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Analgesic effect of intravenous Dexamethasone prior to Spinal Anesthesia among parturient undergo cesarean section at Gandhi Memorial Hospital, ADDIS ABABA, ETHITIOPIA, Prospective Cohort Study, 2018/19

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TITLE

Comparing t the Analgesic effect of Spinal anesthesia with prior administration of intravenous dexamethasone and spinal anesthesia alone in patients undergoing elective cesarean section in Gandhi Memorial, ADDIS ABABA, ETHITIOPIA, Prospective Cohort Study, 2018/19

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Abbreviations/Acronyms

ASA	American Society of Anesthesiologists
BMI	Body Mass effect
CI	Confidence Interval
CS	Cesarean Section
CSE	Combined Spinal Epidural
CSF	Cerebero Spinal Fluid
EAA	Ethiopian Association of Anesthetist
EC	Ethiopian Calendar
ECS	Elective Cesarean Section
EDHS	Ethiopia Demographic and Health Survey
GA	General A anesthesia
Hrs	Hours
IM	Intra Muscular
IV	Intra venous
KG	Kilo Gram
NRS	Numeric rating scale
NSAID	Non-steroidal anti-inflammatory drug
PONV	Post-Operative Nausea And Vomiting
RCT	Random Control Trial
SA	Spinal Anesthesia
SPSS	Statistical Packages for Social Science
WHO	World Health Organization
VAS	Visual Analogue Scale

Abstract

Background: By prolonging the duration of spinal anesthesia sensory block co-administration of adjuvant has the potential to improve efficacy of regional blocks. However this technique has its own complications. Hence, drugs having minimal side effects and prolonged analgesia is always looked for. This is because postoperative pain in obstetric patients is left untreated and it's the main cause of chronic pain among women.

Objective: to determine the effect of preoperative dexamethasone on prolongation of the analgesic effect of spinal anesthesia after elective cesarean section.

Methods: Observational prospective cohort study was conducted at Gandhi Memorial in 64 patients scheduled for elective Cesarean Section under spinal anesthesia and systematic random sampling was used to randomly select patients. Data was checked manually for completeness and then it was coded and entered, cleaned and analyzed with SPSS version 20 computer program. Normality of the data was checked by Shapiro wilk test. Chi square test was used for categorical variables and Manny Whitney test used for comparing numerical variables of skewed data or student's t-test used for comparing numerical variables normally distributed data of two groups. P-value less than 0.05 considered as statistically significant.

Result: The demographic and clinical characteristics were comparable between groups. Groups' comparison indicated significant difference in terms of severity of postoperative pain, in which the dexamethasone group were lower with p value < 0.015. Similarly, time to the requirement of first rescue analgesia was prolonged in dexamethasone group with median (interquartile range) score of 6.5(2.4) as compared to non-dexamethasone group 4.1(1.8). The median score for total consumption of Tramadol in 24hrs post operatively has been lower in dexamethasone group with p value < 0.0001. There is no statistically significant difference in median score of total diclofenac consumption between the two groups with p value of 0.2.

Conclusion: we concluded that preoperative administration of dexamethasone 0.1mg/kg intravenously before administrating spinal anesthesia for cesarean section is efficient in reducing postoperative pain, total Tramadol consumption on the first postoperative day and prolonging the time to the requirement of first rescue analgesia.

1. INTRODUCTION

1.1 Background

Caesarean section can be life-saving to both the mother and the fetus by preventing poor obstetric outcomes. However, there is a growing concern on the increasing percentage of the procedure of live births globally. The risks and costs associated with caesarean deliveries are significant, especially where there was no medical indication. 6.9% of CS performed in Addis Ababa had no medical indication(1) .

According to the latest data from 150 countries, currently 18.6% of all births occur by CS, ranging from 6% to 27.2% in the least and most developed regions, respectively. Latin America and the Caribbean region have the highest CS rates (40.5%), followed by Northern America (32.3%), Oceania (31.1%), Europe (25%), Asia (19.2%) and Africa (7.3%). The use of CS worldwide has increased to unprecedented levels although the gap between higher- and lower-resource settings remains(2).

At national level The Ethiopian national CS rate is low at 1.5%, while in Addis Ababa, the capital city, the CS rate is 21.8%.The total CS rate at St. Paulo's hospital rose from 24.5% in 2002 to 32.8% in 2006 (p= 0.001). An increase in the rate of referral by health care workers and a decrease in hospital instrument deliveries can partially explain the increase in CS rate(3).

The 2016 Ethiopia Demographic and Health Survey found that 2% of live births in the 5 years before the survey were delivered by CS. Among women who had their most recent live birth in a health facility, 79% of those who gave birth by CS spent three or more days at the facility after delivery compared with 5% of those who had a vaginal birth. The WHO advises that caesarean sections be done when medically necessary, but does not recommend a specific rate for countries to achieve at the population level (4).

There are two general categories of anesthesia for CS general anesthesia and regional anesthesia. Regional anesthesia includes both spinal and epidural techniques. General anesthesia is usually reserved for patients that must have anesthesia "right away" because their surgery is being done for a true emergency. In these situations, regional techniques may take too long to perform(5)

.Internationally, obstetric anesthesia guidelines recommend spinal and epidural over GA for most Cesarean sections (6).

Spinal anesthesia has evolved as the preferred anesthetic technique for most cases of CS (5).Spinal anesthesia is induced by injecting small amounts of local anesthetic into the CSF. Spinal anesthesia is easy to perform, reliable and avoids the depressant effects of anesthetic drugs and has the potential to provide excellent operating conditions for CS(7).The International goal for protection of future mothers is 80-90% of all Cesarean section to be carried out under spinal anesthesia(5).

By prolonging the duration of sensory-motor block and limiting the cumulative dose requirement of local anesthetics, co-administration of adjuvant has the potential to improve efficacy of regional blocks and decrease local anesthetic toxicity. They contribute in their own special manner to potentiate the analgesic effect of the local anesthetics(8).

Dexamethasone is a potent anti-inflammatory agent which has been investigated in the last decade for its role as an adjuvant to local anesthetics in neuroaxial as well as peripheral nerve blocks. Systemic anti-inflammatory and immunosuppressive properties may be responsible for the prolongation of analgesia when administered intravenously(9).

1.2 Statement of the problem

Spinal anesthesia is the most commonly used anesthetic technique for lower abdominal surgeries and lower limb surgery. But it has the drawback of short duration of action and lack of postoperative analgesia. Larger dose of analgesic is required to provide pain relief with high incidence of side effects when local anesthetic is used alone for SA(10).

Pain has both sensory and emotional components that interact to produce an overall pain experience. As this evidence suggests that less than half of patients who undergo surgery report adequate postoperative pain relief (11). Inadequately controlled pain negatively affects quality of life, function, and functional recovery, the risk of post-surgical complications, and the risk of persistent postsurgical pain. In addition, researchers appoint that cesarean sections represent the main cause of chronic pain among women and Estimates show immediate postoperative pain incidence rates after cesarean sections amounting to 77.4%with the pain being of high intensity(12).

A prospective cross sectional study was conducted among 252 postoperative patients during February 13 to April 30, 2012 in Ethiopia Incidence of postoperative pain was 91.4%, and remained high over 3 measurements ($p<0.05$), and 80.1% of the patients were undertreated. The mean pain intensity, and pain interference on functional status were 6.72±1.44 and 5.61±1.13 on a 10 point Numerical rating scale respectively; both being strongly correlated($r=0.86$: $p<0.001$)(13).

Studies indicate that treatment of acute pain remains suboptimal due to attitudes and educational barriers on the part of physicians and patients, as well as the intrinsic limitations of available therapies(11).

Although opioids are the preferred treatment for most moderate to severe acute pain,(14)their side effects can impede their use, and thus, their clinical effectiveness. Side effects associated with the use of opioid analgesia, the most commonly administered form for pain control includes nausea and vomiting, delayed recovery of bowel function, sedation, respiratory depression, hyperalgesia and occasionally, prolonged hospital stay. Paradoxically, the administration of opioids to treat pain can be the catalyst that sensitizes patients to painful stimuli. These drugs have the potential to produce very serious, deleterious side effects, including, but not limited to: cardiac arrhythmias, central nervous system depression, seizures, hypotension, allergic reactions, and respiratory depression (15).

