Title: Bilateral Continuous Erector Spinae Blocks for Post-Sternotomy Pain Management: A Pilot Study

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TITLE:

Bilateral Continuous Erector Spinae Blocks for Post-Sternotomy Pain Management: A Pilot Study

A. Specific Aims/Objectives:

Overall Aim: To evaluate the feasibility and potential benefits of investigating bilateral continuous erector spinae blocks (BESB) for postoperative pain management in a small cohort of children undergoing surgical sternotomy prior to planning an appropriately powered, randomized, controlled trial of the same.

Hypothesis: The investigators' primary hypothesis is that utilizing bilateral erector spinae blocks for post-sternotomy pain is a feasible intervention for consideration in a larger trial by demonstrating a 75% or greater successful intervention completion rate without any major adverse outcomes.

B. Background and Significance:

Regional anesthesia—and pediatric regional anesthesia in particular—is a rapidly evolving subfield of anesthesia practice driven with considerable urgency by the growing recognition that even appropriate perioperative narcotic administration can have significant derogatory long-term effects.

Regional anesthetics can provide targeted, continuous analgesia to select dermatomes with minimal additional patient risk and as such have become routine components of opioid-sparing intraoperative and postoperative pain management plans for surgical patients at BCH. In addition to the postulated benefit of reducing overall opioid exposure and potentially reducing the risk for long term physiologic and behavioral dependence upon opioids, regional anesthetics may allow for earlier extubation after selected surgeries, shorter ICU, PACU and inpatient admissions, earlier mobilization, fewer gastrointestinal complications, and improved patient satisfaction scores.

Despite a robust literature supporting the safety and efficacy of regional anesthesia for postoperative pain control across a broad range or surgery types, patient demographics and underlying comorbidities, there are certain classes of surgeries that

have (to date) not benefitted from the advantages that regional anesthetics may provide, most notably spine surgery and cardiac surgery.

Concerns have been expressed with regard to regional anesthetics for cardiac surgeries in particular (this being the primary surgical type associated with sternotomies in a pediatric populations), given that most patients are pharmacologically anticoagulated to some extent during their procedures and are thus at increased risk for bleeding.[1-5] This is further complicated in the pediatric cardiac surgical population as many of these children are intubated for an extended period of time and therefore may not have particularly reliable neurological exams in the setting of neuraxial regional anesthetics—potentially resulting in unrecognized acquired neurological defecits. While there is emerging evidence of improved outcomes with neuraxial regional anesthetics in adult cardiac surgery patients,[6] this has not trickled down to the pediatric population, likely for some of these reasons.

We are fortunate at BCH to have one of the largest concentrated pediatric cardiac surgical populations in the US. We also have an active, and well organized regional anesthesia service. Because of this, we are in a unique position to more thoroughly evaluate the effectiveness and safety of regional anesthetics in children following cardiac surgery. Furthermore we feel it is critical that institutions such as BCH take a leading role in documenting the effects of regional anesthesia on the most important outcome measures when considering perioperative medicine. These include: overall pain management, surgical healing, functional recovery, long term pain symptoms, and emotional/behavioral outcomes after surgery.

Recently, the erector spinae block (ESB) has become popular for providing analgesia after a number of anterior chest and abdominal procedures.[7-10] This is a simple interfascial plane block that can reliably provide unilateral chest and/or abdominal wall analgesia.[11] It has been described in numerous case reports and one case series as an effective block for management of unilateral thoracotomies, unilateral rib fractures, unilateral abdominal incisions and most notably, when used bilaterally, for management of post-sternotomy pain.[12,13] New case reports and series involving the ESB are being published almost weekly at this point with a growing literature specific to cardiac surgical applications.[14,15] Indeed a randomized controlled trial to investigate the analgesic efficacy of bilateral erector spinae plane (BESP) blocks compared with conventional treatment for pain after cardiac surgery in adult patients was published recently (2018) with promising results.[16]

As an interfascial plane block in a compressible anatomical space, the ESB is thought to be safe in anticoagulated (or recently anticoagulated) patients.[17] It is fast becoming a preferred anesthetic option for these pharmacologically or otherwise coagulopathic patients as opposed to neuraxial (e.g. epidural) and paraneuraxial blocks (i.e. paravertebral) nerve blocks, which are largely contraindicated in this setting.

