ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCE
DEPARTMENT OF ANESTHESIA

POSTOPERATIVE ANALGESIC EFFECTIVENESS OF CAUDAL TRAMADOL ADDED TOBUPIVACAINE FOR PEDIATRIC ELECTIVE INFRA UMBILICAL SURGERY AT TIKURANBESA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA. A PROSPECTIVE COHORTSTUDY, 2019 G.C.

BY DUGO ANGASA

MAY, 2019
ADDIS ABABA, ETHIOPIA

ASSESSMENT OF POSTOPERATIVE ANALGESIC EFFECTIVENESS OF CAUDAL TRAMADOL ADDED TO BUPIVACAINE FOR PEDIATRIC ELECTIVE INFRA UMBILICAL SURGERY.

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

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Abstract

Background: Caudal epidural analgesia is one of the most popular and commonly performed regional blocks in pediatric anesthesia. It is a reliable and safe technique that can be used with general anesthesia for intra- and postoperative analgesia in patients undergoing lower abdominal and lower limb surgery. Various adjutants are being used to improve the quality and duration of caudal analgesia. Addition of Tramadol to local anesthetics has been noted to prolong the duration of analgesia after surgery.

Objective: To assess the effectiveness of adding 1mg/kg caudal tramadol to bupivacaine for post-operative analgesia in pediatric patients during elective infra umbilical surgery at Tikur Anbesa specialized hospital from February–May, 2019 G.C.

Method: Hospital based prospective cohort study design was employed. Comparison of two mean with equal sample size formula for two independent cohort was used to get sample size of 56 children's whose age is 1-14 years' old that undergone elective Infraumbilical surgery received caudal block with bupivacaine alone or with tramadol added. A systemic random sampling technique was used to select study participants. Postoperatively severity of pain either by FLACC/NRS, time toanalgesic request and analgesic consumption were evaluated up to 24 hours after operation. Based on normality assumption, analysis was done by independent sample t test, Mann–Whitney *U*-test and $\chi 2$ test as appropriate. Value $p<0.05$ was considered as statistically significant

Result: This study found that tramadol with bupivacaine has prolonged postoperative analgesia with a median duration of 14 hours compared to 5 hours in bupivacaine alone. Moreover, total Paracetamol analgesic consumption was lower in tramadol group with a median total dose of 250mg compared with 437.5mg in bupivacaine group with statistically significant difference within 24 hours ($p<0.018$). Also, reduced the pain score in tramadol group, being statically significant at 4th, 8th and12th hours.

Conclusion and Recommendation: We found caudal tramadol with bupivacaine decrease postoperative pain score, total analgesic consumption and prolong the duration of analgesia. Based on our finding we recommend the use of caudal tramadol with bupivacaine is effective for postoperative analgesia in our setup.

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 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: Dugo Angasa

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Approval of the primary advisor

Name of the primary advisor: Lidya Haddis

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Contents

ABBREVIATION

AAU- Addis Ababa University

AIDS- Acquired Immune Deficiency Syndromes

ASA-American Society of Anesthesiologists

TASH –Tikur Anbesa 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

HIV-Human Immunodeficiency Virus

IASP- International Association Study of Pain

IQR-Inter quartile range

IRB- Institutional Review Board

LA-Local Anesthetics

MOPS- Modified Objective Pain Score

NGO-Non-governmental organization

PONV- Postoperative Nausea and Vomiting

POP- Postoperative Pain

RCT-Randomized Control Trial

SD –Standard deviation

WHO-World Health Organization

NRS-Numerical rating scale

CHAPTER ONE: INTRODUCTION

1.1.BackGround

The history of local and regional anesthesia began with the discovery of the local anesthetic properties of cocaine in 1884. Regional anesthesia is an indispensable component of the practice of pediatric anesthesia. The expansion of regional anesthesia in part due to the recognition of the need for better modalities of pain management as well as the demonstration of the safety of peripheral regional anesthesia in children. Regional anesthesia techniques have become routine interventions in children. The most frequently used regional anesthesia technique is epidural block with a caudal approach which was first described in 1933, and become one of the most popular regional anesthesia techniques combined with general anesthesia to obtain efficient postoperative analgesia for pediatric patients undergoing, lower extremity, perennial, and lower abdominal surgeries. It reduces intraoperative anesthetic agent consumption and preferred in high-risk patients(1–3)

Caudal anesthesia techniques can be easily learnt. By connecting the two posterior superior iliac spines (PSIS) usually locates the sacral hiatus at the apex and palpation of this inverted triangle at the apex should identify the puncture site. It is performed using sterile technique, using a short 23-gauge needle or a 22-gauge IV catheter. The needle is inserted at a 60-degree angle and advanced until a “pop” is felt and then lowered to a 20-degree angle and advanced an additional 2-3 mm to make sure the bevel is in the caudal epidural space. Single shot caudal epidural anesthesia has a reported high success rate, frequently over 90%(4)

Procedures involving the area of T10 to S5 dermatomes in children younger age or weight lower than 30 kg are more adequate. Above this, difficulty in localizing the sacral hiatus limits the use. The main disadvantage of caudal anesthesia is the short duration of action after a single injection of local anesthetic solution. Several adjuvants are being tried to increase the duration, quality of analgesia but, each has its merits and demerits. Tramadol has been shown to provide long lasting analgesia after extradural administration in adults as well as in children. Tramadol has affinity for the u receptors, inhibiting serotonin uptake and noradrenaline, resulting in analgesia almost equivalent to that of pethidine in potency while lacking the depressant effects on the respiratory system(5–9)

1.2. Statement of problem

According to the International Association for the Study of Pain (IASP), Pain is "an unpleasant sensory and emotional experience associated with actual and potential tissue damage". Pediatric patients are the most under treated and present to hospital for pain compared to adults; because of the wrong belief that they neither suffer pain nor they remember painful experiences(10).

Pain is always subjective. Each individual learns the application of the word through experiences related to injury in early life. Pain has afflicted, affected and fascinated generations of human beings over the ages. It is a multidimensional phenomenon with sensory, physiological, cognitive, affective, behavioral and spiritual components. Even with the rapid development of pediatric postoperative pain management, are remained undertreated because of difficulty in pain assessment and side effects of opioid analgesics. Although there are no perfect pain assessment techniques and no absolutely safe analgesics, proper monitoring and an individualized analgesic plan after due consideration of age, operative procedures, and underlying illness, using multimodal analgesics may improve the quality of pain control in children(11–13).

Enhanced inflammatory response to any noxious stimuli lead to perception of more pain and pain-related physiological changes in children as compared to adults. Childrenare under medicated due to the wrong belief that patients may be harmed by the use of these drugs, not respond to pain to the same degree as adults, and errors in dosage and route of administration. The under treatment of acute postoperative pain in children can lead to activation of physiological and biochemical stress response leading to impaired metabolic, endocrine, neurologic, pulmonary and immunologic functions, decreases patient satisfaction, impedes early patient mobilization, lengthens inpatient hospital stay, and increases healthcare costs.,increased morbidity or mortality and this leads recovery room protocols to include pain as a fifth vital sign that needs to be addressed before patients are discharged to the ward. The use of multimodal approach with weaker analgesics along with regional blocks is an effective modality to control pain and prevent severe adverse effects with higher doses of potent analgesic(14–16)

A study of POP in Nigeria also showed that two-thirds of patients complained of moderate to severe pain 24 hrs postoperatively. The provision of anesthesia and analgesia is seen as a low priority in comparison with the treatment of diseases such as malaria, tuberculosis and HIV / AIDS(17).

