Assessment of the accuracy of the manual palpation of surface landmarks versus ultrasound for identification of the correct intervertebral space for spinal anesthesia in children less than 1 year of age

NCT04757805

July 8, 2021

PROTOCOL TITLE: Accuracy of manual palpation vs ultrasound for spinal anesthesia in children less than 1 year of age.

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PRINCIPAL INVESTIGATOR:

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VERSION NUMBER/DATE: ver. 3/July 8, 2021

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	3/17/2021	Adding L3-4 to L4-5 as the appropriate interspace, changing attending anesthesiologist to clinical anesthesia provider (fellow or attending), clarifying research anesthesiologist performing ultrasound, collecting data on years of experience for clinical provider, removing lateral position from the conus medullaris measurement.	No
2	7/1/2021	Changing the PI from Dr. Dontukurthy to Dr. Veneziano, 17.3 - revised the record retention details to six years.	Yes

1.0 Study Summary

Study Title	Assessment of the accuracy of the manual palpation of surface landmarks versus ultrasound for identification of the correct intervertebral space for spinal anesthesia in children less than 1 year of age.
Study Design	Prospective study
Primary Objective	The primary objective of the study is to compare the accuracy of manual palpation of surface landmarks versus ultrasonography for identification of the appropriate interspace for lumbar puncture and spinal anesthesia in infants less than 1 year of age.
Secondary Objective(s)	The secondary objective is to assess the level of the conus medullaris in infants in the sitting and lateral position.
Research Intervention(s)/ Investigational Agent(s)	Ultrasound
IND/IDE #	N/A
Study Population	Main OR surgical patients
Sample Size	50
Study Duration for individual participants	Less than 30 minutes total.
Study Specific Abbreviations/ Definitions	N/A

2.0 Objectives

2.1 The primary objective of the study is to compare the accuracy of manual palpation of surface landmarks versus ultrasonography for identification of the appropriate interspace for lumbar puncture and spinal anesthesia in infants less than 1 year of age.

2.2 The secondary objective is to assess the level of the conus medullaris in infants in the lateral position and also in the sitting position.

2.3 The hypothesis is that ultrasonography will be more accurate than the traditional method of palpation of surface landmarks in the identification of the appropriate interspace for lumbar puncture and spinal anesthesia in children less than 1 year of age.

3.0 Background

3.1 Spinal anesthesia may be used instead of general anesthesia in children for lower abdominal surgical procedures. The conus medullaris ends at L3-L4 in children less than 1 year of age and therefore the L3-4 or L4-5 interspace is

suggested as the optimal site for lumbar puncture for spinal anesthesia. Manual palpation is commonly performed to identify the correct intervertebral space for spinal anesthesia. Studies in adults and children have shown that manual palpation can be inaccurate in up to 30% of cases.[1-3] Traumatic needle placement or the administration of a concentrated local anesthetic agent into the spinal cord can lead to serious morbidity including neurologic damage and even paraplegia.[2,4] Ultrasonography may be used to assess the intervertebral space prior to spinal anesthesia in adults especially in difficult cases and in children to locate the tip of epidural catheter. Introduction of the ultrasound for assessment of the correct intervertebral space for spinal anesthesia may decrease the number of attempts and the possibility the incidence of serious adverse effects.

4.0 Study Endpoints

4.1 The accuracy of manual palpation of surface landmarks for identification of the appropriate interspace (L3-4/L4-5) for lumbar puncture and spinal anesthesia.

4.2 The level of the conus medullaris lateral and sitting.

5.0 Study Intervention/Investigational Agent

5.1 The only intervention being used that is not normally used in general clinical practice is the use of ultrasonography. The technique is non-invasive and poses no risk. Ultrasonography will be performed by an anesthesiologist with training and experience and will add less than 10 minutes to the anesthetic time.

6.0 Procedures Involved*

6.1 Anesthetic management will not vary from the standard technique and will be at the discretion of the anesthesia team. The clinical anesthesia provider (fellow or attending) who will be performing spinal anesthesia will mark the interspace for spinal anesthesia with a marking pen. The study team will record the providers years of experience performing spinal anesthesia. The research anesthesiologist performing the ultrasound will confirm whether or not the appropriate interspace (L3-4/L4-5) has been identified. Also, the interspace where the conus medullaris ends will be identified in the sitting position. Spinal anesthesia will be performed at the space confirmed by ultrasound using our standard clinical care.

