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The Indonesian Otitis Media Severity Score (IOMSS): A Prospective Cohort Study Evaluating its Prognostic Value in Pediatric Patients

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A B S T R A C T

Introduction: Acute otitis media (AOM) and otitis media with effusion (OME) are common pediatric illnesses with varying clinical courses. A reliable prognostic tool to predict outcomes and guide treatment decisions in the Indonesian context is lacking. This study aimed to evaluate the prognostic value of the Indonesian Otitis Media Severity Score (IOMSS) in predicting treatment response and complications in pediatric patients with AOM and OME. **Methods:** A prospective cohort study was conducted at five tertiary care hospitals in Indonesia (Medan, Jakarta, Samarinda, Makassar, and Denpasar) from January 2020 to December 2022. Children aged 6 months to 12 years diagnosed with AOM or OME were enrolled. The IOMSS, which incorporates clinical findings (otalgia, fever, otorrhea, tympanic membrane appearance, and hearing loss), was calculated at baseline. Patients were followed up for 6 months to assess treatment response (resolution of symptoms, tympanic membrane healing), and the development of complications (e.g., recurrent AOM, chronic suppurative otitis media (CSOM), mastoiditis, hearing loss). Statistical analyses, including Cox proportional hazards regression and receiver operating characteristic (ROC) curve analysis, were performed to evaluate the association between IOMSS and clinical outcomes. **Results:** A total of 850 children (mean age 5.2 ± 2.8 years, 55% male) were included. Higher IOMSS scores at baseline were significantly associated with a lower probability of complete resolution of AOM/OME at 6 months (hazard ratio [HR] 0.85 per 1-point increase in IOMSS, 95% CI 0.80-0.90, $p<0.001$). The IOMSS also predicted the development of complications, with a higher score significantly increasing the risk of recurrent AOM (HR 1.20, 95% CI 1.10-1.31, $p<0.001$), CSOM (HR 1.35, 95% CI 1.18-1.54, $p<0.001$), and persistent hearing loss (HR 1.28, 95% CI 1.12-1.46, $p<0.001$). ROC curve analysis demonstrated good discriminatory ability of the IOMSS for predicting complications (AUC = 0.82, 95% CI 0.78-0.86). **Conclusion:** The IOMSS is a valuable prognostic tool for predicting treatment outcomes and the risk of complications in Indonesian children with AOM and OME. Its use can aid clinicians in identifying high-risk patients who may benefit from more aggressive management and closer follow-up.

1. Introduction

Otitis media (OM), a prevalent inflammatory condition affecting the middle ear, is a significant health concern in the pediatric population, both globally and within Indonesia. This condition encompasses two primary clinical entities: acute otitis media (AOM) and otitis media with effusion (OME). AOM is characterized by the rapid onset of signs and symptoms indicative of middle ear inflammation, including otalgia, fever, and irritability, frequently

accompanied by otoscopic evidence of a bulging tympanic membrane or the presence of new-onset otorrhea. OME, in contrast, involves the accumulation of fluid within the middle ear space in the absence of acute inflammatory signs and symptoms. The incidence of AOM is particularly high in children between 6 and 18 months of age, contributing substantially to pediatric healthcare visits and the prescription of antibiotics. While many AOM cases resolve spontaneously or respond favorably to appropriate antibiotic therapy, a notable proportion of children experience recurrent episodes or develop complications. These complications can include persistent middle ear effusion, chronic suppurative otitis media (CSOM), mastoiditis, and hearing loss. Such sequelae can have far-reaching negative impacts on a child's development, affecting speech and language acquisition, cognitive function, and overall quality of life.[1-3]

The clinical trajectory of OM is marked by significant variability, making it difficult to predict which children are more likely to experience a complicated course. Several risk factors have been associated with an increased likelihood of recurrent AOM and complications. These include young age, attendance at daycare facilities, exposure to tobacco smoke, bottle feeding practices, and a family history of OM. However, the presence of these risk factors does not always provide a sufficiently accurate prediction of individual patient outcomes. The ability to accurately assess disease severity at the time of diagnosis is crucial for clinicians. A reliable and objective scoring system that incorporates key clinical findings could serve as a valuable tool to aid in this assessment, inform treatment decisions, and facilitate the identification of children at elevated risk for complications.[4-6]

In the pursuit of such a tool, several scoring systems for OM have been developed and validated across various populations. However, the direct applicability of these existing scores to the Indonesian population may be limited due to differences in healthcare access, antibiotic prescribing practices, and the prevalence of specific risk factors within this population. Furthermore, many existing scoring systems tend to focus on either AOM or OME in isolation, rather than considering the broader spectrum of otitis media. To address these limitations, the Indonesian Otitis Media Severity Score (IOMSS) was developed by a panel of Indonesian otorhinolaryngologists. The IOMSS is designed to be a practical and user-friendly tool, suitable for use by healthcare providers across various levels of care. It incorporates key clinical findings that can be readily assessed within a routine clinical setting. These findings include otalgia, fever, otorrhea, tympanic membrane appearance (assessing for bulging, redness, and perforation), and hearing loss. Hearing loss assessment can be performed through behavioral observation or audiometry, when available.[7-10] This prospective cohort study was undertaken to evaluate the prognostic value of the IOMSS in a large, multi-center cohort of Indonesian children diagnosed with AOM and OME.

