

COMPARISON OF POSTOPERATIVE ANALGESIA EFFECTIVENESS OF
SPINAL BUPIVACAINE ALONE AND IN COMBINATION WITH
TRAMADOL AND FENTANYL DURING CESAREAN DELIVERY AT
ARSI UNIVERSITY TEACHING AND REFERRAL HOSPITAL.
PROSPECTIVE COHORT STUDY



INVESTIGATOR: DULA ABABA (BSc IN ANESTHESIA)

ADVISORS: Mr. Abdurhaman Tune (assistant professor in advanced clinical anesthesia)
Mr. Seyoum Hailu (MSc in advanced clinical anesthesia)
Mr. Ayele Bekele (MSc in advanced clinical anesthesia, PhD fellow)

THESIS TO BE SUBMITTED TO THE DEPARTMENT OF ANESTHESIA, COLLEGE OF
HEALTH SCIENCES, FOR PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR
THE MASTER OF SCIENCE IN ADVANCED CLINICAL ANESTHESIA.

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INVESTIGATOR: DULA ABABA (BSc IN ANESTHESIA)

Gmail : dulaababa@gmail.com

PHONE : +251938005001/0715460684

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Co- Advisors: Mr. Seyoum Hailu (Msc in advanced clinical anesthesia
Mr. Ayele Bekele (MSC in clinical anesthesia, PhD Fellow)

ABSTRACT

Background: Cesarean section is a common obstetric procedure that is usually performed under spinal anesthesia with bupivacaine being the most commonly used local anesthetics. Adjuvants added to bupivacaine during the single shot spinal anesthesia helps in extending postoperative analgesia duration and minimize side effects. Existing studies on intrathecal tramadol and fentanyl reported conflicting results on the postoperative analgesia duration; some reported fentanyl is effective while other may support tramadol.

Objective: To compare the postoperative analgesia effectiveness of spinal bupivacaine alone with that of bupivacaine combined with adjuvants tramadol and fentanyl for elective cesarean section at Arsi University Referral and Teaching Hospital from July to September, 2025.

Methods: An institutional-based prospective cohort was conducted on 93 parturients. Systematic sampling technique was employed. Data was collected with chart review, intraoperative observation and postoperatively patient interview. Shapiro wilk test was used to assess normality of the data. For normally distributed, analysis of variance (ANOVA) while Kruskal Wallis test was applied for not normally distributed data. Time to event variable was analyzed by using Kaplan Meir's survival function. P value less than 0.05 with a power 90% was considered statistically significant

Results: A total of 93 parturients (31 in each group) were included in the final analysis. The duration of postoperative analgesia was significantly longer in the bupivacaine tramadol group to (420.63 ± 14.43 minutes) compared to the bupivacaine fentanyl group (283.83 ± 19.28 minutes) and the bupivacaine alone (154.07 ± 24.63 minutes), $P < 0.0001$. Total postoperative Analgesia consumption was significantly lower in the bupivacaine tramadol group, ($p < 0.0001$). The total obstetric quality of recovery score was highest in the bupivacaine tramadol group 72 (66 -81), followed by bupivacaine fentanyl group 69.5 (54 – 79) and bupivacaine alone 60 (45 -71), $P < 0.0001$.

Conclusion: Addition of preservative free Tramadol to bupivacaine as adjuvants in spinal anesthesia for elective cesarean section increased analgesia duration, decreased 24-hour analgesia consumption, prolong time to first analgesia requests and improved obstetric quality of recovery.

Key Words: Spinal anesthesia, Postoperative pain, Tramadol, Fentanyl

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ACRONYMS (ABBREVIATIONS)

ASA	American society of anesthesiologist
AURTH	Arsi University Referral and Teaching Hospital
ANOVA	Analysis of variance
BA	Bupivacaine alone
BF	Bupivacaine Fentanyl
BMI	Body mass Index
BT	Bupivacaine Tramadol
C/D	Cesarean Delivery
C/S	Cesarean section
CSF	Cerebrospinal fluid
ERAC	Enhanced recovery after cesarean section
GA	General anesthesia
Km	kilometer
LSCS	lower uterine segment cesarean section
Mg	milligram
ml	mililiters
NRS	Numerical Rating Scale
ObsQoR- 11	Obstetric Quality of recovery – 11 points
POP	Postoperative pain
PI	Principal investigator
SA	Spinal anesthesia
SPSS	Statistical package for the social science
µg	microgram

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INTRODUCTION

1.1 Background

Spinal anesthesia is a neuraxial technique where local anesthetics are directly injected into the cerebrospinal fluid within the subarachnoid space. It is commonly used in cesarean section (C/S) surgery because of its safety, affordability, reliability, immediate effect, and its optimal conditions for the procedures (1–3).

In the UK around 28% of women, which amounts to roughly 178,000 give birth by cesarean delivery (C/D) under spinal anesthesia (SA) (4). The rate of cesarean section is reported to be higher in the USA, around 65% (5), and 25% - 30% in Colombia (6). Data from every newborn in the International Network for the Demographic Evaluation of Populations and Their Health Project in Ghana showed a 14.6% of cesarean delivery rate (7). In Ethiopia, the prevalence of cesarean section delivery was 28%; of these, 68% of the cases were operated under spinal anesthesia (8).

Local anesthetics like bupivacaine are widely used in spinal anesthesia due to their effective sensory and motor blockade during the intraoperative period. However, its main disadvantage is lack of long lasting postoperative analgesia (9), which can lead to early breakthrough pain and reliance on systemic analgesia (10). Achieving a subarachnoid block that provides high quality and consistently long-lasting analgesia therefore remains a continuous challenge for the anesthesia providers. To address this, most studies recommended the addition of opioids to local anesthesia during a single-shot spinal anesthesia to reduce the local anesthetic dose, extend postoperative analgesia (11), and eliminate potential side effects associated with parenteral opioids given at postoperative time (12).

It has been reported that many drugs, such as opioids (fentanyl, morphine, pethidine, tramadol, and sufentanil), as well as α_2 agonists (dexmedetomidine and clonidine), can be used as adjuvants to intrathecal local anesthetics to extend postoperative analgesia (12–15). Intrathecal tramadol as adjuvant to bupivacaine in spinal anesthesia has been used for postoperative analgesia in various operations (16), and for labor analgesia, and importantly it appears to have a safe pharmacokinetic profile in the neonate (17). Fentanyl is a lipophilic opioid with quick onset of action that is given to minimize intraoperative complications and prolong postoperative analgesia duration (18). Previous studies comparing postoperative analgesia duration of intrathecal fentanyl and tramadol added to bupivacaine has yielded inconsistent results (18–21).

Assessing which adjuvant provides better and longer lasting postoperative analgesia duration will help anesthesia professional to make evidence-based choices, improve maternal comfort and recovery. Given the lack of agreement regarding the optimal adjuvants between tramadol and fentanyl, this study assessed the postoperative analgesia effectiveness of spinal bupivacaine alone compared with that of bupivacaine combined with tramadol and fentanyl as adjuvants in spinal anesthesia among parturients who underwent elective cesarean section under spinal anesthesia.

1.2 Statement of the Problem

Pain is the most commonly anticipated issue in the postoperative period (22). Even though surgery is a lifesaving, it is related with potential harm, commonly pain during and after the surgery. In spite of improved knowledge of pain mechanisms, increased awareness of postsurgical pain, and improved pain management approaches in recent decades, postoperative pain going to be widespread, unresolved health care problems(23). The absence of long- lasting postoperative analgesia from local anesthetics challenges pain management and exposes the patient to additional analgesic drugs and severe pain afterwards (10,24,25).

Severe acute postoperative pain has been reported in 28%-78% of patients (26), which ranges from moderate to severe in the acute postoperative period (27). Pain severity after cesarean delivery makes it ninth rank among 179 different surgical procedures (28). Studies of developing countries reported 78.4%-92.7% of the incidence of postoperative pain after cesarean section (29). A study conducted in our country reported 85.5% of postoperative pain (POP) after cesarean section within the first 24 postoperative hours (30) and another study reported 91.7% of moderate to severe pain at 12 hours and 84.2% of severe pain after 24 hours of post cesarean section (31).

Findings of studies done in high income countries has demonstrated that early postoperative pain after cesarean section is related to an increased incidence of chronic pain (32), posttraumatic stress syndrome(33), breastfeeding interruption, increased morbidity, and increased opioid use during and after hospitalization, increased medical expenses, decreased patient satisfaction, and delayed functional recovery (34) that predispose to thromboembolic events, ileus, and respiratory impairment with atelectasis and pneumonia (35). Postoperative pain increases plasma circulating levels of catecholamines resulting in adverse effects of all organs (36). Inadequately treated postoperative pain also have an economic impact by increasing the length of hospital stay, time to discharge, readmission rates and time before ambulation (37), all of which can increase the cost of care.

Long- lasting postoperative pain control is very important for a patient who is expected to care of her newborn baby shortly after the operation(38). Adequate treatment of post cesarean section pain is necessary to enhance recovery, improve neonatal outcomes by facilitating breastfeeding success and bonding between mother and child and minimize pain related side effects (39). Several attempts have been made to treat postoperative pain after cesarean sections. Currently combining local anesthetics with opioids during a single shot spinal anesthesia is frequently recommended (40).

A comparative study of tramadol and fentanyl conducted on elective cesarean sections reported significantly improved postoperative pain and extended postoperative analgesia duration with bupivacaine plus fentanyl in spinal anesthesia over bupivacaine with tramadol (18,19). Studies conducted on non-obstetric population showed both intrathecal tramadol and fentanyl added to bupivacaine was equally effective at treating postoperative pain (41). While most direct comparative studies recommend intrathecal tramadol with bupivacaine over bupivacaine with fentanyl in relieving postoperative pain and extending analgesia duration (20,21,42), another study recommends bupivacaine with fentanyl (18,19,43–45).

Most prior studies were conducted in developed country. So different in-patient population, health care system, clinical practice and resources influence the outcome. Despite the importance of effective postoperative pain management after C/S, there is lack of clear data regarding bupivacaine alone, bupivacaine with tramadol and bupivacaine with fentanyl in spinal anesthesia for postoperative pain relief in Sub Saharan Africa particularly Ethiopia. Therefore, the findings of this study compared the postoperative analgesia effectiveness of bupivacaine alone compared with that of bupivacaine combined with adjuvants tramadol and fentanyl among parturients who underwent elective cesarean section under spinal anesthesia.

1.3 Significance of the study

The findings of the study help in facilitating rapid recovery, early discharge, reduced hospital stay and family costs, lowering morbidity rates, and minimizing patient discomfort. The study results help relieving postoperative pain, improve neonatal outcome by increasing breastfeeding success and bonding between mother and child, improve maternal care after cesarean delivery, and reduce pain induced side effects. The findings of this study will address the conflicting idea reported in previous studies. Additionally, the results of this study provide a middle ground between contradictory findings on the intrathecal tramadol and fentanyl effectiveness in prolonging postoperative analgesia. Quality of care was measured by patient satisfaction. As a result, this study result helps in extending postoperative analgesia duration after spinal anesthesia and improve patient satisfaction and reduce family costs expended on the parenteral opioids.