The consequences of widespread opioid misuse have focused the nation's attention on the issue of pain and the limited options for treatment in pain. Postoperative pain is the most undesired consequence of surgery. Surveys continue to reveal that postoperative pain is insufficiently managed throughout the first world, let alone in the Third World(18–20)

Fear of postoperative pain is one of the greatest concerns of patients undergoing surgery. A number of studies conducted in countries with a highly-developed health care system demonstrated that even in the first decade of the 21st century, postoperative pain was not managed well in one third to one-half of patients. In spite of all these reports, the postoperative pain in pediatric patient is not adequately managed despite of its cause of morbidity and even some reported mortality. A large scale survey reported that 40% of pediatric surgical patients experienced moderate or severe postoperative pain and that 75% had insufficient analgesia(21–23)

Combination of tramadol with bupivacaine has an additive effect not only in prolonging duration of postoperative analgesia but also significantly reduces the dose of both drugs there by decreasing the side effects

1.3. Justification of study

The goal of postoperative pain relief is to reduce or eliminate pain with minimum side-effects and as cheaply as possible. Effective pain relief means a smooth postoperative period, increased patient compliance and a nearly discharge from hospital. Clinical and experimental research indicates that pain is perceived, assessed, and treated differently depending on a person's sex, race/ethnicity, and age. When only the local anesthetic drugs are used the duration of postoperative analgesia is limited. So various drugs have been added for central neuraxial blockade along with local anesthetic drug to improve the operative conditions, prolong the duration of postoperative analgesia and to reduce the complication rate but each adjuvant has its own disadvantage

Alternative methods of prolonging caudal analgesia invalidated yet. But it is wise to use easily available, low cost, equally potent with less complication and inexpensive. The cost of tramadol is relatively low, easily available that makes routine use is reasonable in all hospital in Ethiopia. Such studies in resource limited area can improve pain management and patient comfort. Therefore, conducting such a research to find alternatives for pain management in the intraoperative and postoperative period is expected to decrease the side effects of opioids and other drugs.So this difference as well as the setup of the hospital, in terms of experience of anesthetists, type of needle and technique they use results in different out come from the study done before and as our knowledge, in Ethiopia there are no published data for the same title in the same population. The adaptation of caudal tramadol for caudal additive may become a good alternative analgesic technique in children undergoing infra umbilical surgery. This study will also provide necessary information used for future research and studies.

CHAPTER TWO: LITERATURE REVIEWS

Effective control and management of post- operative pain are clearly of primary concern to the patient and also of importance because of potential adverse effects of the physiologic response to pain from surgery. Inadequate treatment of postoperative pain continues to be an important clinical problem, not only leading to worse outcomes in the immediate postoperative period but also an increased risk for persistent postoperative pain. Persistent postsurgical pain, pain that lasts beyond the typical healing period of 1 to 2 months, has become increasingly recognized as a significant issue after surgery and may exceed 30% after some operations, particularly amputations and inguinal hernia repairs(24).

Walters K. conducted a prospective, study in the pediatric patients of 1-12 years, undergoing Infraumbilicalsurgery grouped in to1 ml/kg of 0.25% bupivacaine with tramadol 2 mg/kg in normal saline and other bupivacaine fentanyl received 1 ml/kg of 0.25% bupivacaine with fentanyl 2 µg/kg in normal saline with maximum volume of 12 ml in both groups .All patients were assessed postoperatively for pain by using FLACC in which duration of analgesia was 10–18 h in first group while it was 7-11 hour in second.(25)

A randomized control trial conducted by Gunduz M.et, al in 2001 Turkey included pediatric patients' age of 1- 5 and randomly divided into three groups as caudal tramadol; caudal tramadol bupivacaine; caudal bupivacaine given alone. For 24 h postoperatively, the POPS value showed no statistically significant difference among groups ($P > 0.05$). Postoperative analgesia was maintained for 24 h.(26)

Senel A. et, al in 2001 in Turkish included patients aged 12–84 months, undergoing unilateral herniorrhaphy and allocated them randomly to three groups. Children in group one received 0.25% plain bupivacaine 1 ml/ kg, second group received an identical local anesthetic dose mixed with tramadol 1.5 mg/ kg and other received caudal tramadol 1.5 mg/ kg in 0.9% sodium chloride in the same total volume (1 ml/ kg). Pain assessments were made at 1, 2, 3, 4, 6, 12 and 24 h. Analgesia time \ in second group (13.5±2.2 h) was significantly longer than in the other two groups ($P<0.05$). In group of tramadol with saline, more patients required additional analgesia after surgery than in the other two groups. Pain scores in the three groups were similar up to 4 hour but the mean score in tramadol with saline was higher than first and second 4 and 6 h group after operation. Significantly more patients who had received caudal bupivacaine alone

or with tramadol had lower pain during the first 24 h compared with those in the in 0.9% sodium chloride group(27).

Study done in India in 2004 by Majid Y,et al.with a total of Fifty patients (Age: 3- 14 years) undergoing inguinal and penoscrotal surgeries were randomized in to two equal group. The dose of bupivacaine 0.25% was 0.5 ml / kg for circumcision, 1 ml / kg for inguinal herniotomy, and 1.25 ml / kg for orchiopexia. In second group bupivacaine 0.25% was used in the same dosage as first group but inj. tramadol was added in a dose of 1 mg / kg. Evaluation of pain score after 2,4,6,8,12,and 24 hours of awakening was 1.84(± 0.53) & 1.56(±0.49), 2.28 (±0.46) and 1.96(±0.34), 2.76(±0.42) and 2.4(±0.46), 3.76(±0.54) and 2.96(±0.38), 4.04 (±0.26) and 3.48 (±0.96). The requirement of rescue analgesia after 8 hours in the first group was noted in 64% and 16% for second group. Similarly, after 12 hours rescue analgesic was required in 92% of patients in the first group and 48% in second group. The reduced incidence of need for rescue analgesics at the end of 8 & 12 hours post awakening was statistically significant in second group (28)

In Quasi-experimental study of total 60 patients aged from 1 to 12 years, Asma K, et al.in 2006 demonstrated, addition of 2 mg/kg tramadol with caudally administered bupivacaine produced postoperative analgesia up to 16 ± 4 as compared to 6 hours in bupivacaine administered patients which was significant. Supplemental analgesic doses of Ibuprofen and Paracetamol were required in 24 hours in 92% patients in bupivacaine group.(29)

Prakash S. et, al in India, 2006included 80 pediatric patients undergoing inguinal herniotomy allocated to bupivacaine 0.25% 0.75 ml/ kg (n=20), bupivacaine 0.25% 0.75 ml kg with tramadol 1 mg/ kg (n=20), bupivacaine 0.25% 0.75 ml/ kg with tramadol 1.5 mg/ kg (1.5; n=20), or bupivacaine 0.25% 0.75 ml /kg with tramadol 2mg/kg (n=20) by the caudal route. Postoperative pain was assessed at regular intervals for 24 h. Duration of analgesia was longer and total consumption of rescue analgesic was significantly lower in group (0.25% 0.75 ml /kg with tramadol 2mg/kg 12 hour compared with Group 0.25% 0.75 ml/ kg 4 hour(30).

