Pediatric Regional Anesthesia Network (PRAN): A Multi-Institutional Study of the Use and Incidence of Complications of Pediatric Regional Anesthesia

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BACKGROUND: Regional anesthesia is increasingly used in pediatric patients to provide postoperative analgesia and to supplement intraoperative anesthesia. The Pediatric Regional Anesthesia Network was formed to obtain highly audited data on practice patterns and complications and to facilitate collaborative research in regional anesthetic techniques in infants and children.

METHODS: We constructed a centralized database to collect detailed prospective data on all regional anesthetics performed by anesthesiologists at the participating centers. Data were uploaded via a secure Internet connection to a central server. Data were rigorously audited for accuracy and errors were corrected. All anesthetic records were scrutinized to ensure that every block that was performed was captured in the database. Intraoperative and postoperative complications were tracked until their resolution. Blocks were categorized by type and as single-injection or catheter (continuous) blocks.

RESULTS: A total of 14,917 regional blocks, performed on 13,725 patients, were accrued from April 1, 2007 through March 31, 2010. There were no deaths or complications with sequelae lasting >3 months (95% CI 0–2:10,000). Single-injection blocks had fewer adverse events than continuous blocks, although the most frequent events (33% of all events) in the latter group were catheter-related problems. Ninety-five percent of blocks were placed while patients were under general anesthesia. Single-injection caudal blocks were the most frequently performed (40%), but peripheral nerve blocks were also frequently used (35%), possibly driven by the widespread use of ultrasound (83% of upper extremity and 69% of lower extremity blocks).

CONCLUSIONS: Regional anesthesia in children as commonly performed in the United States has a very low rate of complications, comparable to that seen in the large multicenter European studies. Ultrasound may be increasing the use of peripheral nerve blocks. Multicenter collaborative networks such as the Pediatric Regional Anesthesia Network can facilitate the collection of detailed prospective data for research and quality improvement. (Anesth Analg 2012;115: 1353–64)

Regional anesthesia is increasingly used in pediatric patients to provide postoperative analgesia and intraoperative anesthesia. There is a large body of literature describing the techniques of regional blockade in children, the pharmacokinetics and pharmacodynamics of local anesthetics, use of adjunctive drugs, and reports of complications and pitfalls of various techniques, but detailed and complete information on complication rates and safety, particularly prospectively collected data, is limited.[1,2] There are only 3 large detailed prospective studies of complication rates in pediatric regional anesthesia, 2 from the French-Language Society of Pediatric Anesthesiologists (ADARPEF) and 1, limited to epidural anesthesia, from the United Kingdom (UK) and Ireland.[3–5] The French prospective studies are the largest and most comprehensive. The initial study was published in 1996, before the common use of ultrasound guidance. The most recent ADARPEF study, using the same methodology, comprised 31,132 regional blocks. It reported that the use of peripheral nerve blocks and continuous nerve blocks increased compared with the earlier study, although information regarding imaging and localizing techniques was not presented, and it was unclear whether there was a validation or auditing process to ensure the capture of the total number of blocks performed, which is essential to accurately determine rates.

Other studies were retrospective in design, may not have had accurate denominators, or had total numbers of

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subjects too small to generate accurate incidence data.[6–8] Yet others reflect the practice of a particular institution and cannot be easily generalized to a broader population.[9] Because the incidence of complications in regional anesthesia is relatively small, accurate and meaningful data can only be obtained by enrolling large numbers. This is virtually impossible even at large children's hospitals.

We therefore established a consortium of institutions in the United States (US) where pediatric regional anesthetics are frequently performed (the Pediatric Regional Anesthesia Network [PRAN]) to collect data prospectively and to facilitate large-scale, multicenter collaborative research and quality improvement in pediatric regional anesthesia.[10] Data on all regional blocks performed at each hospital were entered locally into a central database using a web-based data-reporting tool. This report describes the practice patterns, adverse events, and complications in nearly 15,000 regional anesthetics administered to children. We also describe details of the database and data collection tool to serve as a methodological reference for subsequent investigations that report data from PRAN.

METHODS

The PRAN was organized in 2006. Database and web data collection tools were developed with assistance from Axio Research, LLC (Seattle, WA). Data accrual began on April 1, 2007, using 6 pilot centers (Children's Hospital Colorado, Aurora, CO; Seattle Children's Hospital; Children's Hospital of Philadelphia; Children's Memorial Hospital, Chicago, IL; Lucile Packard Children's Hospital at Stanford University, Palo Alto, CA; and Children's Hospital at Dartmouth-Hitchcock Medical Center, Lebanon, NH). This preliminary phase of the study was used to troubleshoot data collection, to test the web instrument, and to acquire pilot data to demonstrate the effectiveness of the study methodology for collecting large-scale information. One center (Philadelphia) dropped out of the Network because of resource issues; the investigators were not able to ensure that all blocks could be collected and entered into the database, and their data have been excluded from the study results. After the first year of data collection, additional centers were added to the Network. Study centers in the PRAN that contributed data to this report are listed in the Appendix.

Approval for the study was obtained from the human subjects review board at each center. All centers were granted waivers of consent and Health Insurance Portability and Accountability Act of 1996 (HIPAA) by their review boards, because data were collected without any alteration in routine patient care, and no patient identifiers were uploaded to the database.

The Network is governed by a Steering Committee, comprised of 2 chairpersons (LDM and DMP) and a representative from each of the pilot centers, that meets monthly by teleconference and biannually in person. The project manager from Axio (CW) is an ex-officio representative on the committee.

Data Collection

Each PRAN study center collected data on every regional anesthetic performed by an anesthesiologist. Blocks performed by others (surgeons, emergency medicine physicians, etc.) were not included, but therapeutic and diagnostic nerve blocks performed by pain service anesthesiologists were entered. These comprised the intraoperative dataset. Data were also collected on continuous blocks during the period of infusion after the patient left the operating room. These variables comprised the postoperative dataset. Complications and adverse events were noted separately during both periods. The anesthesiologist performing the block entered the intraoperative data either on the anesthesia record or on a separate data form; data forms were used when there were not mandatory fields for all required variables on the anesthesia record itself. For single-injection blocks, either the anesthesiologist or their surrogate at follow-up recorded postoperative events. For continuous blocks, the clinicians on the hospital's acute pain service collected the postoperative data. Complications reported after discharge or at follow-up were also recorded where appropriate in the postoperative dataset. If a complication or adverse event was identified, it was followed until its resolution, usually by the clinicians on the pain service. That file remained open until follow-up data were completed and entered in the database.

