ADDIS ABABA UNIVERSITY, COLLAGE OF HEALTH SCIENCE

SCHOOL OF MEDICINE

DEPARTMENT OF ANESTHESIA

EFFECTIVNESS OF EPINEPHRINEWITH INTRATECAL LIDOCAINE FOR SPINAL ANESTHESIA ON ONSET TIME OF SENSORY BLOCK AND TOTAL ANALGESIA CONSUMPTION AT ALERT REFERRAL HOSPITAL, ADDIS ABABA ETHIOPIA, 2019.

Investigator – HenokLengerew (BSc)

Advisor --- Misrak W/Yohannes (BSc, MSc)

A REASERCH SUBMITTED TO ADDIS ABABA UNIVERSITY, COLLAGE OF HEALTH SCIENCE, SCHOOL OF MEDICINE, DEPARTMENT OF ANESTHESIA FOR PARTIAL FULFILMENT OF THE REQUERMENT OF THE MSC IN ANESTHESIA

Addis Ababa

December, 2019

Addis Ababa University

College of health sciences

School of medicine department of anesthesia

Title of research project: Effectiveness of epinephrine with intrathecal Lidocaine for spinal anesthesia on onset time of sensory block and total analgesia consumption at ALERT referral hospital, Addis Abeba Ethiopia

Name of Student – HenokLengerew (BSc)

Contact detail: – email: Henok.lengerew@gmail.com

Phone number: +**251-910-527-750**

Name of Advisor --- MisrakW/Yohannes(BSc, MSc IN CLINICAL ANESTHESIA)

Contact detail: – email: dzewge@gmail.com

Phone number: +**251-928-114-926**

A Research thesis summited to Addis Ababa university collage of health science school of medicine department of anesthesia for partial fulfillment of the requirement for the MSc in anesthesia

Declaration

I, the undersigned, declare that this thesis is my original work in partial fulfillment of the requirements for the degree of MSc in Anesthesia. I understand that plagiarism will not be tolerated and all directly quoted material has been appropriately referenced

Name: _____

Signature: _____

Submission to MSc Tutor, Dept. 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 Anesthesia course

Name Signature

1._____

2._____ _____

3._____ _____

Acknowledgement

My deepest gratitude goes primarily to my advisor Mrs. MisrakW/Yohannes who ultimate support me throughout the whole process of proposal and thesis development.

I also very grateful to Addis Ababa University College of Medicine and Health Sciences, department of Anesthesia for all the supports and add the research program in the curriculum that lay the foundation for my future career development and academic engagement on research

Finally I would also like to thank Addis Ababa university library and its staff,those authors' and researchers of articles, and on-line information for the valuable works I have read and cited

Abstract

Introduction: Spinal anesthesia is one of the most popular and widely used anesthetic procedures. Different techniques used widely to fasten the onset and to prolong the duration and increase the quality of analgesia of Neuraxial block. Currently epinephrine appears promising in influencing onset and duration of local anesthesia.

Objective: to assess Effectiveness of epinephrine with intrathecal Lidocaine for spinal anesthesia on onset time of sensory block and total analgesia consumption at ALERT referral hospital

Methodology: a hospital based cohort study was conducted at ALERT hospital from October 14-Novembr 15, 2019 on 44 ASA class I and II patients whose age above 18 undergoing elective lower abdominal surgery by using systematic random sampling method. Onset of the block, duration of analgesia, analgesia requestand total analgesia consumption were assessed. Distribution of numerical data analyzed using Shapiro Wilk test then after Mann Whitney U test were used to compare asymmetric data. Independent t-test was used to compare mean values of symmetric data. Categorical variable between two groups were analyzed using Chi Square. p value of <0.05 considered as significant.

Results: The onsets of complete sensory blockade were significantly shorter in patients in Epinephrine group with Mean±SD of 8.91±2.46 and Lidocaine alone group 14.05±4.1 with (p=0.024). There was also statistically significant difference on the duration of sensory block in EpinephrinegroupMean± SD of 149.09 ±16.01 and Lidocainealone group 158.68 ± 28.70 with p =0.001. The first analgesia requesting time were significantly longer in EpinephrineGroup than Lidocaine alone(p 0.026.) and total analgesia consumption also shows is statistically significant difference between Epinephrine75(50 ±200 and Lidocainealone 150 (200±150) with p =0.001.Post-operative pain score were also significantly lower at 12 and 24 hour in Epinephrine groupwith p value 0.022and 0.041.

Conclusion and recommendations:- Addition of 0.2mg of Epinephrine to 5% Lidocaine solution in spinal anesthesia for lower abdominal surgeries resulted in rapid onset of sensory blockade and prolongs the duration of sensory blockade and analgesic request time ,it also decrease total analgesia consumption with no significant side effects, so we recommend addition

of 0.2mg of Epinephrine to 5% Lidocaine is effective both to shorten onset of the block and prolong duration of analgesia with additional incentives of decrease total analgesia consumption.

Contents

List of figures and tables

Tables

Figures

List of abbreviation

ALERT	ALLAfrica Leprosy Rehabilitation and Training center
ASA	American Society of Anesthesiologist
BMI	Body Mass Index
BSc.	Bachelor of Science
DBP	Diastolic Blood Pressure
GA	GeneralAnesthesia
Gayni-obs	Gynecologic and obstetrics
IT	Intrathecal
IV	Intravenous
LA	Local anesthesia
MG	Milligram
Min(s)	Minute(s)
MSc.	Masters of Science
NRS	Numerical Rating Scale
NSAID	Non-Steroidal Anti-Inflammatory Drugs
SA	SpinalAnesthesia
SBP	Systolic Blood Pressure
SD	Standard Deviation

Chapter one: - Introduction

1.1 Background

Lower abdominal surgeries broadly cover surgical procedure that involve opening of the abdomen below the level of umbilicus, it commonly refer for Caesarean sectionand it can be safely performed under general or spinal anesthesia even if Neuraxial anesthesia remains the preferred choice for this kind of procedures (1)

Spinal anesthesia is one of the most popular and widely used anesthetic procedures. It is anesthesia of the lower part of the body by the injection of an anesthetic into the spinal cord, usually in the lumbar region and it is simple, cost effective technique that provides complete sensory and motor block, as well as postoperative analgesia with a high success rate**(**2,3)

Lidocaine is one of the commonly employed local anesthetic for sub arachnoid block.Lidocaine (also called lignocaine) was first synthesized under the name “xylocaine” by a Swedish chemist Nils Lofgren in 1943 (4). In addition to Neuraxial block, Lidocaine is alsocommonly used to perform Nerve block and to treat Ventricular tachycardia as Class IB Type. Peri operative hemodynamic status and excellent pain relief are important issues with Lidocaine

Even though spinal anesthesia with Lidocaine is thought be safer (less cardio toxic) and have effective pain control forLower abdominal surgeries, there are reports about its short duration of action for post op analgesia and patients complain immediate post-operative pain it leads the patient for additional opioid or other anti-pain requirement which expose the client for their well-known side effects as nausea, vomiting, sedation, dizziness, respiratory depression and substance dependence and even the usage of NSAID especially prolonged use is also associated with cardiovascular risk, renal impairment, and increased bleeding for some surgical procedures. This summation end up with decreasing patient safety and satisfaction (5)

So to counter this problem Peoples use Different techniques with the aim of prolonging the duration and increase the quality of analgesia of Neuraxial block and to fasten the onset, using a continuous epidural analgesia, which is technically more difficult and more costly, which patientsat governmental hospital may not afford. Hence, an intrathecal additive to local anestheticsis a reliable method of prolonged post-operative analgesiain resource limited area like Ethiopia**(**6,7)

In the current time adding additives or adjuvants is becoming common for its synergistic effect by prolonging the duration of Sensory-Motor block, increase the quality of analgesia, fasten the onset and limiting the cumulative dose requirement of local anesthetics as well.

