ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCE

SCHOOL OF MEDICINE

DEPARTMENT OF ANESTHESIA

POSTOPERATIVE ANALGESIC EFFICACY OF CAUDAL DEXAMETHASONE ADDED TO BUPIVACAINE FOR PEDIATRIC ELECTIVE INFRA UMBILICAL SURGERY AT TIKUR ANBESA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA, PROSPECTIVE COHORT STUDY.

BY: AMANU GASHAW

JUNE, 2018G.C

ADDIS ABABA, ETHIOPIA

ASSESSMENT OF POSTOPERATIVE ANALGESIC EFFICACY OF CAUDAL DEXAMETHASONE ADDED TO BUPIVACAINE FOR PEDIATRIC ELECTIVE INFRA UMBILICAL SURGERY.

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A RESEARCH THESIS TO BE SUBMITTED TO DEPARTMENT OF ANESTHESIA, SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCE, ADDIS ABABA UNIVERSITY, IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR MASTER OF SCIENCE IN ANESTHESIA.

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ADDIS ABABA, ETHIOPIA

Abstract

Background: - Caudal block is the most preferred techniques of postoperative analgesia in pediatrics, despite limited duration of action. Many additives are used to improve the efficacy of caudal blocks, such as opioids or α_2 agonists. Recently, increased use of caudal dexamethasone as post-operative analgesia.

Objective: - To assess the efficacy of adding caudal dexamethasone to bupivacaine on postoperative analgesia in pediatric infra-umbilical surgery at Tikur Anbesa specialized hospital.

Method: - Cohort study design was employed from December,01,2017–February 30, 2018, G.C in two equal group of 30 children aged 1-14 years. Scheduled for Infraumbilical surgery under caudal bupivacaine with dexamethasone as exposed and bupivacaine only as a non-exposed group, based on the independent decision of anesthetist. Pain severity, first analgesia request time as well as analgesic consumption were assessed for 24hrs.Mann –Whitney U test was used to compare the pain severity, first analgesia request time as well as analgesic consumption between the groups in the postoperative time for 24 hours. Chi-square test was used to analyze the homogenous categorical independent variables between these two groups and a p-value less than 0.05 was considered as statistically significant.

Result: - This study found that dexamethasone with bupivacaine has prolonged postoperative analgesia with a median duration of 15.25 hours compared to 7.2hours in bupivacaine alone. Moreover, total analgesic consumption was lower in dexamethasone group with a median total dose of 55mg compared with 402 mg in bupivacaine group with statistically significant difference within 24 hours ($p<0.001$). Also, reduced the pain score in dexamethasone group, Being statically significant at 4^{th}, 8^{th} and 12^{th} hours.

Conclusion and Recommendation: -We found dexamethasone with bupivacaine decrease postoperative pain severity, total analgesic consumption and prolong the duration of analgesia. Based on our finding we recommend the use of caudal dexamethasone with bupivacine as effective postoperative analgesia in our setup.

Keywords: - Caudal Anesthesia, Infra Umbilical Surgery, Caudal Dexamethasone, analgesic efficacy.

Declaration

I, the undersigned, MSc in clinical anesthesia student agree to accept responsibility for the scientific, ethical conduct of the research project and provision of required progress reports as pre-terms and conditions of the research and publications office of Addis Ababa University.

declare that this thesis is my original work in partial fulfillment of the requirement for the degree of master in clinical anesthesia.

Name of the student: Amanu Gashaw

Date_____ signature _____

Approval of the primary advisor

Name of the primary advisor: Mulualem Sitot

Date. _____ signature _____

Acknowledgment

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Also, I would like thank to Addis Ababa University, health science college, and department of anesthesia for adding the research program in the curriculum that lay the foundation for my future career development and academic engagement on research.

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Contents

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Abbreviation /Acronym/

AAU- Addis Ababa University

ASA-American Association of Anesthesiologists

BLSH -Black Lion Specialized Hospital

CB -Caudal Block

CHEOPS-Children's Hospital of Eastern Ontario Pain Scale

CI-Confidence Interval

FLACC-Face Legs Activity Cray Consolable

FMOH- Federal Ministry of Health

IASP- International Association Study of Pain

IQR-Inter Quartile Range

IRB- Institutional Review Board

IV- Intravenous

LA-Local Anesthetics

LMA-laryngeal mask airway

MOPS- Modified Objective Pain Score

NGO-Non-Governmental Organization

NRS-Numeric rating scale

PACU: -Post anesthesia care unit

PI-principal investigator

PONV- Postoperative Nausea and Vomiting

POP- Postoperative Pain

RCT-Randomized Control Trial

SD –Standard Deviation

WHO- World Health Organization

Chapter One Introduction

1.1 Background

Pediatric regional anesthesia was introduced after the discovery of local anesthetic properties of cocaine in the eye by Koller in1884. Many techniques gain popularity for post-operative analgesia because they provided adequate postoperative analgesia, and reduce the requirement of intraoperative anesthetics and also have fewer side effects. The caudal block was now being a popular now a days in pediatric regional anesthesia, it was first used for cystoscopies in children by Campbell in 1933 (1).

This is because of, it is easy to perform, reliable, and safe. Especially, in patients weighing over 10 kg. The block is performed under general anesthesia in the lateral decubitus position using strict aseptic technique and landmarks identified by palpation, the needle is advanced through the sacral hiatus in the midline between the cornea at a 60^{o}-45^{o}angle and after the needle pops through the sacrococcygeal ligament, the needle-to-skin angle is reduced so that the needle is advanced 2–3 mm into the caudal space parallel to the spinal axis. It has efficacy for lower abdominal, perineal and lower extremity surgeries. Side effects include nausea, vomiting, urinary retention, Dural puncture, motor blockage and sedation (1, 2).

Caudal block (CB)has the disadvantage of limited duration. Attempts to prolong with additives like opioids, α2 agonists, tramadol, neostigmine, ketamine are used to improve the efficacy of the CB in children. But these additive have some adverse effects like nausea, vomiting, pruritus, urinary retention, respiratory depression, hypotension, bradycardia, and sedation. Because of these, they were not appropriate for pediatrics. Dexamethasone is glucocorticoid with anti-inflammatory and analgesic effects that also used to prolong caudal block and other different types of nerve block(3, 4).

1.2 Statement of the Problem

Pain is defined by international association for the study of pain(**IASP)** as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage." According to **IASP** pain is undertreated, that have physiological, psychological and economic effects. Post-operative pain can lead to delayed recovery and increased hospital stay(5)

Pain in early life causes structural changes in cortical and subcortical pathways. Specifically, perioperative pain can cause stress. Therefore, analgesia modulates long-term effects of pain in early life(6, 7).

Good postoperative analgesia helps to a reduce postoperative stress response, better patient satisfaction and improved outcome(8). The world health organization (WHO) states that 80% of people worldwide do not receive adequate treatment for pain. Based on that one in four patients had adequate relief of POP (9).

Other studies in Nigeria also showed that two-thirds of patients complained of moderate to severe pain in the first 24-hour postoperative period. Provision of anesthesia and analgesia is given low priority in comparison with the treatment of infectious diseases (10, 11).

Postoperatively many children suffer from moderate to severe pain and become most severe in the first 24–72 h but may persist for days to weeks. 1.5% of all surgical procedures result in chronic pain. Regional techniques reduce consumption of intraoperative analgesics and reduce the stress response to surgery (12, 13).

One way of increasing the duration and efficacy of the block is to use concentrated local anesthetic in larger volumes, which, can result in the unwanted motor blockade, therefore, balancing the efficacy of the block with the safety of the patient still challenging (14).

To avoid these problems, many additives have been used to improve the quality of CB without increasing the total dose of the local anesthesia(LA). But there is great inter-individual variability in the response to all additives. Currently, caudal dexamethasone is used with bupivacaine to improve the blocking effectiveness but its analgesic efficacy has not been extensively studied(15).

The aim of this study is to assess the postoperative analgesic efficacy of caudal dexamethasone added to bupivacaine for pediatric patient undergone Infra Umbilical surgery at Tikur Anbesa specialized hospital.

1.3 Justification of Study

The caudal block is administered for pediatric patients, despite its duration of action. however, alternative methods of prolonging caudal block yet not valid. Different Studies were done on the analgesic effect of caudal dexamethasone in different population but There is variability for pain perception, assessment, recognition, and endurance that affected by social, cultural, cognitive and genetic factors(16). Also, cultural expectations and social norms are given to children by their parents may influence reports of pain(17). As well as the setup of the hospital differs in terms of the experience of anesthetists, type of needle and perioperative anesthesia management, type of analgesia used that can result in a different outcome from the study done.

