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Prevalence of Post-Operative Bleeding and Its Associated Factors in Children Undergoing Open Heart Surgery at a Children's Hospital in a Low and Middle Income Country

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Background

Bleeding in children after cardiac surgery is a frequent complication,[1,2] which has been associated with increased postoperative morbidity, mortality, prolonged length of hospitalization and increased costs.[5,8,20] Significant blood loss has been attributed to surgical sources, patient-related factors or the development of coagulopathy secondary to an inflammatory response activated by: cardiopulmonary bypass (CPB), hypothermia, hemodilution, heparin use, and protamine over dosage.[4,7,13,15,16] Further, other factors specifically associated with infants and neonates include the immaturity of the hemostatic system, the higher degree of bypass hemodilution, and the presence of long and complex cardiac repairs with extensive suture lines, and put them at higher risk of excessive postoperative bleeding (EPOB).[4,13,15,16]

Low and middle-income countries, such as Vietnam, also suffer from limited resources for cardiac surgery; in particular, lack of appropriate CPB circuits for infant and neonatal patients, a shortage in the use of cell-saver technology, and thromboelastometry for hemostasis tests. Further, the high operative patient volumes many centers have may result in pressure on the operative team for rapid operating room (OR) turnover and may further contribute to postoperative hemorrhage and its poor outcomes. Of every 10 to 12 patients undergoing CPB surgery each week at our institution, two to three cases are noted to develop postoperative bleeding. However, a quantitative evaluation of post-operative bleeding has not been well described in our cardiac intensive care unit (CICU). Knowledge of specific factors that result in EPOB would allow for earlier OR and/or CICU interventions resulting in a decrease in EPOB, with a potential reduction in morbidity, mortality, and cost, and could result in saving scarce blood resources in our community allowing for increased surgical opportunity for other CHD children.

Objectives

The goal of this study was to determine the EPOB rate and its associated factors in children with Congenital Heart Disease (CHD) who underwent cardiac surgery with CPB at Children's Hospital 1, Ho Chi Minh City, Vietnam.

Methods

A cross-sectional study was conducted on 295 pediatric patients who underwent open heart surgery and postoperatively attended at CICU at Children's Hospital 1, a tertiary referral

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hospital in Ho Chi Minh City between December 23, 2018 and August 30, 2019.

EPOB was defined as a blood loss that exceeded 10% of the patient's total expected blood volume within the first six post-operative hours after admission to CICU.

Sample size was calculated by using the following formula:

$$n = \frac{Z^2_{(1-\alpha/2)} p(1-p)}{d^2}$$

When ***n*** is the sample size, **Z (1-α/2)** is the statistic corresponding to level of confidence **(Z (1-α/2)** = 1.96 with 95% confidence); α is the significance level (α= 0.05), d is the precision (d= 0.055), P is expected prevalence (obtained from the study by Isabel Znaya Ramifrez-Flores, et al at a hospital in Mexico, p= 0.33).[13] The minimum calculated sample size was 281 samples. The actual sample size included in this study was 295 cases.

Convenience sampling was used.

Inclusion Criteria

- Patients undergoing cardiac surgery with CPB admitted to CICU during the study period.

Exclusion Criteria

- Presence of congenital or acquired coagulopathy before surgery, defined as
  - A platelet count < 100x 10 9 /L
  - Activated thromboplastin time (aPTT) > 45 seconds
  - Prothrombin time (PT) < 70%
  - Fibrinogen < 100 mg/dL
- Patients with kidney disease (creatinine level > 1.5 mg/dL and or renal replacement therapy) or liver disease (aspartate aminotransferase and alanine aminotransferase higher than twice its normal value) before surgery.
- Patients who died in the OR or less than six hours after admission to CICU.

Clinical Data Collection

The following information was prospectively collected: Age, sex, weight, height at the time of surgery, surgical complexity according to the risk adjustment for congenital heart surgery-1 (RACHS-1) classification, type of congenital heart disease (CHD), preoperative and postoperative hemostasis tests (platelet count, aPTT, PT, Fibrinogen), operation time, CPB time, aortic cross clamp time, rectal temperature on arrival to CICU, blood loss volume from the chest tube (CT) every hour during the first six hours and at 24 hours after admission to CICU, the need for chest reopening due to bleeding, transfusion of blood products during and after the surgery.

Ethics

The study was approved by the Scientific Council of Children's Hospital 1 before implementation of the research (Decision No.441/QD-BVND1). The rights and personal information of the patients were protected in accordance with the Council's regulations.

Statistical Analysis

Epidata version 4.0 was used for data entry and SPSS version 20.0 was applied for data analysis. A descriptive analysis was carried out by calculating frequencies, percentages, median and ranges for qualitative and quantitative variables, respectively. We performed a bivariate analysis using chi-square, student's t-test and Mann-Whitney U test, when appropriate. All variables with a P < 0.05 were introduced into a binomial logistic regression analysis to identify independent risk factors for EPOB and predict the probability of EPOB. The threshold of significance was selected as P< 0.05. Adjusted odds ratios (aORs) and 95% confidence intervals (95% CI) were obtained.

Results

Demographics and Prevalence of EPOB

During the study period, 318 cases underwent cardiac surgery with CPB, of which 295 patients were included for analysis, males

TABLE 1 *Demographics & Clinical Characteristics of the Patients Included in the Study*

Variables		Median (IQR)/Frequency (Percentage)	Range
Age (Day)		237 (118,5-514,5)	2-5024
Weight (Kg)		6 (4,5-9,3)	1,7-40
Pulse Oximetry (%)		96 (88-98)	50-100
Nutrition status (WHO 2005)	Normal	150 (50.8)	
	Malnutrition	118 (40)	
	Overweight- Obesity	27 (9.2)	
Type of CHD	Acyanotic	211 (71.5)	
	Cyanotic	84 (28.5)	
Surgical complexity (RACHS-1)	RACHS-1# 1	15 (5.1)	
	RACHS-1# 2	204 (69.2)	
	RACHS-1# 3	36 (12.2)	
	RACHS-1# 4	40 (13.6)	
Operation time (min)		165 (130- 245)	75-460
Cardiopulmonary bypass time (min)		91 (69-147)	24-328
Aortic cross clamp time (min)		55 (39,5-95)	0-213
Rectal temperature on arrival to CICU (Degree C)		35.5 (34.9-36.1)	31.2-38

