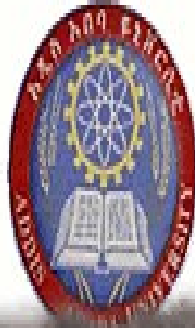


Addis Ababa  
University

(Since 1950)



A RESEARCH THESIS TO BE SUBMITTED TO DEPARTMENT OF  
ANESTHESIA COLLEGE OF HEALTH SCIENCES, ADDIS ABABA  
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THE MASTER DEGREE IN ANESTHESIA.

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Prospective, Institutional based cohort study on the effect of propofol versus thiopentone sodium as an induction agent on prevention of succinylcholine induced fasciculation and myalgia in adult elective surgical patient from january1,2018 to march 20,2018 G.C in Zewditu memorial hospital, Addis Ababa, Ethiopia.

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## *Abstract*

**Background:** - Succinylcholine is a commonly used short acting depolarizing muscle relaxant. It is a relaxant of choice when there is need for quick muscle relaxation of short duration. Though an excellent short acting depolarizing muscle relaxant of choice it still has inherent side effects like postoperative myalgia, muscular fasciculations, hyperkalemia, increase in intra ocular and intra gastric pressure. Out of them post-operative myalgia is the commonly encountered problem that commonly occur in the first 24 hours after succinylcholine administration

**Objectives.** To compare the effect of Propofol versus thiopentone sodium as induction agent on prevention of succinylcholine induced fasciculation and myalgia in adult elective surgical patient from january1,2018 to march 20,2018 G.C in Zewditu memorial Hospital, Addis Ababa, Ethiopia.

**Methods.** prospective, Institutional based cohort study design was conducted on all elective surgical patient who fulfill the inclusion criteria and induced with succinylcholine at Zewditu Memorial Hospital during specified study period. A patient who induced by propofol 3.0mg/kg was taken as Group propofol (n=40) and who induced with Thiopentone sodium 5mg/kg was taken as group thiopentone (n=40). Data was entered in to Epi info version 7 software by investigators and transported to SPSS version 20 statistics window for analysis. Differences of numerical data between groups have been evaluated using independent T-test. Categorical data has been analyzed with the Chi-Square test. A p value of <0.05 was considered as statistically significant.

**Results:** The demographic data of patients in two groups were comparable. The total incidence of succinylcholine induced fasciculation were 18(45%) and 28(70%) in propofol and thiopentone Groups respectively (P=0.007). The severity of fasciculation was reduced more in propofol group than in group thiopentone group (P=0.044). The total incidence of myalgia was 12(30%)

and 21(52.5%) in propofol group and thiopentone group respectively ( $P=0.048$ ). The severity of myalgia was reduced more in propofol group than thiopentone group ( $P=0.041$ ).

**Conclusion and recommendation:** Propofol in comparison with thiopentone sodium is effective in reducing the incidence and severity of fasciculation and myalgia. We recommended to use propofol to reduce succinylcholine induced fasciculation and myalgia which currently suffers our patients.

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## LISTS OF ACRONYM AND ABBREVIATION

ASA: -American society of Anesthesiologists

BMI: -body mass index

BSc: - Bachelor of science

FMOH: -federal ministry of health

GA: - General anesthesia

HGB: -hemoglobin

G.C: - Gregorian calendar

IM:- Intra muscular

IV: -intra venous

NDNMBA: -non-depolarizing neuromuscular blocking agent

NDA: - Non-depolarizing agent

NMBA: -neuromuscular blockade agents

NSAID: -non-steroidal anti-inflammatory drugs

POM: -post-operative myalgia

P: - Propofol

T: - Thiopentone

RSI: - Rapid sequence induction

SCH: -succinylcholine/Suxamethonium

SD: - Standard deviation

SPSS: -statistical package for social science

## CHAPTER ONE INTRODUCTION

### 1.1 BACKGROUND

Succinylcholine is still the accepted standard to facilitate tracheal intubation in developing country including our country specially in rapid sequence induction, despite the recent introduction of short acting nondepolarizing neuromuscular blockers. Fasciculations during induction and post-operative myalgia are unpleasant consequence of the use of succinylcholine which is not acceptable in today anesthesia practice. It may be a source of greater distress to the patient than the surgical wound pain (23). Incidence and severity of fasciculations and myalgia vary widely. The postoperative myalgia is generalized aches and pains that commonly occur at the first 24 hours after succinylcholine administration that mimic the muscular pains which is usually following violent exercise (23). It has been postulated that the muscle pain is secondary to the damage produced in the skeletal muscle by the unsynchronized contraction of adjacent muscle fibers just before paralysis occurs (1). The incidence is variable (20 to 80 percent of patients receiving succinylcholine) and are more common in young, ambulatory patients (19).

The exact mechanism is not known but stimulation of presynaptic acetylcholine receptors and contraction of intrafusal fibers of muscle spindles may contribute. It has been suggested that the underlying mechanism of muscle damage associated with administration of Succinylcholine may involve calcium-induced phospholipids degradation with release of damaging products of fatty acid metabolism (28). Different pretreatment modalities have been advocated to reduce the incidence and severity of fasciculation and myalgia including non-depolarizing neuromuscular blockage(10), intravenous lidocaine(25) nonsteroidal anti-inflammatory drugs(NSAIDs)(17) etc. but all of them come with variable success, except the one pretreatment with small dose of NDNMB which is effective methods, but it is associated with blurred vision, diplopia, and difficult in breathing and higher doses of succinylcholine is needed to obtain optimal intubating conditions which leads to a longer recovery and apnea period. Cost and availability may also limit its usage especially in developing country.

Various drugs have been reported to exhibit some antioxidant activity in vitro (27) whereas Propofol has further been shown to have the ability to form stable radicals and to inhibit the propagation of reactions involving free radicals in experimental animals and man (24&26). Even though a lot of researchers try to alleviate this problem they come with different result and other

intolerable side effects (29-30), so that is why we eager to underwent this study to compare the effect of propofol versus thiopentone sodium as an induction agent on prevention of succinylcholine induced fasciculation and myalgia.

## 1.2. STATEMENT OF THE PROBLEM.

Succinylcholine is accepted as the drug of choice for providing ideal intubating conditions and also for rapid sequence induction. However, its usefulness is limited by the frequent occurrence of post-operative myalgia and rise in biochemical markers including serum creatine kinase and potassium to increased intra cranial pressure, intra ocular pressure and emesis with aspiration (11).

Fasciculation may be observed in 95% of patients, but the incidence of myalgia at 24 hours is about 50% following use of succinylcholine (18). It is generally agreed that post-operative myalgia is unacceptably high in modern anesthesia practice (23). The duration of the discomfort is highly variable. It usually appears on the first day after surgery and lasts for 2 or 3 days but occasionally persists for as long as a week and it is most commonly described as the pain one might suffer after an unaccustomed degree of physical exercise and is usually affecting more than one site of our body that causing disability or limiting activities and difficulty on getting out of bed or turning head which occurs always in the neck, shoulder and upper abdominal muscles (21).

The pathophysiology of succinylcholine induced myalgia is poorly understood, that is why there is no standard treatment available for this complication. Even though there is no published study and document that explain the experience of our country specifically, the severity and incidence of succinylcholine induced fasciculation and postoperative myalgia is almost similarly suffered by our patient more than surgical site pain as our country commonly uses this drug for induction to facilitate tracheal intubation.

Nondepolarizing agents circumvent most of these problems, but none has the same pharmacokinetic profile as succinylcholine. Rocuronium and rapacuronium come closer, but both have longer lasting effects than succinylcholine and so they could not replace this drug because of their longer lasting effects that delay patient in apnea (23). Different pretreatment modalities have been advocated to reduce the incidence and severity of fasciculation and myalgia including non-depolarizing neuromuscular blockage (10) intravenous lidocaine (25) nonsteroidal anti-inflammatory drugs (NSAIDs (17) etc. But all of them come with variable success, except the one pretreatment with small dose of non-depolarizing neuromuscular blockage which is

effective methods, but it is associated with blurred vision, diplopia, and difficulty in breathing and higher doses of succinylcholine is needed to obtain optimal intubating conditions which leads to a longer recovery and apnea period. Cost and availability may also limit its usage especially in developing country. In clinical practice, Propofol has produced conflicting results when administered for the prevention of postoperative myalgia. McClymont (30) found a lower incidence of succinylcholine-induced myalgia in a Propofol group while other study which was done in India in 2014 by using prospective randomized double-blind study stated that a single dose of the drug was not similarly effective (29). This indicates that even though a lot of researchers try to alleviate this problem they come up with different result and other intolerable side effects. that is why it persist in the world in such a challenging way.

