

## Osteopathic Evaluation and Manipulative Treatment in Reducing the Morbidity of Otitis Media: A Pilot Study

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**Objective:** To study the effects of osteopathic manipulative treatment in routine pediatric care for children with recurrent acute otitis media.

**Study Design:** Pilot cohort study with 1-year posttreatment follow-up. At follow-up, subjects' parents or legal guardians and their referring and/or family physicians were contacted to determine recurrence of otitis media since intervention.

**Subjects:** A referred and volunteer sample of pediatric patients ranging in age from 7 months to 35 months with a history of recurrent otitis media (N=8).

**Intervention:** For 3 weeks, all subjects received weekly osteopathic structural examinations and osteopathic manipulative treatment. This intervention was performed concurrently with traditional medical management.

**Results:** Five (62.5%) subjects had no recurrence of symptoms. Of the three remaining subjects in this cohort, one had a bulging tympanic membrane, another had four episodes of otitis media, and the last underwent surgery after recurrence at 6 weeks posttreatment. Closer analysis of the posttreatment course of the last two subjects indicates that there may have been a clinically significant decrease in morbidity for a period of time after intervention.

**Conclusion:** The present study indicates that osteopathic manipulative treatment may change the progression of recurrent otitis media, a finding that supports the need for additional research in this area.

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Otitis media is one of the most common infections in children. It has been estimated that, in the United States, there are more than 20 million physician visits annually for otitis media in the pediatric population.<sup>1</sup> By 3 months of age, approximately 10% of infants will have had an episode of acute otitis media (AOM).<sup>2</sup> By 3 years of age, 50% of children

will have had more than three episodes of AOM.<sup>3</sup> The annual national cost for the management of pediatric otitis media is estimated at \$5.3 billion.<sup>4</sup> Recent studies indicate that the incidence of otitis media may be increasing.<sup>5</sup>

For decades, researchers have sought to understand the cause of middle ear infections in children and determine the best treatment for patients. It seems that the pathogenesis of otitis media involves an interplay between dysfunction of the eustachian tube and viral or bacterial infection, as well as various predisposing factors (*Figure 1*).<sup>6</sup> However, despite hundreds of studies, there have been conflicting conclusions regarding whether many of these factors truly predispose children to otitis media.<sup>3,5,7</sup>

Between 6 and 8 years of age, most children "outgrow" persistent otitis media with effusion (OME) or recurrent episodes of AOM. However, many reports indicate that significant sequelae can develop from otitis media in infancy.<sup>8</sup> Potential sequelae include hearing loss (both conductive and sensorineural); developmental delays in language, behavior, and education; mastoiditis; facial nerve paralysis; vestibular, balance, and motor dysfunction; and meningitis.<sup>8</sup>

The goals of treating patients with recurrent otitis media are to reduce the frequency of pain and fever; minimize hearing loss; reduce the cost of physician visits, surgery, and medications; reduce patient and parental anxiety; and prevent long-term sequelae.<sup>9</sup> The most common approach to clinical management of otitis media in childhood, antibiotic treatment, is designed to eradicate the pathogens that are thought to be a contributing factor to the disease process. Other treatment options for patients with recurrent AOM include antimicrobial therapy for each episode, prophylactic antibiotics, polyvalent pneumococcal vaccination, myringotomy with insertion of tympanostomy tube, and/or adenoidectomy with or without tonsillectomy.<sup>9,10</sup>

Twelve clinical trials have shown some clinical efficacy for the use of prophylactic antibiotic therapy to control recurrent otitis media, though many methodological flaws have been identified in these studies.<sup>11</sup> Nonetheless, the studies demonstrate reduced rates of AOM over a 3- to 12-month period when children are compliant with a course of daily antibiotic treatment. While there has been much debate about the most effective pharmaceutical agent (as well as dosage and duration of therapy) for the management of pediatric AOM,<sup>6,12</sup> clear recommendations have recently been provided by the American