Given the ESB's potentially favorable risk profile versus the other blocks that would subserve the same dermatomes (i.e. it is technically less challenging, more distant from critical structures, and thought to be safe in anticoagulated patients) it could provide both a safer and easier to perform regional anesthesia option for many

patients.[12] In particular, it offers a new option for a subset of anticoagulated patients for whom other regional techniques (epidural, paravertebral) are contraindicated. This is particularly true for the populations of pediatric cardiac surgical patients at BCH if used bilaterally.

Indeed, given the current information available related to the ESB, the regional anesthesia service at BCH has begun employing it when possible in circumstances when a neuraxial or paravertebral block(s) would commonly be used but is/are relatively or absolutely contraindicated. Patients undergoing thoracotomies while anticoagulated for cardiopulmonary bypass, aortic clamping, etc. have been successfully managed with unilateral continuous ESBs.[18] In addition, thoracotomies in patients with acquired (e.g. dilutional) and other pathologic coagulopathies have been managed with ESBs. As such, the ESB has been adopted for routine use in specific patient populations at BCH and has even occasionally been utilized in lieu of the more longstanding routine PVBs or epidural blocks for patients without contraindication for such.

Retrospective review of BCH outcomes data for 47 ESBs done for a variety of surgeries and populations has not revealed any significant differences between PVBs and ESBs in terms of adverse events, postoperative opiate use, median pain scores, or other standard outcomes measures. As this data is observational in nature, it is difficult to draw firm conclusions as to the efficacy of the two blocks. However, since there are distinct known and described advantages associated with regional anesthetics for postoperative pain management, it would be prudent to evaluate these blocks in a controlled, randomized, trial. Prior to such a trial, a pilot study to evaluate the feasibility of such a trial is warranted.

As such, we propose to evaluate the feasibility of investigating bilateral continuous erector spinae blocks (BESB) for patients undergoing surgical sternotomy by means of a pilot study. For this study, ‘feasibility’ will be defined primarily as a successful intervention completion rate of 75% or greater of all subjects with no major adverse outcomes. Secondary measures of feasibility will include aggregate ‘data integrity’ as defined by successful collection of 75% or greater of all possible data points for successfully completed subjects as well as ‘efficient intervention duration’ as evaluated by intervention completion time being less than 40 minutes.

C. Preliminary Studies

While the PVB and, increasingly, the ESB are commonly used for postoperative management of numerous thoracic procedures in adults and children, there is little prospective data available evaluating the efficacy of these blocks and no prospective data at all that we are aware of evaluating the utility of such blocks for management of post-sternotomy pain in a pediatric population.

Retrospective studies and case reports of varying quality exist and they suggest that ESBs are efficacious and low risk, but very few prospective data exist. The ESB has been described as having utility in the adult perioperative environment for patients undergoing breast surgery[19], shoulder surgery[20], thoracotomy/thoracoscopic surgery[9,21], thoracic spinal surgery,[22] and ventral abdominal surgery[7]. Two case

reports have also described its utility in treating patients with chronic pain in the thoracic dermatomes.[23] As noted above, there is at least one published prospective study in adults,[16] but similar studies in pediatric patients are yet to be undertaken. IN general, there is much less published evidence in children; however there are case reports and case series describing its use for patients undergoing thoracic and abdominal surgery[12,24-26].