The findings are particularly relevant in resource-limited settings where optimizing the choice of intrathecal adjuvants can improve pain control while reducing the use of postoperative parenteral opioids. This comparison helps anesthesia professional to make more informed, evidence-based decisions that are tailored to the needs of the patient. Even though effective analgesia may facilitate early mobilization, breastfeeding and bonding, no studies address the effects of spinal anesthesia with bupivacaine alone and adjuvants fentanyl and tramadol on quality of recovery, beyond pain relief. So, this study provided an important finding on the effects of bupivacaine alone and in combination with adjuvants tramadol and fentanyl on the obstetric quality of recovery.

The result of this study provided important information for perioperative care providers (anesthetists in particular) and obstetricians to anticipate pain onset and plan timely management while assisting anesthesia providers in developing protocols on spinal anesthesia adjuvants to ensure prolonged postoperative comfort. The study findings help administrators, program managers and policy makers for the development of standardized anesthesia protocols, formulate or update national clinical guidelines on obstetric anesthesia, optimize resource utilization and an input data source for other researchers interested in this subject area.

LITERATURE REVIEW

Postoperative pain following cesarean delivery is a distressing experience for women that leads to delayed mobility, extended hospital stays, impaired bonding with the newborn, reduced maternal satisfaction, and delayed initiation of breastfeeding. This literature review includes postoperative analgesia duration of spinal anesthesia with bupivacaine alone and with adjuvants fentanyl and tramadol, as well as postoperative analgesia consumption and obstetric quality of recovery within 24 hours after surgery.

2.1 Analgesia duration of intrathecal fentanyl with bupivacaine

Meta-analysis of 17 trials conducted 2016 in Canada on 1064 adult parturients undergoing cesarean delivery under spinal anesthesia reported longer analgesia duration in bupivacaine fentanyl group (mean difference, 91 minutes; 95%CI: 69-113, I) in comparison to bupivacaine alone and there is no significant difference regarding respiratory depression between the two groups (relative risk, 3.20; 95% CI, 0.38–27.26; P = .29; I² = 0%) (46).

Another clinical study conducted 2014 in India on 90 healthy parturients posted for elective or semi- emergency cesarean section reported 259 ± 32.53 minutes of total analgesia duration with 10mg of 0.5% of heavy bupivacaine with 12.5µg of fentanyl and 165 ± 29.8 minutes with 10mg of 0.5% heavy bupivacaine with 0.25ml of CSF (47).

A double blinded prospective randomized controlled study conducted 2015 in India on 80 parturients scheduled for elective cesarean section under spinal anesthesia reported 170 ± 28.42 minutes and 259.63 ± 36.5 minutes of complete analgesia duration with 10mg of 0.5% heavy bupivacaine with 0.25ml of normal saline and 10mg of 0.5% heavy bupivacaine with 12.5µg of fentanyl respectively (48).

Another prospective double blinded randomized study conducted 2018 in India on 220 parturients who underwent cesarean section under spinal anesthesia reported 149.5 ± 6.2 minutes of effective analgesia duration in 2.5ml of 0.5% of heavy bupivacaine with 0.5ml of normal saline and 259.2 ± 5.6 minutes in 2.5ml of 0.5% of heavy bupivacaine with 25µg of fentanyl (49).

Prospective randomized study conducted 2011 in Turk on 60 healthy women scheduled for elective cesarean section reported 276 ± 26 minutes and 121 ± 10 minutes of postoperative analgesia duration with 12.5mg of bupivacaine plus 25µg of fentanyl and 12.5mg of bupivacaine alone respectively (50).

A prospective randomized double blinded controlled study conducted 2011 in Saud Arabia on 50 singleton patients scheduled for elective cesarean section reported prolonged postoperative analgesia duration to 200 ± 9.1 minutes in 7.5mg of 0.5% heavy bupivacaine plus 25 μ g of fentanyl and 153 ± 9.0 minutes in 10mg of 0.5% of heavy bupivacaine alone (51).

A single blinded study conducted 2016 in Tanzania on 79 parturients reported a prolonged analgesia duration to 219.1 ± 18.0 minutes with 10mg of bupivacaine plus 25 μ g of fentanyl group and 120.6 ± 23.6 minutes with 10mg of bupivacaine alone group, $p < 0.001$ (52).

A prospective cohort study conducted at Wollo university in 2022 on 90 elective cesarean sections reported prolonged analgesia duration to 248 ± 35.8 minutes with 8mg of bupivacaine with 25 μ g of fentanyl, 260.3 ± 40.3 minutes of effective analgesia duration with 10mg of bupivacaine with 25 μ g of fentanyl ,and 167 ± 25.88 minutes with 10mg of bupivacaine alone, $p = 0.001$ (53).

An observational cohort study conducted 2017 at Gondar University on 100 emergency C/S reported prolonged analgesia duration to 275.10 ± 42.43 minutes with 10mg of bupivacaine with 25 μ g of fentanyl group and 156.10 ± 34.45 minutes of effective analgesia duration with 12.5mg of bupivacaine alone group, ($P = 0.001$) (54).

2.2 Analgesia duration of Intrathecal Tramadol with bupivacaine

A prospective randomized double blinded study conducted from 2012 to 2013 in Nepal, south Asia region on 60 ASA I and II patients scheduled for lower abdominal surgery under spinal anesthesia (SA) reported prolonged mean duration of analgesia to 231.53 ± 22.00 minutes with 3ml of 0.5% of heavy bupivacaine plus 25mg of tramadol and to 125.40 ± 8.86 minutes with 3ml of 0.5% of heavy bupivacaine with 0.5ml of normal saline, $P = 0.003$ (55).

A single blinded, randomized placebo controlled trial conducted 2015 in India on 100 parturients undergoing cesarean section reported 232.18 ± 80.55 minutes of time for first postoperative analgesia request with 10mg of bupivacaine plus 10mg of tramadol and 176.56 ± 47.39 minutes with 10mg of bupivacaine with 0.2ml of normal saline (56).

A prospective cohort study conducted at Empress Zewditu memorial hospital, Addis Ababa on 62 laboring mothers delivered by cesarean section under spinal anesthesia reported prolonged analgesia duration to 245.33 ± 22.854 minutes with 12.5mg of bupivacaine plus 20mg of tramadol and to 135.00 ± 21.735 minutes with 12.5mg of bupivacaine alone, $p < 0.001$ (57).

2.3 Analgesia duration of Intrathecal Tramadol and Fentanyl with bupivacaine

A prospective randomized study conducted from May 2023 to January 2024 in India on 84 parturients appointed for elective cesarean section under spinal anesthesia reported greatly prolonged analgesia duration to 180.17 ± 3.164 minutes with 3ml 0.5% of heavy bupivacaine plus 20 μ g of fentanyl and to 148.47 ± 3.102 minutes with 3ml of 0.5% hyperbaric bupivacaine with 20mg of tramadol, $P < 0.0001$ (19).

A double randomized blind study conducted 2013 in India on 80 elective cesarean section reported longer median analgesia duration to 300 ; [IQR, (240 – 360)] minutes with 10mg of bupivacaine plus 10mg of tramadol and to 60; [IQR, (233 – 300)] minutes with 10mg of bupivacaine plus 10mg of fentanyl, $p = 0.02$ (20).

A prospective randomized double blinded study done over a period of 18 months in India on 62 parturients scheduled for elective lower segment cesarean section reported prolonged analgesia duration to 9.47 ± 2.08 hours with 9mg of bupivacaine plus 10 μ g of fentanyl and to 6.40 ± 1.25 hours with 9mg of bupivacaine plus 10mg of tramadol, $p = 0.03$ (18).

A double blind randomized study conducted April 2019 in India on 60 patients scheduled for lower segment cesarean section randomly divided to intrathecal block with 10mg of bupivacaine plus 10mg of tramadol and 10mg of bupivacaine plus 10 μ g of fentanyl concluded higher mean analgesia duration in bupivacaine tramadol group (302.1 ± 55.2) minutes compared to bupivacaine fentanyl group (262.6 ± 40.7) minutes $p = 0.003$ (21).

A double-blind randomized study conducted 2019 in Baghdad, Iraq on 70 parturients scheduled for elective cesarean section reported greatly prolonged analgesia duration to 450 ± 109.38 minute with the 12.5mg of bupivacaine plus 25mg of tramadol compared to 12.5mg of bupivacaine with 25 μ g of fentanyl with mean analgesia duration of 441 ± 119.69 minutes, $p = 0.000$ (42).

A prospective randomized study conducted from July 2021 to December 2021 in Saudi Arabia on 90 parturients posted for elective cesarean section reported prolonged mean analgesia duration to 215.00 ± 26.51 minutes in 5mg of bupivacaine with 50mg of tramadol compared to 5mg of bupivacaine with 50 μ g fentanyl and 7.5mg of bupivacaine with 0.5ml of dextrose in water with postoperative analgesia duration of 168.00 ± 30.21 minutes and 118.50 ± 23.60 minutes, respectively ($P = 0.01$) (58).

A prospective randomized study conducted 2012 in Bangladesh, India on 60 parturients scheduled for elective cesarean section reported prolonged mean analgesia duration to 213.00 ± 27.35 minutes in 5mg of bupivacaine with 50mg of tramadol and to 117.75 ± 22.96 minutes with 7.5mg of bupivacaine plus 0.5ml of dextrose in water ,and to $166.00 \pm 29-62$ minutes with 5mg of bupivacaine plus 50 μ g of fentanyl, $P = 0.01$ (59).

A prospective double blind randomized study conducted 2018 in Turkey on 146 patients who underwent elective transurethral procedure reported prolonged mean analgesia duration to $183.75 + 47.01$ minutes in 12.5mg of bupivacaine with 50 μ g of fentanyl and to of $149.81 + 26.78$ minutes with 12.5mg of bupivacaine plus 10mg of tramadol, and to $143.07 + 14.22$ minutes with 12.5mg of bupivacaine plus 1ml of normal saline, $p < 0.05$ (60).

2.4 Postoperative analgesia Consumption

A prospective randomized double-blind study conducted 2020 in India on 60 parturients appointed for elective cesarean section reported that only 2 patients (6.66%) of who received 10mg of bupivacaine with 20mg of tramadol required postoperative tramadol, compared to 9 patients (30%) of who received 10mg of bupivacaine with 0.4ml of normal saline (61).

An institutional based prospective cohort study conducted 2024 in Ethiopia on 164 obstetric patients appointed for elective cesarean section who had taken 10mg of bupivacaine with 20mg of tramadol and or 4mg of dexamethasone reported, fewer opioid and non-opioid medications were consumed in 10mg of bupivacaine with 20mg of tramadol, $P < 0.05$ (62).

