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Osteopathic Medicine and Acute Otitis Media in Children: Does Improving Somatic
Dysfunction Improve Clinical Outcomes?

by

Alex Zaphiris

B.A. (University of California, Los Angeles) 1994

A thesis submitted in partial satisfaction of the requirements for the degree of

Master of Science

in

Health and Medical Sciences

in the

GRADUATE DIVISION

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UNIVERSITY OF CALIFORNIA, BERKELEY

Committee in charge:

Professor W. Thomas Boyce, Chair

Professor Nicholas P. Jewell

Miriam V. Mills, M.D.

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CHAPTER ONE: BACKGROUND AND SIGNIFICANCE

The 21st Edition of Rudolph's Pediatrics describes acute otitis media (AOM) as a purulent middle ear effusion with systemic signs of illness.¹ Ear pain, which is non-specific, is the most common presenting symptom. In order to differentiate between AOM and otitis media with effusion, a clinical diagnosis of AOM requires the use of pneumatic otoscopy and visualization of a tympanic membrane, which bulges laterally with obscuring of the bony landmarks such as the handle of the malleus. A frankly purulent effusion may also be seen through the tympanic membrane. In contrast, otitis media with effusion, shows a normal or retracted tympanic membrane with pneumatic otoscopy.¹

AOM is an exceedingly common infection in children; More than half of infants will have at least one episode of AOM before their first birthday, more than 80% will report this infection by their third birthday, and 93% will have an episode of AOM by the age of seven.² ³ Furthermore, otitis media tends to be a recurrent illness of childhood, with about 50% of infected children having three or more episodes in their first three years of life and almost 20% having three or more episodes within a six-month period.³ The Centers for Disease Control and Prevention (CDC) surveys of office based U.S. physicians showed that AOM was the most frequently diagnosed illness for which an antibiotic was prescribed. On average, children received more than a month of antibiotics to treat AOM each of the first two years of life.⁴

The costs of evaluating and managing otitis media are staggering. In 1996, the combined cost of AOM and its sequelae was estimated to be over \$5 billion every year.⁵ A recent study of a Northern California managed care population found that the non-medical costs of otitis media, such as lost work time and babysitting care are at least equal to medical costs. In addition, the authors found that complex otitis media episodes have disproportionately high costs compared with simple episodes (total costs on average ranged from \$260 for simple episodes to nearly \$1800 for complex episodes with 3 or more relapses).⁶ Finally, Lind used forecasting analysis to estimate that in the coming years, the number of cases of chronic otitis media in the United States will grow to an average of 4.4 million cases, with an average cost of \$11 billion per year.⁷

The long list of risk factors for recurrent otitis media includes: age, sex, season, race, familial aggregation, lack of breast-feeding, group day-care and exposure to tobacco smoke.⁸ Firstly, infants are predisposed to otitis media because their auditory tubes are shorter, wider, and lie more horizontally than those of older children which prevents the auditory tube from functioning optimally.⁸ In addition, children have an increased number of upper respiratory infections, which predispose the child to otitis media. Similarly, cases of otitis media are observed predominantly in the fall and winter, reflecting the seasonal pattern of respiratory infections and children who attend large group day-care, who are exposed to more respiratory infections, have higher rates of otitis media than children in home or family day-care.³ Children with single or recurrent episodes of otitis media are also more likely to have siblings with histories of significant middle ear infections than are children who had fewer or no episodes of otitis media. Considering sex and race, males have a higher incidence of AOM, as do Native Americans,³ Alaskan and Canadian Eskimos, and children living in African villages.⁸ In contrast, black children have one-half to one-third the incidence of white children.³ Passive exposure to tobacco smoke in children, as measured by high concentrations of biochemical marker, serum cotinine, is associated with increased incidence of AOM and increased duration of middle ear effusion following acute infection.⁸ The literature also suggests that supine bottle-feeding and the use of pacifiers past the age of 10 months predispose to ear infections.³ Finally, children with cleft palate and craniofacial abnormalities are predisposed to chronic otitis media because the auditory tube is unable to protect the middle ear from pathogens in the nasopharynx.^{3, 8}

In contrast, infants who are exclusively breast-fed for the first four months of life have half the number of cases of otitis media compared to non-breast-fed infants and 40% that of infants who had breast-feeding supplemented with other foods.³ The data suggests the breast-fed infant receives protection from some component of breast milk, rather than some deleterious quality of cow's milk or formula or position.⁸

Streptococcus pneumoniae is the leading bacterial pathogen responsible for 25-50% of cases of AOM. However, 30% of samples of middle ear fluid from patients with AOM do not contain viable bacteria.⁹ and up to 50% of cases of AOM, are estimated to be viral in origin.¹⁰⁻¹², with RSV being the most commonly isolated virus by tympanocentesis in AOM.¹³

Of note, otitis media is largely a self-limited disease. A recent meta-analysis of 30 studies evaluating 5400 cases of AOM found an 81% rate of spontaneous symptoms resolution and improvement in the appearance of the tympanic membrane.¹⁴

The typical episode of acute episode of otitis media results after the patient has a viral infection or allergic reaction that results in congestion of the respiratory mucosa of the upper respiratory tract; congestion of the mucosa in the auditory tube results in obstruction of the tube at its narrowest segment (the isthmus); the secretions of the middle ear mucosa have no exit and accumulate; if pathogenic bacteria that colonize the nasopharynx are present in the middle ear secretions prior to obstruction, they multiply, and an acute suppurative infection results.^{3, 8, 15}

AOM is diagnosed primarily with pneumatic otoscopy, where a puff of air into the ear canal with a rubber bulb allows the examiner to assess the mobility of the tympanic membrane while directly visualizing the membrane and external canal.³ The normal tympanic membrane is in neutral position (neither retracted or bulging), pearly gray, translucent, and response briskly to positive and negative pressure, indicating an air filled space. The abnormal tympanic membrane may be retracted or bulging, red, and immobile; these findings suggest an acute inflammation and a fluid-filled space.⁸

Tympanometry provides an objective assessment of tympanic membrane compliance and an estimation of middle ear pressure. An air pump varies the canal air pressure, thereby altering the stiffness of the tympanic membrane. The signal is then reflected back into the ear canal and the results are reported on a graph, with air pressure on the x-axis and compliance on the y-axis. A peak between half and full on the y-axis indicates an air filled space, while a flat tracing suggests the presence of middle ear effusion. Most middle ears for which tympanograms are normal will be found to be normal. However, some children with abnormal tympanograms may not have otitis media with effusion.⁸

Historically, the management of AOM in the US has focused on the choice of an appropriate antimicrobial agent. The rationale was based on the perceived reduction in morbidity and mortality coinciding with the introduction of antibiotics in the U.S., the more rapid resolution of the disease, and an active medico-legal environment, especially given the rare but potentially serious complications of AOM¹² which include: hearing impairment during the critical years of speech and language development², tympanic membrane

perforation, acute mastoiditis, meningitis, epidural abscess, and venous sinus thrombosis.³ As a result, American physicians are more likely to begin treatment with antibiotics and then follow-up with the patient after several weeks. While European physicians, treat otitis media with symptomatic relief medications and close observations for several days and prescribe antibiotics for patients who do not show signs of resolution in a few days.¹⁶

However, the evidence that antibiotics give only a marginal benefit has been growing since 1981, when two studies challenged the established practice of treating all cases of AOM with antibiotics.¹² This finding has been upheld by several recent studies. A Cochrane Library review of 7 trials with 2200 children, found that antibiotics had no effect on pain within 24 hours, a 5% absolute reduction in pain with the use of antibiotics at 2 to 7 days, and no effect on recurrence of AOM, complications or deafness at 1 month.¹⁷ Another systematic review found no evidence that antibiotics improved outcomes in children less than 2 years of age with uncomplicated AOM.¹⁸ A meta-analysis of 250 clinical trials found that antibiotic prophylaxis for recurrent AOM offers only modest benefits (antibiotic prophylaxis vs. placebo) 0.11 episode per month decrease over 10 weeks to 2 years.¹⁵ A more recent randomized clinical trial, confirmed that no significant difference was observed in duration of pain, otoscopic or tympanometric findings with or without antibiotics. The median duration of fever was two days in the amoxicillin group versus three in the placebo group. The authors conclude that this modest effect does not justify prescription antibiotics at the first visit, provided close surveillance can be guaranteed.¹⁹ Furthermore, antibiotics are not without their side effects. The rates of adverse effects (vomiting, diarrhea, skin rash) were increased in children on antibiotics compared with placebo (RR=1.55).¹⁷

Nonetheless, in the US, amoxicillin is the drug of choice for treatment of AOM and is prescribed twice as often as other drugs for AOM because of its twenty-year record of clinical success, acceptability, limited side effects and relatively low cost.¹⁵ However, it is ineffective against beta-lactamase producing strains of *Hemophilus influenza* and *Moraxella catarrhalis* and it is likely to be ineffective for resistant strains of *Streptococcus pneumoniae*. If amoxicillin treatment fails, there is no clear second choice. The physician can choose an alternative antibiotic, among them, azithromycin, loracarbef, or a second-generation cephalosporin.³ However, Rosenfeld cautions physicians regarding the disturbing trend towards using more expensive, broad spectrum antibiotics such as cephalosporins, as they

may contribute to rising health care costs and the emergence of antibiotic resistance.¹⁵

Penicillin resistance among *S. pneumoniae* is now unfortunately a reality.¹¹ A 1998 study showed that 29.5% of strains of *S. pneumoniae* had resistance to penicillin, with 17.4% having intermediate resistance. Furthermore, multiple drug resistance was observed in 16% of isolates.²⁰ Unfortunately, many isolates of *H. influenzae* and *M. catarrhalis* produce beta-lactamase, rendering approximately 25% of *H. influenzae* and nearly all of *M. catarrhalis* isolates resistant to ampicillin.¹

Researchers attribute the growing problem of antibiotic resistance to several factors. First, antibiotics are frequently overused to treat pediatric infections, like AOM, many cases of which may not be bacterial in etiology. Multiple partial courses of antibiotic therapy are used due to poor medication compliance or drug discontinuation, most often because of poor tolerance of the medication, prolonged duration of therapy, inconvenient dose frequency, and excessive reliance on day-care centers to administer part of the therapeutic course. Thirdly, the growing popularity of prophylactic antibiotics for recurrent infections, a modified dose of antibiotics given throughout the respiratory season, may have selected resistant strain organisms. Finally, the widespread use of antibiotics in agriculture may have further contributed to the emergence of drug resistance.³

