Effect of Osteopathic Manipulative Treatment on Middle Ear Effusion Following Acute Otitis Media in Young Children: A Pilot Study

Karen M. Steele, DO; Jane E. Carreiro, DO; Judith Haug Viola, DO; Josephine A. Conte, DO; Lance C. Ridpath, MS

Abstract

Context: Childhood acute otitis media (AOM) is highly prevalent. Its usual sequela of middle ear effusion (MEE) can lead to conductive hearing loss, for which surgery is commonly used.

Objective: To evaluate the efficacy of an osteopathic manipulative treatment (OMT) protocol on MEE resolution following an episode of AOM. The authors hypothesized that OMT provided adjunctively to standard care for young children with AOM would reduce the duration of MEE following the onset of AOM.

Methods: We compared standard care only (SCO) and standard care plus OMT (SC+OMT) for the duration of MEE following AOM. Patients were aged 6 months to 2 years. The SC+OMT group received OMT during 3 weekly visits. Weekly tympanometric and acoustic reflectometer (AR) readings were obtained from all patients.

Results: There were 52 patients enrolled, with 43 completing the study and 9 dropping out. No demographic differences were noted. Only ears from each patient with abnormal tympanograms at entry were included. There were 76 ears in the tympanogram analysis (38 from SCO; 38 from SC+OMT) and 61 ears in the AR data analysis (31 from SCO; 30 from SC+OMT). Dependence of bilateral ear disease noted in AR readings was accounted for in statistical analysis. Tympanogram data demonstrated a statistically significant improvement in MEE at visit 3 in patients in the...
SC+OMT group (odds ratio, 2.98; 95% confidence interval, 1.16, 7.62; χ² test for independence, P=.02). The AR data analysis showed statistically significant improvement at visit 3 for the SC+OMT group (z=2.05; P=.02). There was no statistically significant change in MEE before or immediately after the OMT protocol.

Conclusion: A standardized OMT protocol administered adjunctively with standard care for patients with AOM may result in faster resolution of MEE following AOM than standard treatment alone. (ClinicalTrials.gov (http://ClinicalTrials.gov) number NCT00520039.)

Acute otitis media (AOM), along with its complications, is a highly prevalent and costly worldwide problem. In the United States alone, nearly 40% of children have an episode of AOM by age 6 months, which increases to over 60% by 12 months and over 90% by 2 years. The economic cost in the United States in 2000 was estimated at more than $5 billion, and the cost has been observed to be similarly high in other nations. Loss of parental productivity over the 3 months following an episode of AOM accounts for nearly 90% of the approximate $1300 estimated cost per incidence of AOM in the United States. The diagnosis and stratified treatment of patients with AOM was standardized in 2004 by a collaborative work of the American Academy of Pediatrics and the American Academy of Family Physicians and was updated in 2013. Vaccinations have reduced the incidence of certain types of bacterial and viral middle ear infections but have not eliminated the disease. Mastoiditis and other head and neck infections are uncommon complications of AOM.

The most common complication of AOM is persistent middle ear effusion (MEE), which is associated with short-term hearing loss, impaired language acquisition, and behavior problems. However, Renko et al observed normalization of tympanograms (indicating MEE resolution) as early as 7 days after treatment in children with AOM who were treated with antibiotics. Middle ear effusion generally resolves in about 60% of children 1 month after an untreated episode of AOM, and a duration of MEE of 1 to 3 months is usual after an episode of AOM. In 1992, Rosenfeld and Post recommended antibiotics for MEE and van Zon et al reconsidered them once again in 2012. In 1994, the Agency for Health Care Policy and Research published a clinical practice guideline that proposed standardized diagnosis and management of MEE. However, 4 years later, Hsu et al noted that this guideline was not routinely being followed. In 2004, 3 associations—the American Academy of Family Physicians, the American Academy of Otolaryngology—Head and Neck Surgery, and the American Academy of Pediatrics—collaborated on a clinical practice guideline for otitis media with effusion. The guideline recommended watchful waiting for children with the condition who are not at risk for speech, language, or learning problems. For children at risk for speech, language, or learning problems, documentation of at least 3 months of persistent MEE and hearing loss was recommended before proceeding to surgery. The long-term effect of persistent MEE on hearing loss and speech development is still under debate: some studies reported problems in speech development and mild high-frequency hearing loss at age 7 years and into adulthood and others reported no effect or resolution of previously detected problems by late childhood. Additionally, the long-term consequences of an adult having had ventilatory tube insertion as a child have been recognized. The negative effect of persistent MEE on quality of life of the child and his or her parents has been studied for more than 15 years. Because of the prevalence, cost, and complications of MEE, other complimentary and medical treatments are being studied.

