ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCE

DEPARTMENT OF ANESTHESIA

Comparison of Postoperative Analgesic Effect of Dexamethasone with Bupivacaine versus Tramadol with Bupivacaine in Caudal Anesthesia for Children Undergoing Lower Abdominal Surgeries at Tikur Anbesa Specialized Hospital Addis Ababa, Ethiopia 2022/2023.

A prospective cohort study design.

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A research thesis was to be submitted to the Department of Anesthesia, college of health science, Addis Ababa University, in partial fulfillment of the requirements for a Master of Science in clinical anesthesia.

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THE FULL TITLE OF THE RESEARCH PROJECT

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The full title of the research project	Comparison of Postoperative Analgesic Effect of Dexamethasone with Bupivacaine versus Tramadol with Bupivacaine in Caudal Anesthesia for Children Undergoing Lower Abdominal Surgeries at Tikur Anbesa Specialized Hospital Addis Ababa, Ethiopia 2022/2023. A prospective cohort study design.
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ADDIS ABABA UNIVERSITY COLLEGE OF MEDICINE AND HEALTH SCIENCE DEPARTMENT OF ANESTHESIA MASTER OF SCIENCE IN CLINICAL ANESTHESIA

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DECLARATION

I, the undersigned and declare that the thesis entitled comparison of caudal bupivacaine with tramadol and

Caudal bupivacaine with dexamethasone postoperative analgesia effectiveness in pediatric patient undergoing lower abdominal surgery at tikur anbessa specialized hospital,Addis Ababa, Ethiopia 2022/2023. is my original work in partial fulfillment of the requirements of Master,,s degree in in advanced clinical anesthesia. I understand that plagiarism is not tolerated and all directly quoted material has been appropriately referenced.

Investigator

Name _____ Signature_____ Date _____

This thesis work has been submitted for examination with my approval as advisors on the

master,,s degree in in advanced clinical anesthesia course.

Approval of Advisor

Advisor

Name _____ Signature _____ Date _____

Approval of Examiners

Name _____ Signature_____ Date _____

Name _____ Signature_____ Date _____

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List of Abbreviation /Acronym/

AAU- Addis Ababa University

ASA- American society of Anesthesiologists

CB - Caudal Block

CI-Confidence Interval

FLACC-Face Legs Activity Cray Consolable

FMOH- Federal Ministry of Health

HR- heart rate

IV- Intravenous

LA-Local Anesthetics

MOPS- Modified Objective Pain Score

NGO- Non-Governmental Organization

NRS- Numeric rating scale

OR- odds ratio

PACU: -Post anesthesia care unit

PI- principal investigator

PONV- Postoperative Nausea and Vomiting

RCT- Randomized Control Trial

SPA- Society of pediatric anesthesia

SD –Standard Deviation

SBP- systolic blood pressure

TASH-Tikur Anbessa specialized Hospital

WHO- World Health Organization

Abstract

Background: Pain is a stressful condition that is regarded as a global health issue, with children being the most vulnerable and underserved population. one of the most commonly used regional anesthesia techniques in children is Caudal analgesia despite its limitations.Many adjuvants are used to increase the effectiveness of this block. Currently, tramadol and dexamethasone are commonly used caudal adjuvants that increased the effectiveness postoperative analgesia.

Objectives: To compare the postoperative analgesic effect of tramadol with bupivacaine and dexamethasone with bupivacaine for caudal analgesia in elective pediatrics patients undergoing lower abdominal surgery at Tikur Anbessa specialized hospital in Addis Ababa Ethiopia.

Material and methods: from February 1 to April 30, 2023 an institutional-based prospective cohort study design was employed at Tikur Anbessa Specialized Hospital, Addis Ababa Ethiopia. Comparison of two mean with equal sample size formula for two indepndent cohort studies was used to get a sample size of 64 children age 1-8 years underwent elective lower abdominal surgery. Intraoperative information was gathered by trained anesthetists, whereas postoperative data were gathered by trained nurses. The data were analyzed by independent t-test, Mann-Whitney U test , chi-square & fisher exact test were used to analyzed outcome variable as needed.p-value < 0.05 was considered as statistically significant.

Results: Significant differences were observed in terms of time to first analgesic request time which was 15.63±2.22 and 14.14±2.12 in Bupivacaine-Tramadol and Bupivacaine-Dexamethasone group respectively (p=0.02).There also Significant differences in median total analgesia consumption(p=0.005).there was no difference in FLACC score between groups at the 3^{rd},6^{th}, and 24^{th} postoperative hours(p>0.05). However there was a significant difference in the FLACC score(p=0.002) at the 12^{th} hour between groups. Base line vital sign, PACU hemodynamic parameters were comparable between groups.

Conclusion: The patients receiving the combination of Bupivacaine-Tramadol had the lowest dose of Acetamnphon and the longest time until their first analgesic request compared to the Bupivacaine-Dexamethasone groups. combination of bupivacaine-tramadol provides longer analgesia duration and decreases the severity of postoperative pain than bupivacaine-Dexamethasone in a pediatric patient.

Keywords: Tramadol, Dexamethasone, Pediatric, postoperative analgesia, Caudal Anesthesia.

1. CHAPTER ONE INTRODUCTION

1.1. Background

Always pain has been one of the most traumatic experiences of the human psyche. Pain in children is similar to pain in adults and can have similar negative effects on the body. [2]

Post-operative pain is acute pain. Acute pain is "the physiologic response to noxious stimuli that can become pathologic. it is acute in onset and has a short duration, and activates behaviors to avoid actual or potential tissue injuries." acute pain was managed by administered opioid medications intermittently throughout the perioperative period. there is a greater interest in opioid-sparing medications due to opioid crisis. the best and most powerful opioid-sparing technique for many indications is regional anesthesia that is caudal block in children. [3]

Currently, pediatric pain management should try to reduce patients' discomfort to a comfortable level without limiting their degree of mobility by employing a multimodal strategy that includes regional anesthesia. anticipation and effective pain management in pediatric patients is thus critical component of care. Data from the pediatric regional anesthesia network data source reveal that both central and peripheral nerve blocks in anesthetized infants and children are regarded as safe and effective. [6, 7]

The use of cuadal anesthesia techniques accepted a standard of care to children. caudal block commonly used regional anesthesia techniques in children. it is a simple, reliable and safe procedure with fewer side effects to provide intraoperative and postoperative analgesia in pediatric patients. Meredith Campbell was the first person to describe caudal anesthesia as applied to children (here in relation to urologic surgical procedures) in 1933. This concept has evolved over time into a technique of great interest. [10]

It is a method of providing perioperative analgesia for painful lower abdominal surgical interventions. It allows early ambulation, periprocedural Hemodynamic stability and

spontaneous breathing in patient groups at high risk of a difficult airway. [11] It is normally a one-shot technique. However, the relatively short duration even if with long-acting local anesthesia is the procedure's limitations. Although useful in the treatment of chronic pain. the use of local anesthetics is limited by their short duration of action and the dose-dependent adverse effects on the heart and central nervous systems. Adjuvant drugs were introduced into clinical practice to address this shortcoming. [5]

Adjuvants are used in conjunction with local anesthetics to have a synergistic effect by increasing the duration of analgesia and decreasing the total dose requirement of local anesthetics. local anesthetics can cause arrhythmias, respiratory depression, allergic and seizures. Co-administration of adjuvants has the power to increase perineural block effectiveness and decrease local anesthetic side effects by extending the duration of analgesia and decreasing the cumulative dose required for local anesthetics. Bupivacaine is the most often used local anesthetic for caudal blocks in children. The extent of efficacy of the block is determined by the dose, injection site, lipophilicity, and acid-base environment of the drug deposition site. [12]

Tramadol is a weak opioid agonist with sodium and potassium channel-blocking properties as well as additional activities such as preventing norepinephrine and serotonin absorption. It is a centrally acting analgesic effect via opioid receptors. caudal epidural tramadol at doses of 1-2 mg/kg had the mean duration of analgesia was 10-18 h. [13]

Dexamethasone is a well-known corticosteroid that is used perioperatively as an analgesic and antiemetic. There have been studies that show the role of dexamethasone given caudally, epidurally, and in the brachial plexus block. Although caudal dexamethasone had a mean duration of analgesia was 5.9 h (95% CI, 4.0–7.7). [14]

