Title: An Observational Study of the Risk Assessment of Severe Pneumonia for Prediction of Hypoxemia by Pulse Oximetry

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Abstract

Background: Cases of severe pneumonia in children carry a grave prognosis. Clinical presentations and hypoxemia have shown a significant association with mortality.

Objectives: To determine the risk association between pulse oximetry and clinical parameters.

Methods: The observational cross-sectional study was conducted from March 2018 to December 2019. The children aged two months to 5 years were consecutively selected who presented with a diagnosis of Severe Pneumonia or Very Severe Disease as per IMNCI guidelines. Hypoxemia was defined as oxygen saturation <90%. Univariate and multivariate logistic regression was used to find out the odds ratio of variables to predict hypoxemia. Sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) of signs and symptoms was calculated to predict hypoxemia.

Results: Of 400 children enrolled in the study, 159 (39,75%) children were hypoxemic. Cough, cyanosis, intercostal retractions, nasal flaring, grunting, and lethargy were found to be independent risk factors of hypoxemia with an adjusted odds ratio of 3.13, 213.562, 29.178, 57.762, 179.648 and 19.417, respectively. Predictors that carried a high sensitivity for predicting hypoxemia were breathing difficulty (99.37%), intercostal retractions (98.64%), subcostal retractions (98.76%), nasal flaring (99.37%), lethargy (96.86%) and crepitations (99.87%); and those that had high specificity were convulsion (98.53%), cyanosis (97.99%), suprasternal retractions (99.59%), grunting (97.78%) and head nodding (99.17%).

Conclusion: The study provides conclusive results of the risk association of clinical features in predicting hypoxemia in children with severe pneumonia. The easy use of pulse oximeter and significant association of clinical features with hypoxemia may be useful in the clinical practice for better categorisation, diagnosis, and management of children with severe pneumonia.

Keywords: Clinical features, Pulse oximetry, Severe Pneumonia, Hypoxemia, Risk association

What does this study add?

Pulse oximetry can be an easy technique to assess hypoxemia in children. The prediction of hypoxemia can be made independently by the clinical features with which the child presents to the emergency department.

Introduction

In a developing country as India, under five child mortality due to pneumonia holds a substantial proportion (15% deaths), making it a public health problem to deal with (1, 2). An identification of the predictors of respiratory insufficiency can be of great help in reducing child mortality with pneumonia (3-11).

At one end, WHO IMCI clinical guidelines are used to spot severe cases of pneumonia in children. On the other end, determination of hypoxemia has been added in the protocol. This was done because besides the severity of the clinical symptoms, hypoxemia [oxygen saturation (SpO2) <90%] has been identified as a significant predictor of mortality (3,12,13) Hypoxemia can be easily measured by Pulse oximetry in a gold standard manner; its availability remains of concern in varied settings (4). In view of this, many physicians use the Integrated Management of Neonatal and Childhood (IMNCI) clinical algorithms to address hypoxemia in children with severe pneumonia. Still, its accuracy and use have not been well established (5, 6).

In a developing country like India, where pulse oximetry is not available everywhere, it is prudent to know the association of clinical signs and symptoms with hypoxemia so that hypoxemia can be predicted even in the setups without pulse oximetry (7).

The present observational study attempted to determine the association of hypoxemia with various clinical danger signs as measured against gold standard pulse oximetry. The study results shall help to determine the odds risk and accuracy of the various clinical parameters to predict the occurrence of hypoxemia in children with severe pneumonia, which shall guide the administration of oxygen therapy well in advance to decrease the mortality and morbidity of under-five children.

Methods

The observational cross-sectional study was conducted from March 2018 to December 2019 in the department of Pediatrics, DDU Hospital, New Delhi. The children aged two months to 5 years were consecutively selected and subdivided into 2-12 m, 12-24 m and 2-5 y. Only the children with severe Pneumonia or Very Severe Disease as per IMNCI guidelines were included (8, 9). Children with congenital or acquired heart disease, shock, axillary temperature <36˚C and severe anaemia (haemoglobin <7g/dL) were excluded. The study was approved by the institutional ethical committee. Informed consent was obtained from the parents/guardian of the children who satisfied the eligibility criteria.

Definitions and criteria

Pneumonia is defined as a condition in a child with fast breathing (breathing rate per minute higher than normal for the age group). The child has rapid breathing as per the following criteria:

2 months up to 12 months 50 breaths per minute or more

12 months up to 5 years: 40 breaths per minute or more

Severe Pneumonia or Very Severe Disease is defined as the condition where the child has any danger signs such as stridor, fast breathing, chest wall indrawing, and difficulty breathing (laboured breathing).

