Addis Ababa University

College of Health Sciences

School of Medicine

Department of Anesthesia

EFFECTIVENESS OF BILATERAL SUPERFICIAL CERVICAL PLEXUS BLOCK AS PART OF POST-OPERATIVE ANALGESIA FOR PATIENT UNDERGOING THYROIDECTOMY IN EMPRESS ZEWDITU MEMORIAL HOSPITAL, ADDIS ABABA, ETHIOPIA 2017

Investigators

Zemedu Aweke (B.Sc.)

Advisor

Wosenyeleh Admasu (B.Sc. M.Sc.)

THESIS SUBMITTED TO SCHOOL OF MEDICINE, DEPARTMENT OF ANESTHESIA FOR PARTIAL FULFILMENT OF THE REQUIREMENTS OF M.SC. IN ANESTHESIA.

JUNE, 2017

ADDIS ABABA, ETHIOPIA

Declaration

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

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 Advanced Clinical Anesthesia course

Name Signature

1. _____ _____

2. _____ _____

3._____ _____

Acknowledgement

I would like to express my gratitude to my advisors Mr. Wossenyelleh Admasu for his invaluable assistance and guidance during the thesis project. I would also like to extend my appreciation to Dr Girmay Medhin, Ato Nugusu Ayalew and Sileshi Abiy who had helped me a lot in giving additional advice.

I also want to express my great thanks to my sponsoring organization Addis Ababa University for the financial support we obtained. Finally I would like to say thanks to my data collectors and study participants.

Abstract

Introduction: The pain after thyroid surgery is considered of moderate intensity and short duration. Results of previous study shows the opioid consumption is 90% after thyroid surgery. Most randomized controlled trial studies showed significant Reduction in pain intensity and severity of pain in patients for whom BSCPB done when compared to placebo group. There were also significant difference in time to first analgesia request and total analgesia consumption.

Objective: To assess post-operative analgesic effect of Bilateral Superficial Cervical Plexus Block for thyroid surgery under general anesthesia at Empress Zewditu Memorial Hospital.

Methods: This prospective cohort study recruits 66 American Society of Anesthesiologist (ASA) class I and II, age ≥ 18 and euthyroid patient who underwent thyroidectomy randomly. Manny Whitney test were used to compare median pain score, time to first analgesia request in minutes and total analgesia consumption between groups. Homogeneity of categorical independent variable between two exposure groups were analyzed using Chi Square. Box and whisker plot were used to show a median pain score differences between groups and statistical significance were sated at p value < 0.05 with a power of 80%.

Results: The comparison of data showed that during recovery room (PACU) time the median postoperative pain score(NRS) were 3 in exposed group and 5 in non-exposed group (p=0.002). The comparison also shows lower median pain score 2 compared to 4 at 3rd post-operative time (p<0.0001).There were also statistically significant difference at 6th ,12th and 24th hour showing lower median pain score in BSCPB compared to control group. The median time to first analgesia request in minutes were longer (360 minutes) in exposed group compared to 180 minutes in non-exposed group (p= 0.0006).The median tramadol consumption within 24 hour is 0 mg in exposed group compared to 100 mg in non-exposed group(p=0.001).

Conclusion and Recommendation: Bilateral Superficial cervical plexus block done before surgery after induction of anesthesia decrease postoperative pain score, total analgesia consumption and prolong time to first analgesia request for thyroidectomy done under general anesthesia . Based on these we recommend use of BSCPB with 0.25 bupivacaine is effective post-operative analgesia.

Table of Contents

List of Abbreviations

ASA	American Society of Anesthesiologist
BSCPB	Bilateral Superficial Cervical Plexus Block
IASP	International Association for study of pain
IM	Intra Muscular
IV	Intra venous
GA	General Anesthesia
MAP	Mean Arterial Blood Pressure
mg	Milligram
NRS	Numeric Rating Scale
NS	Not statistically significant
NSAIDS	Non-Steroidal Anti-Inflammatory Drugs
PACU	Post Anesthesia Care Unit
PONV	Post Operative Nausea and Vomiting
PR	Pulse Rate
PCA	Patient Controlled Analgesia
SBP	Systolic Blood Pressure
SCM	Sternocliedomastoid muscle
SCPB	Superficial Cervical Plexus Block
SD	Standard Déviation
SPO2	Arterial Blood Saturation
VAS	Visual Analogue Scale
WHO	World Heath Organisation

List Of Tables And Figures

Tables

Figures

1. Introduction

1.1 Background Information

The total goiter prevalence in the global population is estimated to be 15.8% and the highest prevalence of 28.3% were observed in Africa (1). It is estimated that half of Ethiopian population faces iodine deficiency, where 14 million or 40% of those at risks are believed to have goiter. The proportions of Addis Ababa households who consume iodized salt are 30%, which is higher compared to rural areas 13%. Though goiter with iodine deficiency are treated with iodine supplementations, goiter that do not regress in size, rebound growth and presence of pressure symptoms are among indications for surgical treatment (2).

Review of operated cases of thyroid surgery in Tikur Anbessa hospital showed that 472 patients underwent thyroid surgery from 1997 to 2001. A five year retrospective review done in Empress Zewditu Memorial hospital also reveals that thyroid surgery constitute 7% of all operated cases with 334 operations done from 1996 to 2000 (3,4).

Anesthesia for thyroid surgeries is commonly done under general anesthesia. The mean postoperative pain score of 69mm were reported on 100m Visual Analog Scale (VAS). It has been also reported that the morphine consumptions in the first postoperative day is 90%. The proportions of patient with pain score greater than 40mm is 70% on VAS scale (5 ,6).

It has been suggested that cervical plexus block, either superficial or deep or combinations given bilaterally could easily lead to block appropriate for thyroid surgery without any significant side effects (7,8). It is associated with decreased need of opioids for controlling postoperative pain. It also decreases post-operative nausea & vomiting, postoperative pulmonary complications and finally hospital stay of the patient. Cervical plexus block has also been effectively used in other surgeries like carotid endarterectomy, lymph node biopsy (or) excision (9,10).

The use of bilateral superficial cervical plexus block (BSCPB) for retro-sternal goiter and large goiter can have analgesic sparing effect due to the pain arising from the area that cannot be blocked by BSCPB (11).

The cervical plexus lies in the paravertebral region of the upper four cervical vertebrae. It is formed from the anterior rami of C1 – C4 spinal nerves roots. It is deep to the sternocleidomastoid muscle and anterior to the middle scalene muscle, in continuity with the nerve root forming the brachial plexus. The plexus gives rise to numerous branches which supply structures in the head and neck. They can broadly divided in to superficial and deep branches (12).

The superficial branches of the cervical plexus supply the skin of the neck, upper thorax, scalp and ear. These nerves all enter the skin at the middle of the posterior border of the sternocleidomastoid muscle. It further gives rise to four branches of nerves which is greater auricular nerve, transverse cervical nerve, supraclavicular nerve and lesser occipital nerve (13).

Superficial infiltration at lateral border of sternocleidomastoid muscle bilaterally is becoming an alternative to pain management. Opioid analgesics and NSAIDs are being used practically to alleviate postoperative pain after thyroidectomy. To decrease the analgesic requirements and enhance patients' quality of life alternative analgesia technique should be sought (14).

BSCPB, a regional anesthetic technique for anterior neck surgery reduce the opioids and NSAIDs requirements. The technique will also reduce the incidence of PONV by decreasing the opioids requirements and pain which were the risk for PONV (6). It is also known for decreasing intraoperative analgesic requirements when given before surgery (5,15). Moreover, its landmarks are simple and the block is technically easy with a subcutaneous injection, avoiding risk of life-threatening complications associated with deep cervical block. Likewise, the superlative and longstanding analgesia effects of the block, hemodynamic stability, diminish in surgical blood loss and rare complication with the procedure is making it an attractive option for anesthesia management of anterior neck surgeries (16,17).

BSCPB done before operations will decrease anesthesia and analgesic requirements and yields stable operative conditions compared to general anesthesia alone. Regional anesthesia is reported as equally safer compared with general anesthesia in a case report of patient with cardiac disease. BSCPB is easier and safer than the combined superficial and deep cervical plexus block (18,19).

