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Is Prone Positioning Worth the Turn in Pediatrics? Unraveling the Oxygenation Mystery in Ventilated Patients with Acute Respiratory Distress Syndrome: An Observational Study Introducing a Novel SF Ratio Method for Non-Invasive Monitoring in Children

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: Respiratory illnesses are prevalent among children, attributed to factors such as immature immune systems, anatomical variations, and increased susceptibility to infections. Acute respiratory distress syndrome (ARDS) is a significant cause of morbidity and mortality, necessitating various forms of respiratory support in pediatric intensive care units (PICUs). Prone positioning has emerged as a strategy to improve oxygenation in ARDS, but its effectiveness and correlation with non-invasive monitoring parameters remain underexplored.

Subjects and Methods: This prospective observational study, conducted in the PICU of Dr. B.C Roy PGIPS, Kolkata, aimed to assess the impact of prone ventilation on oxygenation in children diagnosed with ARDS. The study, spanning 18 months, included 40 patients aged 3 months to 12 years requiring mechanical ventilation. Parameters such as oxygenation index (OI), oxygen saturation index (OSI), PF ratio, and SF ratio were monitored at different time points during supine and prone ventilation. Prone positioning's effectiveness was evaluated based on improvements in these parameters.

Results: The study revealed a significant improvement in oxygenation status after four hours of prone ventilation compared to supine ventilation. Oxygenation index, OSI, SF ratio, and PF ratio showed statistically significant changes favoring prone positioning. A strong positive correlation between SF ratio and PF ratio was observed at various time points, emphasizing the potential of SF ratio as a non-invasive alternative. Responders and non-responders to prone positioning were identified based on predefined criteria, highlighting individual variability in treatment response.

Conclusion: Prone ventilation demonstrated significant improvements in oxygenation parameters in children with ARDS. The study supports the use of non-invasive SF ratio as a reliable substitute for PF ratio, simplifying monitoring without invasive arterial sampling. This finding has implications for improving ARDS management strategies in pediatric patients, offering a less cumbersome alternative for assessing oxygenation status.

Keywords: Pediatric ARDS; prone ventilation; oxygenation index; SF ratio; Non-invasive monitoring; PICU.

1. INTRODUCTION

Respiratory illnesses are pervasive among children, constituting the most common reason for seeking medical care [1]. Unlike adults, children exhibit a heightened susceptibility to respiratory diseases due to factors such as an immature immune system, anatomical variations in the respiratory tract, an increased basal metabolic rate, and primitive coping mechanisms for acute physiological stressors [2,3]. The prevalence of acute respiratory illnesses, including bronchiolitis, pneumonia, and Acute Respiratory Distress Syndrome (ARDS), underscores the significance of understanding and effectively managing these conditions in pediatric healthcare. Notably, a substantial proportion of children admitted to pediatric intensive care units require ventilator support, ranging from non-invasive measures like facemask oxygen to more invasive interventions such as mechanical ventilation or high-frequency oscillatory ventilation [4].

Acute Respiratory Distress Syndrome (ARDS), initially described in adults, is now increasingly acknowledged in children [5]. The dynamic nature of this syndrome demands constant evolution in management strategies, with the prone position emerging as a pivotal intervention [6]. Prone positioning, as a ventilator strategy, offers multifaceted benefits, enhancing oxygenation through mechanisms such as the reduction of pleural pressure, atelectasis mitigation, and improved ventilation/perfusion matching [7]. Despite its advantages, the conventional monitoring of pediatric ARDS involves invasive procedures like arterial blood gas sampling, presenting challenges, especially in children. Recognizing the need for non-invasive alternatives, this study introduces the concept of the SF ratio (Spo2/Fio2) as a potential surrogate marker for PF ratio, aiming to assess its efficacy in monitoring oxygenation status during prone and supine ventilation in children with ARDS.

2. MATERIALS AND METHODS

2.1 Study Design

This is a prospective analytical observational study.