Epinephrine also known as adrenaline is sympathomimetic drug or hormonethat is endogenously secreted by both adrenal gland and be a part of human fight or flight response(8)**.**In anesthesia as a medication epinephrine is an emergency drug that has been used to treat dropping blood pressure, anaphylaxis even cardiac arrest and also ithas been used for many years as an adjuvant to LAs with the aim to prolong sensory nerve blockade and delay systemic uptake of the LA, thereby reducing the risk of anesthetic toxicity and in an attempt to achieve a spinal anesthetic of intermediate duration. **(**9).

Although there is good evidence for a spinal action of epinephrine(10), some authors deny the analgesic effectiveness of intrathecal epinephrine(11).The mechanism of epinephrine in prolonging the duration of Neuraxial blocks is not completely understood. Possible explanations may be related to vasoconstrictive effect presumably alter the intrathecal clearance of drugs or possible interaction of each agent at a different spinal cord receptor site (16)

1.2Statement of the problem

Prolonged onset following spinal block presents a potential problem in the busy clinical setting and in top emergency conditions. It may reduce the number of case performed in a day. It is also one of the most important cause for frustration of operating room team including surgeon (10). Pain is also a critical component of patient management that consists of both sensory and emotional components that interact to produce an overall pain experience.It places a significant economic strain on society in the form of disability, loss in productivity, and health care costs (13).

In lower abdominal surgery, the Neuraxial delivery of medications has been advocated as a technique of choice because of its likely better patient-oriented outcomes (14)the limited duration of action of intrathecal local anesthetics can be used by anesthesia providers as a justification to avoid the use of this technique**(**15)

Postoperative pain management remain a significant challenge after abdominal surgery and the usual methods of the pain control in half of the patients often doesn't provide an adequate analgesia and post-operative pain can delay patients recovery **(**15)

The prevalence of post-operative pain is still severe and under managed in our country. A study done to evaluate quality of post-operative pain management in Ethiopia showed that moderate to severe postoperative pain was present in 88.2% of patients and pain was inadequately treated in 58.4% of these patients **(**16)

Traditionally the patient's pain is managed with general anesthesia and narcotic medication for surgery, followed by oral medications, including non-steroidal anti-inflammatory drugs, opioid-containing oral analgesics (17). Despite the availability of these analgesic drugs, many patients still do not achieve effective pain control.

Single opioid analgesics may not provide effective pain relief for moderate to severe pain and the role of opioids are questioned because of their known side effects of nausea, vomiting, dizziness, sedation, respiratory depression and substance dependence 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(18, 19).

Currently various strategy options employed to attain post-operative pain control for patients undergoing spinal anesthesia. But what makes management of post-operative pain after such procedure unique is that it needs balance between pain relief and side effects (20, 22, 23).

1.3. Significance of the study

Even if spinal anesthesia is the commonly performed regional anesthesia technique (18) prolonged onset and Postoperative pain is Common problems immediately after abdominal surgery followed by a prolonged hospital stay and major cost drivers in the postoperative period(22).

Epinephrineis one option which is cheap, easily available and found universally.
Some literatures shows conflicting results regarding the effectiveness of intrathecal epinephrine on onset time of sensory block and duration of analgesia is one of the reason for this study even

for the available results it is difficulty to generalize research results from other countries, because the hospital setup and the management style varies in addition to inter-racial and ethnic difference in pain and response.

The result will show alternative management for anesthetists which can improves onset and duration of analgesia and leading to better client satisfaction.

This study was planned to Assess the Effectiveness of epinephrine with intrathecal Lidocaine for spinal anesthesia on onset time of sensory block and total analgesia consumption and it will generate 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 and to evaluate the effectiveness of implemented preventive intervention as well.

HYPOTHESIS

HO1: There is no significant difference in onset of the sensory block between the groups.

HA1: There is significant difference in onset of the sensory block between the groups.

HO2: There is no significant difference in duration of the sensory block between the groups.

HA2: There is significant difference in duration of the sensory block between the groups.

HO3: There is no significant difference in total 24 hour analgesic consumption between groups.

HA3: There is a significant difference in total 24 hour analgesic consumption between groups.

HO4: There is no significant difference in median NRS score between groups.

HA4: There is significant difference in median NRS score between groups.

Chapter two: - Literature review

2.1 Literature Review

We can categorize literatures published under the area of effectiveness of epinephrine with intrathecal Lidocaine for lower abdominal surgeries in to three major parts. Literatures which conclude as intrathecal epinephrine with Lidocaine significantly prolong both onset of analgesia and spinal anesthesia duration with reduced postoperative pain score cover the major portion, others don't denies the use of intrathecal epinephrine on duration of analgesia but their result don't show significant effect in terms of onset .In contrast, some authors reported that epinephrine has no role at all.

Kito K.et al,(1998) conducted a study to assess the efficacy of varied dose of intrathecal Epinephrine with Lidocaine for patients undergoing lower abdominal and urological procedures on four different doses of epinephrine. 80 patients were randomly assigned to 4 groups according to doses of epinephrine. The control group received IT plain 2.5 ml of 5% hyperbaric Lidoacaine; the three study groups in addition received 0.2, 0.4 and 0.6 mg of epinephrine respectively and the result is dose-dependent relationship of spinal analgesia with a significant prolongation at 0.6 mg dose (25)

Goyagi T et al performed a prospective, randomized, double-blind study to evaluate the effect of intrathecal Epinephrine added to local anesthetics on duration of the block total analgesia consumption and post-operative pain severity. Thirty-six patients who scheduled for gynecological surgery were randomly allocated to receive either 12mg of hyperbaric tetracaine(control group, n = 18) or 12 mg of hyperbaric tetracainewith 0.12 mg of epinephrine (epinephrine group, n = 18). The addition of 0.12 mg of epinephrineto local anesthetics for spinal anesthesia prolonged the duration of analgesia (218± 51 versus 300 +/- 50 min) and minimum VAS score with a p value of <0.05 without increasing the incidence of adverse effects as nausea and vomiting when compared with control group(26)

In 2018,a prospective, randomized, placebo-controlled study by Daniel Katz et al, with the aim of assessing the effect of adding subarachnoid epinephrine to hyperbaric bupivacaine for repeated caesarian delivery , the result of the study showed no difference in onset time of sensory block whereas the addition of 200µg epinephrine prolong the duration of sensory block(172 ± 50 versus 120± 15 min) , duration of motor block (165 ± 30 versus 120 ± 45 min) and quality of analgesia as well with a p value of <0.05 (27)

Chiu AA et al, Try to assess the efficacy of epinephrine for prolonging the duration of Lidocaine spinal anesthesia by performingrandomized controlled study in 1995. Seven volunteer were randomly allocated to receive either 50 mgLidocaine(in dextrose7.5%) spinal anesthetics with and without Epinephrine (0.2mg).Addition of Epinephrine significantly prolonged duration of surgical anesthesia by an average of 16-29 min and it also significantly prolonged duration from 153±27 to 234±50 min.They concluded that addition of epinephrine to Lidocaine indicated to prolong duration of anesthesia for lower body operations.(28)

Chambers WAet al, addedepinephrineto1.5 ml of 5% Lidocaine in 7.5% dextrose for spinal anesthesia. They wanted to assess whether this would have an impact regarding time of onset and duration of sensory and motor blockage and on the total analgesia consumption. 40 patients scheduled for transurethral resection of the prostate were randomly assigned to one of the two groups: group1 received 1.5 ml of 5% Lidocaine whereas; group 2 received 1.5 ml of 5% Lidocaine with 0.1, 0.2, or 0.3 ml of 1:1000 epinephrine. Mean onset of sensory blockage is 8.1 ± 0.49in epinephrine group and 10.3 ± 0.85in saline group .mean duration of motor blockage in epinephrine group is 171 ± 11 and 144 ± 0.85in saline group and their conclusion is the addition of epinephrine produced little or no clinically useful prolongation of block, but this only reached statistical significance with regard to total recovery, which took 40 to 50 minutes longer with the epinephrine containing solutions. No difference could be seen between the three doses of epinephrine (29).