### 1.3 SIGNIFICANCY OF THE STUDY

Propofol was produce conflicting results when administered for the prevention of postoperative myalgia, most researcher found a lower incidence of succinylcholine-induced myalgia when induced with Propofol while other studies have found that a single dose of the drug was not similarly effective (29-30). So, the aim of our study is to prove this conflicting result.

This study has significance for our anesthetist who use succinylcholine routinely.

This study has provided rational and evidence-based case specific practical frame work that reduce the incidence of postoperative myalgia and fasciculation.

This study being used as bull's eye in identification of what has been done and what should be corrected to prevent or reduce fasciculation and postoperative myalgia which is taken as source of greater distress to the patient than surgical site wound.

This study has make our patient more beneficiary by alleviating postoperative myalgia which suffers them post-operatively and also decrease postoperative analgesic consumption.

In addition, hopefully, this study will be used as a footstep for next studies to be done on similar problems.

## CHAPTER TWO

### 2.1 LITERATURE REVIEW

Study done in Katihal medical college, Katihar, Bihar on 60 patients in two groups which is randomly allocated in Group-1 whose 40mg/kg magnesium sulphate in 10ml volume pretreatment was given and Group-2 which is placebo group that take equal volume isotonic saline was given, after observation the overall incidence of muscle fasciculation was 66.7% in G-1 against 100% in G-2. (2)

According to study conducted in Kurdistan University of Medical Sciences, Santer in Iran by using randomized double-blind study on 143 patients, who were received 0.5 mg/kg of ketamine and the same volume (5ml) of normal saline). Overall, the incidence of POM in Group K was significantly less, when compared with Group N ( $P < 0.05$ ), but both groups were comparable based on the grade 2 of POM. Result shows (18.1%) of patients in ketamine group had myalgia, whereas in none pretreated group (50%) of patients had myalgia. Grade 1 POM was lower in Group K when compared with Group N (nine in Group K versus 33 in Group N, whereas the incidence of grade 2 POM was comparable among patients of the two groups (3).

Study conducted in Dayanand medical college and hospital, India in 90 patients who were randomly allocated into three groups of 30 patients each: Anesthesia was induced with intravenous injection propofol 2 mg/kg over 60 s followed by injection of succinylcholine 1.5 mg/kg in all study groups. Immediately after giving succinylcholine they started to repeating bolus dose as follows; no dose of propofol in Group I, repeat dose of 0.5 mg/kg propofol in Group II, and repeat dose of 1.0 mg/kg propofol in Group III showed that 66.7% patients in group 3 (who received repeated bolus dose of 1 gm Propofol) was showed 0 grade fasciculation's, in this group, immediately after shifting the patient to the postoperative care unit, 93.3% did not have myalgia (grade 1) and none of the patients ever had grade 3 (moderate) or grade 4 (severe) myalgia. (4)

According to the study conducted in Hanyang University School of Medicine, Seoul, Korea to determine optimal dose of Rocuronium to prevent succinylcholine-induced fasciculation and myalgia on one hundred patients by dividing into five groups. Twenty patients were allocated randomly to each pretreatment group: 0.02 mg/kg Rocuronium (Group 0.02), 0.03 mg/kg

Rocuronium (Group 0.03), 0.04 mg/kg Rocuronium (Group 0.04), 0.05 mg/kg Rocuronium (Group 0.05) and 0.06 mg/kg Rocuronium (Group 0.06). On postoperative day 1, the incidence and severity of myalgia were Group 0.02 (n = 20), 9 (45), Group 0.03 (n = 20), 7 (35), Group 0.04 (n = 20), 4 (20), Group 0.05 (n =20) 4 (20), Group 0.06 (n = 20) ,2(10) respectively (5)

In study done in Gujarat, India on 99 patients who allocated randomly into three equal groups in which group “T” (induced with 5mg/kg thiopentone), group “p1” (induced by 2.5mg/kg Propofol) and group “p2” (induced with 3.5mg/kg Propofol) by using prospective, randomized, controlled clinical study stated that the total incidence of fasciculations were 25(75.76%),16(48.48%)& 26(78.79%) in group p1, p2&T respectively( $p<0.001$ ). Total score of fasciculation was 44(44.44%),22(22.22%)& 53(53.54%) in group p1, p2&T respectively and severity of fasciculation was reduced more in group” p2” than the two. The total incidence of myalgia was 19(57.57%),10(30.3%)&23(69.7%) in group p1, p2&T respectively ( $p<0.001$  as well as indicate that as there is no any correlation between fasciculation and myalgia and explain that the incidence of hypotension after administration of those agent was comparable in all groups (6).

Study conducted on sixty patients undergoing direct laryngoscope at Hacettepe University, Ankara, Turkey between January and March 2010 to assess Effects of dexmedetomidine on succinylcholine-induced myalgia in the early postoperative period result showed in group D, only one patient suffered from mild myalgia, and 29 patients had no myalgia. In group C, 10 patients suffered from mild myalgia, and 20 patients had no myalgia. The incidence and severity of myalgia were significantly higher in group C ( $p=0.014$ ) (7).

Study conducted in army medical college in Pakistan in 60 patients result shows pretreated by 0.5mg/ kg Rocuronium 18 (60 percent) patients had moderate myalgia and pretreated by 0.1mg/kg Rocuronium and 1.5mg/kg Suxamethonium the result 16 (53.3 percent) patients had mild myalgia; moderate myalgia was observed in 3(10 percent) patients while no myalgia was observed in 11 (36.7 percent) patients (8).

A research conducted in institute of liver& biliary science, New Delhi, India on 76 patients who assigned into two groups group-1(gabapentin group) patients received 600mg gabapentin 2hrs before induction, group-2(placebo group) patients received matching placebo at the same time by using double blind placebo control study. The anesthesia was induced with thiopentone 3-

5mg/kg, fentanyl 3µg/kg and succinylcholine 1.5mg/kg and fasciculation were evaluated by a blinded observer and were graded accordingly. Anesthesia was maintained similarly in both groups; the result of the study was stated that group-1 patients had significantly lower incidence of myalgia. In group-1, 15 out of 35 had myalgia whereas 24 patients out of 35 had myalgia in placebo group. The severity of myalgia was also less in group-1 compared to group-2 and there was no grade-2 myalgia in both groups. This study had not demonstrated any significant change in incidence of fasciculation between the groups (9).

A research conducted in university of Tehran, Iran on 79 patient who randomly assigned into three groups group-1(n=26) received placebo, group-2(n=27) received 0.03mg/kg atracurium & group-3(n=26) received 5mg succinylcholine, 90 seconds after pretreatment 4mg/kg thiopentone was administered followed by 1.5mg/kg succinylcholine & observed for fasciculation, the result stated that 3.8% of the patients had no fasciculation in group-1 while 30.8%, 53.8% & 11.5% of the patients had mild, moderate and vigorous fasciculation respectively in this group. In group-2 74.1% had no fasciculation & 25.9% had mild fasciculation, in group-3 23.1% had no fasciculation, while 42.3%, 3.8% & 3.8% of the patients had mild, moderate & vigorous fasciculation respectively (11).

According to study conducted in Kurdistan University of medical science, Sanandaj, Iran on 60 adults who randomly allocated to two groups of each 30 patients, G-1 (Remifentanyl group) were pretreated with 1µg/kg remifentanyl one minutes prior to induction of anesthesia, while G-2 (saline group) received an equivalent volume of saline. Anesthesia was induced in both groups with fentanyl 1µg/kg, propofol 2mg/kg, succinylcholine 1.5mg/kg and the result stated that duration of fasciculation was slightly lower in remifentanyl group, however the severity of fasciculation was not different (12).

