Video Article

Assessment of the Efficacy of An Osteopathic Treatment in Infants with Biomechanical Impairments to Suckling

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Abstract

Breastfeeding can be challenging for mother-infant dyads experiencing biomechanical suckling difficulties. Although lactation consultants (LCs) all over the world have increased their skills in this field and can provide support to help position the infant at the breast, the impact of their intervention might be limited in the presence of stiff structures in the infants. Here we present a protocol for a randomized controlled trial to assess the efficacy of osteopathic treatment, coupled with lactation consultation, for infants' biomechanical suckling difficulties. It proposes a set-up and a sequence of actions to ensure an optimal context for treatment, as well as a blinding of parents and LCs to the intervention. Data such as the infant's latch ability measured with the LATCH Assessment Tool, the mother's nipple pain with a visual analog scale (VAS), and the mother's perceptions are collected by LCs four times over a 10-day period. Osteopathic lesions are documented by the osteopath, using a standardized assessment grid. Structures of interest are coherent with the anatomical zones involved in latching onto the breast. This protocol also proposes a strategy to document systematically an osteopathic profile of infants with biomechanical suckling difficulties in their first weeks of life. The implementation of this protocol confirms its feasibility for osteopathic assessment and treatment and paves the way for future trials to further explore the efficacy of osteopathic techniques for infants with biomechanical suckling difficulties.

Video Link

The video component of this article can be found at https://www.jove.com/video/58740/

Introduction

Over the last thirty years, international recommendations from the World Health Organization[1], followed by national recommendations in many countries[2,3,4], have advocated for breastfeeding. Its health benefits are now well-known[5,6] and breastfeeding exclusively for the first six months of the infant's life and maintaining it for two years or longer is described as the norm[1].

As highlighted by Homdrum and Miller[7], more than half of the mothers who stop breastfeeding within the first month reported biomechanical difficulties. Suckling biomechanical issues typically include suboptimal head extension and rotation, restricted mouth opening or jaw stiffness, biting the nipple, restricted tongue mobility, and inefficient mouth vacuum to stimulate the release of milk from the mother's breast[8]. Any neurological impairment also affects the optimal function of the normal primitive reflexes, crucial to an optimal latch.

The emergence of LCs worldwide has provided a great source of breastfeeding support for mother-infant dyads and has contributed to increasing the scientific knowledge in this specific field. For example, LCs have studied extensively the biomechanics of suckling from birth to weaning. In parallel, they have created tools to assess the function of breastfeeding and to efficiently detect dyads with special needs[9,10].

Osteopathy is a manual practice meant to restore normal functions of the human body, based on the body's capacity for self-regulation[11] and structure-function relationship[1]. During an osteopathic consultation, various palpation techniques are used, based on thorough knowledge of human anatomy and physiology[12]. Some scholars have linked physical restrictions with suckling dysfunction[13,14,15,16,17]. Restrictions of skull sutures or motility of skull bones have also been described to impact an infant's ability to latch[13,14,15,16,17,18]. However, research on the efficacy of osteopathy techniques on biomechanical suckling difficulties is scarce[19,20].

Aside from a few case reports describing an osteopathic intervention to improve an infant's ability to latch[21,22], only one pilot study[23] documented the impact of such interventions. Six infants between three to six weeks of age were recruited and assessed by an LC. Mothers were given breastfeeding advice and then met the osteopath. Four treatments (once a week for four weeks) were performed. Treated infants were compared with six control infants whose mothers received only LC support. The authors found improvement in the milk fat content, which has been shown to be a marker for effective feeding[24]. Due to its small sample, these pilot study results are not generalizable but established the feasibility of a randomized controlled trial coupling the expertise of LCs and osteopaths.

These studies have paved the way for a single-blind randomized controlled trial to assess the efficacy of an osteopathic treatment coupled with lactation consultations on infants' ability to latch. The protocol for this trial is presented herein. The trial took place in a mother-to-mother support group, where LCs provided lactation consultations three days a week, free of charge for parents[25].

