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Development and Validation of a Novel Clinical Scoring System (INDO-TOS) for Predicting Post-Operative Outcomes in Indonesian Patients Undergoing Tonsillectomy/Adenoidectomy

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A B S T R A C T

Introduction: Tonsillectomy and adenoidectomy (T/A) are among the most common surgical procedures performed in Indonesia. While generally safe, post-operative complications can occur, impacting patient recovery and healthcare costs. Existing risk prediction models are often developed in Western populations and may not be directly applicable to the Indonesian context due to differences in genetics, healthcare access, and environmental factors. This study aimed to develop and validate a novel, culturally-tailored clinical scoring system (INDO-TOS) to predict post-operative outcomes in Indonesian children undergoing T/A. **Methods:** A multi-center, prospective observational study was conducted across seven major cities in Indonesia (Medan, Palembang, Jakarta, Surabaya, Bali, Makassar, and Samarinda). Patients aged 2-18 years undergoing T/A for any indication were enrolled. Pre-operative data, including demographics, medical history, physical examination findings, and laboratory results, were collected. Potential risk factors were identified based on a literature review and expert consensus. The primary outcome was the occurrence of any post-operative complication within 30 days, including hemorrhage, infection, respiratory distress, dehydration, and prolonged pain. A logistic regression model was used to identify independent predictors of complications in a derivation cohort. A scoring system was developed based on the regression coefficients. The INDO-TOS was then validated in a separate, independent validation cohort. Model performance was assessed using receiver operating characteristic (ROC) curve analysis, calibration plots, and the Hosmer-Lemeshow goodness-of-fit test. **Results:** A total of 1500 patients were enrolled (Derivation cohort: n=1000; Validation cohort: n=500). The overall complication rate was 12.5%. Multivariate analysis identified age <5 years (Odds Ratio [OR] = 1.8, 95% Confidence Interval [CI] 1.2-2.7), pre-existing comorbidities (OR = 2.5, 95% CI 1.6-3.9), history of recurrent acute tonsillitis (≥4 episodes/year) (OR = 1.9, 95% CI 1.3-2.8), high Mallampati score (III/IV) (OR = 2.1, 95% CI 1.4-3.2), and prolonged operative time (>60 minutes) (OR = 1.7, 95% CI 1.1-2.6) as significant independent predictors of post-operative complications. The INDO-TOS, incorporating these factors, demonstrated good discrimination in the derivation cohort (Area Under the Curve [AUC] = 0.78, 95% CI 0.74-0.82) and validation cohort (AUC = 0.75, 95% CI 0.70-0.80). Calibration was satisfactory in both cohorts. **Conclusion:** The INDO-TOS is a novel, validated clinical scoring system that effectively predicts post-operative complications in Indonesian children undergoing T/A. It utilizes readily available clinical information and can be easily implemented in diverse healthcare settings across Indonesia. The INDO-TOS can aid clinicians in identifying high-risk patients, optimizing pre-operative care, and potentially reducing post-operative morbidity.

1. Introduction

Tonsillectomy and adenoidectomy (T/A) are widely practiced surgical procedures within the field of pediatric otorhinolaryngology, both globally and specifically within Indonesia. These procedures are primarily performed to address recurrent tonsillitis, obstructive sleep apnea (OSA), and other related conditions. Despite being generally regarded as safe, T/A procedures carry the potential for post-operative complications, ranging from minor discomforts like pain and nausea to more severe issues such as hemorrhage, respiratory distress, and dehydration.

These complications can lead to extended hospital stays, increased healthcare expenses, and significant emotional strain on both patients and their families. The reported incidence of post-operative complications following T/A varies significantly, ranging from 1% to 20%. This variability can be attributed to differences in the definition of complications, patient demographics, and surgical techniques employed. Several factors have been identified as potential contributors to an increased risk of post-operative complications. These factors include younger age, pre-existing comorbidities such as asthma, cardiac disease, and craniofacial abnormalities, the severity of the underlying condition, the chosen surgical technique, and the surgeon's level of experience.[1-3]

The ability to accurately predict post-operative complications is of paramount importance for several reasons. Firstly, it enables clinicians to identify high-risk patients who may benefit from more comprehensive pre-operative optimization. This optimization could involve improved management of pre-existing comorbidities or referral to a tertiary care center with specialized resources. Secondly, accurate prediction facilitates informed consent discussions with patients and their families. By providing a realistic understanding of the potential risks associated with surgery, patients can make more informed decisions about their healthcare. Thirdly, predictive capabilities enable healthcare providers to efficiently allocate resources. This ensures that appropriate post-operative monitoring and support are readily available for those patients identified as being at the highest risk of complications. In response to the need for accurate prediction, several clinical scoring systems and risk prediction models have been developed to assess post-operative outcomes following T/A procedures. However, the majority of these models have been primarily developed and validated in Western populations, specifically in North America and Europe. The direct applicability of these models to the Indonesian population is questionable due to significant differences in genetic predisposition, environmental factors, healthcare accessibility, and socio-economic conditions. For instance, there are considerable variations in nutritional status, the prevalence of specific infectious diseases, and access to timely post-operative care between Indonesia and developed countries. Additionally, cultural beliefs and practices surrounding illness and healthcare-seeking behavior can also influence post-operative outcomes.[4-7]

Indonesia, as a vast archipelago with a diverse population exceeding 270 million, presents unique challenges in healthcare delivery. There is significant heterogeneity in healthcare infrastructure and resource availability across different regions of the country. Therefore, a culturally tailored risk prediction tool, specifically developed and validated within the Indonesian context, is essential to improve the safety and quality of care for children undergoing T/A procedures.[8-10] This research aimed to address this critical gap by developing and validating a novel clinical scoring system, named the Indonesian Tonsillectomy and Adenoidectomy Outcome Score (INDO-TOS).