Momose K .et al (1994) Try to evaluate analgesic effect of intrathecal EpinephrineAdded spinal anesthesia with Lidocaine on sixty ASA I and ASA II Patients who were scheduled for lower extremity surgery.a prospective, randomized, double blind, placebo controlled study enrolledand their results was progression of analgesia level was significantly faster and prolongation of duration was significantly greater after adding 0.1mg of epinephrine. No severe complications were found in any patient of either group (30).

Spivey DL et al conducted a study to assess the analgesic effects of intrathecal Epinephrine with Lidocaine spinal anesthesia by prospective controlled, randomized double blind study.Patients were randomly assigned to one of the two groups.one group received Lidocaine in dextrose, and the other, Lidocaine in dextrose plus epinephrine. The result showed no significance difference between the two groups in terms of duration, onset study or any other measured value covered in the research maximum segmental level, time to maximum level (31).

Leicht.et al, showed that addition of 0.3 mg of epinephrine to 1.2mg of local anesthesia per inch body weight in 28 ASA I and ASA II Patients prospective, randomized, double blind, placebo controlled study in 1986. The patient was randomized in to two groups. Group 1 patients receivedLidocaine plus 0.5 ml of normal saline ; Group 2 patients receivedLidocaine plus 0.3 mg of epinephrine and their result showed epinephrine group showed the fastest onset (18.1 ±4.33 min) than (11.6±3.57) in saline group , duration of block also significant in epinephrine group (102.9± 18.1) than 78.1±12.6) and their conclusion was the addition of intrathecal epinephrine significantly fasten onset and prolong the duration of Lidocaine spinal anesthesia without any statistically significant adverse effect (32).

A 2018 meta-analysis study 70 trials (3644 patients, 17 countries, from 1970 to 2017, using Google scholars and PubMed as a data source and assessing the efficacy of intrathecal administration of epinephrine on the onset, duration of analgesia and adverse effects forNeuraxial and Loco regional Anesthesia. On the selected date, Evidence exists that adding epinephrine to intrathecal or loco regional local anesthetics prolongs analgesia and motor block by about the average of 60 minutes. Available evidence is insufficient to conclude on other outcomes in these settings, or that adding epinephrine to local anesthetics has any impact or side effect at all. (33)

CHAPETR THREE:-OBJECTIVE

3.1 General objective

To assess Effectiveness of epinephrine with intrathecal Lidocaine for spinal anesthesia on onset time of sensory block and total analgesia consumption at ALERT referral hospital, Addis Ababa, Ethiopia from October 14-Novembr 15, 2019.

3.2 Specific objectives:-

1. To compare onset of the sensory blockbetween epinephrine and Lidocainealone groupsat ALERT referral hospital, Addis Ababa, Ethiopia
2. To compare the duration of sensory block between epinephrineand Lidocainealone groupsat ALERT referral hospital, Addis Ababa, Ethiopia
3. To compare 24 hour drug consumption between epinephrine andLidocainealone group at ALERT referral hospital, Addis Ababa, Ethiopia
4. To compare the pain severity between epinephrinegroup and Lidocainealone groupat ALERT referral hospital, Addis Ababa, Ethiopia.

CHAPTER FOUR: - METHODOLOGY

4.1 Study area

This particular study was conducted at ALERT hospital which is one of the thirteen government hospitals found in Addis Ababa, capital city of EthiopiaAdministered under ministry of health. ALERT is primarily established for leprosy and tuberculosis rehabilitation and training. But now it has a lot of catchment area, health centers from where different complicated cases are referred to. It has so many departments of specialties beneath it. The acronyms of ALERT stand for All Africa leprosy rehabilitation and training center. Currently it is a 268 bed hospital which provides dermatology, ophthalmology, general surgery, obstetrics and orthopedics service. ALERT hospital has eight major operation tables and two of them are used for orthopedics and trauma cases and two is used for gynecological service. These two units serve both in outpatient and inpatient service with a total of 8600 clients per month.

4.2 Study design and period

- Hospital based cohort study was conducted fromOctober 14-Novembr 15, 2019.

4.3 Source and Study population

Source population

All patients posted for elective lower abdominal surgery under spinal anesthesia at ALERT referral hospital.

Study population

All patients posted forelective lower abdominal surgery under spinal anesthesia at ALERT referral hospital within the study periods.

4.4Study variables

4.4.1 Dependent variables

- The onset time of sensory block
- Duration of sensory block,
- Total analgesia consumption
- Average Postoperative pain severity

4.4.2 Independent variable

- Socio demographic characteristics: age, sex, weight, height, body mass index
- ASA status
- Preoperative surgical diagnosis
- Duration of surgery
- Experience of anesthesia provider
- Base line heart rate, blood pressure
- Amount of local anesthetics used
- Level of the block

4.5Inclusion and exclusion criteria

4.5.1 Inclusion criteria

- All ASA I and ASA II patients aged greater than 18 years and scheduled for elective Lower Abdominal Surgeries under spinal anesthesia.

4.5.2 Exclusioncriteria

- Failed spinal anesthesia
- Uses of local anesthetics other than 5 % Hyperbaric Lidocaine
- Uses of other adjuvant
- Patient who take sedative or analgesics intra-operatively or as a premedication within 24 hrs. preoperatively
- Duration of surgery less than half hour, greater than three hour
- Patients with local sepsis

4.6 operational Definition

Spinal anesthesia- It a type of regional anesthesia in which local anesthetic Agents is administered in subarachnoid space

Epinephrinegroup- patients who takes 0.2 mg of epinephrine and 5% hyperbaricLidocaine

Lidocaine alone group – patients who takes 5% hyperbaric Lidocaine only

NRS: is a simplest and most comment pain intensity assessment tool that include asking a patient to put his or her pain from 0-10 (11 point scale) with the understanding that 0 is equal to no pain at all and 10 equal to the worst imaginable pain (3).

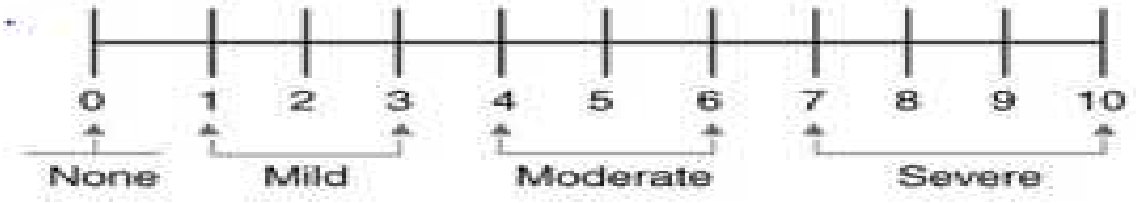

Figure1: NRS pain intensity assessment tool

Failed spinal block- patient feel pain to pinprick stimulation at incision area after 30 minutes

Lower abdominal surgery–Anysurgical procedure below the level of the umbilicus.

Effectiveness –the degree to which epinephrine is successful in producing a desired positive result in terms of onset and analgesia

ASA status: is a surgical risk stratifications validated by American Society of Anesthesiologist

ASA I: a normal healthy patient non-smoking, no or minimal Alcohol use

ASA II: A patient with mild systemic disease only without substantive functional limitation. Example (include but not limited to) current smoker,pregnancy, obesity 30<BMI<40,well controlled medical condition, mild lung disease

Onset of sensory block: timefrom administration of local anesthetics with/without epinephrine to complete analgesia.

Duration of sensory block: time between the administration of the local anesthetic and the first postoperative pain.

Onset of motor block: time from administration of local anesthetics with/without epinephrine to time difficult to lift the leg

Duration motor block: time between the local anesthetic administration and complete recovery of motor functions

Time to first analgesia request:a time from spinal injection to first request for analgesia.

