ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCE

SCHOOL OF MEDICINE

DEPARTMENT OF ANESTHESIA

EFFECTIVENESS OF INTRAOPERATIVE INTRAVENOUS LIDOCAINE INFUSION AS PART OF POSTOPERATIVE ANALGESIA FOR PATIENTS UNDERGOING ABDOMINAL SURGERY UNDER GENERAL ANESTHESIA IN EMPRESS ZEWDITU MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA 2018.

INVESTIGATOR

MIKAELE AZANAW (B.Sc.)

ADVISOR

WOSSENYELEH ADMASU (B.Sc. M.Sc.)

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DECLARATION

I, the undersigned, declare that this thesis is my original work has never been presented in any University, and that all the resources and materials used for the thesis work, have been fully acknowledged and for partial fulfillment of the requirements for the degree of MSc in Advanced Clinical Anesthesia. I understand that plagiarism will not be tolerated and all directly quoted material has been appropriately referenced.

By- **Mikaele Azanaw Nega**

Address-

Tell- +251929140805

E-mail- mikaeleazanaw@yahoo.com

Signature: _____

Submission to MSc.Tutor, Department of Anesthesia, Addis Ababa University.

Date of Submission: _____

This thesis work has been submitted for examination with my/our approval as Advisors and Tutors on the MSc. in Advanced Clinical Anesthesia course.

Name Signature

1. _____

2. _____

3._____

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ABSTRACT

Introduction: Postoperative pain after abdominal surgery is excruciating, due to the damage of muscles and tissues. The importance of pain relief is well-recognized but it is most often seen that pain control is inadequate. Results of previous study shows the opioid consumption is 70% after abdominal surgery. An increasing amount of evidence suggest that intraoperative intravenous lidocaine infusion can influence pain severity, postoperative analgesic requirement and decrease opoid side effects.

Objective: The aim of this study was to assess analgesic effectiveness of intraoperative intravenous lidocaine infusion as part of postoperative analgesia for patients undergoing abdominal surgery under general anesthesia in Empress Zewditu Memorial Hospital.

Methodology: Institutional based prospective cohort study conducted at Zewditu Memorial Hospital among 68 American Society of Anesthesiologist (ASA) class I and II, age ≥ 18 and elective abdominal patients who underwent surgery and were grouped into exsposed and controlled group based on they have given lidocaine (1mg/kg/hr) or not. Systematic random sampling was employed. Mann Whitney U test was used to compare median pain score, time to first analgesia request in minutes and total analgesia consumption between groups. Homogeneity of categorical independent variable between two exposure groups was analyzed using Chi Square or Fisher's exact test. Box and whisker plot were used to show a median pain score differences between groups and p value < 0.05 considered as statistical significance with a power of 80%.

Result: Demographic characteristics were comparable between the groups, p>0.05. Twenty four hour median VAS score (0 to 10 cm) at immediate recovery, 3^{rd}, 6^{th}, 12^{th} and 24^{th} hour showing lower median pain score, p<0.05. The median time to first analgesia request in minutes were longer (180 minutes) in exposed group compared to 45 minutes in non-exposed group (p= <0.0001). The median tramadol consumption within 24 hour is 50 mg in exposed group compared to 100 mg in non-exposed group(p<0.0001).

Conclusion and recommendation: Intraoperative lidocaine infusion decreases postoperative pain score, total analgesia consumption and prolongs time to first analgesia request for abdominal surgery done under general anesthesia. Based on these we recommend use of 1 mg/kg/hr of 2% lidocaine infusion is an effect postoperative analgesia.

Key words: lidocaine, Pain, abdominal surgery, infusion, Visual analogue score(VAS), Zewditu memorial hospital.

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LIST OF ABBREVIATIONS

ASA	American Society of Anesthesiologist
BP	Blood Pressure
GA	General Anesthesia
HR	Heart Rate
IASP	International Association for Study of Pain
IM	Intra Muscular
IVLI	Intra Venous Lidocaine Infusion
i.v	intra venous
MAP	Mean Arterial Pressure
mg/kg/hr	milligram per kilogram per hour
mmhg	millimeter of mercury
NSAIDS	Non-Steroidal Anti-Inflammatory Drugs
OR	Operation Room
PACU	Post Anesthesia Care Unite
PCA	Patient Controlled Analgesia
PONV	Post Operative Nausea and Vomiting
VAS	Visual Analogue Scale
Vs	Vital sign

1 INTRODUCTION

1.1 Background

Abdominal surgery involves a surgical operation on organs inside the abdomen. This may include surgery on the stomach, gallbladder, small intestine, or large intestine (colon), liver, pancreas, spleen, esophagus, and appendix. Some reasons for abdominal surgery include infection, obstruction, tumors, or inflammatory bowel disease(1).

General or regional anesthesia can be appropriate for patients undergoing abdominal surgery. In common practice, balanced anesthesia with inhalational anesthetics, opioids and neuromuscular blockers are used in general anesthesia for abdominal surgical procedures. Abdominal wall incision is the major origin of pain experienced by patients after abdominal surgery. Through systematically administered opiates and central neuraxial techniques cause considerable adverse effect, they remain the mainstay analgesic after abdominal surgery.The mean postoperative pain score of 6.5cm were reported on 10cm Visual Analog Scale (VAS). It has been also reported that the morphine consumptions in the first postoperative day is 70%. The proportions of patient with pain score greater than 3cm is 60% on VAS score(2, 3).

Postoperative pain after abdominal surgery is excruciating, due to the damage to muscles and peripheral nerves. Pain control is an essential component of postoperative care and is often regarded the fifth vital sign. Study of effective modality for postoperative pain management has remained a subject of ongoing clinical researches due to its uniqueness and associated complex physiological consequences with somatic, autonomic and behavioral manifestations. The importance of pain relief is well-recognized but it is most often seen that pain control is inadequate. The role of a well-planned pain management strategy in the immediate postoperative period is crucial to decrease postoperative cognitive impairment, enhanced quality of life, reduced risk of chronic or persistent post surgical pain and morbidity after abdominal surgery, aided by the availability of multitude of drugs, dosages and routes of administration(4-6).

Intravenous (i.v) infusion of lidocaine is one of the methods used by anesthesiology specialists for induction of analgesia. Lidocaine is a relatively safe drug in the amide group, which acts as an analgesic, anti-hyperalgesia and anti-inflammatory agent in low doses and is affective in relieving neuralgia, burn and procedural pains(7, 8).

Pain and side-effects of opioid analgesics especially, such as postoperative nausea and vomiting (PONV), sedation and delayed return of bowel function an (paralytic ileus), urinary retention and development of acute tolerance, is the common reason for prolonging hospital stay. An increasing amount of evidence suggest that perioperative intravenous lidocaine can influence pain severity, postoperative analgesic requirement, recovery of bowel function and the length of hospital stay, without any significant side effects than analgesics alone(5, 9, 10).

The skin and fascia of the anterior abdominal wall overlie the four muscles which help support the abdominal contents and the trunk, with the main nerve supply lying in a plane between the internal oblique and transversus abdominis. This plane contains the anterior rami of the lower six thoracic nerves (T7 to T12) and first lumbar nerve (L1), supplying the skin, muscles, and parietal peritoneum. At the costal margins, the thoracic nerves T7 to T11 enter this neurovascular plane of the abdominal wall, travelling along this plane to pierce the posterior wall of the rectus sheath as anterior cutaneous branches supplying the overlying skin. The nerves T7 to T9 emerge to supply the skin superior to the the umbilicus and the iliohypogastric nerve, and the ilioinguinal nerve supply the skin inferior to the umbilicus(11, 12).

