EFFECTIVENESS OF PERINEURAL ADMINISTRATION OF DEXAMETHASONE WITH LIDOCAINE ON ONSET TIME OF SENSORY BLOCK AND EARLY POST-OPERATIVE ANALGESIA IN AXILLARY BRACHIAL PLEXUS BLOCK FOR ELECTIVE AMBULATORY FOREARM, WRIST AND HAND SURGERY AT ALERT HOSPITAL, ADDIS ABABA, 2018, PROSPECTIVE OBSERVATIONAL STUDY.

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

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College of health sciences
School of medicine department of anesthesia

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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. ________________________________  ____________________
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Abstract

Introduction The axillary brachial plexus block is a popular nerve block for forearm, wrist and hand surgery. Different adjuvant used widely to prolong the duration and fasten the onset of analgesia. Recent evidence demonstrates a potential role of dexamethasone in postoperative pain management, both as a systemic analgesic and as an adjunct to local anesthetics for perineural use.

Objective To assess the effectiveness of perineural administration of dexamethasone on lidocaine with adrenaline on onset of sensory block and early post-operative analgesia for trans-arterial axillary block for ambulatory elective forearm, wrist and hand surgery in ALERT hospital.

Methodology This prospective cohort study recruits 72 American Society of Anesthesiologist (ASA) class I and II and age between 18-60 years patients by systematic random sampling method. Categorical variable between two groups were analyzed using Chi Square. Distribution numerical data analyzed using Shapiro Wilk test. Mann Whitney U test were used to compare asymmetric numeric data including onset time of sensory block and post-operative pain score. Independent t-test were used to compare mean values of symmetric numeric data including duration of sensory block. Additionally first analgesics request time were analyzed by Kaplan Meier method using log rank test. And p value of <0.05 considered as significant.

Results The median onset time of sensory block were comparable between non-exposed group 24(6) and exposed group 24(6) (p=0.068). However, the duration of sensory block significantly longer in exposed group 235.5 ± 37 .51 min than non-exposed group 172.76 ± 28.19 min (p<0.001). The survival time to fist analgesic request were significantly longer in exposed than non-exposed group (p<0.01). Post-operative pain score were significantly lower at 4 and 8 hours in exposed group (p<0.05).

Conclusion and recommendations Addition of 8 mg dexamethasone to 1% lidocaine with adrenaline solution in trans-arterial axillary brachial plexus block for ambulatory elective hand, wrist and forearm surgeries prolongs the duration of sensory blockade and analgesic request time but do not reduce the onset of time sensory block. We recommend addition of dexamethasone to 1% lidocaine with adrenaline solution is effective for prolonging duration of sensory block and first analgesics request time.
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<tr>
<td>ALERT</td>
<td>Africa LEprosy Rehabilitation and Training</td>
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<td>ASA</td>
<td>American Society of Anesthesiologist</td>
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<tr>
<td>BPB</td>
<td>Brachial Plexus Block</td>
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<tr>
<td>B.SC.</td>
<td>Bachelor of Science</td>
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<td>C</td>
<td>Cervical vertebrae</td>
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<tr>
<td>DBP</td>
<td>Diastolic Blood Pressure</td>
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<td>ICBN</td>
<td>Inter Costo Brachial Nerve</td>
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<td>Mg</td>
<td>Milligram</td>
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<td>MN</td>
<td>Median Nerve</td>
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<td>MCN</td>
<td>Musculo Cutaneous Nerve</td>
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<td>MCNA</td>
<td>Median Cutaneous Nerve of the Arm</td>
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<td>MCNF</td>
<td>Median Cutaneous Nerve of Forearm</td>
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<tr>
<td>M.Sc.</td>
<td>Masters of Science</td>
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<tr>
<td>NRS</td>
<td>Numeric Rating Scale</td>
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<tr>
<td>NSAID</td>
<td>Non-Steroidal Anti-Inflammatory Drugs</td>
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<tr>
<td>RN</td>
<td>Radial Nerve</td>
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<tr>
<td>SPHMMC</td>
<td>St. Paul’s Hospital Millennium Medical College</td>
</tr>
<tr>
<td>SBP</td>
<td>Systolic Blood Pressure</td>
</tr>
<tr>
<td>T</td>
<td>Thoracic vertebrae</td>
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<tr>
<td>USA</td>
<td>United States of America</td>
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1. INTRODUCTION

1.1 Background Information

Hand Surgery is a broad term which encompasses the multidisciplinary management of conditions of the hand. It is a specialty that employs combined skills from the overlapping specialties of Orthopedics Surgery, Plastic Surgery and Emergency Medicine.

Regional anesthesia is an excellent adjunct or alternative to general anesthesia for hand and wrist surgery. It provides superior postoperative analgesia and hastens recovery from anesthesia(1). Surgery for the upper extremity, from the shoulder to the hand, can be performed successfully by blocking the brachial plexus at several points until it branches into peripheral nerves(2).

The brachial plexus innervates the upper limb. It originates from the anterior rami of the lower four cervical and first thoracic spinal nerve roots (C5-8, T1). The five roots emerge from the intervertebral foramina to form the superior (C5-6), middle (C7) and inferior (C8-T1) trunks. The trunks enter the floor of the posterior triangle of the neck between scalenus anterior and scalenus medius muscles. They are covered by an extension of the paravertebral fascia, known as the axillary sheath. The trunks divide into anterior and posterior divisions behind the clavicle. Passing over the outer border of the first rib the divisions combine to form three cords, which are named according to their relation to the axillary artery – lateral, medial and posterior. The posterior divisions form the posterior cord, and the anterior divisions form the lateral and medial cords which supply the flexor aspects of the forearm. The cords divide at the level of the lateral border of pectoralis minor, giving rise to the terminal branches named musculocutaneous, median, ulnar, radial, axillary, medial cutaneous nerve of arm (MCNA), and medial cutaneous nerve of forearm (MCNF), which along with the intercostobrachial nerve (ICB) provide the sensory and motor supply to the whole upper extremity. It is a level that the axillary brachial plexus block is performed (2-5).

Local anesthetic may be deposited at any point along the brachial plexus, depending on the desired block effects; there are four common approaches to the brachial plexus block. These
includes interscalene for shoulder and proximal humorous surgical procedures, supraclavicular for entire humorous and elbow, infraclavicular for distal humorous and elbow, and axillary for surgeries distal to elbow(2, 6).

The axillary brachial plexus block is a popular nerve block for forearm, wrist and hand surgery(7). It is useful as both sole anesthesia and/or a supplement to general anesthesia and provide effective postoperative analgesia, reducing the need for opioid analgesics by using long-acting local anesthetics or adjuvant(4, 5).