As a result of this growing problem, many researchers are now calling for more rigorous standards on antibiotic usage. Pelton argues for improved diagnosis of AOM versus otitis media with effusion since some cases of otitis media with effusion, which consists of only fluid in the middle ear, are mistakenly diagnosed as AOM and given antibiotics needlessly.²¹ In order to differentiate between AOM and otitis media with effusion, Pichichero urges physicians to assess mobility of the tympanic membrane with pneumatic otoscopy, since undue reliance on redness of the tympanic membrane contributes to inaccurate diagnoses. He argues that a differentiating feature between AOM and otitis media with effusion is the position of the tympanic membrane; the membrane is usually bulging in AOM and in a neutral or retracted position in otitis media with effusion.²² Rudolph's Pediatrics also discusses the usual position of the tympanic membrane in AOM versus otitis media with effusion and its usefulness in differentiating between the two diseases.¹ Paradise calls for individualizing the duration of antimicrobial treatment for AOM and backing away from antimicrobial prophylaxis to prevent AOM recurrences.²³

In response, the Centers for Disease Control and Prevention and the American Academy of Pediatrics recently published a set of principles to guide the judicious use of antimicrobial agents in pediatric upper respiratory tract infections, requiring proper classification of otitis media as AOM or otitis media with effusion, permission to use antimicrobial agents in the treatment of AOM, discouragement of antibiotics for otitis media with effusion or persistent middle ear effusion, and discouragement of antibiotic prophylaxis except for recurrent AOM (three or more distinct well-documented episodes in six months or four episodes in twelve months).²⁴

Because of concern for impairment of hearing associated with the presence of fluid in the middle ear, pediatric ear surgery has become routine. In fact, myringotomy with the insertion of tympanostomy or ventilatory tubes is currently the most common pediatric surgical procedure requiring general anesthesia. Approximately 1 in 7 to 10 children have had tympanostomy tubes placed.⁸ Incision, drainage and placement of ventilatory tubes are thought to provide immediate improvement; the effusion is drained and the hearing impairment associated with conductive hearing loss due to middle ear fluid disappears. A recent study in the *New England Journal of Medicine*, however, found that delaying the insertion of tympanostomy tubes in infants and young children with persistent otitis media with effusion did not result in any significant speech, language, cognitive, and psychosocial development differences at three years of age.²⁵ Another study of 19-month-old children with persistent otitis media found no differences in the language development between the watchful waiting group and the ventilation tube group.²⁶ Also, the criteria for the procedure are controversial. A utilization review by Kleinman and associates found that approximately 1/4 of procedures for placement of tympanostomy tubes were performed for inappropriate indications.⁸ Finally, the surgery is not without its side effects. General anesthesia is required, the cost is significant, and sequelae such as persistent otorrhea, permanent perforation, scarring of the membrane, or cholesteatoma may result.⁸

Several vaccines have been developed and they have the potential to greatly decrease the number of episodes of otitis media due to pneumococcus. A 23-type pneumococcal vaccine, which has been available for more than 15 years, is effective in children over two years of age. However, since many patients with otitis media are under 2 years old, the vaccine has had limited impact on the incidence of acute otitis media.^{8, 27} In February 2000,

a new heptavalent pneumococcal polysaccharide vaccine (Prevnar), which is conjugated with CRM197, a diphtheria toxin mutant, was licensed for use among infants and children less than 2 years old.^{13, 28} This vaccine produces larger antibody titers in infants less than 2 years old, and is likely to have a more significant impact on the incidence of otitis media.²⁷ A study from Northern CA Kaiser Permanente, found that children who received the vaccine were 20% less likely to require tympanostomy tube, however, the vaccine reduced the number of episodes of otitis media by only 7%.⁹ The Finnish Otitis Media Study showed a 56% reduction in cases of otitis media caused by pneumococcal serotypes contained in the vaccine, with only a 6% overall reduction in cases of otitis media.⁹

A combination of the modest effectiveness of vaccines, hesitancy to overuse antibiotics, the reluctance to resort to surgery and public awareness of adjuvant approaches are causing medical professionals to reevaluate their approach to the problem of otitis media.^{29, 30} Klein, from the Boston Medical Center's Division of Pediatric Infectious Diseases, calls for a multi-prong approach to the problem of antibiotic resistance in otitis media. In addition to reducing the amount of antimicrobials prescribed, educating consumers about appropriate antibiotic use, increasing accurate diagnosis of AOM and otitis media with effusion, investigation of antimicrobials effective against resistant strains, and the development of new vaccines, Klein calls for the "investigation of homeopathic and herbal remedies and other alternative materials and techniques".²⁷

Decongestants and antihistamines can be used to treat congestion of the upper respiratory tract, however, they provide no benefit for the middle ear infection.⁸ 1 to 3 month courses of mucolytics also had no significant effect on resolution of effusion compared to placebo or no treatment.³¹ Garlic extract was found to be bactericidal for many resistant bacteria including: *S. pneumococcus*, *S. aureus* and *H. influenzae*.²⁷ Further clinical studies are needed. Uhari and colleagues conducted a randomized controlled trial of the food additive and sweetener, xylitol, for the prevention of AOM and demonstrated a statistically significant decrease in episodes of otitis media and number of antimicrobials used by the children in the treatment group.^{32, 33} A non-blinded randomized controlled trial comparing homeopathy and standard medical care reported several trends: less hearing loss, more normal tympanograms, fewer referrals to specialists, and fewer antibiotics consumed.³⁴ A prospective randomized feasibility study of chiropractic spinal manipulation for otitis media

with effusion of 22 patients found that recruitment for a randomized controlled trial is feasible and would be enhanced by medical collaboration for otoscopy and tympanometry.³⁵ A recent review article of otitis media on emedicine.com, indicated that an osteopathic technique by Galbreath, is also used to treat otitis media.¹⁶

Galbreath, an osteopathic physician, described a postural treatment for acute otitis media in 1925. He discussed placing the middle ear tract in a vertical position to facilitate drainage of auditory tube and a manipulative treatment consisting of temporomandibular articulation to render the auditory tube patent for physiological drainage of the middle ear. In addition, he discussed incision of the tympanic drum when necessary and tonsillectomy if the middle ear is in danger of inflammation from diseased tonsils. He also recommended bed rest and a light, easily assimilated diet to conserve the patient's strength and treatment of spinal problems to re-establish normal motion in the articular articulations.³⁶

OSTEOPATHIC MEDICINE

Andrew Taylor Still, M.D. developed Osteopathic medicine in post-Civil War America. Still asserted that disease was the result of an alteration in body structure and the resulting alteration in function.

Still based the philosophy and practice of Osteopathy on four principles:

- The body is a unit.
- Structure and function are reciprocally interrelated.
- The body has the inherent capacity to defend itself and repair itself.
- Rational treatment is based on the previous principles.³⁷

Refer to Gilmartin's thesis for a more complete discussion of the history and founding of Osteopathy.³⁸

Today's osteopathic physicians conduct detailed evaluations of the entire body assessing for areas of somatic dysfunction, defined as: tissue texture changes, asymmetry, restriction of motion, and tenderness.³⁷

Osteopathic Manipulative Treatment (OMT) treats areas of somatic dysfunction using a variety of hands-on techniques whose goal is to restore autonomic balance, increase arterial,

venous, and lymphatic function and relieve biomechanical stress patterns from myofascial and membranous tissues in order to optimize their mobile function.³⁹ Treatment is conducted both directly by relieving compression on nerves, vessels, and indirectly through viscerosomatic and somatovisceral mechanism. By improving impaired structure, osteopathic philosophy theorizes that function is maximized, and vice versa, by improving function, structure is maximized.³⁷

Since Galbreath, there have been many reports of osteopathic physicians utilizing OMT to treat otitis media. More recent osteopathic physicians report to treat otitis media in young children by improving the motion of the sacrum, (which is theorized to be locked from birth trauma), stimulating lymphatic flow by treating imbalances in the sacrum, pelvis and rib cage^{40, 41}, correcting temporal bone asymmetries since the external third of the Auditory tube sits in the temporal bone^{42, 43} and treating the upper thoracic vertebrae to regulate sympathetic tone.⁴⁴

In recent years, several clinical studies have been done to examine the efficacy of osteopathic treatment of otitis media. For instance, Schmidt noted symptom improvement in as quickly as 12 hours by treating otitis media with a combination of antibiotics and OMT; no control group was used.⁴⁵ Carreiro treated 18 children with chronic otitis media with effusion. Sixteen out of eighteen patients had "clear" ears by visual inspection with or without pneumatic otoscopy 18 months later. No control population was used in this study.⁴⁶ Steele conducted a pilot study with 10 patients utilizing a randomized controlled methodology to study the use of OMT with otitis media. Researchers conducted chart reviews, measured tympanograms, and assessed somatic dysfunction.⁴⁷ The results were not statistically significant, but the study design provided Mills with a foundation to conduct a feasibility study of 20 children, which showed a trend of the treatment group having a lower incidence of ear infections, more normal tympanograms, less irritability and less antibiotic prescriptions.⁴⁸ Based on this feasibility study, Mills conducted a larger randomized controlled clinical trial with 57 children, with half the patients receiving routine medical care by a pediatrician who is blinded to the randomization and study outcomes and half receiving routine medical care plus OMT. This study found that the children in the treatment group had a statistically significant, or nearly significant, decrease in episodes of otitis media, decrease in number of antibiotic prescriptions and improved tympanograms over the course

of the 6-month study period. Results are under consideration for publication in the Archives of Pediatrics and Adolescent Medicine.⁴⁹

None of these studies has examined the mechanism of OMT in otitis media, including the relationship between somatic dysfunction and clinical condition. There have been however, several clinical studies, which explore the relationship between structure and function in other diseases.

For example, researchers have found that myocardial infarction is accompanied by characteristic paravertebral soft tissue changes, which are readily detectable by palpation. The site of somatic dysfunction was located almost exclusively in the area T1 to T4, which is the location of the sympathetic nervous system innervation to the heart.⁵⁰ In another study, somatic dysfunction was found on the left side from T1 to T5 in 70 patients who were found to have coronary artery disease. In this study, 82% of patients with known coronary artery disease had a positive test (sensitivity) and 57% of patients without coronary artery disease had no somatic dysfunction in the T1 to T5 region (specificity).⁵¹ Beal and Morlock conducted a musculoskeletal palpatory exam on 40 patients with pulmonary disease and found that all the patients showed evidence of somatic dysfunction in the area of T2 to T7 which is the location of the autonomic nerve supply to the lungs.⁵²

Several other studies showed that improved clinical outcomes were associated with improved somatic dysfunction. For instance, Henshaw showed that treatment of somatic lesions at C3 to C5 before surgery could reduce postoperative pulmonary complications of cholecystectomy patients (5.3% vs. 85% complication rate).⁵³ Johnston and Kelso found that patients with hypertension had a characteristic pattern of somatic dysfunction at C6, T2 and T6, and that control of hypertension resulted in improvement of somatic dysfunction at 10 years follow-up.⁵⁴

While researchers have conducted clinical studies on the efficacy of OMT as an adjunct treatment of recurrent AOM, as discussed above, no researchers have examined the clinical effects of improving somatic dysfunction in otitis media.