The pathophysiology of postoperative pain is multifactorial, and predominantly of inflammatory nature from skin incision and tissue damage. Various mechanisms have been described to account for the analgesic effect of intravenous lidocaine including suppression of neuronal excitability (in both myelinated A-ä and unmyelinated C fibers), suppression of central sensitization, inhibition of spinal viscera-motor neurons, anti-inflammatory effects, decreased neural response by blockade or inhibition of nerve conduction and decreased NMDA receptor activity. Also systemic lidocaine infusion decreases pain by inhibiting nerves through the blockade of sodium channels. It is also thought to inhibit spontaneous impulse generation arising from injured nerve fibers and the dorsal root ganglion, and by suppressing primary afferent reflexes in the spinal cord(5, 9, 13).

Intravenous lidocaine is effective for treating visceral pain and may also improve postoperative bowel function. lidocaine infusion administered with 1.5 mg/kg as slow intravenous bolus injection followed by a continuous infusion of 1 mg /kg/hr will decrease anesthesia and analgesic requirements and yields a stable operative and hemodynamic conditions compared to general anesthesia alone(14, 15).

1.2 Statement of the Problem

Pain has both sensory and emotional components that interact to produce an overall pain experience. Pain is defined by the International Association for the Study of Pain (IASP) as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage(11). Poorly controlled acute pain remains one of the most undesirable consequences after abdominal surgery. Despite increased awareness and widespread efforts to address this, reports continue to estimate that a significant number of patients undergoing surgery experience moderate to severe pain, with a majority of them expressing dissatisfaction with their pain management(16).

Pain management after major abdominal surgery has become a serious clinical problem. According to Winfried Meissner study, poor management of post-operative acute pain may lead to the development of chronic pain; this occurs in 10%–50% of patients after various common abdominal operations and 2%–13% are still experiencing pain two years after some operations(11).

In Ethiopia, a study conducted by the Ethiopian Public Health Association in 2005 showed that health care providers believes that pain was undertreated due to unstandardized practice, absence of medications and poor knowledge and attitude among professionals. It has been repeatedly confirmed by studies in the past 3 to 4 decades that 20 to 80% of patients undergoing surgery suffer from inadequately treated pain and pain is classified as a serious public health problem both in the developed and in developing countries. Evidence suggests that pain and ileus causing a prolonged hospital stay are major cost drivers after major abdominal surgeries(17).

Many strategies have been implemented to reduce postoperative pain following abdominal surgery, including steroidal anti-inflammatory drugs, administration of opioid, and neuroaxial anesthesia. However, most of the time they did not show consistent efficacy. Thus, multimodal analgesia regime was recommended for pain management after abdominal surgery(18). Besides of decreasing cost and side effect of opioids, use of lidocaine infusion also support the principle of multimodal analgesia where a variety of analgesic medication and techniques that target different mechanisms of action in the peripheral or central nervous system (which might also be combined with non-pharmacological interventions) might have additive or synergistic effects or alternative analgesia and more effective pain relief compared with single-modality interventions(19-21).

1.3 Justification of the study

Common problems immediately after abdominal surgery cause a prolonged hospital stay and major cost drivers in the postoperative period. Optimal pain relief allowing normal physiologic function cannot be achieved by a single drug or a single technique without imposing additional risks on the patients. So postoperative pain management after abdominal surgery is mandatory. Multimodal analgesia advocates use of different drugs and techniques which act in different sites so as to increase the analgesic effect and also decrease the unwanted effect of single drug therapy. Intravenous (i.v) infusion of lidocaine is one of the methods used by anesthesiology profesionals as part of multimodal analgesia. It is also safe and feasible local anesthetic.

There are also different controversies among different authors worldwide on effect of lidocaine infusion on postoperative period. Even the pain management style also varies due to economic and technological difference to our study area. These controversies were one of the reasons which call for the study. As far as as my knowledge is concerned there is no previous published study done in this topic in the study area even though it has been studied in different part of the world(4, 20).

Conducting such a research which intended to find alternatives to basic pain management and even as an additive analgesia in intraoperative and postoperative period is expected to have of great value since it will decrease consumption and the side effects of opoids and other systemic medications. On the other hand, it can be used as a baseline for further researchers.

2 LITERATURE REVIEW

Lidocaine (lignocaine), developed in 1948, is the first amino amide-type short acting local anesthetic (LA). Originally it was used as an antiarrhythmic drug, when given intravenously. Lidocaine has a very short half life and a favourable safety profile and is therefore the LA of choice for continuous intravenous administration(22).

Systemic administration of lidocaine has been shown to have analgesic actions in patients with chronic neuropathic pain. Lidocaine decreases pain by inhibiting nerves through the blockade of sodium channels. Systemic lidocaine is thought to inhibit spontaneous impulse generation arising from injured nerve fibers and the dorsal root ganglion, and by suppressing primary afferent reflexes in the spinal cord. Intravenous lidocaine is effective for treating visceral pain and may also improve postoperative bowel function(23).

Lidocaine also has antiarrhythmic properties & the preservative free form can be used for attenuation of hemodynamic changes during laryngoscopy & endotracheal intubation(24). Various strategies have been proposed for postoperative pain control. Among those, intravenous lidocaine infusion (IVLI) has gained in interest. However, its clinical benefit remains unclear(25). Pain management improves recovery and also reduces the risk of postoperative acute adverse effects (i.e. pulmonary dysfunction), and chronic adverse effect (i.e. delayed recovery and hospital discharge and chronic pain) after various procedures including abdominal surgeries(8, 26).

A study done in New York Columbia university indicates that intravenous lidocaine provides pain control that is non-inferior for pain scores but inferior for opioid use, compared with epidural infusion. Although patients receiving intravenous lidocaine were administered more opioids, clinically significant adverse effects were reduced(3).

According to a study in Australia showed that the average end-tidal sevoflurane concentration was lower in the lidocaine group compared to saline [1.49% (SD: 0.32) vs. 1.89% (SD: 0.29); 95% CI 0.26–0.5, $p < 0.001$]. In the lidocaine group, the average MAP was 80.3 mmHg (SD: 4.9) compared to 85.1 mmHg (SD: 5.4) in the Saline group (95% CI 2.4–7.1, $p < 0.001$). The mean heart rate also lower in the lidocaine group: 74.9 beats/min (SD: 1.8) vs. 81.5 beats/min (SD: 1.7) in the Saline group, 95% CI 4.1–9.1, $p < 0.001$)(27).

Another study done in Switzerland showed that systemic lidocaine failed to reduce pain intensity, over all opioid requirement in patients undergoing laparoscopic transperitoneal renal surgery(10).

According to studies done in USA and Belgium suggested that no subjects experienced signs or symptoms of lidocaine toxicity (neurologic changes—lightheadedness, dizziness and visual disturbances, and cardiac dysrhythmias(20, 21).

A prospective cohort study done in India showed that Lidocaine infusion decreased VAS score, improve postoperative analgesia, reduced analgesic requirement in immediate post-operative period and hemodynamic stability(28). Meta-analysis involving 45 prospective studies suggested that lidocaine reduced postoperative pain (visual analogue scale, 0 to 10 cm) at 1–4 h (MD −0.84, 95% CI −1.10 to −0.59) and at 24 h (MD −0.34, 95% CI −0.57 to −0.11) after surgery, but not at 48h(MD−0.22,95%CI−0.47 to 0.03)(4).

According to a randomized control trial done in Nepal showed that sixty patients undergoing major upper abdominal surgery were recruited and thirty patients received lidocaine 2.0% (intravenous bolus 1.5 mg/kg followed by an infusion of 1.5mg/kg/h), and 30 patients received normal saline according to randomization. The pain intensity at rest and movement as well as the total postoperative analgesic (morphine) requirement were significantly lower (14.25 ±3.78mg vs.18.5±4.13mg, P<0.001) in lidocaine group. The time for the first dose of analgesic requirement was longer in lidocaine group (60.97±18.05minutes vs.15.73±7.46 minutes, P<0.001). According to this study perioperative infusion of low dose of lidocaine decreases the intensity of postoperative pain, reduces the postoperative analgesic consumption, without causing significant adverse effects in patients undergoing upper abdominal surgery(14).