Large retrospective analyses of multiple pediatric regional anesthesia registries do exist and consistently report a very favorable safety profile for the provision of regional anesthetics in the pediatric population. A recent (2015) consensus statement from the American and European Societies of regional anesthesia (ASRA and ESRA) reported the risk profile of administering regional anesthetics to anesthetized children, citing a risk of postoperative neurologic symptoms of 0.93/1000 cases (>90% of which resolve completely within 1 month) and a rate of local anesthetic systemic toxicity of 0.08/10000 cases.[27]

As noted above, analysis of the retrospective outcomes data for the 47 BCH patients treated with ESBs following unilateral thoracotomy does not reveal significant differences in common outcome measures including postoperative opioid consumption or pain scores as recorded by nurses in our inpatient units. While the numbers at BCH are small, there is no evidence that either of this block type is associated with any greater risk than that demonstrated by aggregate data from the various pediatric regional anesthesia registries. Information currently available suggests that regional blockade, when performed properly, carries a very low risk of morbidity and mortality in appropriately selected infants and children.[28] Furthermore, we have found no evidence of increased adverse events present in the ESB patients when compared to the patients receiving other regional anesthetics in our local analysis. Indeed, two abstracts addressing the safety and efficacy of ESB blocks in BCH patients have recently been accepted for presentation at the major regional anesthesia conference in the US.[29,30]

D. Design and Methods

(1) Study Design

We propose a pilot study. This will be a 10-patient pilot study to evaluate the feasibility of bilateral continuous erector spinae blocks (BESB) for patients undergoing surgical sternotomy. ‘Feasibility’ will be defined primarily as a successful protocol completion rate of 75% or greater of all subjects with no major adverse outcomes. Secondary feasibility outcomes will include aggregate ‘data integrity’ as defined by successful collection of 75% or greater of all possible data points for successfully completed subjects as well as ‘efficient intervention duration’ as evaluated by intervention completion time being less than 40 minutes. Children and adolescents aged 3-21 years of age will be recruited from Boston Children’s Hospital.

(2) Patient Selection, Inclusion/Exclusion Criteria and Recruitment Method

Patients from BCH who meet the criteria below will be considered for recruitment:

Inclusion Criteria:

1. Scheduled as part of the cardiac surgical ERAS program.
2. Scheduled for a primary sternotomy.
3. Ages 5-21 years.

Exclusion Criteria:

1. Patients undergoing reoperative procedures.
2. Significant scoliosis or other anatomic contraindications to ESB.
3. History of bleeding or current therapeutic dose anticoagulant use.
4. Significant intraoperative hemodynamic instability or bleeding, as ascertained by clinicians taking care of the patient.
5. Patients with severe neurodevelopmental delays.
6. Patients with previous chronic pain syndromes.
7. Patients with a history of opioid treatment at any point in the 2 months prior to surgery.
8. Lack of parental consent and/or child assent.

Recruitment Method:

We plan to include national and international pediatric patients who are scheduled for in-patient surgery at BCH over a period of 1 year. Patients will be recruited by members of the study staff. Each morning, a designated member of the study staff will review the upcoming surgical schedule to identify pediatric cases that fit the study criteria (procedure type and age). If these criteria are met, the case will be sent to an investigator for further clinical review. A final eligibility decision will be made by the PI.

1. ***Outpatients*** *with procedures scheduled >2 weeks from identification:* Patients will be sent information on the study (cover letter, brochure, consent form) up to 2 weeks prior to their surgery or scheduled preoperative visit. This will be sent either by USPS mail or by secure electronic mail if an e-mail is on file.
2. ***Outpatients*** *with procedures scheduled 2 weeks or less from identification:* Patients will be contacted by secure electronic email and/or given informational materials at their preoperative visit if we are unable to send mailers reliably VIA USPS. We will allow at least a day for them to consider participating in the study.
3. ***Outpatient*** *telephone follow-up:* Patients sent information packets either by USPS or secure electronic email may be contacted by telephone to confirm receipt of the materials and answer any initial questions after such time as they would normally be expected to have received and reviewed the packets (the next week for USPS and no sooner than 1 day following email). If materials have not been received, patients will be given the opportunity to have those materials sent or be contacted at a preoperative visit.
4. ***Inpatients*** *with no planned discharge and/or preoperative clinic appointments:* Patients who are already inpatient will be approached on the patient floor or other inpatient encounter with study information. We will approach as soon as we have confirmed eligibility and will provide them with recruitment materials

prior to their day of surgery and allow at least 24 hours for a decision to be made.

