ARTICLE

The Use of Osteopathic Manipulative Treatment as Adjuvant Therapy in Children With Recurrent Acute Otitis Media

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Objective: To study effects of osteopathic manipulative treatment as an adjuvant therapy to routine pediatric care in children with recurrent acute otitis media (AOM).

Study Design: Patients 6 months to 6 years old with 3 episodes of AOM in the previous 6 months, or 4 in the previous year, who were not already surgical candidates were placed randomly into 2 groups: one receiving routine pediatric care, the other receiving routine care plus osteopathic manipulative treatment. Both groups received an equal number of study encounters to monitor behavior and obtain tympanograms. Clinical status was monitored with review of pediatric records. The pediatrician was blinded to patient group and study outcomes, and the osteopathic physician was blinded to patient clinical course.

Main Outcome Measures: We monitored frequency of episodes of AOM, antibiotic use, surgical interventions, various behaviors, and tympanometric and audiometric performance.

Results: A total of 57 patients, 25 intervention patients and 32 control patients, met criteria and completed the study. Adjusting for the baseline frequency before study entry, intervention patients had fewer episodes of AOM (mean group difference per month, –0.14 [95% confidence interval, –0.27 to 0.00]; $P = .04$), fewer surgical procedures (intervention patients, 1; control patients, 8; $P = .03$), and more mean surgery-free months (intervention patients, 6.00; control patients, 5.25; $P = .01$). Baseline and final tympanograms obtained by the audiologist showed an increased frequency of more normal tympanogram types in the intervention group, with an adjusted mean group difference of 0.55 (95% confidence interval, 0.08 to 1.02; $P = .02$). No adverse reactions were reported.

Conclusions: The results of this study suggest a potential benefit of osteopathic manipulative treatment as adjuvant therapy in children with recurrent AOM; it may prevent or decrease surgical intervention or antibiotic overuse.

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GUIDELINES FOR management of recurrent acute otitis media[1] (AOM) stress the importance of limiting antibiotic use through careful and accurate diagnosis,[2,3] restricting use to children with recurrent episodes,[4] or shortening the course of treatment,[5,6] but they fail to offer treatment alternatives to surgery. Some physicians assert there is a greater need for surgery than there was 20 years ago,[7] though recent evidence may refute that assertion.[8] Because of the anecdotal experience of many osteopathic physicians, we tried to document whether an alternative or complementary approach has some merit.

Authors of prior articles have addressed the role of structural influences on otorhinolaryngologic function and suggested osteopathic[9-12] or chiropractic[13-15] manipulation. Rosenfeld[16] presumed that homeopathy, garlic, and chiropractic were no better than placebo. Pilot studies by Sawyer et al[17] and Steele et al[18] used prospective randomized controlled designs. Sawyer and colleagues encountered difficulties, given chiropractors' unfamiliarity with tympanometry and otoscopy. Steele, an osteopathic physician, and colleagues documented improvement of tympanogram readings in the treatment group after 2 weeks of osteopathic manipulative treatment (OMT).

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Our study is a multisite prospective randomized controlled trial in children with recurrent AOM. We explore the potential effect of OMT as adjuvant therapy and monitor antibiotic use, episodes of AOM, surgical intervention, audiometric and tympanometric measures, and behavior.

METHODS

OVERVIEW

The methods are patterned after those in a pilot study by one of us (M.V.M.)[19] that involved 17 patients and largely used the design of Steele et al.[18] Results of power analysis suggested we would need 50 children in each group, on the basis of a predicted 50% decrease in antibiotic use, episodes of AOM in the group receiving medical treatment alone, and a 75% improvement in the group receiving medical treatment and OMT. With a type I error rate set at .05, we estimated an expected power of 85% if there were a 10% dropout rate and a power of 80% with a 20% dropout rate.[20]

Four osteopathic physicians participated— in Tulsa, Okla; Biddeford, Me; Kirksville, Mo; and Tucson, Ariz. Institutional review board approval was obtained at each site. Data were collected locally by designated site coordinators. Orientation to the protocol included a Web site[21] for access to data collection forms, fliers, pamphlets for physicians performing OMT and site coordinators, and videotapes and a slide show for potential referring physicians. No reference was made to criteria for diagnosis of AOM to avoid introducing a bias into the pediatricians' usual care and medical record documentation.