The other option to prolong the postoperative analgesia and to control postoperative pain is intaathecal administration of opoids. But it also does have significant adverse effects including pruritus, nausea, vomiting and respiratory failure(16).

Other method of prolonging analgesia is using a continuous epidural analgesia, which is technically more difficult and more costly, which the patients coming to the government hospital may not afford(10) .This has prompted studies to determine the upper safe limit of administration of these drugs. The effects are more profound when the drug is deposited in the intrathecal space resulting in recommendations to reduce intrathecal dosage to avoid respiratory depression(17).

Finally acute postoperative pain is a wide range of problem in obstetric populations. And it’s poorly treated by health professional in Ethiopia like they did globally. So there is a need to prolog the analgesia which is gained by spinal anesthesia with limited adverse effects.

1.3 Justification of the study

Although beneficial in acute and chronic pain management, local Anesthetics do have the potential to produce deleterious effects like cardiac arrhythmias, central nervous system depression, seizures, respiratory depression, hypertension and allergic reaction(18). The duration of sensory block and analgesia is relatively short with single shot subarachnoid block(10). Hence, along with local anesthetic, adjuvant such as fentanyl, morphine, clonidine, ephedrine, pethidine, dexmedetomidine were used in the past. However, these adjuvant may lead to certain side effects such as sedation, nausea, vomiting, pruritus, respiratory depression, hypotension, psychotomimetic effects, etc(19).

Hence, drugs having minimal side effects and prolonged analgesia is always looked for. And there is a need for something to prolong the analgesic effect of spinal anesthesia without resulting adverse events. As far as our knowledge goes, there is no previous study done in our country to assess the postoperative analgesic effect of preoperative intravenous dexamethasone after spinal anesthesia

Even though some studies have been performed to compare quality of anesthesia and postoperative analgesic effect of intravenous dexamtasone with bupivacine and bupivacaine alone, Most of these studies have been conducted on developed, Asian and western populations. The controversies and inter racial difference in pain perception is one of the reasons which call for the study. The expression of pain, pain behaviors and communication regarding one's pain are inextricably tied to socio cultural origins (e.g., familial models). And there are variables thoroughly considered in recent reviews of ethnic disparities in pain (20).

Undertaking such studies in resource limited area can improve postoperative pain treatment and patient comfort by counteracting the effect of high patients to health professional ratio. Poor practices and availability of patient Controlled Analgesia are the other basis for such a research made.

In addition, dexamethasone is the cheapest and widely available drug in Ethiopia. This makes it easily available for majority of Ethiopian clients. And it prevents putting a lot of budgets in expensive drugs.

Therefore conducting such a research which intended to find alternatives for pain management and part of multi-modal analgesia in the postoperative period is expected to have of great value since it will decrease the side effects of opioids and other systemic medications and intraatchal adjuvant.

2. Literature Review

There are a large number of studies of trends in prolonging the spinal analgesia on surgical population. However, since the focus of this research is on intravenous dexamethasone for prolonging spinal anesthesia's analgesia in cesarean section patients, these all will not be reviewed in detail and will only be referred to as appropriate.

Spinal anesthesia is the most widely practicing type of anesthesia for cesarean section and Bupivacaine is appropriate for procedures lasting up to 90-120 minutes. There are many additives to be used to enhance analgesic effect of neuraxial blocks such as clonidine, magnesium, ketamine, opioids, vasoconstrictor agents and steroids, and neostigmine(10).

Despite many research are done on adjuvant to prolong the spinal anesthesia many of the drugs do have concern regarding the safety profile of these adjutants due to their potential neurotoxicity , neurological complications and other complication(16).To avoid complication related to adjuvant like opoids used to prolong spinal anesthesia one must limit the time of spinal anesthesia(18). The effects are more profound when the drug is deposited in the intrathecal space resulting in recommendations to reduce intrathecal dosage to avoid respiratory depression(19).

In the past, intrathecal morphine had been used for postoperative analgesia as it provides excellent and long lasting effect after surgical procedures. But its use is associated with unwanted effects such as nausea, vomiting, itching, urinary retention and respiratory depression(17).

Even if it is not enough some studies showed that preoperative intravenous dexametasone prolong the analgesic effect of spinal anesthesia in some other surgical procedures. But management style varies due to economic and technological difference to our study area. In additions some other studies advocates that administering this drug doesn't have value on postoperative analgesic effect of spinal anesthesia.

Study done in USA Fifty-two women were enrolled and randomized to two groups of 26 patients. Healthy women having cesarean delivery under spinal anesthesia were randomly assigned to receive intravenous dexamethasone 8 mg or placebo after delivery and clamping of the umbilical cord. The median (IQR) opioid consumption in the first 24 hours after cesarean delivery was 12 mg (5–20 mg) in the dexamethasone group compared to 15 mg (5–22 mg) in the placebo group. They conclude that addition of intravenous dexamethasone 8 mg to a multimodal postoperative analgesic regimen that included intrathecal morphine, in women who had a cesarean delivery under spinal anesthesia, did not reduce 24 hour postoperative opioid consumption(21). In which they found a bit different result from other studies.

A study done in Canada on Fifty consecutive patients undergoing elective, unilateral, primary total hip arthroplasty under spinal anesthesia with propofol sedation received in a randomized, double-blind, placebo-controlled manner either 40 mg of dexamethasone or saline placebo IV before the start of surgery. And they found that Dynamic pain was greatly reduced in the dexamethasone group (NRS score: 2.7, 95% CI: 2.2–3.1 vs. 6.8, 6.4–7.2; *P* 0.0001). in which a single, preoperative IV dose of dexamethasone 40 mg has a prolonged suppressive effect on the inflammatory response and decreases dynamic pain 24 h after total hip arthroplasty (22).

In Taiwan a study was done on The Effect of Dexamethasone on Postoperative Pain and Emesis after Intrathecal Neostigmine and they found that a bit different results. They conduct their study on Sixty ASA physical status I patients scheduled for inguinal herniorrhaphy. Spinal anesthesia was performed with intrathecal injection of 15 mg tetracaine plus neostigmine 100 mg in both groups. Pain, PONV, and other side effects were evaluated 24 h after surgery. Finally they found that Duration of absolute analgesia, the time to first rescue analgesic, number of IM injections of 75 mg diclofenac in the first 24 h after the operation, the overall VAS pain score in the first 24 h after the operation, and the postoperative duration of motor block were similar in the two groups. The VAS pain scores at 4-h intervals showed no significant difference between the two groups at any time during the postoperative period(23).

Another prospective, randomized, double blind, placebo controlled study done in Jaipur ,India on the effect of intravenous dexamethasone on postoperative pain, nausea and vomiting after

intrathecal pethidine and bupivacaine in lower limb orthopedic surgery found that pain score on Visual Analogue Scale (VAS) at 6, 12, 18, 24 hours after surgery, mean number of rescue analgesic doses in 24 hours and the incidence of PONV were significantly lower($p<0.05$) in dexamethasone group(24).

A study done in Tata Motors Hospital in, Jamshedpur, India in 2016 Hundred mothers scheduled for Lower Segment CS under spinal anesthesia were randomly assigned to receive either 2ml saline (Group A, n=50) or 8mg IV dexamethasone (Group B, n=50) in this prospective double-blinded study. Is shows that Time to request to first analgesic dose was 15 hours in the study group when compared to 13 hours in the control group ($P=0.024$). However, no difference in APGAR scores, pruritus and urinary retention was noted in both the groups ($P > 0.005$)(25).

A recent study done in 2017 in Marashatra, Indian on the Study the Efficacy of Intravenous Dexamethasone in Prolonging the Duration of Spinal Anesthesia in sixty female patients aged between 25 and 30 years posted for elective cesarean section surgery concluded that administration of dexamethasone 8 mg intravenously prolongs the duration of postoperative analgesia and sensory block in patients undergoing lower segment cesarean section under spinal anesthesia. They also found that significant changes were also seen in VAS score in the postoperative period after 1 h of surgery in group Dexamatasone and group control (26).

