

Does pneumatic otoscopy improve the diagnostic accuracy
of otitis media with effusion in clinical practice?

A randomized single-blind control trial

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ABSTRACT

The study objective was to determine whether pneumatic otoscopy would improve the diagnostic accuracy of otitis media with effusion (OME) in clinical practice over otoscopy only. A randomized single-blind control trial was undertaken in 30 pediatric residents. Residents were randomized into pneumatic otoscopy (intervention) or otoscopy-only (control) groups. Both study groups received one hour of theory on OME; the intervention group also received a 30-minute teaching session that included both video-otoendoscopic examination (VOE) pneumatic assessments and one practice session. Each resident examined 10 ears and made a diagnosis of either normal or OME ears. Tympanograms were considered as the gold standard. The percent correct diagnoses in the intervention and control groups were 60% and 59%, respectively ($p = 0.85$).

In conclusion, pneumatic otoscopy did not significantly improve the diagnosis of otitis media with effusion in clinical settings. Further studies are needed to confirm these findings.

RÉSUMÉ

L'objectif de l'étude était de déterminer si l'apprentissage et la formation portant sur l'otoscopie pneumatique pouvaient augmenter la précision du diagnostic de l'otite moyenne séreuse (avec épanchement) en pratique clinique. Une étude de contrôle, à sélection aléatoire, à simple insu, a été entreprise auprès de 30 résidents en pédiatrie de l'Université McGill. Les résidents ont été affectés de façon aléatoire, soit au groupe d'otoscopie pneumatique (groupe d'intervention), soit au groupe d'otoscopie uniquement (groupe témoin). Les deux groupes de l'étude ont suivi un cours théorique d'une heure portant sur l'otite moyenne séreuse (avec épanchement). Le groupe d'intervention a également pris part à une séance d'enseignement de 30 minutes, y inclus une évaluation de l'examen otoendoscopique avec système vidéo et de l'otoscopie pneumatique et une séance d'entraînement. Chaque résident devait examiner 10 oreilles et poser un diagnostic, soit de normalité, soit d'otite moyenne séreuse (avec épanchement). Le tympanogramme a été utilisé comme norme d'excellence. Le pourcentage de diagnostics justes dans les groupes d'intervention et de témoin était de 60 % et de 59 % respectivement ($p = 0,85$). En conclusion, l'otoscopie pneumatique n'a pas augmenté la précision du diagnostic de l'otite moyenne en pratique clinique.

ABBREVIATIONS

OM	otitis media
AOM	acute otitis media
OME	otitis media with effusion
MEE	middle ear effusion
TM	tympanic membrane
PGY	postgraduate year
VOE	video-otoendoscopic-examination

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CHAPTER I: INTRODUCTION

1.1 Otitis media with effusion (OME)

Otitis media (OM) is defined as an inflammation of the middle ear space. OM is a term that encompasses acute otitis media (AOM) and OME [1, 2]. OME is defined by the presence of middle ear effusion (MEE) behind an intact tympanic membrane (TM) without signs or symptoms of acute infection [1, 2] (Figure 1).

The effusion may be serous, mucoid, purulent, or a combination of these. [3]



Figure 1: OME, oto-endoscopic view of the TM demonstrating MEE

Persistent middle-ear fluid from OME results in decreased mobility of the tympanic membrane and serves as a barrier to sound conduction.[4, 5]

OME is one of the most frequent pediatric diagnoses and one of the most common indications for surgical intervention in the 1-18 year age group [6, 7]. OME may occur spontaneously because of poor Eustachian tube function or as an inflammatory response following AOM. More than two million cases of OME are diagnosed annually in the United States [8]. At least 80% of children will experience one episode or more of OME by age of 3 years [9, 10]. OME is also characterized by a high rate of recurrence, a recurrence rate of 50% was found within 24 months [9]. The median duration of OME in the first 2 years of life is estimated to be 58 to 72 days per year, 15%-20% of a child's life, which represents significant morbidity [9, 11]. Children with OME suffers up to 5 times more episodes of acute infection (AOM) compared to those without OME, and in 50% of cases the effusion directly follows an episode of AOM [12]. MEE persists for one month in 30% to 50% of children, for 2 months in 15% to 25%, and for 3 months in 8% to 15% [11, 13]. Antibiotic treatment has a negligible effect on the long-term resolution of MEE [14-16]. The treatment of persistent OME, which is considered as at least 3 months, is surgical insertion of tympanostomy tubes otherwise known as pressure equalization or ventilation tubes. Tympanostomy tubes permit fluid drainage and aeration of the middle ear and have been shown to reverse sequelae of OME [3, 17].

1.2 Sequelae of untreated OME

Untreated OME causes hearing impairment with potential subsequent delay in speech and cognitive development, especially in young children [18, 19]. Several large prospective studies show that 70% of children with persistent OME suffer mild to moderate conductive hearing loss (15-50 dB averaged across 500-4000 Hz, which is an important frequency range for speech perception) [18, 19]. Poor discrimination of short, similar sounds such as “da” and “ta” was affected in children with OME. Expressive language skills and poor attention were also reported.

Recent studies document effects of OME on balance and the vestibular system. Up to 50% of children with OME might have balance disturbances [20-24]. In a prospective cohort study of children followed from 2 to 7 years of age that was designed to obtain normative developmental data and to assess the effect of MEE on vestibular, balance function, and motor development, a total of 149 children were enrolled and 82 have completed testing at the 4-year point. For all enrolled children, middle ear status was assessed every 4 to 6 weeks using otoscopy, tympanometry, and audiometry. Also, vestibular, balance, and motor function testing {namely the vestibulo-ocular (rotational) and vestibulo-spinal (moving platform posturography) testing} was performed yearly, and was repeated if the child developed MEE or required insertion of tympanostomy tubes. When compared with children with a negative history of significant MEE, children with a positive history had a lower average gain to a rotational stimulus

of 0.1 Hz, 150°/s (0.57 vs. 0.44; $P = .007$). There were no significant differences between groups with respect to other measures. These results suggest that a history of recurrent or persistent MEE affects the vestibular and/or balance function of 4-year-old children when tested in the absence of a concurrent episode of MEE [20], which might have developmental consequences. Children may become clumsy and prone to accidents or falls leading to injury [22]. Abnormal balance and vestibular tests that were documented during OME normalized after the insertion of tympanostomy tubes [23, 25].

In addition, persistent OME may cause atelectasis or retraction pockets of the TM, TM perforation, and cholesteatoma formation. A cholesteatoma is an abnormal growth of squamous epithelium in the middle ear and mastoid [26, 27]. The mechanism of developing a cholesteatoma secondary to OME is hypothesized to be due to squamous metaplasia of the middle ear cuboidal epithelium into keratinizing epithelium [28, 29]. This theory is supported by demonstrating that biopsy specimen from middle ear of children with OME sometimes contains islands of keratinizing epithelium. [29]

Rarely, OME causes facial nerve paralysis, destruction of ossicular chain, and intra-cranial complications. These intracranial complications may result from either from chronic inflammation, secondary infection of the MEE, or as a consequence of cholesteatoma formation. Meningitis, otitic hydrocephalus, sigmoid sinus thrombosis, and epidural, subdural, and brain abscess formation have been reported [30, 31].

1.3 OME Diagnosis

Diagnosis of OME is difficult as there are few presenting symptoms. Unlike AOM, fever and pain are absent, and only minimal hearing loss or feeling of a blocked ear might be present [32-34]. Physical examination of the TM might be the first clue to the physician to detect MEE and hence diagnose OME.

MEE causes changes in the TM that directly and indirectly indicate its presence. The chinchilla has been used as an animal model to understand the pathogenesis of OME and changes in the TM that occur as a consequence of MEE [35-39]. The TM normally is convex, mobile, translucent, and intact. MEE causes the TM's color to change into amber and become opaque obscuring the view of normally viewed middle ear structures. The effusion also impairs TM mobility either by direct mass effect or by causing stiffness in the TM.

1.4 The need for improving OME diagnosis

Accurate diagnosis of OME has been at the forefront of educational needs of the twenty first century with the release of the latest guidelines developed by the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Academy of Otolaryngology-Head and Neck Surgery [2, 8, 40]. Particular attention was paid to the diagnosis of OME and differentiating it from AOM, especially in the era of increasing bacterial resistance and subsequent need to reduce unnecessary exposure to antibiotics [13, 17, 41]. AOM requires antibiotic treatment while antibiotic treatment has a negligible effect on OME [14-16]. The Center for Disease Control (CDC) has identified improvement in

otoscopy skills as a key intervention to curb inappropriate antibiotic usage [42]. Pediatricians and primary care physicians are required to diagnose OME on a nearly weekly basis and their ability to diagnose OME should be similar to otolaryngologists especially in the context of watchful waiting approach to referral and treatment. Yet, recent studies show that the median score for correct diagnosis of OME among general practitioners is only 53 % [43] and that physicians have difficulty in successfully diagnosing a normal TM [44, 45]. Pichichero et al compared the diagnosis of OME and AOM among general practitioners, pediatricians, and otolaryngologists [46]. Using video-based examinations involving nine test ears, otolaryngologists made correct diagnoses in 70% of the time while pediatricians were 50% correct and general practitioners were 45% correct.[46] Similar results were found in United States, South Africa, and Greece. These results highlight the need for additional training and education of primary care providers.