Data Entry

Data from each center were entered into a centralized database maintained by Axio Research, LLC, using a web-based tool developed by the investigators in collaboration with Axio. The website is secure and password protected (each site has its own identity and each user has a unique username and password). No patient identifiers were uploaded or stored on the central server. Study centers, which needed to keep patient identifiers linked to each data file for follow-up until the file was complete, did so with either local paper data sheets or by using software that stored patient data in a "desktop registry" and uploaded the completed data to the central server only after stripping the file of patient identifiers. The website was designed to both maximize the efficiency and ease of data entry and to minimize data entry errors. For an individual data file to be considered complete, all required fields had to be filled in. "Orphan pages" were data files with no demographic information, those with demographics but missing block data, or complication pages with either no demographics or block data; these were detected initially by manual auditing at Axio until this function was automated in the database software. Required pages (web pages that contained data that could not be left blank) looked at "upstream" and "downstream" orphan pages; the software prevented block pages from being created unless a demographics page had been created, and complication pages could not be created unless at least 1 block was submitted. Demographics pages that were left with no block page ever created were also automatically detected. All of these were flagged and listed on the home page for each study center until they were completed or corrected.

Each institution had access to its own data, as well as the aggregate data, to enable comparisons and benchmarking for internal quality assurance and improvement purposes.[10] Individual centers were not able to view data stratified by center or identify their source, but could only see pooled data from other centers.

Data Auditing and Accuracy

Two data audits were performed: the first to confirm that every block performed was collected for entry into the database, ensuring the accuracy of the denominator, and the second to detect transcription errors, confirming and ensuring the accuracy of the data in the database. For the first audit, a member of the research team at each center reviewed every anesthesia record. In some institutions, a redundant list of all anesthetic records that were submitted for billing with a regional block was matched with the cases already identified, and provided an additional confirmation that no cases were missed. In institutions that used data sheets, those data were compared with the anesthesia record. If there were discrepancies or ambiguities that could not be resolved, the anesthesiologist of record was contacted to resolve them. If this audit detected a block that had not been reported on a data sheet, the data were obtained from the anesthesia record, or when necessary, from the anesthesiologist who performed the block.

The second audit, for data accuracy, was performed monthly. Initially, each center randomly selected 10% of that month's cases; if fewer than 50 cases were accrued, 5 cases were randomly selected. In the second year of the project, Axio developed software that randomly selected the cases for auditing. An investigator at each site examined the entries in the database and compared those data with the original source data. Any errors were corrected, and a record was maintained of the number of errors. Every complication and adverse event (rather than a selected sample) was audited for accuracy.

When multiple blocks were performed during a single operation and a complication or adverse event occurred, in rare instances it was not clear during data analysis which block was associated with the complication. These cases were independently reviewed and adjudicated by 3 steering committee members to associate the complication with the correct block. Unanimity was required to assign a complication to a particular block. In 3 instances, the data were ambiguous and a definitive assignment was not possible. In these few cases, the complication was assigned to both blocks in question to achieve the most conservative estimate of risk for each specific block, but was not "double counted" in the total number of block complications in that general category.

Data Parameters

Demographics collected included the date of database entry, the age (in months and years), the subject's weight (in kilograms), ASA physical status (including emergency), and gender.

Blocks were categorized as single-injection or continuous (catheter) blocks, and stratified by anatomical region. If more than 1 block or bilateral blocks were placed, a separate record was entered for each block, because each block was an independent event, each with its own risk of complications and failure. A rectus sheath block was the only exception because the steering committee considered it unlikely that a unilateral rectus sheath block would ever be performed.

Dosing and technical data collected included the physical status of the patient during the block placement (awake, sedated, anesthetized, presence or absence of neuromuscular blockade), the technology used to locate the nerve or confirm catheter placement (none, nerve stimulator, fluoroscopy, ultrasound, or epidurogram), and whether a test dose was administered.

The local anesthetic administered and its concentration, volume, and epinephrine content were recorded, as were the doses of any adjunctive drugs (opioids, clonidine). Related variables, including the starting infusion rate, and the date of catheter removal and reason for removal (no longer needed, dislodgement, development of a complication) were collected for catheter blocks in the postoperative period. Some of these data are not included in this initial report, and will be analyzed and reported in subsequent papers from PRAN.

Table 1a. Intraoperative Complications Measured

Whenever "other" was an option, its details were specified
Positive test dose and method of detection (heart rate increase, arterial blood pressure change, electrocardiogram change, other)
Inadvertent dural puncture (cerebrospinal fluid aspirate)
Inadvertent vascular puncture (blood aspirate)
Abandoned block (unable to place)
Failed block (completed but not successful)
Respiratory: pneumothorax, diaphragmatic paralysis, other
Cardiovascular: arrhythmia, hypotension, cardiac arrest, other
Neurological: seizure, paresthesia, other
Other complications
Interventions needed: none, repeated block in same location, repeated block in different location (specified), altered anesthetic medications (specified), administered other medications (specified), canceled surgery, other
Outcome: resolved without sequelae—no change in treatment; resolved without sequelae—change in treatment (specified); resolved with sequelae lasting <3 mo; resolved with sequelae lasting >3 mo (specified); death
Was length of hospitalization increased as a result of the complication?

Table 1b. Postoperative Complications Measured

Whenever "other" was an option, its details were specified
Unintentional unilateral block
Prolonged block (>12 h for single-injection)
Excessive motor blockade
Catheter problem: occluded, kinked, accidental dislodgement, other
Adverse drug reaction: nausea/vomiting, pruritus, other
Respiratory: respiratory depression, apnea, diaphragm paralysis, other
Neurological: seizure, paresthesia, dysesthesia, paralysis, postdural puncture headache, altered mental status, Horner syndrome, other
Hematoma
Infection: insertion site, deep tissue, other
Other
Location where complication was identified: postanesthesia care unit, intensive care unit, ward, home, other
Days between placement and complication
Intervention: none; change in infusate, rate, or contents; remove catheter; diagnostic test (computed tomography, magnetic resonance imaging, electromyogram, nerve conduction, other); consultation (neurology, neurosurgery, infectious disease, rehab medicine, other); medication (antibiotics, anticonvulsants, other); other
Outcome: resolved without sequelae—no change in treatment; resolved without sequelae—change in treatment (specify); resolved with sequelae lasting <3 mo; resolved with sequelae lasting >3 mo (specify); death
Was length of hospitalization increased as a result of the complication?

