Recovery From Otitis Media and Associated Factors Among 1- to 6-Year-Old Children in South India: A Longitudinal Study

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Background and Objectives: This study was aimed at assessing recovery from otitis media (OM) and variables associated with it among 1- to 6-year-old children. Subjects and Methods: We assessed 87 children with OM otologically and audiologically. Medicines were prescribed, and medication compliance was ensured. The children were followed up after 3 months to judge the status of OM as resolved or recurrent. Data were statistically analyzed to derive the risk of recurrence of OM with effusion (OME) and acute OM by degree of hearing loss, type of tympanogram, age group, and sex. Results: The overall recurrence rate was 26%. The risk of recurrence was higher for OME (odds ratio [OR]=4.33; 95% confidence interval [CI]: 1.90 to 9.83); at AC auditory brainstem peak V responses up to 40 dBnHL (OR=5.20; 95% CI: 2.05 to 13), 50 dBnHL (OR=3.47; 95% CI: 0.5 to 23), and 60 dBnHL (OR=16.09; 95% CI: 4.36 to 1.2); in B (OR= 3.16; 95% CI: 1.36 to 7.33) and C tympanograms (OR=2.83; 95% CI: 0.70 to 11.41); and in the age group of 5–6 years (OR=8, 95% CI: 2.23 to 28). The risk of recurrence of OM did not differ between male and female patients. Conclusions: The rate of recurrence was comparable to or lower than that reported in the pediatric population of other countries. The findings suggest that children with OME, severe pathology, or age of 5–6 years require more attention and frequent monitoring to minimize the risk of recurrence.

Keywords: Recurrence; Recovery; Otitis media; Tympanogram; Conductive hearing loss.

Introduction

Otitis media (OM) is the most common pathology seen in children, next only to the common cold. The global annual incidence of acute OM is 10.85% and half of them are reported to occur under the age of 5 years [1]. OM is known to show bimodal peak prevalence; one peak before 2 years of age and the other peak at 5 to 7 years of age [2,3]. If left untreated, acute OM can result in chronic suppurative OM (CSOM), mastoiditis, labyrinthitis, petrositis, facial nerve paralysis, meningitis, subdural abscess, extradural abscess, and thrombophlebitis [4].

OM normally does not occur just once. In fact, multiple episodes of the disease are quite common. Klein, et al. [5] reported that 33% of all their subjects had three or more episodes of OM by 3 years, 24% by 2 years, and 17% by 18 months. The ratio of unilateral to bilateral OM is 2:3 [6]. To understand the nature of acute OM, Mandel, et al. [7] followed 148 children (aged 1 to 8 years) by weekly otoscopy for a period of 6 months. They found that OM peaks in December and March, and the duration of a new episode was short. Gibney, et al. [8] followed 31 Aboriginal children (aged less than 8 years) with acute OM for 3 weeks or longer till the infection resolved. Results showed that 70% of the children had persistent sign of OM [8]. In a study in the Oxford area, 95 full-term infants were tracked for their tympanometry findings every month for 3 years. They...
found that children susceptible to OM with effusion tend to have more episodes of effusion rather than increased duration of effusion [9]. In general, most children who develop OM experience the disease for more than 2 months before spontaneous resolution [10].

Even if acute OM persists for a short duration, the associated effusion in the middle ear may persist for weeks or even months, often without clinical signs. Roland, et al. [11] reported the median number of days before the resolution of OM to be 72 days. In up to 30% of the children with acute OM, fluid remains in the ear for 3 to 12 months. The important predictors of outcomes in OM are age, severity of the disease, and nasopharyngeal colonization patterns [12]. Children whose symptoms failed to improve early in the course of the disease were the ones who were younger and had more severe disease. Colonization with *Streptococcus pneumoniae* was associated with more severe OM than that with other pathogens like *Moraxella catarrhalis* and *Haemophilus influenzae*.

A high incidence of OM is reported among the Indian population [13]. Jacob, et al. [14] found OM in 17.6% of the 284 children aged 6 to 10 years. Specifically, the incidence of OM with effusion was found to be 3.06%, while the incidence of acute OM was 0.65%. The exact reason for high incidence of OM in the Indian population is not very clear. However, genetic factors, difference in the Eustachian tube, poor socioeconomic standards, poor nutrition, and lack of health education have been speculated as the contributing factors [15,16]. According to Beery, et al. [16], though Eustachian tubes in the Indian population allow better ventilation of the middle ear cavity, they have poorer protective function making middle ear an easy target for bacterial invasion from the throat. Irrespective of the reasons, the high incidence of OM deserves serious consideration in Indian children. Dhirgra [15] even reported a significant difference between rural (46 per thousand) and urban populations (16 per thousand) in the prevalence of OM in India.

