



*ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCE; DEPARTMENT OF ANESTHESIOLOGY,
CRITICAL CARE AND PAIN MEDICINE.*

Ultrasound-Guided TAP Block with Intrathecal Morphine versus Intrathecal Morphine Alone for Post-Cesarean Pain incidence and Control among Elective Patients done under Spinal Anesthesia: A Cohort Study at TASH, Addis Ababa, Ethiopia, 2023.

A Thesis Proposal to Be Submitted to Addis Ababa University, Department of Anesthesiology, Critical Care and Pain Medicine to partially fulfill the Requirements of a Specialty Certificate in Anesthesiology, Critical Care and Pain Medicine.

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AAU, ETHIOPIA.

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List of acronyms and Abbreviations

AAU	Addis Ababa University
ACCPM	Anesthesiology, critical care, and pain medicine
ASA	American Society of Anesthesiologist
CD.	Cesarean Delivery
CS	Caesarean Section
FMOH	Federal Ministry of Health
ITM	Intrathecal Morphine
OR	Operation Room
PS	Purposive Sampling
SPSS	Statistical Package for the Social Sciences
TAP	Transversus Abdominis Plane
TASH	Tikur Anbesa Specialized Hospital

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Summary

Background:

About 80% parturient reported post C/D pain. Quality pain optimization is a priority in women undergoing C/D. Unmanaged perioperative pain results greater opioid use, delayed recovery, impaired feto-maternal bonding, and increased blue and depression.

Despite multimodal analgesia is the core principle for cesarean delivery pain management, the combination of ultrasound-guided TAP block with intrathecal morphine versus intrathecal morphine alone is a bit controversial.

Objective: This study was aimed to assess the effectiveness of ultrasound-guided transversus abdominis plane block with intrathecal morphine versus intrathecal morphine alone for post-C/D pain control among elective patients done under spinal anesthesia at TASH.

Method: A hospital-based prospective cohort survey was conducted among a total of 48 patients. Data was collected using a structured questionnaire. Data was entered, coded and analyzed by using SPSS V. 25. A descriptive analysis was done for the Socio-demographic data. After checking for Normality and Homogeneity of the data, parametric and nonparametric comparative analysis, was done. Chi square test was conducted to measure association between categorical variables. A statistical significance was declared with $p\text{-value} \leq 0.05$.

Result:

The Mann-Whitney U test was performed to compare postoperative pain intensity at rest or during movement between TAP group and ITM group. There was statistically significant difference in NRS at 2hrs post-operative time between TAP group (Median = 0, IQR = 0) and ITM group (Median = 0, IQR = 2), $U = 210.5$, $z = 1.95$, $p = 0.05$. The effect size(r) was calculated as $r = 0.3$. Similarly, in the 6 and 12 hrs postoperatively, TAP group median (IQR) vs ITM median (IQR), U , z , r and (p -value) were 0(1) vs. 4 (2), 0, 6.12, 0.67 and ($p < 0.001$), 1 (0) vs. 3 (1), 68, 4.67, 0.67 and ($p < 0.001$) respectively

The Mann-Whitney U test was performed and showed there was a statistically significant difference in first analgesic request time between TAP (Median = 15, IQR = 12 - 18) and ITM groups

Out of the 24 patients in the TAP group, 2 reported experiencing NRS pain score of ≥ 4 at rest within 24 hours postoperatively, resulting in a pain incidence of 8%. In the ITM group, 22 out of 24 patients reported NRS pain score of ≥ 4 at rest within 24 hours, resulting in a pain incidence of 92 %

Conclusion and recommendations:

In this study combining TAP block with intrathecal morphine has better post cesarean delivery pain control. First analgesics request by the TAP group was longer (15 hr vs 5 hrs for intrathecal alone). The overall incidence of moderate to severe post cesarean delivery pain at rest for the unexposed group was 92%vs 8% for exposed group.

From this study anesthesia providers have to focus on multimodal approach of post cesarean delivery pain management. Combining regional technique with systemic analgesics significantly reduces pain burden in postoperative periods. Utilization of ultrasound for TAP block is strongly advised to reduce complications and optimize effectiveness.

Key Words: Transversus Abdominis Plane Block, Intrathecal Morphine, Cohort Study, Ethiopia.

1. Introduction

1.1. Background

The current International Association for the Study of Pain (IASP) definition of pain as "An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage,"[1]

Cesarean section has historical background which only was done to rescuing the fetus. Now the objectives of C/D have evolved to wellbeing of the mother and the child as well as acknowledging the mother's preferences. [2]

From 1990 to 2014, Cesarean section rates were collected from 150 countries. Currently, 18.6% of all births occur by CS, ranging from 6% to 27.2%. Based on the data from 121 countries, the trend analysis showed that between 1990 and 2014, the global average CS rate increased by 12.4% making it the most commonly performed procedure worldwide. [3]

In Ethiopia the national cesarean delivery rate has increased by 2.7X from 2000-2016 GC. The capital city had the highest cesarean delivery rate (21.4%) in 2016. [4]

Approximately 80% of post C/D patients had acute pain postop; from those 86% had moderate, severe, or extreme pain. [5]

Studies over the past 30 to 40 decades have proven that 20–80% patients suffer postoperatively from untreated pain, there by it is classified as a serious public health problem worldwide. [6], [7], [8]

In studies done in Northwest Ethiopian universities, prevalence of moderate to severe post-surgical pain after a cesarean delivery was 85.5%. [9]According to studies conducted in Jimma Incidence of postoperative pain was 91.4% with poorly documented postop pain management adequacy[10]

Postoperative pain is usually from skin, abdominal wall, and uterine incisions. The uterine afferent fibers are C-fibers with some A-delta fibers. The majority of afferent fibers that relay nociception from the skin are A-delta fibers. Therefore the skin component makes a difference in pain sensation hence requires multimodal types of pain management protocols [11]

Postoperative pain after C/D was associated with preoperative maternal anxiety, previous cesarean delivery, Pfannenstiel incisions, and in patients where regional analgesics methods were not incorporated.[9]

Adequate pain management is vital in patients undergoing cesarean section. Unaddressed post-delivery pain is linked to chronic and persistent pain, greater opioid use, delayed functional recovery, impaired feto-maternal bonding, and higher postpartum blue and depression. Severe acute postop pain will progress to chronic pain after cesarean section.

