

# Sensitivity and specificity of tympanometry in diagnosis of serous otitis media (SOM)

## Abstract

**Background:** Serous Otitis media (SOM) is one of the most commonly encountered pathologies in children population. Fluids collection often leads to hearing loss with subsequent speech and language delay. So early diagnosis and management are of paramount importance to prevent these sequelae. Effective management is often surgical: myringotomy and fluid aspiration. Myringotomy is not only therapeutic procedure, it is also the gold standard diagnostic method. It has been noticed that many ENT Surgeons in Gulf region depend on Tympanometry only for SOM diagnosis and ignore a complete clinical approach (history, physical examination including pneumatic endoscopy), this has ended up to a considerable unnecessary surgeries with high false positive diagnosis. The aim of this study is to evaluate the sensitivity and specificity of Tympanometry in diagnosis of SOM in a local study, and to draw the attention of ENT Surgeons in this part of the world not to rush to book patients for myringotomy based on Tympanometry results only.

**Methods:** This cross-sectional study involved patients aged  $\leq 12$  yo, whom underwent myringotomy for SOM management during the period: from June 2018 to March 2019 at the ENT - department Dubai Hospital. The evaluation included the presenting complaint, physical examination, preoperative tympanometry result and intraoperative findings. Type B tympanometry was considered (positive) for the diagnosis of SOM, while other graph types were deemed (negative). Gold standard SOM diagnosis was the intraoperative existence of fluid (positive), and subsequently absence of fluids was (negative) Intraoperative findings were matched with the preoperative tympanometry results, proper statistical schedules were performed and tympanometry sensitivity and specificity were calculated.

**Results:** The study included 139 patients: 90 patients are male (64.7%) and 49 are female (35.3%) with mean age of 5.2 year (SD=2.1). The most common complaint was hearing loss in 77 patient (55.4%). Type B tympanometry found in 113 patients (82.5%) and fluid was found in 111 patients (79.9%). The sensitivity and specificity of Type B tympanometry: 88.2% and 80.7% respectively. Statistical tests found significant findings with P value < 0.05.

**Conclusions:** SOM is common in age group 3-7years. History of hearing loss along with dull tympanic membrane and type B tympanometry strongly suggest SOM. However, in our study we found out that Type B graph highly suggests SOM, while the absence of this graph not necessarily rule out fluid collections. So Physicians should be aware while interpreting tympanometry graphs and evaluate these results in the context of patients' history and examination. In order to enhance SOM diagnosis, we suggest combining Pneumatic otoscopy findings with Tympanometry graphs. This could be a future research topic: the addition value of Pneumatic otoscopy to Tympanometry graphs in the diagnosis of SOM.

**Keywords:** tympanometry, otoscopic, pneumatic, nintypercent, diagnosis

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## Introduction

Otitis media (OM) is reported as one of the most common illnesses affecting children under five years old worldwide.<sup>1-3</sup> OM may be classified into acute and chronic pathology, it may remain persistent in early childhood.<sup>4</sup> Prolonged hearing loss and delayed speech are potential consequences of chronic otitis media. These long-term impacts in children may cause considerable socio-economic costs to children, parents and the public health system.<sup>5</sup> OM is a serious healthcare concern worldwide, not only because of the distress that it causes upon patients and their family, but also because of the substantial economic burden that imposes on the health care system.<sup>6</sup> Despite the fact that OM is the most commonly diagnosed and treated disease in childhood, there is a tendency that it is over-

diagnosed and over-treated.<sup>7</sup> Over-treatment leads to unnecessary and inappropriate use of antibiotics, and this eventually leads to emergence of multidrug-resistant strains of bacterial pathogens. Serous Otitis Media (SOM) is one type of otitis media and defined as fluid collection in the middle ear cavity without signs or symptoms of acute ear infection.<sup>8</sup> Symptoms usually involve hearing loss or aural fullness but typically do not involve pain or fever. The condition is said to be chronic when the fluid accumulation persists beyond 12 weeks.<sup>9</sup> Diagnosis of SOM is not always easy, and there is significant variability in clinicians' diagnostic skills, especially among primary care physicians and pediatricians.<sup>10,11</sup> What makes the diagnosis more challenging is the fact that symptoms of SOM are neither sensitive nor specific, and some children with SOM are asymptomatic.<sup>12</sup>

