

## Clinical Diagnostic Accuracy of Otitis Media with Effusion in Children, and Significance of Myringotomy: Diagnostic or Therapeutic?

The specific aims of this prospective survey were to determine the accuracy of traditional diagnostic tools, such as pneumatic otoscopy, otomicroscopy, and tympanometry, and evaluate the usefulness of myringotomy as a diagnostic method; also to determine the significance of myringotomy in treating otitis media with effusion (OME). The status of middle ear of 51 children (85 ears) from November 2002 to February 2003 was examined using pneumatic otoscopy, otomicroscopy, and tympanometry, and the presence/absence of middle ear effusion was confirmed by myringotomy. The otomicroscopy was the most sensitive and specific one among three diagnostic tools. But, it had some false positive cases. This study failed to show the therapeutic efficacy of myringotomy. Otomicroscopy seems to have the potential to become the standard for diagnosis of OME and for validation of pneumatic otoscopy in children. However, when otoscopic, otomicroscopic findings and tympanogram of suspected ear show poor correlation, myringotomy can be used to confirm the presence of OME, as the diagnostic modality. As the therapeutic modality, we think that it is proper to limit indications of myringotomy to some selected cases.

Key Words : Middle Ear Ventilation; Tympanostomy; Otitis Media With Effusion; Otomicroscopy; Otoscopy

Dong-Hee Lee, Sang-Won Yeo

Department of Otolaryngology-Head and Neck Surgery,  
College of Medicine, The Catholic University of Korea,  
Seoul, Korea

Received : 19 January 2004  
Accepted : 20 May 2004

### Address for correspondence

Dong-Hee Lee, M.D.  
Department of Otolaryngology-Head and Neck  
Surgery, The Catholic University of Korea, Uijeongbu  
St. Mary's Hospital, 65-1 Gumoh-dong, Uijeongbu  
480-130, Korea  
Tel : +82.31-820-3564, Fax : +82.31-847-0038  
E-mail : leedh0814@catholic.ac.kr

## INTRODUCTION

Otitis media (OM) is one of the serious healthcare concerns worldwide, not only because of the distress that it causes upon patients and their family, but also because of the substantial economic burden that it imposes on the health care system. Despite OM is the most commonly diagnosed and treated disease in childhood for otolaryngologists or pediatricians, there is a tendency that it is over-diagnosed as well as over-treated. Over-diagnosis leads to unnecessary and inappropriate use of antibiotics, and inappropriate antibiotic treatment encourages the emergence of multidrug-resistant strains of bacterial pathogens (1).

OM is defined as an inflammation of the middle ear, without reference to a specific etiology or pathogenesis. Because OM is the leading indication for antibiotics use in community practice, because there are diagnostic criteria distinguishing acute otitis media (AOM) from otitis media with effusion (OME), and because there are guidelines for antibiotics use, the need for precise diagnostic tool should be considered (2).

The diagnosis of OME is not easy, and there is significant variability in the ability of clinicians, especially primary care physicians or pediatricians, to diagnose it (3, 4). Symptoms of OME are neither sensitive nor specific, and most children with OME are asymptomatic (5). In the diagnosis of OME, physical examination is also potentially inaccurate, because

subjective impressions of the appearance of tympanic membrane are difficult to be quantified and graded. Furthermore, children may be uncooperative with the examination.

Other numerous diagnostic tools have been developed to improve the accuracy for diagnosis of OME. In the diagnosis of OME, pneumatic otoscopy remains to be the gold standard (4-6). The use of other diagnostic tools in addition to pneumatic otoscopy, such as impedance audiometry and tympanocentesis, further improve the diagnostic accuracy (5).

This study surveyed the accuracy of several diagnostic tools, such as pneumatic otoscopy, otomicroscopy, and tympanometry, in diagnosing OME. The specific purposes of this study were to 1) determine the accuracy of traditional diagnostic tools, such as pneumatic otoscopy, otomicroscopy, and tympanometry, and evaluate the usefulness of myringotomy as the diagnostic method; 2) also to determine the significance of myringotomy in treating OME.

## MATERIALS AND METHODS

This prospective study was performed on all cases of suspected OME from November 2002 to February 2003. To exclude potential confounding factors, the study was scheduled so that the period of the study was limited to winter. The age of children participated in the study was restricted to be

less than 10 yr-old. A total of 118 children participated in this study.

#### Determining the accuracy of three traditional diagnostic tools and evaluating the meaning of myringotomy as a diagnostic tool

Cerumen was removed carefully. Then, the status of middle ear was examined using pneumatic otoscopy, otomicroscopy, and tympanometry. Finally, myringotomy confirmed the presence/absence of middle ear effusion.