2.2 Study Setting

The study was done in the Paediatric intensive care unit of Dr.B.C Roy PGIPS, a tertiary care centre in Kolkata. PICU receives patients from Paediatric Emergency, Paediatric wards and also from operation theatres for post-operative care.

2.3 Study Population

All consecutive patients admitted to PICU in age group between 3mo to 12yrs who were diagnosed as ARDS (according to PARDS criteria) requiring mechanical ventilation.

2.4 Inclusion Criteria

All children in the age group of 3months to 12yr admitted in PICU of Dr.B.C Roy PGIPS with diagnosis of ARDS and requiring mechanical ventilator support.

2.5 Exclusion Criteria

- Children with suspected or probable congenital heart disease or any anatomic anomalies of lung or chest wall deformities
- Children with chronic lung disease
- Children diagnosed to have condition like raised intracranial pressure,shock,unstable fractures,open wounds
- Children(parents)who decline to give the consent to participate in the study.

2.6 Study Period

The study has been done for a time period of 18months starting from 1st February 2021 to 31st July 2022.

2.7 Sample Size

According to our previous hospital records for past 3 years in Dr.B.C. Roy PGIPS,Kolkata. The mean number of children admitted to paediatric intensive care unit as diagnosis of ARDS and requiring mechanical ventilation were forty per year, so we are expecting the sample size of about forty during the study period.

2.8 Study Tools

1. Pre designed Data Sheet
2. Ventilator: Draeger Savina 300
3. Arterial Blood Gas Analyzer Machine: OPTI Medical ,Model:OPTI CCA-TS
4. Multichannel monitor:Philips,IntelliVue MP30
5. Portable X ray Machine:Allengers-HF,Mars-30
6. Automated Blood Analyzer: Sysmex Xn 350

2.9 Data Collection

Children admitted in PICU and those who fulfill the inclusion and exclusion criteria were recruited after obtaining the consent to take part in the study.

At the time of admission, an initial ABG was done then, their oxygenation status were recorded at following events-

- Half an hour after Supine Ventilation,
- 4hr after Supine Ventilation.

Patients who could not maintain oxygenation in supine ventilation were placed in prone position and a second ABG was done, and oxygenation parameters were recorded-

- Half an hour after Prone Ventilation,
- 4hr after prone Ventilation.

Change in patient positioning was discontinued temporarily or permanently when patient presented with hemodynamic instability , pneumothorax, worsening of oxygenation with vital compromise after the postural change or improvement in ARDS that permits weaning. The PF ratio and SF ratio were calculated using the documented variable – SpO_2, FiO_2, PaO_2 .Data collected were recorded in Data Sheet.

2.10 Statistical Analysis

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and Graph Pad Prism version 5. The statistical analysis employed in this study involved the use of paired samples t-tests to assess the significance of differences between various parameters. Paired differences were calculated for each condition comparison, such as OI 1/2s vs. OI 1/2p, OSI 4s vs. OSI 4p, and so forth. The paired samples t-test is a robust statistical method for comparing means of two related groups, providing insights into whether the observed differences are statistically significant. The mean differences, standard deviations of differences, standard errors of the mean differences, and 95% confidence intervals were calculated for each pair. The t-values, degrees of freedom, and p-values were also determined to evaluate the statistical significance of the observed differences. A critical alpha level of 0.05 was considered to determine significance, with p-values less than 0.05 indicating statistically significant differences between paired conditions. This rigorous statistical approach enhances the robustness and reliability of the findings, enabling a comprehensive understanding of the variations observed in the studied parameters. The correlation analysis employed Pearson's correlation coefficient (r) to explore the relationship between two distinct variables. A significant positive correlation was considered between the variables if $p < 0.05$, two-tailed.

