Safety of Pediatric Regional Anesthesia

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Disclosure

Nothing related to this presentation
Objectives

- Understand the current ASRA/ESRA Practice Advisory on Pediatric Regional Anesthesia.
- Establish the safe environment for pediatric peripheral and neuraxial blocks.
- Prevent potential complications in pediatric regional anesthesia.
What is “Safety”

- The condition of being safe from undergoing or causing hurt, injury - Webster

- The word “safety” refers, of course, to “safety of the patient,” but as human beings, we cannot deny that we constantly consider our own safety, too, especially from a medico-legal point of view. Dalens B et al, RAPM 2014.

- Safety and health care economics, patient satisfaction, better outcome, etc.
When the procedure or outcome of concern is relatively uncommon, precise estimation, although desirable, may be difficult or impossible.

Studies reporting a zero numerator are fairly common in the literature.

Because a confidence interval may be constructed easily from a zero numerator using the “rule of 3” (3/n – 95% confidence interval) we hope that those fortunate enough to report “no problems so far” will quantify the worst or best that a group of future patients can expect.

- 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).

- Centralized prospective database.
- 14,917 regional procedures in 13,725 patients.
- Caudal most common block (40%).
- PNB increasing in popularity (35%).
- No long term sequelae.
The overall estimated incidence (95% confidence interval [CI]) of complications after caudal blocks was 1.9% (1.7%–2.1%).

Patients who developed complications were younger, median (interquartile range) of 11 (5–24) months, compared to those who did not develop any complications, 14 (7–29) months, $P = 0.001$.

Safety concerns should not be a barrier to the use of caudal blocks in children assuming an appropriate selection of local anesthetic dosage.

### Table 2. Incidence of Specific Complications in Caudal Block

<table>
<thead>
<tr>
<th>Complication</th>
<th>Incidence (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Block failure</td>
<td>1% (0.8 to 1.1)</td>
</tr>
<tr>
<td>Blood aspiration</td>
<td>0.6% (0.5 to 0.8)</td>
</tr>
<tr>
<td>Positive test dose</td>
<td>0.1% (0.1 to 0.2)</td>
</tr>
<tr>
<td>Dural puncture</td>
<td>0.08% (0.005 to 0.01)</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>0.005% (– to 0.002)</td>
</tr>
<tr>
<td>Seizure</td>
<td>0.005% (– to 0.002)</td>
</tr>
<tr>
<td>Sacral pain</td>
<td>0.005% (– to 0.002)</td>
</tr>
<tr>
<td>Muscle spasm</td>
<td>0.005% (– to 0.002)</td>
</tr>
</tbody>
</table>

- 4 cases of severe permanent or longstanding neurological injury.
  - 23-month-old female with L3-4 epidural.
  - 12 y/o with T12-L1 epidural.
  - 12 y/o for L3-4 epidural.
  - 11 y/o T7-8 epidural.

- Imaging studies consistent with a vascular injury to the spinal cord.

**Table 1. Provisional Recommendations for Epidural Anesthesia in Anesthetized Children**

1. Limit epinephrine dosing to the test dose (0.5 μg/kg in 0.1 mL/kg).
2. Prevent or promptly treat severe hypotension.
3. Consider severe hypotension following test dosing or loading dosing of an epidural catheter under general anesthesia to be due to subarachnoid placement unless demonstrated otherwise.
4. Consider severe hypertension following test dosing or loading dosing to possibly indicate a painful response to intraneural placement.
5. Perform loss-of-resistance with saline, not air.
6. Consider selective use of Tsui’s nerve stimulation technique or fluoroscopy, as well as ultrasonography for infants, for cases of direct thoracic puncture under general anesthesia.
7. Inject epidural loading doses slowly in anesthetized patients.
8. Use dilute local anesthetic solutions for intraoperative epidural infusions.
9. In the postanesthetic care unit, document the degree of sensory and motor blockade. If blockade appears dense, stop the infusion and observe for clear regression. If there is no regression at all over the next 3 h, consider emergent spine magnetic resonance imaging and neurosurgical consultation as appropriate. Note that wire-wrapped epidural catheters must be removed prior to magnetic resonance imaging.
10. Consider patients receiving high dose corticosteroids and/or morbid obesity as at increased risk for epidural lipomatosis and reduced spinal canal compliance.

