ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCE
SCHOOL OF MEDICINE
DEPARTMENT OF ANESTHESIA

SEVERITY AND ASSOCIATED FACTORS OF POSTOPERATIVE PAIN IN PEDIATRIC SURGICAL PATIENTS AGED TWO MONTHS TO SEVEN YEARS AT SELECTED ADDIS ABABA PUBLIC HOSPITALS, ETHIOPIA 2023: LONGITUDINAL STUDY

Fassil Mihretu (BSc in Anesthesia, MSc Anesthesia student)

Advisores: 1. Eyayalem Melese (Ass't professor of Anesthesia, PhD fellow)

2.Sulayman Jemal (MSc, Lecturer of Anesthesia)

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Name of investigator	Fassil Mihretu
Name of Advisors	1.EyayalemMelese email: eyayalem.melese@aau.edu.et /eyayalem11991@gmail.com 2.Sulayman Jemal (email: Sulaiman.jemal@aau.edu.et)
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Investigator Address	Tel:+251923743831 email:fasilmihretu@gmail.com/fasil.mihretu@wu.edu.et /fasil.mihretu@aau.edu.et

Approval sheet

I hereby certify that I have read and evaluated this thesis entitled **"Severity and associated factors of postoperative pain in pediatric surgical patients aged two months to seven years at selected Addis Ababa Public Hospitals, Ethiopia 2023: Longitudinal Study"** prepared under my guidance by **Fassil Mihretu Rede**. I recommend to be submitted as fulfilling of the thesis requirement.

Primary Advisor	Signature	Date
_____	_____	_____
Co - Advisor	Signature	Date
_____	_____	_____
Examiner	Signature	Date
_____	_____	_____

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Acronyms and Abbreviations

ASA	American Society of Anesthesiologists
AOR	Adjusted odds ratio
CRIES	C--Crying; R--Requires increased oxygen administration; I--Increased vital signs; E--Expression; S—Sleeplessness
CHEOPS	Children's hospital of eastern Ontario pain scale
CI	Confidence Interval
COR	Crude odds ratio
FLACC	F--face, L--legs, A--activity, C-- cry, and C—consolability
FPS-R	Faces pain scale-revised
hr.	Hour
IASP	International Association for the Study of Pain
ICU	Intensive care unit
IV	Intravenous
LMA	Laryngeal mask airway
m-YPAS-SF	modified Yale Preoperative Anxiety Scale-short form
NIPS	Neonatal Infant Pain Profile scale
NCCPC-R	Non-communicating Children's Pain Checklist revised
NSAIDs	Nonsteroidal anti-inflammatory drugs
PO	Per oral
NRS	Numeric rating scale
QIC	Quasilikelihood Information Criterion
SPI	Surgical Pleth Index

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Abstract

Introduction: Post operative pain is a body response to the actual surgical tissue damage that results suffering, prolonged recovery, decreased mental and physical functioning and development of chronic pain. Appropriate postoperative pain assessment and management in pediatric patients reduce pain suffering and increases comfort. However, several perioperative, professional and other factors hinder to estimate the severity and its management mainly in lower income countries.

Objectives: To assess the severity and predictors of postoperative pain in pediatric surgical patients aged 2 months to seven years at selected Addis Ababa Public Hospitals, Ethiopia 2023.

Methods: A prospective longitudinal study was conducted on a cohort of 235 pediatric surgical patients aged 2 months to 7 years at selected Public Hospitals in Addis Ababa from January 2023 to April 2023.The exposure and other variables were acquired by questionnaire, direct observation, and questions posed to service providers. The primary outcome, pain severity, was assessed at 12, 24, and 36 hours postoperatively using a validated pain assessment tool tailored to this age group. Cochran's q test was used to see the difference in the incidence of postoperative pain between each time measurements. Generalized Estimating Equation was used to determine the predictor variables effect on pain severity over time. The direction of association and its significance were demonstrated by an adjusted odds ratio with a 95% confidence interval at a cut off p value of 0.05.

Result: The incidence of moderate to severe postoperative pain in this study is 36.6%, 20% and 10% at 12, 24 and 36 hours respectively. Patients with preoperative pain and preoperative anxiety increases the odds of postoperative pain severity (AOR=3.41, CI=1.15,10.00 and AOR=2.28, CI=1.219,4.277 respectively). Longer duration of surgery and being major surgery were the main predictors of post operative pain level from intraoperative predictors (AOR=6.62, CI=1.90,23.00; AOR=5.2, CI=2.11,12.88 respectively). Patients receiving multimodal analgesia and patients assessed frequently in the postoperative period has significantly reduced postoperative pain level (AOR=0.24; CI=0.091, 0.652; AOR=0.09; CI= 0.022, 0.393 respectively).

Conclusion: Many Pediatric surgical patients in the studied Hospitals have high postoperative pain level, mainly in the first 24 hour, that require treatment. Among other factors, the most

modifiable predictors that affect postoperative pain severity in these population are postoperative pain management and assessment practices.

Keyword: Pediatrics, Pediatric Surgery, Postoperative pain, Severity

1. Introduction

1.1. Background

The term Pediatrics includes children age from birth to 18 years, although there is no similarity between each age categories due to developmental differences. Children aged above 10 to 12 years are well developed and approaching to adult physiologically, pharmacologically and anatomically. They may not require special care either in pain related complains or other medical and surgical problems different from adults compared to small children(1,2). Pain, due to injury, disease or surgical procedures, is the main complaints of hospitalized pediatric patients(3–5).Based on the International Association for the Study of Pain (IASP) revised definition, pain is "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage"(6).Pain can be classified by different parameters as acute, ,chronic, nociceptive or neuropathic based on the duration, etiology and pathophysiology. It can be also classified as mild, moderate or severe by the level expressed by the patients and pain should be seriously followed and treated when it is above mild pain. Post operative pain is a type of nociceptive pain perceived after surgery due to surgical tissue damage that stimulates pain receptors(3,5,7).

There are many pain assessment techniques in pediatrics with different applicability, reliability and validity for specific age group and type of pain. Many of these pain assessment tools are complicated and not well validated to be used in practice (5,8,9).Precise assessment of pain is an integral part of pain treatment and achieved by using appropriate tool for the specific age group(10). 'The Face, legs, activity, cry, Consolability scale (FLACC)' is an observational pain assessment tool specifically designed postoperative pain in pediatric age between 2 month and 7 years. This scale demonstrated high acceptability and validity to assess post operative pain in this population(11–14). The Neonatal Infant Pain Profile scale (NIPS) is the most widely used to asses procedural pain in researches for full-term and preterm neonates. Also, 'CRIES (Cries ,Requires Oxygen, Increased Vital Signs, Expression, Sleeplessness)' is best for post operative

pain in neonates(15–17)**.**The numeric rating scale (NRS) has sufficient validity for pain intensity measurement of surgical patients above 8 years than other self-report methods(18–21).

1.2. Statement of Problem

Post operative pain in pediatrics results different devastating consequences such as; depression and insomnia, fatigability, decreased physical and mental functioning, progression to chronic pain ,prolonged recovery and prolonged hospitalization(7,22).It has strong impact on the quality of life of these children and their families. Pain has higher longer consequences in pediatrics compared to adults by disrupting their threshold to pain, immunity, neurophysiology, behavior, and health seeking attitude. It also affects their capacity to perform different skills in there later developmental stages and may progress to chronic pain in above 10% of patients. Generally, it compromises the quality of life and productivity of these children as well as their families(3–5,7). The incidence and severity of post-surgical pain in pediatrics is not well studied. Some literatures indicate, up to 5 to 75% of children undergoing surgery have significant postoperative pain(23).In Rwanda, nearly half of pediatric surgical patients experience severe pain postoperatively(24).In Ethiopia, a study conducted in pediatric surgical patients at university of Gondor Specialized Hospital showed that the occurrence of moderate to severe pain is nearly 40%(25).

Several factors are proposed as barriers to reduce postoperative pain level in children. It is known that adequate postoperative pain management requires administration of the right analgesics when required and frequent measurement of pain severity(5,26).In pediatric specially in small chilled, it is difficult to assess and treat pain because of their behavioral and cognitive developmental difference from older children and adults. They require individualized pain assessment technique that considers the child's language, age, behavior and cognitive capacity(5,8,9).Postoperative pain in pediatrics is not treated adequately in the past many decades. There are also myths in some places saying pediatrics patients lack ability to perceive pain and remember painful experiences resulting ignorance of children pain (23,27–29).But scientific evidences demonstrated even they may have greater pain compared to adults(30–32).Reduced availability of drugs, instruments, experts for regional analgesia, and professionals attitude and knowledge towards pain management remains a challenging issue in small children

in sub-Saharan African and developing countries(33,34).One unpublished study conducted at Black Lion Specialized Hospital, Ethiopia, on the knowledge and attitudes of health professionals about pediatric post operative pain management indicates, only 50% of Nurses have good knowledge about postoperative pain management(35).Other qualitative study conducted in Ethiopia about postoperative pain management concludes that, the barriers ranged from health professionals' lack of emphasis on pain management to limitation of resources(36).