3. RESULTS

- Our study had total of forty children recruited during the entire study period of eighteen months. Arterial blood gases from each patient were taken for our study in supine and prone ventilation to compare the status of oxygenation in each position. The baseline characteristics of our study population are as follows.
- The median age of our study group was 4 years. The minimum age of our study participant was four month and the maximum age was eleven years. We analyzed them under three sub groups according to their age namely less than one year, one to five years and six to twelve years. Proportion of children in age group between one to five years was higher as compared to other groups.
- Among the forty children recruited, 28 children were male (70%) and twelve children were females (30%).
- We observed that in this study status of oxygenation was higher in the prone position as compared to the supine position with significant change after four hours of prone ventilation [OI(mean± s.d.) 15.146± 6.732vs 10.653± 4.527:p<0.0001, OSI(mean± s.d.) 12.051± 2.788 vs 10.564± 2.214:p<0.0001, SF ratio(mean± s.d.) 127.616± 37.604 vs 140.888± 29.040:p=0.012, PF ratio(mean± s.d.) 121.935± 72.695 vs 157.661± 62.189:p<0.0001]. (Tables 1,2) A responder was defined as having an improvement of more than 10% in the oxygenation index after four hours in prone position or when the mean increase in PF ratio in prone position was greater than 15%..
- In our study we could not find any statistically significant change in oxygenation status half hour after supine vs prone ventilation. (Tables 1,2).

Table 1. Distribution of mean OI 1/2s, OI 1/2p, OI 4s, OI 4p, OSI 1/2s, OSI 1/2p, OSI 4s, OSI 4p, SFR 1/2s, SFR 1/2p, SFR 4s, SFR 4p, PFR 1/2s, PFR 1/2p, PFR 4s, PFR 4p parameters

Paired Samples Statistics					
		Mean	**N**	**Std. Deviation**	**Std. Error Mean**
Pair 1	OI 1/2s	13.463	40	4.822	.762
	OI 1/2p	14.233	40	4.376	.691
Pair 2	OI 4s	15.146	40	6.732	1.064
	OI 4p	10.653	40	4.527	.7158
Pair 3	OSI 1/2s	11.368	40	3.094	.489
	OSI 1/2p	11.487	40	2.031	.321
Pair 4	OSI 4s	12.051	40	2.788	.440
	OSI 4p	10.564	40	2.214	.350
Pair 5	SFR 1/2s	139.05	40	48.803	7.716
	SFR 1/2p	128.201	40	22.331	3.530
Pair 6	SFR 4s	127.616	40	37.604	5.945
	SFR 4p	140.888	40	29.040	4.591
Pair 7	PFR 1/2s	123.421	40	51.287	8.109
	PFR 1/2p	111.082	40	37.675	5.957
Pair 8	PFR 4s	121.935	40	72.695	11.494
	PFR 4p	157.661	40	62.189	9.833

OI-Oxygenation Index, OSI -Oxygenation Saturation Index, SF Ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2); PF ratio-Partial pressure of oxygen (PaO2) / Fraction (FiO2)of inspired oxygen
½-half an hour, 4-four hour,S-in supine position, P- in prone position

Table 2. Paired samples test

		Paired Differences					t	df	p-value
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	**OI 1/2s- OI 1/2p**	-.836	3.526	.557	-1.963	.291	-1.499	39	.142
Pair 2	**OI 4s – OI 4p**	4.492	4.464	.705	3.064	5.920	6.364	39	<.0001
Pair 3	**OSI 1/2s – OSI 1/2p**	-.118	2.501	.395	-.918	.681	-.300	39	.766
Pair 4	**OSI 4s – OSI 4p**	1.487	2.127	.336	.807	2.167	4.422	39	<.0001
Pair 5	**SFR 1/2s – SFR 1/2p**	10.849	40.588	6.417	-2.131	23.830	1.691	39	.099
Pair 6	**SFR 4s – SFR 4p**	-13.271	31.761	5.021	-23.429	-3.113	-2.643	39	.012
Pair 7	**PFR 1/2s – PFR 1/2p**	12.338	35.699	5.645	.921	23.755	2.186	39	.035
Pair 8	**PFR 4s – PFR 4p**	-35.725	51.805	8.191	-52.294	-19.157	-4.362	39	<.0001