Another study done in JIMS, Kolkata on the Effect of Intravenous Dexamethasone on Spinal Anesthesia With Bupivacaine Plus Fentanyl in Patients Undergoing Vaginal Hysterectomy advocates that The total dose of diclofenac, visual analog scale pain score, and the incidence of PONV were significantly lower in the dexamethasone group than in control and Intensity of pain based on VAS scale was the same at the beginning of study ($P>0.05$). However, in hour 6 ($P=0.003$) and hour 24 after surgery ($P=0.001$), the intensity of pain was significantly less in dexamethasone group (27).

Another study done in Iran, on 60 randomized patients who grouped into2 to receive either 2 mL saline or 0.1 mg/kg dexamethasone IV before the administration of intrathecal anesthesia (15 mg and meperidine 15 mg). The patients were undergoing inguinal herniorrhaphy under

spinal anesthesia. The study advocates that visual analog scale pain score at 6-h intervals (*P* 0.001), and the incidence of PONV (*P* 0.05) were significantly lower in the dexamethasone group(28).

A randomized, prospective, double-blind, case-control, clinical trial in orthopedic procedures under spinal anesthesia which is done Babol, Iran advocates that There were no signification differences in demographic data, sensory level, and onset time of the sensory block between two groups. Sensory block duration in the case group was 119±10.69 minutes and in the control group was 89.44±8.37 minutes which was significantly higher in the case group (*P*<0.001). The duration of analgesia was 401.92±72.44 minutes in the case group; whereas it was 202±43.67 minutes in the control group (*P*<0.001). The frequency of complications was not different between two groups (29).

A double blind prospective randomized clinical trial in Bouali Hospital, Islamic Azad University, Tehran, Iran revealed that there was significant difference between pain severities during first 24 hours after operation across the groups and the pain severity was less in dexamethasone group (P <.05). None of the patients in two groups had side effect.(30).

Shahraki and colleagues performed a double-blind prospective randomized clinical trial was performed on 60 patients' candidate for elective caesarean section. Patients were randomly assigned into two groups received 8 mg IV Dexamethasoe and control received 2 ml normal saline). They found significant differences in terms of pain severity (P < 0.001), MAP (P = 0.048) and HR (P = 0.078; marginally significant), which in case group were lower than the control group so they concluded that IV Dexamethasone could efficiently reduce post-operative pain severity and the need for analgesic consumption and improve vital signs after cesarean section(31).

Another study done in Sao Paulo, Brazil; on the Effect of dexamethasone on prevention of postoperative nausea, vomiting and pain after caesarean section: a randomized, placebo-controlled, double-blind trial seventy full-term pregnant patients were studied from 1 January to 30 June 2008 and they advocates that Pain with movement was lower among patients who received dexamethasone at 1, 6, 12 and 24 h. The cumulative incidence of nausea and vomiting

for the period in the post-anesthesia care unit (up to 3 h after surgery) and in the ward (between 3 and 24 h after surgery) was lower in the patients who received dexamethasone(32)**.**

A study done in Egypt in 2015 on Comparison of local, placebo and intravenous dexamethasone on post-Operative pain and recovery after caesarean section. The 120 women were candidate for cesarean section. Group 1 included 40 women received 16 mg Dexamethasone IV drip on 500 cc saline (dexamethasone sodium phosphate USP 8 mg/2 ml amps. Group II included 40 women received 16 mg Dexamethasone subcutaneous injection around the caesarean section scar after skin closure and Group III received Placebo in the form of IV fluids 500 cc saline infusion. Finally they conclude that IV administration of Dexamethasone and local subcutaneous infiltration of wound markedly decreased the sensation of pain and the needs for postoperative analgesics up to 24 h after the operation without postoperative complications(33).

Despite this and other researchers are done on the effect of intravenous dexametasone for prolongation of spinal analgesia, the real effect of the drug on sensory anesthesia prolongation and analgesic requirements is not well defined. And it is also full of controversies in some of the above and other literatures.

Hypothesis Testing

1. **HO**: There is no statistically significant difference in NRS score between two groups.
   HA: There is statistically significant difference in NRS score between two groups.
2. **H0:** There is no statistically significant difference in time to requirement of first rescue analgesia between two groups
   H1: There is statistically significant difference in time to requirement of first rescue analgesia between two groups
3. **H0**: There is no statistically significant difference in total analgesia consumption between two groups
   H1: There is statistically significant difference in total analgesia consumption between two groups.

3. Objective

3.1 General Objective

To determine the effect of preoperative intravenous dexametasone on prolonging the analgesic effect of spinal anesthesia after elective cesarean section in Ghandi Memorial Hospital.

3.2 Specific objectives

- To compare severity of early post-operative pain between two groups in first 24 hours using NRS score
- To compare the time to requirement of the first rescue analgesia between the two groups
- To compare total 24 hour analgesic consumption between two groups.

4. Methods and Materials

4.1 Study Area

The study was conducted at Gandhi Memorial Hospital located in Addis Ababa the capital city of Ethiopia. It was established in 1958 G.C as the only maternity hospital in Ethiopia. The hospital was named Gandhi Memorial Hospital for the memory of the Indian independence movement leader. It is one of the thirteen governmental hospitals found in Addis Ababa which is under admnistration of Addis Ababa city Health Bureau.

The Hospital primarily gives services for women and children. The Hospital provides Gynecologic, Obstetric and many other reproductive health services. The hospital has 110 beds and an average of 25 new borns deliverd each day. The hospital has four operation theatre and average number of electieve caesarian deliveries done at the hospital is four per day.

4.2 Study design and Study period

An institutional based Prospective observational cohort study design was conducted from January, 2019 to may, 2019.

4.3 Source Population

All pregnant mothers who underwent elective caesarian section under spinal anesthesia at Gandhi Memorial Hospital, Addis Ababa, Ethiopia was a source population

4.4 Study Population

Pregnant mothers who underwent by elective caesarian section under spinal anesthesia at Gandhi Memorial Hospital during the study period.

4.5 Eligibility Criteria

4.5.1 Inclusion criteria

Elective cesarean section patients falling in classification of American Society of Anesthesiologists (ASA) as Class II (Annex 6) and Induction of spinal anesthesia using 2.5 ml of 0.5% Isobaric Bupivacaine

4.5.2. Exclusion criteria

- Mothers used combined spinal epidural anesthesia
- Spinal anesthesia changed into General anesthesia or sedation intaoperatively
- Uses of other adjuvant like opoids, catecholamines, clonidenie,tramadol, nesostgimne and other adjuvant.
- Patient who take sedative or analgesics premedication within 24 hrs. preoperatively and intraoperatively
- Chronic steroid therapy and use of corticosteroids
- using local anesthetics other than 12.5 mg of 0.5% isobaric bupivacaine
- Patients who have chronic pain and mothers with social problem, stress and Malingerers
- peripheral neuropathy or nerve injuries
- Bleeding abnormality
- Spinal anesthesia changed into General Anesthesia or sedation intaoperatively
- Patients who took nerve block

4.6 Sample size calculation

Sample size was determined by considering a power of 80%, confidence interval 95% and ratio of two groups to 1:1 which the mean results estimated from pilot study done prior to actual study. The pilot study sample size was determined by taking 10% of previous literatures sample size(26). From pilot study mean score of time to requirement of first rescue analgesic in hrs was 7.6± .0.47 in dexameathsone group and 7.3± 0.3 in non-dexamtasone group (mean, SD). This sample size was determined using G-power version 3.1.9.2 and rechecked by manual calculation.

$$n = \frac{(S_1^2 + S_2^{2)}\,(Z\,1 + Z2)^{\,2}}{(\mu_1 - \mu_2)^2}$$

WHERE n= sample size per group

z1= 1.96 for α error of 5% (95% confidence level)

z2= 0.84 for 80% power

S1 = standard deviation in dexamethasone, S2= standard deviation in non-dexamethasone

Planning to get 80% chance of significant result and Adding 10% of non-response rate a total of 64 patients was involved in the study sample size was n1=32 & n2=32.

4.7 Sampling procedure

Stratified Systematic random sampling technique used till to get the required sample size during the study period. The daily operation schedule list was used as a sampling frame. The situational analysis show that 16 patient who fulfill our inclusion criteria was operated in Gandhi Memorial Hospital log book per week; according to this data we had 128 patients in our study period from whom we collected data from only 64 patients.