Multimodal pain control strategies are advocated. If there is no contraindication neuraxial opioid with systemic opioid-sparing drugs such as NSAIDs and acetaminophen are recommended for all patients who underwent cesarean section with neuraxial anesthesia. [12]

Another analgesic with opioid-sparing techniques includes local anesthetics wound infiltration, TAP block, intrathecal dexamethasone, gabapentin, and ketamine can be used.[12]

TAP block was first described by Rafi in 2001. He suggested a single-shot anesthetic deposited into the plane resulted blockade of nerve fibers responsible for nociception[13]

TAP block technique provides a satisfactory block to nociceptors from parietal peritoneum, skin and muscles of the anterior abdominal wall[14] First portrayed 20 years ago and went through some modifications for it to be used for different surgical techniques involving abdominal wall [13]. Despite its benefits TAP block is overwhelmingly underutilized [15]. To date, there are no LAST published reports following TAP blocks. [16]

Despite this, only 6.1% of post-cesarean section patients received the currently recommended regimen of neuraxial morphine with NSAIDs and acetaminophen. [17]

1.2. Statement of the problem

Cesarean delivery is the commonest performed procedure worldwide and pain is the most postop complaint. [9] Adequacy of pain management is a process indicator of health care quality with consequences for patient outcomes and satisfaction. The reported incidence of moderate to severe postoperative pain worldwide is between 20% and 80%.[8]

In a study done in Sweden on 260 healthy parturient who underwent elective cesarean delivery. Almost 1/3 of patients had pain over one or more incision site after 6 months postop.

Untreated immediate severe postop pain or those who underwent a first cesarean delivery were associated significant independent risk factors.[18]

In a study done in South Africa, of 1231 patients, 2/3rd of the patients had moderate or severe post op pain. Being post Cesarean delivery was one of the risk factor. [19] In a Nigerian study that included a total of 529 patients who underwent C/D concluded that most of the participants received single and weak analgesics contrary to the WHO multi-modal analgesia recommendation for acute pain such as post-cesarean section pain. [20]

In Ethiopian studies, the prevalence of post-cesarean section pain was unacceptably high. In a research done in Addis Ababa the prevalence of moderate to severe post-surgical pain was 49.7% during the first POD. It highlighted us postop pain is still highly unaddressed in our setup . [21] studies done in Jimma, Gonder, and Hawassa the prevalence of moderate to severe post-cesarean pain was 91.4,85.5 and 89.8%respectively[10], [22], [23].

Highly effective post-cesarean delivery analgesia is mandatory for the parturient since breastfeeding and caring for the neonate starts postoperatively. [24]

Multimodal analgesia is the core principle for cesarean delivery pain management [12]. Despite this, only 6.1% post caesarean section patients received the currently recommended regimen of neuraxial morphine with NSAIDs and acetaminophen in the Western world [17]. study done at jimma as needed (prn), single analgesic, no analgesia, or intramuscular orders were 31.3%, 89.29%, 9.7%, and 20.1% of the prescription orders for post-C/D pain management respectively[10] w/ch showed that only few gets multimodal regimen and regional facial plane blocks were not reported or done.

In selected patient population, TAP blocks with or without catheters can provide adequate analgesia and patient satisfaction as epidural analgesia. [16]

Despite a relatively low risk of complications and a high success rate using modern techniques, TAP blocks remain overwhelmingly underutilized [15].

In our setup utilization of multimodal analgesia is not standardized and underutilized. Intrathecal opioids are being used during spinal anesthesia provision for intraoperative adjuvants as well as for post-op analgesia. Although the doses for intrathecal opioid is not standardized. Facial plane blocks are being done inconsistently despite their effectiveness for postoperative analgesia.

The purpose of this study is to compare TAP block performed under ultrasound guidance on top of intrathecal morphine versus intrathecal morphine alone for post cesarean pain.

1.3 significance of the study

Anesthesiology is a discipline involved in the perioperative care of patients. Which is a continuum of care for the patients including; preoperative patient assessment, evaluation, and optimization then planning for the intraoperative management and following the intraoperative course, and lastly planning and strictly following and managing the postoperative course of the patient.

As one of the fast-evolving areas of medicine; anesthesiology care is becoming more advanced from time to time. Despite these multiple studies in our country showed the incidence of post cesarean delivery pain is unacceptably high. The management of post-operative pain was inconsistent and inadequate.

As per WHO recommendation post-operative pain management has to be multimodal since pain anatomy has multiple components that have to be addressed for better pain control and patient satisfaction.

There are multiple methods and strategies for post-cesarean section pain management and control. Multiple studies showed a combination of these modalities has better control of acute pain which prevents progression into persistent and chronic pain, reduced opioid consumption with their associated side effects, reduced hospital stay, health care cost, patient comfort, and overall satisfaction.

A better understanding of the effectiveness of each modality provided alone to the patient or with a combination of different modalities would change the postoperative pain management and general care of patients.

Multiple Ethiopian studies (Addis Abeba, Gonder, jimma, and Hawassa) have assessed the magnitude of the post-cesarean delivery pain incidence, associated risk factors, and management strategies. They concluded that post-cesarean section acute pain burden is unacceptably high, the prevalence of persistent as well as chronic pain is quite high, and pain management strategies were inconsistent and inadequate.

Other studies done by Dilla and Debre Tabor compared the effectiveness of management modalities. A study done in Dilla compared the effectiveness of intrathecal morphine vs. TAP block and their finding was patients with intrathecal morphine had better pain control. A study done at Debre Tabor compared TAP block vs. local wound site infiltration concluding TAP block has better post-op pain control.

In resource-rich setups, there are a lot of alternatives for adequate pain control including patient-controlled techniques (neuraxial as well as intravenous), standardized pain management protocols, and better patient follow-up and care. In resource-limited setups like ours; utilization of simple techniques like TAP block is ideal and easy to implement. Generally, it is agreed in multiple meta-analyses's TAP block is quite effective for post-cesarean section pain control at rest as well as on movement in comparison to other facial plane blocks as well as local wound infiltration. Effectiveness was inconclusive in multiple studies when it was compared with intrathecal morphine Vs. TAP block.

This study aims to assess the effectiveness of adding a TAP block for patients administered with intrathecal morphine for better postoperative pain control, prevention of chronic pain, as well as reducing intrathecal as well as systemic morphine dose and its systemic complications and overall patient satisfaction. There are no similar studies done before this in Ethiopia to address the study area.

Thus, believing this study will provide adequate information on if TAP block is supplemented with intrathecal morphine w/ch is routinely administered during the provision of spinal anesthesia for post-cesarean section pain control.

This will ultimately help anesthesiologists, anesthetists, and policymakers, to increase their knowledge and awareness on areas of the problem, enhance their capacity to adequately control post-op pain, develop evidence-based postoperative pain management modalities, policies, and public health interventions with the ultimate goal of reducing morbidity, mortality and disability due to the health problem.