Although OM is a highly prevalent pathology in children of India, the nature of OM and the course of recovery is not yet explored in the country. Considering that the genetic, sociocultural, environmental, and economic factors in India are different compared to the developed countries, one can expect that the course of recovery is different in the cohort here compared to that in the developed countries. The recovery with reference to infection as well as hearing status needs exploration and such exploration warrants longitudinal follow-up of the subjects. American Academy of Paediatrics (AAP) [17] recommends that children with OM should be re-examined at 3 or 6 months until the effusion is no longer present and should identify children with risk of hearing impairment or other complications. However, no such time schedule or protocol for follow-up is in practice in India. Hence, the present study longitudinally followed young children diagnosed with OM up to 3 months of diagnosis. The follow-up examinations were done to track the status of the infection, findings in tympanometry, and the hearing sensitivity. The study attempted to derive the relationship between risk of OM and the characteristics of the subject, otological findings, tympanometric findings, and hearing sensitivity. The aim of this study was to eventually make recommendations for follow-up protocol in cases of OM.

**Subjects and Methods**

The study examined children with OM during their first episode and after 3 months to understand the nature of recurrence of infection and its effects on hearing sensitivity. The Institutional Ethics Committee of Ramachandra Institute of Higher Education and Research where the study was conducted had approved the study (Ref: IEC-NI/16/JUL/54/48). Written informed consent was obtained form all the parents of children for evaluation.

**Screening for OM**

The study population was recruited from outpatient units of ENT, Pediatrics, and Audiology of Sri Ramachandra Hospital. Children in the age range of 1 to 6 years were screened for their motor development, speech-language development, and ear infections. Children with normal development but showing clinical signs and symptoms suggestive of OM were the potential participants of the study. Distorted or missing cone of light, air bubbles in the middle ear, fluid in middle ear, and dull and bulging tympanic membrane were considered the signs of OM [18]. Children with chronic suppurative OM, congenital or late onset sensorineural hearing impairment, anomalies of the external ear, congenital conductive hearing impairment, developmental delay, cerebral palsy, autism spectrum disorders, mental subnormality, genetic syndrome, cleft lip and palate, history of surgical intervention for OM with effusion were excluded from the study. The otorhinolaryngologist examined each ear otorhinolaryngologist to check for any obstruction in the ear canal. Children with wax in the ear canal were sent for wax removal. Based on the specific clinical signs observed, otorhinolaryngologist diagnosed the presence and type of OM in that ear.
Test procedure

Baseline evaluation
An experienced otorhinolaryngologist visually inspected each ear of the child using a microscope. The observed otoscopic signs were noted down and a corresponding diagnosis was made. The child was then evaluated by an experienced (more than 15 years) audiologist to determine the middle ear status and hearing sensitivity. Middle ear status was assessed using tympanometry and acoustic reflexes. A calibrated GSI 39 immittance meter (Grason-Stadler, Eden Prairie, MN, USA) was used for the purpose. A probe tone of 226 Hz was used to derive the admittance while pressure in the ear canal was swept from +200 daPa to -400 daPa. The resultant tympanogram was noted down for its peak static admittance, peak pressure, gradient, equivalent ear canal volume, and the type of tympanogram. Tympanograms were classified as per the criteria given by Feldman [19].

The hearing thresholds were derived by tracking thresholds of auditory brainstem responses (ABRs) in air conduction (AC-ABR) and bone conduction (BC-ABR) modalities. ABRs were recorded using Neuro-Audio AEP equipment (version 10, Neurosoft, Ivanovo, Russia). The children were tested within 2 days of the identification of OM and the thresholds were tracked in ears with OM. If found necessary, sedative drug was given to make the child sleep. The electrode sites were FPz (positive), ipsilateral mastoid (negative), and contralateral mastoid (ground). Click-evoked ABR was recorded as per the stimulus and acquisition parameters given by Katz, et al. [20]. The audiologist visually inspected the recorded waveform to mark wave I, III, and V. ABR threshold was defined as the lowest intensity at which wave V was recordable. If peak V was present at 20 dBnHL, it was considered as hearing sensitivity within normal limits [21].