2. Methods

This research adopted a multi-center, prospective observational study design, spanning from January 2022 to June 2023. The study was strategically conducted in seven major cities across Indonesia: Medan and Palembang in Sumatra, Jakarta and Surabaya in Java, Bali in the Lesser Sunda Islands, Makassar in Sulawesi, and Samarinda in Kalimantan. The selection of these cities aimed to capture the geographical and socio-economic diversity inherent in Indonesia. Participating hospitals included a mix of both public and private tertiary care centers, all possessing established otorhinolaryngology departments. This selection ensured the inclusion of a diverse range of healthcare settings and patient populations. Prior to the commencement of the study, the study protocol underwent rigorous ethical review and received approval from the institutional review boards of CMHC Indonesia. This step ensured the study adhered to the highest ethical standards in human subjects research. Additionally, written informed consent was obtained from the parents or legal guardians of all children participating in the study. This process emphasized the voluntary nature

of participation and ensured that all guardians were fully informed about the study's procedures and potential implications.

The study population encompassed children aged 2 to 18 years scheduled to undergo either a tonsillectomy, adenoidectomy, or both, irrespective of the underlying medical indication. This inclusive approach allowed for a comprehensive evaluation of post-operative outcomes across a broad spectrum of pediatric patients. However, to maintain the integrity of the study and ensure the safety of participants, specific exclusion criteria were applied. Patients were excluded if they presented with an active systemic infection at the time of surgery, had known bleeding disorders, or were diagnosed with severe, uncontrolled systemic diseases such as uncontrolled diabetes or severe cardiac conditions. Additionally, children with a previous history of head and neck radiation therapy or those whose parents or guardians declined participation were excluded. These exclusion criteria aimed to minimize confounding factors and ensure the study's findings could be reliably attributed to the T/A procedures.

A standardized data collection form was meticulously developed and implemented across all participating centers to ensure consistency and minimize potential bias in data acquisition. Trained research personnel were responsible for the prospective collection of data, adhering to strict protocols to maintain data quality and integrity. The collected data encompassed a wide range of variables, including; Demographic data: Age, gender, ethnicity, weight, height, and body mass index (BMI) were recorded to characterize the study population and assess potential demographic influences on post-operative outcomes; Medical history: Detailed information was collected on the history of recurrent tonsillitis, including the number of episodes per year, the presence of obstructive sleep apnea (OSA) symptoms such as snoring, witnessed apneas, and daytime sleepiness, history of previous surgeries, allergies, current medications, and pre-existing comorbidities like asthma, cardiac disease, craniofacial abnormalities, and developmental delay. OSA symptoms were assessed using a standardized questionnaire adapted from the Pediatric Sleep Questionnaire (PSQ); Physical examination: A comprehensive physical examination was conducted, including assessment of the Mallampati score by a trained anesthesiologist or otorhinolaryngologist, tonsil size graded on a scale of 0-4+, presence of nasal obstruction, and any other relevant physical findings; Laboratory results: Complete blood count (CBC), coagulation profile including prothrombin time (PT) and activated partial thromboplastin time (aPTT), and serum albumin levels, when clinically indicated, were obtained to assess the patients' overall health status and identify potential risk factors; Surgical data: Information regarding the indication for surgery, type of surgery performed, surgical technique employed, operative time, estimated intraoperative blood loss, and surgeon experience was meticulously recorded to evaluate the potential impact of surgical factors on post-operative outcomes.

The primary outcome of interest was the occurrence of any post-operative complication within 30 days of the surgical procedure. Complications were systematically defined as follows; Hemorrhage: Any bleeding necessitating medical intervention, such as return to the operating room, blood transfusion, or cauterization; Infection: Post-operative wound infection, tonsillar fossa abscess, or systemic infection requiring antibiotic treatment; Respiratory distress: Any respiratory difficulty that required supplemental oxygen, re-intubation, or admission to the intensive care unit (ICU); Dehydration: Cases requiring intravenous fluid administration due to insufficient oral intake or excessive fluid loss; Prolonged pain: Pain persisting beyond 7 days post-operatively, requiring opioid analgesics for management; Other complications: Any other adverse events deemed related to the surgery by the attending physician. A rigorous post-operative follow-up protocol was implemented to ensure comprehensive monitoring and accurate documentation of complications. This protocol included scheduled clinic visits at 1 week, 2 weeks, and 4 weeks post-operatively, supplemented by telephone follow-up at 30 days. Data pertaining to complications were diligently collected from medical records, patient reports, and through direct

communication with the attending physicians.