2. Literature review

Multiple studies and metanalysis have suggested that TAP block is effective for post-cesarean delivery pain, lower systemic analgesic requirement, lower pain score at rest and during movement, and overall patient satisfaction. When TAP block was combined with intrathecal morphine the efficacy was controversial.

A literature review and meta-analysis conducted by Mishriky et al. (2012, USA) evaluated the effectiveness of TAP block for cesarean delivery. Nine studies were included. The authors found that TAP block significantly reduced pain scores and opioid consumption in the first 24 hours after surgery compared to placebo or no intervention. They also noted that TAP block was associated with fewer side effects and better patient satisfaction compared to systemic

opioids. In women who received intrathecal morphine, TAP block had a modest effect only during movement in the early postop period. On the other hand, ITM produced better analgesia than TAP block, but opioid-related adverse effects were higher. [25].

Another meta-analysis done by Baeriswyl, M. et al (2015 Switzerland, Canada) analyzed thirty-one controlled trials including 1611 adult participants were identified. Despite the type of surgery, ultrasound-guided TAP block group required lower IV morphine at 6 postoperative hour with $P < 0.00001$. they concluded that Ultrasound-guided TAP block provides marginal postoperative analgesic efficacy after abdominal laparotomy or laparoscopy and cesarean delivery. However, it does not provide additional analgesic effects in patients who also received spinal anesthesia containing a long-acting opioid. [26]

A meta-analysis conducted by Champaneria, R et al (2016 United Kingdom) evaluated twenty published studies showed that TAP blocks was associated with significantly lower pain at rest compared to no TAP blocks and intrathecal morphine $P < 0.0001$. greatest improvement was pain control during movement. And also morphine administration was significantly lowered with TAP group when compared to placebo or no TAP blocks. Their conclusion is, TAP blocks is provide adequate analgesia after cesarean delivery; however significant deference was not demonstrated when long-acting intrathecal opioids are used in conjunction.[27]

In another systematic review and meta-analysis done by Ning Ma et al (2017 Australia) included 56 RCTs and analyzed. Patients who received TAP block had lowered morphine consumption compared to all groups, $P < 0.05$. morphine requirement was similar between the TAP block and wound infiltration groups. First analgesics request time was lower by 93 min from the placebo group ; $p \leq 0.05$. [28] their final conclusion was TAP block provides optimal analgesia and has very few complications compared with wound infiltration and epidural post op analgesic technique.

A systematic review and meta-analysis by Wang Peng et al (2021 China) included a total of 17 studies showing that cumulative morphine requirement was low in TAP group without any difference in pain score. The USG-TAP patients needed a prolonged time for their first analgesic request time and required lower opioid rescue analgesia to breakthrough severe pain in 24 h. USG-TAP blocks also showed higher maternal satisfaction. They recommended that in long acting intrathecal opioids are not feasible or contraindicated TAP block can result satisfactory analgesia. [29]

In one study (USA,2013) Ultrasound-guided bilateral transversus abdominis plane blocks in conjunction with intrathecal morphine for post-cesarean analgesia study done. The exposed group had lower pain score at rest and during movement < 0.001 . the unexposed group did required more analgesics. This significant difference was not repeated at 24 and 48 hours later. ($P = 0.04$) They conclusion is that early post cesarean delivery was better controlled by combining the modalities. [30]

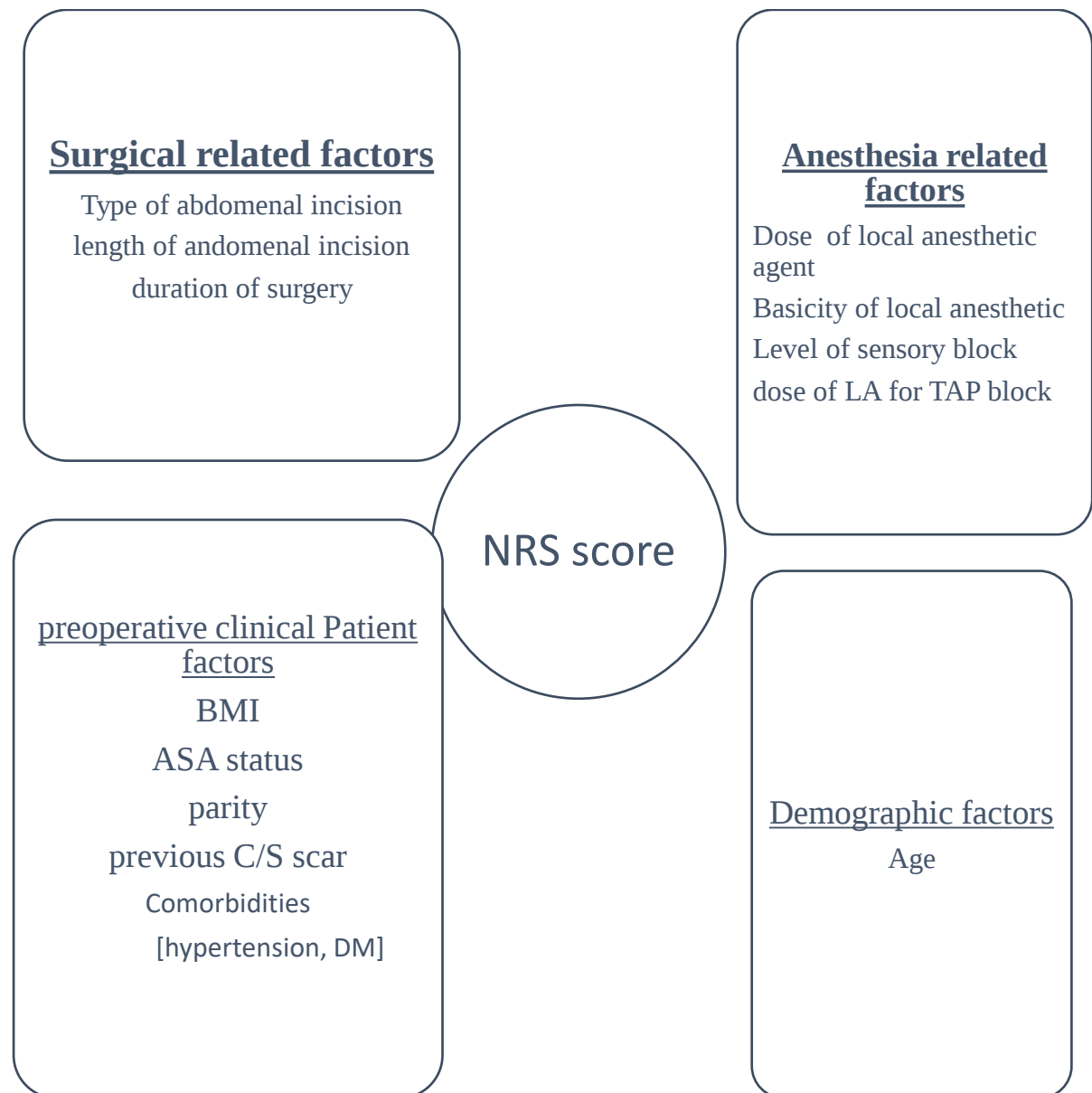
A study was done in 2023(China) on the transversus abdominis plane block in conjunction with intrathecal morphine use after cesarean section in women with severe pre-eclampsia:. Exposed group pain score was reduced; $p = 0.001$ with more satisfaction $P < 0.05$]. there was no difference with pain score with movement.[31] they concluded with TAP block reduced pain score at rest but not opioid requirement .