The presence or absence of adverse events and complications was recorded for every block, and categorized as intraoperative or postoperative dependent on when the complication occurred (Table 1, a and b). Definitions were specified by the Steering Committee. A complication describes a serious event (nerve injury, local anesthetic toxicity, postdural puncture headache, serious cardiac or respiratory events, deep infection). Adverse events describe undesirable side effects (Horner syndrome, pruritus) and events (unintended unilateral block, inability to place a block, failed block, positive test dose, or aspiration of blood from a needle or catheter) that did not result in patient harm or sequelae. The nature of each complication or event and whether an intervention was necessary and its outcome were recorded. A failed block was defined as one that was completed but resulted in no apparent analgesia or blockade. This includes epidural blocks in which epidurography demonstrated the catheter outside the epidural space. An abandoned block was one that could not be placed and the operator aborted further attempts.

Data Analysis

All cases entered into the PRAN database from April 1, 2007, when data collection commenced, through March 31, 2010, are included in this report. The dataset was analyzed only after audits described above were completed. The data in this initial report are descriptive, and are presented in the aggregate. Individual data from each center were not analyzed separately. The incidence of complications is reported in raw numbers and then calculated as percentage rates or occurrences per 1000 or 10,000 where appropriate. When indicated, the data are described with summary statistics including mean ± SD for normally distributed data and median (interquartile range) for non-normally distributed data. Exact binomial 95% confidence intervals (CIs) were calculated for some incidence rates, and are reported in parentheses. Statistical analysis was performed using STATA software (version 11.1; StataCorp LP, College Station, TX). In analyzing the use of imaging and localizing techniques, blocks were divided according to the following variables:

- Regional anesthetic techniques were analyzed by location and by single-injection or continuous catheter techniques.
- Nerve blocks performed >100 times were analyzed individually.
- Nerve blocks performed <100 times were grouped with similar blocks (e.g., upper extremity catheters of all types).
- The most common localizing technique was listed when it was used to perform >3% of the nerve blocks. Those nerve blocks performed using >1 technique (ultrasound, nerve stimulator) were also analyzed, and thus those numbers may add up to >100%.

RESULTS

Fourteen thousand nine hundred seventeen regional blocks, performed on 13,725 patients, were accrued during this initial 3-year study period. The majority of blocks were performed for elective surgery (96%). The demographics are presented in Figure 1. Fifty-three percent of the blocks were performed

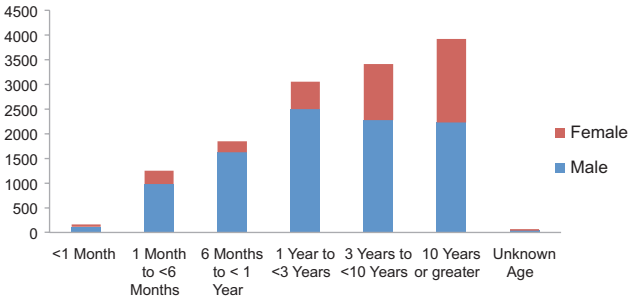

Figure 1. Demographics for 13,725 patients in the Pediatric Regional Anesthesia Network (PRAN) database.

in ASA physical status I, 30% in ASA II, 15% in ASA III, and 0.76% in ASA IV patients. Only 1 block was placed in an ASA physical status V patient. Block type, numbers, and incidences of complications are detailed in Tables 2 and 3. There were no deaths and no serious complications with sequelae lasting >3 months (95% CI 0–2:10,000). The distribution of block types among centers is shown in Figure 2.

Data Audits

The audits for data accuracy detected an error rate of 0.3% of case records, yielding an upper error margin of 0.5%. Each record contained at least 17 and potentially as many as 70 data fields, and the errors were usually confined to a single data field. All detected errors were corrected before data analysis. A small number of cases (0%–4%, depending on block type) had missing data in the imaging and technology field.

Single-Injection Group

Neuraxial Blocks

There were 6210 blocks in this category, of which the majority (6011, or 97%) were caudals and 83 were subarachnoid blocks (Table 2). The vast majority of caudal blocks were performed in young children, predominantly 3 years and younger (Fig. 3). No complications were reported in the caudal group (95% CI 0–6:10,000) or in the other single-injection neuraxial groups with the exception of a teenager who had hypotension from a subarachnoid block. There were 183 adverse events, an incidence of 3% (95% CI 26–35:1000) (Table 3). The most common adverse event (104, or 2% of the total and 57% of all events) was the inability to place the block or block failure. Single-injection caudal blocks were predominantly performed without any technical aids or imaging (93%); ultrasound guidance was used in 3% of cases.

Upper Extremity Blocks

The greatest variation in practice among study centers occurred with upper extremity blocks. Four hundred fifty-five blocks were performed, but 3 sites accounted for nearly all, and 1 site nearly half, of these blocks (Fig. 2). Supraclavicular blocks were performed more often than any other technique. Inability to place the block or a failed block was the most common adverse event. Two (of 164) supraclavicular blocks lasted >12 hours; these were considered prolonged beyond their expected duration. Most upper extremity blocks were placed using ultrasound guidance (82%) (Table 4).

Table 2. Summary of Single-Injection Blocks and Adverse Event Rates for All Centers

	Total procedures	Total adverse events (%)	No sequelae	No sequelae—change in treatment
Neuraxial				
Caudal	6011	172 (3)	60	112
Lumbar	103	5 (5)	1	4
Thoracic	13	2 (15)	0	2
Subarachnoid	83	5 (6)	4	1
Total neuraxial	6210	183 (3)	64	119
Upper extremity				
Interscalene	80	0	0	0
Supraclavicular	164	6 (4)	2	4
Infraclavicular	40	0	0	0
Axillary	99	2 (2)	1	1
Musculocutaneous	5	0	0	0
Elbow	1	0	0	0
Wrist	7	0	0	0
Other	58	0	0	0
Total	455	8 (2)	3	5
Lower extremity				
Lumbar plexus	78	6 (8)	4	2
Fascia iliaca	221	1 (0.5)	0	1
Femoral	872	6 (0.7)	3	3
Sciatic	413	14 (3)	3	11
Popliteal fossa	319	2 (0.6)	0	2
Saphenous	78	0	0	0
Other	325	5 (2)	2	3
Total	2307	33 (1)	11	22
Head and neck				
Supraorbital/ supratrochlear	58	0	0	0
Infraorbital	139	0	0	0
Greater auricular/ superficial cervical	157	0	0	0
Occipital	101	0	0	0
Greater palatine	11	0	0	0
Other	89	0	0	0
Total	556	0	0	0
Other block type				
Intercostal	39	0	0	0
Ilioinguinal/ iliohypogastric	737	3 (0.4)	1	2
Rectus sheath	294	0	0	0
Paravertebral	14	1 (7)	0	1
Penile	230	0	0	0
TAP	140	1 (0.7)	0	1
Other	395	0	0	0
Total	1849	5 (0.3)	1	4

Total adverse event rates reported in parentheses. Rates <1% reported as decimals and >1% rounded to nearest whole number.