Another hospital based observational cohort study conducted 2015 in Ethiopia on 100 patients scheduled for emergency cesarean section under spinal anesthesia with 10mg of bupivacaine with 25mcg of fentanyl and 12.5mg of bupivacaine alone reported, patients undergoing intrathecal anesthesia with bupivacaine fentanyl showed reduced postoperative tramadol consumption within 12 hours (median 50(50) versus 100(50) in 12.5mg of bupivacaine alone (54).

2.5 Obstetric quality of recovery

A multicenter, prospective, double blind, randomized controlled trial, conducted 2019 in China on 300 patients randomly assigned to three groups reported (61.7, [95%CI= 60.8 - 62.2]), (61.7, [95% CI = 61.0 – 62.4]) and (71.6, 95%CI = 71.0 -72.2]) of overall score of quality recovery in 9MG of bupivacaine with saline, 9mg of bupivacaine with 20mcg of fentanyl, and 9mg bupivacaine with 4mcg of dexmedetomidine group respectively, $P < 0.0001$ (63).

In conclusion, the existing literature presents a conflicting picture regarding the superiority of intrathecal fentanyl added to bupivacaine over bupivacaine tramadol. Studies conducted on obstetric and non-obstetric populations with a different dosing regimens favor intrathecal fentanyl (18,19,64) over intrathecal tramadol with bupivacaine, while another studies recommend intrathecal tramadol (20,21,42). This discrepancy highlights the influence of factors such as patient population, type of surgery, and drug dosage, underscoring the need for a direct comparison within the specific context of elective cesarean section in our setting.

2.6 Conceptual Framework

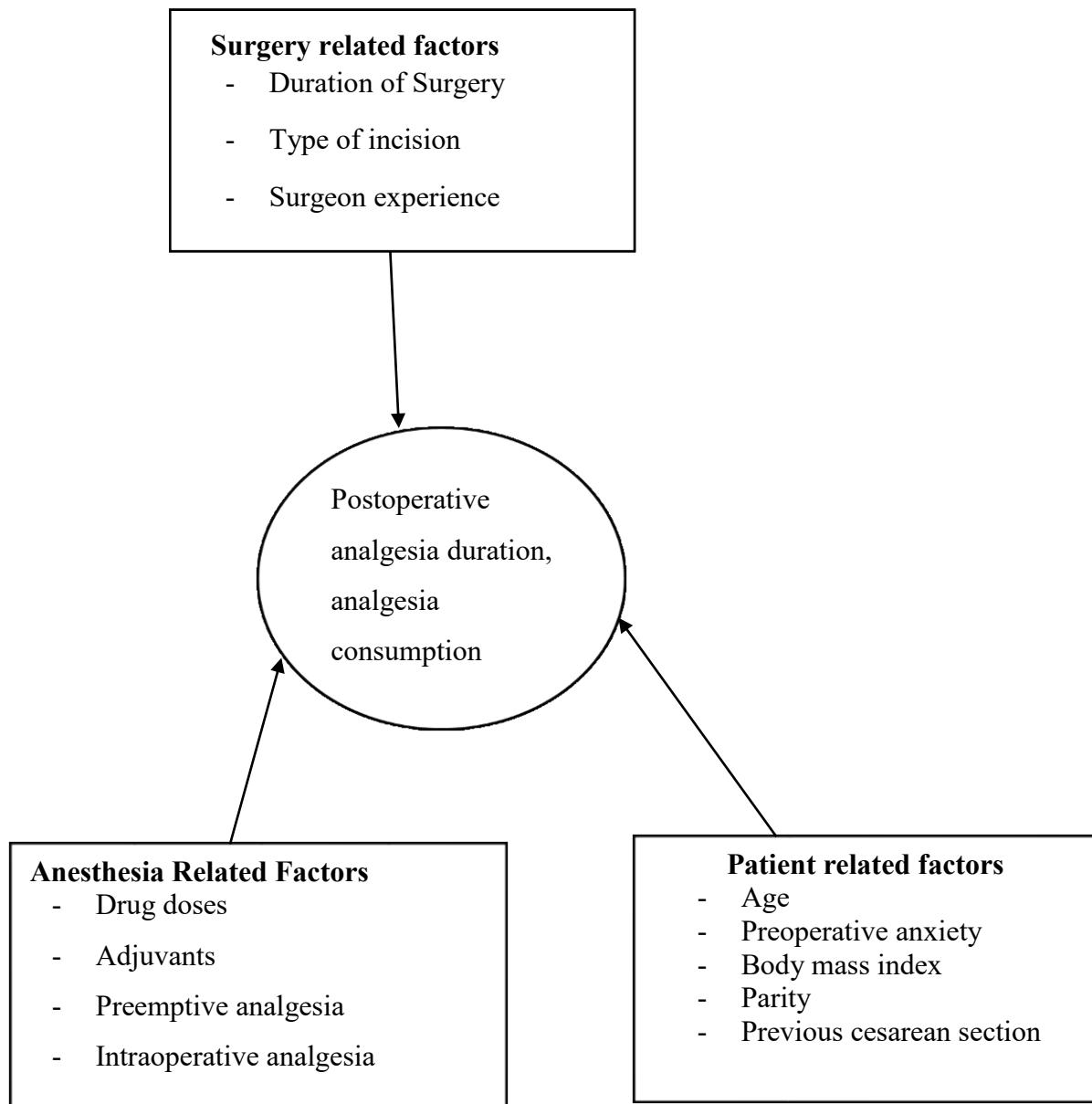


Figure 1. Conceptual frame work.

Conceptual frame work was adapted from different pieces of literatures(53,54,57,65)

Hypothesis

Null Hypothesis: There is no statistically significant difference in the postoperative analgesia effectiveness between the study groups

Alternative Hypothesis: There is statistically significant difference in the postoperative analgesia effectiveness between the study groups.

OBJECTIVES

3.1 General Objectives

To compare the postoperative analgesia effectiveness of spinal bupivacaine alone versus bupivacaine with adjuvants tramadol and fentanyl in patients undergoing elective cesarean section at Arsi University Referral and teaching Hospital from July to September 2025

3.2 Specific Objectives

1. To compare time to first request of analgesia between spinal bupivacaine alone versus bupivacaine with adjuvants tramadol and fentanyl in elective cesarean section at Arsi University Referral and teaching Hospital from July to September 2025
2. To compare total analgesia consumption within 24 hours of postoperative surgery between spinal bupivacaine alone versus bupivacaine with adjuvants tramadol and fentanyl in elective cesarean section at Arsi university referral and teaching hospital from July to September 2025
3. To assess the quality of recovery between spinal bupivacaine alone versus bupivacaine with adjuvants tramadol and fentanyl in spinal anesthesia in elective cesarean section at Arsi University Referral and teaching Hospital starting from July to September 2025

METHODS AND MATERIALS

4.1 Study Area and Period

The study was conducted at Arsi University Referral and Teaching Hospital (AURTH), located in the Arsi zone of the Oromia region, approximately 159 km south east of Addis Ababa in Asella town, from July to September 2025. Arsi University Referral and Teaching Hospital (AURTH) had been established in 1964 as Emperor Haile Selassie Hospital and was later renamed Asella Hospital following the revolution of the Derg regimes in 1975. The hospital underwent its first renovation in 1992 through Ethio-Italian cooperation. From 2008, it served as a teaching hospital for Adama Science and Technology prior to the establishment of Arsi University in 2014 E.C. Arsi University Referral and Teaching Hospital provided medical care for approximately 5 million people annually from the Arsi zone and neighboring zones, providing services in internal medicine, general surgery, orthopedics, plastic surgery, neurology, obstetrics and gynecology, pediatrics, and ophthalmology, with a total capacity of 321 beds. The hospital was equipped with 6 operating rooms and an intensive care unit containing six (6) functional beds. (https://en.wikipedia.org/wiki/Arsi_University)

4.2 Study Design

Institutional based prospective cohort study was conducted from July to September, 2025.

4.3 Source population and Study population

4.3 .1 Source Population

All parturients who underwent cesarean section at Arsi University Referral and Teaching Hospital during the study period.

4.3 .2 Study Population

All elective parturients who underwent cesarean section under spinal anesthesia and fulfilled inclusion criteria during the study period at Arsi University Referral and Teaching Hospital.

4.4 Eligibility Criteria

4.4.1 Inclusion Criteria

ASA II parturients aged 18 to 45 years appointed for elective cesarean section under SA.

4.4.2 Exclusion Criteria

- Failed spinal anesthesia
- Patients with addiction or alcoholics
- Parturients who required systemic analgesia intraoperatively
- Parturients who received other nerve block like TAP block after the procedure
- Parturients with ASA status greater than II

4.5 Sample Size Determination and Sampling Technique

4.5.1 Sample Size Determination

The sample size was determined by using G* Power version 3.1.92, effect size 0.4 (large), α error 0.05 and, power of 90%. The calculated sample size for three groups was 84. After accounting for a 10% dropout rate, the final total sample size was 93. Maintaining a 1:1:1 ratio, 31 participants were recruited for each group.

4.5.2 Sampling Technique

A retrospective situational analysis was conducted at Arsi university Referral and Teaching hospital by reviewing obstetrics log books records covering a three-month period from July to September 2016 E.C for those who fulfilled inclusion criteria. According to the records, a total of 188 parturients delivered by elective C/S under spinal anesthesia during this period. Systematic sampling technique was employed and the sampling interval was calculated using by using $K = N/n = 188/93 = 2.02$ $k = 2$ $K = \text{sampling interval}$ $N = \text{Total population}$ $n = \text{Sample size}$. The first participant was randomly selected by the lottery method, and thereafter, every second individual was included until the desired sample size was achieved.

4.6 Study Variables

4.6.1 Dependent Variable

- Postoperative analgesia duration
- Total analgesia consumption,
- Quality of Recovery

4.6.2 Independent Variables

- Groups of study
- Age
- Weight
- Height
- Body Mass Index
- Duration of surgery
- Previous cesarean section scar

4.7 Operational Definition

First time to request analgesia: Defined as the time from intrathecal injection to first request of analgesia

Duration of surgery: Time in minutes takes from skin incision to closure

Total analgesic consumption: The total analgesia given in the first 24 hours after the end of surgery

Duration of analgesia: The duration in hours between intrathecal injections of drugs up to the first time to analgesia request or up to the first recording of the NRS score ≥ 4 .

Failed spinal anesthesia: Failed spinal anesthesia is inability to achieve an adequate sensory and motor block within the first 15 to 20 minute requiring supplemental analgesia or conversion to general anesthesia (66).

Quality of recovery: It is a score composed of 11 items with grading of each item from 0 to 10, that provides valid, reliable, and responsive global assessment of recovery after elective cesarean delivery; 0 score strongly agree and 10 strongly disagree. A study group with a highest total score considered to have higher quality of recovery and vice versa.(67).

4.8 Data Collection Procedures

Before data collection, data collectors were trained with a brief training about how data collection can be conducted and practical demonstrations to ensure consistency in data gathering process. A data was successfully gathered using structured questionnaire prepared both in English and local languages Amharic and Afaan Oromo. Some information was obtained from the patient chart, anesthesia record chart, and through the observation. The completed questionnaire contained comprehensive data, including sociodemographic data, intraoperative detail, postoperative analgesia assessment, and surgical factors.