According to study conducted at Tehran, Iran, Farabi eye hospital the incidence and severity of myalgia and change in creatine kinase levels were evaluated following administration of 1mg/kg of Succinylcholine either immediately or 2 min after induction of anesthesia with Propofol or Thiopentone in patients undergoing elective dental and ophthalmic surgery. In patients induced with Propofol, the incidence of myalgia was 35 and 60% when Succinylcholine is given immediately and after 2 min respectively. In patients induced with Thiopentone the incidence of myalgia was 35 and 55% when Succinylcholine is given immediately and after 2 min. There

were no statistically significant differences among the groups. Creatine kinase levels increased in both the groups after the operative procedure with the least average increase in the group receiving Succinylcholine immediately after Propofol and the highest increase in the group receiving Succinylcholine 2 min after Thiopentone. There was no statistically significant correlation between the incidence and severity of muscle fasciculations, myalgia and changes in creatine kinase within or between the groups (14).

According to Shoroghi, Mehrdad who try to investigate on effect of thiopentone on severity and duration of succinylcholine induced fasciculation on 300 patients ASA I&II to two groups who received intravenous succinylcholine immediately and 30 seconds after thiopental injection respectively. After premedication and induction of anesthesia, the severity and duration of fasciculation is observed. In the group using succinylcholine immediately after thiopentone injection, the onset of fasciculation was earlier( $p=0.0006$ ) & duration of fasciculation was shorter( $p=0.0002$ ) than another group. In addition, moderate to severe fasciculation was found more in the group using succinylcholine 30 seconds after thiopentone injection( $p=0.038$ ) (15).

A study conducted in Tehran University of medical science, Tehran, Iran on 126 patients who randomly allocated into two groups by using prospective, randomized, double blinded, placebo control study, in group-1 diclofenac patch (diclofenac epilamine patch) was applied to the posterior skin of the neck 30 minutes before induction& in group-2 placebo (which is indistinguishable from the diclofenac patch was at the same time and site. Patch were removed 12hrs later. In both groups, complains of myalgia were in the neck or shoulder muscle or both. No distal limb or trunk myalgia was detected, myalgia score was compared between the two groups, myalgia incidence& severity were significantly lower in diclofenac group in comparison with placebo group (16).

Study conducted in Iran referral Hospital shows that incidences of myalgia after pretreated with diclofenac at 12, 24 and 48 hours after operation were 23.8%, 19.1%, and 12.7% respectively versus incidences of 52.4%, 47.6%, and 44.4% respectively in placebo pretreated group. The incidence and severity of myalgia were significantly lower in patients receiving diclofenac through three evaluation periods (17).

According to study conducted in Ludhiana, Punjab, India on 120 adult patients in two groups, in which G-V patient was given vecuronium 0.01mg/kg & G-R 0.06mg/kg of rocuronium

intravenously 60 seconds before administration of thiopental followed by succinylcholine. In group- R 57 patients did not have myalgia, 3 patients had mild myalgia and none of the patient had moderate and severe myalgia & 29 patients in group-V and 41 patients in group-R did not have fasciculation. 26 patient had mild fasciculation and 5 patient moderate fasciculation in group-V, and 19 patients had mild fasciculation and none of the patients had moderate fasciculation in group-R. This showed that fasciculation seen after succinylcholine were significantly less in group -R than group-V even though there was no statistically significance in myalgia (18).

According to study conducted in America by American society of Anesthesiologists, 2005 for Fifty-two randomized trials (5,318 patients) and the magnitude of myalgia at 24 h was 50%(19).

A study conducted in Bangkok, Thailand on 135 patients who allocated randomly into three groups, group- PS (the control group who received normal saline), group-LS (who received 1.5mg/kg lidocaine intravenous) and group-PR (who received 0.6mg/kg rocuronium). Anesthesia was induced with thiopentone 5mg/kg followed by 1.5mg/kg succinylcholine in group PR&LS or rocuronium 0.6mg/kg in group-PR for tracheal intubation, following administration of those drugs presence and severity of fasciculation was observed by one investigator and result stated that the incidence of muscle fasciculation was lower in LS group compared to PS and there is no fasciculation in PR group. At 24hrs, 60% of the patients in group PS had myalgia compared with 48.9% in group-LS and 31.1% in group-PR. The difference between control group & other two groups was statistically significant( $p < 0.05$ ) and the incidence of myalgia was lower in group-PR than group-PS&LS (21).

In study conducted in Dicle University Hospital, Diyarbakir, Turkey in 90 patients who have received, Thiopental 5mg/kg, propofol 2mg/kg in and propofol 3.5 mg/kg the result shows that 38% patient was complain mild to moderate pain, (40% patients complain mild and 30 % patients was complain moderate pain) and 20% patients complain mild and 10 % patients was complain moderate pain respectively and none of the group did complain severe myalgia (22).

Study done in Loamina, Greece on 50 patients in two groups who allocated randomly with identical induction of anesthesia in which Group-1 maintained with 66% nitrous oxide in oxygen supplemented with isoflurane 1%. In the Group-2 along with nitrous oxide in oxygen, Propofol was infused intravenously at a dose of 10mg/kg/hr. Fentanyl and vecuronium were administered

in both groups as needed, stated that no statistically significant correlation was found between fasciculation and myalgia or creatine kinase among all patients or patients in each group. The myalgia score was (median,25-75<sup>th</sup> percentile) 2(0.5-2) in the isoflurane & 1(0-1) in the continuous Propofol infusion group (24).

As we had seen from those literature due to unknown pathology of succinylcholine induced myalgia various medications including non-depolarizing muscle relaxant (5,8,11,18,21), magnesium sulphate (2), ketamine (3), propofol (4,6,14,22), thiopentone (6,14,15,22), dexmedetomidine (7), gabapentin (9), remifentanil (12), lidocaine (25), diclofenac (17) and others had been tested with varying degree of success.