PATIENT SELECTION

Patients were recruited between February 1999 and July 2001. Children 6 months to 6 years old with recurrent AOM episodes, 3 in the previous 6 months or 4 in the previous year, who had no immunologic or chromosomal anomaly or congenital malformation of the head; no prior manipulation, either osteopathic or chiropractic; and no previous otorhinolaryngologic surgery were eligible. On the basis of suggested guidelines of the Office of Drug Evaluation and Research,[22] criteria for qualification as an episode of AOM included medical record documentation of the following: 1 of 3 systemic symptoms (irritability, fever, or otalgia), plus inflammatory changes of the middle ear (diffuse opaque redness, bulging, or pus behind the tympanic membrane), with clearing of symptoms for at least 2 weeks between episodes. Any patient already referred for consideration of otorhinolaryngologic surgery was excluded.

RANDOMIZATION AND BLINDING

The site coordinator obtained informed consent after medical record review confirmed that the study criteria were met. A random assignment list was computer generated for each site, with a 60:40 distribution in favor of the control patients because a higher dropout rate was expected in that group. A separate nurse at the central site monitored and disclosed the random assignment only during telephone contact at the time of randomization. The parents were admonished not to discuss the study with their physician and were unaware of the study measure results.

The pediatrician provided all care, making decisions related to antibiotics and surgical referrals, and was unaware of group placement and study outcomes. Information regarding the patient's clinical course (episodes of AOM, use of antibiotics, and surgical referrals) came from the pediatrician's medical record, reviewed by the site coordinator, and was unavailable to the physician performing OMT. Baseline and final audiograms and tympanograms were obtained by audiologists who were unaware of group assignment and clinical history.

DATA COLLECTION

Baseline data, from pediatric medical record review, were from the 6 months before randomization. The coordinator obtained demographic information relating to risk factors associated with AOM, baseline behavior ratings, and tympanometric data and scheduled an audiologic evaluation. Children in both groups were scheduled for 9 visits during the study: approximately 3 weekly, 3 biweekly, and 3 monthly. At each visit, the site coordinator obtained interval history about medications, illnesses, injuries, and changes in behavior by using a 5-point scale (5 = "much more"; 1 = "much less") to rate irritability, disobedience, ear pulling, appetite, restful sleep, hearing when spoken to, listening to conversation, talking, and clumsiness. Monthly tympanograms were obtained by the site coordinator.

Since there is no single standard for comparing tympanometric data in the literature,[23] we analyzed those data by using modifications of categories developed by Jerger[24]: type A, normal; type B, poor movement; type C, negative pressure; and type O, open. Baseline and final tympanograms were obtained by the audiologist and site coordinators, and monthly tympanograms were obtained by the site coordinator and analyzed by the audiologist at the central site.

Tympanograms obtained at the monthly visits were scored as 0, 1, or 2 for the number of type A, B, C, and O tympanograms, totaling right and left ears, recorded at that visit. From that score, the group mean for each period was computed for each type. Because of the small sample size, types A and C tympanograms were combined because they indicated some movement of the tympanic membrane, whereas types B and O signified greater abnormality. Audiologists' readings were based on a single recording at baseline and another at study completion and were analyzed in the same fashion.

Audiologic evaluation and review of the pediatric medical record were repeated after 6 months. Parents were asked to rate their satisfaction with their experience of the study on a 5-point scale (5 = very satisfied) and provide additional comments.

OSTEOPATHIC MANIPULATIVE TREATMENT

Osteopathic manipulative treatment was provided to the intervention group at each visit, as indicated by the osteopathic examination results and the child's cooperation. Treatments lasted 15 to 25 minutes, which is usual in most practices. Treatments were gentle techniques on areas of restriction consisting of articulation, myofascial release, balanced membranous tension (according to teachings of William Garner Sutherland, DO, and others[25]), balanced ligamentous tension, facilitated positional release, and/or counterstrain treatments. These techniques are familiar to most recently trained osteopathic physicians, but it is not in the scope of this article to describe them in detail. Despite some expected variation in their application by different physicians, we attempted to standardize their approach by using only physicians with teaching experience in OMT. No high-velocity (popping) techniques were used. The entire body, with attention to the head and neck, was included in the osteopathic evaluation and treatment.