A study done in Korea showed that intraoperative lidocaine infusion reduced by 5% the amount of sevoflurane required at similar bispectral index (P = 0.014). However, there were no significant effects of lidocaine regarding the return of bowel function, postoperative pain intensity, analgesic sparing and level of patient's satisfaction for pain control. Vital signs of the patients remained stable at all times during the operation and PACU in either group. No patient in the lidocaine group showed lidocaine associated arrhythmia, severe bradycardia or hypotension during surgery, or delayed recovery from anesthesia. After transfer to the PACU, no patient of the lidocaine group reported subjective symptoms of lidocaine related adverse side effects(23).

A study done by Jun Heum Yon and colleagues concluded that after Pre-emptive intravenous lidocaine infusion, it is not only effective to improve post operative pain in abdominal surgery, but it is also feasible and safe when administered in appropriate dosages(29). But, another study done in Texas concluded that intraoperative i.v lidocaine had no effect on postoperative opioid consumption and were unable to demonstrate benefit of postoperative i.v lidocaine on pain intensity after laparatomy(30).

According to a study done in Iran that compared the analgesic effect of i.v lidocaine and morphine sulfate in pain management for extremity bone fractures showed that, success rate of i.v lidocaine in relieving the pain caused by extremity fractures was significantly higher than that of morphine sulfate, i.e. 15 minutes success rate was 49.28% in lidocaine and 33.57% in morphine sulfate group ($p = 0.011$), and after 30 minutes it reached to 85.71%and 65.00%, respectively ($p < 0.001$). They conclude from this study, i.v lidocaine could be considered as a reasonable alternative choice for pain management. This study also reporeted that no cases of hypotension, respiratory depression, dysrhythmia and drop in arterial oxygen saturation were detected in either group during the initial 30 minutes after drug injection(7).

Observational study done in Tunisia that compared IV ketamin and lidocaine infusion after neproctomy showed that Ketamine and lidocaine reduced significantly morphine consumption (by about 33% and 42%, respectively) and pain scores compared with the control group CG ($P < 0.001$). Lidocaine and ketamine also significantly improved bowel function in comparison to the CG ($P < 0.001$). Ketamine failed to reduce the incidence of PONV. Lidocaine, but not ketamine, reduced significantly the development of neuropathic pain at 3 months ($P < 0.05$)(31).

A similar study done in Egypt concluded that lidocaine (LG) group had significant lower intraoperative and postoperative fentanyl consumption ($p < 0.001$) compared to placebo(P), with prolonged time of first analgesic request ($p < 0.001$) and lower VAS ($p < 0.001$ or $p < 0.01$) compared to (P). There was also significantly lower postoperative nausea and vomiting (PONV) lidocaine groups compared to control group ($p < 0.01$)(26).

2.1 HYPOTHESIS

Hypothesis was stated based on the three major outcome variables including pain severity by visual analogue score(VAS), time to first analgesic request in minutes and total 24 hour analgesic consumption in milligram.

($\mathbf{H_O}$ indicates null hypothesis and $\mathbf{H_A}$ indicates the alternative hypothesis).

$\mathbf{H_O}$: There is no significant difference in median VAS score between exposed and non-exposed groups.

$\mathbf{H_A}$: There is significant difference in median VAS score between exposed and non-exposed groups.

$\mathbf{H_O}$: There is no significant difference in median time to first analgesic request between exposed and non-exposed groups.

$\mathbf{H_A}$: There is a significant difference in median time to first analgesic request between exposed and non-exposed groups.

$\mathbf{H_O}$: There is no significant difference in median total 24 hour analgesic consumption between exposed and non-exposed groups.

$\mathbf{H_A}$: There is a significant difference in median total 24 hour analgesic consumption between exposed and non-exposed groups.

3 OBJECTIVE OF THE STUDY

3.1 General Objective

The objective of this study was to assess the effectiveness of intra-operative intravenous lidocaine infusion as a part of postoperative analgesia for patients underwent abdominal surgeries in Empress Zewditu Memorial Hospital from February 1, 2018 to April 30, 2018.

3.2 Specific Objective

- To compare pain severity between exposed and non-exposed groups.
- To compare time to first analgesic request between exposed and non-exposed groups.
- To compare total 24 hour analgesic consumption between exposed and non-exposed groups.

4 METHODOLOGY

4.1 Study Area

The study was conducted in Empress Zewditu Memorial hospital, one of the public hospitals in Addis Ababa, capital of Ethiopia. Located in Kirkos sub city woreda 08. This hospital was built, owned and operated by the Seventh-day Adventist Church, but was nationalized during the Derg regime in 1976. The hospital is named after Empress Zewditu, the cousin and predecessor on the throne of Emperor Haile Selassie. Today the hospital is administered by Addis Ababa Health Bureau. According to the nine month report of policy and plan directorate of the hospital compiled on July 2017, the hospital provides service to an estimated 15,700 people annually in different departments who are referred from different part of the city and all over the country. Out of this, 500 patients are expected to undergo abdominal surgeries. The general surgery department of the hospital has 33 surgical beds, 5 senior surgeons and 10 surgery residents. It has five major operation rooms and two PACU.

4.2 Study Design and Period

Institution based prospective observatonal cohort study was employed from February 1 to April 30, 2018.

4.3 Population

4.3.1 Source Population

Elective abdominal patients who were scheduled for surgery at Empress Zewditu Memorial Hospital.

4.3.2 Study Population

Abdominal patients who underwent surgery in Empress Zewditu Memorial Hospital during study period.

4.4 Study Variables

4.4.1 Dependent Variable

- Pain severity by VAS score (0-10cm).
- Time to first analgesic request in minutes.
- Total Analgesia consumption in milligram in the first 24 hours .

4.4.2 Independent Variables

- Socio demographic: Age, sex, Body Mass Index(BMI)
- ASA physical status
- Preoperative surgical diagnosis
- Induction agent
- Maintenance agent
- Surgeon experience
- Perioperative analgesia
- Duration of surgery in minutes
- Duration of anesthesia in minutes
- Estimated intraoperative blood loss

4.5 Operational Definition

Postoperative pain: a patient complaining pain and any pain score other than zero within 24 hours.

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

Intra-operative hemodynamic changes: change in heart rate (HR)and mean arterial pressure (MAP) during surgery.

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

Duration of anesthesia: a time in minutes it takes from pre oxygenation to a time a patient get response to verbal command.

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

Total analgesia consumption: total dose of anti-pain medication given in mg within the first 24 hour after end of surgery.

Extubation time: is a time in minutes estimated from closure of halothane vaporizer to extubation of endotrachal tube.

Vital sign before induction: is a base line HR and MAP of a patient before giving any anesthetic drug**.**

Vital sign after intubation: is the major of HR and MAP of a patient after insertion of endotracheal tube.

Visual analogue score (VAS) is a Gold standard pain intensity assessment tool that involves asking patient how severe he or she feels his or her pain state putting a mark(/) on the line from 0-10 cm and would measure the distance from 0 cm to a marked point(32).

Figure: ***Adopted from McGraw companies for Anaesthesia Guide***

ASA status: is a surgical risk stratifications validated by American Society of Anesthesiologist; described as follows:

ASA I: a healthy patient with no organic/physiological/psychiatric problems.

ASA II: controlled medical conditions with mild systemic effect and no limitation of functional ability.

ASA III: medical condition with severe systemic effect, limitation in functional capacity.

