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DEPARTMENT OF ANESTHESIA

COMPARISON OF CAUDAL BLOCK WITH BUPIVACAINE ALONE VERSUS CAUDAL BLOCK WITH BUPIVACAINE AND INTRAVENOUS DEXAMETHASONE FOR POSTOPERATIVE ANALGESIA OF PEDIATRICS PATIENT UNDERGOING INFRA-UMBILICAL SURGERY UNDER GENERAL ANESTHESIA AT TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA, 2019

RESEARCH THESIS SUBMITTED TO COLLEGE OF HEALTH SCIENCE SCHOOL OF MEDICINE DEPARTMENT OF ANESTHESIA FOR PARTIAL FULFILMENT OF REQUIRMENT FOR MASTERS SCIENCE OF ANESTHESIA

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Abstract

Background Caudal block is a common regional technique used to provide intra and postoperative analgesia of infra-umbilical procedures in pediatric patients. However, the relatively short duration of single shot caudal injection with local anesthetic is amongst the limitations of the procedure. Addition of various adjuvants has been challenged by unacceptable adverse effects & safety not being fully established, especially in preservative containing agents.

Objective The aim of this study was to compare effectiveness of caudal block with bupivacaine alone versus caudal block with bupivacaine and IV dexamethasone for postoperative analgesia of pediatrics patient undergoing infra-umbilical surgery under General anesthesia at Tikur Anbessa specialized Hospital.

Method: In this institutional based prospective cohort study total of 60 ASA I and ASA II age of 1-7 years pediatrics patient undergo infra-umbilical surgery that fulfill inclusion criteria was included. Systematic random sampling technique was applied & they grouped based on their exposure status. Severity of postoperative pain was measured by FLACC score, duration of analgesia and total analgesic consumption was assessed up to 24 hours after operation. Postoperative pain severity & total analgesic consumption was analyzed by Mann-Whitney U test. Independent sample t test was used for analgesia duration as well as Chi-square test was used to analyze categorical variables and p value less than 0.05 was considered as statistically significant.

Result data of 60 patients were analyzed and the result shows postoperative pain severity presented in median in CB with bupivacaine & IV dexamethasone group was 1.5, 3,6 & 3, 6, 6 in CB with bupivacaine alone group at 4^{th}, 6^{th} & 12^{th} hours with p value of (<0.001, <0.001& 0.003) respectively. Duration of analgesia was also significantly prolonged in CB with IV dexamethasone group with mean of 699.3 minutes & 347 minutes in CB alone group with $p < 0.001$. Amount of analgesia given in 24 hours was also significantly reduced in CB with IV dexamethasone group with $p < 0.001$.

Conclusion and recommendation administration of 0.5mg/kg of intravenous dexamethasone in combination with caudal block is good alternative to prolong postoperative analgesia in children undergoing infra-umbilical surgery.

Key-words caudal block, infra-umbilical surgery, IV dexamethasone, pediatrics, postoperative analgesia

Contents

List of tables

List of figures

Abbreviations

AAU- Addis Ababa University

ASA- American Association of Anesthesiologists

BP- Blood pressure

CB - Caudal block

CI- Confidence interval

EAA- Ethiopian Anesthetist Association

ETT-Endotracheal tube

FLACC- Face Legs activity Cry Consolable

FMOH- Federal ministry of health

GA- General Anesthesia

HR- Heart rate

IASP- International Association Study of Pain

IQR- Inter quartile range

IRB- Institutional Review Board

ICU-Intensive care unit

IV- Intravenous

LA- Local Anesthetics

LMA-Laryngeal mask airway

MAP- Mean arterial pressure

Mg- milligram

NGO- Non-governmental organization

OR-Operation room

PACU- Post anesthesia care unit

PI- principal investigator

PONV- postoperative nausea & vomiting

POP- Postoperative Pain

RA- Regional anesthesia

RCT- Randomized Control Trial

SD - Standard deviation

TASH- Tikur Anbessa specialized Hospital

Vs - Versus

V/S- Vital sign

WHO- World Health Organization

Chapter one Introduction

1.1 Background

Pain in the pediatric patient is becoming the major concern throughout the world & researchers give great emphasis for introduction of new drugs as well as modify application of oldest one. According to the Society of Pediatric Anesthesia, alleviation of pain is a 'basic human right', irrespective of age, medical condition, treatment, or medical institution.(1)

The most commonly used RA technique in pediatric practice is the caudal block which was first described for anesthetic use in children by Campbell in 1933. It is the easiest block to perform and to teach, which will be applied in variety of procedures with extensive safety record in children. (2-4)

Caudal block is used to provide intraoperative and postoperative analgesia for infra-umbilical surgery. It is usually a single shot technique. However, the relatively short duration of single shot caudal injection with local anesthetic is amongst the limitations of the procedure.(5, 6)

To prolong single shot caudal block various adjuvants has been added which have adverse effects or safety not being fully established, especially in preservative containing agents. (2, 7)

Dexamethasone is a corticosteroid which has anti-inflammatory as well as analgesic property. Systemic administration will decreases the tissue levels of bradykinin and inhibits the release of neuropeptides from nerve endings. Production of cyclooxygenase 2 enzyme in central nervous system is also inhibited by dexamethasone resulting in decreased production which is responsible for enhanced nociception. (2)

1.2 Statement of the problem

Pain is defined by IASP as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.as result of this report shows pain is widely undertreated which increase burden on patients, family as well as on society on quality of life, employment & mental health.(8)

The greatest burden of inadequate pain management is carried by the elderly, pregnant, and breastfeeding women, children, drug addicted persons and the mentally ill. This burden is more challenging in children because of difficulty in pain assessment, lack of ability to notice pain, difficult in remembering pain full experience due to immaturity and concerns about side effects of opioid analgesics in pediatric.(9-11)

As study done in Ethiopia shows 88.2% of patients safer from moderate to severe postoperative pain in immediate postoperative time & 78% of them experience this pain in the 1st 12 hour. Despite of this 58.4% of those patient didn't get adequate pain management.(12, 13)

Postoperative pain can lead to delayed recovery and increased hospital stay. So good postoperative analgesia will reduce hospital acquired infection, family financial burden as well as it increases patient satisfaction. WHO state that 80% of people do not receive adequate pain treatment which in line with American survey which indicate only one in four patients had adequate postoperative analgesia. (14, 15)

Poorly controlled postoperative pain predispose the patient for nausea & vomiting, urinary retention, increase in heart rate & blood pressure which are devastating for patients with coexisting cardiovascular disease as well as due to immunosuppression it also predispose them for infection.(16)

As study done in USA shows prevalance of pain in pediatrics which reported by child/parent is 72% & from this surgical site pain is the most sited one. Pain after surgery is usually most severe in the first 24–72 h but may persist for several days or weeks. 1.5% of all surgical procedures results in chronic pain. Postoperative pain management is a very important in pediatric patient for satisfied and better coherent parents, early rehabilitation, and a reduced chance of progression to chronic pain.(17, 18)

Regional techniques combined with general anesthetic reduce consumption of intraoperative analgesics and volatile anesthetics, reduce the stress response to surgery and encourage fast and painless recovery from surgery.(19)

Despite Short duration of action Single shot caudal block can provide intraoperative and postoperative analgesia. One way of increasing the duration and efficacy of the block is using concentrated local anesthetic solutions in larger volumes, which, can result in unwanted motor blockade & systemic toxicity as well as adding other additives like opioids which cause respiratory depression, nausea & vomiting, ketamine which affect hemodynamics of the patient, adrenaline which not applied in patient have cardiovascular disease, α2 agonists result in unwanted sedation, hypotension as well as bradycardia & neostigmine which predispose them to postoperative nausea & vomiting. Therefore one of the major challenges in pediatric regional anesthesia is balancing the efficacy of the block with the safety of the patient.(7, 20)

The aim of this study is to bring some changes in prolonging postoperative analgesia duration & avoiding those common adverse effects of pain and drugs which is commonly added to caudal block by administering IV dexamethasone.

1.3 Justification

Severe postoperative pain in kids will predispose them to unpleasant recovery & delayed discharge from hospital which predisposes them to infection & their family to financial burden. Relatively short duration of single shot caudal injection with local anesthetic is amongst the limitations of the procedure. Several attempts are made to prolong the analgesic effects by combining a local anesthetic drug with other additives but their use has been limited by unacceptable adverse effects or safety not being fully established, especially in preservative containing agents as well as giving IV opioids which result in several complications.

Alternative methods of prolonging analgesic effect of caudal block can be made by administering IV dexamethasone which is relatively cheap, easily available in most of our country hospitals and equally potent with less complication. Conducting studies by using easily available & relatively safe drugs in resource limited area can improve pain management and patient comfort as well as minimize complication & financial burden.

