Naturopathic Treatment for Ear Pain in Children

E. Michael Sarrell, MD*‡§; Herman Avner Cohen, MD*‡§; and Ernesto Kahan, MD, MPH‡§

ABSTRACT. *Objective.* **Otitis media is 1 of the most frequent diseases of early infancy and childhood and 1 of the most common reasons for children to visit a physician. In the past 2 decades, there has been a substantial increase in the diagnosis of otitis media worldwide. In the United States, 93% of all children have had at least 1 episode of acute otitis media (AOM) by 7 years of age. Otalgia is the hallmark of AOM. Most affected children either complain of earache or manifest behavior that the parents interpret as indicating ear pain. Treatment of the ear pain early in the course of AOM decreases both parental anxiety and the child's discomfort and accelerates the healing process. The objective of this study was to determine the efficacy and tolerability of naturopathic versus traditional treatment for the management of otalgia commonly associated with AOM in children.**

Methods. **The study was designed as a double-blind trial in an outpatient community clinic. A total of 171 children who were aged 5 to 18 years and had otalgia and clinical findings associated with middle-ear infection were studied. The children were randomly assigned to receive treatment with Naturopathic Herbal Extract Ear Drops (NHED) or anesthetic ear drops, with or without amoxicillin. On enrollment, the children were assigned by computer-numbered randomization to receive NHED (contents: allium sativum, verbascum thapsus, calendula flores, hypericum perfoliatum, lavender, and vitamin E in olive oil) 5 drops 3 times daily, alone (group A) or together with a topical anesthetic (amethocaine and phenazone in glycerin) 5 drops 3 times daily (group B), or oral amoxicillin 80 mg/kg/d (maximum 500 mg/dose) divided into 3 doses with either NHED 5 drops 3 times daily (group C) or topical anesthetic 5 drops 3 times daily (group D). A double-blind design was used, and all ear drops were placed in identical bottles. Treatment was initiated by the nurse in all cases. A single physician (M.S.) evaluated and treated all of the patients included in the study and recorded all of the data. The presence or absence of ear pain was assessed over 3 days with a visual analog scale. Ear pain was assessed by a specially devised observational instrument based on previous reports. One side of the instrument consisted of a linear numbered scale, from 1 (no pain) to 10 (worst possible pain), and a corresponding color scale, ranging from blue to dark red. The reverse side contained a scale of 5 facial expressions, ranging from broad smile (no pain) to a sad and crying face (worst possible pain), and a corresponding color scale, ranging from blue to dark red.**

Results. **There were no significant between-group differences in patient age or gender, degree of fever, main symptoms, associated symptoms, and severity or laterality of acute otitis media. Each group had a statistically significant improvement in ear pain over the course of the 3 days. Patients who were given ear drops alone had a better response than patients who were given ear drops together with amoxicillin. Results were better in the NHED group than in the controls. Nevertheless, the findings indicated that the pain was mostly (80%) self-limited and could be explained simply by the time elapsed. The American Academy of Otolaryngology–Head and Neck Surgery guidelines recommend topical medications as the first line of treatment for ear pain in the absence of systemic infection or serious underlying disease. Because no evidence was found that systemic antibiotics alone improved treatment outcome, if antibiotics do not change the natural course of otitis media, then the main goal of treatment, as in the present study, should be to alleviate the ear pain. The alternative, naturopathic herbal extract medications, may offer many new possibilities in the management of ear pain associated with AOM. Primary care physicians should be aware that at least 10% of their patients may have tried 1 or more forms of alternative/complementary medicine before presenting for consultation. As it was widely reported in the medical literature, these herbal extracts have the potential to meet all of the requirements of appropriate medication that could be routinely used in the pediatric patient, namely in vitro bacteriostatic and bacteriocidal activity against common pathogens, immunostimulation ability, antioxidant activity, and anti-inflammatory effects. They are also well-absorbed with good penetration into the tissue surrounding the tympanic membrane. They have been found to enhance local immunologic activity. Finally, herbal extracts are well-tolerated (owing to their long elimination time), easy to administer, and less expensive than the new antibiotics. There are no documented side effects. On the basis of our findings that the group with the most significant treatment effects (NHED with topical anesthetic) explained only 7.3% of the total pain reduction, we propose that sometimes the general practitioner or pediatrician needs to give the human body a chance to repair itself. Nevertheless, if the physician believes that there is an indication for some treatment, especially if the parents are anxious, then a local treatment such as one used in our study might be adequate.**

