

## Predictive Value of Vasoactive-inotropic Score for Mortality in Newborns Undergoing Cardiac Surgery

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**Objective:** Vasoactive-inotropic Score (VIS) was developed to quantify the amount of inotropic support provided in the postoperative period. We investigated the predictive value of (VIS) for mortality in neonates with congenital heart disease (CHD). **Study design:** Prospective cohort. **Patients:** 119 newborns who underwent cardiac surgery. **Setting:** Tertiary NICU-CHD center of Ankara from November 2016 to January 2019. **Intervention/Measurement:** VIS values were calculated by a standard formula for the first 72 postoperative hours, and the maximum score was recorded. **Primary outcomes:** Duration of mechanical ventilation, NICU length of stay, and mortality. **Results:** At surgery, the median (IQR) age was 15 d (9-31). The patients were divided into two groups according to mortality; Group 1 (Non-survivors) ( $n=36$ ) and Group 2 (Survivors) ( $n=83$ ). Higher VIS score was correlated to longer duration of mechanical ventilation ( $P=0.009$ ,  $r=0.33$ ), and was higher among patients who died ( $P=0.003$ ). Area under the curve (AUC) was 0,83 ( $P<0.001$ , CI: 95% 0.7-0.9) for VIS to identify mortality. At a cut-off value of 15.5, sensitivity and negative predictive values of VIS for mortality were 73.6% and 85.3%, respectively. The higher VIS ( $>15.5$ ) was independently associated with increased odds for mortality (OR: 8.1, 95% CI: 1.8-35.7,  $P=0.005$ ). **Conclusions:** In newborns with CHD, a higher VIS within 72 hours after cardiac surgery is associated with increased duration of mechanical ventilation, and mortality. VIS may be useful for prediction of mortality at early postoperative period.

**Keywords:** Congenital heart disease, Outcome, Repair, Survival.

The incidence of congenital heart disease (CHD) in the neonatal intensive care unit (NICU) has been reported as 3.7% in term and 6.8% in premature infants [1]; in Turkey, the prevalence rate is 7.7% [2]. Over the past three decades, significant technologic advances have improved outcomes in neonatal cardiac surgery [3,5]. There has been much research on the preoperative factors associated with poor outcomes, including patient demographics (anatomy, prematurity, weight, genetic syndrome), biological markers, and the creation of complexity scores [6-8]. However, there is a need to identify and quantify clinical factors during the early postoperative period that are indicative of short-term outcomes including mortality.

The repair or palliation of CHD often results in a decrease in cardiac output during the immediate postoperative period, and inotropic and vasoactive agents are routinely used after cardiac surgery in infants [9]. The Aristotle Basic Complexity (ABC) score in CHD surgery is a consensus-based scoring system developed early in

2000s in order to provide risk adjustment, and thus allow for a standardized comparison of performance between institutions [10-12]. In 1995, Wernovsky, *et al.* [13] created an Inotrope score [IS] aimed to quantify the amount of inotropic support provided in the postoperative period, which is frequently used for outcomes. More recently, Gaies, *et al.* [14] developed and tested vasoactive-inotropic score (VIS) in children <6 months of age undergoing cardiac surgery with cardiopulmonary bypass (CPB). VIS encompasses the original medications from the IS and adds milrinone, vasopressin, and norepinephrine. However, there is little information on the predictive values of VIS for mortality in newborns with CHD [15,16]. Therefore, we aimed to assess the predictive values of VIS for mortality and to compare them with ABC score in this population. We hypothesized that maximum VIS in the first 72 hours after cardiac surgery might predict mortality, and that we could define a cut-point that would effectively discriminate patients likely to have mortality in the postoperative period.

## METHODS

Our Neonatal intensive care unit (NICU) – Congenital heart disease (CHD) center serves as a reference hospital for newborns with CHD. In our NICU, the patients with CHD are followed-up in consultation with pediatric cardiologists. Cardiac surgeries can be performed in two centers (Dr Sami Ulus Training and Research Hospital, Ankara and Turkiye Yuksek Ihtisas Training and Research Hospital, Ankara). Sometimes cardiovascular interventions may be performed late because of wrong/late diagnosis of CHD in another center, delayed transfer of the patients, under-staffing of the departments, and clinical condition of the patients.

This was a prospective study enrolling consecutive newborns with CHD who were admitted to the NICU between November 2016 and January 2019. The newborns who did not require an urgent surgery, or those who died before the surgery were excluded. Informed written consent were obtained from the parents of all participants.