Therefore, conducting such study will give us a base line data to administer IV dexamethasone with caudal block to prolong postoperative analgesia & as multimodal analgesic regime which reduces need of opioids & their complication as well as adverse effect of other additives.

There are some Studies conducted in abroad countries that were done in specific procedure which is difficult to generalize for all infra-umbilical procedures because of different in pain intensity between the procedures as well as the population are genetically different from our country. In our country few studies were conducted in caudal block with other additives but there is no study conducted on effectiveness of IV dexamethasone for prolonging analgesics effect of caudal block.(7)

I hope this study will bring changes on using alternative method for prolonging analgesia duration of caudal block that benefit our society in terms of analgesia, reduction in complication caused by other additives, cost effectiveness & it also used as baseline data for other researchers who interested in this title.

Chapter two Literature Review

Acute pain is defined as pain of short duration which is normal response to tissue injury present in a surgical patient after a procedure. Such pain may be the result of trauma from the procedure or procedure related complications.(21-23)

According to study done in Thailand shows the prevalence of postoperative pain during 24 hours was 69.2%, with 43.6% was moderate to severe pain.(24)

Study done in Nigeria on postoperative pain revealed two-thirds of patients complained of moderate to severe pain in 24hours postoperatively. Other survey done in Uganda also shows that 45% of hospital has only pethidine or morphine & 21% has no any drug. Which show that analgesia has a lower priority than any other aspects of healthcare in developing countries. (25, 26)

Poor management in the case of postoperative acute pain can contribute to medical complications such as pneumonia, deep vein thrombosis, infection chronic pain and depression.(22)

2.1 Caudal block

According to systematic review & meta-analysis done on 2014 in Canada by Harsha Shanthanna *et al*. on comparison of effectiveness of analgesia between caudal block and non-caudal regional techniques shows that Caudal analgesia was found to be better when measured by risk ratio both in early (RR = 0.81 [0.66, 0.99],*P* = 0.04) and late (RR = 0.81 [0.69, 0.96],time *P* = 0.01. (27)

On another side database meta-analysis was done on 2015 in USA by Santhanams *et al.* on complication rate of caudal block between block done in awake versus after general anesthesia. Among 18650 children received CB rate of complications was 4% and 1.9% in having the block awake and with general anesthesia respectively. The advantages of combined CB with GA is to obtain efficient postoperative analgesia for pediatric patients undergoing inguinal hernia, circumcision, hypospadias repair, orchidopexy, lower abdominal surgery, skin grafting, perineal procedures, and lower limb surgery.(4)

Caudal analgesia in combination with general anesthesia may affect hemodynamic due to sympatholytic effects which result in vasodilatation & decrease heart rate. A success or failure of CB can be determined by changes in hemodynamic following incision. Adequate analgesia was

defined by hemodynamic stability, as indicated by the absence of an increase in HR or BP of more than 20% compared with baseline values obtained just before the surgical incision.(28)

2.2 Comparison of drug used for caudal block

Bupivacaine is long acting amide type local anesthetic agent which has been used for more than 30 years due to its long duration of action & beneficial ratio of sensory to motor block.

Levobupivacaine and Ropivacaine are also long acting amide type local anesthetic agent have a better safety profile than bupivacaine, with less risk for CNS and cardiac toxicity.(29)

As study done in India by Jadhav *et al.* indicate analgesic effect of caudal block done with 0.25% levobupivacaine & 0.25% bupivacaine is similar with $p=0.717$.(30)

Other RCT conducted in India by Vrishali Ankalwar *et al.* which compare effectiveness of 0.25% bupivacaine & ropivacaine indicate quality of sensory block & duration of analgesia was comparable with mean duration of analgesia was 4.96±1.26 hours in group 'R' compared with 4.56 ± 1.26 hours in group 'B' ($p>0.05$).(31)

Similar prospective RCT done in Turkey on postoperative analgesic effect of caudal block done with 0.175% bupivacaine & 0.175% ropivacaine indicate analgesic duration was greater in bupivacaine group.($p=0.004$).(32)

Other study done in Italy which compares 0.25% of bupivacaine, levobupivacaine & ropivacaine given for caudal block indicated that analgesic efficacy was comparable between the groups in spite of analgesics duration of bupivacaine is slightly higher than others.(33)

Prospective RCT conducted in Nigeria by Akpoduado D *et al.* Which Compare different dose of bupivacaine, 0.5ml/kg and 0.75 ml/kg of 0.25% bupivacaine showed that duration of analgesia was significantly increased as the dose increases with low side effect profile.(34)

2.3 Effect of dexamethasone

Considering the benefits of dexamethasone, it helps in preventing PONV and it has a good analgesic action when given both IV and perineurally. It is a preferred drug during inflammatory situations like asthma and laryngospasm. It also prevents hyperalgesia through phospholipase A2 and inducible cyclooxygenase inhibition. The controversial role of dexamethasone in post-operative surgical site infections has been solved and overall adverse effects of dexamethasone are rare as compared with its benefits.(35-37)

Study conducted by Rodrigo M *et al.* in Brazil on 2014 which compare analgesic effect of dexamethasone with ketorolac shows there is no significant difference in duration of analgesia between the group.(38)

Another study done in 2003 by Dionne *et al.* shows dexamethasone has decreased inflammation without any effect on postoperative pain.(39)

Controversial to the above findings meta-analysis done in USA on 2013 by Waldron *et al.* indicate perioperative single dose of IV dexamethasone was associated with statistically significant difference in postoperative pain, opioid consumption, PACU stay & analgesia request time. (40)

As an adjuvant, IV dexamethasone has been shown to prolong regional anesthesia. Appropriate dose recommendations are variable in the literature on available studies, but single dose 4-8 mg or 0.05-0.5 mg per kg doses have been shown to be effective to reduce postoperative pain and achieve lower opiate consumption.(41)

2.4 Caudal block alone & caudal block with IV dexamethasone

According to RCT conducted in 2014 by Bangash L.R *et al*. in Pakistan in 100 ASAI & II kids show mean duration of analgesia was 621.60 ± 25.743 in group who took IV dexamethasone with caudal block and 402.40 ± 34.792 minutes in caudal block alone group with a P value of < 0.0001.(16)

As study conducted in Malaysia in 2015 by Azariham Izaham *et al.* on 60 patients shows there were statistically significant differences between CB with 0.5mg/kg IV dexamethasone and CB alone group in the median time to first paracetamol request (800 vs 520 min, p = 0.01) respectively & mean pain scores in the first postoperative day (1.9 ± 2.0 vs 3.5 ± 2.2, p = 0.05) respectively.(42)

According to study done in Korea on 2010 by Hong *et al.* in 77 kids received CB with either dexamethasone 0.5 mg/ kg or the same volume of saline intravenously shows patients in the dexamethasone group required fentanyl for rescue analgesia was 7.9% vs 38.5% in CB alone group. Request for acetaminophen was 23.7% in treatment group vs 64.1% in placebo group. The time to first administration of oral acetaminophen was significantly longer in the dexamethasone group (646 vs 430 min).(28)

As RCT conducted in India in 2012 by Mukesh K *et al.* revealed analgesics duration was significantly different between the groups with mean ± SD of 3.6 +/- 1.3hours in CB alone group, 13.2 +/- 2.4 hours in caudal dexamethasone group and 10.3 +/-2.9 hours in CB with IV dexamethasone group with $p<0.05$ as well as number of rescue analgesia was 2.0 +/- 0.2 in control group 1.2 +/- 0.2 in IV dexamethasone group with $p< 0.05$.(43)

According to prospective double blind RCT conducted in India by Balvir S *et al.* on 2016 in 60 patients show that the time of first rescue analgesia was significantly longer in IV dexamethasone group (10.2 +/- 3.1 hours) as compared to caudal alone Group (3.7 +/- 1.2 hours).Total rescue analgesia doses were recorded to be 2.1 +/- 0.2 in caudal alone Group and 1.1 +/- 0.1 in caudal with IV dexamethasone Group.(44)

Another prospective double blind RCT conducted in India by Srinivasan, *et al.* in 105 patients shows there was a significant difference between the groups in the VAS score measured 6 h after surgery.54.29% of patients achieved a VAS score of >4 in caudal alone group while 0% in CB with IV dexamethasone scored groups VAS >4. The time to first rescue analgesia/duration of analgesia recorded as median (95% CI) was significantly longer in IV dexamethasone group 620.0 (612.1– 625.6 min) compared to caudal alone Group 220.0 min (210.4–239.2 min) ($P < 0.001$).(2)

Similar study was done in India by Bhimireddy V *et al.* on 2017 on effect of single dose of 0.5mg/kg of IV dexamethasone on prolonging the analgesics effect of CB in 60 children undergo infra-umbilical surgery. The result shows that IV dexamethasone 0.5mg/kg when used along with caudal block with Bupivacaine increases the duration of postoperative analgesia without any adverse effect. (45)