Nasreen L,et al conducted a quasi-experimental study in 2006,Pakistan on patients coming for elective hypospadias surgery and grouped in to 0.5 ml/kg of 0.25% plain bupivacaine while other were given 0.5 ml/kg of 0.25% bupivacaine with 1 mg/kg of tramadol in epidural space. In the recovery room, patients were compared for pain scores, sedation score, need for rescue analgesia

and any unwanted side effects for 24 hours postoperatively. Lower pain score was observed in bupivacaine –tramadol group during the first 24 hours. The mean duration of analgesia andthe requirement for rescue analgesics was significant ($p < 0.001$)(31)

Sambrita M, et al .in India,2009groupthose (n=15) received 0.25% bupivacaine 0.5ml/kgand (n=15) received 0.25% bupivacaine 0.5 ml.kg-1 and tramadol 2mg/kg as single shot caudal block. Postoperative pain was assessed by a modified TPPPS (Toddler Preschool Postoperative Pain Scale) and analgesic given only when the score was more than 3. In the first 24 hrs it was observed that the mean duration of time interval between the caudal block and first dose of analgesic was significantly long (9.1hrs) in bupivacaine tramadol group as compared to bupivacaine alone group (6.3hrs) ($p<0.001$). (32)

MuhammedT.et al in Pakistan,2009 included all pediatric patients with ASAI and ASAII age 1 month to 12 years that undergo Infraumbilical surgery and found that all patients was pain free for 12 hrs(33)

Shrestha S, et al in Nepal 2010 done a randomized, control trialof forty pediatric patients grouped as those 'received 0.5 ml/kg of 0.25 % bupivacaine and Group B (n = 20) received 0.5 ml/kg of 0.25 % bupivacaine with 1 mg/kg of tramadol as a single shot caudal block. In the postoperative period pain score, recovery to first analgesic time, total number of analgesics required in 24 hours and side effects were noted and analyzed. It was observed that the mean duration of pain relief was significantly longer in group BT (8.8 hrs and 7 hrs(34)

Muhammed Sh.et al in Victoria, 2012 enrolled a total of 80 patients in the study, 40 Patients to bupivacaine and 40 Patients to bupivacaine tramadol group respectively. Duration of analgesia in bupivacaine group patients was 6.23+0.68 hours while in bupivacaine tramadol group, it was 9.33+0.72 hours. Nausea and vomiting was present in 20% (n=8) patients in bupivacaine group, while in bupivacaine tramadol group, 27.5% (n=11) in the post-operative period which is not significant. (35)

A cross sectional observational study was done in Tanzania 2013 by Muhozya A.with total of 118 ASA I and II children, aged 6 months to 11 years, undergoing perenial, genitourinary and lower abdominal surgeries, were enrolled in the study. Caudal block was performed in 118 children with a success rate of (98.3%). Children were followed up for 24 hours to identify and

manage all detected complications. The hemodynamic parameters were reduced or remained stable in all successful blocks. The average duration of analgesia was (8.20±2.1) hours with a range of 3-12hours. The duration of analgesia was prolonged in younger children when compared to those aged more than 72 months(36)

A randomized control trial done by Khan Q. in Pakistan, 2015 conducted on sample of 36 children, age ranged from 3-8 years of age, who underwent inguinoscrotal operations, one group receiving Tramadol-Bupivacaine (2mg/kg and 0.5mg / kg of 0.25%) and the other group receiving Ketamine and bupivacaine (1mg/kg and 0.5mg/kg of 0.25%), right after anesthesia. The duration of postoperative analgesia was 18.01 ±1.85 hours in Tramadol - bupivacaine group as compared to 11.92 ± 1.69 hours in Ketamine - bupivacaine group which was significant. The sedation score was high in tramadol - bupivacaine group only during 1st hour postoperatively. No other side effects like respiratory depression, urinary retention, pruritus were found in any group. The demand for rescue analgesia was high and significant (2.39±0.51) in Ketamine-bupivacaine group as compared to Tramadol bupivacaine group (0.40±0.60) (37)

Upendra K. et,al in 2017 undergo a prospective study by taking a total of 60 patients, aged between 2 to 7 years undergoing elective lower abdominal, urological and lower extremity surgeries. The patients were randomized to groups receiving 1 ml/kg of 0.25% bupivacaine and other group1 ml/kg of 0.25% bupivacaine plus 1mg/kg of tramadol caudally. He observed that the mean duration of analgesia was significantly longer in group with bupivacaine added tramadol (467.5±164.5 min versus group bupivacaine alone 240.5±69.4 min, $P<0.001$)(38)

A randomized, controlled study done in India in 2018 recruited 75 children was who scheduled for elective infra umbilical surgeries of similar duration Post-operative pain assessed at 30mins, 2 hours, 4, 8, 12, 24 hours after recovery from anesthesia using modified objective pain score (MOPS). Addition of tramadol to bupivacaine provides prolonged analgesia time to more than 10hrs up to 18 hrs in bupivacaine 0.25% 1ml/kg with tramadol 2mg/kg while 4-8 hrs in bupivacaine group(39)

2.1 Hypothesis

HO1: -there is no statically significant difference in severity of post-operative pain in non-exposed group and exposed group

HA1: -there is statically significant difference in severity of post-operative pain in non-exposed group and exposed group

HO2: - there is no statically significant difference in time to first analgesic request in non-exposed group and exposed group

HA2: - there is statically significant difference in time to first analgesic request in non-exposed group and exposed group

HO3: -there is no statically significant difference for the total analgesic consumption in the first 24 hours in non-exposed group and exposed group

HA3: -there is statically significant difference for the total analgesic consumption in the first 24 hours in non-exposed group and exposed group.

CHAPTER THREE: OBJECTIVE

3.1 General objectives

To assess the postoperative analgesic effectiveness of addingcaudaltramadol to bupivacaine in pediatric elective infra umbilical surgery at Tikur Anbesa specialized hospital from February-May, 2019 G.C.

3.2. Specific objective

To compare the severity of postoperative pain by FLACC/NRS

To compare first analgesia request time in minute.

To compare the total analgesic consumption in the first 24 hours.

CHAPTER FOUR: METHODOLOGY

4.1. Study Area and period

The study was conducted at Tikur Anbesa 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 offer diagnosis & treatment for approximately 370,000-400,000 in a year. It provides general medical services for a city of over 3 million people, and those referred from other parts of a country of 100 million people, 44% of whom are less than 15 years of age. 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 that one hundred and thirty of beds, 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. The study was conducted from February -May, 2019 G.C.

4.2. Study design

Hospital based Prospective cohort study design was employed

4.3. Population

4.3.1. Source Population

All pediatric patients scheduled for Infraumbilical surgeries at Tikur Anbesa specialized hospital.