7.0 Data and Specimen Banking*

N/A

8.0 Sharing of Results with Subjects*

Results will not be shared

9.0 Study Timelines*

- An individual study subject's participation in the study should last approximately 15-30 minutes total.
- All study subjects should be enrolled within 1 year of study start.
- The study should be completed within 2 years of study start.

10.0 Inclusion and Exclusion Criteria*

10.1 Potential subjects will be identified by reviewing the surgery schedule in Epic and will be recruited from the Surgery Unit pre-op area prior to their surgery.

10.2 Inclusion criteria: Patients less than 1 year of age scheduled for spinal anesthesia for elective lower abdominal, urologic, or lower extremity surgery at Nationwide Children's Hospital.

10.3 Exclusion criteria:

Parents unwilling for their children to undergo spinal anesthesia for surgery.
Children with known spinal anomalies including sacral dimple.
Children with coagulation abnormalities or receiving anticoagulation which precludes the use of spinal anesthesia.
Children with superficial or deep infections over the spine which precludes the use of spinal anesthesia.

11.0 Vulnerable Populations*

11.1 This study presents no more than minimal risk as it only involves ultrasound which is non-invasive, will add less than 10 minutes to the total anesthetic time, and written consent is normally not required.

12.0 Local Number of Subjects

12.1 50

13.0 Recruitment Methods

13.1 Subjects will be recruited from the surgery unit pre-op area. They will be identified by reviewing OR schedules in Epic.

14.0 Withdrawal of Subjects*

N/A

15.0 Risks to Subjects*

15.1 Although not likely, there may be a potential risk for breach of patient health information. There are no study related physical risks to study subjects associated with this study. All study related procedures are non-invasive.

15.2 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study

staff; and subject information will only be shared and discussed between study staff specific to this study. Subject PHI will be stored in a locked cabinet, and will be stored and maintained in password protected computer files.

16.0 Potential Benefits to Subjects*

16.1 No direct benefit to the subject.

17.0 Data Management* and Confidentiality

17.1 A 2 by 2 contingency table with a chi-squared analysis will be performed to compare the accuracy of surface palpation versus ultrasonography. Other data including time to perform ultrasonography and level at which the conus medullaris ends will be presented as secondary outcomes in tabular format for descriptive purposes without the need for statistical comparison or analysis.

17.2 Research records will be stored in a locked cabinet and password protected computer. Only certified research personnel will be given access to identifiable subject information.

17.3 Once the data collection and analysis are complete and the study results have been published identifiers will be destroyed. Six years after research is complete, per NCH guidelines as this meets both HIPAA and OHRP regulations, all electronic files will be permanently deleted.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 The study will only be monitored by the study investigators.

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific to this study. Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

20.0 Compensation for Research-Related Injury

20.1 None

21.0 Economic Burden to Subjects

21.1 None

22.0 Consent Process

22.1 We are requesting a waiver of informed consent documentation. Subjects will receive a complete explanation of the study and will be asked to consent verbally. Subjects will receive a written summary of the research as outlined in the attached written Study Information Sheet. Subjects will not be asked to sign a consent form.

23.0 Process to Document Consent in Writing

N/A

24.0 Setting

24.1 Subjects will be recruited from Surgery Unit and all study procedures will take place in the OR after the subject has been anesthetized.

25.0 Resources Available

25.1 The department of Anesthesiology and Pain Medicine has 2 research coordinators and 2 research associates that will be enrolling subjects for this study. All study staff will be trained on the study procedures.

26.0 Multi-Site Research*

N/A

27.0 Protected Health Information Recording

1.0 Indicate which subject identifiers will be recorded for this research.

☒ Name
☐ Complete Address
☒ Telephone or Fax Number
☐ Social Security Number (do not check if only used for ClinCard)
☒ Dates (treatment dates, birth date, date of death)
☐ Email address, IP address or url
☒ Medical Record Number or other account number
☐ Health Plan Beneficiary Identification Number
☐ Full face photographic images and/or any comparable images (x-rays)
☐ Account Numbers
☐ Certificate/License Numbers
☐ Vehicle Identifiers and Serial Numbers (e.g. VINs, License Plate Numbers)
☐ Device Identifiers and Serial Numbers
☐ Biometric identifiers, including finger and voice prints
☐ Other number, characteristic or code that could be used to identify an individual
☐ None (Complete De-identification Certification Form)

2.0 Check the appropriate category and attach the required form* on the Local Site Documents, #3. Other Documents, page of the application. (Choose one.)

