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Abstract

Background: The use of Tympanometry to diagnosis Otitis Media with Effusion (OME) in adults is not routine practice in primary care, although it is supported by evidence and clinical practice guidelines. The misdiagnosis of OME frequently leads to inappropriate antibiotic prescribing, contributing to the rise in drug resistant infections.

Purpose: This evidence-based practice, quality improvement project sought to determine if the use of tympanometry by Family Nurse Practitioners (FNPs), to assess adults visiting primary care clinics, improved the accuracy of otitis media diagnoses and decreased unnecessary antibiotic therapy. The project also evaluated whether experience using the tympanometer was correlated with decreased changes in FNP diagnoses after the review of tympanometer tracings.

Methods: A single tympanometer was provided to four FNPs in two primary care clinics. Tympanometry was performed on patients presenting with ear or hearing complaints, without otorrhea, recent ear surgery, or recent trauma to the ear. FNPs performed routine otoscopy exams and made a diagnosis while tympanometry naïve (prior to reviewing tympanometry tracings), and then reviewed tympanometry tracings and either maintained the original diagnosis or changed their diagnosis.

Results: A total of 42 patients were seen during the project timeframe and FNPs changed their diagnoses in 45.2% of cases (n =19) after reviewing tymponometry tracings. Most changes in diagnoses resulted in a shift from abnormal to normal (63.2%), potentially preventing the inappropriate prescribing of antibiotics. In addition, FNPs reported a review of tympanometry tracings informed their clinical decision making 69% of the time. Experience using the tympanometer was not significantly correlated with a decrease in changed diagnoses.

Discussion: While the number of cases was lower than expected, this project supports the use of tympanometers in primary care settings to diagnosis OME in adults.

The Routine Use of Tympanometry to Prevent Unnecessary Antibiotics in Patients with Otalgia: An Evidence-Based Practice, Quality Improvement Project Background & Significance

Approximately 13.6 million office visits in primary care result in otitis media diagnoses each year (Gaddey et al., 2019), most being treated with antibiotic therapy. Eventually, if the symptoms do not subside, the ongoing pain often leads to a specialty evaluation. It is not uncommon in a specialty otolaryngology practice to discover patients with complaints of otalgia, both adults and children, who present with a recent diagnosis of acute otitis media. Though the diagnosis of otitis media can be confirmed in many presenting patients, there are many adult patients whose otoscopic exams are normal when evaluated in the otolaryngology practice and these findings are confirmed by normal tympanometry and/or pneumatic otoscopy. Despite this normal examination, patients often continue to complain of ongoing pain, sometimes severe, with earache or otalgia being the only driving indication for patients seeking otorhinolaryngological interventions (Adegbiji et al., 2021).

In addition to complaints of ear pain, many patients presenting to an otolaryngology practice with a diagnosis of acute otitis media deny hearing difficulty or any other impact on hearing. This is significant since any type of middle ear effusion should cause significant hearing changes. Middle ear effusions can take weeks to months to fully resolve in adults, leaving one to question the accuracy of an otitis media diagnosis in primary care. This is concerning, because an inaccurate diagnosis can lead to unnecessary treatment with antibiotics and contribute to the development of antibiotic resistance (Harmes et al., 2013).

Research evidence has shown that bacteria continue to become increasingly resistant as they are exposed to more and more antibiotics. Spiro et al. (2004) discusses that an epidemic of microbial resistance is occurring in the United States, attributable in large part to the overprescription of antibiotics. Although most upper respiratory infections are caused by viral agents, antibiotics are often inappropriately prescribed for management of those conditions.

Unnecessary treatment with antibiotics can lead to unintended patient outcomes. Antibiotic use can fail to address or resolve a patient's pain, cause unwanted side effects, or delay proper treatment of an undiagnosed condition. In adults who present with otalgia, 40% to 75% present with signs and symptoms of TMJD (Temporomandibular Joint Dysfunction, also referred to as TMJ, TMD, and TMJD) (Macedo et al., 2014). Though the pain with TMJD can be severe, a more concerning diagnosis of SCC (Squamous cell carcinoma) of the base of tongue can produce severe pain as well. Both conditions require unique courses of treatment, neither of which involves antibiotics. Misdiagnosis is a major dissatisfier for patients, in addition to the potential for physical consequences and side effects of unnecessary antibiotic therapy. In contrast, a delay in diagnosis of SCC of the base of tongue can lead to irreversible consequences, including death.

There are many reasons this issue has gained a foothold in clinical practice, including but not limited to insufficient training of seasoned physicians, nurse practitioners, physician assistants, and medical students. It has been suggested that "General Practitioners (GPs) do not consider confirming the presence of effusion to be an important factor when diagnosing Acute Otitis Media (AOM) and GPs lack training in the use of these techniques. Training in tympanometry or pneumatic otoscopy is not standard practice" (Abbott et al., 2014, p. 2). According to Rosenfeld et al. (2016), who authored the clinical practice guideline for recommendations on Otitis Media with Effusion (OME), OME is most often diagnosed by primary care providers who are not validated against experienced otoscopists, and who do not often use a pneumatic attachment. In addition, GPs do not typically have the specialized equipment or education required to diagnose or treat otolaryngologic disorders and therefore refer patients to tertiary institutions for ongoing treatment (Whiteford et al., 2013).

Studies have also confirmed that tympanometry is a useful adjunct to pneumatic otoscopy because it provides objective evidence of middle ear status (Rosenfeld et al., 2016). Although recommended as a first-line diagnostic test for OME, pneumatic otoscopy has varying degrees of validity and accuracy in routine clinical practice. All studies examining test performance of pneumatic otoscopy have used experienced otoscopists with special training, validation, or both. Therefore, Rosenfeld et al (2016) recommends tympanometry when the diagnosis of OME is uncertain after pneumatic otoscopy is used or attempted. Despite these guideline recommendations, tympanometry and pneumatic otoscopy are not readily integrated or utilized in primary care practice with adults.

There has been a great effort to address these problems in children and many of the guideline recommendations are based on pediatric patients. However, there continues to be a gap in knowledge regarding research on middle ear effusions in adults. Recent clinical practice guidelines have stated that primary care clinicians should not diagnose AOM in children who do not have a middle ear effusion as demonstrated by tympanometry or pneumatic otoscopy because non-pneumatic otoscopy is inaccurate (Abbott et al., 2014).