The cost of dexamethasone is relatively low, easily available that makes routine use is reasonable in all hospital in Ethiopia. Such studies in a resource-limited area can improve pain management and patient comfort. Therefore, the finding of this study is expected to decrease the side effects of opioids and other drugs.

As my knowledge in Ethiopia, there is no published study on the area of interest. This study will also provide necessary information used for clinical practice and future studies.

1.4 Hypothesis Testing

H_{o1}: -There is no difference in the severity of postoperative pain between exposed and non – exposed groups.

H_{a1}: -There is difference in the severity of postoperative pain between exposed and non –exposed groups.

H_{O2}: -There is no difference in the time to first analgesic request between exposed and non-exposed groups.

H_{a2}: - There is difference in the time to first analgesic request between exposed and non-exposed group.

H_{O3}: -There is no difference for the total analgesic consumption in the first 24 postoperative hours between exposed and non-exposed groups.

H_{a3}: -There is difference for the total analgesic consumption in the first 24 postoperative hours between exposed and non-exposed groups.

CHAPTER TWO LITERATURE REVIEWS

According to American Pain Society, more than 80% of patients experience postoperative pain and 75% of them moderate or severe pain. Less than half of patients get adequate postoperative analgesia. Opioid-sparing analgesic is popular as they decrease the side-effects(18).

2.1 Complication and Failure Rate of Caudal Anesthesia

Based on database meta-analysis done by Santhanam set.al in 2015 among18650 children received CB rate of complications was 4% and 1.9% in having the block awake and with general anesthesia (GA)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(19).

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 SBP of more than 20% compared with baseline values obtained just before the surgical incision (20).

2.2 Effect of Dexamethasone

Considering the benefits of dexamethasone, it helps in preventing post oprative nausea and vomiting(PONV) and it has a good analgesic action both IV and perineurally. It is a preferred drug during inflammatory situations like asthma and laryngospasm. The controversial role of dexamethasone in post-operative surgical site infections have been solved and overall adverse effects of dexamethasone are rare as compared with its benefits(21).

Dexamethasone used in a regional block to prolong analgesia for peripheral and neuraxial blocks. The routes of administration and dosage are currently controversial to reduce the potential for complications with efficacy. dexamethasone may be used perioperatively in regional techniques in all non-diabetic patients (22).

Other prospective double-blind RCT done on 60 patients in 2014 by Ahmet Sen et.al comparing the efficacy of 0.125% bupivacaine, and 0.125% levobupivacaine + 0.5 μg/kg fentanyl found that time to first rescue analgesic was 246 ± 163 min in bupivacaine group (23).

2.3 Caudal Bupivacaine alone in Different Dose and Concentration

Prospective RCT conducted in 2017 by Akpoduado D et.al. Comparing different dose of bupivacaine, 0.5ml/kg and 0.75 ml/kg of 0.25% bupivacaine. Time to first analgesic requirement significantly increased as we increase the dose. (24).

In a double-blinded prospective RCT on 90 children's in 2015 by Soujanya U.et.al compare 1ml/kg levobupivacaine, 1ml/kg0.25%ropivacaine &1ml/kg 0.25%bupivacaine. Bupivacaine has the slightly higher duration of analgesia with lower pain score compared to levobupivacaine & ropivacaine. But, a residual motor blockade was prolonged in bupivacaine group(25).

A 2014 blinded effectiveness trial, studied in cure hospital for children 1-12 years comparing 1 ml/kg of 0.25% bupivacaine and 1ml/kg of 0.25% bupivacaine with 2.5 MQ/kg neostigmine. The median analgesic duration in bupivacaine was 5.8 ± 2.3 hrs. The PONV incidence was 4.6%in bupivacaine group(26).

2.4 Comparison of Caudal Dexamethasone with Caudal Bupivacaine for Post-Operative Analgesia.

According to RCT conducted by J.-Y. Hong in 2010 on 80 patient's requirement for fentanyl was 7.9% vs 38.5%, acetaminophen required was 23.7% vs 64.1%. The time to first acetaminophen request was 646 vs 430 min. The pain was 25.6% vs 31.6%, dexamethasone group compared with the control group respectively(27).

Another prospective, RCT study conducted in 2014 done by Almajali AZ.et.al in 162 patients compare bupivacaine and bupivacaine with dexamethasone 0.1mg/kg. Found that the mean pain-free period in dexamethasone was 272 min while in bupivacaine group was 186 min. The mean frequency of paracetamol administrations in dexamethasone group is 4, while this was 7 in bupivacaine group(28).

According to prospective double-blinded RCT in Egypt by Karim Girgis in 2014 on 80 children's, comparing bupivacaine of 0.75 ml/kg, bupivacaine 0.75 ml/kg with 0.1mg/kg dexamethasone and bupivacaine 0.75 ml/kg with neostigmine. The time to first analgesic requirement was 11.2 ± 3.5 vs. 7.1 ± 3.2 h in dexamethasone group compared with bupivacaine group. Pain scores were lower in dexamethasone group, with statistical significance at 6, 8, 10, and 12 h. 20% of patients

developed nausea in bupivacaine group compared with only 2.5% of patient in dexamethasone group(29).

According to double-blind RCT study conducted by murni sari, Ahmad arbi in 2015, Malaysia on 64 children received CB with dexamethasone and bupivacaine alone. The time to first paracetamol administration in dexamethasone group was 800 minutes, which was 520 min in bupivacaine group. Pain score was 1.9 ± 2.0 in dexamethasone group compared to 3.5 ± 2.2 in bupivacaine group in the first postoperative days and second postoperative days was 0.8 ± 1.6 vs 2.3 ± 2.0 in dexamethasone group and bupivacaine group respectively. Whereas the frequency of paracetamol administration in dexamethasone group 0.3 ± 0.8, in bupivacaine group it was 1.1 ± 1.0(30)

Another prospective RCT conducted by Elham M.et.al in 2015 on 120 patients comparing dexamethasone, dexmedetomidine, and fentanyl as an additive to bupivacaine. MOPS was comparable in the first 2 h, in the 3rd, 6th and 12^{th} h (31).

An Indian prospective RCT conducted by Sinha c et.al, in 2016 on 60 children CB with dexamethasone 0.1 mg.kg added bupivacaine to prolongation of analgesia in dexamethasone group was 8 h. The median of a total dose of analgesic required in dexamethasone group for the 24 h was 2.5(32).

According to prospective, RCT, conducted on 70 children by Mohamed in 2016 at Elmina using 0.25% bupivacaine alone and bupivacaine plus 0.1mg/ml dexamethasone. The duration of analgesia, the number of patients received rescue fentanyl, rescue doses of rectal paracetamol were (9.2 ± 0.9 h, 4.8 ± 1.1), (16.66%,42.8%), (57.14%, 94.28%) in the dexamethasone group and bupivacaine group respectively. Pain scores were lower in the dexamethasone group than in the bupivacaine group and became significant at 3, 6, 12, and 24 h(33)

An Egyptian, prospective RCT study which is done by Mohamed M.A et.al. Carried out on 105 children's grouped into bupivacaine, dexamethasone and neostigmine group. The duration of postoperative analgesia was prolonged in dexamethasone 521.3 ± 101.1 min as compared to the bupivacaine group 295.9 ± 63.8 min, and , pain score significantly lower at 4,6,8 12 but it is comparable between group at 16 and 24hrs, and analgesia consumption (mg/kg) was 29.14 ± 8.09, 22.29 ±7.61bupivacine and dexamethasone respectively (34).

According to 2016 single-blinded RCT on 100 patients by Solanki M et.al inpatient received 1 ml/kg 0.25% bupivacaine with 0.2 mg/kg of dexamethasone and1 ml/kg 0.25% bupivacaine with 1 μg/kg of clonidine. The duration of analgesia was 18–24 h for dexamethasone group(35).

Study done by world academy of science in 2016 on 100 children received combination of dexamethasone 0.2 mg/kg with 1 ml/kg 0.25% bupivacaine or fentanyl (1 ug/kg) with 1ml/kg 0.25% bupivacaine. Dexamethasone group showed longer time to the first analgesic requirement, lower number of rescue analgesic doses in the first 24 h, lower MOPS scores, a significantly fewer incidence of PONV compared with fentanyl group (36).