Basic demographic and clinical information of the patients including gender, gestational age and birthweight at delivery, postnatal age at surgery, anatomic diagnosis and surgical procedure were extracted from the patients' files and/or hospital computer-based system. Post-operative variables included duration of mechanical ventilation, presence of sepsis, pneumonia, hemato-logical dysfunction, liver dysfunction, renal failure (requiring dialysis), LCOS (oliguria, tachycardia, poor perfusion, or cardiac arrest that required high dose inotropic support), multiorgan dysfunction syndrome (MODS) ( $\geq 2$  organ dysfunctions), NICU length of stay, and mortality. Mortality was defined as the patient dying after surgery but before discharge from hospital, or death after hospital discharge but within 30 postoperative days.

All data were recorded in pre-tested structured forms. SNAPPE-II scores that predicts neonatal mortality on admission were noted for each patient [9,17,18]. For evaluating the cardiac surgery-related mortality risk, operations were categorized by using the ABC [11]. Scoring in ABC system varies between 1.5 and 15 and there are 4 difficulty levels (1.5-5.9=1st level, 6.0-7.9=2nd level, 8.0-9.9=3rd level, 10.0-15.0=4th level).

According to our unit protocol, inotropic and vasoactive medications were initiated in the operating room at the discretion of the attending surgeon and pediatric cardiologist. Decisions regarding ongoing titration of vasoactive/inotropic medications were made by the NICU physician team based on each patient's physiological state and did follow our NICU-CHD guidelines. Considerations involved in the choice of

medications included ventricular function, echocardiographic findings, and physiological parameters. The patients received milrinone and dopamine/dobutamine as first-line inotropic agents. The second-line agents were often epinephrine for hypotension with ventricular dysfunction or vasopressin or terlipressin for hypotension without ventricular dysfunction.

For each patient, VIS values were calculated by a standard formula for the first 72 postoperative hours, and the maximum score was recorded [14]. VIS: Dopamine dose ( $\mu\text{g}/\text{kg}/\text{min}$ ) + dobutamine dose ( $\mu\text{g}/\text{kg}/\text{min}$ ) +  $100 \times$  epinephrine dose ( $\mu\text{g}/\text{kg}/\text{min}$ ) +  $10 \times$  milrinone dose ( $\mu\text{g}/\text{kg}/\text{min}$ ) +  $10,000 \times$  vasopressin dose (Units/kg/min) +  $100 \times$  norepinephrine dose ( $\mu\text{g}/\text{kg}/\text{min}$ ).

Primary outcome was duration of mechanical ventilation. Secondary outcomes were NICU length of stay and mortality at 30 days postoperatively.

*Statistical analyses:* Statistical analyses were performed with IBM-SPSS (version 25, Chicago, SPSS Inc.), and  $P < 0.05$  was considered significant. Normality of data was analyzed by using Kolmogorov-Smirnov test. Demographic and clinical characteristics were compared between groups using Chi-square test for categorical variables and *t*-test or Mann Whitney U test, as appropriate, for continuous variables. Spearman correlation test was used for correlations.

To determine the predictive values for mortality, Area under the curve (AUC) of VIS was defined and compared with ABC. The best cut-off was chosen utilizing sensitivity and specificity from the Receiver operating characteristic (ROC) curve of the selected data. For multiple logistic regression modeling, variables that possibly related to mortality in newborns with CHD (gestational age, birthweight, 5 min APGAR score, age at diagnosis, age at surgery, SNAPPE-II, ABC and VIS) were chosen as candidate covariates.

## RESULTS

During the study period a total of 144 newborns with CHD were admitted to our NICU-CHD center. Among them 25 were not included in the study; 18 discharged without surgery (therapeutic catheterization or clinical follow-up), 7 died preoperatively. Finally 119 newborns who underwent cardiac surgery and followed up in our NICU postoperatively were included in the study.

Of 119 patients (53.3% males), the mean (SD) gestational age and weight were 38.3 (1.6) week and 3110 (550) g, respectively. The median (IQR) ages at diagnosis of CHD and NICU admission were 1.5 (1-5) and 3 (2-9) days. The rate of prenatal diagnosis was 31 (26%). None

of the patient was diagnosed by pulse oximeter screening test for CHD. About 79.8% ( $n=95$ ) of the patients were transferred to our unit from another NICU center. The most common presentation findings for CHD were respiratory distress (28.3%) and cyanosis (28.3%). Left sided ( $n=47$ , 39.5%), right sided ( $n=27$ , 22.7%), and mixing lesions ( $n=36$ , 30.3%) were the commonest (**Table I**).

