

**Truncal ultrasound guided regional anesthesia for implantation and revision of
AICDs and pacemakers in pediatric patients**

NCT04184349

Version Date: 12/19/2019

Title: Truncal ultrasound guided regional anesthesia for implantation and revision of AICDs and pacemakers in pediatric patients.

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Population: Children undergoing pacemaker and/or Automatic Implantable Cardioverter Defibrillator implantation at Children's Memorial Hermann Hospital

Study Duration: Data will be collected from procedure for 48 hours

Purpose

The purpose of this study is to determine the efficacy and safety of truncal blocks for pacemaker and Automatic Implantable Cardioverter Defibrillator implantation in children

Hypothesis Truncal block is effective, safe and feasible for implantation of AICDs and pacemakers in children.

Research Design and Procedures to be Used

Written consent for the study will be obtained from a parent. We will also obtain consent from the patient if they are older than 10 years together with their parents.

The patients will be simply randomized by a pre-determined computer generated random numbers and allocated to one of two groups. The group allocation (LA group or B group) will be concealed in sealed opaque envelopes that will be opened after enrollment of the patients. In one group (the LA group), only the local anesthetic infiltration will be performed. In the block group (the B group), PECS and TTP blocks will be performed. The ultrasound-guided nerve blocks will be performed by the anesthesiologist after induction of anesthesia and endotracheal intubation. The left upper extremity angiogram will be performed prior to block to ensure the correct side for the implant. The local anesthetic group will have wound infiltration as routine care by the electrophysiologist at the time of wound closure. Both of these blocks have been used successfully in our institution and the purpose of the study is to prospectively evaluate whether there is a decrease in amount of narcotic medications need and track complications. There is no deviation from the standard of care as currently practiced.

At our institution, the incision is typically made below the clavicle on the left anterior chest wall and a subcutaneous (pre-pectoralis major) pocket or sub-muscular pocket is created between pectoralis major and minor muscles with sharp and blunt dissection and electrocautery by the electrophysiologist. Based on the literature this area is best covered by a PECS block combined with the transversus thoracic muscle plane block to help cover medial anterior nerve branches. (5) The adult literature describes mainly a combination of serratus plane block combined with transversus thoracic plane block as the generator is placed in the mid axillary line. (4). The dose of 0.2% ropivacaine is 1ml/kg and so for the block group the dose is divided into halves for the PECS block and TTP block (2 injections). For ultrasound-guided peripheral nerve block, we will

use a 22-gauge 4 cm Pajunk needle and a linear probe of the SonoSite. The skin will be cleaned with chlorhexidine prep solution and aseptic technique followed.

Pecs Block

The goal of the Pecs block is to infiltrate the fascial compartment with local anesthetic ropivacaine between the pectoral nerves (the pectoral fascia and clavipectoral fascia). The local anesthetic should cover the pectoral compartment with the pectoral nerves. The block is performed with the patient supine, either with the arm abducted 90 degrees or by his or her side. The transducer is then moved laterally until the pectoralis minor and serratus anterior are identified. With further lateral transducer movement, the third and fourth rib can then be identified. The injection of 0.5 mL/kg of 0.2% ropivacaine is made between the pectoralis major and minor muscles.(Figure 2).

TPP block

A transversus thoracic plane block is added to provide sufficient analgesia to the area around the sternum. The ultrasound is placed on the left parasternal border at T3-4 level and moved medially until the plane between the internal intercostal and transversus thoracis muscles is identified immediately medial to the sternal border. Using an in-plane technique, 0.5mL/kg of 0.2% ropivacaine is injected between the internal intercostal and transversus thoracis muscle plane. (Figure 3).

The adjunctive medication protocol will include scheduled alternating ibuprofen and tylenol unless contraindicated by renal impairment. Both groups of patients will also have oral oxycodone available as needed for moderate breakthrough pain and IV morphine for severe pain. The total dose of local anesthetic for group B will be same as that of group LA.

Primary outcome: We will compare the two groups on their total narcotic dose in milligram morphine equivalents (MME) needed for 48 hours after procedure. This is calculated as intravenous fentanyl (mcg) x0.03+intravenous hydromorphone (mg)x20+intravenous morphine(mg)x3+[number of oral oxycodone 5 mg/acetaminophen 325 mg tabs equivalents]. The 48 hour mark is picked since the local anesthetic duration for either local infiltration or block is 6-12 hours and most patients would be discharged prior to the 48 hour mark. This also allows for sufficient time for complications to develop and tracked as secondary outcomes.

Secondary outcome: VAS pain score in PACU, incidence of pruritus, nausea/vomiting, respiratory depression, local anesthetic toxicity and pneumothorax, these complications would arise early in the post procedure period but would be tracked for 48 hours.

Statistical Analysis

Data will be analyzed within one month after completion of data collection for all enrolled patients. The de-identified data will be uploaded to PI's UTH-Share account and shared with the statistician. We will report the summary statistics of demographics and disease-related characteristics for two groups. The primary endpoint, amount of morphine equivalent administered intra-operative and during the first 24 hours after procedure, will be summarized as median and inter-quartile, and depicted as side-by-side boxplot. Comparison between two groups will be evaluated by Wilcoxon rank sum test. We will report the incidence rates of side effects including pruritis and nausea, as

well as complications including local anesthetic toxicity and pneumothorax. The Wald test will be used for comparing incidence rates between two groups.