ASA IV: poorly controlled medical conditions associated with significant impairment in functional ability that is potential threat to life.

ASA V: critical condition, little chance of survival without surgical procedure.

ASA VI: brain dead patient undergoing organ donation.

4.6 Inclusion and Exclusive Criteria

4.6.1 Inclusion Criteria:

Age greater than 18 years and ASA class I and II, that undergone elective abdominal surgery under general anesthesia was included in the study.

4.6.2 Exclusive Criteria:

- Allergy for local anesthetics
- Chronic opioid use
- Premedication with strong opoids
- Intraoperative use of strong opoids.
- Induction with ketamine
- Liver dysfunction
- Renal insuffiency
- Epilepsy
- Cardiac rhythm disorders with medication of antiarythmic drugs.

4.7 Sample Size and Sampling technique

4.7.1 Sample Size

Two independent sample size formula based on the mean difference of VAS score, time to first analgesia request and total analgesia request among two groups were used to calculate sample size for each group. Having no previous study done in the study area, result adopted from literature has been used to calculate sample size based on the three outcome variable and the largest sample size were used for recruiting study subjects.

$$n = \frac{(S^2_1 + S^2_2)\,(\alpha+\beta)^2}{(x_1 - x_2)^2}$$

The required sample size to show with 95% likelihood that the mean VAS score within 24 hour is not equal between two groups was calculated as:

Where n = the sample size in each of the groups

X_1 = Sample mean in control group

X_2 = Sample mean in treatment group

$X_1 - x_2$ = the difference the investigator wishes to detect

S^2_1= Sample variance in control group

S^2_2 =Sample variance in treatment group

α=conventional multiplier for alpha =0.05, which is 1.96

β = conventional multiplier for power = 0.80, which is 0.842

From the literature the mean VAS score, μ1=3.5 in control group, μ2=1.6 in treatment group and σ1 = 3.1, σ2 = 2.4(15). Substituting for this variables yields

$$n= \frac{(3.1)^2 + (2.4)^2 \times (1.96+0.842)^2}{(3.5-1.6)^2}$$

n=33=n1=n2, using 1:1 ratio between groups a total of 66 patients were required.

By adding 10% for non respondent rate in each group, 72 patients were included in the study. But 4 patients were excluded from the study due to incomplete data. Therefore, 68 patients were analyzed in the study with a response rate of 94.4%.

4.7.2. Sampling technique

Systematic random sampling was used to select study participants. The daily operation schedule list was used as a sampling frame. The situational analysis showed that 10 patients who fulfill our inclusion criteria were operated in Zewditu Memorial Hospital per week that got from surgery logbook record; according to this data we were had 120 patients in our study period from whom we collected data from only 72 patients.

So, sampling interval (k) was calculated as K=N/n=120/72, approximately 2, where N=total study population, n=total sample size. The first participant was selected randomly using lottery method. Then, every two patients were included in this study from the daily operation schedule list until the required sample size was met and grouped based on whether they received lidocaine infusion (exposed group) or not (controlled group).

4.8 Data collection procedures

Questionnaires were prepared in both in English and Amharic languages and it was divided in to three parts, the first one was filled in the preoperative and intraoperative time and collectedby one trained B.Sc anesthetist and the second one was PACU record going to be

recorded by PACU nurse and the third one was filled in the ward which was filled by trained ward nurse.

Anesthesia management for abdominal surgery in study hospital is carried out by M.Sc. B.Sc. and diploma anesthesia professionals. M.Sc. anesthesia professionals including M.Sc. anesthesia students and some B.Sc. anesthetists provide lidocaine infusion using a bolus dose of 1.5mg/kg of lidocaine before induction of anesthesia. Then immediately after induction they continued i.v infusion of 1mg/kg per hour of lidocaine mixed with 500ml of 0.9% normal saline using *aeonmed* infuser for 60 minutes intraoperatively. Those diploma and some anesthesia professionals did not provide lidocaine infusion as supplementary to general anesthesia (GA).

In the postoperative time patients transferred to recovery room and transferred to ward when they recover from anesthesia. In ward patient were usually observed by ward nurses and pain is usually managed by tramadol and diclofenac based on patient complain and sometimes on physician order.

At PACU patients were asked to mark their pain level based on 0-10cm VAS score as soon as patient fully respond to verbal command and recovered from full cognitive ability. VAS score and other variables were documented at 3rd hour, 6^{th} hour, 12^{th} hour and 24^{th} hour at wards after end of surgery. A time in minutes from end of surgery to first analgesia request were documented together with total analgesia consumed in the first 24 hours. In addition, incidence of postoperative nausea and vomiting documented when it was reported within 24 hours.

4.9 Data Quality Control

Pretest was done for one week at Zewditu Memorial Hospital with 5% of the total sample size(two patients in each group) which were not included in the actual study. Collected data were checked for completeness, accuracy and clarity. Incomplete data were not entered a data base prepared on Epi-info. Data clean up and cross-checking was done before analysis on SPSS. Regular supervision was done during data collection by principal investigator and M.Sc. anesthesia students and data was stored in safe and secured place.

4.10 Data Analysis and Interpretation

The data were reviewed from completed structured data retrieval form to ensure completeness and quality of data. After data quality was assured, forms were collected and

assigned consecutive number (code) for ease of data entry. The Data was entered using the Epi-Info version 7.0 and clean-up has been made to check accuracy, consistency and errors identified were corrected and finally transported to SPSS V 20 for analysis.

Shapiro Wilk test with p value <0.05 for non-normally disrbuted data and histogram with bell-shaped were used to test for normal distributions of data while homogeneity of variance were assessed using Levene's test for equality of variance. Numeric data were described in terms of mean ± SD for symmetric datas like age, BMI, heart rate(HR) and median (Interquartile range) for asymmetric numeric datas like 24 hour VAS score and total analgesia consumption. Comparison of numerical variables between study groups were done using unpaired student t-test and Manny Whitney U test based on symmetric and asymmetric data respectively.

Frequency and percentage were used to describe categorical variable and statistical association between groups were tested using Chi-square for datas like sex,surgical procedures and surgions eperiance or Fisher's exact test for data like ASA status. The findings of the study are presented in tables and figures. A p-value <0.05 with power of 80% considered statistically significant.

4.11 Ethical consideration

Ethical clearance and approval to conduct the research was obtained from the university ethical clearance and review committee before the start of the study. The importance of the study were 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.

4.12 Dissemination plan

The results of the study will be presented to the department of anesthesia as part of M.Sc. in advanced clinical anesthesia thesis, communicated through annual students and staff research conference, annual National conference of Ethiopian Anesthetists Association (EAA), different NGOs and Ethiopian ministry of health. Finally it will be sent to national and international journals for publishing.

5 RESULT AND DISCUSSION

5.1 Results

5.1.1 Demographic and Perioperative Characteristics of study participants

A total of Sixty eight patients were included in our study. About 59 (86.8%) of study patients were ASA I and 9 (13.2 %) were ASA II. The mean BMI (kg/m^2) in exposed group is 22.78±1.69 kg/m^2 and non-exposed group is 22.68±1.59kg/m^2 which is comparable in both groups, p=0.802. The mean age in exposure group and control group is comparable with 40.7±7.6 years) and 44.4±8.8 years, P=0.068.

Majority of patients underwent laparatomy and cholicystoctomy surgical procedures in both groups with a proportion of 24 (35.3%) and 22 (32.3%) respectively. The remaining surgical procedures include resection anastomosis 11 (16.2%), colostomy closure 8 (11.8%) and iliostomy closure 3 (4.4%) in both groups.

There was no statistical difference between the two groups in other perioperative characteristics, p>0.05 as showen in table 1.