### 2.3 Conceptual frame work.

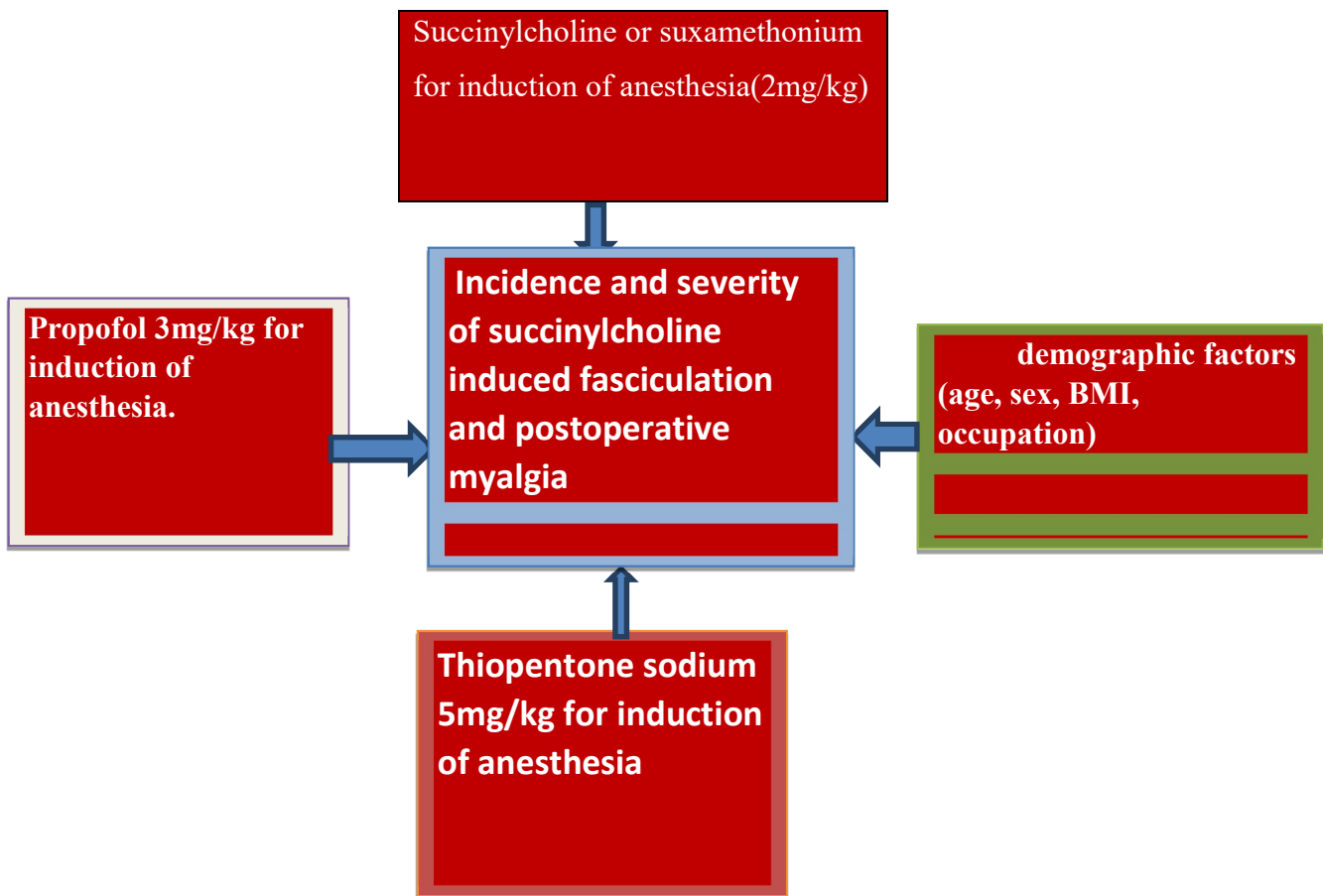


Figure 1: Conceptual frame work. (Adopted from: -22,4 and 6)

## CHAPTER THREE: - OBJECTIVES

### 3.1 GENERAL OBJECTIVES.

To compare the effect of Propofol versus thiopentone sodium as induction agent on prevention of succinylcholine induced fasciculation and myalgia in adult elective surgical patients from january1,2018 to march 20,2018 G.C in Zewditu memorial Hospital, Addis Ababa, Ethiopia.

### 3.2 SPECIFIC OBJECTIVES

To determine incidence and severity of fasciculation on patients who were underwent elective surgical procedure by using propofol versus thiopentone sodium as an induction agent.

To determine incidence and severity of myalgia on patients who were underwent elective surgical procedure by using propofol versus thiopentone sodium as an induction agent.

## CHAPTER FOUR: - METHODOLOGY

### 4.1 Study Area and period.

This study has been carried out at Zewditu memorial hospital which is located in the capital city of our country Addis Ababa, Ethiopia. The Hospital is one of the governmental Hospitals in Addis Ababa city administration, and gives services for specialty of gynecology and obstetrics, neurosurgery, general surgery, internal medicine and pediatrics. It has five operation theatres two post anesthesia care unit and the study have been carried out from January 1, 2018 to March 20, 2018G.C.

4.2 Study design. Prospective, Institutional based cohort study.

### 4.3 population

4.3.1 Source Population. All adult elective surgical patients who underwent surgical procedures under general anesthesia with the use of succinylcholine in Zewditu memorial Hospital, Addis Ababa Ethiopia, 2018 G.C.

4.3.2 Study population. All adult elective surgical patients who underwent surgical procedures under general anesthesia with the use of succinylcholine in Zewditu memorial Hospital who meet inclusion criteria during the study period.

## 4.4 ELIGIBILITY CRITERIA

### 4.4.1 Inclusion criteria: -

- 1) Patients aged between 18 to 60 years (23)
- 2) Patients belonging to ASA Class I and Class II
- 3) BMI below 35kg/m<sup>2</sup>(13)

### 4.4.2 Exclusion criteria:

- 1) Patients with pre-existing musculoskeletal disorders
- 2) Precurarization
- 3) Subjects who had received analgesics within 24 h before scheduled surgery
- 4) Patients receiving sedatives other than those determined by the study protocol
- 5) Patients who are hypersensitive to any of the drugs in the study
- 6) Pregnant mother (31)
- 7) Patient with history of drug abuse

- 8) Patient with history of burn more than 48hrs and less than six months and massive trauma.

#### 4.5 Sampling technique and sample size determination

##### 4.5.1 Sample Size determination

Sample size for study was calculated using double population proportion formula for comparison of two proportions based on the following assumptions: - significance level 5% ( $\alpha=0.05$ ), power of study ( $1-\beta$ ) of 80%. In one study done in India the incidence of fasciculation with Propofol and thiopentone were 48.48% and 78.79% respectively (6). Taking this into consideration, the calculation of sample size has been:  $n$  (in each region) =  $(p_1q_1 + p_2q_2) (f(\alpha, \beta)) / ((p_1 - p_2)^2)$

$n = (0.4848*0.5152 + 0.7879*0.2121) (1.96*0.84)^2 / (0.4848 - 0.7879)^2 = 36$  in each group. By adding 10% of total sample size as a contingency the sample size in each group has been ( $n=40$ ).

$P_1$  = incidence of fasciculation in Propofol group

$P_2$  = incidence of fasciculation in thiopentone group

$q_1 = 1 - p_1$

$q_2 = 1 - p_2$

$\alpha$  = significance level (1.96)

$1 - \beta$  = power of study at 80% (0.84)

**4.5.2 Sampling technique:** Systematic random sampling was used to select study participants. The daily operation schedule list was used as a sampling frame. The situational analysis showed that 28 patients who fulfill our inclusion criteria were operated in Zewditu Memorial Hospital per week that got from surgery logbook record; according to this data we were had 224 patients in our study period from whom we collected data from only 80 patients. So, sampling interval ( $k$ ) was calculated as  $K = N/n = 224/80$ , approximately 3, where  $N$  = total study population,  $n$  = total sample size. The first participant was selected randomly using lottery method. Then, every three patients were included in this study from the daily operation schedule list until the required sample size was met and grouped after induction agent given by anesthetist.