Tympanometry, as an adjunct to otoscopy, may significantly improve provider prescribing behavior, thus decreasing the over-prescribing of antibiotics for OM. Abbott et al. (2014) found that training in the techniques of tympanometry or pneumatic otoscopy must be accompanied by training of clinical practice guidelines. The clinical practice guidelines provide common clinical issues faced by GPs to ensure good patient outcomes and to avoid increased health costs and patient burden (Abbott 2014). Clinical practice guidelines are commonly adopted in specialty practice, therefore, tympanometry is an intervention frequently used in otolaryngology for patients with complaints of otalgia or hearing loss, no matter their age. As described in Spiro et al., (2004) tympanometry measures the compliance of the tympanic membrane as pressure is varied in the ear canal; the method facilitates indirect determination of the presence or absence of fluid in the middle ear space. This modality provides an objective measure of ear canal volume, tympanometric peak pressures, gradients, and static admittance. A graphic curve is generated and can be compared with sample curves that represent various pathologic or normal conditions (Spiro et al., 2004). Better education is needed for all providers in the use of tympanometry, to allow patients access to treatments that will address the source of their ongoing pain.

There is overwhelming support in the literature for the use of tympanometry in the assessment and diagnosis of otalgia. Though studies describe in detail the misdiagnosis of patients with ear disorders, there is not sufficient focus on adult patients in the literature. This leaves a dire need for clinicians to verify and extrapolate findings from studies with children to adult populations.

The current practice in specialty otolaryngology clinics is to perform tympanometry on patients with ear complaints, including otalgia, or hearing loss. The evidence suggests if this practice were implemented by primary care providers, unnecessary use of antibiotics could be avoided. Further, implementation of this evidence-based practice could result in improved healthcare quality through increased provider satisfaction, improved patient care and population health, and reduced financial burdens on the health care system.

Purpose Statement

The purpose of this project was to answer the Problem, Intervention, Comparison, Outcome (PICO) question "Does the use of tympanometry by Family Nurse Practitioners (FNPs), to assess adults visiting primary care clinics, improve the accuracy of otitis media diagnoses and decrease the use of unnecessary antibiotic therapy, compared to standard otoscopy examination?". This important question needs investigating, especially in the adult patient population. Evidence-based practice literature supports findings that otoscopy alone is an imprecise method for the diagnosis of OM, which may lead to inappropriate antibiotic use (Spiro et al., 2004). The purpose of this project is to examine if tympanometry impacts clinical decision making, identification of middle ear effusions or otitis, and confirmation of normal ear examinations.

Review of Literature

Tympanometry is a valuable adjunct to otoscopy or pneumatic otoscopy (Harmes, 2013) when assessing patients for otitis media. There is significant support in the literature to utilize tympanometry regularly in children, however, this data could be extrapolated to adults. According to Stenklev et al., (2004), middle ear pressure and tympanic membrane compliance has no consistently significant changes when using age as a predictor, which supports the use of tympanometry in adults. There is a gap in the literature regarding evaluating adults with tympanometry, however, given research showing no significant changes in middle ear pressure and tympanic membrane compliance based on age, evidence completed in children would support the use of tympanometry in adults.

Evidence also supports the clinical use of tympanometry without using myringotomy as an objective measure of the presence or absence of fluid in the middle ear (Harris et al., 2005). Many older studies used myringotomy as a gold standard comparison to validate the accuracy of tympanometry. Myringotomy is performed by a surgeon who creates a small incision in the tympanic membrane to assess for fluid in the middle ear, which could potentially cause harm to a patient with a normal ear exam. Currently, for diagnosis of effusion in children or adults, tympanometry in combination with otomicroscopy or pneumatic otoscopy is the recommended technique (Perera et al., 2013).

In patients who complain of earache, a large portion have no pathology in the ear (Anwar et al., 2019). In the presence of a 'normal ear', it is important to examine the tonsils, teeth, pharynx, and the nose & paranasal sinuses as the likely sites of origin of earache. With malignancy as a possible pathology at these sites, a thorough and careful examination is advisable (Anwar et al., 2019). Squamous cell carcinoma of the base of tongue has been known to cause ear pain, usually unilateral, though this finding is rarer than that of TMJD or cervicalgia. One study found that 84% of patients with referred ear pain had some form of cervical spine pathology. They concluded that cervical spine degenerative disorders constitute important causes of referred otalgia in the elderly (Anwar et al., 2019). There is also a significant association between TMJD and otalgia (Macedo et al., 2014).

Kusdra et al found the presence of otological symptoms in patients with TMJD was very common, even without a local cause identified in the ears (2018). Commonly reported symptoms were tinnitus, ear pain, ear fullness, dizziness/ vertigo, and hypo- or hyperacusis. The results found a high prevalence of otological symptoms in TMJD patients, supporting a correlation between TMJD and commonly reported symptoms (Kusdra et al., 2018). Abegbiji et al. (2021) notes that TMJD occurs in more than 70% of the general population in developed countries.

In patients with symptoms of ear fullness associated with hearing loss in whom direct examination of the tympanic membrane is difficult or limited, referral for audiometry and tympanometry is appropriate. In patients with symptoms due to otitis media with effusion (OME), audiometry will reveal a mild to moderate conductive hearing loss, and tympanometry will be abnormal (Limb et al., 2021). This is a common scenario in otolaryngological practice.

Tympanometry Use and Reliability

Providers working in specialized otolaryngology practice have advanced training in otoscopy, pneumatic otoscopy, and microscopy, but even experts struggle with the technical requirements for performing pneumatic otoscopy. According to Abbott et al. (2014), for most general practitioners (GPs), pneumatic otoscopy is seen as the more difficult technical skill. They found the most important barrier to using pneumatic otoscopy perceived by GPs was their uncertainty as to whether there was true drum immobility or whether their technique was simply inadequate (Abbott et al., 2014). Unless the provider can maintain a proper seal in the external canal, movement of the tympanic membrane is not visible even in a normal ear exam. Rosenfeld et al. (2016) found that tympanometry, portable and professional (desktop) units, had sensitivity equivalent to pneumatic otoscopy for detecting OME (90% to 94%) but substantially lower specificity (50% to 75% for tympanometry, 80% for otoscopy). Abbot et al. (2014) also found that GPs perceived tympanometry was particularly useful for communicating with carers about ear disease, offering tangible 'proof' to parents of the diagnosis resulting in increased support of the management plan.

