

RESEARCH ARTICLE

# Effect of Integrated Value of Preoperative Hemoglobin Level and Oxygen Saturation on Postoperative Outcomes of Tetralogy of Fallot Repair

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## Abstract

**Background:** Preoperative Hb × SpO<sub>2</sub> level compare with age adjusted hemoglobin level can better evaluate anemia of TOF patients. This study aimed to compare postoperative outcomes of TOF repair between patients with high and low integrated value of preoperative hemoglobin and oxygen saturation than age adjusted hemoglobin.

**Methods:** This comparative cross-sectional study was conducted at the Department of Pediatric Cardiac Surgery of the National Heart Foundation Hospital and Research Institute, for a period from July, 2022 to April, 2024. The study included 101 admitted patients undergoing TOF repair then they were divided into two groups: In group A, 52 patients with Hb × SpO<sub>2</sub> ≥ aaHb while in group B 49 patients with Hb × SpO<sub>2</sub> ≤ aaHb. Data were collected in separate case-record form and analyzed by SPSS 27.0. The statistical analysis was done with unpaired t-test for parametric quantitative data and Mann Whitney test for non-parametric quantitative data and Chi-square test was used for qualitative data. The ‘p’ value of <0.05 was considered as statistically significant.

**Results:** In this study, the mean (± SD) age of the patients in group A was 6.12±4.18 years and group B was 4.85±3.55 years. The difference was statistically not significant (p=0.104). In group A male 31% and female 21%, in group B male 35% and female 14%, but the difference was statistically not significant. Mean (± SD) BSA (m<sup>2</sup>) were 0.72±0.29 vs 0.62±0.25; (p=0.076) in group A and B respectively, but the difference was statistically not significant. Significant differences observed in mean (± SD) preoperative Hb (gm/dl) 17.9 ± 2.98 gm/dl vs 13.2 ± 1.78mg/dl; p < 0.001, mean (± SD) Hb × SpO<sub>2</sub> 14.52 ± 1.79 vs 10.5 ± 1.42; p < 0.001 and mean (± SD) hematocrit value 43.8 ± 9.72 vs 38.2 ± 6.24; p < 0.001 between group A & B. More Patients in group B exhibited > 20 ionotropic score than in group A with proportion of 10(20.4%) vs 5(9.6%). The mean (± SD) ionotropic score was 11.0±5.2 in group A and 13.9±7.7 in group B;(p=0.028).

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Besides this, group B patients had longer duration of inotropic support ( $3.56 \pm 1.11$  days vs  $4.80 \pm 1.97$  days;  $p < 0.001$ ), sepsis 4 (7.7%) vs 12 (24.49%);  $p = 0.021$ , longer ventilation time ( $15.3 \pm 20.6$  hours vs  $37.4 \pm 68.0$  hours,  $p = 0.027$ ), longer ICU stay ( $5.79 \pm 4.17$  days vs  $7.98 \pm 5.35$  days;  $p = 0.023$ ) and longer hospital stays ( $8.73 \pm 4.82$  days vs  $10.9 \pm 5.75$  days;  $p = 0.035$ ) than group A patients. Group A patients had a significantly higher pleural drainage (ml) amount ( $661.2 \pm 849.9$  vs  $317.6 \pm 328.1$ ,  $p = .009$ ) and amount (ml) of transfusion ( $829.4 \pm 961.5$  vs  $430.0 \pm 384.1$ ;  $p = 0.008$ ) than group B patients.

**Conclusion:** TOF repair with  $Hb \times SpO_2 \leq aaHb$  had a poor postoperative outcome in terms of inotrope use, sepsis, mechanical ventilation time, ICU stay and hospital stay. Conversely patients with  $Hb \times SpO_2 \geq aaHb$  had more vulnerability of post-operative bleeding and transfusion requirement. Preoperative  $Hb \times SpO_2$  can be potential tools for prediction of postoperative outcomes of TOF repair.

**Keywords:** Integrated Value, Preoperative Hemoglobin Level, Oxygen Saturation, Tetralogy of Fallot Repair.

## 1. Introduction

Tetralogy of Fallot (TOF) has an incidence rate of approximately 1 in 3,500 neonates and accounts for 7–10% of all congenital cardiac malformations [1]. TOF requires surgical interventions early in life to avoid future complications related to cyanosis, chronic hypoxia, and heart failure [2]. Postoperative mortality following total repair is between 1% - 5% [3]. Death is commonly from chronic heart failure due to secondary cardiomyopathy that results from RV pressure overload and chronic hypoxia and polycythemia [3]. Anemia may impair the body's resistance to surgical stress due to reduction in oxygen-carrying capacity, inadequate tissue oxygenation and organ dysfunction [4]. Preoperative anemia is associated with poor postoperative outcomes such as acute kidney injury in adults undergoing cardiac surgery [5] and in neonates and children undergoing non-cardiac surgery [6]. Preoperative anemia is associated with poor outcome in terms of inotropic support, mechanical ventilation, blood transfusion, reoperation, sepsis, and higher in-hospital mortality in children undergoing non-cardiac surgery. But little is known about this association in children undergoing cardiac surgery for cyanotic heart disease [6]. Preoperative anemia is common in acyanotic children with a ventricular septal defect or an atrioventricular canal defect, with an estimated incidence of 23% [7]. However, the rate of preoperative anemia was only 4.5% in cyanotic children. If the diagnosis of anemia was made based on the integrated value of preoperative Hb & SpO<sub>2</sub> as the presence of actual Hb concentration is lower than age-adjusted hemoglobin (aaHb) level, the anemia rate could increase to 21.6%, which may improve the detection rate of preoperative anemia in cyanotic children. Obviously, the incidence of preoperative anemia in cyanotic children would be seriously underestimated by the actual Hb concentration [8]. In addition, age may also