Axillary approach to brachial plexus blockade has the advantage of being performed away from the pleura and neuraxial structures, so it is ideal of obtaining block with a minimum of discomfort, complications and side effects(8).

There are few contraindications to axillary brachial plexus blocks. Local infection, neuropathy, and bleeding risk must be considered(9). Nerve stimulation, ultrasound, paresthesia or trans-arterial technique may be used to perform axillary brachial plexus block based on availability of resource, skill and the preference of anesthesia provider(6).

Trans-arterial technique is widely accepted technique in resource limited countries like Ethiopia. It is relatively easy to perform, do not require sophisticated and expensive material like nerve stimulator and ultrasound(9). But trans-arterial technique is associated with higher incidence of systemic toxicity and it has lower success rate (paresthesia 95%, nerve stimulator 88%, trans-arterial 81% with p value of (0.047) than other techniques(10).

Tran-arterial technique can be performed by palpating and immobilizing axillary artery by non-dominant hand index and middle finger at the level of insertion of pectoral minor muscle after abducting and flexing the arm right angle at the elbow. Then patient rotate the head to non-operated side and we will insert 22 gage needle through the artery until bright red blood is aspirated. The needle is then slightly advanced until blood aspiration ceases. Injection can be performed posteriorly, anteriorly, or in both locations in relation to the artery and 0.5-0.7ml/kg local anesthetics should be given for sole anesthesia (3, 5, 9).
Different adjuvant used widely to prolong the duration and fasten the onset and increase the quality of analgesia.

Corticosteroids are used clinically for their anti-inflammatory, antiemetic, antipyretic antiallergic effect, and they have been shown to inhibit the release of inflammatory mediators such as, interleukins and cytokines, facilitating the release of anti-inflammatory mediators, decreasing postoperative pain(11).

Dexamethasone is a high-potency, long-acting glucocorticoid with little mineralocorticoid effect that has been used for prophylaxis of post-operative nausea. Single doses of dexamethasone have also been reported to improve analgesia after various operations, whether by Oral, intravenous (I.V.) or perineural route(12).

The mechanism of dexamethasone in prolonging the duration of nerve blocks is not completely understood and is thought to arise from various factors. Possible explanations may be related to a degree of vasoconstriction which results in the absorption of local anesthetics, suppression of the synthesis and secretion of inflammatory mediators(13), reducing the transmission in unmyelinated C-fiber(11). Recent evidence demonstrates a potential role of dexamethasone in postoperative pain management, both as a systemic analgesic and as an adjunct to local anesthetics for perineural use.
1.2 Statement of the problem

Pain is a critical component of patient management that often not only consists of physical disability but also necessitates care to address the psychological, emotional, and economic strain on patients and their caretakers. It places a significant economic strain on society in the form of disability, loss in productivity, and health care costs (14, 15).

The prevalence of hand pathology requiring orthopedic or plastic and reconstructive surgery in Great Britain is raised by 34% over a decade. Commonest indication for hand and wrist surgery is carpal tunnel syndrome (112 per 100,000 per year), followed by wrist ganglion cyst (55 per 100,000), dequervan’s (36 per 100,000 per year), osteoarthritis (34 per 100,000), dupuytrens disease (33 per 100,000), trigger finger or thumb (28 per 100,000), swellings (24 per 100,000 per), rheumatoid arteritis (8 per 100,000) and congenital malformation of hand (6 per 100,000) (16).

A review of referral of emergency surgical patient in St. Paul’s hospital millennium medical college (SPHMMC) showed that orthopedic referrals made the most common conditions referred, 54.5% of all trauma referrals and 42.3% of all the referrals. Among orthopedics patients, fractures accounted 92.0% of the referrals. Upper limb (24.1%) being the 2nd commonest site of fracture after lower limb fracture (70.3%). Radio ulnar fractures among upper limb fractures was the most common conditions referred accounting 50% and hand bone fractures account for 11.9% of referral. Other common upper limb condition for referral were fracture dislocation (3.1%), soft tissue injuries (1.9%), ligament or tendon injury (1.2%), post traumatic gangrene (1.2%), traumatic amputations (0.6%) (17).
Currently, ambulatory surgery constitutes more than 60% of all surgery performed in the USA (18). Orthopedics surgery is increasingly being performed in an ambulatory setting, and currently makes up 38% of all outpatient procedures in France. Furthermore, there is an increasing trend towards performing more extensive and potentially more painful surgical procedures on an ambulatory basis. However, one of the most important factors limiting the growth of ambulatory surgery is our ability to provide adequate postoperative pain relief. Uncontrolled pain is associated with increased incidence of nausea, anxiety and delirium, prolonged post anesthesia care unit stay, delayed discharge from ambulatory facility, and delayed resumption of normal activities (18). Postoperative pain is a common reason for unanticipated hospital admission after outpatient surgery (19). Importantly, postoperative patient satisfaction has been shown to be related to the level of pain intensity (14). Patient satisfaction is a major determinant of the success of ambulatory surgery and is among the most important outcomes that can be influenced by adequate pain management.

The management of pain after ambulatory surgery poses unique challenges because of the need to balance pain relief with concerns of side effects and safety.

Opioid analgesia is not appropriate option for post-operative pain in ambulatory case which is related with nausea, vomiting, respiratory depression, hypotension, constipation and urinary retention. Effective analgesia in ambulatory cases should be achieved with medications causing less nausea and/or with utilization of regional anesthesia techniques in conjunction with non-opioid therapies (20).

NSAIDs, especially in multiple doses, are highly useful analgesic adjuncts. They consistently reduce pain scores, reduce opioid use and opioid related side effects. However, prolonged use of NSAIDs is associated with cardiovascular risk, renal impairment, and increased bleeding for some surgical procedures (21).

Dexmedetomidine is widely used adjuvant for brachial plexus block. But its safety profile is questioned due to its effects on hemodynamic status. Dexmedetomidine can cause side effects such as bradycardia and hypotension with an increased dose (22).
Another alternative for prolonging analgesia in axillary block is the use of catheter for continuous regional anesthesia. But this technique failed to get popularity in outpatient setting due to higher incidence of catheter migration, anesthetic leakage, pump malfunction, the utilization of health care personal(23). The catheter used for continuous regional anesthesia is also not easily accessible in our country.

Prolonged latency following trans-arterial Axillary brachial plexus block presents a potential problem in the busy clinical setting. 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 surgeons(24). Efforts to improve onset time have centered on the choice and modification of local anesthetic solutions.

Alkalization of local anesthetics solution with sodium bicarbonate is well known technique used for fastening of the onset of sensory block in regional anesthesia. But some studies debate on its effectiveness on fastening of onset time(24).