1.2. STATEMENT OF THE PROBLEM

Pain is a stressful condition that is regarded as a global health issue, with children being the most vulnerable and underserved population. [15] In children acute postoperative pain can activate the physiological & biochemical stress response, resulting in compromised neurologic, endocrine, metabolic, immunologic and pulmonary systems. The final outcome may be a much-decreased pain threshold that lasts for a long time after the painful stimuli. [2]

Conventional opioids continue to be the standard of care for the treatment of immediate postoperative pain; however, the risk of opioid-related side effects might limit effective analgesia dose, resulting in poorly managed postoperative pain. [16, 17]. Evidence suggests that less than half receive adequate postoperative pain relief. [18]

In children, it become such a major concern around the world. Health professionals underestimate children's pain and do not prioritize it. The International Association for the Study of Pain started a campaign called "Global Year Against Pain in Children" in 2005 to promote awareness, yet research suggests that pain in children is still undertreated. [5,6, 7]

The use of opioids for acute pain management in pediatric has undoubtedly contributed significantly to the current opioid epidemic. It was responsible for half of all postoperative respiratory failure events up to (41%), particularly in children who are opioid sensitive and have different physiology and pharmacology from adults. [19, 20]

With increased evidence-based practice for postoperative analgesia, advances in pediatric perioperative care continue. However, up to 40% of hospitalized children report moderate to severe pain. [21]

Following surgery, many children experience moderate to severe pain in the first 24 hour of postoperative period. The incidence of chronic pain is 1.5% of surgical patients. The annual

economic impact of chronic pain is estimated to be $19.5 billion for postsurgical patients. Chronic pain disables between 5% to 8% of children. [21, 22]

Postoperative pain is not appropriately treated. According to the WHO, 80% of people do not obtain adequate pain treatment, which is consistent with an American survey that found only one in every four patients received adequate postoperative analgesia. [22] The total incidence of moderate to severe pain in hospitalized children was 27%, and Patients admitted to medical care showed substantially lower rates of moderate-to-severe pain (13% vs. 44% for surgical patients). [16]

If postoperative pain is not addressed and treated, it can have a significant impact on a child's quality of life, altered pain sensitivity, and increases a child's vulnerability to pain later in life. the presence and intensity of acute pain during or following surgery predict the development of chronic pain [4].

Using a concentrated local anesthetic in higher amounts to increase the duration and efficacy of caudal regional block can create undesired side effects; hence, Balancing the block's efficacy with the patient's safety remains challenging.[24]

Currently, to prevent these problems and to increase the quality of caudal block, several additives have been employed. Among the additive opioids, ketamine, and neostigmine have statistically significant complication, like respiratory depression, vomiting, and nausea, on the other hand, different studies conclude that the addition of dexamethasone and tramadol have longer postoperative analgesia duration than the bupivacaine group without statistically significant side effects.

But no one study states one is better adjuvant than the other. there is also great variability in postoperative analgesia duration in tramadol and dexamethasone for caudal block when compared to control group. There is also a variation in the dose of tramadol that is 2mg/kg is better postoperative analgesia duration than 1mg/kg or 1.5mg/kg without significant side effects. [43]

1.3. Justification of Study

Pain is the primary concern of patients who are scheduled for surgery. Studies have found that intense postoperative pain not only increases the trauma of surgery but also impedes patients' early physiological and psychological rehabilitation. [1].

In the pediatric age group, postoperative pain becomes an even greater concern. It is critical to select an analgesic approach that allows for the extension of analgesia into the postoperative period while minimizing the risk of anesthetic complication and ensuring optimal intraoperative sensory and motor blockade.

Adequate postoperative pain management facilitate rapid recovery, early discharge, reduce hospital and family cost, reduce morbidity, and minimizes patient discomfort. Therefore, treatment of pain in children has very importance.

The addition of adjuvants drugs allows to fully utilize the potential of caudal anesthesia and Reduced the need for general anesthesia. The addition of adjuvants is also used to extend the analgesic duration of the block, allow for a smooth anesthesia withdrawal and a calm recovery room stay, and lower the risk of emerging delirium and shivering.

Dexamethasone and tramadol are relatively inexpensive and widely available in our country that makes their routine use reasonable in caudal block. Thus, investigating their potential in caudal analgesia is important and, in a resource, -limited area such studies can improve pain management in the pediatric population undergoing lower abdominal surgery.

The adaptation of adjuvants to caudal block are good analgesia option in children undergoing infraumbilicus surgeries. Dexamethasone and tramadol both are used for caudal adjuvants that increase the analgesia duration of caudal bupivacaine. However, there are no studies comparing caudal dexamethasone vs caudal tramadol, and studies conducted comparing the caudal adjuvants, dexamethasone and tramadol, did not depict the superiority of these additives, particularly in our country. Therefore, we decided to compare and evaluate the postoperative

analgesic effect of caudal dexamethasone with bupivacaine vs caudal tramadol with bupivacaine in pediatrics undergoing lower abdominal surgeries.

The researchers believe that this study will provide information on which medications improve caudal block analgesia duration, which benefits our society in terms of analgesia duration, complication reduction caused by other additions, and cost-effectiveness. It is used as well as an input data source for other researchers interested in this subject area.

2. CHAPTER TWO LITRATURE REVIEWS

Postoperative pain affects more than 80% of patients, with 75% having moderate or severe pain, according to the American Pain Society. Postoperative analgesia is inadequate in less than half of patients. Because they reduce adverse effects, opioid-sparing analgesics are popular. [25] Several earlier researches investigated the use of various adjuvants with local anesthetics in a caudal block.

2.1. Caudal Anesthesia, its complications and failure rate

Caudal block complications are most likely 7/10.000, the lowest of all central blocks. A review of the literature on this technique's complications reveals that it is safe and has a low failure rate. Caudal in children has a higher success rate after a lower caseload than other regional anesthetic procedures. The success rate in children under the age of seven is 99%, but the majority of failures occur in the older when compared to the younger. The most common complication of the caudal block is blocks failure. [26]

According to a 2015 study in Chicago, caudal blocks from the pediatric anesthesia network database, safety concerns should not be a hindrance to using caudal blocks. Because the proper dosage of local anesthetics is titrated. After adjusting for age, blocks performed under general anesthesia were not associated with a higher incidence of complications than blocks performed in awake patients, with an OR (95% CI) of 0.49 (0.24-1.01), $P < 0.06$. [27]

Changes in hemodynamics after incision can determine whether the caudal block is successful or unsuccessful. Hemodynamic stability, defined as the absence of a 20% increase in heart rate or MAP compared to baseline values took over immediately prior to the surgical incision, was used to define adequate analgesia. so, the absence of an increase in heart rate and blood pressure with surgical site incision was defined as a successful block. [28, 29]

2.2. Caudal dexamethasone as additives to bupivacaine

Dexamethasone is a type of corticosteroid medication. It is analgesic, anti-inflammatory, and antiemetic. As a result, it is widely used in the treatment and prevection of nausea and vomiting, as well as in the reduction of airway edema and as an intravenous analgesic in children undergoing otolaryngologic procedures. In addition to this, dexamethasone has an effective adjuvant n increase the duration of analgesia, as proven by a number of studies. [1]

A Comparative Study was done in India on 128 patients in 2017 by Sridhar RB et.al (Dexmedetomidine, Dexamethasone, Magnesium) additive to Ropivacaine Caudal Anesthesia in children Patients Underwent Infraumbilical surgeries. They had duration of analgesia dexmedetomidine (406.2 45.5 min), dexamethasone (450.0 ± 72.6 min), and magnesium (325.0±45.8 min) compared to ropivacaine (285.9 ± 52.7 min). None of the adjuvants caused excessive or prolonged sedation. There were no side effects. [1]

A prospective single-blind study was conducted in India on 100 patients of either sex belonging to ASA I or II physical status in the age group 1-12 years children in 2016 by Nilesh, M.S., et al., to evaluate the analgesic efficacy found that, when dexamethasone was added to caudal bupivacaine, the mean duration of analgesia was 12-15 h, whereas it was 18-24h clonidine with bupivacaine. [44]