Access to safe pediatric surgery is an ongoing challenge in third world countries(37). In Ethiopia, most of the country's population is in this age group(38) and the demand of pediatric surgery is increasing many folds(39). For example, a study conducted in Black lion Specialized Hospital showed 31% of all operations and 33% of all pediatric admissions to the hospital are pediatric surgical patients (40). Unfortunately, there is no adequate study conducted on intensity and situations of pediatric postoperative pain in Ethiopia. Many other studies which were conducted in different countries doesn't' consider the repeated nature of the data during analysis to capturing the dependency of repeated pain severity measurements.

Evidences suggest that, health institutions should establish their pediatrics pain control and assessment protocols for each pediatric age groups as there is no common assessment and treatment approach(3,7,23).However, there is limited evidence about pediatric postoperative pain intensity and its affecting factors in Africa including Ethiopia to establish these protocols. The focus of this study is to give insight about the severity of postoperative pain in small children for stakeholders to fill the current gaps. Since there is no common pain assessment tool which can be applicable for all pediatric age groups(7),pediatric age group from two months to seven years are prioritized for this study because of the following reasons. First, they are the most liable group for surgical intervention. Second, they are not well developed physiologically and behaviorally and they can't complain of their pain adequately for nearby family and health professionals to get appropriate treatment as older children. Generally, Frequent studies which can show the barriers and the requirements to get the standard pain management are needed to attain quality postoperative patient outcome, urging the need of this study in Ethiopia.

1.3. Significant of the study

This study would benefit pediatric surgical patients and their families primarily by recommending their demands to reduce their suffering from pain for responsible stakeholders. The country in large would be benefited as the next generations are in this age group, their general well-being and productivity is important for the prosperity of the country. Mainly, this study would be used as a reference for other researchers and government officials about the situation of postoperative pediatric pain as there is limited information in Ethiopia and Africa in large.

2. Literature review

The in-hospital complications in third world country after pediatric surgery is ten times higher than in developed countries(37). Among many factors postoperative pain is the one but not well studied in these countries(24,41).Literatures indicate that postoperative pain in children has more longer negative impact than in adults(42). Although there is no adequate study on pediatric postoperative pain in Ethiopia, different studies conducted in adult surgical patient show that postoperative pain is not sufficiently managed and there is unexpectedly prevalence of postoperative pain(42,43).

2.1. Severity of postoperative pain

The incidence of post-surgical pain in adult was well studied and ranges from 10-70 % but it is not well studied in pediatrics(7,42).Some literatures indicate up to 5 to 75% of all children undergoing surgery have significant postoperative pain which varies based on the extent of surgery, setting and other parameters(23). A study conducted in one of the developed country, Italy, 37.5% of pediatric patients undergoing thoracotomy had at least one painful experience(44). The incidence of worst procedural pain is nearly 22% in sub Saharan countries(45).A study conducted in Rwanda, one of the low income country, shows nearly half of pediatric surgical patients experience severe pain postoperatively(24).In Ethiopia a study conducted on adult surgical patients show, 88.2% of patients have moderate to severe postoperative pain which is not treated sufficiently in above half of patients(46). Only one study conducted in Ethiopia in pediatric surgical patients at University of Gondor Specialized Hospital showed as the prevalence of moderate to severe pain is nearly 40%(25).

2.2. Factors affecting postoperative pain

Postoperative pain intensity in pediatric varies depending on different factors such as patient and family related factors as anxiety, preemptive analgesia used, the disease process, the surgery type and extent, pain assessment practice, analgesia type and institutional situations(22,47–52). Extent of surgery that means being major surgery and increasing in the incision size is associated with severe post operative pain than the specialty or type of surgery(25). For example, children have different level of pain between adenotonsillectomy and adenotonsillotomy procedures resulting adenotonsillectomy to be most painful procedure (53,54). In two different studies,16 to 20 % of

neurosurgical pediatric patients undergoing craniotomy have moderate to severe pain for whom morphine groups have significant postoperative reduction than fentanyl and tramadol groups(55,56).The other is, patients who have preoperative pain such as oncologic patients may have significant postoperative pain(57). Pre operative anxiety if occur on either the family or the patient my significantly increase postoperative intensity of pediatric pain as shown by different researches(22,49–51).However, this may be correlated to the assessment tools problem since most pediatric assessment tools are behavioral and which may consider anxiety as pain.

There are contradicting ideas about the effect of sex on postoperative pain severity. One study demonstrates, being Male children specifically being the only child in the family had high neuroendocrine response to surgery resulting increased postoperative pain level and the reverse for being female(58).In contrast to this, other study shows that girls complain pain frequently than boys and has low pain tolerance resulting higher pain level than males, although no significant association was observed among the variables(59).Generally, there is a conflicting evidence weather pediatric postoperative pain is stronger in male or women. In the other direction, studies about the efficacy of Music intervention and other psychological supports as none pharmacologic pain management can reduce severity of postoperative pain in children(34).

2.3. Assessment strategies of postoperative pediatric pain

Accurate measurement of patients 'level of pain is a very important first step of appropriate pain management. It is mainly accomplished using appropriate measurement tool applicable for the specific age group, child behavior, cognitive capability, language and other condition(10).There is no common measurement scale applicable for all age groups. These assessment scales have no similar reliability and validity levels(5,8,9).Many of these numerous pain measurement tools are complicated and not well validated to be used in clinical practice. The behavioral scales such as; 'the Children's hospital of eastern Ontario pain scale (CHEOPS)' for 1 to 7 years, 'Non-communicating Children's Pain Checklist revised (NCCPC-R)' 3 to 18 years, 'Face, legs, activity, cry, Consolability scale (FLACC)' for 2 months to 7 years, 'Neonatal facial coding system' for premature and full-term infants, and COMFORT scale for unconscious and ventilated children can be used. Self-report methods such as; Numeric rating scale (NRS), projective methods, visual analogue scales, the faces pain scale-revised (FPS-R) and the Wong Baker Scale can be used for older children(5,60). Now a days, there are different strategies

developed to diagnose and treat postoperative pain early such as mobile applications(36,61) and Surgical pleth index. Surgical Pleth Index (SPI) is a non-invasive allow an measure intraoperative pain sensation to guide intraoperative pain management(62,63).

The Neonatal Infant Pain Profile scale (NIPS) is the most widely used in researches and systematic reviews which is used for full-term and preterm neonates for procedural pain but 'CRIES(Cries ,Requires Oxygen, Increased Vital Signs, Expression, Sleeplessness)' is best for post operative pain in neonates(15–17). The FLACC Scale is the most commonly used pain assessment tool specifically designed for postoperative pain in pediatric age between 2 month and 7 years. This scale demonstrated high acceptability to assess post operative pain in small children by systematic reviews(11–14)**.**The NRS has adequate validity and sensitivity to assess pain intensity for pediatric surgical patients greater than 8 years in different pain researches(18–21).Generally, it is challenging to study pediatric pain due to absence of consistent pain assessment tool applicable for all age groups. Healthcare facilities should establish pediatrics pain control and assessment protocols applicable to their setting.

2.4. Post operative pain management approaches

Techniques manly used to treat and reduce postoperative pain are using different modalities of pain management in the perioperative period. Such modalities are using pharmacological methods and none pharmacological methods. From Pharmacological methods using preemptive analgesia, opioids, paracetamol, Nonsteroidal-inflammatory drugs (NSAIDs), ketorolac, regional anesthesia, different anesthetic agents like ketamine, Dexmedetomidine, Tramadol, Dexamethasone, Lidocaine and multimodal pain management are commonly used. Nonpharmacological pain management methods most commonly used are distraction, breast feeding, family reassurance and psychological support, games, music (3,7,42,60,64,65).However, all these drugs are not used similarly for all pediatric age groups due to the pharmacologic response of the patients, the availability of drugs, and the nature of the surgical procedure making pediatric postoperative pain management difficult(23,66).