Conclusions. **This study suggests that in cases of ear pain caused by AOM in children in which active treatment, besides a simple 2- to 3-day waiting period, is needed, an herbal extract solution may be beneficial. Concomitant antibiotic treatment is apparently not contributory.** *Pediatrics* **2003;111:e574–e579. URL: http://www.pediatrics.org/cgi/content/full/111/5/e574;** ***ear infection, otitis, ear pain, otalgia, naturopathic, acute otitis media.***

From the *Pediatric and Adolescent Ambulatory Community Clinic of the General Health Services and ‡Department of Family Medicine, Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; and §Israel Pediatric Research in Office Setting Network, Tel Aviv, Israel.

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Address correspondence to Ernesto Kahan, MD, MPH, 7 Azarim, Apt 4, Kfar Sava 44459, Israel. E-mail: ekahan@post.ac.il

ABBREVIATIONS. AOM, acute otitis media; NHED, Naturopathic Herbal Extract Ear Drops.

Otitis media is 1 of the most frequent diseases of early infancy and childhood[1] and 1 of the most common reasons for children to visit a physician. In the past 2 decades, there has been a substantial increase in the diagnosis of otitis media worldwide. In the United States, acute otitis media (AOM) is diagnosed >5 million times per year and is the most common reason for prescription of antibiotics in children.[2]

Otalgia is the hallmark of AOM. Most affected children either complain of earache or manifest behaviors that the parents interpret as indicating ear pain.[3] Treatment of the ear pain early in the course of AOM decreases both parental anxiety and the child's discomfort and accelerates the healing process. Some physicians today prescribe topical ear drops, usually a mixture of amethocaine (anesthetic activity) and phenasone (analgesic activity) dissolved in dehydrated glycerin (hygroscopic activity).[1,4] The pain has been shown to be alleviated within 30 minutes of instillation of the drops into the external auditory canal.[4] The preparation has no known systemic effect.

In recent years, patients in the United States and Europe have been increasingly turning to unconventional medications as an alternative therapy for ear pain. However, rigorous scientific data regarding their clinical effectiveness are lacking.[5] They have been found to have analgesic, anti-inflammatory, hygroscopic, occlusive, and anti-infection properties and to lead to decompression of edematous tympanic membrane.[6] In a previous study, we demonstrated that the use of Naturopathic Herbal Extract Ear Drops (NHED; M. Pharm Co, Petah Tiqva, Israel), an herbal extract in an olive oil base, for the management of ear pain commonly associated with AOM in children is as appropriate and effective as anesthetic ear drops.[7] However, because in this evaluation none of the participating subjects received antibiotic treatment, we designed the present study with the purpose of comparing the efficacy of NHED with an anesthetic ear drop solution with and without oral antibiotics in the management of ear pain commonly associated with AOM.

METHODS

The study sample comprised 180 children who were aged 5 to 18 years and had presented at our Pediatric and Adolescent Ambulatory Community Clinic for treatment for ear pain caused by AOM between January 1999 and January 2001. The diagnosis of AOM was based on a clinical complaint of ear pain combined with a finding of middle-ear effusion, in addition to at least 1 other indicator of acute inflammation, namely, marked redness or distinct fullness or bulging of the tympanic membrane. The presence of middle-ear effusion was determined by decreased or absent mobility of the tympanic membrane on pneumatic otoscopy, opacification of the tympanic membrane for reasons other than scarring, or visible bubbles or air-fluid level behind the tympanic membrane and the "C" curve on the tympanogram. Exclusion criteria were as follows: receipt of any kind of eardrops or analgesic within 4 hours preceding the initial examination; known allergy to herbal medication, amethocaine, phenazone, glycerin, or acetaminophen; presence of otorrhea, ear drum perforation or ventilation tubes; known immunodeficiency; otologic or craniofacial malformations; complications of treated or untreated ear disease (including AOM) in the past 2 weeks; an A or B curve on the tympanic pain because A is normal and B is not always associated with AOM; and inability to use a visual analog scale.