Note that in the neuraxial category and the lower extremity category, the total number of complications are fewer than the cumulative sums of the individual types. This is because there were 3 cases in which 2 blocks were done in a single patient, 1 successful block after a complication in the other, and because of ambiguity in the data entry, it was impossible to determine which block was placed first. To assign the most conservative complication rate to the specific block category, the complication was counted against both blocks, but the total number of complications in that general block type is accurate. See text for more details.

There were no serious complications or sequelae reported in any single-injection group.

TAP = transversus abdominis plane.

Lower Extremity Blocks

Two thousand three hundred seven blocks were performed. Adverse events were detected in 33 (1%, 95% CI 1–2:100), and although 22 required a change in management, all resolved without therapy or sequelae. In 14 cases (6:1000), the block failed or could not be placed. Nearly three-quarters (70%) were performed with ultrasound guidance, with only fascia iliaca and lumbar plexus blocks having low ultrasound utilization rates (Table 5).

Head and Neck Blocks

There were 556 blocks in this group, with no complications or adverse events (95% CI 0–7:1000). There were minor differences among sites that frequently performed these blocks regarding the quantity and distribution of each head and neck block, but 2 sites did not perform any head and neck blocks, and 2 others, which joined the PRAN later than the pilot centers, only performed a total of 5 (Fig. 2).

Other Single-Injection Blocks

This group comprised intercostal and truncal blocks. There were 1849 blocks entered into the database, including 737 ilioinguinal-iliohypogastric blocks. There were 5 adverse events and no complications reported. Three blocks failed or could not be placed, a paravertebral block had a positive test dose, and an ilioinguinal block had a positive blood aspiration. Ultrasound imaging was very often used in this group, especially for ilioinguinal, intercostal, rectus sheath, and transversus abdominis plane blocks (Table 6).

Catheter Group

Adverse events occurred more often in the catheter group (Table 7). Nearly 43% were catheter related (265 of 623); by far, the most common (210) were catheter malfunctions (kink, disconnect, or inadvertent dislodgement) in the postoperative period. In 56 instances (9%), the block could not be placed or failed.

Neuraxial Blocks

Two thousand nine hundred forty-six neuraxial catheter blocks were performed. There was a relationship between age and catheter insertion site (Fig. 4). There were 520 adverse events (18%, 95% CI 160–190:1000) and 21 complications (0.7%, 95% CI 4–11:1000), but no complications had sequelae lasting >3 months. Most adverse events (140 or 26%) were catheter-related (dislodgement or kinking) (Table 8, a and b). The cumulative failure rate in this group was 2%. The highest failure rate occurred in thoracic catheters; 3% (5 of 195, 95% CI 10–60:1000) of caudally threaded thoracic catheters and 2% of thoracic catheters (15 of 695, 95% CI 10–40:1000) could not be placed, whereas 1.3% (20 of 1518, 95% CI 8–20:1000) of lumbar catheters and 0.8% (2 of 261, 95% CI 1–27:1000) of caudally advanced lumbar catheters failed. Just over half of these (51%) were completed successfully at either the same or a different level. Thoracic epidurals were associated with a higher incidence of catheter problems (8%) than caudal (2%) or lumbar (5%) epidurals. In addition, there were 40 unintentional unilateral blocks, which were more common with lumbar (23 of 1518, 1.5%) and thoracic (15 of 695, 2.2%) catheters compared with caudal catheters (2 of 730, 0.3%).

There were 46 positive test doses or vascular punctures (2%, 95% CI 12–21:1000). Accidental dural puncture occurred in 26 instances (0.9%, 95% CI 6–13:1000), during 4 caudal, 14 lumbar, and 8 thoracic placements. Four of these

Table 3. Single-Injection Neuraxial Block Complications and Adverse Events by Type

	TD	DP	VP	AB	FB	C	R	N	Other	Total events	Total procedures
Caudal	18	5	38	71	26	1	0	0	13	172	6011
Lumbar	0	2	0	2	0	0	0	0	1	5	103
Thoracic	0	1	0	1	0	0	0	0	0	2	13
Subarachnoid	n/a	n/a	0	2	2	1	0	0	1	6	83
Total	18	7	38	76	28	2	0	0	15	184	6210

TD = positive test dose; DP = dural puncture; VP = vascular puncture; AB = abandoned block; FB = failed block; C = cardiovascular; R = respiratory; N = neurological.

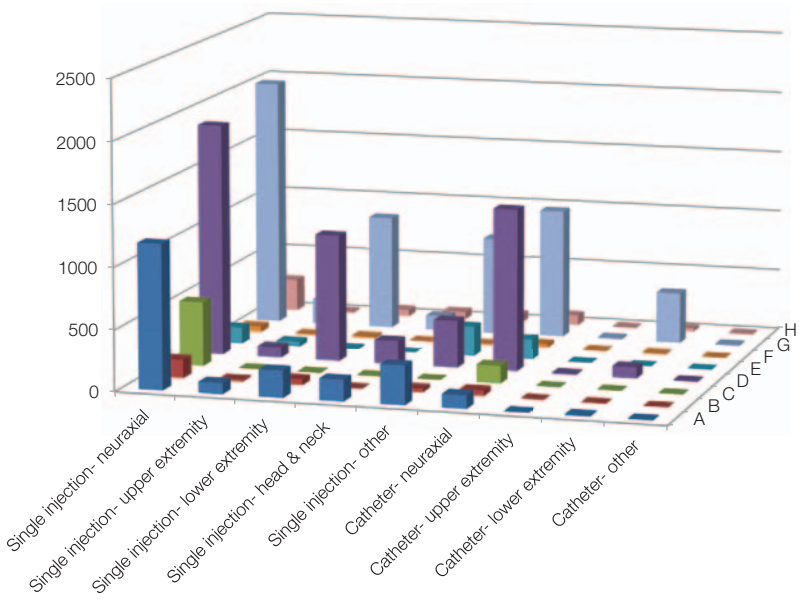

Figure 2. Distribution of blocks by study site. Each letter refers to a single study center and was assigned randomly (i.e., the order does not correspond to the list of study centers in the Appendix).

