A Feasibility Study of Chiropractic Spinal Manipulation Versus Sham Spinal Manipulation for Chronic Otitis media with Effusion in Children

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Background: Pediatric otitis media with effusion is a common and costly condition. Although chiropractors have anecdotally claimed success in treating otitis media, there is little research to support their claims.

Objective: A pilot study was undertaken for the purpose of assessing the feasibility of conducting a full-scale randomized clinical trial investigating the efficacy of chiropractic spinal manipulative therapy (SMT) for children with chronic otitis media with effusion. Methods: This study was a prospective, parallel-group, observer-blinded, randomized feasibility study. Twenty-two patients, ages 6 months to 6 years, received either active chiropractic SMT or placebo chiropractic SMT. Otoscopy and tympanometry were used to create a middle ear status profile, and daily diaries were collected.

Results: Five newspaper advertisements over 6 months generated 105 responses. Twenty patients subsequently qualified and were randomized into the study. Collection of tympanometric and otoscopic data proved to be challenging. Compliance with the treatment and evaluation protocols and

daily diaries was excellent. There were no reports of serious side effects as a result of either the active or placebo chiropractic treatments.

Conclusion: Recruitment for a randomized controlled trial is feasible and could be enhanced by medical collaboration. Patients and parents are able and willing to participate in a study comparing active SMT and placebo SMT. Parents were extremely compliant with the daily diaries, suggesting that similar quality-of-life and functional status measures can be successfully used in a larger trial. We found the objective outcomes assessment involving tympanometry and otoscopy extremely challenging and should be performed by experienced examiners in future studies.

From the Full-Text Article:

Discussion

The objectives of this feasibility study were to assess the ability of the study team to recruit, treat, and evaluate patients from the target population and to determine the usefulness and feasibility of the proposed outcome measures. This study demonstrated that it is feasible to recruit patients with OME through advertisement recruiting. However, for a larger study we believe other methods of patient recruitment should be used. Ideally, patients should be identified and recruited through collaborating medical practices, which would offer several advantages. First, it would aid in identification of patients with earlier-stage OME (or patients at high risk for development of chronic OME), which might be more amenable to chiropractic intervention. Second, medical collaboration would facilitate access to a more generalizable population because 15 of the participants in the pilot study had parents who were chiropractic patients and thus were possibly biased toward chiropractic. This type of bias might influence outcome measures such as symptom scores or even how the parent chooses to use medical care (which was a proposed outcome measure). Finally, medical collaboration would enhance communication between medical physicians and chiropractors, optimizing patient care. We have been successful with this form of recruitment in a pediatric asthma study and believe it would work well for a full-scale otitis media trial.

This study also demonstrated the feasibility of our study treatment procedures. Patient/parent compliance with the treatment protocol was excellent; 10 chiropractic treatment

visits over a 4-week period is a feasible and realistic commitment that can be expected of patients and parents. Patients tolerated the treatments well, with only minimal, self-limiting side effects (ie, back soreness). In addition, parents and chiropractors were willing to participate in a study with a placebo or sham treatment group, as long as patients were allowed access to regular medical care and active treatment was offered to those who received the placebo after study completion.

The feasibility study allowed ample opportunity for us to assess our ability to evaluate children with OME for the purposes of a clinical study. We have learned first-hand that accurate and reliable diagnosis of OME is critical for a study of this nature and is an acknowledged difficulty in the field of otitis media research. [29, 30] Not only is it imperative to make an accurate diagnosis to assess a patient's eligibility, but the presence or absence of effusion is an important outcome measure for OME.

