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DEPARTMENT OF ANESTHESIA

COMPARISION OF CAUDAL BUPIVACAINE ALONE, CAUDAL COMBINED WITH RECTAL DICLOFENAC AND RECTAL PARACETAMOL FOR POSTOPERATIVE ANALGESIA IN PEDIATRICS PATIENT UNDERGOING INFRAUMBILICAL SURGERY AT TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDID ABABA, ETHIOPIA 2018/2019.

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DECLARATION

I, the undersigned and declare that the thesis entitled comparison of caudal alone, caudal combined with rectal diclofenac and rectal paracetamol postoperative analgesia effectiveness in pediatric patient undergoing inframbilical surgery at tikur anbessa specialized hospital, Addis Ababa, Ethiopia 2018/2019. 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

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Approval of Examiners

This thesis work has been submitted for examination with my approval as advisors on the master‘s degree in in advanced clinical anesthesia course.

Advisor

Name _____ Signature _____ Date _____

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ACRONYM

ASA- American Association of Anesthesiologists

AU- Addis Ababa University

BP- Bupivacaine combined with rectal paracetamol

BD- Bupivacaine combined with rectal diclofenac

CA- Caudal alone

CB -Caudal Block

CD- Caudal combined with rectal diclofenac

CP- Caudal combined with rectal paracetamol

CHEOPS-Children's Hospital of Eastern Ontario Pain Scale

CI-Confidence Interval

FDA- Food and drug agency

FLACC-Face Legs Activity Cray Consolable

FMOH- Federal Ministry of Health

IASP- International Association Study of Pain

IQR- Inter Quartile Range

IRB- Institutional Review Board

LMA- laryngeal mask airway

MOPS- Modified Objective Pain Score

NGO- Non-Governmental Organization

NRS- Numeric rating scale

PACU: -Post anesthesia care unit

PI-principal investigator

PONV- Postoperative Nausea and Vomiting

POP- Postoperative Pain

RCT- Randomized Control Trial

SD –Standard Deviation

TASH - Tikur Anbessa Specialized Hospital

WHO- World Health Organization

ABSTRACT

Background: Despite limited duration of action, different additives are used to improve effectiveness of caudal block with some associated side effects. Combining rectal diclofenac and paracetamol to caudal block also enhance effectiveness of analgesia with devoid of side effects.

Objective: To assess postoperative analgesic effectiveness of caudal bupivacaine alone, caudal bupivacaine combined with rectal Diclofenac and rectal paracetamol in pediatric patients undergoing elective infra-umbilical surgery.

Methodology: An institutional based prospective cohort study design was conducted on 90 patients who assigned randomly into three equal groups aged 1- 10 years. Data collection methods include preoperative chart review, intraoperative and postoperative observation by trained nurses and one supervisor. The primary endpoint of the study was pain score. The secondary endpoint of the study was duration of analgesia, postoperative analgesia consumption and adverse effects during 24 hour follow up period. Parametric data were analyzed using (ANOVA) and non-parametric data using Kruskal-Wallis H rank test. Chi-square test used for categorical variable. *P* value < 0.05 considered as Statistical significance.

Result: The postoperative NRS/FLACC score were lower in both CP and CD group than CA with p value < 0.001 at 4^{th} and 8^{th} hour. Furthermore, Time to first analgesic request was significantly longer within Bupivacaine+Diclofenac 735 (540 - 1200 min) compared to paracetamol 445(240 - 840 min p=0.029) and caudal alone 315(240 - 720 min p<0.001).

Conclusion and Recommendation: combination of caudal+diclofenac reduce pain score and provide longer duration of analgesia than both caudal combined with rectal paracetamol and caudal alone in patients undergoing infra umbilical surgery. Based on these we recommend to use caudal+diclofenac combination for infra umbilical procedures to provide effective analgesia.

Key words; Caudal block, Rectal paracetamol, Rectal diclofenac, infra umbilical surgery.

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CHAPTER-1 INTRODUCTION

1.1 Background

Postoperative pain is considered a form of acute pain due to surgical trauma with an inflammatory reaction. It is a combination of several unpleasant, sensory emotional and mental experience precipitated by the surgical trauma and associated with autonomic, endocrine metabolic, physiological and behavioral responses. (1)

Several degree of post-surgical pain is expected after most surgical procedures with variable extent among individuals undergoing similar surgery. Generally, more extensive surgical procedures are associated with greater acute pain. Post-surgical pain is inflammatory by nature which is consequence of peripheral tissue damage due to surgery and it is temporary, subsiding rapidly or persisting only until the healing process is complete.(2)

In a survey study done on postoperative pediatric pain management in Thailand, the prevalence of pain during 24 hours postoperative period was 69.2% but those who had moderate to severe pain was 43.6% .(3)

Developing countries those who have limited resources setting gives little attention to pain management. (4) Based on the study done in Ethiopia which assessed practice and outcome of postoperative pain management also reported the pain incidence was 91.4% & of those 80% of patient under treated among surgical patients.(5)

In pediatrics, caudal block is a common regional technique performed under general anesthesia to provide intraoperative and postoperative analgesia for infra umbilical surgery including lower abdomen, urogenital, orthopedic and peri anal procedures. (6)

Good pain relief with minimal physiological disturbance is important for postoperative pain management. Opioids are effective analgesic for postoperative pain but they are commonly associated with respiratory depression, itching, nausea and vomiting. (7) Its believed that provision of preoperative administration of rectal diclofenac and rectal paracetamol has no any adverse effects on respiratory and gastrointestinal system.

However caudal block has no related safety concern, side effects such as nausea, vomiting, urinary retention, dural puncture, motor blockage and sedation was observed (8). And also the overall incidence of neuraxial complications was 0.7% and a failure rate of 2% in caudal blocks was reported. (9)

Caudal catheter may be used to provide continuous supplementation of analgesia during peri-operative period for infra umbilical procedures in children, but affect postoperative mobility or carry risk of infection. (10)

The adaptation of multi modal analgesic technique as the standard approach for prevention of pain in surgical patients as one of routine protocol to improving the healing process. Administering a combination of anti-pain medication before surgery is one main component of multi modal approaches. Preoperative administration of rectal diclofenac and rectal paracetamol to block cyclo oxygenase synthesis and to reduce postoperative pain intensity as well as to prolong analgesia duration of caudal block. (11)

Therefore it should be beneficial to practice multi modal analgesia by using combination of caudal block with rectal diclofenac and rectal paracetamol that have superior pain control effect, longer duration and less postoperative analgesia consumption as well as does not have adverse effects during intraoperative and postoperative period. (12)

1.2 Statement of the Problem

Pain is the most terrifying symptom during postoperative period. According to international association of pain society, Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"(13).

As a declaration of Montreal despite, "Access to Pain Management is a Fundamental Right", 80% of people worldwide do not receive adequate treatment for pain. Among those two-thirds of patients complained of moderate to severe pain in the first 24-hour postoperative period. (14). Based on a large scale survey done in 2005, 40% of pediatric surgical patients experienced moderate or severe postoperative pain and 75% of them had insufficient analgesia. (15)

Based on 2019, prospective longitudinal study done in Ethiopia on quality of postoperative pain management, the prevalence of moderate to severe postoperative pain was 88.2%, of those 58.4% was inadequately treated. This study also report 53.7% of analgesic agents was prescribed by surgical resident followed by surgeon 43.3% and only 0.3% was prescribed by the anesthesiologist which determines the destiny of pain management and among prescribed drugs the dominant one was Tramadol (93%). (16)

Pain in early life causes structural changes in cortical and sub cortical pathways. Specifically, peri operative pain can cause stress. Therefore, analgesia modulates long-term effects of pain in early life (17, 18).

