Addis Ababa University

College of Health Sciences

Department of Anesthesia

EFFECTIVNESS OF INTRA OPERATIVE INTRAVENOUS DEXAMETHASONE ON POST-OPERATIVE OPIOID CONSUMPTION IN PATIENTS WHO UNDERGO MAJOR ORTHOPEDIC SURGERIES UNDER GENERAL ANESTHESIA AT BLACK LION HOSPITAL IN ADDIS ABABA, ETHIOPIA 2018/19.

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ADDIS ABABA UNIVERSITYCOLLEGE OF HEALTH SCIENCES

SCHOOL OF MEDICINE DEPARTMENT OF ANESTHESIA

MASTER OF ANESTHESIARESEARCH PROPOSAL

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Full title of the research	Effectiveness of intra operative intravenous dexamethasone on post-operative opioid consumption in patients who undergo major orthopedic surgeries under general anesthesia at black lion hospital in Addis Ababa, Ethiopia 2018/19
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Duration of the project	September 21/2018 – May 20 /2019.
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CERTIFICATION

The under signed certify that the research entitled comparison of the Effectiveness of intra operative intravenous dexamethasone on post-operative opioid consumption in patients who undergo major orthopedic surgeries under general anesthesia at black lion hospital in Addis Ababa, Ethiopia 2018/19. Institutional based prospective cohort study is my original work and any literature and/or data cited in this article were listed in the reference section and any assist done during this period has been given an acknowledgement.

Investigators

Name _____ Signature _____ Date _____

Approval of the Board of Examiners

1. Advisor

Name _____ Signature _____ Date _____

2. Internal Examiner

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3. External Examiner

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ABSTRACT

Background: Dexamethasone is a powerful anti-inflammatory and anti-emetic agent that has been found to decrease opioid use and pain intensity. Effective postoperative pain control is an essential component of the care to the surgical patient. This study has been designed to investigate whether dexamethasone can be a good anesthetic adjuvant, in relation to decreasing the demand for post-operative analgesics and pain intensity.

Objectives: To test the effectiveness of intravenous Dexamethasone on decreasing post-operative opioid requirements at black lion hospital, Ethiopia.

Methods: The study was a prospective cohort study carried out at black lion hospital from September 21/2018 – May 20 /2019. A total of 66 patients for elective orthopedics surgery under general anesthesia were studied. Simple random sampling was used. The data were analyzed using independent sample t-tests and Manny Whitney u test for normally and non-normally distributed data respectively. Chi Square test was used to study the categorical variables. Box and Whisker plot were used to show a median pain score between groups and statistical significant were stated at P-value <0.05 with a power of 80%.

Result: Decreased total analgesic consumption was observed in dexamethasone group 2.5 (1.25-5) as compared to control group 10 (5-10) mg with a P value of (P <0.0001). At all the time interval low pain score was observed in dexamethasone group with a P-value of <0.05. However there was no difference between the two groups at 3rd hour (P=0.586). The median time to first dose of analgesics in dexamethasone group was observed to be longer than control group 180 (120-240) minutes as compared to 60 (60-180) minutes.

Conclusion and recommendation; dexamethasone administered after intubation, was better in reducing total opoid consumption, VAS score and first analgesic request time compared with the control group who takes nothing as adjuvant in patients undergoing general anesthesia for major orthopedics surgeries. Therefore, using dexamethasone intraoperatively to reduce opoid consumption especial during postoperative time is essential. Further randomized control trial study may be needed.

Key words; dexamethasone, major orthopedics surgery, opoid consumption**,** pain

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ABBRIVIATION

ASA-American Society of Anesthesiology

ASOD-American society of drug addiction

BLH- black lion hospital

ENT – Ear, Nose, Throat

ETTI – Endo tracheal Tube Intubation

GA – General Anesthesia

KG-Kilo Gram

Mg – milligram

Min – Minute

MOH-ministry of health

RCT - Randomized Controlled Trial

Sd – standard deviation

TENS- transcutaneous electrical nerve stimulation

VAS – Visual Analogue Scale

WT – Weight

WHO- world health organization.

CHAPTER ONE –INTRODUCTION

1.1 BACKGROUND

Inadequately controlled pain has undesirable physiologic and psychological consequences such as increased postoperative morbidity, delayed recovery, a delayed return to normal daily living, and reduced patient satisfaction. Importantly, the lack of adequate postoperative pain treatment may lead to persistent pain after surgery, which is often overlooked.**(1, 2)**

Acute inflammation induced by tissue damage has a major role in development of postoperative pain, nausea and vomiting. Therefore, dexamethasone should be useful in lowering pain, nausea and vomiting, due to its potential anti- inflammatory effect. Dexamethasone is the most powerful anti-inflammatory drug with a long half- life; and its administration is considered safe for periods shorter than two weeks even in amounts above physiological doses.(3, 4) Tissue lesions formed during surgery induce the production of multiple nociceptive mediators such as prostaglandins, which are produced via the arachidonic acid cascade. Glucocorticoids decrease the level of prostaglandin synthesis by indirectly inhibiting the activity of phospholipase A2 and cyclooxygenase II. Glucocorticoids can also modulate the inflammatory response by inhibiting the production of cytokines, including tumor necrosis factor α, interleukin-1β, interleukin-6, C-reactive protein, and leukocyte receptors. For this reason, glucocorticoids can be used in the treatment of acute pain.**(5)**

Opioids are a class of drugs that include the illicit drug heroin as well as the licit prescription pain relievers' oxycodone, hydrocodone, codeine, morphine, fentanyl and others. Opioids are chemically related and interact with opioid receptors on nerve cells in the brain and nervous system to produce pleasurable effects and relieve pain. Drug overdose is the leading cause of accidental death in the US, with 52,404 lethal drug overdoses in 2015. Opioid addiction is driving this epidemic, with 20,101overdose deaths related to prescription pain relievers, and 12,990 overdose deaths related to heroin in 2015.**(6)**

Despite advances in surgical and anesthetic techniques, many patients were still suffering from sever and acute pain in the postoperative period. Many anesthesia modalities and medications have been used in various combinations to reduce the amount of pain experienced by patients after they undergo surgical procedure. Pain is often the patient's common symptom post operatively. It can provide useful clinical information and it is our responsibility to use this information to help the patient and alleviate suffering. Effective analgesia is an essential part of postoperative management.(7)

Mainly opoids are used to control strong pains related to surgery although they have multiple side effects related to their root of administration, dosage. It was best to reduce the demand from the beginning by focusing on multimodal analgesia and other root implementation of a strategy utilizing a multimodal analgesia protocol address and enable pain control management at these multiple complex levels and pathways. Several studies have shown that steroids, particular Dexamethasone administered in various doses, intravenously (IV) , intra-thecally reduced; pain intensity, Morphine/Pethidine consumption, nausea and vomiting (PONV) post-operatively**.(8)**

1.2 Statements of the problem

The Pain from surgery is multi factorial, and different treatments have been advocated to provide pain free time for the patient. This includes, opioids, non-steroidal anti-inflammatory drugs ,local anesthetic agents, N-methyl-D aspartic acid receptor antagonists ,steroids ,Acetaminophen, as well as non-pharmacologic techniques have been applied to control pain.(9)

Single opioid analgesics may not provide effective pain relief for moderate to severe pain, and are associated with side effects such as nausea, vomiting, sedation, constipation, and/or bleeding. These adverse side effects alter the patient's perceived surgical outcomes, and may increase the hospital stay and financial burden on the patient and the medical system**.**(10)

The efficacy of glucocorticoids like dexamethasone in reducing postoperative pain has been investigated in recent years showed that a single dose of dexamethasone as analgesia significantly has advantages in terms of reduction in pain intensity, opioid requirements, analgesia, length of postoperative anesthesia care unit and time to requires first analgesia.(11)

The prevalence of post-operative pain is still severe and under managed in our country. Identifying perioperative factors for the occurrence of moderate/severe post-operative pain may be useful for designing factor specific interventions to relieve patient suffering.**(12)**

Use of Physical Modalities like TENS, acupuncture , massage, cold therapy, localized heat, warm insufflation, continuous passive motion ,and immobilization , imagery, relaxation and hypnosis and pharmacological treatments including, PCA, NSAID, OPOIDS, celecoxib, gabapentin or pregabalin, iv ketamine ,iv lidocain ,local anesthesia infiltrations were the main stay of analgesia for pain management.(13)

1.3 justification of the study

Opoid use is becoming more risky related to addiction and side effects associated with its use multiple losses were recorded. Addiction is a primary, chronic and relapsing brain disease characterized by an individual pathologically pursuing reward and/or relief by substance use and other behaviors.(6)

Currently some studies were done on the methods of analgesia other than opoid use and they are showing good result on pain management and patient outcomes.