Assessment tools for the trial included 1) the LATCH Assessment Tool to measure the main aspects of the biomechanics of suckling[26]; 2) a VAS to assess the mother's nipple pain; 3) a goniometer, a soft plastic instrument to measure the rotation of the infant's head's angles; and 4) *de novo* questionnaires to assess the mother's perception of her infant's ability to latch, as well as sociodemographic data and potential intervention side-effects.

The LATCH Assessment Tool was chosen amongst several others for its specific assessment of the biomechanics of the suckling structures and the global ability of the mother-infant dyad to position themselves comfortably[27]. While breastfeeding assessment tools are currently discussed in the international lactation community[28,29], the tool is easy to use in the clinic, reliable, and widely implemented among this community to detect early breastfeeding difficulties[30]. The choice of the tool also enables comparisons with other studies on breastfeeding. Each letter in "LATCH" corresponds to an item to assess an element of the biomechanics of suckling. "L" is for the ability of the infant's tongue, jaws, and lips to sustain the actions and vacuum, and to activate the milk let-down reflex efficiently (Latch). "A" is for Audible swallowing as it is evidence of suckling effectiveness, "T" is for the Type of the nipple at the end of the feed (inverted, flat, or everted), "C" is for the Comfort of the breast and nipple, and "H" is for the assessment of the ease with which the infant is Held in a comfortable and effective position at the breast. The result is a five-item score out of 10 (normal is 10 out of 10) with an interrater reliability of 0.94[31,32].

The VAS is a 10 cm line to estimate the severity of pain felt by mothers, from 0 (no pain) to 10 (maximum pain). For this trial, the VAS was completed at the beginning of the feed, once the infant was latching on, and once the milk let-down had started.

A soft plastic goniometer was used to assess the passive rotation of the infant's head, as described by Cheng[33]. Assessments were completed immediately before and following the osteopathic assessment for the control group, and before the assessment and following the osteopathic treatment in the treatment group. Intrarater reliability has been reported to range from 0.83 to 0.98 for the head rotation assessment[34].

Finally, a standardized assessment grid was completed by the osteopath for every infant involved in the study, documenting all of the areas exhibiting osteopathic lesions. Osteopathic lesions are areas with lack of mobility or motility, with excess rigidity, or with a lack of tone in the structure. Lesions are classified in three levels of severity, ranging from a structure with limited mobility to a stiff structure with no mobility. In the osteopathic treatment group, all structures addressed during the treatment were documented (**Table 1**).

Data were analyzed with an intention-to-treat analysis using descriptive statistics. Chi-square tests were used to explore potential correlations between all identified lesion sites and a one-point or more improvement on the LATCH Assessment Tool.

Protocol

This randomized controlled trial protocol was approved by the Comité d'éthique et de la recherche en santé de L'humain at the Centre hospitalier Universitaire de Sherbrooke and the Comité d'éthique et de la recherche at the Centre intégré de santé et services sociaux de la Capitale Nationale in Québec City, Canada.

1. Identification of Collaborators and the Preparation of Recruitment

1. Network with LCs and/or a local mother-to-mother support groups where frequent lactation consultations are provided in order to identify where the study will take place.
2. Organize a training session (roughly 2 h) for potential recruiters (LCs from the group identified at step 1.1, external LCs, midwives, and perinatal nurses) on biomechanical suckling difficulties based on Genna's description of the innate sequence of suckling behavior[8], and the eligibility criteria for this study. Include a brief description of potential osteopathic techniques used in this context.
3. Ensure that the LCs identified at step 1.1 are familiar with the tools used in the study and, if necessary, are trained to use the LATCH Assessment Tool, the VAS, and the questionnaires.
    1. Test-run the protocol procedures, such as welcoming the mother-infant dyads, explaining and facilitating the signing of the consent form, and completing the assessment using the tools.
4. Validate the reliability of the osteopathic palpation with other osteopaths experienced in pediatric osteopathy. Train the study osteopath to be able to evaluate and perform the osteopathic treatment needed within 30 min maximum, in order to minimize inconsistencies arising from the infants' behavior, such as sleep stages and suckling skills and stamina.