TABLE 2 *Clinical Characteristics Associated with EPOB*

Variables		Total patients	Bleeding	P
Age group	Neonates	16	10 (62.5%)	< 0.0001
	Infants	174	66 (37.9%)	
	Children	105	20 (19%)	
Weight group	< 5kg	92	43 (46.7%)	< 0.0001
	5-< 10 kg	134	44 (32.8%)	
	≥ 10 kg	69	9 (13%)	
Type of CHD	Acyanotic	211	52 (24.6%)	< 0.0001
	Cyanotic	84	44 (52.4%)	
RACHS-1	RACHS-1# 1	15	0 (0%)	< 0.0001
	RACHS-1# 2	204	52 (25.5%)	
	RACHS-1# 3	36	16 (44.4%)	
	RACHS-1# 4	40	28 (70.7%)	

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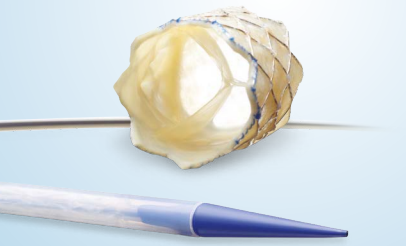

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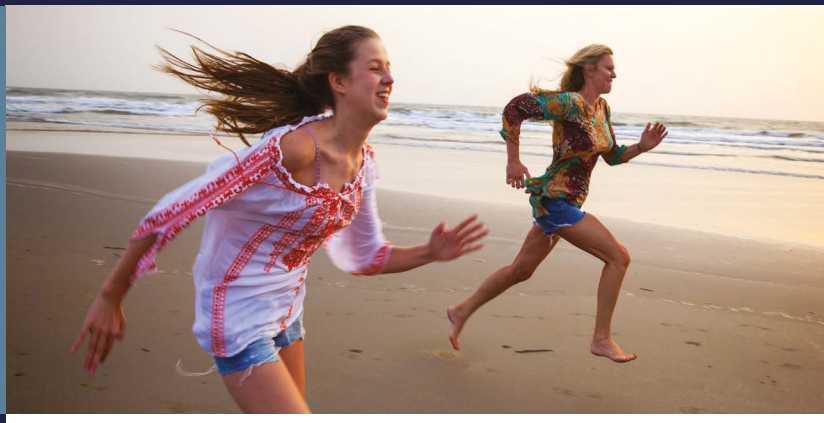

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- **DO NOT implant in the aortic or mitral position. Pre-clinical bench testing of the Melody valve suggests that valve function and durability will be extremely limited when used in these locations.**
- DO NOT use if patient's anatomy precludes introduction of the valve, if the venous anatomy cannot accommodate a 22 Fr size introducer, or if there is significant obstruction of the central veins.
- DO NOT use if there are clinical or biological signs of infection including active endocarditis. Standard medical and surgical care should be strongly considered in these circumstances.
- Assessment of the coronary artery anatomy for the risk of coronary artery compression should be performed in all patients prior to deployment of the TPV.
- To minimize the risk of conduit rupture, do not use a balloon with a diameter greater than 110% of the nominal diameter (original implant size) of the conduit for pre-dilation of the intended site of deployment, or for deployment of the TPV.
- The potential for stent fracture should be considered in all patients who undergo TPV placement. Radiographic assessment of the stent with chest radiography or fluoroscopy should be included in the routine postoperative evaluation of patients who receive a TPV.
- If a stent fracture is detected, continued monitoring of the stent should be performed in conjunction with clinically appropriate hemodynamic assessment. In patients with stent fracture and significant associated RVOT obstruction or regurgitation, reintervention should be considered in accordance with usual clinical practice.

Potential procedural complications that may result from implantation of the Melody device include the following: rupture of the RVOT conduit, compression of a coronary artery, perforation of a major blood vessel, embolization or migration of the device, perforation of a heart chamber, arrhythmias, allergic reaction to contrast media, cerebrovascular events (TIA, CVA), infection/sepsis, fever, hematoma, radiation-induced erythema, blistering, or peeling of skin, pain, swelling, or bruising at the catheterization site. Potential device-related adverse events that may occur following device implantation include the following: stent fracture,* stent fracture resulting in recurrent obstruction, endocarditis, embolization or migration of the device, valvular dysfunction (stenosis or regurgitation), paravalvular leak, valvular thrombosis, pulmonary thromboembolism, hemolysis.

*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

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- RVOT unfavorable for good stent anchorage
- Severe RVOT obstruction, which cannot be dilated by balloon
- Obstruction of the central veins
- Clinical or biological signs of infection
- Active endocarditis
- Known allergy to aspirin or heparin
- Pregnancy

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*The term "stent fracture" refers to the fracturing of the Melody TPV. However, in subjects with multiple stents in the RVOT it is difficult to definitively attribute stent fractures to the Melody frame versus another stent.

For additional information, please refer to the Instructions for Use provided with the product or available on http://manuals.medtronic.com.

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accounted for 57.3% (n=169). Neonates and infants accounted for 64.4% (n=190). **Table 1** gives an outline of main demographics and clinical characteristics of the patients included in the study.

Among the 295 cases, 1.4% (n=4) experienced an emergency procedure, 94.2% (n=278) received elective operation and 4.4% (n=13) got re-do surgery.

Overall, 96 of 295 (32.5% [95% CI, 27.2%-38.2%]) patients suffered from EPOB. Neonates and infants had a 40% (n=76) incidence of EPOB. Only three patients (1%) underwent chest reopening for hemostasis. A total of 2.4% (n=7) patients died in the CICU after surgery.

Risk Factors of EPOB

Clinical characteristics associated with EPOB are summarized in **Table 2**. In comparing the study patients, the proportion of patients with EPOB was more than threefold greater if a patient was a neonate and twofold greater if the patient was an infant.