Nonsteroidal anti-inflammatory drugs (NSAIDs) can reduce postoperative pain by avoiding many side effects of opioids(67). However, NSAIDs may cause bleeding, renal and gastrointestinal toxicity, and potentially delay wound and bone healing(68). Primitive analgesia

by using dipyrone and paracetamol before incision has significant reduction in postoperative pain in pediatric as described in different studies(69,70).Regional analgesia technique, although impracticable in resource limited settings, have reduce postoperative pain in pediatrics comparable to adult practice and confirms the safety of placing blocks under general anesthesia in children(71). Field blocks for example in pediatric cardiac surgery patients(72), pudendal and penile nerve block for circumcision(73),TAP block for appendicitis(74),caudal block(75), ilioinguinal block and iliohypogastric block for inguinal surgery(76,77), Sciatic and Femoral Blockage for lower limb surgery(78) can be used. Regional anesthesia can replace the most feared side effects of opioids and other systemic analgesics. It is widely applied in developed countries, for example a study shows its application increased from 1.2% to 43% from 1996 to 2006 in orthopedic patients in USA (34,74).However, its practice is low specifically in low resource setting increasing the burden of postoperative pain in pediatrics.

Generally, there is a great variation in level of post operative pain in pediatric patients between countries and settings. In low-income countries including Ethiopia, post operative pain management and assessment lag behind despite their population is mainly in this age group**.** The availability of pain assessment tool, level of knowledge in pain assessment and management, limitation of resource and limitation of experts were the major predictors of postoperative pain severity found in many literatures.

2.5. Conceptual framework

The conceptual frameworks of this study taken postoperative pain as dependent variable. Different Preoperative factors, intraoperative factors and postoperative factors as shown below (figure 1) are taken as independent variable which were expected to affect postoperative pain level as extracted from different articles(11,22,27,34,41,48,50,52,56,57,65,68–71,75,79–81)**.**

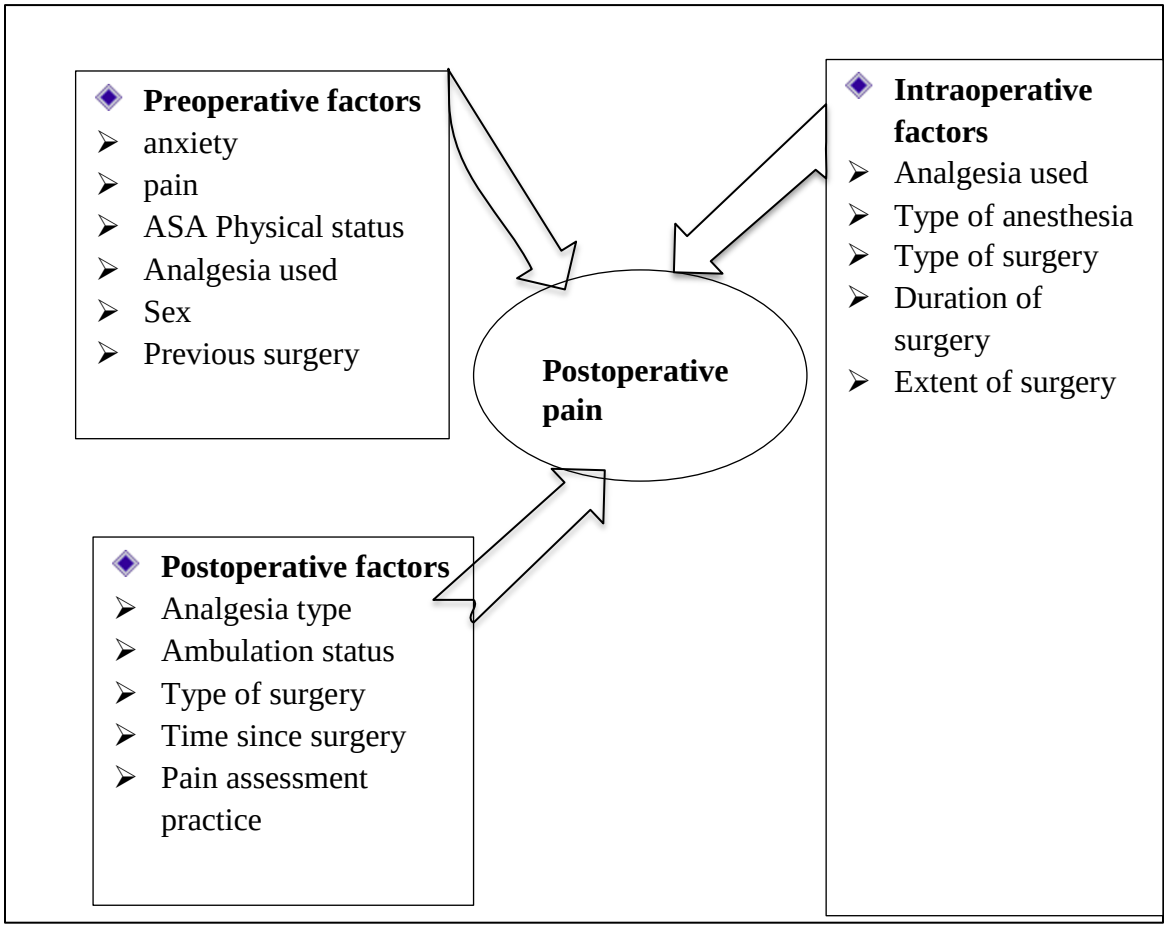

Figure 1: Factors affecting post operative pediatric pain

3. Objectives

3.1. General Objective

To determine the incidence of postoperative pain and its associated factors in pediatric surgical patients aged 2 months to 7 years at selected Addis Ababa Public Hospitals in Ethiopia from January 2023 to April 2023

3.2. Specific objectives

1. To determine the incidence of postoperative pain in pediatric surgical patients aged 2 months to seven years at selected Addis Ababa Public Hospitals, Ethiopia 20223
2. To determine the incidence of postoperative pain by severity in pediatric surgical patients aged 2 months to seven years at selected Addis Ababa Public Hospitals, Ethiopia 20223
3. To identify factors affecting severity of postoperative pain in pediatric surgical patients aged 2 months to 7 years at selected Addis Ababa Public Hospitals, Ethiopia 2023

4. Methods

4.1. Study area and period

The study was conducted in Addis Ababa, the capital city of Ethiopia, which have nearly 5 million projected population and 13 Public Hospitals. These Hospitals are serving patients referred from different part of Ethiopia in addition to the city residents. Among 13 Public Hospitals found in Addis Ababa, three was selected purposefully by considering their pediatric surgical patient load and their level. In addition, these Hospitals are convenient for data collection due to budget constraint since found in the center of the city. This study was conducted in Black Lion Specialized Hospital, Zewuditu Memorial Hospital and Menelik II Specialized Hospital. Black Lion Specialized Hospital has one major pediatric operation theaters with a total of 15 functional operation rooms. Zewuditu Memorial Hospital has 8 operation theaters in which surgical procedures from neonate to geriatric were performed. Menelik II Specialized Hospital has one major separate Pediatric operation theater and 7 others. According to the Hospitals record, on average 5 pediatric patients at Black Lion Specialized Hospital, two pediatric patients at Zewuditu Memorial Hospital and 3 pediatric patients at Menelik II Specialized Hospital underwent elective surgery per day resulting nearly 200 patients per month and 800 patients per four months. Among those, nearly 12% are from birth to 2-month,71 % are from 2 month to 7 years and 19 % are from 7 years to 12 years. This study was conduct from January 5, 2023 to April 25, 2023.

4.2. Study design

Prospective longitudinal study design was used. The key feature of longitudinal study is collecting data repeatedly from the same individual at different points in time and in this study postoperative pain level is measured repeatedly at different time.

4.3. Source population

Source populations were pediatric patients undergoing surgery at Black Lion Specialized Hospital, Zewuditu Memorial Hospital and Menelik II Specialized Hospital from January 5,2023 to April 25,2023.

4.4. Study population

Study populations were pediatric patients aged two months to seven years undergoing surgery at Black Lion Specialized Hospital, Zewuditu Memorial Hospital and Menelik II Specialized Hospital from January 5,2023 to April 25,2023.

4.5. Variables

4.5.1. Dependent Variable

Severity of postoperative pain

4.5.2. Independent variables

Sex, Age, type of surgery, extent of surgery, analgesia type, time since surgery, preemptive analgesia used, preoperative pain, preoperative anxiety, frequency of pain assessment, extent of surgery, previous surgical exposure and institution (Hospital) were independent variables.

4.6. Eligibility criteria

4.6.1. Inclusion criteria

Pediatric patients from 2 month to 7 years undergoing surgery at Black Lion Specialized Hospital, Zewuditu Memorial Hospital and Menelik II Specialized Hospital in the study period

4.6.2. Exclusion criteria

Patients having the following exclusion criteria were excluded from this study: Patients who become critical postoperatively and admitted to ICU (intensive care unit), Children with cognitive impairment, Children with cardiac and respiratory congenital anomaly, day case surgery, emergency surgery, parent refusal to participate, and Patients who have cough preoperatively and developing cough postoperatively.