Therefore, K=N/n= 128/64 = 2 (skip interval) and the first participant (random start) was selected using lottery method. Then, every next patient included in this study from the daily operation schedule list.

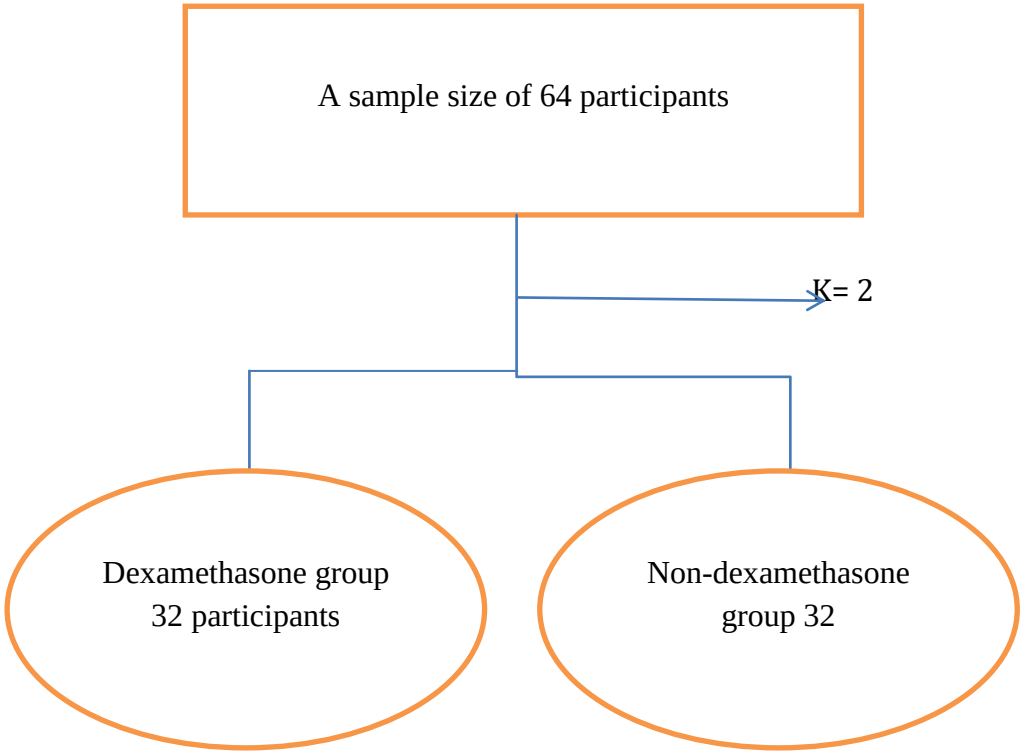

Figure 1: Sampling procedure for elective cesarean section scheduled at Gandhi Memorial Hospital

4.8 Data collection

5.8.1 Data source, Data collection tools, procedure and personnel

Data was collected from selected study participants using pretested questionnaire. Data was collected from January 01, 2019 to March 20, 2019

Anesthesia management for elective CS in the study hospital is carried out by B.Sc and MSc degree holder anesthesia professional. The management and selection pre medicating the patient with 0.1 mg/kg dexametasone before spinal anesthesia depends on the personnel assigned to each case. The data collection was done by Anesthetists and nurses after being familiar with the questionnaires and appropriate training. The principal investigator checked completeness of data every day.

All patients who were scheduled for elective caesarean delivery 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 nurses or anesthetists. Patients were followed for 24hrs. The primary outcome measure is NRS score, with being no pain to 10 the worst imaginable pain. Time to requirement of first rescue analgesia and total postoperative analgesic consumption was used to assess efficacy of analgesia as secondary outcome measures. Additionally time to maximum sensory block onset was assessed.

Anesthesia management for caesarean delivery clients in the study hospital is usually carried out by BSc anesthesia professional. Pre anesthetic evaluation is done before surgery. Patients usually pre medicated with metoclopramide 10mg IV. Vital sign, Organ function test together with history and physical examinations are among the parameters used to decide for anesthesia plan and weather to cancel or proceed. Monitoring equipment applied and prophylactic IV dexamthasone might administer 1minutes before spinal injection depending on anesthetist preference. During this time data collectors identify patients who were given 0.1 mg/Kg IV dexametasone and who were not and assign the study participant to the appropriate group. During preparation of the skin and during spinal anesthesia induction, lactated Ringer's or normal saline solutions were administered for coloading. Sub arachnoids block is done with 0.5% of 2.5ml bupivacaine for all parturient. Level of block was checked with needle pin prick. The level of sensory block was evaluated with cold sensation.

The data collection was done by two anesthetists intraoperatively and one nurse postoperatively after training was given. Data collectors asked and recorded necessary preoperative information, reviewed charts and document intraoperative and postoperative information.

On arrival to the recovery Postoperative pain was assessed in all groups using a NRS for pain assessment. The scale consists of horizontal lines ranging from 0 (no pain) to 10 (worst

imaginable pain). Asked to report their pain based on 11 point NRS score recorded at recovery (0hrs) and then every three hours for the first six hours and every six hours for the remaining postoperative period until 24hr. The pain score was assessed during a quiet breathing period or at rest (static NRS) and after voluntary cough (dynamic NRS). The time to requirement of first rescue to analgesia was recorded from patient chart after admission to recovery and total analgesic consumption of each patient was recorded. The principal investigator checked completeness of data every day.

4.9 Study variables

4.9.1 Dependent Variables

- ✓ NRS score at rest and voluntary coughing (movement)
- ✓ First analgesia request time
- ✓ Total analgesic consumption in 24 hr

4.9.1 Independent variable

- ✓ Dexamethasone exposed status
- ✓ Socio demographic characteristics: age, weight, height, body mass index
- ✓ Duration of the surgery
- ✓ History of previous CS

4.10 Operational Definition

American Society of Anesthesiologists (ASA) physical status classification: developed by the ASA task force which classify patients according to their systemic well-being

ASA class I: normal healthy patient except the surgical compliant he had

ASA class II: a patient with a mild systemic disease without substantive functional limitation including but not limited to current smoker, pregenacy and mild lung disease

ASA class III: a patient with severe systemic disease with substantive functional limitation

ASA class IV: a patient with severe systemic disease that is a constant threat to life

ASA class V: moribund patient who is not expected to survive without the operation

Baseline value: measurement taken before induction or spinal anesthesia given

Dexamethasone group- patients who took 0.1mg/kg dexamethasone and 12.5mg isobaric, and 0.5% Bupivacaine

Non-dexamethasone – patients who took only12.5, isobaric, 0.5% Bupivacaine

Numerical pain rating scale (NRS): is a valid is a method of pain assessment where patients are asked to score their pain ratings on a scale of 0–10, corresponding to current, best, and worst pain experienced over the 24 hours. The median value will be used to represent patient's level of pain(34)

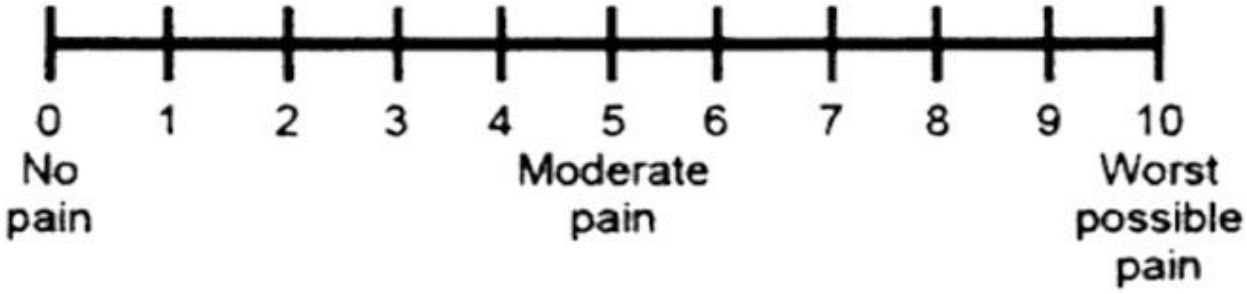

Figure 2 NRS score Adopted from the National Initiative on Pain Control™ (NIPC™)

Time to requirement of fist rescue analgesia: the time from end of the surgery up to first request for analgesia in hrs

Onset of maximum sensory block: time from administration of local anesthetics with/without dexamethasone to complete loss of cold sensation areas about T6 to T8

Incision time- a time from last injection of local anesthetics to beginning of surgical incision
Total post-operative analgesia consumption: total dose and type of medication given in mg within the first 24 hour starting from admission to recovery room

Postoperative pain-pain in surgical patients after the procedure may be due to tissue lesion and the manipulation of organs and structures.