1.3 Literature review

Vieira PA et al,(2010) performed a prospective, randomized, double-blind investigation on 88 individuals undergoing shoulder arthroscopy. Patients received interscalene brachial plexus block using 20 ml of bupivacaine 5 mg /ml with 1: 200,000 epinephrine and clonidine 75 microgram. Patients were randomly assigned to receive either dexamethasone 8 mg or 0.9% NaCl as an adjuvant to the mixture. They concluded that the addition of dexamethasone to a bupivacaine-epinephrine-clonidine interscalene block prolongs sensory block and reduces opioid use(13).

Biradar PA et al, (2013) showed that addition of 8 mg of dexamethasone to 1.5% lidocaine with adrenaline 1:200,000 for supraclavicular brachial plexus block results in a significantly shorter
onset time and a significantly prolonged duration of sensory and motor block. The VAS scores and motor block scores as assessed by Lovett rating scale were not significantly different between groups at 20 min probably because once complete block was established, there was no difference in the intensity of block. The study showed that dexamethasone also shortens the onset time of sensory and motor block, which is in contrast to the previous studies in which there was no difference in the onset of sensory and motor block among groups(25).

Prospective, randomized controlled trial study conducted by Lee et al, 2016 in Korea, compare 2 ml of 100µg dexmedetomidin and 2ml of 10mg dexamethasone with placebo 2 ml normal saline on 51 patients and he conclude that Dexamethasone 10 mg and dexmedetomidin 100µg were equally effective in extending the duration of ropivacaine in ultrasound-guided axillary BPB with nerve stimulation. However, neither drug has significantly effects the onset time(22).

Movafegh A et al, (2006) performed a prospective, randomized, double-blind study to evaluate the effect of dexamethasone added to lidocaine on the onset and duration of axillary brachial plexus block. Sixty patients were randomly allocated to receive either 34 mL lidocaine 1.5% with 2 mL of isotonic saline chloride (control group, n = 30) or 34 mL lidocaine 1.5% with 2 mL of dexamethasone (8 mg) (dexamethasone group, n = 30). The duration of surgery and the onset times of sensory and motor block were similar in the two groups. The duration of sensory (242 +/- 76 versus 98 +/- 33 min) and motor (310 +/- 81 versus 130 +/- 31 min) blockade were significantly longer in the dexamethasone than in the control group (P < 0.01). It was concluded that the addition of dexamethasone to lidocaine 1.5% solution in axillary brachial plexus block prolongs the duration of sensory and motor blockade but has no effect on onset of action. They concluded that further studies were needed to evaluate the optimal dose of dexamethasone to be used for prolonged brachial plexus block as well as the mechanism of this effect(26).

Dawood M. et al evaluate the effect of dexamethasone added to lidocaine on the onset and duration of axillary brachial plexus block by Randomized controlled trial in 2015. He include total of 100 patients, who were scheduled for elective hand and forearm surgery under axillary brachial plexus block, were randomly allocated to group A in which patients received 40 ml 1.5% lidocaine with 2 ml of isotonic saline (0.9%) and group B in which patients received 40 ml 1.5% lidocaine
with 2 ml of dexamethasone (8 mg). After the injection onset of action and duration of sensory blockade of brachial plexus were recorded at 5 minutes and 15 minutes interval. Onset of action was 21.64 ± 2.30 min placebo (A) group and 15.42 ± 1.44 min in dexamethasone (B) group (p<0.001). Duration of nerve block was 115.08 ± 10.92 min in group A and 265.42 ± 16.56 min in group B (p < 0.001). Finally they conclude that addition of dexamethasone to 1.5% lignocaine solution in axillary brachial plexus block prolongs the duration of sensory blockade significantly(27).

In prospective, randomized, placebo-controlled study by Baloda R et al in India, 2016, showed that addition of 8mg of dexamethasone to 0.5% isobaric levobupivacaine effectively and safely shortens the onset of sensory and motor blockade, increases the duration of sensory and motor blockade and increases the duration of postoperative analgesia without any haemodynamic disturbances. There was no statistically significant difference in heart rate, systolic and diastolic blood pressure on addition of dexamethasone to 0.5%levobupivacaine.
1.4 Significance of the study

Faster onset time of analgesia to provide condition suitable for surgery is what is desired in the daily running of operating theatre list and in optimizing efficient usage of theatre time. Axillary block is the second most commonly performed regional anesthesia technique after spinal anesthesia in Ethiopia (1). But most of the orthopedics and plastic surgeon do not prefer axillary block especially in busy setup due to its longer onset time. Providing adjuvant which can reduce onset time of sensory block can enhance operating room team spirit and reducing unnecessary patient’s cancellation. Minimizing cancellation reduce economic burden on patients, hospital and country for health care cost.

Managing post-operative pain in ambulatory orthopedics surgery can avoid unnecessary hospital admissions, facilitate early recovery, reduce hospital stay time and also it increase patient satisfaction. Our study focus on post-operative analgesics effect of perineural dexamethasone in ambulatory surgery. Because of dexamethasone is easily available in our country and administering dexamethasone as adjuvant with local anesthetics not only reduce post-operative pain but it can also reduce the incidence of nausea and vomiting so that it may increase patient satisfaction. Using dexamethasone as adjuvant we can prevent the side effects of opioid like nausea, vomiting, hypotension, respiratory depression and urinary retention.

Many studies have been performed to compare quality of anesthesia and postoperative analgesic effect of perineural dexamethasone for axillary block. Most of these studies have been conducted in the developed world and in western populations with different approach of axillary block. The presence of racial, cultural, genetic and socio demographic difference in the perception of pain has been well documented(14). Due to the increasing usage of regional anesthesia for ambulatory surgery, conducting this type of research can which facilitate shorter onset time and longer duration of analgesia for axillary block contributes for quality of ambulatory anesthesia. There is also controversy regarding the effectiveness of dexamethasone on onset time of sensory block. This research can be used as an input for future researchers related to perineural administration of dexamethasone for peripheral nerve block.
2. Objective of the study

2.1 General objective
To assess the effectiveness of perineural administration of 8 mg dexamethasone on 1% lidocaine with adrenaline on onset time of sensory block and early post-operative analgesia for trans-arterial axillary brachial plexus block for ambulatory elective forearm, wrist and hand surgery in ALERT hospital, Addis Ababa, Ethiopia from January 1, 2018 to May 1, 2018.