1.2 Statement of the Problem

Pain has both sensory and emotional components that interact to produce an overall pain experience. According to International Association for Study of Pain (IASP) pain is defined as unpleasant emotional and sensory experience due to actual or potential tissue damage (20). Unrelieved pain after surgery can interfere with sleep and physical functioning and can negatively affect patient wellbeing on multiple levels (21). Good pain control is important to prevent negative outcomes such as hypertension, myocardial ischemia, arrhythmias respiratory impairments, ileus and poor wound healings. In addition to the significant personal suffering and social burden that result, considerable financial expense is incurred, both directly in extra healthcare costs and indirectly as a result of absenteeism, lost production and welfare payments (22).

Pain after thyroid surgery is regarded as being of moderate intensity and short duration (23). During the first twenty four hour after surgery patients need opioids and non-opioids analgesics. But there is an evidence that shows pain were undertreated. Adequate management of pain needs involvement of patients, physician and resources (24).

Besides of decreasing cost and side effect of opioids, use of BSCPB also support the principle of multimodal analgesia where a variety of analgesic medication and techniques that target different mechanisms of action in the peripheral or central nervous system (which might also be combined with non-pharmacological interventions) might have additive or synergistic effects and more effective pain relief compared with single-modality interventions. WHO analgesic ladder also recommends use of peripheral nerve block as a parts of analgesia system in the perioperative period.

Managing pain with opioids amplifies the risk of nausea and vomiting which further increase risk of bleeding and patient discomfort (25). Sooner et al revealed the incidence of nausea and vomiting after thyroid surgery to be 54% (26, 6). But the use of combined general and regional anesthesia may lighten the level of general anesthesia required and provide prolonged postoperative analgesia (27)

1.3 Justification of the Study

Optimal pain relief allowing normal physiologic function cannot be achieved by a single drug or a single technique without imposing additional risks on the patients. Multimodal analgesia advocates use of different drugs and techniques which act in different sites so as to increase the analgesic effect and also decrease the unwanted effect of single drug therapy. Managing the moderate pain of thyroidectomy with administration of opioids amplifies the postoperative nausea and vomiting inherent with procedure. As far as my knowledge goes, there is no previous study done in our country to assess the analgesic efficacy of BSCPB though, it has been studied in different part of the world (28,29). The controversies regarding the efficacy is one of the reasons which call for the study.

The number of studies done to asses' analgesic efficacy of BSCPB were limited to carotid endarterectomy, where there is insufficient work done to evaluate its effect in thyroidectomies. Undertaking such studies in resource limited area can improve pain treatment and patient comfort by counteracting the effect of high patients to nurse ratio. Poor practices and awareness of Patient Controlled Analgesia (PCA) are the other basis for such a research made. Therefore conducting such a research which intended to find alternatives for pain management in the intraoperative and postoperative period is expected to have of great value since it will decrease the side effects of opioids and other systemic medications. On the other hand, it will open the gate to bring quality education and used as a baseline for further research activities.

2. Literature Review

The extent of pain a patient suffers after surgery is related to the extent of tissue damage and the site of surgery. Operations on the neck and thorax are more painful than operations on the lower abdomen and limbs, though a joint replacement surgery is associated with severe postoperative pain (30,31).

The use of BSCPB for thyroidectomy remains controversial. A study done in France found that the analgesic requirements during and after thyroid surgery who had BSCPB was reduced compared to placebo group. In addition to Ropivacaine which were used to block the superficial cervical plexus, clonidine were found to improve intraoperative analgesia. The proportions of patients requiring Nefopam in the immediate PACU are 79% in placebo group compared to 35% and 34% in Ropivacaine and Ropivacaine with clonidine respectively. Postoperative pain score decreased in all three groups, though it is relatively higher 5 (0 to 10) VAS score in placebo group compared to 3 (0-10) VAS score in the ropivacaine and ropivacaine with clonidine group (32).

Study done in Turkey shows BSCPB done with 0.25% bupivacaine did not decrease analgesic requirements after thyroid surgery. The mean VAS score at first hour is 23 $\pm$ 19.3 in BSCPB group and 20.7 $\pm$ 13.3 in control group ($p>0.05$). the result also shows no statistically significant difference between two groups regarding total PCA (440.1 $\pm$ 210.2 vs. 370.2 $\pm$ 250.8) in BSCPB and control group respectively with $p> 0.05$ (33). Study done in France also shows a two point injection BSCPB given with 0.75% Ropivacaine didn't decrease morphine consumption within 36 hours (34)

Another study done in India demonstrate intraoperative and postoperative analgesic efficacy of BSCPB for thyroidectomy. In this double blind placebo controlled study comparing three different interventions: bupivacaine(B), bupivacaine with clonidine(BC) and saline (S)group found intra-operative fentanyl requirements were significantly lower in B and BC group ($p =0.012$). Time to first analgesic requirements is also significantly higher in B and BC ($p = 0.002$) and postoperative morphine requirements were lower in B and BC $p=0.001$ (35).

Study by Kale S. et al demonstrate the analgesic efficacy of BSCPB for thyroidectomy. The study, which primarily compare pre surgical block with post-surgical block revealed the VAS score was 2.27 for pre surgical block, 2.66 for post-surgical block compared to 4.19 in 0-10 VAS score in those patients without BSCPB. The author did not found any serious complication though pre surgical block is found to be technically easier to perform before anatomical land mark is distorted by surgery. Messner et al also advocate the pre surgical block considering its preemptive analgesia (36,37).

A double blinded placebo controlled study by N. Dieudonne et al found significant decrease in pain intensity in the study group in the postoperative period. The proportion of patient reporting moderate to severe pain were 68% and 93% respectively in saline and bupivacaine group with p value of 0.011. In addition to pain scores cumulative dose of morphine consumption in 24 hour after surgery presented as median were lower in bupivacaine (6mg) compared to the saline group(12mg) with p value of 0.013. Though the number of patients with no morphine administered in PACU is significantly higher in bupivacaine group 21 compared to only 6 in saline group with p value of 0.006, morphine consumption in PACU did not show any significant figures. It has been revealed that total morphine consumption in PACU is 8mg in bupivacaine group where it is 12 mg in saline group p= 0.068 (26).

A study done in Egypt with the objective of assessing intraoperative and postoperative analgesic efficacy of unilateral combined superficial and deep cervical plexus block reveals the techniques reduce the intraoperative anesthetic requirements and also reduce the postoperative analgesic requirements for anterior neck dissection under general anesthesia (38).

Guduff. P et al found the protective effect of SCPB in the development of chronic pain on their study which investigates incidence and risk factor for post thyroidectomy chronic pain. The study confirms the existence of chronic neuropathic pain until 6 month post thyroidectomy though, SCPB is found as protective role in the development of chronic postoperative pain (39).

A study by C, Z LIN and colleagues which were primary aimed to assess efficacy of BSCPB to reduce PONV revealed that the incidence of PONV is reduced when BSCPB is used for thyroidectomies. The reduced incidence of PONV were reported to be associated with the reduced requirements of opioids and reductions in the pain scores (40).

Study done in Nigeria shows that BSCPB were efficient and safe to perform. This prospective descriptive study aimed to assess the feasibility and safety of this technique revealed 88% of the participant are comfortable and found it satisfactory, where the rest 12% complain dissatisfaction with the technique (41).

Santosh U.P and colleagues also evaluate the feasibility of thyroidectomy under cervical plexus block. The authors use both deep and superficial block with sedation as sole anesthetic techniques and found a feasible and all patients tolerated the procedure (42). Kanthan R.K also confirm the efficacy and safety of BSCPB for oral and maxillofacial surgeries on his evaluative study aimed to assess feasibility and effectiveness of BSCPB for maxillofacial and oral surgeries (43).

A study by M.Mamede et al shows the mean arterial blood pressure and heart rate were not significantly changed after BSCPB (44). The finding from Santosh U. P et al also shows as there is no hemodynamic alterations in patient who received BSCPB (42).