4.11 Data processing and analysis

Data was checked manually for completeness and then it was coded and entered, cleaned and analyzed with SPSS version 20 computer program. Descriptive statistics was used to summarize data, tables and figures. Chi square test used for discrete variables and student's t-test used for

comparing numerical variables of normally distributed data or Manny Whitney U test used for skewed data of two groups. Data expressed in terms of mean ± SD for normally distributed data and median ± inter quartile range for skewed data. P-value less than 0.05 considered as statistically significant. The results were presented by using text, tables, and graphs.

4.12 Data quality assurance

To assure the quality of data, training on the objectives and relevance of the study and brief Orientations on the assessment tools provided for data collector. Pretest was done on 5% of sample in zewditu memorial hospital. During data collection, each questioner revised by the investigator for being complete and appropriate. Data clean up and cross-checking was done before analysis on SPSS.

4.13 Ethical consideration

The study conducted after approval by Addis Ababa University, Ethical review board to conduct the study. A legal letter submitted to Ghandi memorial hospital, where the study took place. Verbal informed consent obtained from all parturient after full explanations of the goals and procedures of the study. After taking permission from the hospital and study participant the data collection conducted.

5. Results

5.1 Demographic and clinical characteristics of the patients

Thirty two patients were studied in each group. All patients were included in the study as they were complete and showed consistency of response. All the demographic data were normally distributed (Shapiro Wilk test, p value > 0.05. An independent-samples t-test was conducted to compare the demographic characteristics scores for dexamethasone and non-dexamethasone groups. There was no significant difference in scores between two groups with the value presented in table 1

Table 1: Demographic characteristics of the study participants, who underwent Elective cesarean section at Gandhi memorial hospital, Addis Ababa, Ethiopia.

Characteristics	Dexamethasone group (n=34)	Non-dexamethasone group (n=34)	P value
Age in years	26.2±3.48	26.59±3.41	0.66
Height in cm	164±3.93	162.8±3.48	0.206
Weight in kg	63.7±4.71	62.8±5.4	0.496
BMI	23.8±1.8	23.6±1.98	0.85

Values are presented as: Mean ± SD, independent student t-test and $p<0.05$were taken statistically significant.

A chi-square test indicates there was no significant difference between the dexamethasone and non-dexamthasone groups regarding clinical characteristics' including parity and history of previous CS. Results between groups were comparable. An independent-samples t-test was conducted to compare the surgery time score between two groups. There was no significant difference in scores between two groups

Table 2: Clinical characteristics of patients who underwent Elective cesarean section at Ghandi memorial hospital, Addis Ababa, Ethiopia, 2018/19

Clinical Characteristics		Dexametasone group	Non-dexametasone exposed	P value
Parity	Nulli parous	14(43.8)	15(46.9)	0.8
	Multi parous	18 (56.2)	17(53.1)	
History of previous C.S	Yes	13(20.3)	15((23.4)	0.8
	No	19(29.68)	17(26.5)	
Surgery time		40.7±7.93	39.9±8.02	0.69

Values are presented as frequency (%), chi square test and mean ± standard deviation, independent t-test

5.2 Comparison of Postoperative Numeric Pain rating scale at Rest and voluntary coughing at different time interval

A Mann-Whitney U Test revealed significant difference in the NRS score both at rest and voluntary coughing at 3hr, 6hr, 12hr, 18 hr and 24 hr between dexamthasone and non-dexamthasone groups. There were statistically significant decrements in NRS score both at rest and voluntary coughing in dexametasone group at those hours. There was no statistically significant difference between two groups in NRS score both at rest and voluntary coughing at the end of the surgery.

Table 3 Comparison of postoperative pain using 11 point NRS score (0-10) at rest and voluntary coughing

Time interval		O hr	3hr	6hr	12hr	18hr	24hr
Resting NRS	**dexamethasone**	0(0)	1(1-2.75)	3(2-3)	3.5(2-4)	3(2-3.75)	3(2-4)
	Non – dexamethasone	0(0)	3(1.25-4)	4.5(3-6)	4.5(3-6)	4(3-4.75)	4(3-6)
	P value	1	0.01*	0.0001*	0.016*	0.004*	0.0001*
Coughing NRS	**dexamethasone**	0(0)	2(0-3.75)	4(3-4)	4(3-5)	4(3-4.75)	4 (3-5)
	Non-dexamethasone	0(0)	4(2-5)	5(4-5.75)	5(4-7)	5(3.25-6)	5(3.25-6.75)
	P value	1	0.015*	0.001*	0.036*	0.008*	0.002*

Data are expressed using median (IQR); Mann-Whitney U test *= statistically significant

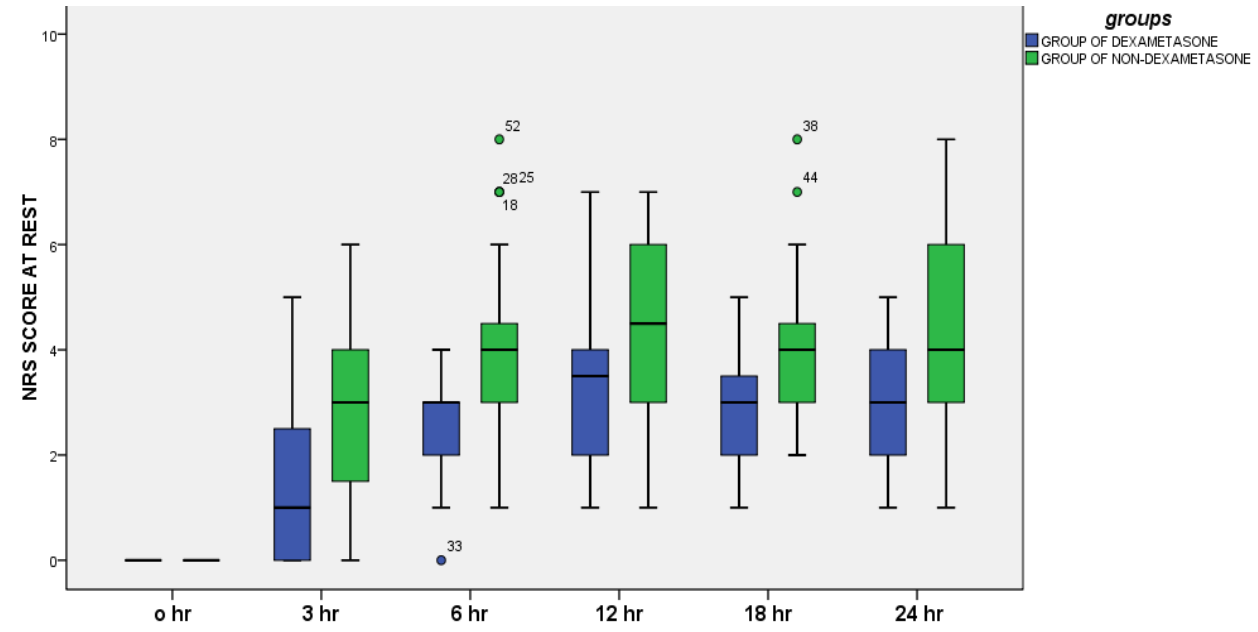

Figure : 3 Comparison of postoperative pain using 11 point NRS score (0-10) at rest