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#### ■ Demographic Factors

- Age (ie, younger more at risk)
- Sex (ie, boys more at risk)
- Low socioeconomic status
- Race (ie, American Indian and Inuit children more at risk)

#### ■ Medical History

- Abnormal ciliary motion
- Allergies
- Benign nasopharyngeal infections and lesions
- Congenital disorders
- Tumor(s)

#### ■ Other Characteristics

- Exposed to tobacco smoke or wood-burning stoves
- Attends day care
- Formula fed (instead of breastfed) during infancy

**Figure 1.** Factors that are thought to predispose infants and children to otitis media. Despite hundreds of studies, however, experts are still in disagreement over how much these factors contribute to otitis media in childhood.

Academy of Pediatrics,<sup>13</sup> as well as the American Academy of Family Physicians and the American Academy of Otolaryngology.<sup>14</sup> Although considered the treatment modality of choice, a prophylactic antibiotic regimen has potential problems, including poor patient-parental compliance, emerging bacterial resistance, adverse drug reactions, and suppression of symptoms without affecting the disease process.<sup>9</sup>

Because the natural course of otitis media has not been clearly delineated, however, researchers' abilities to assess the success of any intervention are limited. A meta-analysis of the control groups in 63 studies was performed to better understand the natural history of untreated recurrent otitis media.<sup>15</sup> With a median observation period of 6 months, 41% of children with recurrent otitis media had no recurrence of AOM. In a controlled study focusing on infants with one episode of AOM in their first 6 months of life or two episodes in 12 months, Teele and coauthors<sup>16</sup> analyzed the effect of oral amoxicillin or sulfisoxazole prophylaxis for at least 7 months after patients had completed no more than a 5-month course of prophylactic antibiotics. One month after completion of prophylaxis, 70% of children receiving amoxicillin, 47% of those given sulfisoxazole, and 32% of control subjects were free of symptoms of AOM. At 7 months postprophylaxis, 38% of patients receiving amoxicillin, 28% taking sulfisoxazole, and 22% in the placebo group were free of symptoms. These results indicate that the

current first-line treatment option for recurrent otitis media is not very effective in providing lasting protection from recurrence.

There has been significant interest in the creation of a vaccine that could be used to prevent otitis media, particularly in this age of increasingly antibiotic-resistant bacteria.<sup>17</sup> The pneumococcal vaccine has been studied extensively, with significant variability in outcomes. In a meta-analysis published by the Cochrane Library,<sup>17</sup> reviewers did not recommend a large-scale use of pneumococcal vaccine for prevention of AOM.

Myringotomy with tympanostomy tube insertion is designed to bypass a dysfunctional eustachian tube, providing ventilation and drainage for the middle ear. In two randomized studies,<sup>18,19</sup> researchers found that tympanostomy tube placement significantly decreased recurrence of AOM. Although many researchers recommend avoiding surgical intervention unless prophylaxis fails,<sup>20-22</sup> neither daily prophylaxis nor surgery has proven more beneficial than standard medical management in the treatment of patients with recurrent otitis media.<sup>10</sup> If children's parents or guardians can ensure compliance with prophylactic antibiotic regimens, prophylaxis is usually tried first. If the child proves noncompliant with prophylaxis—or if those medications fail—surgical intervention is considered. However, a 1994 report indicated that there was no convincing scientific evidence demonstrating the effectiveness of tympanostomy tube insertion in patients with recurrent otitis media.<sup>22</sup> It was also shown that only 41% of tympanostomy tube placements in the United States were justified based on current, medically accepted criteria.<sup>22</sup>

Because the science regarding the etiology and management of recurrent AOM has significant limitations, further research in evaluating novel approaches is warranted. Are there factors that have not been systematically evaluated that are unique to preschoolers, predisposing them to this condition? The current model asserts that common bacteria most often cause otitis media.<sup>2,3,23</sup> If bacterial infection is the primary underlying factor for otitis media, why are antibiotics not more effective?