OI-Oxygenation Index, OSI -Oxygenation Saturation Index, SF ratio-Pulse Oximetric, Saturation (Spo2) / Fraction of inspired oxygen (Fio2); PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2) of inspired oxygen ½-half an hour, 4-four hour, S-in supine position, P- in prone position

Table 3. Correlation between SF ratio and PF ratio at admission (SFR a & PFR a)

Correlations			
		SFR a	**PFR a**
SFR a	Pearson Correlation Coefficient (r)	1.000	.698**
	Sig. (2-tailed)	.	.000
	N	40	40
PFR a	Pearson Correlation Coefficient (r)	.698**	1.000
	Sig. (2-tailed)	.000	.
	N	40	40

***. Correlation is significant at the 0.01 level (2-tailed).*
SF ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2) ,PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2)of inspired oxygen ,a-at admission

- We found that the mean OI ½ hr after supine was (13.463± 4.822) and OI 1/2 hr after prone ventilation was (14.233± 4.376). The mean difference of OI 1/2s vs OI 1/2p was -.836 with 95% confidence interval [-1.963 to .291]. The difference of mean OI 1/2s vs OI 1/2p was not statistically significant (p=.142).
- The mean OSI ½ hr after supine was (11.368± 3.094) and OSI 1/2 hr after prone ventilation was (11.487± 2.031). The mean difference of OSI 1/2s vs OSI 1/2p was -.118 with 95% confidence interval [-.918 to .681]. The difference of mean OSI 1/2s vs OSI 1/2p was not statistically significant (p=.766).
- The mean SF ratio 1/2 hr after supine was (139.05± 48.803) and SF ratio 1/2 hr after prone ventilation was (128.201± 22.331). The mean difference of SFR 1/2s vs SFR 1/2p was 10.849 with 95% confidence interval [-2.131 to 23.830]. The difference of mean SFR 1/2s vs SFR 1/2p was not statistically significant (p=.099).

We observed that in our study there is a strong positive correlation between SF ratio and PF ratio, on admission (Fig 1, Table 3) (r=0.698, SF ratio=52.7+1.06xPF ratio, p<0.0001), half hour of supine ventilation (r=0.723 SF ratio=37.52+0.82xPF ratio, p<0.0001) (Fig 2, Table 4),four hour after supine ventilation (r=0.744 SF ratio=81.85+0.38xPF ratio, p<0.0001) (Fig 3, Table 5),half hour of prone ventilation (r=0.807 SF ratio=79.3+0.44xPF ratio ,p<0.0001) (Fig 4, Table 6), four hour after prone ventilation (r=0.778 SF ratio=92.98+0.3xPF ratio, p<0.0001) (Fig 5,Table 7).

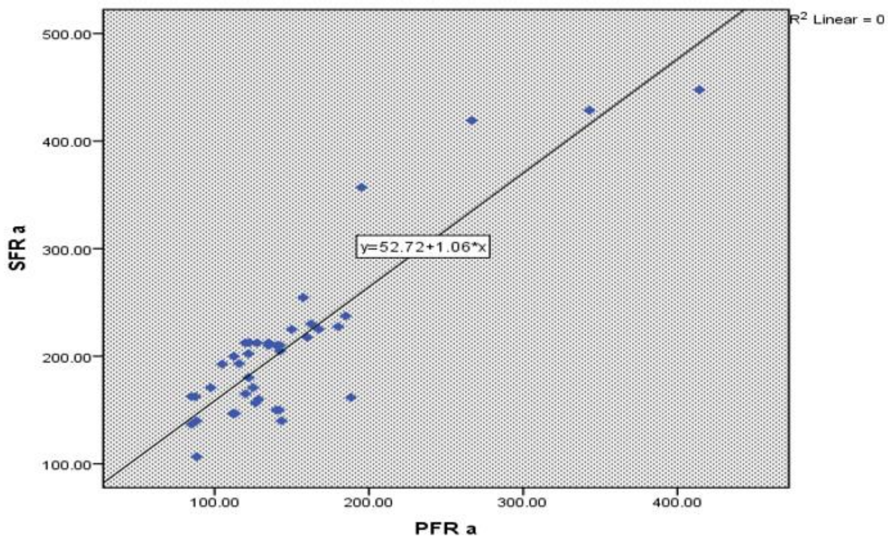

Fig. 1. correlation between SF ratio and PF ratio at admission (SFR a & PFR a)
SF ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2); PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2)of inspired oxygen ,a-at admission