Many tools have been developed to improve the accuracy of SOM diagnosis, however pneumatic otoscopy remains to be the preferred office-based diagnostic method.<sup>13</sup> Other diagnostic tools such as impedance audiometry and tympanocentesis further improve the diagnostic accuracy.<sup>12</sup> Ninetypercent of children (80% of individual ears) have experienced at least one episode of SOM by age of 10 years old.<sup>14</sup> Unlike acute otitis media, prevalence of chronic otitis media with effusion is unknown. Several studies have reported different estimations of the condition according to age. Rates vary from 13% at one year, 14% at two years, 10% at three years and 2.8% among children aged 7-8 years.<sup>15-17</sup> SOM also occurs in adults, this usually occurs following upper respiratory infection, severe nasal allergies and rapid air pressure changes during flight or scuba diving. Incidence of prolonged SOM in adults is much less common than in children.<sup>18</sup> Correct diagnosis is vital for the management of children with SOM. The clinical diagnosis of SOM is made by history, physical examination, pneumatic otoscopy and impedance audiometry. Otoscopic findings in SOM are mainly different combinations of retraction of the pars tensa and wide variations in color of tympanic membrane. Tympanometry provides useful information about the presence of fluid in the middle ear, mobility of the middle ear components, and ear canal volume. Usage of tympanometry has been recommended in conjunction with history and clinical findings in the evaluation of SOM-affected patients. Type B tympanogram with flat curve and normal canal volume is considered diagnostic of SOM. Compared with other types of tympanogram its sensitivity is estimated to be between 56 and 73 percent and specificity between 50 and 98 percent.<sup>19</sup> It has been noticed that ENT surgeons in the Gulf region depend on tympanometry result solely to book their patients for surgery. Hence, the aim of this study is to calculate the sensitivity and specificity of tympanometry in SOM diagnosis in a local study. This topic has been evaluated in other countries, but the importance of our study is: it is the first time to be carried out in Dubai.

## Methods

This cross sectional study was carried out on all myringotomy cases operated at Dubai Hospital from June 2018 to March 2019. Children included in this study were up to 12 years old. The total number of participant was 139 patients. For every single case, we checked the file of the patient looking for the presenting complaint, examination findings and audiometry graph type.

### Evaluating the accuracy of tympanometry

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 -400daPa. 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 0.6ml. Tympanometric curve results were classified according to modified Jerger's classification as types A, B, or C (20) Types A and C curves were interpreted as no middle ear effusion, while Type B as a predictive of middle ear effusion.<sup>20,21</sup> Intraoperative findings of myringotomy were the gold standard of SOM diagnosis, as the actual existence of middle ear fluid confirms the diagnosis. For every single case, we compare the presence/absence of middle ear fluid intraoperatively with the corresponding tympanometry graph. After reviewing of the 139 cases, the sensitivity and specificity of the test -Tympanometry- counted.

## Results

During 12 months period (June 2018-June 2019) 139 EUA EARS cases were carried out in Dubai Hospital, 90 male (64.7%) and 49 female (35.3%). Smallest age was 2 yo, biggest age was 12 yo, and the mean age was 5 yo.

**Presenting complaint (Table 1):** For every single patient, we search for the main reason to visit our clinic.

**Table 1** Presenting complaint

Chief Complaint				
	Frequency	Percent	Valid Percent	Cumulative Percent
No complaint	39	28.1	28.1	28.1
Hearing loss	77	55.4	55.4	83.5
Speech delay	4	2.9	2.9	86.3
Ear itching	14	10.1	10.1	96.4
Irritability	5	3.6	3.6	100.0
Total	139	100.0	100.0	

The chief presenting complaint in the vast majority of our patients was hearing loss (in 55.4% of patients), while 28.1% of our patients have no frank ear problem and the fluid found out accidentally. It is worth noting that 10.1% of our patients presented with ear discomfort and itching.

**Clinical findings (Table 2):** Clinical findings during physical examination were classified into three main categories: Normal findings, retracted tympanic membrane and dull ear drum.

**Table 2** Clinical findings

Clinical Findings				
	Frequency	Percent	Valid Percent	Cumulative Percent
Normal	7	5.0	5.0	5.0
Retracted TM	55	39.6	39.6	44.6
DULL TM	77	55.4	55.4	100.0
Total	139	100.0	100.0	

Opacity and dullness of the tympanic membrane were found in 55.4% of our sample, followed by retraction of the ear drum in 39.6% and normal examination in 5%.

**Tympanometry (Table 3):** Before surgery, all our patients had tympanometry test. The vast majority of tympanometry graphs were

Type B 81.3%, Type C found in 10.8 and normal graph seen in 6.5% of our sample.

**Table 3** Tympanometry

Tympanometry				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Normal	9	6.5	6.6
	Type C	15	10.8	17.5
	Type B	113	81.3	100.0
	Total	139	100	100.0

**Surgical findings (Table 4):** Intra operatively, the surgical findings were documented and came out as following: After myringotomy fluid found in 111 patients (79.9% of our sample), while retraction only without fluid found in 10 patients, the rest 18 patients' findings were normal.