The patients with body weight at the time of surgery less than 5 kg and from 5 to less than 10 kg, had the prevalence rate ratio (PRR) for EPOB 3.6 and 2.5 times higher than children with body weight from 10 kg and above respectively.

TABLE 3 *Surgical and Postoperative Data*

Variables	Bleeding (Median- IQR)	Non- Bleeding (Median-IQR)	p
Operation time (min)	240 (150-300)	150 (125-213)	< 0.0005
Cardiopulmonary bypass time (min)	140 (93-195)	82.5 (66-115)	< 0.0005
Aortic cross clamp time (min)	84 (57-120)	48 (36-77.7)	< 0.0005
Rectal temperature on arrival to CICU (Degree Celsius)	35 (34,3-35,8)	35,8 (35-36,3)	< 0.0005
Postoperative aPTT (second)	45,1 (41,5-50,5)	41,2 (36,5-46,3)	< 0.0005
Postoperative PT (%) Mean- 95% CI)	56,8 (54,9-58,7)	60,7 (59,3-62,1)	0.001
Postoperative Fibrinogen (mg/dl)	1,78 (1,58-2,11)	1,78(1,56-2,07)	0.9
Postoperative Platelet (x 10^9/L)	203 (131-299)	161 (124-219)	0.04

The rate of EPOB in children with cyanotic CHD was twofold greater compared to that of children with acyanotic CHD.

EPOB increased across the RACHS-1 classes. No patient with RACHS-1 Class 1 developed EPOB, while more than 70% of patients with RACHS-1 Class 4 suffered bleeding after procedure (P < 0.0001).

Surgical and postoperative data are outlined in **Table 3**. The median of surgical time, CPB time, aortic cross clamp time, and postoperative aPTT of the bleeding group were significantly higher than the non-bleeding group (p<0.0005). The mean percentage of postoperative PT of the bleeding group was significantly lower than the non-bleeding group. There was no difference in postoperative fibrinogen level between the two groups (p=0.9). The platelet count after surgery in the bleeding group was significantly higher than the non-bleeding group (p=0.04).

The results of bivariate analysis of individual risk factor for EPOB using chi-square test are summarized in **Table 4**. Variables

TABLE 4 *Postoperative bleeding risks model*

Univariate postoperative bleeding risks model			
Risk factor	**Odds ratio**	**95% CI**	**P value**
Neonate & Infant	2.83	1.6-4.99	< 0.0005
Weight at surgery <6 kg	2.5	1.5-4.09	< 0.0005
Cyanotic CHD	3.4	1.98- 5.72	< 0.0005
RACHS-1 score >2	4.4	2.54- 7.67	< 0.0005
CPB time > 90 mins	5.5	3.16- 9.5	< 0.0005
Temperature on arrival to CICU < 35^0 C	3.5	2-6	< 0.0005
Post-operative aPTT > 41 sec	3.9	2.17-6.84	< 0.0005
Blood loss second hour > 2.45 ml/kg/h	65.3	19.51-218.74	< 0.0005
Multivariate postoperative bleeding risk model 1 (excluding early blood loss rate and long postoperative aPTT)			
Risk factor	**aORs**	**95% CI**	**P value**
Neonate & Infant	2.8	1.46- 5.24	.002
CPB time > 90 mins	5.2	2.86- 9.34	< 0.0005
Temperature on arrival to CICU < 35^0 C	1.6	0.88- 3.06	0.285
Multivariate postoperative bleeding risk model 2 (including early blood loss rate and long postoperative aPTT)			
Risk factor	**aORs**	**95% CI**	**P value**
Neonate & Infant	1.7	0.75- 3.93	0.202
CPB time > 90 mins	5.7	2.71- 12.14	< 0.0005
Temperature on arrival to CICU < 35^0 C	1.5	0.71- 3.27	0.285
Post-operative aPTT > 41 sec	2.6	1.19-5.76	0.017
Blood loss second hour > 2.45 ml/kg/h	64.1	17.19-238.96	< 0.0005

independently associated with postoperative bleeding are detailed in **Tables 5 and 6**.

Binomial logistic regressions were performed to ascertain the effects of risk factors including young age (less than one year old at the time of surgery), low body weight (body weight less than 6 kg), cyanotic CHD, high RACHS-1 score (RACHS-1 score >2), prolonged bypass time (bypass time longer than 90 minutes), low core temperature (temperature immediately post CICU admission less than 35°C), prolonged postoperative aPTT (post-operative aPTT >41 sec), high early blood loss rate (CT output at two hours post CICU admission >2.45 ml/kg/h) on the likelihood that participants might have postoperative bleeding.

Variables were added to the model one at a time in order of the magnitude of the chi-square association, starting with the largest estimate. At each step, changes to the model were examined to access multicollinearity and instability in the model. When a standard error increased by more than 10% when another variable was added to the model, the variable was removed to make the model more precise.

In the model summary **Table 5**, risk factors comprising prolonged bypass, high RACHS-1 score, low temperature, cyanotic CHD, young age, low body weight were respectively included in the model. Three variables (high RACHS-1 score, cyanotic CHD and low body weight) were unable to be retained in the model as they increased the standard error more than 10% when added. This logistic regression model was statistically significant, $X^2(3)=59.669$, p<0.0005. The model explained 25.5% (Nagelkerke R^2) of the variance in postoperative bleeding and correctly classified 74.6% of cases. Sensitivity was 60.4%, specificity was 81.4%, positive predictive value was 61% and negative predictive value was 81%.

When the other two risk factors, including high early blood loss rate and prolonged postoperative aPTT, were added to the model, the logistic regression model as showed in **Table 6** was statistically significant, $X^2(5)=151.738$, $p<0.0005$. The explanation of the model for the variance in postoperative bleeding increased from 25.5% to 56.1% (Nagelkerke R^2) and it correctly classified 82% of cases. Sensitivity was 61.5%, specificity was 92%, positive predictive value was 90.8% and negative predictive value was 83.2%. Of the five predictor variables, only three were statistically significant: prolonged bypass time, prolonged postoperative aPTT, and early blood loss rate (as shown in **Table 6**). Group with CT output at the second postoperative hour more than 2.45 ml/kg/min had 64.1 times higher odds to exhibit postoperative bleeding than the other group. Bypass time more than 90 minutes and postoperative activated prothrombin time more than 41 seconds were associated with an increased likelihood of exhibiting postoperative bleeding.

