

## **The Impact of Prenatal Diagnosis on Length of Stay for Neonates with Congenital Heart Disease**

### **1. Study Purpose and Rationale**

Congenital heart disease (CHD) accounts for one third of major congenital anomalies and 1.35 million neonates are born with congenital heart disease worldwide each year<sup>1</sup>. Due to prenatal and early neonatal diagnosis of congenital heart disease in association with advances in NICU care and neonatal cardiac surgery, outcomes for infants born with critical CHD are improving tremendously. Increased length of stay (LOS) for neonates is associated with increased incidence of iatrogenic events, increased risk of nosocomial infections and greater financial burden and resource utilization<sup>2,3</sup>. Thus, identifying factors associated with increased length of stay in this complex patient population is essential to improving medical outcomes for patients and their families as well as containing costs for the healthcare system as a whole.

One of the first studies of ICU LOS in pediatric patients with congenital heart disease, examined a population of patients less than 16 years of age undergoing cardiac surgery between 1985 and 1989 at Oregon Health Sciences University Hospital<sup>4</sup>. The authors excluded high risk and low risk surgical diagnoses, palliative surgeries, and greater than one cardiac defect. They found that preoperative factors associated with increased LOS were major extracardiac malformations, failure to thrive, and oxygen requirement.

Gillespie et al. (2006) examined ICU LOS in infants less than 6 months undergoing cardiac surgery in 2000 at CHOP<sup>5</sup>. They found that higher surgical complexity, pre-operative organ system failure, total support time intra-operatively, total hours of post-operative ventilatory support, post-operative catheterization, post-operative necrotizing enterocolitis and post-operative nasogastric tube feeds were associated with longer LOS. Higher pre-operative weights and surgical repair versus palliation were associated with shorter ICU LOS.

Pogowska-Klimek and colleagues looked at PICU LOS following cardiac surgery in children undergoing cardiac surgery over a one year time period in a hospital in Poland<sup>6</sup>. They found that neonatal age, preoperative mechanical ventilation and preoperative myocardial dysfunction, complexity and duration of procedures as well as post op-complications prolonged ICU LOS greater than 3 days. Acute renal injury requiring dialysis, pneumothorax, pulmonary hypertension or the need for re-operation during the admission prolonged length of stay over 14 days.

A British study determined that children that were above the 95% for LOS in their institution (all pediatric, neonatal and cardiac ICU patients) occupied 30% of bed days and had a three-fold greater mortality. Factors found to be associated with increased LOS after cardiopulmonary bypass in children who fell above 95% for length of stay were preoperative – mechanical ventilation, neonatal status (not defined), medical problems (two of the following: respiratory infections, musculoskeletal abnormality, cerebral palsy, weight below the third percentile for age, gestational age of < 35 weeks, non cardiac surgical procedure in last 7 days), and transfer from abroad; intraoperative – higher operative complexity, increased cardiopulmonary bypass time or ischemic time and circulatory arrest; and postoperative – delayed sternal closure, sepsis, renal failure, pulmonary hypertension, chylothorax, diaphragm paresis, and arrhythmia. A model combining all factors identified preoperative mechanical ventilation, neonatal status,

major medical problems, operative complexity, cardiopulmonary bypass time and postoperative complication score as independently associated with LOS.

While factors have been examined that influence length of stay after pediatric cardiac surgery in general, no studies have looked specifically at the neonatal period prior to hospital discharge nor have they examined the specific relation to prenatal diagnosis.

## **2. Study Design and statistical analysis**

### ***Study Aims:***

1. To determine the effect of prenatal diagnosis on length of stay in neonates with CHD in the NICU
2. To determine average hospital length of stay for neonates with critical congenital heart disease and to break this down by specific diagnosis
3. Compare length of stay of neonates with critical CHD across different eras: 2004-2008 versus 2008-2012 to investigate changes in practice
4. To examine cost impact of length of stay for critical CHD patients

### ***Hypotheses:***

Prenatal diagnosis of congenital heart disease will decrease length of stay for neonates in the NICU

### ***Study Design***

This project will be a retrospective cohort study. Study subjects will be identified by cross-referencing the NICU billing database, CT surgical database and the fetal cardiac database. Information will then be collected from the patients' electronic medical records and entered into our database.

### ***Statistical Analysis***

Using a significance of 0.05 and power of 80% with estimated standard deviation (based on preliminary data) of 11 days, I will be able to detect an effect size of 2-3 days. This power calculation is based on using an unpaired t-test to analyze data. However, I will likely use Wilcoxon Rank Sum test to analyze data in order to account for patients who have died. Those patients will have LOS of infinity and therefore will acquire the highest rank in our analysis. I will hire a statistician to help in determining which factors in addition to prenatal diagnosis effect LOS and will be confounders. By identifying these additional variables I can account for them in multivariate non-parametric analyses of the data to determine the true effect of prenatal diagnosis.

## **3. Study Procedure**

None

## **4. Study Drugs**

None

## **5. Medical Device**

None

## **6. Study Questionnaires**

None

## **7. Study Subjects**

Inclusion Criteria:

- Neonates with congenital heart disease seen in the CHONY NICU between 2006-2012

Exclusion Criteria:

- Non-critical congenital heart disease such as Patent Ductus Arteriosus only

## **8. Recruitment of Subjects**

Study subjects will be identified by cross-referencing the NICU Billing Database, CT surgical database and the fetal cardiac database. Information will be collected from the patient's electronic medical records and entered into our database

## **9. Confidentiality of Study Data**

All patient data accessed will be kept anonymous by assigning each patient a unique identifier available only to study coordinators. Additionally, all data files containing patient information will have encrypted password to prevent unauthorized access.

## **10. Potential Conflict of Interest**

There are no potential conflicts of interest in this trial

## **11. Location of the Study**

Columbia University Medical Center Morgan Stanley Children's Hospital NICU

## **12. Potential Risks**

There are no potential risks to subjects as a result of their clinical data being used in this study.

## **13. Potential Benefits**

There are no direct benefits to patients as a result of their clinical data being used in this study. However, there is potential benefit to the community at large in understanding determinants of length of stay and the potential to reduce health care expenditures.

## **14. Alternative therapies**

This study is not a therapeutic trial.

## **15. Compensation to subjects**

Neither subjects or their families will be compensated for involvement in this trial.

## **16. Costs to subjects**

There will be no costs to subjects in this study.

## **17. Minors as research subjects**

This study is retrospective observational study involving minors as research subjects.

## **18. Radiation or radioactive substances**

No radiation or radioactive substances will be involved in this study

References:

1. Van der Linde et al. Birth Prevalence of Congenital Heart Disease Worldwide: A Systematic Review and Meta-Analysis. *Journal of the American College of Cardiology*. 2011; 58, 21:2241-2247.
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3. Ligi et al. Iatrogenic Events in Admitted Neonates: A Prospective Cohort Study. *Lancet*. 2008; 371: 404-410.
4. Silberbach et al. Predicting Hospital Charge and Length of Stay for Congenital Heart Disease. *Congenital Heart Disease*. 1993; 72: 958-963.
5. Gillespie et al. Determinants of Intensive Care Unit Length of Stay for Infants Undergoing Cardiac Surgery. *Congenital Heart Disease*. 2006; 1:152-160.
6. Pogowska-Klimek et al. Predictors of long intensive care unit stay following cardiac surgery in children. *European Journal of Cardio-Thoracic Surgery*. 2011; 40: 179-184.
7. Brown et al. Risk factors for long intensive care unit stay after cardiopulmonary bypass in children. *Critical Care Medicine*. 2003; 3, 1 : 28-33.