A network meta-analysis was done in china on 112 RCT involving 6800 pediatric patients in 2022 by CHENG, PENG., ET AL., Comparison of adjuvant pharmaceuticals for caudal block in pediatric lower abdominal surgeries. The three most effective adjuvants that prolong the duration of analgesia for the caudal block were discovered to be neostigmine, dexmedetomidine, and dexamethasone. They increased the duration by 8.9 hours (95% CI, 7.1-10.7), 7.3 hours (95% CI, 6.0-8.6), and 5.9 hours (95% CI, 4.0-7.7), respectively. Caudal

neostigmine was increase in postoperative nausea and vomiting, whereas dexmedetomidine and dexamethasone were not any postoperative complications. [14]

A systematic review with meta-analysis of RCT was done in Paris on 12 trials (1054 patients, 512 receiving dexamethasone) in 2015 by Huynh., et al., testing dexamethasone combination with local anesthetic found that prolongation of the duration of nerve block. [30]

A randomized double-blind RCT was conducted in Korea on 80 children in 2014 by Kim, E., et al., to evaluate the analgesic efficacy of dexamethasone with ropivacaine, and found that significantly lower postoperative pain scores at 6- and 24-hours ln dexamethasone group than bupivacaine alone. The number of subjects who were pain-free up to 48 hours after surgery in the dexamethasone group was significantly higher. [$P < 0.001$]. The two groups had comparable postoperative adverse events such as vomiting, fever, wound infection, and wound dehiscence. [31]

A prospective double-blind was done in India on 130 children in 2017 by Arena, Pa., et al., to evaluate the analgesic efficacy found that, when dexamethasone(0.1mg/kg) was added to caudal bupivacaine, the mean duration of analgesia was $1044.92 \pm (48.66)$ min, whereas it was $435.85 \pm (17.95)$ min with plain bupivacaine. [32]

A comparative study was done in Nigeria on 84 children in 2020 by Fogbound, O., et al., For postoperative herniotomy pain, they compared the efficacy of caudal dexamethasone-bupivacaine with caudal bupivacaine alone. At 2, 6, and 8 hours after surgery, the mean MOPS was significantly lower in bupivacaine with dexamethasone than bupivacaine alone; 2.88 ± 0.5 versus 4.10 ± 1.1 ($p < 0.001$), 2.60 ± 0.9 versus 3.2 ± 1.3 ($p < 0.002$), and 2.1 ± 1.1 versus 3.74 ± 0.8 ($p < 0.004$), respectively. The mean analgesia duration in the dexamethasone-bupivacaine was longer than in the bupivacaine alone, 478.17 ± 27.64 minutes versus 183.67 ± 28.43 minutes ($p < 0.001$). [33]

A prospective cohort study was conducted in Ethiopia on 30 children in 2020 by Gashaw et.al to determine the effectiveness of dexamethasone with bupivacaine in caudal block for postoperative analgesia in pediatric infra-umbilical surgery found that the dexamethasone-bupivacaine group had significantly longer postoperative analgesia, with a median of 915 (650-1,440) minutes compared to 433(328-555) minutes in the bupivacaine group (p-0.001). [34]

2.3. Caudal tramadol with caudal bupivacaine

Tramadol is an opioid medication that is a synthetic version of codeine. It has two enantiomers (+) and (-), and the (+) enantiomer has a stronger affinity for opioid -receptors, resulting in greater analgesic efficacy. Tramadol, on the other hand, does not have the same depressive effects on the respiratory system as opioids. Epidural tramadol at doses of 1-2 mg/kg seems to be an attractive option to potent opioids for postoperative analgesia without causing respiratory depression. Epidural tramadol has shown good efficacy for pain relief in a variety of pediatric patients undergoing lower abdominal procedures. [1]

Tramadol is used as an adjuvant with local anesthetics to prolong the duration of analgesia. A quasi-experimental comparative and double-blind study was done in Pakistan on 120 children in 2022 by Ashfaq, S., et al Found that the addition of tramadol appears to provide longer postoperative analgesia (10.1± 2.1 hours), whereas bupivacaine alone provided a shorter mean duration of analgesia (2.90 ±0.79 hours). There were no statistically significant differences in vital sign like MAP or heart rate between groups. [35]

RCT was conducted in Kuwait on 34 children in 2013 by Samad, R. and T.H. Shah comparing tramadol 2mg/kg vs ketamine 1mg/kg with 0.25% 0f 0.5ml/kg of bupivacaine. They found that Caudal tramadol with bupivacaine produced significantly increased postoperative analgesia. The mean analgesia duration in the tramadol – bupivacaine group was 17.88± 1.96 hours when compared to 12.05 ±1.63 hours in the ketamine-bupivacaine group. [17]

Another RCT was conducted in India comparing the analgesic effect of bupivacaine-tramadol and levobupivacaine tramadol found that tramadol bupivacaine group was long analgesia duration than tramadol levobupivacaine group with a mean duration of 21.41 ± 6.62 hours for Group Bupivacaine Tramadol while it was 17.79 ± 6.76 hours for Group Levobupivacaine Tramadol group. [42]

RCT was conducted in Pakistan on 110 children in 2022 by Shamsuddin, A.S., et al., to determine the effectiveness of tramadol 1mg/kg adding to 0.5ml/kg of 0.25% bupivacaine. They found that bupivacaine-tramadol group had significantly longer analgesia durations and a significantly lower need for rescue analgesia (p-value < 0.003). [36]

A comparative clinical study was done in India on 60 children in 2019 by Amitha, s., v, merit, and T. mahadevaiah to compare the effect of the addition of tramadol 2mg/kg and clonidine 2mcg/kg with 0.5ml/ /kg of 0.25% bupivacaine found that postoperative mean analgesia duration was statistically significant (P< 0.001) in tramadol bupivacaine group, reducing the need for analgesics. Sedation, nausea, vomiting, and urinary retention did not differ. [37]

A randomized clinical study was done in Iran on 46 children in 2021 by Rad, R, F., et al, to evaluate the effectiveness of tramadol 2mg/kg found that the tramadol group had a longer period of analgesia and used fewer analgesic drugs than bupivacaine alone (p<0.05) [38]

Another randomized controlled trial was done in Saudi on 100 patients in the age group 1-12 years in 2016 by Solanki, N., et al., to evaluate tramadol or fentanyl are good analgesic effect when combined to bupivacaine for infra umbilical surgeries in children. Group BT received 1 ml/kg of 0.25% bupivacaine in normal saline with tramadol 2mg/kg and Group BF received 1 ml/kg of 0.25% bupivacaine in normal saline with fentanyl 2ng/kg. These found that postoperative mean duration of analgesia was in Group BT was 10-18 h, while it was 7-11 h in Group BF. [39]

Another prospective cohort study was done in Ethiopia on 56 children aged 1-14 years in 2020 by Angasa D., et al to assess the efficacy of adding tramadol to bupivacaine. they found Tramadol combined with bupivacaine provides longer analgesia duration and had a median of 14hours when compared to 5 hours in bupivacaine alone group. [40]

There is great variability of the duration of caudal tramadol with bupivacaine and dexamethasone with bupivacaine. We are also commonly used in our clinical practice. In some studies when comparing tramadol with other adjuvants it has a long duration of analgesia, while dexamethasone has a short duration of analgesia. On the other hand, dexamethasone has a long duration of analgesia in some studies. So, there is no data to conclude which adjuvant is the better or long duration of analgesia when combined with bupivacaine for caudal block. This study was identified which drug is a better adjuvant to increase post-operative analgesia duration.

2.4. Hypothesis:

H01: There is no statistically significant difference in postoperative analgesia duration between the dexamethasone and bupivacaine groups.

HA1; There is statistically significant difference in postoperative analgesia duration between the dexamethasone and bupivacaine groups. .

H02; There is no statistically significant difference in pain severity between the two groups**.**

HA2; There is statistically significant difference in pain severity between the two groups**.**

H03; There is no statistically significant difference between groups in postoperative analgesia usage.

HA3; There is no statistically significant difference between groups in postoperative analgesia usage.

2.5. Conceptual framework

This conceptual framework was created by referring to various literatures related to the analgesic effectiveness of dexamethasone with bupivacaine and tramadol with bupivacaine for lower abdominal surgery in order to identify relationship between variables. It indicates an image of the relationship between postoperative pain and the factors influencing postoperative pain. This structure will serve as a guide for the research.