Table 1: Demographic and perioperative characteristics of elective abdominal surgeries in Empress Zewditu Memorial Hospital, February 1-April 30, 2018. Expressed by using unpaired t-test:(mean±SD), X^2=n(%) and Mann-Whiteny U test=median and IQR.

		Exposed (lidocaine) group (n=34)	Non-exposed group (n=34)
Age (years) (mean±SD)		40.7 ± 7.6	44.4 ± 8.8
BMI(kg/m2) (mean±SD)		22.78 ± 1.69	22.68 ± 1.59
Sex	Male (n, %)	18 (26.5%)	21 (30.9%)
	Females (n, %)	16 (23.5%)	13 (19.1%)
ASA Status	ASA I (n, %)	31 (45.6%)	28 (41.2%)
	ASA II (n, %)	3 (4.4%)	6 (8.8%)
Surgical procedures	Cholicystoctomy	12 (17.6%)	10 (14.7%)
	Laparatomy	11 (16.2%)	13 (19.1%)
	Resection anastomosis	6 (8.8%)	5 (7.4%)

	Colostomy closure	4 (5.9%)	4 (5.9%)
	Iliostomy closure	1 (1.5%)	2 (2.9%)
Induction agent	Thiopental	19 (27.9%)	12 (17.6%)
	Propofol	15 (22.1%)	22 (32.4%)
Surgeon experience	Resident (n, %)	20 (29.4%)	18 (26.5%)
	Senior (n, %)	14 (20.6%)	16 (23.5%)
Estimated intraoperative blood loss (ml) #		130 (120-170)	130 (110-150)
Duration of surgery (minutes)#		78 (74-80)	80 (75-84)
Duration of anesthesia (minutes)#		87.5 85-90)	90 (85-90)
Extubation time (minutes) #		4 (3-5)	5(3-5)

Hint: # = Median (Interquartile range); n (%) = number (proportion) and p >0.05.

5.1.2 Twenty four hour VAS score

The median VAS scores in lidocaine group remained significantly less than that in controlled group ($p<0.05$) and presented as shown below in table 2.

Table 2 Comparison of postoperative pain severity using median(IQR) VAS score (0-10cm) at recovery room, 3rd, 6th, 12th and 24th postoperative time in patients undergoing abdominal surgeries in Empress Zewditu Memorial Hospital, February 1-April 30, 2018. Using Mann-Whiteny U test (median and IQR).

Variables expressed as median (IQR) in (cm)	Exposed(Lidocaine) group (n=34)	Non-exposed group (n=34)	p-value
Recovery room VAS score	2.9 (2.3-3.5)	4.7 (3.6-5.4)	<0.0001
3rd post-operative time VAS score	3.0 (2.0-4.0)	4.2 (2.8-5.3)	0.011
6th post-operative time VAS score	2.4 (1.0-3.6)	3.7 (2.8-4.9)	0.001
12th post-operative time VAS score	2.2 (1.1-3.0)	3.3 (2.8-4.0)	<0.0001
24th post-operative time VAS score	1.0 (0.8-1.7)	1.6 (1.0-2.1)	0.020

The median VAS score were lower in the exposed group at recovery room, 3rd, 6th, 12th, and 24th hour. Using Many Whitney test a significant statistical difference were observed at all time between exposed and non-exposed groups with p value <0.05 as shown in figure 1 below.

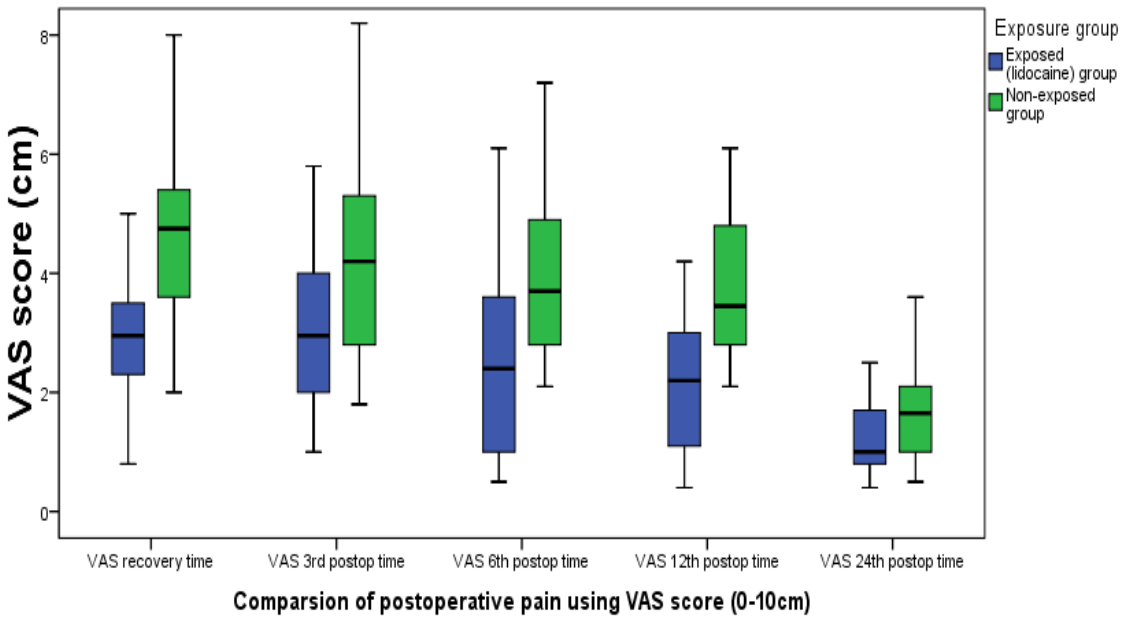

Figure 1 Comparison of median postoperative pain severity using 10 cm VAS score (0-10cm) in patients undergoing abdominal surgeries in Empress Zewditu Memorial Hospital, February 1-April 30, 2018.using Mann-Whiteny U test.

5.1.3 Comparison of Time to First Analgesia Request and Total Analgesia Consumption between Groups.

The median time in minutes were longer 180 minutes in exposed group compared to 45 minutes non-exposed group, p<0.0001. There were also statistically significant differences with regard to median total tramadol consumption within 24 hours. There were no statistical differences between two groups in total diclofenac consumption.

Table 3 Comparison of median time to first analgesia request in minutes and median total analgesia consumption between two groups in the first 24 hour Postoperative periods in patients undergoing abdominal surgeries in Empress Zewditu Memorial Hospital, February 1-April 30, 2018 using Mann-Whiteny U test.

		Exposed (Lidocaine) group (n=34)	Non-exposed group (n=34)	p-value
Time to first analgesia request in minutes		180 (60-240)	45 (45-60)	<0.0001*
Total analgesia consumption within 24 hour	Tramadol (IV)	50 (50-100)	100 (100-150)	<0.0001*
	Diclofenac (IM)	75 (0-75)	75 (75-75)	0.180

Hint: IV: Intra vascular, IM: Intra muscular, *=statistically significant

5.1.4 Incidence of Nausea and Vomiting between exposed and non-exposed group.

The incidence of nausea and vomiting over 24 hours is 45.6 % .The proportions of patients with nausea and vomiting in exposed group (lidocaine) is (35.3%) and (55.9%) in non-exposed group with (X^2 =2.134) and a p value of 0.144.