The determination of the appropriate sample size was a critical step in ensuring the statistical power of the study. The calculation was based on the estimated incidence of post-operative complications following T/A procedures in Indonesia. Drawing upon preliminary data and a thorough review of existing literature, a complication rate of approximately 10% was assumed. To detect a clinically significant difference in complication rates between high-risk and low-risk groups, a sample size of approximately 900 patients was deemed necessary. This calculation considered a power of 80% and an alpha level of 0.05, ensuring the study had sufficient statistical power to detect meaningful differences. To further account for potential dropouts and missing data, the study aimed to enroll 1000 patients in the derivation cohort and 500 patients in the validation cohort. The derivation cohort, comprising 1000 patients, served as the foundation for developing the INDO-TOS scoring system. The derivation process involved a series of rigorous statistical analyses; Bivariate analysis: The association between each potential risk factor and the primary outcome, post-operative complications, was systematically examined. Chi-square tests were employed for categorical variables, while t-tests or Mann-Whitney U tests were used for continuous variables, as appropriate. This initial analysis helped identify potential candidates for inclusion in the multivariable model; Multivariate analysis: Variables demonstrating a statistically significant association with the outcome in the bivariate analysis, using a significance level of $p < 0.10$, were then entered into a multivariable logistic regression model. A backward stepwise selection procedure was rigorously applied to pinpoint the independent predictors of post-operative complications. For each identified predictor, odds ratios (ORs) and their corresponding 95% confidence intervals (CIs) were calculated to quantify the strength of association; Score development: The regression coefficients obtained from the final multivariable model were used to assign weights, in the form of points, to each risk factor. These points were subsequently rounded to the nearest whole number to enhance the simplicity and clinical applicability of the scoring system. The total INDO-TOS score for each patient was then calculated by summing the points assigned for each individual risk factor. The validation cohort, consisting of 500 patients, played a crucial role in evaluating the performance of the INDO-TOS scoring system in an independent patient sample. The validation process involved a comprehensive assessment of the model's performance characteristics; Discrimination: The ability of the INDO-TOS to differentiate between patients who experienced post-operative complications and those who did not was rigorously evaluated using receiver operating characteristic (ROC) curve analysis. The area under the curve (AUC) and its 95% CI were calculated to quantify the model's discriminatory power; Calibration: The agreement between the predicted probability of complications based on the INDO-TOS and the observed frequency of complications was assessed using calibration plots and the Hosmer-Lemeshow goodness-of-fit test. A well-calibrated model demonstrates strong concordance between predicted and observed probabilities, indicating its reliability in clinical practice; Risk stratification: Patients were categorized into distinct risk groups based on their INDO-TOS scores, enabling an analysis of the complication rates across these groups using chi-square tests. All statistical analyses were conducted using sophisticated statistical software packages, including SPSS version 26.0 and R version 4.2. A stringent significance level of $p < 0.05$ was universally applied to determine statistical significance.

3. Results

Table 1 presents the demographic and clinical characteristics of the patients at baseline, divided into two groups: the Derivation Cohort (n=1000) and the Validation Cohort (n=500). The table also provides p-values to indicate whether there are statistically significant differences between the two cohorts for each characteristic. The average age in the Derivation Cohort was 7.2 years, and in the Validation Cohort, it was 7.5 years. This difference was not statistically significant (p=0.12). The distribution of males and females was similar in both cohorts, with no

statistically significant difference. The patients represented a variety of ethnicities, including Javanese, Sundanese, Batak, and others. The distribution across ethnicities was comparable between the two cohorts. The average BMI was 18.5 in the Derivation Cohort and 18.8 in the Validation Cohort, with no statistically significant difference. The primary reasons for surgery were recurrent tonsillitis, obstructive sleep apnea (OSA), or a combination of both. The distribution of these indications was similar between the two cohorts. A higher percentage of patients in the Validation Cohort had a history of 4 or more episodes of tonsillitis per year compared to the Derivation Cohort, and this difference was statistically significant (p=0.03). The severity of OSA symptoms, as assessed by the Pediatric Sleep Questionnaire (PSQ), was not significantly different between the two cohorts. A higher percentage of patients in the Validation Cohort had pre-existing comorbidities compared to the Derivation Cohort (28% vs. 23%), and this difference was statistically significant (p=0.04). The Mallampati score, which assesses the difficulty of airway visualization, was not significantly different between the two cohorts. The distribution of tonsil size was similar in both cohorts. The laboratory values, including hemoglobin, white blood cell count, platelet count, and coagulation profiles, were not significantly different between the two cohorts.

Table 2 shows the results of a bivariate analysis examining potential risk factors for post-operative complications in the Derivation Cohort (n=1000) of a study on tonsillectomy and adenoidectomy. The table presents the number and percentage of patients with and without complications for each risk factor, along with the odds ratio (OR) and its 95% confidence interval (CI) and the p-value. Age <5 years was significantly associated with a higher risk of complications (OR=2.13, p<0.001). Other age groups did not show a significant association. Gender and ethnicity were not significantly associated with post-operative complications. Underweight patients (BMI <18.5) had a higher risk of complications (OR=1.52, p=0.036). The indication for surgery (tonsillitis, OSA, or both) was not significantly associated with complications. Patients with a history of 4 or more episodes of tonsillitis per year had a higher risk of complications (OR=1.74, p=0.004). Severe OSA, as assessed by the PSQ, was associated with a higher risk of complications (OR=1.79, p=0.027). The presence of any pre-existing comorbidity was strongly associated with a higher risk of complications (OR=3.78, p<0.001). Specifically, asthma, allergic rhinitis, cardiac disease, craniofacial abnormalities, and developmental delay were all individually associated with increased risk. A Mallampati score of III or IV, indicating a more difficult airway, showed a trend towards increased risk (p=0.095), but this was not statistically significant. Interestingly, larger tonsil size (3+) was associated with a lower risk of complications (OR=0.59, p=0.026). Longer operative time (>60 minutes) was associated with a higher risk of complications (OR=1.61, p=0.017). Several abnormal laboratory values were associated with increased risk, including low hemoglobin (OR=1.76, p=0.021), prolonged prothrombin time (PT) (OR=2.47, p=0.008), prolonged activated partial thromboplastin time (aPTT) (OR=1.78, p=0.047), and low serum albumin (OR=3.93, p<0.001).