Pain in pediatric patients is usually underestimated and under treated. Because of acute postoperative pain is commonly treated with simple analgesics that often are not very effective and frequently are used at lower doses than would be optimal (19)

That untreated pain may have long-term negative effects on pain sensitivity, immune functioning, neuro physiology, attitudes and health care behavior (20).

However, inadequate controlled postoperative pain remains a widespread problem, provision of postoperative analgesia has given low priority compared to the treatment of infectious diseases (21).

Despite pain management requires a self-report, it's common to observe poor postoperative pain management in pediatrics surgical patients in the presence of different available approaches used to provide effective peri operative analgesia that ranges from oral medication up to invasive epidural (22).

In the management of postoperative pain after infra umbilical procedures various types of additives such as opioid, a2 agonist, ketamine and neostigmine combined with local anesthetic agents are known to improve quality and duration of analgesia. But, associated adverse effects limit their clinical importance and above all FDA not yet approved and licensed those additives to be administer in caudal route. (23).

Especially in Ethiopia there are multiple barriers which limit the access to effective analgesic medication due to economic and accessibility related problem, using newly emerged drugs are too challenging.

Adequate postoperative pain management not only minimizes patient suffering but also can reduce morbidity and facilitate rapid recovery and early discharge from hospital, which can reduce hospital costs (24) Therefore, early diagnosis, monitoring and treatment of pain in children has an invaluable importance.

1.3 Justification of the Study

A single shot caudal block is provided for different infra umbilical surgical procedures in pediatric patients, despite its limited duration of action.

However, alternative methods of improving efficacy of caudal block not valid yet. Different studies were done on analgesic effect of caudal block combined with rectal diclofenac and rectal paracetamol particularly in different population but there is an individual variability in pain perception, recognition and assessment is affected by social, cultural, cognitive, religious and genetic factor (25).

Also, cultural expectations and social norms are given to children by their parents may influence reports of pain (26)

Even though the effect of rectal diclofenac and rectal paracetamol combined with caudal block to improve quality and duration of analgesia by many investigators in many countries , there is a difference in population as well as hospital setup in TASH and this may results in different out come from the study done before.

The presence of a controversy regarding the intensity to reduce pain score. Some study shown rectal paracetamol and rectal diclofenac combined with caudal bupivacaine have comparable effect with caudal alone. (27-29) contrarily, other studies confirm superior effect of caudal combined with rectal paracetamol and rectal diclofenac to reduce intensity of pain compared to caudal alone (30-31)

As far as my knowledge and search in our country there is no similar research done and there is no published evidence on the same topic in the same area. So that, it can be used as a source of information for further researchers and a sole input to the literature.

This study is also helpful for program planners and policy makers so as to devise different strategies which help to improve post-operative analgesia of caudal block.

CHAPTER-2

LITERATURE REVIEW

Based on a large scale survey done, moderate to severe pain experienced in 40% of hospitalized pediatric surgical patients in post-operative period. (32)

However, pain requires a self-report, pediatrics patient during infancy and early childhood are unable to express pain which contributes for the failure to recognition and treatment of pain aggressively. (33)

2.1 Incidence of failure rate and complications of caudal block.

Based on multi center prospective observational study done by Polaner D. et.al in 2012 among 13,725 CB performed between 2007 and 2010 in children who undergoing infra umbilical procedures, the incidence of neuraxial complications was 0.7% and 2 % failure rate was reported. (34)

According to an analysis of 18,650 CB from the pediatric anesthesia network database as reported by Santhanam set.al in 2015, safety concern should not be a barrier to use CB. Since proper dosage of local anesthetics are titrated. (35).

Hemodynamic changes following surgical incision determines a success or failure rate of CB. Hemodynamic stability as indicated by the absence of an increase in HR or SBP of more than 20% from the baseline values measured before incision. (36)

2.2 Effect of Diclofenac

Diclofenac is available in a parenteral, oral and rectal formulation. It is absorbed rapidly and reaches peak plasma concentrations in 10–30 minutes. Rectal route is safe and a convenient in children above 6 months of age providing early onset and long duration of postoperative analgesia. (37 - 38)

Preoperative administration of diclofenac is necessary in order to get immediate optimal postoperative effect. Because, timing of administration to block prostaglandin which sensitizes peripheral pain receptors to noxious stimuli is necessary. (39)

Diclofenac in suppository alone or in combination with other drugs provide excellent preoperative and postoperative analgesia.

Furthermore RCT done in 2012 by Adarsh ES, et.al explained it's free of opioid like side effects such as vomiting, nausea, respiratory depression, itching, decreased gastrointestinal motility, tachycardia, physical dependency and hemodynamic instability. (40)

Based on cross sectional study done on 160 pediatric patients in 2017 by Aleena Hussain, et.al who underwent inguinal hernia repair intramuscular and rectal diclofenac has comparable postoperative analgesia effects. Rather suppository route were preferred in pediatrics due to its longer duration of action, less prone to injury, easy to administer and safer. (41)

According to late study done by V. Gadiyar.et.al in 39 pediatric patients undergoing inguinal or penoscrotal surgery who received 0.125% of 1 ml/kg CA versus who received 0.125% of 1 ml/kg of caudal bupivacaine combined with 1mg/kg rectal Diclofenac, the need for postoperative analgesia, in the form of paracetamol, was significantly greater in the children of CA group which more than 1 times while CD group needs only once & pain score between groups were comparable in 24 hour postoperative period (28).

According to prospective RCT done B.Kanchanamala, V.J. Karthik on 90 children found that FLACC pain score at 30 minutes, 1, 2, 3, 4 and 5 hour during postoperative period was comparable between 0.25% 0f 1mg/kg caudal bupivacaine combined with 1mg/kg rectal diclofenac was comparable with 0.25% 0f 1mg/kg caudal bupivacaine alone. But, the mean duration of analgesia observed was lower in caudal alone group 4.5 hrs. Compared to 7.5 hrs. Caudal + diclofenac with $p>0.05$. (29)

Another 2008 prospective randomized trial study conducted in 60 pediatric children by Neeru Gupta et.al at India using 0.25% of 0.5 ml/kg caudal bupivacaine alone and 0.5ml/kg of 0.125% of caudal bupivacaine combined with 1mg/kg rectal diclofenac the duration of analgesia, were (8.2±1.8, 13 ± 3.3 hr.), number of analgesia doses (1.95 ± 0.44, 1.2 ± 0.5 in the CA & CD group respectively. Pain score were lower in CD than CA group at 30min, 60min, 3hr, 6hr and 12 hr. & incidence of POVV were 10% in both group (31).

Similarly, a prospective RCT done by Harsh et.al in 2016, among 25 children receives 1 ml/kg of 0.125% caudal bupivacaine combined with 2.5 mg/kg rectal diclofenac provides analgesia up to 24 hour in postoperative period with minimum side effects and lesser incidences of nausea and vomiting, sedation, time taken to void urine.(42)

2.3 Effect of paracetamol alone and combined with caudal bupivacaine

Paracetamol is easily available in different route. The mechanism of action is through blocking pain impulse at the level of the spinal cord by its action over NMDA receptors. Oral and per-rectal routes of administration are convenient. The side effects of paracetamol are not usual and not serious and paracetamol also has no risk of addiction. (43)

Even though, according to 2012 study conducted in Egypt high dose rectal paracetamol 40 mg/kg provide comparable postoperative analgesia with 0.25% of 1 ml/kg caudal bupivacaine for children under going circumcision. *(44*) ***Eva Kokinsky*** **and** ***Eva Thornberg*** study conducted in Sweden on post-operative pain control, prevention of the expected postoperative pain by administration of adequate doses and combinations of analgesics, together with pain assessment and the use of local and regional blocks is the best way to minimize postoperative pain. (45)