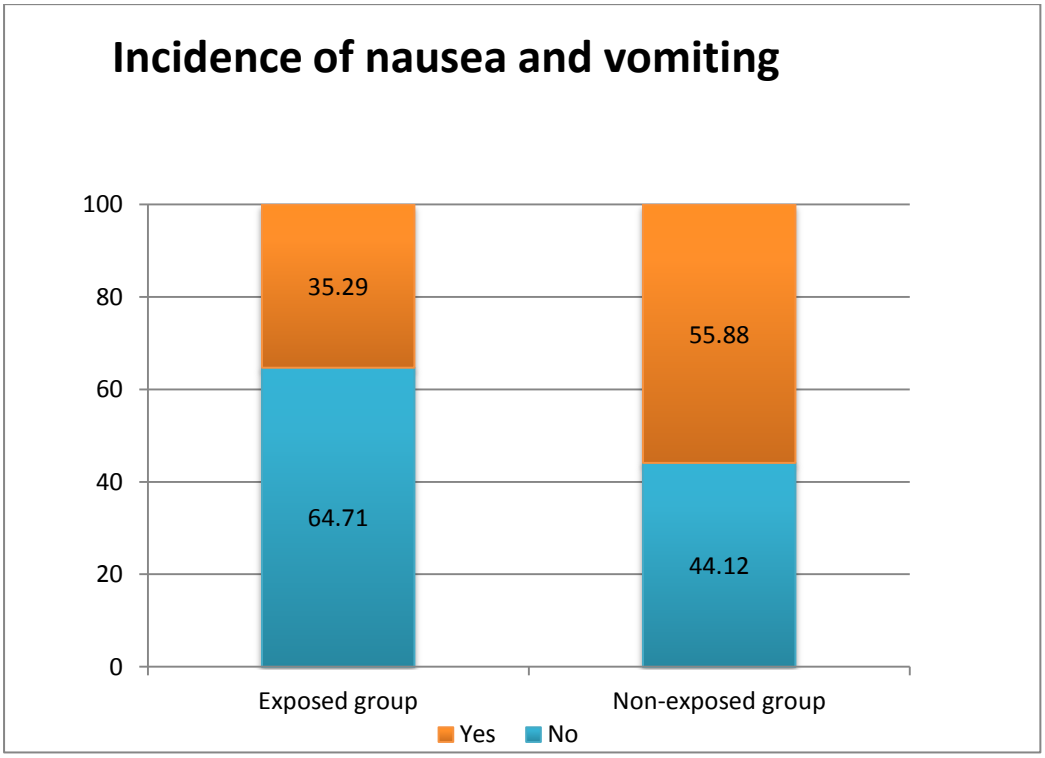

Figure 2 Incidence of nausea and vomiting between two groups in patients undergoing abdominal surgeries in Empress Zewditu Memorial Hospital, February 1-April 30, 2018, association expressed by using chi-square.

5.1.5 Summary of comparison of HR and MAP before induction, after intubation and 24 hour postoperative period between the two groups.

There is no statistical significance result was shown between the two groups in HR and MAP before induction of anesthesia, $p>0.05$ but there is a statistical significance result shown between the two groups in HR and MAP after intuabation with p value < 0.05.

Also Statistically significant result was found in HR and MAP between two groups at immediate recovery room, 3rd and 6th hour's postoperative time, $p<0.05$ but there is no statistically significance regarding HR and MAP at 12th and 24th postoperative, $p>0.05$ as shown below in table 4.

Table 4 Summary of HR (beats/minute) and MAP (mmhg) of before induction, after intubation and in the first 24 hour Postoperative periods in patients undergoing abdominal surgeries in Empress Zewditu Memorial Hospital, February 1-April 30, 2018. Expressed by unpaired t-test (mean ± SD) and Mann-Whiteny U test (median and IQR).

	Exposed (lidocaine) group (n=34)	Non-exposed group (n=34)	P value
Vital sign before induction of Anesthesia			
HR (mean ± SD)	80 ± 9	82 ± 9	0.268
MAP (median and IQR)	92 (89-97)	93 (89-100)	0.299
Vital sign after intubation			
HR (median and IQR)	95 (92-100)	101 (96-109.8)	0.002 *
MAP (mean ± SD)	95 ± 4	104 ± 6	<0.0001*
Immediate recovery room (PACU) vital sign			
HR (median and IQR)	68(67-73)	79(78-89)	<0.0001*
MAP (median and IQR)	87(82-90)	90(87-95)	0.008 *
Vital sign at 3rd hour			
HR (median and IQR)	71(67-76)	81(76-87)	<0.0001*
MAP (median and IQR)	84(78-88)	89(82-93)	0.003 *
Vital sign at 6th hour			
HR (median and IQR)	77(72-88)	87(79-96)	0.013 *
MAP (median and IQR)	81(78-89)	88(86-93)	0.019 *
Vital sign at 12th hour			
HR (median and IQR)	80(74-86)	85(78-91)	0.186
MAP (median and IQR)	84(78-88)	89(79-90)	0.055
Vital sign at 24th hour			
HR (median and IQR)	78(72-84)	79(75-83)	0.551
MAP (median and IQR)	87(79-89)	88(85-90)	0.127

Hint: HR=Heart Rate, MAP=Mean Arterial Pressure IQR=Inter-quartile range,* = statistically significant.

In this study none of the patients experienced lidocaine-related adverse effects.

5.2 Discussion

The present study showed that the median pain score at rest were lower 2.9(2.3-3.5) in exposed group compared to 4.5 (3.6-5.4) in non-exposed group with p value of <0.0001 at immediate recovery room. The median VAS score at 3rd post-operative hour in exposed group is lower 3.0 (2.0-4.0) compared to 4.2 (2.8-5.3) in non-exposed group p value of 0.011. The median postoperative pain score were also lower at 6th, 12th and 24th post-operative time with statistically significant difference of 0.001, <0.0001 and 0.020 respectively.

A meta-analysis in China aimed to assess the efficacy and safety of intravenous infusion of lidocaine for pain management after cholicystectomy concluded that there were significant difference between groups in terms of VAS scores at 24 hours, p<0.05 and significant difference were found regarding opoid consumption at 24 hours, p=0.009(18).

The result of our study is in line with study done in Iran showing the lower pain score in treatment group compared to the control group. This double blinded randomized controlled study demonstrate that the mean ± SD pain score in treatment group is 3.72 ± 0.56 and 5.50 ± 0.53 cm in control with placebo group respectively, p = 0.0001. The likely explanation for the similarity between two studies is the infusion were given starting with loading dose of lidocaine 1.5mg/kg before induction of anesthesia and continue with infusion of 1mg/kg immediately after induction of anesthesia in both studies except the later one study have used intraoperative fentanil (strong opoid) as additional analgesia and VAS score at 24th hour was not significant with p=0.64 due to difference in post operative analgesia used(9).

Our study supports the findings of the study done in Nepal with the mean pain VAS scores in lidocaine group remained significantly less than that in control group with mean VAS score at 3rd hour is 2.5 ± 1.4 and 3.6 ± 1.7 respectively (p<0.001)(14).The analgesic efficacy of lidocaine is due to a selective depression of pain transmission in the spinal cord and a reduction in tonic neural discharge of active peripheral nerve fibers(2, 22).

In contrary to our study a randomized controlled trail done in Switzerland to analyze the effect of perioperative i.v lidocaine in laparascopic renal surgery postoperative pain scores showed there were no significant differences between groups in pain scores over time at rest with analgesic efficacy of lidocaine intraoperative infusion of 1mg/kg/hr. The mean NRS

score at 6th hour is 4±2 in lidocaine group compared to 5±1 in control group with 0-10 NRS scale (p=0.71). The possible explanation for this contradictory result is the use of fixed postoperative pain treatment (co-analgesic agents) like administering metamizole and paracetamol (acetaminophen) every 6 hours postoperatively and difference in study design(10).

Our study showed significantly less total postoperative analgesic (tramadol) requirement in lidocaine group than in control group. The median (IQR) tramadol in mg where 50 (50-100) mg in exposed group compared to 100 (100-150) mg in non-exposed group p<0.0001. We lack similar finding for comparison with the same drug tramadol (weak opoid) since most studies are using strong opioids (morphine) as postoperative pain management protocol and controlling of analgesic agent achieved between groups. The mechanisms of analgesia of this local anesthetic on surgical trauma include neuronal transmission blockage at the place of injury, reducing neurogenic response and systemic anti-inflammatory intrinsic activity. Lidocaine's analgesic property can persist even after the decreasing of its plasmatic levels, which corroborates the nervous conduction blockage theory(5).