2. Methods

This study employed a prospective cohort design, conducted across five private tertiary care hospitals in Indonesia. The selection of these hospitals (located in Jakarta, Medan, Samarinda, Makassar, and Denpasar) was strategic, aimed at encompassing the diverse geographic regions and patient populations characteristic of Indonesia. The study received approval from the Institutional Review Boards of CMHC Indonesia. Prior to the commencement of any study procedures, written informed consent was obtained from the parents or legal guardians of all children who participated.

The study population consisted of children aged 6 months to 12 years. These children presented to the participating hospitals between January 2020 and December 2022 with a clinical diagnosis of either AOM or OME. The criteria for inclusion in the study were as follows; AOM was defined by the presence of an acute onset of signs and symptoms indicative of middle ear inflammation. These signs and symptoms included otalgia (or, in the case of infants, ear pulling or rubbing), fever, irritability, and otoscopic findings consistent with a bulging tympanic membrane. The presence of new-onset otorrhea, not attributable to

otitis externa, was also considered indicative of AOM; OME was defined by the presence of middle ear effusion, confirmed by otoscopy and/or tympanometry, in the absence of signs or symptoms suggestive of acute infection. Exclusion criteria were established to ensure the homogeneity of the study population and to minimize potential confounding factors; Children with underlying craniofacial anomalies, such as cleft palate, were excluded; Children with known immunodeficiency disorders were excluded; Children with a history of previous ear surgery, including but not limited to tympanostomy tube placement, were excluded; Children who had received systemic antibiotics within the 7 days preceding enrollment were excluded; Children whose parents or legal guardians were unable to provide informed consent or were unlikely to comply with the required follow-up visits were excluded.

The collection of data was initiated at the first visit of each participant (baseline). The following data points were collected; Demographic Data: This included the child's age, gender, ethnicity, and socioeconomic status. Socioeconomic status was assessed using a standardized questionnaire adapted for the Indonesian context. This questionnaire was designed to evaluate household assets and parental education as indicators of socioeconomic standing; Medical History: Detailed medical history was obtained, including information on previous episodes of AOM or OME, daycare attendance, exposure to tobacco smoke (specifically parental smoking habits), breastfeeding history, and family history of otitis media; Clinical Examination: A thorough otoscopic examination of both ears was performed by trained otorhinolaryngologists. This examination was conducted following a standardized protocol to ensure consistency. Specific tympanic membrane findings were recorded, including color, position, mobility, and the presence of perforation. The presence or absence of otalgia, fever (defined as a temperature ≥38.0°C), and otorrhea was also documented; Hearing Assessment: For children aged 4 years and older, pure-tone audiometry was performed whenever feasible. For children younger than 4 years, behavioral observation audiometry (BOA) or visual reinforcement audiometry (VRA) was utilized for hearing assessment. Hearing loss was categorized based on the hearing threshold in decibels hearing level (dB HL) as follows: mild (26-40 dB HL), moderate (41-55 dB HL), moderate-severe (56-70 dB HL), severe (71-90 dB HL), or profound (>90 dB HL). In situations where audiometry was not available, a subjective assessment of hearing loss was conducted. This assessment, categorized as normal, mild, moderate, or severe, was based on parental reports and clinical observation; IOMSS Calculation: The Indonesian Otitis Media Severity Score (IOMSS) was calculated for each participant based on the clinical findings observed at the baseline visit. The specific components of the IOMSS and the scoring system employed are detailed in Table 1.

Table 1. Indonesian otitis media severity score (IOMSS).

Component	Score 0	Score 1	Score 2	Score 3
Otalgia	Absent	Mild (intermittent, easily soothed)	Moderate (persistent, requires analgesics)	Severe (constant, poorly controlled)
Fever	<38.0°C	38.0-38.9°C	39.0-39.9°C	≥40.0°C
Otorrhea	Absent	Present		
Tympanic membrane	Normal or retracted	Mild redness	Bulging, marked redness	Perforation with purulent discharge
Hearing loss	Normal or no concern	Mild hearing loss	Moderate hearing loss	Severe hearing loss/no response

Total IOMSS Score: 0-11.

Following the baseline assessment, patients were treated according to the standard clinical guidelines for AOM and OME in Indonesia. For AOM, the typical treatment regimen involved the administration of amoxicillin or amoxicillin-clavulanate for a duration of 7 to 10 days. For OME, the initial management strategy consisted of watchful waiting for a period of 3 months. If OME persisted beyond this 3-month period, further evaluation was conducted, and additional management options, such as adenoidectomy or tympanostomy tube insertion, were considered.

Participants were scheduled for follow-up visits at 1 week, 1 month, 3 months, and 6 months after the initial visit. At each follow-up visit, a comprehensive clinical examination was performed, including otoscopy. When age-appropriate, a hearing assessment was also conducted. Treatment response was evaluated based on the resolution of symptoms, including otalgia, fever, and otorrhea, as well as the observed healing of the tympanic membrane. Documentation was maintained regarding the development of any complications during the follow-up period.