Another prospective RCT done by *L. Raghavan1, K. R. Padmanabhan in 2016 for* pediatric patient undergoing sub-umbilical surgeries; the Post-operative analgesic duration is significantly higher in caudal 0.25% Bupivacaine 1 mL/kg combined with 20 mg/kg rectal paracetamol (353±6.0 minutes) than the 0.25% caudal bupivacaine alone group (253±3.9 minutes) with p value < 0.0001. Furthermore. FLACC pain score, at all post-operative intervals up to 7 hours were significantly lesser in paracetamol group than caudal alone. Moreover the incidence of post-operative nausea and vomiting is 33% in control group and 0% in paracetamol combined with caudal bupivacaine group & The Mean Rescue Analgesic time in rectal paracetamol group is and in the control Group C with significant association, $p<0.0001$. (30)

2.4 Comparison of diclofenac and paracetamol combined with caudal bupivacaine

Preoperative rectal diclofenac administration lower the incidence of restlessness and crying as well as postoperative analgesia consumption compared to paracetamol with p value <0.05. (46) Similarly, prospective RCT done by Ketaki Patwardhan.et.al in 2014 which compares rectal paracetamol versus rectal Diclofenac for pediatric patients undergoing minor surgeries postoperative pain scores in patients who received rectal Diclofenac are better as compared to those in the paracetamol group, $p<0.05$. (47)

As prospective RCT done by T. Nnaji in 2017 at Nigeria in pediatric patients undergoing inguinal hernia repair found lower mean FLACC pain score at 4^{th}, 8^{th}, 16^{th} and 20^{th} hour in

caudal+diclofenac combination group compared to caudal + paracetamol and caudal alone group with p <0.001.The duration of analgesia was prolonged in CD (12.93 ± 4.46 h) compared to CP (7.75 ± 3.12 h) and CA (6.43±2.94 h), which was statistically significant (p=0.01). (12).

Current study carrier out at Iran in 2018 shows the comparative effects of incision site infiltration and caudal block in terms of pain intensity effects, time request to first analgesia and total analgesia consumption within 24 hours. (48)

Another studies also agreed on as combination of caudal+ rectal paracetamol and caudal+diclofenac enhance analgesia duration with various ranges infiltration with rectal paracetamol and rectal diclofenac also enhance analgesia effectiveness. (49_50)

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CHAPTER-3 OBJECTIVE OF THE STUDY

3.1 General Objective

To compare postoperative analgesic effectiveness of caudal alone, caudal combined with rectal diclofenac and caudal combined with rectal paracetamol in pediatric patients undergoing infra umbilical surgery at TASH, Addis Ababa, Ethiopia, from January, 2019 to April, 2019.

3.2 Specific Objective

- To compare postoperative pain severity using NRS/FLACC score among three groups
- To compare time to request first analgesic in minutes among three groups
- To compare total analgesia consumption among three groups
- To compare incidence of adverse effects among three groups.

Hypothesis Testing

Ho1: -There is no difference in the severity of postoperative pain between exposed and non – exposed groups.

Ha1: -There is difference in the severity of postoperative pain between exposed and non – exposed groups.

Ho2: -There is no difference in the time to first analgesic request between exposed and non-exposed groups.

Ha2: - There is difference in the time to first analgesic request between exposed and non-exposed group.

Ho3: -There is no difference for the total analgesic consumption in the first 24 postoperative hours between exposed and non-exposed groups.

Ha3: -There is difference for the total analgesic consumption in the first 24 postoperative hours between exposed and non-exposed groups.

$H_0$4: There is no difference in the incidence of adverse effects between the groups.

H_a4: There is difference in the incidence of adverse effects between the groups.

CHAPTER-4

STUDY METHODOLOGY

4.1 **Study Setting**

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

4.2 **Study design and period**

Institutional based prospective cohort study design was employed at Tikur Anbesa Specialized Hospital from January, 2019 to April, 2019.

4.3 **Study Population**

4.3.1 **Source Population**

All pediatric patients scheduled for infra-umbilical surgery at Tikur Anbesa Specialized Hospital from January, 2019 to April, 2019.

4.3.2 **Study Population**

All pediatric patients underwent infra-umbilical surgery under caudal bupivacaine combined with rectal diclofenac and rectal paracetamol at Tikur Anbesa Specialized Hospital from January, 2019 to April, 2019.

4.4 **Eligibility Criteria**

4.4.1 **Inclusion criteria**

- Elective infra umbilical surgery those who were receive caudal block.
- ASA I and ASA II.
- Pediatric patents age from (1-10).

4.4.2 **Exclusion criteria**

- Failed Caudal Block
- Known allergy to both paracetamol and diclofenac
- Concentration other than 0.25% bupivacaine for caudal.
- Dose other than 1ml/kg bupivacaine
- Other additive added
- Day case surgery

4.5 **Study Variables**

4.5.1 Dependent Variable

- Postoperative Pain severity
- Time to first analgesic request in minutes
- Total Analgesia consumption
- Incidence of adverse effect (nausea vomiting)

4.5.2 Independent Variables

Socio demographic variable

- Age
- Sex
- Weight
- ASA status

Intraoperative variable

- Procedure
- Pre medication
- Induction
- Duration of surgery
- Duration of anesthesia
- Drug used (caudal alone, caudal-diclofenac & caudal-paracetamol)

Hemodynamic variable

- Pulse rate
- Blood pressure

4.6 **Sample size and sampling procedure**

4.6.1 **Sample size**

The outcome measure of our study was to compare pain severity by NRS/FLACC score, time to first analgesic request, total analgesic consumption and incidence of adverse effects between groups after the surgery within 24 hours.

Sample size estimation were determined based on largest sample size used and calculated by using a priori power analysis (G Power version 3.1.9.2) based on the results of a similar study performed by T Nnahji, et.al (12) in Nigeria by taking first analgesia request time: (12.93 ± 4.46 h) in caudal+diclofenac, (7.75 ± 3.12 h) in caudal+ paracetamol and (6.43±2.94 h) in caudal alone group and pooled standard deviation would be 3.42. Controlling for the probability of a Type I error at alpha = 0.017(the alpha level was reduced using a Bonferroni correction, 0.05/3 = 0.017, to allow for comparisons of both exposed group with the non-exposed group), a sample of 31 subject per group would have 80% power to detect a difference between groups.

The calculated sample size was 84; by adding 10%, attrition rate and assuming balanced design the total sample size was 93.

Systematic random sampling technique was used to select study participants on daily operation schedule list. Situational analysis was done in the study area depending upon average values of the previous surgery per 3 months on the log book, 189 patients were operated on pediatric elective infra-umbilical surgery under caudal block.

The sampling interval k was determined by using the formula: k=N/n; where, n = total sample size, N = population per 3 months.93 participants was recruit with the probability of about 49.2%. Patients were sorted by listing infra-umbilical surgery consecutive.

Therefore, the sampling interval is 2 and the first study participant (random start) was selected using lottery method after which data collector recruited 1 patient for every 2 consecutive patients undergone Infra umbilical surgery grouping based on patients who received caudal block was divide into three groups based on exposure status.

