Is Osteopathic Manipulative Treatment effective in Migraine?

Preliminary Report of a Randomized Controlled Trial conducted at the Hospital of Ancona (Marche, Italy) in the period between March 2010 and March 2011.

Epidemiological data

- MIGRAINE is classified at the 19th place by the World Health Organization in the ranking of the disabling disease. 1
- It is a common disorder that affects about 6% of men and 18% of women 2
- On average 88 hours of work are lost each year by those suffering from migraine. 3
- In the U.S. in 1998 were spent $ 13 billion for care and in 2002 was $ 19 billion in lost productivity, missed. 4
- In Europe there is the higher percentage of migraineurs in the whole World 5

Figure 3: Prevalence of current migraine in adults for the different continents.


The aim of This Study is to determine the efficacy of the OMT on a sample of 105 subjects affected by migraine evaluated by the HIT-6 questionnaire.

The study was carried out in the Department of Neurology of the United Hospitals of Ancona in the period March 2010-summer 2011. All patients male and feminine admitted in the unit with a diagnosis of migraine are according with International Headache Society criteria were considered eligible for the study.

Exclusion criteria  Patients with secondary forms of headache, chronic illness, psychiatric illness, post-menopausal women, aged under 18 and over 60 years old were excluded from the study.

According to the sample size calculation using an effect size of 5 points between groups and 35 within groups with a power of 90% and an α equal to 0.05, 105 patients entered in the study and were randomly divided in three groups:

1) OMT only

2) Drugs (triptans) only

3) Sham therapy

All patients were followed up for 8 treatments in 6 month.
Randomization of Operators

Carried out by a researcher of EBOM, operators osteopaths were divided randomly into 3 groups with a:

1) OMT Osteopaths treaters
2) Sham Group Therapy
3) Evaluators
At the baseline Patients were referred by the coordinators of the study to the compilation of a sociodemographic questionnaire (esoqolio) and two paper models on the HIT-6 and the SF-36v2 (respectively the primary and secondary outcome of this study).
The group of evaluators provided for the collection of data of somatic dysfunction of patients suitable for the study using Johnston’s Tests with the first two levels of specificity. This was performed on all patients in the study at the baseline and at the follow-up after 26 weeks.
OMT

Summary of the techniques:

- Craniosacral Therapy
- Fascial Techniques
- Muscle Energy Techniques
- B.L.T.
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<tr>
<th>Week</th>
<th>I treatment</th>
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<td>Week 1</td>
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<td>Week 14</td>
<td>VI treatment</td>
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<tr>
<td>Week 2</td>
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<td>Week 6</td>
<td>IV treatment</td>
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<td>Week 22</td>
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<td>Week 10</td>
<td>V treatment</td>
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<td>Week 26</td>
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Results:

Results presented are based on a smaller sample (N=50) since the study is still running. At baseline, no difference in mean between the three groups in term of socio-demographic characteristics, severity of migraine and quality of life.
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<th>WEIGHT</th>
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<td>Diff</td>
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<td>S-NT</td>
<td>-0.26</td>
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<td>T-NT</td>
<td>-4.39</td>
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<td>T-S</td>
<td>-4.13</td>
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<td>Overall</td>
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<table>
<thead>
<tr>
<th>HIT-6</th>
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<td>S-NT</td>
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<td>T-NT</td>
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<td>T-S</td>
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<td>Overall</td>
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Results at the baseline
HIT-6

95% family-wise confidence level

Differences in mean levels of group
At the end of the follow-up ANOVA showed a statistically significant difference on the primary outcome between the three groups: $F(2,47) = 5.61$, $p= .006$. 
Tukey post-hoc comparisons of the three groups indicate:

- that sham was not statistically different from drug group
  \[ M = -3.47, 95\% CI [-9.31, 2.37], p = .33 \]

- OMT was statistically different from drug group
  \[ M = -9.07, 95\% CI [-15.64, -2.50], p = .004 \]

- OMT was almost statistically significant from sham group
  \[ M = -5.60, 95\% CI [-11.81, -0.61], p = .08 \]
95% family-wise confidence level

Differences in mean levels of group

sham-not treated

treated-not treated

treated-sham

Conclusion

This preliminary data, even though not completed, showed a significant difference between OMT group and the others two, suggesting that the OMT can be considered an efficient procedure in the management of patients with migraine.
Acknowledgments

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- Cerritelli Francesco DO.

- All the Osteopats that give their contribution:

Thanks for your kind attention