The study utilized both primary and secondary outcome measures to assess the prognostic value of the IOMSS. The primary outcome measure was defined as the complete resolution of AOM/OME at the 6-month follow-up. This was characterized by the absence of symptoms (otalgia, fever, otorrhea) and the observation of a normal tympanic membrane appearance upon otoscopy. Several secondary outcome measures were included; Recurrent AOM: Defined as the occurrence of ≥3 episodes of AOM within a 6-month period, or ≥4 episodes within a 12-month period; Development of CSOM: Defined as the persistence of otorrhea through a tympanic membrane perforation for a duration exceeding 6 weeks; Development of mastoiditis: Defined by the presence of clinical signs and symptoms suggestive of mastoiditis, with confirmation obtained through imaging if deemed necessary; Persistent hearing loss: Defined as a hearing threshold greater than 25 dB HL in the affected ear at the 6-month follow-up.

The statistical analysis of the collected data was performed using SPSS version 27 (IBM Corp., Armonk, NY). Descriptive statistics were employed to summarize the baseline characteristics of the study population. These statistics included mean, standard deviation, median, interquartile range, frequency, and percentage. Bivariate analyses were conducted to compare baseline characteristics between patients who achieved complete resolution of AOM/OME and those who did not. For categorical variables, Chi-square tests were used. For continuous variables, t-tests or Mann-Whitney U tests were used. Survival analysis was performed using Cox proportional hazards regression to evaluate the association between the IOMSS (treated as a continuous variable) and the time to complete resolution of AOM/OME. This analysis was adjusted for potential confounding variables, including age, gender, daycare attendance, exposure to tobacco smoke, breastfeeding history, socioeconomic status, and the treatment received. Hazard ratios (HRs) and their corresponding 95% confidence intervals (CIs) were calculated. Logistic regression was used to assess the association between the IOMSS and the development of each secondary outcome (recurrent AOM, CSOM, mastoiditis, persistent hearing loss). This analysis was also adjusted for the same set of confounding variables. Odds ratios (ORs) and 95% CIs were calculated. Receiver Operating Characteristic (ROC) curve analysis was conducted to determine the optimal cutoff value of the IOMSS for predicting the development of complications. The following metrics were calculated: the area under the curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), Youden's Index (J), false positive rate, false negative rate, likelihood ratio positive (LR+), and likelihood ratio negative (LR-). A p-value of <0.05 was adopted as the threshold for statistical significance.

3. Results

Table 2 presents a comprehensive overview of the baseline characteristics of the study population (N=850) and their association with 6-month resolution status (Resolved, n=510; Not Resolved, n=340); Age: The mean age of the study population was 5.2 years with a standard deviation of 2.8 years. The median age

was 5.0 years, with an interquartile range (IQR) of 3.0 to 7.0 years. The "Resolved" group had a lower mean age (4.8 years) compared to the "Not Resolved" group (5.8 years). This difference was statistically significant in the unadjusted analysis ($p < 0.001$), suggesting younger children were more likely to have resolution. However, this age difference was not significant after adjusting for other variables ($p = 0.08$). The table also breaks down the population into age groups. A higher percentage of younger children (6-24 months) achieved resolution (19.6%) compared to those who did not (14.7%). Conversely, a higher percentage of older children (>60-144 months) were in the "Not Resolved" group (47.1%) compared to the "Resolved" group (37.3%); Gender: The study population consisted of 55.0% males and 45.0% females. There was no significant difference in gender distribution between the "Resolved" and "Not Resolved" groups ($p = 0.92$ unadjusted, $p = 0.85$ adjusted); Ethnicity: The study included participants from various ethnic groups in Indonesia, with Javanese being the largest group (35.3%). There was no significant difference in the distribution of ethnicities between the two groups ($p = 0.15$ unadjusted, $p = 0.22$ adjusted); Daycare Attendance: 49.4% of the children attended daycare. A significantly lower percentage of children who attended daycare achieved resolution (35.3%) compared to those who did not (64.7%). This difference was highly significant in both unadjusted and adjusted analyses ($p < 0.001$). Daycare attendance appears to be a strong predictor of not achieving resolution; Tobacco Smoke Exposure: 41.2% of the children had some form of tobacco smoke exposure. Children with tobacco smoke exposure were significantly less likely to achieve resolution (27.5%) compared to those with no exposure (72.5%). This was significant in both unadjusted and adjusted analyses ($p < 0.001$). Specific parental smoking (mother or father) and exposure from other household members also showed similar trends, with higher exposure associated with lower resolution rates; Breastfeeding Duration: 58.8% of children were breastfed for less than 6 months. Children breastfed for less than 6 months were significantly less likely to achieve resolution (39.2%) compared to those breastfed for 6 months or more (60.8%). This difference was highly significant in both unadjusted and adjusted analyses ($p < 0.001$); Socioeconomic Status (SES): SES was categorized as low (47.1%), middle (29.4%), and high (23.5%). Children from low SES families were significantly less likely to achieve resolution (31.4%) compared to middle (68%) or high SES families (33.3%). This difference was highly significant in both unadjusted and adjusted analyses ($p < 0.001$); Previous AOM Episodes: 29.4% of children had no previous AOM episodes, while 41.2% had 1-2 episodes, and 29.4% had 3 or more episodes. Children with no previous AOM episodes were significantly more likely to achieve resolution (35.3%) compared to those with 1-2 episodes (43.1%) or 3 or more episodes (28.2%). This was significant in both unadjusted and adjusted analyses ($p < 0.001$, $p = 0.002$); Diagnosis: 70.6% of children were diagnosed with AOM, and 29.4% with OME. Children with AOM were more likely to achieve resolution (84.3%) than children with OME (15.7%). This difference was significant in both unadjusted and adjusted analyses ($p = 0.008$, $p = 0.03$); IOMSS: The mean IOMSS score was 5.3 with a standard deviation of 2.1. The median was 5. The "Resolved" group had a significantly lower mean IOMSS score (3.8) compared to the "Not Resolved" group (6.9). This difference was highly significant ($p < 0.001$). Children with lower IOMSS scores (0-3) were more likely to achieve resolution (39.2%), while those with higher scores (7-11) were less likely to achieve resolution (19.6%); Hearing Loss at Baseline: 52.9% of children had no hearing loss at baseline. Children with no hearing loss were significantly more likely to achieve resolution (68.6%) compared to those with mild, moderate, or severe/profound hearing loss. This difference was highly significant in both unadjusted and adjusted analyses ($p < 0.001$).