Overuse of Antibiotics

Adegdiji et al., (2021) conducted a study outside the United States and found that patients often self-treated ear pain with a variety of drugs obtained over the counter and from pharmacies. Lack of laws guiding drug procurement, dispensary, and administration in developing countries contributed to this phenomenon. Most of these drugs comprised various types of analgesics and antibiotics. Treatment failure using these medications prompted patients to seek medical intervention (Adegdiji et al., 2021).

While the issue of microbial resistance and the over prescribing of antibiotics in the United States has been a focus of national and professional health organizations, it continues to be a challenge. Patients frequently present to GPs with upper respiratory symptoms with an expectation of receiving antibiotics. As a result, antibiotics are commonly prescribed for presumed OM in the absence of effusions documented with tympanometry (Spiro et al., 2004). Blomgren et al., also revealed the number of AOM diagnoses decreased in almost 80% of otitisprone children, for no other apparent reason than accurate diagnosis (2004).

Based on the evidence, tympanometry is more likely than pneumatic otoscopy to change GP diagnoses and plans of care in children with otitis media. After minimal training, GPs preferred tympanometry due to ease of use and interpretation (Abbott et al., 2014). Nearly onequarter of all providers changed their initial otoscopic diagnoses after being provided with the results of tympanometry (Spiro et al, 2004). A significant number of patients prescribed antibiotics for OM had either normal tympanometry curves or some movement in the curves bilaterally. In an era of increased antimicrobial resistance, the evidence demonstrates that antibiotics are being overprescribed for presumed OM.

The antibiotics frequently used to treat OM are also used in the treatment of drugresistant infections such as gonorrhea, which are in danger of becoming untreatable. According to the Center for Disease Control and Prevention (2021), following the spread of gonococcal fluoroquinolone resistance, the cephalosporin antibiotics have been the foundation of recommended treatment for gonorrhea. The emergence of cephalosporin-resistant gonorrhea would significantly complicate the ability of providers to treat gonorrhea successfully, since there are few antibiotic options left that are simple, well-studied, well-tolerated, and highly effective. This is one example of a drug resistant condition which could continue to worsen if overprescribing of antibiotics continues. Many families of antibiotics which are used for presumed OM infection are now resistant in treating gonorrhea infections. Cephalosporins are another common antibiotic used in otitis media, especially if a patient is penicillin allergic. Antibiotics prescribed for non-infectious otalgia, thought to be otitis media, continue to promote dangerous antibiotic resistance.

Evidence Strengths & Limitations

When discussing the strength of the evidence, it cannot be overstated that significant evidence exists recommending the use of tympanometry in clinical practice when diagnosing any source of otalgia. This includes clinical practice guidelines which have been available for years but are not often implemented in primary care settings. Unfortunately, many clinicians do not have access to tympanometry, but even when available, they may not understand how to interpret the objective measurements. Though many studies support tympanometry, gaps in knowledge exist due to limited studies in adults, who frequently present for evaluation of otalgia. There is also an overall lack of education in otology for physicians, physician assistants, nurse practitioners, and students training in these fields.

A tympanometer could be considered too costly for a practice setting, but it should be noted that patients can be billed for tympanometry. This is a useful and proven intervention to confirm exam findings and should be utilized. More marketing and research should be completed to assess the barriers to obtaining the equipment necessary to perform tympanometry. It is not clear to consumers if high-end machines are necessary for accurate reporting of diagnostics. Comparison of head-to-head studies may be useful in comparing equipment standards and the need for calibration. Owning this equipment may be cost-prohibitive for implementation in smaller practices.

It should also be noted that the evidence reviewed and cited include a variety of methods, designs and formats, with some being clinical practice guidelines, systematic reviews, randomized control trials, and qualitative studies. The levels of evidence were ranked using the American Association of Critical Care Nurse (AACN). Though there were levels of evidence ranked A, B, and C, most articles were ranked as Level C.

Evidence-Based Practice Model

The Johns Hopkins EBP model was created by nurses and has a strong nursing perspective. The domains set forth in the model incorporate professional nurses, nursing practice, education, and research (Gawlinski & Rutledge, 2008). Gawlinski & Rutledge (2008) have described how the model uses the "PET" process, which includes practice question, evidence, and translation. Translation of the findings to best practices leads to overall practice improvement which positively impacts patients. This model, displayed in Figure 1, offered a path to answer this project's clinical question.

Figure 1



Johns Hopkins Evidence Based Practice Model (Dang et al., 2022).

Key Personnel and Stakeholders

Key personnel and stakeholders included Family Nurse Practitioners (FNPs) and medical assistants (Mas) from various clinical sites and the patients being assessed. The project team included the project lead (master's prepared, board-certified FNP), a DNP-prepared faculty

member, a Ph.D. prepared nursing faculty mentor (primary investigator), and a clinical expert (board certified Otolaryngologist). Other stakeholders included the office managers.

Project Resources

Bellarmine University's Nursing Department owned a tympanometer used for the training of undergraduate and graduate students. Use of the department's tympanometer for this project was approved by the Dean. The tympanometer was distributed to the participating FNPs during project implementation. Clinic personnel that identified the tympanometer as a valuable diagnostic tool were provided information on how to purchase a tympanometer for future use.

Methods and Procedures

The Johns Hopkins EBP Model was used to guide this evidence-based practice, quality improvement project. Tympanometry was introduced in multiple clinic settings to determine if tympanometry improved the accuracy of otitis media diagnoses and decreased the use of unnecessary antibiotic therapy. Instructions were provided to FNPs and MAs by the project director. Once implemented, data was collected regarding clinical decision making with and without tympanometry.

Population and Setting

FNPs providing primary care services in outpatient clinics were recruited to participate in this evidence-based practice, quality improvement project. FNPs participating in the project were required to have a minimum of a master's degree in nursing. The FNPs also had to be certified as an FNP by the American Nurses Credentialing Center (AACN) or the American Association of Nurse Practitioners (AANP).

