

Effectiveness of Transverses Abdominals Plane Block as a Part of Postoperative Analgesia for Post Cesarean Delivery Pain Management: A Prospective Cohort Study



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EFFECTIVENESS OF TRANSVERSUS ABDOMINIS PLANE BLOCK AS
A PART OF POSTOPERATIVE ANALGESIA FOR POST CESAREAN
DELIVERY PAIN MANAGEMENT: A PROSPECTIVE COHORT STUDY

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Abstract

Background: Pain after cesarean delivery is experienced through an incision below the umbilicus, which derives from the abdominal wall. As with other patients, these mothers require multimodal pain management that provides high-quality analgesia with minimal side effects. Opioids are widely used to manage pain; however, opioids have adverse effects. TAP block is usually given as a part of postoperative pain management after a cesarian section.

Objective: The main aim of this study was to assess the effectiveness of the transversus abdominis plane block when used as a part of postoperative analgesics after cesarean delivery under spinal analgesia at Jimma University Medical Center.

Method: An institutional-based prospective cohort study design was conducted from August 2022 to October 2022. The study was conducted on 64 parturients who underwent cesarean delivery under spinal anesthesia. Those who took bilateral transverses abdominis block (n = 32) versus (non-TAP) managed with systemic analgesics alone (n = 32) were followed postoperatively. Data were collected through chart review and postoperative pain was assessed during coughing and at rest by using a visual analog scale at the 2nd, 4th, 6th, and 12th hours. In addition, postoperative total analgesic consumption and hemodynamic parameters were assessed. Epi-data 4.6 and SPSS version 26 software were used for data entry and analysis, respectively.

Result: Postoperative VAS pain scores, both during coughing and at rest, were significantly lowered in the TAP block group compared to the non-TAP group ($p < 0.05$). Total analgesic consumption was significantly reduced in the TAP block group with a median total Tramadol dose of 50mg compared with 100mg in the control group within 12 hours ($P < 0.05$). However, no significant differences were found in the postoperative pulse rate, arterial pressure, and nausea/vomiting between the groups ($p > 0.05$).

Conclusion: TAP block reduced postoperative pain and total postoperative analgesics consumption when used as a part of postoperative analgesia for post-cesarean delivery pain control.

Keywords: Transvesus abdominis block, cesarean section, postoperative pain management

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Lists of acronyms and abbreviations

ASA	American society of anesthesiology
BMI	Body mass index
BP	Blood pressure
CD	Cesarean delivery
HR	Heart rate
LA	Local Anesthesia
PACU	Post-anesthesia care unit
PR	Pulse rate
SA	Spinal Anesthesia
TAP	Transvesus abdominis plane
VAS	Visual analog scale

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Chapter one

1. Introduction

1.1 Background information

An operative procedure by which a fetus is delivered through an abdominal and uterine incision is called cesarean section delivery. Cesarean delivery can prevent poor obstetric outcomes and is a life-saving procedure for the mother and the fetus. Cesarean section is a kind of surgical procedure performed around the world (1) that accounts for 21.1% of births globally (2).

WHO (world health organization) report describes the global average cesarean delivery (CD) rate growing from 12.4% to 21% in the year 1990-to 2014. According to the report, Latin America and the Caribbean had the highest cesarean section rate registered (40.5%) and the second-highest was in North America (32.3%). The lowest rate was noticed in Asia (19.2%) and Africa (7.3%) (3). Based on the national population, the rate of cesarean sections in Ethiopia increased from 0.7% in 2000 to 1.9% in 2016 (4).

The decision to perform cesarean delivery is made by weighing the risks and benefits of the procedure for the mother and fetus. Spinal anesthesia has been used for most of cesarean delivery in both developing and developed countries, and its usage is growing gradually for both elective and emergency surgeries (5).

A study done in Brazil revealed that the rate of pain following cesarean delivery was 78% (6). The study conducted in Northwest Ethiopia showed the overall prevalence of moderate to severe postoperative pain after the cesarian section was 85.5% within the first 24 hours (7), and another study showed, 86-95% of patients experience postoperative pain for two months (8). As the literature showed, patients feel a significant amount of pain following abdominal surgery, which originates from the abdominal wall incision and requires appropriate intervention (9).

Postoperative analgesia drugs like non-steroidal anti-inflammatory drugs (NSAIDs), peripheral nerve blocks, opioids, such as morphine, and patient-controlled analgesia (PCA) remain the mainstay of postoperative analgesic regimens. Among the above-listed ways of pain management, NSAID, systemic opioids, and regional nerve blocks are the mainstay of

pain management after cesarean delivery in our study area. However, opioids were full of side effects, including sedation, respiratory depression, constipation, nausea/vomiting, and so forth (10). A typical method to administer postoperative analgesia and minimize opioid usage after the abdominal incision is to block the sensory nerve supply to the anterior abdominal wall, such as the TAP block.

Transversus abdominis plane block was become first defined by Rafi in 2001; it is a technique in which local anesthesia is administered between the internal abdominal oblique muscle and the transversus abdominis muscle to block signals conducted from the abdominal nerves. As a result, the pain will be reduced after abdominal surgery below the umbilicus.

TAP block is simple to perform with fewer complications and once the block is done, it reduces the severity of postoperative pain. It can be performed using both landmark and ultrasound techniques. TAP block is a common peripheral abdominal field block that blocks lower subcostal (T7- T11), hypogastric, and ilioinguinal nerves. The landmark technique, in particular, is guided by a triangle of Petit that is bounded posteriorly by the latissimus dorsi muscle, anteriorly by the external oblique muscle, and the iliac crest forms the base of the triangle (11).

In addition, the landmark approach needs to appreciate the “double pop” sounds resulting from the blunted needle passing through the fascial extensions of muscles in the abdominal wall (external and internal oblique muscles) within the floor of the triangle of Petit. Therefore, the blunt-tipped needle should be used in all landmark techniques to enhance tangible sensitivity and appreciate two separate “pop” sensations (12).

On both sides, about 15-20ml of local anesthetic drugs like bupivacaine have been used to block the nerves that run between the internal oblique and the transversus abdominis muscles (13). Studies showed bilateral administration of drugs through the triangle of Petit using “double pop” resulted in reliable deposition into the transverse abdominal plane (14).

1.2 Statement of the problem

The most frequent surgical procedure performed worldwide is cesarean section delivery, which accounts for 21.1% of births globally (2). Cesarean section pain is experienced through an incision below the umbilicus, which derives from an abdominal wall incision (15). As with other patients, these mothers require a multimodal postoperative pain treatment regimen that provides high-quality analgesia with minimal side effects (16).

A significant element of the pain experienced by patients following abdominal surgery originates from the nerves of the abdominal wall (9). Global adoption of the Enhanced Recovery After Surgery Protocol (ERAS) has increased emphasis on multimodal pain management (17). According to the ERAS protocol, the management of postoperative pain has a significant effect on patient recovery by reducing the physiologic stress response to surgery, reducing hospital stay, and enabling early mobility (18).

