A COMPARISON OF SPINAL ANAESTHESIA WITH AND WITHOUT TRANSVERSUS ABDOMINIS PLANE BLOCK IN PATIENTS UNDERGOING ELECTIVE CAESAREAN SECTION AT WINDHOEK HOSPITAL COMPLEX

A THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE

REQUIREMENT FOR THE DEGREE OF

MASTER OF MEDICINE (ANAESTHESIOLOGY, CRITICAL CARE AND PAIN MANAGEMENT)

OF

THE UNIVERSITY OF NAMIBIA

BY

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APRIL 2025

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ABSTRACT

Background: Pain is a known outcome complication of surgery in the post-operative period, especially after Caesarean section. Lack of pain relief postoperatively also poses great risks for patients' health. The combination of Transversus Abdominis Plane (TAP) block with spinal anaesthesia is emerging as a superior approach for managing postoperative pain, particularly in abdominal surgeries. While spinal anaesthesia provides effective lower body analgesia, it can result in inadequate pain control and side effects like hypotension. TAP block enhances pain relief without the adverse effects associated with spinal anaesthesia. Overall, the integration of TAP block with spinal anaesthesia offers significant advantages in pain management strategies.

Aim: The main objective of this study was to compare the benefit of adding transversus abdominis plane (TAP) block to spinal anaesthesia versus spinal anaesthesia alone in patients undergoing elective Caesarean section.

Setting and Design: This was a randomised single-blinded control study conducted over a period of six months in the maternity theatres of Windhoek Central Hospital and Intermediate Hospital, Katutura.

Methods and Materials: The effect size on pain scores was determined to be the magnitude of the difference between groups, according to a study by Cohen et al. A medium effect size of 0.5, an alpha error of 0.05, and a power of 80% were used to calculate the number of patients required in each group. The result was 64 patients per group. Assuming an average attrition rate of 11% quoted in a similar study, this suggested that 72 patients were required per group so that in total, the study sample size constituted 144 patients. Patients planned for elective caesarean section were randomly allocated to two groups, A and B. Group A received spinal anaesthesia only with 0.5% heavy bupivacaine 9 mg (1.8 ml) and fentanyl 15 mcg. Group B received spinal anaesthesia and TAP block using 40 ml plain bupivacaine 0.25%. (with the same drug doses as in Group A). The analgesic efficacy spinal anaesthesia alone and spinal anaesthesia combined with TAP block was compared over various time intervals (2, 4, 6, 12, and 24 hours postoperatively) both at rest and movement.

Statistical Analysis: Numbers with percentages were used to represent nominal variables, while continuous variables were summarized in terms of mean ± SD or median and interquartile range, as appropriate. A statistician examined the distribution of the data before

using the Student's T-test to compare the results from the study groups. When appropriate, the Z score for a two-population proportion was applied. Statistical significance was defined as a P-value of less than 0.05.

Results: At both rest and movement, spinal anaesthesia alone consistently showed higher pain scores compared to TAP block across all time intervals. Statistically significant differences were observed with p value of (p= <0.001), except for the 2-hour mark at rest where no significant difference of between the two groups was observed (p=0.97).

Conclusion: This study highlights the effectiveness of TAP block as an adjunct to spinal anaesthesia in managing postoperative pain following Caesarean section. Patients who received both spinal anaesthesia and TAP block reported higher levels of satisfaction with their pain relief, compared to those who received spinal anaesthesia alone. These findings underscore the potential benefit of incorporating TAP block into multimodal analgesic approaches to enhance postoperative pain management and patient satisfaction.

Keywords: Spinal Anaesthesia, Transversus abdominis plane block (TAP), Caesarean section, Heavy bupivacaine, Fentanyl, Pethidine

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LIST OF ABBREVIATIONS AND ACRONYMS

C-S Caesarean Section

ERAS Enhanced Recovery After Surgery

GA Gestational age

HVAS Horizontal Visual Analogue Scale

IASP International Association for the Study of Pain

IHK Intermediate Hospital Katutura

IQR Interquartile Range

ITM Intrathecal Morphine

NRS Numerical Rating Scale

NSAIDS Non-Steroidal Anti-Inflammatory Drugs

QL Quadratus Lumborum

RCTs Randomized Controlled Trial

TAP Transversus Abdominis Plane Block

USS Ultrasound Scanning

VAS Visual Analogue Scale

VNRS Verbal Numeric Rating Scale

VRS Verbal Rating Scale

VVAS Vertical Visual Analogue Scale

WCH Windhoek Central Hospital

WHO World Health Organization

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DEDICATION

This study is dedicated to all those who have committed to pursuing their aspirations despite the challenges they may have encountered. Additionally, it is dedicated to my brother Tunga Penelao Kakololo, in remembrance of the dreams he never had the chance to fulfill and the life he lived.

ACKNOWLEDGEMENTS

I express my deepest gratitude to the Almighty for guiding me through the years gone by. My heartfelt appreciation goes out to my family for their unwavering emotional and physical support. I extend my sincere thanks to my supervisor, Prof Brian Jenkins, for his constant encouragement and guidance.

I also wish to acknowledge Mr. Mondjila Amkongo for his invaluable assistance in and statistical expertise. My heartfelt thanks go to the staff of the maternity theatres at the Intermediate Hospital Katutura and Windhoek Central Hospital. Dr. Josephine Amutenya, I am profoundly grateful for your generous assistance; this research would not have been possible without your kindness. And to Prof Tobi Kingsley, your encouragement and assistance during moments of doubt were instrumental; I am truly thankful.

To each and every one of you, I extend my heartfelt gratitude.

DECLARATION

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Tonata Shangelao Ingaveuya Kakololo		April 2024
Name of Student	Signature	Date

CHAPTER 1. INTRODUCTION

1.1 Orientation to the study

According to the World Health Organization in a 2021 report[1], one in five births results in Caesarean section. Although there are no local studies, Caesarean section (C-S) is one of the most common operations in Namibian hospitals. Adequate analgesia following C-S is essential for early patient mobilization, early feeding of the neonate and it contributes to the well-being of both parturient and the newborn[2]. It is also associated with rapid recovery of the patient, leading to a reduction in post-operative complications and reduced length of hospital stay[2]. Furthermore, with adequate analgesia, parturients develop good emotional connections with their newborn[2].

Pain, as defined by the current International Association for the Study of Pain (IASP), is an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage[6]. It is a subjective feeling and an individual response to the cause. Pain is a cardinal symptom of inflammation and is valuable in the diagnosis of many disorders and conditions. It may be mild or severe, chronic or acute, lancinating, burning, dull or sharp, precisely or poorly localized, or referred[6]. The experience of pain is influenced by physical, mental, biochemical, psychological, physiological, social, cultural, and emotional factors [5, 6].

Pain can be classified as acute or chronic. Acute pain is complex, and it is described as an unpleasant experience with an identifiable precipitating cause[6]. Acute pain has defined pathology and can resolve with healing of the underlying injury. Acute pain can also be

interpreted as a reflexive and protective response[6]. On the other hand, chronic pain is described as pain that persists for at least three months beyond the expected course of an acute injury or illness. Chronic pain can also disrupt activities of daily living and sleep, and has no protective purpose [6,7].

Currently, a multimodal approach is the most commonly used strategy for managing analgesia in patients who have undergone C-S. This approach relies on regular use of paracetamol and Non-Steroidal Anti-inflammatory Drugs (NSAIDS) in order to minimize opioid requirement. Patients who require opioids are more likely to experience a higher incidence of side effects which include nausea, vomiting, constipation, respiratory distress, and pruritus[2]. The incidence of opioid-related side effects is often associated with prolonged hospital stay and poor patient satisfaction, and the search for other means of reducing opioid requirement is often the focus for new research.

Transversus Abdominis Plane (TAP) block is a peripheral nerve block that targets the nerves that supply the anterior abdominal wall. Its analgesic effects last between 12 and 24 hours. It blocks abdominal wall neural afferents between T7 and L1, and thus can relieve pain associated with an abdominal incision [2, 3]. The Trans Abdominal Plane is a neurovascular plane which is located between the internal oblique and transverse abdominis muscles[3]. The nerves that supply the anterior abdominal wall pass through this plane to reach their target structures[3]. Therefore, if a local anaesthetic agent is deposited in this space, it results in myocutaneous sensory blockade and can then be incorporated as part of a multimodal analgesic treatment for C-S

post-operative pain[4]. Multiple studies have demonstrated the efficacy of TAP block in patients who underwent abdominal surgeries, including Caesarean section[5]

1.2 Statement of the problem

A C-S results in pain that is frequently described as moderate to severe by patients. The postoperative analgesic management following C-S determines the patient's outcome[6]. Currently in Windhoek Hospital Complex, which comprises of Windhoek Central Hospital (WCH) and Intermediate Hospital Katutura (IHK), a multimodal approach is the most common modality for pain relief for patients undergoing C-S. This modality requires opioids for rescue analgesia. There is therefore the need to explore other methods of analgesia supplementation in this group of patients. The aim of this study is to determine the effectiveness of TAP block, which is known to be associated with fewer side effects than opioids and bridging this "analgesia gap".