4.6.2 **Sampling procedure**

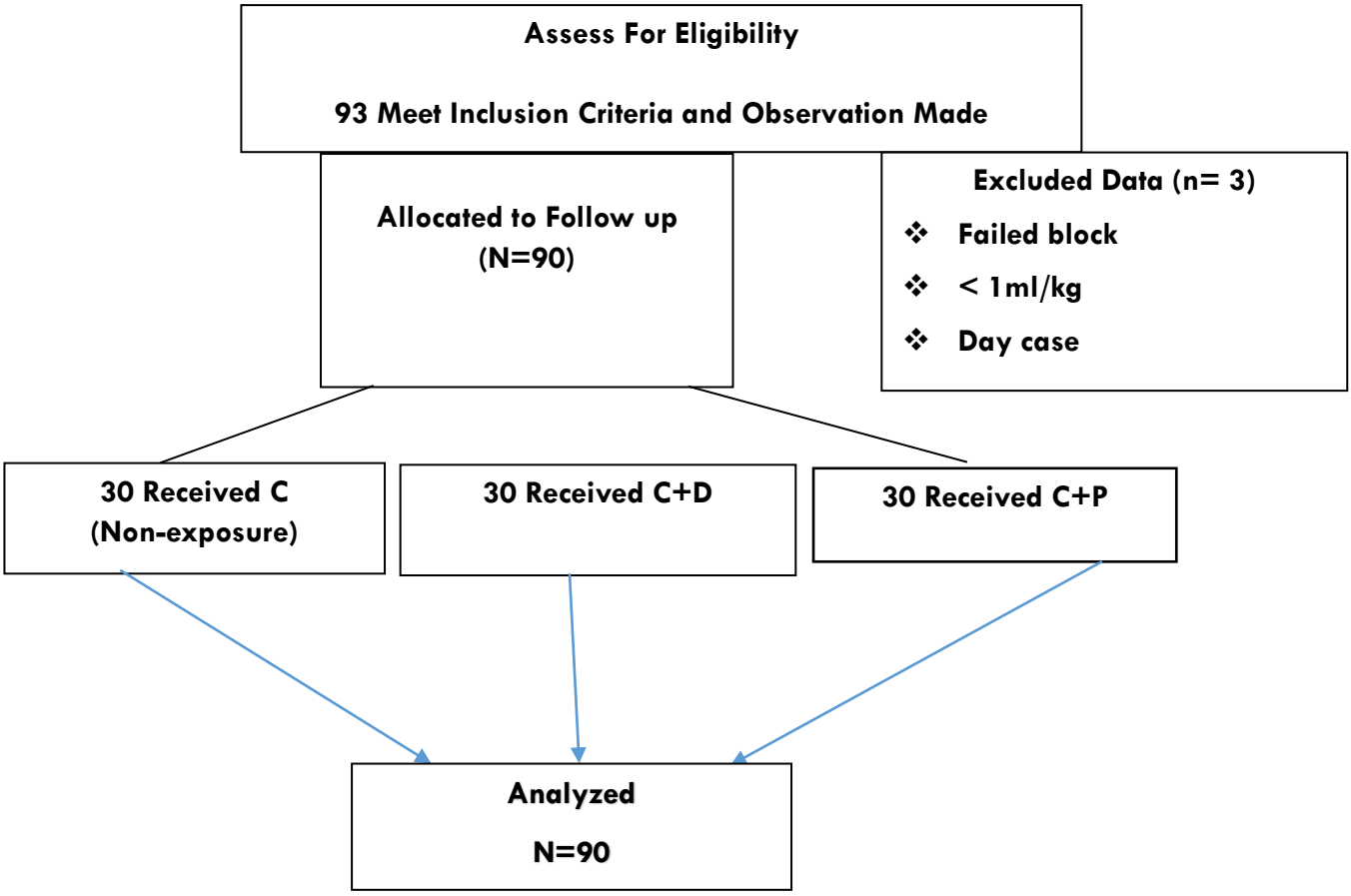


Figure 1; Enrollment chart for patients scheduled for infra-umbilical surgery.

4.7 **Data Collection Tool and Procedures**

After providing training for data collectors, data was collected using pretested questionnaires with multiple close-ended questions. Volunteer families whose child to take part in the study were assessed before surgery by history taking, physical examinations and chart review following informed consent was taken from family. On the morning of the surgery data collector instructed the patient whose age was > 5 on how to self-report pain using the eleven point NRS score (0 to 10) and <5 years was assessed by FLACC score.

All pediatric patients who were included in the study were ASA I/II. On arrival of the patients to the operation theater, and after application of the routine monitoring protocol, including pre-cordial sthetescope, noninvasive blood pressure, and SPO2 were recorded, and general anesthesia was induced by either Propofol/ketamine and after airway was secured by

either laryngeal mask airway or endotracheal intubation. Maintenance anesthesia was used by either Halothane or Isoflorane.

In the study institution provision of intraoperative and postoperative analgesia for infra umbilical procedures was done by 0.25% of 1ml/kg caudal bupivacaine alone, 0.25% of 1ml/kg caudal bupivacaine+Diclofenac(1mg/kg) and 0.25% of 1ml/kg caudal bupivacaine +paracetamol(30mg/kg) combination based on the body weight of child. Patients who receive other than this dose and concentration were excluded.

Baseline vital signs, Induction, incision and CB time were documented. Pre-incision vital signs were measured 10 minutes after the block just before skin incision. Post incision vital signs were measured 10 minutes after skin incision, then, Ability to Maintained value as compared to values before incision indicates a successful block. If the CB was considered unsuccessful those children were given analgesia and excluded from the study.

Caudal block was done based on landmark technique. Once the airway was secured the child is turned onto lateral decubitus position, using strict aseptic technique and the key anatomic landmarks on the sacrum are identified by palpation, the needle is advanced through the sacral hiatus in the mid line between the cornea at a 60°-45° and after the needle pops through the sacrococcygeal ligament, the needle-to-skin angle is reduced so that the needle is advanced 2–3 mm into the caudal space parallel to the spinal axis. The angle of the needle is then flattened and advanced Aspiration for blood and CSF is performed and if negative, injection can proceed. Afterward, either rectal diclofenac 1mg/kg or rectal paracetamol 30mg/kg was administered based on assigned group.

Intraoperative data including CB time and hemodynamic response was collected by anesthetists while postoperative data was collected by four nurses those who got training and the PI was supervised the completeness of the data daily. Vital signs were recorded on admission to PACU and then every 20 minute till the patient was discharged to the ward. FLACC/ NRS scale were used to assess postoperative pain, based on age of patients. Score of greater than 3 indicated pain. Those children were given rescue analgesia. Patients were observed by trained nurses & pain score was documented at PACU, 2nd, 4th, 8th, 12th and 24th postoperative hour. Analgesic consumption, analgesia duration and adverse effects were documented when it was reported within 24 hours during post-operative period.

4.8 **Data quality control and assurance**

Data collectors was trained by principal investigator and pretest was done at Dagmawi Minilik hospital on 9(10% of sample) respondents (3 CA, 3 CP and 3 BD group) who underwent Infra umbilical surgery under CB, which were not included in the main study. During data collection regular supervision and follow up was made appropriately. Data was cross-checked for completeness and consistency every day. All materials used for data collection were arranged sequentially and store in safe and secure place.

4.9 **Data Analysis and Interpretation**

The statistical analysis were performed using SPPS 20 Version software. The data were tested for normality using Shapiro - Wilk test. Homogeneity of variance by Levene's test. Analysis of variance (ANOVA) were used for normally distributed data and Kruskal - Wallis H test used for non-normally distributed or non-parametric data. If these ANOVA and Kruskal - Wallis H test were significant, Tukey post hoc test was used to compare difference between groups one with the others.

Categorical data were analyzed by using the Pearson Chi-squared test with post hoc as required. Data was expressed as a mean and standard deviation (SD) for normally distributed and median (Q1-Q3) for non-normally distributed. A p value < 0.05 considered as statistically significant.

4.10 **Ethical consideration**

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

4.11 **Dissemination Plan**

The results of the study will be presented to the department of anesthesia as part of M.Sc. in advanced clinical anesthesia thesis, communicated through annual students and staff research conference, annual National conference of Ethiopian Anesthetists Association (EAA) and will be send to journals for publishing.

4.12 Terms and Definitions

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

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

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

FLACC scale: is a measurement used to assess pain for children between ages two months and five years or individual that are unable to communicate their pain going to score. (51)

In patients who are asleep: observe for 5 minutes or longer. Observe body and legs uncovered. If possible, re position 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. Re position patient or observe activity. Assess body for tenseness and tone. Initiate consoling interventions if needed.