☐ Patient Authorization will be obtained. (Include the appropriate HIPAA language (see Section 14 of consent template) in the consent form OR attach the HRP-900, HIPAA AUTHORIZATION form.)

☒ Protocol meets the criteria for waiver of authorization. (Attach the HRP-901, WAIVER OF HIPAA AUTHORIZATION REQUEST form.)

☐ Protocol is using de-identified information. (Attach the HRP-902, DE-IDENTIFICATION CERTIFICATION form.) (Checked "None" in 1.0 above)

☐ Protocol involves research on decedents. (Attach the HRP-903, RESEARCH ON DECEDENTS REQUEST form.)

☐ Protocol is using a limited data set and data use agreement. (Contact the Office of Technology Commercialization to initiate a Limited Data Use Agreement.

***Find the HIPAA forms in the IRB Website Library, Templates.**

Attach the appropriate HIPAA form on the "Local Site Documents, #3. Other Documents", page of the application.

3.0 How long will identifying information on each participant be maintained?
Following publication of study results, research records will be stored for a period of 3-5 years and then will be destroyed by placing in a secure shredding bin.

4.0 Describe any plans to code identifiable information collected about each participant. None

5.0 Check each box that describes steps that will be taken to safeguard the confidentiality of information collected for this research:

☒ **Research records will be stored in a locked cabinet in a secure location**

☒ **Research records will be stored in a password-protected computer file**

☐ **The list linking the assigned code number to the individual subject will be maintained separately from the other research data**

☒ **Only certified research personnel will be given access to identifiable subject information**

6.0 Describe the provisions included in the protocol to protect the privacy interests of subjects, where "privacy interests" refer to the interest of individuals in being left alone, limiting access to them, and limiting access to their information. (This is not the same provision to maintain the confidentiality of data.)
Subject information will not be given to any other investigators. Subjects and their information will be closely monitored and guarded by study staff; there will be limited access to patients and their information by trained study staff; and subject information will only be shared and discussed between study staff specific

to this study. Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

Confidential Health Information

1.0 Please mark all categories that reflect the nature of health information to be accessed and used as part of this research.

- ☒ Demographics (age, gender, educational level)
- ☒ Diagnosis
- ☐ Laboratory reports
- ☐ Radiology reports
- ☐ Discharge summaries
- ☒ Procedures/Treatments received
- ☒ Dates related to course of treatment (admission, surgery, discharge)
- ☐ Billing information
- ☐ Names of drugs and/or devices used as part of treatment
- ☐ Location of treatment
- ☐ Name of treatment provider
- ☐ Surgical reports
- ☒ Other information related to course of treatment
- ☐ None

2.0 Please discuss why it is necessary to access and review the health information noted in your response above.
It is necessary to meet the objectives of the study and to analyze the data.

3.0 Is the health information to be accessed and reviewed the minimal necessary to achieve the goals of this research? ☒ Yes ☐ No

4.0 Will it be necessary to record information of a sensitive nature? ☐ Yes ☒ No

5.0 Do you plan to obtain a federally-issued Certificate of Confidentiality as a means of protecting the confidentiality of the information collected? ☐ Yes ☒ No

References

1. Hayes J, Borges B, Armstrong D, et al. Accuracy of manual palpation vs ultrasound for identifying the L3-L4 intervertebral space level in children. Paediatr Anaesth 2014;24:510-15.
2. Olowoyeye A, Fadahunsi O, Okudo J, et al. Ultrasound imaging versus palpation method for diagnostic lumbar puncture in neonates and infants: a systematic review and meta-analysis. BMJ Paediatrics Open 2019;3:e000412.

3. Duniec L, Nowakowski P, Kosson D , Łazowski T. Anatomical landmarks based assessment of intravertebral space level for lumbar puncture is misleading in more than 30%. Anaesthesiol Intensive Ther 2013;45:1-6.
4. Baxter B, Evans J, Morris R, et al. Arch Dis Child Fetal Neonatal Ed 2016;101:F448-50.