All parturients scheduled for elective surgery who fulfilled inclusion criteria and consented to participate in the study were thoroughly assessed before surgery through history taking and chart review. On the morning of surgery, data collectors were instructed, and patients were familiarized with the Numerical rating scale (NRS), where (0 indicated no pain and 10 indicated the worst pain) (68). The questionnaires were completed by first- year MSc students who had received prior orientation on how to extract the necessary information from the patient chart, anesthetic record and through observation, depending on each variable. On arrival in the operating room, standard monitoring with heart rate (HR), noninvasive blood pressure (NIBP), and oxygen saturation was established and patients were preloaded with 10ml/kg of normal saline. Spinal anesthesia was performed in the sitting position at the middle line either at L3/L4 or L4/L5 interspinous space after cleansing the spinal needle insertion site with iodine and alcohol. According to our setup, spinal anesthesia could be administered with 10 - 12.5mg of bupivacaine, either alone or in combination with different adjuvants such as tramadol (20mg – 25mg), morphine (75µg - 100µg), fentanyl (15µg - 25µg), pethidine (15 -25mg), and dexamethasone (2-4mg) as per the attending anesthetist's preference. Once the block was completed patients were put on supine position. Intraoperative vital signs were recorded every 10 minutes. following delivery, oxytocin 10IU IM and 30IU in infusion or 400µg misoprostol sublingually were given as needed to promote uterine contraction. The study included patients who received 10mg of bupivacaine alone, 10mg of bupivacaine with 25µg of fentanyl and 10mg of bupivacaine with 20mg of tramadol as documented in the intraoperative anesthesia records. Specifically the dose of 25µg of fentanyl was chosen according to the review by Hamber and Viscomi (69), while the dose of 20mg of tramadol was adopted from the recommendations of the observational study conducted by Lorato et al (62). Intraoperative data were collected through observation and from the patient chart, and anesthesia record sheet by two first year MSc anesthesia students, whereas postoperative outcome data were collected by

two midwifery staff at the designed follow-up times. Intraoperative data collectors gathered only the intraoperative data and submitted it to the principal investigator, while the postoperative data collectors collected the remaining postoperative data and submitted it independently after 24 hours. Postoperative data, such as duration of effective analgesia, was noted as the time from intrathecal injection to first analgesia request time or Numerical rating score (NRS) ≥ 4 and recorded accordingly. Postoperatively, pain score (NRS) was assessed at 1st, 2nd, 3rd, 4th, 6th, 8th, 12th, and 24th hours after surgery. Postoperative NRS score was assessed by a line that consist of 10cm, with two end points 0 (no pain) and 10 (the worst pain).

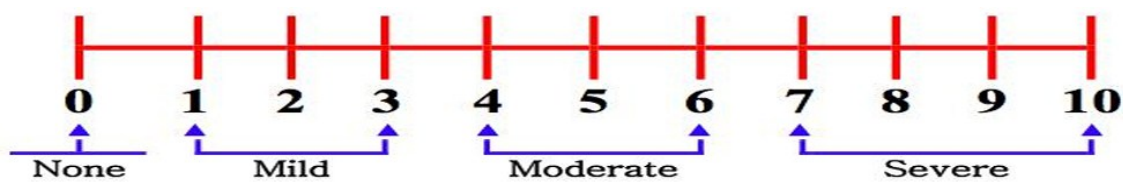


Figure 2. NRS score Adopted from the National Initiative on Pain Control (NICP TM)

The Numerical rating scale was determined by the patient by marking their pain intensity on a line 10cm long. A score of 0 – 3 indicated mild pain, 4 – 6 indicated moderate pain and 7 – 10 represented severe or the worst pain. The point taken by the distance from the left end point to the mark of the patients. The total analgesic consumption was taken from the patient chart after 24 hours of the surgery. Next day after delivery, the quality of recovery of parturients were be assessed by the obstetric quality of recovery- 11 score (ObsQoR – 11). It is a score that is composed of multiple items with grading of each item from 0 to 10, where 0 = strongly agree and 10 = strongly disagree(67). Postoperative pain management of our institutions included 100mg of diclofenac suppository as standing medication, with 75mg IM reserved for rescue analgesia. If pain persisted paracetamol 1g orally was administered as available, followed by tramadol 25-100mg IV for uncontrolled pain. These medications were given up on request. Discharge was planned when the patient was hemodynamically stable, had adequate pain control, could ambulate, and tolerated oral intake. Before discharge, each mother received counselling and scheduled for follow up within 7 -10 days. All perioperative and postoperative events were documented.

4.9 Data Quality Control and Assurance

To assure data quality, two first- year MSC anesthesia students and two midwifery staffs were trained on the study objectives and the contents of the data collection form. One week before the actual data collection began, pre-testing was conducted at Adama Hospital medical college on 10% of the sample size to assess the clarity, validity, consistency and understandability of the data collection tools, and a few modifications were made. The suitability of the data collection format was assessed through discussion with research advisors. The principal investigator supervised the work of the data collectors throughout the data collection period, from the beginning to the end to ensure data accuracy and completeness using the elective cesarean section operation schedule as a sampling frame.

4.10 Data Processing and analysis

All the collected data were arranged, categorized, checked for completeness, coded, and entered into Epi data software version 3.1 using a predesigned data entry template. The cleaned data set was then exported to IBM SPSS Statistics version 25 for analysis. Shapiro-Wilk test was used to assess whether data are normally distributed or not. For data that followed a normal distribution (analgesia duration, time to first analgesia request, and total postoperative analgesia consumption), analysis of variance (ANOVA) was used. Data with statistically significant difference found using ANOVA, post hoc Tukey's honest significant difference (HSD) test was performed to identify pairwise group differences and expressed as mean $\pm$ standard deviation. Non-parametric data (obstetric quality of recovery) were expressed as median and interquartile range, and analyzed using Kruskal-Wallis test, with intergroup comparison carried out using Mann-Whitney U test. Categorical data were presented as numbers and frequencies (%) after analysis using the Pearson chi-squared test. Time to event variable was analyzed by using Kaplan Meir's survival function and survival log rank to detect significant difference. A p-value < 0.05 was considered statistically significant.

4.11 Ethical Considerations

Our study was carried out in accordance with the principles of the Declaration of Helsinki in line with the ethical principles for medical research involving human subjects (70). The research study commenced after obtaining ethical clearance from the Arsi University College of Health Sciences Ethical Review Committee with a project protocol number of CoHS/R/193/2025. Official support letters were sent to hospitals, seeking permission for data collection from the relevant authorities. The study's objectives and benefits were explained verbally, and informed consent was obtained orally from each participant's family. Written consent was obtained from respondents and data was collected confidentially. Participation in the study was voluntary, and participants were allowed to withdraw at any time without facing any restrictions. Participants and their guardians were informed of their right to opt out of the study whenever they wished.

4.12 Dissemination of the Result

The result of the study will be submitted to the College of Health Sciences, Arsi University, and department of anesthesiology, and documents should be disseminated to all responsible bodies in the study area, including the Arsi University postgraduate library. Furthermore, efforts will be made to publish the study's findings. The results of the study will also be presented at other conferences, such as the annual meeting of the Ethiopian Anesthetist Association and others.

RESULTS

A total of ninety-three pregnant mothers aged between 21 and 32 years (mean age $\pm$ SD, 27.16 $\pm$ 2.96), who were scheduled for elective cesarean section under spinal anesthesia were included in the study.

The study groups were similar in socio-demographic characteristics, with no significant differences in terms of mean age ($p = 0.271$), weight ($p = 0.415$), height ($p = 0.547$), gestational age ($p = 0.699$), and duration of surgery ($p = 0.735$) BMI ($p = 0.185$) (Table 1).

Table 1. Socio-demographic characteristics of the study groups.

Variables	Bupivacaine alone (n= 31)	Bupivacaine Fentanyl (n= 31)	Bupivacaine Tramadol (n=31)	P value
Age (Years)	27.73 $\pm$ 2.84	26.50 $\pm$ 2.51	27.23 $\pm$ 3.43	0.271
Weight(kg)	70.93 $\pm$ 5.98	70.37 $\pm$ 5.65	69.13 $\pm$ 4.23	0.415
Height(m)	1.608 $\pm$ 0.52	1.621 $\pm$ 0.46	1.604 $\pm$ 0.39	0.547
BMI (kg/m ²)	27.47 $\pm$ 2.51	26.81 $\pm$ 2.20	26.35 $\pm$ 2.32	0.185
Gestational age(weeks)	37.77 $\pm$ 0.817	37.87 $\pm$ 0.776	37.70 $\pm$ 0.701	0.699
Previous C/S scar				
NO	19(63.3%)	19(63.3%)	15(50%)	0.480
YES	11(36.7%)	11(36.7%)	15(50%)	
Gravidity				
Multigravida	15(50%)	17(56.7%)	14(46.7%)	0.733
Primigravida	15(50%)	13(43.3%)	16(53.3%)	
Duration of surgery	48.00 $\pm$ 4.80	49.07 $\pm$ 5.63	48.50 $\pm$ 5.30	0.735

Some values are presented as mean $\pm$ SD, P values > 0.05 are insignificant, BMI; Body mass index, C/S; cesarean section

Postoperative Analgesia Duration

Postoperatively, one way ANOVA showed statistically significant difference in the duration of postoperative analgesia among the study groups ($p < 0.0001$). Mothers in the bupivacaine tramadol group had a significantly longer postoperative analgesia to (420.63 ± 14.42 minutes) compared to those in the bupivacaine fentanyl (283.83 ± 19.28 minutes) and bupivacaine alone (154.07 ± 24.63 minutes) groups. Post hoc multiple comparisons indicated statistically significant differences in mean analgesia duration between bupivacaine alone and bupivacaine fentanyl groups ($P1 < 0.0001$), between the bupivacaine alone and bupivacaine tramadol groups ($P2 < 0.0001$), as well as between bupivacaine fentanyl and tramadol groups ($P3 < 0.0001$) as shown in Table 2 below.

Table 2. Postoperative mean analgesia duration between study groups.

	Bupivacaine alone		Bupivacaine fentanyl		Bupivacaine tramadol	P	P1	P2	P3
Analgesia duration	154.07 24.63	±	283.83 19.28	±	420.63 14.43	± <0.0001	<0.0001	<0.0001	<0.0001

All values are presented as mean $\pm$ SD, P values represent comparison among three groups, P1 represents comparison among Bupivacaine alone and bupivacaine fentanyl, P2 represents comparison among bupivacaine alone and bupivacaine tramadol, P3 represents comparison among bupivacaine fentanyl and bupivacaine tramadol groups.

