Identifiers: NCT02056288 **Unique Protocol ID**: H-27386

Title: A Comparison of Ultrasound Guided Supraclavicular Block and General Anesthesia to IV Narcotics and General Anesthesia for Post-Operative Pain Relief in Children with Supracondylar Fractures

Date: 19 August 2020

Compare

Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals

Protocol Number: H-27386
Status: Approved
Initial Submit Date: 11/9/2010
Approval Period: 8/19/2020 - 8/18/2021

Section Aa: Title & PI

A1. Main Title

A RANDOMIZED COMPARISON OF ULTRASOUND GUIDED SUPRACLAVICULAR BLOCK AND GENERAL ANESTHESIA TO IV NARCOTICS AND GENERAL ANESTHESIA FOR POSTOPERATIVE PAIN RELIEF IN CHILDREN WITH SUPRACONDYLAR FRACTURES

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A3a. Financial Conflict of Interest

Does any member of study personnel (Investigator (including investigator's spouse and/or dependent children)) that are involved in the design, conduct, or reporting of the research have a Significant Financial Interest (SFI) that would reasonably appear to be affected by the research for which funding is sought and/or associated with an entity/business that would reasonably appear to be affected by the research?

No

Section Ab: General Information

A4. Co-Investigators

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A5. Funding Source:

Baylor College of Medicine (Internal Funding Only)

A6a. Institution(s) where work will be performed:

TCH: Texas Children's Hospital

A6b. Research conducted outside of the United States:

Country:
Facility/Institution:
Contact/Investigator:
Phone Number:

If documentation of assurances has not been sent to the Office of Research, please explain:

A7. Research Category:

A8. Therapeutic Intent

Does this trial have therapeutic intent?
No

A9. ClinicalTrails.gov Registration

Does this protocol/trial require registration on ClinicalTrials.gov due to it: meeting the definition of an Applicable Clinical Trial, being required under the terms and conditions of an award, or being proposed to be published in ICMJE journals?
Yes

Who will be responsible for registering and maintaining the registration of this Applicable Clinical Trial?
The BCM PI will register the trial because either:

- the trial is BCM PI-initiated,
- BCM is the lead site of this multicenter trial, or,
- the industry sponsor has instructed the BCM PI to register the trial, or,
- registration of this trail is required as a term and condition of the reward by the funding agency.

ClinicalTrials.gov Identifier:
NCT02056288

Section B: Exempt Request

B. Exempt From IRB Review

Not Applicable

Section C: Background Information

Supracondylar fracture of the humerus is a very common traumatic injury in pediatric orthopedic practice, accounting for more than half of all elbow fractures and roughly 33% of all pediatric limb fractures. They are classified into 3 types depending on the degree of displacement. Type 1 fractures have no or minimal displacement and can be managed with splinting and casting. However, surgical manipulation via closed reduction and percutaneous pinning with cast placement is usually required in type 2 supracondylar and lateral condyle fractures. Significant tissue interposition in type 3 supracondylar fractures may require an open operation for fracture reduction. These procedures all require general anesthesia, but postoperative pain can delay discharge, increase anxiety, and decrease satisfaction by the patient and parent. In addition, the treatment of pain with parenteral opioids can be associated with side effects like nausea, vomiting, respiratory depression and dysphoria. In adults, regional anesthesia with brachial plexus nerve block provides excellent analgesia while avoiding the side effects of opioids. However, until recently these nerve blocks were not often placed in pediatric patients because of concerns that improper positioning of the needle would result in low success rates, potential injury and toxicity from local anesthetics. Surgeons are also extremely concerned that analgesia from nerve blocks would hinder early diagnosis of a compartment syndrome at the site of injury, increasing the potential for long term injury. Compartment syndrome has an incidence of 0.1-0.3% based on a recent retrospective analysis with the main factor on presentation being a poorly perfused extremity and absent pulses. There are no case reports confirming that this has occurred in children receiving regional analgesia.The recent development of ultrasound guided nerve blocks has permitted a more precise visualization of the needle position and spread of local anesthetics, thus increasing the success rate with lower doses of local anesthetic and reducing needle trauma. Supraclavicular and infraclavicular ultrasound guided blocks of the brachial plexus are relatively easy to perform and have been shown to decrease the time to first rescue analgesia in a retrospective case review. Over 50 brachial plexus blocks have been performed in this patient population during the last 6 months at the Texas Children¿s Hospital, with the other patients receiving IV analgesia. However, there are no prospective data to show the benefits of brachial plexus blockade over systemic analgesia in children with supracondylar fractures.