- $n$  = total sample population

- N=total study population
- K=skip interval

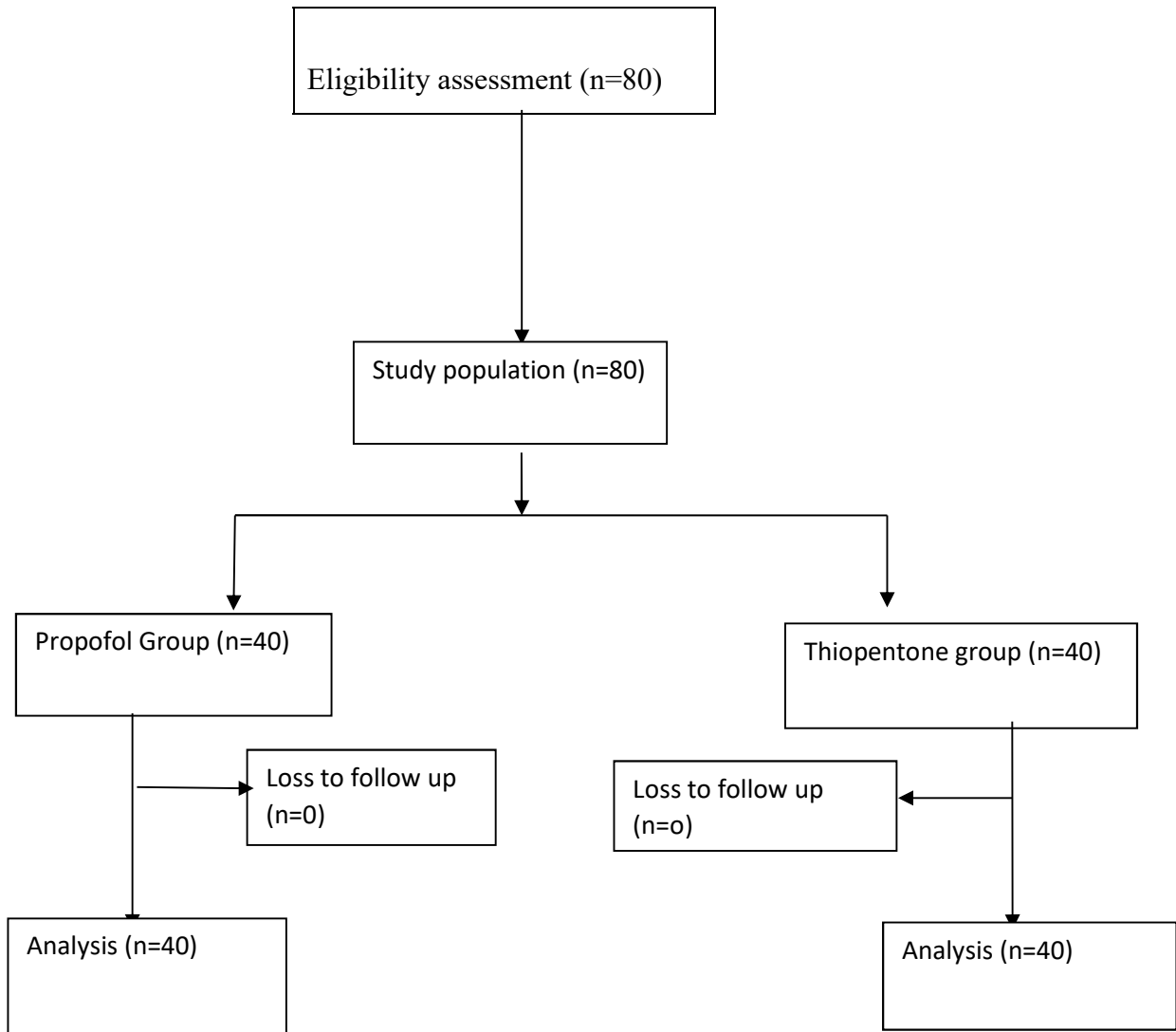


Figure 2: A study flowchart for enrolment of patients who underwent elective surgery under general anesthesia with succinylcholine at Zewditu Memorial Hospital, from January 1, to March 20, 2018.

#### 4.6 Study variables

4.6.1 Dependent Variables: Succinylcholine induced fasciculation and post-operative myalgia.

4.6.2. Independent Variables.

- Age
- Sex

-occupation

- Body mass index(BMI)

- ASA physical status

Types of diagnosis

Types of procedure

Succinylcholine

Propofol

Thiopentone sodium

**4.7 Methods of Data Collection:** - questionnaires and Check list were prepared in English and Amharic which includes demographic data, patients ASA class, types of diagnosis, types of procedure, type and dose of induction agent used, type and dose of muscle relaxant used for intubation and maintenance. Our questioner was including incidence and severity of fasciculation and post-operative myalgia. Data collectors who was trained on how to grade fasciculation and myalgia has been observe the fasciculation and interviewed the patients for post-operative myalgia. Data was collected by two BSc anesthetist intra-operatively for fasciculation observation and by two BSc nurses post-operatively for myalgia and supervised by principal investigator. Regular supervision and follow up was made.

#### 4.7.1. ETHICAL CONSIDERATION.

The study was conducted after obtaining ethical approval from Addis Ababa University, department of anesthesia ethical committee. After the permission from department ethical committee, Official letter has been submitted to the Addis Ababa health bureau, and then the letter of recommendation was obtained and distributed to Zewditu Memorial Hospital.

The purpose of the study has been explained to the patient and family of patients under the study to smooth postoperative interview and written informed consent was obtained by staff anesthetist as usual from family or legal attendants of each patient. Name and other identifying information have not been used in the study. Demographic data including age, weight, height, gender and

ASA status have been recorded and Confidentiality of the information was assured by using code numbers than personal identification names and keeping questionnaires locked.

#### 4.8 Data Quality Control and Assurance.

To ensure quality of data, pre-test of the questionnaire have been performed on 5% of study populations who fulfil the inclusion criteria at Tikur Anbessa specialized Hospital. The completed questionnaire has been submitted and reviewed daily to avoid loss of data. Close supervision and daily information exchange including by telephone has been used as a means to correct problems during the course of the data collection. Consent for the postoperative survey was obtained and confidentiality have been assured to improve the quality of data. Data consistency and completeness have been made throughout the data collection, data entry and analysis.

#### 4.9 Data processes sing and analysis

The data was entered on epi info version 7 and was exported to SPSS version 20 statistics software for analysis. The principal investigator was performed data entry and cleaning. Normality of the distribution of data was tested by using the Shapiro-wilk test ( $p > 0.05$  considered as normally distributed). Descriptive statistics was used to summarize data, tables and figures for display results. We summarized data as mean  $\pm$  SD or Number (percentage). Equality of variances was checked by using Levene's F test (sig value  $> 0.05$  considered as equal variance assumed). Differences of numerical data between groups have been evaluated using independent T-test. Categorical data have been analyzed with the Chi-Square test. A p value of  $< 0.05$  has been considered as statistically significant.

**4.10 Dissemination plan.** Copies of the research will be disseminated to college of health science, school of medicine/department of anesthesia, Zewditu memorial Hospital, Addis Ababa University student research office, Ethiopian Association of Anesthetists, Ethiopian ministry of health. Finally, it will send to national and international journal publishers for publication.

#### 4.11 Operational definitions.

ASAI: - A normal health patient

ASAI: - A patient with mild systemic diseases

Fasciculation: -diffuse uncoordinated muscle contractions seen after intravenous administration Succinylcholine.

Grade 0 fasciculation (Nil): - no visible fasciculation

Grade 1(mild): - Fine Fasciculation of the eyes, face, neck, fingers without movement of limbs

Grade 2(moderate): - Fasciculation of greater intensity at more than two sites or movement of limbs

Grade 3(severe) fasciculation: - Vigorous sustained and widespread Fasciculation

Induction agent: -the first anesthetic agent that result loss of consciousness.

Myalgia: -generalized aches and pains that commonly occur until 24 hours after succinylcholine administration.

Nil: - No muscle pain or stiffness

Mild myalgia: -muscle pain or muscle stiffness at one site but not causing disability or limiting activities.

Moderate myalgia: -muscle pain or muscle stiffness at one or more site but not causing disability or limiting activities.

Severe myalgia: -muscle pain or stiffness at one or more site and causing disabilities or limiting Activity, causing inability to cough without distress and requiring analgesic therapy.

Pretreatment: -administration of any drugs that will use for different purpose intraoperatively.

Repeated dose: -administration of a given drug more than ones.

Precurarization: -administration of a small dose of a non-depolarizing neuromuscular blocking agent (NDMBA) a few minutes before SCH.

Incidence and severity of succinylcholine induced fasciculation and post-operative myalgia was adopted from (22).

## CHAPTER FIVE: - RESULT

### Demographic characteristics of the patients

Total 80 adult elective surgical patients were involved in this research and the mean age of the patients was  $42.8 \pm 10.52$  and  $42.05 \pm 11.195$  in “P” and” T” groups respectively. Among the participant 31(38.8%) and 17(21.3%) were labor workers and civil servant in ‘P’ and ‘T’ groups respectively. The majority of diagnosis was cholelithiasis that account 35(43.8%) of all diagnosis that followed by goiter. From the participant 12(30%) was males and 28(70%) were females in P group and 10(25%) was males and 30(75%) was females in T groups ( $p=0.617$ ). Among the participant 34(85%) was ASAI and 6(15%) was ASAI in P group and 31(77.5%) was ASAI and 9(22.5%) was ASAI in T group ( $p=0.393$ ). (for detail see table 1 below).