Postoperative time for the first analgesia request

A Kaplan Meier estimates showed that the probability of remaining pain free fell to zero in all study groups at different times. According to the Kaplan Meier survival estimates, bupivacaine alone had the shortest analgesic request time reached zero at 180 minutes. The bupivacaine fentanyl group had demonstrated a longer time to analgesia request compared to bupivacaine alone, with majority of patients requiring analgesia between 250 to 350 minutes. The bupivacaine tramadol group had the longest time to first analgesia request, with requests between 350 to 450 minutes. Survival analysis using the log rank test was performed to compare the mean time to first analgesia request between the groups. The bupivacaine alone group (mean time in minutes, 154.07 [95%CI, 146.81 – 161.31]) had significantly shorter first analgesia request time compared to bupivacaine fentanyl group (mean time in minutes, 283.83 [95%CI, 276.93 – 290.73]) and bupivacaine tramadol group (mean time in minutes, 420.63 [95% CI, 415.46 – 425.79]), $P < 0.0001$ with an effect size of 0.97, as shown in figure 4 below.

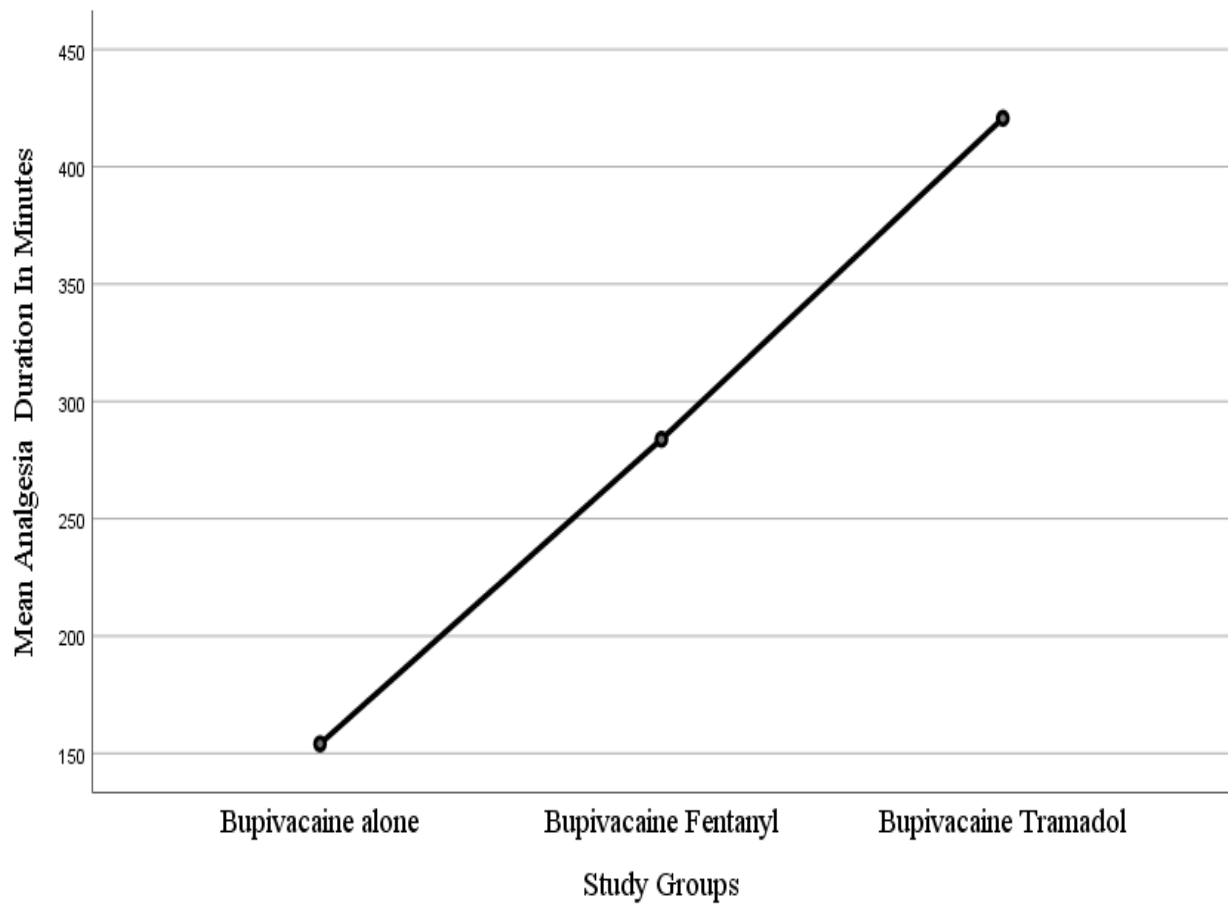


Figure 3. Comparison of meantime analgesia duration among groups of patients who underwent elective cesarean section under spinal anesthesia with either bupivacaine alone, bupivacaine with fentanyl and bupivacaine with tramadol.

Postoperative Total Analgesia Consumption

One way ANOVA demonstrated that the total postoperative analgesia consumption was significantly different among the study groups within the first 24 hours after surgery ($p < 0.0001$). Parturients in the bupivacaine tramadol group consumed a lower dose of paracetamol (1200 ± 281.62) than those in both the bupivacaine alone (1950 ± 152.56) and bupivacaine fentanyl groups (1400 ± 305.12), $P < 0.0001$. Post hoc multiple comparison analysis showed a statistically significant difference in paracetamol consumption between mothers in the bupivacaine alone and bupivacaine fentanyl, ($P_1 < 0.0001$) as well as between bupivacaine alone and bupivacaine tramadol, ($P_2 < 0.0001$), and between bupivacaine fentanyl and bupivacaine tramadol, ($P_3 = 0.009$). The total dose of diclofenac consumed in the first 24 hours after surgery was statistically significant among the study groups ($P = 0.001$). The total dose of diclofenac dose consumed within 24 hours after surgery was lower in the bupivacaine tramadol group (75 ± 16.08) than those in the both bupivacaine with fentanyl (84.17 ± 26.65) and bupivacaine alone group (102 ± 36.76), $P = 0.001$. Post hoc multiple comparison showed a statistically significant difference in diclofenac consumption between parturients in the bupivacaine alone and bupivacaine fentanyl, ($P_1 = 0.033$) as well as between bupivacaine alone and bupivacaine tramadol, ($P_2 = 0.001$). However, insignificant change between mothers who received bupivacaine with tramadol and fentanyl in diclofenac consumption $P = 0.412$. The total tramadol dose consumed in the first 24 hours after surgery was significantly lower in the bupivacaine tramadol group (25.83 ± 4.56) than those in the bupivacaine fentanyl group (50.83 ± 10.34) and bupivacaine alone (75.83 ± 25.83), $P < 0.0001$. Post hoc multiple comparison showed, a statistically significant difference in the tramadol consumption between parturients in the bupivacaine alone and bupivacaine fentanyl, ($P < 0.0001$) as well as between bupivacaine alone and bupivacaine tramadol, ($P < 0.0001$), and between bupivacaine fentanyl and bupivacaine tramadol, ($P < 0.0001$) as shown in the table 3 below.

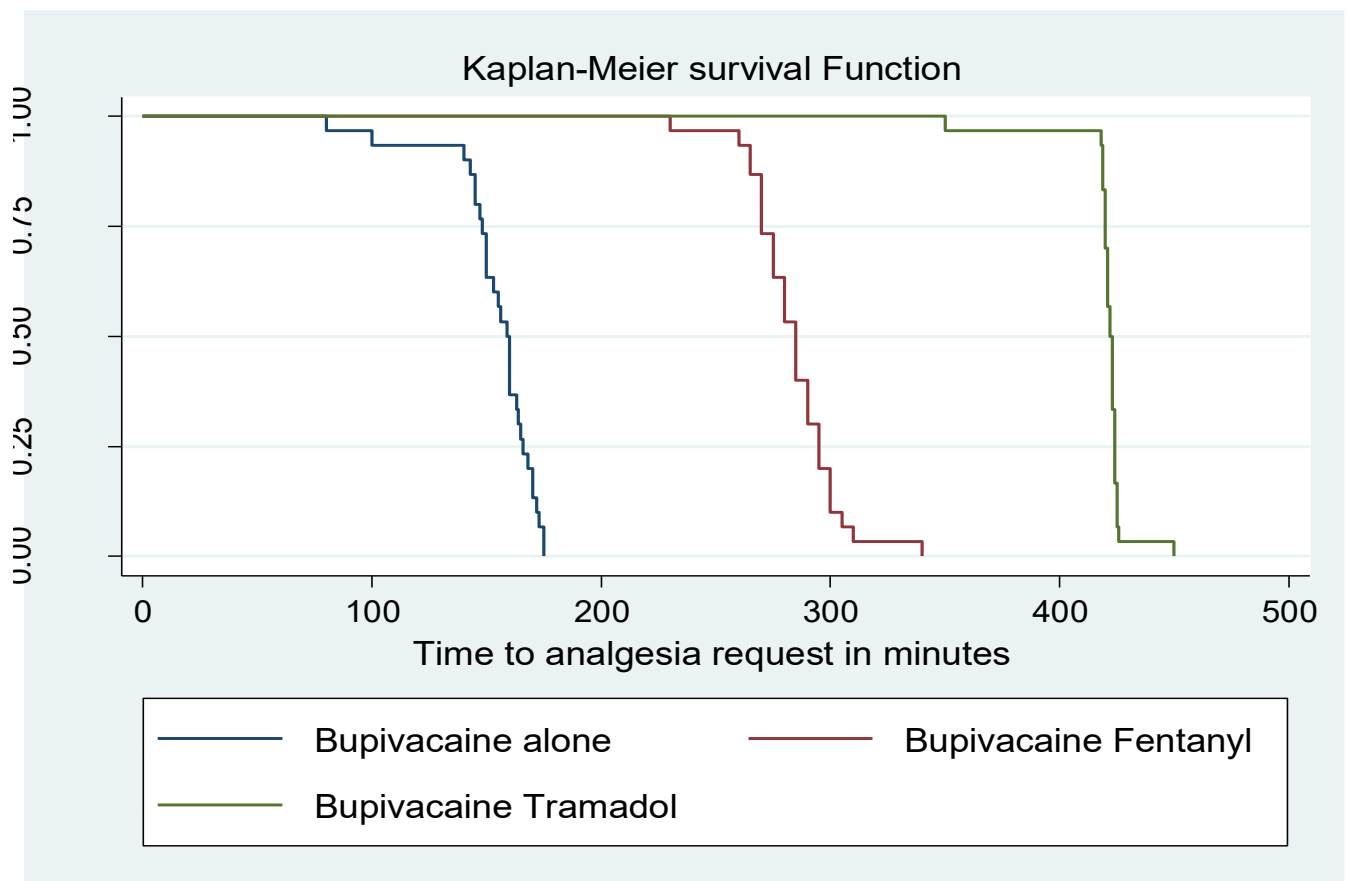


Figure 4. A Kaplan Meier survival curve demonstrating a steady decline in the proportion of patients remaining pain free over time indicating that all participants had requested analgesia at different times by the end of observations.