For more than a century, the osteopathic profession worldwide has provided anecdotal evidence of the beneficial effect of osteopathic manipulative treatment (OMT) to children as a complement to medical treatment. In the United States, a position paper was published through the Osteopathic Cranial Academy describing guidelines for the osteopathic treatment of patients with otitis media. However, to our knowledge, there have been no randomized, large-scale studies confirming the efficacy of this treatment. The present pilot study builds on the 2 known studies published to date in the United States and on a century of case-based literature. We propose an OMT protocol that can be taught to medical practitioners to complement the level of care available to children.

We designed the present dual-site, prospective, randomized, blinded, and controlled pilot study to evaluate the efficacy of a standardized OMT protocol in the management of MEE in young children with AOM. The study was designed to compare the outcomes of a standard care plus OMT treatment group (SC+OMT) to a standard care only (SCO) treatment group. The primary objective was to determine if a standardized OMT protocol given weekly for 3 visits could reduce the duration of MEE in the month following an episode of AOM. The secondary objective was to examine whether improvements in hearing, as read by means of tympanometry, could be demonstrated immediately after OMT. We hypothesized that the addition of OMT to the standard care of children with AOM would result in a shorter duration of MEE in the month following the onset of AOM. A full description of the OMT protocol, study methods, and early challenges encountered conducting the present study has been published.

Methods

The present study was conducted from September 2007 through May 2009 at the clinics of 2 colleges of osteopathic medicine: 1 in the mid-Atlantic (site A) and 1 in the Northeast (site B). The population of the cities in which the colleges were located were 4000 and 66,000, respectively. A research assistant at each site determined patient eligibility and obtained informed consent from the patient’s parent or legal guardian (referred to as parent for the remainder of the present article). Parents were given $25 for each study visit to help defray expenses incurred as a consequence of their child’s participation in the study. Osteopathic physicians, allopathic physicians, and nurse practitioners were recruited to refer patients into the study and were trained on study protocols. All referring practitioners consented to abide by the American Academy of Pediatrics’ 2004 criteria for diagnosis and management of AOM, which was the standard at that time. To ensure that strict criteria were met for diagnosis of AOM, only referrals from these practitioners were accepted into the present study. Because all practitioners agreed to abide by the current treatment guidelines, the standard care provided to study participants was considered to be consistent across both groups and no data on consistency were recorded.

The institutional review boards of both West Virginia School of Osteopathic Medicine (WVSOM) and the University of New England College of Osteopathic Medicine (UNECOM) approved the study protocol. A data safety monitoring board (DSMB) was chartered and performed ongoing analysis.
Effect of Osteopathic Manipulative Treatment on Middle Ear Effusion Following Acute Otitis Media in Young Children: A Pilot Study

During the 2 years of the study.

Patients enrolled in the study were between the ages of 6 months and 24 months with a diagnosis of AOM and an abnormal tympanogram. Patients were excluded from the study if they met any of the following criteria: chromosomal abnormalities, major congenital malformations of the head or neck including torticollis, immunologic abnormalities or deficiencies, or any prior ear, nose, and throat surgical procedure for otitis media. In the event that a child had a normal tympanogram in both ears on the first study visit, he or she was removed from the study. If only 1 ear had a normal tympanogram, the child was enrolled in the study, but all data from the normal ear was excluded from the data analysis. If the episode of AOM was not the child’s first, then either 4 weeks had to have elapsed since the completion of antibiotic treatment for a prior episode of AOM or resolution of the prior episode of AOM had to have been clinically documented. Patients were enrolled in the study within 3 days of receiving the diagnosis of AOM and were followed for 30 days. All patients continued to receive standard medical care from their referring practitioner. Enrolled patients were randomly assigned to the SC+OMT group or SCO group using Research Randomizer (http://www.randomizer.org). Three groups of randomization tables were generated for both sites, and the last ones were used. Each patient at both sites was assigned a unique number and solicited for demographic information by the research assistant at that site.