Table 2. Baseline characteristics of the study population (N=850) and association with 6-month resolution status.

Characteristic	Overall (N=850)	Resolved (n=510)	Not Resolved (n=340)	Unadjusted p-value	Adjusted p-value[a]
Age (years)					
Mean ± SD	5.2 ± 2.8	4.8 ± 2.5	5.8 ± 3.0	<0.001	0.08
Median (IQR)	5.0 (3.0 - 7.0)	4.5 (2.5 - 6.5)	6.0 (4.0 - 8.5)	<0.001	
Age Groups, n (%)					
6 - 24 months	150 (17.6%)	100 (19.6%)	50 (14.7%)		
>24 - 60 months	350 (41.2%)	220 (43.1%)	130 (38.2%)		
>60 - 144 months	350 (41.2%)	190 (37.3%)	160 (47.1%)		
Gender, n (%)					
Male	468 (55.0%)	280 (54.9%)	188 (55.3%)	0.92	0.85
Female	382 (45.0%)	230 (45.1%)	152 (44.7%)		
Ethnicity, n (%)				0.15	0.22
Javanese	300 (35.3%)	185 (36.3%)	115 (33.8%)		
Sumatran (Multiple Subgroups)	180 (21.2%)	110 (21.6%)	70 (20.6%)		
Borneo (Multiple Subgroups)	150 (17.6%)	90 (17.6%)	60 (17.6%)		
Sulawesi (Multiple Subgroups)	160 (18.8%)	80 (15.7%)	80 (23.5%)		
Balinese	60 (7.1%)	45 (8.8%)	15 (4.4%)		
Daycare Attendance, n (%)					
Yes	420 (49.4%)	180 (35.3%)	240 (70.6%)	<0.001	<0.001
No	430 (50.6%)	330 (64.7%)	100 (29.4%)		
Tobacco Smoke Exposure, n (%)					
Any Exposure	350 (41.2%)	140 (27.5%)	210 (61.8%)	<0.001	<0.001
No Exposure	500 (58.8%)	370 (72.5%)	130 (38.2%)		
Parental Smoking (Mother)	100 (11.8%)	30 (5.9%)	70 (20.6%)		
Parental Smoking (Father)	280 (32.9%)	120 (23.5%)	160 (47.1%)		
Other Household Members	70 (8.2%)	20(3.9)	50(14.7)		
Breastfeeding Duration, n (%)					
< 6 months	500 (58.8%)	200 (39.2%)	300 (88.2%)	<0.001	<0.001
≥ 6 months	350 (41.2%)	310 (60.8%)	40 (11.8%)		
Socioeconomic Status (SES), n (%)					
Low	400 (47.1%)	160 (31.4%)	240 (70.6%)	<0.001	<0.001
Middle	250 (29.4%)	170 (33.3%)	80 (23.5%)		
High	200 (23.5%)	180 (35.3%)	20 (5.9%)		
Previous AOM Episodes, n (%)					
0	250 (29.4%)	180 (35.3%)	70 (20.6%)	<0.001	0.002
1-2	350 (41.2%)	220 (43.1%)	130 (38.2%)		
≥3	250 (29.4%)	110 (21.6%)	140 (41.2%)		
Diagnosis, n (%)					
AOM	600 (70.6%)	430 (84.3%)	170 (50.0%)	0.08	0.03
OME	250 (29.4%)	80 (15.7%)	170 (50.0%)		
IOMSS					
Mean ± SD	5.3 ± 2.1	3.8 ± 1.6	6.9 ± 1.9	<0.001	<0.001
Median (IQR)	5 (3-7)	3 (2-5)	7 (6-9)	<0.001	
IOMSS Categories, n (%)					
0-3 (Low)	245 (28.8%)	200 (39.2%)	45 (13.2%)		
4-6 (Medium)	350 (41.2%)	210 (41.2%)	140 (41.2%)		
7-11 (High)	255 (30.0%)	100 (19.6%)	210 (62.1%)		
Hearing Loss at Baseline, n (%)					
No Hearing Loss	450 (52.9%)	350 (68.6%)	100 (29.4%)	<0.001	<0.001
Mild Hearing Loss	200 (23.5%)	100 (19.6%)	100 (29.4%)		
Moderate Hearing Loss	150 (17.6%)	50 (9.8%)	100 (29.4%)		
Severe/Profound Hearing Loss	50 (5.9%)	10 (2.0%)	40 (11.8%)		

[a]Adjusted p-values are from multivariate logistic regression models controlling for all other variables in the table; IQR = Interquartile Range; SES = Socioeconomic Status; AOM = Acute Otitis Media; OME = Otitis Media with Effusion; IOMSS = Indonesian Otitis Media Severity Score.

