ORIGINAL ARTICLE

Consumer acoustic reflectometry by parents in detecting middle-ear fluid among children undergoing tympanostomy

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Abstract

Objective. This study aimed at evaluating the diagnostic accuracy of a consumer model acoustic reflectometer in the hands of parents in the detection of middle-ear fluid among children. **Design.** Prospective diagnostic study according to STARD guidelines. Acoustic reflectometry recorded by the parents was compared with otomicroscopic myringotomy with suction in general anaesthesia, performed immediately afterwards. **Setting.** Secondary care (Kanta-Häme Central Hospital, Finland). **Patients.** Pre-school (<7 years) children undergoing otomicroscopic myringotomy due to recurrent acute otitis media or suspicion of glue ear. **Main outcome measures.** Sensitivity, specificity, and positive and negative predictive values of acoustic reflectometry. **Results.** Consumer model acoustic reflectometry performed by parents reached sensitivity of 94% (95% confidence interval 88–100%) and negative predictive value of 92% (83–100%) with result 1 (green colour) on a scale of 1–5. On the other hand, the method was not very specific and positive predictive value was poor. **Conclusions.** The negative screening result was very reliable. Thus, home screening of otitis among otitis-prone children and home follow-up of resolution of middle-ear fluid afterwards deserves to be studied in the home setting in the future.

Key Words: *Acoustic reflectometry, diagnosis, middle-ear fluid, otitis media, sensitivity, specificity*

Acoustic reflectometry (AR) is a method of assessing the probability of middle-ear fluid (MEF) by an instrument emitting a sound frequency spectrum sweep to the tympanic membrane and analysing the intensity and frequency spectrum of the reflecting sound [1]. The acoustic reflectometer is a small, lightweight, and cordless instrument, the tip of which is inserted at the end of the ear canal and directed towards tympanic membrane during recording, which takes approximately five seconds. It is generally easy to perform and has a high success rate even among crying and struggling children [2], suggesting a possibility for home usage by parents. Newer second-generation acoustic reflectometry (SG-AR) has been proved to be comparable to tympanometry in detecting MEF among children younger than two years [3]. In our previous study [4], SG-AR in the hands of nurses reached a sensitivity and specificity of 96% and 87% among children. Home monitoring with AR was studied by Barnett et al. [5]: parents were able to obtain valid

Prior to the present study, the diagnostic capability of a consumer model acoustic reflectometer has not been validated in the hands of layman consumers, e.g. parents.

- Negative screening result obtained by parents, indicating healthy ear, proved to be very reliable.
- Home screening of middle-ear fluid among otitis-prone children could be applicable in the future, if the results of this study can be later confirmed in the home setting.

readings in 80% of attempts. The professional SG-AR model used in the above-mentioned studies was followed by a consumer model. Block et al. demonstrated that parents are capable of using the consumer AR device, taking accurate readings, and interpreting them [6]. Moreover, the AR readings made by parents showed good concordance with those obtained by trained nurses. In our recent

paper, the consumer model SG-AR and professional SG-AR performed equally well in the hands of otolaryngologists in detecting MEF among children [7]. However, to our knowledge no reports evaluating the diagnostic properties of the consumer model AR in the hands of laymen (i.e. not healthcare professionals) have been published.

Our aim was to evaluate the diagnostic accuracy of the consumer model AR in the hands of parents in detection of MEF among pre-school children. If the method proved to be reliable in the hands of parents, it would encourage future studies in the home setting.

Material and methods

Patients

A total of 78 consecutive pre-school (<7 years) children referred from primary care for ambulatory myringotomy with ventilation grommet insertion due to recurrent AOM or suspicion of glue ear in Kanta-Häme Central Hospital, Hämeenlinna, Finland, between September 2007 and February 2008 were asked to participate in the study. In Finland, recurrent AOM episodes (>3 in six months or >4 in a year) and persistence of MEF for longer than three months are considered indications for referral. Parents of two (3%) children refused to give informed consent. Two children (3%) did not allow their parents to perform the AR recording, resulting in a total study population of 74 children (148 ears). Patient flow is presented in Figure 1. All recruited patients were examined, treated, and included in the analyses as planned. Kanta-Häme Central Hospital is a secondary referral center covering a population of approximately 170 000. Practically all children from the area requiring ambulatory otolaryngological surgery are referred from primary care and treated at the centre. No exclusion criteria were used apart from age.

Consumer model acoustic reflectometry

Before surgery, one of the parents performed the AR recording with the Ear Check™ Middle Ear Monitor consumer model acoustic reflectometer (MDI Instruments Inc., Woburn, MA, USA. At the time of writing, the Ear Check™ trademark was owned by Innovia Medical, Lenexa, KS, USA) with the child sitting upright in a parent's or nurse's lap. The operating principle, use, and interpretation of results were briefly explained, the actual device and its user interface were presented, and a demonstration (one recording from one ear of the child) by a physician was given. The whole process took approximately five minutes, though it was not timed.