*Table 1: Distribution of demographic characteristics of patients who were underwent elective surgical procedures from january1,2018 to march 20,2018 G.C in Zewditu memorial Hospital.*

Variables	Propofol group (n=40) (Mean $\pm$ SD)	Thiopentone group (n=40) (Mean $\pm$ SD)	p-value
Age	$42.8 \pm 10.52$	$42.05 \pm 11.195$	0.758
Weight	$61.25 \pm 8.962$	$61.9 \pm 11.21$	0.734
Height	$1.675 \pm 0.0579$	$1.675 \pm 0.0543$	0.953
BMI	$21.788 \pm 3.180$	$22.08 \pm 3.979$	0.712

*Notes: - Data are presented as mean and standard deviation by using independent t-test*

### Intra operative data

Among those 13(32.5%) experience mild fasciculation, five (12.5%) experience moderate fasciculation and there was no severe fasciculation experienced in ‘P’ Group and 15(37.5%) experience mild fasciculation, 10(25%) experience moderate fasciculation and three (7.5%) experience severe fasciculation in “T” Group. The severity of fasciculation has difference between propofol group and thiopentone group( $P=0.007$ ). Among those 46(57.7%) patient who experienced fasciculation 15(68%) was male and 31(53%) was female. The incidence of succinylcholine induced fasciculation has a difference between female and male ( $P=0.053$ ). Among those participants who developed fasciculation 31(67.39%) and six (13%) were labor workers and civil servant respectively. Revealed that the incidence of succinylcholine induced

fasciculation has a difference among those ( $P=0.138$ ). Among those participants who developed succinylcholine induced fasciculation 35(53.85) and 11(73.33%) were ASAI and ASAII respectively. The incidence of succinylcholine induced fasciculation has a difference between ASAI and ASAII ( $P=0.071$ ). Of the participants who developed succinylcholine induced fasciculation eight (72.72%) were under weight, 32(57.14%) were in normal range and six (54.54%) were overweight in their BMI respectively( $p=0.055$ ). (for detail see table3)

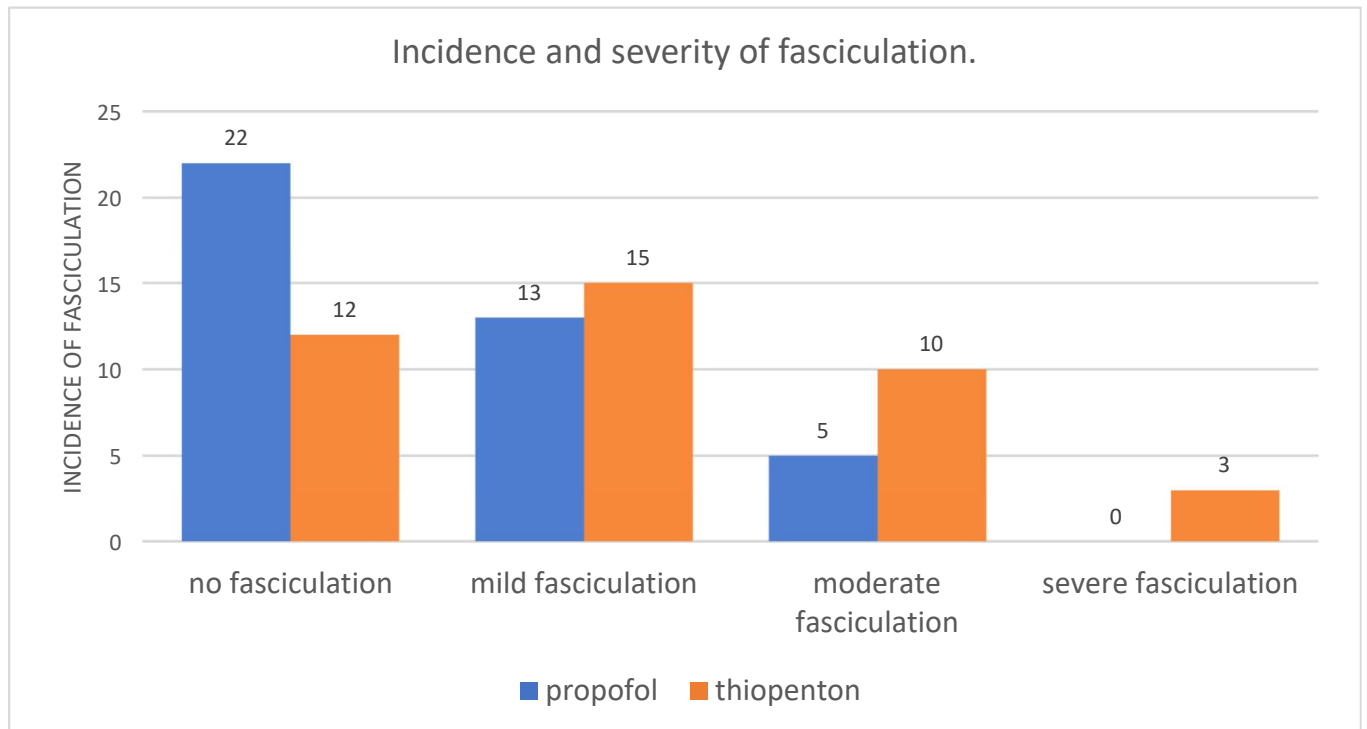


Figure 3: Distribution of succinylcholine induced fasciculation in patient who underwent elective surgical patient at Zewditu Memorial Hospital from January1,2018 to March20,2018 G.C.

#### Post-operative data

Generally, 33(41.25%) of participant develops post-operative myalgia. Among those participants who developed POM 20(25%), 10(12.5%) and 3(3.75%) were experienced mild, moderate and severe post-operative myalgia respectively. Incidence and severity of POM indicated that seven (17.5%) was mild and five (12.5%) was moderate in “P” Group and 13(32.5%) was mild, five (12.5%)was moderate and three (7.5%) was severe myalgia in “T” Group. The incidence and severity of myalgia has a difference between propofol group and thiopentone group ( $P=0.048$ ). Among those participants who experienced myalgia post-operatively 12(36.36%) complain

shoulder pain which is followed by abdomen, arm, and throat pain; From those 15(45.45%) seek analgesia and 14(42.42%) of them were treated by diclofenac. Among those participants who feel post-operative myalgia 4(12.12%) feel at the first hour post-operatively, 18(54.54%) were feel after six hours post operatively; eight (24.24%) were feel after twelve hours post operatively and only three (9.09%) of the participant were feel muscle pain after 24 hours. From those participants who developed POM 27(46.55%) were females and the remaining 6(27.27%) were males (P=0.187). There was no correlation between succinylcholine induced fasciculation and post-operative myalgia (Spearman rho=-0.144). (for detail see figure and table below)

