

# Use of Acoustic Reflectometry for Home Monitoring of Otitis Media in a High-Risk Pediatric Population

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## Abstract

**Objective:** To evaluate use of a home ear-monitoring device to reduce medical utilization and unnecessary office visits for otitis media in young children who have frequent ear problems.

**Study Design:** Prospective study of pediatric patients aged between six months and four years who had two or more office visits for any ear complaint in the previous six months. Subjects were randomized to a study group (n = 237) or a control group (n = 256). Parents of both groups were given general information on ear infections and middle ear fluid and were instructed to follow their usual procedure for scheduling a medical appointment if they were concerned about the child's ears. Each child in the study group received the EarCheck Middle Ear Monitor and detailed instructions for its use at home. The medical charts of both groups were reviewed after one year, and the physician office and emergency department (ED) visits for ear-related concerns were counted. At the end of the study, parents of children in the study group received patient satisfaction questionnaires by mail.

**Main Outcome Measures:** 1) Number of physician office and ED visits made by children in the study and control groups for ear-related problems during the study period; 2) Self-reported parental satisfaction with the health plan's efforts to reduce unnecessary physician office visits for pediatric ear-related problems.

**Results:** Paired t tests indicated no statistically significant difference between the control and study groups in total number of visits for ear-related problems. Mean number of total ear-related visits during the study period was 3.5 for the control group and was 3.4 for the study group; standard deviation was 0.25 for each group. These results were obtained whether the purpose of the medical visit was to rule out suspected ear infection or to conduct follow-up examination after treating an episode of otitis. Patient satisfaction questionnaires were returned by 127 parents of children in the study group and showed generally high satisfaction with the EarCheck Middle Ear Monitor: 70.4% of these respondents stated that they were either satisfied or very satisfied with the product, and 75.6% of respondents stated that they would recommend the product to other parents.

**Conclusions:** Use of a home ear-monitoring device did not decrease the number of medical office visits for ear concerns among a high-risk pediatric population. However, the product was well received by parents of this population, and parents expressed high satisfaction with the purpose of the study.

## Introduction

Frequent visits to rule out acute otitis media or to verify resolution of middle ear fluid accumulation occupy a substantial number of pediatric office appointments and emergency department visits, many of which are unnecessary.<sup>1,2</sup> Clinical studies and experience have shown that acute otitis media is difficult to diagnose by symptoms alone<sup>3</sup> and is frequently overdiagnosed by parents of fussy children. To society, the cost of otitis media is huge in terms of medical costs and time lost from work for parents.<sup>4</sup> An accurate, easy home method for detecting accumulation of fluid in the middle ear could substantially reduce these costs.

Several traditional, in-clinic methods already exist for documenting accumulation of fluid in the middle ear. These methods include pneumatic otoscopy, tympanometry, and tympanocentesis.<sup>5</sup> Each of these methods has distinct drawbacks, including the need for special training, cooperation of the patient, and presence of an airtight seal in the ear canal. Reliability of each method often depends on the skill and technique of the examiner, and results can be difficult to reproduce. None of these methods can be used at home by parents.

A more recent technology using

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acoustic reflectometry has been shown successful for home parental use in detecting middle ear fluid in their children.<sup>6</sup> The device, the EarCheck Middle Ear Monitor, is a simple, painless tool that performs spectral gradient analysis of sound bounced off the tympanic membrane. Using a sensitive microphone and microprocessor to sort readings, the device rates levels of probability of middle ear effusion on a scale ranging from 1 (ie, a 3% probability of effusion) to 5 (ie, a 92% probability of effusion). Because the EarCheck Middle Ear Monitor does not require pressurization of the ear canal or an airtight seal, use of the device causes no discomfort to the child and gives results in less than five seconds. Comparative studies have shown that acoustic reflectometry is as effective as tympanometry and pneumatic otoscopy for diagnosing middle ear effusion<sup>7</sup> and has a high degree of sensitivity and specificity.<sup>8</sup>