DATA ANALYSIS

SPSS version 11.0 (SPSS Inc, Chicago, Ill) was used for all statistical analyses. Behavior, AOM episodes, antibiotic use, audiologic data, months surgery free, parent satisfaction scales, and tympanometric data were analyzed by means of standard linear regression, with correction for baseline status when available, which was also used to identify potential confounding variables. Data for these variables are reported as monthly means to compare possible unequal data collection periods. Surgical data were analyzed by using the χ^2 test. Demographic and baseline clinical information on patients who dropped out was reviewed whenever possible to compare with data on patients who remained in the study.

RESULTS

PATIENTS

Of 146 patients who were referred, 76 (31 intervention patients, 45 control patients) met the criteria and were enrolled. Of those referred, 44 did not qualify because medical record review did not match the criteria for sufficient number of episodes of AOM. Another 26 chose not to participate because of the 6-month commitment, uncertainty about OMT, or planning of surgery in the near future. Nineteen (6 intervention patients, 13 control patients) dropped out during the study, leaving 57 patients with data available for analysis—25 in the intervention group and 32 in the control group. Patients dropped out for 2 reasons: loss of continuity of physician care or the inconvenience of a 6-month study. Of the 13 patients who dropped out for whom we have data, the distribution of baseline variables was similar to the distribution in the patients who remained in the study, except that the intervention patients who dropped out were younger (intervention patients, mean±SD, 13.80±7.43 months; control patients, mean±SD, 21.60±12.96 months), and they were less often firstborn (1 of 5 intervention patients; 2 of 8 control patients). Both groups of patients who dropped out had a similar baseline number of monthly antibiotic prescriptions (intervention patients, mean±SD, 0.77±0.33; control patients, mean±SD, 0.75±0.22). The intervention group's baseline monthly number of AOM episodes was lower (mean±SD, 0.47±0.08) than that in the control group (mean±SD, 0.54±0.12), in contrast to that in the patients who remained in the study.

Demographic variables are summarized in **Table 1**. Children in the control group were more likely to be firstborn, but this is not known to be a risk factor for AOM. Patients in the control group were more likely to have exposure to smokers at home or day care, though intervention patients had more frequent exposure to pets. The relationship of demographic to clinical variables is discussed later. More young children participated, with 68% overall aged 2 years or younger. Children in the intervention group had a slightly higher mean age because there were two 6-year-olds in that group.

Table 1. Baseline Variables in the 57 Patients*

Variable	Intervention Group	Control Group
Entered study October 1–March 31	12 (48)	15 (47)
Female	11 (44)	17 (53)
Day care attendance	14 (56)	16 (50)
Firstborn	6 (24)	18 (56)
Breastfed	10 (40)	14 (44)
History of colic or spitting	9 (36)	9 (28)
Exposure to smoker at home or day care	1 (4)	7 (22)
Exposure to indoor pet	13 (52)	11 (34)
Use of forceps or suction at birth	3 (12)	4 (13)
Age, mo	26.18 ± 20.29	19.88 ± 13.18
Labor length, h	10.63 ± 13.65	10.42 ± 14.34
Mean monthly No. of episodes of acute otitis media†	0.61 ± 0.16	0.51 ± 0.12
Mean monthly No. of antibiotic prescriptions†	0.79 ± 0.31	0.69 ± 0.28
Audiologic data, dB		
Speech awareness threshold	19.55 ± 10.22	14.58 ± 7.57
Response to 500-Hz stimulus	24.78 ± 11.13	23.70 ± 10.50
Response to 1000-Hz stimulus	21.52 ± 10.49	19.52 ± 10.67
Response to 2000-Hz stimulus	24.78 ± 13.86	22.62 ± 11.20
Response to 4000-Hz stimulus	26.36 ± 13.47	26.36 ± 11.36
Tympanometric data‡		
Mean sum of types A and C tympanograms obtained by the audiologist	0.86 ± 0.83	1.16 ± 0.94
Mean sum of types A and C tympanograms obtained by the site coordinator	0.47 ± 0.38	0.51 ± 0.38
Behavior rating scales§		
Irritability, ear pulling, disobedience	3.24 ± 0.57	3.49 ± 0.57
Restful sleep, appetite	2.88 ± 0.94	2.77 ± 0.83
Hearing, talking, listening	2.91 ± 0.65	2.85 ± 0.58
Clumsiness	2.64 ± 1.29	3.25 ± 0.88