Pneumatic otoscope (Beta 200 Diagnostic Otoscope; Heine, Herrsching, Germany) with 3.5V XHL Halogen illuminator was used. Otomicroscope (OPMI1FC-S2; Carl Zeiss, Thornwood, NY, U.S.A.) was used. The tympanic membrane was evaluated for color, position, and mobility. In this study, the appearance of typical normal tympanic membrane was defined to be translucent, pearl gray, fully mobile, and with no evidence of effusion. When one or more findings of followings were seen, OME was diagnosed; opaque tympanic membrane, yellow or amber color, decreased mobility, presence of air fluid level or bubbles, and retracted tympanic membrane.

Impedance audiometer AT235 equipment (Interacoustics AS, Assens, Denmark) was used for tympanogram. The equipment used 226 Hz probe tone frequency, and positive and negative pressure sweep between +200 and -400 daPa. The sweep speed was 600 daPa/sec except near the tympanogram peak where it slowed to 200 daPa/sec, and the compliance range was 0.1 to 0.6 mL. Three consecutive tests were performed to get a reliable curve for interpretation. Tympanometric curve results were classified according to modified Jerger's classification as types A, B, or C (7) Types A and C curves were interpreted as no middle ear effusion, and type B as a predictive of middle ear effusion (7, 8).

The myringotomy was performed to confirm the results of three diagnostic tools. At first, cerumen was removed under direct vision. Thereafter, EMLA 5% cream (Astra, Sodertalje, Sweden) was applied to antero-inferior portion of tympanic membrane under the otomicroscope. After 15 min, EMLA cream was cleaned. After a long curved myringotomy incision was made antero-inferiorly, the middle ear was aspirated until dry. The myringotomy was not tried to children who were irritable or complained of severe pain during EMLA cream was applied. The myringotomy was carried out twice; the first myringotomy was performed on initial visit for diagnos-

tic purpose.

#### Evaluating the myringotomy as a therapeutic tool

If middle ear effusion was confirmed, the patient was treated with a 10-day course of antibiotics and a 30-day course of antihistamine/decongestant combination. If middle ear effusion persisted despite of this treatment, second myringotomy was performed for therapeutic purpose. For OME that persisted more than 3 months despite adequate medical treatment and complicated by hearing loss, ventilation tube insertion was performed.

All statistical analyses were performed using the SPSS software programs (SPSS Inc., Chicago, IL), and a *p* value <0.05 was considered significant.

## RESULTS

One hundred-eighteen patients consisted of 63 males and 55 females. The mean age was 63.6 months (standard deviation, 32.8 months; range, 24-121 months). The mean duration of OME was 39.3 days (standard deviation, 22.8 days; range, 7-96 days). After exclusion of data on perforated ears, discharging ears, failed tympanogram and failed myringotomy, 51 patients were chosen. These 51 patients consisted of 33 males and 18 females. The mean age of this myringotomy group was 75.8 months (standard deviation, 28.8 months; range, 29-108 months). 85 ears of these patients participated in this study, and consisted of 40 right ears and 45 left ears. The mean duration of OME was 37.4 days (standard deviation, 20.7 days; range, 7-93 days) in myringotomy group. No difference between non-myringotomy group and myringotomy group was seen among age and duration of the disease (*p*>0.05).

#### Determining the accuracy of three traditional diagnostic tools and evaluating the meaning of myringotomy as a diagnostic tool

Diagnostic accuracy of pneumatic otoscopy, tympanometry and otomicroscopy was shown in Table 1. Sensitivity of pneumatic otoscopy, tympanometry and otomicroscopy was 97.2%, 87.5%, and 100%, respectively. Specificity of pneumatic otoscopy, tympanometry and otomicroscopy was 38.5%, 0%

Table 1. Diagnostic accuracy of otoscopy, tympanometry, and otomicroscopy

		Otoscopy		Tympanometry		Otomicroscopy	
		+*	-†	+‡	-§	+¶	-¶
Myringotomy	+**	70 ears	2 ears	63 ears	9 ears	72 ears	0 ears
	-††	8 ears	5 ears	13 ears	0 ears	5 ears	8 ears

\*,† indicate respectively presence and absence of findings appropriate to OME. ‡,§ indicate respectively type B and type A or C of tympanometry. ¶,¶ indicate respectively presence and absence of findings appropriate to OME. \*\*,†† indicate respectively presence and absence of middle ear effusion.

and 61.5%, respectively; the otomicroscopy was the most sensitive and specific diagnostic tool. McNemar's  $\chi^2$  test showed no difference in the ability of the diagnostic methods to detect the middle ear effusion (between pneumatic otoscopy and myringotomy;  $p=0.109$ , between tympanometry and myringotomy;  $p=0.523$ , and between pneumatic otoscopy and myringotomy;  $p=0.063$ ). The otomicroscopy showed a good agreement with myringotomy ( $\kappa=0.731$ ). But, pneumatic otoscopy and tympanometry did not agree with myringotomy ( $\kappa=0.440$  and  $\kappa=-0.143$ , respectively).