Informed consent was obtained from 1 of the parents of all of the children eligible to participate. The study was approved by the Committee for Ethics in Human Subjects Research (the Helsinki Committee).

Study Design

On enrollment, the children were assigned by computer-numbered randomization to receive NHED containing abstracts of the herbs calendula officinalis flores (28%), hypericum perforatum herba tota (30%), and verbascum thapsus flores (25%) in olive oil and the essential oils allium sativum in 0.05% in olive oil (10%), lavandulla officinalis (5%), and tocoferol acetate oil (2%) 5 drops 3 times daily, alone (group A); together with oral amoxicillin 80 mg/kg/d (maximum 500 mg/dose) divided into 3 doses (group B); a topical anesthetic alone (amethocaine and phenazone in glycerin) 5 drops 3 times daily (group C); or topical anesthetic with amoxicillin, 5 drops 3 times daily (group D). A double-blind design was used, and all ear drops were placed in identical bottles. Treatment was started by the nurse in all cases. A single physician (M.S.) evaluated and treated all of the patients included in the study and recorded all of the data.

Instruments

Ear pain was assessed by the Pain-O-Meter, a specially devised observational instrument based on previous reports.[7] One side of the instrument consisted of a linear numbered scale, from 1 (no pain) to 10 (worst possible pain). The reverse side contained a scale of 5 facial expressions, ranging from broad smile (no pain) to a sad and crying face (worst possible pain), and a corresponding color scale, ranging from blue to dark red. The procedure is very simple. The child has only to put a pointer on the appropriate face and color, and then the corresponding number on the numerical scale is observed on the reverse side. The Pain-O-Meter used in this study was reported previously as "simple to use, readily understood by the children, and showed a realistic distribution of scores with respect to other types of pain being measured."[8]

Procedure

The same physician (M.S.) taught all parents and children in the study how to use the pain scale (using only the faces and colors). The corresponding numerical responses were recorded. Only children with a score of 3 or more at the time of diagnosis (T_{A0}) were included in the study. Each child included in the study received a bottle of drops, and the nurse initiated the treatment with 5 drops. The contents of the bottles were unknown to both the subjects and the nurse. The drops were to be administered twice more that day (every 8 hours) and then 3 more doses, every 8 hours, on each of 2 additional days. Timing of the measurement of pain was as follows: 15 and 30 minutes (T_{A15}, T_{A30}) with the help of the nurse, after the first instillation of the ear drops; thereafter, parents and patients recorded the pain evaluation at home, before the instillation in the morning (T_{B0}) and 15 and 30 minutes after (T_{B15}, T_{B30}) on day 2, and before instillation in the morning (T_{C0}) and 15 minutes after this instillation (T_{C15}) on day 3. Follow-up was done by physician interview with the parents 24 and 48 hours after treatment to evaluate changes in mean pain score. Treatment was considered successful when the child or the parents reported a reduction in ear pain after 48 hours. In the event that clinically significant otalgia persisted after 3 days, either alone or associated with fever or other signs and symptoms of infection, a reevaluation was planned to determine the need to modify treatment.