Five methods typically are used to identify OME. These are history, otoscopy, tympanometry plus middle ear reflex, audiometry, and tympanocentesis/myringotomy. Each of these methods has its limitations regarding their ability to accurately identify OME.[30] Algorithms have been developed by use of a combination of some of these methods. A two-point scale algorithm developed by Paradise and tested by Cantekin et al [29, 30] uses tympanometry, otoscopy, and acoustic reflex to determine the presence or absence of effusion and has been found to have a sensitivity of 87% and specificity of 70%. More recently, a four-point profile that characterizes the condition of the middle ear has been developed by Le et al [24, 25] by use of quantitative measurements from tympanometry in combination with otoscopy (sensitivity 89%, specificity 78%). An advantage of this algorithm is that it reduces sample size requirements. Additionally, it relies on quantitative tympanometric measurements rather than qualitative classifications. Finally, information is given regarding middle ear status (graded 1 to 4) rather than presence or absence of effusion, acknowledging that the absence of effusion does not necessarily indicate absence of middle ear disease. [31, 32]

In the feasibility study, otoscopic and tympanometric evaluations were performed by two faculty clinicians trained in these methods. However, the validity of their measurements and subsequently the middle ear status profiles are limited by the fact that we were unable to confirm their diagnostic ability against myringotomy. [29, 31, 32] Given the importance of these evaluative procedures for diagnostic and outcome

purposes, it is essential that they be performed by experienced, validated individuals. These would be persons whose otoscopic and tympanometric measurements are compared with the results of myringotomy or another previously validated individual (ie, research nurse or otolaryngologist). In determining the efficacy of a treatment, outcome measures should not be limited to clinical measurements such as otoscopy and tympanometry. Other factors, such as functional, social, and monetary ones, are important aspects of the patient (and parent) experience and need to be considered.[33] Typically, randomized clinical trials on OME fail to capture patient/parent-oriented outcome measures such as functional health and quality of life. At the time the feasibility study was initiated, we were unaware of any diary that had been reliability- and validity-tested for otitis media. Thus we developed a parent diary to track medication use, medical visits, and patient symptoms. Compliance with the daily parent diary was excellent, demonstrating its feasibility as an outcome; however, its reliability and validity are as yet untested. Recently two new instruments measuring functional health status, the Otitis Media Functional Status Questionnaire and the Otitis Media Diary, have demonstrated good reliability and internal consistency for acute otitis media. [33] Future studies should explore the utility of these exciting new instruments for chronic OME. Additionally, the Play Performance Scale for Children, a valid and reliable measure of global pediatric functional status should be considered. This instrument, which is a modification of the adult Karnofsky scale, is based on the ability of the child to play and act normally and seems to be a sensitive measure of functionality in pediatric patients with acute otitis media. [33, 34]

In addition to meeting the objectives of the feasibility study, we also had the opportunity to confront other important issues in performing clinical research on OME. Future studies should incorporate a longer baseline period to ensure a relatively homogenous chronic OME population. The 1-week baseline period used in this study was insufficient to determine whether patients truly had continuous middle ear effusion for at least 8 weeks (which traditionally defines chronic OME). Additionally, a limitation of any study involving manual therapies is that the treatment provider cannot be blinded to the treatment assignment of the patient and therefore may be biased in his or her treatment approach depending on which treatment is being delivered. Although the investigators took great care in training the treating doctors to evaluate, touch, and speak to patients/parents in an identical way for both treatment groups, a limitation is that they truly do not know whether this occurred. Future studies should consider the use of video in

the treatment room, so that patient encounters may be evaluated in this regard.

Conclusion

Feasibility studies are an invaluable tool for clinical research because they allow for the identification of weaknesses and strengths before a costly and time-consuming randomized clinical trial is undertaken. This feasibility study has allowed us to assess our ability to recruit, treat, and evaluate pediatric OME, an arena previously unexplored by chiropractic researchers. We have found that recruitment for a randomized controlled trial is feasible given the methods used and could be enhanced by medical collaboration. Also patients and parents are able and willing to participate in a study comparing active SMT and placebo SMT, although further measures need to be taken to ensure that the groups are treated identically except for the SMT. Parents were extremely compliant with the daily diaries, suggesting that similar quality of life and functional status measures can be successfully used in a larger trial. Importantly, we found the objective outcomes assessment involving tympanometry and otoscopy extremely challenging and for the purposes of reliability and validity, this assessment should be performed by validated examiners in future studies.

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