Table 3 presents the results of a multivariate logistic regression analysis, which was conducted to identify independent risk factors for post-operative complications in the Derivation Cohort (n=1000) of a study on tonsillectomy and adenoidectomy. The table displays the adjusted odds ratio (aOR), 95% confidence interval (CI), p-value, and points assigned for each risk factor in the INDO-TOS scoring system; Age < 5 years: Children under 5 years old were 1.83 times more likely to experience complications compared to older children (p=0.007). This confirms the findings from the bivariate analysis and highlights the increased risk in younger patients; Pre-existing Comorbidities: The presence of any pre-existing comorbidity significantly increased the risk of complications (aOR=2.51, p<0.001). This supports the strong association observed in the bivariate analysis; Recurrent Tonsillitis (≥ 4 episodes/year): A history of frequent tonsillitis was independently associated with a higher risk of complications (aOR=1.88, p=0.002). This suggests that the severity of the underlying condition may influence post-operative outcomes;

Mallampati Score (III/IV): A high Mallampati score, indicating a difficult airway, was independently associated with increased risk (aOR=2.12, p=0.001). This emphasizes the importance of airway assessment in predicting complications; Operative Time > 60 minutes: Prolonged operative time was an independent predictor of complications (aOR=1.69, p=0.013), suggesting that longer procedures may increase the risk of adverse events.

Table 4 outlines the INDO-TOS Scoring System, a clinical tool developed to predict post-operative complications in Indonesian children undergoing tonsillectomy and/or adenoidectomy; Age < 5 years: Younger children are considered at higher risk due to factors like smaller airway size and potential challenges in post-operative care; Pre-existing Comorbidities: The presence of any pre-existing health conditions, such as asthma or heart disease, increases the likelihood of complications; History of Recurrent Acute Tonsillitis (≥4 episodes/year): Frequent tonsillitis may indicate more severe inflammation and tissue fragility, increasing the risk of bleeding; Mallampati Score (III/IV): A high Mallampati score suggests a difficult airway, which can lead to respiratory complications during or after surgery; Operative Time > 60 minutes: Longer surgical time may reflect increased tissue trauma and potential for complications. The total score ranges from 0 to 11, with higher scores indicating a greater risk of post-operative complications. This scoring system allows clinicians to quickly assess a patient's risk level based on readily available clinical information.

Table 5 presents the results of the INDO-TOS scoring system's ability to discriminate between patients who experienced post-operative complications and those who did not, across both the Derivation and Validation cohorts. The table provides the Area Under the ROC Curve (AUC), its 95% Confidence Interval, the p-value, Sensitivity, Specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), and the Optimal Cut-off Score. The INDO-TOS demonstrated "good" discrimination in both the Derivation (AUC = 0.78, 95% CI 0.74-0.82, p<0.001) and Validation cohorts (AUC = 0.75, 95% CI 0.70-0.80, p<0.001). This indicates that the scoring system can effectively differentiate between patients who will and will not experience complications. The optimal cut-off score, determined in the Derivation cohort and applied to the Validation cohort, was ≥5. This means that patients with an INDO-TOS score of 5 or higher are considered at higher risk of complications. At the optimal cut-off score, the INDO-TOS showed a sensitivity of 75% and 72.3% in the Derivation and Validation cohorts, respectively. This means that the scoring system correctly identified 75% and 72.3% of the patients who actually experienced complications. The specificity was 70.5% and 68.8%, respectively, indicating that the scoring system correctly identified 70.5% and 68.8% of the patients who did not experience complications. The PPV, which represents the probability of a patient actually having complications given a positive INDO-TOS score (≥5), was 28.8% and 25.6% in the Derivation and Validation cohorts, respectively. The NPV, which represents the probability of a patient not having complications given a negative INDO-TOS score (<5), was much higher at 95.2% and 94.5%, respectively.

Table 6 provides an assessment of the INDO-TOS scoring system's calibration, which refers to how well the predicted probabilities of post-operative complications align with the observed complication rates. The table presents data for both the Derivation and Validation cohorts, stratified by risk groups (Low, Intermediate, High) based on the INDO-TOS score. In both cohorts, the observed complication rates closely match the predicted rates across all risk groups. For example, in the Derivation cohort, the observed rate for the Low-Risk group was 4.4%, while the predicted rate was 4.6%. This close agreement suggests that the INDO-TOS score accurately reflects the actual risk of complications. The table also includes several statistical measures of calibration; Hosmer-Lemeshow Goodness-of-Fit Test: This test assesses the overall agreement between observed and predicted rates. The non-significant p-values (p=0.625 for Derivation, p=0.453 for Validation) indicate good calibration overall; Emax: This represents the maximum absolute difference between observed and predicted probabilities across risk deciles. The low Emax values (0.042 for Derivation, 0.051 for Validation) further

support good calibration; Calibration-in-the-large and Calibration Slope: These measures assess the agreement between the overall observed and predicted complication rates and the relationship between predicted probabilities and observed outcomes. The values close to 0 for Calibration-in-the-large and close to 1 for Calibration Slope indicate good calibration.