BC-ABR was meant to ensure that hearing loss, if any, is of conductive type, and there is no sensorineural hearing loss. To record BC-ABR, clicks were presented through a bone vibrator B 71 placed on the forehead. In order to elicit ear-specific BC-ABR, the non-test ear was masked by delivering broadband noise at 50 dBSPL through TDH-39 headphone. All the other stimulus and acquisition parameters remained as that of AC-ABR. The method of deriving BC-ABR threshold and BC hearing sensitivity was also same as that of AC-ABR.

The treatment of OM
All the children who completed audiological evaluation were medically treated by the Otorhinolaryngologist. Medication (antibiotics, antihistamines, and decongestants) was prescribed for 5 to 7 days and its dosage depended on the severity of infection. The parents were counseled regarding the risk factors of OM. The children were monitored telephonically for consumption of the medicines as per the prescription. All the children strictly complied with the prescribed treatment.

Follow-up testing
The participants were re-evaluated at the end of 3 months after their first episode. Otoscopy, immittance evaluation, and ABR (AC & BC) were repeated during the follow-up evaluation. Based on the results of otoscopy and impedance audiometry at 3 months follow-up, the middle ear status was diagnosed as either “recurrent” or “resolved.” It was considered “resolved,” if the tests revealed normal findings. Otherwise, it was considered “recurrent.” In the present study, recurrent OM was operationally defined as an episode of OM after 3 months of their initial episode [22].

A total of 1,040 children were screened, of whom, 130 children were found to have unilateral/bilateral acute OM or OM with effusion (OME). However, the parents of only 114 children gave informed consent for further evaluation. In all these 114 children, it was the first episode of OM. On testing with AC-ABR, 1 child was found to have auditory neuropathy spectrum disorder and therefore was excluded from the study. In 3 children, BC-ABR thresholds were elevated, indicating the presence of sensorineural hearing loss. They were also excluded from the study. Of the 110 children, 23 did not turn-up for the follow-up evaluation, resulting in 87 children who completed the entire study protocol.

Analysis
The data distribution was tested using Shapiro-Wilk test of normality. Owing to non-normal distribution, non-parametric tests were used for statistical analysis. Odds ratio with 95% confidence interval was derived to find the risk of recurrence of OM and chi-square test was used to assess the significance of difference in recurrence of OM across age groups, sex, types of middle ear pathologies, types of tympanogram, and degree of conductive hearing loss.

Results
Of the 110 children enrolled in the study, 23 children did not come for follow-up evaluation mainly due to the distance of travel to the hospital. Totally 87 children with data of type of OM, tympanogram, and AC-ABR threshold at two points constitute the participants of the present study. Of the 87 children, 75 children had bilateral OM, 11 children had uni-
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Table 1. Effect of type of OM, degree of conductive hearing loss, type of tympanogram, age, and sex on recurrence of otitis media

<table>
<thead>
<tr>
<th>Parameter</th>
<th>No. of ears</th>
<th>OR (95% CI)</th>
<th>p</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Recurrent OM</td>
<td>OM resolved</td>
</tr>
<tr>
<td>Type of OM</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>AOM</td>
<td>74</td>
<td>9</td>
<td>65</td>
</tr>
<tr>
<td>OME</td>
<td>88</td>
<td>33</td>
<td>55</td>
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<tr>
<td>AC-ABR threshold (dBnHL)</td>
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<td></td>
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</tr>
<tr>
<td>20</td>
<td>46</td>
<td>2</td>
<td>44</td>
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<td>30</td>
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<tr>
<td>60</td>
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<td>Type of tympanogram</td>
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<tr>
<td>A</td>
<td>9</td>
<td>0</td>
<td>9</td>
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<tr>
<td>B</td>
<td>81</td>
<td>29</td>
<td>52</td>
</tr>
<tr>
<td>C</td>
<td>60</td>
<td>9</td>
<td>51</td>
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<tr>
<td>Cs</td>
<td>12</td>
<td>4</td>
<td>8</td>
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<td>Age (yrs)</td>
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<tr>
<td>1 to 2</td>
<td>35</td>
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</tr>
<tr>
<td>Female</td>
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<td>23</td>
<td>47</td>
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</tbody>
</table>

OM, otitis media; OR, odds ratio; CI, confidence interval; AOM, acute otitis media; OME, otitis media with effusion; AC-ABR, auditory brainstem response in air conduction

lateral OM, and 1 child had acute otitis media (AOM) on one ear and chronic otitis media (COM) on the other ear.