Two instruments were used to objectively measure the response of MEE to the OMT protocol: the tympanometer and the acoustic reflectometer (AR). The measures from the tympanometer are recorded on a tympanogram, a chart that displays the rate at which the tympanic membrane vibrates at different pressures. A tympanometer has a greater degree of sensitivity and specificity than does otoscope in the diagnosis of MEE. Standardized protocols exist to categorize the tympanogram graph to determine if the middle ear is likely to be filled with fluid. The “A” and “C1” type tympanograms are considered normal; “O” indicates a tympanic membrane perforation; “not readable” is not classifiable; and “B” and “C2” are abnormal. The AR is a simple handheld device that measures the ability of the tympanic membrane to reflect sound. The AR has been used for more than 15 years and has been validated as a reliable indicator of MEE. It predicts the likelihood that there is fluid in the middle ear on a Likert scale of 1 to 5, with 1 and 2 representing a low probability of middle ear fluid and 5 a high probability of middle ear fluid.

All patients had an initial visit followed by weekly study visits over the next 30 days, resulting in 5 study visits per patient. At the initial visit, all parents were given an AR device, instructed in its use by the research assistant, and asked to measure and record their child’s AR readings daily. At each study visit, tympanometric readings were obtained by the research assistant from each ear. One AR reading was taken from each ear, and a parent questionnaire was administered by the research assistant on visits 2 through 5. This questionnaire surveyed the following areas since the previous visit: child’s sleep pattern, over-the-counter medications used, parent’s level of comfort at taking AR readings, and any unusual behavior. For children in the SC+OMT group, a second series of tympanograms and an AR reading were taken immediately after administration of the OMT protocol, which was performed on visits 1, 2, and 3. Children in the SCO group did not receive OMT or the second set of tympanograms and AR reading on visits 1, 2, and 3.

Both sites had same-day availability of OMT practitioners who were trained by the authors (K.M.S., J.E.C.) and who were instructed in the use of a standardized monthly OMT protocol during the patient recruitment phase of the study from the individual investigator at each site. There were 4 trained OMT practitioners at the WVSOM site and 3 trained OMT practitioners at the UNECOM site. The authors (K.M.S., J.E.C.) participated as OMT practitioners at their respective sites. The OMT protocol used for the treatment group has been published and is included as Figure 1. It used 9 commonly used techniques to address somatic dysfunction in the pelvis, thoracolumbar junction, diaphragm, rib cage, neck, and head and took approximately 20 minutes to complete. If needed, the parent was recruited to distract and entertain the child during the administration of the protocol.

Figure 1.

Standardized osteopathic manipulative treatment protocol used in the present study. Adapted from Steele et al. Abbreviations: ASIS, anterior superior iliac spine; BLT, balance ligamentous tension; MFR, myofascial release.
1. Treatment of the sacroiliac joints laterally using ILM
   The child is supine. The physician contacts the sacrum just medial to the sacral joint with the fingers of one hand and the crest of the ilium with the other hand. The sacrum is stabilized as the ilium is positioned anteriorly and posterior rotation, inferior and superior, until ILM is achieved. In the position is maintained until tissue relaxation occurs.\(^{15}\)

2. Treatment of thoracolumbar junction and diaphragm using ILM
   The child is supine. The physician is seated inside the child. The physician places one hand across the anterior superior iliac spine and one hand across the spinous processes of the lower vertebrae and iliac crest. Alternatively, a hand can be placed on either side of the lower spine. The physician gently moves the thoracolumbar flexion into its sagittal inferior rotation and is used to the thoracic flexion in the position of the same spine. The physician applies a gentle anterior-posterior compression between the two hands until there is a slight decrease in tissue tension. Then the ribs are rotated laterally. The tissue release is followed until it completes.\(^{15}\)