4.3.2. Study Population

All pediatric surgical patient scheduled for infra umbilical surgeries in the study period who were undergone caudal block under general anesthesia with caudal bupivacaine with tramadol or caudal bupivacaine alone and those who fulfill inclusion criteria was included in the study.

4.4. Eligibility criteria

4.4.1. Inclusion criteria

Elective lower abdominal, urologic and orthopedic surgery

ASA status I and II

Pediatric patient age 1-14

4.4.2. Exclusion criteria

Failed block

Preexisting disease (cancer, chronic pain

Simultaneous operation on other (supra umbilical) site

Concentration other than 0.25% bupivacaine for caudal

Other additive added

Dose other than 1ml/kg of bupivacaine and 1mg/kg of tramadol

Day case surgery

Morphine given at time of induction

4.5. Sampling Technique and Sample Size Determination

4.5.1. Sample size determination

Comparison of mean with equal sample size for two independent sample size formula of two independent cohort based on mean pain score among the group where n1=sample for bupivacaine group, n2=sample for tramadol bupivacaine group. Z alpha =0.05, which is 1.96, power = 80%, which is 0.84. Since there is no previous study done in the study area, result adopted from literature was used to calculate sample size.

Previous study on 2004 in India, showed that the mean pain score was 4.04 (±0.26) and 3.48 (±0.96) in the bupivacaine and bupivacaine tramadol group respectively in the first twelve postoperative hours (28)

The required sample size shows that 95% likelihood of the mean pain score difference between two groups was calculated as:

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

Where n = the sample size in each of the groups.

μ1 = Sample mean in bupivacaine group.

μ2= Sample mean in tramadol bupivacaine 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 tramadol bupivacaine group.

Alpha =0.05, which is 1.96.

Power = 0.80 which is 0.84.

Substituting for this variables yields.

$$n = \frac{(0.26)^2 + (0.96)^2 \times (1.96+0.84)^2}{(4.04-3.48)^2}$$

$$n = 25$$

10% x25= 2.5=3 each

using 1:1 ratio between groups and adding 10% contingency, sample size become n1= n2=28 children in each group. Based on the three outcome variable and to get the largest sample size, a total of 56 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 three months on the log book, 184 patients were operated on pediatric elective infra umbilical surgery. The sampling interval K was determined using the formula: K=N/n; where, n = total sample size, N = population per 3 months. 56 participants were recruited with the probability of about 30%. Patients were sorted by listing infra umbilical surgery consecutives. 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 undergoes Infraumbilical surgery after grouping based on whether they received caudal bupivacaine alone or bupivacaine with tramadol till the required sample size was reached.

Exposed(BT):28 patients received 1ml/kg of 0.25% bupivacaine + 1mg/kg tramadol added.

Non-exposed (BA):28 patients received1ml/kg of 0.25 % bupivacaine alone till the required sample size was reached.

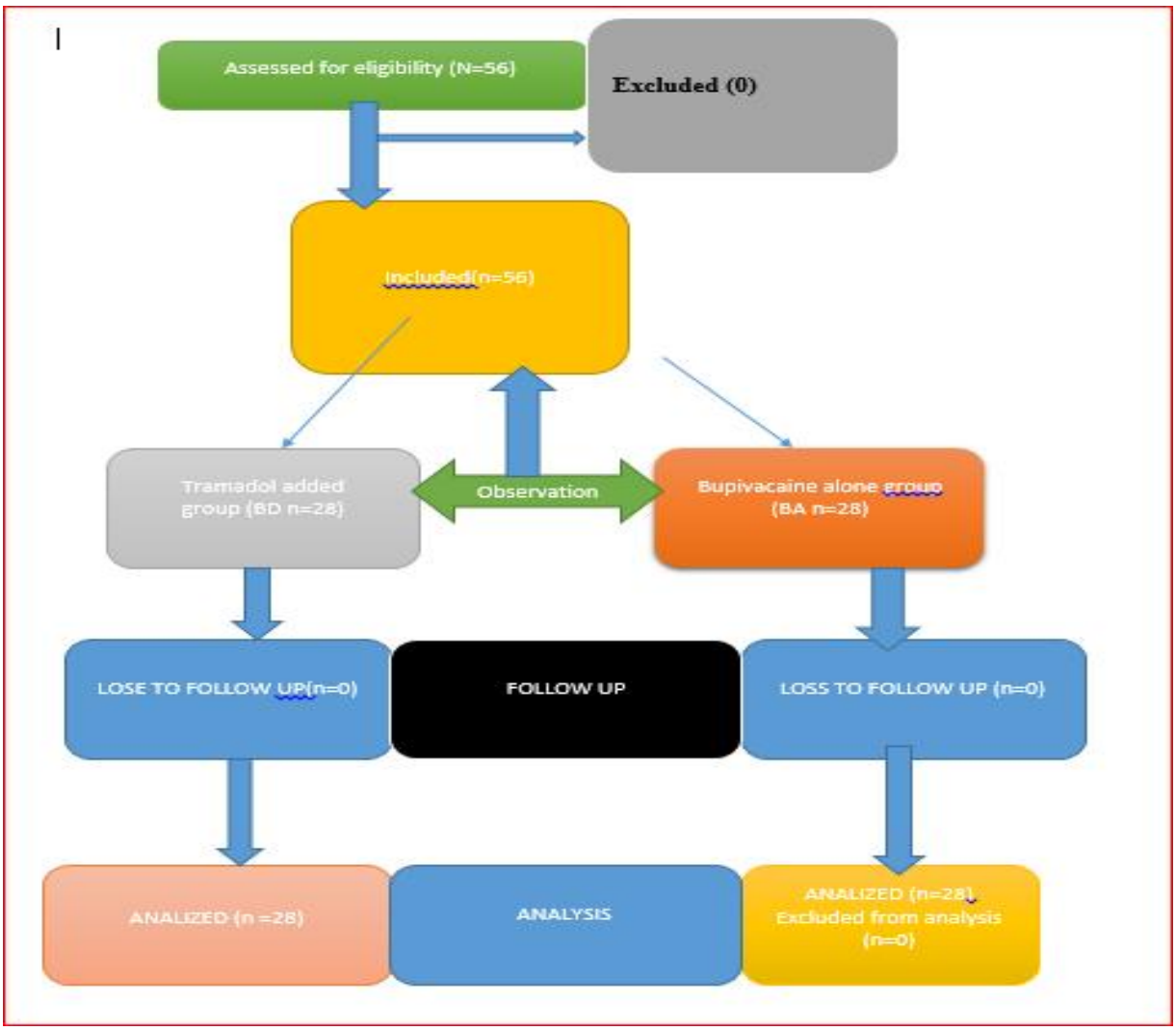


Figure 1 Patient Enrolment Chart BT& BA groups in pediatric elective infra-umbilical surgery at TASH from February-May, 2019

All pediatric patients who were scheduled for elective Infraumbilical surgery and fulfilled inclusion criteria were used after 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 tramadol 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 1mg/kg tramadol added as (group BT). In the postoperative time patients transferred to recovery room and transferred to ward when they recover from anesthesia. In ward patients 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

Duration of analgesia in minute.