<table>
<thead>
<tr>
<th>Age</th>
<th>GA No NMB</th>
<th>GA With NMB</th>
<th>GA total</th>
<th>Sedated</th>
<th>Awake</th>
<th>Under GA [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 mo</td>
<td>643</td>
<td>568</td>
<td>1211</td>
<td>18</td>
<td>100</td>
<td>91.1</td>
</tr>
<tr>
<td>1 to &lt;6 mo</td>
<td>3842</td>
<td>1215</td>
<td>5057</td>
<td>47</td>
<td>190</td>
<td>95.5</td>
</tr>
<tr>
<td>6 to &lt;12 mo</td>
<td>5025</td>
<td>919</td>
<td>5944</td>
<td>47</td>
<td>11</td>
<td>99.0</td>
</tr>
<tr>
<td>1 to &lt;3 y</td>
<td>8806</td>
<td>1616</td>
<td>10,422</td>
<td>128</td>
<td>33</td>
<td>98.4</td>
</tr>
<tr>
<td>3 to &lt;10 y</td>
<td>10,050</td>
<td>2744</td>
<td>12,794</td>
<td>222</td>
<td>15</td>
<td>98.2</td>
</tr>
<tr>
<td>10–18 y</td>
<td>11,808</td>
<td>3275</td>
<td>15,083</td>
<td>1590</td>
<td>515</td>
<td>87.7</td>
</tr>
</tbody>
</table>

- PONS rate of 0.93/1000 (CI 0.7–1.2) under GA and 6.82/1000 (CI 4.2–10.5) in sedated and awake patients.

- LAST under GA was 0.08/1000 (CI, 0.02–0.2) and 0.34/1000 (CI, 0–1.9) in awake/sedated patients.

- 518 interscalene blocks were performed, 390 under GA and 123 with the patient sedated or awake.
- 472 single injection, and 46 catheters
- No LAST, PONS, CV complications, or dural puncture was reported.
- CI: 0 to 7.7/1000 events

- 165 interscalene catheters.

- 142 (86%) were discharged home with the interscalene CPNB in place.

- Success rate for the catheters was 92.1% (CI: 86.9-95.7%).

<table>
<thead>
<tr>
<th>Adverse events</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter dislodged prematurely (failure)</td>
<td>10</td>
</tr>
<tr>
<td>Agitation at home (failure)</td>
<td>1</td>
</tr>
<tr>
<td>No sensory block next morning (failure)</td>
<td>1</td>
</tr>
<tr>
<td>Catheter improperly positioned (failure)</td>
<td>1</td>
</tr>
<tr>
<td>Horner’s syndrome</td>
<td>2</td>
</tr>
<tr>
<td>Contralateral numbness</td>
<td>1</td>
</tr>
</tbody>
</table>
ESRA and ASRA practice advisory


- Controversial topics in PRA picked by experts

- Recommendations based on evidence, and if none was available, expert opinion
### Classification of evidence


<table>
<thead>
<tr>
<th>Evidence Class</th>
<th>Study Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A1</td>
<td>Sufficient number of randomized controlled trials to conduct a meta-analysis</td>
</tr>
<tr>
<td>Category A2</td>
<td>Several randomized controlled trial but not sufficient to conduct</td>
</tr>
<tr>
<td>Category A3</td>
<td>Single randomized controlled trial</td>
</tr>
<tr>
<td>Category B1</td>
<td>Observational comparisons between clinical interventions for a specific outcome</td>
</tr>
<tr>
<td>Category B2</td>
<td>Observational studies with associative statistics</td>
</tr>
<tr>
<td>Category B3</td>
<td>Noncomparative observational studies with descriptive statistics</td>
</tr>
<tr>
<td>Category B4</td>
<td>Case reports</td>
</tr>
</tbody>
</table>
Performing PRA under GA or deep sedation Ivani et al Reg Anesth Pain Med 2015.