*Values are given as either number (percentage) or mean ± SD.
†Calculated from the period 0 to 6 months before patients were placed randomly into groups.
‡Group mean count of 0, 1, or 2 for each period. Both right and left ears are included. Type A meant normal and type C negative pressure.
§On the 5-point scale, 5 meant "much more" and 1 meant "much less" in comparison with behavior in other children.

NEW EPISODES OF AOM

The intervention group had a mean of 0.19 episodes of AOM per month during the study, as compared with a mean of 0.27 in the control group. Adjusting for the baseline frequency of AOM before study entry, intervention patients had fewer episodes of AOM, with a mean difference in episodes per month of –0.14 (95% confidence interval [CI], –0.27 to 0.00; $P=.04$).

Although the intervention group had more episodes at baseline and were slightly older, age was negatively correlated with baseline episodes, as would be expected. The intervention group had a mean improvement across time (difference between baseline and study episodes of AOM) of 0.41 episodes, as compared with the control group mean of 0.24. Adjusting for age, the mean difference between the groups' improvement was 0.16 (95% CI, 0.03-0.28; $P=.02$). No other demographic variable affected the relationship between group and episodes.

ANTIBIOTIC PRESCRIPTIONS

The intervention group had a mean of 0.30 antibiotics prescribed per month during the study, as compared with a mean of 0.42 in the control group. Adjusting for the baseline frequency before study entry, intervention patients had a smaller, though not statistically significant, mean number of antibiotics prescribed per month (mean difference, –0.17 [95% CI, –0.38 to –0.05]; $P=.13$). Specific types of antibiotics and duration of their use were comparable between the 2 groups.

SURGICAL INTERVENTIONS

One patient in the intervention group and 8 patients in the control group ($P=.03$) underwent surgical interven-

tion involving only insertion of ventilatory tubes in each case. Tubes were inserted at 6 months after randomization in the intervention patient and at 2 months (for 2 patients), 3 months (for 4 patients), and 4 and 6 months (for 1 patient each) in the control group. On the basis of this information (mean, 6.00 months for intervention patients and 5.25 for the control patients), comparison of the number of months each patient remained surgery free during the study showed a statistically significant group difference (0.75 [95% CI, 0.16 to 1.34]; $P = .01$).

AUDIOLOGIC EVALUATIONS

Pure-tone testing was performed at 500, 1000, 2000, and 4000 Hz. Speech awareness thresholds improved in both groups with time, with no statistically significant group effect demonstrated. We used linear regression for each frequency, measured in hertz, with the decibel threshold at the final examination as the dependent variable and group and baseline decibel thresholds as independent variables.

TYMPANOMETRIC DATA

The site coordinator's data showed that during months 5 and 6 of the study, the intervention group had a monthly mean sum of types A and C (the more normal) tympanograms of 0.65 (of a possible maximum of 2), as compared with a mean of 0.52 in the control group. Adjusting for the baseline sum, the mean group difference was 0.17 (95% CI, –0.03 to 0.37; $P = .09$). On the basis of the audiologists' tympanograms, the intervention group had a mean sum of 1.41, as compared with the control patients' mean of 1.00 for types A and C tympanograms (adjusted mean group difference, 0.55 [95% CI, 0.08 to 1.02]; $P = .02$).