Table 3 presents the results of a Cox proportional hazards regression analysis, which examines various factors associated with the time it takes for children with AOM/OME to achieve complete resolution within a 6-month period; IOMSS (per 1-point increase): A higher IOMSS score is associated with a lower likelihood of achieving complete resolution. Specifically, for every one-point increase in the IOMSS score, the hazard ratio (HR) is 0.85. This means that children with higher IOMSS scores resolve at a slower rate. This finding is statistically significant; Age (per 1-year increase): The effect of age on the time to resolution is not statistically significant; Gender (Male vs. Female): There is no significant difference in the time to resolution between male and female children; Ethnicity: Ethnicity, when compared to the Javanese reference group, does not show a statistically significant impact on the time to resolution for any of the specific ethnic groups listed (Sumatran, Borneo, Sulawesi, and Balinese); Daycare Attendance (Yes vs. No): Children who attend daycare have a significantly lower likelihood of achieving complete resolution compared to those who do not attend daycare. The hazard ratio is 0.48, indicating a considerably slower resolution rate for daycare attendees; Tobacco Smoke Exposure: Any tobacco smoke exposure is associated with a significantly lower likelihood of complete resolution. The hazard ratio is 0.56. Specifically, parental smoking (both mother and father) and exposure from other household members are all independently associated with a slower rate of resolution, with hazard ratios of 0.70, 0.60, and 0.55 respectively. All of these findings are statistically significant; Breastfeeding (< 6 months vs. ≥ 6 months): Children breastfed for less than 6 months have a significantly lower likelihood of achieving complete resolution compared to those breastfed for 6 months or more. The hazard ratio is 0.40, indicating a substantially slower resolution rate; Socioeconomic Status (SES): Children from low socioeconomic status families have a significantly lower likelihood of achieving complete resolution compared to those from high SES families (HR = 0.53). Children from middle socioeconomic status families also have a significantly lower likelihood of resolution compared to those from high SES families (HR = 0.78), although the effect is less pronounced than for the low SES group; Previous AOM Episodes:Compared to children with no previous AOM episodes, those with 1-2 previous episodes do not show a statistically significant difference in time to resolution. However, children with 3 or more previous AOM episodes have a significantly lower likelihood of achieving complete resolution (HR = 0.62); Diagnosis (AOM vs. OME): Children diagnosed with AOM have a significantly higher likelihood of achieving complete resolution compared to those diagnosed with OME. The hazard ratio is 1.45, indicating a faster resolution rate for AOM cases; Hearing Loss at Baseline: Compared to children with no hearing loss at baseline, those with mild, moderate, or severe/profound hearing loss all have a significantly lower likelihood of achieving complete resolution. The hazard ratios are 0.65, 0.40, and 0.28, respectively, demonstrating a progressively slower resolution rate with increasing severity of hearing loss; Treatment Received: There is no significant difference in time to resolution between children treated with amoxicillin and those receiving other treatments. Children treated with amoxicillin-clavulanate have a slightly higher likelihood of resolution compared to those receiving other treatments. Children who initially underwent watchful waiting (for OME) have a significantly lower likelihood of resolution.

Table 3. Cox proportional hazards regression analysis of factors associated with time to complete resolution of AOM/OME at 6 months.

Predictor variable	Hazard ratio (HR)	95% confidence interval (CI)	p-value
IOMSS (per 1-point increase)	0.85	0.80 - 0.90	<0.001
Age (per 1-year increase)	0.96	0.92 - 1.00	0.06
Gender (Male vs. Female)	01.03	0.88 - 1.20	0.71
Ethnicity			0.28
Javanese (Reference)	1.00		
Sumatran	0.92	0.75 - 1.13	
Borneo	0.88	0.70 - 1.10	
Sulawesi	0.80	0.64 - 1.00	
Balinese	1.15	0.82 - 1.61	
Daycare Attendance (Yes vs. No)	0.48	0.38 - 0.60	<0.001
Tobacco Smoke Exposure			
(Any vs. No)	0.56	0.45 - 0.68	<0.001
(Parental Smoking - Mother)	0.70	0.50 - 0.98	0.04
(Parental Smoking - Father)	0.60	0.48 - 0.75	<0.001
(Other Household Members)	0.55	0.38-0.80	0.002
Breastfeeding			
(< 6 months vs. ≥ 6 months)	0.40	0.32 - 0.50	<0.001
Socioeconomic Status (SES)			
Low (vs. High)	0.53	0.42 - 0.67	<0.001
Middle (vs. High)	0.78	0.62 - 0.98	0.03
Previous AOM Episodes			
0 (Reference)	1.00		
1-2	0.85	0.70 - 1.03	0.09
≥3	0.62	0.48 - 0.80	<0.001
Diagnosis (AOM vs. OME)	1.45	1.18 - 1.78	<0.001
Hearing Loss at Baseline			
No Hearing Loss (Reference)	1.00		
Mild Hearing Loss	0.65	0.52-0.81	<0.001
Moderate Hearing Loss	0.40	0.30-0.53	<0.001
Severe/Profound Hearing Loss	0.28	0.18-0.45	<0.001
Treatment Received			
Amoxicillin	1.10	0.90-1.34	0.36
Amoxicillin-Clavulanate	1.25	1.02-1.53	0.03
Watchful Waiting (OME)	0.70	0.55-0.89	0.003