Chest in-drawing: the lower chest wall (lower ribs) goes in when the child breathes in.

Stridor: a harsh noise that is made when the child breathes in.

Sample size

A total of 400 children were recruited in the study. The sample size calculation was based on the study of Alwadhi V et al. (10). The Fisher formula was used for sample size n =

(Where assuming p is the observed proportion=50.9, in Varun Alwadhi et al. study in UCMS and GTB Hospital in June 2017, $q = 1 - p$=49.1, d is the margin of error= 5, is the ordinate of standard normal distribution at α% level of significance= 1.96 so n=383, but here we took 400 cases because there is a chance of drop out during follow up).

Once the child was found eligible for the study, the demographic profile was collected (age, sex). The physical examination included a recording of vital signs (heart rate, temperature, respiratory rate, and blood pressure), assessment of chest indrawing, stridor, wheezing and other signs of respiratory distress (e.g. head nodding, nasal flaring, grunting, and cyanosis), and chest auscultation for crepitation/wheezing. The respiratory rate was counted for a full minute. For an irritable child, respiratory rate was counted for three minutes. Fast breathing/tachypnea was defined as per WHO cut-offs (11).

To measure SpO2, a digital pulse oximeter (Mediaid Inc. Model-M6ASTER, vital signs monitor) was used with an appropriate-sized probe on a finger or toe, in-room air. Hypoxemia was defined as SpO2 <90% in room air (8).

The outcome measures were the number of children having hypoxemia and clinical predictors of hypoxemia in severe pneumonia.

Statistical analysis

The data entry was done in the Microsoft EXCEL spreadsheet, and the final analysis was done using Statistical Package for Social Sciences (SPSS) software ver 21.0. The presentation of the Categorical variables was done in the form of numbers and percentages (%). On the other hand, the presentation of the continuous variables was done as mean ± SD and median values. P<0.05 was considered statistically significant. The following statistical tests were applied for the results:

1. The comparison of the variables, which were qualitative, were analysed using the Chi-Square test/Fisher's Exact test.

2. Univariate and multivariate logistic regression was used to determine the odds ratio of variables to predict hypoxemia.
3. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of signs and symptoms was calculated to predict hypoxemia.

Results

In our study, out of 400 children, 256 (64%) were males, and 144 (36%) were females. The children had a median age of 1y 2m. All the study children had severe pneumonia with varying symptoms of fast breathing, stridor, and chest indrawing. Table 1 shows the baseline demographic and clinical characteristics of the study population.

Pulse oximetry showed that 159 (39.75%) children were hypoxemic, and 60.25% were non-hypoxemic.(Figure 1)

Patients with a cough had significantly lower chances of hypoxemia with an odds ratio of 0.544 (0.36 to 0.823). Patients with refusal to feed, convulsion, cyanosis, intercoastal retractions, suprasternal retractions, nasal flaring, grunting, head nodding, lethargy had significantly higher chances of hypoxemia with an odds ratio of 4.569 (2.63 to 7.938), 17.195 (0.717 to 412.597), 163.694 (9.64 to 2779.511), 183.922 (11.137 to 3037.265), 132.848 (25.612 to 689.08), 77.64 (15.125 to 398.545), 1017.582 (61.433 to 16855.366), 83.475 (22.924 to 303.963) and 21.711 (8.903 to 52.948) respectively. Age, gender, fever, breathing difficulties, subcostal retractions and crepitations showed no significantly increased risk for hypoxemia ($p>0.05$). (Table 2)

On performing multivariate logistic regression, only cough, cyanosis, intercoastal retractions, nasal flaring, grunting and lethargy were independent risk factors of hypoxemia with an adjusted odds ratio of 3.13, 213.562, 29.178, 57.762, 179.648 and 19.417, respectively.(Table 3)

In our study; predictors that carried an sensitivity of more than 90% for predicting hypoxemia were breathing difficulty (99.37%), intercostals retractions (98.64%), subcostal retractions (98.76%), nasal flaring (99.37%), lethargy (96.86%) and crepitations (99.87%). The specificity of the clinical characteristics, which was more than 90% for predicting hypoxemia, were convulsion (98.53%), cyanosis (97.99%), suprasternal retractions (99.59%), grunting (97.78%) and head nodding (99.17%).(Table 4)

Discussion

In our study, certain clinical presentations (breathing difficulty, intercostals retractions, subcostal retractions, nasal flaring, lethargy and crepitations) carried a significant odds of hypoxemia which may be applied to developing countries as India (1,15).

