Database Management: The Pediatric Regional Anesthesia Consortium Prototype

Lynn D. Martin, MD, FAAP, FCCM
Director, Department of Anesthesiology & Pain Medicine
Children's Hospital and Regional Medical Center
Professor of Anesthesiology and Pediatrics (Adjunct)
University of Washington School of Medicine
Seattle, Washington

Interest in regional anesthesia in neonates, infants and children has increased since the 1980s when the myth that these patients do not experience pain or benefit from therapies designed to treat their pain was dispelled. Regional blocks, originally performed only in a few select centers, are now becoming common practice in many different anesthesia departments throughout the United States and the world. Thus, regional anesthesia is now a well established modality within the field of pediatric anesthesia, primarily designed to provide postoperative pain management and not intra-operative anesthesia (1).

Initial regional anesthesia techniques in children focused primarily on extradural analgesia. Recently there has been increasing interest in regional anesthesia in children beyond the relatively common caudal, epidural or spinal (2). Improvements in equipment designed specifically for infants and children and advances in understanding of the local anesthetic pharmacology in children have significantly contributed to the growth and safety of regional techniques in the pediatric population. However, regional anesthesia is a technically challenging practice that requires skilled and experience practitioners. Recent advances in regional anesthesia techniques, specifically surface mapping of peripheral nerves in children with a nerve stimulator (3) and ultrasound guidance (4), may significantly improve the safety and efficacy of regional anesthesia procedures.

The resurgent interest in pediatric regional anesthesia is based on the common belief that the benefits outweigh the risks of the regional procedure. Reported benefits include excellent analgesia without the risk of respiratory depression as seen with systemic narcotics (5), modification of the surgical stress response (6) rapid awakening and improved (shorten) hospital stay (7). These benefits have recently been extended to the neonatal population as well (8).

Despite this growing interest and practice of regional anesthesia in children, information regarding the safety of these techniques remains scare. One commonly held belief is that performance of regional anesthesia blocks on anesthetized patients is not safe. While performance of blocks on awake and/or sedated patients may be possible with cooperative adults, most pediatric anesthesiologists will argue that the risks are decreased via pharmacologically-induced cooperation in children (11). On the other hand, assessment of the quality and effectiveness of the regional block are clearly more challenging in an anesthetized patient.

Detailed information on the epidemiology and morbidity of regional anesthesia in children are limited (9-10). Published review of the ASA Closed Claims database revealed only 7 of 238 pediatric cases involved a regional anesthetic (12). Current 2006 data from the ASA Claims database reveals 18 cases involving regional anesthesia in children of the 559 pediatric claims (0.3%) (personal communication – Karen Posner, PhD). The best attempt to date to fill this knowledge void was the prospective report from the French-Language Society of Pediatric Anesthesiologists (13). This study of 24,409 regional blocks in children collected over one year (May1, 1993 - April 30, 1994) identified 25 complications in 24 patients (approximate overall complication rate of 0.9 per 1000). All of these complications occurred in central (extradural) blocks, thus making the complication rate for central blocks 1.5 per 1000. Significant variation by age was seen (highest in infants 1-6 months of age) and procedure (caudals - 0.7/1000; lumbar epidurals - 3.7/1000; sacral epidurals – 6.8/1000; thoracic epidurals 0/1000; spinal – 2/1000; peripheral nerve block – 0/1000). All complications were defined by the authors as minor and did not result in any sequelae or medicolegal action. An accompanying editorial highlights some of the possible weaknesses of this study (14). Although this valuable study provided previously unavailable data for pediatric anesthesiologists world-wide, the lack of efficacy data, a potential for selection bias and the applicability of these conclusions to pediatric centers in America are possible shortcomings. Perhaps most importantly, these data are now over one decade old. Thus, clinicians today are still are commonly asking "Has the increased experience and improved techniques (nerve mapping and/or ultrasound guidance) over the last decade improved this complication rate?"