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

Incision starting time: a time in minutes from end ofinjection of local anesthetics to beginning of surgical incision

4.7 Sample Size and Sampling technique

4.7 .1 Sample size

Two independent sample size formula based on the mean difference of onset of sensory block, post-operative NRS score, time to first analgesia request and duration of sensory block two groups from the study by Leicht (29) were used to calculate sample size for each group. The larger result taken from each group (mean onset time of sensory block) was taken to calculate the required sample size. The mean onset of sensory block on this study was 14.6±3.57 minutes in control group and 18.1±4.33 minutes in Epinephrine 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 (α,β) =$(1.96+0.84)^2$= 7.84, when the power = 80% and the level of significance =5%
- ✓ m_1 and s_1^2 are mean and variance of Lidocaine alone group respectively.
- ✓ m_2 and s_2^2 are mean and variance of epinephrinegroup respectively.
- ✓

$$n = \frac{(3.57^2+4.33^2)*7.84}{(18.1-14.6)^2} = 20$$

So that using 1:1 ration between groups and adding 10% contingency a total of 44patients were required.

4.7 .2 Sampling Technique

Eighty patientswere estimated to be performed during study period (within one month) and 49participants were assessed for eligibility on the study timewith the probability of about 61%. Among this three patients were excluded because of addition of other adjuvant and duration of surgery > 3Hr. forty sixpatients were randomized into two groups. After initial randomization, two patient was considered dropouts due to the need for sedation and therefore not subjected to statistical analysis. Systematic random sampling method used for data collection By considering the order of patients based on schedule number, 1patient were selected from the list by lottery method ,starting from this point patient selected every two interval, similar pattern followed for the consecutive patients scheduled for elective lower abdominal surgery till the sample size filled.

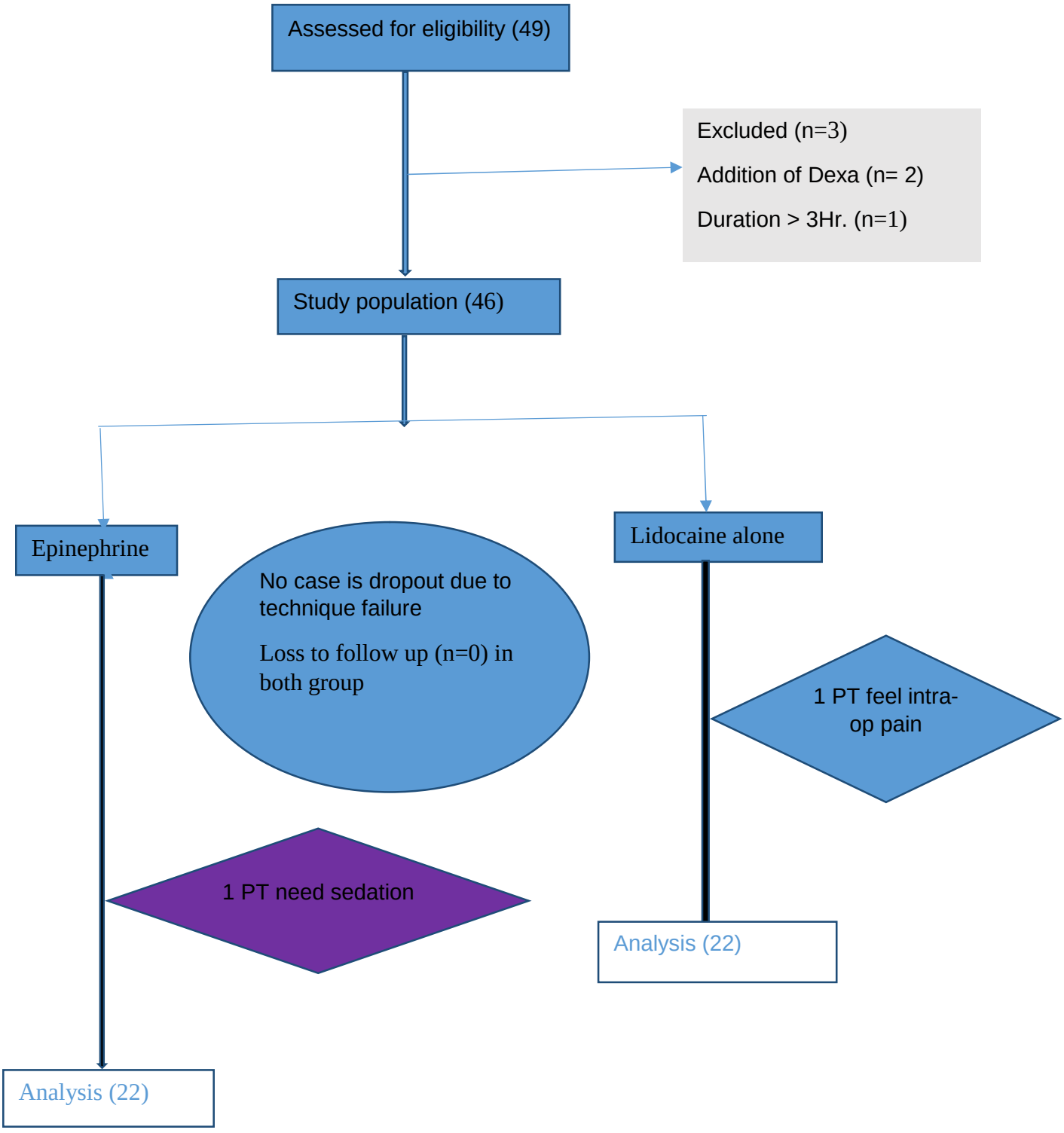
Assessed for eligibility (49)
Excluded (n=3)
Addition of Dexa (n= 2)
Duration > 3Hr. (n=1)
Study population (46)
Epinephrine
Lidocaine alone
No case is dropout due to technique failure
Loss to follow up (n=0) in both group
1 PT feel intra-op pain
1 PT need sedation
Analysis (22)
Analysis (22)

Figure 2 Enrollment chart for patients scheduled for lower abdominal surgery under spinal anesthesia at ALERT hospital, 2019

4.7.3 Anesthesia managements of lower abdominal surgeries in ALERT hospital

Usually elective Gayni-obsand orthopedic patients pre evaluated a week before surgery by anesthesiologists and anesthetists in preoperative evaluation clinic .the aim of pre-operative evaluation include identify coexist diseases, assigning ASA status of patients. Patient also assessed whether they are fit for spinal block or not. Those patient who have contra-indication to spinal block like allergy to local anesthetics, infection at the site of injection, bleeding abnormality, peripheral nerve disease, psychiatric problem and uncooperative patient would not be selected for spinal block, they will proceed with general anesthesia or other alternative seek according to the patient condition.

Those patients who are decided to proceed with spinal block premedicated with metoclopramide 10 mg IV and cimetidine 300 mg, Spinal block is provided by B.Sc. and M.Sc. anesthesia professionals andfor the time being ,since bupivacaine leaflet found in the hospital says not for spinal , all anesthetist withholdit and all of blocks are performed by is 5% hyper baricLidocaine . But there is variability between anesthetists in adding adjuvants tospinal block. Most of the anesthetists add epinephrine mainly to prolong the duration of sensory block and fasten the onset, while some don't believes in use of epinephrine will not and there are also few who use other adjuvants . Our study uses theses variance as means to select as those epinephrine group vs. Lidocaine alone. Dose of local of local anesthetics deposited determine by weight of patient. 100 mgare the common doseafter proper sterile techniquesusing 26/23G spinal needle commonly.

At the end of surgery patient wait in recovery room for six hours for follow up by anesthetist post operatively. Post-operatively all Obstetric take diclophenac suppository and 75 mg intramuscular diclophenac for orthopedic patients is given as a standard treatment and take additional tramadol if needed.