Eustachian tube dysfunction, considered by some researchers as the most important factor underlying the etiology of middle ear infections, may be the key to why otitis media is primarily a disease of childhood.<sup>10,24</sup> Anatomic variation between the adult and pediatric cranium demonstrates some interesting differences. The adult eustachian tube has a cross-sectional area 2.25 to 2.75 times larger than is found in a 2-year-old child.<sup>25</sup> Although the eustachian tube traverses from the temporal bone to the nasopharynx at a 45-degree angle in adults, it does so at only a 10-degree angle in children. Elastin, a component of the eustachian tube, is thought to play an important role in the active opening of the eustachian tube. The amount of elastin in a child's eustachian tube is sparse compared with that in an adult's.<sup>25</sup> It has also been suggested that,

as the human body develops, the muscles that open the eustachian tube increase in size, enhancing their ability to open the tube itself. Perhaps these age-based variations are underlying factors in middle ear pathology.<sup>26</sup>

Although the intrinsic characteristics of the eustachian tube in early childhood appear to make it especially vulnerable to dysfunction, causes for eustachian tube dysfunction may also result from the interplay of other unique pediatric structural features. The cranium in the human infant is quite different from that of the mature adult in that it is made up of thin, single-layered, isolated bony tissue surrounded and interconnected by flexible membranous and more rigid cartilaginous connective tissue. Individual bones in the mature cranium are divided in the fetus to allow for compliance during the demands of delivery and the rapid growth of the brain in the first few years of life. For example, during infancy, the frontal, sphenoid, and temporal bones consist of two bony segments, while the occiput consists of four. Blood vessels and nerves traverse through the connective tissue, and, at the base of the skull, so too does the eustachian tube.

On these islands of bones at the cranial base, a dozen different skeletal muscles are attached, connecting the cranium to structures in the cervical and thoracic regions.<sup>27</sup> Abnormal muscular tone in any of these regions could distort the relationship of the compliant cranial base structures, causing distortion of the flexible eustachian tube. Tightness in the connective tissues could also distort small nerve fibers or blood vessels that serve the middle ear. This tightness could possibly hamper circulation to the middle ear, causing localized congestion and providing a receptive environment for—and/or limiting the host's natural immune response to—an infectious process.

So it seems rational to consider that imbalances or strains between the soft tissues of the child's cranium (caused in delivery or from blunt trauma early in life) or muscular hypertonicity (caused possibly by conditions in the cervical and thoracic regions) may be factors underlying recurrent otitis media. As the eustachian tube develops into a mature structure, it is possible that its growth and a resulting change in spatial relationships to other structures eliminates the factors that predispose the infantile middle ear to inflammation and effusion. It is interesting to note that the cranial vault matures at approximately the same time that the incidence of otitis media drops dramatically (ie, 6 years of age).

Osteopathic physicians have more than 50 years of anecdotal reports of successfully using osteopathic manipulative treatment (OMT) to manage many diseases of childhood, including otitis media.<sup>28</sup> This treatment modality is used to correct distortions or imbalances within the musculoskeletal system and, therefore, may be useful if a child has a structural imbalance that may predispose him or her to otitis media. Pilot studies in the 1990s gave support for using OMT in the treatment of patients with recurrent AOM; however, that sup-

port was very weak because of low subject enrollment numbers and study design flaws.<sup>29-31</sup> A recently published, blinded, controlled multicenter study involving 57 participants showed a decreased incidence of otitis media when osteopathic cranial techniques were used as an adjunctive treatment with current medical treatment models.<sup>32</sup>

Despite limited research, awareness of the structural characteristics of children's craniums provides a plausible reason for why OMT may be beneficial for children with otitis media—and why this treatment modality warrants further study in this application. In the present study, we hypothesized that OMT would reduce the incidence of AOM in children who have recurrent otitis media. Considering the weaknesses of current treatment practices, an effective, noninvasive treatment approach to otitis media would be extremely beneficial to this patient population.