Table 4 presents the results of a logistic regression analysis examining risk factors for secondary outcomes at 6 months. These secondary outcomes include recurrent AOM, CSOM, mastoiditis, and persistent hearing loss; IOMSS (per 1-point increase): A higher IOMSS score is significantly associated with an increased risk of recurrent AOM, CSOM, and persistent hearing loss. Specifically, for each one-point increase in the IOMSS, the odds of recurrent AOM increase by 1.20 times, the odds of CSOM increase by 1.35 times, and the odds of persistent hearing loss increase by 1.28 times. While the trend is present, the association with mastoiditis was not statistically significant; Age (per 1-year increase): Older age is significantly associated with an increased risk of CSOM and persistent hearing loss. For each one-year increase in age, the odds of CSOM increase by 1.10 times, and the odds of persistent hearing loss increase by 1.08 times. Age is also associated with a higher risk of mastoiditis. Recurrent AOM did not show a significant association with age; Gender (Male vs. Female): Gender is not significantly associated with any of the secondary outcomes (recurrent AOM, CSOM, mastoiditis, or persistent hearing loss); Ethnicity: Compared to the Javanese reference group, there are no statistically significant differences in the risk of any secondary outcome for any of the other ethnic groups listed (Sumatran, Borneo, Sulawesi, and Balinese); Daycare Attendance (Yes vs. No): Daycare attendance is significantly associated with an increased risk of recurrent AOM, CSOM, and persistent hearing loss. Children attending daycare have 2.30 times higher odds of recurrent AOM, 1.80 times higher odds of CSOM, and 2.00 times higher odds of persistent hearing loss. The association with mastoiditis was not statistically significant; Tobacco Smoke Exposure: Any tobacco smoke exposure is significantly associated with an increased risk of all secondary outcomes (recurrent AOM, CSOM, mastoiditis, and persistent hearing loss). Children with any tobacco smoke exposure have 1.9 times higher odds of recurrent AOM, 2.1 times higher odds of CSOM, 2.5 times higher odds of mastoiditis, and 1.7 times higher odds of persistent hearing loss. Specific types of exposure (parental smoking - mother, parental smoking - father, and exposure from other household members) are also significantly associated with increased risk for most or all of the secondary outcomes; Breastfeeding (< 6 months vs. ≥ 6 months): Breastfeeding for less than 6 months is significantly associated with an increased risk of recurrent AOM, CSOM, and persistent hearing loss. Children breastfed for less than 6 months have 2.70 times higher odds of recurrent AOM, 2.00 times higher odds of CSOM, and 2.20 times higher odds of persistent hearing loss; Socioeconomic Status (SES): Low SES is significantly associated with an increased risk of recurrent AOM, CSOM, mastoiditis and persistent hearing loss. Children from low SES families have approximately 2 times higher odds of recurrent AOM, CSOM, mastoiditis, and persistent hearing loss compared to children from high SES families. Middle SES, compared to high SES, is not significantly associated with an increased risk of any of the secondary outcomes except for a slightly increased risk of recurrent AOM; Initial Diagnosis (AOM vs. OME): An initial diagnosis of AOM is significantly associated with a decreased risk of recurrent AOM, CSOM, and persistent hearing loss compared to an initial diagnosis of OME; Hearing Loss at Baseline: Compared to children with no hearing loss at baseline, those with mild, moderate, or severe/profound hearing loss have a significantly increased risk of all secondary outcomes (recurrent AOM, CSOM, mastoiditis, and persistent hearing loss). The risk increases with the severity of hearing loss; Treatment Received: The treatment received (Amoxicillin, Amoxicillin-Clavulanate, or Watchful Waiting) is not significantly associated with the risk of recurrent AOM, mastoiditis, or persistent hearing loss. Watchful waiting is associated with a higher risk of CSOM, but Amoxicillin and Amoxicillin-Clavulanate are not.

Table 4. Logistic regression analysis of risk factors for secondary outcomes at 6 months.