And the reason why we did this research was due to difficulty to generalize research results from other countries, because the hospital setup and the management style varies due to technological and developmental difference to our study area. And also there is an inter-racial and ethnic difference in pain and response to drugs so it was difficult to take results from white peoples other races.

As far as my search still there is no published research in my study area and topic so that it can be used as a base line data and information source for further research.

This study was planned to measure the effectiveness of dexamethasone on post-operative opoid consumption for orthopedics surgeries and it generates the information that can help program planners, academicians, to develop effective way of post-operative pain management plan, to select best alternatives for pain management, to develop strategies for pain management and to evaluate the effectiveness of implemented preventive intervention targeted to the problem.

CHAPTER TWO-LITERATURE REVIEW

2.1 POST-OPERATIVE PAIN AND DEXAMETHASONE

Dexamethasone is a synthetic glucocorticoid with minimal mineralocorticoid activity. It is a potent anti-inflammatory, with 25-50-fold the activity of hydrocortisone and up to 16-fold higher than prednisolone. It is commonly used in the perioperative period as prophylaxis for postoperative nausea and vomiting and reduction of airway and cerebral edema. It can be useful in the management of acute and chronic pain. Among its multiple actions, it reduces the release of bradykinin, tumor necrosis factor and interleukins 1, 2and 6, as well as the production of prostaglandins. It also decreases impulse transmission in C-type fibers. Its half-life is 3 hours, its action is more prolonged and has lower protein binding-affinity than other steroids.(14)

Adequate postoperative pain management can reduce the patient's length of hospitalization and decrease postoperative complications. However it was found that there have been knowledge gap on post-operative pain managements Therefore, providing a continuous education program on pain assessment, starting to use pain assessment tools, guidelines and protocols, and documenting assessment tools were recommended.(15, 16)
The efficacy of glucocorticoids for reducing pain and inflammation after surgery has recently been explored. Early studies in patients undergoing dental procedures showed that glucocorticoids were effective in reducing postoperative pain and oedema. A number of recent studies have investigated the potential analgesic benefit of a single perioperative dose of dexamethasone but have inconsistent findings.(17)

There is a growing body of evidence for the beneficial effects from perioperative single-dose intravenous (IV) glucocorticoids for reducing pain, emesis, and fatigue, thereby improving the recovery process and patient satisfaction. The benefits versus risk associated to single preoperative iv. dose of dexamethasone seem positive based on current evidence facilitating the recovery reducing pain and postoperative nausea and vomiting.(18)

Although they are best and effective for managing pain there are multiple side effects related to the consumption of opoids. Some of the side effects include Constipation, Drowsiness Nausea, vomiting, allergy or hypersensitive reaction; addiction and physical dependence etc. poor doctor

consultation, in appropriate intake, starting with strong ones, poor awareness about the side effects make side effects worth. So it was better to reduce or as much as possible to avoid the use of opoids with strong side effects.(19)

Opioids are associated with risks for patients and society that include misuse, abuse, diversion, addiction, and overdose deaths. Therapeutic success depends on proper candidate selection, assessment before administering opioid therapy, and close monitoring throughout the course of treatment. Risk assessment and prevention include knowledge of patient factors that may contribute to misuse, abuse, addiction, suicide, and respiratory depression. Risk factors for opioid misuse or addiction include past or current substance abuse, untreated psychiatric disorders, younger age, and social or family environments that encourage misuse.**(20, 21)**

2.2 DEXAMETHASONE FOR POST OPERATIVE PAIN AND ANALGESIC CONSUMPTION

Dexamethasone decreases total opiod consumption postoperatively Regarding this a Double blind prospective study by As double blind prospective study done in 2015 in West Bengal, India shows that The meperidine consumption in the Dexamethasone group was significantly reduced from the normal saline group (135.4 ± 25.7 vs. 228.8 ± 21.5) milligrams respectively. similarly A retrospective chart review was conducted in 2016 at Hurley Medical Center, Michigan, USA .A total of 102 patients underwent TKA, 55 subjects received dexamethasone (treatment group) and 47 did not (control group) Patients who received dexamethasone required a significant smaller quantity of oral opioids (oral morphine equivalence 37.1 mg) compared to the control group (73.1 mg, P = 0.020) throughout the standard 3-day hospital stay. When we see the pain score No statistically significant difference was noted in immediate postoperative VAS pain scores upon arrival to the post-anesthesia care unit, at 12 and 48 h. However, at 24 h the VAS pain scores were lower for the dexamethasone group (4.57) than for the control group (6.077) P = 0.003 .**(10) (22)**

A 2015 Randomized double-blind trial done at, Hasanuddin University, Indonesia on 30 patients, divided into 15 people each group randomly, so that individual variation is divided evenly in groups, the treatment group and the control group. The intensity of the pain in the two groups did not differ significantly except at observation 24 h pain intensity was found to be lower in the treatment group. Needs opioid morphine until the 4 h postoperative in both groups did not differ significantly, The treatment group requiring opioid morphine lower at 24 h postsurgical than the control group**.(11)** Whereas another randomized, single-centre, single-blinded study was conducted over a six month period At the University Hospital in Jamaica on Shows that Total Pethidine consumption for the control group (A) was significantly higher (5200 mg) than the study Group (B), 3800 mg (p=0.008). Age of patients and length of surgery were not found to influence Pethidine requirements (p=0.338 and 0.131 respectively). Pain intensity was significantly lower in Group of study at the 12-hour assessment, p=0.019, and earlier discharge home was also noted. No adverse effects of Dexamethasone were observed.**(23)**

A randomized, blinded, placebo-controlled, parallel group study done in ,Bogota, Colombia on the analgesic effect of dexamethasone which In the control group (NS group), patients received 2 mL of 0.9% normal saline intravenously at the onset of anesthetic induction. In the treatment group (DM group), patients received 2 mL of a 5 mg/mL dexamethasone phosphate solution at the onset of anesthetic induction shows that The mean morphine dose administered during the postoperative period was lower in the Dexamethasone group, but again the difference was not statistically significant. No correlation was identified between the doses administered during the intraoperative and postoperative periods. (5)

A Systematic review and meta-analysis done at Department of Anesthesiology, Duke University Medical center in 2015. Dexamethasone-treated patients used less opoids at 2 h [20.87 mg morphine equivalents (95% CI: 21.40 to 20.33)] and 24 h [MD 22.33 mg morphine equivalents (95% CI: 24.39, 20.26)], required less rescue analgesia for intolerable pain [relative risk 0.80 (95% CI: 0.69, 0.93)], had longer time to first dose of analgesic [MD 12.06 min (95% CI: 0.80, 23.32)], and shorter stays in the post-anaesthesia care unit [MD 25.32 min (95% CI: 210.49 to 20.15)]. Generally A single iv perioperative dose of dexamethasone had small but statistically significant analgesic benefits.(24) another similar study A prospective, Dose ranging double-blind study done on 2011, subjects were randomized to receive normal saline, dexamethasone