4.7. Sample size

The sample size was calculated by epi info software and manually using single population proportion assumption for first objective and double population proportion assumption for the second objective. It was calculated by considering Z 1-β the desired power (80%), Z1-α/2 critical value (95%), percent of event in unexposed, percent of event in exposed, ratio of subjects in unexposed to exposed, margin of error (5%) and frequency of outcome. Percent of events and frequency of outcomes were taken from different studies which have similarity in scope with this study objective (Table 1). The total number of desired study subjects to identify true risk after

adding 10% non-response rate is 254 by taking the largest of the listed sample sizes (254 for the first objective and 220 for the second objective). The final sample size is 762 after the three-time repeated measurement of the outcome.

Table 1: Sample size for first and second objectives

1. For the first objective (severity of postoperative pain)					
Population size	Frequency of outcome	Margin of error	Sample size	Total sample size after adding 10% non-response rate = (1/1-0.1) *SS	Reference
568	50%	5	229	254	(24)
568	37%	5	220	244	(44)
568	22%	5	180	199	(45)
2. For the second objective (factors affecting postoperative pain level)					
Variables	Ratio of unexposed to exposed	% Of outcome in unexposed	% Of outcome in exposed	Sample size	Total sample size after adding 10% non-response rate = (1/1-0.1) *SS	Reference
Preop anxiety	1	30%	49.4	198	220	(25)
Preop pain	1	23%	54.1%	88	98	(25)
Neuro surgery	1	38%	58.8	182	202	(25)

SS=sample size

On the other hand, the sample size is calculated by using the following formulas manually for the first and second objectives(82).

For the first objective; By using single population proportion formula

$$\text{Sample size}(n)=\frac{(z_{1-\alpha/2})^{2*}(p)(q)}{(d)^2}$$

where, n = Desired sample size, Z1−α/2= Critical value and a standard value for the corresponding level of confidence (at 95% CI or 5% level of significance is 1.96), P = Expected prevalence based on previous research, q= 1-p, d = Margin of error or precision(5%).So, when we take p=50%(q=1-p that is 50%) from the above reference (Table 1), the total sample size becomes 384.When we adjust this by using finite population correction formula [$no = n/1 + (n-1)/N$, where, **N** is total study population (568), **n** is required sample size (384), and **no** is

the new adjusted sample size for finite population (229).The new adjusted sample size becomes 229 and when we add 10% none response rate it becomes 254.

For the second objective; By using double population proportion formula

$$n = \frac{\left[z_\alpha \sqrt{(1+1/m)\bar{p}(1-\bar{p})} + z_\beta \sqrt{p_0(1-p_0)/m + p_1(1-p_1)}\right]^2}{(p_0 - p_1)^2}$$

$$\bar{p} = \frac{p_1 + m p_0}{m+1}$$

$$n_c = \frac{n}{4}\left(1 + \sqrt{1 + \frac{2(m+1)}{nm|p_0 - p_1|}}\right)^2$$

where, n = Total number of desired study subjects to identify true relative risk with two-sided Type-I error, m = Number of none exposed to exposed subject, $Z_{1-ß}$ = It is the desired power (0.84 for 80% power), $Z_{1-a/2}$ = Critical value and a standard value for the corresponding level of confidence (at 95% CI, it is 1.96), p0 = Possibility of event in none exposed, p1=Possibility of event in exposed, P= p1+m p0/m+1 and n_c is the continuity corrected sample size. So, by taking preoperative anxiety as one of the predictor variables, the total sample size becomes 71 in each group means 142 totally and after adjusting by continuity correction formula it becomes 80 in each group and 160 totally. After adding 10% none response rate, the total sample size becomes 200.

4.8. Sampling procedures

The required sample size for each Hospital was calculated by proportionate allocation from the total sample size using this formula;**(sample size/population size) × Hospital size**. This result 127 for Black Lion Specialized Hospital, 51 for Zewuditu Memorial Hospital and 76 for Menelik II Specialized Hospital. After stratifying each age group based on homogeneity within group and heterogeneity between groups by applicability of the most validated pain assessment tool, children age less than two month and greater than 7 years were excluded from this study. Each consecutive surgical patients aged 2 moths to 7 years was selected from the daily operation schedule list of each Hospital until the desired sample size was achieved during the study period.

Nineteen Patients were lost to follow up after included in the study and the final data was collected from a total of 235 participants

4.9. Data collection procedures

The preoperative, intraoperative and post-operative exposure variables and other data was collected by trained data collectors (Anesthetists and Nurses), one for each hospital with close supervision by the investigator. Exposure status to different variables was ascertained by seeing the anesthesia record sheet, by observing the procedure, and by asking the anesthesia and surgery providers directly. Questionnaire was prepared by considering all important variables listed in literature to collect important data (Annex 3). Preoperative and postoperative pain level was assessed by the most validated pain assessment tool for this age group; 'face, legs, activity, cry, and consolability (FLACC)' scale (Annex 4).Preoperative anxiety was assessed by the most appropriate assessment tool for this age group called 'modified Yale Preoperative Anxiety Scale-short form (m-YPAS-SF)'(83)(Annex 4).Preoperative pain and anxiety level was assessed in the holding area at the day of surgery by trained data collectors.

4.10. Outcome measurement

The FLACC pain assessment scale which is most widely used and validated tool for children between 2 month and 7 year(3,13,14) was used to ascertain the level of postoperative pain. The outcome data (intensity of post-operative pain) was collected by other trained data collector who didn't know the exposure status of the patients at 12 ,24, and 36 hours repeatedly.

4.11. Operational definitions

1. **Postoperative pain:** a pain perceived due to surgical intervention in the post-surgery and explained as no pain, mild pain, moderate pain and severe pain.
2. **Severity of postoperative pain:** In this study pain assessed through FLACC scale which have 5 behavioral categories (face, legs, activity, cry, and consolability). The five behaviors are each rated on a 0 to 2 scale and items were summed yielding a 0–10 pain intensity score (Annex 4).A FLACC score of 0 indicate no pain; scores of 1–3 indicate mild pain; scores of 4–6 indicate moderate pain; scores of 7–10 indicate severe pain as used in many pain researches(32,44,54,56). This pain scale was dichotomized in to two

scale (binary) during the analysis by merging no pain and mild pain in the same class and moderate and severe pain in the same class. This is because pain should be seriously followed and treated when it is above mild pain(5).

3. **Preoperative anxiety:** The assessment of anxiety was made through direct observation using the 'modified Yale Preoperative Anxiety Scale-short form (m-YPAS-SF)'. The tool consists of 18 items classified into four domains: general activity (4 items), emotional expressivity (4 items), state of arousal (4 items) and vocalization (6 items). Scoring is made by dividing each item rating by the highest possible rating (i.e., 6 for the 'vocalizations' item and 4 for all other items), add all of the produced values, divide by four, and multiply by 100.Scores range from 22.92 to 100, with scores ≥ of 30 points indicates a state of anxiety.
4. **ASA Physical Status Classification:** It is used to assess patient's pre-anesthesia conditions to estimate the perioperative risks.

    ASA I- healthy patient with no comorbidities
    ASA II-A patient with treated systemic disease
    ASA III-A patient with severe systemic illness
    ASA IV-A patient with life threatening severe systemic disease
    ASA V-A moribund patient who is not expected to survive without the operation
    ASA VI-brain-dead patient whose organs are being removed for donor purposes

5. **Extent of surgery: Major surgery** involves opening the internal body cavity with large incision that results major trauma to the tissues that will leave a large scare such as; craniotomy, thoracotomy, bowel resection etc. **Intermediate or moderate surgery** is less invasive than major surgery such as primary repair of inguinal hernia, excising varicose veins in the leg and tonsillectomy or adenotonsillectomy. **Minor surgical procedures** are those that are minimally invasive with small incision and procedures that are superficial or performed laparoscopically(84). In this study moderate and minor surgeries are merged during the analysis.

6. **Multimodal Analgesia:** is the use of more than one group of analgesic agent targeting different receptors along the pain pathway with the goal of improving analgesia while reducing individual drug side effects(4,65).