2. Selection of Implementation Sites

1. Select a site with at least two hospitable rooms with conveniences for families to host the study. Consider providing drinking water, a comfortable place to breastfeed, and diaper changing facilities. Also, provide pillows or cushions to support the mothers' arms, a footboard for better positioning, and chairs for family members accompanying the mother-infant dyad and the LC (when performing the evaluation).
NOTE: The rooms must be easy to access with a stroller and for mothers with limitations following a C-section delivery. A sofa is optimal, but a rocking chair for the mother plus a small bench for the osteopath is another option.

3. Recruitment and Enrollment of Mother-infant Dyads

1. Identify eligible infants with biomechanical suckling dysfunctions through referrals from LCs, nurses in perinatal care, and midwives, after their first lactation consultation. Refer them to the study.

1. Select infants less than six weeks of age, with biomechanical suckling dysfunctions (suboptimal head extension, restricted head rotation, restricted mouth opening, jaw stiffness, habit of biting the nipple, restricted tongue mobility).
2. Exclude infants with a cleft palate, cleft lip, surgical tongue-tie, or other medical conditions; twins; and infants with prior treatment using any type of manual therapy.

2. On the first appointment following the referral, welcome mother and infant and explain the full study process. Obtain informed consent.
3. Once screened, clearly establish how parents will contact the clinic, to ensure a rapid turn-around for the intervention and to schedule an appointment.
   NOTE: The LC provides an initial lactation consultation prior to the preintervention assessment and, then, determines the LATCH scores and the VAS pre- and postosteopathic intervention.

4. Assessment of Baseline Study Outcomes

1. Ask the mother to give one breast. Observe the infant's suckling rhythm.
2. Assess the infant's baseline ability to latch, using the LATCH Assessment Tool, right at the beginning of the feed. Be aware that, sometimes, infants are in a deep sleep and it may take a long time to awaken them. Be prepared to complete the administrative process quickly if the infant is hungry and upset prior to the feed.
3. Request the mother to complete a VAS at the beginning of the feed.
4. Administer a baseline questionnaire for sociodemographic data, breastfeeding data (*e.g.*, number of feeds per day, number of bottle feeds *versus* breastfeeds, number of diapers changed in the last 24 h), and maternal perceptions of biomechanical difficulties (*e.g.*, infant bites the nipple during the feed, opens his mouth widely to latch, or slips on the nipple while feeding).
5. Ask the mother to remove the infant from the breast when the suckling movement is slowing.
   NOTE: When the assessment is completed, the LC leaves the room.

5. Performance of an Osteopathic Assessment

1. Open the sealed and opaque envelope with the corresponding study number for the mother-infant dyad, which will assign the dyad to the control or treatment group.
2. Ask the mother to sit on a couch with a cushion on her knees and the infant lying back on it. Sit by her side. Connect with the infant by making eye contact. Talk to the infant before putting hands on its body.
3. Begin with a general observation of the infant's posture, tone, and any asymmetries.
4. Assess the infant's head passive rotation left and right with the goniometer. Respect any discomfort manifestation or limitation (for example, ipsilateral shoulder elevation).
5. Observe the infant's body attitude and assess any osteopathic lesions for each part of the body regardless of the allocation group, using the standardized grid described in **Table 1**.
6. Begin the treatment with the pelvic area since it is an important sphere of compression during the birth process[16,35]. Assess the tissue texture and tone in the lower limbs' fascia, sacroiliac joints, sacrum, and hips, as well as the range of motion of the pelvic sphere *versus* the lumbar spine.
7. Move hands from the infant's pelvis to its skull and similarly assess tissue texture and tone and, as appropriate, the range of motion of the abdominal cavity, spine, diaphragm, thorax, and cervical spine. Pay careful attention to the first cervical vertebrae, and assess the anterior structures of the neck, the hyoid bone, and sublingual muscles.
8. Be very precise and gentle as to the placement of fingers at the skull base, as structures are tiny and delicate.
9. Move forward from the base of the skull to the occipital bone, temporal bones, parietal bones, sphenoid bone, frontal bone, and features of the face, including the jaw. Infants yawn frequently; observe the jaw movements and the symmetry of the face.
10. For each structure, record observations of the texture, tone, quality and range of motion, and straining on the standardized grid (**Table 1**).