5. ***International patients****:* For international patients, recruitment materials will not be mailed internationally. If an e-mail is available for an eligible international patient, a secure e-mail via BCH server will be sent if the family is noted to be English-speaking. The e-mail will include all approved recruitment documents. If we are unable to reach an international family via e-mail, eligible international patients and their families will be approached and provided materials in the preoperative clinic. At this time we will provide information about the study, answer all questions and allow at least 24 hours for them to consider participating in the study.
6. Consent will be obtained either at the time of preoperative visit or on the day of surgery or at the bedside for those who are inpatient without pre-op appointments. If a patient expresses interest but does not sign consent at the preoperative visit, these patients may be contacted by phone prior to their surgery to assess their interest in participation.

(3) Description of Study Treatments or Exposures/Predictors

Participants will have their medical record reviewed following enrollment for demographic information including: gender, age, weight and height, procedure, surgeon, laterality (if applicable), and current and historical medication use.

Enrolled patients will have bilateral erector spinae blocks (with catheters for postoperative local anesthetic infusion) placed by the investigators in a sterile fashion after of the surgical procedure is complete as follows:

- The patient is placed in a lateral decubitus position (left or right), with all pressure points padded in routine fashion.
- The area for intervention is prepped with a chlorhexidine solution, and sterile drapes are applied to demarcate the block placement area.
- The T4/5 transverse process on one side is identified with the ultrasound transducer in a parasagittal orientation.
- An 18g Tuohy needle is advanced to the target area under direct ultrasound visualization. The needle tip is advanced until it contacts the transverse process, just below the erector spinae muscle complex.
- Normal saline is injected to confirm appropriate needle tip position. The erector spinae muscle is visualized to be elevated up off of the transverse process with normal saline injection
- With confirmation of appropriate needle tip position, the initial local anesthetic bolus is injected using a weight-based dosing protocol (generally 0.75ml/kg of straight 0.2% ropivacaine).
- Following the bolus injection, a catheter is threaded into the space occupied by the local anesthetic bolus.

- Catheter tip position is verified by one or more of the following: ultrasound visualization of the catheter tip, ultrasound visualization of instilled normal saline and/or ultrasound visualization of a small hyperechoic (i.e. bright on ultrasound) injection of air.
- With the catheter tip position identified, the catheter is tunneled to a cutaneous exit point approximately 2-3cm from the incision using a Crawford needle.
- The catheter is dressed in standard fashion with an adhesive catheter anchor, Dermabond, Mastisol, Tegaderm and tape.
- This is repeated for the contralateral side. To the extent possible, this will be done without repositioning in a contralateral decubitus position.
- A label indicating that each catheter is a nerve-block catheter with its laterality and date of placement noted is applied to each catheter.
- Catheter placement is complete.
- Postoperative infusion of local anesthetic (per weight based protocol) via the nerve block catheter is initiated (the standard infusion is straight 0.2% ropivacaine @ 0.25ml/kg/hr with a usual combined max rate of 15ml/hr).

All patients will have access to rescue opiates as needed by means of the standard PCA/NCA demand protocols utilized at BCH. In addition, all patients will be followed by the Acute Pain Service at BCH, enabling access to additional assessment, catheter and infusion management and opioid treatment as needed 24 hours a day, 7 days a week. Floor/ICU nursing personnel are encouraged to call the Acute Pain Service if they feel pain management is not adequate in any case – this will be reinforced for patients included in this trial. In addition, one of the primary investigators will be available for consultation 24 hours a day to the Acute Pain Service for any desired consultation on study patients.

E. Definition of Primary and Secondary Outcomes/Endpoints

Feasibility:

Primary:

- Feasibility: ‘Feasibility’ will be defined primarily as a successful intervention completion rate of 75% or greater of all subjects with no major adverse outcomes.

Secondary:

- Data integrity: Data integrity will be considered satisfactory if there is successful collection of 75% or greater of all collectible catheter follow-up data points, in aggregate, for successfully completed subjects.
- Efficiency: The treatment will be considered to have an ‘efficient intervention duration’ if the intervention completion time is found to be less than 40 minutes.