Statistical Analysis

The data were processed with SPSSWIN software, version 9.01b (Chicago, IL). χ^2 and Fisher exact tests were used to analyze categorical variables, and analysis of variance and paired t test were used for continuous variables. For performing a more powerful multivariate analysis, data were entered into a multivariate stepwise linear regression model in which the dependent variable was the change in pain level over time (from baseline to day 3) and the independent (explanatory) variables were 1) age (years); 2)

TABLE 1. Characteristics of the Study Groups

Variable	Total	NHED			Anaesthetic			*P*
		With Antibiotics Group B (n = 42)	Without Antibiotics Group A (n = 44)	Total (N = 86)	With Antibiotics Group D (n = 43)	Without Antibiotics Group C (n = 42)	Total (n = 85)	
Age (y), mean [SD]*	6.81 (3.88)	8.0 (0.62)	6.65 (0.62)	7.3 (0.44)	6.5 (0.56)	6.1 (0.54)	6.31 (0.39)	NS (t test)
Temperature (°C; N [%])								
37.5–38.4	132 (77.2)	36 (85.7)	33 (75.0)	69 (80.2)	33 (76.7)	30 (71.4)	63 (74.1)	NS (χ^2)
≥38.5	39 (22.8)	6 (14.3)	11 (25.0)	17 (18.8)	10 (23.3)	12 (28.6)	22 (25.9)	
Severity of ear pain (score; mean [SD])	2.40 (0.64)	2.43 (0.67)	2.32 (0.64)	2.37 (0.65)	2.70 (0.46)	2.19 (0.66)	2.44 (0.63)	NS (t test)
Total symptoms (mean [SD])†	2.38 (1.15)	2.41 (0.99)	2.32 (1.18)	2.36 (1.08)	2.42 (1.33)	2.38 (1.0)	2.40 (1.22)	NS (t test)

NS indicates not significant; SD, standard deviation.
* Mean age of boys is 8.9 years and of girls is 8.5 years.
† Major and associated symptoms of AOM listed individually in Tables 2 and 3, respectively.

drops (dummy variable coded NHED = 1 and anesthetic = 0); 3) mild pain (dummy variable coded mild = 1 and moderate + severe = 0); 4) moderate pain (dummy variable coded moderate = 1 and mild + severe = 0); 5) severe pain (dummy variable coded severe = 1 and mild + moderate = 0); 6) body temperature (dummy variable coded ≥38.5°C = 1 and 37.5°C–38.4°C = 0); 7) antibiotics (dummy variable coded with = 1 and without = 0); 8) number of major related symptoms; and 9) number of associated symptoms. A probability value of <.05 was considered statistically significant. To evaluate the influence of the variable "time" (alone and in interaction with the variable "group") on the variance in the level of pain, we used repeated measurements analysis at 3 time points: 1) day 1 before treatment (T_{A0}); 2) day 2 before instillation (T_{B0}); and 3) at last follow-up (48 hours after the completion of the treatment).

RESULTS

Nine of the 180 children enrolled in the study (1 in group A, 3 in group B, 3 in group C, and 2 in group D) were excluded from the final analysis because of noncompliance: 5 forgot to take the medicine, and 4 could not be reached for the follow-up interview. The remaining patients completed all 3 days of treatment. No adverse events were reported. No patient showed clinically significant otalgia, alone or associated with fever or other findings of infection, after the third day of follow-up.

The characteristics of the study groups, which are detailed in Table 1, the distribution of the main symptoms of AOM, physical examination findings, and the related symptoms (laterality, aspect, color of and presence of air in the tympanic membrane, otorrhea, cough, rhinorrhea, sore throat, headache, postnasal drip, facial pain, lymphadenopathy, malaise, and the overall number of symptoms) showed that there were no statistically significant differences among the 4 groups in clinical presentation. There was also no significant difference in pain score between the children who received NHED and those who received an anesthetic at the onset of treatment (T_{A0}). Both groups showed a significant decrease in pain by the end of the study (Fig 1, Table 2). Treatment was considered successful in the NHED group: their average total level of ear pain dropped from 8.53 at baseline to 0.56 at 30 minutes after instillation of day 2 (T_{B30}), for a reduction of 93.4%. Corresponding values in the patients who were given anesthetic were 8.44 and 1.61, for a reduction of 80.9%. By subgroup, the rates of pain reduction were as follows: NHED alone (group A), 95.9%; NHED plus antibiotics (group B), 90.9%; anesthetic alone (group