3a. Treatment of the rib cage using ILM
   The child is either seated or supine. The physician contacts the rib cage posteriorly at the angle with one hand and anteriorly with the other. The thumbs lie along the lateral aspect of the same ribs. The physician applies a gentle anterior-posterior compression between the two hands until there is a slight decrease in tissue tension. Then the ribs are rotated laterally. The tissue release is followed until it completes.\(^{15}\)

3b. Treatment of the rib cage using ILM
   The child is supine. With one hand, the physician contacts the rib medial to the angle. The other hand contacts the spinous processes of the two corresponding vertebrae. The rib is tractioned laterally. The physician applies a gentle force to the posterior process to rotate the vertebrae into the restrictive bands and ILM is achieved. This position is maintained until tissue relaxation occurs.\(^{15}\)

4. Treatment of cervical-thoracic area (thoracic inlet) using ILM
   The child is supine. The physician places the two hands across the top of the shoulders contacting the upper ribs anteriorly with the fingers and posteriorly with the thumbs. The patient is rotated laterally to release the tension in the posterior muscles. The physician adjusts the position of the hands until there is a slight decrease in tissue tension.\(^{15}\)

5. Treatment of cervical area using ILM
   The child is supine. The physician’s site at the head of the table. The physician contacts the anterolateral aspect of the superior vertebreae with one hand and the adjacent hemivertebrae with the other. Rotation and skimageing can be introduced using this contact. The osteotomies are moved through scholastic and rotation to achieve lateral tension. This position is held until there is release of tissue tension.\(^{15}\)

The procedure is applied to C7 through T3.\(^{15}\)

6. Treatment of crano-cervical junction using ILM with colibroinhibition
   The child is supine. The physician sits at the head of the table. The osseous contact is the parietal bone and the fingers are aligned with the bone. The physician applies the fingers along the surrounding region until there is a change in tissue tension. The osteotomies are then aligned on the sides of the skull on a preauricular axis. The physician applies a slight anterior and lateral pressure until there is a change in tissue tension. The procedure is repeated as needed.\(^{15}\)

7. Veneza utilizes drainage techniques
   The child is supine. The physician is seated at the head of the table. The procedure is similar to the ILM technique. The physician aligns the fingers along the superior nuchal ridge of the skull with the 5th finger and 3. A slight anterior and lateral pressure is applied until there is a change in tissue tension. The fingers are then aligned on both sides of the skull on a preauricular axis. The physician applies a slight anterior and lateral pressure until there is a change in tissue tension. The procedure is repeated as needed.\(^{15}\)

8. Occipital decompression techniques
   The child is supine. The physician is seated at the head of the table. The physician’s fingers contact the occiput such that the index fingers contact the mastoid portion, the middle fingers are aligned with the occipital condyles, and the ring fingers are on the suprascapular. The physician applies gentle traction to the occipital bone and the fingers are then aligned laterally. The procedure is repeated as needed until there is a change in tissue tension. The procedure is repeated as needed.\(^{15}\)

9. Osteophytes bony supraspinatus decompression techniques
   The child is supine. The physician is seated at the head of the table. The physician uses a pincer temporal or frontal-scapular hand test. The physician gently decompresses the suprascapular nerve by moving the supraspinal greater earther anterolateral and the scapular posterior-inferior until the patient feels a bitemporal tissue release.\(^{15}\)

All OMT practitioners—including the investigators K.M.S. and J.E.C.—were blinded to all data collected and patient outcomes but not to patient group assignment. The investigators remained unblinded until the conclusion of the study when the DSMB closed the data files. Referring practitioners were blinded to patient group assignment and study outcomes. Parents were blinded to their child’s group assignment and outcomes data at each study visit. (Nonetheless, because 1 or both parents were in the room at the time of treatment, it was impossible to completely blind them to group assignment.) The research assistants (J.H.V., J.E.C., or a paid employee of WVSOM, depending on the site) were instructed not to reveal any aspect of data collection to the investigators. The audiologist was blinded to patient number, visit number, ear (right or left), date, whether the tympanogram was obtained before or after the OMT protocol, and patient outcomes. The statistician (L.C.R.) was blinded to all data until the DSMB closed the data set and released the data for analysis. An independent biostatistician from another institution, who assisted with study design and served on the DSMB, was not blinded to any aspect of the study.