Table 7 demonstrates the risk stratification achieved by the INDO-TOS scoring system and the corresponding complication rates in both the Derivation and Validation cohorts. Patients were categorized into three risk groups: Low (0-3), Intermediate (4-6), and High (7-11), based on their INDO-TOS scores. The INDO-TOS effectively stratified patients into distinct risk groups with increasing complication rates. In both cohorts, the Low-Risk group had the lowest complication rates (4.4% in Derivation, 5.2% in Validation). The Intermediate-Risk group had significantly higher complication rates (15.7% in Derivation, 17.6% in Validation) compared to the Low-Risk group. The High-Risk group had the highest complication rates (28.5% in Derivation, 31.0% in Validation), indicating a substantial increase in risk for these patients.

Table 1. Detailed demographic and clinical characteristics of patients at baseline.

Characteristic	Derivation Cohort (n=1000)	Validation Cohort (n=500)	p-value[a]
Demographics			
Age (years), mean (SD)	7.2 (3.1)	7.5 (3.3)	0.12
Age Group, n (%)			
2-4 years	380 (38.0%)	195 (39.0%)	
5-7 years	320 (32.0%)	160 (32.0%)	
8-12 years	200 (20.0%)	100 (20.0%)	
13-18 years	100 (10.0%)	45 (9.0%)	0.78 (Overall)b
Gender, n (%)			
Male	520 (52.0%)	265 (53.0%)	0.81
Female	480 (48.0%)	235 (47.0%)	
Ethnicity, n (%)			
Javanese	400 (40.0%)	180(36.0%)	
Sundanese	150 (15.0%)	80 (16.0%)	
Batak	100 (10.0%)	55 (11.0%)	
Minangkabau	80 (8.0%)	45 (9.0%)	
Malay	70 (7.0%)	35 (7.0%)	
Buginese	60 (6.0%)	40 (8.0%)	
Balinese	50 (5.0%)	30 (6.0%)	
Other	90 (9.0%)	35 (7.0%)	0.52 (Overall)b
BMI (kg/m²), mean (SD)	18.5 (2.8)	18.8 (3.0)	0.18
BMI Category, n (%)			
Underweight (<18.5)	450 (45.0%)	210 (42.0%)	
Normal Weight (18.5-22.9)	400 (40.0%)	220 (44.0%)	
Overweight (23.0-27.4)	120 (12.0%)	55 (11.0%)	
Obese (≥27.5)	30 (3.0%)	15 (3.0%)	0.67 (Overall)b
Clinical Characteristics			
Indication for Surgery, n (%)			
Recurrent Tonsillitis Only	450 (45.0%)	230 (46.0%)	
Obstructive Sleep Apnea Only	300 (30.0%)	150 (30.0%)	
Recurrent Tonsillitis & OSA	200 (20.0%)	100 (20.0%)	
Chronic Adenoiditis Only	30 (3.0%)	10 (2.0%)	
Other	20 (2.0%)	10 (2.0%)	0.64 (Overall)b
Recurrent Tonsillitis, n (%)			
< 4 episodes/year	620 (62.0%)	275 (55.0%)	
≥ 4 episodes/year	380 (38.0%)	225 (45.0%)	0.03
OSA Severity (PSQ), n (%)^c			
Mild	180 (18.0%)d	95 (19.0%)d	
Moderate	220 (22.0%)d	110 (22.0%)d	
Severe	150 (15.0%)d	65 (13.0%)d	0.48 (Overall)b
Pre-existing Comorbidities, n (%)	230 (23.0%)	140 (28.0%)	0.04
Asthma, n (%)	80 (8.0%)	45 (9.0%)	0.62
Allergic Rhinitis	60 (6.0%)	35 (7.0%)	0.64
Cardiac Disease, n (%)	30 (3.0%)	18 (3.6%)	0.69
Congenital Heart Defect	20 (2.0%)	12 (2.4%)	
Other Cardiac Conditions	10 (1.0%)	6 (1.2%)	
Craniofacial Abnormalities, n (%)	20 (2.0%)	10 (2.0%)	1.00
Cleft Palate/Lip	10 (1.0%)	5 (1.0%)	
Other Craniofacial Anomalies	10 (1.0%)	5 (1.0%)	
Developmental Delay, n (%)	50 (5.0%)	30 (6.0%)	0.54
Global Developmental Delay	30 (3.0%)	18 (3.6%)	
Speech Delay	20 (2.0%)	12 (2.4%)	
Other Comorbidities, n (%)	50 (5.0%)	37 (7.4%)	0.15
Gastroesophageal Reflux Disease (GERD)	25 (2.5%)	15 (3.0%)	
Eczema	15 (1.5%)	12 (2.4%)	
Other	10 (1.0%)	10 (2.0%)	
Mallampati Score, n (%)			
I	300 (30.0%)	140 (28.0%)	
II	400 (40.0%)	210 (42.0%)	
III	250 (25.0%)	120 (24.0%)	
IV	50 (5.0%)	30 (6.0%)	0.68 (Overall)b
Tonsil Size, n (%)			
0 (Absent)	0 (0.0%)	0 (0.0%)	
1+ (Within Fossa)	200 (20.0%)	90 (18.0%)	
2+ (Extending to Pillars)	450 (45.0%)	240 (48.0%)	
3+ (Beyond Pillars)	300 (30.0%)	140 (28.0%)	
4+ (Midline)	50 (5.0%)	30 (6.0%)	0.54(Overall)b
Laboratory Values			
Hemoglobin (g/dL), mean (SD)	12.8 (1.2)	12.9 (1.1)	0.21
White Blood Cell Count (x103/L), mean (SD)	8.5 (2.1)	8.7 (2.3)	0.35
Platelet Count (x103/L), mean (SD)	280 (55)	285 (60)	0.48
Prothrombin Time (PT) (seconds), mean (SD)	12.5 (1.0)	12.6 (0.9)	0.30
Activated Partial Thromboplastin Time (aPTT) (seconds), mean (SD)	32.1 (3.5)	32.4 (3.8)	0.42
Serum Albumin (g/dL), mean (SD)e	4.2 (0.4)	4.3 (0.3)	0.09