In contrast to the above findings RCT done in India on 2017 by Dongare & karhade in 60 patients which administered 0.1mg/kg of IV dexamethasone with CB shows duration of analgesia was only 194.67±27.76minutes.(46)

An RCT conducted by Sina Ghaffaripour *et al*. in 2016 in Iran in 42 children shows that patient who took IV dexamethasone have reduced pain score & prolonged analgesia duration which is statistical significant with $p<0.0001$.(47)

In 2018 study was conducted in Nigeria by salami *et al.* on 94 patients which compare analgesic effect of CB with0.25 mg/kg IV dexamethasone(group A) & CB alone (group B). This research shows that the time to first analgesics request was 654.18 ± 31.56 and 261.50 ± 10.82 min in

Groups A and B, respectively, *P* = 0.0001. Pain score in the PACU, has statistically significant difference between the two groups with *P* = 0.0001 at 0, 30, 60, 120, 180 and 240 min. (5)

An Egyptian RCT conducted on 2016 which was done in 90 children randomly allocated in 3 group received CB alone in the control group, IV 0.5 mg/kg dexamethasone in IV dexamethasone group and lastly 0.1 mg/kg dexamethasone in the caudal dexamethasone group. the result of this study indicate that the duration of analgesia was 4 ± 0.97,12.95 ±3.66 & 12.90 ± 3.74 hours in bupivacaine alone (B)bupivacaine + IV dexamethasone (BD iv) bupivacaine + caudal dexa(BD)respectively. Analgesic requirement (IV paracetamol 15 mg/kg/dose) in the first 24 hours postoperatively showed a significant difference between the 3 groups with value of 842.5±357.7(B), 440±244.8(BD iv) & 458±192(BD) .(48)

Research hypothesis

HO1: - there is no difference in severity of postoperative pain in caudal block with bupivacaine alone versus caudal block with bupivacaine & IV dexamethasone

HA1: - there is difference in severity of postoperative pain in caudal block with bupivacaine alone versus caudal block with bupivacaine & IV dexamethasone

HO2: - there is no difference in duration of analgesia between caudal block with bupivacaine alone versus caudal block with bupivacaine & IV dexamethasone

HA2: - there is difference in duration of analgesia between caudal block with bupivacaine alone versus caudal block with bupivacaine & IV dexamethasone

HO3: -there is no difference in total analgesic consumption within the first 24 hours in caudal block with bupivacaine alone versus caudal block with bupivacaine & IV dexamethasone

HA3**: -**there is difference in total analgesic consumption within the first 24 hours in caudal block with bupivacaine alone versus caudal block with bupivacaine & IV dexamethasone

Chapter three Objective

3.1 General objective

To compare effectiveness of caudal block with bupivacaine alone versus caudal block with bupivacaine and IV dexamethasone for postoperative analgesia of pediatrics patient undergoing infra-umbilical surgery under General Anesthesia at Tikur Anbessa specialized Hospital from January 1 to May 31, 2019 G.C.

3.2 Specific objective

1) To compare severity of postoperative pain between groups.
2) To compare duration of analgesia between groups.
3) To compare total analgesic consumption within 24hours between groups.

Chapter four methodology

4.1 Study Area

This study was conducted at Tikur Anbessa Specialized Hospital, which is the largest, multi-specialist tertiary care teaching hospital located, in Addis Ababa, Ethiopia, opened since 1972 and, in 1998 transferred to school by FMOH since then it became a university teaching hospital. It provides general medical services for population of the city and those referred from other parts of a country. TASH is now the main teaching hospital for clinical and preclinical trainings of most disciplines. It is also an institution where specialized clinical services that are not available in other public or private institutions are rendered to the whole nation. It has about 800 beds, about 17 operation theatre and approximately 7000-9000 patients undergo surgery in a year including emergency surgery. From beds available in hospital 23% are dedicated to Pediatric patients, 40 which are for elective pediatrics surgery admission; it is the only hospital providing tertiary pediatrics surgical services in Ethiopia.

4.2 Study design and period

Institutional based prospective cohort study design was employed from January 1 to May 31, 2019 G.C.

4.3 Population

4.3.1 Source Population

All pediatrics surgical patient undergone infra-umbilical surgery under General anesthesia & caudal block at Tikur Anbessa Specialized Hospital

4.3.2 Study Population

All elective pediatric surgical patients scheduled for infra umbilical procedures under general anesthesia & caudal block that fulfill inclusion criteria during study period at Tikur Anbessa Specialized Hospital

4.4 Eligibility criteria

4.4.1 Inclusion criteria

ASA I and II physical status age 1-7 patient who undergone infra-umbilical surgery under general anesthesia & caudal block.

4.4.2 Exclusion criteria

- Failed block
- Delayed emergency
- Day case surgery
- Preexisting disease (cancer, chronic pain)
- Simultaneous operation on supra umbilical site
- Patient need postoperative sedation
- Patient who is on chronic opioid medication
- Patient who took addition intraoperative analgesics after block
- Infection at the site of injection or sepsis
- Pre‑existing neurological deficits or spinal deformity
- Patients with coagulopathy
- Allergy to local anesthetic drug
- Other additive added to Caudal block
- Patient need ICU admission postoperatively

4.5 Sample Size and Sampling Technique

4.5.1 Sample size determination

Two independent sample size formulas for equal sample size were used based on 24 hours mean pain score between the groups. The study was designed with type I error of $Z\alpha_{/2}$ =5%, which is 1.96, type II error of Zβ = 20% and power of 80%, which is 0.84. Since there is no previous study done in this topic in our country result adopted from literature was used to calculate sample size.

Study done in Malaysia, showed that the mean pain score in postoperative time was 1.9 ± 2.0, 3.5 ± 2.2 in CB with IV dexamethasone group and CB alone group respectively in the first 24hrs.(42)

$$n_1=n_2= \frac{(s_1^2+s_2^2)\,(Z\,\alpha_{/2} + Z\beta)^2}{(\mu_1 - \mu_2)^2}$$

Where

n_1=sample for CB with bupivacaine& IV dexamethasone group,

n_2=sample for CB with bupivacaine alone group.

μ_1 = Sample mean in CB with bupivacaine & IV dexamethasone group.

μ_2 = Sample mean in CB with bupivacaine alone group.

$(\mu_1 - \mu_2)$= the mean pain score difference between the group

s_1^2 = Sample variance in CB with bupivacaine & IV dexamethasone group.

s_2^2 = Sample variance in CB with bupivacaine alone group.

α = probability of type I error

β= probability of type II error

$$n = \frac{(2^2 + 2.2^2)\times (1.96+0.84)^2}{(1.9-3.5)^2}$$

$$n = \frac{69.3056}{2.56} = 27.1$$

By adding 10% contingency, sample size become $n_1= n_2$=30 children in each group a total of 60 pediatric patients were involved in the study.

4.5.2 Sampling technique

Systematic random sampling technique was used to select study participants on daily operation schedule list. Depending upon average values of the previous surgery in Tikur Anbessa Specialized Hospital per 3 months on the log book, 189 patients were operated on pediatric infra umbilical surgery under GA & caudal block. The sampling interval K was determined using the formula: K=N/n; where, n = total sample size, N = population per 3 months. 189/60=3.15 approximately the sampling interval was 3 and the first study participant was selected using lottery method after which data collector recruit 1 patient for every 3 consecutive patients undergone infra-umbilical surgery grouping based on exposure status of patients who satisfied the inclusion criteria.

Exposed (CB + IV dexamethasone):30 patients received 1ml/kg of 0.25% bupivacaine + 0.5mg/kg IV dexamethasone.

Non-exposed (CB alone):30 patients received 1ml/kg of 0.25 %bupivacaine alone till required sample was reached.