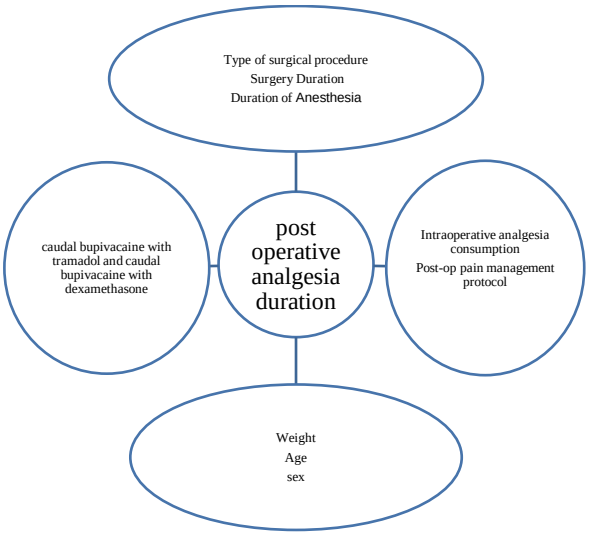

Figure I Conceptual framework

3. CHAPTER THREE- OBJECTIVES

3.1. General Objectives

The General Objectives of this study is to Compare postoperative Analgesia Effectiveness of Bupivacaine with dexamethasone and bupivacaine with Tramadol for Caudal Block in Pediatric Patient Undergoing Lower Abdominal Surgery at Tikur Anbesa Specialized Hospital Addis Ababa Ethiopia, from February 1 to April 30, 2023.

3.2. Specific Objectives

- To Compare the severity of postoperative pain by FLACC score between groups.
- To Compare the postoperative analgesia duration between group.
- To Compare the total postoperative analgesia consumption between group in the 1st 24h postoperatively.

4. CHAPTER FOUR -METHODOLOGY

4.1. Study Area

This research was done at Tikur Anbesa Specialized Hospital in Addis Ababa. The largest multi-specialist tertiary care teaching hospital in Ethiopia opened in 1972 and was transferred to school by the FMOH in 1998; since then, it has become a university teaching hospital, diagnosing and treating around 370,000-400,000 people per year. It serves nearly 3 million Addis Ababa residents as well as those referred from other regions of the country, with 44% of those served being children under the age of 15. It has approximately 800 beds, 17 operating rooms, and Every year, 7000-9000 individuals undergo surgery, including emergency surgery. 140 (23%) of the beds are reserved for pediatric patients, with 40 reserved for elective pediatric surgery admission. It is Ethiopia's sole hospital that offers tertiary pediatric surgery services. It offers several forms of elective surgery five days a week. According to the hospital's anesthesia and surgery log book, 120 elective patients had lower abdominal surgery within three months on average.

4.2. Study design

Institutional based prospective cohort study design was employed.

4.3. Study Period

This study was conducted from February 30, to April 30, 2023.

4.4. Population

4.4.1. Source Population

All pediatric Patients undergoing lower abdominal surgery at Tikur Anbesa Specialized Hospital.

4.4.2. Study Population

All pediatric Patients scheduled for lower abdominal Surgery underwent caudal block in the study period who fulfill the inclusion criteria.

4.5. Study Variables

4.5.1. Dependent Variables

Postoperative analgesic duration and pain severity

4.5.2. Independent Variables

Sociodemographic Variable

- Age
- Sex
- ASA I or II Status
- Weight(kg)

Intraoperative Variable

- Procedure
- Premedication
- Induction
- Duration of surgery
- Duration of anesthesia
- dexamethasone with bupivacaine and tramadol with bupivacaine

hemodynamic Variable

- heart rate
- MAP

4.6. Eligibility Criteria

4.6.1. Inclusion Criteria

- Pediatric elective patients, ASA physical status I or II 1–8 years old, who was received caudal block, and underwent lower abdominal Surgery were included in the study.

4.6.2. Exclusion Criteria

- Failed Caudal Block
- Administered morphine at the moment of induction.
- Added another adjuvant
- Day case surgery
- Vertebral deformity
- Preexisting neurological diseases
- Allergy to the drug.

4.7. Sampling Techniques and Sample size determination

4.7.1. Sample size determination

Because of no previous research had been conducted in the study area, the result from the literature was utilized to determine the sample size based on the primary outcome variable and to obtain the largest sample size. After a review of the study as the primary outcome comparing mean post-operative analgesia duration, the mean and a standard deviation of (10.1±2.1 hours) and (8.6±1.68) for Bupivacaine with Tramadol and Bupivacaine with Dexamethasone group respectively. Then using comparison of the mean with Sample size for two independent cohort studies based on the group. [35, 41]

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

Where

n1= Sample for Bupivacaine with tramadol group.

n2= Sample for Bupivacaine with Dexamethasone group.

μ1 = Sample mean in Bupivacaine with tramadol group.

μ2 = Sample mean in bupivacaine with Dexamethasone group.

μ1 - μ2 = mean difference

(σ1)2 = sample variance in Bupivacaine with tramadol group

(σ2)2 = sample variance in bupivacaine with Dexamethasone group.

A conventional multiplier Alpha=0.05, which is 1.96

A conventional multiplier for power = 0.80 which is 0.84.

Then substituting the variables gives as follow.

N1 = [$\underline{(2.1)^2 + (1.68)^2]\ (1.96+0.84)^2}$ / $(10.1\text{-}8.68)^2$ ……. N= 28.12~28

Using 1:1 ratio between groups and 15 % of contingency is included for dropouts, the total sample of 64 patients or 32 per group were required.

4.7.2. Sampling Technique

The daily operation schedule list was used to select study participants using a systematic random sampling technique. Based on the log book's average values for the previous surgery

in three months, eighty patients were operated on for pediatric elective lower abdominal surgery under the caudal block. K=N/n, where n = total sample size and N = population per 3 months, was used to compute the sampling interval. As a result, the sampling interval was one, and the first study participant (random start) selected by lottery. Patients who met the inclusion criteria were allocated into two groups based on their exposure status.

4.7. Data Collections Tool and procedure

In English, there were organized check list and questionnaires adapted from previous studies that included sociodemographic information, perioperative data, pain severity, Analgesic use, duration of analgesia, first Analgesia request time, and deleterious effects.

Their parents accepted for their children to take part in the study. Data collectors were informed how to assess pain postoperatively at the PACU and ward to the trained nurse in the morning of the operation day. Anesthesia professional, master anesthesia students and anesthesiology residents, provided caudal block when endotracheal intubation is confirmed and plastered. However, there is some variation in the concentration of bupivacaine used.

I took advantage of this opportunity to separate study participants into two groups: those given 1ml/kg of 0.25% bupivacaine with 2mg/kg Tramadol (group BT) and those given 1ml/kg of 0.25% bupivacaine with 0.1mg/kg Dexamethasone (group BD).

The baseline vital sign, the induction, the incision, and the caudal block time were all registered. Prior to the skin incision ten minutes after the block vital signs were recorded. After measuring vital signs ten minutes after skin incision compared to values before incision, the ability to maintain a value indicates an effective block. If the CB is considered ineffective, that means an increase in MAP or HR of more than 20% from the baseline at least 20 minutes after caudal anesthesia is performed. The children were given analgesics and were excluded from

the study. Vital signs were taken upon arrival at PACU and then every 20minutes till the patients discharge from to the ward.

To assess postoperative pain, the FLACC scale was employed. patients were observed by professional nurses and their pain levels were recorded at PACU, 3rd, 6th, 12th, and 24th postoperative hour using FLACC score and Analgesic use, duration of analgesia, first Analgesia request time, and deleterious effects were documented within 24 hours of surgery. Intraoperative information was gathered by trained anesthetists who is not involved in administering the block, whereas postoperative data were gathered by trained nurses. A score of more than or equal to 4 indicated pain. Those children were rescued.

4.8. **Operational Definition**

Duration of anesthesia: A period of time in minutes takes from induction to when a patient responds.

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

Failed Caudal Block: Full or partial failure is defined as a 20% increase in MAP and PR at list after 20 minutes of caudal block. [1]

FLACC scale: is a pain assessment tool for children aged two months to eight years, as well as adults who are unable to verbalize their discomfort. If the patient is asleep, observe for 5 minutes or longer. Examine the exposed body and legs. Reposition the patient if possible. Examine the body for tenseness and tone. In waking patients, observe for 1 to 5 minutes or longer. Examine the exposed legs and body. Reposition the patient or keep an eye on the activities. Examine your body for tenseness and tone. If necessary, initiate consoling interventions.