BEHAVIORAL QUESTIONS

No statistical differences were found between the 2 groups for behavioral questions analyzed according to individual behaviors by month or when scores were averaged and grouped into 2-month periods. When scores for behaviors were combined into various categories related to hearing (hearing when spoken to, listening to conversation, and talking), negative behaviors (irritability, disobedience, and ear pulling), or positive behaviors (sleeping and appetite), there was a modest adjusted mean group difference favoring the intervention group (**Table 2**) for negative behaviors in months 3 and 4, but it did not reach statistical significance ($P = .07$).

PARENT SATISFACTION

No adverse reactions to OMT were reported during the study. In the final questionnaire, several parents reported pleasant effects such as relaxation or a good nap after the treatment. Overall satisfaction with the study was high in both groups (mean, 4.84 and 4.50 for intervention and control groups, respectively, on a scale of 1 to 5; 5 = highly satisfied), though calculation of group difference indicated the differences were significant (0.34 [95% CI, 0.05 to 0.63]; $P = .02$).

COMMENT

The results of this outcomes-oriented study, despite limited patient enrollment, demonstrated statistically significant differences between the groups in several related clinical outcomes.

LIMITATIONS OF STUDY

The dropout rate was higher than we anticipated initially. The patients who dropped out differed demographically from the study patients, though in ways that might have made the groups more equal at baseline; the intervention group tended to be somewhat sicker at baseline than were the control patients. The length of the study contributed to the 25% dropout rate. Future studies would likely be as meaningful with 3 months of observation. The ideal number of treatment sessions needed to produce a beneficial outcome has yet to be determined and would be needed to perform cost-effectiveness analysis.

The issue of whether to include a placebo control for the control group was considered. If we had included a placebo control, any presumed placebo intervention might have had an unintended treatment effect, introducing potential confounding variables and necessitating 3 groups: intervention, placebo intervention, and nonintervention. We chose instead for this study to report any difference in outcomes between 2 groups that were selected to be as equal as possible except for the application of OMT. Placebo effect due to the number of visits was minimized by the design of the study, leaving the influence of touch as potentially having a placebo effect. Larger studies are needed to replicate and elucidate the causal mechanisms of this effect.

The parents knew the child's treatment group, though every effort was made not to let this information affect pediatrician recommendations, which we knew by means of medical record review. Although the osteopathic physicians knew the treatment group, they were not involved in making medical decisions or recommendations for the patients. Using a sham treatment group in future studies would increase blinding and minimize parental bias. The behavior rating scales were not normalized or validated and could likely be simplified for any future study.

POTENTIAL IMPORTANCE OF OMT

Much of the attention in the literature has focused on the microbiologic environment of the middle ear, abnormalities in the muscles that activate the opening of the tube, and mucosal swelling of the pharynx. Given the position of the auditory tube between the temporal and sphenoid bones[26] and its relationship to the muscles of the soft palate, the tensor veli palatini, levator veli palatini, and salpingopharyngeus,[23(pp58-78),27] it is apparent that the tube is vulnerable to extrinsic compression, presumably during birth. The osteopathic concept, which relates form to function, suggests a structural influence on the tube's patency, which may be amenable to OMT.[28,29]

