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

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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; χ^2 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 number NCT00520039.)

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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,[1] which increases to over 60% by 12 months[2] and over 90% by 2 years.[3] 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.[4-6] 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.[7] 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[8] and was updated in 2013.[9] Vaccinations have reduced the incidence of certain types of bacterial and viral middle ear infections[10,11] but have not eliminated the disease. Mastoiditis and other head and neck infections are uncommon complications of AOM.[12]

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.[13-15] However, Renko et al[16] 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,[17] and a duration of MEE of 1 to 3 months is usual after an episode of AOM.[18,19] In 1992, Rosenfeld and Post[20] recommended antibiotics for MEE and van Zon et al[21] 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.[22] However, 4 years later, Hsu et al[23] 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.[24] 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[18,25-27] and into adulthood[28,29]; on the other hand, 1 study[30] 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.[29,31] 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.[32-35] Because of the prevalence, cost, and complications of MEE, other complimentary and medical treatments are being studied.[36-38]

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.[39-43] 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.[44] 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[45,46] 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 man-

agement 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.[47]

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.[8] 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 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.[48] Standardized protocols exist to categorize the tympanogram graph to determine if the middle ear is likely to be filled with fluid.[49,50] 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.[51,52] 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[47] and is included as *Figure 1*. It used 9 commonly used techniques[43,53] 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.

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 blinded to ongoing data analysis by the DSMB and were instructed not to reveal any aspect of data collection to the investigators. The audiologist was blinded to site, 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

1. **Treatment of the sacroiliac joints bilaterally using BLT**
   The child is supine. The physician contacts the sacrum just medial to the sacroiliac joint with the fingers of one hand and contacts the ASIS with the palmar surface of the other hand. The sacrum is stabilized as the innominate is positioned in anterior and posterior rotation, inflare and outflare, until BLT is achieved. This position is maintained until tissue relaxation occurs.[43(p927)]

2. **Treatment of thoracolumbar junction and diaphragm using MFR**
   The child is supine. The physician is seated beside the child. The physician places one hand across the chondral masses of the lower ribs and the other hand across the spinous processes of the lower T12 and L1. Alternatively, a hand can be placed on either side of the lower rib cage. The physician gently moves the thoracolumbar fascia into its superior-inferior, rotation, and sidebending restrictions, applying steady force until tissue relaxation is noted.[53(p163)]

3a. **Treatment of the rib cage using MFR**
   The child is either seated or supine. The physician contacts the rib cage posteriorly at the angles 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 tractioned laterally. The tissue release is followed until it completes.[53(p200)]

-OR-

3b. **Treatment of the rib cage using BLT**
   The child is supine. With one hand, the physician contacts the rib medial to its 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 spinous process to rotate the vertebrae into the restrictive barriers until BLT is achieved. This position is maintained until tissue relaxation occurs.[43(p924)]

4. **Treatment of cervico-thoracic area (thoracic inlet) using MFR**
   The child is supine. The physician places his or her hands across the top of the shoulders contacting the upper ribs anteriorly with the finger tips and posteriorly with the thumbs. Fascial rotation is applied by simultaneously moving one hand anteriorly and the other posteriorly. The physician rotates the cervical fascia into its restrictive barrier and applies a steady force until there is a tissue release.[53(p164)]

5. **Treatment of cervical area using BLT**
   The child is supine. The physician sits at the head of the table. The physician contacts the articular pillar of the superior vertebrae with one hand and the adjacent inferior vertebrae with the other. Rotation and sidebending can be introduced using this contact. The vertebrae are moved through sidebending and rotation to achieve balanced tension. This position is held until there is a release in tissue tension. The procedure is applied to C7 through C3.[43(pp927-929)]

6. **Treatment of cranio-cervical junction using suboccipital inhibition**
   The child is supine. The physician sits at the head of the table. The occiput is held in the palms of the hands with the fingers aligned inferior to inion. The physician lifts his or her fingertips into the suboccipital muscles until the muscles relax.[53(p226)]