1.3 Objectives of the study

Overall objective

- To compare the analgesic effect of TAP block in patients undergoing caesarean section under spinal anaesthesia at Windhoek Hospital Complex.

Specific objectives

- To compare time to first request for analgesia post-Caesarean section in both groups of patients.

- To determine the total dose of pethidine consumed as rescue analgesia in the first twenty-four hours post-Caesarean section in the two groups.
- To assess the participants' level of satisfaction with postoperative pain relief in the postoperative period between the groups.

1.4 Hypothesis of the study

The combination of Transversus Abdominis Plane (TAP) block with spinal anaesthesia provides superior postoperative analgesia and reduces opioid consumption compared to spinal anaesthesia alone in patients undergoing abdominal surgery.

1.5 Significance of the study

This study was performed with the hope that it would improve the management of post-operative pain in patients undergoing Caesarean section in Namibian hospitals, reducing the amount of opioids utilized and the incidence of subsequent opioid-associated side effects.

1.6 Limitations of the study

- Explaining to patients the nature of the study, which is of a technical nature.
- The researcher could unknowingly influence the patients' scoring when helping to complete the patient questionnaire.
- A small or homogenous sample may limit the findings' applicability. If the sample lacks diversity, the results may not reflect the broader population.

- The tools or methods used for data collection may introduce bias. For instance, self-reported measures (like pain levels) can be influenced by personal interpretation, social desirability, or mood at the time of reporting.

- Evaluating subjective experiences such as pain presents challenges in quantification. Variability in how individuals perceive and report their experiences can lead to inconsistent data.

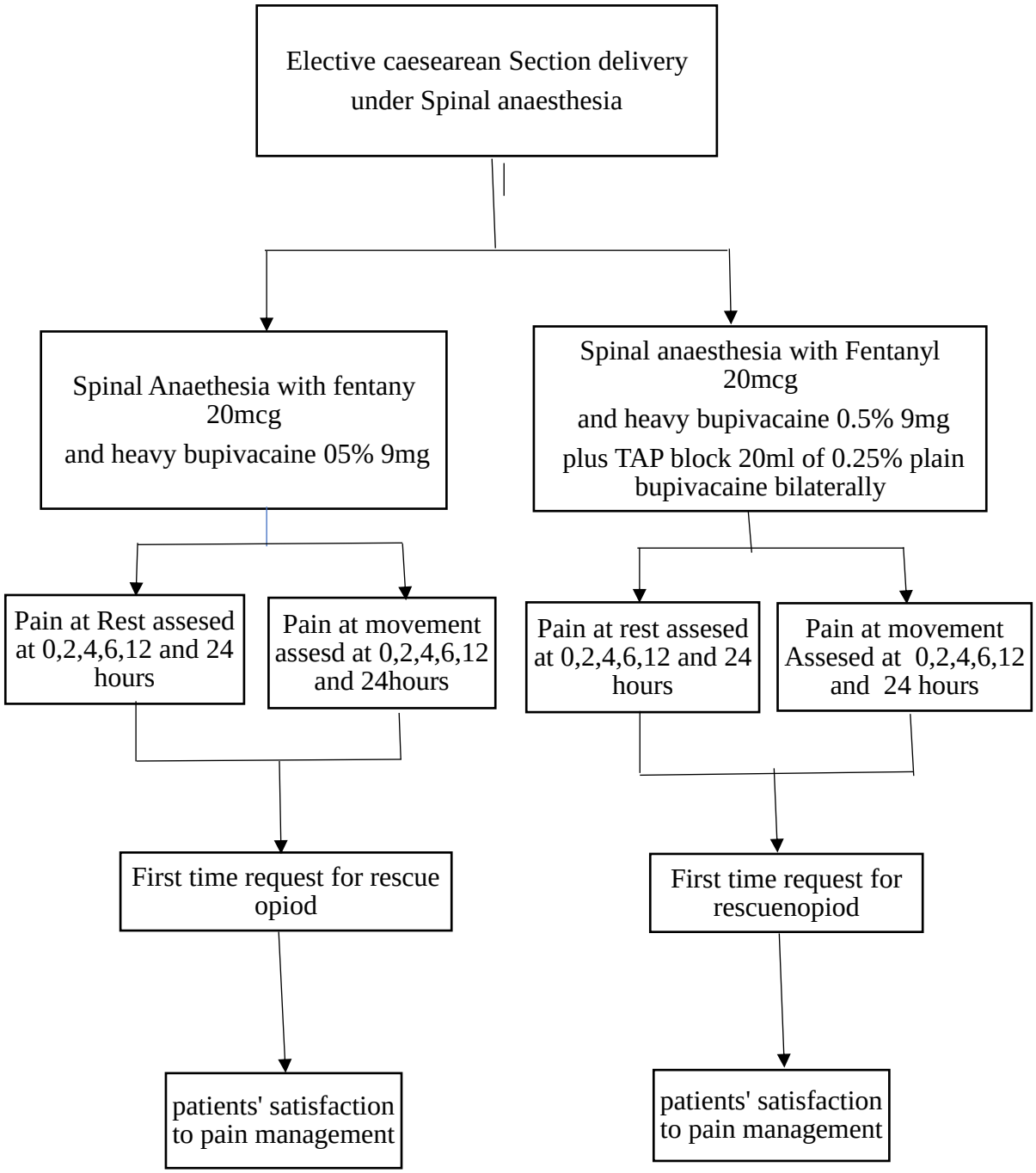
- Cultural norms may influence responses or behaviours, potentially skewing results. Participants might interpret questions or tasks differently based on their cultural background.

- Participants may change their behaviour simply because they know they are being observed, which can affect the validity of the findings.

1.7 Study setting

The study will be performed at Windhoek Central Hospital and Intermediate Hospital Katutura, over a period of six months.

1.8 Theoretical framework



CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

In this literature review the nature of pain, post-operative pain, post-operative pain management in patients with Caesarean sections, measurement of pain, post-operative C-S approaches and literature review of TAP blocks will be reviewed.

2.2 Post-operative pain

Pain is one of the main problems in the post-operative period, especially after Caesarean section[6]. Inadequate relief of postoperative pain poses great risks for patients' health. The harmful effects of pain include neuroendocrine changes, which involve responses of the hypophysis and adrenal glands. These can cause negative repercussions in different organic systems such as the cardiovascular, respiratory, and gastrointestinal, besides effects in the central nervous system[6]. Prolonged severe postoperative pain is also associated with the development of chronic pain. Adequate pain relief after caesarean section using safe and effective analgesic modalities is a universal concern, since pain relief is one of the basic human rights[6].

2.3 Assessment of pain

Pain is individualized and subjective; therefore, the patient's self-reporting of pain is the most reliable gauge of the experience. Pain measures may be categorized as either single-dimensional scales or multidimensional scales[6]. The former assesses a single dimension of pain, typically pain intensity through patient self-reporting. Multidimensional scales measure the intensity, nature, and location of pain as well as, in some cases, the impact that pain is having on a patient's activity or mood. Multidimensional scales are useful in complex or persistent acute or chronic pain[6]. Paediatric patients' pain may be assessed using visual analogue scales. In adults, pain may also be assessed using verbal rating scales and numeric rating scales [7]. A study published in 2017 by Karcioglu in Turkey compared three pain scales in adults[8]. The study compared the visual analogue pain scale, verbal rating scale and numeric rating scale to determine the compliance and usability of each scale, and also to establish if any of the scales was superior to the others[8].

A visual analogue scale is a continuous scale comprising a horizontal (HVAS) or vertical (VVAS) line, usually 100 mm long, anchored by two verbal descriptors, such as 0 for no pain and worst imaginable pain as 9 and 10[9]. The advantages of VAS include easy usage, high sensitivity in detecting treatment effects, and measured pain can be readily analyzed by parametric statistical tests. However, it may be impractical to use VAS during emergencies[8,9].

Numerical rating scales (NRS) are commonly used tools where the patient rates pain on a scale from 0 to 10, with 0 indicating no pain and 10 reflecting the worst possible pain experienced[9].