influence the Hb level of children. The age-adjusted lower limits of normal hemoglobin (aaHb) in healthy children are 14.5 g/dl for neonates, 9 g/dl at 2 months, 10.5 g/dl at 6 months, 11.5 g/dl at 2 years, and 12 g/dl and 13 g/dl in adolescent girls and boys respectively [9]. Based on the theory of an inverse relationship between the severity of compensatory erythrocytosis and resting oxygen saturation, it is presumed that the integrated value of preoperative Hb & SpO<sub>2</sub> can evaluate whether cyanotic children achieved adequate Hb compensation or not [10,11]. If the integrated value of preoperative Hb & SpO<sub>2</sub> of cyanotic children is below the lower limit of normal age-adjusted hemoglobin, this indicates that preoperative Hb concentration is not sufficient and preoperative anemia would be considered [8]. Therefore, compared with the actual Hb concentration, if the value of  $Hb \times SpO_2$  is below the lower limit of normal age-adjusted hemoglobin, that will be a stronger prognostic factor and may be more suitable to evaluate preoperative anemia in children with cyanotic congenital heart disease. Preoperative  $Hb \times SpO_2 \leq aaHb$  is associated with significant severe postoperative events such as invasive ventilation and sepsis especially associated with higher in-hospital mortality [8]. From the perspective of tissue oxygen delivery, preoperative  $Hb \times SpO_2 \leq aaHb$  may be a modifiable risk factor for cardiac surgery [8]. According to the formula for calculating oxygen content [10], improvement of oxygen saturation may also be a strategy to overcome postoperative complication for selected children with cyanotic congenital heart disease [11]. There is no study conducted in our country to see post operative outcomes of TOF patients who have less integrated value of preoperative hemoglobin and oxygen saturation than normal age adjusted hemoglobin level. However, further studies are required to determine the strategy of  $Hb \times SpO_2 \geq aaHb$  can improve postoperative outcomes in cyanotic children.

Therefore, this study integrates preoperative Hb and oxygen saturation to predict postoperative outcomes in children with TOF.

## 2. Methods and Materials

### 2.1 Study Design

Comparative cross-sectional study.

### 2.2 Period of study

The study was conducted from July, 2022 to April, 2024. Literature reviewed on July, 2022 to January, 2023. Title selected on December, 2022. Protocol presented and submitted on February, 2023. Data collected from March, 2023 to February 2024. Data processing and analysis were done on March 2024. After final report writing thesis submitted on April, 2024.

### 2.3 Place of Study

This study was carried out at the department of Pediatric Cardiac Surgery of the National Heart Foundation Hospital and Research Institute, Mirpur, Dhaka. This Institute is 330 bedded tertiary care hospital. This hospital is carrying out all types of modern non-invasive and invasive investigations including interventional cardiology and both closed and open-heart surgery. To provide specialized service to women and pediatric cardiac patients there are 150-bedded specialized Pediatric Cardiac Surgery unit at Darus Salam branch with world class facilities including world class operation theater and standard pediatric cardiac intensive care unit. About 3500 cardiac surgeries performed per year including adult & congenital cardiac surgery. Expert pediatric cardiac surgeons are performing almost all kind of congenital cardiac surgery in this institute.

### 2.4 Study Population

The study was carried out in patients who undergone for total correction of Tetralogy of Fallot meeting the inclusion and exclusion criteria in the Pediatric Cardiac Surgery Department at National Heart Foundation Hospital and Research Institute.

### 2.5 Sample Size Calculation

Prior data indicate that the probability of development of poor outcome among low Hb  $\times$  SpO<sub>2</sub>  $\leq$  aaHb group was 69.6%, while in normal level group the risk was 32.3% [8]. For comparison of two proportion following formula was used to calculate the number of subjects required for each group [12].

$$n = \frac{p_1(1-p_1) + p_2(1-p_2)}{(p_1 - p_2)^2} (Z_{\alpha} + Z_{\beta})^2$$

Z<sub>a</sub> = 1.96 for  $\alpha$  = 0.05 (two-tailed) and

Z<sub>b</sub> = 0.84 for 80% power

P<sub>1</sub> = 0.696 [8].