Though different drugs were used, study done in America reveals total postoperative morphine consumption in lidocaine group is lower than that of control group with mean 17±1.5 mg compared to 25±2.7 mg respectively with p <0.0001. Though our study use the weakest opioid, the opioid conversion factor of 1mg tramadol compared or equal to 0.1mg of morphine which estimates 100mg tramadol to 10mg morphine which is comparable and equivalent analgesic effect(18). The scientific explanation for this similar result is when ststemic lidocaine is administered during operation it will prevent the induction of central hyperalgesia leading to morphine sparing effects by direct inhibition to N-methyl-D-Aspartate (NMDA) receptor, while peripherally decreasing spontaneous neuronal discharge from A delta and C fibers thus decreasing transmission of nociceptive pain)(2, 8, 21).

In contrary to our finding controlled study done in Switzerland, didn't demonstrate analgesic efficacy of lidocaine infusion in terms of total analgesia consumption. The result shows no statistically significant difference between two groups regarding total cumulative postoperative morphine consumption during the first 24 hour (7±9 mg) vs. 11±12 mg) in lidocaine infusion and control group respectively with p=0.23(10). The likely explanation for this contradictory finding is additional intraoperative use of 70% nitrous oxide combination with oxygen as maintenance of anesthesia difference which have additional analgesic effect

and variability in caregiver's response to pain request because the study might be used patient controlled analgesia (PCA) (objective) for more accurate evaluations of pain than VAS score (subjective). Availability of resources or medication used to manage pain up on request also a big reason to this difference observed in the study set up.

A double-blinded study by Saadawy and collaborators in 120 patients submitted to laparoscopic cholecystectomy using the lidocaine infusion for post operative pain management showed that, there was lower need of morphine use at the second postoperative hour. The lidocaine group had lower scores of abdominal pain at rest with 2, 6 and 12 hour postoperative. The scientific reason for result similarity between the studies is that lidocaine and its metabolites interacts with peripheral and central voltage-gated sodium channel on intracellular face of membrane blocking the start and conduction of neural impulse potential and morphine sparing effect(5, 11).

We also observed the median (IQR) of total diclofenac consumption within 24 hours which is not statistically significant between lidocaine and saline groups (75mg (0-75mg) vs. 75mg (75-75mg) respectively (p= 0.180). We lack similar finding for comparison since most studies are using opioids as postoperative pain management protocol and controlling of analgesic agent achieved between groups. Thus, lack of settled standard postoperative pain management protocol in the study hospital was among the possible factor for the similarity of diclofenac consumption between exposed and non-exposed group.

Our study demonstrate the median(IQR) time for the request of the first dose of analgesic was significantly longer in lidocaine group than in control group 180(60-240)minutes vs. 45 (45-60)minutes, $p<0.0001$. Our finding is comparable with study done in Nepal which shows mean time for the first analgesic request time was longer in treatment group compared to control group, 60.97±18.05minutes vs. 15.73±7.46 minutes, respectively, ($p<0.001$)(14).

The persistence of analgesic effect of lidocaine even after the infusion was discontinued in our study indicates prevention of spinal or peripheral hypersensitivity or both to painful stimuli reflecting its effects on inhibition of spontaneous impulse generation arising from injured nerve fibers and from dorsal root ganglion neurons proximal to the injured nerve segments and suppression of primary afferent evoked polysynaptic reflexes in the spinal dorsal horn. These effects have been postulated to be mediated by a variety of mechanisms, including sodium channel blockade, as well as inhibition of G protein–coupled receptors, N-

methyl-D-aspartate receptor, reduces circulating inflammatory cytokines, and prevents secondary hyperalgesia and central sensitization(20).

Our finding shows the overall incidence of nausea and vomiting after elective abdominal surgery in the first 24 hours to be 45.6%. This proportion is higher in the control group with incidence of 55.9% compared to 35.3% in the treatment group. Though there is a proportion difference, there is no statistical difference between two groups with regard to decreasing the incidence of nausea and vomiting in the first 24 hours ($p= 0.144$). This shows a proportion difference compared to study by Samimi et al where the incidence of postoperative nausea and vomiting is 26%, $p=0.081$(8). The likely explanation for this incongruity is, Samimi et al had used propofol as standard induction agent which is known for decreasing incidence of nausea and vomiting and also this might be because the total amount of fentanil which can induce nausea and vomiting, had been significantly lower in lidocaine group in the study and different in type and depth of inhalational anesthetic agent is the other likely explanation.

There is a statistical significant difference between two groups in HR and MAP after intubation, $p<0.05$ but no significance difference between two groups in HR and MAP before induction of anesthesia, $p>0.05$. Attenuation of the sympathetic response (increase in HR and MAP) during laryngoscopy and endotracheal intubation was observed in the lidocaine group. The result of this study is in line with randomized controlled study done in Turkey showed that heart rate after intubation was significantly lower in lidocaine group compared with controlled group ($P<0.05$)(9). The likely scientific explanation for this result is lidocaine affects impulse conduction from sino-atrial (SA) node of the heart and decreases HR and systolic blood pressure.

6 LIMITATION AND STRENGTH

6.1 Limitation of the Study

Difficult to measure the plasma concentration of lidocaine to understand its pharmacokinetics.

Lack of randomization and control of predicting factors.

Lack of double blinding

In addition most of studies we have used for comparison of our result median (IQR) were with mean (SD) of literatures and most of them were randomized control trials (RCT).

6.2 Strength

Same infusion amount was given to every patient with same infusion criteria.

Study participant were homogenous between the exposed and non-exposed group.

7 CONCLUSION AND RECOMMENDATION

7.1 Conclusion

It can be concluded that intaoperative infusion dose of lidocaine 1 mg/kg/hr decreases the intensity of postoperative pain, reduces the postoperative analgesics requirement, prolonges time to first analgesic request and as a part of multimodal approach for post operative analgesia in patients underwent abdominal surgery.

7.2 Recommendation

For Anesthetists:

We recommend that intraoperative intravenous lidocaine infusion(1mg/kg/hr) is an effective postoperative analgesia, prolongs time to first analgesia request and decrease total analgesics consumption after elective abdominal surgery.

For Researchers:

We also recommend additional randomized controlled study.

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ANNEXES

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 of research investigators. The research team includes BSc. anesthetist, one senior advisor from AAU and two Nurses for data collection from Empress Zewditu Memorial Hospital.

Name of Principal investigator: Mikaele Azanaw (2nd year MSc Student)

Advisor's name: - Mr.:- Wossenyeleh Admasu

Name of sponsor: - Addis Ababa University (AAU)

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

This information sheet is prepared by the above mentioned investigators.

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 will be 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 will be kept confidential and only accessed the researcher and research assistant only. This research project will be reviewed and approved by ethical committee of the AAU. If you want to know more information, you can contact the committee through the address below.

Tel: - +251929140805
e-mail:mikaeleazanaw@yahoo.com

Annex II

Consent Form

Dear participant:

This is a research designed to assess effectiveness of intraoperative intravenous lidocaine infusion as part of analgesia for postoperative time for elective abdominal surgery under General anesthesia. 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 assess 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 or NO

Thanks for taking part in the study!!!