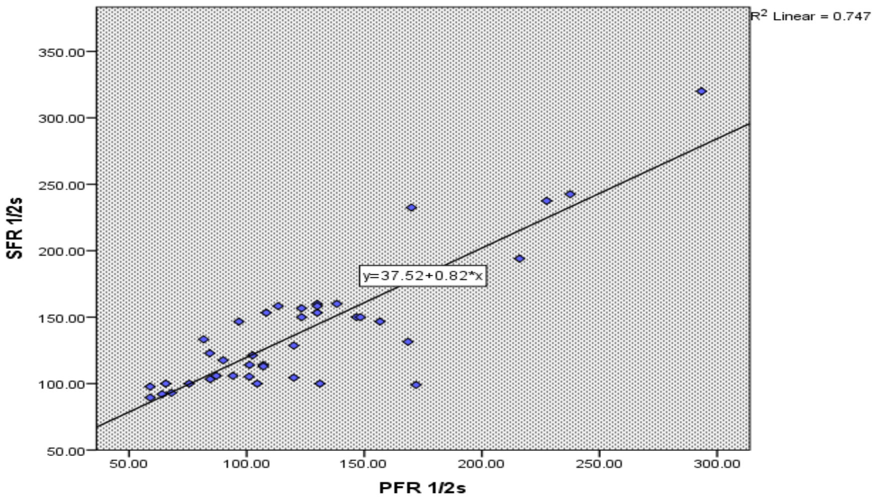

Fig. 2. Correlation between SF and PF ratio ½ hr after
SF ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2); PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2)of inspired oxygen ½-half an hour,S-in supine position

Table 4. Correlation between SF and PF ratio ½ hr after supine ventilation

Correlations			
		SFR 1/2s	**PFR 1/2s**
SFR 1/2s	Pearson Correlation Coefficient (r)	1.000	.723**
	Sig. (2-tailed)	.	.000
	N	40	40
PFR 1/2s	Pearson Correlation Coefficient (r)	.723**	1.000
	Sig. (2-tailed)	.000	.
	N	40	40

***. Correlation is significant at the 0.01 level (2-tailed)*
SF ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2) ,PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2)of inspired oxygen ½-half an hour,S-in supine position

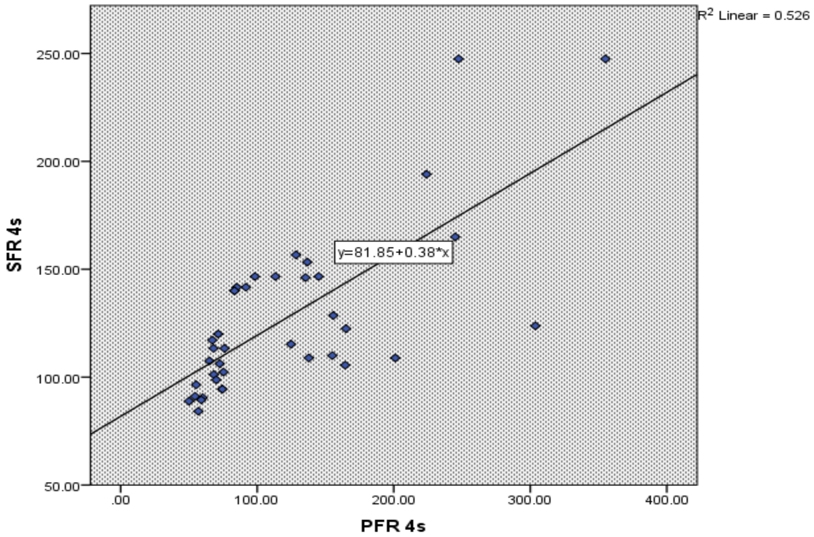

Fig. 3. Correlation between SF and PF ratio 4 hr after supine ventilation

SF ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2); PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2)of inspired oxygen 4-four hour,S-in supine position