**Table 4** Surgical findings

Surgical Findings				
	Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Normal	18	12.9	12.9
	Retraction without fluid	10	7.2	20.1
	Fluid	111	79.9	100.0
	Total	139	100.0	100.0

**Tympanometry sensitivity and specificity (Table 5):** New sets of data were formulated:

**Table 5** 4x4 table to calculate sensitivity and specificity

		Intra Operative	
		+	-
Tympanometry	+	97	6
	-	13	23
		110	27

The results of the studied test (Tympanometry) were classified into positive (Type B) and negative (Type C and A), in reference to presence/absence of fluid. And the results of the gold-standard method of SOM diagnosis (Myringotomy) were plotted into positive for fluid collection and negative for retraction or normal Tympanic membrane. The sensitivity and specificity of tympanometry then calculated and were: 88.2% and 85.2% respectively.

Sensitivity: true positive / (true positive + false negative):  $97 / (97+13) = 88.2\%$

Specificity: true negative / (true negative + false positive):  $23 / (23+6) = 85.2\%$

## Discussion

In the present study, we calculated the sensitivity and specificity of tympanometry in diagnosis of SOM by comparing its graph with the definite diagnosis intra operatively.

**Presenting complaint:** The presenting complaint in vast majority of our patients was hearing loss. Rosenfeld's study<sup>22</sup> similarly showed that most children with SOM visit ENT clinic with concern regarding hearing problems. Although hearing loss in SOM is mild to moderate and fluctuating in nature,<sup>23</sup> it might affect speech and language skills of the affected child. In this study, language delay was the only presenting complaint in 4 patients. Physicians should be aware that patients with SOM might present in atypical and non-specific symptoms like irritability and fullness sensation.<sup>24</sup> In our sample we noticed irritability in 5 patients and ear itching in 14 patients. Despite the above mentioned symptoms, children with SOM could be asymptomatic and the condition is found out incidentally. 28.1% of our sample were asymptomatic and SOM was diagnosed during investigations for another reason.

**Physical examination:** Examination of the tympanic membrane in case of SOM often show changes in its characteristic normal pearly-white color into amber reddish or bluish ones with disappearance of cone of light. These findings were noticed in 77 patients (55.4% of the sample). Erythema is more frequently encountered in acute ear infections<sup>25</sup> rather than chronic pathology like SOM. In some SOM cases the ear drum might be retracted or even in normal position. Our study showed tympanic membrane retraction in 39.6% of the cases while 7 patients (5%) had completely normal findings. This raises an important point, that retracted or even a normally-appeared tympanic membrane doesn't necessarily rule serous otitis media. Bulged ear drum is less likely to be seen in SOM and more likely to be an acute otitis media feature. In a study correlates clinical findings with a definite diagnosis<sup>25</sup> bulging was found in 46 out of 50 AOM cases, while none of 34 SOM children show any sign of bulged ear drum.

**Tympanometry:** Tympanometry measures the compliance of the tympanic membrane, Eustachian tube function, and middle ear function,<sup>26</sup> although it is a handy tool in the ENT outpatient clinics it is not reliable in the first four months after birth.<sup>27</sup> It is generally acceptable that the flat curve in tympanometry (Type B) is an indication of SOM and peaked-graph within the normal pressure range (Type A) is indicative of normal tympanic membrane compliance and normal middle ear pressure, while peaked shifted graph (Type C) refers to a negative pressure in the middle ear cavity. In our study 81.3% of our sample had Type B graph preoperatively, while the percentage of Type C and A were 10.8% and 6.5% respectively.

**Tympanometry sensitivity and specificity:** In this study, we considered Type B graph of tympanometry is positive for the existence of fluid and thus SOM. While Type C and A were considered negative for fluids collection. After reviewing the intraoperative findings of presence or absence of actual middle ear fluid after myringotomy, the sensitivity and specificity of tympanometry were 88.2% and 85.2% respectively. Comparing our results with the international counterparts, a meta-analysis of seven similar studies: the sensitivity and specificity of tympanometry were 84 (95% CI 82-86) and 79 (95% CI 76-83) respectively.<sup>28</sup>

The importance of our study is; it is the first time that the accuracy of tympanometry is being investigated in this part of the world. Our results are compatible with the results on the global scale and it completes the efforts of other researchers in understanding and analyzing tympanometry produced graphs.

## Conclusion

Serous otitis media is one of the most commonly seen conditions in pediatric population. It may cause hearing loss with subsequent speech and language development impact, and it could be asymptomatic and diagnosed accidentally. Tympanic membrane is often dull with change in its color, but it can be retracted or even normally looking. Thus, ENT Surgeons should be aware in history taking and physical examination as middle ear fluids might be covert and progress subtly. Audiologic tests often show a degree of conductive hearing loss, however tympanometry is the most commonly requested test in SOM workup. Neither our study nor other studies showed 100% sensitivity or specificity for this test. SOM patients approach should be comprehensive, combining a detailed history and physical examination along with the audiologic tests including tympanometry. A proper diagnosis means early intervention, and consequently avoiding harmful impacts on the affected children and help insuring a better quality of life.

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## Conflicts of interest

The author declares that there is no conflict of interest to disclose.

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