In a study of TAP block in Uganda (2015). Exposed group had lower pain score during movement. The maximal effect was at 8 hours postoperatively. There was no side effect associated with the exposure. They concluded TAP block has significant importance in resource limited setup . [32]

In a study done in Debre Tabor, Ethiopia (2020) on the effectiveness of TAP block vs. wound infiltration. The study demonstrated TAP block decreased postoperative tramadol and diclofenac requirement, initial analgesic request period , and lowered pain score at 6th, 12th, and 24th hours; $p < 0.05$.

In another study done in Dilla Ethiopia (2022) on comparisons of the effectiveness of intrathecal morphine vs. TAP block. intrathecal group had lower pain score at rest and with movement and longer request to systemic analgesics ; $p = 0.004$. cumulative systemic analgesic provided dose was higher in TAP group than intrathecal group ($p < 0.001$). [12]

Conceptual frame work



3. Objectives

3.1. General Objective

- To determine whether TAP blocks administered in conjunction with intrathecal morphine provide superior analgesia to intrathecal morphine alone for post-cesarean section pain control.

3.2. Specific objectives

- To compare postoperative pain control of TAP block with intrathecal morphine Vs. intrathecal morphine alone.
- To determine postoperative pain incidence at rest on post-cesarean patients within 24 hrs after the surgery.

4. Methodology

4.1. Study area and period

This study was conducted at Tikur Anbessa Specialized Hospital (TASH) in Addis Ababa. Addis Ababa is the capital city of Ethiopia with a population of 5,461,000 according to the 2022 metro area population data in an estimated area of 530.14 square kilometers. In the city 12 governmental hospitals have functional operation rooms and out of this 5 are Federal Hospitals. People from different regions of Ethiopia come to those hospitals to get specialized healthcare services.

Currently, TASH provides surgical services in the following departments Neurosurgery, Cardio-Thoracic surgery, Pediatric surgery, Urological surgery, ENT surgery and orthopedic surgery, gastrointestinal tract surgery, Obstetrics and Gynecology surgery.

This study will be conducted from April 1, 2023 to April 1, 2024 in TASH.

4.2. Study design

Hospital-based, prospective, cohort study was conducted on elective obstetrics patients who undergo cesarean delivery under spinal anesthesia in TASH from November 1, 2023, to April 1, 2024.

4.3. Population

4.3.1. Source population

- All patients who underwent cesarean delivery under spinal anesthesia at TASH.

4.3.2. Study population

- All selected patients who underwent cesarean delivery under spinal anesthesia during the study period at Tikur Anbessa Specialized Hospital from April 1, 2023, to April 1, 2024.

4.4. Sample size determination

Sample size was determined as: **(Table 1)**.

Sample Size: X-Sectional, Cohort, & Randomized Clinical Trials

Two-sided significance level(1-alpha):	95
Power (1-beta, % chance of detecting):	80
Ratio of sample size, Unexposed/Exposed:	1
Percent of Unexposed with Outcome:	69
Percent of Exposed with Outcome:	99
Odds Ratio:	44
Risk/Prevalence Ratio:	1.4
Risk/Prevalence difference:	30

	Kelsey	Fleiss	Fleiss with CC
Sample Size - Exposed	24	23	29
Sample Size-Nonexposed	24	23	29
Total sample size:	48	46	58

References

Kelsey et al., Methods in Observational Epidemiology 2nd Edition, Table 12-15

Fleiss, Statistical Methods for Rates and Proportions, formulas 3.18 &3.19

CC = continuity correction

4.5. Sampling Procedure

All elective patients for c/s in TASH during the study period were used as a sample, until the required sample size was achieved. TASH was selected purposively because of two main reasons: due to the service it provide and for the number of cases flow.

4.6. Data Collection Techniques

4.6.1. Data Collection tool

For data collection structured questionnaires was adopted and used. The questionnaire was prepared in English, translated to Amharic and back to English. We used literature review to develop it.

4.6.2. Method of Data collection

Data was collected by interview and record review using a structured questionnaire by anesthesiology residents with in the first 24 hrs. (2, 6, 12 and 24 post-surgery). Patients were evaluated a day before the surgery. Informed consent was taken on arrival to the pre-

induction room and they were informed that they have a right not to participate in the study and that the data collected from them is confidential. The data collection process supervised by 1 anesthesiology resident from April 1, 2023, up to April 1, 2024. Before the actual data collection, data collectors were provided with half-day training about the aim of the study and the content of the data collection tool.

4.6.3. Data quality assurance

During data collection, both the supervisor and data collectors checked the data for completeness. After each day of data collection, the principal investigator stored the data in a secure place (locked).

4.6.4. Pretest

One week before the actual data collection, the tool was tested on 5% of the sample size (3 patients) for validation i.e. ease of comprehension, relevance in their intended topics, effectiveness in providing useful information, and the degree to which the questions are understood by different individuals. The pretest at menelik hospital, Addis Ababa.

4.6.5. Data analysis

Data was cleared, coded, entered and analyzed by using SPSS (version 25). The analyzed data was presented using text, tables and graphs. Frequencies and percentages were used to describe categorical variables. Numerical data will be described in terms of mean $\pm$ SD for symmetric and median (interquartile range, IQR) for asymmetric data. The continuous data will be tested for normality and homogeneity of variance.

A comparison of sociodemographic and clinical related variables between study groups was performed by using unpaired Student's t-test or Mann-Whitney test will be used according to the nature of data. Statistical difference between groups will be confirmed by Chi-square or Fisher exact test for categorical data. Statistical associations was considered significant whenever the p -value is ≤ 0.05 .