Prospective RCT has done by Sayed k.et.al in 2016 on 90 patients. 0.5 ml/kg bupivacaine 0.25%with IV dexamethasone 0.5mg/kg, 0.5 ml/kg bupivacaine 0.25% with dexamethasone 0.1 mg/kg, and 0.5 ml/kg bupivacaine 0.25% only. The number of patients who didn't need analgesia within the first 24 hours was 1.6% in caudal dexamethasone group vs none in the control group postoperatively only 20% in the caudal dexamethasone group complained of postoperative vomiting in comparison to 70% in the control group(37).

Prospective RCT conducted by Bhimireddy et.al in 2017 on 60 patients received 0.25% bupivacaine 1ml/kg,0.25% bupivacaine 1ml/kg with 0.5mg/kg dexamethasone. The number of patients receiving rescue pethidine was 60 % in bupivacaine group and it was 13.34% in dexamethasone group. The number of patients receiving rescue paracetamol was 96.67% in bupivacaine group and 63.34% in dexamethasone group. The post-operative pain score at the interval of 4, 6, and 24 hours were significant (38).

Recently in India RCT published in 2018 compare 1 ml/kg bupivacaine and 1 ml/kg bupivacaine with 0.1 mg/kg dexamethasone. The mean duration of analgesia was1044.92±392.29 vs 435.85 ±144.72 min, while the mean number of rescue analgesics required was 0.88±0.85 vs 1.769 ±0.523 in dexamethasone and bupivacaine group respectively. Comparable pain score observed for the first 4 h, which was significantly lower in dexamethasone group at 5th, 6th, 16th, 20th, and 24th hrs. 41.5% in dexamethasone group did not receive any rescue analgesic whereas all the patients in bupivacaine group received at least one rescue analgesic dose (39).

Chapter Three –Objective

3.1 General Objective

The general objective of this study was to assess the postoperative analgesic efficacy of adding caudal dexamethasone to bupivacaine in pediatric elective infra-umbilical surgery at Tikur Anbesa Specialized Hospital, 2018, G.C.

3.2 Specific objectives

1) To compare the severity of postoperative pain between BD and BA group.
2) To compare the analgesia duration in minute between BD and BA group
3) To compare the total postoperative analgesic consumption in the first 24 hours between BD and BA group

Chapter Four -Methodology

4.1 Study Area and Period

This study was conducted at Tikur Anbesa Specialized Hospital, in Lideta Sub- City Addis Ababa, Ethiopia, which is the largest, multi-specialist tertiary care teaching hospital opened since 1972 and, in 1998 transferred to school by FMOH since then it became a university teaching hospital offer diagnosis & treatment for approximately 370,000-400,000 in a year. It provides general medical services for over 3 million people in Addis Ababa, and those referred from other parts of a country, 44% of whom are less than 15 years of age. It has about 800 beds, about 17 operation theatre and approximately 7000-9000 patients undergo surgery per year including emergency surgery,140(23%) of beds are dedicated to pediatric patients, 40 of which are for elective pediatrics surgery admission, it is the only hospital providing tertiary pediatrics surgical services in Ethiopia. It provides different types of elective surgery five days per week annually. As documents in the hospital anesthesia and surgery log book on average 189 elective patients were undergone Infraumbilical surgery within three months. The study was conducted from December, 1, 2017 G.C to February 30, 2018 G.C.

4.2 Study Design

Institutional based prospective cohort study design was employed

4.3 Population

4.3.1 Source Population

All pediatric infra-umbilical surgical patients at Tikur Anbesa Specialized Hospital.

4.3.2 Study Population

All pediatric patients scheduled for infra-umbilical surgery under caudal block in the study period who fulfilled inclusion criteria.

4.3.3 Study unit

- Individual patients involved in the study.

4.4 Eligibility Criteria

4.4.1 Inclusion Criteria

- Elective lower abdominal, urologic and orthopedic surgery those recived caudal block.
- ASAI and ASA II.
- Pediatric patents age from (1-14).

4.4.2 Exclusion Criteria

- Failed Caudal Block
- Preexisting disease (DM, Chronic pain)
- Simultaneous Operation on other site (supra umbilical)
- Morphine given at time of induction
- Concentration other than 0.25% bupivacaine for caudal.
- Other additive added
- Dexamethasone given other than caudal route
- Dose other than 1ml/kg bupivacaine and 0.2mg/kg dexamethasone
- Day case surgery

4.5 Sampling Technique and Sample Size Determination

4.5.1. Sample Size Determination

Comparison of mean with equal sample size for two independent cohort study based on mean pain score among the group. Since there is no previous study done in the study area, result adopted from literature was used to calculate sample size based on the primary outcome variable and to get the largest sample size.

The previous study on 2015 in Malaysia, showed that the mean pain score was 1.9 ± 2.0, 3.5 ± 2.2 in dexamethasone and bupivacaine group respectively (30).

$$n_1 = \frac{(\sigma_1^{\,2} + \sigma_2^{\,2})(Z_{\alpha/2} + Z_{\beta})^2}{(\mu_1 - \mu_2)^2}$$

Where

n1=sample for bupivacaine group.

n2=sample for dexamethasone group.

μ_1 = sample mean in bupivacaine group.

μ_2 = sample mean in dexamethasone group.

$\mu_1 - \mu_2$ = the difference the investigator wishes to detect.

$(\sigma_1)^2$ = sample variance in bupivacaine group.

$(\sigma 2)^2$ = sample variance in dexamethasone group.

A conventional multiplier for alpha =0.05, which is 1.96.

Conventional multiplier for power = 0.80 which is 0.84.

Substituting for this variables yields.

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

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

n = 27.1.

Using 1:1 ratio between groups and when 10 % of contingency is included for dropouts, the total sample of 60 patients or 30 patients per group was required, 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 per 3 months on the log book, 189 patients were operated on pediatric elective infra-umbilical surgery under caudal block. The sampling interval k was determined using the formula: k=N/n; where, n = total sample size, N = population per 3 months.60 participants were recruited with the probability of about 31%. Patients were sorted by listing infra-umbilical surgery consecutive. Therefore, the sampling interval was 3 and the first study participant (random start) was selected using lottery method after which data collector recruit 1 patient for every 3 consecutive patients undergone Infraumbilical surgery grouping based on patients who satisfied the inclusion criteria were divided into two groups based on exposure status

- **Exposed(BD)**:30 patients received 1ml/kg of 0.25% bupivacaine + 0.2mg/kg dexamethasone added.
- **Non-exposed(BA):**30 patients received1ml/kg of 0.25 %bupivacaine alone till the required sample size was reached.