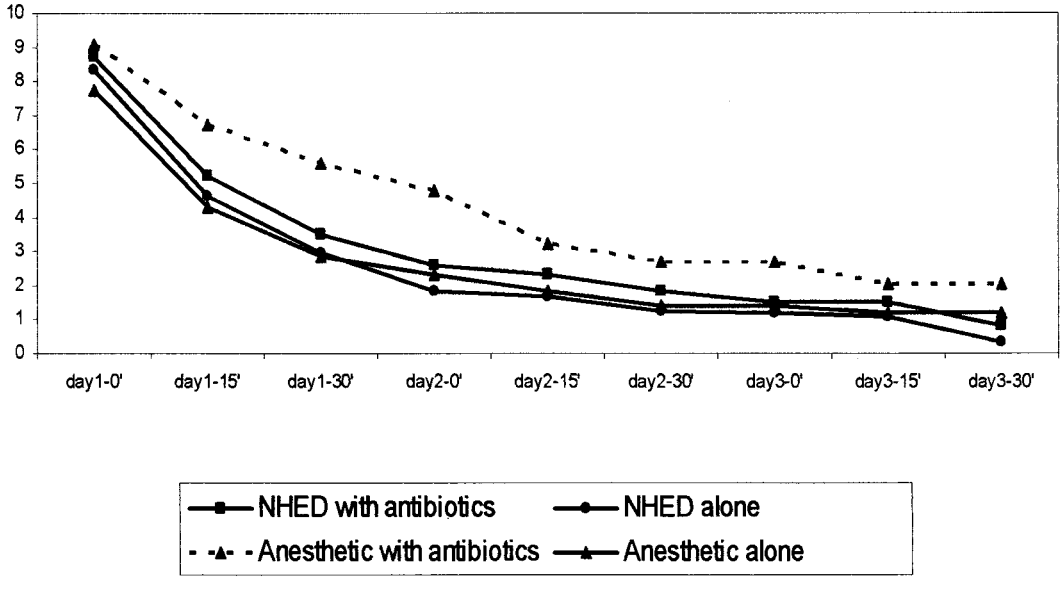

Fig 1. Level of pain (score 0–10) by study group and follow-up time.

TABLE 2. Mean (±SD) Pain Score Over Time by Group

Group	Day 1			Day 2			Day 3		
	0	15 Min	30 Min	0	15 Min	30 Min	0	15 Min	30 Min
A: NHED alone	8.4 (1.5)	4.7 (2.3)	3.0 (2.0)	1.8 (1.7)	1.7 (1.2)	1.3 (0.9)	1.2 (0.6)	1.1 (0.5)	0.3 (0.6)
B: NHED + antibiotic	8.7 (1.5)	5.2 (2.6)	3.5 (2.5)	2.6 (2.6)	2.3 (2.5)	1.8 (2.3)	1.5 (2.3)	1.5 (2.2)	0.8 (2.1)
C: Anesthetic alone	7.8 (1.9)	4.3 (2.3)	2.9 (1.6)	2.3 (1.3)	1.8 (1.1)	1.4 (0.8)	1.4 (0.6)	1.2 (0.5)	1.2 (0.5)
D: Anesthetic + antibiotic	9.1 (1.1)	6.7 (1.9)	5.6 (2.6)	4.8 (2.5)	3.3 (2.9)	2.7 (2.6)	2.7 (2.6)	2.0 (2.0)	2.0 (2.0)

C), 84.7%; and anesthetic with antibiotics (group D), 77.8%.

Analysis by time showed that the NHED group had less pain than the anesthetic group on both day 2 and day 3. The total regression model predicted 22% of the variance in pain between T_{A0} and T_{C30}. The variables found to be significant predictors of pain reduction were drops, severity (pain), and all other symptoms (Table 3).