## Methods

Candidates for inclusion in this study lived in a rural, Midwestern community and were referred to investigators through local family practice and pediatric physicians or by self-referral after reading newspaper advertisements. Children aged 3 years or younger with a documented history of either three episodes of otitis media within 6 months or four episodes within 12 months met the study's inclusion criteria. Excluded from participation in this study cohort were patients taking systemic steroids or other immunosuppressive therapy; receiving allergic desensitization shots; or with a history that included documented structural anomalies of the head or neck, surgical intervention, or chronic suppurative otitis media. Finally, patients were also excluded from participation in the present study if their parents or guardians were unable to ensure patient compliance with prescribed medications. Approval for this study was received from the institutional review board at Kirksville College of Osteopathic Medicine of A.T. Still University of Health Sciences in Mo.

After the parent or legal guardian was interviewed to determine if the patient met the inclusion criteria and was not ineligible for study inclusion based on exclusion criteria, an informed consent form was reviewed with and signed by the patient's parent or legal guardian. The parent or legal guardian was then given a questionnaire to obtain a more complete medical history of the child. The patient's medical records were requested from the referring and/or family physician.

The OMT provided by the primary investigator (B.F.D.) was pragmatic, based on the findings of the physical examinations.

After the 15-day intervention period, no further patient evaluations or manipulative interventions were performed by the primary investigator. On an as-needed basis, subjects continued to receive routine medical care from their referring and/or family physicians during the intervention period and throughout the year before final follow-up.

Table 1  
Characteristics of Subjects in Otitis Media Pilot Study\*

Subject	Age, mo		Pretreatment Recurrence		Risk Factors for Otitis Media*		
	Diagnosis	Intervention	Acute Episodes, No.		Attends Day Care	Family History of Otitis Media	Tobacco Smoke Exposure
			6 Months	12 Months			
A	12	21	3	4	X		
B	19	35	6	12	X		
C	16	27	1	4			X
D	8	33	4	10	X	X	
E	4	7	3	3		X	
F	<1	21	4	7	X	X	
G	2	27	n/a	4	X	X	
H	3	11	8	9	X	X	

\* X denotes that the risk factor was present in the subject noted. No entry indicates that the risk factor was not present. As noted in *Figure 1*, page 328, many factors are thought to predispose infants and children to otitis media. However, no consensus has been reached among experts.  
Abbreviation: n/a indicates data not available.

One year after intervention, the subjects' parents or legal guardians were contacted by telephone (B.F.D.) to document the number of middle ear infections that each subject had since intervention, if any, and what form(s) of intervention subjects had received for any subsequent infections. Medical records from primary care physicians' offices were also reviewed to verify the information reported by subjects' parents and legal guardians.

## Results

A total of 5 boys and 3 girls, aged 7 to 35 months, completed the study protocol (N=8), undergoing osteopathic structural examination and manipulative treatments once a week during a 15-day period over 3 calendar weeks. Because there was a low number of qualified referrals, no control group was established for this study.

Six (75%) of the 8 subjects attended day care. Five (62.5%) subjects had a family history of otitis media. Only 1 (12.5%) subject was exposed to tobacco smoke in the home (*Table 1*).

With regard to initial physical findings, 6 (75%) subjects had internally rotated temporal bones. Seven (87.5%) had occipital condyle restriction on at least one side. Subjects' cranial rhythmic impulses varied from 2 to 10 cycles per minute. Two (25%) subjects presented with sphenobasilar compression synchondrosis. Two (25%) subjects had single predominant ligamentous strain patterns, while 3 (37.5%) had two or more strain patterns. Four (50%) subjects had somatic dysfunction in either the upper thoracic region or the ribs. Six (75%) subjects had some form of sacral somatic dysfunction (*Table 2*).