Discussion

In this study, we found that one-third of our cohort study children developed EPOB, exceeding the amount described in previously published literature. CPB time, postoperative aPTT, CT output at the second hour post CICU admission were all independently associated with postoperative bleeding and could be used to predict the probability of EPOB in children with moderate sensitivity and high specificity.

Compare to other authors utilizing the same published definition, for instance Savan in 2014 reported an incidence of 24%[15] and Farouni in 2015 disclosed a rate of 23%,[3] our EPOB prevalence was elevated. This is probably due to the fact that almost two-thirds of our study population were neonates and infants who had lower body weight at the time of surgery. Previous studies have shown that younger age, especially newborns, are at high risk for bleeding after surgery.[6,19] Therefore, it is not surprising that our neonates and infants were more likely to experience EPOB in both univariate and multiple variate analyses (**Tables 4 and 5**). Children younger than six months of age have lower levels of clotting factors and anticoagulants than older children and adults. Because of this balance, healthy children are at less risk of bleeding or thrombosis. However, this delicate balance can easily be broken by medical interventions, especially after cardiac surgery with CPB.[18]

TABLE 5 *Multivariate postoperative bleeding risk model 1 (excluding early blood loss rate and long postoperative aPTT)*

Risk factor	aORs	95% CI	P value
Neonate & Infant	2.8	1.46- 5.24	.002
CPB time > 90 mins	5.2	2.86- 9.34	< 0.0005
Temperature on arrival to CICU < 35^0 C	1.6	0.88- 3.06	0.285

TABLE 6 *Multivariate postoperative bleeding risk model 2 (including early blood loss rate and long postoperative aPTT)*

Risk factor	aORs	95% CI	P value
Neonate & Infant	1.7	0.75- 3.93	0.202
CPB time > 90 mins	5.7	2.71- 12.14	< 0.0005
Temperature on arrival to CICU < 35^0 C	1.5	0.71- 3.27	0.285
Post-operative aPTT>41 sec	2.6	1.19-5.76	0.017
Blood loss second hour > 2.45 ml/kg/h	64.1	17.19-238.96	< 0.0005

In another study, Miler et al[10] demonstrated that children less than 8 kg had more post-operative bleeding than other children after CPB. Recently, Savan et al[15] showed that children weighing less than 6.5 kg were at increased risk of bleeding. Lower body weight increases the risk of bleeding possibly due to hemodilution in the CPB circuit, heat loss during and after CPB and complex surgical tissue manipulation in more complex surgeries resulting in potential tissue and vessel damage. Our result supported these findings in univariate analysis (**Table 4**).

In addition, the presence of cyanotic CHD & higher RACHS-1 score have been shown to be risk factors for postoperative bleeding.[6,15] High RACHS-1 class was associated with more complex surgeries with extensive aortic suture lines, prolonged CPB, and performed on younger patients. Children with cyanotic CHD may have decreased platelet aggregation, prolonged bleeding time with normal platelet counts, and may have diffuse chronic intravascular coagulation.[4,5,13,15,16] Our findings contributed to these associations in univariate analyses. However, in binomial logistic regression, low body weight, cyanotic CHD and high RACHS-1 score were excluded. A possible explanation for this is that, patient weight, age, type of CHD and RACHS-1 can all be closely interrelated that might make these variables become multicollinearity when included in the model.

Many studies have revealed that bypass time longer than 90 minutes, aortic clamping time over 60 minutes are the risk factors for post bypass bleeding.[11,13] Our results reinforced this.

Previous studies carried out by Williams et al[19] and by Miller et al[10] demonstrated that thrombocytopenia at the end of CPB represented a risk factor for post-surgical bleeding. In our study, by contrast, postoperative platelet count of the bleeding group was higher than that of the non-bleeding group. This is because post-surgical tests were conducted when the patients had already received platelet concentrates at the end of CPB by the anesthesiology team, modifying the results.

In the same context, there was no significant difference in post-surgical fibrinogen between the two groups. During the study period, we noticed that cryoprecipitate was transfused at the end of CPB in almost all patients while the fresh frozen plasma was sent to CICU for transfusion. Since guiding tests such as thromboelastography and rotational thromoelastometry were not used to ascertain which factors should be given to individual patients, the blood product transfusion was made based on our anesthesiologist's experience. This may lead to circulatory overload and ineffective bleeding control, which contribute to an even greater increase in mortality and morbidity for these patients. From published literature, these tests have been demonstrated to be useful in decreasing the exposure to allogenic blood products, lowering mortality and costs.[3,18]

Hypothermia helps reduce the metabolism of organs, protecting the heart and brain during open heart surgery. Without adequate warming after coming off bypass, the patient's body temperature will continue to decrease in CICU, causing serious postoperative complications related to hypothermia such as cardiac dysfunction, postoperative coagulopathies and postoperative infections.[9,12,14,17] When the body temperature is rewarmed to 37°C, the functional quality of platelet and coagulation factors are restored. Our study

Echocardiography Faculty Opportunity

The Heart Institute at Cincinnati Children's invites Pediatric Cardiologist at the Assistant, Associate, or full Professor level with an interest in echocardiography and a strong track record in echocardiography research to advance the academic output and reputation of the echo lab at Cincinnati Children's.

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Appropriate medical credentialing through the Medical Staff Services offices
Completion of all required pre-employment activities
Current Assistant or Associate Professor appointment or eligibility required.

Preferred
Board certification Pediatric Cardiologist

Expectations
The applicant would be expected to participate in clinical service including (but not limited to):
Perform/interpret transthoracic and transesophageal echocardiograms.
Perform a single out-patient clinic on a weekly basis.
Provide limited periods of in-patient and/or consult service coverage.
Participate in all Heart Institute clinical and management conferences.
Perform teaching and instruction commensurate with the training mission of the Heart Institute at Cincinnati Children's
Develop and lead new research programs within the echo lab with significant dedicated time protected for research activities.