1.5 Diagnostic tools for OME

OME is difficult to diagnose by standard otoscopy alone and an adjunctive tool should be used to improve diagnostic accuracy [43]. Various tools have been proposed for the diagnosis of OME other than otoscopy in order to improve diagnostic accuracy. These include tympanocentesis, myringotomy, acoustic reflectometry, micro-otoscopy, tympanometry and pneumatic otoscopy.

1.5.1 Myringotomy and tympanocentesis

Myringotomy (incision of the TM) and tympanocentesis (aspiration of MEE) are the ultimate diagnostic indicators for presence of MEE. Tympanocentesis is reserved for cases of acute infection (AOM) not responding to antibiotic treatment, testing the aspirated MEE to determine the specific causative bacterial pathogen and to detect bacterial resistance to antibiotics if present. Myringotomy is not proven to be sufficient treatment for OME and therefore a one shot diagnostic and therapeutic approach cannot be achieved [47]. Although performed under local anesthesia, it is not routinely used for OME diagnosis in clinical practice because of its invasive nature.

1.5.2 Acoustic reflectometry

Acoustic reflectometry performs spectral gradient analysis of sound reflection off the TM. Using a sensitive microphone and microprocessor to sort readings, the device rates levels of probability of MEE, and hence OME, on a scale ranging from one (i.e., a 3% probability of effusion) to five (i.e., a 92% probability of effusion). The sensitivity and specificity of acoustic reflectometry to detect OME vary from 54% to 94% and from 58 to 83%, respectively [48]. Acoustic reflectometry allows for noninvasive testing that is not affected by the presence of cerumen or by the child crying. The device is easy to use but difficult to implement with children and has not been widely accepted in clinical practice [48-50]. Acoustic reflectometry is slightly less discerning than tympanometry in predicting the presence or absence of MEE in children [51].

1.5.3 Micro-otoscopy

The development of micro-otoscopy revolutionized the field of Otolaryngology. Micro-otoscopy refers to the use of optical (or light) microscope, which uses visible light and a system of lenses to magnify TM image. Micro-otoscopy provides a magnified TM image, which enhances visualization of subtle TM changes in cases of OME and even better detection of MEE, bubbles or air-fluid level. Recent prospective studies showed that oto-microscopy is more sensitive and specific compared to pneumatic otoscopy and tympanometry, in detecting MEE, suggesting that otomicroscopy might become the standard tool to diagnose OME in children [47, 52, 53]. A recent study of 151 ears comparing pneumatic otoscopy and oto-microscopy to myringotomy under local anesthesia as the gold standard, showed that otomicroscopy had a higher sensitivity (98.5%) and specificity (80%) compared to pneumatic otoscopy (93.8% and 40% respectively) [53]. In another study of 135 ears with 52.6% having MEE, the positive and negative predictive values of otomicroscopy for the identification of middle ear effusions were 94.4% (95% CI: 85.5–98.2), and 93.8% (95% CI: 84.0–98.0), respectively [54]. Unfortunately, expense and technical skill issues make its use in primary care settings less likely.

1.5.4 Tympanometry

Tympanometry is well established as a valid and reliable test for the diagnosis of MEE before myringotomy [55-58]. It is a valuable aid in the diagnosis of OME providing an objective result in the examination of the TM and middle ear space [59-61]. The tympanometer records compliance of the TM and provides quantitative information on structural function and the presence of MEE [62]. A normal immittance (type A tympanogram) indicates normal (MEE-free) ear (Figure 2). A flattened tracing with a low static immittance (type B tympanogram) indicates MEE (Figure 3); highly negative middle ear pressures (type C tympanogram) indicate a retracted TM and/or Eustachian tube dysfunction (Figure 4). Type B tympanogram predict OME accurately with sensitivity of 96.6% and specificity of 99% [52, 60]. Unfortunately, the use of tympanometry in primary care practice is limited because of the high cost of the tympanometer-machine and the special training and knowledge required operating it. A hand-held tympanometer is available for use in the clinic setting but is less sensitive (89%) and specific (58%) than the professional one (92% and 61% respectively) [49, 63].

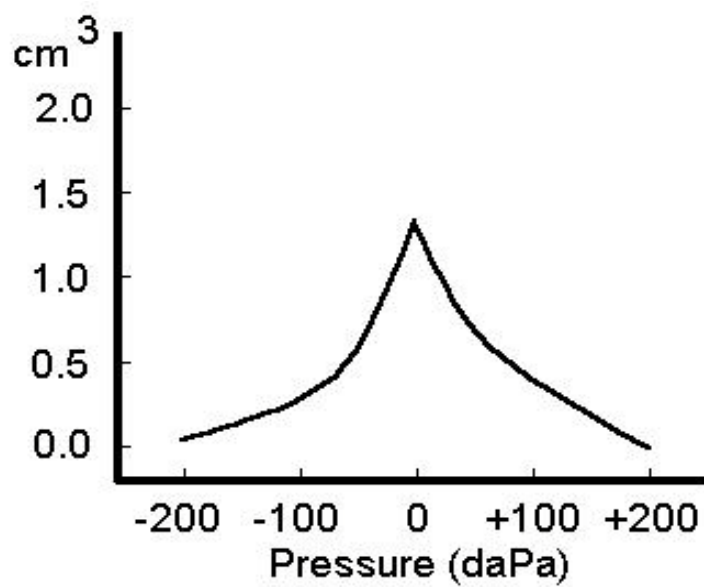


Figure2: Type A tympanogram

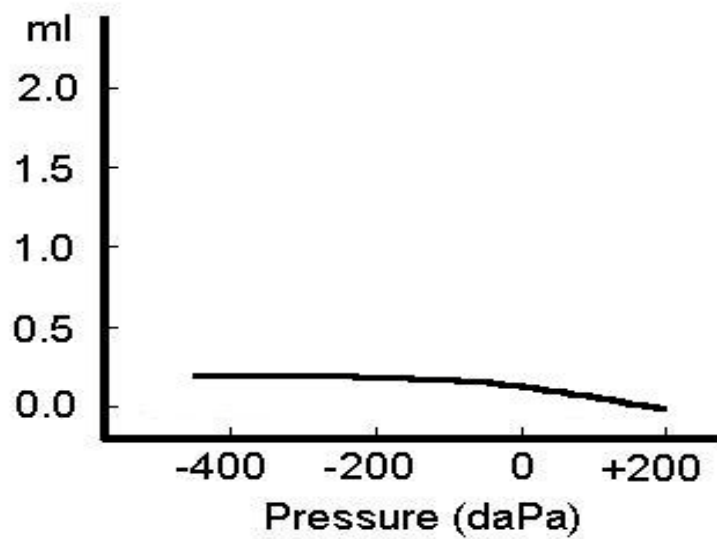


Figure 3: Type B tympanogram

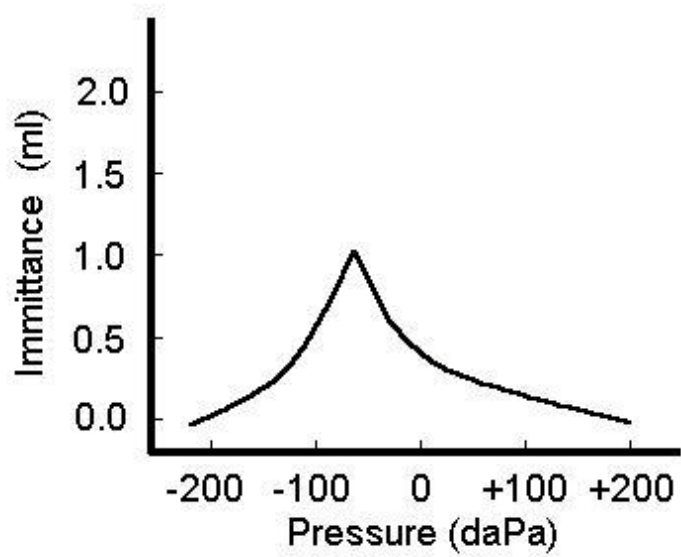


Figure 4: Type C tympanogram

1.5.5 Pneumatic otoscopy

Pneumatic otoscopy checks the mobility of the TM by applying a positive and negative pressure with a hand held device (pneumatic bulb) that attaches to the standard otoscope (Figure 5) [64]. An artificial seal must be obtained between the external auditory canal and the ear speculum to create an airtight chamber. The normal TM with ambient middle ear pressure will show visually detectable mobility, while presence of MEE will interfere with normal TM mobility.

Pneumatic otoscopy is inexpensive, readily available tool and does not require special training. Such characteristics make this diagnostic tool very appealing for the use in primary care settings. Pneumatic otoscopy is believed to be helpful in optimally assessing the presence or absence of MEE [63, 65-68].