At our institution we performed 24 implants in the last 2 years (aicd/ppm, external, 4 were lead revisions, generator changes or pocket revisions. The most common approach used is the left intra-clavicular subcutaneous (pre-pectoral). We anticipate at least 12 patients per year going forward. Based on a 5% two-sided two-sample t test, the size of 12 patients per group provides the power of 94% for detecting difference for effect size 1.5 assuming that the primary endpoint follows a normal distribution

Data and Safety Monitoring:

Both groups will be followed for signs of local anesthetic toxicity, pneumothorax or infection, these will be reviewed at quarterly intervals with the cardiologist/anesthesiologist PIs.

Risks and Potential Benefits

The risks of wound infiltration (LA group) is the potential use of higher doses of narcotic which is associated with more nausea, pruritis and potential for respiratory depression. The block groups use has the risks of insufficient analgesia with the need for rescue medications, the use of a longer block needle has the theoretical risk of injury to deeper structures such as the lung but the use of ultrasound and experience with ultrasound of the anesthesiologist makes it a minimal risk. Risks with either technique are those associated with any injection: infection, bleeding and damage to surrounding structures. Both groups have the risk of local anesthetic toxicity.

The benefit of the block group is the improved analgesia and decrease in the narcotic dose needed with a resulting decrease in narcotic associated side effects.

The secondary outcomes will be incidence of pruritus, nausea/vomiting

Importance of Knowledge That May Be Reasonably Expected To Result

Truncal ultrasound guided blocks are gaining popularity due to their efficacy in the adult population for implantation of pacemakers and AICDs and so far there is a lack of reports of these being used in the pediatric population. Based on our experience with effectiveness of truncal blocks so far we anticipate encouraging other centers to integrate this modality and offer better pain control to their patients.

Ethics

The study has obtained departmental IRB approval and is seeking institutional IRB approval. Given very positive results from the adult population, we believe delaying this study will deprive large groups of children at other institutions from receiving a pain management technique that will improve their comfort and decrease the amount of narcotic needed.

The consent and assent will be explained to family and patient and alternatives which include no randomization will be offered.

A linking log will be used to deidentify data and a data sheet have been attached for review. The data sheets will be securely destroyed as soon as deidentified data is transferred to a electronic form on a secure server. The linking log will be stored in a locked cabinets within a locked office at the medical school.

Any complications will be reviewed quarterly with the EP cardiology/anesthesiology group and will be referred for departmental quality review if there is an increase in the number of complications compared to current base line when both the pain management injections are currently performed as standard of care.

References

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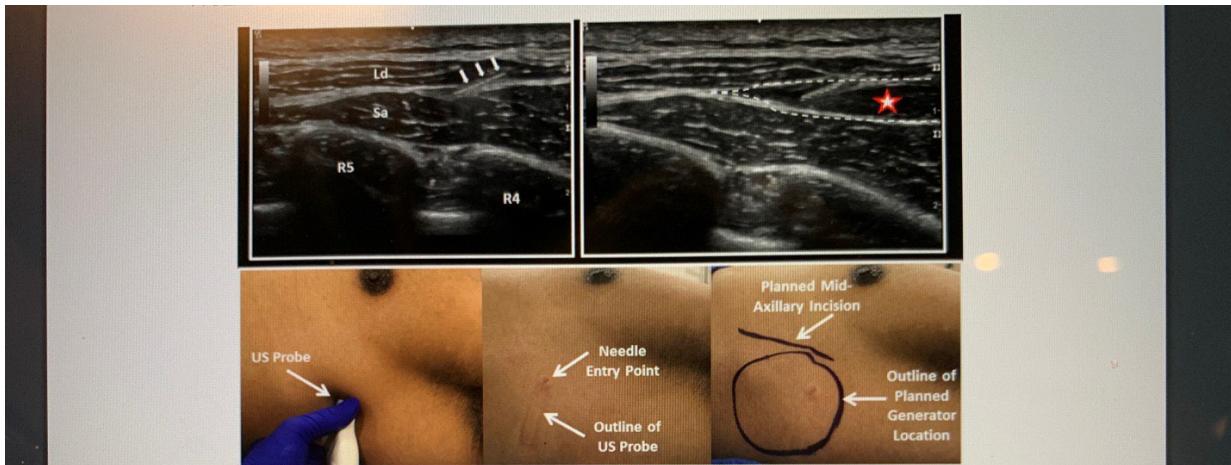


FIGURE 2 Serratus anterior plane block demonstrating the injection site on the chest wall and the corresponding ultrasound images of the injection above and below the serratus anterior muscle. The red star denotes a space filled with a local long-acting anesthetic. Ld, latissimus dorsi; Sa, serratus anterior; R, rib; US, ultrasound

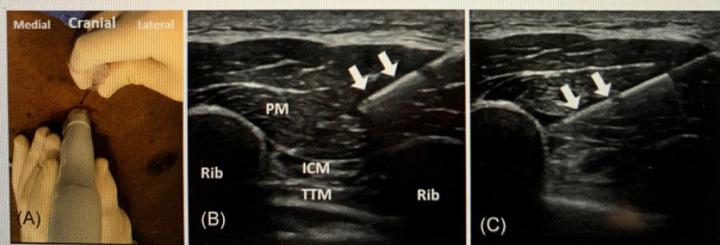


FIGURE 3 Injection site and the corresponding ultrasound image obtained during TTPB. A, Ultrasound transducer and location of needle insertion. B, C, Advancement of the needle (arrows) under ultrasound guidance thru the PM into the space between the ICM and the TTM and injection of anesthetic. ICM, intercostal muscle; PM, pectoralis major; TTC, transverse thoracic muscle; TTM, transverse thoracic muscle; TTPB, transverse thoracic plane block