All data collection, management, and entry were performed by the research assistants, who gathered data obtained from face-to-face interviews with parents, outpatient tests performed during the study visits, and logs completed by the parents. The research assistants converted the information into numeric format, entered it into SPSS, encrypted it, and then sent it to the independent biostatistician for analysis for the DSMB.

There were 3 tympanometric readings and 1 AR reading taken from each ear at each visit, and a second set of 3 tympanometric readings and 1 AR reading taken from each ear immediately following the OMT protocol at the first 3 visits for those patients in the SC+OMT group. Only data on the ears that generated an abnormal tympanogram at entry into the study were analyzed. A blinded audiologist selected the best (ie, most “healthy”) tympanogram for each ear for each visit and assessed each tympanogram in accordance with standard protocols. Tympanograms were classified into categories by the audiologist and converted into a numeric format for data analysis by the independent statistician. Although the statistical analysis performed by the biostatistician serving on the DSMB was in SPSS, the author (L.C.R.) chose to use SAS for final data analysis. To analyze the extent to which patients’ tympanograms changed from abnormal to normal during the 30 days of observation, \(\chi^2\) analyses using SAS statistical software (version 9.2; SAS Institute Inc) were computed by cross-tabulating the treatment group by the normal/abnormal changes in tympanograms. For the AR readings, the first date of a reading of “1” or “2” obtained by the research assistant was considered the date of MEE resolution. As previously stated, a normal tympanogram in either ear at the first study visit automatically removed that ear from the study. A normal AR reading in the presence of an abnormal tympanogram did not remove that ear from the study; however, the AR data from that ear were excluded from the AR data analysis. This exclusion accounts for the different total number of ears in the tympanogram and AR analyses. When there were less than 5 data points in any cell, the Fisher exact test was used. Because it is known that there is a high incidence of contralateral ear disease in children with chronic otitis media,\(^{23}\) tests for independence of right and left ears within patients were performed. Alpha was set at .05.

Results
The researchers and project funders had set a goal of 80 enrolled patients with an estimated 30% dropout rate, resulting in a potential of 160 ears for analysis. In the end, there were 88 patients screened, 52 of whom were enrolled in the study, resulting in a potential 104 ears for analysis. Nine patients dropped out and 43 completed the study (Figure 2). At the end of year 1, there were 18 patients screened and 7 enrolled at WVSOM and 38 patients screened and 26 enrolled at UNECOM. Therefore, the WVSOM site was closed at the end of the first year of the study.

Figure 2.
Participants were excluded from the study if they met any of the following criteria: chromosomal abnormalities; major congenital malformations of the head or neck including torticollis; immunologic abnormalities or deficiencies; or any prior ear, nose, and throat surgery for otitis media. In the event that a child had a normal tympanogram in both ears on the first study visit, they were removed from the study. If only 1 ear had a normal tympanogram, the child was enrolled in the study, but all data from the normal ear were excluded from the data analysis.

At its third and final meeting, on August 3, 2009, the DSMB determined that the study data were collected in a manner appropriate for research standards and that review of the data files showed no reason to question the reliability of the data collected. The data files were closed and released to the researchers for final analysis. There were no serious adverse events reported during the study. All data analyses reported herein are based on an intention-to-treat protocol and include all data from both sites obtained during the 2 years of the study. Compliance with the OMT protocol was defined as completion of the protocol in the scheduled time. No OMT protocol was aborted because of patient noncompliance or lack of tolerance.

Tympanogram data from 76 ears were included (38 from SCO; 38 from SC+OMT). Data from 28 ears were excluded from analysis—2 patients had no interpretable readings during any visit (both from the SC+OMT group), resulting in 4 ears being excluded from the analysis; 24 ears (10 from SCO, 14 from SC+OMT) had a normal tympanogram at the first study visit. For the AR analysis, data from 61 ears were included (31 from SCO; 30 from SC+OMT). Data from 35 ears (15 from SCO; 20 from SC+OMT) were excluded because they had normal AR readings during the first study visit. Four patients lacked any interpretable AR readings during any visit (1 from SCO; 3 from SC+OMT), resulting in data for these 8 ears being excluded from the AR analysis.