4.7. Ethics consideration

Ethical clearance and approval was obtained from the Institutional Review Board, College of Health Science, Addis Ababa University. Permission to conduct and Consent was obtained from Hospitals and Addis Ababa University. Informed Verbal consent was secured from every parent of study participants before the start of the study after telling them about the

objective of the study. Confidentiality and anonymity was assured. They were asked for their willingness to participate in the study.

4.8. Eligibility Criteria

4.8.1. Inclusion criteria

- All obstetrics patients undergoing elective cesarean delivery under spinal anesthesia.

4.8.2. Exclusion criteria

- Patients with local anesthetic and morphine allergy.
- Patients with a history of chronic pain.
- Patients with cognitive impairment

4.9. Study Variables

4.9.1. Dependent Variables

- Post cesarean delivery pain NRS score with in 24 hrs.

4.9.2. Independent variables

- Socio-demographic characteristics –Age, ASA status, BMI.
- Parity, previous cesarean delivery, Co-morbidity
- Surgery related -type of incision, size of incision, surgery duration

4.10. Operational definitions

4.10.1 Postoperative pain incidence:

- ✓ The Incidence of pain in the postoperative period was defined as a patient complaining of pain at rest and NRS pain score of 4 and above within 24 hrs.

4.10.3 Duration of surgery

- ✓ Time in minutes from skin incision to end of surgery.

4.10.4 Time to first analgesia request

- ✓ A time in minutes from the end of surgery to a first-time analgesia was given

4.10.5 NRS

- ✓ NRS is a valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0 to 10 (11-point scale) with the understanding that 0 is equal to no pain and 10 equals the worst possible pain.

4.11. Dissemination plan

After the study is finalized, the result will be presented by the author and will be submitted to the Department of Anesthesiology, Critical Care, and Pain Medicine. Furthermore, the paper can be presented at workshops, seminars, and other professional gatherings and an effort will be made to publish in peer-reviewed journals.

5. Result

A total of 48 patients who underwent elective cesarean section under spinal anesthesia at TASH, were grouped to either the TAP block group (TAP block with intrathecal morphine) or ITM group (intrathecal morphine) alone. Socio demographic and clinical characteristics of patients were analyzed and outcomes were compared for their effectiveness for postoperative pain management. Normality and homogeneity of the data was evaluated. For continuous data, comparison was made by using parametric (independent t- test) or nonparametric (Mann Whitney U test) for symmetric and asymmetric data respectively. Chi square test was performed for the categorical data. Moderate to severe pain (NRS pain score of ≥ 4) incidence rate was calculated.

5.1. Socio demographic and clinical characteristics

The independent t-test was performed to compare age between TAP group and ITM group. There was no statistically significant difference in age between TAP group (M = 28.33, SD = 4.48) and ITM group (M = 29.04, SD = 3.47), $t(46) = 0.61$, $p = 0.54$. The mean difference between the groups was 0.71 with a 95% confidence interval ranging from -1.62 to 3.04.

There was no statistically significant difference observed regarding height, BMI, parity, ASA status, previous scar, co-morbidity, length of incision and duration of surgery between the groups with a p-value of > 0.05 (**Table 2**).

Table 2: Socio demographic and patient related characteristic of mothers who undergo elective cesarean delivery under spinal anesthesia at TASH, Addis Ababa, Ethiopia, 2024.

Variable	TAP group (n=24)	ITM group (n=24)	<i>P</i> value
Age(years)	28.33 $\pm$ 4.48	29.04 $\pm$ 3.47	0.54
Weight(Kg)	71.5(66.5 - 78.0)	70.00(68.00 – 73.75)	0.69
Height(cm)	166.5(163.00 – 169.00)	162.00(158.00 – 168.00)	0.24
BMI	26.29 $\pm$ 2.67	26.57 $\pm$ 2.65	0.71
Parity			.93

Primipara	7 (29.2)	8 (33.3)	
MULTiPara	17(69.8)	16(66.7)	
ASA Status			0.71
II	21 (87.5)	19 (83.3)	
III	3 (12.5)	5 (16.7)	
Previous Scar		9 (37.5}	1.00
Yes	14(58.33)	14(58.33)	
No	10(41.77)	10(41.77)	
Co – Morbidity			0.71
No	21 (87.5)	19 (79.2)	
Yes	3(12.5)	5(20.8)	
Sensory Level			
T4	9(37.5)	12(50.0)	
T6	15(62.5)	12(50.0)	0.56
Length of Incision(cm)			0.51
<10	19(71.2)	17(70.8)	
>= 10	5(28.8)	7(29.2)	
Surgical Time(minutes)			0.35
<60	23(95.8)	20(83.3)	
>= 60	1(4.2)	4(16.7)	
Breakthrough Pain			0.12
Yes	0(0.0)	4(16.7)	
No	24(100)	20(83.3)	

Hint: TAP (transversus abdominis plane block with intrathecal morphine), ITM (intrathecal morphine alone), mean $\pm$ SD, median (Q1 – Q3) and n (%).

5.2. Postoperative pain intensity at rest and during movement

The Mann-Whitney U test was performed to compare postoperative pain intensity at rest or during movement between TAP group and ITM group. There was statistically significant difference in NRS at 2hrs post-operative time between TAP group (Median = 0, IQR = 0) and ITM group (Median =0, IQR = 2), $U = 210.5$, $z = 1.95$, $p = 0.05$. The effect size(r) was calculated as $r = 0.3$. Similarly, in the 6 and 12 hrs postoperatively, TAP group median (IQR) vs ITM median (IQR), U , z , r and (p -value) were 0(1) vs. 4 (2), 0, 6.12, 0.67 and ($p < 0.001$), 1 (0) vs. 3 (1), 68, 4.67, 0.67 and ($p < 0.001$) respectively (**Table 3**).