Currently, opioid analgesics are widely used to reduce pain following surgery; however, systematically administered opioids have many adverse effects on the gastrointestinal tract, and respiratory system, and can lead to addictive potential (19). Given these concerns, minimizing opioid usage is in the best interest of patients recovering from any type of surgery.

A technique for delivery of postoperative analgesia following an abdominal incision is to block the sensory nerve supply to the anterior abdominal wall. In a setup where there is a shortage of advanced equipment to do advanced blocks for postoperative pain management, such as epidural anesthesia, landmark-guided abdominal wall field blocks (such as TAP block) are usually the only option.

Postoperative analgesia drugs such as non-steroidal anti-inflammatory drugs (NSAIDs), peripheral nerve blocks, opioids, and PCA (patient-controlled analgesia), remain the mainstay of postoperative analgesic regimens. Despite this suggestion, however, there is a challenge in achieving this aim because it is associated with poor pain management, nausea, and vomiting. For instance, opioids have had undesirable side effects, such as sedation, respiratory depression, constipation, nausea/vomiting, and so forth (20).

Moreover, a patient who is comfortable at rest may have significant pain during coughing, which could interfere with the normal activity and physiology of the mother. This may cause harmful acute and chronic adverse physiologic responses, such as decreased respiratory motion, coughing, and reduced sputum/secretion expectoration, which can lead to atelectasis, retention of secretion, and pneumonia (21).

As a result, alternative approaches are needed that increase the quality of analgesia, respiratory motion, coughing, and sputum expectoration while reducing the requirement for opioids, and opioid-related side effects. Therefore, local anesthetics and abdominal field blocks such as the TAP block may be another option for postoperative analgesia that made pain management uncomplicated and reduced opioid requirements (22) (23).

In a setup with inadequate and limited equipment, TAP block has been practiced widely for postoperative pain management. TAP block has been practiced as a component of postoperative analgesia, mainly for post-cesarian delivery at Jimma University Medical Center. Therefore, this study aimed to assess the effectiveness of TAP block when used as a part of postoperative analgesia after cesarean section. Thus, the results of this study may show tangible and alternative analgesic techniques for postoperative analgesia in cesarean delivery and may help as baseline data for further study.

1.3 Significance of the study

An ideal technique of pain management for post-cesarean delivery should be cost-effective, associated with fewer complications, safe for the mothers, requires minimal monitoring, and a drug that is not transferred to newborns through breast milk. On top of this, postoperative pain management should at least allow the patients to increase respiratory motion like deep breathing, coughing, and clearing secretion/sputum from the airway.

Several researchers have been examining to find out the safest and most effective way of interventions for post-cesarean section pain management, and they suggested pain management methods such as opioids, local anesthetic skin infiltration, epidural analgesia, intrathecal or intravenous opioids, and abdominal field blocks like TAP block. This study assessed the effectiveness of TAP block when used as a component of postoperative analgesia after cesarean section delivery.

A few studies have been conducted in this field in our country. However, in addition to pain at rest, this research has compared postoperative pain during intentional coughing and the postoperative hemodynamic status of the participants (pulse rate, blood pressure, and the incidence of postoperative nausea and vomiting). To the best of the author's knowledge, there was no study done in our country to fill these gaps. Therefore, this research may fill these gaps to assess the effectiveness of the TAP block when used as a part of postoperative analgesia.

The results of this study may fill the gaps, provide information, and show tangible and alternative analgesic techniques for postoperative pain management in cesarean delivery. The study results may also help program planners and policymakers in formulating strategies, which may help to improve patient safety. There is limited research on this topic. Therefore, this study may also help as a baseline for further studies.

Chapter two

2. Literature review

Surgical operations, particularly cesarean section delivery, are increasing gradually around the world. Documents from the United States confirmed an increased rate of cesarean sections from 21% to 32% from 1996 to 2011, respectively. Data from the WHO showed the cesarean delivery rate has increased to 46% in China and European countries; in Asian and Latin American countries, the rate has grown to 25%. Because cesarian sections are mainly done in a setup where less advanced facilities, it is very challenging to deliver sufficient pain management for the parturients (24).

Now a day CS is increased more significantly, and post-operative pain management is among the immediate consequences; as a result, post-cesarean-section pain management is aimed at maternal comfort, fewer side effects to the mother and the newborn child, and early recovery to normal function. Despite this suggestion, however, there is a challenge in achieving this aim because is associated with poor pain management, nausea, and vomiting (19). Following cesarean delivery, the surgical site was the highest source of pain. The study conducted in Northwest Ethiopia showed the overall prevalence of moderate to severe postoperative pain after the cesarian section was 85.5% within the first 24 hours (7). Another study showed, 86-95% of patients experienced postoperative pain for two months (8).

Systemic analgesic drugs like opioids such as morphine remain the cornerstone for postoperative pain management. However, opioids are full of unwanted side effects such as sedation, nausea, vomiting, and respiratory depression. Alternative approaches that reduce the requirement for strong opioids are required for postoperative analgesia. Therefore, nowadays multimodal analgesia by using peripheral nerve blocks in combination with systemic analgesics is recommended (25).

A systematic review conducted over the Transversus abdominis plane block following cesarean delivery under spinal anesthesia reported that the TAP block decreased visual analog score by 0.8cm and, on top of this, TAP block reduced opioid-related side effects. TAP block decreased the mean of total intravenous morphine consumption by 24mg postoperatively (26).

A study conducted by Qazi Nahida et al. showed that TAP block reduced the requirement of postoperative opioid use, increases the time to first request for additional analgesia, and offers more effective pain relief while reducing opioid-related adverse effects namely, respiratory depression, sedation, and postoperative nausea and vomiting (27). Opioids are common postoperative analgesia following lower abdominal surgery, which can cause respiratory compromise, sedation, nausea, vomiting, bowel dysfunction, and pruritus (28).

A study conducted in India compared the effectiveness of the TAP block with the control group and the results showed patients who received the TAP block with bupivacaine had markedly less mean total pain score (48.07 ± 6.77) compared to the control group (62.63 ± 6.66) in the first 24hrs, (P-value of 0.0001). In comparison with the control group, in the TAP group, two hourly pain scores were smaller until 18 hrs. Tramadol consumption compared between the groups revealed a significant difference postoperatively. The mean total consumption was 439 ± 68.59 mg in the control group and 281 ± 69.66 mg in the TAP block group, with a p-value of 0.0001 (29). A study conducted in Saudi assessing the effectiveness of the TAP block showed that the first dose of rescue required in the TAP group was at 547.133 ± 266.9 minutes and in the non-TAP group was at 49.17 ± 24.95 minutes, which was statistically significant ($p < 0.05$). On top of this, the study revealed that tramadol consumption was significantly reduced in the group with TAP block, which was 103.83 ± 32.18 mg in the group with TAP and 235.83 ± 47 in the control group (30).