The project took place in two separate clinics in the southeast region of the United States (U.S.). The first clinic was associated with a large Health Care Organization (HCO), providing family medicine and primary care to insured patients. That practice was in an urban setting with

a population of approximately 200,000 individuals. The second clinic was a 501c3 non-profit, federally qualified health center, servicing patients regardless of their ability to pay. A variety of health care services were offered in this rural clinic located in a small town with a population of approximately 20,000 individuals, not including the surrounding counties.

Intervention

A tympanometer, calibrated for patient use, was provided to each clinic for approximately three weeks. The project leader delivered and collected the tympanometer. Calibration of the tympanometer was maintained each day of use, based on manufacturer's recommendations to maintain patient safety. Tympanometry was performed by the intake MA on any adult patient presenting with ear or hearing complaints, excluding anyone with otorrhea, recent ear surgery, or recent trauma to the ear. FNPs independently examined patients who presented with ear or hearing complaints, excluding anyone with otorrhea, recent ear surgery, or recent trauma to the ear, while being tympanometry naïve (before reviewing tympanometry tracings). Once the initial assessment and diagnosis was documented, the FNP reviewed the tympanometry tracing and used the information to document the final assessment and diagnosis to inform the clinical decision-making process.

Training on the use and interpretation of tympanometry was provided to participating FNPs by the project leader through a written guide (Appendix A), and in-person on-site training sessions. An instructional video was also created, following training at the first clinical location, to offer the providers a resource they could reference when making interpretations of the tympanometry tracings. The MAs also had in-person training as well as written instructions (Appendix B).

An implementation plan for addressing barriers was consistently utilized and included, sending reminders to utilize the tympanometer and engaging the stakeholders more than once a week to address any concerns or questions that surfaced during data collection. Impromptu meetings via facetime were utilized for any immediate procedural issues or questions. Additionally, there was a video recorded training session for FNPs to assist with tympanometry interpretation.

Measures

This evidence-based practice, quality improvement project was evaluated through two process measures, and two primary outcome measures. The process measure was essential to determine if the project was carried out as intended. The outcome measures were examined to determine if the project was effective in improving the quality of care provided to patients through improved assessment and diagnosis accuracy.

Process Measures. A crude count of patients presenting with ear or hearing complaints, excluding anyone with otorrhea, recent ear surgery, or recent trauma to the ear, with documented tympanometry was the first process measure. This measure was documented by the FNP or MA on a simple tally sheet (Appendix C). The second process measure was collected on the follow-up questionnaire (Appendix D) and asked FNPs how frequently they reviewed tympanometry readings prior to the initial assessment and diagnosis of patients. The project follow-up questionnaire, completed by each provider, also gathered data on identified barriers, unintended consequences, and overall satisfaction with implementing tympanometry in the primary care setting, adding context to the process measures.

Outcome Measures. A documented change in the FNP's assessment and/or diagnosis before and after reviewing tympanometry tracings was the first outcome measure. These data were measured at the nominal level as either no change in assessment and/or diagnosis (1) or change in assessment and/or diagnosis (2) after tympanometry tracing review. This measure

allowed the evaluation of FNP assessment and diagnosis accuracy in patients presenting with ear or hearing complaints when tympanometry naïve.

The second outcome measure was to examine changes in assessment and diagnosis accuracy during phase 1 of the project (first 50% of patients for each FNP) compared to phase 2 of the project (second 50% of patients for each FNP). This measure provided insight into whether an FNP's accuracy in assessing and diagnosing patients presenting with ear or hearing complaints improved as they become more familiar with tympanometry readings. Assessment and/or diagnoses changes after review of tympanometry reading were categorized as phase 1 (1) or phase 2 (2).

Data Collection

Data was collected for each FNP over 21– 27 days, depending on the clinic site and schedule. The goal was for each FNP to document 40 cases or complete data collection within the project timeframe (15 clinic days). FNPs were instructed to stop data collection at 40 patients or the end of the time frame, whichever came first. The data collection form was completed in a paper and pencil format. The only information documented on the form was the FNPs initial assessment and diagnosis, the tympanometry tracing, the final assessment and diagnosis, and whether the tympanometer tracings impacted their clinical decision making. The bottom of the form was folded up to prevent the FNP from seeing the tympanometry tracings until after the initial diagnosis (Appendix E).

Forty forms were placed in individual folders for each provider with a designated twodigit number at the top right of the page. The first number was used for pairing data by provider, and the second number was used to indicate the numeric ordering of completed forms. For example, the number 3 - 2 indicates the form was completed by provider 3 and this was their second completed form. The provider number was not visible on the outside of the folder and folders were randomly distributed to maintain FNP anonymity. Completed forms were returned in the same folder, and folders were placed in a collection box locked in a secure file cabinet. No folders were opened until all data had been collected.

The project leader entered data into Microsoft Excel®. Data were then imported into IBM's Statistical Package for Social Sciences 29 software for analysis (SPSS). All data were stored on an encrypted and password protected computer.

Process Measures. Project protocol compliance was evaluated by determining how many patients who met inclusion criteria had tympanograms performed, calculating compliance rates based on data from the Tympanometery Completion Record (Appendix C). Additionally, FNP compliance with the project protocol that required an initial diagnosis prior to reviewing tympanometer tracings was evaluated using the follow-up questionnaire. FNPs were asked how often they reviewed tympanometry tracings prior to physically assessing the patient. Compliance rates were calculated for each of these measures.

Outcome Measures. The first outcome measure evaluated FNP assessment and diagnosis accuracy in patients presenting with ear or hearing complaints when tympanometry naïve. Documented changes in assessment and/or diagnosis by FNPs after the review of tympanometry readings, compared to their tympanometry naïve assessment and diagnosis, were evaluated through graphical display. Changes in assessment and/or diagnosis were coded as either no change or change in SPSS.

The second outcomes measure evaluated whether an FNP's accuracy in assessing and diagnosing patients presenting with ear or hearing complaints improved as they become more familiar with tympanometry readings. Documented changes in assessment and/or diagnosis by FNPs during phase 1 were compared to documented changes during phase 2. A Chi Square

correlation analysis was also performed to determine if accuracy of assessment and/or diagnosis was correlated with project timing.