Table 3: Comparison of postoperative analgesia consumption between the study groups

Antipain	Bupivacaine alone	Bupivacaine Fentanyl	Bupivacaine Tramadol	P	P1	P2	P3
Paracetamol	1950 ± 152.56	1400 ± 305.12	1200 ± 281.62	<0.0001	<0.0001	<0.0001	0.009
Diclofenac	102 ± 36.76	84.17 ± 26.65	75 ± 16.08	0.001	0.033	0.001	0.412
Tramadol	75.83 ± 25.83	50.83 ± 10.34	25.83 ± 4.56	<0.0001	<0.0001	<0.0001	<0.0001

All values presented as mean ±SD, P1 represents comparison among Bupivacaine alone and bupivacaine fentanyl, P2 represent comparison among bupivacaine alone and bupivacaine tramadol, P3 represent comparison among bupivacaine fentanyl and bupivacaine tramadol.

Obstetric Quality of recovery

Kruskal-Wallis test showed statistically significant total obstetric quality of recovery score between the study groups ($P < 0.0001$). The overall score of quality of recovery in the bupivacaine tramadol group 72(66 -81) was higher than that of bupivacaine fentanyl group 69.5(54 -79) and bupivacaine alone group 60 (45 -71). Post hoc multiple analysis also showed significant difference between bupivacaine with fentanyl and bupivacaine with tramadol in overall score with ($P = 0.040$).

Post hoc multiple comparisons showed, the total score of obstetric quality of recovery – 11 points was significantly different between parturients in the bupivacaine alone and bupivacaine fentanyl groups ($P_1 < 0.0001$), and between bupivacaine alone and bupivacaine tramadol group ($P_2 < 0.0001$), as well as between bupivacaine tramadol and bupivacaine fentanyl group, ($P_3 = 0.040$).

All items in the obstetric quality of recovery – 11 points in the bupivacaine tramadol group was significantly better than that of the bupivacaine alone group, except in terms of the items feeling crazy ($P = 0.630$) and all the items in the obstetric quality of recovery – 11 points in the bupivacaine fentanyl group was significantly better than that of the bupivacaine alone, except in the terms of the items I feel in control ($P = 0.080$) and I have been feeling crazy ($P = 0.338$). From all the items in the obstetric quality of recovery- 11 points, there is no statistically significant difference in terms of the items I have been feeling crazy among the three study groups ($P = 0.630$).

Inter group comparisons by the Mann- Whitney U test demonstrated that among the 11 items of obstetric quality of recovery listed, only two items “ I have had moderate pain”, ($P = 0.002$) and I have had severe pain”, ($P = 0.001$) showed statistically significant differences between the bupivacaine fentanyl and bupivacaine tramadol groups.

Table 4. The 24-hour obstetric quality of recovery – 11 Points of the study groups

Variables	BA	BF	BT	P	P1	P2	P3
I have had moderate pain	4(0 -10)	5(1-10)	6(0-10)	<0.0001	<0.0001	<0.0001	0.002
I have had severe pain	3(2-5)	4(2-8)	5(3-9)	<0.0001	<0.0001	<0.0001	0.001
I have N/V	7(0- 10)	5(3-6)	4(2-8)	<0.0001	<0.0001	<0.0001	0.460
I have been feeling crazy	9(4– 10)	9(5-10)	9(3-10)	0.630	-	-	-
I had shivering	4(2-8)	7(5 -9)	7(4-8)	<0.0001	<0.0001	<0.0001	0.701
I have been comfortable	6(3-10)	8(4-10)	7(5-10)	0.001	<0.0001	0.027	0.064
I am able to mobilize independently	6(1-9)	7(4-9)	7(5-10)	<0.0001	0.005	<0.0001	0.161
I can hold baby without assistance	5(3-9)	6(4-10)	6(5-8)	0.002	0.003	0.001	0.950
I can feed or nurse my baby without assistance	5(3-8)	6(3-10)	7(4-9)	0.001	0.035	<0.0001	0.059
I can look after my personal hygiene/ toilet	6(4-10)	7(5-10)	7.5(6-10)	0.0001	0.001	<0.0001	0.144
I feel in control	6(4-9)	6(5-9)	7(5-10)	0.001	0.080	<0.0001	0.081
Total	60(45-71)	69.5(54 - 79)	72(66 - 81)	<0.0001	<0.0001	<0.0001	0.040

All values are presented as median and interquartile range. BA; Bupivacaine alone, BF; Bupivacaine fentanyl, BT; Bupivacaine tramadol, P1 represents comparison among Bupivacaine alone and bupivacaine fentanyl, P2 represents comparison among bupivacaine alone and bupivacaine tramadol, P3 represents comparison among bupivacaine fentanyl and bupivacaine tramadol, N/V; Nausea and Vomiting.

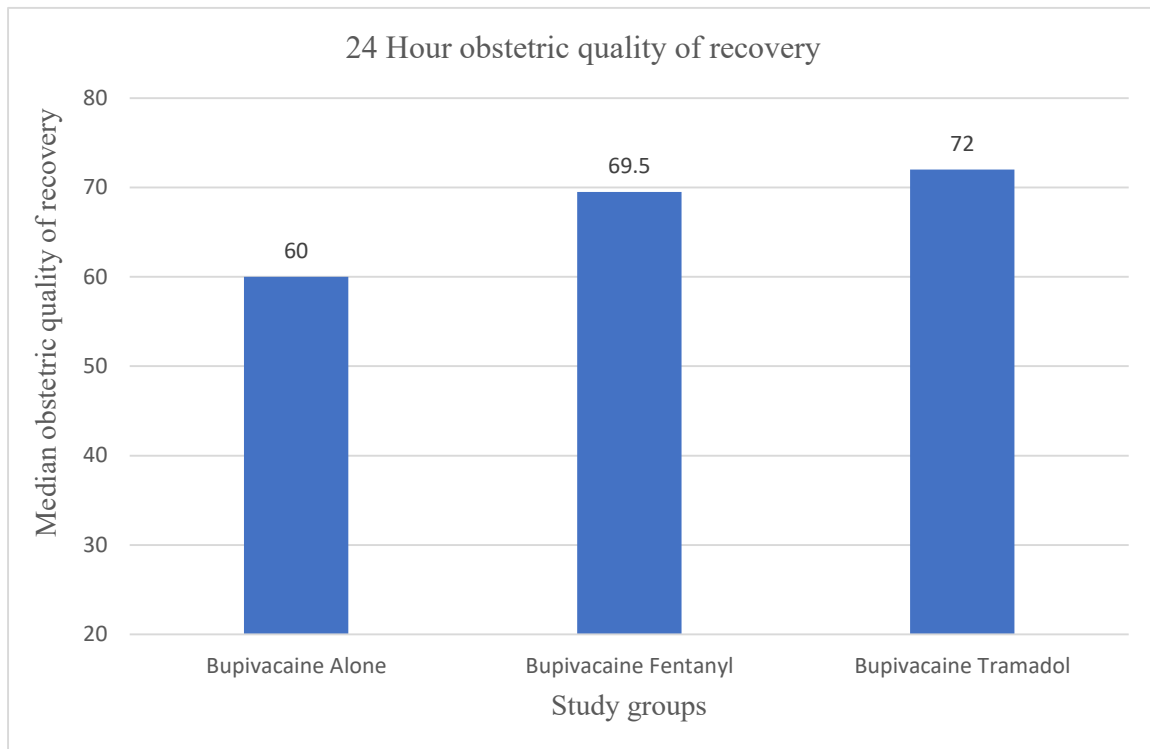


Figure 5. Shows the total score of obstetric quality of recovery within 24 hours among the groups of patients who underwent elective cesarean section under spinal anesthesia with bupivacaine alone and adjuvants fentanyl and tramadol.

DISCUSSIONS

Our result show that the addition of 20mg of preservative free tramadol to 10mg of 0.5% heavy bupivacaine in intrathecal anesthesia for parturients scheduled for elective cesarean section prolonged postoperative analgesia duration to (mean $\pm$ SD, 420.63 $\pm$ 14.43 minutes) and to (mean $\pm$ SD, 283.83 $\pm$ 19.28 minutes) in 10mg of 0.5% heavy bupivacaine with 25 μ g of fentanyl and (mean $\pm$ SD, 154.07 $\pm$ 24.63 minutes) in 10mg of bupivacaine alone ($P < 0.0001$). Study conducted by Abdulhasan et al., (42) reported a mean analgesia duration of 450 $\pm$ 109.38 minutes with 12.5mg of bupivacaine plus 20mg of tramadol and 441 $\pm$ 119.69 minutes with 12.5mg of 0.5% of heavy bupivacaine combined with 25 μ g of fentanyl in a study conducted on the elective cesarean section. We hypothesize that the reason for this discrepancy may be due to the high dose of bupivacaine they used in their study.

Our study figure contrasts the findings of the study conducted in Ethiopia by Abebe et al (57), who reported 245.33 $\pm$ 2.854 minutes of postoperative analgesia duration with 12.5mg of bupivacaine with 20mg of tramadol compared with 12.5mg of bupivacaine alone. This discrepancy may be attributed to the difference in measurement timing as, they started to assess analgesia duration from the end of surgery to analgesia request time, whereas our study started from the time of intrathecal injections).

The results of this investigation validate the hypothesized mechanisms of tramadol's antinociceptive action at the spinal cord level. The prolonged analgesia duration observed in the tramadol bupivacaine group may be attributed to the increase in norepinephrine and serotonin in the spinal cord causing activation of descending inhibition, along with its effects on the opioid receptors (71) and indirect activation of spinal alpha – 2 adrenoreceptors (72) and the activation of the galaninergetic system (73). The results of the present study contrast with those of Wadood et al, who reported mean analgesia durations of 118.50 $\pm$ 23.6 minutes in 7.5mg of 0.5% heavy bupivacaine combined with 5% dextrose in 0.5ml of water, 168.00 $\pm$ 30.21 minutes in 5mg of 0.55 of heavy bupivacaine plus 50 μ g of fentanyl, and 215.00 $\pm$ 26.51 minutes with 5mg of 0.5% of heavy bupivacaine plus 50mg of tramadol (58). This difference in postoperative analgesia duration may be due to the variation in the bupivacaine, tramadol, and fentanyl used.

The findings of the investigation are contradictory to the study conducted by Chatterji et al., grouped 60 parturients into BT, who had been administered 10mg of hyperbaric bupivacaine with 10mg of tramadol, and BF, who had been given 10mg of hyperbaric bupivacaine with 10 μ g of fentanyl (21). They found that the total duration of meantime analgesia between BT

and BF was 302.1 ± 55.2 minutes and 262.6 ± 40.7 minutes, respectively. The likely explanation for this difference is the variation in the doses of tramadol and fentanyl; they assess analgesia duration from intrathecal injections up to a VAS score of > 3 . Our study showed that the addition of $25\mu\text{g}$ of fentanyl to 10mg of bupivacaine increased the total duration of complete analgesia (time from intrathecal injections to patient analgesia request time or $\text{NRS} \geq 4$) to 283.83 ± 24.63 minutes and to 154.07 ± 24.63 minutes of postoperative complete analgesia duration with 10mg of bupivacaine alone. This is in agreement with the findings of Ebrie et al (53), who reported a mean analgesia duration of 167.10 ± 31.45 minutes with 10mg of bupivacaine alone and 260.3 ± 40.3 minutes of postoperative analgesia duration with 10mg of bupivacaine combined with $25\mu\text{g}$ of fentanyl. The study conducted in Ethiopia by Yesuf et al (54), which showed 156.10 ± 34.45 minutes of postoperative analgesia duration with 10mg of bupivacaine alone and 275.10 ± 42.43 minutes of analgesia duration with 10mg of bupivacaine plus $25\mu\text{g}$ of fentanyl, also agreed with the findings of our study.