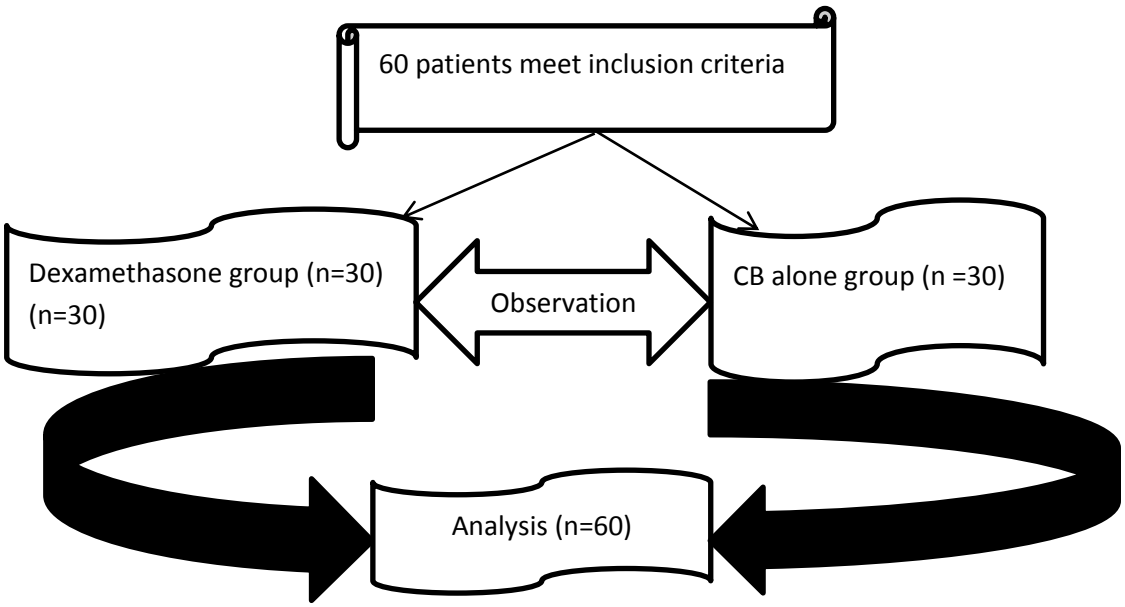

Figure 1.Patient Enrolment Chart of CB with IV dexamethasone & CB alone group in pediatrics patient undergone elective infra-umbilical surgery at TASH from January 1 to May 31, 2019

4.6 study variables

4.6.1 Dependent Variables

- Severity of postoperative pain
- Duration of analgesia.
- Total analgesics consumption in 24 hrs.

4.6.2 Independent Variables

- Age
- Sex
- ASA status
- Weight
- Baseline v/s
- Type of surgery
- Intra operative v/s
- Type of induction agent
- Type of analgesia premedication
- Duration of surgery
- Duration of anesthesia
- Exposure status: CB with bupivacaine and IV dexamethasone versus CB with bupivacaine alone

4.7 Data Collection Tool and Procedure

Structured questionnaires were prepared in English which included socio-demographic, perioperative data, the severity of pain, duration of analgesia & total analgesia consumption.

As the child arrived to OR standard monitoring was applied & Baseline vital signs have been recorded before induction of anesthesia. Based on type of surgery appropriate size ETT or LMA is selected & general anesthesia was induced with propofol (2.5-3mg/kg), ketamine (1-2mg/kg) or halothane (3-5%) & fentanyl 1-2µg/kg or ketamine 0.5mg/kg was given for premedication. Tracheal intubation was facilitated by suxamethonium 1-2mg/kg as well as maintenance of anesthesia was preceded with inhalational anesthetic agent.

CB was done by MSc anesthesia student after confirmation of ETT placement & 10 minute before skin incision with 1 ml/kg of 0.25% bupivacaine in both group & the exposed group was administered 0.5mg/kg of IV dexamethasone additionally. Induction, caudal block & skin incision time was documented. Pre-incision vital signs were measured 10 minute after block & just before skin incision. Post incision vital signs were measured within 10 minutes after skin incision, then, if vital sign not increased by 20 % from base line block is taken as successful but if the CB was considered unsuccessful those children were given analgesia & excluded from the study. The patient is catheterized for follow up of urine output. Duration of surgery & anesthesia was also documented. All intraoperative data was documented by MSc anesthesia students. Patients were transferred to PACU & remained there for at least one hour.

FLACC score was used to assess postoperative pain & recorded by trained nurses at PACU, 2nd, 4th, 6th, 12th and 24^{th} hours. WHO pain ladder was applied in treating pain in study area. Pain score, analgesia duration and total analgesia consumption were documented for 24 hours postoperatively & Completeness of the data was supervised by the PI daily.

4.8 Data Quality Control and Assurance

Data collectors was trained by principal investigator and pretest was done for reliability at Minilik II hospital on 10% of sample in patients who undergone Infra umbilical surgery under CB with IV dexamethasone & CB alone, which were not included in the main study. During data collection regular supervision and follow up was made appropriately. Each data was cross-checked for completeness and consistency every day. All materials used for data collection were arranged sequentially and store in safe and secure place.

4.9 Operational definitions

Duration of anesthesia: a time in minutes from induction of anesthesia to admission to PACU.

Duration of surgery: time in minutes from skin incision to closure.

Postoperative pain: any pain score that occur other than zero after surgery within 24 hours.

Duration of analgesia: total time in minute from caudal block to first analgesia was given.

Total analgesia consumption: total dose & type of analgesics given in mg within the first 24 hours after end of surgery.

Failed block increase in vital sign from baseline more than 20% during skin incision 10 minute after caudal block.(28)

FLACC scale: is a measurement used to assess pain for children from two month to seven years or individual that are unable to communicate their pain. In this scale patient face, leg, activity, cry & consolability will be assessed.

In patients who are asleep: observe for 5 minutes or longer. Observe body and legs uncovered. If possible, reposition the patient. Touch the body and assess for tenseness and tone

In patients who are awake: observe for 1 to 5 minutes or longer. Observe legs and body uncovered. Reposition patient or observe activity. Assess body for tenseness and tone. Initiate consoling interventions if needed.

Each category is scored on the 0–2 scale, which results in a total score of 0–10.

- 0: Relaxed and comfortable
- 1–3: Mild discomfort
- 4 –6: Moderate pain
- 7–10: Severe discomfort or pain or both

Delayed emergency Failure to regain the expected level of consciousness within >30 min after cessation of anesthetic agent administration.

Number of analgesia request how many times patient took analgesia in 24 hours.

4.10 Data Analysis and Interpretation

Data was checked manually for completeness and then coded and entered into statistical package for social science (SPSS) version 25 computer program for analysis. Test of normality was done by using histogram and Shapiro-Wilk test (weight, base line vital sign, V/S before & after skin incision & duration of analgesia was found normally distributed) & homogeneity of variance was done by Levene's test of equality of variance for weight, base line vital sign, V/S before & after skin incision & duration of analgesia while (age, duration of anesthesia, duration of surgery, severity of pain & total analgesia consumption) was not normally distributed when checked using histogram & Shapiro-Wilk test. Independent sample t test was used to analyses continuous & normally distributed data while Mann-Whitney U test was applied for non-normally distributed data. Chi-square test & fisher exact test was used to analyze categorical variables. Data was presented as mean ± SD for normally distributed median (IQR) for not normally distributed and categorical data was presented by number & percentages. P value < 0.05 was considered as statistically significant.

4.11 Ethical Consideration

Before data collection, the proposal was reviewed by the ethical committee of college of health science and official letter was obtained from anesthesia department. We get permission from TASH clinical director office after explanation of the purpose of study & submission of official letter. The objective of the study was also explained to the children's parent included in the study. Verbal consent was obtained from the children's parent and confidentiality of the information assured by using code numbers rather than name of the patient and keeping questionnaires locked.

4.12 Dissemination Plan

Copies of the research will be disseminated to college of health science, school of medicine/department of anesthesia, AAU student research office, Ethiopian association of anesthetists, FMOH & for NGOs that work on pediatric health. Finally, it will be send to journals for publication.

Chapter five Results

5.1 Demographic and Perioperative Characteristics

During a study period total of sixty patient's data were recruited and included for final analysis based on whether they received CB with bupivacaine alone or CB with bupivacaine & IV dexamethasone for postoperative analgesia.

Patient's characteristics were comparable between the two groups with regard to Demographic data with p value greater than 0.05 as shown in table 1.

Table 1.Demographic characteristics of pediatrics patient undergone elective infra-umbilical surgery at TASH from January 1 to May 31, 2019

Variables		CB with IV dexamethasone	CB alone	P value
Age (year) *		3(2-5)	3(2-5)	0.822
Sex	Female	8(26.7%)	9(30%)	0.774
	Male	22(73.3%)	21(70%)	
ASA	ASA I	25(83.3%)	24(80%)	0.739
	ASAII	5(16.7%)	6(20%)	
Weight(kg) **		13.9±3.89	13.63±3.37	0.778

NB *=median (interquartile range) **=mean ±standard deviation

As shown in table 2 the perioperative data collected was baseline vital sign, type of surgery, type of analgesia premedication, induction agent, duration of anesthesia & duration of surgery which were comparable between the groups with p value greater than 0.05.