Section D: Purpose and Objectives

The primary hypothesis to be tested in this study is that ultrasound guided nerve block would result in better and more prolonged postoperative analgesia reflected by lower pain scores through the study. The study is designed as a prospective, randomized, patient and observer-blinded comparison between light sevoflurane anesthesia combined with ultrasound guided supraclavicular nerve block and general anesthesia combined with standardized postoperative systemic analgesia, in children undergoing closed reduction with percutaneous pinning of supracondylar humerus fractures.

Section E: Protocol Risks/Subjects

E1. Risk Category

Category 2: Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.

E2. Subjects

Gender:
Both

Age:
Adolescent (13-17 yrs), Child (3-12 yrs)

Ethnicity:
All Ethnicities

Primary Language:
English, Spanish

Groups to be recruited will include:
Patients

Which if any of the following vulnerable populations will be recruited as subjects?

Children

Vulnerable populations require special protections. How will you obtain informed consent, protect subject confidentiality, and prevent undue coercion?

Subjects/parents/guardians will be approached in the waiting area on the day of surgery prior to the start of the procedure. The study will be verbally explained with emphasis on the voluntary nature of study participation. A written consent form will be provided with ample time given to consider the study. A translator will be available for Spanish speakers. Participants will be assured that every effort will be made to protect privacy and to prevent breach of confidentiality.

E3. Pregnant woman/fetus

Will pregnant women and/or fetuses (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E4. Neonates

Will neonates of uncertain viability or nonviable neonates (as described in 45 CFR 46 Subpart B) be enrolled in the research?

No

E5. Children

Will children be enrolled in the research?

Yes

Section F: Design/Procedure

F1. Design

Select one category that most adequately describes your research:

y) Drug, Phase IV, Single Center

Discuss the research design including but not limited to such issues as: probability of group assignment, potential for subject to be randomized to placebo group, use of control subjects, etc.

randomized, observer-blinded comparison between light sevoflurane anesthesia combined with ultrasound ¿guided supraclavicular nerve block and general anesthesia combined with standardized postoperative systemic analgesia

Inclusion Criteria:

(1) Supracondylar fracture (2) Age 2-17 years (3) American Society of Anesthesiologists Status 1 -3 (4) Scheduled for closed reduction with percutaneous pinning under general anesthesia

Exclusion Criteria:

(1) Pulseless extremity (2) Compromised neurologic status on exam (specifically assessment of radial, ulnar, and median nerve) (3) Known allergy to local anesthetics (7) Not scheduled for closed reduction with percutaneous pinning under general anesthesia (4) Bleeding diathesis (5) ASA status 4 or higher. (6) Sleep apnea by polysomnography

F2. Procedure

Written consent will be obtained by the investigators prior to the surgical procedure using the IRB approved consent form. The medical record will be examined and the use of any analgesic medications in the 24 hours prior to the procedure will be recorded. Patients will be taken to the OR and anesthetized using standard procedures of the Texas Children¿s Hospital (TCH) department of anesthesia, including monitoring according to the American Society of Anesthesiologists guidelines (EKG, pulse oximetry, BP, temperature and end-tidal expired carbon dioxide and inhalation anesthetic gases). If the Attending Anesthesiologist believes the child is at risk for aspiration of gastric contents, a rapid sequence induction with propofol 3-4 mg/kg and succinylcholine 1mg/kg IV will be performed with cricoid pressure, in keeping with standard practices. In other patients an IV will be started after induction of anesthesia. An age appropriate endotracheal tube or appropriate sized LMA will be inserted in all patients. Anesthesia will be maintained with sevoflurane, nitrous oxide and oxygen, adjusted to keep blood pressure and heart rate within 20% of baseline values, in keeping with standard practices. All patients will receive ketorolac 0.5mg/kg IV.