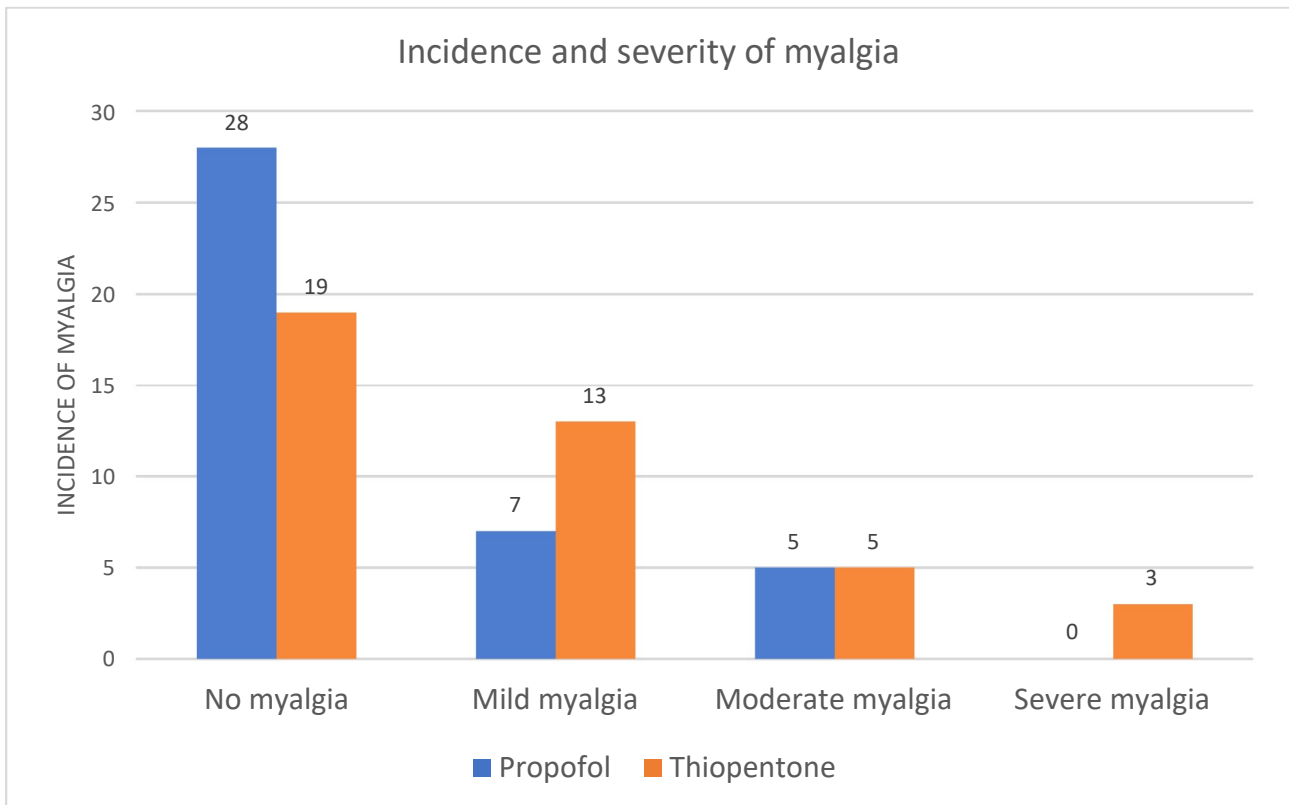


Figure 4: Distribution of succinylcholine induced myalgia in patient who underwent elective surgical patient at Zewditu Memorial Hospital from January1,2018 to March 20,2018 G.C

Table 2:- Incidence and severity of succinylcholine induced fasciculation and myalgia in patient who induced by propofol versus thiopentone sodium in Zewditu memorial Hospital; From January 1,2018- March 20, 2018

Parameter		Propofol group (n=40) (%)	Thiopentone group (n=40) (%)	p-value
Fasciculation	Incidence	18(45%)	28(70%)	0.044
	Nil	22(55%)	12(30%)	0.007
	Mild	13(32.5%)	15(37.5%)	
	Moderate	5(12.5%)	10(25%)	
	Severe	0(0%)	3(7.5%)	
Myalgia	Incidence	12(30%)	21(52.5%)	0.041
	Nil	28(70%)	19(47.5%)	0.048
	Mild	7(17.5%)	13(32.5%)	
	Moderate	5(12.5%)	5(12.5%)	
	Severe	0(0%)	3(7.5%)	

Notes: - Nil: - No fasciculation/myalgia; chi-square test was used for analyze

Table 3:- Incidence and severity of succinylcholine induced fasciculation among patients with different body mass index(BMI) who underwent elective surgical procedure at Zewditu Memorial Hospital, Addis Ababa, Ethiopia, 2018.

Variables		Frequency (%)				P-value
BMI		Under weight (<18.5)	Normal range (18.5-24.9)	Over weight (25-29.9)	Stage I obese (30-34.9)	-
Fasciculation	Nil	3(27.3%)	24(42.9%)	5(45.5%)	2(100%)	0.055
	Mild	4(36.4%)	19(33.9%)	5(45.5%)	0(0%)	
	Moderate	3(27.3%)	11(19.6%)	1(9.1%)	0(0%)	
	Severe	1(9.1%)	2(3.6%)	0(0%)	0(0%)	
Myalgia	Nil	7(63.6%)	32(57.1%)	7(63.6%)	1(50%)	0.949
	Mild	2(18.2%)	15(26.8%)	2(18.2%)	1(50%)	
	Moderate	2(18.2%)	6(10.7%)	2(18.2%)	0(0%)	
	Severe	0(0%)	3(5.6%)	0(0%)	0(0%)	

## CHAPTER SIX: - DISCUSSION

In our study 18(45%) and 28(70%) were experienced fasciculation in propofol group and Thiopentone sodium group respectively. Incidence and severity of fasciculation has a difference between 'p' group and 'T' group significantly ( $P=0.007$ ). In comparison with this study the study results reported from Gujarat, India on 99 patients who allocated randomly into three equal groups by using prospective, randomized, controlled clinical study stated that the total incidence of fasciculations were 25(75.76%),16(48.48%)& 26(78.79%) in group p1, p2&T respectively( $p<0.001$ ). Severity of fasciculation was reduced more in group "p2" than the two (6).

In our study 12(30%) and 21(52.5%) were complained post-operative myalgia in "P" Group and "T" Group respectively. Incidence and severity of myalgia has a difference between propofol group and thiopentone group significantly ( $P=0.048$ ). In the study conduct in Gujarat, India on 99 patients in 2013 into three groups by using prospective randomized study compared to this study stated that the total incidence of myalgia was 19(57.57%),10(30.3%)&23(69.7%) in group p1, p2&T respectively ( $p<0.001$ ) (6).

In our study 28(70%) of the patient in thiopentone sodium group developed mild to severe succinylcholine induced fasciculation. In contrast to this study, the study done in Iran farabi eye hospital stated that 47.4% to 59.3% was developed moderate to severe succinylcholine induced fasciculation (14). The difference may arise from different dose of succinylcholine that was used in ours and their study. In line with our study, study conducted Shoroghi, Mehrdad who try to investigate on effect of thiopentone on severity and duration of succinylcholine induced fasciculation on 300 patients ASA I&II to two groups who received intravenous succinylcholine immediately and 30 seconds after thiopental injection respectively. Moderate to severe fasciculation was found more in the group using succinylcholine 30 seconds after thiopentone injection( $p=0.038$ ) (15).

In study conducted at Diyarbakir, Turkey in 2003 by using 90 patients in three groups in which group-p1 took 2.5mg/kg propofol, group-T took 5mg/kg thiopentone and group-p2 took 3.5mg/kg propofol stated that the severity of fasciculation was significantly reduced in group-p2( $P=0.01$ )(21);which is in line with our study.

Our study showed that 13(32.5%) experienced mild, five (12.5%) experienced moderate and three (7.5%) experienced severe myalgia in Thiopentone group and seven (17.5%) experienced mild five (12.5%) experienced moderate myalgia in “P” group. There was no severe myalgia in Propofol group which is comparable with study done in Turkey on 90 patients in three groups who have received G-1 thiopentone 5mg/kg, Group-2 propofol 2mg/kg and group-3 propofol 3.5mg/kg stated that 38% patient was complain mild to moderate pain, and 20% patients complain mild and 10 % patients was complain moderate pain respectively and none of the group did complain severe myalgia (26). In contrast to our study, a meta-analysis reported from American society of Anesthesiologist stated that, the average incidence of myalgia in the first 24 hours with thiopental was 49.2% and with propofol was 65.4%(18). The difference may arise from the different dose of propofol used in meta-analysis.

Our study also revealed that 13(32.5%) and five (12.5%) experienced mild and moderate fasciculation in Propofol group respectively; 15(37.5%), 10(25%) and three (7.5%) experienced mild, moderate and severe fasciculation in Thiopentone group respectively. In contrast to our study, study reported from India on repeated bolus dose of propofol in three groups stated that 66.7% patients in group 3 (who received repeated bolus dose of 1gm Propofol) was showed 0 grade fasciculation's (4).

In comparison with this study the study conducted in Queen's University of Belfast in 80 adult patients, 40 patients were induced with thiopentone 3-5mg/kg and the remaining 40 induced with propofol 2-3 mg/kg) and Within each group half the patients (n = 20) were receive Succinylcholine 1 mg.kg in 1sec or at 2 min after the induction agent, 24 hrs. after surgery the result showed that the incidence of muscle pains was 35, 60, 35 and 55% in groups PI, PII, TI and TII respectively (29).

This study revealed that there is no correlation between succinylcholine induced fasciculation and post-operative myalgia (Spearman rho=-0.144). It was comparable with study conducted in Gujarat, India on 99 patients who allocated randomly into three equal groups by using prospective, randomized, controlled clinical study concluded that there is no correlation between fasciculation and myalgia (Pearson's r correlation r=-0.139) (6).