The osteopathic manipulative procedures used by the primary investigator included gentle balanced membranous tension (cranial) and myofascial release. Manual treatment during the initial visit was focused on the following body regions: head and face, neck, thoracic, ribs, lumbar, and pelvis. Because many somatic dysfunctions noted in previous weeks had resolved by weeks 2 and 3, OMT provided later in the study protocol usually focused on patients' remaining somatic dysfunctions, which were located predominantly in the thoracic, rib, and cranial regions.

One year after the 3-week intervention period, the rate of recurrence was assessed for each subject. The primary investigator conducted telephone interviews with the subjects' parents or legal guardians, and referring and/or family physicians provided patient records for review and confirmation of questionnaire results (*Table 2*). A summary of these results follows:

### ■ Subject A

□ Pretreatment history: monthly "ear problems" in 14 months. Three episodes of AOM within 6 months prior to study enrollment, with the first episode at 12 months of age. Multiple physician visits for OME.

□ Posttreatment follow-up: no recurrence (or medical treatment) at 1-year follow-up.

### ■ Subject B

□ Pretreatment history: 12 episodes in previous 12 months.

□ Posttreatment follow-up: no recurrence (or medical treatment) at 1-year follow-up.

### ■ Subject C

□ Pretreatment history: three episodes in 3 months and four

**Table 2**  
**Otitis Media Pilot Study:**  
**Structural Findings and Treatment Response**

Subject and Somatic Dysfunctions Noted at Initial Visit	Somatic Dysfunction*						Posttreatment Recurrence Within 12 Months Acute Episodes, No.
	Visit 2			Visit 3			
	Resolved	Improved	Unresolved	Resolved	Improved	Unresolved	
<b>■ A</b>							<b>0</b>
□ Head (base)		X		X			
– Sphenobasilar synchondrosis	X			X			
□ Ribs (upper)		X			X		
□ Sacrum	X			X			
<b>■ B</b>							<b>0</b>
□ Head (base, bilateral)		X		X			
□ Ribs (mid-level, right side)	X			X			
□ Pelvis (right side)		X		X			
<b>■ C</b>							<b>0<sup>†</sup></b>
□ Head (base)		X			X		
– Sphenobasilar synchondrosis		X		X			
□ Thorax (upper, right side)	X			X			
□ Lower extremity (knee, right side)	X			X			
<b>■ D</b>							<b>1<sup>‡</sup></b>
□ Head (base bilateral)		X		X			
□ Ribs (upper bilateral)		X			X		
□ Sacrum			X	X			
<b>■ E</b>							<b>0</b>
□ Head (base, bilateral)			X		X		
□ Ribs (mid-level)		X		X			
□ Pelvis	X			X			
<b>■ F</b>							<b>1<sup>§</sup></b>
□ Head (anterior, right side)		X			X		
□ Head (base, right side)			X		X		
– Sphenobasilar synchondrosis	X		X				
<b>■ G</b>							<b>0</b>
□ Head (face)		X		X			
□ Head (base, right side)		X		X			
□ Ribs (mid-level, left side)	X			X			
□ Pelvis (left side)		X			X		
<b>■ H</b>							<b>4</b>
□ Head (anterior, right side)	X			X			
□ Head (base, right side)		X			X		
□ Pelvis			X	X			
□ Lower extremity (knee)	X			X			

\* For each somatic dysfunction noted in the first patient visit, X denotes the status of the dysfunction in subsequent visits.

† For Subject C, only an 8-month follow-up evaluation of the patient's medical record was possible because the subject was lost to follow-up.

‡ After a recurrence at 6 weeks after intervention, Subject D underwent tonsillectomy, adenoidectomy, and myringotomy with ventilation tube placement.

§ Subject F had one acute otitis media episode of a bulging tympanic membrane, for which he received one course of antibiotics.

episodes in previous 11 months.

- Posttreatment follow-up: no recurrence within 8 months. (Family relocation prevented further observation.)