F. Data Collection Methods

All patients will be assigned a unique personal identifier that will not be linked to any patient identifying information. Data will be collected during the study in case report forms and then will be entered into a password-protected, secure database or automatically collected via the Regional Anesthesia Outcomes Database and uploaded to that same database.

While in the OR, the time required for installing and dressing the catheters, functional assessments, and any complications during placement will be recorded. The surgical procedure and the total surgical time will also be recorded along with any relevant surgical complications.

Each subsequent day of the study (Day 1=24 hours, Day 2 =48 hours), the catheter will be assessed for following adverse events: Presence or absence of catheter dislodgement (catheter out or no longer in a clinically effective position), catheter occlusion, catheter leakage (presence of local anesthetic under occlusive dressing), skin irritation (presence of hyperemic cutaneous reaction not present at dressing placement), and catheter infection (presence of purulent material) by a member of the study team. Intubation status (including extubation time, where indicated), catheter boluses and catheter rate adjustments (if present) will be recorded. Patients' costs and charges will be collected electronically in order understand the healthcare value of this novel pain management strategy

Research information collected on paper (or other physical media) during the study will be stored in locked cabinets with access limited to the Principal Investigator and research personnel affiliated with the study. Information that has been generated as, or transferred to, electronic media will be kept on password protected, secured data servers. All health information is protected by HIPAA (Health Insurance Portability and Accountability Act) and all health records will be kept confidential. Patients' birthdate, name, and all other identifying information will be removed when analyzing and reporting the data. Any personal identifying information will be stored separately from the other information provided by or about the patient and no personal identifying information will be reported in any publications or presentations. Identifying information will be kept in a password protected, secure file with limited access by research personnel. Once data collection is complete, identifying information will be destroyed.

G. Data Management Methods

All relevant information retrieved from the electronic medical record, by the PI and/or a member of the research team will be translated into an electronic form. Data collected in paper case report forms will be entered into a standard, secured database for intake and checking, and will be protected by encryption and password. Only authorized users are permitted access to the data files, and daily server back-up activities are executed to ensure data safety. All data will be stored on a password-

secured research computer, and all data entered into the computers will be password protected. Procedures to ensure accurate and reliable data collection will include well-designed data forms and training.

H. Study Timeline

We plan to enroll a total of 10 patients in the pilot study. We will then match enrolled patients from the pilot study to patients within the enhanced recovery after cardiac surgery (ERAS Cardiac) program (IRB # P00029161) in a 1:2 ratio for a total of 30 patients altogether. All patients in this study will already be part of the enhanced recovery after cardiac surgery clinical program (a quality improvement program). We anticipate that it would take approximately 8 months to complete enrollment and data collection for this study.

I. Adverse Event Criteria and Reporting Procedures

Adverse or unanticipated events will be reported as required to the Boston Children's Hospital IRB by the PI according to institutional reporting requirements.

An Adverse Event refers to any untoward medical occurrence whether or not it is considered intervention-related.

As noted above, analysis of the retrospective outcomes data for the 47 BCH patients treated with ESBs demonstrates no evidence that this block type is associated with any greater risk than that demonstrated by aggregate data from the various pediatric regional anesthesia registries. Information currently available suggests that regional blockade, when performed properly, carries a very low risk of morbidity and mortality in appropriately selected infants and children.[28]

Nevertheless, as there exist little prospective outcomes data related to the ES block, we will implement a rigorous system to follow and report any adverse events, including interim analyses by a non-blinded statistician, as described below:

Adverse Event Monitoring:

Adverse outcomes will be carefully tracked for all patients enrolled in the study. Enrollment will be halted and the IRB informed by the PI if any of the following conditions are met:

- 1 of any of the following serious adverse events:
  - Patient death.
  - Pneumothorax
  - Hematoma at the site of the catheter/block—causing pain or any neurological symptoms for the patient.
  - Persistent neurologic symptoms lasting more than 3 days after a single shot block or catheter is removed.