A randomized controlled trial in India evaluated the effectiveness of the TAP block for pain control following surgery; showed that patients with TAP block showed less VAS pain score both during movement and at rest compared to non-TAP ($p < 0.001$). The requirement for more analgesics and consumption was higher in the control group than in the TAP group (31). A study conducted by *Ashok Jadon et al.* on the effectiveness of TAP block after cesarean delivery showed that the median (IQR) of tramadol consumption was low in the TAP group compared to the control group ($p < 0.001$). The median VAS score, both on movement and at rest, was significantly lower in the TAP group compared to the control group ($p < 0.001$). Median (IQR) pain score on movement was 0.5 (0-2) and 2.5 (2-3) in the 2nd hour, 1.5 (0.5-3) and 3 (2.5-5) in the 4th hour, 2 (2-3.5) and 3 (2.5-7) in 6th hour, 3 (2-4)

and 4 (3-7) in 12th hour postoperatively with p-value < 0.001 in TAP block vs control groups, respectively (32).

Research conducted by *Mc Donnell et al.* demonstrated the efficacy of TAP block for post-caesarean section delivery, showed the median (IQR) VAS pain scores both at rest and on movement to be decreased after the TAP block group, at many time points (2nd, 4th, 6th, and 12th hours). The authors revealed total postoperative analgesic consumption was significantly reduced in the TAP block compared with the control group (33).

A study conducted in Iraq on the TAP block after cesarean delivery showed that the pain scores both at rest and during movement were significantly lower in the TAP group compared to the control group with a p-value of <0.05. On top of this, the results showed that narcotic consumption was reduced to 50% in the TAP block group. Pethidine was requested by 30% and 14% in the control and TAP block groups, respectively (34).

Various studies have reported that TAP block provided effective postoperative analgesia after surgery in the lower abdominal or pelvic surgical procedures (35). Total tramadol consumption was reduced in patients with the TAP block in comparison with a patient who did not receive a TAP block (36). TAP block reduced respiratory complications related to poor pain management (37). In comparison with the non-TAP block, patients with the TAP block had significantly less mean total pain scores within the first 24 hr postoperatively (38).

A controlled trial study conducted in India showed that mean tramadol use was significantly less at 8 and 12 h after surgery in the TAP group compared to the non-TAP group. Tramadol consumption during the first 24hr postoperatively was significantly reduced in the TAP group compared to the non-TAP group (75 ± 22 vs 168 ± 45mg in the TAP group and non-TAP- group, respectively, p< 0.0001). Total tramadol consumption was reduced approximately by 50% in the TAP group compared to the non-TAP group (127 ± 24 vs. 253 ± 52 mg in the TAP group and non-TAP group, respectively, P < 0.0001) (39).

The study conducted by *Anna Kupiec et al.* (40) showed a lower VAS score in the TAP block group at all time points (3rd, 6th, & 12th hour) after a cesarian section. Another study conducted by *Ebru Salman et al.* revealed that the VAS score was reduced in the TAP block

group compared with the control group at all postoperative time points (2nd, 4th, 6th, & 12th hour) both at rest and during coughing with a p-value of <0.001 (41). A study conducted by Marcos et al. revealed that the analgesics consumption was also significantly reduced in the TAP block group up to 12 hours postoperatively (p<0.05) (42).

A study conducted after cesarean surgery in China, however, showed no significant difference was found between the two groups in VAS pain score at all time intervals postoperatively (2nd hour, 4th hour, 6th hour, and 12th hour with a p-value of 0.12, 0.13, 0.26, and 0.89, respectively) (43). In addition, a study conducted on gynecological malignancy surgery showed no significant difference in total analgesic consumption within 24 hours postoperatively (44). Research conducted by Kahsay DT et al. in Eritrea on the efficacy of post-operative TAP block following cesarean section showed VAS pain scores were decreased in TAP block at intentional coughing, deep breathing, and mobilization (p < 0.05). On the other hand, in the control group, the consumption of morphine and diclofenac was higher (p < 0.001) (45).

A prospective cohort study by Tarekegn F et al. in Debretabor, Ethiopia showed that when bilateral TAP block was used as multimodal analgesia following cesarean delivery under spinal anesthesia, it decreased total postoperative analgesic consumption of tramadol, reduced the severity of postoperative-pain-and it also prolonged the time for first analgesic request with (mean ± SD) was (286.0 ± 166.31) vs (76.25 ± 22.05), in TAP and non-TAP groups, respectively (46). Another prospective cohort study done in Gondor showed that the TAP block after lower abdominal surgery decreases postoperative severity of pain and tramadol consumption (47).

Chapter three

3. Objectives

3.1 General objectives

To assess the effectiveness of transversus abdominis plane block as a part of postoperative analgesia compared to systemic analgesics alone in parturients undergoing cesarean delivery under spinal anesthesia.

3.2 Specific objectives

- To compare postoperative pain score using VAS during intentional coughing and at rest between a patient who received TAP block and (non-TAP) received standard systemic analgesia alone in the first 12 postoperative hours
- To compare the total amount of analgesic consumption between the groups in the first 12 postoperative hours
- To compare postoperative hemodynamic parameters between the groups in the first 12 postoperative hours

Chapter four

4. Methodology

4.1 Study area and period

The study was conducted at Jimma University Medical Center from August 2022 to October 2022. The study area is in Jimma town; Oromia regional state, which is 355km away from Addis Ababa. Jimma University Medical Center is one of the famous teaching hospitals in Ethiopia and has different specialties, such as obstetrics, gynecology, pediatrics, surgery, dermatology, psychiatry, and inpatient services.

4.2 Study design

An institution-based prospective cohort study design was conducted at Jimma University Medical Center.

4.3 Population

4.3.1 Sources of population

All parturients who underwent cesarean section delivery under spinal anesthesia at Jimma University Medical Center and took TAP block or (non-TAP) received a standard intravenous analgesic agent alone.

4.3.2 Study population

All parturients who underwent cesarean section under spinal anesthesia and took TAP block or (non-TAP) received a standard intravenous analgesic agent alone during the study period, August 2022 to October 2022, at Jimma University Medical Center.

4.4 Study variables

Dependent Variables: pain score, analgesic consumption, and postoperative hemodynamic

Independent Variables: Socio-demographic characteristics: age, weight, height, BMI, and education. Anesthesia and surgery-related: duration of surgery, the dose of LA used for spinal anesthesia, the experience of the anesthesia provider, parity, and the number of cesarean deliveries. Baseline hemodynamic parameters: baseline heart rate, and MAP.

4.5 Sample size and sampling technique

Sample size

The sample size was determined based on the mean VAS pain score from the previous study, mean \pm SD (4.5 ± 1.3) vs (5.4 ± 1), mean and standard deviation for the TAP group and control, respectively (48). A priori power analysis was conducted in G* power (using version 3.1.9) to determine the sample size (49). 58 participants were required at the alpha value of 0.05 and 80% power of the study.