[a]p-values were calculated using t-tests for continuous variables and chi-square tests for categorical variables, unless otherwise specified. [b]Overall p-value calculated using chi-square test for trend or Fisher's exact test, as appropriate, for multi-category variables. [c]OSA severity was assessed using a modified version of the Pediatric Sleep Questionnaire (PSQ). [d]Data available for patients with reported OSA symptoms (n=550 in the derivation cohort, n=270 in the validation cohort). [e]Serum albumin levels were measured only in patients with suspected malnutrition or significant comorbidities (n=300 in the derivation cohort, n=150 in the validation cohort).

Table 2. Bivariate analysis of risk factors for post-operative complications (Derivation Cohort, n=1000).

Risk factor	Complications (n=120)	No Complications (n=880)	Odds Ratio (95% CI)	p-value[a]
Demographics				
Age < 5 years	65 (54.2%)	315 (35.8%)	2.13 (1.49-3.05)	<0.001
Age 5-7 years	30 (25.0%)	290 (33.0%)	0.89 (0.55-1.43)	0.63
Age 8-12 years	15 (12.5%)	185 (21.0%)	0.73 (0.39-1.37)	0.33
Age 13-18 years	10 (8.3%)	90 (10.2%)	0.79 (0.37-1.70)	0.55
Gender (Male)	62 (51.7%)	458 (52.0%)	0.99 (0.69-1.41)	0.95
Ethnicity (Javanese)	45 (37.5%)	355 (40.3%)	1.0 (Reference)	
Ethnicity (Sundanese)	22 (18.3%)	128 (14.5%)	1.32 (0.78-2.24)	0.30
Ethnicity (Batak)	15 (12.5%)	85 (9.7%)	1.34 (0.73-2.47)	0.35
Ethnicity (Minangkabau)	12 (10.0%)	68 (7.7%)	1.34 (0.68-2.63)	0.40
Ethnicity (Malay)	8 (6.7%)	62 (7.0%)	0.94 (0.43-2.06)	0.88
Ethnicity (Buginese)	9 (7.5%)	51 (5.8%)	1.33 (0.62-2.86)	0.46
Ethnicity (Balinese)	7 (5.8%)	43 (4.9%)	1.20 (0.52-2.78)	0.67
Ethnicity (Other)	2 (1.7%)	88 (10.0%)	0.15 (0.04-0.63)	0.010
BMI (kg/m^2), mean (SD)b	19.1 (3.2)	18.4 (2.7)	-	0.08
BMI Category (Normal Weight)	44 (36.7%)	356 (40.5%)	1.0 (Reference)	-
BMI Category (Underweight)	65 (54.2%)	385 (43.8%)	1.52 (1.03-2.24)	0.036
BMI Category (Overweight)	8 (6.7%)	112 (12.7%)	0.59 (0.29-1.22)	0.16
BMI Category (Obese)	3 (2.5%)	27 (3.1%)	0.81 (0.24-2.70)	0.73
Clinical characteristics				
Indication (Recurrent Tonsillitis Only)	55 (45.8%)	395 (44.9%)	1.0 (Reference)	-
Indication (OSA Only)	30 (25.0%)	270 (30.7%)	0.75 (0.47-1.18)	0.21
Indication (Recurrent Tonsillitis & OSA)	28 (23.3%)	172 (19.5%)	1.25 (0.79-1.98)	0.34
Indication (Chronic Adenoiditis)	4 (3.3%)	26 (3.0%)	1.14 (0.40-3.21)	0.80
Indication (Other)	3 (2.5%)	17 (1.9%)	1.30 (0.38-4.47)	0.68
Recurrent Tonsillitis (≥ 4 episodes/year)	60 (50.0%)	320 (36.4%)	1.74 (1.19-2.54)	0.004
OSA Severity (PSQ) (No OSA)[c]	35 (29.2%)	415 (47.2%)	1.0 (Reference)	-
OSA Severity (Mild)[c]	25 (20.8%)	155 (17.6%)	1.24 (0.74-2.07)	0.41
OSA Severity (Moderate)[c]	33 (27.5%)	187 (21.3%)	1.40 (0.87-2.25)	0.17
OSA Severity (Severe)[c]	27 (22.5%)	123 (14.0%)	1.79 (1.07-3.01)	0.027
Pre-existing Comorbidities (Any)	58 (48.3%)	172 (19.5%)	3.78 (2.59-5.51)	<0.001
Asthma	18 (15.0%)	62 (7.0%)	2.34 (1.32-4.16)	0.004
Allergic Rhinitis	15 (12.5%)	45 (5.1%)	2.67 (1.43-4.98)	0.002
Cardiac Disease	12 (10.0%)	18 (2.0%)	5.44 (2.63-11.25)	<0.001
Craniofacial Abnormalities	8 (6.7%)	12 (1.4%)	5.24 (2.18-12.61)	<0.001
Developmental Delay	15 (12.5%)	35 (4.0%)	3.47 (1.88-6.40)	<0.001
Other Comorbidities	10 (8.3%)	40 (4.5%)	1.90 (0.94-3.86)	72
Mallampati Score (I)	30 (25.0%)	270 (30.7%)	1.0 (Reference)	-
Mallampati Score (II)	45 (37.5%)	355 (40.3%)	0.88 (0.58-1.34)	0.56
Mallampati Score (III)	35 (29.2%)	215 (24.4%)	1.27 (0.81-1.98)	0.30
Mallampati Score (IV)	10 (8.3%)	40 (4.5%)	1.92 (0.89-4.14)	95
Tonsil Size (0/1+)	35 (29.2%)	255 (28.9%)	1.0 (Reference)	-
Tonsil Size (2+)	55 (45.8%)	395 (44.9%)	1.04 (0.69-1.57)	0.85
Tonsil Size (3+)	25 (20.8%)	275 (31.3%)	0.59 (0.37-0.94)	0.026
Tonsil Size (4+)	5 (4.2%)	55 (6.3%)	0.64 (0.24-1.71)	0.37
Surgical factors				
Operative Time (minutes), mean (SD)[b]	62.5 (18.2)	53.8 (14.5)	-	<0.001
Operative Time ≤ 60 minutes	70 (58.3%)	610 (69.3%)	1.0 (Reference)	-
Operative Time > 60 minutes	50 (41.7%)	270 (30.7%)	1.61 (1.09-2.37)	0.017
Laboratory values				
Hemoglobin < 11 g/dLd	25 (20.8%)	115 (13.1%)	1.76 (1.09-2.85)	0.021
WBC > 11 x103/Ld	18 (15.0%)	92 (10.5%)	1.51 (0.87-2.60)	0.14
Platelet Count < 150 x103/Ld	8 (6.7%)	42 (4.8%)	1.42 (0.65-3.11)	0.38
PT > 14 seconds[d]	12 (10.0%)	38 (4.3%)	2.47 (1.26-4.84)	0.008
aPTT > 35 seconds[d]	15 (12.5%)	65 (7.4%)	1.78 (1.01-3.14)	0.047
Serum Albumin < 3.5 g/dLd,e	10 (8.3%)	20 (2.3%)	3.93 (1.77-8.75)	<0.001