4.12. Data Analysis procedures

The collected data was entered into EpiData 3.1 and the main outcome, pain severity, is dichotomized in to two (binary outcomes) for ease of analysis as used in many pain researches. Patients who experience mild pain and no pain were merged as no pain to mild pain and patients experience above mild pain are merged as moderate to severe pain. Then after cleaning and coding, the data was exported to Stata/MP15 in wide form and transformed to long form for ease longitudinal data analysis. This study is longitudinal i.e., repeated measurements from the same individual is correlated (outcomes are dependent). So, Generalized Estimating Equation (GEE) which is suitable for repeatedly measured categorical outcome variables was used to see the marginal effects of different independent variables on post-operative pain and Cochran's q test was used to see the difference in the incidence of post operative pain between each time measurement. After seeing the nature of the data, an autoregressive working correlation structure were selected before analysis. The GEE equation, which allows to adjust for the dependency of observations within one subject, is as follows:

$$'Yit=\beta 0+\sum_{j=1}^{J}\beta 1jXijt+.... +CORRit+\varepsilon it'$$

in which Yit is the observed outcome (postoperative pain level) for the subject i at time t, β0 is the intercept, Xijt is the covariate j for the subject i at time t, β1j is the regression coefficient for covariate j, J is the number of covariates, CORRit is the working correlation structure, and εit is the "error" for subject i at time t.

Variables with a p value of less than 0.25 in the uni-variable analysis were included in the multivariable analysis. Since GEE is robust to multicollinearity, the standard errors are small and all the independent variables are categorical, specific multicollinearity test was not done. An adjusted odds ratio with a 95% confidence interval and p value of less than 0.05 is used to show the effect of determinant factors on the outcome variable. Descriptive and analytical statistics was presented by using tables and graph for proportions, frequency and associations of indicated variables. The best fitting working correlation structure was selected by seeing the smallest QIC

(Quasilikelihood Information Criterion) from different working correlation structures. Based on this an autoregressive correlation structure has the smallest QIC.

4.13. Data quality management

To have appropriate data, the data collectors were trained and pretest was done for the pain assessment tools on 5% of study populations at Black Lion Specialized Hospital. Inter rater reliability of the pain assessment tool was done by 3 different raters from the same study participant and it was good (ICC=0.8 with similar Cronbach's alpha). Content and face validity of the questionnaire was done by my advisors and professional experts. The investigator supervises the data collection process. Ascertainment of the outcome (severity of pain) was ensured by observing the patients postoperatively using validated age specific pain assessment tools.

4.14. Ethical consideration

Ethical clearance was obtained from Addis Ababa University institutional review board after submission of the proposal. In addition, ethical clearance was obtained from Addis Ababa Public Health Research and Emergency Management Directorate. Each study Hospital were consulted after ethical approval for permission before proceeding the data collection process. This study has no risk on the participants since it is an observational study rather than taking participants time for examination. There were no special benefit and inducements for the participants of this study. A separate informed consent sheet was prepared by considering the participants' autonomy, beneficence, competency and voluntariness (Annex 1 and 2).

4.15. Dissemination of results

The final thesis will be submitted to Addis Ababa University Library, Addis Ababa Public Health Research and Emergency Management Directorate, Black Lion Specialized Hospital, Zewuditu Memorial Hospital, and Menelik II Specialized Hospital. Any effort will be made to published the manuscript in a reputable journal.

5. Result

5.11. Participant characteristics

Participants of this study were 254 pediatric patients undergoing different type of surgery in three Hospitals aged between 2 months to 7 years. The final sample included 235 participants after excluding 19 participants who were lost to follow up due to different reasons. Each patient had 3 observations in this cohort postoperatively at three time point and there is no missing data from each time measurement. Ninety-nine (42%) were females and 136 (58%) were males. General anesthesia with endotracheal tube or LMA (laryngeal mask airway) is the anesthesia type majority of the surgery (91.6%) was done (Table 2).

Table 2: Characteristics of Pediatric patients undergoing surgery at selected Addis Ababa Public Hospitals, Ethiopia, January 2023 to April 2023

Category (n=235)	**Frequency**	**Percentage**
Age		
2 months to 2 years	128	54.45
2 years to 5 years	53	22.55
5 years to 7 years	54	22.97
Participants per Hospital		
Black Lion Specialized Hospital	128	54.47
Zewuditu Memorial Hospital	49	20.85
Menelik II Specialized Hospital	58	24.68
Sex		
Male	136	57.87
Female	99	42.13
Type of Surgery		
Urologic Surgery	55	23.40
GI (gastrointestinal) Surgery	66	28.09
Orthopedic Surgery	29	12.34
Cardiothoracic Surgery (CTS)	19	8.09
Ear, Nose and throat Surgery (ENT)	24	10.21
Neuro Surgery	42	17.84
Type of sole anesthesia		
General Anesthesia with Endotracheal tube or LMA	214	91.6
Sedation	18	7.66
Regional Anesthesia	3	1.28

5.12. Trends of preoperative, intraoperative and postoperative analgesics usage

The most commonly used analgesic agent in the preoperative period is Paracetamol suppository. It was given for 80% of patients and Fentanyl was used rarely. However, Fentanyl is the most commonly used intraoperative analgesia in 76.5% of participants followed by multimodal analgesia (62.2%) and Paracetamol products (39%). Ketamine and Dexamethasone were also administered frequently in the intraoperative period in 43.8% and 36 % of participants respectively but not primarily for the purpose of analgesia. The most widely used regional analgesia is caudal epidural. It was given to 35% of participants followed by local infiltration (15%) intraoperatively. Peripheral nerve blocks and spinal anesthesia were used rarely in these surgical population in the intraoperative period. Postoperatively, Paracetamol preparations alone were used in 53% of participants from the aggregate result of the repeated measurements followed by multimodal analgesia (38%). Regional analgesia and none pharmacological pain management techniques were not practiced adequately while opioids used rarely in the postoperative period (Table 3).

5.13. Postoperative pain assessment, analgesia administration and record practice

Majority of surgical Pediatric patients were assessed for pain once at each 12 hours. On average, 59%, 20% and 18% were assessed one, two and above two times respectively. Nearly 4.5% of pediatric surgical patients were not assessed for pain postoperatively. The ordered postoperative analgesia was administered in 83% of patients appropriately. Only 58% patients' analgesia consumption was recorded in each time interval of drug administration and intake (Table 4).

5.14. Severity of postoperative pain

The crude incidence of post operative pain in Pediatric surgical patients is 67%,55%, and 41% at 12,24 and 36 hours respectively. The incidence of moderate pain was 25.5%,17.5% and 10.2% at 12,24 and 36 hours respectively. The incidence of severe pain was 9.36%, 1.28 %, and 0.43 % at 12, 24 and 36 hours respectively (Table 5). Postoperative moderate to severe pain occurred in 36.6%, 20% and 10% of patients at 12, 24 and 36 hours respectively (Figure 2). The overall average incidence of moderate to severe postoperative pain over the three-time repeated measurements is 22.41%. However, as shown by Cochran's q test, the magnitude of postoperative pain is significantly different between each time measurements (p=0.00).

Table 3: types of analgesics used for perioperative pain management of Pediatric surgical patients at selected Addis Ababa Public Hospitals, Ethiopia, January 2023 t0 April 2023

Category(n=235)	Frequency	Percentage
Preoperative analgesia used		
Paracetamol suppository	17	7.23
Fentanyl	2	0.85
Intraoperative analgesia used		
Fentanyl	183	76.59
Morphine	5	2.12
Paracetamol (Iv or suppository)	92	39.14
Ketamine	103	43.82
Dexamethasone	85	36.17
Iv Lidocaine	62	26.38
Only Opioids	66	28.09
Only Paracetamol (Iv or Suppository)	9	3.83
Only regional analgesia	10	4.26
Multimodal analgesia	148	62.8
Intraoperative regional analgesia used		
Local infiltration	36	15.32
Intercostal nerve block	4	1.70
Caudal Epidural	85	36.17
Spinal Anesthesia	2	0.85
Not used	108	45.96
Post operative analgesia used over the repeated measurements(n=705)		
Only opioids (Fentanyl or Morphine)	26	3.68
Only Paracetamol (Iv, syrup, Po or suppository)	375	53.19
Only NSAIDs (Diclofenac or Ibuprofen syrup)	33	4.68
Nonpharmacological method	12	5.1
Multimodal	271	38.44

Table 4: Postoperative pain assessment, analgesia administration and record practice of Pediatric surgical patients at selected Addis Ababa Public Hospitals, Ethiopia over the three-time period measurements, January 2023 to April 2023

Category(n=705)		Frequency	Percentage
Pain assessment frequency	None	31	4.40
	One time	401	58.88
	Two time	144	20.43
	Three and above	129	18.30
Analgesia given based on order	Yes	588	83.40
	No	117	16.60
Analgesia given recorded	Yes	413	58.58
	No	292	41.42
Pain assessment tool used	yes	56	7.9
	No	647	91.77

Table 5: Incidence of postoperative pain at 12, 24 and 36 hours from all Pediatric surgical patients at selected Public Hospitals in Addis Ababa, Ethiopia, January 2023 to April 2023