Table 2. Study Outcome Measures*

Variable	Intervention, Mean ± SD	Control, Mean ± SD	Group Difference,† Mean (95% Confidence Interval)
Monthly No. of episodes of acute otitis media during the study	0.19 ± 0.21	0.27 ± 0.26	−0.14 (−0.27 to 0.00)‡
Monthly No. of antibiotic prescriptions during the study	0.30 ± 0.35	0.42 ± 0.47	−0.17 (−0.38 to 0.05)
Months in study surgery free	6.00 ± 0.00	5.25 ± 1.46	0.75 (0.16 to 1.34)‡
Audiologic data, dB			
Final speech awareness threshold (n = 51)	16.59 ± 10.84	14.58 ± 7.91	−0.97 (−6.10 to 4.16)
Final response to 500-Hz stimulus (n = 51)	20.43 ± 13.14	21.52 ± 11.80	−1.45 (−8.64 to 5.73)
Final response to 1000-Hz stimulus (n = 49)	16.74 ± 12.02	17.88 ± 8.62	−1.31 (−6.59 to 3.98)
Final response to 2000-Hz stimulus (n = 49)	18.26 ± 15.35	20.00 ± 10.15	−2.63 (−10.31 to 5.05)
Final response to 4000-Hz stimulus (n = 49)	22.05 ± 15.63	23.64 ± 13.89	−1.59 (−10.55 to 7.37)
Tympanometric data§ (n = 52)			
Final mean sum of types A and C tympanograms obtained by the audiologist	1.41 ± 0.80	1.00 ± 0.96	0.55 (0.08 to 1.02)‡
Mean sum of types A and C tympanograms obtained by the site coordinator, months 5-6	0.65 ± 0.40	0.52 ± 0.42	0.17 (−0.03 to 0.37)
Mean behavior rating scores, months 1-2‖			
Irritability, ear pulling, disobedience	3.06 ± 0.29	3.20 ± 0.36	−0.15 (−0.33 to 0.03)
Restful sleep, appetite	3.04 ± 0.33	2.88 ± 0.36	0.16 (−0.03 to 0.35)
Hearing, talking, listening	3.33 ± 0.35	3.23 ± 0.26	0.09 (−0.07 to 0.25)
Clumsiness	2.96 ± 0.23	3.11 ± 0.35	−0.08 (−0.25 to 0.09)
Mean behavior rating scores, months 3-4‖ (n = 54)			
Irritability, ear pulling, disobedience	3.08 ± 0.40	3.17 ± 0.33	−0.11 (−0.32 to 0.10)¶
Restful sleep, appetite	3.05 ± 0.48	2.81 ± 0.50	0.28 (−0.02 to 0.54)
Hearing, talking, listening	3.53 ± 0.59	3.27 ± 0.54	0.33 (0.04 to 0.62)
Clumsiness	2.94 ± 0.56	2.82 ± 0.57	0.14 (−0.16 to 0.43)
Mean behavior rating scores, months 5-6‖ (n = 49)			
Irritability, ear pulling, disobedience	2.97 ± 0.51	3.23 ± 0.33	−0.20 (−0.45 to 0.04)
Restful sleep, appetite	3.06 ± 0.46	3.05 ± 0.60	0.02 (−0.30 to 0.33)
Hearing, talking, listening	3.56 ± 0.58	3.37 ± 0.51	0.26 (−0.05 to 0.57)
Clumsiness	2.88 ± 0.48	2.84 ± 0.52	0.04 (−0.26 to 0.33)
Parent satisfaction# (n = 55)	4.84 ± 0.37	4.50 ± 0.63	0.34 (0.05 to 0.63)‡

*Data were obtained in all 57 patients, except when otherwise noted.
†All group differences were adjusted for baseline except months in study surgery free and parent satisfaction, with 0 for control and 1 for intervention.
‡$P<.05$.
§Group mean count of 0, 1, or 2 for each period. Both right and left ears are included. Type A meant normal and type C negative pressure.
¶$P = .07$.
‖On the 5-point scale, 5 meant "much more" and 1 meant "much less" in comparison with behavior in the previous month.
#On the 5-point scale, 5 meant very satisfied and 1 meant very dissatisfied.

What This Study Adds

Current treatment guidelines for recurrent AOM management give little guidance as to how to refrain from potentially unnecessary use of antibiotics or surgery. Alternative and complementary medicine approaches hold promise but are poorly documented in the literature.

Osteopathic manipulative treatment has a potential applicability in children with recurrent AOM, which can be explained by the anatomic relationships of the auditory tube. Results of this study suggest a potential benefit of OMT as adjuvant therapy, demonstrating improvement in episodes of AOM, frequency and timing of surgical intervention, and normalcy of tympanograms.

The finding that demographic variables did not explain the difference between the groups in improvement in clinical outcomes supports the notion that the differences seen during the course of the study were related to the intervention. Children in both groups improved considerably during the 6 months, which is the natural course of AOM. However, the children who met the eligibility criteria for this study would have also fit the Agency for Health Care Policy and Research guidelines for consideration of surgical intervention,[1] if they also had compromised hearing. Findings in this study suggest that OMT may provide a benefit during this window of risk for surgery. Although a larger study is needed, it appears that OMT offers a potential benefit as adjuvant therapy for children with recurrent AOM.

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