With the support of leadership from both the Society for Pediatric Anesthesia (SPA) and the quality improvement subcommittee of the American Academy of Pediatrics (AAP) section on anesthesiology and pain medicine, a group of interested pediatric anesthesiologists met at the winter 2006 SPA/AAP joint meeting in Sanibel, Florida. The premise for this gathering was to develop a web-based electronic data collection tool(s) that could be used to prospectively identify all of the regional anesthesia blocks and associated complications performed at each participating center. Once these tool(s) were created and tested, prospective multicenter data collection would commence, possibly leading to extramurally funded scientific studies.

From the initial meeting, a steering committee (Lynn Martin – Seattle Children's/U Washington; David Polaner – Denver Children's/U Colorado; Joe Cravero – Dartmouth-Hitchcock; Elliott Krane – Stanford; John Rose – CHOP/U Penn; Santhanam Suresh – Children's Memorial/Northwestern) was formed and began working with staff at Axio Research Corporation (Seattle) in the development of the web-based data collection tools. The prototype of this secure electronic database is currently undergoing beta testing at the steering committee sites. Once development and testing is completed, additional centers throughout the United States will be invited via SPA and AAP membership lists to participate in the prospective data collection. Participating centers will have to met specific enrollment criteria: (1) willingness and ability to prospectively collect data for **every** regional anesthetic performed in their center, (2) willingness and ability to prospective define and evaluate **all** identified complications of the regional blocks, and (3) willingness and ability to receive institutional IRB approval prior to study participation and (4) willingness and ability to provide initiation and annual database fees.

All participating centers will complete a data set describing their center characteristics. Non-identifying (anonymous) demographic data (gender, month/year of birth, ASA physical status, and weight is collected for each patient. In addition, data regarding the block performed by an anesthesiology department member (faculty, fellow, resident, or CRNA) will be entered. This data set is divided into two classes (single shot or catheter). Within each class, the blocks are further divided into neuraxial (epidural or spinal), peripheral nerve block (upper or lower extremity) or other blocks. Other data collected include the concentration and volume (i.e., dose) of agent(s) used, technology used for block placement (nerve mapping, ultrasound guidance, etc.), mental status during placement (i.e., awake, sedated, anesthetized, etc.) and test dosing information. Drop boxes are utilized to facilitate accurate and ease of data entry whenever possible.

Specific data concerning every identified complication will be prospectively collected. The complication data has been divided into intra-operative and post-operative groups defined by the time period the complication was recognized. Patients experiencing more than one complication will have each complication reported separately. Data will also include whether a treatment intervention was needed and the outcome of the complication (i.e. resolved without sequelae, resolved with temporary sequelae, permanent sequelae, death). The multicenter nature of this effort will facilitate data collection on a large scale, thereby providing sufficient power to make valid comments regarding rare adverse events. By collecting basic data for all regional anesthetics, this data set will also be able to provide true incidence data as opposed to the ASA Closed Claims Project where denominator data are not available.

The database will allow generation of both center-specific and cumulative group data from all centers in an anonymous manner. Each center will receive quarterly and annual center reports with comparisons to group descriptive data. This center-specific data would provide the opportunity to identify centers with lower complication rates (i.e., best practice?). Information such as this could then be widely distributed, thereby improving the overall quality of regional anesthesia for children. Furthermore, information gathered from the prospective database could be used to stimulate the completion of the badly needed randomized controlled outcomes studies in children. Finally, demonstration of a functional multicenter pediatric anesthesia **research network** could serve as a proof-of-concept for a federally-funded pediatric anesthesia network as already exists for the neonatal, pediatric, and adult critical care populations and pediatric oncology patients to name a few.

In summary, collaborative efforts by SPA and the AAP section on anesthesiology and pain medicine have led to the development of a prototype electronic web-based regional anesthesia database for children. This tool will allow for large multicenter prospective data collection of the current practice of regional anesthesia in participating centers and ultimately provide updated information regarding the true risks of regional anesthesia in children. This effort may ultimately serve as the stimulus to begin the prospective multicenter randomized controlled trials needed to truly define evidence-based “best practice” for regional anesthesia in children.

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