It can also be used with older children who are able to understand numbers[9]. The pain scores are interpreted as:

0 = no pain

1-3 = mild pain

4-6 = moderate pain

7-10 = severe pain

NRS can be used with most children older than eight years of age, and behavioural observation scales are required for those unable to verbalize[8,9]. For patients with cancer-related pain, the NRS is the most frequently used instrument to measure pain intensity.

In a Verbal Rating Scale (VRS) adjectives are used to describe different levels of pain. The respondent is asked to mark the adjective which fits best to the pain intensity. As in the VAS, two endpoints such as 'no pain at all' and 'extremely intense pain' should be defined. Between these extremes, different adjectives that describe different pain-intensity levels are placed in order of pain severity. Mostly, four- to six-point VRS are used in clinical trials[8,9]. A different form of VRS is the behavioural rating scale where different pain levels are defined by behavioural parameters[9]. Some patients may have problems in defining which answer fits best to their pain situation. Moreover, the intervals between different adjectives describing pain may not be equal, which may reduce the assessment data level to ordinal data level[9]. Respondents may also interpret the different terms used to describe pain differently. Therefore, the interpretation of a VRS does not always allow the researcher to draw conclusions about the

magnitude of a change in pain intensity between two assessments in different patients; inter-respondent comparison may therefore be problematic[9], but in larger study groups of patients these factors of individual variation may be expected to tend to the median measurement. A verbal numeric rating scale will be utilized in this research study.

2.4 Post-operative Caesarean section approaches

Enhanced Recovery After Surgery (ERAS) is a multifaceted approach aimed at improving recovery through various evidence-based practices, one of which includes the reduction of opiate use. This reduction is a complementary goal within the ERAS framework, reflecting a shift in guidelines to combat prior overuse while enhancing overall patient recovery. In Caesarean section, Mullman et al. carried out a study during 2018 to 2019[12] in which a pre–post design was used to assess changes in opioid use, length of stay, and costs among all patients undergoing C-S before and after implementation of an evidence-based ERAS pathway for the preoperative, intraoperative, and postoperative management of patients. The study concluded that an ERAS approach for Caesarean delivery is associated with improved outcomes, including decreases in opioid use, length of stay and costs. Part of the multimodal analgesia management included a TAP block that was administered post-Caesarean section before transfer to the recovery room[10]. Even though this study focused mostly on the intraoperative and post postoperative part of ERAS, the contribution of the TAP block was clearly demonstrated[12].

Despite the effective analgesic profile of TAP blocks in abdominal surgeries, there are some concerns about its efficacy. For instance, it has been documented that TAP block is not effective for visceral pain[13]. This has led to the development of the Quadratus Lumborum (QL) block, which involves the deposition of local anaesthetic agents more posteriorly in the quadratus lumborum muscles[14]. Kumar and colleagues[15] published a comparative study of TAP block and QL block as postoperative analgesic techniques for lower abdominal surgeries. The investigators noted that patients who had QL block had lower pain scores up to 16 hours and less total analgesic consumption. Nevertheless, ultrasound-guided TAP block continues to be used for lower abdominal surgeries and it improves the quality of postoperative analgesia as a result of easier localization of the transversus abdominis plane[16]. As of now, no studies have been done in Namibia in relation with post operative pain management. However, a study done in Ethiopia comparing TAP block and wound infiltration in women undergoing Caesarean sections concluded that TAP block provided longer-lasting and more efficient analgesia, reduced tramadol consumption, and extended the time to the first analgesia request for a parturient delivered by Caesarean section by 24 hours[17]. Using a numerical rating scale, the pain for wound infiltration and TAP block was determined to be the same for the first 6 hours[17]. As a result, there is a need to investigate this in our setting so that the postoperative multimodal analgesia treatment options are expanded.

2.5 Literature of TAP

Transversus abdominis plane (TAP) block is a regional technique for analgesia of the anterolateral abdominal wall. It was first introduced by Rafil in 2001 as a landmark-guided technique (using the triangle of Petit) to achieve a field block[18]. It involves the injection of a local anaesthetic solution into a plane between the internal oblique muscle and transversus abdominis muscle. With the advancement of ultrasound technology, TAP block has become technically easier and safer to perform. Thus, there is a surge of interest in TAP block as a therapeutic adjunct for analgesia after abdominal surgeries. Ultrasound-guided TAP block is classified into four corresponding areas namely subcostal, lateral, posterior and oblique subcostal[18]. The subcostal approach blocks the T6-T9 thoracic nerves, which innervate the anterior cutaneous branches, providing analgesia to the upper abdomen just below the xiphoid processes and parallel to the costal margin. The lateral approach blocks T10-T12 thoracic nerves, also blocking the anterior cutaneous nerves and thus providing analgesia to anterior abdominal wall at the infraumbilical area, from midline to midclavicular line. The posterior approach aims to block the T9-T12 thoracic nerves covering the anterior and lateral cutaneous branches. It provides analgesia to the anterior abdominal wall at the infraumbilical area, and possibly the lateral abdominal wall between costal margin and iliac crest. Finally, the oblique subcoastal approach blocks the T6-L1 thoracic nerves and thus the anterior cutaneous nerves. It provides analgesia to the upper and lower abdomen and has a wider range of block compared to the other three approaches mentioned earlier[18].

In the past decade, there has been growing evidence to support the effectiveness of TAP blocks for a variety of abdominal surgeries such as Caesarean section, hysterectomy, cholecystectomy, colectomy, prostatectomy, and hernia repair[12,18]. Although its analgesic effect covers only somatic pain with short duration, single-shot TAP block plays a valuable role as a supplement to multimodal analgesia. The use of TAP block to supplement spinal anaesthesia has been demonstrated to help prevent or reduce the incidence of opioid-associated side effects, with significant improvement in proved patients' comfort and satisfaction [12,18]

In a meta-analysis conducted by Charlton and colleagues[19], eight studies involving 358 participants were included. The authors found that TAP block resulted in significantly less morphine consumption at 24 and 48 hours postoperatively. Similarly, another recent meta-analysis which included 31 randomized control trials (RCTs), suggested that TAP block resulted in reduced IV morphine consumption at 6 and 24 hours postoperatively[20]. Although Ultrasound Scanning (USS) guided TAP blocks were employed here with obvious resulting improvement in the quality of blocks, the benefits of TAP blocks on reducing opioid requirement is established[20].

Complications of TAP block include visceral damage such as abdominal hematoma, liver laceration, kidney perforation and spleen laceration[21]. The incidence of these complications has reduced since ultrasound-guided block has become a standard of care[21]. Other complications are caused by local anaesthetic toxicity and include ventricular arrhythmias, transient femoral nerve palsy and seizures[22]. To reduce the risk of local anaesthetic toxicity, a

low concentration, high volume of local anaesthetic solution is suggested[22,23]. In addition, it is recommended to have lipid emulsion and other emergency drugs immediately available to treat symptoms of local anaesthetic toxicity[22,23].

Transient femoral nerve palsy is a side-effect that is self-limiting, but may cause a delay in discharging patients[23]. Using a test solution to locate the needle tip under ultrasound guidance helps to identify correct positioning of the TAP and avoid spread of the anaesthetic toward the femoral nerve[23].

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Study Design:

This study utilized a randomized controlled double-blind design, employing a researcher-administered questionnaire. Patients scheduled for elective Caesarean section at Windhoek Central Hospital (WCH) and Intermediate Hospital Katutura (IHK) were randomly assigned to either Group A or Group B. The assessor of pain scores was blinded to the study allocation. Both groups received spinal anaesthesia. The researcher skilled in the technique of TAP block performed the block for Group A patients at the end of surgery, while drapes were still in place. Both groups had plaster over the site of injection of the local anaesthetic agents to blind assessors to the study group.

3.2 Study Setting:

The study was conducted at the maternity hospitals of WCH and IHK in Windhoek.

3.3 Study Population:

All eligible patients scheduled for elective Caesarean section at Windhoek Central Hospital and Intermediate Hospital Katutura were screened for recruitment into the study.

Inclusion criteria

All women of childbearing age scheduled for elective caesarean section at WHC and IHK, with gestational age between 37 to 42 weeks.