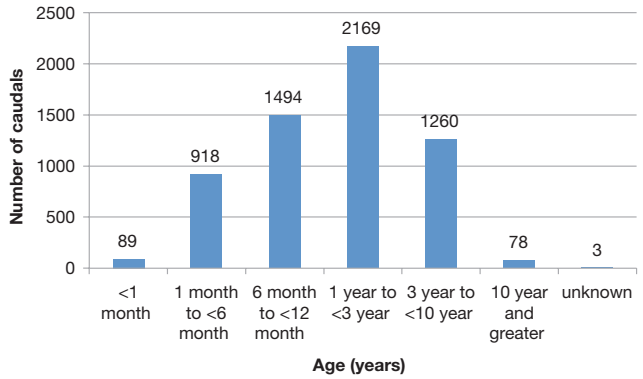

Figure 3. Single-injection caudal placement by age. Age data are missing for 3 patients.

patients developed postdural puncture headaches, and all required epidural blood patches after failing conservative therapy. The onset of headache in those patients who had a successful epidural catheter placed on a second attempt was delayed until after the infusion was stopped. One epidural catheter eroded through the dura on the second day of infusion; this also required a blood patch.

Neurological events were noted only in patients with lumbar or thoracic catheters. Four cases of Horner syndrome (0.6%, 95% CI 2–14:1000) were noted in patients with thoracic catheters; all resolved when the infusion rate was reduced. Three patients (0.1%, 95% CI 0.2–3:1000) had paresthesiae in the postoperative period, all of which resolved without sequelae. One patient with paresthesia also had allodynia and was prescribed gabapentin in the immediate postoperative period; the symptoms resolved by the time of hospital discharge.

Thirty-two local inflammations or infections were reported, resulting in an incidence of 11% (95% CI 8–17:1000). Most infections were localized to the insertion site and treated by removal of the catheter. Antibiotics were prescribed in only 3 patients, and all cases resolved without sequelae. There were no cases of deep infection, abscess, or meningitis reported (95% CI 0–13:10,000). Superficial infections requiring antibiotic treatment were diagnosed at a median of 3 days (2–4 days) after catheter placement. In addition, 8 caudal catheters were removed because the dressings were soiled with fecal matter and 10 were removed because of the presence of fever without an evident source. In all these patients, there was no concomitant evidence of infection related to the epidural catheter. Lumbar epidurals (0.6%, 95% CI 3–11:1000) were associated with a lower rate of infection than caudal (0.15%, 95% CI 8–27:1000) or thoracic (0.17%, 95% CI 9–30:1000) epidurals. Central neuraxial catheters were left in place for a mean of 2.2 days (median 2 days, range 0–20 days, SD 1.64 days).

Six postoperative respiratory complications were recorded, 5 of which were related to respiratory depression, for an incidence of 0.2% (95% CI 1–5:1000). These events occurred in a wide range of ages: one neonate, one

Table 4. Use of Localizing Techniques for Single-Injection Upper Extremity Blocks

	Total	None	Nerve stimulator	Fluoroscopy	Ultrasound
Interscalene/parascalene	80	2	16 (20%)	0	78 (98%)
Supraclavicular	164	2	22 (13%)	0	158 (96%)
Infraclavicular	40	1	11 (28%)	0	38 (95%)
Axillary	99	14	12 (12%)	1	77 (78%)
Musculocutaneous	5	2	0	0	3 (60%)
Elbow	1	0	0	0	1 (100%)
Wrist	7	7	0	0	0
Other	58	33	2 (3%)	3	19 (33%)
Totals	455	61	64 (14%)	4	375 (82%)

More than 1 technology can be used for a block, thus totals may exceed 100%.

Table 5. Use of Localizing Techniques for Single-Injection Lower Extremity Blocks

	Total	None	Nerve stimulator	Fluoroscopy	Ultrasound	Other
Lumbar plexus/psoas compartment	78	8	60 (77%)	9 (12%)	9 (12%)	1 (1%)
Fascia iliaca	221	166	4 (2%)	0	48 (22%)	0
Femoral	872	35	313 (36%)	1 (0.1%)	760 (87%)	0
Sciatic	413	13	195 (47%)	0	303 (73%)	0
Popliteal fossa	319	11	151 (47%)	2 (0.6%)	265 (83%)	0
Saphenous	78	9	5 (6%)	0	65 (83%)	0
Other	325	119	36 (11%)	20 (6%)	169 (52%)	0
Totals	2307	361	764 (33%)	32 (1%)	1619 (70%)	1 (0.4%)

More than 1 technology can be used for a block, thus totals may exceed 100%.

Table 6. Use of Localizing Techniques for Single-Injection Other Block Types

	Total blocks	None	Nerve stimulator	Fluoroscopy	Ultrasound
Intercostal	39	8	0	0	30 (77%)
Ilioinguinal/iliohypogastric	737	158	2	3	563 (76%)
Rectus sheath	294	32	2	0	256 (87%)
Paravertebral	14	8	0	1	4 (29%)
Penile	230	224	0	0	2 (0.9%)
TAP	140	2	0	0	129 (92%)
Other	395	198	3	44	147 (37%)
Totals	1849	630	7	48	1131 (61%)

TAP = transversus abdominis plane.

2-month-old, one 35-month-old, one 4-year-old, and a 15-year-old patient. They were remedied by decreasing the concentration of, or completely removing, the opioid component of the epidural infusate.

Seven cases of postoperative hypotension possibly related to continuous epidural infusions were reported, for an incidence of 2:1000. All were treated with a change or decrease in infusion rate. Six were teenagers and the other 5 years of age. All but one had a thoracic epidural.

Most epidural catheters were placed without subsequent verification of the position of the catheter tip (88% of caudal-sacral and 77% of caudal-lumbar) with the exception of just over half (55%) of the catheters threaded from the sacral hiatus to the thoracic level. Epidurograms were used to verify correct catheter placement in 9% of catheters advanced from the sacral hiatus to the sacral or lumbar region and in 25% of those threaded to the thoracic level. Ultrasound was used to verify placement in 11% of caudal-to-thoracic epidural catheter placements and stimulating catheters in 0.5% (Table 9).

Upper Extremity Catheters

Only 26 upper extremity catheters were placed. Adverse events were noted in 6 (23%, 95% CI 90–440:1000), but no complications were reported (95% CI 0–13:100). There were 3 catheter problems (50%), 2 failed blocks, and 1 prolonged block. Most (24 of 26, 92%) continuous upper limb blocks were placed with ultrasound guidance. In 5 of those, nerve stimulation was also used.

