Safety and Feasibility of Osteopathic Manipulative Treatment (OMT) in Addressing Plagiocephaly

Emily Varrasso[1] OMS-II, Rosita Saul[2] OMS IV, Disha Goel[3] OMS-III, Jessica Martone[4] PhD, MSW, Jennifer Belsky[5] DO, Kimberly Wolf[3,4] DO

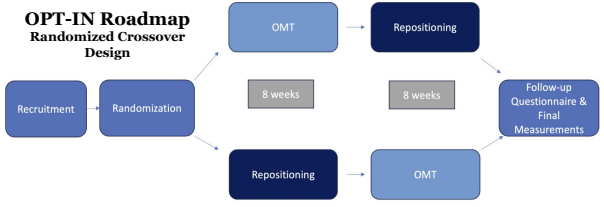
1: Ohio University Heritage College of Osteopathic Medicine, 2: Nova Southeastern University, 3: Touro University California College of Osteopathic Medicine,
4: Osteopathy's Promise to Children, San Diego, 5: Riley Hospital for Children at Indiana University Health

Background

- Positional plagiocephaly (PP) = asymmetrical flattening of the cranium due to sustained pressure
- Cranial anatomy of infants leaves them vulnerable to PP which leads to compensatory shifts of other cranial structures[1]
- PP incidence may be as high as 46.6% at 7 to 12 weeks of age [2-4]
- Since the initiation of the AAP's "Back to Sleep" campaign, the incidence of PP has risen 600%[5-6]
- Safety in this study defined as no report of significant adverse events attributed to OMT
- Feasibility aimed to assess the degree to which a patient and their family could easily complete the entire treatment protocol
- **Objective: To examine how safe and feasible OMT is for the treatment of PP in infants enrolled between 0-4 months of age**

Methods

- Assessed safety and feasibility through feedback survey, focus groups, and side effects/complications tracked through weekly surveys & monitored monthly by an internal data and safety committee
- 132 participants recruited; 75 met eligibility criteria and enrolled. Of those, all 67 have completed the 16 week intervention, 6 withdrew, and 2 became ineligible
  - **44** parents completed feedback survey on experience with OMT
  - **13** parents participated in a focus group to share feedback on the treatment received and what they learned about OMT
  - **67** parents reported side effects or complications



Results

- Multiple races represented including Hispanic and Native/American Indian, with only 40% of participants identifying as white, which is below the average of 66% for most pediatric clinical trials[7]
- Income ranges from less than $40,000 to $200,000+, with 36% earning below $100,000 and participants representing 41 different zip codes
- Among participants who have completed the 16-week intervention, there is 100% compliance for the 10 study visits
- Safety was evaluable if weekly survey completed and family had at least one visit in which safety was assessed. Concurrent symptoms were selected for 74 visits out of 495 (15%)
- 37 families out of 67 (55%) had at least one visit in which a concurrent symptom was reported. Of those, majority (59%) identified a concurrent symptom at only one visit. All concurrent symptoms were resolved, typically within a few hours (43%) and not bothersome to family (96%)
- Most frequent concurrent symptoms were fussiness/irritability (57%), did not sleep well (21%), "other" (12%), discomfort/pain (5%) & "unsure" (5%)
- No significant adverse events occurred, showing OMT is safe and well-tolerated by infants

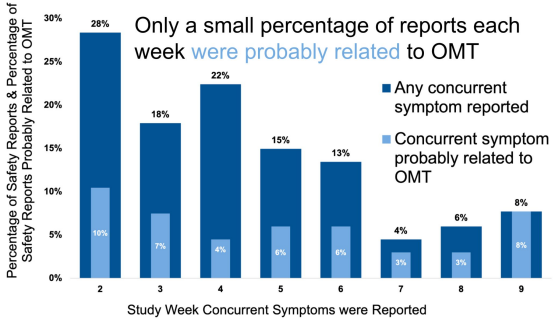


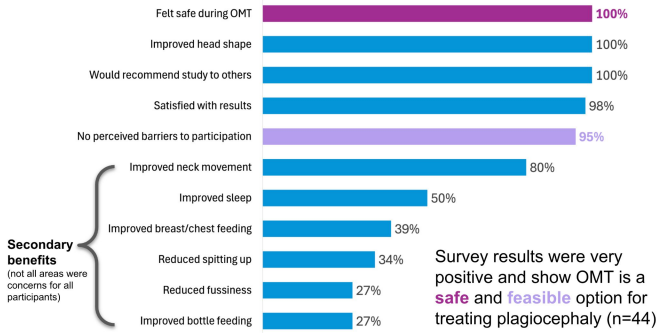
Benefits
Parents noted improvement in their baby's head shape, as well as numerous other benefits.

Parental relief
Parents who were feeling overwhelmed and felt dismissed by other providers experienced feelings of relief with OMT.

Gentle & safe
Parents noted OMT was gentle, safe, effective, amazing, and not scary.

Awe
Parents described OMT as a godsend and noted that it works well, is thorough, effective, and magical.





Conclusion

- OMT is a **favorable, non-invasive treatment for infants with PP**, and there were no significant adverse events in this study.
- Concurrent symptoms reported were **mild, not bothersome to the family, and resolved quickly**.
- Parental feedback revealed that OMT was **"gentle, effective, and awesome"**

References