Post-operative nausea and vomiting: when a patient has at least one episode of nausea or vomiting within 24 hours of surgery.

Duration of analgesia: The duration in hours between the caudal placement of the drugs and the first recording of the FLACC score ≥4 or a first analgesia request time:

Total analgesic consumption: The Total analgesia given with in the first 24hours after the end of surgery.

Pediatrics; A patient under the age of 1-8 years old.

4.9. Data Quality Control and Assurance

The principal investigator trained data collectors. Regular supervision and follow-up were carried out during data collection. Every day, the data was double-checked for completeness and consistency. All data collection items were organized consecutively and stored in a safe and secure location.

4.10. Data Analysis and Interpretation

Data were carefully reviewed for completeness entered into epidata then coded, which was then transferred to the SPSS version 26 computer programme for analysis. The data's normality was evaluated using various tests (plot, skewness, and kurtosis) as well as a histogram curve and the Shapiro-Wilk normality test. An Independent student T-test was used for comparing normally distributed continuous variables between groups and a X^2 test for categorical variables. a non-parametric alternative, the Mann-Whitney U Test, was used to evaluate the pain severity and analgesia consumption between groups in the postoperative for 24 hours.

4.11. Ethical Consideration

Prior to data collection, the proposal was examined by the College of Health Science's ethical committee, and the formal letter was received from the anesthesia department. After submitting an official letter, obtain authorization from the TASH clinical director's office. Furthermore, the study's goal was stated to both hospital administration and the children's parents who participated in the study.

4.12. Dissemination Plan

Copies of the study will be distributed to the college of health sciences, school of medicine, department of anesthesia, the AAU student research office, the Ethiopian Association of anesthetist, Ethiopian society of pediatricians, various NGOs working on pediatric health, and the Ethiopian FMOH. Finally, it will be submitted for publication to national and international journal publishers.

5. CHAPTER FIVE RESULT

5.1. Demographic and base line Anesthetic Data

During the study period a total of 64 patients (32 from each group) were included for final analysis. The demographic data & baseline patient characteristics for both groups were comparable, with no statistically significant difference. Males were a large number of study participants.

Table 1. Demographic Data & Baseline Anesthesia Characteristics

Variable	Group BT	Group BD	P-Value
Age (year)*	3.03 ±1.534	3.16 ±1.668	.756
Gender(M) #	31	30	1.00
(F) #	1	2	
ASA Status(I) #	30	28	0.672
(II) #	2	4	
Weight(kg)*	13.25 ±2.918	13.38 ±3.087	.868
Baseline Heart rate*	131.00 ±17.124	129.47 ±13.584	.693
Baseline MAP*	62.03±7.715	63.44 ±6.560	.435
Premedication#			
Atropine	12	14	
Atropine & Ketamine	6	7	
Not premedicate	14	11	
Induction#			
Fentanyl/paracetamol	28/4	29/3	
Propofol/ Ketamine	24 /8	27/ 5	
Maintenance#			
Isoflurane/Halothane	22/10	23/9	
Duration of Surgery *	2.3953 ±.86764	2.6984±.86009	.165
Duration of Anesthesia *	2.8125 ±.99531	3.0609 ±.96618	.315

***Means** SD, **# case number** Values are presented as Mean ±standard deviation or case number/proportion, independent t-test was used and $p<0.05$ Statistically significant.

5.2. Hemodynamic Response between groups

The hemodynamic response including HR, MAP was comparable between groups. Before skin incision, after skin incision, at PACU, 20min, 40min, and 60min in PACU.

Table 2. **Comparison of Hemodynamic Response between groups**

Hemodynamic Response		Group BT	Group BD	P-Value
Before Incision	HR	132.06±14.921	130.59 ±12.043	0.666
	MAP	59.19±6.626	59.88±6.063	0.667
After Incision	HR	131.25 ±15.32	130.19 ±11.716	0.756
	MAP	57.50±6.584	60±4.472	0.378
At Arrival PACU	HR	126.13±13.976	123.78±11	0.47
	MAP	60.34±6.394	59.81±5.397	0.71
At 20min PACU	HR	124.00±13.486	123.56 ±10.746	0.88
	MAP	59.63 ± 4.884	60.16 ±5.074	0.67
At 40min PACU	HR	122.47 ± 13.088	121.78 ±11.842	0.82
	MAP	60.50± 5.978	61.09 ±5.642	0.68
At 60min PACU	HR	120.94± 11.859	120.34±11.100	0.83
	MAP	60.53±5.340	62.19±5.527	0.22

Values are presented as; Mean ±standard deviation, independent t-test was used and $p<0.05$ Statistically significant.

5.3. Post-Operative FLACC Score Between Groups

The Mann-Whitney U test show that the median FLACC score were not statistically significant at 1st, 3rd, 6th, and 24th h ($p>0.05$) between groups. However, there was a statistically significant difference in FLACC score between groups at 12th hour ($p=0.002$).

Table 3 Comparison of postoperative pain severity score between groups

FLACC Score	BT Group	BD Group	P-Value
Arrival at PACU M(IQR)	0(0-0.75)	0(0-1)	0.188
At 3rd postoperative hour M(IQR)	1(1-2)	2(1-2)	0.080
At 6th postoperative hour M(IQR)	2(2-4)	3(2-4)	0.080
At 12th postoperative hour M(IQR)	4(3-4)	4(4-5)	0.002*
At 24th postoperative hour M(IQR)	2(2-2.75)	2(2-4)	0.188

NB. Bupivacaine-Tramadol, Bupivacaine-Dexamethasone, M(IQR)=median and interquartile RANGE, Mann-Whitney U test was used *statistically significant($p<0.05$)

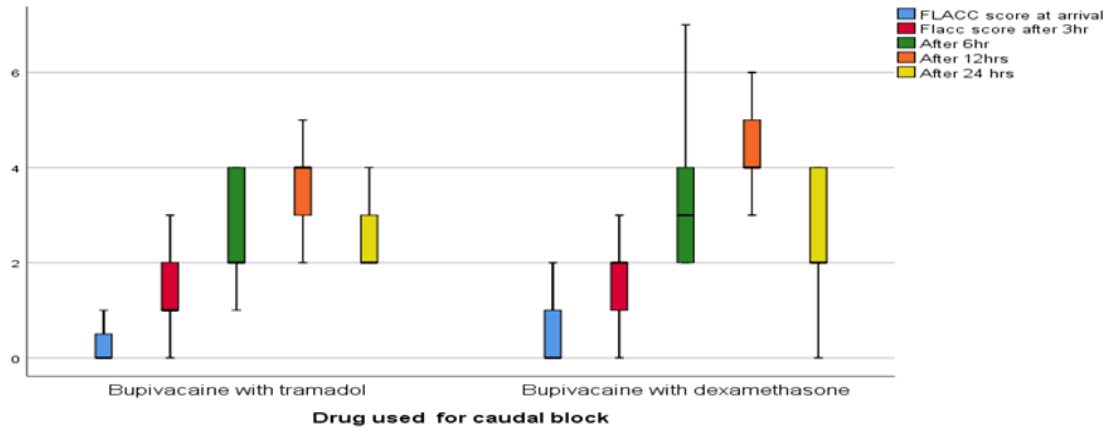

Figure II. Comparison of postoperative pain severity score between group

5.4. Duration till First Analgesia Request Time

The mean analgesia request time in the Bupivacaine-Tramadol group was (15.63 ±2.22) significantly longer when compared with Bupivacaine-Dexamethasone (14.14 ±2.12) group with a p-value of 0.029.

5.5. Total postoperative analgesia consumption between groups

We found that the median of analgesia consumption of Paracetamol was similar between groups. However, the total postoperative analgesia consumption was lower in caudal tramadol-bupivacaine 150(0-500) than caudal dexamethasone-bupivacaine group 250(150-500) which is statistically significant (p=0.009) as shown below.

Table 4. Comparison of postoperative Analgesia duration and Total analgesia consumption

	Group BT	Group BD	p-Value
Till First Analgesia Request Time(hr.)	15.63±2.22	14.14±2.12	0.029
Total analgesia consumption Acetaminophen (mg) M(IQR)	150(0-500)	250(150-500)	0.009

BT: Bupivacaine-Tramadol, Bupivacaine-Dexamethasone, M(IQR)=median and interquartile range Mann-Whitney U test & Independent T- test were used, statistically significant p<0.05.

