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Pediatrics, PGY-2

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Title: Clinical Outcomes of Early Post-Operative Extubation in the Fontan Procedure

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Research Project Description, CRC Course

1) Introduction

a) Rationale

The third stage of the single-ventricle palliation, the Fontan procedure, creates a single circuit between the systemic and pulmonary circulations. In this circuit, pulmonary blood flow no longer relies on active, pulsatile flow via the right ventricle, but instead passive flow from the systemic venous system. Cardiac output then also depends on this passive venous blood flow. It follows that applying positive pressure ventilation to this passive intrathoracic system would decrease both pulmonary blood flow and cardiac output. It is for this reason early extubation in post-operative Fontan patients has been theoretically evaluated and employed in clinical practice to improve post-operative hemodynamics in this specific patient population.

b) Literature Review

It has been shown in the literature that hemodynamic performance is enhanced with spontaneous, negative pressure ventilation via statistically significant reductions in mean pulmonary arterial pressures and increased in cardiac index (Lofland et al, 2001). Although these are excellent hemodynamic measures and are likely good predictors of clinical outcomes, significant changes in clinical outcomes are not as well documented. Given this, Alghamdi et al performed a systemic review in an attempt to derive evidence based recommendations for early extubation in all cardiac surgeries. This did reveal early extubation was associated with lower early mortality as well as demonstrated a trend towards decreased length of ICU and hospital stays, however they stated “studies to date are poor, heterogeneous, and not suitable to determine a causal effect”.

As early extubation after the Fontan has been increasing, more literature is emerging to evaluate clinical outcomes. Mutsuga and colleagues performed a retrospective review to determine if fast track extubation in the operating room was feasible and safe. They found not only could it be done, but it decreased immediate post-operative measures including lower central venous pressure and higher blood pressures one hour after arriving in PICU as well as long term decrease in ICU length of stay, shortened time to chest tube removal, and overall shorter hospital length of stay.

Very recently and out of the same institution as Mutsuga, Kawaguchi et al published a retrospective review demonstrate that early extubation does lead to a significant decrease in length of PICU stay, but investigators were unable to find

a significant difference in fluid balance. This study provides proof of a significant change in practices/clinical outcomes and an excellent framework for further investigation; however, the researchers reviewed an earlier and shorter time frame (pre-policy 2005-2007 vs post-policy 2008-2011) with admittedly a new cardiac team, allowing room for further investigation and possibly new findings.

2) Hypothesis

It is known that early post-operative extubation exhibits improved hemodynamic performance in post-operative Fontan patients, but we hypothesize that this can also lead to the improved primary clinical outcomes of decreased length of stay in the Pediatric Intensive Care Unit, intravenous fluid requirements, and inotropic support. We also hope to prove there is no increased rate of respiratory failure or death compared to those maintained on positive pressure ventilation post-operatively

3) Methods

a) Conceptual and Operational Definitions: The main outcomes to be measured will be length of PICU stay (expressed in 24 hour periods), overall fluid requirements (expressed in mL/kg/day), and inotropic support (using vasoactive-inotrope scope). We will also be collecting and comparing exploratory data, including laboratory values (ABGs, coagulation studies) although these will not be primary outcomes as they are not systematically collected in the post-operative period. Finally, clinically significant outcomes such as reintubations and death will be reported and compared in the two groups but will not serve as primary outcomes.

b) Study Design: retrospective pre-post intervention data analysis (pre-arm from 2005-2010 and post-arm 2010-2015)

c) Statistical Analysis: unpaired t-tests comparing the pre- and post-2010 study arms on both primary and exploratory outcomes. However, if data is not evenly distributed, a cox regression will be used.

d) Sample Size: Our sample size is yet to be determined given the data has not yet been collected, however it will be a fixed number population. If extrapolating from the results from the Kawaguchi et al paper, we can estimate the sample size for each group in order to determine a clinically significant reduction in length of PICU stay (pre-arm mean = 7.5 days, post-arm mean = 3.4, SD = 5.7). A power analysis yields sample sizes of 32 subjects per group.

*Note: this is done using a t-test power analysis, using the presumption the data will be evenly distributed

4) Subject Selection: All patients aged 0-18 admitted to MSCHONY who underwent the Fontan procedure for congenital heart disease between January 2005- December 2015.

5) Miscellaneous

- a) Study drugs: N/A
- b) Medical devices: N/A
- c) Study Questionnaires: N/A
- d) Recruitment of subjects: medical database
- e) Confidentiality: all patient data will be de-identified prior to analysis
- f) Potential conflict of interest: none
- g) Location of study: Columbia University Medical Center
- h) Potential Benefits: Proving early extubation of post-operative Fontan patients leads to improved clinical outcomes could to improved post-operative management and improvement in patient morbidity/mortality.
- i) Alternative therapies: N/A
- j) Compensation of Subjects: N/A
- k) Cost to Subjects: N/A
- l) Minors as Research Subjects: Chart review and data analysis of post-operative Fontan patients will be conducted. Little to no risk is imposed on the children in the study.
- m) Radiation or Radioactive Substances: N/A

References:

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