Anatomical Considerations in Otitis Media

The literature on otitis media has focused on auditory tube dysfunction as the primary

anatomical explanation for otitis media in early childhood, since a well-functioning auditory tube prevents infection by drainage and clearance of middle ear secretions into the nasopharynx.⁸ Anatomically, the auditory tube travels from the middle ear through the petrous portion of the temporal bone and the pharyngeal muscles (tensor veli palatini, levator veli palatini, and salpingopharyngeous), to open in the lateral wall of nasopharynx.^{46, 55, 56} The lateral third of the auditory tube sits in the petrous portion of the temporal bones, while the medial two-thirds is cartilaginous.^{37, 56} At its narrowest diameter, the auditory tube sits at the junction of the osseous and cartilaginous parts of the temporal bone. At birth, the auditory tube is oriented horizontally. But, as the basicranium enlarges to accommodate the growing brain, the temporal bone composite changes. Over the first 5-7 years of life, the pharynx becomes more vertical, the mandible grows longitudinally, the temporomandibular fossa is displaced laterally and the tympanic cavity is displaced superiorly. Gradually, the temporal bones rotate laterally and superior, which shifts the orientation of the auditory tubes from a horizontal to a slightly anterior declined plane.⁴⁶ This anatomical maturation explains why young children are most at risk for otitis media and why children over six are said to “outgrow” otitis media.

In order to understand the pathophysiology of otitis media, researchers have primarily investigated abnormalities in the active opening mechanism of the auditory tube, via the muscles surrounding the tube and mucosal swelling of the pharynx.⁵⁶⁻⁵⁹ Defective innervation of the tensor veli palatini, ciliary dysfunction, and secretory IgA deficiency resulting in bacterial colonization of the nasopharynx have also been examined.³ Although the auditory tube travels through the temporal bone and its position changes with the postnatal development of the childhood skull,^{46, 56} researchers have paid little attention to the cranial bones themselves and their possible effect on auditory tube patency.

It has long been known that children with craniofacial malformations are at risk for recurrent otitis media.⁵⁶ These are children, with structural abnormalities affecting the bones of the face and skull, (i.e. cleft lip and palate) which are acquired through birth defects, developmental processes, disease or accident. From studying the high incidence of otitis media in patients with craniofacial defects, Bluestone and Klein theorize that defects in the base of the skull influence the relationship between the auditory tube and the tensor veli palatini and affect auditory tube function.⁵⁶ Here, osteopathic and allopathic physicians seem

to concur that due to structural abnormalities of the skull, the structure and function of the auditory tube is compromised and these children are predisposed to recurrent otitis media.

Osteopathic physicians trained in the cranial concept, study extensively the relationships between the bones of the skull and they utilize this knowledge of anatomy when approaching a patient with otitis media. Cranial osteopathy was developed by William Garner Sutherland, D.O., based on his recognition of the inherent associated mobility of the cranial bones and their membranous attachments and the inherent motility of the central nervous system.⁴² In 1899, Sutherland was observing a disarticulated human skull when an idea came to him that he was unable to dismiss in spite of his own standard anatomical training. He observed that the articular surfaces of the sphenosquamous area were "beveled like the gills of a fish indicating articular mobility for a respiratory mechanism." He spent the next 30 years attempting to disprove his observation, however he found it impossible to prove that the bones of the cranium were fused and did not move. He discovered instead, that all the articular surfaces of the cranial bones are designed for movement and that the articular configurations within the sutures were similar in every living human.³⁹

Today, basic science and osteopathic researchers also observe that the bones of the skull are not fused^{39, 60} and that a small amount of connective tissue remains between the bones. The cranial sutures of animals, which have been studied, show ligaments with a consistent fiber organization and many free nerve endings and the sutures of squirrel monkeys do not obliterate at any age.⁶⁰

Although it is not emphasized in medical education, a small amount of motion exists between each of the bones in the skull and face and in the brain itself. Both physicians trained in osteopathic cranial manipulation, and basic science researchers have detected this motion of the cranium. In as early as 1971, the European Neurology literature described waves of changing pressure in the brain, which are slower and longer than those associated with respiration or cardiovascular pulse, usually 6-7 per minute. These waves termed, Traube-Hering-Mayer waves, are mediated through the parasympathetic and sympathetic nervous systems and were initially demonstrated using ultrasound.⁶¹ Since then, computed tomography was used to further identify brain movement and CSF fluctuation.⁶² Then, in 1987, UCSF Radiology researchers, Feinberg and Mark, used in vivo quantitative magnetic resonance velocity imaging methods to show reproducible magnitudes and directions of CSF

flow and pulsatile brain motion confirming that brain motion exists.⁶³

Independently, osteopathic researchers corroborated these findings. Osteopathic physician, Frymann, collaborated with an electrical engineer to create a device, which used calipers applied to the cranial vault, which were connected through transducer to a chart recorder. In this way, Frymann recorded the Traube-Hering-Mayer wave, as a rhythmic motion of human cranium, separate from respiration, cardiovascular pulse and voluntary muscular activities.⁶⁴ Animal studies corroborated Frymann's results. Using two different measurements of transparietal motion, squirrel monkeys showed a cyclic cranial bone movement, separate from cardiac and respiratory rates, ranging from 5 to 7 cycles per minute.⁶⁵ More recent studies of the sagittal suture motion in cats showed rotary and transitory movement as well.³⁹ A recent study in a peer-reviewed journal, found that cranial manipulation affected Traube-Hering-Mayer waves and that since it has been known that the autonomic nervous system affects Traube-Hering-Mayer waves, cranial manipulation appears to affect the autonomic nervous system.⁶⁶

Although the amount of mobility in each of the studies has been across a single suture, when aggregated with all the sutures in the skull, there is sufficient motion to be detected by palpation. The palpation capability of the human hand has also been studied, using a clamshell device, which simulates motion of the parietal bones. For trained and untrained evaluators alike, the perception threshold was calculated to be 0.5 to 0.25 mm per second.³⁹

Osteopathic theory proposes that a healthy person has a small, but significant amount of motion between each of the bones in the skull and face and that a loss of this physiological motion disrupts homeostasis and susceptibility to illness is increased.³⁹

Considering an infant and the mechanics of the delivery process, the bones of the infant skull are malleable to facilitate the birth process.⁶⁷ While, a posterior presentation allows the smallest diameter of the baby's head to pass through the mother's pelvis, this position however, puts the occiput at the base of the skull under extreme force. The obvious "crooked head" or plagiocephaly, which many babies are born with, is evidence that the skull molds to facilitate passage through the birth canal. Pediatricians teach that baby's heads remold after birth with no clinical effects.

However, osteopathic researcher, Frymann conducted a study of 1,250 newborns and

demonstrated that 10% of infants had “crooked heads” which were visible. An additional 78% of infants had palpable membranous articular strains, or tightening of the membranes, which line the CNS, which were diagnosed by the osteopathic physicians. Thus, nearly 9 out of 10 infants in the study were found to have musculoskeletal strains originating at the time of birth.⁶⁷

Frymann also studied the relationship between cranial strains and clinical effects. She studied 1250 infants with vomiting, hyperactive peristalsis, tremor, hypertonicity, and hyperirritability and found an increased prevalence of symptoms with an increased restriction of cranium.⁶⁸ In another study, 200 grade school children were studied using a cranial osteopathic examination and a blinded psychological and educational test to examine the relationship of cranosacral dysfunctional findings and problems in childhood development. The results showed a positive correlation of cranial motion restriction in the children who displayed multiple psychosocial and educational problems.⁶⁹

In sum, Bluestone and Klein wrote that children with craniofacial malformations have an increased incidence of otitis media, which the authors theorize to be due to a compressed occiput.⁵⁶ Osteopathic physicians theorize that labor and delivery exert a compressive force on the occiput, which affects the temporal bones and the Auditory tube, predisposing the child to otitis media. Otitis media is an exceedingly common infection of early childhood and with the growing problem of antibiotic resistance, new treatment approaches are being designed. While osteopathic physicians have long used OMT to improve somatic dysfunction, restore physiological motion and improve otitis media, it is a treatment modality, which has been understudied. A recent study on the efficacy of OMT as an adjunct treatment of otitis media indicates promising results. However, no one has studied the theorized mechanism of OMT, such as the improvement of somatic dysfunction.

CHAPTER TWO:

OSTEOPATHIC MEDICINE AND OTITIS MEDIA:

DOES IMPROVING SOMATIC DYSFUNCTION IMPROVE CLINICAL OUTCOMES?

Introduction

Acute otitis media (AOM) is an exceedingly common infection in children under 7 years old, with 50% of children having 3 or more infections by the age of 3.^{2,3} It is estimated that over \$5 billion are spent each year to treat AOM.⁵ Antibiotics have been the standard of care treatment for AOM; however, the growing problem of antibiotic resistance is causing pediatricians to re-evaluate the strategy of treating all cases of AOM with immediate antimicrobials.^{11, 14} Recent guidelines for antibiotic use encourage more precise diagnosis of AOM (bulging tympanic membrane, in addition to ear pain and signs of systemic illness), discourage antibiotics of persistent effusion and discourage antibiotic prophylaxis.²⁴ In response, researchers have also begun to explore other alternative treatments for otitis media, including garlic extract, xylitol, homeopathy and osteopathic manipulation.^{27, 32-34, 45-49}

Osteopathy is a western medical science, where physicians recognize structural alterations in the musculoskeletal system that directly cause, maintain or exacerbate disease states. By addressing these structural changes through osteopathic manipulative treatment (OMT), a system of hands-on therapeutics, the osteopathic physician directly restores function. Little research has been done to quantitatively assess treatment and outcomes. Historically, osteopathic medicine has been in the shadow of allopathic medicine and has not been fully understood by allopathic physicians. Perhaps with more research, osteopathic medicine will become more utilized as an adjunct health care model.

While there have been several studies on the efficacy of OMT in the treatment of otitis media, none have examined the relationship of otitis media to somatic dysfunction. Somatic dysfunction is assessed by an osteopathic evaluation of bony structures, muscles, and connective tissue of the entire body and is defined as: the presence of asymmetries, tissue texture abnormalities, and limitations in range of motion in the musculoskeletal system.³⁷ Somatic dysfunction tests a core theory in osteopathic philosophy, namely that structure and

function, are reciprocally interrelated. Impaired structure, or somatic dysfunction, results in impaired function and impaired function, leads to impaired structure. Osteopathic physicians diagnose somatic dysfunction and treat it with osteopathic manipulative treatment in order to improve clinical outcomes. The degree of somatic dysfunction is recorded in a standardized fashion as 0= no somatic dysfunction, 1= mild, 2= moderate, 3= severe. Similar to the auscultation of the heart and description of a murmur as I/VI or II/VI, osteopathic diagnosis takes time, patience and experience to develop.