Postoperative pain severity	Incidence at each time of measurement					
	At 12 hr.	95% CI	At 24 hr.	95% CI	At 36 hr.	95% CI
Mild pain	32.3%	0.26- 0.38	36.6%	0.30-0.42	30.64	0.25-0.36
Moderate pain	25.5%	0.20- 0.34	17.5	0.13- 0.22	10.2%	0.07-0.15
Severe pain	9.36%	0.06- 0.14	1.28%	0.01- .034	0.43%	0.001- 0.03

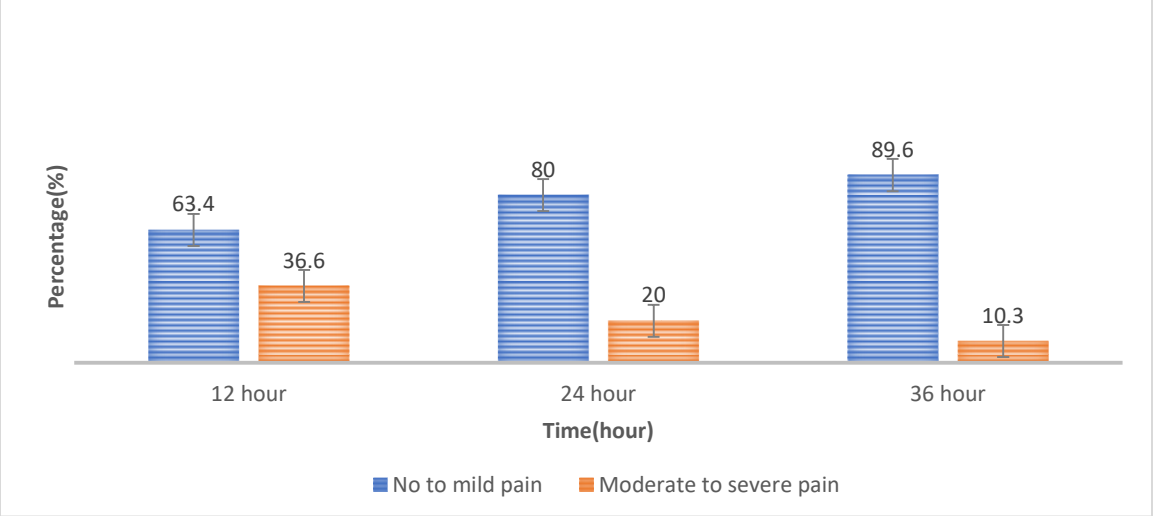

Figure 2: Postoperative pain level of Pediatric surgical patients at selected Addis Ababa Public Hospitals at each time measurements

5.15. Factors associated with postoperative pain

After the univariable analysis by using GEE model, previous surgery exposure, preemptive analgesic, sex, age, type of hospital, and maintenance analgesia used were excluded from the multivariable analysis as their effect on postoperative pain were not important at 0.25 level of significant. After adjusting for other variables, the following preoperative, intraoperative and post operative factors were identified. From preoperative factors, the odds of developing postoperative pain increased 3.41 and 2.28 times in patients having preoperative pain and preoperative anxiety respectively than that of not exposed to pain and anxiety (AOR=3.41, CI=1.15,10.00 and AOR=2.28, CI=1.219,4.277 respectively). Other preoperative factors such as, preemptive analgesia usage and ASA physical status have no significant role in Pediatric postoperative pain severity after 12 hours (Table 6).

From the intraoperative predictors, duration of surgery and extent of surgery are the main predictors of postoperative pain after 12 hours. The odds of post operative pain increased 5.2 times in major surgeries compared to minor and moderate surgeries (AOR=5.2; CI= 2.11,12.88). The odds of postoperative pain increase 6.2 times when surgery duration is greater than 2 hours when compared to duration less than 1 hour (AOR=6.62; CI= 1.907,23.00). Other intraoperative factors such as type of maintenance analgesia used and type of surgery have no significant role in determining postoperative pain level after 12 hours (Table 6).

Most important postoperative factors that determine the severity of postoperative pain after 12 hours are; time since surgery, type of postoperative analgesia used and frequency of postoperative pain assessment. The odds of postoperative pain reduced 0.24 times in patients taking multimodal analgesia compared to those taking single analgesic agents (AOR=0.24; CI= 0.091, 0.652). Also, the odds of postoperative pain were reduced 0.92 times when time elapsed by 12 hours (AOR= 0.92; CI= 0.903, 0.941). Patients assessed for pain within each 12 hours more frequently have reduced postoperative pain. For example, the odds of postoperative pain were reduced 0.09 times in those assessed above three times within each 12 hours than not assessed (AOR=0.09; CI= 0.022, 0.393). Postoperative movement in the ward has no significant role in determining postoperative pain in this age group (Table 6).

Table 6: Predictors of postoperative pain in Pediatric surgical patients at selected Addis Ababa Public Hospitals, Ethiopia, January 2023 to April 2023

Variables n=705	Category	No to mild pain	Moderate to severe pain	COR	P	AOR (95%CI)	P
Pain assessment frequency at each 12 hours	No	20	11	1	1	1	1
	One times	303	98	0.40	0.054	0.13(.037, .46)	0.002**
	Two times	111	33	0.32	0.026	0.11(.028,.45)	0.002**
	Above two	113	16	0.13	0.001	0.09(.022,.39)	0.001**
Type of surgery	Urologic	133	32	1		1	1
	GI	145	53	1.57	0.193	0.66(.28,1.53)	0.341
	Orthopedics	60	27	1.95	0.109	2.28(.79,6.59)	0.125
	CTS	43	14	1.51	0.402	1.50(.47,4.79)	0.488
	ENT	59	13	1.00	0.995	1.09(.35,3.36)	0.883
	Neuro	107	19	0.754	0.520	0.59(.19,1.82)	0.362
Preemptive analgesia	No	493	149	1	1	1	1
	Yes	54	9	0.53	0.22	0.60(.15,2.40)	0.477
Preoperative pain	No	514	131	1	1	1	1
	Yes	33	27	3.1	0.003	3.41(1.15,10.0)	0.026*
Preoperative anxiety	No	397	95	1	1	1	1
	Yes	150	63	3.5	0.000	2.28(1.21,4.27)	0.01*
ASA	One	357	90	1	1	1	1
	Two	169	50	1.14	0.618	1.07(.55,2.07)	0.83
	Three	21	18	2.81	0.028	2.05(.60,6.95)	0.25
Movement	No	499	153	1	1	1	1
	Yes	48	5	0.19	0.015	0.33(.08,1.34)	0.122
Time since surgery	-	-	-	.935	0.000	0.92(.90, .94)	0.000**
Duration of	Below 1hr.	189	15	1	1	1	1

surgery in hour	One to 3hr.	269	82	4.03	0.000	3.43(1.15,10.1)	0.026*
	Above 3hr.	89	61	8.6	0.000	6.62(1.90,23.0)	0.003**
Extent of surgery	Minor to Moderate	258	18	1	1	1	1
	Major	289	140	6.9	0.000	5.2(2.11,12.88)	0.000**
Postoperative analgesia used	Others	43	16	1	1	1	1
	Paracetamol	284	91	0.76	0.446	0.81(.34,1.94)	0.638
	Multimodal	220	51	0.353	0.006	0.24(.09, .652)	0.005**

*-----significant

**-----very significant

6. Discussion

The incidence of postoperative pain is very high in the studied Hospitals although it shows reduction in the occurrence and severity over time. For example, 67% of the studied patients

have either mild, moderate or severe pain at 12 hour and 41% at 36 hours. Pain is recommended to be treated with serious follow-up when it is above mild pain by many guidelines(5). The incidence of moderate to severe pain in this study is 36.6%,20% and 10% at 12,24 and 36 hours respectively relatively lower than the total pain incidence at each time. A study conducted in Rwanda shows, above half of pediatric surgical patients had severe postoperative pain in the first 48 hour after surgery(24) which is comparably very high than the result of this study. Similar study conducted in Ethiopia, University of Gondar, indicates that the overall prevalence of moderate to severe pain within the first 24 hour is 40% although the study is different in design(25).Different perioperative factors affects the level of postoperative pain in pediatric surgical patients in the studied hospitals. The most determinant in many studies are intraoperative and postoperative pain assessment and management practices (32) which are consistent with the result of this study.