Similarly, the present study aligns with the findings of a study conducted by Idowu et al who reported pain-free periods of 276 ± 26 minutes and 121 ± 10 minutes using 12.5mg of bupivacaine combined with $25\mu\text{g}$ of fentanyl and 12.5mg of bupivacaine alone, respectively (50). Our study is also in line with the study conducted by Shashikala Tk et al, who grouped 90 parturients into the BF group, who had been given 2ml of 0.5% heavy bupivacaine with $12.5\mu\text{g}$ of fentanyl, and the BC group who received 2ml of 0.5% of heavy bupivacaine with 0.25ml of CSF (47). They reported that the total mean analgesia duration between the BF and BC groups was 259.4 ± 35.3 minutes in group BF and 165 ± 29.8 minutes in group BC, respectively.

The result of this study aligns with the study conducted by Ali et al (49), who reported 149.5 ± 6.2 minutes of effective analgesia duration with 2.5ml of 0.5% of heavy bupivacaine with 0.5ml of normal saline and 259.2 ± 5.6 minutes of analgesia duration with 2.5ml of 0.5% of heavy bupivacaine combined with $25\mu\text{g}$ of fentanyl.

A prospective study conducted by Venkata HG et al (51) reported a postoperative analgesia duration of 153 ± 9.0 minutes in group S (who had received 10mg of bupivacaine alone) and 200 ± 9.1 minutes in group C (who had received 7.5mg of bupivacaine combined with $25\mu\text{g}$ of fentanyl). The findings of group S are consistent with those of our study; however, the postoperative analgesia duration observed in group C was considerably shorter than in our study. We hypothesize that this discrepancy may be primarily due to the lower dose of bupivacaine (7.5mg) used in their study compared to ours.

In this research it is demonstrated that the addition of 20mg of intrathecal tramadol to bupivacaine leads to a notable increase in the time to first analgesia request to 420.63 ± 14.43 minutes compared to 10mg of bupivacaine with $25\mu\text{g}$ of fentanyl and 10mg of bupivacaine alone with times to first analgesia request of 283.83 ± 19.28 and 154.07 ± 19.30 minutes, respectively. However, a single blinded randomized study conducted by Prasad et al in India reported 232.18 ± 80.55 minutes of time for first postoperative analgesia request with 10mg of bupivacaine with 10mg of tramadol and 176.56 ± 47.39 minutes in 10mg of bupivacaine with 0.2ml of normal saline in his study conducted on cesarean sections (56). The probable reason for the difference in time to first analgesia request between the patients in the bupivacaine tramadol may be due to the dose of tramadol they used (10mg) and the study was conducted with two groups (bupivacaine tramadol and bupivacaine alone). In contrast to our study, another study from Nepal showed 134 ± 5.6 minutes of time to first analgesia request with 12mg of bupivacaine alone and 164 ± 9 minutes of first time to analgesia request with 10mg of bupivacaine with $20\mu\text{g}$ of fentanyl (74). This might be due to the experience (perception) of pain being affected by genetics and cultural, and social factors in different ethnicities across the world (75). Similar to this study, Ebrie et al reported 294.6 ± 99.5 minutes of time to first analgesia request with 10mg of bupivacaine plus $25\mu\text{g}$ of fentanyl and 177 ± 25.88 minutes of time to first analgesia request with 10mg of bupivacaine alone (53). In addition, study done by Biswas BN et al used $12.5\mu\text{g}$ of intrathecal fentanyl with 10mg of 0.5% heavy bupivacaine and 10mg of 0.5% of heavy bupivacaine with 0.25ml of normal saline reported 248 ± 11.76 minutes and 150 ± 10.48 minutes of time to first analgesia request in bupivacaine fentanyl and bupivacaine alone, respectively (48). In the above study, analgesia request time was shorter than in our study and this might be due to the small sample size ($n=20$) and the small dose of intrathecal fentanyl ($12.5\mu\text{g}$) used for comparison.

Similarly, the study done on cesarean section with 7.5 to 15mg of bupivacaine based on the height of the patient combined with 0.5ml of normal saline or $25\mu\text{g}$ of fentanyl reported 2.5 ± 1.9 hours of time to first patient controlled analgesia demand in the bupivacaine with normal saline group and 4.3 ± 1.4 hours of time to first analgesia request in the bupivacaine combined with $25\mu\text{g}$ of fentanyl (76).

Findings from this study showed that there was a statistically significant difference in the total analgesia consumption between the study groups within 24 hours of surgery. Specifically, the combination of tramadol with bupivacaine was associated with a lower total analgesia requirement in the first 24 hours. The study conducted by Bansal et al. reported decreased postoperative tramadol requirement only (6.66%) in the T group (10mg of bupivacaine with

20mg of tramadol) compared to group C (10mg of bupivacaine with 0.4ml of normal saline), in which 30% of patients required postoperative tramadol (61). This study supports the findings of our study, which also demonstrated decreased postoperative analgesia consumption in the bupivacaine tramadol group. Although no significant difference was observed in postoperative tramadol use between bupivacaine fentanyl and bupivacaine tramadol, Subedi et al. reported that only 23% of patients in the bupivacaine tramadol group required postoperative tramadol, compared to 34% in the bupivacaine fentanyl group (20), a finding that supports the present study's finding. The results of our study showed much improved quality of recovery with the use of intrathecal bupivacaine with tramadol 72 (66-81) and bupivacaine with fentanyl 69.5 (54-79) compared to bupivacaine alone 60 (45-71), suggesting parturients with intrathecal tramadol had a good quality of recovery than parturients with bupivacaine fentanyl. Li et al. (63) reported a total obstetric quality of recovery score of 61.7 [95% CI = 61.0 62.4]) in the bupivacaine normal saline group, which is consistent with results of the present study; however, the bupivacaine fentanyl group demonstrated a reduced total quality of recovery (61.5 [95% CI = 60.8-62.2]), which may be attributed to the relatively small dose of fentanyl (20µg) and bupivacaine (9mg) used in the study.

LIMITATIONS AND STRENGTHS

Limitations of the study

The sample size is relatively small, which may limit the statistical power to detect the subtle differences between the groups and reduce the generalizability of the findings to wider populations.

The study focuses only on the analgesia duration, time to first analgesia request, and quality of recovery but not on the side effects of each adjuvant for the mothers as well as the neonates, which significantly affects patient satisfaction.

The obstetric quality of recovery-11 points (ObsQoR-11) questionnaire was directly translated from the English version into the local language (Amharic and Afaan Oromo) for use in this study; however, the translated version had not been formally validated. This may represent a limitation, as the lack of validation could have affected the reliability and cultural equivalence of participant's responses.

Strengths of the Study

The outcome variable was collected prospectively during the postoperative period, which may ensure that data were obtained in real time rather than relying on the patient's memory, thereby reducing the risk of recall bias. The study directly compared bupivacaine alone, bupivacaine with fentanyl, and bupivacaine with tramadol, providing valuable comparative evidence on commonly used regimens and allowing meaningful comparison.

The sociodemographic characteristics were comparable among the study groups, suggesting that the observed differences in the analgesic outcomes are less likely due to baseline variations.

The intraoperative and postoperative data were collected by different data collectors. The postoperative data was collected by individuals who were blinded to the study groups, which may reduce the risk of observer bias arising from prior knowledge and group allocation.

The chosen dosages were based on the regimens previously validated in published studies, which were cited accordingly. The dose of bupivacaine selected for all study groups was the same, which may help to ensure that any observed differences in analgesic effectiveness or quality outcome are attributed to the adjuvants rather than to variations in the local anesthetic dose.

CONCLUSION AND RECOMMENDATION

Conclusion

It can be concluded that the addition of 20mg of preservative free tramadol to bupivacaine for elective cesarean delivery under spinal anesthesia provides extended postoperative analgesia duration, prolonged time to first analgesia request, and less postoperative analgesia consumption, and improved 24 hours of obstetric quality of recovery in comparison to bupivacaine fentanyl and bupivacaine alone.

Recommendation

Based on the findings of this study, we recommend the use of preservative free tramadol as additives to bupivacaine for parturients who undergo elective cesarean section under spinal anesthesia to achieve extended postoperative analgesia duration, prolonged time to first analgesia request and to achieve a good maternal quality of recovery.

It is also recommended that a randomized controlled trial be conducted in the future, as this design would provide stronger evidence by minimizing bias, ensuring compatibility between groups, and enhancing the validity and generalizability of the findings.

We also recommend multicenter study as it enhances the representativeness of the sample and improves the generalizability of the results to a wider population.

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ANNEX I

Information sheet

This questionnaire is designed to assess postoperative analgesia effectiveness of spinal bupivacaine alone versus bupivacaine with tramadol and fentanyl at ARSI UNIVERSITY REFERRAL AND TEACHING HOSPITAL ASELLA, ETHIOPIA, 2025. There is no risk to take part in the study; all information is confidential. Participants names will not keep in the form. Their participation in the study will be voluntary. They are not obliged to participate and may discontinue at any time. Moreover, this research thesis is approved by the college of Health Science and the anesthesia department.

Consent form

Greeting

Hello, am-----, I am a master's student doing my graduate research at ARSI UNIVERSITY REFERRAL AND TEACHING HOSPITAL, DEPARTMENT OF ANESTHESIA.

The goal of this questionnaire is to collect data on the bupivacaine alone, bupivacaine with tramadol, and fentanyl in spinal anesthesia on the postoperative pain for patients undergoing cesarean section at ARSI UNIVERSITY REFERRAL AND TEACHING HOSPITAL. The study will benefit those who had cesarean section surgery in relieving postoperative pain with fewer side effects.

We will ask you a few questions that will take a few minutes each at two different times. The answers to those questions should be kept private.

We will not include your name in the survey. You have the right to refuse to answer any questions and to interrupt the interview at any time.

Do I have your permission to continue? If yes, continue to the next page. If no skip to the next participant.

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 -----

Akkam Jirtu.....

Ani Barataa maastersii ta'ee qorannoo koo eebbifamtootaa Arsii Yuunivarsitii Referral and Teaching Hospital keessatti hojjechaa jira. Galmi gaaffilee kanaa dhukkubsattoota Arsii Yuunivarsitii Referral and Teaching Hospital keessatti Yaalii baqaqsanii hodhuu booda dhukkubbii namatti dhagaa`amu irratti Bupivacaine qofa, bupivacaine tramadol waliinii fi bupivacaine fentanyl waliin walitti dabalamuun spinal anesthesiadhaaf kennaman irratti odeeffannoo walitti qabuu ilaallata. Qorannoon kun dhukkubbii Yaalii baqaqsanii hodhuu da`umsaaf godhamuun booda namatti dhagaa`amuuf, miidhaa cinaa salphaa ta`een dhukkubbii yaala baqaqsanii hodhuu booda namatti dhagaa`amu xiqqeessuun fayyadamoo gochuu nidanda`a.