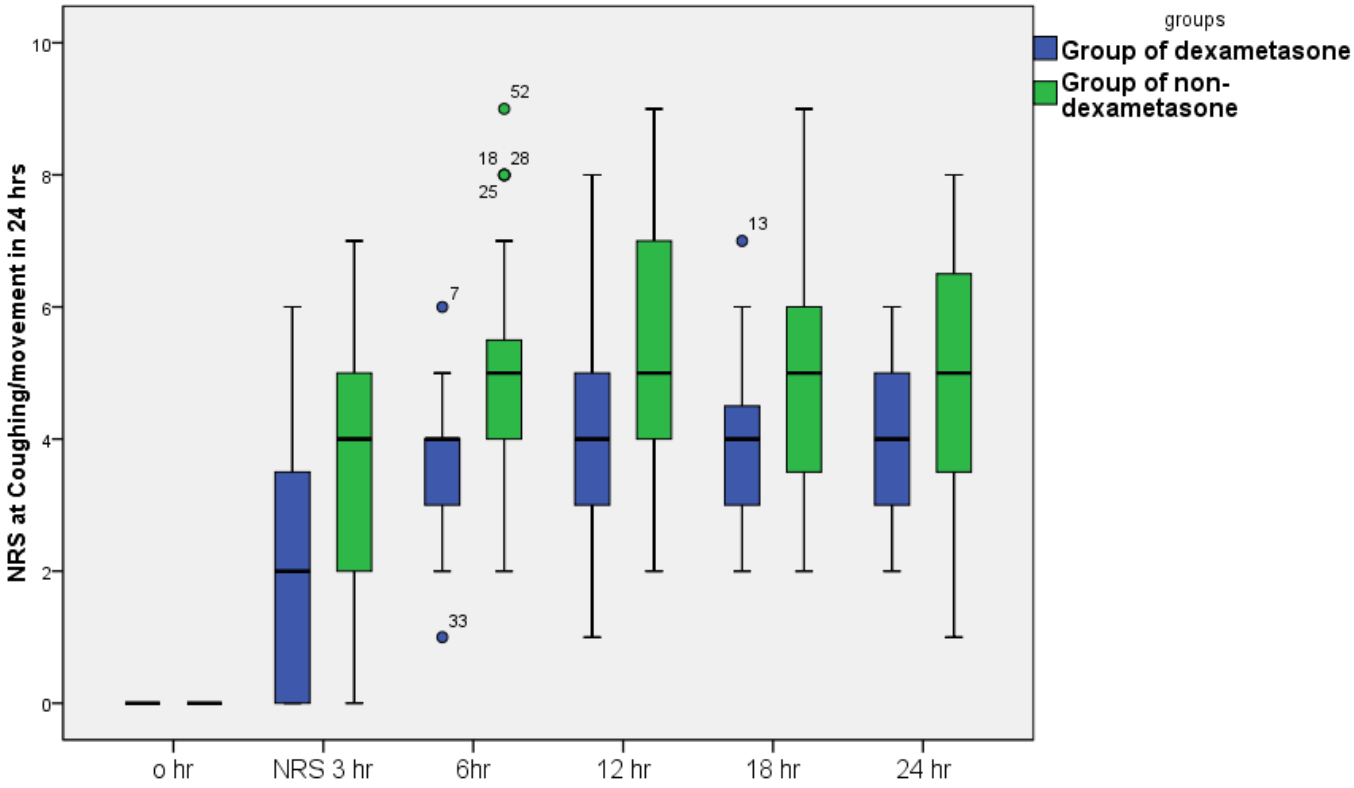

Figure: 4 Comparison of postoperative pain using 11 point NRS score (0-10) on voluntary coughing

5.3 Comparison of time to first analgesia request

The data for the time to the requirement of first rescue analgesia was not normally distributed. Mann Whitney U test' used for analysis and median score used to present the values. A Mann-Whitney U Test revealed significant difference in the time to the requirement of first rescue analgesia of dexamthasone group (Median= 6.58hrs, n =32) and non-dexamethasone group (Median = 4.1hrs, n =32), in which the result in dexamethasone group is significantly higher than non-dexamethasone group.

5.4 Comparison of cumulative analgesia consumption between groups

A Mann-Whitney U Test revealed significant difference in total Tramadol consumption of dexamethasone and non-dexamethasone groups. Otherwise there is no statistically significant difference in total diclofenac consumption between the two groups.

Table 4 : Total analgesic consumption between two groups

Observation	Dexamethasone group	Non-dexamethasone group	P value
Total Tramadol consumption	0.0 (0.0-37.5)	50(0-50)	0.0001
Total Diclofenac consumption	75(0)	75(0)	0.204

Value are presented as median (inter quartile range), Mann-Whitney U test, p value <o.o5 statistically significant

5.5 comparison of onset of sensory block between dexamethasone and non-dexamethasone group

An independent-samples t-test was conducted to compare the minute to achieve maximum sensory level for dexamethasone and non-dexamethasone groups. There was no significant difference in scores between two groups**.**

Table 5 : the minute to reach maximum sensory level

	Dexamethasone group	Non-dexamethasone group	P value
Minute of to achieve maximum sensory level	4.06±1.73	4.64±1.42	0.14

Values are presented as mean ± standard deviation, independent samples t-test, p value <0.05 statistically significant

6. Discussion

In our study, confounding factors such as demographic characteristics, duration of surgery and History of previous CS were all comparable between the groups thus; the difference in pain severity, time requirement of first rescue analgesia and total 24 hr analgesic consumption between groups was likely due to in exposure of dexamethasone between the groups.

In our study it was seen exposure of dexamethasone decrease postoperative pain, reduced total Tramadol consumption, and prolonged the median time to requirement of first rescue analgesia in postoperative period after elective cesarean section compared to patients who didn't take dexamethasone. Strong anti-inflammatory properties of dexamethasone have caused to introduction of "dexamethasone induced postoperative pain reduction" theory. some previous studies demonstrate that administration of intravenous dexamethasone have benefit on postoperative analgesia management in different surgeries undergoing under spinal anesthesia(24,27,31,32). Although analgesic mechanism of dexamethasone is still unclear, it is believed that Inhibition of cyclooxygenase (COX) enzyme, which takes part in the biosynthesis of prostaglandins (PGs) and thromboxane (TX), is the mechanism of action. PGs and TXs are important mediators of fever, pain, and inflammation(35).

Dose of IV dexamethasone differs in different types of surgeries ranging from 4 mg to 16mg. however; the optimal dose is still not defined. In a study conducted by oliveria et al, comparison into 3 groups, low dose (0.1mg/kg), 0.2mg/kg and >o.2mg/kg. They concluded that a dose of dexamethasone at 0.1mg/kg is an effective adjuvant in multimodal strategies to reduce postoperative pain and analgesic consumption. This is similar to the dose which used in our study(36).

Comparing the NRS score between dexamethasone and non-dexamethasone groups was the main interest of our study. We observed that NRS median score of 1(1-2.75) at 3^{rd} hr, 3(2-3) at 6^{th} hr, 3.5(2-4) at 12^{th} hr and 3(2-4) at 24^{th} hr at rest for dexamethasone groups and 3.5(1.25-4) at 3^{rd}, 4.5(3-6) at 6^{th}, 4.5(3-6) at 12^{th} hr and 4(3-6) at 24^{th} hr for non-dexamethasone group. This was significantly lower for dexamethasone group with p value 0.01, 0.0001, 0.016, 0.004 and 0.0001 respectively. This observation was in line with a randomized control study done in Egypt by Ahmed M. Maged, et al in 2017 in patients undergoing cesarean section under spinal anesthesia.

Which showed that mean VAS Score at 6, 12 and 24 in Dexamethasone group were 4.12±1.22, 5.58±1.5 and 7.7±1.6 in order given, which were significantly lower compared to placebo group with mean VAS score 6.95±2.29, 7.7±1.7 and 8.45±1.5 respectively with p value <0.0001(33). The similarity with our study may be due to the resembling of the method and the sentiment that dexamethasone having Strong anti-inflammatory properties which decrease the pain score.