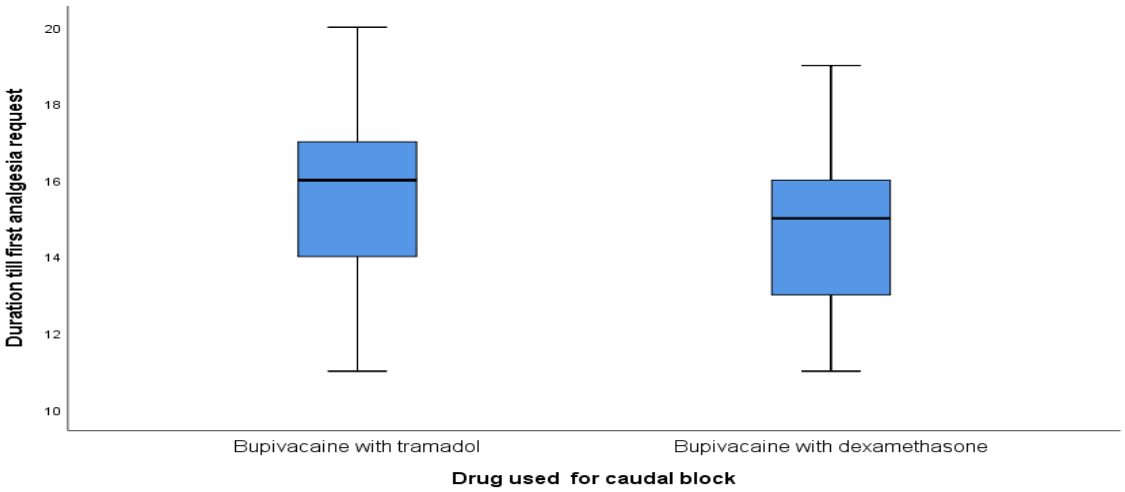

Figure III Comparison of postoperative Analgesia duration between group

5.6. The incidence of adverse effect between groups

The incidence of nausea and vomiting in the 1st 24 hours was 6.25% between groups. There was no statistically significant difference in terms of incidence of nausea and vomiting between BT and BD groups which was 2(6.25%) in each group p>0.05.

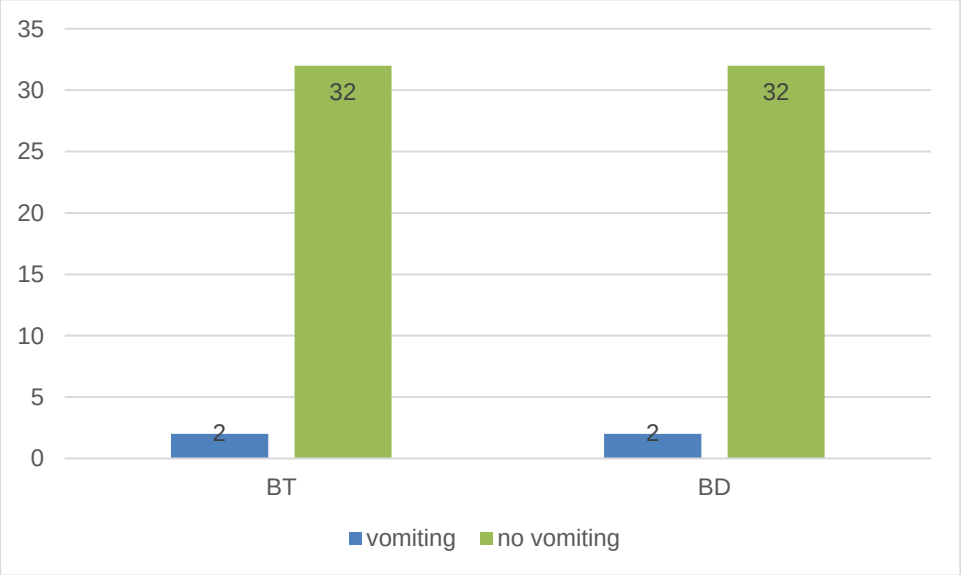

Figure IV: incidence of post-operative nausea and vomiting between groups in the 1st 24hour.

Values are presented as number, fisher exact-test was used & p<0.05 was statistically significant

6. CHAPTER SIX DISCUSSION

This study compared the effectiveness of caudal Dexamethasone with Bupivacaine and caudal Tramadol with Bupivacaine for postoperative analgesia in pediatric patients undergoing lower abdominal Surgeries.

In this study demographic data, baseline vital signs, before and after skin incision and PACU hemodynamic variables were comparable between groups. surgery and anesthesia duration were also comparable between groups($p>0.05$). our study participant also more male. this is due to the nature of infraubilical procedure that are common in male. Different studies show that lower abdominal surgery was common in male. [34, 40]

This study found that the median postoperative pain score in the BT group was comparable to the BD group at PACU, 3rd, 6th, & 24th postoperative hours.

The lack of a statistically significant difference between the groups in the early postoperative period at PACU, 3rd and 6th postoperative hour could be due to the action of caudal bupivacaine, may have persisted in both group in early postoperative period and tramadol and dexamethasone analgesic effect.

This study found that the median postoperative pain score was lower at the 6th & 12th hours in the tramadol-bupivacaine group when compared to dexamethasone -bupivacaine group. the difference was statistically significant at 12th hour between groups with(p-0.002). there is no published data yet that compare postoperative pain score between caudal tramadol-bupivacaine and dexamethasone -bupivacaine combination. however, there is a study that compares tramadol-bupivacaine to bupivacaine alone, dexamethasone -bupivacaine to bupivacaine alone, and with other additives. the result of this study was in line with RCT study seen by solanki, n., et al., in 2016 in saudi on 100 patients found that pain score was lower in the tramadol-

bupivacaine group, which was statistically significant difference in the 10^{th} & 12^{th} hours when compared with bupivacaine-fentanyl group. [39]

Another prospective cohort study was done in Ethiopia in 2020 by Angasa D., which found that the tramadol-bupivacaine group had lower pain scores at the 8^{th} and 12^{th} hours which is statistically significant (0.001,0.005) respectively when compared to Bupivacaine alone.

This study found that caudal Tramadol with Bupivacaine has a better analgesic effect as compared to caudal Dexamethasone with Bupivacaine. the mean duration of analgesia was (15.63±2.22) hours in Tramadol-Bupivacaine group and (14.14±2.12) hours in the Dexamethasone-Bupivacaine group and this result was statistically significant (p=0.029).

In contrast to this result, A prospective cohort study was done in Ethiopia in 2020 by Angasa D., et al to assess the efficacy of adding tramadol to bupivacaine. they found Tramadol combined with bupivacaine provides longer postoperative analgesia, with the median duration of 14 hours compared to 5 hours in bupivacaine alone. [40]

The possible reason is due to the drug dose of tramadol which was 1mg/kg and this study used 2mg/kg. this dose difference of Tramadol was conducted in England in children having inguinal herniotomy, caudal tramadol 2 mg/kg combination with bupivacaine provided an extended duration of postoperative analgesia and reduced the need for rescue analgesic compared to tramadol 1 mg/ kg or 1.5 mg /kg. [43]

This result was also comparable with RCT conducted in Kuwait in 2013 by Samad, R. and T.H. Shah comparing tramadol 2mg/kg vs ketamine 1mg/kg with bupivacaine. They found that Caudal tramadol with bupivacaine produced significantly increased postoperative analgesia which was 17.88± 1.96 hours in the tramadol – bupivacaine groups as compared to 12.05 ±1.63 hours in the ketamine – bupivacaine group. [17]

Another prospective, randomised controlled trial conducted in Saudi Arabia Solanki, N., et al. in 2016 to evaluate the analgesic effect of tramadol or fentanyl combined to bupivacaine for infra umbilical operations in paediatric patients. The Bupivacaine-Tramadol group got 1 ml/kg of 0.25% bupivacaine in normal saline and 2 mg/kg tramadol. These found the bupivacaine - tamadol group had a mean analgesia duration of 10-18h. [39] whereas Another RCT study that found bupivacaine with dexamethasone had a mean analgesia duration of 12-15hours. [44]

In contrast to this study result, a prospective cohort study was conducted in Ethiopia on 60 pediatric patients aged 1-14 years in 2020 by Gashaw et.al to evaluate the analgesic effect of bupivacaine conbined with dexamethasone. They reported that combining bupivacaine and dexamethasone provided longer postoperative analgesia, with a median duration of 915 minutes compared to 433 minutes with bupivacaine alone. [34]

The possible reason might be the inclusion of children of varying ages, with varying pain thresholds and the ability to express pain, could have resulted in heterogeneity in pain scores. The age range of the children in this study was 1-8 years while 1-14 years for that study.