In the present study, 159 (39.75%) children were hypoxemic. The values were comparable to the 33.5% hypoxemia (n=200) in the study by Kushwah MS et al. (16), (2018). Our analysis also had results similar to Basnet S et al. (17), (38.7%) and Ibraheem RM et al. (18), (41.5%).

However, this value was higher than one of the earlier studies by Lodha R (2004) (19) (25.6%) but less than a recent Delhi based study by Alwadhi V et al. (10), (2017), who reported hypoxemia in 50.9% of children with 112 cases of severe pneumonia. The difference may be the changed approach (syndromic management) of pneumonia cases based on IMNCI, different sample sizes, study design, study type, and age group included in the study.

Very few studies have explored the usefulness of pulse oximetry and its correlation with clinical features in children with severe pneumonia in a remote day-to-day paediatric OPD clinic. We observed that cough, cyanosis, intercoastal retractions, nasal flaring, grunting, and lethargy were independent risk factors of hypoxemia. Cyanosis and grunting showed the highest risk associated with hypoxemia, self-explanatory as the degree of hypoxemia relates to decreased SpO2 and cyanosis. This risk association has been explored in the previous study by Alwadhi V et al. (10), (2017). In their research, head nodding, age-specific tachypnea, and inability to drink/breastfeed were found to be significant independent risk factors for hypoxemia. The risk factors in our study and theirs were pretty different, suggesting that hypoxemia may occur in children depending upon the conglomerate of symptoms. Though the danger symptoms showed a risk of association with hypoxemia, they failed to reach statistical significance in our study.

The risk association of clinical features and hypoxemia as seen in our study can be interpreted in two ways (1) Hypoxemia can be predicted from the clinical features in the settings where pulse oximetry is not available, and the treatment can be instituted for better management (2) pulse oximetry alone may be used for a better classification of the cases of severe disease as it shows association with clinical features irrespective of the aetiology of the disease (2).

Based on the statistical analysis, the risk association of only a few danger signs like central cyanosis and lethargy showed good risk association and accuracy of predicting the hypoxemia, whereas head nodding, refusal to feed, unconsciousness, convulsions), or chest indrawing failed to show risk association.

As expected, the association of various danger signs of severe illnesses did not associate with SpO2. It suggests that individual features alone have a limited predictive value for hypoxemia. Similar to our study, as shown in other studies, a combination of clinical signs and pulse oximetry values could lead to better performance (1, 2, 10, 17). However, the results can be helpful in younger children where identification of severe illness becomes difficult, and the outcomes are dismal.

In our study, we determine the sensitivity, specificity, PPV and NPV of all factors for hypoxemia. It was found that sensitivity and NPV were high for breathing difficulty, intercostals retractions, subcostal retractions, nasal flaring, lethargy and crepitations. Since sensitivity measures “how often a test correctly generates a positive result for people who have the condition”, it suggests that these clinical features may be used as the first sign for screening of hypoxemia in the busy clinic OPD, which may help to start immediate oxygen therapy to the patients. Among other studies, sensitive predictors of hypoxemia have been reported to be Subcostal and intercostal recession (20), Inability to drink (10), fever, breathing difficulty and crept (16). The reason for these standard clinical features to show high sensitivity for hypoxemia may be ascribed to the fact that breathing difficulties and retractions may arise out of increased airway resistance and lung collapse leading to oxygen

desaturation and hypoxemia. Since these may be the earliest signs which cause the beginning of hypoxemia, they show high sensitivity for predicting hypoxemia.

The specificity and PPV were found to be high for convulsion, cyanosis, suprasternal retractions, grunting, and head nodding. Since specificity measures "a test's ability to correctly generate a negative result for people who don't have the condition", a high-specificity correctly helps in ruling out the child who doesn't have hypoxemia and won't generate many false-positive results. Concurrently, the specific clinical features were the ones that are considered to be the danger signs in the current IMNCI classification of the disease. Among the previous studies also, cyanosis, head nodding and grunting were present were specific predictors in Zhang L et al. (21), Agarwal et al. (22), Pramila Ramawat et al. (20), and Meenakshi S Kushwah et al. (16). Convulsions were specific predictors in Chisti MJ et al. (23).

Limitations and strengths of the study

One of the main strengths of this study is that it included children with only very severe disease /severe pneumonia. Since this category of children carries a dismal prognosis, knowledge of clinical presentations with higher odds of hypoxemia may help improve the outcome in the future. The study results may be clinically applicable in the local primary health care centres where such presentations are standard.