Patients will be randomized in a 1:1 ratio into one of two study groups: ultrasound guided supraclavicular block or IV opioids, based on a computer generated random number by using Random Allocation Software For Parallel Group Randomized Trials. The assignment will be made only after written informed conset has been obtained. There will be an equal chance a child will be assigned to one of the two groups. Patients randomized to the systemic analgesia group will receive 1mcg/kg of fentanyl IV after induction. Patients randomized to the supraclavicular block group will receive an ultrasound guided nerve block with 0.2 ml/kg ropivacaine 0.5% (maximum 10 ml), using the technique described by Marhofer et al. In order to decrease variance in success rates, the ultrasound guided nerve block will be performed by the Regional Anesthesia team. The Regional Anesthesia team has become well established at Texas Children's Hospital and all members of the team have successfully performed >100 ultrasound guided supraclavicular blocks in the past. Supraclavicular blocks were performed using the higher frequency of the probe and placing it in a coronal-oblique-plane in

the supraclavicular fossa. The brachial plexus will be identified as a cluster of hypoechoic nodules, lateral to the round pulsating hypoechoic subclavian artery and lying on top of the hyperechoic first rib. The cupola of the lung will be identified. If the transverse colli artery is visualized cephalically surrounding the plexus, the probe will be moved toward a better coronal oblique plane, directing the ultrasound beam slightly caudally, in order to keep the artery away from the plexus. The needle will be was carefully introduced using an in-plane (IP) technique from lateral to medial, toward but not into the brachial plexus. The entire needle image will be visualised at all times to ensure it does not enter the vessel, nerve plexus or pleura. The spread of local anesthetic to all targets of the plexus will be observed on the ultrasound image.

The time taken to place the block will be recorded from the time the ultrasound probe is first placed on the child until completion of local anesthetic injection. The observer collecting postoperative data will not be present when the block is placed, and a band-aid will be placed over the supraclavicular fossa in all patients to maintain blinding of the observer to the group assignment. During the operation patients can receive intraoperative fentanyl, 1 mcg/kg IV at a time, if the attending anesthesiologist believes it is clinically indicated. At the end of the operation, anesthetic gases will be discontinued while the patient breathes 100% oxygen. The trachea will be extubated when the patient responds to commands, and the child will then be taken to the Post Anesthetic Care Unit (PACU) in keeping with standard practices . A validated pain scale (verbal rating scale where 0 = no pain and 10 = worst possible pain ever) will be used throughout to assess the severity of pain in the postoperative period. In keeping with current practice, patients with pain scores>4 will be treated with morphine 0.05mg/kg IV at 10 minute intervals until the score is below 4. Oral acetaminophen with hydrocodone (Lortab elixir 0.15mg/kg hydrocodone) will be administered to children for pain scores between 2- 3. Supplemental oxygen, rescue antiemetic and antipruritic drugs will be administered in keeping with standard practices of TCH and the clinical judgment of the Attending Anesthesiologist. The duration of supplemental oxygen therapy, any medication administered and complications (side effects such as nausea, vomiting, itching, respiratory depression, prolonged awakening) will be recorded on the case report form.

The blinded observer will record pain scores within 15 minutes of arrival in the PACU and at 30 minutes, 1,2,6,12,24, and 48 hours after arrival in the PACU. If the child is sleeping at this time, the scores will be recorded when awake. The observer will also document any additional medication, the dose and the time given.

Prior to discharge home, parents will be educated on use of the 0-10 pain scale and given a diary to keep an accurate record of postoperative pain issues through the study period. The goal is to capture maximum pain scores at rest and with movement. Patient and parental satisfaction with pain management and with the global perioperative experience will also be graded on a numeric scale 0-10 scale.