Another RCT was conducted in India comparing the analgesic effect of bupivacaine-tramadol and levobupivacaine tramadol found that tramadol bupivacaine group was long analgesia duration 21.41 ± 6.62 hours. [42]

In terms of total postoperative analgesia consumption, we found that the median postoperative analgesia consumption was lower in caudal tramadol-bupivacaine 150(0-500) than in caudal dexamethasone-bupivacaine group 250(150-500) which is statistically significant (P=0.009). Despite the limits of existing data comparing the consumption of postoperative analgesia between caudal tramadol-bupivacaine and caudal dexamethasone-bupivacaine, a prospective cohort study was done in 2020 by Angasa D., et al to assess the efficacy of adding tramadol to bupivacaine they found lower analgesia consumption in the caudal tramadol-

bupivacaine[paracetamol 250(187.5-250)] compared to the bupivacaine alone group with p-value(0.001).[40] Similarly, Gashaw et al,. conducted a prospective cohort study in Ethiopia in 2020 to investigate the efficacy of adding Dexamethasone to bupivacaine. They observed that Dexamethasone in combination with bupivacaine reduced postoperative analgesic consumption with a median of 0(0-500) mg paracetamol compared to the bupivacaine alone 402(0-1500) group within the first 24 hours after surgery. ($p < 0.004$.) [34]

In regard to Postoperative Adverse effect, in our study there is no any reported complication during 24hours except vomiting and nausea. We observed vomiting and nausea had an incidence of 4(6.25%) in both groups. They did not utilise antiemetic drugs after surgery. this result was in line with a study conducted in Ethiopia in 2020, found that 6.7% incidence of nausea and vomiting. [34, 40]

Limitations of the study

This study did not include a cost analysis, but as already discussed Dexamethasone and Tramadol are both cheap and easily available.

Strength of study

Homoginiety of participant especially it is very important in the pain assessment of the participant.

7 CONLCUSION AND RECOMMENDATION

In this study result, a combination of caudal tramadol with bupivacaine provides longer postoperative analgesia duration when compared to a combination of caudal dexamethasone with bupivacaine. It also decreased postoperative analgesia consumption than the combination of caudal dexamethasone with bupivacaine.

There is a great variability of the duration of analgesia of the two drugs in different study, so we recommend to do further researches specially RCT.We recommend to do the cost analysis since postoperative analgesia duration increase.

8 Reference

1. Kour, L., et al., Comparison of analgesic efficacy of dexamethasone versus tramadol in combination with ropivacaine in caudal anesthesia for children undergoing lower abdominal surgeries. Anesthesia, Essays and Researches, 2020. **14**(3): p. 515.
2. Kulshrestha, A. and S.J.S. Bajwa, Management of acute postoperative pain in pediatric patients. Anaesthesia, Pain & Intensive Care, 2021: p. 101-107.
3. Burnett, G., S. DeMaria, Jr., and A.I. Levine, Regional Anesthesia and Acute Pain Management. Otolaryngol Clin North Am, 2019. **52**(6): p. 1065-1081.
4. Tutelman, P.R., et al., Epidemiology of chronic pain in children and adolescents: a protocol for a systematic review update. BMJ open, 2021. **11**(2): p. e043675.
5. Salami, O.F., et al., Effects of low-dose intravenous dexamethasone combined with caudal analgesia on post-herniotomy pain. Nigerian Postgraduate Medical Journal, 2017. **24**(4): p. 230.
6. Sathyamoorthy, M., Pediatric regional anesthesia: an Update. Current Anesthesiology Reports, 2017. **7**(2): p. 150-155.
7. Visoiu, M., Paediatric regional anaesthesia: a current perspective. Current opinion in anaesthesiology, 2015. **28**(5): p. 577-582.
8. Bennett, M., Assessing pain in children in the perioperative setting. Journal of Perioperative Practice, 2019. **29**(1-2): p. 9-16.
9. Suresh, S., D.M. Polaner, and C.J. Coté, Regional anesthesia, in A practice of anesthesia for infants and children. 2019, Elsevier. p. 941-987. e9.
10. Wiegele, M., P. Marhofer, and P.-A. Lönnqvist, Caudal epidural blocks in paediatric patients: a review and practical considerations. British journal of anaesthesia, 2019. **122**(4): p. 509-517.

11. Brown, T., History of pediatric regional anesthesia. Pediatric Anesthesia, 2012. **22**(1): p. 3-9.
12. Swain, A., et al., Adjuvants to local anesthetics: Current understanding and future trends. World journal of clinical cases, 2017. **5**(8): p. 307.
13. Kumar, P.P. and G. Madhavi, Comparison of caudal tramadol versus caudal fentanyl with bupivacaine for prolongation of postoperative analgesia in pediatric patients. 2017.
14. Xiong, C., et al., Comparison of adjuvant pharmaceuticals for caudal block in pediatric lower abdominal and urological surgeries: A network meta-analysis. Journal of Clinical Anesthesia, 2022. **81**: p. 110907.
15. Mekonnen, Z.A., et al., Prevalence and contributing factors associated with postoperative pain in pediatric patients: A cross-sectional follow-up study. Perioperative Care and Operating Room Management, 2021. **23**: p. 100159.
16. Gan, T.J., Poorly controlled postoperative pain: prevalence, consequences, and prevention. Journal of pain research, 2017. **10**: p. 2287.
17. Samad, R. and T.H. Shah, Comparison of caudal tramadol-bupivacaine and ketamine-bupivacaine for postoperative analgesia in children. J surg pak int, 2013. **18**(3): p. 548.
18. Chou, R., et al., Management of Postoperative Pain: a clinical practice guideline from the American pain society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists' committee on regional anesthesia, executive committee, and administrative council. The journal of pain, 2016. **17**(2): p. 131-157.
19. Kaye, A.D., et al., Exparel for postoperative pain management: a comprehensive review. Current Pain and Headache Reports, 2020. **24**(11): p. 1-10.

20. Chidambaran, V., S. Sadhasivam, and M. Mahmoud, Codeine and opioid metabolism–implications and alternatives for pediatric pain management. Current opinion in anaesthesiology, 2017. **30**(3): p. 349.

21. Walker, S.M., Pain after surgery in children: clinical recommendations. Current opinion in anaesthesiology, 2015. **28**(5): p. 570.

22. Fisher, E., et al., Efficacy and safety of pharmacological, physical, and psychological interventions for the management of chronic pain in children: a WHO systematic review and meta-analysis. Pain, 2022. **163**(1): p. e1-e19.

23. Eshete, M.T., et al., Quality of postoperative pain management in Ethiopia: A prospective longitudinal study. Plos one, 2019. **14**(5): p. e0215563.

24. Suresh, S., et al., Regional anaesthesia to improve pain outcomes in paediatric surgical patients: a qualitative systematic review of randomized controlled trials. British journal of anaesthesia, 2014. **113**(3): p. 375-390.

25. Chou, R., et al., Guidelines on the management of postoperative pain. J Pain, 2016. **17**(2): p. 131-157.

26. Zadra, N. and F. Giusti, Caudal block in pediatrics. Minerva Anestesiologica, 2001. **67**(9 Suppl 1): p. 126-131.

27. Suresh, S., et al., Are caudal blocks for pain control safe in children? An analysis of 18,650 caudal blocks from the Pediatric Regional Anesthesia Network (PRAN) database. Anesthesia & Analgesia, 2015. **120**(1): p. 151-156.

28. Nanjundaswamy, N.H., et al. A comparative study of ultrasound-guided caudal block versus anatomical landmark-based caudal block in pediatric surgical cases. in The Indian Anaesthetists Forum. 2020. Medknow Publications.

29. Hong, J.Y., S. Ahn, and H.K. Kil, Changes of dorsalis pedis artery flow pattern after caudal block in children: observational study using a duplex sonography. Pediatric Anesthesia, 2011. **21**(2): p. 116-120.