### ■ Subject D

- Pretreatment history: 11 episodes of otitis media and 14 upper respiratory tract infections in previous 2 years. First episode of otitis media was at 8 months of age. Subject was referred for intervention as a last resort to avoid surgery.
- Posttreatment follow-up: no recurrence for 1 month posttreatment, which had not happened since the onset of otitis media. In the second month posttreatment, because of a return of symptoms, the subject underwent tonsillectomy, adenoidectomy, and myringotomy with ventilation tube placement.

### ■ Subject E

- Pretreatment history: three middle ear infections at presentation, when subject was 7 months of age. The first infection occurred when the subject was 4 months old.
- Posttreatment follow-up: no recurrence (or medical treatment) at 1-year follow-up.

### ■ Subject F

- Pretreatment history: seven episodes at presentation, when the subject was aged 21 months. The subject was taking a course of oral antibiotics during the initial visit. First suspected episode was at 3 weeks of age. At 6 months of age, this subject had four episodes.
- Posttreatment follow-up: no recurrence for 7 months posttreatment, when there was one documented episode of a bulging tympanic membrane for which the subject received one course of antibiotic treatment.

### ■ Subject G

- Pretreatment history: nine documented episodes of AOM and six notations of persistent effusion at presentation, when the subject was aged 27 months. The subject's first episode was at 2 months of age.
- Posttreatment follow-up: no recurrence of AOM at 1-year follow-up. However, there was a persistent middle ear effusion noted in the medical record at 5 months posttreatment, and the subject received a course of systemic steroids as a result.

### ■ Subject H

- Pretreatment history: nine episodes recorded at presentation, when the subject was aged 11 months. The subject's first episode of otitis media was at 3 months of age. The subject had received several types of antibiotics for AOM. One month prior to study enrollment (ie, June 1992), the subject completed a prescribed course of a prophylactic amoxicillin and clavulanic acid combination therapy.
- Posttreatment follow-up: no recurrence for 3 months. Thereafter, beginning in the fifth month posttreatment, the subject had four episodes of AOM and received multiple courses of antibiotic therapy. The subject's physician prescribed antibiotics prophylactically for the subject after 9 months and

maintained them through the conclusion of the present study. The subject had several bouts of persistent diarrhea during this time.