3. Objective of the Study

3.1 General Objective

To asses analgesic effectiveness of bilateral superficial cervical plexus block (BSCPB) for post thyroidectomy pain control in Empress Zewditu Memorial Hospital from December 20, 2016 to May 30, 2017

3.2 Specific Objective

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

4. Methodology

4.1 Study Area

This study was conducted in Empress Zewditu Memorial Hospitals, one of the public hospitals in Addis Ababa, capital of Ethiopia. Located in Kirkos sub city woreda 08. This hospital was built, owned and operated by the Seventh - day Adventist Church, but was nationalized during the Derg regime in 1976. The hospital is named after Empress Zewditu, the cousin and predecessor on the throne of Emperor Haile Selassie. Today the hospital is operated by the Ethiopian Ministry of Health. It has four major operation room and two PACU.

4.2 Study Design and Period

Hospital based prospective cohort study was employed from December 20, 2016 to May 30, 2017. Study participant were followed starting from immediate PACU till 24^{th} hours prospectively.

4.3 Population

4.3.1 Source Population

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

4.3.2 Study Population

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

4.4 Study Variables

4.4.1 Dependent Variable

- Pain severity which will be assessed by NRS score (0-10)
- Time to first analgesic request in minutes

- Total Analgesia consumption in milligram in the first 24 hours (Tramadol, Diclofenac and others.

4.4.2 Independent Variables

- Socio demographic characteristics: age and sex
- ASA physical status
- Preoperative surgical diagnosis
- Induction agent
- Surgeon experiance
- Anti-thyroid medication
- Duration of surgery and duration of anesthesia in minutes
- Estimated intraoperative blood loss
- Exposure variables; BSCPB done and BSCPB not done

4.5 Operational Definition

Postoperative pain: the presence of pain in the postoperative period was defined as a patient complaining pain and any pain score other than zero within 24 hours.

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

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

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

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

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

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 (45).

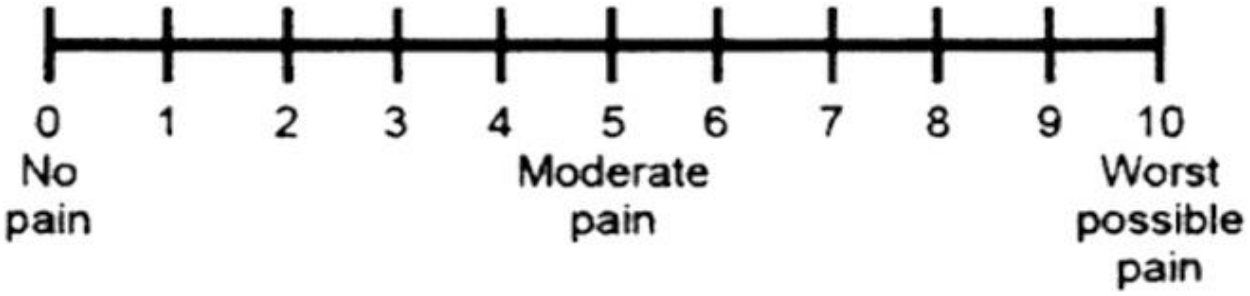


Figure 2 : Adopted from the National Initiative on Pain Control™ (NIPC™)

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

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

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

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

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

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

ASA VI: brain dead patient undergoing organ donation

4.6 Inclusion and Exclusive Criteria

4.6.1 Exclusive Criteria

Sub sternal goiter, age less than 18, emergency re-operation, preoperative pain on the neck were excluded from the study.

4.6.2 Inclusion Criteria

ASA I and II euthyroid patient scheduled for thyroidectomy were included in the study.

4.7 Sample Size and Sampling procedure

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

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

$$n = \frac{(S^2_1 + S^2_2)\,(a+b)^2}{(X_1 - X_2)^2}$$

Where n = the sample size in each of the groups

X_1 = Sample mean in control group

X_2 = Sample mean in treatment group

$X_1 - X_2$ = the difference the investigator wishes to detect

S^2_1 = Sample variance in control group

S^2_2 = Sample variance in treatment group

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

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

From the literature the mean VAS score, μ1= 3.99 in control group, μ2= 3.046 in treatment group and= $\sigma_1 = 1.27$, $\sigma 2 = 1.55$ (46)

Substituting for this variables yields

$$n = \frac{(1.27)^2 + (1.55)^2 \times (1.96+0.842)^2}{(3.99-3.046)^2}$$

n = 35, using 1:1 ratio between groups a total of 70 patients were required.

Patients aged 18 and above who underwent open thyroidectomy were recruited into the study during postoperative period at Recovery room. With 97 patients estimated to undergo thyroidectomy during study period 70 participants were recruited with the probability of about 75%. Considering the consecutive patients scheduled for thyroidectomy data collection where made on 3 patients for every 4 patients underwent surgery in both groups. Patients where sorted based on time sequence of PACU admission after which data collector recruit 3 patient for every 4 consecutive patients underwent thyroidectomy after grouping based on whether they received BSCPB or not. One number selected by lottery method used for exclusion and selection made on the rest of numbers in both groups till the required sample size is reached. We spent two extra week to reach the number of exposed group equal to unexposed group.

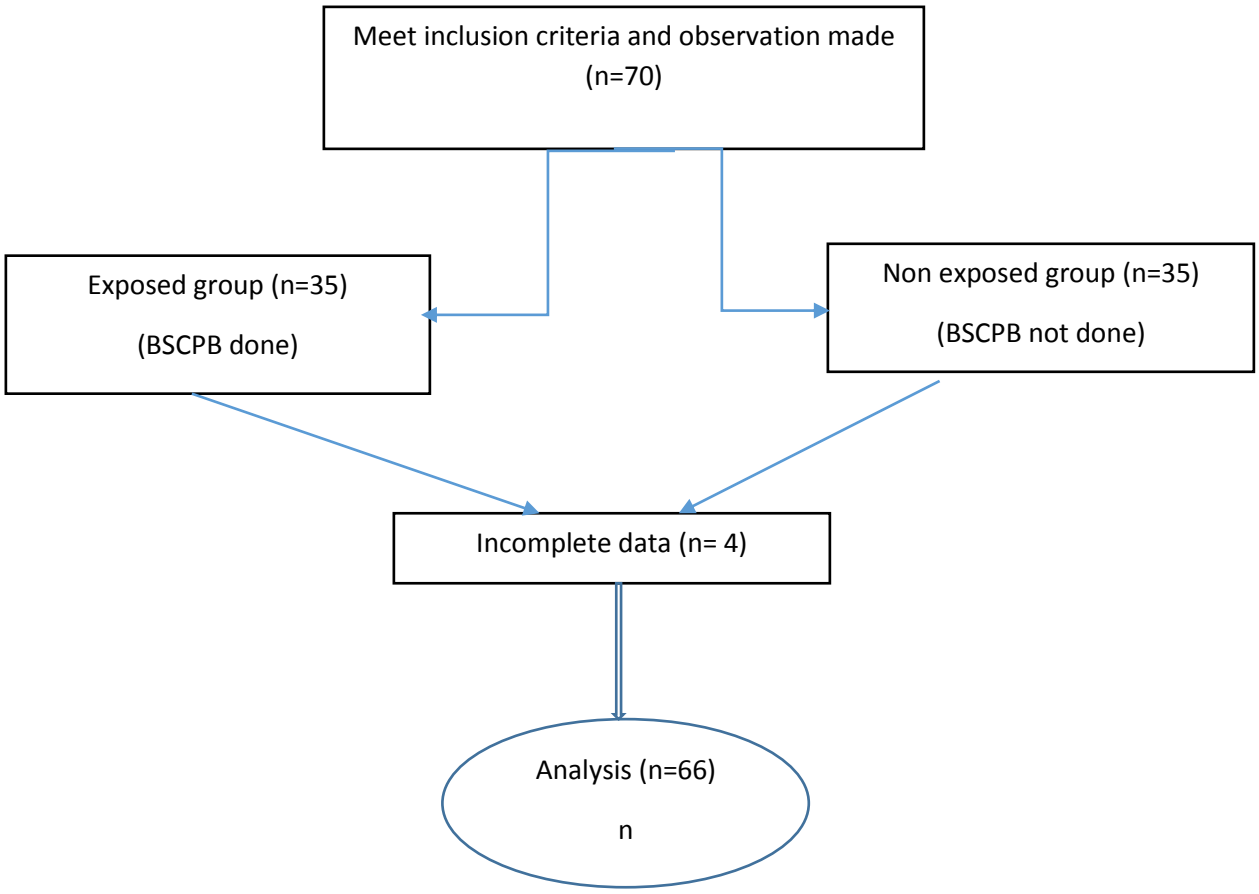


Figure 1: Enrollment chart for elective thyroid patients scheduled at Empress Zewditu Memorial Hospital

All patients who were scheduled for elective thyroidectomy who fulfill inclusion criteria and volunteer to take part in the study were instructed on how to self-report pain using the eleven point NRS score 0 to 10 in the morning of operation day at ward with trained nurse.