Exclusion criteria

Patients for emergency caesarean section, patients for caesarean section under general anaesthesia, patients' refusal to participate and patients with any psychological orders. Also failed spinal anaesthesia which is then converted to general anaesthesia. Height below 160 cm and above 175 cm

3.4 Sample Size Calculation:

In this study, the primary outcome was opioid consumption, measured as the total amount consumed in milligrams by patients in the first 24 hours post-surgery, to assess the effectiveness of TAP blocks compared to spinal alone group. Secondary outcomes included pain scores evaluated using a standardized scale at multiple time points 2, 6, 12, and 24 hours post-surgery, the time to first rescue analgesic, patient satisfaction assessed through a questionnaire at 24 hours and the incidence of side effects related to opioid use during the first 24 hours

Effect size is the magnitude of the difference between groups, typically used in medical education research studies that compare different educational interventions. A 2020 study by Sultan et al. noted that TAP blocks are more effective than inactive control groups at reducing 24 hr opioid consumption with a medium effect which was the primary outcome.

The effect size on pain scores was determined to be the magnitude of the difference between groups, according to a study by Cohen et al. A medium effect size of 0.5, an alpha error of 0.05, and a power of 80% were used to calculate the number of patients required in each group. The result was 64 patients per group. Considering an average attrition rate of 11% found in a

study, this resulted in 72 patients required per group. In total, the study sample size constituted 144 patients.

3.5 Randomization and Blinding:

All eligible patients scheduled for elective caesarean section were approached, and consent was obtained. A list of computer-generated numbers was used to generate a sequence of sealed envelopes. Each opaque sealed envelope contained a unique identification number, which determined if the patient would receive spinal anaesthesia only (Group A) or spinal anaesthesia and TAP block (Group B). The envelopes were mixed thoroughly so the order was randomized. The patient then picked the first pending envelope by choosing the first envelope on top of the stack.

Anaesthesia and procedure

All participants were pre-assessed for surgery a day before the operation. Investigations included full blood count, urea and electrolytes, as well as a blood cross-match and standby. They all received a bolus of 500mls normal saline before the operation.

Spinal anaesthesia was performed in a sitting position with a 25-gauge pencil point or Quincke spinal needle at the level of L3-L4. The procedure was performed under aseptic technique. All patients received 9 mg (1.8 ml) of 0.5% heavy bupivacaine and fentanyl as an adjuvant 15 mcg. In total, they received 2.1 ml.

The TAP block was completed immediately after surgery, and before the patient was transferred to the post anaesthesia care unit (PACU). A registrar using aseptic techniques and ultrasound guidance performed it. The needle was introduced in the plane of the ultrasound probe directly and advanced until it reached the plane between the internal oblique and transversus abdominis muscles. Aspiration was done before injection was performed. Upon reaching the plane, 2 ml of normal saline was injected to confirm the correct needle position, after which 20 ml of plain bupivacaine 0.25% was injected. This was done bilaterally.

In the first 24 hours, the patients were given intravenous paracetamol 1g 6 hourly, intramuscular (IM) diclofenac 75 mg 12 hourly, and pethidine was administered as rescue analgesia at patient request in a dose of 50mg intramuscular (IM).

The patients were followed up postoperatively at 2 hours, 4 hours, 6 hours, 12 hours, and 24 hours. The questionnaire was filled out with the help of an assessor who was blinded to patients' treatment groups allocation.

The patients' vital signs were monitored post-operatively. The blood pressure, heart rate, oxygen saturation as well as respiratory rate were monitored. If there were any alarming signs, then a doctor was notified and came to review the patient immediately. Emergency drugs were available as a precaution to manage adverse effects of TAP block.

3.6 Measurement of variables

A verbal numeric rating scale was used for pain assessment at 2, 4, 6, 12, and 24 hours after the completion of the operation, assessing pain both at rest and on movement. Time of request for the first opioid and the total dosage of opioid used in the 24-hour period were recorded. Patients' satisfaction scale (the postoperative analgesic scale) was defined as: 0 = very satisfied, 1 = satisfied, 2 = somewhat satisfied, 3 = dissatisfied. The verbal numeric rating scale (VNRS) was used from 0 = no pain to 10 = most severe pain imaginable, which the patient self-reported to the assessor.

Data collection and analysis

Data was collected using a structured questionnaire (Appendix B and C) from patients undergoing elective caesarean section after signing the informed consent letter (Appendix A).

The structured questionnaire contained patient details such as Hospital number, Age, Weight, Height, Gestational Age in weeks, Parity, Hospital, and obstetric indication for elective C-S. Operative details included the date of operation, time of spinal anaesthesia, time of the start of operation, and time of completion of the operation. Anaesthetic details included the time of spinal anaesthesia and time of TAP.

The data was analyzed using the statistical tool for social sciences (SPSS version 26, IBM Corp.). Numbers with percentages were used to represent nominal variables, while continuous

variables were summarized in terms of mean ± SD or median and interquartile range, as appropriate. Tables and figures were utilized to present the information.

A statistician analyzed data using the Mann Whitney U test and Fischer's exact test for the distribution of the data before applying the Student's T-test to compare the results from the study groups. When appropriate, the Z score for a two-population proportion was applied. Statistical significance was defined as a P-value of less than 0.05.

Approval for the study was obtained from the ethics committees of the University of Namibia, with ethical clearance number SOM09/2023, granted on July 6, 2023. Additionally, the Ministry of Health and Social Services approved it with reference number 22/3/1/2 on August 15, 2023. The study was done for a period of six months, from 1st September 2023 to 28 February 2024.

Informed Consent:

Written consent was obtained from patients the day before the operation.

Voluntary Participation:

Participation was voluntary, with no financial benefits. Participants could withdraw from the study at any time without loss of benefit or extra risk.

Confidentiality of Data and Anonymity:

No participant's names were used, only hospital numbers and age.

Beneficence to Participants:

Every patient received the existing standard of spinal anaesthesia and pain management irrespective of grouping. The interventional arm had an additional TAP. TAP is a recognized approach that has been used globally and should improve the quality of patient care.

Non-Maleficence to Participants:

All patients had access to treatment at any given time, with no analgesia withheld for any reason. Normal safety standards were observed, including aseptic technique and immediate availability of emergency equipment and drugs to manage side effects/complications.

Justification:

The TAP approach was expected to significantly improve outcomes for patients in the Namibian hospitals.

Ethical consideration and clearance

Ethical clearance was diligently sought and obtained from the Research Ethics Committees of both the University of Namibia and the Ministry of Health and Social Services. Prior to commencing the study, explicit permission was secured from Windhoek Central Hospital and Katutura Intermediate Hospital. Informed consent, either written or verbal, was obtained from all participants before undergoing surgery. Participants were assured that they could opt out of the study at any time without compromising their access to necessary treatment. Patient

autonomy was highly valued throughout the study process. Participation from patients was entirely voluntary, and there were no financial incentives involved in the study.

Dissemination of results

The results will be disseminated:

To the School of Medicine, particularly the Department of Surgical Sciences

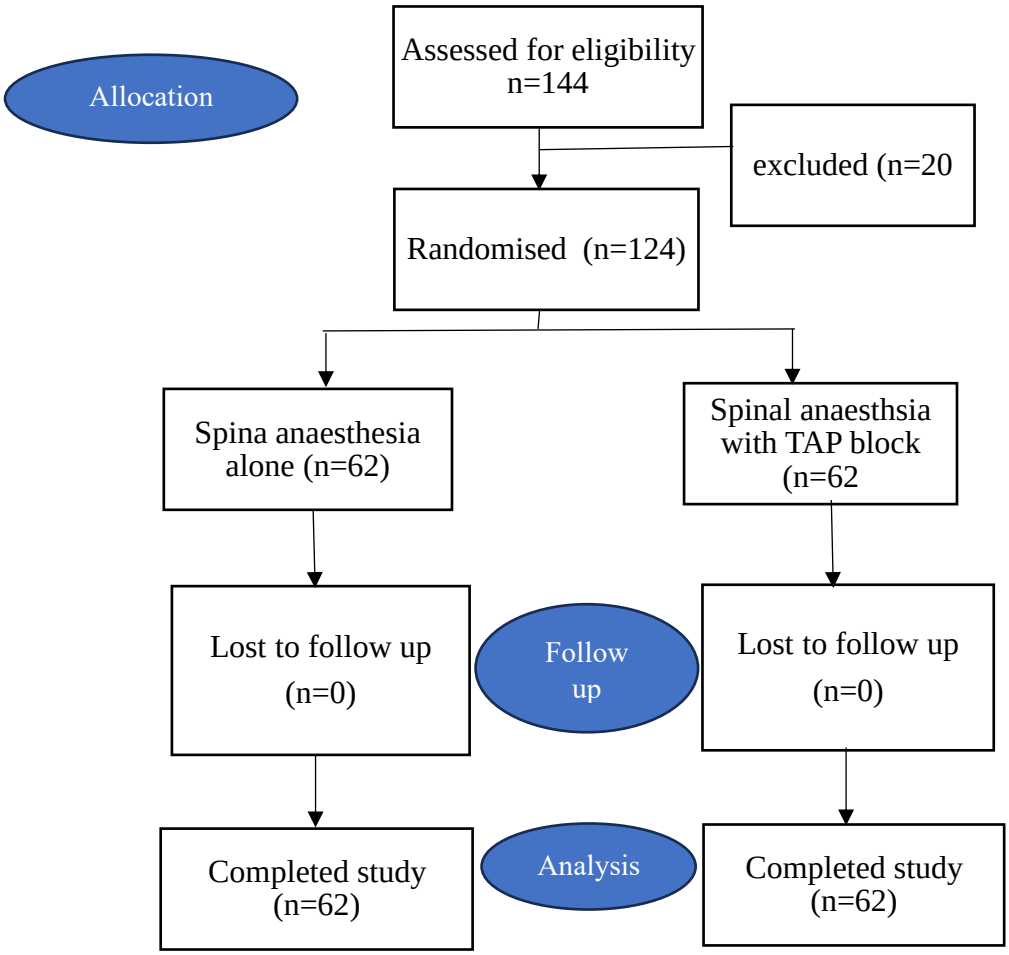
To the Departments of Anaesthetics and Obstetrics in WCH and IHK