It is noteworthy that this contribution held true even after controlling for the concomitant use of antibiotics and the variable "all other symptoms," which may explain the influence of pain from sites other than the ear. The variable "drops" explained 7.3% of the total variance. On a separate analysis of repeated measurements, "time" (3 days) proved to be very significant ($P < .001$). This analysis also demonstrated that there was an interaction between "drops" and "time."

DISCUSSION

Studies of treatment regimens for AOM are difficult to design for a number of reasons. The diagnosis is clinical as there is no objective method available to confirm it. Not all ear pain is caused by AOM. The appearance of the tympanic membrane is identical in early AOM and in otitis media with effusion, which is also a cause of ear pain. The presence of fluid in the middle ear can be determined by tympanometry and pneumatic otoscopy, but effusions are present in both AOM and otitis media with effusion. The response to treatment is difficult to measure as there is no way of objectively assessing resolution of the infection within the middle ear. Reduction of fever can be assessed objectively, but improvement in pain can be assessed only with the use of visual analog scales. In these circumstances, it is not surprising that the studies that have compared antibiotic treatment with placebo have shown only a seemingly modest response to active treatment. In addition, it is clear than AOM is a self-limiting condition.

The present study evaluated the effectiveness of a nonconventional topical medication (NHED) compared with traditional anesthetic ear drops, with and without antibiotics, in alleviating the symptoms of otitis media that are important to the patient's sense of well-being. Because pain is subjective and varies in intensity according to its source and the mechanism of relief, self-reporting is considered the most reliable means of measurement. Furthermore, children have a limited ability to describe their pain experience accurately, so we selected participants older than 5 years, although otitis media is more prevalent in the 2- to 3-year age group. We also used the Pain-O-Meter because even younger children who may not be able to cope with numerical symbols understand the concepts of more/less and higher/lower and can apply them to facial representations.[1,8,9]

The major finding of the study was the statistically significantly greater pain relief on both days 2 and 3 of treatment in the patients who were given ear drops alone than in the patients who were given ear drops and antibiotics. Nevertheless, all of the variables in our study model explained only 22% of the reduction in pain and suggested that the remaining relief may be accounted for by the passage of time alone. On repeated measurements analysis, time (3

TABLE 3. Stepwise Linear Regression Model of Change in Pain Level (Score 0–10) From Baseline to Last Follow-up

Independent Variables	B	Significance	R^2
Intercept	6.868	.0001	-
Drops†	1.218	.0001	0.073
Severity			
Mild‡	Rejected#	Rejected#	–
Moderate§	Rejected#	Rejected#	–
Severe‖	1.021	0.001	0.055
Age (y)*	Rejected#	Rejected#	-
With antibiotics	Rejected#	Rejected#	-
All related symptoms	Rejected#	Rejected#	-
Temperature¶	Rejected#	Rejected#	-
All other symptoms	−0.401	.0001	0.07

R^2 of variables in last step = 0.198; R^2 of variables not in last step = 0.022; Total R^2 = 0.22
Independent variables: * age; † drops (dummy variable), NHED = 1, anesthetic = 0; ‡ mild pain (dummy variable), mild = 1, moderate + severe = 0; § moderate pain (dummy variable), moderate = 1, mild + severe = 0; ‖ severe pain (dummy variable), severe = 1, mild + moderate = 0; ¶ fever (dummy variable), ≥38.5°C = 1, 37.5–38.4°C = 0.
Variables rejected from the model because of lack of significance ($P < .05$).

days) proved to be the most effective treatment variable; this finding is similar to a recent report from England.[10]

The minor (if any) contribution of antibiotics to pain relief noted here agrees with earlier studies of similar samples wherein antibiotics had no appreciable benefit over placebo in treating AOM[2] or in lessening its sequelae.[1,11] Two studies noted that the ear pain of AOM subsided within 3 to 4 days, with or without antibiotics.[12,13] Accordingly, meta-analyses of European and Australian studies showed only a marginal effect (1 in 20) of antibiotics on AOM.[12,14] This finding may also confirm previous reports showing that antibiotics might even interfere with the healing process in the middle-ear fluid by encouraging the growth of resistant organisms or viruses[15] or interfere with the protective mechanism of bacterial/permeability, increasing protein against mucosal changes in the middle ear, which inhibits the inflammatory activity of bacterial lipopolysaccharide.[16]