### Evaluating the myringotomy as a therapeutic tool

The following criterion was used for defining "treatment failure" in the myringotomy group; the presence of middle ear effusion at two consecutive weekly visits after the second myringotomy was considered as "treatment failure". 73 ears (85.9%) of 85 ears in the myringotomy group met this treatment failure criterion in this study. Forty-seven ears (64.4%) of 73 ears in the myringotomy group were cured by further long-term medical treatment. In 26 ears (35.6%) who did not show any improvement despite medical treatment, ventilation tube (Paparella type I vent tube, Medtronic Xomed, Inc., FL, U.S.A.) was inserted finally. In 12 (of 8 patients) of 26 ears (of 17 patients), ventilation tube insertion was performed under local anesthesia, which was in the same manner as in myringotomy.

## DISCUSSION

Otitis media is the most common bacterial infection and the most frequent indication for antibiotics or surgical therapy in pediatric population. It is also a common problem that causes hearing loss in a substantial proportion of children. The morbidity associated with OM is substantial, and the costs of medical and surgical therapy for children 5 yr of age and younger account for >\$5 billion in health care expenditures annually in the United States (9, 10). The number of operative procedures performed annually in the United States is estimated at about 600,000 (11).

Classification of otitis media without perforation of tympanic membrane is currently based on the temporal sequence of the disease process (not severity). The terms "acute, subacute, and chronic" are recommended (12). Acute otitis media is an inflammation of the middle ear that presents with a rapid onset of signs and symptoms, such as pain, fever, irritability, anorexia, or vomiting. Chronic stage implies middle ear effusion that has been present for 3 months or longer, and has many synonyms, including serous OM, secretory OM, and "glue ear". The subacute stage is the time in between.

Unless clinician knows the patient's previous middle ear status, duration of disease can be very difficult to determine. So, it is simply classified into two major classes of OM; AOM

and OME (9). AOM is typified by the symptoms and signs of acute infection (fever, pain; a red, bulging tympanic membrane; and middle ear effusion). Chronic OME indicates a middle ear effusion without pain, redness, or bulging of the tympanic membrane. Middle ear effusion (MEE) denotes a liquid in the middle ear cleft regardless of etiology.

For a clinician, the diagnosis of OME usually depends upon a high index of suspicion and the presence of symptoms, but primarily on the pneumatic otoscopic findings. Most children with OME are asymptomatic, but some may complain of hearing loss and, less commonly, tinnitus and earfullness. In some children, the attention of an alert parent or teacher may be drawn to a suspected hearing loss. Older children will describe a frank hearing loss or, more commonly, a "plugged" feeling or "popping" in their ears. However, these symptoms are neither sensitive nor specific, and most children with OME are asymptomatic; these are different from AOM, which has typical history. Despite the high prevalence of OME, this is the reason why accurate diagnosis remains difficult.

This study compared the diagnostic accuracy of pneumatic otoscopy, tympanometry, and otomicroscopy; the confirmation of middle ear effusion was based on the results of myringotomy. In otoscopic examination, eight false positive ears were found; of these, two ears were appeared as amber color, two ears as opaque, and two ears as bubble. These eight ears were type B in tympanogram. Of these eight ears, three ears (one amber ear, two opaque ears) were found as normal in otomicroscopic examination. Two false negative ears showed type B tympanogram, and were found as OME in otomicroscopic examination; one ear had serous effusion and the other mucoid effusion (Table 1).

In tympanogram, thirteen false positive ears were found; of these, five ears appeared as normal in otoscopic and otomicroscopic examination. Nine false negative ears, which showed type C tympanogram, were found as OME in otoscopic and otomicroscopic examination. Of these, one ear had serous effusion, two ears purulent, and six ears mucoid effusion (Table 1).

In otomicroscopic examination, five false positive ears were found; of these, one ear appeared as amber color, two ears as opaque, one ear as bubble, and one ear as retracted position. These five ears were type B in tympanogram. No false negative ear was found in otomicroscopic examination (Table 1).