A summary of the study will be forwarded for publication

CHAPTER 4

4. RESULTS

A total of one hundred and forty-four (n=144) parturients were recruited for this study. Twenty (n=20) patients were not eligible due to exclusion criteria. In each group sixty-two (n=62) patients were analyzed.



Demographic characteristics

Figure 1: **Consort Flow diagram**

Table 1:Demographic representation of the population.

Variable	Measures of Central Tendency		Percentiles	
Age	Mean ± STD	30 ± 6.958	25th	25
	Mode	27	50th	29
	Median	29	75th	35
	Variance	48.4		
	Minimum	19		
	Maximum	47		
Weight	Mean ± STD	72.1 ± 6.1639	25th	68
	Mode	70	50th	70
	Median	70	75th	75
	Variance	37.994		
	Minimum	64		
	Maximum	90		
Height	Mean ± STD	189.7 ± 184.6	25th	165
	Mode	165	50th	168
	Median	168	75th	170
	Variance	34.083		
	Minimum	65		
	Maximum	162.2		
BMI	Mean ± STD	25.6 ± 1.5150	25th	24.5
	Mode	25	50th	25
	Median	25	75th	26.3
	Variance	2.295		
	Minimum	23.3		
	Maximum	29.4		
GA	Mean ± STD	39.2 ± 0.7899	25th	39
	Mode	39	50th	39
	Median	39	75th	40
	Variance	0.624		

As shown in Table 1 above, the median age with an interquartile range (IQR) was 29 years (IQR: 10 years). Additionally, the median weight the was 70 kg (IQR: 7 kg). Height had a median of 168 cm (IQR: 5 cm). The mean BMI of the patients was 25.6 kg/m² (SD: ±1.5150 kg/m²). In addition, about 75% of the patient's BMI was below 26.3 kg/m^2. While the mean gestational age (GA)of the patients was 39.2 weeks (SD: ±0.7899 weeks), with 75% of the patients' GA lower than 40 weeks.

4.1 Analgesic effect of TAP block

Table 2 below presents a comparison of the analgesic efficacy between spinal anaesthesia alone and spinal anaesthesia combined with TAP block over various time intervals (2, 4, 6, 12, and 24 hours) both at rest and movement. Pain scores, measured on a verbal numerical scale, were consistently higher in the group that received spinal anaesthesia alone compared to the group that received spinal anaesthesia combined with TAP block. Statistical differences were observed with p-value of <0.001 except for the 2-hour mark at rest of (p=0.97).

Table 2: Comparison of Pain Scores 1 Comparison of Pain Scores Between Spinal Anaesthesia Alone and Spinal Anaesthesia with TAP Block

Group	**2h**	**4h**	**6h**	**12h**	**24h**
At movement					
Spinal alone (n=62)	0.40 ± 0.69	0.48 ± 1.75	4.32 ± 1.81	5.32±1.81	6.74±1.95
Spinal + TAP block (n=62)	0.06 ± 0.36	0.48 ± 1.11	1.71 ± 1.89	4.44 ± 2.04	4.92 ± 1.80
p-value	**<0.001***	**<0.001***	**<0.001***	**0.003***	**<0.001***
At rest					
Spinal alone (n=62)	0.08 ± 0.45	1.13 ± 1.32	3.15 ± 1.75	5.23 ± 1.59	7.11 ± 1.82
Spinal + TAP block (n=62)	0.03 ± 0.18	0.23 ± 0.91	0.66 ± 1.14	3.58 ± 2.16	4.58 ± 1.84
p-value	0.97	**<0.001***	**<0.001***	**<0.001***	**<0.001***
***Mann-Whitney U p<0.05**					

Table 2 above compares two groups, Spinal only and Spinal with TAP block, over different time intervals. Pain scores were significantly lower in the spinal + TAP block group compared to spinal alone, particularly during movement at all time points (p<0.05). At rest, significant differences emerged from 4 hours onwards (p<0.001). The addition of TAP block to spinal

anaesthesia provided superior pain management, especially during movement and for extended periods post-operation. This combined approach may lead to improved patient comfort and potentially faster recovery.

4.2 Time to first request analgesia

Figure 2: **Time taken for opioids' request.**

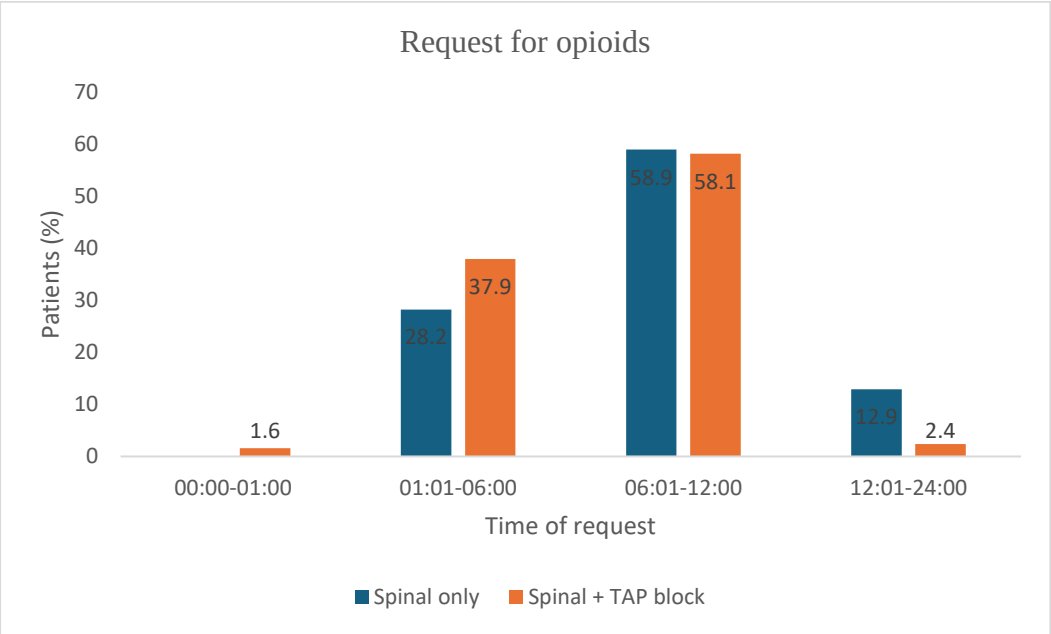


Table 3: **Below presents the mean values that were consistent at 4 hours, 6 hours, and 12 hours, and 24 hours, with no significant difference.**

Time	Spinal alone n(%)	Spinal + TAP Block n (%)	P-value
00:00-01:00	0(0)	2(1.6)	0.94
01:01-06:00	35(28.2)	47(37.9)	
06:01-12:00	73(58.9)	72(58.1)	
12:01-24:00	16(12.9)	3(2.4)	
Total	124(100)	124(100)	

Table 3 and Figure 1 summarise the time taken to request opioids between patients who received spinal anaesthesia alone and spinal anaesthesia with TAP block. The majority of spinal only patients (58.9%) requested for their first opioids between 6-12 hours. Results indicate that 28.2% of patients requested opioids between 1-6 hours. In this study, only 12.9% of the patients of patients requested opioids between 1-6 hours. Similar to the spinal only, the majority of TAP block patients (58.1%) requested their first opioids between 6-12 hours. Unlike the patients who received spinal only, 37.9% requested first opioids within 1-6 hours. Only 2.4% of the participants requested opioids within the first hour, while 1.6% of them took longer than 12 hours. Fisher's Exact test shows that there were no statistically significant differences in the time taken to request for opioids in both groups