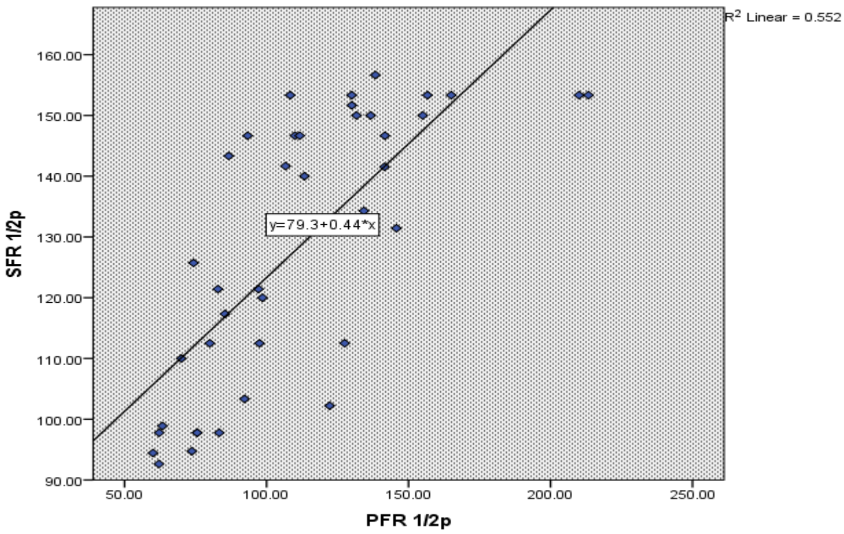

Fig. 4. Correlation between SF and PF ratio 1/2hr after prone ventilation

SF ratio-Pulse Oximetric, Saturation (Spo2) / Fraction of inspired oxygen (Fio2, PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2) of inspired oxygen ½-half an hour,p-in prone position

Table 5. Correlation between SF and PF ratio 4 hr after supine ventilation

Correlations			
		SFR 4s	**PFR 4s**
SFR 4s	Pearson Correlation Coefficient (r)	1.000	.744**
	Sig. (2-tailed)	.	.000
	N	40	40
PFR 4s	Pearson Correlation Coefficient (r)	.744**	1.000
	Sig. (2-tailed)	.000	.
	N	40	40

***. Correlation is significant at the 0.01 level (2-tailed)*

SF ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2) ,PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2)of inspired oxygen 4-four hour,S-in supine position

Table 6. Correlation between SF and PF ratio 1/2hr after prone ventilation

Correlations			
		PFR 1/2p	**SFR 1/2p**
PFR 1/2p	**Pearson Correlation Coefficient (r)**	1.000	.807**
	Sig. (2-tailed)	.	.000
	N	40	40
SFR 1/2p	**Pearson Correlation Coefficient (r)**	.807**	1.000
	Sig. (2-tailed)	.000	.
	N	40	40

***. Correlation is significant at the 0.01 level (2-tailed)*
SF ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2) ,PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2)of inspired oxygen ½-half an hour,p-in prone position

Table 7. Correlation between SF and PF ratio 4hr after prone ventilation

Correlations			
		PFR 4p	**SFR 4p**
PFR 4p	**Pearson Correlation Coefficient (r)**	1.000	.778**
	Sig. (2-tailed)	.	.000
	N	40	40
SFR 4p	**Pearson Correlation Coefficient (r)**	.778**	1.000
	Sig. (2-tailed)	.000	.
	N	40	40