P<sub>2</sub> = 0.323 [8].

The minimum sample size of each group = 25

### 2.6 Grouping of Patients

Integrated value of Preoperative Hemoglobin level and Preoperative Oxygen Saturation were compared with age adjusted Hemoglobin level. Patients with equal or high integrated value than age adjusted value were included in group A. Patients with equal or low integrated value than age adjusted value were included in group B.

*Group A:* 52 patients with Integrated value of Preoperative Hemoglobin level and preoperative Oxygen saturation  $\geq$  Age adjusted hemoglobin

*Group B:* 49 patients with Integrated value of Preoperative Hemoglobin level and preoperative Oxygen saturation  $\leq$  Age adjusted hemoglobin

### 2.7 Selection Criteria:

#### 2.7.1 Inclusion Criteria

- Patients of Tetralogy of Fallot with consent of legal guardian

#### 2.7.2 Exclusion Criteria

- Patient with severely malnourished
- Pulmonary Atresia
- Preoperatively very sick patient requiring resuscitation at same admission
- Emergency cardiac surgery
- Preoperatively culture-positive sepsis
- Major non-cardiac congenital anomaly
- Patient got a blood transfusion before the operation
- Patient with coagulation defect
- Patients of hemoglobinopathies like Thalassemia, Sickle cell disease, etc.

### 2.8 Sampling Technique

A convenience sampling technique was applied in this study.

### 2.9 Data Collection Instruments

A semi-structured questionnaire was developed in

English using the selected variables according to the specific objectives. It contained questions related to socio-demographic characteristics and recorded desired preoperative, per-operative, and postoperative variables from admission records, history sheets, and relevant medical reports. A comprehensive checklist containing some preset options was used to simplify data collection and decrease the chances of error in observation.

## 2.10 Study Procedure

Patients admitted to the Pediatric Cardiac Surgery Department of NHFH&RI who matches the inclusion criteria were approached for enrollment in the study. This comparative cross-sectional study was conducted in NHFH&RI from July' 2022 to April' 2024. Informed consent took from legal guardian of each subject before enrollment. Detailed history, clinical examination, and relevant investigation reports of all patients recorded in the data collection sheet preoperatively. Hemoglobin measured by cyanmethemoglobin method by digital hemoglobin meter: SKU: KC-10-DT. Preoperative SpO<sub>2</sub> measured by using pulse oximeter: Model: IPD-500D, which uses spectrophotometry to determine the proportion of oxygenated & deoxygenated hemoglobin. All the relevant data were collected and compiled in a master folder first. The data entered in the available latest version of Statistical Package for the Social Sciences (SPSS) for analysis. All the patients were divided into two groups according to the integrated value of preoperative Hb and preoperative SpO<sub>2</sub>. Standard anesthetic protocol was maintained. Patient were taken to the operating room. oxygenation done with a face mask. Peripheral venous catheterization and central venous catheterization in the internal jugular vein performed with all aseptic precautions. Following the surgical procedure, all the patients brought to the Pediatric Cardiac Intensive Care Unit (PCICU) where they monitor until the patients are stable enough to be shifted to the ward. Post-operative patient's condition including any complication noted. Postoperative outcomes (Duration of inotropic support, Vasoactive inotropic score, Sepsis, Postoperative pleural drainage amount, Reoperation, Blood transfusion, Acute kidney injury, Cardiac arrest, Duration of mechanical ventilation, ICU stay, Postoperative hospital Stay, In-hospital death) observed. Patients discharged routinely unless otherwise any of them was complicated by any factor. All data collected, summarized, and statistically analyzed.

## 2.11 Surgical Technique

All operations performed under standard cardiopulmonary bypass through median sternotomy. Aorto-bicaval cannulation performed and standard CPB established. Aorta cross-clamped; standard cooling protocol followed. VSD closure done. Adequate infundibular resection performed. The main pulmonary artery, pulmonary annulus, and RVOT augmented by applying a pericardial patch wherever required, patient weaning from CPB, decannulation, chest closure in layer with standard fashion.

## 2.12 Statistical Analysis:

Statistical analyses were performed using Windows-based computer software devised with Statistical Packages for the Social Sciences (SPSS-27) (SPSS Inc, Chicago, IL, USA). Descriptive and inferential statistical methods were applied to analyze data. All comparisons were made here between the  $Hb \times SpO_2 \geq aaHb$  and  $Hb \times SpO_2 \leq aaHb$  groups. In descriptive statistics, continuous data with normal distribution were summarized by mean  $\pm$  SD, continuous data with skewed distribution were summarized by median and categorical data were summarized as frequency distribution and percentage. To make comparisons between groups and draw conclusions from data, several inferential statistics were used including unpaired t-test for parametric quantitative data and Mann Whitney test for non-parametric quantitative data and Chi-square test was used for qualitative data,  $p < 0.05$  was considered as a level of significant. For all analytic tests, the statistical significance threshold was set at 5% and a p-value of  $\leq 0.05$  was considered statistically significant.