4.3 Total opioid consumption dose in 24 hours

Table 4: **Comparative Analysis of Opioid Doses in Spinal anaesthesia alone vs spinal anaesthesia with TAP Block over 24 Hours.**

The total dose of opioids in 24 hours		
	The total dose of opioids for spinal alone in 24 hours	The total dose of opioids for TAP Block in 24 hours
Mean±SD	167.74±70.62	120±46.56
Median (IQR)	200(100)	100(75)
Percentiles 25, 50, 75	100	75
	200	100
	200	150

Table 5: **Opioids consumption in 24 hours. Statistical difference.**

Total dose of opioids in 24hours				
Type of Opioid Admin	Mean Rank	Mann-Whitney U	Z	P-Value
Spinal alone	75.27	1130.5	-4.042	**<.001***
Spinal +TAP block	49.73			
***Mann-Whitney U p<0.05**				

The results show that spinal alone had statistically significant differences in the total doses given to patients, compared to T Spinal + TAP Block

Table 4 above presents the total dose between patients who received spinal anaesthesia alone and spinal anaesthesia with TAP block. The spinal anaesthesia alone group showed higher variability in opioid dosage, with a mean ± SD of 167.74±70.62mg and a median (IQR) dosage of 200(100) mg, indicating a higher median opioid dosage. The TAP Block had a lower mean dosage of 120±46.56 mg, with a median (IQR) dosage of 100(75) mg, indicating a lower median opioid consumption.

Table 4 A Mann-Whitney U test was performed to determine whether there were differences in the total dose given to spinal anaesthesia alone and TAP Block patients. The results show that spinal anaesthesia alone had statistically significant differences in the total doses given to patients, compared to TAP Block $z = -4.04$, $p=<0.001$.

4.4 Participants level of satisfaction

Figure 3: **Patients' level of satisfaction**

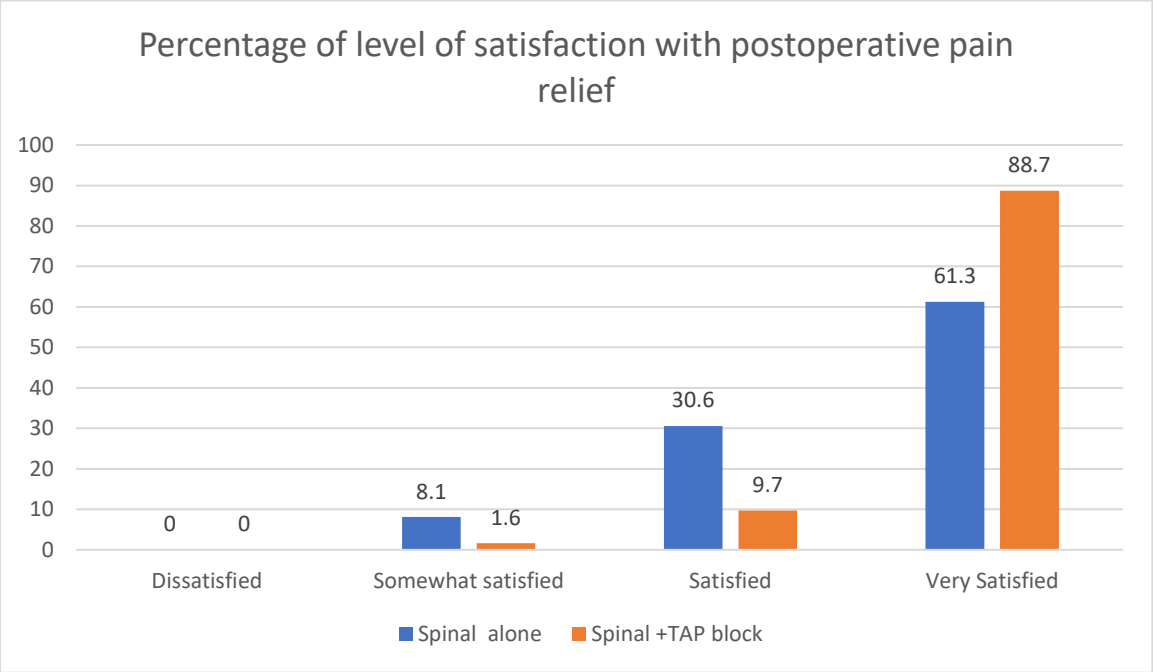


Figure 2 compares the satisfaction levels between patients who received the spinal-only treatment and those who received the TAP block treatment. The majority (88.7%) of the spinal-only patients reported being very satisfied with their postoperative pain relief. While a smaller proportion (9.7%) indicated being satisfied, only 1.6% were dissatisfied with the level of pain relief. Among the TAP Block patients, 61.3% were very satisfied with their pain relief. Compared to spinal alone, more patients (30.6%) who received TAP block reported being satisfied. Only 8.1% were somewhat satisfied. None of the patients reported being dissatisfied with the level of pain relief.

Safety outcomes

No side effects were noted or reported among any of the other patients. This absence of adverse effects encompassed various potential complications, such local anesthetic toxicity, bleeding at the injection site, injuries to internal organs, or the occurrence of infections.

CHAPTER 5: DISCUSSION

5.1 Analgesic effect of TAP block

The results indicates that the combination of spinal anaesthesia with a TAP block provided higher analgesic efficacy compared to spinal anaesthesia alone across various time intervals, both at rest and during movement. Statistical analysis revealed strong significance ($p<0.001$ for most comparisons), underscoring the efficacy of the TAP block in enhancing analgesic effects, while pain scores were comparable at the 2-hour mark at rest. This suggests that although spinal anaesthesia is effective initially, the addition of TAP block contributes to superior pain management, especially during movement and for extended periods post-operation. In the initial hours post-surgery, there may be a higher demand for opioid rescue medication, which could indicate inadequate pain control during this critical period. The findings should be contextualized by acknowledging that while the TAP block may reduce overall pain scores at later time intervals, the increased need for opioids during the first six hours could imply that patients are still experiencing significant discomfort. This observation highlights the need for effective multimodal analgesia right from the outset of postoperative care. It raises questions about whether the timing and administration of analgesic techniques could be optimized to improve early pain management. Future studies might focus on the timing of interventions and their influence on opioid requirements, as well as examining the potential benefits of integrating these strategies more seamlessly in the immediate postoperative setting.

Another reason for the variations in opioid needs during the first six hours is that patients in the ward receive analgesics regardless of whether they request them. This practice was noted to be a routine procedure among the staff.

Nayak31 conducted a study comparing the effectiveness of the transversus abdominis plane (TAP) block to spinal fentanyl alone. In this study, one group received the TAP block for pain management, while the other group was administered intrathecal fentanyl. Nayak found that the transversus abdominis plane (TAP) block provided effective pain relief comparable to that of intrathecal fentanyl. The study indicated differences in onset time and duration of analgesia between the two methods, with TAP blocks potentially offering advantages in certain aspects of pain management. Additionally, Nayak observed varying side effects associated with each technique, contributing valuable insights into the use of regional anesthesia and opioid delivery methods in clinical practice. By highlighting the advantages of TAP blocks in terms of pain relief, onset time, and duration, Nayak's research supports the exploration of alternative analgesic methods in my own work. Additionally, his observations regarding side effects provide a valuable framework for evaluating the safety and efficacy of pain management strategies in my study, helping to inform clinical decisions and optimize patient outcomes.

In another study by Innamorato[32] comparing opioid free spinal anaesthesia versus TAP block, they found that at 2 and 6 hours after the surgical procedure, there was a significant reduction in both resting and movement-related pain. However, at 12 h a reduction in pain during

movement was demonstrated, while no benefit was observed at rest. The proportion of women experiencing NRS scores of 4 or lower was higher in the block group at 2 h for both resting pain and pain during movement. At 6 and 12 h, a significant difference was observed only for pain during movement. In comparison with this study, the results are not quite identical as the patients who received spinal +TAP had a significant reduction of pain comparing to those who received spinal alone at all time intervals however it gives an insight of the end goal in the relief of pain.