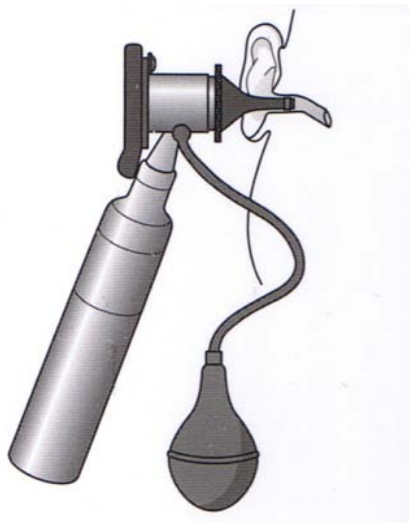


Figure 5: Pneumatic otoscope

Many previous clinical studies that tested the validity of pneumatic otoscopy to detect MEE showed positive results [49, 69]. However, these studies were neither randomized nor controlled. Moreover, all previous clinical trials were conducted in known (diseased) MEE-containing ears. Moreover, the examiner level of training was not mentioned or a single examiner performed all the experiments. Melker studied the value of pneumatic otoscopy in primary care compared to tympanometry in diagnosing OME [69]. All pneumatic assessments on 111 children were done by one trained nurse. The sensitivity of pneumatic otoscopy was low (45%) but the specificity was high (99%). In contrast, Takahashi et al. showed that TM mobility was less often impaired in ears with OME than expected with more than half of the cases (30 ears) having good mobility, suggesting that pneumatic otoscopy might not have a significant diagnostic value for OME [70].

As popular as pneumatic otoscopy for the diagnosis of OME was in the eighties and early nineties, its has faded over the years by both otolaryngologists and primary care physicians perhaps because of the innovation of newer diagnostic tools. Newer generations of physicians were less trained and less comfortable using pneumatic otoscopy. In the twenty first century, the development of video-otoendoscopy (VOE) revitalized the diagnostic capability of OME. The addition of pneumatic assessment during VOE, by insufflating air through a side port, added

more information about the mobility of the TM and hence OME diagnosis [42, 71, 72]. VOE Sensitivity reached 97.8%, specificity 100%, and accuracy 98% [52].

The first and only study to quantitatively validate the benefits of pneumatic otoscopy in improving clinicians' otoscopic accuracy was conducted by Kaleida et al [71]. Otoscopic assessment using VOEs suggested that pneumatic assessment does indeed improve the ability to detect both MEE-containing and MEE-free ears. Even more skilled clinicians, who scored higher on the VOE, demonstrated greater improvement in accuracy following pneumatic assessment than clinicians with lower accuracy on visual assessment. A mean absolute improvement in the accuracy from the static test (61%) to the pneumatic test (76%) was 15%, and the relative improvement in sensitivity and specificity from static viewing to pneumatic viewing was 24% and 42% respectively. However further research is necessary to confirm such improvement in diagnostic accuracy in clinical practice attributable to performance of pneumatic otoscopy using appropriate study methodology, randomization of clinicians to intervention and control groups and assessment on live patients.

1.6 Rationale for study

Pneumatic otoscopy has been advocated to improve clinician's diagnostic accuracy in detecting OME in the pediatric population. Whereas the use of pneumatic assessment as a diagnostic tool was validated using video-otoendoscopic examination (VOE), it has not been validated using pneumatic otoscopy in clinical practice.

The rationale of our study is to determine whether pneumatic otoscopy education and training would improve the diagnostic accuracy of OME in clinical practice. To our knowledge this is the first study of its kind. We hypothesized that the addition of pneumatic-assessment to otoscopy (i.e. pneumatic otoscopy) will improve resident's diagnostic accuracy of OME in children using a randomized single-blind control study design.

CHAPTER II: MATERIAL AND METHODS

2.1 Objective

To determine if pneumatic otoscopy improves the diagnostic accuracy of OME in clinical practice.

2.2 Hypothesis

The addition of pneumatic assessment to otoscopy improves pediatric resident's diagnostic accuracy of OME in children.

2.3 Study design

The study design was a randomized single-blind controlled trial.

2.4 Study site

The study site was at the Otolaryngology pre-operative clinic at the Montreal Children's Hospital. Institutional scientific and ethic review board approval was obtained. The choice of this site serving as patient/ear population was made because tympanostomy tube insertion surgery for OME is one of the commonest otolaryngology procedures performed at this site; hence, a large proportion of the clinic patients/ears would have OME to ensure a sufficient number of diseased ears. Similarly, ears of patients being pre-operatively assessed for other surgeries would serve as controls.

2.5 Study population

Pediatric residents at Montreal Children Hospital {Post graduate level (PGY) 1-4} served as the study population. Participation was voluntary and informed consent was obtained.

2.6 Patients' ears

Inclusion criteria: Ears of children between the ages of 1 and 18, awaiting assessment in the preoperative clinic, served as our sample.

Exclusion criteria: Ears of children less than 1 year of age (due to unreliable tympanogram results), ears with active otorrhea, cerumen impaction, Cholesteatoma, TM perforation, tympanostomy tube already in place, or previous ear surgery. The study took place over a consecutive 4-month period (October 2008-Jan 2009).

2.7 Resident recruitment

Residents received an invitation letter via e-mail for participation. The Otolaryngology specialist coordinated residents' recruitment and assigned one resident from each study group to a specified clinic date that suited their schedule. The principal investigator had no role in resident recruitment.

2.8 Patient recruitment

The clinic nurse approached children or their guardians on the same day of the clinic for consent to participate in the study. Participating children or their guardians were asked not to communicate with the residents. Residents were asked not to communicate with the children or their guardians, or amongst each other.

2.9 Randomization

Pediatric residents (fixed sample size) were randomized, by the drawing of long and short straws, into the two study arms according to PGY level {senior (PGY 3&4) or junior (PGY 1&2)} prior to receiving the intervention. The two study arms were pneumatic otoscopy (intervention) or otoscopy-only (control) groups. The principal investigator was blinded to the groups' randomization.

2.10 Control group

Both study groups received one hour of didactic teaching on OME by an Otolaryngology specialist. Various diagnostic signs seen on otoscopy were discussed by showing still images of normal and OME ears. This was the only education and training given to the control group.

2.11 Intervention group

The intervention group received, in addition to the teaching described above, a 30-minute teaching about pneumatic otoscopy use and interpretation, in the form of video-otoendoscopic examination (VOE) pneumatic-assessments. Residents were shown normal and abnormal TM mobility by viewing VOE pneumatic-assessments of normal and OME. A total of 25 video-assessments were used. One practice session for each resident was performed to ensure familiarity with the use of the instrument.

2.12 Data collection

Three weeks after the intervention, one resident from each study arm attended the same clinic to examine the same 10 ears when possible. Residents were asked to complete a standardized form (appendix 6.2) noting their diagnosis (normal vs. OME). Residents were also asked to state their level of confidence in their diagnosis according to a predetermined scale (uncertain, little confident, confident, or very confident). Each resident examined the ears alone; the resident from the other study arm and the principal investigator were outside the examination room. At the end of the ten examinations and prior to leaving the examination room, each resident put the completed form into a sealed envelope. Following residents' assessments, the principal investigator performed a tympanogram for each ear (appendix 6.3) making a diagnosis of normal ear (type A tympanogram) or OME ear (type B tympanogram). Ears with type C results (indicating negative middle ear pressure) were excluded. The tympanograms

were performed after both residents exited the examination room. The principal investigator had formal training on tympanometry by a pediatric audiologist prior to commencing the study.

After all residents in the study completed their ear examinations, the sealed envelopes were opened and the data were entered into a spreadsheet for analysis. Please refer to appendix 6.1 for data collection scheme.

2.13 Outcome

The main study outcome was the percentage of correct diagnoses made in each study group. Secondary outcomes were the mean number of correct OME and normal ear diagnoses made per study group.

2.14 Statistical Analysis

Each resident was given a score based on the number of correct diagnoses made (Range 0-10). We calculated the number of correct diagnoses of both OME and normal ears and compared these results to those of the tympanograms performed by the principal investigator. The overall percentages of correct diagnoses by each study group were compared using chi-square analysis. A two tailed t-test for independent samples were used to compare the mean number of correct diagnosis of OME and normal ears in the intervention and control groups. Also a non-parametric Mann-Whitney test was used to compare the median values of correct diagnosis of OME and normal ears in the intervention and control groups. Analysis of covariance (ANCOVA) was performed to control for

PGY level. Multiple linear regression analysis was used to determine the relationship between PGY levels, level of confidence, and mean correct diagnoses. The sensitivity, specificity, positive and negative predictive values for pneumatic otoscopy and otoscopy-only in diagnosing OME were calculated.

2.15 Power calculation

Because we had a fixed number of pediatric residents and taking into consideration the fact that we had repeated measures (each candidate will diagnose several children) we inflated our sample size by a "variance inflation factor" (VIF). $VIF = [1 + \{(m-1) \times r\}]$. m = the average number of measures repeated (the average number of children each candidate will see). r = Intraclass Correlation (ICC) - the correlation between the results of the tests for each candidate.

For a power of 0.8 and an alpha of 0.05 and a test of two proportions Sample size per group {for low correlation ($r = 0.1$), $VIF = 1.9$ } was estimated at 59 ear examinations (six residents performing 10 ear examinations each) and for a median correlation {($r = 0.3$), $VIF = 3.7$ } Sample size per group was estimated at 115 ear examinations (12 residents performing 10 ear examinations each). Calculations were based on the difference in the correct diagnoses between the two study groups that we hypothesized to be 10%.

CHAPTER III: RESULTS

Thirty residents were randomized and received the educational component of the intervention. Of these, three (10%) dropped out of the study at the time of otoscopy assessment. A total of 27 residents (90%) participated in the ear assessment component of the intervention; 13 (48%) residents were in the intervention group and 14 (52%) were in the control group (Table 1).

