

Osteopathic Manipulative Treatment (OMT) for the Management of Feeding Dysfunction in Breastfed Newborns

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Background:

The choice to breastfeed is one of the first and most important decisions a new mother can make. The benefits of breastfeeding are well-established, from reduced incidence of common childhood infections such as otitis media and RSV bronchiolitis to reduced incidence of SIDS and decreased infant mortality.¹ Thus, offering support to a breastfeeding mother should be a key aspect of our care as physicians in the perinatal period. Osteopathic physicians are uniquely equipped to offer an additional tool to potentially improve the breastfeeding experience: osteopathic manipulative treatment (OMT). OMT is a practice of manual medicine created by Andrew Taylor Still, MD, DO in the late 19th century. The discipline encompasses a variety of musculoskeletal techniques ranging widely from myofascial release to high-velocity/low-amplitude spinal manipulation, and targets visceral and somatic dysfunction involving virtually every organ system.

Nipple feeding requires coordinated suck and swallow, which depends on cranial nerves IX, X and XII for proper function of intrinsic tongue and external stabilizing muscles. Infants with cranial dysfunction may be suffering from inhibition of those nerves as they exit their relative foramen.

The incidence of cranial dysfunction among newborns appears to be significant, ranging from 36%² to 88%³ in the literature. Several studies have been performed that demonstrate some benefit from OMT in the newborn population, including decreased gastrointestinal symptoms and length of stay in NICU neonates^{4,5}. The osteopathic research that addresses feeding dysfunction in newborns receiving OMT does demonstrate some benefit, although most of these studies have a sample size too low to glean clinical significance from the findings. One 2011 case report⁶ outlined the benefit of OMT in premature twins with nipple feeding dysfunction who were able to avoid placement of gastrostomy tubes after osteopathic intervention. A small study from Fraval in 1998⁷ followed six infants with feeding dysfunction, most of whom improved with OMT as estimated by breastmilk fat content. More recently, Herzhaft-Leroy et al⁸ developed a single-blinded, randomized controlled trial comparing 97 breastfed infants with feeding dysfunction who received either OMT and lactation support or lactation support alone; this study used LATCH scores to gauge feeding quality and found that the OMT group had a greater improvement in LATCH scores versus lactation support alone. While this most recent study was a larger-scale randomized controlled trial, a weakness of this and prior studies remains lack of a treatment protocol.

Given the relative paucity of research into the role of breastfed newborns with feeding dysfunction, and no studies utilizing a standardized OMT protocol, our study seems timely, relevant, and poised to contribute meaningful findings among osteopathic literature.

Objective:

The purpose of this study is to evaluate whether utilization of osteopathic manipulative treatment protocol as an adjunct to standard lactation support will improve feeding dysfunction in breastfed newborns.

Hypothesis:

Infants receiving OMT in the treatment arm of the study will have more significant improvement in their LATCH score compared to infants in the control arm of the study receiving lactation support alone.

Methods:

This project is an IRB-approved, single-blinded, randomized, controlled, prospective study that is currently taking place at UnityPoint Health (UPH)– Methodist in Peoria, Illinois. Inclusion criteria includes term infants ≥ 37 weeks gestation in the Level I nursery receiving lactation support and identified by lactation as having a newborn component to feeding dysfunction, who must be available for at least two inpatient treatment sessions and whose parent has provided informed consent. Exclusion criteria includes all infants: <37 weeks gestation, in Level II or III nursery, wards of the state, receiving speech therapy or physical therapy, already receiving OMT, not breastfeeding, or infants breastfeeding but found to have a maternal factor contributing to feeding dysfunction (e.g. nipple problem).

All breastfed mother-infant dyads at UPH - Methodist are offered evaluation by a lactation consultant, and breastfeeding sessions are routinely scored by either registered nurses or lactation consultants using the LATCH tool, with scores entered into a flowsheet on the electronic medical record. LATCH is a validated tool designed by Jensen et al⁹ to evaluate five components of breastfeeding: latch, audible swallowing, type of nipple, comfort of mother, and help mother needs holding infant to breast. There are two points per component, for a maximum score of 10; for the purposes of our study, the nipple component will be excluded, so the maximum score will be 8. LATCH has demonstrated reliability in subsequent studies, with higher scores predictive of longer breastfeeding duration and increased maternal satisfaction with breastfeeding.¹⁰⁻¹²