The study results must be interpreted because of certain limitations. First, we catered to lower and middle socioeconomic status children where there may be a primary delay in the diagnosis and treatment leading to severe disease. Thus it may not apply to all populations. Second, the children were not followed up for the outcome in terms of hospital stay and mortality. This is due to the cross-sectional design of the study rather than a prospective cohort. But still, we were able to achieve the objectives of the study. Lastly, the inter-intraobserver variability of the Pulse oximeter may affect the SpO2 values based on which the children were classified into hypoxemic and non-hypoxemic. The saturation levels taken at 90% are not standardised across the geographical regions and thus may affect the significant risk factors that predict hypoxemia.

Conclusion

The study provides conclusive results of the risk association of clinical features in predicting hypoxemia in children with severe pneumonia. The danger signs predominantly carry a high specificity, and the primary clinical signs have a high sensitivity for predicting hypoxemia. The easy use of pulse oximeter and significant association of clinical features with hypoxemia may be useful in the clinical practice for better categorisation, diagnosis and management of children with severe pneumonia.

Ethical clearance: Institutional ethics committee of DDU Hospital, New Delhi; No. F.2D(33)/DDDUH/DNB/2017/7513 dated 10 April 2018.

Contributors: SS, RK, RKJ: concept and design; SS, RK, RKJ, TKL: data collection, literature review; SS, CM, RK, RKJ: drafting of the manuscript, CM, RKJ: data analysis, statistics and data interpretation. SS, CM, RKJ, TKL: intellectual input, critical revision and

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Table 1:-Distribution of baseline demographic and clinical characteristic of study subjects.

Characteristic	Frequency	Percentage
Age		
2 months to < 1 year	200	50.00%
1 year to <2 year	74	18.50%
2 to 5 years	126	31.50%
Gender		
Female	144	36.00%
Male	256	64.00%
Fever	214	53.50%
Cough	174	43.50%
Refusal to feed	292	73.00%
Breathing difficulty/Rapid breathing	399	99.75%
Convulsion	5	1.25%
Cyanosis	40	10.00%
Intercoastal retractions	312	78.00%
Subcoastal retractions	398	99.50%
Suprasternal retractions	73	18.25%
Nasal flaring	297	74.25%
Grunting	108	27.00%
Head nodding	76	19.00%
Lethargy	290	72.50%
Crepitations	398	99.50%

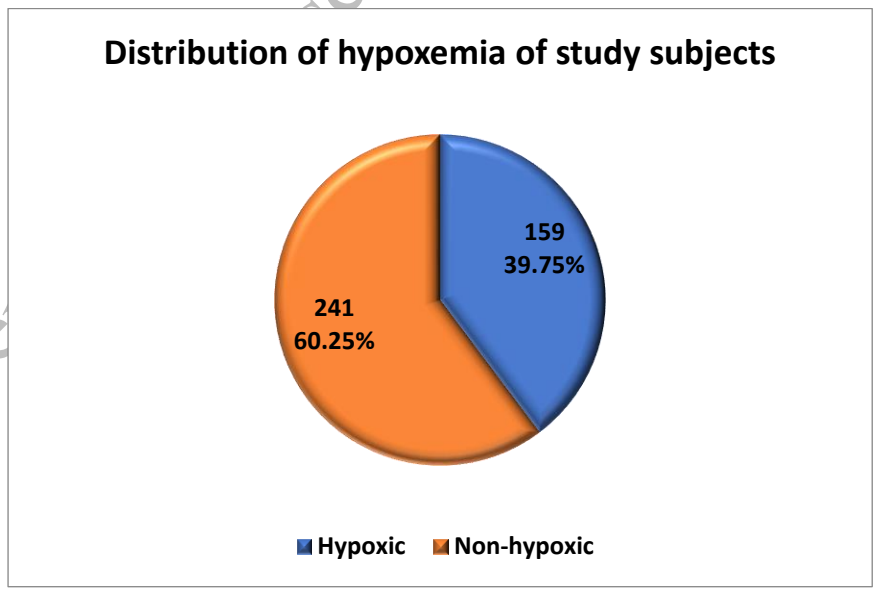

Figure 1:-Distribution of hypoxemia of study subjects.