Table 1: Residents' distribution between the two groups according to PGY level

	Intervention (n= 13)	Control (n= 14)
Junior		
PGY 1	4	6
PGY 2	4	3
Total	8	9
Senior		
PGY 3	5	2
PGY 4	0	3
Total	5	5

Although our inclusion age was 1-18 years, most children fell between 2-6 years which was expected. The two study groups examined 269 ears, six ears were excluded because of type C tympanogram-results; therefore, 263 ears were included in the final analysis. Of these, 50.6% (133 ears) were normal and 49.4% (130 ears) were OME.

The intervention group examined 124 ears; of which 53.2% (66 ears) were normal and 46.8% (58 ears) were OME. The control group examined 139 ears; of which 48.2% (67 ears) were normal and 51.8% (72 ears) were OME. Both the intervention and control groups examined the same proportions of normal and diseased (OME) ears. The results from pneumatic otoscopy and otoscopy-only groups in diagnosing OME and normal ears are listed in tables 2 and 3 respectively.

As a diagnostic tool, pneumatic otoscopy was less sensitive {55% (95%CI 41.6-68)} than otoscopy only {62.7% (95%CI 50-73.9)} but more specific {66.6% (95%CI 53.8-77.5)}. The positive predictive value for pneumatic otoscopy was 59.2% (95%CI 54.1-72.1) while the negative predictive value was 62.9% (95%CI 50.4-73.9). The positive predictive value for otoscopy-only was 58.3% (95%CI 46.1-69.6) while the negative predictive value was 62.7% (95%CI 50-73.9) (Table 4).

Table 2: Results from pneumatic otoscopy group in diagnosing OME.

	Number OME absent	Number OME present	Total
Pneumatic positive	22	32	54
Pneumatic negative	44	26	70
Total	66	58	124

Table 3: Results from otoscopy-only group in diagnosing OME.

	Number OME absent	Number OME present	Total
Otoscopy positive	30	42	72
Otoscopy negative	42	25	67
Total	72	67	139

Table 4: Sensitivity, specificity, positive and negative predictive value for pneumatic otoscopy and otoscopy-only tools in diagnosing OME:

	Pneumatic otoscopy	Otoscopy-only
Sensitivity	55% (95%CI 41.6-68)	62.7%(95%CI 50-73.9)
Specificity	66.6%(95%CI 53.8-77.5)	58.3%(95%CI 46.1-69.6)
PPV	59.2%(95%CI 54.1-72.1)	58.3%(95%CI 46.1-69.6)
NPV	62.9%(95%CI 50.4-73.9)	62.7%(95%CI 50-73.9)

PPV= Positive predictive value

NPV= Negative predictive value

The overall percentages of correct diagnoses for the intervention group was 58.6% and 60% for the control group, a chi-square analysis showed no significant statistical difference between the two study groups, $X^2(df=1) = 6.56$, $p = 0.3$, Yates corrected 3.521, correlation coefficient (C) = 0.2 (Figure 6).

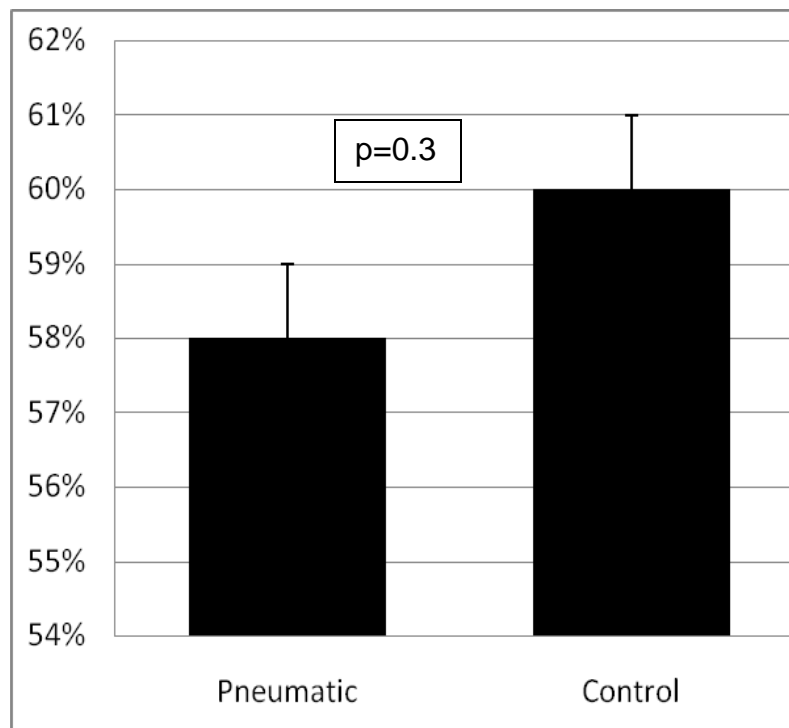


Figure 6: Percentage of overall correct diagnosis

The mean number of correct diagnoses of OME ears for the intervention group was 5.37 (95% CI [3.5-7.3]) vs. 4.97 (95% CI [3.4-6.6]) for the control group, a difference that was not statistically significant, $t(23) = 0.35$, $p = 0.7$ (Figure 7).

Similarly, the median values for correct diagnoses of OME ears between the two groups did not differ, $U(12, 12) = 72.5$, $p = 0.97$.

The mean number of correct diagnoses of normal (MEE-free) ears for the intervention group was 4.7 (95% CI [2.8-6.45]) vs. 5.52 (95% CI [3.7-7.3]) for control group, with no statistically significant difference, $t(25) = -0.72$, $p = 0.47$ (Figure 7). Similarly, the median values for correct diagnoses of normal ears between the two groups did not differ, $U(14, 13) = 108$, $p = 0.4$.

Analysis of Covariance was performed on the data and there was no difference in the mean number of correct diagnoses between the intervention and control groups when residency training level was controlled for, $F = 0.035$ ($df = 1$), $p = 0.85$. In addition, a multiple linear regression analysis showed no correlation between correct diagnosis and PGY level ($p = 0.2$) or level of confidence ($p = 0.4$).

See appendix 6.12 for detailed statistical analysis.

Comparing residents performance, there was no difference in the mean number of correct diagnoses between senior and junior residents, whether using pneumatic otoscopy or not, $t(25) = -1.58$, $p = 0.13$ (Figure 8).