Consistent somatic dysfunction findings have been identified in myocardial infarction, coronary artery disease and pulmonary disease.⁵⁰⁻⁵² Several other studies showed that improved clinical outcomes were associated with improved somatic dysfunction, i.e., pulmonary complications of cholecystectomy and controlled hypertension.^{53, 54}

While, a recent study examined the efficacy of OMT as an adjunct to the routine care of otitis media,⁴⁹ no one has examined the relationship between somatic dysfunction and otitis media, and whether improvement of somatic dysfunction can improve otitis media.

METHODS

The current study is a secondary analysis of a dataset collected as part of a randomized controlled trial of osteopathic manipulative treatment and otitis media, which was discussed previously.⁴⁹ Children, aged 6 months to 6 years, with recurrent AOM, defined as three episodes in six months or four episodes in 12 months, with no chromosomal abnormalities, no prior ENT surgery and no prior OMT, were enrolled in the study. Episodes of AOM were determined by chart review using the following criteria (based on guidelines from the Center for Drug Evaluation and Research): one of three 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 two weeks between episodes.⁷⁰

Patients were recruited between February 1999 and July 2001 from four outpatient settings in Oklahoma, Maine, Missouri, and Arizona, with the majority of patients enrolled from the Tulsa site. Patients were referred by their pediatricians, who were blinded to group

placement and study measures, and site coordinators trained in study protocols collected data locally.

The site coordinator obtained informed consent from eligible patients who were then assigned to a treatment or control group using a computer-generated randomization. Both the treatment and control groups received care by their pediatrician, who provided all medical care and made decisions related to antibiotics and surgical referrals. The pediatricians were unaware of group placement and study outcomes. In addition to routine medical care, the treatment group received nine OMT sessions over a six-month period, performed by an osteopathic physician who was blinded to the patient's clinical course as per the pediatrician. The patients in the control group had an equal number of encounters with the study staff, which asked both groups about interval history regarding medications and illnesses.

Various outcome measures were assessed at baseline and final. The number of episodes of otitis media and number of antibiotic prescriptions in the six months prior to the study and during the six months of the study period were determined by chart review. An audiologist, blinded to randomization and study outcomes, evaluated baseline and final tympanograms. Somatic dysfunction was assessed by complete osteopathic evaluation at baseline and final on all children by an osteopathic physician who was blinded to study outcomes (Figure 1). A questionnaire was administered to parents to collect demographic information relating to risk factors associated with AOM (Table 1).

Osteopathic Manipulative Treatment

OMT was provided to the treatment group at each encounter, as indicated by the osteopathic examination of the entire body, with particular attention to the head and neck, and the child's cooperation. The treatment was guided by the patient's condition and response to treatment, which then determined the techniques used. As a result, this was a study of osteopathic treatment, not a specific osteopathic technique.⁷¹ Treatments utilized gentle techniques on areas of restriction consisting of articulation, myofascial release, balanced membranous tension (based on teachings of William Garner Sutherland and others), balanced ligamentous tension, facilitated positional release, and counter-strain techniques.⁴² These techniques are familiar to most recently trained osteopathic physicians; refer to

Greenman's Principles of Manual Medicine, for more detail.⁷² In order to limit individual physician variation, only physicians with teaching experience in cranial osteopathy, or who had passed a certifying exam of the Cranial Academy of the American Academy of Osteopathy were utilized in the study.

STUDY HYPOTHESIS

The improvement of somatic dysfunction is the mechanism by which OMT results in the improvement of clinical outcomes: decreased episodes of otitis media, decreased antibiotic prescriptions and improved tympanogram scores (see Figure 3).

RESEARCH QUESTIONS

1. Does the treatment group have decreased somatic dysfunction from baseline to final as compared to the control group?
2. What is the relationship between change in somatic dysfunction and change in:
 - otitis media?
 - antibiotic usage?
 - tympanograms?

MEASURES AND METHODS

The independent variables are baseline osteopathic evaluations for the entire musculoskeletal system, recorded in a standardized fashion, (0=no dysfunction, 1=mild, 2=moderate, 3=severe). Baseline osteopathic evaluations with a mean of 2.0 or greater were selected, so that the areas of the body that had the greatest somatic dysfunction could be assessed for improvement.

The dependent variables are: average monthly episodes of otitis media, (prior six month average and study six month average), average monthly antibiotic prescriptions (prior six month average and study six month average), and baseline and final tympanogram score. The tympanogram scores were determined by assigning a numerical value to a curve shape

based on Cantekin's findings for the incidence of effusion with a particular curve shape. For example, 0 = "b flat" (roughly more than 85% associated with effusion), 1 = "b gradual" (65-80%), 2 = "c gradual" (45-60%), 3 = "c sharp", "a gradual", and "a high peak" (20-35%), and 4 = "a sharp" (less than 15%).⁷³ The scores from the left and right ears were averaged.

SPSS version 11.0 (SPSS Inc, Chicago, Ill) was used for data analyses. The first research question, hypothesized that there would be a difference in somatic dysfunction between baseline and final in the treatment and control groups. In order to test this hypothesis, independent sample t-test was used. Eight areas of somatic dysfunction were found to have a baseline somatic dysfunction of greater than 2.0, left and right anterior head, left and right posterior head, left and right upper thorax, and left and right middle thorax. In order to simplify the analysis, these eight areas of somatic dysfunction were combined into a mean baseline somatic dysfunction variable, which was compared to the mean final somatic dysfunction by group.

Next, regarding the question of whether this improvement in somatic dysfunction results in an improvement in clinical outcomes (otitis media, antibiotic usage and tympanograms) as compared to the control group whose somatic dysfunction was not treated. To test the hypothesis, linear regression analysis was used, with the change in somatic dysfunction as the predictor variable and change in clinical outcome as the outcome variable. A change score was calculated for each of the 8 areas of somatic dysfunction, using the difference between somatic dysfunction at baseline and month 6 of the study and, a change score was calculated for each of the 3 outcomes, episodes of otitis media (study 6-prior 6), antibiotic prescriptions (study 6-prior 6) and tympanogram score (months 5 and 6-months 0 and 1) (Figures 7, 8, 9, 10 and Table 3).

RESULTS

A total of 76 (31 intervention, 45 control) patients met criteria and were enrolled, out of 146 who were referred. Of those referred, 44 did not qualify because the chart review did not support the criteria for sufficient episodes of acute otitis media. Another 26 chose not to participate, because of the six-month time commitment, uncertainty about manipulation, or because they were planning surgery in the near future. Nineteen (6 intervention and 13

control) patients dropped out during the study, leaving 57 patients available for data analysis, 25 in the intervention group, and 32 in the control group (Figure 2). Patients dropped out for two reasons: loss of continuity of physician care, or inconvenience of a six month-long study. Of the 13 patients who dropped out for whom we have data, the relationships among study outcomes between the intervention and control groups were similar to that found in the patients who remained in the study, except that the intervention dropout patients were younger.

Demographic variables are summarized in table 1. Children in the control group were more likely to be first born than the treatment group, 56% vs. 24%, $p=0.014$, 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 than the treatment group, 6% vs. 0%, $p=0.05$. Treatment and control groups did not differ significantly from each other with regards to age ($p=0.19$) (Table 1). When controlling for age, smoking and firstborn status, the treatment group had a statistically significant, or nearly significant, decrease in the number of episodes of otitis media, decreased antibiotic prescriptions and improved tympanogram type. A paper reporting the results is under consideration at the Archives of Pediatrics and Adolescent Medicine.⁴⁹

Research Question #1

The mean somatic dysfunction at baseline for the treatment group was 2.27 and for the control group was 2.37 ($p=0.326$). The mean somatic dysfunction at final for the treatment group was 1.35 and for the control group 2.30 ($p<0.001$). The mean change in somatic dysfunction between baseline and final for the treatment group was .92 and for the control group .07 ($p<0.001$). This is consistent with the hypothesis that the treatment group receives OMT, which improves somatic dysfunction (Figures 4, 5, 6 and Table 2).

Research Question #2

Improvement in somatic dysfunction was associated with a trend towards improvement in average monthly episodes of otitis media and average monthly antibiotic

prescriptions ($B=0.09$, $p=0.13$ and $B=0.12$, $p=0.26$ respectively) with statistically significant improvement in tympanogram score ($B=-0.57$, $p=0.04$) (Figures 11, 12, 13 and Table 4).

The linear regression scatterplots illustrate the relationship between the change in somatic dysfunction and the change in clinical outcomes. Zero on the x-axis indicates no change in somatic dysfunction, a positive number indicates an improvement in somatic dysfunction from baseline to final (i.e. 1 may be due to a score of 3 at baseline and 2 at final, $3-2=1$), and a negative number indicates a worsening in somatic dysfunction from baseline to final. On the y-axis, the same scale applies for change in average monthly episodes of otitis media and antibiotics. Zero indicates no change in the clinical outcome, a positive number is a decrease in episodes of otitis media or antibiotic prescriptions from baseline to final and a negative number is an increase in otitis media or antibiotics from baseline to final. For the change in tympanogram plot, the direction is reversed. Zero indicates no change in tympanogram score, while a positive number is a worsening and a negative number is an improvement in tympanogram.

In the first two graphs, the treatment group is clustered in the top right quadrant, indicating that an improvement in somatic dysfunction and an improvement in episodes of otitis media or antibiotic prescriptions. In the third plot, a negative score on the y-axis indicates an improvement in tympanograms. Here, the treatment group is clustered in the lower right quadrant, which is consistent with the hypothesis, that improvement in somatic dysfunction predicts an improvement in tympanograms. In all three graphs, the best-fit line is in the direction of the hypothesis, with a positive slope in the first two (otitis media and antibiotics) and a negative slope in the third (tympanograms). Review of the unstandardized coefficient and p-values, indicates that an improvement in somatic dysfunction predicts statistically significant improvement in tympanograms, a 1 unit improvement in somatic dysfunction (i.e. from 3 to 2, or severe to moderate or 2 to 1, moderate to mild) is predictive of a .57 improvement in tympanogram score, or going from a flatter tympanogram graph (b type) to a more peaked graph (more a and c types) which is indicative of increased motion in the tympanic membrane.

DISCUSSION

The treatment group had a statistically significant improvement in their somatic dysfunction as compared to the control group. This is consistent with osteopathic philosophy, which states that OMT diagnoses and treats somatic dysfunction. The control group did not receive OMT and they did not have a significant change in their somatic dysfunction over the course of the study period. Despite the small sample size, an improvement in somatic dysfunction indicates a trend in improvement of otitis media and antibiotics and a significant improvement in tympanogram score.