Lower Extremity Catheters

Five hundred forty-four lower extremity catheters were placed; some of these were continuous ambulatory catheters using elastomeric infusion devices in patients discharged home with outpatient follow-up, but the database does not distinguish between outpatient and inpatient catheters. There was 1 possible complication (95% CI 0–1:100), a case of prolonged paresthesia or numbness of the foot after a lumbar plexus block in a patient with spina bifida. The paresthesia resolved in <3 months; however, some of the symptoms might have been present preoperatively. There were 98 adverse events (18%, 95% CI 150–210:1000), of which 65 (67% or 12% of all catheters) were catheter-related problems. Vascular punctures occurred in 6 (3%, 95% CI 10–70:1000) lumbar plexus and 4 (2%, 95% CI 10–60:1000) femoral catheter placements. Seven blocks (5 sciatic, a lumbar plexus and a popliteal fossa) were judged to have excessive motor blockade. In 8

Table 7. Summary of Continuous Catheters and Complication/Adverse Event Rates for All Centers

	Total procedures	Total adverse events (%)	No sequelae—no change in treatment	No sequelae—change in treatment
Caudal				
Sacral	274	36 (13)	12	24
Lumbar	261	38 (15)	10	28
Thoracic	195	26 (13)	12	14
Epidural				
Lumbar	1518	243 (16)	57	186
Thoracic	695	177 (25)	23	154
All neuraxial catheters	2946	520 (18)	114	406
Upper extremity				
Interscalene	9	4 (44)		
Supraclavicular	7	1 (14)		
Infraclavicular	8	0		
Axillary	0	0		
Other	1	1 (100)		
Total	26	6 (23)		
Lower extremity				
Lumbar plexus	181	36 (20)		
Fascia iliaca	0	0		
Femoral	169	29 (17)		
Sciatic	150	29 (19)		
Popliteal	33	3 (9)		
Other	8	0		
Total	544	97 (18)		
Other catheter				
Intercostal	1	0		
Ilioinguinal	1	0		
Fascia iliaca	0	0		
Rectus sheath	0	0		
Paravertebral	3	0	0	1
Other	19	1 (5)	0	1
Total	24	1 (4)	0	1

Total adverse event rates reported in parentheses. Rates <1% reported as decimals and >1% rounded to nearest whole number.

Level of insertion data is missing for 3 neuraxial patients, none of whom had complications.

There were no deaths or complications with sequelae lasting >3 mo.

cases, catheters could not be placed or the block failed. There were 3 superficial infections, 1 each with a femoral nerve, sciatic, and popliteal fossa catheter, all of which resolved completely with antibiotics, local care, or removal of the catheter. Continuous peripheral nerve blocks of the lower limbs were frequently placed with ultrasound guidance (64%) and/or nerve stimulation (63%), and rarely without any localizing technique (6%) (Table 10).

Truncal and Other Blocks

There were 24 catheters placed for paravertebral, transversus abdominis plane, or other truncal locations. Only 1 adverse event was noted, a catheter-related problem.

DISCUSSION

This is the first prospective, observational, multicenter study of the practice of pediatric regional anesthesia and its complications from the US. The PRAN database, corroborating the findings of European investigators, suggests that regional anesthesia in pediatrics is remarkably safe, with a very low rate of complications. Our data also show that peripheral nerve blocks are very often used for infants and children in the US, and that the use of ultrasound guidance may be driving that practice for many of these blocks.

The intent of the PRAN is to accrue large numbers on regional anesthetics of all types in children so that assessments of practice patterns, risks, and complications can be obtained. The study methodology was designed to establish an accurate denominator for the data by subjecting the data to multiple audits so that rates of complications could be determined with certainty.

Since the inception of the network, several minor revisions of the website and database occurred. The majority did not affect the data collected and were made to improve clarity and ease of use. One exception, however, was the elimination of the "inadequate analgesia" complication data field. This was originally intended to measure block efficacy and was defined as a pain score higher than 5. The PRAN steering committee, upon interim examination of the

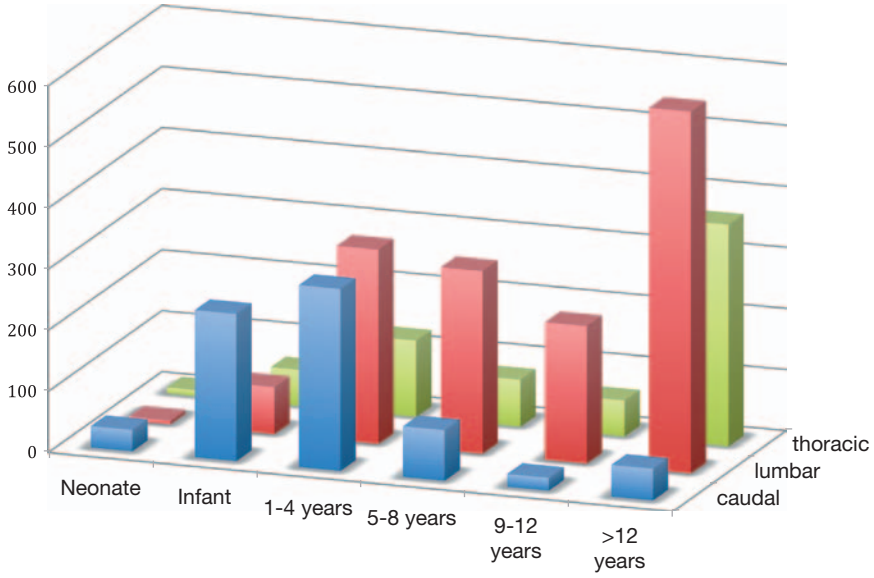

Figure 4. Continuous catheter placement by age and level of insertion. Age or insertion level data are missing for 6 patients.

Table 8a. Continuous Neuraxial Blocks: Intraoperative Adverse Events and Complications

	TD	DP	VP	AB	FB	R	C	N	IO
Caudal-sacral	3	2	11	2	2	0	0	0	5
Caudal-lumbar	4	2	4	1	1	0	0	0	2
Caudal-thoracic	3	0	0	4	1	0	0	0	2
Lumbar	1	14	8	12	8	0	1	0	7
Thoracic	2	8	10	5	10	0	0	0	3
Totals	13	26	33	24	22	0	1	0	19

TD = positive test dose; DP = dural puncture; VP = vascular puncture; AB = abandoned block; FB = failed block; R = respiratory; C = cardiovascular; N = neurological; IO = infection other.
Level of insertion data missing for 3 patients (no complications).

Table 8b. Continuous Neuraxial Blocks: Postoperative Adverse Events and Complications

	UUB	PB	EMB	CP	ADR	RP	NP	H	I	PO
Caudal-sacral	1	0	1	5	1	1	0	0	2	2
Caudal-lumbar	1	0	4	6	8	0	0	0	2	3
Caudal-thoracic	0	0	1	5	2	0	0	0	7	1
Lumbar	23	1	35	71	30	5	8	0	9	23
Thoracic	15	0	9	54	26	0	15	0	12	14
Totals	40	1	50	141	67	6	23	0	32	43

UUB = unintentional unilateral blockade; PB = prolonged blockade; EMB = excessive motor blockade; CP = catheter problem (dislodgment, occlusion); ADR = adverse drug reaction; RP = respiratory problem; NP = neurological problem; H = hematoma; I = infection; PO = postoperative other.