Our study is also in line with the study done in India by Priyanka Sunil, et al on the efficacy of iv dexamethasone in prolonging the duration of spinal anesthesia in elective cesarean section in which they found significantly lower mean VAS scores for dexamethasone group at 6^{th}, 12th, 18th and 24^{th} hrs. The mean vas score for dexamethasone group was 3 at 6^{th} hr, 3 at 12^{th} hr, 4 at 18^{th} hr and 5 at 24^{th} hr and for non-dexamethasone group 5 at 6^{th} hr, 5 at 12^{th} hr, 5.5 at 18^{th} hr and 6 at 24^{th} hr (26). The 3hr VAS score is also comparable to a study done by Prabha Parthasarath, et al, in Patients Undergoing Surgery under Spinal Anesthesia with mean score of 1.93±0.58 in dexamethasone group and 3.65±0.70 in control group with p value <0.001.(37)

A randomized controlled trial done by U. Ituk, et al , in 2018 on The effect of a single intraoperative dose of intravenous dexamethasone 8 mg on post-cesarean delivery analgesia observed that median(inter quartile range) NRS Score at rest during 6^{th} hr, 12^{th} hr and 24^{th} hr in Dexamethasone group were 1(0-2),1(0-1) and 1(0-2) in order given, which were not significantly different compared to placebo group with median NRS score 1(1-3),2(1-3) and 1(1-3) respectively with p value >0.05, Which was in contrary to our finding showing that NRS median score of 3(2-3), 3.5 (2-4) and 3(2-4) in dexamethasone group and 3(1.25-4), 4.5(3-6) and 4(3-6) in non-dexamethasone groups and statistically significant difference between two groups(27). The disparity with our study may be due to a difference in study design, dose of dexamethasone used and the time of dexamethasone administration. They administer the dexamethasone after delivery and clamping of the umbilical cord, which contrast the idea that preoperative administration may allow enough time for intracellular diffusion and be relevant to reducing postoperative pain

Observing the time to the requirement of first rescue analgesia in hrs was another interest of our study. A study done in India by Prabha Parthasarath, et al in Patients Undergoing Surgery under Spinal Anesthesia found that mean Time of request for first analgesic dose (hr) is 3 for dexamethasone group and 6.6 for control group with p value <0.001 which was in line with our

finding showing median score (interquartile range) of 4.1(1.8) non-dexamethasone and 6.5(3.68) in dexamethasone group(37).

0ur result is in contrary with study done by Priyanka, et al, in 2017 on cesarean section patients. They observed that Mean time for first rescue analgesia in hr is 8.6 and 4.4 in dexametasone and placebo group respectively with p value <0.001. According to their finding there is high score of time to the requirement of the first analgesia for dexamethasone group compared to our study. The disparity with our study may be due to the different doses of intravenous dexamethasone used by two studies(26).

Our study observed that The median score for total consumption of Tramadol in 24hr post operatively has been 0mg in exposed group as compared to 50mg in non-exposed group with p value <0.0001.our result is in line with the study done by Ahmed M. Maged, et al on cesarean section patients which shows administering intravenous dexamethasone reduce total opoid consumption in the first 24 hrs postoperatively. Otherwise we found that there was no statistically significant difference in median score of total diclofenac consumption between the two groups with median score of 75mg (0mg) in both groups. In contrast to our finding Study done by Sourabh Roy , et al found that the Total dose of diclofenac (mg) mean (range) were 7.5 (0-75) and 31.5 (0-225) in dexamethasone and control group respectively(27). And another study done by prahaba ,et al found that There was difference in terms of total diclofenac use between treatment (average of 160 mg) and control (average of 217 mg) groups ($P < 0.001$)(37). The difference with our finding might be explained by disparate management of postoperative pain between the hospitals. They only used diclofenac IM injection for postoperative pain management.

The study conducted by Prahaba, et al found that there is no statistically significant difference between control (3.23±0.62) and treatment (3.1±0.66) group in mean Time to achieve maximum sensory level (min) with p value 0.43 (37). Their result is corresponding to our result with mean time in dexamethasone group (4.06±1.73) and non-dexamethasone group (4.64±1.42) with p value 0.14. A study done by Siddesh N Kadur, et al also concluded that there is no statistically significant difference between the two groups in time to achieve maximum sensory block.(24).

7. Strength and limitation of the study

7.1 Limitation of the study

Lack of randomization and control of the cofounding factor it the main limitation of this study. Lack of former study on this and related title in our country was one of our limitations to lay a foundation for understanding the problem. Moreover, we observed up the patients only up to 24hrs which is short duration of postoperative hour.

7.2 Strength of the study:

Study participant were uniform between the dexamethasone and non-dexamethasone group in which the difference on analgesic effect might be owing to exposure of the drug. With regard to our awareness this is the first study in our study title so, it will be conductive as baseline information for other researchers.

8. Conclusion and Recommendations

8.1 Conclusion

We concluded that preoperative administration of dexamethasone 0.1mg/kg intravenously for patients underwent cesarean section with spinal anesthesia was efficient in reducing postoperative pain, total Tramadol consumption on the first postoperative day and prolonging the time to the requirement of first rescue analgesia.

8.2 Recommendations

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

For Anesthetists

We recommend anesthetist to administer IV dexamethasone bolus dose of 0.1mg/kg before spinal injection for patients undergoing elective CS for better postoperative pain management as a part of multi modal analgesia. It provides better postoperative pain management in terms of reducing pain score, total analgesic consumption and prolonging the first analgesic request time.

For researchers

Considering this study as a baseline further long term multicenter and randomized control study which involves different surgical procedures is recommended.

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Annex

Annex 1: Declaration

I, the undersigned, senior clinical Anesthesia student declare that this thesis is my original work in partial fulfillment of the requirement for the degree of Masters of clinical Anesthesia.

Name: _____

Signature: _____

Place of submission: Department of Anesthesia, College of Health Sciences, School of Medicine Addis Ababa University.

Date of Submission: _____

This thesis work has been submitted for examination with my approval as university advisor.

Advisor

Name	Signature
_____	_____

ASSURANCE OF INVESTIGATOR

The undersigned agrees to accept responsibility for the scientific, ethical and technical conduct of the research project and for provision of required progress reports as pre terms and conditions of the research and publications office of the Addis Ababa University.

Name of the student: _____

Date: _____ Signature: _____

Approval of the advisor

Advisors

	Name	Signature	Date
1.	_____	_____	_____

Annex 2: Information sheet to get permission for the research

Introduction

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

The research team includes MSc students, two senior advisors from AAU one nurse and two anesthetists for data collection from Ghandi Memorial Hospital.

Name of Principal investigator: - Adamu Tesfaye

Advisor's name: - Ms.:- Eyayalem Melese

Ms.:- Tibite Daneil

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

Tel: - +251922396380

E-mail adam281et@gmail.com

Annex 3: Consent form English version

Verbal consent before conducting the interview

Hello greeting, my name is _____

I am member of department of anesthesia research team undergoing study, so I will ask you some questions relevant to study.

Almost a third of patients undergoing surgery experience moderate to severe pain post operatively, this pain brings about many psychological, physiological and social problems. The main aim of the study is to assess the intravenous dexametasone for prolongation of spinal analgesia on elective cesarean section patients. By participating in this research you will be giving a valuable data for understanding and identifying the effect of dexametason for prolonging spinal analgesia. Some data will be taken from your chart to identify factors for the pain. Your name, your responses or anything describing you will not be mentioned to anyone. Everything will be confidential in a secure way; you will have the full right to refuse not to participate in the research. You will not be given any incentives or be benefited or injured in any way. The results that we find will be used as a base line data for further actions in reducing post-operative pain. The interview will only take 10 min. Please feel free to ask any questions data collector nearby.

Do I have your permission to continue?