Demographic Analysis
Tests of independence were performed to determine if there were any demographic differences between the treatment groups, and none were found (Table 1 and Table 2). The mean age of children at visit 1 was 12.4 months in the SCO group and 11.8 months in the SC+OMT group (95% confidence interval [CI] for difference, −1.8, 2.9; 2-sample t test, P=.63). There were 11 females and 13 males in the SCO group, and 10 females and 16 males in the SC+OMT group (χ² test for independence, P=.06). The number of ear infections in the previous 12 months was 2 for the SCO group and 1.5 for the SC+OMT group (95% CI for difference, −0.5, 0.2; 2-sample t test, P=.62).

Table 1.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>SCO (n=24)</th>
<th>SC+OMT (n=26)</th>
<th>95% CI for Difference</th>
<th>P Valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at visit 1, mo</td>
<td>12.4 (4.5)</td>
<td>11.8 (3.6)</td>
<td>(-1.8, 2.9)</td>
<td>.63</td>
</tr>
<tr>
<td>No. of ear infections in past 12 mo</td>
<td>2 (3.7)</td>
<td>1.5 (1.8)</td>
<td>(-0.5, 0.2)</td>
<td>.62</td>
</tr>
<tr>
<td>No. of children younger than 6 years in home</td>
<td>1.4 (0.7)</td>
<td>1.5 (0.6)</td>
<td>(-1.3, 2.1)</td>
<td>.49</td>
</tr>
</tbody>
</table>

aP value is based on t test.
Effect of Osteopathic Manipulative Treatment on Middle Ear Effusion Following Acute Otitis Media in Young Children: A Pilot Study

Table 2.
Demographic Frequency Data for Young Children With Middle Ear Effusion by Group, No. (%)

<table>
<thead>
<tr>
<th>Question</th>
<th>SCO (n=24)</th>
<th>SC+OMT (n=26)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does child have influenza immunization? (Y/N)</td>
<td>17 (70.8)</td>
<td>16 (61.5)</td>
<td>.31a</td>
</tr>
<tr>
<td>Does child attend day care? (Y/N)</td>
<td>14 (58.3)</td>
<td>12 (46.2)</td>
<td>.39a</td>
</tr>
<tr>
<td>Gender of child? (M/F)</td>
<td>13 (54.2)</td>
<td>16 (61.5)</td>
<td>.60a</td>
</tr>
<tr>
<td>Does child have <em>Haemophilus influenzae B</em> immunization? (Y/N)</td>
<td>23 (95.8)</td>
<td>23 (88.1)</td>
<td>.20</td>
</tr>
<tr>
<td>Does child have pneumonia immunization? (Y/N)</td>
<td>22 (91.7)</td>
<td>28 (100)</td>
<td>.21b</td>
</tr>
<tr>
<td>Number of children younger than 6 years in home? (1 or ≥2)</td>
<td>22 (91.7)</td>
<td>25 (92.3)</td>
<td>.37b</td>
</tr>
<tr>
<td>Does anyone smoke tobacco in home? (Y/N)</td>
<td>3 (12.5)</td>
<td>2 (7.7)</td>
<td>.66b</td>
</tr>
<tr>
<td>Hours/week child in day care? (1-19 or ≥20)</td>
<td>4 (26.6)</td>
<td>3 (25.0)</td>
<td>1.00b</td>
</tr>
</tbody>
</table>

a$^2$ P value based on $\chi^2$ test.
b$^2$ P value based on Fisher exact test.

**Abbreviations:** M/F, male/female; SC+OMT, standard care plus osteopathic manipulative treatment; SCO, standard care only; Y/N, yes/no.