4.8 Data collection methods

Questionnaireswas prepared in English and after providing training for data collectors,data wascollected using pretested questionnaires. All patients selected for the study were asked for their consent and instructed on how to self-report pain for pin pinprick stimulation, first post-operative pain and pain using NRS. Sociodemographic data, baseline status was filled from patient chart. The onset time of sensory blockade was assessed by response to pinprick at 3 minutes interval for the first 30 minutes and thereafter at 5 minute interval until regression at least T 12 level, onset of motor also addressed by asking the patient to move his or her leg using the following scale (34).0 able to raise extended leg 1unable to raise extended leg 2 unable to flex the knee 3 unable to flex the ankle at 2, 5 and 10 minute before the start of surgery. Duration of sensory block was assessed every 20 minutes by B.Sc. anesthetists who was not present during the injection and unaware of the solution used. First analgesia request time was also filled from the chart and document the time, doses and the roots of analgesics. Severity of pain in NRS assessed at 2, 6, 12 and 24hours after incision staring time by anesthetist or recovery nurse depending on the time.

4.9 Data quality control

A structured questionnaire was prepared in English for data collection. Pretest was done for two days at St. Paulo's hospital with 5% of total sample size which were not included in the actual study. Collected data were checked for completeness, accuracy and clarity. Based on the findings of the pre-testing, appropriate amendments and revisions was made before the final administration of the questionnaire for actual data collection.There wasa discussions on any kind of problem the data collectors was face during the data collection processand Regular supervision was done during data collection by principal investigator.

4.10 Data analysis and interpretation

Data were cleaned, entered, coded and analyzed by using SPSS version 23. Data distribution was tested for normality using Shapiro Wilk test and presented in terms of mean ± SD for symmetric data like age, Weight, baseline heart rate, baseline mean arterial pressure, onset of sensory block incision time, duration of sensory block duration of surgery and median (Interquartile range) for asymmetric numeric data like, baseline NRS, post-operative NRS, first analgesics request time. Homogeneity of variance was assessed using Levene's test for equality of variance. Comparison of numerical variables between study groups were done using independent t- test for normally distributed numerical data and Mann Whitney U test for non-parametric data. Frequency and percentage were used to describe categorical variable (sex, ASA, diagnosis) and statistical difference between groups were tested using Chi square. Ap value <0.05 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 was explained & verbal informed consent was obtained from each participant by the data collectors. The consent form was in line with the ethical principle of "autonomy" was involve a sentence says their decision to participate or not to participate will have no effect on their ability and right to receive services at the health center.Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients.

4.12. Dissemination of the study results

The results of the study will be presented to the department of anesthesia as part of M.Sc. in advanced clinical anesthesia thesis and it will be submitted to College of Health Sciences, Department of anesthesia and also a copy of this material will be given to ALERT, Addis Ababa University student research office.After presentation on workshops and seminars, hopefully it will be published in peer reviewed reputable journals.It also serve as a reference material to researchers, experts and policy makers for intervention.

CHAPTER FIVE: - RESULT AND Discussion

5.1 RESULTS

Primarily 49 patients were enrolled in the study period. From those three patients were excluded because of addition of dexamethasone and duration of surgery > 3Hr.Fourty six patients were randomized into two groups. After initial randomization, two patients were considered dropouts due to the need for intraoperative sedation and feel intraoperative pain therefore not subjected to statistical analysis. Therefor forty four patients included and were randomly divided in to epinephrine (22 client) and Lidocaine alone (22 client).

5.1.1 Demographic and operative characteristics

No statistically significant differences were found between the groups with respect to age, Weight, gender, ASA status, baseline numeric rating scale and duration of surgery (Table-1).

Table 1: Demographic and perioperative characteristics of patients underwentlower abdominal surgery under spinal anesthesia at ALERT hospital, Addis Abeba Ethiopia, 2019

Variables	Epinephrine	Lidocaine alone	Total	p-value
Age**	28.68± 6.92	33.54± 9.95		0.141
Sex*				
Male	17 (77.3%)	14(63.6%)	31 (100%)	0.458
Female	5 (22.7 %)	8 (36.4%)	13(100%)	
ASA status*				
ASA I	12(54.5 %)	14 (63.6 %)	56(100%)	0.376
ASA II	10 (45.5 %)	8(36.4 %)	16 (100%)	
Weight**	64.77± 10.37	61.36± 11.33		0.304
Duration of surgery (minutes)**	63.4 ± 48.19	68.18 ± 52 .18		0.01
Baseline NRS***	2(3)	2(3)		0.138
Baseline Heart Rate (bpm)**	97.68± 15.2	91.82± 12.9		0.570
Baseline MAP (mmHg)	92.38± 6.23	92.51± 6.37		0.455

*Frequency (percentage), Chi squire test used

**Mean± standard deviation, independent t-test used for analysis

***Median (IQR), Mann Withney test used

Experience of anesthesia provider and level of the block achieved

No statistically significant difference observed in the highest sensory level of anesthesia achieved, the mean highest level being achieved was between T-4 and T-6in both epinephrine and Lidocaine alone groups. Experience of anesthesia provider is also comparable between the groups(Table-2).

Table 2:-Comparison of experience of anesthesia provider between the groups for patients underwent lower abdominal surgery under spinal anesthesia at ALERT hospital,

		Epinephrine	Lidocaine alone	P value
Experience of anesthesia	BSc less than 6 month	4(18.2%)	3(13.60%)	0.170
	BSC greater than 6 month	18(81.8%)	19(86.4%)	

Values are presented as frequency (percentage), and analyzed using Chi X^2 test

$p<0.05$ considered as significant

5.1.2 Onset of sensory block

According to our data there was statistically significant difference on onset time of complete sensory block between epinephrineMean± standard deviation of 8.91±2.46 and Lidocaine14.05±4.1 with (p=0.024) and even if there may be a number of associated factor this significant difference has its own impact on incision starting time, as a result incision starting time also show this difference with a P value of 0.017.

Table 3: Comparison of Onset of sensory block and incision starting time between groups for patients who were given spinal anesthesia in ALERT hospital, Addis AbebaEthiopia,2019

Variables	Epinephrine	Lidocaine alone	P value
Onset time of complete sensory block (minutes)	8.91±2.46	14.05±4.1	0.024
Incision starting time (minutes)	24.41± 4.87	26.95±6.48	0.045

Values presented as mean± standard deviation,independent t-test used for analysis

p<0.05 considered as significant

Surgical Diagnosis

The distribution of the surgical diagnosis is analyzed using Fisher's exact test used test and it is comparable between the groups with P value of 0.134.