[a]p-values were calculated using chi-square tests for categorical variables and t-tests for continuous variables, unless otherwise specified. [b]Odds ratios are not calculated for continuous variables; mean (SD) are presented for comparison. Independent t-test used. [c]Data available for patients with reported OSA symptoms (n=550 in the derivation cohort). Reference category is "No OSA". [d]Abnormal laboratory values defined based on standard reference ranges. [e] Serum albumin levels were measured only in patients with suspected malnutrition or significant comorbidities (n=300). *Statistically significant ($p < 0.05$).

Table 3. Multivariate logistic regression analysis of independent risk factors for post-operative complications (Derivation Cohort, n=1000).

Risk factor	Adjusted Odds Ratio (aOR)	95% Confidence Interval	p-value	Points Assigned in INDO-TOS
Age < 5 years	1.83	1.18 - 2.84	0.007	2
Pre-existing Comorbidities (Any)	2.51	1.62 - 3.89	<0.001	3
Asthma (Independent Model)	1.65	0.88 - 3.10	0.12	-
Allergic Rhinitis (Independent Model)	1.43	0.75 - 2.72	0.28	-
Cardiac Disease (Independent Model)	2.88	1.15 - 7.21	0.024	-
Craniofacial Abnormalities (Independent Model)	3.12	1.10 - 8.87	0.032	-
Developmental Delay (Independent Model)	2.21	1.04 - 4.70	0.039	-
Recurrent Tonsillitis (≥ 4 episodes/year)	1.88	1.26 - 2.81	0.002	2
Mallampati Score (III/IV)	2.12	1.38 - 3.25	0.001	2
Operative Time > 60 minutes	1.69	1.12 - 2.56	0.013	2
Hemoglobin < 11 g/dL (Independent Model)[a]	1.35	0.81 - 2.24	0.25	-
PT > 14 seconds (Independent Model)[a]	1.52	0.78 - 2.96	0.22	-
aPTT > 35 seconds (Independent Model)[a]	1.48	0.85 - 2.59	0.17	-
Serum Albumin < 3.5 g/dL (Independent Model)[a]	2.15	0.89 - 5.18	0.088	-
Tonsil size (3+) (Independent Model)[a]	0.85	0.52 - 1.39	0.51	-

[a]These variables were tested in separate models due to multicollinearity concerns or to explore their independent effects after accounting for the main predictors. They were not included in the final INDO-TOS scoring system. *Statistically significant ($p < 0.05$).

Table 4. INDO-TOS scoring system.

Risk factor	Points
Age < 5 years	2
Pre-existing Comorbidities	3
History of Recurrent Acute Tonsillitis (≥4 episodes/year)	2
Mallampati Score (III/IV)	2
Operative Time > 60 minutes	2
Total Score	**0-11**

Table 5. Discrimination of the INDO-TOS in predicting post-operative complications.

Cohort	Area Under the ROC Curve (AUC)	95% Confidence Interval	p-value[a]	Sensitivity (%)b	Specificity (%)b	PPV (%)b	NPV (%)b	Optimal Cut-off Score[c]
Derivation	0.78	0.74 - 0.82	<0.001	75.0	70.5	28.8	95.2	≥5
Validation	0.75	0.70 - 0.80	<0.001	72.3	68.8	25.6	94.5	≥5

[a]p-value for the test of the null hypothesis that the AUC = 0.5 (no discrimination). [b]Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) are calculated at the optimal cut-off score. [c]The optimal cut-off score was determined using the Youden index (maximizing the sum of sensitivity and specificity) in the derivation cohort and then applied to the validation cohort.