Gaaffiiwwan muraasa tokkoon tokkoon isaanii daqiiqaa muraasa fudhatan yeroo addaa addaa lamatti isin gaafanna. Deebiin gaaffilee Sanaa dhuunfaatti qabama. Maqaa keessan qorannoo kana keessatti hin haammachiifnu. Gaaffii kamiyyuu deebisuu diduu fi yeroo barbaaddanitti gaaffii fi deebii addaan kutuufi deebii keessan kennuu dhiisuuf mirga guutuu qabdu.

Gaaffii kana itti fufee isin gaafachuuf eyyama keessan qabaa? Yoo eeyyee ta'e gara fuula itti aanuutti darbi. Yoo lakkii jette gara hirmaataa itti aanutti dabarsi.

Gaaffii fi deebii

Koodii -----

Maqaa -----

Mallattooo-----

Guyyaa af gaaffiii----- yeroo itti jalabame-----

Yeroo itti xumurame-----

Bu`aa af gaaffiii 1. Xumurame 2. Deebii kennaan hin jiru 3. Nidide 4. Gartokkoon

Xumurame

Suppervaayizera. (mirkanesseera) maqaa----- mallattooo-----

Guyyaa -----

ANNEX II: QUESTIONNAIRE

Section 1: SOCIODEMOGRAPHIC DATA

S NO	QUESTIONS	Response
101	MRN	
102	DIANGNOSIS	
103	AGE (years)	
104	WEIGHT (kg)	
105	HEIGHT (m)	
106	BODY MASS INDEX (kg/m ²)	
107	GRAVIDITY	PRIMIGRAVIDA ----- MULTIGRAVIDA -----
108	GESTATIONAL AGE (IN WEEKS)	
109	PREVIOUS CESAREAN SECTION SCAR	YES NO IF YES HOW MANY----- -

SECTION 2: INTRAOPERATIVE DATA

S No	QUESTIONS	RESPONSE
201	Group (anesthetic agent used) and their dose	☐ Bupivacaine only Dose----- ☐ Bupivacaine plus Tramadol Dose----- ☐ Bupivacaine plus Fentanyl Dose -----
202	Time of spinal anesthesia	

	injections	Hour-----Minute----- - according to local time -
203	Duration of surgery(min)	Hour -----Minute-----
204	Time of discharge from Theatre	Hours-----Minute----- -

SECTION 3: POSTOPERATIVE ANALGESIA ASSESSMENT

S No	Questions	Response
301	Time of first complaint of pain	Hours----- minute -----
302	Time of first analgesia request	Hours ----- Minute -----
303	Total duration of analgesia (starting from spinal anesthesia injections to time of first analgesia request)	-----in Minutes
304	Total analgesia consumption within 24 hours of postoperative period	Paracetamol-----mg Diclofenac ----- Opioids (name)-----dose ----- Other specify: Name _----- Dose _____
305	Time after Surgery 1 hours after surgery 2 hours after surgery 3 hours after surgery	Pain Score by NRS (0 -10) ----- ----- -----

4 hours after surgery	-----
6 hours after surgery	-----
8 hours after surgery	-----
12 hours after surgery	-----
24 hours after surgery	-----

Section 4: Assessing Quality of Recovery Score following cesarean delivery

(Have you been feeling in the last 24 hours?) (0- 10), 0 = Strongly agree 10 = strongly disagree

1. I have moderate pain

0 1 2 3 4 5 6 7 8 9 10

—

2. I have had severe pain

0 1 2 3 4 5 6 7 8 9 10

—

3. I have had nausea or vomiting

0 1 2 3 4 5 6 7 8 9 10

4. I have been feeling crazy

0 1 2 3 4 5 6 7 8 9 10

5. I have had shivering

0 1 2 3 4 5 6 7 8 9 10

6. I have been comfortable

0 1 2 3 4 5 6 7 8 9 10

7. I am able to mobilise independently

0 1 2 3 4 5 6 7 8 9 10

8. I can hold baby without assistance

0 1 2 3 4 5 6 8 9 10

9. I can feed or nurse my baby without assistance

0 1 2 3 4 5 6 7 8 9 10

10. I can look after my personal hygiene/ toilet

0 1 2 3 4 5 6 7 8 9 10

11. I feel in control

0 1 2 3 4 5 6 7 8 9 10

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304	NRS	□□□ □□□ □□□□□□ □□□ ----- □□□ □□□ 3 rd □□□ ----- ----- □□□ 4 th □□□ ----- □□□ □□□ 6 th □□□ ----- □□□ □□□ 8 th □□□ ----- “ 12 th “ “ _____ “ “ 24 th “ “ _____
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7.

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0 1 2 3 4 5 6 7 8 9 10

9.

0 1 2 3 4 5 6 7 8 9 10

10. /

0 1 2 3 4 5 6 7 8 9 10

11.

0 1 2 3 4 5 6 7 8 9 10

Kutaa 1. Gaaffii

Daataa Hawwaasoodiimogiraafii

Tartiiba lakkoofsaa	Gaaffii	Deebii
101	MRN	
102	Maqaa dhukkubaa	
103	Umurii	
104	Ulfaatina	
105	Hojjaa	
106	Indeksii ulfaatina qaamaa	
107	Baay`ina da`umsaa	Kan hin qabnee Baay`ee kan deesse
108	umurii ulfaa (torbanootaan)	
109	Kanaan dura Yaalii baqaqsanii da`uu kan biraa qabdi	Eeyyee----- Lakkii ----- Yoo qabaattu, meeqa-----

Kutaa 2. Daataa yeroo baqaqsanii hodhuu

Tartiiba lakkoofsaa	Gaaffii	Deebii
201	Garee(qorichoota anesthesia fayyadamamee) fi doosii isaa	Bupivacaine Qofa----- Doosii----- Bupivacaine Tramadolii wajjin----- doosii isaa ----- Bupivacaine Fentanyl wajjin Doosii isaa----- -
202	Yeroo itti spinal anesthesian kenname	Sa`atii-----Daqiiqaa-- ----- akka biyya keenyaatti
203	Turtii yaaliin baqaqsanii hodhuu ture	Sa`atii-----Daqiiqaa--- ----(akka biyya keenyaatti)
204	Sa`atii itti Kutaa baqaqsanii yaaluutii baate	Sa`atii-----Daqiiqaa-----

Kutaa 3. Madaallii Dukkubbii baqaqsanii hodhuu booda

Tartiiba lakkoofsaa	Gaaffii		Deebii
301	Yeroo itti jalqaba dhukkubbiin itti dhagaa`ame.		Sa`atii-----daqiiqaaa----- -
302	Yeroo itti jalqaba qorsa dhukkubbii hir`isu gaafatte		Sa`atii ----- Daqiiqaa ----- -----
303	Yeroo waliigalaa qorsi dhukkubbii namatti hir`isu ture( yeroo spinal anesthesian kenname irra hanga yeroo itti qorsi dhukkubbii hir`isu gaafatameetti jiru)		Daqiiqaaa-----
304	Hamma waliigalaa qorsa dhukkubbii hir`isuuf sa`atii 24 keessatti kennamee		Paracetamol-----mg Diclofenac-----mg Tramadol----- Opioids biraa(maqaa)----- doosii-----
305	Yeroo baqaqsanii yaaluu boodaa	Sadarka dhukkubbii(NRS)	
	Sa`atii sa`atii 1ffaa	NRS score-----	
	; 2ffaa		
	; 3ffaa		
	; 4ffaa		
	; 6ffaa		
	; 8ffaa		
	; 10ffaa		
	; 12ffaa		
	; 24ffaa		

Kutaa 4. Qabxii qulqullina fayyummaa madaalu kan Yaalii baqaqsanii da`uu boodaa(0-10); 0 = cimseen waliigala, 10 = guutummaa guutuutti itti walii hin galu)

1. Dhukkubbiin giddugaleessa ta'e na mudateera.

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

2. Dhukkubbiin cimaa ta'e na mudateera

0	1	2	3	4	5	6	7	8	9	10
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3. ol nama jechuun yookaan immoo ol deebisaan na mudateera.

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

4. Miirri sammuun na dhibamuu yookaan waan akka maraatummaa natti dhagaa`Ameera

0	1	2	3	4	5	6	7	8	9	10
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5. Raafamuun yookaan immoo qorri cimaan nama raasu natti dhagaa`amee ture

0	1	2	3	4	5	6	7	8	9	10
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—

6. Naaf mijataa ta'ee jira/naaf mijatee ture

0	1	2	3	4	5	6	7	8	9	10
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7. of danda`ee socho`uu dandeera

0	1	2	3	4	5	6	7	8	9	10
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—

8. Gargaarsa malee Daa`ima qabachuu danda`eera

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

—

9. Gargaarsa malee daaima koo nyaachisuu yookaan hoosisuu danda`eera.

0	1	2	3	4	5	6	7	8	9	10
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10. Qulqullina dhuunfaa koo mana fincaanii fayyadamuu jalqabeera

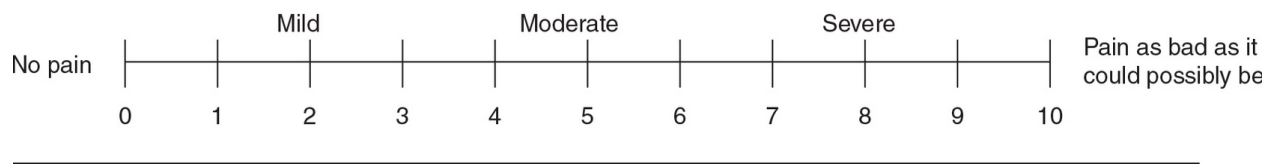
0	1	2	3	4	5	6	7	8	9	10
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11. ofii koo to`achuun koo natti dhagaa`ama

0	1	2	3	4	5	6	7	8	9	10
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Numerical Rating scale (NRS) Assessment method



0 = No pain

1- 3 = mild pain

4-6 = Moderate pain

7- 10 = Severe pain

Declaration of Investigator

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

Name: _____ Signature _____ Date _____

Name of advisors

1) Name _____ Signature: _____ date: _____

2) Name _____ Signature _____ Date _____

3) Name _____ Signature _____ Date _____

Submission to MSc Tutor, Dept. of Anesthesia, ARSI UNIVERSITY.

Date of Submission: _____

This thesis work has been submitted for examination with our approval as Advisors and Tutors on the Master of Science degree in Anesthesia

Internal examiner:

Name _____ signature _____

1. _____ date _____

External examiner:

Name _____ signature _____ Date _____

1. _____

2. _____