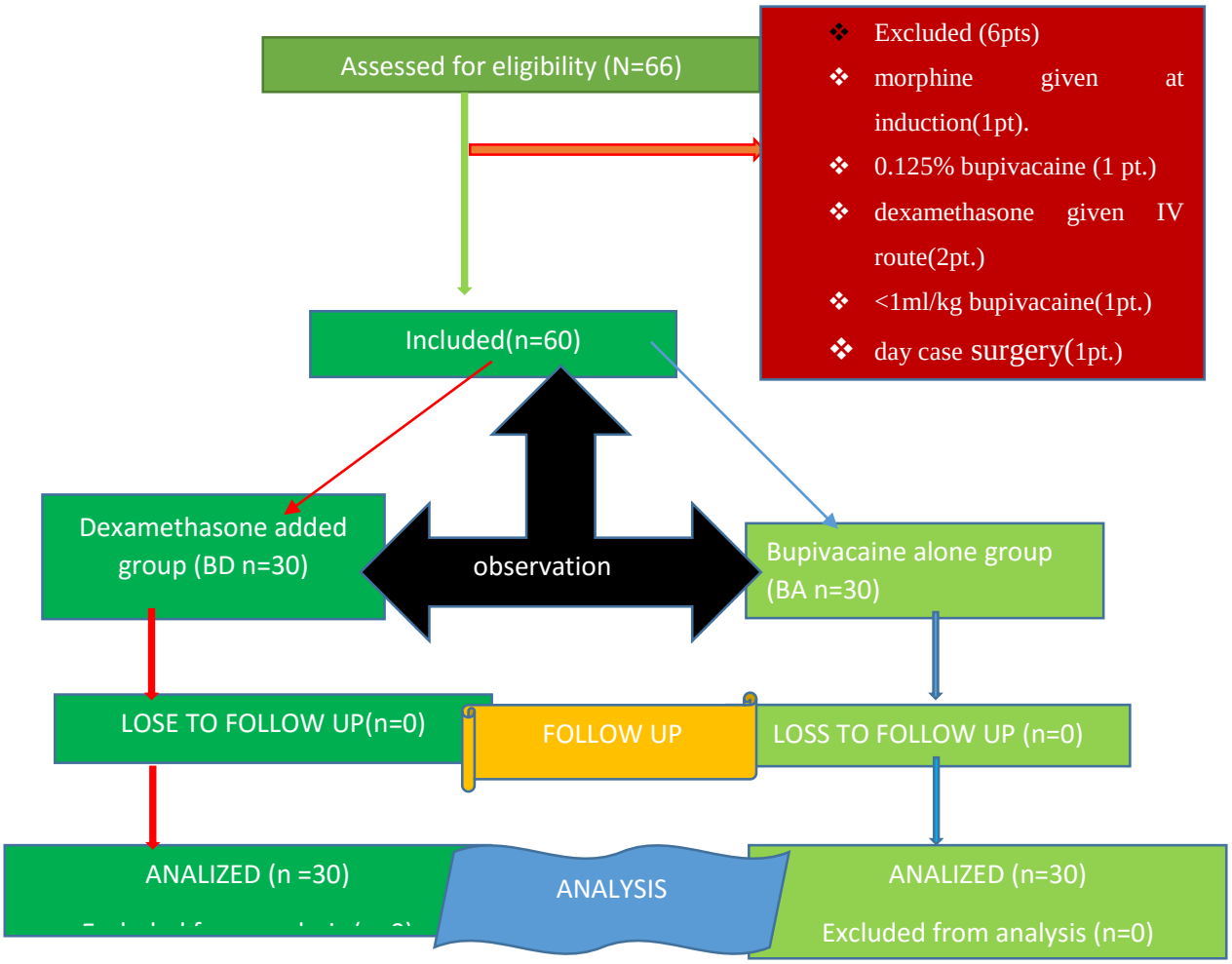

Figure 1 Patient Enrolment Chart BD & BA groups in pediatric elective infra-umbilical surgery at TASH. From December 1, 2017, to February 30, 2018.

All pediatric patients who were scheduled for elective Infraumbilical surgery and fulfilled inclusion criteria and parents consented for their child to take part in the study in the morning of operation day after instructed on how data collector asses pain postoperatively at PACU and ward with the trained nurse.

Anesthesia management for pediatric Infraumbilical surgery in the study hospitals are carried out by anesthesia professional including M.Sc. anesthesia student and anesthesiology residents.

After endotracheal intubation or laryngeal mask airway (LMA) insertion is confirmed successful and secured with adhesive plaster, anesthesia professionals including M.Sc. anesthesia student and anesthesiology residents provide CB with bupivacaine but there is variability in the use of dexamethasone additive, concentration of bupivacaine. I use this opportunity to group study subjects in to patient received 1ml/kg of 0.25% bupivacaine alone as (group BA) and 1ml/kg 0.25% bupivacaine with 0.2mg/kg dexamethasone added as (group BD). In the postoperative time patients transferred to recovery room and transferred to ward when they recover from anesthesia. In ward patient were usually observed by ward nurses and pain is usually managed by paracetamol suppository and for older children's tramadol and diclofenac based on patients complain.

4.6 Study Variables

4.6.1 Dependent Variables

Post-operative analgesic efficacy.

4.6.2 Independent Variables

Sociodemographic variable

- Age
- Sex
- Weight
- ASA status

Intraoperative variable

- Procedure
- Premedication
- Induction
- Duration of surgery
- Duration of anesthesia
- Exposure variable: caudal bupivacaine and caudal bupivacaine with dexamethasone

Hemodynamic variable

- Pulse rate
- Blood pressure

4.7 Data Collection Tool and Procedure

Structured checklists and questionnaires were prepared in English which included socio-demographic, perioperative data, the severity of pain, first analgesic request time, analgesic consumption and adverse effects.

Baseline vital signs, Induction, incision and CB time were documented. Pre-incision vital signs were measured 10 minutes after the block just before skin incision. Post incision vital signs were measured 10 minutes after skin incision, then, Ability to Maintained value as compared to values before incision indicates a successful block. If the CB was considered unsuccessful those children were given analgesia and excluded from the study. patients where remained for at least one hour in PACU. Vital signs were recorded on admission to PACU and then every 20 minute till the patient was discharged to the ward. FLACC/ NRS scale were used to assess postoperative pain, based on age of patients. Score of greater than 3 indicated pain. Those children were given rescue analgesia. Patients were observed by trained nurses & pain score was documented at PACU, 2^{nd}, 4^{th}, 8^{th}, 12^{th} and 24^{th} postoperative hour. Analgesic consumption, analgesia duration and adverse effects were documented when it was reported within 24 hours postoperatively. Intraoperative data was collected by anesthetists while postoperative data was collected by four nurse after getting training and the PI supervise the completeness of the data daily.

4.8 Data Quality Control and Assurance

Data collectors was trained by principal investigator and pretest was done at Dagmawi Minilik hospital on 6(10% of sample) respondents (3 BD group and 3 BA group) who were undergone Infra umbilical surgery under CB, which were not included in the main study. During data collection regular supervision and follow up was made appropriately. Was cross-checked for completeness and consistency of data every day. All materials used for data collection were arranged sequentially and store in safe and secure place.

4.9 Data Analysis and Interpretation

Data was checked manually for completeness and then coded and entered in to epi info version 7 then transferred to SPSS version 20 computer program for analysis. Descriptive statistics was used to summarize by central tendencies, count, frequency tabulation (frequency and cross-tabulation), tables and figures. There was also used conducted to cheek for chi-square (x^2) for independence of the groups. The data were cheeked the normality level with different tests (plot, skewness and kurtosis, curve with histogram and normality test using Shapiro-Wilk and Kolmogorov-Smirnov however, the data was not normally distributed when checked using all tests and plots. Therefore, non-parametric alternative, Mann –Whitney U Test was used to compare the pain severity, first analgesia request time as well as analgesic consumption between the groups in the postoperative time for 24 hours, Chi-square (x^2) test was used to analyze the homogenous categorical independent variables and incidence of PONV between these two groups and Fisher exact test was used the assumption for x^2 not meet, but the data was homogeneous as tested by Levene's test of equality of variance. Continuous data was presented as median (IQR) and categorical data was presented by frequencies (percentages), 95% confidence level was used to estimate population parameter. With further comparison at each time interval, p-value < 0.05 was considered as statistically significant.

4.10 Ethical Consideration

Prior to data collection, the proposal was reviewed by the ethical committee of college of health science and official letter was obtained from anesthesia department. Get permission from TASH clinical director office after submission of official letter. Moreover, the objective of the study was explained to both hospital administration and the children's parent included in the study. Verbal consent from the children's parent was obtained and confidentiality of the information assured by using code numbers than personal identification names and keeping questionnaires locked.

4.11 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, Ethiopian society of pediatrician, different NGOs that work on pediatric health,

Ethiopian FMOH. Finally, it will be send to national and international journal publishers for publication.

4.12 Operational Definition

Duration of anesthesia: a time in minutes it takes from induction to a time to a patient get response to verbal command. Will be measured by noting the start time recorded on the anesthesia record and subtracting it from the admission time on the PACU data sheet.

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

Failed caudal: fully or partial failure measured by greater than 10 mmHg increase MAP and greater than 20 BPM increase PR at list after 20 minutes of caudal block performed.

FLACC scale: is a measurement used to assess pain for children between age two months and seven years or individual that are unable to communicate their pain going to score.

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(40).

NRS: is a valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0-10(11-point scale) with the understanding that 0 is equal to no pain and 10 equal to the worst possible pain(41)

Post-operative nausea and vomiting: when a patient's experience at least one episode of either nausea or vomiting within 24 hours.

Duration of analgesia: a time in minutes was defined as the time taken from the caudal placement of drug till the first recording of FLACC/NRS score >3

Total analgesia consumption: the total of analgesia given within the first 24 hours after the end of surgery.

CHAPTER FIVE RESULT

5.1 Demographic and Perioperative Characteristics

A total of 60 patients (30 patients in each group) were finally involved for analysis of this cohort study with non response rate of 10%. The demographic characteristics of patients and baseline

anesthesia characteristic were homogeneous with no statistically significant difference among the groups such as age, sex, weight, duration of surgery and ASA status (Table I).