- 0: relaxed and comfortable
- 1–3: mild discomfort
- 4 –6: moderate pain
- 7–10: severe discomfort or pain or both.

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 (52).

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

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

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

CHAPTER- FIVE; RESULT

5.1 Demographic and baseline anesthetic characteristics Data

During the study period total of 90 (30 each group) patients were included for final analysis. The demographic and baseline patient characteristics were comparable for all three group with no statistical difference. Majority of study participant were male due to higher incidence of urogenital procedures are confined to male gender. But, there is no significant statistical difference between groups.

Variables	Group CA	Group CP	Group CD	P-value
Age (year) *	4.96 ±2.3	4.63±2.25	4.46±2.26	0.97
Gender (M /F)#	21/9	19/11	23/7	0.530
ASA I / II #	26/4	27/3	25/5	0.749
Weight(kg)*	13.96±2.63	13.46±2.69	14.1±2.34	0.769
Baseline Heart Rate	129±10.49	131±11.38	133.5±11.93	0.827
Baseline MAP	60.17±5.37	63.96±3.4	62.97±4.13	0.231
Atropine pre medication	16/14	18/12	20/10	0.574
Analgesia pre medication#				0.574
Fentanyl	6	9	4	
Tramadol	13	10	10	
Morphine	3	5	5	
None	8	6	11	
Induction agent#				
Ketamine/ Propofol	12/26	15/15	14/16	0.731
Maintenance agent#				
Halothane/ Isoflorane	19/11	19/11	18/12	0.954
Surgery duration (min) *	105.16±18.91	101±19	102.3±17.86	0.598
Anesthesia duration (min) *	119.66±17.66	116.5±8.34	113.83±15.46	0.573
Surgical incision length	15(14-16)	15(15-17)	14(15-17)	0.765

Table 1; Demographic Data and baseline anesthetic characteristics

* Mean±SD, # Case number

Values are presented as mean ± SD or Case number/ proportion), (n/%) (ANOVA & Chi-Square Test)

5.2 Hemodynamic response between groups.

The hemodynamic response including both pulse rate and mean arterial pressure was comparable between groups before incision, after incision and at 20 min, 40 min and 60 min PACU.

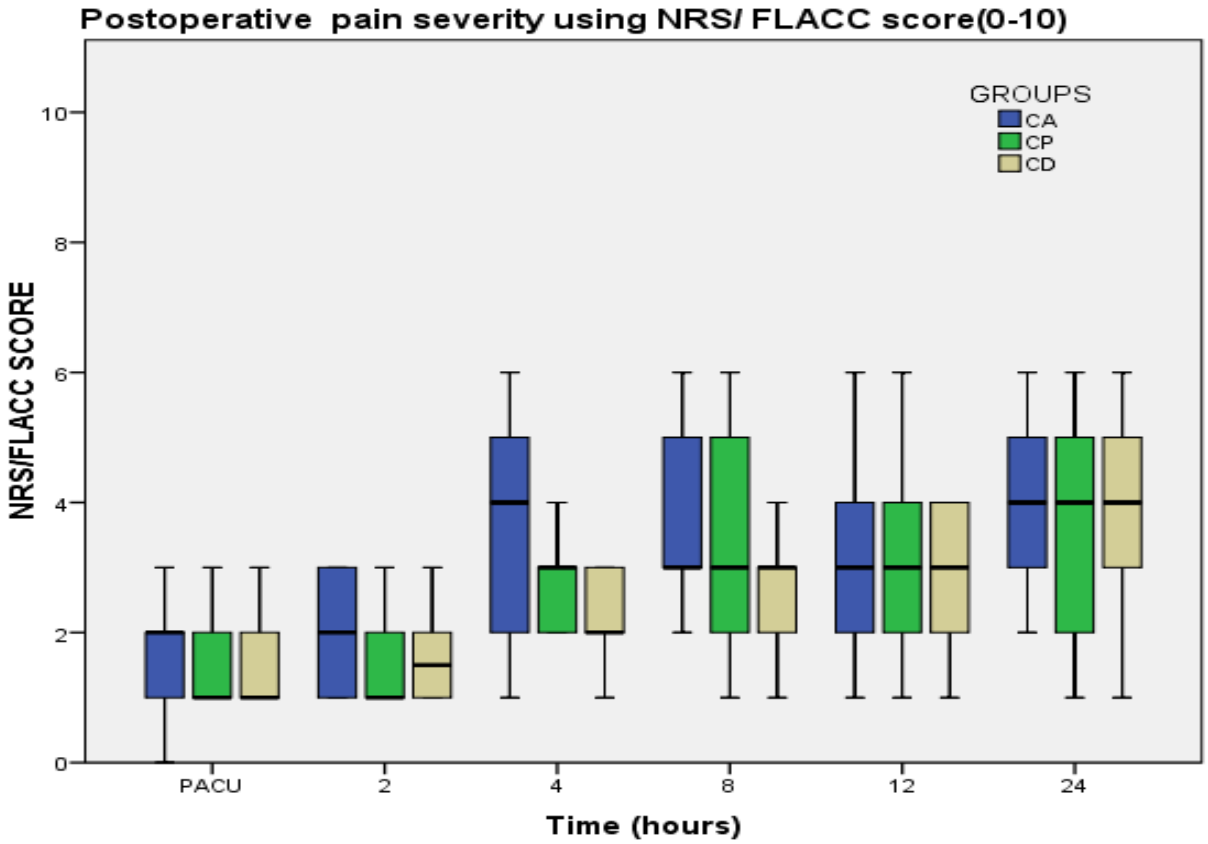
Hemodynamic Response		Group CA	Group CP	Group CD	P-value
Before incision	**PR**	121.7±8.38	122.56±10.36	124.83±8.09	0.384
	MAP	62.93±3.18	64.4±3.81	64.26±3.31	0.196
After incision	**PR**	130.16±7.6	166.4±3.89	129.5±9.25	0.264
	MAP	65.93 ±3.17	6.26±8.89	65.36±3.20	0.509
Arrival at PACU	**PR**	135.23±7.75	131.66±8.636	132.7±9.41	0.509
	MAP	66.7±2.66	7.06±3.18	66.03±2.51	0.350
AT 20 min PACU	**PR**	126.43±7.66	124.66±8.636	123.8±9.73	0.494
	MAP	65.26±2.75	5.6±3.47	65.18±3.04	0.516
AT 40 min PACU	**PR**	121.46±7.1	121.5±8.53	119.13±9.49	0.498
	MAP	64.43±2.71	64.86±2.94	64.03±2.55	0.503
AT 60 min PACU	**PR**	123.06±9.43	119.5±6.98	116.06±9.49	0.197
	MAP	64.1±2.36	64.53±2.88	63.7±2.45	0.460

Table 2; Comparison of hemodynamic response between groups.

Value are presented as: Mean±SD, One way ANOVA test & $p<0.05$ is statistically significant.

5.3 Postoperative NRS/FLACC Score between groups

The Kruskal-Wallis test showed that median NRS/FLACC score were not significant at 1^{st}, 2^{nd}, 12^{th} and 24^{th} hours ($p>0.05$) between three groups. There was statistically significant difference results at 4^{th} and 8^{th} hour between groups ($p=0.001$ & 0.012) respectively. Post hoc analysis reveals a significant reduction of pain score in caudal + diclofenac combination compared to caudal+paracetamol combination and caudal alone group at both 4^{th} and 8^{th} hour with p = 0.007, < 0.001 & p< 0.032, = 0.003 respectively. Again there was a statistically significant difference between caudal+paracetamol and caudal alone group at 4^{th} hour with p = 0.026. However there was lower median value in caudal+paracetamol than caudal alone it's not statistical significant with $p > 0.05$.



Value are presented as: Median (IQR), Kuruska-walih H rank test and Tukey post hoc test) & $p<0.05$ is statistically significant.