2.2 Specific objectives:
- To compare onset time of the sensory block between exposed and non-exposed groups
- To compare the duration of sensory block between exposed and non-exposed groups
- To compare the time to first analgesia request between the exposed and non-exposed groups
- To compare severity of early post-operative pain between exposed and non-exposed groups in first 8 hours after incision.
3. METHODOLOGY

3.1 Study area

This study was conducted in ALERT hospital which is located in Addis Ababa, capital city of Ethiopia. ALERT is one of those government owned hospital which is primarily established for leprosy and tuberculosis rehabilitation and training. The acronyms of ALERT stand for All Africa leprosy rehabilitation and training. Currently it is a 240 bed hospital which provide dermatology, ophthalmology, general surgery, obstetrics and orthopedics service. ALERT hospital has five major operating room and two of them is used for orthopedics and trauma cases and one is used for plastic and reconstructive surgeries.

3.2 Study design and period

➢ An Institutional based prospective observational cohort study was conducted from January 1 to June 1, 2018.

3.3 Source population

➢ All patient who underwent ambulatory elective forearm, wrist and hand surgery under trans-arterial axillary brachial plexus block at ALERT hospital.

3.4 Study population

➢ All patients who underwent ambulatory elective forearm, wrist and hand surgery under trans-arterial axillary brachial plexus block within study period at ALERT hospital.

3.5 Study variables

3.5.1 Dependent variables

- The onset time of sensory block
- Duration of sensory block,
- First analgesia request time
- The severity of pain in 6 hours post-operative period.
3.5.2 Independent variable

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

3.6 Inclusion and exclusion criteria

3.6.1 Inclusion criteria

- ASA I and ASA II patients scheduled for elective ambulatory forearm, wrist and hand surgery under tans-arterial axillary brachial plexus block.

3.6.2 Exclusion criteria

- Age less than 18 and greater than 60
- Duration of surgery less than half hour, greater than two hour
- BMI > 35 kg/m²
- Chronic opioid use
- Failed axillary block
- Uses of local anesthetics other than 1 % lidocaine with adrenaline
- Uses of other adjuvant
- Patient who take sedative or analgesics premedication within 24 hrs. preoperatively
- Bleeding abnormality
- Known allergy to local anesthetics
- History of diabetics mellitus
- History of peptic ulcer
- Septic patients
- Peripheral neuropathy or nerve injuries
3.7 Operational definitions

Exposed group - patients who were given 8 mg dexamethasone and 1% lidocaine with adrenaline

Non exposed – patients who were given 1% lidocaine with adrenaline only

Time for first analgesia request: the time from perineural injection to first request for analgesia(28).

Ambulatory surgery - surgery which do not require an overnight stay

Onset of sensory block: time from administration of local anesthetics with/without dexamethasone to complete analgesia to pinprick on areas of upper extremity innervated by all five nerves (radial, musculocutaneous, median, ulnar, medial cutaneous nerve of forearm) of brachial plexus(27).

Onset of motor block: time from administration of local anesthetics with/without dexamethasone to loss of gripping force

The duration of sensory considered as the time interval between the administration of the local anesthetic and the first postoperative pain(26).

The duration motor block is defined as the time interval between the local anesthetic administration and complete recovery of motor functions.

Incision time - a time from last injection of local anesthetics to beginning of surgical incision

Failed axillary block - patient feel pain to pinprick stimulation at incision time at area of upper extremity to be tested or require isolated nerve block during or before surgery(6).
NRS: is a valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0-10 (11 point scale) with the understanding that 0 is equal to no pain and 10 equal to the worst possible pain(29).

Figure 1: NRS pain intensity assessment tool

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

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

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

Event: analgesia request

Censored: patients who lost from the follow up or if the patient not requesting analgesia during the follow up period

3.8 Sample Size and Sampling technique

3.8.1 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 in Iran(26) 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±5 minutes in control group and 11±4 minutes in dexamethasone group.
\[ n = \left( s_1^2 + s_2^2 \right) f (\alpha, \beta) / (m_1 - m_2)^2 \]

Where \( n \) = the sample size in each of the groups

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

\[ n = (5^2 + 4^2) \times 7.84 = 36 \]
\[ (14-11)^2 \]

So that the sample size is 36 for each group

3.8.2 Sampling Technique

Systematic random sampling method used for data collection. There was 110 ambulatory hand, wrist and forearm surgeries estimated to be performed during study period (within 4 and \( \frac{1}{2} \) months) and 72 participants were recruited with the probability of about 65% (2/3). By considering the order of patients based on schedule number for each group, 2 patients were selected from the first 3 patients by lottery method for both group, similar pattern and interval followed for the next every three consecutive patients scheduled for elective ambulatory forearm, wrist and hand surgery till the sample size filled.
3.9 Anesthesia management of ambulatory hand, wrist and forearm surgery in ALERT Hospital

Hand, wrist and forearm surgeries in the study area are usually performed as an outpatient every Friday. Axillary brachial plexus block is widely used anesthesia technique for ambulatory (outpatient) hand, wrist and forearm surgery. Anesthesia management for upper limb surgery includes preoperative evaluation to identify coexist diseases, assigning ASA status of patients. Patient also assessed whether they are fit for axillary block or not. Those patient who have contra-indication to axillary 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 axillary block, they will proceed with general anesthesia.

Axillary block is provided by B.Sc. and M.Sc. anesthesia professionals and all of blocks are performed by Trans-arterial technique. Usually preferred local anesthetics for ambulatory surgery is 1% lidocaine with adrenaline. But there is variability between anesthetists in adding dexamethasone to axillary block. While some of the anesthetist add dexamethasone to prolong the
duration of sensory block and fasten the onset, the others will not and our study uses theses variance as means to select as those exposed vs. non-exposed. Dose of local of local anesthetics to be given determine by weight of patient. 0.5 -0.7 ml/kg of 1% lidocaine with adrenaline is used and half of the volume administered posterior to axillary artery the rest half is administered anterior to axillary artery using 22 gage needle, additional 5 ml of lidocaine will be administered for musculocutaneous nerve block between coracobrachealis and biceps muscle at upper one-third of humorous, another 5 ml of lidocaine subcutaneously infiltrated circularly starting from insertion of deltoid muscle through medial aspect of arm to triceps muscle, to prevent tourniquet pain. Small tourniquet (glove) will be applied for all patient at the beginning of axillary block to reduce the distribution of local anesthetics to distal part of the arm.

After completion of surgery patient wait in recovery/ waiting room for six hours for follow up by anesthetist post operatively. The only analgesics drug used in post-operative period is diclophenac and all of patient who request analgesia will be given 75 mg diclophenac intramuscularly.