Time to readiness for discharge will also be measured from the time the patient enters the PACU to when the patient attains an Aldrete score of 9-10. This is a standardized scale used to assess discharge readiness at TCH and is listed below:

Aldrete Scoring System Activity Can move voluntarily or on command 4 extremities 2 2 extremities 1 0 extremities 0 Respiration Can deep-breathe and cough freely 2 Dyspnea, shallow or limited breathing 1 Apneic 0 Circulation Preoperative BP (mmHg) BP ± 20 mmHg of baseline 2 BP ± 20-50 mmHg of baseline 1 BP ± 20 mmHg 0 Consciousness Fully Awake 2 Arousable on calling 1 Not responding 0 Color Normal 2 Pale, dusky, blotchy 1 Cyanotic 0 Score of 10: ready for discharge

If the patient is discharged before the end of a 48 hour period after surgery, they will be given a diary to complete to list all medications given, and to assess their pain at various time intervals (12,24, 48 hours after surgery), along with their satisfaction with pain control. The patient will be contacted after discharge to obtain the data in the diary. Phone calls will also be placed on POD #1,2, & 3 to the family following to assess measured endpoints (pain, medication usage, satisfaction, resolution of nerve block). We will examine the differences in subjects who did or did not return the diaries regarding group assignments, age, gender, ASA physical status, duration of surgery, intraoperative opioids medications, time of the PACU stay, mean and peak pain scores and recorded opioid consumption in the PACU before discharge.

At the time of their follow up visit to the surgeon, a complete physical examination will be done including a neurological evaluation for any nerve injury.

Section G: Sample Size/Data Analysis

G1. Sample Size

How many subjects (or specimens, or charts) will be used in this study?

Local: 188 Worldwide: 188

Please indicate why you chose the sample size proposed:

In a retrospective IRB approved study, the peak pain scores in the PACU were 2.8 ± 2.9 in the group receiving systemic analgesia without a regional block. A group size of 34 would have an 80% power of detecting a clinically relevant difference in the peak pain scores of 2 at the 0.05 level of significance, assuming the same SD in pain scores in the treatment group. We will recruit 40 patients in each group to allow for dropouts and incomplete data. This group size would

have a 90% power of detecting a 75% increase in time to first analgesia in the regional anesthesia group compared to the IV analgesia group, based on the retrospective study.

G2. Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study?

The primary endpoint of the study will be the peak or maximum pain score in the postoperative period. The secondary endpoints in the study will include (1) Opioid consumption in morphine equivalents (2) Time to first analgesia request (3) Time to achieving discharge readiness (4) Incidence of side effects such as vomiting, respiratory depression, itching, dysphoria, compartment syndrome (5) Patient and parental satisfaction. In order to keep the statistical analysis robust, we will also examine the differences in subjects who did or did not return the diaries regarding: a. group assignments b. age c. gender d. ASA physical status e. duration of surgery f. intraoperative opioids medications g. time of the PACU stay h. mean and peak pain scores and i. recorded opioid consumption in the PACU before discharge. These are known factors k that affect postoperative pain and failure to show a difference in these factors may suggest that the missing 48 hour data can be considered to be missing at random. We will also examine the PACU pain and opioid consumption data(first 2 hr after surgery) for all cases and separately for cases where the diaries were returned with the 48 hour data. If the conclusions regarding the secondary endpoints of pain in the PACU were not altered and the known factors affecting postoperative pain did not differ between those who did and did not return the diaries, it may suggest the conclusions are still robust. Our current plan will be modified to include not only daily phone calls from researchers, but Epic Mychart as well for protected email communication to better gather data.

Descriptive statistics will be used for each group. The peak and mean pain scores, age, weight, opioid consumption, time to first analgesia and discharge readiness and satisfaction scores will be compared between the two groups using Students t test if the data is normally distributed, and nonparametric tests if the data are skewed. A Fisher¿s exact test or a Chi Square test with Yates correction will be used to compare the number of patients in each group with side effects as listed above. P values of <0.05 will be considered to be statistically significant.