The consumer model SG-AR device presents the result as categorically growing risk of MEF (1 to 5).

Figure 1. Flow chart of the patients and their acoustic reflectometry (AR) recordings in the present study: Percentages calculated both among successful AR recordings and among all studied ears.*

This result is also simplified to trichotomized, colour-coded classification (1 = green, "Fluid unlikely", 2 = yellow, "Monitor", 3–5 red, "Consult doctor"). These results correspond to consumer instructions of "Healthy ear, no visit to doctor necessary", "Uncertain finding, repeat the recording later", and "Fluid likely, visit to doctor necessary", respectively (phrasing by authors). The device gives an error signal when it cannot obtain a valid reading (e.g. if the ear canal is blocked or the tympanic membrane is perforated). In the case of an error sign in the first recording, the ear was examined up to three times. The parent then logged the AR result obtained (1–5 or error) and its interpretation (see consumer instructions above), simulating the situation at home, on a structured form in which the AR result was ticked in a 1:1 scale colour picture of the user interface of the device. The form was put into an envelope which was sealed, to be opened after the study was finished. A physician was present but blinded to the AR result and interpretation. Time interval between the AR recording and myringotomy was three hours maximum.

Statistical methods

Sensitivity (ability to find true positives and avoid false negatives), specificity (ability to find true negatives and avoid false positives), positive (PPV)

(probability of MEF when test positive), and negative predictive value (NPV) (probability of healthy ear when test negative) of the AR made by the parents in detecting MEF were calculated with their respective 95% confidence intervals using otomicroscopic myringotomy in general anaesthesia with glass tip suction as the reference method of assessing the presence of MEF. Any amount of secretion present was considered positive for MEF. In order to evaluate the diagnostic properties of both green (AR 1) as test negative and red (AR 3–5) as test positive, two separate dichotomizations were necessary: in one, findings “in between” (yellow, AR 2) were regarded as test negative, and in the other test positive. The correlation of the AR recording obtained by the parents (1–5 or error) and her or his interpretation of it was evaluated descriptively (percentage agreement). A chi-squared test was used to test for differences in categorical data. The study was designed and executed according to the STARD recommendations [8].

Results

Mean age of the patients was 37 months (range 10–76), 42 (57%) were boys. MEF was present in 57 (39%) ears in otomicroscopic myringotomy. No cases of retracted tympanic membranes (negative middle ear pressure) without MEF were encountered on otomicroscopy. However, this may be due to mask ventilation during general anaesthesia which causes positive pressure in the middle ear, inflating the ear drum. The AR results achieved by the parents are presented in Table I. The recording failed (error signal) in 27 (18%) ears, resulting in a total of 121 ears (82%) with interpretable reading and, thus, eligible for specificity and sensitivity analyses (see Figure 1). The error frequency was

higher among small children (29% vs. 13% among children $<$ and $\geq$ 2 years, $p = 0.017$).

The sensitivities, specificities, and positive and negative predictive values of AR made by parents are presented in Table II. Taking the colour red (AR result 3–5) as test positive yielded a specificity of 85% and PPV of 79%. With this dichotomization, sensitivity was 72% and NPV (green and yellow, AR 1–2) 79%. Among older children (≥ 3 years), positive test result (red, AR 3–5) had better diagnostic accuracy (specificity 88%, 95% CI 76–100; PPV 90%, 95% CI 79–100). In the whole study population, green alone (AR 1) as test negative gave a sensitivity of 94% and NPV of 92%. With this dichotomization, specificity and PPV (red and yellow, AR 2–5) were not good (Table II). The interpretation of the AR result by parents was correct in all but one (99%) recording.

Discussion

Summary of main findings

The consumer model AR in the hands of parents reached a sensitivity of 94% and negative predictive value of 92% with AR result 1 (green) as test negative in detecting MEF among children facing tympanostomy due to recurrent acute otitis or suspicion of glue ear. In other words, among test-negative ears only 8% were false negatives. Specificity and positive predictive values were modest regardless of the cut-off point used. Positive test (red, AR 3–5) found 67% of ears with MEF, but 21% of the test-positive ears were healthy.

Comparison with existing literature

The present study is the first attempt to evaluate the diagnostic accuracy of a consumer model AR in the hands of layman parents in detecting MEF among

Table I. Consumer model acoustic reflectometry (AR) results achieved by parents when screening for middle-ear fluid (MEF) among pre-school children (< 7 years), categorized by middle-ear status.¹

AR test result according to manufacturer-stated risk groups of MEF	AR result categorized (1–5) as growing risk of MEF	Middle-ear status ¹	
		MEF ²	No MEF
Red colour code, “Consult doctor”	5 (n = 28, 19%)	24 (86%)	4 (14%)
	4 (n = 11, 7%)	7 (64%)	4 (36%)
	3 (n = 9, 6%)	7 (78%)	2 (22%)
Yellow colour code, “Monitor”	2 (n = 35, 24%)	12 (34%)	23 (66%)
Green colour code, “Fluid unlikely”	1 (n = 38, 26%)	3 (8%)	35 (92%)
Error ³	(n = 27, 18%)	4 (15%)	23 (85%)
Total	(n = 148)	57 (39%)	91 (61%)

Notes: ¹Otomicroscopic myringotomy and suction in general anaesthesia. ²Mucous (glue ear) in 47 (82%), serous in 9 (16%), purulent (acute otitis media) in 1 (2%). ³Error explained by otomicroscopy in five (19%) cases: two patent grommets, one tympanic membrane perforation, two ear canals blocked by cerumen.