5.2 Time to first request analgesia

The study found that there were no statistically significant differences in the time taken to request opioids between the two groups. This suggests that both spinal anaesthesia alone and spinal anaesthesia with a TAP block are effective in providing initial postoperative pain relief. Patients in both groups experienced comparable levels of pain control during the immediate postoperative period. Despite the lack of statistical significance, there were some notable differences in the distribution of opioid request times between the two groups. Patients who received spinal anaesthesia with a TAP block had a higher percentage of requests within the first 6 hours postoperatively compared to those who received spinal anaesthesia alone. This suggests that the addition of a TAP block may offer more immediate pain relief in the early postoperative period for some patients. Nayak et al[31] found the first analgesic request time in TAP block was significantly higher (7.65 ± 1.23 vs. 4.10 ± 0.32, $P < 0.001$) and the total analgesic requirement was significantly less in 24 h. The time to achieve the maximum level

of sensory block was significantly longer in Group F and the duration of sensory block was significantly more in Group F as compared to Group T (222.13 ± 2.29 vs. 195.77 ± 6.86, $P <$ 0.001). another study by Innamorato[32] found that the use of NSAIDs differed significantly between the two groups after the administration of the block at 2, 6, and 12 h. In the TAP block group, no patients required additional analgesia 2 h after the surgical procedure, while in the control group, NSAIDs were administered to a total of 6 patients ($p = 0.01$). At 6 h, the consumption of ketoprofen differed significantly between the two groups ($p = 0.0383$), as well as at 12 h ($p = 0.0003$). There was no difference between the two groups at 24 h

The findings of the study by Innamorato[32] have important clinical implications for postoperative pain management in patients undergoing caesarean section. They suggest that both spinal anaesthesia alone and spinal anaesthesia with a TAP block are effective strategies for managing postoperative pain. The time of request is shorter in spinal anaesthesia alone even when compared with other studies whereby rescue opioid was requested immediately at two (2) hours, meanwhile in TAP block it was requested only after (six) 6 hours. There was no significant difference at twenty-four (24) hours.

5.3 Total opioid consumption dose in 24 hours

The results show that spinal anaesthesia alone had statistically significant differences in the total doses given to patients, compared to Spinal anaesthesia with TAP block z = -4.04, p=<0.001. Less opioids were consumed by the TAP group. It was however observed that more of the spinal anaesthesia with TAP block requested opioids earlier within the first 12 hours.

This This suggests a potential benefit of incorporating TAP blocks into perioperative pain management as part of the multimodal regimen to minimize opioid usage and its associated side effects.

5.4 Patients level of satisfaction

The satisfaction levels reported by patients who underwent either spinal anaesthesia alone or spinal anaesthesia combined with a TAP block provide valuable insights into their postoperative pain management experiences.

For patients who received the combined treatment of spinal anaesthesia and TAP block, an overwhelming majority (88.7%) expressed high levels of satisfaction with their postoperative pain relief, with the vast majority reporting being very satisfied. This indicates that the addition of a TAP block to spinal anaesthesia may contribute to significantly improved pain relief outcomes, as reflected by the high satisfaction rates among these patients. Moreover, the small proportions of patients who indicated satisfaction or dissatisfaction further emphasize the overall positive perception of pain relief among this group. These results are the same as similar study done by Nagalakshmi et al.

Importantly, none of the patients in either group reported being dissatisfied with the level of pain relief they experienced, indicating a generally positive perception of pain management outcomes regardless of the treatment modality.

CHAPTER 6

6.1 Conclusion

Our study indicates that the addition of TAP block to spinal anaesthesia might improve postoperative analgesia provision following C-S. The findings reveal that patients who received TAP block experienced better pain relief and consumed fewer opioids within a 24-hour period. Consequently, we conclude that TAP block constitutes a valuable adjunct to multimodal post operative pain management in our setting. To reduce opioid usage and mitigate its side effects through multimodal analgesia, the integration of TAP block is essential, given its proven efficacy in addressing postoperative pain during the initial hours. Further research is warranted within our hospitals to explore strategies for administering multimodal analgesia to postoperative patients, aiming for minimized side effects and sustained pain relief.

6.2 Limitations

The study was done in healthy patients ASA I and II who were scheduled for elective caesarean section. We did not encounter any ultrasound-guided TAP block complications. Acknowledgements are made that there were no provisions made to record the side effects related to opioids consumption or relation of vital signs in relation to pain which should be considered in the future.

Pain perception varies individually. Despite belonging to a certain demographic, patients may exhibit either high or low tolerance levels, which can significantly influence their experience.

The hospital staff should be informed and encouraged to be more receptive to researchers, fostering an environment of welcome. This approach will facilitate smooth data collection processes.

6.3 Recommendations

At Windhoek Hospital Complex (IHK and WCH), pethidine serves as the primary opioid rescue analgesic, despite its numerous side effects and potential for opioid addiction. Observation in the wards reveals that patients typically do not actively request analgesics. Instead, analgesia is administered as per the prescription without considering the patient's level of pain. It is imperative to assess patients individually and tailor their pain management accordingly. The incorporation of TAP block into multimodal analgesia is recommended, particularly in cases where opioid-free spinal anaesthesia or short-acting opioid spinal anaesthesia is utilized.

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ANNEXURES

APPENDIX 1: INFORMED CONSENT LETTER

A COMPARISON OF SPINAL ANAESTHESIA WITH AND WITHOUT TRANSVERSUS PLANE BLOCK IN PATIENTS UNDERGOING ELECTIVE CAESAREAN SECTION AT WINDHOEK HOSPITAL COMPLEX.

Principal investigator: Dr. Tonata Kakololo

Phone numbers: +264814289772

Sponsor of the Research: None

Research approval number:

Purpose of the research:

The study will compare the duration of analgesia in patients done spinal anaesthesia alone and patients done TAP block plus spinal anaesthesia and also the requirement of opioid dose in 24 hours.

Procedure of the research:

You are being selected to participate in the study because you meet the following inclusion criteria: you are a woman of childbearing age undergoing elective caesarean section. If you agree to take part in this study, you will be asked questions about the level of pain you have at

rest and during movement after the elective caesarean section surgery has been done. If you agree to participate after reading this consent form, on the day of the operation you will receive spinal anaesthesia or Spinal anaesthesia and TAP block. You will be assessed at 0h, 2h,4h, 6h, 12h, and 24h after the surgery. A verbal numeric rating scale (VNRS) will be used from 0 = no pain to 10 = most severe pain imaginable, which you would self-report to the investigator. The spinal anaesthesia would be performed according to the standard operating protocols. Standard monitoring and care during and after the surgery will be given to you. Clinical parameters such as your blood pressure, pulse rate and oxygen saturation will be measured at regular intervals throughout surgery and postoperatively.

Potential risks:

The potential risks are those for every surgery done under spinal anaesthesia, such as a fall in blood pressure, slowing or increasing of the heart rate, failure of the spinal block to provide adequate anaesthesia as well as nausea and vomiting. However, these effects are treatable if they do occur.

Potential benefits:

The goal of this study is to improve the management of postoperative pain management in patients undergoing caesarean section.

Financial implication for joining the research:

Participation in this research will not cost you anything except the usual hospital charges for medical services rendered. There will be no waiver of prescribed hospital fees. There will be no payment for participating in this research.

Confidentiality:

To ensure confidentiality, a number will be assigned to you and your name will not be written on the questionnaire. The principal investigator will store the data obtained in a computer system with a password only known by her.

Voluntariness:

Participation in this survey is voluntary. We will greatly appreciate your help in taking part in this survey. You are free to decline participation in the survey.

Alternatives to participation:

Your treatment in the hospital will not be affected by your refusal to participate in this research. You have a right to withdraw from the research at any given time, if you choose to.

Consequences of participants' decision to withdraw from the research and procedure for orderly termination of participation:

As a participant, you are free to withdraw from the research at any point in time. You must note that information gathered about you before this withdrawal may have been analyzed and used in reports and publications. These cannot be withdrawn anymore. However, we promise to comply with your wishes as much as possible.

What happens to participants at the termination of the research?

The outcome of this research will be made available to the University of Namibia as well as the Ministry of Health and Social Security. As a participant of this research, you will be notified if any further information is required or any further participation.

AUTHORIZATION

I GIVE CONSENT TO BE PART OF THIS STUDY THAT HAS CLEARLY BEING OUTLINED TO ME. MY SIGNATURE INDICATES THAT I HAVE READ AND UNDERSTOOD THE INFORMATION PROVIDED ABOVE. I HAVE HAD ALL MY QUESTIONS ANSWERED AND HAVE DECIDED TO VOLUNTARILY PARTICIPATE.

RESEARCH PARTICIPANT:

Signature:

_____

Date: _____

STAFF OBTAINING CONSENT:

Signature:

_____

Date: _____

A COPY OF THIS CONSENT FORM WILL BE PROVIDED TO YOU.

