A PROSPECTIVE OBSERVATIONAL STUDY TO COMPARE THE PULSE OXIMETRIC SATURATION (Spo2) /FRACTION OF INSPIRED OXYGEN (Fio2) (SF RATIO) AND PARTIAL PRESSUREOF OXYGEN (Pao2) / Fio2 (PF RATIO) AMONG CRITICALLY ILL CHILDREN REQUIRING RESPIRATORY SUPPORT IN A PAEDIATRIC INTENSIVE CARE UNIT

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ABSTRACT

Introduction: Acute respiratory illness is an important cause of morbidity and mortality in children. Bronchiolitis, Pneumonia and Acute respiratory distress syndrome are some of the important disorders for which children require respiratory support. 30 to 64% of all children admitted in paediatric intensive care unit require ventilator support.

Aims: To do a prospective observational study, comparing the relationship between Pao2/Fio2 (PF) ratio and Spo2 /Fio2 (SF) ratio in critically ill children requiring respiratory support in a Paediatric ICU of a tertiary care center in North India.

Materials and Methods: The critically ill children who required respiratory support in the form of mechanical ventilation , attending to our pediatric ICU in last 6 months are taken in our study. Total 125 patients included in this study.

Result: In our study, we also compared SF ratio and oxygenation index more than four and found a good correlation with an AUC of 0.739.The recent PARDS guidelines have given Oxygen saturation Index (OSI) cut off more than 5 to diagnose ARDS. When we compared oxygenation index more than 4 with oxygen saturation index, we found a good AUC of 0.897 in the ROC with 91% sensitivity and 73% specificity to diagnose ARDS. Thus, we validated this guideline in our study.

Conclusion: Our study shows that SF ratio can be used as a reliable, non-invasive, surrogate marker for PF ratio to diagnose ARDS and also as a screening tool to assess the severity of respiratory illness in resource limited settings where arterial blood gas is not available

Keywords: ARDS, Oxygen saturation Index, arterial blood gas and Spo2.

INTRODUCTION

Respiratory illness in children is the most common reason for which they seek medical care[1]. Respiratory diseases are more commonly seen in children than in adults. There are multitudes of reasons which make the children prone for respiratory illness. Immaturity of the immune system, anatomical variations in the respiratory tract, increased basal metabolic rate, primitive mechanisms to cope with acute physiological stressors and increased susceptibility for infections make the children susceptible for respiratory illness over the adults[2, 3].

Acute respiratory illness is an important cause of morbidity and mortality in children. Bronchiolitis, Pneumonia and Acute respiratory distress syndrome are some of the important disorders for which children require respiratory support. 30 to 64% of all children admitted in paediatric intensive care unit require ventilator support [4]. The respiratory support required for children may vary from non-invasive supports like facemask oxygen, high flow nasal canula therapy to invasive form of ventilation like invasive mechanical ventilation or high frequency oscillatory ventilation.

There are various parameters used in monitoring of children who are critically ill. Few of these parameters includes pulse oximeter saturation, Arterial blood gas, arterial blood pressure monitoring etc. Partial pressure of oxygen (PaO2) / Fraction (FiO2) of inspired oxygen, (PF ratio) a derived parameter from Arterial blood gas is used to diagnose and monitor the course of acute respiratory distress syndrome.

Children who are admitted in paediatric intensive care units are usually monitored round the clock using multi-channel monitors which includes pulse Oximetry. Oxygenation status plays a major role in the management of ARDS. Since the original description of ARDS in early 60's PF ratio has been used as a marker for the oxygenation status, which also has been changed in the recent PARDS consensus guidelines. While considering the oxygenation status, focus has now shifted from PF ratio to oxygenation index, as studies have proven that oxygenation index is good in predicting the mortality and outcome in ARDS [5], however the oxygenation index also will require PaO2 for its calculation. It is very cumbersome to perform the arterial blood gas in children as it requires multiple pokes, unless the child has an arterial line. Any reliable non-invasive method would be an ideal technique to monitor the progression or worsening of the lung disease. The need for an invasive procedure to determine PaO2 has led to an intensive search for an alternative method to monitor children with ARDS.