For further question ask investigator

Tel: - +251929140805

e-mail:mikaeleazanaw@yahoo.com

Annex III

የመጠይቅ ፈቃድ

የተከበራችሁ የጥናቱ ተካፋዮች

የዚህ ጥናት ዋና አላማ በ አዲስ አበባ ጤና ቢሮ ስር በሚገኘዉ የዘዉዲቱ መታሰቢያ ሆስፒታል ኦፕራሲዮን ክፍል የሆድ እና አንጀት ክፍል (Abdominal surgery) ቀዶ ህክምና ለሚደረግላቸዉ ህመማን ከጠቅላላ አነስቴዝያ በተጨማሪ በደም ስር የሚሰጠዉን የህመም ማስታገሻ አይነት (intravenous lidocaine infusion) ከኦፕራሲዮን በኋላ ህመም በምን ያህል እንደሚቀንስ ለማወቅ ነዉ።።

በኢጋጣሚ እርስዎም በዚህ ጥናት እንዲሳተፉ ተመርጠዋል።። የዚህ ጥናት ጥቅም እርስዎ በሚሰጡት ምላሽ መሰረት መረጃዎችን በማማላት 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 የሆነ ምላሽንና ከልብ የመነጨ ተሳትፎዎን እንዲሰጡን በአክብሮት እንጠይቃለን።።

ለመሳተፍ ፈቃደኛ ነዎት ?

ሀ/ አዎ ፊርማ ---------

ለ/ አይደለሁም

ለመሳተፍ ፈቃደኛ ስለሆኑ እናመሰግናለን።።

Annex IV

Pre-operative and intraoperative check list

Section I: Socio Demographic Data (chart review)

Card number:----------		**Bed No**----------	**Code**----------
S.No	**Question**	**Response**	
101	Age		
102	ASA (I/II)	A. ASA I B. ASA II	
103	Sex (M/F)	A. Male B. Female	
104	Weight(kg)		
105	Height(m)		
106	BMI(kg/m2)		

Section II: Data during preoperative period

S.No	**Question**	**Response**	**Code**
201	Base line Heart rate	____bpm	
202	Base line Blood pressure(MAP)	____/____(____)mmhg	
203	Base line RR & spo2	_____br/m &_____%	
204	Diagnosis	_____	
205	Surgery Procedure:	_____	

206	Does the patient have any Coexisting disease?	1.yes 2.no If ,yes encircle/specify	A. Respiratory B. Cardio Vascular C. Renal D. Liver E. Diabetes Mellitus Other specify_____ __

Section III: Question related to anesthetic and surgical interventions

S.no	Question	Response	Code
301	Does the patient received any analgesic drug before Induction of Anesthesia?	1. YES 2. NO	
302	If YES specify type and dose	_____(___mg)	
303	Type of Induction agent	1. IV 2. Inhalational 3. Awake	
304	Induction agent type and dose	Thiopental ----------mg Propofol ----------mg Diazepam ----------mg Suxamethonium--------mg Vecuronium ----------mg Pancuronium----------mg	Halothane -------MAC Isoflurane -------MAC Sevoflurane -------MAC
305	Does Ketamine used as Induction agent?	1. YES 2. NO	
306	Time from lidocaine infusion to skin incision in minutes		
307	Vital sign before skin	MAP: _____mmhg HR: _____bpm	

		Sao2 _____%	
308	Vital sign after skin incision	MAP: _____mmhg HR: _____bpm Sao2 _____%	
309	Additional Intraoperative analgesia given?	1. YES 2. NO	
310	If yes specify type, time and dose of the drug given	_____,_____mg	
311	Maintenance of Anesthesia	Halothane Isoflurane Pancronium _____mg Suxamethonium _____mg Vecoronium _____mg	
312	Does the patient extubated in the OR?	YES NO	
313	If yes is a patient responsive	YES NO	
314	Extubation time /minute		
315	Experience of the surgeon	1. Resident 2. Senior	
316	Infusion time/minute		
317	Duration of surgery		
318	Duration of anesthesia		

Section IV: Hemodynamic changes in HR and MAP before induction and after intubation.

S.no	Time	Hemodynamic change	
		HR(beats/min)	MAP(mmhg)
401	Before induction		
402	After intubation		

Section V**: Hemodynamic parameters in post-operative period Immediately at Arrival of Recovery Room, 3rd hr, 6th hr, 12th and 24thhr.**

S.No	**V/S**	**Immediately At Arrival of Recovery Room**	**3rd hr. post op**	**6th hr. post op**	**12th hr. post op**	**24th hour post op**
501	Time (local)					
	BP(mmHg) **SBP/DBP(MAP)**					
	PR (bpm)					
	Respiratory rate					
	SPO2 (%)					
	VAS Score					
	Analgesia given Type and mg					
	Other medication given in mg					

502. Does the patient have nausea within the first 24 hours of surgery? A. YES B. NO

503. Does the patient develop vomiting within first 24 hours of surgery? A. YES B. NO

504. Duration in minutes till Initial analgesic requirement after the patient arrived in the recovery

A. Arrived at _____pm/am {time per 12hr/date/month/Eth .year}
B. Analgesic required time _____PM/AM {time per12hr/date/month/Eth. year}
C. Duration till first analgesic request _____

505. Total and type of analgesic consumption within 24 hours after the patient arrived in recovery/ward_____.

506. Does the patient have any sign of the following clinical signs in 24 hours postoperative time? If yes encircle it? You can encircle more than one.

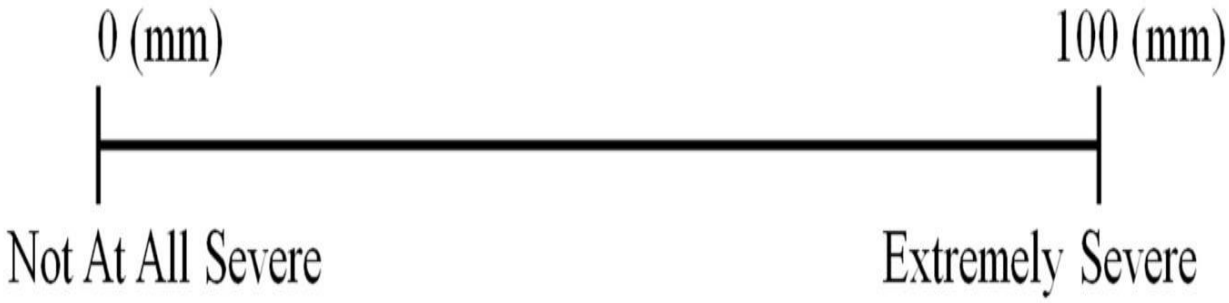
A. Tinnitus
B. Perioral numbness
C. Drowsiness
D. Metallic taste
E. Somnolence
F. Dizziness
G. Blurred vision
H. Confusion
J. Others…….

APPENDICES

English version

Visual analogue scale (VAS) is a line, usually 10 cm long, with each end-point clearly marked and described. Patients are asked to pick a number on the line that represents their pain level or intensity.

Note how severe you feel your disease state is with a mark (|) on the line below.



The scale will be taken 5 times within the first 24 hours. Patients will be asked to rate their pain will be assessed and recorded at 0 min (immediately on acceptance of patient at recovery room) and 0-3, 3-6, 6-12, and 12-24 hours post-operatively.

<u>አማርኛ ትርጉም</u>

<u>የሚታይ አምሳያ መለኪያ (VAS)</u>

0(cm) 10(cm)

ምንም በጠም ከፍተኛ

1. ይህ መለኪያ በመጀመሪያዉ 24 ሰአት 5 ጊዜ የሚወሰድ ሲሆን የህመሙ መጠን ከዜሮ ወደ አስር ሲለካ እየጨመረ ይሄዳል፡፡

<u>በሽተኛዉ የሚጠየቃቸዉ ጥያቄዎች</u>

i.አሁን የሚሰማዎትን የህመም መጠን ከዜሮ እስከ አስር ባለዉ ክፍት ቦታ ምልክት በማድረግ ይግለጡ?