Among these three tools, otomicroscopy was the most sensitive and specific. In addition, only otomicroscopy showed a good agreement with myringotomy ( $\kappa=0.731$ ). So we suggest that routine use of the otomicroscope improves the ability to make the subtle judgments. Generally, most clinicians who use otoscope have good sensitivity for the presence of middle ear effusion, but being confident about the absence of effusion (specificity) takes experience and practice (9). In this study, otoscopic examination had high sensitivity (89.7%), but low specificity (71.4%); we think that this low specificity is the major demerit as the main diagnostic tool.

In this study, five ears got abnormal appearance of tympanic

membrane under otoscopic and otomicroscopic examination, as well as type B tympanogram; but no effusion was found in myringotomy. Otoscopic finding, otomicroscopic finding and tympanogram were not agreed in nineteen ears (22.4%). Eleven ears of these nineteen were confirmed as OME by myringotomy. And in nine ears of these eleven, otoscopic and otomicroscopic findings were abnormal, but tympanogram showed type C. Considering Jerger's study that the majority of middle ear problems account for the predominance of type B and C, we think that type C tympanogram may suggest the presence of middle ear effusion (8). So we think that when otoscopic finding, otomicroscopic finding and tympanogram of suspected ear are poorly correlated, myringotomy can be helpful to confirm OME. Especially in the cases of abnormal otoscopic and otomicroscopic findings, but of type C tympanogram, we think that there is a need for myringotomy to confirm the diagnosis. So we suggest that although routine operation of myringotomy is impractical in clinical practice, it can be helpful as the diagnostic procedure in uncertain cases. This study showed that myringotomy under local anesthesia may be unexpectedly tolerable in children; the youngest child who got myringotomy was a 29 months-old boy in this study.

Treatment of OME should generally be considered for children with middle ear effusion of 3 months or longer, since many studies have shown asymptomatic middle ear effusion lasting from 1 day to several months, with most resolving within 1 month (9, 12). Gates and others reported that 45% of cases cleared by 1 month and 60% cleared by 2 months (13, 14). In addition to chronic OME, the decision to treat can be affected by the conditions of hearing loss, discomfort, frequent OME episodes, vertigo or unsteadiness, changes of tympanic membrane, middle ear pathology, and associated upper respiratory tract disease (12).

The issue of antibiotic therapy of OME has received much attention because of over-publicized disputes among reports (9). Of the medical options, only antibiotic therapy has been consistently shown to be of benefit (12). However, it is generally accepted that although there is statistical evidence of efficacy, the effectiveness of antibiotic therapy is slight (9). We also think that nothing can justify clinicians in prescribing inappropriate antibiotic treatment routinely. Therefore accurate diagnosis of OME is important.

Although the efficacy of surgical therapy has clearly been established, there remains a wide range of opinions about its indications (9). Debates focus primarily on duration of effusion and whether persistent effusion and its resultant conductive hearing loss are harmful to the child's development. Surgical therapy does not cure patients with OME, but it does substantially reduce morbidity when medical therapy has failed.

For OME that persists more than 3 months despite adequate antibiotic therapy, surgical treatment is an option for children with hearing loss and is also recommended when the effusion and hearing loss persist for 4 to 6 months (9, 12).

Other more urgent indications for surgical treatment, regardless of duration of effusion, relate to structural abnormalities of the tympanic membrane; these abnormalities are retraction pockets in contact with ossicles or pockets in which epithelial debris accumulates, thus heralding an incipient cholesteatoma (9).

After a decision is made to treat the patient surgically, a second decision remains about the type of procedure to be used. Generally, myringotomy and ventilation tube insertion have been advocated. Aspiration of the middle ear effusion by myringotomy has been studied as one of treatment method for OME. However, the results from this simple and temporary procedure have been disappointing (15-17). Most clinicians agree that if a child is to receive an anesthesia for such treatment, then ventilation tube should be inserted because the cost: benefit ratio for myringotomy is too low to justify it as an independent procedure. In our study, only 12 ears (14.1%) showed the therapeutic efficacy of myringotomy. This result is too disappointing to become a routine and independent treatment method for OME.

In this study, it was shown that some children who are well bearable to myringotomy could get insertion of ventilation tube under local anesthesia; it was a 41 months-old boy who was the youngest child that had ventilation tube insertion under local anesthesia. Of 26 ears (of 17 patients) that received ventilation tube insertion, 12 ears (46.2%) of 8 patients (47.1%) got ventilation tube insertion under local anesthesia. We think that clinicians can judge whether ventilation tube insertion can be performed under local anesthesia by reaction that child shows during myringotomy. We hope that myringotomy before ventilation tube can be helpful for unnecessary general anesthesia to be avoided in children.

With frequent misdiagnosis of otitis media and subsequent increased antibiotic resistance, it seems clear that the focus is best spent on exact diagnosis and proper choice of antibiotics.