## 3. Results

Age distribution of patients in the study Groups ( $n=101$ ). In Table-1, the mean ( $\pm$  SD) of age were  $6.12 \pm 4.18$  years in Group A vs  $4.85 \pm 3.55$  years in Group B. The differences were not statistically significant ( $p=0.104$ ). Most of the patients distributed at 0.5-5 years of age. 25 (48.1%) patients distributed in Group A and 36 (73.5%) patients distributed in Group B. In 5-10 years of age range, 19 (36.5%) patients were distributed in Group A and 10 (20.4%) patients were distributed in Group B. In 11-15 years of age range, 3 (5.8%) vs 2 (4.1%) patient were distributed in Group A & Group B respectively. In 16-20 years of age range, 5 (9.6%) vs 1 (2.0%) patients were distributed in group A & Group B respectively.

**Table 1.** Age distribution of patients in the study Groups (n=101)

Age Group (years)	Group A (n=52)	Group B (n=49)	p-value
0.5-5	25(48.1%)	36(73.5%)	
5-10	19(36.5%)	10(20.4%)	
11-15	3(5.8%)	2(4.1%)	
16-20	5(9.6%)	1(2.0%)	
Total	52(100.0%)	49(100.0%)	
Mean $\pm$ SD	6.12 $\pm$ 4.18	4.85 $\pm$ 3.55	0.104
Range (min-max)	(1.08-16.92)	(1.17-15.92)	

p-value obtained by Unpaired t-test,  $p < 0.05$  was considered as a level of significant

Table-2 shows the sex distribution of the study patients. In Group A, 31 patients (59.6%) were male and 21 patients (40.4%) were female, while in Group B, 35 patients (71.4%) were male and 14 patients (28.6%) were female. No significant difference in the distribution of males and females between Group A and Group B ( $p = 0.212$ ).

**Table 2.** Sex distribution of the study Groups (n=101)

Sex	Group A (n=52)	Group B (n=49)	p-value
Male	31(59.6%)	35(71.4%)	0.212
Female	21(40.4%)	14(28.6%)	
Total	52(100.0%)	49(100.0%)	

p-value obtained by Chi-square test,  $p < 0.05$  was considered as a level of significant

Table-3 shows, mean ( $\pm$  SD) weight of the children in Group A were 16.5 $\pm$ 7.42 kg and in Group B were 14.75 $\pm$ 8.92 kg ( $p = 0.298$ ), mean ( $\pm$  SD) height of the children in Group A were 105.3 $\pm$ 22.5 cm and in Group B were 97.3 $\pm$ 24.7 cm ( $p = 0.092$ ) & the mean ( $\pm$  SD) BSA of the children in Group A were 0.72 $\pm$ 0.29m<sup>2</sup> and in Group B 0.62 $\pm$ 0.25m<sup>2</sup> ( $p = 0.076$ ).

**Table 3.** Comparison of anthropometric data between two Groups (n=101)

Anthropometric variables	Group A (n=52)	Group B (n=49)	p-value
Height (cm)	105.3 $\pm$ 22.5	97.3 $\pm$ 24.7	0.092
Weight (kg)	16.5 $\pm$ 7.42	14.75 $\pm$ 8.92	0.298
BSA (m <sup>2</sup> )	0.72 $\pm$ 0.29	0.62 $\pm$ 0.25	0.076

p-value obtained by Unpaired t-test,  $p < 0.05$  was considered as a level of significant

Comparison of preoperative Hb, SpO<sub>2</sub> and Hb  $\times$  SpO<sub>2</sub> between two Groups (n=101)  
 Table -4 shows, mean ( $\pm$  SD) Hb was 17.9  $\pm$  2.98 g/dL in Group A and 13.2  $\pm$  1.78 g/dL in Group B ( $p < 0.001$ ). Similarly, the mean ( $\pm$  SD) integrated value of preoperative Hemoglobin and Oxygen saturation were (14.52  $\pm$  1.79) in Group A and (10.5  $\pm$  1.42) ( $p < 0.001$ ) in group B. These results suggest that patients in Group A have higher preoperative hemoglobin levels and Hb  $\times$  SpO<sub>2</sub> values compared to those in Group B. However, there is no statistically significant difference in mean ( $\pm$  SD) SpO<sub>2</sub> (%). Mean ( $\pm$  SD) SpO<sub>2</sub> (%) in Group A were 82.1  $\pm$  9.61 and in Group B were 80.4  $\pm$  10.67 ( $p = 0.389$ ).