Limitations and Implications

While the dataset used was from the largest randomized clinical trial of OMT and AOM, the relatively small sample size is a limitation of the study. A larger study population is necessary to explore other research questions such as: What is the relationship between specific areas of somatic dysfunction and left or right ear infections? What is the relationship between OMT and growth of head circumference in children with AOM? Are children who are first born susceptible to recurrent AOM and do they respond differently to OMT? Subsequent studies should also consider shortening the study period in order to facilitate increased patient enrollment.

It is also a limitation of the study that the osteopathic physicians were not blinded to group status. However, these physicians were not involved in the medical diagnosis or treatment of patients. Additionally, the same physician who conducted the osteopathic evaluations at baseline and final also conducted the osteopathic treatments. However, had a second physician been used, the study would have been evaluating inter-rater reliability which is a different study design. This same critique has been made of other non-pharmacological treatment modalities such as psychotherapy and acupuncture.

Much of the attention in the literature has focused on the microbiological 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,⁵⁵ and its relation to the muscles of the soft palate, the tensor veli palatine, levator veli palatine, and the salpingopharyngeous,^{55, 74} it is apparent that the tube is vulnerable to extrinsic compression, presumably during birth. Within the osteopathic concept, which relates form to function, there is the suggestion of a structural influence on the tube's patency, which may be amenable to manipulation.⁷⁵

Children in both groups improved considerably over the six-month period, which is the natural course of otitis media. However, the children who received OMT had on average .41 less episodes of otitis media per month, or 2.5 less episodes over six months, compared to .24 less episodes per month or 1.4 less episodes over 6 months for the control group. That is, the children who received OMT in addition to routine care had 1 less episode over 6 months compared to routine care alone. The children who received OMT received .49 less antibiotic prescriptions per month compared to .27 less for the control group, for a total of nearly a prescription and a half of antibiotics over 6 months. With the typical prescription of amoxicillin 20-40 mg/kg/day for 10 days, this is equivalent to over 2 weeks of amoxicillin treatment prevented. This small difference has potentially huge benefits considering the antibiotic resistance dilemma. Finally, the treatment group had a .61 improvement in their tympanogram score and the control group had a .09 improvement in their tympanogram score, indicating improvement in tympanogram graphs from a flat line to a peaked curve. Since tympanogram results are important criteria in determining candidacy for surgical placement of tympanostomy tubes, an improvement in tympanograms may help prevent many unnecessary surgeries.

These results of the primary study prompted this researcher to inquire into the mechanism of OMT. Osteopathic physicians claim to treat otitis media by evaluating and improving somatic dysfunction. This study found that both treatment and control patients had high levels of somatic dysfunction at baseline and that the most severe somatic dysfunction improved in treatment patients and persisted in control patients.

This study indicates that by improving somatic dysfunction, osteopathic medicine offers a potential benefit as an adjuvant treatment for children with recurrent otitis media and it suggests that pediatricians of the future may want to include osteopathic manipulative treatment as an adjunct to antibiotics in treating otitis media.

FIGURE 1. Study Design: Osteopathic Manipulative Treatment (OMT) and Clinical Outcomes in Children with Recurrent Acute Otitis Media (AOM).

