Low Dose IV Dexamethasone in Prolonging Caudal Anesthesia in Children Undergoing Genitourinary Surgery

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Introduction:

Caudal injection of local anesthetic is a neuraxial technique routinely performed on young children for postoperative analgesia after lower abdominal and lower extremity surgical procedures. One of the major limitations of the use of single shot neuraxial injections for this purpose is the limited duration of action of the injected local anesthetic. Adjuvant medications, such as clonidine and epinephrine, have been added to the local anesthetic to prolong the duration of the neuraxial block, with varying results. Dexamethasone is a synthetic glucocorticoid steroid commonly used in the perioperative setting for a multitude of indications, including the prolongation of local anesthetic based analgesia. The administration of dexamethasone either intravenously or via perineural injection can significantly increase the duration of analgesia derived from a local anesthesia based peripheral nerve block. Literature also suggests that the effect of dexamethasone is equivalent when given intravenously or perineurally. Interest in dexamethasone enhanced caudal analgesia exists, and a previous study noted that caudal anesthesia can be prolonged by intravenous dexamethasone. The study was criticized for using a higher dose of dexamethasone (0.5 mg/kg) than is routinely used in the pediatric population outside of airway procedures, which may expose patients to dose related side effects of dexamethasone. A large meta-analysis has suggested that 0.1 mg/kg is effective for analgesic prolongation, but no direct study of low dose intravenous dexamethasone in combination with caudal anesthesia has been performed.

Rationale/Specific Aim

As dexamethasone is an inexpensive and commonly used medication, it would be beneficial to know if a similar prolongation of analgesia occurs when a local anesthetic is given neuraxially in combination with low dose intravenous dexamethasone. This project will investigate the efficacy of low dose intravenous (IV) dexamethasone in prolonging the duration of post-operative analgesia provided by an intraoperative caudal injection of local anesthetic.

Inclusion/Exclusion:

Inclusion Criteria:

- Age 2 years-10 year
- Scheduled for elective inpatient genitourinary surgical procedure
- Caudal anesthesia within standard of care for surgical procedure
- Have provided parental consent and assent in accordance with the Institutional Review Board requirements

Exclusion Criteria

- Abnormal/difficult anatomy
- Known allergy to ropivacaine or dexamethasone
- History of documented chronic pain
- Existing infection at site of intended injection

Enrollment:

All patients will be enrolled in the study the day of surgery, in area private hospital setting. Subjects/subject parents may be approached to consent either before or after surgery, provided all inclusion criteria is met and no exclusion criteria. The study will be explained by a member of the research team with extensive knowledge of the protocol. All medications and techniques utilized for this study are commonly accepted for routine care for these patients.

Study Procedures:

1. Study design: prospective data collection.
2. Comparison Groups: We will collect data on 94 subjects having a GU procedure and caudal as standard of care. We will collect information on 47 subjects who receive caudal only. We will collect information on an additional 47 subjects who receive a caudal and IV dexamethasone. No other adjuvant medication will be used.
3. Study and timeline of interventions
    a. Preoperative: Patients enrolled in this study may receive 0.5mg/kg up to 15mg total of oral midazolam if deemed necessary for anxiolysis by operating room or study anesthesiologist, 15 to 30 minutes prior to anesthetic induction.
    b. Intraoperative: Subjects will undergo induction of anesthesia by inhalation of sevoflurane and oxygen. An intravenous catheter (IV) will be placed, followed by 2-3mg/kg of propofol if necessary. The airway device (LMA or ETT) will then be placed. Following confirmation of airway placement, the patient will be rolled in left or right lateral decubitus position and caudal epidural will be placed under sterile conditions. To be enrolled as caudal + IV dexamethasone, subjects must receive IV dexamethasone right after caudal placement. Should the IV dexamethasone be given at the end of the surgical procedure, subject will be considered a screen failure. All patients will be maintained on sevoflurane in accordance to patient anesthetic requirements as determined by anesthesia provider.
    c. Postoperative: All patients will receive routine PACU care. Pain and anxiety scores will be recorded according to routine PACU practice. All patients will have their pain orders written by the anesthesia acute pain service and pain scores monitored per hospital protocol. The patient will have a final pain evaluation by the Acute Pain Service attending the day following caudal placement.
    d. Measured end-points:
        i. Type of procedure
        ii. Time of caudal
        iii. Length of surgical procedure
        iv. Time to first analgesic dose
        v. Amount of pain medicine received in PACU
        vi. Amount of pain medicine received during floor stay
        vii. Pain scores over 24 hour period as obtained by floor nurse during routine care

viii. Patient/parent satisfaction
ix. Highest pain level in 24 hour period
x. Adverse events

Risks to patient/ adverse event response:

Per inclusion criteria, patients enrolled in this study will be receiving anesthesia, surgery, and a caudal as standard of care. IV dexamethasone will be given at the discretion of the anesthesiologist. Risks related to the study are limited to potential loss of confidentiality.

Subject Withdrawal:

A patient may withdraw from enrollment at any time. At the time of withdrawing, data already collected will be kept and utilized, but no more data for the study will be collected.

Statistical Considerations:

A two tailed paired t-test will be utilized to evaluate a clinically significant difference of 2 hours between the two groups. Each group will contain 47 participants in order to achieve a power of 0.9 and Alpha of 0.05.

Privacy/Confidentiality:

Participant privacy is an important goal of the researchers. Only the principal investigator and IRB approved study personnel will have access to identifiable data. PHI will be stored in the locked Anesthesiology Offices.

Follow up/Record Retention:

The participation in the study begins with induction of anesthesia and ends after the 24 hour follow up. The patient data related to the study will be passed on to the principal and co-investigators, and the anesthetic record will be placed in the patient's medical chart. Data will be entered and stored securely in a REDCap database. Following completion of the study and after the require amount of time per Indiana Laws, all copies of data collected will be physically destroyed.

References:

1. Desmet, M. **I.V. and perineural dexamethasone are equivalent in increasing the analgesic duration of a single-shot interscalene block with ropivacaine for shoulder surgery: a prospective, randomized, placebo-controlled study.** Br J Anaesth. 2013 Sep;111(3):445-52. doi: 10.1093/bja/aet109. Epub 2013 Apr 15.
2. Effect of dexamethasone in combination with caudal analgesia on postoperative pain control in day-case paediatric orchiopexy Hong.*Br. J. Anaesth. (2010) 105 (4): 506-510. doi: 10.1093/bja/aeq187*
3. **Perioperative Single Dose Systemic Dexamethasone for Postoperative Pain** *A Meta-analysis of Randomized Controlled Trials* Gildasio S. De Oliveira, Jr., M.D.,* Marcela D. Almeida, M.D.,† Honorio T. Benzon, M.D.,‡Robert J. McCarthy, Pharm.D.

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