Severity of postoperative pain by FLACC /NRS SCALE

Total number of analgesics consumption in 24 hrs.

4.6.2. Independent Variables

Age

Sex

Weight

ASA status

Baseline v/s

Type of surgery

Duration of surgery

Duration of anesthesia

Caudal bupivacaine and caudal bupivacaine with tramadol

4.7. Procedure for Pain Assessment

Pediatric patients who were scheduled for elective Infraumbilical surgery who fulfill inclusion criteria and parents' consent to take part in the study was instructed on how data collector use to assess pain in the morning of operation day. In the postoperative time patients were transferred to PACU and to ward when they recover from anesthesia. Patients were observed by trained nurses and pain was managed based on patient complain. Either FLACC/ NRS score were assessed &documented at 1^{st}, 2^{nd}, 4^{th}, 8^{th}, 12^{th} and 24^{th} postoperatively and first analgesia request as well as total analgesia consumption were documented when it is reported within 24 hours.

4.8. Plan for Data Collection

Structured check lists and questionnaires were prepared in English which includes socio demographic data, preoperative vital signs, ASA classification, duration of anesthesia, duration of surgery, and dose of analgesia if given. Total volume of drug, dose of additive, Dose of local anesthesia and post operatively severity of pain and rescue analgesic consumption was recorded for 24. Data collection was done using a designed check list and observational structured questionnaires, Intraoperative data was collected from anesthesia sheet by one Anesthetists while postoperative data was collected by three nurse after getting training with pain assessment tool, measured and the principal investigator supervise the completeness of the data daily.

4.9. Data Quality Control and Assurance

Pretest was done at Minilik II hospital on 10 % of sample and during data collection, regular supervision and follow up was made appropriately. Principal Investigator cross checked for completeness and consistency of data every day. All materials used for data collection was arranged sequentially and stored in safe and secure place.

4.10. Data Processing and Analysis

Data was checked manually for completeness and then coded and entered in to SPSS version 20 computer program for analysis. Descriptive statistics were used to summarize data, tables and figures to display the result. Continuous and normally distributed variables were expressed as

mean±SD, skewed databy median (IQR) and categorical data by proportion. Frequency and cross tabulation was conducted to describe relevant variables in relation to the outcome variables. And after checking for the normality assumption, analysis was done by independent sample t test for comparing means of two independent samples for comparing baseline continuous variables. Comparisons between different categories were evaluated using the $\chi 2$ test. After normality was tested by Shapiro wilk test ordinal and non-normally distributed variables were analyzed using the Mann–Whitney *U*-test.P value <0.05 was considered as statistically significant.

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. Ethical Consideration

Prior to data collection, the proposal reviewed by the ethical committee of college of health science and official letter was obtained. After submission of official letter we got permission from TASH clinical director office. Moreover, the objective of the study explained to both hospital administration and the children's parent who 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.

4.13. Operational definition

Duration of anesthesia: A time in minutes it takes from induction to a time to a patient get response to verbal command. It 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

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

Postoperative pain: the presence of pain in the postoperative period was defined as a patient complaining pain and any pain score other than zero within 24 hours.

Time to first analgesia request: a time in minutes from the end of surgery to a first time analgesia were given.

Failed caudal: Measured by greater than 15% mmHg increase SAP or PRwithin 15 min of skin incisioncompared with baseline values obtained just before the surgical incision(40)

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

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

FLACC scale: is a measurement used to assess pain for children between age two month 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.

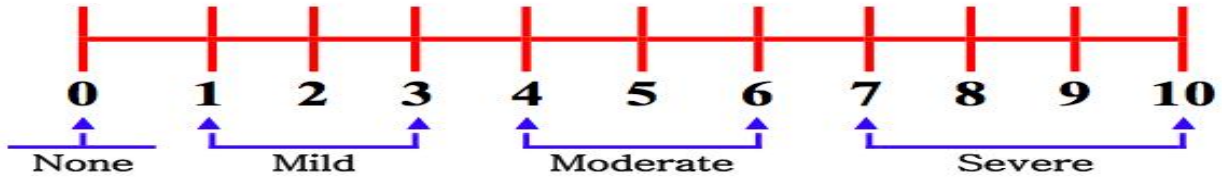
0: Relaxed and comfortable

1–3: Mild discomfort

4 –6: Moderate pain

7–10: Severe discomfort or pain or both(41).

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(42)



CHAPTER FIVE: RESULT

5.1 Demographic and Perioperative Characteristics

A total of 56 patients (28 patients in each group) were finally involved for analysis of this cohort study.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 1).

Table 1Demographic and baseline anesthetic characteristics between BT & BA groups in pediatric elective infra-umbilical surgery at TASH May, 2019

Variable	BT group(n=28)	BAgroup(n=28)	P-value
Age (years)M(IQR)	7(3-10)	4.5(3-7.75)	0.065
Sex Male n(%) Female n(%)	17(60.714) 11(39.285)	15(53.571) 13(46.428)	0.589
ASA status ASA I n(%) ASA II n(%)	21(75) 7(25)	19(63.3) 9(32.1)	0.554
Weight(kg) M(SD)	16.107±5.328	14.4±4.558	0.220
Baseline HR M(IQR)	120(110-130)	180(70-86)	0.249
Baseline MAP M(IQR)	82.5(76-86)	20(120-130)	0.210
Procedure Lowerabdominal n(%) Urologic n(%) Orthopedics n (%)	13(46.4) 7(25) 8(28.571)	6(21.428) 12(42.857) 10(35.714)	0.128
Premedication Atropine n(%) None n(%)	5(17.857) 23(82.142)	8(28.571) 20(71.428)	0.342
Analgesia Paracetamol n(%)PremedicationNone n(%)	3(10.714) 25(89.285)	2(7.142) 26(92.857)	0.639
Induction agent Propofol n(%) Ketamine n(%)	17(60.7) 11(39.28)	12(42.857) 16(57.142)	0.181
Maintenance Halothane n(%) Isoflurane (%)	16(57.14) 12(42.85)	11(39.28) 17(60.7)	0.181
Surgery time(min) M(IQR)	120(90-150)	120(90-145)	0.926
Anesthesia time (min)M(IQR)	130(100-155)	130(103.75-150)	0.698

NB: **BT**=bupivacaine with tramadol added **BA**= bupivacaine alone , **M(SD)=**Mean(standard division **)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 , chi-square test (x2) and t- test 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 BT and BA groups (Table 2).