Although pneumatic otoscopy has been the gold standard, but its specificity is low. Considering high specificity and sensitivity, we suggest that otomicroscopy should be the standard for diagnosis of OME in children. Although tympanometry is useful for assessing and screening OME in children because of the ease and speed of its operation, it should be always kept in mind that there are many false positive and false negative cases and that interpretation of tympanogram must require consideration and matching with findings of tympanic membrane. In the cases that otomicroscopic finding and tympanogram of suspected ear are poorly correlated, it is only myringotomy that confirms the presence of OME; this may be the diagnostic significance of myringotomy.

This study showed that there was no therapeutic effect of myringotomy on treatment of OME. So we think that it is proper to limit indications of myringotomy to OM with severe pain; to obtain specimen for bacteriologic culture; to suppurative complication of AOM, such as facial paralysis, meningitis, or other central nervous system event; to AOM not res-

ponding to empirical antibiotic therapy; and to AOM in immunosuppressed patients.

## REFERENCES

1. Nyquist AC, Gonzales R, Steiner JF, Sande MA. *Antibiotic prescribing for children with colds, upper respiratory tract infections, and bronchitis*. *JAMA* 1998; 279: 875-7.
2. McCaig LF, Hughes JM. *Trends in antimicrobial drug prescribing among office-based physicians in the United States*. *JAMA* 1995; 273: 214-9.
3. Lyon JL, Ashton A, Turner B, Magill M. *Variation in the diagnosis of upper respiratory tract infections and otitis media in an urgent medical care practice*. *Arch Fam Med* 1998; 7: 249-54.
4. Pichichero ME. *Acute otitis media: Part 1. Improving diagnostic accuracy*. *Am Fam Physician* 2000; 61: 2051-6.
5. Bluestone CD, Klein JO. *Diagnosis*. In: Bluestone CD, Klein JO, ed. *Otitis media in infants and children*. 2nd Ed. Philadelphia: W.B. Saunders Company, 1995: 89-144.
6. Pelton SO. *Otoscopy for the diagnosis of otitis media*. *Pediatr Infect Dis J* 1998; 17: 540-3.
7. Palmu A, Puhakka H, Rahko T, Takala A, Kilpi T. *Predicting the development and outcome of otitis media by tympanometry*. *Int J Pediatr Otorhinolaryngol* 2002; 62: 135-42.
8. Jerger J. *Clinical experience with impedance audiometry*. *Arch Otolaryngol* 1970; 92: 311-24.
9. Gates GA. *Acute Otitis Media and Otitis Media with Effusion*. In: Cummings CW, Fredrichson JM, Harker LA, Krause CJ, Richardson MA, Schuller DE, ed. *Otolaryngology Head & Neck Surgery*. 3rd Ed. St.Louis: Mosby Inc, 1999: 461-77.
10. Gates GA. *Cost-effectiveness considerations in otitis media treatment*. *Otolaryngol Head Neck Surg* 1996; 114: 525-30.
11. Stool SE, Field MJ. *The impact of otitis media*. *Pediatr Infect Dis J* 1989; 8 (Suppl 1): S11-4.
12. Kenna MA. *Otitis Media with Effusion*. In: Bailey BJ, ed. *Head&Neck Surgery- Otolaryngology*. 2nd Ed. Philadelphia: Lippincott-Raven, 1998: 1297-310.
13. Chole RA, Hubbell RN. *Antimicrobial activity of Silastic tympanostomy tubes impregnated with silver oxide: a double-blind randomized multicenter trial*. *Arch Otolaryngol Head Neck Surg* 1995; 121: 562-5.
14. Gates GA, Avery C, Cooper JC, Hearne EM, Holt GR. *Predictive value of tympanometry in middle ear effusion*. *Ann Otol Rhinol Laryngol* 1986; 95 (1 Pt 1): 46-50.
15. Gates GA, Wachtendorf C, Hearne EM, Holt GR. *Treatment of chronic otitis media with effusion: results of myringotomy*. *Auris Nasus Larynx* 1985; 12 (Suppl 1): S262-4.
16. Mandel EM, Rockette HE, Bluestone CD, Paradise JL, Nozza RJ. *Myringotomy with and without tympanostomy tubes for chronic otitis media with effusion*. *Arch Otolaryngol Head Neck Surg* 1989; 115: 1217-24.
17. Mandel EM, Rockette HE, Bluestone CD, Paradise JL, Nozza RJ. *Efficacy of myringotomy with and without tympanostomy tubes for chronic otitis media with effusion*. *Pediatr Infect Dis J* 1992; 11: 270-7.