0.05 mg kg(-1) or dexamethasone 0.1 mg kg(-1) before induction. shows that At 24 h, subjects receiving dexamethasone 0.1 mg/kg had consumed less opioid analgesics, reported less sore throat, muscle pain, confusion, difficulty in falling asleep, and nausea compared with dexamethasone 0.05mg/kg and saline which may be beneficial for improving recovery after ambulatory surgeries. (3)

In Another meta-analysis of randomized controlled trials Twenty-four randomized clinical trials with 2,751 subjects were included. Opioid consumption was decreased to extent with moderate -0.82 (-1.30 to -0.42) and high -0.85 (-1.24 to -0.46) dexamethasone, but not decreased with low-dose dexamethasone -0.18. Preoperative administration of dexamethasone appears to produce a more consistent analgesic effect compared with intraoperative administration.(25)

A randomized, triple-blind, placebo-controlled trial done on 2017 in KhonKaen University, KhonKaen, Thailand where eighty patients were randomly allocated into two groups to receive either intravenous 0.2 mg/kg dexamethasone (group D = 40) or normal saline (group P = 40) before anesthetic induction. Shows that Total post-operative morphine consumption within 48 h was significantly lower in group D (34.5 vs. 42.5 mg, p = 0.031); however, the respective morphine consumption at each assessment was similar between groups. The respective VAS pain score at rest and upon movement in both groups was not significantly different for any time comparison. The study concluded that a single dose of dexamethasone before induction can decrease post-operative morphine consumption within 48 hours after the procedure. (26)

In another RCT allocating 34 patients randomly to receive celecoxib 200 mg or placebo capsules Fourteen patients received 20 mg dexamethasone intravenously during surgery gives the result that , patients with intraoperative dexamethasone (n = 14) required only 10.29 mg 24-hour PCA, in contrast to the 34.25 mg needed in those who did not receive intraoperative dexamethasone. In addition, 24 hours after the operation, pain scores on movement were signicantly lower in the dexamethasone subgroup. (27)

Another systematic review and meta-analysis of randomized controlled trials shows that The opioid consumption at 48hours was collected from 3 studies. There was no significant heterogeneity between 3 studies (x =1.19, df=2, I =0%, P=.55); and then, the fixed-effect mode was used to count the data. The outcome of analysis demonstrated that opioid consumption at

48hours in dexamethasone group was significantly lower than that in control group (SMD =−0.63, 95%CI: −0.91 to −0. 35, P<.001(28)

Another randomized control trial which randomizes 60 patients into 2 groups to receive either 2 mL saline or 0.1 mg/kg dexamethasone IV before the administration of intrathecal anesthesia. Indicates IM diclofenac requirements and the incidence of PONV were significantly lower in the dexamethasone group than the control group ($P < 0.05$). The VAS pain scores at 6-h intervals were significantly lower in the dexamethasone group.(29)

A prospective, double-blind, placebo-controlled study, 70 patients scheduled for mastectomy with axillary lymph node dissection were analyzed after randomization to treatment with 8 mg intravenous dexamethasone (n = 35) or placebo (n = 35).Dexamethasone treatment significantly reduced postoperative pain just after surgery (VAS score, 4.54 ± 1.55 vs. 5.83 ± 2.00; p = 0.004), at 6 h (3.03 ± 1.20 vs. 4.17 ± 1.24; p < 0.0005) and at 12 h (2.09 ± 0.85 vs. 2.54 ± 0.98; p = 0.04). Analgesics were required in more patients of the control group (21 vs. 10; p = 0.008).(30)

A double- blind prospective study, the effect of Single-Dose Administration of Dexamethasone on Postoperative Pain in Patients Undergoing Laparoscopic Cholecystectomy carried out between 2012 and 2013 shows that total consumed postoperative meperidine, in intravenous dexamethasone receiving group was significantly less than placebo receiving group ($P = 0.03$). mean postoperative pain intensity based on VAS score at two, six and 12 hours after entrance to PACU in dexamethasone receiving group was significantly lower compared with placebo group ($P < 0.05$). (31)

In randomized double-blind placebo controlled trial on dexamethasone for postoperative analgesia in children undergoing hypospadias repair The maximum episode of post-operative rescue medication consumption in dexamethasone group was 4 episodes in only one patient and the minimum was one episode in 11 patients. In comparison numbers in placebo group were five episodes in seven patients and three episodes in four patients. The result indicated that there was statistically significant difference between two groups in terms of episodes of rescue medication consumption ($Chi2= 31.4$, $p<0.000$). Generally Single dose of intravenous dexamethasone (0.5 mg/kg) in combination with penile block decreased the post-operative pain measures, and total

post-operative analgesic requirement. It also increased the onset of the first analgesic requirement compared to penile block alone.(32)

Randomized double blinded controlled study in Ireland shows that. The pain scores at rest 6 h after the surgery were lesser in the dexamethasone group compared with the placebo group [0.8(1.3) vs. 3.9(2.9), mean (SD) $p = 0.0004$]. Pain scores on passive movement six hours after the surgery tended to be lesser in the dexamethasone group [3.2(2.6) vs. 5.5(3.8), mean(SD) $p = 0.055$] although this did not achieve statistical significance. Cumulative morphine consumption 24 h after the surgery (mg) was lesser in the dexamethasone group than in the placebo group [7.7(8.3) vs. 15.1(9.4), mean(SD) respectively; $p = 0.04$]. (33)

Generally, what we understanding from the above literature reviews was opoids are the main stays for effective pain management even though they have multiple side effects. But current updates are going on to reduce demands for opoids such as the use of regional blocks, multimodal analgesia system, use of steroids with analgesic effect like dexamethasone. Most of the researches done previously shows good results towards the use of dexamethasone for post-operative analgesia and opoid consumption.

CHAPTER THREE -OBJECTIVE

3.1 General objectives

To assess the effectiveness of intravenous Dexamethasone on post-operative analgesic consumption on patients undergoes major orthopedic surgeries under general anesthesia at black lion hospital from September 21/2018 – May 20 /2019.

3.2 Specific objective

- To assess consumption of opoid for controlling post-operative pain between dexamethasone and control groups
- To compare severity of early post-operative pain scores between dexamethasone and control groups in first 12 hours after the procedure
- To describe time to first analgesics request time between dexamethasone and control groups

CHAPTER FOUR –METHODOLOGY

4.1 Study Area and period

This study was conducted at BLH which is located in the capital city of Ethiopia Addis Ababa has about 2,355 m above the sea level with the total population of 3,384,569 according to the 2007 population census, with annual growth rate of 3.8%. The hospital is one of the specialized referral hospitals in the country and it was administered by Addis Ababa University. Black Lion is the largest referral hospital in Ethiopia and sees approximately 370,000- 400,000 patients a year. The hospital has 800 beds, with 169 specialists, 65 non-teaching doctors. Anesthesia department was one of the basic departments in the hospital based on ministry of health data from 2012 it begins the first work on 1974G.C in collaboration with WHO currently it has 39 working nonacademic staffs. It got eight major operating theatre rooms and also has four rooms for orthopedics surgery. The study was conducted from September 21/2018 – May 20 /2019.

4.2 Study design

An Institutional based prospective cohort study was conducted from September 21/2018 – May 20 /2019.

4.3 Population

4.3.1 Source Population

All adult patients scheduled for elective orthopedics surgeries at BLH.

4.3.2 Study Population

All ASAI and ASA II adult patients scheduled for elective orthopedics surgeries at BLH in the study period under GA.

4.4 Study variables

4.4.1 Independent Variables

Socio demographic characteristics: age, sex, weight, Exposure to dexamethasone, ASA status Preoperative surgical diagnosis ,Duration of surgery ,Duration of anesthesia, Preoperative pain,

4.4.2. Dependent Variables

- analgesics consumption
- post-operative pain severity
- rescue analgesia request time

4.5 Eligibility criteria

4.5.1 Inclusion criteria

-All American Society of Anesthesiologist (ASA) class I and II patients

-Patients age between 18 and 65 years

4.5.2 Exclusion criteria

- ASA III and IV , History of allergy of the study drugs ,known opoid abuse patients , systemic fungal infection ,patients taking systemic analgesics, patients refusing to participate in the study, those who doesn't want their chart information to be seen, refuse to tell VAS score.