3.10 Data collection methods

After providing training for data collectors, data was collected using pretested questionnaires. All patient selected for the study was 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 of each nerve was assessed every 3 minutes by pinprick stimulation on corresponding cutaneous innervation of the musculoculocutaneous nerve (lateral part of forearm), medial nerve (palmar side of index finger), ulnar nerve (palmar side of little finger), radial nerve (dorsum of thumb), MCN of forearm (median part of forearm) and compared with the same stimulation on the contra-lateral hand on all of branch of brachial plexus. Duration of sensory block was assessed every 20 minutes by B.Sc. anesthetist who are not performed the block. First analgesia request time were also filled from the chart and document the time, doses and the roots of analgesics. Severity of pain in NRS assessed at 2, 4, 6 and 8 hours after incision staring time by ward nurse.
3.11 Data quality control

To assure the reliability and validity of the data, structured questionnaire was pretested on 5% of the sample size before actual data collected. Training and orientation about the objectives and relevance of the study, each items included in the study tools and the whole process of data collection was provided for data collectors and supervisors. Data quality control included in the study tools and the whole process of data collection was provided for data collectors and supervisors. During data collection, regular supervision and follow up was undertaken. Supervisors was check each questionnaire daily with further cross check by principal investigator for completeness and consistency of data.

3.12 Data analysis and interpretation

Data were cleaned, entered, coded and analyzed by SPSS version 20. Shapiro Wilk test were used to test for distributions of data and presented in terms of mean ± SD for symmetric data like age, weight, height, BMI, baseline heart rate, baseline systolic blood pressure, incision time, duration of surgery, duration of sensory block and median (Interquartile range) for asymmetric numeric data like baseline diastolic blood pressure, baseline NRS, volume of local anesthetics, onset of sensory block, post-operative NRS, first analgesics request time. Homogeneity of variance were 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 skewed numerical data. First analgesics request was analyzed by Kaplan-Meier survival analysis with log-rank test. Frequency and percentage were used to describe categorical variable (sex, ASA, diagnosis, experience, nausea) and statistical difference between groups were tested using Chi square and fisher exact test as they needed. A p value <0.05 considered statistically significant.
3.13 Ethical consideration

Ethical clearance was obtained from the university ethical clearance committee before the start of the study. The purposes and 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.

3.14 Dissemination Plan

The copies of final results will be disseminated to college of health science and medicine, Hospitals and health centers in Addis Ababa, Addis Ababa Health Bureau and Federal Ministry of Health. After presentation on workshops and seminars, it will be published in local, national and international journals and magazines.
4. RESULT

Eighty three patient assessed for eligibility criteria and 11 patient excluded because of not meeting inclusion criteria (figure-1). Out of 72 patients who was initially included in the study, four patients were lost from follow up during the study. No statistically significant differences were found between the groups with respect to age, BMI, gender, ASA status, baseline numeric rating scale, volume of local anesthetics given, and duration of surgery (Table-1).

Table 1: Demographic and perioperative characteristics of patients underwent ambulatory elective hand, wrist and forearm surgery under axillary block at ALERT hospital

<table>
<thead>
<tr>
<th>Variables</th>
<th>Non-exposed group (n=34)</th>
<th>Exposed (n=34)</th>
<th>Total</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender***</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>23 (48.9%)</td>
<td>24 (51.1%)</td>
<td>47 (100%)</td>
<td>0.793</td>
</tr>
<tr>
<td>Female</td>
<td>11 (52.4%)</td>
<td>10 (47.6%)</td>
<td>21 (100%)</td>
<td></td>
</tr>
<tr>
<td>Age*</td>
<td>33.44± 11.01</td>
<td>34.29± 8.15</td>
<td></td>
<td>0.718</td>
</tr>
<tr>
<td>ASA status***</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA I</td>
<td>25 (47.2%)</td>
<td>28 (52.8%)</td>
<td>53 (100%)</td>
<td>0.384</td>
</tr>
<tr>
<td>ASA II</td>
<td>9 (60%)</td>
<td>6 (40%)</td>
<td>15 (100%)</td>
<td></td>
</tr>
<tr>
<td>BMI*</td>
<td>22.01±2.47</td>
<td>22.62± 1.73</td>
<td></td>
<td>0.244</td>
</tr>
<tr>
<td>Baseline Heart Rate (bpm)*</td>
<td>72.56± 4.59</td>
<td>74.35± 5.08</td>
<td></td>
<td>0.132</td>
</tr>
<tr>
<td>Baseline SBP (mmHg)*</td>
<td>124.79± 9.48</td>
<td>121.91± 8.02</td>
<td></td>
<td>0.181</td>
</tr>
<tr>
<td>Baseline DBP (mmHg)**</td>
<td>80(14)</td>
<td>75.5(10)</td>
<td></td>
<td>0.144</td>
</tr>
<tr>
<td>Baseline NRS**</td>
<td>1(2)</td>
<td>1(2)</td>
<td></td>
<td>0.267</td>
</tr>
<tr>
<td>Volume of local anesthetics (ml)**</td>
<td>40(5)</td>
<td>35(5)</td>
<td></td>
<td>0.267</td>
</tr>
<tr>
<td>Duration of surgery (minutes)*</td>
<td>83.62± 16.97</td>
<td>86.29± 12.90</td>
<td></td>
<td>0.467</td>
</tr>
</tbody>
</table>

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

** Median (IQR), Mann Withney test used

*** Frequency (percentage), Chi squire test used
The distribution of the surgical diagnosis is comparable between the groups (p=0.66) (table-2).

**Table 2: Comparison of surgical diagnosis and experience of anesthesia provider between the groups for patients underwent ambulatory hand, wrist and forearm surgery under axillary block at ALERT hospital, 2018**

<table>
<thead>
<tr>
<th>Surgical diagnosis</th>
<th>Non-exposed</th>
<th>Exposed</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extensor tendon injuries</td>
<td>4 (57.1%)</td>
<td>3 (42.9%)</td>
<td>0.66 *</td>
</tr>
<tr>
<td>Flexor tendon injuries</td>
<td>3 (42.9%)</td>
<td>4 (57.1%)</td>
<td></td>
</tr>
<tr>
<td>Carpal tunnel syndrome</td>
<td>4 (50%)</td>
<td>4 (50%)</td>
<td></td>
</tr>
<tr>
<td>Dupuytren contracture</td>
<td>4 (80%)</td>
<td>1 (20%)</td>
<td></td>
</tr>
<tr>
<td>Malignancy</td>
<td>0 (0%)</td>
<td>3 (100%)</td>
<td></td>
</tr>
<tr>
<td>Post burn contracture</td>
<td>9 (56.2%)</td>
<td>7 (43.2%)</td>
<td></td>
</tr>
<tr>
<td>Fracture</td>
<td>4 (44.4%)</td>
<td>5 (55.6%)</td>
<td></td>
</tr>
<tr>
<td>Arthrodesis</td>
<td>6 (46.2%)</td>
<td>7 (53.2%)</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>36 (50%)</td>
<td>36 (50%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Experience of anesthesia provider</th>
<th>Non-exposed</th>
<th>Exposed</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSc less than 1 year</td>
<td>13 (61.9%)</td>
<td>8 (38.1%)</td>
<td>0.185 * *</td>
</tr>
<tr>
<td>BSC greater than 1 year</td>
<td>17 (47.2%)</td>
<td>19 (52.8%)</td>
<td></td>
</tr>
<tr>
<td>MSc</td>
<td>4 (36.4%)</td>
<td>7 (63.6%)</td>
<td></td>
</tr>
</tbody>
</table>

Values are presented as frequency (percentage),

*Fisher’s exact test used       * *Chi X² test used

**Onset time of sensory block**
There was statically insignificant difference on onset time of complete sensory block between exposed group median (IQR) of 24 (6) and non-exposed group 24(6) with (p=0.068).