Anesthesia management for thyroid surgery in study hospitals are carried out by B.Sc. and M.Sc. anesthesia professional. After endotracheal intubation is confirmed successful and secured with adhesive plaster, M.Sc. anesthesia professionals including M.Sc. anesthesia student provide BSCPB with 20 ml of 0.25% bupivacaine. Those B.Sc. anesthesia professionals didn't provide BSCPB as supplementary to general anesthesia (GA). In the postoperative time patients transferred to recovery room and transferred to ward when they recover from anesthesia. In ward patient were usually observed by ward nurses and pain is usually managed by tramadol and diclofenac based on patient complain and sometimes on physician order.

At PACU patients were asked to report their pain based on 11 point NRS score as soon as patient fully respond to verbal command. NRS score and other variables were documented at 3rd hour, 6^{th} hour, 12^{th} hour and 24^{th} hour at wards after end of surgery. A time in minutes from end of surgery to first analgesia request were documented together with total analgesia consumed in the first 24 hours. In addition, incidence of postoperative nausea and vomiting documented when it was reported within 24 hours.

4.9 Data Quality Control

Collected data were checked for completeness, accuracy and clarity. Incomplete data were not entered a data base prepared on Epi-info. Data clean up and cross-checking was done before analysis on SPSS. Supervision were done during data collection by principal investigator and M.Sc. anesthesia students.

4.10 Data Analysis and Interpretation

After obtaining ethical clearance data were entered into Epi-info 7 and transported to SPSS V 20 for analysis. Shapiro Wilk test were used to test for distributions of data while homogeneity of variance were assessed using Levene's test for equality of variance. Numeric data were described in terms of mean ± SD for symmetric and median (Interquartile range) for asymmetric numeric data. Comparison of numerical variables between study groups were done using unpaired student t- test and Manny Whitney test based for symmetric and asymmetric data respectively. Frequency and percentage were used to describe categorical variable and statistical difference between groups were tested using Chi square. A p value <0.05 with power of 80% considered statistically significant.

4.11 Ethical consideration

Ethical clearance was obtained from the university ethical clearance committee before the start of the study. The importance of the study were explained & verbal informed consent was obtained from each participant by the data collector. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients. Participant's involvement in the study was on voluntary bases, participants who were not willing to participate

in the study & those who wish to quit their participation at any stage was informed to do so without any restriction.

4.12 Dissemination plan

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

5. Result and Discussion

5.1 Results

5.1.1 Demographic and Perioperative Characteristics

Sixty six patients were analyzed based on whether they received BSCPB (Bilateral Superficial Cervical Plexus Block) after induction of anesthesia for analgesia supplementation as exposed group and those who underwent surgery without supplementation of BSCPB as Non-exposed group.

There was no statistical difference between two groups in age with p value of 0.429. Majority of study participants were female owing to the higher incidence of thyroid disease in females but there is no statistical difference between two groups. The demographic status and peri-induction data were comparable between two groups with p value greater than 0.05 as shown in table 1.

Table 1: Demographic and operative characteristics of elective thyroid patient in empress Zewditu memorial hospital

	Exposed group (BSCPB) (n=33)	Non-exposed group (n=33)	p-value
Age (years)#	30 (10)	32 (20)	0.429
Sex /Females (n, %)	28 (84.8%)	30 (90.1%)	0.708
ASA Status ASA I (n, %) ASA II (n, %)	 31 (47%) 2 (3%)	 28 (42%) 5 (8%)	0.427
Preoperative diagnosis Benign mass (n, %) Neoplastic mass (n, %)	 31 (47%) 2 (3%)	 28 (42%) 5 (8%)	0.424
Anti-thyroid medication uses (yes)	13 (39.4%)	9 (27.3%)	0.433
Induction agent Thiopental Propofol	 30 (45%) 3 (5%)	 27 (41%) 6 (9%)	0.473
Surgeon experience Resident (n, %) Senior (n, %)	 23 (35%) 10 (15%)	 28 (42%) 5 (8%)	0.240
Estimated intraoperative blood loss (ml)#	180 (200)	150 (150)	0.689
Duration of surgery (minutes)#	110 (40)	110 (43)	0.508
Duration of anesthesia (minutes)#	125 (48)	125 (43)	0.763

Hint: # = Median (Interquartile range); n (%) = number (proportion)

5.1.2 Immediate Recovery Room Vital Sign

The recovery room vital sign (PR, SBP, DBP, MAP, Sao2) taken immediately in the recovery room before any medication was given were comparable between two groups except there is significant difference between two groups in terms of baseline heart rate.

Table 2: Vital sign in the first 24 postoperative periods

Vital sign	Exposed group (BSCPB) (n=33)	Non-exposed group (n=33)	p-value
Immidiate recovery room (PACU) vital sign			
PR (mean± Sd)	79.06± 11.34	85.24±10.60	0.026*
SBP in mmhg (median and IQR)	112 (14)	118 (20)	0.073
DBP in mmhg (mean± Sd)	70.70 ± 11.31	73.76 ± 7.88	0.207
MAP in mmhg (mean± Sd)	84.12 ± 11.30	85.85 ± 8.27	0.481
SaO2 in % (median and IQR)	94 (6)	94 (5)	0.806
Vital sign at 3rd hour			
SBP in mmhg (median and IQR)	112 (110-120)	116(110-124.5)	0.484
DBP in mmhg (median and IQR)	74 (69.5-80)	70 (70-80)	0.959
PR (median and IQR)	79 (74.5-84)	80 (77-90)	0.134
Vital sign 6th hour			
SBP in mmhg (median and IQR)	112 (109.5-125)	110 (107.5-130)	0.871
DBP in mmhg (median and IQR)	70 (60-79)	70 (67-79)	0.498
PR (median and IQR)	80 (73.5-85.5)	82 (78-90)	0.094
Vital sign at 12th hour			
SBP in mmhg (median and IQR)	110 (100-121.5)	110(110-120)	0.804
DBP in mmhg (median and IQR)	72 (70-80)	70 (60-79)	0.079
PR (median and IQR)	80 (77-85)	82 (77-87)	0.170
Vital sign at 24th hour			
SBP in mmhg (median and IQR)	110 (110-120)	110 (110-122.5)	0.551
DBP in mmhg (median and IQR)	70 (70-79)	70 (65-80)	0.705
PR (median and IQR)	80 (76-86)	80 (80-84)	0.477

IQR – Intequartile range , PR – Pulse rate, SBP- Systolic blood pressure, DBP- Diastolic blod pressure, MAP- Mean arterial blood pressure, * = statistically significant.

There is no statistically significant difference regarding the postoperative Systolic Blood pressure, Diastolic Blood pressure and Heart rate at 3rd, 6th, 12th and 24th postoperative time as shown below.

5.1.3 Comparison of Postoperative Pain Severity by Numeric Pain Rating scale

The median (IQR) NRS score between groups at different time were presented as shown below.