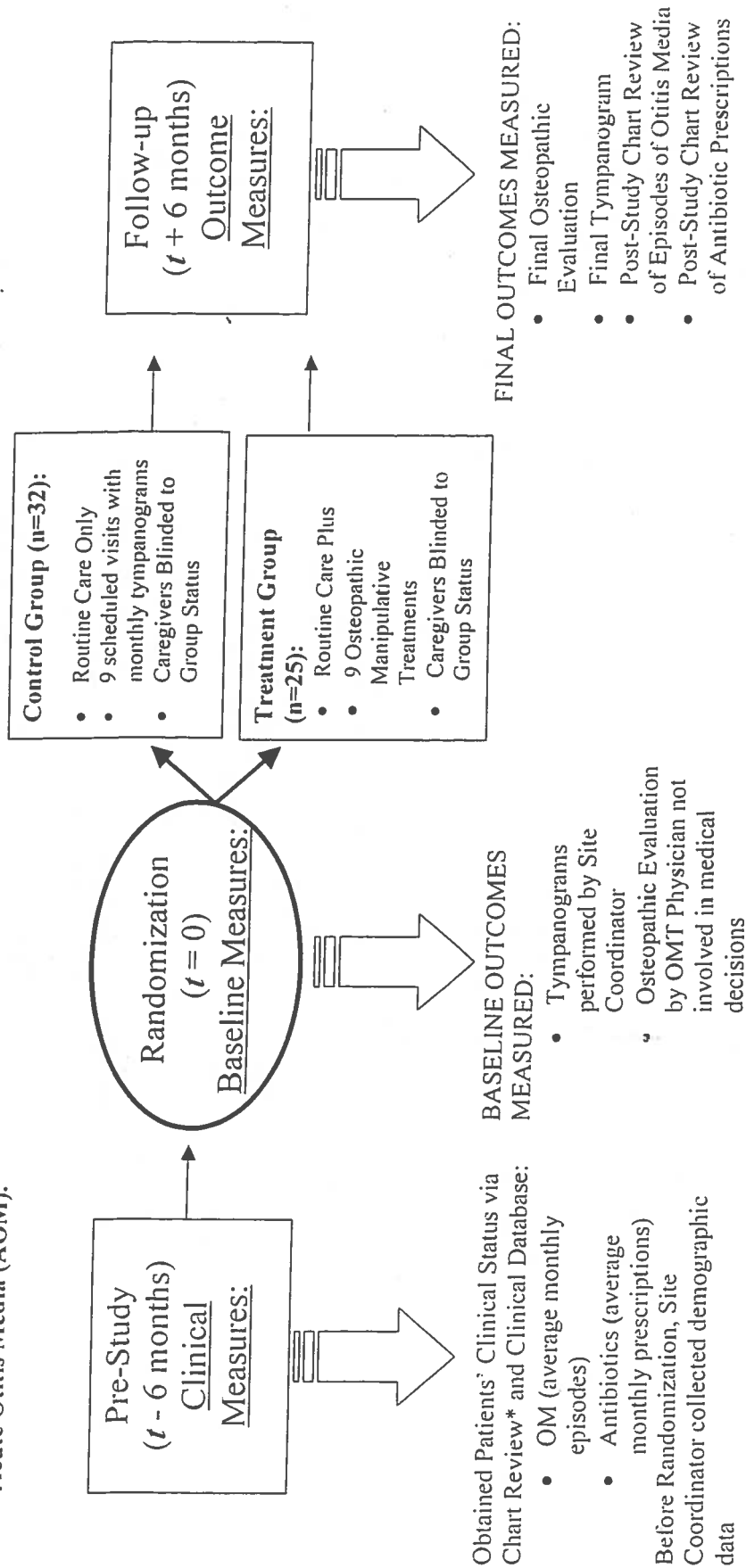


FIGURE 2. Patient Enrollment

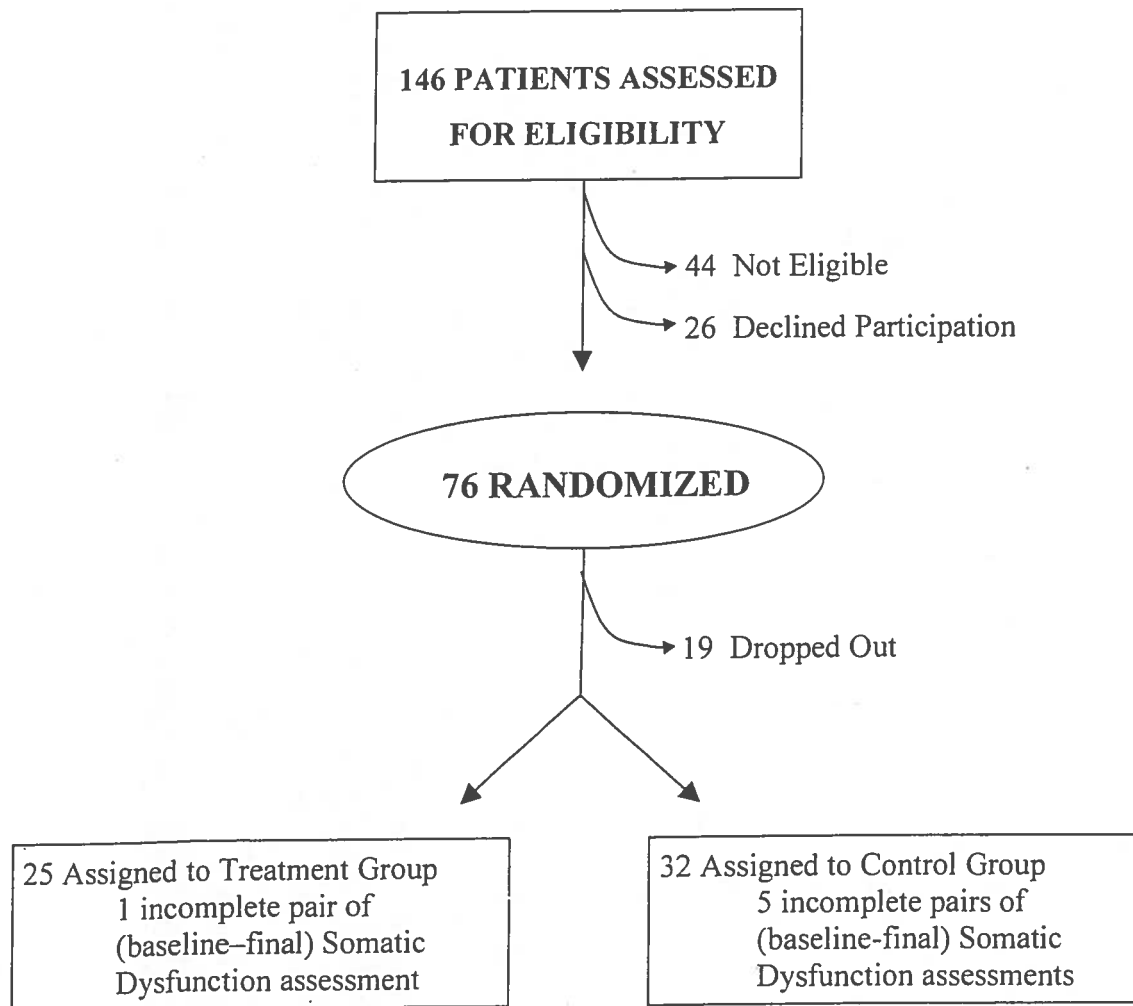


FIGURE 3. Flow Chart of Study Hypothesis

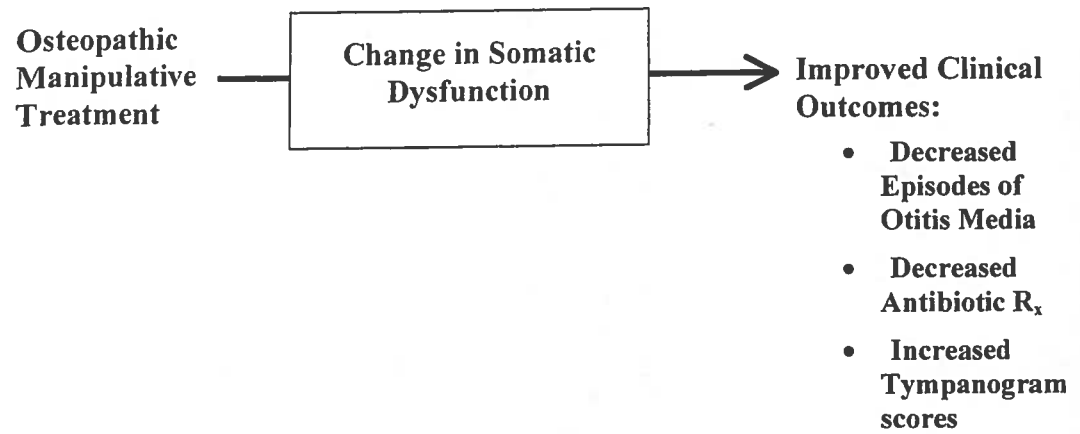


FIGURE 4. Frequency of Mean Somatic Dysfunction at Baseline

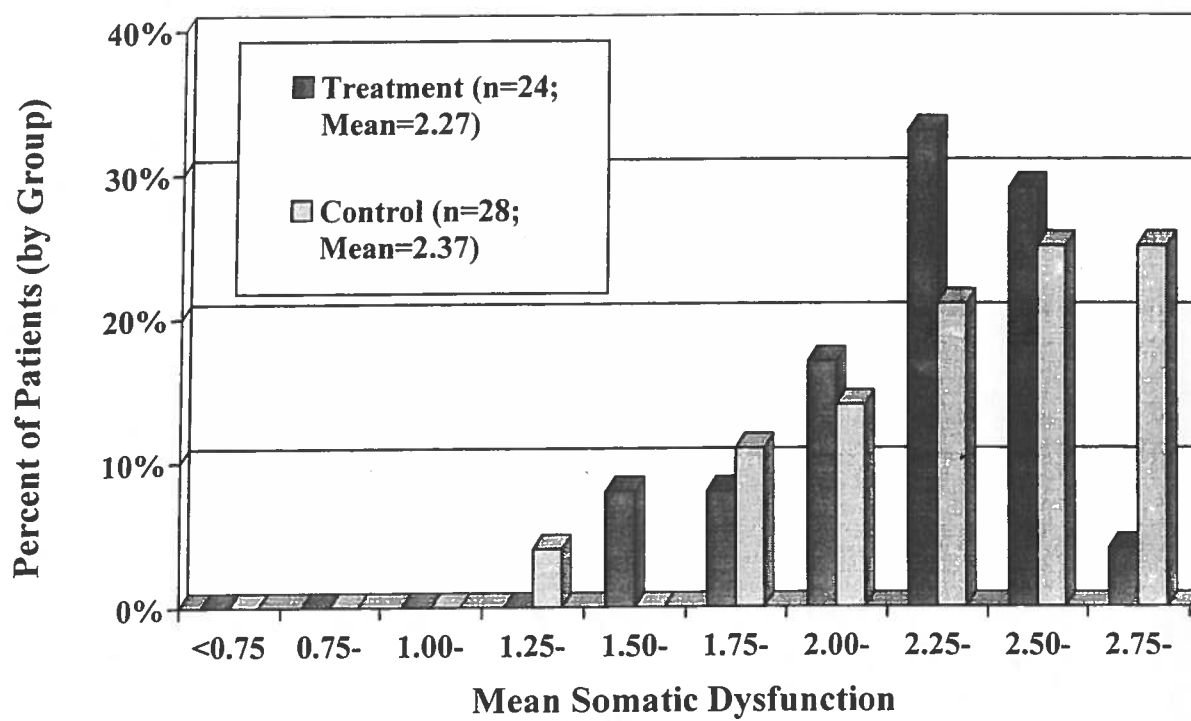


FIGURE 5. Frequency of Mean Somatic Dysfunction at Final

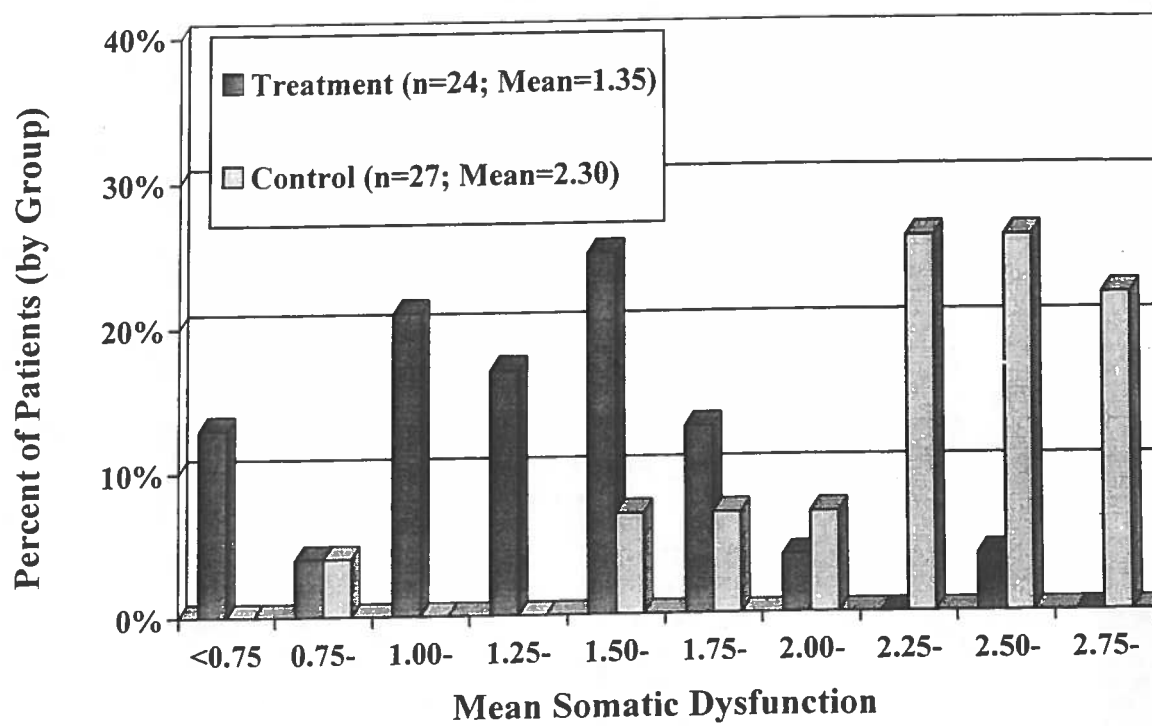


FIGURE 6. Frequency of Mean Change in Somatic Dysfunction (baseline-final)

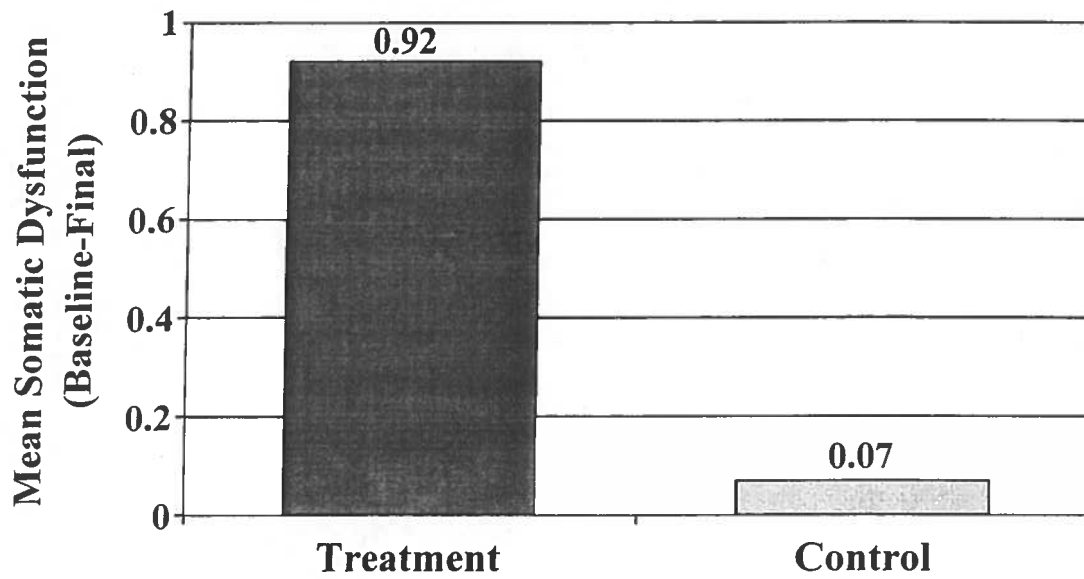


FIGURE 7. Clinical Outcomes (baseline and final)

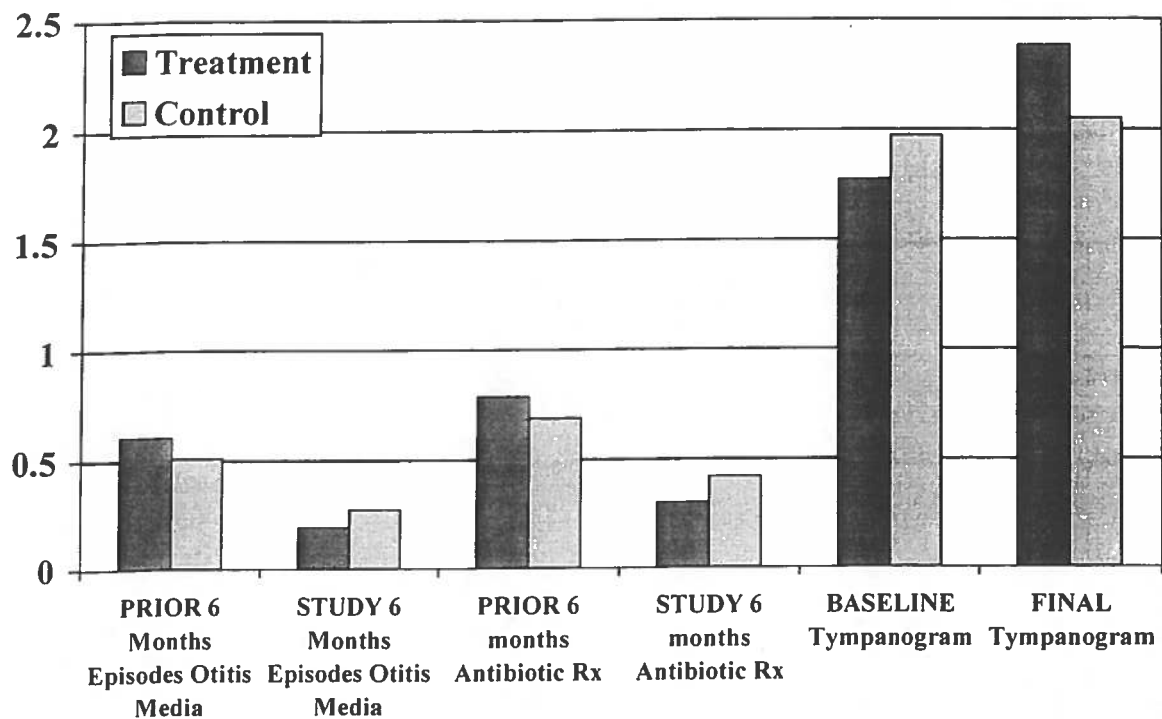


FIGURE 8. Mean Average Change in Episodes of Otitis Media (Prior 6 – Study 6)