Section H: Potential Risks/Discomforts

H1. Potential Risks/Discomforts

Describe and assess any potential risks/discomforts; (physical, psychological, social, legal, or other) and assess the likelihood and seriousness of such risks:

All patients in this study will undergo general anesthesia. Risks of general anesthesia consist of airway issues like sore throat, laryngospasm, pulmonary aspiration and hypoxia. Postoperative nausea and vomiting can also occur in up to 40% of children. Serious side effects of general anesthesia can include heart rhythm disturbances, stroke, brain damage, and even death (1 in 200,000). These risks are present even if the child does not participate in the study as the procedure requires general anesthesia. The risks of IV pain medications are the same whether they are on this study or not and will be explained separately (since those risks are not specific to the study). The dose of opioids used in the study population is not different from our current standard practice. Therefore, the side effect profile should be no higher than any other patient undergoing a similar procedure at our institution even if they do not participate in the study. The risks of ultrasound guided supraclavicular block include accidental vascular puncture, local anesthetic toxicity, pneumothorax, and permanent nerve injury. In adults undergoing ultrasound guided regional anesthesia, this has been reported to occur in 0.1 -0.3%. There are few large scale studies in children, the landmark article by in 2006 quotes a complication rate of 23 instances out of 24000 regional anesthestics performed with an incidence of 0 for peripheral nerve blocks. Therefore we believe the risk related to receiving regional blockade as very unlikely. A prospective randomized study was performed in adults undergoing arthroscopy with regional anesthesia. The rate of postoperative neurologic symptoms was 0.4% [2]. Again following standard practice protocols, this risk is no higher than any other patient receiving a supraclaviular ultrasound guided regional blockade at Texas Children's Hospital.

We are unaware of any risks from ultrasound which is used routinely in pregnant women for assessment of the fetus. There is also a risk of loss of confidentiality of data despite the steps taken to prevent this as listed in section K.

H2. Data and safety monitoring plan

Do the study activities impart greater than minimal risk to subjects?

Yes

NOTE: The answer to the questions in H2 requires the completion of the form: 'Section H – Data and Safety Monitoring Plan' as an attachment in Section S.

H3. Coordination of information among sites for multi-site research

Is the BCM Principal Investigator acting as the SPONSOR-INVESTIGATOR for this multi-site research?

No or Not Applicable

Is BCM the COORDINATING CENTER for this multi-site research?

No or Not Applicable

Section I: Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the planned work.

Patients in the nerve block group may benefit from participating in the study as they may need less additional pain medication after surgery and have fewer side effects from these drugs. If a patient is assigned to the IV group, there are no benefits besides those benefits the patient would experience regardless of participation in the study.

Describe potential benefit(s) to society of the planned work.

Data from this study can be used to determine if children with supracondylar fractures will benefit from regional anesthesia in addition to general anesthesia.

Do anticipated benefits outweigh potential risks? Discuss the risk-to-benefit ratio.

There are no additional risks or benefits in the IV group as this is standard of care. The possible benefits from regional blockade include less pain with less overall opioid usage and less side effects from these drugs. The additional risks of neuropathy, pneumothorax, or other complications are low, and estimated at 0.4%-3% (PBID- 17377115; 19282715). Brachial plexus regional anesthesia is commonly performed at our institution for children having upper extremity surgery. The benefits to society include greater knowledge of the benefits of regional anesthesia in this situation and increased use of this modality in future.

Section J: Consent Procedures

J1. Waiver of Consent

Will any portion of this research require a waiver of consent and authorization?

No

J1a. Waiver of requirement for written documentation of Consent

Will this research require a waiver of the requirement for written documentation of informed consent?

No

J2. Consent Procedures

Who will recruit subjects for this study?

PI
PI's staff

Describe how research population will be identified, recruitment procedures, any waiting period between informing the prospective participant and obtaining consent, steps taken to minimize the possibility of coercion or undue influence and consent procedures in detail.

Patients presenting with supracondylar fracture will be identified from the Texas Children's Hospital operating room schedule that is routinely available to Pediatric Anesthesiology. They will be approached in the Day Surgery Unit or the holding area and the study will be explained to them. Voluntary participation will be emphasized during recruitment of patients. A copy of the written consent form will be given to parents with time allowed to read and consider enrollment. All questions will be fully answered. A Spanish translator will be available for Spanish speakers.

Are foreign language consent forms required for this protocol?

Yes

Which of the following ways will you document informed consent in languages other than English?