## 6.1 STRENGTH OF STUDY

Study participant were homogenous between the propofol and thiopentone sodium groups.

## 6.2 LIMITATION OF THE STUDY

Lack of prior study on this and related tittle in our country was one of our limitation to lay a foundation for understanding the problem.

Most studies we used for comparison were randomized control trial.

## CHAPTER SEVEN

### CONCLUSION AND RECOMMENDATION

#### 7.1. Conclusion

Propofol in comparison with thiopentone sodium is effective in reducing the incidence and severity of succinylcholine induced fasciculation and myalgia. Reduction of post-operative succinylcholine induced myalgia result in reduction of post-operative analgesic requirement.

#### 7.2 Recommendation

According to this study we recommended anesthesia professional to use propofol which significantly reduce incidence and severity of fasciculation and myalgia. We recommend researcher to undergo further study by including adverse effect of those drugs between groups

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ANNEX III. INFORMATION AND CONSENT FORM.

Hello, my name is \_\_\_\_\_ from Addis Ababa University, college of health science, post graduate studies. I will be going to conduct study on reduction of fasciculation and postoperative myalgia which resulted by succinylcholine. So, you are kindly requested to be included in this study, which will have importance in reduction of postoperative myalgia& increase patient satisfaction. The interview will take about 5 minutes, your information will never have passed from individual to individual or from institution to institution without your agreement. Your participation is voluntarily & you have a right to not participate fully or partially. If you agree to be part of this study, I will start my question by asking general identification points. Only honest answer would contribute for improvement of our health service. The study has approval from AAU. May I continue?

YES	NO
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If you say “yes” for the above question here there is a consent form that you will going to sign to be part of the study.

I have been briefly informed about the study and I clearly understood the objective of the study, since it does not affect my personal life, I do not need any remedy. Consequently, I here to approve my consent to take part in the study as interview with my signature.

Signature \_\_\_\_\_ Date \_\_\_\_\_

ሰላም፣ ስም \_\_\_\_\_ ይባላለሁኝ የአክዩ ጠ/ሳ/ኮ ድህረ ምረቃ ፕሮግራም ተማሪ ስሆን፣ አንድ አንድ የአኒስተዥያ መዳኒቶች የሚያመጡት የጡንቻ መርገብገብ እና ከ ሆፕታሊቲዎን በኋላ የጡንቻ ህመም ለመቀነስ ጥናት ላይ ስሆን የእርሶ በ በጎ ፍቃደኝነት መሳተፍ አስፈላጊ መሆኑን እየገለፅኩ ጥያቄው ከ 5 ደቂቃ በላይ አንደማይወስድ ላረጋግጥሎት እወዳለው፤ በተጨማሪም የእርሶ ማረጃ ከሰው ወደ ሰው ወይም ከተቋም ወደ ተቋም ያለ እርሶ ፍቃድ እንደማይተላለፍ ቃል እየገባው፣ የእርሶ ተሳታፊነት በሙሉ ፍቃደኝነቶ ብቻ የምረጋገጥ መሆኑን እያረጋግጥሎት፣ በመጨረሻም የጥናቱ ተሳታፊ መሆን ከፈለጉ ከዚ በታች የተገለፀውን የስምምነት ወረቀት አምብቦ እንድፈርሙልኝ በ ትህትና እጠቃለው፤

የጥናቱ ይዘት በትክክል የተገለፀልኝ ስሆን አላማውንም ተረድቻለው፣ በመሆኑም ያለምንም ማመንታት የጥናቱ አካል መሆንን በፍርማዎ አረጋግጣለው፤

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## ANNEX II. QUESTIONNAIRES AND CHECK LIST

Addis Ababa University College of public Health and Medical Science school of Medicine, department of Anesthesia.

A data collection format, for patients who will be undergo elective surgical procedures from January 1, 2018 to march 20, 2018 in Zewditu memorial Hospital, Addis Ababa, Ethiopia. The purpose of this study to compare the effect of Propofol versus thiopentone sodium as an induction agent on prevention of succinylcholine induced fasciculation and myalgia.

First of all, I would like to acknowledge for your willingness to participate in this study and also, I would like to assure I will keep the confidentiality of this record in case that you may not want to be public

Instructions:

- A. Fill the blank space provided.
- B. Encircle the alternatives when necessary.
- C. Check the questions for completeness.

Part 1. Identification:

1.1. Patient MRN \_\_\_\_\_ 1.2. Age (in year) \_\_\_\_\_ 1.3. Sex: A. Male B. Female

1.4. BMI \_\_\_\_\_ Kg/m<sup>2</sup> and 1.5. Occupation A. farmer B. Merchant C. Labor D. civil servant F. other

1.6. Ethnic group A. Oromo B. Amhara. C. Tigre D. Gurage F. Wolayita F. other specify \_\_\_\_\_

Part 2 Preoperative evaluation

2.1. Diagnosis \_\_\_\_\_ 2.2. procedure \_\_\_\_\_

2.3 ASA I \_\_\_\_\_ II \_\_\_\_\_ III \_\_\_\_\_ IV \_\_\_\_\_

3. Induction agent used (dose in mg/kg)

- A. Propofol \_\_\_\_\_ mg/kg                      B. Thiopental \_\_\_\_\_ mg/kg  
 C. opioid used at induction \_\_\_\_\_ mg/kg

Part 4. muscle relaxant used for intubation dose in mg/kg

- A. Succinylcholine \_\_\_\_\_ mg/kg

Part 5: Incidence and severity of fasciculation

- A. No fasciculation  
 B. Mild fasciculation (involves eyes, face, neck, fingers without movement of limbs)  
 C. Moderate fasciculation (Fasciculation of greater intensity at more than two sites or movement of limbs)  
 D. Severe fasciculation (Vigorous sustained and widespread Fasciculation)

Part 6: anesthetic agent used for intra operative maintenance

- A. Propofol infusion (rate/min) \_\_\_\_\_                      B. Halothane (MAC) \_\_\_\_\_  
 C. Isoflurane (MAC) \_\_\_\_\_                                      D. Sevoflurane (MAC) \_\_\_\_\_  
 E. Desflurane (MAC) \_\_\_\_\_                                      F. Analgesic agent \_\_\_\_\_  
 G. Ketamine \_\_\_\_\_

Part 7. muscle relaxant used for intra operative maintenance dose in mg

- A. vecuronium \_\_\_\_\_                      B. Atracurium \_\_\_\_\_  
 C. Pancuronium \_\_\_\_\_                      D. Rocuronium \_\_\_\_\_

Part 8: patients compliant post-operative muscle pain

8.1. Do you have any pains and aches or stiffness in your muscles other than the operation site?

- A . Yes                      B. No

8.2. If you answer yes for Que.8.1 in which part of your body feel this pain?

A Neck, B. Shoulder, B. Arm, C. Throat, D. Abdomen, and F. Buttocks.

8.3. Did you take any medication for the pain?    A. Yes                      B. No

8.4 If you answer yes for Que.8.3 what are this medication you have taken?

A. NSAID \_\_\_\_\_ B. Opioid \_\_\_\_\_

8.5. Does this pain restrict your normal activity? A. yes B. No

A. Can you get out of bed? C. Can you able to turn your head? C. Can you cough without distress or pain?

8.6 When did you start feeling this pain?

A. After first 1hr of pop time B. After 6hrs of pop time C. After 12 hrs of POP time

D. After 24hrs of POP time

9. Incidence and severity of myalgia. A. Nil myalgia

B. Mild myalgia (minor stiffness limited to one area of the body).

C. Moderate myalgia (muscle pain or stiffness noticed spontaneously by the patient, which require analgesic therapy).

D. Severe myalgia (generalized, severe or incapacitating discomfort, limiting activity, causing inability to cough without distress and requiring analgesic therapy).

Name of data collector \_\_\_\_\_ Status/profession \_\_\_\_\_ Signature \_\_\_\_\_

Thank you!!!