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# Analgesics Pain Relief Medications their Mechanisms

**David Dbeis***

Department of Perioperative and Pain Medicine, Stanford University School of Medicine, Palo Alto, USA

**Corresponding author:** David Dbeis, Department of Perioperative and Pain Medicine, Stanford University School of Medicine, Palo Alto, USA, E-mail: daviddbeis@gmail.com

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## Introduction

Postoperative mortality is higher in neonates than in older children, with additional risk factors including co-morbidities, preoperative instability requiring intensive support, sepsis, emergency surgery, birth at younger gestational ages, and complications of prematurity. Severe perioperative critical events are also more common in neonates than in older children. Reported perioperative outcomes frequently relate to clinical indicators (i.e., adverse cardiorespiratory events, changes in vital signs, or laboratory measures) in neonates, whereas patient-centered and comfort measures (i.e., pain, analgesia, nausea and vomiting, and behavior) are common for older ages.

The APRICOT study recruited over 30 000 children across 33 European countries and identified a higher incidence of critical events in 361 neonates. The subsequent NEonate and Children audiT of Anaesthesia pRactice IN Europe (NECTARINE) prospective multicenter observational study focused on patients up to 60 weeks postmenstrual age requiring anesthesia for surgical or diagnostic procedures, and reported perioperative critical events, morbidity and mortality for 5609 infants undergoing 6542 procedures. Severe critical events requiring interventions occurred in 35.2% of cases, and the triad of hypotension, hypoxemia, and anemia had a major impact on morbidity and mortality.

## Classification of Analgesics

Differences in the incidence and management of severe perioperative critical events across countries participating in the APRICOT cohort highlighted variability in pediatric and neonatal anesthesia practice, and raised issues related to training, resources, clinical experience, workload, and infrastructure. As a result, the Trial Steering Committee agreed that secondary analyses for nations contributing large numbers of patients to NECTARINE could test the hypothesis that primary outcome measures were not different from the remaining cohort.

This manuscript relates to UK recruitment of neonates and infants (</=60 weeks postmenstrual age) requiring general anesthesia for surgery or nonsurgical procedures in the NECTARINE prospective cohort study. The primary aim of this subgroup analysis was to report the incidence of severe critical perioperative events in UK centers, with particular emphasis on cardiovascular, respiratory events, and management of difficult airways. Secondary aims were to compare 30-day morbidity and mortality between UK and participating nonUK centers and explore potential differences in anesthesia practice.

The NEonate-Children sTudy of Anaesthesia pRactice IN Europe (NECTARINE) is a European prospective multicenter observational cohort study with participating centers in 31 countries. The study protocol, standardized case report form (CRF) and additional document. The Association of Paediatric Anaesthetists of Great Britain and Ireland (APAGBI) endorsed the study, coordinated a call for UK participating centers, and provided funding for centralized follow-up in the UK. Ethics approvals (National Health Service [NHS] National Research Ethics Service, 16/LO/0238, 16-3-2016; NHS Health Research Authority, 21-3-2016) for parental consent prior to, or within 24 h of anesthesia, and for follow-up were obtained. Thirty-day follow-up was performed via medical records. Standardized follow-up at 90 days was performed by the Great Ormond Street Hospital Somers Clinical Research Facility, following secure transfer of recruited subject information. The recruiting hospital and/or family doctor was contacted initially to confirm the patient's status. Parents had the option to agree to access of the child's medical records but decline direct telephone contact at 90 days. Recruitment commenced at 4 centers on 1-4-2016, an additional 13 centers on 1-5-2016, and ceased on 5-7-2016.

## Considerations for Analgesic Use

Data were collected by the anesthesia team onto a standardized CRF, that included details of the following: patient demographics and medical history, preanesthesia assessment, baseline parameters, surgery/procedure, anesthesia management, and perioperative critical events. CRF data was entered into a secure internet-based electronic case record form (OpenClinica, Boston, MA, USA). Following data cleaning and resolution of queries, the final NECTARINE dataset was exported for analysis in October 2019 and national datasets were subsequently available to Lead Investigators.

Eight predetermined critical events that required intervention by the anesthesia team related to: oxygenation; carbon dioxide (CO2) and alveolar ventilation; blood pressure; heart rate and electrocardiogram (ECG) rhythm; cerebral oxygenation (if monitoring with near-infrared spectroscopy was available);

blood glucose and plasma sodium; hemoglobin levels; and body temperature. The physiological parameter threshold that triggered an intervention(s), and the type and timing of intervention(s) were recorded. Perioperative data collection continued until the patient was discharged from the postanesthesia care unit (maximum 120 min) and/or transferred to a neonatal or pediatric intensive care unit. Thirty-day data included patient status (i.e., at home or in hospital), time in intensive care and morbidity/complications. Mortality data were collected at 30- and 90-day follow-up.

Quantitative variables are reported as median [25, 75 interquartile range] and compared with Mann–Whitney, or if normally distributed as mean ± standard deviation and compared with Student's t-test. All tests were two-sided. p values are reported to a minimum of $p < 0.001$, and $p < 0.05$ was considered statistically significant. Patient categorical data are summarized as absolute numbers and percentages, and comparisons performed with chi-squared test with p values and odds ratio [95% CI] reported. Throughout, group values and analyses are based on available data, and any missing data are reflected by the reduced sample size (n). The statistical analysis plan for the full NECTARINE cohort was based on an expected percentage of severe perioperative critical events of 11% and estimated a sample of 4941 patients for a logistic regression analysis with more than one covariate. Therefore, analyses for the current subgroup data are restricted to descriptive comparisons. Analysis was performed with SPPS Statistics V27 (IBM, Portsmouth, UK; June 2020).

Inotrope/vasopressor infusions were required preoperatively in 25 cases and were part of anesthesia management from the beginning in an additional 18 cases. Subsequent intraoperative cardiovascular instability requiring intervention was reported in 148/876 (16.9%) cases. Perioperative cardiovascular instability was more commonly associated with the following: younger postmenstrual and chronological age at the time of anesthesia; preoperative intensive support; ASA-PS score III-IV; current cardiovascular and metabolic co-morbidities; and the need for urgent or emergency surgery.

Critical changes in blood pressure triggered interventions in 142 cases, of which 65 cases required a single intervention and 46 cases required multiple (3 or more) interventions. Baseline systolic blood pressure increased with postmenstrual age at the time of anesthesia (Spearman's $\rho = 0.41$ [95% CI 0.34, 0.47]) was variable across all ages but lower in patients who subsequently developed cardiovascular instability. Management of hypotension included administration of intravenous fluid in 134 cases, pharmacological interventions in 57 cases, or both. The change in blood pressure that triggered an intervention was variable (average decrease for fluids 41 ± 22%, and for drugs 42 ± 24%). Heart rate disturbances triggered 11 interventions. Successful treatment was reported in 135 cases, but cardiovascular instability persisted in 4 (3 admitted from intensive care and all transferred to intensive care postoperatively). Thirty cases required interventions for both hypotension and hypoxia and included 7 cases (0.8%) with the composite event of hypotension, hypoxia, and anemia requiring red blood cell transfusion.