At surgery, the median (IQR) age was 15 days (9-31). Overall mortality rate was 30.3%. The patients were divided into two groups according to mortality; Group 1 (Non-survivors) ( $n=36$ ) and Group 2 (Survivors) ( $n=83$ ). **Table II** shows demographic and clinical details of all patients by groups. Gestational age, birthweight, and gender were similar in groups. Duration of mechanical ventilation was longer in Group 1 ( $P<0.001$ ); postoperative complications were more frequent among non-survivors ( $P<0.001$ ). NICU length of stay was shorter in non-survivors ( $P=0.03$ ); VIS score was significantly higher in Group 1 compared to Group 2 ( $P=0.003$ ).

Greater VIS score was correlated to longer duration of mechanical ventilation ( $P=0.009$ ,  $r=0.33$ ). No correlation was detected with VIS, ABC, and NICU length of stay ( $P>0.05$ ). As seen in **Fig. 1**, VIS was the more successful in predicting deaths compared to ABC.

**TABLE I** TYPE OF CONGENITAL HEART DISEASES (CHD) IN NEONATES ENROLLED IN THE STUDY ( $N=119$ )

Type of CHD	No. (%)
<i>Left sided lesions</i>	47 (39.5)
Coarctation of aorta/left ventricular hypoplasia	33 (27.7)
Hypoplastic left heart syndrome	8 (6.7)
Aortic interruption	6 (5.0)
<i>Right sided lesions</i>	27 (22.7)
Pulmonary stenosis/atresia	20 (16.8)
Double outlet right ventricle	5 (4.2)
Hypoplastic right heart syndrome	1 (0.8)
Tetralogy of Fallot	1 (0.8)
<i>Mixing pathologies</i>	36 (30.3)
Transposition of great arteries	28 (23.5)
TAPVC	3 (2.5)
Truncus arteriosus	4 (3.4)
Univentricular heart disease	1 (0.8)
<i>Others</i>	9 (7.6)
Atrioventricular septal defect	4 (3.4)
PDA	5 (4.2)

CHD: Congenital heart disease, PDA: Patent ductus arteriosus, TAPVC: Total anomalous pulmonary venous connection.

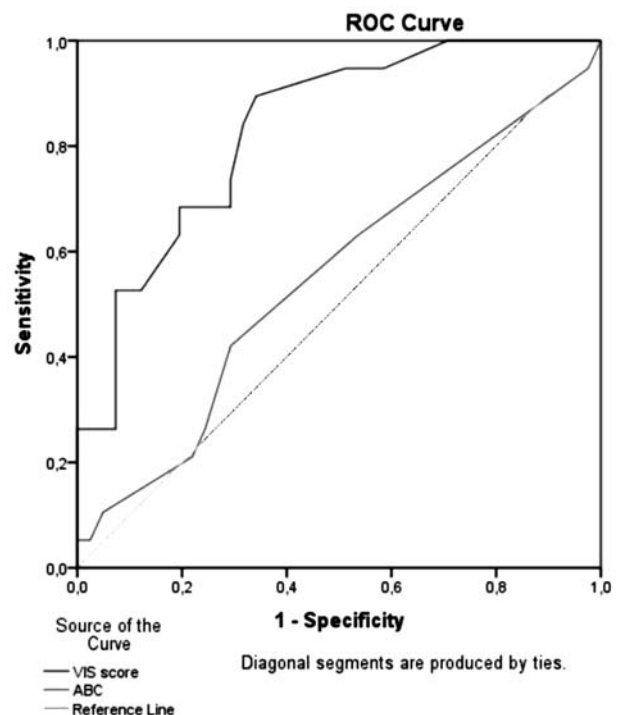
Area under the curve (AUC) was 0.83 ( $P<0.001$ , 95% CI: 0.7-0.9) for VIS to identify mortality. AUC was 0.55 for ABC ( $P=0.52$ ). At a cut-off value of 15.5, as defined by ROC analysis, sensitivity, specificity, the positive and negative predictive values of VIS for mortality were 73.6%, 70.7%, 53.8%, and 85.3%.