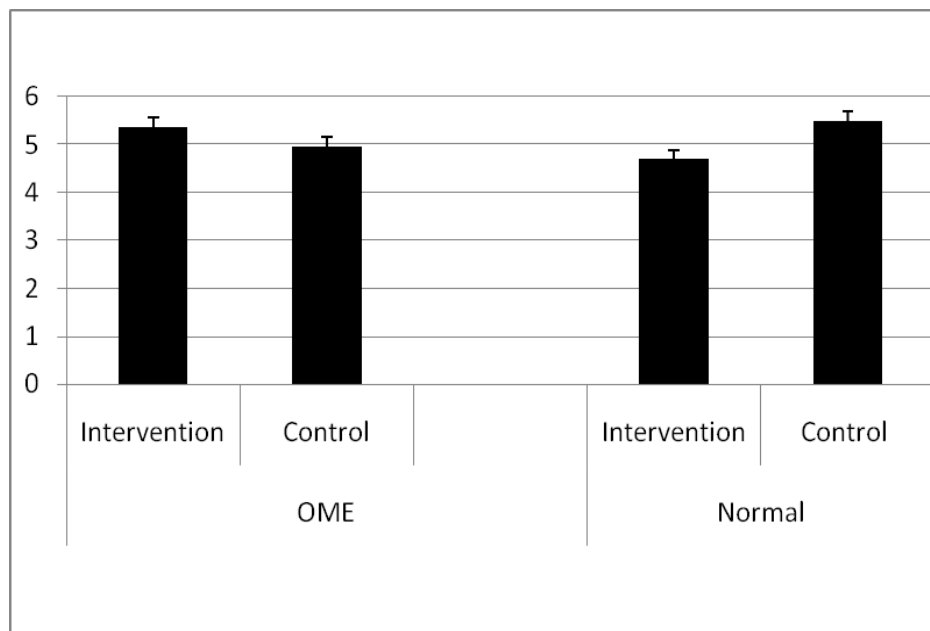


Figure 7: Mean number of correct diagnoses OME & normal ears

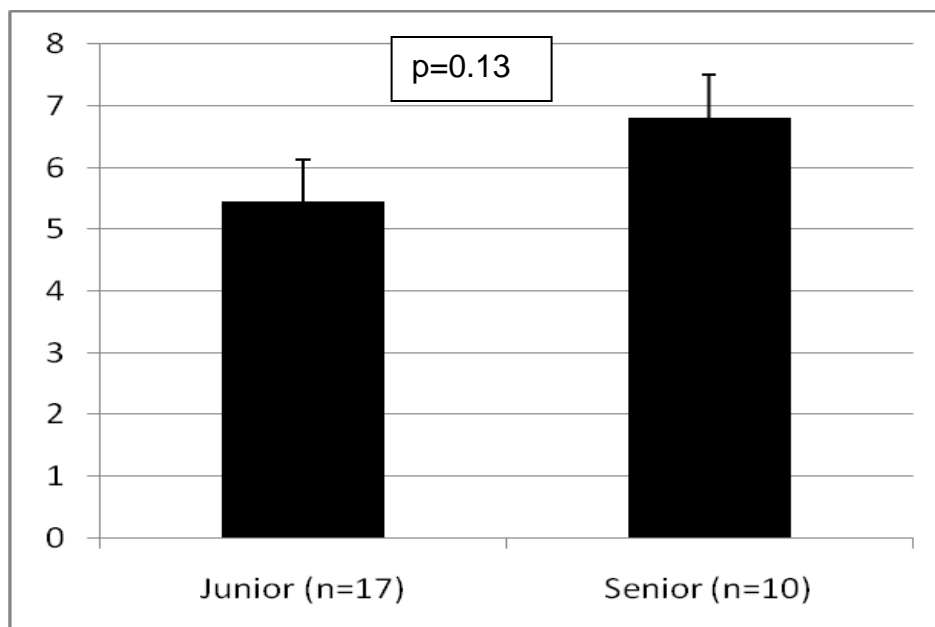


Figure 8: Mean number of correct diagnoses by PGY level

Examination of the same set of ears was achieved in 60% of the total examinations. Residents' results from the two study groups who examined the same set of ears (8 residents from each study group) were compared. The same results were obtained (mean correct diagnoses for the intervention group = 6.13 (95% CI [4.4-7.9]), and the mean correct diagnoses for the control group = 5.75 (95% CI [4-7.5]). An unpaired t-test (two tailed) showed no significant statistical difference between the two group means, $t(14) = 0.36$, $p = 0.7$. Similarly, the median values for correct diagnoses between the two groups using the non-parametric Mann-Whitney test for independent samples did not differ, $U(8, 8) = 33.5$, $p=0.8$.

CHAPTER IV: DISCUSSION

Our study is the first to examine whether an educational and training pneumatic otoscopy intervention would improve the diagnostic accuracy of OME in clinical practice. In contrast to other studies, this randomized controlled trial showed that pneumatic otoscopy did not improve the diagnostic accuracy of OME compared to otoscopy alone in pediatric residents. Furthermore, the addition of pneumatic otoscopy did not improve the diagnostic accuracy of MEE-containing (OME) or MEE-free (normal) ears over otoscopy alone.

Takahashi et.al showed than mild cases of OME could have normal mobility and that TM mobility significantly correlated with aeration in the middle ear space [70]. Mastering the amount of pressure applied via the pneumatic device is not an easy task and likely varies from one examiner to the other. Residents might have applied too much pressure that mild cases of OME ears would appear to have normal TM mobility. On the rare occasion, residents might have detected an air fluid level or bubbles, correctly diagnosing OME while the tympanogram may show a normal (Type A) tracing. Our use of the tympanometry as the gold standard, although used in many previous trials, may be criticized. Myringotomy is the gold standard to document OME. In our study, children who had normal ears (control) were not scheduled to undergo tympanostomy tube surgery, and therefore it was not ethical for research purposes to subject those children to an

invasive diagnostic procedure that is not normally applied. In our study of 263 ears comparing pneumatic otoscopy and otoscopy-only to tympanometry as our gold standard, pneumatic otoscopy was less sensitive than otoscopy alone (55% vs. 62.7%) but more specific (66.6% vs. 58.3%) in detecting middle ear effusion. Pneumatic otoscopy had a similar positive predictive value (59.2% vs. 59.3%) and negative predictive value (62.9% vs. 62.7%) to otoscopy-only in diagnosis of OME.

Our results contrast with the previous video-otoendoscopic examination (VOE) - study that showed benefit from pneumatic assessment [71]. Perhaps pneumatic otoscopy is not a simple clinical skill as previously implied. Poor seal, moving child and cerumen are factors that may make pneumatic otoscopy much more difficult to apply clinically, in contrast to the ideal setting of VOE. The actual benefit in improving the diagnosis of OME using pneumatic-VOE might be attributable to the magnified images, which the VOE provides, rather than to the pneumatic assessment itself. Many otologist know the benefits of otomicroscopy over pneumatic otoscopy including higher magnification, brighter light, a constant intensity of light, and a natural color of the light. A recent study of 151 ears comparing pneumatic otoscopy and oto-microscopy to myringotomy under local anesthesia as the gold standard, otomicroscopy had a higher sensitivity (98.5%) and specificity (80%) compared to that of pneumatic otoscopy (93.8% and 40% respectively). [53]

Recruiting children from the pre-operative clinic was for purposes of study efficiency. Sufficient number of diseased and normal ears was obtained in a half-day for each resident to complete the examinations without asking them to come back again for more examinations. The study commenced three weeks after the educational intervention and closed four months later. One can argue that residents who performed their examinations early on during the study time might have been fresher in knowledge and memory of diagnosis of OME and therefore score higher, although we paired residents from each group therefore the overall score should not have be affected. We managed to have residents examine the same set of ears only 60% of the time (8 resident from each group) but this met our sample size and power calculation (6 resident from each group) for a low correlation. Results with this ear-matched control were unchanged.

The need to improve the diagnosis of OME, which gained attention in recent years [2, 8, 40] was supported by our study findings, which showed that a large percentage (approximately 40%) of the residents' diagnoses was wrong. Senior PGY level did not influence the accuracy of diagnosis whether using pneumatic otoscopy or not. These findings are very concerning as the additional two to three years of pediatric residency training did not improve the diagnostic accuracy of OME, one of the most common pediatric diagnoses.

In addition, increasing level of confidence did not correlate with accurate diagnosis of OME. Few studies suggested that the lack of correlation between confidence level or mark and career length could suggest that experience is not

sufficient to compensate for lack of formal training in the diagnosis OME [43]. This was supported by similar confidence levels of medical students and general practitioners in identification of TM features [73]. Training programs should dedicate more time during residency to improving the knowledge and skills necessary to diagnose OME.

Study limitations

The study findings should be interpreted in light of its limitations. We believe that the failure to demonstrate diagnostic benefit of pneumatic otoscopy may be due to the application of the instrument in a clinical setting, as opposed to the poor diagnostic ability of the instrument itself. Certainly, 1.5 hours of teaching is not enough time to master the use of a pneumatic otoscope as a diagnostic tool. For this reason, we had conducted the study on pediatric residents and not on medical students or residents from other programs with less exposure to OME. Our training sessions were intended to supplement the education they had received during medical school and residency. We asked the pneumatic group to keep practicing on patients until the examination date but unfortunately, the pneumatic device was unavailable outside the otolaryngology clinic. It is possible that if we tested the intervention group after increased familiarity with the tool, we might have found different results. Silva et al described a protocol for otolaryngology residents training in pneumatic otoscopy to improve sensitivity and specificity. It took his residents two months to improve sensitivity range from 50-73% to 82-100% and specificity range from 58-83% to 70-95% [74].

Expert otoscopists stress the importance of assessing mobility along with assessing color, position, and translucency of the TM in order to diagnose OME [67, 75, 76]. The intervention group may have been biased to rely too much on pneumatic findings and ignore or place less emphasis on the otoscopic findings. At present, we cannot attribute the failure of pneumatic otoscopy to improve the diagnostic accuracy of OME to either the inability of the instrument itself or the intervention. Future studies may examine whether the number of practice sessions influences acquisition of pneumatic otoscopy skill.

Conclusions

Pneumatic otoscopy education, training, and use did not improve the diagnostic accuracy of OME in clinical practice compared to otoscopy alone in pediatric residents. Thus, the question of how OME can be diagnosed more accurately in the primary care settings without using expensive clinical or audiometric equipment remains unanswered.

Senior trainees' diagnosis of OME was not significantly better than the junior ones. Training programs should dedicate more time during residency to improving the knowledge and skills necessary to diagnose OME.

CHAPTER V: REFERENCES

1. Gould, J.M. and P.S. Matz, *Otitis media*. *Pediatr Rev*. **31**(3): p. 102-16.
2. *Diagnosis and management of acute otitis media*. *Pediatrics*, 2004. **113**(5): p. 1451-65.
3. Daly, K.A., L.L. Hunter, and G.S. Giebink, *Chronic otitis media with effusion*. *Pediatr Rev*, 1999. **20**(3): p. 85-93; quiz 94.
4. Williamson, I., *Otitis media with effusion*. *Clin Evid*, 2002(7): p. 469-76.
5. Williamson, I., *Otitis media with effusion*. *Clin Evid*, 2002(8): p. 511-8.
6. Bluestone, C.D., *Studies in otitis media: Children's Hospital of Pittsburgh-University of Pittsburgh progress report--2004*. *Laryngoscope*, 2004. **114**(11 Pt 3 Suppl 105): p. 1-26.
7. Darrow, D.H., N. Dash, and C.S. Derkay, *Otitis media: concepts and controversies*. *Current Opinion in Otolaryngology & Head & Neck Surgery*, 2003. **11**(6): p. 416-23.
8. *Otitis media with effusion*. *Pediatrics*, 2004. **113**(5): p. 1412-29.
9. Teele, D.W., J.O. Klein, and B. Rosner, *Epidemiology of otitis media during the first seven years of life in children in greater Boston: a prospective, cohort study*. *J Infect Dis*, 1989. **160**(1): p. 83-94.
10. Tos, M., *Epidemiology and natural history of secretory otitis*. *Am J Otol*, 1984. **5**(6): p. 459-62.
11. Schwartz, R.H., W.J. Rodriguez, and K.M. Grundfast, *Duration of middle ear effusion after acute otitis media*. *Pediatr Infect Dis*, 1984. **3**(3): p. 204-7.
12. Alho, O.P., et al., *Chronic otitis media with effusion in infancy. How frequent is it? How does it develop?* *Arch Otolaryngol Head Neck Surg*, 1995. **121**(4): p. 432-6.

