Trends In Opioid and Sedative/Amnestic Exposure In Infants Undergoing Cardiac Surgery:
An Analysis Of Data From The Pediatric Health Information Systems Database

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Introduction

Opioid and sedative-amnestic medications are vital to critically ill patients immediately after congenital heart surgery to: Reduce pain and anxiety, reduce metabolic demand and maintain stability

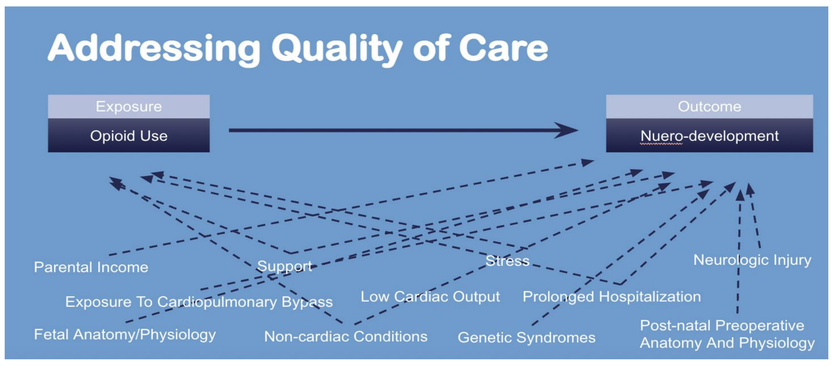
However, prolonged exposure to these agents may have deleterious effects on vulnerable infants' development. To our knowledge, there is little data about trends in the use of these agents in infants undergoing heart surgery. Increased understanding about these trends would address a knowledge gap that might help guide future quality improvement and research efforts to determine the optimal care of these patients.

AIM 1: Characterize exposure of infants (<1 year) undergoing open-heart surgeries for acquired and congenital heart disease to opioids, benzodiazepine, and adjuvant agents.

1. Hypothesis: There will be significant variation in the total exposure to opioids and benzodiazepines between hospitals even after adjusting for case mix
2. Hypothesis: The likelihood of receiving antipsychotics, ketorolac, and other non-opioid and benzodiazepine medications will also vary significantly between centers

AIM 2: Characterize trends in the exposure of infants (<1 year) undergoing open-heart surgeries for acquired and congenital heart disease

1. Hypothesis: After adjusting for case mix the total exposure to opioid and benzodiazepine will have increased across the study period (2011-2021)



Methods

PHIS: The PHIS is a comparative pediatric database that includes **clinical** and **resource utilization data** for inpatient, ambulatory surgery, Emergency Department, and observation unit patient encounters for **45 children's hospitals**.

Features

- Data: Patient abstract, diagnoses **(ICD-9/10),** procedures, **billed transactions and utilization**
- Patient types: **Inpatient**, observation, ambulatory surgery and ED

Cohort definition

1. **Inclusion:** All subjects undergoing heart surgery (see Table 1) at PHIS centers between 1/1/2011 and 12/31/2021 (10 Years)
2. **Exclusion**
   1. **Subject level (apply first):**
      1. Isolated Patent ductus arteriosus (PDA) closure
      2. Previous hospitalization in life with heart surgery at same PHIS hospital
   2. **Site level**
      1. Sites without participation in at least 5 of the 11 years.
      2. Sites with less than 400 total cases over the study period
   3. **Post-hoc:** (consider at analytic phase)
      1. Death before discharge (to avoid underestimate of expected dosages)
      2. Transfer to other hospital as disposition (to avoid underestimate of dosages)

Outcomes

1. Cumulative total exposure to opioids and/or sedative amnestics
   - If dosages are available this will be expressed as a morphine equivalent or diazepam equivalent
   - If not available – will use total days of exposure
2. Daily exposure (As a secondary outcome) we will use total exposure/days
   - Opioid
   - Sedative/amnetics
3. Exposure to each of the following (yes/no and days of treatment)
   1. Gapapentin
   2. Antipsychotics
   3. Ketorolac
   4. IV Tylenol
   5. Tylenol and NSAID

Covarients

Patient-level

Admit age in days/months, Sex, Race, Insurance: Public, Private, Other, Birthweight , SGA and or prematurity, RACHS I and RACHS II (Risk Adjustment For Congenital Heart Surgery) levels (1,2,3, 4,5/6) for CHD (Congenital Heart Defects), SYSTEMIC DISEASE FLAGS (may not be able to use since many are post-hoc), Genetic syndrome , ECMO flag, TOTAL INPATIENT COST (ADJUSTED AND UNADJUSTED)

Hospital-level

Hospital surgical volume (by year) , Hospital STAT4/5 or Hospital RACHS 4 volume

★ **Current research progress: data extraction and analysis**

Future directives

1. Look into other substituent amnestic medications with less effects on neurodevelopmental growth of infants that can be used instead.
2. International observational study to evaluate the total exposure to these agents in a cohort of patients undergoing surgery and evaluate whether there are significant trends in the use of these agents.

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