When gestational age, birthweight, 5 min APGAR score, age at diagnosis, age at surgery, SNAPPE-II, ABC and VIS were entered in the model, multivariate analysis showed that higher VIS ( $>15.5$ ) was independently associated with increased odds for mortality (OR: 8.1, 95% CI: 1.8-35.7,  $P=0.005$ ).

## DISCUSSION

In this study, we compared ABC and VIS scores in newborns after cardiac surgery. Our findings confirm that VIS, assessed in the first 72 hours after surgery, predicts mortality better than ABC in this population.

The ABC score, a procedure-adjusted scoring system, contains the sum of the potential for mortality, morbidity, and the anticipated surgical difficulty of the procedures. ABC is an appropriate tool for evaluating many CHD procedures. O'Brien, *et al.* [19] reported that when 'prolonged hospital stay' ( $>21$  days) was chosen as a marker of morbidity, there was a significant positive



**FIG. 1** Receiver operating characteristic (ROC) curve for Aristotle basic complexity (ABC) score, and vasoactive-inotropic score (VIS) for prediction of  $<30$ -day mortality after cardiac surgery.

**TABLE II** DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE PATIENTS BY MORTALITY GROUPS

	<i>Non-survivors (n=36)</i>	<i>Survivors (n=83)</i>	<i>P value</i>
Gestational age (wk)	37.9 (2.1)	38.4 (1.2)	0.18
Gender (male), <i>n</i> (%)	10 (52.6)	22 (53.7)	0.94
Birthweight (g)	2986 (624)	3167 (514)	0.24
*APGAR, 5 min	9 (8-9)	9 (7-9)	0.87
*Admission age (d)	2 (1-9)	4 (2-10)	0.21
*Age at diagnosis (d)	1 (1-3)	2 (1-7)	0.09
*Age at surgery (d)	14 (8-28)	17 (9-33)	0.07
<i>CHD type, n%</i>			
Left sided	14 (38.9)	33 (39.8)	
Right sided	8 (22.2)	19 (22.9)	
Mixing	13 (36.1)	23 (27.7)	
Other	1 (2.8)	8 (9.6)	0.82
<i>Operation type, n%</i>			
COA. resection/Hypoplastic arch repair	8 (22.2)	25 (30.1)	
BT shunt	6 (16.7)	20 (24)	
Pulmonary banding	1 (2.8)	8 (9.6)	
Arterial switch	10 (28)	18 (21.7)	
Pulmonary valvulasty	1 (2.8)	1 (1.2)	
Hybrid procedure	4 (11.1)	-	
Truncal repair	3 (8.3)	1 (1.2)	
Norwood	3 (8.3)	-	
TAPVC	-	3 (3.6)	
PDA ligation	-	5 (6.0)	0.04
APW repair	-	1 (1.2)	
ASD/VSD repair	-	1 (1.2)	
*Duration of mechanical ventilation (d)	15 (8-23)	7 (4-11)	<0.001
<i>Postoperative complications, n(%)</i>			
LCOS/Arrhythmia	10 (27.7)	7 (8.4)	
Sepsis/Pneumonia	4 (11.1)	9 (10.8)	
Renal failure (dialysis)	4 (11.1)	3 (3.6)	
Necrotizing enterocolitis	3 (8.3)	-	
Pulmonary hemorrhage	2 (5.5)	1 (1.2)	
MODS	5 (13.8)	1 (1.2)	<0.001
Diaphragm paralysis	-	4 (4.8)	
SNAPPE-II	20.8 (16.1)	15.9 (12)	0.19
Aristotle basic complexity score (ABC)	7.6 (2.3)	7.1 (1.7)	0.37
Vasoactive inotropic score (VIS)	49.8 (45.4)	13.9 (18.5)	0.003
NICU length of stay (d)	22 (15)	36 (28)	0.03

*ASD/VSD: Atrial/ventricular septal defect, APW: Aorticopulmonary window, CHD: Congenital heart disease, LCOS: Low cardiac output syndrome, MODS: Multiorgan dysfunction syndrome, NICU: Neonatal intensive care unit, PDA: Patent ductus arteriosus, SNAPPE-II: Score for Neonatal Acute Physiology with Perinatal Extension-II, TAPVC: Total anomalous pulmonary venous connection, All variables are expressed as mean (SD) except \*median (IQR).*

correlation with the ABC score. Similarly, Ereke, *et al.* [20] found that a longer ICU stay showed a significant

correlation with ABC scores. In the current study, maximum score for ABC was 14.5 in non-survivors and

**WHAT IS ALREADY KNOWN?**

- There is little data on the predictive ability of Vasoactive-inotrope Score (VIS) for mortality in newborns with congenital heart disease (CHD).