Table 3.
Scoring Method for Data From Visit 3 Acoustic Reflectometer Readings of Young Children With Middle Ear Effusion (MEE)

<table>
<thead>
<tr>
<th>Response</th>
<th>Score</th>
<th>SCO</th>
<th>SC+OMT</th>
</tr>
</thead>
<tbody>
<tr>
<td>MEE in both ears, resolution in neither$^a$</td>
<td>0</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>MEE in both ears, resolution in 1</td>
<td>0.5</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>MEE in both ears, resolution in both</td>
<td>1</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>MEE in 1 ear, no resolution</td>
<td>0</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>MEE in 1 ear, resolution</td>
<td>1</td>
<td>2</td>
<td>5</td>
</tr>
</tbody>
</table>

$^a$Wilcoxon rank sum test statistic (P value) was 2.05 (.02).

**Abbreviations:** SC+OMT, standard care plus osteopathic manipulative treatment; SCO, standard care only.
Parental Response Analysis

No differences were noted between parental group responses for any visit.

Pre-OMT and Post-OMT Analysis

A significant difference was found in ears during the first visit for the AR reading (Fisher exact test, \(P=.01\)) but not for the tympanogram (Fisher exact test, \(P=.12\)). However, it should be noted that all ears with resolution of MEE before first-visit OMT were excluded from the data set. Because of this, the number of resolutions before first-visit OMT was automatically set at 0. Therefore, although the test for AR for visit 1 was statistically significant, it did not produce a valid result. No statistically significant changes between the pre-OMT and the post-OMT readings were found immediately after OMT during visit 2, either in readings from tympanometer (OR, 1.36; 95% CI, 0.37, 5.05; \(\chi^2\) test for independence, \(P=.65\)) or AR (OR, 0.94; 95% CI, 0.30, 2.93; \(\chi^2\) test for independence, \(P=.65\)). Likewise, no statistically significant differences were noted before and after the OMT protocol administration on visit 3, either in readings from tympanometer (OR, 1.29; 95% CI, 0.46, 3.61; \(\chi^2\) test for independence, \(P=.63\)) or from AR (OR, 0.94; 95% CI, 0.30, 2.93; \(\chi^2\) test for independence, \(P=.93\)) (Table 4).

Table 4.
Acoustic Reflectometer and Tympanogram Readings From Before and After OMT Protocol in Young Children With Middle Ear Effusion, SC+OMT Group, Visits 2 and 3

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>No. (% before OMT)</th>
<th>No. (% after OMT)</th>
<th>Odds Ratio (P Value)</th>
<th>(P Value^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acoustic Reflectometer</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 2</td>
<td>11 (42.3)</td>
<td>16 (66.7)</td>
<td>2.73 (.04)</td>
<td>.08</td>
</tr>
<tr>
<td>Visit 3</td>
<td>18 (66.7)</td>
<td>17 (65.4)</td>
<td>0.94 (.54)</td>
<td>.92</td>
</tr>
<tr>
<td><strong>Tympanogram</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 2</td>
<td>5 (16.1)</td>
<td>6 (20.7)</td>
<td>1.36 (.32)</td>
<td>.65</td>
</tr>
<tr>
<td>Visit 3</td>
<td>12 (38.7)</td>
<td>13 (44.8)</td>
<td>1.29 (.31)</td>
<td>.63</td>
</tr>
</tbody>
</table>

\(a^p\) value is based on \(\chi^2\) test.

Abbreviations: OMT, osteopathic manipulative treatment; SC+OMT, standard care plus OMT.

Discussion

The use of OMT for the management of MEE has a long history in the osteopathic medical profession. Despite a century of experiential clinical efficacy of OMT for pediatric patients with AOM and MEE, few studies to date have scientifically studied OMT for these patients. The present study used a prescribed OMT protocol and 2 different measures—the tympanogram and the AR reading—to record and determine resolution of MEE following AOM. The results from the present study demonstrate a statistically significant improvement in the rate of resolution of MEE in affected “ears” receiving adjunctive OMT compared with those receiving standard care alone after 1 week and 2 OMT sessions when using the AR data, and after 2 weeks and 3 OMT sessions with the tympanogram data. Because the tympanometer is considered the more rigorous instrument for determining MEE, we will focus the rest of the discussion on tympanogram data. In the general US pediatric population, 70% of children still have MEE present at 2 weeks after onset of AOM.\(^{22}\) By comparison, 18.5% of ears in the treatment group had persistent MEE 2 weeks after entry into the study.