13. Renko, M., et al., *Disappearance of middle ear effusion in acute otitis media monitored daily with tympanometry*. Acta Paediatr, 2006. **95**(3): p. 359-63.
14. Rosenfeld, R.M. and D. Kay, *Natural history of untreated otitis media*. Laryngoscope, 2003. **113**(10): p. 1645-57.
15. Teele, D.W., J.O. Klein, and B.A. Rosner, *Epidemiology of otitis media in children*. Ann Otol Rhinol Laryngol Suppl, 1980. **89**(3 Pt 2): p. 5-6.
16. Wheeler, M.T., *Tympanometry in children with treated acute otitis media*. Lancet, 1986. **1**(8480): p. 529-32.
17. Rosenfeld, R.M., et al., *Clinical practice guideline: Otitis media with effusion*. Otolaryngol Head Neck Surg, 2004. **130**(5 Suppl): p. S95-118.
18. anonymous, *Joint Committee on Infant Hearing 1994 Position Statement*. American Academy of Pediatrics Joint Committee on Infant Hearing. Pediatrics, 1995. **95**(1): p. 152-6.
19. Olatoke, F., et al., *The prevalence of hearing loss among schoolchildren with chronic suppurative otitis media in Nigeria, and its effect on academic performance*. Ear, Nose, & Throat Journal, 2008. **87**(12): p. E19.
20. Casselbrant, M.L., et al., *Past history of otitis media and balance in four-year-old children*. Laryngoscope, 2000. **110**(5 Pt 1): p. 773-8.
21. Casselbrant, M.L., et al., *Visual-induced postural sway in children with and without otitis media*. Ann Otol Rhinol Laryngol, 1998. **107**(5 Pt 1): p. 401-5.
22. Casselbrant, M.L., R.J. Villardo, and E.M. Mandel, *Balance and otitis media with effusion*. Int J Audiol, 2008. **47**(9): p. 584-9.
23. Koyuncu, M., et al., *Effects of otitis media with effusion on the vestibular system in children*. Otolaryngol Head Neck Surg, 1999. **120**(1): p. 117-21.
24. Cohen, H., et al., *Balance in children with otitis media with effusion*. Int J Pediatr Otorhinolaryngol, 1997. **42**(2): p. 107-15.
25. Golz, A., et al., *Effect of middle ear effusion on the vestibular labyrinth*. J Laryngol Otol, 1991. **105**(12): p. 987-9.

26. Isaacson, G., *Diagnosis of pediatric cholesteatoma*. Pediatrics, 2007. **120**(3): p. 603-8.
27. Swarts, J.D. and C.D. Bluestone, *Eustachian tube function in older children and adults with persistent otitis media*. Int J Pediatr Otorhinolaryngol, 2003. **67**(8): p. 853-9.
28. Sade, J., *Cellular differentiation of the middle ear lining*. Ann Otol Rhinol Laryngol, 1971. **80**(3): p. 376-83.
29. Sade, J., A. Babiacki, and G. Pinkus, *The metaplastic and congenital origin of cholesteatoma*. Acta Otolaryngol, 1983. **96**(1-2): p. 119-29.
30. Tos, M., *Upon the relationship between secretory otitis in childhood and chronic otitis and its sequelae in adults*. J Laryngol Otol, 1981. **95**(10): p. 1011-22.
31. Bales, C.B., et al., *Lateral sinus thrombosis as a complication of otitis media: 10-year experience at the children's hospital of Philadelphia*. Pediatrics, 2009. **123**(2): p. 709-13.
32. Beery, Q.C., et al., *Tympanometric pattern classification in relation to middle ear effusions*. Annals of Otology, Rhinology & Laryngology, 1975. **84**(1 Pt 1): p. 56-64.
33. Cantekin, E.I., Q.C. Beery, and C.D. Bluestone, *Tympanometric patterns found in middle ear effusions*. Annals of Otology, Rhinology, & Laryngology - Supplement, 1977. **86**(4 Pt 3 Suppl 41): p. 16-20.
34. Zielhuis, G.A., et al., *Environmental risk factors for otitis media with effusion in preschool children*. Scandinavian Journal of Primary Health Care, 1989. **7**(1): p. 33-8.
35. Magnuson, K. and S. Hellstrom, *Early structural changes in the rat tympanic membrane during pneumococcal otitis media*. European Archives of Oto-Rhino-Laryngology, 1994. **251**(7): p. 393-8.
36. von Unge, M., et al., *Shape and displacement patterns of the gerbil tympanic membrane in experimental otitis media with effusion*. Hearing Research, 1995. **82**(2): p. 184-96.

37. Larsson, C., et al., *Pars flaccida displacement pattern in purulent otitis media in the gerbil*. *Otology & Neurotology*, 2003. **24**(3): p. 358-64.
38. Vicente, J., et al., *Evolution of middle ear changes after permanent eustachian tube blockage*. *Archives of Otolaryngology -- Head & Neck Surgery*, 2007. **133**(6): p. 587-92.
39. Alzbutiene, G., et al., *Tympanic membrane changes in experimental acute otitis media and myringotomy*. *Medicina (Kaunas, Lithuania)*, 2008. **44**(4): p. 313-21.
40. Varrasso, D.A., *Otitis media: the need for a new paradigm in medical education*. *Pediatrics*, 2006. **118**(4): p. 1731-3.
41. Pelton, S.I., *Otitis media: re-evaluation of diagnosis and treatment in the era of antimicrobial resistance, pneumococcal conjugate vaccine, and evolving morbidity*. *Pediatr Clin North Am*, 2005. **52**(3): p. 711-28, v-vi.
42. Jones, W.S., *Video otoscopy: bringing otoscopy out of the "black box"*. *Int J Pediatr Otorhinolaryngol*, 2006. **70**(11): p. 1875-83.
43. Buchanan, C.M. and D.D. Pothier, *Recognition of paediatric otopathology by General Practitioners*. *Int J Pediatr Otorhinolaryngol*, 2008. **72**(5): p. 669-73.
44. Pichichero, M.E., *Diagnostic accuracy, tympanocentesis training performance, and antibiotic selection by pediatric residents in management of otitis media.[see comment]*. *Pediatrics*, 2002. **110**(6): p. 1064-70.
45. Pichichero, M.E., *Diagnostic accuracy of otitis media and tympanocentesis skills assessment among pediatricians*. *European Journal of Clinical Microbiology & Infectious Diseases*, 2003. **22**(9): p. 519-24.
46. Pichichero, M.E. and M.D. Poole, *Comparison of performance by otolaryngologists, pediatricians, and general practitioners on an otoendoscopic diagnostic video examination*. *Int J Pediatr Otorhinolaryngol*, 2005. **69**(3): p. 361-6.