Table 3: Comparison of postoperative pain severity using 11 point NRS score (0-10)

Variables expressed as median (IQR)	Exposed group (BSCPB) (n=33)	Non-exposed group (n=33)	p-value
Recovery room NRS score	3 (2-4)	5 (3-6)	0.002
3rd post-operative time NRS score	2 (1-3)	4 (3-5)	<0.0001
6th post-operative time NRS score	2 (0-3)	3 (3-4)	<0.0001
12th post-operative time NRS score	1 (0-2)	0 (0-3.5)	0.004
24th post-operative time NRS score	0 (0-1)	2 (0-3)	<0.0001

The median NRS score were lower in the exposed group at recovery room, 3rd, 6th, 12th, and 24th hour. Using Many Whitney test a significant statistical difference were observed at all time between exposed and non-exposed groups as shown in figure 2 below.

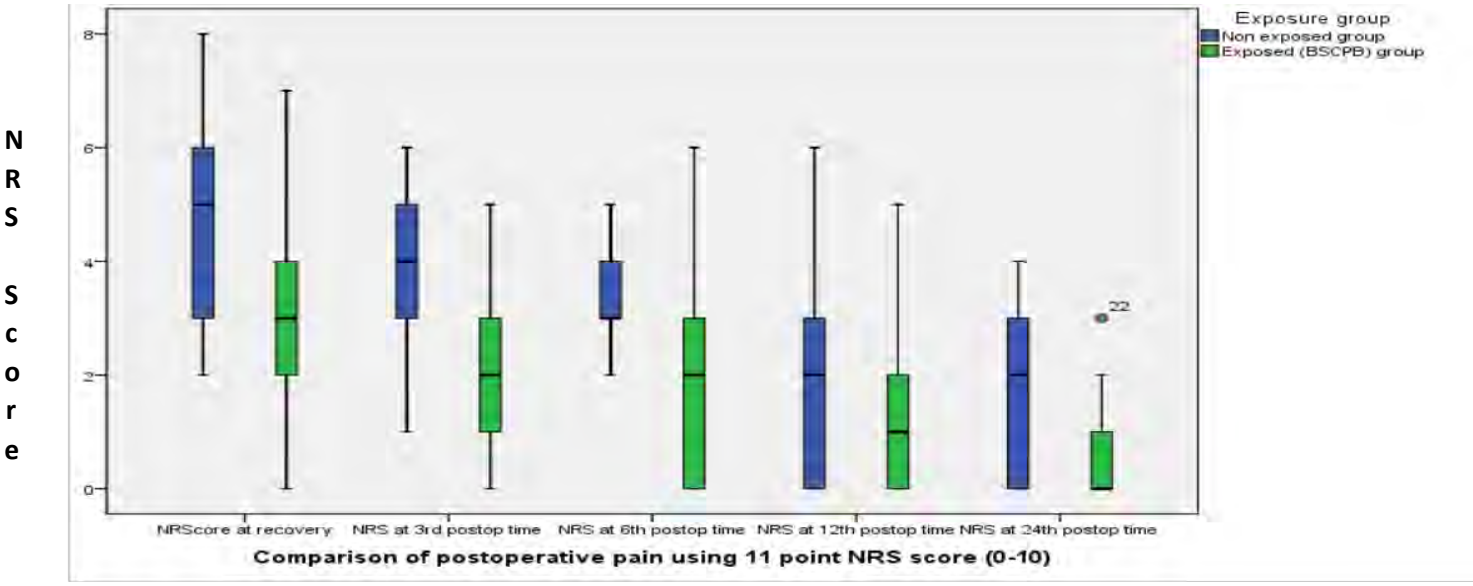


Figure 2: Comparison of postoperative pain severity using 11 point NRS score (0-10)

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

The media time in minutes were longer 360 minutes in exposed group compared to 180 minutes non-exposed group p=0.006 There were also statistically significant difference with regard to median tramadol consumption within 24 hours. There were no statistical difference between two

Table 4: Comparison of time to first analgesia request in minutes and total analgesia consumption between two groups

	Exposed group (BSCPB) (n=33)	Non-exposed group (n=33)	**p-value**
Time to first analgesia request	360 (190-720) minutes	180 (65-360) minutes	0.006
Total analgesia consumption within 24 hour Tramadol (IV)	0 (0-50) milligram	100 (25-150) milligram	0.001
Diclofenac (IM)	75 (0-75) milligram	75 (0-75) milligram	0.775

Hint: IV: Intra vascular, IM: Intra muscular

5.1.5 Incidence of Nausea and Vomiting between exposed and non-exposed group

The incidence of nausea and vomiting over 24 hours is 69.7%. The proportions of patients with nausea and vomiting is lower (63.63%) in exposed group (BSCPB) compared to non-exposed group which is 75.7% ($X^{2=}$ 0.646) with a p value of 0.42.

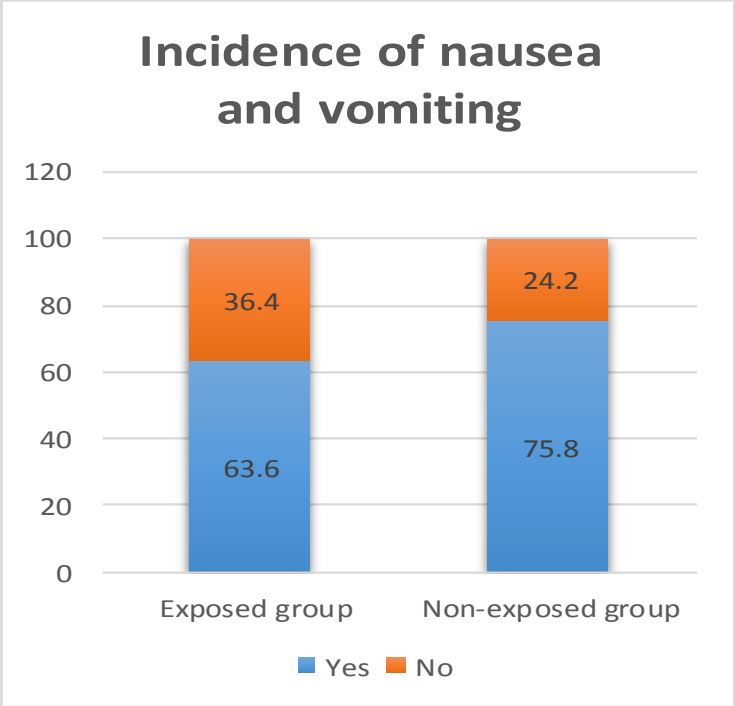


Figure 3: Incidence of nausea and vomiting between two groups

5.2 Discussion

Our study demonstrate the median (IQR) pain score were lower 3 (2-4) in exposed group compared to 5 (3-6) in non-exposed group with p value of 0.002 at immediate recovery room. The median NRS score at 3rd post-operative time is 2 (1-3) in exposed group is lower compared to 4 (3-5) in non-exposed group ($p<0.0001$). The median postoperative pain score were also lower at 6th, 12th and 24th post-operative time with statistically significant difference of <0.0001, 0.004 and <0.0001 respectively.

The result of this study is in line with study done in France showing the lower pain score in treatment group compared to the control group. This randomized controlled trial demonstrate the median (IQR) pain score in treatment group is 3 (0-10) and 5 (0-8) in control with placebo group respectively $p = 0.01$ (**Error! Bookmark not defined.**). The likely explanation for the similarity between two studies is the block were given immediately after induction of anesthesia in both studies. Though the later one uses ropivacaine 0.487%, we didn't notice a significant difference in the immediate recovery room (PACU) pain score difference due to difference in medication used.

Our study also shows comparable result with study done in India where pre-surgical and post-surgical BSCPB where compared with those without the block. The mean VAS score in the first 48 hours is 2.27 in BSCPB done presurgically compared to 4.19 on 0-10 VAS scale in control group $p<0.05$ (7).

In contrary to our study a randomized controlled trail done in turkey didn't shows analgesic efficacy of BSCPB done with 0.25% bupivacaine. The mean VAS score at first hour is 23 $\pm$19.3 in BSCPB group compared to 20.7 $\pm$ 13.3 in control group with 0-100 VAS scale ($p>0.05$) (33). The possible explanation for this contradictory result is difference in study design and pain management practice in study set up.