Table I Demographic and baseline anesthetic characteristics between BD & BA groups in pediatric elective infra-umbilical surgery at TASH. from December 1, 2017 G.C to February 30, 2018.

variable		BD group(n=30)	BA group(n=30)	P-value
Age (years)M(IQR)		3 (2-6.25)	3.5(2-7.25)	0.298
Sex	Male n (%)	18(60)	19(63.3)	0.791
	Female n(%)	12(40)	11(36.7)	
ASA status	ASA I n(%)	27(90)	26(88.7)	0.688
	ASA II n(%)	3(10)	4(11.3)	
Weight(kg) M(IQR)		14 (10-20)	15(11.5-20)	0.369
Baseline HR M(IQR)		125 (120-145)	130(113.75-150)	0.959
Baseline MAP M(IQR)		61(56-66)	63(57-65)	0.588
Procedure	Lower abdominal n(%)	10(33.3)	9(30.0)	0.956
	Urologic n(%)	13(43.3)	14(46.7)	
	Orthopedics n (%)	7(23.3)	7(23.3)	
Premedication	Atropine n(%)	17(56.7)	16(53.3)	0.795
	None n(%)	13(43.3)	14(46.7)	
Analgesia premedication	Paracetamol n(%)	10(33.3)	8 (26.7)	0.950
	Tramadol n(%)	9(30)	10(33.3)	
	Ketamine n(%)	5(16.7)	5(16.7)	
	None n(%)	6(20)	5(23.3)	
Induction agent	Propofol n (%)	21(70)	22(73.3)	0.774
	Ketamine n(%)	9(30)	8(26.7)	
Maintenance	Halothane n(%)	18(60)	17(56.7)	0.793
	Isoflurane n (%)	12(40)	13(43.3)	
Surgery time(min) M(IQR)		110 (60-120)	110 (60-120)	0.456
Anesthesia time (min)M(IQR)		125(78-160)	125(74-136)	0.450

NB **BD**=bupivacaine with dexamethasone added **BA**= bupivacaine alone =**M(IQR)=**median (interquartile range), **n (%)** =number (proportion), **PR**= Pulse rate in beat per minute, **MAP**= mean

arterial blood pressure in mmHg, Mann –Whitney U test and chi-square test (x^2) was used, p-value < 0.05 considered statistically significant.

5.2 Hemodynamic response before and after caudal anesthesia in between groups

There was no statistically significant difference in vital signs (PR and MAP) before skin, immediately at PACU, at 20, 40 and 60 minutes BD and BA groups (Table II).

Table II Hemodynamic response of Caudal anesthesia given in between BD & BA groups in pediatric elective infra-umbilical surgery at TASH. from December 1, 2017, to February 30, 2018.

Vital sign		BD group (n=30)	BA group(n=30)	P-value
Before incision	PR M(IQR)	124(120-142)	122(113-144)	0.750
	MAP M(IQR)	62(55-70)	60(56-70)	0.700
After Incision	PR M(IQR)	130(116-146)	131(120-148)	0.812
	MAP M(IQR)	60 (54-73)	60(56-69)	0.589
Arrival to PACU	PR M(IQR)	135 (120-146)	140(120-152)	0.988
	MAP M(IQR)	63 (59-68)	66 (60-70)	0.374
AT20 min PACU	PR M(IQR)	132(120-144)	120(120-150)	0.777
	MAP M(IQR)	60.5(56-64)	60(56-69)	0.836
AT40 min PACU	PR M(IQR)	125(120-142)	120(114-144)	0.678
	MAP M(IQR)	58(56-64)	61(58-64)	0.177
AT60tminPACU	PR M(IQR)	120(117-130)	120(107-147)	0.941
	MAP M(IQR)	57(54-62)	58(56-65)	0.226

NB **BD**=bupivacaine with dexamethasone added, **BA**= bupivacaine alone, **M(IQR)** =median (interquartile range), **PR**= Pulse rate in beat per minute, **MAP** = mean arterial blood pressure in mmHg, Mann –Whitney U test was used, p-value < 0.05 is significant.

5.3 Comparison of postoperative pain severity

As assessed by FLACC/NRS the median pain score was comparable in between the exposed and non-exposed groups at PACU, 2nd hours and at 24th hours postoperatively with p= (0.742, 0.630&0.123) respectively. But were lower in (BD) group with a statistically significant difference at 4th, 8th and 12th hours postoperatively. Table (III)

Table III Comparison of postoperative pain severity score between BD & BA groups in pediatric elective infra-umbilical surgery at TASH. from December 1, 2017, to February 30, 2018.

FLACC/NRS SCORE	BD group (n=30)	BA group (n=30)	P-value
Postoperative PACU M(IQR)	0(0-2)	0(0-2)	0.742
2^{nd} postoperative hour M(IQR)	2(0-3)	2(0-3)	0.630
4^{th} postoperative hour M(IQR)	2(2-3)	4(3-4.25)	<0.001*
8^{th} postoperative hour M(IQR)	2.5(2-3)	4(3.75-5)	<0.001*
12^{th} postoperative hour M(IQR)	3(1-4)	4(3-5.25)	0.008*
24^{th} postoperative hour M(IQR)	2.5(1-3)	3.5(0.75-4.25)	0.123

NB BD=bupivacaine with dexamethasone added, **BA**= bupivacaine alone, **M(IQR**)=median and interquartile range, Mann –Whitney U test was used *statistical significance ($p<0.05$).

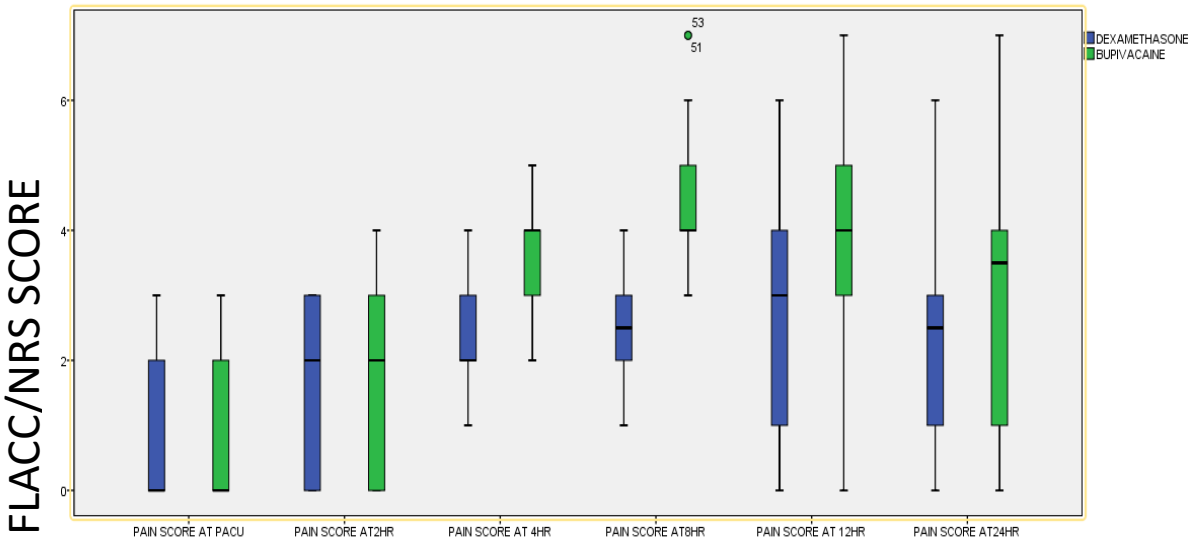

Figure 2 Comparison of postoperative pain severity score between BD & BA group in pediatric elective infra-umbilical surgery at TASH. From December 1, 2017, to February 30, 2018

5.4 Comparison of time to first analgesia request between groups

The Mann Whitney U test result for time to first analgesia request found that dexamethasone group prolongs the analgesia duration with a median and interquartile range of 915(650-1440) minute compared with 433(328-555) minute in bupivacaine group (p <0.001). (fig3).

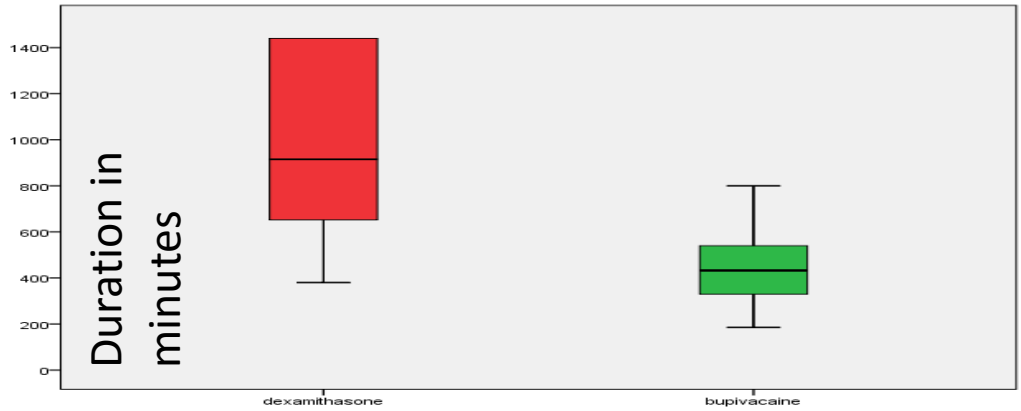

Figure 3 Comparison of time to first analgesia request between BD and BA groups in pediatric elective infra-umbilical surgery at TASH. from December 1, 2017, to February 30, 2018.