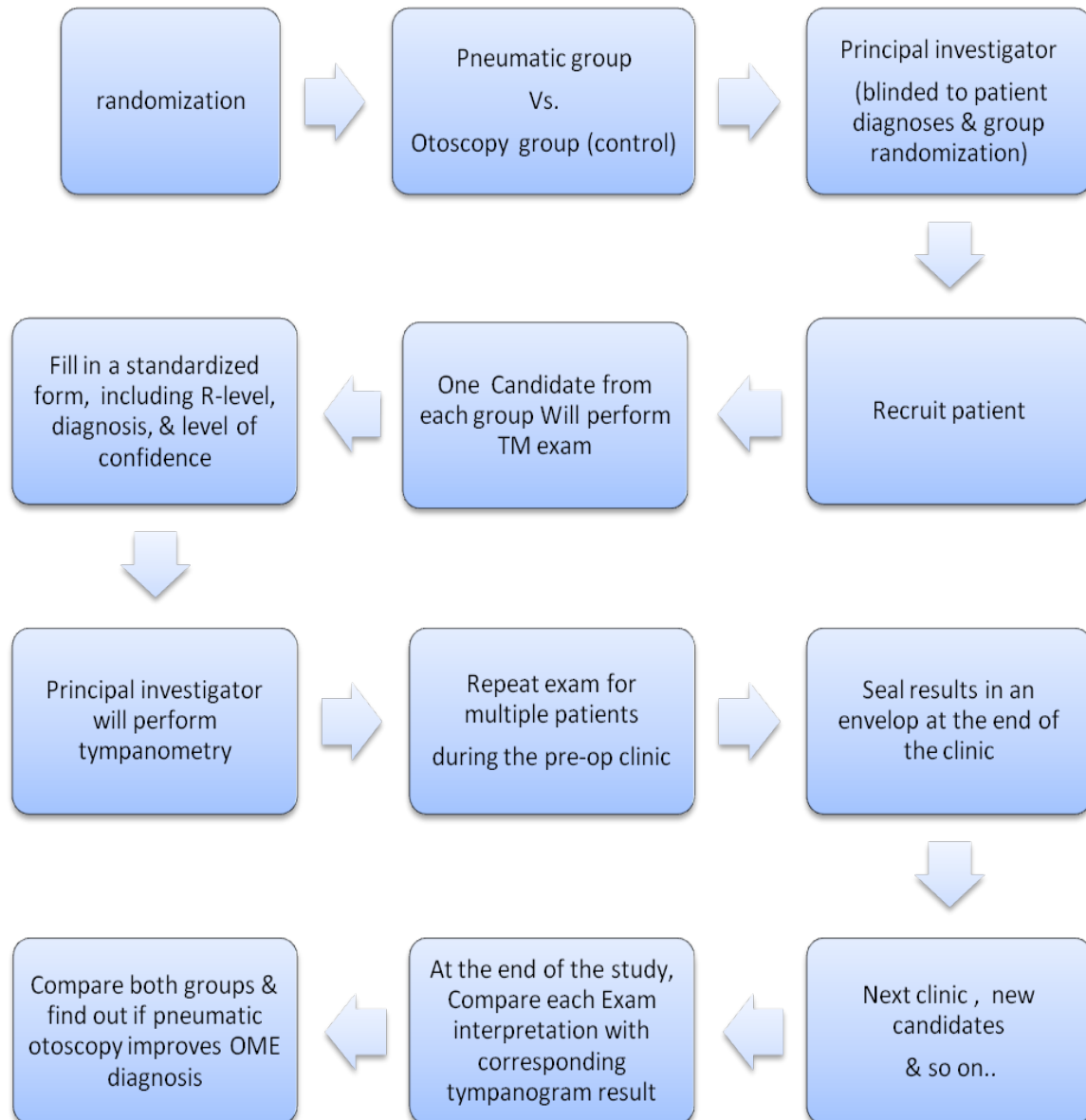
47. Lee, D.H. and S.W. Yeo, *Clinical diagnostic accuracy of otitis media with effusion in children, and significance of myringotomy: diagnostic or therapeutic?* J Korean Med Sci, 2004. **19**(5): p. 739-43.
48. Lampe, R.M. and R.H. Schwartz, *Diagnostic value of acoustic reflectometry in children with acute otitis media.* Pediatric Infectious Disease Journal, 1989. **8**(1): p. 59-61.
49. Takata, G.S., et al., *Evidence assessment of the accuracy of methods of diagnosing middle ear effusion in children with otitis media with effusion.* Pediatrics, 2003. **112**(6 Pt 1): p. 1379-87.
50. Babb, M.J., et al., *Modern acoustic reflectometry: accuracy in diagnosing otitis media with effusion.* Ear, Nose, & Throat Journal, 2004. **83**(9): p. 622-4.
51. Chianese, J., et al., *Spectral gradient acoustic reflectometry compared with tympanometry in diagnosing middle ear effusion in children aged 6 to 24 months.* Arch Pediatr Adolesc Med, 2007. **161**(9): p. 884-8.
52. Shiao, A.S. and Y.C. Guo, *A comparison assessment of videotelescopy for diagnosis of pediatric otitis media with effusion.* Int J Pediatr Otorhinolaryngol, 2005. **69**(11): p. 1497-502.
53. Lee, D.H., *How to improve the accuracy of diagnosing otitis media with effusion in a pediatric population.* Int J Pediatr Otorhinolaryngol, 2010. **74**(2): p. 151-3.
54. Young, D.E., et al., *The accuracy of otomicroscopy for the diagnosis of paediatric middle ear effusions.* Int J Pediatr Otorhinolaryngol, 2009. **73**(6): p. 825-8.
55. Cantekin, E.I., et al., *Identification of otitis media with effusion in children.* Ann Otol Rhinol Laryngol Suppl, 1980. **89**(3 Pt 2): p. 190-5.
56. Bluestone, C.D. and E.I. Cantekin, *Design factors in the characterization and identification of otitis media and certain related conditions.* Ann Otol Rhinol Laryngol Suppl, 1979. **88**(5 Pt 2 Suppl 60): p. 13-28.

57. Margolis, R.H., *Tympanometry for prediction of middle ear effusion*. Arch Otolaryngol, 1979. **105**(4): p. 225.
58. Shanks, J. and C. Shelton, *Basic principles and clinical applications of tympanometry*. Otolaryngol Clin North Am, 1991. **24**(2): p. 299-328.
59. Brookhouser, P.E., *Use of tympanometry in office practice for diagnosis of otitis media*. Pediatric Infectious Disease Journal, 1998. **17**(6): p. 544-51; discussion 580.
60. Palmu, A.A. and R. Syrjanen, *Diagnostic value of tympanometry using subject-specific normative values*. International Journal of Pediatric Otorhinolaryngology, 2005. **69**(7): p. 965-71.
61. Margolis, R.H., et al., *Tympanometry in newborn infants--1 kHz norms*. J Am Acad Audiol, 2003. **14**(7): p. 383-92.
62. Onusko, E., *Tympanometry*. Am Fam Physician, 2004. **70**(9): p. 1713-20.
63. Kaleida, P.H., *Evidence assessment of the accuracy of methods of diagnosing middle ear effusion in children with otitis media with effusion*. J Pediatr, 2004. **145**(1): p. 138.
64. Eavey, R.D., et al., *An education model for otitis media care field-tested in Latin America*. Otolaryngol Head Neck Surg, 1993. **109**(5): p. 895-8.
65. Karma, P.H., et al., *Otoscopy diagnosis of middle ear effusion in acute and non-acute otitis media. I. The value of different otoscopic findings*. Int J Pediatr Otorhinolaryngol, 1989. **17**(1): p. 37-49.
66. Finitzo, T., et al., *Tympanometry and otoscopy prior to myringotomy: issues in diagnosis of otitis media*. International Journal of Pediatric Otorhinolaryngology, 1992. **24**(2): p. 101-10.
67. Pelton, S.I., *Otoscopy for the diagnosis of otitis media*. Pediatr Infect Dis J, 1998. **17**(6): p. 540-3; discussion 580.
68. Mains, B.T. and J.G. Toner, *Pneumatic otoscopy: study of inter-observer variability*. Journal of Laryngology & Otology, 1989. **103**(12): p. 1134-5.

69. de Melker, R.A., *Evaluation of the diagnostic value of pneumatic otoscopy in primary care using the results of tympanometry as a reference standard*. Br J Gen Pract, 1993. **43**(366): p. 22-4.
70. Takahashi, H., et al., *The diagnostic and prognostic value of eardrum mobility in otitis media with effusion*. Eur Arch Otorhinolaryngol, 1999. **256**(4): p. 189-91.
71. Jones, W.S. and P.H. Kaleida, *How helpful is pneumatic otoscopy in improving diagnostic accuracy?* Pediatrics, 2003. **112**(3 Pt 1): p. 510-3.
72. Cho, Y.S., et al., *Video pneumatic otoscopy for the diagnosis of otitis media with effusion: a quantitative approach*. Eur Arch Otorhinolaryngol, 2009. **266**(7): p. 967-73.
73. Fisher, E.W. and A.G. Pfeleiderer, *Assessment of the otoscopic skills of general practitioners and medical students: is there room for improvement?* Br J Gen Pract, 1992. **42**(355): p. 65-7.
74. Silva, A.B. and A.J. Hotaling, *A protocol for otolaryngology-head and neck resident training in pneumatic otoscopy*. Int J Pediatr Otorhinolaryngol, 1997. **40**(2-3): p. 125-31.
75. Dowell, S.F., B. Schwartz, and W.R. Phillips, *Appropriate use of antibiotics for URIs in children: Part I. Otitis media and acute sinusitis. The Pediatric URI Consensus Team*. Am Fam Physician, 1998. **58**(5): p. 1113-8, 1123.
76. Kaleida, P.H. and S.E. Stool, *Assessment of otoscopists' accuracy regarding middle-ear effusion. Otosopic validation*. Am J Dis Child, 1992. **146**(4): p. 433-5.

CHAPTER VI: APPENDICIES

6.1 Data collection scheme



6.2 Standardized resident form

Resident level (R-level):

Date of exam:

Dear Candidate,

You are assigned to this pre-operative clinic. You would expect to examine an average of 10 ears.

Examine the tympanic membrane *only* (don't focus on external ear).

Remember, this is a blinded trial, so don't ask the patients about their diagnoses and kindly stick to your randomized group examination method.

Diagnosis:

State your diagnosis of Normal ear (N) or Middle ear fluid present (OME).

Also, state how confident you are of your diagnosis

Level of confidence:

1. Uncertain/ not confident at all
2. Little confident
3. Confident
4. Very confident

Patient #1:

Left ear
Diagnosis: Normal - MEE
Confidence level: 1 2 3 4

Right ear
Diagnosis: Normal - MEE
Confidence level: 1 2 3 4

Patient #2:

Left ear
Diagnosis: Normal - MEE
Confidence level: 1 2 3 4

Right ear
Diagnosis: Normal - MEE
Confidence level: 1 2 3 4

Patient #3

Left ear
Diagnosis: Normal - MEE
Confidence level: 1 2 3 4

Right ear
Diagnosis: Normal - MEE
Confidence level: 1 2 3 4

Patient #4

Left ear
Diagnosis: Normal - MEE
Confidence level: 1 2 3 4

Right ear
Diagnosis: Normal - MEE
Confidence level: 1 2 3 4

Patient #5

Left ear

Diagnosis: Normal - MEE

Confidence level: 1 2 3 4

Right ear

Diagnosis: Normal - MEE

Confidence level: 1 2 3 4

6.3 Tympanogram results' sheet

(Filled by the principal investigator: A=Normal, B= flat tympanogram)

Date:

Patient #	left ear	right ear
1		
2		
3		
4		
5		

6.4 Statistical calculations

1. Chi-square comparing the overall correct diagnosis showed no statistical difference :

$X^2(df = 1) = 6.569, p = 0.3$, Yates corrected 3.521, correlation coefficient

(C) = 0.227

2. Analysis Of Covariance (ANCOVA) was performed (Residency level being the covariant) and showed no difference between the two groups when residency level was controlled for.