The proportions of patients who had NRS greater than 4 at any time during 24 hour is 40.9% in our study were majority of them 30.3% from control group and 10.6% are from BSCPB group with significant p value of 0.003. As shown by blinded controlled study by N. Dieudonne et al , the proportions of patient who require additional morphine in the recovery room is 69% were

39.1% of them are from placebo group and 29.9% from Bupivacaine group with a p value of 0.006. Though the same assessment tool NRS were used, adherence of patient to NRS between two populations may be attributed to proportion difference observed. In addition to this our study asses proportions of patient who had NRS greater than 4 within 24 hour compared to randomized study uses NRS >4 at recovery room where pain incidence is higher (26).

Our study demonstrate the total post-operative Tramadol consumption were lower in exposed group. The median (IQR) tramadol in mg where 0 (0-50) mg in exposed group compared to 100 (25-150) mg in non-exposed group p=0.001. Our finding is comparable with study done in Turkey which shows median tramadol consumption were lower in treatment group compared to control group, 0 (0-50) vs. 40 (0-180) mg respectively $p<0.05$ (47).

Though different drugs were used, study done in France reveals total postoperative morphine consumption in bupivacaine group is lower than that of control group with median (range) 6mg (2-39) compared to 12mg (2-39) respectively with p value of 0.013. Use of BSCPB before surgery decrease total tramadol consumption within 24 hour in our study compared with those without the block (0mg (0-50mg) Vs. 100mg (50-150mg) respectively with p-value of 0.001.Though our study use the weakest opioid, the opioid conversion factor of tramadol compared to morphine (0.1) estimate 100mg tramadol to 10mg morphine which is comparable and equi-analgesic, (26,48).

In contrary our finding study done in Turkey didn't demonstrate analgesic efficacy of BSCPB in terms of total analgesia consumption. The result shows no statistically significant difference between two groups regarding total PCA (440.1 ± 210.2 vs. 370.2 ± 250.8) in BSCPB and control group respectively with $p> 0.05$. Another study done in France also didn't found analgesic efficacy of BSCPB after thyroidectomy where a two point injection BSCPB given with 0.75% Ropivacaine didn't decrease morphine consumption within 36 hours (33, 26). The likely explanation for this contradictory finding is design difference and variability in Nurses response to pain request. Availability of resources or medication used to manage pain up on request also attributes to this difference observed at to set up.

We also observed the median (IQR) of total diclofenac consumption within 24 hours which is not statistically significant between treatment and control groups (75mg (0-75mg) vs. 75mg (0-

75mg) respectively (p= 0.775). We lack similar finding for comparison since most studies are using opioids as postoperative pain management protocol and controlling of analgesic agent achieved between groups. Thus, lack of standard postoperative pain management protocol in the study hospital were among the possible factor for the similarity of diclofenac consumption between exposed and non-exposed group.

With regard to time to first analgesia request our study showed significant difference between exposed and non-exposed group. The median (IQR) minute is 360 (190-720) vs. 180 (65-360) between exposed group and non-exposed group respectively (p = 0.006). The result is comparable with study done in Taiwan with median time in minutes of 410.1 9 (15-1050) minutes in treatment group with levobupivacaine, 360.8 (15-870) minutes in treatment group with bupivacaine 0.5% longer than the placebo group with NS 82.1 (15-259) minutes. The median time in minutes required for analgesia request were higher in Bupivacaine and Levobupivacaine group compared to saline having a significant p value of 0.0004 (29).

Our finding shows the overall incidence of nausea and vomiting after thyroid surgery in the first 24 hours to be 69.7%. This proportion is higher in the control group with incidence of 75.7% compared to 63.63% in the treatment group. Though there is a proportion difference, there is no statistical difference between two groups with regard to decreasing the incidence of nausea and vomiting in the first 24 hours (p= 0.422). This shows higher figures compared to study by Andrieu et al where the incidence of PONV is 36% (32).

The likely explanation for this incongruity is Andrieu et al used premedication with Hydroxyzine and use of propofol as standard induction agent which is known for their prophylaxis for nausea and vomiting.

6 Strength and Limitation

6.1 Limitation of the Study

The main limitation of this study were :

Lack of randomization and control.

Variability in the performance of the BSCPB since different anesthetist were involved. The success rate of the block were not assessed since it given after general anesthesia.

Pain severity were not assessed at movement.

Lack of standard pain management protocol in the study hospital.

Use of secondary data for preoperative and intraoperative variables were among limitation of this project.

Most studies we used for comparison were randomized control trial.

6.2 Strength

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

7 Conclusion and Recommendation

7.1 Conclusion

The result of our study demonstrate bilateral superficial cervical plexus block (BSCPB) performed after induction of anesthesia with 0.25% bupivacaine is an effective and useful postoperative analgesia.

7.2 Recommendation

We recommend that BSCPB done after induction of anesthesia for thyroid surgery is an effective post-operative analgesia.

We also recommend additional randomized controlled study.

References

1. David A. K. Watters and Jack Wall. Thyroid surgery in the tropics. ANZ J. Surg. 2007; 77: 933–940 Royal Australasian College of Surgeons.

2. DHS Ethiopia 2011, Final report Central Statistical Agency Addis Ababa, Ethiopia.

3. Kotisso B et al. Thyroid in Tikur Anbessa Hospital: a five year review. Ethiop.med journal. July 2004, 42(3):205-9.

4. Messele G and Tadesse B. Changes in pattern of thyroid surgical diseases in Zewditu Hospital. Ethiop Med J. 2003 Apr; 41(2):179-84.

5. Gozal Y, Shapira SC, Gozal D, Magora F. Bupivacaine wound infiltration in thyroid surgery reduces postoperative pain and opioid demand. Acta Anaesthesiol Scand 1994; 38: 813–5

6. Sonner JM et al . Nausea and vomiting following thyroid and parathyroid surgery. J Clin Anesth 1997; 9:398–402.

7. Kale S et al. Evaluation of the Analgesic Effect of Bilateral Superficial Cervical Plexus Block for Thyroid Surgery: A Comparison of Presurgical with Postsurgical Block. Indian J Surg December 2015, 77 (Suppl 3):S1196–S1200.

8. Hisham Negmi et al. The Influence of Bilateral Superficial Cervical Plexuses Block (BSCBs) as Pre-emptive Analgesia on Patient Satisfaction after Thyroid Surgery. Alexandria Journal of Anesthesia and Intensive Care- 8(4)11-17 December 2005.

9. Denise J et al. Nerve blocks; Ronold D. Miller; 7th edition Miller's Anesthesia; Churchill Livingstone; 2010.1664-1665.

10. Ban C.H Tsui and Richard W. Rosenquist. Peripheral Nerve Blockade: Paul G.Barash: 6th edition: Clinical Anaesthesia; Lippincott Williams & Wilkins; 2010.963-964.

11. Isaak Kesisoglou: superficial selective cervical plexus block following total thyroidectomy: a randomized trial, head & neck, August 2010: 984-988.

12. Roger D. et al .Superficial and deep cervical plexus block: Technical considerations. Journal of the American Association of Nurse Anesthetists June 1995/ Vol. 63/No. 3.

13. David L.B. Atlas of regional anesthesia. Illustrations by Jo Ann Clifford and Joanna Wild King.—4th ed.2010.p 179-79

14. Shih ML, et al. Bilateral superficial cervical plexus block combined with general anesthesia administered in thyroid operations. World J Surg. 2010; 34:2338–2343.

15. Porreca F and Ossipov MH. Nausea and vomiting side effects with opioid analgesics during treatment of chronic pain: mechanisms, implications, and management options. Pain Med 2009; 654-662.

16. Motamed C et al. Intraoperative i.v. morphine reduces pain scores and length of stay in the post anesthetic care unit after thyroidectomy. Br J Anaesth 2004; 93: 306–7.

17. Kanthan RK. The use of superficial cervical plexus block in oral and maxillofacial surgical practice as an alternative to general anesthesia in selective cases. Ann Maxillofac Surg 2016;6:48.

18. Navaid Akhtar and S. Akbar Abbas. Regional Anesthesia in Thyroid Surgery. Journal of the College of Physicians and Surgeons Pakistan 2014, Vol. 23 (12): 885-887.