5.5 Comparison of total analgesia consumption between groups

All patient from BA group needs at list single dose of analgesia while it was 70% in exposed(BD) group. The median total analgesic consumption in dexamethasone group was 55 mg and 402 mg in bupivacaine alone group with statistically significant difference within 24 hours($p<0.001$). And there was a statistically significant difference in paracetamol consumption between the dexamethasone and bupivacaine group. (Table IV).

Table IIV Comparison of total analgesia consumption between BD & BA group in pediatric elective infra umbilical surgery at TASH. from December, 1, 2017 to February 30, 2018

Variable		BD group(n=30)	BA=group(n=30)	P-value
Proportion of pt. need analgesia in 24h n(%)		21(70)	30(100)	0.002*
Total dose of analgesia in mg M(IQR)		55(0-250)	402(95-812)	<0.001*
Dose of analgesia	Paracetamol M(R)	0(0-500)	402(0-1500)	0.004*
	Tramadol M(R)	0(0-150)	0(0-250)	0.099
	Diclofenac M(R)	0(0-50)	0(0-200)	0.711
No of dose request in 24hM(IQR)		1(0-1.25)	2(2-4)	<0.001*

NB **BD**=bupivacaine with dexamethasone added, **BA**= bupivacaine alone, **M(IQR)=**median (interquartile range), **M(R)**=median (range) **n (%)=**number (proportion), chi-square test (x^2) and Mann –Whitney U test was used, *statistical significance ($p<0.05$).

The proportion of patient received paracetamol postoperatively in bupivacaine group and dexamethasone group was 66.7% and 43.3% respectively. (fig4)

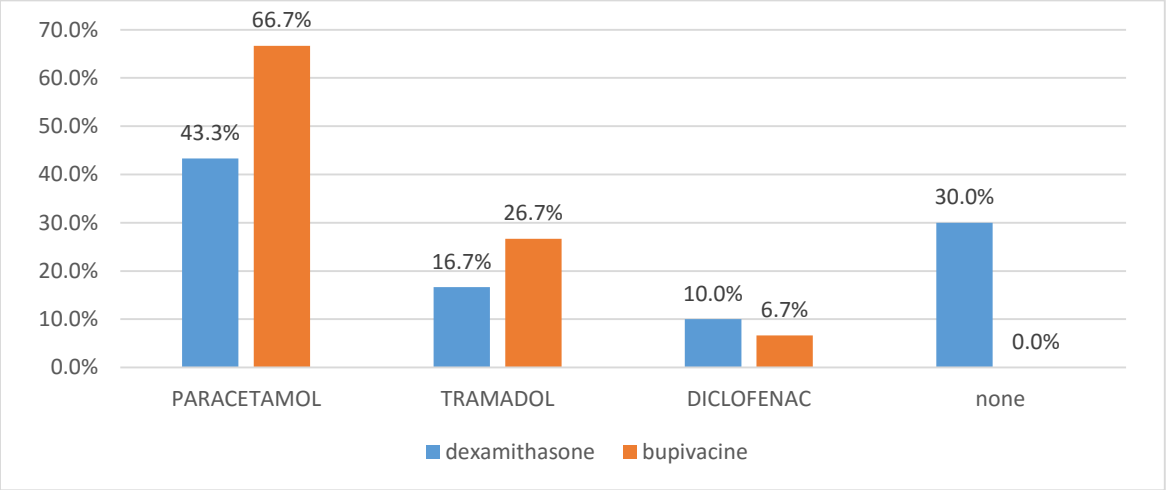

Figure 4 Proportion of postoperative analgesia given between BA & BD group in pediatric elective infra-umbilical surgery at TASH. from December 1, 2017 G.C to February 30, 2018

5.6 Incidence of PONV and other complication Between BA & BD Groups

The proportions of patients with PONV was lower in dexamethasone added group compared to bupivacaine alone group which was statically significant (x2 =9.31) (p=0.002). None of them used anti-emetic drugs postoperatively and no patients developed other complications such as sedation or prolonged motor block during the first 24 hr. from both groups. (fig 5).

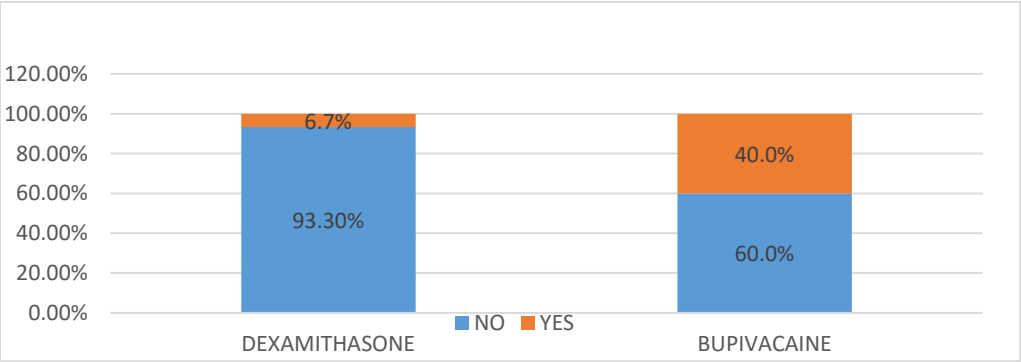

Figure 5 The incidence of PONV over 24 hours between BA & BD groups in pediatric elective infra-umbilical surgery at TASH. from December 1, 2017, to February 30, 2018

CHAPTER SIX

6.1 DISCUSSION

In our prospective cohort study demographic data, baseline, before and after skin incision and PACU hemodynamic variables were comparable in both groups. Our study also demonstrates pain score was comparable in dexamethasone added group compared to bupivacaine alone group immediately at PACU, 2nd and 24th postoperative hour.

The reason for no statically significant difference among the groups early in post-operative period at PACU and 2nd postoperative time could be due to the action of caudal bupivacaine which has analgesic effects might have been persisted in both groups in the early postoperative period as well as the analgesic effect of dexamethasone started immediately and at 24 postoperative hours it could be as a result of gradual decrease in the plasma concentration as well as loss of the systemic absorption of caudally administered dexamethasone over time(21).

In our study, the median postoperative pain scores were lower at the 4th, 8th and 12th postoperative hour in the exposed compared to non-exposed group and the difference was statically significant between the groups with ($p<0.001$, <0.001,0.008) respectively. The decrease in pain score in dexamethasone (exposed) group could be due to the effects of dexamethasone which has an action at the spinal cord level, in addition to its action on the peripheral tissues, after systemic absorption from the epidural space(22).

The result of this study were in line with RCT studies done in Egypt by Girgis k et.al and Mohamed M. Ab et.al which found pain score was a statistically significant difference at 6,8,10,12 h and at 4,6,8 12 hrs. respectively(29, 34)

The possible explanation may be a similarity in pain assessment, the pain was assessed using the ten points objective pain score and similarity in postoperative analgesia, paracetamol 15 mg/kg, was given if the pain score > 3 for postoperative pain management.

In contrary to our study, a study was done in 2016 by Mohamed et.al and Bhimireddy et.al found that pain score was statically significant different at a 24th postoperative hour in dexamethasone group compared to control group with ($p=0.04$, 0.02.) respectively(33, 38).

And our study is also in contrast with another study done in India by Parameswari. A. et.al in 2018 which also found that there was a statistically significant difference in pain score at 16^{th}, 20^{th}, and 24^{th} hour postoperative in dexamethasone group compared to control group(39)
The reason for this difference may be due to the inclusion of children in the different age, with variable thresholds for pain and ability to communicate pain could have led to variability in the pain scores. In our study, the age of children's was 1-14 years and this may be also due to the difference in anesthesia management and use of strong opioid in those studies.

With regard to time to first analgesia request, our study showed a significant difference between dexamethasone added group compared with bupivacaine alone group with median prolongation of 915 minutes 432 minute respectively ($p < 0.001$).