4.6 Sampling Technique and Sample Size Determination

4.6. 1. Sample size determination

Sample size for the study is calculated using Comparison between two means (Equal sample sizes) formula based on the mean difference of post-operative opoid consumption, post-operative VAS score of two groups from the study in, West Bengal, India were used to calculate the sample size for each group.(14)

The largest result taken from each group (mean pain score) was taken to calculate the required sample size. The mean score at 12hr being one of measurements on this study was 2.8 ± 1.3 for dexamethasone group and 4.2 ± 2.4 for the control group.

$n = (s_1^2 + s_2^2) f(\alpha,\beta) / (m_1 - m_2)^2$

Where n = the sample size in each of the groups

- ✓ α= type I error (level of significance)
- ✓ β= type II error (1-β = power of the study)
- ✓ Power = the probability of getting a significant result
- ✓ $f(\alpha,\beta) = (1.96+0.84)^2 = 7.84$, when the power = 80% and the level of significance =5%
- ✓ m_1 and s_1^2 are mean and variance of control group respectively.
- ✓ m_2 and s_2^2 are mean and variance of dexamethasone respectively.

$$n = \frac{(2.4^2+1.3^2)*7.84}{(4.2-2.8)^2} = 30$$

So that the sample size is 30 for each group

Taking 10% for non-response rate or sudden withdrawal the total sample size was 66.

4.6.2. Sampling technique

Patients age 18 and above who underwent major orthopedic surgery under general anesthesia recruited by simple random sampling technique into the study. The daily operation schedule list was used as a sampling frame. Around 200 patients estimated to undergo elective surgery during the study period, 66 participants were recruited. Dividing the estimated patient undergo for elective surgery during the study period to the calculated sample size, which yields approximately K= 3. And selected the random start using lottery method, it is 3, every kth unit is selected. The data collectors differentiate those who took dexamethasone and participant who didn't take dexamethasone either of the two groups was included. This continued till the required sample size was reached

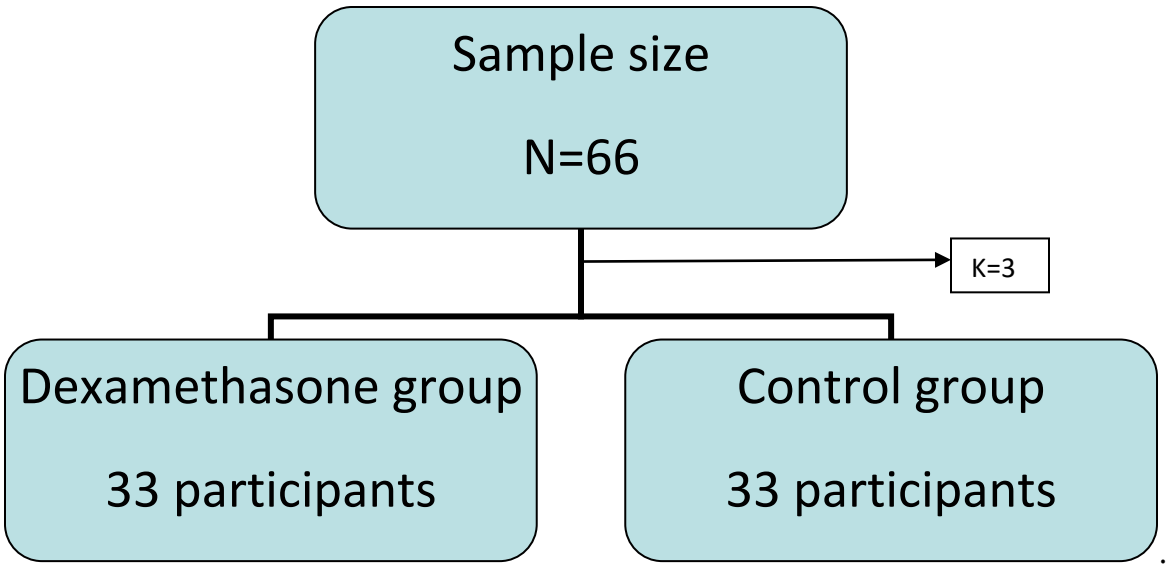


Figure 1 sampling procedure for elective orthopedics surgery at BLH from January to April 2018/19

4.7 Plan of Data Collection

All patients who were scheduled for elective orthopedics surgery who fulfill inclusion criteria and volunteer to take part in the study were instructed on how to self-report pain using VAS score 0 to 10 in the morning of operation day at ward with trained nurses or anesthetists. Around 66 orthopedics patients who fulfill inclusion criteria were followed for 12 hrs. One of The primary outcome measures is VAS score, with 0 being no pain to 10 the worst imaginable pain. Time to first analgesic request and total postoperative analgesic consumption was used to assess efficacy of analgesia as secondary outcome measures.

Anesthesia management for orthopedics surgery clients in the study hospital is usually carried out by MSc and BSc anesthesia professional. Pre anesthetic evaluation is done in the evening of days before surgery. Vital sign, Organ function test together with history and physical examinations are among the parameters used to decide for anesthesia plan, weather to cancel or proceed. General anesthesia is done with the common trend of the hospital All study patients got standard monitoring. General anesthesia was induced and tracheal intubation was facilitated with suxamethonium (2 mg/kg), and for procedures done with LMA the LMA was placed without muscle relaxant. patients were ventilated with 100% oxygen, and the inhalation anesthetic agent achieved maintenance of anesthesia. After induction dexamethasone given to the group with the

standard dose of 0.1mg/kg with the maximum dose of 8mg. Questionnaire was prepared in English for clear understanding by the patient which includes socio demographic data and clinical characteristics, pain parameters and amount of opoids consumed. All patients selected for the study was asked for their consent and instructed on how to self-report pain, post-operative pain using VAS. After providing training for data collectors, data were collected by two MSC anesthesia students and one Bsc nurse using pretested questionnaires. Both observations and chart reviews were used to collect the appropriate data. Reviewing Patients' chart where employed for demographic, anesthesia and surgery related factors and the observation where including recording of First analgesia request time, The total post-operative opoid consumption and Severity of pain in VAS was assessed and recorded at, 3,6,9,12 hours after surgery

4.8 Data Processing and Analysis

After obtaining ethical clearance from Addis Ababa University School of Medicine department of anesthesia ethical committee. Data were entered into Epi-info 7 and exported to SPSS V 25 for analysis. Shapiro-Wilk test were used for continuous variables to test normality of data while homogeneity of variance for weight were assessed using Levine's test for equality of variance. Numeric data were described in terms of mean ± SD for symmetric (weight) and median (Interquartile range) for asymmetric numeric data (analgesic consumption, VAS score, first rescue analgesic request time).

Comparisons of numerical variables between study groups were done using unpaired student t-test and Manny Whitney U test for symmetric and asymmetric data respectively. Frequency and percentage were used to describe categorical variable and statistical difference between groups were tested using fissure exact test. A p value<0.05 considered statistically significant**.**

4.9 Data Quality Control and Assurance

Data collectors were trained by principal Investigators.

Pretest was done for 1 week at BLH with 10 % of the total sample size. During data collection, regular supervision and follow up was made.

Principal Investigator cross checked for completeness and consistency of data every day.

All materials used for data collection was arranged sequentially and data was stored in safe and secure place.

4.10 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, annual National conference of Ethiopian Anesthetists Association (EAA) and sent to journals for publishing.

4.11 Operational definitions

VAS: is a valid pain intensity assessment tool that involves asking a patient to put a mark on a line which shows from no pain to sever pain. (34).