6. Performance of Osteopathic/Sham Intervention

NOTE: The osteopathic techniques described in this protocol are key osteopathic approaches available for infants with biomechanical suckling difficulties. They focus on improving the infant's ability to latch, improving pelvic mobility, improving head rotation and extension, improving mouth opening, and freeing the XII cranial nerve, which is responsible for the tongue motion.

1. Lie the infant down on his/her back on a pillow on his/her mother's knees. Sit alongside the mother on the couch, at the infant's head.
2. Perform the osteopathic treatment.
   1. Start the osteopathic treatment by addressing areas previously identified as dysfunctional.
   2. Begin by treating the pelvic area. Place the hands on each side of the infant's pelvis, covering the iliac bones. Ensure that thumbs are on the anterior part of the iliac bones and fingertips are at the sacroiliac joint on each side. Using indirect technique, place the restricted structure in a comfortable position. Use continuous feedback until the complete loosening of the structure is achieved (known as a release)[17,36].
   3. Place fingers of both hands around the occipital bone, tips of the ring fingers contacting the condyles area, index fingers contacting the mastoid area and middle fingers between the occipital bone and the first cervical vertebra, as described for the condylar decompression technique[37]. Gently separate the fingers in the various spatial plans until the tissues soften and the condyles move freely.
      NOTE: At the upper cervical spine, spots are very close together and fragile.
   4. Place one hand under the occipital bone and the other on the frontal and sphenoidal bones, avoiding eyes, in a fronto-occipital hold[17]. Place the occiput and sphenoid in their position of least resistance. Monitor the decrease in resistance and readjust the positioning of the structures until the release occurs.

5. Place one hand cupping under the occipital bone and the first three cervical vertebrae and the index finger and thumb of the other hand on each side of the hyoid bone. Wait until a release of the hyoid bone is felt through the structures in the other hand. Monitor and reassess, as done in a myofascial release technique[36].
6. End the osteopathic treatment by a global body harmonization. Put one hand on the pelvic area and the other on the skull. Gently balance the body volumes, addressing fascia, muscles, bones, and fluid, at least until a coherent and global release is perceived.

3. Perform a sham intervention.
    1. Place hands on areas far from those with detected dysfunctions, without any intention of treatment.
    2. Answer questions from the parents about osteopathy and the infant's psychomotor development.
4. Postpone the infant feed until the end of the intervention. Use a pacifier or the mother's finger if necessary to soothe the infant.
5. Assess the infant's left and right passive head rotation with the goniometer.
6. Make sure the evaluation and sham manipulation or the evaluation and osteopathic treatment have the same 30 min duration in order to keep the parents and the LCs blind as to treatment allocation.
7. Leave the room. Fill in the standardized assessment grid (**Table 1**). Record details of the treatment performed.

7. Reassessment of the Mother-infant Dyad

NOTE: The LC re-enters the treatment room.

1. Take time to set up the mother and the infant comfortably, to ensure the best conditions to take the breast again. Reassess the infant's ability to latch with the LATCH Assessment Tool.
2. Ask the mother to complete a second VAS.
3. Perform a usual lactation consultation.
4. Schedule a second appointment 48 h later. Inform the mother that there will be another breastfeeding evaluation, meaning that she will have to manage to feed her infant during this meeting.

8. Final Face-to-face Assessment

NOTE: For this assessment, parents will only meet an LC.