In a recent Gallup survey sponsored jointly by The American Academy of Otolaryngology-Head and Neck Surgery and MDI instruments, Inc (manufacturer of the EarCheck Middle Ear Monitor), 80% of mothers said they would be either comfortable or very comfortable monitoring their own children for middle ear fluid at home.<sup>9</sup> Consumer studies have shown that, regardless of their educational level, parents can easily be taught how to use the EarCheck Middle Ear Monitor at home to detect middle ear fluid in their children and to take appropriate action on the basis of instrument readings.<sup>6,10</sup> Concerns that parents might misinterpret the readings or insist on phone prescriptions have proved unwarranted.

The present study evaluated the effectiveness of home ear monitoring in reducing the number of unnecessary office visits for ear-related problems in a high-risk pediatric population. We hypothesized that 1) parents would be able to successfully use the EarCheck tool at home to check for middle ear fluid in their children; 2) parents would be able to use this information in deciding when to bring the child for an office visit; and 3) parents would be less likely to bring their children to the doctor for unnecessary ear-related visits if readings were normal. We also hypothesized that this improvement in quality of care and service to our pediatric patients would result in improved parental satisfaction.

## Materials and Methods

### Study Design

Patients for this study were enlisted from the Kaiser Permanente (KP) Roseville Pediatric Department. To identify prospective subjects and to solicit volunteers for the study, informational posters were displayed in

the waiting room and in examination rooms; referrals from physicians and nurse practitioners were accepted; and medical assistants and registered nurses practicing in the clinic identified patients who met the study criteria, which consisted of the following characteristics:

- age between six months and four years;
- in the past six months, had two or more office visits for any ear complaint (including diagnosed otitis media and serous otitis media), to rule out ear infection, or to recheck otitis diagnosed previously;
- no ventilation tubes in ear;
- no facial or ear deformity;
- no chronic perforation of the tympanic membrane; and
- current patient at KP Roseville and available for follow-up.

Patients identified as eligible for the study were sent to a registered nurse in the clinic for enrollment in the study. Inservice training was provided to each participating registered nurse to ensure that they fully understood the study and to demonstrate proper use of the EarCheck instrument.

A chart of random numbers was used to randomize patients into either the study or control group. Both groups received general information on ear infections and middle ear fluid as well as a consent form to sign. Parents of patients in the control group were instructed to follow their usual procedure; ie, when parents were concerned about the child's condition, they called the clinic for an appointment to have the child's ears checked. No further instructions were provided.

Parents of patients in the study group each received an EarCheck Middle Ear Monitor for home use along with detailed instructions from a clinic registered nurse on proper use and interpretation of the information obtained from the monitor. These parents were told to use the EarCheck Monitor when their child had an upper respiratory infection and any other symptom that suggested possible ear infection. If parents obtained a reading of 1 (fluid unlikely) or 2 (monitor) for the child, they were asked to continue monitoring at home unless they noticed other worrisome symptoms (eg, high fever or cough) that might warrant an office visit. If they obtained a reading of 3 or higher (consult physician) and the child had symptoms suggestive of ear infection, the parents were told to schedule an appointment. Parents were clearly told that antibiotics would not be prescribed over the phone on the basis of EarCheck readings and that, regardless of the reading obtained, the parents could schedule an appointment

for any reason they thought necessary. Parents were asked to demonstrate use of the monitor on their own child and to confirm their understanding of the readings. Parents were also given a phone number to call the registered nurse with any questions or concerns. The consent form and study design were approved by the Kaiser Permanente Northern California Institutional Review Board.

At completion of the one-year study period, questionnaires were sent to parents of all patients in the study and control groups. Questions for the control group asked only if the parents had purchased an EarCheck Middle Ear Monitor on their own during the study period and if they thought that a home monitoring device might be helpful in deciding when to bring their child to the office to be seen for ear problems. The questionnaire contained an additional area for comments. Parents of patients in the study group responded to a group of closed-ended questions with responses given on a scale of 1 to 5. An additional area for comments was provided at the end of the questionnaire.