- no pain(0–0.5), mild pain (0.55–4.4), moderate pain(4.5–7.4), and severe pain (7.5– 10)

Figure 2; VAS pain intensity assessment tool

ASA-American society of anesthesiologists

ASA PS I - A normal healthy patient based on the classification

ASA PS II - A patient with mild systemic disease

ASA PS III–A patient with a severe systemic disease that limits activity

ASA PS IV - A patient with an incapacitating disease that is a constant threat to life

Dexamethasone group- patients who take 8 mg intravenous dexamethasone and

Control group – patients who didn`t take dexamethasone.

Time for first analgesia request- the time in hours measured from the end of the procedure to time where request for analgesia (25)

Elective Orthopedics surgery – a planned and scheduled surgery for cases related to lower extremity bone problems

Total analgesia consumption: is total amount of analgesic drugs in milligrams used in 12 hours counted after the procedure has done

MAC – the dialed concentration of Inhalation agents on the vaporizer

4.12 Ethical Consideration

Ethical clearance was obtained from Addis Ababa University School of Medicine department of anesthesia ethical committee before the start of the study. The importance of the study was explained & verbal informed consent was obtained from each participant by the data collector. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients. Participant's involvement in the study was on voluntary bases, participants who were not willing to participate in the study & those who wish to quit their participation at any stage was informed to do so without any restriction. In addition all the responses were kept confidential and anonymous.

CHAPTER FIVE- RESULT AND DISCUSSION

5.1 RESULT

5.1. 1 Demographic and clinical characteristics of the patient

A total of sixty six respondents were participated in this study. Out of 66 respondents 33 were dexamethasone group "1" who given dexamethasone 0.1mg/kg as an anesthetics adjuvant and 33 were the control group " 2" who get nothing as an anesthetics adjuvant immediately after intubation. There was no significant difference between two groups in age, weight, ASA status, types of surgical procedures, duration of surgery and anesthesia duration. The demographic status and clinical characteristics of data were comparable between groups (table 1).fissure exact test value was used for categorical variables with cell count below 5.

Table 1; socio demographic characteristics of the study participants who underwent elective surgery under general anesthesia for major orthopedics surgeries at BLH 2018/19.

Characteristics		Dexamethasone (n=33)	Control (n=33)	P value
Sex	Female	3(4.5%)	6(9.1%)	0.475
	Male	30(45.5%)	27(40.9%)	
Age(yrs)(median & IQR)		25 (20-37)	27 (20-37)	0.695
Weight (mean ± SD)		62.63 ± 7.87	60.39 ± 8.42	0.268
ASA	ASA I	28(42.4%)	29(43.9%)	1
	ASA II	5(7.6%)	4(6.1%)	
Allergy to drugs	Yes	0(0)	2(6.1%)	0.492
	No	33(100%)	31(93.9%)	
Procedure	ORIF	17(51.5%)	20(56.1%)	0.883
	PLATING	5(12.1%)	3(9.1%)	
	SEQUESTRECTOMY	4(12.1%)	3(9.1%)	
	BIOPSY	3(9.1%)	4(12.1%)	
	SIGN NAIL	4(12.1%)	3(9.1%)	
Previous surgical history	Yes	9(13.6%)	13(19.7%)	0.296
	No	24(36.4%)	20(30.3%)	

(n = number of participant, SD =standard deviation, (%) = percentage, ASA=American society of anesthesiology physical status, IQR = inter quartile range)

There were no significant difference between the two groups regarding anesthesia induction, induction and maintenance relaxant, inhalation agent and intra op analgesia (table 2). All patients were induced with propofol in both groups.

Table 2;General anesthetic management among dexamethasone and control group.

Characteristics		Dexamethasone (n=33)	Control (n=33)	P value
Relaxant for induction	Sux	28(42.4%)	31(47%)	0.427
	No relaxant	5(7.6%)	2(3%)	
Inhalation for maintenance	Halothane	24(36.4%)	27(40.9%)	0.378
	Isoflurane	9(13.6%)	6(9.1%)	
Relaxant for Maintenance	Sux	0(0%)	1(1.5%)	0.21
	Vec	13(19.7%)	24(36.4%)	
	Panc	1(1.5%)	0(0%)	
	No relaxant	19(28.8%)	24.2(12.1%)	
Intra operative analgesia	Morphine	3(9.1%)	2(6.1%)	0.446
	Pethidine	0(0%)	2(6.1%)	
	Fentanyl	11(33.3%)	14(42.4%)	
	Tramadol	10(30.3%)	5(15.2%)	
	None	9(27.3%)	10(30.3%)	
duration of surgery (min)		158.44(152.1-163.3)	165 (120-180)	0.34
Duration of anesthesia (min)		165 (160-175)	185(127.5-210)	0.642

5.1.2 Total analgesic consumption within 12 hours

- **Use of morphine in equivalent milligram**; equivalent analgesic transformation was done on tramadol based on the guidelines on the American faculty of pain medicine.(35) A Mann-Whitney U Test revealed that there was a significant difference in the total median dose (milligram) of morphine equivalent administered during postoperative 12 hours 10 (5-10) vs 2.5 (1.25-5) (Z= -5.202 , P=0.000 , r = 0.64, u=152.5)

- **Use of diclofenac;** the total postoperative diclofenac consumption in 12 hours was significantly lower in dexamethasone group than in control group 50 (12.5-75) Vs 75 (50-75) (Z= -2.546 , P=0.011, r = 0.312 ,U=356.0)

- **Table 3; comparison of post-operative analgesic consumption in postop time within 12 hours.(median ± inter quartile range)**

	Group D(n = 33)	Group C (n = 33)	P value
Morphine equivalent(mg)	2.5 (1.25-5)	10 (5-10)	P<0.00
Diclofenac consumption(mg)	50 (12.5-75)	75 (50-75)	P=0.011

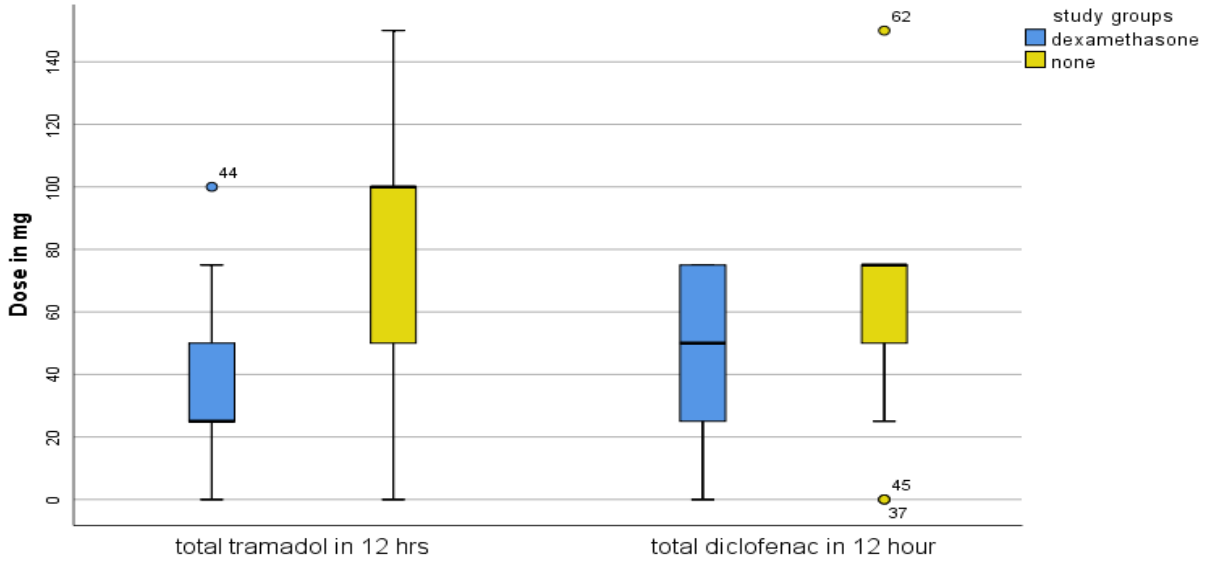


figure 3 ; comparison of median of postoperative analgesic consumption in milligram for two groups of patients who undergo GA for major orthopedics surgeries

Cumulative tramadol consumption over different time interval between groups were differently significant in the table below we list the median of tramadol and diclofenac consumption at different period of time postoperatively.