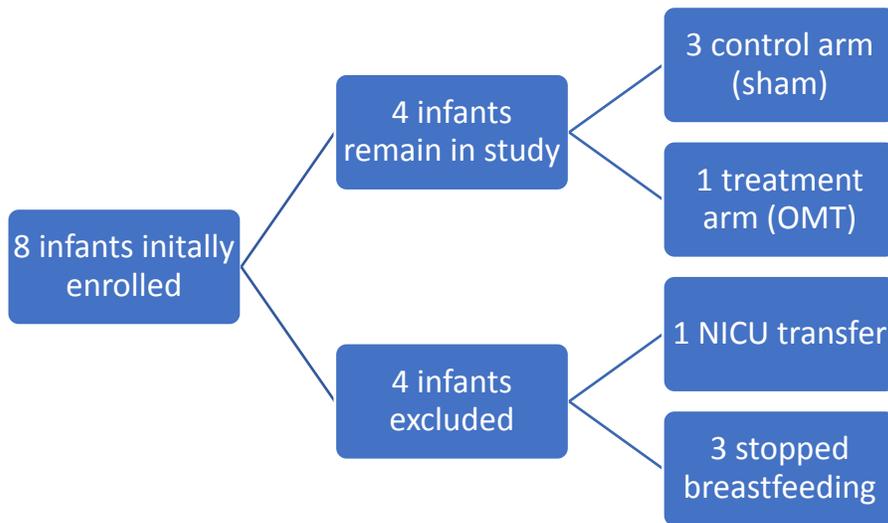
Eligible infants are enrolled in the study after evaluation by a lactation consultant, who then notifies an on-call provider on the research team. The infant's mother is provided with a brochure explaining OMT and outlining potential benefits in newborns. The on-call provider then presents to bedside to provide informed consent and administer either the treatment protocol or sham OMT. Infants are enrolled Monday through Thursday, and treatments are performed Monday through Friday. Enrolled infants are added to a password-protected, numerical list and randomized into their group based upon whether they land on an even number (sham) or an odd number (OMT). If multiple infants are enrolled at the same time, they are added to the list in alphabetical order. Group assignments are blinded to the parents, nursing staff, and lactation consultants; only the providers are aware of which infants are receiving OMT. A brief note acknowledging that the infant has been enrolled in the study is entered into the electronic medical record, but both the OMT and sham treatments are documented on paper, kept in a locked document folder in the residency teaching clinic, and scanned into the electronic medical record two weeks after discharge so as to keep the nursing and lactation staff blinded to groupings.

The OMT treatment protocol includes the following four techniques: condylar decompression, cervical Still technique, thoracic inlet release and balancing of the hyoid bone. Infants in the control arm receive "sham" OMT during which the provider simply assesses the head, neck and chest regions for somatic dysfunction but provides no active treatment.

A research team provider follows up on the day following enrollment to provide a second treatment. After discharge, each enrolled infant’s LATCH scores are reviewed, categorized as pre- or post-treatment, and documented.

Results

From December 2017 to this date, eight infants have been enrolled in this study. Four infants were later excluded from the study after chart review indicated that they had either been transferred to the NICU (1) or stopped breastfeeding prior to discharge (3). This leaves four infants remaining in the study, three of which are in the control arm of the study and received sham treatment; only one currently enrolled infant is in the treatment arm of the study and received OMT.



Of the four currently enrolled infants, none were exclusively breastfeeding during their hospitalization. Two babies received bottled formula feeds on less than three occasions or less, one baby received bottled donor breast milk feeds on several occasions, and one baby received tube and syringe feeds of maternal breast milk.

The pre-treatment latch scores were collected and averaged as follows:

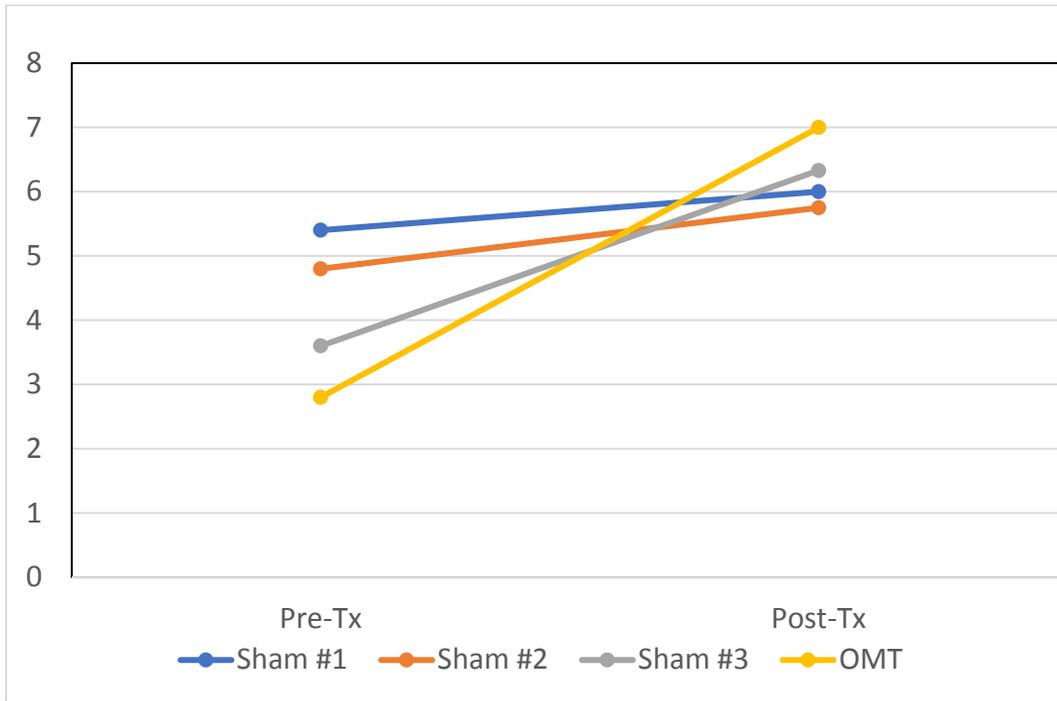
	Pre #1	Pre #2	Pre #3	Pre #4	Pre #5	Average	
Sham #1	3	4	4	8	8	5.4	
Sham #2	4	5	4	6	5	4.8	
Sham #3	6	5	4	0	5	4.6	
OMT	3	0	7	0	4	2.8	treatment scores

Post-LATCH

were collected and averaged as follows:

	Post #1	Post #2	Post #3	Post #4	Post #5	Average
Sham #1	5	7	7	5	6	6.0
Sham #2	7	5	7	4	n/a	5.75
Sham #3	6	6	7	n/a	n/a	6.33
OMT	8	8	6	6	n/a	7.0

The “Sham #1” infant’s LATCH average improved by 0.6, from 5.4 to 6.0. The “Sham #2” infant’s LATCH average improved by 0.95, from 4.8 to 5.75. The “Sham #3” infant’s LATCH average improved by 1.72, from 4.6 to 6.33. The “OMT” infant’s LATCH average improved by 4.2—the largest margin—from 2.8 to 7.0.



Discussion:

Given that this study is ongoing with a very small number of enrollees to date, the discussion will be limited to current perceived strengths and shortcomings of the study, as well as plans for the future.

Study strengths include the randomized, single-blinded format that includes an OMT treatment protocol, which decreases variability and enhances reproducibility. The intervention is also low-risk, cost-effective, and welcomed by families as an adjunct to lactation support.

Presently, a primary limitation of this study is a lack of workflow with lactation consultants. By design, the lactation team is a rate-limiting factor in the enrollment of infants; an initial evaluation by lactation is required so that a newborn component to feeding dysfunction can be identified. The lactation consultants have been an interested and engaged party in the planning of this study, but the actual execution has been a challenge as the consultants report often forgetting the study or recalling which infants would be eligible. Another limitation is that both nursing staff and lactation consultants are assigning LATCH scores, depending on who is observing a given breastfeeding session. While the LATCH system has demonstrated inter-operator reliability in multiple studies, there is always some inherent variability amongst various staff members of different professional backgrounds and experience levels.

Another possible factor contributing toward the low enrollment rate is that UnityPoint Health – Methodist appears to have a lower than average breastfeeding rate, with approximately 47-49% of mothers exclusively breastfeeding based upon a sampled average¹³. This remains well below the national breastfeeding initiation rate which was reported as 81.1% in the 2016 CDC Breastfeeding Report Card.¹⁴

Additionally, the target population in this study is entirely composed of newborns with feeding dysfunction, so there are significant differences in the forms of intervention the infant is receiving in terms of lactation support. As outlined above, no infant is exclusively breastfeeding; feeds are occurring at variable intervals and using a variety of techniques or tools depending upon the needs of the infant. The lactation team's interventions may confound any demonstrable improvement in the treatment group.

While the treatment protocol remains a strength of the study as described above, it may also be a limitation in that infants cannot be assessed and treated based upon their individualized somatic dysfunction diagnoses. The protocol is thorough, targeting key areas involved in a coordinated suck/swallow, but some dysfunction may be left untreated as it lies outside the protocol. On the flip side, there is always a risk that "sham" OMT may inadvertently provide some active treatment simply by placing or moving our hands over tissue in key areas; this may confound data in the control arm.

Future plans for this study include implementation of more aggressive, proactive strategies to engage lactation in the enrollment process. In order to be adequately powered, the study requires over 80 enrollees per treatment arm. Drs. Kapraun and Watts, in coordination with Drs. Fons and Knepp, will continue working on this project and look forward to reporting on significant progress at this time next year.

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