Table 9. Use of Localizing Techniques for Continuous Neuraxial Blocks

	Total blocks	None	Nerve stimulator	Fluoroscopy	Ultrasound	Epidurogram	Other
Caudal-sacral	274	241	0	8 (3%)	14 (5%)	15 (5%)	0
Caudal-lumbar	261	200	2	10 (4%)	20 (8%)	31 (12%)	0
Caudal-thoracic	195	107	1	25 (13%)	22 (11%)	48 (25%)	1
Lumbar	1518	1337	5	30 (2%)	24 (2%)	93 (6%)	0
Thoracic	695	587	3	23 (3%)	19 (3%)	58 (8)	0
Totals	2946	2475	11	96 (3%)	99 (3%)	245 (8%)	1

Table 10. Use of Localizing Techniques for Continuous Lower Extremity Blocks

	Total blocks	None	Nerve stimulator	Fluoroscopy	Ultrasound
Lumbar plexus/psoas compartment	181	22 (12)	153 (85)	9 (5)	23 (13)
Fascia iliaca	0	0	0	0	0
Femoral	169	5 (3)	102 (60)	1	156 (92)
Sciatic	150	5 (3)	72 (47)	1	131 (85)
Popliteal fossa	33	0	13 (39)	0	31 (94)
Other	8	0	1	0	7 (88)
Totals	544	33 (6)	342 (63)	11 (2)	349 (64)

data, decided that the measurement criteria of inadequate analgesia were not adequately defined to preclude inaccuracies and ambiguities. These data were therefore not analyzed and are not reported, limiting our ability to delineate an incidence of "block ineffectiveness," that is, how many blocks were technically successful but provided suboptimal or inadequate analgesia.

Limitations

This study was prospective and observational in nature. The study population was accrued from a limited number of academic medical centers with corresponding geographic and demographic diversity; the participating centers were not a random sample of hospitals providing pediatric regional anesthetic care in the US. Therefore, it should be noted that the reported complication rates are subject to selection and study population bias, design effect, and multiple other confounding variables that may not only impact the reported rate of adverse events, but also the reported CIs. Hence, we did not attempt to draw direct cause and effect from these data with respect to adverse outcomes. This large dataset will allow the identification of important adverse events to be researched further and will generate future prospective, randomized trials in the areas of concern that have been identified. PRAN was founded to provide a platform to conduct such studies that will address questions generated by observational data.

In most cases, a team of faculty and residents or fellows performed the regional blocks. Although we did not collect information on the level of training, we believe that, because

of the nature of the participating institutions, most faculty had subspecialty training in pediatric anesthesiology. The relatively small number of study centers, as compared with the ADARPEF and UK studies, may also impose some limitation of diversity of practice on our results, although the character of the centers was fairly diverse.

Although our study design was prospective, it still relied on self-reporting, as have other multicenter, prospective, observational studies.[3–5] Voluntary reporting carries a significant risk of underreporting,[11] but other prospective studies have suggested that this probably has little effect on the true incidence of complications.[12] The PRAN data differ significantly from other studies in that there is rigorous auditing to ensure that all regional anesthetics at each study center are collected and reported. As a consequence, the denominators of this dataset are highly accurate and may be the most precise incidence information to date.

In analyzing the complications it must be noted that although the total number of cases in the database is large, the quantity of some individual blocks remains relatively small. Thus, risk data on these blocks remain tentative and of speculative accuracy until a larger number are accumulated. Similarly, although a wide distribution of ages is represented, the number of cases in the youngest cohorts remains relatively small, and until greater numbers of very young patients are accrued, valid conclusions cannot be drawn with regard to safety for any specific block in these age groups. The same is true for weight; only 1 block was reported in a premature infant weighing <1000 g. The reason for the low neonatal numbers compared with the UK and ADARPEF is uncertain but may reflect practice in the US. Without a denominator for all neonatal operations performed with or without regional blockade, it is unclear whether this is an avoidance of regional anesthesia in neonates or simply a lower case volume performed in this age group at the PRAN institutions. Because the PRAN is an ongoing project, enough data should eventually be collected to make more confident and meaningful estimates of the complication rates in all regional anesthesia procedures in all age groups.

Many complications (e.g., paresthesia) are difficult to diagnose in infants and nonverbal children who cannot describe their symptoms accurately or even alert clinicians to their presence. Nevertheless, the incidence of serious complications that were detected in this prospectively acquired unselected population is extremely small, and no sequelae lasting >3 months were reported in close to 15,000 regional anesthetics. There were no serious complications such as epidural abscess, epidural hematoma, or persistent neurological deficit. In these instances, we must rely on CIs to provide an upper limit of possible incidence rates.[13] For example, although there was no mortality reported in 9156 neuraxial blocks, a mortality of 0 to 3.3:10,000 is still consistent with our data.

A final limitation of our methodology is that despite our best attempts at complete reporting, we cannot be sure that some late complications did not develop after patients were discharged from our care and thus escaped detection. Although all centers followed up on known complications until their resolution, there was no uniform or mandated system to actively query all patients without complications at discharge to determine whether new late complications developed beyond the proximate perioperative period. This is particularly relevant for single-injection blocks in patients who were discharged home on the day of surgery. Although each patient's parents or guardians were queried by telephone within several days of discharge, the specificity and rigor of those calls were not uniform, and it is possible (although unlikely) that some complications might have gone unreported.

Complications and Adverse Events

Catheter problems (dislodgement, kinking, malfunction) were especially common, accounting for approximately one-third of all postoperative adverse events. This problem has only been reported with upper extremity blocks, but we found that it occurs with all kinds of catheters, suggesting that devising better methods of placement and fixation should be a high priority.[14]

Similar to the ADARPEF studies and the UK epidural audit, the incidence of neurological complications was very low.[3–5] The number of dural punctures, however, was higher than expected. The second ADARPEF study reported a dural puncture rate of 0.1%, most often occurring during caudal blocks in infants, with only one during a thoracic epidural placement; none had postdural puncture headaches. Our incidence of dural puncture was more than twice that, and postdural puncture headaches were more common. The number of dural punctures during thoracic epidural placement is of particular concern, even though none resulted in any reported neurological sequelae.