Short-Form consent documents

J3. Privacy and Intrusiveness

Will the research involve observation or intrusion in situations where the subjects would normally have an expectation of privacy?

No

J4. Children

Will children be enrolled in the research?

Yes

J5. Neonates

Will non-viable neonates or neonates of uncertain viability be involved in research?
No

J6. Consent Capacity - Adults who lack capacity

Will Adult subjects who lack the capacity to give informed consent be enrolled in the research?
No

J7. Prisoners

Will Prisoners be enrolled in the research?
No

Section K: Research Related Health Information and Confidentiality

Will research data include identifiable subject information?
Yes

Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
Yes

Specific information concerning alcohol abuse:
No

Specific information concerning drug abuse:
No

Specific information concerning sickle cell anemia:
No

Specific information concerning HIV:
No

Specific information concerning psychiatry notes:
No

Demographic information (name, D.O.B., age, gender, race, etc.):
No

Full Social Security #:
No

Partial Social Security # (Last four digits):
No

Billing or financial records:
No

Photographs, videotapes, and/or audiotapes of you:
No

Other:
No

At what institution will the physical research data be kept?
Paper copies of data forms will be stored in a locked cabinet in the Pediatric Anesthesiology office. The office is secured by ID badge keycard access. Electronic files will be maintained on password secured computers. Data will be coded.

How will such physical research data be secured?
The Pediatric Anesthesiology office is secured by ID badge keycard access. Electronic files will be maintained on password secured computers. Data will be coded.

At what institution will the electronic research data be kept?
The Pediatric Anesthesiology office

Such electronic research data will be secured via BCM IT Services- provided secured network storage of electronic research data (Non-Portable devices only):
Yes

Such electronic research data will be secured via Other:

Yes, (describe below):
Password-protected files

Will there be anyone besides the PI, the study staff, the IRB and the sponsor, who will have access to identifiable research data?

No

Please describe the methods of transmission of any research data (including PHI, sensitive, and non-sensitive data) to sponsors and/or collaborators.

N/A

Will you obtain a Certificate of Confidentiality for this study?

No

Please further discuss any potential confidentiality issues related to this study.

Study findings will be published at professional meetings and/or peer reviewed publications. No patient identifier will be included in reports of study findings.

Section L: Cost/Payment

Delineate clinical procedures from research procedures. Will subject's insurance (or subject) be responsible for research related costs? If so state for which items subject's insurance (or subject) will be responsible (surgery, device, drugs, etc). If appropriate, discuss the availability of financial counseling.

The subjects will be responsible for costs of all clinical procedures performed for the car of the patient. This would include costs for procedures that will be performed even if the patient did not participate in the study (e.g., OR and laboratory fees, physician fees for surgery, anesthesia, nursing care and hospital fees for equipment including regional blockade.

If subjects will be paid (money, gift certificates, coupons, etc.) to participate in this research project, please note the total dollar amount (or dollar value amount) and distribution plan (one payment, pro-rated payment, paid upon completion, etc) of the payment.

Dollar Amount:

0

Distribution Plan:

Section M: Genetics

How would you classify your genetic study?

Discuss the potential for psychological, social, and/or physical harm subsequent to participation in this research. Please discuss, considering the following areas: risks to privacy, confidentiality, insurability, employability, immigration status, paternity status, educational opportunities, or social stigma.

Will subjects be offered any type of genetic education or counseling, and if so, who will provide the education or counseling and under what conditions will it be provided? If there is the possibility that a family's pedigree will be presented or published, please describe how you will protect family member's confidentiality?

Section N: Sample Collection

None

Section O: Drug Studies

Does the research involve the use of ANY drug* or biologic? (*A drug is defined as any substance that is used to elicit a pharmacologic or physiologic response whether it is for treatment or diagnostic purposes)

No

Does the research involve the use of ANY gene transfer agent for human gene transfer research?
No

O1. Current Drugs

Is this study placebo-controlled?
No

Will the research involve a radioactive drug?
No

Section P: Device Studies

Does this research study involve the use of ANY device?
No

Section Q. Consent Form(s)

None

Section R: Advertisements

None