Human Subjects Protection

Ensuring ethical standards is paramount when collecting data on human subjects. Data collection folders were randomly assigned to providers to maintain their anonymity. Additionally, no identifiable patient information was collected, and all findings were reported in aggregate form. This evidence-based practice, quality improvement project had no more than a minimal risk to providers and patients. Approval to conduct this project under the definition of quality improvement was obtained through Bellarmine University's Institutional Review Board (IRB) prior to data collection.

Results

During the project, 42 patients presented with ear or hearing complaints, without otorrhea, recent ear surgery, or recent trauma to the ear. The percentage of patients evaluated by each provider included 57.1% (n=24) for provider 1, 7.1% (n=3) for provider 2, 21.4% (n=9) for provider 3, and 14.3% (n=6) for provider 4. The project took place from April 26, 2023, to June 20, 2023. The project timeframe was limited due to the tympanometer malfunctioning and requiring it to be sent back to the manufacturer for repair.

Process Measures

The records of all 42 patients who presented with ear or hearing complaints, without otorrhea, recent ear surgery, or recent trauma to the ear, had printed tympanometry tracings on the patient record. In addition, the FNPs reported never reviewing tympanometry readings prior to the initial assessment and diagnosis of patients. Overall, there was a 100% compliance rate with the project protocols.

All providers answered that they "always" followed the project protocol and that they were "very satisfied" with the tympanometer. A total of 5 comments were received on the follow-up questionnaire. Data were categorized by barriers, unintended consequences, and overall satisfaction with implementing tympanometry in the primary care setting. Table 1 provides detailed comments from project participants.

Table 1

Categories	Comments
	I am concerned that performance of the tympanogram could create added stress and additional work for MA's who were working short staffed. Despite these concerns, the benefits of having the machine available would outweigh any potential impact on office workflow dynamics.
Potential Barriers	Two providers included concerns of misdiagnosis and overuse of antibiotics among patients evaluated in clinics not using tympanometry.
	This was a relatively seamless process for our office. The only thing I would consider that was slightly prohibitive was just finding time that the staff was able to attend a training to learn how to use the device but once it was a part of our process it was a smooth transition.
Unintended consequences	It did add some extra work to the MA/nurse's job. However, otherwise there were no consequences.
Overall Satisfaction	One clinic requested a copy of the cost benefit analysis of the device and information on the coding process for billing patients, because they planned to write a formal request for the purchase of a tympanometer. The information offered by the tympanometer allowed me to be more confident in my diagnosis. It gave me visual evidence to show patients when defending my decision not to prescribe antibiotics, particularly when patients persisted in their requests for antibiotic therapy.

Follow-up Questionnaire Data by Category

Results indicated that 45.2% (n=19) of encounters resulted in the FNP changing their initial diagnosis post-tympanometry tracing review. Phase 1 tympanometry encounters (first 50% of patients for each FNP) resulted in 26.2% (n=11) of initial diagnoses being changed post-tympanometry tracing review. Phase 2 tympanometry encounters (last 50% of patient for each FNP) resulted in a lower rate of changes in provider diagnosis at 19.0% (n = 8). There was not a statistically significant correlation between Project phase and change in provider diagnosis (χ^2 (1) = .423, p = .516).

Of the encounters where the initial provider diagnosis was changed (n = 19), 63.2% (n = 12) changed from abnormal to normal after providers viewed the tympanometry tracings. Further analysis revealed that some diagnoses changed from normal to abnormal following consideration of tympanometry tracings 36.8% (n = 7). There were 23 (53.8%) encounters that did not result in a change in diagnosis after viewing the tympanometry tracings.

The project documentation form also inquired if the provider felt the tympanometry tracings impacted their clinical decision making. FNPs responded that tympanometry impacted clinical decision making in 29 cases (69%) when making a diagnosis. This left 31% (n=13) of encounters where FNPs did not feel the tympanometry impacted their clinical decision making. It should be noted that there were a limited number of available symptomatic patients during the project timeframe and the tympanometer malfunctioned, limiting the number of patient assessments for all FNPs.

Discussion

There were 42 patients who presented with ear or hearing complaints during the project timeframe. This was fewer patient encounters than the team initially set out to review. In hindsight, it may have been better to start data collection during peak allergy levels for the

geographic location. Allergies can often escalate ear related symptoms which would have resulted in more cases.

Process Measures

Although the number of cases was lower than expected, data revealed that FNPs and MAs were diligent in performing tympanograms on patients who met the inclusion criteria. These findings suggest that the addition of tympanometry in primary care clinics is feasible. Further, this quick assessment technique could provide useful diagnostic information for providers encountering patients with ear and hearing complaints.

Outcome Measures

Evaluation of outcomes data revealed that nearly half of FNP diagnoses during the project period were changed after review of the tympanometer tracings. Most diagnoses changed from abnormal to normal, likely avoiding inappropriate prescribing of antibiotics. The remaining 36.8% of diagnoses changed from normal to abnormal, potentially preventing a misdiagnosis and the need for a return visit to the clinical or emergency department.

FNPs recognized the tympanometer was helpful in guiding their diagnoses and reported that a review of tympanometer tracings assisted with their clinical decision making 69% of the time. This was an important finding given that without the project, FNPs would not have had the assistance of tympanometry tracings. Interestingly, the data were not always easily interpreted as FNPs frequently reported tympanometry tracings assisted with clinical decision making even when their diagnoses did not change. This led the team to determine that the tympanometry tracings may have reinforced and/or validated assessment findings when the FNP was not confident with what they were visually seeing with otoscopy. This led the team to create an "Updated Tympanometer Record" (Appendix F) that included a section that asked if the tympanometer tracings informed clinical decision making, and if so, how it impacted clinical decision making (changed to a different diagnosis, confirmed the initial diagnosis, used as evidenced to reassure patients). These data extrapolated for review and compared to changes in diagnoses in future project cycles.

Another consideration is that the FNP and/or MAs may have been unable to accurately perform the intervention on some or all patients. Additionally, FNPs may have misinterpreted the tympanometer tracings. A review of clinical decisions by the project team leader, an FNP with over 12 years of otolaryngology experience, found that some diagnoses did not align with findings from the tympanometer tracings. Therefore, a second section was added to the updated tympanometry record to document the FNPs certainty with the final diagnoses. This addition should assist with data interpretation in the next cycle of the project.