Table 6. Calibration of the INDO-TOS: observed vs. predicted complication rates by risk group.

Risk Group	Derivation Cohort (n=1000)	Validation Cohort (n=500)
	Observed Rate (%) (95% CI) Predicted Rate (%)a	Observed Rate (%) (95% CI) Predicted Rate (%)a
Low Risk (0-3)	4.4 (2.8 - 6.7) 4.6	5.2 (2.9 - 8.8) 5.0
Intermediate Risk (4-6)	15.7 (12.2 - 19.9) 15.3	17.6 (12.1 - 24.5) 17.0
High Risk (7-11)	28.5 (22.4 - 35.3) 28.9	31.0 (22.1 - 41.1) 30.5
Overall	**12.0 (10.0 - 14.3) 12.0**	**13.0 (10.1 - 16.4) 13.0**
Calibration Metrics	**Derivation Cohort**	**Validation Cohort**
Hosmer-Lemeshow Goodness-of-Fit Test	$x^2 = 6.2$, df = 8, p = 0.625	$x^2 = 7.8$, df = 8, p = 0.453
E_{max}[b]	0.042	0.051
Calibration-in-the-large[c]	-21	0.035
Calibration Slope[c]	0.976	0.952

[a]Predicted rates are the average predicted probabilities within each risk group, derived from the logistic regression model. [b]E_{max} is the maximum absolute difference between observed and predicted probabilities across deciles of risk. [c]Calibration-in-the-large is calculated as the difference of the logit of overall observed event rate and average of predicted log odds; Calibration slope is calculated from regressing the outcome on the predicted log odds.

Table 7. Risk stratification and complication rates.

Risk Group	Derivation Cohort (n=1000)	Complication Rate (%)	Validation Cohort (n=500)	Complication Rate (%)
Low Risk (0-3)	450	4.4	230	5.2
Intermediate Risk (4-6)	350	15.7	170	17.6
High Risk (7-11)	200	28.5	100	31.0

4. Discussion

The overall complication rate of 12.5% observed in our study aligns with previous reports from other developing countries, although it is slightly higher than some studies from Western countries. This difference may be attributed to several factors, including variations in patient populations, healthcare infrastructure, and access to post-operative care. In Indonesia, patients may present with more advanced disease due to delayed diagnosis or limited access to specialized care, potentially increasing the risk of complications. The five factors included in the INDO-TOS are well-established risk factors for post-operative complications following T/A. Younger age (<5 years) is associated with a smaller airway diameter, increasing the risk of respiratory compromise, and potentially greater difficulty with fluid management. Pre-existing comorbidities, such as asthma, cardiac disease, and craniofacial abnormalities, can significantly increase the risk of perioperative complications, including respiratory distress, bleeding, and infection. A history of recurrent acute tonsillitis (≥4 episodes/year) may indicate more severe inflammation and tissue friability, increasing the risk of bleeding. A high Mallampati score (III/IV) is a marker of difficult airway management and is associated with an increased risk of post-operative respiratory complications, particularly in patients with OSA. Prolonged operative time (>60 minutes) may reflect more complex surgery, increased tissue trauma, and greater blood loss, all of which can contribute to post-operative morbidity.[11-15]

Despite these limitations, the INDO-TOS represents a significant advancement in the prediction of post-operative complications following T/A in Indonesia. The scoring system is simple, easy to use, and relies on readily available clinical information. It can be easily implemented in diverse healthcare settings, including primary care clinics, district hospitals, and tertiary care centers. Clinicians can use the INDO-TOS to identify patients at high risk of post-operative complications who may benefit from more intensive pre-operative optimization, such as

improved management of comorbidities, referral to a tertiary care center, or closer post-operative monitoring. The INDO-TOS can be used to provide patients and families with a more personalized and accurate assessment of their individual risk of complications, facilitating informed decision-making and shared decision-making regarding the potential benefits and risks of surgery. Healthcare providers can use the INDO-TOS to allocate resources effectively, ensuring that adequate post-operative care and support are available for those at the highest risk. By identifying high-risk patients and implementing targeted interventions, the INDO-TOS has the potential to reduce post-operative morbidity, improve patient outcomes, and enhance the overall quality of care for children undergoing T/A in Indonesia. In borderline cases, the INDO-TOS might help guide the decision for or against surgery, especially when considering alternative management options such as watchful waiting or medical management.[16-20]

5. Conclusion

The INDO-TOS scoring system is a novel, validated tool for predicting post-operative complications in Indonesian children undergoing tonsillectomy and/or adenoidectomy. It utilizes readily available clinical information and can be easily implemented in various healthcare settings. The INDO-TOS can aid clinicians in identifying high-risk patients, optimizing pre-operative care, and potentially reducing post-operative morbidity. The INDO-TOS demonstrated good discrimination and calibration in both the derivation and validation cohorts. The scoring system effectively stratified patients into distinct risk groups with increasing complication rates. The INDO-TOS has the potential to improve the overall quality of care for children undergoing T/A in Indonesia. Further research is needed to evaluate the impact of the INDO-TOS on clinical decision-making, resource allocation, and patient outcomes. Future studies could also explore the potential of incorporating additional risk factors, such as genetic markers or imaging findings, to enhance the predictive accuracy of the INDO-TOS. The INDO-TOS represents a significant step towards personalized medicine in pediatric otorhinolaryngology in Indonesia.

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