Table 4;Comparison of median of postoperative analgesic consumption in milligram for two groups over different time period.

	Time interval	3h	6h	9h	12h
Tramadol consumption	Dexamethasone group	0(0- 25)	0(0-12.5)	0(0)	0(0)
	Controlled group	0(0-50)	50(0-50)	0(0-50)	0(0-50)
	P value	0.091	0.01	0.015	0.829
Diclofenac consumption	Dexamethasone group	0(0-25)	0(0-25)	0(0-12.5)	0(0-25)
	Control group	0(0-25)	0(0-25)	0(0-25)	25(0-25)
	P value	0.617	0.335	0.341	0.112

Value are presented as: Median (IQR),

5.1.3 VAS score

Since the VAS pain score was not normally distributed, Mann Whitney U test was used to test the VAS. The median pain score is shown in (Tables 3). Overall, VAS scores tended to decrease in group one (dexamethasone group) but in this study there is No statistically significant difference noted in immediate postoperative three hours VAS scores with in two groups (P = 0.586). There was significant reduction in VAS score at 6^{th} hour post operative time when we compare with control group with median and IQR 2(2-4) VS 4 (3-5) ($p<0.01$,r = 0.50,u=235.0 Z= -4.07). the mean VAS scores at 9^{th} hour post operatively was also significantly differ from the base line when we compare with control group(P=0.025 , z= -2.234 , u = 374.00 r =0.27). VAS score was also lower in Dexamethasone group than the control group at 12^{th} hour post-operative value (P=0.007 Z= -2.704, r =0.33, u= 338.0). The magnitude of the difference in in means (mean difference =1.06, 95% CI).

Table 5;post-operative pain intensity in vas score between dexamethasone and control groups in study participants who underwent GA for major orthopedics surgery.

VAS	(Group D) median ± IQR	(Group C) median ± IQR	*P* value
Post op up to 3rd hr	3 (2-3)	3 (2-3)	0.586
VAS at 6th hr	2 (2-4)	4 (3-5)	0.000**
VAS at 9th hr	2 (2-4)	4 (3-4)	0.025**
VAS at 12th hr	3 (1-4)	4 (3-5)	0.007**

Key: Data are expressed using median (IQR); **= statistically significant
(, IQR = inter quartile range, group D = dexamethasone group , group C= Control group ,

VAS = visual analog score, at 3rd, 6th,9th ,12th hr = at three ,six, nine, twelve hour post operatively,)

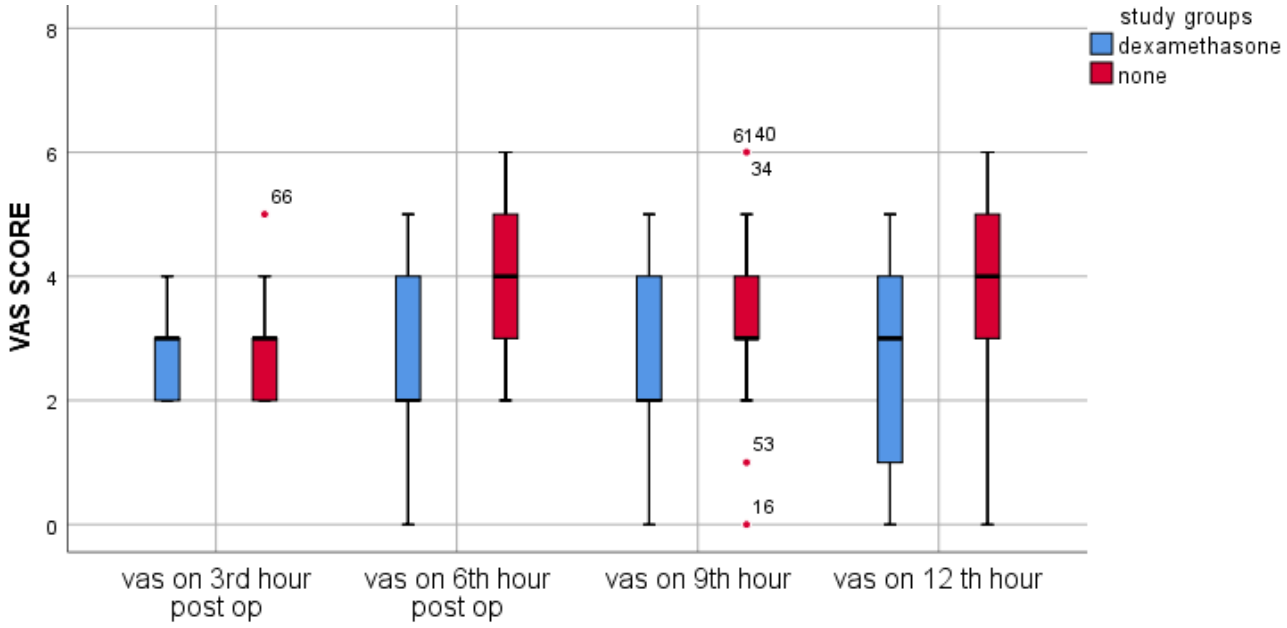


Figure 4, comparison of postoperative pain severity using VAS score at third, six, nine and twelve hours after the procedure

5.1.4 First analgesic request time

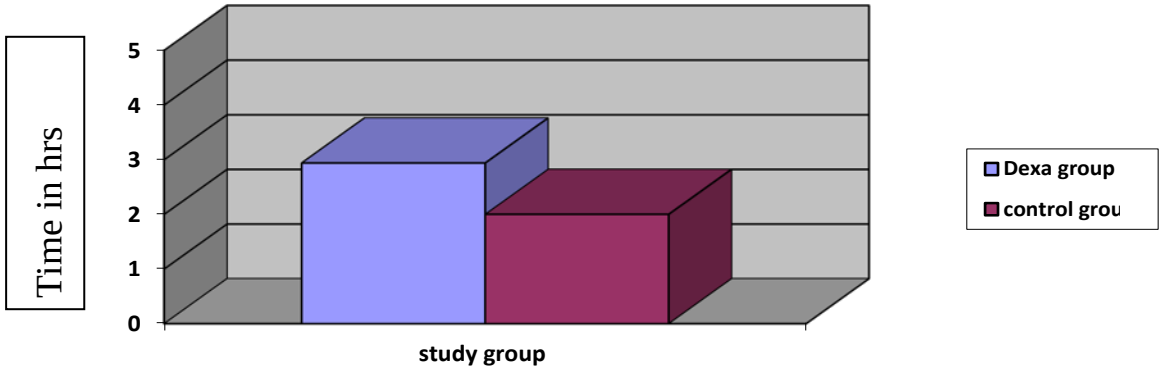
The median time to first dose of analgesics in Patients who received dexamethasone is observed to be 180 (120-240) minutes as compared to 60 (60-180) minutes in control group this difference is statistically significant with (P<0.0001, Z =-3.66, r = 0.52 , U = 269.5) with median and IQR.