Performing PRA under GA or deep sedation

- The performance of PRA under GA/DS is associated with acceptable safety and should be viewed as the standard of care (Evidence B2 and Evidence B3).

- The overall risk for complications is 0.66% (95% CI, 0.6%–0.7%), whereas the risk of paralysis is estimated at 0 (95% CI, 0%–0.004%) (Evidence B2 and Evidence B3).

- Rare complications may occur. In the event of an unexpected clinical outcome, especially unanticipated motor blockade during continuous postoperative regional block after the use of PRA, a high index of suspicion for neurological injury is warranted and appropriate diagnostic and therapeutic measures must be performed without delay (Evidence B4).
Test Dose and Intravascular Injection

- Because of the difficulty interpreting a negative test dose, the use of test dosing should remain discretionary. Any injection of an LA solution should be performed slowly, in small aliquots (0.1–0.2 mL/kg) and with intermittent aspiration and observation of the ECG tracing (Evidence B4).

- Any modification of the T wave or of the heart rate within 30 to 90 seconds after the injection of a test dose should thus be interpreted as an accidental IV injection until disproven (Evidence B3).

- Imaging modalities (ultrasound, fluoroscopy) may help to avoid or visualize accidental intravascular needle placement in peripheral blocks, but data are lacking in PRA to determine the value of these techniques (expert opinion).
Air - LOR or saline - LOR or a combination may be used but use the lowest volume necessary (expert opinion).

In neonates and infants keep the volume of air in the syringe to < 1 ml (expert opinion).

Air, right to left shunt and air embolism (insufficient evidence).

- No evidence to suggest that the use of PRA increases the risks or delays the diagnosis of ACS.
- Discuss with patient and/or patient’s family preoperatively.
- Low concentration of LA (Evidence B4), low infusion rates, close monitoring in high risk cases, using additives with care, and early monitoring of compartment pressures when ACS is suspected.
An ounce of prevention is worth a pound of cure. Ben Franklin
Safe environment and preventing potential complications - Preoperative

- Assess indication and thoroughly understand procedure and anatomy
- Preoperative huddle
- Adequate expertise
- Assess patient and obtain Informed consent (marking for block ?) and risk vs benefit
- Equipment
- Medication (LA and resuscitation drugs)
Safe environment and preventing potential complications - Intraoperative

- Adequate monitoring
- **BLOCK TIME OUT**
- Adequate site prep, sterile gloves, mask and gown (when indicated)
- Ultrasound guidance
- Inject LA in after negative aspiration, in small aliquots with repeated aspiration, pay attention to imaging, if used, while injecting. Secure catheter.
- Document procedure.
Wrong site/side block

- Preventable

- In many states, is reported as wrong side surgery

- Site marking, block time out, “silence” during time out and when performing the block

- When it happens- inform, involve risk management, consider doing the block on the correct side/site if possible, RCA

- Survey of RAPM members in ASRA meeting 2013

**Regional Block Preprocedural Checklist**

1. Patient is identified, 2 criteria
2. Allergies and anticoagulation status are reviewed.
3. Surgical procedure/consent is confirmed.
4. Block plan is confirmed, site is marked.
5. Necessary equipment is present, drugs/solutions are labeled.
6. Resuscitation equipment is immediately available: airway devices, suction, vasoactive drugs, lipid emulsion.
7. Appropriate ASRA monitors are applied; intravenous access, sedation, and supplemental oxygen are provided, if indicated.
8. Aseptic technique is used: hand cleansing is performed, mask and sterile gloves are used.
9. “Time out” is performed before needle insertion for each new block site if the position is changed or separated in time or performed by another team.
Survey of Wrong Site Regional Anaesthetics
H. Simmons, R. Brits Department of Anaesthetics, East Lancashire Hospitals NHS Trust, Lancashire 2011