Project Barriers & Limitations

There are many factors that could have influenced data collection and should be considered in future project cycles. One of the biggest challenges to this project was the limitation of tympanometers. Since there was only one tympanometer, it had to be shared between FNPs within the same practice location, so there may have been competing needs for use of the machine. Thus, MAs may have been rushed to use the machine, impacting the quality of the tympanometer readings. Workflow patterns were also an issue in some cases, specifically at the second clinic site which was understaffed. In these cases, FNPs at the clinic performed ear exams and completed the initial assessment, then they obtained the tympanogram themselves, when the MA was unavailable. FNPs then reviewed the tympanometry tracings before making a final diagnosis. These procedures aligned with the protocol as the provider made their initial diagnosis while tympanometer naïve, however, it was not an ideal scenario.

Another concern that may have affected data collection results was the need for clarity of the project documents. Once the data forms were available for data entry, it was difficult to understand if the provider used the machine to reinforce their diagnosis and how the tympanometry affected their clinical decision making. As a result, the tympanometer record was updated for the next cycle of data collection to include a rating system for certainty of diagnosis (Appendix F).

Though education was provided regarding interpretation of the tympanometry, most providers were anxious about using the machine to correctly interpret the status of the middle ear. More education may be needed due to some inconsistencies in documenting on the tympanometer record, in the cases where there was no change in diagnosis or when the diagnosis was not consistent with the tympanometry tracing. Though the printed tympanometry graph was consistent with the listed diagnosis 81% (n=34) of the time, it was not consistent with the diagnosis on 7.1% (n=3) of the cases. The remaining printed tympanometry graphs were not legible, likely due to their heat sensitive paper, or revealed significant artifact. Even in cases where the tympanometry did not match the listed diagnoses, it is a rare case in which there are diagnostic clues on physical exam which would outweigh the information listed on the tympanometry graph, leading a provider to a different diagnosis. An example of this would be when there is an obvious perforation of the tympanic membrane but the tympanometer is reading a borderline normal Ear Canal Volume (ECV), which would not support a perforation. To clarify the documented diagnoses, the tympanometer record (Appendix F) has been edited to include a Likert scale to distinguish the certainty of diagnoses and whether or not the provider is using this to confirm a diagnosis, or to have evidence to reassure the patient of a specific diagnosis.

During the final days of data collection at the second clinical site the tympanometer began having an "airflow error" which could not be cleared. The machine was not operating normally and could not be calibrated, so it was removed from service and sent back to the manufacturer for repair. In the future, to maintain the timeline necessary to continue data collection and allow FNPs to see the efficiencies of utilizing the tympanometer, it is recommended that there be at least two tympanometers available. Because this stage of the project was near the end of the assigned timeframe and had achieved 42 encounters (n=42), the data collection process was discontinued 3 days short of the planned end to data collection. Though this limited the potential symptomatic patient encounters, it was critical that patients were protected from injury once the machine malfunctioned.

Conclusion

Although the findings from this project were not statistically significant, including a larger number of available symptomatic patients in the future would increase the power, and better determine if increased experience using a tympanometer is correlated with decreased changes in FNP's diagnoses. Future considerations including prior training in otology and certainty of the FNP's diagnosis would be important variables to account for in future projects and studies. It is also important to note that 28.6% of the patients were thought to have abnormal findings when their exam was normal. When considering the effects of potential unnecessary treatments, such as antibiotic therapy, a 28% decrease in overall unnecessary prescriptions would not only decrease the financial burden of health care costs but would also decrease the promotion of antibiotic resistance. In the next cycle of this project, we plan to implement the device not only in primary care, but also in urgent care settings, where complaints of ear pain and hearing problems are more common. An increase in cases may provide the necessary power to determine if experience using tympanometers routinely in practice is correlated with a decrease in diagnoses changes after reviewing tympanometer tracings.

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Appendix A – Provider Interpretation Guide



Key Components and Terminology:

Ear Canal Volume (ECV)

ECV provides a measurement of air volume in the ear canal between the tympanometer probe tip and the tympanic membrane (or the amount of space measured in the ear canal with the machine can push the tympanic membrane to 200 daPa). The owner's manual states the normal Ear Canal Volume (ECV) reading is 0.6 to 2.5 ml. This parameter is worth noting when the tympanogram lacks a curve.

Normal Adult ECV measurements are: 0.6 to 2.5 ml.

ECV Interpretation

Small ECV measurement (< 0.3 ml) - probe may be positioned against the ear canal or against cerumen (ear wax)

Normal ECV measurement (0.6 to 2.5 ml) with a Type B (flat line- no movement of the TM) indicates a likely middle ear effusion.

Large ECV measurements (> 2.6 ml)- could signal a patent PE tube or a perforation of the tympanic membrane can cause larger than normal ECV measurements.



(daPa) Peak Pressure/Peak

This is the highest middle ear pressure it takes to get compliance reading or peak admittance (below) or in other words the measurement of the point on top the graph. This can be a positive or negative number and falls on the X-axis of the graph. The peak, if normal, should fall within the normal box on the graph. On the example the reading below is -40 and is considered

normal. A reading is considered normal if it results as -100 to +50 on the printout. When the pressures measure at or beyond -150 (Negative 150) it is more consistent with an middle ear environment hospitable to middle ear fluid, but at -200 (negative 200) there is a much higher probability that fluid has wept in to the middle ear space causing a serous effusion.

Normal listed in the owner's manual include +50 to -50 daPa, but -100 can also be considered normal. Usually, you will not identify positive numbers that are higher than +50.

An example of what a patient may be feeling is like when you are in the mountains, and your ears need to pop- that is negative pressure. If you blow your nose too hard and force air behind the tympanic membrane (via the eustachian tube) you can see positive pressure readings. Both may give the sensation of pressure or muffled sensation to the ears, though they may appear completely normal on visible inspection.