T-tests - Means: Difference between two independent means (two groups)

Analysis: A priori: Compute the required sample size

Input:	Tail(s)	= Two
	Effect size d	= 0.760351
	α err prob	= 0.05
	Power (1- β err prob)	= 0.8
	Allocation ratio N2/N1	= 1
Output:	Noncentrality parameter δ	= 2.8953303
	Critical t	= 2.0032407
	Df	= 56
	Sample size group 1	= 29
	Sample size group 2	= 29
	Total sample size	= 58
	Actual power	= 0.8120256

Each number of the TAP block group and the non-TAP group was 29; using a 1:1 ratio between groups. An additional 6 (10%) patients were added to ensure that a minimum of 58 patients were needed. A total of 64 parturients were included in the study.

Sampling technique

All patients who underwent a cesarean delivery under spinal anesthesia during the study period and met the inclusion criteria were recruited into the study until the required sample size was reached. Patients were sorted based on the time sequence of post-anesthesia care unit admission. The data collector then recruited patients who had undergone cesarean delivery under spinal anesthesia and fulfilled the inclusion criteria after grouping based on whether they received a TAP block or not.

4.6 Data collection procedure

Before data collection, training was given to the data collectors with a brief lecture and practice about the VAS score method. A questionnaire and checklist were prepared by the investigator. Once the patient arrived in the operation room, pulse rate, blood pressure, and SPO2 were recorded before spinal anesthesia. Spinal anesthesia was given with 10-12 mg of 0.5% bupivacaine between L4 and L3 under an aseptic technique.

After completion of the surgery, using the landmark technique, a bilateral TAP block has been usually performed with 20 ml of 0.25% bupivacaine for postoperative pain management. The TAP group parturients received a bilateral TAP block with 20 ml of 0.25% bupivacaine at the end of the surgery. Non-TAP group patients were treated with standard systemic analgesics. The block was performed by using a standard landmark technique immediately after skin closure.

After the block, patients were transferred to the post-anesthesia care unit. In PACU, they were observed by the responsible PACU team (nurses, anesthetists, medical interns), and postoperative pain has usually been managed by tramadol and diclofenac based on patient compliance and sometimes based on a physician's order. This follow-up and management continued in the ward by ward nurses and medical interns. Postoperative hemodynamic parameters (HR and BP) and any analgesics or other medications that are given to the patient have been documented along with the dose and time.

All parturients who fulfilled the inclusion criteria and volunteers to take part in the study were included in the study following informed consent. The data collector then recorded the sociodemographic and intraoperative information of the participants from anesthesia and patients' card. Following the instruction of the patient on how to self-report pain using a VAS score, data collectors assessed the pain score, total analgesic consumption, postoperative blood pressure, pulse rate, and incidence of nausea and vomiting. Pain assessment was performed postoperatively at the 2nd, 4th, 6th, and 12th hours during a quiet breathing period/rest and intentional coughing in the first 12hrs postoperative periods. At the time of pain assessment, the incidences of nausea, vomiting, heart rate, and arterial blood pressure were also assessed.

4.7 Inclusion and Exclusion Criteria

4.7.1 Inclusion Criteria:

All (ASA II) parturients who underwent cesarean delivery under spinal anesthesia.

4.7.2 Exclusion Criteria:

A parturient presented with a decreased level of consciousness, a history of chronic opioid usage, a history of chronic pain disorder, abuse of substances, patient refusal, use of the adjuvant in spinal anesthesia, if additional analgesic drugs were given intraoperatively, the surgery took >1 hour and parturient with BMI > 35kg/m² were excluded.

4.8 Operational definition

TAP (transversus abdominis plane block) group: Parturients who were exposed to bilateral transversus abdominis block with 40 ml (20 ml on each side) of 0.25% bupivacaine.

Systemic analgesics alone/non-TAP: Parturients who were not exposed to the TAP block but took standard systemic analgesics alone.

VAS on coughing and at rest: In which patients were asked to give a score for their pain during intentional coughing and at rest/ during a quiet normal breathing period, respectively.

Effectiveness of TAP block: The role of TAP block as part of postoperative analgesia in terms of significantly reducing VAS pain score and decreasing analgesic consumption, compared to the non-TAP (control) group postoperatively.

Visual Analog scale (VAS): A valid pain assessment tool in which the patient is instructed to point to the position on the line to show how much pain they are currently feeling. The far left end shows 0= ('No pain') and the far right end indicates 10= ('Worst pain ever').



Pain severity is rated as, 0 = no pain, 1-3 = mild pain, 4-6 = moderate pain, 7-10 = severe pain

Total postoperative analgesia consumption: Total dose and type of analgesic drugs that were given in mg within the first 12 hours, starting from admission to the recovery room.

Hemodynamic parameters: The participant's postoperative blood pressure, heart rate, and incidence of nausea/vomiting at the time of study

Postoperative nausea and vomiting: At least one episode of either nausea or vomiting within 12 hours.

Exposed group: Parturients who took the TAP block

Non-exposed group: Parturients who will not take TAP but standard systemic analgesic alone

Failed TAP block: VAS scores on coughing ≥ 4 at 2nd hour postoperatively

Lost follow-up: Any follow-up followed for less than 12 hours for any reason

Duration of surgery: Time in minutes from skin incision to end of surgery

4.9 Data Analysis

Data were analyzed using Epi-data 4.6 for data entry and SPSS version 26 software for data analysis. To test for the normality of data, the Shapiro-Wilk normality test was used and Levine's test was used to assess the homogeneity of variance. To compare numeric variables between the two groups, an independent t-test was used for normally distributed data and a non-parametric Mann-Whitney U test was done for non-normally distributed data. To compare the categorical variable between groups, Chi-square and Fisher's exact tests were used. Numeric data were presented as mean \pm SD for normally distributed data; non-normally distributed data were presented as median \pm IQR. Categorical data were presented as frequency (percentage). P-value < 0.05 was considered statistically significant.

4.10 Data quality control

Before, the actual data collection questionnaire was pretested to ensure its validity and reliability. Orientation was given to the supervisor and data collectors about the objectives and relevance of the study. Informed consent was obtained from each study participant and regular supervision and follow-up were undertaken throughout data collection. The questionnaires were checked daily for their completeness and consistency of data. Data clean-up and cross-checking of missing data was done by double entry method before analysis on SPSS.

4.11 Ethical consideration

Ethical approval to conduct this study was obtained from the Jimma University Research and Ethical review board and the formal letter was forwarded to the medical director of Jimma University Medical Center. Confidentiality was ensured by avoiding participants' names from being mentioned in the data. Data collection was carried out using the local languages (Amharic and Afaan Oromo).

4.12 Dissemination Plan

The final results will be disseminated to the College of Health Science and Medicine, Jimma University Medical Center, Jimma Health Bureau, a federal and regional ministry of health, and the Ethiopian Association of Anesthetists. After a presentation at annual research conferences, the research will be submitted to a journal for publication.