- Distractions
  - Multiple people in the OR
  - Teaching/Training
  - Use of unfamiliar techniques
  - Change to routine anaesthetic technique
  - Time pressures

- Terminology
  - Ambiguous terminology e.g. the right side instead of correct side
  - Incorrect or confusing terms
Survey of Wrong Site Regional Anaesthetics
H.Simmons, R. Brits
Department of Anaesthetics, East Lancashire Hospitals NHS Trust, Lancashire 2011

- Language barriers
- Surgical site marking
  - Distant from block site and not visible during procedure
  - Very few mark block sites
- Checking procedures
  - Not done the same way as it is for the surgical procedure.

- 2009-2015
- RCTs where UGRA was compared to PNS and other techniques
- Mostly adult studies
- Case series were also used to provide supplemental evidence about incidence of complications.
- Search criteria included complications - LAST, PONS, hemidiaphragmatic paralysis, pneumothorax

- No meaningful impact on PONS
- Reduces the incidence and severity of HDP but is inconsistent
- Lower predicted incidence of pneumothorax following supraclavicular block
- Reduces the risk of LAST by about 65%.
  - Ultrasound guidance provided a 42% reduction in minimal effective anesthetic volume.


Local anesthetic and additives

- UG decreases minimal effective volume
- Use the right concentration and amount/rate
- Consider additives carefully
- Epinephrine- Yes or no?
- Always be prepared to treat LAST
Safe environment and preventing potential complications - Postoperative

- Monitor for symptoms and signs of ACS

- Follow up to ensure that the block has resolved completely; join PRAN or keep a database.

- Postop instructions: Care of insensate area, fall risk, catheter care, watch for complications and instructions to clamp catheter when appropriate, 24 hour access to pain management. Also, call 911 for emergencies.

- Appropriate infusions

- Infusion devices (Iliev P et al, Ped Anesth 2015)

<table>
<thead>
<tr>
<th>Complications</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excessive leakage</td>
<td>15</td>
</tr>
<tr>
<td>Accidental catheter removal</td>
<td>24</td>
</tr>
<tr>
<td>Accidental vascular injury</td>
<td>1</td>
</tr>
<tr>
<td>Catheter failure</td>
<td>4</td>
</tr>
<tr>
<td>Repeat bolus needed</td>
<td>10</td>
</tr>
<tr>
<td>Local anesthetic related side effects</td>
<td>5</td>
</tr>
<tr>
<td>Catheter site problems</td>
<td>3</td>
</tr>
<tr>
<td>Difficulty removing catheter</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>64</td>
</tr>
</tbody>
</table>
Asleep or Awake Rethinking “Safety”. Dalens et al. Reg Anesth Pain Med 2014

- Is the indication appropriate?
- Is the technique fully explained to the patient and his representatives, with a consent form signed?
- Do I benefit from all the state-of-art equipment to perform the procedure in optimal conditions?
- Have I mastered the procedure adequately and am I comfortable with the indication?
- Is there a medical reason why I need to impose the performance of the technique in a way that is not in accordance with the desires of the patient/patient’s family

- We must remain cognizant, however, that performing a block procedure conveys a risk of damage whether the patient is anesthetized or awake.
Summary

- Current data indicates that the safety of PRA is not compromised when performed under GA or deep sedation and the incidence of severe side effects is very low.
- Rare adverse events can occur even in experienced hands; Incorporate standard of practice.
- Judicious use of PRA does not increase the risk or mask symptoms of ACS.
- Ultrasound guidance decreases the incidence of LAST.
Absence of evidence is not evidence of absence.