**Table 4.** Comparison of preoperative Hb, SpO<sub>2</sub> and Hb  $\times$  SpO<sub>2</sub> between two Groups (n=101)

Preoperative variables	Group A (n=52)	Group B (n=49)	p-value
Hb (%)	17.9 $\pm$ 2.98	13.2 $\pm$ 1.78	<0.001
SpO <sub>2</sub> (%)	82.1 $\pm$ 9.61	80.4 $\pm$ 10.67	0.389
Hb $\times$ SpO <sub>2</sub>	14.52 $\pm$ 1.79	10.5 $\pm$ 1.42	<0.001

p-value obtained by Unpaired t-test,  $p < 0.05$  was considered as a level of significant

In table-5, There are mean ( $\pm$  SD) Preoperative Hematocrit (%) were (43.8 $\pm$ 9.72 vs 38.2 $\pm$ 6.24;  $p < 0.001$ ), mean ( $\pm$  SD) platelet count (cells/cmm) were (278769.2 $\pm$ 87561.2 vs 286744.9 $\pm$ 84832.7;  $P = 0.643$ ), mean ( $\pm$  SD) total WBC count (cells/cmm) were (10288.5 $\pm$ 2482.1 vs 10732.7 $\pm$ 2914.0;  $p = 0.411$ ),

mean ( $\pm$  SD) bleeding time (min) were ( $3.40 \pm 0.57$  vs  $3.27 \pm 0.45$ ;  $p=0.178$ ), mean ( $\pm$  SD) clotting time (min) were ( $5.65 \pm 0.52$  vs  $5.57 \pm 0.54$ ;  $p=0.436$ ), mean ( $\pm$  SD) INR were ( $1.34 \pm 0.27$  vs  $1.35 \pm 0.18$ ;  $p=0.756$ ) between Group A & Group B respectively. Significant differences were observed in hematocrit ( $p < 0.001$ ), with Group A having a higher mean value compared to Group B. However, there were no statistically significant differences in platelet count ( $P=0.643$ ), total WBC count ( $p=0.411$ ), bleeding time ( $p=0.178$ ), clotting time ( $p=0.436$ ) & INR ( $p=0.756$ ) between the two Groups ( $p>0.05$ ).

**Table 5.** Comparison of preoperative variables between two Groups ( $n=101$ )

Preoperative attributes	Group A ( $n=52$ )	Group B ( $n=49$ )	p- value
Hematocrit (%)	$43.8 \pm 9.72$	$38.2 \pm 6.24$	$<0.001$
Platelet count (cells/cmm)	$278769.2 \pm 87561.2$	$286744.9 \pm 84832.7$	0.643
Total WBC (cells/cmm)	$10288.5 \pm 2482.1$	$10732.7 \pm 2914.0$	0.411
Bleeding time (min)	$3.40 \pm 0.57$	$3.27 \pm 0.45$	0.178
Clotting time (min)	$5.65 \pm 0.52$	$5.57 \pm 0.54$	0.436
INR	$1.34 \pm 0.27$	$1.35 \pm 0.18$	0.756

*p-value obtained by Unpaired t-test,  $p < 0.05$  was considered as a level of significant*

Table-6 compares per operative variables between Group A and Group B. Significant differences were observed in ACC ( $p = 0.045$ ). Group A having a longer mean ( $\pm$  SD) ACC ( $99.8 \pm 33.29$  minutes) compared to Group B ( $87.4 \pm 28.27$  minutes). However, there was no statistically significant difference in CPB time between the two Groups ( $p = 0.086$ ). Group A having a mean ( $\pm$  SD) CPB time ( $131.8 \pm 39.78$  minutes) compared to Group B ( $119.5 \pm 30.23$  minutes).

**Table 6.** Comparison of per operative variables between two Groups ( $n=101$ )

Per operative attributes	Group A ( $n=52$ )	Group B ( $n=49$ )	p-value
Aortic cross clamp time- ACC (min)	$99.8 \pm 33.29$	$87.4 \pm 28.27$	0.045
Cardiopulmonary bypass time-CPB (min)	$131.8 \pm 39.78$	$119.5 \pm 30.23$	0.086

*p-value obtained by Unpaired t-test,  $p < 0.05$  was considered as a level of significant*

Table -7 shows, Significant differences were observed in the mean ( $\pm$  SD) VIS. In Group A & Group B, mean ( $\pm$  SD) Vasoactive Inotropic Score-VIS were ( $11.0 \pm 5.2$  vs  $13.9 \pm 7.7$ ;  $p = 0.028$ ) respectively. In comparison between Group A & Group B, VIS  $<5$  were in 2(3.8%) patients in Group A & 0(0.0%) patients in Group B. VIS 5-9 were in 29 (55.8%) patients in Group A & 23 (46.9%) patients in Group B. VIS 10-14 were in 10 (19.2%) patients in Group A & 13 (26.5%) patients in Group B. VIS 15-19 were in 6 (11.5%) patients in Group A & 3 (6.1%) patients in Group B. Higher proportion of Group-B patients 10 (20.4%) exhibited  $> 20$  inotropic score than in Group A patients 5(9.6%).