- Local anesthetic systemic toxicity (any symptoms leading to this diagnosis by a study team participant)

- >2 of any of the following minor/moderate adverse events in aggregate:
  - Persistent bleeding at the site of the catheter insertion or block placement.
  - Leakage of local anesthetic from the catheter insertion site that leads to discontinuation of the catheter infusion.
  - Redness or superficial infection of the catheter site or site of the block placement.
  - Skin irritation at the site of the catheter insertion or block placement that results in greater than 3 cm of induration or is associated with pain.

If there is a pause for any of the above reasons, continuance of the protocol will be at the discretion of the IRB in consultation with the study team. No individual care data will be reported unless there is a serious adverse effect. Reports will be done in an aggregated fashion.

Special note regarding ropivacaine:

Ropivacaine use in ESB catheters is the standard for clinical management in this patient population at this institution. It is routinely used at BCH for all nerve blocks and regional anesthetics. Known potential adverse advents of this mode of delivery of this medication include hypersensitivity, allergic reaction, hypotension and cardiac arrhythmias if injected intravascularly. The presence of any of these will be assessed by the primary anesthesiologist intraoperatively and treated appropriately at the time of block placement and initial bolus and further assessed for such daily by members of the research team and Acute Pain Service. Any occurrence of a possible adverse event or events will be documented and reported to the DSMB, the IRB and the Department of Anesthesia Quality Assurance Physician as appropriate. In the event of a serious adverse event, it will be reported to the DSMB and IRB immediately and the study halted until a thorough investigation into the cause can be made.

The relative safety of ropivacaine for use in regional anesthesia is supported by the information contained the Pediatric Regional Anesthesia Network (PRAN) database. The PRAN is a consortium of major pediatric centers in North America that manages a prospective data registry on pediatric regional anesthesia. From their database, which at this time comprises more than 130,000 pediatric regional anesthetics from numerous major centers in the US and Canada, ropivacaine is documented to be used in greater than 85% of pediatric regional with a safety profile at least equivalent to, if not better than, bupivacaine.[31]

Further, ropivacaine is very well studied in pediatrics. There is an extensive body of prospective clinical trials and clinical outcomes studies on ropivacaine pharmacokinetics, safety and clinical outcomes from infancy through adolescence. Our prescribing practices at BCH in the Regional Anesthesia and Acute Pain Services are derived from that body of PK information and consensus recommendations.

We therefore regard ropivacaine as the established standard of care for pediatric regional anesthesia and have selected it for use in this study.

J. Quality Control Method

Data quality control will be assured through automated and manual methods. The study database enhances data quality through required entry fields for critical data and automatic flags for missing or out-of-range data. Efforts will be made to minimize data entry error by the development of a user-friendly database and all data entry will be double-checked with the source files. Data will be audited for accuracy by investigators after being entered into the database.

K. Data Analysis Plan

At the time of data analysis, datasets will be downloaded from the standard, secure database and merged into Statistical Analysis Systems 9.3 (or more recent) for purposes of analysis. Missing data will be accounted for when the data is coded into respective variables.

Descriptive statistics will be generated in order to summarize demographic characteristics of patients enrolled. Data will be evaluated subsequently with regard to the above-mentioned criteria for ‘feasibility.’

Adverse events and complications (if any) associated with the blocks will be recorded and categorized.

Matched groups will be compared for demographic data, Patients costs and charges, risk factors, diagnosis, procedure, and cardiopulmonary bypass and clamp times to ensure their similarities. Once data collection is complete, identifying information will be destroyed.

L. Sample Size Considerations

As this is not a powered study but rather a pilot study to evaluate the feasibility of a protocol, no power analysis has been performed. The investigators believe, given their experience with this block in other surgical populations, that a cohort of 10 patients will be satisfactory to assess the primary outcome of ‘feasibility.’ However, the investigators recognize that the sample size is such that no statistically significant conclusions related to potential benefits may be realizable. Nevertheless, such data should be sufficient to power a more formal study.

M. Study Organization

Drs. Morgan Brown, Roland Brusseau, Andrea Gomez Morad, Viviane Nasr and Nathalie Roy will serve as principal investigators. Patient screening, recruitment,

enrollment, and data collection will be performed by a designated member of the research team.