Although we did not detect any deep neuraxial infections, the 95% CI for serious infection based on this PRAN data analysis and sample size is 0 to 13:10,000, similar to the findings in previous studies.[3,4,13,15] The UK audit reported 25 local and 3 serious (epidural abscess and meningism) infections,[4] for an overall incidence of 0.3% for local and 0.02% for serious infection. Another review from a single institution examined >10,000 epidurals placed during a 17-year period and found a low infection rate (0.06%, 95% CI 0.03–0.13) in epidurals placed for postoperative analgesia. The criteria for infection in that study were strict, and did not include local erythema or induration that resolved spontaneously.[16]

Respiratory complications were noted in several patients receiving central neuraxial opioids, but all cases were detected by respiratory monitoring before serious consequences developed and responded to a reduction in the infusion rate or opioid concentration. This highlights the importance and efficacy of careful and vigilant monitoring of respiratory status in these patients.

No local anesthetic toxicity was reported in any block. The 95% CI of 0–2:10,000 is consistent with rates in the ADARPEF and UK audits.[3–5] However, positive test doses were noted in several types of blocks, as was aspiration of blood through the needle or catheter. This suggests that test dosing and incremental injection whenever large volumes of local anesthetic are used remain important safety measures to detect intravascular injection and prevent toxicity.

Practice Patterns

The PRAN database offers an opportunity to examine practice patterns and complications. The common use of

peripheral nerve blocks, which comprised nearly one-third of all blocks in the PRAN database, mirrors the findings of the most recent ADARPEF study.[5] This may reflect a change in surgical practice (more laparoscopic surgery) or change in anesthetic practice (ultrasound) toward the perceived safer option of peripheral nerve block and away from the putative risks associated with neuraxial blocks.[17–19] The ADARPEF study did not report the frequency of ultrasound use, but our data enable us to speculate that the availability of ultrasound guidance for peripheral nerve blocks in particular may be driving the increased use of these blocks in pediatric practice compared with historical data.[20–22] This is not surprising, because good visual definition of most peripheral nerves can be obtained with portable ultrasound probes. Real-time ultrasound imaging can verify correct needle placement and local anesthetic delivery around the nerve.[23] We also document a shift in the practice of upper extremity blocks, most likely attributable to the advent of ultrasound guidance. In the past, axillary blocks were reported to be the most common upper extremity block in pediatric practice; however, 74% of the brachial plexus blocks in the PRAN database are supraclavicular, infraclavicular, or interscalene. More than 96% were placed using ultrasound guidance, as were nearly 83% of femoral, sciatic, popliteal fossa, and saphenous nerve blocks. Nerve stimulation seems to have a lesser role in pediatric regional techniques in the PRAN network, but remained commonly used for deeper blocks of the lower extremity as an adjunct to ultrasound. We postulate that this might be because deeper nerves at the limit of ultrasound penetration are less well defined and practitioners resorted to stimulation to confirm nerve location, or perhaps in some cases because of lack of ultrasound skills or training.

Although new data suggest that epidurography detects a much higher rate of unsuspected misplacement of epidural catheters than previously assumed, this information was published toward the end of the study period in this report.[24,25]

CONCLUSIONS

Regional anesthesia can be performed safely in children with a relatively low risk of complications. In this large prospective cohort of nearly 15,000 blocks in children from several academic medical centers, the majority of complications or adverse events were detected at the time of needle or catheter placement. There were no long-term sequelae. The PRAN data from pediatric institutions in the US compares favorably with those of other audits supporting the safety of regional anesthesia in children.

The high incidence of catheter-related issues may be a consequence of the catheter size, the connectors used, methods of fixation, or simply the novelty of peripheral nerve catheters. It is clear from these data that improved catheter stability is an important advance that must be achieved for more effective continuous neural blockade in children.

We believe that because of the rigorous auditing, these data represent one of the most accurate attempts at a large-scale estimate of complication rates in pediatric regional anesthesia. As more institutions and larger numbers of patients are enrolled, the PRAN database project may be the best way to achieve meaningful risk assessment in pediatric regional anesthesia, and may be a mechanism to organize future large-scale clinical comparison studies. ■

APPENDIX: PRAN Participating Institutions and Investigators as of January 2012

Seattle Children's Hospital, Seattle, WA* (Lynn Martin, Adrian Bosenberg, Sean Flack)
Children's Hospital Colorado, Aurora, CO (Denver Children's)* (David Polaner)
Children's Hospital at Dartmouth, Lebanon, NH* (Andreas Taenzer)
Children's Memorial Hospital, Chicago, IL* (Santhanam Suresh, Carmen Simion, Polina Voronov)
Lucile Packard Children's Hospital at Stanford University, Palo Alto, CA* (Elliot Krane)
Children's Medical Center, Dallas, TX (Peter Szmuk)
Columbia University, New York, NY (Susumu Ohkawa)
The Cleveland Clinic, Cleveland, OH (Sara Lozano)
University of Texas- Houston, TX† (Maria Matuszczak, Ranu Jain)
Children's Hospital, Boston, MA† (Hyun Kee Chung, Navil Sethna, Christopher Lee)
Texas Children's Hospital, Houston, TX† (Robert Power, Kim Nguyen, Nancy Glass)
University of New Mexico, Albuquerque, NM† (Nicholas Lam, Tim Peterson)
Oregon Health Sciences University/ Doernbecher Children's Hospital, Portland, OR† (Jorge Pineda)
Nationwide Children's Hospital, Columbus, OH (Tarun Bhalla)

* Denotes a pilot institution.
† Denotes an institution that has joined the network after the closing date of the data set included in this report.

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DISCLOSURES

Name: David M. Polaner, MD, FAAP.
Contribution: This author helped design the study, conduct the study, collect and analyze the data, and write the manuscript.
Attestation: David M. Polaner has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
Name: Andreas H. Taenzer, MD, MS, FAAP.
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Attestation: Andreas H. Taenzer has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

Name: Benjamin J. Walker, MD.
Contribution: This author helped analyze the data, and write the manuscript.
Attestation: Benjamin J. Walker has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
Name: Adrian Bosenberg, MB, ChB, FFA.
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Attestation: Adrian Bosenberg has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
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Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Attestation: Elliott J. Krane has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
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Attestation: Santhanam Suresh has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
Name: Christine Wolf, MBS.
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Attestation: Christine Wolf has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.
Name: Lynn D. Martin, MD, MBA, FAAP, FCCM.
Contribution: This author helped design the study, conduct the study, analyze the data, and write the manuscript.
Attestation: Lynn D. Martin has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.
This manuscript was handled by: Peter J. Davis, MD.

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