**Table 7.** Comparison of postoperative inotropic supports between two Groups ( $n=101$ )

Vasoactive Inotropic Score-VIS	Group A( $n=52$ )	Group B( $n=49$ )	p-value
2-5	2(3.8%)	0(0.0%)	
6-9	29(55.8%)	23(46.9%)	
10-14	10(19.2%)	13(26.5%)	
15-19	6(11.5%)	3(6.1%)	
20-24.	5(9.6%)	10(20.4%)	
Total	52(100.0%)	49(100.0%)	
Mean $\pm$ SD	$11.0 \pm 5.2$	$13.9 \pm 7.7$	0.028

*p-value obtained by Unpaired t-test,  $p < 0.05$  was considered as a level of significant*

In table -8, mean ( $\pm$  SD) duration of inotropic support were  $3.56 \pm 1.11$  days in Group A and  $4.80 \pm 1.97$  days in Group B;  $p < 0.001$ , mean ( $\pm$  SD) pleural drainage amount were  $661.2 \pm 849.9$  ml in Group A and  $317.6 \pm 328.1$  ml in Group B;  $p = 0.009$ , mean ( $\pm$  SD) amount of transfusion were  $829.4 \pm 961.5$  ml. in Group A and  $39.8 \pm 37.7$  ml in Group B;  $p = 0.008$ . Presence of sepsis were 4(7.7%) vs 12(24.49%),  $p = 0.021$  in Group A & Group B respectively. There were no statistically significant differences in the incidence of

AKI 0(0.0%) vs 3(6.1%);  $p=0.07$ , peritoneal dialysis 0(0.0%) vs 2(4.1%),  $p=0.141$ , reoperation 10(19.2%) vs 4(8.2%),  $p=0.108$  & cardiac arrest 3(5.8%) vs 2(4.1%),  $p=0.696$  between Group A and Group B respectively.

**Table 8.** Comparison of postoperative morbidity between two Groups ( $n=101$ )

Postoperative attributes	Group A (n=52)	Group B (n=49)	p-value
Duration of ionotropic support (Days)	3.56±1.11	4.80±1.97	<0.001†
Pleural drainage amount (mL) Mean ± SD	661.2±849.9	317.6±328.1	0.004‡
Median	385.0	200.0	
Amount of transfusion (mL) Mean ± SD	829.4±961.5	430.0±384.1	<0.001‡
Median	500.0	300.0	
Transfusion (mL/kg) Mean ± SD	46.6±38.1	39.8±37.7	0.145‡
Median	36.3	25.0	
Sepsis	4(7.7%)	12(24.49%)	0.021*
Peritoneal dialysis	0(0.0%)	2(4.1%)	0.141*
AKI	0(0.0%)	3(6.1%)	0.07*
Reoperation	10(19.2%)	4(8.2%)	0.108*
Cardiac arrest	3(5.8%)	2(4.1%)	0.696*

p-value obtained by †Unpaired t-test and ‡Mann-Whitney test for Quantitative data and \*Chi-square test was used for Qualitative data.

In table -9, mean ( $\pm$  SD) duration of mechanical ventilation time were 15.3±20.6 hours in Group A and 37.4±68.0 hours in Group B;  $P=0.027$ , mean ( $\pm$  SD) ICU stay were 5.79±4.17 days in Group A and 7.98±5.35 days in Group B;  $p=0.023$ , and mean ( $\pm$  SD) hospital stay were 8.73±4.82 days in Group A and 10.9±5.75 days in Group B;  $p=0.035$ . Patients in Group B have longer durations of mechanical ventilation time, ICU stay, and hospital stay compared

to those in Group A. Additionally, the percentage of patients requiring mechanical ventilation for more than 24 hours were 9 (17.3%) in Group A; 19 (38.8%) in Group B ( $p=0.016$ ), ICU stay more than 7 days were 14 (26.9%) in Group A and 25 (51.0%) in Group B ( $P=0.013$ ) and hospital stay for more than 10 days were 16 (30.8%) in Group A & 28 (57.1%) in Group B ( $p=0.008$ ).

**Table 9.** Comparison of postoperative attributes between two Groups ( $n=101$ )

Postoperative	Group A (n=52)	Group B (n=49)	p-value
Mechanical ventilation time			
<24 hrs	43(82.7%)	30(61.2%)	0.016*
>24 hrs	9(17.3%)	19(38.8%)	
Mean ± SD	15.3±20.6	37.4±68.0	0.027†
ICU stay			
<7 days	38(73.1%)	24(49.0%)	0.013*
>7 days	14(26.9%)	25(51.0%)	
Mean ± SD	5.79±4.17	7.98±5.35	0.023†
Hospital stay			
<10 days	36(69.2%)	21(42.9%)	0.008*
>10 days	16(30.8%)	28(57.1%)	
Mean ± SD	8.73±4.82	10.9±5.75	0.035†

p-value obtained by Unpaired t-test for Quantitative data, \*Chi-square test was used for Qualitative data,  $p<0.05$  was considered as a level of significant.