**WHAT THIS STUDY ADDS?**

- In newborns with CHD undergoing surgery, VIS measured in early postoperative period (<72 hours), may be useful for prediction of mortality.

11 in survivors, without significantly. We could not find any association between ABC and length of NICU stay or mortality. This may be caused by early death of more severely ill patients in our population. In non-survivors, although they were diagnosed at 2 day of life, surgery was not undertaken until average 14 days because of sepsis, hemodynamic instability or inadequate equipment.

Kumar, *et al.* [21] performed a retrospective analysis of 208 patients who underwent cardiac surgery for CHD and reported that VIS was an excellent tool to measure illness severity, deciding interventions, and during parental counseling in the pediatric cardiac surgery ICUs.

Sanil and Aggarwal [22] computed peak VIS within the initial 24 and 48 h after 51 consecutive open heart transplants. They have observed that the patients with peak VIS  $\geq 15$  constituted the high VIS group and these patients had significantly longer ICU stay, inotropic requirement and ventilatory durations, and higher rates of short-term morbidities. Recently, Yamazaki, *et al.* [23] reported that amount of cardiovascular support with high VIS at the end of surgery might predict morbidity and mortality in adults. Gaies, *et al.* [14] conducted a study among 391 infants with 141 (36%) neonates and determined empirically high VIS to be maximum VIS  $>15$  in the first 24 h. They reported high VIS was significantly associated with 30-day mortality, duration of mechanical ventilation and ICU stay. In our study, VIS scores were significantly higher among deceased patients; maximum score was 140 in non-survivors and 75 in survivors, respectively.

Davidson, *et al.* [16] reported that higher VIS at 48 hours after cardiothoracic surgery was strongly associated with increased length of ventilation, prolonged ICU and total hospital stay in neonates and infants. Similarly, we found a strong association between VIS and duration of mechanical ventilation, but not NICU stay. During the postoperative period, newborns generally require high levels of inotropic and vasoactive support, and clinicians were less likely to extubate the patient. It is likely that therapies capable of improving postoperative VIS would directly improve intubation times as well. The relationship between high VIS and prolonged NICU stay is also an

important issue. In many cases, NICU length of stay prolonged due to factors not directly associated with VIS such as sepsis, pneumoniae, MODS, poor feeding, phrenic nerve injury, and chylothorax. It is possible that high VIS is simply a marker for poor physiology in the early postoperative period. However, this poor physiology may later lead to prolonged therapies, feeding intolerance, impaired cardiac and pulmonary functions. In this study, no correlation between VIS and NICU length of stay can be explained with the earlier death of the patients with higher VIS.

Our study has a number of limitations. It reflects a single NICU experience in a well defined neonatal population. The performance of the surgeries in two different centers might have affect the postoperative outcome of the patients. Although the clinical management was under protocol, patient progression may have been affected by variations in the practices of neonatologist in charge. However, it is an important study that defines predictive values of VIS in newborns with CHD after cardiac surgery by comparing them with ABC.

The Vasoactive-Ventilation-Renal (VVR) score is a novel disease severity index that incorporates validated markers of cardiovascular, pulmonary, and renal function [24]. Recently, in a multicenter cohort study performed on newborns who underwent cardiac surgery, Cashen, *et al.* [24] showed that the VVR was a reliable predictor of postoperative outcome and outperformed more traditional measures of disease complexity and severity. Another score available is Society of Thoracic Surgeons - European Association for Cardio-Thoracic Surgery Congenital Heart Surgery Mortality Categories (STAT Mortality Category) [25] for prediction of morbidity and mortality risk in newborns underwent CHD surgery.

The results of this study showd that VIS is more useful than ABC in prediction of neonatal mortality in newborns after cardiac surgery. A high VIS ( $>15.5$ ) within 72 hours should trigger clinician awareness that the infant in question continues to be at risk for poor outcome. Further research should be designed as multi-centered and adequately powered to detect small differences in short term outcomes, especially mortality.

Long term follow-up is needed to evaluate neurologic outcome and long term morbidity and mortality.

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