19. DiNorcia J and Allendorf J. Thyroid surgery performed under local anesthesia and same day surgery. In: Mechanick JI, editor. Emergent biotechnological to clinical practice guidelines. New Delhi: CRC Press; 2011.p. 249-69.

20. IASP Pain Terminology. International Association for the Study of Pain Committee on Taxonomy. Washington DC, IASP, 2014. Available at: http:// www.iasp pain.org/Taxonomy#Pain [Last accessed 23 June 2015]

21. Sinatra R. Cause and consequences of inadequate management of acute pain. Pain med 2010; 11:1859-71.

22. Meissner et al. improving the management of post-operative acute pain: priorities for change. Current Medical Research & Opinion Volume 31, Number 11 November 2015.2131-2143,DOI:10.1185/03007995.2015.1092122.

23. Wheeler MH. The technique of thyroidectomy. J R Soc Med 1998; 91(Suppl 33): 12-16.

24 . Grant PS. Analgesia delivery in the ED. Am J Emerg M 2006;24:806-9

25. Nanthaprabu et al. Analgesic Efficacy of Ropivacaine With or Without Clonidine in Bilateral superficial Cervical Plexus Block in Thyroid Surgeries. Ann. Int. Med. Den. Res. 2016; 2(5):AN38-AN41

26. Dieudonne N et al. Prevention of postoperative pain after thyroid surgery: A double-blind randomize study of bilateral superficial cervical plexus blocks. Anesthesia Analg 2001 ;(92):1538-42.

27. Abd El-Rahman et al. Superficial and Deep Cervical Blockades Combined with General Anesthesia in Patients Undergoing Total Laryngectomy. KASR EL AINI MEDICAL JOURNAL VOL. 18, NO 4, October 2012 13.

28. Steffen T, et al. Randomized controlled trial of bilateral superficial cervical plexus block versus placebo in thyroid surgery. Br J Surg. 2010 Jul; 97(7):1000-6. Doi: 10.1002/bjs.7077.

29. Ming-Lang S. et al. Bilateral Superficial Cervical Plexus Block Combined with General Anesthesia Administered in Thyroid Operations. World J Surg (2010) 34:2338–2343.

30. Abrishami A, et al predictors of postoperative pain and analgesic consumption: a qualitative systematic review. Anesthesiology 2009, 111:657-77.

31. Ekstein MP and Weinbroum AA. Immediate postoperative pain in orthopedic patients is more intense and requires more analgesia than in post laparotomy patients. Pain med 2011;12:308-13

32 . Andrieu G, et al. Analgesic efficacy of bilateral superficial cervical plexus block administered before thyroid surgery under general anesthesia. Br J Anaesth. 2007 Oct; 99(4):561-6. Epub 2007 Aug 6.

33 Eti Z. et al. Does bilateral superficial cervical plexus block decrease analgesic requirement after thyroid surgery? Anesth Analg. 2006 Apr; 102: 1174-6.

34. Alexander herbland et al BSCPB with 0.75 ropivacaine before or after surgery did not reduce post-operative pain after thyroidectomy. Regional anesthesia and pain medicine. Vol 31 no 1. January –February, 2006: 34-39

35. Karthikeyan et al. Randomized Controlled Trial on the Efficacy of Bilateral Superficial Cervical Plexus Block in Thyroidectomy. Article in Pain Practice · December 2012 DOI: 10.1111/papr.12022 · Source: PubMed. Retrieved on: 31 July 2016.

36 . Kale S. et al. Evaluation of the Analgesic Effect of Bilateral Superficial Cervical Plexus Block for Thyroid Surgery: A Comparison of Presurgical with Postsurgical Block. Indian J Surg DOI 10.1007/s12262-015-1244-5.

37. Messner M, Albrecht S, Lang W, Sittl R, Dinkel M (2007) the superficial cervical plexus block for postoperative pain therapy in carotid surgery. A prospective randomized controlled trial. Eur JVasc Endovasc Surg 33(1):50–54

38 . Salwa M. et al. Efficacy of unilateral combined (superficial and deep) cervical plexus block as a preemptive analgesia for unilateral neck dissection surgery. Egyptian Journal of Anesthesia (2012) 28, 275–279.

39. P. Guduff et al. Chronic pain after thyroidectomy: Incidence, typology, risk factors.

40. C-Z LIN et al. Bilateral Superficial Cervical Plexus Block Reduces Postoperative Nausea and Vomiting and Early Postoperative Pain after Thyroidectomy. The Journal of International Medical Research 2012; 40: 1390 – 1398.

41. IK Kolawole & GA Rahman . Cervical plexus block for thyroidectomy, Southern African Journal of Anesthesia and Analgesia, 9:5, 2003:10-17

42. Santosh U.P et al. Thyroidectomy under cervical plexus block: An Otolaryngologists perspective. National Journal of Otorhinolaryngology and Head & Neck Surgery, Vol. 1(10) No. 1, April 2013.

43. Kanthan RK. The use of superficial cervical plexus block in oral and maxillofacial surgical practice as an alternative to general anesthesia in selective cases. Ann Maxillofacial Surg 2016; 6:48.

44. Martins Mamede 1, Helder Raful. Comparison between general anesthesia and superficial cervical plexus block in partial thyroidectomies. Rev Bras Otorrinolaringol 2008; 74(1):99-105.

45. McCaffery, M., Beebe, A., et al. (1989). Pain: Clinical manual for nursing practice, Mosby St. Louis, MO.

46. Isaak Kesisoglou et al: superficial selective cervical plexus block following total thyroidectomy: a randomized trial, head & neck 2009: 984-988

47 Ebru Çanakçı: Effect of bilateral superficial cervical block on postoperative analgesia in thyroid surgery performed under general anesthesia. Ege Journal of Medicine. 2015; 54(4):182-186.

48. Eastern Metropolitian Region Palliative Care Consortium (Victoria). Opioid conversion ratios-Guide to palliative care practice 2016. www.emrpcc.org.au.

Annex I

Information sheet to get permission for the research

Introduction

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

The research team includes MSc students, one senior advisor from AAU and two Nurses for data collection from Empress Zewditu Memorial Hospital.

Name of Principal investigator: - Zemedu Aweke (2nd year MSc Student)

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

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.

Tel: - +251912406236

E-mail:zemeduawoke@yahoo.com

Annex II

Consent form

Dear participant:

This is a research designed to assess effectiveness of Bilateral Superficial Cervical Plexus Block (BSCPB) as part of analgesia for postoperative time for thyroid patient under General anesthesia. As a chance you were included in the study. So, we kindly request your involvement in the study and honest response to achieve the objective of the study. Your response completely confidential and you have full right either to refuse a single question or leave the study. However, your honest response to those 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

Tel: - +251912406236
E-mail:zemeduawoke@yahoo.com

Annex III

የመጠይቅ ፈቃድ

የተከበራችሁ የጥናቱ ተካፋዮች

የዚህ ጥናት ዋና አላማ በ አድስ አበባ ጤና ቢሮ ስር በሚገኘዉ የዘዉድቱ መታሰቢያ ሆስፒታል ኦፐራሲዮን ክፍል ለአንገት እጢ እብጠት (thyroid goiter) ቀዶ ህክምና ለሚደረግላቸዉ ህሙማን ከጠቅላላ አነስቴዝያ በኋላ የሚሰጠዉን የላይኛዉ የአንገት ቆዳ ላይ ነርቮችን (superfacial cervical nerves)ለብቻ በማደንዘዝ ከኦፐራሲዮን በኋላ ህመም በምን ያህል እንደሚቀንስ ለማወቅ ነዉ።

በአጋጣሚ እርስዎም በዚህ ጥናት እንዲሳተፉ ተመርጠዋል። የዚህ ጥናት ጥቅም እርስዎ በሚሰጡት ምላሽ መሰረት መረጃዎችን በማማላት በሚገኘዉ ዉጤት መሰረት መረጃዎችን በማጠናቀር ውጤቱን እየተሰራበት ካለው ጋር ለማነጻጸር እንዲቻል ነዉ። ጥናቱ በትክክል አላማውን እንዲመታ የእርሶዎን ድጋፉ እንጠይቃለን።