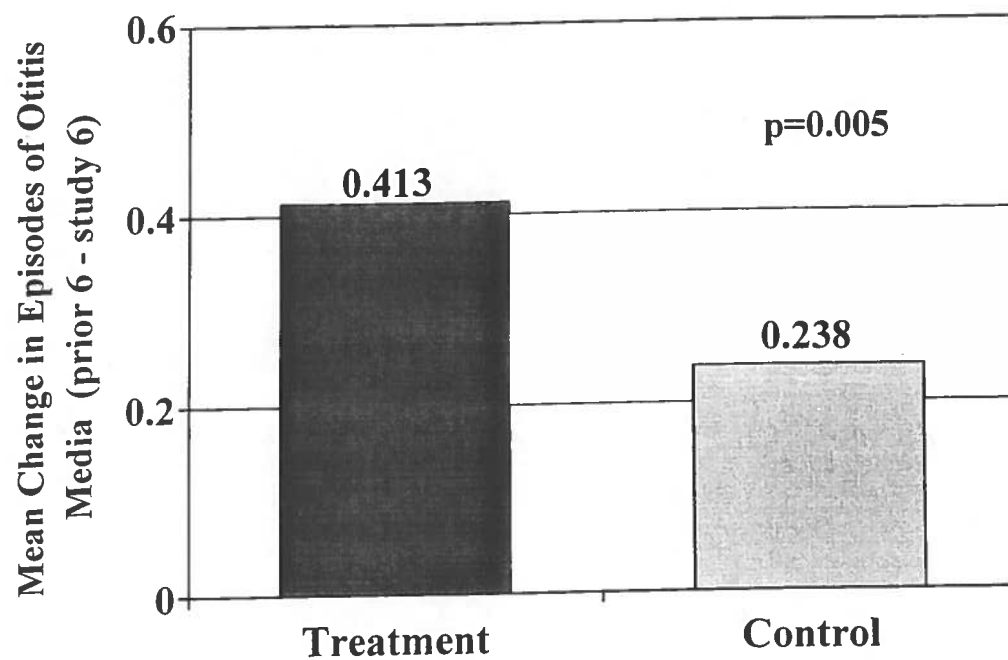


FIGURE 9. Mean Average Change in Antibiotic Prescriptions (Prior 6 – Study 6)

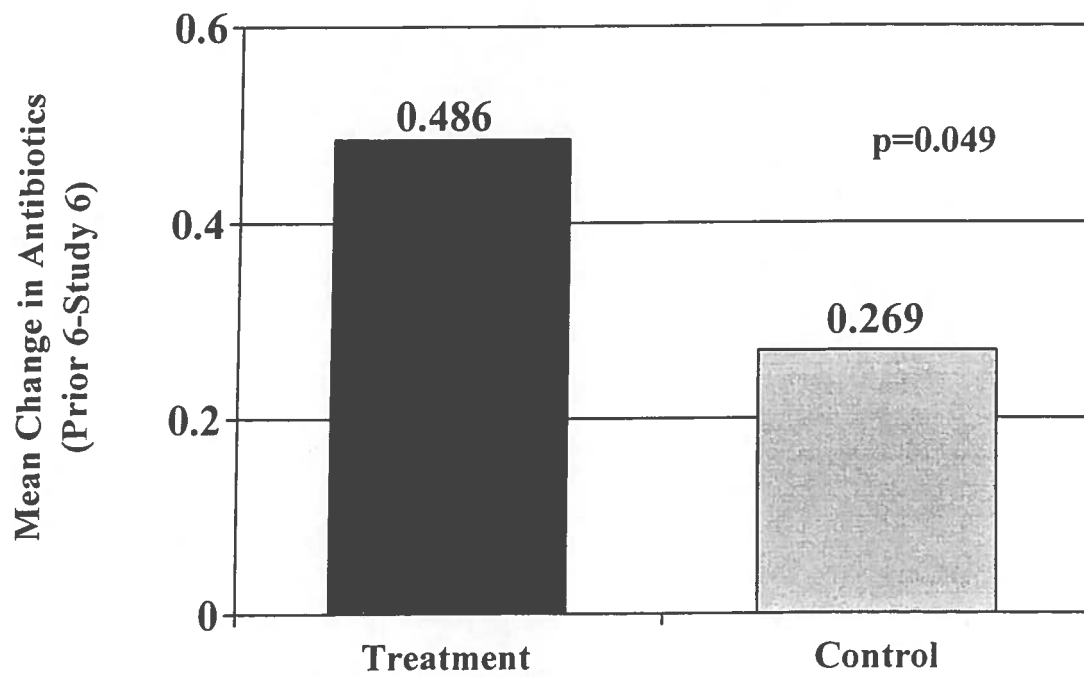


FIGURE 10. Mean Change in Tympanogram Score (baseline-final)

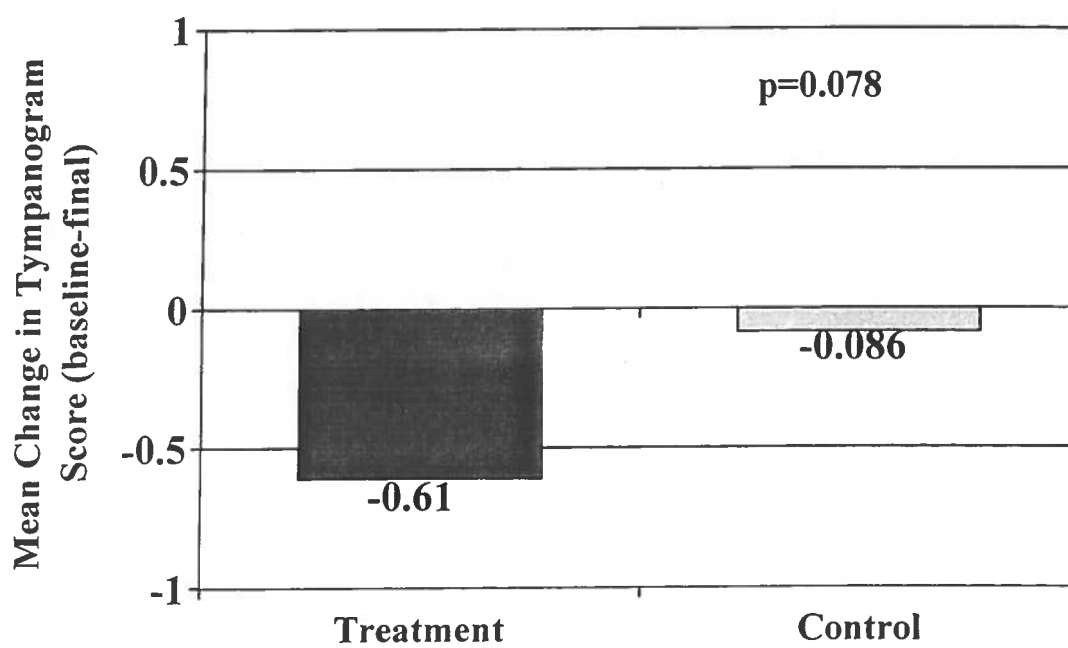


FIGURE 11. Plot of Linear Regression of Mean Change in Somatic Dysfunction with Change in Episodes of Otitis Media

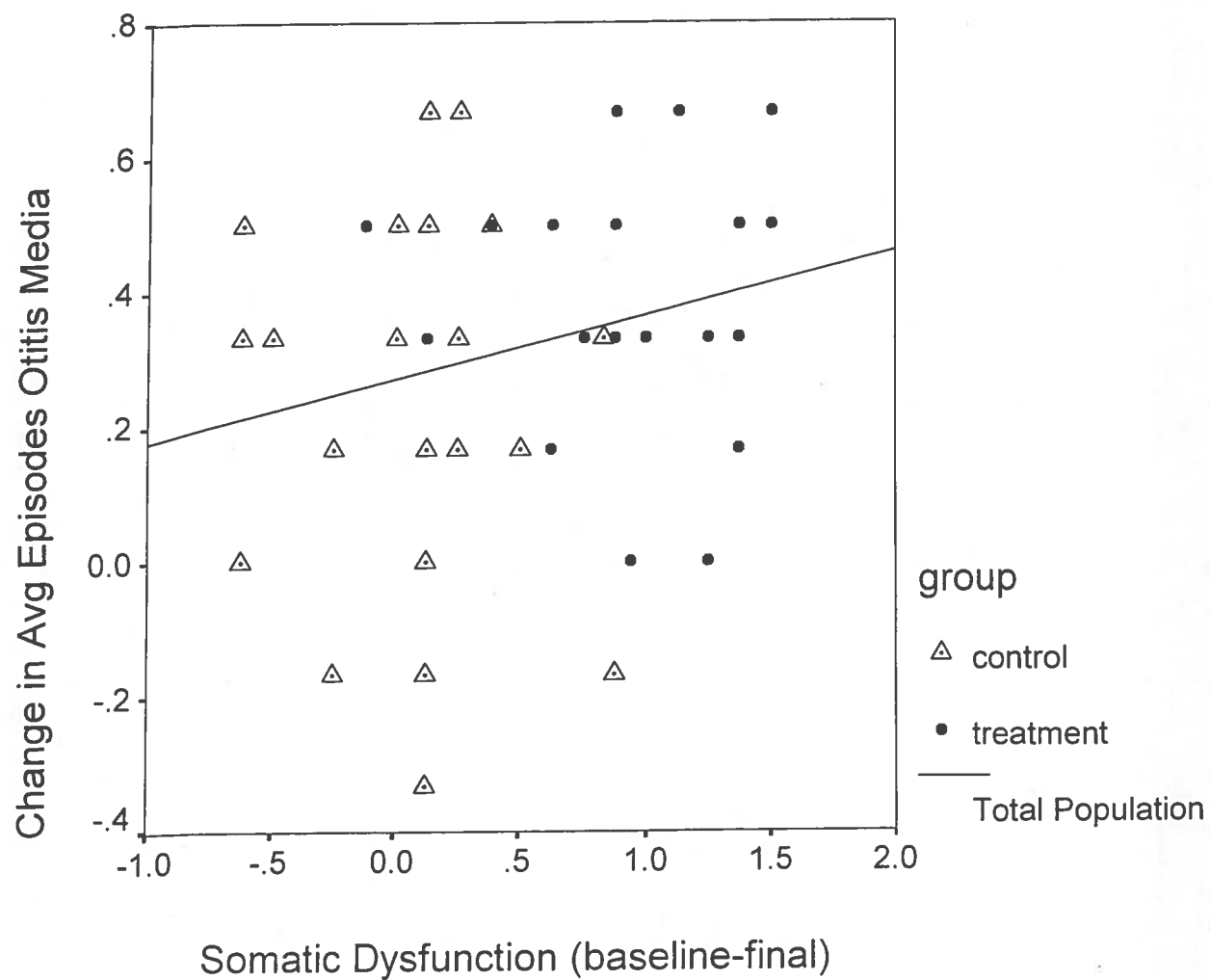


FIGURE 12. Plot of Linear Regression of Mean Change in Somatic Dysfunction with Change in Antibiotic Prescriptions