SF ratio appears as a response to the search of an appropriate alternative for monitoring children with ARDS. Pulse Oximetric Saturation (Spo2) / Fraction of inspired oxygen (Fio2) ratio (SF ratio) can be calculated easily, as we know both the variables. Various studies from abroad have shown a good correlation between the PF ratio and SF ratio. An American study done in children to compare the SF and PF ratio showed a good correlation between SF ratio and PF ratio. Similar observation was seen in the study done Iranian children [6]. Although results from the above studies have shown that SF ratio can be used as a surrogate marker for PF ratio, the results varied in different centers. However data from Indian children are not available in this regard. Hence we have planned to do this study to compare and analyze the relationship between PaO2/FiO2 (PF) ratio and SpO2 /FiO2(SF) ratio in critically ill children requiring respiratory support (Invasive, Non-invasive ventilation & high flow oxygen device) in our PICU.

AIM-To do a prospective observational study, comparing the relationship between Pao2/Fio2 (PF) ratio and Spo2 /Fio2 (SF) ratio in critically ill children requiring respiratory support in a Paediatric ICU of a tertiary care centre in South India.

MATERIALS AND METHODS

- The critically ill children who required respiratory support in the form of mechanical ventilation , attending to our pediatric ICU in last 6 months are taken in our study. Total 125 patients included in this study
- **Study area:** Burdwan Medical College and Hospital

Study Duration: 6 months

Sample Size: 125

INCLUSION CRITERIA

1) All children who needs oxygen supplementation and requiring respiratory support – either invasive, non-invasive mechanical ventilation or high flow nasal canula therapy

2) Children with ARDS (Diagnosed based on PARDS criteria) requiring invasive mechanical ventilation /non-invasive ventilation

EXCLUSION CRITERIA

1) Children with suspected or probable Congenital heart disease or any anatomic anomalies of lung,

2) Children with Chronic Lung disease,

3) Children diagnosed to have conditions like Methaemoglobinemia,

4) Children (parents) who decline to give consent to participate in the study.

RESULT AND DISCUSSION

Respiratory diseases constitute a significant amount of morbidity and mortality in children. As various studies have mentioned, they are the number one cause for under five deaths globally. Hence it is of paramount importance to diagnose and treat these respiratory diseases early.

In the PICU setup, ARDS is one of the important contributors of morbidity and mortality. Partial pressure of Oxygen obtained from arterial blood gas is considered to be the gold standard in determining arterial oxygenation status. In critically ill children and young infants obtaining arterial blood gas may be difficult and also increases risk of hospital acquired infection. Moreover, in primary and secondary hospital setting facility for doing arterial blood gas is rarely available. In these setting, SF ratio could be used as a screening tool to assess the severity of respiratory illness and regulates appropriate management and timely referral. Hence, to determine ARDS, SF ratio is being tried as a surrogate marker to PF ratio.

In our study, male children contributed to 66.4% and the remaining 33.6% were female children. The mean age group of our study population was 4 years, 8 months. We had twenty seven patients with ARDS at our study cohort showing equal distribution in all the age groups. Likewise, in other intensive care units, mortality in children with ARDS is significant (33%).

The spectrum of diagnoses in our children had a varying range involving all the systems. Children with CNS diseases formed the majority among the admission to our PICU contrary to the Egyptian study done by Hanna et al looking at the profile of PICU patients which showed Pneumonia as the commonest cause. Another large study done at Royal Children's Hospital (RCH), Melbourne looking at the profile of children found congenital cardiac disease as the commonest cause for the PICU admission followed by respiratory disease. This variation could be attributed to multiple factors including the geographical distribution, prevalence of epidemics and available healthcare system.