It is well known that presence of written pain management protocols, consistent pain assessment tools and frequent pain assessment and management are vital to reduce suffering from postoperative pain in pediatrics(42,46,85).In the studied population, patients who were assessed frequently specifically more than one times within each 12 hours have significant reduction of pain postoperatively. This implies, health professional who assessed the patient tried to treat the pain at the time as leaving patients in suffering is in human. However, only 37% pediatric surgical patients were assessed above one times within each 12 hours. Most patients were assessed once in each 12 hours mainly in the morning when the senior physicians, residents and other health professionals undergoing round. In addition, there is no consistent pain assessment tool designed for pediatrics in each hospital and patients pain level was not well documented even in assessed patients. Actually, finding consistent pain assessment tool applicable for all pediatric age group and accurate pain assessment in pediatrics is a global common challenge(3,5).Developed countries tried best alternatives and approaches to detect post operative pain using technologies such as mobile apps and computers to have accurate assessment of pain (36,61,63).In many developing countries specially in sub-Saharan countries pain assessment is neglected(33) showing appreciable assessment initiatives in the studied hospitals comparably.

Post operative pain management is the pillar to reduce the severity of postoperative pain but hindered by different factors in lower income countries such as the availability of drugs, cost and the health professional's empathy, knowledge and attitude towards pain management(24,25,42). For example, in the studied hospitals ketorolac and rectal diclofenac were not available and Iv Paracetamol is too costly for most of patient even if its availability is appreciable. These drugs are recommended by The European Society for Pediatric Anesthesiology (ESPA) for minor to moderate surgeries like hernia and circumcision to be routinely used as a base line treatment postoperatively(23). Regional analgesia mainly Caudal analgesia and local infiltration at the wound site were practiced for intraoperative analgesia but the analgesic effect wear off beyond 12 hours. Peripheral nerve blocks which have longer duration of action beyond 12 hour (34,42,73,75) were used rarely. Different types of peripheral nerve blocks were performed frequently in the developed world for different type of surgeries starting from neonatal age with rare complications(71,74,77).In the studied Hospitals, the availability of equipment's such us nerve stimulator and ultrasound as well as shortage of experts in pediatric nerve block would be the expected reasons of its lower practice.

Patients taking multimodal analgesia have reduced postoperative pain as shown by different studies for different types of surgeries. For example, studies in neurosurgical, thoracic surgery and other patients indicate, taking multimodal analgesia had reduced post operative pain level significantly with different efficacy depending on the class of drugs combined(44,56). Also in this study, patients taking multimodal analgesia have significant reduction of postoperative pain severity nearly 0.24 times than patients taking single analgesic agent. The effect of multimodal analgesia using paracetamol and NSAIDs is the recommended way of postoperative pain management to reduce opioid consumption(67).In the studied Hospitals, even though many of patients took paracetamol only, most patients who took multimodal analgesia gets the combination of ibuprofen syrup and paracetamol which is in line with the global recommendation. Analgesic agents such as Ketamine, dexamethasone and fentanyl were used intraoperatively in the studied hospitals frequently but not used for postoperative pain management. Different literatures recommended tramadol, Ketamine and Dexamethasone to be used as part of multimodal analgesia postoperatively and fentanyl to break through postoperative pain in children(42,64,66).

Patients having preoperative anxiety are more likely to have postoperative acute and chronic pain as shown by different studies(49,50).In this study, patients having preoperative anxiety have higher post operative pain incident (AOR=2.28) which is comparable with other studies result. For instant in Gondar University Hospital, patients with preoperative anxiety are 2.24 times more likely to develop postoperative moderate to severe pain than the control. In many literatures the effect of anxiety is diminished by none pharmacological pain management techniques and involvement of the parent(22). Nonpharmacologic interventions, such as distractions, relaxation, play therapy, music therapy, and other methods are available at many Hospitals which has been noted to decrease anxiety and improve pain control and patient cooperation(49,65,80). However, none of these techniques were practiced adequately in these Hospitals and this may be the cause of higher anxiety related postoperative level. Patients having pre operative pain have significant post operative pain in this study. Different scholars also support this finding with nearly similar incidents of postoperative pain severity(25,57).Some studies show preemptive analgesia usage such as Dipyrone and paracetamol reduce post operative pain in tonsillectomy and other patients(4,69,70).In contrary, this study demonstrates as it have no effect. However, the outcome was measured at 12-hour interval, the mean effect of preemptive analgesia used wear off by this time and it is difficult to determine whether it reduces pain level or not.

Type of surgical procedure or the specialty were not found a significant determinant factor for postoperative pain in this study. The main determinants are the extent and duration of surgery than the type of surgery. Major surgeries involve opening the body that results major trauma to the tissues than minor and intermediate surgeries. That is why major surgeries and surgeries with longer duration (AOR of 5.2 and 6.62 respectively) have more intense pain than minor and intermediate surgeries and short duration surgery in this study which is in line with other studies. For instance, in surgical pediatric patients at Gondor University Hospital, patients having greater than 10cm incision size have 3.9 times higher pain level than less than 5 cm incision size(25). Sex has contradicted effect on postoperative pain level as shown in few studies. One study indicates being male increase pain level due to stronger neuroendocrine response and the other say the reverse(58,59). This study showed that sex have no role in post operative pain severity. Time since surgery is other important factor that determines postoperative pain severity. The worst incidence of pain experience is higher in the first 24 hour in many literatures and similarly

in this study, when time elapsed by 12 hour the odds of postoperative pain was reduced 0.92 times.

7. Strength and Limitation

This study is relatively stronger in the design than previous studies of similar setting by considering the repeated nature of the postoperative outcome measurements using GEE model in the analysis to capture the dependency and predict the true effect of different factors on postoperative pain severity. This study also uses consistent pain assessment tool best applicable for the study groups which is called FLACCE(13,14). As a limitation, this study measures the outcome variable at a specific time intervals and it doesn't measure weather the patient was in pain previously from that point of measurement or after that time measurement since there is no validated pain assessment tool in pediatrics which considers this. And also, this study doesn't include all pediatric surgical patients due to absence of common pain assessment tool for all age group.

8. Conclusion

The incidence of moderate to severe pain is still high although there is an appreciable initiation to reduce postoperative pain in the studied hospitals. A great attention is given to reduce post operative pain in developed countries in small children, but low-income countries including Ethiopia lag behind that despite their population is mainly in this age group**.** The availability of consistent pain assessment tools, low emphasis towards pain management and assessment, limitation in resource and shortage of experts are undeniable reasons. Frequency of pain assessment, documentation and pain management practice needs high improvement to reduce postoperative pain suffering and its consequences in these Hospitals.

9. Recommendation

Each Hospitals should prepare consistent pain assessment tools and pain management protocols for health professionals working there. Health professionals needs to give more attention to frequent pain assessment, multimodal analgesia usage and application of none pharmacological pain management methods. Frequent and further researches and assessments about the severity of postoperative pain are required from researchers. The government should have adequate supply of important analgesic agents and equipment necessary to manage postoperative pain in small children.

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Annex

Annex 1: information sheet

This questionnaire is prepared to assess the severity and associated factors of postoperative pain in pediatric surgical patients at selected Addis Ababa Public Hospitals in Ethiopia from January 2023 to April 2023.The principal investigator of this research is Fassil Mihretu, doing my MSc in advanced clinical Anesthesia at Addis Ababa University. This research is intended for a PARTIAL FULFILLMENT OF MASTER OF SCINSCE IN ANESTHESIA. This questionnaire has four parts: part one sociodemographic characteristics; part two preoperative and intraoperative patients' conditions; part three: Conditions during Emergence /Recovery and part four postoperative pain assessment tool. This questionnaire may take 30 minutes totally (10 minute in each observation). By using the pain assessment tool, the child will be observed at three instants of times postoperatively i.e., at 12-hour, 24 hour and 36 hours. Participation in this study doesn't have special benefits, risks and inducement. Any patient who becomes comatose and who will be admitted to intensive care unit at any time postoperatively will be allowed to withdraw the study.

If you want to communicate me for any inconvenience and clarifications here are my addresses

Name: Fasil Mihretu

Tel: +251923743831.

Email: fasilmihretu@gmail.com

Annex 2: Informed consent form English and Amharic

Questionnaire identification number_____ card number……

Greeting,

Hello, I am Fassil Mihretu. I am MSc student in Addis Ababa University Department of Anesthesia doing my thesis at these hospitals. The purpose of this questionnaire is “to assess severity and associated factors of postoperative pain in pediatric surgical patients at selected Addis Ababa Public Hospitals in Ethiopia from December 2022 to March 2023’ ’If you are voluntary for your child, we will ask and observe your children which will take few minutes. The answer to those questions is confidential. We will not write your child’s name in the questionnaire and assessment tool. The data after your child response will be putted in a secured locker which have strong key. No part of your child’s personal identification information will be described in the analysis and dissemination of the result. Participating in this study has no inducement, risks and direct benefit to you.