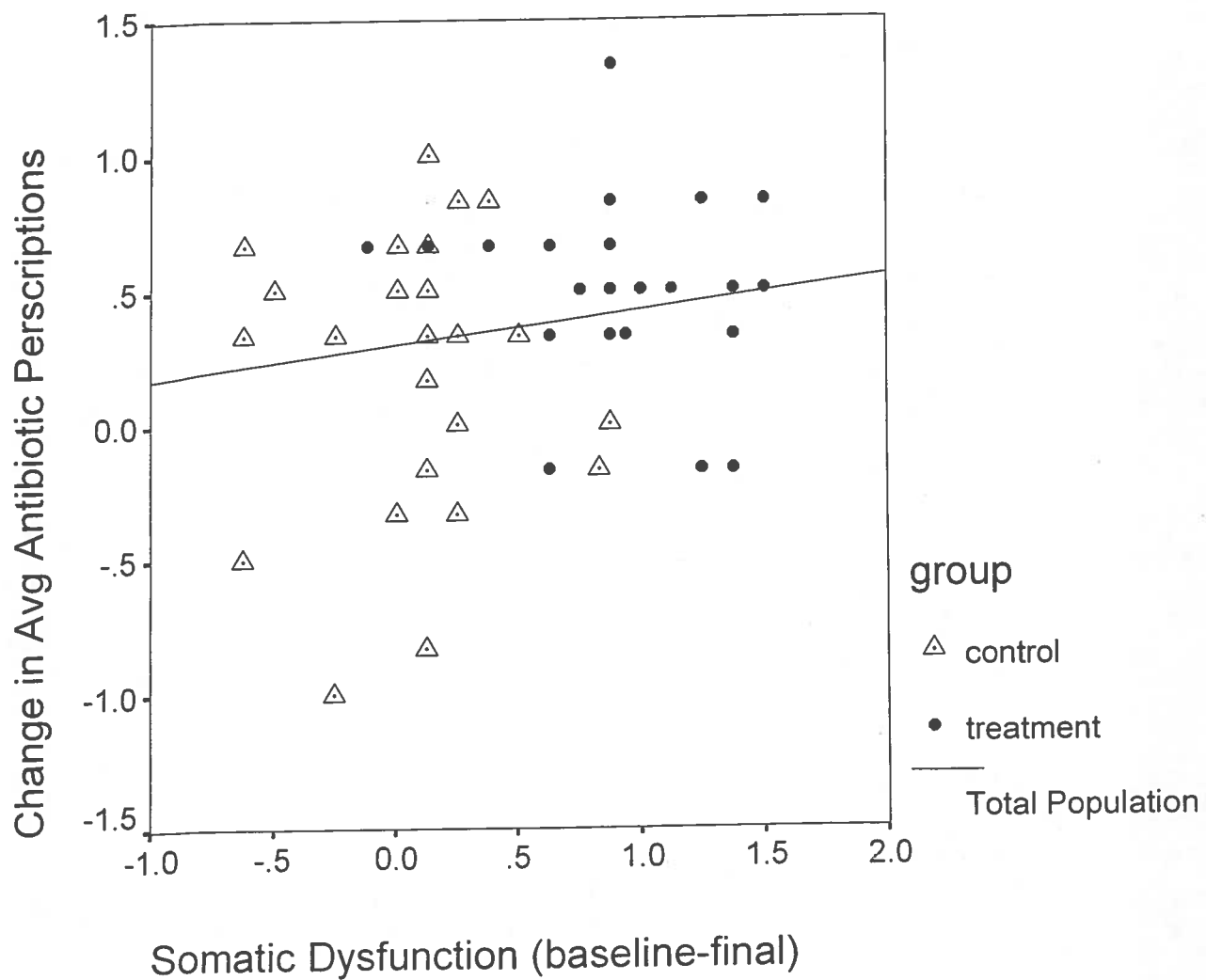


FIGURE 13. Plot of Linear Regression of Mean Change in Somatic Dysfunction with Change in Tympanogram Score

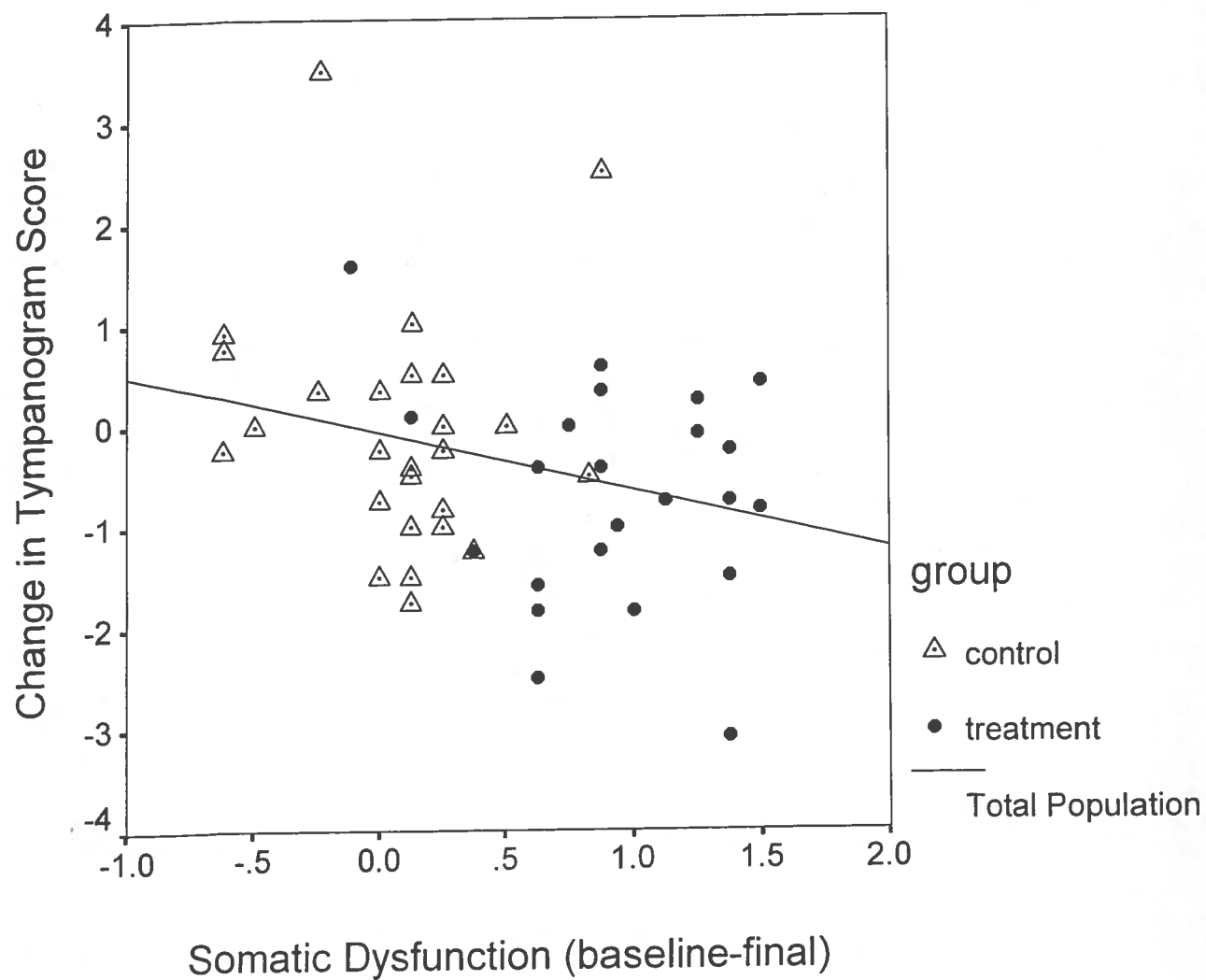


TABLE 1. Baseline Demographic Variables

	Treatment Group, n=25	Control Group, n=32
	N(%)	N(%)
Female	11 (44)	17 (53)
Day care attendance	14 (13)	16 (17)
First born	6 (11)	18 (14)
Breast fed	10 (40)	14 (44)
History of colic or spitting	9 (36)	9 (28)
Exposure to smoker, home or daycare	1 (4)	7 (22)
Exposure to indoor pet	13 (52)	11 (34)
Use of forceps or suction at birth	3 (12)	4 (13)
Age in months	26.18 (20.29)*	19.88 (13.18)
Labor length in hours	10.63 (13.65)	10.42 (14.34)

*Mean (SD) hereafter

TABLE 2. Comparison of Mean Somatic Dysfunction at Baseline and Final in Treatment and Control Groups.

	Baseline	Final	Change
Treatment (n=24)	2.27	1.35	0.92
Control (n=27)	2.37	2.30	0.07
p-value	0.326	<0.001	<0.001

TABLE 3. Comparison of Outcome Variables in Treatment and Control Groups.

	Mean Avg Change in Episodes	Mean Avg Change in Antibiotics	Mean Avg Change in Tympanograms
Treatment (n=25)	0.413	0.486	-0.61
Control (n=32)	0.238	0.269	-0.086
p-value	0.005	0.049	0.078

TABLE 4. Linear Regression of Mean Change in Somatic Dysfunction with Mean Change in Clinical Outcomes.

	Unstandardized Coefficient (B)	Standard Error	p-value
Change in Average Episodes of Otitis Media	0.09	0.06	0.13
Change in Tympanogram Scores	-0.57	0.27	0.04
Change in Average Monthly Antibiotic Prescriptions	0.12	0.11	0.26

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