(Pk) Peak Admittance/Compliance

Compliance is plotted vertically on the tympanogram (Y-axis). Maximum compliance of the middle ear system occurs when the pressure in the middle ear cavity is equal to the pressure in the external auditory canal. The maximum compliance value occurs at the highest peak of the curve on the graph (does the peak (point of the graph) sit in the "normal" box on the graph). The degree of compliance (tympanic membrane movement) is also noted in **milliliters (ml)** as the height of the peak on the vertical axis of the tympanogram.

Compliance tells you how much movement there is of the ear drum (whether the peak of the graph is short or tall – or rather the ear drum is stiff or has a short peak – top of the graph (Type As) or hypermobile and flimsy – with a high peak at the top of the graph- meaning it is a tall graph. (Type Ad).

This is also a measurement used to calculate otoacoustic emissions (OAE). The machine can also measure these OAEs, but I have that feature turned off since it can be confusing, and we will not be focusing on OAEs.

Compliance and Pressure Measurement Interpretation

Typical tympanogram heights and widths, measuring compliance and pressure are classified into types depending on the shape of the peak. These types of peaks are classified as types

(Pk) Peak Admittance/Compliance



A, Ad, As, B, or C.

These instructions and images on this page were modified from the Washington Manual Survival Guide Series: Otolaryngology Survival Guide (Layland, M. & Lin, T., 2003) and Northside Audiology found at https://northsideaudiology.com.au/interpreting-test-results/

CLASSIFICATIONS:







Steps to Interpret Waveform Output:

- 1. Is there an adequate waveform (compliance)?
 - A. If yes then go to 2, If no go to 3
- 2. Is the peak of the normal appearing waveform (Compliance) in the normal box?
 - Yes = probably normal Type A tympanogram (this would be normal or it could be eustachian tube dysfunction if they are symptomatic- meaning ear is normal in appearance and has normal tympanometry but they complain of "ear pressure").
 - b. No= classify what type of tympanogram the patient has.
 - Is it a Type As (Stiff TM = low peak), Type Ad (Flimsy TM= high peak because of additional movement), or is it a Type C (normal appearing graph but shifted to the left on the page because the peak pressure (daPa) would be higher than -150, causing the peak and graph to fall to the left of the normal box)
- 3. If there is no peak you only note a flat line, then look at the ECV (Ear Canal Volume)
 - a. If there is a flat line (Type B tympanogram) with an <u>extremely low ECV</u> Machine did not take adequate pressure or was blocked- please try to obtain tympanogram again.
 - b. If there is a flat line (Type B tympanogram) with a <u>normal ECV</u>- Probable middle ear effusion, correlate with physical exam findings.
 - c. If there is a flat line (Type B tympanogram) with a <u>large ECV-</u> Probable TM perforation, correlate with exam findings.

These instructions and images on this page were modified from the Washington Manual Survival Guide Series: Otolaryngology Survival Guide (Layland, M. & Lin, T., 2003) and Northside Audiology found at https://northsideaudiology.com.au/interpreting-test-results/

Appendix B - Medical Assistant Training Instructions

Instructions for Medical Assistant (Or Person Obtaining the Tympanogram)

The following information is a condensed version of the instructions. A full copy of the owner's

manual will be made available during the data collection process at your facility.

A. Daily Calibration

The operation of the MicroTymp 4 should be checked daily using the 4 in 1 test cavity assembly supplied with the instrument.

1. Select the DAILY CHECK option in the main menu:

DAILY CHECK	۵
INSERT PROBE	
Cancel	

2. Wait until "INSERT PROBE" is displayed.

Insert the probe, without an ear tip, into the hole at the **2ml end of the test cavity**. Make sure that the probe is pushed fully home and is held tight against the stop. The probe must be square to the end of the test cavity. The display should show the volume of the 2ml test cavity to within ± 0.1ml.

	DAILY CHECK	٩
Volume:	2.0 ml	
Cancel		

B. PERFORMING A TEST

No specific action is required by the patient during the automatic test. However, the patient must be advised to remain still and avoid speaking or swallowing while the probe is applied to the ear.

1. From the MAIN MENU select NEW TEST:

This information is taken from the Welch Allyn Owners Manuel for the MicroTymp4 Tympanometer (2021).

MAIN MENU	٩
NEW TEST	
CONFIGURATION	
VIEW THE LAST TEST	
	Select

2. Select the ear(s) required for test:

	SELECT EAR	٩
	BOTH: L, R	
	LEFT	
	RIGHT	
Back	↑↓	Select

The message "Deleting last test" will be displayed momentarily and a message displayed to insert the probe into the ear to be tested:

3. Once the select button is pressed, follow the instructions on the screen.

	TESTING LEFT EAR	•
	INSERT PROBE	
Cancel		

4. Place the ear tip into the ear canal to obtain a seal and the following messages will be displayed:



This information is taken from the Welch Allyn Owners Manuel for the MicroTymp4 Tympanometer (2021).

5. Information about the Ear Seal with then show on the display.

TESTING LEFT EAR	٩
Obtaining ear seal	
Low : 	
High : ■■■■	
Cancel	

6. The number of bars shown indicates the robustness of the seal. The probe should be adjusted in the ear until two or more bars are shown for Low and High. Once an adequate seal is detected the following message will be seen and a tympanogram measurement is made.

TESTING LEFT EAR							
	Seal Obtained						
	Taking Tympanogram						
Cancel							

Taking a tympanogram takes about 3 seconds. It is important not to move the probe and to ask the patient to remain very still during the test.

7. When the measurement is complete withdraw the probe and the tympanogram will be displayed on the screen:



- 8. The message "Saving as last test" will be displayed briefly and the results will be saved in the "last test" memory. The results will remain available until a new test is started, even if the MicroTymp 4 is turned off. If both ears were chosen for test the entire sequence will now be repeated for the right ear.
- 9. When the selected ears have been tested and the results saved the PROCESS RESULTS menu will be

displayed. This accesses the following functions: PRINT (Print the results)

SAVE RESULTS (Save the results in the internal database)

VIEW TEST (Review the results as described above)

This information is taken from the Welch Allyn Owners Manuel for the MicroTymp4 Tympanometer (2021).