### Data Collection

During the enrollment period, which lasted from April 2000 through August 2000, 493 patients were enrolled in the study. Of these 493 patients, 256 were randomly assigned to the control group, and 237 were assigned to the study group and received an EarCheck Middle Ear Monitor. Each patient was then observed for 12 months, beginning at time of enrollment. No attempt was made to contact parents of patients during this time, but several parents returned to the clinic with a defective monitor or reported having difficulty using the device due to cerumen occlusion. In all cases, the registered nurse in the clinic was able to successfully resolve these problems with ear irrigation, further parental training, or a new monitor.

Blinded chart reviews were conducted by the lead author, who personally reviewed each chart to determine the reason for the office visit. Entries were cross-checked with the computer to ensure that all emergency department visits or office visits were recorded. Chart review yielded the following information:

- Total number of clinic visits and emergency department visits for ear-related problems during the study period;
- Number of visits to rule out new ear infection during the study period, and number of times the ears were normal at these visits;
- Number of visits for follow-up of a known ear

infection (ie, an ear recheck) during the study period, and number of times the ears were normal at these follow-up visits.

- Number of antibiotic prescriptions written for ear infections during the study period, including intramuscular administration of ceftriaxone.

## Results

### Review of Medical Charts

Of the 492 enrolled patients, 454 patients (55.1% male, 44.9% female) completed the study. Of the control group, 13 patients were removed from the study because tubes were placed, and six patients were removed from the study because their Health Plan membership was terminated (eg, due to a move from the Health Plan service area); in addition, one patient died of a neuroblastoma and was therefore removed from the study. In the study group, 24 patients were removed from the study because tubes were placed, and five additional patients moved or for another reason lost Health Plan coverage. The gender of the patients was approximately equal. Of the 452 patients who completed the study, 52.6% were aged 1 to 2 years, 31.3% were aged 6 to 12 months, 11.4% were aged 3 to 4 years, and 5% were aged 4 to 5 years.

Results of paired t tests indicated no statistically significant difference between control and study groups in total number of visits for ear-related problems. The mean number of ear-related visits during the one-year study period was 3.5 for the control group and was 3.4 for the study group (standard deviation 0.25 for each group). The mean number of office visits for suspected ear infections (ie, not for ear recheck) was 2.71 for the control group and was 2.69 for the study group (standard deviation 0.18 for the control group, 0.19 for the study group). The mean number of visits for ear recheck during the same period was 0.8 for the control group and was 0.67 for the study group (standard error 0.1 for the control group, 0.08 for the study group). The number of prescriptions for antibiotic drugs was similar: the control group had a mean of 1.8 antibiotic prescriptions written per patient, and the study group had a mean of 1.9 antibiotic prescriptions written per patient. Additional statistical analyses were performed (pooled t test, Satterthwaite t test, and folded F test) with no statistical difference between the control and study groups for each category.

### Patient Satisfaction Questionnaires

In addition to evaluating appointment utilization, this study also examined patient satisfaction with the

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EarCheck Monitor in terms of several criteria: overall satisfaction with the product; ease of use; comfort with making decisions based on readings; improved understanding about ear infection and the need for antibiotic therapy; and cost. A total of 127 (53.5%) questionnaires was received from parents of the 237 patients in the study group. Results of the questionnaire suggest that parents were generally satisfied with the home EarCheck Monitor and found it useful. Most parents were either very satisfied or satisfied with the monitor overall (70.4%) and with its ease of use (70.1%). The training provided for using the monitor was satisfactory to 95.3% of respondents.

All but nine parents stated that they had used the monitor during the study period, and 76.7% stated that they were either comfortable or very comfortable making decisions about their child's ear problems on the basis of the information provided by the EarCheck Monitor. Parents expressed mixed feelings about whether they believed the EarCheck Monitor reduced the number of office visits for their child: 63.3% stated that they strongly agreed or agreed, 17.5% stated that they were unsure, and 19.2% stated that they disagreed or strongly disagreed.