Figure 2; *Comparison of postoperative using NRS/FLACC score.*

5.4 Time to First Request Analgesia

The median time to first analgesia requirement in the caudal alone group was M (IQR; 315(210-720 minutes) was significantly shorter when compared to caudal+paracetamol 445(240-840 minutes p=0.005) and caudal+diclofenac 735(540-1200 minutes p<0.001). Likewise, first analgesic requirement in the caudal+paracetamol was significantly shorter than caudal+diclofenac group (p<0.001).

5.5 Total postoperative analgesia consumption with in 24 hour between groups.

There was statistically significant difference in median total rectal paracetamol consumption within 24 hours during postoperative period between the groups as shown in Table 3. Post hoc analysis of total rectal paracetamol consumption in 24 hour showed significantly higher in caudal alone group when compared to caudal+paracetamol (p <0.001) and caudal+diclofenac (p<0.001) combination group respectively. Again the median rectal paracetamol consumption was higher in caudal+ paracetamol compared to caudal+diclofenac combination group (p=0.013).

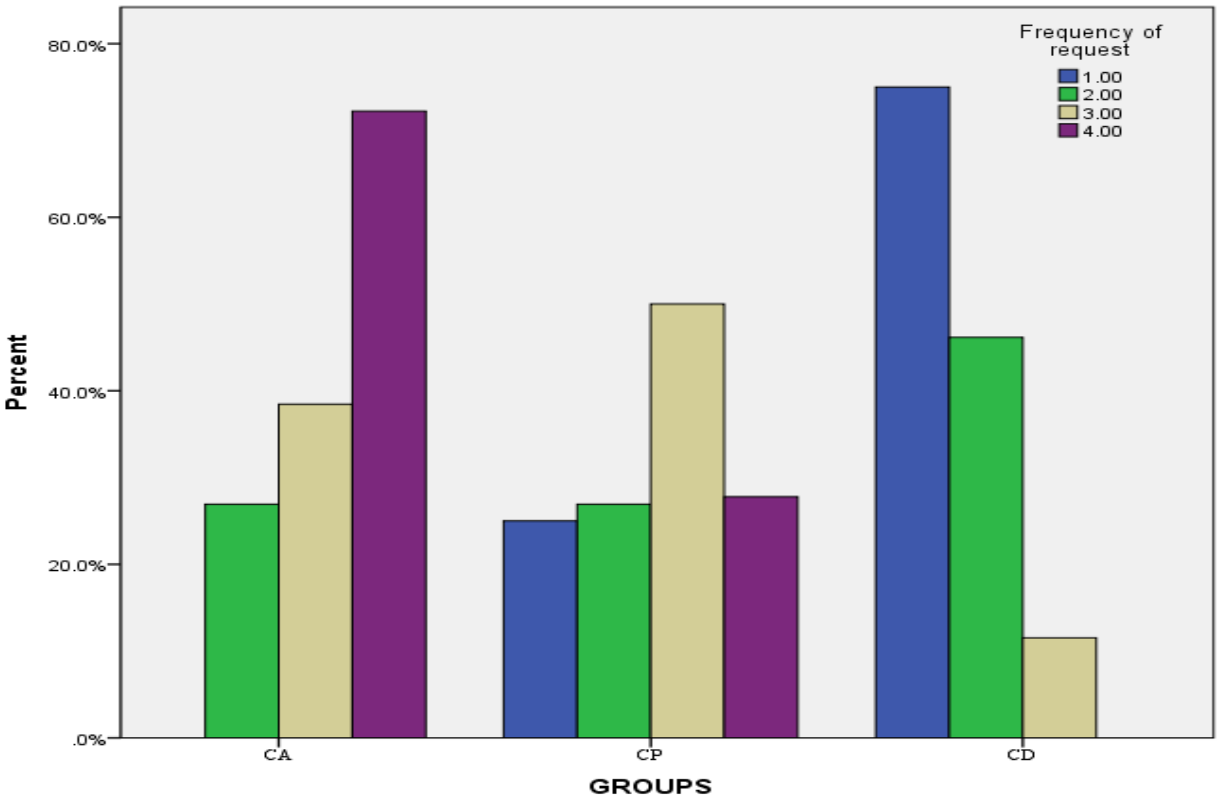
	Group CA	Group CP	Group CD	P-value
First analgesic request time (minutes)*	315(210-720)	445(240-840)	735(540-1200)	<0.001
Total analgesics consumption				
Rectal paracetamol	500(0-1125)	250(0-1000)	125(0-500)	<0.001
Tramadol in mg (IV)	0(0-150)	0(0-100)	0(0-50)	0.181
Diclofenac in mg (IM)	0()-100)	0(0-75)	0(0-75)	0.783

Table 3; Comparison of time to first analgesia request and total analgesia consumption within 24Hr

Value are presented as: Median (IQR), Kuruska-walih H rank test and Tukey post hoc test) & $p<0.05$ is statistically significant.

5.6 Frequency of analgesia request time between groups.

All patients at least request analgesia one or more times between groups within 24 hour postoperative period. Post hoc analysis revealed a significant reduction of the median frequency of analgesia request in caudal+diclofenac group 1.5(1-3) times compared to caudal+ paracetamol combination 3(1-4, $p<0.001$) and caudal alone group 3(2-4, $p<0.001$). Again median frequency of request in caudal+ paracetamol combination was lower than caudal alone group ($p=0.016$).

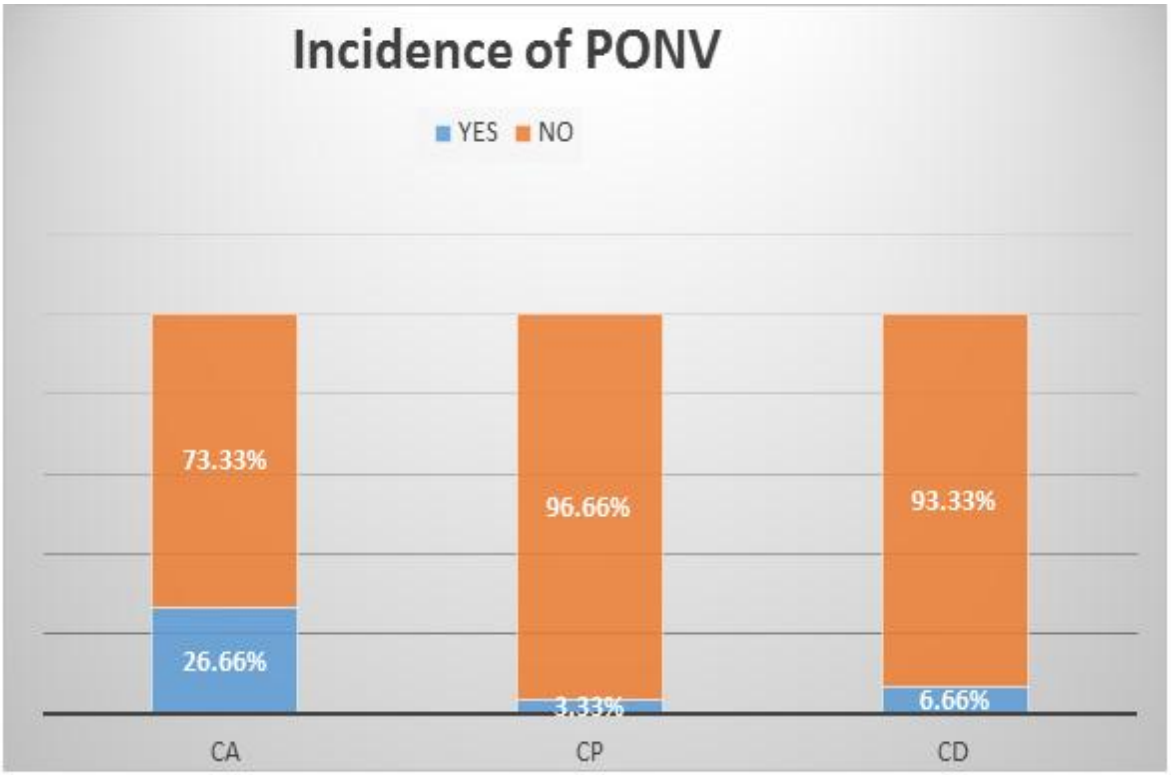


Values are presented as % (n). (Chi-Square Test)

Figure 3; Frequency of analgesia request between groups.