Table 6; Comparison of time for the first analgesic request between two groups

	Group D (*n* = 33) median and IQR	Group C (*n* = 33) median and IQR	*P* value
first analgesic request (in minutes)	180 (120-240)	60 (60-180)	0.000

IQR = inter quartile range, first analgesic request, the time first analgesics given post operatively

Figure 5 ; Comparison of mean time in hour for the first analgesia post operatively



5.2 Discussion

Dexamethasone is a high-potency, long-acting glucocorticoid that has been widely used in the field of orthopedics. Dexamethasone has been reported to inhibit peripheral phospholipase, which decreases the pain-aggravating agents from the cyclooxygenase and lipoxygenase pathways. Glucocorticoids reduce pain by inhibiting prostaglandin synthesis, which leads to inflammation, and reducing vascular permeability that results in tissue edema. Glucocorticoids are also lipophilic molecules that can cross the blood-brain barrier. Previous studies have shown the analgesic effect of dexamethasone in general and orthopedic surgery with great post-operative advantage. (36)

In our study there was a statistically significant difference in a median total analgesic consumption between the dexamethasone and the control group with median and inter quartile range with the value of 2.5 (1.25-5) for dexamethasone group and 10 (5-10) for the control group. This result shows similarity with 2016 randomized, double blinded controlled study done by Szilard Szucs and David Jessop, where the median patient controlled analgesia consumption was decreased for dexamethasone group by Cumulative morphine consumption 24 h after the surgery (mg) was lesser in the dexamethasone group than in the placebo group [7.7(8.3) vs. 15.1(9.4), mean(SD) respectively; p = 0.04]. The similarity in median total opioid consumption compared with the current study, might be due to a similarity in anaesthesia technique and analgesic administration technique. In the previous study, general anaesthesia and patient controlled analgesic administration technique were use, whereas general anaesthesia and nurse controlled analgesic administration techniques were used in our study.)(37) similarly Another systematic review and meta-analysis done by N. H. Waldron, C. A. Jones, at Duke university medical center shows the result that Patients receiving dexamethasone used significantly less opioids (mg morphine equivalents) [MD 20.87 (95% CI: 21.40 to 20.33, P = 0.002) (I2¼52%)](17)

In contrast to with our result, a study done at bogota Colombia with two groups of dexamethasone and normal saline group which indicates that The mean morphine dose administered during the postoperative period was slightly lower in the DM group, but the

difference was not statistically significant (95% CI, −2.2 to 1.70; p = 0.79). The mean morphine dose administered during the postoperative period was lower in the DM group, but again the difference was not statistically significant 6.4 (0.7) Vs 6.6(0.6) with a P value of P=0.8.(38) this difference in total analgesic consumption of non-significant result might be because of large amount of the sedatives and analgesics given intra-operatively 2-3 mg of midazolam was administered intravenously at the start of induction, followed by 3–5 mg/kg of thiopental sodium, 0.05–0.1 mcg of remifentanil·kg^{-1}·min^{-1}, and inhaled sevoflurane at a minimum alveolar concentration of 0.5–1 (1-2% of sevoflurane) and FiO_2 of 0.7 was maintained. All patients received 50 mg of diclofenac intravenously immediately after intubation and 0.1 mg/kg of morphine intravenously approximately 20 min before the end of surgery. Especially the morphine affect the postoperative pain intensity and analgesic consumption.

Also In our study there was a statistically significant difference in VAS score at 6^{th} hour post operatively with median and IQR in dexamethasone group 2 (2-4) when we compare to control group 4 (3-5) with P value of 0.000. There was also a statistically significant difference VAS score in dexamethasone group 2 (2-4) when we compare to control group 4 (3-4) with a P value of 0.025 at 9th hour post operatively. and 12^{th} post-operative hour vas score with median and IQR was also significantly different when we compare study group with the control group 3 (1-4) Vs 4 (3-5) with the P value of 0.007. But there was no statically significant difference at 3^{rd} hour VAS score with median and inter quartile range which was lower in dexamethasone group 3 (2-3) Vs 3 (2-3) with its P value 0.586. This result was in agreement with A prospective, randomized, double blind, placebo controlled study done on 30/2004 Jaipur (India) again shows similar finding with our study with comparing dexamethasone and control groups. Which shows that a non-significant result for Mann Whitney U test in the first four hours (1.96 (0.94) VS 2.21 (0.7) with a P value of P= 0.20. but there was a significant lower values of VAS score for the dexamethasone group than the control group for both hours for 6^{th} hour (3.96 ± 1.64 VS 5.90 ± 1.49) with P value of 0.001. There was also a significant value at 12^{th} hour (4.12 ± 1.59 Vs 5.11 ± 1.57) with a P value of P=0.001. This study had good similarity with our study for the VAS score and the cause of non-significant result might be because of the effect of intraoperative administered strong analgesic agents and which might not be wear off to that hour. (37) Another 2016 randomized, double blinded controlled study done by Szilard Szucs and David Jessop shows similar result with our study related to VAS score and analgesic

consumption which says The pain scores at rest 6 h after the surgery were lesser in the dexamethasone group compared with the placebo group [0.8(1.3) vs. 3.9(2.9), mean(SD) p = 0.0004]. (39)

In contrast to with our result, a study done at bogota Colombia with two groups of dexamethasone and normal saline group which indicates that Overall, VAS scores tended to decrease in both the DM and NS groups across time. There were no statistical differences in the VAS scores at different postoperative time points except for the fourth hour; the DM group exhibited a higher VAS score than the NS group at this time point (DM, 3.96/10;NS, 2.46/10; 95%confidence interval [CI] 0.096–2.91; $p = 0.0366$) It might be because of the intra operatively administer strong analgesics premedication and all patients receive femoral nerve block, additionally they got paracetamol 1gm IV intra-operatively and every six hour postoperatively. In our study patients did not get any supplemental nerve block and continuous regular analgesia.(38)

Similarly our study shows a statistically significant difference on the median time for the first analgesic request time between dexamethasone and the control group. Which shows a prolonged time for the first analgesics in dexamethasone group 180 (120-240) and relatively short time in minutes for the control group 60 (60-180) with a P value of (P=0.000). This result was in similarity with a systematic review and meta-analysis done by N. H. Waldron, C. A. Jones, at Duke university medical center which compares first analgesic request time between dexamethasone and the control group the time to first dose of analgesic for Patients treated with dexamethasone had a significantly longer time to first dose of analgesic [MD 12.06 (95% CI: 0.80, 23.32, P =0.04) min (I2¼94%)].(17) This similarity of the results might be from the similarities in the surgical procedures and techniques of anesthetic management between our study and those studies included in the meta analysis. Similarly A 2015 randomized, double-blind controlled trial done by Woo JH, Kim YJ, Kim DY, Cho's shows similar result with our study that Inclusion of dexamethasone 2.5, 5.0 and 7.5 mg resulted in significant (P < 0.001) increases in time to the first analgesic request by factors of 1.6, 2.2 and 1.8, respectively. The percentages of patients not requiring analgesics in the first 48 h postoperatively with dexamethasone 0.0, 2.5, 5.0 and 7.5 mg were 3, 22, 39 and 33%, respectively (P < 0.001).(40)

Generally our study shows a statistically significant result that intraoperative dexamethasone was effective in controlling post-operative pain intensity in VAS score, total analgesic consumption and first analgesic request time when we compare patients with dexamethasone as adjuvant with those patient didn`t take dexamethasone as an adjuvant.

In our study, IV dexamethasone1mg/kg administered after induction was found to be the most effective in controlling post-operative pain intensity in VAS score, total analgesic consumption and first analgesic request time . As the result of our study shows in group D the median analgesic morphine consumed was 2.5 (1.25-5) whereas in group C the median analgesic morphine consumed was 10 (5-10) which was significantly different ($p = 0.000$). pain score was also significantly lower dexamethasone group than the control group ($p<0.05$) whereas the dexamethasone group has a significantly longer time for the first analgesia time with a median of 180 minutes when we compare with the median of 60 minutes for the control group($p=0.000$).

CHAPTER SIX - STRENGETH AND LIMITATION

6.1 Limitation of the Study

- The main limitation of this study were :
- Lack of standard pain management protocol in the study hospital
- Lack of randomization and control

6.2 STRENGTH

- Study participant were homogenous between the dexamethasone and control group.
- Similar types of analgesia were used between the groups.
- There was adequate sample size within the planed period of time.
- Most of the studies we used for comparison were randomized control trial.
- Lack of prior study on this and related title in our country

Chapter seven: Conclusion and Recommendation

7.1. Conclusion

The findings of our study demonstrate that dexamethasone 0.1mg/kg IV, administered after intubation, was better in reducing total opoid consumption for pain management compared with the control (non- dexamethasone) group in patients undergoing general anesthesia for major orthopedics surgeries. Also our result shows that it also reduces the pain intensity post operatively up to 12 hours. However we got a comparable result between two group in pain intensity (VAS score) up to three hour postoperatively. And our result shows that dexamethasone increases the median time for first analgesic request post operatively when we compare it with the shorter time of the control group.