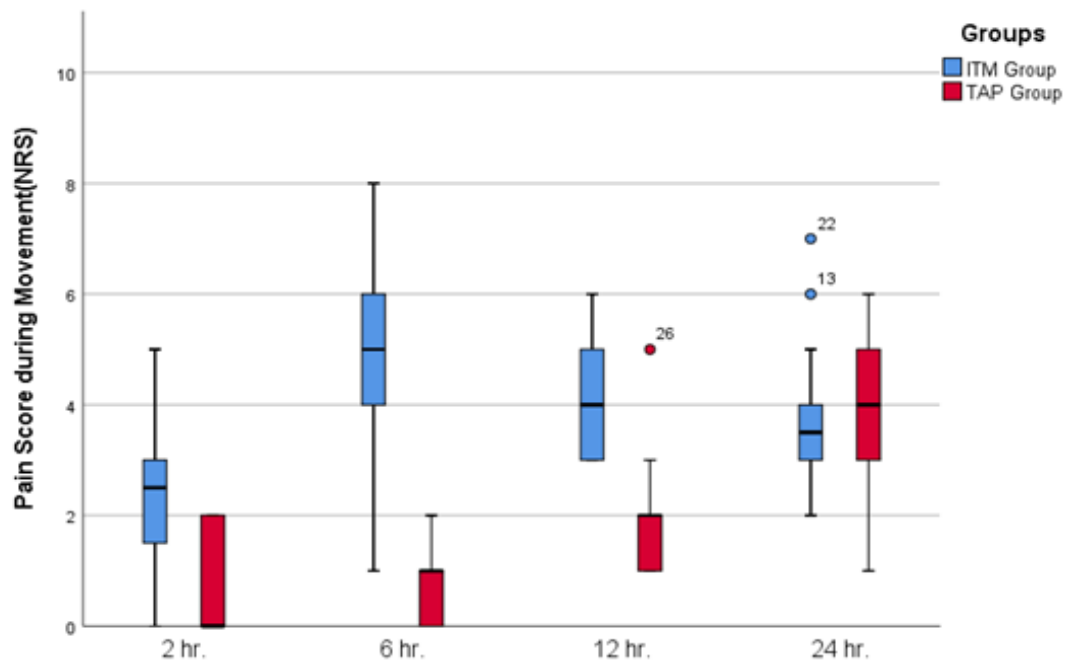
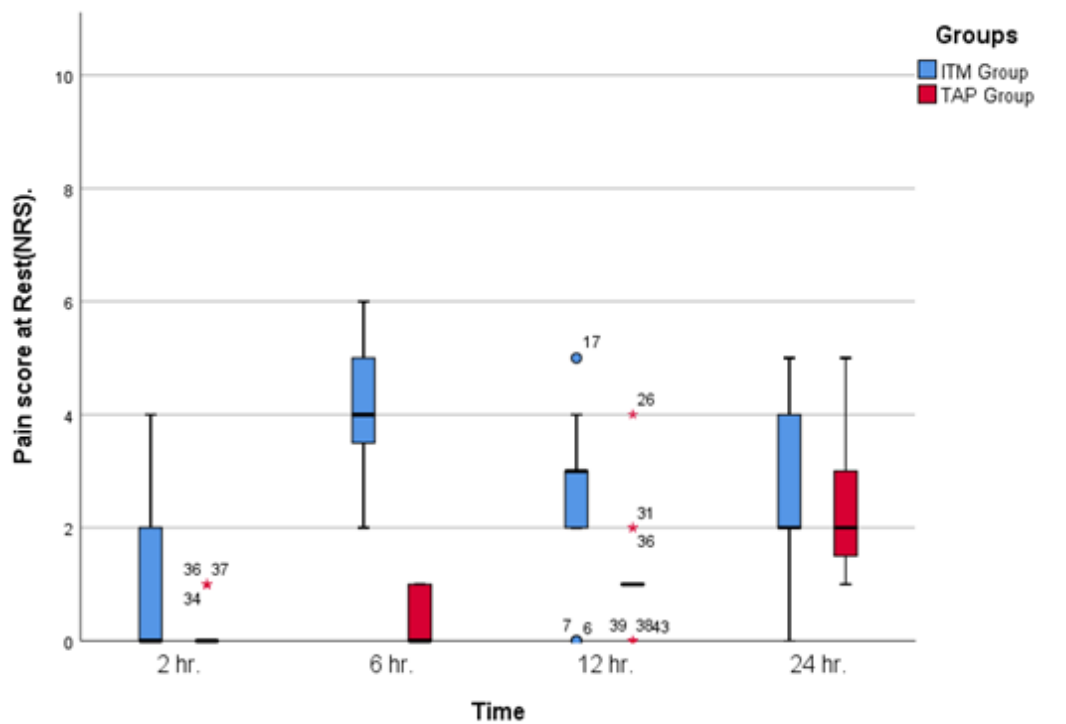
Table 3: At rest and during movement NSR pain scores of mothers who undergo elective cesarean delivery under spinal anesthesia at TASH, Addis Ababa, Ethiopia, 2024.

NRS		TAP group		ITM group		U	z	r	P value
		Median	IQR	Median	IQR				
2hr. Post op.	R	0	(0-0)	0	(0-2)	210.5	1.95	0.28	0.058
	M	0	(0-2)	2.5	(1.25-3)	105	3.91	0.56	< 0.001
6hr. Post op.	R	0	(0-1)	4	(3.25-5)	0	6.12	0.88	< 0.001
	M	0	(0-1)	5	(4-6)	11	5.78	0.83	< 0.001
12hr. Post op.	R	1	(1-1)	3	(2-3)	68	4.67	0.67	< 0.001
	M	2	(1-2)	4	(3-5)	29	5.45	0.79	< 0.001
24hr. Post op.	R	2	(1.25-3)	2	(2-4)	242.5	0.97	0.14	0.33
	M	4	(3-5)	3.5	(3-4)	270.5	0.37	0.05	0.71

Hint: **NRS**= Numeric Rating Scale, **C/S**= Cesarean Section, **R**= at rest, **M**, during movement

TAP (transversus abdominis plane block with intrathecal morphine), **ITM** (intrathecal morphine alone)

U= Mann Whitney U, **r**= Effect size



5.3. Postoperative pain Incidence and Time to first analgesic request within 24hrs postoperatively.

Out of the 24 patients in the TAP group, 2 reported experiencing NRS pain score of ≥ 4 at rest within 24 hours postoperatively, resulting in a pain incidence of 8%. In the ITM group, 22 out of 24 patients reported NRS pain score of ≥ 4 at rest within 24 hours, resulting in a pain incidence of 92 % (**Figure 1**).