Risk factor	Recurrent AOM (OR, 95% CI)	CSOM (OR, 95% CI)	Mastoiditis (OR, 95% CI)	Persistent hearing loss (OR, 95% CI)
IOMSS (per 1-point increase)	1.20 (1.10-1.31)	1.35 (1.18-1.54)	1.25 (0.98-1.60)	1.28 (1.12-1.46)
Age (per 1-year increase)	1.05 (0.98-1.12)	1.10 (1.02-1.19)	1.15 (1.05-1.26)	1.08 (1.01-1.16)
Gender (Male vs. Female)	0.95 (0.75-1.20)	1.12 (0.70-1.78)	0.88 (0.35-2.20)	1.05 (0.78-1.41)
Ethnicity				
Javanese (Reference)	1.00	1.00	1.00	1.00
Sumatran	1.10 (0.80-1.52)	0.85 (0.45-1.60)	1.20 (0.48-3.00)	0.90 (0.60-1.35)
Borneo	0.95 (0.68-1.33)	1.30 (0.70-2.41)	1.15 (0.45 - 2.91)	0.98 (0.65-1.48)
Sulawesi	1.25 (0.90-1.74)	1.45 (0.80-2.63)	0.90 (0.30-2.70)	1.30 (0.90-1.88)
Balinese	0.80 (0.45-1.42)	0.70 (0.25-1.96)	1.50 (0.40-5.63)	0.75 (0.40-1.41)
Daycare Attendance (Yes vs. No)	2.30 (1.80-2.90)	1.80 (1.20-2.70)	1.50 (0.80-2.80)	2.00 (1.50-2.70)
Tobacco Smoke Exposure				
(Any vs. No)	1.9 (1.5-2.4)	2.1 (1.4-3.2)	2.5 (1.2-5.2)	1.7 (1.3-2.2)
(Parental Smoking - Mother)	1.50 (1.00-2.25)	1.80 (1.00-3.24)	2.0 (0.8-5.4)	1.3 (0.8-2.1)
(Parental Smoking - Father)	1.8 (1.3-2.5)	2.0 (1.2-3.3)	2.4(1.1-5.0)	1.6 (1.1-2.2)
(Other Household Members)	2.2 (1.5-3.3)	2.5 (1.4-4.5)	3.0 (1.3-7.0)	2.0 (1.3-3.0)
Breastfeeding				
(< 6 months vs. ≥ 6 months)	2.70 (2.10-3.40)	2.00 (1.30-3.10)	1.80 (0.90-3.60)	2.20 (1.70-2.90)
Socioeconomic Status (SES)				
Low (vs. High)	2.00 (1.60-2.50)	1.90 (1.20-3.00)	2.20 (1.00-4.80)	1.80 (1.40-2.30)
Middle (vs. High)	1.30 (1.00-1.69)	1.20 (0.75-1.92)	1.30 (0.60-2.81)	1.25 (0.95-1.64)
Initial Diagnosis (AOM vs OME)	0.45 (0.35-0.58)	0.60 (0.38-0.95)	0.8 (0.3-2.0)	0.55(0.40-0.76)
Hearing Loss at Baseline				
No Hearing Loss (Reference)	1.00			
Mild Hearing Loss	2.5 (1.8-3.4)	2.0(1.2-3.4)	1.8(0.7-4.5)	4.0(2.8-5.6)
Moderate Hearing Loss	4.0 (2.8-5.7)	3.5(1.9-6.3)	2.5 (0.9-7.4)	7.5(4.8-11.8)
Severe/Profound Hearing Loss	6.2(3.5-11.0)	5.8 (2.6-13.1)	3.2(1.0-10.1)	12.0(6.5-22.3)
Treatment Received				
Amoxicillin	0.95	1.20	1.50	0.90
Amoxicillin-Clavulanate	0.80	0.75	0.9	0.88
Watchful Waiting (OME)	2.50	3.00	2.00	2.8

*p<0.05, **p<0.01, **p<0.001. OR = Odds Ratio, CI = Confidence Interval.

Table 5 presents the results of a Receiver Operating Characteristic (ROC) curve analysis, evaluating the Indonesian Otitis Media Severity Score's (IOMSS) ability to predict complications of otitis media. The Area Under the Curve (AUC) for the IOMSS in predicting complications is 0.82, with a 95% confidence interval of 0.78 to 0.86. The AUC is a measure of the test's overall discriminatory ability. An AUC of 0.82 indicates that the IOMSS has good accuracy in distinguishing between children who will develop complications and those who will not. The table further provides data for various IOMSS cutoff

values (≥5, ≥6, ≥7, and ≥8) to illustrate how the test's performance changes at different thresholds. Sensitivity measures the test's ability to correctly identify children who *will* develop complications (true positive rate). Sensitivity decreases as the cutoff score increases. At a cutoff of ≥5, the sensitivity is 90%, meaning the test correctly identifies 90% of children who go on to develop complications. At a cutoff of ≥8, the sensitivity drops to 60%. Specificity measures the test's ability to correctly identify children who *will not* develop complications (true negative rate). Specificity increases as the cutoff score increases. At a cutoff of ≥5, the specificity is 45%, meaning the test correctly identifies 45% of children who do not develop complications. At a cutoff of ≥8, the specificity rises to 85%. PPV is the probability that a child with a positive test result (score above the cutoff) will *actually* develop complications. PPV increases as the cutoff score increases. At a cutoff of ≥5, the PPV is 58%, meaning that 58% of children with a score of 5 or higher will develop complications. At a cutoff of ≥8, the PPV increases to 78%. NPV is the probability that a child with a negative test result (score below the cutoff) will *not* develop complications. NPV decreases as the cutoff score increases. At a cutoff of ≥5, the NPV is 85%, meaning that 85% of children with a score below 5 will not develop complications. At a cutoff of ≥8, the NPV decreases to 70%. The Youden's Index is a single statistic that captures both sensitivity and specificity. It is calculated as Sensitivity + Specificity - 1. A higher Youden's Index indicates better overall diagnostic effectiveness. The Youden's Index peaks at the cutoff of ≥7 and ≥8 (0.45). False positive rate (1-Specificity) is the proportion of children without complications who are incorrectly identified as having a high risk. The false positive rate decreases as the cutoff score increases. False negative rate (1-Sensitivity) is the proportion of children with complications who are incorrectly identified as having a low risk. The false negative rate increases as the cutoff score increases. The likelihood ratio positive is the likelihood that a positive test result is obtained in a child with complications compared to a child without complications. LR+ increases as the cutoff score increases, indicating a stronger association with complications at higher cutoffs. The likelihood ratio negative is the likelihood that a negative test result is obtained in a child with complications compared to a child without complications. LR- decreases as the cutoff score increases, indicating a weaker association with the absence of complications at higher cutoffs.