Table 2 Hemodynamic response of caudal anesthesia given between BT & BA groups in pediatric elective infra-umbilical surgery at TASH May, 2019

Vital sign		BTgroup (n=28)	BA group(n=28)	P-value
Before incision	PR M(IQR)	122(113.25-130)	129(120-130)	0.118
MAP M(IQR)		83(80-88)	81.5(72.25-86)	0.249
After Incision	PR M(IQR)	121.5(120-130)	125(122-130)	0.16
MAP M(IQR)		85(80.90)	83(73.5-88)	.168
Arrival to PACU	PR M(SD)	121.571±9.859	122.892±0.	0.649
MAP M(SD)		80.86±7.768	77.857±8.154	0.164
AT20 min PACU	PR M(SD)	118.857±9.228	122.642±9.911	0.146
MAP M(SD)		80.785±7.656	77.571±9.570	0.171
AT40 min PACU	PR M(SD)	119.178±10.410	122.392±9.911	0.316
MAP M(SD)		80.071±8.986	76.892±9.06	0.197
AT60 min PACU	PR M(SD)	121.535±9.221	124.785±9.484	0.199
MAP M(SD)		83.392±7.790	80.464±9.406	0.210

NB BT=bupivacaine with Tramadol added, **BA**= bupivacaine alone,**M(SD)=**Mean(standard division),**M(IQR)** =median (interquartile range), **PR**= Pulse rate in beat per minute, **MAP** = mean arterial blood pressure in mmHg, Mann –Whitney U test and t-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= (0.368, 0.238&0.590) respectively. But were lower in (BT) group with a statistically significant difference at 4th, 8th and 12th hours postoperativelywith p=(0.018, 0.002 and 0.041) respectively.

Table 3Comparison of postoperative pain severity score between BT & BA groups in pediatric elective infra-umbilical surgery at TASH.May, 2019

FLACC/NRS SCORE	BT group (n=28)	BA group (n=28)	P-value
Postoperative PACU M(IQR)	0(0-0.75)	0(0-1)	0.368
2nd postoperative hour M(IQR)	3(2-3.75)	3(2-4)	0.238
4th postoperative hour M(IQR)	4(3-5)	5(4-6)	0.018
8th postoperative hour M(IQR)	4(3-5)	5.5(5-7)	0.002
12th postoperative hour M(IQR)	3(2.25-5)	4.5(4-6)	0.041
24th postoperative hour M(IQR)	4(2-4.75)	4(4-5)	0.065

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

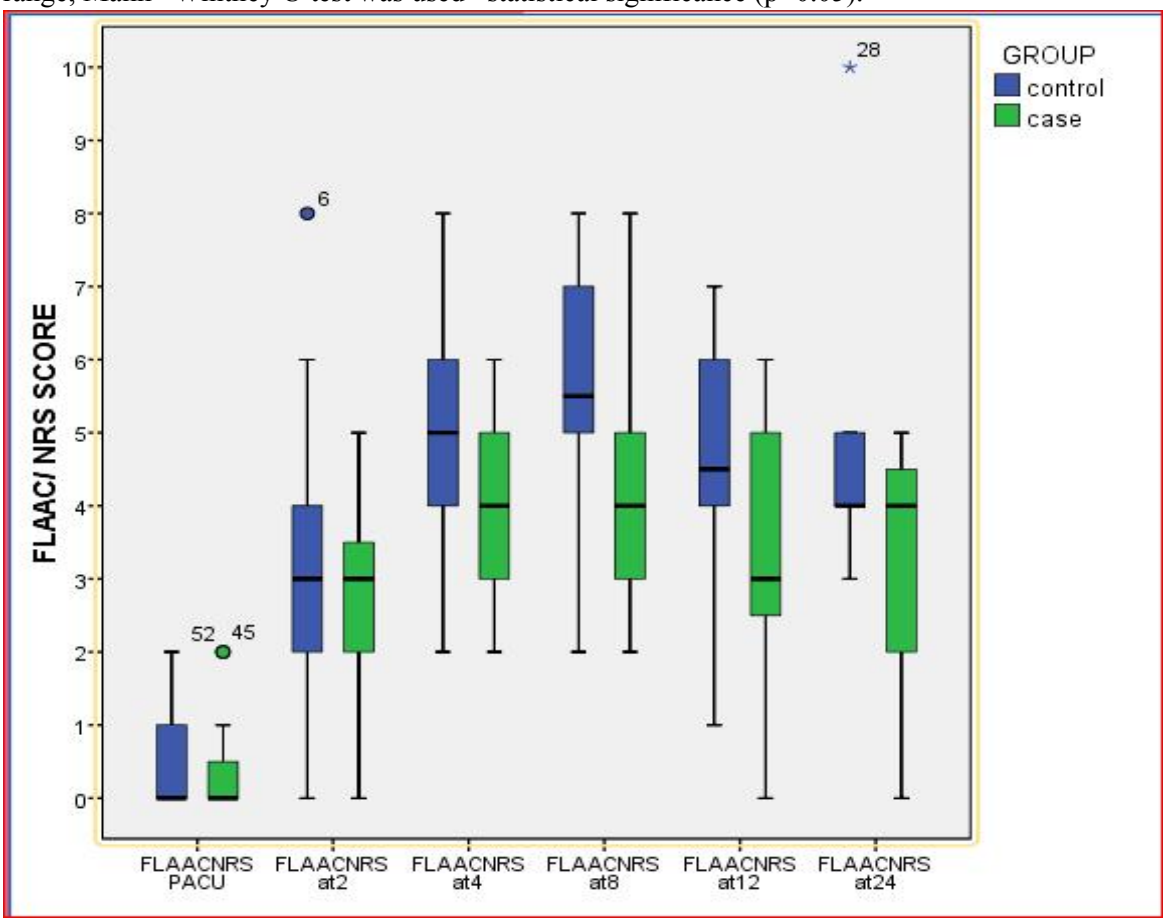


Figure 2Comparison of postoperative pain severity score between BD & BA group in pediatric elective infra-umbilical surgery at TASH. May, 2019

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 tramadol group prolongs the analgesia duration with a median and interquartile range of 840(735-900)minute compared with 300(240-360) minute in bupivacaine group (p <0.001).