የማንኛውም

ግለሰብ ስም አይመዘገብም እንዲሁም ሀሳቡ ብቻውን ይፋ እንዲዎጣ አይደረግም:: ሙሉ በሙሉ በሚስጥር የተጠበቀ ነው፡ በጥናቱ መሳተፍ አለመሳተፍ የራስዎ መብት ብቻ ነዉ። ግልፅ የሆነ ምላሽንና ከልብ የመነጨ ተሳትፎዎን እንዲሰጡን

በአክብሮት እንጠይቃለን።

ለመሳተፍ ፈቃደኛ ነዎት ሀ/ አዎ ፊርማ ---------- ለ/ አይደለሁም

ለመሳተፍ ፈቃደኛ ስለሆኑ እናመሰግናለን።

Annex IV

Pre-operative and intra-operative check list

Section I: Socio Demographic Data (chart review)

Card number:		**Bed no:**	**Code**
S.no	**Question**	**Response**	
101	Age		
103	ASA (I/II)	A. ASA I B. ASA II	
104	Sex (M/F)	A. Male B. Female	

Section II :Data during preoperative period

Ser. number	Question	Response	
201	Base line Heart rate	____bpm	
202	Base line Blood pressure(MAP)	____/____(____)mmhg	
203	Base line RR & spo2	_____br/m &_____%	
204	Diagnosis	_____	
205	Procedure:	_____	
206	Does the patient in Euthyroid state(chart review)?	1. YES 2. NO	
207	Does the patient is taking ant thyroid or b-blockers?	1.YES 2. NO	
208	If yes for the Q number 207 which one?	1. Methimazole 2. PTU 3. Propranolol	

209	Is the patient Pregnant?	1. YES 2.NO	
210	Does the patient has bleeding disorder or coagulations profile revealed abnormal?	1. YES 2. NO	
211	Does the patient have sub sternal goiter or identified to undergo lymph node dissection?	1. YES 2. NO	
212	Does the patient take premedication?	1. YES 2.NO	
213	If yes for the above question, what was the drug?	A. Diclofenac B. diazepam C. tramadol D. Paractamol E. pethedine F. morphine G. corticosteroid other ,specify_____	
214	Does the patient have any co morbidity?	1.yes 2.no If ,yes encircle/specify	A. Respiratory B. Cardio Vascular C. Renal D. Liver E. Diabetes Mellitus Other specify_____

Section III: Question related to anesthetic and surgical interventions

S.no	Question	Response	Code
301	Does the patient received any analgesic drug before Induction of Anesthesia?	1. YES 2. NO	
302	If YES specify type and dose	_____(____mg)	
303	Type of Induction agent	1. IV 2. Inhalational 3. Awake	
304	Induction agent type and dose	Thiopental ----------mg Propofol ----------mg Diazepam ----------mg Suxamethonium--------mg Vecuronium ----------mg Pancuronium----------mg	Halothane -------MAC Isoflurane --------MAC Sevoflurane ------MAC
305	Does Ketamine used as Induction agent?	1. YES 2. NO	
306	Time from BSCPB to skin incision in minutes		
306	Vital sign before skin incision	BP:_____mmhg PR:_____bpm Sao2_____%	
307	Vital sign after skin incision	BP:_____mmhg PR:_____bpm Sao2_____%	
308	Additional Intraoperative analgesia given	1. YES 2. NO	
309	If yes specify type, time and dose of the drug given	_____,_____mg	
310	Maintenance of Anesthesia	Halothane Isoflurane Pancronium_____mg Suxamethonium_____mg Vecoronium_____mg	
311	Does the patient extubated in the OR?	YES NO	
312	If yes is a patient responsive	YES NO	
	Experience of the surgeon	1. R3 2. R4 3. Senior	

323	Estimated intraoperative blood loss		
314	Duration of surgery		
315	Duration of anesthesia		

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

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

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

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

404. Does the patient have an episode of shivering within first 24 hours? A. YES B. NO

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

A. Arrived at _____pm/am {time per 24hr/date/month/ETH .year}
B. Analgesic required time _____PM/AM {time per24hr/date/month/Eth. year}
C. Duration till first analgesic request _____

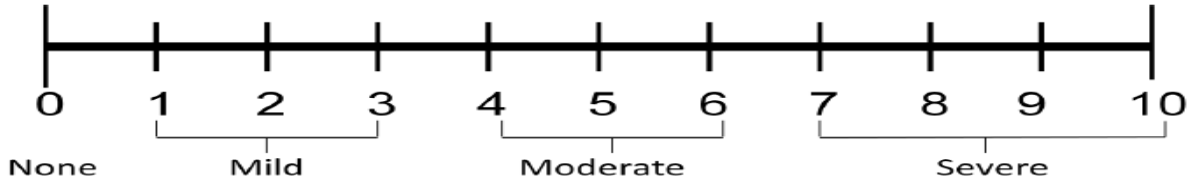
406. Total and type of analgesic consumption within 24 hours after the patient arrived in recovery/ward_____

407. Is patient re-operated within 24 hours? A. YES B. NO

Appendix

English version

The numeric Rating scale (NRS)



The scale will be taken 5 times within the first24 hours. Patients will be asked to rate their pain will be assessed and recorded at 0 min (immediately on acceptance of patient at recovery room) and 0-3, 3-6, 6-12,12-24 hours post-operatively.

The patient will be asked one of the following questions:

a. What number on a 0 to 10 scale would you give your pain right now?

b. When the explanation suggested above is not sufficient for the patient, further explanation or conceptualization of the scale will be done:

0 = No Pain

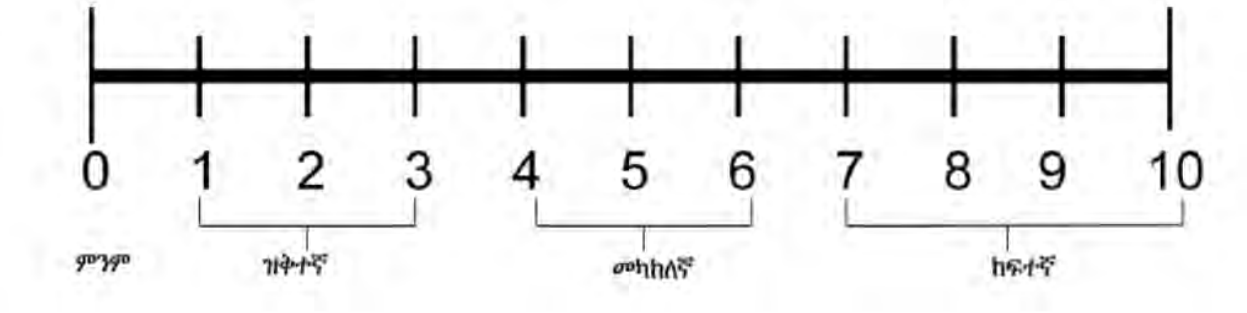
1-3 = Mild Pain (nagging, annoying, interfering little with ADLs)

4–6 = Moderate Pain (interferes significantly with ADLs)

7-10 Severe Pain (disabling; unable to perform ADLs)

አማርኛ ትርጉም

በቁጥር አምሳያ መለኪያ (VNRS)



1. ይህ መለኪያ በመጀመሪያዉ 24 ሰአት 5 ጊዜ የሚወሰድ ሲሆን.
    a. በሽተኛዉየሚጠየቃቸዉጥያቄዎች
        i. አሁንየሚሰማዎትንህመምበየትኛዉቁጥርይወክሉታል ;
        ii. ከዜሮእስከአስርካሉትቁጥሮችአሁንየሚሰማዎትንህመምየትኛዉቁጥርይገልፀዋል ;
2. ከላይየተሰጠዉማብራሪያበቂሳይሆንሲቀር፣ለበሽተኛዉየበለጠመረጃመስጠትአስፈላጊሆኖይገኛል
    a. 0- ምንምህመምየለም
    b. 1-3 - ትንሽህመምአለ
    c. 4-6 - መካከለኛህመምአለ
    d. 7-10 - ከባድህመምአለ