5.7 Incidence of Nausea and Vomiting

The incidence of nausea and vomiting over 24 hours is 36.65% between groups. The proportions of patients with nausea and vomiting was lower in (3.33%) and (6.66%) CD compared to (26.66%) CA group (X2=8.907) with a p value of 0.012. Post hoc test shows significant difference between CA & CP with p value= 0.015. Again CD reduce PONV compared to CA group with p value= 0.043. No serious complications or life-threatening events occurred between groups within 24 hour.



Values are presented as %(n). (Chi-Square Test)

Figure 4; Incidence of Postoperative nausea/ vomiting between groups.

CHAPTER SIX: DISCUSSION

In our study, confounding factors such as demographic and baseline anesthetic characteristics including hemodynamic variables between groups were comparable. So as, the difference in regards to severity of pain, duration of analgesia, total analgesia consumption along with frequency of analgesia request and incidence of adverse effects within 24 hours postoperative period was likely due to rectal diclofenac and rectal paracetamol effects in the exposed group.

Our study showed significant difference in median (IQR), NRS/FLACC score at 4^{th} and 8^{th} hr. between groups. Median pain score significantly lower in caudal+diclofenac group compared to caudal+paracetamol and caudal alone group at 4^{th} hour ($p = 0.007$, <0.001) and at 8^{th} hour ($p= 0.032$, $=0.003$) respectively. Again caudal+paracetamol pain score was lower compared to caudal alone at 4^{th} hour ($p=0.026$). This result was comparable with 2017, prospective RCT done in Nigeria by Tnahji et.al which found lower mean FLACC pain score in caudal+diclofenac group compared to caudal+paracetamol and caudal alone group at 4^{th} hour (2.50 ± 0.68, 3.11 ± 0.63 & 3.34 ± 0.76, $p<0.001$ and 8^{th} hour (3.04 ± 0.50, 3.57 ± 0.69 & 3.63 ± 0.67, $p<0.001$) respectively. (12) The possible justification might be the same dose and volume of bupivacaine, rectal paracetamol and diclofenac was used.

In contrary to our finding, a clinical trial done by ozyuvaci.et.al at turkey in 2004 showed a comparable CHEOPS score between caudal +paracetamol and caudal alone at 4^{th} hr. (5.6 ± 0.83, 5.5 ± 0.83, $p=0.65$). (27) Possible reason might be lower volume used 0.5ml/kg bupivacaine and 20 mg/kg paracetamol in their study compared to 1ml/kg and 30 mg/kg in our study. And also prospective RCT done by Kanchanamala BN .et.al in 2018 observed no significant effect of FLACC score between caudal+diclofenac and caudal alone group at 4^{th} hour ($p>0.05$).(29) Possible reason might be lower dose of 1mg/kg caudal bupivacaine was used in this study instead of 2.5mg/kg.

With regards to analgesia duration we observed lower median time to request first analgesia in Caudal alone 315(240 - 720) compared to caudal+paracetamol 445(240 - 840) and caudal diclofenac group 735(540 - 1200) minutes), $p < 0.001$. Similarly, T. nhaji observed lower mean time to request first analgesia in Caudal alone (6.43 ± 32.94) compared to combination of caudal+paracetamol (7.75 ± 3.12) and caudal+diclofenac (12.98 ± 4.46) hour, $p=0.01$. (12).

However the statistical significant difference of median first analgesia request time between caudal+paracetamol and caudal alone in our group was similar to the prospective RCT done by B. Kanchanamala. BJ in 2018 observed longer mean duration of analgesia between Caudal+Diclofenac (7.53333 ±0.5074160) compared to Caudal alone group (4.5667 ± 0.97911), p value <0.05 (29) which is shorter than our finding. Possible reason might be higher bupivacaine dose (2.5mg/kg) was used in our study compared to 1mg/kg. Similarly prospective randomized study done by Raghavani et.al in 2016, found significant difference of longer mean duration of analgesia in caudal+paracetamol (353 ±6.0) compared to caudal alone (253 ±3.9 minute) p value < 0.001 (30) which is shorter than our result. The time difference might result due to higher dose of 30mg/kg rectal paracetamol used in our study instead of 20mg/kg.

With regards to total postoperative analgesia consumption and frequency of request, we observed lower rescue analgesia in caudal+diclofenac 125(0-500) and caudal+ paracetamol 250(0-1000) compared to 500(0-1125) mg rectal paracetamol among caudal alone group. P<0.001. Despite limitation of published data which compare postoperative analgesia consumption between caudal+paracetamol and caudal+diclofenac, particular study done in 2016 by Raghavani et.al found higher analgesia consumption in caudal alone compared to caudal+paracetamol group within 24 postoperative period p<0.0001.(30) Similarly the study done in India by Neeru Gupta 2008 reported higher postoperative analgesia consumption in Caudal alone compared to Caudal+diclofenac combination group $P < 0.05$. As well as this study found lower number of analgesia dose 1.2±0.5 in caudal+diclofenac group was required compared to caudal alone 1.95±0, p<0.05 which is consistent to our finding. (31).

However study which compare postoperative analgesia consumption and frequency of analgesia request between Caudal+paracetamol and Caudal+diclofenac for pediatric patients undergoing infra umbilical procedures are not published yet. Multiple studies in different pediatric surgical procedures observed lower postoperative total analgesia consumption in rectal diclofenac alone compared to rectal paracetamol alone group with various ranges. (P value < 0.05) which is consistent to our finding. (46-47)

Based on 2012 study done by Hosseini Jahromi SA.et.al in Iran found comparative analgesia effectiveness between caudal alone and incision or wound site infiltration for infra-umbilical procedure in pediatrics in terms of pain score, duration and postoperative analgesia consumption. (46)

Similarly multiple studies also found superior analgesia effectiveness of rectal diclofenac or rectal paracetamol combined with wound site infiltration compared to wound site infiltration alone group as it improves analgesia quality in caudal block. (49-50)

Regards to the incidence of adverse effects between groups. In our study other than postoperative nausea vomiting there was no reported adverse effects. We observed lower Incidence of PONV (3.33%) in caudal +paracetamol and (6.66%) in caudal+diclofenac compared to 26.66% in caudal alone group. This result was consistent with prospective RCT carried out by L. Raghavan, K. R.et.al found higher incidence of PONV which was 33% in caudal alone group compared with 0% caudal+paracetamol combination group $P = 0.01$. (30) Another study done by C. M. Amminnikutty,et.al in 2018 found lower incidence of vomiting 0% in incision site infiltration combined with rectal diclofenac compared to 20% incision site infiltration alone group.. $P = 0.01$. (50).

However, there is no published study which compare incidence of PONV between caudal+diclofenac and caudal+paracetamol combination group our study demonstrate comparable effect between them.

Limitation of the study

Discussion was limited due to inadequate published data.

Strength of the study

Study participant were homogeneous.

CHAPTER SEVEN: CONCLUSION AND RECOMMENDATION

7.1 Conclusion

Rectal diclofenac combined with caudal bupivacaine provide more effective analgesia compared to both rectal paracetamol combined with caudal bupivacaine and caudal bupivacaine alone. And also rectal paracetamol combined with caudal bupivacaine provide more effective analgesia compared to caudal alone.