Table 2 Perioperative characteristics of pediatrics patient undergone elective infra-umbilical surgery at TASH from January 1 to May 31, 2019

Varaibles		CB with IV dexamethasone	CB alone	P value
Baseline V/S **	HR	130.8±17.33	131.8±18.13	0.817
	BP (MAP)	67.7±5.7	68.3±6.5	0.704
	Spo2	96.67±1.52	96.77±1.5	0.798
Type of surgery	lower abdominal	8 (26.7%)	11(36.7%)	0.709
	Urologic	12(40%)	8 (26.7%)	
	Ano-rectal	4(13.3)	5(16.7%)	
	Orthopedics	6(20%)	6(20)	
Induction agent	Propofol	15(50%)	15(50%)	0.924
	Ketamine	10(33.3%)	11(36.7%)	
	Halothane	5(16.7%)	4(13.3%)	
Analgesia premedication	fentanyl	12(40%)	13(43.3%)	0.793
	Ketamine	18(60%)	17(56.7%)	
Duration of surgery(min) *		80(60-100)	85(60-120)	0.795
Duration of anesthesia(min)*		95(75-115)	95(73-140)	0.894

NB *=median (interquartile range) **=mean ±standard deviation

5.2 Hemodynamic change before & after skin incision between the groups

Independent sample t test was used to analyses vital sign before & after skin incision result shows that mean ±SD of vital sign has no statistically significant difference after caudal block between the groups with p value greater than 0.05 as shown in table 3.

Table 3 Hemodynamic change before& after skin incision of pediatrics patient undergone elective infra-umbilical surgery at TASH from January 1 to May 31, 2019

Variable		CB with IV dexamethasone	CB alone	P value
V/S before incision	HR**	128.6±15.7	129.7±17.9	0.813
	MAP**	65.2±7	67.3±6.3	0.219
V/S after incision	HR**	122.8±16.6	123.4±17.2	0.879
	MAP**	62.4 ±7.4	64.2±6.8	0.332

NB **=mean ±standard deviation

5.3 Comparison of postoperative pain severity

Comparison of the groups for severity of pain was done by Mann-whitney U test which showed that the intensity of pain in CB with IV dexamethasone group is lower at 4,6,12 hours as compared to CB alone group and it was significantly different with p value of (<0.001, <0.001 & 0.003) respectively. How ever the pain intensity was not significantly different at PACU, 2nd & 24th hours with p value of (0.736, 0.923 &0.816) respectively.

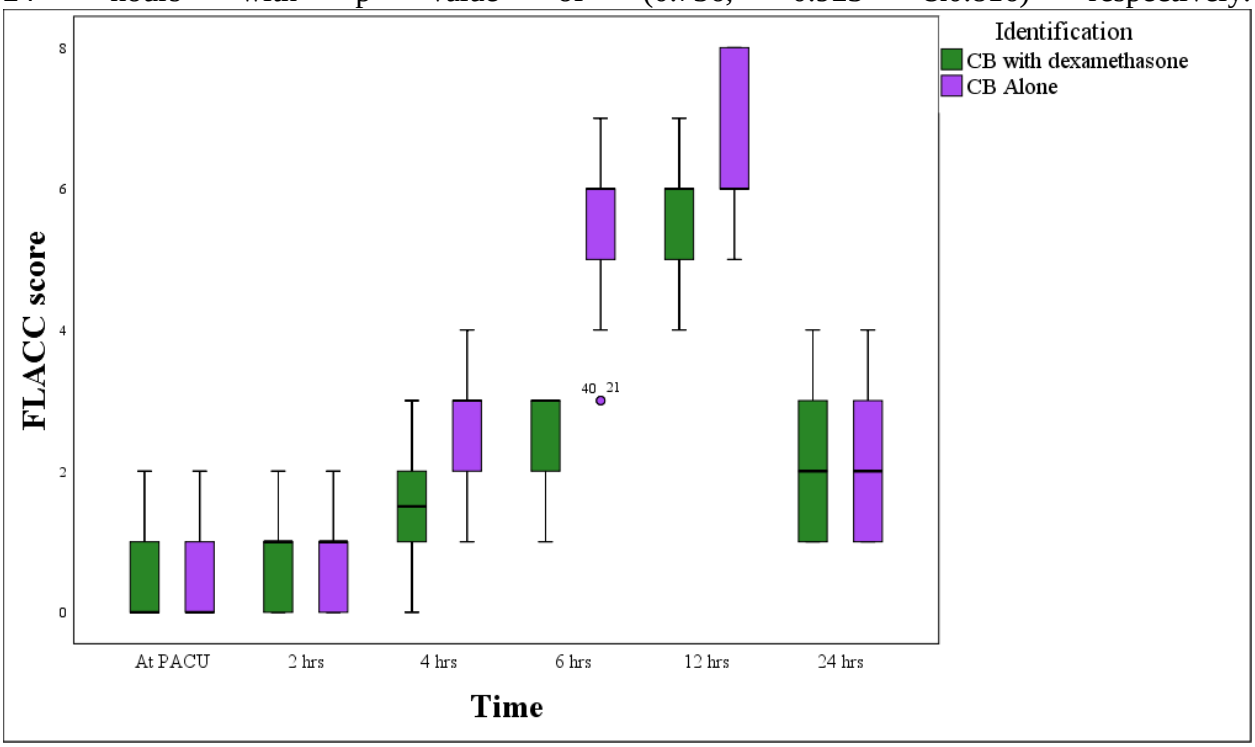

Figure 2.Comparison of postoperative severity of pain of pediatrics patient undergone elective infra-umbilical surgery at TASH from January 1 to May 31, 2019

5.4 comparison of duration of analgesia & total analgesia consumption between the groups

As result of Independent sample t test & Mann-whitney U test revealed that duration of analgesia & total analgesia consumption in 24 hours was significantly different between the two groups with p value less than 0.05 as shown in table 4.

Table 4 Comparison of analgesia duration, total analgesia consumption of pediatrics patient undergone elective infra-umbilical surgery at TASH from January 1 to May 31, 2019.

Variables		CB with IV dexamethasone	CB alone	P value
Duration of analgesia in minutes**		699.3±57.55	347±40.53	<0.001
Total dose of analgesia given(mg)*	Paracetamol	250(250-375)	500(375-625)	<0.001
	Tramadol	0(0-2.5)	0(0-25)	0.041
Number of analgesia request*		1(1-2)	2(2-3)	<0.001

NB *=median (interquartile range) **=mean ±standard deviation

As figure 3 shows there was no statistical significant difference between the groups on proportion of patient took paracetamol & tramadol shows with p=0.112 & p=0.095 respectively.

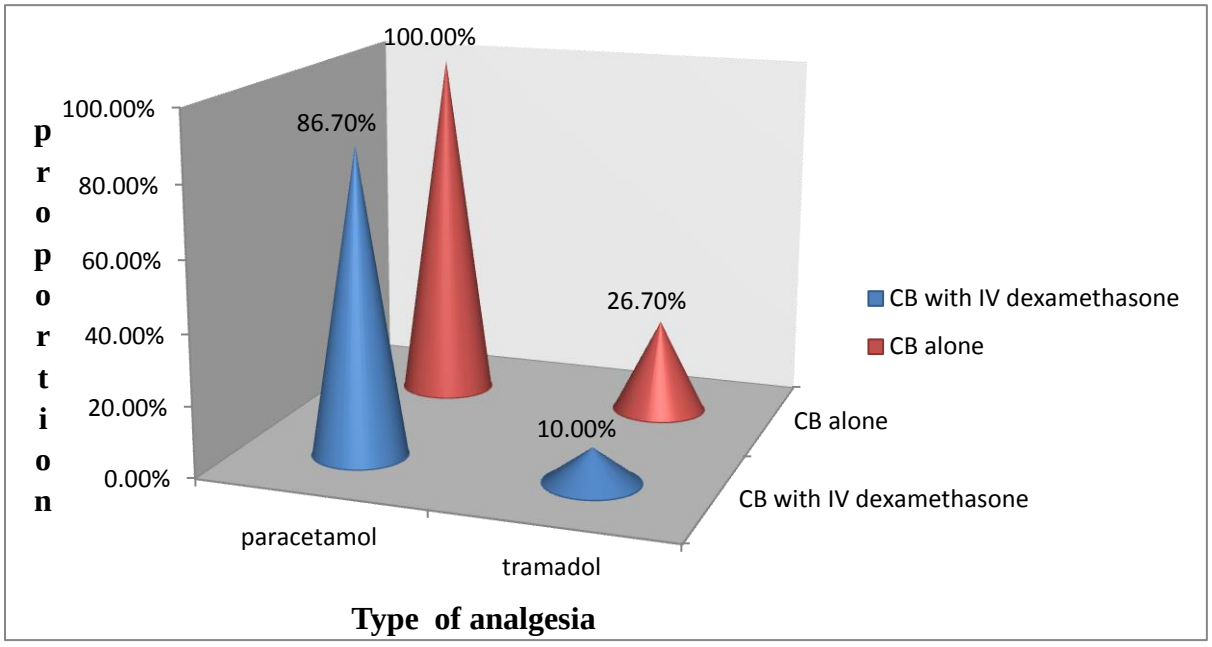

Figure 3 Comparison of proportion of paracetamol & tramadol given in 24 hours of pediatrics patient undergone elective infra-umbilical surgery at TASH from January 1 to May 31, 2019

Chapter six

Discussion

Pediatrics patient with significant postoperative pain may develop anxiety, fright, insomnia which predispose them to exaggerated pain perception which make recovery period unpleasant. Other deleterious consequences of pain include sleep disturbance, nausea, and vomiting as well as result in prolonged hospital stay.(49-51)

So providing them comfort in postoperative period is a highly desirable yet challenging task.