Chapter five

5. Results

5.1 Demographic and perioperative characteristics

During the study period, 64 patients who underwent cesarean section delivery under spinal anesthesia were included for final analysis. 32 patients received bilateral TAP block with 20ml of 0.25% bupivacaine (exposed group) and 32 patients were without TAP block (unexposed group) but treated with parenteral systemic analgesics. There was no statistically significant difference between the two groups regarding the demographic data and perioperative characteristics (age, height, weight, BMI, duration of surgery, ASA physical status) (p -value > 0.05) as shown in Table 1.

Table 1: Socio-demographic and perioperative characteristics of the data at Jimma University Medical Center, Jimma, Ethiopia, 2022

	TAP groups	Non-TAP groups	P-value
Age (year)	26.72±4.2	26.25±4.5	0.670
Height (m)	1.62±0.05	1.63±0.06	0.477
Weight (kg)	60.6±5.6	58.7±5.1	0.252
BMI (kg/m ²)	22.6±1.9	21.8±1.3	0.212
Education			
• Literate (n, %)	29 (45.3%)	30 (46.8%)	0.990
• Illiterate (n, %)	3 (4.7%)	2 (3.2%)	
Parity			
• Primiparous (n, %)	11 (17.2%)	10 (15.6%)	0.790
• Multiparous (n, %)	21 (32.8%)	22 (34.4%)	
Duration of surgery(min)	42.8±7.4	42.2±6.2	0.704

Number of C/S			
• One (n, %)	22 (34.4%)	21 (32.8%)	
• Two (n, %)	9 (14%)	8 (12.5%)	0.410
• Tree (n, %)	1 (1.6%)	3 (4.7%)	
Dose of bupivacaine for SA	10.4±9	10.8±1	0.201
Baseline HR	88.8±8.6	89.2±9.3	0.846
Baseline MAP	93.2±6	94.4±4	0.414

Values are presented as: mean ±SD, Number (%), independent t-test, chi-square, and p<0.05 was statistically significant.

5.2 Comparison of the postoperative hemodynamic parameters

The difference in hemodynamic parameters was not statistically significant. Though the difference in postoperative arterial blood pressure and heart rate is not statistically significant between the two groups (p-value >0.05), the non-TAP group showed a high pulse rate compared to the TAP group. The data were presented in table 2 and figure 1.

Table 2: Post-operative arterial blood pressure and heart rate of respondents who underwent cesarean section at Jimma University Medical Center, Jimma, Ethiopia, 2022

	Time	TAP group	Non-TAP group	p-value
Systolic BP (mmHg)	2hr	111 (20)	115 (15)	0.329
	4hr	118 (14)	119 (16)	0.392
	6hr	118 (11)	117 (10)	0.180
	12hr	120 (12)	121 (7)	0.990
Diastolic BP (mmHg)	2hr	70 (11)	70 (18)	0.705
	4hr	70 (11)	71 (12)	0.627
	6hr	72 (6)	72 (10)	0.254
	12hr	75 (8)	75 (10)	0.919

Values are presented as Median (IQR), Mean \pm SD, Mann-Whitney test, independent t-test, and p<0.05 is statistically significant

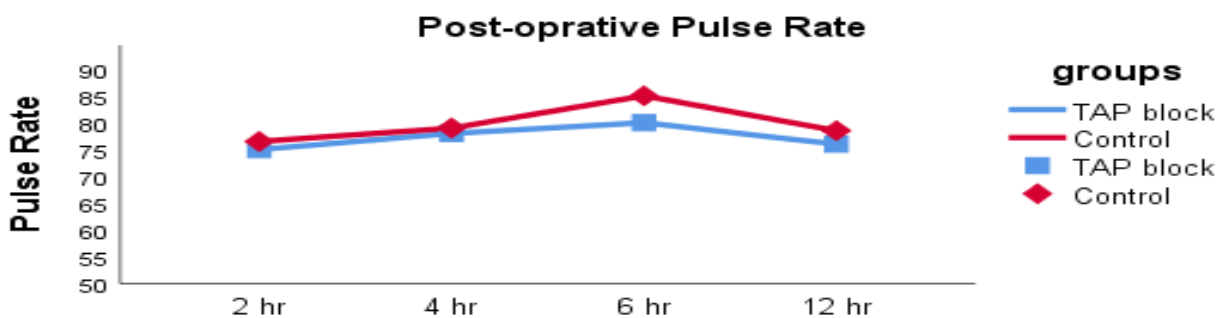


Figure 1: Postoperative pulse rate of patients who underwent cesarean section at Jimma University Medical Center, Jimma, Ethiopia, 2022. Values are median

5.3 Comparison of postoperative Visual Analogue Pain Scale on Coughing

The Mann-Whitney U test was conducted to determine if there were differences in VAS pain scores between the groups. The test revealed that the VAS pain score during coughing was significantly reduced in the TAP block group compared to the non-TAP group at each time interval, i.e., at the 2nd, 4th, 6th, and 12th hours ($p < 0.05$) as shown in figure 2.

The median (IQR) of the VAS pain score at the 2nd hour was 1 (0.1-1.5) in the TAP group compared with the 2 (1-2) control group ($p = 0.005$). VAS at the 4th hour in the TAP block was 2 (1.5-3), compared with 4 (3-4) in the systemic alone group ($p < 0.001$). VAS score at the 6th hour was 3 (2.5-4) vs 5 (3.6-5) in the TAP block vs systemic alone group, respectively, with a p-value of 0.001. The 12th hour also showed a significant reduction in the VAS score between TAP block 4 (3-5.5) and systemic alone group 5.5 (5-7) with a p-value of 0.001.

