first nine patients to complete the treatment protocol in this pilot study.
- This further validates the effects of OMT on migraine headache in regard to decreased disability, severity, pain intensity and number of days with migraine.
- The results are in agreement with previous studies including Voight, et al (2011) and Cerritelli, et al (2013).

Future Studies

- At St. Luke's University Health Network, we plan to enroll 70 participants in both the intervention group and a control group not receiving OMT.
- We hypothesize to continue to reproduce these significant results demonstrating OMT techniques to improve the severity and disability associated with migraine headaches.
- Future studies with larger sample size compared to control participants not receiving OMT or sham OMT should produce similar results.

Acknowledgements:

Acknowledgement to the Family Medicine and Internal Medicine residents that participated in the treatment of participants:
Abby Rhoads DO, Patricia Donovan DO, Bram Sakdiponephong DO, Benjamin Veres DO, Awan Rahman DO, Tess Chamakkala DO, Anthony Cianciolo DO, Max Widawski DO.
Cara Ruggeri DO, Internal Medicine Osteopathic Program Director.

References:

1.Burch R, Rizzoli P, Loder E. The Prevalence and Impact of Migraine and Severe Headache in the United States: Figures and Trends From Government Health Studies. Headache. 2018 Apr;58(4):496-505. doi:10.1111/head.13281. Epub 2018 Mar 12.
2.Francesco Cerritelli, et al. Is osteopathic manipulative treatment effective in migraine?. International Journal of Osteopathic Medicine. March 2013Volume 16, Issue 1, Pages e1–e2.
3.Karen Voigt. Efficacy of Osteopathic Manipulative Treatment of Female Patients with Migraine: Results of a Randomized Controlled Trial. Journal of alternative and complementary medicine (New York, N.Y.) 17(3):225-30 ,March 2011.
4. Zein-Hammoud M, Standley PR. Modeled Osteopathic Manipulative Treatments: A Review of Their in Vitro Effects on Fibroblast Tissue Preparations. J Am Osteopath Assoc. 2015 Aug;115(8):490-502. doi: 10.7556/jaoa.2015.103.