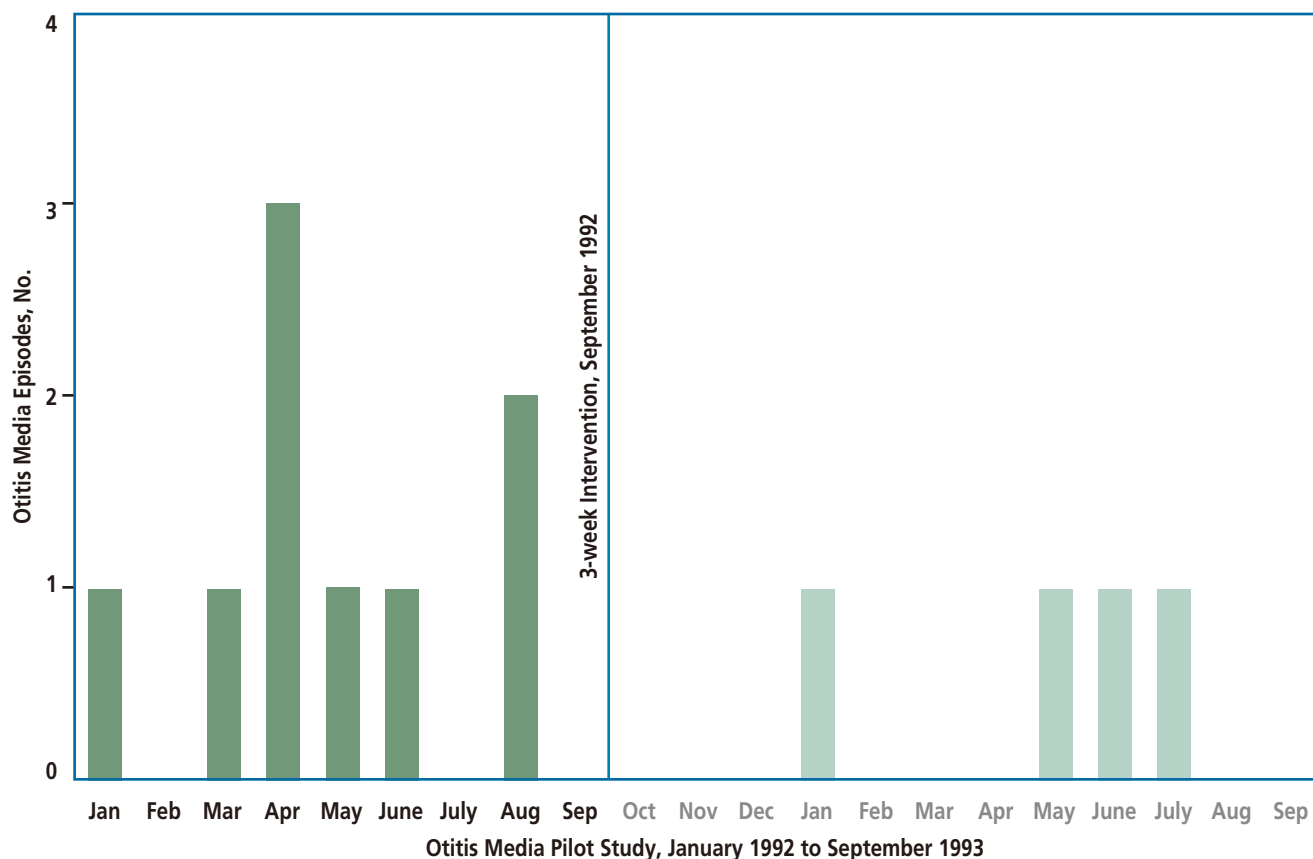
### Comment

Five (62.5%) of 8 subjects who completed the 3-week intervention with OMT had no documented episode of AOM at 1-year follow-up. One (33.3%) of the 3 subjects (Subject F) in the symptom-free group had one episode of a bulging eardrum with an upper respiratory tract infection and was treated with antibiotics. Although it was not clear in the subject's medical record if the episode met the criteria for AOM, we chose to interpret the medical record conservatively and recorded it as a case of AOM. Closer evaluation of the two other cases with recurrent AOM may show a potential short-term benefit from this treatment modality because there was an initial reduction in the morbidity of otitis media after treatment with OMT when the posttreatment year is compared with the year prior to intervention.

In a review of 13 clinical trials looking at antibiotic prophylaxis in children with recurrent AOM, Darrow and colleagues<sup>10</sup> indicated that there was a reduction of 1.5 episodes of AOM per patient per year.<sup>33</sup> Overall, 62.5% of the subjects in this study had a resolution of symptoms after receiving 3 weekly sessions of OMT for their specific somatic dysfunctions (Table 2). Extrapolating from these data, the authors suggested that it would require 8 months of prophylaxis to prevent a single episode of AOM.<sup>10</sup> If the present study's findings were reproduced in a large blinded study, OMT would likely earn a place as an important part of routine management for recurrent otitis media. Such research should also be supplemented with cost-effectiveness analysis, an area of research that the osteopathic medical profession must continue to encourage.<sup>34</sup>

It could be argued that the outcomes from these cases were secondary to a placebo response. A meta-analysis of the control groups in 63 studies showed that, within a median observation period of 6 months, 41% of children without medical intervention had no recurrence of AOM.<sup>15</sup> In the cases reported in the present study, over 60% of subjects had resolution of their symptoms 1 year after intervention with OMT. Because of the small sample size in this study, however, no conclusions can be made. Yet, there may be enough of a trend to suggest that OMT is potentially valuable in the treatment of patients with otitis media at a level significantly higher than that associated with the placebo response alone.