7. **Venous sinus drainage technique**
   The child is supine. The physician is seated at the head of the table. The physician aligns his or her fingertips along the superior nuchal ridge of the occiput with the fifth fingers at inion. A slight anterior and lateral pressure is applied until there is a change in tissue texture. The physician's fingertips are then aligned on both sides of the occiput on a cephalocaudad axis. The physician applies a slight anterior and lateral pressure until there is a change in tissue texture. The thumbs are then crossed to contact the parietal bones on opposite sides of the sagittal suture starting at lambda. The physician applies a slight inferior and lateral pressure until there is a change in tissue texture. The thumbs are moved anteriorly along the sagittal suture and the technique is repeated. The fingertips are then aligned on each side of the metopic suture. The physician applies a slight posterior and lateral pressure until there is a change in tissue texture.[53(p265)]

8. **Occipital decompression technique**
   The child is supine. The physician is seated at the head of the table. The physician's fingertips contact the occiput such that the index fingers contact the mastoid portion, the middle fingers are aligned with occipital condyles, and the ring fingers are on the supraoccput. The physician applies a gentle traction to the occiput posteriorly and then laterally while resisting movement at the mastoid portions until a slight tissue tension release is felt in the occiput equally bilaterally.[53(p277)]

9. **Sphenobasilar symphysis decompression technique**
   The child is supine. The physician is seated at the head of the table. The physician uses a posterior temporal or frontal-occipital hand hold. The physician gently decompresses the sphenobasilar symphysis by moving the sphenoid greater wings anterior-superior and the occiput posterior-inferior until the physician feels a bilateral tissue texture release.[53(p270)]

Figure 1.
Standardized osteopathic manipulative treatment protocol used in the present study. Adapted from Steele et al.[47]
Abbreviations: ASIS, anterior superior iliac spine; BLT, balance ligamentous tension; MFR, myofascial release.

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, χ^2 analyses using SAS statistical software (version 9.2; SAS Institute Inc) were computed by crosstabulating 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,[54] 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.

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.

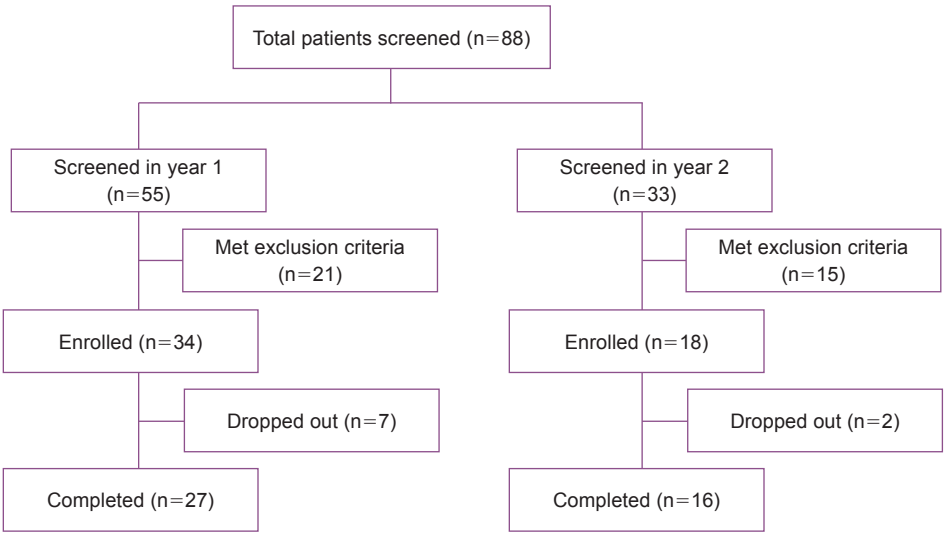

Figure 2.
Participants were excluded from the study if they met any of the following criteria: chromosomal abnormalities; major congenital malformations of the head or neck including torticollis; immunologic abnormalities or deficiencies; or any prior ear, nose, and throat surgery for otitis media. In 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.

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 (χ^2 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, $P=.62$).

Tympanogram Analysis

Analysis of tympanograms showed a statistically significant improvement in the SC+OMT group at visit 3 (2 weeks from entry into the study) compared with the SCO group (odds ratio [OR], 2.98; 95% CI, 1.16, 7.62; χ^2 test for independence, $P=.02$). Changes from abnormal to normal tympanogram occurred in 26 ears and did not occur in 12 ears, a 68.4% rate of resolution in MEE in 2 weeks. In the SCO group, 16 ears resolved at visit 3 and 22 did not, a 42.1% resolution rate. To determine if 2 ears belonging to the same patient could be treated independently, a Fisher exact test was performed, which confirmed independence of the ears for the tympanogram data ($P=.1107$). Therefore, a traditional χ^2 test and OR test were used for the tympanogram data.