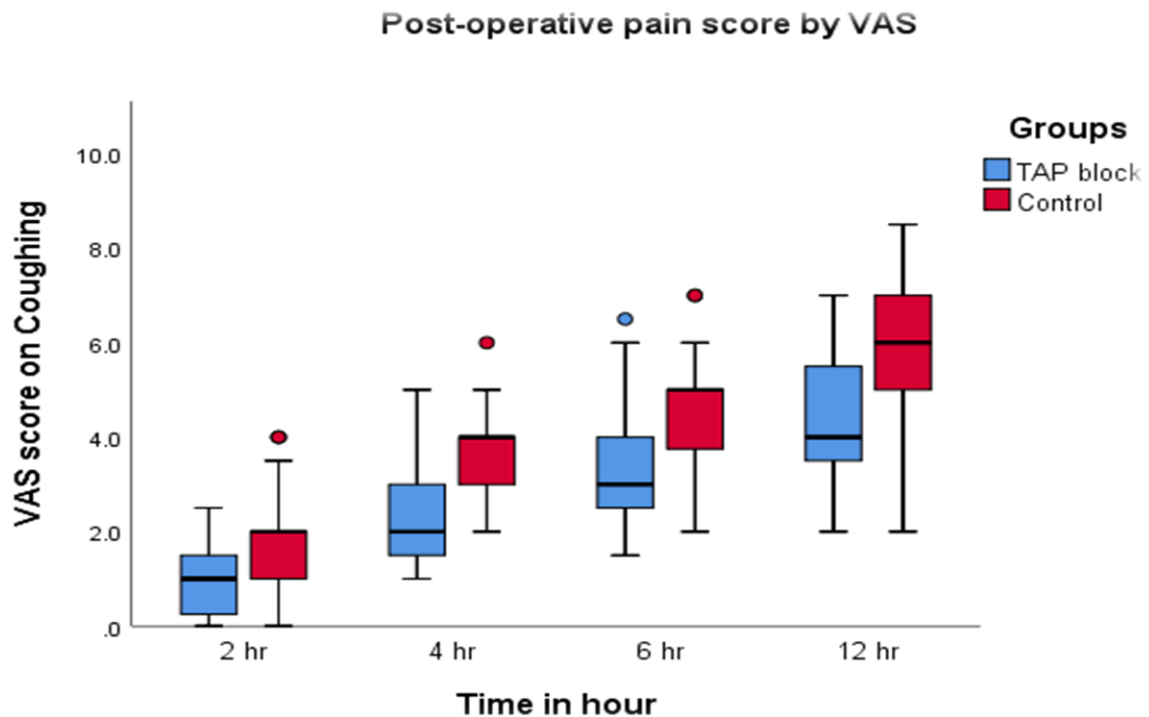


Figure 2: Comparison of postoperative pain of the participant using (VAS score) during coughing at Jimma University Medical Center, Jimma, Ethiopia, 2022

5.4 Comparison of postoperative Visual Analogue Pain Scale at Rest

The VAS pain scores at rest were significantly reduced in the TAP block group compared to the non-TAP at each time interval i.e., at the 2nd, 4th, 6th, and 12th hours ($p < 0.05$) as shown in figure 3.

The median (interquartile range) of the VAS scores at the 2nd hour was 0 (0-0.4) in the TAP group compared with 0.6 (0-1.5) in the systemic alone group ($p = 0.001$). VAS at the 4th hour in the TAP block was 1 (1-2), compared with 2 (2-3) in the systemic alone group ($p < 0.001$). VAS score at the 6th hour was 2 (1.4-3) vs 3 (2.5-4) in the TAP block vs systemic alone group, respectively, with a p-value of < 0.001 . The 12th hour also showed a significant reduction in the VAS score between the TAP block 3 (2-4) and the systemic alone group 4 (3-5) with a p-value of 0.002.

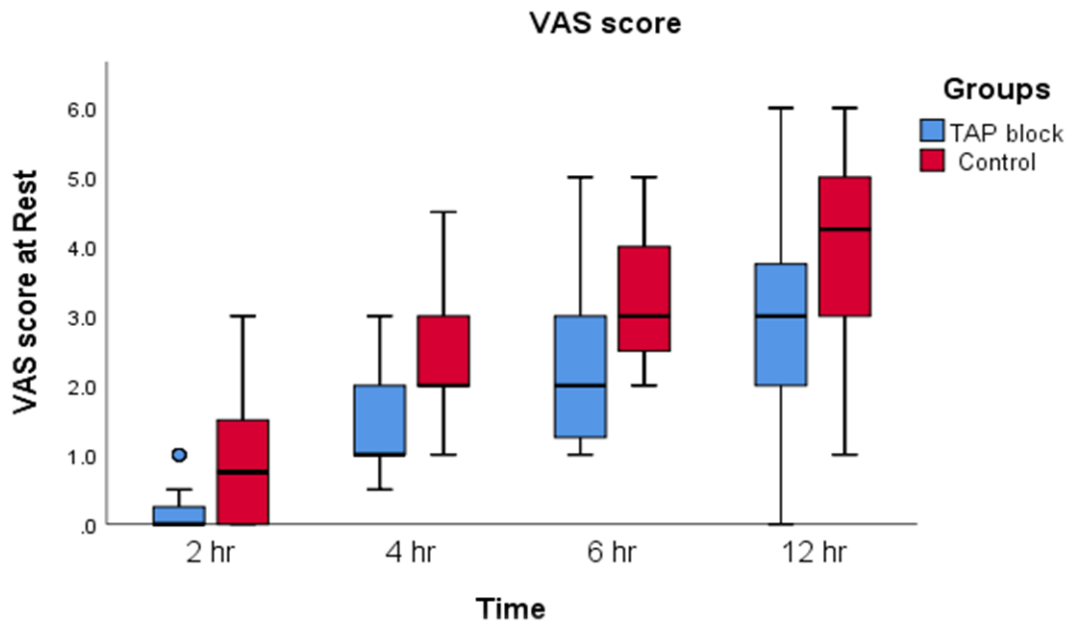


Figure 3: Comparison of postoperative pain of the participant using (VAS score) at rest at Jimma University Medical Center, Jimma, Ethiopia, 2022

5.5 Comparison of total postoperative analgesics consumption

The median (interquartile range) total tramadol consumption was significantly reduced in the TAP block group 50 (50-100) mg compared to the systemic alone group 100 (50-100) mg, within 12 postoperative hours with a p-value of 0.007. Patients with the TAP group showed a reduced total tramadol consumption over 12 hours postoperatively; TAP vs non-TAP block was 1,925mg and 2,850mg, respectively, as shown in Table 3.

In addition, the median (interquartile range) of total diclofenac consumption was 75 (75-75) mg in the systemic alone group, compared with 75 (0-75) mg patients who received a TAP block at all-time points within 12 postoperative hours), $p = 0.021$, as shown in Table 3.

Table 3: Comparison of total analgesics consumption between groups at Jimma University Medical Center, Jimma, Ethiopia, 2022

	TAP group	Non-TAP group	p-value
Total analgesia consumption			
• Tramadol in mg	50 (50, 100)	100 (50, 100)	0.007
• Diclofenac in mg	75 (0, 75)	75 (75, 75)	0.021

Values are presented as median (IQR), Mann-Whitney U test, and $p < 0.05$ was statistically significant

5.6 Incidence of Nausea and Vomiting

The incidence of nausea and vomiting over 12 hours postoperatively was 15%. To determine if there was a difference in the incidence of nausea/vomiting between the groups, a fisher exact test was conducted and it showed that the difference in the incidence of nausea and vomiting was not statistically significant over 12 hours postoperatively ($p>0.05$).

Though it is not statistically significant, the proportions of participants with nausea and vomiting were lower (9%) in the TAP groups compared to the systemic alone group, which was (18%) with a p-value of 0.47 as shown in Figure 4.