## 4. Discussion

Increase level of hemoglobin is a compensatory mechanism for improving tissue oxygen delivery for the patient of congenital cyanotic heart disease such

as Tetralogy of Fallot [2]. Inappropriate compensation leads to preoperative anemia. Though actual oxygen carrying capacity of hemoglobin can be evaluated by integrated value of preoperative hemoglobin and

oxygen saturation. Only hemoglobin level may mislead to diagnose anemia in case of cyanotic heart disease patient, as because erythrocytosis is masking the absolute anemic patient [8]. In this study, demographic characteristics were not in any appreciable variations between the two Groups. No significant difference in the distribution of males and females between Groups ( $p=0.212$ ). Similarly, in comparable study by Eroglu et al.,[13] reported on trans annular patch repair of TOF patients, a mean age of  $7.0 \pm 3.1$  years. There was no significant difference in age between patients and controls ( $p = 0.32$ ,  $0.73$  for age). Our study was similar with this study by age distribution. In our study usual age for TOF repair were 2 to 5 years. Though some adolescent patient undergone TOF repair, but this percentage is very minimum. Gender distribution does not play role in patient selection. In this study, Anthropometric characteristics did not significantly differ between the two Groups in the study population, suggesting that preoperative anthropometric factors did not play a significant role in determining the relationship between  $Hb \times SpO_2$  levels and postoperative outcomes in Tetralogy of Fallot repair ( $p>0.05$ ). In a relevant study Eroglu et al.,[13] reported in study on TOF patients, a mean body surface area of  $0.86 \pm 0.19$  m<sup>2</sup>. There was no significant difference in body surface area between patients and controls ( $p = 0.89$ ,  $0.07$  for body surface area respectively). TOF repair is preparable in early age. Maximum of patients in this study were in 2-5 years age limit. For this reason, anthropometric characteristics is similar with younger age group. Our study findings consistent with previous study. In our study, preoperative hemoglobin (Hb) and integrated value of Hb and  $SpO_2$  ( $Hb \times SpO_2$ ) were higher in group A than Group B. However, there is no statistically significant difference in  $SpO_2$  level between the two Groups. As because TOF is a cyanotic disease, some compensatory changes occur to overcome cyanotic consequence. If adequate compensation occurs, preoperative hemoglobin increases and integrated value of hemoglobin level and oxygen saturation also increase. If adequate compensation does not occur then preoperative hemoglobin and integrated value of preoperative hemoglobin and oxygen saturation remain lower than age adjusted hemoglobin level. It is presumed that; inadequate compensation can cause adverse postoperative events. In our study we use age adjusted hemoglobin level for defining anemia. In our study, patients age differs from 2 years to 16 years. This wide age range does not consistent with a single cut

off value for defining anemia. In a meta-analysis by Padmanabhan et al.,[14] showed, for defining anemia, level of hemoglobin was used in 20 studies, level of hematocrit in 1 study and both the level were used in 1 study. Anemia was defined based on WHO definition in 12 studies. Dimopoulos et al [4], Miceli et al [5] & Goldberg et al [15] defined anemia based on WHO definition while Faraoni et al.,[6] use hematocrit value for categorizing anemia. But in a very relevant way Khan et al., [7], Zhou et al.,[8] & Bromberg et al.,[10] use age adjusted hemoglobin level for defining anemia. In this study, significant differences were observed in hematocrit level ( $p < 0.001$ ), with Group A having a higher mean ( $\pm$  SD) hematocrit value than Group B. However, there were no statistically significant differences in platelet count ( $P=0.643$ ), total WBC count ( $p=0.411$ ), bleeding time ( $p=0.178$ ), clotting time ( $p=0.436$ ) & INR ( $p=0.756$ ) between the two groups ( $p>0.05$ ). Guevara et al.,[2] reported, Hemoglobin (mg/dl) were  $13.6 \pm 3.9$  vs  $15.7 \pm 2.9$ ;  $p=0.061$ ; Hematocrit (%) were  $42.1 \pm 10.9$  vs  $47.7 \pm 9.4$ ;  $p=0.068$ ; Platelet count (1/mL) were  $287,759 \pm 109,781$  vs  $271,800 \pm 160,597$ ;  $p= 0.677$ ; respectively between survivor and non- survivor among TOF patients to see erythrocytosis related mortality. Although their study could not find any association between preoperative hematocrit and outcome, this disagreement was because of lower mean hematocrit (43%) in our study. In our study, significant differences were observed in ACC ( $p = 0.045$ ), with group A having a longer ACC compared to group B. However, there was no statistically significant difference in CPB time between the two groups. Our finding aligns with the results reported by Guevara et al.,[2], that means there is no significant relationship between bypass time with outcomes. Though Eroglu et al.,[13] found no significant relation in between outcomes and both ACC time and CPB time. Repairing TOF often involves addressing complex issues, such as RVOT repair by patch or reconstruction by conduit contributing to the relatively longer durations of aortic cross-clamp and CPB times. We observed in our study, patients in group A required less postoperative inotropic support compared to those in group B. There were higher mean ( $\pm$  SD) Vasoactive Inotropic Score-VIS ( $p = 0.028$ ) and longer duration of Inotropic support (days) in group B patients than group A patients ( $p<0.001$ ). Higher proportion of group-B patients exhibited  $> 20$  inotropic score than in group A patients. There were more sepsis patient ( $P=0.021$ ) in group B in comparison to group A. Significant differences were observed in the mean ( $\pm$