1. Set up the mother and infant comfortably to create the best conditions to breastfeed. When the infant is ready (it may take some time), assess the ability to latch with the LATCH Assessment Tool.
2. Ask the mother to complete a second VAS at the beginning of the feeding.
3. Administer a second questionnaire for breastfeeding follow-up, maternal perceptions of the infant's ability to latch, and perception of their allocated group.
4. Perform a second lactation consultation.
5. Offer osteopathic treatment for infants in the control group.
6. Make a phone appointment one week following this second visit.

9. Assessment of the mother-infant dyad 10 days post enrolment

1. Call the mother to complete the 10-day questionnaire, including breastfeeding follow-up and potential side effects. Remind the mother to complete the postal questionnaire, which includes a VAS and satisfaction component regarding their participation in the protocol.
2. Wait to receive the postal questionnaire. Call back 1x if necessary.

Representative Results

Ninety-seven mother-infant dyads were recruited and randomly assigned to one of the two study groups. The participants' characteristics and delivery mode are summarized in **Table 2**. Only 1/3 had a natural birth, meaning that the other 2/3 experienced epidural and vacuum (15.9%), forceps-assisted (2.9%), or C-section (18.8%) births. In this study, all infants had skull lesions (**Table 3**). The posterior quarter represented by the occipital and the temporal bones was the main area identified; in particular, the right side of this quarter. The pelvis was the second most common lesion site, followed by the face. Lesion sites are described in detail in **Table 4**; the majority of lesions being situated at the level of the occipital bones, temporal bones, and skull sutures, followed by the sacrum.

The infants' head rotation, as assessed with the goniometer prior to and following the osteopathic intervention (sham manipulation or osteopathic treatment), was improved (statistically significant change) by the osteopathic treatment, for both right and left head rotation (**Table 5**).

Table 1: Standardized assessment grid for osteopathic lesions. Please click here to download this file.

Participants Main Characteristics		
	Control group n=48	Treatment group n=49
First baby, n (%)	34 (70.8)	35 (71.4)
Natural birth, n (%)	18 (37.5)	19 (38.8)
Epidural, n (%)	35 (72.9)	36 (73.5)
Vertex presentation, n (%)	26 (54.2)	27 (55.1)
Infant mean age in days at T0 (IQR)	15 (7.5, 18)	15 (7.5, 22.4)

Table 2: Participants' main characteristics. The control and treatment groups are similar in terms of participant characteristics.

Areas	**n (%; 95% CI)**
Skull	97 (100,0 ; 0,95, 1)
Anterior quarter	22 (22,7 ; 0,16, 0,32)
Posterior quarter	82 (84,5 ; 0,76, 0,90)
Right posterior	*54 (55,7 ; 0,46, 0,65)*
Left posterior	*28 (28,9; 0,21 , 0,38)*
Face	72 (74,2; 0,65 , 0,82)
Neck	50 (51,5; 0,42 , 0,61)
Thorax	52 (53,6; 0,44 , 0,63)
Cervical spine	41 (42,3; 0,33 , 0,52)
Spine (except cervical)	18 (18,6; 0,12 , 0,27)
Pelvic	80 (82,5; 0,74 , 0,89)

Table 3: Area of osteopathic lesions. All infants involved in this study had skull lesions, with a majority in the posterior quarter.

Structures	n (%; IC 95%)
Skull	
Occipital bone	95 (97.9; 0.92, 1)
Temporal bones	71 (73.2; 0.64, 0.81)
Sphenoid	52 (53.6; 0.44, 0.63)
Parietal bones	32 (33.0; 0.24, 0.43)
Sutures	76 (78.4; 0.69, 0.85)
Face	
Frontal bone	60 (61.9; 0.52, 0.71)
Ethmoid	14 (14.4; 0.09, 0.23)
Maxilla	3 (3.1; 0.01,0.09)
Mandible	31 (32.0; 0.24, 0.42)
Orbit asymmetry	15 (15.5; 0.10, 0.24)
Neck	
Hyoid bone	38 (39.2; 0.30, 0.49)
Digastric muscle	3 (3.1; 0.01, 0.09)
Supramandibular muscle	31 (32.0; 0.24, 0.42)
Sternocleidomastoid muscle	6 (6.2; 0.03, 0.14)
Thorax	
Left clavicle	14 (14.4; 0.09, 0.23)
Right clavicle	10 (10.3; 0.05, 0.19)
First ribs	3 (3.1; 0.01, 0.9)
soft thoracic tissues	26 (26.8; 0.19, 0.37)
Diaphragm	44 (45.4; 0.36, 0.55)
Spine	
Atlas/Axis	41 (42.3; 0.33, 0.52)
Other cervical vertebrae	11 (11.3; 0.06,0.19)
Thoracic vertebrae	17 (17.5; 0.11, 0.27)
Lumbar vertebrae	3 (3.0; 0.01, 0.09)
Pelvic	
Sacrum	80 (82.5; 0.74, 0.89)
Sacrum compaction	37 (44.6; 0.29, 0.49)
Dura mater traction	26 (31.3;0.19, 0.37)
Hip bones	4 (4.1;0.02,0.10)