We created a standardized OMT protocol for the present study, rather than the empiric treatment used in the 2 previously published studies,\(^{45-46}\) to enable the methods to be reliably replicated. Because ours was a pilot study that tested a new standardized treatment protocol, we chose not to create a sham OMT protocol, which we felt would add another variable. The small amount of data studied, particularly the number of ears, limits the strength of the conclusions that can be obtained from the present study. Reasons for the small numbers include the small population base at the WVSOM site, the general reluctance of parents to enroll their child in a research study, and parental concern that their child could be assigned to the control group. These factors were the main reasons that we opted not to include a sham OMT group in our study design. The lack of a sham treatment group, however, remains a substantial limitation, and follow-up studies will need to include a sham group. Also, for future studies, we would recommend using a validated quality-of-life measure to determine if there are any changes in quality-of-life issues between treatment groups. Despite the small number of ears studied and the lack of a sham group, our results demonstrated statistical significance, as reflected by our use of a rigorous intention-to-treat analysis.

If the results from the present study can be replicated, it is feasible that the incidence of persistent MEE leading to tympanostomy with tube placement may be reduced in children who received the OMT protocol used in the present study for 2 weeks after onset of an AOM. The protocol consists of manipulative techniques which are part of the basic competencies for osteopathic medical students and can be taught to others with manual medicine.
training or to interested medical practitioners.

Conclusion

A standard OMT protocol administered adjunctively with standard care for patients with AOM resulted in faster resolution of MEE at 2 weeks than standard care alone. These results support the clinical observation that OMT is an effective, nonpharmaceutical, nonsurgical, adjunctive treatment for young children with MEE. Larger studies with a sham treatment group are needed to confirm these results.

Acknowledgments

After the data were released to the investigators by the DSMB, the principal investigator (K.M.S.) had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. We thank the American Academy of Osteopathy for its generous funding of the present study and WVSOM and UNECOM for further support. We also thank the following individuals who provided invaluable assistance: des Anges Cruser, PhD, MPA, for assistance during the design phase; Miriam V. Mills, MD, for assistance in the design of the OMT protocol and the tympanogram analysis; Hollis H. King, DO, PhD, for serving as Chairperson of the study DSMB; Edward Bridges, PhD, Reuben Paul Bell, DO, MS, MDiv, and Dr Mills for serving on the DSMB; and Scott Dean, PhD, for assistance with design of study forms, service on the DSMB, and initial statistical analysis of the data. We received invaluable financial support and encouragement on the design of this study and review of the final manuscript from Jerome O. Klein, MD.

We acknowledge the work of Erin Burns, PA-C, MSPA, who was a research assistant to this study at WVSOM, and thank the following osteopathic physicians for participating in the study as OMT protocol practitioners: James Krubs, DO; John Garlitz, DO; Heather Ferrill, DO; Doris Newman, DO; and Stephanie Waecker Collins, DO.

Financial Disclosures: None reported.

Support: This clinical trial was funded by the American Academy of Osteopathy in 2003 ($12,685) and in 2007 ($99,970).

References


Effect of Osteopathic Manipulative Treatment on Middle Ear Effusion Following Acute Otitis Media in Young Children: A Pilot Study


http://jaoa.org/article.aspx?articleid=2094747
Effect of Osteopathic Manipulative Treatment on Middle Ear Effusion Following Acute Otitis Media in Young Children: A Pilot Study


RELATED TOPICS
Ophthalmology and Otolaryngology
Osteopathic Manipulative Treatment
Pediatrics

Advertisement

Take effective vaccination steps with your adolescent patients now!
View this CME webinar for the latest developments and recommendations.

BACK TO TOP

Menu
Info

HOME
ISSUES
TOPICS
SUBSCRIBE
CONTACT US
ABOUT
AUTHORS
REVIEWERS
REPRINTS/PERMISSIONS
ADVERTISE
OSTEOPATHIC.ORG
PRIVACY POLICY

FOLLOW US ON TWITTER

© 2015 by the American Osteopathic Association