Table 5. ROC curve analysis of the IOMSS for predicting complications of otitis media.

Metric	Overall AUC (95% CI)	IOMSS Cutoff ≥5	IOMSS Cutoff ≥6	IOMSS Cutoff ≥7	IOMSS Cutoff ≥8
Area Under the Curve (AUC)	0.82 (0.78-0.86)	-	-	-	-
Sensitivity (%)	-	90	82	75	60
Specificity (%)	-	45	60	70	85
Positive Predictive Value (PPV) (%)	-	58	62	65	78
Negative Predictive Value (NPV) (%)	-	85	81	80	70
Youden's Index (J)	-	0.35	0.42	0.45	0.45
False Positive Rate (1-Specificity)	-	55	40	30	15
False Negative Rate (1-Sensitivity)	-	10	18	25	40
Likelihood Ratio Positive (LR+)	-	1.64	02.05	2.50	4.00
Likelihood Ratio Negative (LR-)	-	0.22	0.30	0.36	0.47
Number of Patients with Complication(s)	355	-	-	-	-
Number of Patients without Complication(s)	495	-	-	-	-

4. Discussion

This multi-center prospective cohort study provides compelling evidence supporting the Indonesian Otitis Media Severity Score (IOMSS) as a robust prognostic tool for predicting treatment outcomes and the risk of complications in Indonesian children diagnosed with both AOM and OME. The key finding is the significant association between higher IOMSS scores at baseline and a diminished likelihood of complete resolution of otitis media at the 6-month follow-up. Furthermore, the IOMSS demonstrates a strong predictive capacity for the development of complications, notably recurrent AOM, chronic suppurative otitis media (CSOM), and persistent hearing loss.[11,12]

The IOMSS stands out as a simple and clinically relevant scoring system, intentionally designed to incorporate clinical findings that are easily and readily assessable. This ease of use is a crucial factor for its potential widespread adoption, as it does not necessitate specialized equipment or extensive training. Consequently, the IOMSS is suitable for implementation across various healthcare settings, ranging from primary care clinics to resource-limited environments within Indonesia. The components of the score—otalgia, fever, otorrhea, tympanic membrane appearance, and hearing loss—are reflective of the key clinical manifestations of otitis media and their respective severity. This direct correlation with the disease's clinical presentation enhances the tool's interpretability and clinical utility.[13,14]

The findings of this study align with previous research that has evaluated other otitis media scoring systems. For instance, the Acute Otitis Media Severity of Symptoms (AOM-SOS) scale, developed in the United States, has demonstrated its ability to predict treatment failure and the need for additional medical care in children with AOM. Similarly, the Otitis Media-6 (OM-6) questionnaire, a parent-reported measure of OM-related symptoms, has been validated as a predictor of quality of life and healthcare utilization. While these existing scores have proven valuable in their respective contexts, it is important to acknowledge that they were developed in different populations and may not be directly applicable to the Indonesian context. The IOMSS fills a critical gap by providing a culturally and contextually relevant tool specifically designed and validated for Indonesian children.[15-17]

The significant association observed between the IOMSS and the risk of complications underscores its substantial clinical utility. The capacity to identify children at an elevated risk of developing complications enables clinicians to implement more targeted and proactive interventions. This may involve closer follow-up to monitor the child's condition more frequently, the administration of more aggressive antibiotic therapy in cases of AOM to combat the infection more effectively, or earlier consideration of surgical management, such as tympanostomy tube insertion for children experiencing recurrent AOM or persistent OME. Such a personalized approach to the management of otitis media, guided by the IOMSS, has the potential to significantly improve patient outcomes and alleviate the long-term burden associated with OM-related complications. The identification of a cutoff value of >=7 holds particular relevance, as it allows for the identification of a high-risk population that would benefit from these targeted interventions.[18-20]

5. Conclusion

In conclusion, this study provides strong evidence for the IOMSS as a valuable prognostic tool in the management of otitis media in Indonesian children. The IOMSS effectively predicts treatment outcomes and the risk of complications, including recurrent AOM, CSOM, and persistent hearing loss. Its simplicity and reliance on readily available clinical findings make it suitable for use in various healthcare settings within Indonesia. The IOMSS can aid clinicians in identifying high-risk patients who would benefit from more intensive management and closer follow-up. This has the potential to improve patient outcomes and reduce the burden of otitis media and its complications. The findings underscore the importance of utilizing contextually relevant tools for risk stratification and management of pediatric otitis media.

6. References

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