DEM Journal Club

Article Appraisal

Article: Major Adverse Events and Relationship to Nil per Os Status in Pediatric Sedation/Anesthesia Outside the Operating Room: A Report of the Pediatric Sedation Research Consortium.

Date of Journal Club: April 6, 2017

Resident Reviewer Name(s) and Residency Affiliation: Jared Baylis (RCPS-EM PGY-3) and Luke Armstrong (CCFP-EM)

Faculty Methodology/Bio-statistics Resource Person: Dr. Rob Stenstrom

Background and Study Objective(s):

The quest to truly define whether Nil Per Os (NPO) status is linked with adverse events in procedural sedation has historically been fraught with dogma. It is widely accepted that the main goal of having patients fast before a procedure is to theoretically decrease the risk of aspiration, but this is difficult to study as aspiration is a rare event. Existing guidelines from the American Society for Anesthesiologists (ASA) recommend fasting times of 2 hours for clear liquids, 4 hours for breast milk, and 6 hours for 'light meals'. These recommendations are related to elective surgeries, regional anesthesia and procedural sedation.

However, from an Emergency Department perspective, it is often practically difficult to apply these guidelines, both in terms of procedure urgency as well as patient flow in the department. One previous study by Roback et al. found no increased risk of adverse events (defined as desaturation (<90%), vomiting, apnea, or laryngospasm) when comparing pediatric patients who were within the ASA fasting guidelines compared with those who were not. In 2013, the American College of Emergency Physicians (ACEP) came out with a level B (moderate clinical certainty) clinical policy on procedural sedation and analgesia in the ED, stating: "Do not delay procedural sedation in adults or pediatrics in the ED based on fasting time. Preprocedural fasting for any duration has not demonstrated a reduction in the risk of emesis or aspiration when administering procedural sedation and analgesia."

Appropriate fasting times in the emergency department related to procedural sedation are controversial and the current guidelines are based on expert opinion and small studies with low aspiration rates. The authors of this study set out to investigate any associations between NPO status and major adverse events outside the operating room using the large pediatric population of the Pediatric Sedation Research Consortium.

Study Design:

This was a prospective observational multi-centre cohort study based on data collected between September

2007 and November 2011. There were 139,142 patients 18 yrs old or younger during this time-period in the registry. NPO status was known for 107,947 (77.6%). The missing data on the remaining 22.4% of the cohort was analyzed separately and did not include any aspiration events. The exposure was any pharmacological intervention made to facilitate an invasive procedure or test outside of the OR under heading of "procedural sedation/anesthesia". NPO was defined as no solid foods for at least 8 hrs, no non-clear fluids for at least 6 hrs, and no clear fluid for at least 2 hrs as compared to the non-NPO group. There were two primary outcomes, the first was aspiration, while the second was a major adverse event. Aspiration was defined as an event where emesis was noted or food material was found in the oropharynx associated with new cough, wheeze, increase in respiratory effort, change in CXR indicative of aspiration, or new need for oxygen therapy after recovery from sedation. Major adverse event was defined as aspiration, death, cardiac arrest, or unplanned admission to hospital.

Results:

Aspiration occurred at a rate of 0.97 per 10,000 sedations in those who were NPO compared to 0.79 per 10,000 in those who were not NPO. Major complications occurred at a rate of 5.57 per 10,000 in those who were NPO compared to 5.91 per 10,000 in those who were not NPO. Secondary analyses looked at other factors (other than NPO status) during procedural sedation that were associated with higher risk of adverse events, including age, ASA status, type of practitioner administering the sedation/anesthetic, elective vs emergent procedure, type of procedure and patient diagnosis.

Validity of Results:

The odds ratio (OR) for aspiration comparing NPO with not NPO was 0.81 with 95% confidence intervals of 0.08-4.08. For major adverse events, the OR was 1.06 with 95% confidence intervals of 0.55-1.93. What this data demonstrates, is that even with a large number of patients sedated, the event rate was still very low. While this is fortunate for patients, it leads to large confidence intervals around the point estimate making the results less reliable.

Generalizability of Results:

Approximately 21% (30,089 of 139,142) of the sedation/anesthesia was provided by emergency physicians many of whom worked in 'sedation teams' that provided procedural sedation as a sole practice. Very few of the sedations (1,311) were categorized as emergent. Additionally, from our experience in large BC Emergency Departments, the majority of our pediatric sedations involve Ketamine as a sole agent, whereas in this study the majority of sedations (>70%) involved Propofol with or without another agent.

While this study has the benefit of having strength in numbers, and demonstrates no significant association between NPO status and major adverse events, the above factors unfortunately limit the generalizability of these results to our practice in Canadian Emergency Departments.

The Bottom Line:

This is the largest study to date investigating any association between NPO status and major adverse events, including aspiration, in the pediatric population. It offers the biggest sampling of pediatric sedation outcomes and provides further evidence that aspiration and adverse events are quite rare. While this prospective observational study has its limitations and was not based in the ED, we believe it lends support to the 2013 ACEP procedural sedation guidelines in pediatric patients regarding NPO status. Ultimately, the risks of any procedure or sedation in the Emergency Department still need to be discussed with the patient and parents and always preparing for adverse events is the key to a successful Emergency Medicine career.