The Use of Patient Registries to Detect Risk Factors of Anesthesia and Sedation Complications

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Beginning in the 1980s, prospective studies confirmed what was previously suspected from case reports: that prematurely born infants were at a higher risk of developing central and obstructive apneas after general anesthesia compared with their term counterparts. This finding resulted in the extended use of cardiorespiratory monitoring (ie, usually overnight) in these infants after exposure to anesthetic agents before discharge from the hospital. Although a number of centers reported varying results, this increased risk seemed to last until ∼5 or 6 months into the first year of life. Similarly, an increased risk of postprocedure oxyhemoglobin desaturation was found in preterm infants after chloral hydrate sedation for MRIs. Although most pediatric anesthesiologists would agree that prematurity is a strong risk factor for additional respiratory complications (eg, bronchospasm, laryngospasm), surprisingly little information has been published on the subject.

With this in mind, the Pediatric Sedation Research Consortium (PSRC) was created and, in this issue of Pediatrics, Havidich et al report their analysis of sedation- and anesthesia-related adverse events across a wider range of patients, procedures, and anesthetic or sedative agents than has ever been previously reported. In their cohort of >57,000 children who required radiologic or painful medical procedures, the authors found that children born preterm (<37 weeks’ gestation) were almost twice as likely as those born at term to develop a sedation-related adverse event. Most importantly, this increased risk persisted beyond infancy and into early adulthood.

This novel (but not surprising) finding that prematurely born children have an increased risk of sedation-related respiratory complications throughout all ages of childhood should now influence the way in which sedation practitioners and anesthesiologists approach risk management in this population. In other words, I will no longer roll my eyes when, during our preanesthetic discussion, my resident begins her description of our 17-year-old patient as an “ex 28-weeker.”

Now that we know about this increased risk, what is the best way to determine how to change our management of these vulnerable children? There are 2 main approaches. The first is to analyze data contained in prospectively created patient registries, as was done with the PSRC. When properly designed and executed, patient registries can provide useful information about patient outcomes, safety, and comparative effectiveness. This approach allows the use of a relatively large number of data points to determine patterns and correlations that would otherwise be too difficult to detect in a prospective trial with a smaller and less random sample. However, a weakness of using such a data set lies in the large variety of the types of patient encounters that are available for comparison. For example, the PSRC includes children with varying degrees of weight, prematurity, and baseline lung function. It includes practitioners with different levels of expertise, as well as a variety of anesthetic and sedative agents, which may pose a challenge for interpretation.

A companion to this article can be found online at www.pediatrics.org/cgi/doi/10.1542/peds.2015-0463.
of different types of anesthetic and sedative medications. One cannot reasonably compare outcomes between an anesthesiologist, who in the course of caring for a child undergoing an upper endoscopy, will use endotracheal intubation and inhaled anesthetic agents, versus a pediatric hospitalist who administers less potent intravenous sedation agents to a child undergoing an MRI. Each type of procedure has inherent differences in practitioner expertise, procedural requirements, and patient characteristics. The use of subgrouping and stratification methods can ensure lack of bias between comparative groups, and the use of visual analytic techniques can guide clinicians toward optimal treatment strategies when formal prospective trials have not yet been performed.

The second approach is to use the results gleaned from patient registry studies to design smaller and more focused, hypothesis-driven controlled studies to determine the root causes of complications and effective interventions in specific populations at risk. Often, however, careful protocol-based prospective studies are not the best approach for determining outcomes that lack rigorous definitions (eg, coughing or increased secretions) in a clinical situation that is so rarely carefully protocolized in real life. One has to wonder whether the internal validity gained from a prospective study becomes too narrow for a broad subject such as pediatric sedation and its outcomes. Perhaps the best approach is to use both methods. For example, if an analysis of a large registry of children undergoing an MRI with a specific sedative agent found that prematurely born infants had a greater incidence of respiratory complications, a subsequent prospective study would compare the efficacy of certain interventions (eg, positioning, oxygen supplementation, capnography) to decrease those risks under similar conditions.

In the current era of diminishing resources to perform controlled clinical trials, the analysis of patient registries such as the PSRC will guide clinicians toward optimal outcomes. The accumulation of greater numbers of patients into these registries will allow increasingly granular analyses to improve the treatment of specific populations and to identify more focused interventions for improving the safety of pediatric anesthesia and sedation.

ABBREVIATION
PSRC: Pediatric Sedation Research Consortium

REFERENCES
The Use of Patient Registries to Detect Risk Factors of Anesthesia and Sedation Complications
Ronald S. Litman
Pediatrics 2016;137; DOI: 10.1542/peds.2015-4579 originally published online February 25, 2016;

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Pediatrics 2016;137;
DOI: 10.1542/peds.2015-4579 originally published online February 25, 2016;

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