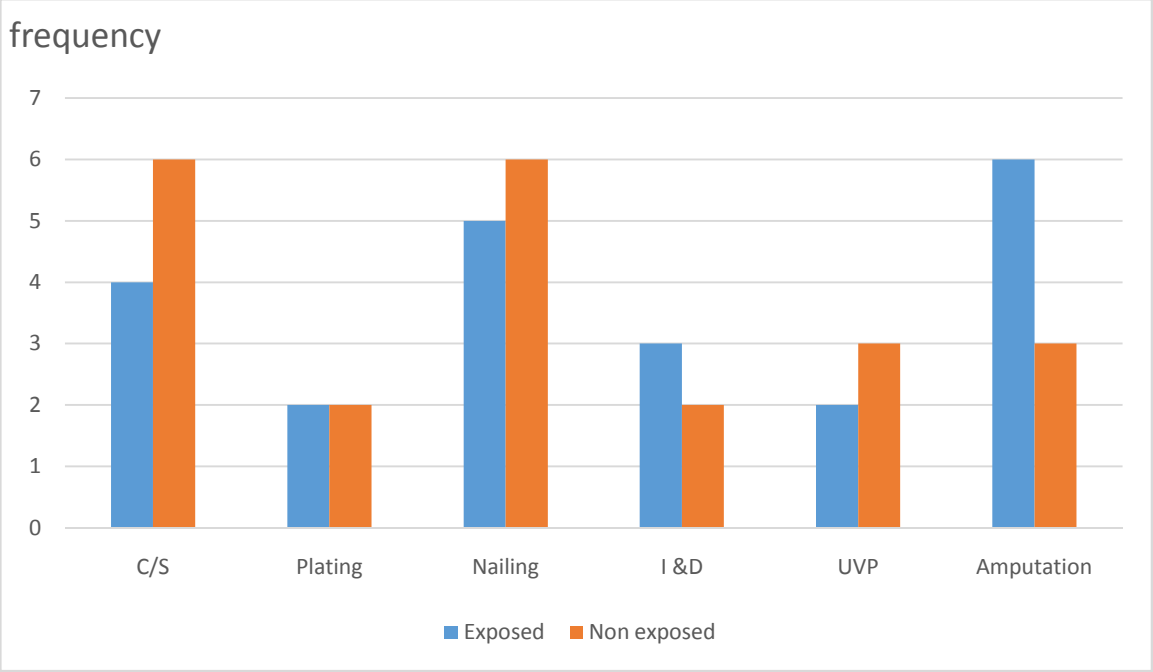

Figure 3*Comparison of frequency of surgical diagnosis between the groups in a patient undergoing lower abdominal surgery under spinal anesthesia at ALERT hospital*, Addis Abeba Ethiopia, 2019

5.1.3 Duration of sensory block

Duration of sensory block also showed a statistically significance difference,expressed as Mean± standard deviation of 158.68 ± 28.70 in epinephrine group and 149.09± 16.01 in Lidocaine alone group, Analyzed using independent t-test and get a P value of 0.01

5.1.4 Time to first analgesia request and total analgesia consumption

Time to first analgesia request

Regarding with the time of the first rescue analgesic requirement, in our study there was statistically significant difference which is 216.5 (165-245 min) and 172.6 (140-190min) in median (IQR) for epinephrine group and Lidocaine alone group respectively with a p =0.026.

Total analgesia consumption

The total analgesia consumption for tramadol with in the first 24 hour expressed as median (minimum-maximum)between epinephrine and Lidocaine alone group is 75(50- 200) and 150 (200-150) respectively with p value of 0.001

5.1.5 Early Post-operative pain score

It was found out that there was insignificant difference on severity of pain at 2 hour and 6 Hr. after incision (p 0.062& 0.075 respectively). But there is a statistical significant difference between the groups in 12 and 24 with p value of **0.022** and **0.041**

Table 4:- *Comparison of postoperative pain severity using 11 point NRS score (0-10) between the groups for a patients underwent lower abdominal surgery under spinal anesthesia at ALERT hospital, Addis Abeba Ethiopia, 2019*

	Epinephrine	**Lidocaine alone**	**p-value**
NRS in 2nd postop time	0 (0)	0 (0)	0.062
NRSin 6th postop time	2.5(2.25)	3.5(2)	0.075
NRSin 12th postop time	2.5(2)	4(2)	**0.022**
NRS in 24th postop time	3(2)	3(2.5)	**0.041**

Values are presented as Median (IQR) Mann Whitney U test used for analysis
p<0.05 considered as significant

5.2 DISCUSSION

The present study determined to assess Effectiveness of epinephrine with intrathecal Lidocaine for spinal anesthesia on onset time of sensory block and total analgesia consumption at ALERT referral hospital, Addis Abeba Ethiopiaand the result was promising both in terms of onset and duration of analgesia, which can have a positive impact on improving clinical practice and can avoid both unnecessary patient cancelation and hospital admission if practiced by all anesthesia provider in uniform manner.

Our study shows that the addition of 0.2 mg 0f epinephrine in 0.2 mg of epinephrine and 5% hyperbaric Lidocaine fasten time from injection to the highest level (onset) of sensory block with mean ±SD of 8.91±2.46 in epinephrine group than 14.05±4.1 in Lidocaine alone group with (p=0.024), there is also a significant difference in terms of incision starting time between epinephrine and Lidocaine alone group with again mean ± SD of 24.41± 4.87 and 26.95±6.48 respectively with a P value of 0.045.

The result of this study in line with study done in America(29) on 28neurologically normal ASA Class I orIIpatients between the ages of 18 and 60, undergoing lower abdominal surgeryto assess the effect of 0.3 mg of epinephrine to 5% Lidocaine in terms of onset time and duration of sensory and motor blockage.The result is onset of sensory and motor blockage was significantly shorter in patients receiving 0.3 mg of epinephrine to 5% Lidocaine and also show enhancement of post-operative analgesia, with no significance side effect.The similarity of this study wasthe block is done by 5% Lidocaine in both group

Our study also shows comparable result to a study conducted in France (21)on 80 ASA I or II patients a prospective randomized, double blind study to evaluate the effect of 0.2, 0.4 and 0.6 mg of epinephrine on 5% hyper baric Lidocaine The result is onset of sensory and motor blockage showed dose-dependent relationship with a significant prolongation at 0.6.The similarity of this study was we use similar Baricity,type and dose of local anesthesia and alsoequal milligram of epinephrine in between.

In Contrary a study conducted in Virginia Mason Medical Center Washington (27) on eight ASA I patients to evaluate the effect of the effect of 0.2mg of epinephrine to 5% Lidocaine with 7.5% dextrose and the result was the onset of sensory block were comparable between the two groups with a P value >0.05. This difference might be due to difference in dose of local anesthesia we used in our study the average doses of local anesthesia we used is 96 mg whereas in this study all patients in received the same dose of Lidocaine, regardless of their height (50 mg).

In terms of duration of sensory block, duration of sensory block after spinal anesthesia was significantly longer (158.68±28.70) in epinephrine group compared to (149.09±16.01) minutes in Lidocaine alone group (p=0.01).this scenario goes in line with astudy (22) on Thirty-six ASA I or II patients who scheduled for gynecological surgery to evaluate the effect 0.12 mg of epinephrine to local anesthetics for spinal anesthesia and the result was The addition of 0.12 mg of epinephrine to local anesthetics for spinal anesthesia prolonged the duration of analgesia (218± 51 versus 300 +/- 50 min)

A study done by momose and his colleague (26) added 0.1mg of epinephrine to Lidocaine for performing spinal block. He include total of sixty ASA I and ASA II Patients, who were scheduled for elective lower extremity surgery, randomly allocated to groups. Group A in which patients received 3ml 2% Lidocaine and group B in which patients received 3ml 2% Lidocainewith 0.1 mg of epinephrine. Their results was progression of analgesia level was significantly faster and prolongation of duration was significantly greater ($p < 0.001$) which is consistent with present study.

This result of epinephrine may not be Limited to Lidocaine , there are studies which shows the addition of epinephrine was found to have an impact on duration of sensory block even for bupivacaine. A 2017 study by Daniel Katz et al (23) to evaluate the effects of adding subarachnoid epinephrine to hyperbaric bupivacainefor repeated caesarian delivery, showed that the addition of 0.2mg of epinephrine prolong the duration of sensory block(172 ± 50 versus 120±

15 min), duration of motor block (165 ± 30 versus 120 ± 45 min) and quality of analgesia as well with a p value of <0.05(25)which is consistent with present study.

In contrary to our study a study conducted in England (24) on 40 patients scheduled for transurethral resection of the prostate to assess whether the addition of different dose of epinephrine (0.1, 0.2, or 0.3 ml of 1:1000 epinephrine) would have an impact regarding time of duration of sensory and motor blockage and the result was mean duration of motor blockage in epinephrine group is 171 ± 11 and 144 ± 0.85 in saline group and their conclusion is the addition of epinephrine produced little or no clinically useful prolongation of block. Possible explanation for this difference might be the averageage of patients in our study was 31yrs. and in this study, 64 yr. Age is approve be a main influence on the rate ofabsorption of local anesthetics used in spinal anesthesiaadditional effect of epinephrine onthe duration of Lidocaine spinal anesthesia might beminimized in the older age group.