Interested candidates should address all inquiries to:

Andrew Redington, MD
Co-Director, The Heart Institute
Cincinnati Children's Hospital Medical

Email a letter of intent and CV c/o **Deborah.Mancini@CCHMC.org**

observed that the median patient's body temperature on arrival to the CICU was significantly lower in the bleeding group in univariate analysis (p< 0.0005), but this finding lost significance after multivariate analysis (p=0.28). One possible interpretation of this result is that the effect of temperature on blood loss can be explained by its relationship to the cofounders of bypass time and aPTT.

EPOB often begins early in the postoperative period. In this study, it was observed that CT output at the second hour after admission to CICU tended to peak and was most significantly associated with CT output later in the postoperative period. This finding revealed that high early CT output may be a useful advance warning signal of probable EPOB. This concept was also demonstrated in previously published studies. In 1999, William et al[19] indicated that 64% of patients who bled excessively in the CICU met the criteria for excessive CT output within two hours after arrival in the CICU.

Our finding provided additional support for previous studies regarding prognosis models for EPOB. Recently, Savan et al[15] have proposed a predictive model of bleeding including three factors: weight, cyanotic CHD, hemostasis time. Our three predictors are not entirely similar to these studies, possibly due to our different research population and practice.

When the high early CT output and long postoperative aPTT were excluded from the model, prolonged CPB time and younger age became the variables most significantly associated with EPOB. Other pediatric cardiac studies have reported age and CPB time are the most significant variables and an easy, early and practical method for identifying children at risk of EPOB.[4,15,19]

Our study has several limitations. First, due to the nature of this cross-sectional study, postoperative events were not measured in chronological order. Consequently, a cause and effect relationship cannot be assumed. Second, from multivariate analysis by logistic regression, we can calculate the probability of bleeding after pediatric cardiac surgery. However, these are preliminary results and need to be confirmed in a larger cohort study. Our sample size was calculated based on the prevalence of EPOB, it was not sensitive enough for detecting significant association between some variables and EPOB in logistic regression model. Finally, as our practice of blood and blood product transfusions relied on the experience and practices of individual anesthesiologists, we were unable to use the amount of blood transfusion as an indicator of blood loss when defining bleeding as some previous studies did.

Conclusion

Our study showed that 32.5% of the study cohort children developed EPOB. CPB time, postoperative aPTT, early CT output at the second hour can be used to predict the probability of EPOB in children with a sensitivity of 61.5% and specificity of 92%. A quality improvement program is needed to reduce the EPOB rate and its complications at our institute. The findings of this study will enable us to identify children who will potentially bleed excessively postoperatively in our CICU and to refine our protocols for preoperative preparation and postoperative management of these children.

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Nicklaus Children's Hospital
Heart Program

Outstanding Opportunity for a BC/BE Pediatric Cardiac Intensivist in Miami

The Heart Program at Nicklaus Children's Hospital, a 309-bed freestanding children's hospital, and Nicklaus Children's Pediatric Specialists, the physician multispecialty group practice of Nicklaus Children's Health System, have an exceptional opportunity for a BC/BE pediatric cardiac intensivist.

Our Cardiac Intensive Care Unit (CICU) was the first in the Southeast and provides care for newborns and children receiving treatment for congenital heart defects. With a longstanding tradition of excellence, our cardiac critical care team is currently comprised of six full-time attending physicians and six full-time nurse practitioners. We have an illustrious cardiology fellowship and have offered advanced training in cardiac critical care medicine for more than 20 years. The desired candidates should be board certified or eligible in pediatric critical care medicine or pediatric cardiology. Preference will be given to individuals with dual training in pediatric critical care and cardiology or those board eligible in either cardiology or pediatric critical care who have completed a minimum of one year of advanced training in cardiac intensive care medicine. Applicants should exhibit a strong interest in clinical care, education and academics. Nicklaus Children's Hospital is an affiliate of the Florida International University Herbert Wertheim College of Medicine. Candidates possessing all levels of experience shall be considered.

Our state-of-the-art Advanced Pediatric Care Pavilion houses a 34-bed cardiac in-patient unit with an adjustable acuity model that allows all rooms to accommodate critically ill patients with heart disease. The Heart Program offers a full range of services, including the management of patients following congenital heart surgery, interventional catheterization and invasive electrophysiology. Our cardiac surgical program, led by Dr. Redmond Burke, is one of the most transparent in the world. It remains the only cardiovascular surgical program to offer real-time outcomes reporting (**https://rto.nicklauschildrens.org**).

Founded in 1950, the rebranded Nicklaus Children's Hospital is renowned for excellence in all aspects of pediatric medicine and has numerous subspecialty programs that are ranked among the best in the nation. It is also home to the largest pediatric teaching program in the southeastern U.S. Our organization consistently appears on employer award lists such as Fortune magazine's "Best Workplaces In Health Care," Becker's "150 Great Places to Work in Healthcare" and People magazine's "50 Companies That Care." Join a phenomenal team that brings lifelong health and hope to children and their families through innovative and compassionate care.

The Heart Program at Nicklaus Children's, a world leader in pediatric cardiology and cardiovascular surgery for the care of children with congenital heart disease, serves as a beacon to families confronting the reality of a child or newborn with a heart defect.

Competitive compensation and benefits package.

Qualified candidates please contact:

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NicklausChildrens.org/NCPS
DFW

Phoenix Children's Earns Adult Congenital Heart Association Accreditation

Pediatric Health System is One of Only 38 Programs Nationwide to Earn Adult Congenital Heart Disease Accreditation

Phoenix Children's recently achieved accreditation as an Adult Congenital Heart Disease (ACHD) Comprehensive Care Center from the Adult Congenital Heart Association (ACHA), a nationwide organization dedicated to education, advocacy and research to improve the lives of those born with heart defects. Phoenix Children's is one of only 38 programs nationwide to receive accreditation and is the only hospital in Arizona to earn this distinction.

"ACHA accreditation signals to parents that their child will receive the best quality of care throughout their life," said Wayne J. Franklin, MD, FACC, Co-Director of the Heart Center and Director of Adult Congenital Heart Disease at Phoenix Children's.