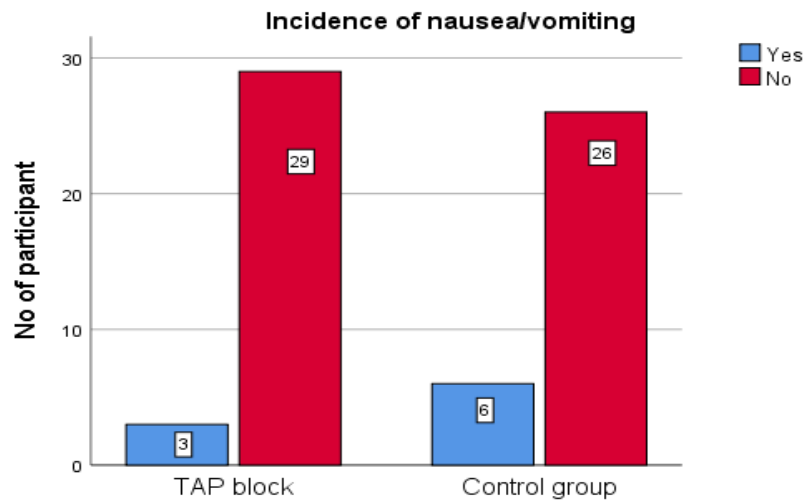


Figure 4: Incidence of postoperative nausea and vomiting at Jimma University Medical Center, Jimma, Ethiopia, 2022

Chapter six

6.1 Discussion

Our study showed that bilateral Transversus abdominis block as a part of postoperative analgesia resulted in significantly decreased postoperative pain at the 2nd, 4th, 6th, and 12th hours ($p < 0.05$), and reduced total analgesics consumption within the first 12 hours postoperatively when compared with the non-exposed group in the postoperative period after cesarean section delivery under spinal anesthesia. A bilateral TAP block with 20 ml of 0.25% bupivacaine reduced the postoperative VAS pain scores by 33% during coughing, and at rest.

Following cesarean delivery, the surgical site was the highest source of pain. The study in Northwest Ethiopia showed the overall prevalence of moderate to severe postoperative pain after the cesarian section was 85.5% within 24 hours (7) and according to the literature, 86-95% of patients experienced postoperative pain for two months (8). Prominent Peripheral regional analgesia like transversus abdominis block has been started as part of postoperative multimodal analgesia for different types of abdominal surgeries (50) (51).

A patient who is comfortable at rest may have significant pain during coughing, which could interfere with the normal activity and physiology of the mother. This may cause detrimental acute and chronic adverse physiologic responses, such as decreased respiratory motion, coughing, and sputum expectoration, which leads to atelectasis, retention of secretion, and pneumonia (52). VAS pain scores were recorded during intentional coughing in both study groups. In our study, the VAS pain score was significantly reduced in the TAP group compared with the non-TAP block at all time points during intentional coughing. This was comparable with a study conducted in India, which revealed that patients with TAP block showed less pain during movement and at rest at all time intervals ($p < 0.05$) (31).

In our study, 75% of participants scored between 0 - 1.5 in the TAP group compared to systemic alone between 0 and 2. The remaining 25% of participants scored up to 2.5 vs 3.5 in the TAP vs systemic group, respectively. At the 4th hour, 75% of participants scored pain between 1.5 - 3 vs 3 - 4, and the remaining 25% of participants scored up to 5 vs 6 in the TAP vs systemic alone group, respectively. At the 6th hour, 75% of participants scored pain between 1.5 - 4 vs 2 - 5, and the remaining 25% of participants scored between 4 - 6 vs 5 - 6

in the TAP vs systemic alone group, respectively. At the 12th hour, 75% of participants scored pain between 3 - 5 vs 3 - 7, and the remaining 25% had pain scores up to 7 vs 8.5 in the TAP group vs non-TAP group, respectively. The results of our study were in line with a study conducted by *Ashok Jadon et al.* with a median (interquartile range) VAS score of pain on movement 0.5 (0-2) and 2.5 (2-3) in 2nd hour, 1.5 (0.5-3) and 3 (2.5-5) in 4th hour, 2 (2-3.5) and 3 (2.5-7) in 6th hour, 3 (2-4) and 4 (3-7) in 12th hour postoperatively with p-value < 0.001 in TAP block vs control groups respectively (32).

We found that the median (interquartile range) pain score was significantly lowered in the TAP block group at the 2nd, 4th, 6th, and 12th hour during intentional coughing and at rest with a p-value of <0.05. This was comparable with the study done by *Anna Kupiec et al.* (40) which showed a lower VAS score in the TAP block group within the first 12 hours at all time intervals after a cesarian section (P<0.05). This was also in line with a study conducted in South Korea, which revealed that the TAP block group reduced pain scores significantly up to 12 hours postoperatively compared to the control group (p<0.05) (53).

Our finding also showed comparable results to the study by *Mc Donnel et al.* which showed the median (IQR) VAS pain score at rest and on movement was decreased in the TAP block group, at many time points (2nd, 4th, 6th, and 12th hours (33). Our finding also showed comparable results with the study conducted by *Ebru-Salman et, al.* that revealed, the VAS score was reduced in the TAP block group in comparison with control at all postoperative time points (2nd, 4th, 6th, & 12th hour) during coughing with a p-value of <0.001 (41).

The results of this study showed that when TAP block was added as a component of postoperative multimodal analgesia, it reduced VAS pain scores at all-time intervals after a single shot. This result is in line with a study done in America in 2017 that showed TAP block was effective in lowering pain after cesarian section with a p-value of <0.05. Contrary to our finding, a study conducted by *Yang Yu et al.* found that compared to the control group, the TAP group showed a statistically insignificant median (IQR) pain score in the 6th at movement and 12th at rest postoperative hour with a p-value of 0.85 and 0.66, respectively. The possible explanation for this discrepancy could be because of a difference in the type and volume of drug being used in the study (their study used 15ml of 0.25% ropivacaine compared to 20ml of 0.25% bupivacaine) (54).

The present study showed comparable results in VAS pain score at rest with *Ashok Jadon et al.* with a median (IQR) of 0 (0-1) and 2 (1-4) in 2nd hour postoperatively, 1 (0-2) and 3 (1.5-4) in 4th hour postoperatively, 1.5 (1-2) and 2 (2-5.5) in the 6th hour postoperatively, 2 (2-3) and 3 (2-4) in the 12th hour postoperatively with a p-value of < 0.05 in the TAP block vs control groups, respectively (32). Our study was also incomparable to a study done in China after cesarean surgery; which showed no significant difference was found between the two groups in VAS pain score at all time intervals (2nd hour, 4th hour, 6th hour, and 12th hour with a p-value of 0.12, 0.13, 0.26, and 0.89 respectively). This inconsistency in our study could be because of a difference in the type of drug used between our study (0.25% bupivacaine) and China (0.33% ropivacaine) (43).