1. If yes, continue to the next page

2. If no, skip to the next participant

Informed consent Certified by

Interviewer: Code _____Name_____ signature_____

Date of interview _____Time started _____ Time completed_____

Result of interview: 1. Completed 2. Respondent not available 3. Refused 4. Partially completed

Supervisor (Checked): Name_____ signature _____Date_____

Annex 4: Consent form; Amharic version

የመጠይቅ ፈቃድ

የተከበራችሁ የጥናቱ ተካፋዮች

ጤና ይስጥልን እኔ_____እባላለሁ፡፡በቀዶ

ጥገና;ወሊድየሰመመንመድሃኒትበሚሰጥበትግዜላይየሚከሰቱየደምግፊትእናየልብምትለውጦችላ
ይየሚሰራጥናትመረጃሰብሳቢነኝ::
ጥናቱለእርሶምንምአይነትየገንዘብጥቅምአያስገኝምነገርግንየጥናቱውጤትበህክምናዘርፍላይያሉ
ትንችግሮችለመቅረፍእናየታካሚዎችንደህንነትየሚያረጋግጡህጎችእንዲስተካከሉእናሥራላይእንዲ
ውሉየበኩሌንአስተዋፅያያበረክታሉ፡፡ስምዎበዚህጥናትላይአይፃፍም፡፡ስለዚህምየእርሶምላሽሚስ
ጥራዊነቱየተጠበቀነው::በዚህመጠይቅላይለመሳተፍመስማማትምሆነአለመስማማትይችላሉ፡፡ባለ
መስማማቶምንምየሚጎዱትነገርየለም፡ጥያቄዎቹንበሚጠየቁበትበማንኛውምስዓትላይየማይመች
ነገርካጋጠመዎትለማቋረጥየምትችሉእናበሚመችዎትበማንኛውምስዓትመቀጠልየምትችሉመሆኑ
ንልናረጋግጥልዎትእንዎዳለን፡፡የምናገኘዉመረጃወደፊትበችግሩላይለመዉሰድለሚታቀደዉተግባር
እንደመሰረትየሚያገለግልይሆናል፡፡ቃለምጠይቁከ10 ደቂቃበላይአይወስድም.

በምርምሩለይለመሳተፍፈቃድዎንአግኝቻለሁ;

1. መልሱአዎከሆነቃለመጠይቁይቀጥላል
2. መልሱአይደለምከሆነወደሚቀጥለውተሳታፊእለፍ፡፡ቃለመጠይቁንየሞላስም ----------
   - ኮድ ---------- ፊርማ ----------

ቃለመጠየቁየተጀመረበትስዓት ---------- ያለቀበትስዓት ----------

ቃለመጠየቁንያስሞላስም ---------- ፊረማ ----------

የተቆጣጣሪስም ---------- ፊርማ፡፡

Annex 5 ; Data collection Questioner

Part 1.Sociodemographic and clinical factors

Ser. Number	Question	Response	Code
101	Patient age(yrs.)	_____	
102	Weight (kg)	_____	
103	Height (meter)	_____	
104	Body mass index (kg/m2)	_____-	
105	Gestational age(weeks)	_____	
106	Parity	1. Nulliparous 2. Multiparous	
107	History of previous CS	1.yes 2.no	
108	Number of previous c-section	1)10 2) 1 3).2 4) 3 and above	
119	Allergy to any of the following drugs	1. Diclofenac 2. Opioids 3. Local anesthetics 4. Others_____	
110	Does the patient has preexisting medical problem 1. Yes 2. No If yes specify _____		

Part 2 Data during preoperative period

Ser NO **Code**

201. Base line heart rate _____b/mi

202. Base line blood pressure _____mmhg

203. Diagnosis of the surgery_____

204. Duration of the surgery. Started at _____and ends at_____

205. Premedication _____

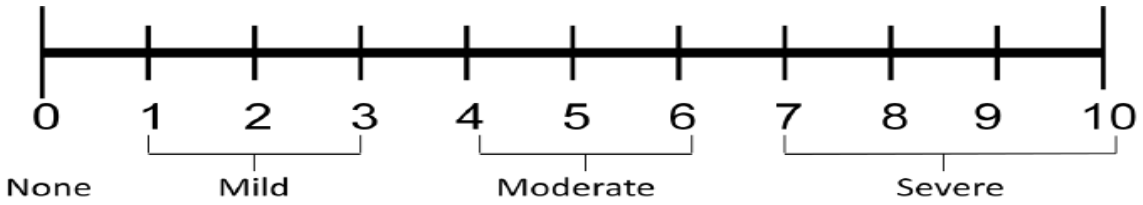
206. dexametasone used A. YES B. No

207. Experience of the surgeon _____

Ser. Number	Questions	Response	Code
301	Spinal injection to incision starting time (minutes)	_____min	
302	Spinal injection time	_____am/pm local time	
303	Time to reach Level of highest sensory block (t6-8)	_____	
304	Incision starting time to delivery of the child (minute)	_____	
305	Type of uterine incision	a. transverse b. vertical	
306	Duration of surgery	_____min	
317	Does any complication occurred intraoperatively?	1. Yes If Yes Specify_____ 2. No	

Data during post-operative period

401. The visual Analogue score



The scale will be taken 4 times within the first 24 hours. Patients will be asked to rate from 0 t0 10 and recorded at 0 min (immediately on acceptance of patient at recovery room) and 6, 12, as well 24 hours post-operatively.

The patient will be asked one of the following questions:

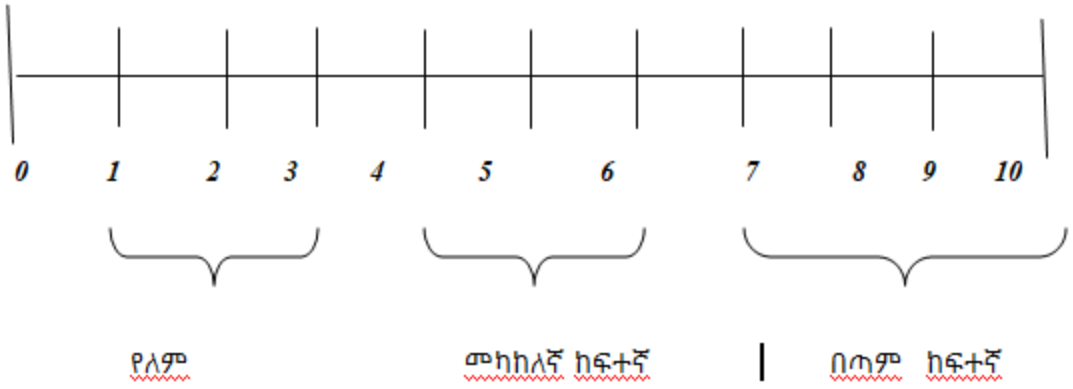
a. What number on a 0 to 10 scale would you give your pain right now?
b. When the explanation suggested above is not sufficient for the patient, further explanation or conceptualization of the scale will be done:

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)



መለኪያዉበ 24 ሰአትዉስጥ5 ጊዜየሚለካሲሆንታካሚዎችየሚሰማቸዉየህመምመጠንበየ 6 ሰአትልዩነትእንዲያሳዩንእንጠይቃለን

ታካሚዎችየሚከተሉትንጥያቄዎችይጠየቃሉ፤-

ሀ . አሁንከተገለጹትቁጥሮችማለትም (0-10) ባሉትዉስጥየእርስዎየህመምመጠንስንትላይነው

ለ. ከላይየተገለጸዉበቂካልሆነተጨማሪማብራሪያይሰጡታል፡

0ህመምየለም

1-3 መካከለኛህመም (መነጫነጭ፣መርበሽ፣ወ.ዘ.ተ)

4-6 ከፍተኛህመም (ከህመሙበተያያዘስራንበአግባቡአለመስራት)

7-10 በጣምከፍተኛህመም (እለታዊትግባራትንማከናወንአለመቻል)

402. Total drug consumption within 24 hours after patient arrived in the recovery

Drug _____ Dose _____

Drug _____ Dose _____

403. Severity of pain on NRS postoperatively Severity of pain on movement/coughing type and dose of analgesics given

At 0 hr. _____ _____

At 3hr_____ _____

At 6hrs._____ _____

At 12hrs._____ _____

At 18hrs_____ _____

At 24hrs._____ _____

404. Value of hemodynamic post- operatively.

	OHR	**3hr**	**6hr**	**12hr**	**18hr**	**24hr**
MAP						
HR						

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 rescue analgesic consumption within 24 hrs after patient arrive in the recovery is _____
407. Any post operative complication , A yes B. NO specify _____

Annex 6: American Society of Anesthesiologists (ASA) physical status classification of patients.

ASA PS Classification	Definition	Examples, including, but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30<BMI<40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (<3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	
*The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)		

Adopted from American society of anesthesiologist ASA PHYSICAL STATUS CLASSIFICATION SYSTEM, approved by the ASA House of Delegates IN 2016(38)

Annex 7: conceptual framework