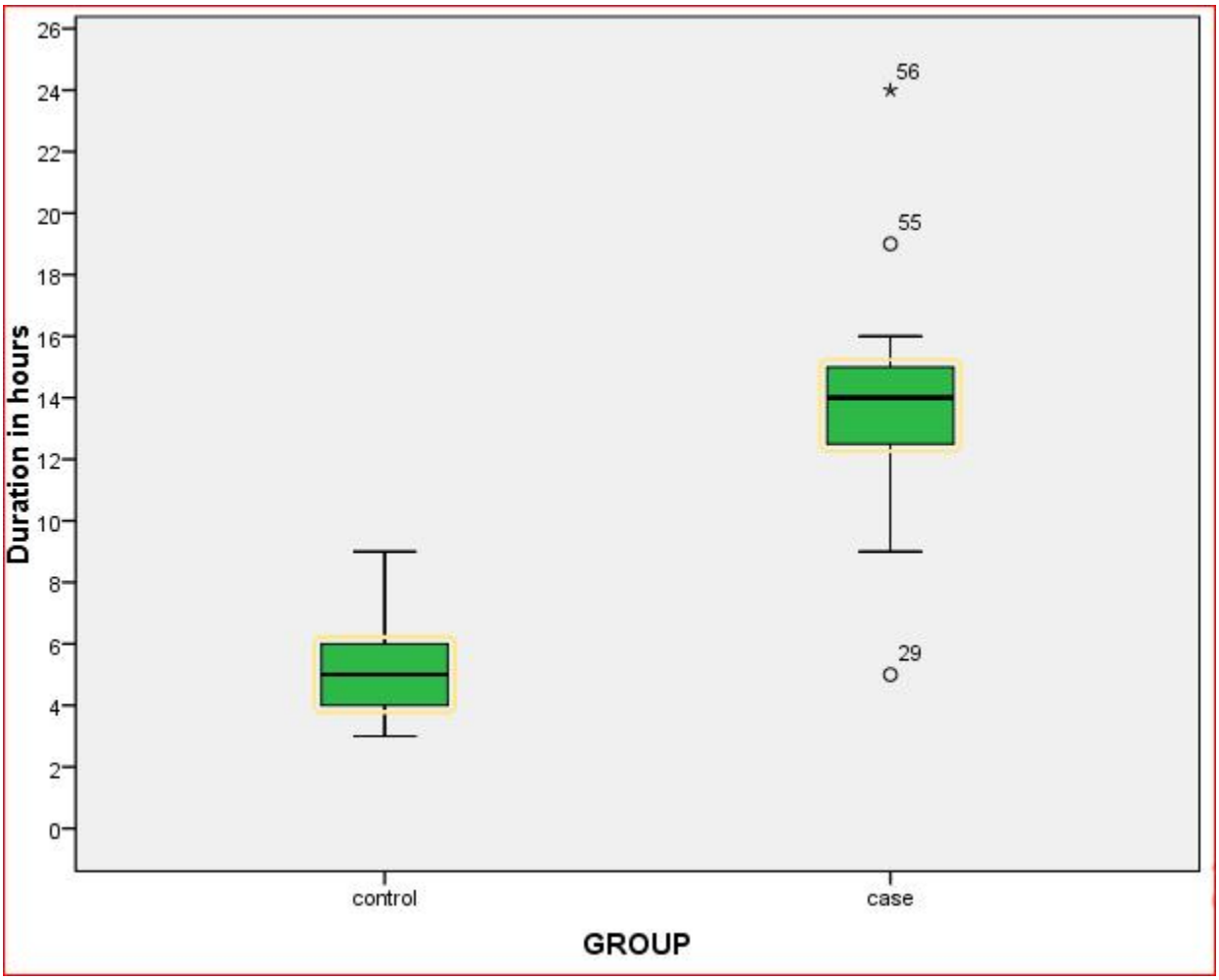


Figure 3Comparison of time to first analgesia request between BT and BA groups in pediatric elective infra-umbilical surgery at TASH. May, 2019

5.5 Comparison of total analgesia consumption betweengroups

The median total Paracetamol analgesic consumption in Tramadol group was 250 and 437.5in bupivacaine alone group with statistically significant difference within 24 hours ($p<0.018$). And there was a statistically significant difference in Paracetamol consumption between the tramadol and bupivacaine group. (Table 4).

Table 4Comparison of total analgesia consumption between BT & BA group in pediatric elective infra umbilical surgery at TASH. May, 2019

Variable		BT group(n=28)	BA=group(n=28)	P-value
Paracetamol	M(IQR)	250(187.5-250)	437.5(250-500)	0.018
Tramadol	M(IQR)	50(50-100)	100(50-100)	0.378
Diclofenac M(IQR)		62.5(50-75)	75(37.5-137.5)	0.671
No of dose request in 24h M(IQR)		1(1-2)	2(2-2.75)	<0.001

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

CHAPTER SIX: 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 tramadol 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 tramadol. Tramadol has been shown to provide effective, long-lasting analgesia after caudal administration in children.(40)

In our study, the median postoperative pain scores were lower at the 4th, 8th and 12th postoperative hour in the exposed group compared to non-exposed group and the difference was statically significant between the groups with (0.018, 0.001,0.005) respectively.Tramadol acts at opioid receptors and also appears to modify transmission of pain impulses by inhibition of monoamines reuptake. In addition, the (+) enantiomer inhibits serotonin reuptake and the (-) enantiomer is a norepinephrine reuptake inhibitor 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 tramadol over time(40)

The result of this study were in line with RCT studies done by Muhammad A.,et al in 2012 and Gunduz M. et al in 2001 in Turkey found that pain score was a statistically significant difference at 4,6,8 ,10 and 12. no significant difference in post-operative pain score at 24 hrs (26,35)

The possible explanation may be a similarity in pain assessment, the pain was assessed using the ten point objective pain score and similarity in dose of tramadol as postoperative analgesia, Paracetamol was given if the pain score > 3 for postoperative pain management

In contrary to our study,Yassin M,et al found that Pain scores were non-significant and comparable in the first 6 hours post awakening in children with tramadol bupivacaine group and bupivacaine only group(29)

The possible explanation for this difference may be due to the inclusion of children in the different age and increment in bupivacaine dose depending on the type of surgery.

In contrary to our study, a study done in 2009 by Nasreen L, et al found that pain score was statically significant different at a 24th postoperative hour in tramadol group compared to control group with p<0.001(31)

The probable 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 in which he used nitrous oxide for maintenance that has synergetic effect with other anesthetic agents and use of strong opioid in those studies

With regard to time to first analgesia request, our study showed a significant difference between tramadol added group compared with bupivacaine alone group with median prolongation of 840 minutes and 300 minutes respectively (p <0.001).

The result of our study was comparable with a study done by Muhammed T.et al,Pavthra V, et al , and S.Prakash, et al which showed that the duration of analgesia was 12 hrs , 8-12 hrs and 12hrswith statistically significant difference in tramadoland bupivacaine group respectively(33,39)

In contrary to our study, a studydone by Rukhsana S,et al,2013 and Khalid A.,et al 2006 found thatduration of postoperative analgesia was 17.88± 1.96 and 16.06 ± 4.04 hours in tramadol – bupivacaine group (29,43)

The probable reason for this increased duration of analgesia may be due to the use of increased dose of tramadol 2mg/kg which was 1mg/kg in our study.

But Upendra k,et.al in 2017 and Doda M, et alin 2009 found that the time of first analgesic request was decreased to 240.5 ± 69 vs. 467.5±64.5minutes and 6.3± 2.93 vs. 9.1±3.14 hrs inbupivacaine only group and tramadol bupivacainegroup which was significant respectively(38,44).

The probable reason for the decrement in first analgesic request time may be that he used strong opioid pethidine 0.5mg/kg intravenously as rescue analgesia.

In our study, the median total dose of Paracetamol analgesia in milligram was lower (250) in tramadol group compared to bupivacaine group (437.5 mg) with a statically significant difference.

Our study was in line with, an experimental study doneby Nasreen L,et al in 2009 and Quratulain K,et al in Pakistan in 2013for pediatric patients undergoing Infraumbilical surgery showed that the total rescue analgesia was 10%%, 95 and was 0.40±0.6 and 2.39±0,51 for bupivacaine tramadol group and in bupivacaine group with $p<0.001$ respectively(31,37)

The probable reason for the similarity with our finding may be similarity in pain assessment tool, pain score used for rescue analgesia and analgesia used for post-operative pain which was Paracetamol suppository.

6.1 Limitation of the Study

Lack of standard pain management protocol in the study hospital.