7.2. Recommendation

For anesthetists

- Dexamethasone administered after intubation for elective surgeries underwent general anesthesia for orthopedics surgery is effective reduction of post-operative VAS score and analgesic consumption so It is better to use dexamethasone regularly in patients undergoing elective surgery under general anesthesia for orthopedics surgery to reduce pain and analgesic consumption post operatively.

For further researchers

- Further study with Randomized control trial need to be conducted.

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Annex I

Information sheet to get permission for the research

Introduction

This information sheet is prepared to explain the research project that you are asked to join by a group research investigators.

The research team includes MSc anesthesia students, senior advisor from AAU and Bsc nurses for data collection from BLH Hospital.

Name of Principal investigator: - Fasil abebe

Advisor's name: - Mr.:- Wosenyeleh admassu AND mss Lemlem weldemaryam

Name of sponsor: - AAU

Name of organization: - AAU, Health science college, anesthesia department

This information sheet is prepared by the above mentioned investigator.

Risk

There is no any risk or harm that you will face by participating in this research. Any personal information recorded will not be copied and transferred to other bodies. No need of writing participants' name but by a code. Every piece of information was kept confidentially.

Benefits

There is no incentive or payment to be gained by taking part in this project. The information collected from this research project was kept confidential and only accessed the researcher and research assistant only. This research project was reviewed and approved by ethical committee of the AAU. If you want to know more information, you can contact the committee.

Annex II

Consent form

Dear participant:

Hello my name is Fasil Abebe, I am master's student in anesthesia from Addis Ababa University. This is a research designed to assess the effectiveness of dexamethasone on post-operative opid consumption in patients undergoing major orthopedics surgeries. As a chance you were included in the study. So, we kindly request your involvement in the study and honest response to achieve the objective of the study. Your response completely confidential and you have full right either to refuse a single question or leave the study. However, your honest response to those questions will help us to asses and understand the effect. So, we are requesting you to give honest response and keep participation.

Would you willing to participate in the study please?

YES. ☐

NO ☐

Thanks for taking part in the study!!!!

Fasil abebe

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Email – fasilabebe7@gmail.com

Annex III

የመጠይቅ ፈቃድ

የተከበራችሁ የጥናቱ ተካፋዮች

የዚህ ጥናት ዋና አላማ በፈድራል ጤና ጥበቃ ሚኒስተር ስር በሚገኘው በጥቁር አምበሳ ሆስፒታል ኦፕራሲዮን ክፍል የአጥንትቀዶ ህክምና ለሚደረግላቸዉ ህሙማን የሚሰጠዉ ሙሉ ማደንዘዣ ላይ ዴክሳሜታሶን የሚባለው መድሀኒት ከኦፕራሲዮን በኋላ የምንወስዳቸውን ህመም ማስታገሻ መድሃኖች ፍልጎት በምን ያህል እንደሚቀንስ ለማወቅ ነዉ።

በአጋጣሚ እርስዎም በዚህጥናት እንዲሳተፉ ተመርጠዋል። የዚህ ጥናት ጥቅም እርስዎ በሚሰጡት ምላሽ መሰረት መረጃዎችን በማጣላት በሚገኘዉ ዉጤት መሰረት መረጃዎችን በማጠናቀር ውጤቱን እየተሰራበት ካለው ጋር ለማገናዘብ እንዲቻል ነዉ። ጥናቱ በትክክል አላማውን እንዲመታ የእርሶዎን ድጋፉ እንጠይቃለን። የማንኛውም ግለሰብ ስም አይመዘገብም እንዲሁም ሀሳቡ ብቻውን ይፋ እንዲዎጣ አይደረግም:: ሙሉ በሙሉ በሚስጥር የተጠበቀ ነው። በጥናቱ መሳተፍ አለመሳተፍ የራስዎ መብት ብቻ ነዉ። ግልፅ የሆነምላሽን ና ከልብ የመነጨ ተሳትፎዎን እንዲሰጡን በአክብሮት እንጠይቃለን። ለመሳተፍ ፈቃደኛ ነዎት

ሀ/ አዎ ፊርማ ----------

ለ/አይደለሁም--------

ለመሳተፍ ፈቃደኛ ስለሆኑ እናመሰግናለን።

Annex IV

Questioner

Data collection tool for patient who will undergo general anesthesia for major orthopedic surgeries at black lion hospital in 2018/19.

INSTRUCTIONS

A. Fill the blank space provided.

B. Encircle the alternatives when necessary.

C. Check the questions for completeness.

Section 1: Socio-demographic and basic characteristics of the patient.

S.NO	Question	Possible responses	Code
101	Age (in year)		
102	Weigh (in kg)		
103	Height (in meter)		
104	Body mass index (in kg/m2)		

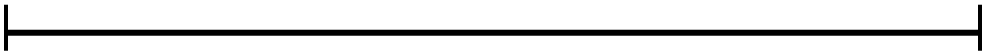
105	Sex	1. Male 2. Female	
106	ASA status	1. I 2. II	
107	Allergy to any of the following drugs	1. Diclofenac 2. Opioids 3. Antibiotics 4. No allergy 5. Other …….	
108	Diagnosis		
109	Procedure		
110	Previous surgery	1. Yes 2. no	

Section 2 ; Question on perioperative anesthesia management

S. No.	Parameter	Values	Code
201	analgesia during induction?	1. Tramadol 100mg 2. Diclofenac 75	
202	Iv agent used for induction	1,propofol,dose……. 2,thiopental,dose……	
203	Does ketamine used as induction	1. yes 2. no	
204	Muscle relaxant for induction	1,Suxamethonium dose…… 2,vecronium,dose…….	
205	Types of study medication used	1. Dexamethasone dose……. 2. None	
206	Inhalation agents used for maintenance	1. halothane, 2. Isoflurane, 3. other…….	
207	Muscle relaxants for maintenance	1. Sux dose…… 2. Vecronium 3. pancronium 4. no relaxant used	
208	Any additional analgesic drug required and given intraoperatively? (type and dose)	1,morphine 2, pethidine 3, fentanyl	

		4, tramadol 5, none	
209	If the patient took one of the above time and dose of the drug given		
210	Duration of surgery in minute		
211	Duration of anesthesia in minute		

Section 5: questions related to severity of pain and analgesic consumption



No pain sever pain

501, Severity of pain on VAS type and dose of analgesics given

3hrs after operation ……..…. analgesics given ……..

6 hrs after operation……..... analgesics given ……..

9hrs after operation…… analgesics given ……..

12 hrs after operation…… analgesics given ……..

Section 6 : question about over all analgesic consumption in the past 12 post-operative hours and the first analgesic request.

	Question	Possible response	Code
601	Time before the first request of further analgesia	1.within first hour after the procedure 2, within two hour 3, within three hour ***4.*** other time(specify)	
602	Total amount of analgesics given in the last 12 hours	• tramadol ----------mg • diclofenac ----------mg	

Data collector name…….

Signature……

Annex V:

American Society of Anesthesiologists (ASA) physical status classification of patients.

Class Definition

1. Normal healthy patient
2. Patient with mild systemic disease (no functional limitations)
3. Patient with severe systemic disease (some functional limitations)
4. Patient with severe systemic disease that is a constant threat to life (functionality incapacitated)
5. Moribund patient who is not expected to survive without the operation
6. Brain-dead patient whose organs are being removed for donor purposes

E If the procedure is an emergency, the physical status is followed by “E” (for example, “2E