*Table 3: Comparison of Onset time of sensory block and incision starting time between groups for ambulatory patients who were given axillary block in ALERT hospital, 2018*

<table>
<thead>
<tr>
<th>Variables</th>
<th>Non-exposed group</th>
<th>Exposed group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset time of complete* sensory block (minutes)</td>
<td>24(6)</td>
<td>24(6)</td>
<td>0.068</td>
</tr>
<tr>
<td>Incision starting time ** (minutes)**</td>
<td>33.56±4.12</td>
<td>32.22±4.23</td>
<td>0.203</td>
</tr>
</tbody>
</table>

*Values are presented as Median (IQR) Mann Whitney U test used for analysis

**Values presented as mean± standard deviation (independent t-test used for analysis)

p<0.05 considered as significant.
The onset time of sensory block for four major branches of brachial plexus (ulnar, radial, musculocutaneous and medial) analyzed by many Whitney test and there was no significant different observed between the groups. Figure 3 shows the median time to onset of analgesia in each of the terminal nerves of the brachial plexus.

Figure 3: Comparison of median onset time of analgesia (in minutes) for all nerves of axillary block in a patients underwent ambulatory hand, wrist and forearm surgery at ALERT hospital, 2018
Duration of sensory block

The duration of sensory blockade were significantly longer in the exposed group than non-exposed group. We used independent sample t-test for analysis of the duration of sensory block and the mean duration of sensory block in non-exposed group was 172.76 ± 28.19 min while in exposed group it was 235.5 ± 37.51 min with p < 0.001. Figure 4 show that cumulative frequency distribution patient recovered from analgesia at a given time. We used Fisher exact test for at 130 min and Chi square test for at 172, 214, 256 and 298 minutes and it showed that there is a significant difference between the groups on cumulative frequency of patient recovered from analgesia at 172, 214 and 256 minutes.

Figure 4: Comparison of cumulative frequency of patients recovered from analgesia at a given time between the groups, 2018

* Indicate p < 0.05,
Time to first analgesia request

Kaplan–Meier curves for the first analgesic request used, first analgesics request considered as an event and patients not receiving any analgesics 7 hours after local anesthetics injection and lost from follow up are censored to the right as presented in Figure 4. Significant differences between these curves (log-rank test) were obtained between exposed and non-exposed groups (P<0.001). At 150 min 12% of patient in non-exposed group and 3% of patients in exposed group, at 200 minutes 70% of patients in non-exposed group and 15 % patients in exposed group and at 250 minutes and at 250 minutes 97% of patient in non-exposed group and 59% in exposed group request first analgesia. The median (IQR) time to first anesthesia request was 210 (185 to 230) minutes in non-exposed group and 270 (240 to 330) minutes in exposed group.

Figure 5: Kaplan–Meier curves for the first analgesic request (p<0.001)
Early Post-operative pain score

The median (IQR) NRS score between groups at 2, 4, 6 and 8 hours starting from incision were presented as shown below table 4. There was a significant difference in pain severity between the groups at 4 and 8 hours.

Table 4: Comparison of postoperative pain severity using 11 point NRS score (0-10) between the groups for a patients underwent ambulatory hand, wrist and forearm surgery under axillary block at ALERT hospital, 2018

<table>
<thead>
<tr>
<th></th>
<th>Non exposed group</th>
<th>Exposed group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 hour after incision in NRS</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0.79</td>
</tr>
<tr>
<td>4 hour after incision in NRS</td>
<td>5(3)</td>
<td>2(3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6 hour after incision in NRS</td>
<td>4 (2)</td>
<td>4 (2)</td>
<td>0.289</td>
</tr>
<tr>
<td>8 hour after incision in NRS</td>
<td>3(2)</td>
<td>1(1)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Values are presented as median (interquartile range), and man Whitney test U used for analysis, p <0.05 considered as significant
Post-operative nausea

There was a significant difference 6 hour post-operative incidence of nausea between non exposed group 12 (35.3%) and exposed group 4 (11.8%) and (p=0.045) (figure -6) but there was no significant difference on the incidence of vomiting between the groups.

Figure 6: Comparison of incidence of nausea and vomiting between the groups in a patient undergoing ambulatory hand, wrist and forearm surgery under axillary block at ALERT hospital, 2018
5. DISCUSSION

Our study showed that addition of 8 mg dexamethasone to 1% lidocaine with adrenaline prolong the duration of sensory block but did not fasten the onset time of complete sensory block. The median time to onset of complete sensory block was similar in exposed group 24(6) minutes and in non-exposed groups 24(6) minutes (p=0.068). The onset time of sensory block in the all four (ulnar, radial, musculocutaneous and medial nerves) branch of brachial plexus block was also similar between the groups. The median (IQR) onset time of sensory block in no-exposed group and exposed group of ulnar nerve was 21(6) and 21(6) minutes (p=0.114), radial nerve 18(6) and 16.5 (9) minutes (p=0.115), musculocutaneous 24(6) and 24(3) minutes (p=0.165), median nerve 18(5) and 18(6) minutes (p=0.126) respectively. The time taken to start incision (incision time) was also comparable between the groups (p=0.203).

Previous studies on addition of dexamethasone on local anesthetics in brachial plexus block have yielded conflicting results regarding the onset time of sensory block.

Similar to our study, Zaman et al.(7) showed that there was no significant difference in the onset of sensory blockade of axillary block between groups. This randomized control trial study evaluates the effect of ketamine and dexamethasone in a combination with lidocaine on the onset and the duration of axillary block in hand and forearm soft tissue surgery. They compare 38 ml of 1% lidocaine + 8 mg dexamethasone and 1% lidocaine + 50 mg ketamine and 38ml of lidocaine only. The onset of sensory block was 5± 1.09 in lidocaine only group and 5.65± 2.48 in dexamethasone group which was statically insignificant (p= 0.515). But the onset time was moderately earlier than our result. The technique of axillary block they employed was Ultrasound guided, might be responsible for earlier onset of sensory block in all groups(3).