Similarly, parental opinions varied as to whether the study improved understanding of middle ear infection: 66.9% of parents stated that they strongly agreed or agreed, 15% stated that they were unsure, and 18.1% stated that they disagreed that the study improved their understanding of ear infections. Similar results were obtained from parents when they were queried about whether the study improved their understanding of when antibiotics were needed for their child's ear problems. Overall, most parents (75.6%) stated that they would either highly recommend or recommend this product to other parents. Most stated their belief that the retail price of the monitor (\$110) was excessive and that they would be willing to pay \$40 to \$50 for a home ear monitor.

## Discussion

### Utilization of Medical Office Resources

This study evaluated use of a home ear monitoring device to reduce the number of office visits in a high-utilizing population of children: those younger than five years who had two or more ear-related medical visits in the preceding six months. The findings did not support the hypothesis that parents with a home ear-monitoring device were less likely to bring their chil-

dren for office and emergency department visits because of ear-related concerns. No statistical difference was seen between the control and study groups in total number of ear-related visits during a one-year period, number of new office visits, number of rechecks for known ear infection, or number of antibiotic prescriptions written.

Several explanations for these findings are possible. First, many parents stated they needed the reassurance of a doctor's assessment despite the readings on the EarCheck Monitor. Some parents did not trust the monitor readings; other parents had difficulty obtaining consistent readings. Many parents believed simply that visual examination was needed if they suspected ear infection. Moreover, other than the requirement of making a small copayment at each visit, parents had no substantial disincentive to making an appointment. Fewer parents of patients in the study group might have scheduled visits if the copayment had been higher or if the parents had not been members of a Health Plan.

In addition, many parents of patients in the study group brought their children for "ear-related visits," regardless of the EarCheck readings, because these parents were concerned about comorbid conditions (eg, purulent nasal discharge, cough, or fever). All parents were encouraged to schedule appointments, regardless of readings, when worrisome symptoms were apparent. Another limitation was the small sample size, which reduced our level of confidence in the study results. A larger study might have revealed statistically significant differences, particularly if the cost savings to patients was greater.

### Patient Satisfaction Surveys

Despite the finding that office visits were not fewer in the study group than in the control group, the EarCheck Monitor was definitely popular with parents. Most parents were satisfied with the EarCheck Monitor and believed that it provided useful information. Parents also appreciated the effort made to reduce the number of unnecessary visits to the urgent care clinic or emergency department. Many parents stated that the monitor provided some sense of control when they had an irritable child who might or might not have an ear infection.

A sample of comments from parents provides a good example of patient satisfaction with the EarCheck Middle Ear Monitor:

*"The product was great. It stopped me a few times from an unneeded doctor visit. My child would be cranky or pulling at his ears, and it would end up be-*

ing nothing. The monitor would tell me to monitor my child, so I wouldn't go to the doctor."

"My child had numerous ear infections—the EarCheck confirmed my suspicions, and we were able to get her treated earlier. It's great!"

"I don't think it reduced the visits, but it gave me a better understanding of ear infection versus a cold. It confirmed that I needed to go [for a visit]."

"It was great to be able to check to see if fluid was present when my son had a cold. It saved me countless trips to the doctor just for an ear check."

"The EarCheck is a wonderful invention! It was accurate every time and is a wonderful diagnostic tool for any parent. It eliminates any guessing about fluid in the ears. More than once, it definitely kept us from making ear check appointments."

"I would recommend the EarCheck Monitor to anyone with a child. It saved me many times wondering if there was infection or not. Thank you!"

"I appreciate this study and have used this monitor a lot. I even let my daycare provider borrow it for her own children and for others at daycare." ❖

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## Being Better

He who stops being better, stops being good.

*Oliver Cromwell, 1599-1658, Lord Protector of England*