Sedation and Neurotoxicity: An Analysis of an at Risk Pediatric Population

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Background: In December 2016, the FDA issued a “Drug Safety Communication” warning that repeated use of sedation drugs or prolonged sedation (> 3 hours) in children ≤ 3 years of age may affect the brain development. Children meeting the FDA risk criteria for procedural sedation (PS) outside the operating room (OR) are not well defined. Our primary objective was to describe the prevalence of children undergoing repeated or prolonged sedation and to determine characteristics of children “at risk.”

Methods: Retrospective chart review of all children < 3 years receiving PS from 2014 to 2016. Demographics, imaging modality, duration of sedation, and the reason for sedation were collected and analyzed using descriptive statistics. Characteristics of patients requiring repeated/prolonged sedation were summarized.

Results: A total of 2,950 patients with 3,653 sedation encounters were included in our sample. The median age was 16.9 months, and 54% were male. Majority of sedations (86.4%) were for MRI. The median number of sedations/patient was 1 (range 1-7), and the median duration was 66 minutes. Propofol was used in over 99% of sedations. 40 patients (1.4%) required prolonged sedation, and 298 patients (10.1%) had multiple sedations during the study period. Overall 327 patients, 11.1% (95% CI: 10.0% - 12.3%) required repeated and/or prolonged sedation. Patients requiring repeated or prolonged sedation were those that required MRI of the brain with and without contrast and for patients requiring imaging related to neurologic or neuro-oncologic concerns.

Conclusion: The majority of children under the age of 3 are not at risk for repeated or prolonged PS. Children with neurological concerns or requiring imaging of the brain are at risk for prolonged/repeated PS. In this subset of patients, appropriateness of the imaging or delayed imaging should be considered before sedation.