The analgesic effectiveness of Epinephrine given at peripheral Neuraxial blockage is well explained as local vasoconstriction and allowing a greater amount of local anesthetic drug to be absorbed by the nerve fibers and by Reducing the local blood flow at which the drug leaves the nerve fibers(20), Although there is good evidence for peripheral action of epinephrine, since the absorption of local anesthetics from the subarachnoid space is a relatively slow process and the drug disappears from the subarachnoid space is by absorption directly from capillaries and in the arachnoid and pia maters is by diffusion, The mechanism of intrathecal epinephrine in prolonging the duration of nerve blocks is not completely understood and the only evidence then is the clinical observation.

Regarding with the time of the first rescue analgesic requirement, in our study there was statistically significant difference which is 216.5 (165-245 min) and 172.6 (140-190min) in median (IQR) for epinephrine group and Lidocaine alone group respectively with a (p=0.026).this result goes in line with a study by momose and his colleague (26) which show not only 0.2mg of epinephrine but also 0.1 mg of epinephrine also have a significant effect on first rescue analgesic requirement with a P value < 0.05.

In the present study, regarding Severity of post-operative pain, it was found out that there was insignificant difference on severity of pain at 2 hour and 6 Hr. after incision (p 0.062 & 0.075 respectively). The possible explained might be patients in both groups didn't recovered from spinal analgesia at 2 hour and all patients take anti- pain at immediate postop period. But a statistical significant difference is observed in pain score between the groups at 12 and 24 Hours (p 0.022 and 0.042) this result Concur a study by chiu et al and his colleague (23) shows epinephrine reduce post-operative NRS score at 4, 6 and12 hours.

In terms of the total analgesia consumption with in the first 24 hour expressed as median (minimum-maximum) between epinephrine and Lidocaine alone group is 75(50- 200) and 150 (200-150) respectively with p value of 0.001.

6. LIMITATIONS AND STRENGTHS OF THE STUDY

6.1 Limitations

- Lack of standard pain management protocol in the study hospital.
- Subjectivity of pain measurement scale

6.2 Strengths

Study participant were homogenous between epinephrine and Lidocaine alone group

Uses of probability sampling method.

Same amount of epinephrine was given to every single person.

7. CONCLUSION and RECOMMENDATION

7.1 CONCLUSION

We conclude that, the Addition of 0.2mg of Epinephrine to 5% Lidocaine solution in spinal anesthesia forlower abdominal surgeries resulted in rapid onset of sensory and motor blockade and prolongs the duration of sensory blockade and analgesic request time ,it also decrease total analgesia consumption with no significant side effects.

7.2 RECOMMENDATION

Based on the findings of the present study, the following recommendations are forwarded:-

For ALERT Hospital anesthesia staff to use 0.2mg of Epinephrine to 5% Lidocaine solution for elective lower abdominal surgeriesin a uniform manner

For Ethiopian society of anesthetists should give an update for every anesthetist's country wide on the use of addition of 0.2mg of Epinephrine to 5% Lidocaine solution for elective lower abdominal surgeries in terms of both to shorten onset of the block and prolong duration of analgesia and to decrease the total analgesia consumption.

For universities, colleges and teaching hospitals which give anesthesia trainings the addition of 0.2mg of Epinephrine to 5% Lidocaine solution is effective both to shorten onset of the block and prolong duration of analgesia with additional incentives of prolonging first analgesics request time in spinal block for elective lower abdominal surgeries and finally **for researchers** to considering this study as a baseline a further long term multicenter study.

We finally strongly recommend Randomized controlled trial studies

8. REFERENCES

1. Leland L, Raj Sabar, Alan DK: Chapter 13- Local Anesthetics: P Prithvi Raj Textbook of Regional Anesthesia. 2003 edition; p236.
2. AttariMA,,MirhosseniSA:spinal versus General anesthesia for elective lumbar spinal surgery.2011;16:524
3. James A Krukowski, David D Hood, James C Eisenach, Kathryn A Mallak and R Lamar Parker: Intrathecal Epinephrine for post cesarean section analgesia: Dose response- Anesthesia and Analgesia 1997;84; 1269-1275.
4. Bray KE, Katz S, Adriana J. The effect of vasoconstrictors upon the duration of spinal anesthesia. Anesthesiology 1949;10:40-53.
5. S.S.Perioperative pain management in ambulatory surgery. international anesthesia research society 2012;8(1):1-2.
6. Liu Spencer S, Hodgson Peter S, Moore James M, Trautman Walter J, Burkhead Daniel L: Dose response effects of spinal Epinephrine added to Bupivacaine spinal anesthesia in volunteers- Anesthesiology 1999; Mar 90(3); 710-717.
7. Chiari A, Eisenach JC: Spinal anesthesia: Mechanisms, agents, methods, and safety- Reg Anesthesia and Pain Medicine 1998; 23; 357–62.
8. Bernadette veering.focus on adjuvants in regional anesthesia. European journal of anesthesiology. 2015;19(5) :165–70.
9. Vaida CT, Moss I', Caplan LM, Tumdorf H. Prolongation ofLidocaine spinal anesthesia with phenylephrine. Anesth Analg1986;65:781-5.

10. Chambers WA, LITTLEWOOD, D. G., LOGAN, M. R. effect epinephrine on lidocaine with spinal anesthesia. AnesthAnalg. 1991;60: 417-20
11. Chiari A, Eisenach JC: Spinal anesthesia: Mechanisms, agents, methods, and safety- Reg Anesthesia and Pain Medicine 1998; 23; 357–62.
12. Vaida CT, Moss I', Caplan LM, Tumdorf H. Prolongation ofLidocaine spinal anesthesia with phenylephrine. Anesth Analg1986;65:781-5.
13. Nesioonpour S, Akhondzadeh R: The effect of preemptive analgesia with bupivacaine on postoperative pain of inguinal hernia repair. Anesth Analg,2012;10:1007–29
14. Davies JM, Posner KL, Lee LA, Cheney FW, Domino KB. Liability associated with obstetric anesthesia: a closed claims analysis. Anesthesiology. 2009; 110:131Y139.
15. Rawal N, Holmstro¨m B, Crowhurst JA, Van Zundert A. The combined spinal-epidural technique. AnesthesiolClin North Am. 2000; 18:267Y295.
16. Ruben SL, Ekmann EF: the effect of initiatingapreventive multimodal analgesia regime on long term patient outcome. Anesth Analg,2007;105:228
17. Vaida CT, Moss I', Caplan LM, Tumdorf H. Prolongation ofLidocaine spinal anesthesia with phenylephrine. Anesth Analg1986;65:781-5.
18. Million T,Eshete ,PetrraL,quality of post-operative pain management in Ethiopia,2019;14(5):2
19. Vadivelu N. Challenges of pain control and the role of the ambulatory pain specialist in the outpatient surgery setting. Journal of Pain Research 2016;9:425-9.
20. White PF. the advantages of non-opioid analgesic techniques in the management of acute and chronic pain Expert Opinion on Pharmacotherapy. 2017;18(4):329-33.
21. Merga Haile NDaLA. Practice of regional anesthesia and analgesia in Ethiopian hospital International Journal of Medicine and Medical Sciences 2015;7(7):56-8.
22. S.S.Perioperative pain management in ambulatory surgery. international anesthesia research society 2012;8(1):1-2.
23. Tewodros EW: knowledgeand attitude towards pain management among health professionals, 2014; 18; 32.
24. Chiari A, Eisenach JC: Spinal anesthesia: Mechanisms, agents, methods, and safety- Reg Anesthesia and Pain Medicine 1998; 23; 357–62.