Table 2:-Risk assessment of clinical characteristic for hypoxemia in severe pneumonia children

Characteristic	Hypoxemic (n=159)	Non-hypoxemic (n=241)	Total	P value	Odds ratio (95% C.I)
Age					
2 months to < 1 year	75 (47.17%)	125 (51.87%)	200 (50%)	0.447	1
1 year to <2 year	34 (21.38%)	40 (16.60%)	74 (18.50%)		1.416 (0.826 to 2.428)
2 to 5 years	50 (31.45%)	76 (31.54%)	126 (31.50%)		1.097 (0.695 to 1.734)
Gender					
Female	63 (39.62%)	81 (33.61%)	144 (36%)	0.22	1
Male	96 (60.38%)	160 (66.39%)	256 (64%)		0.772 (0.509 to 1.169)
Signs and symptoms					
Fever	94 (59.12%)	120 (49.79%)	214 (53.50%)	0.067	1.455 (0.971 to 2.18)
Cough	55 (34.59%)	119 (49.38%)	174 (43.50%)	0.004	0.544 (0.36 to 0.823)
Refusal to feed	141 (88.68%)	151 (62.66%)	292 (73%)	<.0001	4.569 (2.63 to 7.938)
Breathing difficulty/Rapid breathing	158 (99.37%)	241 (100%)	399 (99.75%)	0.398	0.219 (0.002 to 20.31)
Convulsion	5 (3.14%)	0 (0%)	5 (1.25%)	0.01	17.195 (0.717 to 412.597)
Cyanosis	40 (25.16%)	0 (0%)	40 (10%)	<.0001	163.694 (9.64 to 2779.511)
Intercoastal retractions	159 (100%)	153 (63.49%)	312 (78%)	<.0001	183.922 (11.137 to 3037.265)
Subcoastal retractions	159 (100%)	239 (99.17%)	398 (99.50%)	0.52	3.334 (0.08 to 138.327)
Suprasternal retractions	72 (45.28%)	1 (0.41%)	73 (18.25%)	<.0001	132.848 (25.612 to 689.08)
Nasal flaring	158 (99.37%)	139 (57.68%)	297 (74.25%)	<.0001	77.64 (15.125 to 398.545)
Grunting	108 (67.92%)	0 (0%)	108 (27%)	<.0001	1017.582 (61.433 to 16855.366)
Head nodding	74 (46.54%)	2 (0.83%)	76 (19%)	<.0001	83.475 (22.924 to 303.963)
Lethargy	154	136	290	<.0001	21.711 (8.903 to

	(96.86%)	(56.43%)	(72.50%)		52.948)	
Crepitations	159 (100%)	239 (99.17%)	398 (99.50%)	0.52	3.334 (0.08 to 138.327)	

Table 3:-Multivariate logistic regression to find out significant risk factors of hypoxemia.

Variable	Beta coefficient	Standard error	P value	Odds ratio	Odds ratio Lower bound (95%)	Odds ratio Upper bound (95%)
Cough	1.141	0.539	0.034	3.130	1.087	9.010
Refusal to feed	1.057	0.704	0.133	2.879	0.725	11.433
Convulsion	-3.210	2.013	0.111	0.040	0.001	2.085
Cyanosis	5.364	1.512	0.0004	213.562	11.031	4134.713
Intercoastal retractions	3.373	1.386	0.015	29.178	1.929	441.346
Suprasternal retractions	2.340	2.086	0.262	10.379	0.174	619.233
Nasal flaring	4.056	1.377	0.003	57.762	3.883	859.283
Grunting	5.191	1.592	0.001	179.648	7.935	4067.016
Head nodding	-2.076	2.214	0.349	0.125	0.002	9.623
Lethargy	2.966	0.832	0.0004	19.417	3.800	99.230

Table 4:- Sensitivity, specificity, PPV and NPV of different signs and symptoms for predicting hypoxemia.

	Sensitivity	Specificity	PPV	NPV
Fever	59.12	50.21	43.93	65.05
Cough	34.59	50.62	31.61	53.98
Refusal to feed	88.68	37.34	48.29	83.33
Breathing difficulty	99.37	0.56	39.6	0.66
Convulsion	3.14	98.53	98.66	61.01
Cyanosis	25.15	97.99	98.79	66.94
Intercostal retraction	98.64	36.51	50.96	99.65
Subcostal retraction	98.76	0.83	39.95	98.66
Suprasternal retraction	45.28	99.59	98.63	73.39
Nasal Flaring	99.37	42.32	53.2	99.03
Grunting	67.92	97.78	98.88	82.53
Head Nodding	46.54	99.17	97.37	73.77
Lethargy	96.86	43.57	53.1	95.45
Crepitation	99.87	0.83	39.95	97.78

PPV: Positive predictive value
NPV: Negative predictive value