ANOVA Table on Dependent Variable (X)

Source	SS	df	MS	F	p
Treatment	0.138	1	0.138	0.037	0.84963
Error	93.714	25	3.749		

ANCOVA-Corrected Summary Table

Source	SS	df	MS	F	p
Treatment	0.127	1	0.127	0.035	0.85262
Error	86.268	24	3.594		

Means	Unadjusted	Adjusted
Group 1	6.00	6.00
Group 2	5.86	5.86

Note: bw = 0.52

rTotal = 0.282
 rTreatment = 1.000
 rError = 0.282

3. An independent t-test comparing the overall scores for the two groups was performed and showed no difference:

Datasim Output:

? Design Twogroup S/T

? Read score.txt

Reading data for C1-C2....

Group	C1	C2
(pneumatic)	6	7
(control)	9	6
	6	4
	6	5
	8	6
	4	3
	5	10
	3	8
	7	4
	8	6
	7	7
	7	6
	2	6
	4	

? Mean

Group	
C1	C2
5.86	6.00

? Twot (independent t-test comparing the scores for two groups).

C1 vs C2: $t(25) = -.19$, $p = .8496$, $SE = .7457$

Confidence Intervals for Estimated Mean of Population

For .95 CI: 5.8571 ± 1.1735

For .99 CI: 5.8571 ± 1.6353

Confidence Intervals for Estimated Mean of Population

For .95 CI: 6 ± 1.104

For .99 CI: 6 ± 1.5445

Also a non-parametric Mann-Whitney test was performed and showed no difference between the two groups:

U Test Results

n_1	n_2	U	P (two-tailed)	P (one-tailed)
14	13	92.5	0.94387*	0.471935*
normal approx z = 0.0727892			0.941974*	0.470987*

*These values are approximate.

The two samples are not significantly different ($P \geq 0.05$, two-tailed test).

<http://elegans.swmed.edu/~leon/stats/utest.cgi?n1=14&n2=13&U=92.5&formtype=stats>

4. An independent t-test comparing the mean correct diagnosis of MEE ears between the intervention and control groups was performed and showed no difference.

Datasim output:

? Design Twogroup S/T

? Read score.txt

Reading data for C1 (pneumatic group)-C2 (control) ..

? Display

Group

C1	C2
.0	6.3
7.5	5.0
5.0	.0
5.0	5.0
5.7	6.7
4.0	5.0
10.0	5.0
5.0	2.5
6.7	7.5
8.0	7.8
7.5	7.8
.0	6.0
	.0

? Mean

Group	
C1	C2
5.367	4.969

? Twot

C1 vs C2: $t(23) = 0.35$, $p = .7281$, $SE = 1.1292$

Confidence Intervals for Estimated Mean of Population

For .95 CI: 5.3667 ± 1.9078

For .99 CI: 5.3667 ± 2.697

Confidence Intervals for Estimated Mean of Population

For .95 CI: 4.9692 ± 1.5973

For .99 CI: 4.9692 ± 2.2347

95% CI [3.5-7.3]

95% CI [3.4-6.6]

Also a non-parametric Mann-Whitney test was performed and showed no difference between the two groups:

U Test Results

n_1	n_2	U	P (two-tailed)	P (one-tailed)
12	12	72.5	0.977402	0.488701
normal approx				
z = 0.0288675			0.97697*	0.488485*

*These values are approximate.

The two samples are not significantly different ($P \geq 0.05$, two-tailed test).

5. An independent t-test comparing the mean correct diagnosis of normal ears between the intervention and control groups was performed and showed no difference.

Datasim output:

Design Twogroup S/T

? Read normal.txt

Reading data for C1-C2....

? Display

Group	
C1	C2
8.30	5.00
5.00	9.00
.00	6.00
3.30	6.70
3.30	8.60
2.00	.00
10.00	5.00
5.00	3.30
3.75	8.30
.00	10.00
6.00	.00
6.70	8.00
7.14	3.33
	4.00

? Mean

Group

C1	C2
4.6531	5.5164

? Twot

C1 vs C2: $t(25) = -.72$, $p = .476$, $SE = 1.192$

Confidence Intervals for Estimated Mean of Population

For .95 CI: 4.65 ± 1.8218

For .99 CI: 4.65 ± 2.5489

Confidence Intervals for Estimated Mean of Population

For .95 CI: 5.5143 ± 1.8312

For .99 CI: 5.5143 ± 2.5519

95% CI [2.8-6.45]

95% CI [3.7-7.3]

Also a non-parametric Mann-Whitney test was performed and showed no difference between the two groups:

U Test Results

n_1	n_2	U	P (two-tailed)	P (one-tailed)
14	13	108.0	0.429238*	0.214619*
normal approx			0.409402*	0.204701*
z = 0.824945				

*These values are approximate.

The two samples are not significantly different ($P \geq 0.05$, two-tailed test).

6. An independent t-test comparing the overall scores for two groups who examined the same ears was performed and showed no difference.

Datasim output:

Design Twogroup S/T

? Read sim1.txt

Reading data for C1-C2....

? Display

Group	
C1	C2
4	6
7	6
6	8
3	4
10	5
7	8
6	7
6	2

? Mean

Group	
C1	C2
6.13	5.75

? Twot

C1 vs C2: $t(14) = .36$, $p = .7234$, $SE = 1.0383$

Confidence Intervals for Estimated Mean of Population

For .95 CI: 6.125 ± 1.7523

For .99 CI: 6.125 ± 2.5988

Confidence Intervals for Estimated Mean of Population

For .95 CI: 5.75 ± 1.7129

For .99 CI: 5.75 ± 2.5403

95% CI [4.4-7.9]

95% C[4-7.5]

Also a non-parametric Mann-Whitney test was performed and showed no difference between the two groups:

U Test Results

n_1	n_2	U	P (two-tailed)	P (one-tailed)
8	8	33.5	0.878478	0.439239
normal approx			0.874826*	0.437413*
z = 0.157532				

*These values are approximate.

The two samples are not significantly different ($P \geq 0.05$, two-tailed test).

7. Regression analysis was performed to see if residency level and or confidence level correlated with better mean correct diagnoses which neither did.

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.326 ^a	.106	.032	1.86963

a. Predictors: (Constant), confidence, resident_level

ANOVA^b

Model	Sum of Squares	df	Mean Square	F	Sig.
1 Regression	9.959	2	4.980	1.425	.260 ^a
Residual	83.893	24	3.496		
Total	93.852	26			

a. Predictors: (Constant), confidence_level, resident_level

b. Dependent Variable: score

Coefficients^a

Model	Un-standardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
1 (Constant)	4.096	1.192		3.435	.002
resident_level	.495	.359	.267	1.379	.181
Confidence_level	.308	.364	.164	.846	.406

a. Dependent Variable: score

VassarStats Printable Report:)

Values entered: pneumatic otoscopy

	Condition		Totals
	Absent	Present	
Test Positive	22	32	54
Test Negative	44	26	70
Totals	66	58	124

	Estimated Value	95% Confidence Interval	
		Lower Limit	Upper Limit
Prevalence	0.467742	0.378349	0.559161
Sensitivity	0.551724	0.416244	0.680359
Specificity	0.666667	0.538828	0.774988
For any particular test result, the probability that it will be:			
Positive	0.435484	0.347633	0.527389
Negative	0.564516	0.472611	0.652367
For any particular positive test result, the probability that it is:			
True Positive	0.592593	0.450627	0.721421

False Positive	0.407407	0.278579	0.549373
For any particular negative test result, the probability that it is:			
True Negative	0.628571	0.504303	0.738642
False Negative	0.371429	0.261358	0.495697
likelihood Ratios: [C] = conventional [W] = weighted by prevalence			
Positive [C]	1.655172	1.095627	2.500481
Negative [C]	0.672414	0.497958	0.907989
Positive [W]	1.454545	0.984456	2.149108
Negative [W]	0.590909	0.428534	0.814809

VassarStats Printable Report:

Values entered: otoscopy-only

	Condition		Totals
	Absent	Present	
Test Positive	30	42	72
Test Negative	42	25	67
Totals	72	67	139

	Estimated Value	95% Confidence Interval	
		Lower Limit	Upper Limit
Prevalence	0.482014	0.397077	0.567961
Sensitivity	0.626866	0.499679	0.739432
Specificity	0.583333	0.461245	0.696479
For any particular test result, the probability that it will be:			
Positive	0.517986	0.432039	0.602923
Negative	0.482014	0.397077	0.567961
For any particular positive test result, the probability that it is:			
True Positive	0.583333	0.461245	0.696479

False Positive	0.416667	0.303521	0.538755
For any particular negative test result, the probability that it is:			
True Negative	0.626866	0.499679	0.739432
False Negative	0.373134	0.260568	0.500321
likelihood Ratios: [C] = conventional [W] = weighted by prevalence			
Positive [C]	1.504478	1.081731	2.092435
Negative [C]	0.639659	0.459956	0.88957
Positive [W]	1.4	1.000609	1.958807
Negative [W]	0.595238	0.428885	0.826114