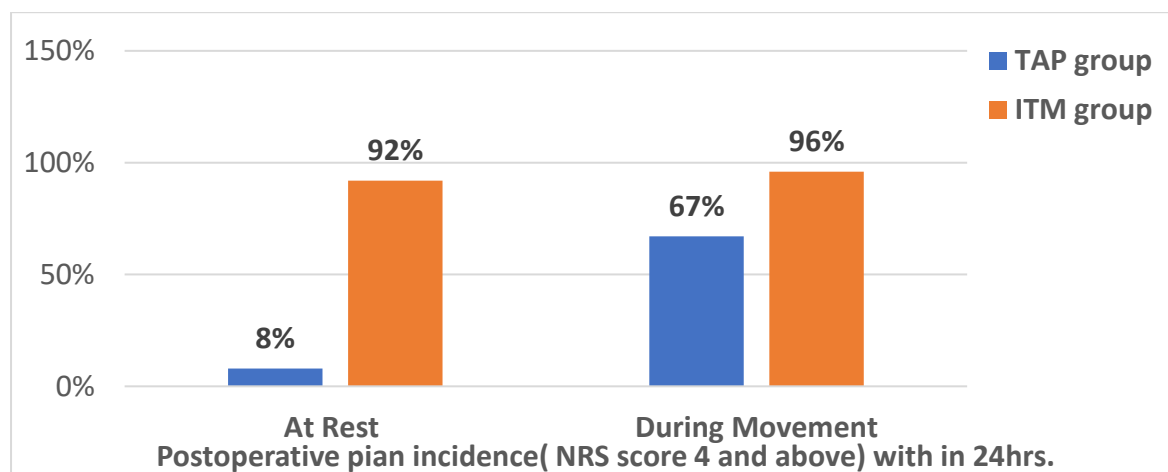
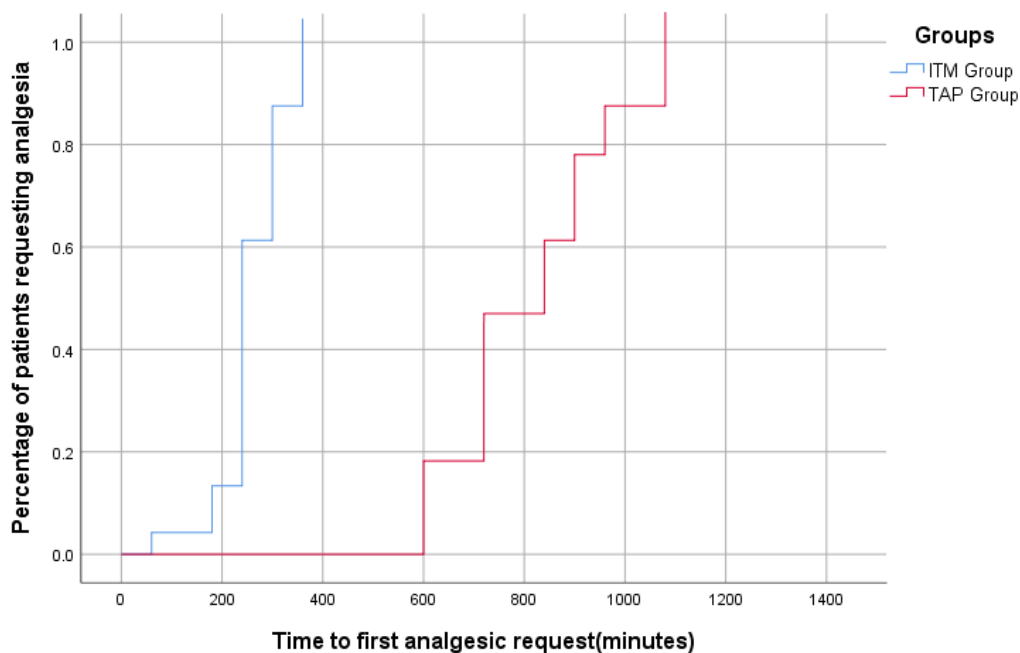


Figure 1: Postoperative pain incidence among mothers who undergo elective cesarean delivery under spinal anesthesia at TASH, Addis Ababa, Ethiopia, 2024.

The Mann-Whitney U test was performed and showed that there was a statistically significant difference in the time to first analgesic request between TAP (Median = 15, IQR = 12 - 18) and ITM groups (Median = 5, IQR = 4 - 7.5), $U = 18.5$, $z = 5.6$, $p = <0.001$. The magnitude of the difference between the two groups was large ($r=0.8$).



6. Discussion

This , prospective, cohort study demonstrated that supplementing a standard multimodal analgesic regimen with a TAP block resulted in reduced pain scores at rest and with movement, also demonstrated delayed first analgesic request time, in comparison to intrathecal morphine alone.

Cesarean section is the most frequently performed surgery worldwide as well as in our country. Postoperative analgesic regimen has to be optimal, effective analgesia, with the least side effects for both the mother and the newborn.[3],[4][8]

A multimodal analgesia is proposed to achieve these goals with minimal single agent related adverse outcome. There is no single recommendation on which modalities to include in this multimodal analgesics.it has been shown that incorporation of regional analgesics technique is improving the patient satisfaction as well as reducing systemic analgesics need and their related side effects.

Multiple studies proven that neuraxial long-acting opioids administered during spinal anesthesia provides adequate pain control, it is linked with unacceptably higher rates of adverse effects.

In clinical situations where there is difficulty or medical contraindication for opioid use regional anesthetics will be the sole technique reserved to address the postoperative pain burden.

In this study, TAP blocks performed in conjunction with intrathecal morphine provided superior early post cesarean section analgesia compared with intrathecal morphine alone. Markedly lower NRS pain scores, longer time to systemic analgesics request (TAP group Median = 15 hrs, IQR = 12 - 18) and ITM groups (Median = 5 hrs, IQR = 4 - 7.5), and lower moderate pain incidence were noted in the TAP group at two hours after the blocks up to 12 hrs; however, there was no difference in pain score at rest at hour of evaluation this might be because of spinal anesthesia wasn't wear off yet.

According to my study 8.3 % of the unexposed group had severe pain over 24 hrs while none of exposed groups had severe pain over 24 hrs.

The effect the exposure was not sustained when patients were reevaluated at 24 hours. The implication of this finding is that the intrathecal group may have been experiencing more moderate to severe pain than the TAP group throughout postoperative day 1.

The result of this study aligns fairly well with the previous study done by Lee, Allison J et al(2013).[24]although on their study evaluation period was more prolonged up to 48 hours but interval gap is wide (24 hrs) w/ch might miss the most efficient period for exposed group.

Multiple metaanalysis including Mishriky et al. (2012, USA), Baeriswyl, M. et al (2015 Switzerland, Canada), Champaneria, R et al (2016 United Kingdom), Wang Peng et al (2021 China)[25], [26], [27], [28] have assessed the effectiveness of TAP block for post cesarean delivery pain control and concluded to be effective but when it is combined with intrathecal morphine the effectiveness becomes controversial or not effective at all. My study didn't agree on the conclusion on effectiveness of combined TAP block with intrathecal morphine the reason might be they were using better patient controlled analgesics which could make VAS and patient satisfaction bit difficult to assess.