Most studies we used for comparison were randomized control trial.

6.3 Strength of the Study

Study participants were homogenous socio demographic characteristics

CHAPTER SEVEN: CONCLUSION AND RECOMMENDATION

7.1 Conclusion

In our study caudal anesthesia performed after induction of anesthesia for Infra Umbilical surgery withTramadol- Bupivacaine combination provided a long time post-operative pain relief, had a lower total analgesic consumption and longer first analgesic request time when compared to bupivacaine alone.

7.2 Recommendation

According to the finding of the study, we recommend the addition of tramadol with bupivacaine in caudal anesthesia for infra-umbilical surgery 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: QESTIONNAIRE

Addis Ababa University, College of Health Sciences, Department of Anesthesia Prospective Cohort Study, On Post-Operative Analgesic Effectiveness of Caudal tramadol Added to Bupivacaine for Pediatric Infra Umbilical Surgery in TASH, From February - May, 2019

Section I: Socio-Demographic Data

		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	

II .Data During Pre and Intraoperative Period

S. No.	Question	Response	Code
201	Diagnosis	…….	
202	Procedure	…….	
203	Base line HR	…….bpm	
204	Base line BP	……../……..(…….) 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) of 0.25% 1ml/kg bupivacaine only or 2……(ml) of 0.25% 1ml/kg bupivacaine with ……(mg) of 1mg/kg tramadol	
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	……...	

III. Post-Operative Observation Vital sign at recovery room

V/s/arrival time…	Arrival	20min	40min	60min
PR				
BP				
FLAAC/NRS SCORE				
Analgesia given				

Ward follow up for 24

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

303) First analgesic request 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_____

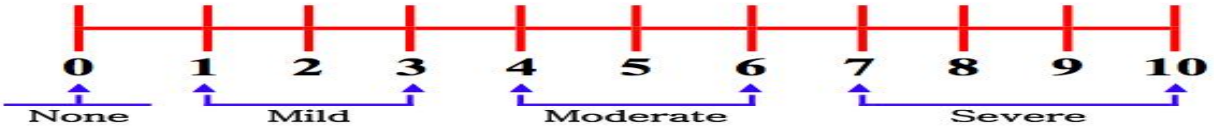
ANNEX II: PAIN ASSESSMENT TOOL

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.The scale will be taken 6 times within the first 24 hours. Patients will be asked to rate their pain and recorded at 0 min (immediately on acceptance of patient at recovery room) and 0-1, 1-2,2-4, 4-8, 8-12,12-24 hours post-operatively.

The patient will be asked one of the following questions:

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

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



FLACC scale: is a measurement used to assess pain for children between age two month 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 = 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)

FLACC Behavioral Pain Assessment Tool			
	0	**1**	**2**
Face	No particular expression or smile	Occasional grimace/frown withdrawn or disinterested	Frequent/constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless or 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 cry	Moans or Whimpers, occasional complaint	Crying steadily, screams or sobs, frequent complaints
Cancelability	Content or relaxed	Reassured by occasional touching, hugging or being talked to, distractible	Difficult to console or comfort

ANNEX III: INFORMATIONSHEET

Title of The Research Project: Is to Assess Postoperative Analgesic Effect of Caudal Tramadol Added to Bupivacaine for Pediatric Infra Umbilical Surgery, In Elective Surgical Pediatric Patients fromFebruary –May, 2019, at Tikur Anbesa Specialized Hospital, Ethiopia.

Name of the principal investigator: **Dugo Angasa**

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 tramadol to bupivacaine on the duration of a caudal block for prevention of postoperative pain during pediatric infra-umbilical surgery at TASH.

The research group includes the principal investigator, four data collectors, and twoadvisors from AAU.

Purpose of the research project: - the main concern of this study was to assess the effect of adding tramadol 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: Thisstudy included 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.

Benefits, risk or discomfort: There will be no direct benefit to study participants, but they will be monitored and followed 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, Name: Dugo Angasa Phone: +251913904952E-mail: angasadhugo@gmail.com

ANNEXIV: STUDY SUBJECTS CONSENT FORM

Addis Ababa University, College of Health Sciences Department of Anesthesia Prospective Cohort Study, On Post-Operative Analgesic Effect of Caudal Tramadol Added to Bupivacaine for Pediatric Infra Umbilical Surgery in TASH, From February, 2019 G.C to May, 2019Hello! My name is _____ I am the member 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 effect of caudal tramadol 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.

ANNEXV:የጥናቱተሳታፊለመሆንየስምምነትቅፅ

አዲስአበባዩኒቨርስቲ፣ጤናሳይንስኮሌጅአንስቴዝያት/ትክፍል

የተከበራችሁየጥናቱተካፋይዎላጆች/የቅርብዘመዶች

ጤናይስጥልን፡ስሜ----------ይባላልበአዲስአበባዩኒቨርስቲምርምርስርተሳታፊነኝፈቃደኛ

ከሆኑልጀዎንበጥናቱለማሳተፍፈልገንነበርሰሙንከቀዶህክምናተራአግኝተንነዉየማንኛውምግለሰብ

ስምአይመዘገብምእንዲሁምሀሳቡብቻውንይፋእንዲዎጣአይደረግም:: ሙሉበሙሉበሚስጥር

የተጠበቀነው፡፡፡ይህጥናትቀዶህክምናለሚደረግላቸዉህፃናትከጠቅላላአነስቴዝያበኋላበቀዶ

ህክምናውበፊትየመሰጠው(caudal anesthesia) ላይየሚሰጥበመዳኒቶች (bupivacaine ብቻውን bupivacaine htramadol) ሲቀላቀል)ለህመምማሰታግሻለምንያክልጊዜእንደሚቆያለማዎቅ

በጥቁርአንበሳልዩየማስተማሪያሆስፒታልከታህሳስአንድእስከየካቲትሰላሳድረስከእነብረትበታችባለዉ

የሰውነትክፍልለቀዶህክምናየሚመጡእዲሜያቸውከእንድእስከአስራትያሉህፃናትንለሃያአራትሰአት

ወደፊት፣የህመምመጠን፣የመስታገሻየሚጠይቁበትንጊዜ፣ምንያህልየማሰታግሻመድሀኒትበሃያአራት

ሰአትእነድተጠቀሙእንዲሁምየማስታዎከ፣የማሰተኛትእግርአለመታዘዝመኖርመከታተልሲሆን

ልጅዎንለመሳተፍየእርስዎንፍቃድግድለውመሳተፍበፍላጎትብቻነው፡፡ስለዚህስምምነትዎንበአክብሮት

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) 2nd, 4th, 8th 12th and 24th 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 አማርኛትርጉምበቁጥርአምሳያመለኪያ (NRS)

ይህ መለኪያ በመጀመሪያው 24 ሰአት 6 ጊዜ የሚወሰድ ሲሆን በሽተኛው የሚጠየቃቸው ጥያቄዎች አሁን

የሚሰማዎትን ህመም በየትኛው ቁጥር ይወክሉታል;

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

ለ) ከላይ የተሰጠው ማብራሪያ በቂ ሳይሆን ሲቀር፣ ለበሽተኛው 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