Phoenix Children's is well-equipped to address adult congenital heart problems and provide the increasingly specialized care these patients need. With the shortage of cardiologists trained to treat ACHD, Phoenix Children's accreditation represents the organization's efforts to address this deficit in healthcare and provide an elevated standard of care for children who grow up to become adults living with Congenital Heart Disease.

"Not only do we have incredible examples of accomplished adult heart patients, but parents can also have the peace of mind knowing that they won't have to leave Phoenix Children's to continue their child's cardiac treatment as they grow up," said Jordan Awerbach, MD, MPH, Associate Director of the Adult Congenital Heart Disease Program at Phoenix Children's.

With nearly two million adults living with ACHD in the United States, the accreditation process aims to address the expert care required for this unique patient population. The rigorous accreditation evaluates the hospital's commitment to ACHD medical services, site compliance with best practices and protocols, and personnel requirements, including board-certified ACHD physicians, to ensure the quality of specialized patient care and experience to treat this disease.

"There are now more adults than children in the US with CHD," said Mark Roeder, President and CEO of the Adult Congenital Heart Association. "Accreditation will elevate the standard of care and have a positive impact on the futures of those living with this disease. Coordination of care is key, and this accreditation program will make care more streamlined for ACHD patients, improving their quality of life."

"Phoenix Children's is one of few systems qualified to address congenital heart problems from fetal life to adulthood," said Daniel Velez, MD, Co-Director of the Heart Center and Division Chief of Cardiothoracic Surgery at Phoenix Children's. "The subset of ACHD is rapidly increasing, and we will continue to provide these patients with our expert care."

The ACHD Program at Phoenix Children's cares for children transitioning from pediatric to adult cardiology care and ACHD patients across the broad spectrum of heart disease. The program sees more than 1,000 ACHD patients each year and performs over 50 ACHD heart surgeries annually. It is part of Phoenix Children's Heart Center, recognized by U.S. News & World Report as a nationally-ranked specialty.

About the Adult Congenital Heart Association

The Adult Congenital Heart Association (ACHA) is a national not-for-profit organization dedicated to improving the quality of life and extending the lives of adults with Congenital Heart Disease (CHD). ACHA serves and supports the nearly two million adults with CHD, their families and the medical community—working with them to address the unmet needs of the long-term survivors of congenital heart defects through education, outreach, advocacy, and promotion of ACHD research. For more information about ACHA, contact 888-921-ACHA or visit: **www.ACHAheart.org**.

About Phoenix Children's

Phoenix Children's is one of the nation's largest pediatric health systems. It comprises Phoenix Children's Hospital–Main Campus, Phoenix Children's Hospital–East Valley at Dignity Health Mercy Gilbert Medical Center, four pediatric specialty and urgent care centers, 11 community pediatric practices, 20 outpatient clinics, two ambulatory surgery centers and six community-service-related outpatient clinics throughout the state of Arizona. The system has provided world-class inpatient, outpatient, trauma, emergency and urgent care to children and families for more than 35 years. Phoenix Children's Care Network includes more than 850 pediatric primary care providers and specialists who deliver care across more than 75 subspecialties. For more information, visit:

http://www.phoenixchildrens.org

https://www.phoenixchildrens.org/centers-programs/adult-congenital-heart-disease

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Director of Cardiology Clinical Services

The Heart Institute is seeking an exceptional individual to lead the Clinical Services within the Division of Cardiology, actively participating with the Division Chief and Heart Institute Leadership in the supervision and development of clinical services, strategic planning, program coordination and expansion. The applicant should have demonstrated evidence of strong leadership skills and recognized expertise as academic physician. A commitment to excellence, integrity, collegiality and professionalism is a must. Applicants should be at the Associate Professor level (or above), and Board Certified in Pediatric Cardiology.

Director of Pediatric Non-Invasive Imaging (Echocardiography Laboratory)

For this leadership level position, we are seeking an outstanding board-certified pediatric cardiologist with strong expertise in non-invasive imaging including all forms of echocardiography and/or cardiac MRI & cardiac CT. Applicants should be at the Associate Professor level (or above). In addition, evidence of solid leadership skills to take the Director role and help build up the Non-Invasive Imaging Program, working closely with division chief and hospital leadership. Candidates must have completed a 4th year pediatric imaging advanced fellowship and demonstrated an academic commitment in the field of imaging, with dedication to teaching, research and quality improvement. Candidates must be Board Certified in Pediatric Cardiology.

Expert Pediatric Electrophysiologist

The applicant should be experienced in the management of pediatric EP and adult congenital heart disease electrophysiology with excellent clinical, teaching and research skills. Clinical skills should include radiofrequency/cryoablation, transvenous pacemaker/AICD insertion, ventricular tachycardia ablation and complex congenital heart disease EP cases. The well-established pediatric electrophysiology program is currently staffed by two experienced EP physicians and two dedicated EP RN. The EP team also works in close conjunction with the Heart-Vascular Institute of UPMC-Presbyterian adult hospital. According to academic rank and seniority candidate may be eligible to leadership position.

Adult Congenital Heart Disease Faculty

The Division of Cardiology at UPMC Children's Hospital of Pittsburgh / University of Pittsburgh School of Medicine is recruiting faculty to join the Adult Congenital Heart Disease (ACHD) program. This well-established program is currently supported by 2 ACHD physicians (including one ACDH Director), 2 advanced practice providers, a dedicated RN, research coordinator and social worker. The applicant should have expertise in the management of adult congenital heart disease with prominent clinical, teaching and research skills. He or she will work closely with division chief, ACHD Director, and hospital leadership to support program expansion. Candidates must be Board-Eligible/Certified in Pediatric Cardiology or Adult Cardiovascular Diseases and in Adult Congenital Heart Disease.

All positions come with a competitive salary and faculty appointment commensurate with experience and qualification requirements at the University of Pittsburgh School of Medicine.

Submit Your Interest or Learn More

Interested individuals should send a letter of intent, curriculum vitae, and three (3) letters of references to the following individual. Informal inquiries are also encouraged.