The results of our study were also comparable with the study of Movafegh et al(26), in their study evaluated the effects 8 mg dexamethasone added to 1.5 % lidocaine on the onset time and duration of sensory and motor blockage of axillary brachial plexus block in 60 patients scheduled for elective hand and forearm surgery. In their study the onset times of sensory block (14± 5 min in dexamethasone group versus 11±4 min in control group) were similar between groups.
In contrary to our result, Biradar et al.(25) shown on their prospective randomized, double blind study to evaluate the effect of 8 mg dexamethasone added to 1.5% lidocaine with adrenaline in supraclavicular brachial plexus block, that the onset of sensory block significantly more rapid in the dexamethasone group than in the control group (p=0.001)(25). The possible explanation of this difference might be we used different brachial plexus block technique (axillary versus supraclavicular block), or study design effect and local anesthetics concentration difference may attribute for contradictory results.

Dawood et al(27) evaluate the effect of 8 mg dexamethasone added to 40ml of 1.5% lidocaine on the onset and duration of axillary brachial plexus block through randomized control trial. After recruitment of 100 patient scheduled for elective hand and forearm surgery under axillary brachial plexus block they were able to conclude that the addition of dexamethasone to 1.5% lignocaine fasten the onset of analgesia and prolongs the duration of sensory blockade significantly. The onset of sensory block was significantly different between placebo group 21.64 ± 2.30 min and dexamethasone group 15.42 ± 1.44 min (p <0.001).This result contradictory result could be due to different reasons first they used a nerve stimulator technique (trans-arterial technique used in our study) which can affect the onset time of analgesia. Secondly the average doses of local anesthetics they used (600 mg vs. 400 mg) is larger. The dissimilarity in design might contributes for difference.

In our study duration of sensory block of axillary brachial plexus block was significantly longer (235 ±37) in exposed group compared to (172± 28) minutes in non-exposed group (p<0.01). According to the studies of Movafegh et al.(26), the duration of sensory block of axillary block was significantly longer in lidocaine + dexamethasone group (242±76) than in lidocaine only group (98±33)(p<0.01) which is consistent with present study. But the duration of sensory block in lidocaine only group was moderately shorter than our result (98±33 vs. 172±28). This difference might be due to the uses of epinephrine solution on the present study which believed to cause prolonged sensory block(30).

A Randomized control trial study of Yaghoobi et al.(31) Evaluate postoperative analgesic effect of dexamethasone and fentanyl added to lidocaine through axillary block in Forearm Fracture. The duration of sensory block was significantly longer in dexamethasone group (206 ± 25.05) than lidocaine alone group (106 ± 18.03) which is similar to present study.
The above result could not be surprising because even IV dose of dexamethasone was found to have an impact on duration of sensory block. In a study by Rosenfeld et al.(32) compare perineural versus intravenous dexamethasone as adjuncts to local anesthetics brachial plexus block for shoulder surgery ,they found that both technique significantly prolong the duration of sensory block and reduce the doses of anti-emetics.

The mechanism of dexamethasone in prolonging the duration of nerve blocks is not completely understood and is thought to arise from various factors. There are several theories to explain this effect of dexamethasone; among those is the one representing on degree of vasoconstriction produced by steroids and this in turn decreases the absorption of local anesthetics. Secondly, theory indicates that dexamethasone increases the inhibitory activity of potassium channels on pain sensory nerves. Another theory refers to anti-inflammatory action of dexamethasone and blocking transmission of nociceptive C fibers(13, 28).

In present study the first analgesia request time was analyzed by kaplan-meier analysis with log rank test and showed that there is a significant difference on survival time from first analgesic request between the groups (log rank p value<0.001). The median (IQR) time to first anesthesia request was 210 (185 to 230) minutes in non-exposed group and 270 (240 to 330) minutes in exposed group. Four of patients lost from follow up due to personal reasons and three patient from exposed group and one from non-exposed not given analgesia at all during follow up periods. Since the duration of follow up is shorter, we were unable to show total analgesics consumption. Yet none of our study participant we given analgesia more than once.

Similar to our study randomized control trial by woo et al.(33) Showed that perineural addition of 2.5, 5 or 7.5 mg of dexamethasone to 0.5% ropivacaine for interscalene block increase first analgesia request time in dose dependent manner.

Desmet et al (34)compare perineural and intravenous dexamethasone on 0.5% ropivacaine on interscalene block and demonstrate that Patients included in Ropivacaine only group had a 3.91 times (95% CI 2.63–5.81) higher probability for analgesic need during the first 48 h compared with patients in Ropivacaine with perineural dexamethasone and Ropivacaine with intravenous dexamethasone groups (P<0.001).
Severity of post-operative pain assessed for eight hours at 2, 4, 6, and 8 hours starting from incision by numeric rating scale (NRS). The result showed that there was insignificant difference on severity of pain at 2 hour after incision. This may be due to majority of patient in both groups not recovered from analgesia at 2 hour from incision. At 4 and 8 hrs. There was a significant difference in pain score between the groups. This result is comparable with study of Biradar et al. Showed(25) that dexamethasone reduce post-operative VAS score at 2, 3 and 4 hours. Six hour pain score is also not significantly different between the groups. This can be explained by at this time majority of patients taken the first analgesia in non-exposed group than exposed group.

There is debate whether perineural corticosteroids may be harmful; there is, however, some consensus. Reports of neurotoxicity seem to be related to the vehicle polyethylene glycol and the preservative benzyl alcohol in some preparations, as well as the presence of insoluble steroid particulate matter in the injectate(35). Dexamethasone is non-particulate and is available in a preservative-free formulation; this was used in our study.
6. LIMITATIONS AND STRENGTHS OF THE STUDY

6.1 Limitations
There was some limitation on the study. One is variability of surgical procedure which are difficult to categorize based on cutaneous innervation of brachial nerves. Since Trans- arterial techniques is blinded technique, doses of local anesthetics administered may not distribute equally to all four nerves. The other challenge we face during the study is the doses of dexamethasone is not adjusted based on weight even if there is no significant different on weight between the group. Lack of pain management protocol in the study area and shorter follow up period are also some of limitation of the study.

6.2 Strengths
Study participant were homogenous between the two groups

Uses of probability sampling method
7. CONCLUSION
We conclude that, the addition of 8 mg dexamethasone to 1% lidocaine with adrenaline solution in trans-arterial axillary brachial plexus block for ambulatory elective hand, wrist and forearm surgeries prolongs the duration of sensory blockade and analgesic request time but do not reduce the onset time of sensory block.