There is widespread awareness that the indiscriminate use of antibiotics in pediatric patients results in antibiotic resistance. The respective resistance rates to penicillin of *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Moraxella catarrhalis* are reportedly 58%, 50%, and almost 100%, respectively[17,18]; the increasing tendency to microbial antibiotic resistance compounds the problem.[19] Furthermore, the rates of spontaneous resolution of infection with these 3 agents are 16%, 50%, and 80%, respectively.[20] These findings have prompted the American Academy of Otolaryngology–Head and Neck Surgery to recommend topical medications as the first line of treatment for ear pain in the absence of systemic infection or serious underlying disease. They have not found evidence that systemic antibiotics alone improved treatment outcome.[21]

If antibiotics do not change the natural course of otitis media, then the main goal of treatment, as in the present study, should be to alleviate the ear pain. The alternative, naturopathic herbal extract medications, may offer many new possibilities in the management of ear pain associated with AOM. Primary care physicians should be aware that at least 10% of their patients may have tried 1 or more forms of alternative/complementary medicine before presenting for consultation.[13,22] These herbal extracts have the potential to meet all of the requirements of appropriate medication that could be routinely used in the pediatric patient,[7,23,24] namely in vitro bacteriostatic and bacteriocidal activity against common pathogens,[25] immunostimulation ability,[26] antioxidant activity,[27] and anti-inflammatory effects.[28] They are also well-absorbed with good penetration into the tissue surrounding the tympanic membrane. They have been found to enhance local immunologic activity. Finally, herbal extracts are well-tolerated (owing to their long elimination time), easy to administer, and less expensive than the new antibiotics. There are no documented side effects.

On the basis of our findings in the regression model, the use of drops (NHED or topical anesthetic) produced the most significant independent treatment effects but explains only 7.3% of the total pain reduction, whereas the use of antibiotics had no independent effect. In consequence, we propose that sometimes the general practitioner or pediatrician needs to give the human body a chance to repair itself. Nevertheless, if the physician believes that there is an indication for some treatment, especially if the parents are anxious, then a local treatment, such as the one used in our study, might be adequate.

In conclusion, this study suggests that in cases of ear pain caused by otitis media in which active treatment, besides simply a 2- to 3-day waiting period, is needed, herbal extract solution may be very beneficial. Concomitant antibiotic treatment is apparently not contributory.