Caudal block has been found to be an excellent and safe technique for providing postoperative analgesia in pediatric population with a high success rate. However the single shot of caudal block provides analgesia for a limited period of time. To increase this duration, various methods have been utilized.(2-7)

Dexamethasone is a corticosteroid that decreases the tissue levels of bradykinin and inhibits the release of neuropeptides from nerve endings. COX-2 enzyme in central nervous system is also inhibited by dexamethasone resulting in decreased production which is responsible for enhanced nociception.(2)

Our study revealed that administration of IV dexamethasone with CB will significantly reduce pain severity, prolong analgesia duration as well as it reduces analgesia consumption in 24 hours. We found that the median FLACC score was lower in CB with IV dexamethasone group at 4^{th}, 6^{th} & 12^{th} hours which is statistically significant with p value of (<0.001,<0.001& 0.003) respectively.

Our result is comparable with RCT done by Sina Ghaffaripour et al. & Sayed K *et al.* which found statistically significant difference at (4^{th}, 8^{th} & $12^{th)}$ & (4^{th} 8^{th} & 16^{th}) hour respectively.(47, 48)

In contrast to our study RCT conducted in India by Bhimireddy V *et al.* found that there was no significant difference in pain score at 12 hour. The possible explanation for difference might be difference in type of procedure included in the study he include patient undergone herniotomy only rather than all infra umbilical procedures & use of strong opioid during request of analgesia.(45)

In our finding it was clearly seen that there is significant difference in duration of analgesia between CB with IV dexamethasone group & CB alone group with mean value of 699.3 ±57.55 versus 347±40.53 min respectively ($p < 0.001$).

Our result is consistent with studies done by Srinivasan, *et al.,* Salami, *et al.*, & Bangash. *et al.*, which revealed significant difference in duration of analgesia between groups 620vs 220, 654.18 ± 31.56 min vs 261.50 ± 10.82 min, 621.6 ± 25.743 vs 402.4 ± 34.792 min respectively .(2, 5, 16)

As RCT conducted by hong *et al.*, Azarinah I *et al.* & Mukesh K *et al*. Shows analgesia duration was significantly prolonged in patients who took IV dexamethasone with CB group with mean duration of 646±149 vs 430±205 min, 800 vs 520 min, 10.3± 2.9 vs 3.6 ±1.3 hours respectively.(28, 42, 43)

Other RCT done by, Balvir S *et al.* & Sayed K *et al.* was also in line with our finding which indicate analgesia duration was significantly prolonged in dexamethasone group than CB alone group.(44, 48)

In contrast to our result RCT done in India by Dongare *et al.* showed that duration of analgesia in CB with IV dexamethasone was only 194.67±27.76 minutes. The possible reason might be difference in dose administered which is 0.1mg/kg in his study rather than 0.5mg/kg which we used in our study.(46)

Our study showed that all patients in CB alone group and 86.7% of CB with IV dexamethasone group needed paracetamol in 24 hours which was not significantly different with p value of 0.112.

This finding is comparable with result of Sayed K *et al*. found that there was no significant difference in proportion of patient took paracetamol between the groups with $p > 0.05$. (48)

In contrast to our finding Bhimireddy V *et al.* found proportion of patient required analgesia in control group was 96.67% vs 63.34% in dexamethasone group with $p < 0.05$.the possible reason of difference might be due to inclusion of only one procedure in contrast to all infra-umbilical procedures included in our study which have different pain intensity. (45)

Regarding to total analgesia consumption we demonstrated that patients who took IV dexamethasone needed reduced amount of paracetamol in 24hours than CB alone group with median value of 250mg vs 500mg respectively with p <0.001.

As study conducted in Egypt by Sayed k *et al.* shows total paracetamol consumption was significantly reduced in IV dexamethasone group with 440±244.8 versus 842.5±357.7 in CB alone group which is consistent with our result.(48)

Other RCT done by Mohamed M.A *et al.* also found that analgesia consumption was lower in dexamethasone group than CB with bupivacaine alone group.(52)

In present study we found that tramadol consumption was also significantly reduced in dexamethasone group than CB with bupivacaine alone group with p value of 0.041.
Study conducted in India by Dhanger, *et al*. is comparable with our result which indicated that tramadol consumption was significantly reduced in dexamethasone group with p value of 0.001.(53)

In our finding the median frequency of analgesia request in 24 hours was 1 in CB with bupivacaine & IV dexamethasone group & 2 in CB with bupivacaine alone group which has statistical significance difference with p <0.001.

The above finding is comparable with result of Mukesh K *et al*. which indicated that number of analgesia request was 2.0 ± 0.2, in control group & 1.2±0.2 treatment group.(43)

Similarly Balvir S et al & Sayed k *et al*. also found that analgesia request frequency was lower in dexamethasone group than CB alone group1.1±0.1, 2.1± 0.2, 1.80 ± 0.52, 3.30 ± 0.65 respectively.(44, 48)

Limitation our study has some limitations

Fail to control the sound of the room.

All of our result is compared with randomized clinical trail

Small sample size

Strength our study is the first study in this title in our country & we try to include all infra umbilical procedures.

Conclusion We conclude that administration of 0.5mg/kg intravenous dexamethasone in combination with caudal block prolong duration of analgesia, reduced pain scores and analgesic consumption postoperatively, in children undergoing infra-umbilical surgery.

Recommendation

Anesthetist

We recommend administration of 0.5mg/kg IV dexamethasone with caudal block for reduction of postoperative pain in pediatrics patient who undergo infra umbilical surgery.

Researchers

We also recommend researcher's to conduct RCT in similar title with large sample size.

Acknowledgment

First of all, I would like to thank Addis Ababa University to give me a chance to prepare this thesis. Next, I would like to express my heart-full gratitude and thanks to my advisors Meron Abrar & Fiseha Fente for their invaluable support and comments. I would like also to extend my appreciation to Nugusu Ayalew & Simeneh Mola MSc in advanced clinical anesthesia that had helped me a lot in giving additional advice.

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Reference

1. Frank H. The society of paediatric anaesthesia: 15th annual meeting. New Orleans, Louisiana, October 2001. Anesth Analg 2002;94:1661‐8.
2. Bharath Srinivasan. Comparison of caudal and intravenous dexamethasone on post‐operative analgesia in paediatric inguinal herniotomy. Indian Journal of Anesthesia Dec 2016;60(12).
3. Berger MJTM. Caudal blocks. pediatrics anesthesia. pediatrics Anaesthesia. 2012;22:44-50.
4. Suresh S. caudal block safety in children. Wwwanesthesia-analgesiaorg. January 2015;120(1).
5. Salami SOF. Efficacy of low‐dose intravenous dexamethasone on caudal analgesia in the paediatric age group Nigerian Postgraduate Medical Journal. 0ctober- december 2017;24(4).
6. Silvani P CA, Agostino MR, Salvo I. Caudal anesthesia in pediatrics. An update Minerva Anestesiol. 2006;72:753-9.
7. Getu Ataro MB. Effectiveness of Caudal Epidural Block using Bupivacaine with Neostgmine for Pediatric Lower Extremity Orthopedic Surgery in Cure Ethiopia Children's Hospital. J Anesth Clin Res. 2014;5(12).
8. IASP. IASP Pain Terminology. Taxonomy Co, editor. Washington DC. International Association for the Study of Pain. 2014.
9. Vittinghoff m. Postoperative pain management in children. Pediatrics anesthesia. 2018:1-14.
10. Youn YLa. Postoperative pain control in children. Korean J Anesthesiol March 2016;66(3).
11. Kahsay H. Assessment and treatment of pain in pediatric patients. Curr Pediatr Res. 2017;21(1):148-57.
12. Eshete MT BP, Siebeck M,, Tesfaye M HA, Michael GG, et al. . Quality of postoperative pain management in Ethiopia: A prospective longitudinal study. . PLoS ONE 2019;14(5).
13. Admassu WS HA, Abdissa ZD Severity and Risk Factors of Post-Operative Pain in University of Gondar Hospital, Northeast Ethiopa. J Anesth Clin Res. 2016;7:: 675.
14. Wels D. Management of postoperative pain. S Afr Fam Pract, . 2012;54(3):25-8.
15. Baeyer C. Special Interest Group on Pain in Childhood,Pediatric Pain Letter,Commentary Pain assessment in Sub-Saharan Africa. Africa International Association for the Study of Pain 2009;11(3):20-5.
16. Bangash AH. comparision of caudal block alone with caudal block plus IV dexamethasone for post-operative Biomedical Oct. – Dec., 2014 30(4).
17. Shomaker K. pain prevalance & treatment pattern. hospital pediatrics. 2015;5(7).
18. Good Practice in Postoperative and Procedural Pain Management. 2012.
19. Kulshrestha AB. Management of acute postoperative pain in pediatric patients. Anaesth Pain &Intensive Care. 2014;18(1):101-7.
20. Suresh KS BWaGSDOJ. Regional anaesthesia to improve pain outcomes in paediatric surgical patients: a qualitative systematic review of randomized controlled trials. British Journal of Anaesthesa. 2014;113(3):375-90.
21. South african acute pain guidelines. 2015.