Jacqueline Kreutzer, MD, FSCAI, FACC – Chief, Division of Pediatric Cardiology
UPMC Children's Hospital of Pittsburgh, 4401 Penn Avenue, Pittsburgh, PA 15224
Telephone: 412-692-6903 and e-mail: Jacqueline.kreutzer@chp.edu

About Us

Regionally, nationally, and globally, UPMC Children's Hospital of Pittsburgh is a leader in the treatment of childhood conditions and diseases, a pioneer in the development of new and improved therapies, and a top educator of the next generation of pediatricians and pediatric subspecialists. UPMC Children's is ranked on the *U.S. News & World Report* Honor Roll for Best Children's Hospitals for 2020–2021.

Every year, more than 17,000 patients with congenital heart disease choose the Heart Institute at UPMC Children's Hospital of Pittsburgh when they need the most advanced, experienced, and comprehensive cardiac care available. The Heart Institute was named to *U.S. News & World* Report list of top Pediatric Cardiology and Heart Surgery programs, **ranking #2 nationally**. For four consecutive reporting periods, UPMC Children's pediatric cardiovascular surgery program was awarded a 3-star rating by the Society of Thoracic Surgeons. Learn more at chp.edu/our-services/heart.

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University of Maryland Children's Hospital Welcomes Acclaimed Surgeon Joseph Forbess, MD to Children's Heart Program

Dr. Joseph Forbess, one of the nation's most skilled surgeons in complex pediatric and neonatal cardiovascular cases, will serve as the program's Surgical Director

Leaders at University of Maryland Medical Center (UMMC) and the University of Maryland School of Medicine (UMSOM) recently announced that nationally renowned pediatric and neonatal cardiovascular surgeon Joseph M. Forbess, MD, MBA, is the new Surgical Director of the Children's Heart Program at the University of Maryland Children's Hospital. He has also been appointed Professor of Surgery in the Division of Cardiac Surgery at UMSOM.

"We welcome Dr. Forbess to the Children's Heart Program, an institution known worldwide for successfully treating the youngest cardiac patients—many with highly complex needs that can't be met anywhere else. Dr. Forbess brings pioneering innovations in surgery that will make a profound difference for these patients and their families," said Bert W. O'Malley, Jr., MD, President and Chief Executive Officer of UMMC, where the children's hospital is located.

Dr. Forbess is universally regarded as one of the top pediatric and neonatal cardiovascular surgeons in the field. He has consistently led programs that have both achieved 3-star rankings (the highest possible) from the Society of Thoracic Surgeons, and national prominence in the US News and World Report rankings. For the past three years, he was a Professor of Surgery at Northwestern University Feinberg School of Medicine. He also served as Chief of Pediatric Cardiovascular Surgery for Advocate Children's Hospital and Co-Director of the Advocate Children's Heart Institute in Park Ridge, Ill. Dr. Forbess will join K. Barry Deatrick, MD, Assistant Professor of Surgery at UMSOM and pediatric cardiovascular surgeon, to continue to build Maryland's nationally ranked Children's Heart Program.

"On behalf of the University of Maryland School of Medicine Department of Pediatrics and the University of Maryland Children's Hospital, I want to welcome Dr. Forbess to the Children's Heart Program, where his skills and drive to innovate will help save many young lives. We are thrilled that he is joining our team to provide the best complex pediatric care available—nationally and globally," said Steven J. Czinn, MD, the Drs. Rouben and Violet Jiji Endowed Professor of Pediatrics and Chair of the University of Maryland School of Medicine Department of Pediatrics and Director of the University of Maryland Children's Hospital.

Dr. Forbess brings an extensive background in research, with more than 100 research articles published in peer-reviewed journals focusing on surgical techniques and treatments for cardiac disease in neonates and young children. One of his latest research grants was to study the use of advanced wireless wearable sensors for home monitoring in pediatric patients with Congenital Heart Disease.

He recently developed an implantable miniaturized oximeter and has participated in the development of a synthetic cardiovascular graft that is now in clinical use. Presently, Dr. Forbess is leading a basic research effort that is focused on the development of surgical techniques to stimulate and amplify the innate regenerative capacity of the heart muscle.

"Dr. Forbess will be a highly valued addition to our cardiac surgery division with his expertise in the pediatric field, as we work to provide the most sophisticated level of care to children with cardiac conditions, ranging from rhythm abnormalities to the most complex heart operations," said James S. Gammie, MD, Professor of Surgery and Division Head of Cardiac Surgery at UMSOM.

Dr. Forbess obtained his undergraduate (BS) and MD degrees from Harvard University. He completed his General Surgery Residency and Cardiothoracic Fellowship at Duke University. He went on to complete a Congenital Heart Fellowship at Boston Children's Hospital and remained on the faculty there for several years. He subsequently was recruited to Emory University in Atlanta and then to University of Texas-Southwestern where he was Professor of Surgery, Chairman of the Division of Pediatric Heart Surgery, and the Pogue Distinguished Chair in Pediatric Cardiac Surgery Research. Dr. Forbess also has a healthcare-focused MBA Degree from the University of Texas -Dallas School of Management.

"I am thrilled to have Dr. Forbess join our faculty," said Christine Lau, MD, MBA, the Buxton Professor and Chair of the Department of Surgery at UMSOM. "As one of the preeminent surgeons in his field, he will be the linchpin to continue to grow our pediatric cardiac surgery program, which has been recognized as one of the nation's leading children's heart programs."

UMSOM Dean E. Albert Reece, MD, PhD, MBA, also praised the addition of Dr. Forbess to the school and Children's Heart Program.

"We are very pleased to welcome this gifted cardiac surgeon to the UM Medicine," said Dr. Reece, who is also Executive Vice President for Medical Affairs, UMB, and the John Z. and Akiko K. Bowers Distinguished Professor. "As we continue to push the boundaries of science in search of new therapeutic and surgical tools for our tiniest patients, Dr. Forbess will help us continue the transformation that is already taking place in our Children's Heart Program."