The result of our study was comparable with a study done by Solanki M. et al, Girgis K. et.al, Murni S.et.al, Mohamed et.al and Parameswari A. et.al which showed the duration of analgesia for dexamethasone group was 18–24 hrs,11.2 ± 3.5 vs. 7.1 ± 3.2 h, 800 vs. 520 minute, 9.2 ± 0.9 h, 4.8 ± 1.1 and 1044.92 ±392.29 min vs. 435.85 ±144.72 minute with statistically significant difference in dexamethasone and bupivacaine group respectively(29, 30, 33, 35, 39).
But Sinha C et.al found the time of first analgesic request with median and interquartile of 8 (7-8) hours, J.-Y. Hong et.al, found dexamethasone prolong only 640 minute and Almajali Z.et.al found also only 4hrs. though statistically significant(27, 28, 32).
The possible explanation for this contradictory result is different in the route of administration Hong and his collages give 0.5mg/kg IV dexamethasone, and the concentration of 0.125% bupivacaine used in addition to their parents assessed and recorded the pain scores, since Almajali Z.et.al give diary for the parent to register the pain and time of administration of oral paracetamol at home.
In our study, the median total dose of analgesia in milligram was lower (55 mg) in dexamethasone group compared to bupivacaine group (402 mg) with a statically significant difference.
Our study was in line with, Egyptian study by Mohamed M.A et.al in which total analgesia consumption in mg was lower (22.29 ±7.61) in dexamethasone group compared to bupivacaine group which was 29.14 ± 8.09 and Sayed k.et.al also found that the mean and standard deviation of total amount of paracetamol (mg) was 842.5±357.7 in control and 458±192mg in dexamethasone group with statistically significant difference(34, 37).

In our study, the median frequency of analgesics required by patients with dexamethasone added group was one compared to two in bupivacaine alone group which was statically significant ($p<0.001$).

Our study is Consistent with previous studies by Parameswari. A. et.al,Sari.M et.al and Sayed K.et.al which found statistical significant difference in the mean number of rescue analgesics required by patients in Dexamethasone added and bupivacaine only groups was 0.88 ±0.85 vs. 1.769 ±0.523, 0.3 ± 0.8 vs. 1.1 ± 1.0 and 1.80 ± 0.52 vs 3.30 ± 0.65 (0.005, 0.02, $p<0.05$) respectively(30, 37, 39).

Our study is contradicted with Indian double-blind RCT study Sinha C.et.al which found the median total dose of analgesic required in dexamethasone group for the 24 h was 2.5(2.3-2.7) and Almajali z.et.al also shows the mean frequency of paracetamol in dexamethasone group is 4, while this was 7 in bupivacaine group(28, 32).

The likely explanation for this difference may be the dose of dexamethasone, the concentration of bupivacaine and variability of the nurse in a perception of pain and expectation of post-operative pain.

Our study also demonstrates all patient in bupivacaine alone group and 70 % of dexamethasone added group request analgesia at least once within 24 hours postoperatively.

This study was consistent with Parameswari A.et.al found the number of patients who received at least one analgesic dose within the first 24 hours was 58.5% and 100% in dexamethasone group and bupivacaine group respectively with a statistically significant difference(39).

our study contradicts with the study done by Sayed k.et.al which found no statistically significantly different in the proportion of patients who need analgesia within the first 24 hours in dexamethasone group and bupivacaine alone group which was 98.4%, and 100% respectively(37). This may be due to the difference in the dose of dexamethasone that Sayed and his collages used 0.1mg/kg caudally.

In our study the proportion of patient received paracetamol postoperatively was 66.7% and 43.3% in bupivacaine group and dexamethasone group respectively.

Our study also shows comparable result with study done by J.Y. Hong et.al Mohamed.AZ.et.al and Bhimireddy.V.et.al stastically significant difference,dispite slite difference in proportion

found that patients received rescue doses of paracetamol was 94.28% vs. 57.14%, 96.67% vs. 63.34% and 64.1% vs. 23.7% in bupivacaine and dexamethasone group respectively(27, 33, 38).

The reason for variability in the proportion of analgesic may be due to dose difference in dexamethasone and a wide variety of infra-umbilical surgeries, the varying degree of invasiveness of the different procedures could have contributed to varying degrees of pain. However, the different types of surgeries were equally distributed between the two groups.

In our study, there was no significant difference in total post-operative tramadol consumption between groups even though there is less tramadol consumption in dexamethasone added group($p=0.099$). and, there was no statistically significantly different in diclofenac consumption in the postoperative time between dexamethasone and bupivacaine group ($p = 0.711$).

We lack similar finding for comparison since most studies are using other opioids as postoperative pain management protocol and controlling of analgesic agent achieved between groups
The likely explanation for this could be the absence of standard postoperative pain management protocol in study hospital, maybe also due to variability in nurse's response to pain request.
In this study, we found a statistically significant difference in the incidences of PONV in dexamethasone and bupivacaine group which was lower in dexamethasone added groups ($p= 0.02$). Our finding showed the incidence of PONV was 6.7 % and 40% in dexamethasone and bupivacaine group respectively.

The likely explanation for low incidences of PONV in dexamethasone group may be due to antiemetic action dexamethasone via prostaglandin antagonism, serotonin inhibition in the gut, and release of endorphins(21).

Our study is comparable to study conducted by Girgis K.et.al which found 2.5% of patients in dexamethasone group and 20% in bupivacaine group of patients developed PONV (29).

In contrary to our study Getu A. et.al in his study at cure hospital in Ethiopia found the incidence of PONV was lower in bupivacaine group which was 4.6% (26).

The likely explanation for this inconsistency could be Getu A. et. al used ondansetron premedication for all patient as standard which is known for its prophylactic antiemetic effect.

Other study contrary to our study Sayed K.et.al also found 20% of dexamethasone group and 70% of control group develop PONV(37).

The likely explanation for this inconsistency may be Sayed K.et.al use 0.1 mg/kg dexamethasone that may contribute to a high incidence of PONV though statistically significant.

6.2 Limitation of the Study

The main limitation of this study was:

Lack of standardization.
Lack of standard pain management protocol in the study hospital.

6.3 Strength of the Study

Study participants were homogenous

Chapter Seven Conclusion and Recommendation

7.1 Conclusion

In our study Caudal anesthesia performed after induction of anesthesia for Infra Umbilical surgery with dexamethasone added to bupivacaine statstically significantly difference in postoperative pain score from 4^{th} -12^{th} hours, total analgesia consumption and time to the first analgesia in 24^{th} postoprative hours is effective for postoperative analgesia.

7.2 Recommendation

According to the finding of the study, we recommend the addition of dexamethasone with bupivacaine in caudal anesthesia for infra-umbilical surgery which is effective for postoperative analgesia.

We also recommend additional randomized clinical trial needed to evaluate the most effective dose and the most reliable route of administration with a minimal side effect.

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Annex I: Questionnaire

Addis Ababa University, College of Health Sciences, Department of Anesthesia Prospective Cohort Study, On Post-Operative Analgesic Efficacy of Caudal Dexamethasone Added to

Bupivacaine for Pediatric Infra Umbilical Surgery in TASH, From December, 1, 2017g.C to February 30, 2018 G.C

Section I: Socio-Demographic Data

Card number:		Bed no.	Code
Serial no.	Question	Response	
101	Age		
102	Weight		
103	ASA I/II	A. ASA I B. ASA II	
104	Sex M/F	A. Male B. Female	

Section II: Data During Pre and Intraoperative Period

S. No.	Question	Response	Code
201	Diagnosis	……..	
202	Procedure:	.....	
203	Baseline heart rate	……BPM	
204	Baseline blood pressure	……./……..(……..)mmHg	
205	A Dose the patent take analgesic premedication	1. Yes 2.no	
206	If yes for the above question, what was the drug? Specify the dose?	A. Paracetamol …….mg B. Diclofenac…….mg C. Tramadol…….mg D. Pethidine ….mg E. Morphine……mg F. Others/specify…..mg	
207	Premedication, induction & maintenance	……./……./……	
208	Time of caudal block	……	
209	A drug used for the caudal block?	1 …. (ml)bupivacaine only or 2 ……(ml)bupivacaine with ……(mg)dexamethasone	
210	Vital sign before skin incision?	BP…/…… (……) mmHg PR:…….bpm	
211	Vital sign after skin incision?	BP……../.... (……) mmHg	

		PR:…….BPM	
212	Duration of surgery		
213	Duration of anesthesia		

Section III Post-Operative Observation Vital sign at recovery room

V/s/arrival time……	Arrival	20min	40min	60min
PR				
BP				
FLACCSCORE				
Analgesia given				

Ward follow up for 24

S.no	Arrival time----------LT	At arrival	After 2hrs.	After 4hrs.	After 8hrs	After 12hrs	After 24hrs
301	FLACC/NRS score						
302	Analgesia given Type and mg						

303) Frist Analgesic Required Time _____Lt/Pm/Am (Time Per24hr/Date/Month/E.C)

304) Duration till First Analgesic Request _____

305)Analgesia Given Other Than for Pain----------

306) Total and Type of Analgesic Consumption Within 24 Hours After the Patient Arrived at Recovery/Ward_____

Section IV complications observed

401) Does the patient have nausea within the first 24 hours of surgery? A. YES B. NO

402) Does the patient develop vomiting within first 24 hours of surgery? A. YES B. NO

403) Does the patient develop leg weakness within first 24 hours of surgery? A. YES B. NO

404) Does the patient develop sedation within first 24 hours of surgery? A. YES B. NO

405) Does the patient develop any other complication other than the above? A. YES B .NO

Annex II 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.			