22. Winfried Meissner FC, Dominique Fletcher, Frank Huygen, Bart. Improving the management of post-operative acute pain. Current Medical Research & Opinion. November 2015;31(11).
23. Practice Guidelines Anesthesiology 2012;116:248-73.
24. Thienthong S. Postoperative pediatric pain management. anesth,pain & intensive care. Jan-Mar2014;18.
25. M. Size SJ. Pain management in developing countries. the Association of Anesthetists of Great Britain and Ireland. 2007;62(1):38-43.
26. Hodges SC MC, Okello M, McCormick BA,Walker IA, Wilson IH. Anaesthesia services in developing countries: defining the problems. Anaesthesia 2007;62:4-11.
27. Harsha Shanthanna BS, and Gordon Guyatt. A Systematic Review and Meta-Analysis of Caudal Block as Compared to Noncaudal Regional Techniques for Inguinal Surgeries in Children. BioMed Research International. 2014;17.
28. J.YHong. Dexamethasone in paediatric postoperative pain. British Journal of Anaesthesia 2010;105(4):506-10.
29. Beer DD. caudal additive in children –solution or problems. Br J Anaest. Apr 2003;90(4):487-98.
30. P. A. Jadhav. Levobupivacaine versus bupivacaine for caudal analgesia Pediatric Anesthesia and Critical Care Journal. 2017;5(2):66-73.
31. Ankalwar V. Caudal Epidural Ropivacaine versus Bupivacaine in Pediatric Patients for Infra-Umbilical Surgeries. International Journal of Health Sciences & Research june 2015;5(6):124.
32. Cinar SO. Infant caudal anesthesia. Pak J Med Sci. 2015;31(4).
33. Locatelli PI, V. Sonzogni, A. Zanella, V. Gatti3, A. Spotti,, Fumagalli SDMaR. Caudal levobupivacaine 0.25% in children. British Journal of Anesthesia 2005;94(3):366-71.
34. DD Akpoduado CI, NP Edomwonyi. Dosing pattern for caudal anesthesia for herniotomy. Nigerian Journal of Clinical Practice. February 2017;20(2).
35. Bhavna Gupta. Role of dexamethasone in peri-operative anesthesia management: A review of literature. Anesthesiol Open J 2017;2(2):33-9.
36. Richardson AB BA, Wellman SS, Attarian DE, Bolog¬nesi MP, et al. Perioperative dexamethasone administration does not increase the incidence of postoperative infection in total hip and knee arthroplasty A Retrospective Analysis. J Arthroplasty. 2016;31:1784-7.
37. Chunwoo Yang SMJ, Yu Kyung Bae, and Sang-Jin Park. The effect of ketorolac and dexamethasone on the incidence of sore throat in wom¬en after thyroidectomy: a prospective double-blinded rand¬omized trial. Korean J Anesthesiol. 2017;70:64-71.
38. Rodrigo Mathias Freire de Menezes Carneiro. Preemptive analgesia of dexamethasone as compared to ketorolac tromethamine in simple tooth extractions Rev Dor São Paulo. apr-jun2014;15(2):83-6.
39. Dionne RA GS, Rowan J, Kent A, Brahim JS. Dexamethasone suppresses peripheral prostanoid levels without analgesia in a clinical model of acute inflammation. J Oral Maxillofac Surg. 2003;61(9):997-1003.
40. N. H. Waldron CAJ, T. J. Gan, T. K. Allen and A. S. Habib. Perioperative dexamethasone and postoperative pain. British Journal of Anaesthesia 2013;110(2):191-200.
41. C.G. Valdivia-Sánchez MLP-D. Dexamethasone in preventive analgesia. Gaceta Médica de México. 2017:153.

42. Azarinah I. Dexamethasone Improves Caudal Block Analgesia MEJ ANESTH 2015;23(2).
43. Mukesh KP. Comparative study of Use of Caudal Versus Intravenous Dexamethasone in Epidural Block Amongst Children. Indian journal basic & applied researchmarch 2012;1(2):227-31.
44. Balvir SS. Caudal and Intraveneous Dexamethasone as Adjuvant to Epidural Block. Int J Med Res Prof 2016;2(4):190-93.
45. Bhimireddy Venkata reddy MIK. Evaluation of Dexamethasone with Bupivacaine for infra-umbilical surgeries in children. Sch J App Med Sci. Mar 2017;5(3):975.
46. Dongare Dhanashree SK. Comparison of Analgesic Efficacy of Caudal Dexamethasone with Intravenous Dexamethasone as an Adjuvant to Caudal Block in Pediatric Patients Undergoing Urogenital Surgeries. Anesth Essays Res. 2017;11:1009-12.
47. Ghaffaripour S. Efficacy of dexamethasone on postoperative analgesia. Pak J Med Sci. 2016;32(1).
48. Sayed KA-E. Efficacy on Postoperative Pain and Vomiting in Pediatric Patients. Pain Physician. August 2016;19:841-8552.
49. Chatterjee U. Preemptive analgesia in paediatric surgery. Afr J Paediatr Surg. 2011;8:267-8.
50. Jaichandran VV IB, Jagadeesh V, et al. Amultimodal approach to postoperative pain relief in chil dren undergoing ambulatory eye surgery. Indian J Anaesth. 2008;52:794.
51. Anand VG KM, Thavamani A, Bridgit MJ. Effects of dexmedetomidine added to caudal ropivacaine in paediatric lower abdominal surgeries. Indian J Anaesth. 2011;55:340-6.
52. Mohamed M. Abu Elyazed GME. Dexamethasone versus neostigmine as an adjuvant to bupivacaine 0.25% for caudal analgesia in children undergoing open inguinal hernia repair. Egyptian journal of anaesthesia. 2017;33:283-8.
53. Dhanger S. Low Dose Intravenous Dexamethasone in Supraclavicular Block. Indian Journal of Pain. September‑December 2016 30(3).

Annex I: Information sheet

Title of the Research Project: comparison of caudal block with bupivacaine alone versus caudal block with bupivacaine & IV dexamethasone for postoperative analgesia of pediatrics patient undergoing infra-umbilical surgery under General Anesthesia at Tikur Anbessa Specialized Hospital from January 1 to May 31, 2019 G.C

Name of the principal investigator: Timsel Girma

Name of the organization: Addis Ababa University, school of medicine, department of anesthesia.

Name of the sponsor: Addis Ababa University.

Introduction the main concern of this information was prepared with the aim of assessing the effect of giving IV dexamethasone with CB done with bupivacaine for prolongation of post-operative analgesia for pediatric patient undergoing infra umbilical surgery at Tikur Anbessa Specialized Hospital. The research group includes the principal investigator, five data collectors, and two advisors from AAU.

Purpose of the Research project the main concern of this study is to compare caudal block with bupivacaine alone versus caudal block with bupivacaine & IV dexamethasone for postoperative analgesia of pediatrics patient undergoing Infra-umbilical surgery under General Anesthesia at Tikur Anbessa Specialized Hospital. The finding of this study is expected to be used by decision makers, FMOH, EAA, department of anesthesia and health practitioners.

Procedure

This study will include all elective pediatric patients coming for infra umbilical surgery during the study period. They will be selected as part of the study participants whose parents are willing to participate in this study and willing to have consent. Anyone (child's parent) can have autonomy to refuse to participation in study.

Benefits, Risk or Discomfort

There is no direct benefit to study participants, but they will be monitoring and followed for 24 hours. And the result of this study will be used for further improvement of the service. There is no risk due to participating in this study.

Confidentiality: The information collected from the study subjects will be keep confidential and stored in the file, without their name by assigning a code number to each.

Right to refusal or withdraw

Study subjects family will have full right to refuse participation of their child in this research.