The University of Maryland Children's Hospital is ranked by US News & World Report as one of the "Best Children's Hospitals for Cardiology and Heart Surgery." Among children's hospitals nationally, the Children's Heart Program at the hospital ranks among the top 50 in the nation out of nearly 200 qualified pediatric heart centers. The hospital is known for pioneering novel approaches to improve the lives of patients with many different types of pediatric heart conditions, including successfully treating adults with Congenital Heart Disease; pioneering new ways to track, monitor, and treat heart conditions for babies in utero; and developing hybrid surgical and catheterization procedures for the most complex pediatric heart conditions as appropriate.

Learn more about the Children's Heart Program: **https://www.umms.org/childrens/health-services/pediatric-cardiology**

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Pediatric Cardiologist

Are you making an outsized difference to the public health and well-being of Americans? Would you like to? The physicians, scientists and other dedicated professionals at the U.S. Food & Drug Administration, Center for Drug Evaluation and Research, Office of New Drugs located in Silver Spring, MD, contribute to the public health of millions of Americans every day. We pride ourselves on our dedicated and skilled staff and are looking for committed individuals to help us achieve our mission. OND's mission is to ensure that safe and effective drugs and biologics are available to Americans. We provide guidance to drug companies on a wide variety of clinical, scientific and regulatory matters and make decisions on whether new drugs or new uses of already marketed drugs should be approved.

The Division of Cardiology and Nephrology within the Office of New Drugs is seeking highly qualified physicians to serve as clinical reviewers for drugs used for pediatric cardiovascular conditions. We are seeking individuals who are board certified or board eligible in pediatric cardiology. We are particularly interested in individuals with expertise and/or interest in pulmonary arterial hypertension, pediatric heart failure/cardiomyopathy, or pediatric arrhythmias. Graduating fellows and junior faculty are encouraged to apply.

Primary responsibilities of the clinical reviewer include the following:

- Determines whether clinical trials of new drugs and therapeutic biologics in humans are soundly conceived and supported to justify human testing
- Reviews clinical protocols and provides input regarding study design
- Together with other team members, interacts with investigators and drug companies to guide development of drugs and therapeutic biologics
- Determines whether marketing applications should be approved based on an evaluation of the evidence of safety and effectiveness
- Consults, when needed and where appropriate, with other medical specialists and scientists within and outside FDA
- Assists in the development and conduct of training programs, educational activities, workshops and conferences
- Keeps abreast of the progress in medical and related sciences by reviewing the scientific literature and participating in staff seminars where cases and topics of interest are discussed

As a clinical reviewer, you will have the opportunity to:

- Advance the public health through new drug development;
- Experience teaching and training opportunities;
- Interact with pharmaceutical companies, world-renown disease experts, patients and advocacy groups; and
- Work with a wide range of scientific disciplines in a team-oriented atmosphere.

This position allows for one half-day per week of patient care, if interested.

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Applicants must have a Doctor of Medicine or Doctor of Osteopathy degree from an accredited medical school. Graduates of foreign medical schools must be certified by the Education Commission for Foreign Medical Graduates. Candidates must be U.S. citizens. Permanent U.S. residents may apply for staff fellowship appointments. Excellent oral and written communication skills and an ability to work effectively in a team are necessary to be successful in this role. A competitive candidate will have experience working with clinical data with enough knowledge and understanding of clinical trial design to evaluate extensive, long-range scientific programs, and their implications on the drug development process. Prior human subject research experience is desired, but not required.

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Please reference source code: #21-011EG in the subject line.

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BioIntelliSense and American College of Cardiology Join Forces to Advance Remote Cardiac Care and to Offer the BioButton COVID-19 Screening Solution at ACC.21

BioIntelliSense, Inc., a continuous health monitoring and clinical intelligence company, today announced the company has formed a strategic collaboration with the American College of Cardiology (ACC) that combines innovative medical-grade wearable devices and data science to advance remote patient monitoring programs for cardiac care. The ACC will also offer the BioButton™ COVID-19 Screening Solution to provide an added layer of safety at the *70th Annual Scientific Session & Expo* held May 15 – 17, 2021 in Atlanta.

BioIntelliSense

The FDA-cleared BioSticker and medical-grade BioButton wearable devices allow for continuous vital sign monitoring of temperature, heart rate and respiratory rate at rest to enable early detection of adverse vital sign trends through its proprietary biosensor technology and advanced analytics. The strategic collaboration will combine ACC's clinical expertise in heart health with BioIntelliSense's effortless user experience and multi-parameter monitoring to make remote cardiac care scalable, reliable, and cost effective.

ACC.21 will bring together cardiologists and cardiovascular specialists from around the world to share the newest discoveries in treatment and prevention. The ACC is committed to creating a healthy and safe environment for attendees, exhibitors and staff in line with all current directives and recommendations that will enable attendees to make informed and safe decisions about their attendance. In addition to all CDC recommended COVID-19 safety protocols, *ACC.21* conference attendees will have the option to participate in the BioButton COVID-19 Screening Solution for continuous vital sign and symptom monitoring for COVID-like infection. *ACC.21* is the first major medical conference to use the BioButton solution.

James Mault, MD, CEO of BioIntelliSense, commented, "We are proud to form a strategic collaboration with the American College of Cardiology to advance virtual care and remote patient monitoring (RPM) programs that can transform cardiac care. Together with the ACC, we can provide the cardiology community with medical-grade monitoring devices, clinically validated algorithms and RPM education that will have a profound impact on routine patient care globally. The inclusion of BioButton COVID-19 Screening Program to the safety measures for the ACC Scientific Session will also serve to provide their cardiovascular professional membership an opportunity to experience the simplicity of virtual care and effortless remote monitoring."

"The ACC – and the cardiovascular community as a whole – has a long history of advancing innovative solutions to transform cardiovascular care and patient outcomes," said ACC President Athena Poppas, MD, FACC. "We are excited by the opportunity to partner with BioIntelliSense and be on the cutting edge of an innovative technology with real-time health data and feedback."

AMERICAN COLLEGE of CARDIOLOGY

For more information on how BioIntelliSense is redefining remote patient monitoring through medical-grade and cost-effective data services, please contact us at **info@biointellisense.com** or visit our website at **BioIntelliSense.com**.

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