Figure 6 FLACC SCORE

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 bo

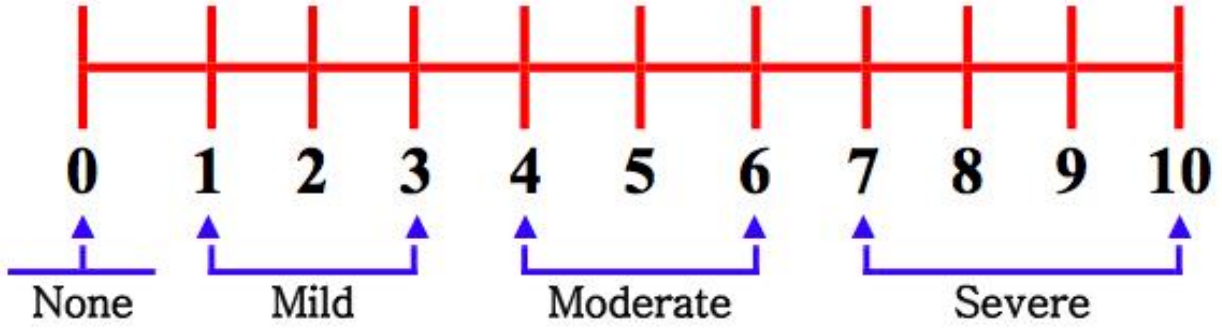

Figure 7 numeric rating scale

Annex III Information Sheet

Title of The Research Project: is to Assess Postoperative Analgesic Efficacy of Caudal Dexamethasone Added to Bupivacaine for Pediatric Infra Umbilical Surgery, In Elective Surgical Pediatric Patients for Infra Umbilical Surgery from December 1, 2017, To February 30, 2016, At Tikur Anbesa Specialized Hospital, Ethiopia.

Name of the principal investigator: Amanu Gashaw

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 adding dexamethasone to bupivacaine on the duration of a caudal block for prevention of post-operative pain during pediatric infra-umbilical surgery at TASH. The research group includes the principal investigator, four data collectors, and one advisor from AAU.

Purpose of the research project: - the main concern of this study to assess the effect of adding dexamethasone to bupivacaine on the duration of a caudal block for prevention of post-operative pain

during pediatric infra-umbilical surgery at TASH. The finding of this study is expected to be used by decision-makers, FMOH, EAA, department of anesthesia and health practitioners.

Procedure

This study including 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 can have refused to participate in the study.

Benefits, risk or discomfort

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

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

Right to refuse or withdraw

Study subjects will have full right to refuse from participating in this research.

Person to contact

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

- Name: Manu Gashaw
- Phone: +251910092228
- E-mail: amanu495@gmail.com

Annex IV: Study Subjects Consent Form

Addis Ababa University, College of Health Sciences Department of Anesthesia Prospective Cohort Study, On Post-Operative Analgesic Efficacy of Caudal Dexamethasone Added to Bupivacaine for Pediatric Infra Umbilical Surgery in TASH, From December, 1, 2017g.C to February 30, 2018 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 chart. If you are willing to participate in this research on postoperative analgesic efficacy of caudal dexamethasone added to bupivacaine. So you are kindly requested to your child to participate in this study. I obtained the child name from the list of operation for surgery. Participation is voluntary. We strictly keep confidentiality. This observation will for 24 hours. Therefore, we kindly request your child to

participate in the observation? I understood about the objectives of the research and the roles I will have in the research. I have agreed to participate in the research. A) Agree B) Disagree
If agrees, the observation will be started.

Annex V: የጥናቱ ተሳታፊ ለመሆን የስምምነት ቅፅ

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

የተከበራችሁ የጥናቱ ተካፋይ ዎላጆች/የቅርብ ዘመዶች

ጤና ይስጥልን፡ስሜ----------ይባላል በአዲስ አበባ ዩኒቨርስቲ ምርምር ስር ተሳታፊ ነኝ ፈቃደኛ ከሆኑ ልጀዎን በጥናቱ ለማሳተፍ ፈልገን ነበር ሰሙን ከቀዶ ህክምና ተራ አግኝተን ነዉ የማንኛውም ግለሰብ ስም አይመዘገብም እንዲሁም ሀሳቡ ብቻውን ይፋ እንዲዎጣ አይደረግም:: ሙሉ በሙሉ በሚስጥር የተጠበቀ ነው፡ ።።ይህ ጥናት ቀዶ ህክምና ለሚደረግላቸዉ ህፃናት ከጠቅላላ አነስቴዝያ በኋላ በቀዶ ህክምናው በፊት የመሰጠው(caudal anesthesia) ላይ የሚሰጥ በመዳኒቶች (bupivacaine ብቻውን bupivacaine ከ dexamethasone) ሲቀላቀል)ለህመም ማሰታግሻ ለምን ያክልጊዜ እንደሚቆያ ለማዎቅ በጥቁር አንበሳ ልዩ የማስተማሪያ ሆስፒታል ከታህሳስ አንድ እስክ የካቲት ሰላሳ ድረስ ከእነብረት በታች ባለዉ የሰውነት ክፍል ለቀዶ ህክምና የሚመጡ እዲሜያቸው ከ እንድ እስከ አስራት ያሉ ህፃናትን ለሃያ አራት ሰአት ወደፊት፣የህመም መጠን፣የመስታገሻ የሚጠይቁበትን ጊዜ ፣ምን ያህል የማሰታግሻ መድሀኒት በሃያ አራት ሰአት እነድተጠቀሙ እንዲሁም የማስታዎክ፣የማሰተኛት እግር አለመታዘዝ መኖር መከታተል ሲሆን ልጅዎን ለመሳተፍ የእርስዎን ፍቃድ ግድ ለው መሳተፍ በፍላጎት ብቻ ነው።።ስለዚህ ስምምነትዎን በአክብሮት እንጠይቃለን።። የጥናቱን አላማ እንደሁም የኔን ሃለፊነት ተረድቻለሁ ሰለዚህ ልጀ እንዲሳተፍ

ሀ) ፈቅጀለሁ ለ) አልፈቅድም

ከፈቀደ ክትትሉ ይጀመራል።።

Appendix I English Version of Numeric Rating Scale (NRS)

The scale was taken 6 times within the first 24 hours. Patients was asked to rate their pain was assessed and recorded (immediately on acceptance of patient at recovery room) 2^{nd}, 4^{th}, 8^{th} 12^{th} and 24^{th} hours postoperatively.

The patient were asked one of the following questions:

A. What number on a 0 to 10 scale would you give your pain right now?

B. When the explanation suggested above is not sufficient for the patient, further explanation or conceptualization of the scale will be done:

- 0 = no pain
- 1-3 = mild pain (nagging, annoying, interfering little with ADLS)
- 4–6 = moderate pain (interferes significantly with ADLS)
- 7-10= severe pain (disabling; unable to perform ADLs)

Appendix II አማርኛ ትርጉም በቁጥር አምሳያ መለኪያ (NRS)

ይህ መለኪያ በመጀመሪያዉ 24 ሰአት 6 ጊዜ የሚወሰድ ሲሆን በሽተኛዉ የሚጠየቃቸዉ ጥያቄዎች አሁን የሚሰማዎትን ህመም በየትኛዉ ቁጥር ይወክሉታል;

ሀ) ከዜሮ እስከ አስር ካሉት ቁጥሮች አሁን የሚሰማዎትን ህመም የትኛዉ ቁጥር ይገልፀዋል.

ለ) ከላይ የተሰጠዉማብራሪያ በቂ ሳይሆን ሲቀር፣ለበሽተኛዉ የበለጠ መረጃ መስጠት አስፈላጊ ሆኖ ይገኛል

- 0- ምንም ህመም የለም
- 1-3 - ትንሽ ህመም አለ
- 4-6 - መካከለኛ ህመም አለ
- 7-10 - ከባድ ህመም አለ