Person to contact

For any questions or concerns you can contact the principal investigator using the following addresses:

- Name: Timsel Girma
- Phone: +251926175309/+251944060952

E-mail: timsikebron15@gmail.com

Annex II: Study subjects consent form

Addis Ababa University, College of Health Sciences Department of Anesthesia

Prospective Cohort Study, On comparison of caudal block with bupivacaine alone versus caudal block with bupivacaine and IV dexamethasone for postoperative analgesia of pediatrics patient undergoing Infra-umbilical surgery under General Anesthesia at Tikur Anbessa Specialized Hospital from January 1 to May 31, 2019 G.C.

Hello! My name is _____ I am of the members of the research team and I am here to ask you some questions and to collect some important information from your child's chart.

If you are willing to allow your child to participate in this research (which compare effectiveness of CB with bupivacaine alone versus CB with bupivacaine and IV dexamethasone for postoperative analgesia). So you are kindly requested to your child to participate on this study. I obtained the child name from the list of operation for surgery. Participation is voluntary & we strictly keep confidentiality. This observation will done for 24 hours on severity of pain, analgesia duration & total analgesics consumption of pediatrics patient whose age is one to seven & undergo infra-umbilical surgery under general anesthesia in Tikur Anbessa Specialized Hospital from January 1 to May 31, 2019 G.C. Therefore, we kindly request your child to participate in the observation? I understood about the objectives of the research and my roles in the research. I have agreed to participate in the research. A) Agree **B**) Disagree

If agrees, the observation will be started.

Annex III የጥናቱ ተሳታፊ ስመሆን የስምምነት ቅፅ

አዲስ አበባ ዩኒቨርስቲ፣ጤና ሳይንስ ኮሌጅ አንስቴዝያ ት/ት ክፍል

የተከበራችሁ የጥናቱ ተካፋይ ምላሾች/የቅርብ ዘመዶች ጤና ይስጥልን፡ስሜ----------ይባላል በአዲስ አበባ ዩኒቨርስቲ ምርምር ስር ተሳታፊ ስሆን ስምናደርገው ምርምር ልጆትን ተሳታፊ ልናደርገው የፈለግን ሲሆን ይሄን ስማድረግ የርሶን ፍቃደኝነት እንጠይቃለን። የልጆትን ስም ከቀዶ ህክምና ተራ ሳይ ያገኘን ሲሆን፤ የማንኛውም ግለሰብ ስምና ማንኛውም ሚስጥር ይፋ ማይደረግና ማይመዘገብ መሆኑን እረጋግጥሎታለው። ይህ ጥናት ቀዶ ህክምና ስሚደረግላቸዉ ህፃናት ከጠቅላላ አንስቴዝያ በኋላ ከቀዶ ህክምናው በፊት የሚገረግ የህመም ማስታገሻ ህክምና(caudal anesthesia) ላይ የሚሰራ ሲሆን (CB with bupivacaine alone versus CB with bupivacaine and IV dexamethasone) ህመምን የማስታገስ አቅማቸው ስምን ያህል ግዜ እንደሚቆይ ስማውቅ ሲሆን ምርምሩ በጥቁር አንበሳ ልዩ የማስተማሪያ ሆስፒታል ከታህሳስ አንድ እስክ ግንቦት ሰላሳ አንድ 2019 እንደ አውሮፓውያን አቆጣጠር ይደረጋል። ይሄ ጥናት ከአንብረት በታች ባለዉ የሰውነት ክፍል ቀዶ ህክምና ስሚደረግላቸው እጢሚያቸው ከ አንድ እስከ ሰባት አመት ያሉ ህፃናትን የሚያካትትና ሰሃያ አራት ሰአት ወደፊት፣የህመም መጠን፣ ከቀዶ ህክምና በኋላ የህመም ማስታገሻ ሳይወስዱ የቆዩበት ሰዓት፣ እና ምን ያህል የማስታገሻ መድሀኒት በሃያ አራት ሰአት ውስጥ እንድተጠቀሙ መከታተል ነው። ልጅዎን ስማሳተፍ የእርስዎን ፍቃደኝነት ስለምንፈልግ ያለማንም አስገዳጅነት ፍቃደትን እንጠይቃለን። የጥናቱን አላማ እንዲሁም የኔን ሃለፊነት ተረድቻለሁ ስለዚህ ልጄ እንዲሳተፍ ሀ) ፈቅጃለሁ ለ) አልፈቅድም

- ከፈቀዱ ክትትሉ ይጀመራል።

Annex IV: Questionnaire

Addis Ababa University, College of Health Sciences, Department of Anesthesia Prospective Cohort Study, On effectiveness of CB with bupivacaine alone versus CB with bupivacaine and IV dexamethasone for postoperative analgesia in TASH from January 1 to May31 2019 G.C.

Instruction: For each of the questions, please circle an alternative(s) that fit the response or fill the blank space provided.

Date of data collection _____

Questionnaire identification number (card no) _____

I) socio demographic data

s.no	Question	Response	Code
101	Age		
102	Sex	A Female	
		B Male	
103	ASA	A ASA I	
		B ASA II	
103	Weight	_____kg	

II preoperative data

S.no	Question	Response	Code
201	Base line HR	____bpm	
202	Base line BP	_____mmHg	
203	Base line RR & Spo2	_____bpm & ____%	

III Intraoperative data

S.no	Question		Response		Code
301	Type of surgery				
302	Analgesia premedication				
303	Type of induction agent				
304	Induction time		_____am/pm		
305	Caudal block;	Time	_____am/pm		
		Bupivacaine 0.25%	_____mg		

306	dose of IV dexamethasone given		_____mg		
307	Vital sign before skin incision	BP	_____mmHg		
		HR	_____bpm		
308	Incision time		_____am/pm		
309	Vital sign after skin incision	BP	_____mmHg		
		HR	_____bpm		
310	Additional intraoperative analgesia given		a) yes b) no		If no skip to 312
311	If yes specify drug, the time & dose		_____at_____ &____mg		
312	Duration of surgery		_____ minute		
313	Duration of anesthesia		_____ minute		

IV Post-Operative Observation Vital sign at PACU

S.no	Question		Response				Code
	Arrival time_____am/pm		Arrival	20minute	40minute	60minute	
401	HR						
402	BP						
403	FLACC SCORE						
404	Analgesics given	Type & dose	_____ _& _____mg	_____ _& _____mg	_____ _& _____mg	_____ _& _____mg	

V Ward follow up for 24hrs

S.no	Question		Response						Code
	Arrival time_____am/pm		At Arrival	After 2hrs	After 4hrs	After 6hrs	After 12hrs	After 24hrs	
501	FLACC score								
502	Analgesia given	Type & dose	_____&____mg	_____&___mg	_____&___mg	_____&___mg	_____&___mg	_____&___mg	
503	Analgesic required time		_____pm/am						
504	Duration till first analgesic request		_____min						
505	Total and type of analgesic consumption within 24 hours after the patient arrived in recovery/ward		PCM _____ mg Diclofenac _____ mg Tramadol _____ mg Pethidine _____ mg						
506	How many times analgesics were given in 24hrs?								

Annex V pain assessment tool

How to score in patients who are awake: observe for 1 to 5 minutes or longer. Observe legs And body uncovered. Reposition patient or observe activity. Assess body for tenseness and tone.

Initiate consoling interventions if needed.

In patients who are asleep: observe for 5 minutes or longer. Observe body and legs uncovered. If possible, reposition the patient. Touch the body and assess for tenseness and tone

FLACC scale

Behavioral Observation Pain Rating Scale

Categories	Scoring		
	0	1	2
Face	No particular expression or smile; disinterested	Occasional grimace or frown, withdrawn	Frequent to constant frown, clenched jaw, quivering chin
Legs	No position or relaxed	Uneasy, restless, tense	Kicking, or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No crying (awake or asleep)	Moans or whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or talking to. Distractable	Difficult to console or comfort
Each of the five categories (F) Face; (L) Legs; (A) Activity; (C) Cry; (C) Consolability is scored from 0-2, which results in a total score between 0 and 10.			

Each category is scored on the 0–2 scale, which results in a total score of 0–10.

- **0:** Relaxed and comfortable
- **1–3:** Mild discomfort
- **4 –6:** Moderate pain
- **7–10:** Severe discomfort or pain or both

Declaration

I, the undersigned, declare that this thesis is my original work & I understand plagiarism is not tolerated so any literature cited in this thesis is listed in reference list & acknowledgment was given for those assisted me in this study.

Name: _____

Signature: _____

Submission to MSc Tutor, Dept. of Anesthesia, Addis Ababa University.

Date of Submission: _____

This thesis work has been submitted for examination with my/our approval as Advisors and Tutors on the Master of Science degree in Anesthesia

Name Signature

1. _____ _____
2. _____ _____
3._____ _____