25. OmalisM,Lauretti GR: Epidural morphine and epinephrine for post-operative analgesia after orthopedic surgery. Anesth Analog 2002; 95:1698–1701.
26. Kito K, Kato H, Shibata M, Adachi T, Nakao S, Mori K. The effect of varied doses of epinephrine on duration of lidocaine spinal anesthesia in the thoracic and lumbosacral dermatomes. AnesthAnalg. 1998; 86:1018Y1022.
27. Goyagi T, Nishikawa T. The addition of epinephrine enhances postoperative analgesia by intrathecal morphine. AnesthAnalg. 1995; 81: 508-513.
28. Daniel K, Joshua H, David G, Ryan W, Hung M, the effect of adding subarachnoid epinephrine to hyperbaric bupivacaine and morphine for repeated caesarian delivery . International anesthesia research society.2017;61:49-52.
29. Chiu AA, Spencer L,Gleen S. The effect of epinephrine on lidocaine with spinal anesthesia. AnesthAnalg. 1995; 80: 735-9.
30. Chambers WA, LITTLEWOOD, D. G., LOGAN, M. R. effect epinephrine on lidocaine with spinal anesthesia. AnesthAnalg. 1991; 60: 417-20.
31. Momose K, Masui:The effect of intrathecal Epinephrine Added spinal anesthesia with lidocaine and tetracaineKorean journal of anesthesia Med. Anesth Analg.1994;93:1560-4.
32. Spivy DL.Epinephrine does not prolong Lidocaine spinal anesthesia in term parturientsjournal of anesthesiaMed. Anesth Analg.1985;64(5):468-470.
33. Leicht CH: Prolongation of lidocaine spinal anesthesia with epinephrine phenylephrine. AnesthAnalg 1986; 4:41-46
34. Clément Tschopp, Martin R. Tramèr, Alexis Schneider, MarounZ, MD,* and Nadia Elia,. Benefit and Harm of Adding Epinephrine to a Local Anesthetic for Neuraxial and Locoregional Anesthesia: A Meta-analysis of Randomized Controlled Trials with Trial Sequential Analyses. International Anesthesia Research Society. 2018;101:109-34
35. Gregory and Richardson :the use of pain assessment tool in clinical practice 2014;3(2):140-146

Annex

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 students, senior advisor from AAU and three anesthetists for data collection from ALERT Hospital.

Name of Principal investigator: - HenokLengerew

Advisor's name: - Ms.:- Misrak W/Yohannes

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 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.

Annex II

Consent form

Hello. My name is HenokLengerew and I am working with Addis Abeba University to study the Effectiveness of epinephrine with intrathecal Lidocaine for spinal anesthesia on onset time of sensory block and total analgesia consumption at ALERT referral hospital, Addis Abeba Ethiopia 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.

We know that you have valuable insights on these issues and we want to encourage you to speak as openly and freely as you can—there are no right and wrong answers. Participation in this study is voluntary, and if we should come to any question you don't want to answer, just let me know and I will go on to the next question; or you can stop the interview at any time. However, we hope you will participate in the assessment since your views are important.

We want you to know that all the information generated from this interview is for research purposes only and it will not be used for any other purpose. All the information you volunteer will be kept confidential and no reference will be made to your name. The interview will take a

about 10minutes, and your open and candid contribution will be highly appreciated and you may withdraw your participation at any time without consequences.

Would you willing to participate in the study please? YES/NO

Thanks for taking part in the study!!!!

For further question ask investigator

Tele - +251910527750

Email - Henok.lengerew@gmail.com

Annex III

የመጠይቅፈቃድ
የተከበራችሁየጥናቱተካፋዮች

የዚህጥናትዋናአላማበፈድራልጤናጥበቃሚኒስተርስርበሚገኘውየአለርት ሆስፒታል ኦፕራሲዮን ክፍልከወገብበታችመድሀኒትወስደውቀዶ ህክምና ለሚደረግላቸዉ ህሙማን የሚሰጠዉ ማደንዘዣ ላይ መድሀኒት ከኦፕራሲዮን በኋላ ህመም በምን ያህል እንደሚቀንስ በምን ያኅል ፍጥነት ማደንዘዣ እንደሚሰራ ለማወቅ ነዉ።።

በአጋጣሚእርስዎምበዚህጥናትእንዲሳተፉተመርጠዋል።።የዚህጥናትጥቅምእርስዎበሚሰጡትምላሽመሰረትመረጃዎችንበማማላ ትበሚገኘዉዉጤትመሰረትመረጃዎችንበማጠናቀርውጤቱንእየተሰራበትካለውጋርለማገናዘብእንዲቻልነዉ።።ጥናቱበትክክልአ ላማውንእንዲመታየእርሶዎንድጋፋእንጠይቃለን።።የማንኛውምግለሰብስምአይመዘገብምእንዲሁምሀሳቡብቻውንይፋእንዲዎጣ አይደረግም።
ሙሉበሙሉበሚስጥርየተጠበቀነው።።በጥናቱመሳተፍአለመሳተፍየራስዎመብትብቻነዉ።።ግልፅየሆነምላሽንናከልብየመነጨተሳ ትፎዎንእንዲሰጡንበአክብሮትእንጠይቃለን።።ለመሳተፍፈቃደኛነዎት
ሀ/ አዎፌርማ ----------
ለ/አይደለሁም--------

ለመሳተፍፈቃደኛስለሆኑእናመሰግናለን።።

Annex III

Questionnaire

Addis Ababa university collage of Health science school of medicine department of anesthesia, Prospective observational Cohort study on Effectiveness of epinephrine with intrathecal Lidocaine for spinal anesthesia on onset time of sensory block and total analgesia consumption at ALERT referral hospital

Card no ---------- **Code ----------**

SECTION 1:- Socio-demographic data

S.No	Questions	Answer
101	Age	
102	Sex	1 Male 2 female

103	**Weight**	
104	**ASA**	**1 ASA I** **2 ASA II**

SECTION II: - PRE-OP DATA

S.No	Questions	Answer
201	Baseline HR	
202	Baseline MAP	
203	Baseline NRS	
204	Diagnosis	
205	Procedure	
206	Any sedative or Analgesic pre-medication	1 Yes 2 No

207	If Yes, what was the drug?	Type Dose Time Rout 1. Tramadol 2. Diclophenac 3. Petidine 4. Others ----------

SECTION III: -About the Anesthetist

301	Experience of anesthesia	BSc less than 6 month
		BSc greater than 6 month

SECTION IV: -Question related to spinal anesthesia block

401	Types of Local anesthetic for the block	1. 5% Lidocaine only 2. 5% Lidocaine and 0.2mg epinephrine 3. Other specify

402	Level of block	1. Up to T-10 2. Up to T-8 3. Up to T-6 4. Above T-6
403	Amount of local anesthetics	

SECTION V: - Questions related to onset of axillary block

S. No.	Parameter	Values
501	Local anesthetics injection time	
502	Onset time of sensory block	
503	Incision starting time	
504	Duration of surgery	
505	Does the patient take any sedative or analgesic intraoperative period if yes specify	

SECTION VI: - questions related to duration of block

Sno.	Questions	Answer
601	Sensory recovery time(LT)	
602	Full Recovery time of motor function(LT)	
603	First analgesia request time(LT)	

SECTION VII: -related to severity of pain in postoperative period

Severity of pain on NRStype and dose of analgesics given

2 Hrs. after operation ---------- Analgesics given _____

6 Hrs. after operation ---------- Analgesics given _____

12 Hrs. after operation ---------- Analgesics given _____

24 Hrs. after operation ----------Analgesics given _____

SECTION VIII: - Post-operative analgesics consumption

		Post-operative analgesics consumption							
		Trama dol	diclo	pethid	morphine	Paraceta	fenta	ketam	iboprof
801	Immediately at recovery								

802	2hr. after operation								
803	6 hrs. after operation								
804	12 hrs. after operation								
805	24 hrs. after operation								