Do I have your permission to continue? Yes……No……

የ ማኪይቅ ፈቃድ

ማላያ ቁጥር ……ካርድ ቁጥር ……..

ጤፍ ይስጥልኝ፡ ፡ እኔ **ፋሲልል ምህረቱ** እባላለሁ፡ ፡ ወሎዩኒቨርሲቲ የሁለተኛ አሞት አንስቴዥያ ማስተርስ ተማሪ ስሆን በዚህ ሆስቲታል የመሚቂያ ጥናቴን በማራት ላይ እገኛለሁ፡ ፡ የዚህ ጥናት አላማ ህጻናት ከ ቀዶ ጥገና በሁላ የሚሮራቸዉን የህማም ደረጃ ማለየትና ተያያዝ ጉዳዮችን ማጥናት ነው ፡ ለማኪይቁ የሚሰጡት ሜልስ ወይም የሚሰበሰበዉ ሚጃ ዉጤቱን በሞትንተንም ጊዜ ሆነ በህትሞት ጊዜ ሚስጥራዊነቱ የተጠበቀ ነዉ፤ ስምዎት ማኪይቁ ላይ አይፃፍም፡ ማኪይቁ ከተሰበሰበ በሁላ ጠንካራ ቁልፍ ባለዉ ማስቀሜጫ በጥንቃቄ ይቀማጣል፡ ፡ በዚህ ጥናት ላይ ማሳተፍ የሚያጣዉዳት የለም፡ የሚያስገኝዉቀጥተኛ የሆነ ም ጥቅምየለም፡ ለተሳትፎ የሚሰጥክፍያ የለም ፡

ከልጅዎት ሚጃ አንድሰበሰብ ፈቃደኛ ነዎት? አዉ……አይደለሁም……

Signature/ፊርማ---------- Date/ቀን ----------

Annex 3: Questionnaire

Date_____ Bed number…….

Card number- _____ Code no …….

Part I: Sociodemographic characteristics

No	Questions	Response
101	Sex	1. Male 2. Female
102	Age	----------month/yrs
103	Weight	----------kg
104	Height	----------m

Part II: Preoperative and intraoperative patients' conditions

No	Questions	Response
201	What was the dx?	……..
202	Urgency of the surgery	1. Emergency 2. Urgent 3. Elective
203	Coexisting diseases	1. Diabetes mellites 2. Hypertension 3. COPD 4. Asthma 5. heart disease 6. Others (specify) …….7. None
204	Preoperative vital signs	BP: ---PR: --- RR: ----TO: --- SPO2---
205	Preoperative anxiety using m YPAS-SF tool	1.yes 2. No
206	Preoperative pain level Using FLACC tool	1.No 2. Mild 3. Moderate 4. Severe
207	ASA Class of the patient	1.ASA 1 2.ASA 2 3. ASA 3 4. ASA 4
208	Preoperative premedication and analgesia	1.Diazepqm…….mg 2. Cimetidine……mg 3. Dexamethasone….mg 4.Lidocaine…….mg 5. paracetamol -----mg 6. others(specify)…. 7. None
209	Type of anesthesia	1.General anesthesia with ETT 2. General anesthesia with LMA 3.Spinal anesthesia 4. Sedation 5. Peripheral nerve blocks 6. Local infiltration
210	Induction drug used if GA	1.Ketamine….m 2. Propofol….mg 3. Thiopentone…mg 4. Gas induction.....
211	Intraoperative analgesia given	1.Paracetamol… mg 2. Diclofenac…mg 3. Opioids ……mg, specify

		4.Tramadol…….mg 5. Ketamine …mg 6. Regional analgesia…… 7.Others (specify) …….
212	Intubating muscle relaxant	1.Succinylcholine…….mg 2. Vecuronium…….mg 3.Panccuronium……mg 4. Others…… …mg 5. None
213	Surgical position	
214	Maintenance muscle relaxant	1. Succinylcholine------mg 2. Vecuronium-------mg 3. Panccuronium --------mg 4. others……... 5. None
215	Anesthesia maintenance	1.TIVA 2. Halothane 3. Isoflurane 4.Others (specify)……
216	Type of surgery	1.Urologic 2.GI Surgery 3. Neurologic surgery 4. Gynecological surgery 5.Orthopedic surgery 6.ENT 7. Maxillofacial 8. Cardiothoracic surgery 9.Oncologic surgery 10. Others (specify)
217	Surgical procedure	
218	Extent of surgical procedure	1. Minor 2. Moderate 3. Major
219	Surgery duration	……Minute (start time……. end time…….)
220	Anesthesia duration	……. Minute
221	Exposed for surgery before	A. Yes (1 times,2 times, more than two times) B.NO

Part III: Conditions during Emergence /Recovery and postoperatively

No	Questions	Response
301	Patients hemodynamic during postoperative time	1.at 12-hour A. Stable B not stable C. Critical 2.at 12-hour A. Stable B not stable C. Critical 1.at 36-hour A. Stable B not stable C. Critical
302	Ordered analgesia postoperatively	
303	Dose analgesia given based on order	**12hr.** A. Yes B. No **24hr.** A. Yes B. No **36hr**. A. Yes B. No
304	Total postoperative analgesia given in mg with type of analgesia	12hr---------- 24hr---------- 36hr……
305	Does pain assessment performed	1. first 12 hr A. Yes B. No, if yes how many times……. 2. next 12 hr A. Yes B. No, if yes how many times……. 3.3rd 12 hr A.Yes B. No, if yes how many times…….
306	Does pain assessment tool used	**12hr.** A. Yes B. No **24hr.** A. Yes B. No

		36hr. A. Yes B. No		
307	Intensity of postoperative pain as assessed by FLACC tool	**1. at 12 hr** A.No pain B.Mild pain C.Moderate pain D. Severe P	**2. at 24 hr** A.No pain B.Mild pain C.Moderate p D. Severe P	**3. at 36 hr** A.No pain B.Mild pain C.Moderate P D. Severe P
308	Does the patient move in the ward	**12hr.** A. Yes B. No **24hr.** A. Yes B. No **36hr**. A. Yes B. No		
309	Does the analgesia given recorded	**12hr.** A. Yes B. No **24hr.** A. Yes B. No **36hr**. A. Yes B. No		
310	Does none pharmacological pain management used	**12hr.** A. Yes B. No **24hr.** A. Yes B. No **36hr**. A. Yes B. No		

Annex 4: Post operative pain intensity and preoperative anxiety assessment tools

1. FLACC pain assessment tool

Behavior	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal 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 cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams, sobs, frequent complaints
Consolability	Content, relaxed	Reassured by touching, hugging or being talked to, distractible	Difficult to console or comfort

2. The m YPAS-SF preoperative anxiety assessment tool

A. Activity

1 = Looking around, curious, playing with toys, reading (or other age-appropriate behavior); moves around holding area/treatment room to get toys or go to parent; may move toward OR equipment

2 = Not exploring or playing, may look down, may fidget with hands or suck thumb (blanket); may sit close to parent while waiting, or play has a definite manic quality

3 = Moving from toy to parent in unfocused manner, nonactivity derived movements; frenetic/frenzied movement or play; squirming, moving on table, may push mask away or clinging to parent

4 = Actively trying to get away, pushes with feet and arms, may move whole body; in waiting room, running around unfocused, not looking at toys or will not separate from parent, desperate clinging

B. Vocalizations

1 = Reading (nonvocalizing appropriate to activity), asking questions, making comments, babbling, laughing, readily answers questions but may be generally quiet; child too young to talk in social situations or too engrossed in play to respond

2 = Responding to adults but whispers, "baby talk", only head nodding

3 = Quiet, no sounds or responses to adults

4 = Whimpering, moaning, groaning, silently crying

5 = Crying or may be screaming "no"

6 = Crying, screaming loudly, sustained (audible through mask)

C. Emotional Expressivity

1 = Manifestly happy, smiling, or concentrating on play

2 = Neutral, no visible expression on face

3 = Worried (sad) to frightened, sad, worried, or tearful eyes

4 = Distressed, crying, extreme upset, may have wide eyes

D. State of Apparent Arousal

1 = Alert, looks around occasionally, notices watch what anesthesiologist does with him/her (could be relaxed)

2 = Withdrawn child sitting still and quiet, may be sucking on thumb or face turned into adult

3 = Vigilant looking quickly all around, may startle to sounds, eyes wide, body tense

4 = Panicked whimpering, may be crying or pushing others away, turns away

Scoring: Divide each item rating by the highest possible rating (i.e., 6 for the 'vocalizations' item and 4 for all other items), add all of the produced values, divide by four, and multiply by 100