APPENDIX 2: QUESTIONNAIRE SECTION A

A COMPARISON OF SPINAL ANAESTHESIA WITH AND WITHOUT TRANSVERSUS PLANE BLOCK IN PATIENTS UNDERGOING ELECTIVE CAESAREAN SECTION AT WINDHOEK HOSPITAL COMPLEX.

Section A

Patient Details

a. Hospital number

b. Age

c. Weight

d. Height

e. BMI

f. Gestational age in weeks

g. Parity

h. Hospital

1. Obstetric Indication for Elective C/S:

1. Operative, Anaesthetic and Pain

a. Date

b. Time the spinal anaesthesia was administered (0h)

c. Time operation ended

d. Time TAP block was administered

APPENDIX 3: QUESTIONNAIRE SECTION B

SECTION B

Postoperative pain assessment (verbal numeric rating scale)

1. 2h /10 at rest /10 at movement
2. 4h /10 at rest /10 at movement
3. 6h /10 at rest /10 at movement
4. 12h /10 at rest /10 at movement
5. 24h /10 at rest /10 at movement
6. Time of request of the first dose of opioid
7. Total dose of opioid required in 24 hours
8. Patients satisfaction with the post-operative analgesic effect (0-3 scale)

- Very satisfied 0
- Satisfied 1
- Somewhat satisfied 2
- Dissatisfied 3

APPENDIX 4: ETHICAL CLEARANCE CERTIFICATE

UNAM
UNIVERSITY OF NAMIBIA

ETHICAL CLEARANCE CERTIFICATE

Ethical Clearance Reference Number: SOM09/2023 **Date: 6/07/2023**

This Ethical Clearance Certificate is issued by the University of Namibia Ethics Committee (REC) in accordance with the University of Namibia's Research Ethics Policy and Guidelines. Ethical approval is given in respect of undertakings contained in the Research Project outlined below. This Certificate is issued on the recommendations of the ethical evaluation done by the ethics committee.

Title of Project: A comparison of spinal anaesthesia plus tranversus abdominis plane block versus spinal anaesthesia alone in patients undergoing elective Caesarean section

Student: Kakololo Tonata

Student Number: 200403036

Supervisor(s): Brian Jenkins

Centre for Research Services

Take note of the following:

1. Any significant changes in the conditions or undertakings outlined in the approved Proposal must be communicated to the ethics committee. An application to make amendments may be necessary.
2. Any breaches of ethical undertakings or practices that have an impact on ethical conduct of the research must be reported to the ethics committee
3. The Principal Researcher must report issues of ethical compliance to the ethics committee (through the Chairperson) at the end of the Project or as may be requested by the ethics committee
4. The ethics committee retains the right to:

i) Withdraw or amend this Ethical Clearance if any unethical practices (as outlined in the Research Ethics Policy) have been detected or suspected,

ii) Request for an ethical compliance report at any point during the course of the research.

The ethics committee wishes you the best in your research.

Mareli Claassens

A/Prof Mareli Claassens (Chairperson Ethics Committee)

Prof. Davis Mumbengegwi (Head, Multidisciplinary Research)

APPENDIX 5: APPROVAL LETTER FROM MINISTRY OF HEALTH AND SOCIAL SERVICES

REPUBLIC OF NAMIBIA

MINISTRY OF HEALTH AND SOCIAL SERVICES

Ministerial Building
Harvey Street
Private Bag 13198, Windhoek

OFFICE OF THE EXECUTIVE DIRECTOR

Tel: No: 061 -203 2507
Fax No: 061-222 558
Andreas.Shipanga@mhss.gov.na

Ref: 22/3/1/2
Date: 15 August 2023

Enquiries: Mr. A. Shipanga

Ms. Tonata Kakololo
P.O. Box 44
Ohangwena

Dear Ms. Kakololo

Re: Academic Research Proposal Approval – UNAM – Masters of Medicine (Anaesthesiology, Critical Care and Pain Management).

Title: A comparison of spinal anaesthesia with and without transversus plane block in patients undergoing elective caesarean section at Windhoek Hospital Complex.

1. Reference is made to your application to conduct the above-mentioned study.
2. The proposal has been evaluated and found to have merit.
3. **Kindly be informed that permission to conduct the study has been granted under the following conditions:**
   - 3.1 The data to be collected must only be used for completion of the Masters of Medicine;
   - 3.2 No other data should be collected other than the data stated in the proposal;
   - 3.3 No any specimen should be collected from Human Subjects;
   - 3.4 Stipulated ethical considerations in the protocol related to the protection of Human Subjects' information should be observed and adhered to; any violation thereof will lead to termination of the study at any stage;
   - 3.5 A quarterly report to be submitted to the Ministry's Research Unit;
   - 3.6 Preliminary findings to be submitted upon completion of the study;
   - 3.7 Final report to be submitted upon completion of the study;
   - 3.8 Separate permission should be sought from the Ministry for the publication of the findings.
4. All the cost implications that will result from this study will be the responsibility of the applicant and **not** of the MoHSS.

Yours sincerely,

EXECUTIVE DIRECTOR

BEN NANGOMBE
EXECUTIVE DIRECTOR

All official correspondence must be addressed to the Executive Director

My NAMIBIA
MY COUNTRY, MY PRIDE

APPENDIX 6: APPROVAL LETTER FROM WINDHOEK CENTRAL HOSPITAL

REPUBLIC OF NAMIBIA

MINISTRY OF HEALTH AND SOCIAL SERVICES

Private Bag 13215
Windhoek
Namibia

Harvey Street
Windhoek Central Hospital

Tel. No: (061) 2033024
Fax No: (061) 222886
Email: Selma.Iipinge@mhss.gov.na

Enquiries: Ms. S.Iipinge | Ref: 22/3/1/2 MFE | Date: 28 September 2023

OFFICE OF THE SENIOR MEDICAL SUPERINTENDENT

Dr.Tonata S.I Kakololo
University of Namibia
Windhoek
0814289772

Dear Dr.Kakololo

SUBJECT: PERMISSION TO CONDUCT A RESEARCH STUDY ON THE COMPARISON OF SPINALANAESTHESIA AND WITHOUT TRANSVERSUS PLANE BLOCK IN PATIENTS UNDERGOING ELECTIVE CAESAREAN SECTION AT WINDHOEK CENTRAL HOSPITAL COMPLEX.

Reference is made to the above mentioned subject:

Kindly be informed that permission has been granted to conduct the research study on the above mentioned subject under the following conditions:

1. Patient client information should be kept confidential at all times
2. The purpose for research is only for your study purposes as you have requested and does not include any remuneration.
3. **Preliminary findings to be submitted to Customer care office, Windhoek Central Hospital upon completion of the study.**

Thank you for your kind cooperation.

Yours faithfully

.....

DR.S.SHALONGO

SENIOR MEDICAL SUPERINTENDENT

MINISTRY OF HEALTH AND SOCIAL SERVICES
Private Bag 13216
28 SEP 2023
Windhoek, Namibia
WINDHOEK CENTRAL HOSPITAL

APPENDIX 7: LETTER OF APPROVAL FROM INTERMEDIATE HOSPITAL KATUTURA

9-0/0001

REPUBLIC OF NAMIBIA

Ministry of Health and Social Services

Private Bag 13215
WINDHOEK
Namibia

Intermediate Hospital Katutura
Independence Avenue
WINDHOEK

Telephone (061) 203 4011
Tele fax (061) 222706
Email:Ndateelela.Amukuhu@mhss.gov.na

Enquiries: Ms. N.A.N. Amukuhu

Date: 28 September 2023

OFFICE OF THE CHIEF MEDICAL OFFICER

MS. TONATA KAKOLOLO
UNIVERSITY OF NAMIBIA

Dear Ms. Kakololo,

SUBJECT: APPROVAL TO CONDUCT ACADEMIC RESEARCH

We trust this communication reaches you well, the above subject bears reference.

We write to inform you that as per your academic research application, you have been granted permission to conduct a study on ***"A COMPARISON OF SPINAL ANAESTHESIA WITH AND WITHOUT TRANSVERSUS PLANE BLOCK IN PATIENTS UNDERGOING ELECTIVE CAESAREAN SECTION"*** at the Intermediate Hospital Katutura.

Your research is subject to the following information:

a) You must provide this office with a copy of your findings

We trust that the above finds you in order.

YOURS IN HEALTH,

3/10/2023

DR. F.M.SHIWEDA
CHIEF MEDICAL OFFICER

MINISTRY OF HEALTH AND SOCIAL SERVICES
2023-10-03
INTERMEDIATE HOSPITAL KATUTURA

"Your Health, Our Concern"