Table II. Sensitivity, specificity, and positive and negative predictive values of consumer model acoustic reflectometry (AR) in hands of parents in detecting of middle ear fluid (MEF) among pre-school (< 7 years) children using two different cut-off points.

AR test results according to manufacturer-stated risk groups of MEF (and AR scores)	Sensitivity% (95% CI)	Specificity% (95% CI)	Positive predictive value PPV% (95% CI)	Negative predictive value NPV% (95% CI)
Red ¹ colour (3–5) vs. Yellow ² and green ³ colour (1–2)	72 (59–84)	85 (77–94)	79 (69–90)	79 (70–89)
Red ¹ and yellow ² colour (2–5) vs. Green ³ colour (1)	94 (88–100)	51 (39–64)	60 (49–71)	92 (83–100)

Notes: CI = confidence interval. ¹High probability of middle-ear fluid. Categories 3–5 in Ear Check Middle Ear Monitor™, “Consult doctor”. ²Moderate probability of middle-ear fluid. Category 2 in Ear Check Middle Ear Monitor™, “Monitor”. ³Low probability of middle-ear fluid, healthy ear. Category 1 in Ear Check Middle Ear Monitor™, “Fluid unlikely”.

children. In two previously published studies on home monitoring of children with AR, one used a professional model device and the parents were healthcare professionals [5], and the other concentrated on consumer usage issues such as technical success rate of AR recordings and persistence of results between consecutive recordings, but did not report any parameters of diagnostic performance [6]. When compared with results gained with the consumer model AR by otolaryngologists [7], diagnostic accuracy by parents in this study was similar but the error frequency higher (18% vs. 9%). This was expected, since physicians instinctively know in what direction to point the instrument and how to “open” the ear canal by retracting the ear lobe. The technical success rate reached in the present study is in line with the results of Barnett et al. [5], even though parents in that study were nurses and doctors. In our study, the parents’ interpretation of the AR result was almost flawless. This is in agreement with Block et al. [6].

Strengths and limitations of the study

The recordings with the consumer model AR were performed by layman parents of child patients. The AR was blinded, i.e. the otolaryngologist performing myringotomy and evaluating the presence of MEF was not aware of the AR result. Dropout rate was low: among the children fulfilling the inclusion criteria 95% were examined.

The parents were unfamiliar with the AR device and received only a short tutorial on its use. The actual recording included in this study was therefore their first attempt to use the device. Despite this, practically all AR recordings were interpreted correctly – thus, the consumer model AR device seems to be easy to master. The children studied were facing general anaesthesia and surgery soon afterwards. Perhaps the recording would be easier to perform and thus the success rate of AR better, when performed at home, where the child is relaxed and the parents can repeat the AR freely. On the other hand, performance by parents could also be better in

hospital immediately after guidance by medical personnel compared with home recording. In our patient series, MEF was caused mainly by chronic glue ear or serous otitis media, not AOM as would be normally the case when screening sick children with upper respiratory infection symptoms in primary care or at home. Thus, the results of this study should be generalized to detection of glue ear and to following-up of resolution of MEF after AOM rather than to detection of AOM at sick visits. The incidence (i.e. pre-test probability) of MEF in this study was higher than would be expected among an unselected child patient population with upper respiratory infection symptoms [9]. Therefore, the PPV is probably an overestimate of the true value. Middle ear infections are often binaural, and therefore the decision to study individual ears may affect the statistics of this study to some extent. However, our aim was to evaluate the method, i.e. the ease of use of the device in the hands of parents and the reliability of the recording rather than to form recommendations for practical use, in which case the use of “patients” instead of “ears” as statistical units would have been appropriate.

Implications for clinical practice and future research

General practitioners welcome easy, quick, and reliable near-patient tests for distinguishing common infections, if there were research evidence supporting them [10]. In home screening of MEF by parents good sensitivity and good negative predictive value would be in key position. In this study, where parents screened their children for MEF in hospital, sensitivity and NPV were excellent. This encourages future research on the consumer model AR in screening of MEF by parents in a true home setting.

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Ethical approval

This study was approved by the Ethical Committee of Kanta-Häme Central Hospital.

Conflicts of interest

The authors have no financial, personal, or other conflicts of interest regarding this work.

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