30. Huynh, T.M., E. Marret, and F. Bonnet, Combination of dexamethasone and local anaesthetic solution in peripheral nerve blocks: A meta-analysis of randomised controlled trials. European Journal of Anaesthesiology | EJA, 2015. **32**(11): p. 751-758.

31. Kim, E., et al., Analgesic efficacy of caudal dexamethasone combined with ropivacaine in children undergoing orchiopexy. British journal of anaesthesia, 2014. **112**(5): p. 885-891.

32. Parameswari, A., et al., Analgesic efficacy of dexamethasone as an adjuvant to caudal bupivacaine for infraumbilical surgeries in children: A prospective, randomized study. Journal of Anaesthesiology, Clinical Pharmacology, 2017. **33**(4): p. 509.

33. Fagbohun, O., et al., The efficacy of dexamethasone/bupivacaine combination versus plain bupivacaine only for caudal block in paediatric herniotomy:-a comparative study. Nigerian Quarterly Journal of Hospital Medicine, 2020. **30**(1-4): p. 011-017.

34. Gashaw, A., et al., Postoperative analgesic efficacy of caudal dexamethasone added to bupivacaine vs bupivacaine alone for pediatric elective infra-umbilical surgery at (Tikur Anbesa Specialized Hospital), Ethiopia: prospective cohort study. International Journal of Surgery Open, 2020. **24**: p. 170-176.

35. Ashfaq, S., et al., A Comparative Study on Caudal Bupivacaine with and without Tramadol for Analgesia Postoperatively in Paediatric Inguino Scrotal Surgeries. Pakistan Journal of Medical & Health Sciences, 2022. **16**(04): p. 520-520.

36. Shamsuddin, A.S., et al., Comparison of Caudal Bupivacaine and Bupivacaine-tramadol Combination for Postoperative Analgesia in Children Undergoing Lower

Abdominal Surgeries. Pakistan Journal of Medical & Health Sciences, 2022. **16**(03): p. 1129-1129.

37. Amitha, S., V. Metri, and T. Mahadevaiah, A comparative clinical study between clonidine and tramadol with bupivacaine in caudal epidural for postoperative analgesia in pediatric surgery. Anesthesia, Essays and Researches, 2019. **13**(2): p. 389.

38. Rad, R.F., et al., Postoperative Pain Management: Efficacy of Caudal Tramadol in Pediatric Lower Abdominal Surgery: A Randomized Clinical Study. Anesthesiology and Pain Medicine, 2021. **11**(4).

39. Solanki, N., et al., Comparison of caudal tramadol versus caudal fentanyl with bupivacaine for prolongation of postoperative analgesia in pediatric patients. Saudi Journal of Anaesthesia, 2016. **10**(2): p. 154.

40 Angasa, D., et al., Postoperative analgesic efficacy of caudal tramadol added to bupivacaine compared to bupivacaine alone for pediatric elective infra umbilical surgery at Tikur Anbessa Specialized Hospital, Ethiopia, a prospective cohort study. International Journal of Surgery Open, 2020. **27**: p. 32-38.

41 Abd-Elshafy, S.K., et al., A new look on adding dexamethasone as an adjuvant to caudal bupivacaine; efficacy on postoperative pain and vomiting in pediatric patients. Pain physician, 2016. **19**(6): p. E841.

42. Girwalkar-Bagle, A., W. Thatte, and S. Choudhari, Preemptive caudal anaesthesia in children with bupivacaine-tramadol and levobupivacaine-tramadol: a randomized, double-blind, prospective study. Anaesthesia, Pain & Intensive Care, 2019: p. 13-19.

43. Prakash, S., et al., Efficacy of three doses of tramadol with bupivacaine for caudal analgesia in paediatric inguinal herniotomy. BJA: British Journal of Anaesthesia, 2006. **97**(3): p. 385-388.

44. Nilesh, M.S., et al., Enhancement of bupivacaine caudal analgesia by using dexamethasone or clonidine in children undergoing subumbilical surgery. Ain-Shams Journal of Anaesthesiology, 2016. **9**(2): p. 274

Annex I: 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 And tramadol with bupivacaine for Pediatric undergoing lower abdominal Surgery in TASH, From December 1, 2022 to February 30, 2023 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. I am anesthesia provider. We are doing study on caudal block in pediatric under going lower abdominal surgery. you are kindly requested to your child to participate in this study. If you are willing for your child to participate in this research on postoperative analgesic efficacy of caudal dexamethasone added to bupivacaine or tramadol added to bupivacaine. I obtained the child name from the list of operation for surgery. Participation is voluntary. We strictly keep confidentiality. This observation will be for 24 hours. So, 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 ….

A) Agree

B) Disagree If agrees, the observation will be started.

Annex I: 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 ልጆዎን 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 ከ Tramadol ወየም bupivacaine ከ dexamethasone) ሲቀላቀል)ለህመም ማስታግሻ ለምን ያክልጊዜ እንደሚቆያ ለማዎቅ በጥቁር አንበሳ ልዩ የማስተማሪያ ሆስፒታል ከመጋቢት አንድ እስክ ግንቦት ሰላሳ ድረስ ከእነብረት በታች ባለዉ የሰውነት ክፍል ለቀዶ ህክምና የሚመጡ እዲሜያቸው ከ1 እስከ 8 ያሉ ህፃናትን ለሃያ አራት ሰአት ወደፊት የህመም መጠን፣የመስታገሻ የሚጠይቁበትን ጊዜ ፣ምን ያህል የማሰታግሻ መድሀኒት በሃያ አራት ሰአት እነድተጠቀሙ እንዲሁም የማስታዎከ፣የማስመለስ መኖር መከታተል ሲሆን ልጅዎን ለመሳተፍ የእርስዎን ፍቃድ ግድ ነው፡ ፡ መሳተፍ በፍላጎት ብቻ ነው፡፡ስለዚህ ስምምነትዎን በአክብሮት እንጠይቃለን፡፡ የጥናቱን አላማ እንደሁም የኔን ሃለፊነት ተረድቻለሁ ሰለዚህ ልጀ እንዲሳተፍ

ሀ) ፈቅጀለሁ

ለ) አልፈቅድም

ከፈቀደ ክትትሉ ይጀመራል፡፡

Annex III: Pain Assessment Tool

Table-I

FLACC scoring system Chart.

Face

0-No particular expression or smile

1-Occasional grimace or frown, withdrawn, disinterested

2-Frequent to constant quivering chin, clenched jaw

Legs

0-Normal position or relaxed

1-Uneasy, restless, tense

2-Kicking, or legs drawn up

Activity

0-Lying quietly, normal position, moves easily

1-Squirming, shifting back and forth, tense

2- Arched, rigid or jerking

Cry

0-No cry (awake or asleep)

1-Moans or whimpers; occasional complaint

2- Crying steadily, screams or subs, frequent complaints

Consolability

0. Content, relaxed

1. Reassured by occasional touching, hugging or being talked to, distractible

2. Difficult to console or comfort

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.

ANNEX IV 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 vs Caudal tramadol Added to Bupivacaine for Pediatric undergoing lower abdominal Surgery in TASH, From February to April 30, 2023 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	A. MALE B. FEMALE	

Section II: Data During Pre and Intraoperative Period

Serial no.	Question	Response	Code
201	Diagnosis		
202	Procedure		
203	Base line heart rate	--------BPM	
204	Base line blood pressure	--------/---- Spo2…….	
205	Premedication, induction & maintenance	-------/----------/------- --------/---------/-------	

206	Time of caudal block	--------	
207	A drug used for the caudal block?	1. bupivacaine with tramadol 2. bupivacaine with dexamethasone.	
208	Vital sign before skin incision? 10’ after caudal block	HR ------ BP----- Spo2	
209	Vital sign after skin incision? 10’ after skin incision	HR----- BP------ Spo2	
210	Duration of surgery	------	
211	Duration of anesthesia	----------	

Section III Post-Operative Observation Vital sign at recovery room

Vital sign	Arrival time	At 20min	40min	60min
HR				
BP				
FLACC SCORE				
ANALGESIA GIVEN				

Ward follow up for 24

Se..no,	Time-----	At arrival	After 3hr	After 6hr	After 12hr	After 24hr
301	Flacc 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. 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 with in the first 24 hours of surgery?

A. YES

B. NO

402. Does the patient develop vomiting with in first 24 hours of surgery?

A. YES

B. NO

403. Does the patient develop any other complication other than the above?

A. YES

B .NO