According to our study, the median total Tramadol consumption over 12 hours was 50 (50-100) milligrams in the TAP block group compared with 100 (50-100) milligrams in the control group (p=0.007). When TAP block was added as a component of multimodal analgesia with a single injection of 20ml of 0.25% bupivacaine, total Tramadol consumption was reduced by near to 32% in the first 12 postoperative hours as compared with the control group. (34). This was in line with a study by *Kupiec et al.* which showed that Tramadol consumption was reduced in the TAP block by nearly 28% in the first 12 postoperative hours compared to the control group (40).

The total Tramadol consumption reduction in our study was comparable to the study conducted in Saudi and Iraq. A possible explanation for this could be because of the same volume and percentage of bupivacaine used between our study and Saudi and Iraq (39) (34). This was also in line with a study conducted by *Marcos et al.* which showed that analgesics consumption was also significantly reduced in the TAP block group up to 12 hours postoperatively (p<0.05) (42). The reason TAP block is resulting in reduced Tramadol consumption and has a long-duration of analgesic effect might be because of the less vascularized site of the block, which allowed a delayed clearance of the local anesthetist (55).

In our study, the median (IQR) Diclofenac consumption was significantly reduced in the TAP block group compared to the control group, which was 75 (0-75) vs 75 (75-75) ($p=0.021$), respectively. This was comparable with a study done in Eritrea that showed Diclofenac consumption was significantly reduced in the TAP block group and high in the control group ($p < 0.001$) (45).

In our study, the incidence of nausea and vomiting was statistically insignificant ($p = 0.47$). There were no participants from the TAP group who received an antiemetic, but two participants from the control group received an antiemetic. This was supported by a study conducted by *Baat et al.* which showed postoperative nausea and vomiting incidence to be 5 (10%) and 2 (5%) for the control and TAP block group, respectively ($p = 0.39$) (56). However, a study by *Yanchao et al.* found that the incidence of nausea and vomiting was significantly higher in the control group compared with the TAP block group ($p < 0.05$). This discrepancy could be because of follow-up time variation. They followed for 24 hours compared to 12 hours in the current study (43).

6.2 Limitation

The limited availability of similar studies for comparison was a limitation of our study.

6.3 Strength

We have tried to make a comparable study group in terms of socio-demographic distribution, perioperative factors that affect the study outcome, and the same surgical procedures. Therefore, the difference observed may be because of the exposure factor.

Chapter seven

7. Conclusion and recommendation

7.1 Conclusion

Based on our results, we concluded that a bilateral single injection of TAP block with 20 ml of 0.25% bupivacaine reduced postoperative pain scores compared to the non-TAP group. Total postoperative analgesics consumption was also reduced when the TAP block was used as part of postoperative analgesia for post-cesarean section pain management.

7.2 Recommendation

We recommend that the transversus abdominis plane block should be added as a component of postoperative multimodal analgesia for post-cesarean section delivery pain management.

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ANNEXES

Informed consent

The data collector will read the following paragraph for the study participant: to conduct the research; I would like to ask a few questions for about 3 - 5 minutes at four different times. The information you will provide is very helpful to the outcome of the study. Therefore, we kindly request you to give us your truthful answer. Your name will not be mentioned in this form and all information that you provide will remain confidential. Are you willing to participate in the study? Yes- (continue), No- (Thank you and stop)

Date _____ Signature

The signature of the interviewer certifies that informed consent has been obtained verbally

Questionnaire in English

Department of Anesthesia College of medicine and health science, Jimma University

Questionnaire identification number _____

Good morning/ Good afternoon. Thank you for your interest in talking with me.

I am _____. I am working in the research team of Jimma University's Department of Anesthesia. I would like to ask you a few questions about your experience with surgical cesarean pain. The study aims to gather information about the analgesic effectiveness of bilateral TAP block after cesarean delivery. This study will help control postoperative pain in those who will undergo cesarean sections by decreasing the need for other analgesic drugs and reducing the risk of opioid-related side effects. Therefore, the answer to those questions is confidential. We will ask you a few questions for about a few minutes at four different times. Your name will not be written in the form. You have the right to refuse, not to answer any question that you are not comfortable with. In addition, you can interrupt at any point between interviews. Do you have any questions about the study? Do I have your permission to continue?

Socio-demographic data

S.no	Questions	Response	code
1	Patient's card no		
2	What is the age?		
3	What is the height?		
4	What is weight?		
5	BMI		
6	Which ASA status is the patient?	ASA I	1
		ASA II	2
7	Parity	Primiparous	1
		Multiparous	2
8	Number of the previous c/s	One	1
		Two	2
		Three	3
		Four and above	4
9	Uterine incision for non c/s	yes (specify)	1
		No	2
10	Education	Literate	1
		Illiterate	2

Data during the preoperative period

S. no	questions	Responses	code
11	Baseline heart rate Bpm	
12	Baseline blood pressure mmHg	
14	Indications/diagnosis		
15	Does the patient receive any premedication?	Yes	1
		No	2
16	If yes write type and dose	_____ ()mg	

Question -related to spinal anesthesia and surgery

S. no	Parameter	Values	code
17	Duration of surgery	_____ minutes	
18	The dose of bupivacaine used for SA	_____ mg	
19	Types of incision	Transverse (Pfannenstiel)	1
		Vertical	2
20	Surgeon experience	R3	1
		R4	2
		Senior	3
21	Groups/Types of postop pain management	TAP with 40ml of 0.25% bupivacaine	1
		IV/IM analgesic alone	2
22	Anesthetist/Anesthesiologist experience	1. BSc 2. MSc Y1 3. MSc Y2 4. MSc, 5. R1 R2, R3 & senior	

Postoperative hemodynamic parameter

S.no	Time (in hours)	Parameter	Value	Code
25	At 2 hours of the postoperative period	HRbpm	
		BPmmHg	
26	After 4 hours of the postoperative period	HRbpm	
		BPmmHg	
27	After 6 hours of the postoperative period	HRbpm	
		BPmmHg	
28	At 12 hours of the postoperative period	HRbpm	
		BPmmHg	

29. Does the patient have nausea/vomiting within the 12 hours of surgery? A. Yes B. No

Question related to total analgesia consumption for 12 postoperative hours

S.no	Question	Response (mg/mcg)	Code
30	Tramadol		1
31	Diclofenac		2
32	Pethidine		3
33	Others		4

Question-related to the severity of pain

Time	Pain score (at rest)	Pain score on VAS (on movement/coughing)
At 2hrs		
At 4hrs		
At 6hrs		
At 12hrs		

To measure the severity of pain: A Visual analog scale (VAS)

Patients make a mark of their pain intensity on a line that is 10cm long.

VAS (0 = No pain, 10 = Most intense imaginable pain)



DECLARATION

I, the undersigned, declare that this thesis is my original work, has not been presented for a degree in this or any other University, and all sources of material used for the thesis have been fully acknowledged.

Name: _____

Signature: _____

Name of the institute: _____

Date of admission: _____

This thesis has been submitted for the examination with my approval as a University advisor.

Name and signature of the first advisor

Name and signature of the second advisor