N. Potential Benefits

There are no known direct benefits to the patients partaking in the study. Currently no data exists to recommend these blocks over conventional management. The results of this study may allow the investigators to develop an appropriately powered, randomized controlled trial to evaluate the utility of this intervention which might be used to inform such management decisions for future patients.

O. Privacy Provisions

Information will only be made available to individuals who are part of the research team. Any results from tests performed for research purposes will not be placed in the medical record. Medical information collected for this study will only become part of your child's medical record if the information is determined to be pertinent to the care your child receives at Children's Hospital Boston. Disclosure of personal information may occur only when required by law.

P. Confidentiality Provisions

All identifying information such as dates of birth, names, and medical record numbers will be removed from the study database. All patients will be assigned to an ID number that will not be linked to any patient identifying information. Data collected for research purposes will not be entered into patient's medical record. All data will be electronically secured in a password protected private folder. Only research investigators and personnel affiliated with the study will have access to patient information.

Every effort will be made by research staff to keep patient information confidential. To ensure patient confidentiality, all research data will be secured in locked filing cabinets in a locked office. Any publications that result from this study will not be linked with personal identifiable information that would disclose the identity of study subjects.

Q. References

1. Hemmerling T, Choiniere JL, Basile F, Prieto I. Regional anesthesia in cardiac surgery and immediate extubation after cardiac surgery: a different view. Can J Anaesth 2005;52:883.
2. Djaiani G, Fedorko L, Beattie WS. Regional anesthesia in cardiac surgery: a friend or a foe? Semin Cardiothorac Vasc Anesth 2005;9:87-104.
3. Riedel BJ. Regional anesthesia for major cardiac and noncardiac surgery: more than just a strategy for effective analgesia? J Cardiothorac Vasc Anesth 2001;15:279-81.
4. Mychaskiw G, 2nd, Heath BJ. Regional anesthesia and pediatric cardiac surgery. Anesth Analg 2000;91:1562.

