

Too Much of a Good Thing Is Wonderful

Observational Data for Perioperative Research

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MANY of our clinical decisions are based on animal models, small *in vivo* studies, retrospective chart reviews, or tradition. As anesthetic safety has improved over the past few decades, the infrequent events that comprise current anesthesia morbidity are difficult to analyze using traditional research tools. Intraoperative blood pressure management research exemplifies this challenge. Although we measure, document, and treat blood pressure continuously during each case throughout our careers, systemic blood pressure remains one of the most understudied aspects of anesthetic care *in vivo*. In this issue of ANESTHESIOLOGY, Bijker *et al.*¹ provide an important contribution to the perioperative medicine literature in this arena.

Bijker *et al.* evaluate the relationship between intraoperative "hypotension" and 1-yr all-cause mortality.¹ Unfortunately, because no standardized definition of hypotension has been adopted, the authors evaluated 48 different forms of hypotension for an outcome effect. Despite—or perhaps because of—this exhaustive search, the authors struggle to provide compelling evidence for an association between any definition of hypotension and mortality. Using traditional multivariate modeling techniques, they were unable to identify a relationship. However, classification and regression tree analysis demonstrated an association between mortality and mean arterial pressure hypotension less than 60 mmHg, independent of patient age or duration of surgery. Of note, it is unclear whether this analysis controlled for patient comorbidities. The analysis of Bijker *et al.* includes only 1,705 patients with 88 deaths at 1 yr—with 45 patients (52%) succumbing to cancer or unknown causes. The many independent variables to be considered—patient age, duration of surgery, surgical risk, comorbidities, and 48 definitions of hypotension—are modeled against only 88 outcome events, a challenge

to any statistical technique. The work of Bijker *et al.* and similar studies hampered by small sample size highlight the current opportunity for large data set research and the need for and impact of multicenter perioperative outcomes databases.

The challenge of small sample sizes combined with infrequent adverse events forces the anesthesia community to expand its research tool set. Just as the analysis by Lindenauer *et al.*² of more than 700,000 patients complemented early small trials of perioperative β blockade,³ we must use prospective, detailed, perioperative clinical data sets to investigate infrequent anesthetic adverse events. Investigators in the United States have begun to use large national data sets to evaluate fundamental perioperative outcomes: anesthetic-related mortality, stroke, and acute kidney injury. One major advantage of these data sets—the Multiple Cause of Death Public Use Data File, Nationwide Inpatient Sample, and National Surgical Quality Improvement Program Participant Use Data File—is the consistency of data collection and facile access to data. However, each data set has an alternate primary purpose—public health reporting, billing, or surgical outcomes research—and cannot be modified to evaluate specific anesthetic management questions. For example, it is impossible to identify patients who received epidural analgesia as an adjunct to a general anesthetic using the National Surgical Quality Improvement Program data set. The lack of detailed anesthetic intervention information limits these data sets to process-of-care or risk stratification research.

Recognizing these limitations and the need for detailed perioperative clinical data, the American Society of Anesthesiologists established the Anesthesia Quality Institute in 2008. A not-for-profit corporation established with seed funds from the American Society of Anesthesiologists, the Anesthesia Quality Institute is the fruition of years of effort by quality improvement champions within our field. It has grown from initial work performed nearly a decade ago by the Committee on Performance and Outcomes Measurement, which defined the clinical outcomes of interest to providers and patients alike. The Anesthesia Quality Institute will house the National Anesthesia Clinical Outcomes Registry, a patient data registry that will be combined with other data sources to enable provider benchmarking, quality improvement, research, public reporting, credentialing, and maintenance of certification. Because the National Anesthesia Clinical Outcomes Registry will be designed and developed by anesthesiologists, it will contain anesthesia-specific data elements that are essential for comprehensive perioperative clinical research. It represents

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a leap forward for a field known for its patient safety culture. With an executive team now in place, the Anesthesia Quality Institute is beginning its execution phase.

The emerging awareness regarding the potential impact of hemodynamic management on long-term outcomes coincides with a rapid increase in the adoption of anesthesia information management systems (AIMS). Historically, an important research limitation of these systems was the absence of preoperative risk stratification data elements. However, recent AIMS implementations have expanded beyond the intraoperative record. Discrete preoperative comorbidity elements in the anesthesia history and physical, postoperative laboratory values, and adverse events are now incorporated into many AIMS. We have used our large single-center AIMS database to provide insight regarding outcomes ranging from cardiac adverse events and acute kidney injury to airway management. Much like the current work by Bijker *et al.*, our single-center data identified a mean arterial pressure below 50 mmHg as an independent risk factor for acute renal failure and cardiac adverse events after noncardiac surgery. However, given the multifactorial etiology of most adverse events, our analyses were also limited by a “small” sample size of 15,102 and 7,740 patients.^{4,5} Although our institution performs 50,000 operative cases each year, the need to control for variant surgical risk, anesthetic techniques, and patient comorbidities reduces the number of cases available for statistical analysis.

As a result, we must consider the need for combining detailed, granular perioperative clinical information across multiple institutions. To that end, the Multicenter Perioperative Outcomes Group held its inaugural meeting in the summer of 2008.* With more than 30 institutions now involved, this group hopes to realize the long-standing vision of AIMS interoperability for research. Combining data across institutions for the purpose of research exposes political, regulatory, clinical, and technical challenges that have proved insurmountable in the past. Institutional review boards struggle with the prospective collection of volumes of deidentified patient data to create a research infrastructure. Departments with distinct research priorities, methodology biases, and technical capabilities must agree on data extraction standards and techniques. Most importantly, the veracity of the AIMS data must be confirmed.

On the technical front, consolidation in the AIMS industry has decreased the number of disparate database structures. Some data types, such as physiologic monitors, ancillary devices, and intraoperative medications, are easier to combine because there are relatively few distinct clinical concepts. The Committee on Performance and Outcomes

Measurement has established a basic set of outcome measures than can be complemented by automated collection of postoperative laboratory, pharmacy, radiology, and vital status data. The Anesthesia Patient Safety Foundation has enabled groups to incorporate anesthesiology terms into international medical lexicons.†

However, a “standardized anesthesia intraoperative record” remains a prominent void for not only AIMS, but also paper anesthesia records. Although the American Society of Anesthesiologists has published monitoring standards, there is no guidance regarding documentation of procedures, airway management, intraoperative interventions, or emergence—in contrast to other specialties such as obstetrics.‡ Multicenter research using AIMS has required the development of a standardized anesthesia record extract. Many idiosyncratic documentation patterns have been encountered. These documentation variations are magnified as one attempts to integrate data internationally. Language differences, country-specific regulatory pressures, region-specific practice patterns, and patient variations result in vastly different documentation and care despite similar clinical situations. Although this variability presents profound data aggregation challenges, it is the foundation for productive research. Identifying the optimal clinical strategy demands evaluating options practiced worldwide, not just at one specific center.

Despite these challenges, integration of AIMS data with complementary data sources such as national surgical speciality registries, laboratory data, radiology information, pharmacy data, and national death records unlocks the knowledge creation potential of the perioperative period. Each incremental data element can create new value out of existing data. As the healthcare field focuses on comparative effectiveness research initiatives, we must realize that evaluating the effectiveness of our perioperative decisions is also long overdue. Large, international data sets based on AIMS will be a valuable tool in this endeavor.

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* <http://mpog.med.umich.edu/>. Accessed August 12, 2009.

† http://www.apsf.org/initiatives/data_dictionary.msp. Accessed August 12, 2009.

‡ http://www.acog.org/bookstore/Patient_Records_C62.cfm. Accessed August 12, 2009.