***. Correlation is significant at the 0.01 level (2-tailed)*
SF ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2) ,PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2)of inspired oxygen 4-four hour,p-in prone position

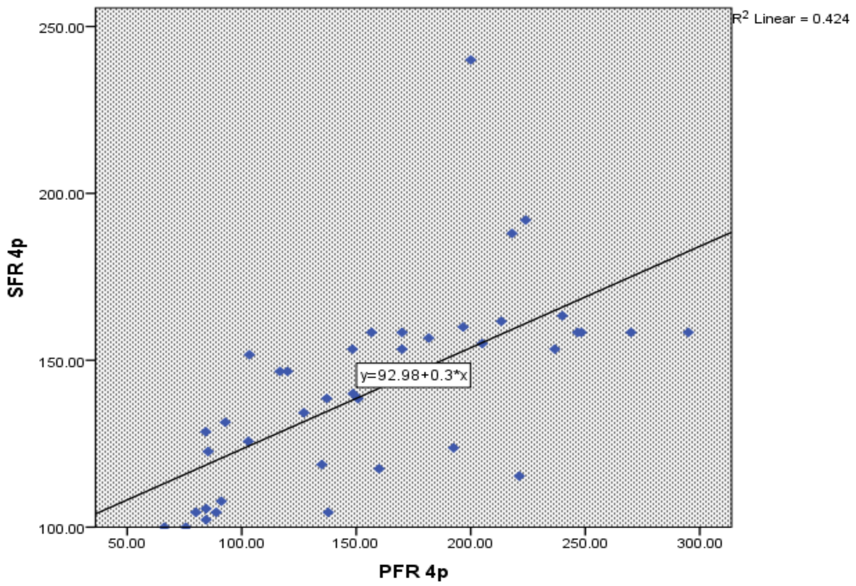

Fig. 5. Correlation between SF and PF ratio 4hr after prone ventilation
SF ratio-Pulse Oximetric,Saturation (Spo2) / Fraction of inspired oxygen (Fio2); PF ratio-Partial pressure of oxygen (PaO2) /Fraction (FiO2)of inspired oxygen 4-four hour,p-in prone position

4. DISCUSSION

- In this study, male population was higher than the female population and male: female ratio was 2.3:1.
- In our study the mean oxygenation index at 4hr supine ventilation (OI 4s) (mean± s.d.) of patients was 15.146± 6.732 and the mean oxygenation index at 4hr prone ventilation (OI 4p) (mean± s.d.) of patients

was 10.653± 4.527 (Table 1). A responder was defined as having an improvement of more than 10% in the oxygenation index after four hours in prone position. Twenty-nine children (72.5%) were responders and eleven children were non-responders. The mean difference of OI 4s vs OI 4p was 4.492 with 95% confidence interval [3.064 to 5.920]. The difference of mean OI 4s vs OI 4p was statistically significant (p<0.0001). The results of our study was found to be similar to studies done by Lupton Smith Et al and Curley and Martha Aq Et.al [8,9] .