8. RECOMMENDATION
We recommend that addition of 8 mg dexamethasone to 1% lidocaine with adrenaline is effective for prolonging the duration of sensory block and first analgesia request time in trans-arterial axillary brachial plexus block for ambulatory elective hand, wrist and forearm surgery.

We also recommend additional randomized controlled study.
9. REFERENCES


Annex I

Information sheet to get permission for the research

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

The research team includes MSc students, senior advisor from AAU and three anesthetist for data collection from ALERT Hospital.

Name of Principal investigator: - Simeneh mola
Advisor’s name: - Ms.: - Betelihem girma
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

Dear participant:

This is a research designed to compare effectiveness of dexamethasone with lidocaine for axillary brachial plexuses block in patients undergoing forearm, hand and wrist surgery. 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 question will help us to asses and understand the effect. So, we are requesting you to give honest response and keep participation.

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

Thanks for taking part in the study!!!!

For further question ask investigator

Tele - +2519938444243

Email - ksimenehmola@yahoo.com
Annex III
Annex IV

Questionary

Section 2: Socio-demographic and basic characteristics of the patient (chart review).

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
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<td>CODE</td>
<td></td>
</tr>
<tr>
<td>202</td>
<td>Card number</td>
<td></td>
</tr>
<tr>
<td>203</td>
<td>Patient age(yrs.)</td>
<td></td>
</tr>
<tr>
<td>204</td>
<td>Weight(kgs)</td>
<td></td>
</tr>
<tr>
<td>205</td>
<td>Height(m)</td>
<td></td>
</tr>
<tr>
<td>206</td>
<td>Sex</td>
<td>1. Male</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Female</td>
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<tr>
<td>207</td>
<td>ASA category</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>2. ASA 2</td>
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</table>

Section 3: Baseline status of the patient

<table>
<thead>
<tr>
<th>s.no.</th>
<th>Parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>301</td>
<td>BMI</td>
<td></td>
</tr>
<tr>
<td>302</td>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>303</td>
<td>Procedure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Experience anesthesia provider</td>
<td>1. BSc less than 1 year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. BSc greater than 1 year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. MSc</td>
</tr>
<tr>
<td>304</td>
<td>Does the patient take sedative OR analgesics premedication?</td>
<td>1. Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. NO</td>
</tr>
<tr>
<td>305</td>
<td>Type dose time rout</td>
<td></td>
</tr>
</tbody>
</table>
If yes for the above question, what was the drug?

1. tramadol  
2. diclofenac  
3. pethidine  
4. paracetamol  
5. morphine  
6. others

<table>
<thead>
<tr>
<th></th>
<th>Baseline NRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>306</td>
<td>Tourniquet applied on the patient?</td>
</tr>
<tr>
<td>307</td>
<td>Any intervention for tourniquet pain</td>
</tr>
<tr>
<td>308</td>
<td>If yes the above question what was the intervention</td>
</tr>
<tr>
<td>309</td>
<td>Is there any tourniquet pain</td>
</tr>
<tr>
<td>310</td>
<td>Baseline Heart rate</td>
</tr>
<tr>
<td></td>
<td>Baseline Blood pressure with MAP</td>
</tr>
</tbody>
</table>
Section 4: Question related to Axillary block and surgery.

| 401 | Types of Local anesthetic for the block | 1. Lidocaine 1% with adrenaline only  
|     |                                    | 2. Lidocaine 1% with adrenalin and 8mg dexamethasone  
|     |                                    | 3. Other specify  
| 402 | Volume of local anesthetics |  
| 403 | Techniques of axillary block | A. Paresthesia  
|     |                                 | B. Trans-arterial  
|     |                                 | C. Ultrasound  
|     |                                 | D. Nerve stimulator  
|     |                                 | E. Other ________  
| 404 | Numbers of injection | A. One  
|     |                               | B. Two  
|     |                               | C. Three  
|     |                               | D. Other____
### Section 5: Questions related to onset of axillary block

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Parameter</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>501</td>
<td>Local anesthetics injection time</td>
<td>RN</td>
</tr>
<tr>
<td>502</td>
<td>Onset time of sensory block</td>
<td>MCN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MN</td>
</tr>
<tr>
<td></td>
<td></td>
<td>UN</td>
</tr>
<tr>
<td>503</td>
<td>Onset time of motor block</td>
<td></td>
</tr>
<tr>
<td>504</td>
<td>Incision starting time</td>
<td>(Hrs. /min).</td>
</tr>
<tr>
<td>505</td>
<td>Duration of surgery</td>
<td></td>
</tr>
<tr>
<td>506</td>
<td>Does the patient take any sedative or analgesic intraoperative period if yes specify</td>
<td>1. Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. No</td>
</tr>
</tbody>
</table>

### Section 6: questions related to duration of block

<table>
<thead>
<tr>
<th>S. no.</th>
<th>Questions</th>
<th>answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>601</td>
<td>Sensory recovery time(LT)</td>
<td></td>
</tr>
<tr>
<td>602</td>
<td>Full Recovery time of motor function(LT)</td>
<td></td>
</tr>
<tr>
<td>603</td>
<td>First analgesia request time(LT)</td>
<td></td>
</tr>
</tbody>
</table>
Section 7: related to severity of pain in postoperative period

<table>
<thead>
<tr>
<th></th>
<th>Severity of pain in NRS</th>
</tr>
</thead>
<tbody>
<tr>
<td>703</td>
<td>2 hr. after skin incision</td>
</tr>
<tr>
<td>705</td>
<td>4 hr. after skin incision</td>
</tr>
<tr>
<td>706</td>
<td>6 hr. after skin incision</td>
</tr>
<tr>
<td>707</td>
<td>8 hr. after skin incision</td>
</tr>
</tbody>
</table>

Section 8: Post-operative analgesics consumption

<table>
<thead>
<tr>
<th></th>
<th>Post-operative analgesics consumption</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tramadol</td>
</tr>
<tr>
<td>801</td>
<td>Immediately at recovery</td>
</tr>
<tr>
<td>802</td>
<td>1 hr. after operation</td>
</tr>
<tr>
<td>803</td>
<td>2 hrs. after operation</td>
</tr>
<tr>
<td>804</td>
<td>3 hrs. after operation</td>
</tr>
<tr>
<td>805</td>
<td>4 hrs. after operation</td>
</tr>
<tr>
<td>806</td>
<td>5 hrs. after operation</td>
</tr>
<tr>
<td>807</td>
<td>6 hrs. after operation</td>
</tr>
</tbody>
</table>

Does the patient has nausea within 6 hrs. Post-operative period 1 yes 2 no

Does the patient has vomiting within 6 hrs. Post-operative period 1 yes 2 no