Table 4: Osteopathic lesions. Osteopathic lesions were identified in all infants (both control and intervention groups).

Degrees	**Control group, mean (25th, 75th percentiles)**	**Treatment group, mean (25th, 75th percentiles)**	**p value**
Right head rotation T0	81.15 (70, 90)	80.82 (70, 90)	
Right head rotation T1	83.02 (76, 90)	90.21 (90, 90)	p=0.001
Left head rotation T0	81.56 (70, 90)	80.61 (70, 90)	
Left head rotation T1	83.68 (76, 90)	90.71 (90, 90)	p=0.001

Table 5: Head rotation of the infants. Mean degrees of the infants' head rotation before and after the osteopathic or sham intervention
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Discussion

This study is one of the first randomized controlled trials to assess the efficacy of an osteopathic treatment for infants with biomechanical suckling difficulties. When performed promptly, this intervention might reduce the risk of stopping breastfeeding earlier than originally intended.

With no prior models, this trial was designed pragmatically, including the need to act quickly to address breastfeeding difficulties and nipple pain that may be experienced with a newborn. The protocol also minimizes the difficulties of dyads having to commute several times in the early days postpartum.

Structures identified with osteopathic lesions correspond to the anatomical zones involved in suckling. The results provide a first osteopathic profile of lesions found in infants younger than six weeks of age with biomechanical suckling issues. This study expands critical thinking about structures involved in the function of suckling. The standardized assessment grid developed for this project has been found helpful and valuable to communicate with other health professionals about the lesions that have been treated.

A central practical detail is the willingness of the infant to latch during the first visit. The LC must assess a latch pre- and postintervention. This was best achieved by feeding the infant at the first breast, assessing the first latch with the LATCH Assessment Tool, disengaging the infant from the breast, performing the osteopathic intervention (sham or osteopathic manipulation) and assessing the latch again at the second breast. Often, particularly in the control group, infants cried and tried to crawl onto their mother's chest, which can make sham intervention challenging. In the treatment group, infants were found to be more relaxed and, at times, even fell asleep.

A possible protocol modification would be to replace the soft goniometer with an arthrodial protractor, keeping the osteopath's hands free when assessing the rotation of the infant's head.

The 97 dyads were referred by perinatal nurses or LCs from the health service network and from mother-to-mother support groups, over a 12-month period. This suggests that the first step of the protocol, namely networking and the LCs' training, is efficacious. Many authors[32,38] support the idea that dyads are assessed and referred better when this is done during the first 24 h of the infant's life by well-trained lactation support personnel. This remains to be further investigated.

Finally, the study population included infants of an average of two weeks of age, with all younger than six weeks. It would be interesting to assess, in a further trial, the best timing for osteopathic intervention, as well as signs and symptoms that may be used by parents or LCs to detect cases most likely to benefit from an osteopathic intervention.

This first randomized controlled trial published in the field of breastfeeding and osteopathy paves the way for future research with a standardized collection of osteopathic data from infants with biomechanical suckling difficulties, by coupling osteopathic treatment with lactation consultation.

Disclosures

The authors have nothing to disclose.

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