The course of recurrent otitis media in Subject H also anecdotally documents an interesting pattern (Figure 2). As noted in the "Results" section, Subject H experienced nine episodes of otitis media by the time he entered the study at 11 months of age. He had undergone several courses of sulfamethoxazole and trimethoprim combination therapy, cefaclor, amoxicillin and clavulanic acid, as well as amoxi-



**Figure 2.** Timeline for Subject H describing recurrence of otitis media before and after intervention with osteopathic manipulative treatment.

cillin monotherapy. He had finished a course of prophylactic amoxicillin and clavulanic acid 1 month before his evaluation and treatment in September 1992. In January 1993, following intervention, this subject had one reported recurrence of otitis media, with a second incident occurring in May 1993. During the winter season, when there is usually an increase in the recurrence of otitis media—especially in previously infected children—this subject had only one episode. It was not until the late spring and summer that the subject redeveloped persistent middle ear pathology that continued through the next fall and winter despite appropriate medical management. Intervention with OMT took place immediately prior to the period of reduced incidence of otitis media and may have contributed to this subject's reduction in morbidity from recurrent AOM.

As reported in the literature, patients who develop otitis media before 6 months of age have up to an 80% likelihood of developing persistent middle ear problems and sequelae.<sup>3,7</sup> Two of the four subjects who had their first episode of otitis media before 6 months of age (Subject E and Subject G) had no recurrence at 1-year follow-up. A third subject (Subject F) had

one reported occurrence of a bulging tympanic membrane. A summary of Subject H's history at 1-year follow-up appears in the previous paragraph. Therefore, at least two (and possibly three) of the four subjects who had otitis media before 6 months of age were free of symptoms for 1 year after receiving OMT.

When comparing this small cohort to other studies on recurrent otitis media in children of this age, the subjects described in the present study demonstrate improved outcomes. For example, in the controlled study by Teele and coauthors,<sup>16</sup> after a 7-month follow-up of patients taking one of two prophylactic antibiotics or a placebo, the percentage of patients who were free of symptoms during that time was 38%, 28%, and 22%, respectively. Despite the small sample size in the present study, there was a statistically significant difference for the OMT subjects when compared with Teele and colleagues' placebo group ( $P=.05$ ).<sup>16</sup> In addition, the data suggest a statistically significant difference from the second prophylactic antibiotic group ( $P=.09$ ). There was no significant difference for the OMT subjects when compared with Teele et al's first prophylactic antibiotic group ( $P=.29$ ).<sup>16</sup>

To improve future studies on otitis media, researchers will note that regular examinations for middle ear pathology and structural abnormalities during the posttreatment year would have provided clearer and more rigorous documentation of the posttreatment period. We also found that records from family and/or referring physicians were, at times, not complete enough for us to differentiate between different types of otitis media. Delineating between AOM and OME, for example, is critical for future studies.

If the cases described in the present study indicate an actual trend, use of OMT in treating infants may significantly reduce the morbidity and financial burden necessary to treat children diagnosed with recurrent otitis media.

Yet, because of small sample size and the lack of a control group (ie, sham manipulative treatment group), no generalizations can be made from this study. However, this cohort study does provide support, along with other published pilot projects, to additional research that analyzes the usefulness of OMT for children with otitis media.

## Conclusion

Osteopathic evaluation and treatment was shown to be beneficial in treating 5 (63%) of 8 subjects in this cohort with documented recurrent otitis media. After three weekly sessions of OMT, at least 50% of those subjects who experienced their first episode of otitis media during their first 6 months of life had resolution of their symptoms at 1-year follow-up. Blinded studies with larger cohorts are necessary to determine the effectiveness of this treatment modality in pediatric patients with otitis media.

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