Paediatric Index of Mortality was originally developed by RCH for the prognostication of children getting admitted to pediatric intensive care units. PIM 2 score was introduced in 2003, which was used in our study [7]. The maximum number of mortality was seen in children who had higher PIM 2 score, which is more than thirty in our study. The mean PIM 2 score at our study group was 27.38. However the same was not statistically significant as the p value was just above the acceptable range (p value - 0.06). The probable reason for the statistical insignificance in our study population may be due to the increased number of deaths in the children belonging to PIM 2 score of 5 to 15. This increase in number of deaths among children with lower score range may be further explained by hospital acquired infection.

In our study, we have shown that, SF ratio of less than 180 corresponds well with PF ratio criteria used for ARDS. This value of 180 is derived from the linear regression equation. With the SF ratio value being less than 180, the sensitivity and specificity to discriminate ARDS in children is 70% and 65% respectively. The positive predictive value and the negative predictive was 80.9% and 57.3%.

Thomas et al in their study among children where they found an SF ratio cutoff value of 212, which could predict the ARDS in children with a sensitivity of 76% and specificity of 83% [8]. The same study also found that SF ratio cutoff less than 253 could predict acute lung injury with 93% sensitivity and 43% specificity.

A prospective study done by Rice et al, in adults identified higher values of SF ratios to correlate with the PF ratio criteria used for ALI and ARDS. They found a cutoff less than 235 and 315 for ARDS and ALI respectively, with 85% sensitivity and 85% specificity for ARDS with AUC of 0.929 and 91% sensitivity and 56% specificity for diagnosing ALI with AUC of 0.920. Practically, this means patients saturating 95% with Fio2 of 30% will be considered as acute lung injury and those saturating 94% with 40% Fio2 will be considered as ARDS.

The recent PARDS guidelines also had kept a higher cut off of 264 to diagnose ARDS in places where arterial blood gas is not available. In practical situations, a child who is on a respiratory support with FiO2 of 36% when saturating 94% will be considered as ARDS.

As per our study cut off value for SF ratio of 180, children will fall in the category of ARDS only when they require FiO2 of 50% with 90% saturation or at a saturation of 94%, when the FiO2 requirement goes up beyond 52%.

We did look at other cut off values for SF ratio considering the sensitivity, specificity and relevancy of clinical situation. For example, if you consider the SF ratio cut off at<220, any saturation of 88% or less with Fio2 of 40% or more will be characterized as ARDS. For the same child we increase the Fio2 to 45% and if the Spo2 improves to 99%, still we classify the patient to have ARDS as the SF ratio being less than 220. But at bed side, practically we tend to titrate the Fio2, till the Spo2 improves more than 90 to 94%. In that case, we may be increasing Fio2 from 40 to 50% gradually. If at thisFio2 of 50% (i.e., Face mask oxygen 8 to 10 lit/min), the patient saturates only 90% or less (i.e., SF ratio<180), then the patient is more likely to have ARDS. Hence, we consider that SF ratio with a cut off <180 is more relevant and practical to diagnose Paediatric ARDS in our clinical setting.

As per PALICC group consensus recommendation, children who receive fio2 of ≥ 40% (i.e. if they are on a low flow o2 device <1 year ; 2 l/min., 1 – 5 years old : 4 l/m, 5 – 10 years : 6 l/m, >10 years : 8 l/m of oxygen) to attain a Spo2 between 88 to 97% (SF ratio 220 to 242) is categorized as at risk of developing Paediatric ARDS [9].

Although we made an attempt to correlate PF ratio less than 200 with SF ratio, which found to be correlating well with 90% sensitivity and 59% specificity along with good AUC of 0.8, the recent PARDS guidelines have not mentioned anything in particular to PF ratio less than 200. The term acute lung injury is not being used anymore and the current PALICC guidelines clearly mention PARDS as PF ratio less than 300 (non-invasive ventilation) or Oxygenation index more than 4 for children with invasive ventilation.