SD) duration of mechanical ventilation time ( $P=0.027$ ), mean ICU stay ( $p=0.023$ ), and mean hospital stay ( $p=0.035$ ) between group A & group B. Specifically, patients in group B have longer durations of mechanical ventilation time, ICU stay, and hospital stay compared to those in group A. Additionally, the percentage of patients requiring mechanical ventilation for more than 24 hours is more in group B ( $p=0.016$ ), ICU stay more than 7 days more in group B ( $P = 0.013$ ) and hospital stay for more than 10 days is more in group B ( $p= 0.008$ ). These findings suggest that patients in group B experience prolonged duration of ionotropic support, postoperative mechanical ventilation, ICU stay and hospital stay compared to those in group A. However, there are no statistically significant differences in the incidence of AKI ( $p=0.07$ ), peritoneal dialysis ( $p=0.141$ ), reoperation ( $p=0.108$ ) & cardiac arrest ( $p=0.696$ ). Zhou et al.,[8] similarly reported, Cyanotic Children with  $Hb \times SpO_2 \leq$  age adjusted hemoglobin (aaHb) had adverse composite outcome such as cardiac arrest, sepsis, reoperation, severe hemorrhage, duration of invasive ventilation and length of hospital stay incidence (69.6% vs. 32.3%,  $P < 0.001$ ) than those with  $Hb \times SpO_2 \geq$  aaHb. Similarly, Padmanabhan et al., [14] reported, Anemia was associated with acute kidney injury (OR, 3.13; 95% CI, 2.37-4.12;  $I^2$ ;  $P < .001$ ) infection (OR, 2.65; 95% CI, 1.98-3.55;  $P < .001$ ). Dimopoulos et al., [4]; Faraoni et al.,[6] & Miceli et al [5] in their study reported also similar results in association between anemia and postoperative outcomes among the patient got surgical treatment for various diseases. In this study we also observed, mean ( $\pm$  SD) pleural drainage amount ( $p = 0.009$ ) & mean ( $\pm$  SD) amount of transfusion ( $P= 0.008$ ) were significantly higher in group A than group B. Guevara et al [2] also found a significantly positive correlation between preoperative erythrocytosis and postoperative blood loss. Conversely Faraoni et al.,[6]; Khan et al.,[7] & Bromberg et al.,[10] found significant association with anemia and post operative blood loss, blood transfusion and post operative outcomes. Though their study were conducted among either on noncyanotic children or adult patient. In fact, hypoxia and erythrocytosis related hemostatic defect might be responsible for this discrepancy. In Summary, Anemia detection by integrated value of hemoglobin and  $SpO_2$  would be reliable method for congenital cyanotic heart disease patient [8]. Presence of preoperative  $Hb \times SpO_2 \leq$  age adjusted hemoglobin (aaHb) is related to poor post operative outcomes such as post operative ionotropic use, mechanical ventilation time, sepsis, ICU & hospital stay.

Preoperative  $Hb \times SpO_2 \leq$  age adjusted hemoglobin (aaHb) patients are in more risk of developing poor post operative outcomes than patients with  $Hb \times SpO_2 \geq$  age adjusted hemoglobin (aaHb). Preoperative  $Hb \times SpO_2 \geq$  age adjusted hemoglobin (aaHb) have association with post operative bleeding and need for blood transfusion.

## 5. Conclusion

Preoperative anemia is difficult to evaluate in case of congenital cyanotic heart disease such as Tetralogy of Fallot due to hypoxemia induced secondary erythrocytosis. Preoperative  $Hb \times SpO_2$  level compare with age adjusted hemoglobin level can better evaluate preoperative anemia. Our findings suggest that the presence of preoperative  $Hb \times SpO_2 \leq$  aaHb was associated with poor postoperative events such as post operative ionotropic use, mechanical ventilation time, sepsis, ICU & hospital stay. It is assumed that, A compensatory erythrocytosis have association with non-amenable significant post operative bleeding and need for blood transfusion.

## Study Limitation

It was a single-center study

Meanwhile, preoperative measurements of  $SpO_2$  were noninvasive

Age adjusted hemoglobin level for defining anemia is not validated

## Recommendations

Based on our study we strongly recommend for Considering Integrated value of Preoperative Hemoglobin level and Preoperative Oxygen saturation rather than using hemoglobin level only for detection of anemia in cyanotic children. Age adjusted hemoglobin level is more admissible for detection of anemia rather than using an absolute cut of value for cyanotic children.

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