AR Analysis

Unlike the tympanogram data, there was a statistically significant dependence between left and right ears on the same patient, making the χ^2 test invalid for the AR analysis. Therefore, a scoring system was applied to each patient. For patients with only 1 eligible ear, a score of 1 was given if the ear had resolution of MEE at visit 3, and a score of 0 was given if the ear had not re-

Table 1.
Demographic Data for Young Children With Middle Ear Effusion, Mean (Standard Deviation)

Characteristic	Group SCO (n=24)	Group SC+OMT (n=26)	95% CI for Difference	*P* Value[a]
Age at visit 1, mo	12.4 (4.5)	11.8 (3.6)	(−1.8, 2.9)	.63
No. of ear infections in past 12 mo	2 (3.7)	1.5 (1.8)	(−0.5, 0.2)	.62
No. of children younger than 6 years in home	1.4 (0.7)	1.5 (0.6)	(−1.3, 2.1)	.49

[a] *P* value is based on *t* test.

Abbreviations: CI, confidence interval, SC+OMT, standard care plus osteopathic manipulative treatment; SCO, standard care only.

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

Question	Group SCO (n=24)	Group SC+OMT (n=26)	*P* Value
Does child have influenza immunization? (Y/N)	17 (70.8)	16 (57.1)	.31[a]
Does child attend day care? (Y/N)	14 (58.3)	12 (46.2)	.39[a]
Gender of child? (M/F)	13 (54.2)	16 (61.5)	.60[a]
Does child have *Haemophilus influenzae B* immunization? (Y/N)	23 (95.8)	23 (82.1)	.20[b]
Does child have pneumonia immunization? (Y/N)	22 (91.7)	28 (100)	.21[b]
Number of children younger than 6 years in home? (1 or ⩾2)	22 (91.7)	25 (96.2)	.37[b]
Does anyone smoke tobacco in home? (Y/N)	3 (12.5)	2 (7.7)	.66[b]
Hours/week child in day care? (1-19 or ⩾20)	4 (28.6)	3 (25.0)	1.00[b]

[a] *P* value based on χ^2 test.
[b] *P* value based on Fisher exact test.

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

solved. For patients with 2 eligible ears, a score of 1 was given if both ears resolved, 0 if neither ear resolved, and a half point (0.5) if only 1 of the 2 had resolution of MEE after visit 3 (*Table 3*). A nonparametric Wilcoxon rank sum (ie, Mann-Whitney) test showed that the average score for the OMT group was higher (better) at a statistically significant rate at visit 3 than the SCO group ($z=2.05$, $P=.02$).

Parental Response Analysis

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

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

Response	Score	SCO	SC+OMT
MEE in both ears, resolution in neither[a]	0	4	1
MEE in both ears, resolution in 1	0.5	4	1
MEE in both ears, resolution in both	1	4	6
MEE in 1 ear, no resolution	0	4	2
MEE in 1 ear, resolution	1	2	5

[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.

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; χ^2 test for independence, $P=.65$) or AR (OR, 0.94; 95% CI, 0.30, 2.93; χ^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; χ^2 test for independence, $P=.63$) or from AR (OR, 0.94; 95% CI, 0.30, 2.93; χ^2 test for independence, $P=.93$) (*Table 4*).

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.[55] 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

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

Outcome Measure	No. (%)		Odds Ratio (*P* Value)	*P* Value[a]
	Before OMT	After OMT		
Acoustic Reflectometer				
Visit 2	11 (42.3)	16 (66.7)	2.73 (.04)	.08
Visit 3	18 (66.7)	17 (65.4)	0.94 (.54)	.92
Tympanogram				
Visit 2	5 (16.1)	6 (20.7)	1.36 (.32)	.65
Visit 3	12 (38.7)	13 (44.8)	1.29 (.31)	.63

[a] *P* value is based on χ^2 test.

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

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.

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