7.2 Recommendation

- Based on our finding, we recommend to use combination of caudal+diclofenac and alternatively combination of caudal+paracetamol for infra umbilical procedure to provide effective analgesia.
- We also recommend using caudal+paracetamol as alternative for provision of better postoperative analgesia
- We recommend the researcher to evaluate analgesia efficacy by high level randomized clinical trial.

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ANNEX

Annex-I: Questionnaire

Addis Ababa University, College of Health Sciences, Department of Anesthesia Prospective Cohort Study, On Post-Operative Analgesic Efficacy of rectal Diclofenac and rectal paracetamol combined with Caudal Bupivacaine for Pediatric Infra Umbilical Surgery in TASH, From December, 1, 2018 G.C to February 30, 2019 G.C.

Section I: Socio-Demographic Data

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

Section II: Data during Pre and Intraoperative Period

S. No.	Question	Response	Code
201	Diagnosis	……..	
202	Procedure:	……..	
203	Baseline Heart rate	…….BPM	
204	Baseline blood pressure	……./……..(……..) mmHg	
205	A Does the patent take analgesi pre-medication	1. Yes 2.no	
206	If yes for the above question, w was the drug? Specify the dose'	A. Tramadol …….mg B. Fentanyl …….mg C. Morphine …….mg D. Others/specify…..mg	
207	Premedication, induction & maintenance	……./……./……	
208	Time of caudal block	…….	

209	A drug used for the caudal bloc	1 …. (ml)bupivacaine only or 2 ……(ml)bupivacaine with ……(mg)rec diclofenac 3 ….. (ml)bupivacaine with ……(mg)rectal paracetamol	
210	Vital sign before skin incision?	BP…/…… (……) mmHg PR:…….bpm	
211	Vital sign after skin incision?	BP……../.... (……) mmHg	

Section III Post-Operative Observation Vital sign at recovery room

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

Ward follow up for 24

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

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

304) Duration till First Analgesic Request _____

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

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

Section IV complications observed

401) Does the patient have nausea within the first 24 hours of surgery?

A. YES B. NO

402) Does the patient develop vomiting within first 24 hours of surgery?

A. YES B. NO

403) Does the patient develop leg weakness within first 24 hours of surgery?

A. YES B. NO

404) Does the patient develop sedation within first 24 hours of surgery?

A. YES B. NO

405) Does the patient develop any other complication other than the above?

A. YES B .NO

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Annex-II: Pain Assessment Tool

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

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

FLACC scale

Behavioral Observation Pain Rating Scale

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

Figure 5; *FLACC scale*

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

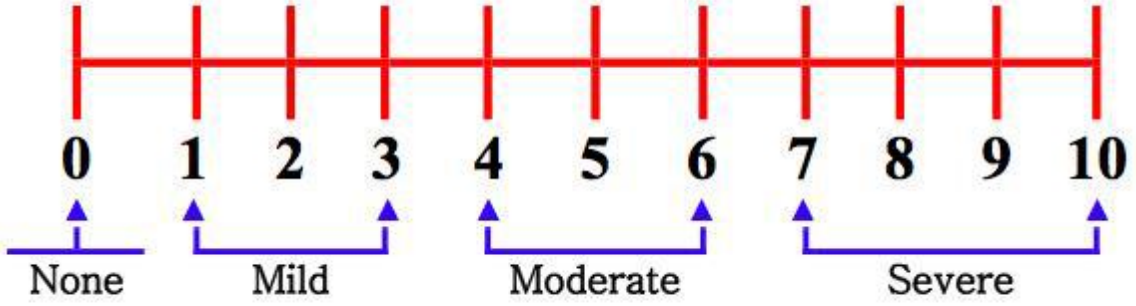

Figure 6; *Numeric rating scale*

English Version of Numeric Rating Scale (NRS)

The scale will take 6 times within the first 24 hours. Patients will 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 will be 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)

አማርኛ ትርጉም በቁጥር አምሳያ መለኪያ (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 የተሰጠውማብራሪያ በቂ ሳይሆን ሲቀር፣ ለበሽተኛው የበለጠ መረጃ መስጠት አስፈላጊ ሆኖ ይገኛል

0- ምን ም ህመም የለ ም

1-3 - ትንሽ ህመም አለ

4-6 - መካከለኛ ህመም አለ

7-10 - ከባድ ህመም አለ

Annex-III: Information Sheet

Title of The proposal: is to compare Postoperative Analgesic Efficacy of Caudal bupivacaine combined with rectal diclofenac versus rectal paracetamol for Pediatric patients undergoing Elective Infra Umbilical Surgery from December 1, 2018, To February 30, 2019, At Tikur Anbesa Specialized Hospital, Ethiopia.

Name of the principal investigator: Dereje Zewdu

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 rectal paracetamol and rectal combined with caudal bupivacaine on post-operative analgesic effectiveness during pediatric infra-umbilical surgery at TASH. The research group includes the principal investigator, four data collectors, and one ad visor from AAU.

Purpose of the research project: - the main concern of this study to assess the effect of rectal paracetamol and rectal diclofenac combined with caudal bupivacaine. The finding of this study is expected to be used by decision-makers, FMOH, EAA, department of anesthesia and health practitioners.

Procedure –

This study will including all elective pediatric patients coming for infra-umbilical surgery during the study period. They will be selected as part of the study participants whose parents are willing to participate in this study and willing to have consent. Anyone have the right to refused to participate in the study.

Benefits, risk or discomfort

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

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

Right to refuse or withdraw

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

Person to contact

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

Name: Dereje Zewdu

Phone: +251912404631

E-mail: derejezewdu1529@gmail.com

Annex-IV: Study Subjects Consent Form

Addis Ababa University, College of Health Sciences Department of Anesthesia Prospective Cohort Study, On Post-Operative Analgesic Effectiveness of Caudal Bupivacaine combined with rectal diclofenac and paracetamol for infra umbilical surgery in pediatrics in TASH, From January. 2019 G.C to June, 2019 G.C

Hello! My name is _____ I am of the members of the research team and I am here to ask you some questions and to collect some important information from your chart. If you are willing to participate in this research on Post-Operative Analgesic Effectiveness of Caudal Bupivacaine combined with rectal diclofenac and paracetamol for infra umbilical surgery in pediatrics. 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.

የጥናቱ ተሳታፊ ለመሆን የስምምነት ቅፅ

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

የተከበራችሁ የጥናቱ ተካፋይ ሥላጆች/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 ብቻውን bupivacaine ከ rectal diclofenac & rectal paracetamol) ሲቀላቀል)ለህመም ማስታግሻ ለምን ያክልጊዜ እንደሚቆያ ለማዎቅ በጥቁር አንበሳ ልዩ የማስተማሪያ ሆስፒታል ከታህሳስ አንድ እስክ የካቲት ሰላሳ ድረስ ከእነብረት በታች ባለዉ የሰውነት ክፍል ለቀዶ ህክምና የሚመጡ እዲሜያቸው ከ እንድ እስከ አስራት ያሉ ህፃናትን ለሃያ አራት ሰአት ወደፊት፣የህመም መጠን፣የመስታገሻ የሚጠይቁበትን ጊዜ ፣ምን ያህል የማሰታግሻ መድሀኒት በሃያ አራት ሰአት እነድተጠቀሙ እንዲሁም የማስታዎክ፣የማሰተኛት እግር አለመታዘዝ መኖር መከታተል ሲሆን ልጅዎን ለመሳተፍ የእርስዎን ፍቃድ ግድ ለው መሳተፍ በፍላጎት ብቻ ነው፡፡ስለዚህ ስምምነትዎን በአክብሮት እንጠይቃለን፡፡ የጥናቱን አላማ እንደሁም የኔን ሃለፊነት ተረድቻለሁ ሰለዚህ ልጆ እንዲሳተፍ

ሀ) ፈቅጀለሁ ለ) አልፈቅድም