In our study, we also compared SF ratio and oxygenation index more than four and found a good correlation with an AUC of 0.739.The recent PARDS guidelines have given Oxygen saturation Index (OSI) cut off more than 5 to diagnose ARDS. When we compared oxygenation index more than 4 with oxygen saturation index, we found a good AUC of 0.897 in the ROC with 91% sensitivity and 73% specificity to diagnose ARDS. Thus, we validated this guideline in our study.

In general, previous studies done to correlate SF and PF ratio shows varying cut off values for SF ratio in each study. But, there exists a strong correlation between the two ratio's, which is the common baseline message available from all the studies. As per the objectives of our study, we have brought out an SF ratio cut off of 180 for our children to diagnose ARDS clinically in our context. This can be applied to the places where arterial blood gases are not available and this can also be used in PICU to monitor the course and progress of ARDS.

The usage of SF ratio instead of PF ratio has added following benefits in our clinical setting [10]:

- S/F ratio using Pulse oximetric measurement of saturation, helps in easier assessment of oxygenation status and helps in early identification of children at risk of ARDS
- Placement of arterial lines in critically ill children and young infants is difficult and they are not used routinely. Hence, having a non-invasive tool (SF) as a surrogate marker for PF ratio will help for screening purposes
- In ICU settings, PF ratios are used in calculating few scores like Paediatric risk of mortality score, Paediatric index of mortality 2, Paediatric logistic Organ dysfunction (PELOD score) thereby helps in risk assessment and characterization of the disease. In situations where, ABG is not done and PF ratios are not available, a normal value is substituted. Hence in these conditions, SF ratio can be used to get a proper overall risk assessment instead of using the scores without proper arterial blood gas values
- Association between SF and PF ratio is stronger in paediatric population.

However, it is said that arterial oxygen saturation (Sao2) marks the severity of pulmonary disease than PF ratio. So, based on this, Spo2 being an accepted substitute for arterial oxygen saturation, SF ratio is used reliably than PF ratio in appropriate clinical settings.

- SF ratio can be reliably used in secondary level settings as a noninvasive screening tool to assess the severity of respiratory illness where ABG facility is not available.

CONCLUSION

- Our study shows that SF ratio can be used as a reliable, non-invasive, surrogate marker for PF ratio to diagnose ARDS and also as a screening tool to assess the severity of respiratory illness in resource limited settings where arterial blood gas is not available.

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TABLE: CLINICAL DIAGNOSES IN OUR STUDY POPULATION

Clinical diagnosis	Frequency	Percentage
CNS diseases	27	21.6%
Sepsis	15	12%
Pneumonia	11	8.8%
Post op laparotomy	10	8%
AGE with severe dehydration	5	4%
Others (Miscellaneous)	57	45.6%

TABLE: SENSITIVITY/SPECIFICITY/PPV/NPV FOR PF <200 VS SF RATIO.

PF Ratio	SF ratio	Sensitivity	Specificity	PPV	NPV	ROC
<200	<166	83%	60%	58.3%	84.8%	**0.8078**
	<180	**90%**	**59%**	**63.1%**	**84.3%**	
	<194	91%	57%	44.8%	94.8%	
	<196	91%	57%	44.3%	94.7%	
	<200	93%	56%	62.2%	86.6%	

TABLE: BASELINE FINDINGS IN OUR STUDY POPULATION.

Variables	**Mean+/-SD, (Median)**	**Min-Maximum**
Mean airway Pressure	11.61+/-6.74 mmHg	4-68 mmHg
Oxygenation index	7.67, (4.65)	0.6-73
Oxygen saturation index	9.68, (5.55)	1-160
SF ratio	180+/-60.41	25-400
PF ratio	248+/-156	24-808
Fio2	54.21+/-45.25%	25-100%