MAIN MENU (Return to the main menu)

The results of the last test performed remain available even if the MicroTymp 4 has been turned off. To view these results select VIEW THE LAST TEST from the main menu. After selecting the required ear the tympanogram will be displayed. It will then be possible to view the results and select the PROCESS RESULTS menu as if the test had just been completed. **NOTE: Results of the last test will be erased as soon as a new test is started. Test results should be saved to the internal database or printed to ensure that data is not lost.**

10. The Welch Allyn MicroTymp 4 will switch off automatically if no key is pressed for 90 seconds. The printout of the test results may include date of the instrument's calibration. Use the ▲ and ▼ keys to select if the calibration date is printed or hidden. Press the ► key to confirm and save the selection or the ◄ key to cancel.

C. Printing:

1. Return the Welch Allyn MicroTymp 4 to the charging cradle (which is connected to the printer by a cable.

2. To print the results of the last test select SEND TO PRINTER from the PROCESS RESULTS menu on completion of the test.



3. Press \blacktriangleright when the printer is ready.

Once the print operation has been carried out the PROCESS RESULTS menu is displayed.

1. Affix printout to a new <u>Tympanometry Record</u> from the study envelope. No patient or provider information should be listed on the document.

This information is taken from the Welch Allyn Owners Manuel for the MicroTymp4 Tympanometer (2021).

Appendix C – Tympanometry Completion Record

Tympanometry Evidence-Based Practice, Quality Improvement Project Tympanometry Completion Record

Providers # _____

Please provide a tally mark or number for each patient that met criteria for tympanometry and for each patient that received a tympanometry assessment, as well as completion of daily calibration of tympanometer. Page 1

Day of the Week	Tympanometer Daily Calibration Complete	Patients Presenting with Ear or Hearing Complaints, without Contraindications	Tympanometry Complete
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			

Page 2

Never

Rarely

Appendix D – Follow-Up Questionnaire

Tympanometry Evidence-Based Practice, Quality Improvement Project Follow-Up Questionnaire

2.					
	Please list an	y barriers to implem	nenting tympanon	netry in your office se	etting:
•	Please list an	y unintended conse	quences of impler	menting tympanome	try in your office set
•	setting:	our overall satisfacti	ion with the imple	ementation of tympa	nometry in your offi
	1	2	3	4	5
	Very	Somewhat	Neutral	Somewhat	Very
	Satisfied	Satisfied		Dissatisfied	Dissatisfied
	How often di	d you review tympa	nometry readings	prior to completing	your initial assessm
.	and diagnosi	s of patients?	, 0		

Often

Always

Appendix E – Tympanometry Record

Tympanometry Record

Prov	viders # _	т	ympanom	eter Nur	nber: _		Obtai	ned Succ	essful	ly	Yes 📃) I	No [
STE	P 1: BEF	ORE OBS	ERVING 1	ΓΥΜΡΑΙ	νομει	RY REA	DING:							
	Doci	ument Ph	ysical Exa	ım Findi	ngs:									
		RT LT		RT L	т	RT	LT		RT	LT			RT	LT
External	Normal		Swelling		Ervt	nema 🦵		Otorrhea			Cerumen/or	Impaction		
Auditory Canal Tympanic	Normal		Injection		Ervt	nema		Other:						
Membrane Middle Ear	Clear (No		Purulent		Sero	us		Other:						
Space	fluid)		effusion		effu	sion		other						
Dia	gnosis (<u>k</u>	<u>efore</u>	Normal E	ar Exam	n 🗌	Sei	ous ot	itis med	lia 🗌		Acute oti	itis med	lia 🗌	
Tyn	npanome	etry):												
Oth	er Findii	ngs/Diagr	iosis:											
				F	old paper	so the bott	om edge	stops at this	line.					
<u>STE</u>	<u>p 2:</u> INT	ERPRET A	ND ANAL	YZE AV	AILABL	E TYMP.	ANOM	ETRY:						
	1.5	2m3						. 1 6						
								[cm3					
	ł							F		1				
	ŀ							ŀ		1				
	400	daPa	0 +2	200				400	da	Pa	6 ' +	200		
									_					
L	eft Ear T	ympanon	netry Prin	tout				Right E	ar Tyr	npan	ometry I	rintout	t	
				FC	DLD HEI	RE								
Dia	gnosis u s	sing												
Tym	npanome	etry: N	Iormal Ea	r Exam		Serou	s otitis	s media		А	cute otit	is medi	a 🗌]
Oth	er Findii	ngs/Diagr	osis:											
ا - : م	+	o		مانما م	d de ei-		ing?	V-		ו				
טוט	rympan	ometry Ir	iipact you		in uecis		iiig :	re	:>	J				

Appendix F – Updated Tympanometry Record																
Providers #			Tympanometer Number:							Obtained Successfully Yes					No 📃)
<u>STEI</u>	STEP 1: BEFORE OBSERVING TYMPANOMETRY READING:															
	Document Physical Exam Findings:															
		RT	LT		RT	LT		RT	LT		RT	LT			RT	LT
Auditory Canal	Normal			Swelling			Erythem	na		Otorrho			Cerumen/	or Impactio	ⁿ	
Tympanic Membrane	Normal			Injection			Erythem	na 📃		Other:						
Middle Ear Space	Clear (No fluid)			Purulent effusion			Serous effusion			Other:						
Diagnosis (before Tympanometry)- Normal Ear Exam Serous otitis media Acute otitis media																
Oth	Certainty of Diagnosis BEFORE viewing tympanometry:															
Certainty of Diagnosis BEFORE viewing tympanometry:																
tympanometry Very certain Somewhat certain Somewhat unsure Not sure at all																
Fold paper so the bottom edge stops at this line.																
Left Ear Tympanometry Printout Equation 1.5 cm ³ Left Ear Tympanometry Printout Right Ear Tympanometry Printout																
Diagnosis <u>AFTER</u> using Tympanometry: Normal Ear Exam Serous otitis media Acute otitis media																
Other Findings/Diagnosis:																
Cert	Certainty of FINAL Diagnosis AFTER using tympanometry:															
Certainty of di tympanometry	Very cer	Somewh	ewhat certain			ewhat u	Insure Not sure at all									
Did	tympano	omet	ry in:	ipact yo	our clini	cal d	ecisio	n maki	ng?		Yes 🔽		No			
If you selected YES how did tympanometry help you the most (Choose only 1)					Changed to a different diagnosis			Confirme initial dia	ed the Used as evidence to Reassure patients				Other:		_	