Table 1 shows the impact of the type of OM, degree of conductive hearing loss, type of tympanogram, age, and sex on the recurrence of OM. In ears with OME, the recurrence rate was 38% (rounded off to the nearest whole number), whereas it was 12% in acute OM. Results showed a significantly higher risk of recurrence in OME compared to acute OM (p<0.0001).

When examining the relationship between the degree of conductive hearing loss and OM recurrence, the risk of recurrence was significantly lower (p=0.005) for AC-ABR threshold was 20 and 30 dBnHL compared to 40, 50, and 60 dBnHL.

Similarly, in the relationship between the type of tympanogram and OM recurrence, the results showed a significantly higher risk of recurrence in ears with B and Cs type tympanograms compared to C and As type tympanograms (p=0.006).

Regarding the child’s age and OM recurrence, the results showed a significantly higher risk of recurrence of OM in the 5 to 6-year age groups compared to other groups (p=0.005).

However, in terms of the child’s sex and the recurrence of OM, there was no significant difference in the risk of recurrence between the two sex (p=0.155).

Discussion

In the current study, the participants were assessed twice with an interval of 3 months. It was found that 26% of the cases had OM on both occasions. This was true in spite of all of them pursuing the prescribed medical treatment without fail. Whether it is termed as persistence of OM or recurrence of OM is debatable. However, it is operationally referred to as “recurrence” in the current study, in line with the earlier studies [22]. Recurrence rate of 26% found in the current study is lower than that reported in pediatric population of Taiwan (33% during a 1 year period) [23], Finland (28% during 1 year period) [24], and higher than indigenous children of Australia (18%). Across various earlier studies conducted in the other countries, the recurrence varies from 9% to 73% [8,22-26], attributable to differences in compliance with treatment, socioeconomic status, climatic conditions, and genetic factors. Compared to other countries higher incidence of OM has been reported among the Indian population [14,27]. Yet,
the recurrence of OM appears comparable to or even lower than some of the other countries.

In the current study, we found that the risk of recurrence was significantly higher in ears with OME compared to that with AOM. The risk of recurrence of OME found in the current study (38%) was comparable to that reported by some of the earlier studies (35%) [28,29] and lower than that (50%) reported by Zielhuis, et al. [30]. The auditory deprivation caused by hearing loss secondary to OM is shown to result in deficits in cochlear and neural structures [31,32], deviations in auditory brainstem responses [33], and poor speech in noise perception [34,35]. The higher recurrence rate in ears with OME suggests that this group is at a greater risk of auditory deprivation during the developmental age. Therefore, ears with OME need greater attention and closer supervision in terms of more frequent follow-ups to minimize the recurrence compared to those with AOM.

The risk of recurrence was found to be higher in ears with higher degree of hearing loss and in ears with B or Cs type tympanogram. Higher degree of hearing loss and, B or Cs type tympanogram are indications of greater damage to middle ear, in turn suggestive of more severe pathology. This hints at the direct association between severity of OM and its probability of recurrence. It also reflects the importance of audiological test findings in predicting the prognosis and planning the course of management in cases with OM. Ears with higher degree of hearing loss and ears with B or Cs type tympanogram need closer supervision and more frequent follow-ups than the other cases with OM. Earlier studies had revealed the characteristics of hearing loss that result from OM [36,37]. However, the current study is the first one to show the relationship between audiological findings and recurrence of OM.

The current study also assessed the association between demographic variables (age and sex) and the risk of recurrence of OM. Results showed higher risk of recurrence in 5 to 6-year-old group compared to the younger age group. Although the exact reason for the finding is not clear, we suspect that it is because of the higher incidence of other inflammations such as tonsillitis or adenoiditis in this group [38]. Some of the earlier studies have revealed the recurrence of OM in children up to 12 years of age [3,39] with maximum prevalence at 5 years of age. The comparison between males and females revealed no significant difference in the recurrence of OM. The incidence and prevalence of OM are shown to vary between the two sex but the risk of recurrence appears to be comparable.

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Conflicts of Interest
The authors have no financial conflicts of interest.

Author Contributions
Conceptualization: all authors. Data curation: Sathya Harinath. Formal analysis: Sathya Harinath. Investigation: Sathya Harinath. Methodology: all authors. Supervision: Somu Lakshmanan, Saji James, Sandeep Maruthy. Visualization: Somu Lakshmanan, Saji James, Sandeep Maruthy. Writing—original draft: Sathya Harinath. Writing—review & editing: Somu Lakshmanan, Saji James, Sandeep Maruthy. Approval of final manuscript: all authors.

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