5. Hammer GB. Regional anesthesia for pediatric cardiac surgery. J Cardiothorac Vasc Anesth 1999;13:210-3.
6. Peterson KL, DeCampli WM, Pike NA, Robbins RC, Reitz BA. A report of two hundred twenty cases of regional anesthesia in pediatric cardiac surgery. Anesth Analg 2000;90:1014-9.
7. Chin KJ, Adhikary S, Sarwani N, Forero M. The analgesic efficacy of pre-operative bilateral erector spinae plane (ESP) blocks in patients having ventral hernia repair. Anaesthesia 2017;72:452-60.
8. Chin KJ, Malhas L, Perlas A. The Erector Spinae Plane Block Provides Visceral Abdominal Analgesia in Bariatric Surgery: A Report of 3 Cases. Reg Anesth Pain Med 2017;42:372-6.
9. Forero M, Rajarathinam M, Adhikary S, Chin KJ. Erector spinae plane (ESP) block in the management of post thoracotomy pain syndrome: A case series. Scand J Pain 2017;17:325-9.
10. Forero M, Rajarathinam M, Adhikary S, Chin KJ. Continuous Erector Spinae Plane Block for Rescue Analgesia in Thoracotomy After Epidural Failure: A Case Report. A A Case Rep 2017;8:254-6.
11. Ivanusic J, Konishi Y, Barrington MJ. A Cadaveric Study Investigating the Mechanism of Action of Erector Spinae Blockade. Reg Anesth Pain Med 2018;43:567-71.
12. Ueshima H, Otake H. Clinical experiences of erector spinae plane block for children. J Clin Anesth 2018;44:41.
13. Wong J, Navaratnam M, Boltz G, Maeda K, Ramamurthi RJ, Tsui BCH. Bilateral continuous erector spinae plane blocks for sternotomy in a pediatric cardiac patient. J Clin Anesth 2018;47:82-3.
14. Leyva FM, Mendiola WE, Bonilla AJ, Cubillos J, Moreno DA, Chin KJ. Continuous Erector Spinae Plane (ESP) Block for Postoperative Analgesia after Minimally Invasive Mitral Valve Surgery. J Cardiothorac Vasc Anesth 2018;32:2271-4.
15. Monahan A, Guay J, Hajduk J, Suresh S. Regional Analgesia Added to General Anesthesia Compared With General Anesthesia Plus Systemic Analgesia for Cardiac Surgery in Children: A Systematic Review and Meta-analysis of Randomized Clinical Trials. Anesth Analg 2019;128:130-6.
16. Krishna SN, Chauhan S, Bhoi D, et al. Bilateral Erector Spinae Plane Block for Acute Post-Surgical Pain in Adult Cardiac Surgical Patients: A Randomized Controlled Trial.
17. De Cassai A, Tonetti T. Local anesthetic spread during erector spinae plane block. J Clin Anesth 2018;48:60-1.
18. Tsui BCH, Navaratnam M, Boltz G, Maeda K, Caruso TJ. Bilateral automatized intermittent bolus erector spinae plane analgesic blocks for sternotomy in a cardiac patient who underwent cardiopulmonary bypass: A new era of Cardiac Regional Anesthesia. J Clin Anesth 2018;48:9-10.
19. Kimachi PP, Martins EG, Peng P, Forero M. The Erector Spinae Plane Block Provides Complete Surgical Anesthesia in Breast Surgery: A Case Report. A A Pract 2018.
20. Forero M, Rajarathinam M, Adhikary SD, Chin KJ. Erector spinae plane block for the management of chronic shoulder pain: a case report. Can J Anaesth 2018;65:288-93.
21. Adhikary SD, Pruett A, Forero M, Thiruvenkatarajan V. Erector spinae plane block as an alternative to epidural analgesia for post-operative analgesia following video-assisted thoracoscopic surgery: A case study and a literature review on the spread of local anaesthetic in the erector spinae plane. Indian J Anaesth 2018;62:75-8.
22. Ueshima H, Otake H. Clinical experiences of ultrasound-guided erector spinae plane block for thoracic vertebra surgery. J Clin Anesth 2017;38:137.
23. Ramos J, Peng P, Forero M. Long-term continuous erector spinae plane block for palliative pain control in a patient with pleural mesothelioma. Can J Anaesth 2018;65:852-3.
24. Hernandez MA, Palazzi L, Lapalma J, Forero M, Chin KJ. Erector Spinae Plane Block for Surgery of the Posterior Thoracic Wall in a Pediatric Patient. Reg Anesth Pain Med 2018;43:217-9.
25. Munoz F, Cubillos J, Bonilla AJ, Chin KJ. Erector spinae plane block for postoperative analgesia in pediatric oncological thoracic surgery. Can J Anaesth 2017;64:880-2.
26. Thomas DT, Tulgar S. Ultrasound-guided Erector Spinae Plane Block in a Child Undergoing Laparoscopic Cholecystectomy. Cureus 2018;10:e2241.
27. Ivani G, Suresh S, Ecoffey C, et al. The European Society of Regional Anaesthesia and Pain Therapy and the American Society of Regional Anesthesia and Pain Medicine Joint Committee Practice

Advisory on Controversial Topics in Pediatric Regional Anesthesia. Reg Anesth Pain Med 2015;40:526-32.
28. Polaner DM, Drescher J. Pediatric regional anesthesia: what is the current safety record? Paediatr Anaesth 2011;21:737-42.
29. Foz C ES, Alrayashi W, Kordun A, Cravero JP. Erector Spinae Plane block in children undergoing coarctation of aorta repair. American Society of Regional Anesthesia. Las Vegas, NV2019.
30. Eklund SE FC, Alrayashi W, Kordun A, Cravero JP. Erector Spinae Plane Blocks in Patients Undergoing Periacetabular Osteotomy. American Society of Regional Anesthesia. Las Vegas, NV2019.
31. Suresh S, De Oliveira GS, Jr. Local anaesthetic dosage of peripheral nerve blocks in children: analysis of 40 121 blocks from the Pediatric Regional Anesthesia Network database. Br J Anaesth 2018;120:317-22.