- The patient was classified as a responder when the mean increase in PF ratio in prone position was greater than 15%. In our study twenty four patients were responders and sixteen patients were non-responders. The responders showed an increase in PaO2/FiO2 ratio of 37% from 120±65 to 165±56 (p<0.001),when they were placed from supine to prone position suggesting that there is improvement in oxygenation in prone ventilation which was similar to the studies done by J.Casado flores et.al [10].
- In our study oxygenation index was significantly better in prone position at 4hr (10.653±4.527, p<0.0001) as compared to supine position at 4hr (15.146 ± 6.732). The mean OSI 4s (mean± s.d.) of patients was 12.051± 2.788 and the mean OSI 4p (mean± s.d.) of patients was 10.564± 2.214 which is statistically significant (p<0.0001).The mean OI at 1/2s (mean± s.d.) of patients was 13.463± 4.822 and the mean OI at 1/2p (mean± s.d.) of patients was 14.233± 4.376. The mean difference of OI 1/2s vs OI 1/2p was -.836 with 95% confidence interval [-1.963 to .291]. The difference of mean OI 1/2s vs OI 1/2p was not statistically significant (p=.142), implying that there is no significant difference in oxygenation status at half-an hour of supine vs prone ventilation. In our study we also found that the PF ratio at 4hr prone ventilation showed significant improvement as compared to supine position (157.661± 62.189 (mean± s.d) vs 121.935± 72.695) which is statistically significant(p<0.0001). Hence our study concluded that Oxygenation was found to be significantly superior at 4hr after prone ventilation. The results of our studies were similar to that of studies conducted by Kornecki Alik Et.al, Whu J et.al, Relvas MS et.al and Romero et.al [11-13] implying that even brief periods of ventilation in prone position results in improvement of oxygenation status, so it may be concluded that in children with ARDS, oxygenation is significantly superior in the Prone position than in the Supine position.
- In our study it showed the mean (±SD) increase in the ratio of the partial pressure of arterial oxygen to the fraction of inspired oxygen (PF ratio) was greater in the prone than in supine position (157.661± 62.189 vs. 121.935± 72.695, p<0.0001) after 4hr of change in position. The mean pao2/fio2 ratio in 4hr supine (mean± s.d.) patients was 121.935± 72.695and the mean pao2/fio2 ratio in 4hr prone (mean± s.d.) patients was 157.661± 62.189. The mean difference of PFR 4s vs PFR 4p was -35.725 with 95% confidence interval [-52.294 to -19.157]. The difference of mean PFR 4s vs PFR 4p was statistically significant (<0.0001) .Our findings were consistent with studies conducted by Gattinoni et.al ,M Darban et.al and Chua EX et.al [7,14,15] which showed in comparison to the supine position, prone position significantly improved the PaO_2/FiO_2 ratio This finding shows the importance of prone status in the process of oxygenation in ventilated patients.
- The mean spo2/fio2 ratio in 4hr supine (mean± s.d.) of patients was 127.616± 37.604 and the mean spo2/fio2 ratio in 4hr prone (mean± s.d.) of patients was 140.888± 29.040 which is statistically significant (p=0.012). The mean pao2/fio2 ratio in 4hr supine (mean± s.d.) patients was 121.935± 72.695 and the mean pao2/fio2 ratio in 4hr prone (mean± s.d.) patients was 157.661± 62.189. (p<0.0001). Our study demonstrated that there is an increase in oxygenation status from supine to prone ventilation after 4 hours of the position change, similar results were obtained by study conducted by L'her E et.al [16] .
- In our study there was strong positive correlation between PF ratio and SF ratio at admission (r=0.698; p<0.0001), after half hour of supine ventilation (r=0.723; p<0.0001),after 4hr of supine ventilation(r=0.744; p<0.0001), after half hour of prone ventilation(r=0.807; p<0.0001) and after 4hr of prone ventilation(r=0.778; p<0.0001). The results

were similar to the studies conducted by Lohano et al (r=0.688), Ahmed et al (r=0.603) [17,18] indicating a positive correlation.

5. CONCLUSIONS

Our study demonstrated that there is an increase in oxygenation status from supine to prone ventilation. Our study finding suggests that non-invasive SpO2/FiO2 ratio can reliably be used in place of PaO2/FiO2 ratio in children on mechanical ventilation as a strong correlation was observed between them. The advantage is invasive arterial sampling can be replaced by non-invasive pulse oximetry for oxygen saturation.

6. LIMITATIONS OF THE STUDY

As researchers, we acknowledge the inherent limitations of the current study, encompassing:

a) A modest sample size, with only 40 cases, which may be deemed insufficient for the scope of this investigation.
b) The exclusive execution of the study within a single center.
c) The study conducted in a tertiary care hospital introduces the potential for hospital bias, a factor that cannot be entirely eliminated.

CONSENT

As per international standards, parental written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

It is not applicable

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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