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REFERENCES

1. Schechter NL. Management of pain with acute medical illness. In: Schechter NL, Berde CB, Yaster M, eds. *Pain in Infants, Children, and Adolescents.* Baltimore, MD: Williams & Wilkins; 1993:537–538
2. Hendley JO. Otitis media. *N Engl J Med.* 2002;347:1169–1174
3. Browning GG. Childhood otalgia: acute otitis media. *Br Med J.* 1990;300:1005–1006
4. Hoberman A, Paradise JL, Reynolds EA, Urkin J. Efficacy of Auralgan for treating ear pain in children with acute otitis media. *Arch Pediatr Adolesc Med.* 1997;151:675–678
5. Eisenberg DM, Kessler RC, Foster C, Norlock FE, Calkins DR, del Blanco TL. Unconventional medicine in the United States: prevalence, costs, and patterns of use. *N Engl J Med.* 1993;328:246–252
6. Ghelardin C, Galeotti N, Salvatore G, Mazzanti G. Local anaesthetic activity of the essential oil of Lavandula angustifolia. *Plant Med.* 1999;65:700–703
7. Sarrell EM, Mandelberg A, Cohen HA. Efficacy of naturopathic extracts in the management of ear pain associated with acute otitis media. *Arch Pediatr Adolesc Med.* 2001;155:796–799
8. Goodenough B, Addicoat L, Champion GD, et al. Pain in 4 to 6 year old children receiving intramuscular injections: a comparison of the Faces Pain Scale with other self-report and behavioral measures. *Clin J Pain.* 1997;13:60–73
9. Gaston-Johansson F. Measurement of pain: the psychometric properties of the Pain-O-Meter, a simple inexpensive pain assessment tool that could change health care practice. *J Pain Symptom Manage.* 1996;12:172–181
10. Little P, Gould C, Williamson I, Moore M, Warner G, Dunleavey J. Pragmatic randomized controlled trial of two prescribing strategies for childhood acute otitis media. *Br Med J.* 2001;322:336–342
11. Fiss DM, Leiberman A, Dagan R. Medical sequelae and complications of acute otitis media. *Pediatr Infect Dis J.* 1994;13:S34–S40
12. Del Mar C, Glasziou P. Acute otitis media in children. Are antibiotics always appropriate? *Aust Fam Phys.* 1998;27:83–86
13. Van Buchen FL, Peeters MF, Van 'T Hof MA. Acute otitis media: a new treatment strategy. *Br Med J.* 1985;290:1003–1007
14. Thoroe J, Lous J. Acute otitis media and antibiotics. Evidence-based guidelines for antibiotic therapy? *Ugeskr Laeger.* 1999;161:5413–5417
15. Del Cas F, Baquero-Artigao F, Garcia-Perea G. Influence of recent antibiotics therapy on antimicrobial resistance of streptococcus pneumonia in children with acute otitis media in Spain. *Pediatr Infect Dis J.* 1998;17:94–97
16. Griffin S. Protein fragment prevents mucosal damage in rat model of otitis media with effusion. *Infect Immunol.* 2000;11:2992–2994

17. Nikaido H. Prevention of drug access to bacterial targets: permeability barriers and active efflux. *Science.* 1994;264:382–388
18. Dagan R. Clinical significance of resistant organisms in otitis media. *Pediatr Infect Dis J.* 2000;19:378–382
19. Applebaum PC. Antimicrobial resistance in *Streptococcus pneumoniae*: an overview. *Clin Infect Dis.* 1992;15:77–83
20. Friedland IR, McCraken GH. Management of infection caused by antibiotic-resistant *Streptococcus pneumoniae. N Engl J Med.* 1994;331:377–382
21. Hannley MT, Denny JC 3rd, Holzer SS. Use of ototopical antibiotics in treating three common ear diseases. *Otolaryngol Head Neck Surg.* 2000; 122:934–940
22. Spigelblatt L, Laine-Ammara G, Pless IB, Guyver A. The use of alternative medicine by children. *Pediatrics.* 1994;94:811–814
23. Murray RH, Ruble AJ. Physicians and healers: unwitting partners in health care. *N Engl J Med.* 1992;326:61–64
24. Shaparenko BA, Slivko AB, Bazarova OV, Vishnevetskaia EN, Selezneva GT. Use of medicinal plants for the treatment of chronic suppurative otitis. *Zh Ushn Nos Gorl Bolezn.* 1979;3:48–51
25. Yoshida H, Katsuzaki H, Ohta R, et al. An organosulfur compound isolated from oil-macerated garlic extract, and its antimicrobial effect. *Biosci Biotechnol Biochem.* 1999;63:588–590
26. Mukherjee PK, Suresh B. The evaluation of wound-healing potential of *Hypericum hookerianum* leaf and stem extracts. *J Altern Complement Med.* 2000;6:61–69
27. Zitterl-Eglseer K, Sosa S, Jurenitsch J, et al. Anti-oedematous activities of the main triterpendiol esters of marigold (*Calendula officinalis* L.). *J Ethnopharmacol.* 1997;57:134–144
28. Atta AH, Alkofahi A. Anti-nociceptive and anti-inflammatory effects of some Jordanian medicine plant extracts. *J Ethnopharmacol.* 1998;60: 117–124

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E. Michael Sarrell, Herman Avner Cohen and Ernesto Kahan

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