Incidence of moderate to severe post cesarean delivery pain at rest in non-exposed group is 92% w/ch is almost similar from local studies done in northwest Ethiopia, jimma and hawasa w/ch ranged from 86-91.4%.[10][23][29][30] .

7. Conclusion, future direction and implications

7.1 Conclusion

In this study combining TAP block with intrathecal morphine has better post cesarean delivery pain control. First analgesics request by the TAP group was longer (15 hr vs 5 hrs for intrathecal alone). The overall incidence of moderate to severe post cesarean delivery pain at rest for the unexposed group was 92%vs 8% for exposed group.

8. Strength and limitation

Strength: Fairly adequate sample size, it also clearly addressed its main objectives,as a pilot study it could help further future research.

Limitation: Being single center study, inter performer variation for TAP block, lack of local literatures in similar topics, and dose of bupivacaine was not controlled, cumulative postop systemic analgesics' were not completely recorded

9. Recommendation

From this study anesthesia providers have to focus on multimodal approach of post cesarean delivery pain management. Combining regional technique with systemic analgesics significantly reduces pain burden in postoperative periods. Utilization of ultrasound for TAP block is strongly advised to reduce complications and optimize effectiveness.

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11. Declaration

I the undersigned; agree to accept all responsibilities for the scientific and ethical conduct of the research project. I will provide timely progress reports to my advisor and seek the necessary advice and approval from my advisor in the course of the research. I will communicate timely to my advisor all stakeholders involved.

Name of the student: Dr. Sisay Ebistu (MD, ACCPM R3)

Signature: _____

Date: _____

Approval of the Advisor:

Name of the advisor: Dr Birhane Tesfay (Assistant prof, of ACCPM)

Email:brhanetesfay16@yahoo.com

Signature: _____

Date: _____

Approval of the Advisor:

Name of the advisor: Dr Blen Ayele(pediatric anesthesiologist)

Email:blenque5@gmail.com

Signature: _____

Date: _____

12. Annex

12.1. Annex 1: Information sheet

Addis Ababa University, school of public health, from specialty program. A questionnaire to assess the effectiveness of TAP block provided with intrathecal morphine Vs. intrathecal morphine alone for post-cesarean delivery pain control in Addis Ababa University at Tikur Anbessa Specialized Hospital.

Good morning/good afternoon. My name is -----; we come from Addis Ababa University. We are working with an investigator, Dr. Sisay Ebistu doing his thesis to partially fulfill the specialty certificate of Anesthesiology, critical care, and pain medicine. We are interviewing you about the post-operative pain experience and severity both during rest and movement. We are going to ask you some questions that are not difficult to answer. Your name will not be written in this format and will never be used in connection with any of the information you are going to tell me. You are not obliged to answer any question that you do not want to answer and you may end this interview at any time you want to. However, your honest answers to these questions will help us to assess the effectiveness of the performed TAP block on your pain experience and severity. This helps to solve post-cesarean pain in the future to control and prevent it. We would like to appreciate your help in responding to these questions, and the interview will not take more than 30 minutes.

Name Dr Sisay Ebistu

Phone +251911416097/+251939224191

Email: sisayhibstu143@gmail.com

12.2. Annex 2: Informed consent

I am the individual asked to be a study participant. Based on the information provided by the principal investigator, I understand that it is not necessary to write my name, the information I tell her/him will not be used for other purposes and the information obtained from me will help to identify the magnitude of post-cesarean pain and effectiveness of the performed procedure and helps to solve the identified problems in the future to control and prevent it in the future.

So, I agree to be a study participant.

1. Yes..... 2. No.....

If yes go to the next section. If no go to the next participant

Questioner code -----

Name of data collector-----

Signature-----

12.3. Annex 3: Questionnaire

MRN -----

12.3.1. Table 4: Sociodemographic factors

No	Factors	Response
101	Age	 years
102	Weight	Kg
103	Height	Cm
104	BMI	kg/m2

12.3.2. Table 5: Patient related factors

NO.	Factor	Response
201	ASA status	A. II B. III C. IV

202	PONV	A. Yes b. No
203	Parity	_____
204	Previous scar	A. Yes B. No
205	Number of previous scars	_____
206	Co morbidity	A. Asthma B. Diabetes C. pre-eclampsia D. Others-----

12.3.3. Table 6: Surgical and anesthetic-related variables of obstetrics patients who underwent cesarean delivery under spinal in TASH.

301	Type of local anesthetics	A. bupivacaine B. others (specify)_____
302	Baricity	A. Hyperbaric B. Isobaric C. hypobaric
303	Dose of LA	_____
304	Intrathecal morphine dose	_____
305	Premedication given	A. metoclopramide B. dexamethasone C. cimetidine D. others(specify)_____

306	Preoperative analgesics given	A. yes B. no
	If yes for 306	Specify (medication, dose and route of administration) _____
307	Sensory level	Pre incision End of the procedure.....
308	Sedation needed	A. yes B. no
	If yes specify the agent	_____
309	Type of incision	A. Pfannenstiel B. Midline
310	Length of incision	A. < 10 cm B. ≥10 cm
311	Surgical time	A. <60 minutes B. ≥60 minutes

12.3.4. Table 7: post-operative systemic analgesic management

401	First analgesic request	Specify (in Hrs.) _____
402	Postoperative standing systemic analgesics	A. Paracetamol B. Tramadol C. Ibuprofen D. Diclofenac

		E. Morphine F. Others _____
	Specify doses, routes, frequency	_____ _____
403	Breakthrough pain	A. Yes B. No
	If <u>yes</u> specify the time (from post operative hrs.) and NRS	_____
	If <u>yes</u> specify analgesics given (name, dose, route, etc.	_____
404	Overall satisfaction	A. Very satisfied B. Satisfied C. Neither satisfied nor unsatisfied D. Unsatisfied E. Very unsatisfied

12.3.5 Table 8: post-operative pain assessment by NRS

post operatively hours	Numeric rating scale (NRS)	
	At rest	During movement
immediately POST OP		
At 6 h		
At 12 h		
At 24 h		

Participant's Signature _____ Date _____

Researcher's Signature _____ Date _____

Ultrasound-Guided TAP Block with Intrathecal Morphine versus Intrathecal Morphine Alone for PostCesarean Pain incidence and Control among Elective Patients done under Spinal Anesthesia by Sisay Ebistu

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